



Republic of Yemen
Ministry of Higher Education & Scientific Research
Council of Academic Accreditation & Quality



Assurance of Higher Education (CAQA)

21 September University for medical and Applied Science

Faculty of Engineering and Computer
Department of Biomedical Engineering
Program of Biomedical Engineering

Course Specification of
Clinical Engineering
Course Code. (07.02.718)

2024



T4: This Template is Developed and Approved by CAQA-Yemen, 2023

| | | | | |
|--------------------|--------------|-------------------------|-------------------------|-----------------------|
| Prepared by: | Reviewed by: | Head of the Department: | Quality Unit: | Dean: |
| Dr. Awadh Alkubati | Dr. ----- | Dr. Awadh Al-Kubati | Dr. Mohammed Al-shamahi | Dr. Abdulrahman Obaid |

I. General Information:

| | | | | | | |
|-----|--|--|----------------------|-------------------|-------------------------|----------|
| 1. | Course Title: | Clinical Engineering | | | | |
| 2. | Course Code: | 07.02.718 | | | | |
| 3. | Credit Hours: | Credit Hours | Theory Contact Hours | | Practical Contact Hours | |
| | | | Lecture | Tutorial /Seminar | Lab | Clinical |
| | | 3 | 2 | 2 | -- | -- |
| 4. | Level/ Semester at which this Course is offered: | 3 ^{ed} Level / 1 st Semester | | | | |
| 5. | Pre –Requisite (if any): | None | | | | |
| 6. | Co –Requisite (if any): | None | | | | |
| 7. | Program (s) in which the Course is Offered: | Bachelor of Biomedical Engineering | | | | |
| 8. | Language of Teaching the Course: | English/Arabic | | | | |
| 9. | Location of Teaching the Course: | Faculty of Medical Technology | | | | |
| 10. | Prepared by: | Dr. Awadh Alkubati | | | | |
| 11 | Date and Number of Approval by Council: | | | | | |
| 12 | Date of Approval: | | | | | |

II. Course Description:

This course aims to provide a comprehensive understanding of Clinical Engineering, focusing on the roles and responsibilities of clinical engineers within healthcare systems. It covers essential topics such as medical device classifications, technology assessment, and procurement processes. The course emphasizes practical applications and management of medical devices, preparing students to address real-world challenges in clinical settings and improve healthcare quality.

| | | | | | |
|---|---|-------------------|----|--|--|
| III. Course Intended Learning Outcomes (CILOs) : Upon successful completion of the course, students will be able to: | | Referenced PILOs | | | |
| A. Knowledge and Understanding: | | I, P or M/A | | | |
| a1 | Explain the difference between Biomedical Engineers and Clinical Engineers, including their roles in the healthcare system. | M | A1 | Explain the appropriate models, theories, mathematical foundations, and techniques related to biomedical engineering technology context. | |

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|--|--|---|----|---|
| a2 | Articulate the classifications of medical devices, including categories and associated standards | M | A2 | Clarify the biomedical devices maintenance principles and how these are important for solving biomedical devices and equipment's problems in health environment. |
| B. Intellectual Skills: | | | | |
| b1 | Evaluate and apply quality improvement methodologies in healthcare based on different quality standards. | M | B3 | Assess the features of biomedical devices systems, engineering diagnostic skills, technological expertise, and analytical methods that related to identify and addressing of biomedical devices systems failures. |
| b2 | Analyze the medical equipment procurement process, understanding its stages and components | M | B2 | Analyze the impacts of problems related to the Biomedical equipments and its solution principles in a creative manner by using a systematic and analytical thinking methods. |
| C. Professional and Practical Skills: | | | | |
| c1 | Manage medical device inventory records, including data entry, monitoring inventory, and analyzing related information. | P | C1 | Relate integrally knowledge of life science, biomedical engineering technology practice concepts, principles of engineering and techniques evaluation to solve problems relevant to biomedical engineering. |
| c2 | Develop a maintenance policy for medical devices, including recommendations for preventive and corrective maintenance and management of the device life cycle. | P | C2 | Evaluate an engineering technique, modern analytical tools and required computer programs to analyzing and solve the problems of medical devices. |
| D. Transferable Skills: | | | | |
| d1 | Communicate effectively with interdisciplinary teams in a hospital setting, presenting technical information clearly. | M | D1 | Function effectively as an individual, team member, or leader in activities relevant to biomedical engineering, and collaborating to achieve a shared objective. |
| d2 | Apply management skills in handling procurement and | M | D2 | Acquire entrepreneurial skills and effectively manage tasks, |

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| | operational projects, using management tools and negotiation techniques. | | | time, processes and resources. |
| I= Introduced, P=Practiced or M/A= Mastered/Advanced | | | | |

