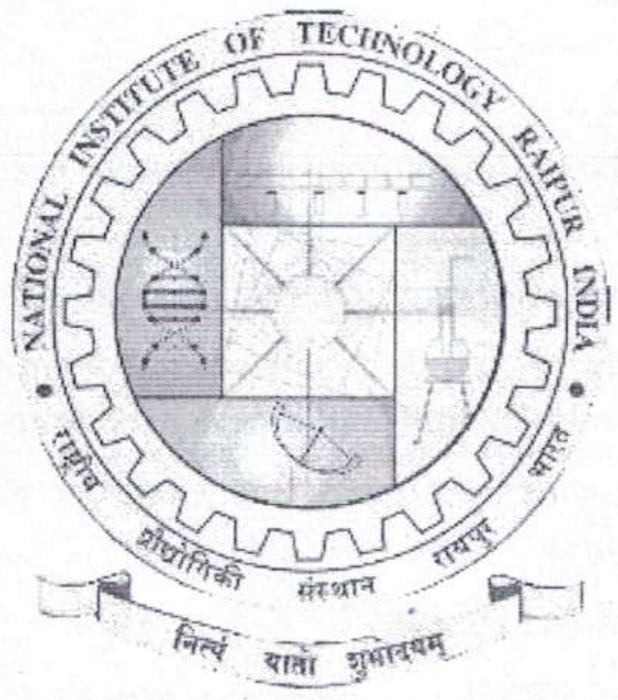
Course Structure and Curriculum

Master of Technology

in

Medical Devices

(Effective from 2025-2026)



Biomedical Engineering Department

National Institute of Technology Raipur- 492010

VISION AND MISSION OF THE INSTITUTE

VISION

To be a leader in technical and management education in India and to establish a unique identity for the development of high-quality human and knowledge resources in diverse areas of technology and management.

MISSION

To mould young students into rational thinking engineers/individuals who are motivated by a passion for professional excellence driven by human values and proactively engaged in betterment of society

VISION AND MISSION OF THE DEPARTMENT

VISION

To provide society with world class competitive professionals in Biomedical Engineering by making the department as the best through its faculty and graduates, which is a driving force in creating engineering knowledge and novel Biomedical Technology that improve the human condition through advancement of healthcare and Biomedical Sciences.

MISSION

- To educate students to understand the human body as an integrated system through quantitative engineering analysis.
- To use the above understanding to design better therapeutic strategies, devices, and diagnostics.
- To serve society by conducting research that develops quantitative linkages across scales in the human body and uses that development to build new tools to improve human health.
- To serve our wider constituencies by offering our expertise to other health-related professionals, industries, and state communities

Program Educational Objectives (PEOs)

The *Program Educational Objectives* (PEOs) embody the expected accomplishments of students, who successfully graduate from the program. The PEOs for the proposed program are as follows.

PEO-1	Apply technical knowledge and skills as Biomedical Engineers to provide the solutions for the industries and government organizations pertaining to medical devices sectors
PEO-2	Utilize effective communication, team, and project management skills to work productively within their professions and communities.
PEO-3	Conduct themselves in a responsible, professional and ethical manner.
PEO-4	Inculcate an attitude for lifelong learning process

Mapping of *Program Educational Objectives* (PEOs) to *Mission Statements* (MS)

(Program Articulation Matrix)

Mission Statements	PEO-1	PEO-2	PEO-3	PEO-4
MS-1	3	2	3	3
MS-2	2	3	2	3
MS-3	2	3	2	3
MS-4	3	2	2	3

1-Slight; 2-Moderate; 3-Substantial

Program Outcomes (POs):

The following *POs* attainment would help the successful students passing through the program to achieve the aforementioned PEOs.

PO1: Possess knowledge of modern technological concepts, conduct in-depth studies and experiments and solve practical problems related to Medical Devices.

PO2: Work on multi-disciplinary projects to enhance skills, make effective oral presentations and prepare technical documents effectively.

PO3: Develop professional and ethical attitude and become socially responsible citizens.

PO4: Ability to understand global issues and conduct independent research in the emerging areas related to Medical Devices or interdisciplinary areas.

Mapping of *Graduate Attributes* (GAs) to *Program Educational Objectives* (PEOs)

PEOs	PO1	PO2	PO3	PO4
PEO-1	√	√	√	√
PEO-2	√	√	√	√
PEO-3	√	√	√	
PEO-4	√	√	√	√

Course Outcomes (COs)

Course outcomes are narrower statements that describe what students are expected to know and are able to do at the end of each course. These relate the skills, knowledge and behavior that students acquire in their progress through the course.

Four Cos needs to be identified for each of the course and to be mapped with POs

Program Specific Outcomes (PSOs)

PSO-01	Graduating students will be able to apply fundamental knowledge of mathematics, science and biomedical engineering to investigate, identify, formulate and design complex problems in the engineering and computational medical devices and allied multidisciplinary areas ensuring the use of latest technological developments in the section of critical care medical equipment and in-vitro diagnostic medical equipment, while creating sensor fabrication and regenerative medicine fabrication facilities.
PSO-02	Graduating students will be able to develop and apply the appropriate techniques and modern engineering tools to solve complex real-life problems by working with a multidisciplinary team and inculcate skills for life-long and self-learning.

Steps followed to assess POs through COs

Following steps are being followed to assess POs through CO's:
Step 1: Relationships between each course's outcomes (CO's) and PO's have been established. Step 2: Quantification of relationnel values between PO's & CO's and their corresponding weights using the scale from 1 (Least relation) to 3 (Very strong relation).
Step 3: Attainment of course outcome (CO's).
Step 4: Attainment of COs for one semester through appropriate rubrics

Based on the attainment of CO for the particular course, the attainments of POs for the same are calculated as mentioned below:
The PO attainment for the subjects is calculated by multiplying the normalized values of each of the PO with the attained CO of the course. The same procedure is carried out for all the courses (Theory courses (T), Laboratory courses (L) and Project (P) etc.) of the M. Tech Medical Devices.

Engineering PG program.

POi Attainment= (sum of Individual POi attainment/ sum of Individual Normalized POi) The overall attainment of the POs for a session is calculated based on the formula: Overall PO Attainment (PO) = 0.5×Theory+0.1×Lab+0.4×Project

Using the above formula overall PO attainment for M.Tech. Medical Devices will be evaluated. Overall attainment will be reviewed to conclude that the assessment tools are systematically in place.

CO/PO	PO1	PO2	PO3	PO4
CO1	√	√	√	√
CO2	√	√	√	√
CO3	√	√	√	
CO4	√	√	√	√

Preamble

Biomedical engineering is an interdisciplinary department. Its focus is on creating systems that experimentally and computationally analyze any medical engineering system, uses modern tools such as digital twins, integrative biosensors, AI/ML, Data Science, Additive Manufacturing, biomimetics, smart bio-materials, and information to support medical fraternity with engineering solutions. One of the Institute's core departments, the Department of Biomedical Engineering, was founded in 2003. At the moment, it provides UG, and PhD courses. The Department is continuously improving its facilities in the fields of healthcare integrated AI-ML, Medical Device Design Engineering, Regenerative medicine and biomaterial engineering, biophysics, and biosensor engineering. The Biomedical Engineering Department at NIT Raipur boasts a highly qualified and knowledgeable staff. The Department of Biomedical Engineering not only has strength in the traditional areas of AI-ML in healthcare, Medical Devices, and Regenerative materials and mechanics, use of modern computational tools, but it also supports a number of other disciplines, including Material Science, Computational techniques, and Chemical Sciences.

Details of Master of Technology in Medical Devices

The Department of Biomedical Engineering at the National Institute of Technology (NIT), Raipur is pleased to announce the launch of a comprehensive Master of Technology (M. Tech) program in Medical Devices. This program is being introduced with the goal of advancing knowledge and encouraging innovation in the field of medical devices. Students will be provided with a comprehensive understanding of theoretical underpinnings, practical applications, and cutting-edge innovations in the area through the completion of this program, which is designed to meet the requirements of industry 4.0 and the present needs of the industry.

