



# Medical Instrument Design and Development: From Requirements to Market Placements

*Claudio Becchetti, Alessandro Neri*

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This book explains all of the stages involved in developing medical devices; from concept to medical approval including system engineering, bioinstrumentation design, signal processing, electronics, software and ICT with Cloud and e-Health development.

Medical Instrument Design and Development offers a comprehensive theoretical background with extensive use of diagrams, graphics and tables (around 400 throughout the book). The book explains how the theory is translated into industrial medical products using a market-sold Electrocardiograph disclosed in its design by the Gamma Cardio Soft manufacturer.

The sequence of the chapters reflects the product development lifecycle. Each chapter is focused on a specific University course and is divided into two sections: theory and implementation. The theory sections explain the main concepts and principles which remain valid across technological evolutions of medical instrumentation. The Implementation sections show how the theory is translated into a medical product. The Electrocardiograph (ECG or EKG) is used as an example as it is a suitable device to explore to fully understand medical instrumentation since it is sufficiently simple but encompasses all the main areas involved in developing medical electronic equipment.

Key Features:

- Introduces a system-level approach to product design
- Covers topics such as bioinstrumentation, signal processing, information theory, electronics, software, firmware, telemedicine, e-Health and medical device certification
- Explains how to use theory to implement a market product (using ECG as an example)
- Examines the design and applications of main medical instruments
- Details the additional know-how required for product implementation: business context, system design, project management, intellectual property rights, product life cycle, etc.
- Includes an accompanying website with the design of the certified ECG product ([www.gammacardiosoft.it/book](http://www.gammacardiosoft.it/book))
- Discloses the details of a marketed ECG Product (from Gamma Cardio Soft) compliant with the ANSI standard AAMI EC 11 under open licenses (GNU GPL, Creative Common)

This book is written for biomedical engineering courses (upper-level undergraduate and graduate students) and for engineers interested in medical instrumentation/device design with a comprehensive and interdisciplinary system perspective.

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