SAHRDAYA AUTONOMOUS
COLLEGE OF ENGINEERING & TECHNOLOGY
A CENTRE OF EXCELLENCE IN SCIENCE & TECHNOLOGY | MANAGED BY IRINJALAKUDA DIOCESAN EDUCATION TRUST
Approved by AICTE & Affiliated to APJ Abdul Kalam Technological University | Accredited by:
Estd.2002

M. Tech

Curriculum & Syllabus (2025)

Semester I & II

Discipline: Biomedical Engineering

Stream: Biomedical Engineering

(SHR/AC/Auto/Acad. Council/M.Tech/3/Syll./BME/S1-S2)

Recommended by Board of Studies on 16/06/25
Approved by Academic Council on 05/07/25

SEMESTER I							
SLOT	**COURSE CODE**	**COURSE NAME**	**MARKS**		**L-T-P**	**HOURS**	**CREDIT**
			CIA	**ESE**			
A	251TBM100	Advanced Mathematics for Biomedical Engineering	40	60	3-0-0	3	3
B	251TBM001	Human Physiology for Biomedical Applications	40	60	3-0-0	3	3
C	251TBM002	Biomedical Signal Acquisition & Processing	40	60	3-0-0	3	3
D	251EBMXXX	Program Elective1	40	60	3-0-0	3	3
E	251EBMXXX	Program Elective 2	40	60	3-0-0	3	3
S	241RGE100	Research Methodology and IPR	40	60	2-0-0	2	2
T	251LBM100	Biomedical Signal Acquisition & Processing Lab	100	--	0-0-2	2	1
Total			340	360		19	18

PROGRAM ELECTIVE I						
SLOT	**SL.NO**	**COURSE CODE**	**COURSE NAME**	**L-T-P**	**HOURS**	**CREDIT**
D	1	251EBM011	Time-Frequency Analysis of Biomedical Signals	3-0-0	3	3
	2	251EBM012	Computational Neuroscience	3-0-0	3	3
	3	251EBM013	Real-Time Biomedical Signal Processing	3-0-0	3	3
	4	251EBM014	Multimodal Biomedical Data Fusion	3-0-0	3	3

PROGRAM ELECTIVE II						
SLOT	**SL.NO**	**COURSE CODE**	**COURSE NAME**	**L-T-P**	**HOURS**	**CREDIT**
E	1	251EBM021	Medical Device Design and Regulatory Affairs	3-0-0	3	3
	2	251EBM025	Quality Systems and Risk Management in Medical Devices	3-0-0	3	3
	3	251EBM023	Human Factors and Usability Engineering in Medical Devices	3-0-0	3	3

	4	251EBM024	Digital Health and Software as a Medical Device (SaMD)	3-0-0	3	3
-	5	241RGE101	Research and Publication Ethics	2-0-0	2	2

SEMESTER II							
SLOT	**COURSE CODE**	**COURSE NAME**	**MARKS**		**L-T-P**	**HOURS**	**CREDIT**
			CIA	**ESE**			
A	252TBM100	Medical Imaging systems	40	60	3-0-0	3	3
B	252TBM001	Computational Biomedical Image Analysis	40	60	3-0-0	3	3
C	252EBMXXX	Program Elective 3	40	60	3-0-0	3	3
D	252EBMXXX	Program Elective 4	40	60	3-0-0	3	3
E	252EBMXXX	Industry/ Interdisciplinary Elective	40	60	3-0-0	3	3
S	252PBM100	Mini Project	100	60	0-0-4	4	2
T	252LBM100	Advanced Signal and Image Processing Lab	100	--	0-0-2	2	1
Total			400	300		21	18

PROGRAM ELECTIVE III						
SLOT	**SL.NO**	**COURSE CODE**	**COURSE NAME**	**L-T-P**	**HOURS**	**CREDIT**
C	1	252EBM031	Medical Image Reconstruction and Computer Vision	3-0-0	3	3
	2	252EBM032	Biomedical Image Analysis and Interoperability Standards	3-0-0	3	3
	3	252EBM033	Deep Learning for Medical Imaging	3-0-0	3	3
	4	252EBM034	Immersive Technologies in Medical Imaging	3-0-0	3	3

PROGRAM ELECTIVE IV						
SLOT	**SL.NO**	**COURSE CODE**	**COURSE NAME**	**L-T-P**	**HOURS**	**CREDIT**
D	1	252EBM041	Advanced Quality Management Systems for Medical Devices	3-0-0	3	3
	2	252EBM042	Integrated Design Control and Risk Governance	3-0-0	3	3

	3	252EBM043	Clinical Evaluation and Trials for Devices	3-0-0	3	3
	4	252EBM044	Intellectual Property Rights & Ethics in MedTech	3-0-0	3	3

INTERDISCIPLINARY ELECTIVE						
SLOT	**SL.NO**	**COURSE CODE**	**COURSE NAME**	**L-T-P**	**HOURS**	**CREDIT**
E	1	252EBM051	Machine Learning for Biomedical Engineers	3-0-0	3	3
	2	252EBM052	IoT and Embedded Systems in Healthcare	3-0-0	3	3
	3	252EBM053	Clinical Data Analytics	3-0-0	3	3

INDUSTRY ELECTIVE						
SLOT	**SL.NO**	**COURSE CODE**	**COURSE NAME**	**L-T-P**	**HOURS**	**CREDIT**
E	1	252EBM051	Biomedical Data Analytics and Machine Learning	3-0-0	3	3
	2	252EBM052	Tissue Engineering and Biomaterials and Industry Applications	3-0-0	3	3
	3	252EBM053	Healthcare Technology Innovation and Entrepreneurship	3-0-0	3	3

SEMESTER I

251TBM100	ADVANCED MATHEMATICS FOR BIOMEDICAL ENGINEERS	CATEGORY	L	T	P	CREDIT
		DISCIPLINE CORE	3	0	0	3

Preamble:

To develop analytical capability and to impart knowledge in Mathematical and Statistical methods and their applications in Engineering.

Course Outcomes:

After the completion of the course, the student will be able to

CO 1	Solve linear equations using matrix and linear transformations.
CO 2	Apply the concepts of Eigen value problems in matrix diagonalization and perform singular value decomposition.
CO 3	Analyse systems represented using ordinary differential equations.
CO 4	Analyse experimental data using statistical methods.
CO 5	Solve problems from linear algebra, ordinary differential equation and statistics using advanced software tools

Mapping of course outcomes with program outcomes:

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3			3	3	2	
CO 2	3			3	3	2	
CO 3	3			3	3	2	
CO 4	3			3	3	2	
CO 5	3			3	3	2	

Assessment Pattern:

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	20
Create	

Mark distribution:

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern (40 Marks):

- Evaluation shall only be based on application, analysis or design-based questions.

Evaluation Method	Marks
Micro project/Course based project	20 Marks

Course based task/Seminar/Quiz	10 Marks
Test paper, 1 no (Test paper shall include minimum 80% of the syllabus)	10 Marks
Total	40 Marks

- All COs must be assessed by using at least one assessment method of Continuous Internal Evaluation.

End Semester Examination Pattern (60 Marks):

- The end semester examination will be consisting of two parts; Part A and Part B.
- Part A contain 5 numerical questions (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students), with 1 question from each module, having 5 marks for each question. Students shall answer all questions.
- Part B contains 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student shall answer any five. Each question can carry 7 marks.
- Total duration of the examination will be 150 minutes.

Model Question paper:

Course Code: 221TIC100

Course Name: MATHEMATICS FOR BIOMEDICAL ENGINEERS

Max. Marks: 60 **Duration: 2.5 Hours**

PART A

Answer all Questions. Each question carries 5 Marks

1. Describe the linear transformations of the x-y plane that are represented with standard basis (1,0) and (0,1) by the matrices

$$A = [1\ 0\ 0\ -1]\ \ B = [1\ 0\ 2\ 1]\ C = [0\ 1\ -1\ 0]$$

Find the eigen values and eigen vectors of

$$A = [-2\ 2\ -3\ 2\ 1\ -6\ -1\ -2\ 0]$$

2. Solve the fourth order ODE y^{iv}- $5y^{ii}$ + 4y=0.
3. A sample of 400 male students is found to have a mean height 67.47 inches. Can it be reasonably regarded as a sample from a large population with mean height 67.39 inches and standard deviation 1.30 inches? Test at 5% level of significance.
4. Calculate the correlation coefficient between X and Y and comment on their relationship:

X	–3	–2	–1	1	2	3
Y	9	4	1	1	4	9

PART B

Answer any five Questions. Each question carries 7 Marks

5. Find all solutions or indicate that no solution exists.

$$7x+9y-14z=36$$
$$-x-3y+2z=-12$$
$$2x+y-4z=4$$

6. Diagonalize A and compute $S\Lambda^k S^{-1}$ to prove this formula for A^k

$$A = [2\ 1\ 1\ 2\ ] \text{ has } A^k = \frac{1}{2}[3^k + 1\ 3^k - 1\ 3^k - 1\ 3^k + 1\ ]$$

Solve the initial value problem

$$y''' + y'' + 3y' + y = 30e^{-x}\ , y(0) = 3,\quad y'(0) = -3,\quad y''(0) = -47.$$

7. Set up an analysis of variance table for the following per acre production data for three varieties of wheat, each grown on 4 plots and state if the variety differences are significant.

Plot of land	Per acre production data		
	Variety of wheat		
	A	B	C
1	6	5	5
2	7	5	4
3	3	3	3
4	8	7	4

8. In an assay of heparin, a standard preparation is compared with a test preparation by observing the log clotting times (y, in seconds) of blood containing different doses of heparin (x is the log dose). Replicate readings are made at each dose level). Separately for each preparation, standard and test:

Log Clotting times				Log Dose
Standard		Test		
1.806	1.756	1.799	1.763	0.72
1.851	1.785	1.826	1.832	0.87
1.954	1.929	1.898	1.875	1.02
2.124	1.996	1.973	1.982	1.17
2.262	2.161	2.140	2.100	1.32

a) Estimate the regression parameters, the log clotting time for a log dose of 1.0 (are estimates for different preparations different?), and draw the regression line

b) Test to see if the two factors are independent; state your hypotheses and choice of test size.

9. The grades of five students in Mathematics and Chemistry courses are:

Mathematics	6	4	8	5	3.5
Chemistry	6.5	4.5	7	5	4

Determine the regression line and calculate the expected grade in Chemistry for a student who has 7.5 grade in Mathematics.

10. Check whether or not the following vectors are linearly independent, by solving

$$c_1v_1+c_2v_2+c_3v_3+c_4v_4 = 0$$

$v_1 = [1\ 1\ 0\ 0\ ],\quad v_2 = [1\ 0\ 1\ 0\ ],\quad v_3 = [0\ 0\ 1\ 1\ ],\quad v_4 = [0\ 1\ 0\ 1\ ].$

Check also if they span R^4 by trying to solve $c_1v_1+c_2v_2+c_3v_3+c_4v_4 = (0,0,0,1)$.

Syllabus

MATHEMATICS FOR BIOMEDICAL ENGINEERS

Module 1 (8 Hours)

Linear Algebra: Linear Systems (Refer Chapter 7 of R1)

Linear system of equations- Linear independence- Vector spaces -Solutions of Linear systems -Inner Product spaces- Orthogonal bases and Gram Schmidt orthogonalization- Matrix Transformations- Linear Transformations-Matrix of a Linear Transformation- Existence and uniqueness-Problem solving using MATLAB.

Module 2 (8 Hours)

Linear Algebra: Matrix Eigenvalue Problems (Refer Chapter 8 of R1)

Eigen values and Eigen vectors- Symmetric, skew-symmetric and orthogonal matrices- Eigen bases- diagonalization- SVD-complex matrices and forms- Applications to differential equations, Problem solving using MATLAB

Module 3 (8 Hours)

Ordinary Differential Equations (Refer Chapter 3 & 5 of R1)

Ordinary differential equations: Solution of Ordinary linear differential equations of nth order, Homogenous Linear ODEs- Superposition principle, General Solutions-Homogenous Linear ODEs with constant coefficient- Non-homogenous Linear ODEs- Power series methods for solutions of ODEs, Problem solving using MATLAB

Module 4 (8 Hours)

Biostatistics (Refer Chapter 4 & 5 of R4)

Introduction to Statistical Tests of Significance - Basic Concepts- Hypothesis Tests- Rejection region- *p* values- Type I and Type II Errors- Estimation of Parameters: Basic concepts- Estimation of Means- Estimation of Proportions, One-Way Analysis of Variance, Problem solving using MATLAB

Module 5 (8 Hours)

Correlation and Regression (Refer Chapter 2 of R5 & Chapter 8 of R4)

Correlation – Pearson's correlation coefficient and Spearman's rank correlation; Simple Regression Analysis- Simple Linear Regression Model- Multiple Regression Analysis- Regression Model with Several Independent Variables- Estimation of Parameters- Analysis-of-Variance Approach, Problem solving using MATLAB.

Course Plan:

No	Topic	No. of Lectures
1	**Linear Algebra: Linear Systems**	
1.1	Linear system of equations- Linear independence- Vector spaces	2
1.2	Solutions of Linear systems - Inner Product spaces- Orthogonal bases and Gram Schmidt orthogonalization	3
1.3	Matrix Transformations- Linear Transformations-Matrix of a Linear Transformation- Existence and uniqueness, Problem solving using MATLAB	3

2	**Linear Algebra: Matrix Eigenvalue Problems**	
2.1	Eigen values and Eigen vectors- Symmetric, skew-symmetric and orthogonal matrices- Eigen bases	2
2.2	Diagonalization- SVD-complex matrices and forms	3
2.3	Applications to differential equations, Problem solving using MATLAB	3
3	**Ordinary differential equations**	
3.1	Solution of Ordinary linear differential equations of nth order, Homogenous Linear ODEs- Superposition principle, General Solutions	3
3.2	Homogenous Linear ODEs with constant coefficient- Non-homogenous Linear ODEs	3
3.3	Power series methods for solutions of ODEs, Problem solving using MATLAB	2
4	Biostatistics	
4.1	Introduction to Statistical Tests of Significance - Basic Concepts- Hypothesis Tests- Rejection region-*p* values- Type I and Type II Errors	2
4.2	Estimation of Parameters: Basic concepts- Estimation of Means- Estimation of Proportions	3
4.3	One-Way Analysis of Variance, Problem solving using MATLAB	3
5	**Correlation and Regression**	
5.1	Correlation – Pearson's correlation coefficient and Spearman's rank correlation	2
5.2	Simple Regression Analysis- Simple Linear Regression Model	3
5.3	Multiple Regression Analysis- Regression Model with Several Independent Variables- Estimation of Parameters- Analysis-of-Variance Approach, Problem solving using MATLAB	3

Reference Books:

1. Kreyszig, Erwin. Advanced Engineering Mathematics 10th Edition with Wiley Plus Set. John Wiley & Sons, 2007.
2. David C.Lay, Steven R.Lay and J.J.McDonald: Linear Algebra and its Applications, 5th Edition Pearson Education Ltd., 2015
3. Strang, Gilbert. Linear algebra and its applications. Belmont, CA: Thomson, Brooks/Cole, 2006
4. Le, Chap T., and Lynn E. Eberly. Introductory biostatistics. John Wiley & Sons, 2016.
5. King, Andrew P., and Robert Eckersley. Statistics for biomedical engineers and scientists: How to visualize and analyze data. Academic Press, 2019.

251TBM001	HUMAN PHYSIOLOGY FOR BIOMEDICAL APPLICATIONS	CATEGORY	L	T	P	CREDIT
		PROGRAM CORE	3	0	0	3

Preamble:

The purpose of the training in Physiology for Engineers is to produce experts with necessary knowledge, skills and attitude to impart education and to carry out research in Biomedical engineering area.

Course Outcomes:

After the completion of the course the student will be able to

CO 1	Define the basic concepts of anatomical and physiological terminologies relating to cell, blood components and joints with their functions.
CO 2	Able to analyse the functioning of human Nervous system
CO 3	Able to analyse the functioning of human cardiac system and skeletal system
CO 4	Able to analyse the functioning of human muscular, respiratory, digestive and urinary system
CO 5	Able to analyse the functioning of endocrine and sensory systems

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2		2			3	
CO 2	2		2			3	
CO 3	2		2			3	
CO 4	2		2			3	
CO 5	2		2			3	

Assessment Pattern:

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	20
Create	

Mark distribution:

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern (40 Marks):

- Evaluation shall only be based on application, analysis or design-based questions.

Evaluation Method	Marks
Micro project/Course based project	20 Marks
Course based task/Seminar/Quiz	10 Marks
Test paper, 1 no (Test paper shall include minimum 80% of the syllabus)	10 Marks
Total	40 Marks

- All COs must be assessed by using at least one assessment method of Continuous Internal Evaluation.

End Semester Examination Pattern (60 Marks):

- The end semester examination will be consisting of two parts; Part A and Part B.
- Part A contain 5 numerical questions (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students), with 1 question from each module, having 5 marks for each question. Students shall answer all questions.
- Part B contains 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student shall answer any five. Each question can carry 7 marks.
- Total duration of the examination will be 150 minutes.

Model Question paper:

Course Code: 221TIC001

Course Name: PHYSIOLOGY FOR ENGINEERS

Max. Marks: 60 **Duration: 2.5 Hours**

PART A

Answer all Questions. Each question carries 5 Marks

11. With neat figure describe the connective tissues
12. List and outline the functions of 12 pair of cranial nerves
13. Explain why the walls of the ventricles are thicker than those of the atria.
14. Explain the structure of pharynx with neat figure and also mention its function.
15. Write a note on Auditory defects.

PART B

Answer any five Questions. Each question carries 7 Marks

16. (a)With necessary figure and example explain the physiological negative feedback mechanism of the control of body temperature.

    (b) Patients with kidney failure can be kept alive by dialysis, which removes toxic waste products from the blood. In a dialysis machine, blood flows past one side of a selectively permeable dialysis membrane, and dialysis fluid flows on the other side of the membrane. Small substances, such as ions, glucose, and urea, can pass through the dialysis membrane, but larger substances, such as proteins, cannot. If you wanted to use a dialysis machine to remove only the toxic waste product urea from blood, what could you use for the dialysis fluid?

    a. A solution that is isotonic and contains only protein
    b. A solution that is isotonic and contains the same concentration of substances as blood, except for having no urea in it
    c. Distilled water
    d. Blood

    defend your answer with proper explanation.
17. Discuss various types of tissues with necessary diagram.
18. (a)Explain the functional components of nervous system with neat diagram.

    (b) A patient suffered brain damage in an automobile accident. It was suspected that the cerebellum was the part of the brain affected. On the basis of what you know about cerebellar function, how could you determine that the cerebellum was involved? What symptoms would you expect to see?
19. Describe the ventricles of the brain with neat diagram
20. (a)What is cardiac output? Explain the factors determining the cardiac output, along with ECG waveform.

    (b)The cardiac output of athletes and non-athletes at rest can be equal, but while they are exercising, the total cardiac output is much greater in an athlete than in a non-athlete. Athletes have a lower heart rate than non-athletes at rest and when exercising at the same level of exertion. Explain.
21. (a)Explain the different lung volume and capacities in detail.

    (b)A student ate a full bag of salty (sodium chloride) potato chips but drank no liquids. What effect did this have on urine concentration and the rate of urine production? Explain the mechanisms involved.
22. (a)Explain the anatomy and physiology of eye.

    (b)An elderly male with normal vision developed cataracts. He was surgically treated by removing the lenses of his eyes. What kind of glasses would be recommended to compensate for the removal of his lenses

Syllabus

Module I (6 Hours)

Introduction to Anatomy & Physiology

Definition & relationship of structure & function; Functional organization of body– cells, tissues, organs & systems – Types; Homeostasis – intracellular & extracellular fluids -homeostatic control systems – negative & positive feedback and feed forward mechanisms; Definition of anatomical positions and planes.

Skeletal system: Types of Bone and function – Physiology of Bone formation – Types of joints and function – Joint movements – flexion, extension, abduction & adduction - Types of cartilage and

function.

Module II (8 Hours)

Nervous and Muscular Systems

Cells of Nervous systems – Types of Neuron and Synapses – Mechanisms of Nerve impulse; Nervous System: Organization, Central nervous system: Overview, Cerebrum – Cerebral cortex – General organization – motor, sensory, language & association areas – major functions. Basal ganglia, Thalamus & Hypothalamus – functions. Cerebellum, Brain Stem – basic structure & functions, Spinal cord – nerves, spinal reflex; Blood: Components of Blood and functions – plasma– haematocrit – plasma proteins – erythrocytes – haemoglobin – anemia – blood typing – transfusion reaction – universal donor & acceptor – leukocytes – functions & types – platelets– blood clotting.

Muscular system: Parts of Muscle – types – Muscle contraction and relaxation.

Module III (8 Hours)

Cardiovascular System

Heart – Anatomy – location – pump – valves - major arteries & veins – cardiac muscle – electrical activity – pacemaker – normal & ectopic – cardiac action potential cardiac cycle; cardiac rhythm & rate – normal & abnormal, myocardial ischemia & infarction, atherosclerosis – Heart sounds & murmurs. Cardiac output – stroke volume;

Blood: Components of Blood and functions – plasma– haematocrit – plasma proteins – erythrocytes – haemoglobin – anaemia – blood typing – transfusion reaction – universal donor & acceptor – leukocytes – functions & types – platelets– blood clotting.

Module IV (9 Hours)

Respiratory system, Urinary and Digestive System

Respiratory: Parts of Respiratory Systems – Types of respiration - Mechanisms of Breathing Urinary System: Kidneys – functions, anatomy & basic processes– nephron – types – components. Basic renal processes – basics of glomerular filtration, tubular reabsorption & secretion – urine excretion & plasma clearance – micturition.

Digestive System: Organs of Digestive system – Anatomy and physiology of Gastrointestinal tract- Digestion and Absorption. Disorders of Gastrointestinal tract.

Module V (8 Hours)

Sensory and Endocrine Systems

Sensory System: Structure of the Eye and visual pathway, Visual process, Field of vision, Pupillary reflexes, Colour vision. Structure and functions of auditory system – hearing & balance; Organs of taste, smell & touch – structure & basic mechanisms.

Hormones – Types - hormone receptors – Adenohypophysis and neurohypophysis, Thyroid gland, Para thyroid gland, Islets of Langerhans, Adrenal modules, and adrenal cortex.

Course Plan

No	Topic	No. of Lectures
1	Introduction to Anatomy & Physiology	
1.1	Definition & relationship of structure & function. Concept of homeostasis – intracellular & extracellular fluids.	2
1.2	Functional organization of body– cells, tissues, organs & systems – Types.	2

1.3	Homeostatic control systems – negative & positive feedback and feed forward Mechanisms	2
2	Nervous Systems:	
2.1	Cells of Nervous systems – Types of Neuron and Synapses – Mechanisms of Nerve impulse	2
2.2	Nervous System: Organization, Central nervous system: Overview, Cerebrum – Cerebral cortex – General organization – motor, sensory, language & association areas – major functions. Basal ganglia, Thalamus & Hypothalamus – functions. Cerebellum, Brain Stem – basic structure & functions, Spinal cord – nerves, spinal reflex.	3
2.3	Blood: Components of Blood and functions – plasma– haematocrit – plasma proteins – erythrocytes – haemoglobin – anemia – blood typing – transfusion reaction – universal donor & acceptor – leukocytes – functions & types – platelets– blood clotting.	3
3	Cardiovascular System:	
3.1	Heart – Anatomy – location – pump – valves - major arteries & veins – cardiac muscle – electrical activity – pacemaker – normal & ectopic – cardiac action potential cardiac cycle.	3
3.2	cardiac rhythm & rate – normal & abnormal, myocardial ischemia & infarction, atherosclerosis – Heart sounds & murmurs. Cardiac output – stroke volume.	3
3.3	Skeletal system: Types of Bone and function – Physiology of Bone formation – Division of Skeleton Types of joints and function – Types of cartilage and function.	2
4	Muscular, Respiratory system, Digestive System and Urinary System	
4.1	Muscular: Parts of Muscle – Movements.	2
4.2	Respiratory: Parts of Respiratory Systems – Types of respiration - Mechanisms of Breathing – Regulation of Respiration	2
4.3	Digestive System: Organs of Digestive system – Anatomy and physiology of Gastrointestinal tract- Digestion and Absorption. Disorders of Gastrointestinal tract.	2
4.4	Urinary System: Kidneys – functions, anatomy & basic processes– nephron – types – components. Basic renal processes – basics of glomerular filtration, tubular reabsorption & secretion – urine excretion & plasma clearance – micturition.	3
5	Sensory and Endocrine Systems	
5.1	Sensory System: Structure of the Eye, Visual process, Field of vision, Visual pathway, Pupillary reflexes, Colour vision, Errors of refraction. Structure of ear, Auditory defects. Organs of taste and smell –structure & basic mechanisms.	4
5.2	Concept of hormone – Types of hormones and hormone receptors – Adenohypophysis and neurohypophysis, Thyroid gland, Para thyroid gland, Islets of Langerhans, Adrenal modules and adrenal cortex..	4

Reference Books:

1. Arthur C. Guyton, Textbook of Medical Physiology, Prism Books (Pvt) Ltd & W.B. Saunders Company.
2. Tina Sanders, Dr Valerie Scanlon Essentials of Anatomy and Physiology F.A. Davis Company.
3. Elaine N. Marieb, Katja Hoehn Human Anatomy & Physiology Benjamin Cummings.
4. Marieb, Elaine N, Essentials of human anatomy and physiology, Pearson Education, 2006.
5. B. R. Mackenna, R. Callander, Illustrated physiology, churchill livingstone, 1997.

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251TBM002	Biomedical Signal Acquisition & Processing	DISCIPLINE CORE	3	0	0	3

Preamble:

This course introduces the fundamentals of biomedical signals and systems, focusing on their acquisition, characteristics, and physiological origins. It covers essential signal processing techniques including filtering, time-frequency analysis, and feature extraction for biomedical applications. Advanced topics such as machine learning, signal compression, and real-world applications like BCI and wearable devices are also explored.

Course Outcomes:

The COs shown are only indicative. For each course, there can be 4 to 6 COs. After the completion of the course the student will be able to

CO 1	Explain the nature, sources, and characteristics of various biomedical signals and systems
CO 2	Describe and analyze techniques and instrumentation used for biomedical signal acquisition, including electrodes and noise mitigation strategies
CO 3	Apply time-domain, frequency-domain, and time-frequency domain analysis techniques to extract information from biomedical signals.
CO 4	Design and implement digital filtering and event detection methods for processing and interpreting biomedical signals
CO 5	Utilize advanced techniques such as machine learning, dimensionality reduction, and signal compression for real-world biomedical signal applications

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO4	PO5	PO6	PO7
CO 1	3		3			3	
CO 2	3		3	2	3		
CO 3	3		3	3	3		
CO 4	3		3	3	3		
CO 5	3	2	3	2	3	3	2

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	20
Create	

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern:

Continuous Internal Evaluation: 40 marks

- Problem assignments including unsolved exercise problems from reference text books: 20 marks
- Quiz: 10 marks
- Test paper (1 number): 10 marks

Quiz shall include topics from at least 50% of the syllabus. Test paper shall include minimum 80% of the syllabus

End Semester Examination Pattern:
End Semester Examination: 60 Marks.

There will be two parts: Part A and PartB

- Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question. Students should answer all questions.
- Part B will contain 7 questions with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question Paper

A P J ABDUL KALAM TECHNOLOGICAL UNIVERSITY
M.TECH DEGREE EXAMINATION
SEMESTER:
Branch:

Biomedical Signal Acquisition & Processing **Time: 2.5 Hours** **Marks: 60**

Part A

Answer ALL Questions. Each question carries 5 marks

1. Differentiate between Linear Time-Invariant (LTI) and nonlinear systems. How are LTI concepts applied in biomedical signal modeling?
2. Describe the working principle of surface electrodes. Discuss the major noise sources encountered during ECG signal acquisition
3. Explain the concept of Power Spectral Density (PSD). How is it useful in analyzing EEG signals?

4. What is an adaptive filter? Explain the use of the LMS algorithm in biomedical signal noise cancellation.
5. Briefly describe how machine learning techniques like SVM or k-NN can be applied for biomedical signal classification.

Part B

Answer ANY FIVE Questions, one from each module (5 x 7 marks = 35marks)

6. Describe the characteristics and origin of ECG and EEG signals. How do these signals differ in terms of their frequency content and clinical relevance?
7. Explain the concept of convolution and correlation in LTI systems. How are these operations used in analyzing biomedical signals?
8. Discuss different types of bio-potential electrodes and their applications. Highlight their advantages and limitations in clinical settings.
9. Illustrate the effects of aliasing in biomedical signal acquisition. How can aliasing be prevented through appropriate sampling techniques?
10. Compare and contrast the use of FFT and STFT in analyzing non-stationary biomedical signals. Provide examples where each method is preferred.
11. Explain the differences between FIR and IIR filters. Discuss their applicability and limitations in processing ECG signals
12. How are Principal Component Analysis (PCA) and Independent Component Analysis (ICA) used in biomedical signal separation? Provide examples from EEG or EMG analysis

Syllabus

Module 1 - Introduction to Biomedical Signals and Systems (8 Hours)

Nature and characteristics of biomedical signals: ECG, EEG, EMG, EOG, PCG, **Sources of biomedical signals** – biological, physiological origins; **Signal classification**: Deterministic vs. stochastic, periodic vs. aperiodic; **Basic system theory**: LTI systems, convolution, correlation, system response; **Biomedical signal modeling**: Signal-plus-noise model, linear and nonlinear models.

Module 2: Biomedical Signal Acquisition (8 Hours)

Principles of signal acquisition: electrodes, transducers, amplifiers; **Bio-potential electrodes**: surface, needle, microelectrodes; **Noise sources in biomedical signal acquisition**: motion artifact, baseline wander, power line interference; **Signal conditioning circuits**: filters, instrumentation amplifiers, isolation techniques; **ADCs and sampling**: Nyquist criterion, aliasing, resolution, quantization

Module 3: Time and Frequency Domain Analysis (8 Hours)

Time-domain features: peak detection, slope, duration, amplitude metrics; **Frequency-domain analysis:** DFT, FFT, power spectral density estimation; **Time-frequency analysis**: Short-time Fourier transform (STFT); Introduction to wavelet transform and its application in biomedical signals; Biomedical signal classification and interpretation

Module 4: Signal Filtering and Processing Techniques (8 Hours)

Digital filter design: FIR and IIR filter structures, design criteria; **Adaptive filtering**: LMS and RLS algorithms for noise reduction; Baseline correction, artifact removal techniques; **Event detection**: QRS detection in ECG, spike detection in EEG; **Case studies**: ECG denoising, EMG signal enhancement.

Module 5: Advanced Processing and Applications (8 Hours)

Feature extraction for classification and diagnosis; Machine learning basics in biosignal analysis: SVM, k-NN, decision trees; PCA and ICA in biomedical signal separation; Biomedical signal compression and data reduction techniques; **Applications**: Brain-computer interfaces (BCI), wearable sensors, telemedicine

Course Plan

No	Topic	No. of Lectures
	Module I	
1.1	**Nature and characteristics of biomedical signals**: ECG, EEG, EMG, EOG, PCG, etc.	2
1.2	**Sources of biomedical signals** – biological, physiological origins	1
1.3	**Signal classification**: Deterministic vs. stochastic, periodic vs. aperiodic.	1
1.4	**Basic system theory**: LTI systems, convolution, correlation, system response.	2
1.5	**Biomedical signal modeling**: Signal-plus-noise model, linear and nonlinear models.	2
	Module II	
2.1	**Principles of signal acquisition**: electrodes, transducers, amplifiers.	1
2.2	**Bio-potential electrodes**: surface, needle, microelectrodes.	1
2.3	**Noise sources in biomedical signal acquisition**: motion artifact, baseline wander, power line interference,	2
2.4	**Signal conditioning circuits**: filters, instrumentation amplifiers, isolation techniques.	2
2.5	**ADCs and sampling**: Nyquist criterion, aliasing, resolution, quantization.	2
3	**Module III**	
3.1	**Time-domain features**: peak detection, slope, duration, amplitude metrics.	2
3.2	**Frequency-domain analysis:** DFT, FFT, power spectral density estimation.	2
3.3	**Time-frequency analysis**: Short-time Fourier transform (STFT).	1
3.4	Introduction to wavelet transform and its application in biomedical signals.	1

3.5	Biomedical signal classification and interpretation.	2
4	**Module IV**	
4.1	**Digital filter design**: FIR and IIR filter structures, design criteria.	2
4.2	**Adaptive filtering**: LMS and RLS algorithms for noise reduction.	1
4.3	Baseline correction, artifact removal techniques	2
4.4	**Event detection**: QRS detection in ECG, spike detection in EEG.	2
4.5	**Case studies**: ECG denoising, EMG signal enhancement.	1
5	**Module V**	
5.1	Feature extraction for classification and diagnosis	2
5.2	**Machine learning basics in biosignal analysis**: SVM, k-NN, decision trees	2
5.3	PCA and ICA in biomedical signal separation; Biomedical signal compression and data reduction techniques	2
5.4	**Applications**: Brain-computer interfaces (BCI), wearable sensors, telemedicine	2

Textbooks

1. Rangayyan, R. M. – *Biomedical Signal Analysis: A Case-Study Approach*, Wiley-IEEE Press, 2nd Edition, 2015.
2. Cromwell, L., Weibell, F. J., & Pfeiffer, E. A. – *Biomedical Instrumentation and Measurements*, Prentice Hall, 2nd Edition, 2010.
3. Webster, J. G. – *Medical Instrumentation: Application and Design*, Wiley, 4th Edition, 2009.