Course Structure and Detailed Curriculum

Semester wise Credit Distribution					
Semester	I	II	III	IV	**Total**
Credits	20	20	20	20	**80**

M.Tech (Medical Devices)

SEMESTER I

CODE	SUBJECT		L	T	P	C
	Program Core (03)		**3**	**1**	**0**	**3**
BM311101BM	Regulatory and Quality Compliance of Critical care and IVD Instruments		**3**	**1**	**0**	**3**
BM311102BM	Critical Care and IVD Instrumentation		**3**	**1**	**0**	**3**
BM311103BM	Advanced fabrication processes in medical devices		**3**	**1**	**0**	**3**
	2 Electives are offered in Sem I		**3**	**1**	**0**	**3**
BM311201BM **BM311202BM** **BM311203BM**	**List of Elective - I Sem I**	Foundation of human biology for medical devices Physiological control system in medical device Medical Imaging system				
BM311204BM **BM311205BM** **BM311206BM**	**List of Elective - II Sem I**	Electrical Safety of Patients Fluidics in Medical Devices: Diagnostic and IVD Devices Principles Mathematical modeling in medical device perspective				
BM311401BM	**Medical Device Lab 1:** Quality testing procedure for medical equipment		**0**	**0**	**3**	**2**
BM311402BM	**Medical Device Lab 2:** Fabrication Methods of Medical Device		**0**	**0**	**3**	**2**
BM311403BM	**Seminar and Report Writing / Industrial Training**		**0**	**0**	**1**	**1**
Total Credit			**20**			

SEMESTER II

CODE	SUBJECT		L	T	P	C
	Program Core (03)					
BM312101BM	Basics of Biosensors and Bioelectronics		**3**	**1**	**0**	**3**
BM312102BM	Tissue Engineering and Device Interaction		**3**	**1**	**0**	**3**
BM312103BM	IoT and AI-ML in medical devices		**3**	**1**	**0**	**3**
	2 Electives are offered in Sem II		**3**	**1**	**0**	**3**
BM312201BM **BM312202BM**	**List of Elective-III Sem II**	Bioelectricity Design, Fabrication, and Testing of Medical Devices and Implants				
BM312203BM **BM312204BM** **BM312205BM**	**List of Elective-IV Sem II**	Characterization of Medical Device Sterilization Techniques for Medical Devices Drug Delivery system				
BM312401BM	**Medical Device Lab 4:** Biosensor and Bioelectronics		**0**	**0**	**3**	**2**
BM312402BM	**Medical Device Lab 5:** Tissue Engineering and Device Interaction		**0**	**0**	**3**	**2**
BM312403BM	**Seminar and Report Writing / Industrial Training**		**0**	**0**	**3**	**1**
Total Credits						**20**

SEMESTER III

CODE	SUBJECT		L	T	P	C
	Hands on Training (any four course to be taken)		**4**	**0**	**8**	**8**
BM313301BM **BM313302BM** **BM313303BM** **BM313304BM** **BM313305BM** **BM313306BM** **BM313307BM** **BM313308BM**	**Seminar and Report Writing (Technical White Paper) / Hands on Training**	ECG and Bedside Monitor System Defibrillator and Heart Lung Machine Ventilator and Anesthesia Machine Hemodialyzer and Endoscope Single and Multi-Channel Semi auto biochemistry Analyzer Full Auto Biochemistry Analyzer and Arterial Blood Gas Analyzer ELISA and PCR Instrument Blood Cell Count Analyzer and Mass Spectroscopy Instrument				
BM313501BM	Minor M. Tech Thesis		**0**	**0**	**24**	**12**
Total Credits						**20**

SEMESTER IV

CODE	SUBJECT	L	T	P	C
BM314501B	M.Tech Project	**0**	**0**	**40**	**20**
Total Credits					**20**

Semester wise learning outcome:

Semester I:

First semester the course covers practical applications of regulatory and quality compliances of medical devices, helping students comprehend and solve complex engineering challenges in designing. In the course of the foundation of human biology for medical devices, students will be able to develop critical thinking and correlation of medical devices while integrating them as extracorporeal systems / parts of the human system. Mathematical models shall be extensively used in this semester for developing models of medical devices parametric characterization, as well as for modeling biological control systems for integrating and synchronizing with medical devices. Advanced fabrication processes shall also be elaborated for developing different types of biosensors for integrating with medical devices. Electives offered in this semester are going to make the foundation of either critical care instrumentation, or fluidics instrumentations in medical devices. Three hands-on labs will cover mathematical modeling of medical devices, quality testing procedures for medical devices, and illustration of fabrication processes of medical devices. This course is crucial to the program since it develops students' professional and interpersonal skills. This course integrates mathematical topics with computational tools to prepare for medical devices expertise.

Semester II:

Biosensor and bioelectronics of medical devices will be taught this semester. Medical Devices M. Tech disciplines are chosen for their interdisciplinary teaching and field relevance. Courses in tissue engineering and device interaction, bioelectricity shall be taught, while emphasizing the integration of medical devices with the human body. In this semester, IoT and AI-ML integration to medical devices shall also be elaborated. It will also be associated with an integrated laboratory session. Data-driven computational simulations, optimization, and decision-making are growing. Electives include electrical safety of patients and diagnostic and IVD devices. Three Engineering Labs: biosensor and bioelectronics lab, tissue engineering and device interaction lab, and AI and ML in medical device lab. This semester shall also consist of industrial training at the end of the semester. This internship lets students correlate their coursework with industrial scenarios, and shall innovate them to draw better engineering solutions to medical device designing. Fundamentals, specialization, and cutting-edge technology make the Medical Device M. Tech course noteworthy. Industrial needs are satisfied by teaching regulatory affairs, quality controls, and device design of medical devices widely and allowing students to specialize in electives and labs.

Semester III:

A variety of specialist electives hands on training sessions are available to students, such as training on ECG and Bedside monitor machine, Defibrillator and heart lung machine, ventilator and anesthesia machine, hemodialyzer and endoscope machine, single and multi-channel semi -auto and full auto biochemistry analyzer machine, arterial blood gas analyzer machine, ELISA and PCR machine, and Blood cell count analyzer machine. Students can gain practical experience in machine handling, troubleshooting, components observation and understanding, and analysis of the results / performance of characteristic curves of various parameters derived from the machine with respect to variation in testing point voltages and currents; and correlated to other fluidic and optical parameters. Students shall complete an extensive project in the last semester, where they put their medical device designing knowledge to use by solving real-world problems.

Semester IV:

During the last semester, students get the opportunity to showcase their expertise in medical devices by

doing a comprehensive and original research project. This Master of Technology program in

Medical Devices is designed to give students a well-rounded education in the subject by covering both the fundamentals and the most recent developments in the area. We strive to graduate students who can make significant contributions to Medical Device innovation through innovative research, technological advancements, and practical applications in industry.

Feasibility and Applicability:

The M. Tech in Medical Devices uniquely emphasizes practical applications, providing hands-on experience in solving complex engineering challenges related to medical device design. Its applicability is strengthened by seamlessly integrating device design principles, aligning with contemporary trends, and employing an interdisciplinary approach that addresses a broad range of engineering problems. The program's industry relevance is further highlighted by its focus on device designing integration, offering specialized electives and practical components with live medical devices from the sector of therapeutic and IVD medical devices, ensuring graduates are well-equipped for real-world applications.

Practical Applications: The course covers practical applications of medical device regulatory affairs, providing students with hands-on experience in solving complex engineering challenges.
AI Integration: Incorporation of AI principles, including probability and statistics, enhances the course's feasibility by aligning it with contemporary technology trends.
Interdisciplinary Approach: The interdisciplinary teaching approach, combining computational mechanics with AI and ML, makes the course feasible for addressing diverse engineering problems. **Sensor development:** The integration of AI and ML in computational sensor development addresses real-world engineering problems creatively, preparing students for data-driven simulations, optimization, and decision-making.
Specialized Electives: Electives from the domain of critical care devices and IVD devices shall enhance applicability by allowing students to specialize in areas aligned with industry demands.
Hands on Training Sessions: The inclusion of courses on hands-on training sessions of medical devices at factory setup shall build confidence among students, as well as make them comfortable to recruit medical devices to work on real time medical device designing problems.

Job Perspectives:

Graduates with an M. Tech in Medical Devices are well-positioned for diverse and high-demand roles across industries. In sectors like data analytics, pharmaceutics, IVD associations, Medical Device manufacturing associations, device quality control and regulatory issues, BIS in medical devices, Patent officers in medical devices, they can contribute to optimizing designs, analyzing results, evolving modification in innovative designs, and utilizing AI for data-driven decision-making. Specialized expertise in areas such as biofluid dynamics and flows modeling opens avenues in healthcare sectors. Additionally, proficiency in high-performance computing gained during the program equips graduates for roles in research institutions and technology-driven companies. The unique blend of medical device designing and AI skills prepares them for careers at the forefront of technological advancements, addressing complex challenges in specific industries with a strong foundation in both theory and practical application.

Versatility: Graduates can explore various career paths due to the program's versatility, covering areas such

as optimization engineering, biosensor development, device development, and fluidics in IVD. **Industry Relevance:** Addressing industrial needs through broad coverage of medical devices and specialization in electives ensures graduates are equipped with skills relevant to industry demands.
Project-Based Learning: Practical experience gained through labs, minor projects, and extensive projects in each semester enhances graduates' readiness for industry roles.
Innovation and Research: The focus on a comprehensive and original research project in the final semester prepares graduates to contribute to innovative advancements in medical devices, fostering research-oriented job opportunities.

