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Usability Testing of Medical Devices-Michael E. Wiklund P.E. 2015-12-23 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
Medical Device Use Error-Michael Wiklund 2016-01-06 Medical Device Use Error: Root Cause Analysis offers practical guidance on how to methodically discover and explain the root cause of a use error-a mistake-that occurs when someone uses a medical device. Covering medical devices used in the home and those used in clinical environments, the book presents informative case studies about the use errors
Usability Engineering als Erfolgsfaktor-Thomas Geis 2015-07-14 Die DIN EN 62366:2008-09 und die IEC 62366-1:2015-02 "Medizinprodukte - Anwendung der Gebrauchstauglichkeit auf Medizinprodukte" legen Forderungen an einen vom Hersteller durchzuführenden Prozess zur Analyse, Spezifikation, Entwicklung sowie Verifizierung und Validierung der Gebrauchstauglichkeit fest, soweit sie sich auf die Sicherheit von Medizinprodukten auswirkt. Die Autoren erläutern konkret, welche Informationen im Rahmen der Anforderungen der DIN EN 62366 für ein Medizinprodukt dokumentiert werden müssen und in welcher Form das am besten geschieht (Verzahnung von Regulatory Affairs und Usability-Engineering). So können sowohl die Bereiche Regulatory Affairs als auch das Produktmanagement ihre Effizienz bei der Dokumentation des Usability-Engineering-Prozesses wirksam steigern.
Medical Device Use Error-Michael Wiklund 2016-01-06 Medical Device Use Error: Root Cause Analysis offers practical guidance on how to methodically discover and explain the root cause of a use error-a mistake-that occurs when someone uses a medical device. Covering medical devices used in the home and those used in clinical environments, the book presents informative case studies about the use errors
Safety Risk Management for Medical Devices-Bijan Elahi 2018-06-29 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
Clinical Engineering-Roberto Miniati 2015-12-23 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
Think Like a UX Researcher-David Travis 2019-01-10 Think Like a UX Researcher will challenge your preconceptions about user experience (UX) research and encourage you to think beyond the obvious. You'll discover how to plan and conduct UX research, analyze data, persuade teams to take action on the results and build a career in UX. The book will help you take a more strategic view of product design so you can focus on optimizing the user's experience. UX Researchers, Designers, Project Managers, Scrum Masters, Business Analysts and Marketing Managers will find tools, inspiration and ideas to rejuvenate their thinking, inspire their team and improve their craft. Key Features A dive-in-anywhere book that offers practical advice and topical examples. Thought triggers, exercises and scenarios to test your knowledge of UX research. Workshop ideas to build a development team's UX maturity. War stories from seasoned researchers to show you how UX research methods can be tailored to your own organization.
Medical Device Software Verification, Validation and Compliance-David A. Vogel 2010 HereOCOs the first book written specifically to help medical device and software engineers, QA and compliance professionals, and corporate business managers better understand and implement critical verification and validation processes for medical device software.Offering you a much broader, higher-level picture than other books in this field, this book helps you think critically about software validation -- to build confidence in your softwareOCOs safety and effectiveness. The book presents validation activities for each phase of the development lifecycle and shows: why these activities are important and add value; how to undertake them; and what outputs need to be created to document the validation process.From software embedded within medical devices, to software that performs as a medical device itself, this comprehensive book explains how properly handled validation throughout the development lifecycle can help bring medical devices to completion sooner, at higher quality, in compliance with regulations."
Applied Human Factors in Medical Device Design-Mary Beth Privitera 2019-06-15 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
Usability Testing of Medical Devices-Michael E. Wiklund P.E. 2015-12-23 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
ISO 13485:2016-Itay Abuhav 2018-05-11 This book will be a substantial revision, which will reflect the new version of the ISO 13485:2016. This represents the standard protocols that all medical device manufacturers must follow, in the fabrication of their products. It will focus on changes in the structure of the quality management system; change in the documentation for quality managemeent systems and finally, present the different methods of implementation of the standard requirements within the organization.This new version was initiated in 2016, thus all apprpriate enterprises using the old standard must convert to the new version, now available.The Second Edition will clarify, explain and demonstrate the new version.
