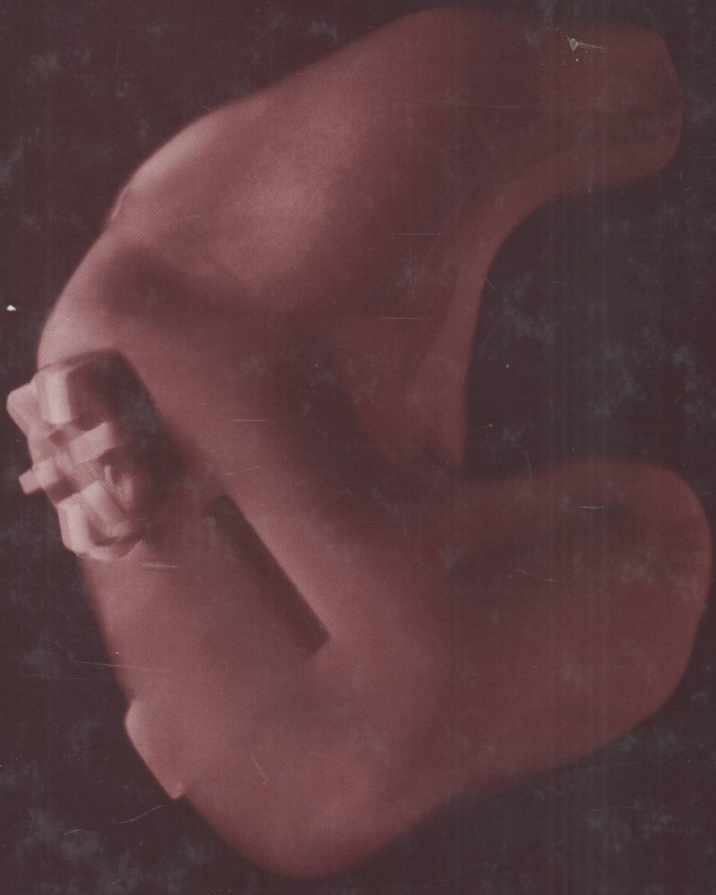
Reliable Design of Medical Devices

Second Edition



Richard Fries

CRC Taylor & Francis
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CRC Taylor & Francis
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Boca Raton London New York

A CRC title, part of the Taylor & Francis imprint, a member of the Taylor & Francis Group, the academic division of T&F Informa plc.

Published in 2006 by
CRC Press
Taylor & Francis Group
6000 Broken Sound Parkway NW, Suite 300
Boca Raton, FL 33487-2742

Printed in the United States of America on acid-free paper
10 9 8 7 6 5 4 3 2 1

International Standard Book Number-10: 0-8247-2375-9 (Hardcover)
International Standard Book Number-13: 978-0-8247-2375-0 (Hardcover)
Library of Congress Card Number 2005043942

Library of Congress Cataloging-in-Publication Data

Fries, Richard C.
Reliable design of medical devices / Richard C. Fries.--2nd ed.
p. cm.
Includes bibliographical references and index.
ISBN 0-8247-2375-9
1. Medical instruments and apparatus--Reliability. 2. Medical instruments and apparatus--Design and construction. 3. Medical instruments and apparatus--Quality control. 4. Medical instruments and apparatus--Standards. I. Title.

R856.6.F749 2005
681'.761--dc22 2005043942

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Preface

The design and functional complexity of medical devices have increased during the past 50 years, evolving from the use of a metronome circuit for the initial cardiac pacemaker to functions that include medical book-keeping, electrocardiogram analysis, delivery of anesthesia, laser surgery, magnetic resonance imaging, and intravenous delivery systems that adjust dosages based on patient feedback. As device functionality becomes more intricate, concerns arise regarding efficacy, safety, and reliability. Both the user and the patient want the device to operate as specified, perform in a safe manner, and continue to perform over a long period of time without failure. To be successful, the designer and manufacturer of medical devices must ensure that all devices meet these requirements.

In almost every major medical system developed or acquired by commercial or governmental organizations, software or firmware plays a major part and has become an increasing management concern. In many cases it takes too long to develop, causing the entire system to slip its schedule, and commensurately raising development costs. When delivered, it may not perform as expected. Requirements that were to be implemented in software have had to be scaled down to achieve a reasonable delivery schedule, or the software is shipped with known bugs. As a result, major management attention has been focused on the productivity of software development, the costs associated with its development, and the resultant quality of the delivered product.

Software productivity, or the rate at which software can be delivered, is limited by current development practice. Software scientists generally believe that software productivity will not dramatically improve without major technological breakthroughs creating more automated programming techniques. Many scientists believe, however, that the rigorous employment of modern disciplined software engineering practice can achieve significant software quality improvement over current practice without a corresponding increase in cost. By concentrating on engineering practices to achieve software quality and reliability, concomitant improvements in the overall reliability of the device will also be obtained.

