

# ES3F0-15 Medical Device: Design, Maintenance and Assessment

**23/24**

**Department**

School of Engineering

**Level**

Undergraduate Level 3

**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

ES3F0-15 Healthcare Technology Engineering Design

[Module web page](#)

### Module aims

To develop a firm understanding of the principles of modern design, manufacturing, maintenance and assessment of healthcare technologies, and particularly medical devices. This module will follow the World Health Organization (WHO) healthcare technologies definition, which includes: medical devices (including medical software), equipment, treatments and drugs for health and care (i.e., prevention, diagnoses, treatment, rehabilitation and end of life management).

Students will learn how to generate and collect relevant clinical evidence, how to assess clinical needs, and how to consider cost-efficacy constraints, ethical issues, regulatory frameworks and management methods and tools.

### 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 exemplar medical devices will be presented (e.g., electrocardiography, medical devices for radiology unit, assistive technologies, point of care devices, diagnostics, active implantable devices, monitors and medical devices for intensive care units or surgery units, principal medical devices for surgery or technologies for minimally invasive surgery).
  - o Block diagrams and technical requirements for exemplar medical locations or settings: hospital wards; surgery units, emergency units.
  - o Information and communication technologies for healthcare
  - o Human centered design
  - o User need elicitation to inform the design of medical devices
- Part 2: clinical engineering
  - o The medical device life cycle
  - o European legislation for medical devices and comparison with the USA Food and Drugs Administration (FDA)
  - o Medical software
  - o Risk management in hospital: patient and healthcare professionals safety
  - o Healthcare technology management
- 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 incremental cost-efficacy analysis
  - 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:

- Describe the physical and physiological principles that underpin complex medical devices for prevention, diagnosis, treatment, rehabilitation or end of life.
- Apply methods to design advanced healthcare technologies
- Analyse the appropriateness of innovative health care technologies by reading a health technology assessment report.
- Analyse 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.
- Participate in multidisciplinary working group for the design and development of medical devices.
- Identify, classify and priorities the main ethical issues arising from the design, regulation and use of medical devices

## **Indicative reading list**

1. Miniati, Roberto, Ernesto Iadanza, and Fabrizio Dori. Clinical engineering: from devices to systems. Academic Press, 2015.
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", Elsevier Academic Press, 2020, ISBN: 9780128134672
4. Selected articles from scientific journals, including:

## **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	8 sessions of 1 hour (5%)
Demonstrations	(0%)
Online learning (independent)	18 sessions of (0%)
Private study	138 hours (92%)
Total	150 hours

## Private study description

Guided independent learning 138 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 A2

	Weighting	Study time
Individual Assignment 2000 words max	40%	
Group Project Max 3500 words + peer assessment	60%	

## 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 3 of UESA-H161 BEng Biomedical Systems Engineering
- Year 3 of UESA-H163 MEng Biomedical Systems Engineering

This module is Core optional for:

- Year 4 of UESA-H164 MEng Biomedical Systems Engineering with Intercalated Year
- Year 3 of UESA-H115 MEng Engineering with Intercalated Year
- Year 3 of UESA-H11L Undergraduate Engineering (with Intercalated Year)

This module is Optional for:

- Year 3 of UESA-H113 BEng Engineering
- Year 3 of UESA-H114 MEng Engineering
- Year 4 of UESA-H115 MEng Engineering with Intercalated Year
- UESA-H11L Undergraduate Engineering (with Intercalated Year)
  - Year 3 of H11L Engineering (with Intercalated Year)
  - Year 4 of H11L Engineering (with Intercalated Year)

This module is Option list A for:

- Year 4 of UESA-H111 BEng Engineering with Intercalated Year
- UESA-H112 BSc Engineering
  - Year 3 of H112 Engineering
  - Year 3 of H112 Engineering