GANPATUNIVERSITY

FACULTY OF ENGINEERING& TECHNOLOGY

Programme			Bachelor of Technology			Branch/Spec.	Biomedical Engineering		
Semester			V			Version	1.0.0.0		
Effective from Academic Year					2024-25	Effective for the Batch admitted in			July 2022
Course Code			2BM51PE03		Course Name	Clinical Engineering & Patient Safety			
Teaching Scheme						Examination Scheme(Marks)			
(Per week)	Lecture(DT)		Practical(Lab.)		Total		CE	SEE	Total
	L	TU	P	TW					
Credit	3	-	-	-	3	Theory	40	60	100
Hours	3	-	-	-	3	Practical	-	-	-

Pre-requisites

Understanding of healthcare systems, and familiarity with medical technology and regulatory standards.

Course Outcomes

On successful completion the course, the students will be able to:

CO1	**Remember** key concepts in clinical engineering and patient safety, including regulatory standards and guidelines relevant to medical device management.
CO2	**Understand** the integration of patient safety principles into clinical engineering practices within healthcare systems.
CO3	**Apply** knowledge to assess and maintain the proper functionality of medical devices, ensuring compliance with safety standards.
CO4	**Explain** potential risks associated with medical devices, hazards and case studies.

Theory Syllabus

Unit	Content	Hrs.
1	INTRODUCTION TO CLINICAL ENGINEERING Overview of clinical engineering, Historical perspective and development in healthcare systems, Regulatory standards and guidelines, Medical device management basics, Roles and functions of Clinical engineer in a Hospital.	7
2	PATIENT SAFETY FUNDAMENTALS Principles of patient safety, Human factors in medical device usage, Integration of patient safety into clinical engineering practices, Cost-effectiveness and resource optimization.	6
3	RISK ASSESSMENT IN CLINICAL ENGINEERING Understanding and assessing risks associated with medical devices, Hazard analysis, Risk mitigation strategies, Root cause analysis (RCA), Health care failure mode analysis (HFMEA), JCAHO standards , Risk management.	7
4	MEDICAL DEVICE MAINTENANCE AND CALIBRATION Principles of medical device maintenance, Importance of routine maintenance in preventing failures, Calibration procedures and practices, Preventive maintenance strategies, The system risk model (SRM), Identifying critical components and failure modes, Clinical Information system (CIS), Physiological monitoring process - PMS and CMS architecture.	7
5	INCIDENT REPORTING AND ANALYSIS Importance of incident reporting, Analysis of incidents related to medical devices, Implementing corrective and preventive actions.	5
6	CASE STUDIES AND BEST PRACTICES Real-world case studies on clinical engineering challenges and solutions, Best practices in medical device management and patient safety, Examination of actual incidents and challenges faced in clinical engineering.	7
7	EMERGING TRENDS IN CLINICAL ENGINEERING Telehealth and remote monitoring technologies, Advancements in medical device technologies,	6

	Future directions in clinical engineering, Potential impact of emerging technologies on patient care.	
Practical content		
NA		
Text Books		
1	Clinical Engineering Handbook by Joseph F. Dayro Pub.: Elsevier Academic Press	
2	Patient Safety and Quality: An Evidence-Based Handbook for Nurses by Ronda Hughes Pub.: AHRQ Publication	
Reference Books		
1	Radiation Oncology Physics: A Handbook for Teachers and Students by E. B. Podgorsak Pub.: IAEA Publication	
2	The Physics of Radiation Therapy by Faiz M. Khan Pub.: Lippincott Williams & Wilkins	
3	Clinical Engineering (Principles and Application in Engineering) by Yadin David, Joseph. D. Bronzino Pub.: CRC Press	
ICT/MOOCs Reference		
1	https://www.course ra.org/specializations /patient-safety	
2	https://www.classcentral.com/course/quality-healthcare-6316	

Mapping of CO with PO and PSO:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**PO12**	**PSO1**	**PSO2**	**PSO3**
CO1	2	2	1	1	1	0	0	1	2	1	1	1	2	3	2
CO2	1	2	2	1	2	1	0	2	2	1	1	1	2	3	2
CO3	1	2	1	1	1	0	0	1	2	1	1	1	2	3	2
CO4	1	2	1	1	1	0	0	1	2	1	1	1	1	2	2