

# Usability Engineering Iec 62366 1 2015

**Michael E. Wiklund, P.E.,Jonathan Kendler,Allison Y. Strohlic**

**Medical Devices** ,2020 The amendment included in this consolidated version of ANSI/AAMI/IEC 62366-1:2015 and ANSI/AAMI/IEC 62366-1:2015/A1:2020 corrects identified inaccuracies in ANSI/AAMI/IEC 62366-1:2015 while making no fundamental changes to the usability engineering process as originally conceived in that document--Title page.

*Usability Testing of Medical Devices* Michael E. Wiklund, P.E.,Jonathan Kendler,Allison Y. Strohlic,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

**Usability Engineering** ,2015

**Mensch und Computer 2015 - Usability Professionals** Anja Endmann,Holger Fischer,Malte Krökel,2015-09-14 Usability Professionals Workshop deals with the practical applications of human-machine interaction research. It is organized by the German ACM specialty section of the UPA (Usability Professionals Association). The volume presents the latest research findings through case studies and practice reports along with in-depth discussions.

The ASQ Certified Medical Device Auditor Handbook Scott A Laman,2021-02-05 The ASQ Certified Medical Device Auditor Handbook (formerly The Biomedical Quality Auditor Handbook) was developed by the ASQ Medical Device Division (formerly Biomedical Division) in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the medical device community. It principally serves as a resource to candidates preparing for the Certified Medical Device Auditor (CMDA) certification exam. The fourth edition of this handbook has been reorganized to align with the 2020 certification exam Body of Knowledge (BoK) and reference list. The combination of this handbook with other reference materials can provide a well-rounded background in medical device auditing. Updates to this edition include: • A discussion of data privacy, data integrity principles, and the Medical Device Single Audit Program (MDSAP) • Current information about federal and international regulations • New content regarding human factors and usability engineering, general safety and performance requirements, labeling, validation, risk management, and cybersecurity considerations • A thorough explanation of quality tools and techniques

Usability Engineering als Erfolgsfaktor Thomas Geis,Christian Johnner,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.

**APPLICATION OF USABILITY ENGINEERING TO THE DEVELOPMENT OF A PERSONALISED DECISION SUPPORT SYSTEM FOR TYPE 1 DIABETES SELF-MANAGEMENT.** ,2017 Background and AimsPEPPER (Patient Empowerment through Predictive PERsonalised decision support) is an EU-funded research project which aims to improve the self-management behaviour of adults with type 1 diabetes (T1D). Human factors and ergonomics play a key role in the development of this system. MethodThe usability engineering process for PEPPER adheres to the international standard IEC 62366-1:2015 - Application of usability engineering to medical devices. The iterative methodology includes multiple stages of formative evaluation and redevelopment involving both patients and clinicians. The first stage is an analytical study using heuristic evaluation and the keystroke-level model. The second stage is a laboratory study with users to measure performance with regard to the usability goals of simplicity, effectiveness, efficiency, and satisfaction. Finally, a contextual diary study is undertaken to understand the day-to-day user experience with PEPPER during a clinical feasibility study. ResultsThe results of the analytical study produced a series of redesign recommendations to improve usability prior to the user study. Video analysis of the latter showed that users made few errors and most tasks were completed, indicating high simplicity and effectiveness respectively. The SUS questionnaire was used to determine satisfaction, excellent scores for the handset (74.3%) and good for the server (66.3%). The diary study is not yet completed. ConclusionThe usability evaluation protocol used in PEPPER adheres to international standards. The iterative development methodology has potential to improve patient acceptance and safety. Background and AimsPEPPER (Patient Empowerment through Predictive PERsonalised decision support) is an EU-funded research project which aims to improve the self-management behaviour of adults with type 1 diabetes (T1D). Human factors and ergonomics play a key role in the development of this system. MethodThe usability engineering process for PEPPER adheres to the international standard IEC 62366-1:2015 - Application of usability engineering to medical devices. The iterative methodology includes multiple stages of formative evaluation and redevelopment involving both patients and clinicians. The first stage is an analytical study using heuristic evaluation and the keystroke-level model. The second stage is a laboratory study with users to measure performance with regard to the usability goals of simplicity, effectiveness, efficiency, and satisfaction. Finally, a contextual diary study is undertaken to understand

the day-to-day user experience with PEPPEP during a clinical feasibility study. Results The results of the analytical study produced a series of redesign recommendations to improve usability prior to the user study. Video analysis of the latter showed that users made few errors and most tasks were completed, indicating high simplicity and effectiveness respectively. The SUS questionnaire was used to determine satisfaction, excellent scores for the handset (74.3%) and good for the server (66.3%). The diary study is not yet completed. Conclusion The usability evaluation protocol used in PEPPEP adheres to international standards. The iterative development methodology has potential to improve patient acceptance and safety. This project has received funding from the EU Horizon 2020 programme, grant agreement No. 689810.

