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# Golden Accomplishments in Biomedical Engineering

## *50 Years of the IEEE Engineering in Medicine and Biology Society and the Emergence of a New Discipline*

One of the fastest growing fields of technology—a field of astounding recent achievements and even more ambitious hopes—is biomedical engineering. Laboratory instrumentation, medical imaging, cardiac pacemakers, artificial limbs, and computer analysis of the human genome are some of its familiar products. Defined as the use of the principles and techniques of engineering to solve problems in biology and medicine, biomedical engineering today holds a prominent place as a means of improving medical diagnosis and treatment, as a business, and as an academic discipline. Yet 50 years ago it barely existed.

It was in 1952 that a group of electronics engineers, members of the Institute of Radio Engineers (IRE), established an organization within the IRE to consider "problems in biology and medicine which might be aided in solution by use of electronic engineering principles and devices." This Professional Group on Medical Electronics, as it was called, grew steadily and expanded its area of interest. In 1963 the IRE and the American Institute of Electrical Engineers (AIEE) merged to form the Institute of Electrical and Electronics Engineers (IEEE), and the IRE Professional Group on Medical Electronics merged with the AIEE Committee on Electrical Techniques in Medicine and Biology. Over the years since, the IEEE Engineering in Medicine and Biology Society (EMBS), while growing into the largest international member-based society of biomedical engineers, has made, through its meetings, publications, and other activities, invaluable contributions in the advancement of the field.

The 50th anniversary of the Society is an appropriate time to look back at the origins and growth of both the field of biomedical engineering and the EMBS. The Society, under the leadership of Past Presidents Banu Onaral and Andrew Szeto and current President Henrietta Galiana, has funded and directed a history project, the principal products of which are a narrative history and a set of oral-history interviews.

The story to be told is a large and exciting one, and not all of it can be told here. The present account gives most attention to the aspects of biomedical engineering to which IEEE members (and, earlier,

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AIEE members and IRE members) contributed, which is to say that this account emphasizes the electrical, electronic, and computing aspects of biomedical engineering. Mechanical engineering and chemical engineering have, of course, made enormous contributions to biomedical engineering. These areas, though only occasionally mentioned in the narrative, are well represented in the oral-history interviews, excerpts of which appear in this issue in a separate article.

It must also be said that the number of professional societies that have arisen to foster biomedical engineering is very large. Some of them have broad scope, such as the European Society for Engineering and Medicine, and some of them narrow scope, such as the North American Society of Pacing and Electrophysiology. The geographic scope of professional societies may be regional, national, continental, or global. This account, of course, focuses on the IEEE Engineering in Medicine and Biology Society and its predecessor organizations in the AIEE and the IRE, and it mentions other societies only occasionally. And even within the bounds thus established, many choices had to be made. For example, an extremely large topic whose history is only sketchily presented here is biomedical engineering education.

The research and writing of this narrative account, as well as the conducting and editing of the oral histories, were carried out mainly by Frederik Nebeker and other staff of the IEEE History Center at Rutgers University. David Geselowitz, chair of the EMBS history committee, gave the greatest assistance, and other EMBS members contributed, especially Herman Schwan, Andrew Szeto, and Max Valentinuzzi. Others who deserve many thanks are the EMBS staff, headed by Executive Director Laura J. Wolf, and those who contributed oral-history interviews. Also, the section that looks at the future contains contributions by John W. Clark, L.A. Geddes, as well as Elise Fear and Faustina Hwang with contributions from EMBS student members.

The author of this history is well aware of the fact that, despite the assistance of all these people, many shortcomings remain. In an attempt at exculpation he appeals to Murphy's Law, another of the contributions of biomedical engineering to modern society. (In 1949 the U.S. Air Force performed tests of rapid deceleration on pilots. Volunteers were strapped to a rocket-propelled sled, and their physiological conditions were monitored through electrodes contained in a harness designed by Captain Edward A. Murphy. After discovering one day that the electrodes had been wired incorrectly, Murphy commented "If there are two or more ways of doing something, and one of them can lead to catastrophe, then someone will do it.")

## The Roots of Biomedical Engineering

### History of the Technologies

In the 1780s Luigi Galvani, studying what was called "animal electricity," initiated a line of research known as electrophysiology. By 1900 it had established the electrical nature of the nerve impulse and its velocity and revealed much about electrolytic conduction in animal tissues. Concepts of electrical engineering, such as resistivity, capacitance, and polarization, were applicable. Indeed, the mathematical model that William Thomson (later Lord Kelvin) proposed in 1855 for the Atlantic telegraph cable was modified, shortly after the turn of the century, to describe the mechanism of conduction along a nerve fiber.

Modern hemodynamics may be considered to have started with the conviction of William Harvey expressed in 1616 that the heart propels blood around a closed system. In 1840 a French physician named J.L.M. Poiseuille showed that the major pressure drop in the cardiovascular system occurred in the capillaries. He then studied the pressure drop in small glass tubes and developed the relation between pressure drop, flow, and tube diameter. A theory for wave propagation in elastic tubes such as blood vessels was developed by Thomas Young as early as 1808.

The physicist Hermann von Helmholtz may well be considered one of the first biomedical engineers. He invented the ophthalmoscope and the ophthalmometer. He determined the velocity of nerve pulse transmission, and he developed the basic physics for understanding fields in a volume conductor produced by bioelectric sources. And he studied the mechanism of hearing and invented the Helmholtz resonator.

***It was especially through instrumentation—for measuring and imaging—that engineering influenced biomedicine.***

It was especially through instrumentation—for measuring and imaging—that engineering influenced biomedicine. In 1888 Augustus Desiré Waller showed that, with a capillary electrometer, one could record the changing heart voltages from the body surface. X-ray imaging, invented by Wilhelm Röntgen in 1895, had an enormous impact on medicine; already in 1896 Siemens and General Electric began selling X-ray equipment. Indeed, it has been argued that it was X-ray technology that "triggered the transformation of the hospital from a passive receptacle for the sick poor to an active curative institution for all members of society." Other important medical instruments were the electrocardiograph and the electroencephalograph, the former coming into clinical use in the 1920s, the latter in the 1930s. Devices such as thermocouples, galvanometers, and phototubes found many applications in biomedical research in the 1930s. An example of biomedical research indebted to engineering both for concepts and instrumentation is the work of Edward D. Adrian and Charles Sherrington, recognized by the 1932 Nobel Prize for Physiology or Medicine, for elucidating the electrical nature of neural activity. (The 1944 Nobel Prize for Physiology or Medicine recognized work in the same area by Joseph Erlanger and Herbert Gasser.)

Sometimes the biomedical application stimulated the technological advance, as with the string galvanometer invented by Willem Einthoven to improve electrocardiography (ECG). Another example is the differential amplifier, a basic component of electronics, which was invented by B.H.C. Matthews in 1934 to amplify action potentials of nerves.

Not only research but also medical practice was changed. Many research instruments, such as X-ray machines, electrocardiographs, and electroencephalographs, came to be regularly used in diagnosis. Throughout the 19th century there were attempts to use electrical technology in treatment, but only a few, such as cardiorespiratory resuscitation by electrical stimulation, were of much effectiveness. In the early decades of the 20th century, a few techniques of obvious utility were introduced: X-ray

therapy, electrosurgery, and diathermy (the generation of heat in living tissues by electromagnetic radiation).

There was an older therapeutic tradition that should be mentioned. From the late 18th through early 20th century, promoters sold a wide variety of electrical devices, most of which passed a current through or near the body, to cure physical and psychological ailments. The use of magnets was popular also. Devices to administer an electric shock, electric baths, and electric belts became popular, and the practitioners of electrical medicine, as it was called, attracted millions of customers. In the 1880s a cellar room of the U.S. Capitol was equipped with medical electrical equipment for the use of Congressmen, and *Electrical Review* reported in 1887, "A great many members take electricity, and some go to the basement of the Capitol for it every day during the season."

Though such applications of electricity continue to the present, they have been vastly overshadowed by science-based treatments. The great expansion of medical research in the 20th century, coupled with new technological capabilities, led to countless advances. It was during World War I that the manufacture of electron tubes (mainly for radio) began on a large scale, and beginning in the 1920s electron tubes permitted short-wave diathermy, new types of electrosurgery, and medical applications of telemetry. (Short-wave diathermy began in Europe in about 1925 and was used to treat a variety of ailments; microwave diathermy began after World War II when the klystron and the magnetron became available to investigators.) New research techniques included the ultracentrifuge (developed by The Svedberg) and electrophoresis (developed especially by Arne Tiselius), both recognized in Nobel Prizes.

Electron-tube amplification was put to work, for example, in a commercial ECG machine introduced by Siemens & Halske in 1921; this machine used an oscilloscope also. It was the highly sensitive string-galvanometer of Einthoven, rather than electron-tube amplification, that made possible the first recording of brain waves from scalp electrodes. This electroencephalography or EEG, as it was called, was developed by the German psychiatrist Hans Berger in the mid 1920s, though he did not publish his results until 1929. Clinical EEGs evolved in the 1930s and expanded quickly in the early 1940s. It was also in the early 1940s that the field of electrocorticography—multichannel recordings from the exposed brain cortex—emerged; it was used to locate epileptic foci.

One of the most important tools of 20th-century biomedical research, the electron microscope, was invented at the beginning of the 1930s by two German groups independently, one at the University of Berlin headed by Hans Hermann Knoll and Ernst Ruska and the other at Siemens-Schuckert headed by Reinhold Rüdenberg. This was, of course, the transmission electron microscope, in which the electrons used to form the image passed through the sample. Knoll proposed a scanning electron microscope, in which the electrons were reflected off the sample, and an early form was built by Manfred von Ardenne in 1938. In the United States Vladimir Zworykin and others at RCA built a scanning electron microscope in 1942. In 1939 the Japan Society for the Promotion of Science began a program to construct electron microscopes, and by the end of World War II nearly 20 electron microscopes had been placed in use. Japanese companies began manufacturing electron microscopes in the late 1940s, and in 1955 Japan had half as many electron microscopes in use as the United States and five times as many as Germany, France, or England.

Radiology was no doubt the most highly developed application of engineering to medicine. Technical advances

## Believe It...Or Not!


**Devices to deliver electric shock for therapeutic purposes were popular in the late 18th century through the early 20th century. Top: For women, an ad for an electric corset (circa 1885) proposed cures for ailments ranging from weak backs to kidney disorders. Right: For men, an ad for an electric belt from 1902 offers a 10-day free trial.**

COURTESY OF FRANCES RICHMOND, ALFRED E. MANN INSTITUTE OF BIOMEDICAL ENGINEERING

included improved X-ray tubes, notably the high-vacuum hot-cathode tube developed by William Coolidge at General Electric in 1913, and means of visualizing soft tissues. It had been discovered around the turn of the century that ingestion of radio-opaque bismuth compounds made parts of the digestive tract visible in X-ray images, and in the late 1920s Portuguese investigators, including Egas Moniz and dos Santos, developed angiography, the X-ray visualization of blood vessels after injection of a radio-opaque substance. The image-intensifier tube, invented by Irving Langmuir of General Electric, greatly improved fluoroscopy. Though the computational demands made the technique impractical, the mathematics of tomography (constructing a three-dimensional (3-D) image from two-dimensional (2-D) cross sections) were invented independently by a number of people in different countries, including André Marie Edmond Bocage in France, Bernard Zeidses des Plantes in Holland, Alessandro Vallebona in Italy, and Ernst Pohl and Gustave Grossmann in Germany. As we will see in later sections, it was the electronic digital computer that made computed tomography a practical technique.

Sonar, invented near the end of World War I for detecting submarines, became an important military technology, and in the 1940s attempts were made to adapt the technique to medical imaging. In 1941 Donald Sproule developed a pulse-echo ultrasonic instrument; one transducer generated the pulses and a second one registered the echoes in the intervals between the generated pulses. In 1944 Floyd Firestone patented what he called a "Reflectoscope"; it used the same transducer for generating pulses and detecting echoes. In the 1950s and 1960s, as we will see in the next two sections, the technique reached clinical usefulness.

## The Electron Microscope

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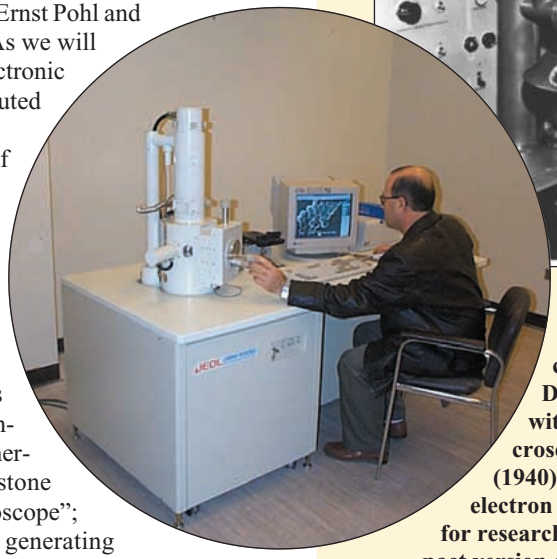


COURTESY OF DR. HANI AMASHA

**The electron microscope was one of the most important tools of 20th century biomedical research. Top: Dr. James Hillier of RCA is shown with the first commercial electron microscope in the Western hemisphere (1940). Hillier won an award for making electron microscopy a practical technology for research. Left: A more modern and compact version of the device from 1986.**

It was also in the 1940s that nuclear magnetic resonance was first demonstrated, independently by Felix Block at Stanford and Edward Purcell at Harvard, building on the work of I.I. Rabi. The electronic digital computer, another product of the 1940s, was developed in several countries independently, though probably the most influential early machine was the ENIAC, built for the U.S. Army at the University of Pennsylvania and completed in 1946. Biomedical applications of these advances came in the 1950s.

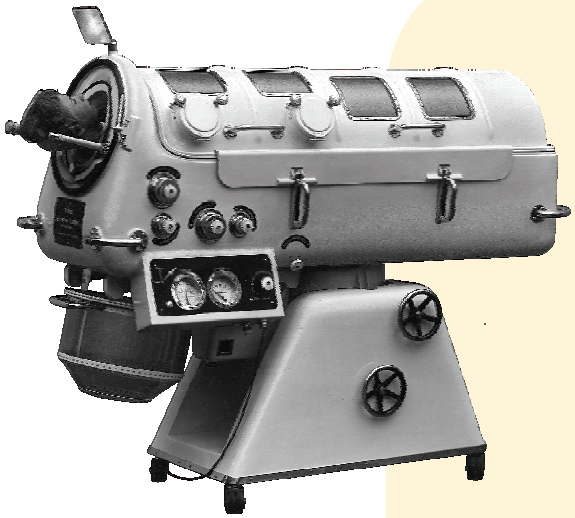
World War II was a great stimulus to the study of control systems, particularly with radar systems and guidance systems. This and other work, such as some of the investigations in aviation medicine, prompted some people after the war to take a systems approach to biological and medical studies. The construction of mathematical models of physiological systems, which became known as systems physiology, became an important activity. Research areas where mathematical models were constructed include hemodynamics, respiration, temperature regulation, nerve-impulse propagation, muscular control systems, and eye movements.

### Prehistory of the Profession

In the 1920s and 1930s more and more investigators used the concepts and techniques of physics and engineering in biological and medical research, and a few institutions were established to promote this approach. In the United States in the 1920s, the Johnson Foundation for Medical Physics at the University of Pennsylvania and the Biophysics Department of the Cleveland Clinic were both established. The Rockefeller Foundation, established in 1913, supported research in this area. In Germany, Siemens, a major supplier of X-ray and diathermy equipment, maintained a biophysical laboratory at Erlangen. The emergence of biomedical engineering, it should be pointed out, was intertwined with the emergence of biophysics and medical physics; only gradually did these fields assume distinct identities.

It was in the 1920s that a particularly influential institution was established in Frankfurt-am-Main: the Institute for the Physical Foundations of Medicine (Institut für physikalische Grundlagen der Medizin). The founding director was Friedrich Dessauer, who did important work on the biological damage caused by X rays. In 1934 Boris Rajewsky became director of the institute; he did important work on the biological effects of ionizing and nonionizing radiation. In 1938 Rajewsky gained the sponsorship of the Kaiser Wilhelm Society, and the Institute for the Physical Foundations of Medicine became attached to the larger, newly formed Kaiser Wilhelm Institute for Biophysics (Kaiser Wilhelm Institut für Biophysik). This institute became

## The Iron Lung



PHOTOS OF COURTESY OF MATTHIAS WITT, DRÄGER MEDICAL AG & CO.

**The iron lung, developed in 1927 by Philip Drinker, became well known in the early 1950s for patients whose breathing capabilities were compromised by poliomyelitis. Left: A Drager E52 iron lung with electric drive from 1952. Above: An iron lung installed in a 1953 "emergency car."**

affiliated with the University of Frankfurt and established a Ph.D. program in biophysics.

In 1925 the first International Conference of Radiology met in London, and a Commission on X-ray Units was set up to define units of radiation. At the second International Conference on Radiology, which met in Stockholm in 1928, the curie and the roentgen were established as units of radiation.

In the United States the Massachusetts Institute of Technology implemented a research and teaching program in "biological engineering" in 1937. It consisted of five sections: bio-electrical engineering (concerned with X rays and cathode rays), electro-physiology, biophysics, microbiology, and nutritional biochemistry. However, the program quickly evolved into plain biology, despite the championship of Vannevar Bush and Karl Compton of the engineering approach. In the late 1940s the University of California at Los Angeles initiated a program in "biotechnology." It was concerned mainly with what elsewhere was called "human factors research." (By 1962 some 500 engineers and physiologists in the United States were identified with human factors research.)

In the 1940s those concerned with applying electrical technologies to biology and medicine might have belonged to the American Institute of Electrical Engineers (AIEE) or the Institute of Radio Engineers (IRE) or both. The domain of the IRE, founded in 1912, had expanded from radio engineering to almost all areas of electronics, and the domain of the AIEE, founded in 1884, included traditional electrical engineering and many newer areas of development. (In 1963 the AIEE and the IRE merged to form the Institution of Electrical and Electronics Engineers (IEEE).)

In 1948 the American Institute of Electrical Engineers (AIEE) formed a Committee on Electrical Techniques in Medicine and Biology and held the first conference on the subject. Called the U.S. Conference on Medical Electronics, it took place in New York City in 1948. At about the same time the IRE formed a committee concerned with medicine and biology. The AIEE, the IRE, and the Instrument Society of America joined in forming the Joint Executive Committee on Electrical Techniques in Medicine and Biology. It was this committee that organized the annual conference. In the next section the activities in the 1950s of the AIEE and the IRE, including the annual conference, are described.

