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UNIVERSITI TUN HUSSEIN ONN MALAYSIA

**FINAL EXAMINATION
(ONLINE)
SEMESTER II
SESSION 2020/2021**

COURSE NAME : MEDICAL EQUIPMENT
MANAGEMENT AND SAFETY

COURSE CODE : BEJ 35202 / BEU 40902

PROGRAMME CODE : BEJ

EXAMINATION DATE : JULY 2021

DURATION : 2 HOURS

INSTRUCTION : ANSWER ALL QUESTIONS

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THIS QUESTION PAPER CONSISTS OF FIVE (5) PAGES

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- Q1** (a) Systematic planning and execution is a program that assures the availability of safe and appropriate technological tools at the lowest life-cycle costs with the best possible performance. Propose **THREE (3)** activities to improve the implementation of Technology Assessment (TA). (3 marks)
- (b) Assuming that you are a biomedical engineer working in Hospital Sultanah Aminah, Johor Bahru. During a meeting with the chief executive officer and the hospital administration, it has come to everyone’s attention that there are on-going user problems with the medical equipment and high percentage of the equipment awaiting repair. This has resulted in maintenance costs emerging as a large single expense.
- (i) Analyze the problem and establish **FOUR (4)** possible reasons behind this on-going issues. (8 marks)
- (ii) Based on your answers in **Q1(b)(i)**, develop a plan with detailed objectives to address the issues. (8 marks)
- (c) Simple scoring system known as equipment management (EM) number can be established to determine scheduled maintenance frequency.
- (i) Calculate the EM numbers for all the devices in **Table Q1(c)**. Show your formula and calculations clearly. (4 marks)

Table Q1(c)

Devices	Function	Risk	Maintenance
Ventilator	10	5	5
Infant Incubator	10	5	4
Centrifuge	4	3	5
Fetal monitor	6	3	3

- (ii) Evaluate and conclude which equipment should be included in the control program and the routine inspection, respectively. Due to extreme pressure to manage cost, take into consideration during evaluation that only 2 equipment are currently allowed into the equipment control program. (4 marks)

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- Q2**
- (a) Virtua is the largest healthcare system in southern New Jersey, a fast-growing organization with more than 8,400 employees, operating four hospitals, two nursing homes, two ambulatory-care centers, a home healthcare agency and 19 physician-services sites. In your opinion, what can be implemented by hospital in Malaysia to grow into a large healthcare system like Virtua.
(5 marks)
 - (b) Information network utilizes computing and telecommunications technologies.
 - (i) Tabulate the configuration differences between five main information network in healthcare system. Use appropriate illustration where necessary.
(10 marks)
 - (ii) Based on your answers in **Q2(b)(i)**, determine the information network that most benefit the healthcare system. Justify your answer clearly.
(3 marks)
 - (c) The International Electrotechnical Commission (IEC) is a non-profit, non-governmental international standards organization that prepares and publishes International Standards for all related electrotechnology.
 - (i) Determine the IEC standard that a biomedical engineer need to refer to and fulfil to ensure safety and effectiveness of medical equipment.
(1 mark)
 - (ii) Indicate **THREE (3)** parameters that are tested by safety analyzer to fulfill the IEC standard in **Q2(c)(i)**.
(3 marks)
 - (d) Summarize **THREE (3)** non-functional current using appropriate diagram. Label clearly the current path.
(6 marks)
- Q3**
- (a) Clinical research is necessary to establish the safety and effectiveness of health and medical products and practices.
 - (i) Define Good Clinical Practice (GCP).
(2 marks)
 - (ii) Give **THREE (3)** benefits of GCP towards subjects involved in the clinical trial.
(3 marks)

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(b) Adam has cancer, and the traditional treatments have been only intermittently successful. Adam is then recruited by his oncologist in a randomized, single-blinded and placebo arm of the clinical trial. However, after six months into the study, Adam is not experiencing any signs of improvement, and in fact is getting worse. Preliminary data from both treatment arm and placebo arm suggest that the drug is beneficial. During an examination with his Doctor, Adam requested that if he is in the placebo arm that his Doctor should switch him to the treatment arm, so that he can receive the possible benefits of the new treatment.

(i) Establish whether or not Adam's Doctor is aware that Adam is in the placebo arm. Justify your answer.

(3 marks)

(ii) Determine **FOUR (4)** ethical problems that is faced by Adam and his Doctor.

(4 marks)

(iii) Based on your answers in **Q3(b)(ii)**, propose ethical solutions that will restore the main obligation of Adam's Doctor.

(4 marks)

Q4 (a) Medical device is classified based on the risk associated with the vulnerability of the human body design and manufacture design.

(i) Differentiate Class A, Class B, Class C and Class D medical devices in terms of risk level.

(4 marks)

(ii) Classify stethoscope, artificial pacemaker, infusion pump and ECG into the correct classes.

(8 marks)

(b) Medical device could be interpreted as any instruments intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease.

(i) Illustrate the life cycle and stages of regulatory control of an active medical device.

(7 marks)

(ii) Develop a new medical device that may assist or be used by Doctors and nurses in patient care during the outbreak of Covid-19 pandemic. Explain the function of the newly developed medical device. Use appropriate diagram and label the parts clearly.

(8 marks)

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- (iii) Classify the class type of the medical device that you have developed in **Q4(b)(ii)** based on the risk associated. Justify your answer. (2 marks)

-END OF QUESTIONS-

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