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Universiti Tun Hussein Onn Malaysia

UNIVERSITI TUN HUSSEIN ONN MALAYSIA

**FINAL EXAMINATION
SEMESTER II
SESSION 2022/2023**

COURSE NAME : MEDICAL EQUIPMENT
MANAGEMENT AND SAFETY

COURSE CODE : BEJ 35202

PROGRAMME CODE : BEJ

EXAMINATION DATE : JULY/AUGUST 2023

DURATION : 2 HOURS

INSTRUCTION : 1. ANSWER ALL QUESTIONS.

2. THIS FINAL EXAMINATION IS
CONDUCTED VIA **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

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- Q1** (a) Standards and recommendations for integrating developing healthcare technologies and practices differ by context, jurisdiction, and technology. Regulatory entities, professional groups, and industry standards organizations produce guidelines and best practices to safely and effectively integrate developing healthcare technologies into current healthcare systems.
- (i) Name **TWO (2)** integration standard related to the developing healthcare sector.
(2 marks)
- (ii) Analyze the fundamental components and guiding principles of **ONE (1)** of the integration standard in **Q1(a)(i)**.
(4 marks)
- (iii) Evaluate the advantages and disadvantages of the standard in **Q1(a)(ii)** from your perspective.
(4 marks)
- (b) Describe the primary obstacles to healthcare data protection. Provide **FOUR (4)** potential solutions to the problem.
(5 marks)
- (c) As a biomedical engineer at a company, it is your job to create and make a patient-specific biomedical implant based on images of the patient's bones taken with a medical imaging device. Describe the steps that need to be taken to make sure that the implant made meets the patient's needs. The steps should be focused on data acquisition, data transmission, data processing and data storing.
(12 marks)
- Q2** (a) State **THREE (3)** physiological effects of electrical shocks.
(3 marks)
- (b) Explain **THREE (3)** main goals for guidelines for good clinical practice.
(6 marks)
- (c) Develop an outline of electrical safety programs for medical devices to ensure the safety of the patient in accordance with the acts and regulations.
(10 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) ISO 9000 is the general standard related to the fundamentals of implementation of a quality management system. Draw a figure to illustrate the concept of ISO 9000. (6 marks)
 - (b) Explain **TWO (2)** benefits of hospital accreditation to:
 - (i) Staff (2 marks)
 - (ii) Patient (2 marks)
 - (iii) Hospital (2 marks)
 - (c) 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)
 - (d) Sarah plans to purchase a medical device from a vendor in China via Shopee. In accordance with the Medical Device Act of 2012 (Act 737), explain what she must consider prior to purchasing the device online. (4 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