## The 1950s: First Steps Toward a Discipline of Biomedical Engineering

### History of the Technologies

The 1950s was a decade of economic growth in the United States and of economic recovery in Europe and Japan. The increasing prosperity allowed much greater expenditures on health care and biomedical research. Appropriations for the National Institutes of Health (NIH), for example, increased from $52 million to $430 million. Engineering in medicine gained prominence for the cardiac pacemaker, the heart-lung machine, and the iron lung. The latter device, developed in 1927 by Philip Drinker, became well known for treating victims of poliomyletis in the early 1950s.

A public-health concern of the 1950s was atomic radiation, especially from fallout from the testing of atomic weapons. (There were radiation hazards in some industries where radioactive substances were handled and in hospitals, where radium tubes were used.) The Geiger counter (invented by Hans Geiger and Walther Müller in 1928) was seen as the "watchdog of the atomic age." The devices became common, and "Volks-Geiger counters" were marketed for use by individuals. Another concern was the health hazard of exposure to microwaves in and near radar installations, in hospitals (in 1955 there were some 20,000 microwave diathermy machines in use by physicians in the United States), and from the newly developed microwave oven. In 1953 the U.S. Navy and Air Force held a series of meetings that considered whether radar transmitters posed serious

dangers. In 1954 General Electric held a meeting on the hazards of microwave radiation, and in 1955 the Mayo Clinic held a symposium on the physiologic effects of microwaves. A precursor of the environmental movement of the 1960s and 1970s was the establishment, by Leslie Silverman of the Harvard School of Public Health and many others, of the field of industrial hygiene. Another important contribution of chemical engineers in the 1950s was in the processing of blood, such as techniques for fractionating blood plasma.

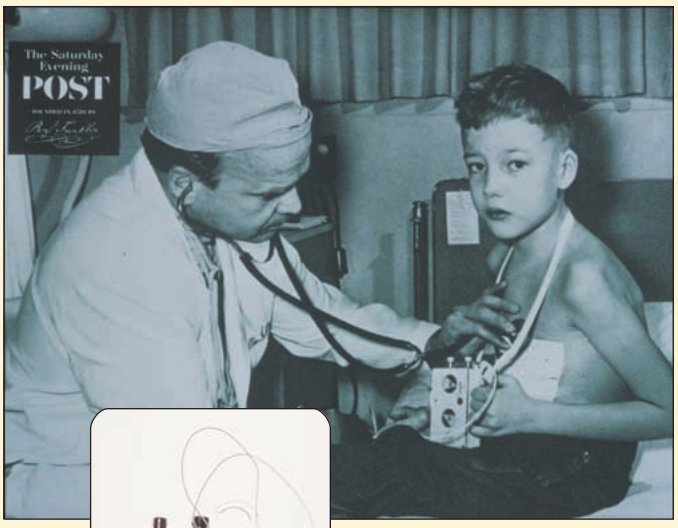
Engineering contributed to cardiology in numerous ways. Attracting the most attention was the cardiac pacemaker. In 1952 Paul M. Zoll, working with engineers of the Electrodyne Company, developed an external pacemaker, which stimulated the heart through large electrodes placed on the chest wall. Somewhat more satisfactory was the direct pacing of the heart that C. Walton Lillehei and colleagues achieved in 1957: electrodes placed in the heart muscle were connected to an external pulse generator. A fully implantable pacemaker was developed in 1958 and 1959 by Wilson Greatbatch and William M. Chardack. (Independently and slightly later, Adrian Kantrowitz and General Electric engineers also developed an implantable pacemaker.)

Having an even greater impact was the defibrillator. Here too, Paul Zoll was a pioneer; he performed the first human transthoracic defibrillations in 1955. (C.S. Beck had successfully performed open-chest human defibrillation in 1947.)

A third great advance for cardiology in this decade was the heart-lung machine, which provided a mechanical substitute, during cardiac surgery, for heart and lungs and thus made open-heart surgery a possibility. In 1953 John H. Gibbon used such a device, developed with the assistance of IBM engineers, and later C. Walton Lillehei and Richard DeWall developed an improved heart-lung machine.

The well-established technology of electrocardiography benefited from improved electronics, notably for amplification. A "Symposium on Electrodes and Amplifiers in Biological Research," held at the University of Pennsylvania in June 1956, was influential in this and other branches of biomedicine. Trials of sending electrocardiograms through telephone lines began in 1952, though the technique had been attempted as far back as 1905 by Willem Einthoven. The electronic digital

PHOTOS COURTESY OF MARK BROWN, MEDTRONIC

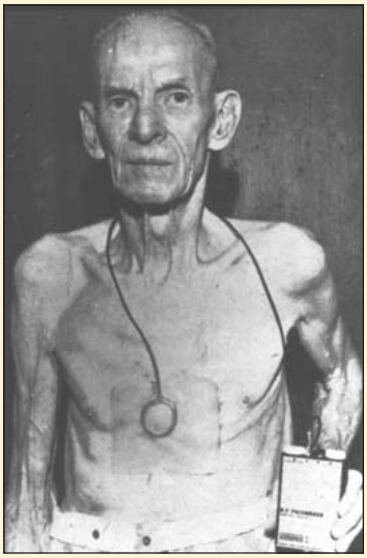




**Electrical stimulation of the heart was accomplished in the late 1950s through electrodes placed in the heart muscle that were connected to an external pulse generator. Inset: The Medtronic 5800 prototype (1958) won an IEEE "Engineering Milestones" Award. Top: Dr. C. Walton Lillehei with a child who received one of the first Medtronic external pacemakers.**

## Pacemakers Keep the Beat

COURTESY OF ROBERT SCHOENFELD, ROCKEFELLER UNIVERSITY



**A battery operated, transistorized version of a radio frequency coupled cardiac pacemaker (circa 1960). The patient has the receiver coil implanted in his chest. The external unit is connected to the transmitter coil, which is taped to the chest just above the implanted receiver coil and inductively coupled to it.**

COURTESY OF ALVIN WEINBERG, ST. JUDE MEDICAL

**The first implantable pacemaker was developed through collaboration by cardiac surgeon Dr. Ake Senning and Dr. Rune Elmqvist in Sweden. Arne Larsson in 1958 was the first person to receive the device. This pacemaker used two transistors and was the size of a hockey puck.**

## Now Hear This

**Hearing aids help the hearing impaired by amplifying sound and filtering unwanted noise. Below: An ad from 1914 shows a Mears "Ear Phone" that offered eight different sound strengths and tone adjustments. Right: This ad from the 1960s for a Zenith slip-on hearing aid is an example of aids that combined microphone, transistor, and battery into one unit that could be concealed more easily.**

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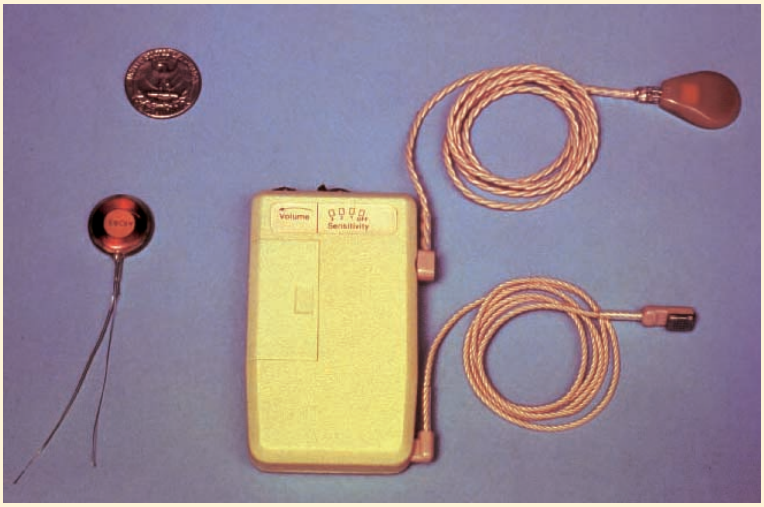
**The Sonotone 1010 was an important transitional hearing aid because it mixed transistors and tubes. In 1953 it won the First Annual Audio Engineering award for technical excellence in hearing aids.**




COURTESY OF JAY RUBINSTEIN, UNIVERSITY OF IOWA

**Different from hearing aids, cochlear implants stimulate the auditory nerve. This House-3M cochlear implant was the first device to prove that electrical stimulation of the human ear could provide beneficial speech information to the deaf. Despite the fact that modern multichannel implants provide much more speech information, there are still many people using the House implant who derive substantial benefit.**

computer, just then becoming a practical device, was applied to cardiology in the late 1950s by Hubert Pipberger and his colleagues for automatic analysis of the ECG. He and others organized an international conference in 1959 titled "Conference on Modern Concepts of Electrocardiography and Methods of ECG Data Processing," which was extremely influential. The related field of EEG, too, saw important advances. For example, in 1959 MIT professor Walter Rosenblith and his colleagues published "Processing Neuroelectric Data," which described work on averaging of evoked responses, the use of correlation techniques and power spectra for the EEG, statistical models for neuroelectric phenomena, and the use of digital computers for the processing of data.

Transistors first became commercially available in the 1950s, and applications in biomedicine followed fast. Indeed, it was hearing-aid companies that first marketed products containing transistors, the first appearing in late 1952. The implantable pacemaker used transistors, as did the endoradiosonde. The latter, also called the radio pill and gutnick (it appeared in 1957, the year of Sputnik), was developed by Bertil Jacobsen, R. Stuart Mackay, Vladimir Zworykin, and others, and it was used in many medical and biological studies (including in tortoises for the 1964 Galapagos International Scientific Project). Other early applications of transistors were improved physiological amplifiers and portable equipment for studying physiological functions in ambulant subjects.

X-ray imaging advanced as fluoroscopic image intensifiers came onto the market. In these devices, based ultimately on a patent issued to Irving Langmuir in 1934, X rays strike a screen, triggering the release of electronics, which are accelerated and strike phosphors at the end of the tube. By the 1960s these image intensifiers permitted a radiation dosage of a tenth or a hundredth of what was used before to acquire the same diagnostic information. The specialized technique of mammography began to be developed.

Related to X-ray imaging is the formation of images from radioisotopes introduced into the patient. In 1951 Benedict Cassen built the "scintiscanner," which produced a crude picture by moving a scintillation detector over the area to be scanned and recording the intensity levels with a dot-producing mechanism. An improvement was the "photoscan," invented by David Kuhl in 1954; the output from a photomultiplier tube controlled a beam of light that exposed photographic film. More sophisticated was the gamma or Anger camera, which Hal Anger began developing in the late 1950s.

Two other advances in images in the 1950s should be mentioned: the development of the scanning electron microscope (which could, unlike the earlier transmission electron microscope, produce images of surfaces, including those of opaque objects) and a color-translating ultraviolet microscope, which displayed the UV spectrum in visible light.

The therapeutic use of high-energy radiation and particles also made great advances in the 1950s. Megavoltage radiotherapy, first from tele-cobalt units and then from linear accelerators, came into use. Investigation of the therapeutic use of electron beams from betatrons began in about 1948, first perhaps in Germany, soon in several countries. In the late 1950s high-voltage electrons from the Stanford linear accelerator were used in clinical studies. Experimental trials of the therapeutic use of ion beams (protons, deuterons, and alpha particles) from the Berkeley synchrocyclotron were first reported in 1952. (Ion beams produce highly localized radiation damage; the scattering of particles is very small, as compared with electrons, and negligible amounts of radiation fall outside the beam.)

One of the most significant events of the decade was the development of automatic chemical analyzers. In 1956 Leonard T. Skeggs Jr. invented an automatic analyzer, which could carry out ten different tests on a single substance and could analyze 5,000 substances daily. Based on Skeggs's continuous-flow techniques, Technicon introduced its Auto Analyzer in 1957, and by 1960 most large hospitals in the United States were using it. This device allowed a hundredfold increase in the number of laboratory tests over a ten-year period, and in the mid 1980s, some 50,000 were in use. Automatic scanning systems were also invented in the 1950s. Notable are the Cytoanalyzer of the Airborne Instruments Laboratory (Mineola, New York) for automatically reading slides to determine the presence or absence of abnormal cells and a machine for automatic counting of bacterial cultures.

***The emergence of biomedical engineering was intertwined with the emergence of biophysics and medical physics; only gradually did these fields assume distinct identities.***

It was in the 1950s that computers became important tools for research and for administration. At the beginning of the decade there was much interest in analog computers. F.S. Grodin, for example, used an analog computer to simulate a respiratory system. By the end of the decade, however, digital computers prevailed in almost all applications. Their use in data handling and data analysis has been mentioned above. A major difficulty in their use, however, was the development of satisfactory techniques for analog-to-digital conversion (discussed in the next section). There were hopes that computers would greatly improve medical diagnosis. A conference devoted to computers in biology and medicine took place in Minneapolis in 1958, and the following year there was a major conference on computers in medical care, held at the Rockefeller Institute in New York. At the latter conference it was reported, "Two features of the computer particularly captivated physicians: its capacity to store a prodigious amount of data in a little space; and, with dispatch, to search for and to establish complicated associations that existed within the data." The same year there appeared an influential paper by R.S. Ledley and L.B. Lusted that outlined methods by which a computer might assist a physician in making a diagnosis.

A great many other activities of the 1950s might be reported. There were advances in instrumentation, such as the "bristle flowmeter" invented in 1952 by Gerhard Brecher (using a newly available mechanoelectrical transducer) to measure blood flow; within a few years measurements made with this device had answered three long-standing questions. There was important work in ergonomics or human engineering in the many studies of the pilot-aircraft system, as the development of high-performance military aircraft called attention to the interaction between man and machine. Control systems for medical devices, such as the

iron lung mentioned earlier, was an important area of study. A number of people began applying engineering concepts in biology; in a 1959 paper, for example, Lawrence Stark analyzed the action of the pupil as a servomechanism.

One of the most important programs taking an engineering approach to understanding living organisms was that begun by Herman Schwan in the late 1940s in Philadelphia, first at the U.S. Navy's Aeromedical Equipment Laboratory and then at the University of Pennsylvania. Schwan focused on the biological materials themselves, seeking to determine the full range of their physical properties, including how energy in various forms interacts with molecules, membranes, cells, and tissues. The resulting understanding would, he believed, serve as a basis for solving problems encountered in research, diagnosis, and treatment. Schwan developed appropriate instruments to measure conductivity and permittivity of biological materials, greatly extending the frequency range of measurements of the dielectric constant of tissues and cell suspensions. He considered also the ultrasonic properties of tissues. Schwan worked to give biophysical explanations of the observed properties. Such understanding could then be applied to practical problems, such as the health hazards of electric fields.

## History of the Profession

Every year the IRE held its major convention in New York City. (Though the majority of its members lived in North America, the IRE was, from its founding in 1912, an international organization.) At the 1951 IRE convention there was a symposium on dc amplifiers, and the symposium elicited considerable discussion concerning the recording of bioelectric potentials. This gave L.H. Montgomery, a professor at Vanderbilt University, the idea that there might be sufficient interest to form an IRE Professional Group on Medical Electronics. (In recognition of the rapid ramification of electronics following World War II, there emerged within the IRE, beginning in 1948, so-called Professional Groups devoted to particular areas of electronics.) Montgomery wrote to a number of colleagues and then arranged with Vladimir Zworykin at the RCA Laboratories in Princeton, New Jersey, to hold a meeting there to discuss the idea. (Zworykin, famous for his work in developing television, was a pioneer in electron microscopy and by the 1950s had become primarily concerned with medical applications of electronics.) The meeting was successful in that a petition to establish a Professional Group was started—Zworykin was given the honor of being the first to sign it—and then circulated by mail. The petition was presented to the IRE on about 1 February 1952, and the IRE gave its tentative approval on 7 April 1952 pending minor revisions to the constitution for the Group.

Article III, Section 1 of the constitution of the Professional Group on Medical Electronics (PGME) includes the following statements: "The Group will provide a forum for the presentation of research and development problems in biology and medicine which might be aided in solution by use of electronic engineering principles and devices, and conversely, the presentation of new developments in electronic engineering which might find wide, or special, application to biological and medical research. The Group will provide means for the personal exchange of information in this area of medical and biological research and for establishing rapport between the workers in these fields."

An early action of the newly formed IRE Professional Group was to collaborate with the AIEE on the Annual Conference on Electronic Instrumentation and Nucleonics in Medicine, which, as mentioned in the previous section, the AIEE had begun in about 1948. For the conference held in November 1952 the Professional Group gave assistance in procuring papers. For the 1953 annual conference the Group sponsored the meeting, along with the AIEE and the Instrument Society of America (ISA). In 1954 the AIEE, IRE, and ISA formed the Joint Executive Committee on Medicine and Biology, which from that point on organized the annual conferences. In 1954 the name was changed to the Conference on Electrical Techniques in Medicine and Biology. Attendance and participation gradually increased throughout the decade, reaching 500 attendees and 60 to 70 papers presented.

The PGME was led by an Administrative Committee, headed by a Chairman, a Vice-Chairman, and a Secretary-Treasurer. The other members varied in number from three to 12, and there were also, from 1956 on, one or more Advisory Members. Table 1 is a list of the chairmen during the 1950s. Membership in PGME rose from about 500 at the end of 1952 to more than 2000 in 1959.

The first regular publication of the Professional Group, which began in 1952, was a newsletter. In November of the following year the *IRE Transactions on Medical Electronics* began; Julia F. Herrick was the first editor, and she was succeeded by Lee B. Lusted in September 1959. Local branches of the Professional Group, called Chapters, began to form. The first two, both approved on 7 April 1953, were organized by, respectively, Wilson Greatbatch of the Buffalo-Niagara IRE Section and A.J. Morris of the San Francisco IRE Section. By the end of 1955 there were Chapters in the Connecticut Valley Section, the Los Angeles Section, the Philadelphia Section, and the Washington, DC, Section. Nine more Chapters were established by the end of the decade.

**Table 1. The Chairmen during the 1950s of the IRE Professional Group on Medical Electronics.**

| | |
|---|---|
| 1952 | L.H. Montgomery |
| 1953 | L.H. Montgomery |
| 1954 | Julia F. Herrick |
| 1955 | Vladimir Zworykin |
| 1956 | Vladimir Zworykin |
| 1957 | Lee B. Lusted |
| 1958 | Urner Liddel |
| 1959 | Walter E. Tolles |

There were other organizations concerned with biomedical engineering. Besides the AIEE, there were other engineering societies, the Instrument Society of America, and medical organizations. There was increasing interest in biophysics, and in the United States a biophysical society was established in the mid 1950s. In addition, there were some specialized organizations, such as the American Society for Artificial Internal Organs (hemodialysis was one of its important topics). Yet PGME held a prominent place. In 1956 Otto Schmitt wrote that "PGME has been the primary outlet for all of biophysics in the fields of engineering and applied sciences and so carries a much greater responsibility than is implied by medical electronics alone. …because professional medical societies have by some chance been less aggressive in promoting biophysics while engineering groups have been exceptionally active, most of those potential biophysicists are finding themselves associated with PGME and, to a lesser extent, with comparable affiliates of other engineering societies." And at the end of the decade PGME was the largest organization concerned with biomedical engineering.