Springer Handbook of Medical Technology-Rüdiger Kramme 2011-10-02 This concise, user-oriented and up-to-date desk reference offers a broad introduction to the fascinating world of medical technology, fully considering today's progress and further development in all relevant fields. The Springer Handbook of Medical Technology is a systemized and well-structured guideline which distinguishes itself through simplification and condensation of complex facts. This book is an indispensable resource for professionals working directly or indirectly with medical systems and appliances every day. It is also meant for graduate and post graduate students in hospital management, medical engineering, and medical physics.
Handbook of Human Factors in Medical Device Design-Matthew Bret Weinger 2010-12-13 Developed to promote the design of safe, effective, and usable medical devices, Handbook of Human Factors in Medical Device Design provides a single convenient source of authoritative information to support evidence-based design and evaluation of medical device user interfaces using rigorous human factors engineering principles. It offers guidance
Software Process Improvement and Capability Determination-Rory O'Connor 2011-05-20 This book constitutes the refereed proceedings of the 11th International Conference on Software Process Improvement and Capability Determination, SPICE 2011, held in Dublin, Ireland, in May/June 2011. The 15 revised full papers presented and 15 short papers were carefully reviewed and selected from numerous submissions. The papers are organized in topical sections on process modelling and assessment, safety and security, medi SPICE, high maturity, implementation and improvement.
Designing for Safe Use-Michael Wiklund 2019-03-11 How do you prevent a critical care nurse from accidentally delivering a morphine overdose to an ill patient? Or ensure that people don't insert their arm into a hydraulic mulcher? And what about enabling trapped airline passengers to escape safely in an emergency? Product designers and engineers face myriad such questions every day. Failure to answer them correctly can result in product designs that lead to injury or even death due to use error. Historically, designers and engineers have searched for answers by sifting through complicated safety standards or obscure industry guidance documents. Designing for Safe Use is the first comprehensive source of safety-focused design principles for product developers working in any industry. Inside you'll find 100 principles that help ensure safe interactions with products as varied as baby strollers, stepladders, chainsaws, automobiles, apps, medication packaging, and even airliners. You'll discover how protective features such as blade guards, roll bars, confirmation screens, antimicrobial coatings, and functional groupings can protect against a wide range of dangerous hazards, including sharp edges that can lacerate, top-heavy items that can roll over and crush, fumes that can poison, and small parts that can pose a choking hazard. Special book features include: Concise, illustrated descriptions of design principles Sample product designs that illustrate the book's guidelines and exemplify best practices Literature references for readers interested in learning more about specific hazards and protective measures Statistics on the number of injuries that have arisen in the past due to causes that might be eliminated by applying the principles in the book Despite its serious subject matter, the book's friendly tone, surprising anecdotes, bold visuals, and occasional attempts at dry humor will keep you interested in the art and science of making products safer. Whether you read the book cover-to-cover or jump around, the book's relatable and practical approach will help you learn a lot about making products safe. Designing for Safe Use is a primer that will spark in readers a strong appreciation for the need to design safety into products. This reference is for designers, engineers, and students who seek a broad knowledge of safe design solutions. .
