Medical Device Technologies A Systems Based Overview Using Engineering Standards Academic Press Series In Biomedical Engineering

Rare diseases collectively affect millions of Americans of all ages, but developing drugs and medical devices to prevent, diagnose, and treat these conditions is challenging. The Institute of Medicine (IOM) recommends implementing an integrated national strategy to promote rare diseases research and product development.

This book offers comprehensive, easy to understand guidance for medical device technology innovators on how to work through the United States FDA regulatory review process, while also providing insight on the various intellectual property concerns that many medical device innovators face. In the first portion of this book, readers are introduced to important concepts concerning FDA compliance for medical devices, as well as strategies for successfully navigating the FDA regulatory review process. Specifically, the first portion discusses the expansive range of medical devices and then walks through the most common routes to market: the PMA and 510(k) application processes. In the second portion of this book, readers are introduced to the various types of intellectual property rights that are available for medical device technology inventions and innovations, and can explore ways to overcome unique intellectual property challenges faced by many medical device technology innovators. In the third portion of the book, specific strategies are discussed to navigate the interface between the FDA regulatory process and the process of obtaining intellectual property protection. This book also includes a number of descriptive examples, case studies and scenarios to illustrate the topics discussed, and is intended for use by medical device designers, developers and innovators.

WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas: * policy framework for health technology * medical device regulations * health technology assessment * health technology management * needs assessment of medical devices * medical device procurement * medical equipment donations * medical equipment inventory management * medical equipment maintenance * computerized maintenance management systems * medical device data * medical device nomenclature * medical devices by health-care setting * medical devices by clinical procedures * medical device innovation, research and development. These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels. HTA is the systematic evaluation of properties, effects, and/or impacts of health technology. Its main purpose is to inform technology-related policy-making in health care, and thus improve the uptake of cost-effective new technologies and prevent the uptake of technologies that are of doubtful value for the health system. It is one of three complementary functions to ensure the appropriate introduction and use of health technology. The other two components are regulation, which is concerned with safety and efficacy, and assessment of all significant intended as well as unintended consequences of technology use; and management, which is concerned with the procurement and maintenance of the technology during its life-cycle. The performance of health systems is strengthened when the linkages and exchange among these elements are clearly differentiated but mutually supportive. This document integrates health technology assessment into the WHO framework for evidence-informed policy-making. Health systems are strengthened when HTA is integrated into the human and

material resources, data, transparent decision- and policy-making, and linked to the overall vision of equity and accountability. Good governance can rely on health technology assessment to provide a policy approach that is accountable for its decisions to the population. The loss of hearing - be it gradual or acute, mild or severe, present since birth or acquired in older age - can have significant effects on one's communication abilities, quality of life, social participation, and health. Despite this, many people with hearing loss do not seek or receive hearing health care. The reasons are numerous, complex, and often interconnected. For some, hearing health care is not affordable. For others, the appropriate services are difficult to access, or individuals do not know how or where to access them. Others may not want to deal with the stigma that they and society may associate with needing hearing health care and obtaining that care. Still others do not recognize they need hearing health care, as hearing loss is an invisible health condition that often worsens gradually over time. In the United States, an estimated 30 million individuals (12.7 percent of Americans ages 12 years or older) have hearing loss. Globally, hearing loss has been identified as the fifth leading cause of years lived with disability. Successful hearing health care enables individuals with hearing loss to have the freedom to communicate in their environments in ways that are culturally appropriate and that preserve their dignity and function. Hearing Health Care for Adults focuses on improving the accessibility and affordability of hearing health care for adults of all ages. This study examines the hearing health care system, with a focus on non-surgical technologies and services, and offers recommendations for improving access to, the affordability of, and the quality of hearing health care for adults of all ages.

