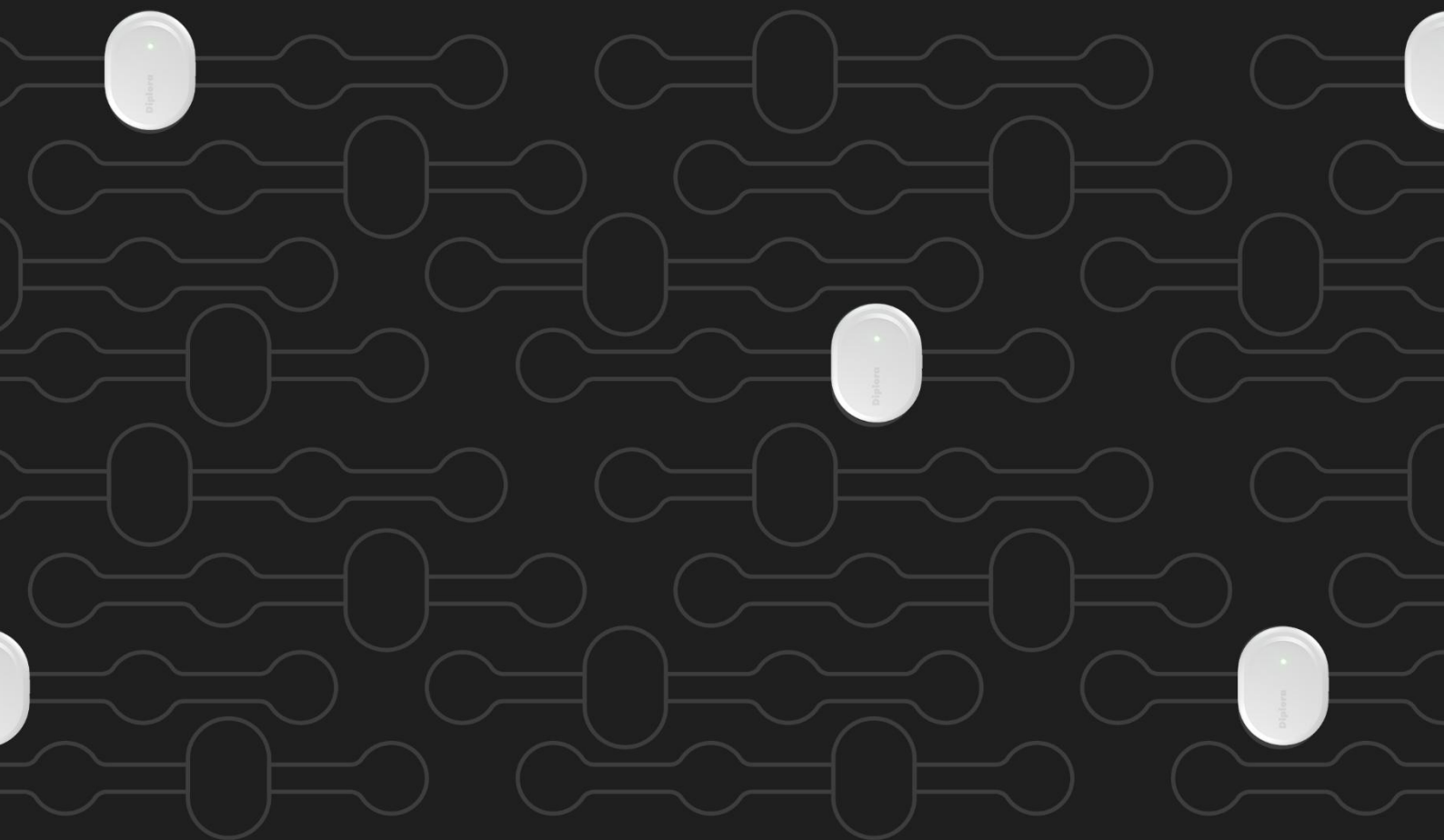


# DIPLORA CARDIGO

*DESIGNING A WEARABLE  
ECG FOR SPORTIVE  
CARDIAC PATIENTS*



**Wouter Kruihof**  
Integrated Product Design  
MSc. Graduation Thesis

**TU Delft**  
**Diplora**

# DIPLORA CARDIGO

## “Designing a Wearable ECG for Sportive Cardiac Patients.”

MSc. Graduation Thesis  
September, 2025

**Wouter Kruithof**  
Integrated Product Design  
Faculty of Industrial Design Engineering  
Delft University of Technology

Chair  
**Dr. Ir. Sonja Paus-Buzink**  
Human-centred design  
Applied Ergonomics and Design

Mentor  
**Ir. JanWillem Hoftijzer**  
Human-centred design  
Human Information Communication Design

Company Mentors  
**Ir. Auke de Leeuw**  
**Dr. Ir. Taco Kind**  
Diplora



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## Abbreviations

GP: General practitioner

AF: Atrial fibrillation

DC: Diagnostic center

ECG: Electrocardiogram

PC: Poly carbonate

## Glossary

**Electrode:** a small, plastic patch that sticks to the skin and measures the electrical activity of the heart.

**Leads:** linear directional potential differences measured in the heart. In general, more leads result in more accurate cardiac measurements and allows the detection of more (rare) arrhythmia. Leads consist of multiple electrodes.

**Arrhythmia:** a problem with the rate or rhythm of heartbeats.

**Proarrhythmic:** the aggravation of an existing arrhythmia.

**Atrial fibrillation (AF):** an abnormal heart rhythm characterized by rapid and irregular beating of the atrial chambers of the heart.

## Executive summary

Cardiovascular diseases are the leading cause of death globally. Diplora, the client of this project, is developing a product service system that improves the quality of life for patients that require (preventative), at home, heart monitoring whilst maintaining high diagnostic capabilities. The objective of this thesis is to design a comfortable, sustainable and viable monitoring product solution that integrates into this developing product service system.

An ergonomic product design is key for a comfortable wearing experience and was thus developed through user participated research with physical prototypes. As a true testament to comfort, freedom-of-movement and mobility, the device was developed to endure sportive activities. Ergonomically relevant requirements were found and then implemented in the final design proposal. Design aspects that have the highest positive impact on comfort were found to be: minimal (adhesive) contact area with the skin, high conformity to skin wrinkling and a smooth low-profile design of the enclosure.

The result of this thesis is a product vision consisting of a modular ECG device that attaches to a custom electrode patch. The device is optimized for small scale production and initial clinical testing. It is waterproof, durable and designed with minimal need for adhesives, fasteners and production steps to keep cost down whilst not compromising on sustainability, aesthetics or performance.

Ergonomic performance of the final design proposal has been verified through final user testing (with both men and women) and resulted in an average comfort score of 9.3 out of 10. During sportive activities and sleeping this score was as high as 9.8.

Diplora has decided to proceed with this design proposal and is actively developing it towards production and initial clinical testing. This thesis lays a solid foundation for further development of the wearable Diplora ECG, helping Diplora realize a more accessible, sustainable and comfortable cardiac telemonitoring future.

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# 1. PROJECT INTRODUCTION

According to the World Health Organization (2019), cardiovascular diseases (CVDs) are the leading cause of death globally, taking an estimated 17.9 million lives each year. Between 15-20% of deaths worldwide are caused by sudden cardiac death (SCD) and 38% of worldwide premature deaths (under the age of 70) were caused by CVDs. The WHO presses the need for identifying and diagnosing those who are at high risk of CVDs to ensure appropriate treatment which can prevent premature deaths.

Devices that measure the heart's activity are called electrocardiogram devices (ECGs). A tool the current healthcare system misses is one that is of low burden to patients, detects a wide spectrum of arrhythmia and is low of impact on the environment. The current healthcare system for cardiac monitoring contains many inefficiencies, causing long waiting times and the possibility of missing diagnosis. Furthermore, existing portable and wearable long term monitoring devices are not capable of detecting the full spectrum of arrhythmia or are extremely hindering to patients' daily lives. The application of these devices requires expert intervention which forces patients to travel. Telemonitoring, also known as E-health, can streamline this process by delivering self-applicable diagnostic tools to the patients' homes.

Some diagnostic devices become e-waste after their short use period of only seven days. Re-use of devices has not been adopted enough. Plastics account for 25% of the waste generated by hospitals. And 91% of plastics are not recycled and end up in landfills or nature (Jain & LaBeaud, 2022).

In this project, the telemonitoring solution envisioned by Diplora is further explored, validated and developed into a system-integrated product proposal.

## 1.1. PROJECT BRIEF AND SCOPE

The project brief for this graduation project was defined in collaboration with Diplora and the Tu Delft. This project aims to develop Diplora's vision of a wearable ECG. This product should fit in a novel telemonitoring system that includes stakeholders like general practitioners, diagnostic centers and most importantly, cardiac patients. Diplora developed a first prototype which requires much improvement to become viable (Figure 1). This project has a special focus on sporters. Intensive sporters are known to be proarrhythmic, meaning they have a higher likelihood of developing arrhythmia like atrial fibrillation (Heidbuchel, 2017). In an effort to provide insight into the hearts health during the activity the patient loves, this project will focus on designing a wearable ECG for people that live a very active lifestyle. The 2024 Heart Rhythm Society expert consensus statement highlights that individualized evaluation and treatment strategies are crucial for sporters return to play after having experienced heart troubles (Lampert et al., 2024).

The scope of this project is set around the physical design concept and user interaction challenges of the Diplora wearable ECG. This involves comfort, device feedback, usability, material selection, ergonomics and sustainability concerns. Diplora's novel product service system falls only inside the scope during the analysis phase and is used for gathering product related requirements. Electronics and software are developed by Diplora and are out of scope for this project.



*Figure 1 Diplora's first prototype*

### **The initial assignment:**

“Design a wearable ECG device, suitable for multiple days of consecutive use by people with an active lifestyle to collect high quality heart related data.”

## 1.2. DESIGNING FOR SPORTERS

Sporters endure very challenging scenarios for electrical wearables. Designing for sporters is therefore a challenge. It has multiple benefits however. If the device is comfortable during sports and can handle challenging scenarios, it will also work for non-sporters who endure less straining and challenging scenarios. Sportive wearables must endure scenarios that involve water, sweat, lots of movement and skin stretching. The ideal device is one that is hardly felt and does not limit the (sportive) patient their mobility or performance.

An additional advantage of designing an ECG solution that is usable by sportive patients, is its useability for revalidating heart patients. They undergo sportive training schemes to support heart healing after a surgical interference. Interviews indicate that they would like reassurance of their heart health progress.

This project will focus on, and test with, **gym-goers** and **runners** to accommodate for a broad set of challenging scenarios. Gym-goers encounter deep stretching, maximum muscle tension and often work with heavy gym-equipment close to the body. Runners are subjected to lots of repetitive motion and variable weather conditions. Wetness will challenge the adhesive qualities of the patch whilst repetitive motion challenges skin comfort. Frequent showers are expected for both, which also tests resilience to wet conditions.

Diplora's final ECG solution should work for a wide demographic. This includes sporters, non-sporters, elderly, young people, men and woman. As visualized in Figure 2 and Figure 3, sports and movement are important activities in life for both young and old, men and woman. The goal for this project is to design a diagnostic device that empowers patients to continue practicing the sports they love, and thus has improved real-life diagnostic data generation for professionals and provides a sense of freedom and reassurance for patients.

### **Sporter desires**

Interviews provided insight into the most important product aspects for sporters. Unaffected mobility, safety and the device being light weight and low profile are the most important aspects for sporters. The device being waterproof (sweat, dust and shower proof) is a necessity for its resilience in sportive situations. It should not interfere with gym equipment.



Figure 2 Elderly sporters



Figure 3 Young sporters

### 1.3. APPROACH & METHODOLOGY

To indicate the steps taken, Figure 4 illustrates the project processes. In reality, the process of the entire project was not as linear. This report is built up in a structure that is easy to follow for its reader. Many back-and-forth iterations were done between phases and project processes. Each chapter includes learnings from the beginning and the end of the project, everything is intertwined. Chapter 5 can be seen as a midpoint in this project where the analysis phase of the project is (mostly) concluded and formulates key design challenges for the design phase.

This project had a major focus on 'research through design'. This involves a lot of physical prototyping and testing with participants.



Figure 4 Project phases overview

## **1.4. DIPLORA THE COMPANY**

Diplora is a startup that develops a product service system for long-term cardiac monitoring using AI-driven insights. The Diplora sensor, that is in development, streamlines arrhythmia detection and provides actionable insights through reconstructed 12-lead ECG data. This empowers general practitioners (GPs) and intermediate care providers to make confident, informed decisions about treatment or referrals, ultimately improving patient outcomes.

### **The team**

The current team is led by the two founders: Auke de Leeuw and Taco Kind. They assembled a multidisciplinary team consisting of electrical engineers, medical students, data engineers, industrial design engineers and advisory professors from the Hague University of Applied Sciences. Both national and international students participate. The composition of the team is very flexible and varies between 6 to 10 people.

### **Mission**

The overarching goal of Diplora is to save lives by avoiding CVDs caused by arrhythmia. Diplora wants to improve the cardiac patient experience and provide a better telemonitoring solution that simultaneously alleviates pressure from the healthcare system. Now, patients must endure long waiting lists for hospital visits, cardiologists appointments and holter researches. Improved monitoring products and healthcare systems ultimately result in a higher quality of life for both the patient and the healthcare provider. By designing a product that is re-usable, Diplora combats pollution and healthcare waste. Diplora wants their ECG solution to be applicable by the patient themselves.

### **SWOT Analysis**

A SWOT analysis was conducted to evaluate strengths, weaknesses, opportunities and threats for Diplora. Most strengths are related to the team and its wide expertise. Also, the implementation of the latest technology is a strength for Diplora. Weaknesses are related to the lack of validation and technical proof of concept. Since Diplora is partly dependent on EU grants, a limited start-up budget cuts options. Most threats relate to market competition of similar products and high certification costs. There are plenty of opportunities however: contributing to more accessible cardiac monitoring, contributing to more sustainable healthcare and improve waiting times for both the patient and health care expert by creating a solution that is independently applicable by the patient themselves. The full SWOT visual can be found in APPENDIX: SWOT ANALYSIS.

## 1.5. MAIN COMPETITION

To illustrate the competition Diplora will face, this subchapter briefly analyses the market in which Diplora will operate.

The main competing devices (in the European market) are the Bittium Faros and the Smart Cardia (Figure 5). Both are relatively small devices, using (at least) 3 leads and are wearable for 7 consecutive days, or more. Both cover the entire spectrum of cardiac monitoring, including screening, post-operative follow-up, and remote patient monitoring (also athletes). The Bittium has an option for wires or a patch. Both use custom, low cost, disposable patches. The Smart Cardia also measures other vitals like oxygen saturation, respiration, temperature, activity and sleep. The stickers can stay on for 14 consecutive days.



Figure 5 Bittium Faros (Wired and Patch configuration) (left), Smart Cardia (right)

As the number of leads is a big determinant of the ECGs monitoring capabilities, only ECGs with 3 or more leads are further analyzed in this subchapter. This results in the following selection of competing devices (Figure 6): Smart Cardia, Bittium Faros, Cardioline Walk Free, Philips E-Patch, CardioCore and the First Call Minipatch. The most important features are listed in Table 1.



Figure 6 Competing ECGs (left to right): Smart Cardia, Bittium Faros, Cardioline Walk Free, CardioCore and the First Call Minipatch

Device	Photo	Number of Leads	Max Recording Time	Weight	Live Streaming	Water Resistance
Smart Cardia Patch		7	Up to 14 days	Not specified	Yes	IPX5 (Waterproof)
Bittium Faros		1-3	Up to 14 days	18g	Yes	IP67 (Waterproof)
Cardioline Walk Free		3	Up to 9 days	30g	No	Not specified
QardioCore		3	Not specified	130g	Yes	IP65 (splash-resistant)
First Call Mini Patch		3	Up to 5 days	Not specified	Yes (Cellular & Wi-Fi)	Waterproof (IP rating not specified)

Table 1 Competitor features overview

## Price

The last important product aspect is price. Diplora wants to compete in this aspect with a maximum product selling price of €265 (production cost not exceeding €150). A product with similar or better performance that costs less than its competitor is more attractive for healthcare insurers. Prices vary a lot between brands, even if their features are comparable. The Bittium Faros costs between €1000-1800, depending on which website is consulted. The price of the Smart Cardia is undisclosed publicly. The portable 12-lead ECG by QT Medical, seen in Figure 7, is sold for \$3,499.00 (Portable Hospital-Grade 12-Lead ECG-QT Medical, n.d.). This means it is very possible to compete with product price if it remains Diplora's desire to undercut.



Figure 7 Portable 12-lead ECG by QT Medical

## 1.6. ECG VARIATIONS

This subchapter compares the five main types of ECG devices to better understand the product segment Diplora operates in and how to compare their product to the existing market. Each type is described individually to illustrate their use case, benefits and shortcomings.

### 12-lead ECGs

There are various tools available for diagnosing heart rhythm abnormalities, each with its own strengths and limitations. The 12-lead ECG (Figure 8) is typically used by cardiologists in hospital settings and provides an accurate snapshot for diagnosing arrhythmias. However, it only captures a moment in time, making it unsuitable for detecting transient arrhythmias or for use outside a clinical setting. For sports, a 12-lead exercise ECG is available. It is used for a supervised test performed during physical activity, aimed to reproduce arrhythmias and detect exercise-related cardiac anomalies. This method, however, requires trained personnel and additional equipment to measure vital signs.



Figure 8 Hospital-grade 12-lead ECG (Poetscornermc, 2023)

### Holter and event monitors

Currently, often holters and event monitors are used for continuous monitoring (Figure 9). These are hefty, carryable devices with generally seven leads that record ECG activity intermittently or continuously for up to 74 hours. They are useful for capturing infrequent or asymptomatic arrhythmias and can wirelessly transmit data to nearby devices. Still, according to Carrington et al. (2022) they often fail to diagnose symptoms due to limited test periods or user-related issues.

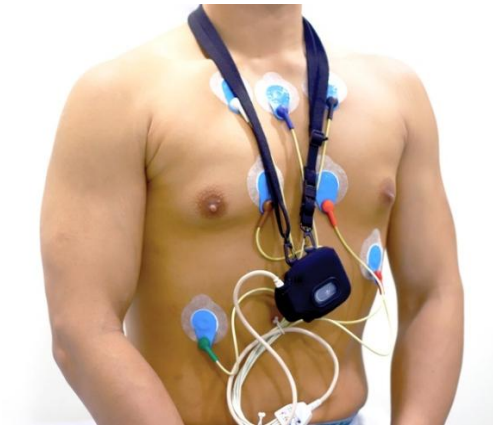


Figure 9 Holter monitor (Centre, n.d.)

### Prescribed patches and wearable ECG devices

The most important category for this project: extended rhythm recording through prescribed patches and wearable ECG devices. These offers up to 30 days of monitoring and often allows users to timestamp events with a physical button. These devices, typically using one to three leads, are the most practical for prolonged cardiac monitoring due to their compact size. They do however have an inferior capability in distinguishing between arrhythmia compared to 7-lead hollters or 12-lead ECGs due to their lower lead count and thus limited data acquisition. Diplora solves this compromise by reconstructing a 12 lead signal from only 3 leads using artificial intelligence (AI).



Figure 10 Wearable 1-lead ECG monitor - Zio patch (Taylor, 2020)



Figure 11 Bittium Faros in both patch and wire configuration

Diplora wants to introduce a device that fits in this product category. Figure 12 illustrates the main components of multiple ambulatory ECG devices. Number 1 illustrates a conventional holler that is hung around the neck, uses wires and standard electrode patches (also seen in Figure 9). Number 2 illustrates a smaller device, like the Bittium Faros,

that hangs on the chest from a standard electrode patch and uses dangling wires to connect to the other electrodes. Number 3 illustrates a 1-lead patch that can be applied by the patient themselves (also seen in Figure 10). Number 4 illustrates a small ECG device with a custom patch with 3 leads (4 electrodes). Solutions like number 1, 2 and 4 require a trained professional for proper placement. An analysis of patches that can be applied by patients themselves, similar to number 3, can be found in chapter 0.

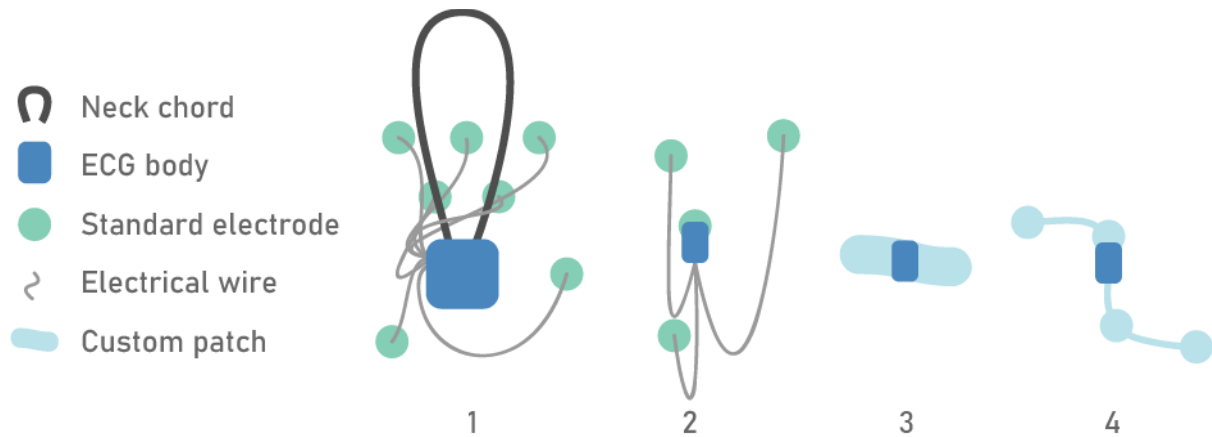


Figure 12 A holter, three wearable ECG devices and their main components

### Smart health devices

Smartwatches (Figure 12), fitness bands and health monitoring jewelry (Figure 11) are widely available to consumers, but do not provide continuous ECG readings, only heart rate measurements. Heart rate is measured in beats per minute (BPM) and does not provide any insight into the heart its electrical activity. Amongst other vital signs, they can detect basic heart related conditions like atrial fibrillation (*irregular heart rhythm*), bradycardia (*slower-than-normal heart rate*), and tachycardia (*faster-than-normal heart rate*). However convenient or aesthetically attractive, they lack precision and tend to produce a high number of false positives. Some smartwatches can measure an actual ECG signal if the user holds the watch with their other hand. This is only a single-lead snapshot measurement of short duration and thus, is very unlikely to detect any transient arrhythmia. They are wearable during sportive activities.



Figure 13 Oura ring - Smart ring (Oura Ring. Smart Ring for Fitness, Stress, Sleep & Health., n.d.)



Figure 14 Smart watch (Hunterrehab, 2020)

### **Implantable Cardiac Monitor (ICM)**

Finally, the Implantable Cardiac Monitor (ICM) is a small, USB-sized device implanted under the skin on the chest. This is a leadless solution to monitor heart rhythms for up to five years. It is often the best choice when other external monitors fail to detect infrequent symptoms. Despite its effectiveness, it is invasive and relatively expensive, costing around 2800 euros (Carrington et al., 2022).



Figure 15 Implantable Cardiac Monitors (Insertable Cardiac Monitors | Abbott, n.d.)

(A comprehensive table of each type its description, benefits and limitations can be found in APPENDIX: ECG TYPES OVERVIEW)

## **1.7. TECHNICAL ECG BASICS**

This subchapter clarifies the basic working principles of an ECG which helps to understand the origin of certain design requirements.

The heart can be seen as an electrical pump. It beats due to electrical impulses generated by a natural pacemaker called the sinoatrial (SA) node. These impulses spread through the atria and ventricles (the four chambers of the heart), causing them to contract in a coordinated way. These contractions make blood flow through the body.

Electrodes are placed on the skin and detect tiny voltage changes caused by the muscle contractions in the heart. Multiple electrodes create leads which can be seen as directional lines between one and another electrode. These leads (directional lines) provide insight into the heart its functioning from multiple directions. Amongst other health indicators, this can be used to determine which chamber contracts when and in what manner. Certain arrhythmias are localized to parts of the heart (e.g. atria vs. ventricles), so viewing from different perspectives helps identify the origin.

Since ECGs detect tiny voltage changes caused by muscle contractions, any muscle other than the heart will influence the ECG signal. This causes noise artifacts. These muscle-induced noise artifacts can be so disruptive that no clear signal can be extracted, even after noise filtration. Knowing this, it might be necessary to inform patients about this phenomenon and instruct them to sit upright and relax so that mainly the heart is being read by the ECG.

## **1.8. KEY INSIGHTS**

- Both plastic and e-waste should be avoided as much as possible, especially for the healthcare system.
- The device should be applicable by the patient themselves.
- The device should avoid positions where gym-goers rest their body on equipment.
- From the competitor analysis it can be concluded that Diplora operates in a challenging market that consists of a feature-competitive product landscape.
- A wearable solution that is technologically superior and applicable by the patients themselves will set Diplora apart from its competitors.
- Budget is a key limiting factor for Diplora as it is still a startup. Costs should be kept to a minimum.
- Diplora needs a differentiating brand identity.
- Dangling wires should be avoided against noise artifacts.
- The maximum retail price should not exceed €265
- The maximum production cost should not exceed €150.

## 2. UNDERSTANDING THE PRODUCT CONTEXT

Understanding the who, what, when and where around the product is required for developing a well-integrated wholistic design. This chapter illustrates the way the current cardiac healthcare system works and how Diplora wants to improve it. Then, the intended life cycle of the product is explained. A list of stakeholders is presented that dives deeper into the requirements and wishes of each party surrounding the product. All these topics provide requirements for the final product.

### 2.1. PATIENT JOURNEYS

A patient journey provides insight into the experience of a patient in a healthcare system. It maps out a patient their travels and interactions with both products and people. The patient journey map in this project includes three routes: using holters, wearable ECGs and finally the Diplora ECG. The holter- and wearable ECG route depict the current status quo for handling patients of whom the complications are suspected to be heart related. Holters and wearable ECGs are included as an option in this patient journey description to compare the experience of those devices to Diplora's envisioned telemonitoring solution.

For each route, there are many possible journeys. For that reason, only the most commonly occurring journey-options (according to Diplora's internal knowledge and GP interviews) are considered. In the existing healthcare system, there are many possibilities for stagnation and extra waiting time which often involve a lot of back-and-forth travel for the patients.

#### **Journey steps: Holter monitor**

Figure 16 describes the holter route. When a patient has a complaint, they first call their GP. The GP will then invite the patient for a visitation. After the visitation is completed, the GP can refer the patient to a cardiologist if they suspect the heart complication requires more expertise. As stated in the introduction, a cardiologist first takes a snapshot measurement of the heart using a 12-lead ECG. These have a very low chance of detecting transient arrhythmia. If this snapshot doesn't lead to conclusive test results (which it rarely does), the cardiologist will opt for longer term monitoring using a holter. These are generally worn for 1 to 3 days. Holters are generally only applied at hospitals or diagnostic centers by trained personnel (called cardiac technicians). How holters are experienced during the research period can be read below. After the research period is over, the patient returns to the hospital where the device is removed, cleaned and stored. The data is then extracted from the holter monitor and sent to a diagnostic center for analysis, or the data is analyzed by an internal cardiac technicians. This analysis takes a week on average. If there are no

conclusive results after this research is completed, or the patient did not experience any symptoms during this period, the research is repeated.

Another common route for patients is to be referred to a diagnostic center instead of a cardiologist after visiting the GP. Here, a holter will be provided to the patient immediately. The following steps remain the same as the cardiologist route depicted in Figure 16.

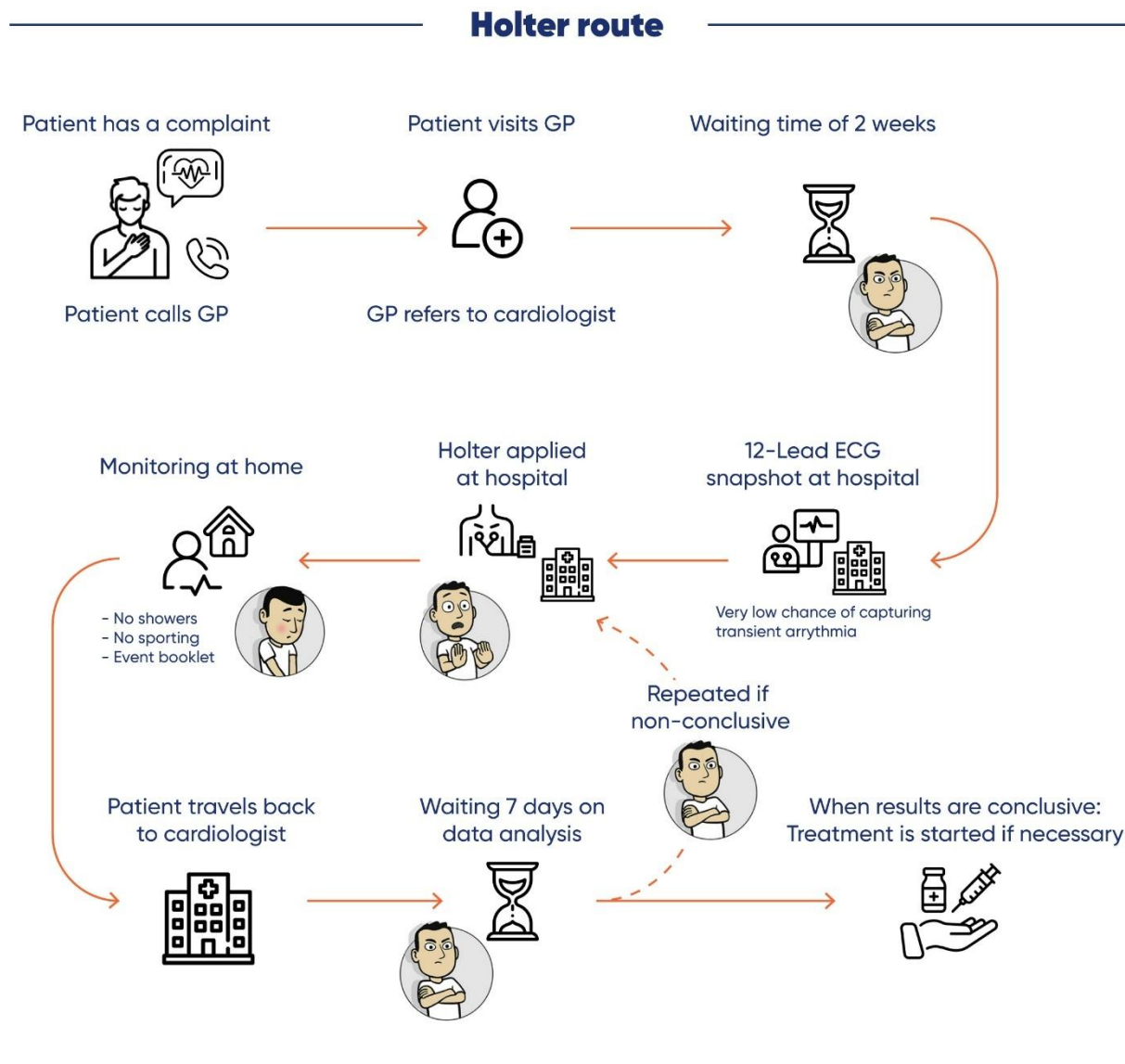


Figure 16 Holter route

## Journey steps: Wearable ECG

Figure 17 describes the wearable ECG route. This route is already shorter than the holter route with less waiting time. The general experience of wearing a wearable ECG is much improved compared to holters due to their improved freedom and discretion.

