SRM VALLIAMMAI ENGINEERING COLLEGE

(An Autonomous Institution)

SRM Nagar, Kattankulathur – 603 203

DEPARTMENT OF MEDICAL ELECTRONICS

QUESTION BANK

V SEMESTER

1910502-MEDICAL INSTRUMENTATION

Regulation – 2019

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Prepared by

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DEPARTMENT OF MEDICAL ELECTRONICS

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SUBJECT : 1910502 -MEDICAL INSTRUMENTATION

SEM / YEAR : V / III

UNIT I – BASIC CONCEPTS OF MEDICAL INSTRUMENTATION AND BIO SENSORS

BASIC CONCEPTS OF MEDICAL INSTRUMENTATION: Terminology of medicine and medical devices, generalized medical instrumentation system, alternative operational modes, medical measurement constraints-classification of biomedical instruments biostatistics-regulations of medical devices.

BIO POTENTIAL & BIO SENSORS: Origin of bio potential and its propagation. Electrode–skin interface, half-cell potential. Types of electrodes and its application. Recording problems - measurement with two electrodes.

BIOSENSOR: Need of sensors, working principle of biosensor, various types of biosensors and its applications, bio transducers, bio interface.

PART – A

Q.No	Questions	BT Level	Competence
1	What is the role of biosensors in medical field?	BTL-1	Remembering
2	List the components are available in biosensors.	BTL-1	Remembering
3	How are biological signals generated in humans?	BTL-2	Understanding
4	Identify the types of Biopotential electrodes used to measuring bio signal	BTL-2	Understanding
5	Discusses the origin of bioelectric signal.	BTL-2	Understanding
6	Categorize the difference between active and passive bio signals?	BTL 4	Analyzing
7	Examine the function of electrode-electrolyte interface and electrode tissue interface are used in human tissue?	BTL 4	Analyzing
8	What are the changes that occur at the electrode-electrolyte interface when current is passed?	BTL-1	Remembering
9	Draw the equitant circuit Half-cell potential electrode electrolyte interface	BTL-1	Remembering
10	Interpret on need of biosensors are used in measuring bio signals?	BTL 4	Analyzing
11	Discover the biosensors describe its main components working principle and applications in healthcare?	BTL 3	Applying
12	Show the bio transducers used for measuring redox enzymes?	BTL 3	Understanding
13	Explain the different processing methods are involved in generalised medical instrumentation system.	BTL 4	Analyzing
14	Using sing an example, Explain Surface attachment of a biological element in human body.	BTL 3	Applying

15	Outline the different types of biosensors and give the suitable applications.	BTL 4	Analyzing
16	What is an intelligent medical instrument?	BTL-1	Remembering
17	Explore a diagram showing various parts of an implantable medical device	BTL 3	Applying
18	Show the various types of equipment classification based on method of electrodes.	BTL 3	Applying
19	Name five types of bio-signals and explain their origin.	BTL-1	Remembering
20	Estimate the different properties of Electrode in skin interface.	BTL 3	Applying
21	What are the advantages of Silver-Silver chloride electrode?	BTL-1	Remembering
22	Mention the types of microelectrodes. What are their applications?	BTL 4	Analyzing
23	Describe the three main elements of a biosensor?	BTL-2	Understanding
24	Write the different between Metal microelectrode and Micropipette?	BTL 3	Applying
	Part-B		
1	Summarize with the help of a diagram of electromyogram signal and give its characteristic values in terms of amplitude and frequency. (13)	BTL-2	Understanding
2	Draw the diagram for electrode-tissue interface for surface electrodes used with electrode jelly. Explain metal-electrolyte and electrolyte skin interface. (13)	BTL-1	Remembering
3	(i) Define contract potential. What are the factors on which contact potential depends (7) (ii) How we can reduce the contact potential? Explain. (6)	BTL-1	Remembering
4	Classify the various types of electrodes used for recording of ECG signal? Give a brief description of at least 3 types of electrodes. (13)	BTL-2	Understanding
5	Explain the method used for measurement of foetal heart rate from direct foetal ECG. What are the types of electrodes used for the purpose? (13)	BTL-2	Understanding
6	Demonstrate the various types of electrodes used with surgical diathermy? Explain the difference between cutting and coagulating waveforms used in electrosurgery technique (13)	BTL-3	Applying
7	What is a biosensor? Describe with the help of a diagram the construction of a blood glucose biosensor. (13)	BTL-1	Remembering
8	How they are classifying the electrochemical biosensors. Explain working principle any two and give their applications (13)	BTL 4	Analyzing
9	write shot nots on the following (i) Types of electrodes and its application (7) (ii) types of biosensors and its applications (6)	BTL-1	Remembering
10	Discriminate following regulations based on medical devices (i) Biomedical instruments biostatistics (7) (ii) Generalized medical instrumentation system (6)	BTL 4	Analyzing
11	Write in terms of constructional and working details of the following types of real time electrodes (i) Skin interface electrode (6) (ii) Half-cell potential electrode (7)	BTL-3	Applying

