Course of Medical Design (BM017IU)

Semester 1, 2024-2025

Instructor: Dr. Tran Le Giang

LAB 1 HANDOUT

1. Objectives

- Understanding the process of designing a medical device
- Initialization of the course's final project

2. Introduction to the design process

2.1. Identify problems

The starting point for designing a medical product often comes from two areas, either a need for:

- a new type of product that aims to solve a particular problem, or
- an improved version of the existing product, targeting a specific group of users

Usually, the design work is based on a client's request. A client is a company or an entrepreneur who may finance a new product. New ideas can also be invented after extensive research into a particular subject. Once you have a problem to solve in mind, it is time to come up with a *design objective and initial requirements*, sometimes called *design brief*. This is a short statement about your design intent and what the product will be like. This may include:

- what and where the problem is
- type of the product (diagnosis or assistive devices, laboratory equipment…)
- product's function
- target user (Who is it for? What makes it appeal to them?)
- how often and when the product is used
- the material used

It is important to have a design brief with your clients so everyone can get a full understanding of what is required.

2.2. Conduct initial research

Initial research helps you collect all the relevant information necessary to create a new product. Data can be gathered in many ways, such as:

- Looking at existing or similar products and comparing their specifications; experiments and testing of the working products.
- Looking at what materials, the finishes, or processes are available to you.
- Looking at how people use the products
- Information from other sources such as research papers, the internet, or surveys.

You must think about which data is relevant to the problem and leave what is not. This ensures you have a full understanding of the problem and situation.

2.3. Establish design specification

Initial research helps guide your design specification. Design specification is a document that develops the brief, listing key constraints of the designs. The specification needs to be clear and succinct, using data wherever possible. It is a working document and will need reviewing with the clients on a regular basis. It is also the criterion for evaluating your project when it is finished.

Some of the specifications for consideration are:

- Function (how does it work? special features?)
- Performance (how well does it work?)
- Manufacturing process
- Materials and their properties
- Accuracy/Reliability (the quality levels that aspects of the product need to achieve)
- Cost
- Key size and weight (and how they are important for this product?)
- Safety (what makes the product safe?)

Other factors such as ergonomics (easy, comfortable to use? easy to adjust?), environment concerns (how to leave minimal effect on the environment? use recycled materials?) and aesthetics (specific style? feelings about the product?) can also be included in the specifications.

2.4.Brainstorming and coming up with ideas

Having the specification as a guidance and data as resources, it is time to start generating a wide range of preliminary ideas. These initial ideas are usually quick outline ideas, with sketches and notes as a way of communicating ideas to the clients and peers. It is critical to generate as many ideas as you can, and make sure all your ideas are recorded so they can be referred to later.

2.5. Communicating ideas to others

After having ideas, it is important to communicate them to the clients or your peer so that they have a clear understanding of your solutions and give feedback. Communication can take many forms, depending on what you are trying to communicate. Some useful forms are:

a) Mechanical parts

If you are discussing possible solutions at an early state, rough sketch with annotation (including explanation of the material and finish, assembly instructions, and rough dimension) may be most suitable to explain your thinking. To depict 3D objects in 2D image, *isometric drawings*, *perspective drawings* or *exploded views* are often used. You can have computer-added design drawings to make the drawings clearer and more realistic.

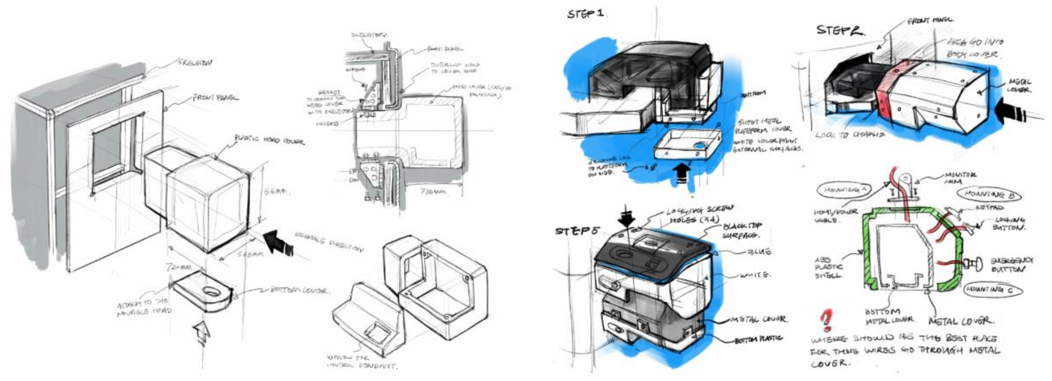

Figure 1.Quick concept sketch and equipment enclosure instructions [1]