Trends in Development of Medical Devices covers the basics of medical devices and their development, regulations and toxicological effects, risk assessment and mitigation. It also discusses the maintenance of a medical device portfolio during product lifecycle. This book provides up-to-date information and knowledge on how to understand the position and benefits of new introduced medical devices for improving healthcare. Researchers and industry professionals from the fields of medical devices, surgery, medical toxicology, pharmacy and medical devices manufacture will find this book useful. The book's editors and contributors form a global, interdisciplinary base of knowledge which they bring to this book. Provides a roadmap to medical devices development and the integration of manufacturing steps to improve workflows Helps engineers in medical devices industries to anticipate the special requirements of this field with relation to biocompatibility, sterilization methods, government regulations Presents new strategies that readers can use to take advantage of rapid prototyping technologies, such as 3D printing, to reduce imperfections in production and develop products that enable completely new treatment possibilities

From bandage to the bioreactor, this book looks at five different device technologies from inception to healthcare practice, drawing on medical sociology, science and technology studies and political science. It examines 'evidence', regulation and governance processes, and diverse stakeholders in innovating the technologies that shape health care.

Medical devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the FDA 510(k) process. In recent years, individuals and organizations have expressed concern that the 510(k) process is neither making safe and effective devices available to patients nor promoting innovation in the medical-device industry. Several high-profile mass-media reports and consumer-protection groups have profiled recognized or potential problems with medical devices cleared through the 510(k) clearance process. The medical-device industry and some patients have asserted that the process has become too burdensome and is delaying or stalling the entry of important new medical devices to the market. At the request of the FDA, the Institute of Medicine (IOM) examined the 510(k) process. Medical Devices and the Public's Health examines the current 510(k) clearance process and whether it optimally protects patients and promotes innovation in support of public

health. It also identifies legislative, regulatory, or administrative changes that will achieve the goals of the 510(k) clearance process. Medical Devices and the Public's Health recommends that the U.S. Food and Drug Administration gather the information needed to develop a new regulatory framework to replace the 35-year-old 510(k) clearance process for medical devices. According to the report, the FDA's finite resources are best invested in developing an integrated premarket and postmarket regulatory framework.

"Biomedical Devices and Technology is a textbook for an introductory seminar course on biomedical devices and technology. The book covers devices and systems in diagnostic, surgical, and implant procedures, prepared by the much-respected faculty members at the UCLA School of Medicine"--

The rapid growth of home health care has raised many unsolved issues and will have consequences that are far too broad for any one group to analyze in their entirety. Yet a major influence on the safety, quality, and effectiveness of home health care will be the set of issues encompassed by the field of human factors research--the discipline of applying what is known about human capabilities and limitations to the design of products, processes, systems, and work environments. To address these challenges, the National Research Council began a multidisciplinary study to examine a diverse range of behavioral and human factors issues resulting from the increasing migration of medical devices, technologies, and care practices into the home. Its goal is to lay the groundwork for a thorough integration of human factors research with the design and implementation of home health care devices, technologies, and practices. On October 1 and 2, 2009, a group of human factors and other experts met to consider a diverse range of behavioral and human factors issues associated with the increasing migration of medical devices, technologies, and care practices into the home. This book is a summary of that workshop, representing the culmination of the first phase of the study.

Description based on: v. 2, copyrighted in 2012.

This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Medical Device Technologies: A Systems Based Overview Using Engineering Standards, Second Edition is a comprehensive overview of medical device technology, with a unified approach to each device area covering technical operation, clinical need, regulatory issues and standards and historical devices. It takes a systems-based view, balancing breadth with depth to give an accessible introduction to this field. Close ties are drawn between the design, the

product and the patient. Exercises at the end of each chapter include traditional homework problems, analysis exercises and four questions from assigned primary literature. Eight laboratory experiments in both electrical and mechanical medical devices are explored. Each medical device chapter begins with an exposition of appropriate physiology, mathematical modeling or biocompatibility issues and clinical need. A device system description and system diagram provide details on technology function and administration of diagnosis and/or therapy. This systems approach enables the reader to quickly identify the relationships between devices. An accompanying instructor site containing answers to end of chapter exercises, image collections, datasets and solutions for the lab experiments is also included. Covers current research, design issues and engineering standards Includes three significant Food and Drug Administration (FDA) recall case studies which have impacted FDA medical device regulation Presents exercises at the end of each chapter, including problems, analysis exercises and four questions from assigned primary literature Provides eight laboratory experiments that are detailed to provide hands-on reinforcement of device concepts