12	Outline the terminology used in medicine and medical devices based on concept of medical instrumentation system (13)	BTL 4	Analyzing
13	Outline the recording problems are occurred when using biosensor of two electrodes, Explain. (13)	BTL 4	Analyzing
14	(i) Summarize the origin of bio potential signal and its propagation. (6) (ii) Discover the signals are meet the artifact for measuring bio instrumentation for need sensor (7)	BTL-3	Applying
15	What kind of electrodes are used in electrical biosensor? And give the classification of electrochemical biosensors and Explain. (13)	BTL-1	Remembering
16	Describe the following, a). Body surface Electrodes, (6) b). Needle Electrode. (7)	BTL-2	Understanding
17	Illustrate the biosensors are fetch in to human body when we receive the signal, what are the recording problems are arrived? (13)	BTL-3	Applying
	Part-C		
1.	Express with the help of a block diagram a generalized medical instrumentation system and its various subsystems. (15)	BTL-1	Remembering
2.	(i) Examine a study of bio potential and bio sensors based on the measurement of two electrodes. (8) **(ii)** Illustrative suitable diagram of bio sensors-based electrodes and give the list the applications. (7)	BTL 4	Analyzing
3.	Describe the classification of biomedical instruments and give the regulations of medical devices with shoutable examples. (15)	BTL-2	Understanding
4.	Interpret the various types of equipment classification based on method of protection and based on degree of protection. (15)	BTL-3	Applying
5.	Illustrate the following medical Instrumentation function a). Working Principle of Biosensors, (8) b). Electrode with skin interface. (7)	BTL-3	Applying

UNIT II - ELECTRODE CONFIGURATIONS & BIO AMPLIFIER			
Bio signals characteristics – frequency and amplitude ranges. ECG – Einthoven‘s triangle, standard 12 lead system. EEG – 10-20 electrode system, unipolar, bipolar and average mode. EMG– unipolar and bipolar mode. **BIO AMPLIFIER:** Need for bio-amplifier - single ended bio-amplifier, differential bio-amplifier, isolation amplifiers – transformer and optical isolation - isolated DC amplifier and AC carrier amplifier. Chopper amplifier.			
PART – A			
Q.No	**Questions**	**BT Level**	**Competence**
1	Name the characteristics of Biosignals?	BTL-1	Remembering
2	What is the frequency range of human bioelectrical signals?	BTL-1	Remembering
3	Distinguish between ECG and EMG of bio signals?	BTL-2	Understanding
4	Illustrate the leads Makeup the einthoven's triangle?	BTL-3	Applying

