



UNIVERSITY OF RUHUNA

Faculty of Engineering

End-Semester 8 Examination in Engineering: July 2022

Module Number: EE8218

Applications in Biomedical Engineering

[Three Hours]

[Answer all questions, each question carries 10 marks]

[Page 3 of question paper should be attached to the answer script]

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- Q1 a) Name and explain the importance of two (02) properties of good bioelectrodes. [1.0 Mark]
- b) Name and describe two (02) methods of noise reduction in biosignals acquisition. [1.0 Mark]
- c) Compare a biological neuron with an artificial neuron. [2.0 Marks]
- d) Compare and contrast the following neural signal acquisition methods in terms of each of their temporal resolution, spatial resolution and invasiveness. [3.0 Marks]
- Electroencephalogram (EEG)
 - Electrocorticography (ECoG)
 - Local Field Potentials (LFP)
 - Spikes
- e) Answer the following regarding the Hodgkin-Huxley (HH) model of an action potential. [3.0 Marks]
- i) Briefly explain what is meant by the HH model of an action potential.
 - ii) Draw the equivalent electrical circuit of the HH model.
- Q2 a) Briefly explain knock-in and knock-out technologies in gene research. [1.0 Mark]
- b) Explain one (01) application of Virtual reality (VR) or Augmented Reality (AR) in biomedical engineering. [1.0 Mark]
- c) Write a brief paragraph on wearable devices used in medicine using an example. You should focus on the following: [2.0 Marks]
- What is the parameter measured and how it is being measured?
 - What is the importance of measuring the selected parameter?
 - What is the population targeted with the device?
 - What are the risks associated with the device?
- d) A research laboratory focusing on electronics, is interested in studying the

behaviour, function and nature of lung tissues. Name a method that they can use for this and briefly explain what this method is.

[3.0 Marks]

e) A person has a spinal cord injury (SCI) at C-5 level and was diagnosed as motor complete. A research laboratory is looking into implementing a brain-computer interface (BCI) with this person.

i) Shade the areas in Figure Q2 where the person does not have any motor function.

ii) Explain the working of a BCI with the use of a diagram.

iii) Do you recommend a BCI for the above person? Briefly justify your answer.

[3.0 Marks]

Q3 a) ISO 14971 states the definition of a risk. Briefly describe how risk is evaluated in medical devices.

[1.0 Mark]

b) Why is it important to have guidelines for regulation of repaired medical equipment?

[1.0 Mark]

c) Write a brief essay about the preventative healthcare system in Sri Lanka giving an example.

[2.0 Marks]

d) Write a brief essay about aspects of biocompatibility of medical devices.

[3.0 Marks]

e) Table Q3 gives a device that was recalled by FDA in 2020. Analyze this device recall and write a brief essay on ways that this could have been prevented.

[3.0 Marks]

Q4 a) Set up a **basic model** of the normal cardiorespiratory system to study the effect of Oxygen Metabolism in Body Tissues on spontaneous breathing and systemic arterial and venous blood gases.

[1.0 Mark]

b) Briefly describe one (01) issue in conceptual models in biomedical engineering.

[1.0 Mark]

c) i) Briefly explain the role of "medical imaging" in medicine.

ii) State two (02) medical imaging modalities which deliver anatomical information of human body in three dimensions.

[2.0 Marks]

d) i) Justify the statement, "Medical image segmentation is often a complex image segmentation problem."

ii) Briefly explain the importance of "inter-model registration".

[3.0 Marks]

e) As a biomedical engineer you were assigned to implement a medical image processing tool to evaluate tumor ingrowth based on CT scans taken at two different time points. Propose an image analysis pipeline to implement this tool.

