



Medical Device Use Error: Root Cause Analysis

Michael Wiklund, Andrea Dwyer, Erin Davis

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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 (mistakes) that people make when using a medical device, the potential consequences, and design-based preventions.

Using clear illustrations and simple narrative explanations, the text:

- Covers the fundamentals and language of root cause analysis and regulators' expectations regarding the thorough analysis of use errors
- Describes how to identify use errors, interview users about use errors, and fix user interface design flaws that could induce use errors
- Reinforces the application of best practices in human factors engineering, including conducting both formative and summative usability tests

Medical Device Use Error: Root Cause Analysis delineates a systematic method of analyzing medical device use errors. The book provides a valuable reference to human factors specialists, product development professionals, and others committed to making medical devices as safe and effective as possible.

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