5	Outline the frequency range of EEG.	BTL 4	Analyzing
6	Estimate the significance of einthoven's triangle explain the lead system of ECG measurement?	BTL-2	Understanding
7	Outline the function of chopper amplifier?	BTL 4	Analyzing
8	Describe the difference between active and passive bio signals?	BTL-2	Understanding
9	Name the application of Isolation Amplifier.	BTL-2	Understanding
10	Write the challenges of designing of bio potential amplifier?	BTL-1	Remembering
11	Interpret what type of electrodes used for EMG?	BTL-3	Applying
12	Apply when the differential amplifier is operated single ended?	BTL-3	Applying
13	Predict the two stages in a typical isolation amplifier?	BTL 4	Analyzing
14	Draw the Block diagram of Isolation amplifier.	BTL-1	Remembering
15	List the advantages of DC chopper?	BTL-1	Remembering
16	What are the essential features required for bio potential amplifiers?	BTL-1	Remembering
17	Generalize which factors is affect EMG signal quality?	BTL 4	Analyzing
18	Analyses how to measured ECG and EMG	BTL 4	Analyzing
19	Point out the principle of EMG.	BTL 4	Analyzing
20	What does an abnormal EMG sound like?	BTL-1	Remembering
21	Which leads make up the einthoven triangle?	BTL 4	Analyzing
22	Describe the 10-20 electrode system in EEG recording?	BTL-3	Applying
23	Where are the electrodes T1 and T2 placed?	BTL-2	Understanding
24	When differential amplifier is single-ended?	BTL-3	Applying
PART – B			
1	Analyses the type of Chopper Amplifier and draw the circuit diagram and explain the working principle of each and list the application. (13)	BTL 4	Analyzing
2	Explain the working principle of isolation amplifiers in detail, give the relation of their types and write of their merits. (13)	BTL-3	Applying
3	i). Estimate the detail about ECG Isolation amplifier, (6) (ii). Discusses the advantage and disadvantage of the isolation amplifier. (7)	BTL-2	Understanding
4	(i) Describe detail about requirements of biological amplifiers (6) (ii) Draw the voltage and frequency range of common bio potential signals (7)	BTL-1	Remembering
5	Categorize the need of an ‘Isolation Amplifier’? Explain the working of optically isolated isolation amplifier. (13)	BTL 4	Analyzing
6	Relate the isolated DC amplifier and AC carrier amplifier used to measured low frequency signal and expires the operation of low frequency amplifier. (13)	BTL-3	Applying
7	Schedule the operation of transformer isolated amplifier and give the detail about merits of isolated amplifier. (13)	BTL-3	Applying
8	Explain the differential amplifier and why it is preferred for applications in recording of bioelectric signals? (13)	BTL-2	Understanding

9	(i) How is a single ended amplifier different from a differential Amplifier? (7) (ii) Explain the working principle of single ended amplifier? (6)	BTL-1	Remembering
10	Illustrate the essential features required for bio potential amplifiers? Write detail about need for bio-amplifier with example (13)	BTL-3	Applying
11	(i) What is the frequency range of human bioelectrical signals? Give the primary characterise of bio signals? (7) (ii) give the standard position of electrode in ECG and explain(6)	BTL 4	Analyzing
12	Express the characteristics of Bio signals? Give the brief description of their functionality and related clinical applications. (13)	BTL-2	Understanding
13	Explain the Wilson central terminal 12 lead system of ECG measurement? And give the suitable expression. (13)	BTL-2	Understanding
14	What are the 4 landmarks of the skull that are used for the 10 - 20 electrode placement and explain? (13)	BTL-1	Remembering
15	Summarize the following electrode configuration, a). ECG standard 12 lead systems, (6) b). EEG unipolar mode and bi polar mode. (7)	BTL-2	Understanding
16	Show the function of following amplifier characteristics, a). Differential Bio-Amplifier, (7) b). Optical isolation. (6)	BTL-1	Remembering
17	Discriminate the electrode configuration EMG– unipolar and bipolar mode. And explain. (13)	BTL 4	Analyzing
	Part-C		
1	Enumerate the various types of depth and needle electrodes used to measure EEG and EMG potentials (15)	BTL-1	Remembering
2	Explain the placement of electrodes to measure EMG waveform and recording procedure. (15)	BTL-2	Understanding
3	(i) Why isolation amplifiers are needed in the biomedical instrumentation? Explain with an example (8) (ii) Explain the construction and working of Transformer type and optical isolation amplifier (7)	BTL-3	Applying

4	An electrocardiograph has a broad frequency response so that its amplifier has a first-order time constant of 16 s. The electrocardiograph amplifier has a broad dynamic range of input voltage, but any input voltage grater then ± 2 mV will be out the range of its display and cut off. Will recording the ECG of a patient, a transient occurs that has an amplitude of 10 mV, and this cases the ECG to fall out of the range of the instruments display. If the ECG R wave has an amplitude of 1 mV, How long will it take for the entire signal to be visible on display? (15)	BTL-3	Applying
5	Analysis the following bio electrode and amplifier function, a). EEG-10-20 electrode average mode, (5) b). Bio signal characteristics, (5) c). Optical Isolation Amplifier. (5)	BTL 4	Analyzing

UNIT III - MEASUREMENTS OF BLOOD PRESSURE, BLOOD VOLUME AND CARDIAC OUTPUT

PRESSURE: Direct and indirect measurements-harmonic analysis of blood pressure waveforms-heart sounds-phonocardiography.

Blood volume: Electromagnetic flow meters-ultrasonic flowmeters-chamber plethysmography-photo plethysmography.