[3.0 Marks]

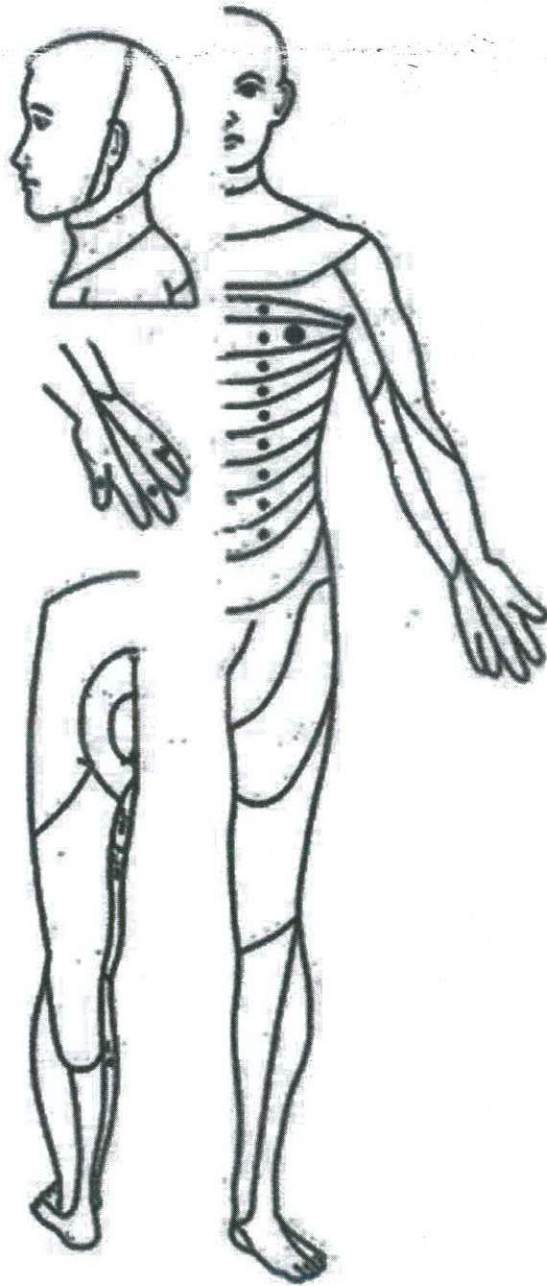


Figure Q2

Table Q3

Source: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=183871>

Date Initiated by Firm	24-Sep-20
Create Date	2-Nov-20
Recall Status¹	Terminated 3 on May 20, 2022
Recall Number	Z-0323-2021
Recall Event ID	86521
Product Classification	Prosthesis, hip, semi-constrained, metal/polymer, cemented - Product Code JDI
Product	ZCA All Poly Acetabular Cup Longevity Crosslinked Polyethylene, I.D. 22 mm, Neutral, O.D. Cup with Spacers, 43mm
	Item Number: 00-8065-540-22
	Hip prosthesis component
Code Information	All lots
Recalling Firm	Zimmer Biomet, Inc.
Manufacturer	1800 W Center St Warsaw IN 46580-2304
For Additional Information Contact	411 Technical Services 574-371-3071
Manufacturer Reason for Recall	Sterilant (hydrogen peroxide) used in acetabular cup hip prosthesis component was not evaluated to confirm the biocompatibility of the residual sterilant. Cannot rule out the potential for adverse tissue reactions.
FDA Determined Cause	Device Design
Action	<p>Zimmer Biomet issued URGENT MEDICAL DEVICE RECALL AND NOTICE OF US FIELD DISCONTINUATION letter to Distributors. Risk Manages, Physicians on/9/24/20 stating reason for recall, health risk and action to take:</p> <ol style="list-style-type: none"> 1. Review this notification and ensure that affected personnel are aware of the contents. 2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility. 3. Complete Attachment 1 Certificate of Acknowledgement and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form will be returned even if you do not have affected products at your facility. 4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation. 5. If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com. <p>Surgeon Responsibilities:</p> <ol style="list-style-type: none"> 1. Review this notification for awareness of the contents. 2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule.
Quantity in Commerce	412 units total
Distribution	US Nationwide
Total Product Life Cycle	TPLC Device Report