



**UNIVERSITI TUN HUSSEIN ONN MALAYSIA**

**FINAL EXAMINATION  
SEMESTER II  
SESSION 2023/2024**

- COURSE NAME : MEDICAL EQUIPMENT  
MANAGEMENT AND SAFETY
- COURSE CODE : BEJ35202
- PROGRAMME CODE : BEJ
- EXAMINATION DATE : JULY 2024
- DURATION : 2 HOURS
- INSTRUCTION :
1. ANSWER ALL QUESTIONS
  2. THIS FINAL EXAMINATION IS CONDUCTED VIA  
 Open book  
 Closed book
  3. STUDENTS ARE **PROHIBITED** TO CONSULT THEIR OWN MATERIAL OR ANY EXTERNAL RESOURCES DURING THE EXAMINATION CONDUCTED VIA CLOSED BOOK

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

**TERBUKA**

**CONFIDENTIAL**

**Q1** Medical informatics, commonly referred to as health informatics, integrates the domains of healthcare with technology and data analysis to enhance healthcare delivery. It employs computerized systems to acquire, store, retrieve, and analyze healthcare data.

(a) Describe **FOUR (4)** primary obstacles to healthcare data protection and provide potential solutions to the problem.

(6 marks)

(b) Information network utilizes computing and telecommunications technologies.

(i) Classify the **FOUR (4)** main information network available in healthcare system. Use appropriate illustration to show your comparison.

(10 marks)

(ii) Based on your answers in **Q1(b)(i)**, determine the information network that most benefit the healthcare system. Justify your answer clearly.

(2 marks)

**Q2** Testing of active medical device ensures the device does not cause electrical hazards to patients, maintenance personnel and users.

(a) Differentiate micro shock and macro shock.

(2 marks)

(b) Discuss the physiological effects that may occur due to different leakage current ranging from 1 mA to more than 5 A.

(10 marks)

(c) IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment.

(i) Summarize **THREE (3)** unwanted current using appropriate diagram. Label clearly the current path.

(9 marks)

(ii) **Table Q2.1** shows the safety analyzer test results according to IEC60601 Standards. Examine the safety status of the medical device.

(3 marks)

**Table Q2.1 Safety Analyzer test results**

<b>Test</b>	<b>Type</b>	<b>Result</b>	<b>Limit</b>
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

- (d) 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)

**Q3** Electromagnetic interference (EMI) denotes the disruption induced by electromagnetic radiation upon electronic devices resulting in adverse consequences such as signal deterioration, operational malfunction, or functional impairment.

- (a) Name **FOUR (4)** electromagnetic interference (EMI) sources.

(4 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) Recommend **FOUR (4)** technical improvements to overcome the issue of EMI for an implantable medical device.

(8 marks)

- (iii) Point out **SIX (6)** strategies that can be implemented to improve the management of electromagnetic interference (EMI) and electromagnetic compatibility (EMC).

(12 marks)

- Q4** ISO 9000 is the general standard related to the fundamentals of implementation of a quality management system.
- (a) Draw a figure to illustrate the concept of ISO 9000. (3 marks)
  - (b) Malaysian Society for Quality in Health is an independent accrediting body that accredits hospitals in Malaysia. As one of the accreditation panels, summarize the surveying activities required during the accreditation visits in the hospital. (5 marks)
  - (c) Borhan is planning to buy a medical device from a seller in China Via Shopee.
    - (i) Explain what element he should consider before buying the device online in accordance with Medical Device Act 2012 (Act 737). (4 marks)
    - (ii) State the appropriate acts or regulations to support your explanation. (4 marks)

– END OF QUESTIONS –