Perspectives on Evolution of Miniaturization

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As medical devices get smaller and more devices move out of the hospitals, what is the next step in this evolution?

Steve Duckworth
Head of Global Segment Medical and Pharmaceutical, BU Masterbatches Clariant

“Today, it is often the patient, rather than a doctor, who is the user and so medical devices must be attractive as well as convenient and functional. Devices become more like any other consumer product and color and other visual elements are increasingly important. Devices also need to be safe and convenient to use outside of a controlled medical environment. This means designers need to think about things like colors to assist in product identification, gripping surfaces for ease of handling, and lubricity in moving components to make the device easier to operate. With increasing consumer concern about the environment, issues like sustainability, recyclability, compostability and source reduction become more important, but respecting the key design criteria of safety and reliability in use.

“Properly chosen, the plastics used in today’s devices and packaging deliver many advantages. These include the fact that they can be tailored to the consumer’s needs and preferences with bright colors and surface effects, and additives to improve functionality. However, the plastic resin, the colorant and any additives, as

well as the final device or packaging, need to meet ever more demanding regulatory requirements. Given that colorants and additives also influence processing and part shrinkage, all of the elements of design have to be considered together.

“At Clariant, the next step in this evolution has already begun with the introduction of a package of dedicated services and expertise for medical device and pharmaceutical packaging that helps improve product reliability and offer innovative material performance. In this collaborative environment, device developers can more easily sort out their options, avoid regulatory pitfalls and get new products successfully to the market faster.”

Jessica Willing-Pichs
Principal, Research & Product Strategy, Ximedica

This question can only be properly answered in the context of two key driving forces. The first is the drop in average length of hospital stays and bed counts per 1,000 in the U.S. despite increased hospital admissions, a trend that is also transpiring globally. Influencing factors include continual payor pressure to contain costs of patient care and the growth in minimally invasive, outpatient procedures. This means that patients today are proactively undertaking more of their recovery at home armed with prescriptions, medical equipment, and quickly delivered discharge instructions but with nominal clinical support or case management. The impact of this on the future of medical device design means that healthcare products are being forced to fundamentally simplify their interfaces without compromising clinical functionality. A lay user in the haze of discomfort and painkillers will need to correctly operate a device without any previous experience and slight patience for complex instruction manuals. In fact, we should increasingly expect product manuals to be tossed aside with product packaging.

The second key driving force governing the future of medical device designed for

the home is a rapidly shifting expectation and diminishing tolerance for how technology behaves, physically and aesthetically integrating into the lives of consumers. It is not enough for a clunky medical device to be re-engineered with a smaller footprint; it must also lose its “institutionality”. A patient at home wants to be someone on the mend, increasingly mobile and untethered, wearing their own normal clothes and re-engaging with their social networks as quickly as possible. To be embraced as part of that ride to recovery, medical devices must become wireless and portable, thin enough to be worn on or against the skin or thrown in a pant pocket. Home devices will be expected to power up instantly, discretely assessing and reporting topline progress on demand. Consumers will want to create seamless feedback loops with remote, selective care providers (professional and familial), requiring open integration with local wifi and cellular infrastructures. Tomorrow’s patients will demand nothing less as they eagerly adopt the technology advancements of other gadgets in their consumer lives.

John Beigel
Technical Expert and Member of the Board of Directors, MEDER Electronic

With the advent of micromachining technology (MEM devices), the reed sensors in particular, have caught up with the miniaturization of the other technologies. For several years, MEDER/Standex have been supplying a MEM reed sensor that only uses 1.17 square mm of PCB space (or 0.0009 square inches). Made on a wafer housing over 10,000 reed sensors, they draw no current until activated, therefore making them ideal for portable medical devices. Their small size, no power draw, hermetically sealed packaging, operating capability from -40°C to 150°C, and very long life have made them the design-in switching favorite for: in the canal hearing aids, pacemakers and implantable defibrillators, micro-glucose detection and administration systems, camera in a pill video monitoring, animal and fish tracking devices, carotid artery plaque detection monitors, implantable muscle stimulation, incontinence prevention systems, and

more.

