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Introduction and Preface

As we enter the new millennium, the prospects for the field of Biomedical Engineering are bright. Individuals interested in pursuing careers in this field continue to increase and the fruits of medical innovation continue to yield both monetary rewards and patient well being. These trends are reflected in this second edition of the *Biomedical Engineering Handbook*. When compared to the first edition published in 1995, this new two-volume set includes new sections on "Transport Phenomena and Biomimetic Systems" and "Ethical Issues Associated with Medical Technology". In addition, over 60% of the chapters has been completely revised, incorporating the latest developments in the field. therefore, this second edition is truly an updated version of the "state-of-the-field of biomedical engineering". 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 serve as an excellent review of the major areas of activity in each biomedical engineering subdiscipline, such as biomechanics biomaterials, clinical engineering, artificial intelligence, etc., and finally it can serve as the "bible" for practicing biomedical engineering professionals by covering such topics as a "Historical Perspective of Medical Technology, the Role of Professional Societies and the Ethical Issues Associated with Medical Technology".

Biomedical Engineering is no longer an emerging discipline; it has become an important vital interdisciplinary field. Biomedical engineers are involved in many medical ventures. 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 serve as members of the health care delivery team (clinical engineering, medical informatics, rehabilitation engineering, etc.) seeking new solutions for difficult heath care 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 of biomedical engineering as we enter the 21st century. Before presenting this detailed information, however, it is important to provide a sense of the evolution of the modern health care system and identify the diverse activities biomedical engineers perform to assist in the diagnosis and treatment of patients.

Evolution of the Modern Health Care System

Before 1900, medicine had little to offer the average citizen, since its resources consisted mainly of the physician, his education, and his "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 health care 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 the physician 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 health care practices, in which specialized physicians and nurses located within the hospital 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 (chemistry, physics, engineering, microbiology, physiology, pharmacology, etc.) at the turn of the 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 disease. For example, in 1903, Willem Einthoven, the 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 biologic 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 their discoverer 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 health care 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 health care 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, i.e., 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 lung and heart vessels and valves), were developed. As a result, accurate diagnosis 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.

Following World War II, technological advances were spurred on by efforts to develop superior weapon systems and 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 various physiologic 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 physiologic 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, as well as implantable drug delivery systems, a reality.
7. 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.
8. 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.

The impact of these discoveries and many others has been profound. The health care system consisting primarily of the "horse and buggy" physician is gone forever, replaced by a technologically sophisticated clinical staff operating primarily in "modern" hospitals designed to accommodate the new medical technology. This evolutionary process continues, with advances in biotechnology and tissue engineering altering the very nature of the health care delivery system itself.

The Field of Biomedical Engineering

Today, many of the problems confronting health professionals are of extreme interest to engineers because they involve the design and practical application of medical devices and systems — processes that are fundamental to engineering practice. These medically related design problems can range from very complex large-scale constructs, such as the design and implementation of automated clinical laboratories, multiphasic screening facilities (i.e., centers that permit many clinical tests to be conducted), and hospital information systems, to the creation of relatively small and "simple" devices, such as recording electrodes and biosensors, that may be used to monitor the activity of specific physiologic processes in either a research or clinical setting. They encompass the many complexities of remote monitoring and telemetry, including the requirements of emergency vehicles, operating rooms, and intensive care units. The American health care system, therefore, encompasses many problems that represent challenges to certain members of the engineering profession called *biomedical engineers.*

Biomedical Engineering: A Definition

Although what is included in the field of biomedical engineering is considered by many to be quite clear, there are some disagreements about its definition. For example, consider the terms *biomedical engineering, bioengineering,* and *clinical* (or *medical*) *engineering* which have been defined in Pacela's *Bioengineering Education Directory* [Quest Publishing Co., 1990]. While Pacela defines *bioengineering* as the broad umbrella term used to describe this entire field, *bioengineering* is usually defined as a basic research–oriented activity closely related to biotechnology and genetic engineering, i.e., 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 bioengineers of the future 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