| (A) Alignment of Course Intended Learning Outcomes (Knowledge and Understanding) to Teaching Strategies and Assessment Methods: | | | |
|--|---|---|--|
| | Course Intended Learning Outcomes | Teaching Strategies | Assessment Strategies |
| a1 | Explain the difference between Biomedical Engineers and Clinical Engineers, including their roles in the healthcare system. | <ul style="list-style-type: none"> - Interactive lectures - Discussions | <ul style="list-style-type: none"> - Quizzes - Mid-term theoretical exam - Final theoretical exam - Assignment |
| a2 | Articulate the classifications of medical devices, including categories and associated standards | | |
| (B) Alignment of Course Intended Learning Outcomes (Intellectual Skills) to Teaching Strategies and Assessment Methods: | | | |
| | Course Intended Learning Outcomes | Teaching Strategies | Assessment Strategies |
| b1 | Evaluate and apply quality improvement methodologies in healthcare based on different quality standards. | <ul style="list-style-type: none"> - Interactive lectures - Discussions - Problem-based learning - Presentation | <ul style="list-style-type: none"> - Quizzes - Mid-term theoretical exam - Final theoretical exam - Assignment |
| b2 | Analyze the medical equipment procurement process, understanding its stages and components | | |
| (C) Alignment of Course Intended Learning Outcomes (Professional and Practical Skills) to Teaching Strategies and Assessment Methods: | | | |
| | Course Intended Learning Outcomes | Teaching Strategies | Assessment Strategies |
| c1 | Manage medical device inventory records, including data entry, monitoring inventory, and analyzing related information. | <ul style="list-style-type: none"> - Lectures - Interactive Exercises - Problem Sets - Presentation | <ul style="list-style-type: none"> - Quizzes - Mid-term theoretical exam - Final theoretical exam - Assignments - Class Participation |
| c2 | Develop a maintenance policy for medical devices, | | |

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| | including recommendations for preventive and corrective maintenance and management of the device life cycle. | | |
| (D) Alignment of Course Intended Learning Outcomes (Transferable Skills) to Teaching Strategies and Assessment Methods: | | | |
| | Course Intended Learning Outcomes | Teaching Strategies | Assessment Strategies |
| d1 | Communicate effectively with interdisciplinary teams in a hospital setting, presenting technical information clearly. | <ul style="list-style-type: none"> - Presentations - Role-Playing - Group Discussions | <ul style="list-style-type: none"> - Assignments |
| d2 | Apply management skills in handling procurement and operational projects, using management tools and negotiation techniques. | | |

IV. Course Contents:

A. Theoretical Aspect:

| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|--|---|-----------------|---------------|---------------------------|
| 1 | Introduction | <ul style="list-style-type: none"> - Introduction to the course. - Course outlines. - Project description. - History of engineering and technology in health care. | 1 st | 2 | -- |
| 2 | Biomedical Engineer VS Clinical Engineer | <ul style="list-style-type: none"> - Difference between CE and BE - What is CE? - Clinical Engineer relationship | 2 nd | 2 | a1 |
| 3 | Duties and responsibilities of biomedical engineering and clinical engineering | <ul style="list-style-type: none"> - Clinical Engineering - Clinical Engineer Departments - Engineering Concepts - Clinical & Hospital Engineering - Hospitals Organization and the Role of Clinical Engineer - Typical Engineering Responsibilities - Difference between Engineering or Maintenance | 3 ^{ed} | 2 | a1, b1 |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|---------|---|--|-------------------------------------|---------------|---------------------------|
| 4 | Medical Device Classifications | <ul style="list-style-type: none"> - Medical Device – Categories - Medical Device – Classification - Types of Standards - Scope of Regulation: Medical Device | 4 th | 2 | a2, b1 |
| 5 | Biomedical Technology Assessment | <ul style="list-style-type: none"> - Technology assessment. - Prerequisites for technology assessment. - Technology procurement. - Outsourcing CE Service. | 5 th | 2 | b2, c1 |
| 6 | Hospital organization and management | <ul style="list-style-type: none"> - Hospital organization - Classification of services - Clinical Engineer Must Understand - Professional Groups - Hospital organization and its Functions - Organizational Structure of a Hospital: <ul style="list-style-type: none"> o Importance of Understanding Organizational Structure of Hospital o Hospital Departments are grouped according to similarity of duties. | 6 th | 2 | b2 |
| 7 | Mid-Term Theoretical Exam | <ul style="list-style-type: none"> - All previous topics | 7 th | 2 | a1, a2, b1, b2, c1 |
| 8 | Medical Devices Inventory Management, Medical Devices Records | <ul style="list-style-type: none"> - Equipment inventory Purpose of document - Key elements for data included in an inventory - Stages of inventory management - Process of Inventory Management - Practices of Medical Device Inventory Management. | 8 th | 2 | c1 |
| 9 | Examination of Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> - Equipment inventory - Definitions and Importance - Purpose of document - Data included in an inventory - Stages of inventory management - Process of Inventory Management - Practices of Medical Device Inventory Management | 9 th | 2 | b2, d2 |
| 10 - 11 | Examination of Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> - Procurement - Procurement Management Process - Components of the Procurement Process - Workflow for The Medical Equipment Procurement Process - Purchase Requisition Form and | 10 th - 11 th | 2 | b2, d2 |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|--|------------------------|---|------------------|---------------|---------------------------|
| | | <ul style="list-style-type: none"> Purchase Order Form? – Quote or Quotation – Pre-approved Suppliers – Procurement Committee – Evolution of Procurement – Types of Procurement – Differences between Procurement and Purchasing – Procurement Operations – Key Procurement Objective – Steps of Effective Procurement Management | | | |
| 12 | Clinical quality | <ul style="list-style-type: none"> – Quality in Healthcare: Definitions – Quality Improvement Methodologies – Organizations – Aims of health care quality – Types of Quality Problems | 12 th | 2 | b1 |
| 13 | Standards | <ul style="list-style-type: none"> – Definitions and Specifications – Codes and Regulations – Purpose of standards – Development and promulgation of standards – Standards organization – Identification of standards | 13 th | 2 | a2 |
| 14 | Maintenance | <ul style="list-style-type: none"> – Definitions and maintenance objectives – Management policy for medical devices – Organizations of maintenance and Service contract – Maintenance and repair recommendations – Total productive maintenance (TPM) – Medical device life cycle | 14 th | 2 | c2 |
| 15 | Project Presentation | <ul style="list-style-type: none"> – Student's presentations. | 15 th | 2 | d1 |
| 16 | Final Theoretical Exam | <ul style="list-style-type: none"> – All topics. | 16 th | 2 | a1, a2, b1, b2, c1, c2 |
| Number of Weeks /and Units Per Semester | | | 16 | 32 | |

