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Bioelectronics and Medical Devices: From Materials to Devices-Fabrication, Applications and Reliability reviews the latest research on electronic devices used in the healthcare sector, from materials, to applications, including biosensors, rehabilitation devices, drug delivery devices, and devices based on wireless technology. This information is presented from the unique interdisciplinary perspective of the editors and contributors, all with materials science, biomedical engineering, physics, and chemistry backgrounds. Each applicable chapter includes a discussion of these devices, from materials and fabrication, to reliability and technology applications. Case studies, future research directions and recommendations for additional readings are also included. The book addresses hot topics, such as the latest, state-of the-art biosensing devices that have the ability for early detection of life-threatening diseases, such as tuberculosis, HIV and cancer. It covers rehabilitation devices and advancements, such as the devices that could be utilized by advanced-stage ALS patients to improve their interactions with the environment. In addition, electronic controlled delivery systems are reviewed, including those that are based on artificial intelligences. Presents the latest topics, including MEMS-based fabrication of biomedical sensors, Internet of Things, certification of medical and drug delivery devices, and electrical safety considerations Presents the interdisciplinary perspective of materials scientists, biomedical engineers, physicists and chemists on biomedical electronic devices Features systematic coverage in each chapter, including recent advancements in the field, case studies, future research directions, and recommendations for additional readings

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 In addition, there is a vast amount of accumulated but unpublished inside knowledge on what is needed to perform a safe, in vivo MRI.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.

Human-Robot Interaction: Safety, Standardization, and Benchmarking provides a comprehensive introduction to the new scenarios emerging where humans and robots interact in various environments and applications on a daily basis. The focus is on the current status and foreseeable implications of robot safety, approaching these issues from the standardization and benchmarking perspectives. Featuring contributions from leading experts, the book presents state-of-the-art research, and includes real-world applications and use cases. It explores the key leading sectors—robotics, service robotics, and medical robotics—and elaborates on the safety approaches that are being developed for effective human-robot interaction, including physical robot-human contacts, collaboration in task execution, workspace sharing, human-aware motion planning, and exploring the landscape of relevant standards and guidelines. Features Presenting a comprehensive introduction to human-robot interaction in a number of domains, including industrial robotics, medical robotics, and service robotics Focusing on robot safety standards and benchmarking Providing insight into current developments in international standards Featuring contributions from leading experts, actively pursuing new robot development

Clinical Engineering: A Handbook for Clinical and Biomedical Engineers, Second Edition, helps professionals and students in clinical engineering successfully deploy medical technologies. The book provides a broad reference to the core elements of the subject, drawing from a range of experienced authors. In addition to engineering skills, clinical engineers must be able to work with both patients and a range of professional staff, including technicians, clinicians and equipment manufacturers. This book will not only help users keep up-to-date on the fast-moving scientific and medical research in the field, but also help them develop laboratory, design, workshop and management skills. The updated edition features the latest fundamentals of medical technology integration, patient safety, risk assessment and assistive technology. Provides engineers in core medical disciplines and related fields with the skills and knowledge to successfully collaborate on the development of medical devices, via approved procedures and standards Covers US and EU standards (FDA and MDD, respectively, plus related ISO requirements) Includes information that is backed up with real-life clinical examples, case studies, and separate tutorials for training and class use Completely updated to include new standards and regulations, as well as new case studies and illustrations

"Clinical neurophysiology is the neurology subspecialty that focuses on the electrical activity within the nervous system. In all realms and types of testing performed in the practice of clinical neurophysiology, electrical signals that are spontaneously or intrinsically generated or induced by external stimulation are recorded and analyzed to determine the integrity and function of the central and peripheral systems. The underlying basis of all signals ultimately reflects the function of the neurons at a cellular level. Thus, while the clinical neurophysiologist focuses on the interpretation of these signals during testing in the laboratory, hospital, or operating room, a solid understanding of the function of each of the contributing cellular structures from which the signals are generated is necessary. This chapter reviews the basic principles underlying the activity of excitable cells as they apply to the basic neurophysiology of neurons and myocytes"--

This Standard specifies the terms and definitions, requirements, test methods and the requirements for instructions of hot melt gutta percha filling machine. This Standard is applicable to hot melt gutta percha filling machines, which complete root canal filling by heating and melting gutta percha. This Standard is not applicable to equipment and instruments used merely for cutting off gutta percha.