Medical device development is therefore a complex process that requires the careful integration of diverse disciplines, technical activities, standards, regulatory requirements, and administrative project controls. The need for systematic approaches to product development and maintenance is necessary to ensure a safe and effective device for the user and patient, an economical

and competitive success for the manufacturer, and a reliable, cost-effective investment for the user.

Reliability engineering provides the theoretical and practical tools by which the probability and capability of systems and their components to perform required functions can be specified, predicted, designed-in, tested, and demonstrated. It is an integral part of the product development process and of problem solving activities related to manufacturing and field failures. Reliability, however, is more than a science. It is also a philosophy – a way of structuring professional activities so details are planned before action is taken and problems are anticipated so they may be eliminated prior to occurring in the field.

The primary goal of this text is to acquaint the developer of medical devices, as well as the purchaser of medical equipment, with the basic concepts and major issues of medical device reliability, to describe current product development processes and techniques, and to provide a basis for evaluating new technologies. Developers may use this information to improve their own design, validation, and manufacturing processes. Purchasers may use this information to ask more pertinent questions and make a more educated assessment of their suppliers. This text may also be used by non-medical developers and purchasers because the reliability process is relevant to all product development.

The text provides a practical approach to the formation and operation of a reliability assurance program. The emphasis of the book is on the practical, hands-on approach to product development. The mathematics included in the text is that which is necessary to conduct everyday tasks. Equations, where needed, are merely given, not derived. It is assumed the reader has a basic knowledge of statistics. For those wishing to delve deeper into the mathematics of the subject, references are given at the end of each chapter.

The layout of the text follows the typical product development process. Section 1 introduces the reader to the basics of reliability engineering and failures. Failures and reliability are discussed from the hardware, software, and systems levels.

Section 2 deals with myriad device standards and regulations, both domestic and international. Particular emphasis is placed on FDA regulations, the medical device directives, and the quality system regulation.

Section 3 deals with the specification of a medical device. The section covers the definition of a medical device, defining the device and establishing product requirements, safety and risk analysis, liability, and intellectual property.

Section 4 deals with the design of a medical device. The discussion begins with a review of Six Sigma methodology and some of the tools involved, including axiomatic and robust design. The section then addresses both hardware and software design, software coding, the use of metrics, and human factors.

Section 5 discusses verification and validation. The section begins with a review of various types of testing, then discusses in detail hardware and

software testing. The section concludes with the analysis of test data that has been accumulated and the calculation of reliability parameters.

Section 6 deals with manufacturing as a continuation of the product development process. A device may be designed reliably, but if it is not manufactured reliably, it will not be a success. Configuration management and its many implications are reviewed. Finally, techniques for the analysis of field data are discussed in relation to building an efficient database for all product development personnel.

Reliability engineering is essential to the success of any medical device company. It helps develop a more profitable product, contributes to a more satisfied customer base, reduces the risk of liability, and builds confidence in meeting requirements of standards and regulatory agencies. Knowledge of reliability engineering is also an asset in evaluating potential vendors of medical devices and addressing device problems. It is hoped this text will assist in establishing and operating a viable reliability engineering program. In addition it is hoped this text will assist the purchaser of medical devices in developing an effective program of vendor evaluation.

I am deeply indebted to many people for their encouragement, help, and constructive criticism in the preparation of this book. I particularly want to thank my wife, June, who constantly encouraged me and who sacrificed much quality time together during the writing of this text.

Richard C. Fries, PE, CRE

Editor

Richard C. Fries holds degrees in biology from Loyola University in Chicago and in electrical/biomedical engineering from Marquette University in Milwaukee. He has nearly 30 years' experience in the health care field, holding positions in reliability engineering, software design, programming, quality assurance, platelet studies, and pharmaceutical research. He is currently the corporate manager of reliability engineering for Baxter Healthcare, in Round Lake, Illinois.

Mr. Fries is a licensed professional engineer in the state of Wisconsin and is certified as a reliability engineer by the American Society for Quality. He is also certified as an ISO 9001 TickIT lead auditor. He is co-inventor of United States Patent 5,682,876.

He is currently a member of the Industrial Advisory Board for the Biomedical Engineering Department and a member of the Advisory Board for the Reliability Engineering Curriculum at Vanderbilt University. He is a project advisor and lecturer for a senior biomedical engineering design course at Vanderbilt. He is a member of the Industrial Advisory Board and a guest lecturer for the Biomedical Engineering Department at Marquette University.

He is past co-chair of the AAMI Medical Device Software Task Force and past chair of the HIMA Software Task Force. He was a member of Working Group 1 to ISO TC210, and is currently a member of the IEEE Software Engineering Standards Subcommittee.

Mr. Fries is the author of several books and numerous articles in professional journals on reliability engineering, medical device design, software quality, standards and regulations.

Dedication

To
Avery Grace Fries
whose humor, smile, and zest for life
make being your grandfather a most enjoyable occupation

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