Similar organizations were formed in other countries. In June 1957 Zworykin convened an international conference on medi-

cal electronics in Paris. This led to the establishment of the International Federation for Medical Electronics the following year, with the IRE PGME as one of the member societies.

It was also in the 1950s that the first medical engineering programs were set up. R. Stuart Mackay set up a medical engineering program between the Berkeley and San Francisco campuses of the University of California, and in 1956 the first student completed his doctorate. Herman Schwan began training graduate students in the early 1950s at the University of Pennsylvania. Master's programs were set up at Iowa State University in 1957 and at Drexel University in Philadelphia in 1959. Also, in Britain biomedical engineering emerged as an identifiable discipline in the 1950s.

***The 1950s saw the first steps toward establishing biomedical engineering as a discipline, with professional societies, regular meetings and publications, and formalized training programs.***

The 1950s, then, not only saw remarkable advances in biomedical technologies but also the first steps toward establishing biomedical engineering as a discipline, with professional societies, regular meetings and publications, and formalized training programs.

## The 1960s: Biomedical Applications of the Computer

### History of the Technologies

The 1960s were tumultuous years. In the United States, the civil rights movement gained momentum, protest against U.S. involvement in the war in Vietnam escalated, and the women's liberation movement became prominent. In both Europe and the United States young people questioned the established order, sometimes campaigning for change (as in the 1968 student strikes in Paris) and sometimes "dropping out" (as the Hippies advocated). The decade was, nevertheless, one of strong economic growth.

It was in the 1960s that the U.S. government instituted Medicare (health care for the elderly) and Medicaid (health care for the indigent). These programs channeled more money to health care, and, because they reimbursed providers for all "necessary and proper" expenses (that is, permitted "cost-plus" reimbursement), they encouraged the use of new medical technologies. The government advanced the field of biomedical engineering more directly through a major NIH program to promote the introduction of engineering into biomedical research. This effort, initiated by Frederick Stone and J.H.U. Brown of the NIH Division of General Medical Sciences, did much to establish training programs and a research base for biomedical engineering.

In the 1960s there was considerable concern about exposure to radio-frequency (RF) radiation. Following development of standards by a project sponsored by the IEEE and the U.S. Navy, the American National Standards Institute in 1966 issued its first standard for a safe exposure limit to RF radiation (10 $mW/cm^2$). This standard evoked controversy; researchers in the Soviet Union had recommended a safe exposure limit three orders of magnitude lower. Also in 1966 it was discovered that some GE television sets emitted X rays. Congress passed the Radiation Control for Health and Safety Act of 1968, requiring the Secretary of Health, Education, and Welfare to develop standards for electronic products.

In the 1960s technology became even more prominent in cardiology. Indeed, a good deal of the work done by biomedical engineers in the 1960s concerned the cardiovascular system. For example, in the four 1963 issues of the *IEEE Transactions on Bio-Medical Electronics*, 15 papers out of a total of 28 papers dealt with cardiovascular research. Among many advances in ECG was the application of techniques of digital signal processing, such as digital filtering and averaging. (It was in the 1960s that the field of digital signal processing first became prominent.) An example is the work done at the Biomedical Computing Laboratory of the Washington University School of Medicine (St. Louis) that used signal processing techniques to obtain the fetal electrocardiogram from electrodes on the mother's abdomen and shoulders.

Pacemakers became more common. In 1965 Wilson Greatbatch completed the design and building of an inhibited demand pacemaker (which worked only when needed); this prototype led to the Medtronic Model 5841, which was the first commercially available demand pacemaker. Also in 1965 L. Lemberg and colleagues reported on a trans-chest pacemaker that provided pacing only if needed (that is, if there was no beating otherwise).

In 1965 the NIH's National Heart Institute (NHI) hired six firms to do a feasibility study of the artificial heart. There was a great deal of optimism about the prospect, and one Nobel Laureate remarked that the artificial heart should be no more difficult than an earth satellite. As a result of the studies, in 1966 the NHI concluded that there was a need for an artificial heart and that there were no insurmountable difficulties. Congress approved spending at the rate of $10 to $12 million a year (a rate that continued to 1984). NHI expected that an artificial heart would be devised in four or five years. In 1969 Denton Cooley did implant an artificial heart in a patient whose heart had failed; the device functioned for 64 hours until a suitable donor heart was located.

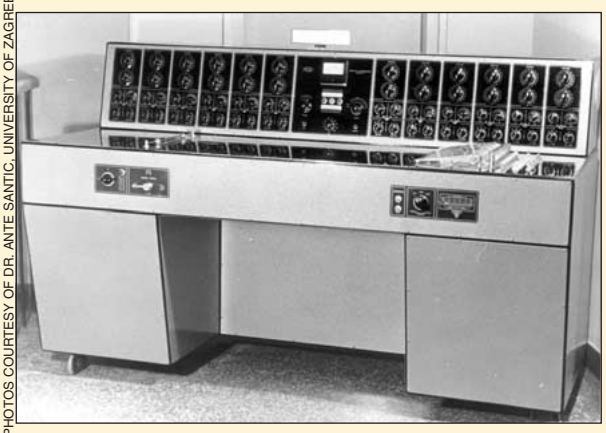
The transthoracic defibrillator, invented in the 1950s, took essentially its modern form in 1962 when Bernard Lown, a Harvard cardiologist, along with Barouh Berkovits, an electrical engineer, developed the direct-current defibrillator. The first mechanical heart valves were implanted in 1960, and their use grew rapidly. (What may have been the first implantation of an artificial component in the human circulatory system was the ball check-valve that C.A. Hufnagel placed in the descending aorta of a patient in 1951.) Cardiac bypass surgery became common in the late 1960s, and this intensified the development of effective heart-lung machines.

The U.S. Air Force had long been interested in the physiological aspects of high-altitude flight. The creation of NASA (National Aeronautics and Space Administration) in 1958 and interest in human travel into space greatly increased the interest in biomedical telemetry (measuring physiological variables and transmitting that information by radio). Thus in the 1950s and 1960s there was a great deal of work in this area. The first conferences in biomedical telemetry took place in the 1960s, and several books on the subject were published, notably R. Stuart Mackay's *Bio-Medical Telemetry* (1968). An indication of the size of the field is that a book on biomedical telemetry published

## The Lab Goes High-Tech

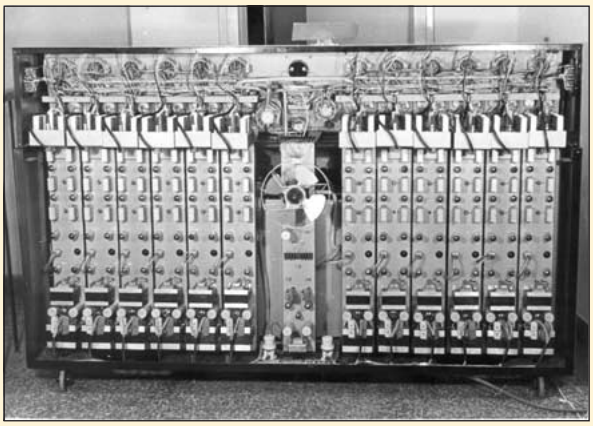
PHOTO COURTESY OF DR. IRVING ENGELSON, IEEE.

**The first decade where bioengineers routinely had access to computers was the 1960s, and there seemed to be countless ways computers could assist in research and health care. Above: Dr. Irving Engelson is shown in 1960 standing near the Electroencephalographic Statistical Analyzing Computer (ESAC), which he designed and used for electroencephalograph studies.**



PHOTOS COURTESY OF DR. ANTE SANTIC, UNIVERSITY OF ZAGREB

**Front (above) and rear (below) views of a 12-channel electroencephalograph developed in Southeastern/Central Europe in 1960 at the Institute of Electrical Engineering in Zagreb, Croatia.**



in 1970 had several thousand references. In 1974 the International Society on Biotelemetry was founded, and it began publishing a journal titled *Biotelemetry and Patient Monitoring*. Telemetry had many applications in research and health care, and it contributed to the efforts, which began in the 1960s, to provide medical diagnosis and treatment to remote locations (telemedicine).

A great deal of the work in biomedical engineering in the 1960s concerned computers. This was the first decade in which scientists and engineers routinely had access to a computer, and it was a decade of great enthusiasm for applying computers to many fields. At the beginning of the decade there seemed to be countless ways computers could assist in biomedical research and health care, and some of them had already begun to be realized, as we saw in the preceding section.

In 1960 the director of the National Institutes of Health, James Shannon, set up an Advisory Committee on Computers in Research (ACCR). Its purpose was to stimulate the use of computing in biomedical science, and in the first two years the committee, chaired by Lee B. Lusted, spent more than $50 million on computer-related biomedical research. The first special meeting of the ACCR was a ten-day "Workshop on Biomedical Computing," held in 1961 at Ohio State and directed by Ralph W. Stacy. Such activities and the funding provided by ACCR gave great impetus to the new field.

At the beginning of the decade there was still some interest in analog computers (especially for biological simulations) and in special-purpose computers. For example, in 1961, working with Jerome Cox, Maynard Engebretson completed a special-purpose computer (HAVOC) for recording evoked average responses from infants to ascertain the amount of hearing deficit. There was also interest in so-called hybrid computers, which, it was thought, would combine the advantages of analog and digital computers.

In the 1960s a number of neurophysiologists starting using computers such as the Computer of Average Transients in their labs to help analyze their data. The NIH funded the Lincoln Laboratories to develop a small laboratory computer for biomedical applications. Charles Molnar was a key member of the team that produced the so-called LINC computer, which some people consider to be the first personal computer (since earlier computers were intended for a large number of users).

People interested in using a computer in research often had to develop themselves the equipment to convert analog signals to digital signals, as for example, a technique for high-speed sampling of multichannel information reported by Carl Barus in 1956. This continued throughout the 1960s. For example, in 1967 Louis Siegel presented a method of digitizing graphic records. Even at the end of the decade biomedical engineers designed their own systems for converting data on magnetic tape to digital form.

The computer enormously facilitated the use of statistics as an aid in medical diagnosis. A pioneer in this area, Wilfred Card, argued that statistics and the computer could effect a transition: the medical knowledge applied in a particular case would no longer be drawn exclusively from the private world of a single clinician but would draw explicitly on the public world of science.

One of the most important efforts to use the computer to mechanize scientific reasoning and to formalize scientific knowledge in a specific field was the DENDRAL project at Stanford, initiated in 1965. The program took ten years to develop. It

rivaled the skill of expert organic chemists in predicting the structures of molecules in certain classes of compounds. (A recent version of the interactive structure generator, GENOA, has been licensed by Stanford University for commercial use.) DENDRAL led to the development of other rule-based reasoning programs, the most important of which was MYCIN, described in the next section.

In 1967 Frederick Brooks at the University of North Carolina started Project GROPE to develop a haptic interface for molecular forces. GROPE II was a six-dimensional system (three forces and three torques), but on computers available in 1976 it could produce forces in real time for very simple models only. The project was revived in 1986 when VAX computers became available, and GROPE III was completed in 1988. The principal value of the system seems to be in giving chemists a better understanding of molecular interactions.

Reflecting the interest in using computers for biomedical research was the establishment in the 1960s of two journals: *Computers in Medicine and Biology* and *Computers and Biomedical Research*. Databases began to assist researchers. For example, an Atlas of Protein Sequence (later the Protein Identification Resource), a knowledge base for protein sequences, appeared in 1962; it was the work mainly of Margaret Dayhoff and Robert Ledley. An electronic gateway to the medical literature, MEDLINE, first became available in 1966.

One application of computers was the so-called neural network, an interconnection of processors in a manner suggestive of the interconnection of neurons in animal nervous systems. A milestone of this work was the 1969 book *Perceptrons* by Marvin Minsky and Seymour Papert. Though it attracted attention to neural networks, it was not optimistic about the future of the field and relatively little work was done on the subject until the early 1980s.

Computers began to be used for hospital administration, too. Important work was done by the department of Medical Methods Research set up in 1961 by Kaiser-Permanente in California. Morris Collen and others began to develop "a comprehensive health care information system to provide an integrated, continuing patient medical record." Initially they concentrated on a computer system for multiphasic screening. There were many visitors to the Oakland multiphasic center in the late 1960s, and interest in such techniques spread. In the 1960s other hospitals served as sites for the development of computerized handling of patient information. Most of the early systems, however, were failures. From the successes came the first commercially available systems in the early 1970s, such as the Technicon system, described in the next section.

Instruments for research and health care underwent great improvement. Partly as a result, the number of laboratory tests performed in hospitals increased rapidly. The Yale-New Haven Hospital, a typical case, performed 48,000 laboratory procedures in 1954, 98,000 in 1959, and 200,000 in 1964, with only a slight increase in the number of patients. Automatic equipment, such as Technicon's Sequential Multiple Analyzer (SMA), saved time and reduced costs. The SMA 12/30 instrument, put on the market in 1963 for $30,000, performed 12 tests per sample at a rate of 30 samples an hour. Several years later came the SMA 12/60, which could handle 60 samples an hour. These products were highly successful. Another example is the automatic retinoscope (for eye examinations). Aran Safir received a patent for an automatic retinoscope in 1964, and in the 1980s there were some 20 such devices on the market.

Instrumentation played a large role in creating the intensive care unit (ICU). In 1960 in the United States the concept was almost unknown. Monitoring equipment, which became much more available in the 1960s, was vital. The mechanical ventilator, which became available in a compact, bedside form in the 1950s, was also important. (The use of the ventilator led to the concept of brain death, first described in 1959.) More and more hospitals set up intensive-care units in the 1960s and 1970s. By 1979 there were 55,000 ICU beds in the United States, and they were continuing to increase.

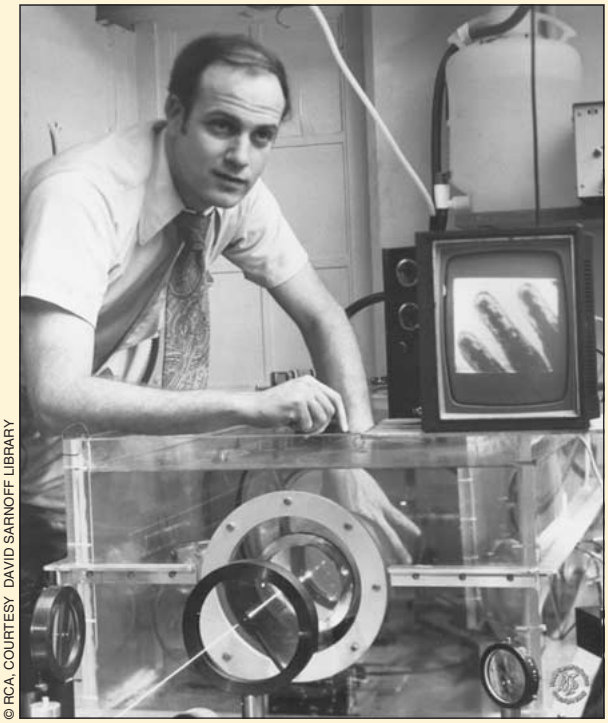
***Biomedical engineering was seen as both part of the problem—for raising the costs of health care—and part of the solution—by improving health care.***

A new imaging technology attracted much attention: ultrasound imaging. Ultrasound had been used for therapeutic purposes (mainly in physical therapy but also to treat cancer) in the 1920s and 1930s, and in the 1940s pulsed reflected ultrasound was used in industry to detect flaws in materials and construction. In the late 1940s and 1950s a number of groups in various countries—Japan, Austria, France, and the United States among them—pioneered in creating medical images using ultrasound. Among the most influential were George Ludwig at MIT, John Julian Wild and John M. Reid in Minnesota, and Douglass Howry at the University of Colorado. As the pioneering cross-sectional imaging technology, ultrasound imaging helped prepare the way for other such technologies discussed in the next chapters.

In the early 1960s a number of products reached the commercial market, such as the Kelvin-Hughes Diasonograph and the Smith Kline echocardiograph. The range of application of ultrasound increased, and the technology advanced. Some examples are the work on Doppler ultrasound by a group headed by Robert Rushmer and Dean Franklin at the University of Washington, the array transducer (a ten-element concave transducer) introduced in 1965 by the German opthalmologist Werner Buschmann, and the Vidoson, designed by Richard Soldner of Siemens, which appeared in 1967 (the transducer rotated at the focus of a parabolic mirror in a water-filled enclosure).

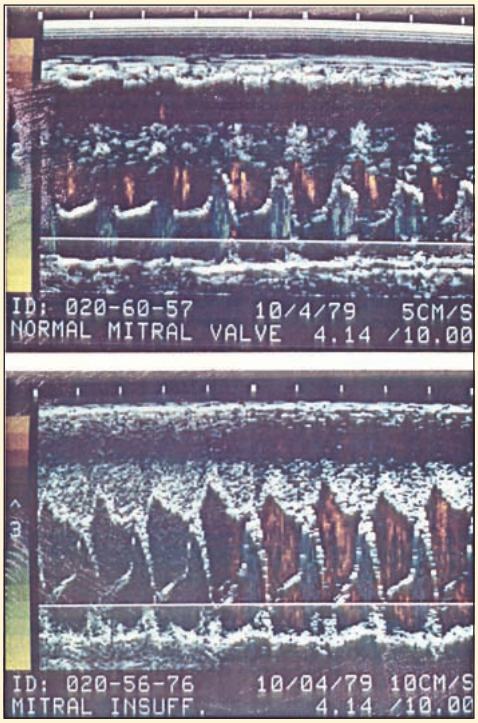
In the mid 1960s infrared thermography (which registered differences in the heat emitted by tissues) was developed for medical diagnosis. J. Gershon-Cohen of the Albert Einstein Medical Center introduced IR imaging to the United States in 1965. It did not become widely adopted and was used mainly as a screening technique for breast cancer. Interest in the technique peaked in the mid 1970s, when there were 2,000 to 3,000 thermography clinics in the United States. Following a major comparative study by Stephen Feig, first reported in 1975, the medical community began to lose interest in the technique, and its use faded gradually.