Moderating Usability Tests-Joseph S. Dumas 2008-04-09 Moderating Usability Tests provides insight and guidance for usability testing. To a large extent, successful usability testing depends on the skills of the person facilitating the test. However, most usability specialists still learn how to conduct tests through an apprentice system with little formal training. This book is the resource for new and experienced moderators to learn about the rules and practices for interacting. Authors Dumas and Loring draw on their combined 40 years of usability testing experience to develop and present the most effective principles and practices – both practical and ethical – for moderating successful usability tests. The videos are available from the publisher's companion web site. Presents the ten "golden rules that maximize every session's value Offers targeted advice on how to maintain objectivity Discusses the ethical considerations that apply in all usability testing Explains how to reduce the stress that participants often feel Considers the special requirements of remote usability testing Demonstrates good and bad moderating techniques with laboratory videos accessible from the publisher's companion web site
Software Process Improvement-Fergal McCaffery 2008 This book constitutes the proceedings of the Doctoral Symposium of the 15th European Software Process Improvement Conference, EuroSPI 2008, held in Dublin City University, Dublin, Ireland in September 2008. The purpose of the EuroSPI Doctoral Symposium was to provide an opportunity for graduate students to present and explore their research interests under the guidance of a panel of distinguished experts in the field and to bring together Ph.D. students within the Systems & Software Process Improvement and Innovation field to discuss their research in an international forum.
Hazard Analysis Techniques for System Safety-Clifton A. Ericson, II 2015-06-12 Explains in detail how to perform the most commonly used hazard analysis techniques with numerous examples of practical applications Includes new chapters on Concepts of Hazard Recognition, Environmental Hazard Analysis, Process Hazard Analysis, Test Hazard Analysis, and Job Hazard Analysis Updated text covers introduction, theory, and detailed description of many different hazard analysis techniques and explains in detail how to perform them as well as when and why to use each technique Describes the components of a hazard and how to recognize them during an analysis Contains detailed examples that apply the methodology to everyday problems
Writing Human Factors Plans & Reports for Medical Technology Development-Michael E. Wiklund 2018
Using Human Factors Engineering to Improve Patient Safety-John W. Gosbee 2005 Human factors engineering (HFE) is concerned with understanding human characteristics and how humans interact with the world around them, and applying that knowledge to the design of systems that are safe, efficient and comfortable. This book describes how to use HFE tools and principles to curb preventable errors and minimize patient harm.
Designing Usability into Medical Products-Michael E. Wiklund 2005-02-11 Advocating a user-centered approach to medical technology design, Designing Usability into Medical Products covers the essential processes and specific techniques necessary to produce safe, effective, usable, and appealing medical systems and products. Written by experts on user-centered research, design, and evaluation, the book provides a range of alternative approaches to the subject. Wiklund and Wilcox explore how to make medical devices safe and effective by involving users in the design process. They discuss specific design and evaluation methods and tools, present case studies of user-friendly medical technologies and corporate human factors programs, and supply related resources for medical design professionals. The book conveys an in-depth understanding of the user-centered design process, covers design methods for FDA compliance, and offers guidance on performing a variety of hands-on user research, user interface design, and user interface evaluation. The authors make a compelling case for treating the user's needs and preferences as a top design priority, rather than an afterthought. They demonstrate that high-quality customer interactions with systems and products leads to effective medical diagnosis and treatment, increases the physical and mental well being of patients and caregivers, and leads to commercial success in a crowded marketplace.
Software Process Improvement and Capability Determination-Terry Rout 2015 This book constitutes the refereed proceedings of the 15th International Conference on Software Process Improvement and Capability Determination, SPICE 2015, held in Gothenburg, Sweden, in June 2015. The 17 revised full papers presented together with three short papers were carefully reviewed and selected from 48 submissions. The papers are organized in topical sections on industrial frameworks; implementation and assessment; process improvement; agile processes; assessment and maturity models; process and education.
Handbook of Medical Device Regulatory Affairs in Asia-Jack Wong 2013-03-27 Medical device regulation in Asia has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors. Handbook of Medical Device Regulatory Affairs in Asia covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. Government bodies, the medical device industry, and academics and students will find this book immensely useful in understanding the global regulatory environment and in their research and development projects.