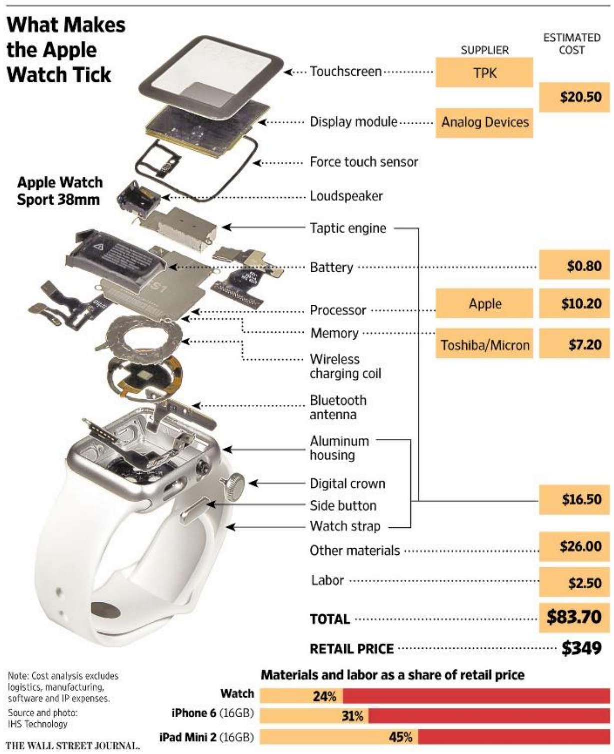

Figure 2. Example of an Apple Watch Sport 1st generation's exploded view [2]

b) Hardware and electronic components

Block diagram, sometimes called *hardware architecture diagram,* is commonly used to explain your hardware design. It breaks the product down into functional sections, called *blocks*, and illustrates how each block interacts with each other. The blocks are connected by lines showing data or control flow. This helps in conceptualizing the system architecture and pinpointing where specific electronic components are needed.

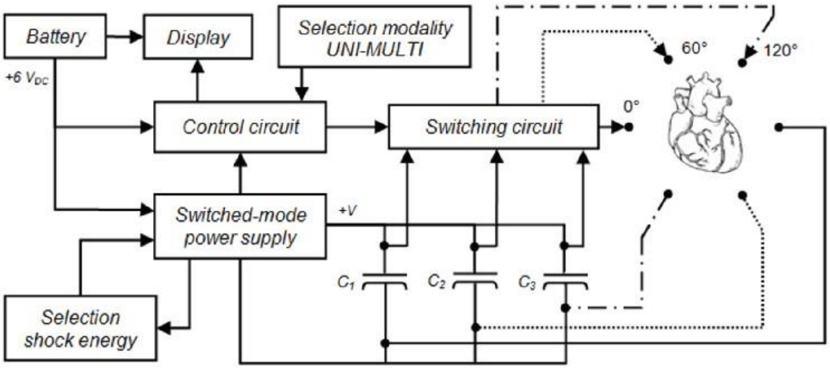

Figure 3. Multi-directional defibrillator block diagram [3]

Decision matrix, on the other hand, assists in evaluating and comparing different components based on criteria such as cost, performance, availability, and power consumption. It allows an objective selection process for each block, ensuring that the chosen components align with the project's requirements.

Hardware interface diagram delves deep into the data flow between hardware components and offers value when troubleshooting the layout and connections of hardware components. Each component has specific points, called interfaces, that can be connectors, GPIO pins and communication protocols like I2C, SPI or UART. There are lines showing how components are physically connected, and arrows indicating how data moves between them.

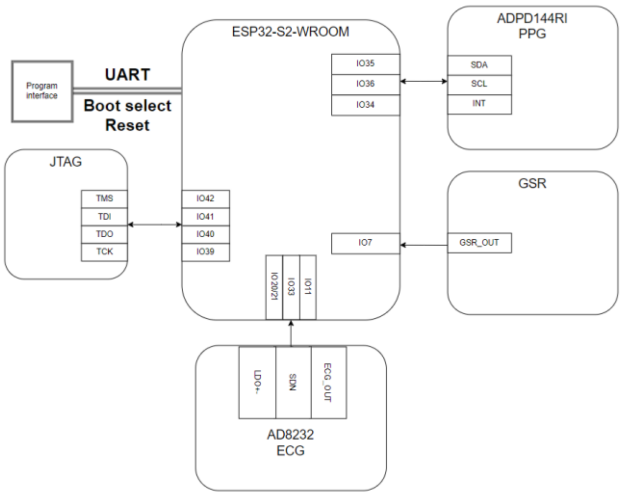

Figure 4. Example of a project's interface diagram using ECG and PPG modules.

c) Firmware and software

Flowchart is an important tool to visualize the sequence of operations in firmware or software. It outlines each step, describes how data flows and decisions are made within the system, making it most suitable to explain algorithm design or procedural documentation. Each instruction is in a rectangular box and decisions are in diamond-shaped boxes. The start and end of a sequence is in a terminal point.