Reference Books

1. Ingle, V. K., & Proakis, J. G. – *Digital Signal Processing Using MATLAB*, Cengage, 3rd Edition, 2011.
2. Sörnmo, L., & Laguna, P. – *Bioelectrical Signal Processing in Cardiac and Neurological Applications*, Elsevier Academic Press, 2005.
3. Khandpur, R. S. – *Handbook of Biomedical Instrumentation*, McGraw-Hill, 3rd Edition, 2014.
4. Acharya, U. R., et al. – *Advanced Biomedical Signal Processing*, Wiley, 2007.

PROGRAM ELECTIVE 1

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM011	TIME-FREQUENCY ANALYSIS OF BIOMEDICAL SIGNALS	PROGRAM ELECTIVE 1	3	0	0	3

Preamble:
This course aims to equip students with the theoretical foundations and practical skills necessary for analyzing non-stationary biomedical signals using time-frequency methods. It emphasizes the application of STFT, wavelet transforms, and advanced distributions like Wigner-Ville in real-world biomedical contexts. Through hands-on sessions and case studies, students will gain proficiency in extracting meaningful features for diagnostic and research purposes.

Pre-requisites:
Basics of signals and systems, introductory digital signal processing, familiarity with biomedical signal types (e.g., ECG, EEG, EMG).

Course Outcomes: After the completion of the course the student will be able to

CO 1	Identify the nature and challenges of real biomedical signals and recognize the need for time-frequency analysis in biomedical contexts. **(Understand)**
CO 2	Apply STFT to analyse real biomedical signals and Understand trade-offs in resolution and windowing. (**Apply)**
CO 3	Evaluate and implement wavelet transforms for various biomedical signal tasks for specific applications. **(Evaluate)**
CO 4	Interpret advanced TFDs and address interference issues and select appropriate TFDs for real biomedical analysis scenarios. **(Analyze)**
CO 5	Analyse and use time-frequency features for biomedical classification and Understand application-driven TFD selection and analysis. **(Apply)**

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3	2	2	1		2	1
CO 2	3	3	2	2		2	1
CO 3	3	3	2	2	2	2	1
CO 4	3	2	3	2		2	1
CO 5	3	3	3	3	3	2	2

Programme Outcomes

POs	Definition
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyze	20
Evaluate	10
Understand	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks
Course based task/Seminar/Data collection and interpretation: 15 marks

Test paper, 1 no.: 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern: 60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

FIRST SEMESTER M. TECH DEGREE EXAMINATION			Name Register No:
Course code	251EBM011	Course name	Time-Frequency Analysis of Biomedical Signals
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Explain the differences between time-domain, frequency-domain, and time-frequency representations.	5
2	Compute and interpret a spectrogram of a synthetic signal with two frequency components.	5
3	Apply DWT to identify high-frequency noise in an EEG signal and propose how to remove it.	5
4	Compare and evaluate STFT and WVD in terms of time-frequency localization and clarity.	5
5	Explain the concept of instantaneous frequency and its application in biomedical signals.	5
	PART B (Answer any five questions.)	
6	Illustrate the necessity of joint time-frequency analysis in biomedical signal interpretation.	7
7	Critically evaluate STFT's limitations when applied to high-resolution EMG recordings.	7
8	Develop a wavelet-based signal compression strategy for telemedicine applications.	7

9	Analyze how different kernels in Cohen's class reduce interference terms and improve interpretability of EEG signals.	7
10	Explain how instantaneous frequency can be derived and used to detect abnormalities in biomedical signals.	7
11	Evaluate the performance of time-frequency-based classifiers for arrhythmia detection using confusion matrices.	7
12	Propose a hybrid time-frequency approach combining WVD and wavelets for improved localization in bio signals.	7

Syllabus

Module 1 – Fundamentals of Biomedical Signals and Time-Frequency Motivation

Overview of biomedical signals: ECG, EEG, EMG, PPG, Time-domain vs. frequency-domain analysis, Stationary vs. non-stationary signals, Review of Fourier Transform and limitations in biomedical applications, Concept of joint time-frequency analysis, Types of time-frequency representations (TFRs), Introduction to Cohen's class of distributions.

Compute and visualize spectrograms using different windows and parameters-Analyse QRS segments in ECG and alpha rhythms in EEG. (Practical study)

Module 2- Short-Time Fourier Transform (STFT) and Spectrograms

Definition and derivation of STFT, Spectrogram: visual interpretation, Time-frequency resolution trade-off (Heisenberg uncertainty), Windowing: types, effects, and selection, Application of STFT to ECG (QRS complex), EEG, and EMG, Limitations and best practices.

Compute and visualize spectrograms using different windows and parameters-Analyse QRS segments in ECG and alpha rhythms in EEG. (Practical study).

Module 3- Wavelet Transform and Multiresolution Techniques

Introduction to Wavelets: concept of scale and translation, Continuous Wavelet Transform (CWT): definition and properties, Discrete Wavelet Transform (DWT): filter banks and decomposition, Choice of mother wavelet for biomedical signals, Applications: R-peak detection in ECG-Denoising EEG and EMG-Sleep stage analysis.

DWT-based ECG denoising and R-peak detection-Use of MATLAB or Py Wavelets for EEG analysis. (Practical study).

Module 4- Advanced Time-Frequency Distributions (WVD and Cohen's Class)

Wigner-Ville Distribution (WVD): theory, bilinear structure, and properties, Cross-terms and methods of suppression, Pseudo-WVD and Smoothed Pseudo-WVD, Other members of Cohen's class (e.g., Choi-Williams), Comparison with linear methods (STFT, Wavelet), Biomedical applications: seizure onset in EEG, muscle fatigue in EMG

Visualization and comparison of WVD vs. STFT on EEG seizure data-Energy localization and interpretation. (Practical study)

Module 5- Applications, Feature Extraction, and Research Case Studies

Time-frequency features: energy, entropy, instantaneous frequency, Time-frequency-based feature extraction for classification, Case studies: Epileptic seizure detection-ECG-based arrhythmia detection-EMG analysis for motor function Introduction to time-frequency machine learning pipelines, Current research trends and datasets (e.g., PhysioNet). Feature extraction from STFT and Wavelet Representations-Classification of EEG segments (e.g., seizure vs. normal) using simple ML models. (Practical study)

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Fundamentals of Biomedical Signals and Time-Frequency Motivation**	
1.1	Overview of biomedical signals: ECG, EEG, EMG, PPG	1
1.2	Time-domain vs. frequency-domain analysis.	1
1.3	Stationary vs. non-stationary signals	1
1.4	Review of Fourier Transform and limitations in biomedical applications	1
1.5	Concept of joint time-frequency analysis	1
1.6	Types of time-frequency representations (TFRs)	1
1.7	Introduction to Cohen's class of distributions.	1
1.8	Compute and visualize spectrograms using different windows and parameters. Analyse QRS segments in ECG and alpha rhythms in EEG. (Practical study)	1
2	**Module 2- Short-Time Fourier Transform (STFT) and Spectrograms**	
2.1	Definition and derivation of STFT	1
2.2	Spectrogram: visual interpretation	1
2.3	Time-frequency resolution trade-off (Heisenberg uncertainty)	1
2.4	Windowing: types, effects, and selection	1
2.5	Application of STFT to ECG (QRS complex), EEG, and EMG	1
2.6	Limitations and best practices	1
2.7	Compute and visualize spectrograms using different windows and parameters	1
2.8	Analyse QRS segments in ECG and alpha rhythms in EEG	1
3	**Module 3- Wavelet Transform and Multiresolution Techniques**	
3.1	Introduction to Wavelets: concept of scale and translation	1
3.2	Continuous Wavelet Transform (CWT): definition and properties	1
3.3	Discrete Wavelet Transform (DWT): filter banks and decomposition	1
3.4	Choice of mother wavelet for biomedical signals	1
3.5	Applications: R-peak detection in ECG-Denoising EEG and EMG sleep stage analysis.	2

3.6	Implement wavelet transforms for various biomedical signal tasks.	1
3.7	Choose appropriate wavelets for specific applications.	1
4	**Module 4- Advanced Time-Frequency Distributions (WVD and Cohen's Class)**	
4.1	Wigner-Ville Distribution (WVD): theory, bilinear structure, and properties	1
4.2	Cross-terms and methods of suppression.	1
4.3	Pseudo-WVD and Smoothed Pseudo-WVD	1
4.4	Other members of Cohen's class (e.g., Choi-Williams)	1
4.5	Comparison with linear methods (STFT, Wavelet)	1
4.6	Biomedical applications: seizure onset in EEG, muscle fatigue in EMG	1
4.7	Visualization and comparison of WVD vs. STFT on EEG seizure data.	1
4.8	Energy localization and interpretation.	1
5	**Module 5- Applications, Feature Extraction, and Research Case Studies**	
5.1	Time-frequency features: energy, entropy, instantaneous frequency	1
5.2	Time-frequency-based feature extraction for classification	1
5.3	Case studies: Epileptic seizure detection, ECG-based arrhythmia detection, EMG analysis for motor function.	1
5.4	Failure modes and mechanisms: Failure modes and mechanisms in MEMS,	1
5.5	Introduction to time-frequency machine learning pipelines	1
5.6	Current research trends and datasets (e.g., PhysioNet)	1
5.7	Feature extraction from STFT and Wavelet representations.	1
5.8	Classification of EEG segments (e.g., seizure vs. normal) using simple ML models.	1
		40

Text Book

1. Leon Cohen, *Time-Frequency Analysis*, Prentice-Hall.
2. Rangaraj M. Rangayyan, *Biomedical Signal Analysis*, Wiley-IEEE Press

Reference Books

1. Mallat, S., *A Wavelet Tour of Signal Processing*, Academic Press.
2. Research articles from IEEE EMBC, IEEE TBME, and journals like *Biomedical Signal Processing and Control*

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM012	COMPUTATIONAL NEUROSCIENCE	PROGRAM ELECTIVE 1	3	0	0	3

Preamble:

Computational Neuroscience is an interdisciplinary field that combines principles from neuroscience, mathematics, computer science, and engineering to understand the brain's information processing mechanisms. This subject explores how neural systems encode, transmit, and compute information, offering a quantitative and theoretical framework for studying brain function. By developing and analyzing computational models of neural activity, students gain insights into the structure and dynamics of neural circuits, cognitive processes, and behavior. The course aims to bridge the gap between biological data and theoretical understanding, preparing students to contribute to advancements in neuroscience research, artificial intelligence, and neural engineering.

Course Outcomes: After the completion of the course the student will be able to

CO 1	To understand the fundamental principles of how the brain processes information. (Understand)
CO 2	To learn mathematical models and computational techniques for analyzing neural systems (Apply)
CO 3	To simulate and interpret neuronal behavior using computational tools. (Apply)
CO 4	To bridge the gap between experimental neuroscience and theoretical modeling. (Analyze)
CO 5	To explore the application of computational neuroscience in areas such as artificial intelligence, cognitive science, and neural engineering. (Analyze)

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2		1			2	
CO 2	3		1			2	
CO 3	3	3	2	3	2	2	1
CO 4	3		1			2	
CO 5	1	3	3	3	3	2	1

Programme Outcomes

POs	Definition
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred) : 15 marks
Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	251EBM012	Course name	**COMPUTATIONAL NEUROSCIENCE**
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Define computational neuroscience. What are its main objective	5
2	Compare the leaky integrate-and-fire model with the simple integrate-and-fire model.	5
3	What is rate coding in neural systems? Give a simple example.	5
4	Explain the concept of Hebbian learning with a suitable equation.	5
5	Differentiate between feedforward and recurrent neural networks.	5
	PART B (Answer any five questions.)	
6	Describe the Hodgkin-Huxley model. Why is it considered a biophysical model?	7

7	Derive the membrane potential equation for the leaky integrate-and-fire neuron and explain its behavior with input current.	7
8	Discuss the differences between rate coding, temporal coding, and population coding. Give examples.	7
9	Explain Spike-Timing Dependent Plasticity (STDP). How does it affect learning in neural circuits?	7
10	How is information theory used in neural coding? Define entropy and mutual information in this context.	7
11	Design a simple model of a neural network for decision-making. What are the key assumptions and expected outputs?	7
12	Explain how computational models contribute to understanding cognitive processes like memory or perception.	7

Syllabus

Module 1 – Introduction to Computational Neuroscience
Introduction to Computational Neuroscience and Scope and Applications, Anatomy of Neurons and Synapses, Levels of Modeling: Biophysical, Phenomenological, Abstract, Hodgkin-Huxley Model (Conceptual Overview), Need for Modeling in Neuroscience, Tools and Software Overview (e.g., MATLAB, Python, NEURON).

Module 2- Neuron Models and Dynamics
Basic Electrical Properties: Membrane Potential, RC Circuits, Integrate-and-Fire Models, Leaky Integrate-and-Fire Model: Derivation & Simulation, Numerical Simulation Techniques, Comparison of Models (LIF, SRM, and Hodgkin-Huxley).

Module 3- Neural Coding and Information Processing
Rate Coding, Temporal Coding, Population Coding, Receptive Fields and Tuning Curves, Noise in Neural Responses and Signal Reliability, Introduction to Information Theory in Neural Coding, Case Studies / Simulation Exercises.

Module 4- Synaptic Plasticity and Learning
Synaptic Transmission: Excitatory/Inhibitory Synapses, Hebbian Learning and Variants, Spike-Timing Dependent Plasticity (STDP), Unsupervised Learning and Principal Component Analysis, Reinforcement Learning Basics (Reward-Based Learning.

Module 5- Neural Networks and Cognitive Modeling
Feedforward and Recurrent Neural Networks, Attractor Networks and Memory Models, Population Coding and Decision-Making, Models of Perception and Motor Control, Brain-Machine Interfaces and AI Applications.

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Computational Neuroscience**	
1.1	Introduction to Computational Neuroscience and Scope and	1

	Applications,	
1.2	Anatomy of Neurons and Synapses	1
1.3	Levels of Modeling: Biophysical, Phenomenological	2
1.4	Abstract, Hodgkin-Huxley Model (Conceptual Overview	2
1.5	Need for Modeling in Neuroscience	1
1.6	Tools and Software Overview (e.g., MATLAB, Python, NEURON).	1
2	**Module 2- Neuron Models and Dynamics**	
2.1	Basic Electrical Properties: Membrane Potential, RC Circuits,	1
2.2	Integrate-and-Fire Models, Leaky Integrate-and-Fire Model:	2
2.3	Derivation & Simulation	2
2.4	Numerical Simulation Techniques	2
2.5	Comparison of Models (LIF, SRM, and Hodgkin-Huxley).	1
3	**Module 3- Neural Coding and Information Processing**	
3.1	Rate Coding, Temporal Coding	1
3.2	Population Coding, Receptive Fields and Tuning Curves	2
3.3	Noise in Neural Responses and Signal Reliability	1
3.4	Introduction to Information Theory in Neural Coding	2
3.5	Case Studies / Simulation Exercises.	2
4	**Module 4- Synaptic Plasticity and Learning**	
4.1	Synaptic Transmission: Excitatory/Inhibitory Synapses	2
4.2	Hebbian Learning and Variants, Spike-Timing Dependent Plasticity (STDP),	2
4.3	Unsupervised Learning and Principal Component Analysis	2
4.4	Reinforcement Learning Basics (Reward-Based Learning.	2
5	**Module 5- Neural Networks and Cognitive Modeling**	
5.1	Feedforward and Recurrent Neural Networks	2
5.2	Attractor Networks and Memory Models	1
5.3	Population Coding and Decision-.	2
5.4	Making, Models of Perception and Motor Control	1
5.5	Brain-Machine Interfaces and AI Applications	2
		40

Text Book

1. Dayan, P., & Abbott, L. F. *Theoretical Neuroscience: Computational and Mathematical Modeling of Neural Systems*
2. Trappenberg, T. P. *Fundamentals of Computational Neuroscience*

3. Gerstner, W., Kistler, W., Naud, R., & Paninski, L. *Neuronal Dynamics: From Single Neurons to Networks and Models of Cognition*

Reference Books

1. Eugene M. Izhikevich – *Dynamical Systems in Neuroscience: The Geometry of Excitability and Bursting*
2. Thomas Trappenberg – *Introduction to Computational Models of Neural Systems*
3. Randall C. O'Reilly & Yuko Munakata – *Computational Explorations in Cognitive Neuroscience*
4. Peter Dayan & Laurence F. Abbott – *Theoretical Neuroscience Workbook*
5. Michael A. Arbib – *The Handbook of Brain Theory and Neural Networks*

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM013	Real-Time Biomedical Signal Processing	PROGRAM ELECTIVE 1	3	0	0	3

Preamble:

This course introduces students to the principles and methods used to process biomedical signals in real time. It focuses on signals like ECG, EEG, and EMG, which are important in medical diagnosis and monitoring. Students will learn how to acquire these signals, remove noise and artifacts, and analyze them using time and frequency domain techniques. The course also covers the use of digital signal processing (DSP) tools and hardware for real-time implementation. By the end of the course, students will be able to design and implement basic real-time systems for biomedical applications, preparing them for research or industry roles in healthcare technology.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Analyze different types of biomedical signals and identify their origin and character ***(Analyze)***
CO 2	Apply signal preprocessing techniques for artifact removal and noise reduction in biomedical signals. ***(Apply)***
CO 3	Evaluate time and frequency domain features of real-time biomedical signals using DSP tools. ***(Evaluate)***
CO 4	Design and implement real-time signal processing algorithms for selected biomedical applications. ***(Create)***

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3		3		2		
CO 2			2	3	3		
CO 3	2		3		3		
CO 4			3	3	3		

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration

100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks

Test paper, 1 no.: 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY **FIRST SEMESTER M.TECH DEGREE EXAMINATION**			Name Register No:
Course code	251EBM013	Course name	Real-Time Biomedical Signal Processing
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Explain the origin and characteristics of ECG and EMG signals. How do these signals differ in terms of source and frequency content?	5
2	Describe the role of instrumentation amplifiers in biomedical signal acquisition. Why is isolation important in biomedical instrumentation?	5
3	Compare and contrast Short-Time Fourier Transform (STFT) and Wavelet Transform for analyzing non-stationary biomedical signals like EEG.	5
4	Explain the working of the LMS adaptive filter. How is it used in real time noise cancellation in biomedical signals such as fetal ECG?	5
5	Discuss the real-time implementation of the Pan-Tompkins algorithm for QRS detection. What are the key steps involved?	5

	PART B (Answer any five questions.)	
6	Discuss the classification and characteristics of biomedical signals with suitable examples. How does the non-stationary nature of these signals affect their analysis?	7
7	With the help of a block diagram, explain the process of biomedical signal acquisition. Describe various sources of noise and outline suitable preprocessing methods to remove motion artifacts and power line interference.	7
8	Discuss a case study involving PET-CT fusion for oncology Explain the Discrete Wavelet Transform (DWT) and its advantages in biomedical signal analysis. Illustrate how DWT is used for ECG signal denoising with an example.	7
9	Describe the working principle of Independent Component Analysis (ICA). How can ICA be used to separate artifacts (like eye blinks) from EEG signals? Support your answer with a suitable case.	7
10	Compare and contrast Principal Component Analysis (PCA) and Independent Component Analysis (ICA) in the context of biomedical signal processing. When would you prefer one over the other?	7
11	Explain the architecture of a Digital Signal Processor (DSP) suitable for biomedical applications. How do features like pipelining and real-time interrupt handling support biomedical signal processing tasks?	7
12	Design a real-time biomedical signal processing system for detecting epileptic seizures using EEG signals. Explain the selection of signal processing techniques and real-time constraints involved in implementation.	7

Syllabus

Module 1 – Introduction to Biomedical Signals and Systems (8 hours)

Introduction to physiological systems and biomedical signals (ECG, EEG, EMG, PCG), Basic characteristics: non-stationarity, low amplitude, variability, Basic anatomy and electrical modeling of bio-signal sources, Systems perspective: Linear and nonlinear system modeling, Noise sources in biomedical signals (motion artifacts, EM interference, etc.), Biomedical instrumentation and signal paths, Review of signal and system basics (LTI systems, convolution, etc.)

Module 2- Signal Acquisition and Preprocessing (8 hours)

Bio-electrodes and their configurations (surface, needle, microelectrodes), Signal conditioning: amplifiers (instrumentation, isolation), filters, Analog-to-Digital Conversion: sampling, quantization, resolution, Practical sampling and anti-aliasing filtering, Preprocessing: baseline wander removal, drift correction, and artifact reduction, Real-time constraints in acquisition systems

Module 3- Time and Frequency Domain Analysis (8 hours)

Time domain analysis: peaks, RMS, zero-crossing, statistical features, Frequency domain analysis: DFT, FFT, spectral analysis, Short-Time Fourier Transform (STFT) for transient signals, Wavelet Transform: DWT, CWT for biomedical signals (esp. EEG, EMG), Power Spectral Density (PSD)

estimation: Welch's method, Time-frequency representation examples: ECG QRS detection, EEG band energy

Module 4- Adaptive and Statistical Signal Processing (8 hours)
Adaptive filtering: LMS, RLS algorithms for noise cancellation (e.g., fetal ECG), Principal Component Analysis (PCA): signal decorrelation, dimensionality reduction, Independent Component Analysis (ICA): separation of mixed signals (EEG artifacts), Feature extraction techniques (statistical, morphological, frequency-domain), Detection and classification using thresholding, SVM, and k-NN (introductory), Case study: arrhythmia classification using ECG features

Module 5- Real-Time Implementation and Applications (8 hours)
Introduction to real-time systems and constraints in biomedical applications, DSP hardware platforms: TMS320C6713/6748, ARM Cortex, Raspberry Pi, Real-time OS and embedded systems concepts (RTOS, interrupts, latency), Case Study 1: Real-time QRS detection using Pan-Tompkins algorithm, Case Study 2: Real-time EEG seizure detection using wavelets, Tools: MATLAB Simulink, LabVIEW, Python with real-time plugins.

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Biomedical Signals and Systems**	
1.1	Introduction to physiological systems and biomedical signals (ECG, EEG, EMG, PCG)	2
1.2	Basic characteristics: non-stationarity, low amplitude, variability	1
1.3	Basic anatomy and electrical modeling of bio-signal sources	1
1.4	Systems perspective: Linear and nonlinear system modeling	1
1.5	Noise sources in biomedical signals (motion artifacts, EM interference, etc.)	1
1.6	Biomedical instrumentation and signal paths	1
1.7	Review of signal and system basics (LTI systems, convolution, etc.)	1
2	**Module 2- Signal Acquisition and Preprocessing**	
2.1	Bio-electrodes and their configurations (surface, needle, microelectrodes)	1
2.2	Signal conditioning: amplifiers (instrumentation, isolation), filters	2
2.3	Analog-to-Digital Conversion: sampling, quantization, resolution	1
2.4	Practical sampling and anti-aliasing filtering	1
2.5	Preprocessing: baseline wander removal, drift correction, and artifact reduction	2
2.6	Real-time constraints in acquisition systems	1
3	**Module 3- Time and Frequency Domain Analysis**	
3.1	Time domain analysis: peaks, RMS, zero-crossing, statistical features	1
3.2	Frequency domain analysis: DFT, FFT, spectral analysis	2
3.3	Short-Time Fourier Transform (STFT) for transient signals	1

3.4	Wavelet Transform: DWT, CWT for biomedical signals (esp. EEG, EMG)	2
3.5	Power Spectral Density (PSD) estimation: Welch's method	1
3.6	Time-frequency representation examples: ECG QRS detection, EEG band energy	1
4	**Module 4- Adaptive and Statistical Signal Processing**	
4.1	Adaptive filtering: LMS, RLS algorithms for noise cancellation (e.g., fetal ECG)	2
4.2	Principal Component Analysis (PCA): signal decorrelation, dimensionality reduction	1
4.3	Independent Component Analysis (ICA): separation of mixed signals (EEG artifacts)	1
4.4	Feature extraction techniques (statistical, morphological, frequency-domain)	1
4.5	Detection and classification using thresholding, SVM, and k-NN (introductory)	2
4.6	Case study: arrhythmia classification using ECG features	1
5	Module 5- Real-Time Implementation and Applications	
5.1	Introduction to real-time systems and constraints in biomedical applications	1
5.2	DSP hardware platforms: TMS320C6713/6748, ARM Cortex, Raspberry Pi	1
5.3	Real-time OS and embedded systems concepts (RTOS, interrupts, latency))	1
5.4	Case Study 1: Real-time QRS detection using Pan-Tompkins algorithm	2
5.5	Case Study 2: Real-time EEG seizure detection using wavelets	2
5.6	Tools: MATLAB Simulink, LabVIEW, Python with real-time plugins	1
		40 Hrs

Text Books

1. Rangaraj M. Rangayyan, *Biomedical Signal Analysis: A Case-Study Approach*, Wiley-IEEE Press, 2nd Edition, 2015
2. John G. Proakis, Dimitris G. Manolakis, *Digital Signal Processing: Principles, Algorithms, and Applications*, Pearson Education, 4th Edition, 2007.
3. John G. Webster (Ed.), *Medical Instrumentation: Application and Design*, 4th Edition, Wiley, 2009.
4. Rakesh Kumar, *Bio-Medical Signal Processing*, S.K. Kataria & Sons, 1st Edition, Reprint 2024.
5. Ram Bilas Pachori, *Time-Frequency Analysis Techniques and Their Applications*, CRC Press, 1st Edition, 2023.

Reference Books

1. S.R. Mahadeva Prasanna, *Speech, Audio, Image and Biomedical Signal Processing using Neural Networks*, Springer, 1st Edition, 2008.
2. P. Prasant, Pradeep Devendra Gaikwad, S. Praveena, Satyanarayana Naga V.K., *Biomedical Signal Processing*, Rademics, 1st Edition, 2024.
3. Butta Singh (Editor), *Computational Tools and Techniques for Biomedical Signal Processing*, IGI Global, 1st Edition, 2016.
4. Jaydip Sen et al., *Machine Learning: Algorithms, Models, and Applications*, arXiv, 2022.
5. Laxminarayana K., *Biomedical Signal Processing*, Cengage Learning India, 2021.

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM014	MULTIMODALBIOMEDICAL DATA FUSION	PROGRAM ELECTIVE 1	3	0	0	3

Preamble:

This course introduces the principles and practices of integrating multiple biomedical modalities such as EEG, ECG, MRI, and PET to enhance clinical diagnosis and monitoring. It covers data acquisition, preprocessing, fusion strategies, and real-world applications across various healthcare domains. Emphasis is placed on practical tools, ethical considerations, and emerging trends like AI-driven multimodal fusion, tailored for working professionals.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Identify and describe the characteristics of various biomedical data modalities such as EEG, ECG, MRI, and PET. ***(Cognitive Knowledge Level: Understand)***
CO 2	Apply suitable preprocessing techniques for multimodal biomedical data using tools like EEGLAB, ImageJ, or Python. ***(Cognitive Knowledge Level: Apply)***
CO 3	Analyze synchronization issues, data alignment, and fusion strategies across multiple modalities. ***(Cognitive Knowledge Level: Analyze)***
CO 4	Evaluate real-world fusion applications in neurological, cardiac, and oncological case studies for diagnostic enhancement. ***(Cognitive Knowledge Level: Evaluate)***
CO 5	Design and present a basic multimodal biomedical fusion workflow incorporating ethical considerations and emerging technologies ***(Cognitive Knowledge Level: Create)***

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1			2	2	2		
CO 2	2		2	2	3		
CO 3	2	1	2	3	3	2	
CO 4	3	2	3	3	3	2	1
CO 5	3	3	3	3	3	3	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred) : 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no. : 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	251EBM014	Course name	MUTIMODAL BIOMEDICAL DATA FUSION
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	List and briefly explain any five biomedical data modalities commonly used in clinical applications.	5
2	What are the major challenges in multimodal data synchronization and alignment?	5
3	Explain the difference between data-level, feature-level, and decision-level fusion with examples.	5
4	Compare PET and CT modalities in terms of spatial and functional characteristics.	5
5	Write short notes on: (a) Artifact removal (b) Dimensionality reduction techniques.	5
	PART B (Answer any five questions.)	
6	Design a basic multimodal fusion pipeline involving EEG and fMRI for detecting neurological disorders.	7
7	Evaluate the advantages and limitations of feature-level fusion using	

	real-time biomedical datasets.	
8	Discuss a case study involving PET-CT fusion for oncology applications.	7
9	With an example, explain how multimodal fusion is applied in telemedicine or wearable health monitoring systems.	
10	Explain temporal and spatial alignment in multimodal data. Why is it critical for fusion accuracy?	7
11	What are the ethical considerations in collecting and processing multimodal biomedical data?.	7
12	Discuss emerging trends in multimodal biomedical fusion, especially the role of AI and generative models.	7

Syllabus

Module 1 – Introduction to Multimodal Biomedical Data

Biomedical modality overview: EEG, ECG, MRI, CT, PET, Ultrasound, EOG, EMG. Data characteristics: temporal, spatial, resolution, and functional significance. Motivation for fusion: complementary insights, improved diagnosis, enhanced accuracy. Levels of fusion: data-level, feature-level, decision-level, Challenges in multimodal integration

Module 2- Data Acquisition and Preprocessing

Overview of multimodal data acquisition pipelines, Synchronization and alignment challenges,.Data cleaning: noise filtering, artifact removal. Preprocessing tools: EEGLAB (for EEG), ImageJ (for images), Python basics, Simple preprocessing exercises with real/sample datasets.

Module 3- Fusion Techniques and Strategies

Data-level fusion: sensor fusion, interpolation methods, Feature-level fusion: concatenation, transformation, dimensionality reduction (PCA, t-SNE). Decision-level fusion: voting, probabilistic methods, Temporal and spatial alignment techniques.Tools and software: MATLAB/Python-based libraries.

Module 4- Applications and Case Studies

Neurological disorder diagnosis (EEG + fMRI), Cardiac monitoring (ECG + PPG + Imaging), Oncology (PET-CT fusion), Assistive technologies (EEG + Eye tracking), Telemedicine and wearable data fusion.

Module 5- Project, Ethics, and Future Directions

Design of a simple multimodal fusion pipeline, Common pitfalls and error handling, Ethical issues in multimodal data usage, Introduction to AI and ML for multimodal data (non-mathematical view). Emerging trends: multimodal generative AI, real-time fusion in smart healthcare

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Multimodal Biomedical Data**	
1.1	Biomedical modality overview: EEG, ECG, MRI, CT, PET,	2

	Ultrasound, EOG, EMG.	
1.2	Data characteristics: temporal, spatial, resolution, and functional significance.	2
1.3	Motivation for fusion: complementary insights, improved diagnosis, enhanced accuracy.	1
1.4	Levels of fusion: data-level, feature-level, decision-level	2
1.5	Challenges in multimodal integration	1
2	**Module 2- Data Acquisition and Preprocessing**	
2.1	Overview of multimodal data acquisition pipelines, Synchronization and alignment challenges.	3
2.2	Data cleaning: noise filtering, artifact removal	1
2.3	Preprocessing tools: EEGLAB (for EEG), ImageJ (for images), Python basics	2
2.4	Simple preprocessing exercises with real/sample datasets.	2
3	**Module 3- Fusion Techniques and Strategies**	
3.1	Data-level fusion: sensor fusion, interpolation methods,	2
3.2	Feature-level fusion: concatenation,	1
3.3	Transformation, dimensionality reduction (PCA, t-SNE).	1
3.4	Decision-level fusion: voting, probabilistic methods	1
3.5	Temporal and spatial alignment techniques.	1
3.6	Tools and software: MATLAB/Python-based libraries.	2
4	**Module 4- Applications and Case Studies**	
4.1	Neurological disorder diagnosis (EEG + fMRI)	2
4.2	Cardiac monitoring (ECG + PPG + Imaging)	1
4.3	Oncology (PET-CT fusion)	1
4.4	Assistive technologies (EEG + Eye tracking)	2
4.5	Telemedicine and wearable data fusion.	2
5	**Module 5- Project, Ethics, and Future Directions**	
5.1	Design of a simple multimodal fusion pipeline, Common pitfalls and error handling	2
5.2	Ethical issues in multimodal data usage	2
5.3	Introduction to AI and ML for multimodal data (non-mathematical view)	2
5.4	Emerging trends: multimodal generative AI, real-time fusion in smart healthcare.	2
		40 Hrs

Text Books

1. James S. Duncan, Nicholas Ayache, *Medical Image Analysis: Progress Over Two Decades and the Challenges Ahead*, IEEE Transactions on Pattern Analysis and Machine Intelligence, 2000.
2. Mubarak Shah, *Fundamentals of Multimedia*, Pearson Education, 2nd Edition, 2014.

