Universiti Tun Hussein Onn Malaysia

UNIVERSITI TUN HUSSEIN ONN MALAYSIA

FINAL EXAMINATION
SEMESTER I
SESSION 2022/2023

COURSE NAME	:	MEDICAL EQUIPMENT MANAGEMENT AND SAFETY
COURSE CODE	:	BEJ 35202
PROGRAMME CODE	:	BEJ
EXAMINATION DATE	:	FEBRUARY 2023
DURATION	:	2 HOURS 30 MINUTES
INSTRUCTION	:	1. ANSWER **ALL** QUESTIONS.
		2. THIS FINAL EXAMINATION IS CONDUCTED VIA **OPEN BOOK.**
		3. STUDENTS ARE **NOT PROHIBITED** TO CONSULT THEIR OWN MATERIAL OR ANY EXTERNAL RESOURCES DURING THE EXAMINATION CONDUCTED VIA OPEN BOOK.

THIS QUESTION PAPER CONSISTS OF **FOUR (4)** PAGES

Q1 (a) Name **FOUR (4)** computer applications for diagnostics.

(4 marks)

(b) Point out the main challenges of healthcare data protection. Suggest **FOUR (4)** techniques to overcome the issue.

(9 marks)

(c) As a biomedical engineer in a company, you are required to design and produce a patient-specific biomedical implant from bone images taken from a medical imaging device. Outline the strategies that need to be implemented to ensure that the implant created meets the requirements of the patient. The strategy should be focused on data acquisition, data transmission, data processing and data storing.

(12 marks)

Q2 (a) State the physiological effects of electrical shocks.

(4 marks)

(b) Explain **THREE (3)** main goals for guidelines for good clinical practice.

(6 marks)

(c) Plan or organize electrical safety programs for medical devices to ensure the safety of the patient in accordance with the acts and regulations.

(12 marks)

(d) **Table Q2(d)** shows the safety analyzer test results according to IEC60601 Standards. Examine the safety status of the medical device.

(3 marks)

Q3 (a) Name **FIVE (5)** electromagnetic interference (EMI) sources.

(5 marks)

(b) Highlight the importance of establishing acceptable emission and immunity limits.

(4 marks)

(c) Implantable medical device is the most susceptible medical device to EMI. This device must have high EMC to avoid electromagnetic interference-induced health risks, even death during the treatment.

(i) Name **TWO (2)** implantable medical devices available in the market.

(2 marks)

(ii) Propose **TWO (2)** technical improvements to overcome the issue of EMI for an implantable medical device.

(4 marks)

(d) Point out **FIVE (5)** strategies that can be implemented to improve the management of electromagnetic interference (EMI) and electromagnetic compatibility (EMC).

(10 marks)

Q4 (a) ISO 9000 is the general standard related to the fundamentals of implementation of a quality management system. Illustrate the concept of ISO 9000.

(6 marks)

(b) Explain **TWO (2)** benefits of hospital accreditation to:

(i) Staff

(ii) Patient

(iii) Hospital

(6 marks)

(c) Malaysian Society for Quality in Health is an independent accrediting body that accredits hospitals in Malaysia. As one of the accreditation panels, outline the surveying activities required during the accreditation visits in the hospital.

(5 marks)

(d) Borhan is planning to buy a medical device from a seller in China Via Shopee. Explain what element he should consider before buying the device online in accordance with Medical Device Act 2012 (Act 737). State the appropriate acts or regulations to support your explanation.

(8 marks)

– END OF QUESTIONS –

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Table Q2(d)

Test	Type	Result	Limit
Supply voltage	Live - Neutral	243.1 V	240±10%
Supply voltage	Live - Ground	215.2 V	240±10%
Supply voltage	Ground - Neutral	3.3 V	5 V
Current consumption		20 mA	As per unit
Insulating resistance	Mains to case	7200 MΩ	> 2 MΩ
Enclosure leakage current	Open Supply, Reverse Mains	0.0 µA	100 µA