ES97F-15 Medical Device: Design, Maintenance and Assessment

21/22

Department
School of Engineering
Level
Taught Postgraduate Level
Module leader
Leandro Pecchia
Credit value
15
Module duration
10 weeks
Assessment
100% coursework
Study location
University of Warwick main campus, Coventry

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
- Characterize, describe, explain, identify, locate and recognize the main components of the principal healthcare technologies for prevention, diagnosis, treatment and rehabilitation using functional diagrams and block diagrams
- Apply methods to systematically evaluate, design and manage advanced healthcare technologies
- Critically assess the appropriateness of innovative health care technologies by reading a health technology assessment report
- 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
- Participate in multidisciplinary working group for the systematic design and development of innovative medical devices

Indicative reading list

Reading lists can be found in Talis

Subject specific skills

TBC

Transferable skills

TBC

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.

Assessment

You must pass all assessment components to pass the module.

Assessment group A3

Assessment component	Weighting	Study time	Eligible for self-certification
Design a medical device	60%		No

For this assignment, students will participate in a multidisciplinary working group for systematically designing a medical device. The deliverables of this project are expected to consider current medical device regulations and needs arising from low-resource healthcare settings.
The assessment will mainly focus on the process adopted by the students and the relevant technical documentation they will produce. A working prototype will also be welcome.
This assignment will require three deliverables: an interim report (the project charter), the final report and group presentation.

Interim report (week 21, credits 1.5)
This will be the Project Charter as defined in project management manuals.
Your submission should be prepared using the Arial font (minimum size 10pt) in a single-column format and must not exceed 1000 words (excluding title, abstract, figures, references and appendix). The appendix should only be used to provide additional information, which might be helpful for the reader but not essential for the report.
The report must be submitted electronically via Tabula before the end of Thursday in (Academic) Week 21. You are reminded to ensure that your submission is of an appropriate file size. It is the student's responsibility to ensure that files are submitted satisfactorily.
Report assignment could vary, but you are expected to include the following details:

- the role of each group member in the project
- two or three possible implementations and the reasons why you decided to adopt one of those
- Design and implementation methods/tools/strategy

Final report (week 32, credits 4.8)
This report will be the Technical Documentation of your medical device, as defined by the current regulation on medical devices (Annex II, EU Medical Device Regulation 2017/745), which is summarized in the British Standard Institute (BSI) guide titled "Technical Documentation and Medical Device Regulation", which students can find online , and includes:

1. Device description and specification, including variants and accessories
2. Information to be supplied by the manufacturer
3. Design and manufacturing information
4. General safety and performance requirements
5. Benefit–risk analysis and risk management
6. Product verification and validation

	Weighting	Study time	Eligible for self-certification

Beyond this document, it can be relevant to remark that all Warwick Students have access to the BSI online website (https://bsol.bsigroup.com/), where they can download standards and other relevant documents.
This submission should be prepared using the same format adopted for the interim project and must not exceed 3200 words. The report must be submitted electronically via Tabula before the end of Thursday in (Academic) Week 32. You are reminded to ensure that your submission is of an appropriate file size. It is the student's responsibility to ensure that files are submitted satisfactorily.

Group Presentation (week 32, credits 2.7)
This presentation will give students the possibility to present their work and their prototype. You may help your presentation with a PowerPoint (or an equivalent software) presentation. Each group is expected to give a 20min presentation, followed by 10-minute questions. Each student is expected to contribute to the presentation preparation and delivery. Group presentations are expected to run in week 32 (details on the room and timing will follow).

Assessment Criteria
Each deliverable will be assessed considering the following criteria: completeness, correctness, clarity, style of presentation.

Feedback
The Module leader will send to all the students via email detailed feedback.

Reassessment component is the same

Assessment component

Health Technology Review	40%		No

Report
Students are required to select one medical device (assigned by the Module Leader) and write an essay describing:

1. The working principle (e.g., underlying chemical, physical, biological or physiological phenomena relevant for the medical device);
2. Device main components/parts (i.e. using block diagrams) and their working principles;
3. Medical device classification according to European or FDA classification;
4. Relevant factors affecting design, assessment, purchasing and maintenance;
5. References.

Presentation
It is expected that the student will give a 10min presentation on the medical device assigned,

	Weighting	Study time	Eligible for self-certification

using a Power Point presentation (or equivalent technology).
The presentation is expected to illustrate the following:

1. The working principle of the device (i.e. physical, biological or physiological);
2. Device main components/parts (i.e. using block diagrams);
3. Medical device classification according to European or FDA classification;
4. Relevant factors affecting design, assessment, purchasing and maintenance

Assessment Criteria
The report and the presentation will be assessed using the following criteria: content, clarity and style.

Feedback
Each deliverable will be assessed considering the following criteria: completeness, correctness, clarity, style of presentation.

Reassessment component is the same

Feedback on assessment

Coursework and Group Project marked with detailed comments
Face-to-face feedback in seminars

Availability

Courses

This module is Core for:

- Year 1 of TESA-H800 Postgraduate Taught Biomedical Engineering

This module is Option list A for:

- Year 4 of UESA-H114 MEng Engineering

This module is Option list B for:

- Year 4 of UESA-HH31 MEng Systems Engineering
- Year 4 of UCSA-G408 Undergraduate Computer Systems Engineering