Usability Testing of Medical Devices covers the nitty-gritty of usability test planning, conducting, and results reporting. The book also discusses the government regulations and industry standards that motivate many medical device manufacturers to conduct usability tests.Since publication of the first edition, the FDA and other regulatory groups h

"The concise, easy-to-access resource is aimed at nurses who are new to the operating room and the experienced nurses who guide them... The $30 book contains a wealth of current, evidence-based clinical practice information that perioperative nurses need daily." --Dan O'Connor, Outpatient Surgery Magazine "This pocket-size book offers concise information for rapid reference, step-by-step instructions for perioperative practices, and evidence-based content based on current perioperative standards and recommended practices. …Novice nurses, students, and seasoned preceptors will be delighted to learn how easily this go-to guide will provide immediate reference to perioperative practices and information, all while fitting into a pocket for easy retrieval." —Kay Ball, PhD, RN, CNOR, FAAN Associate Professor, Nursing, Otterbein University, Westerville, Ohio Past President, Association of periOperative Registered Nurses From the Foreword This is a concise, easy-to-access resource for nurses who are new to the operating room (OR) and the experienced nurses who guide them. Condensing volumes of OR content into one pithy, pocket-size book, it contains a wealth of current, evidence-based clinical practice information perioperative nurses need daily. Based on current standards and recommended practices, it is organized to provide speedy access to critical information. Its lucid, step-by-step format helps new nurses to better understand the complex skills and techniques required in the OR. Focusing on safety and specific patient interventions, orientation information including supplies needed and important protocols is covered. It addresses personal and patient preparation, environmental concerns, and documentation requirements, and describes the wide range of specific technical skills needed by both circulating and scrub nurses. Each chapter introduces concepts and sets clear learning objectives. Also included is an overview of the most common surgical procedures. New perioperative nurses in orientation and their preceptors will find this book to be a welcome addition to the learning process. Key Features: Provides must-have OR orientation information for new nurses and their preceptors Contains key information on patient preparation, aseptic technique, surgical procedures, anesthesia considerations, and documentation Based on the most up-to-date evidence in the literature Includes Fast Facts in a Nutshell feature to reinforce important information

Risiken lassen sich nicht ausschließen – aber minimieren Klinisches Risikomanagement ist wesentlicher Bestandteil ärztlichen und pflegerischen Handelns. 35 Experten erläutern aus ihrer Fachperspektive Grundlagen und Konzepte, zeigen praktische Lösungen auf und stellen notwendige Werkzeuge, u.a. Checklisten, Standard Operating Procedures, Critical Incident Reporting-Systeme, Mortalitäts- & Morbiditäts-Konferenzen, Peer Reviews, Ursachenanalysen, Qualitäts- und Patientensicherheitsindikatoren sowie Methoden der Risikoerfassung und Bewertung vor. Risikorelevantes Managementwissen und Erkenntnisse aus der Human Factor Forschung fließen in die Themen wie Führung, Teamentwicklung, Schulungen und Trainings, Mitarbeitermotivation, Patientensicherheit und Entwicklung einer Sicherheitskultur ein. Das zentrale Anliegen dieses Handbuchs ist es, die wesentlichen Elemente des klinischen Risikomanagement umfassend und aus verschiedenen Blickwinkeln darzustellen. Es werden sowohl medizinische, managementbezogene, ökonomische als auch juristische Themen angesprochen, um dem Leser alles an die Hand zu geben, ein effizientes Risikomanagement - am eigenen Bedarf orientiert - zu implementieren. Die Zielgruppe dieses Buches sind dementsprechend Entscheidungsträger und Führungskräfte, sowie die vielen Umsetzer vor Ort, wie Geschäftsführer, Ärztliche Direktoren, Pflegedirektoren, Chefärzte, Oberärzte in Führungspositionen, Pflegedienstleitungen, Stationsleitungen, Risikomanager, Qualitätsmanager- und Beauftragte, Personalmanager, Hygienemanager- und Beauftragte, IT-Führungskräfte, Apotheker, Medizintechniker, Krisenmanager und Juristen.