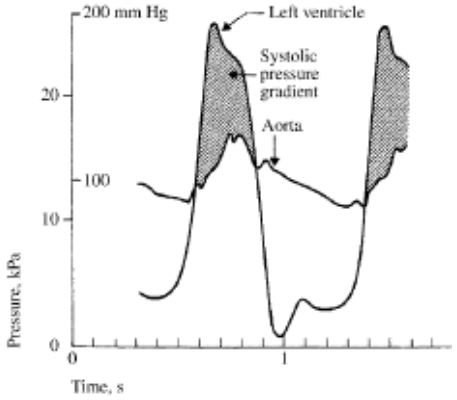
CARDIAC OUTPUT MEASUREMENTS: Indicator dilution, thermal dilution and dye dilution method, Electromagnetic and ultrasound blood flow measurement.

PART – A

Q.No	Questions	BT Level	Competence
1	What are the direct method of measuring blood pressure?	BTL-1	Remembering
2	Discuss what type of sphygmomanometer is commonly used in measuring indirect blood pressure?	BTL-2	Understanding
3	Which type of typical set-up of a fluid-filled system for measuring blood	BTL-3	Applying
4	Employ the equation of natural frequency of the system blood presser and specify the parameters.	BTL-3	Applying
5	Identify the Principle of blood pressure measurement based on Korotkoff sounds	BTL 4	Analyzing
6	List the Criteria for oscillometric blood pressure, write the shoutable equation of Diastolic blood pressure	BTL-1	Remembering
7	Analyses of harmonic blood pressure, draw the waveforms of harmonic pressure	BTL 4	Analyzing
8	Outline the mean of Phonocardiogram.	BTL 4	Analyzing
9	Discriminate the frequency range of heart sounds	BTL 4	Analyzing

10	Express the Characteristics of amplifiers with commonly employed filters in phonocardiography systems	BTL-2	Understanding
11	Name the methods are available to Phonocardiography based blood pressure	BTL-1	Remembering
12	How do you find the magnitude of voltage in an electromagnetic blood flow meter?	BTL-2	Understanding
13	Estimate the principle of electromagnetic blood flow meter?	BTL-3	Applying
14	Express the Residual Blood Volume.	BTL-2	Understanding
15	Determine the principle of ultrasonic flow meter?	BTL-3	Applying
16	What are the types of flow meters?	BTL-1	Remembering
17	Find the difference between the Ac and DC flow meter.	BTL-1	Remembering
18	Identify what are the two primary factors determine cardiac output?	BTL 4	Analyzing
19	What gas law is used as the basis for body plethysmography?	BTL-2	Understanding
20	Compute the Photoplethysmography measure?	BTL-3	Applying
21	List the types of measurements in blood pressure?	BTL-1	Remembering
22	Sketch the phonocardiography waveform using cardiac cycle.	BTL-2	Understanding
23	Write the equation of blood volume calculation in both males and females?	BTL-3	Applying
24	What units are used for cardiac output?	BTL 4	Analyzing
	PART – B		
1	Predict which method is using direct methods of measuring blood pressure? Draw a typical set up of a pressure measuring system by direct method. (13)	BTL-3	Applying
2	What type of transducer is used for measuring direct blood pressure? Draw a simple circuit for calculating systolic and diastoylic blood pressure (13)	BTL-1	Remembering
3	Discoverer the origin of heart sounds and the sensors used for recording the same. What are the special characteristics of the amplifiers used in phonocardiography? (13)	BTL-3	Applying
4	Illustrate the Specifications of the Photoplethysmography, draw the electrical circuit and explain (13)	BTL-3	Applying
5	(i) What is thermal dilution method for cardiac output measurement? (5) (ii) Explain the block diagram of the processing and computing circuit of thermal dilution method for cardiac output. (8)	BTL-1	Remembering
6	Explain the impedance technique for measuring of increasing cardiac output and indicate its advantages. (13)	BTL 4	Analyzing
7	Describe the working of an electromagnetic flowmeter with the help of a block diagram. Explain the working of each sub-system. (13)	BTL-2	Understanding
8	Name the various methods for measurement of blood flow and explain one of them in detail. (13)	BTL-1	Remembering