B. Practical Aspect (Lab/Clinical) (if any):

| No. | Tasks/ Experiments | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|--------------------|-----------------|---------------|---------------------------|
|-----|--------------------|-----------------|---------------|---------------------------|

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| No. | Tasks/ Experiments | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|---|--------------------|-----------------|---------------|---------------------------|
| 1 | None | | | |
| 2 | | | | |
| 3 | | | | |
| Number of Weeks /and Units Per Semester | | | | |

C. Tutorial Aspect (if any):

| No. | Exercise | Exercise Content | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|---|--|-----------------|---------------|---------------------------|
| 1 | History of Engineering in Healthcare | <ul style="list-style-type: none"> Prepare a historical summary of the development of engineering and technology in healthcare. Identify key milestones in the evolution of medical devices. | 1 | 2 | -- |
| 2 | Comparing Biomedical Engineers and Clinical Engineers | <ul style="list-style-type: none"> Create a report detailing the differences between biomedical engineers and clinical engineers. Analyze case studies that illustrate the role of each in the healthcare system. | 1 | 2 | a1 |
| 3 | Responsibilities of Biomedical and Clinical Engineers | <ul style="list-style-type: none"> Design an organizational chart showing the departments involved in clinical engineering within hospitals. Write an essay discussing the difference between engineering and maintenance in healthcare. | 1 | 2 | a1, c2 |
| 4 | Medical Device Classification | <ul style="list-style-type: none"> Develop a classification list for medical devices, including categories and applicable standards. Analyze real-world examples to apply the classifications. | 1 | 2 | a2 |
| 5 | Biomedical Technology Assessment | <ul style="list-style-type: none"> Conduct a case study on assessing biomedical technology and its applications. Create a model for evaluating the technology needs of a hospital. | 1 | 2 | b1 |
| 6 | Hospital Organization and Management | <ul style="list-style-type: none"> Create an organizational chart of a hospital showing the administrative structure and functional divisions. | 1 | 2 | d1 |

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| No. | Exercise | Exercise Content | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|--|--|--|-----------------|---------------|---------------------------|
| | | <ul style="list-style-type: none"> Write a report on the role of clinical engineers within the hospital. | | | |
| 7 | Medical Devices Inventory Management | <ul style="list-style-type: none"> Develop a model for managing medical device records, including key data entries. Analyze inventory management data and provide recommendations for improvement. | 1 | 2 | c1 |
| 8 | Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> Study public procurement law with a focus on the procurement process. Prepare a report on procurement procedures and approvals in hospitals. | 1 | 2 | b2, d2 |
| 9 | Healthcare Quality | <ul style="list-style-type: none"> Analyze quality improvement methodologies in healthcare and prepare a report. Study examples of quality issues in hospitals and propose solutions. | 1 | 2 | b1 |
| 10 | Medical Device Standards | <ul style="list-style-type: none"> Prepare a report on global standards for medical devices and how they are applied. Analyze practices for developing and promulgating standards in healthcare. | 1 | 2 | a2 |
| Number of Weeks /and Units Per Semester | | | 10 | 20 | |

V. Assignments:

| No. | Assignments | Week Due | Mark | Aligned CILOs (symbols) |
|--------------|--------------|----------|-----------|-------------------------|
| 1 | Assignment 1 | Week 8 | 5 | a1, a2, b1, c1, d1 |
| 2 | Assignment 2 | Week 14 | 5 | a2, b2, c2, d2 |
| Total | | | 10 | |

VI. Schedule of Assessment Tasks for Students During the Semester:

| | | | | |
|--------------------|--------------|-------------------------|-------------------------|-----------------------|
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| No. | Assessment Method | Week Due | Mark | Proportion of Final Assessment | Aligned Course Learning Outcomes |
|-------|---------------------------|------------------------|------|--------------------------------|----------------------------------|
| 1 | Assignments and Quizzes | Weeks 4, 8, 12, 14, 15 | 10 | 10% | a1, a2, b1, b2, c1, c2, d1, d2 |
| 2 | Mid-Term Theoretical Exam | Week 7 | 20 | 20% | a1, a2, b1, b2, c1 |
| 4 | Final Theoretical Exam | Week 16 | 70 | 70% | a1, a2, b1, b2, c1, c2 |
| Total | | | 100% | 100% | - |

VII. Learning Resources:

1- Required Textbook(s) (maximum two):

1. Bruley, D. F., 2017, Clinical Engineering: A Handbook for Clinical and Biomedical Engineers, 1st Edition, Cambridge, Cambridge University Press.
2. Kumar, R., & Soni, R., 2017, Biomedical Engineering: Bridging Medicine and Technology, 2nd Edition, Boston, Academic Press.

2- Essential References:

1. Christensen, C. M., & Raynor, M. E., 2013, The Innovator's Prescription: A Disruptive Solution for Health Care, 1st Edition, New York, McGraw-Hill Education.
2. Goh, C. H., & Xu, Y., 2018, Medical Device Regulations and Standards, 1st Edition, London, CRC Press.
3. Eckert, R., 2015, Principles of Biomedical Engineering, 3rd Edition, Oxford, Oxford University Press.

