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Incredible Shrinking Medical Devices

Flash-Based Mixed-Signal and Low-Power FPGAs Address Portability and Miniaturization Trends

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Introduction

Increasing healthcare costs, the prevalence of chronic diseases, an aging baby boomer community, and large emerging markets in countries such as China, India, and Brazil are creating tremendous demand for affordable, robust, reliable medical devices to improve the treatment and care of millions of patients worldwide, and to cure an increasing range of diseases. In turn, medical device designers are exploring new technologies from various industries to improve the diagnostic, monitoring, and therapeutic capabilities of next generation devices.

Talking about home-based testing, monitoring, diagnostics, clinical equipment, or imaging applications, two trends have emerged to make medical devices more affordable and more accessible for patients: miniaturization and portability. Medical manufacturers are moving entire systems—from home-based and clinical devices to imaging applications—into a portable unit the size of a cell phone or smaller. What was once huge equipment tethered to a wall has become available in mobile clinics, ambulances, and in a doctors bag for house calls.

With the trends toward miniaturization and portability come implications for reliability, form factor, power consumption, and battery life when considering the semiconductor technologies used in medical applications.

Medical instruments, from home-based and clinical applications to imaging devices, are often very complex and highly use-specific. In addition to their core elements, medical devices also include unique functional blocks to complete their task. These changing features and requirements, complex functionality in a small footprint, low-power, high accuracy, and reliable operation make medical devices an excellent market for reprogrammable nonvolatile semiconductor technologies like mixed-signal and low-power flash-based field programmable gate arrays (FPGAs).

Semiconductors in Medical Applications

Designers have leveraged standard products for their medical devices. Yet, as the pressure to deliver superior and less invasive healthcare grows, so too does the rate of medical device technology innovation. Advancements in the semiconductor industry are enabling this acceleration by delivering smaller, cheaper, more reliable solutions able to integrate critical functions such as analog circuits, and embed microprocessors in a single device. New packaging technologies and methodologies have also improved the cost and reliability of the assembly of packages with small footprints. For example, chip-scale packages have reduced semiconductor package sizes to the dimensions of the die inside. Other innovations, such as the use of a known good die or foldable printed circuit boards, have also provided considerable miniaturization in the overall space occupied by the electronic portion of the medical device.

With low-power requirements and an allowance for the use of small batteries, small processors are helping to fuel the emergence of new wearable and implantable medical devices. Similarly, several advancements in FPGA technologies are furthering the development of portable, miniaturized medical applications. For example, the function of several standard chips can be integrated into one reprogrammable FPGA device, reducing footprint, cost, power, and increasing reliability. This integration has also addressed the obsolescence issue that plagues risk-averse medical product designers who use standard products. These customers need field-proven technology that can not become obsolete, enabling them to continue to meet stringent medical instrument guidelines.

With inherent flexibility and reprogrammability advantages, FPGAs have already played a significant role in the growth of medical electronic devices. Looking forward, the semiconductors with the greatest opportunities are those that can satisfy the more stringent demands of this marketplace—high reliability, small form factor, and extremely low-power.

In fact, market analyst firm Gartner Dataquest has marked medical applications one of the fastest growing segments for semiconductors. In September 2008, Gartner estimated the medical electronics market for semiconductors to be approximately $3.42 billion in 2008 and growing to $4.48 billion by 2012 with FPGAs making up approximately $323 million of that total.

Reliability

Complex and shrinking medical instruments must be reliable enough to withstand a wider range of operating conditions. It used to be enough for the machine to work in a spotless operating room, clinic, or laboratory. Modern medical devices must deliver the same accuracy and reliability in a mobile clinic or in an ambulance.

The medical device is only as reliable as the semiconductor devices used within. Therefore, it is critical for the component, such as the application-specific standard product (ASSP), microprocessor, or FPGA, to be inherently reliable. The reliability of the device and the system can be impacted by power-up requirements and firm-error immunity of the devices, as well as functional integration and the number of devices on the board.