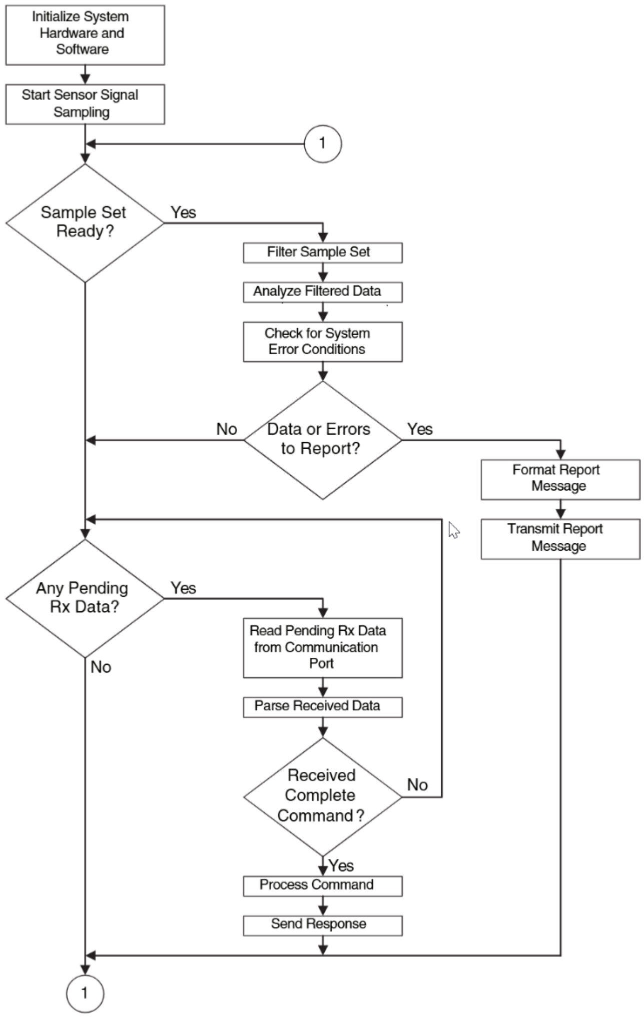

Figure 5. Example of a sensor signal-processing flow chart [4]

Based on the complexity of your system, you can further explain detailed software processes and user-system interactions using *software architecture diagram* and *sequence diagram*.

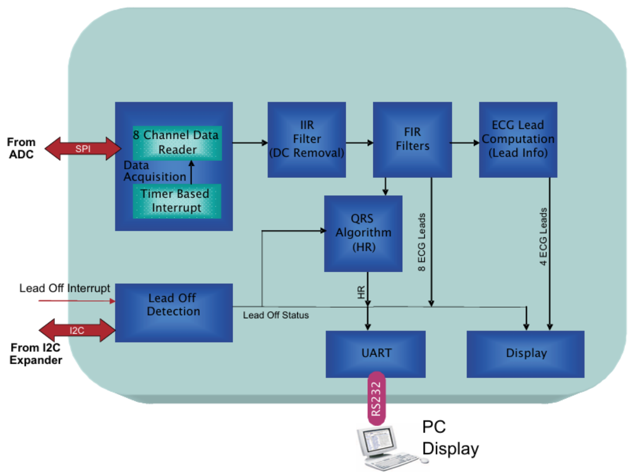

Figure 6. Software architecture example for an ECG DSP subsystem [5]