9	Categorise the different between direct and indirect presser measurements, Explain any one in detail. (13)	BTL 4	Analyzing
10	Analysis the harmonic analysis of blood pressure waveforms, write detail in harmonic analysis of blood presser. (13)	BTL 4	Analyzing
11	Write short notes on following. (i) Heart sounds (6) (ii) Ultrasonic flowmeters. (7)	BTL 4	Analyzing
12	Express the types of blood flow meter and explain Square Wave Electromagnetic Flowmeters with shoutable diagram. (13)	BTL-2	Understanding
13	Outline the principle of ultrasonic flowmeters and give the suitable diagram. (13)	BTL-3	Applying
14	Summarize the operation of ultrasound blood flow measurement and thermal dilution blood cardiac measurement. (13)	BTL-2	Understanding
15	What is the function of Intravascular pressure sensor? Explain their classification and functions? (13)	BTL-1	Remembering
16	Sketch the correlation of the four heart sounds with electrical and mechanical events of the cardiac cycle? And explain. (13)	BTL-2	Understanding
17	In block-diagram from, show the elements required for an automatic indirect system for measuring blood pressure (13)	BTL-3	Applying
PART – C			
1	List the difference between Indicator dilution, thermal dilution and explain with shoutable diagram (15)	BTL-1	Remembering
2	Express operation of chamber plethysmography, photo plethysmography. (15)	BTL-2	Understanding
3	Summarise how the blood presser measured using direct and indirect method, explain briefly and give defence of both methods. (15)	BTL-2	Understanding
4	Demonstrate the following blood presser and blood volume method (15) (i) Harmonic analysis of blood pressure waveforms (ii) Chamber plethysmography (iii) Dye dilution method	BTL-3	Applying

5	Calculate the approximate area of the aortic value for the patient with the aortic and left-ventricular pressures as show in figure. The patients cardic output was measured by thermodilution as 6400ml/min and heart rate as 78 bpm. Blood density is 1060 kg/m^3. (15)  	BTL 4	Analyzing

UNIT – IV: CLINICAL LABORATORY INTRUMENTS			
Blood gas and acid base Physiology –Electro chemical sensor, Chromatology, Electrophoresis - Blood cell counter, Auto analyzer, Centrifuge, Blood gas analyzers, colorimeter, flame photometer, spectrophotometer.			
PART – A			
Q.No	**Questions**	**BT Level**	**Competence**
1	List the 4 types of acid base imbalance?	BTL-1	Remembering
2	Identify the physiology of acid base balance?	BTL-2	Understanding
3	Which blood gas causes changes in pH?	BTL 4	Analyzing
4	Determine the four components of blood gasses?	BTL-3	Applying
5	Indicate the ABG of an important assessment tool for the client's acid base homeostasis?	BTL 4	Analyzing
6	What kind of blood tests are indicate multiple myeloma?	BTL-2	Understanding
7	Analyse what does abnormal blood protein mean?	BTL 4	Analyzing
8	Interpret what does an electrophoresis blood test show?	BTL-3	Applying
9	How long does a hemoglobin electrophoresis test take?	BTL-2	Understanding
10	Estimate the terms of mean cell volume (MCV)	BTL-2	Understanding
11	Show the error due to Temperature Variation for blood cell.	BTL-3	Applying
12	Is there an automated type of electrophoresis?	BTL-1	Remembering
13	identify the application of electrophoresis	BTL-1	Remembering
14	Show the effect of Blood on Electrodes	BTL-3	Applying
15	Distinguish between Flame Photometer and spectrophotometer?	BTL 4	Analyzing
16	What wavelength does a colorimeter use?	BTL-1	Remembering
17	Describe the sample concentration of full scale in blood	BTL-2	Understanding
18	Relate the three essential parts of flame photometer	BTL-3	Applying
19	Draw the Schematic diagram of a flame photometer	BTL-2	Understanding

