BIOMEDICAL DEVICE TECHNOLOGY

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To my wife, Elaine
and
my daughters, Victoria and Tiffany

PREFACE

For many years, the tools available to physicians were limited to a few simple handpieces such as stethoscopes, thermometers, and syringes; medical professionals primarily relied on their senses and skills to perform diagnosis and disease mitigation. Today, diagnosis of medical problems is heavily dependent on the analysis of information made available by sophisticated medical machineries such as electrocardiographs, ultrasound scanners, and laboratory analyzers. Patient treatments often involve specialized equipment such as cardiac pacemakers and electrosurgical units. Such biomedical instrumentations play a critical and indispensable role in modern medicine.

In order to design, build, maintain, and effectively deploy medical devices, one must understand not only their design and construction but also how they interact with the human body. This book provides a comprehensive approach studying the principles and design of biomedical devices as well as their applications in medicine. It is written for engineers and technologists who are interested in understanding the principles, design, and applications of medical device technology. The book is also intended to be used as a textbook or reference for biomedical device technology courses in universities and colleges.

The most common reason of medical device obsolescence is changes in technology. For example, vacuum tubes in the 1960s, discrete semiconductors in the 1970s, integrated circuits in the 1980s, microprocessors in the 1990s, and networked multiprocessor software-driven systems in today's devices. The average life span of medical devices has been diminishing; current medical devices have a life span of about 5 to 7 years. It is unrealistic to write a book on medical devices and expect that the technology described will remain current and valid for years. On the other hand, the principles of medical device applications, the origins of physiological signals and their methods of acquisition, and the concepts of signal analysis and processing will remain largely unchanged. This book focuses on the functions and principles of medical devices (which are the invariant components) and uses specific designs and constructions to illustrate the concepts where appropriate.

The first part of this book discusses the fundamental building blocks of biomedical instrumentations. Starting from an introduction of the origins of biological signals, the essential functional building blocks of a typical medical device are studied. These functional blocks include electrodes and transducers, biopotential amplifiers, signal conditioners and processors, electrical safety and isolation, output devices, and visual display systems. The next section of the book covers a number of biomedical devices. Their clinical applications, principles of operations, functional building blocks, special features, performance specifications, as well as common problems and safety precautions are discussed. Architectural and schematic diagrams are used where appropriate to illustrate how specific device functions are being implemented.

Due to the vast variety of biomedical devices available in health care, it is impractical to include all of them in a single book. This book selectively covers diagnostic and therapeutic devices that are either commonly used or whose principles and design represent typical applications of the technology. To limit the scope, medical imaging equipment and laboratory instrumentations are excluded from this book.

Three Appendices are included at the end of the book. These are appended for those who are not familiar with these concepts yet an understanding in these areas will enhance the comprehension of the subject matters in the book. They are: A–1. A Primer on Fourier Analysis; A–2. Overview of Medical Telemetry Development; and A–3. Medical Gas Supply Systems.

I would like to take the opportunity to acknowledge Euclid Seeram, who encouraged and inspired me to embark in writing, and Michael Thomas for agreeing to publish and giving me the extra time to finish this book.

Anthony Y. K. Chan

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MEDICAL DEVICES

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BIOMEDICAL DEVICE TECHNOLOGY

Chapter 1

OVERVIEW OF BIOMEDICAL INSTRUMENTATION

OBJECTIVES

- Define "medical device."
- Analyze biomedical instrumentation using a systems approach.
- Explain the origin and characteristics of biopotentials and common physiological signals.
- Explain the importance and approaches of human factor engineering in medical device design.
- List common input, output, and control signals of medical devices.
- Identify the special constraints encountered in the design of biomedical devices.
- Define biocompatibility and list common biomaterials used in medical devices.
- Explain the tissue responses and approaches to achieve biocompatibility.
- Identify the basic functional building blocks of medical instrumentation.

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6. Human Machine Interface
7. Input, Output, and Control Signals
8. Constraints in Biomedical Signal Measurements
9. Concepts on Biocompatibility
10. Functional Building Blocks of Medical Instrumentation

INTRODUCTION

Medical devices come with different designs and complexity. They can be as simple as a tongue depressor, as compact as a rate-responsive demand pacemaker, or as sophisticated as a surgical robot. Although most medical devices use similar technology as their commercial counterparts, there are many fundamental differences between devices used in medicine and devices used in other applications. This chapter will look at the definition of medical devices and the characteristics that differentiate a medical device from other household or commercial products.

According to the United States Food and Drug Administration (FDA), a "medical device" is defined as:

> "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
>
> - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
> - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

A "medical device" is similarly defined in the Canadian Food and Drugs Act, as:

> "Any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:
>
> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or the symptoms thereof, in humans or animals;
> (b) restoring, correcting or modifying a body function, or the body structure of humans or animals;

(c) the diagnosis of pregnancy in humans or animals; or
(d) the care of humans or animals during pregnancy, and at, and after, birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug."

Apart from the obvious, it is clear from these definitions that in vitro diagnostic products such as medical laboratory instruments are medical devices. Furthermore, accessories, reagents, or spare parts associated with a medical device are also considered to be medical devices. An obvious example of this is the electrodes of a heart monitor. Another example, which may not be as obvious, is the power adapter to a medical device such as a laryngoscope. Both of these accessories are considered as medical devices and are therefore regulated by the premarketing and postmarketing regulatory controls.

CLASSIFICATION OF MEDICAL DEVICES

There are many different approaches to classify or group medical devices. Devices can be grouped by their functions, their technologies, or their applications. A description of some common classification methods follows.

Classified by Functions

Grouping medical devices by their functions is by far the most common way to classify medical devices. Devices can be separated into two main categories: diagnostic and therapeutic.

Diagnostic devices are used to determine physical signs and diseases and/or injury without alteration of the structure and function of the biological system. However, some diagnostic devices may alter the biological system to a certain extent due to their applications. For example, a real-time blood gas analyzer may require invasive catheters (which puncture the skin into a blood vessel) to take PCO_2 measurement. A computer tomography scanner will impose ionization radiation (transfer energy) on the human body in order to obtain the medical images.

Diagnostic devices whose functions are to determine the changes of certain physiological parameters over a period of time are often referred to as monitoring devices. As the main purpose of this class of devices is trending, absolute accuracy may not be as important as their repeatability. Examples of monitoring devices are heart rate monitors used to detect variation of heart rates during a course of drug therapy, and noninvasive blood pressure