THE

Biomedical Engineering

HANDBOOK

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CRC PRESS   IEEE PRESS
A CRC Handbook Published in Cooperation with IEEE Press

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Library of Congress Cataloging-in-Publication Data

The biomedical engineering handbook / editor-in-chief, Joseph D. Bronzino.
p. cm. — (The electrical engineering handbook series)
Includes bibliographical references and index.
ISBN 0-8493-8346-3
1. Biomedical engineering—Handbooks, manuals, etc. I. Bronzino, Joseph D., 1937– . II. Series.
[DNLM: 1. Biomedical Engineering—handbooks. QT 29 B615 1995]
R856.15.B86 1995
610′.28—dc20
DNLM/DLC
For Library of Congress 95-6294
CIP

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International Standard Book Number 0-8493-8346-3
Library of Congress Card Number 95-6294
Printed in the United States of America 1 2 3 4 5 6 7 8 9 0
Printed on acid-free paper

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Introduction

In the 20th century, technological innovation has progressed at such an accelerated pace that it has permeated almost every facet of our lives. This is especially true in the field of medicine and the delivery of health care services. Today, in most developed countries, the modern hospital has emerged as the center of a technologically sophisticated health care system serviced by an equally technologically sophisticated staff.

With almost continual technological innovation driving medical care, engineering professionals have become intimately involved in many medical ventures. As a result, the discipline of biomedical engineering has emerged as an integrating medium for two dynamic professions, medicine and engineering. In the process, biomedical engineers have become actively involved in the design, development, and utilization of materials, devices (such as ultrasonic lithotripsy, pacemakers, etc.), and techniques (such as signal and image processing, artificial intelligence, etc.) for clinical research, as well as the diagnosis and treatment of patients. Thus many biomedical engineers now serve as members of health care delivery teams seeking new solutions for the difficult health care problems confronting our society. The purpose of this handbook is to *provide a central core of knowledge from those fields encompassed by the discipline of biomedical engineering*. Before presenting this detailed information, 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

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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 a 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 permitted 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.

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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:

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