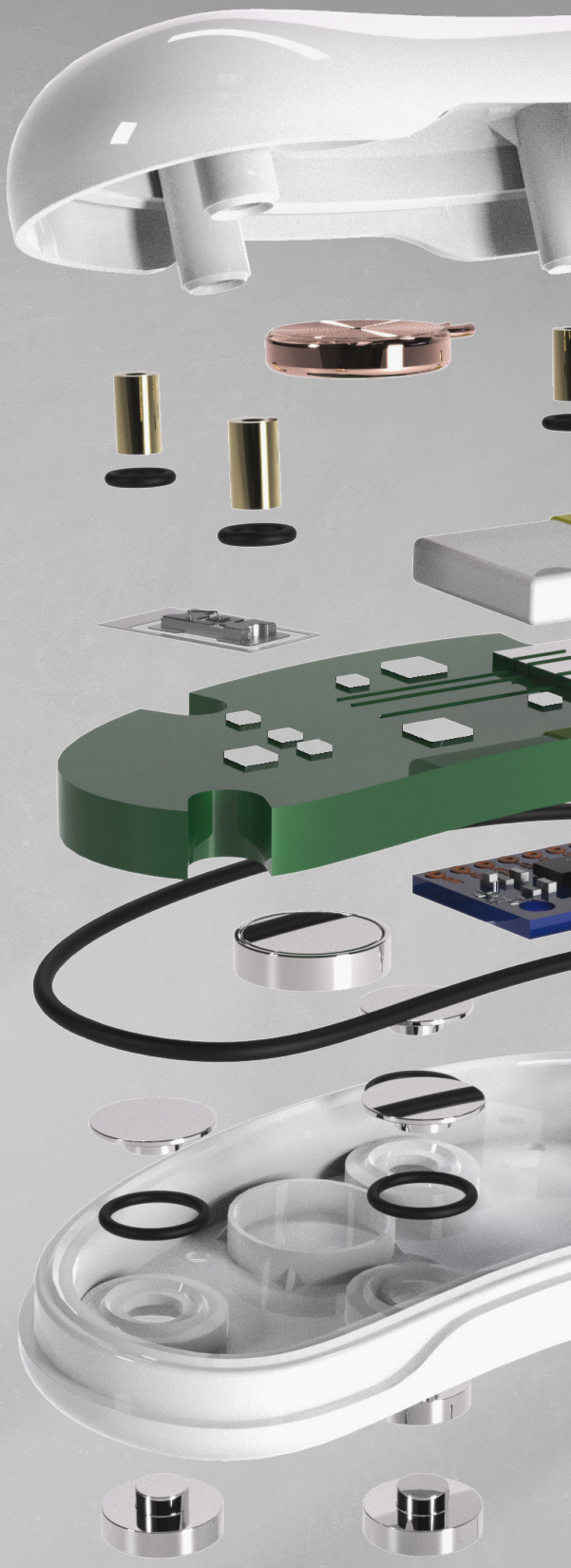
REDESIGNING DIPLORA'S ECG-WEARABLE

A User-Centred, Reusable Design for Extended Cardiac Diagnosing



MEGAN SEKER

MASTER INDUSTRIAL DESIGN ENGINEERING

MARCH 2025

ACKNOWLEDGEMENTS

MSC THESIS
INDUSTRIAL DESIGN ENGINEERING
DELFT UNIVERSITY OF TECHNOLOGY

REDESIGNING DIPLORA'S ECG WEARABLE

Megan Seker
4672461

Defended on 14 march 2025

TU Delft supervisory team
Chair | Dr. Ir. R.H.M. (Richard) Goossens
Department of Applied Ergonomics & Design
Mentor | C.P.J.M. (Caroline) Kroon
Department of Design for Sustainability

Company Team | Diplora B.V.
Managing director | A.M. (Auke) de Leeuw
Technical director | T. (Taco) Kind

Welcome to my graduation thesis! It was my pleasure, but of course I could not have done it without some remarkable people.

