Reg.No. \_\_\_\_\_\_\_\_\_\_\_\_



**End Semester Examination – Nov/Dec – 2017**

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| **Code :** | **15EI2029** | **Duration :** | **3hrs** |
| **Sub. Name :** | **PATIENT AND DEVICE SAFETY** | **Max. marks :** | **100** |

**ANSWER ALL QUESTIONS (5 x 20 = 100 Marks)**

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| **Q. No.** | **Sub Div.** | **Questions** | **Course**  **Outcome** | **Marks** |
| 1. | a. | Describe the various steps involved in the “External Visual Inspection” of electro medical devices. | CO2 | 12 |
| b. | Comment on software reliability. | CO3 | 8 |
| (OR) | | | | |
| 2. | a. | Evaluate the different types of reliability of medical devices with suitable illustrations. | CO2 | 15 |
| b. | Identify the steps involved in safety testing. | CO1 | 5 |
|  |  |  |  |  |
| 3. | a. | Develop a case study related to Risk Perception and the various factors elevating and reducing perceived risk. | CO1 | 10 |
|  | b. | List the various medical device safety parameters and describe in detail. | CO2 | 10 |
| (OR) | | | | |
| 4. | a. | Describe electronic reliability curve with a neat sketch. | CO1 | 5 |
|  | b. | Illustrate the properties of tolerable failures. | CO3 | 5 |
|  | c. | Classify reliability and quality. | CO2 | 5 |
|  | d. | Write short notes on the importance of earthing of medical equipments. | CO1 | 5 |
|  |  |  |  |  |
| 5. | a. | Discuss in detail the risk management process and its analysis. | CO1 | 12 |
|  | b. | Evaluate the safety classes in device safety. | CO3 | 8 |
| (OR) | | | | |
| 6. | a. | List the basic assumptions in safety technology. | CO1 | 5 |
|  | b. | Discuss the effect of body resistance in determining voltage hazards. | CO3 | 10 |
|  | c. | Comment on electrostatic discharges. | CO2 | 5 |
|  |  |  |  |  |
| 7. | a. | Describe the effect of alternating electric currents and the various stages of excitation. | CO2 | 10 |
|  | b. | Define the standard condition to operate electro medical devices. | CO2 | 10 |
| (OR) | | | | |
| 8. | a. | Analyse various effects of magnetic coupling. | CO2 | 10 |
|  | b. | Interpret the environmental aspects with respect to safety. | CO1 | 10 |
|  | |  |  |  |
|  | | **Compulsory**: |  |  |
| 9. | a. | Differentiate Good Laboratory practices and manufacturing practices. | CO3 | 10 |
|  | b. | Explain in brief the process involved in choosing the appropriate directive. | CO3 | 10 |

ALL THE BEST