Medical Device Technologies introduces undergraduate engineering students to commonly manufactured medical devices. It is the first textbook that discusses both electrical and mechanical medical devices. The first 20 chapters are medical device technology chapters; the remaining eight chapters focus on medical device laboratory experiments. Each medical device chapter begins with an exposition of appropriate physiology, mathematical modeling or biocompatibility issues, and clinical need. A device system description and system diagram provide details on technology function and administration of diagnosis and/or therapy. The systems approach lets students quickly identify the relationships between devices. Device key features are based on five applicable consensus standard requirements from organizations such as ISO and the Association for the Advancement of Medical Instrumentation (AAMI). The medical devices discussed are Nobel Prize or Lasker Clinical Prize winners, vital signs devices, and devices in high industry growth areas Three significant Food and Drug Administration (FDA) recall case studies which have impacted FDA medical device regulation are included in appropriate device chapters Exercises at the end of each chapter include traditional homework problems, analysis exercises, and four questions from assigned primary literature Eight laboratory experiments are detailed that provide hands-on reinforcement of device concepts

Background papers 1 to 9 published as technical documents. Available in separate records from WHO/HSS/EHT/DIM/10.1 to WHO/HSS/EHT/DIM/10.9

This fourth edition is a substantial revision of a highly regarded text, intended for senior design capstone courses within departments of biomedical engineering, bioengineering, biological engineering and medical engineering, worldwide. Each chapter has been thoroughly updated and revised to reflect the latest developments. New material has been added on entrepreneurship, bioengineering design, clinical trials and CRISPR. Based upon feedback from prior users and reviews, additional and new examples and applications, such as 3D printing have been added to the text. Additional clinical applications were added to enhance the overall relevance of the material presented. Relevant FDA regulations and how they impact the designer’s work have been updated. Features Provides updated material as needed to each chapter Incorporates new examples and applications within each chapter Discusses new material related to entrepreneurship, clinical trials and CRISPR Relates critical new information pertaining to FDA regulations. Presents new material on "discovery" of projects "worth pursuing" and design for health care for low-resource environments Presents multiple case examples of entrepreneurship in this field Addresses multiple safety and ethical concerns for the design of medical devices and processes

This book introduces human factors engineering (HFE) principles, guidelines, and design methods for medical device design. It starts with an overview of physical, perceptual, and

cognitive abilities and limitations, and their implications for design. This analysis produces a set of human factors principles that can be applied across many design challenges, which are then applied to guidelines for the design of input controls, visual displays, auditory displays (alerts, alarms, warnings) and human-computer interaction. Specific challenges and solutions for various medical device domains, such as robotic surgery, laparoscopic surgery, artificial organs, wearables, continuous glucose monitors and insulin pumps, and reprocessing, are discussed. Human factors research and design methods are provided and integrated into a human factors design lifecycle, and a discussion of regulatory requirements and procedures is provided, including guidance on what human factors activities should be conducted when, and how they should be documented. This hands-on professional reference is an essential introduction and resource for students and practitioners in HFE, biomedical engineering, industrial design, graphic design, user-experience design, quality engineering, product management, and regulatory affairs.

Wearable and Implantable Medical Devices: Applications and Challenges, Fourth Edition highlights the new aspects of wearable and implanted sensors technology in the healthcare sector and monitoring systems. The book's contributions include several interdisciplinary domains, such as wearable sensors, implanted sensors devices, Internet-of-Things (IoT), security, real-time medical healthcare monitoring, WIBSN design and data management, encryption, and decision-support systems. Contributions emphasize several topics, including real-world applications and the design and implementation of wearable devices. This book demonstrates that this new field has a brilliant future in applied healthcare research and in healthcare monitoring systems. Includes comprehensive information on wearable and implanted device technology, wearable and implanted sensors design, WIBSN requirements, WIBSN in monitoring systems and security concepts Highlights machine learning and computing in healthcare monitoring systems based on WIBSN Includes a multidisciplinary approach to different healthcare applications and their associated challenges based on wearable and implanted technologies