**Designing Usability into Medical Products** Michael E. Wiklund, Stephen B. Wilcox, 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

**Handbook of Human Factors in Medical Device Design** Matthew Bret Weinger, Michael E. Wiklund, Daryle Jean Gardner-Bonneau, 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

**The Combination Products Handbook** Susan Needle, 2023-05-16 Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. According to the US Food and Drug Administration (FDA), “a combination product is one composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device and a biological product.” Examples include prefilled syringes, pen injectors, autoinjectors, inhalers, transdermal delivery systems, drug-eluting stents, and kits containing drug administration devices co-packaged with drugs and/or biological products. This handbook provides the most up-to-date information on the development of combination products, from the technology involved to successful delivery to market. The authors present important and up-to-the-minute pre- and post-market reviews of international combination product regulations, guidance, considerations, and best practices. This handbook: Brings clarity of understanding for global combination products guidance and regulations Reviews the current state-of-the-art considerations and best practices spanning the combination product lifecycle, pre-market through post-market Reviews medical product classification and assignment issues faced by global regulatory authorities and industry The editor is a recognized international Combination Products and Medical Device expert with over 35 years of industry experience and has an outstanding team of contributors. Endorsed by AAMI – Association for the Advancement of Medical Instrumentation.

**Technical specifications for pre-market assessment of blood pressure measuring device with cuff, automated and semi-automated** World Health Organization,2023-09-21 To provide technical specifications to blood pressure measuring device with cuff, automated and semi-automated for manufacturers who intend to seek their WHO prequalification (PQ). Manufacturers should consider the technical specifications outlined as minimum requirements for participating in the PQ programme in order to ensure that the blood pressure measurement device has been designed, evaluated and validated in conformity with these requirements and is therefore safe and effective.

**Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics** ,2020-12-09

**Technical specifications for pre-market assessment of medical masks** World Health Organization,2023-10-19

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

**Rehabilitation Robotics: Challenges in Design, Control, and Real Applications** Francisco Romero Sánchez,Luciano Loporini Menegaldo,Josep M. Font-Llagunes,Massimo Sartori,2022-08-31

*Introduction to Bioinformatics and Clinical Scientific Computing* Paul S. Ganney,2022-12-19 This textbook provides an introduction to computer science theory, informatics best practice, and the standards and legislation that apply to computing in a healthcare environment. It delivers an accessible discussion of databases (construction, interrogation and maintenance); networking (design and low-level application); programming (best practice rather than the specifics of any one language - design, maintenance, safety). It can be used to accompany the NHS Modernising Scientific Careers syllabus. It is also targeted towards those creating software rather than those using it, particularly computer scientists working in healthcare, specifically those in or close to the Physical Sciences, including radiotherapy, nuclear medicine, and equipment management and those working with genomics and health informatics. Features Combines all topics into one comprehensive introduction. Explores practical applications of theory to healthcare. Can be used to accompany the NHS Modernising Scientific Careers syllabus.

**Advanced Models and Tools for Effective Decision Making Under Uncertainty and Risk Contexts** González-Prida, Vicente,Carnero, María Carmen,2020-09-04 Business industries depend on advanced models and tools that provide an optimal and objective decision-making process, ultimately guaranteeing improved competitiveness, reducing risk, and eliminating uncertainty. Thanks in part to the digital era of the modern world, reducing these conditions has become much more manageable. *Advanced Models and Tools for Effective Decision Making Under Uncertainty and Risk Contexts* provides

research exploring the theoretical and practical aspects of effective decision making based not only on mathematical techniques, but also on those technological tools that are available nowadays in the Fourth Industrial Revolution. Featuring coverage on a broad range of topics such as industrial informatics, knowledge management, and production planning, this book is ideally designed for decision makers, researchers, engineers, academicians, and students.

**RISK MANAGEMENT FOR THE MEDICAL DEVICE INDUSTRY** Dr. Akash Sharma, Ms. Vriti Gamta , Mr. Gaurav Luthra,2023-07-25 Risk Management for the Medical Device Industry: A Guide based on ISO 14971 is an essential resource for professionals in the fast-paced medical device industry. Authored by Dr. Akash Sharma, Ms. Vriti Gamta, and Mr. Gaurav Luthra, experts in regulatory affairs and quality management systems, this practical guide offers comprehensive insights into risk management and compliance. Covering the entire risk management lifecycle, it includes case studies, best practices, and practical examples, along with discussions on integrating risk management with quality management systems and emerging technologies. Equip yourself with the knowledge and tools to ensure safety and effectiveness in the global market.

**Digital Respiratory Healthcare** Hilary Pinnock,Vitalii Poberezhets,David Drummond,2023-12-01 Respiratory care is undergoing a period of major change as it cautiously begins to embrace digital transformation. Catalysed by the need for remote consultation in the pandemic, time-honoured approaches to delivering care are now being challenged by technology-based initiatives. This Monograph deftly guides the reader through the potential benefits and pitfalls of such change, breaking the discussion down into three areas: technological opportunities and regulatory challenges ; social benefits, challenges and implications; exemplars of digital healthcare. Each chapter reviews contemporary literature and considers not 'if' but 'how' a digital respiratory future can provide optimal care. The result is an authoritative, balanced guide to developing digital respiratory health.

**Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing** ,2021-06-08 The purpose of this document is to provide technical guidance to in vitro diagnostic medical device (IVD) manufacturers that intend to seek WHO prequalification of rapid diagnostic tests (RDTs) for the detection of human immunodeficiency virus (HIV). The minimum performance requirements for WHO prequalification are summarized in this document, and apply equally to RDTs intended solely for HIV detection and those in which HIV detection is one component of a multi-detection assay (for example, an HIV/syphilis dual-detection RDT). This document applies to RDTs intended to be used as an aid to diagnosis of HIV infection. The current version of this document does not address IVDs that discriminate between the detection of HIV-1 and HIV-2 infection, IVDs intended as confirmatory tests, or the requirements for accompanying quality control materials.

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