Course Structure for M.Tech. (2 year), M.Tech. + Ph.D. Dual Degree in Biomedical Devices from AY 2025-2026

Scope of the Program:

The M.Tech. program in **Biomedical Devices** is designed for providing students with outstanding and higher fundamental education coupled with applied research to pursue their career in Biomedical Engineering. These students will be an asset to medical device industries, hospitals, research institutions and teaching organizations with outstanding technical expertise in interdisciplinary domains. The structure of this program is to give a holistic perspective and to provide a blend of industry and research-oriented courses to train in the design and development of medical devices. This program also covers the aspects of safety and regulations of medical devices for business and clinical purposes. High quality, engaging career-based postgraduate education, rigorous fundamental-applied curriculum, and contemporary delivery in terms of teaching, assignments, term projects, and conducting labs. High-quality applied and translational research will result in excellent advanced research training, connecting deeply with industry, in turn enhancing the quality of research.

Minimum Educational Qualification (MEQ) (For Indian applicants):

i. B.E./B.Tech. /AMIE or equivalent in Biomedical Engineering (BM), Biotechnology (BT), Chemical Engineering (CH), Computer Science and Information Technology (CS), Electrical Engineering (EE), Electronics and Communication Engineering (EC), Engineering Physics (EP), Instrumentation Engineering (IN), Mechanical Engineering (ME), Metallurgy & Materials Science (MT), Engineering Sciences (XE), Pharmaceutical Technology (PY) (with the first division as defined by the awarding Institute/University)

OR

ii. M.Sc. or equivalent in Biotechnology (BT), Electronics / Electronic Sciences (EC), Ergonomics (ER), Materials Science (MS), Physics (PH), (with the first division as defined by the awarding Institute/University),

OR

iii. *Health Sciences such as MBBS (Medicine) / BDS (Dental), B. Pharm. (Duration 4 years or more) (with the first division as defined by the awarding Institute/University)

Qualifying Examination (QE):

Valid GATE score in Biomedical Engineering (BM), Chemical Engineering (CH), Computer Science and Information Technology (CS), Electrical Engineering (EE), Electronics and Communication Engineering (EC), Physics (PH), Instrumentation Engineering (IN), Mechanical Engineering (ME), Metallurgy & Materials Science (MT), Life Sciences (XL), Biotechnology (BT), Engineering Sciences (XE).

***Non-GATE** (i.e., Option iii in MEQ) students must pass in all India-level postgraduate entrance examinations for corresponding disciplines such as INI_CET/NEET-PG/NEET-MDS/JIPMER/ PGI Chandigarh/AFMC-Pune/DNB Part I for MBBS/BDS, GPAT/ All India level selection examination for B.Pharm. Eligibility/rank certificates for all such all India-level entrance examinations are required. The candidate should have qualified the entrance exam (as per the qualification criterion of the

respective exam for that exam year and category) and the score obtained should be valid (as per the duration of validity for the respective exam) at the time of application to the M.Tech. program.

Categories of Admission:

Indian applicants: Teaching Assistantship **(TA)**; (ii) Highly motivated sponsored candidate **(SW)** on full-time basis from highly reputed R and D organizations such as DRDO, ISRO, BHEL, C-DAC, ADE, ADA, etc. and highly reputed Industries; (iii) Defense Forces **(DF)**: Candidates sponsored by the Defense Forces; (iv) Regular Institute Staff **(IS)** of IIT Indore on part-time basis only.

Candidates of SW, DF and IS categories will not be provided any scholarship.

Selection Criteria: The admission of students (under TA category) to M.Tech. in Biomedical Devices program will be based on:

a) their qualifying discipline and the valid GATE score and written test or interview or both.
b) for non- GATE candidates, admission will be based on a valid score in the respective qualifying exam and written test or interview or both.

Duration of the Program: Two years (Full-time).
Total Intake: 30 TA (27 through GATE, 3 Non-GATE).
Scholarship (only for TA category Indian students): As per MoE norms.

