techtrends *By Robert Cravotta, Technical Editor*

Positive prognosis

ELECTRONICS IS TRANSFORMING HEALTH CARE, MAKING DIAGNOSTICS, MONITORING, AND MEDICAL PROCEDURES MORE DISTRIBUTED.

THE INCREASING incorporation of electronics into medical-equipment designs is providing the impetus for the miniaturization and increasing data-collection and -analysis capabilities of medical devices. The opportunity for new medical tools, such as for diagnostics or treatment, grows in correlation with increases in real-time data-processing capacity, decreases in device power consumption, and shrinkages in packages that result from component-integration efforts. As more medical data becomes digital, the opportunities for making that data ubiquitously accessible become more compelling.

New medical tools are enabling the medical community to more effectively shift its focus from treating problems to early diagnosis and prevention. Increasing real-time data-processing capacities and shrinking devices are impacting medical equipment not just in hospital and laboratory environments, but also in doctors' offices and patients' homes. Hospital and laboratory environments include large-scale and leading-edge equipment, including diagnostic-imaging systems and systems for minimally invasive procedures that can provide the highest precision diagnosis and patient care. Doctor-office and patient medical equipment is usually the result of scaling down and miniaturizing hospital or laboratory procedures.

Diagnostic-imaging systems produce high-quality images of the inside of the human body; they represent a significant opportunity for semiconductor manufacturers and engineering companies to deliver improved digital-image processing. MRI (magnetic-resonance imaging) uses strong magnetic and radio-frequency waves to produce images of internal organs and structures. MRI has advanced beyond a tomographic-imaging technique, which produces images as a thin slice through the human body to a volume imaging technique. Other diagnostic imaging systems include CT (computed tomography), which uses a computer to enhance an X-ray procedure, and nuclear/PET (positron-emission tomography), which measures the concentrations of positron-emitting radioisotopes within a patient's tissues. Diagnostic-imaging systems need increasing computing capacity to apply real-time and postprocessing algorithms that enable radiologists to better visualize the images and extract more relevant information for identifying and diagnosing pathology.

The increasing set of available diagnostic images represents a growing image-data-overload challenge. Radiologists not only have more images to examine, which represents storage and access challenges, but also can extract more information from the images, which represents an image-analysis challenge. The ability to extract more information from a set of image data is taking analysis beyond the limits of human capacity. An unassisted viewer would be unable to perceive some abnormalities, which require exposure through medical-image processing to be observable.

Permanent storage of a patient's imaging data enables multiple people to examine the data in different contexts, possibly with different interpretations of the data. Medical images differ from images you acquire and use in other fields. They demand accuracy and urgent delivery, are subject to significant variability between individuals, and carry a potentially high cost of error if they lead to incorrect conclusions. It is difficult in a timely fashion to transfer undigitized patient-imaging data, such as film, to multiple people, especially if those people are not at the same site. As medical-image-processing algorithms continue to evolve, it may be possible to discern new and important information from a patient's imaging-data archive—if the resolution and precision of the archived images is sufficient. The approaches to data overload in other application may not apply to the medical environment.

Data compression minimizes the storage requirements for medical images. Lossless-compression methods allow you to perfectly reconstruct an image, but the storage requirements for a typical medical image will reduce 2-to-1 to only 4-to-1. Lossy-compression techniques can achieve higher compression ratios, but they prevent you from perfectly reproducing the original image. Debate is ongoing in the medical community about whether using lossy-compression techniques for medical-image archiving is reasonable. However, shrinking the image-storage size does not solve the storage and retrieval challenge if the volume of new imaging data grows faster than storage-space and network-transfer capacities.

AT A GLANCE

▷ Medicine is shifting its focus to early diagnosis and prevention.

▷ Medical-data overload is a growing problem. Data and image processing can help.

▷ The trend is for medical equipment to support noninvasive and minimally invasive procedures.

▷ Connectivity and data sharing are emerging requirements driving change in new and legacy systems.

