



TEST DISCIPLINE: ELECTRONICS- EMC
PRODUCT GROUP: EMI / EMC TEST FACILITY
GENERAL DETAILS

Customer / Applicant	Tekna Manufacturing Pvt. Ltd. C19, Industrial Estate Guindy Chennai, Tamil Nadu, 600032 IN		
Manufacturer	Same as applicant		
Program	Others		
Test Lab Location	(d) Others*	Refer to Cover page for address	
Item Under Test	Hyperbaric Chambers (Monoplace and Multiplace)		
Model	Modular Rectangular 6000-XYZ		
Number of Samples	01		
Sample Identification	001	Refer Summary of Test results for multiple samples	
Manufacturer Serial Number	Console: MUC-18-003 Pressure vessel: U 021/01		
Condition of IUT on receipt	Good		
Date of Receipt	16 May 2019		
Applicable Standard	IEC 60601-1-2:2014, Edition 4.0		
Date of Testing (Start date)	16 May 2019	End Date	2 July 2019
UL general^ ambient condition	Temperature in °C		23 ±5°C
	Relative humidity in %		<70 %
Date of Reporting	22 July 2019		
Test In-charge	Vinod Kumar T		

* Fill in the rows with information or add hyphen (-)

 Vinod Kumar T Engineer Project Associate	 Sreejo Gopinath Project Engineer
Prepared by	Approved by

Test Report Iec 60601 1 2 Medical Electrical Equipment

Olaf Dössel, Wolfgang C. Schlegel

A red circular graphic with a gradient, appearing as a partial circle or a stylized 'C' shape, located to the right of the author names.

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Medical Device Regulatory Practices Val Theisz, 2015-08-03 This book is intended to serve as a reference for professionals in the medical device industry particularly those seeking to learn from practical examples and case studies Medical devices like pharmaceuticals are highly regulated and the bar is raised constantly as patients and consumers expect the best quality healthcare and safe and effective

Medical Instrument Design and Development Claudio Becchetti, Alessandro Neri, 2013-07-29 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 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

Medical Device Regulations Aakash Deep, 2022-01-13 Medical Device Regulations A Complete Guide describes a brief review of various regulatory bodies of major developed and developing countries around the world The book covers the registration procedures of medical devices for pharmaceutical regulatory organizations Sections provide guidance on dealing with the ethical considerations of medical device development compliance with patient confidentiality using information from medical devices the interoperability between and among devices outside of healthcare and the dynamics of implementation of

new devices to ensure patient safety The author brings forth relevant issues challenges and demonstrates how management can foster increased clinical and non clinical relations to enhance patient outcomes and the bottom line by demystifying the regulatory impact on operational requirements Provides clear information on regulatory pathways for the design and commercialization of Medical Devices in different countries Explains the difference between standards and mandatory regulations for each region along with discussions of regulations from USFDA USA CDSCO India EMEA European Union SFDA China and PMDA Japan Compiles regulations for medical devices and pharmaceuticals worldwide helping readers create globally compliant products Inspection of Medical Devices Almir Badnjević, Mario Cifrek, Ratko Magjarević, Zijad Džemić, 2023-11-26 This comprehensive guide invites nations worldwide to embark on a transformative journey implementing independent third party verification systems that ensure medical devices comply with both international and national regulations Prepare to be captivated as we delve into the intricate processes unveil essential procedures and illuminate the paramount importance of establishing traceability for medical device measurements Imagine a world where medical devices undergo rigorous independent safety and performance verification guaranteeing the utmost reliability for patient diagnoses and treatment This book takes you on a compelling exploration of precisely that vision Focusing on cutting edge diagnostic and therapeutic devices it captures the very essence of the latest international directives and regulations ensuring you stay ahead of the curve This new edition goes beyond the conventional delving into the realms of innovation and progress Unveiling in depth maintenance regimes within healthcare institutions we provide you with invaluable insights into post market surveillance As the world embraces the transformative potential of artificial intelligence we pave the way for evidence based management of medical device maintenance a concept poised to reshape the healthcare landscape Imagine a future where medical devices are seamlessly integrated into the legal metrology system while fully operational national laboratories for medical device inspection set new standards of excellence This book vividly illustrates how such a powerful union can elevate the reliability of medical devices in diagnosis and patient care Brace yourself for a paradigm shift that not only enhances efficacy but also leads to significant cost reductions within your country s healthcare system Join us on this extraordinary journey as we unveil the untapped potential of medical device inspection With our innovative approach and unrivaled expertise together we can revolutionize healthcare transforming the lives of countless patients worldwide Get ready to be inspired informed and empowered welcome to the future of healthcare **Annual Report of the Office of Science and Technology** Center for Devices and Radiological Health (U.S.). Office of Science and Technology, 1997