Overall, the M. Tech in Medical Devices course appears feasible, applicable to real-world engineering challenges, and promising in terms of job perspectives, aligning well with industry needs and technological advancements.

Admission Criterion

The admission criterion for the course will be identical to that of the present PG program being conducted at the Department and will be in accordance with the rules of the Institute and CCMT. The eligibility is as follows:
B. Tech in Biomedical Engineering and related branches, Mechanical Engineering, Chemical Engineering, Material Science Engineering, Electrical Engineering, Electronics and Telecommunication Engineering, Bachelor of Pharmacy, MBBS, BDS and related GATE examination qualifications will be eligible for admission.

Number of seats : 30 (Reservation as per Government norms)

Resources

Manpower:
Presently the Department has a faculty strength of 10 regular faculties. All these faculties belong to the proposed stream and in future the strength is going to be increased.

Infrastructure, Labs and Equipment:
The lab requisition for the proposed course is evaluated on the basis of the scheme offered above. Requisite number of **classrooms** is available with the department. In addition to that, infrastructural support is also committed by the Ministry of Pharmaceuticals and Fertilizers.

Course Code: BM311101BM	Subject Name: Regulatory and Quality Compliance of Critical care and IVD Instruments	Credits (L-T-P-Cr) : 3-1-0-3

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Analyze the regulatory environment for medical devices in India and globally.	PO1
CO2	Apply knowledge of the Indian Medical Device Rules (2017) for the classification and registration of medical devices.	PO2
CO3	Evaluate the risk management process in the development and manufacturing of medical devices.	PO2
CO4	Apply ISO 13485 and GMP guidelines in the design and manufacture of medical devices.	PO1
CO5	Apply the steps in the regulatory approval process for medical devices in India	PO2
CO6	Evaluate clinical trial protocols for medical device approval and conformity assessment.	PO3
CO7	Evaluate the ethical, legal, and social challenges in the regulation of medical devices.	PO3
CO8	Create strategies to address emerging compliance challenges in the medical device industry.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3
CO5	2	1	-	1	3	3
CO6	3	3	2	2	3	3
CO7	3	3	3	3	3	3
CO8	2	3	2	1	3	3

Unit	Syllabus

Unit 1	**Introduction to Medical Device Regulations and Standards Topics Covered:** • **Introduction to Medical Devices**: Types, classifications, and categories of medical devices. • **Regulatory Bodies in India**: CDSCO (Central Drugs Standard Control Organization), National Pharmaceutical Pricing Authority (NPPA), and their roles. • **Overview of Indian Medical Device Rules, 2017**: Classification, registration, and regulatory requirements for medical devices in India. • **Global Regulatory Landscape**: FDA (USA), CE (Europe), TGA (Australia), and WHO guidelines. **ISO 13485**: Quality management systems for medical devices.
Unit 2	**Quality Management Systems and Risk Management Topics Covered:** • **ISO 13485:2016**: Quality management system requirements for medical devices. • **Risk Management in Medical Devices**: ISO 14971 for risk assessment and management in medical devices. • **Good Manufacturing Practices (GMP)**: Regulations and guidelines for medical device manufacturing in India. • **Clinical Evaluation and Validation**: Requirements for In Vitro Diagnostic (IVD) and Critical Care Devices. **Post-market Surveillance and Vigilance**: Regulatory requirements for market monitoring and reporting adverse events.
Unit 3	**Regulatory Approval and Conformity Assessment Topics Covered:** • **Regulatory Approval Process in India**: Application for medical device registration, importation, and market authorization. • **Clinical Trials and Ethical Considerations**: Requirements and ethical considerations for clinical trials in medical device approval. • **Conformity Assessment**: CE marking, US FDA approval, and their role in product certification. • **Device Labeling and Packaging Compliance**: Regulatory requirements for medical device labeling in India. **Inspection and Audits**: Role of CDSCO in inspections and audits.
Unit 4	**Compliance Challenges and Future of Medical Device Regulations Topics Covered:** • **Emerging Technologies in Medical Devices**: Impact of AI, robotics, and digital health technologies on regulations. • **Challenges in Compliance**: Issues related to counterfeit medical devices, import restrictions, and evolving standards. • **Global Harmonization of Medical Device Regulations**: Trends towards international regulatory standards and their implications for India. • **Ethical, Legal, and Social Aspects**: Ethical concerns in medical device approvals and patient safety. **Case Studies**: Analyzing regulatory issues and compliance failures in the medical device industry.

References

1. MEDICAL DEVICE REGULATIONS: Global overview and guiding principles by WHO
2. "Indian Medical Device Regulations" by CDSCO Guidelines. CDSCO - Medical Device Rules, 2017\
3. "A Practical Field Guide for ISO 13485:2016: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes" by Erik V. Myhrberg, Joseph Raciti, Brandon L. Myhrberg.
4. "Safety Risk Management for Medical Devices" by European Institute of Innovation and Tec Elahi, Bijan, International System Safety Society (ISSS).
5. "Fundamentals of Medical Device Regulations" by Gert Bos and Jocelyn Jennings
6. "Medical Device Guidelines and Regulations Handbook" by Nandakumar Palani, Prakash Srinivasan Timiri Shanmugam, Pugazhenthan Thangaraju, Thamizharasan Sampath

Course Code: BM311102BM	Subject Name: Critical Care and IVD Instrumentation	Credits (L-T-P-Cr) : 3-1-0-3

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students should able to understand and realize the need for critical care medical devices	PO1
CO2	Should be able to apply the basic knowledge of engineering to know the application and utility of different recording and therapeutic devices in the medical sector.	PO2
CO3	Student should be able to design and develop the prototype of critical care medical devices	PO3
CO4	Create strategies to address emerging critical care instruments and their challenges in the medical device industry.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	P O 1	P O 2	P O 3	P O 4	PSO 1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Unit	Syllabus
Unit 1	**Principles and instrumentation of cardiac care recording and therapeutic instruments** Electrocardiograph, Vectorcardiography, Phonocardiograph, Biofeedback Instrumentation, Cardiac Monitor, Cardiotocography, Method of monitoring fetal heart rate, monitoring labor activity, Pulse oximeter and intravascular oximeter, Cardiac pacemaker, implantable pacemakers, recent development in implantable pacemaker, pacing system analyzer, DC defibrillator, Implantable defibrillator, Types of implantable defibrillator, Pacer-cardioverter defibrillator, defibrillator analyzer, left ventricular assist device (LVAD)
Unit 2	**Principles and instrumentation of CCU based instruments** Instrumentation in CCU: Anesthesia machine, heart lung machine, capnograph, oxygenators, IABP, neonatal-ICU related devices, bioanalytical and biocatalytical instruments; Mechanics of respiration and Pulmonary function measurement, Spirometry, Pneumotachometers, Measurement of lung volume, Pulmonary function analyzers, Respiratory gas analyzer, Artificial ventilation,, Humidifiers, Nebulizers, and Aspirators; Function of the kidneys and artificial kidney, Dialyzers, Principle and membranes for hemodialyzers, Hemodialyzer machine, Home (portable) kidney machines, The stone disease problem and shock wave, Lithotriptor. Special care units and advanced monitoring systems: Bedside Monitors, Patient monitoring circuits and real data acquisition, ECG/Physiological Telemetry, Automated drug delivery systems.

Unit 3	**Principle and instrumentation of semi and full auto biochemistry analyzer**, Arterial blood gas analyzer: physical principle of analytes detection, block diagrams, components integration, electrical communication, optical filtering and signal conditioning, signal to noise ratio enhancement procedures. Principle and instrumentation of ELISA and PCR instruments: physic-chemical principles, blocks of fluidics actions, ELISA biochemical reaction kinematics, amplification techniques, PCR biochemistry, instrumentation, filtering techniques, amplification and signal conditioning techniques
Unit 4	**Unit 4: Principle and instrumentation of Blood Cell Count Analyzer and Mass Spectroscopy instruments:** Impedance techniques, optical techniques of blood cell counting, different assays, physical principles, implementing instrumentation dynamics; mass spectroscopy instruments instrumentation principles. Principle and instrumentation of Point of care devices: concepts, principles, architecture, sensor integration, sensitivity and specificity evaluation.

