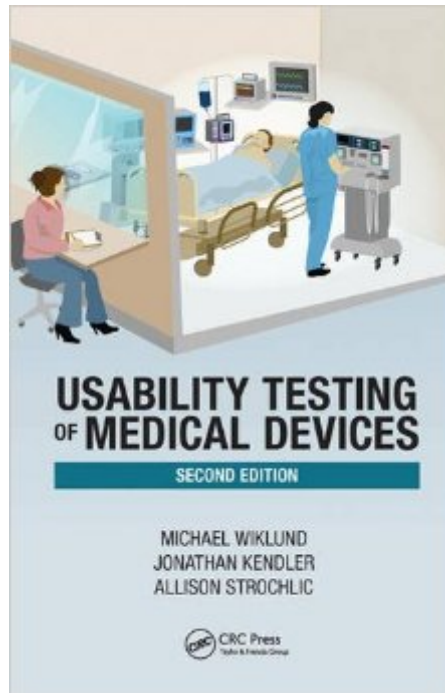The book was found

Usability Testing Of Medical Devices, Second Edition

Synopsis

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 have modified their regulations and expectations regarding how medical device manufacturers should approach usability testing. Reflecting these changes, this Second Edition provides updated guidance to readers with an interest or direct role in conducting a usability test of a medical device or system. Key updates involve the 2011 FDA guidance on human factors engineering, requirements set forth by the third edition of IEC 60601 and closely related IEC 62366-1:2015, linking usability test tasks to risk analysis results, and analyzing root causes of use errors that occur during usability tests. Written by seasoned human factors specialists, Usability Testing of Medical Devices, Second Edition is an informative, practical, and up-to-date handbook for conducting usability tests of medical devices. The book helps ensure a smooth and painless development processâ •and thus, safe and effective medical devices.

Book Information

Hardcover: 477 pages

Publisher: CRC Press; 2 edition (December 16, 2015)

Language: English

ISBN-10: 1466595884

ISBN-13: 978-1466595880

Product Dimensions: 6.1 x 1.1 x 9.3 inches

Shipping Weight: 1.6 pounds (View shipping rates and policies)

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