3. A. A. Petrosian and L. N. Cooper, *Biomedical Signal and Image Processing*, CRC Press, 1998.

Reference Books

1. Yu-Dong Zhang, Shui-Hua Wang, *Multimodal Machine Learning in Healthcare: Techniques and Applications*, Academic Press, 2024.
2. Oleg S. Pianykh, *Digital Imaging and Communications in Medicine (DICOM): A Practical Introduction and Survival Guide*, Springer, 2nd Edition, 2012.
3. Andreas Maier et al., *Medical Imaging Systems*, Springer, 2018.
4. Ayman El-Baz, Jasjit S. Suri, *Multi-Modality State-of-the-Art Medical Image Segmentation and Registration Methodologies*, Springer, 2011.
5. Jerry L. Prince, Jonathan Links, *Medical Imaging Signals and Systems*, Pearson, 2nd Edition, 2014

PROGRAM ELECTIVE II

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM021	Medical Device Design and Regulatory Affairs	PROGRAM ELECTIVE 2	3	0	0	3

Preamble:

This course in Medical Device Design and Regulatory Affairs imparts advanced knowledge and skills essential for developing safe, effective, and compliant medical devices. It covers design principles, risk management, human factors, and global standards such as ISO 13485, ISO 14971, and IEC 60601. Regulatory frameworks including CDSCO, FDA, and EU MDR are addressed alongside essential documentation practices. Real-world case studies are integrated throughout the course to reinforce practical understanding and application, enabling learners to contribute effectively to innovation, quality systems, and regulatory processes in the medical device sector.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Explain design fundamentals, product documentation, and global medical device classification standards.
CO 2	Apply risk analysis and human factors engineering to develop safer, user-centric device designs.
CO 3	Analyze the application of safety standards in design control of medical devices.
CO 4	Develop regulatory documentation aligned with CDSCO, US FDA, and EU MDR frameworks.
CO 5	Evaluate QMS compliance through internal audits, CAPA, and traceability to ISO 13485.

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2	2	3	2	1	1	1
CO 2	2	1	3	3	2	1	1
CO 3	2	2	3	3	3	2	1
CO 4	2	3	3	3	2	1	2
CO 5	3	3	3	2	2	2	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Understand	13
Apply	13
Analyse	13
Evaluate	20
Create	20

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Technical Report on Case Study (based on Modules 1–3) 15

- Analyze a real or hypothetical medical device design
- Include classification, risk management, and applicable safety standards

Seminar/Presentation on Regulatory or Quality Frameworks (Modules 4–5) 15

- Prepare and deliver a presentation on regulatory pathways (CDSCO/FDA/EU MDR) or ISO 13485 compliance structure

Test Paper (covering minimum 80% of syllabus) 10

End Semester Examination Pattern: 60 Marks

There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDI]L KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	**251EBM023**	Course name: Medical Device Design and Regulatory Affairs	
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	How does the integration of Human Factors Engineering (HFE) influence the design process of medical devices? Provide examples illustrating its impact on device usability.	5
2	Assess the effectiveness of IEC 62366-1:2015 in mitigating use-related risks in medical devices. How does it compare to ISO 14971:2019 in terms of risk management integration?	5

3	Critique the strengths and limitations of formative and summative evaluation methods in usability testing. Which is more effective at different stages of device development?	5
4	Evaluate the role of the Usability Engineering File in regulatory submissions. How does it support compliance with standards like IEC 62366-1:2015?	5
5	Assess the effectiveness of Use-Related Risk Analysis (URRA) in identifying potential hazards in medical device use. How does it integrate with overall risk management processes?	5
	PART B (Answer any five questions.)	
6	Compare and contrast the roles of usability engineering and human factors engineering in medical device development. In what ways do they intersect and diverge?	7
7	Analyze the FDA's guidance on human factors and usability engineering. How does it influence the development lifecycle of medical devices?	7
8	Develop a usability testing plan for a new medical device, detailing formative and summative evaluation techniques, and identifying potential use-related risks.	7
9	Analyze the components of a Human Factors Engineering Report. How do these elements contribute to the overall safety and efficacy of a medical device?	7
10	Analyze the impact of human error on medical device safety. How can task analysis and Human Error Assessment and Reduction Technique (HEART) mitigate these risks?	7
11	Develop a post-market surveillance plan that incorporates human factors considerations to monitor and improve device usability over time.	7
12	Create a checklist for preparing a regulatory submission that includes all necessary documentation and aligns with FDA and CE marking requirements.	7

Syllabus

Module 1: Medical Device Design Fundamentals and Classification

Introduction to medical device innovation, Idea feasibility and generating concepts, Proof of concept and prototype development ,Identification of device requirements, Product specification and specification review, Design specifications (hardware/software) , Design documentation- Device History Record (DHR) - Device Master Record (DMR) - Design History File (DHF), Medical Device Classification-Indian Classification (CDSCO – IMDR) - US FDA Classification (Class I, II, III) -EU Classification (Class I, IIa, IIb, III), Case Study: Automatic BP Monitor, ECG Machine

Module 2: Risk Analysis and Human Factors in Design

Risk management in medical device design, Hazard identification and risk trace matrix, Failure Mode and Effects Analysis (FMEA) - Design FMEA -System FMEA, Hardware/software design reviews, Design of Experiments (DOE), Safety margins and environmental protection, Product misuse and associated risks, Biocompatibility and sterilization standards, Human factors engineering and usability testing, Bill of materials (mechanical, electrical, software)

Case Study: Drug Infusion System

Module 3: Medical Device Safety Standards and Design Controls

Design controls in medical device development, Risk management (ISO 14971), Biocompatibility (ISO 10993), Electrical safety (IEC 60601-1), EMC standards (IEC 60601-1-2), Usability engineering (IEC 62366 / IEC 60601-1-6), Software/hardware validation, Human factors and design safety.
Case Study Report: Prepare a report analyzing the design and safety standards applied in a real-world Class II/III medical device (e.g., ECG monitor or infusion pump). Include mapping to ISO 14971, IEC 60601-1, and usability engineering standards with justification of chosen design controls and risk mitigations.

Module 4: Medical Device Regulatory Landscape

Regulatory frameworks (CDSCO, US FDA, EU MDR), Design Docket and Device Master File documentation, Regulatory pathways (510(k), PMA, CE), In-vitro/in-vivo requirements, Patent/IP strategy for medical devices.
Regulatory Submission File Creation: Create a mock regulatory submission dossier for a hypothetical diagnostic device including: Executive summary, IMDR-compliant Design Docket (Schedule IV/V), US FDA pathway identification (510k or PMA), and a basic IP landscape or patent strategy note.

Module 5: Medical Device Compliance and Quality Systems

ISO 13485:2016 implementation, Internal auditing procedures, Quality documentation and traceability, ICMED 13485 (India-specific certification), Regulatory inspection preparedness, Harmonization of multiple standards.
Internal Audit & CAPA Report Simulation: Conduct a simulated internal audit (based on ISO 13485 QMS clauses) of a mock medical device manufacturer. Submit a detailed report covering: Non-conformities, Root cause analysis, CAPA (Corrective and Preventive Actions), and a traceability matrix to compliance clauses (ISO 13485 / ICMED 13485).

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Human Factors and User-Centered Design**	
1.1	**Definition and Scope of Human Factors Engineering (HFE)**- Understanding HFE in the context of medical devices.	1
1.2	Distinction between usability engineering and human factors engineering.	1
1.3	**Importance of User-Centered Design**- Principles of user-centered design in medical devices.	1
1.4	Benefits of user-centered design for patient safety and device effectiveness.	1
1.5	**Key Concepts in Usability Engineering**- Usability, user interface and context of use.	1
1.6	User tasks, user profiles, and use environments.	1
1.7	**Impact of Poor Usability on Patient Safety**- Case studies of usability failures and their consequences.	1
1.8	Strategies to mitigate use-related errors.	1
2	**Module 2- Human Factors Standards and Regulatory Guidelines**	

2.1	**IEC 62366-1:2015 – Application of Usability Engineering to Medical Devices-** Overview and structure of IEC 62366-1	1
2.2	Usability engineering process as per the standard, Integration with risk management processes.	1
2.3	**ISO 14971:2019 – Application of Risk Management to Medical Devices-** Risk management principles and process.	1
2.4	Relationship between human factors and risk management.	1
2.5	**FDA Guidance on Human Factors and Usability Engineering-** Overview of FDA guidelines.	1
2.6	Application of guidelines in medical device development.	1
2.7	**Integration of Standards into Quality Management Systems-** Documentation and compliance requirements.	1
2.8	Audit and review processes.	1
3	**Module 3- Usability Evaluation Methods**	
3.1	**Formative Evaluations-** Purpose and timing of formative evaluations, Methods.	1
3.2	Heuristic evaluation, cognitive walkthroughs, task analysis.	1
3.3	**Summative Evaluations**- Purpose and timing of summative evaluations, Methods.	1
3.4	Usability testing, user trials, performance metrics.	1
3.5	**Identifying Use-Related Risks and Design Issues-** Analyzing usability test results.	1
3.6	Identifying potential hazards and hazardous situations.	1
3.7	**Analyzing and Interpreting Usability Data**- Qualitative and quantitative data analysis.	1
3.8	Reporting findings and recommendations.	1
4	**Module 4- Documentation and Regulatory Submissions**	

4.1	**Structure and Content of the Usability Engineering File-** Required documentation and records.	1
4.2	Traceability and linkage to design controls.	1
4.3	**Human Factors Engineering Reports**- Purpose and components of the report	1
4.4	Documentation of usability evaluations and risk assessments.	1
4.5	**Linking Usability Documentation to Risk Management Files-** Integration with ISO 14971 risk management files.	1
4.6	Ensuring consistency and completeness.	1
4.7	**Preparing for Regulatory Submissions-** FDA, CE marking, and other regulatory requirements.	1
4.8	Best practices for documentation and reporting.	1
5	**Module 5- Integrating Human Factors into Risk Management**	
5.1	**Identifying Use-Related Hazards and Hazardous Situations-** Use-Related Risk Analysis (URRA).	1

5.2	Task Analysis, Human Error Assessment and Reduction Technique (HEART).	1
5.3	**Assessing Risks Associated with Use Errors-** Risk Estimation, Severity Levels, Likelihood Determination.	1
5.4	**Implementing Mitigations-** Design Modifications.	1
5.5	User Training, Labeling and Instructions for Use (IFU).	1
5.6	**Post-Market Surveillance and Continuous Improvement-** Monitoring Device Performance.	1
5.7	Feedback Mechanisms.	1
5.8	Iterative Design Process.	1
		40

Text Book

1. Usability Testing of Medical Devices (2nd Edition) by Michael E. Wiklund, Jonathan Kendler, and Allison Y. Strochlic
2. Handbook of Human Factors in Medical Device Design edited by Matthew B. Weinger, Michael E. Wiklund, and Daryle Jean Gardner-Bonneau
3. Designing Usability into Medical Products by Michael E. Wiklund and Stephen B. Wilcox

Reference Materials

1. IEC 62366: Application of Usability Engineering to Medical Devices
2. ISO 9241: Ergonomics of Human-System Interaction
3. FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM025	Quality Systems and Risk Management in Medical Devices	PROGRAM ELECTIVE 2	3	0	0	3

Preamble: This course provides a comprehensive understanding of quality systems and risk management practices specific to medical device development. It focuses on global and Indian regulatory frameworks, standards like ISO 13485 and ISO 14971, design and risk controls, auditing procedures, and quality improvement tools critical to compliance, safety, and innovation in the medical technology industry.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand the regulatory, quality assurance, and lifecycle management of medical devices. (Understand)
CO 2	Analyze key global and Indian medical device regulations including ISO, FDA, and MDR. (Analyze)
CO 3	Apply risk management standards and tools including ISO 14971 in medical device design. (Apply)
CO 4	Evaluate design, process control, and usability risk management tools like FMEA, FTA, and IEC 62304/62366. (Evaluate)
CO 5	Formulate quality improvement and audit strategies including PMS, Six Sigma, and Lean practices. (Create)

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2		2	2			
CO 2	2	2	3	3	2		
CO 3	3		3	3	3		
CO 4	2		3	3	3		
CO 5	3	3	3	3	2	2	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks.

Test paper, 1 no.: 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

SAHRDAYA COLLEGEBOF ENGINEERING AND TECHNOLOGY (AUTONOMOUS) FIRST SEMESTER M. TECH DEGREE EXAMINATION			Name Register No:
Course code	241EEC009	Course name	Quality Systems and Risk Management in Medical Devices
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	What are the major clauses of ISO 13485:2016?	5
2	Explain the classification system for medical devices under MDR 2017.	5
3	Define and distinguish between hazard and risk in the context of ISO 14971.	5
4	What is FMEA? How is it applied in medical device risk management?	5
5	List any four tools used for continuous improvement in QMS.	5
	PART B (Answer any five questions.)	
6	Compare the medical device regulatory frameworks of India, the US, and the EU.	7
7	Explain how CAPA is implemented as part of a QMS.	7
8	Analyze the importance of Unique Device Identification (UDI) globally.	7
9	Design a sample Risk Management Plan for a wearable ECG device	7
10	How do IEC 62304 and IEC 62366 contribute to safe medical software and usability?	7
11	Discuss materiovigilance with reference to post-market surveillance in India.	7

12	Illustrate with examples the application of Six Sigma in a medical device company.	7

Syllabus

Module 1 – Introduction to Quality Systems (8 Hours)

Introduction to medical devices: Classification and lifecycle, Quality Management Systems (QMS): Concepts of Quality, QA, QC, Global Standards: ISO 13485:2016 – clauses and implementation, Indian context: Schedule M III of Indian Medical Device Rules (MDR 2017), Design control, document control, and traceability, Case studies: QMS implementation in Indian device companies.

Module 2- Regulatory Frameworks and Standards (8 Hours)

Indian regulatory framework: CDSCO, MDR 2017, Device classification (A to D), licensing and GSR updates, US FDA QSR (21 CFR Part 820): Design control, CAPA, DHF, DMR, EU Medical Device Regulation (MDR 2017/745): CE marking, conformity assessment, Role of international bodies: IMDRF, WHO PQ, Harmonization efforts: Global convergence and Indian adoption of international standards, Overview of UDI (Unique Device Identification) in India and globally

Module 3 Risk Management – Principles and Process (8 Hours)

Risk management overview: Definition, principles (ISO 14971:2019), Indian regulatory expectations for risk analysis, Risk analysis techniques: Hazard Identification, Risk Estimation, Risk Evaluation, Risk control measures and benefit-risk analysis, Development of a Risk Management Plan and Risk Management File, Examples from Indian device startups and SMEs

Module 4- Implementation and Tools (8 Hours)

Integrating risk management with QMS, CAPA (Corrective and Preventive Actions), Design and process FMEA, Fault Tree Analysis (FTA), Software risk management – link to IEC 62304, Human factors and usability engineering (IEC 62366)

Module 5- Auditing, Documentation, and Continuous Improvement (8 Hours)

Types of audits: Internal, external, regulatory (CDSCO, FDA inspections), Audit preparation, nonconformity handling, and remediation, Post-market surveillance (PMS) in India and globally, Materiovigilance and vigilance reporting: Forms, formats, flowcharts, Continuous improvement: Six Sigma, Lean, PDCA, Quality metrics and dashboarding in Indian MedTech companies

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Quality Systems**	
1.1	Introduction to medical devices: Classification and lifecycle, Case studies: QMS implementation in Indian device companies	2
1.2	Quality Management Systems (QMS): Concepts of Quality, QA, QC	1
1.3	Global Standards: ISO 13485:2016 – clauses and implementation	1
1.4	Indian context: Schedule M III of Indian Medical Device Rules (MDR 2017), Design control, document control, and traceability	2

1.5	Case studies: QMS implementation in Indian device companies	2
2	**Module 2- Regulatory Frameworks and Standards**	
2.1	Indian regulatory framework: CDSCO, MDR 2017, Device classification (A to D), licensing and GSR updates,	2
2.2	US FDA QSR (21 CFR Part 820): Design control, CAPA, DHF, DMR, EU	1
2.3	Medical Device Regulation (MDR 2017/745): CE marking, conformity assessment,	2
2.4	Role of international bodies: IMDRF, WHO PQ	1
2.5	Harmonization efforts: Global convergence and Indian adoption of international standards, Overview of UDI (Unique Device Identification) in India and globally	2
3	**Module 3- Risk Management – Principles and Process**	
3.1	Risk management overview: Definition, principles (ISO 14971:2019), Indian regulatory expectations for risk analysis, ,	2
3.2	Risk analysis techniques: Hazard Identification, Risk Estimation, Risk Evaluation	2
3.3	Risk control measures and benefit-risk analysis, Development of a Risk Management Plan and Risk Management File,	2
3.4	Examples from Indian device startups and SMEs	2
4	**Module 4- Implementation and Tools**	
4.1	Integrating risk management with QMS	2
4.2	CAPA (Corrective and Preventive Actions)	1
4.3	Design and process FMEA	1
4.4	Fault Tree Analysis (FTA),	1
4.5	Software risk management – link to IEC 62304	1
4.6	Human factors and usability engineering (IEC 62366)	2
5	**Module 5- Auditing, Documentation, and Continuous Improvement**	
5.1	Types of audits: Internal, external, regulatory (CDSCO, FDA inspections), Audit preparation, nonconformity handling, and remediation, post-market surveillance (PMS) in India and globally,	3
5.2	Materiovigilance and vigilance reporting: Forms, formats, flowcharts	2
5.3	Continuous improvement: Six Sigma, Lean, PDCA, Quality metrics and dashboarding in Indian MedTech companies	3
		40

Text Book

1. R. C. Fries, *Medical Device Quality Assurance and Regulatory Compliance*, 2nd ed., Boca Raton, FL, USA: CRC Press, 2012.

2. N. S. Prasad and R. R. Gupta, *Medical Device Regulations in India: Law, Regulation, and Practice*, Gurgaon, India: LexisNexis, 2022.
3. J. E. Rulis and D. H. Morton, *Quality Systems and Controls for Medical Devices*, Bethesda, MD, USA: PDA/DHI Publishing, 2011.

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM023	HUMAN FACTORS AND USABILITY ENGINEERING IN MEDICAL DEVICES	PROGRAM ELECTIVE 2	3	0	0	3

Preamble: Human Factors Engineering (HFE) and Usability Engineering (UE) focus on optimizing the interaction between users and Medical devices. This approach involves understanding how users perceive information, interpret data, and manipulate device controls, as well as how devices respond to user inputs. By addressing these aspects, HFE and UE aim to reduce use-related hazards and ensure that devices are intuitive and effective in real-world clinical settings. International standards such as IEC 62366 and ISO 14971 provide structured methodologies for incorporating usability considerations into the design process. These standards emphasize the importance of user-centered design, risk management, and iterative testing to identify and mitigate potential use errors.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Define the role and significance of human factors in the medical device development process, emphasizing the importance of user-centered design to enhance safety and effectiveness.
CO 2	Identify and interpret relevant human factors standards and guidelines, such as IEC 62366, ISO 14971, and FDA regulations to ensure compliance throughout the product lifecycle.
CO 3	Analyze usability evaluations to identify potential use-related risks and design issues, facilitating the creation of user-friendly and safe medical devices.
CO 4	Prepare documents including the Usability Engineering File and Human Factors Engineering Reports to demonstrate compliance and support regulatory submissions.
CO 5	Incorporate human factors considerations into the risk management process, identify use-related hazards and implementing mitigations to reduce adverse events and product recalls.

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3	2	2	2		2	2
CO 2	3	3	2	2		2	2
CO 3	3	3	3	3	2	3	3
CO 4	3	3	3	3	2	3	3
CO 5	3	3	3	3	2	3	3

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications

shall be referred): 15 marks
Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern: 60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY **FIRST SEMESTER M.TECH DEGREE EXAMINATION**			Name Register No:
Course code	**251EBM023**	Course name: Human Factors and Usability Engineering in Medical Devices	
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	How does the integration of Human Factors Engineering (HFE) influence the design process of medical devices? Provide examples illustrating its impact on device usability.	5
2	Assess the effectiveness of IEC 62366-1:2015 in mitigating use-related risks in medical devices. How does it compare to ISO 14971:2019 in terms of risk management integration?	5
3	Critique the strengths and limitations of formative and summative evaluation methods in usability testing. Which is more effective at different stages of device development?	5
4	Evaluate the role of the Usability Engineering File in regulatory submissions. How does it support compliance with standards like IEC 62366-1:2015?	5
5	Assess the effectiveness of Use-Related Risk Analysis (URRA) in	5

	identifying potential hazards in medical device use. How does it integrate with overall risk management processes?	
	PART B (Answer any 5 questions)	
6	Compare and contrast the roles of usability engineering and human factors engineering in medical device development. In what ways do they intersect and diverge?	7
7	Analyze the FDA's guidance on human factors and usability engineering. How does it influence the development lifecycle of medical devices?	7
8	Develop a usability testing plan for a new medical device, detailing formative and summative evaluation techniques, and identifying potential use-related risks.	7
9	Analyze the components of a Human Factors Engineering Report. How do these elements contribute to the overall safety and efficacy of a medical device?	7
10	Analyze the impact of human error on medical device safety. How can task analysis and Human Error Assessment and Reduction Technique (HEART) mitigate these risks?	7
11	Develop a post-market surveillance plan that incorporates human factors considerations to monitor and improve device usability over time.	7
12	Create a checklist for preparing a regulatory submission that includes all necessary documentation and aligns with FDA and CE marking requirements.	7

Syllabus

Module 1 – Introduction to Human Factors and User-Centered Design

Definition and Scope of Human Factors Engineering (HFE)- Understanding HFE in the context of medical devices, Distinction between usability engineering and human factors engineering. **Importance of User-Centered Design**- Principles of user-centered design in medical devices, Benefits of user-centered design for patient safety and device effectiveness. **Key Concepts in Usability Engineering**- Usability, user interface and context of use, User tasks, user profiles, and use environments. **Impact of Poor Usability on Patient Safety**- Case studies of usability failures and their consequences, Strategies to mitigate use-related errors.

Module 2- Human Factors Standards and Regulatory Guidelines

IEC 62366-1:2015 – Application of Usability Engineering to Medical Devices- Overview and structure of IEC 62366-1, Usability engineering process as per the standard, Integration with risk management processes. **ISO 14971:2019 – Application of Risk Management to Medical Devices-** Risk management principles and process, Relationship between human factors and risk management. **FDA Guidance on Human Factors and Usability Engineering-** Overview of FDA guidelines, Application of guidelines in medical device development. **Integration of Standards**

into Quality Management Systems- Documentation and compliance requirements, Audit and review processes.

Module 3- Usability Evaluation Methods

Formative Evaluations- Purpose and timing of formative evaluations, Methods: heuristic evaluation, cognitive walkthroughs, task analysis. **Summative Evaluations**- Purpose and timing of summative evaluations, Methods: usability testing, user trials, performance metrics. **Identifying Use-Related Risks and Design Issues-** Analyzing usability test results, Identifying potential hazards and hazardous situations. **Analyzing and Interpreting Usability Data**- Qualitative and quantitative data analysis, Reporting findings and recommendations.

Module 4- Documentation and Regulatory Submissions

Structure and Content of the Usability Engineering File- Required documentation and records, Traceability and linkage to design controls. **Human Factors Engineering Reports**- Purpose and components of the report, Documentation of usability evaluations and risk assessments. **Linking Usability Documentation to Risk Management Files-** Integration with ISO 14971 risk management files, Ensuring consistency and completeness. **Preparing for Regulatory Submissions-** FDA, CE marking, and other regulatory requirements, Best practices for documentation and reporting.

Module 5- Integrating Human Factors into Risk Management

Identifying Use-Related Hazards and Hazardous Situations- Use-Related Risk Analysis (URRA), Task Analysis, Human Error Assessment and Reduction Technique (HEART). **Assessing Risks Associated with Use Errors-** Risk Estimation, Severity Levels, Likelihood Determination. **Implementing Mitigations-** Design Modifications, User Training, Labeling and Instructions for Use (IFU). **Post-Market Surveillance and Continuous Improvement-** Monitoring Device Performance, Feedback Mechanisms, Iterative Design Process.

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Human Factors and User-Centered Design**	
1.1	**Definition and Scope of Human Factors Engineering (HFE)**- Understanding HFE in the context of medical devices.	1
1.2	Distinction between usability engineering and human factors engineering.	1
1.3	**Importance of User-Centered Design**- Principles of user-centered design in medical devices.	1
1.4	Benefits of user-centered design for patient safety and device effectiveness.	1
1.5	**Key Concepts in Usability Engineering**- Usability, user interface and context of use.	1

1.6	User tasks, user profiles, and use environments.	1
1.7	**Impact of Poor Usability on Patient Safety**- Case studies of usability failures and their consequences.	1
1.8	Strategies to mitigate use-related errors.	1
2	**Module 2- Human Factors Standards and Regulatory Guidelines**	
2.1	**IEC 62366-1:2015 – Application of Usability Engineering to Medical Devices-** Overview and structure of IEC 62366-1	1
2.2	Usability engineering process as per the standard, Integration with risk management processes.	1
2.3	**ISO 14971:2019 – Application of Risk Management to Medical Devices-** Risk management principles and process.	1
2.4	Relationship between human factors and risk management.	1
2.5	**FDA Guidance on Human Factors and Usability Engineering-** Overview of FDA guidelines.	1
2.6	Application of guidelines in medical device development.	1
2.7	**Integration of Standards into Quality Management Systems-** Documentation and compliance requirements.	1
2.8	Audit and review processes.	1
3	**Module 3- Usability Evaluation Methods**	
3.1	**Formative Evaluations-** Purpose and timing of formative evaluations, Methods.	1
3.2	Heuristic evaluation, cognitive walkthroughs, task analysis.	1
3.3	**Summative Evaluations**- Purpose and timing of summative evaluations, Methods.	1
3.4	Usability testing, user trials, performance metrics.	1
3.5	**Identifying Use-Related Risks and Design Issues-** Analyzing usability test results.	1
3.6	Identifying potential hazards and hazardous situations.	1
3.7	**Analyzing and Interpreting Usability Data**- Qualitative and quantitative data analysis.	1
3.8	Reporting findings and recommendations.	1
4	**Module 4- Documentation and Regulatory Submissions**	
4.1	**Structure and Content of the Usability Engineering File-** Required documentation and records.	1
4.2	Traceability and linkage to design controls.	1
4.3	**Human Factors Engineering Reports**- Purpose and components of the report	1
4.4	Documentation of usability evaluations and risk assessments.	1
4.5	**Linking Usability Documentation to Risk Management Files-** Integration with ISO 14971 risk management files.	1
4.6	Ensuring consistency and completeness.	1

4.7	**Preparing for Regulatory Submissions-** FDA, CE marking, and other regulatory requirements.	1
4.8	Best practices for documentation and reporting.	1
5	**Module 5- Integrating Human Factors into Risk Management**	
5.1	**Identifying Use-Related Hazards and Hazardous Situations-** Use-Related Risk Analysis (URRA).	1
5.2	Task Analysis, Human Error Assessment and Reduction Technique (HEART).	1
5.3	**Assessing Risks Associated with Use Errors-** Risk Estimation, Severity Levels, Likelihood Determination.	1
5.4	**Implementing Mitigations-** Design Modifications.	1
5.5	User Training, Labeling and Instructions for Use (IFU).	1
5.6	**Post-Market Surveillance and Continuous Improvement-** Monitoring Device Performance.	1
5.7	Feedback Mechanisms.	1
5.8	Iterative Design Process.	1
		40

Text Book

1. Usability Testing of Medical Devices (2nd Edition) by Michael E. Wiklund, Jonathan Kendler, and Allison Y. Strochlic
2. Handbook of Human Factors in Medical Device Design edited by Matthew B. Weinger, Michael E. Wiklund, and Daryle Jean Gardner-Bonneau
3. Designing Usability into Medical Products by Michael E. Wiklund and Stephen B. Wilcox

Reference Materials

1. IEC 62366: Application of Usability Engineering to Medical Devices
2. ISO 9241: Ergonomics of Human-System Interaction
3. FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM024	DIGITAL HEALTH AND SOFTWARE AS A MEDICAL DEVICE (SaMD)	PROGRAM ELECTIVE 2	3	0	0	3

Preamble: Digital health solutions—and in particular Software as a Medical Device—are reshaping diagnosis, therapy, and population-level care. This course equips postgraduate biomedical engineers with the interdisciplinary knowledge needed to design, validate, deploy, and oversee SaMD that is safe, effective, secure, and compliant with global regulations. Students will bridge medical science, software engineering, regulatory science, data governance, and patient-centric design, enabling them to contribute to high-impact digital health innovations.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Explain global regulatory frameworks (IMDRF, FDA, EU MDR) and key standards governing SaMD. **(Understand)**
CO 2	Apply risk-based software life-cycle and quality-management principles (IEC 62304, ISO 13485, ISO 14971) to SaMD design. (**Apply)**
CO 3	Design and analytically validate AI/ML-enabled SaMD using appropriate clinical datasets, performance metrics, and statistical methods. **(Create)**
CO 4	Assess cybersecurity, privacy, human-factors, and ethical considerations in SaMD throughout its life-cycle. **(Evaluate)**
CO 5	Formulate post-market surveillance and continuous-improvement strategies including real-world evidence collection for deployed SaMD. **(Create)**

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5		PO 6	PO 7
CO 1	2		3	2			2	
CO 2	2		3	3	3			
CO 3	3	2	3	3	3			
CO 4			3	2			3	
CO 5	3	2	3	3	3		3	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
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PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	**40**	**60**	**2.5 hours**

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks

Test paper, 1 no.: 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDI]L KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	251EBM024	Course name	*DIGITAL HEALTH AND SOFTWARE AS A MEDICAL DEVICE (SaMD)*
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	What is Software as a Medical Device (SaMD)? How is it different from Software in a Medical Device (SiMD) and wellness apps?	5
2	Describe the main steps in the software development life cycle for SaMD as per IEC 62304. Give a simple example of how these steps are followed.	5
3	Why is it important to test AI/ML models on separate training and testing datasets in SaMD? What can go wrong if this is not done?	5
4	Evaluate the effectiveness of privacy-preserving machine learning techniques (e.g., federated learning) in protecting patient data while ensuring model performance in SaMD.	5
5	Design a post-market surveillance plan for an SaMD deployed via a cloud-based platform. Include monitoring strategies, feedback loops, and regulatory reporting mechanisms.	5
	PART B (Answer any five questions)	

6	Analyze the role of various stakeholders (e.g., regulators, clinicians, developers, patients) in the digital health ecosystem. How do their interactions influence the development and deployment of SaMD?	7
7	Evaluate how risk management as per ISO 14971 is integrated into the software development process for SaMD. Discuss how identifying hazards early can impact product safety and regulatory approval.	7
8	Describe the typical pipeline for developing an AI/ML model in SaMD—from data collection to clinical validation. Explain how errors or bias at each stage can affect the final performance of the device.	7
9	Analyze how the STRIDE threat modeling approach can be applied to identify and mitigate security risks in SaMD. Illustrate your answer with at least two specific threat examples.	7
10	Evaluate the ethical challenges faced by AI-driven SaMDs related to bias, fairness, and transparency. Suggest possible methods to address these issues during development and deployment.	7
11	Explain how DevSecOps and CI/CD practices can be adapted for SaMD development. How do these practices support compliance and product safety in regulated environments?	7
12	Discuss the role of real-world evidence and digital biomarkers in post-market surveillance of SaMD. How do these tools improve patient outcomes and product reliability over time?	7

Syllabus

Module 1 – Foundations of Digital Health & SaMD (9 hours)

IMDRF definition & classification; distinctions among SiMD, SaMD, wellness apps; digital health ecosystem; global market landscape; stakeholder mapping; overview of relevant standards (IEC 62366, ISO 14155, ISO 81001-1).

Module 2- Software Life-cycle & Quality Management (9 hours)

IEC 62304 software processes; integration with ISO 13485 QMS; documentation and traceability (requirements → verification); risk management per ISO 14971; safety classification; V-model & agile adaptations; design controls and design history file (DHF).

Module 3- AI/ML-Enabled SaMD: Design & Validation (9 hours)

Good Machine-Learning Practice (GMLP) principles; data curation & shift; model development pipeline; performance & clinical validation metrics; locked vs adaptive algorithms; human factors & usability engineering; clinical evaluation protocols; regulatory submission dossiers.

Module 4- Cybersecurity, Privacy & Ethics (9 hours)

Threat modeling (STRIDE), secure-by-design principles, IEC 81001-5-1; secure coding & penetration testing; data protection regulations (GDPR, HIPAA); privacy-preserving ML;

algorithmic bias & fairness; explainability & transparency; ethical frameworks for digital health interventions.

Module 5- Deployment, Post-Market & Emerging Trends (9 hours)
DevSecOps and CI/CD in SaMD; software updates & ch ange control; post-market performance monitoring (ISO 20416); real-world evidence and digital biomarkers; integration with wearables, DTx, telemedicine; cloud & edge deployment models; regulatory sandboxes; future directions (generative AI, synthetic data, adaptive algorithms).

