

Chapter 9 Protection against mechanical hazards from medical device equipment / systems

ID	Clause	Applicable	Traces to risk relevant items / Qualification / Comment
RIC 22	<p>9.2.1 Hazards associated with moving parts - General</p> <p>Demonstrate the assessment of risks associated with moving parts and if applicable how they are prevented from harming the operator/patient.</p> <p>This include assessing reasonably foreseeable misuse.</p>	Yes	<p>HZA 1 : User squeezes hand when reaching inside the device.</p> <p>File: UCC-564-331 Complexis Risk Assessment Document.docx</p>
RIC 23	<p>9.2.4 Emergency stopping devices</p> <p>Demonstrate how the emergency stop reduces risk to an acceptable level.</p> <p>Demonstrate how it is ensured that the emergency stop does not introduce any further hazards or interfere with the complete operation of necessary to remove the original hazard.</p>	No	There is no emergency stop.
RIC 24	<p>9.2.5 Release of patient</p> <p>Demonstrate how the restrained patient can be released quickly and safely in case of loss of power, emergency stop or breakdown of the device and, in general, situations where the patient is subjected to unacceptable risk.</p>	Yes	<p>HZA 2 : User cannot get released from harness.</p> <p>File: UCC-564-331 Complexis Risk Assessment Document.docx</p>
RIC 25	<p>9.5.1 Protective means of expelled parts</p> <p>Demonstrate the assessment of risks associated with expelled parts from the device.</p>	No	No parts can get expelled from device.
RIC 26	<p>9.6.2.2 Infrasound and ultrasound energy</p> <p>Demonstrate the risks associated with infrasound and ultrasound.</p>	To be assessed	

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**Devashish Shrivastava,J. Thomas
Vaughan**

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Handbook of Medical Device Regulatory Affairs in Asia Jack Wong, Raymond Tong, 2018-03-28 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 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 Each chapter provides substantial background materials relevant to the particular area to have a better understanding of regulatory affairs

Medical Regulatory Affairs Jack Wong, Raymond K. Y. Tong, 2022-01-27 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 *Medical Device Quality Assurance and Regulatory Compliance* Richard C. Fries, 1998-08-11 Acquaints developers of medical devices with the basic concepts and major issues of medical quality assurance and regulatory documents describes the requirements listed in these documents and provides strategies for compliance with these requirements **Development of Biopharmaceutical Drug-Device Products** Feroz Jameel, John W. Skoug, Robert R. Nesbitt, 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 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

Human Factors in Healthcare Avi Parush,2022-05-31 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

Proceedings of the 11th International Conference on Robotics, Vision, Signal Processing and Power Applications Nor Muzlifah Mahyuddin,Nor Rizuan Mat Noor,Harsa Amylia Mat Sakim,2022-02-11

