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MRI from Picture to Proton John Wiley & Sons
In vivo magnetic resonance imaging (MRI) has evolved into a versatile and critical, if not ‘ gold standard ’ , imaging tool with applications ranging from the physical sciences to the clinical ‘ -ology ’ . In addition, there is a vast amount of accumulated but unpublished inside knowledge on what is needed to perform a safe, in vivo MRI. The goal of this comprehensive text, written by an outstanding group of world experts, is to present information about the effect of the MRI environment on the human body, and tools and methods to quantify such effects. By presenting such information all in one place, the expectation is that this book will help everyone interested in the Safety and Biological Effects in MRI find relevant information relatively quickly and know where we stand as a community. The information is expected to improve patient safety in the MR scanners of today, and facilitate developing faster, more powerful, yet safer MR scanners of tomorrow. This book is arranged in three sections. The first, named ‘ Static and Gradient Fields ’ (Chapters 1-9), presents the effects of static magnetic field and the gradients of magnetic field, in time and space, on the human body. The second section, named ‘ Radiofrequency Fields ’ (Chapters 10-30), presents ways to quantify radiofrequency (RF) field induced heating in patients undergoing MRI. The effect of the three fields of MRI environment (i.e. Static Magnetic Field, Time-varying Gradient Magnetic Field, and RF Field) on medical devices, that may be carried into the environment with patients, is also included. Finally, the third section, named ‘ Engineering ’ (chapters 31-35), presents the basic background engineering information regarding the equipment (i.e. superconducting magnets, gradient coils, and RF coils) that produce the Static Magnetic Field, Time-varying Gradient Magnetic Field, and RF Field. The book is intended for undergraduate and post-graduate students, engineers, physicists, biologists, clinicians, MR technologists, other healthcare professionals, and everyone else who might be interested in looking into the role of MRI environment on patient safety, as well as those just wishing to update their knowledge of the state of MRI safety. Those, who are learning about MRI or training in magnetic resonance in medicine, will find the book a useful compendium of the current state of the art of the field.

Quality and Reliability Engineering: Recent Trends and Future Directions CRC Press
Parallel transmission enables control of the RF field in high-field Magnetic Resonance Imaging (MRI). However, the approach has also caused concerns about the specific absorption rate (SAR) in the patient body. The present work provides new concepts for SAR prediction. A novel approach for generating human body models is proposed, based on a water-fat separated MRI pre-scan. Furthermore, this work explores various approaches for SAR reduction.

Human Factors Engineering and Ergonomics CRC Press
This book offers all countries a guide to implementing verification systems for medical devices to ensure they satisfy their regulations. It describes the processes, procedures and need for integrating medical devices into the legal metrology framework, addresses their independent safety and performance verification, and highlights the associated savings for national healthcare systems, all with the ultimate goal of increasing the efficacy and reliability of patient diagnoses and treatment. The book primarily focuses on diagnostic and therapeutic medical devices, and reflects the latest international directives and regulations. Above all, the book demonstrates that integrating medical devices into the legal metrology system and establishing a fully operational national laboratory for the inspection of medical devices could significantly improve the reliability of medical devices in diagnosis and patient care, while also reducing costs for the healthcare system in the respective country.

Medical Instrument Design and Development Springer Science & Business Media
El propósito de este manual es proporcionar a los administradores de la tecnología una herramienta de fácil consulta que les oriente en la gestión del mantenimiento de los equipos biomédicos. Se espera que la aplicación de esta metodología contribuya adicionalmente a mejorar el índice de disponibilidad programada de los equipos, ya que este proceso se hace bajo las recomendaciones del fabricante y el cumplimiento de los estándares de seguridad establecidos por las normas.