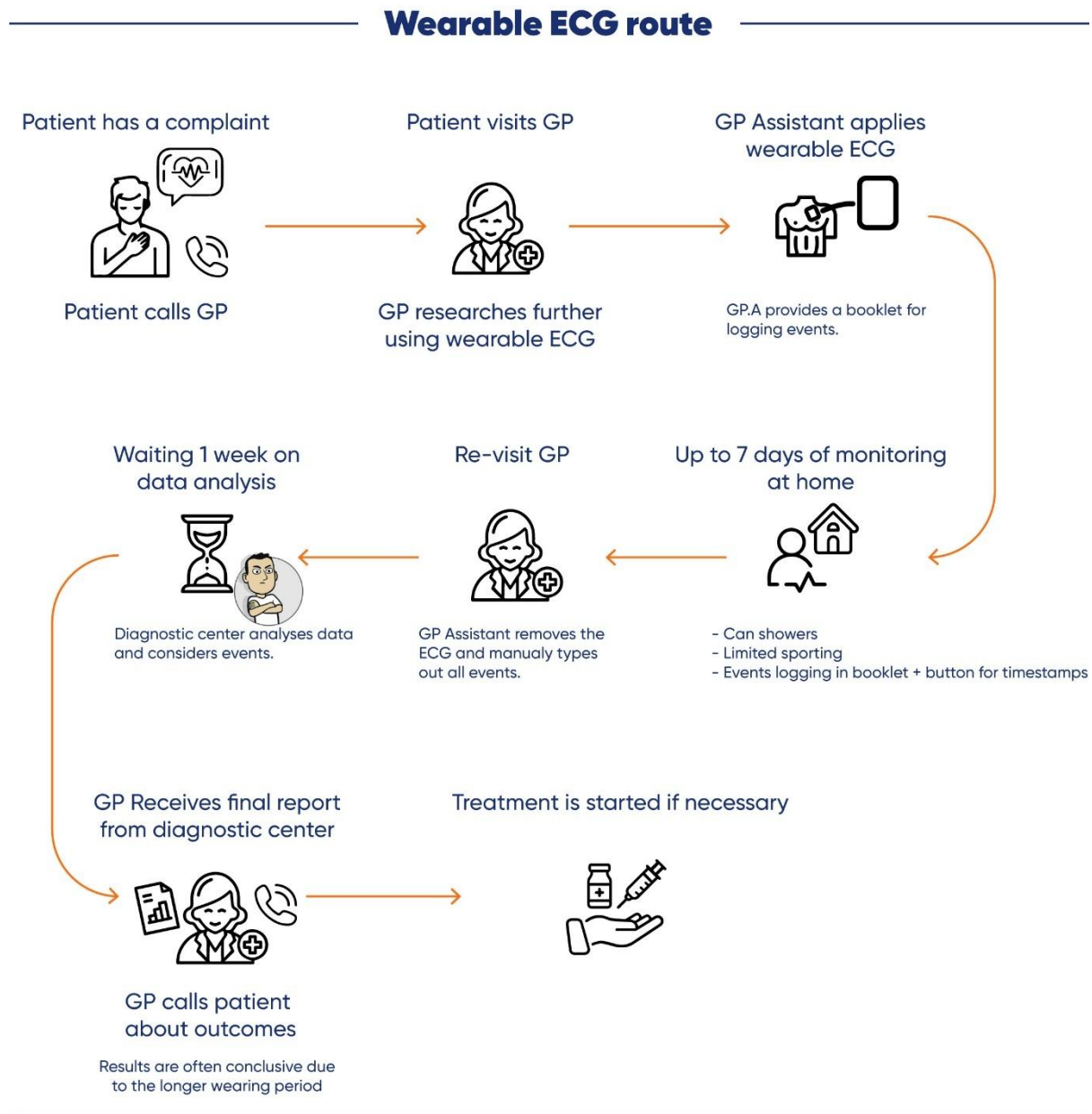


Figure 17 Wearable ECG route

## **Journey steps: Diplora's vision**

For the Diplora vision there are three options in the beginning. The Diplora ECG can be applied at the GP by a GP assistant, given to the patient at the GP without being applied, or be ordered for delivery at the home of the patient.

The patient will now wear the Diplora ECG for 5 to 14 days. During this period, the ECG streams all the gathered data to Diplora's cloud where it is immediately processed by AI. When the monitoring period is finished, a report is instantly generated and sent to the GP. The GP can now inform the patient of the results, theoretically, before the patient even returned the device. With this report, the GP can make an educated decision whether to start a treatment themselves, or to refer the patient to another healthcare expert.

As Figure 18 illustrates, the holter and cardiologist route have more hurdles and more waiting time than the relatively streamlined patient journey Diplora envisions. The route of the existing wearable ECGs is shorter than that of holters, but still includes waiting periods. Holters and existing wearable ECGs require patient travels whilst Diplora's telemonitoring system does not necessarily. Holters and existing wearable ECGs also require much manual labor performed by GP assistants and the diagnostic center. This labor mostly entails paper document scanning and visual inspection of ECG data. According to interviews this is a big burden and time consuming for GP assistants. Together with the data analysis performed by a diagnostic center, his manual labor adds 7 days to the time that is needed to create a final report.

Emotions experienced by the patients are depicted in Figure 18. For holter, waiting, shame and belittlement during wear, more waiting and a big chance of repetition play a role in the overall negative experience of this route. Wearable ECG are much better but still require waiting on data analysis. It is also required to visit the GP for these two options.

The Diplora ECG on the other hand has no waiting time outside of the wearing period and delivery time. Travel is not required, but optional for patients that prefer human contact (mostly elderly). This means the GP can have a stack of Diplora ECGs present for patients coming by but also order ECG to the patient their home is preferred instead.

## Timeline differences

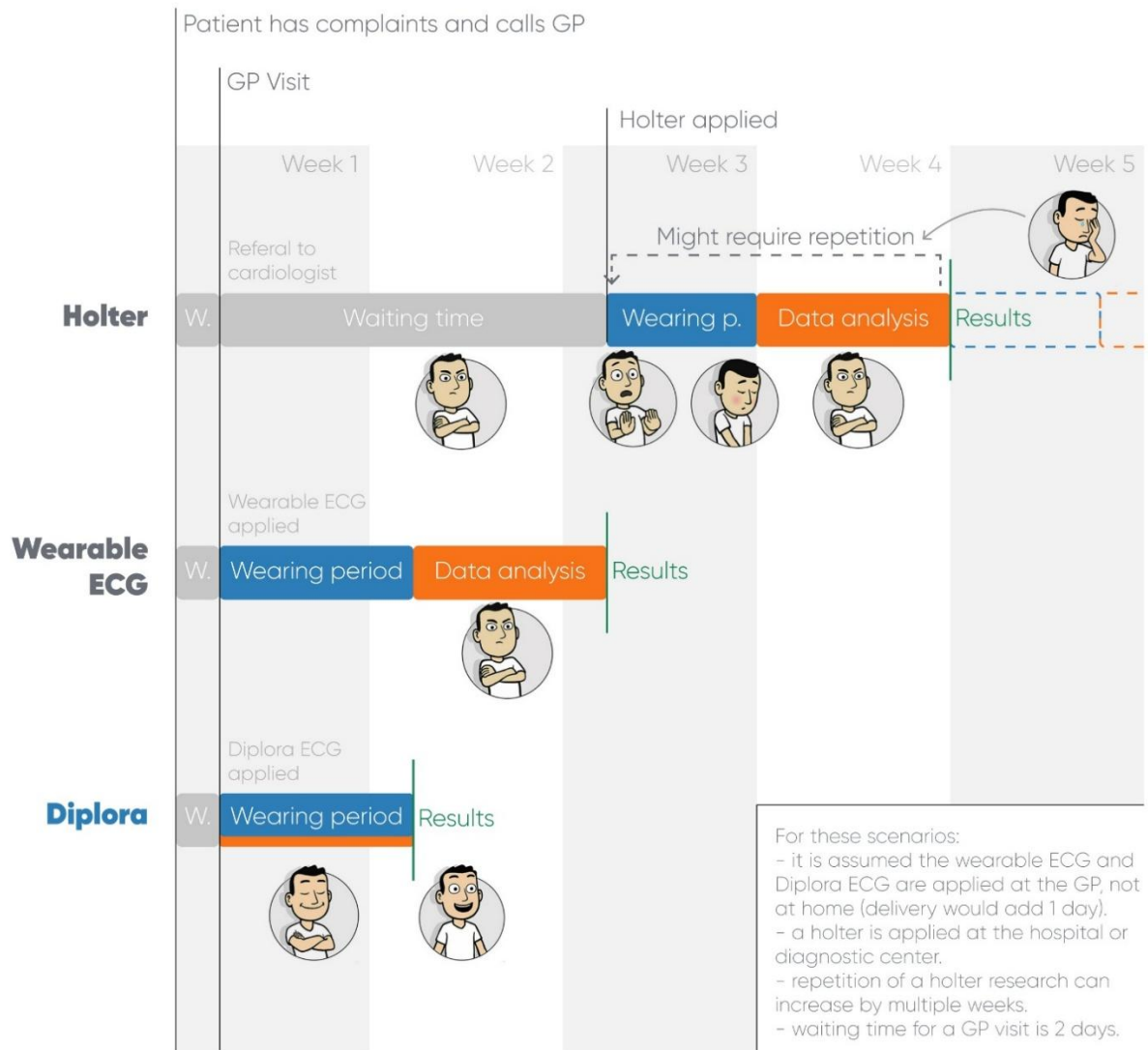


Figure 18 Timeline differences Holter, Wearable ECG and Diplora ECG

## **Holter experiences**

Qualitative research was conducted through interviews (n=3). Holters are experienced as “bricks” around a patient their neck. It limits their movement and sense of freedom. Sporting is not possible. This obstructs the detection of transient arrhythmia that occur during increased activity (Guasch & Mont, 2016). Daily activities suffer. Taking a shower becomes a lengthy event instead of a quick refresh. Showering with the holter on is not possible. Some holters, however, allow patients to remove all the electrodes before a shower. They must be re-applied after they’re finished, following a strict placement protocol. Electrodes must be placed correctly for proper measurements. In general, an instruction visual is presented in the event diary that comes with the holter. All the different wire colors should be connected to the correct electrodes. This is a very mistake-sensitive process.

Some holter wearers mention a feeling of shame when wearing a holter. As a holter is very visible, all participants mentioned being approached by others wondering “if they were okay”. This made them feel belittled. A discreet solution is thus preferred. Sleep is experienced as very uncomfortable due to the wires and flinging around of the casing.

## **Wearable ECG experiences**

Ergonomics and comfort wise, wearable ECGs are better than holters. Their current trade-off is a lower measurement accuracy due to less leads. Contrary to holters, wearable ECGs can be worn during most sportive activities. Excessive sweating, however, is generally not recommended and will cause patches to come loose and then need replacement.

Their application can often be done autonomously by the patient. Most wearable ECGs only consist of one lead and have a small patch not much longer than 15cm. Application requires shaving, rubbing with an abrasive paper (skin layer removal for improved conductivity), positioning and orientation of the ECG, and finally peeling away multiple films and pushing the device and patch onto the skin. Most patches do cause mild skin irritation.

If the wearable ECG has wires, there are often only two or three. If the patient prefers, these wires can be taped to the body to avoid flinging. There does not seem to be a clear preference between the wearing of a patch and wires according to GP assistant interviews and desk research. A finite answer requires more participant research on this specific topic. Cardiomatics, an online automated long-term ECG analysis platform, notices an increase in devices using patches compared to wires (Samborski, 2024). This can indicate the industry is steering to the use of patches instead of wires. Diplora prefers the aesthetics of a patch for their product.

## 2.2. DIFFERENCE IN MALE AND FEMALE EXPERIENCE OF WEARABLE ECGS

To this date, medical devices have mainly been tested on men. This causes a discrepancy in effectiveness and comfort between genders (The Appropriateness of Medical Devices Is Strongly Influenced by Sex and Gender, n.d.). To accommodate everyone's needs, it is important to design a device that works for both males and females. This subchapter researches the current differences in experiences between men and woman. As a start, online research is conducted and is later expanded upon through participant validation.

### Online opinions

To get a first indication of how both men and women experience ECG patches and whether there are any differences, online exploratory research was conducted. It was found that woman share significantly more about their experience wearing a mobile ECG than men do. Most women complain about their ECG. This could indicate that wearing a mobile ECG is a bigger burden for woman than for men.

Figure 19 provides an overview of expressions by woman wearing a wearable ECG. Many captions used by woman refer to their discomfort of having to wear an ECG patch. Most complaints are not about physical discomfort, but rather about visual appearance (emotional discomfort). Captions and voice-overs include 'tan lines', 'hot girl summer' and "this is f\*ng embarrassing..." (Figure 20) and are indicators of woman struggling with the feeling that is evoked by wearing an ECG.

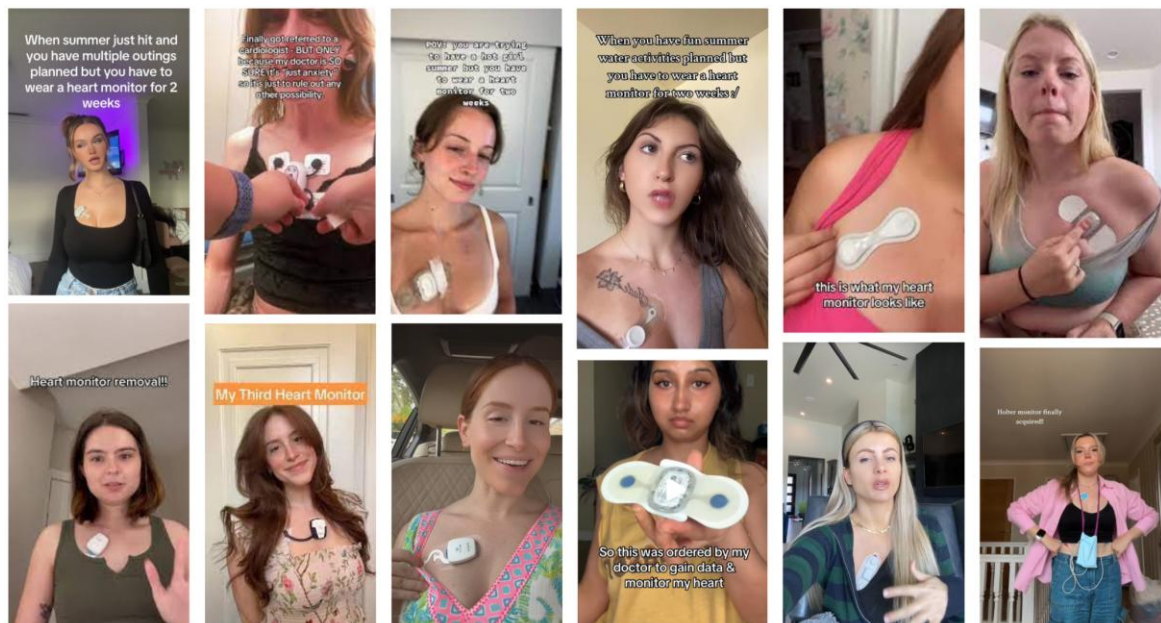


Figure 19 Collection of ECG patches and holters worn by woman

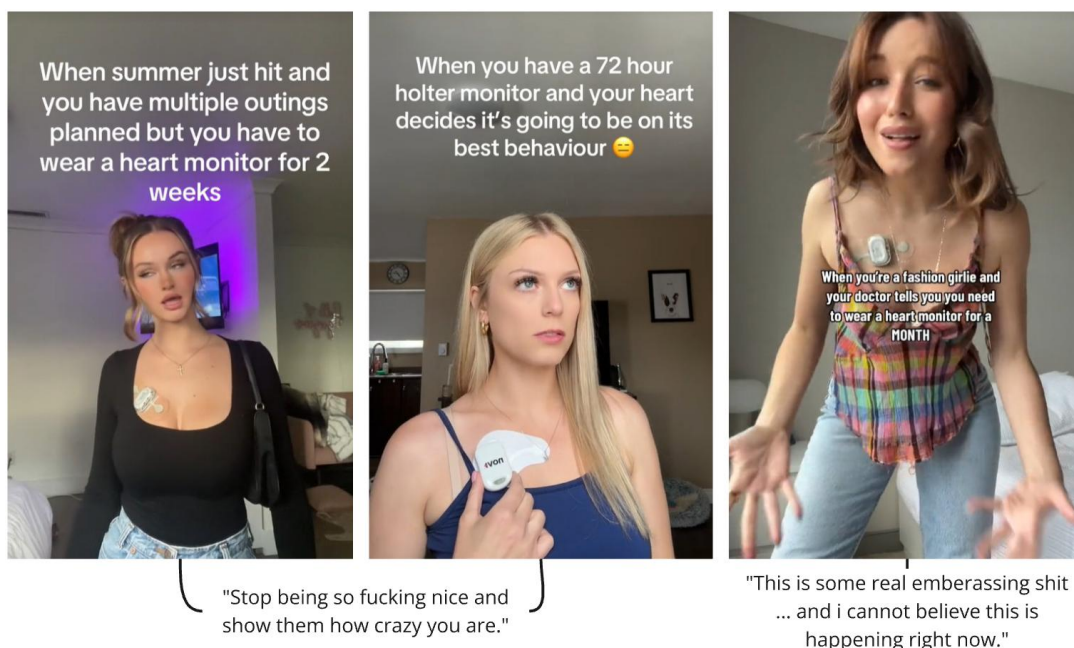


Figure 20 Selection of the types of voice-overs and captions used by woman expressing their discomfort

It was also found that some woman positioned their device wrongly. This could either be because of (unintentionally) not following the added manual instructions or due to their own discomfort/visibility concerns and therefore choosing to not place it in its intended position. As can be seen in Figure 21, the patch is placed in very different directions and even in different positions.



Figure 21 Different placements of the Zio patch

Online, there are noticeably less men sharing about their holter/wearable ECG experience. Therefore, it was harder to gather data on the general male experience with these devices. The big majority of ECG related research pictures include only men. This further indicates that devices are designed around men and might therefore cause men to complain less about the devices.

For gathering qualitative data, the AT-Sense sensor was used during a 7-day self-tests (male). No major complaints were found. Aforementioned complaints, like mild skin irritation, did occur. Not a single time was the device noticed. Even when people were

asked to look for it directly, hardly anyone would notice. The general experience was comfortable. A full report on this test can be found in APPENDIX: CASE STUDY AT-SENSE.



Figure 22 Multiple men wearing ECGs

## 2.3. STAKEHOLDERS

All (potential) stakeholders together form a network in which the product should function. Each stakeholder has their own set of views, experiences and desires.

### Medical professionals

**General practitioner (GP)** The general practitioner will have the initial patient contact and prescribes medication, lifestyle changes or a holter device when further research is required for the patient. If the GP suspects a severe condition that is beyond the GPs capability to treat or analyze, a referral to the cardiologist is made. GPs are often unsure about a patient their heart related complaints as their knowledge of heart conditions is limited compared to a cardiologist. They often opt for a cardiologist visit just to be sure. GPs state that a device that generates a report that provides deeper insight into a patient their heart condition is therefore beneficial to GPs and their decision forming.

**GP Assistant** GP assistants apply wearable ECGs at the GP clinic. They also clean, charge and store these devices. Cleaning is done using an alcohol wipe. Storage and charging are done in a drawer dedicated to these devices. Assistants mention that reading some patients their notes can be very difficult. A digital solution is preferred.

**Cardiologist** Cardiologists get in contact with patients who are referred by the GP. It can take weeks for a patient to reach a cardiologist due to their full schedule. The measurements performed by a GP during visitation are only brief and most people that visit a cardiologist leave without knowing more about their troubles. This is partly due to irregularly occurring complaints. If nothing is found but more research is required, a cardiologist plans a holter research for the patient. Based on an interview with a graduating cardiology student, cardiologists tend to like what they have and do not see reason for change or improvement in their current workflow or patient care.

### Patients

**Patient** Eventually, the patient can be anybody. The main objective for the patient is to get help with their troubles. Of the people that were interviewed for this project, all interviewees cared most about the outcome of a monitoring research. Since it is about their own health, people are willing to make sacrifices on comfort or their looks, especially if it is temporary. One interviewee illustrated this by comparing to a scenario of a broken leg: *“When I break a leg, I would rather have plaster on it and walk with uncomfortable crutches, than walk around with a broken leg that does not heal properly. So, it should work before it is comfortable”*.

**Sporters** For this project there is a specific focus on sportive patients. For sporters specifically, it is very important that a device is comfortable and low profile during prolonged wear and during their workout or training. The device should also not interfere with any equipment.

Palpitations usually are not constant and rarely happen at time of resting (Carrington et al., 2022). A (top)sporter needs to train in conditions that are generally hard for electrical

devices and skin adhesives. The most common and severe heart related injury amongst sporters is sudden cardiac death (SCD) that occurs during sportive activities (Sharma et al., 2017). It is debated whether an ECG should be part of the screening of apparently healthy young sporters. *"In Italy this screening is compulsory by law and this country is a strong advocate of the use of an ECG as part of this screening. However, others have stated that costs are too high for the yield (expressed in dollars per prevented sudden cardiac death) and an ECG is not included in the screening protocol of the American Heart Association."* (ECGs in Athletes - ECGPedia, n.d.). A more affordable and comprehensive screening device like Diplora is creating could help with the cause against SCD amongst sportive people. Sudden cardiac arrest happens rarely to both young and old sporters, but increases by an average of 8-fold for older sporters according to a study conducted in Denmark (Kim et al., 2024). This indicates the importance of heart care increases significantly for elderly.

For sporters, it is currently possible to do a cardiac test during intense activity. For instance, during a VO2 Max test. Here, a sporter runs on a treadmill or sits on a spinning bike whilst being connected to measurement devices. This provides them with insights about their performance and general health. Generating more than 3-leads of ECG data whilst the sporter performs their own sport, is currently not possible. The Diplora ECG will be able to do this.

## **Businesses**

**Diplora** Diplora is the company that is developing the wearable ECG device. They focus on sales, funding, electronics and data management (AI). For Diplora, budget is an important constraint.

**Production facilities** The production facility will be responsible for the production of the device and its assembly. They will also be involved in the prototyping stage and check whether the latest design is producible. Most likely, the main production partner will use their network to source the different components from multiple suppliers and factories.

**Diagnostic center** This center gathers and analyses patient data and translates the data into reports made for GPs and cardiologists. They can also be the logistical partner that takes in used devices and sends newly prepared ones out to patients.

**Insurance companies** Insurance companies can be attracted to the Diplora ECG because it is a low cost monitoring solution compared to a cardiologist visit and a holter research.

## **Designer**

**Designer** The designer of this project has his own learning related goals and ambitions for this project. One of which is to make a physical model that is close to production ready. If two solutions are fulfilling the requirements similarly, the designer will select a preferred solution based on alignment with his learning objectives.

## 2.4. ENVISIONED PRODUCT JOURNEY

This subchapter sketches the life of the Diplora ECG in steps. Starting at its creation, then usage and finally End of Life (EoL). Each step provides challenges and design requirements. Assumptions about the functioning of the product are made on Diplora's vision and research done on existing devices that have similar functionality, like the Philips ePatch (Figure 23).



Figure 23 Philips ePatch

### **An overview of Diplora's product journey vision**

A product service system like Diplora wants for their product is not new. Philips has a wearable 1-lead ECG (Figure 23) that is also re-usable and returnable by mail. Similar to the Philips ePatch, Diplora wants their product service system to be a closed loop wherein the product is re-used by many patients. According to documentation found on Philips website, their patch is designed to function for 300 cycles (300 patients). Figure 24 visualizes the product journey vision for the Diplora ECG. This subchapter focuses on the main cycle loop between patient, DC and GP. Production and EoL life are discussed in more detail in the following chapters.

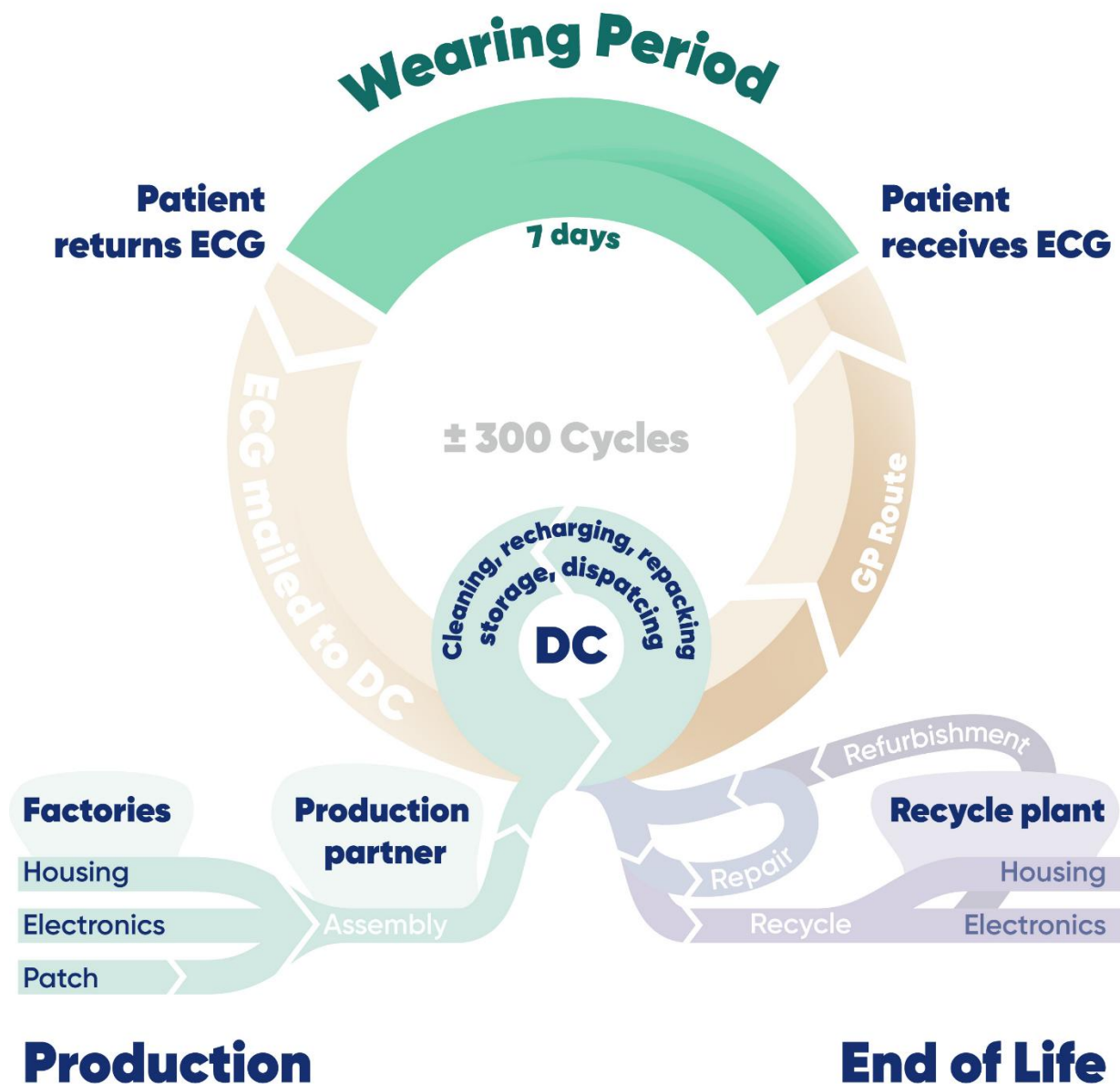


Figure 24 Product journey

### Production

The journey starts at production. For this project, potential production partners were visited. A brief report on this can be found in APPENDIX: VISITING PRODUCTION PARTNERS. Parts like plastic housing shells, electronics and the patch are sourced from multiple factories. This can require multiple steps for one part. The patch, for instance, requires a roll-to-roll fabricator first and finally a medical converter that places electronic connection parts or sockets. When all parts are at the production partner its facility, the device is assembled and quality checked before it is dispatched to a diagnostic center.