In reviewing the above-mentioned terms, however, *biomedical engineering* appears to have the most comprehensive meaning. Biomedical engineers apply electrical, mechanical, chemical, optical, and other engineering principles to understand, modify, or control biologic (i.e., human and animal) systems, as well as design and manufacture products that can monitor physiologic functions and assist in the diagnosis and treatment of patients. When biomedical engineers work within a hospital or clinic, they are more properly called *clinical engineers.*

Activities of Biomedical Engineers

The breadth of activity of biomedical engineers is significant. The field has moved significantly from being concerned primarily with the development of medical devices 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, each of which is presented in this Handbook. These areas include:

- Application of engineering system analysis (physiologic modeling, simulation, and control) to biologic problems
- Detection, measurement, and monitoring of physiologic 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*)
- Computer analysis of patient-related data and clinical decision making (i.e., medical informatics and artificial intelligence)
- Medical imaging, i.e., the graphic display of anatomic detail or physiologic function
- The creation of new biologic products (i.e., *biotechnology* and *tissue engineering*)

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 physiologic systems variables

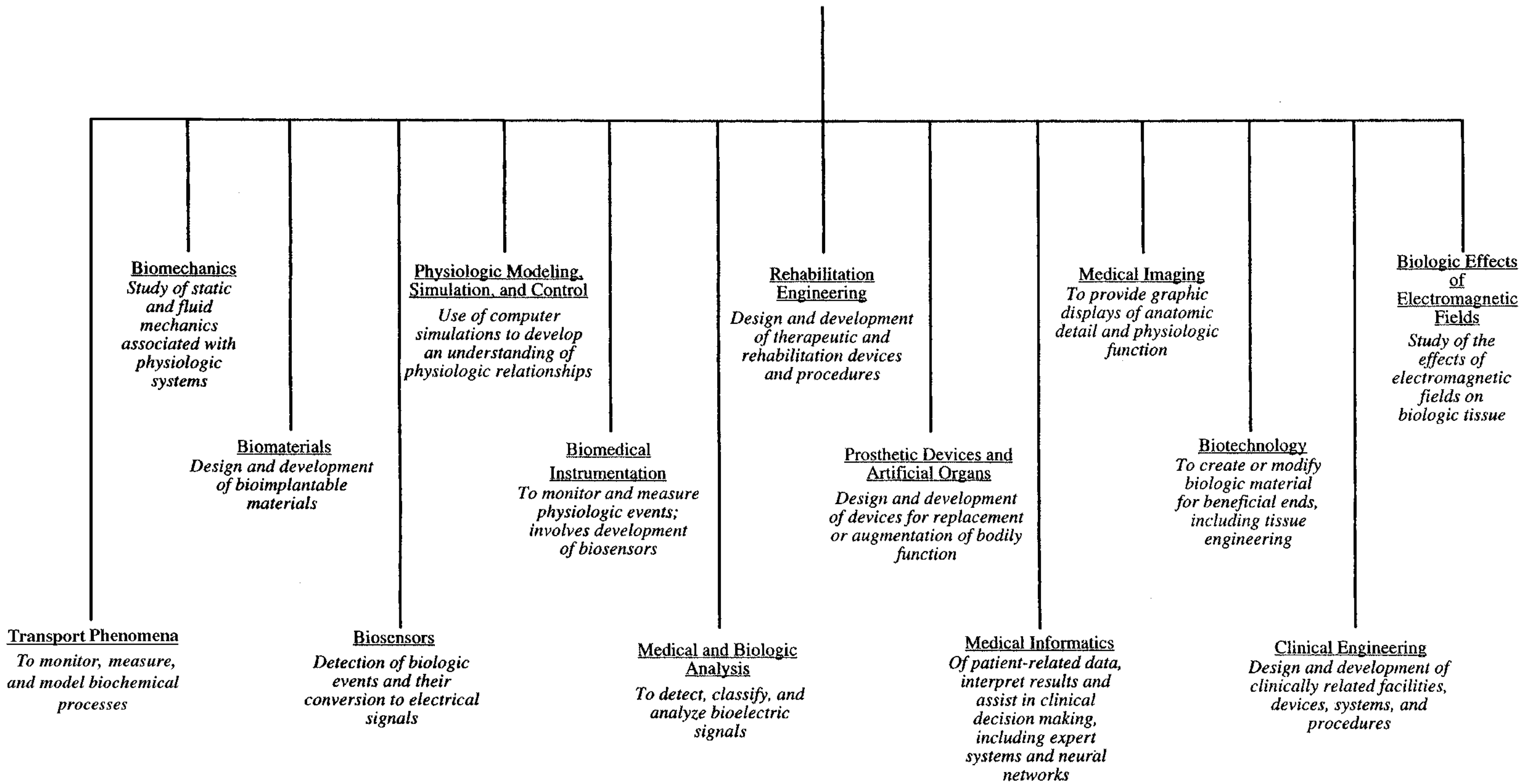
- Development of expert systems for diagnosis of disease
- Design of closed-loop control systems for drug administration
- Modeling of the physiologic systems of the human body
- Design of instrumentation for sports medicine
- Development of new dental materials
- Design of communication aids for the handicapped
- Study of pulmonary fluid dynamics
- Study of the biomechanics of the human body
- Development of material to be used as 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 the clinical chemistry laboratory 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 health care 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 health 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 health care system more effective and efficient.