3- Electronic Materials and Web Sites etc.:

Websites:

1. U.S. Food and Drug Administration (FDA) - Medical Devices: <https://www.fda.gov/medical-devices>
2. International Organization for Standardization (ISO) - Medical Devices: <https://www.iso.org/committee/54818.html>

Journals:

1. Biomedical Engineering Online: <https://biomedical-engineering-online.biomedcentral.com/>
2. Journal of Clinical Engineering: <https://www.tandfonline.com/toc/ucen20/current>

Other Web Sources:

1. Clinical Engineering Handbook: <https://www.elsevier.com/books/clinical-engineering-handbook/pereira/978-0-12-800930-0>
2. National Institute for Health and Care Excellence (NICE) - Guidelines and Resources: <https://www.nice.org.uk/guidance>

VIII. Course Policies: (Based on the Uniform Students' By law (2007))

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|---|---|
| 1 | Class Attendance: Class Attendance is mandatory. A student is considered absent and shall be banned from taking the final exam if his/her absence exceeds 25% of total classes. |
| 2 | Tardiness: |

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| | A student will be considered late if he/she is not in class after 10 minutes of the start time of class. |
| 3 | Exam Attendance/Punctuality: No student shall be allowed to the exam hall after 30 minutes of the start time, and shall not leave the hall before half of the exam time has passed. |
| 4 | Assignments & Projects: Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same. |
| 5 | Cheating: Cheating is an act of fraud that results in the cancelation of the student's exam or assignment. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply. |
| 6 | Forgery and Impersonation: Forgery/Impersonation is an act of fraud that results in the cancelation of the student's exam, assignment or project. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply. |
| 7 | Other policies: The University official regulations in force will be strictly observed and students shall comply with all rules and regulations of the examination set by the Department, Faculty and University Administration. |

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Faculty of Medical Technology

Department of Biomedical Engineering

Program of Biomedical Engineering

Course Plan (Syllabus) of Clinical Engineering

Course Code. (07.02.718)

| I. Information about Faculty Member Responsible for the Course: | | | | | | |
|---|--|--------------|-----|-----|-----|---------|
| Name of Faculty Member: | | Office Hours | | | | |
| Location & Telephone No.: | | | | | | |
| E-mail: | | SAT | SUN | MON | TUE | WED THU |

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II. Course Identification and General Information:

| | | | | | | |
|-----|--|------------------------------------|----------------------|-------------------|-------------------------|----------|
| 11. | Course Title: | Clinical Engineering | | | | |
| 12. | Course Code: | 07.02.718 | | | | |
| 13. | Credit Hours: | Credit Hours | Theory Contact Hours | | Practical Contact Hours | |
| | | | Lecture | Tutorial /Seminar | Lab | Clinical |
| | | 3 | 2 | 2 | -- | -- |
| 14. | Level/ Semester at which this Course is offered: | 3ed Level / 1st Semester | | | | |
| 15. | Pre –Requisite (if any): | None | | | | |
| 16. | Co –Requisite (if any): | None | | | | |
| 17. | Program (s) in which the Course is Offered: | Bachelor of Biomedical Engineering | | | | |
| 18. | Language of Teaching the Course: | English/Arabic | | | | |
| 19. | Location of Teaching the Course: | Faculty of Medical Technology | | | | |
| 20. | Prepared by: | Dr. Awadh Alkubati | | | | |
| 11 | Date and Number of Approval by Council: | | | | | |
| 12 | Date of Approval: | | | | | |

III. Course Description:

This course aims to provide a comprehensive understanding of Clinical Engineering, focusing on the roles and responsibilities of clinical engineers within healthcare systems. It covers essential topics such as medical device classifications, technology assessment, and procurement processes. The course emphasizes practical applications and management of medical devices, preparing students to address real-world challenges in clinical settings and improve healthcare quality.

IV. Course Intended Learning Outcomes (CILOs) :

Upon successful completion of the Course, student will be able to:

A. Knowledge and Understanding:

a1 Explain the difference between Biomedical Engineers and Clinical

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|--|--|
| | Engineers, including their roles in the healthcare system. |
| a2 | Articulate the classifications of medical devices, including categories and associated standards |
| B. Intellectual Skills: | |
| b1 | Evaluate and apply quality improvement methodologies in healthcare based on different quality standards. |
| b2 | Analyze the medical equipment procurement process, understanding its stages and components |
| C. Professional and Practical Skills: | |
| c1 | Manage medical device inventory records, including data entry, monitoring inventory, and analyzing related information. |
| c2 | Develop a maintenance policy for medical devices, including recommendations for preventive and corrective maintenance and management of the device life cycle. |
| D. Transferable Skills: | |
| d1 | Communicate effectively with interdisciplinary teams in a hospital setting, presenting technical information clearly. |
| d2 | Apply management skills in handling procurement and operational projects, using management tools and negotiation techniques. |