Course Structure for two-year Full-time M.Tech. in Biomedical Devices

1st Year: Semester-I

Course code	Course Title	Contact Hours (L-T-P)	Credits
BSE 614*	General Physiology	2-1-0	3
BSE 635*	Biomaterials and Nano-biotechnology	2-1-0	3
BSE 637*	Bioelectronics and Biomedical Sensors	2-1-0	3
BSE 644/444*	Biomedical Signal and Image Processing	2-1-0	3
BSE 6XX	Medical Device Design and Dissection	0-1-4	3
BSE 6XX/4XX	Modeling and Controls in Medical Devices	2-1-0	3
BSE 6XX	Elective-I	2-1-0	3
BSE 6XX	Clinical Immersion	0-0-2	1
Total minimum credits earned during the semester			**22.0**
Additional course (as per the requirement basis)			
HS 641*	English Communication Skills	2-0-2	P/NP

1st Year: Semester-II

Course code	Course Title	Contact Hours (L-T-P)	Credits
BSE 643/443*	Applied Biomechanics	2-1-0	3
BSE 6XX/4XX	Measurement and Testing of Medical Devices	2-1-0	3
BSE 6XX	Design of Implantable and Surgical Devices	2-0-2 (Half Semester)	1.5
BSE 6XX	Regulatory Framework and Quality Compliance	2-2-0 (Half Semester)	2
BSE 6XX	Medical Device Laboratory	0-0-3	1.5
BSE 698	PG Seminar Course	0-2-0	2
BSE 6XX	Advance Clinical Immersion Training	0-0-2	1
BSE XXX	Elective-II	2-1-0	3
ZZ XXX	Elective-III	2-1-0	3
Total minimum credits earned during the semester			**20.0**

2nd Year: Semester–III

Course code	Course Title	Contact Hours (L-T-P)	Credits
BSE 6XX/4XX	Preclinical and Clinical Trial Design	2-1-0	3
BSE 7XX	M.Tech. Research Project (Stage–I)	0-0-30	15
Total minimum credits to be earned during the semester			**18**

2nd Year: Semester–IV

Course code	Course Title	Contact Hours (L-T-P)	Credits
BSE 8XX	M.Tech. Research Project (Stage–II)	0-0-36	18
Total minimum credits to be earned during the semester			18
Total minimum credits to be earned during the program			**78**

** Already approved existing course*

Courses for Electives

	Course code	Course Title	Contact Hours (L-T-P)	Credits
Stream 1: Medical devices and Instrumentation	BSE 604/404*	Biomedical Imaging	2-1-0	3
	BSE 636*	Biomedical Instrumentation	2-1-0	3
	BSE 640*	Biomedical Microsystems	2-1-0	3
	BSE 6XX/4XX	Wearable Devices and Sensors	2-1-0	3
Stream 2: Regenerative Medicine	BSE 646*	Biofabrication	1-0-4	3
	BSE 639*	Tissue Engineering and Regenerative Medicine	2-1-0	3
	BSE 638*	Mechanobiology and Electrophysiology	2-1-0	3
	BSE 608*	Advanced Drug Delivery Systems	2-1-0	3

** Already existing course*

 # Suggestive institute electives related to the program:

Course code	Course Title	Contact Hours (L-T-P)	Credits
ME 679*	Additive Manufacturing	2-1-0	3
ME 604*	Microfluidics	2-1-0	3

[@]In addition to this course list, a student can also opt from the PG courses being offered by the other department/school as well as BSBE**.**

** Already existing course*

NOTE: 1. Request for conversion from M.Tech to M.Tech + PhD dual degree will be considered after evaluating the research potential of the promising and motivating PG students at the end of the **third semester of their program.** Confirmation of the PhD program in the FA category will be subject to successfully qualifying for CSIR/UGC-JRF or equivalent fellowship.

2. If the student opts for a Dual Degree Programme but cannot complete the requirements of a PhD, an **exit option** with the M.Tech degree can be earned at the end of the final semester of the normal M.Tech programme by getting the M.Tech research project examined in the standard manner as per the requirements for the award of an M.Tech degree.

