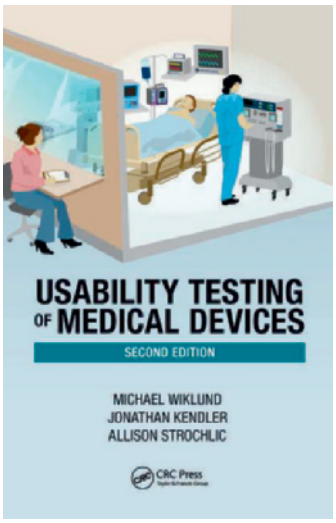
Reading Room



***Usability Testing of Medical Decides*, Second Edition**

Authors: Michael E. Wiklund, Jonathan Kendler, and Allison Y. Strochlic

Publisher: CRC Press, 2016

ISBN: 978-1-1665-9588-0

Pages: 455

Usability Testing for Medical Devices is a solid and practical book, with lots of "how to" material packed into a handsome volume. It has good human factors engineering characteristics: compact form factor, high-quality paper, good application of color (with many full-color photographs), and effective use of graphical elements to guide the reader. A smattering of low-resolution "clip art" images made me cringe at first, but as I went along I came to regard them as part of the book's informal style of speaking in the first person, addressing the reader directly, and not taking itself too seriously.

Audience

The book includes a long list of "professionals and role players" that are its intended audience. My perception is that the book is of greatest value to people who design medical devices and bring them to market. A wealth of information on regulatory compliance, particularly with regard to Food and Drug Administration (FDA) expectations, both written and unwritten, is included.

As a clinical engineer, I am particularly interested in how healthcare organizations select medical devices and how they use them in patient care. Speaking from that perspective, I can say the book has much to offer for healthcare technology management professionals.

My consulting practice also includes forensic engineering activities, such as investigation of medical device–related incidents. I have encountered far too many cases in which a patient care provider needed a medical device to achieve a clinical objective and was unable achieve it. That's my working definition of "use error" (which the book carefully distinguishes from the blame-assigning term, "user error").

My experience is that poor design and, in particular, poor usability are at the root of many cases of use error. As a result, I am a firm believer that usability testing is essential for not only medical device designers but also clinical engineering professionals and others responsible for selecting medical devices. Devices that are difficult to use safely and effectively are accidents waiting to happen. Even a moderately well-executed assessment process could have provided early warning.

Assessment

As the authors write, "We doubt that many of you will choose to read the book cover to cover in a marathon session, such as one might consume a Danielle Steel or Stephen King novel." To address that fact, they have broken the book into task-oriented chapters and provided a detailed table of contents to guide readers to material of interest (e.g., "Writing a test plan" [chapter 7], "Choosing a participant sample and recruiting participants" [chapter 8]).

Considering the book from the clinical engineering perspective, one of the chapters I focused on was "Conducting the test" (chapter 12). This 40-page chapter contains useful material and practical advice for healthcare organizations conducting assessments of new medical devices. Those of us working in the clinical environment do not, by and large, need to be as rigorous in our assessments as medical device companies facing FDA scrutiny. However, we absolutely need to be careful and responsible. In short, we need to learn from the experts when we design our assessment processes.

My recommendation is to add *Usability Testing for Medical Devices* to your collection. Read the introductory chapters right away. Gather and review the key references (clearly noted throughout the text and pulled together in the "resources" section). Then, when the next opportunity for medical device assessment presents itself, dig into the book and design a process that works. ■

About the Reviewer

Matthew F. Baretich, PE, PhD, is president of Baretich Engineering, Inc., based in Fort Collins, CO. He is the author of the AAMI Electrical Safety Manual *and a subject matter expert for AAMI's web-based tool Benchmarking Solutions—Healthcare Technology Management. He is a member of the* BI&T *Editorial Boad. Email: mfb@baretich.com*