BIOMEDICAL DEVICE TECHNOLOGY

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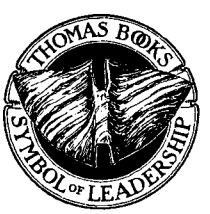
Second Edition

BIOMEDICAL DEVICE TECHNOLOGY

Principles and Design

By

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



CHARLES C THOMAS • PUBLISHER, LTD.
Springfield • Illinois • U.S.A.

Published and Distributed Throughout the World by

CHARLES C THOMAS • PUBLISHER, LTD.
2600 South First Street
Springfield, Illinois 62704

ISBN 978-0-398-09083-8 (hard)
ISBN 978-0-398-09084-5 (ebook)

First Edition, 2008
Second Edition, 2016

Library of Congress Catalog Card Number: 2015022181

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Printed in the United States of America
MM-R-3

Library of Congress Cataloging-in-Publication Data

Chan, Anthony Y. K., author.
Biomedical device technology : principles and design / by Anthony Y. K. Chan. -- Second edition.
p.; cm.
Includes bibliographical references and index.
ISBN 978-0-398-09083-8 (hard) -- ISBN 978-0-398-09084-5 (ebook)
I. Title.
[DNLM: 1. Biomedical Technology–instrumentation. 2. Equipment Design. 3. Equipment and Supplies. W 26]

R856
610.284–dc23

2015022181

To

my wife

Elaine,

my daughters

Victoria and Tiffany,

and my brothers and sisters

Agnes, Barbara, Philip, Paul and 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 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 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 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, hazards, 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.

In this second edition of the book, almost every chapter has been revised–some with minor updates and some with significant changes and additions. For those who would like to know more, a collection of relevant published papers and book references has been added at the end of each chapter. Based on feedback, a section on "common problems and hazards" has been included for each medical device. In addition, more information is provided on the indications of use and clinical applications. Two new areas of medical device technology have been added in the two new chapters on Cardiopulmonary Bypass Units and Audiology Equipment.

I gratefully acknowledge the reviewers, educators, and professionals who provided me with insightful 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 encouraging me to work on this second edition.

Anthony Y. K. Chan

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PART IV–MEDICAL DEVICES

BIOMEDICAL DEVICE TECHNOLOGY

Part I

INTRODUCTION

Chapter 1

OVERVIEW OF BIOMEDICAL INSTRUMENTATION

OBJECTIVES

- Define the term 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.
- Identify 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.
- Identify 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 a rate-responsive demand pacemaker, or as sophisticated as a surgical robot. Although most medical devices use technology similar to 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 is

> Any instrument, apparatus, implement, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, 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 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