3. The enhancement in the scholarship, if any, from M.Tech. to PhD will be from the beginning of the fifth semester or from the date on which all requirements for the award of M.Tech. degree are fulfilled, whichever is later**.**

Course Code	**BSE 6XX/4XX**
Title of the Course	**Medical Device Design and Dissection**
Course Category	**Core**
Credit Structure	L-T-P-Credits 0-1-4-3
Name of the Concerned Department	Biosciences and Biomedical Engineering
Pre–requisite, if any	Nil
Course Objective	• Overview of basic engineering design concepts and principles in developing medical diagnostic devices. • Providing relevant fundamental design philosophies for the students to apply for the design of diagnostic devices. • Giving an understanding of the mechanical/electromechanical functioning of medical devices through hands-on dissection.
Course outcomes	1. Creating the skill of identifying medical device opportunities through observations, interviews, and research. 2. Exposure to clinical need identification, stakeholder interviews, ideation, and prototyping 3. Practical experience in design and techniques used in medical devices.
Course Syllabus	**Introduction:** Clinical Foundations of Medical Device Innovation, Common diagnostic devices and principle. **Need statement:** Need findings and Need statement development, Framework for conceptualization, Disease state fundamentals, Stakeholder analysis, Need statement filtering. Concept generation and screening. **Identification of Design parameters and design controls**: Design History File, Design Proposal, Declaration of Design and Performance, Inputs, Outputs, Specifications, Verification, Validation, Transfer Concept finalization, and prototyping. List of representative experiments or mini-projects: Structural and functional studies of various medical devices, including ● Stethoscope ● ECG Machine ● Pulse oximetry ● Hemodialysis machine ● Nebulizer ● Syringe pump ● Patient monitoring systems ● Ventilators ● X-ray imaging system ● Ultrasound scanners
Suggested Books	**Reference Books**: 1. P. G. Yock, S. Zenios, and J. Makower, **Biodesign the Process of Innovating Medical Technologies**, 2nd edition, Cambridge University press, 2016. ISBN: 9780521517423.

	2. M. Kutz, **Biomedical Engineering & Design Handbook, Volumes I and II**, 2nd edition, McGraw-Hill Education, 2009. ISBN: 9780071498401. 3. K. Otto and K. Wood, **Product Design: Techniques in Reverse Engineering and New Product Development**, 1st edition, Pearson, 2001. ISBN: 978-0130212719.

Course Code	**BSE 6XX/4XX**
Title of the Course	**Modeling and Controls in Medical Devices**
Course Category	**Core**
Credit Structure	L-T-P-Credits 2-1-0-3
Name of the Concerned Department	Biosciences and Biomedical Engineering
Pre–requisite, if any	Nil
Course Objective	• Covers principles and concepts of control systems and estimation theory for biomedical systems and devices. • Providing relevant biomedical applications of the control systems and estimation techniques.
Course outcomes	1. An in-depth understanding of control systems relevant to medical devices. 2. Understand the principles and concepts of control systems for modeling and estimation applicable to biomedical devices.
Course Syllabus	**Basic concepts of statistical decision theory**: models and detector structures; performance evaluation; Chernoff bounds and large deviations; sequential detection, quickest change detection, robust detection. Applications in noninvasive diagnosis, parameter estimation. **Filters:** Linear minimum variance filter and properties, processing and estimation of movements from noisy sensor recording, sensor fusion. **Control Fundamentals** ● Mathematical modeling of Electrical/Mechanical systems, Force-Velocity, Force-Current analogy. Block diagram, signal flow graph. Laplace transformation. ● Transient response; transient performance specifications Steady-state errors; final value theorem; system type; steady-state performance specifications. ● Root locus analysis and stability; closed-loop root locations and transient performance. ● Frequency response analysis methods; frequency response performance specifications ● Feedback control techniques: Proportional, Integral, Derivative, Proportional-Integral, Proportional- Derivative, Proportional- Integral-Derivative control **Case study**: Control of mechanical ventilator.
Suggested Books	**Text Books:** 1. K. Ogata, **Modern Control Engineering**, 5th edition. Pearson, 2015, ISBN: 9789332550162.

	2. O. Boubakar, **Control Theory in Biomedical Engineering Application in Physiology and Medical Robotics**. 1st edition, Academic Press. 2020. ISBN: 9780128213506. **Reference Book:** 3. J. S. Bendat and A. G. Pearsol, **Random Data - Analysis and Measurement Procedures**. 4th edition, Wiley, 2010, ISBN: 978-0470248775.