Development of Biopharmaceutical Drug-Device Products-Feroz Jameel 2020-03-13 The biotechnology/biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates (ADCs), Bispecific T-cell engager (BITES), Dual Variable Domain (DVD) antibodies, and fusion proteins that are currently being used as therapeutic agents for immunology, oncology and other disease conditions. Regulatory agencies have raised the bar for the development and manufacture of antibody-based products, expecting to see the use of Quality by Design (QbD) elements demonstrating an in-depth understanding of product and process based on sound science. Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self-administration are being marketed as combination products. A survey of the market indicates that there is a strong need for a new book that will provide "one stop shopping" for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development. The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry, academia or regulatory agencies. With insightful chapters from experts in the field, this new book reviews first principles, covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody-based products. It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development, formulation strategies for new modalities, and the analytical techniques used to characterize them. It also addresses important considerations for later stage development such as the development of robust formulations and processes, including process engineering and modeling of manufacturing unit operations, the design of analytical comparability studies, and characterization of primary containers (pre-filled syringes and vials).Finally, the latter half of the book reviews key considerations to ensure the development and approval of a patient-centered

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delivery system design. This involves the evolving regulatory framework with perspectives from both the US and EU industry experts, the role of international standards, design control/risk management, human factors and its importance in the product development and regulatory approval process, as well as review of the risk-based approach to bridging between devices used in clinical trials and the to-be-marketed device. Finally, case studies are provided throughout.The typical readership would have biology and/or engineering degrees and would include researchers, scientific leaders, industry specialists and technology developers working in the biopharmaceutical field.
Behavioral Analysis and Measurement Methods-David Meister 1985-03-26 This book consolidates and describes, for the first time, all of the individual behavioral methods used to study work performance.
The Engineering Design of Systems-Dennis M. Buede 2016-02-04 New for the third edition, chapters on: Complete Exercise of the SE Process, System Science and Analytics and The Value of Systems Engineering The book takes a model-based approach to key systems engineering design activities and introduces methods and models used in the real world. This book is divided into three major parts: (1) Introduction, Overview and Basic Knowledge, (2) Design and Integration Topics, (3) Supplemental Topics. The first part provides an introduction to the issues associated with the engineering of a system. The second part covers the critical material required to understand the major elements needed in the engineering design of any system: requirements, architectures (functional, physical, and allocated), interfaces, and qualification. The final part reviews methods for data, process, and behavior modeling, decision analysis, system science and analytics, and the value of systems engineering. Chapter 1 has been rewritten to integrate the new chapters and updates were made throughout the original chapters. Provides an overview of modeling, modeling methods associated with SysML, and IDEF0 Includes a new Chapter 12 that provides a comprehensive review of the topics discussed in Chapters 6 through 11 via a simple system – an automated soda machine Features a new Chapter 15 that reviews General System Theory, systems science, natural systems, cybernetics, systems thinking, quantitative characterization of systems, system dynamics, constraint theory, and Fermi problems and guesstimation Includes a new Chapter 16 on the value of systems engineering with five primary value propositions: systems as a goal-seeking system, systems engineering as a communications interface, systems engineering to avert showstoppers, systems engineering to find and fix errors, and systems engineering as risk mitigation The Engineering Design of Systems: Models and Methods, Third Edition is designed to be an introductory reference for professionals as well as a textbook for senior undergraduate and graduate students in systems engineering.
Health Care Comes Home-National Research Council 2011-06-22 In the United States, health care devices, technologies, and practices are rapidly moving into the home. The factors driving this migration include the costs of health care, the growing numbers of older adults, the increasing prevalence of chronic conditions and diseases and improved survival rates for people with those conditions and diseases, and a wide range of technological innovations. The health care that results varies considerably in its safety, effectiveness, and efficiency, as well as in its quality and cost. Health Care Comes Home reviews the state of current knowledge and practice about many aspects of health care in residential settings and explores the short- and long-term effects of emerging trends and technologies. By evaluating existing systems, the book identifies design problems and imbalances between technological system demands and the capabilities of users. Health Care Comes Home recommends critical steps to improve health care in the home. The book's recommendations cover the regulation of health care technologies, proper training and preparation for people who provide in-home care, and how existing housing can be modified and new accessible housing can be better designed for residential health care. The book also identifies knowledge gaps in the field and how these can be addressed through research and development initiatives. Health Care Comes Home lays the foundation for the integration of human health factors with the design and implementation of home health care devices, technologies, and practices. The book describes ways in which the Agency for Healthcare Research and Quality (AHRQ), the U.S. Food and Drug Administration (FDA), and federal housing agencies can collaborate to improve the quality of health care at home. It is also a valuable resource for residential health care providers and caregivers.