Inspection of Medical Devices John Wiley & Sons
Clinical Systems Engineering: New Challenges for Future Healthcare covers the critical issues relating to the risk management and design of new technologies in the healthcare sector. It is a comprehensive summary of the advances in clinical engineering over the past 40 years, presenting guidance on compliance and safety for hospitals and engineering teams. This contributed book contains chapters from international experts, who provide their solutions, experiences, and the successful methodologies they have applied to solve common problems in the area of healthcare technology. Topics include compliance with the European Directive on Medical Devices 93/42/EEC, European Norms EN 60601-1-6, EN 62366, and the American Standards ANSI/AAMI HE75: 2009. Content coverage includes decision support systems, clinical complex systems, and human factor engineering. Examples are fully supported with case studies, and global perspective is maintained throughout. This book is ideal for clinical engineers, biomedical engineers, hospital administrators and medical technology manufacturers. Presents clinical systems engineering in a way that will help users answer many questions relating to clinical systems engineering and its relationship to future healthcare needs Explains how to assess new healthcare technologies and what are the most critical issues in their management Provides information on how to carry out risk analysis for new technological systems or medical software Contains tactics on how to improve the quality and usability of medical devices

Practical Radiation Protection in Healthcare Springer Science & Business Media
International conference supported by Indian Statistical Institute, held at Bangalore, 20-22 December, 2011; selected papers.

Analysis and Application of Analog Electronic Circuits to Biomedical Instrumentation, Second Edition Oxford University Press, USA
Federal regulatory agencies have embraced Hazard Analysis Critical Control Point (HACCP) as the most effective method to offer farm-to-table food safety and quality in the United States—but it is important to look beyond HACCP. The ASQ Certified Food Safety and Quality Auditor (CFSQA) Handbook serves as a baseline of knowledge for auditors of food safety and quality systems that covers other aspects of food production, including preventive controls. This handbook assists certification candidates in preparing for the ASQ Certified Food Safety and Quality Auditor (CFSQA) examination. Its chapters cover the HACCP audit and auditor, preventive principles, and quality assurance analytical tools. The updated fourth edition also includes: • The history of primitive and modern food preservation methods, including the introduction of HACCP methods • The evolution of prerequisite programs, such as chemical and microbiological controls • The importance of other food system support programs, such as product traceability and recall, facility design, and environmental control and monitoring • Preliminary tasks for developing a HACCP plan

Views on Evolvability of Embedded Systems Springer Nature
As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct adequate, efficient bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence. In addition, advances in the analytical technology used to detect drug and metabolite levels have made bioequivalence testing more complex. The second edition of Handbook of Bioequivalence Testing has been completely updated to include the most current information available, including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements. New topics include: A historical perspective on generic pharmaceuticals New guidelines governing submissions related to bioequivalency studies, along with therapeutic code classifications Models of noninferiority Biosimilarity of large molecule drugs Bioequivalence of complementary and alternate medicines Bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies New FDA guidelines for bioanalytical method validation Outsourcing and monitoring of bioequivalence studies The cost of generic drugs is rising much faster than in the past, partly because of the increased costs required for approval—including those for bioequivalence testing. There is a dire need to re-examine the science behind this type of testing to reduce the burden of development costs—allowing companies to develop generic drugs faster and at a lower expense. The final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers. It suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans. Backed by science and updated with the latest research, this book is destined to spark continued debate on the efficacy of the current bioequivalence testing paradigm.

Computer Safety, Reliability, and Security CRC Press
Analysis and Application of Analog Electronic Circuits to Biomedical Instrumentation, Second Edition helps biomedical engineers understand the basic analog electronic circuits used for signal conditioning in biomedical instruments. It explains the function and design of signal conditioning systems using analog ICs—the circuits that enable ECG, EEG, EMG, ERG, tomographic images, biochemical spectrograms, and other crucial medical applications. This book demonstrates how op amps are the keystone of modern analog signal conditioning system design and illustrates how they can be used to build instrumentation amplifiers, active filters, and many other biomedical instrumentation systems and subsystems. It introduces the mathematical tools used to describe noise and its propagation through linear systems, and it looks at how signal-to-noise ratios can be improved by signal averaging and linear filtering. Features Analyzes the properties of photonic sensors and emitters and the circuits that power them Details the design of instrumentation amplifiers and medical isolation amplifiers Considers the modulation and demodulation of biomedical signals Examines analog power amplifiers, including power op amps and class D (switched) PAs Describes wireless patient monitoring, including Wi-Fi and Bluetooth communication protocols Explores RFID, GPS, and ultrasonic tags and the design of fractal antennas Addresses special analog electronic circuits and systems such as phase-sensitive rectifiers, phase detectors, and IC thermometers By explaining the "building blocks" of biomedical systems, the author illustrates the importance of signal conditioning systems in the devices that gather and monitor patients’ critical medical information. Fully revised and updated, this second edition includes new chapters, a glossary, and end-of-chapter problems. What’s New in This Edition Updated and revised material throughout the book A chapter on the applications, circuits, and characteristics of power amplifiers A chapter on wireless patient monitoring using UHF telemetry A chapter on RFID tags, GPS tags, and ultrasonic tags A glossary to help you decode the acronyms and terms used in biomedical electronics, physiology, and biochemistry New end-of-chapter problems and examples

