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## Med-Info

International expert information  
for the medical device industry

## 3<sup>rd</sup> edition of IEC 60601-1:2005+A1:2012

### This Med-Info is addressed to

- Manufacturers of medical electrical equipment and systems
- Manufacturers of components of medical electrical equipment

### Background

The IEC 60601-1:2005 (3<sup>rd</sup> edition) was published in December 2005. It is the 3<sup>rd</sup> edition of the basic standard, replacing the previous version IEC 60601-1:1988+A1:1991+A2:1995.

Amendment 1 (A1:2012) was published in July 2012. The current version of the standard is thus called IEC 60601-1:2005+A1:2012, also known as Edition 3.1.

As basic standard for medical electrical equipment, this standard deals with the general requirements concerning basic safety and the essential performance.

### What is the new standard called?

IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. The German version is published as DIN EN 60601-1:2013.

### Why did a new edition of the basic standard become necessary and which are the most important changes compared to the second edition?

- a) User protection was adjusted to the requirements of IEC 60950-1 for information technology. This has often led to alleviated requirements and thus allows, under certain conditions, the use of components already approved in IEC 60950-1.
- b) Introduction of risk management as an alternative for compliance of individual aspects of the standard and for covering risks not subject to a standard.
- c) More precise adjustment of the insulation coordination to environmental conditions (e.g. degree of pollution, overvoltage category, etc.).
- d) Integration of some collateral standards into the basic standard (e.g. IEC 60601-1-1 systems).
- e) Expansion of the scope of application of the standard beyond basic safety by integration of the essential performance (= functional safety).
- f) The most national deviations for America (previously in UL 60601-1) have been included in the 3<sup>rd</sup> edition.
- g) Introduction of the term "expected service life".
- h) Section 9, "Mechanical hazards", has been expanded significantly.
- i) Key changes in A1:2012:
  - correction of problems that emerged when the standard was applied
  - reduction of references to risk management
  - clarification of the term "Essential Performance"

# Iec 60601 1 Third Edition

**Sabine Zange**

A red circular graphic with a gradient, appearing as a semi-circle or a partial circle, located to the right of the author's name.

## Iec 60601 1 Third Edition:

**Reliable Design of Medical Devices, Third Edition** Richard C. Fries, 2012-09-06 As medical devices become even more intricate concerns about efficacy safety and reliability continue to be raised Users and patients both want the device to operate as specified perform in a safe manner and continue to perform over a long period of time without failure Following in the footsteps of the bestselling second edition *Reliable Design of Medical Devices Third Edition* shows you how to improve reliability in the design of advanced medical devices Reliability engineering is an integral part of the product development process and of problem solving activities related to manufacturing and field failures Mirroring the typical product development process the book is organized into seven parts After an introduction to the basics of reliability engineering and failures it takes you through the concept feasibility design verification and validation design transfer and manufacturing and field activity phases Topics covered include Six Sigma for design human factors safety and risk analysis and new techniques such as accelerated life testing ALT and highly accelerated life testing HALT What's New in This Edition Updates throughout reflecting changes in the field An updated software development process Updated hardware test procedures A new layout that follows the product development process A list of deliverables needed at the end of each development phase Incorporating reliability engineering as a fundamental design philosophy this book shares valuable insight from the author's more than 35 years of experience A practical guide it helps you develop a more effective reliability engineering program contributing to increased profitability more satisfied customers and less risk of liability *Introduction to Biomedical Engineering Technology* Laurence J. Street, 2016-09-19 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 **Federal Register**, 2014

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

**Introduction to Biomedical Engineering Technology, 4th Edition** Laurence J. Street, 2022-08-10 This updated fourth edition provides current information on devices and is divided into diagnostic and treatment sections Devices are described with the theory of operation and relevant anatomical and physiological considerations Aspects of BMET work including test equipment standards and information technology are also discussed The text covers a wide variety of diagnostic and treatment devices currently used in hospitals that students will likely encounter in their career Principles of operation and examples of use are provided This book is unique in that it is written by an experienced biomed tech with 30 years experience in hospitals rather than by engineers with little frontline experience It is also unique in that it provides ancillary materials on the web and is the only guide divided into diagnostic and treatment device sections This new edition also includes two new chapters on computers information technology and networking as well as health technology management From the previous edition The book presents a comfortable balance between clinical applications basic technical information and various pictures of medical technologies one will encounter in the field Additionally related anatomy and physiology principles and essential technical terms are a nice complement to the technologies presented The everyday duties and responsibilities of a biomed are captured by the various true to life scenarios introduced throughout the book Joey Jones Madisonville Community College Kentucky USA This book is intended for students in biomedical engineering technology and healthcare technology management BMET HTM programs as well as biomedical engineering students Field service representatives medical device designers and medical device sales representatives will also find it useful

**The Biomedical Quality Auditor Handbook, Third Edition** Heather Crawford, 2017-09-08 The Biomedical Quality Auditor Handbook was developed by the ASQ Biomedical Division in support of its mission to promote the awareness and use of quality principles concepts and technologies in the biomedical community This third edition correlates to the 2013 exam Body of Knowledge BoK and reference list for ASQ's Certified Biomedical Auditor program It includes updates and corrections to errors and omissions in the second edition Most notably it has been re organized to align more closely with the BoK