20	Write the Various components of a spectrophotometer	BTL 4	Analyzing
21	What are the important critical care analytes of blood levels?	BTL-1	Remembering
22	Write the blood gases related parameter of following metrics Po_2, Pco_2, pH, Hematocrit and total haemoglobin.	BTL-2	Understanding
23	Sketch the schematic diagram Po_2 electrode.	BTL-3	Applying
24	Classify the type of support media are used in electrophoresis.	BTL 4	Analyzing
	PART – B		
1	What is the function of a blood gas analyser? Why is it necessary to maintain acid-base balance in the body? Indicate the normal blood pH value. (13)	BTL-1	Remembering
2	Write the equation giving relationship between potential generated and pH (nearest equation) for a glass electrode. Define slope factor and draw a graph showing relationship between pH and emf at 25 °C. (13)	BTL-2	Understanding
3	Draw a diagram showing the constructional details of microcapillary electrode for measurement of blood pH. What is the effect of blood on the working of the glass electrode and measures taken to minimize the effect? (13)	BTL-1	Remembering
4	Express following Physiology method and explain with net diagram (i) Calculation of Size of Cells (7) (ii) Methods Of Cell COUNTIN (6)	BTL-2	Understanding
5	Illustrate what are the commonly used methods for blood cell counting? Explain the principle of electrical conductivity method. (13)	BTL 4	Analyzing
6	Draw the block diagram of a Coulter Counter and explain its working. What is the size of the orifice for red and white cells and platelet? (13)	BTL-2	Understanding
7	Define and explain the following (a) Packed Cell Volume (PcV) (4) (b) Mean Cell Volume (McV) (3) (c) Mean Cell Haemoglobin value (McH) (3) (d) Mean Platelet Volume (MPV) (3)	BTL-1	Remembering
8	Illustrate and draw the block diagram of electro chemical sensor chromatology and explain its working. (13)	BTL-3	Applying
9	Discover the function of following (i) Essential parts A flame photometer with diagram (7) (ii) Schematic diagram of a flame photometer. (6)	BTL-3	Applying
10	Analyze the principle of colorimeter, write the Sample concentration of colorimeter and Multi-channel Colorimeter (13)	BTL 4	Analyzing
11	Explain the working principle of optical filer in spectrometers and write the classification and draw suitable block diagram with explanation. (13)	BTL-2	Understanding
12	Describe the three-essential part of flame photometer, and draw the essential part of flame photo meter, explain each block in detail. (13)	BTL-1	Remembering

13	(i) Interpret what are the component of the ABG analyzer? (5) (ii) How pH, PCO_2 and PO_2 are measured in a blood gas analyser and briefly state the underlying principle behind each of those measurements. (8)	BTL-3	Applying
14	How to find the blood cell count using Optical method? Explain with shoutable block diagram. (13)	BTL 4	Analyzing
15	A blood specimen has a hydrogen ion concentration of 40 nmol/liter and a Pco_2 of 60 mm Hg. What is the pH? What type of acid-base abnormality does the patient exhibit? (13)	BTL-2	Understanding
16	Sketch the schematic diagram of a pH electrode? How to measure pH values of blood using pH electrode, and Explain. (13)	BTL-3	Applying
17	Explain how the cellulose acetate electrophoresis work, To find the proteins in plasma, urine and CSF? (13)	BTL 4	Analyzing
PART – C			
1	(i) 1 litre of blood contains 0.45 litres of red cells and if there are 5 X 10^{12} red cells per litre, find the mean volume of one cell. (7) **(ii)** if there are 15 g of Hb per decilitre (dl) of blood, there will be 150-gram Hb per litre of blood. Supposing the number of red cells is 5 X 10^{12} per litre, find the mean cell haemoglobin. (8)	BTL-3	Applying
2	Describe the internal bock diagram of flame photometer? Explain their function. What is the special clinical application of a flame photometer? (15)	BTL-1	Remembering
3	Write the following and explain (i) Schematic diagram of a Blood Cell Counter (8) (ii) Blood Cell Auto analyzer. (7)	BTL-3	Applying
4	Calculate pH, PCO_2 and PO_2 are measured based on in a blood gas analyser and briefly those measurements. (15)	BTL-2	Understanding
5	Calculate the RBC indices (MCV, MCH and MCHC) from the following data RBC = 5 million/µl, Hb = 15 g/dl, HCT = 45% (15)	BTL 4	Analyzing

UNIT V - DESIGN AND DEVELOPMENT OF BIOMEDICAL DEVICES AND SYSTEMS

The Essentials of Design—Overview- Biomedical Engineering Design in Industrial Context- Fundamental Design Tools- Product Definition- Product Development Hardware Development Methods and Tools- Software Development Methods and Tools, Biomaterials and Material Testing- Biological Engineering Designs. Developing Biomedical Devices- Emerging Issues in Healthcare- Innovation and Rights- Industrial Designs- Patent Classification- Examples of Industrial Design Requirements Evaluations