### **At the Diagnostic Center**

The diagnostic center (DC) mainly carries the responsibility for cleaning, recharging, repacking and storing the ECGs before they are dispatched to the next patient. Diplora can also coordinate the DC to send the Diplora ECGs to GPs so they have stock and can apply the devices to patients directly. When a used device comes in, the DC has three options: re-use, repair or recycle at EoL. Re-use means the standard preparation protocol before shipping to the next patient. Repair means disassembly and fixing or replacing failing components before it is cleaned and shipped. Recycling means complete disassembly, parts separation into different waste streams and ideally keeping functioning parts for refurbishment in the repair step. This happens in a recycling facility.

### **At the GP**

Demand for inventory of these ECGs has varied between GPs that were interviewed. Some GPs do not want more devices laying around. For these GPs it is possible to request the Diplora ECG for delivery to the patient. The GP will receive the final report without ever touching the device. This does not require any storage space or inventory management for the GP. Most GPs have been eager for having devices at hand. They mentioned that many patients find human contact important, especially elderly. These GPs can have a small inventory of Diplora ECGs at hand and apply them for their patients. The patient will then take the storage box of the ECG like all patients and return the device by mail after their wearing period is over.

### **Use by the patient**

The patient receives an ECG and wears it for up to 7 days. This period is visualized in an exemplary scenario seen in Figure 25. Upon receipt, the patient can start the application process. Secure application requires shaving, degreasing of the skin using alcohol wipes and finally application. Some devices incorporate scraping the skin with sandpaper to scrub away dead skin cells. This is claimed to cause better adhesion, but is very uncomfortable. From self-testing, this has not been found significantly beneficial.

When the device is securely placed on the skin, the device will be able to pick up an ECG signal. This wakes the device from its sleep modes and will now start gathering ECG data. The patient can now connect their device to their phone, using the Diplora app. Now, the monitoring has begun and data is being streamed to the cloud for processing.

During wear, it is expected that patients live their lives like normal. This includes sporting, taking showers and sleeping like normal. When a patient experiences a complaint during their wearing period, they can double tap the ECG to make a timestamp in the app. This will then be listed as an event in the app. At any convenient time, the patient can open the app and describe what they experienced. This helps with the analysis done by the AI and provides better insight for medical professionals. The app can accommodate for multiple complaints like headaches, dizziness or palpitations. If required, the patient can re-apply a new patch if their first one starts to loosen too much.

After the patient is done wearing the ECG, they can pack it up and return it to the DC by mail. Here, it is processed and prepared for the next patient.

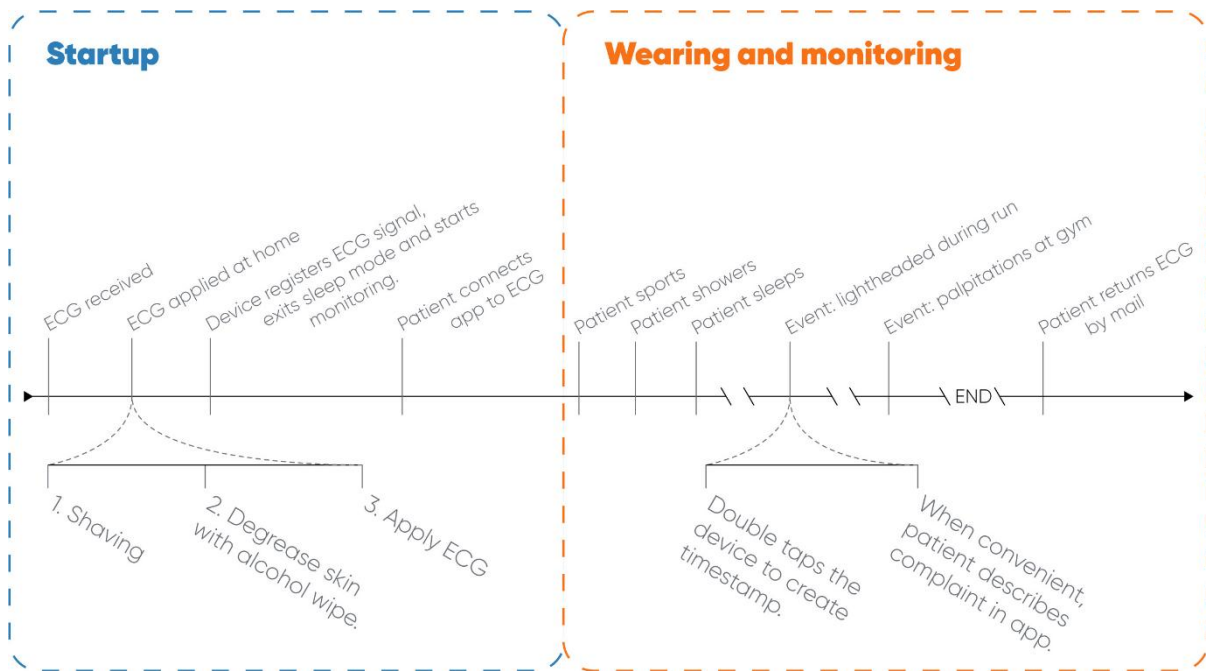


Figure 25 Events timeline wearing period (7 days)

## 2.5. KEY INSIGHTS

### Patient journey:

- A patient should be able to apply the device themselves.
- To prevent a sense of shame and belittlement, the design should be as discreet as possible.
- Since sportive people sweat much, their patches will detach relatively quickly. Therefore, sportive people might need more patches for re-application, then non-sportive people.
- Caregivers should be able to help in applying the Diplora ECG to the patient.
- When re-applying a patch, orienting the device must be intuitive and easy.
- Orientation should be visible on ECG itself, not on peeled away films, so that the patient can reposition the device when being re-applied. (small arrow pointing up)

### Product journey:

- The product should fit through a mail slot to make delivery convenient.
- Even if a patient has their patch and device applied at the GP, packaging including spare patches and instructions should still be provided for at-home replacements.
- To compete with existing wearable ECGs, the Diplora ECG should be able to withstand 300 cycles.
- The final product solution should have a convenient inventory management system with patient linkage to connect a (re-used) ECG to a (new) patient.
- As the device is used between many patients, keeping track of devices is important. This requires a UDI system (Unique Device Identification) using RFID tags in- or barcodes on the devices.

### Stakeholders

Patients primarily care about their health, and thus the outcome of the monitoring research. Comfort comes second. For this project it is assumed that the device its electronics works reliably, so comfort and critical device functions remain the highest priority for this project. A reliable connection mechanism and self-applicability are examples of these critical device functions that ultimately help with a reliable monitoring research. Since the ECG is specifically designed with sporters in mind, low-profile aesthetics are important too.

# 3. TECHNOLOGY RESEARCH

This chapter lists and analysis notable advancements in the domain of wearable healthcare technology, explores their feasibility and aims to answer technical questions through research and comparisons. This leads to well-considered building blocks that can be used in the concept generation phase.

Incorporating new and superior technologies has the potential to improve user experience, performance and sustainability. Together with the state-of-the-art electronics and software developed by Diplora, these technologies have the potential to become a differentiating factor for Diplora as a developing company.

## 3.1. PATCHES - CHALLENGES AND ADVANCEMENTS

The current standard of medical patches used for monitoring cardiovascular activity comes with a set of challenges. Mainly sustainability related as there is a lack of standardized EOL protocols for patch disposal. Many patches incorporate synthetic polymers and are single use to ensure hygiene and monitoring accuracy. Patches are often made of composites consisting of inseparable materials. Polymer materials, conductive inks, and electronic components are often irreversibly bonded.

The rising interest in telehealth asks for better patches. Patches that are minimally invasive and more sustainable in their production, use, and disposal. Especially skin adhering patches that contain flexible electronics pose great functional improvements but remain a challenge in terms of sustainability.

### Bio-material patches

The VTT Technical Research Centre of Finland developed an ECG that uses nano-cellulose for their patches and printed carbon for the electrodes (Figure 26). This patch is made of only bio- materials and minimizes carbon footprint material wise. They call it 'cellulose e-skin'. VTT states that durability for multiday use remains an issue due to poor moisture and tear resistance. Even if one patch per day would have a total carbon footprint lower than a single patch made of silicone, patients will have a worse experience being forced to apply a new patch every day.



Figure 26 Biodegradable single-use skin patch for wearable ECG (Behfar & Jaiswal, 2023)

## Flexible and embedded electronics

VTT also researched flexible patches with electronics integrated into them directly. The result is a functioning, wireless ECG that is capable of livestreaming ECG data. The mayor benefit of this design is its miniature and flat formfactor. Their downside is strength and durability. Inks contain silver or copper particles to print circuits onto flexible substrates.

Re-usability is not possible because everything is embodied into a single patch and has to be disposed of for hygienic and durability reasons. Once the battery is dead, it can be taken out and properly disposed of, but the rest of the electronics are stuck in the patch which makes proper recycling of parts extremely difficult.

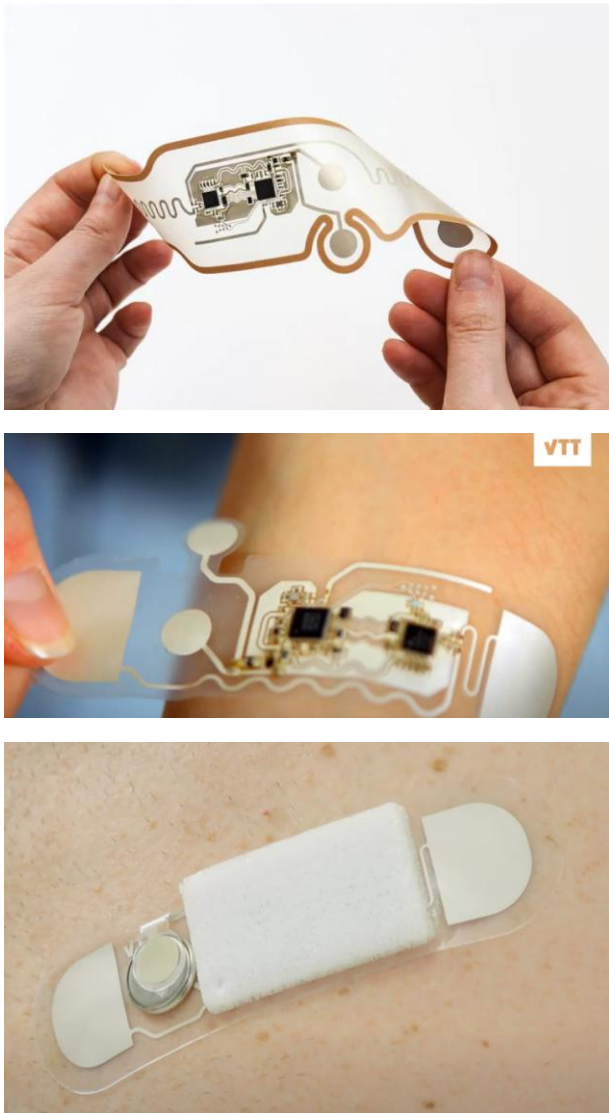


Figure 27 Wireless smart-patch prototypes

## Bio-degradable patch

Another research also noticed this separation problem and explored the possibility of using printed and embedded electronics in a bio-degradable patch (Jaiswal et al., 2023).

The idea revolves around the patch decomposing (in 6 weeks) after which the electronics are sieved out of the compost. This method remains very experimental and requires special processing. If Diplora were to go down the route of biodegradable patches with integrated electronics, they would require a partner that is able to do the processing for them. Logistically, this is a challenge on multiple levels.

## Flexible ultrasound patch

The UC San Diego Jacobs School of Engineering developed a wireless wearable patch that measures real time cardiac vital signs using ultrasound (Lin et al., 2023). The system is composed of an ultrasound probe, a flexible circuit, and a commercially available rechargeable lithium battery (Figure 28 and Figure 29). It is encapsulated in a soft and flexible material resembling silicone, but is not further specified. The main concern is protection of the flexible electronics and the maintenance of performance under repeated mechanical stress due to movement.

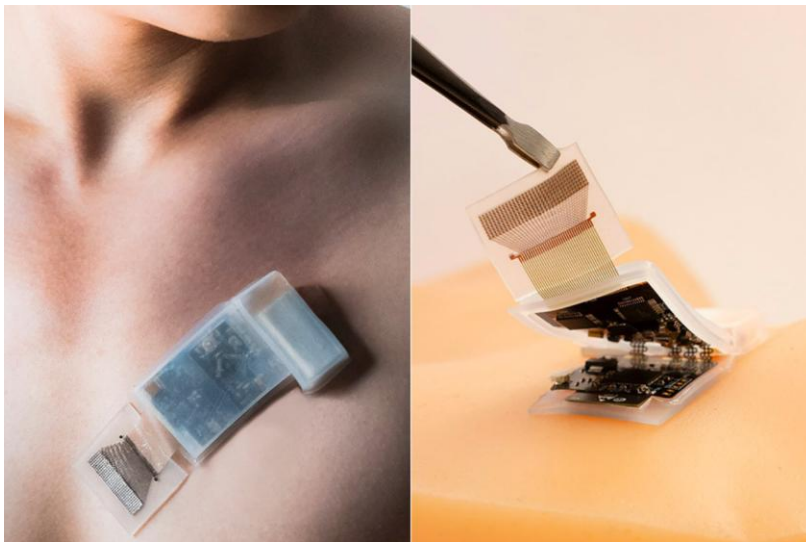


Figure 28 Flexible ultrasound patch (Lin et al., 2023)

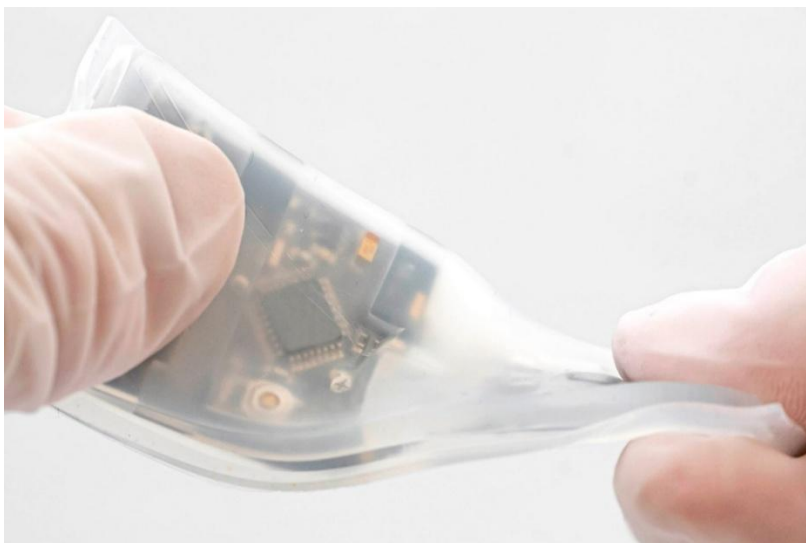


Figure 29 Flexible ultrasound patch, flexibility demonstration (Lin et al., 2023)

## Conclusion

Low impact and sustainable smart patches (with or without integrated electronics) are not ready for market yet. Development seems promising in theory but durability remains a bottleneck.

If the final design wants to incorporate the benefits of patches made of biomaterials, it should allow for quick manual separation of the patch and any electronics or casings. Then, the patch can be thrown away causing minimal environmental impact. However, bio-material based- and bio-degradable patches that are wearable for 7 days require more research for viability.

Flexible control circuit are very promising but require more research on damage accumulation caused by fatigue (Sun et al., 2019) over extended wearing times. Yang et al. (2017) noticed electrically measurable degradation after 10.000 cycles of heavy 90 degree twisting of flexible electronics. If the ergonomic benefits are substantial, it might be worth pursuing.

Soft encapsulation might have ergonomic benefits versus a hard casing and is complementary to flexible circuits and electronics. It becomes an option if the mechanical durability and reliability persist over extensive wear.

## 3.2. ELECTRODE TYPES

Electrodes are essential components of an ECG. They are conductive contact point between the ECG device and the skin. Electrodes come in many types with each their own set of strengths and weaknesses. This subchapter explains their workings and compares them to select the most viable option for Diplora.

### Metal dry electrodes

Metal dry electrodes (Figure 30), often used in EEG headbands as seen in Figure 31, can also be used to measure ECG signals. Their contact time is short when used in a headband. Over prolonged use they cause discomfort and pain (Chen et al., 2014). This renders metal dry electrodes a bad fit for this project.

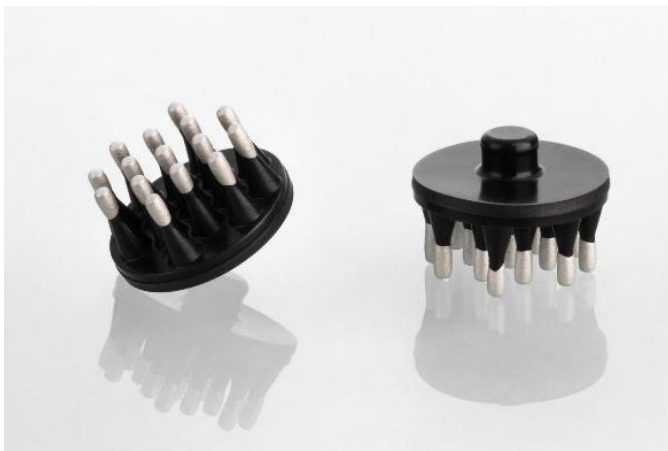


Figure 30 Metal dry electrode (SoftPulseTM - Soft Dry Electrodes for Bio-monitoring, 2022)



Figure 31 EEG using dry electrodes (Systems, 2025)

## Polymer dry electrodes

Polymer dry electrodes as seen in Figure 32, are proven to provide a similar stable signal to traditional wet gel electrodes (Chen et al., 2014). They do not cause skin irritation like wet electrodes sometimes do. Participants of the study conducted by Chen et al. (2014) found the polymer dry electrodes comfortable and suitable for extended use. These electrodes consist of multiple bendable pins to ensure contact with the skin through hairs. The length of the pins varies. For them to be viable, they should ideally be flatter to avoid bumps in the patch.

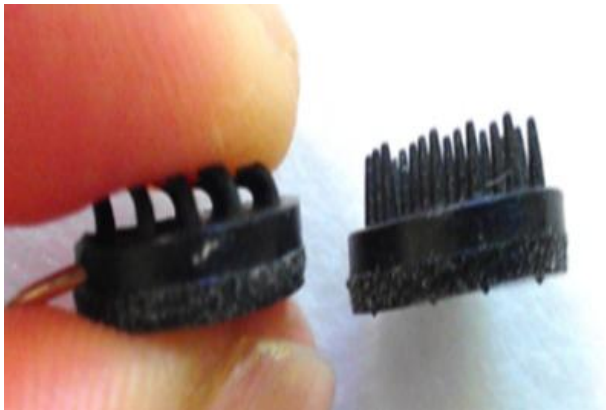


Figure 32 Polymer dry electrodes (Chen et al., 2014).

## Ultra-thin dry electrodes

In an effort to develop electrodes that provide better comfort and less skin irritation, Elango et al. (2023) created ultra-thin, light weight and gel-free electrode. They claim it can be recycled and performs as well as the industry standard gel-electrodes. The patches are close to invisibly thin (150 nm thick). Because the material that is used is gold, it is required that these patches are highly re-usable for financial and sustainable viability. The prototype consists of the electrodes, an electric circuit and a soft patch that covers the entire device and presses the contact points of the circuit onto the electrodes. These ultra-thin electrodes require more research and design for them to become integrated in a user friendly product.

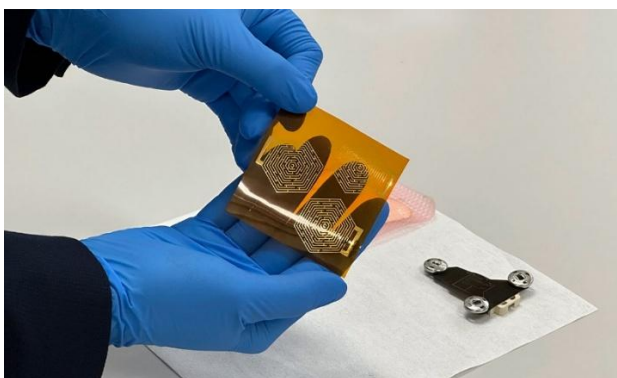


Figure 33 Dry electrode RMIT (Wearable Heart Monitor Ticks All the Boxes for Better Healthcare: Study, n.d.)

## Dry microneedle electrodes

Dry microneedle electrodes as seen in Figure 34, are small and dry silicon-based electrode patches with micro needles on them that pierce through the first layer of skin without any discomfort (Figure 35). This creates secure contact with the skin and produces a reliable signal (Fu et al., 2020). They require a sophisticated, costly, but eco-friendly fabrication processes and are fragile in use. Due to their poor biocompatibility and fragility, these electrodes are unsuitable for long-term monitoring.

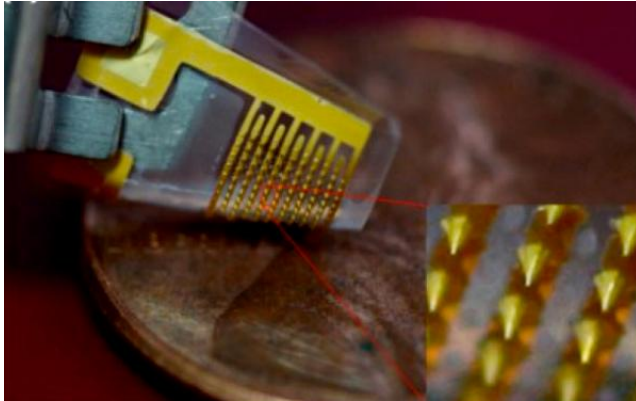


Figure 34 Microneedle electrode (Fu et al., 2020)

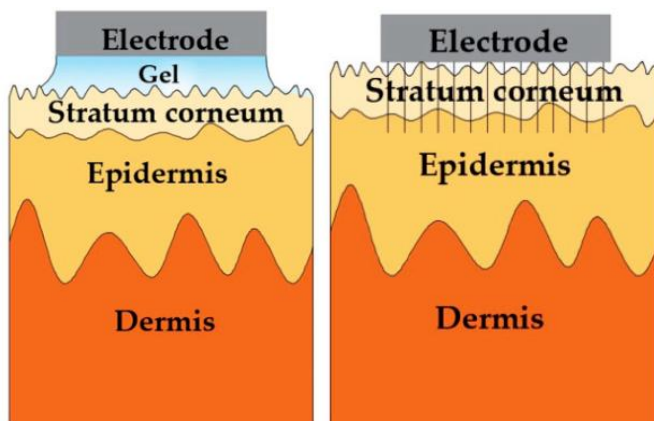


Figure 35 Gel versus microneedle electrode (Fu et al., 2020)

## Wet electrodes (gel electrodes)

The current most conventional type of electrodes are wet electrodes. They use gel as a flexible and conductive contact area to the skin. They produce a reliable signal, also during movement (Sapien Labs, 2022). They can however cause skin irritation and tend to dry out in prolonged use, which decreases the signal quality (Fu et al., 2020). They require the patient to prep their skin by means of shaving and cleaning with alcohol. These patches are the industry standard and are readily available as off the shelf product. Gel electrodes are cheap, but as described earlier, they are hard to recycle due to their composition of different inseparable materials.

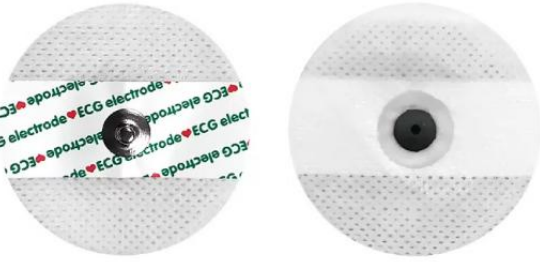


Figure 36 Wet gel electrodes

## Conclusions

As Diplora is a developing startup, the safe option is going with wet electrodes. They are generally comfortable and produce a reliable signal, also during movement.

An option worth exploring further in the future are dry polymer electrodes. If these are based on the material 'PEDOT:PSS', they can be engineered to have desired single-use lifetimes that balances stability during use with rapid breakdown after disposal (Lee et al., 2022).

### 3.3. KEY INSIGHTS

- Bio-material patches are great for sustainability, but not durable enough yet.
- Soft encapsulation and flexible electronics might have ergonomic benefits versus a hard casing, but lacks reliability.
- Wet (gel) electrodes are the best options for people with an active lifestyle. These patches provide the best signal quality during movement.

# 4. PRODUCT FUNCTIONS AND REQUIREMENTS

This chapter lists the requirements for the wearable ECG. These requirements are distilled from the analysis phase. In the concept generation phase they are used to measure and evaluate design decisions. Since this project concentrates mainly on ergonomics and comfort, these requirements mainly focus on topics that influence embodiment decisions.

## 4.1. PRODUCT- AND FUNCTION RELATED REQUIREMENTS

This subchapter focuses on the physical product itself, not the system. Designing the system falls out the scope of this project, but is considered as a significant influential factor to embodiment decisions. A properly integrated product is strongly intertwined with its surrounding system. System functions are only mentioned here if they have a direct influence on the embodiment of the product. Software related requirements (AI analysis, app, etc) are out of scope for this project and thus not listed.

### Basic functions

- The wearer should be able to sport with the device on.
- The wearer should be able to sleep with the device on.
- The wearer should be able to shower with the device on.
- The product should be as comfortable as possible during wear.
- The product should not hinder the wearer during sports, specifically for gym-goers and runners.
- The product should not interfere with gym equipment.
- The product should not cause irritation during repetitive motion (i.g. due to bouncing weight).
- The product should not cause irritation during stretching of the body.
- The product should be water and sweat proof.
- The product should be usable on a similar comfort level for both men and woman.
- The product should accommodate both men and woman between p5 and p95.
- The product should accommodate for woman with large breasts.
- The product should accommodate for elderly and their aged skin (more folds, thinner and more fragile).

### **Enclosure specific requirements**

- The enclosure should fit a PCB with a minimal area of 1000mm<sup>2</sup>
- The enclosure should fit a LiPo battery of at least 500mAh
- The enclosure should be made of medical grade materials.
- The enclosure should be cleanable with alcohol wipes.
- The enclosure should be organically shaped whilst geometric and sharp shapes should be avoided.
- The enclosure should minimize crevasses or any other geometry that allows grease and dirt to buildup.

### **Patch specific requirements**

- The patch should maintain strong adherence to the skin, even during motion and wet conditions.
- The patch should be flexible enough to accommodate for the natural length of skin stretching that occurs during exercise.
- The patch should be flexible enough to accommodate for comfortable wrinkling of the skin during compression.
- The patch should accommodate for the optimal electrode positions.
- The patch should be made out of an hypoallergenic material.
- The patch should contain electrodes that are placed between 7 and 9 cm apart.

### **Autonomous application**

- The patient should be able to apply the device autonomously.
- The product should be intuitive to orient (i.g. contain orientation markings).
- The connection method between the patch and enclosure should be intuitive.

### **Aesthetics and form**

- The product design must be low-profile to accommodate for sporters needs.
- The product should look like sportive electronics rather than medical equipment to avoid belittlement and improve confidence.

### **Shipment and packaging**

- The product should fit through a standard Dutch mail slot of 26.5 by 3.2 centimeters (Acm-Consuwijzer, 2024) in shipment packaging.

## **Sustainability**

- The product design and manufacturing method should be optimized for longevity (300 cycles of re-use).
- The product design should allow for disassembly and repair or replacement of both internal and external parts.
- The product should be design in such a manner that materials can be separated in dedicated waste streams.
- The patch should contain as little different materials as possible (i.g. plastic connectors, electronic connectors, lamination, foils, tear-offs, etc.) to avoid mixed waste streams.

## **Production**

- The production cost of the device should not exceed €150 per device (patches excluded).
- The production method should be economically viable for an initial production of 500 devices (according to internal research).

## Feedback and interaction requirements

What feedback the patient receives should be carefully considered. Giving patients more feedback can result in counterintuitive and counterproductive scenarios. A study showed that AF patients who wore a device that notified them of an anomaly, were more stressed and called the clinic substantially more often than the counter group of AF patients who did not wear any device (Heart Rate Monitoring: Wearable Devices Can Drive Anxiety, Possibly Affect Health, 2024). An interviewed GP said the clinic does not want to use a device that causes people to call more often than strictly required. Giving the ECG an alarm function or any other health related live feedback will categorize the device as a diagnostic tools on the MDR certification, which Diplora wants to avoid due to the increased regulation complexity and cost.

### Feedback and interaction

- The product should allow the patient to create a timestamp when an event occurs.
- The product should allow for unambiguously informing the user of its operational states:
  - o On, Off and Sleep mode
  - o Recording status
  - o Battery indication
  - o Manual event registration

## **MDR and IEC 60601 compliance**

MDR stands for "EU Medical Device Regulation". It governs the entire lifecycle of a medical device in the European Union, from design to post-market surveillance. It functions as a legally binding certification for all medical devices placed on the EU market and gets the official CE marking.

IEC 60601 is an international technical standard (developed by the IEC - International Electrotechnical Commission). Its purpose is to ensure the electrical safety, mechanical safety, and essential performance of medical electrical equipment. Complying to the IEC is mandatory for the MDR certification.