Well-suited to medical applications due to their inherent high reliability, nonvolatile flash-based FPGAs are single chip, and live at power-up. In addition to the system operation benefits and the reduction in power consumption, the live-at-power-up feature offered by flash-based FPGAs contributes to the reduction of the number of total components used on the board, increasing reliability. In comparison, significant additional circuitry may be required when utilizing static random access memory (SRAM)-based FPGAs. In addition to a boot PROM and or additional system memory for unsecure configuration code, a CPLD may be needed for system configuration and supervisory tasks. Clock and reset signal generation is also required upon power-up to help initialize components on board. These issues reduce reliability, add complexity and cost to the system design, and slow down the development process.

Reliability can also be severely impacted by the susceptibility of the device to single-event errors where alpha and neutron radiation causes loss of configuration data. For example, programable logic devices based on SRAM technology are susceptible to soft errors, the transient corruption of a single bit of data, and firm errors, the loss of the underlying FPGA configuration, which can cause system-level functional failure. Neutron and alpha radiation do not have adverse effects on true nonvolatile flash-based FPGAs at ground and sea levels or at high altitudes, making them more suitable for medical applications where failure is not an option.

The integration of diverse functions into a single chip can increase reliability through the elimination of discrete devices. For example, the integration of analog functions (sensing) and nonvolatile memory for data logging can significantly improve reliability.

Small Form Factor

For a large portion of medical applications, the enabling factor is getting just enough processing power into a given space. For example, portable glucose meters are about the size and shape of a PDA. In the case of implanted devices, such as cardiac pacemakers, neurostimulators for treating central nervous system disorders, and hearing aids, advances in semiconductors have led to significant size reductions, enabling less intrusive placement of these devices.

For example, advances in packaging technologies and methodologies for small footprint devices have improved such that miniaturization is not only possible, but cost effective while maintaining reliability. For example, chip-scale packaging combines the size and electrical performance of bare die assembly with the reliability of encapsulated devices. With some chip-scale alternatives, the semiconductor package has been reduced to the dimensions of the die inside, making it ideal for size-sensitive medical applications.

Single-chip and flash-based FPGAs offer increased reliability due to a reduction in the number of components used on the board. The integration of diverse functions into a single mixed-signal FPGA also reduces component count. The removal of these devices also minimizes board space and ultimately, the form factor for the end application.

Low-Power

In an implanted device, the benefit of minimal power consumption, minimal heat dissipation, and extended battery life are clear. As electronic components get smaller, medical devices that were once fixed are portable, making them sensitive to power consumption. Ultrasonic imagers, once stationary due to their size and weight, are now available in laptop like form factor, and handheld sizes that weigh from three to seven pounds. Automatic external defibrillators are now commonplace. Portable oxygen concentrators extract oxygen from the air and can be carried over the shoulder like a purse. All of these devices are enabled by ultra low-power consumption and extended battery life.

The design considerations regarding power consumption can be complicated. For designers of portable medical electronics, selecting chips on advanced process geometries means not only the ability to achieve higher levels of integration with a smaller overall die size, but also increased leakage and increased static power. Because of the complexity of medical devices, power consumption in standby mode becomes more critical, making low leakage a design requirement. As a result, a mainstream process technology, such as 130 nm with lower leakage is often more desirable than an aggressive technology node that increases standby or static power consumption.

FPGA technology is increasingly utilized in low-power applications, which makes achieving lower system power an increasingly important challenge. The various FPGA technologies have significantly different power profiles and these differences can have a profound impact on the overall system design and power budget.

The power profile of an FPGA is determined by the base technology of the interconnect element used. For example, nonvolatile flash-based FPGAs utilize a single flash cell to form their efficient interconnect. In comparison, SRAM-based FPGAs utilize a six-transistor, SRAM cell to perform the interconnection between routing lines and logic cells, resulting in higher static and dynamic power.