Clinical Engineering Handbook, Second Edition, covers modern clinical engineering topics, giving experienced professionals the necessary skills and knowledge for this fast-evolving field. Featuring insights from leading international experts, this book presents traditional practices, such as healthcare technology management, medical device service, and technology application. In addition, readers will find valuable information on the newest research and groundbreaking developments in clinical engineering, such as health technology assessment, disaster preparedness, decision support systems, mobile medicine, and prospects and guidelines on the future of clinical engineering. As the biomedical engineering field expands throughout the world, clinical engineers play an increasingly important role as translators between the medical, engineering and business professions. In addition, they influence procedures and policies at research facilities, universities, and in private and government agencies. This book explores their current and continuing reach and its importance. Presents a definitive, comprehensive, and up-to-date resource on clinical engineering Written by worldwide experts with ties to IFMBE, IUPESM, Global CE Advisory Board, IEEE, ACCE, and more Includes coverage of new topics, such as Health Technology Assessment (HTA), Decision Support Systems (DSS), Mobile Apps, Success Stories in Clinical Engineering, and Human Factors Engineering

Americans praise medical technology for saving lives and improving health. Yet, new technology is often cited as a key factor in skyrocketing medical costs. This volume, second in the Medical Innovation at the Crossroads series, examines how economic incentives for innovation are changing and what that means for the future of health care. Up-to-date with a wide variety of examples and case studies, this book explores how payment, patent, and regulatory policies--as well as the involvement of numerous government agencies--affect the

introduction and use of new pharmaceuticals, medical devices, and surgical procedures. The volume also includes detailed comparisons of policies and patterns of technological innovation in Western Europe and Japan. This fact-filled and practical book will be of interest to economists, policymakers, health administrators, health care practitioners, and the concerned public.

Medical device professionals encounter numerous challenges from successfully developing a medical device company to understanding and navigating the various intellectual property issues that arise as they seek to protect and commercialize their inventions. This is an essential resource for understanding the nuances of protecting and launching a medical device in the United States and abroad. Written by IP and patent attorneys with experience representing the unique business needs of startups, entrepreneurs, and early-stage companies, this guide covers creating and leveraging patent portfolios; freedom to operate; limiting risk of infringement; trademarks in the context of medical devices; strategies for licensing and monetizing patents; and more.

The objective of the workshop that is the subject of this summary report was to present the challenges and opportunities for medical devices as perceived by the key stakeholders in the field. The agenda, and hence the summaries of the presentations that were made in the workshop and which are presented in this summary report, was organized to first examine the nature of innovation in the field and the social and economic infrastructure that supports such innovation. The next objective was to identify and discuss the greatest unmet clinical needs, with a futuristic view of technologies that might meet those needs. And finally, consideration was given to the barriers to the application of new technologies to meet clinical needs.

Internet of Things in Biomedical Engineering presents the most current research in Internet of Things (IoT) applications for clinical patient monitoring and treatment. The book takes a systems-level approach for both human-factors and the technical aspects of networking, databases and privacy. Sections delve into the latest advances and cutting-edge technologies, starting with an overview of the Internet of Things and biomedical engineering, as well as a focus on ‘daily life.’ Contributors from various experts then discuss ‘computer assisted anthropology,’ CLOUDFALL, and image guided surgery, as well as bio-informatics and data mining. This comprehensive coverage of the industry and technology is a perfect resource for students and researchers interested in the topic. Presents recent advances in IoT for biomedical engineering, covering biometrics, bioinformatics, artificial intelligence, computer vision and various network applications Discusses big data and data mining in healthcare and other IoT based biomedical data analysis Includes discussions on a variety of IoT applications and medical information systems Includes case studies and applications, as well as examples on how to automate data analysis with Perl R in IoT

This book provides a comprehensive approach to studying the principles and design of biomedical devices as well as their applications in medicine. It is written for engineers and technologists who are interested in understanding the principles, design and applications of medical device technology. The book is also intended to be used as a textbook or reference for biomedical device technology courses in universities and colleges. It focuses on the functions and principles of medical devices (which are the invariant components) and uses specific designs and constructions to illustrate the concepts where appropriate. This book selectively covers diagnostic and therapeutic devices that are either commonly used or that their principles and design represent typical applications of the technology. In this second edition, almost every chapter has been revised—some with minor updates and some with significant changes and additions. For those who would like to know more, a collection of relevant published papers and book references is added at the end of each chapter. Based on feedback, a section on “Common Problems and Hazards” has been included for each medical device. In addition, more information is provided on the indications of use and clinical

applications. Two new areas of medical device technology have been added in the two new chapters on “Cardiopulmonary Bypass Units” and “Audiology Equipment.”

