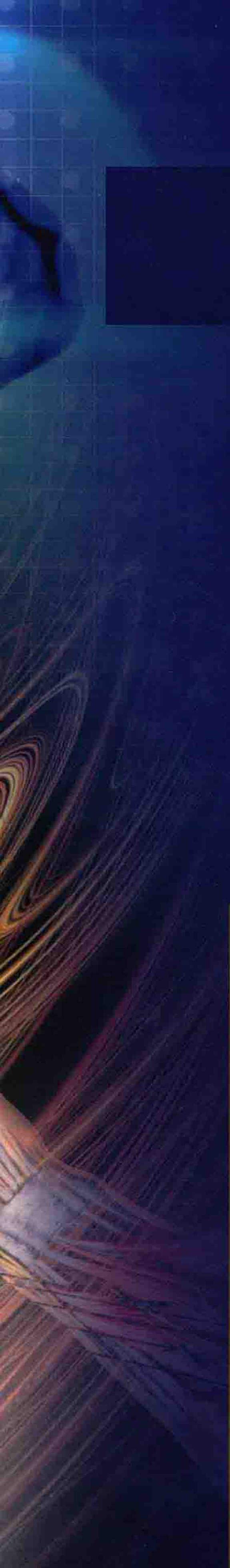
THE BIOMEDICAL ENGINEERING HANDBOOK

FOURTH EDITION



Biomedical Signals, Imaging, and Informatics

Edited by

Joseph D. Bronzino

Donald R. Peterson

CRC Press
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Preface

During the past eight years since the publication of the third edition—a three-volume set—of *The Biomedical Engineering Handbook*, the field of biomedical engineering has continued to evolve and expand. As a result, the fourth edition has been significantly modified to reflect state-of-the-field knowledge and applications in this important discipline and has been enlarged to a four-volume set:

- Volume I: *Biomedical Engineering Fundamentals*
- Volume II: *Medical Devices and Human Engineering*
- Volume III: *Biomedical Signals, Imaging, and Informatics*
- Volume IV: *Molecular, Cellular, and Tissue Engineering*

More specifically, this fourth edition has been considerably updated and contains completely new sections, including

- Stem Cell Engineering
- Drug Design, Delivery Systems, and Devices
- Personalized Medicine

as well as a number of substantially updated sections, including

- Tissue Engineering (which has been completely restructured)
- Transport Phenomena and Biomimetic Systems
- Artificial Organs
- Medical Imaging
- Infrared Imaging
- Medical Informatics

In addition, Volume IV contains a chapter on Ethics because of its ever-increasing role in the Biomedical Engineering arts.

Nearly all the sections that have appeared in the first three editions have been significantly revised. Therefore, this fourth edition presents an excellent summary of the status of knowledge and activities of biomedical engineers in the first decades of the twenty-first century. As such, it can serve as an excellent reference for individuals interested not only in a review of fundamental physiology but also in quickly being brought up to speed in certain areas of biomedical engineering research. It can serve as an excellent textbook for students in areas where traditional textbooks have not yet been developed and as an excellent review of the major areas of activity in each biomedical engineering sub-discipline, such as biomechanics, biomaterials, bioinstrumentation, medical imaging, and so on. Finally, it can serve as the "bible" for practicing biomedical engineering professionals by covering such topics as historical perspective of medical technology, the role of professional societies, the ethical issues associated with medical technology, and the FDA process.

Biomedical engineering is now an important and vital interdisciplinary field. Biomedical engineers are involved in virtually all aspects of developing new medical technology. They are involved in the design, development, and utilization of materials, devices (such as pacemakers, lithotripsy, etc.), and techniques (such as signal processing, artificial intelligence, etc.) for clinical research and use, and they serve as members of the healthcare delivery team (clinical engineering, medical informatics, rehabilitation engineering, etc.) seeking new solutions for the difficult healthcare problems confronting our society. To meet the needs of this diverse body of biomedical engineers, this handbook provides a central core of knowledge in those fields encompassed by the discipline. However, before presenting this detailed information, it is important to provide a sense of the evolution of the modern healthcare system and identify the diverse activities biomedical engineers perform to assist in the diagnosis and treatment of patients.