When evaluating the respective programmable technologies, there are five components to the FPGA power profile that must be considered: inrush current, configuration current, static power, dynamic power, and power during sleep or low-power mode. Unlike SRAM-based FPGAs, flash-based FPGAs have no power-up or configuration power components. They offer lower static and dynamic power consumption over a large temperature range and support low-power modes that allow further minimization of power consumption when the system is idle.

The industrys lowest power programable platform, Microsemi feature-rich 2 μW IGLOO® FPGAs can absorb additional glue logic and multiple functions into a single chip, thereby reducing bill-of-materials, board area, power consumption, and cost. With IGLOOs power saving Flash*Freeze mode, one of several power modes the IGLOO family offers to optimize power consumption, designers can tap the lowest power solution for portable medical applications—up to 1700 times lower than competing SRAM-based programmable solutions.

Home-Based Applications

Home-based applications have been used for testing and monitoring only. are expected to do much more. Next-generation medical applications are now communicating with each other or integrating several different medical devices into a single monolithic unit. For example most mainstream glucose meters now communicate wireless with the insulin pump to adjust the insulin. Advances in insulin pump devices have allowed periodic intelligent measurement of the patients glucose in addition to insulin injection based upon the glucose results. Often battery-powered, all of these feature-rich, home-based medical devices, such as home infusion pumps, digital ear thermometers, respiratory therapy products, and portable blood glucose, cholesterol, and blood pressure monitors, require low-power operation, small form factor, and high reliability.

Several functional blocks are common to most portable home-based applications, including bio-sensor(s); amplification and analog to digital conversion of the sensor input; power management, such as system power control and power sequencing; microcontrollers for low-power operation and control; and user interfaces and control for human machine interface (HMI) and display. Additional requirements may drive the need for interfaces to multiple storage standards, wired and wireless interfaces, and audio feedback or notification.

These devices may also require integrated functionality, such as data logging and wireless communications, while maintaining the same or lower power, footprint, and cost. For example, blood pressure meters are now benefiting from more extensive data logging features as well as communication ports for real-time sharing of information with the healthcare provider. Offering unprecedented integration, Microsemi single-chip, mixed-signal Fusion FPGAs can perform the system, power, and thermal management of home-based test and monitoring devices—from system power-down and power-up functions to data logging and temperature sensing.

Because of the clear need for low-power consumption and extended battery life in home-based devices, Microsemi 5 µW IGLOO FPGA with its ultra low-power Flash*Freeze mode is ideal. The ability to support multiple interface standards and needs makes reprogrammable FPGAs, like those from Microsemi, suitable for portable home-based medical electronics, offering the benefits of rapid development, fast time-to-market, and integration. In an insulin pump, for example, Microsemi IGLOO FPGAs can be used for HMI, display, communication, storage, and microcontroller functions. This leads to a quick validated design, which saves time, board space, and cost.

HMI and Miniature Motor Control

In next-generation portable home-based medical devices, keypads, light emitting diodes (LEDs) for backlight and display, touch screens, speakers, and miniature motors are becoming more commonplace. As a result, designers face several challenges, including redesigning for rapidly changing customizable HMI controller requirements, smaller form factor, reliability requirements, and the provision for improved battery life.

Designers of portable medical applications have relied on microcontrollers, ASSPs, or CPLDs to handle HMI and miniature motor control functions. Microcontrollers and ASSPs do not provide adequate flexibility and CPLDs do not offer the levels of integration or sophistication of FPGAs. Therefore, reprogrammable flash-based FPGAs, such as Microsemi feature-rich, ultra low-power IGLOO FPGAs, are best suited to serve as flexible HMI or miniature motor controllers.

Display

According to market analyst firm iSuppli, the small-to-medium display (sub-10 inches) is the fastest growing segment of the market. True enough, lower costs and ease of mass manufacturing have increased LCD panel demand in various home-based medical markets. As newer displays with enhanced capabilities and features are continuously being launched, designers are challenged to keep up with these new technologies while minimizing cost, size, and time to market. Microsemi low-power IGLOO FPGAs can address these challenges.