Metallic Biomaterials Processing and Medical Device Manufacturing details the principles and practices of the technologies used in biomaterials processing and medical device manufacturing. The book reviews the main categories of metallic biomaterials and the essential considerations in design and manufacturing of medical devices. It bridges the gap between the designing of biomaterials and manufacturing of medical devices including requirements and standards. Main themes of the book include, manufacturing, coatings and surface modifications of medical devices, metallic biomaterials and their mechanical behaviour, degradation, testing and characterization, and quality controls, standards and FDA regulations of medical devices. The leading experts in the filed discuss the requirements, challenges, recent progresses and future research directions in the processing of materials and manufacturing of medical devices. Metallic Biomaterials Processing and Medical Device Manufacturing is ideal for those working in the disciplines of materials science, manufacturing, biomedical engineering, and mechanical engineering. Reviews key topics of biomaterials processing for medical device applications including metallic biomaterials and their mechanical behavior, degradation, testing and characterization Bridges the gap between biomaterials design and medical device manufacturing Discusses the quality controls, standards, and FDA requirements for biomaterials and medical devices

This book highlights recent advances in soft and stretchable biointegrated electronics. A renowned group of authors address key ideas in the materials, processes, mechanics, and devices of soft and stretchable electronics; the wearable electronics systems; and bioinspired and implantable biomedical electronics. Among the topics discussed are liquid metals, stretchable and flexible energy sources, skin-like devices, in vitro neural recording, and more. Special focus is given to recent advances in extremely soft and stretchable bio-inspired electronics with real-world clinical studies that validate the technology. Foundational theoretical and experimental aspects are also covered in relation to the design and application of these biointegrated electronics systems. This is an ideal book for researchers, engineers, and industry professionals involved in developing healthcare devices, medical tools and related instruments relevant to various clinical practices.

Addressing the exploding interest in bioengineering for healthcare applications, this book provides readers with detailed yet easy-to-understand guidance on biomedical device engineering. Written by prominent physicians and engineers, Medical Devices: Surgical and Image-Guided Technologies is organized into stand-alone chapters covering devices and systems in diagnostic, surgical, and implant procedures. Assuming only basic background in math and science, the authors clearly explain the fundamentals for different systems along with such topics as engineering considerations, therapeutic techniques and applications, future trends, and more. After describing how to manage a design project for medical devices, the book examines the following: Instruments for laparoscopic and ophthalmic surgery, plus surgical robotics Catheters in vascular therapy and energy-based hemostatic surgical devices Tissue ablation systems and the varied uses of lasers in medicine Vascular and cardiovascular devices, plus circulatory support devices Ultrasound transducers, X-ray imaging, and neuronavigation An absolute must for biomedical engineers, Medical Devices: Surgical and Image-Guided Technologies is also an invaluable guide for students in all engineering majors and pre-med programs interested in exploring this fascinating field.

This unique and comprehensive outcomes-based Code of Practice is the essential guide needed to plan, commission and provide good quality and effective Technology Enabled Care Services. The Code acts as a quality framework for procurement and provision of services, worldwide.

New drugs, new devices, improved surgical techniques, and innovative diagnostic procedures