First, I would like to thank my supervisory team Richard and Caroline!

Richard, thank you for the always very nice coffee chats. The cappucino at the Erasmus was great, and I always loved our little chats. You always helped me think of the next step, planning-wise, but also who to best ask for help. You pointed me towards experts and helped me deepen my own knowledge of the medical field.

Next, I want to thank you Caroline for always helping me put everything into perspective. By asking critical and sharp questions, you helped me to keep on track, and to not let go of my personal goals and values. Your practical and hands-on knowledge always helped me further, and helped me to feel confident in my design considerations.

Of course, I also want to thank Taco en Auke and the entire Diplora Team. Thank you for the endless enthusiasm and interest in everything that I showed. I really appreciated the freedom and encouragement I received so much of during this whole project. I truly hope your aspirations will come true, and that this report will be of help along the way.

Next, I want to thank my mom en Ed for the never ending support. My own personal IDE@home, where endless brainstorms, solutional thinking and a tremendous arts-and-crafts section were at full disposal.

And thank you Jelle, for encouriging me to take on this project. You were always wonderful in getting my thoughts back on track, pushing me to just keep going and saw the potential in my ideas before I even saw it myself.

I also want to thank all my fellow graduates on the 2nd floor. What a wholesome little community it was up there. Thank you for all the brainstorms, coffee breaks and motivational get togethers.

And then of course, thank you reader! For having a look at my 6-months of thinking, iterating, designing, iterating, testing and iterating.

Enjoy the read!

Megan.

ABBREVIATIONS

ECG - Electrocardiogram
A test that records the electrical activity of the heart to detect abnormalities in the heart rhythm or structure. An ECG is the recording, so not the machine that makes it.

GP - General practitioner

HCP - Healthcare Provider
A professional or organisation delivering medical care, such as doctors, nurses, or clinics.

AF - Atrial Fibrillation

CVD's - Cardiovascular diseases

IMU - Inertial Measurement Unit
Measures motion, orientation, and acceleration by combining an accelerometer, gyroscope, and sometimes a magnetometer, enabling precise tracking of movement and position in three-dimensional space.

PC - Polycarbonate

MDR - Medical Device Regulation
European regulations governing the safety and performance of medical devices to ensure they meet strict quality standards.

ISO - International Organization for Standardization
An international standard-setting body, relevant for medical devices

FMEA - Failure Mode and Effects Analysis
A structured approach to identifying and prioritising potential failure modes in a product or process.

MRL - Medical Readiness Level

TRL - Technology Readiness Level

GLOSSARY

Co-creation - A collaborative process where stakeholders, including users, designers, and other experts can work together to create or improve a product, service, or system.

Holter - A portable device used to cont
inuously monitor a patient's heart activity, typically over a 24-72 hour period, to detect arrhythmias or other cardiac conditions.

Leads - Electrodes or configurations used in an ECG system to measure the electrical activity of the heart from specific angles or positions on the body.

Artifact rejection - Identifying and filtering out unwanted noise or interference, such as muscle movement, poor electrode contact, or external electrical disturbances from ECG signals

Cardiologist - A medical specialist who diagnoses and treats diseases and conditions of the heart and blood vessels.

Tele-monitoring - The use of technology to remotely monitor patients' health conditions, such as heart activity, and transmit data to healthcare providers for analysis.

E-Health - The use of digital tools and technologies, such as apps, wearable devices, and telemedicine platforms, to deliver healthcare services and manage health data.

Patch (ECG Patch) - A medical adhesive equipped with electrodes, designed to measure electrical signals from the heart for ECG recordings.

Iteration - The process of repeatedly testing and refining a design or product based on feedback and insights.

Sustainability - The practice of designing and producing products in a way that minimises environmental impact and promotes reuse or recycling.