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Foundations of Digital Health & SaMD**	
1.1	Introduction to Digital Health and SaMD: Definitions and Scope (IMDRF, WHO)	2
1.2	SaMD vs SiMD vs Wellness Devices: Use cases and distinctions	1
1.3	Digital Health Ecosystem: Stakeholders, systems, platforms	2
1.4	Overview of Global Market and Regulatory Landscape	2
1.5	Introduction to Key Standards: ISO 81001-1, ISO 14155, IEC 62366	2
2	**Module 2- Software Life-cycle & Quality Management**	
2.1	Software Development Life Cycle (SDLC) for SaMD per IEC 62304	3
2.2	Quality Management System (QMS) & ISO 13485 Integration	2
2.3	Risk Management per ISO 14971 – Process and Implementation	2
2.4	Design Controls and Documentation: V-model, DHF, Traceability	2
3	**Module 3- AI/ML-Enabled SaMD: Design & Validation**	
3.1	Good Machine Learning Practices (GMLP) and Regulatory Position	2
3.2	Data Preparation: Curation, Bias, Distribution Shifts	2
3.3	Algorithm Development Pipeline: Training, Validation, Testing	2
3.4	Clinical Validation Metrics and Protocol Design	2
3.5	Human Factors and Performance Benchmarks	1
4	**Module 4- Cybersecurity, Privacy & Ethics**	
3.1	Threat Modeling and Secure Design (STRIDE, IEC 81001-5-1)	2
3.2	Secure Coding Practices, Vulnerability Testing	1
3.3	Data Protection Laws: GDPR, HIPAA – Relevance to SaMD	2
3.4	Ethics in AI/ML: Bias, Fairness, Transparency	2
3.5	Privacy-Preserving ML and Algorithmic Accountability	2
5	**Module 5- Deployment, Post-Market & Emerging Trends**	

5.1	DevOps/DevSecOps, CI/CD in Medical Software	2
5.2	Software Updates, Change Management, Version Control	1
5.3	Post-Market Surveillance (ISO 20416), Real-World Evidence	2
5.4	Integration with Telemedicine, Wearables, and DTx Platforms	2
5.5	Future Trends: Generative AI, Adaptive Algorithms, Synthetic Data	2
		45

Text Book

1. S. Syed-Abdul, E. Gabarron, A. Lau, *Digital Health: A Transformative Approach to Healthcare Delivery*, Elsevier, 2020
2. IMDRF, *Software as a Medical Device (SaMD): Clinical Evaluation*, International Medical Device Regulators Forum, 2017

Reference Books

1. J. Dyro, *Clinical Engineering Handbook*, Academic Press, 2004
2. A. Rajaraman, J. Wing (Eds.), *AI for Healthcare*, Springer, Latest Edition
3. HIMSS, *HIMSS Dictionary of Health Information and Technology Terms, Acronyms, and Organizations*, HIMSS, Latest Edition
4. B. Meskó, *The Guide to the Future of Medicine: Technology and the Human Touch*, Webicina Kft, 2014
5. ISO, IEC, *IEC 62304: Medical Device Software – Software Life Cycle Processes*, ISO/IEC, Latest Edition

241RGE101	RESEARCH AND PUBLICATION ETHICS	CATEGORY	L	T	P	CREDIT
		PEC	2	0	0	2

Preamble: This course provides exposure to the core concepts, principles, and practices of research publication ethics. It enables learners to understand the ethical foundations of academic publishing, including authorship guidelines, plagiarism, data integrity, peer review processes, and conflict of interest management. The course equips researchers with the skills to identify and address ethical issues in scholarly communication, apply appropriate standards and policies for responsible research conduct, and ensure transparency and accountability in the dissemination of research findings. It also fosters critical thinking and ethical decision-making to uphold integrity and rigor in the academic publishing process across various disciplines.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand the importance of publication ethics[Understand]
CO 2	Identify and avoid various types of ethical issues while publishing papers and writing reports [Apply]
CO 3	Use various tools that are helpful in checking similarity index[Apply]
CO4	Infer about open access publication and be able to use various search indices[Analyze]
CO 5	Grade the reports and articles in order to minimize the similarity index[Evaluate]
CO 6	Categorize the journals based on their quality and metrics[Analyze]

Program Outcomes (PO)

Outcomes are the attributes that are to be demonstrated by a graduate after completing the course.

PO1: An ability to independently carry out research/investigation and development work in engineering and allied streams

PO2: An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.

PO3: An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program

PO4: An ability to apply stream knowledge to design or develop solutions for real world problems by following the standards

PO5: An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tool to model, analyze and solve practical engineering problems.

PO6: An ability to engage in life-long learning for the design and development related to the stream related problems taking into consideration sustainability, societal, ethical and environmental aspects

PO7: An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	✓	✓	✓			✓	
CO 2	✓	✓	✓			✓	
CO 3	✓	✓	✓		✓	✓	
CO 4	✓	✓	✓		✓	✓	
CO 5	✓	✓	✓		✓	✓	
CO 6	✓	✓	✓		✓	✓	

Assessment Pattern

Bloom's Category	**End Semester Examination**
Apply	70%-80%
Analyze	30%-40%
Evaluate	

Create	

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern:

Continuous Internal Evaluation: 40 marks

End Semester Examination Pattern:

The end semester examination will be conducted by the respective College.

There will be two parts; Part A and Part B.

Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question. Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks

Total duration of the examination will be 150 minutes.

Note: The marks obtained for the ESE for an elective course shall not exceed 20% over the average ESE mark % for the core courses. ESE marks awarded to a student for each elective course shall be normalized accordingly. For example, if the average end semester mark % for a core course is 40, then the maximum eligible mark % for an elective course is 40+20 = 60 %

Syllabus

MODULE 1: PHILOSOPHY AND ETHICS

Introduction to philosophy: definition, nature and scope, concept, branches; Ethics: definition, moral philosophy, nature of moral judgements and reactions.

MODULE 2: SCIENTIFIC CONDUCT

Ethics with respect to science and research, Intellectual honesty and research integrity, Scientific misconducts: Falsification, Fabrication, and Plagiarism (FFP), Redundant Publications: duplicate and overlapping publications, salami slicing, Selective reporting and Misrepresentation of data.

MODULE 3: PUBLICATION ETHICS

Publication ethics: definition, introduction and importance, Best practices / standards setting initiatives and guidelines: COPE, WAME, Conflicts of interest, Publication misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types, Violation of publication ethics, authorship and contributorship, Identification of publication misconduct, complaints and appeals, Predatory publishers and journals.

MODULE 4: OPEN ACCESS PUBLISHING

Open access publications and initiatives, SHERPA/RoMEO online resource to check publisher copyright & self-archiving policies, Software tool to identify predatory publications developed by SPPU, Journal finder / journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggester, etc.

MODULE 5: PUBLICATION MISCONDUCT, DATABASES AND RESEARCH METRICS

Subject specific ethical issues, FFP, authorship, Conflicts of interest, Complaints and appeals: examples and fraud from India and abroad, Use of plagiarism software like Turnitin, Ouriginal (Urkund) and other open source software tools.

Indexing databases, Citation databases: Web of Science, Scopus, Impact Factor of journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score, Metrics: h-index, g index, i10 index, altimetric

	Course Plan	
No	**Topic**	**No. of Lectures (24 Hours)**
	Module 1	**4**
1.1	Introduction to Philosophy: Definition, Nature, and Scope	1
1.2	Branches of Philosophy and Concepts	1
1.3	Definition and Scope of Ethics; Moral Philosophy	1
1.4	Nature of Moral Judgments and Reactions	1
	Module 2	**4**
2.1	Ethics in Science and Research: Honesty and Integrity	1
2.2	Scientific Misconduct: Falsification, Fabrication, and Plagiarism (FFP)	1
2.3	Redundant Publications, Salami Slicing	1

2.4	Selective Reporting and Misrepresentation of Data	1
	Module 3	**4**
3.1	Introduction and Importance of Publication Ethics Best Practices: COPE, WAME Guidelines	1
3.2	Authorship, Contributorship, Conflicts of Interest	1
3.3	Publication Misconduct: Types, Identification, Complaints, Appeals	1
3.4	Predatory Journals and Publishers	1
	Module 4	**4**
4.1	Concept and Types of Open Access Publications	1
4.2	SHERPA/RoMEO and Publisher Policies	1
4.3	Predatory Publications: SPPU Software Tool	1
4.4	Journal Finder Tools: JANE, Elsevier, Springer	1
	Module 5	
5.1	Ethical Issues: Authorship, FFP, Conflicts of Interest	1
5.2	Real Examples of Misconduct (India and Abroad)	1
5.3	Plagiarism Detection Tools: Turnitin, Ouriginal, Open-Source Tools	2
5.4	Citation and Indexing Databases: Scopus, Web of Science	1
5.5	Journal Metrics: Impact Factor, SNIP, SJR, IPP, CiteScore	2
5.6	uthor Metrics: h-index, g-index, i10 index, Altmetrics	1

References

1.Research and Publication Ethics by Dr. K. Manjunatha and Dr. H. S. Vijayakumar

241RGE100	RESEARCH METHODOLOGY & IPR	CATEGORY	L	T	P	CREDIT
		General Coursec	2	0	0	2

Preamble:

This course introduces the strategies and methods related to scientific research. The students are also trained in the oral presentation with visual aids and writing technical thesis/reports/research papers. The salient aspects of publication and patenting along with the crucial role of ethics in research is discussed.

Course Outcomes

After the completion of the course, the student will be able to

CO 1	Approach research projects with enthusiasm and creativity.
CO 2	Conduct literature survey and define research problem
CO 3	Adopt suitable methodologies for solution of the problem
CO 4	Deliver well-structured technical presentations and write technical reports.
CO 5	Publish/Patent research outcome.

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	✓	✓				✓	
CO 2	✓	✓				✓	
CO 3	✓	✓				✓	
CO 4	✓	✓				✓	
CO 5	✓	✓				✓	
CO 6	✓	✓				✓	

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	70 %
Analyse	30 %
Evaluate	
Create	

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern:

Course based task: 15 marks

Some sample course based tasks that can be performed by the student given below.

- *Conduct a group discussion based on the good practices in research.*
- *Conduct literature survey on a suitable research topic and prepare a report based on this.*

Seminar: 15 marks Test

paper: 10 marks

End Semester Examination Pattern:

Total Marks: 60

The examination will be conducted by the respective college with the question provided by the University. The examination will be for 150 minutes and contain two parts; Part A and Part B. Part A will contain 6 short answer questions with 1 question each from modules 1 to 4, and 2 questions from module 5. Each question carries 5 marks. Part B will contain only 1 question based on a research article from the respective discipline and carries 30 marks. The students are to answer the questions based on that research article.

Model Question paper

QP Code:			**Total Pages:**
Reg No.: _____		**Name: _____**	
APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY **FIRST SEMESTER M. TECH DEGREE EXAMINATION, Month & Year**			
Course Code: 221RGE100			
Course Name: RESEARCH METHODOLOGY & IPR			
Max. Marks: 60		**Duration: 2.5 Hours**	

PART A

		Answer all questions. Each question carries 5 marks	**Marks**
1		Discuss the salient recommendations for great research recommended by Richard Hamming in his famous talk "You and Your Research"	**30**
2		What are the characteristics of a good research question? Discuss with an example.	
3		Explain the difference between continuum, meso-scale and micro scale approaches for numerical simulation.	
4		Discuss any four rules of scientific writing.	
5		What are the requirements for patentability?	
6		What are the differences between copyright and trademark protection?	
		Read the given research paper and write a report that addresses the following issues **(The paper given can be specific to the discipline concerned)**	
7		What is the main research problem addressed?	**3**
8		Identify the type of research	**3**
9		Discuss the short comings in literature review if any?	**6**
10		Discuss appropriateness of the methodology used for the study	**6**
11		Discuss the significance of the study and summarize the important results and contributions by the authors	**6**
12		Identify limitations of the article if any.	**6**

Syllabus and Course Plan

No	Topic	No. of Lectures
1	**Introduction**	
1.1	Meaning and significance of research, Skills, habits and attitudes for research, Types of research,	1
1.2	Characteristics of good research, Research process	1
1.3	Motivation for research: Motivational talks on research: "You and Your Research"- Richard Hamming	1
1.4	Thinking skills: Levels and styles of thinking, common-sense and scientific thinking, examples, logical thinking, division into sub-problems, verbalization and awareness of scale.	1
1.5	Creativity: Some definitions, illustrations from day to day life, intelligence versus creativity, creative process, requirements for creativity	1
2	**Literature survey and Problem definition**	
2.1	Information gathering – reading, searching and documentation, types of literature.	1
2.2	Integration of research literature and identification of research gaps	1
2.3	Attributes and sources of research problems, problem formulation, Research question, multiple approaches to a problem	1
2.4	Problem solving strategies – reformulation or rephrasing, techniques of representation, Importance of graphical representation, examples.	1
2.5	Analytical and analogical reasoning, examples, Creative problem solving using Triz, Prescriptions for developing creativity and problem solving.	1
3	**Experimental and modelling skills**	
3.1	Scientific method, role of hypothesis in experiment, units and dimensions, dependent and independent variables, control in experiment	1
3.2	precision and accuracy, need for precision, definition, detection, estimation and reduction of random errors, statistical treatment of data, definition, detection and elimination of systematic errors,	1
3.3	Design of experiments, experimental logic, documentation	1

3.4	Types of models, stages in modelling, curve fitting, the role of approximations, problem representation, logical reasoning, mathematical skills.	1
3.5	Continuum/meso/micro scale approaches for numerical simulation, Two case studies illustrating experimental and modelling skills.	1
4	**Effective communication - oral and written**	
4.1	Examples illustrating the importance of effective communication, stages and dimensions of a communication process.	1
4.2	Oral communication –verbal and non-verbal, casual, formal and informal communication, interactive communication, listening, form, content and delivery, various contexts for speaking- conference, seminar etc.	1
4.3	Guidelines for preparation of good presentation slides.	1
4.4	Written communication – Rules of scientific writing, form, content and language, layout, typography and illustrations, nomenclature, reference and citation styles, contexts for writing – paper, thesis, reports etc. Tools for document preparation-LaTeX.	1
4.5	Common errors in typing and documentation	1
5	**Publication and Patents**	
5.1	Relative importance of various forms of publication, Choice of journal and reviewing process, Stages in the realization of a paper.	1
5.2	Research metrics-Journal level, Article level and Author level, Plagiarism and research ethics	1
5.3	Introduction to IPR, Concepts of IPR, Types of IPR	1
5.4	Common rules of IPR practices, Types and Features of IPR Agreement, Trademark	1
5.5	Patents- Concept, Objectives and benefits, features, Patent process – steps and procedures	2

Reference Books

1. E. M. Phillips and D. S. Pugh, "How to get a PhD - a handbook for PhD students and their supervisors", Viva books Pvt Ltd.
2. G. L. Squires, "Practical physics", Cambridge University Press
3. Antony Wilson, Jane Gregory, Steve Miller, Shirley Earl, Handbook of Science Communication, Overseas Press India Pvt Ltd, New Delhi, 1st edition 2005
4. C. R. Kothari, Research Methodology, New Age International, 2004
5. Panneerselvam, Research Methodology, Prentice Hall of India, New Delhi, 2012.

6. Leedy P. D., Practical Research: Planning and Design, McMillan Publishing Co.
7. Day R. A., How to Write and Publish a Scientific Paper, Cambridge University Press, 1989.
8. William Strunk Jr., Elements of Style, Fingerprint Publishing, 2020
9. Peter Medawar, 'Advice to Young Scientist', Alfred P. Sloan Foundation Series, 1979.
10. E. O. Wilson, Letters to a Young Scientist, Liveright, 2014.
11. R. Hamming, You and Your Research, 1986 Talk at Bell Labs.

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251LBM100	**Biomedical Signal Acquisition & Processing Lab**	**LABORATORY 1**	**0**	**0**	**2**	**1**

Preamble: This lab provides hands-on experience in acquiring, processing, and analyzing biomedical signals such as ECG, EMG, EOG, and PPG. Students will understand basic operations on synthetic and physiological signals, apply acquisition tools, and perform signal pre-processing and feature extraction. Using tools like MATLAB, they will design simple systems to interpret physiological functions. The lab bridges theory with practical biomedical applications.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understanding the fundamentals of bio-signals and their significance in interpreting physiological systems.
CO 2	Demonstrate the use of signal acquisition tools and instrumentation to record biomedical signals (ECG, EOG, EMG, PPG, RR, etc.) and Equipment Analyzers (Apply)
CO 3	Analyze biomedical signals using time-domain and frequency-domain techniques to identify key features (analyze)
CO 4	Design and implement a basic biomedical signal processing system using software tools such as MATLAB to preprocess, extract features from, and interpret physiological system involved (Create)

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3		3		3	2	
CO 2	3		3		3	3	
CO 3	3	**2**	3	3	3	3	3
CO 4	3		3		3	2	

Assessment Pattern

Bloom's Category	Continuous Evaluation
Apply	40
Analyse	20
Evaluate	20
Create	20

Mark distribution

Total Marks	CIE	ESE

100	**100**	**-**

Continuous Internal Evaluation Pattern: 100 Marks

The laboratory courses will be having only Continuous Internal Evaluation and carries 100 marks. Final assessment shall be done by two examiners; one examiner will be a senior faculty from the same department.

List of Experiments

Sl. No	CO Mapping	Practical Exercises
1	**CO1**	Fundamental Operations and Preprocessing Techniques for Synthetic and Biomedical Signals using MATLAB Any one of these 1. Synthetic signal • Signal Generation with Parametric variations in frequency, amplitude, phase • Basic Signal Operations • Preprocessing Techniques: Filtering, Normalization, baseline correction and smoothening 2. Biomedical Signals: (ECG, EMG and PPG) • Signal acquisition / Database • Performing fundamental manipulations on the acquired signal • Preprocessing Techniques: Filtering, Normalization, baseline correction and smoothening
2	**CO2, CO3**	**Familiarization of Biomedical signal acquisition device:** • Familiarization with BSL Student 4.x software and the MP36 system for bio-signal acquisition – ECG, EMG and PPG (Electrode placement configuration)

3	**CO2, CO3**	**Familiarization of Biomedical signal acquisition device:** ● Familiarization with LabChart and PowerLab for ECG recording and analysis.
4	**CO2, CO3**	**Familiarization of Biomedical signal acquisition device:** ● Familiarization with LabChart software and the PowerLab data acquisition system for EMG (Isometric Contraction & Isotonic Contraction) and its analysis
5	**CO2, CO3**	**Familiarization of Biomedical signal acquisition device:** ● Familiarization with LabChart software and the PowerLab data acquisition system for PPG and its analysis
5	**CO2, CO3**	**Familiarization of Biomedical signal acquisition device:** ● Familiarization with LabChart software and the PowerLab data acquisition system for Respiration Rate and its analysis
6	**CO2, CO3**	**Familiarization of Biomedical signal acquisition device:** ● Familiarization with Electronic Stethoscope for Heart Sound Data acquisition and analysis
7	**CO2, CO3**	Feature Extraction from Physiological Signals Using MATLAB Any one of this: ● ECG Signal Analysis: Time and Frequency Domain Feature Extraction ● PPG Signal Analysis: Time and Frequency Domain Feature Extraction ●
8	**CO2, CO3**	Feature Extraction from Physiological Signals Using MATLAB Any one of this: ● EEG Signal Analysis: Time and Frequency Domain Feature Extraction ● EMG Signal Analysis: Time and Frequency Domain Feature Extraction
9	**CO4**	Design and develop a logic-based biomedical signal analysis system for physiological monitoring using MATLAB (non-AI approach). (Input: Simulator O/P, Acquisition device O/P/ Open Data Repository) Any One of these: ● Design and Implementation of an Arrhythmia Detection Algorithm Using Simulated ECG Signals

		• Development of a Heart Rate Monitoring and Rhythm Analysis System Using PPG Signals
10	**CO4**	Design and develop a logic-based biomedical signal analysis system for physiological monitoring using MATLAB (non-AI approach). (Input: Simulator O/P, Acquisition device O/P/ Open Data Repository) Any one of this: • Design and Implementation of a Muscle Activity Detection System Using EMG Signals • Design and Implementation of an Eye Movement Detection System Using EOG Signals
10	**CO1, CO2**	Hands-on training in equipment testing, calibration, and data interpretation with industry collaboration – Electrical safety and functional testing Any Two of these: • Testing Calibration of Syringe pump / infusion Pump • Testing Calibration of Defibrillator • Testing Calibration of Multiparameter Patient Monitoring system • Testing Calibration of Electrosurgical system

Reference Books

1. *S. Attaway, MATLAB: A Practical Introduction to Programming and Problem Solving, 6th ed. Elsevier, 2022.*
2. *Biomedical Signal Analysis Using MATLAB by Kayvan Najarian*
3. *E. N. Bruce, Biomedical Signal Processing and Signal Modeling. Hoboken, NJ, USA: Wiley-Interscience, 2001.*
4. *K. Najarian and R. Splinter, Biomedical Signal and Image Processing Using MATLAB. Boca Raton, FL, USA: CRC Press, 2005.*
5. *National Accreditation Board for Testing and Calibration Laboratories. (2021). NABL 141: Guidelines for Calibration Laboratories. Quality Council of India - https://nabl-india.org*
6. *IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, 3rd ed., IEC, Geneva, Switzerland, 2005 (Amendments in 2012 and 2020).*
7. *J. G. Webster, Medical Instrumentation: Application and Design, 4th ed. Hoboken, NJ, USA: Wiley, 2009.*

8. *ADINSTRUMENTS: https://www.adinstruments.com/lt/human-physiology*

Prepared by Sony N S

SEMESTER 2

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252TBM100	MEDICAL IMAGING SYSTEMS	PROGRAM CORE	3	0	0	3

Preamble:

The course Medical Imaging Systems equips students with foundational and applied knowledge of imaging modalities, image acquisition and reconstruction techniques, and quantitative analysis frameworks. It emphasizes the integration of engineering, physics, and computational tools to interpret and enhance biomedical images. The curriculum also addresses the emerging role of artificial intelligence in medical imaging, molecular and functional imaging methods, and regulatory frameworks governing clinical translation.

Course Outcomes:

After the completion of the course the student will be able to

CO 1	Explain the physical principles, instrumentation, and comparative features of major biomedical imaging modalities.
CO 2	Apply mathematical and computational techniques to perform image acquisition, signal processing, and reconstruction using classical and advanced algorithms.
CO 3	Describe the principles of functional and molecular imaging, and evaluate the use of contrast agents, molecular probes, and hybrid imaging modalities in biomedical research and diagnostics.
CO 4	Analyse medical image data using quantitative techniques and implement AI-based methods such as deep learning and radiomics for diagnostic support and image interpretation.
CO 5	Evaluate clinical integration, regulatory compliance, and safety standards related to medical imaging systems.

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3	2	3			3	
CO 2	3	2	3	2	3		
CO 3	3	2			2		
CO 4	2		2	2	3	3	
CO 5	2		2	2	3	3	2

Assessment Pattern:

Bloom's Category	End Semester Examination

Apply	20
Analyse	20
Evaluate	20
Create	

Mark distribution:

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern (40 Marks):

- Evaluation shall only be based on application, analysis or design-based questions.

Evaluation Method	Marks
Micro project/Course based project	20 Marks
Course based task/Seminar/Quiz	10 Marks
Test paper, 1 no (Test paper shall include minimum 80% of the syllabus)	10 Marks
Total	40 Marks

- All COs must be assessed by using at least one assessment method of Continuous Internal Evaluation.

End Semester Examination Pattern (60 Marks):

- The end semester examination will be consisting of two parts; Part A and Part B.
- Part A contain 5 numerical questions (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students), with 1 question from each module, having 5 marks for each question. Students shall answer all questions.
- Part B contains 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to

theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student shall answer any five. Each question can carry 7 marks.

- Total duration of the examination will be 150 minutes.

Model Question paper:

Course Code: 252TBM100

Course Name: MEDICAL IMAGING SYSTEMS

Max. Marks: 60 **Duration: 2.5 Hours**

PART A

Answer all Questions. Each question carries 5 Marks

1. A patient undergoes CT imaging with a detector array spacing of 1 mm and a gantry rotation time of 0.5 s. If the image matrix is 512×512 and the field of view is 250 mm, calculate the pixel resolution. Comment on the impact of pixel resolution on spatial resolution of the CT image.
2. A 1D signal is sampled at 500 Hz for image reconstruction. Apply the Nyquist theorem to determine the maximum frequency that can be reconstructed without aliasing. Also explain how undersampling leads to artifacts in reconstructed images.
3. A radiotracer used in PET has a half-life of 110 minutes. If 5 mCi of activity is injected into a patient, calculate the remaining activity after 3 hours. How does this affect imaging quality?
4. Given a binary image segmentation result, calculate the Dice Similarity Coefficient (DSC) if the ground truth has 60 foreground pixels, the predicted segmentation has 50 foreground pixels, and 40 pixels overlap. Interpret the result.
5. List the key components of the ISO 13485 quality management system and explain how one of these components ensures safety in the design of an MRI system.

PART B

Answer any five Questions. Each question carries 7 Marks

6. Compare the contrast mechanisms and spatial resolution of MRI, CT, and Ultrasound imaging. In what clinical contexts is each modality preferred?
7. Derive the mathematical steps of the Filtered Back Projection (FBP) algorithm used in CT image reconstruction. How does it address the blurring problem associated with simple back-projection?
8. Explain the working principle of fluorescence imaging. Discuss how fluorophores are selected based on excitation and emission spectra and their implications for deep tissue imaging.

9. What is radiomics? Describe the typical pipeline from image acquisition to feature extraction and model validation in a radiomic study for cancer diagnosis.
10. Discuss the workflow and data communication standards (e.g., DICOM, PACS) involved in integrating a medical imaging modality into a hospital system. Illustrate with a suitable example.
11. Explain compressed sensing in medical image reconstruction. How does it differ from traditional methods in terms of sampling and reconstruction time?
12. Describe the regulatory pathway for approving a novel radiotracer for PET imaging. Include discussion on preclinical validation, clinical trials, and ethical considerations?

Syllabus

Module I (8 Hours): Fundamentals of Biomedical Imaging Modalities

Overview of biomedical imaging: structural vs functional. Physics and instrumentation of: X-ray, CT (Computed Tomography), MRI (Magnetic Resonance Imaging), Ultrasound Imaging, Nuclear Imaging: PET, SPECT, Comparison of modalities: spatial & temporal resolution, contrast mechanisms

Module II (8 Hours): Image Acquisition, Reconstruction, and Processing

Image formation principles: projection, sampling, Fourier domain. Reconstruction algorithms: Filtered back projection, Iterative reconstruction, Compressed sensing. Signal processing in imaging. Introduction to mathematical foundations of inverse problems. Real-time image processing pipelines, FPGA/GPU acceleration, pipelining architectures.

Module III (8 Hours): Functional and Molecular Imaging

Fundamentals of PET, SPECT, fMRI. Contrast agents: paramagnetic, fluorophores, radionuclides. Molecular probes: targeting biomarkers, pharmacokinetics. Optical & fluorescence imaging. Hybrid modalities: PET-CT, PET-MRI, Image registration across modalities

Module IV (8 Hours): Quantitative Image Analysis and AI in Imaging

Quantification techniques: Region-of-interest (ROI) analysis, histogram analysis, segmentation, registration, feature extraction, Image descriptors (LBP, HOG, Gabor filters) Biomarker quantification and image-based metrics. Machine Learning and Deep Learning in medical imaging, Generative models in image synthesis and augmentation. AI model validation, interpretability, and ethics

Module V (8 Hours): Clinical Applications, Translation, and Regulatory Framework

Clinical workflow integration of imaging systems, PACS, DICOM standards. Preclinical to clinical translation of imaging agents and modalities. Regulatory aspects: FDA/EMA guidelines, ISO 13485, HIPAA, Standards for software as a medical device (SaMD). Safety and risk analysis in imaging systems, Imaging quality assurance protocols (ACR, IAEA guidelines). Human factors and usability testing

Course Plan

No	Topic	No. of Lectures
1	**Fundamentals of Biomedical Imaging Modalities**	
1.1	Introduction to Biomedical Imaging: Structural vs Functional Imaging	1
1.2	X-ray Imaging: Physics, instrumentation, and image characteristics	1
1.3	CT Imaging: Image acquisition, detectors, and 3D reconstruction	2
1.4	MRI: Principles, instrumentation, pulse sequences, relaxation mechanisms	1
1.5	Ultrasound Imaging: Acoustic principles, transducers, Doppler effect	1
1.6	Nuclear Imaging: PET and SPECT – Physics, tracers, detectors	1
1.7	Comparative analysis: Spatial/temporal resolution, contrast mechanisms	1
2	**Image Acquisition, Reconstruction, and Processing**	
2.1	Image formation principles: Projection geometry, sampling, Fourier domain	2
2.2	Reconstruction techniques: Filtered back projection and iterative reconstruction	2
2.3	Compressed sensing in imaging	1
2.4	Signal processing for image quality enhancement	1
2.5	Mathematical foundation of inverse problems	1
2.6	Real-time processing: FPGA/GPU acceleration and pipelining	1
3	**Functional and Molecular Imaging**	
3.1	Functional imaging basics: PET, SPECT, and fMRI	2
3.2	Contrast agents: Types (paramagnetic, fluorophores, radionuclides)	1
3.3	Molecular imaging probes: Biomarker targeting, pharmacokinetics	2
3.4	Optical and fluorescence imaging	1
3.5	Hybrid imaging modalities: PET-CT, PET-MRI	1
3.6	Image registration across modalities	1
4	**Quantitative Image Analysis and AI in Imaging**	
4.1	Quantification methods: ROI, histogram analysis, segmentation	1
4.2	Registration and feature extraction (LBP, HOG, Gabor filters)	2
4.3	Biomarker quantification, image-based phenotyping	2
4.4	ML & DL for medical imaging: Classification, detection, prediction	1
4.5	Generative models, image synthesis & augmentation	1
4.6	AI model validation, interpretability, ethical considerations	1
5	**Clinical Applications, Translation, and Regulatory Framework**	
5.1	Clinical workflow: Imaging integration, PACS, DICOM	2

5.2	Translation of imaging agents from preclinical to clinical	2
5.3	Regulatory frameworks: FDA, EMA, HIPAA, ISO 13485	1
5.4	Standards for Software as a Medical Device (SaMD)	1
5.5	Risk analysis, safety protocols in imaging systems (IAEA, ACR)	1
5.6	Usability testing and human factors in imaging system development	1

Reference Books

1. Bushberg, J. T., Seibert, J. A., Leidholdt, E. M., & Boone, J. M. (2022). *The essential physics of medical imaging* (4th ed.). Wolters Kluwer.
2. Webb, A., Bronzino, J. D., & Peterson, D. R. (2022). *Introduction to biomedical imaging* (3rd ed.). CRC Press.
3. Prince, J. L., & Links, J. M. (2024). *Medical imaging signals and systems* (3rd ed.). Pearson.
4. Barrett, H. H., & Myers, K. J. (2023). *Foundations of image science* (2nd ed.). Wiley.
5. Cherry, S. R., Sorenson, J. A., & Phelps, M. E. (2023). *Physics in nuclear medicine* (5th ed.). Elsevier.
6. Wang, L. V., & Hu, S. (2022). *Biomedical optics: Principles and imaging* (2nd ed.). Wiley.
7. Zhou, S. K., Rueckert, D., & Fichtinger, G. (Eds.). (2023). *Handbook of medical image computing and computer assisted intervention* (2nd ed.). Academic Press.
8. Greenspan, H., & Lusted, L. B. (2022). *Deep learning for medical image analysis* (2nd ed.). Academic Press.
9. Pysz, M. A., & Willmann, J. K. (2023). *Molecular imaging in oncology*. Springer.
10. Mollet, P., & Kybic, J. (2022). *Clinical PET and SPECT imaging*. Springer.