Some aforementioned requirements are noted specifically to comply with these two certification types. Many requirements, however, are either too technical (EMC radiation compliance, cytotoxicity, etc.) or too detailed (legibility of lettering on Instructions for Use, Unique Device Identification, etc.) to incorporate in this graduation project. Requirements for software and related processes are ignored for this project. The stated requirements regarding ergonomics, interactions and safety are incorporated in the requirements listed for this project.

## 4.2. REQUIRED ELECTRONICS

This subchapter lists all the electronic components that are required to fulfil the product its intended functions. The essentially required electronics have an influence on the embodiment of the product due to their physical presence. Only the essentially required electronics are listed in this chapter because the concept generation phase will have an influence on product interactions and the additional selected electronics required for those product interactions. For instance, choosing to double tap the device for an interaction only requires an IMU, but a physical button requires additional hardware.

### Essentially required electronics

- PCB (printed circuit board)
  - o Bluetooth 6.0 chip
    - The latest Bluetooth version that allows very efficient low power data streaming. It is so new that most phones do not have it yet. It will work with older versions, but without the power efficiency benefit.
  - o IMU (inertia Measurement Unit)
    - A gyroscope with an accelerometer in one which measures movement and orientation
  - o Analogue ECG frontend
    - Converts the analogue ECG signal into a digital signal.
  - o Flash memory
    - Data storage.
  - o Multicolor LED
    - Status indication light
  - o USB-C charging port
    - Recharging (Diplora wants to avoid custom connections that can also be used for recharging because of the added complexity on the PCB)
- Battery
  - o A small and rechargeable 500mAh Lithium battery accommodates for at least 7 days of charge.
- Flat (piezo) buzzer
  - o Provides sound cues

### Embodiment related requirements influenced by the necessary electronics:

- The product should be rechargeable.
- The product should incorporate a watertight USB-C connection port.
- The product should accommodate for a 500mAh battery.
- The product should accommodate for a PCB area of 33x33mm.
- The product should accommodate for visible LED lights.
- The product should accommodate for an integrate piezo buzzer.

## **Livestreaming and battery dimensions**

Some function-options have an (indirect) influence on the physical dimension of the product. One of which is livestreaming ECG data. Continuously livestreaming data is a very energy hungry feature. This would require a big battery. A big battery results in a big enclosure and heavier ECG. So, if livestreaming does not create substantial benefits for the user, it might be better to go with a different method of data retrieval. An analysis of these options is found in APPENDIX: DATA STREAMING CONSIDERATIONS.

## **4.3. REQUIRED ELECTRODES AND THEIR POSITIONING**

Proper positioning of the electrodes is crucial for measuring a useful signal. The positions of the electrodes determine which diseases can or cannot be measured by the ECG. Selecting these positions results in design requirements for the design phase.

This subchapter considers and evaluates the electrode positioning mainly from a technical perspective. An ergonomical perspective is provided in chapter 4.4. There, the important balance-consideration between function (technical) and comfort (ergonomics) is made.

### **Number of leads**

Trobec and Tomašić (2011) studied the ideal electrode placement to emulate a 12 lead ECG from 2, 3 and 4 differential leads and compared them to results measured using the EASI lead system. The EASI lead system is an alternative to the conventional 12-lead electrocardiography, designed to simplify electrode placement and improve patient comfort. It is most prevalent in environments where rapid or continuous ECG monitoring is essential, such as intensive care units and emergency departments (EASI ECG | WiKI, n.d.). The study showed that three leads (4 electrodes) have sufficient accuracy to emulate a 12-lead ECG. Using more than three leads showed diminishing returns. This is in line with Diplora's desire to use 3 leads.

### **Ideal position for signal quality**

Lee et al. (2020) evaluated multiple electrode patch shapes for ECG reconstruction. They spread thirty-five electrodes over the chest and analyzed performance using different sets of electrodes, making square and triangle shapes. It included a 5cm x5cm square, a 10cm x 10cm square and right-angled triangles (Figure 37).

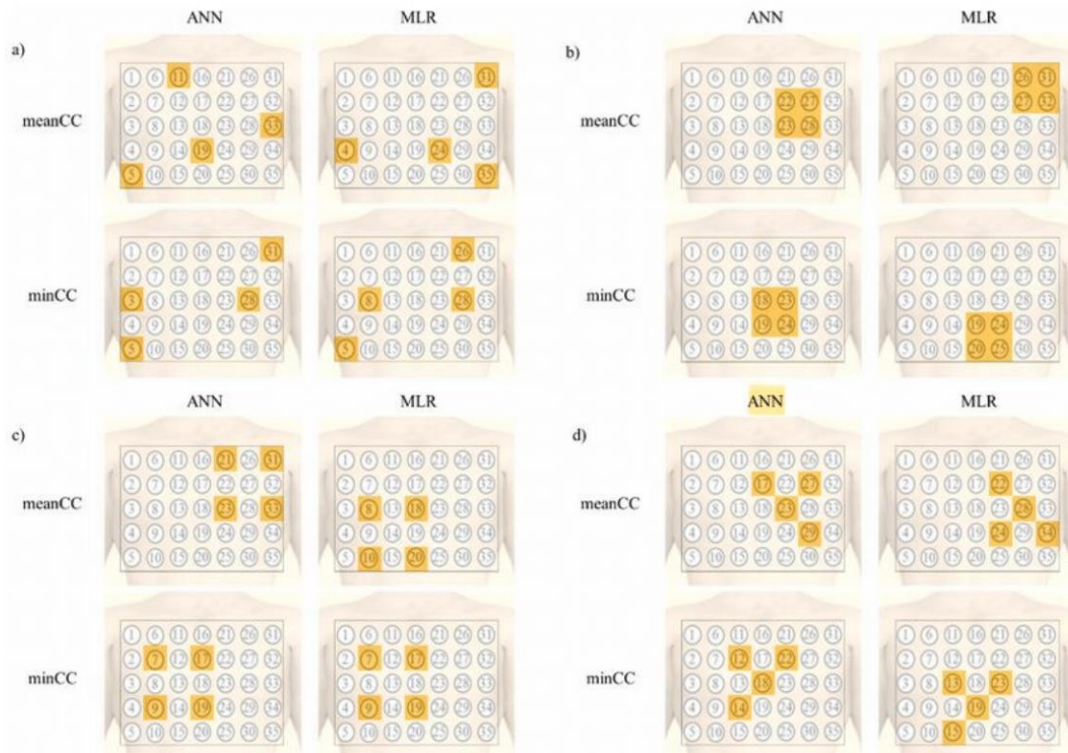


Figure 37 Electrode placement research by Lee et al., 2020

To accommodate for potential misplacements (by the patient), every shape options was also measured after it was shifted by one electrode in the array. It was found that electrodes positioned at the bottom central chest area produced high quality reconstructions.

This study, however, was only conducted on male subjects. An ECG patch in the center of the chest might result in ergonomic discomfort for woman. This will be verified in the user studies.

According to the study (Nedios et al., 2014), a distance of 8cm between electrodes would yield the best balance between signal amplitude and practicality for ambulatory ECG devices.

## Breast tissue

Simoes et al. (2012) investigated the effect of breast tissue on the ECG signal and found no significant signal degradation when patches are placed on or around the breasts. Breast size had no significant impact on signal quality. The study found that woman prefer to have the ECG patch under the breast rather than on the breast. This was confirmed by interviews conducted for this design project. Additionally, woman did not mind electrodes around the breasts. On the breast tissue, however, should be avoided.

## Precordial lead considerations

Precordial leads are constructed using electrodes positioned in the bottom-breast area (Figure 38). According to Diplora's internal research, having an electrode in the proximity of V3 (Figure 38) is desired for optimal signal reconstruction. These findings are in line with

the research conducted by Lee et al. (2020). Better signal reconstruction improves diagnoses. The necessity of a precordial lead is still being debated and researched by Diplora. Diplora will conduct clinical trials using their AI software to validate which electrode positions are required. For the continuation of this project, it is assumed that V3 is strictly necessary and will thus be designed for.

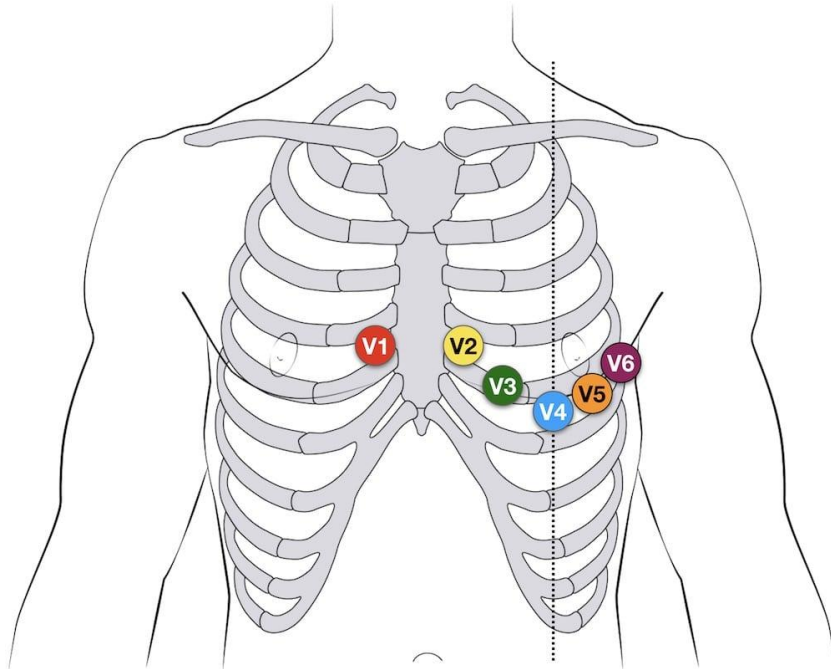


Figure 38 Electrode positioning for precordial leads (Cadogan, 2022)

### AI placement compensation

Diplora expects their AI solution to be able to adjust for inaccurately placed electrodes (which is ideal for electrodes placed by patients themselves). Diplora considers implementing a feature that signals patients on (in)correct electrode placement that helps them reposition electrodes that are not adjustable for by the AI.

## 4.4. PRELIMINARY ERGONOMICS RESEARCH

The function of this subchapter is to discover and define the initial ergonomic aspects and anthropometric requirements for the ECG design.

A preliminary ergonomics research was done to determine feasible base-shapes for the ECG device and its positioning. Both physical- and mentally perceived comfort have been considered. The volume of these shapes are based on the essentially required electronics.

### Geometric versus organic shapes

One of the concerns for this project is discreetness. It was assumed people would be bothered by wearing a device that creates a visible bump under their clothing. Sporters were interviewed and indicated that they prefer a low-profile solution. During qualitative research, participants initially reacted indifferently to the shape being either organic (Figure 39) or geometric (Figure 40) when asked about visibility of the device. After feeling the shapes on their body, organic shapes were preferred as these were softer on their skin. Participants also perceived a smoothly shaped device as safer.

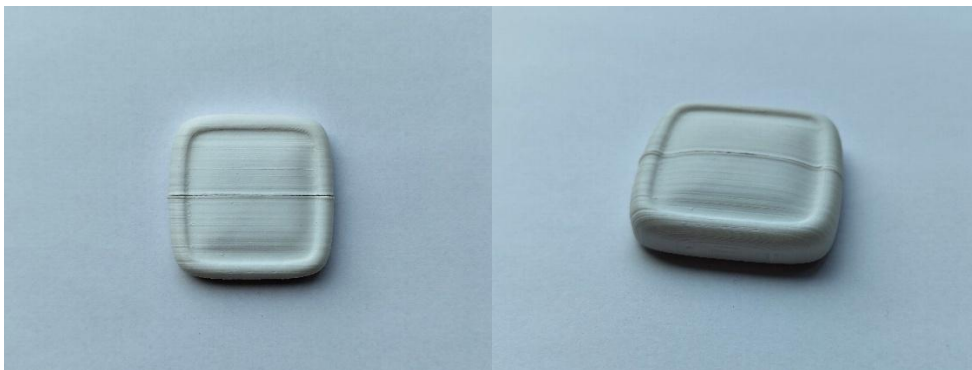


Figure 39 Smooth and organic shape



Figure 40 Geometric shapes, height versus length

## **Ergonomically relevant differences between males and females**

Both male and female participants (N = 9 (5F, 6M), age range: 22-80 years) were asked to explore different positions for the device on their chest. Figure 41 provides a visual indication of the area that was researched and shows the preference of participants as a heat map. Constraints were placed on the area of evaluation (dotted line) as literature and exploratory conversations indicated positions outside of this area are not desirable due to practical or technical reasons. The heatmap ranges from comfortable (green) to undesirable (red). Orange indicates an area where a device would not cause immediate discomfort, but would only be tolerable if strictly required due to functional necessity. Both male and female heatmaps are illustrated on a 3D model from Dined (stature (F/M): P=50, age range: 18-66) (*DINED*, n.d) (Figure 42 and Figure 42). The blue area was initially researched but was later found to deviate from the reasonable electrode positions too far.

### **Female specific comments:**

Visibility was estimated to be of no major concern since the device is worn only temporarily. This contradicts findings of the social media research and requires prolonged testing to find the true emotional impact. Comfort is more important than discretion. A flat and long enclosure is preferred over a thick and short enclosure. The area between the underside of the ribs and bottom of the breasts was not a comfortable position due to abdominal skin folds and a bra strap. According to women, not being able to sleep on one side would not be a problem because it is worn temporarily.

Placing the device between the breasts is not an option as this was estimated to be very uncomfortable for women with larger breasts. Laying down would cause the breast to fold over the device and cause pinching. On the side of the chest under the bra strap is no option as this creates a pressure point. The preferred shape was very organic and rounded. Placing electrodes on breast tissue should be avoided. An electrode on the sternum is acceptably comfortable but should not be placed on the underside of the breast.

### **Male specific comments:**

Men preferred organic and rounded shapes. Longer shapes, placed on the sternum, are most comfortable vertically. Opinions were indifferent on placement on soft tissue (breast muscle) or bony areas (right under the clavicle or on sternum). A thicker and short shape was preferred over the slimmer long shape. The flat area on the ribs under the breast feels very stable, also during motion.

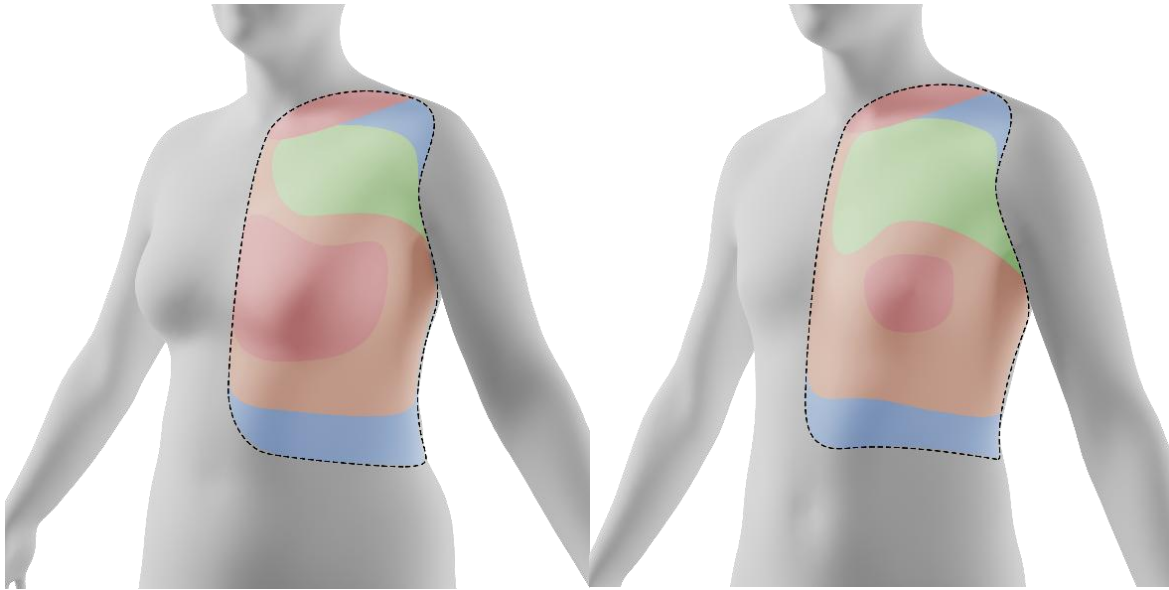


Figure 41 Ergonomic research area and heat map for both male and female

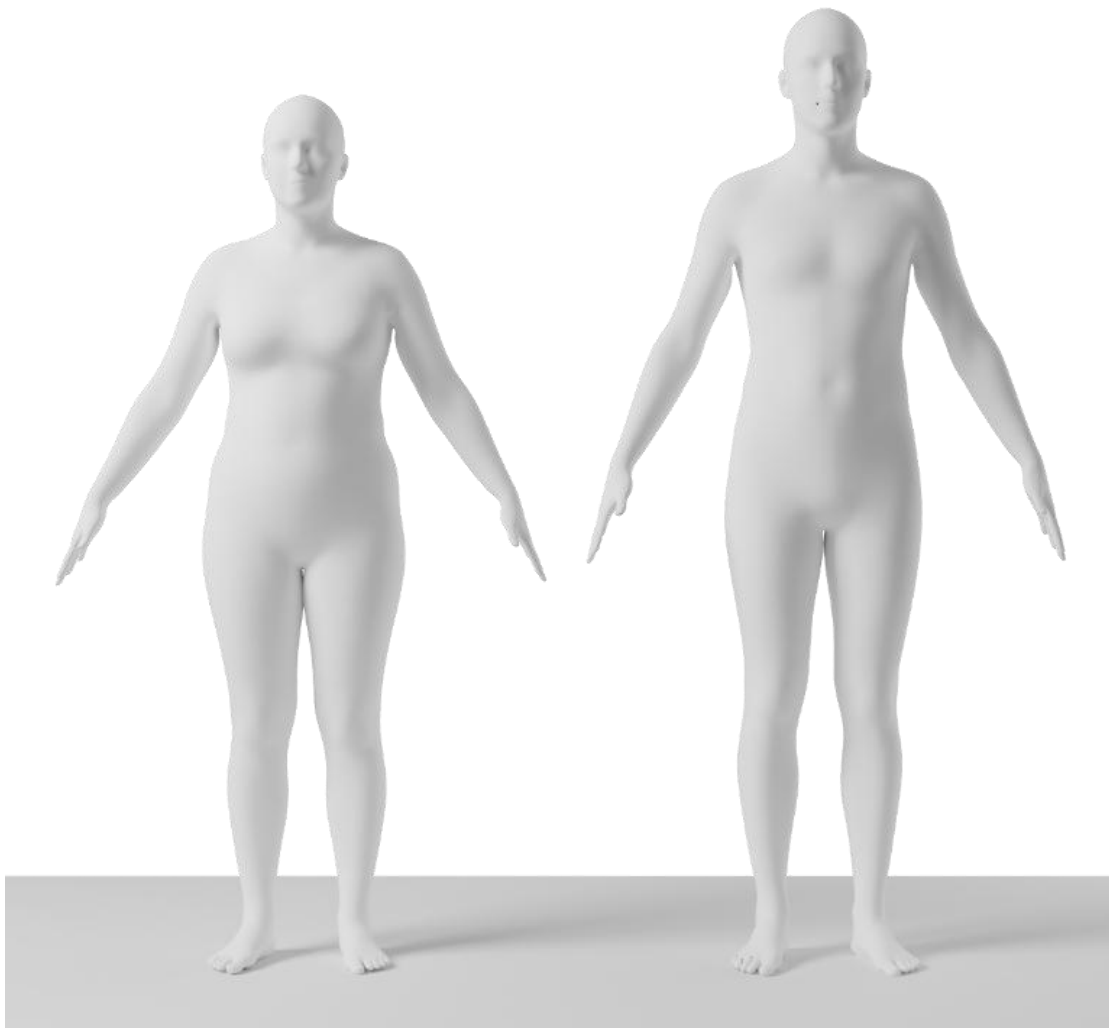


Figure 42 Dined models

## **Key insights**

- For both men and women, the upper area of the chest (under the clavicle) is the most comfortable area for placing the device.
- The shape of the device should be long and flat rather than short and thick.
- Rounded, organic shapes are preferred over geometric shapes.
- Electrodes should not be placed on breast tissue for optimal comfort.
- A distance of 8cm between electrodes provides the best balance between comfort and signal quality.

## 5. REFINING THE SCOPE

This chapter briefly iterates on the initial design assignment to accommodate for developments in Diplora's desires and the knowledge gained during the research phase. One of these desires is for the product to be modular, so that the device can be used with a wire attachment or a custom patch. The problem statement has been adjusted to reflect the two main objective of designing a well-functioning ECG that is also comfortable during wear for 7 days. It also incorporates one of the main distinctive features of the envisioned Diplora ECG: self-applicability.

### **Adjusted problem statement:**

*"Design a modular, wearable and self-applicable ECG for multiple consecutive days of comfortable wearing that is tailored to people with an active lifestyle."*

Even though the to be designed device is modular, this project will focus on the device and a patch solution only. The wired solution and other topics like packaging and branding are moved to the recommendations. Sustainability, ergonomics and the application process remain prominent factors in the syntheses phase.

## 6. DESIGNING THE ECG

This chapter explains the design process and elaborates on all the major design decisions taken. It provides substantiation for each decision based on knowledge gathered through iterative prototyping and evaluation (research through design). From this chapter, building blocks for the final design proposal are derived.



## 6.1. DESIGN PROCESS OVERVIEW AND STRUCTURE

The process the whole project can be simplified and summarized in a double diamond figure (Figure 43). The first diamond shape illustrates research as the Discovery phase (diverging), which narrows (converges) towards concrete requirements: Define. The design phase is represented by the second diamond shape. In this second diamond, researching through design Develops viable product designs by exploring divers design options (diversion). Finally, the process converges through a selection process and Delivers a final design proposal.

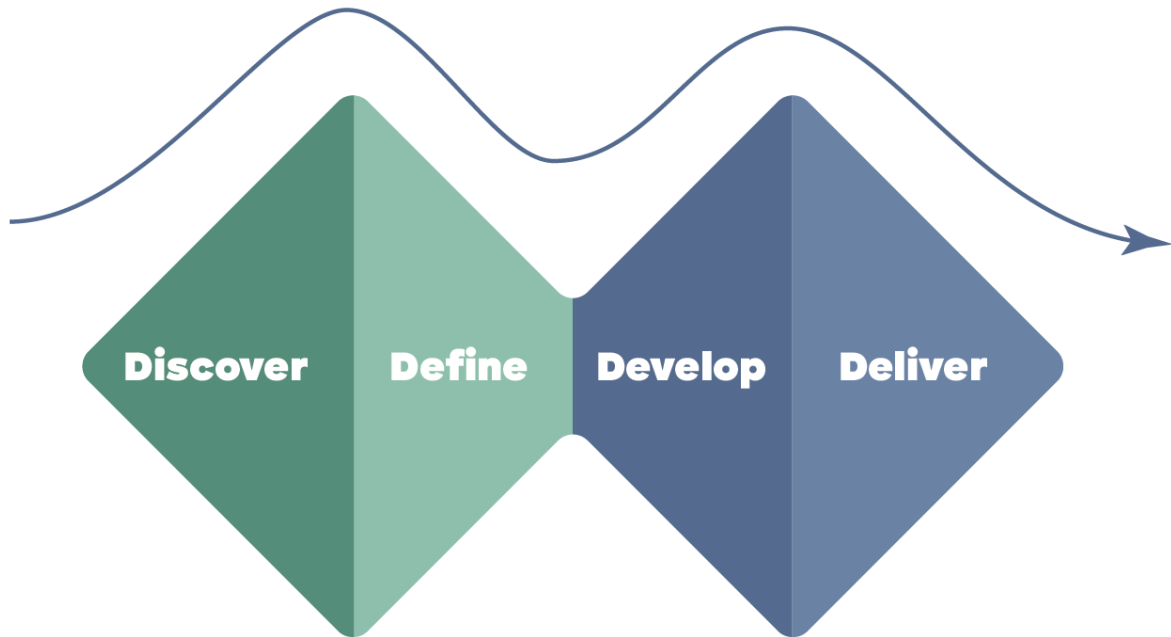


Figure 43 Double diamond - Design process visualization

### The three main component trajectories

The three main product components are: **Enclosure**, **Patch** and **Connection**. These three main product components became regular topics during the design process. For legibility reasons, they are explained and expanded upon individually as if they had their own separate trajectories. In reality, all product components are highly interdependent and significantly influenced one another throughout the design phase.

All the information gathered from the three separate research- and prototyping trajectories, function as building blocks for the final design proposal. Figure 44 illustrates the back-and-forth nature of this design process. The main product components, visualized as three trajectories, are interdependent on each other and go through their individual iteration cycles. In the final design proposal they come together as one assembled product.

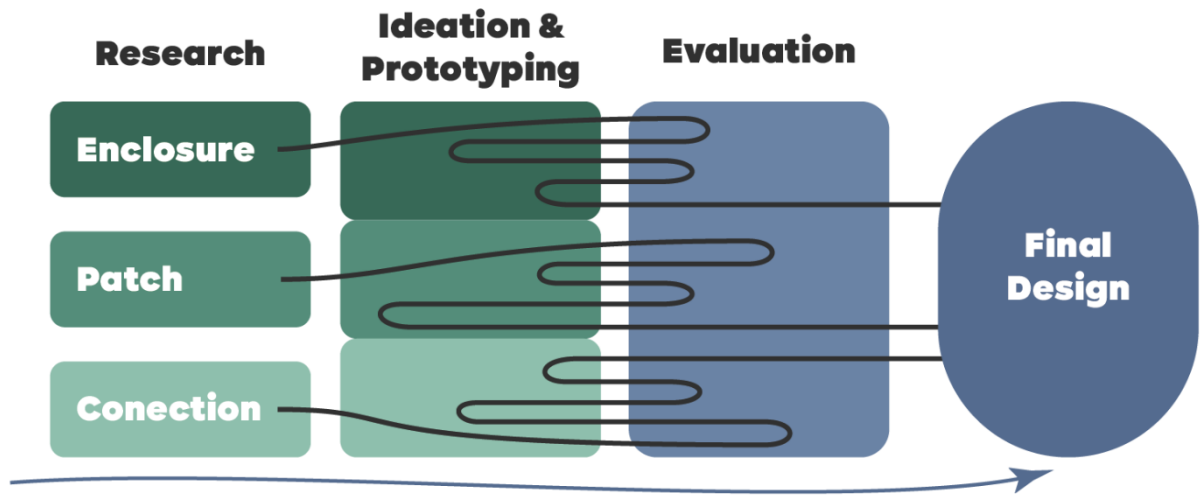


Figure 44 Iterative design loops visualization

## 6.2. MAIN CONCEPTUAL DIRECTIONS

Four main concept directions were identified (Figure 45). For each, advantages, concerns and disadvantages are considered. To conclude this subchapter, all positive and negative attributes are weighed against each other to find a concept for continuation.

The configuration concepts illustrated in Figure 45 are for illustrative purposes only and do not determine shape, electrode positioning or any other details. Monitoring devices like ECG vests are not desired by Diplora and are thus excluded from the scope of this project.

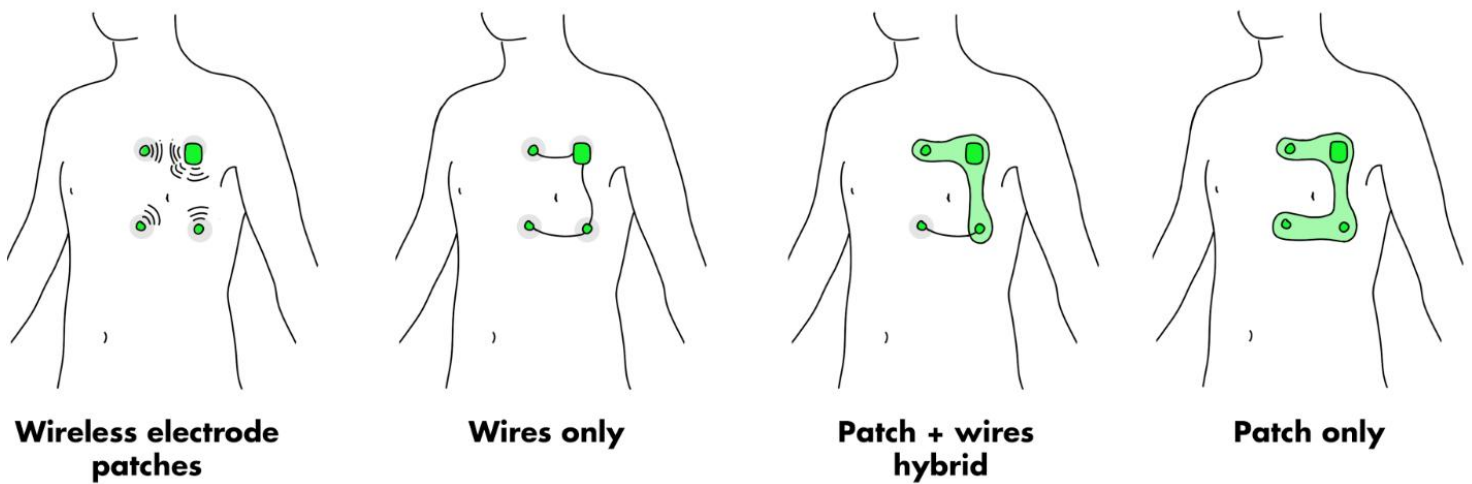


Figure 45 Overarching concept directions

## Wireless electrode patches

This concept consists of three transmitting patches and one receiver unit. The main **advantages** of this concept are freedom of mobility and adjustability. Anthropological adaptability is high for this concept due to the lacking physical constraints for distance between electrodes, meaning that any body shape or size fits. The amount of leads is very modular as transmitting patches can be left out to get a 1-lead solution. The main **disadvantages** regard practicalities such as per unit weight, losing devices and the cumbersome charging of each individual unit. Diplora ruled out this concept due to budget concerns.