Evolution of the Modern Healthcare System

Before 1900, medicine had little to offer average citizens, since its resources consisted mainly of physicians, their education, and their "little black bag." In general, physicians seemed to be in short supply, but the shortage had rather different causes than the current crisis in the availability of healthcare professionals. Although the costs of obtaining medical training were relatively low, the demand for doctors' services also was very small, since many of the services provided by physicians also could be obtained from experienced amateurs in the community. The home was typically the site for treatment and recuperation, and relatives and neighbors constituted an able and willing nursing staff. Babies were delivered by midwives, and those illnesses not cured by home remedies were left to run their natural, albeit frequently fatal, course. The contrast with contemporary healthcare practices in which specialized physicians and nurses located within hospitals provide critical diagnostic and treatment services is dramatic.

The changes that have occurred within medical science originated in the rapid developments that took place in the applied sciences (i.e., chemistry, physics, engineering, microbiology, physiology, pharmacology, etc.) at the turn of the twentieth century. This process of development was characterized by intense interdisciplinary cross-fertilization, which provided an environment in which medical research was able to take giant strides in developing techniques for the diagnosis and treatment of diseases. For example, in 1903, Willem Einthoven, a Dutch physiologist, devised the first electrocardiograph to measure the electrical activity of the heart. In applying discoveries in the physical sciences to the analysis of the biological process, he initiated a new age in both cardiovascular medicine and electrical measurement techniques.

New discoveries in medical sciences followed one another like intermediates in a chain reaction. However, the most significant innovation for clinical medicine was the development of x-rays. These "new kinds of rays," as W. K. Roentgen described them in 1895, opened the "inner man" to medical inspection. Initially, x-rays were used to diagnose bone fractures and dislocations, and in the process, x-ray machines became commonplace in most urban hospitals. Separate departments of radiology were established, and their influence spread to other departments throughout the hospital. By the 1930s, x-ray visualization of practically all organ systems of the body had been made possible through the use of barium salts and a wide variety of radiopaque materials.

X-ray technology gave physicians a powerful tool that, for the first time, permitted accurate diagnosis of a wide variety of diseases and injuries. Moreover, since x-ray machines were too cumbersome and expensive for local doctors and clinics, they had to be placed in healthcare centers or hospitals. Once there, x-ray technology essentially triggered the transformation of the hospital from a passive receptacle for the sick to an active curative institution for all members of society.

For economic reasons, the centralization of healthcare services became essential because of many other important technological innovations appearing on the medical scene. However, hospitals remained institutions to dread, and it was not until the introduction of sulfanilamide in the mid-1930s and penicillin in the early 1940s that the main danger of hospitalization, that is, cross-infection among patients, was significantly reduced. With these new drugs in their arsenals, surgeons were able to perform their operations without prohibitive morbidity and mortality due to infection. Furthermore, even though the different blood groups and their incompatibility were discovered in 1900 and sodium citrate was used in 1913 to prevent clotting, full development of blood banks was not practical until the 1930s, when technology provided adequate refrigeration. Until that time, "fresh" donors were bled and the blood transfused while it was still warm.

Once these surgical suites were established, the employment of specifically designed pieces of medical technology assisted in further advancing the development of complex surgical procedures. For example, the Drinker respirator was introduced in 1927 and the first heart–lung bypass in 1939. By the 1940s, medical procedures heavily dependent on medical technology, such as cardiac catheterization and angiography (the use of a cannula threaded through an arm vein and into the heart with the injection of radiopaque dye) for the x-ray visualization of congenital and acquired heart disease (mainly valve disorders due to rheumatic fever) became possible, and a new era of cardiac and vascular surgery was established.

In the decades following World War II, technological advances were spurred on by efforts to develop superior weapon systems and to establish habitats in space and on the ocean floor. As a by-product of these efforts, the development of medical devices accelerated and the medical profession benefited greatly from this rapid surge of technological finds. Consider the following examples:

1. Advances in solid-state electronics made it possible to map the subtle behavior of the fundamental unit of the central nervous system—the neuron—as well as to monitor the various physiological parameters, such as the electrocardiogram, of patients in intensive care units.
2. New prosthetic devices became a goal of engineers involved in providing the disabled with tools to improve their quality of life.
3. Nuclear medicine—an outgrowth of the atomic age—emerged as a powerful and effective approach in detecting and treating specific physiological abnormalities.
4. Diagnostic ultrasound based on sonar technology became so widely accepted that ultrasonic studies are now part of the routine diagnostic workup in many medical specialties.
5. "Spare parts" surgery also became commonplace. Technologists were encouraged to provide cardiac assist devices, such as artificial heart valves and artificial blood vessels, and the artificial heart program was launched to develop a replacement for a defective or diseased human heart.
6. Advances in materials have made the development of disposable medical devices, such as needles and thermometers, a reality.
7. Advancements in molecular engineering have allowed for the discovery of countless pharmacological agents and to the design of their delivery, including implantable delivery systems.
8. Computers similar to those developed to control the flight plans of the Apollo capsule were used to store, process, and cross-check medical records, to monitor patient status in intensive care units, and to provide sophisticated statistical diagnoses of potential diseases correlated with specific sets of patient symptoms.
9. Development of the first computer-based medical instrument, the computerized axial tomography scanner, revolutionized clinical approaches to noninvasive diagnostic imaging procedures, which now include magnetic resonance imaging and positron emission tomography as well.
10. A wide variety of new cardiovascular technologies including implantable defibrillators and chemically treated stents were developed.
11. Neuronal pacing systems were used to detect and prevent epileptic seizures.
12. Artificial organs and tissue have been created.
13. The completion of the genome project has stimulated the search for new biological markers and personalized medicine.
14. The further understanding of cellular and biomolecular processes has led to the engineering of stem cells into therapeutically valuable lineages and to the regeneration of organs and tissue structures.