References

Biomedical Instrumentation, R S Khandpur
Carr and Brown Introduction to Biomedical Equipment Technology, 4th Edition, Pearson

Course Code: BM311103BM	**Subject Name:** Advanced fabrication processes in medical devices	**Credits (L-T-P-Cr): 3-1-0-3**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students should be able to understand the workflow for personalized medical devices	PO1
CO2	Students should be able to identify and apply the concepts of additive manufacturing in developing medical devices	PO2
CO3	Students should be able to analyze and evaluate the physics and the technology behind the micro and nano fabrication methods for developing medical devices.	PO3
CO4	Students should be able to justify and create different bio fabrication processes for designing different medical devices.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	P O 1	P O 2	P O 3	P O 4	PSO 1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Unit	**Syllabus**

Unit 1	**Introduction to personalized medical devices** • **Need for Medical Device Personalization:** Introduction to Personalization of Medical devices, Advantages of personalized medical devices. • **In-silico testing of medical devices** Introduction and importance to in-silico testing, Importance and application for in-silico testing. • **In-vivo and ex-vivo testing of medical devices** Importance and comparison of the in-vivo and ex-vivo testing of medical devices, Static loading, Dynamic loading, Impact - Charpy and Izod tests, Thermogravimetric analysis, Differential Scanning Calorimetry, Thermomechanical analysis.
Unit 2	**Additive manufacturing technology and rapid form copying for enhancing the development process of bio devices** • **Introduction to Additive Manufacturing and Rapid Product Development:** Design optimization, Rapid prototyping and manufacturing technologies, Di Matteo's process, Baese's process. • **Additive Manufacturing processes with impact on biomedical field:** Overview of various additive manufacturing techniques, Materials used for additive manufacturing - powder, liquid, and solid, Selective laser sintering (SLS), Stereo-lithography, Digital light processing (DLP), Direct laser writing, Fused deposition modeling, Selective Laser Melting, Additive Manufacture of Conventional Biodevices for In Vitro or In Vivo Trials, Biomodels for implantable hard and soft tissue replacement.
Unit 3	**Micro and nano manufacturing technologies for biodevices** • **Introduction to Micro and Nano Manufacturing Technologies:** Micromachining, Subtractive Micromachining, Chemical Micromachining, Manufacturing of microporous structure, Micro-replication technologies, thin film deposition technologies, Additive micro-manufacturing. • **Subtractive micromachining for biodevices:** Introduction, Materials used, Process description, milling, drilling, lathing, micromachining using laser, electron beams, ion beams, X -rays. • **Photolithographic Approaches for 2D Biodevices:** Introduction, Materials used in photolithography, Process description, classifications of various lithography processes, types of photoresists, Physical Vapor deposition, Chemical vapour deposition, solution deposition processes, applications of photolithography process in developing different biomedical devices.
Unit 4	**Bio fabrication, and in silicon, Invitro and in-vivo testing of biodevices** • **Introduction to manufacturing of biological systems** Introduction, layer by layer deposition process, bioprinting technology, fabrication of biomedical scaffolds, Self assembled processes. • **Advancement and challenges linked to Biodevices** Introduction, Challenges related to polymers, bio-polymers, ceramics, composites, biomimetic scaffolds, advancement and challenges linked with bio design tools, advancement and challenges related to bio-manufacturing technologies.

References

1. Handbook on Advanced Design and Manufacturing Technologies for Biomedical Devices, Andres Diaz Lantana, DOI: https://doi.org/10.1007/978-1-4614-6789-2, ISBN: 978-1-4614-6788-5, Published: 08 May 2013, Springer New York, NY
2. VLSI Technology, S.M. Sze, 1988, New York: McGraw-Hill, ISBN: 978-0070627352

Course Code: BM311201BM	**Subject Name: Foundation of human biology for medical devices**	**Credits (L-T-P-Cr): 3-1-0-3**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Understand the basics of cell and tissue structures in the human body.	PO1

CO2	Understand the anatomy and physiology of different organ systems.	PO2
CO3	Apply the knowledge of basic physiology to detect pathological conditions.	PO2
CO4	Evaluate how the brain controls different organs and their functions.	PO3
CO5	Identify the basic physiology of the urinary system and how dialysis can be detected and done.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

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CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3
CO5	2	1	-	1	3	3

Unit	Syllabus
Unit 1	**Human Cell and Tissues:** Cell and its organelles, Transport system across cell membrane, Cell Junctions, Arrangements of cell as tissue, Different types of tissues and their structure and functions.
Unit 2	**Cardiovascular and Respiratory system:** Anatomy of heart and blood vessels, Characteristics of Heart muscles, Physiology of heart, cardiac cycle, blood pressure, Regulation of blood pressure, Cardiac output and their regulation. Different types of blood vessels and their characteristics. Anatomy of respiratory system, Mechanism of respiration, Exchange of gases, Transport of oxygen and carbon Dioxide, Regulation of respiration rate.
Unit 3	**Nervous system:** Neurons - its types and functions, Glial cells, Arrangement of neurons, Central nervous system, Autonomic Nervous system, Spinal Cord
Unit 4	**Urinary physiological system and anatomical features:** Nephron and types, Structure and functions, Urine formation, Concentrated and dilute, Dialysis

References

1. Human Anatomy and Physiology, Guyton.14th Edition,
2. Principles of Anatomy and Physiology by Gerard J Tortora and Bryan Derrickson, 13th Edition, John Wiley & Sons, Inc.
3. Essentials of Medical Physiology by K Sembulingam, 6th Edition, Jaypee Brothers Medical Publishers

Course Code: BM311202BM	**Subject Name:** Physiological control system in medical device	**Credits (L-T-P-Cr): 3-1-0-3**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level

CO1	Students should understand the fundamental concepts of control systems and mathematical modeling.	PO1
CO2	Students should be able to develop mathematical models for various dynamic systems.	PO1
CO3	Students should be able to analyze the transient and steady-state behavior of control systems implemented in medical devices.	PO2
CO4	Students should be able to assess and ensure the stability of control systems.	PO3
CO5	Students should be able to apply modern simulation tools to model, simulate, and design medical control systems	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	3	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	3	3	2	3	3	3
CO5	3	3	2	3	3	3

Unit	Syllabus
Unit 1	**Introduction to Control Systems and Mathematical Modeling** Control System: Terminology and Basic Structure, Difference between Closed Loop and Open Loop Control Systems, Feedback and feedforward mechanisms, Block diagrams, Block diagram reductions, Signal flow graphs models, Mason's gain formula, Mathematical modelling of: electrical systems, mechanical systems, electro-mechanical systems, Transfer functions, Overview of control mechanisms in medical devices, Case studies: Regulation of Cardiac Output, Regulation of Glucose Insulin, Thermoregulation, etc.
Unit 2	**Time Response of Dynamical Systems** Time response of dynamical systems: Impulse and Step response of standard first and second order systems, Transient response, Steady state response, Measures of performance of the standard first order and second order system, Effect on an additional zero and an additional pole, Steady state error, Analytical design for medical devices using PD, PI and PID control systems like infusion pumps for drug delivery, ventilator systems for respiratory support, surgical robots, etc.
Unit 3	**Frequency Response and System Analysis** Closed loop frequency response, Performance specification in frequency domain, Frequency response of standard second order system, Bode Plot, Polar Plot, Nyquist plots, Design of compensators using Bode plots - Cascade lead compensation, Cascade lag compensation, Cascade lag-lead compensation, Software tools for simulation (MATLAB, Python, Simulink).
Unit 4	**Stability Analysis** Concept of stability, Bounded Input, Output stability, Routh stability criterion, Relative stability, Root locus concept, Guidelines for sketching root locus, Nyquist stability criterion, Software tools for simulation (MATLAB, Python, Simulink).

References

1. Khoo M.C.K., 2018. PHYSIOLOGICAL CONTROL SYSTEMS Analysis, Simulation, and Estimation Second Edition, John Wiley & Sons, Inc., Hoboken, New Jersey.
2. Franklin G.F., Powell J.D., Emami-Naeini A., Feedback Control of Dynamic Systems, Pearson, Upper Saddle River, New Jersey, 5th edition, 2006.
3. Ogata K., Modern Control Engineering, Prentice-Hall of India Pvt Ltd., New Delhi, 3rd edition, 2000.
4. Golnaraghi F., Kuo B.C., Automatic Control Systems, Tenth Edition. India: McGraw-Hill Education, 2017.