## Wires only

Initially, Diplora wanted to avoid the cluttered nature of a wired solution. However, during concept generation and prototyping, a fully wire-based solution seemed to have advantages that were initially overlooked. **Advantages** include: better anthropometric adaptability compared to patches, less adhesive contact area with the skin and finally cost. It can use industry standard electrode patches which are cheap relative to a custom designed and produced electrode patch. It also saves the cost of an entire MDR certification process as only the device has to get certified and not an additional custom patch. This cost reduction can accumulate to €100.000, which is significant for a small startup. **Disadvantages** are related to aesthetics, practicality and durability (according to GPs, wires tend to break quickly). In regards of safety, wires are worse than a patch since they can get snagged and violently get ripped off the skin. Using adhesive tapes to keep the wires close to the skin is a sloppy solution currently used on wired wearable ECG monitors.

## Patch and wires hybrid

This option has very specific advantages compared to a 'Wires only' or 'Patch only' solution but carries disadvantages from both. The drawing in Figure 45 shows three electrodes in a patch and one on a wire. For modularity, different configurations and combinations can be designed so a product can adapt from a 1-lead to a 3-lead ECG. Since this adaptability is not exclusive to a patch and wires hybrid, this solution does not provide enough benefits for continuation.

## Full patch

A full patch was Diplora's initial desire, due to aesthetic reasons mainly. It also has many practical and functional **advantages**. It is low-profile, light weight, secure and induces less motion artifacts than wires do. Concerns regard a bigger contact area with the skin. Supposedly making it more susceptible to uncomfortable skin wrinkling during motion. A bigger patch might also introduce more waste. Clear **disadvantages** are its higher cost due to added certification processes and a higher per-use cost than commercially available electrodes. It will also, supposedly, require multiple size variations to accommodate different body shapes and sizes.

## Weighted objectives evaluation

A weighted objectives analysis is an evaluation tool for comparing design concepts. Each objective is assigned a score that correlates to the desired product functions in this project. Objectives that can only be roughly estimated have a lower weight and thus lower influence. Potentially important objectives that require more research are excluded from this weighted objective evaluation as their uncertainty should not yet influence the design direction. The “wireless electrode patches” concept is not considered in this evaluation as it was ruled by Diplora due to budget constraints.

<i>Objective</i>	<i>Weight</i>
<i>Mobility</i>	30
<i>Anthropometric adaptability</i>	25
<i>Aesthetics and low profile</i>	15
<i>Ease of application</i>	10
<i>Cost (certification + production)</i>	10
<i>Disposable waste (less is better)</i>	10
<i>Total</i>	100%

	Wires only		Patch and wires hybrid		Full patch	
	Score	Total	Score	Total	Score	Total
Mobility	8	240	7	210	8	210
Anthropometric adaptability	8	200	7	175	6	150
Aesthetics and low profile	2	30	2	30	8	120
Ease of application	7	70	5	50	6	60
Cost	9	90	4	40	6	60
Disposable waste	8	80	7	70	7	70
		710		575		700

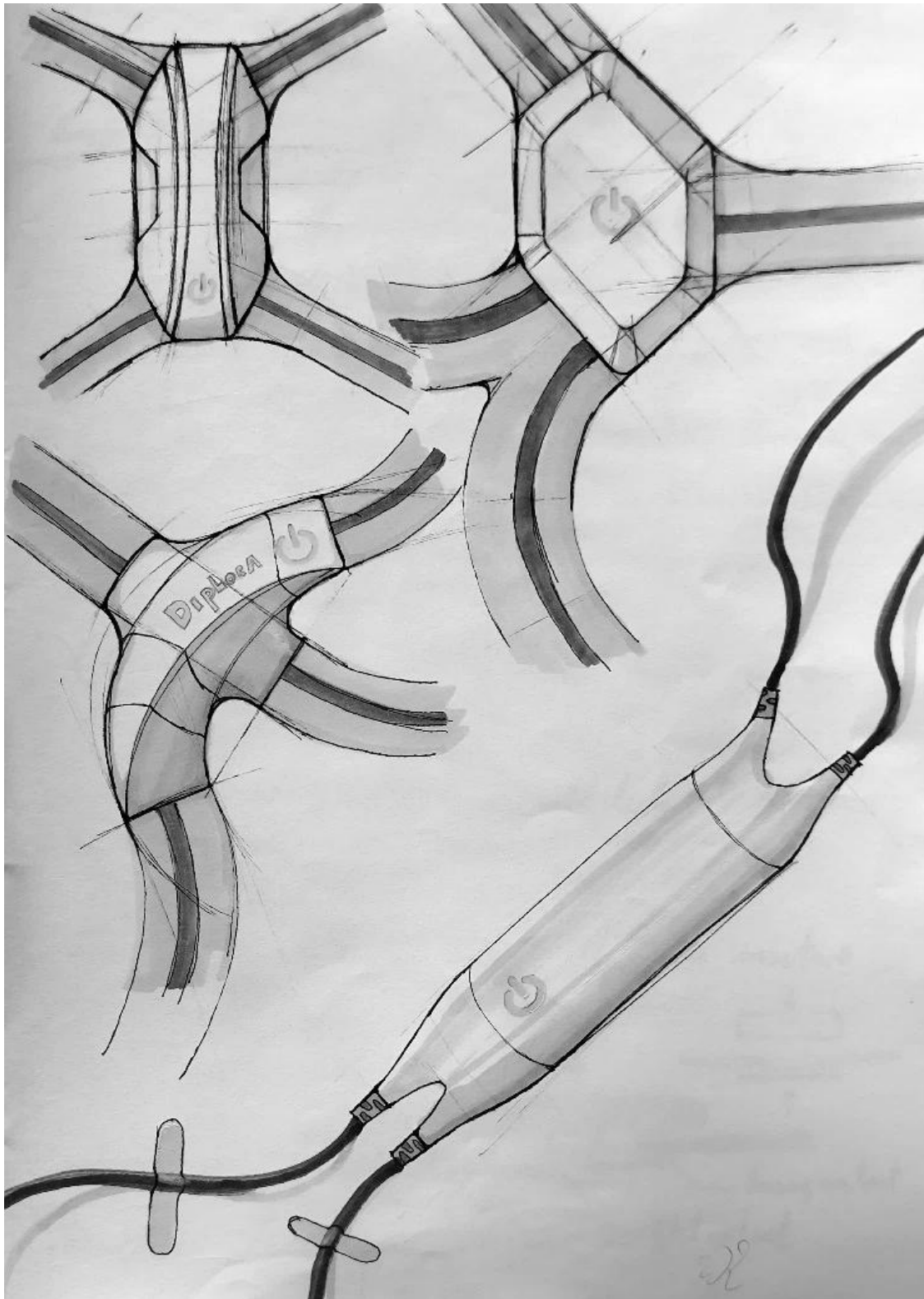
### **Conclusion weighted objectives evaluation**

Since the concepts "*Wires only*" and "*Full patch*" are very close in their score, the concept for continuation is decided on personal preference, alignment with the learning goals and the alignment with Diplora's initial preference for a patch solution.

Since it was found throughout this project that a modular solution is preferred by Diplora, the to be designed patch solution will incorporate a universal USB-C connection that can connect to either a patch or a wired solution. This leaves both options on the table for Diplora to explore after this graduation project is finished. The main focus however, is designing a solution with a patch.

### 6.3. MAIN DESIGN TOPIC 1: ENCLOSURE

This subchapter describes the prototyping findings of the enclosure specifically. It focuses on the development of shape, geometrical details and methods for securing the device to a patient. Knowledge on comfort is gathered through user- and self-testing.



## Digital configuration prototyping

For the research on positioning of the device (found in Chapter 4), basic shapes were 3D printed based on the known (possible) dimensions and volume occupation of the required electronics (Figure 46). The visible electrical components on the PCB are for illustrative purposes only. The PCB can be any two dimensional shape with a minimal area of  $1000\text{mm}^2$ . The battery can vary in dimension on any axis. For these digital configuration prototypes, commercially available battery sizes were used.

These digital configurations, shown in Figure 47, are the basic shapes with minimal volumes used in the preliminary ergonomics research. Figure 48 demonstrates three examples of configuration prototypes enclosed in a shape that resembles the final design. An estimated wall thickness of 1.5mm was used as margin to the outside shell whilst also leaving space for rib structures.

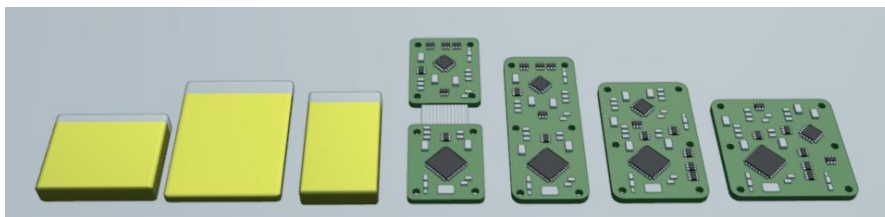


Figure 46 Required electronics (left: batteries, right: PCBs) in multiple sizes

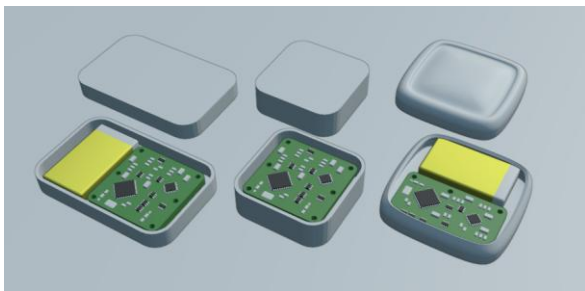


Figure 47 Basic shapes, fitted with electronics



Figure 48 Examples of digital configuration prototypes

## Determining the amount of bend in the enclosure

A concave shape can be added to the device to prevent wobbling on the chest. User testing concluded that a bend of 10 degrees provided the most stability and comfort, regardless of its rotation. Four shapes were tested at 0, 10, 20 and 30 degrees (top to bottom).



*Figure 49 Sideview of bending prototypes in 0, 10, 20 and 30 degrees (top to bottom)*

## Enclosure rigidity

For potential ergonomic benefits, a (semi)flexible enclosure was considered (Figure 50 Figure 51). This enclosure would be made of materials like TPU or silicone and have (partially) flexible electronics on the inside. Over molding the electronics in a flexible material was considered, but discontinued due to lack of serviceability and impossible material separation after a completed service period.

Throughout the project it became apparent that other attributes contribute much more to a comfortable wearing experience than the flexibility of the enclosure does. Minimal adhesive area was found as the main determinant for comfort. For this reason, a rigid enclosure with minimal contact area is preferred for better protection and serviceability.

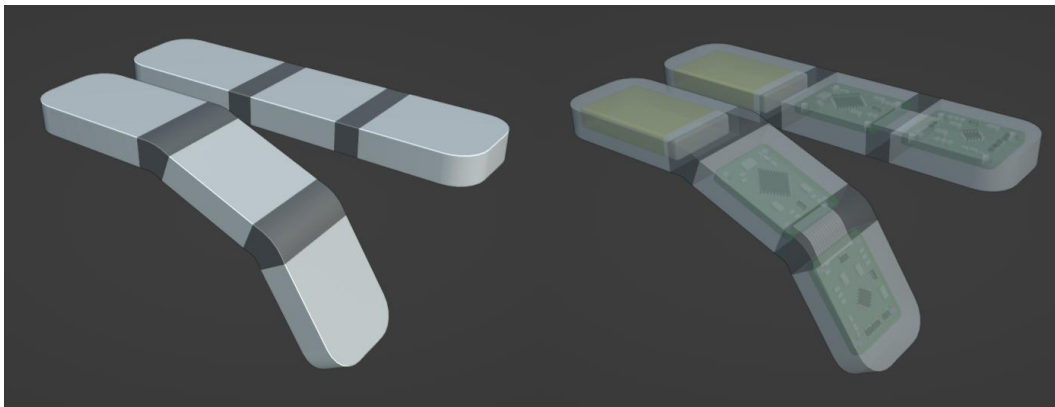


Figure 50 Semi-flexible enclosure

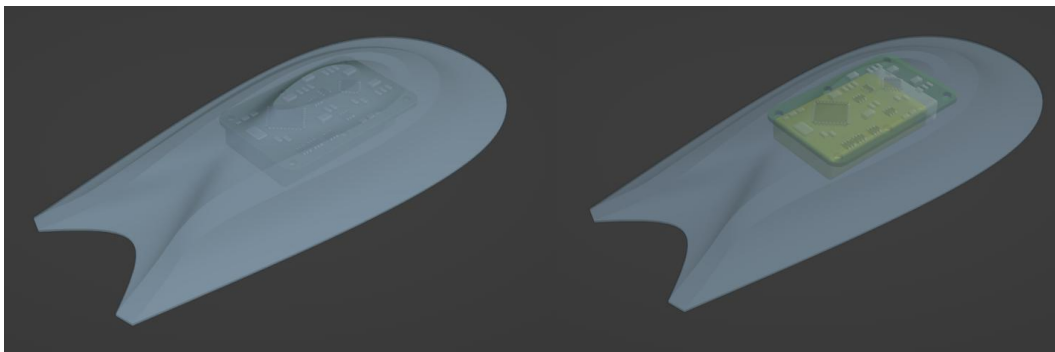


Figure 51 Flexible silicone enclosure with encapsulated electronics

## Securing the device

The flexible lid surrounding a rigid enclosure (demonstrated in Figure 52) initially had securing purposes, as illustrated in Figure 53. Figure 54 and Figure 55 show the evolution from a rigid body with a flexible lid, towards a fully rigid and rounded body without a lid. A rounded body with minimal skin contact was found to be the most comfortable due to its minimal obstruction of skin deformation (Figure 56). Using a lid and a Tegaderm film to secure the device to the body was experienced as harder and much less comfortable than an rounded enclosure directly connected to the patch (Figure 57).



Figure 52 Flexible lid demonstration

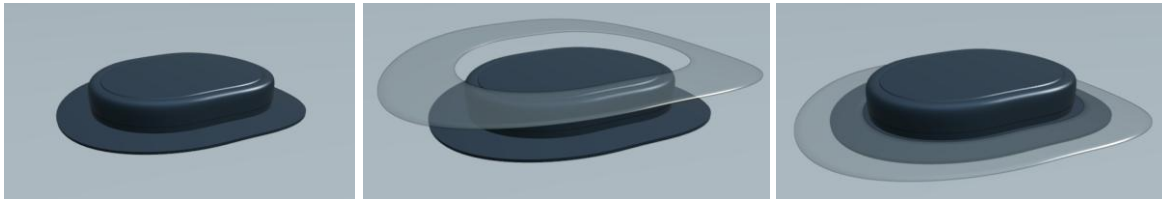


Figure 53 Securing the device to the body using a Tegaderm film



Figure 54 Evolution from flexible lid, to no lid

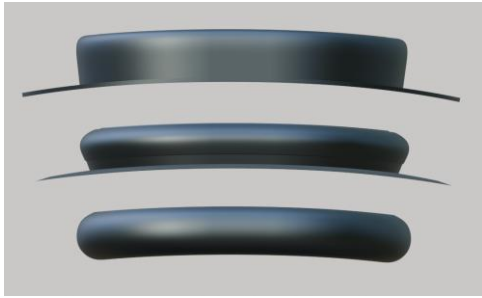


Figure 55 Evolution of the decreasing lid area, in sideview (top to bottom)

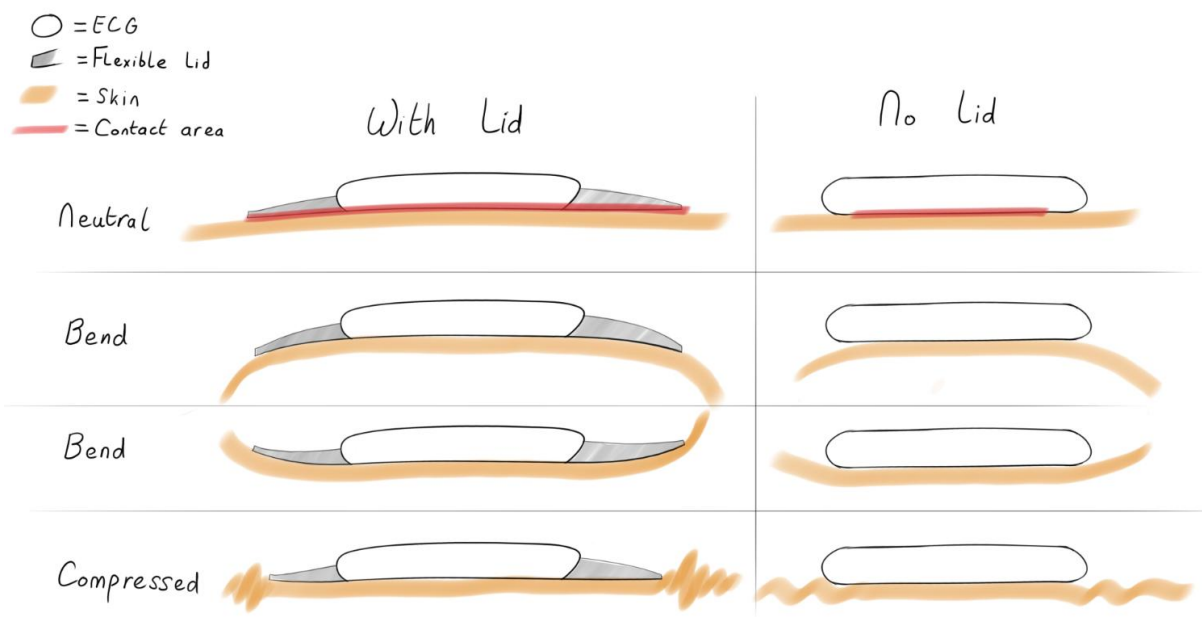


Figure 56 Illustration demonstrating the improved skin conformity with minimal contact



Figure 57 Enclosure directly connected to the patch

### Use testing

User testing concluded that it was too hard for an untrained patient to apply the Tegaderm film themselves, using only a mirror (Figure 58). A limitation of this research was improper backing of the flimsy Tegaderm film. A more rigid backing would have helped with alignment. It was decided to discontinue the use of a flexible lid and Tegaderm film solution due to its susceptibility to human error and inferior comfort compared to a directly patch-mounted solution.



*Figure 58 User testing: application using Tegaderm film*

## Closing method

Sustainability, durability and serviceability played prominent roles in selecting the closing method for the enclosure. The device has to be serviceable and thus, openable. For this reason, methods like material welding and over molding, which create a permanent seal, were excluded. A snap-fit solution is not desirable for strength, durability and waterproofing reasons. Using adhesives or screws with a rubber gasket remained the most viable options and are evaluated in this subchapter.

### Screws

The main advantage for screws is quick serviceability. Using a rubber gasket can make a wearable waterproof. The Samsung Galaxy Watch 3, for instance, is rated IPX68 (Figure 59). A downside to screws is the likely need for screw inserts when used in a plastic enclosure. These inserts obstruct easy recycling of the enclosure. Screws tend to require a thicker enclosure.

For aesthetic reasons, a sticker can be placed over the screw holes. This, however, would make servicing harder as the sticker needs to be removed (likely using a heat gun) which defies the purpose of using screws in the first place.

Furthermore, the device is not required to be serviceable by patients themselves. Easy access is therefore not required. For this medical device, it is not desired consumers can easily open the casing. At the EOL, Diplora will be responsible for opening the device and proper material separation.



Figure 59 Galaxy Watch 3 opened up showing screws and a rubber gasket (Zwink, 2021)

## Adhesive

Adhesives have the benefit of being very strong, durable and creating waterproof seals. They do, however, complicate and elongate the service procedures. It is often required to debond the adhesive using a heat gun (heat-induced bond failure) and requires careful prying to open the enclosure. The apple Watch Series 10 uses adhesives. It makes it very thin (low profile) and extremely water resistant up to 50 meters deep (swimproof). An adhesive seal also leaves less crevasses and holes for dirt to accumulate.



*Figure 60 Apple Watch Series 10 pried to open after heat gun (Diaz-Kokaisl, 2025)*

## Final verdict

For the Diplora ECG it is decided to use adhesives as a closing method. If the selected adhesive is debondable by heat, then the enclosure remains openable and thus serviceable. For a device that needs to be waterproof, robust, low profile and does not require patients to do repairs themselves, using adhesives is advantageous.

## Device orientation

It was found that a vertical rotation of the device is more comfortable than a horizontal rotation due to the chest mainly expanding and contracting horizontally during sports and regular movement (Figure 61). A vertical rotation minimally obstructs skin contraction (which avoids uncomfortable skin wrinkling) and is therefore the best option for unrestricted mobility. This finding is emphasized by early prototypes that still used the lid (Figure 62).

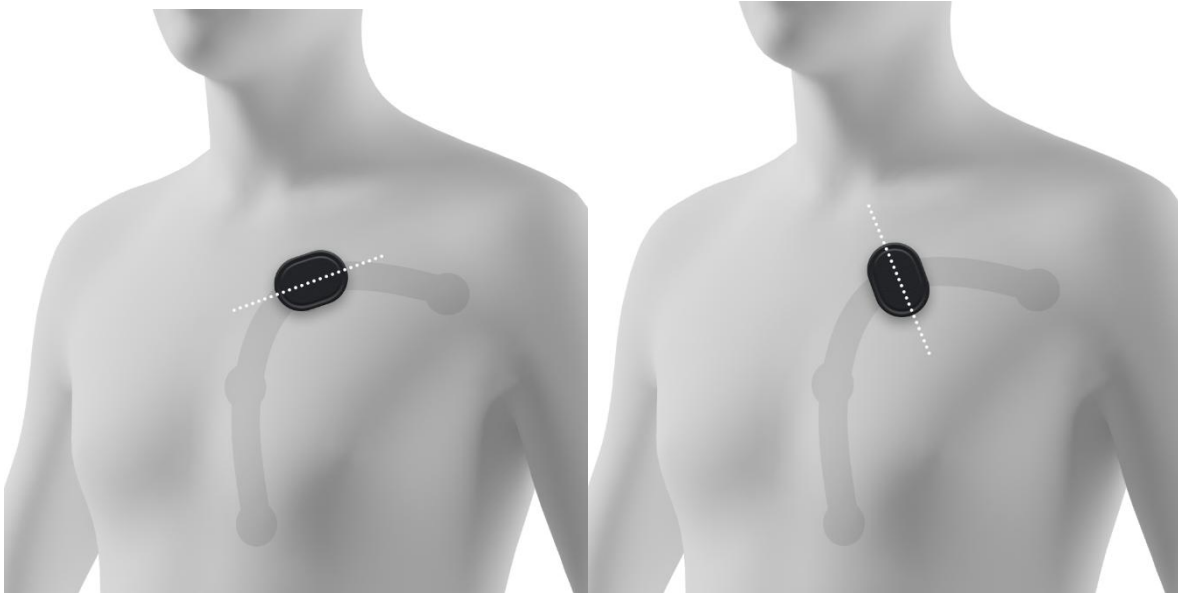


Figure 61 Device rotation (left: horizontal, right: vertical)



Figure 62 Uncomfortable horizontal orientation of the ECG

## 6.4. MAIN DESIGN TOPIC 2: PATCH

This chapter prototypes the patch. Geometry variations, materials, layering and positioning are researched. Prototyping a patch with production level layering and materials (like conductive silver chloride wiring) is hard to achieve during a graduation project. Therefore, mock-ups were made with estimations on factors like stretchability and geometry to find important design factors that contribute to a comfortable wearing experience. These factors can be used for finding requirements for the final design proposal and future development by Diplora.

### Basic construction of ECG patches

This subchapter briefly explains the construction basics of ECG patches. An ECG patch is made of layers (Figure 63). Materials can vary, but their function and order is often similar. This project will emulate ECG patches and their properties because the production of real ECG patch prototypes is too complex.

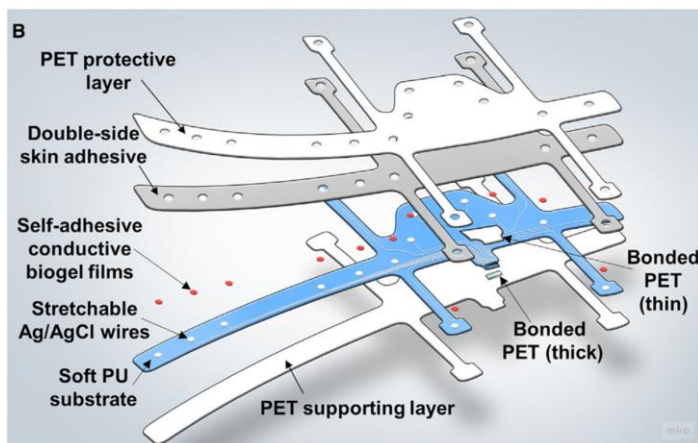


Figure 63 An 18-lead patch design by Deng et al., 2024



Figure 64 Basic ECG patch layering

#### Layering:

1. **Protective release liners and paper/plastic packaging** (provides structure to the patch during application and prevents accidental folding, peels off after application)
2. **Soft substrate** (PU, soft and flexible outer layer of the patch)
3. **Printed-circuit/conductive wiring layer** (thin carbon or Ag/AgCl conductive ink traces)
4. **Skin adhesive + conductive contact points** (often acrylate based adhesive + conductive hydrogel)
5. **Backing substrate** (often a thin PET layer that protects the adhesive side)

## Patch placement

Multiple patches were worn to find the most important factors that facilitate a comfortable wearing experience during sportive activities. Materials, position and geometry were researched. It was found that unobstructed skin wrinkling and elongation are the main determinators of comfort. A thin and flexible patch is the most comfortable.

Patches were worn for as long as they remained comfortable and properly attached to the skin, not exceeding the 7 day limit recommended by the manufacturers. Transparent medical dressing tape (3M Tegaderm) and two types of sport tape (FysioTape) were used in this research (Figure 65 and Figure 66). The Tegaderm tape is of medical grade, very thin and conforms well to the skin. The FysioTapes are made of viscose with an adhesive layer underneath. The 'Sport' variant of FysioTape (black) was found to be the most practical for prototyping and resembled the medical Tegaderm more than the slightly thicker 'Classic' FysioTape (red).

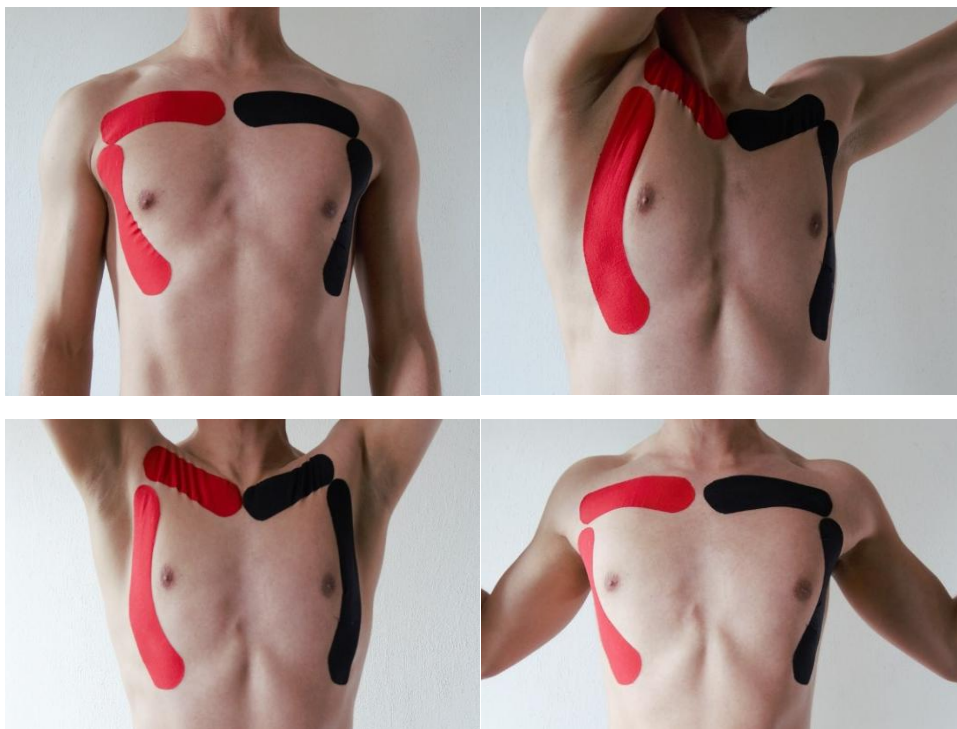


Figure 65 FysioTape Classic (red) and Sport (black) tested on elongation and skin wrinkling

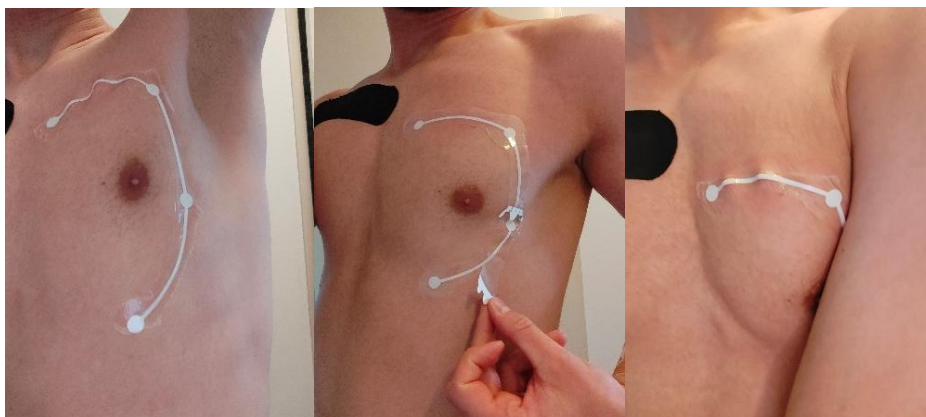


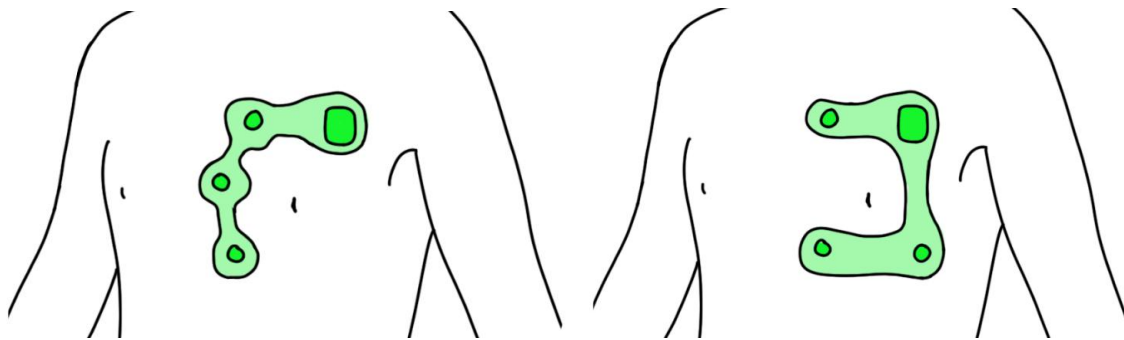
Figure 66 Tegaderm dressing tape with PLA wiring insert

### **Sternum vs Side placement**

Both Figure 65 and Figure 66 show tapes in on the side of the chest. Initially, this placement was chosen because women are concerned for discomfort caused by any object or patch between their breasts. As the project progressed, it became clear that measuring V3 (located near the bottom of the sternum) was necessary. Further user testing then found that a patch on the sternum was still comfortable for woman and does not cause added discomfort from a patch between the breasts.

