Reducing Size While Improving Functionality and Safety in Next-Generation Medical Device Design

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System designers face multiple challenges in the medical device market, including reducing size, increasing functionality and extending battery life for implantable devices while ensuring safety through optimal security, reliability and efficacy. For equipment used in radiotherapy environments, designers also must consider the impact of single event upsets (SEUs) caused by ionizing radiation, which can lead to unintended and unexpected configuration changes.

Miniaturization has become the key growth driver for life-critical devices such as implantable cardioverter-defibrillators (ICDs) and cardiac rhythm management (CRM) products. One way to reduce size is to ensure that the radio frequency (RF) technology used to improve medical device functionality consumes ultra low-power, so that small batteries can be used. Fig. 1 shows the Pillcam wireless endoscopy imaging capsule from Given Imaging Ltd., which applies these techniques using a custom RF transceiver from Microsemi that reduces battery size by enabling the capsule to consume less than 7.5 milliwatts of power while relaying up to 14 images per second during an eight-hour procedure.

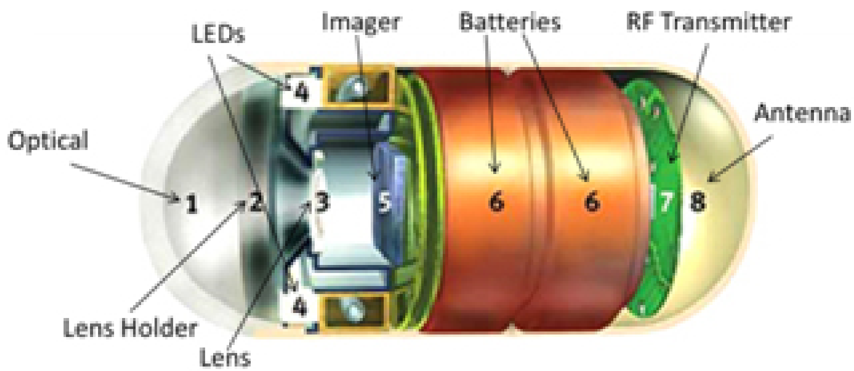

Figure 1. Pillcam wireless endoscopy imaging capsule

Size can also be reduced by using space-efficient semiconductor packaging techniques such as chip-on-board assembly, chip-on-chip and, more recently, advanced 2-D and 3-D packaging. These packaging techniques can reduce overall circuit space in cardiac rhythm management (CRM) devices by up to 80 percent. One of the most effective techniques is the stacked-die approach, which simultaneously reduces interconnect lengths and impedances while increasing yield. Die stacking allows designers to combine multiple wafer process technologies in a small volume while improving test access. The Thin Interconnected Package Stacks (TIPS) project has made solid progress on next-generation stacked-die solutions. Funded by the IMEC R&D lab for nano-electronics in partnership with corporate and institutional organizations, the TIPS project has delivered a packaging approach that reduces device height and other dimensions while delivering the advantage of a single module.

Field programmable gate arrays (FPGAs) are also an important contributor to device miniaturization. For instance, designers have traditionally built human-machine interface (HMI) and miniature motor controllers for portable medical devices using a combination of microcontrollers, application-specific standard product (ASSP) chips and small programmable logic devices. Not only does this approach make it difficult to reduce equipment size, it also is less than ideal for optimizing channel count for critical sensors and actuators. In contrast, FPGA-based solutions fit significantly more functionality into the smaller package size required for devices that must have small form factors. At the same time, they offer the additional advantage of enabling users to upgrade designs so they can support new standards or deliver additional functionality.

FPGAs also help to reduce power consumption as compared to alternative solutions. As an example, the liquid crystal display (LCD) panels used in portable medical devices can consume up to half the application’s power budget. The answer is to design the system so that the LCD and control logic are placed into power-savings mode whenever possible, greatly reducing battery drain. This approach is very straightforward with FPGAs, but difficult to implement with off-the-shelf ASSPs that are not designed with the requirements of the medical market in mind.