Cumulated Index Medicus Springer
A practical guide for medical physicists and those whose work involves any aspect of hospital radiation protection. It provides guidance on methods that may be used to tackle the tasks that a physicist working in this area might encounter.

Neurophysiological Monitoring During Intensive Care and Surgery KIT Scientific Publishing
100 Jahre DUBBEL 1914 erschien die erste Auflage des Taschenbuch für den Maschinenbau, herausgegeben von Heinrich Dubbel. Seitdem ist der DUBBEL das Standardwerk der Ingenieure in Studium und Beruf mit den Schwerpunkten „Allgemeiner Maschinenbau“ sowie „Verfahrens- und Systemtechnik“. Die laufende Neubearbeitung garantiert die Dokumentation des aktuellen Stands der Technik. Dieses etablierte Referenzwerk mit „Norm-Charakter“ überzeugt durch - detaillierte Konstruktionszeichnungen - Tabellen und Diagramme mit quantitativen Angaben - Berechnungsverfahren - ein umfangreiches Literaturverzeichnis Der DUBBEL stellt das erforderliche Basis- und Detailwissen des Maschinenbaus zur Verfügung. Für die Jubiläumsauflage wurden alle Kapitel aktualisiert. Neu hinzugekommen ist die Medizintechnik, die fertigungstechnischen Kapitel wurden stark überarbeitet. Auch erhalten die Leser des Werkes Zugang zur MDesign Formelsammlung. Die ausführliche Darstellung der Mathematik ist als DUBBEL Mathematik separat erhältlich.

Clinical Engineering WIT Press
Many of us in science have this "Aha!" moment when the mental puzzle is put together and you get a clear picture of a product, which will change the world. Moreover, you have a clear understanding of how it can be a commercial success. So, you decide to start a new company, a startup, and have a clear path to success. However, soon you come face to face with reality, where things are much more complicated. Only a minute fraction of startups survives and becomes successful. This is particularly true in the complex world of medical devices. There are many good books on startups but this book is specifically about startups specializing in medical devices, which are very different from other ones. It is written by a MedDev entrepreneur for first-time MedTech entrepreneurs.

Handbook of Bioequivalence Testing, Second Edition Cambridge University Press
The first comprehensive guide to the integration of Design forSix Sigma principles in the medical devices development cycle Medical Device Design for Six Sigma: A Road Map for Safetyand Effectiveness presents the complete body of knowledge forDesign for Six Sigma (DFSS), as outlined by American Society forQuality, and details how to integrate appropriate designmethodologies up front in the design process. DFSS helps companiesshorten lead times, cut development and manufacturing costs, lowertotal life-cycle cost, and improve the quality of the medicaldevices. Comprehensive and complete with real-world examples, thisguide: Integrates concept and design methods such as Pugh ControlledConvergence approach, QFD methodology, parameter optimizationtechniques like Design of Experiment (DOE), Taguchi Robust Designmethod, Failure Mode and Effects Analysis (FMEA), Design for X,Multi-Level Hierarchical Design methodology, and Response Surfacemethodology Covers contemporary and emerging design methods, includingAxiomatic Design Principles, Theory of Inventive Problem Solving(TRIZ), and Tolerance Design Provides a detailed, step-by-step

implementation process foreach DFSS tool included Covers the structural, organizational, and technical deploymentof DFSS within the medical device industry Includes a DFSS case study describing the development of a newdevice Presents a global prospective of medical device regulations Providing both a road map and a toolbox, this is a hands-onreference for medical device product development practitioners,product/service development engineers and architects, DFSS and SixSigma trainees and trainers, middle management, engineering teamleaders, quality engineers and quality consultants, and graduatestudents in biomedical engineering.

