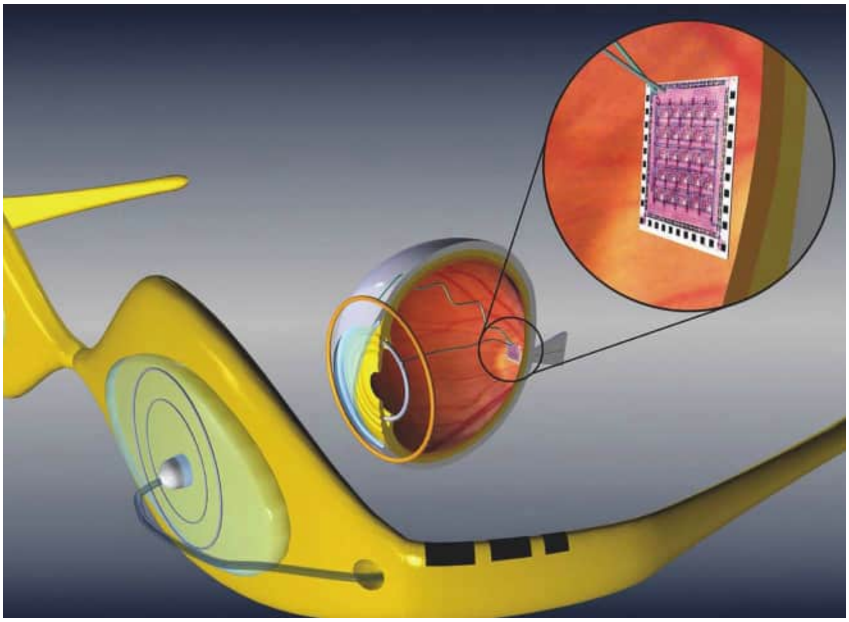

Figure 1 The artificial eye performs digital processing on data that a digital camera captures and passes the processed results to the patient through an electrode implanted directly on the patient's retina (courtesy Biomimetic Micro-Electronic Systems at the University of Southern California).

BY ROBERT CRAVOTTA • TECHNICAL EDITOR

INTERFACING electronics to people

ELECTRONIC EMBEDDED SYSTEMS CONTINUE TO FIND THEIR WAY INTO MORE MEDICAL SYSTEMS.

As electronic embedded systems are finding their way into and replacing more mechanical-control systems, it might reasonable to expect to see them finding their way into organic systems, such as the human body. Indeed, electronic embedded systems are interfacing with the human body in more ways each day to perform a variety of functions ranging from health monitoring, managing and maintaining the function of systems such as the heart, replacing failed organs by controlling the insertion of drugs or enzymes into the body, and even restoring the use of limbs and senses. In some cases, these capabilities have been around for decades, and the evolution of the electronics is reducing the cost of these systems as well as improving the reliability and life-cycle replacement of these systems. In other cases, these capabilities are emerging as possibilities in the lab but requiring more refinement to become practical in the real world.

In each of these cases, the electronic systems more intimately interface with the patient's body than they did previously. Some of the ways to interface with the body are intrusive, such as implantable devices, which spend their entire operational life within the body of the patient. The heart pacemaker is a common example of an implantable device. Devices that patients can swallow are emerging platforms for diagnostics and therapeutic procedures. Insulin- and drug-delivery pumps are intrusive systems that often comprise components that reside internally and externally to the patient; these systems can deliver precise amounts of insulin or drugs. A growing market is emerging for implantable neurostimulation, or spinal-cord-stimulation, devices with control units outside the patient's body for the treatment of chronic pain or for managing epileptic seizures.

