Design and Development of Medical Electronic Instrumentation

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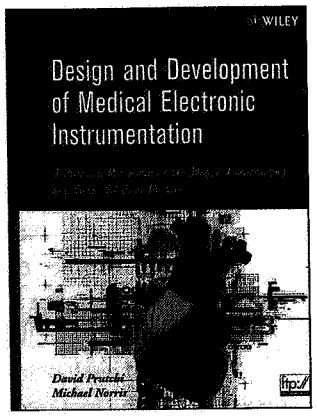

The idea of such a compendium of design examples, accompanied by an excellent explanation of the application of those circuits to physiologic devices is unique and will provide a substantial source for both academic and personal uses. The first use that comes to mind is an intermediate course in medical electronic device design. The second is for a personal resource of design ideas that can be adopted for devices in several allied device fields. The third area of use suggested by the authors is for hobbyists, with the large source of ready made and tested circuits available.

The index, although adequate for general reference to text topics, is perhaps the weakest of the otherwise excellent resource materials in the book (a four-page index for nearly 500 pages). The Internet FTP site offered as independent support to the text also becomes support specific to three of the eight chapters, and has more than 50 freeware packages in 13 folders and is rich in itself with sources of helpful software for various applications of sensors, signal generators, signal analyzers, testing and calibration. There is even an "Epilogue" dealing with the regulatory environment in which the medical device designers find themselves, and explains in an excellent general manner, the requirements and difficulties encountered in designing and preparing safe and effective devices for this special market.

Audience: The target audience for this manual is stated as being one that has "understanding of circuit design as well as experience in electronic prototype construction." Other assumptions include that the reader has "a basic knowledge of physiology, especially how electrically excitable cells work, as well as how the aggregate activities of many excitable cells result in the various biopotential signals that can be detected from the body." In a sense, the book is admittedly narrowly directed, but in fact, turns out to be broadly applicable to all of the biomedical engineering fields dealing with electrical signals and their detection from and application to the body. Areas the book does not deal with are the large applications of motorized systems, such as for fluid movement or medical therapies with field generators, delivery of radiation therapy, any physical therapy equipment, or any plastic disposable (non-electrified) devices.

Features: The book was carefully created with attention to the several topics necessary for the understanding of design of devices focusing on physiological signal detection and delivery. The eight chapters were sequenced for the student as well as the experienced designer. One can use this book for both intermediate instruction as well as for ideas on circuitry for specific applications. Each chapter has copious introductory remarks intended to bring the student with basic understanding up to the level needed for the chapter material. The first chapter, "Biopotential Amplifiers," starts with the seven amplifier characteristics and moves through discussion of surface electrodes, amplifiers, electrode buffer arrays, and body potential drivers that remove competing signals.

The second chapter on "Bandpass Selection for Biopotential Amplifiers" deals with signals of physiological frequency and how to assure only as much as practical, that those signals of interest are the ones isolated and conditioned for recording/detection. Some of the problems addressed are electrode noise, power noise (the signal of 50 or 60Hz), fluorescent lamp noise, and noise from many other sources that tend to interfere with the signals of interest that often fall right in the range of such interfering signals.

The third chapter, "Design of Safe Medical Device Prototypes," refocuses the discussion to the general area of medical device design. This chapter becomes applicable to many device types by discussing standards for electrical shock protection. The authors mention that the FDA and international standards are there to aid the designers to produce devices that are inherently safe and provide a true benefit to the patient and operator through prevention of inherent risks. Topics that are discussed in sufficient detail to give a strong review of the topic for design engineers include electrical shock protection levels and detection and prevention of leakage currents.

The fourth chapter "Electromagnetic Compatibility [EMC] and Medical Devices" is also a widely applicable

chapter, in that all electronic medical devices must be resistant to the influence of external electrical fields, as well as not generating such fields that would influence the operation of other medical devices. This chapter deals with the EN-60601-1-2 Immunity Requirements of the several new IEC-61000-4 series of eight standards, and is an excellent review of the basics of those standards. A clear and important point is made that prevention is better than any cure for EMC problems.

The fifth chapter, "Signal Conditioning, Data Acquisition, and Spectral Analysis," focuses on the sensor physiological interface and how the resultant signal is conditioned, acquired, and analyzed. The chapter presented excellent discussion on signal conditioning, data sampling, example software, an introduction to array signal processing, and an extensive discussion of the mathematical tool of Fast Fourier Transforms to interpret the compound signals acquired by the device.

The sixth chapter, "Signal Sources for Simulation, Testing, and Calibration," was an excellent chapter on providing tools to simulate physiological signals, such as the classical electrocardiogram, generated by both analog and digital means. Hard-wired analog circuits and PC-programmable waveform generators were discussed, with considerable detail devoted to actual circuits, software, even with a discussion of firmware (including a state diagram) for a cardiac stimulator.

The seventh chapter, "Stimulation of Excitable Tissues," dealt with the design and use of stimulating devices using monopolar, bipolar, and field electrode systems. An extensive table displayed some of the many applications of electrodes to stimulate physiological tissue.

The final (eighth) chapter focuses on "Cardiac Pacing and Defibrillation." This is certainly where all this was going, as the authors explained the history of cardiac pacing, the simple pacing state-machines, programmable pacemakers, and communicating with such an implantable device. There is software in this chapter depicting the pacemaker state machine and power consumption. The subject of software testing is discussed, with its brevity being one of the few downsides of this text, as more could be extremely helpful. The topic of defibrillation, which is important in the area of delivery of physiological waveforms, is discussed in seven pages with some detail. At last, the devices and components used for these devices are discussed in detail.

Assessment: With the authors declaring this to be a "Practical Perspective of the Design, Construction, and Test of Medical Devices," this book nearly lives up to its name. It is a comprehensive presentation of design, test, and discussion relating primarily to those devices in the physiological signal acquisition and delivery areas, also focusing on device electrical safety. Putting such a valuable compendium together was likely a monumental task for the authors. This reviewer will find this text a valued part of his library for the several areas extremely well elucidated. And talking with a few colleagues, the reviewer confirmed that this text will have wide appeal in the medical device design area, not just with hospital biomedical engineers, but also those who design the devices. ■

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