## Ultrasound Technology Meets Medicine



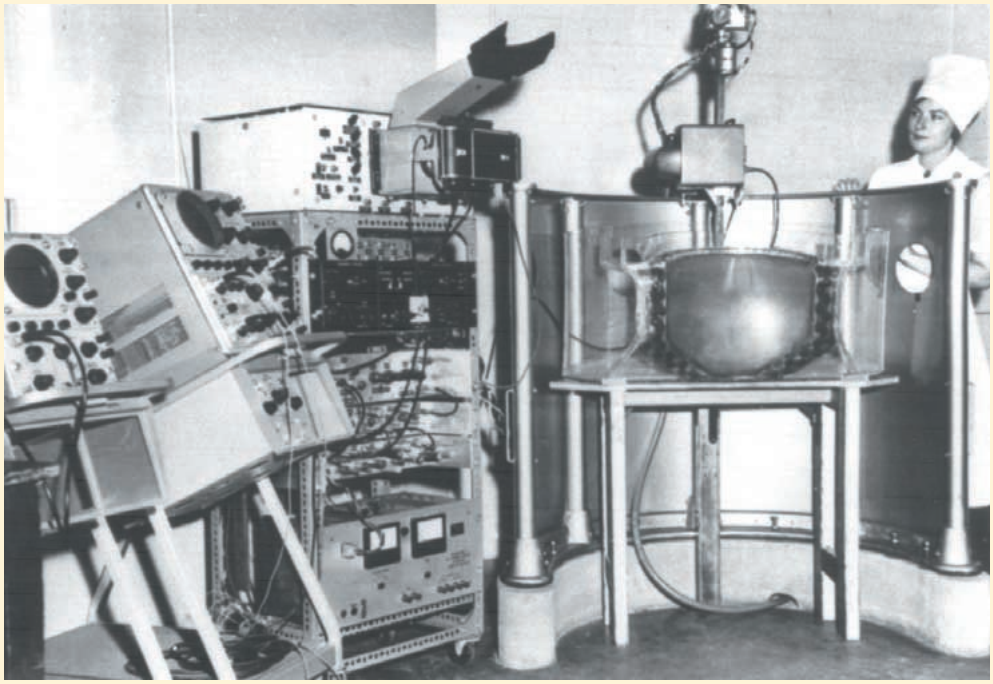
© RCA, COURTESY DAVID SARNOFF LIBRARY

**With its roots in military applications and previously used for therapeutic purposes, in the 1960s ultrasound technology became the pioneering cross-sectional imaging technology and helped prepare the way for other such imaging technologies. In this photo, Dr. Rueben Mezrich of RCA's David Sarnoff Research Center demonstrates an ultrasonic imaging system in 1974.**




COURTESY OF TED WEILER

**These images from the University of Washington in 1979 are believed to be some of the first digital M/Q mode ultrasound color-flow Doppler images ever produced. The top image shows normal mitral valve flow and the bottom image shows regurtitant mitral valve flow.**



COURTESY OF MICHAEL DADD

**This obstetric scanner was installed at the Royal Hospital for Women in Sydney, Australia. The first patient was examined in May 1962.**

An important area of work, as mentioned in the previous chapter, was hearing aids. These devices, however, cannot help those with complete hearing loss. In the late 1950s, A. Djourno and C. Eyries began experimenting with implanted systems to stimulate the auditory nerve (today known as cochlear implants). A number of other researchers took up the work in the 1960s, and in the late 1960s and early 1970s several multiple-electrode cochlear implant systems were developed. Success was difficult to achieve, but by the end of 1985 more than 150 patients worldwide had received multichannel systems.

### History of the Profession

On 1 January 1963 the American Institute of Electrical Engineers and the Institute of Radio Engineers merged to form the Institute of Electrical and Electronics Engineers. The AIEE, which dated back to 1884, originally consisted mainly of engineers concerned with electric power and its applications and with telegraphy and telephony. The IRE, which dated back to 1912, originally consisted almost entirely of engineers working on radio. In the 1940s and 1950s, however, the two organizations overlapped more and more: electronic techniques were being adopted in virtually all branches of electrical engineering (so that AIEE members concerned themselves with electronics), and radio engineering had ramified into numerous branches of electronics (so that IRE members worked in many areas other than radio). A contributing force for the merger was the members of the AIEE and IRE technical committees for biomedical engineering, as almost all of them favored it and had been collaborating with their counterparts in the other society for years.

At the merger it was decided to carry over to the IEEE the IRE system of Professional Groups. The IRE Professional Group on Medical Electronics became the IEEE Professional Technical Group on Bio-Medical Engineering, the name change reflecting the fact that many members, particularly former AIEE members, were concerned with nonelectronic topics. Table 2 is a list of the chairmen during the 1950s. The members who served as editor of *Transactions* during the 1960s were Lee B. Lusted, Edward F. MacNichol, Robert L. Schoenfeld, and David Geselowitz.

The Society began an awards program. First to be instituted was the William J. Morlock Memorial Award (which later became the EMBS Career Achievement Award). The awardees in the 1960s are listed in Table 3. In 1968 the Society announced a new prize in memory of Samuel A. Talbot to "recognize achievements by young scientists and engineers under the age of 30 for creative contributions to the field of biomedical engineering."

**Table 2. The Chairmen during the 1960s of the IRE Professional Group on Medical Electronics and the IEEE Professional Technical Group on Bio-Medical Engineering.**

| | |
|---|---|
| 1960 | Herman P. Schwan |
| 1961 | George N. Webb |
| 1962 | Otto H. Schmitt |
| 1963 | Robert L. Schoenfeld |
| 1964 | Murray Eden |
| 1965 | Murray Eden |
| 1966 | J.E. Jacobs |
| 1967 | Herman P. Schwan |
| 1968 | Herman P. Schwan |
| 1969 | D.G. Fleming |

The diversity of work in biomedical engineering and the diversity of background of the people contributing to this field made it difficult for a single organization to represent everyone. In the 1960s there were efforts by some leaders of the PGME to achieve greater autonomy within the IEEE in order to accommodate a more diverse membership. These efforts met considerable resistance, and partly as a result the Biomedical Engineering Society was formed in 1968.

Because there were quite a few professional groups, several umbrella organizations were established to facilitate cooperation. In the late 1960s the Alliance for Engineering in Medicine and Biology was formed, with Pat Horner as its executive director. This alliance assumed the task of organizing the annual conference that had earlier been organized by the Joint Executive Committee on Medicine and Biology, mentioned in the preceding section, and the name changed from Annual Conference on Electrical Techniques in Medicine and Biology to the Annual Conference of Engineering in Medicine and Biology. Within the United States, the National Academy of Engineering (NAE) was established in 1964. The NAE created a number of sections, including one on bioengineering. (The bioengineers elected to the NAE are listed on the NAE Web site.)

**Table 3. The winners of the William J. Morlock Memorial Award (which later became the EMBS Career Achievement Award) during the 1960s.**

| | |
|---|---|
| 1961 | Britton Chance |
| 1963 | Otto Schmitt |
| 1965 | Edward F. MacNichol, Jr. |
| 1967 | Herman P. Schwan |
| 1968 | Wilson Greatbatch |

There was interest also on the international plane in facilitating cooperation among professional groups. The International Federation for Medical Electronics was formed, with the IRE PGME as one of its members. The first full-fledged technical conference was held in London in July 1960. In the 1960s the name was changed first to International Federation for Medical Electronics and Biological Engineering, and shortly thereafter to the International Federation for Medical and Biological Engineering. And in 1963 the International Federation launched the journal *Medical Electronics and Biological Engineering*.

It was in the late 1960s that the term "biomedical engineering" became established. The term "medical electronics" was too narrow. "Engineering in medicine and biology" was too long. In the United State the Engineers Joint Council Committee on Engineering Interaction with Biology and Medicine officially recommended the term "bioengineering" in 1966, but this did not become standard. J.H.U. Brown, head of the NIH program described above, promoted the term "biomedical engineering."

Besides professional societies, publications, conferences, and educational programs, another characteristic of the professionalization of a discipline is the formal establishment of standards. The first such activity for the PGME was that of the Subcommittee on Instrumentation, set up by the PGME Committee on Electrocardiography. In 1967 the Subcommittee published a set of standards for ECG, and industry paid attention to these standards. An international milestone occurred when the International Electrotechnical Commission (IEC) established the IEC Technical Committee 62: Electromedical Equipment. TC62, which held its first meeting in 1968, concerned itself with all aspects of standardization of biomedical equipment.

At the beginning of the decade only a handful of universities had formal programs in biomedical engineering. At the University of Pennsylvania in 1960, Herman Schwan obtained university approval for an independent Ph.D. program in biomedical

engineering. In the United States the number of universities having a recognized program increased from 40 in 1965 to 180 in 1971. The range of biomedical engineering increased. For example, in 1963 MIT began offering a course titled "Chemical engineering in medicine," which may have been the first such course in the United States. Universities also began to offer undergraduate programs in biomedical engineering.

The 1960s stand out in the history of biomedical engineering as the decade in which computers became widely applied in research and health care and as the decade in which biomedical engineering was established as an academic discipline.

## The 1970s: New Means of Medical Imaging

### History of the Technologies

In the early 1970s it was believed there was a crisis in health care in the United States, with costs out of control and performance unsatisfactory in many areas. Biomedical engineering was seen as both part of the problem—for raising the costs of health care—and part of the solution—by improving health care.

The high cost of medical technology was brought forcefully to U.S. public attention at the beginning of the decade, when the media made public the way patient selection for dialysis was being carried out in Seattle. In 1972 Congress agreed to meet the cost of dialysis for every patient considered likely to benefit. Costs soon far exceeded the original estimates; the 1983 cost to the government for providing dialysis was $2.2 billion. This created alarm, as it was thought that other technologies that were both effective and costly would soon become available. Before long this indeed happened with CT scans, coronary bypass surgery, and heart and liver transplants.

It was in part a response to the rising cost of medical care that health maintenance organizations (HMOs) emerged in the 1970s as a principal way of providing medical care in the United States, as cost containment was one objective of the HMO. At the same time, HMOs made great use of new technologies. One commentator wrote, "An HMO is a working version of the utilization of modern technology in health care, including computers, communication systems, automatic analysis, and systems theory, all applied to the business of modern health-care delivery."

Another response to the rising costs was a change made in 1978 to reimbursement procedures for Medicare and Medicaid that reduced incentives for the use of new medical technologies. That same year Secretary of Health Joseph Califano Jr. said that his department was concerned about the allegedly extravagant use of medical technology, and the sales of computerized axial tomography (CAT) scanners fell dramatically.

The government also took a more active role in the health-technologies market. In 1976 Congress passed the Medical Device Amendments, which required FDA approval of a device before it could be marketed (through a process called premarket approval). And in 1978 Congress established the National Center for Health Care Technology to evaluate existing and emerging technologies. The first technology to be studied was CAT scanning.

The 1970s stand out for the development of new techniques of medical imaging. Attracting the most attention was computerized tomography (CT), which uses X-ray machines and computers to generate cross-sectional images. Important work done in the 1970s included two papers by Allan Cormack on a scanning method that projected gamma rays through an object on a rotating platform and a prototype transmission CT scanner built by David Kuhl and Roy Edwards in Philadelphia. In London, Godfrey Hounsfeld developed a CT scanner. He first produced a CT image of a patient on 1 October 1971, and his scanner was presented at the 1972 British Institute of Radiology Congress. Within a few years there were hundreds of CT scanners throughout the world. A whole-body CT scanner was developed by Robert Ledley in 1973, and it was put into routine clinical use in February 1974. In 1979 Allan Cormack and Godfrey Hounsfeld received the Nobel Prize in Medicine for their work on computerized axial tomography, the former for his mathematical models, the latter for his engineering of an effective machine.

Nuclear magnetic resonance (NMR) imaging, which takes advantage of the fact that different chemical elements respond differently in magnetic fields, began in the mid 1970s. A contributing factor was advances in magnet technology, since high-intensity fields are necessary for high-resolution images. In 1972 Raymond Damadian applied for a patent on an NMR "Apparatus and method for detecting cancer in tissue," and in 1973 Paul C. Lauterbur published a paper in *Nature* that presented a method for forming a 2-D NMR map. A live human NMR image (of a finger) was reported in 1976 by Mansfield and Maudsley, and in 1977 Damadian succeeded in making an NMR image of the human chest. In April 1980 Damadian's company displayed a prototype of a commercial machine and began taking orders. In 1992 some 4000 NMR scanners were in use.

Positron emission tomography (PET), which forms images from the positrons emitted by radioactive chemicals injected into, or swallowed by, a patient, made its commercial debut in 1977. A group head by Michael Ter-Pogossian at Washington University in St. Louis built a positron imaging device in 1972, and Ter-Pogossian and Michael Phelps published a paper on their system of PET in 1975. This new imaging technology was not, however, adopted as rapidly as CT imaging: at the end of the decade only about 40 institutions had set up PET centers.

Ultrasound imaging, which, as related above, became widely practiced in the 1960s, underwent improvement. The 1970s saw the advent of a related technology, the scanning acoustic microscope. Conceived by C.F. Quate in 1973, the device, which uses ultrasound, became available commercially in 1975.

As in the preceding decades, there was much work by biomedical engineers on the heart, circulation, and blood. Indeed, studies in these areas accounted for almost half of the articles in the first five volumes of the journal *Annals of Biomedical Engineering*; which commenced in 1972. The principal explanation for this focus is, of course, the well-established tradition of such work, but in the 1970s there was also much concern for the high death rate for heart-related problems, hence generous funding in these areas.

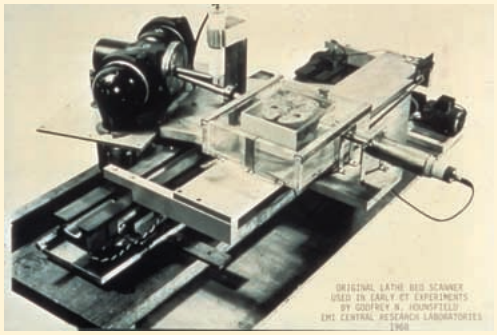
In 1970 was the first successful use of a totally implanted standby defibrillator (by J.C. Schuder and co-workers). A rechargeable cardiac pacemaker was marketed from 1973 to 1978, and it was successfully used in hundreds of patients, and at about the same time a nuclear-powered pacemaker was developed. The introduction of the lithium battery into pacemaker use by Wilson Greatbatch, however, led to the discontinuation of the manufacture of both rechargeable and nuclear pacemakers. Medtronic worked to develop an implantable blood pump to take over part of the heart's workload, giving time for a donor heart to be located, but ended the program in the late 1970s because of declining federal support and the limited market. In the late 1970s at the University of Utah, Robert Jarvik and Wilhelm Kolff developed

several artificial hearts and tested two of them (Jarvik 5 and Jarvik 7) in calves. The FDA gave approval for use of the Jarvik 7 in a patient, and in 1982 a team headed by William C. DeVries replaced the diseased heart of Barney Clark with the Jarvik 7. (Clark died after 112 days.) At Pennsylvania State University a team led by William Pierce developed the Pierce-Donachy pump, a pneumatic ventricular assist device. It was first used in a patient in 1976 as a bridge to transplant. A commercial version manufactured by Thoratec has been implanted in over 3,000 patients worldwide. Also in the 1970s was the development of an alternative to the mechanical respirator: extracorporeal membrane oxygenation (ECMO). The rationale for ECMO is that by oxygenating the patient's blood outside the body, the patient's lungs can rest and heal themselves. The 1970s also saw advances in electrocardiographic telemetry from ambulances and in the remote diagnosis of an ECG through a telephone network.

Improvements in instrumentation, particularly automation, continued to affect health care. In the 1970s the rate of laboratory testing in U.S. hospitals increased just as much as in the 1960s. In 1971 some 2 billion tests were performed, five years later some 4.5 billion. Part of the explanation for the increase was what came to be called "defensive medicine," the practice of physicians to order many diagnostic procedures lest they be sued for malpractice for not having used all available technology. A larger part of the explanation was the increased efficiency and lower cost of testing that automation provided.

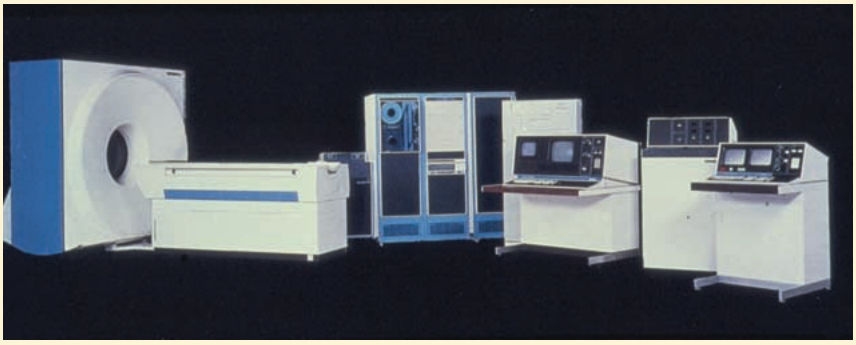
Already in the early 1970s roughly 80% of the 15,000 clinical laboratories in the United States used automatic equipment, and in the 1970s the NIH made the automation of clinical laboratories an area of particular emphasis in its support of research and development. One example of a successful product was DuPont's ACA (Automatic Clinical Analyzer), introduced in 1970. The ACA was designed for specialty and emergency tests, as well as small batches of routine tests. It thus complemented the large batch analyzers already available in many hospitals, providing automation in small hospitals, clinics, and group practices. Also in 1970 Beckman Instruments introduced an automatic glucose analyzer, which soon became standard worldwide for measurement of glucose in biological fluids such as blood, and the next year Beckman introduced an automatic urea nitrogen analyzer.