Joseph D. Bronzino
Editor-in-Chief

The Discipline of Biomedical Engineering



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Joseph D. Bronzino, Ph.D., P.E., Vernon Roosa Professor of Applied Science at Trinity College, Hartford, Connecticut, and director of the Biomedical Engineering Alliance for Connecticut (BEACON), teaches graduate and undergraduate courses in biomedical engineering in the fields of clinical engineering, electrophysiology, signal analysis, and computer applications in medicine. He earned his B.S. in electrical engineering from Worcester Polytechnic Institute, M.S. in electrical engineering from the Naval Postgraduate School, and Ph.D. in electrical engineering also from Worcester Polytechnic Institute. Deeply concerned with the discipline of biomedical engineering, as well as with ethical and economic issues related to the application of technology to the delivery of health care, Dr. Bronzino has written and lectured internationally. He is the author of over 200 articles and 8 books: *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 and Applications* (Research Foundation of the State University of New York, 1989), *Medical Technology and Society: An Interdisciplinary Perspective* (MIT Press, 1990), *Management of Medical Technology* (Butterworth/Heinemann, 1992), *The Biomedical Engineering Handbook* (CRC Press, 1995), *The Introduction to Biomedical Engineering* (Academic Press, 1999), and *The Biomedical Engineering Handbook, 2nd Edition* (CRC Press, 2000). Dr. Bronzino is a fellow of both the Institute of Electrical and Electronic Engineers (IEEE) and the American Institute of Medical and Biological Engineering (AIMBE), a past president of the IEEE Engineering in Medicine and Biology Society (EMBS), a past chairman of the Biomedical Engineering Division of the American Society for Engineering Education, and a charter member of the American College of Clinical Engineering (ACCE) and the Connecticut Academy of Science and Engineering (CASE). Dr. Bronzino has extensive experience in the formulation of public policy regarding the utilization and regulation of medical technology. He has served as a past chairman of both the IEEE Health Care Engineering Policy Committee (HCEPC) and the IEEE Technical Policy Council in Washington, D.C.

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Contents

SECTION I Physiologic Systems

SECTION II Bioelectric Phenomena

Section III Biomechanics

Section IV Biomaterials

Section V Biomedical Sensors

Contents

SECTION XII Tissue Engineering

SECTION XIII Prostheses and Artificial Organs

SECTION XIV Rehabiliation Engineering

SECTION XVI Physiological Modeling, Simulation, and Control

SECTION XVII Clinical Engineering

SECTION XX Ethical Issues Associated with the Use of Medical Technology