Course Code: BM311203BM	Subject Name: Medical Imaging Systems

S.No.	Outcomes
CO1	Students shall understand the electronic transitions in atoms and associate it with characteristic and bremsstrahlung x-ray auger electron production
CO2	Students shall explain different x-day based imaging techniques like fluoroscopy, mammography, CT
CO3	Students shall understand the principle and acquisition modes/parameters of MRI, ultrasound imaging and nuclear imaging techniques
CO4	Students shall appraise other imaging techniques like endoscopy, microscopy, Optical coherence tomography

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Unit	Syllabus
Unit 1	Structure of atom, Characteristic emission, interaction of radiation with material, production of x-rays, radiography, fluoroscopy, CT
Unit 2	MRI – physics & instrumentation, Ultrasound Imaging – physics & instrumentation
Unit 3	Nuclear Imaging Molecular Imaging with Positron Emission Tomography, Radionuclide Production and Radiopharmaceuticals, Cardiac Imaging, Musculoskeletal Imaging,
Unit 4	Other imaging techniques – endoscopy, microscopy, Optical coherence Tomography, System Theory & Image processing

References

1. Andreas Maier · Stefan Steidl, Vincent Christlein, Joachim Hornegger, Medical Imaging Systems, An Introductory Guide, Springer Open 2018
2. Ramond M Reilly, Medical Imaging for Health Professionals, Technologies & Clinical Applications, 2019 John Wiley & Sons, Inc.
3. Ehsan Samei, Donal J Peck (2019). Hendee's Physics of Medical Imaging, 5th Edition, Wiley Blackwell

Course Code: BM311204BM	Subject Name: Fluidics in Medical Devices: Diagnosis and IVD Principles	Credits (L-T-P-Cr) : 3-1-0-3

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students shall be able employ instrumentation fundamentals in IVD device constructions.	PO1
CO2	Students shall be able to design and develop prototypes of IVD medical devices.	PO2
CO3	Students shall be able to analyze the instrumentation of semi and full auto biochemistry analyzer and arterial blood gas analyzer	PO2
CO4	Students shall be able to examine the principle and instrumentation of ELISA and PCR instruments	PO1
CO5	Students shall be able to determine the testing points of blood cell count analyzer and mass spectroscopy instruments	PO2
CO6	Students shall be able to design prototype of point of care devices	PO3
CO7	Students shall be able to correlate the fluidics principles for IVD device development	PO3
CO8	Students shall be able to categorize different fabrication techniques used for fluidic bed development for IVD devices	PO4
CO9	Students shall be able to determine efficacy of different molecular techniques on IVD devices	PO3
CO10	Students shall be able to develop prototype for cell-based chip for biotechnology application	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3
CO5	2	1	-	1	3	3
CO6	3	3	2	2	3	3
CO7	3	3	3	3	3	3
CO8	2	3	2	1	3	3
CO9	3	3	2	2	3	3
CO10	3	3	3	3	3	3

CO5	Employ safety analysis methodologies such as hazard analysis, safe switching of power systems, flash hazard calculations, and measurement techniques to mitigate risks associated with electrical faults.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO 1	PO 2	PO 3	PO 4	PSO 1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3
CO5	3	3	2	2	3	3

Course Code: BM311206BM	**Subject Name: Mathematical modeling in medical device perspective**	**Credits (L-T-P-Cr) : 3-1- 0-3**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Understand the fundamentals of CAD/CAM and imaging tools used in medical device design	PO1
CO2	Apply mathematical and computational models for the simulation and analysis of biomedical systems	PO2
CO3	Perform geometric and finite element modeling for the design of biomedical implants and devices.	PO3
CO4	Implement manufacturing techniques, including CNC machining and additive manufacturing, for medical devices	PO3
CO5	Integrate information systems and computational techniques for optimized medical device production.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO 1	PO 2	PO 3	PO 4	PSO 1	PSO2
CO1	2	-	-	1	3	3
CO2	3	2	-	2	3	3
CO3	3	3	3	3	3	3
CO4	3	2	2	-	3	3
CO5	2	-	-	1	3	3

Unit	**Syllabus**

Unit 1	**Fundamentals of CAD/CAM in Medical Device Design:** Introduction to CAD/CAM Hardware & Software, basic principles and applications. **Imaging tools for promoting design personalization:** Medical Image capturing systems, Introduction to semi-automatic image processing algorithms and 3D modeling and analysis to perform simulations and development of medical devices.
Unit 2	**Design of Industrial Products:** Introduction to Modelling System, Geometric Modeling: surface and solid modeling, CAD Standards, Introduction to Drafting System, Implementation of Finite Element Analysis in Medical Devices.
Unit 3	**Manufacturing Aspects of medical devices:** Introduction to Computer Numerical Control, CNC Hardware Basics, CNC tooling, Machine Tools and Control Systems. **Precision Machining and Material Modeling:** Biocompatible materials, sterilization, and regulatory aspects.
Unit 4	**Role of Information Systems:** Information Requirements of Manufacturing, Group Technology and Computer Aided Process Planning, Production Planning and Control

References

1. Rao, P. N. (2004). CAD/CAM: principles and applications.
2. Groover, M., & Zimmers, E. W. J. R. (1983). CAD/CAM: computer-aided design and manufacturing. Pearson Education.
3. Miller, K. (2010). Computational biomechanics for medicine. P. M. Nielsen (Ed.). New York: Springer.
4. Smid, P. (2003). CNC programming handbook: a comprehensive guide to practical CNC programming. Industrial Press Inc..
5. Gilchrist, A. (2016). Middleware industrial internet of things platforms. In Industry 4.0: The Industrial Internet of Things (pp. 153-160). Berkeley, CA: Après.

Course Code: BM311401BM	**Subject Name: Quality testing procedure for medical equipment Lab**	**Credits (L-T-P-Cr) : 0-0- 3-2**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Evaluate Mechanical and Electrical Integrity of Medical Device Components	PO1
CO2	Analyze Performance Metrics of Medical Devices	PO2
CO3	Design and Implement Quality Assurance Testing Procedures	PO3
CO4	Integrate Regulatory Standards into Device Quality Optimization	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO 1	PO 2	PO 3	PO 4	PSO 1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Experiments	**Experiment Title**
E1	Quality testing for mechanical properties of the device components

E2	Quality testing of sensitivity testing of the output response of device components
E3	Quality testing of output resolution of medical devices (IVD and CCD)
E4	Quality testing of leakage current from medical devices
E5	Quality testing of Line Isolation Monitoring system of medical devices
E6	Quality testing of specificity of IVD devices
E7	Quality testing of device design optimization

Course Code: BM311402BM	**Subject Name: Fabrication Methods of Medical Device Lab**	**Credits (L-T-P-Cr) : 0-0- 3-2**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students are able to understand the basics of fabrication tools used for developing medical devices.	PO1
CO2	Students can apply and develop solutions based on structuring different medical devices using fabrication tools.	PO2
CO3	Students can also analyze and evaluate the problems and challenges faced during fabricating the medical devices.	PO3
CO4	Students should be able to intervene and hypothesize different future advanced medical devices using bio fabrication processes	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Experiments	**Experiment Title**
E1	3D printing technique demonstration - FDM and SLA
E2	Demonstration of polymeric extruders for filament synthesis
E3	Metal 3D printing Demonstration
E4	Lithography based fabrication of fluidic system for IVD devices
E5	Laser engraver technique demonstration for medical device parts fabrication
E6	Fabricating medical device parts using laser engraver

E7	Conducive ink-based printing method demonstration for micro-electronic circuit printing of medical devices
E8	3 axis CNC Milling

Course Code: BM312101BM	**Subject Name: Basics of Biosensors and Bioelectronics**	**Credits (L-T-P-Cr) : 3-1- 0-3**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students will be able to know about different biological components for biosensor design.	PO1
CO2	Students will be able to understand about different transducers used on biosensors	PO2
CO3	Students will be able to understand and design the operational amplifiers for signal processing	PO2
CO4	Students will be able to get basic idea of filter design and operations	PO3
CO5	Students will be able to understand and create sensor workflow and processing	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	P O 1	P O 2	P O 3	P O 4	PSO 1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3
CO5	3	3	2	2	3	3

Unit	Syllabus
Unit 1	**Biosensor architecture and principles for analytical and critical care parameters** Biosensors- various components of biosensors, Advantages and limitations, Biocatalysis based biosensors, Bio affinity-based biosensors & Microorganisms based biosensors, biologically active material and analyte. Types of membranes used in biosensor constructions
Unit 2	**Sensor integrated transducers and its working principle** Various types of transducers: Potentiometers, Strain gauges, Bridge circuits, Variable inductance and LVDT; Capacitive type; Piezoelectric transducers; Thermistors, Thermocouple, Resistive Temperature detector; Principles and applications - Calorimetric, Optical, Potentiometry, Amperometry, Chronoamperometry, Voltammetry, Coulometry, Conductometric / Resistometric, Impedimetric, Chemiluminescence - based Biosensors.
Unit 3	**Operational amplifiers and integrated circuits:** Operational amplifiers: Basic Differential Amplifiers, Ideal and practical consideration of OpAmp, Basic operations like summer, adder, log transform, Instrumentation amplifiers, Integrator, differentiator, Linear and nonlinear applications
Unit 4	**Signal conditioning circuits for biosensor applications:** Signal acquisition components, Nyquist criteria, fundamentals of FFT, Design of Filters by passive and active components, Analog and digital filter design, A2D and D2A convertor

References
1. Biosensors and its instrumentation, Carr and Brown, 4th Edition, Pearson 2. Electronic Circuits Part-II by U A Bakshi and A P Godse 3. Carr and Brown- Introduction to Biomedical Equipment Technology, 4th Edition, Pearson 4. Brian R Eggins - Biosensors an Introduction, First edition, John Wiley & Sons Publishers, 1996 5. Loic J Blum, Pierre R Coulet - Biosensors Principles and Applications, First edition, Marcel Dekker, Inc, 1991.