Human-Computer Interaction and International Public Policymaking-Dr Jonathan Lazar 2016-05-02 This monograph lays out a discussion framework for understanding the role of human-computer interaction (HCI) in public policymaking. It takes an international view, discussing potential areas for research and application and their potential for impact. The aim is to provide a solid foundation for discussion, cooperation and collaborative interaction, and to outline future programs of activity. It starts with an introduction to HCI and public policy and goes on to discuss how HCI research and practices already inform public policy, providing representative examples. It then discusses how public policy influences HCI and provides representative public policy areas that are relevant to HCI, and where HCI could have even more impact in the future. It concludes by laying out a framework for involvement and suggested actions by the HCI community in public policy internationally. This monograph summarizes the observations and recommendations from a daylong workshop at the CHI 2013 conference in Paris, France. The workshop invited the community s perspectives regarding the intersection of governmental policies, international and domestic standards, recent HCI research discoveries, and emergent considerations and challenges. It also incorporates contributions made after the workshop by workshop participants and by individuals who were unable to participate in the workshop but whose work and interests were highly related and relevant."
Information Appliances and Beyond-Eric Bergman 2000 Information appliances and other interactive products "beyond the desktop" present user interface design challenges that are only beginning to be understood. In this one-of-a-kind book, interaction designers examine the issues they confronted in their projects: Microsoft Windows CE, a vehicle navigation system, interactive children's toys, and more. You'll enjoy reading their engaging and sometimes surprising stories, but more importantly you'll gain insights that will benefit your own design and development work. * Begins with an interview in which design expert Don Norman details his vision of "making technology invisible." * Includes an eight-page, full-color insert containing screen shots, product diagrams, and other illustrations. * Presents inside accounts of information appliance success stories including: * An interview with Rob Haitani, lead interaction designer of the original PalmPilot * The design and evaluation methodologies behind Nokia's mobile phones * The high-level information appliance design considerations emphasized by Sun Microsystems * Essential reading for interaction designers, human factors engineers, usability specialists, software engineers and project managers working in all of these areas.
Contextual Inquiry for Medical Device Design-Mary Beth Privitera 2015-05-29 Contextual Inquiry for Medical Device Design helps users understand the everyday use of medical devices and the way their usage supports the development of better products and increased market acceptance. The text explains the concept of contextual inquiry using real-life examples to illustrate its application. Case studies provide a frame of reference on how contextual inquiry is successfully used during product design, ultimately producing safer, improved medical devices. Presents the ways contextual inquiry can be used to inform the evaluation and business case of technology Helps users understand the everyday use of medical devices and the way their usage supports the development of better products Includes case studies that provide a frame of reference on how contextual inquiry is successfully used during the product design process
A Guide To Task Analysis-B Kirwan 2003-09-02 This work shows readers how to target task analysis TA resources effectively over the life cycle of a project from conceptual design Through To Systems Operation, Noting The Role Of TA In Safety And Quality assurance, minimizing operator error,
The Wiley Handbook of Human Computer Interaction Set-Kent Norman 2017-12-28 Once, human-computer interaction was limited to a privileged few. Today, our contact with computing technology is pervasive, ubiquitous, and global. Work and study is computer mediated, domestic and commercial systems are computerized, healthcare is being reinvented, navigation is interactive, and entertainment is computer generated. As technology has grown more powerful, so the field of human-computer interaction has responded with more sophisticated theories and methodologies. Bringing these developments together, The Wiley Handbook of Human-Computer Interaction explores the many and diverse aspects of human-computer interaction while maintaining an overall perspective regarding the value of human experience over technology.