Added advantages of placement on the sternum regard stability. The sternum undergoes very little stretching, bending, shearing or torsion during any kind of body movement. This stability avoids any skin discomfort caused by the patch stretching or wrinkling.

Additionally, the patch can be shorter and still reach the V3 electrode position. Compared to a side placement, the sternum has very little muscle activity directly underneath the skin. This benefits signal clarity.



*Figure 67 Sternum patch (left) and a side patch (right)*

## Patch shape

The geometrical (Figure 68) impact of the patch was researched. As the previous subchapter stated, minimal adhesive contact with the skin was found to be the biggest determinant of comfort during movement. For this reason, contact area has been minimized on every part of the patch whilst balancing secure adhesion. It was found that the most comfortable and secure option was a patch of which its complete surface is attached to the body (no non-adhesive areas like in a wired version). Thickness should be minimal whilst flexibility must be high. This ensures great skin conformity during both stretching and compression.

The electrodes connect to the skin through a small circular area of conductive gel, which is non-adhesive. This non-adhesive area therefore has a wider circular area surrounding the gel to secure the to the skin. Figure 69 shows the first prototype minimizing adhesive contact area of both the patch and the device.

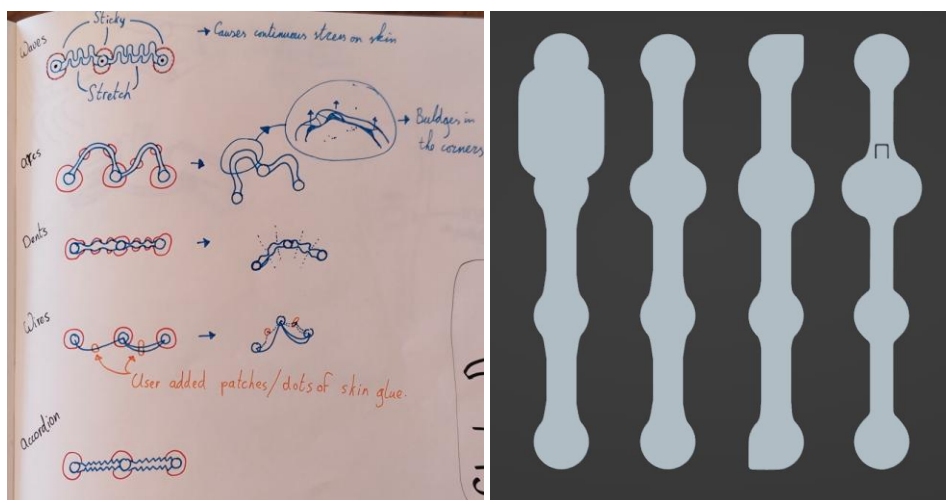


Figure 68 Geometrical iteration on patch



Figure 69 Minimal adhesive contact area prototypes

## Geometry of conductive silverchloride wiring

The final production patch will need conductive silverchloride (AgCl) wiring to connect the electrodes of the patch to the internal electronics of the device. This conductive material is relatively rigid (Youngs modulus of  $\sim 22$  GPa). For this reason, flexibility must come from geometry rather than material properties. AgCl wires in smart patches are estimated to be  $10\mu\text{m}$  thick and roughly 2mm wide (Kim et al., 2022). The conductive AgCl wiring was prototyped with a single layer of 3D printed PLA ( $\sim 4$  GPa). Using these values, it was estimated that a PLA dummy circuit had to be roughly twice as thick to prototype for a similar rigidity and flexibility as a silver chloride wiring. A single 3D printed layer of PLA is 10 times thicker than  $20\mu\text{m}$ , and the width cannot decrease much for practical reasons. Therefore, it can be assumed that the wiring in the final patch can be less wavy than the PLA dummy circuit used in this research.

A straight line as previously shown in Figure 66 became very uncomfortable after only 5 hours of wearing due to strong skin wrinkling during contraction and too little deformation during elongation. A waving pattern solved this issue (Figure 70).



Figure 70 Wave pattern of the conductive silver chloride

Another considered option for flexibility was a straight line that flexes away from the body during compression, like the Bittium Faros does (Figure 71). A downside to this option is that these protruding wires are snatch-able and can thus more easily be ripped of unintentionally. Also, if the patient (unintentionally) places the patch completely flat during application, elongation is no longer possible.



Figure 71 Straight conductive wiring on Bittium patch

## Sizes

For determining whether multiple sizes need to be provided, a Dined experiment was conducted on 5 personas for both males and females. Stature and chest circumference were used in this research as they influence the chest dimensions both vertically (*stature*) and horizontally (*chest circumference*). Figure 72 shows the measurements of 5 personas for both males and females. A patch was determined to fit well when it reached V3 and was long enough to properly align the electrode on the other end of the patch to the top right of the chest.

It was found that 3 sizes would be required for accommodating every body type. The small version (S) would need 7cm between each electrode, medium (M) 8cm and large (L) 9cm. Men did not require the large variant. The large variant was only needed for woman with larger breasts. A visual representation of the adjusted patch sizes can be seen in Figure 97 Figure 73 and Figure 74.

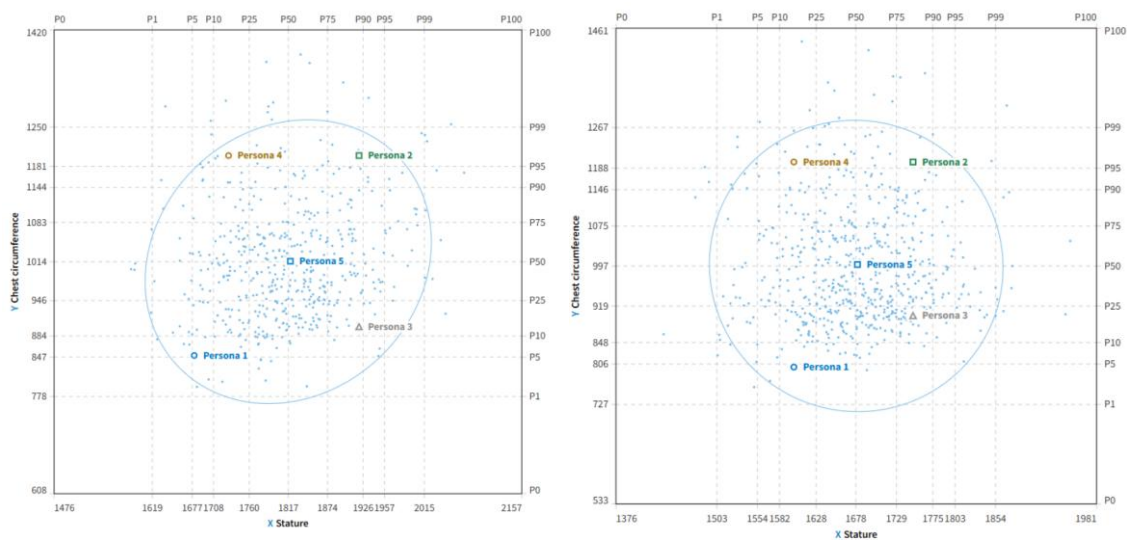


Figure 72 Dined diagram showing the male (left and female (right) persona measurements based on chest circumference and stature

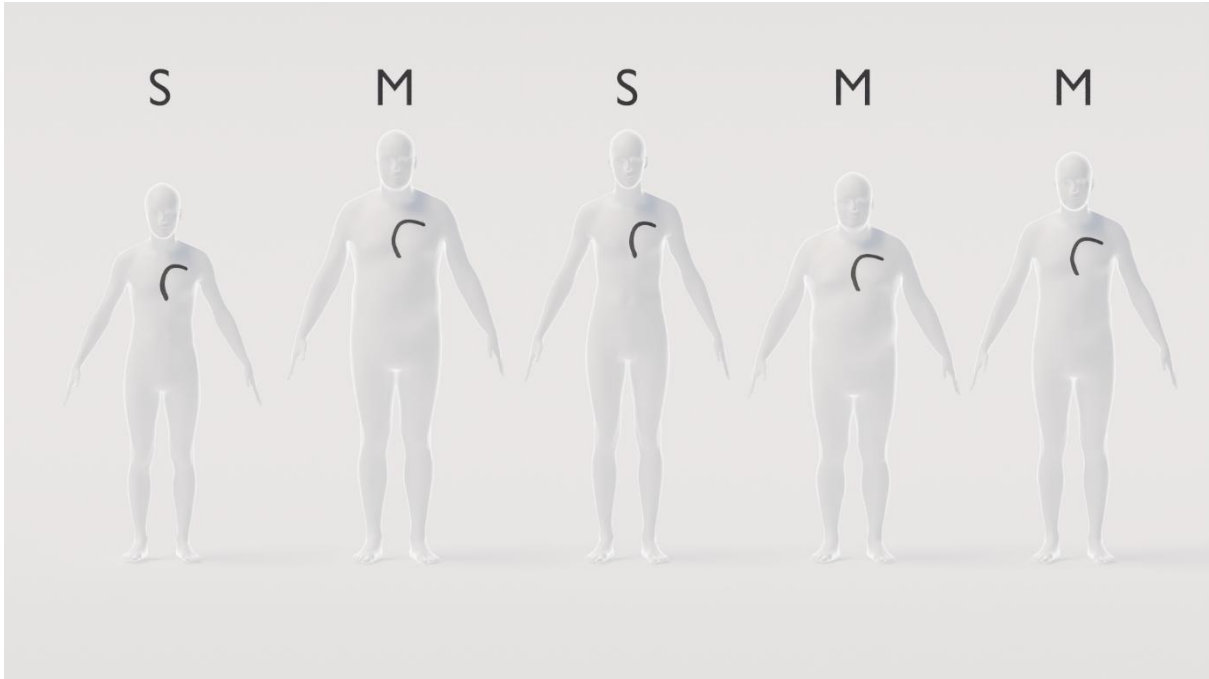


Figure 73 Male Dined models with size indication (persona 1-5 from left to right)

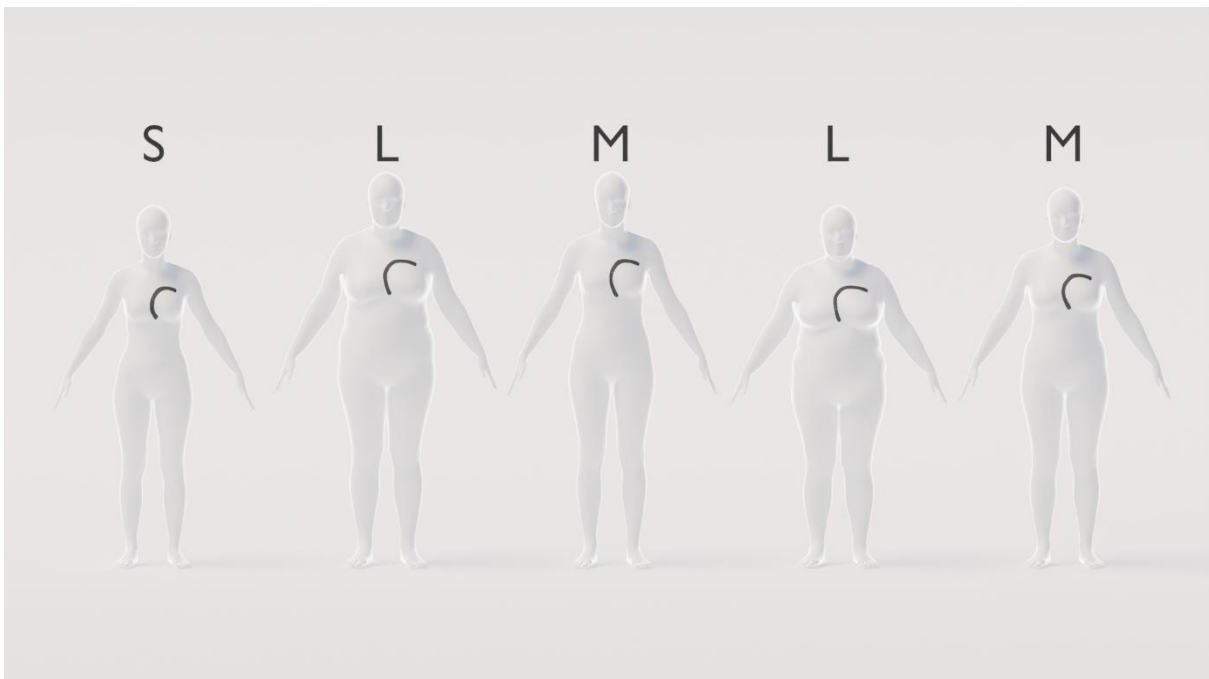


Figure 74 Female Dined models with size indication (persona 1-5 from left to right)

## 6.5. MAIN DESIGN TOPIC 3: ELECTRICAL AND MECHANICAL CONNECTION

This subchapter explores the possibilities for the most technically challenging design topic of this project. There are many complicated requirements to the connection between a patch and the device. For Diplora, **sustainability**, **reliability** and **modularity** are important factors for their product.

**Sustainability:** The patch is the biggest influencer on sustainability as it is a single-use, disposable product component that is currently hard to recycle. Minimal material usage, minimal fusing, use of low-impact materials and as few material combinations as possible are important for this reason. Current consumable ECG patches consist of many fused materials (i.e.: metals, plastics, adhesives) which are practically inseparable. Ideally, low-impact materials are used. Some existing wearable ECGs require additional adapters which Diplora wants to avoid.

**Reliability:** The final product should be waterproof, secure during motion and easy to apply whilst minimizing human error. Unambiguous alignment between patch and device should guarantee a dependable electrical- and mechanical connection.

**Modularity:** Diplora desires a product that can use both a patch and a wired solution. Therefore, the connection should utilize a universal electrical connection method.

This subchapter describes the ideation and prototyping results to quickly understand what has been considered and which concepts yielded the most promising results. The results remain conceptual but are estimated to be feasible based on the knowledge gathered in the technology research.

First, the mechanical- and electronic connection methods are presented separately. Not all the listed mechanical and electronics connection methods are feasible together. Generally, one electrical connection methods prefers one mechanical connection method. To conclude this subchapter, all the promising methods are combined in final connection concepts of which one is used in the final design.

## Mechanical connection

This subchapter describes the mechanical connection options that were considered (Figure 75) and highlights the three options with the most potential that were used during prototyping.

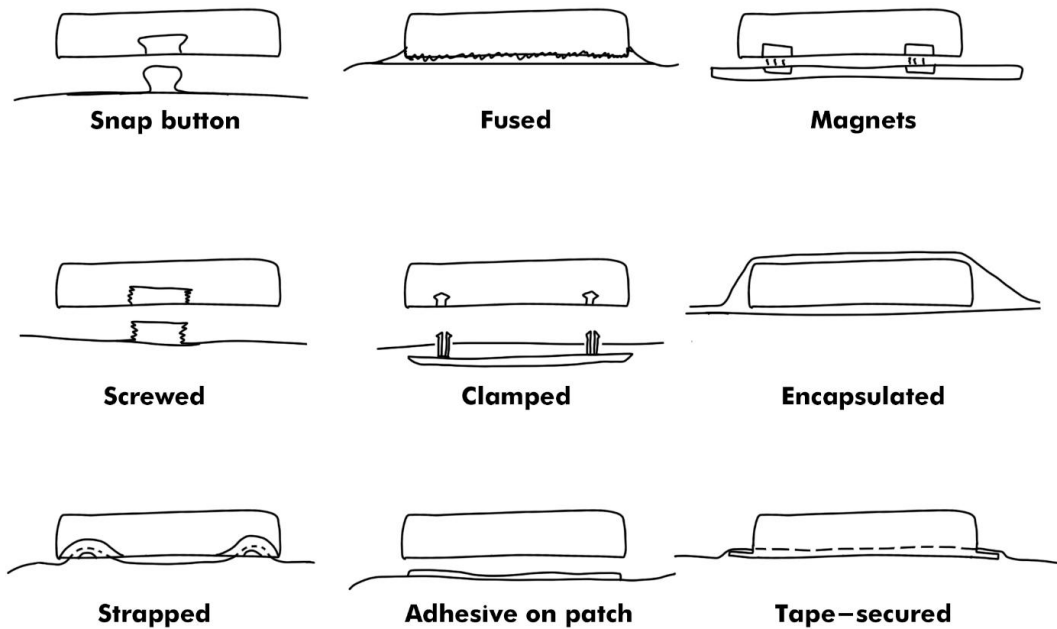


Figure 75 Basic connection method concepts

Method	Description / Advantage	Concern
<b>Snap Buttons</b>	Standard ECG buttons mechanically- and electrically connect the device to the patch.	Significant added thickness to the enclosure and metal waste in patches.
<b>Fusing</b>	Patch and enclosure are permanently fused together. Strong connection but only usable once, then discarded.	Inseparable waste and lots of electronic waste.
<b>Magnets</b>	A quick magnetic clip-on mechanism that aligns with electrical contact points.	Requires plastic bed on patch side; may not hold during daily use; creates lots of waste.
<b>Screwing</b>	Strong twist-on screwing connection.	Requires a plastic screw on the patch side, which is ideally avoided.
<b>Clamping</b>	Clamping the patch between two enclosure parts.	Straps patch through the enclosure which creates pressure contact for an electrical signal.
<b>Encapsulation</b>	Film or plastic encapsulation keeps the device in place on the patch.	Increased waste, especially when plastic encapsulation is used.
<b>Strapping</b>	The patch is strapped through the enclosure of the device.	Likely requires overhang in the mold, which is ideally avoided to save on cost.
<b>Tape-secured</b>	The device is adhered to the patient by a tape that overlaps the device lid.	Patch and device are only held against each other; unassisted attachment may be difficult for a patient.
<b>Adhesive area</b>	Adhesive area with controlled adhesion strength sticks enclosure to patch (enough to stick, but low enough to peel deliberately).	Requires fine-tuning of acrylic adhesive strength.

Based on their assumed maximum connection potential and minimal patch related waste, **snap buttons**, **tape securing** and an **adhesive area** were prototyped. The best found solution is presented and explained in the next chapter.

## **Electrical connection**

Designing a revolutionary type of patch is not the main objective of this thesis. The main challenge for the electrical connection between the patch and the device lies in sustainability: ideally not combining materials such as metals, adhesives, and plastics. For this reason, the introduction of additional metal or plastic components is avoided as much as possible, in order to minimize inseparable patch waste.

Identified where two main approaches for establishing an electrical connection: pressure or spring based contact (Figure 76) and friction or clicking based contact (Figure 77). Various combinations of electrical and mechanical connection methods are possible. Compliance and harmony between electrical- and mechanical connection techniques varies and is explored in the next subchapter.

## Pressure or spring based connection

### Advantage

### Concern

#### Pogo pins array

Spring-loaded electrical pins that protrude from the device enclosure and connect with exposed patch contacts. No added metal parts on patch side which minimizes material waste. Can be waterproof.

Connection may be insecure during motion; adds complexity to the device.

#### Conductive gel + conductive enclosure areas

Apart from connecting the electrode to the skin, conductive gel can be used for connecting the patch to the device. This method is used in the ATSense, which is dissected in APPENDIX: CASE STUDY AT-SENSE. Eliminates need for metal parts on patch side if device has exposed contacts.

Requires strong mechanical seal around contacts to prevent gel washing away during showers or wet activities.

Figure 76 Pressure or spring based connection

## Friction or clicking based connection

### Advantage

### Concern

#### Stainless steel snap buttons

Industry standard; ensures reliable electrode signal and strong enough to function as a mechanical connection.

Added metal parts on the patch reduce material separability.

#### Ribbon cable

Very flat and low-profile; assumably requires little extra material beyond what's already in the patch.

Sensitive to mishandling by users.

#### USB-C

Versatile; one port can be used for both charging and electrode connectivity. Simplifies enclosure design—only charging port needed, no additional protrusions.

Added metal parts reduce material separability; not strong enough mechanically to secure the device to the patch.

Figure 77 Friction or clicking based connection

## Combined connection concepts

The most sustainable solution would be a patch with minimal material mixing whilst using materials with minimal impact. This could be achieved in a solution with matching conductive areas between the patch and device. The patch can use the silver chloride it already uses for wiring as an exposed conductive area. The device could use pogo pins to apply continuous pressure on the exposed contact areas of the patch. The device is secured to the patch using an adhesive area on the patch. No metal or plastic connection parts are needed in this solution. For this concept, it is doubted that there will be a reliable connection during movement.

The concept direction that best balances sustainability with practicality became a patch with an acrylic adhesive area that secures the device to the patch and uses a USB-C connection to electrically connect the device to its electrodes. The downside to this solution is the added male USB-C connector on the patch side. This adds waste. Acrylic glue can be engineered to adhere strong enough to stick securely and low enough to peel deliberately (Kowalski et al., 2013). To keep the device minimally complex, whilst also being modular, it was decided to use the USB-C for both charging and connection the electrodes. This means that a wired solution connected using the USB-C port is also still an option. A wide variety of concept sketches can be seen in Figure 78.

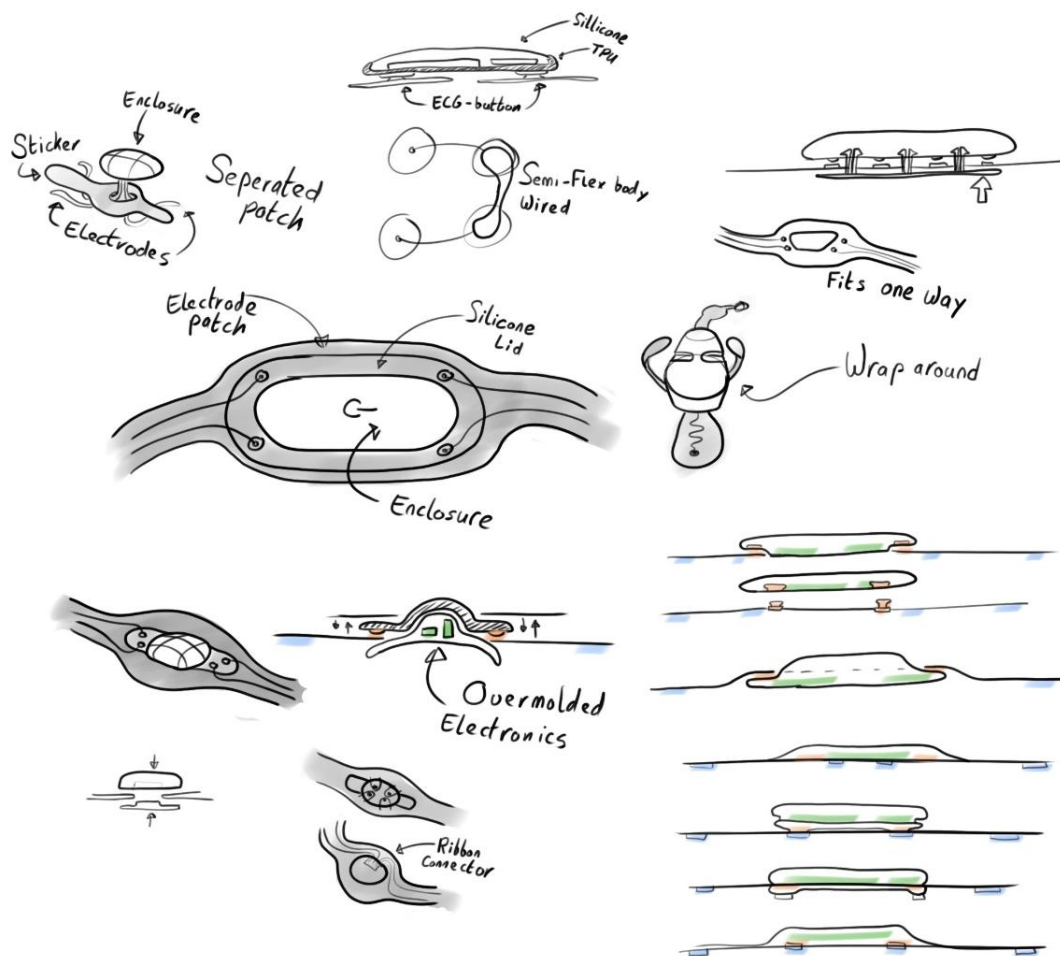


Figure 78 Combined connection concept sketches

## Sustainability of metal connectors

Even though ideally avoided completely, Diplora desires a USB-C connector over other options due to its versatility. It is estimated that one male USB-C connector weighs similar to four male snap fit buttons (~2 grams) and thus has a comparable impact in terms of material waste.

USB-C: copper, nickel (Figure 79)



Figure 79 USB-C connector

Snap buttons: stainless steel, copper, nickel (Figure 80)



Figure 80 Snap button connectors

## 6.6. MODULARITY: PATCH OR WIRES

Initially, Diplora desired a solution with a custom patch and had a strong aversion to wires. During this project however, it became clear that this would drastically increase the cost of the initial product launch because a custom patch design requires its own MDR certification process. Thus, when a wired concept (Error! Reference source not found. Figure 81) with standardized patches (that do not require separate certification) was presented to Diplora, their interest shifted to this wired version for their initial product launch due to budget reasons.

As the comfort advantages of a custom patch became evident however, the desire for a modular solution emerged. This modular solution will initially use the wired option. When Diplora has more capital, the additional investment into a custom patch can be made. This patch should connect to the same enclosure. An additional advantage of this modular approach is the flexibility to adjust the number of leads to suit each patient (Figure 82).

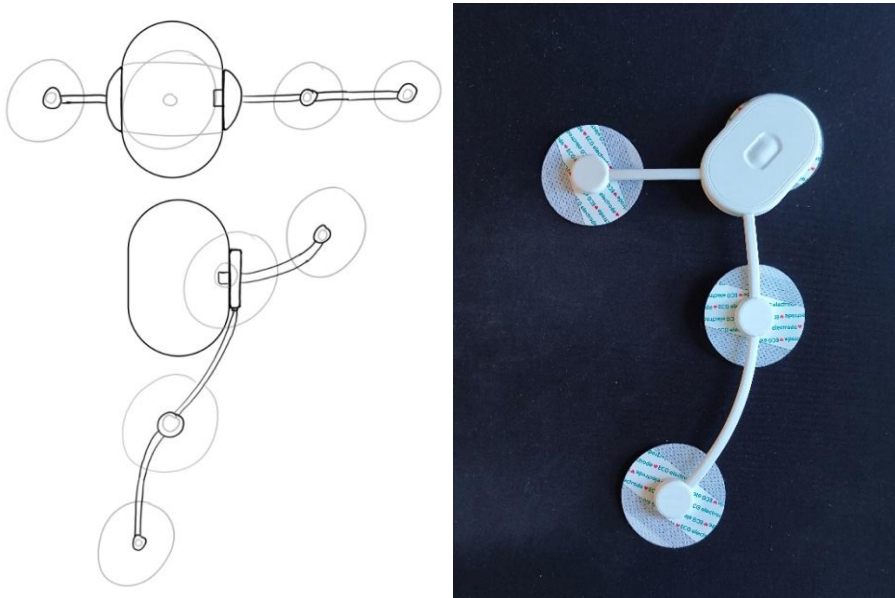


Figure 81 Wired prototype

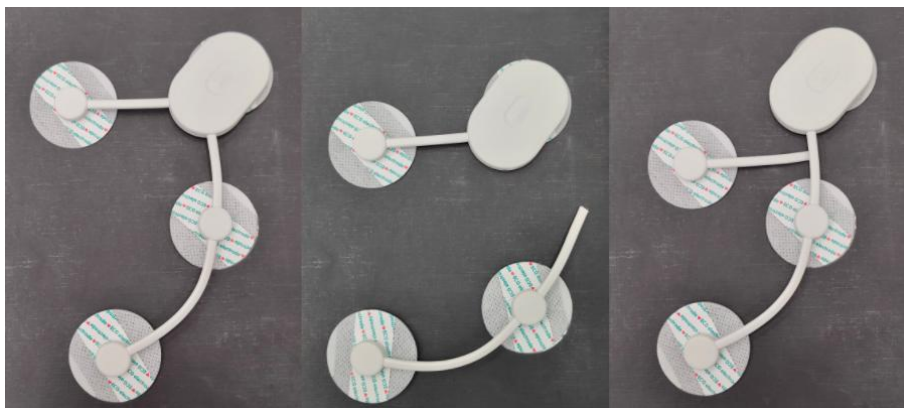


Figure 82 Modularity ideation wired prototype

## 7. FINAL PRODUCT

The final result of this thesis project is a compact wearable ECG concept. The product is designed to be comfortable for both men and women who live an active lifestyle that involves sportive activities. It is self-applicable by the patient and small enough to be transported by mail. These features integrate the product into the vision of Diplora's product service system that will provide accessible ambulatory heart monitoring to everyone.