Ian Hardy
Sr. Process Engineer, Crane Aerospace & Electronics – Microelectronics Solutions

The primary benefits of technology miniaturization in the implant world are 1) less invasive surgeries with quicker recipient recoveries, and 2) more complex devices with applications towards a wider variety of ailments. As implantable devices begin to bridge current technological gaps, we're likely to see the medical implant market gain significant ground on competing drug-based therapies that offer similar outcomes but with undesirable side effects. Additionally, treatment options will become more accessible, transitioning from primarily hospital-based therapies to primarily home-based therapies for a wider variety of medical conditions. The driving force underpinning this eventual technological shift is continued shrinking of current electronics assembly technology, increasing packaging density without sacrificing device reliability. Medical device developers won't be able to bridge this gap alone. Ultimately, it has to be incumbent upon the device manufacturers to transcend the traditional CM "build to print" role and become active collaborators in device development and improvement in order to solve our customers' problems and advance medical device technology.

Chad Marak
Director of Technical Marketing and TVS Diode Array Product Line, Semiconductor Business Unit, Littelfuse Inc.

Improved electrostatic discharge (ESD) protection is becoming increasingly important as medical devices get smaller and more complex. Because of their reduced size, these medical devices are becoming more easily transportable. This makes them suitable for use outside of the hospital, where they are more susceptible to damage from the additional human interaction and handling due to ESD. At the same time, users will expect these devices to deliver the same reliability and accuracy “at home” as they would in a clinic or hospital. Failure isn’t an option. For these reasons, the manufacturers will need to include more sophisticated ESD protection on all of their medical devices.

To that end, Littelfuse provides a multitude of devices that can protect sensitive electronics against ESD and other electrical transients. There are discrete, low profile 0201 form factors as well as multi-channel arrays to provide flexibility to the designer or manufacturer. Furthermore, all products are rated at minimum of ±8kV ESD, the highest level recommended by the IEC61000-4-2 standard, and have extremely low leakage specifications to ensure battery life and measurement accuracy.

Trygve Olsen
Program Development Manager, Hutchinson Technology Inc.

Device manufactures will be challenged by the desire for more functionality in an ever reducing size (and cost). Parallels to what the medical device community faces can easily be seen in product evolution from the electronics, computing, and telecom industries. One enabling strategy that has been effective in those industries is adding functionality to individual components in an assembly. An example of this is placing electrical conductors on a structural element to gain space and eliminate wires. In addition to reducing form factor, this strategy can also reduce costs through reduced component counts and assembly time, with the extra benefit of streamlining the supply chain.

Generally, added functionality and reduced size/cost are not complementary requirements. Simple evolution of existing designs isn't enough. Finding new solutions to size and functionality requirements will drive device manufactures to new technologies or to combine existing technologies into a more complex component. An example might be to combine etching, coating, and forming to achieve a 3D part with built in standoff pads, electrical insulation, and assembly aids. This would generate a more complex component, but can simplify the overall assembly, and be instrumental in achieving the desired functionality improvements and lowered overall cost.

Chris Ault
Product Manager, QNX Software Systems

As medical devices migrate from the hospital to the patient's home or workplace, two concepts will become increasingly important: manageability and security. Remote medical devices must often provide continuous care, regardless of their location. Consequently, IT teams will need to manage and control the devices remotely, whether to monitor device operation, ensure quick response to patients in distress, or deliver over-the-air firmware updates. The complexity of this task will grow exponentially with the number and variety of devices deployed.

Secure networks will be essential to ensuring remote control of such devices. That said, the devices themselves must also be designed to withstand assaults, without loss of service or corruption of data. It isn't enough to prevent hackers from accessing the networking level or user-application level of a connected medical device. The device software must also implement mechanisms to prevent or contain denial-of-service attacks, whether the device is a drug infusion pump or a wearable sensor patch.

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