Course Code: BM31210BM	Subject Name: Tissue Engineering and Device Interaction	Credits (L-T-P-Cr) : 3-1-0-3

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students shall be able to evaluate cellular morphology in degenerative tissues	PO1
CO2	Students shall be able to classify different grades of degeneration in human tissues	PO1
CO3	Students shall be able to develop various kinds of scaffold at multi-scalar domain	PO2
CO4	Students shall be able to evaluate the properties of scaffold based on the parametric sweep of scaffold development strategies	PO2
CO5	Students shall be able to develop the design of tissue engineering bioreactor	PO3
CO6	Students shall be able to model transport phenomena of culture fluid in designed bioreactors	PO3
CO7	Students shall be able to evaluate the interaction between host tissues and implanted scaffolds	PO4
CO8	Students shall be able to comprehensively analyse the regulatory issues related to case specific scaffold implantation strategies.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3
CO5	3	3	2	2	3	3
CO6	3	3	3	3	3	3
CO7	2	3	2	1	3	3
CO8	3	3	2	2	3	3

Unit	Syllabus

Unit 1	**Scaffold fabrication and characterization technique** Classification of scaffolds, principles of various scaffold fabrication techniques, modeling of scaffold fabrication techniques, classification of characterization techniques of scaffolds, its characterization, evaluation report analysis, cell scaffold interaction study, influence of scaffold topographical features on cellular morphology
Unit 2	**Bioreactor designing for various types of tissue constructs** Fundamentals of tissue engineering bioreactors, forces associated with bioreactors, bioreactor instrumentation, design approach of bioreactors, classification of tissue engineering bioreactors, bioreactors for coplanar tissue construct, tubular construct, 3D solid tubular construct, 3D non-conventional structure construct, microenvironment of bioreactors and their analysis, biosensors integration bioreactors
Unit 3	**Basic of nano-biomedicine** Error-tolerant digital microfluidic lab on chip: control-path design and rollback-recovery mechanism, error-propagation estimates for checkpoint insertion, control path synthesis, evaluation of protein assay; Ion pore formation in membranes: protein-lined ion channel-lipid bilayer coupling, analytical drug-induced lipid- lined ion channel formation, membrane permeabilization by defects with possible non channel effects, nano particle transport to cellular interior through membrane permeabilization
Unit 4	**Regenerative device interaction with host tissues and its regulatory issues** Microenvironmental evaluation of interaction between scaffold and host tissues, boundary conditions of host tissue - scaffold interaction, characterization of this interaction, regulatory issues related to scaffold materials, its sight of insertion, process of manipulators, and targeted degenerated morbidities

References

Principles of tissue engineering and applications, Joseph Bronzino
Molecular, Cellular, and tissue Engineering. Bronzino, Peterson; Second Edition. CRC Press.
Handbook of Nanoscience, Engineering and Technology. Goddard, Brenner, Lyshevski, Iafrate. Third Edition, CRC Press.

Course Code: BM312103BM	**Subject Name: IoT and AI-ML in medical devices**	**Credits (L-T-P-Cr) : 3-1- 0-3**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students will be able to understand the fundamental concepts of IoT, AI, and ML and their applications in medical devices.	PO1
CO2	Students will be able to apply IoT-enabled biosensors and bio-signal acquisition systems integrated with AI-ML algorithms for healthcare monitoring.	PO2
CO3	Students will be able to analyze and evaluate IoT architectures and AI models for their effectiveness, scalability, and limitations in healthcare applications.	PO3
CO4	Students will be able to create and implement IoT-based intelligent medical devices, addressing ethical and regulatory considerations in healthcare innovation.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3

CO4	2	3	2	1	3	3	

Unit	Syllabus
Unit 1	Introduction to AI and ML: **Basics of Artificial Intelligence**: Definition, history, applications in healthcare, and medical devices, **Feature extraction and optimization of network, Machine Learning Fundamentals**: Supervised, unsupervised, and reinforcement learning; overview of key ML algorithms (e.g., linear regression, decision trees, and k-means clustering), **AI in Healthcare**: Real-world applications, such as disease prediction, diagnostic tools, and personalized medicine, **Data Preparation and Processing**: Cleaning, normalization, and feature extraction **Ethical Considerations in AI. Fuzzy logic and Fuzzy system.**
Unit 2	Deep learning fundamentals **Background:** Introduction to neural networks, activation functions, and backpropagation, **Convolutional Neural Networks (CNNs)**: Applications in image processing (e.g., medical imaging analysis), **Recurrent Neural Networks (RNNs)**: Applications in time-series data analysis. **Autoencoders and GANs**: Data generation and denoising in healthcare IoT, **Model Evaluation Metrics**: Sensitivity, specificity, accuracy, and ROC-AUC in medical applications.
Unit 3	IoT architectures for medical devices and the role of AI in making IoT devices **IoT Fundamentals**: IoT architecture, components, and protocols (e.g., MQTT, CoAP) in healthcare, **IoT for Medical Applications**: Remote monitoring, smart wearables, and patient tracking, **Edge Computing vs. Cloud Computing**: Real-time data processing and integration with AI algorithms, **AI in IoT**: Enabling intelligent IoT devices, predictive maintenance, and smart diagnosis.
Unit 4	IoT enabled biosensor and bio-signal acquisition device principles **Biosensors**: Types, working principles, and integration with IoT for health monitoring, **Signal Acquisition and Processing**: Techniques for collecting and preprocessing bio-signals (e.g., ECG, EMG, EEG), **IoT Device Design Principles**: Power management, communication protocols, and data security, **AI-Driven Analytics**: Processing bio-signals using AI and ML models (e.g., anomaly detection, trend analysis), **Design Challenges**: Scalability, interoperability, and robustness of IoT-enabled biosensors in healthcare, **Case Studies**: Development of IoT-based medical devices like glucose monitors, heart rate monitors, and wearable devices.

References

1. The Internet of Medical Things (IoMT): Healthcare Transformation (Advances in Learning Analytics for Intelligent Cloud-IoT Systems) by R. J. Hemalatha (Editor), D. Akila (Editor), D. Balaganesh (Editor), Anand Paul (Editor)-Whiley
2. The Internet of Things by Samuel Greengard (Author), MIT Press
3. Chen, Y. W., & Jain, L. C. Deep learning in healthcare. Paradigms and Applications; Springer: Berlin/Heidelberg, Germany.
4. Jain, V., & Chatterjee, J. M. Machine learning with a health care perspective. Cham: Springer, 1-415.

Course Code: BM312201BM	**Subject Name: Bioelectricity**	**Credits (L-T-P-Cr): 3-1-0-3**

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students will be able to demonstrate biopotential and current in cell membrane channels	PO1
CO2	Students will be able to apply transport equation in ion channels	PO2
CO3	Students will be able to analyze and evaluate action potential generation and impulse propagation	PO2
CO4	Student shall be able to evaluate impulse propagation	PO3

CO5	Students shall be able to model extracellular fields and electrical stimulation of excitable tissues	PO4
CO6	Students shall be able to develop models of cardiac tissue and neuromuscular junction engineering	PO4

Articulation Matrix:(COPO-PSO Mapping)

CO	PO 1	PO 2	PO 3	PO 4	PSO 1	PSO 2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3
CO5	3	3	2	2	3	3
CO6	3	3	3	3	3	3