Suggested Course code	**BSE 6XX**
Title of the course	**Clinical Immersion**
Course Category	Core
Credit Structure	L-T-P-Credits 0-0-2-1
Name of the Concerned Department	Biosciences and Biomedical Engineering
Prerequisite, if any	None
Course Objectives	• Exposure to clinically used medical devices and understanding the clinically faced issues with the devices.
Course Outcomes	At the end of the course, students will have practical experience in device operation and real clinical needs.
Course Content	Visit hospitals and learn the devices used in clinical settings. Interactions with clinical doctors, staff, and technicians. Identification of actual clinically relevant problems, their documentation, report preparation, and exploration of these as project ideas to address those problems.
Suggested Books (Text Books, Reference Books)	**Reference Books:** 1. R. S. Khandpur, **Handbook of biomedical instrumentation**, 3rd edition, Tata McGraw Hill Publishing Company Limited, 2014, ISBN: 9789339205430. 2. K. Willson, K. Ison, and S. Tabakov, **Medical Equipment Management**, 1st edition, CRC Press, 2013, ISBN: 9781420099591.

Suggested Course code	**BSE 6XX/ BSE 4XX**
Title of the course	**Measurement and Testing of Medical Devices**
Course Category	Core
Credit Structure	L-T-P-Credits 2-1-0-3
Name of the Concerned Department	Biosciences and Biomedical Engineering
Prerequisite, if any	None
Course Objectives	• Covers principles and concepts of biomedical measurements and origins of biopotential • This will provide various facets of medical device development

Course Outcomes	1. The students will be able to describe the medical device measurements and facets of medical device development. 2. It helps to apply principles and concepts of electronics, and signal processing in medical measurements.
Course Content	**Biomarkers**: Cell resting potential and action potentials, origin of bioelectric potentials, pressure, motion, and force measurement. Measurement of flow, biomarkers used in diagnostic medical devices. **Instrumentation types**: Fundamental & importance of instrumentation, types of instruments, selection of instruments, performance of instruments, error in measurement, calibration & standard, calibration of instruments. Methods & analysis, introduction to transducer & types, process instrumentation, recording instruments, indicating & recording instruments. **Medical measurements**: Types of medical measurements, characteristics, considerations in the design of medical devices, precision, accuracy, noise characterization and filtering, Electrocardiogram, Electroencephalogram, Electromyogram. **Medical devices case studies**: Principles of diagnostic and therapeutic equipment: blood pressure monitors, pulse oximeters, pH meters, pacemakers, defibrillators, nerve and muscle stimulators, dialysis machines, nebulizers, inhalators, aspirators, humidifiers, ventilators and spirometry. Infrared and near-infrared application, ultra-violet lamp and laser application, endoscopy, laparoscopy.
Suggested Books (Text Books, Reference Books)	**Text Books:** 1. J. G. Webster. **Medical Instrumentation: Application and Design**, 4th edition. John Wiley & Sons, 2015. ISBN: 9788126553792. 2. R. A. Normann, **Principles of Bioinstrumentation**, 1st edition, John Wiley & Sons,1988. ISBN: 9780471605140. **Reference Book:** 3. P. David and N. Michael, **Design and development of Medical Electronic instrumentation**, 1st edition, Wiley, 2004. ISBN 9780471676232.

Course Code	**BSE 6XX/4XX**
Title of the Course	**Design of Implantable and Surgical Devices**
Course Category	**Core**
Credit Structure	L-T-P-Credits 2-0-2-3 **(3/2 = 1.5, Half Semester)**
Name of the Concerned Department	Biosciences and Biomedical Engineering
Pre–requisite, if any	Nil
Course Objective	• Imparting rational approaches to the development of implantable medical devices. • Students will be able to work in groups to develop the design for