## X Rays + Computers = Computerized Tomography




COURTESY OF DR. ROBERT SENZIG, GE MEDICAL SYSTEMS CT IMAGING

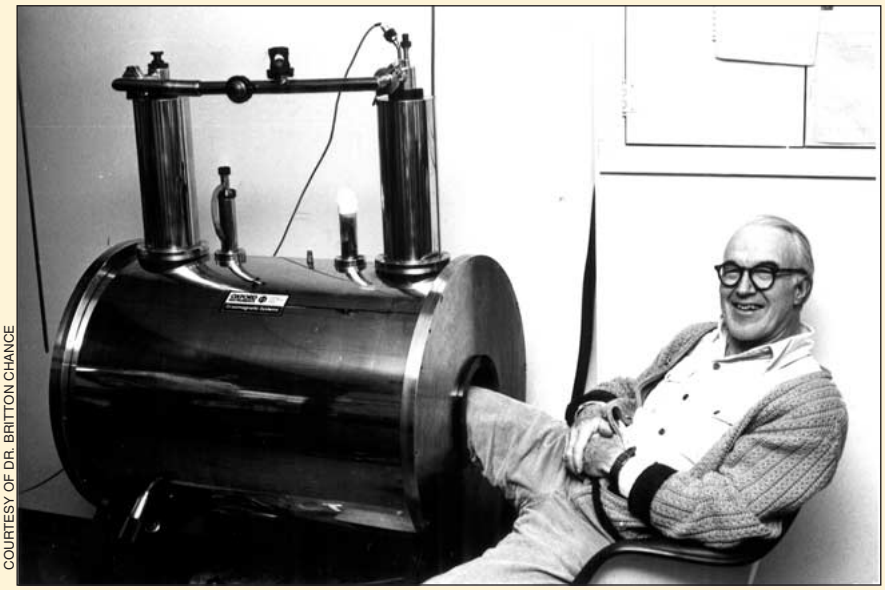
**Computerized tomography (CT), which uses X-ray machines and computers to generate cross-sectional images, was the imaging technique attracting the most attention in the 1970s. Godfrey Hounsfeld first produced a CT image of patient in 1971. His scanner was presented at the 1972 British Institute of Radiology Congress and within a few years there were hundreds of CT scanners throughout the world. Hounsfeld won a Nobel Prize in Medicine for his engineering of the CT machine. Above: EMI's original lathe bed scanner used by Hounsfeld in early CT experiments in 1968. Below: A GE Medical Systems CT scanner from 1976.**



COURTESY OF DR. ROBERT SENZIG, GE MEDICAL SYSTEMS CT IMAGING

An instrumentation trend of the 1960s and 1970s was the replacement of analog techniques by digital techniques. A subheading of a 1974 *Spectrum* article on instrumentation was "The digital takeover is now a reality." Another trend of the 1970s was the incorporation of microprocessors in instruments. (It was in 1971 that Intel introduced the first microprocessor, the 4004.) For example, in 1978 Beckman introduced the ASTRA (Automated Stat/Routine Analyzer) System, which combined the efficiency of Beckman's dedicated analyzers with the flexibility made possible by the microprocessor. In the mid 1970s the Technicon SMA 12/60, mentioned in the preceding section, was succeeded by a computer-controlled instrument known as the SMAC (Sequential Multiple Analyzer Plus Computer). The SMAC did 20 tests on each sample at the rate of 150 samples per hour, and in the late 1980s this machine was the workhorse of most large clinical laboratories. Automatic devices that classified and counted blood cells began to be used in the 1970s. For example, in 1976 Perkin-Elmer's introduced the "diff 3" Blood Smear Analysis System that used image processing and pattern recognition techniques to count and classify both white and red blood cells.

Microprocessors were used in many other ways. At the 1978 Annual Conference on Engineering in Medicine and Biology



COURTESY OF DR. BRITTON CHANCE

**With the help of improved magnet technology, nuclear magnetic resonance (NMR) imaging, which takes advantage of the fact that different chemical elements respond differently in magnetic fields, began in the mid 1970s. The high-intensity fields are necessary for high-resolution images. Above: Dr. Britton Chance has his leg inside one of the early NMR magnets in 1980 at the University of Pennsylvania.**

## *Chemicals + Magnets = NMR Imaging*


PHOTOS COURTESY OF ROLAND SAAM

**This double-decker bus with an installed NMR scanner (circa 1990) provides a portable scanning service for preventative noninvasive medical check ups, and it is still in use today by a research team at the Royal Brompton Clinical Magnetic Resonance Unit, London, UK. It was the idea of Prof. David Longmore, who founded the first NMR unit in London.**

there were 35 papers dealing with applications of microprocessors. Some microprocessor applications for the disabled were the following: communications device for nonverbal, motor-impaired persons; hand-held telephone terminal for the deaf; voice synthesizer; a device for epileptic-seizure control through biofeedback; and a device for control of an artificial leg.

Mainframe computers became important for hospital administration. In 1971 Technicon Corporation contracted with El Camino Hospital in Mountain View, California, to provide an information system. By 1974 the system had gained acceptance by physicians and others at El Camino, and the hospital entered into a long-term agreement with Technicon. Functions of the systems included patient records, patient status, scheduling of treatment, scheduling of testing, requisitioning of medication, staffing, "electronic rounds" (reviewing clinical status of patients), and financial records. From 1972 on, Technicon installed information systems in other hospitals. The systems lowered costs through labor savings, reduction in length of patient stay, reduction in forms usage, advance of billing date, reduction in wasted meals and supplies, reduction in bad debt losses, and reduced re-work resulting from fewer errors.

***In the last quarter of the 20th century the field of biomedical engineering benefited enormously from the actions of the Whitaker Foundation, which was established in 1975.***

It was in the 1970s that clinical laboratory information systems became widespread. The DEC-based CLINLAB and the Hicks LCI systems were landmarks. By 1980 most laboratory systems included a terminal at every workstation or instrument interface and consolidated patient data in a common database.

There also were significant attempts to make computer-based expert systems. In 1972 a group at the University of Pittsburgh headed by Jack D. Myers devised the program INTERNIST-I for clinical decision making. This and later versions were of educational value to clinical practitioners as well as medical students. In 1973 Edward Shortcliffe and collaborators published a description of MYCIN, an expert system to aid physicians in the selection of antibiotics. Shortcliffe had captured specialist knowledge in the form of heuristic rules. In 1979 MYCIN performed well in a clinical evaluation of its accuracy, but it was never used in practice.

The high level of activity in hospital administration systems, laboratory information systems, expert systems, and so on led to recognition of a field of medical informatics. In 1974 the first world conference on medical informatics, called MEDINFO, was held.

In the 1970s there was considerable movement into clinical engineering. The adoption of new technologies had given rise to problems: incompatibility of devices made by different companies, design deficiencies, incomplete operating instructions, improper maintenance of equipment, and difficulty in making management decisions about advanced technologies. To address these problems, engineers participated in greater numbers in health care teams in clinics and hospitals, and clinical engineering departments were established in larger hospitals.

In the mid 1970s electrical techniques for pain control began to be widely used, both as external and implanted devices. Other than cardiac pacemakers, the most widely used neuroaugmentative device was the dorsal column neurostimulator (to lessen intractable pain, to stimulate the bladder, and to control spasticity).

Some other devices developed in the 1970s might be mentioned. Dornier System, a West German company, introduced a device, called the lithotripter, that focuses shock waves on kidney stones. The device began to be used in Germany in the late 1970s, and it received FDA approval for marketing in the United States. in 1984. By the end of 1985 the lithotripter had treated some 50,000 patients worldwide. In the late 1970s a joint venture of Chalmers University of Technology and the Institute for Applied Engineering in Sweden developed the bone-anchored hearing aid (BAHA). The device was not well received because of the large size and mechanical discomfort, but in the 1980s important improvements resulted from circuit miniaturization, new biocompatible materials, and new surgical techniques. In 1978 HC Electronics began selling the Phonic Mirror HandiVoice, which simulates the human voice for nonvocal children and adults (who use a keyboard to indicate what is to be spoken). And a reading aid for the blind, the Optacon, came into use in the mid 1970s. It consists of a "retina" of 144 phototransistors, circuitry, and an array of vibratory piezoelectric reeds (to reproduce an enlarged version of the letter being read). Some 1,200 were in use worldwide in 1974.

By the 1970s the biomedical engineering industry had become a significant sector of the economy. In the United States some 5,000 companies provided products with total annual sales of approximately $1.5 billion. And at the beginning of the decade on the order of 7,500 people in the United States had professional involvement with biomedical engineering.

### History of the Profession

In the 1970s there was much concern about the dangers of microwave ovens, heightened by a great deal of misinformation in the popular media. This prompted leaders of IEEE, specifically members of the Technical Activities Board, to form in 1972 the IEEE Committee on Man and Radiation (COMAR) "to have a voice within IEEE to the media, the general public, and the Congress about what the facts are about microwaves." In March 1973 the Consumers' Union announced their decision not to recommend any microwave ovens because of doubt about their radiation safety. In the spring of 1974 the IEEE held a press conference with COMAR Chairman Mark Grove to announce opposition to the CU position. There was caution within IEEE, in part because its position might not be seen as disinterested, since some IEEE members had financial stakes in the microwave oven business. In later years COMAR studied and issued statements about radiation from cellular ground stations, dielectric heaters, electromagnetic pulse simulators, police radar, and other sources.

The IEEE Engineering in Medicine and Biology Society continued its growth. One indication was increased publication. In 1971 the *Transactions* moved from quarterly to bimonthly publication, and in 1979 it moved from bimonthly to monthly publication. It was reported at the time that "Coupled with this expansion

**Table 4. The Chairmen and, from 1973 on, the Presidents of the IEEE Engineering in Medicine and Biology Society during the 1970s.**

| | |
|---|---|
| 1970 | David G. Fleming |
| 1971 | Richard J. Johns |
| 1972 | Richard J. Johns |
| 1973 | Robert Plonsey |
| 1974 | Robert Plonsey |
| 1975 | L.L. Wheeless, Jr. |
| 1976 | Richard J. Gowen |
| 1977 | Thelma A. Estrin |
| 1978 | Eli Fromm |
| 1979 | Eli Fromm |

is the policy commitment that at least 25% of the pages published be identifiable as applied, that an active program for the incorporation of tutorial and applied reviews be undertaken." The editors of the *Transactions* were, during the 1970s, David Geselowitz (to 1973), Hun H. Sun (to 1979), and Theo C. Pilkington (to 1984). The highest office in the Society changed its designation in 1973 from Chairman to President. The office holders are listed in Table 4.

The highest honor of the Society, the Morlock Award, (which later became the Career Achievement Award), was granted only three times in the decade. The winners are listed in Table 5.

**Table 5. The winners of the William J. Morlock Memorial Award (which later became the EMBS Career Achievement Award) during the 1970s.**

| | |
|---|---|
| 1973 | Donald Gene Childers |
| 1974 | Dean L. Franklin |
| 1979 | Robert Plonsey |

An important event was the decision by the Society to hold its own annual conference. The First Annual Conference was held 6-7 October 1979 in Denver. EMBS continued to participate in the annual conference organized by the Alliance for Engineering in Medicine and Biology. Indeed, from 1979 until 1985 EMBS held its conference immediately preceding, and in the same city as, the older annual conference.

In the last quarter of the 20th century the field of biomedical engineering benefited enormously from the actions of the Whitaker Foundation, which was established in 1975 as part of the legacy of Uncas Whitaker, founder of AMP Inc., a manufacturer of electrical connectors. It became the largest private sponsor of biomedical engineering research in the United States. An objective that the foundation has particularly sought to advance is the reduction in the cost of health care.

The number and size of degree-granting programs in biomedical engineering continued to increase in the 1970s, though it remained the case that the vast majority of workers in the field had not received such degrees. (At the beginning of the decade, it was estimated that of 7,500 biomedical engineers in the United States, only 400 of them came from formal advanced-degree programs in biomedical engineering.) And there was still concern that someone trained as a biomedical engineer would, in the workplace, be regarded as "neither fish nor fowl" (neither physician nor engineer).

Though it had begun earlier, the 1970s was marked by the acceptance of undergraduate programs in biomedical engineering. A survey of engineering schools in the United States in 1974 found that 121 had programs or degrees in biomedical engineering (49 of them granting degrees in biomedical engineering); enrollment in 1974 by degree was 1,530 for the B.S., 1,306 for the M.S., and 933 for the Ph.D.

In the 1970s, then, the discipline of biomedical engineering grew in size and further defined itself in professional organizations and in educational programs. Behind the discipline growth, of course, were the many improvements in technologies that were useful in research and in health care.

## The 1980s: Endoscopy, Lasers, and Fear of Electromagnetic Fields

### History of the Technologies

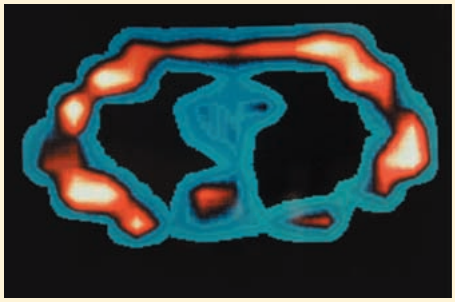
The 1980s saw continued growth for the health-care industry. In the United States, expenditures increased from $248 billion in 1980 to $666 billion in 1990. Adjusted for inflation, this was a 70.7% increase. This resulted not only from economic growth but also from a further prioritizing of health care: the part of the GNP claimed by the health-care industry increased from about 9% in 1980 to 12.2% in 1990. And, as in the 1970s, there was great concern over rising medical costs. Partly as a result, the enrollment in HMOs continued its rise: from 9.1 million at the start of the decade to 38.6 million at the end.

Another response was the so-called Diagnostic Related Groups (DRG) program started in October 1983. It called for Medicare payments according to predetermined prices affixed to particular diagnoses. Other third-party payers adopted such prospective payment systems, in contrast to the earlier cost-plus reimbursement that meant that hospitals could count on recouping expenditures for new technologies. The flat-rate payment put emphasis on cost containment and thus retarded the adoption of new technologies, such as magnetic resonance imaging (MRI) equipment. Though the medical devices themselves made up only 2.5% of health-care costs, critics often pointed to it as a major cause of medical inflation.

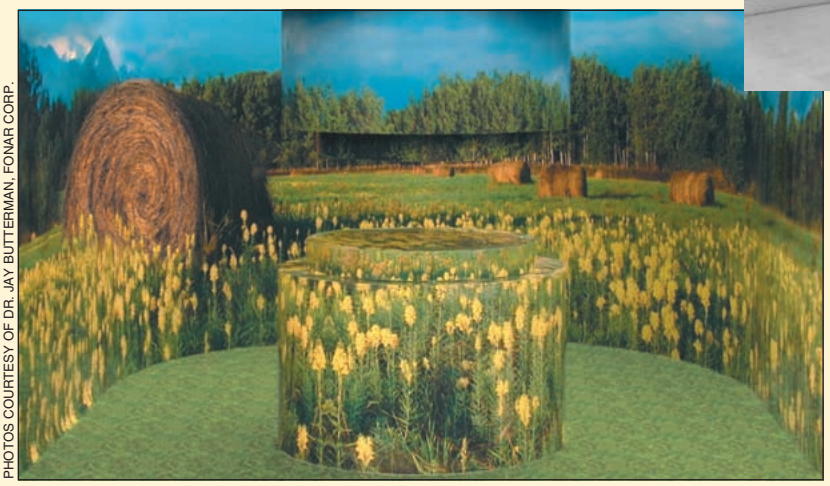
Cardiac medicine remained an area of particular interest for biomedical engineers. In 1986 the FDA gave market approval to the rate-responsive pacemaker (Activitrax) made by Medtronic. Clinical trials in the United States began in 1983, and by 1987 12,000 patients worldwide had received the device (7,000 of them in the United States). An automatic implantable defibrillator was developed in the late 1970s, and the first was implanted in a human on 4 February 1980 at Johns Hopkins University Hospital. Following further clinical trials, the FDA approved the implantable defibrillator in October 1985, and several companies, including Cardiac Pacemakers Inc., began producing and selling the device.

In the 1980s emphasis moved from permanent to temporary artificial hearts. For example, in 1984, for the first time the Stanford LVAS (left-ventricular assist system), which takes on the work of the left ventricle, was implanted in a patient in 1984. Its purpose was to sustain a patient waiting for the transplantation of a natural heart. In 1986 temporary artificial hearts were implanted by 11 different surgical teams in five countries. Early that year NIH announced that it would cancel all outstanding research contracts for the development of an implantable artificial heart in order to concentrate efforts on assist devices, but a few months later, following protests by senators from states where there were major artificial-heart programs, NIH reversed itself and reinstated the cancelled contracts.

In 1980 Harold Swan and William Gantz introduced balloon-tipped catheters for clinical use (earlier Andreas Gruentzig had introduced a stiff-walled angioplasty catheter), and the open-



**A major achievement of the 1980s was magnetic resonance imaging. In 1983, only 14 machines were in use in the United States; however, in 1984 there were more than 90, with 140 in use worldwide. Left: The team that produced the first whole body human image (above) via MRI in 1977: (from left to right) Dr. Damadian and graduate students Larry Minkoff (the subject used for the image) and Michael Goldsmith.**

PHOTOS COURTESY OF DR. JAY BUTTERMAN, FONAR CORP.

**The 1982 FONAR Beta 3000 permanent magnet (above), and for the claustrophobic, the FONAR-360 from 1998, where the MRI scanner is hidden behind the landscape, 360 degrees open to reduce the claustrophobia. It can also be used for MRI-guided surgical interventions.**

## *Imaging Expands with MRI*

ing up of blood vessels using such catheters, known as balloon angioplasty, soon became common (some 300,000 being performed in the United States in 1991). The use of metallic stents to hold blood vessels open, though first reported experimentally by Charles Dotter in 1969, came into clinical use in the 1980s.

A major advance of the 1980s was endoscopy, sometimes called keyhole surgery, which came to be widely practiced. Tiny instruments could be passed through small tubes inserted in the body either through natural openings or incisions. Mechanical miniaturization and fiber-optic techniques made it possible to replace a wide range of traditional surgical procedures, both diagnostic and corrective, by new minimally invasive ones. The U.S. market for endoscopy products reached $533 million in sales in 1988.

Surgery benefited greatly from the use of lasers. At the beginning of the decade the applications were limited, and most employed one of three continuous-wave lasers. At the end of the decade there were a great many medical applications, and these used a variety of pulsed and continuous-wave lasers. Among the new applications were pulse-dye lasers for fragmentation of kidney stones, excimer lasers for reshaping the cornea, pulse-dye lasers for the treatment of port-wine stain, and argon-pumped pulse-dye lasers for treatment of cancer. Lasers could be used in endoscopy, such as the laser catheter for cleaning arteries of plaque made by Trimedyne Inc. that received FDA approval in 1987.

A momentous advance of the 1980s was the adoption of MRI. In 1984 the FDA gave approval to four companies to market MRI machines. In October 1983 only 14 MRI machines were in use in the United States; a year later the number was more than 90, with more than 140 installed worldwide. At the beginning of the decade, superconducting solenoids, to achieve

higher field strengths, were introduced, and in 1987 techniques for extremely rapid MRI made it possible to create a movie of a beating heart.

PET, which, as we saw, was introduced the previous decade, became more widely used. The technique was especially valuable because it could chart metabolic processes. But the cost of PET scanning remained so high that it was used almost exclusively for research. The use of smaller cyclotrons contributed to lowering the cost, which in 1988 was one-third of what was it was five years earlier.

The decade also saw important improvements to ultrasound imaging and X-ray computed tomography. For example, in 1985 Douglas Boyd developed superfast CT, and in 1989 a spiral CT was first marketed. (Instead of sequential scanning of consecutive slices, spiral CT is a mode for continuous volume scanning.)