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252TBM001	COMPUTATIONAL BIOMEDICAL IMAGE ANALYSIS	PROGRAM CORE	3	0	0	3

Preamble: This course introduces the fundamental principles and computational methods used for analyzing biomedical images. Biomedical image analysis has become a cornerstone in medical diagnosis, therapy planning, and biomedical research. Through this course, students will learn image processing, computer vision, and machine learning techniques tailored to biomedical imaging modalities such as X-ray, MRI, CT, and ultrasound. Emphasis is placed on practical approaches, algorithmic understanding, and hands-on implementation.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Explain the fundamentals of biomedical imaging and image representation. **(Cognitive Knowledge Level: Understand)**
CO 2	Apply image preprocessing and enhancement techniques to biomedical images. **(Cognitive Knowledge Level: Apply)**
CO 3	Analyze and segment biomedical images using appropriate computational methods. **(Cognitive Knowledge Level: Analyze)**
CO 4	Evaluate feature extraction, classification, and registration techniques in medical image data. **(Cognitive Knowledge Level: Evaluate)**
CO 5	Develop simple end-to-end biomedical image analysis pipelines using software tools. **(Cognitive Knowledge Level: Create)**

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	**3**		**2**		2	**3**	
CO 2	**3**	2	**1**			**2**	
CO 3	**3**	**3**	**2**	**3**	**3**	**3**	**2**
CO 4	**3**		**2**	3		**3**	
CO 5	**3**	**3**	**3**	**2**	**3**	**2**	**2**

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY **FIRST SEMESTER M.TECH DEGREE EXAMINATION**			Name Register No:
Course code	241EEC009	Course name	COMPUTATIONAL BIOMEDICAL IMAGE ANALYSIS
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	

1	Define DICOM and its significance in biomedical imaging.	5
2	Differentiate between Gaussian and median filters in image preprocessing.	5
3	What is histogram equalization? Mention its application in medical image enhancement.	5
4	Explain Otsu's thresholding method for image segmentation.	5
5	List any three texture features used in medical image analysis and state their relevance.	5
	PART B (Answer any five questions.)	
6	Describe and compare MRI and CT imaging techniques with their applications.	7
7	Explain the steps involved in morphological operations with suitable examples.	7
8	Discuss the watershed algorithm for image segmentation. What are its advantages and limitations?	7
9	Explain the role of GLCM in texture feature extraction. Illustrate with an example.	7
10	Describe the process and importance of image registration in medical diagnostics.	7
11	Outline the architecture and working of the U-Net model used in medical image segmentation.	7
12	Illustrate the development of a simple image analysis pipeline for tumor detection using open-source tools.	7

Syllabus

Module 1 – Fundamentals of Biomedical Imaging and Image Representation

Overview of biomedical imaging modalities: X-ray, CT, MRI, Ultrasound, PET, Digital image fundamentals: sampling, quantization, resolution, bit depth, Color vs grayscale images, DICOM format,Image statistics: histogram, mean, variance, entropy, Visualization and annotation tools

Module 2- Image Preprocessing and Enhancement

Noise types and sources in biomedical images, Filtering techniques: mean, median, Gaussian, Wiener, Image normalization, contrast stretching, histogram equalization, Edge detection: Sobel, Prewitt, Canny Morphological operations: dilation, erosion, opening, closing

Module 3- Image Segmentation Techniques

Thresholding (global, adaptive, Otsu's method), Region-based segmentation (region growing, watershed), Clustering techniques: K-means, fuzzy C-means, Active contour models (snakes), level sets, Introduction to deep learning-based segmentation (U-Net architecture overview)

Module 4- Feature Extraction, Classification and Registration

Texture features: GLCM, LBP, Shape descriptors: perimeter, area, compactness, Feature selection and dimensionality reduction (PCA, t-SNE), Classification: SVM, k-NN, decision trees, Image registration: rigid, affine, non-rigid; mutual information

Module 5- Applications and Tools in Biomedical Image Analysis

Case studies: tumor detection, organ segmentation, vessel analysis, Introduction to AI in radiology and pathology, Software tools: ITK, SimpleITK, ImageJ, 3D Slicer, Python libraries (OpenCV, scikit-image, MONAI), Building image analysis pipelines, Ethical considerations and validation in biomedical image processing

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Fundamentals of Biomedical Imaging and Image Representation**	
1.1	Overview of biomedical imaging modalities: X-ray, CT, MRI, Ultrasound, PET	1
1.2	Digital image fundamentals: sampling, quantization, resolution, bit depth,	2
1.3	Color vs grayscale images, DICOM format	1
1.4	Image statistics: histogram, mean, variance, entropy	2
1.5	Visualization and annotation tools	2
2	**Module 2: Image Preprocessing and Enhancement**	
2.1	Noise types and sources in biomedical images	1

2.2	Filtering techniques: mean, median, Gaussian, Wiener	2
2.3	Image normalization, contrast stretching, histogram equalization	1
2.4	Edge detection: Sobel, Prewitt, Canny	2
2.5	Morphological operations: dilation, erosion, opening, closing	2
3	**Module 3- Image Segmentation Techniques**	
3.1	Thresholding (global, adaptive, Otsu's method)	1
3.2	Region-based segmentation (region growing, watershed)	2
3.3	Clustering techniques: K-means, fuzzy C-means	2
3.4	Active contour models (snakes), level sets	2
3.5	Introduction to deep learning-based segmentation (U-Net architecture overview)	1
4	**Module 4- Feature Extraction, Classification and Registration**	
4.1	Texture features: GLCM, LBP	1
4.2	Shape descriptors: perimeter, area, compactness	1
4.3	Feature selection and dimensionality reduction (PCA, t-SNE)	1
4.4	Classification: SVM, k-NN, decision trees	1
4.5	Image registration: rigid, affine, non-rigid; mutual information	1
5	**Module 5- Applications and Tools in Biomedical Image Analysis**	
5.1	Case studies: tumor detection, organ segmentation, vessel analysis	1
5.2	Introduction to AI in radiology and pathology	1
5.3	Software tools: ITK, SimpleITK, ImageJ, 3D Slicer, Python libraries (OpenCV, scikit-image, MONAI)	1
5.4	Building image analysis pipelines	1

5.5	Ethical considerations and validation in biomedical image processing	1
		40

Text Books

1. Geoff Dougherty – *Digital Image Processing for Medical Applications*, Cambridge University Press
2. Rafael C. Gonzalez and Richard E. Woods – *Digital Image Processing*, Pearson

Reference Books

1. Isaac Bankman (Ed.) – Handbook of Medical Image Processing and Analysis, Academic Press
2. Suri et al. – Advanced Algorithmic Approaches to Medical Image Segmentation, Springer
3. Shanbao Tong and Kuncheng Li – Biomedical Informatics and Computational Biology for Healthcare, Springer
4. Tustison et al. – Introduction to Medical Image Processing with ITK, Springer, 2004

PROGRAM ELECTIVE III

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM031	**MEDICAL IMAGE RECONSTRUCTION AND COMPUTER VISION**	**PROGRAM ELECTIVE 3**	**3**	**0**	**0**	**3**

Preamble: This course provides a comprehensive understanding of medical image reconstruction techniques and computer vision applications in biomedical contexts. Emphasis is placed on foundational principles, algorithmic development, and practical implementation using real-world medical datasets. Through this course, students will gain experience in image formation models, tomographic reconstruction, segmentation, registration, and machine learning applications in medical imaging.

Pre-requisites: Basic knowledge of linear algebra, signal and image processing, introductory machine learning, and medical imaging modalities.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Identify the nature and challenges of real biomedical signals and recognize the need for time-frequency analysis in biomedical context Understand image acquisition models and reconstruction principles for modalities like CT and MRI. **(Cognitive Knowledge Level: Understand)**
CO 2	Apply image reconstruction algorithms (e.g., FBP, iterative methods) to medical imaging tasks. (**Cognitive Knowledge Level: Apply)**
CO 3	Analyze and implement computer vision techniques such as segmentation and registration in clinical images **(Cognitive Knowledge Level: Evaluate)**
CO 4	Evaluate and apply machine learning and deep learning tools in the medical image analysis pipeline. **(Cognitive Knowledge Level: Analyze)**
CO 5	Design and assess complete image analysis workflows for clinical problems.**(Cognitive Knowledge Level: Apply)**

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO1	3		2	2	1	2	1
CO 2	3	3	2	2	2	2	1
CO 3	3	3	3	2	2	2	1
CO 4	3	2	3	2	2	2	1
CO 5	3	3	3	3	3	2	2

Programme Outcomes

PO's	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to integrate biomedical engineering principles with clinical and industrial needs to develop translational solutions and innovate for healthcare advancement.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyze	20
Evaluate	10
Understand	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and

quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY **FIRST SEMESTER M. TECH DEGREE EXAMINATION**			Name Register No:
Course code	251EBM031	Course name	Medical Image Reconstruction and Computer Vision
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Explain the difference between analytical and iterative reconstruction methods in CT.	5
2	Describe the concept of compressed sensing and its application in MRI.	5
3	Discuss any two segmentation techniques used in medical image analysis.	5
4	Explain the role of mutual information in image registration.	5
5	Describe one clinical application where computer vision is used in medical imaging	5
	PART B (Answer any five questions.)	
6	Derive the filtered back projection (FBP) algorithm and explain its limitations.	7
7	Compare and contrast ART and MLEM methods for image reconstruction.	7
8	Propose a workflow for brain tumor detection using machine learning.	7
9	Discuss how CNNs are used in organ segmentation tasks with examples.	7

10	Explain image registration techniques used in longitudinal patient studies.	7
11	Analyze the advantages of deep learning over traditional ML in radiology.	7
12	Discuss any one research trend in computer vision for medical imaging	7

Syllabus

Module 1 – Introduction to Medical Imaging and Image Reconstruction

Overview of medical imaging modalities (CT, MRI, PET, SPECT, Ultrasound). Principles of image formation. Introduction to inverse problems in imaging. Analytical reconstruction methods – Filtered Back Projection (FBP) for CT. Fourier slice theorem and Radon transform. Practical: Simulating simple CT projections and applying FBP reconstruction

Module 2- Iterative Reconstruction Techniques

Iterative methods: Algebraic Reconstruction Techniques (ART, SIRT), statistical reconstruction (MLEM). Regularization and sparsity-based reconstruction. Introduction to compressed sensing in medical imaging. Applications in low-dose CT and accelerated MRI.Practical: Implementing ART and MLEM in simulated 2D phantoms.

Module 3- Computer Vision for Medical Imaging

Image pre-processing (denoising, enhancement). Edge detection and feature extraction. Image segmentation: thresholding, region-growing, active contours, graph cuts. Image registration: rigid, affine, deformable registration. Mutual information and optimization techniques. Practical: Registration and segmentation tasks on publicly available medical datasets.

Module 4- Machine Learning for Medical Image Analysis

Supervised and unsupervised learning in medical imaging. Feature engineering and selection. Classification techniques: SVM, decision trees, k-NN. Introduction to deep learning (CNNs) for image segmentation and detection. Transfer learning in radiological image analysis. Practical: Image classification using ML and CNNs (e.g., tumor detection in MRI).

Module 5- Applications, Research Trends and Case Studies

Case studies: Low-dose CT reconstruction, fMRI activation mapping, organ segmentation. Clinical applications in oncology, neurology, and cardiology. Emerging trends: federated learning, explainable AI, multi-modal imaging. Public datasets and benchmarks. Practical: Use PhysioNet, TCIA, or other datasets for mini-project analysis.

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Medical Imaging and Reconstruction**	
1.1	Medical imaging modalities: X-ray, CT, MRI, PET, Ultrasound	2
1.2	Physics of image formation: attenuation, relaxation, reflection	2
1.3	Mathematical foundation: Radon Transform, inverse problems	2
1.4	Introduction to image reconstruction challenges and artifacts	1
1.5	Hands-on: Simple CT reconstruction using filtered back projection (FBP)	1
2	**Module 2- Image Reconstruction Techniques**	
2.1	Analytical methods: FBP, Fourier slice theorem	2
2.2	Iterative methods: Algebraic Reconstruction Technique (ART), SIRT	2
2.3	Noise modeling, regularization, and convergence criteria	2
2.4	Applications in low-dose and sparse-view CT	1
2.5	Hands-on: Implement FBP and iterative reconstruction in Python	1
3	**Module 3- Medical Image Processing and Computer Vision**	
3.1	Preprocessing: noise filtering, histogram normalization, edge enhancement	2
3.2	Segmentation: thresholding, region growing, watershed, active contours	2
3.3	Image registration: rigid, affine, deformable methods	2
3.4	Hands-on: Tumor segmentation and image registration in MRI	2
4	**Module 4- Machine Learning and Deep Learning in Medical Imaging**	

4.1	Feature extraction: texture, shape, intensity-based features	2
4.2	Traditional ML: SVM, k-NN, Random Forest for classification	2
4.3	Deep learning: CNN architectures, U-Net, ResNet in imaging	2
4.4	Hands-on: Disease classification using CNN on X-ray dataset	2
5	**Module 5- Applications, Evaluation, and Case Studies**	
5.1	Clinical applications: brain imaging, cardiac imaging, cancer detection	2
5.2	Quantitative metrics: PSNR, SSIM, Dice coefficient, ROC curve	2
5.3	Ethical issues and AI in radiology, explainability in ML	2
5.4	Hands-on: Comparative study of reconstruction and classification pipelines	2
		40

Text Books

1. Z. Liang and P. Lauterbur, Principles of Computerized Tomographic Imaging, SIAM
2. J. Semmlow, Biosignal and Medical Image Processing, CRC Press

Reference Books

1. Rafael C. Gonzalez and Richard E. Woods, Digital Image Processing, Pearson
2. Doi K., Computer-Aided Diagnosis in Medical Imaging: Historical Review, Current Status and Future Potential
3. IEEE Transactions on Medical Imaging, IEEE Transactions on Biomedical Engineering, and related journals

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM032	BIOMEDICAL IMAGE ANALYSIS AND INTEROPERABILITY STANDARDS	PROGRAM ELECTIVE 3	3	0	0	3

Preamble: Biomedical imaging plays a critical role in modern healthcare, enabling non-invasive diagnosis, surgical planning, and longitudinal disease tracking. However, the full potential of these imaging modalities can only be realized when integrated with standards that ensure interoperability, consistency, and secure exchange of medical data.This course provides an in-depth exploration of both computational techniques for biomedical image analysis and the interoperability standards—such as DICOM, HL7, and FHIR—that enable seamless communication between imaging devices, hospital information systems, and AI-based diagnostic tools. The course blends theoretical foundations with practical implementation, offering students insights into real-world clinical and research applications.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand and explain the various biomedical imaging modalities and image representation techniques. **(Cognitive Knowledge Level: Understand)**
CO 2	Apply advanced image analysis techniques including segmentation, registration, and feature extraction. (**Cognitive Knowledge Level: Apply)**
CO 3	Analyze and evaluate interoperability standards like DICOM, HL7, and FHIR for clinical imaging workflows. **(Cognitive Knowledge Level: Evaluate)**
CO 4	Design secure and standards-compliant image data exchange systems. **(Cognitive Knowledge Level: Create)**
CO 5	Integrate image analysis pipelines with healthcare data systems for real-time clinical decision support. **(Cognitive Knowledge Level: Create)**

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3		2		2	3	
CO 2	3	2					
CO 3		3	2	3	2	3	2
CO 4	3		2	2		3	
CO 5	3	3	3	2	3	2	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
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PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred) : 15 marks
Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no. : 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	241EEC009	Course name	Biomedical image analysis and interoperability standards
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Explain the significance of voxel resolution in 3D medical imaging.	5
2	Differentiate between rigid and non-rigid image registration with examples.	5
3	List and describe any four metadata fields commonly found in a DICOM file.	5
4	What is HL7? Mention two key differences between HL7 v2 and v3.	5

5	Briefly explain the role of FHIR in healthcare interoperability.	5
	PART B (Answer any five questions.)	
6	Compare CT and MRI in terms of physics, image characteristics, and clinical applications.	7
7	Describe the steps involved in edge detection and segmentation using the U-Net architecture.	7
8	Explain the structure and components of a DICOM file. How does it support interoperability in radiology?	7
9	Discuss the workflow of integrating a PACS system with an EHR using HL7 and DICOM standards.	7
10	Illustrate the architecture and functioning of a SMART on FHIR application for medical imaging data visualization.	7
11	What is the IHE framework? Explain its relevance in designing interoperable healthcare imaging systems.	7
12	Design a standards-compliant image analysis pipeline that includes acquisition, preprocessing, analysis, and integration with clinical systems.	7

Syllabus

Module 1 – Biomedical Imaging Fundamentals and Representations

Overview of imaging modalities: X-ray, CT, MRI, PET, Ultrasound, Imaging physics and contrast mechanisms, Digital image representation: pixel and voxel models, 2D vs 3D images, Introduction to DICOM standard and metadata structure, Image acquisition pipelines and PACS systems

Module 2- Biomedical Image Processing and Analysis

Noise reduction techniques (Gaussian, anisotropic diffusion), Edge detection and feature extraction, Segmentation techniques: thresholding, clustering, deformable models, CNN-based segmentation (U-Net), Image registration: rigid, affine, and non-rigid methods, 3D visualization and volume rendering techniques

Module 3- Interoperability Standards – DICOM, HL7, and FHIR

DICOM protocol in depth: services, SOP classes, data structures, HL7 v2.x and v3: message types and clinical use cases, FHIR (Fast Healthcare Interoperability Resources): RESTful services, resources, profiles, Interfacing medical imaging with EMRs/EHRs, Security and privacy in standard-based image exchange (HIPAA, GDPR compliance)

Module 4- System Integration and Workflow Engineering

Image acquisition, transfer, storage, and retrieval in clinical workflow, IHE (Integrating the Healthcare Enterprise): Profiles for radiology, Interface engines and middleware: Mirth Connect,

DCM4CHEE, AI-based decision support: integration with radiology workflow, Case studies: tele radiology, cancer registry, cloud-based imaging solutions

Module 5- Applications and Tools in Biomedical Image Analysis

Practical use of DICOM toolkits: DCMTK, pydicom, Orthanc, Biomedical image analysis tools: ITK, SimpleITK, 3D Slicer, MONAI, FHIR-based app development: SMART on FHIR, Postman, Python client, Implementation of a standards-compliant end-to-end image analysis pipeline, Ethical and legal issues in medical imaging data sharing

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Fundamentals of Biomedical Imaging and Image Representation**	
1.1	Overview of imaging modalities: X-ray, CT, MRI, PET, Ultrasound	1
1.2	Imaging physics and contrast mechanisms	2
1.3	Digital image representation: pixel and voxel models, 2D vs 3D images,	1
1.4	Introduction to DICOM standard and metadata structure	2
1.5	Image acquisition pipelines and PACS systems	2
2	**Module 2: Biomedical Image Processing and Analysis**	
2.1	Noise reduction techniques (Gaussian, anisotropic diffusion),	1
2.2	Edge detection and feature extraction	2
2.3	Segmentation techniques: thresholding, clustering, deformable models	1
2.4	CNN-based segmentation (U-Net),	2
2.5	Image registration: rigid, affine, and non-rigid methods, 3D visualization and volume rendering techniques	2
3	**Module 3- Image Segmentation Techniques**	
3.1	DICOM protocol in depth: services, SOP classes, data structures,	1
3.2	HL7 v2.x and v3: message types and clinical use cases,	2
3.3	FHIR (Fast Healthcare Interoperability Resources): RESTful services, resources, profiles	2
3.4	Interfacing medical imaging with EMRs/EHRs	2
3.5	Security and privacy in standard-based image exchange (HIPAA, GDPR compliance)	1
4	**Module 4- System Integration and Workflow Engineering**	
4.1	Image acquisition, transfer, storage, and retrieval in clinical workflow	1

4.2	IHE (Integrating the Healthcare Enterprise): Profiles for radiology	1
4.3	Interface engines and middleware: Mirth Connect, DCM4CHEE	1
4.4	AI-based decision support: integration with radiology workflow	1
4.5	Case studies: teleradiology, cancer registry, cloud-based imaging solutions	1
5	**Module 5- Applications and Tools in Biomedical Image Analysis**	
5.1	Practical use of DICOM toolkits: DCMTK, pydicom, Orthanc	1
5.2	Biomedical image analysis tools: ITK, SimpleITK, 3D Slicer, MONAI	1
5.3	FHIR-based app development: SMART on FHIR, Postman, Python client	1
5.4	Implementation of a standards-compliant end-to-end image analysis pipeline	1
5.5	Ethical and legal issues in medical imaging data sharing	1
		40

Text Books

1. Geoff Dougherty – Digital Image Processing for Medical Applications, Cambridge University Press
2. Charles E. Kahn – Introduction to PACS and Medical Imaging Informatics, Springer

Reference Books

1. Oleg S. Pianykh – *Digital Imaging and Communications in Medicine (DICOM): A Practical Introduction*, Springer
2. Arvind Kumar Bansal – *Medical Informatics*, CRC Press
3. Marcela Genero et al. – *Interoperability in Healthcare Information Systems: Standards and Implementations*, Springer
4. HL7 & FHIR official documentation: https://www.hl7.org, https://www.hl7.org/fhir
5. Online tools and platforms: pydicom, Orthanc,

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM033	Deep Learning for Medical Imaging	PROGRAM ELECTIVE 3	3	0	0	3

Preamble: This course introduces the fundamentals and applications of deep learning in biomedical signal and medical image analysis. It covers core techniques like CNNs, RNNs, segmentation, and real-time processing, with practical case studies in disease detection. Emphasis is placed on data preprocessing, model development, and deployment in clinical settings, preparing students for research and innovation in healthcare AI.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand the basic principles of deep learning and its relevance to biomedical signals imaging. ***(Understand)***
CO 2	Apply deep learning models such as CNNs and RNNs to classify and analyze biomedical signals and medical images.***(Apply)***
CO 3	Analyze medical image segmentation and registration techniques, and interpret model outputs using Explainable AI (XAI). ***(Analyze)***
CO 4	Design and implement real-time deep learning systems for diagnostic applications using case studies and deployable platforms. ***(Create)***

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3	2	3	1	2	2	1
CO 2	2	1	3	3	3	2	1
CO 3	3	1	3	2	3	2	1
CO 4	3	2	3	3	3	2	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks
Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.Test paper shall include minimum 80% of the

syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	**252EBM033**	Course name	**Deep Learning for Medical Imaging**
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Explain the key challenges of applying deep learning to biomedical signals and images. How do these challenges differ from conventional computer vision applications?	5
2	Describe the role of Recurrent Neural Networks (RNNs) in biomedical signal processing. Provide an example application in ECG or EEG analysis.	5
3	Compare and contrast transfer learning with training a deep neural network from scratch for medical image classification. Mention any two commonly used pre-trained models.	5
4	What is U-Net architecture? Discuss its significance in medical image segmentation with a relevant example.	5
5	Explain the importance of real-time constraints in biomedical applications. Describe how the Pan-Tompkins algorithm supports real-time QRS detection.	5
	PART B (Answer any five questions.)	
6	Explain the architecture of a basic neural network and describe how it can be adapted for biomedical image classification. Discuss any two biomedical-specific challenges in training deep models.	7

7	Discuss the architecture and working of a Convolutional Neural Network (CNN) in processing biomedical time-series data such as ECG. Provide an example use case.	7
8	Describe how deep learning techniques are used for noise reduction and artifact removal in EEG signals. Include any suitable preprocessing strategies.	7
9	Compare the performance and applicability of CNN architectures like VGG16 and ResNet in medical image classification tasks. Explain the advantages of using pre-trained models.	7
10	What is the role of Explainable AI (XAI) in medical imaging? Discuss with examples how interpretability can affect clinical decision-making.	7
11	Explain how U-Net architecture performs medical image segmentation. Highlight its encoder-decoder structure and significance in extracting fine details from biomedical images.	7
12	Describe a real-time deep learning system for seizure detection using EEG. Include a discussion on model deployment challenges on edge devices such as Raspberry Pi or Jetson Nano.	7

Syllabus

Module 1 – Fundamentals of Deep Learning for Biomedical Applications (8 hours)

Introduction to Medical Imaging & Biomedical Signals, Overview of Deep Learning and Neural Networks, Activation Functions, Optimizers, Loss Functions, Data Challenges in Biomedical Context: Scarcity, Labeling, Introduction to Tools: TensorFlow, Keras, PyTorch

Module 2- Deep Learning Techniques for Biomedical Signal Processing (8 hours)

Preprocessing of Biomedical Signals (EEG, ECG), CNNs and RNNs for Biomedical Time-Series Classification, Case Study: Arrhythmia and Seizure Detection, Noise Handling and Signal Augmentation

Module 3- Deep Learning for Medical Image Classification and Detection (8 hours)

Convolutional Neural Networks (CNNs) in Imaging, Transfer Learning and Pre-trained Models (VGG, ResNet), Medical Image Classification (X-ray, MRI, CT), Tumor and Lesion Detection Techniques

Module 4- Segmentation, Registration & Explainable AI (8 hours)

Semantic and Instance Segmentation (U-Net, Mask R-CNN), Medical Image Registration Techniques using DL, Explainable AI (XAI) for Medical Diagnosis, Interpretability Challenges in Medical Imaging

Module 5- Applications, Case Studies & Deployment (8 hours)

Case Study 1: Brain Tumor Detection from MRI, Case Study 2: COVID-19 Detection from Chest X-Rays, Deploying Models on Edge Devices (Raspberry Pi, Jetson Nano), Challenges in Clinical Integration & Ethics

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Fundamentals of Deep Learning for Biomedical Applications**	
1.1	Introduction to Medical Imaging & Biomedical Signals	1
1.2	Overview of Deep Learning and Neural Networks	2
1.3	Activation Functions, Optimizers, Loss Functions	2
1.4	Data Challenges in Biomedical Context: Scarcity, Labeling	1
1.5	Introduction to Tools: TensorFlow, Keras, PyTorch	2
2	**Module 2- Deep Learning Techniques for Biomedical Signal Processing**	
2.1	Preprocessing of Biomedical Signals (EEG, ECG)	2
2.2	CNNs and RNNs for Biomedical Time-Series Classification	2
2.3	Case Study: Arrhythmia and Seizure Detection	2
2.4	Noise Handling and Signal Augmentation	2
3	**Module 3- Deep Learning for Medical Image Classification and Detection**	
3.1	Convolutional Neural Networks (CNNs) in Imaging	2
3.2	Transfer Learning and Pre-trained Models (VGG, ResNet)	2
3.3	Medical Image Classification (X-ray, MRI, CT)	2
3.4	Tumor and Lesion Detection Techniques	2
4	**Module 4- Segmentation, Registration & Explainable AI**	
4.1	Semantic and Instance Segmentation (U-Net, Mask R-CNN)	3
4.2	Medical Image Registration Techniques using DL	2
4.3	Explainable AI (XAI) for Medical Diagnosis	2
4.4	Interpretability Challenges in Medical Imaging	1
5	**Module 5- Applications, Case Studies & Deployment**	
5.1	Case Study 1: Brain Tumor Detection from MRI	2
5.2	Case Study 2: COVID-19 Detection from Chest X-Rays	2
5.3	**Deploying Models on Edge Devices (Raspberry Pi, Jetson Nano)**	2
5.4	Challenges in Clinical Integration & Ethics	2
		40 Hrs

Text Books

1. R. Indrakumari, T. Ganesh Kumar et al. *Deep Learning in Medical Image Analysis: Recent Advances and Future Trends*CRC Press, 2025
2. Ngangbam Herojit Singh et al. *Deep Learning in Biomedical Signal and Medical Imaging* CRC Press, 2024
3. Saba, L., et al. *Deep Learning Techniques for Biomedical and Health Informatics* Academic Press, 2021

Reference Books

1. A. Ravishankar Rao *Biomedical Image Analysis* CRC Press, 2020
2. Shreyas Malakarjun Patil, *Hands-On Medical Image Processing with Python*, Packt, 2021
3. U. Rajendra Acharya, *Deep Learning for Biomedical Applications*,Elsevier, 2021
4. Sanjay Saxena, *Biomedical Signal and Image Processing in Deep Learning*,Springer, 2023.
5. Aboul Ella Hassanien et al., *Machine Learning and Deep Learning in Medical Data Analytics and Diagnosis*,Springer, 2020

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM034	IMMERSIVE TECHNOLOGIES IN MEDICAL IMAGING	PROGRAM ELECTIVE 4	3	0	0	3

Preamble: This course aims to impart knowledge on the fundamental concepts of immersive technologies such as VR, AR, and MR in medical imaging. It also covers the development and preprocessing of medical images for XR applications. Challenges related to integration, real-time rendering, and usability in clinical environments are addressed. The course extensively covers tools, standards, and ethical considerations essential for effective deployment in healthcare.

Course Outcomes: After the completion of the course the student will be able to

CO 1	**Understand** the core concepts and classifications of immersive technologies (VR, AR, MR, XR) and their significance in medical imaging.***(Understand)***
CO 2	**Apply** preprocessing and 3D reconstruction methods to convert medical imaging data into formats suitable for immersive visualization.***(Apply)***
CO 3	**Analyze** the use of hardware, software tools, and platforms required for immersive application development in clinical and research settings.***(Analyze)***
CO 4	**Evaluate** the role of immersive technologies in various medical applications such as diagnosis, surgery planning, rehabilitation, and education.***(Evaluate)***
CO 5	Create immersive medical applications by integrating imaging data, interaction design, and validation standards for real-world deployment.***(Create)***

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2		3			2	
CO 2	2		2	3	3		
CO 3	2		3	2	3		2
CO 4	2	2	3	3		2	
CO 5	3	3	3	3	3	2	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

TotalMarks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications

shall be referred): 15 marks
Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	252EBM034	Course name	IMMERSIVE TECHNOLOGIES IN MEDICAL IMAGING
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Differentiate between Virtual Reality (VR), Augmented Reality (AR), and Mixed Reality (MR) in terms of their components and typical applications in medical imaging.	5
2	Explain the significance of segmentation and registration in the preprocessing of medical images for XR visualization	5
3	List and briefly describe the key features of Unity or Unreal Engine used for developing immersive medical applications..	5
4	Discuss any two clinical case studies where immersive technologies were effectively used in diagnosis or surgical planning.	5

5	What are the ethical and regulatory considerations while deploying immersive applications in a clinical setting?	5
	PART B (Answer any five questions.)	
6	Describe the evolution of immersive technologies and discuss the technical architecture of a typical XR system used in medical imaging.	7
7	Explain the complete preprocessing pipeline of CT/MRI data for immersive application, including denoising, resampling, and 3D reconstruction.	
8	Illustrate the process of integrating a DICOM viewer into a Unity-based XR environment for diagnostic simulation.	7
9	Analyze how immersive simulations can be used for medical education and surgical rehearsal, citing appropriate examples.	
10	Evaluate the usability challenges in immersive medical applications and suggest strategies for improved user experience (UX) and patient safety.	7
11	Propose a conceptual framework for a VR-based patient education tool using 3D medical images. Include system components, user interface, and evaluation plan.	7
12	Compare and contrast different 3D reconstruction techniques (such as surface rendering, volume rendering, and mesh generation) used in immersive medical imaging applications.	7

Syllabus

Module 1 – Introduction to Immersive Technologies in Healthcare

Introduction to Immersive Technologies: VR, AR, MR, XR – Concepts, Degrees of immersion, HCI paradigms in medical XR, Historical evolution of immersive tech in healthcare, Overview of medical imaging modalities (CT, MRI, PET, US), Application domains: surgical planning, rehabilitation, patient care, User experience and interaction design in clinical environments.

Module 2- Medical Imaging Preprocessing for XR Applications

DICOM format, PACS, image retrieval, metadata interpretation, Image segmentation: thresholds, region growing, AI-assisted techniques, Tools for segmentation: ITK, 3D Slicer, MITK, ITK-SNAP, 3D reconstruction techniques: volumetric and surface rendering, Model optimization: mesh simplification, file conversions (STL, OBJ, glTF), Case walkthrough: preprocessing pipeline for a brain or cardiac dataset.

Module 3- XR Development Tools, Frameworks, and Hardware Integration

Unity3D and Unreal Engine overview – use in medical simulations, AR/VR SDKs – Vuforia, ARKit, ARCore, MRTK, HoloLens SDK, XR hardware ecosystem: HMDs, sensors, trackers, haptics, XR interaction models: hand tracking, voice commands, haptic feedback, Rendering optimization: LOD,

frame rate tuning, GPU shaders, Hands-on mini-project: Build a simple AR/VR application with medical data.

Module 4- Clinical Applications and Case Studies

Immersive surgical planning and intraoperative guidance, Radiology: volume interaction, lesion annotation, 3D printing integration, Functional imaging: fMRI, EEG/MEG visualization in immersive space, Rehabilitation: stroke, neurorehab, gamified therapy using VR, Immersive learning: anatomy, simulation-based training, patient education, Case discussion: recent research articles or hospital implementation

Module 5- Standards, Validation, Ethics, and Future Trends

Evaluation metrics: performance (latency, accuracy), user experience, Usability assessment techniques and feedback systems, Regulatory aspects: HIPAA, FDA, CDSCO, privacy and clinical safety, Ethical implications: bias, cognitive impact, overreliance, Interoperability standards: HL7, FHIR, DICOM Web, Future directions: digital twins, XR-AI convergence, healthcare metaverse.

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Fundamentals of Immersive Technologies in Healthcare**	
1.1	Introduction to Immersive Technologies: VR, AR, MR, XR – Concepts	1
1.2	Degrees of immersion; HCI paradigms in medical XR	1
1.3	Historical evolution of immersive tech in healthcare	1
1.4	Overview of medical imaging modalities (CT, MRI, PET, US)	1.5
1.5	Application domains: surgical planning, rehabilitation, patient care	2
1.6	User experience and interaction design in clinical environments	1.5
2	**Module 2- Industrial Classified Sensors**	
2.1	DICOM format, PACS, image retrieval, metadata interpretation	1.5
2.2	Image segmentation: thresholds, region growing, AI-assisted techniques	1.5
2.3	Tools for segmentation: ITK, 3D Slicer, MITK, ITK-SNAP	1.5
2.4	3D reconstruction techniques: volumetric and surface rendering	1.5
2.5	Model optimization: mesh simplification, file conversions (STL, OBJ, glTF)	1.5
2.6	Case walkthrough: preprocessing pipeline for a brain or cardiac dataset	1.5
3	**Module 3- XR Development Tools, Frameworks, and Hardware Integration**	

3.1	Unity3D and Unreal Engine overview – use in medical simulations	2
3.2	AR/VR SDKs – Vuforia, ARKit, ARCore, MRTK, HoloLens SDK	1.5
3.3	XR hardware ecosystem: HMDs, sensors, trackers, haptics	1.5
3.4	XR interaction models: hand tracking, voice commands, haptic feedback	1
3.5	Rendering optimization: LOD, frame rate tuning, GPU shaders	1
3.6	Hands-on mini-project: Build a simple AR/VR application with medical data	1
4	**Module 4- MEMS in Sensor Technology**	
4.1	Immersive surgical planning and intraoperative guidance	2
4.2	Radiology: volume interaction, lesion annotation, 3D printing integration	1.5
4.3	Functional imaging: fMRI, EEG/MEG visualization in immersive space	1
4.4	Rehabilitation: stroke, neurorehab, gamified therapy using VR	1.5
4.5	Immersive learning: anatomy, simulation-based training, patient education	1
4.6	Case discussion: recent research articles or hospital implementations	1
5	**Module 5- Standards, Validation, Ethics, and Future Trends**	
5.1	Evaluation metrics: performance (latency, accuracy), user experience	1.5
5.2	Usability assessment techniques and feedback systems	1
5.3	Regulatory aspects: HIPAA, FDA, CDSCO, privacy and clinical safety	1.5
5.4	Ethical implications: bias, cognitive impact, overreliance	1.5
5.5	Interoperability standards: HL7, FHIR, DICOM Web	1
5.6	Future directions: digital twins, XR-AI convergence, healthcare metaverse	1.5
		40 Hrs

Text Books

1. Gaurav Shukla, Ramesh R., Augmented and Virtual Reality for Medical Imaging and Computer-Assisted Intervention, Springer Nature, 2021.
2. Dinesh K. Saini, S. K. Singh, Virtual and Augmented Reality in Biomedical Engineering, Narosa Publishing House, New Delhi, 2020.
3. Grigore C. Burdea, Philippe Coiffet, Virtual Reality Technology, Wiley-IEEE Press, 2nd Edition, 2003.