PART – A

Q.No	Questions	BT Level	Competence
1	What are the stages of medical device development?	BTL-1	Remembering
2	How do you design a medical device?	BTL-2	Understanding
3	Point out the factors to be considered in designing a medical instrument?	BTL 4	Analyzing
4	Analyze stages phases are there in a medical new product design and development?	BTL 4	Analyzing
5	Indicate the key criteria in which decides whether a software needs to be classified as a medical device?	BTL-2	Understanding
6	Name examples of medical devices?	BTL-1	Remembering
7	Write some common work contexts for biomedical engineers?	BTL-3	Applying
8	Illustrate the contexts for biomedical engineers and give some suitable example.	BTL-3	Applying
9	Categorize the function of ASTM F543?	BTL 4	Analyzing
10	Interpret the development of FDA stages in medical Instrument	BTL-3	Applying
11	Does a Medical Device need FDA Approval?	BTL-3	Applying
12	Generalized the factors to be considered in designing a medical instrument?	BTL-2	Understanding
13	List the major issues in healthcare?	BTL-1	Remembering
14	Why are intellectual property rights important for innovation?	BTL-2	Understanding
15	What does an industrial designer do?	BTL-3	Applying
16	What is CPC classification?	BTL-1	Remembering
17	How do you find the classification of a patent?	BTL 4	Analyzing
18	Describe the IPC and CPC classification?	BTL-2	Understanding
19	What are the examples of industrial design?	BTL-1	Remembering
20	What are some examples of products an industrial designer might work on?	BTL 4	Analyzing
21	Sketch the environmental interactions of biological engineering designs.	BTL-2	Understanding
22	What is a biological system?	BTL-1	Remembering
23	Outline the hemocompatibility tests in five different categories.	BTL-3	Applying
24	List some of the risk analysis activities for this project	BTL 4	Analyzing

PART – B

1	Describe the overview of biomedical engineering design in Industrial context, explain any one of the examples of biomedical industry context. (13)	BTL-2	Understanding

2	Name the common types of Industrial Context NAICS Code 541715 and give example. (13)	BTL-1	Remembering
3	Write Short notes on the following (i) Biological Engineering Designs (7) (ii) Emerging Issues in Healthcare (6)	BTL-1	Remembering
4	Summarise the process of development in biomedical devices and explain with suitable examples. (13)	BTL-2	Understanding
5	Elaborate software development methods and tools biomaterials and material testing in biomedical industry (13)	BTL-2	Understanding
6	Explain innovation, rights in detail of medical equipment industry. (13)	BTL-2	Understanding
7	Highlight the different types of Hardware Product Development tools are available in industry. (13)	BTL 4	Analyzing
8	Interpret the biomedical device development of different types of hardware devices are available in market. (13)	BTL-3	Applying
9	Analyze how the basic mechanical property and testing methods are used biomedical materials with give the suitable material testing method. (13)	BTL 4	Analyzing
10	What are the emerging trend in healthcare technology, explain any five healthcare technology with shoutable examples. (13)	BTL-1	Remembering
11	How long does it take to develop a Medical Device? What are the FDA stages? How much does it cost to develop a medical FDA device? (13)	BTL 4	Analyzing
12	Illustrate Role of the IPR in invention system in medical Equipment industry and write IPR across in Nation. (13)	BTL-3	Applying
13	Interpret the Classification of patten and layout of classification symbols with Explain with suitable example. (13)	BTL-3	Applying
14	What kind of qualifications do you need to be an industrial designer? Explain with suitable example of Industrial Design Requirements Evaluations.	BTL-3	Applying
15	Illustrate the steps in the biological evaluation of medical devices as category and choice of test program. (13)	BTL 4	Analyzing
16	What are the biological control tests used? And explain for every test. (13)	BTL-1	Remembering
17	How to evaluate the biological object using biological test? (13)	BTL-3	Applying
	PART – C		
1	Summarize the risk factors to design in healthcare equipment and write the intraocular property of emerging issues in new druges. (15)	BTL-2	Understanding
2	Illustrate the difference between the IPR accurse system and IPR accurse nation. and Explain IPR accurse system (15)	BTL-3	Applying
3	What is the biggest problem in healthcare today? Explain any five problems with shoutable examples. (15)	BTL-1	Remembering

4	Testing at the Micro- or Nano-scale tools biomaterials and material testing (15)	BTL-3	Applying
5	Describe in detail with software design levels of software development methods and tools. (15)	BTL 4	Analyzing