

Introduction to Medical Devices and its Design (IMDD)

Degree: Biomedical Engineering degree at Universitat Pompeu Fabra

Year: 4th year

Trimester: 1st

Number of ECTS credits: 5 ECTS credits

Lectures: 21h

Seminars: 10h

Labs: 12h

Languages of teaching: English and Spanish (E and S, respectively, below)

Coordinators: David Andreu (labs) / Oscar Camara (seminars)

Speakers: There will be thirteen different speakers from industrial, clinical and academic institutions related to medical devices.



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Introduction to the subject

The IMDD subject introduces different aspects of medical devices in several clinical applications, with special emphasis in cardiovascular and neurological pathologies. For each presented technology, most of the following aspects will be treated: basic physiology and pathology of the disease leading to the clinical need for the device; precedent technologies to the device; the specific device, design and materials; insertion and deployment methods; risks and advantages; limitations; examples; indications and use cases; FDA regulations; security in medical devices and implants; optimization of implanted devices; interaction device-tissue.

Lectures of the IMDD subject will be given by academics involved in medical device research, physicians from large local hospitals and engineers from six different device companies, including large multi-national enterprises and SMEs. This unique combination of healthcare professionals will provide a complete overview of the medical device sector and may open up career opportunities to the students. The IMDD seminars will consist in short demos of some of the presented devices/techniques and visits to hospitals to witness their daily use in clinical routine.

Labs of the IMDD subject will be centred on a project to plan and design a personalized medical device with computational tools, preparing a presentation/demo targeting a hypothetical investor, clinician or device company. 3D printing facilities will be available to create a prototype of the device to support the demo.

Competences to work

The main goal of the IMDD subject is to present the relevant aspects of the medical device pipeline, from having an idea to commercialize a product, in a variety of clinical applications, including cardiovascular and neurology pathologies. The organization of the IMDD subject will put students in direct contact with healthcare professionals working in this sector, improving their knowledge on possible career opportunities.

Topics (lectures and seminars)

Introduction to the subject and 3D printing project (1h)

Module 1 - Cardiovascular (7h lectures, 5h seminars)

- A. Radiofrequency Ablation and navigation in cardiac arrhythmias. Lecture by **BioSense Webster** (*David Andreu*, E). L1 (2h). Host: Oscar Camara.
- B. Radiofrequency Ablation and navigation seminars. Visit to **Hospital Clínic de Barcelona** (*David Andreu*, E). S1 (2h).
- C. Pacemakers, Insertable Loop recorders and Cardiac Resynchronization Therapy Devices (and ICDs). Seminar by **Medtronic** (*María García*, E). L2 (2h). Host: Oscar Camara
- D. Remote monitoring and MRI-compatible devices. Seminar by **Biotronik** (*Josep Asenjo*, S). L3 (1h) + S2 (1h).
- E. Percutaneous Implantation of cardiac valves. Lecture by Dr. *Salvatore Brugaletta* (**Hospital Clínic de Barcelona**, E). L4 (2h). Host: Oscar Camara.
- F. Haemodynamic unit. Visit to **Hospital Clínic de Barcelona** (*Xavier Freixa*, E). S3 (2h).

Module 2 - Neurology (6h lectures, 2h seminars)

- A. Neuro-stimulation devices I. Lecture by **Starlab/Neuroelectrics** (*Guillem Mitjà*, E). L5 (2h).
- B. Deep-brain stimulation (DBS) system. Seminar by Starlab/Neuroelectrics, (*Guillem Mitjà*, E). S4 (2h).
- C. Cochlear implants. Lecture by Dr. *Jesús Rodríguez* (**Hospital Sant Joan de Déu de Barcelona**, E). L6 (2h). Host: Oscar Camara
- D. Interventional neuroradiology. Lecture by Dr. *Juan Macho* (**Hospital Clínic de Barcelona**, E). L7 (2h). Host: Oscar Camara

Module 3 - Other applications and environment around devices (7h lectures, 3h seminar)

- A. Abdominal ablation. Lecture by Dr. *Fernando Burdío* (**Hospital del Mar, IMIM**, E). L8 (1h) + S5 (1h). Host: Oscar Camara.
- B. Medical Device Pipeline: From an idea to the patient. Lecture by **Apeiron Medical** (*Rita Quesada*, E). L9 (1h) + S6 (1h). Host: Oscar Camara
- C. Innovations in the medical devices industry: up close and personal experiences. Lecture by Prof. *Antoni Ivorra* (**Universitat Pompeu Fabra**, E). L10 (2h)
- D. Creating a company for safe prostate biopsies. Lecture by Sr. Quim Castellví (**Universitat Pompeu Fabra**, E). L11 (1h) + S7 (1h).

- E. 3D printing technologies. Lecture by Sr. Daniel Almeida (Materialise, E). L12 (2h).
Host: Oscar Camara.

Labs

The labs will be organized in 6 teams of 4-5 people. Each team will be asked to give a presentation / show a demo in Week 10 of a personalized device they must plan and design during the subject, with the intention to convince a possible investor, device company or clinician of the benefits of the designed device. Freedom will be given to the teams for selecting the organ and device to work on, although some exemplary projects will be given in the first sessions. If possible, the designed device needs to be adapted to the patient-specific geometry of the chosen organ, extracted from a medical image. Several image processing and modelling tools should be used in order to generate the organ meshes and personalized device designs. These meshes could also be introduced to 3D printers to obtain a printed version of the device to be used in the demo. 3D printing facilities have recently been acquired in Campus Poblenou (Àrea Tallers, 54) and will be accessible to IMDD students through fixed time slots of 8h-12h.

Most of the following aspects needs to be treated during the presentation: basic physiology and pathology of the disease leading to the clinical need for the device; precedent technologies to the device; the specific device, design and materials; insertion and deployment methods; risks and advantages; limitations; examples; indications and use cases; FDA regulations; security in medical devices and implants; optimization of implanted devices; interaction device-tissue. An exploratory market and business analysis is also required at the presentation.

The pipeline for designing the personalized device could be divided in the following steps: a) original idea and motivation; b) extracting personalized organ geometry; c) mesh representation of organs; d) device design with modelling tools; e) 3D printing prototypes; f) final presentation. Lab sessions during the course will then be devoted to obtain feedback from teachers on these different steps of the project, as follows.

Session 1 - Introduction to possible projects, printing technologies and computational tools. Week 1 (1h)

Session 2 - Presentation of each team's project and acceptance by teachers.

Week 2 (2h)

Session 3 - Presentation of image processing and mesh construction results. Week

4 (2h)

Session 4 - Presentation of organ 3D printing results and first device models.

Week 6 (2h)

Session 5 - Presentation of 3D printing and model results of devices. Week 9 (2h)

Session 6 - Rehearsal of the presentations. Week 10 (1h)

Session 7 - Final presentations. Week 10 (2h)

Assessment

- Final exam (30%)
 - Test (yes/no questions) based on the concepts acquired during lectures and seminar sessions
 - Minimal mark of 5.0
- Participation in lectures (2.5%)
 - Questions to speakers
 - Assistance (on time) to lectures
- Report on seminars (7.5%, groups of 3 people)
 - Group report (max of 3 pages) on visit to Hospital Clínic de Barcelona including: type of intervention during the visit; discussion of the case; type of disease; incidence of disease; type of data used; if any device was used; if imaging systems were used; role of engineer; organization of the Unit of Haemodynamics; discuss on planning of intervention, guidance, follow-up.
- Personalized device project (60%)
 - Oral presentation: organization, clarity, credibility, supporting material, communication skills;
 - Innovation/quality device; market/business analysis
 - Best device chosen by students / teachers