Design and Development of Medical Electronic Instrumentation David Prutchi, Michael Norris, 2005-01-28 Design and Development of Medical Electronic Instrumentation fills a gap in the existing medical electronic devices literature by providing background and examples of how medical instrumentation is actually designed and tested The book includes practical examples and projects including working schematics ranging in difficulty from simple biopotential amplifiers to

computer controlled defibrillators Covering every stage of the development process the book provides complete coverage of the practical aspects of amplifying processing simulating and evoking biopotentials In addition two chapters address the issue of safety in the development of electronic medical devices and providing valuable insider advice

Bioelectronics and Medical Devices Kunal Pal,Heinz-Bernhard Kraatz,Anwasha Khasnobish,Sandip Bag,Indranil Banerjee,Usha Kuruganti,2019-06-15 Bioelectronics and Medical Devices From Materials to Devices Fabrication Applications and Reliability reviews the latest research on electronic devices used in the healthcare sector from materials to applications including biosensors rehabilitation devices drug delivery devices and devices based on wireless technology This information is presented from the unique interdisciplinary perspective of the editors and contributors all with materials science biomedical engineering physics and chemistry backgrounds Each applicable chapter includes a discussion of these devices from materials and fabrication to reliability and technology applications Case studies future research directions and recommendations for additional readings are also included The book addresses hot topics such as the latest state of the art biosensing devices that have the ability for early detection of life threatening diseases such as tuberculosis HIV and cancer It covers rehabilitation devices and advancements such as the devices that could be utilized by advanced stage ALS patients to improve their interactions with the environment In addition electronic controlled delivery systems are reviewed including those that are based on artificial intelligences Presents the latest topics including MEMS based fabrication of biomedical sensors Internet of Things certification of medical and drug delivery devices and electrical safety considerations Presents the interdisciplinary perspective of materials scientists biomedical engineers physicists and chemists on biomedical electronic devices Features systematic coverage in each chapter including recent advancements in the field case studies future research directions and recommendations for additional readings

Healthcare Technology Management - A Systematic Approach Francis Hegarty,John Amooore,Paul Blackett,Justin McCarthy,Richard Scott,2017-01-06 Healthcare Technology Management A Systematic Approach offers a comprehensive description of a method for providing safe and cost effective healthcare technology management HTM The approach is directed to enhancing the value benefit in relation to cost of the medical equipment assets of healthcare organizations to best support patients clinicians and other care providers as well as financial stakeholders The authors propose a management model based on interlinked strategic and operational quality cycles which when fully realized delivers a comprehensive and transparent methodology for implementing a HTM programme throughout a healthcare organization The approach proposes that HTM extends beyond managing the technology in isolation to include advancing patient care through supporting the application of the technology The book shows how to cost effectively manage medical equipment through its full life cycle from acquisition through operational use to disposal and to advance care adding value to the medical equipment assets for the benefit of patients and stakeholders This book will be of interest to practicing clinical engineers and to students and lecturers and includes self directed learning

questions and case studies Clinicians Chief Executive Officers Directors of Finance and other hospital managers with responsibility for the governance of medical equipment will also find this book of interest and value For more information about the book please visit the website **Technical specifications for pre-market assessment of blood pressure measuring device with cuff, automated and semi-automated** World Health Organization,2023-09-21 To provide technical specifications to blood pressure measuring device with cuff automated and semi automated for manufacturers who intend to seek their WHO prequalification PQ Manufacturers should consider the technical specifications outlined as minimum requirements for participating in the PQ programme in order to ensure that the blood pressure measurement device has been designed evaluated and validated in conformity with these requirements and is therefore safe and effective