and equipment emerge rapidly. But development of these technologies has outpaced evaluation of their safety, efficacy, cost-effectiveness, and ethical and social consequences. This volume, which is "strongly recommended" by The New England Journal of Medicine "to all those interested in the future of the practice of medicine," examines how new discoveries can be translated into better care, and how the current system's inefficiencies prevent effective health care delivery. In addition, the book offers detailed profiles of 20 organizations currently involved in medical technology assessment, and proposes ways to organize U.S. efforts and create a coordinated national system for evaluating new medical treatments and technology.
Machine Learning and the Internet of Medical Things in Healthcare discusses the applications and challenges of machine learning for healthcare applications. The book provides a platform for presenting machine learning-enabled healthcare techniques and offers a mathematical and conceptual background of the latest technology. It describes machine learning techniques along with the emerging platform of the Internet of Medical Things used by practitioners and researchers worldwide. The book includes deep feed forward networks, regularization, optimization algorithms, convolutional networks, sequence modeling, and practical methodology. It also presents the concepts of the Internet of Things, the set of technologies that develops traditional devices into smart devices. Finally, the book offers research perspectives, covering the convergence of machine learning and IoT. It also presents the application of these technologies in the development of healthcare frameworks. Provides an introduction to the Internet of Medical Things through the principles and applications of machine learning Explains the functions and applications of machine learning in various applications such as ultrasound imaging, biomedical signal processing, robotics, and biomechatronics Includes coverage of the evolution of healthcare applications with machine learning, including Clinical Decision Support Systems, artificial intelligence in biomedical engineering, and AI-enabled connected health informatics, supported by real-world case studies
Author Joseph Dyro has been awarded the Association for the Advancement of Medical Instrumentation (AAMI) Clinical/Biomedical Engineering Achievement Award which recognizes individual excellence and achievement in the clinical engineering and biomedical engineering fields. He has also been awarded the American College of Clinical Engineering 2005 Tom O'Dea Advocacy Award. As the biomedical engineering field expands throughout the world, clinical engineers play an evermore important role as the translator between the worlds of the medical, engineering, and business professionals. They influence procedure and policy at research facilities, universities and private and government agencies including the Food and Drug Administration and the World Health Organization. Clinical Engineers were key players in calming the hysteria over electrical safety in the 1970's and Y2K at the turn of the century and continue to work for medical safety. This title brings together all the important aspects of Clinical Engineering. It provides the reader with prospects for the future of clinical engineering as well as guidelines and standards for best practice around the world. * Clinical Engineers are the safety and quality faciltators in all medical facilities.
Recognize market opportunities, master the design process, and develop business acumen with this 'how-to' guide to medical technology innovation. Outlining a systematic, proven approach for innovation - identify, invent, implement - and integrating medical, engineering, and business challenges with real-world case studies, this book provides a practical guide for students and professionals.
In the past 50 years the development of a wide range of medical devices has improved the quality of people's lives and revolutionized the prevention and treatment of disease, but it also has contributed to the high cost of health care. Issues that shape the invention of new medical devices and affect their introduction and use are explored in this volume. The authors examine the role of federal support, the decision-making process behind private funding, the need for

reforms in regulation and product liability, the effects of the medical payment system, and other critical topics relevant to the development of new devices.

Successful product design and development requires the ability to take a concept and translate the technology into useful, patentable, commercial products. This book guides the reader through the practical aspects of the commercialization process of drug, diagnostic and device biomedical technology including market analysis, product development, intellectual property and regulatory constraints. Key issues are highlighted at each stage in the process, and case studies are used to provide practical examples. The book will provide a sound road map for those involved in the biotechnology industry to effectively plan the commercialization of profitable regulated medical products. It will also be suitable for a capstone design course in engineering and biotechnology, providing the student with the business acumen skills involved in product development.

Electrofluidodynamic Technologies (EFDTs) for Biomaterials and Medical Devices: Principles and Advances focuses on the fundamentals of EFDTs - namely electrospinning, electrospraying and electrodynamic atomization - to develop active platforms made of synthetic or natural polymers for use in tissue engineering, restoration and therapeutic treatments. The first part of this book deals with main technological aspects of EFDTs, such as basic technologies and the role of process parameters. The second part addresses applications of EFDTs in biomedical fields, with chapters on their application in tissue engineering, molecular delivery and implantable devices. This book is a valuable resource for materials scientists, biomedical engineers and clinicians alike. Presents a complete picture of Electrofluidodynamic technologies and their use in biomedicine Provides a comprehensive, professional reference on the subject, covering materials processing, fabrication and the use of novel devices for tissue engineering and therapeutics Focuses on technological advances, with an emphasis on studies and clinical trials