In addition to intrusive systems with implantable components, electronics subsystems are also enabling medical practitioners and some devices to perform their functions less intrusively than previously. Laparoscopic surgery is an area in which electronics are enabling surgeons to perform procedures in a minimally invasive fashion that results in less stress on a patient's body (**Reference 1**). A number of companies are working on noninvasive glucometers that would enable continuous monitoring of blood-glucose levels; this emerging type of device allows patients to measure their

AT A GLANCE

- Medical-equipment designs are incorporating electronic subsystems into more devices.
- Interfacing electronics with the human body presents higher technical hurdles for designers to overcome.
- Advances in medical equipment are enabling more autonomous or semiautonomous systems.
- The human body may represent the next focus and challenge of network standards.

blood-glucose levels without pricking their fingers to extract blood for testing. The noninvasive glucometers in development are attempting to use a variety of approaches to measure blood-glucose levels, such as by shining light on the skin and detecting the infrared absorption, using radio-wave impedance to measure the absorption of electromagnetic waves through the skin and blood, or using reverse iontophoresis to draw interstitial fluid through virtually intact skin.

A HIGHER HURDLE

Embedded systems for use in medical and health-care applications are subject to a set of regulatory oversights that industrial and commercial applications need not contend with. The extent that these systems must satisfy regulatory requirements correlates with the roles these systems take on. Life-sustaining systems face more rigorous control, whereas diagnostic and monitoring systems undergo less stringent requirements to reach the market. According to Mir Imran, chairman of several companies, including InCube Laboratories and Guidant, "Many electronic medical systems are under development that the public is not aware of because they still need to complete the regulatory process."

The regulatory requirements for electronic medical systems do not currently directly flow down to the semiconductor providers; rather, the burden falls squarely on the shoulders of the end-product integrator. According to a number of semiconductor providers, teams developing medical systems, especially implantable ones, often ask about smaller packages, higher device and memory reliability, high-resolution analog-to-digital-conversion capability, battery monitoring, and lower power consumption.

Low-power-consumption concerns also often require the system to support multiple low-power or sleep modes because the systems may not always be fully active. Another concern of end-system integrators is the shelf life of the device before implanting it in a patient, because the power supply must reside in a sealed casing and physicians cannot place it into the casing at the time of implantation. A significant time lapse may occur between when a vendor manufactures a system and a physician implants it in a patient.

Other concerns of design teams to meet and maintain regulatory certification include how long a semiconductor manufacturer will provide and support a component and the company's commitment to maintaining pin-compatible devices. If the team needs to recertify the system, the cost of the recertification process may become unjustifiable. A design team may do an end-of-life purchase if the supplier places a component on end-of-life status; in some cases, the volume of these purchases are thousands rather than millions of units. Changes in the device's pins would require a recertification effort, so pin-compatible devices are essential.

Implantable systems generally represent market volumes much smaller than the market volumes for consumer multimedia applications. Whereas the consumer markets account for millions of units, implantable medical systems may account for hundreds or thousands of units. Gene Frantz, technical fellow at Texas Instruments, points out, "Some of these developers are doing the early work on three important challenges facing implantable electronics in the human body: how to operate the system on body heat, how to not boil the water surrounding the device, and how to survive the corrosion from existing in a salt-water environment." Although the electronics can reside in a hermetically sealed casing, the sensors must directly interface with the tissue and the salt-water environment within the patient's body.

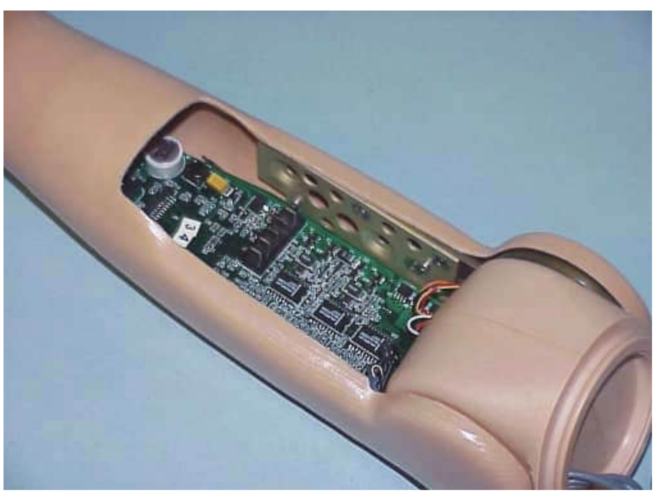

Figure 2 The Boston Digital Arm prosthetic arm from Liberating Technologies acts as a platform and central controller for various add-on peripherals, such as a wrist, a hand, a gripper, and shoulder actuators (courtesy Rehabilitation Institute of Chicago).