EXECUTIVE SUMMARY

Cardiovascular diseases (CVDs) are the leading cause of death globally with 33% (Dattani et al., 2023). Unfortunately, cardiovascular research has been primarily performed on men over the centuries (Wittekoek, 2017). It was not until the 1960s that more research was conducted on the female heart (Hartstichting Nederland, 2024). This was urgently needed, as heart conditions are responsible for more fatalities in women than in men, and the specific symptoms express themselves differently across gender (Wittekoek, 2017). Something else that doesn't help is that cardiac analysis and -monitoring systems are predominantly designed with male physiology in mind (Market Analysis, 2024). This gap in care calls for a solution that is inclusive, user-friendly, and effective for all users, regardless of gender.

Whenever someone – male or female – suspects something is wrong with their heart, a general practitioner (GP) is consulted. Yet here, another problem arises. GPs often encounter patients with symptoms like palpitations, dizziness, or fatigue. To disclose whether the patient could have a suspected intermittent arrhythmia – such as atrial fibrillation, bradycardia, supraventricular tachycardia, ventricular tachycardia, or second- or third-degree atrioventricular block – long-term ECG tracking is often needed. However, as traditional ECG Holters are typically worn for only 24 to 72 hours, most of the conditions mentioned may not be detectable with such short-term ECG monitoring.

The company Diplora B.V. aims to address this need by developing an intelligent AI-driven ECG system where a sensor continuously collects 3-lead ECG input and reconstructs a 12-lead ECG for deeper clinical insights. By streamlining arrhythmia detection and providing actionable, real-time insights, the system empowers GPs and intermediate care providers to make confident, informed decisions regarding treatment or specialist referral. This innovation improves diagnostic accuracy, enhances early intervention, and contributes to better patient outcomes.

To embody this AI system, and to redesign the traditional ECG Holter, the project focused on three goals:

■ PRIMARY GOAL

"Redesigning a wearable ECG device, prioritising user confidence, optimised for a reusable, two-week wearing period"

■ SIDE OBJECTIVE 1

Optimise the overall interaction of the app & process of application of the device and patch. This, to also support and empower the users confidence during the interaction.

■ SIDE OBJECTIVE 2

Explore strategies for repair, reuse and recycling and incorporate these findings in the main objective.

The research was structured around four pillars: product requirements, optimal placement, user needs, and sustainability. These pillars formed the foundation for the iterative design process, which focused on six key themes: comfort, attachment, application, adjustability, feedback, and practicalities. Confidence emerged as the overarching topic, tying these themes together, ensuring the final design addressed both physical and psychological user needs. With the created personas Edith and Emily in mind, multiple iterations were tested with diverse user groups.

Key findings from the research and iterative phases revealed critical insights into user behaviour and design requirements. Participants highlighted the importance of clear feedback mechanisms, intuitive application methods, and designs that accommodated diverse body shapes. Comfort and attachment were important in ensuring long-term wearability, while the use of sustainable materials and modular components was evaluated for environmental impact reduction.

The final design integrates all these insights into a solution combined of three main components: the device, the patch, and the app / manual. The device features a durable and waterproof casing, designed for comfort and effective placement. The patch is made from a Mepitel One-inspired material, ensuring secure attachment and user comfort. The app provides intuitive guidance for the device setup and monitoring, emphasising on confidence and usability. Together, these elements form a system that addresses both functional and emotional needs.

Moving forward, several recommendations have been identified to ensure the project's success. The device proves to be desirable, as shown by positive user feedback, but some additional refinements could benefit the feasibility and viability of the product. Manufacturing processes must be optimised for cost efficiency, the patch requires additional iterations to improve durability and adhesion, and clinical testing under MDR guidelines remains necessary. The FMEA analysis identified potential risks that need addressing, considering the device, patch and overall system. A roadmap has been developed to guide future steps, with short-, mid-, and long-term goals on the horizon.