Design for Health: Applications of Human Factors delves into critical and emergent issues in healthcare and patient safety and how the field of human factors and ergonomics play a role in this domain. The book uses the Design for X (DfX) methodology to discuss a wide range of contexts, technologies, and population dependent criteria (X's) that must be considered in the design of a safe and usable healthcare ecosystem. Each chapter discusses a specific topic (e.g., mHealth, medical devices, emergency response, global health, etc.), reviews the concept, and presents a case study that demonstrates how human factors techniques and principles are utilized for the design, evaluation or improvements to specific tools, devices, and technologies (Section 1), healthcare systems and environments (Section 2), and applications to special populations (Section 3). The book represents an essential resource for researchers in academia as well as practitioners in medical device industries, consumer IT, and hospital settings. It covers a range of topics from medication reconciliation to self-care to the artificial heart. Uses the Design for X (DfX) methodology A case study approach provides practical examples for operationalization of key human factors principles and guidelines Provides specific design guidelines for a wide range of topics including resilience, stress and fatigue management, and emerging technologies Examines special populations, such as the elderly and the underserved Brings a multidisciplinary, multi-industry approach to a wide range of healthcare human factors issues

The goal of this textbook is to provide undergraduate engineering students with an introduction to commonly manufactured medical devices. It is the first textbook that discusses both electrical and mechanical medical devices. The first 20 chapters are medical device technology chapters; the remaining 8 chapters are medical device laboratory experiment chapters. Each medical device chapter begins with an exposition of appropriate physiology, mathematical modeling or biocompatibility issues, and clinical need. A device system description and system diagram provide details on technology function and administration of diagnosis and/or therapy.

The systems approach enables students to quickly identify the relationships between devices. Device key features are based on five applicable consensus standard requirements from organizations such as ISO and the Association for the Advancement of Medical Instrumentation (AAMI). Key Features: The medical devices discussed are Nobel Prize or Lasker Clinical Prize winners, vital signs devices, and devices in high industry growth areas Three significant Food and Drug Administration (FDA) recall case studies which have impacted FDA medical device regulation are included in appropriate device chapters Exercises at the end of each chapter include traditional homework problems, analysis exercises, and four questions from assigned primary literature Eight laboratory experiments are detailed that provide hands-on reinforcement of device concepts

Medical Coatings and Deposition Technologies is an important new addition to the libraries of medical device designers and manufacturers. Coatings enable the properties of the surface of a device to be controlled independently from the underlying bulk properties; they are often critical to the performance of the device and their use is rapidly growing. This book provides an introduction to many of the most important types of coatings used on modern medical devices as well as descriptions of the techniques by which they are applied and methods for testing their efficacy. Developers of new medical devices and those responsible for producing them will find it an important reference when deciding if a particular functionality can be provided by a coating and what limitations may apply in a given application. Written as a practical guide and containing many specific coating examples and a large number of references for further reading, the book will also be useful to students in materials science & engineering with an interest in medical devices. Chapters on antimicrobial coatings as well as coatings for biocompatibility, drug delivery, radiopacity and hardness are supported by chapters describing key liquid coating processes, plasma-based processes and chemical vapor deposition. Many types of coatings can be applied by more than one technique and the reader will learn the tradeoffs given the relevant design, manufacturing and economic constraints. The chapter on regulatory considerations provides important perspectives regarding the marketing of these coatings and medical devices.

Terahertz Biomedical and Healthcare Technologies: Materials to Devices reviews emerging advances in terahertz biomedical and healthcare technologies, including advances in fundamental materials science research, device design and fabrication, applications, and challenges and opportunities for improved performance. In addition, the improvement of materials, optical elements, and measuring techniques are also explored. Other sections cover the design and development of wide bandgap semiconductors for terahertz device applications, including their physics, device modeling, characterization and fabrication concepts. Finally, the book touches on potential defense, medical imaging, internet of things, and the machine learning applications of terahertz technologies. Reviews the latest advances in the fundamental and applied research of terahertz technologies, covering key topics in materials science, biomedical engineering and healthcare informatics Includes applications of terahertz technologies in medical imaging, diagnosis and treatment Provides readers with an understanding of the machine learning, pattern recognition, and data analytics research utilized to enhance the effectiveness of terahertz technologies