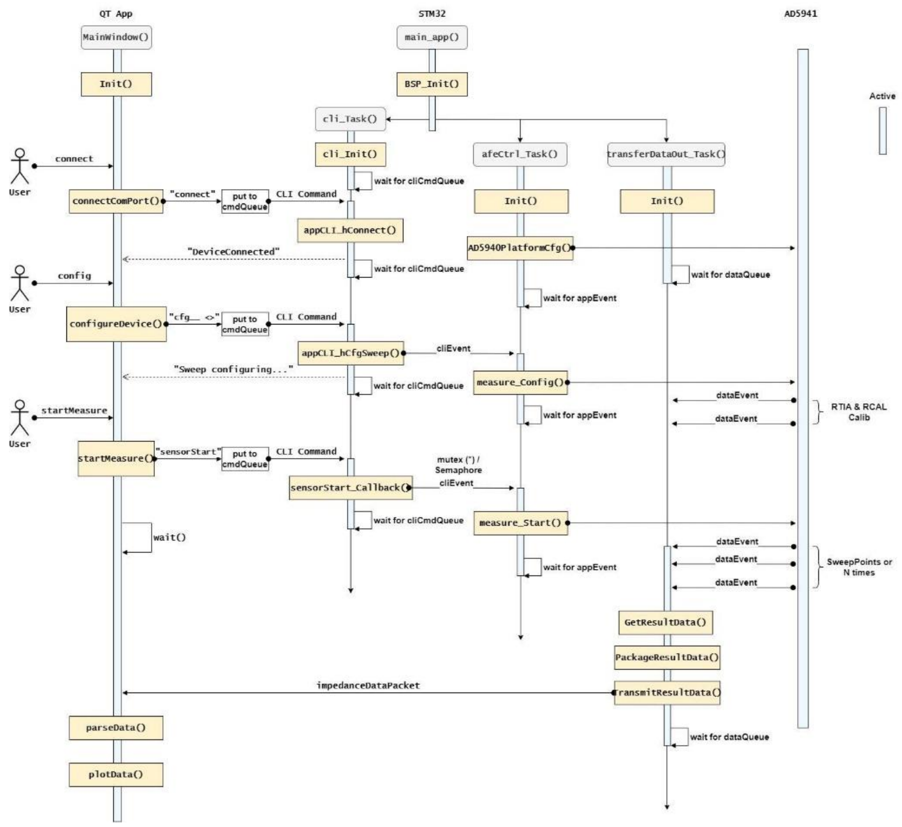

Figure 7. Example of a sequence diagram for measuring bioimpedance using QT application [6]

2.6.Prototype development and evaluation

To evaluate and select the best idea, scale or life-size models, called *prototypes*, are created, allowing testing of mechanical functions and evaluation of their form. *Paper*, *corrugated cardboard*, *balsa wood*, *acrylic*, *foam board*, *Styrofoam* or *polymorph* can be used to construct a prototype as they are cheap and easy to work with. *3D printing* is also a common method for design modeling. Make quick prototypes for concept ideas and development. Make more detailed, permanent prototypes for sharing ideas with clients and peers for evaluation and critique.

Design is a cyclical process. Continual testing and evaluating should be carried out throughout the design cycle. Tests can be completed through software or real-world experiment, such as *user trial/field test* – when the intended users work with either a prototype or the finished product; *functional test* – which carries out in set-up conditions many times to simulate the product or parts of it, being used; *materials test* – including density, tensile, heat, conductivity/insulation, hardness test…; or through informal evaluation such as *peer review.* Keep a *logbook* of all testing being carried out as a reference for evaluation. Then modifications are made based on the evaluating results. The products get better over time through incremental and small gains changes.

Figure 8. Cyclical process of any product design [7]

3. Lab activities

Show the block diagram and flow chart on how to use the syringe pump. Discuss the design objective and initial requirements, then sketch initial ideas for your group's final project.

4. References

[1] Yang, D. (n.d.). *3 ways medical device sketching helps the design process.* StarFish Medical. https://starfishmedical.com/blog/medical-device-sketching-design-process/

[2] Olivarez-Giles, N. (2015, April 30). *What makes the Apple Watch Tick.* The Wall Street Journal. https://www.wsj.com/articles/what-makes-the-apple-watch-tick-1430437769

[3] Viana, M. A., Bassani, R. A., Petrucci, O., Marques, D. A., & Bassani, J. W. M. (2016). System for open-chest, multidirectional electrical defibrillation. *Research on biomedical engineering*, *32*, 74-84.

[4] Huddleston, C. (2006). *Intelligent sensor design using the microchip dsPIC*. Elsevier.

[5] Markandey, V. (2010). *Application Report*: *ECG Implementation on the TMS320C5515 DSP Medical Development Kit.* Texas Instruments.

[6] Tran, N. L. (2023). *Portable bioimpedance measurement device using IC AD594* [Unpublished undergraduate thesis]. Ho Chi Minh City University of Science.

[7] Harris, J., Bell, D., Hughes, C., McLain, M., Ross, S., Wooff, D. (2018). *Cambridge IGCSE™ Design & Technology Student's Book* (2nd ed.). Collins.

5. Manual information

- This manual is developed by:
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- Last updated: Semester 1, 2024-2025