The proceeding is a collection of research papers presented at the 11th International Conference on Robotics Vision Signal Processing Power Applications RoViSP 2021 The theme of RoViSP 2021 Enhancing Research and Innovation through the Fourth Industrial Revolution IR 4 0 served as a platform for researchers scientists engineers academicians as well as industrial professionals from all around the globe to present and exchange their research findings and development activities through oral presentations The book covers various topics of interest including Robotics Control Mechatronics and Automation Telecommunication Systems and Applications Electronic Design and Applications Vision Image and Signal Processing Electrical Power Energy and Industrial Applications Computer and Information Technology Biomedical Engineering and Applications Intelligent Systems Internet of things Mechatronics Mobile Technology **Medical Device Regulation** Elijah Wreh,2023-02-22 Medical Device Regulation provides the current FDA CDRH thinking on the regulation of medical devices This book offers information on how devices meet criteria for being a medical device which agencies regulate medical devices how policies regarding regulation affect the market rules regarding marketing and laws and standards that govern testing This practical well structured reference tool helps medical device manufacturers both in and out of the United States with premarket application and meeting complex FDA regulatory requirements The book delivers a comprehensive overview of the field from an author with expertise in regulatory affairs and commercialization of medical devices Offers a unique focus on the regulatory affairs industry specifically targeted at regulatory affairs professionals and those seeking certification Puts regulations in the context of contemporary design Includes case studies and applications of regulations *Clinical Anesthesia* Paul G. Barash,2009 The premier single volume reference in the field of anesthesia Clinical Anesthesia is now in its Sixth Edition with thoroughly updated coverage a new full color design and a revamped art program featuring 880 full color illustrations More than 80 leading experts cover every aspect of contemporary perioperative medicine in one comprehensive clinically focused clear concise and accessible volume Two new editors Michael Cahalan MD and M Christine Stock MD join Drs Barash Cullen and Stoelting for this edition A companion Website will offer the fully searchable text plus access to enhanced podcasts that can be viewed on your desktop or downloaded to most Apple and BlackBerry devices **Electrical Product Compliance and Safety Engineering, Volume 2** Steli Loznen,Constantin Bolintineanu,2021-09-30 This second volume of an Artech House bestseller presents an enhanced approach toward product compliance and safety engineering Written by experts in the field this new volume presents practical material useful for novice and advanced practitioners Safety aspects of product approvals energy management environmental concerns material science radiation hazardous location and global market access are explored Practical features related to global market access are presented including specific documentation and local labeling requirements as well as language used for safety instructions and user manuals Compliance and safety aspects of specific applications such as information technology equipment audio video multimedia medical household alarms systems luminaires including LED lamps and lamp control

industrial machinery and semiconductor manufacturing are discussed Environmental attributes including temperature atmospheric pressure relative humidity vibration shock and packaging transportation and how they affect product safety are analyzed Information about testing environmental HALT and HASS is also provided focusing on the compliance of electrical products with dedicated environmental regulation Similarities and differences between ATEX and IECEx are defined Materials including metal corrosion adhesives insulation materials and information about safety of hazardous materials are examined

Safety and Biological Effects in MRI Devashish Shrivastava,J. Thomas Vaughan,2020-10-30 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

XXIX Brazilian Congress on Biomedical Engineering - Volume 2: Tissue Engineering, Clinical Engineering and Computational Modeling in Biomedical Engineering Alcimar Barbosa Soares,Renata Ferranti Leoni,George Cunha Cardoso,2025-08-30 This book reports on the latest research and developments in Biomedical Engineering with a special emphasis on topics of interest and findings achieved in Latin America This second volume of a 3 volume set covers a wide range of topics advances in biomaterials tissue engineering and artificial organs nanotechnology applied to health health

management topics and advanced diagnostic tools computational modeling and simulation for biomedical applications topics in education in bioengineering and issues in biological metrology and medical devices Throughout the book a special emphasis is given to low cost technologies and to their development for and applications in clinical settings Based on the XXIX Brazilian Congress on Biomedical Engineering CBEB 2024 held on September 2 6 2024 Ribeir o Preto SP Brazil this book provides researchers and professionals in the biomedical engineering field with extensive information on new technologies and current challenges for their clinical applications

Anesthesia Equipment E-Book Jan Ehrenwerth, James B. Eisenkraft, James M Berry, 2013-03-12 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 Access the complete text and images online fully searchable at www.expertconsult.com

MRI from Picture to Proton Donald W. McRobbie, Elizabeth A. Moore, Martin J. Graves, Martin R. Prince, 2007-02-15 MRI from Picture to Proton presents the basics of MR practice and theory in a unique way backwards The subject is approached just as a new MR practitioner would encounter MRI starting from the images equipment and scanning protocols rather than pages of physics theory The reader is brought face to face with issues pertinent to practice immediately filling in the theoretical background as their experience of scanning grows Key ideas are introduced in an intuitive manner which is faithful to the underlying physics but avoids the need for difficult or distracting mathematics Additional explanations for the more technically inquisitive are given in optional secondary text boxes The new edition is fully up dated to reflect the most recent advances and includes a new chapter on parallel imaging Informal in style and informed in content written by recognized effective communicators of MR this is an essential text for the student of MR

