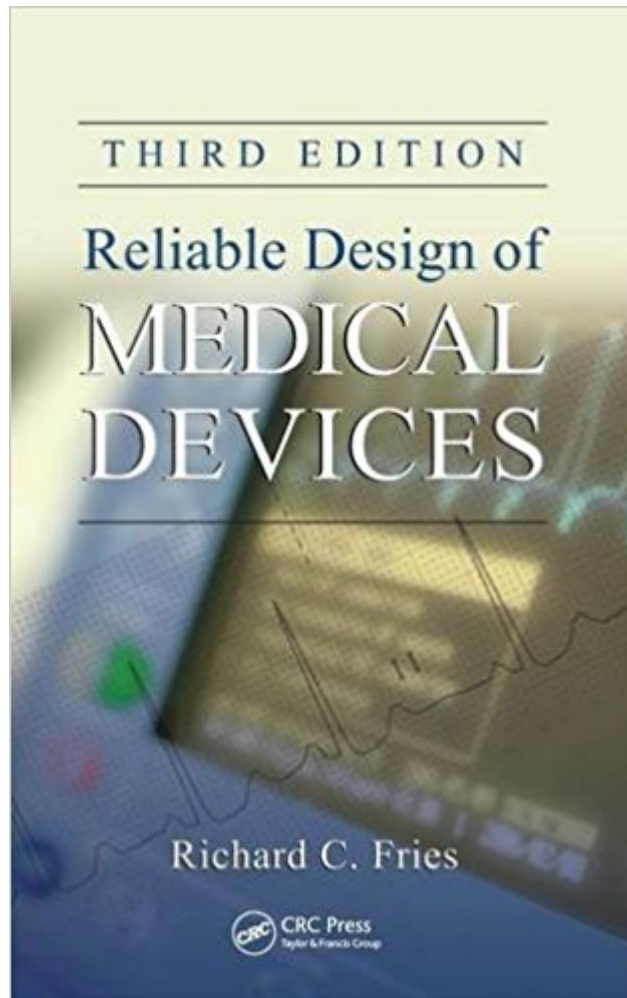




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Reliable Design Of Medical Devices, Third Edition



Synopsis

As medical devices become even more intricate, concerns about efficacy, safety, and reliability continue to be raised. Users and patients both want the device to operate as specified, perform in a safe manner, and continue to perform over a long period of time without failure. Following in the footsteps of the bestselling second edition, *Reliable Design of Medical Devices, Third Edition* shows you how to improve reliability in the design of advanced medical devices. Reliability engineering is an integral part of the product development process and of problem-solving activities related to manufacturing and field failures. Mirroring the typical product development process, the book is organized into seven parts. After an introduction to the basics of reliability engineering and failures, it takes you through the concept, feasibility, design, verification and validation, design transfer and manufacturing, and field activity phases. Topics covered include Six Sigma for design, human factors, safety and risk analysis, and new techniques such as accelerated life testing (ALT) and highly accelerated life testing (HALT). What's New in This Edition Updates throughout, reflecting changes in the field An updated software development process Updated hardware test procedures A new layout that follows the product development process A list of deliverables needed at the end of each development phase Incorporating reliability engineering as a fundamental design philosophy, this book shares valuable insight from the author's more than 35 years of experience. A practical guide, it helps you develop a more effective reliability engineering program contributing to increased profitability, more satisfied customers, and less risk of liability.

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"This book focuses on an important topic ... that engineers need to understand in all of its aspects—philosophy, design, and testing and evaluation. They also need to know how they fit in to the larger picture (manufacturing, packaging, etc.). This book provides both an overview of those facets, along with details to implement them. It is thus a valuable resource for students, researchers, and industry [professionals] who wish to develop a product."—Jon Sensinger, Rehabilitation Institute of Chicago, Illinois, USA "My interest is piqued. I think it can be a very interesting and useful resource for engineers and other stakeholders involved in the medical device design and production process."—Carl Nelson, University of Nebraska-Lincoln, USA "Don't let the name fool you—this book is about much more than reliability engineering. While this book opens with a discussion of reliability and failure, it quickly transitions to discussing the entire product development process, from concept through verification, and even includes design transfer and post-market field actions. There is a lot of wisdom in this book. You can tell that the author has seen a lot of projects and wants the reader to avoid the mistakes that he has encountered."—Reading Room, Biomedical Instrumentation and Technology, September/October 2013

Richard Fries, PE, CSQE, CRE, is president of ISORel, Inc., a consulting firm located in Fitchburg, Wisconsin. He is a licensed professional engineer in the state of Wisconsin and is certified by the American Society for Quality as a Reliability Engineer and a Software Quality Engineer. Mr. Fries is a member of the IEEE Software Engineering Subcommittee. He was a member of the AAMI Medical Device Software Committee that developed IEC 62304. He was also a member of the AAMI Technical Committee that developed ISO 13485.

Book is a good survey book but nothing new. If you need more detail use Clyde C. Reveling's book. Has much of the same material but in much more detail on how to do things not just what to do.

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