15. Developments in nanotechnology have yielded nanomaterials for use in tissue engineering and facilitated the creation and study of nanoparticles and molecular machine systems that will assist in the detection and treatment of disease and injury.

The impact of these discoveries and many others has been profound. The healthcare system of today consists of technologically sophisticated clinical staff operating primarily in modern hospitals designed to accommodate the new medical technology. This evolutionary process continues, with advances in the physical sciences such as materials and nanotechnology and in the life sciences such as molecular biology, genomics, stem cell biology, and artificial and regenerated tissue and organs. These advances have altered and will continue to alter the very nature of the healthcare delivery system itself.

Biomedical Engineering: A Definition

Bioengineering is usually defined as a basic research-oriented activity closely related to biotechnology and genetic engineering, that is, the modification of animal or plant cells or parts of cells to improve plants or animals or to develop new microorganisms for beneficial ends. In the food industry, for example, this has meant the improvement of strains of yeast for fermentation. In agriculture, bioengineers may be concerned with the improvement of crop yields by treatment of plants with organisms to reduce frost damage. It is clear that future bioengineers will have a tremendous impact on the quality of human life. The potential of this specialty is difficult to imagine. Consider the following activities of bioengineers:

- Development of improved species of plants and animals for food production
- Invention of new medical diagnostic tests for diseases
- Production of synthetic vaccines from clone cells
- Bioenvironmental engineering to protect human, animal, and plant life from toxicants and pollutants
- Study of protein–surface interactions
- Modeling of the growth kinetics of yeast and hybridoma cells
- Research in immobilized enzyme technology
- Development of therapeutic proteins and monoclonal antibodies

Biomedical engineers, on the other hand, apply electrical, mechanical, chemical, optical, and other engineering principles to understand, modify, or control biological (i.e., human and animal) systems as well as design and manufacture products that can monitor physiological functions and assist in the diagnosis and treatment of patients. When biomedical engineers work in a hospital or clinic, they are more aptly called clinical engineers.

Activities of Biomedical Engineers

The breadth of activity of biomedical engineers is now significant. The field has moved from being concerned primarily with the development of medical instruments in the 1950s and 1960s to include a more wide-ranging set of activities. As illustrated below, the field of biomedical engineering now includes many new career areas (see Figure P.1), each of which is presented in this handbook. These areas include

- Application of engineering system analysis (physiological modeling, simulation, and control) to biological problems
- Detection, measurement, and monitoring of physiological signals (i.e., biosensors and biomedical instrumentation)
- Diagnostic interpretation via signal-processing techniques of bioelectric data
- Therapeutic and rehabilitation procedures and devices (rehabilitation engineering)
- Devices for replacement or augmentation of bodily functions (artificial organs)