Anesthesia Equipment: Principles and Applications, 2nd Edition, by Dr. Jan Ehrenwerth and Dr. James B. Eisenkraft, offers expert, highly visual, practical guidance on the full range of delivery systems and technology used in practice today. It equips you with the objective, informed answers you need to ensure optimal patient safety. Consult this title on your favorite e-reader with intuitive search tools and adjustable font sizes. Elsevier eBooks provide instant portable access to your entire library, no matter what device you're using or where you're located. Make informed decisions by expanding your understanding of the physical principles of equipment, the rationale for its use, delivery systems for inhalational anesthesia, systems monitoring, hazards and safety features, maintenance and quality assurance, special situations/equipment for non-routine adult anesthesia, and future directions for the field. Ensure patient safety with detailed advice on risk management and medicolegal implications of equipment use. Apply the most complete and up-to-date information available on machines, vaporizers, ventilators, breathing systems, vigilance, ergonomics, and simulation. Visualize the safe and effective use of equipment thanks to hundreds of full-color line drawings and photographs.

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

This book constitutes the refereed proceedings of the 33nd International Conference on Computer Safety, Reliability, and Security, SAFECOMP 2014, held in Florence, Italy, in September 2014. The 20 revised full papers presented together with 3 practical experience reports were carefully reviewed and selected from 85 submissions. The papers are organized in topical sections on fault injection techniques, verification and validation techniques, automotive systems, coverage models and mitigation techniques, assurance cases and arguments, system analysis, security and trust, notations/languages for safety related aspects, safety and security.

Successful digital healthcare depends on the effective flow of a complete chain of information; from the sensor, via multiple steps of processing, to the actuator, which can be anything from a human healthcare professional to a robot. Along this pathway, methods for automating the processing of information, like signal processing, machine learning, predictive analytics and decision support, play an increasing role in providing actionable information and supporting personalized and preventive healthcare concepts in both biomedical and digital healthcare systems and applications. ICT systems in healthcare and biomedical systems and devices are very closely related, and in the future they will become increasingly intertwined. Indeed, it is already often difficult to delineate where the one ends and the other begins. This book presents the intended proceedings of the dHealth 2020 annual conference on the general topic of health Informatics and digital health, which was due to be held in Vienna, Austria, on 19 and 20 May 2020, but which was cancelled due to the COVID-19 pandemic. The decision was nevertheless taken to publish these proceedings, which include the 40 papers which would have been delivered at the conference. The special topic for the 2020 edition of the conference was Biomedical Informatics for Health and Care. The book provides an overview of current developments in health informatics and digital health, and will be of interest to researchers and healthcare practitioners alike.

Reader friendly: Adapted keeping in mind the curriculum of the final year undergraduate student with exam and clinical oriented Clinical Notes boxes. The text is streamlined for improved readability Full Color Design: Incorporates more than 500 illustrations including color photos and around 100 tables and boxes to better show techniques and detail Added Chapters: Six new chapters on ... have been included in this edition Online Chs : The website features three online chapters for additional study

The 2 volume-set of LNCS 12190 and 12191 constitutes the refereed proceedings of the 12th International Conference on Virtual, Augmented and Mixed Reality, VAMR 2020, which was due to be held in July 2020 as part of HCI International 2020 in Copenhagen, Denmark. The conference was held virtually due to the COVID-19 pandemic. A total of 1439 papers and 238 posters have been accepted for publication in the HCII 2020 proceedings from a total of 6326 submissions. The 71 papers included in these HCI 2020 proceedings were organized in topical sections as follows: Part I: design and user experience in VAMR; gestures and haptic interaction in VAMR; cognitive, psychological and health aspects in VAMR; robots in VAMR. Part II: VAMR for training, guidance and assistance in industry and business; learning, narrative, storytelling and cultural applications of VAMR; VAMR for health, well-being and medicine.