Reference Books

1. Villard, Pierre; Subsol, Gérard; Chabanas, Mathieu, Augmented Reality and Virtual Reality in Medical Imaging, Springer, 2021.
2. Zhou, Feng; Duh, Henry B.-L.; Billinghurst, Mark, Trends in Augmented Reality Tracking, Interaction and Display, Springer Briefs, 2020.
3. Nassir Navab, Joachim Hornegger, William M. Wells, Alejandro Frangi, Handbook of Medical Image Computing and Computer-Assisted Intervention, Academic Press, 2020.
4. John Vincent Guttag, Introduction to Computation and Programming Using Python: With Application to Computational Modeling and Understanding Data, MIT Press, 2016.
5. Alan B. Craig, Understanding Augmented Reality: Concepts and Applications, Morgan Kaufmann, 2nd Edition, 2013.

PROGRAM ELECTIVE IV

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM041	ADVANCED QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES	PROGRAM ELECTIVE 4	3	0	0	3

Preamble: This course delves into the intricacies of ISO 13485:2016, the globally recognized standard for medical device QMS, emphasizing its application in real-world scenarios. Students will explore essential components such as risk management, regulatory compliance, documentation control, and continuous improvement processes. Through a blend of theoretical insights and practical case studies, the course aims to foster a deep understanding of the regulatory landscape and the critical role of quality management in safeguarding public health.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Demonstrate how to apply ISO 13485:2016 requirements within their own organization's quality management system.
CO 2	Understand the relationship between ISO 13485:2016 and various global regulatory requirements, including the European Medical Device Regulation (MDR) and the U.S. FDA's Quality System Regulation (QSR).
CO 3	Plan and execute internal audits to assess compliance with ISO 13485:2016, including identifying non-conformities and implementing corrective actions.
CO 4	Apply principles of continual improvement to enhance the effectiveness of the quality management system.
CO 5	Develop clear and concise audit reports that provide actionable insights for continuous improvement.

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3	2	3	2	3	2	2
CO 2	2		2		2	3	

		3		3			3
CO 3	3	3	2	3	3	2	3
CO 4	2	3	3	3	3	3	2
CO 5	2	3	3	2	3	3	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern: 60 Marks

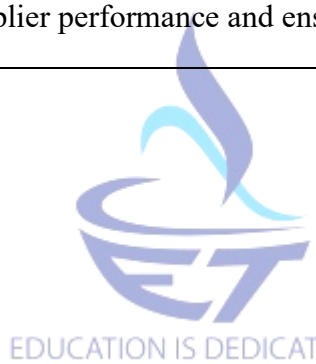
The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY **FIRST SEMESTER M.TECH DEGREE EXAMINATION**			Name Register No:
Course code	252EBM041	Course name: Advanced quality management system for medical devices	
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Assess the impact of non-compliance with ISO 13485:2016 on patient safety and regulatory approval processes.	5
2	Critique the effectiveness of ISO 14971:2019 in managing risks associated with Software as a Medical Device (SaMD)	5
3	Assess the effectiveness of design verification and validation techniques in ensuring the safety and efficacy of medical devices.	5
4	Assess the impact of process validation (IQ, OQ, PQ) on product quality and regulatory compliance.	5
5	Critique the effectiveness of CAPA systems in addressing non-conformities and preventing recurrence in medical device manufacturing.	5
	PART B (Answer any five questions.)	
6	Design a quality management system framework that integrates ISO 13485:2016 and FDA 21 CFR 820, ensuring compliance and efficiency.	7
7	Investigate the limitations of traditional risk assessment methods like FMEA and propose enhancements using advanced techniques such as Bayesian networks.	7

8	Examine the role of Design History Files (DHF) in maintaining compliance with regulatory requirements and propose improvements for documentation practices.	7
9	Design a traceability system that integrates Device Master Records (DMR) and Device History Records (DHR) to ensure product accountability.	7
10	Examine the role of root cause analysis methodologies (e.g., 5 Whys, FMEA) in identifying underlying issues and propose improvements to existing practices.	7
11	Develop a comprehensive risk management plan for a new medical device, incorporating ISO 14971:2019 standards and advanced risk assessment methods.	7
12	Investigate the challenges in supplier management and propose strategies to enhance supplier performance and ensure product quality.	7



Syllabus

Module 1 – Introduction to Medical Device Quality Management Systems

Overview of QMS in Medical Devices: Role and importance of QMS in ensuring the safety and efficacy of medical devices. Regulatory Frameworks: Introduction to key regulations such as ISO 13485:2016- Risk management throughout the product life cycle, Design and development controls, Supplier management and purchasing controls, Production and process controls, post-market surveillance and feedback mechanisms. FDA 21 CFR 820- Design controls, Production and process controls, Corrective and preventive actions, Document controls, Purchasing controls, Identification and traceability and their global implications. Quality Management Principles: Fundamental principles guiding quality management practices in the medical device sector.

Module 2- Risk Management in Medical Devices

ISO 14971 Standard: Application of risk management processes as per ISO 14971 to identify, evaluate, and mitigate risks associated with medical devices. Risk Assessment Techniques: Failure Mode and Effects Analysis (FMEA), Fault Tree Analysis (FTA), Hazard and Operability Study (HAZOP), Preliminary Hazard Analysis (PHA), Bowtie Analysis. Post-Market Surveillance: Objectives of PMS, Key Activities in PMS- Monitoring, Analysis, Action and Reporting. Integration of Risk Management into the Product Life Cycle- Design and Development, Production and Manufacturing and Post-Market Phase.

Module 3- Design and Development Controls

Design Control Processes: Design and Development Planning, Design Inputs and Outputs, Design Reviews, Design Verification and Validation, Design Changes, Risk Management Documentation. Design History File (DHF): Documentation requirements and best practices for maintaining a DHF. Verification and Validation: Design Verification Techniques- Functional Testing, Environmental Testing, Biocompatibility Testing, Sterility and Package Integrity Testing. Design Validation Techniques- User Needs Assessment, Usability Testing, Clinical Trials, Human Factors Engineering.

Module 4- Production and Process Controls

Process Validation: Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), Validation Protocols, Documentation, Revalidation. Supplier Management: Selection Criteria, Evaluation and Approval, Supplier Agreements, Performance Monitoring. Production Records and Traceability: Device Master Record (DMR), Device History Record (DHR), Traceability Requirements, Record Retention.

Module 5- Corrective and Preventive Actions (CAPA)

CAPA System Implementation: System Overview, Process Steps- Identification of Non-Conformities, Investigation and Root Cause Analysis, Corrective Action, Verification of Effectiveness, Documentation and Record-Keeping. Root Cause Analysis: Introduction to Root Cause Analysis, RCA Methodologies- 5 Whys Analysis, Failure Mode and Effects Analysis (FMEA), Fault Tree Analysis (FTA), Pareto Analysis, Data Collection and Analysis. Effectiveness Verification: Verification Methods, Monitoring and Measurement, Documentation and Reporting, Continuous Improvement.

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Medical Device Quality Management Systems**	
1.1	**Overview of QMS in Medical Devices**: Role and importance of QMS in ensuring the safety and efficacy of medical devices.	1
1.2	**Regulatory Frameworks**: Introduction to key regulations such as **ISO 13485:2016**- Risk management throughout the product life cycle, Design and development controls.	2
1.3	Supplier management and purchasing controls, Production and process controls, Post-market surveillance and feedback mechanisms.	1
1.4	**FDA 21 CFR 820**- Design controls, Production and process controls, Corrective and preventive actions.	2
1.5	Document controls, Purchasing controls, Identification and traceability and their global implications.	1
1.6	**Quality Management Principles**: Fundamental principles guiding quality management practices in the medical device sector.	1
2	**Module 2- Risk Management in Medical Devices**	
2.1	**ISO 14971 Standard:** Application of risk management processes as per ISO 14971 to identify, evaluate, and mitigate risks associated with medical devices.	2

2.2	**Risk Assessment Techniques:** Failure Mode and Effects Analysis (FMEA), Fault Tree Analysis (FTA).	2
2.3	Hazard and Operability Study (HAZOP), Preliminary Hazard Analysis (PHA), Bowtie Analysis.	1
2.4	**Post-Market Surveillance:** Objectives of PMS, Key Activities in PMS- Monitoring, Analysis, Action and Reporting.	1
2.5	**Integration of Risk Management into the Product Life Cycle-** Design and Development, Production and Manufacturing and Post-Market Phase	2
3	**Module 3- Design and Development Controls**	
3.1	**Design Control Processes**: Design and Development Planning, Design Inputs and Outputs,	2
3.2	Design Reviews, Design Verification and Validation.	1
3.3	Design Changes, Risk Management Documentation.	1
3.4	**Design History File (DHF)**: Documentation requirements and best practices for maintaining a DHF.	2
3.5	**Verification and Validation**: Design Verification Techniques- Functional Testing, Environmental Testing, Biocompatibility Testing, Sterility and Package Integrity Testing.	1
3.6	Design Validation Techniques- User Needs Assessment, Usability Testing, Clinical Trials, Human Factors Engineering.	1
4	**Module 4- Production and Process Controls**	
4.1	**Process Validation**: Installation Qualification (IQ), Operational Qualification (OQ).	1
4.2	Performance Qualification (PQ), Validation Protocols, Documentation, Revalidation.	2
4.3	**Supplier Management**: Selection Criteria, Evaluation and Approval, Supplier Agreements, Performance Monitoring.	2
4.4	**Production Records and Traceability**: Device Master Record (DMR), Device History Record (DHR).	2
4.5	Traceability Requirements, Record Retention.	1

5	**Module 5- Corrective and Preventive Actions (CAPA)**	
5.1	**CAPA System Implementation**: System Overview, Process Steps- Identification of Non-Conformities.	1
5.2	Investigation and Root Cause Analysis, Corrective Action, Verification of Effectiveness.	1
5.3	Documentation and Record-Keeping. **Root Cause Analysis**: Introduction to Root Cause Analysis.	1
5.4	RCA Methodologies- 5 Whys Analysis, Failure Mode and Effects Analysis (FMEA).	2
5.5	Fault Tree Analysis (FTA), Pareto Analysis, Data Collection and Analysis.	1
5.6	**Effectiveness Verification**: Verification Methods, Monitoring and Measurement, Documentation and Reporting, Continuous Improvement.	2
		40

Reference Materials

1. ISO 13485:2016: A Complete Guide to Quality Management in the Medical Device Industry by Itay Abuhav
2. ISO 14971:2019 - Medical Devices — Application of Risk Management to Medical Devices by ISO
3. Developing an ISO 13485-Certified Quality Management System by Dr. Ilkka Juuso

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM042	INTEGRATED DESIGN CONTROL AND RISK GOVERNANCE	PROGRAM ELECTIVE 4	3	0	0	3

Preamble: This advanced course provides a comprehensive framework for risk governance in medical device development, production, and post-market performance. It explores the integration of quality systems, risk-based decision-making, and global regulatory strategies, emphasizing both Indian (CDSCO) and international (FDA, EU MDR, IMDRF) requirements. Students will be equipped to manage risk documentation, clinical evaluation, audit preparedness, and lifecycle regulatory compliance in both startup and industrial MedTech environments.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand risk governance principles and regulatory frameworks across India, US, EU, and global bodies. (Understand)
CO 2	Apply risk-based approaches to the creation of design dossiers, technical files, and device documentation. (Apply)
CO 3	Analyze clinical risk evaluation, post-market surveillance, and risk-benefit justification. (Analyze)
CO 4	Evaluate regulatory audit and inspection requirements through risk-informed audit readiness. (Evaluate)
CO 5	Formulate comprehensive risk-based strategies for lifecycle governance and vigilance planning. (Create)

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2		2	2			
CO 2	3		3	3	3		
CO 3	2		3	3	3		
CO 4	2		3	3	3		

CO 5	**3**	**3**	**3**	**3**	**2**	**2**	**2**

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams.
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program.
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

TotalMarks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Module-based Activities (5 × 6 = 30 Marks)
Activities are included in the course syllabus and should be completed by the student. Each task carries 6 marks.
Test paper, 1 no.: 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

SAHRDAYA COLLEGEBOF ENGINEERING AND TECHNOLOGY (AUTONOMOUS) FIRST SEMESTER M. TECH DEGREE EXAMINATION			Name Register No:
Course code		Course name	
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Explain the distinction between organizational risk governance and product-level risk management with examples.	5
2	What are the key components of a Device Master File (DMF) under India's Medical Device Rules?	5

3	Describe how a Clinical Evaluation Report (CER) justifies benefit-risk in EU MDR submissions.	5
4	How does the QSIT methodology assess risk control during FDA inspections?	5
5	What is the role of Materiovigilance Programme of India (MvPI) in risk monitoring?	5
	PART B (Answer any five questions.)	
6	Compare and contrast the risk classification systems and regulatory impact in India (CDSCO), EU (MDR), and US (FDA).	7
7	Draft a simplified **risk-benefit analysis** for a Class C diagnostic device intended for both Indian and European markets.	7
8	How is risk documented in a Design Dossier? Explain with reference to EU MDR Annex II & III.	7
9	Illustrate the audit lifecycle of a Class B medical device manufacturer with reference to CDSCO and EU inspections.	7
10	Describe how risk-based PMS and vigilance systems feed into lifecycle risk governance using a real-world example.	7
11	Evaluate how IEC 62304 and IEC 62366 integrate into software and usability risk control in SaMD development.	7
12	Prepare a sample outline for a Post-Market Surveillance (PMS) Plan for a wearable health-monitoring device.	7

Syllabus

Module 1 – Comprehensive risk-based strategies for lifecycle governance and vigilance planning (8 Hours)

Principles of risk governance and ISO 14971/ISO TR 24971, Risk-based decision making in CDSCO, FDA, EU MDR, Organizational vs product-level risk, Risk-benefit analysis in submission strategy, IMDRF, WHO, GHTF convergence initiatives, Case study: Risk classification for a Class C Indian device

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Module 2- Risk-Informed Documentation and Technical Files (8 Hours)

Risk-based Design Dossiers and Technical Files (EU MDR Annex II/III), CDSCO DMF and PMF with risk elements, US FDA: 510(k), PMA design risk integration, Labeling, IFU, UDI: capturing residual risk, SaMD documentation using IEC 62304, Assignment: Create a sample Risk File for a device with Indian/EU markets

Module 3 Clinical Evaluation and Risk-Benefit Analysis (8 Hours)

Clinical Evaluation Reports (CER), PMCF (EU MDR), Indian clinical investigation pathway and risk categorization, Equivalence and literature-based clinical justifications, Risk justification in FDA PMA vs 510(k), Performance risk management in IVDs, Workshop: Develop a benefit-risk profile for a diagnostic device

Module 4- Audits, Compliance, and Risk-Based Readiness (8 Hours)

CDSCO, EU Notified Body, and FDA audit methodologies, QSIT audit tool and risk signals, Non-conformity response and CAPA risk prioritization, Internal audit planning by risk class, Risk dashboards, audit trail, traceability, Activity: Simulated CDSCO audit exercise

Module 5- Auditing, Documentation, and Continuous Improvement (8 Hours)

Risk-based PMS planning and vigilance protocols, Materiovigilance in India, MIRs in EU, FSCA planning, risk signal detection, periodic safety updates, Lifecycle change management and documentation, Post-approval risk reassessment strategies, Mini project: Create a PMS plan for a wearable health device

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Formulate comprehensive risk-based strategies for lifecycle governance and vigilance planning**	
1.1	Principles of risk governance and ISO 14971/ISO TR 24971,	2
1.2	Risk-based decision making in CDSCO, FDA, EU MDR	1
1.3	Organizational vs product-level risk	1
1.4	Risk-benefit analysis in submission strategy	2
1.5	IMDRF, WHO, GHTF convergence initiatives	2
2	**Module 2- Risk-Informed Documentation and Technical Files**	
2.1	Risk-based Design Dossiers and Technical Files (EU MDR Annex II/III)	2
2.2	CDSCO DMF and PMF with risk elements	1
2.3	US FDA: 510(k), PMA design risk integration	2
2.4	Labeling, IFU, UDI: capturing residual risk	1
2.5	SaMD documentation using IEC 62304	2
3	**Module 3- Clinical Evaluation and Risk-Benefit Analysis**	
3.1	Clinical Evaluation Reports (CER), PMCF (EU MDR)	2
3.2	Indian clinical investigation pathway and risk categorization,	2

3.3	Equivalence and literature-based clinical justifications	2
3.4	Risk justification in FDA PMA vs 510(k), Performance risk management in IVDs	2
4	**Module 4- Audits, Compliance, and Risk-Based Readiness**	
4.1	CDSCO, EU Notified Body, and FDA audit methodologies	2
4.2	QSIT audit tool and risk signals	1
4.3	Non-conformity response and CAPA risk prioritization,	1
4.4	Fault Tree Analysis (FTA),	1
4.5	Internal audit planning by risk class	1
4.6	Risk dashboards, audit trail, traceability	2
5	**Module 5- Auditing, Documentation, and Continuous Improvement**	
5.1	Risk-based PMS planning and vigilance protocols	2
5.2	Materiovigilance in India, MIRs in EU, FSCA planning, risk signal detection, periodic safety updates	3
5.3	Lifecycle change management and documentation, Post-approval risk reassessment strategies,	3
		40

Text Book

1. R. C. Fries, *Medical Device Quality Assurance and Regulatory Compliance*, 2nd ed., Boca Raton, FL, USA: CRC Press, 2012.
2. N. S. Prasad and R. R. Gupta, *Medical Device Regulations in India: Law, Regulation, and Practice*, Gurgaon, India: LexisNexis, 2022.
3. J. E. Rulis and D. H. Morton, *Quality Systems and Controls for Medical Devices*, Bethesda, MD, USA: PDA/DHI Publishing, 2011.

Reference Books

1. **ISO 13485:2016**, *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, International Organization for Standardization, Geneva, Switzerland, 2016.
2. **ISO 14971:2019**, *Medical Devices – Application of Risk Management to Medical Devices*, International Organization for Standardization, Geneva, Switzerland, 2019.
3. **Central Drugs Standard Control Organization (CDSCO)**, *Medical Device Rules, 2017*, Ministry of Health and Family Welfare, Government of India, New Delhi, India, 2017. [Online]. Available: https://cdsco.gov.in
4. **U.S. Food and Drug Administration (FDA)**, *21 CFR Part 820 – Quality System Regulation*, Code of Federal Regulations, U.S. Government Publishing Office, Washington, DC, USA, 2023. [Online]. Available: https://www.ecfr.gov

5. **European Parliament and Council**, *Regulation (EU) 2017/745 on Medical Devices (EU MDR)*, Official Journal of the European Union, L117, May 5, 2017.
6. **World Health Organization (WHO)**, *WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices*, WHO Press, Geneva, Switzerland, 2017. [Online]. Available: https://www.who.int

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM043	CLINICAL EVALUATION AND TRIALS FOR DEVICES	PROGRAM ELECTIVE 4	3	0	0	3

Preamble: This course provides structured training in the clinical evaluation and clinical investigation of medical devices in accordance with ISO 14155:2020 and EU MDR requirements. It focuses on understanding clinical data sources, the process of clinical evaluation (CEP to CER), demonstration of equivalence, Good Clinical Practice (GCP), and post-market surveillance tools such as PMCF, PSUR, and SSCP. The course enables learners to contribute effectively to planning, executing, and reporting clinical investigations and evaluations to support safe and effective device deployment globally.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Interpret ISO 14155:2020 and MDR guidelines in clinical evaluation and investigation of medical devices. (Understand)
CO 2	Prepare and critique essential documents such as CEP, CIP, IB, CRFs, and CER. (Apply)
CO 3	Appraise clinical data from literature, equivalence, clinical trials, and post-market surveillance. (Analyze)
CO 4	Evaluate regulatory requirements including CECP, SSCP, PMCF, and PSUR for device lifecycle management. (Evaluate)
CO 5	Design and manage a GCP-compliant clinical investigation and report findings with regulatory adequacy (Create)

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3		3	2	1	1	
CO 2	1	3	2	1	3	1	
CO 3	3	1	3	1	3	2	

CO 4	**2**	**1**	**3**	**3**	**2**	**3**	**1**
CO 5	**3**	**2**	**3**	**3**	**2**	**2**	**3**

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Understand	12
Apply	19
Analyse	12

Evaluate	19
Create	112

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

1. **Review Assignment based on Peer-Reviewed Clinical Studies** – *15 Marks*
   Students shall prepare a structured review article based on at least **10 peer-reviewed original clinical publications** related to medical device clinical evaluation, ISO 14155 trials, or PMCF. The review must include **critical appraisal**, classification of data sources (investigational, literature, equivalence, post-market), and **conformity assessment insights**.

2. **Course-Based Task / Seminar / Regulatory Documentation Exercise** – *15 Marks*
   Students can perform one of the following:
   Conduct a **mini-seminar** on CECP, SSCP, or PMCF strategies.
   Submit **sample sections of a Clinical Evaluation Plan (CEP), CIP, or CER** based on a given device scenario.
   Perform and report a **systematic literature search and equivalence mapping** using MDCG 2020-13 guidelines.

3. **Test Paper (covering minimum 80% of the syllabus)** – *10 Marks*

End Semester Examination Pattern:60 Marks

There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

SAHRDAYA COLLEGEBOF ENGINEERING AND TECHNOLOGY (AUTONOMOUS) FIRST SEMESTER M. TECH DEGREE EXAMINATION			Name Register No:
Course code		Course name	
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Describe the importance of MDR Article 61 in clinical evaluation.	5
2	What are the functions of a Clinical Investigation Plan (CIP)?	5
3	How is clinical data obtained from literature and equivalence studies?	5
4	What is the role of PMCF in the lifecycle of medical devices?	5
5	List the major steps to initiate a GCP-compliant clinical investigation.	5
	PART B (Answer any five questions.)	
6	Explain how ISO 14155:2020 ensures safety and ethical compliance in clinical investigations.	7
7	Draft a sample Clinical Evaluation Plan (CEP) for a new diagnostic device and explain the justification of its structure.	7
8	Analyze the equivalence criteria used in literature-based clinical evaluation. Support with examples.	7
9	Evaluate the process of CECP and its importance in high-risk device regulatory pathways.	7
10	Design a clinical investigation strategy for a wearable cardiac monitor, ensuring ISO 14155 and GCP compliance.	7
11	Describe the contents and function of a Summary of Safety and Clinical Performance (SSCP).	7
12	. Explain the critical documentation involved in initiating and closing a clinical investigation.	7

Syllabus

Module 1: Fundamentals of Clinical Evaluation and Data Sources

What is Clinical Evaluation (per MDR Article 61 and Annex XIV) - Types and Sources of Clinical Data: - Clinical investigations - Literature and equivalence (MDCG 2020-5, 2020-13) - Post-market data (PMS, PMCF) - Introduction to CEP, CER, and Clinical Evaluation Lifecycle

Activity: Review and map different data sources for a Class II device's clinical evaluation

Module 2: ISO 14155 and Good Clinical Practice

Overview of ISO 14155:2020 - Good Clinical Practice (GCP) principles and comparison to pharma trials - Roles of sponsor, investigator, ECs, and Competent Authorities - Key documents: CIP, IB, CRFs, informed consent

Case Study: Ethics and GCP in a wearable heart monitor trial

Module 3: Designing and Conducting Clinical Investigations

Clinical investigation lifecycle: planning to termination - Risk-based approach and safety reporting - Site qualification, monitoring, and device accountability - Data management and documentation requirements

Assignment: Draft CIP sections (objectives, methodology, safety reporting plan)

Module 4: Equivalence, Literature Search & Regulatory Considerations

Equivalence demonstration: technical, biological, clinical - Designing a literature search (MDCG 2020-13 protocol) - Clinical Evaluation Consultation Procedure (CECP) - Clinical evidence thresholds and justification strategy

Task: Develop a search protocol and evaluate equivalence for a spinal implants

Module 5: Post-Market Clinical Follow-Up and Lifecycle Reports

PMCF plan and implementation (MDCG 2020-7, 2020-8) - Periodic Safety Update Report (PSUR) (MDR Article 86) - Summary of Safety and Clinical Performance (SSCP) (MDR Art. 32) - Lifecycle management and CER updates .

Project: Draft a PMCF strategy and SSCP for a Class III implantable device

Course Plan

No	Topic	No. of Lectures
1	**Module 1: Fundamentals of Clinical Evaluation and Data Sources**	
1.1	Introduction to Clinical Evaluation (MDR Article 61 and Annex XIV). Types of Clinical Data: Overview	2
1.2	Data from Clinical Investigations Literature and Equivalence (MDCG 2020-5, 2020-13)	2
1.3	Post-Market Data: PMS and PMCF; Introduction to CEP and CER	2
1.4	Clinical Evaluation Lifecycle	1
1.5	Activity: Mapping Clinical Data Sources for a Class II Device	1
2	**Module 2: ISO 14155 and Good Clinical Practice**	
2.1	Overview of ISO 14155:2020	1
2.2	Good Clinical Practice (GCP) – Key Principles	1
2.3	GCP vs. Pharma Trials	1
2.4	Roles: Sponsor, Investigator, ECs, and Competent Authorities	1
2.5	Key Documents: CIP and IB	1
2.6	Key Documents: CRFs and Informed Consent	1
2.7	Case Study: Ethics and GCP – Wearable Heart Monitor Trial	1
3	**Module 3: Designing and Conducting Clinical Investigations**	

3.1	Clinical Investigation Lifecycle: From Planning to Termination	1
3.2	Risk-Based Approach in Clinical Investigations	1
3.3	Safety Reporting Procedures	1
3.4	Site Qualification and Monitoring	1
3.5	Device Accountability and Site Management	1
3.6	Data Management in Clinical Investigations	1
3.7	Documentation Requirements	1
3.8	Assignment: Drafting CIP Sections (Objectives & Methodology)	1
3.9	Assignment: Safety Reporting Plan	1
4	**Module 4: Equivalence, Literature Search & Regulatory Considerations**	
4.1	Equivalence Demonstration: Technical, Biological, Clinical	1
4.2	Designing Literature Searches (MDCG 2020-13 Protocol)	1
4.3	Hands-on: Drafting a Literature Search Protocol	1
4.4	Clinical Evaluation Consultation Procedure (CECP)	1
4.5	Clinical Evidence Thresholds and Justification Strategies	1
4.6	Task: Equivalence Assessment for Spinal Implant	1

5	**Module 5: Post-Market Clinical Follow-Up and Lifecycle Reports**	
5.1	PMCF Plan and Implementation (MDCG 2020-7, 2020-8)	1
5.2	Periodic Safety Update Report (PSUR) – MDR Article 86	1
5.3	Summary of Safety and Clinical Performance (SSCP) – MDR Art. 32	1
5.4	Lifecycle Management of Clinical Evaluation	1
5.5	CER Updates and Regulatory Continuity	1
5.6	Project Briefing: PMCF Strategy and SSCP Drafting	1
5.7	Project Workshop: PMCF Drafting	1
5.8	Project Workshop: SSCP Drafting	1
5.9	Final Presentations and Review	1
5.10	Course Recap and Evaluation	1
		40

Textbooks

1. R. C. Fries, *Medical Device Quality Assurance and Regulatory Compliance*, 2nd ed., Boca Raton, FL, USA: CRC Press, 2012.
2. K. B. Witkin and H. A. F. Stover, *Clinical Evaluation of Medical Devices: Principles and Case Studies*, Totowa, NJ, USA: Humana Press, 1997.
3. M. Nyåkern, *Clinical Investigation of Medical Devices under the EU MDR*, Online Companion Book, Medical Device HQ, 2023.
4. K. Ginsberg, *Good Clinical Practice: A Question & Answer Reference Guide*, Latest ed., Barnett Educational Services.

5. J. S. Kahan, *Medical Device Development: Regulation and Law*, 2nd ed., New York, NY, USA: Springer, 2020.
6. T. Christaki, *Medical Device Clinical Trials: Risk Management and Safety*, Hoboken, NJ, USA: Wiley, 2021.
7. S. Jahanfar, *Postmarket Surveillance and Vigilance for Medical Devices*, Amsterdam, Netherlands: Elsevier, 2023.
8. P. H. King and R. C. Fries, *Design of Biomedical Devices and Systems*, 3rd ed., Boca Raton, FL, USA: CRC Press, 2013.

Standards Documents and Guidelines

1. International Organization for Standardization, *ISO 14155: Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice*, 3rd ed., Geneva, Switzerland: ISO, 2020.
2. European Commission, *MDCG 2020-5: Clinical Evaluation – Equivalence*, Brussels, Belgium: Medical Device Coordination Group, 2020.
3. European Commission, *MDCG 2020-13: Clinical Evaluation Assessment Report Template*, Brussels, Belgium: Medical Device Coordination Group, 2020.
4. European Commission, *MDCG 2020-7 and 2020-8: PMCF Plan and PMCF Evaluation Report Templates*, Brussels, Belgium: Medical Device Coordination Group, 2020.
5. European Commission, *MDCG 2019-9: SSCP Guidance*, Brussels, Belgium: Medical Device Coordination Group, 2019.
6. European Commission, *MDR 2017/745: Medical Device Regulation (EU)*, Official Journal of the European Union, 2017.

Reference Books

1. World Health Organization (WHO), *Medical Device Regulations: Global Overview and Guiding Principles*, Geneva, Switzerland: WHO Press, 2003.
2. G. Hall, *EU Medical Device Regulation – MDR: An Introduction and Overview*, Independently Published, 2022.
3. World Health Organization (WHO), *WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices*, WHO Press, Geneva, Switzerland, 2017. [Online]. Available: https://www.who.int

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
251EBM044	INTELLECTUAL PROPERTY RIGHTS & ETHICS IN MEDTECH	PROGRAM ELECTIVE 4	3	0	0	3

Preamble:

The purpose of the training in Intellectual Property Rights & Ethics in MedTech is to produce professionals equipped with the knowledge, skills, and ethical perspective required to protect, manage, and commercialize innovations in the biomedical domain. The course aims to prepare students to navigate global IP systems, apply strategic IP tools in medical technology development, and address emerging legal and ethical challenges, particularly in the context of digital health, AI, and patient-centric innovations

Course Outcomes:

After the completion of the course the student will be able to

CO 1	Define the fundamental types of intellectual property rights and explain their relevance to biomedical technologies within Indian and global legal frameworks.
CO 2	Apply patent filing procedures, prior art search techniques, and IP lifecycle strategies specific to medical device and digital health innovations.
CO 3	Compare licensing models and explain the process of technology transfer and commercialization for academic and early-stage MedTech innovations.
CO 4	Evaluate ethical issues in medical innovation and intellectual property, including AI-based diagnostics and access to life-saving technologies.
CO 5	Analyse legal risks, enforcement mechanisms, and dispute resolution options related to intellectual property in the MedTech industry.

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2	2	2			3	
CO 2	2	2	2	2			
CO 3	2	2	2	2			2
CO 4	2		2			3	
CO 5	2		2	2		3	2

Assessment Pattern:

Bloom's Category	End Semester Examination
Apply	20
Analyze	20
Evaluate	20

Create	

Mark distribution:

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern (40 Marks):

- Evaluation shall only be based on application, analysis or design-based questions.

Evaluation Method	Marks
Micro project/Course based project	20 Marks
Course based task/Seminar/Quiz	10 Marks
Test paper, 1 no (Test paper shall include minimum 80% of the syllabus)	10 Marks
Total	40 Marks

- All COs must be assessed by using at least one assessment method of Continuous Internal Evaluation.

End Semester Examination Pattern (60 Marks):

- The end semester examination will be consisting of two parts; Part A and Part B.
- Part A contain 5 numerical questions (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students), with 1 question from each module, having 5 marks for each question. Students shall answer all questions.
- Part B contains 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student shall answer any five. Each question can carry 7 marks.
- Total duration of the examination will be 150 minutes.

Model Question paper:

Course Code: 221TIC001

Course Name: INTELLECTUAL PROPERTY RIGHTS & ETHICS IN MEDTECH

Max. Marks: 60 **Duration: 2.5 Hours**

PART A

Answer all Questions. Each question carries 5 Marks

13. List the four main types of Intellectual Property Rights and match each with one example from MedTech applications.
14. Outline the steps involved in performing a Freedom-to-Operate (FTO) analysis for a novel wearable health monitoring device.
15. A university MedTech startup wants to license its diagnostic device IP. Compare exclusive and non-exclusive licenses and suggest one with justification.
16. Refer to the NITI Aayog Responsible AI framework. List three ethical principles it emphasizes and explain their importance in MedTech AI solutions.
17. Given a situation where a company's patented diagnostic software is reused by another without permission, identify possible legal routes in India for enforcement.

PART B

Answer any five Questions. Each question carries 7 Marks

18. Explain the patentability criteria under Indian law with reference to biomedical device innovations. Support your answer with an example.
19. Describe the differences in patent examination procedures across India, Europe, and the United States, specifically in the context of MedTech inventions.
20. Discuss the role of public-funded incubators and innovation support systems in enabling the commercialization of medical technology developed in academic institutions.
21. Evaluate the ethical implications of using AI-based tools in medical diagnostics. Highlight concerns such as algorithmic bias, lack of transparency, and user accountability.
22. What are the common types of intellectual property infringement encountered in medical technology development? Discuss with reference to real-world legal scenarios.
23. Develop an IP management roadmap for a medical device startup that includes strategies for protecting innovation, managing licensing, and mitigating infringement risks.
24. Examine the ethical challenges related to the collection and use of patient data in AI-driven healthcare systems. How can these challenges be addressed through national-level policy frameworks?