MINIMIZING INVASIVENESS

The list of medical-diagnostic, surgical, and assistive tasks that can employ noninvasive and minimally invasive techniques, such as endoscopy, laparoscopy, and robotic-assisted surgery, is growing. However, using minimally invasive medical techniques is not a new idea (see **sidebar** "Minimally invasive techniques"). The written records of the ancient Greek physician Hippocrates describe a rectal examination using a speculum, a medical instrument that dilates a bodily passage or cavity, so you can examine the interior. The descriptions in these records indicate that Hippocrates used minimally invasive approaches to diagnose and treat life-threatening conditions.

If you can perform a medical procedure noninvasively—that is, without exposing the patient to a risk of infection—you may be able to greatly expand the applicability of that procedure. This opportunity is the driving force behind emerging noninvasive diagnostic-medical-equipment designs and is the avenue that many semiconductor- and engineering-design businesses are using to enter the medical environment. Noninvasive systems are not subject to the same stringent safety requirements as equipment that supports invasive procedures.

Glucometers, both discrete and continuously sampling systems, are examples of minimally invasive systems that exist for use in a patient's home. Noninvasive glucometers are still under development, but it is not entirely a technological challenge that has kept them out of the market. The companies marketing glucometers make their money from the test strips and lancets, and the noninvasive glucometers require no analogous consumables, because they read glucose levels with a beam of light.

By properly defining the consumables, you can create a business model that is better for both users and providers. A hearing aid with a permanent battery is an example of a consumable that benefits both the user and the provider (**Reference 1**). By making the battery permanent, you make the whole hearing aid the consumable. But doing so greatly simplifies the mechanical design, allows you to increase the size of the microphone, and lowers the cost of the device to 5% of a permanent hearing aid, and it eliminates the difficult task for the user of changing the tiny batteries.

For many noninvasive designs, delivering the smallest device—one that you can use in a doctor's office or even in a patient's home—is more important than lowering the device's cost. Because it enables you to choose smaller batteries, a design with low power consumption is important to battery-powered designs that must fit within size, height, width, thickness, weight, and environmental-ruggedness constraints. Size and weight are critical for continuously monitoring systems, because patients wear them.

WEARABLE SENSORS

Wearable sensors are attracting more interest because of the need to be able to monitor patients over long periods, especially when a patient's condition includes a risk that may require immediate intervention. The main motivations for wearable sensors are that they can measure physiological parameters in a time frame that is otherwise impossible in a hospital, laboratory, or office environment; support mobility; and encourage continuous use. Wearable sensors can better capture significant rare events. They can measure physiological responses across a range of activities, including sleep and rest. The disadvantages of wearable sensors include a demand for high durability and the fact that they must satisfy severe constraints in size, form factor, power consumption, processing power, and communication interfaces.

Wearable and continuously monitoring systems enable a more accurate analysis of a person's health than analyzing data that you collect only when the patient visits a hospital or a doctor's office. As life expectancy continues to increase, and more chronic diseases surface, home-based or continuous monitoring may provide early indications of treatable conditions. Candidates for home-based monitoring require automated procedures simple enough that patients can correctly perform them. The medical-engineering community has proposed several designs for noninvasive, continuously monitoring systems, such as ring, wrist, patch, and shirt sensors.

A ring sensor has the most stringent size and weight constraints, but it would provide the potential for long-term wearability and reliable contact with the patient's skin. Downloading data from a ring sensor may require a wired connection, because the ring sensor would have a limited power supply. The size of the ring sensor would depend on the individual. Because a wrist sensor can be slightly larger and heavier than a ring sensor, it may be able to accommodate a wireless download of the monitoring data. A wrist sensor can also more easily accommodate various wrist sizes, but incorporating sensors that require direct skin contact may be more complicated.

A patch sensor, comparable in size to an ordinary adhesive bandage, expands the options for where on the patient's body the monitoring device could reside, but its softer, more flexible casing could present safety challenges to housing the power supply in the event of an impact on the casing. It may also be impossible to leave a patch sensor in one place for many days or weeks. A wearable shirt-sensor platform would provide the loosest constraints on size and weight. The power supply and data interface could reside in a belt-wearable container. You could then wear the shirt sensor under another shirt or jacket. However, you would need to be able to remove and clean the shirt sensor, or replacement costs could become prohibitive.