Within a healthcare enterprise, patient vital signs and other automated measurements are communicated from connected medical devices to end-point systems, such as electronic health records, data warehouses and standalone clinical information systems. Connected Medical Devices: Integrating Patient Care Data in Healthcare Systems explores how medical

This book is a practical guide for individuals responsible for creating products that are safe, effective, usable, and satisfying in the hands of the intended users. The contents are intended to reduce the number of use errors involving medical devices that have led to injuries and deaths. The book presents the strong connection between user interface requirements and risk management for medical devices and instructs readers how to develop specific requirements that are sufficiently comprehensive and detailed to produce good results – a user-friendly product that is likely to be used correctly. The book’s tutorial content is complemented by many real-world examples of user interface requirements, including ones pertaining to an inhaler, automated external defibrillator, medical robot, and mobile app that a patient might use to manage her diabetes. The book is intended for people representing a variety of product development disciplines who have responsibility for producing safe, effective, usable, and satisfying medical devices, including those who are studying or working in human factors engineering, psychology, mechanical engineering, biomedical engineering, systems engineering, software programming, technical writing, industrial design, graphic design, and regulatory affairs.

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.

DUBBEL - Taschenbuch für den Maschinenbau – erscheint in einer neu bearbeiteten und aktualisierten 25. Auflage. Das Standardwerk der Ingenieure in Studium und Beruf mit den

Schwerpunkten „Allgemeiner Maschinenbau“ sowie „Verfahrens- und Systemtechnik" ist das erforderliche Basis- und Detailwissen des Maschinenbaus und 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. Für die 25. Auflage wurden alle Kapitel intensiv bearbeitet und auf den aktuellen Stand von Wissenschaft und Technik gebracht. Insbesondere hervorzuheben sind hierbei die fertigungstechnischen Kapitel; die KapitelRegelungstechnik und Mechatronik wurden gemeinsam neu strukturiert. Das Kapitel Grundlagen der Konstruktionstechnik wurde zu Grundlagen der Produktentwicklung erweitert sowie um das Toleranzmanagement und die Entwicklung varianter Produkte ergänzt. Das Kapitel Energietechnik ist komplett überarbeitet, die Kapitel Werkstofftechnik und Maschinendynamik sind umstrukturiert und überarbeitet, und das Kapitel Biomedizinische Technik ist nun ein eigenes Kapitel. Der Zugang zur MDESIGN Formelsammlung Dubbel Edition ist weiterhin gewährleistet und bietet einen echten Mehrwert.

As modern technologies continue to develop and evolve, the ability of users to interface with new systems becomes a paramount concern. Research into new ways for humans to make use of advanced computers and other such technologies is necessary to fully realize the potential of 21st century tools. Human-Computer Interaction: Concepts, Methodologies, Tools, and Applications gathers research on user interfaces for advanced technologies and how these interfaces can facilitate new developments in the fields of robotics, assistive technologies, and computational intelligence. This four-volume reference contains cutting-edge research for computer scientists; faculty and students of robotics, digital science, and networked communications; and clinicians invested in assistive technologies. This seminal reference work includes chapters on topics pertaining to system usability, interactive design, mobile interfaces, virtual worlds, and more.