***In the 1980s there was a revival of interest in the study of human metabolism.***

Medical imaging became big business. In 1988 in Europe sales of medical imaging equipment totaled $1.46 billion (X ray 62%, ultrasound 20%, CT 8.5%, nuclear imagers 5%, and MRI 3%). In the United States the ultrasound imaging market alone reached nearly $600 million in 1988. As these figures suggest, in the 1980s biotechnology became a major sector of the economy, recognized as such by economists with careful measurements of national investments and outputs. Another example is provided by cardiac monitoring equipment, whose total sales in the United States reached the $2 billion level in 1990.

In 1963 Richard McFee and B.M. Baule created the first magnetocardiogram, a depiction of the magnetic field of the heart, using coils with several million turns of wire. Later David Cohen used the superconducting quantum interference device (SQUID) to record both a magnetocardiogram and a magnetoencephalogram. Several investigators developed the theory for the generation of these fields. Toward the end of the 1980s there appeared commercial systems using SQUIDs to create images of biomagnetic fields: in 1989 both Siemens Medical Systems and Biomedical Technologies announced such biomagnetic measurement systems. Used initially in neurological research, they gave information about overall brain activity and permitted the localization of brain activity within a few millimeters. (In both respects, the electroencephalogram and the magnetoencephalogram provide complementary tools.)

The expanding capabilities of solid-state electronics had many other biomedical applications as well. For example, microchips transformed cardiac monitoring equipment: what had been bulky, expensive, and confined to the laboratory or hospital became small, inexpensive, and usable by the individual. One such monitoring device was the pulse oximeter, which noninvasively measured blood oxygen levels, giving warning of insufficient oxygenation. In many instances, solid-state transducers replaced larger, handmade devices. In the late 1980s, for example, biomedical pressure transducers were introduced that sold for 5% of the price of earlier devices, which made possible disposable pressure sensors for clinical applications.

The new capabilities expanded the range of animal electronics, which are the sensing and imaging technologies for research or for use on farms or in animal- and food-processing plants. Electronic sensors were used, for example, to measure animal weight, to feed dairy cows based on their milk production, and to detect diseased animals. Zoological research, too, benefited. For example, in 1989 engineers at Oak Ridge National Laboratory developed a tiny solar-powered transmitter that could be glued to the thorax of a honeybee. (At the time the movement of Africanized honeybees was a cause of concern.)

Another advance in instrumentation during the 1980s was the fluorescence polarization instrument for measurement of serum drug levels (the Abbot Laboratories TDx system), which achieved widespread clinical use by 1985. Also noteworthy was the FDA approval in 1989 of the nitroprusside infusion controller; this was the first medical device that continuously monitored a physiological parameter (blood pressure) and then used the information to control the injection rate of a drug without human intervention.

A breakthrough advance was the invention in 1981, by Gerd Binnig and Heinrich Rohrer, of the scanning tunneling microscope. (In 1986 Binnig and Rohrer, along with Ernst Ruska, inventor of the electron microscope, won the Nobel Prize for Physics.) This led to, among other things, the atomic force microscope (AFM). In the mid 1990s use of AFM in the biological sciences increased rapidly, and in 1997 there was an issue of *IEEE Engineering in Medicine and Biology Magazine* devoted to the subject.

In the 1980s there was a revival of interest in the study of human metabolism. It had been vigorously pursued in the late 19th and early 20th centuries, but then interest in it waned, partly because of lack of suitable instrumentation. In the 1980s there was a revival of interest in the topic among biomedical engineers, one indication of which was a special issue of *IEEE Engineering in Medicine and Biology Magazine* on the topic.

Several other advances of the 1980s might be mentioned. Shock-wave lithotripsy (the use of acoustic waves to destroy kidney stones) reached the marketplace. The U.S. patent for two-photon excitation (TPE) fluorescence microscopy was filed in 1989. TPE had been first proposed in the 1970s, and it became an extremely important technique in the 1990s. Between March 1982 and January 1985, an implantable peristaltic pump developed by Medtronic was placed in more than 150 people to deliver morphine, chemotherapy agents, or heparin (against blood clotting). At Johns Hopkins University, a team led by Christopher Saudek developed the Programmable Implantable Medication System (PIMS). The FDA gave approval for human implant in May 1986. PIMS was used to deliver insulin automatically in diabetes patients according to programming stored in its microprocessor.

The decade of the 1980s saw several advances in correcting deafness. A joint venture of Ehime University and Sanyo Electric Company developed an implantable middle-ear device that achieved direct vibratory coupling to the ossicles. The cochlear implant, which consists of an internal receiver embedded under the skin behind the ear that is connected to electrodes in the cochlea (part of the inner ear), received FDA market approval in 1984 (for a single-electrode unipolar implant) and 1985 (for a 22-electrode device). A related device called the central electroauditory prosthesis (CEP) was also developed; it is simi-

lar to the cochlear implant except that the electrode wiring is placed directly on the brain stem rather than in the cochlea.

Another technology involving connection to the nervous system was functional electrical stimulation (FES). In 1983 programs at several institutions, Case Western Reserve and Illinois Institute of Technology among them, demonstrated FES that enabled sufferers of spinal-cord injuries to walk again and that restored grasping functions to the hands of quadriplegics. Other FES devices restored bladder control in patients and assisted in the treatment of scoliosis.

An important stimulus to the development of FES and other types of rehabilitation engineering in the United States had been the passage of the Rehabilitation Act of 1973. This act led to the establishment of more than a dozen research-and-development centers for rehabilitation engineering under the jurisdiction of the National Institute for Handicapped Research (later the National Institute on Disability and Rehabilitation Research). The act also recognized various areas of rehabilitation engineering as particularly important, and the different research centers focused on different sets of problems.

***In 1982 the Society inaugurated a magazine "to provide published material of broad member interest," the first issue appearing in March of that year.***

The participation of people in wheelchairs in athletics, particularly marathons and other races, increased markedly in the 1980s. This led to improvements in wheelchair design and much greater public awareness of the needs of people who use wheelchairs (one consequence of which was the passage of the Americans with Disabilities Act in 1990). A long-term program of systematic research and development in wheelchair design began at the University of Virginia's Rehabilitation Engineering Center in 1977, and in the 1980s there was drastic improvement in powered wheelchairs. The adoption in the late 1980s of voluntary standards for manual and powered wheelchairs was important, as the standards enabled comparisons using objective criteria served as criteria for third-party payer acceptance.

A significant advance in the use of artificial materials in biomedicine was the 1986 approval by the FDA of Gore-Tex (expanded polytetrafluoroethylene) as an artificial ligament. (Gore-Tex was already being used for sutures and blood-vessel grafts, as well as in sportswear.) In 1987 the passive soft tissue implant market in the United States totaled $234.4 million. The most important products were vascular grafts, fabrics and meshes, and vascular access devices. A recent innovation was a surface coating for Dacron vascular grafts to eliminate time-consuming preclotting of the graft.

In the 1980s computers became ubiquitous in biomedical research and in hospitals, clinics, and doctor's offices. These were mainly personal computers, which first became common in the early 1980s. Researchers and hospitals used, in addition, minicomputers and mainframe computers. And in the 1980s the application of supercomputers in biomedicine attracted attention, as they were used to model complex systems (such as the cardiovascular system), in image processing (such as real-time CT scanning), in studies of macromolecular structures (such as gene sequences), and in designing large-scale database systems.

Work on expert systems, mentioned in earlier sections, continued in the 1980s. A frequent objective was an expert system that explains its behavior in useful ways, so that it is easily used as an adviser rather than as a decision maker. There was work also on procedures for reasoning under uncertainty; two new approaches in the 1980s were the use of fuzzy logic and the application of the Dempster-Shaffer theory of evidence. Applications of fuzzy logic in biomedicine gradually increased, and in 1994 *IEEE Engineering in Medicine and Biology Magazine* devoted one issue to the topic, presenting 14 articles. Another notable advance was an expert system on a chip: S.M. Weiss, C.A. Kulikowski, and R.S. Galen at Rutgers University developed the SPE/EXPERT system for serum protein electrophoresis analysis (designed to process signals from the scanning densitometer of the Cliniscan instrument).

Two other mathematical techniques received increased attention. A 1982 paper by J.J. Hopfield revived interest in neural networks. And chaos theory was applied to a few biomedical areas, such as cardiology (in modeling the beating of aggregates of embryonic heart cells). The first book devoted to the physiological aspects of chaos appeared in 1988.

### History of the Profession

As in previous decades, biomedical engineering came to the fore with certain public-health issues. In the 1980s the fear of microwaves diminished, but concern over the use of video-display terminals (VDTs) became extreme. In 1982 there was a Congressional hearing on VDTs and RF heat-sealers. COMAR issued a position paper on VDTs and one on RF heat-sealers; the later was critical of industry's efforts to control exposure near the heat-sealers. Toward the end of the decade the possible health effects of the electric and magnetic fields from electric power lines became a subject of widespread interest, and there were U.S. Congressional hearings on the subject on 6 October 1987 and much new research. This concern continued into the 1990s, and public fears were gradually allayed.

**Table 6. The Presidents of the IEEE Engineering in Medicine and Biology Society during the 1980s.**

| | |
|---|---|
| 1980 | Morton D. Schwartz |
| 1981 | Morton D. Schwartz |
| 1982 | Lee E. Ostrander |
| 1983 | Alfred R. Potvin |
| 1984 | Joseph D. Bronzino |
| 1985 | Joseph D. Bronzino |
| 1986 | Dov Jaron |
| 1987 | Dov Jaron |
| 1988 | Willis J. Tompkins |
| 1989 | Willis J. Tompkins |

Degree-granting programs continued to become more common. At the beginning of the decade approximately 100 engineering schools in the United States had a degree program in biomedical engineering. It was reported toward the end of the decade that there was an approximate match between the number of degrees granted and the number of career opportunity available (in contrast to the early years of biomedical engineering programs, when there were fewer positions available than trained people).

The IEEE Engineering in Medicine and Biology Society expanded its already wide range of activities. Membership was

fairly stable, declining slighting in the early 1980s but reaching at the end of the decade a membership total of 7,500. The number of Chapters continued to increase; at the end of the decade there were more than 30. The presidents of the Society are list in Table 6. In 1988 the Society AdCom decided to authorize the hiring of an Executive Officer, commenting "The person hired for this position would help increase the visibility and viability of EMBS and would provide an interface between EMBS and IEEE, year-to-year continuity, conference management, and general support of EMBS."

**Table 7. The winners of the EMBS Career Achievement Award (formerly the Morlock Award) during the 1980s.**

| | |
|---|---|
| 1985 | David B. Geselowitz |
| 1986 | Leslie A. Geddes |
| 1987 | Otto Schmitt |
| 1988 | R. Stuart Mackay |

In 1982 the Society inaugurated a magazine "to provide published material of broad member interest," the first issue appearing in March of that year. Also in 1982 the *IEEE Transactions on Medical Imaging* made its debut. This came about through an agreement among four IEEE Technical Societies in 1980. The EMBS and the Nuclear and IEEE Plasma Science Society each undertook a one-third interest in the venture, and the IEEE Signal Processing Society and the IEEE Ultrasonics Society each undertook a one-sixth interest. The EMBS Medical Imaging Committee had, as its primary activity, overseeing the operation of the *IEEE Transactions on Medical Imaging*. In 1989 the IEEE Publications Committee voted to initiate the *IEEE Transactions on Neural Networks*, starting in 1990 as a quarterly publication. EMBS was involved as one of the Societies of the IEEE Neural Networks Committee, the sponsoring organization.

The highest honor of the society, the William J. Morlock Memorial Award, was renamed the EMBS Career Achievement Award. It was granted only four times in the decade. The winners are listed in Table 7. In 1983 Eli Fromme received special recognition for service to the Society (and therefore is regarded as the first recipient of the EMBS Service Award, which was formally instituted in 1990, as described in the following section).

In biomedical engineering, as in other branches of engineering, the establishment of standards is an extremely important activity. For example, in 1980 the Medical Research Programme of the European Community started a project to establish standards in quantitative ECG. The measurement database thus established became "an internationally recognized yardstick for evaluation and improvement of European, American, and Japanese ECG programmes" The EMBS Standards Committee was active, working to develop standards for a local-area network specifically for use in the health-care environment, for a Medical Information Bus (MIB), and for a Medical Data Interchange (MEDIX).

As mentioned in the preceding section, EMBS had been a member of the Alliance for Engineering in Medicine and Biology (AEMB). AEMB organized an annual conference, and until 1986 EMBS held its annual conference immediately preceding the AEMB conference and in the same city. Leaders of EMBS felt, however, that EMBS was not getting its share of the profits from the joint endeavor, and beginning in 1986, EMBS held its conference apart from that of AEMB. The separation was beneficial to the Society's financial position, but it led to the demise of the AEMB conference. (In 1988 the constituent societies of AEMB decided to hold separate conferences and to assist with the founding of the American Institute for Medical and Biological Engineering.) In 1987, EMBS, in connection with IEEE Educational Activities, held a video conference on "New Technologies in Biomedical Engineering."

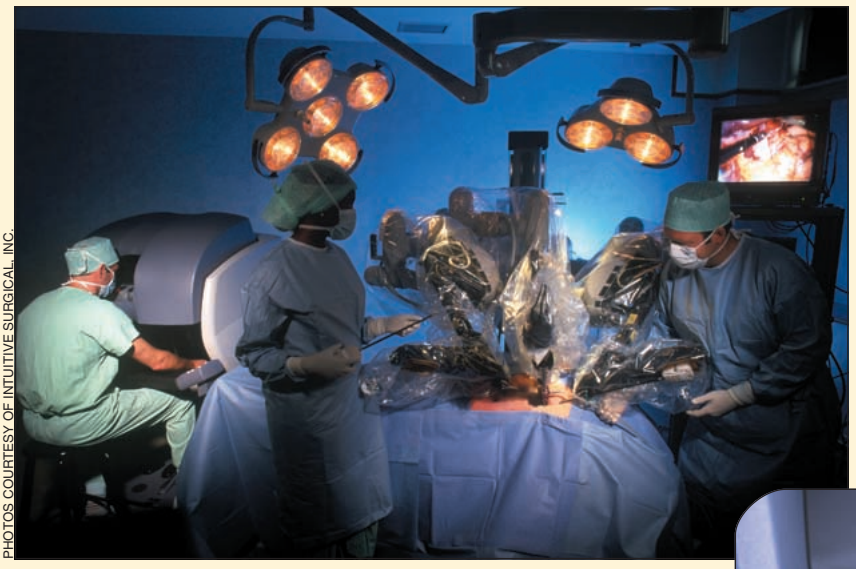
## The 1990s: The Human Genome Project, Robotics, and Internationalization

### History of the Technologies

The Human Genome Project was perhaps the most prominent scientific and technological effort of the 1990s. With the objective of learning the entire sequence of human DNA, the project, which began in 1991, was funded by the U.S. National Institutes of Health, the U.S. Department of Energy, and the Welcome Trust. Some of the engineering products that have been vital to this effort are automatic sequencers, robotic liquid-handling devices, and software for databasing and sequence assembly. A major shift was occurring in bioengineering toward consideration of processes at the cellular and molecular level rather than at the organ-system level.

Robotics, here and in countless other areas of biomedicine, attracted considerable attention. A survey at the beginning of the decade found approximately 400 applications of robotics to medicine. One area was the laboratory. For example, a lab robot (a modified Tecan Robotic Sample Processor) was used to culture and harvest bone marrow, lymph nodes, fibroblasts, and other tissues. The largest area for medical robotics was in rehabilitation: tactile sensors (as used in the Utah-MIT dextrous four-finger hand), prosthetics (such as the artificial arm), orthotics, assistive devices for the blind (as the Japanese (MITI) project MELDOG, designed to provide the functions of a guide dog), and systems for rehabilitation after surgery (as continuous-passive-motion machines). In surgery there are some robots that assist surgeons (such as for stereotactic neurosurgery) and some that perform surgery themselves (such as a robot to perform prostatectomies). On 25 March 1991 at Shaftesbury Hospital in London, a surgical robot SARP (Surgical Assistant Robot for Prostatectomy), under computer control, carried out an operation for the first time. And in 1993 the FDA authorized clinical testing of a robotic surgical procedure for implanting artificial hips.

There were many advances in implantable devices. For example, in 1997 the FDA gave approval to market a device that controls tremor (such as tremor resulting from Parkinson's disease) with a pulse generator implanted in the chest that sends signals to an electrode placed in the thalamus (a region of the brain that controls bodily movement). This was the first time the FDA approved an active device for implantation in the brain. (Earlier-approved brain implants, such as shunts, to drain fluids, and clips, to seal off aneurysms, are passive devices.) Also in 1997, the FDA approved the Freehand System, developed by P. Hunter Peckham at Case Western Reserve University, which uses FES to restore function to a paralyzed hand of a quadriplegic. This was the first implantable FES system to receive FDA approval for wide use. In early 2000 about 160 quadriplegics were using Freehand. By the mid 1990s in the United States, two to three million patients a year were being treated with an artificial implant of some kind, including supporting devices (such as pacemakers) and prostheses (such as cardiac valves and hip joints).



PHOTOS COURTESY OF INTUITIVE SURGICAL, INC.

**One of the applications robotics has found in biomedicine has been assisting surgeons. Left: the da Vinci Surgical System in action at St. Pierre University in Brussels, Belgium. The surgeon is seated to the left at a console from which he guides robotic instruments that replicate natural hand and wrist movements. From the console the surgeon views a true-to-life 3-D image (below).**

## Surgical "Aids"

Providing alternatives to artificial materials in therapy is the objective of the newly emerging field of tissue engineering or cell therapy. Among the products under development in the 1990s were the following: cell-based skin substitutes for wounds; corneal grafts to restore vision; transplanted cells for bone, cartilage, and ligament repair; transplants in or near the brain and spinal cord for treating neurodegenerative disease; pancreas substitution systems for diabetics; liver assist devices for hepatic failure; and tubular structures for repair of blood vessels, ureters, and fallopian tubes. Such tissue-engineering products were entering clinical trials in the late 1990s.

Medical imaging continued its vigorous expansion in the 1990s. An indication of medical usefulness is provided by a 1997 survey which found that there were 4.3 million MRI scans in the United States per year, 21 million CAT scans, and 208 million uses of X rays. The oldest modality, X-ray imaging, began the move to digital techniques. For example, in 1998 the General Electric digital detector Revolution made its medical debut in the Full Field Digital Mammography System introduced in Europe. Unlike other digital X-ray devices that pieced together a large image from small ones, the GE system created a single image at once. Magnetic resonance imaging made important advances. A number of techniques were developed to decrease MRI acquisition times, such as turboflash developed by Siemens and fast SPGR and fast spin-echo developed by GE; these methods made possible complete scans in only a few minutes. A major new technique was introduced in 1991: using MRI to map human brain activity by observing changes in cortical blood oxygenation. Called functional MRI (fMRI), it has since become a major methodology in brain science and other areas of research.