Syllabus

Module I (8 Hours): Foundations of Intellectual Property in MedTech

Introduction to IPR: Types and relevance in MedTech (Patents, Copyrights, Trade Secrets, etc.) Patentability criteria in biomedical innovations. Overview of global IP frameworks: Indian Patent Act, EPC (Europe), and USPTO guidelines. Introduction to TRIPS, compulsory licensing
Case study: Bayer vs. Natco – India's first compulsory license for a cancer drug

Module II (8 Hours): Patent Strategy, Filing & IP Lifecycle in MedTech

Invention disclosure and Prior art search. Claim drafting for MedTech patents. Indian Patent Office vs. EPO and USPTO procedures. Patent opposition and revocation mechanisms. Filing strategies: National, PCT, and Direct Foreign Filing. Freedom-to-operate (FTO) analysis.
Case study: Abbott vs. J&J - Medtronic vs. Edwards Lifesciences

Module III (8 Hours): Technology Transfer, Licensing & Commercialization in MedTech

Licensing models: Exclusive, non-exclusive, cross-licensing. Licensing in digital MedTech and AI: Challenges in ownership and reusability. University-Industry IP transfer mechanisms. Role of Technology incubators and Accelerators (BIRAC, BioNEST) in Indian MedTech innovation. Valuation of MedTech IP assets - startups and incubated technologies

Case study: Stanford Biodesign, Sree Chitra (SCTIMST) tech transfer, OpenMRS

Module IV (8 Hours): Ethics in MedTech Innovation and IP

Ethics in patenting life-saving technologies. IP and global health equity (COVID-19, vaccines, AI diagnostics). Patenting dilemmas in AI-based MedTech (black-box algorithms, bias, explainability). Ethical frameworks: India (NITI Aayog), EU (Trustworthy AI), US (FDA's GMLP). Social responsibility in Biomedical IP**.**

Case Study: DeepMind & NHS (UK); Privacy and consent challenges in using hospital data for AI development in health.

Module V (8 Hours): IP Enforcement, Legal Risk, and Dispute Resolution in MedTech

IP litigation: Infringement types and enforcement (India, EU, US). Alternate Dispute Resolution (ADR) in IP (Arbitration/Mediation). Device design infringement vs. algorithmic IP violations. Medico-legal interface: Data rights, software copyright vs. patent, patient safety. Legal compliance risks in public health products.

Case Study: Masimo vs. Apple; Case on IP infringement involving health monitoring sensors

Course Plan

No	Topic	No. of Lectures
1	**Foundations of Intellectual Property in MedTech**	
1.1	Introduction to IPR: Types and relevance in MedTech (Patents, Copyrights, Trade Secrets)	2
1.2	Patentability criteria in biomedical innovations	1
1.3	Overview of global IP frameworks: Indian Patent Act, EPC, USPTO	2
1.4	Introduction to TRIPS and compulsory licensing	1
1.5	Case Study: *Bayer vs. Natco* – India's first compulsory license	1
2	**Patent Strategy, Filing & IP Lifecycle in MedTech**	
2.1	Invention disclosure and prior art search	2
2.2	Claim drafting for MedTech patents	1
2.3	Indian Patent Office vs. EPO and USPTO procedures	1
2.4	Patent opposition and revocation mechanisms	1
2.5	Filing strategies: National, PCT, and Direct Foreign Filing	1
2.6	Freedom-to-operate (FTO) analysis,	1
2.7	Case Study: *Abbott vs. J&J*, *Medtronic vs. Edwards Lifesciences*	1
3	**Technology Transfer, Licensing & Commercialization**	
3.1	Licensing models: Exclusive, non-exclusive, cross-licensing	2
3.2	Licensing in digital MedTech and AI: Challenges in ownership and reusability	1
3.3	University–industry IP transfer mechanisms	2
3.4	Role of incubators and accelerators (e.g., BIRAC, BioNEST) in India	1
3.5	Valuation of MedTech IP assets: Startups and incubated technologies	1
3.6	Case Study: *Stanford Biodesign*, *Sree Chitra SCTIMST*, *OpenMRS*	1
4	**Ethics in MedTech Innovation and IP**	
4.1	Ethics in patenting life-saving technologies	1
4.2	IP and global health equity: COVID-19, vaccines, AI diagnostics	2
4.3	Ethical dilemmas in AI-based MedTech (black-box, bias, explainability)	2
4.4	Ethical frameworks: India (NITI Aayog), EU (Trustworthy AI), US (FDA GMLP)	1
4.5	Social responsibility in biomedical IP	1

4.6	Case Study: *DeepMind & NHS* – Privacy and consent in hospital data for AI development	1
5	**IP Enforcement, Legal Risk & Dispute Resolution**	
5.1	IP litigation: Infringement types and enforcement (India, EU, US)	2
5.2	Alternate Dispute Resolution (ADR): Arbitration, Mediation, IP tribunals	2
5.3	Device design vs. algorithmic IP violations	1
5.4	Medico-legal interface: Data rights, copyright vs. patent, patient safety	1
5.5	Legal compliance risks in MedTech and public health products	1
5.6	**Case Study**: *Masimo vs. Apple* – Sensor technology infringement in wearable health devices	1

Reference Books

1. Reddy, G. B. (2023). Intellectual Property Rights and the Law (11th Reprint ed.). Gogia Law Agency. ISBN: 9788194227281.
2. Goldstein, P., & Trimble, M. (2023). International Intellectual Property Law: Cases and Materials (6th ed.). Foundation Press. ISBN: 9781685614348.
3. Palfrey, J. (2011). Intellectual Property Strategy. MIT Press. ISBN: 9780262516792.
4. Wallach, W., & Allen, C. (2010). Moral Machines: Teaching Robots Right from Wrong. Oxford University Press. ISBN: 9780199737970.

Government & Institutional resources:

1. Indian Patent Act
2. WIPO IP Handbook
3. USPTO MPEP
4. EU Intellectual Property Office
5. BIRAC Guidelines
6. NITI Aayog Responsible AI Report

INTERDISCIPLINARY ELECTIVES

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM051	MACHINE LEARNING FOR BIOMEDICAL ENGINEERS	INTERDISCIPLINARY ELECTIVE	3	0	0	3

Preamble: This course introduces the foundational concepts and practical implementations of machine learning in biomedical domains. Students will gain hands-on experience with medical datasets, classification techniques, signal/image analysis, and regulatory considerations, thereby equipping them to contribute to intelligent healthcare technologies and clinical decision support systems

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand the principles and core algorithms of machine learning relevant to biomedical data. **(Understand)**
CO 2	Analyze and preprocess various types of biomedical datasets (signals, images, clinical records). (**Analyze)**
CO 3	Design and evaluate ML models for classification, regression, and clustering in biomedical contexts. **(Apply / Evaluate)**
CO 4	Implement ML workflows using Python and apply them to real-world biomedical case studies. **(Apply)**
CO 5	Examine the ethical, regulatory, and validation aspects of deploying ML models in healthcare. **(Evaluate)**

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2	1	3	2	2	1	
CO 2	3	1	3	2	3	2	
CO 3	3	2	3	3	3	2	1

CO 4	**3**	**2**	**3**	**3**	**3**	**1**	**2**
CO 5	**2**	**2**	**2**	**2**	**2**	**3**	**1**

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyze	20

Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred) : 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no. : 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY	Name
	Register No:

FIRST SEMESTER M.TECH DEGREE EXAMINATION			
Course code	252EBM051	Course name	*MACHINE LEARNING FOR BIOMEDICAL ENGINEERS*
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Explain the differences between supervised and unsupervised learning. Provide examples of biomedical data types suitable for each and discuss one common biomedical dataset used in machine learning.	5
2	Describe the process of feature extraction from biomedical signals such as ECG. Why is dimensionality reduction important, and how does Principal Component Analysis (PCA) help in this context?	5
3	Compare and contrast Support Vector Machines (SVM) and Decision Trees as classification algorithms. Include their working principles and advantages in biomedical applications.	5
4	Explain the architecture of a Convolutional Neural Network (CNN) and discuss how CNNs are used for medical image classification.	5
5	Discuss the importance of explainable AI in healthcare. Explain two methods used for interpreting machine learning model decisions and their relevance in clinical settings.	5
	PART B (Answer any five questions.)	
6	Given a biomedical dataset (e.g., ECG signals), outline the steps you would take to prepare this data for a machine learning task. Highlight the importance of each step in the ML pipeline.	7

7	Evaluate the advantages and disadvantages of different feature selection techniques in biomedical applications. Recommend the best approach for high-dimensional gene expression data and justify your choice.	7
8	Design a classification model using Random Forest for a biomedical application such as cancer detection. Describe the process from training to evaluation.	7
9	Explain how transfer learning can be utilized to improve the performance of deep learning models in medical image classification when labeled data is limited.	7
10	Critically evaluate the limitations and ethical concerns of deploying deep learning models in clinical decision-making systems.	7
11	Analyze a biomedical machine learning case study (e.g., diabetic retinopathy detection) and identify the key factors that influenced the success or failure of the model in clinical practice.	7
12	Evaluate the impact of regulatory frameworks like FDA approval on the development and deployment of AI-based medical devices. How do these regulations affect innovation and patient safety?	7

Syllabus

Module 1 – Introduction to Machine Learning & Biomedical Data

Types of biomedical data (EEG, ECG, MRI, EMR, genomics); supervised vs. unsupervised learning; machine learning pipeline overview (problem definition to evaluation); biomedical data sources (MIMIC, PhysioNet, UCI); basics of Python programming; introduction to NumPy and Pandas libraries; using scikit-learn for ML modelling.

Module 2- Data Preprocessing & Feature Engineering

Data cleaning techniques (handling missing data, outliers, normalization); feature extraction from biomedical signals and images; feature selection and dimensionality reduction methods (PCA, t-SNE); signal preprocessing (filtering, windowing, resampling); data annotation and labeling best practices.

Module 3- Machine Learning Algorithms

Classification algorithms (k-NN, decision trees, SVM); regression models (linear, ridge, lasso regression); clustering techniques (k-means, DBSCAN, hierarchical clustering); model validation strategies (cross-validation, train-test split); evaluation metrics (accuracy, ROC, AUC, F1-score).

Module 4- Deep Learning for Biomedical Applications

Neural network basics (perceptron, multi-layer perceptron); convolutional neural networks (CNNs) for medical imaging; recurrent neural networks (RNNs, LSTMs) for time-series signals; transfer learning and pre-trained models (ResNet, VGG); model deployment tools (TensorFlow Lite, ONNX).

Module 5- Case Studies, Ethics & Regulatory Aspects

Biomedical ML case studies (diabetic retinopathy diagnosis, ECG classification); explainable AI techniques (SHAP, LIME); bias and fairness in healthcare ML; ethical considerations and regulatory standards (FDA, CE, IEC 62304); reproducibility and validation in clinical deployments.

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Machine Learning & Biomedical Data**	
1.1	Types of biomedical data (signals, images, text, genomics)	2
1.2	Supervised vs. Unsupervised learning	1
1.3	Overview of ML pipeline (problem definition to evaluation)	2
1.4	Biomedical data sources (e.g., MIMIC, PhysioNet, UCI)	1
1.5	Python basics, NumPy, Pandas introduction	2
1.6	scikit-learn: installing and using ML models	1
2	**Module 2- Data Preprocessing & Feature Engineering**	
2.1	Data cleaning (missing data, outliers, normalization)	2
2.2	Feature extraction from biosignals and images	2
2.3	Feature selection and dimensionality reduction (PCA, t-SNE)	2
2.4	Signal-specific preprocessing (filtering, windowing, resampling)	2

2.5	Data annotation and labeling best practices	1
3	**Module 3- Machine Learning Algorithms**	
3.1	Classification: k-NN, Decision Trees, SVM	3
3.2	Regression models: Linear, Ridge, Lasso	1.5
3.3	Clustering: k-means, DBSCAN, hierarchical	1.5
3.4	Model validation: cross-validation, train-test split	1.5
3.5	Evaluation metrics: accuracy, ROC, AUC, F1-score	1.5
4	**Module 4- Deep Learning for Biomedical Applications**	
4.1	Basics of neural networks (Perceptron, MLP)	2
4.2	Convolutional Neural Networks (CNNs) for medical imaging	2.5
4.3	Recurrent Neural Networks (RNNs, LSTMs) for signals	2
4.4	Transfer learning & pre-trained models (e.g., ResNet, VGG)	1.5
4.5	Model deployment basics (ONNX, TensorFlow Lite)	1
5	**Module 5- Case Studies, Ethics & Regulatory Aspects**	
5.1	Case study: Disease diagnosis using ML (e.g., diabetic retinopathy)	2
5.2	Case study: ECG classification or patient monitoring	2
5.3	Explainable AI (SHAP, LIME, interpretability in healthcare)	1
5.4	Bias and fairness in biomedical ML models	1
5.5	Ethical and regulatory standards (FDA, CE, IEC 62304 overview)	2
5.6	Reproducibility and validation in clinical settings	1
		45

Text Books

1. Kevin P. Murphy, Suchi Saria, *Machine Learning for Healthcare*, Cambridge University Press, 2021
2. Kayvan Najarian, Robert Splinter, *Biomedical Signal and Image Processing*, CRC Press, 2010

Reference Books

1. Andreas Holzinger, *Machine Learning for Health Informatics*, Springer, 2016
2. S. N. Srihari, *Biomedical Data Analysis and Visualization: Machine Learning Applications*, Wiley, 2020
3. John L. Semmlow, *Biosignal and Medical Image Processing*, CRC Press, 2014
4. Xiaohui Liang, *Deep Learning and Convolutional Neural Networks for Medical Imaging and Clinical Informatics*, Springer, 2020
5. Kevin B. Korb, Ann E. Nicholson, *Bayesian Artificial Intelligence*, CRC Press, 2010

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM052	IOT AND EMBEDDED SYSTEMS IN HEALTHCARE	INTERDISCIPLINARY ELECTIVE	3	0	0	3

Preamble: The integration of IoT and embedded systems is transforming modern healthcare through smart diagnostics, remote monitoring, and personalized treatment. Embedded systems power medical devices, while IoT ensures seamless connectivity and real-time data sharing. These technologies improve efficiency, accessibility, and patient outcomes across clinical and home settings. A foundational understanding of both fields is essential to innovate and implement next-generation healthcare solutions.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand the role of IoT and embedded systems in healthcare and explain the architecture and protocols. ***(Understand)***
CO 2	Analyze the design and integration of sensors and embedded devices for health monitoring applications***.(Analyze)***
CO 3	Apply AI/ML techniques on embedded platforms for health data interpretation***.(Apply)***
CO 4	Evaluate cloud computing and cybersecurity solutions for healthcare IoT systems. ***(Evaluate)***
CO 5	Design and discuss real-time smart healthcare applications using IoT and embedded platforms. ***(Create)***

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	2		3	2	2		
CO 2			3	3	3		
CO 3	3		3	3	3		
CO 4	3	2	3	3	3	3	
CO 5	3	3	3	3	3	3	2

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

TotalMarks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks
Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	**252EBM052**	Course name	**IoT and Embedded Systems in Healthcare**
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Explain the role of IoT in modern healthcare systems with suitable examples.	5
2	Describe any two biomedical sensors and their applications in health monitoring.	5
3	What is embedded machine learning? Mention its benefits in healthcare.	5
4	Briefly explain the role of blockchain in healthcare data security.	5
5	Write a short note on the use of augmented reality in medical education.	5
	PART B (Answer any five questions.)	
6	Compare various wireless communication technologies (Wi-Fi, BLE, Zigbee, 5G) used in IoT-based healthcare.	7
7	Discuss the architecture of an IoT-based remote patient monitoring system.	7
8	Explain real-time data acquisition and the role of edge devices with block diagrams.	7
9	How is signal conditioning performed in embedded health monitoring systems?	7
10	Explain how CNN can be used to detect cardiac anomalies using ECG	7

	data.	
11	Describe any two cybersecurity challenges and solutions in healthcare IoT systems.	7
12	Discuss a case study on AI-based diagnosis and its benefits in clinical decision-making.	7

Syllabus

Module 1 – Introduction to IoT and Embedded Systems in Healthcare (8 hours)

Overview of IoT in Healthcare: Scope, Benefits, and Challenges, Embedded System Basics: Architecture, Components, and Design Flow, Use Cases: Remote monitoring, wearable devices, smart beds, Role of Communication Technologies: Wi-Fi, BLE, ZigBee, and 5G

Module 2- Healthcare Sensors, Devices and Data Acquisition Systems (8 hours)

Biomedical Sensors and Wearables: ECG, temperature, SpO_2, motion sensors, Signal Conditioning and ADC Interfacing in Embedded Devices, Real-Time Data Acquisition and Transmission Protocols, Edge Devices for Health Monitoring: Raspberry Pi, Arduino, Jetson Nano

Module 3- Embedded Intelligence and Machine Learning in Healthcare Systems (8 hours)

Basics of Embedded AI: Concept and Deployment Strategies, Machine Learning for Health Data: Supervised vs Unsupervised Models, Deep Learning Applications: CNNs for ECG, EEG, X-ray analysis, Embedded ML Frameworks: TensorFlow Lite, Edge Impulse

Module 4- Cloud, Cybersecurity and Interoperability in Healthcare IoT (8 hours)

Cloud Computing for Healthcare IoT: Data Storage and Remote Access, Data Security and Privacy Issues: HIPAA, Blockchain for healthcare, Interoperability Standards: HL7, FHIR, DICOM, Threats and Countermeasures: Cyber-attacks, Authentication, Encryption

Module 5- Applications and Case Studies in Smart Healthcare Systems (8 hours)

Case Study 1: Smart ICU and Patient Monitoring Systems, Case Study 2: AI-based Diagnosis and Decision Support, Augmented and Virtual Reality for Medical Training, Future Trends: Digital Twins, Metaverse in Healthcare

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to IoT and Embedded Systems in Healthcare**	

1.1	Overview of IoT in Healthcare: Scope, Benefits, and Challenges	2
1.2	Embedded System Basics: Architecture, Components, and Design Flow	2
1.3	Use Cases: Remote monitoring, wearable devices, smart beds	2
1.4	Role of Communication Technologies: Wi-Fi, BLE, ZigBee, and 5G	2
2	**Module 2- Healthcare Sensors, Devices and Data Acquisition Systems**	
2.1	Biomedical Sensors and Wearables: ECG, temperature, SpO_2, motion sensors	2
2.2	Biomedical Sensors and Wearables: ECG, temperature, SpO_2, motion sensors	2
2.3	Real-Time Data Acquisition and Transmission Protocols	2
2.4	Edge Devices for Health Monitoring: Raspberry Pi, Arduino, Jetson Nano	2
3	**Module 3- Embedded Intelligence and Machine Learning in Healthcare Systems**	
3.1	Basics of Embedded AI: Concept and Deployment Strategies	2
3.2	Machine Learning for Health Data: Supervised vs Unsupervised Models	2
3.3	Deep Learning Applications: CNNs for ECG, EEG, X-ray analysis	2
3.4	Embedded ML Frameworks: TensorFlow Lite, Edge Impulse	2
4	**Module 4- Cloud, Cybersecurity and Interoperability in Healthcare IoT**	
4.1	Cloud Computing for Healthcare IoT: Data Storage and Remote Access	2
4.2	Data Security and Privacy Issues: HIPAA, Blockchain for healthcare	2
4.3	Interoperability Standards: HL7, FHIR, DICOM	2
4.4	Threats and Countermeasures: Cyber attacks, Authentication, Encryption	2
5	**Module 5- Applications and Case Studies in Smart Healthcare Systems**	
5.1	Case Study 1: Smart ICU and Patient Monitoring Systems	2
5.2	Case Study 2: AI-based Diagnosis and Decision Support	2
5.3	Augmented and Virtual Reality for Medical Training	2
5.4	Future Trends: Digital Twins, Metaverse in Healthcare	2
		40 Hrs

Text Book

1. Yatindra Kumar, Shahi Kant Verma, Manish Kumar Jha, *IoT-Enabled Healthcare Systems: Applications, Benefits and Challenges*, CRC Press, 2022.
2. Adesh Kumar, Surajit Mondal, *Embedded Devices and Internet of Things: Technology, Applications and Security*, Springer, 2022.
3. Preeti Nagrath, Jafar Alzubi, *Smart Distributed Embedded Systems for Healthcare Applications*, CRC Press, 2021.

Reference Books

1. Raj Kamal, *Internet of Things: Architecture and Design Principles*, McGraw Hill Education, 2017.
2. Raj Kamal, *Embedded Systems: Architecture, Programming and Design*,McGraw Hill Education, 3rd Edition, 2021.
3. Parul Agarwal, Rajiv Pandey, *AI and IoT in Healthcare: A Practical Perspective*, CRC Press, 2021.
4. Himanshu Singh, *Machine Learning for Healthcare Applications*, Wiley India, 2021.
5. Bhavani Thuraisingham, *Cybersecurity in IoT-enabled Healthcare Systems*, CRC Press, 2020.

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM053	CLINICAL DATA ANALYTICS	INTERDISCIPLINARY ELECTIVE	3	0	0	3

Preamble: This course introduces key concepts in clinical data types, management, and preprocessing, along with statistical analysis and machine learning techniques for healthcare. It covers emerging AI applications, data privacy, and real-time clinical analytics to support effective decision-making and improve patient outcomes.

Course Outcomes: After the completion of the course the student will be able to

CO 1	**CO1**: Analyze the fundamental principles and working mechanisms of different types of sensors used in biomedical and industrial applications. ***(Cognitive Knowledge Level: Analyze)***
CO 2	**CO2**: Apply various design parameters such as sensitivity, range, resolution, and response time in developing sensors for industrial and biomedical classification. ***(Cognitive Knowledge Level: Apply)***
CO 3	**CO3**: Evaluate sensor standards, calibration techniques, and testing methodologies for ensuring accuracy, repeatability, and reliability in real-time measurements. ***(Cognitive Knowledge Level: Evaluate)***
CO 4	**CO4**: Analyze the role of MEMS technology in miniaturization, integration, and enhancement of sensor performance in advanced applications. ***(Cognitive Knowledge Level: Analyze)***
CO 5	**CO5**: Create application-specific sensor qualification strategies by performing failure mode analysis, reliability testing, and standard conformance checks. ***(Cognitive Knowledge Level: Create)***

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	**3**		**2**		**2**		
CO 2			**2**	**3**	**3**		
CO 3	**2**			**3**	**3**		
CO 4	**3**		**2**		**2**		
CO 5	**3**		**3**	**3**	**3**	**2**	**2**

Programme Outcomes

PO#	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state-of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to develop cognitive load management skills related to project management and finance which focus on Entrepreneurship and Industry relevance.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	10
Create	10

Mark distribution

Total Marks	CIE	ESE	ESE -Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred) : 15 marks
Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no. : 10 marks.
Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY FIRST SEMESTER M.TECH DEGREE EXAMINATION			Name Register No:
Course code	252EBM053	Course name	*CLINICAL DATA ANALYTICS*
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Compare and contrast structured and unstructured clinical data with examples.	5
2	Explain data normalization and its importance in machine learning applications in healthcare.	5
3	How is ANOVA used in comparing treatment effectiveness across multiple groups?	5
4	Discuss the role of SVM in binary classification of clinical datasets.	5

5	What is federated learning and how does it ensure patient data privacy?	5
	PART B (Answer any five questions.)	
6	Discuss the major healthcare data standards (such as HL7, FHIR, DICOM). How do they ensure seamless data exchange across hospital information systems?	7
7	Explain the steps involved in preprocessing clinical data for machine learning. Include examples of missing value handling, outlier detection, and feature scaling.	
8	Explain the role of logistic regression in disease prediction models. Illustrate its application with an example relevant to biomedical data.	7
9	Explain the structure and components of a Hospital Information System (HIS). How do systems like EHR, LIS, and RIS integrate within HIS to improve clinical workflow and patient care?	7
10	What are digital twins in healthcare? Discuss their architecture, implementation, and role in patient-specific clinical simulation.	7
11	Explain the concepts of sensitivity, specificity, precision, and recall in the context of clinical data classification. Illustrate with an example from a diagnostic test scenario.	7
12	Describe the role of data visualization in clinical analytics. How can tools like Python's Matplotlib or Seaborn be used to identify trends and patterns in patient data? Provide suitable examples.	7

Syllabus

Module 1 – Introduction to Clinical Data and Healthcare Information Systems

Overview of Clinical Data Types: EHR, EMR, PACS, LIS, RIS, Wearable and Biosignal Data, Structured vs. Unstructured Clinical Data, Healthcare Information Systems (HIS) and Interoperability Standards: HL7, FHIR, Medical Coding Systems: ICD-10, SNOMED CT, LOINC, CPT, Data Quality, Integrity, and Use of Open Clinical Databases: MIMIC-IV, PhysioNet.

Module 2- Clinical Data Management and Preprocessing Techniques

Data Cleaning and Transformation: Handling Missing Values, Noise, Outliers, Feature Extraction and Dimensionality Reduction: PCA, t-SNE, Auto encoders, Data Normalization and Encoding Techniques for Categorical Data, Ethical and Legal Aspects: Data Anonymization, HIPAA/GDPR Compliance, Clinical Data Management Platforms: REDCap, OMOP CDM, i2b2

Module 3- Statistical Analysis and Visualization for Clinical Decision Support

Descriptive Statistics: Mean, Median, Mode, Standard Deviation, Inferential Statistics: t-tests, Chi-square tests, ANOVA, Correlation and Regression, Survival Analysis: Kaplan-Meier Estimator, Hazard Functions, Clinical Performance Metrics: Sensitivity, Specificity, Accuracy, Precision, F1-score, Data Visualization Tools: Python (Matplotlib, Seaborn) and Tableau.

Module 4- Predictive Modeling and Machine Learning in Healthcare

Introduction to Supervised Learning: Logistic Regression, Decision Trees, Random Forest, SVM, Unsupervised Learning Techniques: Clustering (k-means, Hierarchical), Model Validation and Evaluation: Train-Test Split, Cross-validation, ROC Curves, Confusion Matrix, Explainability and Bias in Clinical Models: LIME, SHAP, Case Studies: Predicting Readmission, Sepsis, Diabetic Retinopathy Screening.

Module 5- Clinical Applications and Emerging Trends in AI and Big Data

Real-time Hospital Analytics: Patient Flow, ICU Triage, ED Optimization, Natural Language Processing (NLP) in Clinical Notes and Radiology Reports, AI in Medical Imaging and Digital Pathology, Federated Learning and Multi-institutional Data Analysis, Integration with IoT and Wearable Health Devices, Cloud Platforms and Emerging Technologies: AWS Health Lake, Google Cloud Healthcare, Digital Twins

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Clinical Data and Healthcare Information Systems**	
1.1	Overview of Clinical Data Types: EHR, EMR, PACS, LIS, RIS, Wearable and Biosignal Data	2
1.2	Structured vs. Unstructured Clinical Data.	1
1.3	Healthcare Information Systems (HIS) and Interoperability Standards: HL7, FHIR	2
1.4	Medical Coding Systems: ICD-10, SNOMED CT, LOINC, CPT	2
1.5	Data Quality, Integrity, and Use of Open Clinical Databases: MIMIC-IV, PhysioNet	1
2	**Module 2- Clinical Data Management and Preprocessing Techniques**	
2.1	Data Cleaning and Transformation: Handling Missing Values, Noise, Outliers	3
2.2	Feature Extraction and Dimensionality Reduction: PCA, t-SNE, Autoencoders	2
2.3	Data Normalization and Encoding Techniques for Categorical Data	1
2.4	Ethical and Legal Aspects: Data Anonymization, HIPAA/GDPR Compliance	1
2.5	Clinical Data Management Platforms: REDCap, OMOP CDM, i2b2	1
3	**Module 3- Statistical Analysis and Visualization for Clinical Decision Support**	
3.1	Descriptive Statistics: Mean, Median, Mode, Standard Deviation	1
3.2	Inferential Statistics: t-tests, Chi-square tests, ANOVA, Correlation and Regression	3
3.3	Survival Analysis: Kaplan-Meier Estimator, Hazard Functions	1

3.4	Clinical Performance Metrics: Sensitivity, Specificity, Accuracy, Precision, F1-score	1
3.5	Data Visualization Tools: Python (Matplotlib, Seaborn) and Tableau	2
4	**Module 4- Predictive Modeling and Machine Learning in Healthcare**	
4.1	Introduction to Supervised Learning: Logistic Regression, Decision Trees, Random Forest, SVM	3
4.2	Unsupervised Learning Techniques: Clustering (k-means, Hierarchical), PCA	2
4.3	Model Validation and Evaluation: Train-Test Split, Cross-validation, ROC Curves, Confusion Matrix	1
4.4	Explainability and Bias in Clinical Models: LIME, SHAP	1
4.5	Case Studies: Predicting Readmission, Sepsis, Diabetic Retinopathy Screening	1
5	**Module 5- Clinical Applications and Emerging Trends in AI and Big Data**	
5.1	Real-time Hospital Analytics: Patient Flow, ICU Triage, ED Optimization	2
5.2	Natural Language Processing (NLP) in Clinical Notes and Radiology Reports.	1.5
5.3	AI in Medical Imaging and Digital Pathology	1.5
5.4	Federated Learning and Multi-institutional Data Analysis	1
5.5	Integration with IoT and Wearable Health Devices	1
5.6	Cloud Platforms and Emerging Technologies: AWS HealthLake, Google Cloud Healthcare, Digital Twins	1

Text Book

1. Chandan K. Reddy and Charu C. Aggarwal, *Healthcare Data Analytics*, CRC Press, 2015.
2. Ramesh Sharda, Dursun Delen, Efraim Turban, *Analytics, Data Science, & Artificial Intelligence: Systems for Decision Support*, Pearson Education, 2020.
3. Amit Kumar Tyagi, *Big Data Analytics for Intelligent Healthcare Management*, Springer India, 2022.

Reference Books

1. Edward H. Shortliffe and James J. Cimino, *Biomedical Informatics: Computer Applications in Health Care and Biomedicine*, Springer, 4th Edition, 2014.
2. Enrico Coiera, *Guide to Health Informatics*, CRC Press, 4th Edition, 2021.
3. Hui Yang and Eva K. Lee, *Healthcare Analytics: From Data to Knowledge to Healthcare Improvement*, Wiley, 2016.
4. Peter Szolovits, *Artificial Intelligence in Medicine*, MIT Press, 2019.

5. Dean F. Sittig, *Clinical Information Systems: Overcoming Adverse Consequences*, CRC Press, 2019.
6.

INDUSTRY ELECTIVES

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM051	BIOMEDICAL DATA ANALYTICS AND MACHINE LEARNING	INDUSTRY\ INTERDISCIPLINARY ELECTIVES	3	0	0	3

Preamble:

The course *Biomedical Data Analytics and Machine Learning* equips students with foundational and applied expertise in statistical methods, data preprocessing, and computational modelling tailored for biomedical engineering. It emphasizes the integration of data science principles, machine learning algorithms, and domain-specific biomedical knowledge to analyze and interpret complex health data. The curriculum highlights practical implementation using real-world biomedical datasets, advanced machine learning and deep learning approaches, and the ethical and regulatory frameworks guiding clinical adoption.

Course Outcomes:

After the completion of the course the student will be able to

CO 1	Explain fundamental statistical concepts and hypothesis testing methods relevant to biomedical data analysis.
CO 2	Identify and preprocess diverse biomedical data types, applying appropriate data cleaning, integration, and visualization techniques.
CO 3	Apply supervised machine learning algorithms to biomedical datasets and evaluate model performance using clinically meaningful metrics.
CO 4	Design and implement advanced machine learning and deep learning models for complex biomedical data, including imaging and sequential data.
CO 5	Analyze ethical, legal, and regulatory considerations in biomedical data analytics, emphasizing patient privacy, bias mitigation, and clinical translation.

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3	2	3			3	
CO 2	3	2	3	2	3		
CO 3	3	2	3		2		
CO 4	2		2	2	3	3	
CO 5	2		2	2	3	3	2

Assessment Pattern:

Bloom's Category	End Semester Examination
Apply	20
Analyse	20
Evaluate	20
Create	

Mark distribution:

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern (40 Marks):

- Evaluation shall only be based on application, analysis or design-based questions.

Evaluation Method	Marks
Micro project/Course based project	20 Marks
Course based task/Seminar/Quiz	10 Marks
Test paper, 1 no (Test paper shall include minimum 80% of the syllabus)	10 Marks
Total	40 Marks

- All COs must be assessed by using at least one assessment method of Continuous Internal Evaluation.

End Semester Examination Pattern (60 Marks):

- The end semester examination will be consisting of two parts; Part A and Part B.
- Part A contain 5 numerical questions (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the

students), with 1 question from each module, having 5 marks for each question. Students shall answer all questions.

- Part B contains 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student shall answer any five. Each question can carry 7 marks.
- Total duration of the examination will be 150 minutes.

Model Question paper:

Course Code: 252TBM100

Course Name: MEDICAL IMAGING SYSTEMS

Max. Marks: 60 **Duration: 2.5 Hours**

PART A

Answer all Questions. Each question carries 5 Marks

1. A clinical trial is conducted to test the efficacy of a new drug. The control group has a mean recovery time of 14 days (SD = 3 days, n = 40), and the treatment group has a mean recovery time of 12 days (SD = 2.5 days, n = 40). Perform a hypothesis test at a 5% significance level to determine if the new drug significantly reduces recovery time. Show all steps and calculations.
2. Given a dataset containing missing values, outliers, and mixed data types (numerical, categorical, image), outline a step-by-step preprocessing pipeline to prepare this data for machine learning analysis in a biomedical context.
3. You are given a biomedical dataset with patient features and disease outcome (binary). Describe how you would select features and evaluate the performance of a logistic regression model on this dataset. Include the metrics you would use and why.
4. A hospital wants to implement a deep learning model for automated detection of tumour in MRI images. List the key steps involved in developing and validating a convolutional neural network (CNN) for this application.
5. Discuss the ethical and regulatory considerations involved in deploying a machine learning model that predicts patient risk for a genetic disorder using electronic health record (EHR) data.