Unit	Syllabus
Unit 1	**Bioelectric potential and currents in cell membrane channels** Current in solution, moles and amperes, ionic composition, notation for ion species, Nernst-Planck equation, mobility, temperature variations, flux due to diffusion plus electric field, membrane structure, Nernst potential, Gibbs- Donnan Equation, parallel conductance model, channel structure by electron microscopy, ion channels detection by biophysical methods, macroscopic channel kinetics, channel statistics, Concept of passive and active transport.
Unit 2	**Action potential generation and impulse propagation** Voltage clamp and **patch clamp**, Hodgkin-Huxley membrane model, Hodgkin-Huxley Conductance equations, GHK constant field equation, core conductance model, cable equation, propagation of signal in nerve fibers.
Unit 3	**Extracellular fields and Electrical stimulation of excitable tissues** Spherical cell stimulation, stimulation of fibers, axial current transient, field stimulus of an individual fiber, fiber input impedance, axial current transient, field stimulus of an individual fiber, fiber input impedance, extracellular potentials from fibers and cells
Unit 4	**Cardiac engineering and Neuromuscular junction engineering** Intercellular communication, cardiac cellular models, electrocardiography, neuromuscular junction, Quantal transmitter release, Poisson statistics, transmitter release of calcium and magnesium, post junctional response to transmitter

References

Bioelectricity, Robert Plonskey

Course Code: BM312202BM	Subject Name: Design, Fabrication, and Testing of Medical Devices and Implants	Credits (L-T-P-Cr): 3-1-0-3
Pre-requisites: NIL		

Course Outcome

S.No	Outcomes	PO Level
CO1	Understand medical device design principles, biomaterials, and human factors engineering	PO1

CO2	Apply fabrication techniques like 3D printing, machining, and surface modifications	PO2
CO3	Ensure regulatory compliance with CDSCO, BIS, ISO 13485, and ISO 14971 standards.	PO3
CO4	Evaluate device performance through preclinical testing, clinical trials, and validation	PO3
CO5	Develop and test prototypes using CAD modelling, prototyping tools, and quality assurance methods.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3
CO5	2	3	2	1	3	3

Unit	Syllabus
Unit 1	**Introduction to Medical Device/Implant Design** Overview of medical devices and implants: Definition, classification, and significance in healthcare. Design thinking and innovation: Identifying unmet clinical needs, brainstorming solutions, and conceptual design. Human Factors Engineering: Ensuring usability and ergonomics in device design. Biomaterials Selection: Criteria for choosing appropriate materials considering biocompatibility and functionality.
Unit 2	**Engineering Principles, Prototyping, and Fabrication Techniques** Mechanical and electrical principles relevant to medical devices. Prototyping techniques: From conceptual sketches to functional prototypes. Computer-Aided Design (CAD): Utilizing CAD tools for precise modelling. Fabrication techniques: Additive manufacturing principles and applications: Understanding layer-by-layer fabrication and its advantages in creating complex geometries. Materials Used: Investigating biocompatible materials suitable for 3D printing implants and devices. Case Studies: Reviewing successful implementations of 3D-printed medical devices. Machining, Forming, Molding, and Assembly: Overview of conventional manufacturing processes used in medical device production
Unit 3	**Regulatory Standards and Quality Assurance** Indian Regulatory Framework: Overview of the Medical Devices Rules, 2017, and the role of the Central Drugs Standard Control Organization (CDSCO). International Standards: Understanding ISO 13485 and its implications for quality management systems. Product Lifecycle Management: From design and development to post-market surveillance. Risk Management: Implementing ISO 14971 for identifying and mitigating potential risks.
Unit 4	**Testing, Validation, and Clinical Evaluation** Preclinical Testing: Bench tests, in vitro studies, and animal testing protocols. Clinical Trials: Designing and conducting clinical investigations to assess safety and efficacy. Performance Evaluation: Ensuring devices meet intended performance criteria. Compliance with Testing Standards: Adherence to standards set by the Bureau of Indian Standards (BIS) and other international bodies.

References

1. Denend, L. (2015). Biodesign. Cambridge University Press.
2. Baura, G. D. (2011). Medical device technologies: a systems-based overview using engineering standards. Academic Press.
3. Wiklund, M. E., Kendler, J., & Strochlic, A. Y. (2015). Usability testing of medical devices. CRC press.
4. Weinger, M. B., Wiklund, M. E., & Gardner-Bonneau, D. J. (Eds.). (2010). Handbook of human factors in medical device design. CRC Press.
5. Durfee, W., & Iaizzo, P. (2014). Medical device innovation handbook. Lulu. com.

Course Code: BM312203BM	Subject Name: Characterization of Medical Device	Credits (L-T-P-Cr) : 3-1-0-3

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Students shall understand the fundamentals of material properties	PO1
CO2	Students shall master various characterization techniques	PO2
CO3	Students shall analyze and interpret characterization data	PO3

CO4	Students shall be able to identify and quantify extractables and leachable from medical devices	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	P O 1	P O 2	P O 3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Unit	Syllabus
Unit 1	Need for characterization of medical devices, Material Characterization Techniques – Light Microscopy – Optical principles, instrumentation, specimen preparation, imaging modes, confocal microscopy, X- Ray Diffraction methods – Generation of X-rays, absorption, Diffraction basics, wide angle x-ray diffraction and scattering, X – ray spectroscopy for elemental analysis
Unit 2	Principle and instrumentation of Transmission Electron Microscopy, Scanning Electron microscopy, Scanning probe microscopy, Electron spectroscopy for surface analysis, vibrational spectroscopy for molecular analysis, Thermal Analysis
Unit 3	General principles of chemical compatibility assessments – extraction and leaching, types of extraction, examples of extraction sequence, recommended extractions, principle of extraction, Additional factors to consider
Unit 4	ISO 10993-18 (2012), ISO 10993-18 (2020), linking extraction conditions to medical devices categories, chemical testing of extracts, chemical characterization process for medical devices, compositional assessment, extraction able assessment, leachable assessment ISO 10993-17, - toxicological risk assessment,

References

1. Yang Leng , Materials Characterization Introduction to Microscopic and Spectroscopic Methods, John Wiley & Sons (Asia), 2008
2. Dennis Jenke, Extractables and Leachables: Characterization of Drug Products, Packaging, Manufacturing and Delivery Systems, and Medical Devices 1st Edition, Wiley, 2022

Course Code: BM312204BM	**Subject Name: Sterilization Techniques for Medical Device**	**Credits (L-T-P-Cr) : 3-1- 0-3**

Pre-requisites: NIL

S.No.	Outcomes
CO1	Demonstrate an understanding of the fundamental principles of sterilization
CO2	Assess the effectiveness of different sterilization methods based on factors such as microbial load, material compatibility, and operational requirements.

CO3	Identify and describe the different sterilization techniques (e.g., heat, chemical, filtration, radiation) and the mechanisms by which they kill or inactivate microorganisms.
CO4	Understand and adhere to local and international sterilization guidelines and standards to ensure safety and efficacy in sterilization practices.

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	PO4	PSO1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Unit	Syllabus
Unit 1	Various materials used in medical devices, Types of sterilizations – dry heat, steam, ethylene oxide, hydrogen peroxide, water quality used for steam sterilization, air quality used for drying, Cleaning of medical devices, cleaning products, cleaning methods, mechanical cleaning
Unit 2	Preparation and packaging for reprocessing, post cleaning inspection, Packaging and wrapping material – packaging techniques, materials, specific guidelines for various sterilization techniques, Labelling, Chemical disinfectants, Decontamination of endoscopes
Unit 3	Sterilization of reusable medical devices, Immediate use steam sterilization (IUSS) system ("flash" sterilization), Reuse of single- use medical devices, Transporting medical devices to and from a decontamination facility, Processing of instruments in dental practice
Unit 4	Radiation Sterilization, Gamma irradiators, Electron accelerators, Dosimetry and the radiation sterilization process, microbiological aspects of radiation sterilization, Regulatory issues for radiation sterilization centers - ISO 13485, ISO 11137:2006

References

1. Trends in Radiation Sterilization of Health Care Products, International Atomic Energy Agency, Vienna, 2008
2. Decontamination and Reprocessing of Medical Devices for Health-care Facilities

Course Code: BM312205BM	Subject Name: Drug Delivery System	Credits (L-T-P-Cr) : 3-1-0-3

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Understanding the fundamentals of the drug delivery system and its need in biomedical applications.	PO1

CO2	Apply the fundamental aspects of the drug delivery system.	PO2
CO3	Analyse the pharmacokinetics behind a drug delivery system.	PO2
CO4	Evaluate the physics and principles of matrix-based drug delivery systems like hydrogel based, transdermal patch, and fundamentals of vaccine delivery.	PO3
CO5	Summarize a comprehensive knowledge on drug delivery systems needed for the pharmaceuticals industries.	PO4

Articulation Matrix: (CO-PO-PSO Mapping)						
CO	PO1	PO2	P O 3	P O 4	PSO1	PSO2
CO1	3	1	-	1	3	3
CO2	3	2	2	3	3	3
CO3	2	3	3	3	3	3
CO4	3	3	3	2	3	3
CO5	2	3	3	3	3	3

Unit	Syllabus
Unit 1	**Introduction to Drug Delivery System:** Overview, dosage form-tablet, capsule, parenteral etc. classification of drug delivery system, chemically controlled system, diffusion-controlled system, controlled release mechanism-Membrane reservoir system, Matrix system, swelling controlled release system, biodegradable controlled release system.
Unit 2	**Fundamental Principles of Drug Delivery:** Introduction of pharmacokinetics and pharmacodynamics, diffusive transport, diffusion in heterogeneous system, passage of drug through membrane drug release kinetics from different biopolymer matrices.
Unit 3	**Pharmacokinetics:** Common routes of systemic drug administration, drug absorption, bioavailability, determinants of bioavailability disintegration, dissolution, drug distribution, drug elimination.
Unit 4	**Matrix based Drug Delivery System:** Delivery materials, polymer-based matrices; hydrogels- drug carriers, transdermal and trans- mucosal drug delivery system, measuring in vitro diffusions, measuring controlled release kinetics, drug targeting approaches, biocompatibility aspects of matrices Immunity and immunological preparations: immunity, types, immunological preparations; bacterial vaccines, vaccines containing living viruses, vaccines containing toxoids Fundamentals of vaccine delivery.