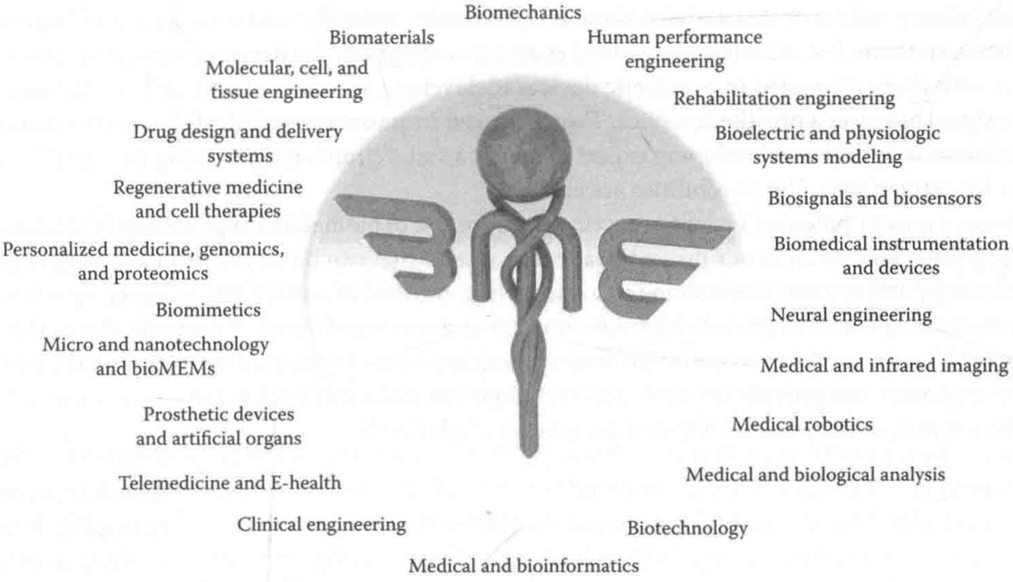

FIGURE P.1 The world of biomedical engineering.

- Computer analysis of patient-related data and clinical decision making (i.e., medical informatics and artificial intelligence)
- Medical imaging, that is, the graphic display of anatomic detail or physiological function
- The creation of new biological products (e.g., biotechnology and tissue engineering)
- The development of new materials to be used within the body (biomaterials)

Typical pursuits of biomedical engineers, therefore, include

- Research in new materials for implanted artificial organs
- Development of new diagnostic instruments for blood analysis
- Computer modeling of the function of the human heart
- Writing software for analysis of medical research data
- Analysis of medical device hazards for safety and efficacy
- Development of new diagnostic imaging systems
- Design of telemetry systems for patient monitoring
- Design of biomedical sensors for measurement of human physiological systems variables
- Development of expert systems for diagnosis of disease
- Design of closed-loop control systems for drug administration
- Modeling of the physiological systems of the human body
- Design of instrumentation for sports medicine
- Development of new dental materials
- Design of communication aids for the handicapped
- Study of pulmonary fluid dynamics
- Study of the biomechanics of the human body
- Development of material to be used as a replacement for human skin

Biomedical engineering, then, is an interdisciplinary branch of engineering that ranges from theoretical, nonexperimental undertakings to state-of-the-art applications. It can encompass research, development, implementation, and operation. Accordingly, like medical practice itself, it is unlikely that any single person can acquire expertise that encompasses the entire field. Yet, because of the interdisciplinary nature of this activity, there is considerable interplay and overlapping of interest and effort between them. For example, biomedical engineers engaged in the development of biosensors may interact with those interested in prosthetic devices to develop a means to detect and use the same bioelectric signal to power a prosthetic device. Those engaged in automating clinical chemistry laboratories may collaborate with those developing expert systems to assist clinicians in making decisions based on specific laboratory data. The possibilities are endless.

Perhaps, a greater potential benefit occurring from the use of biomedical engineering is identification of the problems and needs of our present healthcare system that can be solved using existing engineering technology and systems methodology. Consequently, the field of biomedical engineering offers hope in the continuing battle to provide high-quality care at a reasonable cost. If properly directed toward solving problems related to preventive medical approaches, ambulatory care services, and the like, biomedical engineers can provide the tools and techniques to make our healthcare system more effective and efficient and, in the process, improve the quality of life for all.

Joseph D. Bronzino
Donald R. Peterson
Editors-in-Chief

Editors

Joseph D. Bronzino is currently the president of the Biomedical Engineering Alliance and Consortium (BEACON; www.beaconalliance.org), which is a nonprofit organization dedicated to the promotion of collaborative research, translation, and partnership among academic, medical, and industry people in the field of biomedical engineering to develop new medical technologies and devices. To accomplish this goal, Dr. Bronzino and BEACON facilitate collaborative research, industrial partnering, and the development of emerging companies. Dr. Bronzino earned a BSEE from Worcester Polytechnic Institute, Worcester, Massachusetts, in 1959, an MSEE from the Naval Postgraduate School, Monterey, California, in 1961, and a PhD in electrical engineering from Worcester Polytechnic Institute in 1968. He was recently the Vernon Roosa Professor of Applied Science and endowed chair at Trinity College, Hartford, Connecticut.