This volume presents the proceedings of the CLAIB 2014, held in Paraná, Entre Ríos, Argentina 29, 30 & 31 October 2014. The proceedings, presented by the Regional Council of Biomedical Engineering for Latin America (CORAL) offer research findings, experiences and activities between institutions and universities to develop Bioengineering, Biomedical Engineering and related sciences. The conferences of the American Congress of Biomedical Engineering are sponsored by the International Federation for Medical and Biological Engineering (IFMBE), Society for Engineering in Biology and Medicine (EMBS) and the Pan American Health Organization (PAHO), among other organizations and international agencies and bringing together scientists, academics and biomedical engineers in Latin America and other continents in an environment conducive to exchange and professional growth. The Topics include: - Bioinformatics and Computational Biology - Bioinstrumentation; Sensors, Micro and Nano Technologies - Biomaterials, Tissue Engineering and Artificial Organs - Biomechanics, Robotics and Motion Analysis - Biomedical Images and Image Processing - Biomedical Signal Processing - Clinical Engineering and Electromedicine - Computer and Medical Informatics - Health and home care, telemedicine - Modeling and Simulation - Radiobiology, Radiation and Medical Physics - Rehabilitation Engineering and Prosthetics - Technology, Education and Innovation

Healthcare Technology Management: A Systematic Approach offers a comprehensive description of a method for providing safe and cost effective healthcare technology management (HTM). The approach is directed to enhancing the value (benefit in relation to cost) of the medical equipment assets of healthcare organizations to best support patients, clinicians and other care providers, as well as financial stakeholders. The authors propose a management model based on interlinked strategic and operational quality cycles which, when fully realized, delivers a comprehensive and transparent methodology for implementing a HTM programme throughout a healthcare organization. The approach proposes that HTM extends beyond managing the technology in isolation to include advancing patient care through supporting the application of the technology. The book shows how to cost effectively manage medical equipment through its full life cycle, from acquisition through operational use to disposal, and to advance care, adding value to the medical equipment assets for the benefit of patients and stakeholders. This book will be of interest to practicing clinical engineers and to students and lecturers, and includes self-directed learning questions and case studies. Clinicians, Chief Executive Officers, Directors of Finance and other hospital managers with responsibility for the governance of medical equipment will also find this book of interest and value. For more information about the book, please visit: www.htmbook.com

This new edition provides major revisions to a text that is suitable for the introduction to biomedical engineering technology course offered in a number of technical institutes and colleges in Canada and the US. Each chapter has been thoroughly updated with new photos and illustrations which depict the most modern equipment available in medical technology. This third edition includes new problem sets and examples, detailed block diagrams and schematics and new chapters on device technologies and information technology.

This book presents the state of the art in clinical plasma medicine and outlines translational research strategies. Written by an international group of authors, it is divided into four parts. Part I is a detailed introduction and includes basic and recent research information on plasma sciences, plasma devices and mechanisms of biological plasma effects. Parts II and III provide valuable clinical insights f.e. into the treatment of superficial contaminations, ulcerations, wounds, treatment of cells in cancer, special indications like in heart surgery, dentistry, palliative treatment in head and neck cancer or the use of plasma in hygiene. Part IV offers information on how and where to qualify in plasma medicine and which companies produce and supply medical devices and is thus of particular interest to medical practitioners. This comprehensive book offers a sciences based practical to the clinical use of plasma and includes an extended selection of scientific medical data and translational literature.

The purpose of this guidance document is for the appropriate selection procurement utilization and maintenance of oxygen concentrators. This document also focuses on recommendations for the appropriate use and maintenance of oxygen concentrators in an effort to increase the availability management and quality of oxygen concentrators and ultimately to improve health outcomes in LRS. This document is intended to serve as a resource for the planning and provision of local and national oxygen concentrator systems for use by administrators clinicians and technicians who are interested in improving access to oxygen therapy and reducing global mortality associated with hypoxaemia.