Understanding Laser Accidents Ken Barat, 2018-09-13 Understanding Laser Accidents provides a comprehensive reference addressing a wide a spectrum of laser accidents The under reporting and misreporting of laser accidents creates a blind spot for the laser management of institutions laser users and laser safety officers This book attempts to lift that veil By giving details of why laser accidents occur accident preparation where to find laser accident

information elements of laser accident investigation role of lessons learned and regulatory oversight of laser use Chapters include a look at pilot illumination fiber telecommunication light show incidents and more as well as a detailed and honest review of three laser events that hold a mirror up to researchers and industrial laser users Provides a comprehensive single source devoted to laser accidents Covers elements of laser accident preparedness Provides detailed analysis of some laser accidents that share common threads across the research and industrial environment Contains information on where to find laser accident information Extensive information on the illumination of pilots Reviews laser regulatory oversight non beam hazards and laser safety tools

Medical Device Regulatory Practices Val Theisz, 2015-08-03 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

Clinical Anesthesia (SAE) Dr. Nishkarsh Gupta, Dr. Anju Gupta, 2021-06-01

Neurorehabilitation Technology David J. Reinkensmeyer, Volker Dietz, 2016-08-03 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

Principles of Biomedical Engineering Sundararajan V. Madhally, 2010 Describing the role of engineering in medicine today this comprehensive volume covers a wide range of the most important topics in this burgeoning field Supported with over 145 illustrations the book discusses bioelectrical systems mechanical analysis of biological tissues and organs biomaterial selection compartmental modeling and biomedical instrumentation Moreover you find a thorough treatment of the concept of using living cells in various therapeutics and diagnostics Structured as a complete text for students with some engineering background the book also makes a valuable reference for professionals new to the bioengineering field This authoritative textbook features numerous exercises and problems in each chapter to help ensure a solid understanding of the material

International Encyclopedia

of Ergonomics and Human Factors - 3 Volume Set Informa Healthcare, Waldemar Karwowski, 2006-03-15 The previous edition of the International Encyclopedia of Ergonomics and Human Factors made history as the first unified source of reliable information drawn from many realms of science and technology and created specifically with ergonomics professionals in mind It was also a winner of the Best Reference Award 2002 from the Engineering Libraries

Medical Instrument Design and Development Claudio Becchetti, Alessandro Neri, 2013-07-29 This book explains all of the stages involved in developing medical devices from concept to medical approval including system engineering bioinstrumentation design signal processing electronics software and ICT with Cloud and e Health development Medical Instrument Design and Development offers a comprehensive theoretical background with extensive use of diagrams graphics and tables around 400 throughout the book The book explains how the theory is translated into industrial medical products using a market sold Electrocardiograph disclosed in its design by the Gamma Cardio Soft manufacturer The sequence of the chapters reflects the product development lifecycle Each chapter is focused on a specific University course and is divided into two sections theory and implementation The theory sections explain the main concepts and principles which remain valid across technological evolutions of medical instrumentation The Implementation sections show how the theory is translated into a medical product The Electrocardiograph ECG or EKG is used as an example as it is a suitable device to explore to fully understand medical instrumentation since it is sufficiently simple but encompasses all the main areas involved in developing 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 using ECG as an example Examines the design and applications of main medical instruments Details the additional know how required for product implementation business context system design project management intellectual property rights product life cycle etc Includes an accompanying website with the design of the certified ECG product www.gammacardiosoft.it book Discloses the details of a marketed ECG Product from Gamma Cardio Soft compliant with the ANSI standard AAMI EC 11 under open licenses GNU GPL Creative Common This book is written for biomedical engineering courses upper level undergraduate and graduate students and for engineers interested in medical instrumentation device design with a comprehensive and interdisciplinary system perspective

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