Processors that can operate on the power they harvest from deltas in body heat may emerge not too far in the future, according to several semiconductor companies. A 1° temperature difference can supply a system with 2 μW of power. The impact of crossing this power threshold is that an electronic embedded system would have virtually unlimited battery power because it could always acquire the power it required from its environment—in this case, a human body. This feature could enable implantable control systems to remain in a patient's body for longer than the few to 10 years of current implantable sys-

Figure 3 The advanced prosthetic device acting as Jesse Sullivan's left arm receives inputs rerouted from the nerves in his chest and the muscle activity that myoelectrode sensors detect (courtesy Rehabilitation Institute of Chicago).

tems. Body movement is another possible source of power for these future low-power systems. A contemporary approach to extending the battery life of implanted systems is to use rechargeable batteries or to place the power supply outside the body. In the case of implantable power systems, this approach often means the patient must periodically remain with a charging station for some time. The benefit the system provides for the patient offsets the inconvenience of being periodically tethered to a charging station. Another method researchers are exploring for recharging implanted batteries involves trickle-charge methods.

Heat dissipation is a significant concern for high-density computing systems, such as central-office communication equipment or server farms. It is also a concern for systems that are implanted in parts of the body in which the circulation of fluid is insufficient to remove the heat that the implanted system generates, especially if the system is usually operating, versus dormant. An example of this type of system is a permanent, microelectronic, retinal implant. The implant is the work of Mark S Humayun, MD, PhD, and his research team at the Biomimetic MicroElectronic Systems Engineering Research Center at the University of Southern California (Los Angeles).

The retinal-implant system attempts to restore partial sight to patients who have lost vision due to age-related macular degeneration or retinitis pigmentosa. The research has focused on patients that could once see rather than patients who were born blind. The Model 1 system combines a small camera and a DSP to transmit images to an implanted 4×5-mm retina chip with 16 electrodes in a 4×4 configuration. The Model 2 version of the system is 20% of the original model's size and supports 60 electrodes. The Model 3 version under development will have 1000 electrodes and a special chip coating that will allow the chip to conform to the shape and movement of the eye (**Figure 1**).

CLOSED-LOOP CONTROL

Closed-loop control is an essential capability for many systems performing continuous sampling and control. Narrowly defined, life-sustaining systems, such as implanted heart defibrillators and pacemakers, autonomously sense the environment and act on the data they receive to perform their function. For many systems today, the loop is not autonomously closed; rather, the patient closes the loop. In devices such as insulin pumps, the patient must be aware of and explicitly control how the insulin pump operates. Factors such as the patient's intake of carbohydrates; amount of stress; amount of physical exertion, such as engaging in sports; and amount of rest affect the timing and dosing of insulin. Companies such as Medtronic MiniMed are investigating how to produce an artificial pancreas by incorporating the insulin pump into an autonomous, closed-loop system that could continuously monitor blood-glucose levels.

The prosthetics market, though relatively small, will likely garner much attention when researchers make advances. The recent stories about Jesse Sullivan, "the world's first bionic man," are one example of this technology. In May 2001, working as a high-power lineman, the 54-year-old Sullivan had a life-changing event: He was electrocuted so severely that doctors had to amputate both of his arms (**Reference 2**). Todd Kuiken, MD,

THE MAGIC OF THE BIONIC-MAN SETUP IS THE MYOELECTRODE INTERFACE THAT SITS DIRECTLY ON THE SKIN AND MEASURES MUSCLE CONTRACTIONS.

PhD, and other researchers at the Rehabilitation Institute of Chicago developed a prosthetic-arm and -hand assembly for Sullivan. (You can watch a video of Sullivan demonstrating the use of his arm at the Web version of this article at www.edn.com/060302df1.) The technology represents the effort of one group of people, and the interface to Sullivan's nervous system represents another team's efforts to provide a glimpse of where prosthetics could be heading. However, even though the prosthetic arm is under Sullivan's control, he currently must use his eyes to conscientiously and explicitly close the system's control loop; no other feedback mechanism to the controller yet exists.