Although a wireless data interface would be preferable for these devices, it is unclear whether the devices should use medical or commercial standards. The advantages of a dedicated channel for

MINIMALLY INVASIVE TECHNIQUES

Many current medical innovations are enabling noninvasive and minimally invasive medical-diagnostic and -treatment techniques, such as endoscopy and laparoscopy, for a rapidly growing list of medical-diagnostic and surgical tasks. The term "endoscopy" derives from the Greek words "endo," meaning "inside," and "skopeein," meaning "to see."

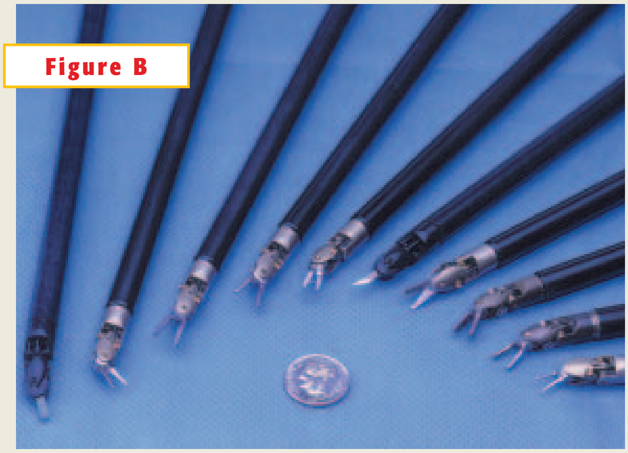
Medical endoscopy relies on an endoscope, a long and slender tool that enables you to visually inspect the interior of a person's body in a minimally invasive fashion. You may insert an endoscope into a person's body via orifices or small cuts as an alternative to larger cuts that would allow you to directly view the interior of a person's body.

Major challenges for endoscopy are how to provide bright enough light to the interior area and how to route the reflected light back to the viewer. Early lighting attempts include focusing sunlight through a flask of water, using candlelight, and placing mirrors along the endoscope tubing to better direct the light. In 1853, Antoine Jean Desormeaux, a French surgeon, successfully extended German physician Philip Bozzini's Lichtleiter—a light conductor initially intended to see inside corpses—to perform endoscopy on a patient. He later improved the lighting by burning alcohol and turpentine, which produce a brighter and more condensable beam of light than a candle. The

Figure A

Dual-lens three-chip digital cameras provide a 3-D, high-resolution view of the inside of the patient during minimally invasive surgery (courtesy Intuitive Surgical).

Figure B



A selection of specialized instruments that can fit through 1-cm ports enable surgeons to precisely perform complex laparoscopic manipulations (courtesy Intuitive Surgical).

proprietary wireless medical communications to a medical-equipment provider are significant; however, using the medical standard would mean higher implementation costs to the user, and the network would support no other activity. Using a commercial standard would lower the implementation cost to use these devices outside a hospital, but more uncertainty in the data link would occur because the medical device shares the network with nonmedical devices.

Some wearable-sensor applications may only collect data and periodically download it to a server. Other applications may require the sensor device to respond in real time to an anomaly. In such cases, it is essential that the device recognize abnormal conditions and minimize false alarms. Calibration for such systems is challenging at best when you consider that readings can vary not only among individuals, but also among activity levels and individuals' overall health. Postprocessing the sensor readings that you then feed back to the sensor as new algorithms may improve usability.

CONNECTIVITY AND MIGRATION

Medical-equipment-network awareness and connectivity are enabling location transparency for collecting and accessing patient data. A physician must be able to access test results, regardless of whether the testing takes place in a doctor's office or in an emergency room. Connectivity is enabling physicians to use patient data from any location and to collaborate with other specialists without being in one location. The assumption is that all of the patient's data is electronically stored. Even if all of the data is electronically stored and accessible on a network, a challenge of how to view the data arises. Data from one medical device may be in a different form from data from another medical device. Medical-equipment manufacturers and medical practitioners need to coordinate how to collect, store, and transfer data; how to apply computer analysis; and how to display a patient's data.

Patient data may be textual, 2-D images, or even 3-D-image representations with color and motion. Adopting a markup language may provide a usable approach. This language, like the language that Internet pages use, describes to the displaying device what needs to be displayed. It would help facilitate the use of desktop and portable workstations as well as handheld, PDA-like devices, which all have different interface and display capabilities, for data collection and display.