	surgical/implantable devices. • Providing relevant fundamental design philosophies of surgical and implantable devices.
Course outcomes	The students will be able to identify biomedical device functional requirements, derive specifications, draft solution matrices and propose device design specifications.
Course Syllabus	**Design principles**: Four design principles for medical devices, and clinical problems requiring implants for solution. **Device requirements:** Paradigm for designing medical devices/implants, functional requirements, effects of the device on the body. benefit/risk ratio, biocompatibility. **Types of engineered implants:** Principles of implant design, design parameters, permanent versus absorbable devices, tissue engineering scaffolds, biomaterial selection, implants for bone. **Surgical devices**: disruptive innovation of surgical devices, surgical devices, laparoscopic surgical devices and robotic surgical devices, medical ethics and federal regulation. List of representative experiments / mini project: • Design of polymeric scaffolds • Design flexible electrodes • Design of a pacemaking circuit • Modeling and analysis of Laparoscopic scissor • Bite force measurement • Validation of implants through animal cell culture
Suggested Books	**Text Books:** 1. P. Ogrodnik, **Medical Device Design: Innovation from Concept to Market**.1st edition, Academic Press, 2012, ISBN: 9780123919427. 2.B. D. Ratner,A. S. Hoffmann,F. J. Schoen, J. E. Lemons. **Biomaterials science: An introduction to materials in medicine**, 3rd edition, Academic Press, 2013, ISBN: 9780080470368. **References Book:** 3. M. Kutz, **Biomedical Engineering & Design Handbook, Volumes I and II**, 2nd edition, McGraw-Hill Education, 2009, ISBN: 9780071498401.

Course Code	**BSE 6XX**
Title of the Course	**Regulatory Framework and Quality Compliance**
Course Category	**Core**
Credit Structure	L-T-P-Credits 2-2-0-4 **(4/2 = 2, Half Semester)**
Name of the Concerned Department	Biosciences and Biomedical Engineering

Pre–requisite, if any	Nil
Course Objective	• Understand the risk management process throughout the life span of medical devices. • Gain knowledge of the roles of manufacturers, importers/vendors, government, users, and the public in device safety and performance. • Learn about international regulatory frameworks and the work of the Global Harmonization Task Force (GHTF).
Course outcomes	1. Students will be able to understand regulatory compliance frameworks globally. 2. Able to be proficient in risk management and quality assurance, as well as capable of conducting health-economic evaluations.
Course Syllabus	**Introduction to Medical Device Regulation**: Overview of medical devices and health technology assessment, highlighting key regulatory and reimbursement hurdles. Role and mission of the Central Drug Standard Control Organization (CDSCO), Food and Drug Administration (FDA), and World Health Organization (WHO) in medical device regulation through case studies. **Life Span and Regulatory Frameworks**: Utilization of devices lifespan diagram; Roles of stakeholders in risk management. Critical elements in medical device life span. Common regulatory framework and the tools of Global Harmonization Task Force (GHTF). Regulatory programs and international actions for product control steps. **Risk-based approach to trial management**: Risk in trial design and execution, adaptive trial designs and contingency planning-ensuring trial integrity. **Health Economics, Risk Management, and Case Studie**s: Health-economic methods and case studies, including cost analysis, outcomes analysis, cost-effectiveness, and budget impact analysis. Regulatory pathways and FDA classifications, including pre- and post-market activities, Total Product Lifecycle.
Suggested Books	**Text Books:** 1. C. F. Richard. **Medical Device Quality Assurance and Regulatory Compliance**, 1st edition., CRC Press, 2019. ISBN: 978-0367400361. 2. S. Weinberg. **Cost-contained regulatory compliance: For the Pharmaceutical, Biologics, and Medical Device Industries**, 1st edition, John Wiley& Sons Inc., 2011. ISBN: 978-0470552353. **Reference Book:** 3. L. Williams. **How-to write quality compliance documentation: policy and setting the tone for controlling process**. London Press, 2020. ISBN: 979-8663416344

Suggested Course code	**BSE 6XX/ BSE 4XX**
Title of the course	**Medical Device Laboratory**
Course Category	Core
Credit Structure	L-T-P-Credits 0-0-3-1.5
Name of the Concerned Department	Biosciences and Biomedical Engineering

Prerequisite, if any	None
Course Objectives	To gain hands-on experience in different medical device operations and their use in clinics, finding common artefacts, and device testing.
Course Outcomes	1. At the end of the course, students will have practical experience in device operation and testing in the biomedical engineering domain. 2. Students will learn to build and develop medical devices.
Course Content	List of representative experiments or mini-project : ● Building Bio-signal Amplifiers & Filters. ● Signal acquisition and processing algorithms for biomedical devices in Matlab ● Developing an Electrocardiography circuit and measurements ● Building pulse oximetry circuits and testing ● Building digital stethoscope circuits and measurements ● 3-D printed biomaterial scaffold development and evaluation ● Tensile, compression, and flexure testing of biomaterials ● Microscopy: Imaging of biological specimens using fluorescence staining and staining methods, physical parameter extraction from images.
Suggested Books (Text Books, Reference Books)	**Reference Books:** 1. J. G. Webster, **Medical Instrumentation: Application and Design**, 4th edition. John Wiley & Sons, 2015, ISBN: 9788126553792. 2. P. David and N. Michael, **Design and development of Medical Electronic instrumentation**, 1st edition, Wiley, 2004. ISBN 9780471676232.