PART B

Answer any five Questions. Each question carries 7 Marks

6. A researcher is analyzing gene expression data from two groups: healthy and diseased. Explain how you would use statistical methods to identify genes that are significantly differentially expressed between the groups. Illustrate with a suitable example.
7. Case Study: You receive a multi-institutional biomedical dataset with inconsistent data formats, missing demographic information, and variable measurement units. Describe your approach to data integration and harmonization to ensure reliable downstream analysis.
8. Problem: A machine learning model for early sepsis detection in ICU patients is showing high accuracy but poor recall. Analyze possible reasons and suggest strategies to improve recall without sacrificing overall model reliability.
9. Case Study: You are tasked with developing a deep learning model for predicting patient survival based on time-series physiological data (e.g., heart rate, blood pressure). Discuss the choice of model architecture, data preprocessing, and evaluation metrics for this problem.
10. A company plans to commercialize an AI-powered diagnostic tool for diabetic retinopathy screening. Outline the regulatory pathway, including clinical validation and ethical considerations, required for this product to be adopted in clinical practice.
11. Given a biomedical dataset with highly imbalanced classes (rare disease detection), design an approach to handle the imbalance during model training and evaluation. Discuss the pros and cons of at least two techniques?
12. You are asked to present the results of a large-scale genomic study to a team of clinicians. Describe how you would use data visualization and summary statistics to communicate key findings effectively to a non-technical audience?

Syllabus

Module I (8 Hours): Foundations of Biomedical Statistics and Data Science

Introduction to probability theory and statistical distributions in biomedical research. Hypothesis testing, p-values, and confidence intervals for clinical data interpretation. Regression analysis (linear, logistic) with biomedical datasets. Introduction to Bayesian statistics in medical diagnostics. Experimental design and statistical power in clinical and laboratory studies. Fundamentals of statistical programming in R and Python for biomedical applications.

Module II (8 Hours): Biomedical Data Types and Pre-processing

Overview of biomedical data types: genomic, imaging, clinical, and physiological signals. Data acquisition methods and challenges in biomedical informatics. Data cleaning, normalization, and transformation techniques for heterogeneous biomedical datasets. Handling missing, imbalanced, and noisy data in clinical and research settings. Data integration and harmonization across multi-modal biomedical sources. Visualization and exploratory data analysis for biomedical datasets.

Module III (8 Hours): Machine Learning Fundamentals for Biomedical Applications

Supervised learning: linear and logistic regression, decision trees, and ensemble methods for biomedical prediction. Model evaluation metrics: accuracy, sensitivity, specificity, ROC curves, and AUC in clinical context. Cross-validation, overfitting, and bias assessment in biomedical machine learning. Feature selection and dimensionality reduction techniques for high-dimensional biomedical data. Practical implementation of machine learning algorithms using real-world biomedical datasets.

Module IV (8 Hours): Advanced Machine Learning and Deep Learning in Biomedicine

Deep learning architectures: convolutional neural networks (CNNs) for medical imaging, recurrent neural networks (RNNs) for sequential biomedical data. Transformer models and their applications in genomics and medical text analysis. Unsupervised learning: clustering and dimensionality reduction for pattern discovery in biomedical data. Transfer learning, federated learning, and reinforcement learning in biomedical research. Scalability and computational considerations for large-scale biomedical machine learning.

Module V (8 Hours): Ethics, Regulation, and Clinical Implementation

Ethical principles and challenges in biomedical data analytics and AI. Patient privacy, data protection, and HIPAA compliance in medical data science. Bias detection, fairness, and equity in biomedical machine learning applications. Regulatory frameworks: FDA approval and clinical validation of AI-based medical devices. Case studies on successful and failed clinical implementations of biomedical AI.

Course Plan

No	Topic	No. of Lectures
1	**Foundations of Biomedical Statistics and Data Science**	
1.1	Introduction to Biomedical Data Science: Scope and Applications	1
1.2	Probability Theory and Statistical Distributions in Biomedicine	1
1.3	Hypothesis Testing and Confidence Intervals in Clinical Research	1
1.4	Regression Analysis: Linear and Logistic Models	1
1.5	Bayesian Statistics in Medical Diagnostics	1
1.6	Experimental Design and Statistical Power in Biomedical Studies	1
1.7	Introduction to Statistical Programming (R/Python)	1
1.8	Case Study: Statistical Analysis of a Biomedical Dataset	1
2	**Biomedical Data Types and Preprocessing**	
2.1	Overview of Biomedical Data Types: Genomic, Imaging, Clinical, Physiological	1
2.2	Data Acquisition Methods in Biomedical Research	1
2.3	Data Cleaning: Handling Missing Values and Outliers	1
2.4	Data Normalization and Transformation Techniques	1
2.5	Data Integration and Harmonization across Modalities	1
2.6	Exploratory Data Analysis and Visualization	1

2.7	Preprocessing for High-Dimensional Data (e.g., Genomics)	1
2.8	Case Study: Preprocessing a Multi-modal Biomedical Dataset	1
3	**Machine Learning Fundamentals for Biomedical Applications**	
3.1	Supervised Learning: Concepts and Biomedical Use Cases	1
3.2	Regression and Classification Algorithms (Logistic Regression, Decision Trees)	1
3.3	Ensemble Methods and Their Biomedical Applications	1
3.4	Model Evaluation: Accuracy, Sensitivity, Specificity, ROC, AUC	1
3.5	Cross-Validation and Avoiding Overfitting	1
3.6	Feature Selection and Dimensionality Reduction	1
3.7	Hands-on: Building and Evaluating a Model on Biomedical Data	1
3.8	Case Study: Machine Learning for Disease Prediction	1
4	**Advanced Machine Learning and Deep Learning in Biomedicine**	
4.1	Introduction to Deep Learning: Neural Networks Basics	1
4.2	Convolutional Neural Networks (CNNs) for Medical Imaging	1
4.3	Recurrent Neural Networks (RNNs) and Sequential Data Analysis	1
4.4	Transformer Models in Genomics and Medical Text	1
4.5	Unsupervised Learning: Clustering and Dimensionality Reduction	1
4.6	Transfer Learning and Federated Learning in Healthcare	1
4.7	Model Scalability and Computational Considerations	1
4.8	Case Study: Deep Learning for Biomedical Image Segmentation	1
5	**Ethics, Regulation, and Clinical Implementation**	
5.1	Ethical Principles in Biomedical Data Science	1
5.2	Patient Privacy, Data Protection, and HIPAA Compliance	1
5.3	Bias Detection and Mitigation in Medical AI	1
5.4	Regulatory Frameworks: FDA Approval, Clinical Validation	1
5.5	Data Governance and Security in Healthcare	1
5.6	Societal Impact and Health Equity in AI Deployment	1
5.7	Case Study: Clinical Implementation of an AI Tool	1
5.8	Professional Responsibility and Future Trends	1

Reference Books

1. Holmes, S., & Huber, W. (2023). Modern Statistics for Modern Biology (2nd ed.). Cambridge University Press.
2. Vittinghoff, E., Glidden, D. V., Shiboski, S. C., & McCulloch, C. E. (2022). Regression Methods in Biostatistics: Linear, Logistic, Survival, and Repeated Measures Models (3rd ed.). Springer.
3. Biehl, R. E. (2021). Data Warehousing for Biomedical Informatics: Modern Approaches to Data Engineering. Academic Press.

4. Dinov, I. D. (2023). Data Science and Predictive Analytics: Biomedical and Health Applications using R (2nd ed.). Springer.
5. Malley, J. D., Malley, K. G., & Pajevic, S. (2022). Statistical Learning for Biomedical Data: Machine Learning Applications in Medicine and Biology. CRC Press.
6. Al-Jabery, K., Obafemi-Ajayi, T., Olbricht, G., & Wunsch, D. (2024). Computational Learning Approaches to Data Analytics in Biomedical Applications (2nd ed.). Academic Press.
7. Nylen, E. L., & Wallisch, P. (2023). Neural Data Science: A Primer with MATLAB and Python (2nd ed.). Academic Press.
8. Kramer, M., & Eden, U. (2024). Case Studies in Neural Data Analysis: Modern Techniques for Brain Signal Processing. MIT Press.
9. Char, D. S., Shah, N. H., & Magnus, D. (2023). Ethics in Medical AI: Principles, Practices, and Implementation. MIT Press.
10. Rajkomar, A., Hardt, M., Howell, M. D., Corrado, G., & Chin, M. H. (2022). Ensuring Fairness in Machine Learning to Advance Health Equity. Nature Medicine Press.

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM052	TISSUE ENGINEERING AND BIOMATERIALS AND INDUSTRY APPLICATIONS	INDUSTRY\ INTERDISCIPLINARY ELECTIVES	3	0	0	3

Preamble: This course introduces students to the fundamental concepts of tissue engineering and biomaterials with a strong emphasis on their translation to clinical and industrial applications. The course integrates materials science, cell biology, and biomedical engineering principles to design and develop biological substitutes that restore, maintain, or improve tissue function. Through hands-on case studies, students explore the commercialization and regulatory landscape of biomaterial-based products.

Pre-requisites: Basic knowledge of cell biology, biomaterials, biomedical engineering, and biochemistry

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand the principles of tissue engineering and biomaterials selection biological applications. **(Understand)**
CO 2	Evaluate the interactions between cells and materials, including immune responses and biocompatibility. **(Analyze)**
CO 3	Analyze various scaffolding techniques, surface modifications, and their functional roles. **(Analyze)**
CO 4	Demonstrate knowledge of clinical translation, regulatory compliance, and industrial scalability. **(Application)**
CO 5	Design application-driven tissue engineering strategies for specific organs or pathologies. **(Create)**

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3		2	2	2	1	1

CO 2	3	3	2	2	2	2	1
CO 3	3	3	2	2	3	2	1
CO 4	3	3	3	3	3	3	2
CO 5	3	3	3	3	3	2	2

Programme Outcomes

PO's	PO
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to integrate biomedical engineering principles with clinical and industrial needs to develop translational solutions and innovate for healthcare advancement.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	20
Analyze	20
Evaluate	10
Understand	10

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks

Course based task/Seminar/Data collection and interpretation: 15 marks
Test paper, 1 no.: 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

The end semester examination will be conducted by the respective College. There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations, problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

APJ ABDUL KALAM TECHNOLOGICAL UNIVERSITY **FIRST SEMESTER M. TECH DEGREE EXAMINATION**			Name Register No:
Course code	252EBM052	Course name	Tissue Engineering and Biomaterials and Industry Applications
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	List key properties required for biomaterials used in tissue engineering.	5
2	What are the stages of host response to implanted materials?	5
3	Compare electrospinning and solvent casting in scaffold fabrication.	5
4	Define GMP and explain its role in biomaterials manufacturing.	5
5	Discuss a recent trend in organ-on-chip technologies.	5
	PART B (Answer any five questions.)	
6	Discuss how biomaterial characteristics affect cell behavior and provide two examples.	7
7	Design a scaffold-based approach for peripheral nerve regeneration.	7
8	Describe the regulatory challenges faced during clinical translation of tissue-engineered products.	7
9	Explain strategies for surface modification to improve cell-material interaction.	7
10	Analyze the pros and cons of using smart biomaterials in soft tissue engineering.	7
11	Explain bioprinting technology and its role in personalized implants.	7

12	Propose a commercialization strategy for a scaffold-based product for bone regeneration.	7

Syllabus

Module 1 – Introduction to Tissue Engineering and Biomaterials

Fundamentals of tissue engineering. Structure and function of native tissues. Basic components: cells, scaffolds, and bioreactors. Classification of biomaterials: polymers, ceramics, metals, composites. Requirements for biomaterials in tissue engineering: biocompatibility, biodegradability, mechanical properties.

Practical: Review of material properties and cell compatibility from published literature.

Module 2 – Biomaterial-Cell Interactions

Protein adsorption and cell adhesion mechanisms. Surface properties affecting interactions. In vitro assessment of cytotoxicity, cell proliferation, and differentiation. Host response: inflammation, immune response, fibrosis. Strategies for surface modification and functionalization.

Practical: Simulated evaluation of in vitro biocompatibility metrics

Module 3 – Scaffold Fabrication Techniques

Fabrication techniques: electrospinning, solvent casting, gas foaming, freeze drying, 3D printing. Scaffold architecture and design parameters. Smart materials and stimuli-responsive scaffolds. Applications: bone, cartilage, nerve, skin. Degradation kinetics and mechanical performance.

Practical: Design of scaffold models and assessment criteria.

Module 4 – Clinical Translation and Regulatory Aspects

Pathway from bench to bedside. Clinical trials and ISO standards for biomaterials. Regulatory bodies: FDA, EMA. Good Manufacturing Practice (GMP). Ethical and societal implications. Case studies of successful translation of tissue-engineered products.

Practical: Case analysis of a clinically approved tissue product.

Module 5 – Industry Applications and Trends

Bioprinting and organ-on-chip technologies. Application in drug screening and disease modeling. Commercialization strategies, IP protection, market analysis. Industry challenges: scalability, cost, reproducibility. Emerging trends in regenerative medicine and personalized implants.

Practical: Project proposal development for a tissue-engineering-based startup id

Course Plan

No	Topic	No. of Lectures
1	**Module 1 – Introduction to Tissue Engineering and Biomaterials**	
1.1	Fundamentals of tissue engineering. Structure and function of native tissues	2
1.2	Basic components: cells, scaffolds, and bioreactors.	2
1.3	Classification of biomaterials: polymers, ceramics, metals, composites.	2
1.4	Requirements for biomaterials in tissue engineering: biocompatibility, biodegradability, mechanical properties.	1
1.5	Practical: Review of material properties and cell compatibility from published literature.	1
2	**Module 2 – Biomaterial-Cell Interactions**	
2.1	Protein adsorption and cell adhesion mechanisms.	2
2.2	Surface properties affecting interactions. In vitro assessment of cytotoxicity, cell proliferation, and differentiation.	2
2.3	Host response: inflammation, immune response, fibrosis.	2
2.4	Strategies for surface modification and functionalization.	1
2.5	Practical: Simulated evaluation of in vitro biocompatibility metrics	1
3	**Module 3 – Scaffold Fabrication Techniques**	
3.1	Fabrication techniques: electrospinning, solvent casting, gas foaming, freeze drying, 3D printing.	2
3.2	Scaffold architecture and design parameters. Smart materials and stimuli-responsive scaffolds	2
3.3	Applications: bone, cartilage, nerve, skin. Degradation kinetics and mechanical performance.	2

3.4	Practical: Design of scaffold models and assessment criteria	2

4	**Module 4- Clinical Translation and Regulatory Aspects**	
4.1	Pathway from bench to bedside. Clinical trials and ISO standards for biomaterials	2
4.2	Regulatory bodies: FDA, EMA. Good Manufacturing Practice (GMP)	2
4.3	Ethical and societal implications. Case studies of successful translation of tissue-engineered products.	2
4.4	Practical: Case analysis of a clinically approved tissue product.	2
5	**Module 5- Industry Applications and Trends**	
5.1	Bioprinting and organ-on-chip technologies. Application in drug screening and disease modeling.	2
5.2	Commercialization strategies, IP protection, market analysis. Industry challenges: scalability, cost, reproducibility.	2
5.3	Emerging trends in regenerative medicine and personalized implants.	2
5.4	Practical: Project proposal development for a tissue-engineering-based startup idea.	2
		40

Text Book

1. Lanza, R., Langer, R., & Vacanti, J. (Eds.). (2020). Principles of Tissue Engineering. Academic Press.

Reference Books

2. Ratner, B. D., Hoffman, A. S., Schoen, F. J., & Lemons, J. E. (Eds.). (2012). Biomaterials Science: An Introduction to Materials in Medicine. Academic Press.
3. Temenoff, J. S., & Mikos, A. G. (2008). Biomaterials: The Intersection of Biology and Materials Science. Pearson.
4. Research papers from journals such as Tissue Engineering, Acta Biomaterial, and Advanced Healthcare Materials

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252EBM053	HEALTHCARE TECHNOLOGY INNOVATION AND ENTREPRENEURSHIP	INDUSTRY\ INTERDISCIPLINARY ELECTIVES	3	0	0	3

Preamble: This course, Healthcare Technology Innovation and Entrepreneurship, equips learners with the knowledge and skills to identify, design, and develop impactful innovations in the healthcare sector. It integrates key concepts from innovation theory, clinical immersion, design thinking, regulatory and ethical alignment, intellectual property, funding strategies, valuation, and go-to-market planning. Through a structured, case-based learning approach, learners will apply theory to real-world scenarios, preparing them to navigate the complexities of medtech entrepreneurship and contribute effectively to the healthcare innovation ecosystem.

Pre-requisites: Basic biomedical engineering knowledge, medical device design, clinical workflows, and introductory regulatory awareness.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Explain healthcare innovation and entrepreneurship concepts. **(Understand)**
CO 2	Illustrate clinical immersion and design thinking methods. **(Apply)**
CO 3	Analyze regulatory, ethical, and business model alignment. **(Analyze)**
CO 4	Apply funding, IP, valuation, and market entry strategies. (**Apply)**
CO 5	Evaluate scale-up and sustainability in global health innovation. **(Evaluate)**

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3	2	3	2	1	2	3

CO 2	2	2	3	3	3	3	3
CO 3	2	3	3	3	2	3	3
CO 4	3	3	3	3	3	2	2
CO 5	2	2	3	3	2	3	3

Programme Outcomes

PO's	**PO**
PO 1	An ability to independently carry out research/investigation and development work in engineering and allied streams
PO 2	An ability to communicate effectively, write and present technical reports on complex engineering activities by interacting with the engineering fraternity and with society at large.
PO 3	An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor's program
PO 4	An ability to apply stream knowledge to design or develop solutions for real-world problems by following the standards
PO 5	An ability to identify, select and apply appropriate techniques, resources and state- of-the-art tools to model, analyze and solve practical engineering problems.
PO 6	An ability to engage in lifelong learning for the design and development related to the stream-related problems taking into consideration sustainability, societal, ethical and environmental aspects
PO 7	An ability to integrate biomedical engineering principles with clinical and industrial needs to develop translational solutions and innovate for healthcare advancement.

Assessment Pattern

Bloom's Category	End Semester Examination
Apply	24
Analyze	26
Evaluate	12
Understand	12

Mark distribution

Total Marks	CIE	ESE	ESE Duration
100	40	60	2.5 hours

Continuous Internal Evaluation Pattern: 40 Marks

Preparing a review article based on peer reviewed original publications (minimum 10 publications shall be referred): 15 marks

Course based task/Seminar/Case Study/Data collection and interpretation:
15 marks Test paper, 1 no.: 10 marks.

Test paper shall include minimum 80% of the syllabus.

End Semester Examination Pattern:60 Marks

There will be two parts; Part A and Part B. Part A will contain 5 numerical/short answer questions with 1 question from each module, having 5 marks for each question (such questions shall be useful in the testing of knowledge, skills, comprehension, application, analysis, synthesis, evaluation and understanding of the students). Students should answer all questions. Part B will contain 7 questions (such questions shall be useful in the testing of overall achievement and maturity of the students in a course, through long answer questions relating to theoretical/practical knowledge, derivations,

problem solving and quantitative evaluation), with minimum one question from each module of which student should answer any five. Each question can carry 7 marks.

Model Question paper

ABDUL KALAM TECHNOLOGICAL UNIVERSITY **FIRST SEMESTER M. TECH DEGREE EXAMINATION**			Name Register No:
Course code	252EBM053	Course name	Healthcare Technology Innovation and Entrepreneurship
Max. Marks	60	Duration	2.5 Hour

	PART A (Answer ALL questions)	
1	Define and differentiate between incremental and radical innovation in healthcare with relevant examples.	5
2	Describe a clinical immersion technique you would use to identify unmet needs in a hospital setting and explain how you would validate those needs.	5
3	Analyze how aligning design inputs with regulatory compliance can influence the development timeline of a medical device.	5
4	Outline the key components of a pitch deck tailored for a seed funding round for a healthcare startup.	5
5	Evaluate the key challenges in scaling up a healthcare innovation based on WHO's Nine Steps to Scaling-Up framework.	5
	PART B (Answer any five questions.)	
6	Discuss the role of the quadruple helix innovation ecosystem in healthcare and how it influenced the success of GE Healthcare's Vscan.	7

7	Apply design thinking steps to propose a solution for a common clinical problem identified during immersion. Highlight how user personas and journey mapping aid the process.	7
8	Critically assess how aligning design inputs with regulatory frameworks and ethical guidelines affects product development and clinical trial success.	7
9	Analyze how intellectual property management and funding strategies influenced the growth and valuation of Medtronic MiniMed's insulin pump startup.	7
10	Evaluate different sustainability models for healthcare startups and propose strategies to overcome challenges in the scale-up phase.	7
11	Develop a pitch deck outline for a healthcare startup targeting seed funding, incorporating key deliverables such as TAM, IP, and revenue model.	7
12	Examine how lean canvas and business model canvas approaches can be integrated with regulatory and ethical considerations to create a robust healthcare startup plan.	7

Syllabus

Module 1: Foundations of Innovation and Entrepreneurship in Healthcare

Healthcare system characteristics and innovation impact. Types of innovation: incremental, radical, technological, organizational, business model. Entrepreneurial mindset and healthcare entrepreneurship process. Healthcare innovation ecosystems: stakeholders, triple helix, quadruple helix models.

Case Study: Analyze GE Healthcare's Vscan portable ultrasound innovation focusing on ecosystem, innovation types, and stakeholder roles; what types of innovation are present, how did stakeholders interact, and which entrepreneurial strategies supported success?

Module 2: Clinical Immersion, Problem Identification, and Design Thinking

Clinical immersion methods: shadowing, observation, data collection. Identifying unmet clinical needs: needs filtering, validation, need statements. Design thinking process: empathize, define, ideate, prototype, test. Ideation frameworks: SCAMPER, brainstorming, NABC. Human-centered design: user personas, journey mapping, co-creation.

Case Study: Apply clinical immersion and design thinking in developing the ReWalk robotic exoskeleton for paraplegics; how did clinical immersion inform design, which design thinking steps were critical, and how were user needs validated?

Module 3: Strategic Integration of Regulation, Ethics, and Business Models

Healthcare business models: lean canvas, business model canvas, value proposition. Ethics in healthcare innovation: clinical trials, informed consent, IEC, ICMR guidelines. Regulatory framework application: CDSCO IMDR, EU MDR, FDA classifications (overview). Aligning design inputs with compliance requirements. Strategic innovation planning: vision, goals, milestones

Case Study: Integrate regulatory and ethical strategies in Dexcom's FDA approval and clinical trials of their continuous glucose monitor; what regulatory challenges were faced, how was ethical compliance ensured, and how did regulation influence business planning?

Module 4: Intellectual Property, Funding Strategies, Valuation, and Market Entry

Intellectual property: patents, copyrights, trademarks, timing of filing. Funding lifecycle: grants, Angel, Seed, venture capital, IPO. Pitch deck development: tailoring for funding stages, key deliverables (TAM, IP, revenue model). Startup valuation methods: DCF, VC method, scorecard method. Go-to-market strategies: pricing, early adopters, pilot programs

Case Study: Evaluate funding rounds, IP management, and valuation milestones of Medtronic MiniMed insulin pump startup; which funding types were used at different stages, how did IP affect valuation, and what pitch elements attracted investors?

Module 5: Scaling-Up, Sustainability, and Global Perspectives

WHO Nine Steps to Scaling-Up Health Innovations Barriers to scale-up: funding, operational, policy challenges Sustainability models: financial, environmental, social Measuring impact and outcomes Global innovation case studies: frugal innovation, India/EU/US examples Lessons learned: partnerships, policy alignment

Case Study: Analyze Aravind Eye Care System's global scale-up, sustainability, and overcoming barriers in affordable eye care; what were the main scale-up barriers, how was sustainability maintained, and what lessons apply to MedTech startups?

Course Plan

No	Topic	No. of Lectures
1	**Module 1: Foundations of Innovation and Entrepreneurship in Healthcare**	
1.1	Introduction to healthcare innovation: characteristics and impact	2
1.2	Types of innovation: incremental, radical, technological, organizational	2
1.3	Entrepreneurship theories and innovation ecosystems in healthcare	2
1.4	Case Study: Innovation ecosystem and success story of GE Healthcare's Vscan	2
2	**Module 2: Clinical Immersion, Problem Identification, and Design Thinking**	
2.1	Clinical immersion techniques and observational data collection	2
2.2	Identifying and validating unmet clinical needs	2
2.3	Design thinking process: empathize to test, ideation frameworks	2
2.4	Case Study: Application of design thinking in solving a clinical problem	2
3	**Module 3: Strategic Integration of Regulation, Ethics, and Business Models**	
3.1	Healthcare business models: Lean Canvas and Business Model Canvas.	2
3.2	Regulatory frameworks: CDSCO, FDA overview, ethics and clinical trials	2
3.3	Strategic innovation execution: aligning design and compliance	2
3.4	Case Study: Regulatory and ethical challenges in a medical device launch	2
4	**Module 4: Intellectual Property, Funding Strategies, Valuation, and Market Entry**	

4.1	Intellectual property types, filing strategies, and patent basics	2
4.2	Funding lifecycle: grants, angel, seed, VC, IPO	2
4.3	Startup valuation methods and go-to-market strategies	2
4.4	Case Study: Funding, IP, and valuation milestones of Medtronic MiniMed insulin pump startup	2
5	**Module 5: Scaling-Up, Sustainability, and Global Perspectives**	
5.1	Scale-up planning and WHO's Nine Steps framework	2
5.2	Sustainability models and measuring impact	2
5.3	Global innovation trends: frugal innovation and personalized healthcare	2
5.4	PCase Study: Sustainability and scale-up challenges in a healthcare startup	2
		40

Text Books

1. Pareras, L. G. (2011). *Innovation and Entrepreneurship in the Healthcare Sector*. Greenbranch Publishing.
2. Kearney, C. (2022). *Leading Innovation and Entrepreneurship in Healthcare: A Global Perspective*. Edward Elgar.

Reference Books

1. World Health Organization. *Nine Steps for Developing a Scaling-Up Strategy* (ISBN: 9789241500319). Available at:https://www.who.int/publications/i/item/9789241500319
2. Biotechnology Industry Research Assistance Council (BIRAC) Guidelines: https://birac.nic.in/
3. Indian Council of Medical Research (ICMR) Guidelines: https://www.icmr.gov.in/
4. Harvard i-lab MedTech Valuation Workshop (materials available through Harvard i-lab website) https://i-lab.harvard.edu/
5. AngelList — Startup Funding Stages Overview: https://angel.co/learn/startup-funding-stages
6. Digits.com — Startup Funding Basics: https://digits.com/blog/startup-funding-stages-explained/

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252PBM100	**MINI PROJECT**	**PROGRAM CORE**	**0**	**0**	**4**	**2**

Mini project can help to strengthen the understanding of student's fundamentals through application of theoretical concepts and to boost their skills and widen the horizon of their thinking. The ultimate aim of an engineering student is to resolve a problem by applying theoretical knowledge. Doing more projects increases problem solving skills.

The introduction of mini projects ensures preparedness of students to undertake dissertation. Students should identify a topic of interest in consultation with PG Programme Coordinator that should lead to their dissertation/research project. Demonstrate the novelty of the project through the results and outputs.

The progress of the mini project is evaluated based on three reviews: two interim reviews and a final review. A report is required at the end of the semester.

Evaluation Committee: Programme Coordinator, One Senior Professor, and Guide.

Sl. No	Type of Evaluations	Marks	Evaluation Criteria
1	Interim Evaluation 1	20	
2	Interim Evaluation 2	20	
3	Final Evaluation by Committee	35	Will be evaluating the level of completion and demonstration of functionality/specifications, clarity of presentation, oral examination, knowledge, involvement
4	Report	15	Committee will be evaluating the technical content, adequacy of references, template followed, and permitted plagiarism level (not more than 25%)
5	Supervisor/Guide	10	
	Total Marks	**100**	

CODE	COURSE NAME	CATEGORY	L	T	P	CREDIT
252LBM100	Advanced Signal and Image Processing Lab	LABORATORY 1	0	0	2	1

Preamble: This lab provides practical experience in signal and image processing using MATLAB. Students will explore core concepts from image pre-processing (noise reduction, enhancement) to key processing techniques like filtering, edge detection, and segmentation. The course introduces basic AI/ML methods for feature extraction and classification, culminating in a case study implementation that integrates the entire pipeline on real-world datasets.

Course Outcomes: After the completion of the course the student will be able to

CO 1	Understand and implement fundamental image preprocessing techniques such as noise reduction, contrast enhancement, and normalization (Understand)
CO 2	Apply core image processing methods like edge detection, segmentation, and morphological operations using suitable software tools. (Apply)
CO 3	Analyze and extract relevant features from images/signals for classification or interpretation using basic image processing algorithms (Analyze /Evaluate)
CO 4	Design and develop a basic end-to-end application integrating preprocessing, feature extraction, and AI-based analysis for real-world signal or image datasets. (Create)

Mapping of course outcomes with program outcomes

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7
CO 1	3	-	3	-	3	-	-
CO 2	3	-	3	-	3	-	-
CO 3	3	**3**	3	3	3	3	2
CO 4	3	**3**	3	3	3	3	2

Assessment Pattern

Bloom's Category	Continuous Evaluation
Apply	40
Analyse	20
Evaluate	20
Create	20

Mark distribution

Total Marks	CIE	ESE
100	100	-

Continuous Internal Evaluation Pattern: 100 Marks

The laboratory courses will be having only Continuous Internal Evaluation and carries 100 marks. Final assessment shall be done by two examiners; one examiner will be a senior faculty from the same department.

List of Experiments

Sl. No	CO Mapping	Practical Exercises
1	CO1, CO2	Implementation of Fundamental Image Preprocessing Techniques ● Noise reduction methods: Special and Frequency domain filtering & any one advanced fitters
2	CO1, CO2	Implementation of Fundamental Image Preprocessing Techniques ● Image Enhancement Methods: Contrast Enhancement, Sharpening and Edge enhancement
3	CO1, CO2	Implementation of Fundamental Image Preprocessing Techniques ● Segmentation Techniques: Region-Based, Edge-Based,
4	CO1, CO2	Implementation of Fundamental Image Preprocessing Techniques ● Morphological Operations - Dilation & Erosion, Opening & Closing, Top-Hat / Bottom-Hat and Hit-or-Miss Transform
5	CO1, CO2	Implementation of Fundamental Image Preprocessing Techniques ● Feature Extraction Techniques - Statistical Features (Mean, Variance, Skewness, Kurtosis) and Frequency Domain Features
6	CO1, CO2	● Implementation of Fundamental Image Preprocessing Techniques Color Image Processing - Color Space Conversions: RGB ↔ HSV, LAB, YCbCr

7	**CO1, CO2**	Implementation of Advanced Image Preprocessing Techniques • Object Detection & Tracking: Template Matching, Optical Flow, Blob Detection.
8	**CO3, CO4**	Design and Develop a Logic-Based Medical Image Processing System for Diagnostic Feature Analysis Using MATLAB (Non-AI Approach) Any one of this or similar type: • Design and Implementation of an Abnormality Detection System in Chest X-rays Using Classical Image Processing Methods • Design and Implementation of a Brain Tumor Detection System in MRI Images • Implementation of a Dental X-ray Analysis System for Tooth Boundary Detection
9	**CO3, CO4**	Familiarization to Statistics and Machine Learning Toolbox: MATLAB Feature-Based Image Classification Techniques: k-NN, SVM, Decision Tree and Logistic Regression Any Two of these or similar: • X-ray Image Classification Using k-NN – normal or pneumonia • Skin Lesion Classification Using SVM • Brain MRI Tumor Detection Using Decision Trees • Breast Cancer Detection from Mammogram Images
10	**CO3,CO4**	Familiarization to Statistics and Machine Learning Toolbox: MATLAB Unsupervised Medical Image Segmentation Using Clustering Algorithms • K-Means Clustering • Hierarchical Clustering

Reference Books

1. *S. Attaway, MATLAB: A Practical Introduction to Programming and Problem Solving, 6th ed. Elsevier, 2022.*

2. *Biomedical Signal Analysis Using MATLAB by Kayvan Najarian*
3. *E. N. Bruce, Biomedical Signal Processing and Signal Modeling. Hoboken, NJ, USA: Wiley-Interscience, 2001.*
4. *K. Najarian and R. Splinter, Biomedical Signal and Image Processing Using MATLAB. Boca Raton, FL, USA: CRC Press, 2005.*
5. *National Accreditation Board for Testing and Calibration Laboratories. (2021). NABL 141: Guidelines for Calibration Laboratories. Quality Council of India - https://nabl-india.org*
6. *IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, 3rd ed., IEC, Geneva, Switzerland, 2005 (Amendments in 2012 and 2020).*
7. *J. G. Webster, Medical Instrumentation: Application and Design, 4th ed. Hoboken, NJ, USA: Wiley, 2009.*
8. *ADINSTRUMENTS: https://www.adinstruments.com/lt/human-physiology*


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