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Usability Engineering Iec 62366 1

For example, clause 4.2 of EN

60601-1-6:2010 states that a usability engineering process complying with IEC 62366 shall be performed. For this reason, the principal standard that medical device ...

European Medical Device Usability Requirements

Another IEC standard, IEC/CD 62366, "Medical Devices—Application of Usability Engineering to Medical Devices," is currently under development. IEC 60601-1-6 was written for electromechanical devices, ...

Understanding Usability Standards for Medical Devices

Safety engineering principles ... standards for human-factor usability aren't well developed. For example,

one such document is IEC 62366 Annex D 1.4. It is weak in that it only supplies general ...

How To Design Safe Medical Products

As connected technologies drive innovation and transform healthcare, medtech companies look to ICS' user experience (UX) and software engineering ... use ISO-13485 and IEC-62366 compliant ...

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

Safety Risk Management for Medical Devices, Second Edition teaches the essential safety risk management methodologies for medical devices compliant with the requirements of ISO 14971:2019. Focusing exclusively on safety risk assessment practices required in the MedTech sector, the book outlines sensible, easily comprehensible, state-of the-art methodologies that are rooted in current industry best practices, addressing safety risk management of medical devices, thus making it useful for those in the MedTech sector who are responsible for safety risk management or need to understand risk management, including design engineers, product engineers, development engineers, software

engineers, Quality assurance and regulatory affairs. Graduate-level engineering students with an interest in medical devices will also benefit from this book. The new edition has been fully updated to reflect the state-of-the-art in this fast changing field. It offers guidance on developing and commercializing medical devices in line with the most current international standards and regulations. Includes new coverage of ISO 14971:2019, ISO/TR 24971 Presents the latest information on the history of risk management, lifetime of a medical device, risk management review, production and post production activities, post market risk management Provides practical, easy-to-understand and state-of the-art methodologies that meet the requirements of international

regulation

Applied Human Factors in Medical Device Design describes the contents of a human factors toolbox with in-depth descriptions of both empirical and analytical methodologies. The book begins with an overview of the design control process, integrating human factors as directed by AAMI TIR 59 and experienced practice. It then explains each method, describing why each method is important, its potential impact, when it's ideal to use, and related challenges. Also discussed are other barriers, such as communication breakdowns between users and design teams. This book is an excellent reference for professionals working in human factors, design, engineering, marketing and regulation. Focuses on

meeting agency requirements as it pertains to the application of human factors in the medical device development process in both the US and the European Union (EU) Explains technology development and the application of human factors throughout the development process Covers FDA and MHRA regulations Includes case examples with each method

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."

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

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.

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

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

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completed.ConclusionThe usability evaluation protocol used in PEPPER 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.

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

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