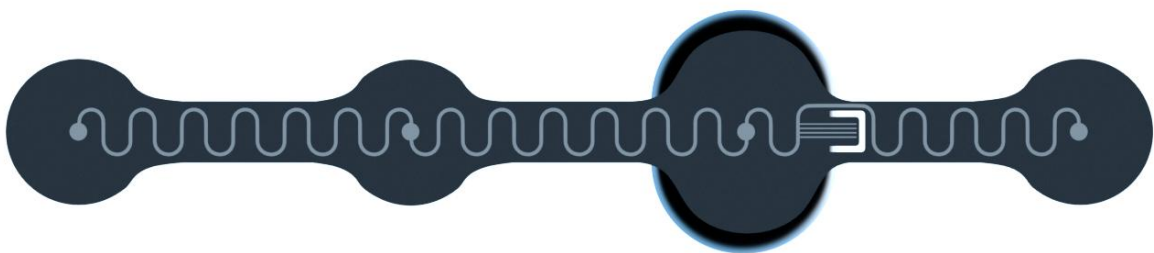
The product consists of a reusable ECG monitoring device that is interchangeable between patients and uses expendable electrode patches that are optimized for both comfort and minimal waste generation. The design is sleek, low-profile and discreet, aligning with the desires of sportive users.

Its positioning on the chest is optimized for comfort, compliance with gym equipment and the required electrode positioning for proper measurements. Due to the use of a versatile USB-C interface, development of a wired solution remains possible alongside the use of patches.

This chapter describes the final design proposal in detail.



## 7.1. DIPLORA CARDIGO – VISUAL SHOWCASE





## 7.2. DEVICE INTERACTIONS

This subchapter describes the regular user scenario and includes all the main interactions between the patient and the device. These interactions consist of four main steps: **receiving** the device, **applying** the device, **wearing** the device and finally **returning** the device.

### Receival

Device interactions start upon receipt of the device (Figure 83). First contact is either through receiving the device by mail or receiving the Diplora ECG directly from the GP. Designing the packaging of the device falls outside the scope of this thesis project. Suggestions regarding a packaging solution can be found in chapter 9 "Recommendations". Protection during transport, environmental impact, user experience and cleanliness should be considered for the packaging of a medical device.

#### The package received by the patient consist of:

- Box / packaging (*returnable*)
- ECG device
- Two electrode patches (one extra in case of misalignment or involuntary detachment)
- Visual instruction manual
- Return label

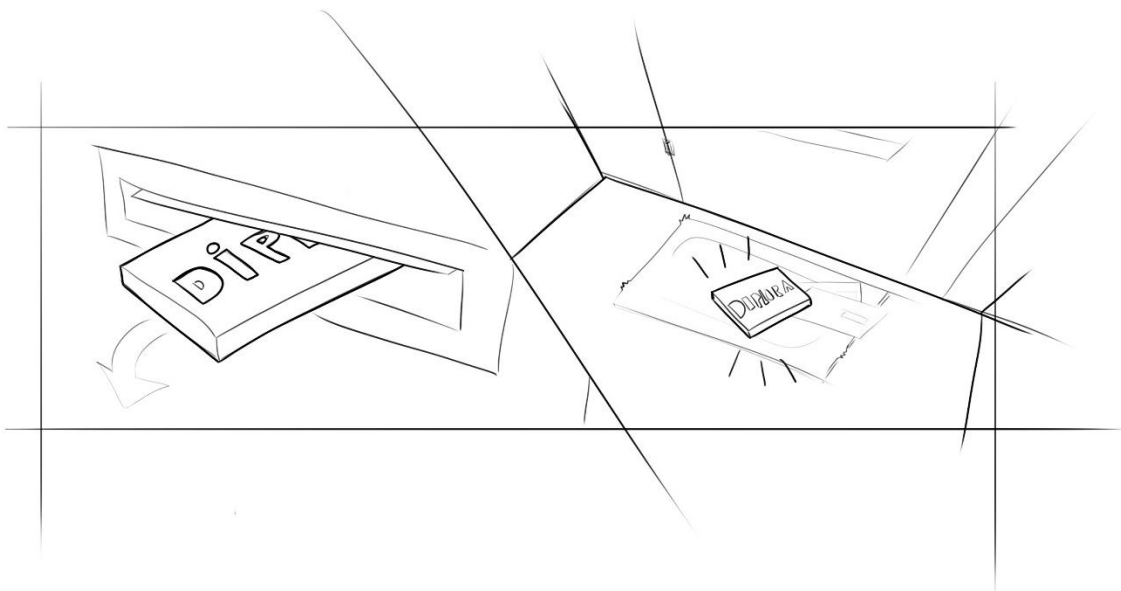


Figure 83 Receiving the Diplora ECG

## Application

Applying the device requires two main steps. First, the device is connected and adhered to the patch (Figure 84). Secondly, the device is applied to the patient.

### Attaching patch to enclosure

1. Plug in the device to the USB-C of the patch
2. Peel away the adhesive liner
3. Place the device on the adhesive area



Figure 84 Attachment steps

### Attaching: patch to patient

1. Peel away Liner part 1 (Figure 85)
2. Attach part 1 to the chest on a V3 position (Figure 86)
3. Peel away Liner part 2
4. Slowly apply the patch from bottom to top whilst copying the curvature as the instruction visuals suggest.

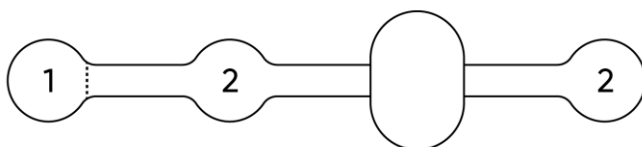


Figure 85 Liner parts

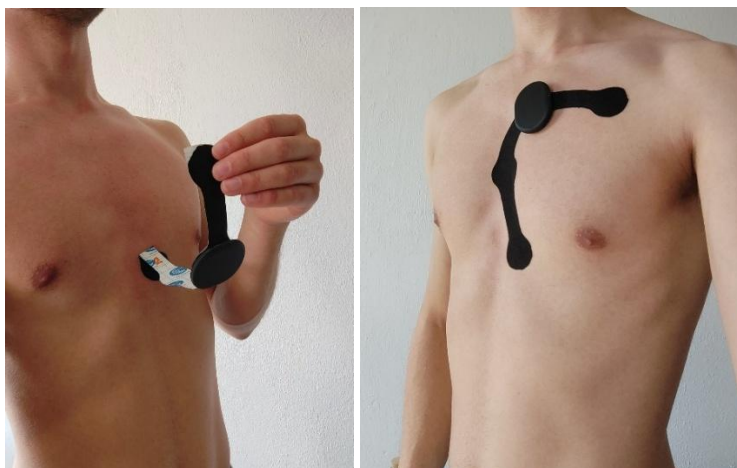


Figure 86 Attachment demonstration

According to Diplora, the electronics in the device can detect when it is plugged into the patch. This 'awakens' it from its battery saving '*slumber mode*' in which it is transported. The device will now look to measure an ECG signal. When it picks up this signal, it will go into pairing mode and seek for a phone to connect with through Bluetooth. Once the phone is connected, measurements and simultaneous livestreaming of ECG data commences.

## **Wearing**

During wear, there are only minimal interactions with the device. Due to medical device classifications not desired by Diplora, the device will not give any health related feedback to the patient. It will however give feedback on its operational state, connectivity and battery usage. This is mandatory for compliance with MDR certification.

## **User input**

To register an event, the patient can double tap the device. This marks a timestamp on the gathered ECG data which makes reading out events easier for the diagnostic healthcare professionals. The patient can add details to their experienced symptoms in the app at any time that is convenient to them.

### Operational state signals

The device includes two electrical components that provide feedback. One is a piezo buzzer for sound cues, the other a multicolor LED for visual cues (Figure 87). The piezo buzzer can make a high pitched sound to inform the patient of a registered interaction. The multicolor LED can function as a status indicator for connectivity progress, battery status and as a cue for registered user input, by turning on and off in patterns. During nominal functioning, the LED should be turned off to save battery. This topic requires more research and validation. Suggestions are made in chapter 9 "Recommendations".



Figure 87 Visual cues

### Returning

First, the patient detaches the patch and disposes of it. Then, the ECG device is returned using the packing it was initially received in, using the added return label. The patient will always return the device by mail, independent of whether they received it that way or directly from their GP. This alleviates any logistical pressure on the GP in the returning phase. The package is sent to a diagnostic center where it is cleaned, charged and prepared for the next patient.

## 7.3. DESIGN

All aspects of the final design are intentional. It balances cost, aesthetics and practicalities. This subchapter elaborates on these intentional design decisions.

### Form

The final form of the device combines both **practical** and **aesthetic** choices. The product had to become a medical device that accommodates sporters. For this reason, a shape language befitting both was pursued. The shape language of sportive wearables like fitness trackers, smartwatches and heart rate monitors was studied. The shape language of sportive wearables can be described as streamlined, ergonomic, and dynamic. It emphasizes smooth, pill-like or aerodynamic forms that suggest speed, comfort, and performance.

This project counts over 25 shape iterations. After prototyping 3D printed shapes for user participated ergonomics research and self-testing, the final oblong (pill-) shape emerged. It portrays both a medical and sportive shape language. For personal preference, the design leans more towards the sportive side. According to the final user test, this was successfully achieved.

For practical reasons, the shape is smooth with minimal crevasse. This makes cleaning the device easy. Development of the Diplora brand.

The shape is intentionally rounded and smooth to have minimal chance of clothing to snatch and tear. The bottom is tapered inwards to create a smaller adhesive contact area. Minimized contact area with the skin allows for good unobstructed skin deformation, which is comfortable.

### Alignment

To indicate proper alignment, alignment features (affordance) has been utilized in the design. Figure 88 shows these features and their intended alignment. The oval shaped indent on the bottom of the device and the oval shape of the adhesive area indicate these areas should match. This, together with the position of the USB-C port and the regulatory markings on the back intuitively indicate proper device orientation and positioning. The Diplora logo and the indentation opposite of it, indicate the top of the device. The indentation accentuates the LED indicator.

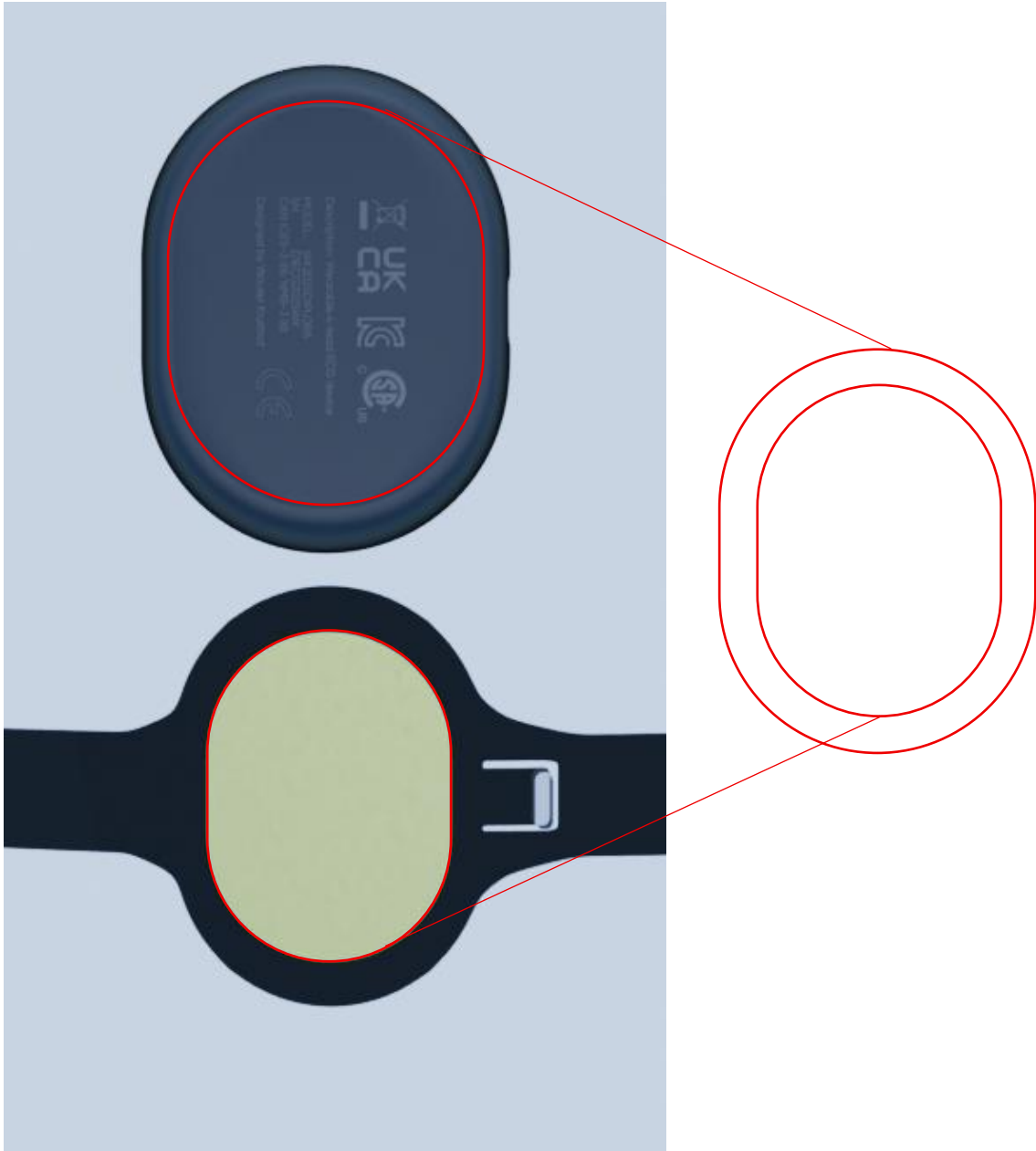


Figure 88 Unambiguous alignment through alignment features

## Detailing

### The Diplora logo

The matt finish of the product is created by the injection molding process. In this same manner, the embossed glossy Diplora logo can be created directly by the injection mold. This saves production steps much like the regulatory markings.



Figure 89 Topside device

### Regulatory markings

Regulatory markings and product information are required on the device. They are generally placed on the back of the device and can either be physically embossed into the shell or pad printed onto it. Physically embossing has the benefit of requiring less production steps, whilst pad printed text looks more aesthetic and can be easier to read when contrasting colors are used. As the device is attached to the patch with an adhesive area, physically embossing is recommended as pad printed markings might wear over time.



Figure 90 Bottom side device (any regulatory markings are for illustrative purposes only)

## 7.4. PRODUCT ARCHITECTURE

### Device

- Top shell
- Piezo Buzzer
- Light Tube
- Spring contacts
- Waterproof USB-C
- Main PCB
- Bio-based PU foam cushioning
- LiPo battery
- Bio-based PU foam cushioning
- Bottom shell

### Patch

- Acrylic adhesive pad area + peel
- PU/Fabric
- Bending USB-C connection
- Conductive silver chloride wiring (AgCl)
- Skin adhesive layer (skin safe acrylic adhesive)
- Conductive hydrogel patches

### Exploded view

Figure 91 shows the exploded view of the device.

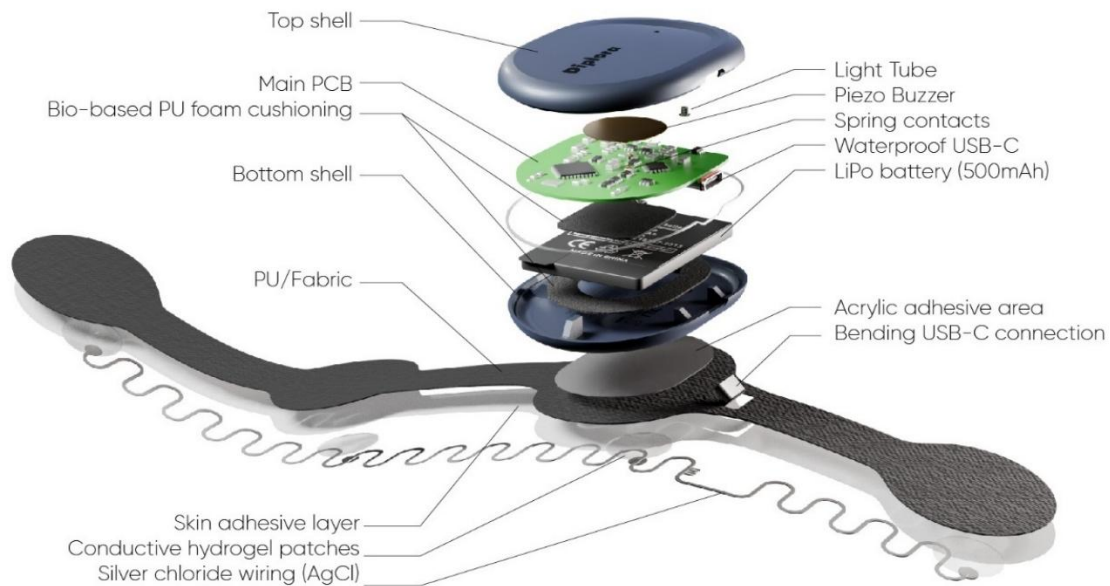


Figure 91 Exploded view

## 7.5. ASSEMBLY STEPS

### Top shell subassembly

1. The light tube is inserted into upper shell and ultrasonically welded in place
2. Piezo adhered to upper PC shell (Figure 92)



*Figure 92 Top shell subassembly*

### Bottom shell subassembly

1. Insert the bottom bio-based PU foam cushioning
2. Battery placed in bottom shell (Figure 93)
3. Add the top bio-based PU foam cushioning
4. PCB is pressure fitted in the bottom shell ribs
  - a. USB-C connector is installed on the PCB beforehand and aligns with the cutout in the enclosure.
5. Connect the battery to the PCB (Figure 94)



Figure 93 Inserting battery

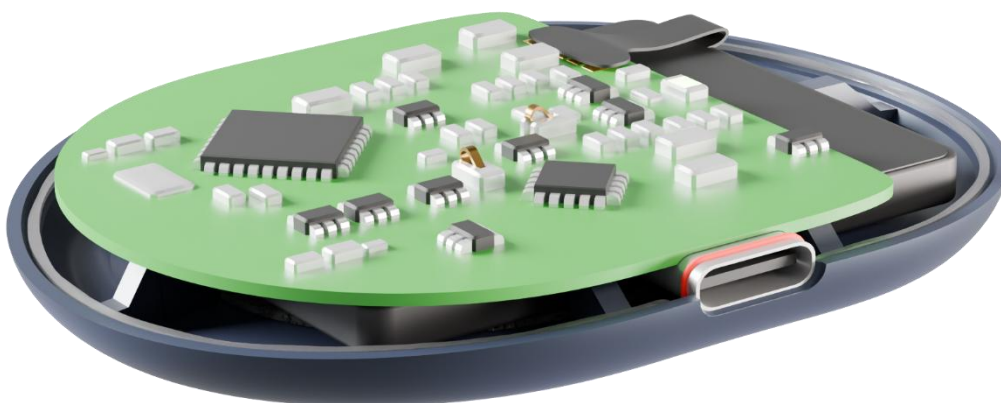


Figure 94 Inserting PCB and connecting Battery

### Final assembly

1. Add the reversible glue strip on the inside of the bottom shell
2. Mate the two shells together (Figure 95)
  - a. The piezo buzzer in the top shell makes contact with the two spring connectors on the PCB (Figure 96).
  - b. The entire stack of components is mechanically clamped in place by the bio-based PU foam.



Figure 95 Final assembly

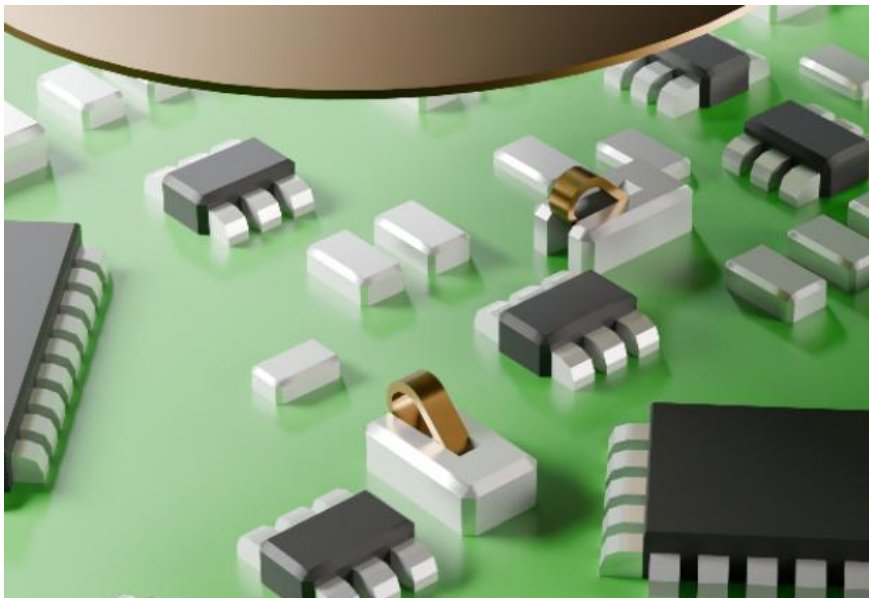


Figure 96 Spring connectors, connecting the piezo buzzer

## **7.6. DESIGN FOR MANUFACTURING**

This subchapter elaborates on material- and production choices.

### **Enclosure**

#### **Minimal production cost**

Production cost- and steps have been kept to a minimum. For instance by designing the mold to emboss glossy regulatory text on the back, rather than adding a pad printing step during production. Overhangs in the enclosure have been avoided to circumvent the need for sliders in the injection mold. Injection molds with sliders are more expansive than ones without sliders. Or by incorporating a single versatile USB-C instead of adding additional conductive areas to the outside of the casing to make electrical contact with the patch, which would complicate production.

#### **PC (polycarbonate)**

Polycarbonate is durable, impact resistant and biocompatible. It has a high glass transition temperature ( $T_g$ ) of about  $147^\circ\text{C}$ . This facilitates the debonding of the enclosure adhesives (generally at  $80^\circ\text{C}$ ) without damaging the shells. It is also cleanable by alcohol. The design incorporates a PC light tube since transparent PC has great optical clarity. This light tube is inserted and then ultrasonically welded into the enclosure which creates a watertight molecular bond. Further feasibility of PC as a material for the shells should be estimated by production specialists.

#### **Injection molding**

For initial prototyping, cheap 3D printed molds can be used to test the design and create the first prototypes for clinical testing. Draft angles were added to the enclosure shells to facilitate mold ejection and overhangs have been avoided completely.

## Patch

Interviews with potential production partners for Diplora indicated that a roll-to-roll production process and finalization by a medical converter would be required to create the custom ECG patches (APPENDIX: CONTACT STICKER MANUFACTURER).

### Skin adhesive

Ideally, the adhesive and materials used in the patch are hypoallergenic (relatively unlikely to cause an allergic reaction). Some hypoallergenic adhesive options are acrylic-based, silicone-based, or hydrocolloid & hydrogel Adhesives. The technology research concluded that these options differ in adhesive strength, breathability and moisture resistance. For long term wear, silicone adhesives are used generally. A final choice for the patch its composition of adhesives and materials requires expert opinion.

### Enclosure adhesive pad

The patch uses a *removable* or *clean-peel* acrylic adhesive pad to attach the device. Such an adhesive does not leave any residue upon removal. This means that the acrylic adhesive is tuned to have a controlled adhesion strength. This makes the bond enough to stick during use, but low enough to peel when intended by the patient (Márquez et al., 2022). Acrylic adhesives are generally hydrophobic and will thus not dissolve in water.

This avoids the need for an additional plastic bracket to keep the ECG device in place. This choice was made to avoid material mixing as much as possible and to streamline the process at the medical converter (the production facility that places connectors and adheres layers on medical patches). According to an interview with a roll-to-roll manufacturer, this will save on production cost (APPENDIX: CONTACT STICKER MANUFACTURER).

## Designing for End of Life

Paints, irreversible adhesives and construction epoxy resins are deliberately avoided to maximize the material purity after recycling. An example of this is the use of light tube in the top shelf that is also made of PC and ultrasonically welded so no adhesives are necessary. No additional (internal) fasteners are required to hold the PCB and battery in place as they are mechanically clamped by the two shells. Non-recyclable foam parts are made of bio-based PU to help reduce the carbon footprint of the device.

Disassembly requires only a heat gun and a flat pointy surface to pry with. After opening, all parts should come lose by only mild force. Parts can now be separated by type and find their waste streams accordingly.

## 7.7. SUSTAINABILITY AND R-STRATEGIES

The topic of sustainability is vital for this project. Diplora acknowledges the problem of pollution caused by the healthcare industry and wants to do better. This chapter elaborates on the sustainability related design decision that were taken.

### Strategy

There are many methods and strategies for designing a sustainable product lifecycle. The value hill theory depicted in Figure 97 provides insight into methods for retaining the value of a product for as long as possible. In a linear economy, a product is made, used and then thrown away (where it loses all its value). The value hill theory proposes multiple R-strategies to retain the value of the product for as long as possible before it is finally discarded. This keeps the product in its 'use' faze.

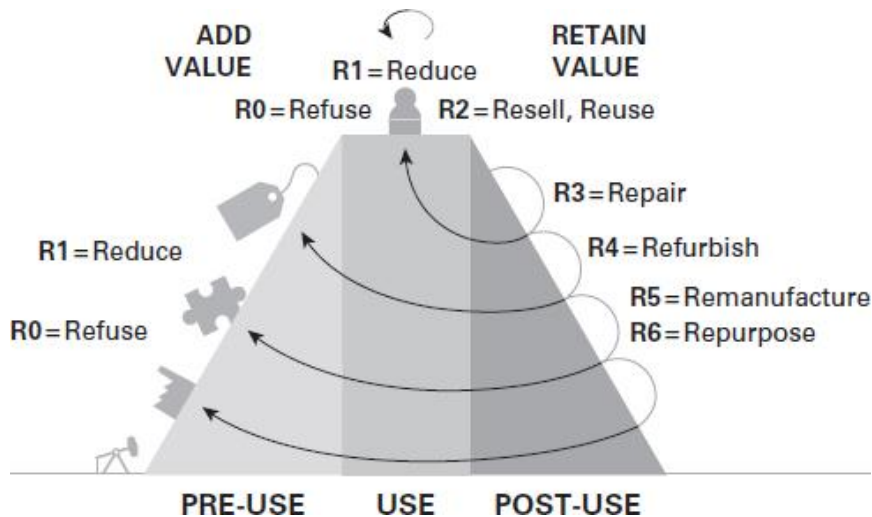


Figure 97 Value hill theory for a circular economy

On way in which Diplora keeps the value of their product high is by re-using the device between multiple patients. Making a strong and robust device prevents the need for repair or refurbishment.

For the single-use patch, different strategic choices are required for minimal negative impact. Re-using a patch is not an option due to hygiene. Repairing, refurbishing or remanufacturing are not viable due to the complex layering and adhesives used in patches. To adhere to the scope of this project, the focus remained on R1 (Reduce) for the design of the patch. Reducing material combinations and avoiding plastic brackets on each patch saves waste compared to existing solutions.

## 7.8. FINAL USER VALIDATION

The aim of a final user test was to validate ergonomically related requirements of the final concept (N=7 (M=4, F=3)).

The prototypes (Figure 98 and Figure 99) used in this study resembled the estimated weight of the final concept (~25 grams). Patients were instructed to live their life as normal. Including daytime activities, sleeping, taking showers and partaking in sportive activities. Patients were also asked to provide their height and chest circumference to validate the need for multiple patch sizes, as suggested by the Dined research. Alongside physical comfort, mental comfort was evaluated as well. Attributes such as 'trustworthiness' were inquired on to provide insight on whether the design language of the ECG device is befitting the image Diplora wants to portray as a brand.

Chest circumference ranging from 85 to 123cm

Length ranging from 170 to 192



Figure 98 Prototype used for final user validation



Figure 99 Multiple prototypes

**Quotes:**

- When I went to the bathroom at night, I was spooked when I saw the device in my reflection. I completely forgot I was wearing it at all!
- I only felt it when wearing a cross body bag, otherwise I would forget it is there.
- I would not wear a pretty summers dress when wearing the device.
- Applying the tape might be easier when it is thicker.
- It is very comfortable when wearing a bra. I tried multiple and the device was never in the way!

**Observations**

- The weight of the device had no perceivable negative influence on the comfort during sport.
- From all the participants that went to the gym, none experienced the ECG to interfere with gym equipment.
- Participants did not adjust their choice of sportwear.
- Participants did not chose to avoid certain social activities when wearing the prototype.