New medical designs can plan for and incorporate the evolving storage, connectivity, and display issues, but it may be difficult to migrate legacy medical systems to accommodate these issues. Consider doing an incremental migration of your legacy-software design to a flexible and connection-aware model to lower your risk. Begin your software-migration planning by mapping your software to a

success of this tool earned Desormeaux the historical reputation of being the "father of endoscopy."

The advent of the light bulb further improved the lighting challenge, but the introduction of fiber optics into the endoscope enabled brighter lighting and better viewing quality. An endoscope used two sets of fiber bundles, one for transporting light inside, and one for transporting the reflected light back to the viewer. Lighting and optic quality continue to be areas of significant improvement in modern endoscopy. In 1983, endoscope manufacturers for the first time replaced the return fiber bundle with a digital camera and wire. The digital image data from the camera enabled physicians to display the captured images on a monitor and manipulate the image with a video processor.

Today's endoscopes are flexible tubes that vary from 3 to 15 mm in diameter and have user-side controls to direct the direction and angle of their camera ends. Continuing electronics miniaturization now allows endoscopes to use dual-lens digital cameras that deliver clearer, higher resolution images with up to 15-times-3-D magnification to support minimally invasive surgery, such as laparoscopic surgery (**Figure A**). The dual-lens system provides the depth perception that a surgeon needs to accurately manipulate delicate tissue layers.

Laparoscopic surgery takes place under a patient's skin, through several small cuts, rather than through one larger cut. The size of the cuts, approximately 1 cm, is driven by the size of the tools that the physician must insert into the patient (**Figure B**). Smaller cuts translate into less pain, less risk of infection, less scarring, and a faster recovery time. Using an endoscope during laparoscopic surgery can provide the surgeon with better visibility than can peering through a 4-in. cut in the patient, especially with small patients, such as children. Surgeons with the appropriate experience can perform laparoscopic surgeries on children that weigh as little as 2 kg (4.2 lbs).

Like endoscopy, electronic advancements are contributing directly to laparoscopic surgery's evolution. Laparoscopic surgical robotics, such as Intuitive Surgical's da Vinci and Computer Motion's Zeus, are examples of newer technology that the laparoscopic surgical community is exploring. The first use of a robotic arm in a minimally invasive surgery was in 1994; the arm more safely held the endoscope and reduced the need for a skilled camera operator. In 2000, surgical robotics supported minimally invasive heart-valve repair as part of a US Food and Drug Administration-approved Phase I clinical study.

Robotic-assisted surgery is a learned skilled with a steep learning curve. As a surgeon develops proficiency with the robotics, procedures can take less time than analogous standard surgeries. Robotic-assisted surgery can filter out a surgeon's hand tremors, facilitating steadier motions and incisions. It also allows surgeons to sit at a control console to manually manipulate the tools rather than stand directly over patients, which helps reduce surgeon fatigue on longer, more complex procedures. Robotic-assisted surgery also enables surgeons to remotely participate in procedures—an ability that is especially valuable for procedures that only a few specialists can perform.

Aside from the learning curve to become proficient with a robotic system, a significant detractor for robotic-assisted surgery is that there is no tactile feedback when operating the equipment. Being able to feel the difference between normal and cancerous tissue can be helpful. Development work is under way to provide this feedback in the future.

new set of architectural components. If the migration would require you to split large and complex components, it may be better for you to rebuild those components from scratch.

Make sure that each component in your new architecture uses a consistent mechanism to implement common operations or services, such as intracomponent communication and synchronization, data and event logging, and error handling. As you incrementally migrate your legacy system, be sure to provide tools or methods so that your customers can maintain backward compatibility with their patient data and medical devices. Use software wrappers with well-defined and consistently implemented APIs to facilitate an incremental migration.

Emerging and evolving medical equipment is using more embedded processing to enable a shift in focus to early diagnosis, prevention, and minimally invasive procedures. Aggressive efforts to miniaturize through device integration are helping to bring more medical procedures into patients' homes. Connectivity and data sharing among medical equipment and locations are key emerging capabilities, so make sure your hardware and software architectures are flexible enough to accommodate them, or you may be forced to play catch-up with your competitors through an architectural migration.□

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