U.S.N.										

B.M.S. College of Engineering, Bengaluru-560019

Autonomous Institute Affiliated to VTU

January / February 2025 Semester End Main Examinations

Programme: B.E. **Semester: VII**

Branch: Medical Electronics Engineering **Duration: 3 hrs.**

Course Code: 22MD7PCMDD **Max Marks: 100**

Course: Medical Device Development

Instructions: 1. Answer any FIVE full questions, choosing one full question from each unit.
2. Missing data, if any, may be suitably assumed.

		UNIT - I	*CO*	*PO*	Marks
1	a)	In the context of medical devices, exemplify who can recall a device and why?	*CO1*	*PO4*	**10**
	b)	"A 25-year-old male patient who was admitted in the Emergency ICU for the past 6 days (on a ventilator) suddenly had a drop in his oxygen saturation levels. The doctor in charge noticed that the lung movements were present but the patient was struggling to breath. He suspected that the endotracheal tube was blocked with dried up secretions. He tried to unblock the secretions by carrying out suctioning but the oxygen saturation kept dropping and was now close to 50%. The doctor then removed the endotracheal tube and then tried to re-intubate the patient. The saturation kept dropping and after a couple of attempts the doctor was able to insert a new endotracheal tube. In the meantime, due to the low oxygen saturation for the entire duration, hypoxic brain injury was suspected." Derive the following from the above clinical observation ● Problem ● Need-statement ● Possible must have ● Possible nice to have	*CO2*	*PO1*	**10**
		OR			
2	a)	What is a Need Specification Document? Briefly explain how need research is carried out by understanding the problem, population and outcome.	*CO1*	*PO4*	**10**
	b)	"A patient (male) in mid 50s came to the emergency room with numbness and lack of strength in all the limbs. The condition was worse on the right side. He was not able to move his legs and only	*CO4*	*PO6*	**10**

			his left hand could move. He had sustained injury to his back after a fall from height 1 week ago after which he had been to a local hospital where a CT scan of his brain was carried out. His spinal injury was missed and now his paralysis is severe and may not recover with surgery. If he was brought in early (within a few hours of the injury) his paralysis could have been prevented." Derive the following from the above clinical observation ● Problem ● Need-statement ● Possible must have ● Possible nice to have			
			UNIT - II			
	3	a)	A group of research students are working on a fetal monitoring system. Analyze the following for the device: functional requirement, safety, performance, user interface and usability.	*CO3*	*PO2*	**10**
		b)	Analyze the procedural steps required to obtain CDSCO approval for a medical device, and evaluate their significance in ensuring regulatory compliance.	*CO5*	*PO12*	**10**
			OR			
	4	a)	With the help of an example, discuss the key factors you would consider when segmenting the market for a medical device company.	*CO2*	*PO9*	**10**
		b)	There is a structured process for concept generation. This includes major steps Internal and External Search. Compare the Internal and external search and how it will be helpful in leading to optimum concept solutions.	*CO3*	*PO4*	**10**
			UNIT - III			
	5	a)	Explain the concept of "Serviceability of Medical Devices" and discuss how "Serviceability – Customer Impact" affects customer satisfaction and business performance.	*CO1*	*PO7*	**10**
		b)	With suitable examples discuss the different levels of Severity of Harm.	*CO3*	*PO6*	**10**
			OR			
	6	a)	Explain Design for Manufacturing (DFM) for Electronic Sub System in detail.	*CO2*	*PO5*	**10**
		b)	What is an insulin pump? Explain its working principle with a block diagram.	*CO3*	*PO2*	**10**

<table>
<tr><td></td><td></td><td></td><td colspan="4">UNIT - IV</td></tr>
<tr><td></td><td>7</td><td>a)</td><td>What is the role of human factors in design control? Discuss in Detail.</td><td>CO4</td><td>PO7</td><td>10</td></tr>
<tr><td></td><td></td><td>b)</td><td>Why is design Review important in the product development process? Explain in Detail</td><td>CO2</td><td>PO5</td><td>10</td></tr>
<tr><td></td><td></td><td></td><td colspan="4">OR</td></tr>
<tr><td></td><td>8</td><td>a)</td><td>Explain Design Verification and Design Validation in Design Engineering.</td><td>CO3</td><td>PO4</td><td>10</td></tr>
<tr><td></td><td></td><td>b)</td><td>Write a note on HE75 Human Factor engineering standards using intended and unintended actions.</td><td>CO4</td><td>PO6</td><td>10</td></tr>
<tr><td></td><td></td><td></td><td colspan="4">UNIT - V</td></tr>
<tr><td></td><td>9</td><td>a)</td><td>Draw the network diagram using forward and backward pass for the table shown below and also identify the critical path. Assume a random number of weeks between 2 to 10 for each activity.
<table>
<tr><td>Activity</td><td>A</td><td>B</td><td>C</td><td>D</td><td>E</td><td>F</td><td>G</td><td>H</td><td>I</td><td>J</td></tr>
<tr><td>Predecessor Activity</td><td>-</td><td>A</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>F,G</td><td>D,E, H</td><td>I</td></tr>
</table></td><td>CO5</td><td>PO10</td><td>10</td></tr>
<tr><td></td><td></td><td>b)</td><td>What is the critical path in project management? Can there be more than one critical path in a project? Explain with examples and discuss how multiple critical paths can affect project planning.</td><td>CO2</td><td>PO10</td><td>10</td></tr>
<tr><td></td><td></td><td></td><td colspan="4">OR</td></tr>
<tr><td></td><td>10</td><td>a)</td><td>Use the network diagram below and find the critical path by constructing a complete project schedule network diagram.
<table>
<tr><td>Activity</td><td>Weeks</td><td>Precedence</td></tr>
<tr><td>A</td><td>4 Weeks</td><td>-</td></tr>
<tr><td>B</td><td>6 Weeks</td><td>-</td></tr>
<tr><td>C</td><td>4 Weeks</td><td>B</td></tr>
<tr><td>D</td><td>12 Weeks</td><td>A</td></tr>
<tr><td>E</td><td>7 Weeks</td><td>A, C</td></tr>
<tr><td>F</td><td>9 Weeks</td><td>B</td></tr>
<tr><td>G</td><td>5 Weeks</td><td>E, F</td></tr>
</table></td><td>CO5</td><td>PO10</td><td>10</td></tr>
</table>

		b)	Describe the Backward pass methods used in precedence network analysis. Apply these methods to the given activity data.	*CO5*	*PO10*	**10**

Activity	**Weeks**	**Precedence**
A	5	-
B	7	-
C	4	A
D	3	B
E	6	B
F	9	-
G	4	E, F
H	2	C, D

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