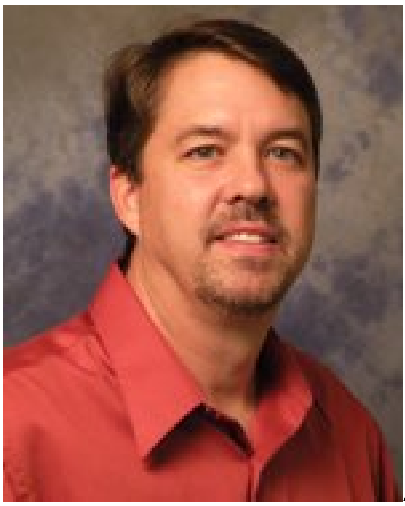
Roundtable Q&A: Medical Electronics

Question 1: What is the most significant challenge in the miniaturization of medical electronic devices?

Alan Cohen
Medical Practice Team Lead and Director of Systems Engineering, Logic PD

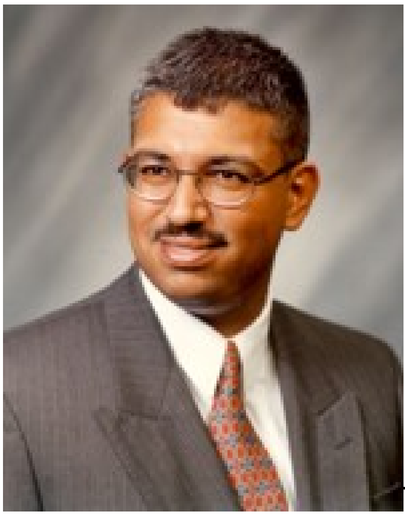
A variety of challenges can be encountered depending on the application. Batteries are typically the largest components in miniature devices. Small devices require small batteries, and small batteries mean low power; designing for low power is challenging. Battery capacity, safety, recharge/replacement, vendor qualification, and component availability all need to be addressed. Power dissipation can be challenging in some devices—running, say, a 1GHz CPU plus DSP in a small sealed device requires some thought. Thermal modeling will reduce this risk. Design for manufacturing is another challenge due to small parts and assemblies, so working closely with manufacturing folks throughout development is important.

Steven Dean
Global Healthcare Segment Lead, Freescale

Advanced packaging technologies will help reduce overall

size and improve circuit performance. Technologies that employ 3-dimensional volumetric efficiency like Redistributed Chip Packaging (RCP) could be one enabler. RCP is an interconnect technology that makes the package a functional part of the die and/or system, providing advantages such as elimination of wire bonds, package substrates, and bumping. An RCP platform allows for significant flexibility, offering ultra thin packages (<125 µm including solder bumps), multilayer stacked packages, 2D multi-die, 3D heterogeneous systems, integration of multiple die, surface mounted devices and integrated passive devices, memory, MEMs sensors, etc. For several leading customers and especially for key medical implantable companies, the RCP technology is providing a “game changing” opportunity.

Deepak Hariharan
Business Manager, Electronics Division, Adhesives Research Inc.



There are two primary challenges that must be addressed in respect to adhesives for medical electronic devices. As medical electronic devices become smaller, the challenge for adhesive manufacturers is to create an adhesive that provides adequate bond strength. This can be particularly challenging when bond lines are thin and narrow. Equally important is functionality. Many of our adhesives, such as our electrically conductive technologies, are used for bonding while also offering added capabilities that affect the overall functionality of the product’s design. As products become smaller, the adhesive must deliver the same functionality in a smaller footprint.

Steve Kennelly
Senior Manager, Medical Products Group, Microchip Technology Inc.

Like the very idea of size, the challenges of miniaturizing electronic medical devices are relative. In general, it always comes down to putting enough of something into the allotted volume. Frequently, the largest component is the battery. In this case, the device’s power consumption and service life are directly proportional to its size. Even in field-powered devices, the size of the energy-harvesting components can be a major part of the total device volume. In devices that are not battery-size limited, other common challenges to miniaturization can include connector standards, mechanical strength, and drug volume in the case of drug-delivery devices.