References

Text Books:

1. Drug Delivery: Fundamentals and Applications, Second Edition. (2016). United States: CRC Press.
2. Drug Delivery: Principles and Applications. (2016). Germany: Wiley.

Reference Books:

1. Shargel, L., Yu, A. B. (2016). Applied Biopharmaceutics & Pharmacokinetics, Seventh Edition. Singapore: McGraw- Hill Education.
2. Basic Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations. (2016). United Kingdom: Wiley.

Course Code: BM312401BM	Subject Name: Biosensor and Bioelectronics lab	Credits (L-T-P-Cr) : 0-0-3-2

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	To make student understands the basic working of capacitive based biosensors	PO1
CO2	To make student understands the basic working of chemical biosensors	PO2
CO3	To get familiar with different types of amplifiers used in device design	PO3
CO4	To understand and design active filters using ICs	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO 1	PO 2	PO 3	PO 4	PSO 1	PSO2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Experiments	Experiment Title
E1	To design and set up a stable multivibrator of 1000 Hz frequency and 60% duty cycle using IC 555
E2	Evaluation of transfer characteristics of a capacitive biosensor.
E3	Evaluation of transfer characteristics of a chemical biosensor
E4	Evaluation of transfer characteristics of a self-assembly biosensor
E5	Evaluation of transfer characteristics of a differential operational amplifier
E6	Evaluation of transfer characteristics of an instrumentation amplifier
E7	Evaluation of transfer characteristics of operation amplifier-based filters
E8	Evaluation of transfer characteristics of an integrated sensor circuit with DAQ system

Course Code: BM312402BM	Subject Name: Tissue Engineering and Device Interaction Lab	Credits (L-T-P-Cr) : 0-0-3-2

Pre-requisites: NIL

Course Outcome

S.No.	Outcomes	PO Level
CO1	Able to evaluate physical characteristics of developed scaffolds	PO1

CO2	Able to implement cellular integration with scaffolds	PO2
CO3	Able to design customized bioreactor for tissue engineering application	PO3
CO4	Able to interpret cell membrane interaction with substrate in different bioreactor conditions	PO4

Articulation Matrix: (CO-PO-PSO Mapping)

CO	PO1	PO2	PO3	P O 4	PSO1	PSO 2
CO1	2	1	-	1	3	3
CO2	3	3	2	2	3	3
CO3	3	3	3	3	3	3
CO4	2	3	2	1	3	3

Experiments	Experiment Title
E1	Development of polyelectrolyte complex based scaffold using electrospinning technique
E2	Scaffold physical and mechanical characterization
E3	Cell adhesion study on developed scaffold and its mechano-transduction evaluation using AFM
E4	Topography patterning by self-assembly method using lithography on synthesized scaffold
E5	Evaluation of cell adhesion traction forces on patterned surface topographic scaffold
E6	Evaluation of therapeutic bioreactor interface on cell viability
E7	Evaluation of therapeutic bioreactor interface on cell membrane turgidity

Course Code: BM313301BM	**Subject Name: ECG and Bedside Monitor System**	**Credits (L-T-P-Cr) : 2-0- 2-3**
Pre-requisites: NIL		

Experiments	Experiment Title
E1	ECG machine disassembling session
E2	Bedside monitor disassembling session
E3	Identification of testing points on ECG machine session
E4	Identification of testing points on Bedside monitor machine session
E5	Troubleshooting methodologies of ECG machine session
E6	Troubleshooting methodologies of bedside monitor session

Course Code: BM313302BM	**Subject Name: Defibrillator and Heart Lung Machine**	**Credits (L-T-P-Cr) : 2-0- 2-3**

Pre-requisites: NIL	
Experiments	**Experiment Title**
E1	Defibrillator machine disassembling session
E2	Heart lung machine disassembling session
E3	Identification of testing points on Defibrillator machine session
E4	Identification of testing points on Heart Lung Machine session
E5	Troubleshooting methodologies of Defibrillator machine session
E6	Troubleshooting methodologies of Heart lung machine session

Course Code: BM313303BM	**Subject Name: Ventilator and Anesthesia Machine**	**Credits (L-T-P-Cr) : 2-0- 2-3**

Experiments	**Experiment Title**
E1	Ventilator machine disassembling session
E2	Anesthesia machine disassembling session
E3	Identification of testing points on Ventilator machine session
E4	Identification of testing points on Anesthesia Machine session
E5	Troubleshooting methodologies of Ventilator machine session
E6	Troubleshooting methodologies of Anesthesia machine session

Course Code: BM313304BM	**Subject Name: Hemodialyzer and Endoscope**	**Credits (L-T-P-Cr) : 2-0- 2-3**

Experiments	**Experiment Title**
E1	Hemodialyzer machine disassembling session
E2	Endoscope machine disassembling session
E3	Identification of testing points on Hemodialyzer machine session
E4	Identification of testing points on Endoscope Machine session
E5	Troubleshooting methodologies of Hemodialyzer machine session
E6	Troubleshooting methodologies of Endoscope machine session

Course Code: BM313305BM	**Subject Name: Single and Multi- Channel Semi auto biochemistry Analyzer**	**Credits (L-T-P-Cr) : 2-0- 2-3**

Experiments	Experiment Title
E1	Single Channel Semi auto biochemistry Analyzer machine disassembling session
E2	Multi-Channel Semi auto biochemistry Analyzer machine disassembling session
E3	Identification of testing points on Single Channel Semi auto biochemistry Analyzer machine session
E4	Identification of testing points on Multi Channel Semi auto biochemistry Analyzer Machine session
E5	Troubleshooting methodologies of Single Channel Semi auto biochemistry Analyzer machine session
E6	Troubleshooting methodologies of Multi-Channel Semi auto biochemistry Analyzer machine session

Course Code: BM313306BM	Subject Name: Full Auto Biochemistry Analyzer and Arterial Blood Gas Analyzer	Credits (L-T-P-Cr) : 2-0- 2-3

Pre-requisites: NIL

Experiments	Experiment Title
E1	Full Auto Biochemistry Analyzer machine disassembling session
E2	Arterial Blood Gas Analyzer machine disassembling session
E3	Identification of testing points on Full Auto Biochemistry Analyzer machine session
E4	Identification of testing points on Arterial Blood Gas Analyzer Machine session
E5	Troubleshooting methodologies of Full Auto Biochemistry Analyzer machine session
E6	Troubleshooting methodologies of Arterial Blood Gas Analyzer machine session

Course Code: BM313307BM	Subject Name: ELISA and PCR Instrument	Credits (L-T-P-Cr) : 2-0- 2-3

Experiment	Experiment Title
E1	ELISA machine disassembling session
E2	PCR machine disassembling session
E3	Identification of testing points on ELISA machine session
E4	Identification of testing points on PCR Machine session
E5	Troubleshooting methodologies of ELISA machine session
E6	Troubleshooting methodologies of PCR machine session

Course Code: BM313308BM	Subject Name: Blood Cell Count Analyzer and Mass Spectroscopy Instrument	Credits (L-T-P-Cr) : 2-0- 2-3

Experiments	Experiment Title
E1	Blood Cell Count Analyzer machine disassembling session
E2	Mass Spectroscopy machine disassembling session
E3	Identification of testing points on Blood Cell Count Analyzer machine session
E4	Identification of testing points on Mass Spectroscopy Machine session
E5	Troubleshooting methodologies of Blood Cell Count Analyzer machine session
E6	Troubleshooting methodologies of Mass Spectroscopy machine session