Mosby's Respiratory Care Equipment-J. M. Cairo 2009-05-01 Stay ahead of the curve with the most clinically relevant equipment text on the market, now updated with the latest equipment and most in-depth information. You'll appreciate the thorough and systematic coverage of equipment used by respiratory therapists in all areas of practice including neonates and pediatrics, cardiovascular diagnostics, and the growing field of sleep medicine. Chapters combine theory with the latest advances in new devices and techniques, computer-assisted technologies, pharmacological agents, and clinical practice guidelines. Unlike other texts, Mosby's Respiratory Care Equipment explains the mechanics of the equipment while maintaining a focus on the clinical applications. Instead of just reading a technical description of ventilators you'll learn how to select modes, set parameters, monitor the equipment, and respond to alarms. This how to approach prepares you to work with the entire spectrum of equipment.
Medical Devices and the Public's Health-Institute of Medicine 2011-10-25 Medical devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the FDA 510(k) process. In recent years, individuals and organizations have expressed concern that the 510(k) process is neither making safe and effective devices available to patients nor promoting innovation in the medical-device industry. Several high-profile mass-media reports and consumer-protection groups have profiled recognized or potential problems with medical devices cleared through the 510(k) clearance process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the entry of important new medical devices to the market. At the request of the FDA, the Institute of Medicine (IOM) examined the 510(k) process. Medical Devices and the Public's Health examines the current 510(k) clearance process and whether it optimally protects patients and promotes innovation in support of public health. It also identifies legislative, regulatory, or administrative changes that will achieve the goals of the 510(k) clearance process. Medical Devices and the Public's Health recommends that the U.S. Food and Drug Administration gather the information needed to develop a new regulatory framework to replace the 35-year-old 510(k) clearance process for medical devices. According to the report, the FDA's finite resources are best invested in developing an integrated premarket and postmarket regulatory framework.
Catheters Other Than Intravascular Catheters. Test Methods for Common Properties-British Standards Institute Staff 1997-07 Catheters, Cannulas, Medical instruments, Medical equipment, Corrosion tests, Tensile testing, Mechanical testing, Leak tests, Pressure testing, Flow rates, Flow measurement, Test equipment, Testing conditions, Specimen preparation
Risk Assessment-Marvin Rausand 2020-03-31 Introduces risk assessment with key theories, proven methods, and state-of-the-art applications Risk Assessment: Theory, Methods, and Applications remains one of the few textbooks to address current risk analysis and risk assessment with an emphasis on the possibility of sudden, major accidents across various areas of practice—from machinery and manufacturing processes to nuclear power plants and transportation systems. Updated to align with ISO 31000 and other amended standards, this all-new 2nd Edition discusses the main ideas and techniques for assessing risk today. The book begins with an introduction of risk analysis, assessment, and management, and includes a new section on the history of risk analysis. It covers hazards and threats, how to measure and evaluate risk, and risk management. It also adds new sections on risk governance and risk-informed decision making; combining accident theories and criteria for evaluating data sources; and subjective probabilities. The risk assessment process is covered, as are how to establish context; planning and preparing; and identification, analysis, and evaluation of risk. Risk Assessment also offers new coverage of safe job analysis and semi-quantitative methods, and it discusses barrier management and HRA methods for offshore application. Finally, it looks at dynamic risk analysis, security and life-cycle use of risk. Serves as a practical and modern guide to the current applications of risk analysis and assessment, supports key standards, and supplements legislation related to risk analysis Updated and revised to align with ISO 31000 Risk Management and other new standards and includes new chapters on security, dynamic risk analysis, as well as life-cycle use of risk analysis Provides in-depth coverage on hazard identification, methodologically outlining the steps for use of checklists, conducting preliminary hazard analysis, and job safety analysis Presents new coverage on the history of risk analysis, criteria for evaluating data sources, risk-informed decision making, subjective probabilities, semi-quantitative methods, and barrier management Contains more applications and examples, new and revised problems throughout, and detailed appendices that outline key terms and acronyms Supplemented with a book companion website containing Solutions to problems, presentation material and an Instructor Manual Risk Assessment: Theory, Methods, and Applications, Second Edition is ideal for courses on risk analysis/risk assessment and systems engineering at the upper-undergraduate and graduate levels. It is also an excellent reference and resource for engineers, researchers, consultants, and practitioners who carry out risk assessment techniques in their everyday work.