V. Course Contents:

A. Theoretical Aspect:

| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|--|---|-----------------|---------------|---------------------------|
| 1 | Introduction | <ul style="list-style-type: none"> – Introduction to the course. – Course outlines. – Project description. – History of engineering and technology in health care. | 1 st | 2 | -- |
| 2 | Biomedical Engineer VS Clinical Engineer | <ul style="list-style-type: none"> – Difference between CE and BE – What is CE? – Clinical Engineer relationship | 2 nd | 2 | a1 |
| 3 | Duties and responsibilities of biomedical engineering and clinical engineering | <ul style="list-style-type: none"> – Clinical Engineering – Clinical Engineer Departments – Engineering Concepts – Clinical & Hospital Engineering – Hospitals Organization and the Role of Clinical Engineer – Typical Engineering Responsibilities – Difference between Engineering or Maintenance | 3 ^{ed} | 2 | a1, b1 |
| 4 | Medical Device | – Medical Device – Categories | 4 th | 2 | a2, b1 |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|---------|--|--|-------------------------------------|---------------|---------------------------|
| | Classifications | <ul style="list-style-type: none"> - Medical Device – Classification - Types of Standards - Scope of Regulation: Medical Device | | | |
| 5 | Biomedical Technology Assessment | <ul style="list-style-type: none"> - Technology assessment. - Prerequisites for technology assessment. - Technology procurement. - Outsourcing CE Service. | 5 th | 2 | b2, c1 |
| 6 | Hospital organization and management | <ul style="list-style-type: none"> - Hospital organization - Classification of services - Clinical Engineer Must Understand - Professional Groups - Hospital organization and its Functions - Organizational Structure of a Hospital: <ul style="list-style-type: none"> o Importance of Understanding Organizational Structure of Hospital o Hospital Departments are grouped according to similarity of duties. | 6 th | 2 | b2 |
| 7 | Mid-Term Theoretical Exam | <ul style="list-style-type: none"> - All previous topics | 7 th | 2 | a1, a2, b1, b2, c1 |
| 8 | Medical Devices Inventory Management, Medical Devices Records | <ul style="list-style-type: none"> - Equipment inventory Purpose of document - Key elements for data included in an inventory - Stages of inventory management - Process of Inventory Management - Practices of Medical Device Inventory Management. | 8 th | 2 | c1 |
| 9 | Examination of Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> - Equipment inventory - Definitions and Importance - Purpose of document - Data included in an inventory - Stages of inventory management - Process of Inventory Management - Practices of Medical Device Inventory Management | 9 th | 2 | b2, d2 |
| 10 - 11 | Examination of Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> - Procurement - Procurement Management Process - Components of the Procurement Process - Workflow for The Medical Equipment Procurement Process - Purchase Requisition Form and Purchase Order Form? | 10 th - 11 th | 2 | b2, d2 |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|--|------------------------|---|------------------|---------------|---------------------------|
| | | <ul style="list-style-type: none"> - Quote or Quotation - Pre-approved Suppliers - Procurement Committee - Evolution of Procurement - Types of Procurement - Differences between Procurement and Purchasing - Procurement Operations - Key Procurement Objective - Steps of Effective Procurement Management | | | |
| 12 | Clinical quality | <ul style="list-style-type: none"> - Quality in Healthcare: Definitions - Quality Improvement Methodologies - Organizations - Aims of health care quality - Types of Quality Problems | 12 th | 2 | b1 |
| 13 | Standards | <ul style="list-style-type: none"> - Definitions and Specifications - Codes and Regulations - Purpose of standards - Development and promulgation of standards - Standards organization - Identification of standards | 13 th | 2 | a2 |
| 14 | Maintenance | <ul style="list-style-type: none"> - Definitions and maintenance objectives - Management policy for medical devices - Organizations of maintenance and Service contract - Maintenance and repair recommendations - Total productive maintenance (TPM) - Medical device life cycle | 14 th | 2 | c2 |
| 15 | Project Presentation | <ul style="list-style-type: none"> - Student's presentations. | 15 th | 2 | d1 |
| 16 | Final Theoretical Exam | <ul style="list-style-type: none"> - All topics. | 16 th | 2 | a1, a2, b1, b2, c1, c2 |
| Number of Weeks /and Units Per Semester | | | 16 | 32 | |

| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours |
|-----|-------------------|--|-----------------|---------------|
| 1 | Introduction | <ul style="list-style-type: none"> - Introduction to the course. - Course outlines. - Project description. - History of engineering and technology in health care. | 1 st | 2 |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours |
|-----|---|--|-----------------|---------------|
| 2 | Biomedical Engineer VS Clinical Engineer | <ul style="list-style-type: none"> - Difference between CE and BE - What is CE? - Clinical Engineer relationship | 2 nd | 2 |
| 3 | Duties and responsibilities of biomedical engineering and clinical engineering | <ul style="list-style-type: none"> - Clinical Engineering - Clinical Engineer Departments - Engineering Concepts - Clinical & Hospital Engineering - Hospitals Organization and the Role of Clinical Engineer - Typical Engineering Responsibilities - Difference between Engineering or Maintenance | 3 ^{ed} | 2 |
| 4 | Medical Device Classifications | <ul style="list-style-type: none"> - Medical Device – Categories - Medical Device – Classification - Types of Standards - Scope of Regulation: Medical Device | 4 th | 2 |
| 5 | Biomedical Technology Assessment | <ul style="list-style-type: none"> - Technology assessment. - Prerequisites for technology assessment. - Technology procurement. - Outsourcing CE Service. | 5 th | 2 |
| 6 | Hospital organization and management | <ul style="list-style-type: none"> - Hospital organization - Classification of services - Clinical Engineer Must Understand - Professional Groups - Hospital organization and its Functions - Organizational Structure of a Hospital: o Importance of Understanding Organizational Structure of Hospital o Hospital Departments are grouped according to similarity of duties. | 6 th | 2 |
| 7 | Mid-Term Theoretical Exam | <ul style="list-style-type: none"> - All previous topics | 7 th | 2 |
| 8 | Medical Devices Inventory Management, Medical Devices Records | <ul style="list-style-type: none"> - Equipment inventory Purpose of document - Key elements for data included in an inventory - Stages of inventory management - Process of Inventory Management - Practices of Medical Device Inventory Management. | 8 th | 2 |
| 9 | Examination of Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> - Equipment inventory - Definitions and Importance - Purpose of document - Data included in an inventory - Stages of inventory management - Process of Inventory Management - Practices of Medical Device Inventory | 9 th | 2 |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours |
|--|---|---|-------------------------------------|---------------|
| | | Management | | |
| 10 - 11 | Examination of Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> - Procurement - Procurement Management Process - Components of the Procurement Process - Workflow for The Medical Equipment Procurement Process - Purchase Requisition Form and Purchase Order Form? - Quote or Quotation - Pre-approved Suppliers - Procurement Committee - Evolution of Procurement - Types of Procurement - Differences between Procurement and Purchasing - Procurement Operations - Key Procurement Objective - Steps of Effective Procurement Management | 10 th - 11 th | 2 |
| 12 | Clinical quality | <ul style="list-style-type: none"> - Quality in Healthcare: Definitions - Quality Improvement Methodologies - Organizations - Aims of health care quality - Types of Quality Problems | 12 th | 2 |
| 13 | Standards | <ul style="list-style-type: none"> - Definitions and Specifications - Codes and Regulations - Purpose of standards - Development and promulgation of standards - Standards organization - Identification of standards | 13 th | 2 |
| 14 | Maintenance | <ul style="list-style-type: none"> - Definitions and maintenance objectives - Management policy for medical devices - Organizations of maintenance and Service contract - Maintenance and repair recommendations - Total productive maintenance (TPM) - Medical device life cycle | 14 th | 2 |
| 15 | Project Presentation | <ul style="list-style-type: none"> - Student's presentations. | 15 th | 2 |
| 16 | Final Theoretical Exam | <ul style="list-style-type: none"> - All topics. | 16 th | 2 |
| Number of Weeks /and Units Per Semester | | | 16 | 32 |
| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours |
|-----|--|--|-----------------|---------------|
| 1 | Introduction | <ul style="list-style-type: none"> - Introduction to the course. - Course outlines. - Project description. - History of engineering and technology in health care. | 1 st | 2 |
| 2 | Biomedical Engineer VS Clinical Engineer | <ul style="list-style-type: none"> - Difference between CE and BE - What is CE? - Clinical Engineer relationship | 2 nd | 2 |
| 3 | Duties and responsibilities of biomedical engineering and clinical engineering | <ul style="list-style-type: none"> - Clinical Engineering - Clinical Engineer Departments - Engineering Concepts - Clinical & Hospital Engineering - Hospitals Organization and the Role of Clinical Engineer - Typical Engineering Responsibilities - Difference between Engineering or Maintenance | 3 ^{ed} | 2 |
| 4 | Medical Device Classifications | <ul style="list-style-type: none"> - Medical Device – Categories - Medical Device – Classification - Types of Standards - Scope of Regulation: Medical Device | 4 th | 2 |
| 5 | Biomedical Technology Assessment | <ul style="list-style-type: none"> - Technology assessment. - Prerequisites for technology assessment. - Technology procurement. - Outsourcing CE Service. | 5 th | 2 |
| 6 | Hospital organization and management | <ul style="list-style-type: none"> - Hospital organization - Classification of services - Clinical Engineer Must Understand - Professional Groups - Hospital organization and its Functions - Organizational Structure of a Hospital: o Importance of Understanding Organizational Structure of Hospital o Hospital Departments are grouped according to similarity of duties. | 6 th | 2 |
| 7 | Mid-Term Theoretical Exam | <ul style="list-style-type: none"> - All previous topics | 7 th | 2 |
| 8 | Medical Devices Inventory Management, Medical Devices Records | <ul style="list-style-type: none"> - Equipment inventory Purpose of document - Key elements for data included in an inventory - Stages of inventory management - Process of Inventory Management - Practices of Medical Device Inventory Management. | 8 th | 2 |
| 9 | Examination of Public | <ul style="list-style-type: none"> - Equipment inventory - Definitions and Importance | 9 th | 2 |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours |
|---------|--|---|-------------------------------------|---------------|
| | Procurement Law and Procurement Methods | <ul style="list-style-type: none"> - Purpose of document - Data included in an inventory - Stages of inventory management - Process of Inventory Management - Practices of Medical Device Inventory Management | | |
| 10 - 11 | Examination of Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> - Procurement - Procurement Management Process - Components of the Procurement Process - Workflow for The Medical Equipment Procurement Process - Purchase Requisition Form and Purchase Order Form? - Quote or Quotation - Pre-approved Suppliers - Procurement Committee - Evolution of Procurement - Types of Procurement - Differences between Procurement and Purchasing - Procurement Operations - Key Procurement Objective - Steps of Effective Procurement Management | 10 th - 11 th | 2 |
| 12 | Clinical quality | <ul style="list-style-type: none"> - Quality in Healthcare: Definitions - Quality Improvement Methodologies - Organizations - Aims of health care quality - Types of Quality Problems | 12 th | 2 |
| 13 | Standards | <ul style="list-style-type: none"> - Definitions and Specifications - Codes and Regulations - Purpose of standards - Development and promulgation of standards - Standards organization - Identification of standards | 13 th | 2 |
| 14 | Maintenance | <ul style="list-style-type: none"> - Definitions and maintenance objectives - Management policy for medical devices - Organizations of maintenance and Service contract - Maintenance and repair recommendations - Total productive maintenance (TPM) - Medical device life cycle | 14 th | 2 |
| 15 | Project Presentation | <ul style="list-style-type: none"> - Student's presentations. | 15 th | 2 |
| 16 | Final Theoretical Exam | <ul style="list-style-type: none"> - All topics. | 16 th | 2 |

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| No. | Units/Topics List | Sub Topics List | Number of Weeks | Contact Hours |
|---|-------------------|-----------------|-----------------|---------------|
| Number of Weeks /and Units Per Semester | | | 16 | 32 |