**Average scores (out of 10):**

Ease of application	8.3
Comfort in general	9.3
Comfort during sportive activities	9.8
Comfort during sleep	9.8
Mental comfort	9.5

**Design:**

Medical	6.4
Sportive	8.5
Trustworthy	8.3
Discreet and low-profile	8.1

**User validation conclusions:**

The patch will need multiple sizes as the medium version used in this research was too large for one third of the participants.

Both mental and physical comfort are perceived high enough for participants to live their life like normal without any obstruction or hindrance. However, some woman might avoid wearing dresses during warm weather since the design is located above the breasts.

As intended, the device its design language is perceived as more sportive than medical whilst scoring high on trustworthiness. For sportive activities, the device is perceived as discreet.

## 8. DISCUSSION & CONCLUSION

This thesis resulted in the proof of concept of a wearable ECG device for sportive cardiac patients. Design decisions were based on knowledge gathered from prototyping for ergonomic user testing, technology research and interviews with stakeholders other than the patient alone (GPs, production partners, and roll-to-roll patch manufacturers).

The project had a strong focus on the embodiment of the product. Production steps were evaluated and adjusted to accommodate for the desires of the company, the planet and the product user. This aligns with the learning goals of designing a product that approaches production readiness and is of high value to the client Diplora. The client has confirmed to proceed with the design outcome of this project. Due to the modular design, Diplora will be able to launch their product as a wired version before making the investment in custom patches.

## **8.1. Limitations**

### **Patch**

Creating high quality patch prototypes requires specialist expertise, materials and equipment. Prototyping with manufacturers falls outside the boundaries of this thesis. For this reason, assumptions had to be made on the performance of the patch. It was assumed that a medically produced patches will wear similarly, or better than the prototypes made of sport tape.

The design of the patch and its positioning of electrodes is based on external research only. Validation of these assumptions where no conducted in this project. Diplora will verify this and their AI in the future.

The attachment process should still be user tested with actual USB-C connectors. Steps where minimized and alignment features were added to the patch and device, of which it was assumed would be sufficient for unambiguous application. It is assumed that the male USB-C plug (patch side) will not be torn away during sport or cause any discomfort to the skin.

### **Stakeholder involvement**

This project focused mainly on the patient side of the product. That means that the desires of GPs were less prioritized. Furthermore, assumptions where made on the desires of production partners, diagnostic centers and other stakeholders in the product service system envisioned by Diplora. Assumptions where made on effective product geometry for product cleaning with alcohol wipes. Or that the device can be stored in a vertical charging rack. Actual cleaning steps, charging steps and implementation of a UDI (unique device identifier) system are examples of yet to be researched factors for successfully implementing the device into the system.

### **Interaction with the device**

It was assumed that lights and sounds are sufficient as indicators to the wearer. Due to personal experience it was assumed that vibrations are not desirable and would hardly be felt. Or, if felt, experienced as obtrusive.

### **Branding**

Diplora did not have a developed brand identity during this project. Assumptions where made on what would fit the brand.

# 9. RECOMMENDATIONS

Based on the outcomes of this project, several recommendations are proposed to guide further development of the Diplora wearable ECG device.

## Product-Level Recommendations

### Hardware refinement:

- Patches are wasteful single use consumables. So, frequently update on material innovation and search for materials with a lower environmental impact than the standard silicones, plastics and adhesives used for patch manufacturing.

### Comfort & usability:

- Most houses or bathrooms have only little table space around a place with a mirror. Add a small piece of adhesive to the visual instruction manual so people can hang it from their wall or mirror. This could be more comfortable and avoid mistakes if people can see the manual directly besides their own reflection.
- Improve unambiguous alignment with notches in the pill shaped alignment grooves, indicating the position of the USB-C. This might help to orient more easily.
- Consider pre-bending the patch to guide and nudge the patient in proper placement of the patch. A PET liner can help with this. (Also desired according to the final user research.)

### Performance validation:

- Structural FEM analysis should be conducted to determine adequate shell thickness and proper placement of inner rib structures.
- For the initial clinical trial run, use 3D printed molds for production. ABS can be used for the shells. Any other transparent plastic can be used for the light tube insert. Sustainability is less important for this trail run where data gathering is more important.
- Start prototyping patches together with factories to validate and engineer an adhesive acrylate tape that sticks to the PC enclosure properly.

### Production:

- Optimize the patch design patterning before roll-to-roll production. This minimizes material waste after cutting out the patches.
- Diplora is encouraged to assess the trade-off between product durability and recyclability. A more durable but less recyclable product might last longer and have an overall lower carbon footprint than a less durable, but recyclable product.

### Compliance (with MDR/IEC 60601 standards):

- The product created in this project complies with requirements from multiple standards. Make sure to re-iterate these requirements once the product is adjusted for a wired solution.



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# 11. APPENDICES

## 11.1. APPENDIX: SWOT ANALYSIS

A SWOT analysis (Figure 100) is a strategic planning tool that evaluates strengths, weaknesses, opportunities and threats for a company in a visual oversight. The attributes are based on the state of Diplora at the beginning of this project only. Alongside understanding the external market, this analysis identifies the most promising focus areas for this design project. It helps to recognize growth opportunities, prepares for potential risks, identifies areas for improvement and indicates strengths to leverage.



Figure 100 SWOT analysis Diplora

## 11.2. APPENDIX: ECG TYPES OVERVIEW

The following table (Table 2) was partly interpreted on the research of Carrington et al. (2022).

Table 2 ECG type overview table

Test	Description	Benefits	Limitations
12-lead ECG	Used by cardiologists in hospitals.	Accurately diagnoses arrhythmia.	Will not obtain transient arrhythmia as it only takes a snapshot, infeasible for outside of hospital settings.
12-lead exercise ECG	ECG recording during exercise and recovery.	Supervised. Tries to reproduce arrhythmia and anomalies during mild activity.	Requires trained staff. Not all patients can exercise on a treadmill or alike.
Holters and event monitor (generally 7 leads)	Big carryable devices for intermittent or continuous ECG recording. Helps diagnose the cause of symptoms like palpitations that. Wear duration: 24H to 74 to 7 days of monitoring.	Picks up (rare) arrhythmia either symptomatic or asymptomatic. Wireless transmission of rhythm strips is possible.	Often non-diagnostic due to limited period for testing Failed diagnosis of the symptoms is common in patients who live alone or are unfamiliar with technology.
Extended rhythm recording using patches and wearables (1 to 3 leads)	Prescribed, wearable ECG device recording for up to 30 days.	(Self-applied) device for continuous and prolonged monitoring. Often has a button for logging event.	Often single lead. Limited capacity of discriminating atrial or ventricular ectopic beats (distinguishing premature beats in either the upper or bottom chambers of the heart).
Smartphones and smartwatches (generally no ECG signal, only BPM)	Small devices that connect to a user's phone. Can detect atrial fibrillation, bradycardia, tachycardia, and normal sinus rhythm.	Practical and versatile. Consumer buyable.	Hard to interpret recordings due to lack in precision. High number of false positives.
Implantable Cardiac Monitor (ICM)	USB sized implant with a 5 year lasting battery. Simple procedure: injected to the subcutaneous tissue on the chest (beneath the skin).	A good option if other monitors fail to reveal arrhythmia with infrequent symptoms.	Very costly to the patient (2800 euros). Requires invasive procedure.

## 11.3. APPENDIX: WIRES VERSUS PATCHES VERSUS TEXTILE

From the beginning, Diplora wanted to omit wires. Diplora deemed it cluttered, messy and limiting. Other options for electrodes are patch integrated dry electrodes and textile embedded electrodes using silver shrouded wire (Arquilla et al., 2020). To find the best option, this subchapter compares comfort and reliability for these three electrode options.

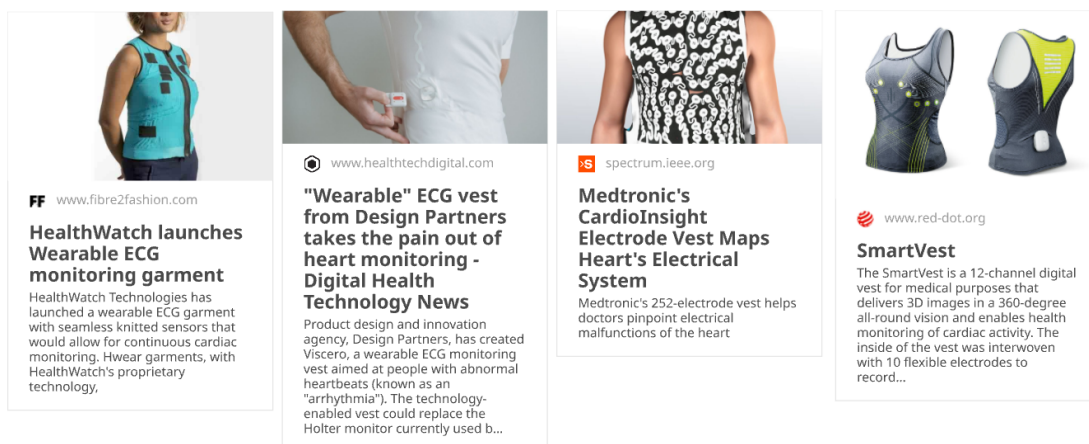
### Textile integrated electrodes

Another option is textile embedded electrodes. With discreetness being its main benefit. A study conducted by Arquilla et al. (2020) indicated that there is no significant difference in comfort experienced between ECG garments and electrode patches.

A clear downside to garments with embedded electrodes is their need to be washed. Everyone needs to wash their garments once in a while to avoid unpleasant odors. No measurements can be conducted in the time the garment is cleaned in the washing machine. Providing the patient with two garments could be a solution. While one garment is worn, the other is cleaned and dried. This however, is a continuing hassle. Hygiene (pathogen contamination) after repeated exchange between patients also becomes an issue (López et al., 2025).

Optimal comfort at 1-4 kPa pressure

Benefit: don't cause skin irritation like adhesives in patches can cause (Soroudi et al., 2019).



### Wires versus a patch

Bittium, a corporation that produces an ECG similar to what Diplora wants to create, commented on one of their videos: "From the patient's point of view, the measurement period is considerably more pleasant while wearing a patch electrode than the corresponding one performed with cable electrodes." (Bittium, 2021). Bittium provides both patch variants and wired variants as seen in Figure 101 till Figure 104.



Figure 101 Bittium OmegaSnap 3-CH



Figure 102 Bittium OmegaSnap 3-CH Patch



Figure 103 Bittium OmegaSnap 1-CH



Figure 104 Bittium Faros with wires

Wei et al. (2024) finds there are three main unmet needs in remote and outside of the hospital vital signs monitoring devices: **longer-term wear, skin comfort and signal quality.** For their studies, Wei et al. (2024) compared the signal quality of dry electrodes to their gel variant. Measurements of heart rate were compared to the Shimmer 3 (Figure 105) and Cosmed K5 (Figure 106) as baseline models. There was a good agreement for the heart rate with a Lin's concordance coefficient of 0.98 which suggest dry electrodes are viable for use in heart monitor patches. Also, participants reported a generally positive experience with regards to comfort, with only mild irritations due to adhesives in the patch.

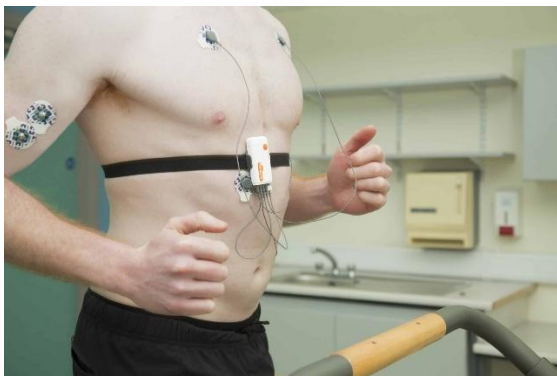


Figure 105 Shimmer 3 ECG



Figure 106 Cosmed K5

## **11.4. APPENDIX: INTERVIEW GP AND ASSISTANT**

**April 3rd 2025**

The device this GP uses is the Bittium Faros and uses two wires and three electrodes. The main casing is placed on the center of the chest, roughly 10cm above the nipples.

- "Some elderly hardly use their phone, an app would not work for them to do note taking of their activity or noting of events. For them a physical booklet works best. But still, people often forget to log their activity."
- "Elderly often want to get advice from a person, not a screen as this is more what they know and understand."
- "There also was one old man of 90 and he was super digital! He had everything apple and was more up to date than I am myself!"

Insight from a report: People log very little of their activities, might make it hard to really know what they've been doing. Many people also completely forget. How bad is that?

## **11.5. APPENDIX: VISITING PRODUCTION PARTNERS**

March/18/2025 - Two potential production partners where visited: Dekimo and Aim.

Dekimo is an electronics manufacturer situated in a -somewhat- dated factory, previously utilized for the production of Pioneer radios. They can produce the PCBs inhouse and have a network of contacts who can produce shell parts of the ECG enclosure. They can assemble, check, package and distribute the product. Temporarily, the product can also be stored at their facility. Dekimo showcased a small puck-like product, that had similar requirements to what Diplora designing. It is water tightened with an O-ring and closed using a single screw with a sticker over it. Dekimo provided several practical tips for production and how to prepare for it. Mainly, before advancing into production, Diplora is required to provide a design that is more defined.

Aim is very similar to Dekimo. Other than Dekimo, they have a strong focus on big medical devices, ranging from chiropractor beds to temperature controlled ventilation devices used in operation rooms. Compliance with a small product was therefore doubted. They can assist in lifecycle management, after life service (repairs), EMC testing, designing for manufacturing (DFM) and can in general accompany and guide in the 'New product introduction' process for startups.

Both production partners already had the required certification or were willing to get certified.

## **11.6. APPENDIX: CONTACT STICKER MANUFACTURER**

May 8 2025 - Mekoprint, a screen printing specialist based in Denmark, was initially considered as a one-stop solution for producing the complete custom ECG patch. However, it became clear that their final product is only a first step in the production chain. Mekoprint proposed collaborating with a medical converter, capable of applying adhesives, conductive gels, and final packaging, as well as potentially integrating a connector.

A connector system could also be added by the medical converter. This, however, is a difficult topic and can be done in many methods. Mekoprint could not advise on this topic but did share some projects of other clients who struggled with a similar problem.

Another concern is certification. Mekoprint lacks the ISO 13485 certification, which is a key requirement for Diplora's manufacturing partners. Mekoprint pressed that this has not posed issues for other clients.

## **11.7. APPENDIX: INTERVIEW QUOTES OF PAST HOLTER WEARERS.**

N=5

- Everybody would come up to me and ask me if I was okay, that was really annoying an belittling.
- This big device is pretty heavy for a small girl. It is a clunky device with many dangling wires.
- Holters have many buttons that I'm scared of accidentally pressing.
- Because of the holter I cannot shower without assistance.
- It is really annoying when going to the toilet or when I have to change clothing because of all the wires that have to go in, over, out, and I don't even know where.
- One of the wires came of and I needed assistance from a nurse for putting it on again.
- There are many buttons and lights I don't understand, but I don't really care, as long as they can measure me properly. I hope I don't accidentally press something though...
- It is like a brick around my neck.
- I just throw it on the table when I'm sitting and eating.
- The symptoms where missed due to a long wait time. I got the holter too late.

## 11.8. APPENDIX: CASE STUDY AT-SENSE

To gather in-depth knowledge on existing wearable ECG devices, a specifically selected ECG patch for consumers was worn for a week. The patch is the AT-Sens patch. It was selected for multiple reasons (as listed below). The main reason being its design being similar to what Diplora is aiming for. Both certain physical aspects (such as size and materials) and the app connectivity. Therefore, this device provides practical experience to validate whether these characteristics are desired, what current ECG devices can do and what their shortcomings are.

- Wearable for a week
- Comes with an app that can provide a live ECG signal
- Logging events with descriptions

It is tough to find wearable ECGs that can be bought by a consumer. Diplora found one and gave it to me for testing purposes. The purpose was to find out what current ECG devices can do and what their shortcomings are.

### About the AT-Sense

The idea behind the AT-Sense is very similar to that of Diplora: you receive the device by mail, you stick it on your chest, you go by your business as usual and after a couple days you take it off and send it back to an institution that reads out the collected data. This institution generates a report and this report is shared with your caregiver (GP, Cardiologists, etc.).

Points of interest that stood out on the AT-Sense before it was bought and their corresponding research questions:

- Its extensively long proclaimed time continuous monitoring (7 to 14 days).
  - o How is it able to measure for that long? What kind of internal storage does it have? Or does it continuously offload to a phone?
- Its tiny size
  - o How can a device claiming to measure for this long of a period be so small? What chip technology is on the inside and what makes it technically function that allows it to operate over such a long time period?
- Its design
  - o How is it manufactured and how is it "Shower proof" (IP57)?
  - o How does the comfort compare to my other self-test?
  - o What materials is it made of and why?
  - o How did they incorporate stickers and patches in their design?
  - o What if you misplace the device first try?
  - o What is the general interaction like: button (event monitoring), connectivity with the app, data streaming.
  - o How is data presented, what can I as a user of the app read of the data presented?
  - o How does it handle data? Does it store it locally? How much, how long? Does it connect to a PC?
  - o How did they design the PSS?

- Why can I buy one when it seems like I should only be able to attain one through a GP or other healthcare professional?
- Is there data transparency? How do they handle this personal data?
- Its intractability, there's a button for supposedly events logging.
  - What can this button do, what is it used for?

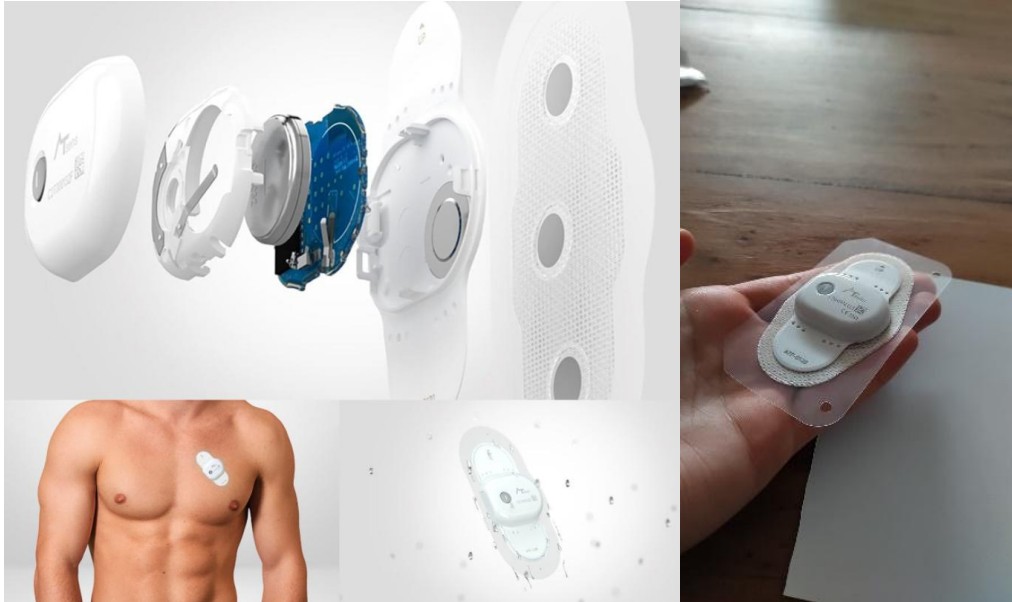
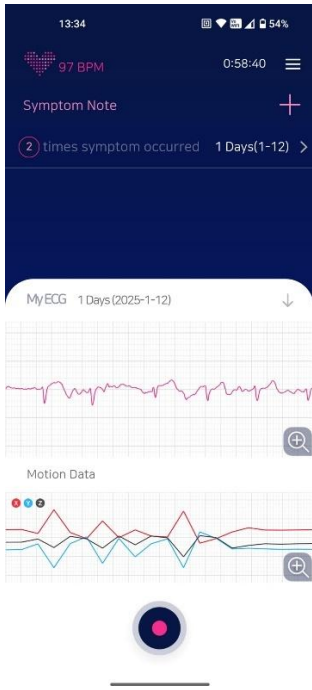


Figure 107 AT-Sense ECG

### The AT-Sense app

The app gives you the option to live stream the data to your phone for 60 minutes a day. Supposedly it only allows for 60 minutes a day because streaming the data to a phone over Bluetooth costs a lot of energy.



## Product tear-down research.

Tearing down existing products will teach me how to design electronic devices that survive immersion in water and other challenging scenarios.



## Findings

Comfort is generally high, no major complaints, pain or other burdens. There was mild skin redness after removal, which faded after a couple hours.

Reliability: there was a lot of noise visible in the live data feed. Especially muscle activation and movement had a big impact.

The button was easy to find, even through clothing.

The build quality is high. It is a very dense and robust device.

## **11.9. APPENDIX: DATA STREAMING CONSIDERATIONS**

### **Continuous wireless live data streaming**

High battery usage

Continuous and live data streaming provides the shortest possible reaction time in case of a threatening event. In theory this sounds advantageous. However, acting on data gathered live comes with its own set of risks and costs. It creates a more complex product system integration that requires people to monitor events that are labeled as dangerous by the device. At the time of writing this report it is unknown whether the data that is generated by the Diplora ECG is reliable enough to act up on immediately. The risk here is inducing unnecessary stress to the patient and unnecessary deployment of medical personnel.

From a practical perspective, if serious damage is done to the device (for instance an electrical failure due to moisture), no data will be lost and the patient is not required to wear a device again.

This method comes with more serious technical costs. The battery has to be significantly larger to handle the power intensive data streaming. The device must also be in at least semi-continuous range of phone which limits freedom during sport. For instance when a patient goes to the pool, they cannot take their phone inside since most pools do not allow phones. If it were allowed, leaving the phone on the side of the pool causes the phone to go in and out of reach every time a lap is made. So, the device should be able to gather data for a time of at least 2 hours where the patient is not obligated to be near their phone during a workout. Saving space, weight and money on on-board storage is therefore not possible.

### **Semi-continuous wireless data streaming**

Moderately low battery usage

In this method, data will only be streamed live during the application process to verify the patch has been placed correctly. When the signal is clear and the position is proper, livestreaming data can be disabled which saves on battery. The patch now will continue monitoring full time and the gathered data will be read once the wearing period is over. The advantage is dramatically increased battery life.

### **Continuous data gathering, no wireless streaming**

Low battery usage

If there is no option for live streaming data, there is no way of gathering insight on correct positioning and signal clarity. Only after the wearing period of roughly a week, will the caregiver know whether the process has been a success or not. Therefore, having no option of live read-outs is not desirable.

It is possible to stream data over a physical connection during the application process. This will be beneficial during placement and saves battery compared to a wireless connection. This is more cumbersome and should ideally be avoided. It would introduce more complexity and failing points for water resistance in the design of the enclosure. Ideally everything is wireless, also charging and data reading at the diagnostic center.

## 11.10. APPENDIX: APPROVED PROJECT BRIEF



### Personal Project Brief – IDE Master Graduation Project

Name student Wouter Kruithof

Student number 4,668,480

#### PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT

Complete all fields, keep information clear, specific and concise

**Project title** Designing a 24/7 wearable ECG device for sporters.

*Please state the title of your graduation project (above). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.*

#### Introduction

*Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)*

When people experience heart difficulties, they are often directed to cardiologists through their GP (general practitioner). Waiting lists can be multiple weeks. Cardiologists use a big 12 lead ECG (electrocardiogram) to monitor heart activity for only 30 minutes. More often than not, nothing of significance can be found, so the patient leaves none the wiser whilst cardiologists are unnecessarily overbooked with patients. Many heart related irregularities or arrhythmia cannot be found during a cardiologist appointment because they only occur briefly and unpredictably. Current at-home monitors/holters are bulky, not attachable by the patient themselves and lack the accuracy for a proper medical reading (image 1). Eventhough Diplora's old prototype (image 2) was a step forward, it still falls short.

Sudden cardiac death (SCD) is the leading cause of mortality in athletes during sport and can be preemptively monitored using proper ECG measurements. There are no ECG devices that are catered to people who live an active lifestyle (sporters and athletes) who want to conduct measurements during their sportive activity (Sharma et al., 2017). Those people encounter more extreme circumstances in terms of movement, temperature, sweat and water. A device for these circumstances will also benefit revalidating heart patients who have to be active after their surgery (De Nederlandse Hartstichting, n.d.).

Diplora (the company involved) is a small startup that aims to create a wearable ECG device that is as good as a 12 lead ECG used in hospitals, using only 3 leads and advanced data processing. They are developing the electronics in-house.

Sharma, S., . . . Corrado, D. (2017). International Recommendations for Electrocardiographic Interpretation in Athletes. *Journal of the American College of Cardiology*, 69(8), 1057–1075. <https://doi.org/10.1016/j.jacc.2017.01.015>

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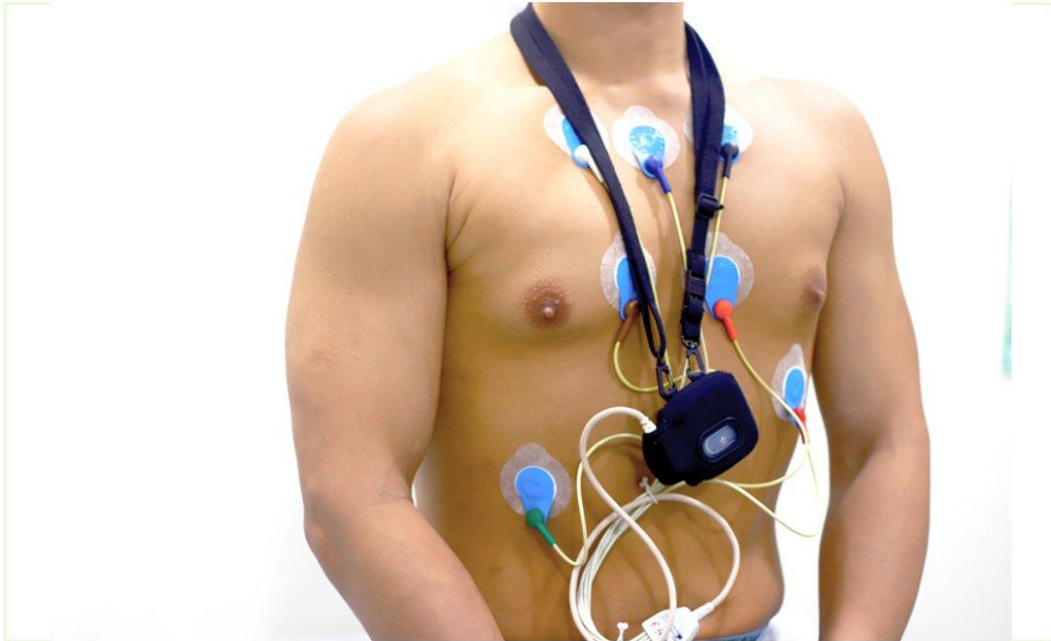


image / figure 1 Old bulky holters



image / figure 2 Diplora's 3 Lead ECG prototype

## Personal Project Brief – IDE Master Graduation Project

### Problem Definition

*What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice.  
(max 200 words)*

There are currently no devices available that can do 24/7 high quality heart measurements similar to the clinical 12 lead ECG monitors preferred by cardiologists. Available 3 lead ECG monitors cannot handle the technically challenging daily activities sportive people encounter.

Diplora has developed a technique to emulate 12 lead ECG data from data collected by 3 leads, which could make 24/7 high quality heart measurements feasible, also for sportive people.

However, further clinical testing is needed to verify whether the emulated 12 lead data will be acceptable for cardiologists for (initial) diagnoses. These verification studies require a working prototype. (These clinical tests are out of scope for this graduation project.)

Next to safety and effectiveness, sustainability is an emerging important topic for medical devices. Most small 24/7 holters are thrown away after use. Diplora wants to create a product service system that is as sustainable as possible. This requires reusability. Which is a challenge in terms of hygiene and medical device regulations.

### Assignment

*This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence) As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:*

Design a wearable ECG device, suitable for multiple days of consecutive use by people with an active lifestyle to collect high quality heart related data.

*Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)*

I will start with research. First by creating a stakeholder and patient journey map which provides insights on who I am designing for (and with). Then, user research conducted with holter patients and experts (cardiologists and general practitioners) through interviews. I also want to know precisely what technically challenging daily scenario's people with an active lifestyle encounter. So interviews with sporters will be conducted to find their needs. Simultaneously I will research how products are currently being made reusable by doing desktop research and reverse engineering existing devices. What are the technical challenges? What are specific medical device regulations? This will lead to a list of design requirements.

I want to research through design. I will do many iterations of physical low fidelity prototyping. There will be multiple small design prints which involve users and experts. Finally, I want to present two things. One, a design proposal that includes shape, materials and sustainability findings. And secondly, a physical high fidelity working prototype, which can be used for clinical trials.

### **Motivation and personal ambitions**

*Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other).*

*Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five.  
(200 words max)*

I love physical prototyping, form development, technical challenges, CMF design and developing the user interaction. It's what I'm naturally drawn to. I want to show my of an intrinsic and wholistic design process. In collaboration with Diplora, we made this project exactly that. Graduating with this project will teach me a lot about the beginning stages of a startup, what role I play and what experience I bring to the table as an Industrial design engineer.

I believe I can show my competence in many design areas during this project and at the same time learn more about communicating design challenges with other experts, for instance, electrical engineers and data scientists. Everything is connected to each other and influences each other. I also wish to gain experience in the final steps of product design: production. I want to plan my project in such a way that I can contact a supplier and learn from that interaction as well. During this project I want to incorporate well-considered and practically evaluated decisions on recyclability and sustainability.

Personal learning ambitions:

- Entrepreneurship and networking
- Working closely in and with a very multidisciplinary team
- Getting better at SLA printing (resin) and hone in on my model/prototype making skills