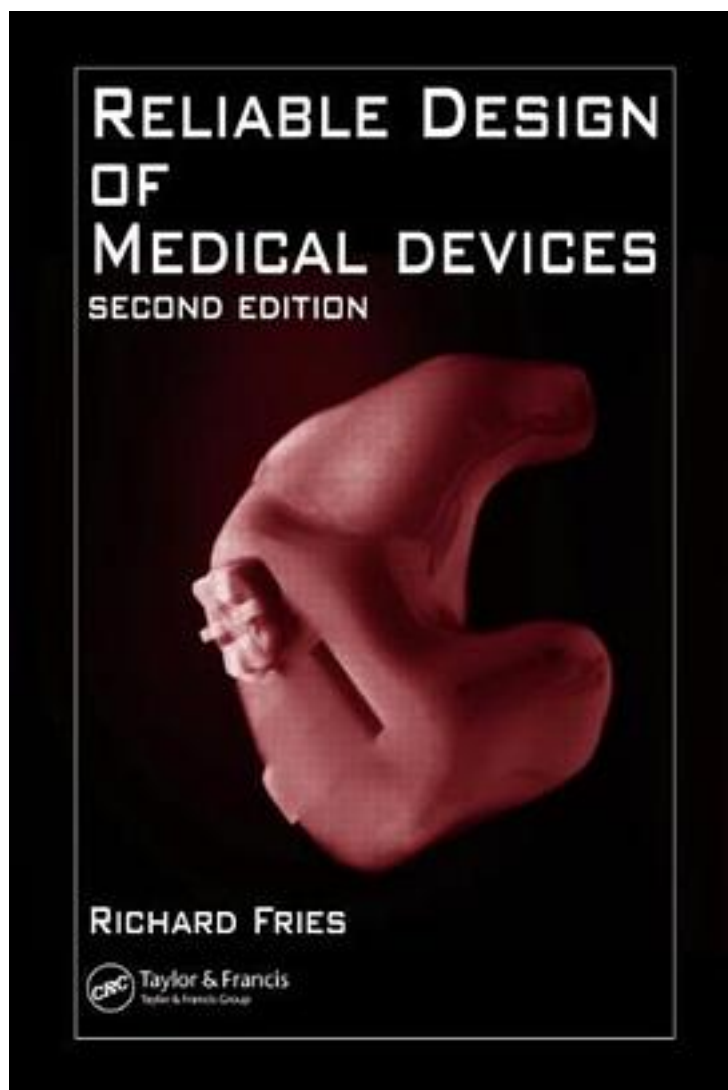


Reliable Desi of Med Dev 2e



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As medical devices increase in complexity, concerns about efficacy, safety, quality, and longevity increase in stride. Introduced nearly a decade ago, "Reliable Design of Medical Devices" illuminated the path to increased reliability in the hands-on design of advanced medical devices. With fully updated coverage in its Second Edition, this practical guide continues to be the benchmark for incorporating reliability engineering as a fundamental design philosophy. The book begins by rigorously defining reliability, differentiating it from quality, and exploring various aspects of failure in detail. It examines domestic and international regulations and standards in similar depth, including updated information on the regulatory and standards organizations as well as a new chapter on quality system regulation. The author builds on this background to explain product specification, liability and intellectual property, safety and risk management, design, testing, human factors, and manufacturing. New topics include design of experiments, CAD/CAM, industrial design, material selection and biocompatibility, system engineering, rapid prototyping, quick-response manufacturing, and maintainability as well as a new chapter on Six Sigma for design. Supplying valuable insight based on years of successful experience, "Reliable Design of Medical Devices, Second Edition" leads the way to implementing an effective reliability assurance program and navigating the regulatory minefield with confidence.

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