Biomedical Engineering and Design Handbook, Volume 2-Myer Kutz 2009-07-13 A State-of-the-Art Guide to Biomedical Engineering and Design Fundamentals and Applications The two-volume Biomedical Engineering and Design Handbook, Second Edition, offers unsurpassed coverage of the entire biomedical engineering field, including fundamental concepts, design and development processes, and applications. This landmark work contains contributions on a wide range of topics from nearly 80 leading experts at universities, medical centers, and commercial and law firms. Volume 2 provides timely information on breakthrough developments in medical device design, diagnostic equipment design, surgery, rehabilitation engineering, prosthetics design, and clinical engineering. Filled with more than 400 detailed illustrations, this definitive volume examines cutting-edge design and development methods for innovative devices, techniques, and treatments. Volume 2 covers: Medical Product Design FDA Medical Device Requirements Cardiovascular Devices Design of Respiratory Devices Design of Artificial Kidneys Design of Controlled-Release Drug Delivery Systems Sterile Medical Device Package Development Design of Magnetic Resonance Systems Instrumentation Design for Ultrasonic Imaging The Principles of X-Ray Computed Tomography Nuclear Medicine Imaging Instrumentation Breast Imaging Systems Surgical Simulation Technologies Computer-Integrated Surgery and Medical Robotics Technology and Disabilities Applied Universal Design Design of Artificial Arms and Hands for Prosthetic Applications Design of Artificial Limbs for Lower Extremity Amputees Wear of Total Knee and Hip Joint Replacements Home Modification Design Intelligent Assistive Technology Rehabilitators Risk Management in Healthcare Technology Planning for Healthcare Institutions Healthcare Facilities Planning Healthcare Systems Engineering Enclosed Habitat Life Support
Field Methods Casebook for Software Design-Dennis Wixon 1996-10-05 Now you can learn firsthand field research methods pioneered by designers at a wide variety of hardware and software companies The case studies presented in this book are real-world demonstrations of field research methods being applied for the first time to the design of hardware and software products at a wide range of companies—Microsoft, Lotus Development Corporation, Claris Corporation, Digital Equipment Corporation, as well as many others. The first field methods book devoted exclusively to the areas of interface design and human/computer interaction, this collection offers design practitioners a unique opportunity to study a wide range of techniques developed by their peers to investigate user work in context and to provide a basis for grounded product design. Presenting the case studies in a consistently coherent, straightforward manner, the authors extrapolate useful lessons from each, analyzing the costs and benefits, advantages and disadvantages of each approach, as well as offering a wealth of practical advice and guidance on how to adapt the described methods to your own design endeavors. Field Methods Casebook for Software Design: Describes the latest field research methods as they have been used in product design Provides concrete and detailed examples of data-gathering techniques and data analysis processes geared specifically to design issues This book is an indispensable resource for user interface designers, usability engineers, and all those involved with software design.
Anesthesia Equipment-Jan Ehrenwerth 1993 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. "This is a comprehensive, up-to-date reference textbook covering all aspects of physics and equipment for the modern American anaesthetist. It may be helpful to those studying for American fellowship examinations but is not suited to preparation for the UK FRCA examinations." Reviewed by: I.Wrench on behalf of the British Journal of Anaesthesia, Feb 2014?
Audio/video, Information and Communication Technology Equipment-Standards Australia (Organization) 2018

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