Dr. Bronzino is the author of over 200 journal articles and 15 books, including *Technology for Patient Care* (C.V. Mosby, 1977), *Computer Applications for Patient Care* (Addison-Wesley, 1982), *Biomedical Engineering: Basic Concepts and Instrumentation* (PWS Publishing Co., 1986), *Expert Systems: Basic Concepts* (Research Foundation of State University of New York, 1989), *Medical Technology and Society: An Interdisciplinary Perspective* (MIT Press and McGraw-Hill, 1990), *Management of Medical Technology* (Butterworth/Heinemann, 1992), *The Biomedical Engineering Handbook* (CRC Press, 1st Edition, 1995; 2nd Edition, 2000; 3rd Edition, 2006), *Introduction to Biomedical Engineering* (Academic Press, 1st Edition, 1999; 2nd Edition, 2005; 3rd Edition, 2011), *Biomechanics: Principles and Applications* (CRC Press, 2002), *Biomaterials: Principles and Applications* (CRC Press, 2002), *Tissue Engineering* (CRC Press, 2002), and *Biomedical Imaging* (CRC Press, 2002).

Dr. Bronzino is a fellow of IEEE and the American Institute of Medical and Biological Engineering (AIMBE), an honorary member of the Italian Society of Experimental Biology, past chairman of the Biomedical Engineering Division of the American Society for Engineering Education (ASEE), a charter member of the Connecticut Academy of Science and Engineering (CASE), a charter member of the American College of Clinical Engineering (ACCE), a member of the Association for the Advancement of Medical Instrumentation (AAMI), past president of the IEEE-Engineering in Medicine and Biology Society (EMBS), past chairman of the IEEE Healthcare Engineering Policy Committee (HCEPC), and past chairman of the IEEE Technical Policy Council in Washington, DC. He is a member of Eta Kappa Nu, Sigma Xi, and Tau Beta Pi. He is also a recipient of the IEEE Millennium Medal for "his contributions to biomedical engineering research and education" and the Goddard Award from WPI for Outstanding Professional Achievement in 2005. He is presently editor-in-chief of the Academic Press/Elsevier BME Book Series.

Donald R. Peterson is a professor of engineering and the dean of the College of Science, Technology, Engineering, Mathematics, and Nursing at Texas A&M University in Texarkana, Texas, and holds a joint appointment in the Department of Biomedical Engineering (BME) at Texas A&M University in College Station, Texas. He was recently an associate professor of medicine and the director of the

Biodynamics Laboratory in the School of Medicine at the University of Connecticut (UConn) and served as chair of the BME Program in the School of Engineering at UConn as well as the director of the BME Graduate and Undergraduate Programs. Dr. Peterson earned a BS in aerospace engineering and a BS in biomechanical engineering from Worcester Polytechnic Institute, in Worcester, Massachusetts, in 1992, an MS in mechanical engineering from the UConn, in Storrs, Connecticut, in 1995, and a PhD in biomedical engineering from UConn in 1999. He has 17 years of experience in BME education and has offered graduate-level and undergraduate-level courses in the areas of biomechanics, biodynamics, biofluid mechanics, BME communication, BME senior design, and ergonomics, and has taught subjects such as gross anatomy, occupational biomechanics, and occupational exposure and response in the School of Medicine. Dr. Peterson was also recently the co-executive director of the Biomedical Engineering Alliance and Consortium (BEACON), which is a nonprofit organization dedicated to the promotion of collaborative research, translation, and partnership among academic, medical, and industry people in the field of biomedical engineering to develop new medical technologies and devices.

Dr. Peterson has over 21 years of experience in devices and systems and in engineering and medical research, and his work on human–device interaction has led to applications on the design and development of several medical devices and tools. Other recent translations of his research include the development of devices such as robotic assist devices and prosthetics, long-duration biosensor monitoring systems, surgical and dental instruments, patient care medical devices, spacesuits and space tools for NASA, powered and non-powered hand tools, musical instruments, sports equipment, computer input devices, and so on. Other overlapping research initiatives focus on the development of computational models and simulations of biofluid dynamics and biomechanical performance, cell mechanics and cellular responses to fluid shear stress, human exposure and response to vibration, and the acoustics of hearing protection and communication. He has also been involved clinically with the Occupational and Environmental Medicine group at the UConn Health Center, where his work has been directed toward the objective engineering analysis of the anatomic and physiological processes involved in the onset of musculoskeletal and neuromuscular diseases, including strategies of disease mitigation.

Dr. Peterson's scholarly activities include over 50 published journal articles, 2 textbook chapters, 2 textbook sections, and 12 textbooks, including his new appointment as co-editor-in-chief for *The Biomedical Engineering Handbook* by CRC Press.

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