Suggested Course code	**BSE 6XX**
Title of the course	**Advance Clinical Immersion Training**
Course Category	Core
Credit Structure	L-T-P-Credits 0-0-2-1
Name of the Concerned Department	Biosciences and Biomedical Engineering
Prerequisite, if any	None
Course Objectives	● Providing exposure to clinically used medical devices and understanding the clinically faced issues with the devices.
Course Outcomes	Students will have practical experience in device operation and real clinical needs.
Course Content	Visit hospitals for exposure to advanced devices while they are in use in the clinical settings, and understanding the design requirements. Identification of challenges, gaps and new requirements for devices in focused areas, such as Radiology and Neurorehabilitation. Interactions with clinical doctors, staff, and technicians.

	Collation of actual clinically relevant problems, their documentation, report preparation, and exploration of these as project ideas to address those problems.
Suggested Books (Text Books, Reference Books)	**Reference Book:** 1. R. S. Khandpur, **Handbook of biomedical instrumentation**, 3rd edition, Tata McGraw-Hill Publishing Company Limited, 2014, ISBN: 9789339205430. 2. K. Willson, K. Ison, and S. Tabakov, **Medical Equipment Management**, 1st edition, CRC Press, 2013, ISBN: 9781420099591.

Course Code	**BSE 6XX/4XX**
Title of the Course	**Preclinical and Clinical Trial Design**
Course Category	**Core**
Credit Structure	L-T-P-Credits 2-1-0-3
Name of the Concerned Department	Biosciences and Biomedical Engineering
Pre–requisite, if any	Nil
Course Objective	• Learn preclinical and clinical research conduct, ensuring compliance with national and international regulations for marketing approval. • Learn to use a risk-based approach to ensure the safety and effectiveness of medical devices. • Explore statistical considerations for effective study design and address ethical issues related to preclinical and clinical research.
Course outcomes	1. Students will be able to make plans and decide on preclinical and clinical trials development and documentation. 2. Able to understand concepts in the design of clinical trials.
Course Syllabus	**Introduction:** Overview of drug development process, Stages from discovery to market approval, preclinical versus clinical trials, Regulatory agencies and guidelines, Role of Central Drug Standard Control Organization, European Medicines Agency, Indian Pharmaceutical Association, and Food and Drug Administration. **Preclinical trial design:** Non-clinical testing fundamentals-importance and types (in vitro, in vivo, ex vivo). Preclinical models, selection criteria, model types and relevance to human conditions. Safety and toxicity testing-adverse effects and dose determination. **Clinical trial phases and design:** Real-world evidence, Early feasibility studies, Patient preference, Phases-I (safety), II (efficacy), III (confirmatory), and IV (post-marketing), trial design-randomized controlled trials, cohort studies, case-control studies, cross-sectional studies. Endpoints and outcomes-primary and secondary endpoints, surrogate markers. Sample size calculation-statistical consideration and power analysis. **Clinical trial reporting and post-trial considerations**: Consolidated Standards of Reporting Trials guidelines, and ethics in reporting results.

	Post-trial considerations, long-term follow-up, and post-marketing surveillance.
Suggested Books	**Text books:** 1. L. Friedman, C. Furberg, D. DeMets, D. Reboussin and C. Granger, **Fundamentals of Clinical Trials**, 5th edition, Springer, 2015. ISBN: 9783319307732. 2. J. Cook, **An Introduction to Clinical Trials**, 1st edition, Oxford University Press, 2023. ISBN: 9780198885238. 3. D. Machin, S. Day, and S. Green, **Textbook of Clinical Trials**, 2nd edition, Wiley, 2010. ISBN: 9788126524945. **Reference Book:** 4. D. Machin, P. Fayers and BC Tai, **Randomized Clinical Trials: Design, Practice and Reporting**, 1st edition, Wiley-Blackwell, 2021. ISBN: 9781119524649.