This revised, updated second edition provides an accessible, practical overview of major areas of technical development and clinical application in the field of neurorehabilitation movement therapy. The initial section provides a rationale for technology application in movement therapy by summarizing recent findings in neuroplasticity and motor learning. The following section then explains the state of the art in human-machine interaction requirements for clinical rehabilitation practice. Subsequent sections describe the ongoing

revolution in robotic therapy for upper extremity movement and for walking, and then describe other emerging technologies including electrical stimulation, virtual reality, wearable sensors, and brain-computer interfaces. The promises and limitations of these technologies in neurorehabilitation are discussed. Throughout the book the chapters provide detailed practical information on state-of-the-art clinical applications of these devices following stroke, spinal cord injury, and other neurologic disorders. The text is illustrated throughout with photographs and schematic diagrams which serve to clarify the information for the reader. Neurorehabilitation Technology, Second Edition is a valuable resource for neurologists, biomedical engineers, roboticists, rehabilitation specialists, physiotherapists, occupational therapists and those training in these fields.

This book (vol. 2) 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.

This book is intended to serve as a reference for professionals in the medical device industry, particularly those seeking to learn from practical examples and case studies. Medical devices, like pharmaceuticals, are highly regulated, and the bar is raised constantly as patients and consumers expect the best-quality healthcare and safe and effective medical technologies. Obtaining marketing authorization is the first major hurdle that med techs need to overcome in their pursuit of commercial success. Most books on regulatory affairs present regulations in each jurisdiction separately: European Union, USA, Australia, Canada, and Japan. This book proposes practical solutions for a coherent, one-size-fits-all (or most) set of systems and processes in compliance with regulations in all key markets, throughout the life cycle of a medical device. It also contains key information about international harmonization efforts and recent regulatory trends in emerging markets; important terminology needed to understand the regulators' language; and examples, case studies, and practical recommendations that bridge the gap between regulatory theory and practice.

Have you ever experienced the burden of an adverse event or a near-miss in healthcare and wished there was a way to mitigate it? This book walks you through a classic adverse event as a case study and shows you how. It is a practical guide to continuously improving your healthcare environment, processes, tools, and ultimate outcomes, through the discipline of human factors. Using this book, you as a healthcare professional can improve patient safety and quality of care. Adverse events are a major concern in healthcare today. As the complexity of healthcare increases-with technological advances and information overload-the field of human factors offers practical approaches to understand the situation, mitigate risk, and improve outcomes. The first part of this book presents a human factors conceptual framework, and the second part offers a systematic, pragmatic approach. Both the framework and the approach are employed to analyze and understand healthcare situations, both proactively-for constant improvement- and reactively-learning from adverse events. This book guides healthcare professionals through the process of mapping the environmental and human factors; assessing them in relation to the tasks each person performs; recognizing how gaps in the fit between human capabilities and the demands of the task in the environment have a ripple effect that increases risk; and drawing conclusions about what types of changes facilitate improvement and mitigate risk, thereby contributing to improved healthcare outcomes.

Plastics in Medical Devices: Properties, Requirements, and Applications, Third Edition provides a comprehensive overview on the main types of plastics used in medical device applications. The book focuses on the applications and properties that are most important in medical device design, such as chemical resistance, sterilization capability and biocompatibility. The roles of additives, stabilizers and fillers as well as the synthesis and production of polymers are covered and backed up with a wealth of data tables. The book also covers other key aspects in detail, including regulations, compliance, purchasing controls and supplier controls, and process validation. This updated edition has been thoroughly revised with regard to new plastic materials, applications and requirements. This is a valuable resource for engineers, scientists and managers involved in the design and manufacture of medical devices. Presents detailed coverage of commercially available plastics used in medical device applications, organized by polymer type and supported by data Includes up-to-date regulatory requirements and practical information on purchasing and supplier controls, process validation and risk management Supports the development, marketing and commercialization of medical devices and materials for use in medical devices

This is the first edition of 'The Engineering of Reliable Embedded Systems': it is released here largely for historical reasons. (Please consider purchasing 'ERES2' instead.) [The second edition will be available for purchase here from June 2017.]

