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

Autonomous Institute Affiliated to VTU

July 2023 Semester End Main Examinations

Programme: B.E.   **Semester: VI**
Branch: Medical Electronics Engineering   **Duration: 3 hrs.**
Course Code: 19ML6PCMDD   **Max Marks: 100**
Course: Medical Device Development   **Date: 10.07.2023**
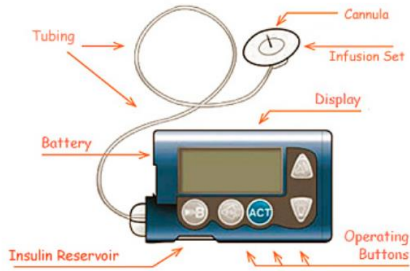
Instructions: 1. Answer any FIVE full questions, choosing one full question from each unit.
2. Missing data, if any, may be suitably assumed.

			UNIT - I	CO	PO	Marks
1	a)		Give an overview of the Biodesign process practiced during medical device development process	CO1	PO1	**10**
	b)		What are the main advantages of creating a solution after a thorough understanding of a clinical problem (identified through clinical observations)? Give examples if required.	CO1	PO1	**10**
			OR			
2	a)		"A 19 years old male patient who was admitted in the Emergency ICU for the past 6 days (on ventilator) suddenly had a drop in his oxygen saturation levels. The doctor in charge noticed that the lung movements were present but 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 mean time due to the low oxygen saturation for the entire duration, hypoxic brain injury was suspected" **Read the following observations and create a problem statement and need statement for each.**	CO2	PO2	**10**
	b)		Read the following observation *"A medical resident in training struggles to intubate a patient (place a breathing tube into a patient's trachea) in the emergency room, leading to a drop in the patient's oxygen levels."* Create a problem statement and need statement based on the above observation. Explain how does your need statement meet all the characteristics of a typical "need statement". **Problem:** For the unskilled practitioner, the time required to place an endotracheal breathing tube in an emergency setting can, at least in some cases, be extensive and can dramatically impact the outcome for the patient.	CO2	PO2	**10**

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			Need: A way to reduce the time required for unskilled medical practitioners to place endotracheal tubes in an emergency setting.			
			UNIT - II			
	3	a)	Using the concept of ISO 14971, do a Safety Risk analysis. Provide two scenarios and for each of the scenario, identify two hazards and explain the related foreseeable sequences of events, hazardous situations and the harm that can occur.	*CO1*	*PO1*	**10**
		b)	Give a detailed <u>clinical workflow</u> of a medical device in use; How does the process of creating the clinical workflow helps the medical device development	*CO2*	*PO2*	**10**
			OR			
	4	a)	Perfint manufactured a device called Maxio which requires to accurately positioning a needle to ablate the tumor. Derive the functional and performance requirement for this device.	*CO2*	*PO2*	**10**
		b)	"Product Requirement is not just Feature and Functionalities". Justify this statement by giving at least 5 different type of requirements with an example for each	*CO2*	*PO2*	**10**
			UNIT - III			
	5	a)	The figure shows the Insulin Pump used by a diabetic patient i) Discuss the high impact Safety and usability risks of Insulin Pump. ii) How do the safety usability risks change when the display and controls are managed by a smartphone connected to the base unit by Bluetooth?	*CO3*	*PO3*	**10**
		b)	"Verification of Design Outputs (intermediate) and Design Review are the error correcting mechanisms that are essential for the efficiency and effectiveness of the process, which leads to the desired product". For an Electronic Medical Device, Enumerate all the intermediate design outputs and explain how will they be verified/reviewed for the correctness.	*CO4*	*PO3*	**10**
			UNIT - IV			
	6	a)	What is risk involved in designing medical devices? How do you mitigate this using risk management?	*CO2*	*PO1*	**10**

		b)	Analyze the following observations (root cause) for the error w.r.t Usability engineering
			Participant did not breathe out completely before taking puff from inhaler.
			    i. While measuring blood glucose,
			    ii. Participant drew blood sample from fingertip still wet with disinfectant.
			    iii. Participant retrospective role.
				CO2	*PO1*	**10**

UNIT - V

			CO4	PO3	**20**
7		The following table gives the days required to build a room for MRI machine to be installed in a new hospital in a new building. Perform critical path analysis and find the critical path along with its mitigation strategy.			

Task No.	Name	Predecessors	Number of days
110	Excavation		4
120	Build Forms	110	2
130	Place Rebar	110	6
210	Pour Concrete	120, 130	1
310	Setting & Curing	210	5
320	Strip Forms	310	5

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