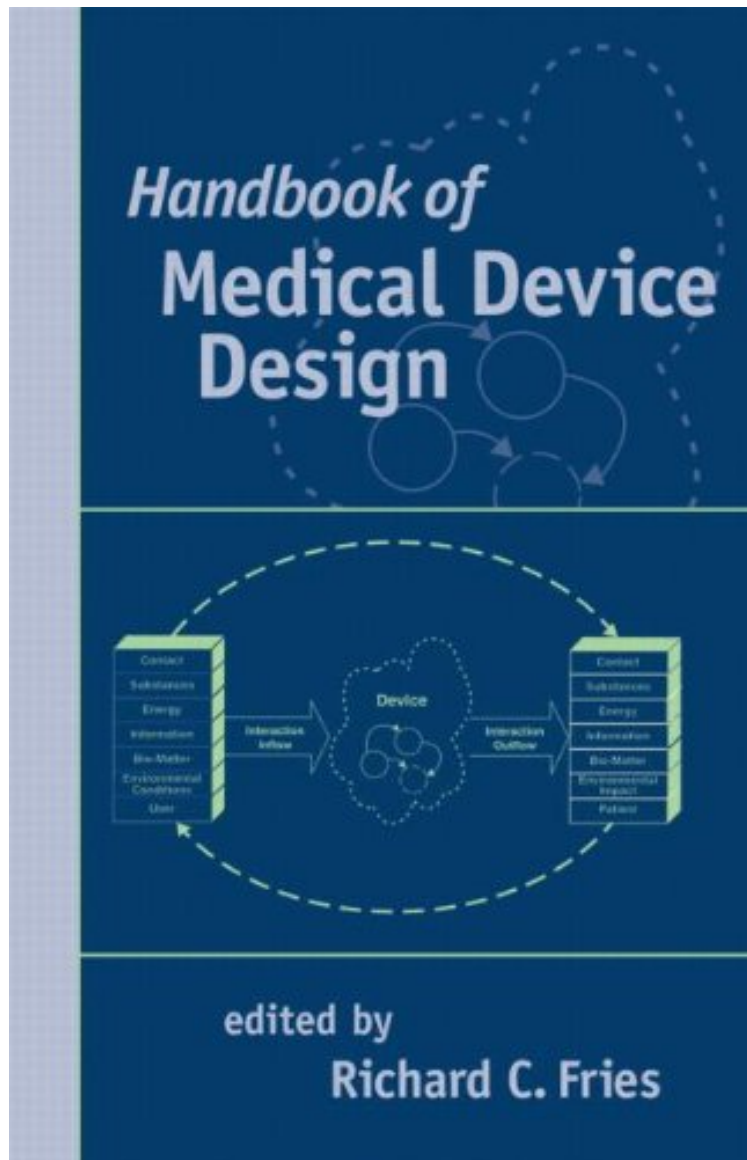


Handbook of Medical Device Design

Richard C. Fries

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The Handbook of Medical Device Design provides a review of regulatory and standards issues in medical device design, including FDA regulations, types of 510 (k), the ISO 9000 series, and medical device directives. It identifies

how to determine and document customer needs and device requirements. It also establishes reliability and quality metrics for the duration of the product development cycle. Topics include