Guest Editors’ Introduction

Computer-Based Medical Systems

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To those involved with their development, computer-based medical systems offer unique professional rewards because their application can directly benefit the well-being of mankind.

Imagine for a moment the enormous satisfaction of watching a computer-based heart-lung machine you helped develop sustain the life of a 40-year-old man whose heart is stopped during open-chest surgery. With the machine’s aid, the surgical team is extending this individual’s productive life. The relationship the perfusionist (the machine’s operator) has with the machine is very personal — almost spiritual. Her professional role depends on the machine’s performance, since its function literally means the difference between life or death to the patient.

No one in the operating room thinks about the real-time performance of nine on-board processors and the thousands of lines of C code within the machine — it’s simply taken for granted that the machine will work. Yet, millions of dollars and many man-years of effort were applied to making sure the machine would work as the perfusionist, the thoracic surgeon, and, most importantly, the patient require.

Computer-based medical systems fall into two general categories. Like the heart-lung machine, they can be hardware-based systems with embedded computers, or they can be software-based systems that require advanced PCs or mainframes for their computational or information management power. The first two articles in this issue are examples of the former; the remaining articles deal with the latter.

Hardware-based systems. Manufacturers of hardware-based systems face special commercialization challenges compared to the providers of software-based systems.

Today’s complex medical device designs can have upwards of 20 processors and 400,000 lines of C++ code to perform functions that discrete component designs performed 10 years ago. Demonstrating
that the system performs as intended is often difficult.

For example, in developing a cochlear implant in which the processor encodes analog voltages to digital stimuli for direct nerve stimulation, no amount of bench testing or animal testing can predict how well a human will hear with this bioelectronic device. The only way to determine the device's success is to surgically implant it. In contrast, complex systems like nuclear therapy machines must be developed with validation as a critical design requirement to prevent unusual operator inputs from creating mega-overdoses to the patient (which has happened).

As Table 1 shows, medical devices can be characterized by function as controllers, information managers, or diagnostic tools. Especially to manufacturers of life-support systems, quality assurance is critical. It is

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**Table 1.** Computer-based medical systems categorized as controllers, information managers, or diagnostic tools.

<table>
<thead>
<tr>
<th>Controllers</th>
<th>Information Managers</th>
<th>Diagnostic Tools</th>
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<tbody>
<tr>
<td>Fault tolerant</td>
<td>Patient records</td>
<td>Clinical lab equipment</td>
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<td>Total artificial hearts</td>
<td>Network/communication</td>
<td>Blood pressure machines</td>
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<td>Heart-lung machines</td>
<td>Interfaces</td>
<td>Apnea monitors</td>
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<td>Fail safe:</td>
<td>Neural networks</td>
<td>Magnetic resonance imaging</td>
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<td>Drug infusion</td>
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<td>Computerized tomography</td>
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<td>Implantable defibrillators</td>
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<td>Positron emission tomography</td>
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<td>Nuclear radiation machines</td>
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<td>Ultrasound machines</td>
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<td></td>
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<td>Thermometers</td>
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<td>Audiometers</td>
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<td>EKG machines</td>
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<td>ICU monitors</td>
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</table>

(Continued on p. 12)

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For more information

Many applications of computer-based medical systems are not addressed in this issue. The following is an overview of the wide variety of possibilities.

**Clinical assessment and risk evaluation.** Pinette et al. review the use of personal computers in obstetrics, particularly in antepartum and intrapartum evaluation, and address the direction of computer technology in fetal assessment.

Regarding the dilemma of abdominal diagnosis, Patterson-Brown and Vipart describe patient interviews with and without computer-aided diagnostic programs, coupled with various diagnostic means including ultrasonography and laparoscopy. Likewise, Sturman and Perez speculate that the accuracy of microcomputer programs in diagnosing acute abdominal pain can be improved to ultimately outperform the average clinician.

Intravascular ultrasound imaging of diseased vessels is available in the prevention, diagnosis, and treatment of coronary artery disease. White and Yock describe this field and show how the application of fast Fourier transforms to the Doppler and real-time video spectral displays allows instantaneous modification in positioning catheters within the pulsating coronary arteries to minimize artifacts. In an effort to asease risk, Vetterott et al. describe computerized methods of obtaining and processing signal-averaged electrocardiograms to identify those at risk for subsequent ventricular arrhythmias.

Computers are used to increase accuracy, efficiency, and sophistication in evaluating and treating the hearing impaired. Yanz and Siegel review the field and demonstrate how improvement can be made through software changes alone — without the need to purchase more instrumentation.

**Artificial intelligence and expert systems in clinical diagnosis.** With an ever-expanding body of knowledge regarding diagnostic procedures, attempts are being made to employ computers as diagnostic-assistance devices. For example, Beltrame et al. describe the use of artificial intelligence in biomedical image processing. Computer-based expert systems are even applied in the fields of psychiatry (Morelli et al.) and in the treatment of sexual dysfunction (Binik et al.). However, Szolovits and colleagues, who present a complete overview, believe the optimal use of expert systems still escapes developers.

**Medical management.** Therapy is being directly affected by computer-based medical systems. For example, Linkens and Huculalhurci discuss computer control systems and pharmacological drug administration. Albisser describes
attempts to use microprocessors to manage diabetes mellitus through the use of closed-loop control. Defibrillation has emerged as the single most effective intervention for resuscitating patients from cardiac arrest. Cummins\textsuperscript{13} reviews the electrophysiological basis of defibrillation and ways to increase the effectiveness of counter-shocks, particularly for refractory ventricular fibrillation, which depends entirely on the performance of a microprocessor.


equally important to the regulatory agencies charged with assuring product safety.

Regulatory agencies throughout the world are developing new ways to monitor product safety, but few standards exist for medical products with embedded software. In addition to the software within a device, regulatory agencies are concerned with all software involved in making the product, including the production-equipment software and the automated-test-equipment software. It is incumbent on engineers to demonstrate that all software is developed and validated under established practices.

Software-based systems. Generally, software-based systems are characterized by their processing ability. They range from health information systems to database managers. Their role is to support knowledge management.

For example, patients are no longer dependent on the knowledge of the local doctor alone. The best medical knowledge is now available to all doctors at their office terminals. Virtually all recent medical knowledge and literature have been automated into Index Medicus by the National Library of Medicine. Artificial intelligence is now required to assimilate the information cataloged in these computer systems. A whole new discipline, variously called medical informatics, medical computing, or computational medicine, is evolving.

Individual patient data are also made more accessible and manageable by computer-based medical systems. Computers are now used in hospitals to track patients, to process and disseminate test results, to assure appropriate medication, to seek insurance reimbursement, and to record patient outcomes as a quality-of-care metric. Similar uses are moving into doctors' offices.

The articles in this issue barely sample the recent, exciting advances in computer-based medical systems — the subject is broad and beyond the scope of a single magazine issue. We hope you enjoy the examples we selected.

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References


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Kriewall received his bachelor's and master's degrees in electrical engineering from the University of Michigan and Stanford University, respectively. He received his PhD in biomedical engineering from Michigan in 1974. He is a senior member of the IEEE and a member of the Engineering in Medicine and Biology Society and the Computer Society.

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