B. Case Studies and Practical Aspect:

| No. | Tasks/ Experiments | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|---|--------------------|-----------------|---------------|---------------------------|
| 1 | None | | | |
| 2 | | | | |
| 3 | | | | |
| Number of Weeks /and Units Per Semester | | | | |

| No. | Tasks/ Experiments | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|---|--------------------|-----------------|---------------|---------------------------|
| 1 | None | | | |
| 2 | | | | |
| 3 | | | | |
| Number of Weeks /and Units Per Semester | | | | |

C. Tutorial Aspect:

| No. | Exercise | Exercise Content | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|---|---|-----------------|---------------|---------------------------|
| 1 | History of Engineering in Healthcare | <ul style="list-style-type: none"> Prepare a historical summary of the development of engineering and technology in healthcare. Identify key milestones in the evolution of medical devices. | 1 | 2 | -- |
| 2 | Comparing Biomedical Engineers and Clinical Engineers | <ul style="list-style-type: none"> Create a report detailing the differences between biomedical engineers and clinical engineers. Analyze case studies that illustrate the role of each in the healthcare system. | 1 | 2 | a1 |
| 3 | Responsibilities of Biomedical and Clinical Engineers | <ul style="list-style-type: none"> Design an organizational chart showing the departments involved in clinical engineering within hospitals. | 1 | 2 | a1, c2 |

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| No. | Exercise | Exercise Content | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|--|--|-----------------|---------------|---------------------------|
| | | <ul style="list-style-type: none"> Write an essay discussing the difference between engineering and maintenance in healthcare. | | | |
| 4 | Medical Device Classification | <ul style="list-style-type: none"> Develop a classification list for medical devices, including categories and applicable standards. Analyze real-world examples to apply the classifications. | 1 | 2 | a2 |
| 5 | Biomedical Technology Assessment | <ul style="list-style-type: none"> Conduct a case study on assessing biomedical technology and its applications. Create a model for evaluating the technology needs of a hospital. | 1 | 2 | b1 |
| 6 | Hospital Organization and Management | <ul style="list-style-type: none"> Create an organizational chart of a hospital showing the administrative structure and functional divisions. Write a report on the role of clinical engineers within the hospital. | 1 | 2 | d1 |
| 7 | Medical Devices Inventory Management | <ul style="list-style-type: none"> Develop a model for managing medical device records, including key data entries. Analyze inventory management data and provide recommendations for improvement. | 1 | 2 | c1 |
| 8 | Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> Study public procurement law with a focus on the procurement process. Prepare a report on procurement procedures and approvals in hospitals. | 1 | 2 | b2, d2 |
| 9 | Healthcare Quality | <ul style="list-style-type: none"> Analyze quality improvement methodologies in healthcare and prepare a report. Study examples of quality issues in hospitals and propose solutions. | 1 | 2 | b1 |
| 10 | Medical Device Standards | <ul style="list-style-type: none"> Prepare a report on global standards for medical devices and how they are applied. | 1 | 2 | a2 |

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| No. | Exercise | Exercise Content | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|--|----------|--|-----------------|---------------|---------------------------|
| | | <ul style="list-style-type: none"> Analyze practices for developing and promulgating standards in healthcare. | | | |
| Number of Weeks /and Units Per Semester | | | 10 | 20 | |

| No. | Exercise | Exercise Content | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|-----|---|--|-----------------|---------------|---------------------------|
| 1 | History of Engineering in Healthcare | <ul style="list-style-type: none"> Prepare a historical summary of the development of engineering and technology in healthcare. Identify key milestones in the evolution of medical devices. | 1 | 2 | -- |
| 2 | Comparing Biomedical Engineers and Clinical Engineers | <ul style="list-style-type: none"> Create a report detailing the differences between biomedical engineers and clinical engineers. Analyze case studies that illustrate the role of each in the healthcare system. | 1 | 2 | a1 |
| 3 | Responsibilities of Biomedical and Clinical Engineers | <ul style="list-style-type: none"> Design an organizational chart showing the departments involved in clinical engineering within hospitals. Write an essay discussing the difference between engineering and maintenance in healthcare. | 1 | 2 | a1, c2 |
| 4 | Medical Device Classification | <ul style="list-style-type: none"> Develop a classification list for medical devices, including categories and applicable standards. Analyze real-world examples to apply the classifications. | 1 | 2 | a2 |
| 5 | Biomedical Technology Assessment | <ul style="list-style-type: none"> Conduct a case study on assessing biomedical technology and its applications. Create a model for evaluating the technology needs of a hospital. | 1 | 2 | b1 |
| 6 | Hospital Organization and Management | <ul style="list-style-type: none"> Create an organizational chart of a hospital showing the administrative structure and functional divisions. Write a report on the role of clinical engineers within the hospital. | 1 | 2 | d1 |

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| No. | Exercise | Exercise Content | Number of Weeks | Contact Hours | Learning Outcomes (CILOs) |
|---|--|--|-----------------|---------------|---------------------------|
| 7 | Medical Devices Inventory Management | <ul style="list-style-type: none"> Develop a model for managing medical device records, including key data entries. Analyze inventory management data and provide recommendations for improvement. | 1 | 2 | c1 |
| 8 | Public Procurement Law and Procurement Methods | <ul style="list-style-type: none"> Study public procurement law with a focus on the procurement process. Prepare a report on procurement procedures and approvals in hospitals. | 1 | 2 | b2, d2 |
| 9 | Healthcare Quality | <ul style="list-style-type: none"> Analyze quality improvement methodologies in healthcare and prepare a report. Study examples of quality issues in hospitals and propose solutions. | 1 | 2 | b1 |
| 10 | Medical Device Standards | <ul style="list-style-type: none"> Prepare a report on global standards for medical devices and how they are applied. Analyze practices for developing and promulgating standards in healthcare. | 1 | 2 | a2 |
| Number of Weeks /and Units Per Semester | | | 10 | 20 | |

