# BIOMEDICAL DEVICE TECHNOLOGY

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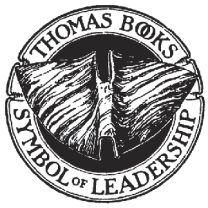
Third Edition

# BIOMEDICAL DEVICE TECHNOLOGY

## Principles and Design

*By*

**ANTHONY Y. K. CHAN, PH.D., P.ENG., CCE**

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*This book is dedicated with love to*

*my wife Elaine,*

*my daughters Victoria and Tiffany,*

*and*

*in memory of*

*my brother David*

# 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, video endoscopic equipment and pulmonary analyzers. Patient treatments often involve specialized tools and systems such as cardiac pacemakers, electrosurgical units, and minimally invasive surgical instruments. Such biomedical devices play a critical and indispensable role in modern-day medicine.

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

The most common reason for 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. Some are even shorter. Therefore, 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 and their applications, the origins of physiological signals and their methods of acquisitions, and the concepts of signal analysis and processing will remain largely unchanged. This book focuses on the applications, 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, and output devices. The next section of the book covers a selection of biomedical devices. Their principles of operations, functional building blocks, special features, performance specifications are discussed. Architectural and schematic diagrams are used where appropriate to illustrate how specific device functions are being implemented. In addition, indications of use and clinical applications of each device are included. Common problems and hazards, and risk mitigation of each device are discussed. For those who would like to know more, a collection of relevant published papers and book references has been added to the end of each chapter.

Due to the vast variety of biomedical devices available in healthcare, 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.

Four 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 A1-A Primer on Fourier Analysis, A2-Overview of Medical Telemetry Development, A3-Medical Gas Supply Systems, and the newest addition A4-Concepts of Infection Control in Biomedical Device Technology.

In this third edition, many chapters have gone through revisions, some with significant updates and additions to keep up with new applications and advancements in medical technology. Based on requests, review questions are added for each chapter to help readers to assess their comprehension of the content material.

I am thankful to the readers, educators, and professionals who provided me with invaluable suggestions for this revision. I also would like to take the opportunity to thank Professor Euclid Seeram for inspiring me into book publishing, and Michael Thomas for his continuing support in publishing this new edition.

Anthony Y. K. Chan

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# BIOMEDICAL DEVICE TECHNOLOGY

# Part I

# INTRODUCTION

# 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.
- Introduce human factors engineering in medical device design.
- List common input, output, and control signals of medical devices.
- Discuss special constraints encountered in the design of biomedical devices.
- Define biocompatibility and list common implant materials.
- Explain tissue responses to foreign materials and state approaches to avoid adverse tissue reaction.
- Describe the basic functional building blocks of medical instrumentation.

## CHAPTER CONTENTS

## INTRODUCTION

Medical devices come with different designs and complexity. They can be as simple as a tongue depressor, as compact as an implantable pacemaker, or as sophisticated as a heart lung machine. Although most medical devices use similar technology as other consumer or industrial devices, 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 consumer products.

According to the International Electrotechnical Commission (IEC), a medical device means:

> Any instrument, apparatus, implement, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:
> a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
>  - diagnosis, prevention, monitoring, treatment, or alleviation of disease,
>  - diagnosis, monitoring, treatment, alleviation of, or compensation for an injury,
>  - investigation, replacement, modification, or support of the anatomy or of a physiological process,
>  - supporting or sustaining life,
>  - control of conception,
>  - disinfection of medical devices,
>  - providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and
> b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which can be assisted in its function by such means.

The United States Food and Drug Administration (FDA) defines a medical device 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.

In the Canadian Food and Drugs Act, a medical device is similarly defined 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 the above 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 laryngoscope. Both of these accessories are considered as medical devices and are therefore regulated by the premarket and postmarket regulatory controls.

## CLASSIFICATION OF MEDICAL DEVICES

There are many different ways to classify or group together 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 for the analysis or detection of diseases, injuries, or other medical conditions. Ideally, a diagnostic device should not cause any change to the structure or function of the biological system. However, some diagnostic devices may disrupt the biological system due to