

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Autumn Examinations 2011/2012

Module Title: Medical Devices

Module Code: BIOE 7008

School: School of Engineering

Programme Code: SGMPE_7_Y3

SNHSC_8_Y2

Programme Title: BSc in Good Manufacturing Practice and Technology

BSc (Hons) in Nutrition & Health Science

**External Examiner(s): Dr. Stephen Fitzpatrick and Ms. Bernadette Whelan
Dr. Alison Gallagher**

Internal Examiner(s): Ms. Mary Quirke

Instructions: Question 1 is compulsory, all candidates must attempt question 1 (40%). Answer TWO other questions each worth 30%.

Duration: 2 hours

Sitting: Autumn 2012

Note to Candidates: Please check the Programme Title and the Module Title to ensure that you are attempting the correct examination.
If in doubt please contact an Invigilator.

Please answer question one it is compulsory.

Q1 Please answer **FIVE** of the following questions

- (a) Discuss four factors influencing the future direction of medical devices. (8 marks)
- (b) Distinguish between the functions of intraocular lenses and contact lenses, both medical devices used in ophthalmology. Give three other differences between these devices. (8 marks)
- (c) Explain the circumstances under which a medical device manufacturer may apply for an Investigational Device Exemptions (IDE)? (8 marks)
- (d)
 - i. What are field safety correction actions (FSCA) and give 4 examples of FSCA?
 - ii. How are field corrective actions classified? (8 marks)
- (e) Name the major body systems. Identify the functions and organs associated with **four** body systems. (8 marks)
- (f) Differentiate between anatomy and physiology. What is pathology of the body? What role do medical devices play in relation to each of the above? (8 marks)

Answer 2 of the following questions

- Q2 (a) (i) What is a medical device? (5 marks)
- (ii) How would you classify a medicinal product that uses a combination of a medical device and a pharmacological product? (5 marks)
- (b) Why is “reimbursement” important to manufacturers of medical devices? (5 marks)
- (c) What role does the WHO play with regards to medical devices? (5 marks)
- (d) What are the main steps towards getting a product on to market in the US using the 510 (k) process? (10 marks)
- (e) What role do notified bodies play in getting medical devices to market in Europe? (5 marks)

- Q3(a) Describe the functions of arteries, veins and capillaries. (10 marks)
- (b) Explain, with the aid of a diagram how the blood flows through the heart. (10 marks)

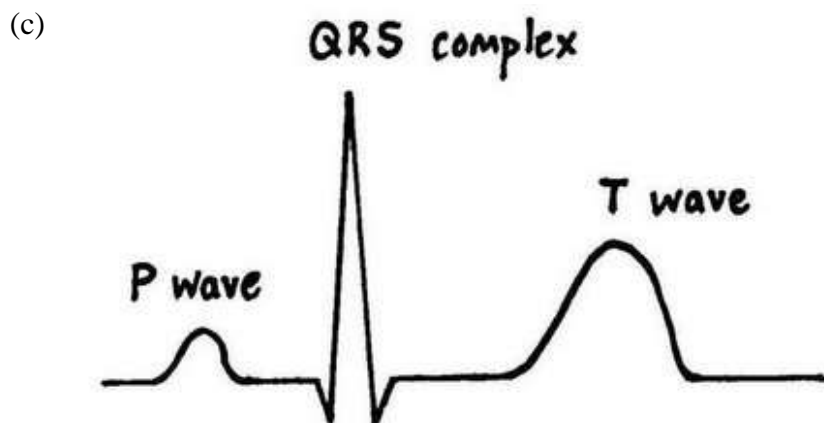


Figure 1. This is a typical ECG for one complete cardiac cycle.

What do the P wave, QRS complex and T wave, correspond to in terms of cardiac conduction and cardiac cycle in Figure 1 above? (10 marks)

- Q 4. (a) i. Describe with the use of a diagram the process by which bone is repaired following a fracture.
ii. How may medical devices assist in the process (10 marks)
described in Q 4. (a) (i)?
- (b) Answer the following questions with reference to respiratory air volumes and capacities.
- (i) What is tidal volume? (2 marks)
- (ii) Distinguish between inspiration and expiratory reserve volumes. (4 marks)
- (iii) How is vital capacity determined? (2 marks)
- (iv) How is total lung capacity determined? (2 marks)
- (c) (i) Name the three layers of the eye wall and describe the functions of each layer. (5 marks)
- (ii) Explain how light is focused on the retina. (5 marks)