VI. Teaching Strategies of the Course:

- Interactive lectures
- Discussions
- Presentation
- Problem-based learning
- Interactive Exercises
- Problem Sets
- Role-Playing
- Group Discussions

VII. Assessment Methods of the Course:

- Quizzes

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- Mid-term theoretical exam
- Final theoretical exam
- Assignments
- Class Participation

V. Assignments:

| No. | Assignments | Week Due | Mark | Aligned CILOs (symbols) |
|--------------|--------------|----------|-----------|-------------------------|
| 1 | Assignment 1 | Week 8 | 5 | a1, a2, b1, c1, d1 |
| 2 | Assignment 2 | Week 14 | 5 | a2, b2, c2, d2 |
| Total | | | 10 | |

VI. Schedule of Assessment Tasks for Students During the Semester:

| No. | Assessment Method | Week Due | Mark | Proportion of Final Assessment | Aligned Course Learning Outcomes |
|--------------|---------------------------|------------------------|-------------|--------------------------------|----------------------------------|
| 1 | Assignments and Quizzes | Weeks 4, 8, 12, 14, 15 | 10 | 10% | a1, a2, b1, b2, c1, c2, d1, d2 |
| 2 | Mid-Term Theoretical Exam | Week 7 | 20 | 20% | a1, a2, b1, b2, c1 |
| 4 | Final Theoretical Exam | Week 16 | 70 | 70% | a1, a2, b1, b2, c1, c2 |
| Total | | | 100% | 100% | - |

VI. Schedule of Assessment Tasks for Students During the Semester:

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|--------------------|--------------|-------------------------|-------------------------|-----------------------|
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| No . | Assessment Method | Week Due | Mark | Proportion of Final Assessment | Aligned Courses Learning Outcomes |
|------|-------------------------|---------------------------------|------|--------------------------------|---|
| 1 | Assignments and Quizzes | Weeks 4, 8, 12, 14, 15 | 10 | 10% | a1 , a2 , b1 , b2 , c1 , c2 , d1 , d |

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| No . | Assessment Method | Week Due | Mark | Proportion of Final Assessment | Aligned Courses Learning Outcomes |
|------|---------------------------|----------|------|--------------------------------|-----------------------------------|
| 2 | Mid-Term Theoretical Exam | Week 7 | 20 | 20% | a1, a2, b1, b2, c1 |
| 4 | Final Theoretical Exam | Week 16 | 70 | 70% | a1, a2, b |

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| No . | Assessment Method | Week Due | Mark | Proportion of Final Assessment | Aligned Courses Learning Outcomes |
|-------|-------------------|----------|-------|--------------------------------|-----------------------------------|
| | | | | | 1, b2, c1, c2 |
| Total | | | 100 % | 100% | - |

VII. Learning Resources:

1- Required Textbook(s) (maximum two):

- Bruley, D. F., 2017, Clinical Engineering: A Handbook for Clinical and Biomedical Engineers, 1st Edition, Cambridge, Cambridge University Press.
- Kumar, R., & Soni, R., 2017, Biomedical Engineering: Bridging Medicine and Technology, 2nd Edition, Boston, Academic Press.

2- Essential References:

- Christensen, C. M., & Raynor, M. E., 2013, The Innovator's Prescription: A

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- Disruptive Solution for Health Care, 1st Edition, New York, McGraw-Hill Education.
5. Goh, C. H., & Xu, Y., 2018, Medical Device Regulations and Standards, 1st Edition, London, CRC Press.
 6. Eckert, R., 2015, Principles of Biomedical Engineering, 3rd Edition, Oxford, Oxford University Press.

3- Electronic Materials and Web Sites etc.:

Websites:

3. U.S. Food and Drug Administration (FDA) - Medical Devices:
<https://www.fda.gov/medical-devices>
4. International Organization for Standardization (ISO) - Medical Devices:
<https://www.iso.org/committee/54818.html>

Journals:

3. Biomedical Engineering Online: <https://biomedical-engineering-online.biomedcentral.com/>
4. Journal of Clinical Engineering: <https://www.tandfonline.com/toc/ucen20/current>

Other Web Sources:

3. Clinical Engineering Handbook: <https://www.elsevier.com/books/clinical-engineering-handbook/pereira/978-0-12-800930-0>
4. National Institute for Health and Care Excellence (NICE) - Guidelines and Resources: <https://www.nice.org.uk/guidance>

VIII. Course Policies: (Based on the Uniform Students' By law (2007))

| | |
|---|--|
| 1 | Class Attendance: Class Attendance is mandatory. A student is considered absent and shall be banned from taking the final exam if his/her absence exceeds 25% of total classes. |
| 2 | Tardiness: A student will be considered late if he/she is not in class after 10 minutes of the start time of class. |
| 3 | Exam Attendance/Punctuality: No student shall be allowed to the exam hall after 30 minutes of the start time, and shall not leave the hall before half of the exam time has passed. |
| 4 | Assignments & Projects: Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same. |
| 5 | Cheating: Cheating is an act of fraud that results in the cancelation of the student's exam or assignment. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply. |
| 6 | Forgery and Impersonation: Forgery/Impersonation is an act of fraud that results in the cancelation of the student's exam, assignment or project. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply. |
| 7 | Other policies: The University official regulations in force will be strictly observed and students shall comply with all rules and regulations of the examination set by the Department, Faculty and University Administration. |

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