In portable devices, LCDs can consume up to 50 percent of the applications power budget, escalating the need for a power-efficient solution. To addres LCD display control within portable applications, a low-power, reprogrammable solution is required to adapt to evolving standards and technologies and deliver the desired power consumption, footprint, and time-to-market. Offering significantly lower power consumption and longer battery life than competitive programmable logic offerings, IGLOO FPGAs are well suited to this need.

Within 1 microsecond (µs), IGLOO devices easily enter and exit Flash*Freeze mode, and consume as little as 5 µW while retaining the contents of the system memory and data registers. As a result, the flash-based IGLOO FPGA can enable both the LCD panel and the controller to function in a power-saving mode with the LCD data and backlight disabled, representing significant battery savings for LCD applications.

Unlike the ASSP display controllers they can displace, Microsemi low-power IGLOO devices can be quickly reprogrammed to adapt and support a variety of LCD displays and changing display technologies, therefore enabling the easy migration between panels as necessary. Further, these feature-rich FPGAs can absorb additional glue logic and more complex LCD controls into a single chip, thereby reducing board area.

Storage

Storage technology has made tremendous progress in the last decade. The rapid advances and ready availability of small form factor flash storage devices are helping to drive the explosion of portable medical devices in the market place. Further, as the storage device market proliferates, with ever-changing protocols and interface standards, design teams are challenged to shrink design cycle times and yet create next-generation portable devices with additional features.

The implementation of each functional block in a medical device differ, depending on the feature demands of the application. Designers can choose from a myriad of sensors to capture and measure physical quantities such as time, temperature, pressure, brightness, positions, speed, PH, gas concentration, and levels of chemicals in the blood. These sensors transform the measurement into voltage, current, frequency, capacitance, or some other electrical quantity used for processing. Measured signals can be used by a microcontroller in real time or they can be stored in an electrically erasable programmable read-only memory (EEPROM) or flash memory, along with the measurement date and time for processing later. Ultra low-power FPGAs, such as Microsemi flash-based IGLOO devices, enable the implementation of a variety of storage functions without having to redesign the whole system based on changing storage interface requirements.

Microprocessor

Many medical devices, such as an insulin pump, are typically controlled by a microprocessor. These microprocessors perform various functions, such as processing data from bio-sensors, storing measurements, and analyzing results.

For these applications, designers often select a microprocessor with a rich instruction set and proven track record, ensuring reliable operation and maximizing the investment in code generation can be leveraged in the next-generation medical products.

ARM® Cortex®-M1 32-bit processor offers the optimal balance between size, cost, and low-power operation when used with Microsemi M1-enabled mixed-signal Fusion and low-power IGLOO FPGAs. Optimized for use in FPGAs, the ARM Cortex-M1 processor runs a subset of the classic Thumb®-2 instruction set, so existing Thumb code can be utilized without change.

Clinical Applications

From diagnostic lab equipment, drug delivery systems, automatic external defibrillators (AEDs), and hemodialysis machines, clinical medical devices are often microprocessor-based, electro-mechanical instruments that use a common set of building blocks: power control and temperature management; a user interface that includes a keypad, LCD monitor, and audio control; flash or EEPROM for data logging; and device interfaces for connections to other machines, among others. Though there are many similarities, individual medical applications are highly use-specific and often very complex. An EKG machine cannot remove waste products from the blood and a hemodialysis machine cannot diagnose heart disease.

In addition to their core building block elements, clinical medical devices also include unique functional blocks to complete their task. Ultrasound machines include a transducer probe and transducer pulse controls, but hemodialysis machines use a dialyzer. Changing features and requirements, complex functionality in a small footprint, low-power, high accuracy, and reliable operation make clinical medical devices an excellent market for reprogrammable nonvolatile semiconductor technologies.

With varying densities, performance, and features, Microsemi low-power, flash-based FPGAs are also suitable for clinical equipment applications. As an example, Microsemi flash-based ProASIC3 FPGAs have been used in portable patient monitoring systems due to the inherent ultra low-power, performance, reliability, and enhanced security they offer.