Safety Risk Management for Medical Devices, Second Edition teaches the essential safety risk management methodologies for medical devices compliant with the requirements of ISO 14971:2019. Focusing exclusively on safety risk assessment practices required in the MedTech sector, the book outlines sensible, easily comprehensible, state-of the-art methodologies that are rooted in current industry best practices, addressing safety risk management of medical devices, thus making it useful for those in the MedTech sector who are responsible for safety risk management or need to understand risk management, including design engineers, product engineers, development engineers, software engineers, Quality assurance and regulatory affairs. Graduate-level engineering students with an interest in medical devices will also benefit from this book. The new edition has been fully updated to reflect the state-of-the-art in this fast changing field. It offers guidance on developing and commercializing medical devices in line with the most current international standards and regulations. Includes new coverage of ISO 14971:2019, ISO/TR 24971 Presents the latest information on the history of risk management, lifetime of a

medical device, risk management review, production and post production activities, post market risk management Provides practical, easy-to-understand and state-of the-art methodologies that meet the requirements of international regulation

Applied Human Factors in Medical Device Design describes the contents of a human factors toolbox with in-depth descriptions of both empirical and analytical methodologies. The book begins with an overview of the design control process, integrating human factors as directed by AAMI TIR 59 and experienced practice. It then explains each method, describing why each method is important, its potential impact, when it's ideal to use, and related challenges. Also discussed are other barriers, such as communication breakdowns between users and design teams. This book is an excellent reference for professionals working in human factors, design, engineering, marketing and regulation. Focuses on meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union (EU) Explains technology development and the application of human factors throughout the development process Covers FDA and MHRA regulations Includes case examples with each method

Medical Device Regulatory PracticesAn International PerspectiveCRC Press

Medical Devices and Regulations: Standards and Practices will shed light on the importance of regulations and standards among all stakeholders, bioengineering designers, biomaterial scientists and researchers to enable development of future medical devices. Based on the authors' practical experience, this book provides a concise, practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards. Provides readers with a global perspective on medical device regulations Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards Includes a useful case study demonstrating the design and approval process

This book constitutes the thoroughly refereed conference proceedings of the Third International Workshop on Risk Assessment and Risk-driven Testing, RISK 2015, held in conjunction with the OMG Technical Meeting in Berlin, Germany, in June 2015. The revised 8 full papers were carefully reviewed and selected from 12 submissions. This workshop addresses systematic approaches that combine risk assessment and testing. Also, the workshop was structured into the three sessions namely Risk Assessment, Risk and Development and Security Testing.

Combining and integrating cross-institutional data remains a challenge for both researchers and those involved in patient care. Patient-generated data can contribute precious information to healthcare professionals by enabling monitoring under normal life conditions and also helping patients play a more active role in their own care. This book presents the proceedings of MEDINFO 2019, the 17th World Congress on Medical and Health Informatics, held in Lyon, France, from 25 to 30 August 2019. The theme of this year's conference was 'Health and Wellbeing: E-Networks for All', stressing the increasing importance of networks in healthcare on the one hand, and the patient-centered perspective on the other. Over 1100 manuscripts were submitted to the conference and, after a thorough review process by at least three reviewers and assessment by a scientific program committee member, 285 papers and 296 posters were accepted, together with 47 podium abstracts, 7 demonstrations, 45 panels, 21 workshops and 9 tutorials. All accepted paper and poster contributions are included in these proceedings. The papers are grouped under four thematic tracks: interpreting health and biomedical data, supporting care delivery, enabling precision medicine and public health, and the human element in medical informatics. The posters are divided into the same four groups. The book presents an overview of state-of-the-art informatics projects from multiple regions of the world; it will be of interest to anyone working in the field of medical informatics.

This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Experts from influential international regulatory bodies, including the US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency, Japan Pharmaceuticals and Medical Devices Agency, Saudi Food and Drug Authority, Korea Testing Laboratory, Taiwan FDA, World Health Organization, Asian Harmonization Working Party, Regulatory Affairs Professionals Society, and British Standards Institution, have contributed to the book. Government bodies, the medical device industry, academics, students, and general readers will find the book immensely useful for understanding the global regulatory environment and in their research and development projects.