MORE AT EDN.COM

Go to www.edn.com/060302df1 for a video of "bionic man" Jesse Sullivan demonstrating the use of his prosthetic arm.

For more on electronics in health care, go to www.edn.com/article/CA402151.

The prosthetic arm is the Boston Digital Arm from Liberating Technologies (**Figure 2**). It is a platform that provides an elbow to the patient, but it can also act as the controller for additional prosthetic devices, such as wrists, hands, grippers, and shoulder-lock actuators. Its software enables it to operate with a variety of input devices, including touchpads, servo controls, switches, and myoelectrodes. Myoelectrodes pick up the signals from muscle contractions, whereas movement of a residual limb can actuate the touchpads, servo transducers, and switches. The software can pass through the inputs from these devices to the peripherals, or it can directly control the peripherals based on these inputs through attached PWM interfaces. As part of the evolution toward a closed-loop system, researchers are developing an analogue of spinal loops.

The magic of the bionic-man setup is the myoelectrode interface that sits directly on the skin and measures muscle contractions. Sullivan basically uses the same nerve signals he used to control his arm and hand before his accident. In general, the muscle contractions that control the arm are those that would normally occur when he tries to move a set of muscles in the arm or the hand. After Sullivan's accident, he no longer had muscles to contract, so researchers moved the nerves to muscles on its chest (**Figure 3**). By inferring his intent from the muscle contractions, the prosthetic arm, wrist, and hand systems can respond appropriately.

COMMUNICATION

Our world is an increasingly connected one, and personal medical devices are not exempt from this trend. The human body is possibly the next great challenge for networking standards. As more medical devices enter the home, the need increases to reduce the cost of medical care by transmitting relevant data to the doctor's office without a physical visit. The medical standards for network connectivity differ from those commercially available to homes. To support connectivity in home monitoring systems, design teams are exploring commercially available interfaces, including USB connections. Medical devices that support USB connection may also help push and increase the robustness of the wireless-USB standard.

Wireless communication with implanted devices is a growing capability, especially because it avoids the need for a physical interface implanted in the patient's skin. Home-based RF communication within the MICS (Medical Implant Communication Service) medical-communications band of 402 to 405 MHz for implanted medical devices is replacing inductive communication because it can help a patient avoid an office visit to communicate with the implanted device. The Bluetooth technology is emerging as a future method for wireless connection to implanted devices, especially to create a connection to a cell phone to contact the doctor's office or communicate with the patient.

The data-communication requirements for implanted devices typically could support data rates of approximately 100 kHz. The low data rates help these systems minimize both the patient's body's absorption of the data signals and data-communication events to conserve power. Typically, the systems run at low data rates with higher data rates for burst communications. The communication may involve dumping collected data for analysis by a physician and for patches or parameter updates for the implanted-device controller.

Other concerns for designers of electronic medical systems are how to deal with technological obsolescence and how to upgrade or change the systems. The rate of improvement for many of these systems is so significant that the devices every couple of years become smaller and more effective than the earlier versions. One way of handling the upgrade issue is to use software-programmable control systems. Another way is to place the controller outside the patient and have it wirelessly communicate with the sensors, pumps, and motors that reside within the patient.

The cell phone presents an interesting opportunity for convergence with future medical devices. For example, it could act as the gateway between the medical device and the doctor's office. It could also act as a user terminal to directly collect or deliver feedback to or from the patient. However, the most profound convergence opportunity of the cell phone stems from the fact that it is currently the closest thing to a universal personal controller that everyone carries with or keeps near themselves, virtually all the time. This feature makes the cell phone a possible candidate as a form factor for external controllers for semiautonomous implanted systems. As implanted systems become more common and less costly, it is not inconceivable to consider multiple such systems in patients. The cell-phone form factor could act as the master controller for such patients to avoid interference or anomalous interactions between multiple implanted devices. EDN

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