Springer Handbook of Medical Technology CRC Press

An authoritative guide to theory and applications of heat transfer in humans Theory and Applications of Heat Transfer in Humans 2V Set offers a reference to the field of heating and cooling of tissue, and associated damage. The author—a noted expert in the field—presents, in this book, the fundamental physics and physiology related to the field, along with some of the recent applications, all in one place, in such a way as to enable and enrich both beginner and advanced readers. The book provides a basic framework that can be used to obtain ‘decent’ estimates of tissue temperatures for various applications involving tissue heating and/or cooling, and also presents ways to further develop more complex methods, if needed, to obtain more accurate results. The book is arranged in three sections: The first section, named ‘Physics’, presents fundamental mathematical frameworks that can be used as is or combined together forming more complex tools to determine tissue temperatures; the second section, named ‘Physiology’, presents ideas and data that provide the basis for the physiological assumptions needed to develop successful mathematical tools; and finally, the third section, named ‘Applications’, presents examples of how the marriage of the first two sections are used to solve problems of today and tomorrow. This important text is the vital resource that: Offers a reference book in the field of heating and cooling of tissue, and associated damage. Provides a comprehensive theoretical and experimental basis with biomedical applications Shows how to develop and implement both, simple and complex mathematical models to predict tissue temperatures Includes simple examples and results so readers can use those results directly or adapt them for their applications Designed for students, engineers, and other professionals, a comprehensive text to the field of heating and cooling of tissue that includes proven theories with applications. The author reveals how to develop simple and complex mathematical models, to predict tissue heating and/or cooling, and associated damage.

Manual de gestión de mantenimiento del equipo biomédico CRC Press

This book (vol. 3) presents the proceedings of the IUPESM World Congress on Biomedical Engineering and Medical Physics, a triennially organized joint meeting of medical physicists, biomedical engineers and adjoining health care professionals. Besides the purely scientific and technological topics, the 2018 Congress will also focus on other aspects of professional involvement in health care, such as education and training, accreditation and certification, health technology assessment and patient safety. The IUPESM meeting is an important forum for medical physicists and biomedical engineers in medicine and healthcare learn and share knowledge, and discuss the latest research outcomes and technological advancements as well as new ideas in both medical physics and biomedical engineering field.

11th Mediterranean Conference on Medical and Biological Engineering and Computing 2007 Springer

Evolvability, the ability to respond effectively to change, represents a major challenge to today's high-end embedded systems, such as those developed in the medical domain by Philips Healthcare. These systems are typically developed by multi-disciplinary teams, located around the world, and are in constant need of upgrading to provide new advanced features, to deal with obsolescence, and to exploit emerging enabling technologies. Despite the importance of evolvability for these types of systems, the field has received scant attention from the scientific and engineering communities. Views on Evolvability of Embedded Systems focuses on the topic of evolvability of embedded systems from an applied scientific perspective. In particular, the book describes results from the Darwin project that researched evolvability in the context of Magnetic Resonance Imaging (MRI) systems. This project applied the Industry-as-Laboratory paradigm, in which industry and academia join forces to ensure continuous knowledge and technology transfer during the project’s lifetime. The Darwin project was a collaboration between the Embedded Systems Institute, the MRI business unit of Philips Healthcare, Philips Research, and five Dutch universities. Evolvability was addressed from a system engineering perspective by a number of researchers from different disciplines such as software-, electrical- and mechanical engineering, with a clear focus on economic decision making. The research focused on four areas: data mining, reference architectures, mechanisms and patterns for evolvability, in particular visualization & modelling, and economic decision making. Views on Evolvability of Embedded Systems is targeted at both researchers and practitioners; they will not only find a state-of-the-art overview on evolvability research, but also guidelines to make systems more evolvable and new industrially-validated techniques to improve the evolvability of embedded systems.