Interest in biomagnetic imaging continued to grow. (A biomagnetometer, by sensing the tiny magnetic field near the surface of the brain, provides a noninvasive indicator of localized brain function, which is useful, for example, in locating epileptic foci.) In 1990, Biomagnetic Technologies of San Diego delivered units of its 37-channel Magnes biomagnetometer to several hospitals, and Siemens installed a 37-channel unit called the Krenikon at the University of Nürnberg. A related technique, magnetic stereotaxis (a system for locating, in three dimensions, precise areas of the brain), entered clinical testing in 1997.

In 1991 PET images of the human brain as it performs the task of recalling a word were made public for the first time. The images showed that the recall process was going on in unexpected parts of the brain. Stimulated by advances made by the military and NASA for night vision and space exploration, the 1990s saw renewed interest in infrared imaging, especially for breast-cancer screening. (At the 1994 EMBS conference, IR imaging was one of the emerging technologies topics, and a special issue of *IEEE Engineering in Medicine and Biology Magazine* was devoted to the subject in 1998.) In 1995 Martin Nuss and co-workers at AT&T Bell Laboratories (now Lucent Technologies) first demonstrated terahertz-pulse imaging, in which laser pulses of T-rays (electromagnetic waves that lie between infrared radiation and microwaves in the electromagnetic spectrum) are used to create images. This technique is able to distinguish very similar materials, such as burned and healthy tissues.

Innovations in imaging technology have been vital for advances in endoscopic surgery. The computer-chip video camera, the 3-chip camera (which produces color images), and 3-D video systems are important milestones. According to Roger Barr, "Catheter-based sensing and surgery, while still invasive, are remarkably less so. Through ingenious development and incredibly skilled practitioners, crude tools have been replaced by smaller, more sophisticated devices that are remotely maneuvered while carrying surgical tools, multiple electrodes, RF transmitters, and imaging sensors."

Medical imaging attained even more prominence through the Visible Human Project, a digital depiction of every millimeter of the cadaver of a human ("the first digital human being"), which went online 29 November 1994. This representation of anatomy has contributed to highly realistic simulation systems used to train physicians in bronchoscopy, arthroscopy, venipuncture, and other procedures.

***The Human Genome Project was perhaps the most prominent scientific and technological effort of the 1990s.***

Medical devices in general continued to improve. Some new products of the 1990s were the tympanic or ear thermometer, introduced in 1991, which measured infrared heat from the eardrum and surrounding tissue, and the intra-arterial blood-gas monitoring system. The latter, introduced by Puritan-Bennett Corporation in 1992, determined in real time the hydrogen-ion concentration and partial pressures of oxygen and carbon dioxide (instead of determining these quantities from blood samples taken at infrequent intervals). Two other new devices that incorporated biosensors —and provided point-of-care diagnosis—were a handheld blood analyzer introduced by i-Stat Corporation and a device for testing thyroid disorders developed by Biocircuits Corporation. The Lasette laser finger perforator, which draws blood from the fingertip for glucose testing, became the first medical laser device cleared by the FDA for consumer use. Medical technology, of course, had long since entered the realm of consumer electronics. In the 1990s, in the United States some 1.5 million hearing aids were sold every year. Consumers were offered devices to measure heart rate and blood pressure; more than 750,000 heart-rate monitors are sold each year in the United States.

The use of computers in biomedicine became even more pervasive than in the preceding decade. With much of the work both in research and in health care taking place in software design, it became much easier for individuals and groups from less wealthy countries to contribute to the field internationally (whereas, experimentation and equipment prototyping are much more expensive activities). Increased travel and, more importantly, improved communication also facilitated wider participation in biomedical research and development. The Internet became an especially effective means of communication. For example, Medline, an electronic gateway to medical literature, had become much used since its introduction in 1966. But use increased by an order of magnitude in 1998 when the PubMed version of Medline became available on the Internet as a free service.

As in earlier decades, computers facilitated mathematical modeling. With faster computers and better models, it became possible in many areas to obtain quantitative estimates of the consequences of specific interventions, the models being idealizations of the biological mechanisms rather than statistical or empirical substitutes. Among the new techniques was fractals. The June 1992 issue of *IEEE Engineering in Medicine and Biology Magazine* was devoted to fractals in biomedical engineering. Among the articles were ones on fractal mechanisms in the electrophysiology of the heart, on the fractal nature of ion channel kinetics, and on fractal dimension in the analysis of medical images.

In the early 1990s neural networks were a promising but unproved technology in medicine and biology. At the end of the decade neural networks had come into routine use for certain diagnoses. According to Evangelia Micheli-Tzanakou, "In the later part of the 1990s, neural networks have been combined with fuzzy logic, wavelet analysis, and other feature-extraction methods to yield greater confidence in predicting outcomes and in classifying patterns of normal and abnormal situations. The field has grown to the point of having several major journals dedicated to neural networks."

In mid decade the biomedical industry in the United States had sales of $40 billion and was the fastest growing sector of the U.S. economy. But this success was decried by those who blamed higher health-care costs on new technology. Many of the plans advanced in the 1990s to contain costs chose technology as an area for downsizing. Biomedical engineers pointed out that the most expensive medical equipment, diagnostic imagers, accounted for only half a percent of health-care spending and that prices of comparable products had actually declined in recent years (though utilization had expanded considerably). More and more people belonged to HMOs; in 1997 three-fourths of U.S. workers with health benefits received coverage through an HMO. (In the United States, HMO enrollment increased from about six million in 1976 to about 50 million in 1995.) Among the ways HMOs worked to contain costs were discouraging experimental procedures, controlling access to specialists and hospitals, and delaying acceptance of new technologies.

### History of the Profession

Public-health issues were often in the news in the 1990s. There was widespread concern that the use of cell phones might cause brain cancer, and the telecommunications industry began a $20 million study to examine the potential health hazards of wireless communications. In the 1960s and 1970s plastic surgeons in the United States began to use silicone for breast enlargement. Dow Corning developed a silicone gel, which was put into a plastic container to make a breast implant. By 1992 an estimated two million women had received silicone gel breast implants. Many problems associated with the implants were reported, and at the beginning of the 1990s the FDA instituted a moratorium on further implants. In the United States, regulation of medical devices became even stricter in 1990 with the passage of the Safe Medical Devices Act; one of its requirements is that manufacturers track where certain implantable products go. Some people believe that the regulatory climate in the United States is prompting U.S. companies to move development and manufacturing to countries with less stringent oversight.

Public unease with biotechnology was reflected in the approval on 17 May 1992 by Swiss voters of a referendum on biotechnology and reproductive medicine; this prompted the Federal Assem-

bly to propose an amendment to the constitution demanding regulations for the protection of humans, animals, and plants against the misuses of genetic engineering and reproductive medicine. In Germany the Green Party, which was first elected to the Bundestag in 1984, has led opposition to biotechnology. It was genetic engineering that elicited the most concerns.

The IEEE Engineering in Medicine and Biology Society reflected the increased internationalization of the discipline in its membership, as it gave increased attention to attracting and serving members outside North America (notably by the EMBS International Committee). Members from outside the United States and Canada made up 26% of the Society in 1991 and 32% in 1995, and about 35% of conference attendees resided outside of North America. The EMBS participated in several undertakings to promote biomedical engineering in Latin America, one of the most important of which was sponsorship of the Latin American Regional Council on Biomedical Engineering (known by its Spanish and Portuguese acronym of CORAL). And in 1995, EMBS, for the first time, sponsored a regional conference in India, bringing together the regional biomedical engineering community, as several other organizations were co-hosts. In 2001 EMBS held its annual conference in Istanbul, and in 2003 Cancun, Mexico, will host the conference. The internationalization is apparent also in the EMBS leadership: in 2001 four of the seven Executive Committee officers were based outside of the United States, and the 2001 EMBS President was from France and the 2002 EMBS President is from Canada.

**Table 8. The Presidents of the IEEE Engineering in Medicine and Biology Society 1990-2002.**

| | |
|---|---|
| 1990 | Charles J. Robinson |
| 1991 | Charles J. Robinson |
| 1992 | Gerald F. Harris |
| 1993 | Gerald F. Harris |
| 1994 | Janie M. Fouke |
| 1995 | Janie M. Fouke |
| 1996 | Susan M. Blanchard |
| 1997 | John D. Enderle |
| 1998 | Robert Kearney |
| 1999 | Banu Onaral |
| 2000 | Andrew Y.J. Szeto |
| 2001 | Christian Roux |
| 2002 | Henrietta Galiana |

In 1995 the EMBS Constitution and Bylaws were changed to provide one-year terms for the President-Elect, the President, and the Past President ("the three Ps," as IEEE, which uses the same model, calls them). The presidents of the Society are listed in Table 8. The Executive Officer, Susan Blanchard, resigned at the end of 1992, and the Executive Committee negotiated a contract with the Canadian Medical and Biological Engineering Society for the services of its secretariat in Ottawa (whose executive secretary was Sally Chapman). Later in the decade the Society authorized a permanent staff, located at the IEEE offices in Piscataway, New Jersey, to assist the volunteer leaders of the Society, and in 1999 Laura Wolf was hired as EMBS Technical Activities Manager.

In 1996 the EMBS AdCom arrived at a mission statement: "The Engineering in Medicine and Biology Society of the IEEE advances the application of engineering sciences and technology to medicine and biology, promotes the profession, and provides global leadership for the benefit of its members and humanity by disseminating knowledge, setting standards, fostering professional development, and recognizing excellence." In mid decade an IEEE administrative change brought COMAR (the Committee on Man and Radiation), formerly part of the United States Activities Board, under EMBS auspices.

The highest award of the Society, the EMBS Career Achievement Award, was granted nine times in the 1990s. The winners are listed in Table 9. In 1990 the Administrative Committee established a new award, the Society Service Award "to recognize those EMBS members who have given exceptional and extraordinary service to the Society" (Table 10).

**Table 9. The winners of the EMBS Career Achievement Award 1990-2001.**

| | |
|---|---|
| 1990 | Richard J. Johns |
| 1991 | Walter Welkowitz |
| 1992 | Edwin L. Carstensen |
| 1993 | John M. Reid |
| 1994 | Wilson Greatbatch |
| 1995 | Floyd Dunn |
| 1996 | Max E. Valentinuzzi |
| 1997 | J. Lawrence Katz |
| 1999 | Fernand A. Roberge |
| 2000 | Max Schaldach |
| 2001 | John Webster |

**Table 10. The winners of the Society Service Award of EMBS during 1990-2001.**

| | |
|---|---|
| 1990 | Alvin Wald |
| 1992 | Swamy Laxminarayan |
| 1994 | Barry Feinberg |
| 1995 | Charles Robinson |
| 1996 | Michael R. Neuman |
| 1998 | Susan M. Blanchard |
| 1999 | Jean-Louis Coatrieux |
| 2000 | Jack Iverson |
| 2001 | Metin Akay |

Society publications expanded in the 1990s. In 1993 the *IEEE Transactions on Rehabilitation Engineering* began publication, and subscriptions exceeded 1,600 in the first year. Three years later still another Transactions was approved: the *IEEE Transactions on Information Technology in Biomedicine*, scheduled to begin publication in March 1997. In 1992 the EMBS Student Activities Committee began publication of the *EMBS Student Newsletter*, published three times a year.

In the early 1990s EMBS membership grew, reaching at peak of 9,426 in 1993, but then gradually declined over the remainder of the decade, equaling 8,204 at the end of 1999. Even so, EMBS was the largest international member-based professional society of biomedical engineers. Most members, 60%, described themselves as working in industry; 15% reported an academic position, and 25% listed "other." Among IEEE Societies EMBS ranked second in 1994 for percentage of women members (9.7%, while for IEEE overall the figure was 5.7%). Also, EMBS was the first Society to have a woman succeed a woman as President, and in 1996 three of the seven Executive Committee members were women.

## Looking Backward and Forward

Engineering advanced spectacularly in the 20th century, especially chemical engineering, electrical engineering, electronics, and computing. Indeed, the last two did not even exist at the start of the century. These branches of engineering have proved especially useful in biology and medicine. So part of the explanation of the rise of biomedical engineering must be sought outside biology and medicine, and the explanation is a complex one, involving remarkable economic growth, the channeling of re-

sources toward science and engineering, and the opening up of new realms of engineering; that is, new sets of instrumentalities.

Coupled with the spectacular advances in engineering is the increase in social resources devoted to health care. In the United States expenditures on health care increased from 5% of the gross domestic product (GDP) in 1950 to 13.4% of GDP in 1992. This almost threefold increase in resource allocation is multiplied fourfold by the overall economic growth (corrected for inflation) during these years, so the resources going into health care were 12 times as great in the early 1990s.

Some of these resources have permitted, first, research into the underlying mechanisms of disease and, second, development of new ways of preventing, curing, and alleviating disease. Engineering has played a huge role in both: new instruments and computers have transformed almost all types of scientific research in the last half century, and most modes of intervention involve engineering.

The individual achievements of biomedical engineering have been astounding. Exploratory surgery is almost a thing of the past, having been replaced by medical imaging. Tissue engineering has made great advances, including the creation of synthetic structures that the body recognizes as its own and the growth of a patient's own tissue in vitro for later transplantation back into his body. Microelectronics has been used to restore some control over paralyzed limbs. Cochlear implants allow the profoundly deaf to hear well enough to carry on a conversation. Artificial silicon retinas have been implanted in the eyes of blind patients. Computer-based simulators are beginning to be used in surgical training. And many other important achievements might be named.

Controversy, too, has increased the prominence of medical technology. It has been blamed for the huge increases in health-care costs. It has been criticized for dehumanizing medical care, as patients confront machines in the hospitals and receive computerized bills and health records. Some people have objected to the use of animals in research. And new technologies have raised new ethical issues, such as what measures should be taken to prolong life.

In prospect are advances that will increase still further the role of biomedical engineering. Natural organs may be regrown after injury or disease. Molecular nanotechnology may provide microscopic means for targeted delivery of medications. An all-inclusive lifelong health record (text, images, instrumental readings, and so on), under control of the patient, may be readily accessible. Precise understanding of genetic defects may permit more effective treatment by conventional means, and gene transfer may alleviate or correct problems resulting from genetic defects. Treatment at a distance, especially treatment in the home, may become common.

At the end of the 1990s the EMBS Committee on Emerging Technologies identified 11 technologies that appear to hold a potential for revolutionary impact in the first decade of the 21st century: advanced computer modeling and simulation of physiological systems; high-performance computing and distributed systems; Web-based means for interacting and for disseminating information; advanced medical imaging modalities; biomedical informatics; computer hardware, smart biosensors, implantable devices, and novel instrumentation; human performance engineering; high-throughput methods for genetic engineering; artificial organs and assist devices; rehabilitation engineering; and health-care evaluation systems. The committee went on to recommend specific ways the EMBS may take the lead in facilitating progress in these areas, many of which require interdisciplinary research.

As the work of this committee suggests, EMBS has broadened the range of its concerns and increased its efforts to collaborate with other professional organizations. Two notable examples are the 1999 and 2002 annual conferences, which were held in conjunction with the Biomedical Engineering Society, and the 2000 annual conference, which was held in conjunction with the World Congress on Medical Physical and Biomedical Engineering. One of the most important EMBS initiatives is the development of a Web-based infrastructure for biomedical engineering, facilitating interaction among all the people involved in creating and effectively using biomedical technologies and making information resources readily available. An important part of this is the EMBS move toward electronic publishing, with concern for customizing electronic products and services.

Besides the activities of EMBS, the professional community has benefited enormously from the work of the Whitaker Foundation in promoting research and education in biomedical engineering, as well as support from the NIH and NSF. New material support as well as greater prominence came from the establishment in 2000 of a new institute at the National Institutes of Health: the National Institute of Biomedical Imaging and Bioengineering.

A look back at the development of biomedical engineering reveals countless individual achievements and a remarkable growth of the profession; there are many signs that this development will continue unabated in the new century.

### Forecasting Progress in Biomedical Engineering

*by J.W. Clark*

Biomedical engineering (BME) is an interdisciplinary field whose scope is exceptionally wide and ranges from nanomedicine to space medicine, from molecular and cellular engineering to robotics applied in surgery, and from neuromuscular systems to many devices such as mechanical heart pumps and the artificial lung. Interest and growth in BME has increased dramatically in the past several years, and the common expectation is that it will play a major partnership role in medical and life science research and health-care delivery. The recent establishment of the National Institute of Biomedical Imaging and Bioengineering within the National Institutes of Health underscores the validity of this assumption, and to many it indicates preparation for the future.

New technological developments traditionally drive advances in BME. Some advances represent significant improvements in existing technologies. For example, cardiac balloon/stent angioplasty is an established technique for opening clogged coronary arteries, but coating the stent (wire coil for propping open the artery) with a special new biomaterial containing time-released immunosuppressant drugs can prevent rampant cell growth that reclogs the artery (a major problem in angioplasty). This is a perfect problem for an engineer seeking to bridge the gap between new discoveries in molecular biology and gene therapy and clinical cardiology.

Other advances deal more directly with the development of new technology itself as well as its application in medicine. The field of BME is virtually exploding with new discoveries and important new applications for medicine. Research into the basis of how cells and tissues interact with photons is providing new image contrast

mechanisms, whereas technological advances such as micro-electromechanical systems (MEMS) and point-spread function engineering are improving the performance of microscopes. These advances in both contrast mechanisms and performance form the basics of a new microscopy that will find ready use in tomorrow's research. Pilot and early clinical studies using these new optical technologies are already being reported. Many BMEs work in areas that contribute significantly to a specific technology but where thw work does not result in a product (as in the benchtop-to-bedside examples cited above). This trend will continue and BME will provide an umbrella for a wide variety of engineering activity.

***EMBS was the first Society to have a woman succeed a woman as President, and in 1996 three of the seven Executive Committee members were women.***

Biomedical engineering leaders are currently challenged by the task of better defining the infrastructure of biomedical engineering, its multidisciplinary nature, and the processes employed to educate new engineers in this changing field. Clear to many is the fact that multidisciplinary skills and knowledge are necessary requisites for any student, and that fundamental system design should play a role in the education of all BMEs. Curriculum design is an international problem that will continue to receive a great deal of attention, as BME Programs search for teaching talent, meaningful ways in which technology can be put to work in providing an increased effectiveness and efficiency in instruction, and new modes of instruction (e.g., exploiting web-based learning). The objective is to determine the optimal structure of the professional BME educational curriculum, one that maintains quantitative rigor yet contains parallel educational paths designed to satisfy the particular educational needs of different BME career paths.

It is an exciting time to be associated with a growing field that has such potential and to have as a challenge the reformation and design of a new professional educational curriculum that will serve this discipline.