Today’s flash-based FPGAs also provide important, built-in security capabilities to ensure that only legitimate upgrades can be executed.There also are other important security issues to consider. Today’s medical devices are at risk of theft, counterfeiting, after-marketing tampering, and overbuilding, in which subcontractors manufacture more units than have been ordered so they can sell the surplus equipment. Each of these risks carries significant consequences in the medical device market. Consider a situation in which the wrong software is downloaded to an insulin pump, or counterfeit parts are used in its design, either of which could potentially cause the pump to deliver inaccurate doses and seriously injure the patient.

Protecting medical devices from tampering requires both hardware and firmware checks; otherwise, consumers may restore the factory settings prior to filing a claim, and there will be no way to detect the attack. Hackers also can potentially modify the functionality of service and infrastructure equipment, further hampering attack detection, response and countermeasures.

It is important to use antifuse and flash- based FPGAs since they are significantly harder to reverse-engineer than SRAM-based FPGAs. Once programmed, flash-based FPGAs retain all programming information within the die. Because the programming cells are nonvolatile, they also retain their state between power cycles. This contrasts with SRAM-based FPGAs, which must reload the configuration at power-up, exposing the programming bitstream to potential hackers. The only way hackers can intercept a flash-based FPGA’s bitstream is to acquire it from the configuration file used to update the device in the field. However, this, too, can be prevented by encrypting them in the FPGA, and using flash memory to permanently store all encryption keys and settings.

Finally, designers of equipment used in radiotherapy environments must ensure immunity to dangerous SEUs, which occur when a high-energy particle or ion impacts at the depletion region of an N-P junction. Charges ranging from femtocoloumbs to picocoloumbs can collect in the region, which can create voltage and current transients. With SRAM-based FPGAs, the resulting linear energy transfer (LET) can be sufficient to overpower the junction and cause an SEU, in the form of a change in state (bit flip) of the memory element (SRAM cell, register, latch, or flip-flop).

The situation is very different for flash memory cells. Flash is a nonvolatile storage structure that contains a floating gate, located between a control gate and the MOSFET structure below, encased in good dielectric (see Fig. 2). When an ion strikes in or near the depletion region of a flash cell, it still deposits a charge. However, the critical amount of charge needed to flip a stored bit (QCRIT) is significantly larger for a flash cell than an SRAM cell, and the flash cells used for configuration also feature a very robust construction. As a result, flash cells used for FPGA configuration are immune to these SEUs.

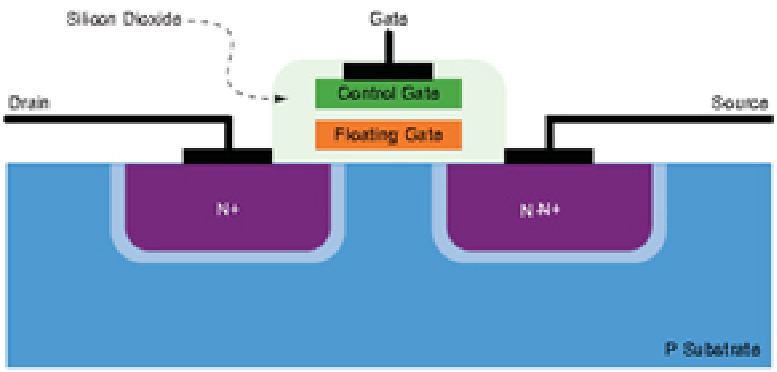

Figure 2. Flash Memory Cell

Miniaturization is increasingly important for medical devices. At the same time, designers must deliver improved functionality, battery life, and safety, which require optimized security, reliability and efficacy. A combination of ultra low-power chip design and advanced packaging can help significantly reduce device size, as can the latest FPGA technology, which packs more functionality into a smaller space as compared to alternative approaches, while also improving power efficiency. Opting for flash-based FPGA technology can simultaneously reduce the risk of life-threatening security breaches, while also providing immunity to SEUs for equipment used in radiotherapy environments.

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