Clinical Engineering Handbook Joseph Dyro,2004-09-15 As the biomedical engineering field expands throughout the world clinical engineers play an evermore important role as translators between the medical engineering and business professions They influence procedure and policy at research facilities universities as well as private and government agencies including the Food and Drug Administration and the World Health Organization The profession of clinical engineering continues to seek its place amidst the myriad of professionals that comprise the health care field The Clinical Engineering Handbook meets a long felt need for a comprehensive book on all aspects of clinical engineering that is a suitable reference in hospitals classrooms workshops and governmental and non governmental organization The Handbook s thirteen sections address the following areas Clinical Engineering Models of Clinical Engineering Practice Technology Management Safety Education and Training Design Manufacture and Evaluation and Control of Medical Devices Utilization and Service of Medical Devices Information Technology and Professionalism and Ethics The Clinical Engineering Handbook provides the reader with prospects for the future of clinical engineering as well as guidelines and standards for best practice around the world From telemedicine and IT issues to sanitation and disaster planning it brings together all the important aspects of clinical engineering Clinical Engineers are the safety and quality facilitators in all medical facilities The most definitive comprehensive and up to date book available on the subject of clinical engineering Over 170 contributions by leaders in the field of clinical engineering **FAA Implementation of the Aviation Medical Assistance Act of 1998 (should**

Defibrillators be Required on Aircraft and at Airports) United States. Congress. House. Committee on Transportation and Infrastructure. Subcommittee on Aviation,2002 Technical specifications of radiotherapy equipment for cancer treatment ,2021-03-05 **Federal Register** ,2014 *Compendium of Biomedical Instrumentation, 3 Volume Set* Raghbir Singh Khandpur,2020-02-25 An essential reference filled with 400 of today s current biomedical instruments and devices Designed mainly for the active bio medical equipment technologists involved in hands on functions like managing these technologies by way of their usage operation principle of operation which covers physics engineering electronics and data processing brief specifications and major applications Devices listed range from the accelerometer ballistocardiograph

microscopes lasers and electrocardiograph to gamma counter hyperthermia system microtome positron emission tomography uroflowmeter and many more Covers almost the entire range of medical instruments and devices which are generally available in hospitals medical institutes at tertiary secondary and peripheral level facilities Presents broad areas of applications of medical instruments technology including specialized equipment for various medical specialties fully illustrated with figures photographs Contains exhaustive description on state of the art instruments and also includes some generation old legacy instruments which are still in use in some medical facilities Compendium of Biomedical Instrumentation is a must have resource for professionals and undergraduate and graduate students in biomedical engineering as well as for clinical engineers and bio medical equipment technicians Handbook of Antennas for EMC, Second Edition Thereza M. MacNamara, John McAuley, 2018-09-30 Finally a completely revised updated and expanded edition of the Artech House classic Handbook of Antennas for EMC The second edition features a wealth of brand new material including chapters on recent techniques standards and measurements This invaluable resource provides a thorough understanding of the practical aspects and underpinnings of antennas in EMC systems Professionals find summaries of important underlying mathematics without the heavy theoretical emphasis that characterizes much of the existing literature Professionals discover which antennas to choose for electromagnetic EM compatibility and compliance Moreover this authoritative book offers a solid understanding of the main characteristics of an antenna in a qualitative manner Essential reading for EMC engineers this volume provides the knowledge needed to determine the right antenna for specific applications and offers guidance in conducting EMC testing **XIV Mediterranean Conference on Medical and Biological Engineering and Computing 2016** Efthymoulos Kyriacou, Stelios Christofides, Constantinos S.

Pattichis, 2016-03-31 This volume presents the proceedings of Medicon 2016 held in Paphos Cyprus Medicon 2016 is the XIV in the series of regional meetings of the International Federation of Medical and Biological Engineering IFMBE in the Mediterranean The goal of Medicon 2016 is to provide updated information on the state of the art on Medical and Biological Engineering and Computing under the main theme Systems Medicine for the Delivery of Better Healthcare Services Medical and Biological Engineering and Computing cover complementary disciplines that hold great promise for the advancement of research and development in complex medical and biological systems Research and development in these areas are impacting the science and technology by advancing fundamental concepts in translational medicine by helping us understand human physiology and function at multiple levels by improving tools and techniques for the detection prevention and treatment of disease Medicon 2016 provides a common platform for the cross fertilization of ideas and to help shape knowledge and scientific achievements by bridging complementary disciplines into an interactive and attractive forum under the special theme of the conference that is Systems Medicine for the Delivery of Better Healthcare Services The programme consists of some 290 invited and submitted papers on new developments around the Conference theme presented in 3