Bringing a Medical Device to the Market John Wiley & Sons

Safety Risk Management for Medical Devices demystifies risk management, providing clarity of thought and confidence to the practitioners of risk management as they do their work. Written with practicing engineers, safety management professionals, and students in mind, this book will help readers tackle the difficult questions, such as how to define risk acceptance criteria and how to determine when to stop risk reduction. This book delivers not only theory, but also practical guidance for applying the theory in daily risk management work. The reader is familiarized with the vocabulary of risk management and guided through a process to ensure compliance with the international standard ISO 14971—a requirement for all medical devices. This book outlines sensible, easily comprehensible, and state-of the-art methodologies that are rooted in current industry best practices. Opening chapters introduce the concept of risk, the legal basis for risk management, and the requirements for a compliant risk-management process. The next group of chapters discusses the connection between risk management and quality systems, usability engineering and biocompatibility. This book delves into the techniques of risk management, such as fault tree analysis and failure modes and effects analysis, and continues with risk estimation, risk control, and risk evaluation. Special topics such as software risk management, clinical investigations, and security are also discussed. The latter chapters address benefit-risk analysis, and production and postproduction monitoring. This book concludes with advice and wisdom for sensible, efficient, and successful safety risk management of medical devices. Teaches industry best practices on medical-device risk management in compliance with ISO 14971 Provides practical, easy-to-understand, and step-by-step instructions on how to perform hazard analysis and manage the risks of medical devices Offers a worked-out example applying the risk management process on a hypothetical device

Theory and Applications of Heat Transfer in Humans CRC Press

The AAMI recommended practice, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, is a breakthrough standard in terms of its scope. AAMI has updated ST79 with the release of ST79:2010/A4:2013. Of particular importance, A4:2013 provides four new figures demonstrating the wrapping of items for steam sterilization and adds an annex focused on Moisture assessment. As of Oct. 25, 2013, purchasers of ST79 will receive ANSI/AAMI ST79:2010 and A1:2010 and A2:2011 and A3:2012 and A4:2014 as a single consolidated document. Among other changes from the 2006 edition of ST79, this revised and expanded second edition of ST79 includes guidance on the use and application of Class 6 emulating indicators, a chemical monitoring device fairly new to the United States. Because ST79 essentially consolidates five AAMI steam sterilization standards (whose content was reviewed and updated to reflect current good practice prior to being incorporated into ST79), it truly is a comprehensive guideline for all steam sterilization activities in healthcare facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all healthcare personnel who use steam for sterilization.

Safety Risk Management for Medical Devices Springer Science & Business Media

This book explains all of the stages involved in developingmedical devices; from concept to medical approval including systemengineering, bioinstrumentation design, signal processing,electronics, software and ICT with Cloud and e-Healthdevelopment. Medical Instrument Design and Development offers a comprehensivetheoretical background with extensive use of diagrams, graphics andtables (around 400 throughout the book). The book explains how thetheory is translated into industrial medical products using amarket-sold Electrocardiograph disclosed in its design by the GammaCardio Soft manufacturer. The sequence of the chapters reflects the product developmentlifecycle. Each chapter is focused on a specific University courseand is divided into two sections: theory and implementation. Thetheory sections explain the main concepts and principles whichremain valid across technological evolutions of medicalinstrumentation. The Implementation sections show how the theory istranslated into a medical product. The Electrocardiograph(ECG or EKG) is used as an example as it is a suitable device toexplore to fully understand medical instrumentation since it issufficiently simple but encompasses all the main areas involved indeveloping medical electronic equipment. Key Features: Introduces a system-level approach to product design Covers topics such as bioinstrumentation, signal processing,information theory, electronics, software, firmware, telemedicine,e-Health and medical device certification Explains how to use theory to implement a market product (usingECG as an example) Examines the design and applications of main medicalinstruments Details the additional know-how required for productimplementation: business context, system design, projectmanagement, intellectual property rights, product life cycle,etc. Includes an accompanying website with the design of thecertified ECG product (ahref="http://www.gammacardiosoft.it/book"www.gammacardiosoft.it/book/a) Discloses the details of a marketed ECG Product (from GammaCardio Soft) compliant with the ANSI standard AAMI EC 11under open licenses (GNU GPL, Creative Common) This book is written for biomedical engineering courses(upper-level undergraduate and graduate students) and for engineersinterested in medical instrumentation/device design with acomprehensive and interdisciplinary system perspective.

Handbook of Superconductivity John Wiley & Sons

Biomedical engineering brings together bright minds from diverse disciplines, ranging from engineering, physics, and computer science to biology and medicine. This book contains the proceedings of the 11th Mediterranean Conference on Medical and Biological Engineering and Computing, MEDICON 2007, held in Ljubljana, Slovenia, June 2007. It features relevant, up-to-date research in the area.