*Medical-Grade Software Development* Ilkka Juuso, Ilpo Pöyhönen, 2023-11-13 This book is a practical guide to meeting IEC 62304 software development requirements within the context of an ISO 13485 quality management system QMS The book proves this can be done with a minimum amount of friction overlap and back and forth between development stages It essentially shows you how you should shape your medical software development processes to fit in with the QMS processes in the smartest and leanest way possible By following the advice in this book you can reuse processes from your QMS ensure your product realization processes meet the requirements for medical software development and marry all the requirements

together using tried and tested solutions into one efficient system The expertise of the authors here goes beyond just the experiences of one real world project as they tap into over 30 years of experience and countless software and software assessment projects to distill their advice The book takes a hands on approach by first teaching you the top 25 lessons to know before starting to develop a process for medical software development It then walks you through the expectations placed on the key aspects of such a process by the key standards The book progresses from an overview of both standards and the general requirements involved to a detailed discussion of the expected stages from software development and maintenance to risk management configuration management and problem resolution The book provides insightful advice on how the requirements of the IEC 62304 software development life cycle can be married with an ISO 13485 QMS how the development of the technical file should be organized and how to address conformity assessment the daily after approval and the recent trends that will affect the industry in the coming years The book is modeled after the IEC 62304 standard and adopts its clause structure in the numbering of sections for easy reference The book does not attempt to replicate either standard For the ISO 13485 standard it recites the necessary requirements succinctly For IEC 62304 the discussion is in depth and also addresses the impact of ISO 13485 on the requirements discussed In this way the book drills into both standards to expose the core of each requirement and shape these into a practical cohesive workflow for developing maintaining and improving a Lean software development pipeline

#### **Mission-Critical and Safety-Critical Systems**

**Handbook** Kim Fowler,2009-11-19 This handbook provides a consolidated comprehensive information resource for engineers working with mission and safety critical systems Principles regulations and processes common to all critical design projects are introduced in the opening chapters Expert contributors then offer development models process templates and documentation guidelines from their own core critical applications fields medical aerospace and military Readers will gain in depth knowledge of how to avoid common pitfalls and meet even the strictest certification standards Particular emphasis is placed on best practices design tradeoffs and testing procedures Comprehensive coverage of all key concerns for designers of critical systems including standards compliance verification and validation and design tradeoffs Real world case studies contained within these pages provide insight from experience

**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](http://www.expertconsult.com) *Human-Computer Interaction: Concepts, Methodologies, Tools, and Applications* Management Association, Information Resources, 2015-10-02 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

**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

**Inspection of Medical Devices** Almir Badnjević, Mario Cifrek, Ratko Magjarević, Zijad Džemić, 2017-10-26 This book offers all countries a guide to implementing verification systems for medical devices to ensure they satisfy their regulations It describes the processes procedures and need for integrating medical devices into the legal metrology framework addresses their independent safety and performance verification and highlights the associated savings for national healthcare systems all with the ultimate goal of increasing the efficacy and reliability of patient diagnoses and treatment The book primarily focuses on diagnostic and therapeutic medical devices and reflects the latest international directives and regulations Above all the book demonstrates that integrating medical devices into the legal metrology system and establishing a fully operational national laboratory for the inspection of medical devices could significantly improve the reliability of medical devices in diagnosis and patient care while also reducing costs for the healthcare system in the respective country

***Medical Device Use Error*** Michael Wiklund, Andrea Dwyer, Erin Davis, 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

***Handbook of Research on Advancements in Robotics and Mechatronics*** Habib, Maki K., 2014-12-31 The field of mechatronics integrates modern engineering science and technologies with new ways of thinking enhancing the design of products and manufacturing processes This synergy enables the creation and evolution of new intelligent human oriented machines The Handbook of Research on Advancements in Robotics and Mechatronics presents new findings practices technological innovations and theoretical perspectives on the the latest advancements in the field of mechanical engineering This book is of great use to engineers and scientists students researchers and practitioners looking to develop autonomous and smart products and systems for meeting today s challenges

***Clinical Engineering*** Azzam Taktak, Paul Ganney, David Long, Richard Axell, 2019-12-01 *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

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](http://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

Cardiac Fibrillation-defibrillation Max E. Valentinuzzi, 2010 This compendium gives a comprehensive overview of the advances in fibrillation defibrillation knowledge recognition of fibrillation as a unique life threatening cardiac arrhythmia discovery of the electric discharge in its double role of culprit and savior and technological improved contributions The book stands on the well known philosophy of Education Based on Problems or EBP that is take fibrillation as a medical daily problem and search for that knowledge technique or principle trying to solve it The book is interdisciplinary multidisciplinary and transdisciplinary It addresses undergraduate and



graduate biomedical engineering students physicians going into cardiology clinical engineers and clinical engineering technicians nurses paramedics and emergency medical personnel *Cumulated Index Medicus* ,1999 Computer Safety, Reliability, and Security Francesca Saglietti,Norbert Oster,2007-09-22 This book constitutes the refereed proceedings of the 26th International Conference on Computer Safety Reliability and Security SAFECOMP 2007 The 33 revised full papers and 16 short papers are organized in topical sections on safety cases impact of security on safety fault tree analysis safety analysis security aspects verification and validation platform reliability reliability evaluation formal methods static code analysis safety related architectures **Medical Regulatory Affairs** Jack Wong,Raymond Tong,2025-04-16 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 The updated fourth edition includes specific contributions that address the needs of startups

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