### The Biomedical Engineers of Tomorrow Predict the Future

*by Elsie Fear and Faustina Hwang, with contributions from EMBS Student Members*

EMBS student members were asked to give their thoughts on the future of engineering in medicine and biology. Here is a summary of predictions from the next generation of biomedical engineers.

Students foresee many developments in diagnostics: imaging at a cellular and sub-cellular level, for example, to diagnose cancer without biopsies; improved signal and image processing methods for early detection; new techniques for noninvasive measurements; and integration of genome information for both diagnosis and therapy. In the area of information technology, students predict that advances in telecommunications and mobile computing will play an increasingly important role, giving professionals ubiquitous access to important information. This will facilitate the advancement of areas such as telemedicine, which will then become more common and effective. We will see significant developments in micro- and nanotechnology, for example, in fusing "soft" organic materials with "hard" inorganic materials, which will lead to new implants with increased biocompatibility. We will also see increased efforts in the development of technologies for the early and rapid detection of dangerous pathogens as a defense against the threat of biological warfare. Other hot areas include brain-machine interfaces, tissue and organ engineering, drug delivery, bioinformatics, and cellular and physiological modeling.

With so many exciting developments predicted for the future, EMBS student members were also asked what challenges lie ahead. One of the most important challenges is said to be successful integration of the talents of people in engineering, medicine, and biology. Students say that the divide between the disciplines needs to be overcome—progress in this field requires cross-disciplinary understanding. Other challenges include dealing with economic constraints and resolving ethical issues as well as improving the safety, reliability, and usability of biomedical technology.

What about the limitations? Very few technical limitations were identified, rather the major stumbling blocks were seen to come from other sources. Ever-present friction over social and moral issues as well as rigorous certification requirements imposed by government agencies were cited as factors that could impede rapid progress in this field. Other limitations would be dictated not by technology but rather by what patients would allow. Some students offered a more optimistic outlook—we are limited only by our imaginations.

### Where Is Biomedical Engineering Going?

*By L.A. Geddes*

I have been asked the question in the title many times. To answer the question it is appropriate to ask, "Where did biomedical engineering come from?" Answering this second question may permit forecasting the future more clearly.

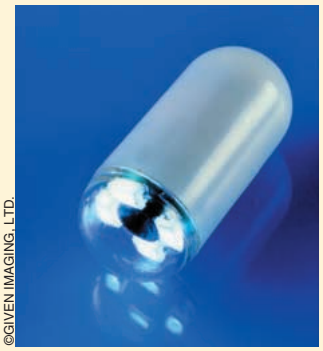
In the 1800s physiologists and physicians, many of whom were physicists, were making instruments to investigate the laws of nature as well as to aid patients. A significant observation was made then by Oliver Wendell Holmes (1809-1881), physician, anatomist, attorney, dean of the Harvard Medical School and the man who coined the term "anesthesia," who stated: "Medicine appropriates everything from every source that can be the slightest use to anybody who is ailing in any way, or is likely to be ailing from any cause."

An important step that involved physical scientists in medicine came when Roentgen (1845-1923) discovered X rays in 1895, which gave birth to radiology and medical physics, a specialty that is alive and well today.

The discovery that made possible many medical instruments was the invention of the vacuum tube by De Forest in 1907. He called it the "audion," which was first used as a detector of feeble radio signals; shortly later it was used as an amplifier and later as a generator of high-frequency alternating current. The audion found its way into many medical devices; some were beneficial—others were without benefit.

The need for communications in World War I (1914-1918), and the radio amateur's desire for communications equipment better than the spark-gap, stimulated the production of vacuum tubes. In fact, commercial radio, which became the largest market for vacuum tubes, was the outcome from amateur

## Today's Technology, Tomorrow's Challenges



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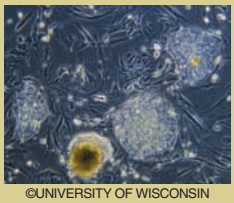
**The swallowable pill endoscope is a miniature telecamera that acquires images as it travels through the gastrointestinal tract. The imaging system consists of a swallowable capsule (shown here), a data recorder, and a workstation. The patient swallows the capsule, which contains a camera, lights, transmitter, and battery. The capsule acquires images and transmits video signals to sensors that are attached to the patient's body. The sensors also help estimate the capsule's location as it travels through the gastrointestinal tract, propelled by peristalsis.**



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**Stem cells can be cultured in the lab and developed into skin cells, muscle, blood cells, neurons and all the other cell types that comprise human tissue and organs. The cells can be used to treat cell-based diseases. This is a 5X view of a colony of undifferentiated human embryonic stems cells being studied in developmental biologist James Thomson's research lab at the University of Wisconsin. The embryonic stem cell colonies are the rounded, dense masses of cells.**

**If the challenges presented by genetic engineering and gene therapy can be met by future bioengineers, then treatment or correction of genetic disorders and diseases could become reality. Due to advances in gene isolation, it has become possible to inject a single gene into a single cell to alter its function. One such method is electroporation, where a pore is created in the cell membrane by the use of a high-voltage pulse. Electrode design, pulse intensity, duration, repetition rate, and cell membrane properties are aspects of this field that will benefit from the expertise of the bioengineer.**

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radio. The operator of amateur radio station W8XK in 1920 originated the first music broadcasts that gave rise to the first commercial radio station, which later became KDKA, Pittsburgh; it is still on the air with the same call letters. All of these events produced a pool of technically trained electronics people and many new electromedical devices appeared. Radar in World War II (1939-1945) produced even more need for electronics, and after the war more new medical devices were created. Invention of the transistor in 1947 made devices smaller and energy efficient, and most importantly, it gave birth to the first implanted electronic medical device, the cardiac pacemaker that paved the way for many other implanted and external medical devices. The appearance of the integrated circuit and the microprocessor made it possible to create very sophisticated automatic medical devices. The biomedical engineer now had a very large tool kit.

*Medical Device Types*

Biomedical and clinical engineers are concerned with a wide variety of medical devices made possible by the large inventory of technology, and it is useful to classify them because it can shed light on what engineers working in the life and medical sciences do at present and will do in the future. Basically there are three types of medical devices: 1) diagnostic, 2) therapeutic, and 3) assistive or rehabilitative. The diagnostic device presents information to the human senses, familiar examples being the bioelectric recorders (ECG, EEG, EMG, etc.), imaging devices (X ray, CT scanner, MRI, ultrasonic imagers, etc.).

The latest imaging device approved by the FDA is a swallowable pill endoscope, which is a miniature telecamera that acquires images as it travels through the gastrointestinal tract. The imaging system consists of a swallowable capsule, a data recorder, and a workstation. The patient swallows the capsule, which measures 26 mm in length and 11 mm in diameter and contains a camera, lights, transmitter, and battery. The capsule acquires two images per second and transmits video signals to sensors that are attached to the patient's body. The sensors also help estimate the capsule's location as it travels through the gastrointestinal tract, propelled by peristalsis. The wireless data recorder, which is worn on a waist belt, receives signals from the sensors and stores the image data. The patient's normal activities are not restricted while the images are being recorded. The battery has an eight-hour expected life, which is long enough to view the small intestine, but not the large intestine. The body excretes the disposable capsule naturally approximately eight to 72 hours after ingestion. After images are recorded, the physician downloads the data from the recorder into the workstation, and software processes the data to produce a video of the small intestine. After images are recorded, the physician can then view, edit, and archive the video as well as save individual images or video clips.

It is interesting to observe that swallowable-pill transmitters appeared in the late 1950s and early 1960s. Called endoradiosondes, they transmitted environmental pressure, pH, and temperature to an external receiver as they passed through the gastrointestinal tract. Interestingly, Vladimir Zworkyn, the father of electronic television, created and used an endoradiosonde. However, he could not make it send pictures because the technology was not available then.

The diagnostic device is really an extender of the human senses, providing new sensory modalities. For example, the eye cannot see X rays; nor can one feel the feeble bioelectric signals that appear on the body surface.

The therapeutic device is used by the physician or his delegated representative to cure or halt a disease process. The "prosthetic" and "orthotic" devices are examples of such devices. A prosthetic device is a substitute for a missing part. An orthesis is a straightening device; i.e., a brace. The most familiar therapeutic agent is a drug; however, the cardiac pacemaker, defibrillator, auditory and visual prosthesis, pain-suppression stimulator, the high-voltage X ray, the laser, and other devices that produce ion-

izing radiation as well as high-energy ultrasound are therapeutic devices. The surgeon uses many devices such as the electrosurgical unit and endoscope, and the latter often includes a video camera. Programmed drug infusion pumps are now widely used. The new area of tissue engineering (see below) is starting to produce new therapeutic modalities.

It is becoming increasingly popular to couple diagnostic and therapeutic devices, resulting in automatically controlled therapeutic systems. A familiar example is the demand cardiac pacemaker that monitors the heart continuously, and if a preprogrammed time elapses without a beat, it provides a stimulus. Likewise, the implanted cardioverter defibrillator monitors the ventricles continuously, and if fibrillation occurs, a therapeutic shock is delivered to restore normal beating. An even simpler example is pressure-transducer control of a drug infusion to maintain a constant blood pressure.

**Biomedical engineers of the future will have to be more aware of applicable governmental regulations.**

The assistive or rehabilitative device is used when a disease has been cured or halted, but there remains a deficit. Familiar examples are eyeglasses, a cane, a brace or crutch, dentures, a hearing aid, an artificial larynx, a transcutaneous electrical nerve stimulator (TENS), a respirator, etc. These devices are largely used by the patient and can be life supporting and are designed to provide the user with an improved quality of life and allow him/her to be more independent.

*Governmental Regulations*

Biomedical engineers of the future will have to be more aware of applicable governmental regulations, which set standards for efficacy and safety. After the mid 1940s an enormous variety of medical devices became available to physicians and a large number of these made no claims regarding safety and efficacy. It is important to note that many of these devices played lifesaving roles in the hands of competent physicians. However, many devices had technological flaws and provided little or no benefit to a patient. For example, the *Federal Register* of 9 March 1976 noted that a committee chaired by Dr. Theodore Cooper, then director of the National Heart Institute, issued a report indicating that in the ten years prior to 1969, medical devices caused 10,000 serious injuries and over 750 deaths. An intrauterine device, marketed in the early 1970s, was linked to 16 deaths and 25 miscarriages. Significant defects in cardiac pacemakers had resulted in 34voluntary recalls, involving 23,000 units.

Taking note of these facts, the lawmakers passed the Medical Device Legislation Amendment Bill of 1976 (HR-111124, *Federal Register*, 9 March 1976), which was signed into law. The Bill amended the federal Food, Drug and Cosmetic Act to give the FDA jurisdiction over the safety and effectiveness of medical devices intended for human use in the United States.

A special feature of the Bill allows the FDA to exempt a device from the requirements if the device is intended solely for investigational use and if the proponent of the device submits a plan demonstrating that the testing of the device will be supervised by an institutional review committee, ensures appropriate patient consent, and maintains certain records and reports. The testing protocol must be scientifically sound and the benefits and knowledge to be gained must outweigh the risk to the patient. This provision thereby provides a means for the creation of new medical devices.

After enactment of the law, the FDA classified all medical devices into three classes: 1) not dangerous and good manufacturing procedure is all that is required; 2) devices for which efficacy and safety have been established; 3) devices for which there is no or inadequate efficacy and safety information; this class includes all life-supporting and life-sustaining devices. To sell such devices, the manufacturer must provide efficacy and safety studies carried out under tightly controlled conditions. Veterinary products are exempt.

Accidents do occur with medical devices; some are the result of misuse; some are due to a manufacturing or design defect and some are due to environmental factors. Every accident associated with a medical device must be reported to the FDA in the form of a Medical Device Report (MDR), now a Manufacturer and User Device Experience (MAUDE) report. These reports are public documents and are available from the FDA. The biomedical engineer of the future must be aware of the three interests of the FDA: 1) safety, 2) efficacy, and 3) incident-report filing.

*Tissue Engineering*

Tissue engineering is one of the newest engineering specialties. It can be loosely defined as the use of engineering principles, facilities, and theory to design and create tissues and devices to replace structures that have impaired function or have lost their function. As such, this new specialty brings together engineers, cell biologists, histologists, and surgeons in a team to improve the quality of life and to lengthen it. The activities range from the creation of new biocompatible devices, ranging from those made from nonbiological materials (typically polymers, ceramics, and metal, all treated to be accepted by the host), to materials on which specially selected cells are grown on a scaffold matrix, some types of which are biodegradable. The cell types are selected to provide a function that is impaired or missing in the host.

The obvious desired characteristics of a tissue-engineered material are: 1) it should provide the impaired or missing function, 2) it should be biocompatible without treating the host to accept it, 3) it should not do more than is needed (i.e., it should not continue to promote unchecked growth, like cancer cells), 4) it should not have any immune or toxic side effects, and 5) it should remodel to become host tissue, indistinguishable histologically from native adjacent host tissue.

A significant body of research has been conducted during the past decade showing that tissue repair scaffolds, derived from native extracellular matrix (ECM), can induce constructive remodeling of missing or severely damaged tissues. Use of these scaffold materials is associated with tissue healing that includes differentiated cell and tissue types such as functional arteries and veins, innervated smooth muscle and skeletal muscle, ligament, cartilage, and specialized epithelial structures. These differentiated cells are highly organized and the remodeled tissue resembles native tissue by the end of the repair process. The source of cells that contribute to this remodeling process has been the subject of considerable investigation, which is ongoing.

One of these ECMs, derived from porcine small intestine submucosa (SIS), has remodeled to become smooth, cardiac, and skele-

tal muscle and tendon, ligament, and bone. It has remodeled to become a vein, an artery, the cusp of a heart valve, and even a vocal cord. It is an excellent wound dressing for pressure and diabetic ulcers. The active factors in SIS are under investigation and the FDA has given approval for orthopedic use and soft-tissue repair. Tissue engineering is a fertile field for future biomedical engineers.

*Bionanotechnology*

Nanotechnology builds devices one atom at a time, seemingly without limit to the type of device. Biosensors on chips are a reality. The term biochip is becoming popular and can be defined as a microscale biosensor. It is possible to create sensors for specific proteins by attracting them to their antibodies on a chip and detecting their presence by electrical impedance or by fluorescence. The term "laboratory-on-a-chip" is now becoming popular for these nanosensors, which are examples of the diagnostic instrument.

Microelectrode fabrication using nanotechnology techniques is here and expanding. Such microelectrodes can be used to detect the electrical activity of a single cell in a cell cluster. Typically, an array of $10 \times 10$ or more micron-size electrodes are on a chip and each electrode is connected to a FET follower deposited on the electrode. Such arrays have been implanted into the brain.

Arrays of nanotechnology microelectrodes have been used to stimulate cortical nerve cells. They have also been implanted to stimulate peripheral nerves.

The engineering problems associated with bionanotechnology electrodes are sufficient to challenge any biomedical engineer. Such electrodes must produce a minimal inflammatory response, must not be allergenic, must establish a stable electrical interface with the tissue and if used for stimulation, and must not decompose and liberate toxic ions when used for chronic stimulation.

*Stem Cells*

Stem cells are progenitor cells that have the ability to become any type of cell. Fetal stem cells are the most numerous; but they can be isolated from the adult with difficulty. Stem cells have the ability to repair and even replace injured tissue. The multiple ways of using stem cells is under investigation and future biomedical engineers will certainly be involved with all phases of stem-cell research and therapy.

*Genetic Engineering*

The term "genetic engineering" has been around for a long time and has been practiced for even longer, examples being in the plant and animal kingdom to breed offspring with more desirable characteristics. However, it is only recently, due to advances in gene isolation, that it has become possible to inject a single gene into a single cell to alter its function.

Although there are many ways of coaxing foreign genes into cells, two are popular: 1) the use of viruses and 2) electroporation. With the first method the selected gene is attached to a friendly virus that carries the gene through the cell membrane. When in the cell, the foreign DNA competes with the cell's own DNA to create a cell with different characteristics.

Electroporation is the creation of a pore in the cell membrane by the use of a high-voltage pulse. The interesting feature of this method is that the pore remains open for only a short time (seconds to minutes). With electroporation (which is really controlled dielectric breakdown), the desired cell is placed in a solution containing the DNA that is to be inserted. A high-voltage pulse, applied to electrodes in the solution in which the cell resides, produces pores. The DNA in the solution enters the cell and the pores close, capturing the foreign DNA in the cell.

Electroporation can also be used to fuse two cells together. The two cells are placed in contact with each other and a high-voltage pulse makes pores where the cells are in contact and the cells fuse to become a single large cell containing two types of DNA.

Incidentally, new cells created by genetic engineering are patentable because they constitute a new form of life not created by nature. They are the result of man's handiwork and therefore patentable.

Quantitating electroporation is a problem well suited to the talents of a future biomedical engineer. Electrode design, pulse intensity, duration, repetition rate, and cell membrane properties are fodder for the guns of future biomedical engineers.

The clinical use of gene therapy has been put on hold by the FDA because of a single death. However, it is anticipated that when the cause of this death has been established, gene therapy will resume at some time in the future.

*Attributes of a Biomedical Engineer of the Future*

It is as difficult to predict the future of biomedical engineering as it is to predict the life span of a person. Perhaps extrapolation from the past to the present and to the future provides the best prediction. However, no matter what the activities of a future biomedical engineer may be, he/she must have certain attributes. In 1726, Jacob Leuopold, a mechanic who made mechanical theaters in Europe, stated the qualifications of future mechanics when he wrote:

*A mechanic ought to be a person who not only understands well and thoroughly all handicrafts, such as wood, steel, iron, brass, silver, gold, glass, and all such materials to be treated according to the arts, and who knows how to judge on physical principles, how far each according to its nature and property is adequate or suitable to withstand and endure this or that, so that everything receives its necessary proportion, strength, and convenience, and neither too much nor too little is done in the matter; but he must also be able to arrange according to mechanical sciences or rules for any required proportion, or effect according to present or proposed force or load; for which purpose he must also have learned from geometry and arithmetic all that is necessary for calculation of the parts of the machine. And when he desires thoroughly to understand his profession, he must have a complete grasp of all the arts and professions for which he will have to make and invent machines; for otherwise he knows not what he is doing, and has also no power to improve anything, or invent anything new, such as is chiefly demanded of a mechanic. But above all he has to be a born mechanic, so that he shall not only be skilled in invention by natural instinct, but shall also grasp with little trouble all arts and sciences, in such a way that it may be said of him: what his eyes see, that also his hands are able to do; and that love of his art lets him avoid no trouble, labor, or cost, because throughout his whole life he has daily to learn something new and to experiment.*

If we substitute "biomedical engineer" for "mechanic" and "technology" for "handicrafts" and "mechanical science," we have established the credentials for biomedical engineers of the future, no matter what he or she may do.