plenary sessions 29 parallel scientific sessions and 12 special sessions **IV Latin American Congress on Biomedical Engineering 2007, Bioengineering Solutions for Latin America Health, September 24th-28th, 2007, Margarita Island, Venezuela** Carmen Müller-Karger, Sara Wong, Alexandra La Cruz, 2007-11-07 The IV Latin American Congress on Biomedical Engineering CLAIB2007 corresponds to the triennial congress for the Regional Bioengineering Council for Latin America CORAL it is supported by the International Federation for Medical and Biological Engineering IFMBE and the Engineering in Medicine Biology Society IEEE EMBS This time the Venezuela Society of Bioengineering SOVEB organized the conference with the slogan Bioengineering solution for Latin America health Neuromodulation Elliot Krames, P. Hunter Peckham, Ali R. Rezai, 2018-01-05 Neuromodulation Comprehensive Textbook of Principles Technologies and Therapies Second Edition serves as a comprehensive and in depth reference textbook covering all aspects of the rapidly growing field of neuromodulation Since the publication of the first edition seven years ago there has been an explosion of knowledge in neuromodulation optogenetics bioelectronics medicine and brain computer interfacing Users will find unique discussions of the fundamental principles of neuromodulation and therapies and how they are applied to the brain spinal cord peripheral nerves autonomic nerves and various organs The book focuses on comprehensive coverage of spinal cord stimulation non interventional and interventional brain stimulation peripheral nerve stimulation and the emerging fields of neuromodulation including optogenetics and bioelectronics medicine Provides a comprehensive reference that covers all aspects of the growing field of neuromodulation Written by international leading authorities in their respective fields of neuromodulation pain management functional neurosurgery and biomedical engineering Includes new chapters on optogenetics bioelectronics medicine and brain computer interfacing World Congress on Medical Physics and Biomedical Engineering September 7 - 12, 2009 Munich, Germany Olaf Dössel, Wolfgang C. Schlegel, 2010-01-04 Present Your Research to the World The World Congress 2009 on Medical Physics and Biomedical Engineering the triennial scientific meeting of the IUPESM is the world's leading forum for presenting the results of current scientific work in health related physics and technologies to an international audience With more than 2 800 presentations it will be the biggest conference in the fields of Medical Physics and Biomedical Engineering in 2009 Medical physics biomedical engineering and bioengineering have been driving forces of innovation and progress in medicine and healthcare over the past two decades As new key technologies arise with significant potential to open new options in diagnostics and therapeutics it is a multidisciplinary task to evaluate their benefit for medicine and healthcare with respect to the quality of performance and therapeutic output Covering key aspects such as information and communication technologies micro and nanosystems optics and biotechnology the congress will serve as an inter and multidisciplinary platform that brings together people from basic research R D industry and medical application to discuss these issues As a major event for science medicine and technology the congress provides a comprehensive overview and in depth first hand information on new developments advanced technologies and current and

future applications With this Final Program we would like to give you an overview of the dimension of the congress and invite you to join us in Munich Olaf D ssel Congress President Wolfgang C **Biomedical Engineering Design** Joseph Tranquillo,Jay Goldberg,Robert Allen,2022-02-19 Biomedical Engineering Design presents the design processes and practices used in academic and industry medical device design projects The first two chapters are an overview of the design process project management and working on technical teams Further chapters follow the general order of a design sequence in biomedical engineering from problem identification to validation and verification testing The first seven chapters or parts of them can be used for first year and sophomore design classes The next six chapters are primarily for upper level students and include in depth discussions of detailed design testing standards regulatory requirements and ethics The last two chapters summarize the various activities that industry engineers might be involved in to commercialize a medical device Covers subject matter rarely addressed in other BME design texts such as packaging design testing in living systems and sterilization methods Provides instructive examples of how technical marketing regulatory legal and ethical requirements inform the design process Includes numerous examples from both industry and academic design projects that highlight different ways to navigate the stages of design as well as document and communicate design decisions Provides comprehensive coverage of the design process including methods for identifying unmet needs applying Design for X and incorporating standards and design controls Discusses topics that prepare students for careers in medical device design or other related medical fields

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