Single-chip, flash-based mixed-signal FPGAs offer integrated analog capabilities, flash memory, FPGA fabric, and often an embedded industry-standard microprocessor. As a result, they can perform the system, power, and thermal management and control functions of clinical medical devices—from system power-down or power-up functions and data logging to temperature and voltage sensing. Flash-based mixed-signal FPGAs are uniquely suited to clinical medical applications because of their high levels of integration, intelligent power and system management capabilities, small footprint, and high reliability. These advantages help clinical medical applications meet battery specifications, reduce design footprints, minimize heat dissipation, and ensure reliable operation of these shrinking medical applications.

The mixed-signal FPGA enables several discrete components to be removed automatically from the system board and integrated into a single, highly reliable device. These include the flash memory, pulse width modulator (PWM), discrete analog ICs, clock sources, and real-time clocks. Because flash-based FPGAs store their configuration information in on-chip flash cells, no external configuration data needs to be loaded at system power-up, unlike SRAM-based FPGAs. Therefore, these flash-based, mixed-signal FPGAs do not require separate system configuration components, such as EEPROMs or microcontrollers, to load device configuration data at every system power-up. This reduces system costs, board space requirements, and increases security and system reliability for medical devices.

Accurately measuring the temperature and controlling power of the system can increase cost and increase the reliability of the machine, thereby increasing the life of the product and of the patient. The analog circuitry of mixed-signal FPGAs allows these critical features to be easily integrated and implemented.

Another suitable clinical application for mixed-signal FPGAs is robotic surgery. Set to become the new standard in surgical procedures, robotic surgery has substantially simplified complex procedures as well as dramatically reduced patient recovery time and overall cost. These technologies can use digital cameras to deliver high-resolution images and the depth perception that a surgeon needs to accurately perform minimally invasive surgery.

Imaging Applications

Some medical imaging applications remain tethered to the wall, ultrasound machines have benefited the most from the markets trends toward miniaturization and portability. Ultrasound systems weighed hundreds of pounds and were large and expensive. In the past it was more practical to bring the bed-ridden patient, bed and all, to the ultrasound machine rather than vice versa. Only in the case of the critically ill patients who could not be moved was the ultrasound system maneuvered, with difficulty, to the patient.

Over time, portable ultrasound technologies emerged, but achieving image quality on par with the larger devices proved to be a challenge, as was achieving the battery life, high power computing, and efficient memory access that these applications require.

High-quality handheld systems enable routine bedside scanning. This has not only improved patient access to safe, noninvasive diagnostic medicine, but has reduced the time and costs associated with such diagnostics.

Flash-based, low-power and mixed-signal FPGAs can be utilized in data acquisition cards for filtering and data alignment, control cards, data consolidation cards for data buffering or FIFO and alignment as well as many system management and control functions.

Conclusion

Increasing healthcare costs, the prevalence of chronic diseases, and aging populations are creating tremendous demand for affordable, accessible, and reliable medical devices to improve global healthcare. In response, two trends have emerged for many types of medical devices: miniaturization and portability.

Medical home-based, clinical and imaging devices are often very complex and highly use-specific. Designers of shrinking medical applications also face rapidly changing features and requirements as well as demand for complex functionality in a small footprint, low-power, high accuracy, and reliable operation, making flexibility, integration, and reprogrammability paramount. As a result, the medical market is an excellent market for nonvolatile programmable semiconductor technologies, such as Microsemi flash-based mixed-signal and low-power FPGAs.

Microsemi Power Matters.™

Microsemi Corporate Headquarters
One Enterprise, Aliso Viejo,
CA 92656 USA

Within the USA: +1 (800) 713-4113
Outside the USA: +1 (949) 380-6100
Sales: +1 (949) 380-6136
Fax: +1 (949) 215-4996

E-mail: sales.support@microsemi.com

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