Dirk Smith
Chief Technical Officer, Minnetronix Inc.

Challenges in miniaturizing medical electronics vary depending on the technology and medical application. For start-up companies in new markets, miniaturization is often dependent on utilizing commercially available technology due to the cost, time, and expertise required to develop custom, miniaturized components. With the reliance on existing technology and components comes vulnerability to obsolescence and constraints from suppliers regarding use of their components in medical devices. Companies with established markets often have the advantage of pursuing custom miniaturization, shifting the challenges to developing and validating custom components and methods in a timely, cost-effective manner while complying with regulatory and safety requirements.

Question 2: What are the critical considerations to address when designing for low power?

AC: It would be great if we could wave a magic “low-power” wand and run on nanoamps, but the reality is that achieving minimal power consumption is quite tricky and time consuming. It requires very methodical planning from the start as there are many hardware and software implications. Having solid requirements (e.g., desired battery life) is critical, as is developing solid use cases and state tables. For each state, determine which devices can be put into low power states, and use this information with use cases to predict battery life, inform component selection, etc.

SD: Power management is critical in the development of consumer medical or in wearable and implantable devices. One way to improve power management is by controlling which circuits are consuming power or “turned-on” during specific operations or device states. The Freescale Kinetis K50 microcontroller, along with the other members of the Kinetis family, leverages 10 power modes. In addition to these low power modes, the peripherals on the K50 are designed for low power flexibility as well. For example, the K50 op amp has a low power configuration bit that allows operation at less than 200 µA.

DH: One critical factor to consider when designing for low power is power losses due to resistance of the adhesive. If an adhesive’s resistance becomes unstable during various cycling conditions or during natural aging, the device will eventually malfunction. Another important factor is to consider any interaction that could occur between the adhesive and the bond surfaces. Chemical interactions between the adhesive and bonded surfaces will lead to conductive instability over time. In addition to chemical interactions, physical interactions could potentially result with damage of bonded surfaces, particularly with delicate coatings such as indium tin oxide (ITO).

SK: It’s always important to look at the system power when doing a low-power design. In the case of semiconductor components, almost everything now has multiple power modes, allowing designers to trade off power consumption with other performance parameters in real-time. Designers should make sure that their power analyses take into account the amount of time that each component will spend in each operating mode. Another important consideration is peak power vs. average power. Some popular battery chemistries are unable to sustain currents above 10 mA or so, which sometimes necessitates energy storage to handle brief peaks.

DS: Miniaturization and design for low power often go hand in hand, as battery capacity and volume are critical to both. As such, the challenge of identifying, designing, and validating components suitable and sustainable for low power designs remains critical. Low power designs must be cognizant of EN60601-1 safety requirements and the need to meet EMC standards and product-specific reliability targets. In implementing low power designs, designers should consider low power microprocessors, powering electronic components only when necessary (utilizing sleep modes), optimizing bandwidth/power consumption tradeoffs for wireless systems, and maximizing efficiencies of power regulation and energy delivery subsystems.

Question 3: What can be done to alleviate concerns with regard to the

security of wireless medical devices?

AC: Security needs to be approached holistically at the system level. Wireless security is just one part of securing the entire product. The first step is to understand the requirements that we're trying to meet. Are we trying to meet patient confidentiality standards such as HIPAA and HITECH? Or protecting the efficacy and safety of a device (e.g., preventing a hacker from interfering with an infusion pump)? A general rule is that it's better to use a standard protocol (e.g., WPA2 over WiFi) then to create your own and hope that you can outsmart hackers. It can be useful to have an independent team review designs with the goal of trying to break security.

