

# ES97F-15 Medical Device: Design, Maintenance and Assessment

**24/25**

**Department**

School of Engineering

**Level**

Taught Postgraduate Level

**Module leader**

Thomas Popham

**Credit value**

15

**Module duration**

15 weeks

**Assessment**

100% coursework

**Study location**

University of Warwick main campus, Coventry

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## Description

### Introductory description

ES97F-15 Healthcare Technology Engineering Design, Maintenance and Assessment

[Module web page](#)

### Module aims

To develop a firm understanding of the principles of modern design, maintenance and assessment of healthcare technologies, including: medical devices, novel treatment and therapeutic technologies, technologies for a healthy life-course, systems and environments for care delivery. This module will provide the student with a firm grounding in methods and tools for design, management and assessment of health technologies for prevention, diagnosis, treatment and rehabilitation.

### Outline syllabus

This is an indicative module outline only to give an indication of the sort of topics that may be covered. Actual sessions held may differ.

The module will be organized in 3 parts:

- Part 1: health technology design
  - o Physical and physiological principles, block diagrams and ordinary maintenance issues of the following medical devices will be presented: electrocardiography, vectorcardiography, ecocardiotochography, medical devices for radiology unit, ultrasound imaging, assistive technologies, point of care devices, diagnostics, active implantable devices (pacemakers and defibrillators), monitors and medical devices for intensive care units or surgery units, principal medical devices for surgery and minimally invasive surgery.
  - o Block diagrams and ordinary maintenance issues of the following care plants or settings: hospital wards; heating, ventilation and air conditioning; electrical power plant; surgery units, emergency units.
  - o Information and communication technologies for healthcare
  - o Human centred design
  - o User need elicitation to inform the design of medical devices
- Part 2: clinical engineering
  - o The medical device life cycle
  - o Requirement Analysis and Strategic planning
  - o European legislation for medical devices and comparison with the USA Food and Drugs Administration (FDA) standards
  - o Medical software as medical device: implications
  - o Risk management in hospital: patient and healthcare professionals safety
  - o Maintenance of medical devices
  - o Healthcare technology replacement planning
  - o Healthcare technology procurement process
- Part 3: health technology assessment
  - o Introduction to the evidence based medicine
  - o Methods for systematic literature reviews
  - o Standard methods to measure the impact of medical devices: the quality of life
  - o Cost minimization analysis
  - o Cost-utility, cost-effectiveness and cost-benefit assessment

## Learning outcomes

By the end of the module, students should be able to:

- Understand the physical and physiological principles that underpin complex medical devices for prevention, diagnosis, treatment and rehabilitation. Compare and contrast the main aims, principles and components of these four categories of medical devices [M1]
- Characterize, describe, explain, identify, locate and recognize the main components of the principal healthcare technologies for prevention, diagnosis, treatment and rehabilitation [M1]
- Apply methods to systematically evaluate, design and manage advanced healthcare technologies [M5]
- Critically assess the appropriateness of innovative health care technologies by reading a health technology assessment report [M4]
- Participate in multidisciplinary studies aiming to critically evaluate the technological feasibility and cost-effectiveness of a new medical device. Identify, classify, prioritize medical or epidemiological needs and participate in studies aiming to identify the most suitable

technological solutions to satisfy those needs [M5]

- Participate in multidisciplinary working group for the systematic design and development of innovative medical devices, taking into account a variety of user needs and industry standards. [M5, M16]
- Evaluate environmental and societal impact of design solutions (to include the entire life cycle of the product or process) and minimise adverse affects [M7]
- Identify, classify and prioritise the main ethical issues arising from the design, regulation and use of medical devices [M8]

## **Indicative reading list**

1. Iadanza, Miniati, Dori, Clinical Systems Engineering, Elsevier, 2005, eBook ISBN: 9780128038246
2. Tony Easty, "Human Factors for Health Technology Safety: Evaluating and improving the use of health technology in the real world" (to be published in June 2014)
3. E. Iadanza, "Clinical Engineering Handbook", II Edition, Elsevier Academic Press, 2019, eBook ISBN: 9780128134689
4. Y. David et al., "Clinical Engineering", CRC Press, 2003
5. Selected articles from scientific journals, including:
  - a. Annual review of biomedical engineering, ISSN: 1523-9829
  - b. The Health Technology Assessment Journal, ISSN: 2046-4924 (Online)

## **Subject specific skills**

Ability to conceive and make a valid argument to support an engineering decision

Ability to develop solutions using published and validated literature

Ability to be pragmatic, taking a systematic approach and the logical and practical steps necessary for, often complex, concepts to become reality

Ability to seek to achieve sustainable solutions to problems and have strategies for being creative and innovative

Ability to be risk, cost and value-conscious, and aware of their ethical, social, cultural, environmental, health and safety, and wider professional engineering responsibilities

Ability to communicate across engineering disciplines in a constructive way to progress a project

## **Transferable skills**

Apply problem solving skills, information retrieval, and the effective use of general IT facilities

Communicate (written and oral; to technical and non-technical audiences) and work with others

Exercise initiative and personal responsibility, including time management, which may be as a team member or leader

Awareness of the nature of engineering business and enterprise in the creation of economic and

social value

Overcome difficulties by employing skills, knowledge and understanding in a flexible manner

Ability to formulate and operate within appropriate codes of conduct, when faced with an ethical issue

Appreciation of the global dimensions of engineering, customers, commerce and communication

Be professional in their outlook, be capable of team working, be effective communicators, and be able to exercise responsibility and sound management approaches.

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## Study

### Study time

Type	Required
Lectures	1 session of 1 hour (1%)
Seminars	3 sessions of 1 hour (2%)
Project supervision	10 sessions of 1 hour (7%)
External visits	(0%)
Online learning (independent)	16 sessions of 1 hour (11%)
Private study	120 hours (80%)
Total	150 hours

### Private study description

Guided independent learning 120 hr

### Costs

No further costs have been identified for this module.

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## Assessment

You must pass all assessment components to pass the module.

### Assessment group A5

	Weighting	Study time
Medical device design project	60%	
Report and peer assessment		

**Weighting****Study time**

Individual Project/Report

40%

**Feedback on assessment**

Coursework and Group Project marked with detailed comments

Face-to-face feedback in seminars

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**Availability****Courses**

This module is Core for:

- Year 1 of TESA-H800 Postgraduate Taught Biomedical Engineering