SD: To "alleviate" concerns in the context of wireless security of medical devices couldn't be more appropriate in light of the recent Black Hat hacking of insulin pumps and the like. Security requirements in this space are somewhat obvious. The need for data confidentiality and privacy, data integrity and authenticity, immediate availability of data, and overall secure data management are paramount. Regardless of wireless protocol, encrypted communications must be leveraged to the fullest. Further, many possible solutions exist for embedded systems such as employing symmetric keys for encryption and decryption, symmetric key hashing and digital signatures, random key distribution, and many others. Ensure that your MCU or MPU includes protected flash memory, a memory protection unit, necessary hardware cryptographic acceleration, secure key storage, and tamper detection and secure real time clock.

SK: The need for secure wireless data transmission is by no means unique to medical devices. Banking, access control, accessory authentication, and scores of other applications have similar requirements that have been met by a variety of means. There are a number of algorithms that have become industry standards for data encryption, any of which may be sufficient for some systems. Hardware serialization, challenge-response protocols, and transmission speed limits can be used as well. The most important thing is to make security a part of the design from the beginning to maximize the number of options.

DS: Security of wireless communications is not new outside the medical industry; however, it is a growing concern linked to the proliferation of wireless medical products. Medical devices can take advantage of existing methodologies that have been proven effective in other security-sensitive industries. As a baseline, medical products should implement protocols capable of security methods including encryption. For added robustness, systems can minimize their range of communication (i.e., broadcast no further than required) and utilize short burst communication periods. More broadly, security must be considered in a program's risk management process and specified and verified as an essential design element.

Question 4: Any comments on medical electronics you would like to share with medical device manufacturers?

AC: There are lots of specific tips around miniaturization, power, and wireless design in medical electronics. However, they all have in common the need for thorough planning and methodical design that is a big step beyond larger devices. An extra 2 mA wasted due to a design oversight is fine in, say, a wall-powered clock-radio, but that 2 mA can reduce the battery life of an implantable device by more than 95%. Every detail counts so being methodical will pay very big dividends.

SD: When considering design trade-offs, requirements such as performance, size, weight, and power should be considered. These requirements, along with the availability of existing off-the-shelf solutions and desired system flexibility, should help drive design partitioning. Packaging technologies, as well as low power microcontrollers, sensors, and RF technologies, allow for an innovative design to meet the requirements of portable consumer medical, wearable, and implantable devices. Further optimization to meet the device specifications for any of these parameters may dictate the development of a custom ASIC, however the design of a custom IC can be expensive and time consuming depending on complexity. The early engagement of an experienced IC development team can help with the design partitioning and process selection and greatly increases the likelihood of success, reduce risk, and reduce that cost.

DH: The growing complexity of sensitive electronic components over the last decade has significantly shaped the way adhesive manufacturers formulate adhesives. While there are a number of adhesives available on the market today for use in electronic applications, it is our experience that an improper choice can lead to reliability and performance problems down the road. Product developers are advised to work directly with technical personnel at an adhesive company specializing in the customization of adhesives for electronics, so that all the product design requirements are taken into account when recommending an adhesive product. There will be many instances where a standard product will not meet all the needs of an application, requiring some customization to the adhesive product.

SK: Don’t be afraid to get your suppliers involved early in the design phase. Chances are that your medical device will include innovation from a number of different disciplines. I have seen countless cases where designs have been improved or problems have been overcome with the help of someone who is an expert in their particular field. Make sure that you are using all the resources at your disposal.

DS: As device companies continue to leverage technology from consumer products, component obsolescence is a growing challenge, driven by the long product life expectations for medical devices. Strengthening relationships with suppliers can help mitigate obsolescence and lead-time issues. Another important consideration, particularly for low-power, miniaturized products, is the value of Design for Manufacturability. Building DFM into the development process from the start throughout all functional areas will benefit product cost, reliability, and sustainability. Finally, recognize that as technology evolves so do regulatory standards. Development teams should assess implications and compatibility of new technology with regulatory requirements throughout development via reviews and testing.