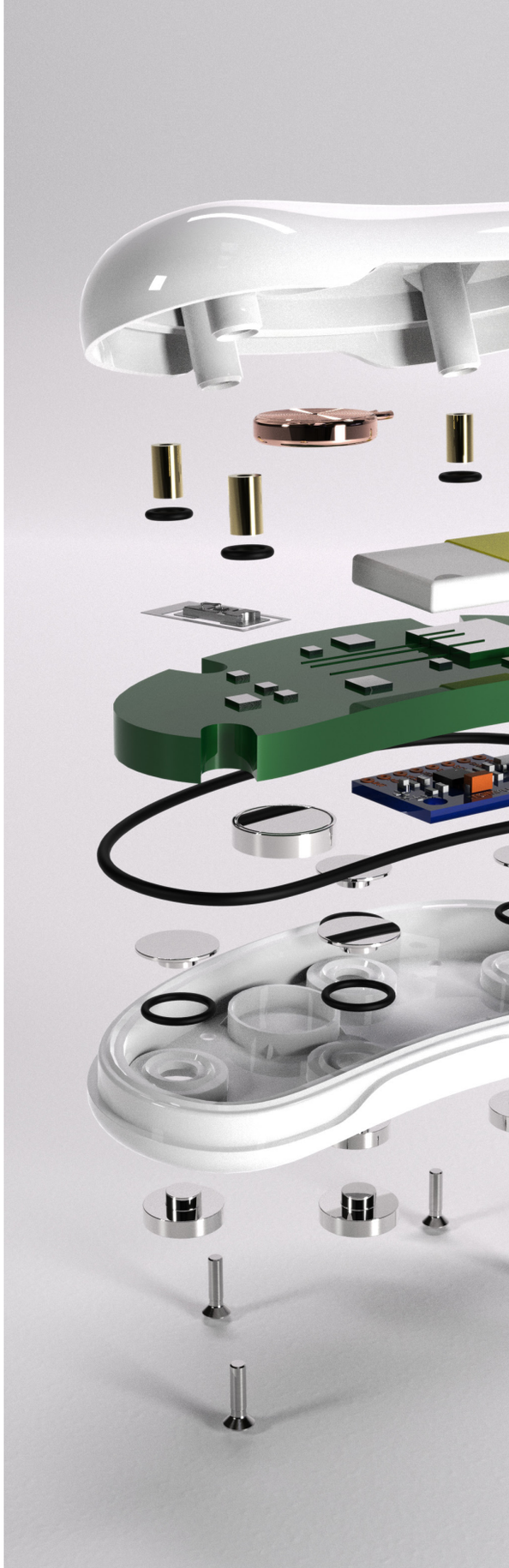


TABLE OF CONTENTS

01 PROJECT INTRODUCTION

This chapter introduces the context of this project in healthcare. It highlights the urgent need to transition towards sustainable healthcare practices, that are suitable for everyone. The project background, the identified problem and the client of this project are being elaborated. It highlights this research's structure and approach and can be viewed as a reading guide for this document.

CHAPTER 1.1

BACK GROUND

Each year, millions of people around the world visit their doctors with heart-related complaints, ranging from irregular heart rhythms to severe chest pain. Cardiovascular diseases remain the leading cause of death globally, responsible for an estimated 17.9 million deaths annually, accounting for 32% of all deaths worldwide (World Health Organization, 2021). Despite significant advancements in healthcare technology, early detection of heart conditions remains a challenge.

In current healthcare systems, when a patient suspects something is wrong with their heart, the general practitioner (GP) typically refers them to a cardiologist. However, the wait to see a cardiologist can be long, and even when an appointment is secured, the ECG performed at the hospital is often a single snapshot that may not capture irregular heart rhythms, such as arrhythmias. If no abnormalities are detected, the patient is often required to return for further testing, which often includes wearing a Holter monitor, as can be seen in Figure 1.

Holter monitors are wearable devices that can record the heart's activity over 24 hours or more, from which an ECG can be produced, enabling continuous monitoring in a patient's daily life (Hopkins Medicine, 2025). A Holter typically has between three and eight electrodes, dependent on the model or desired accuracy. As per reference, an ECG created in the hospital is typically created with 10 electrodes, generating 12-leads. Here, every lead is the measured electrical activity of the heart from a specific angle.

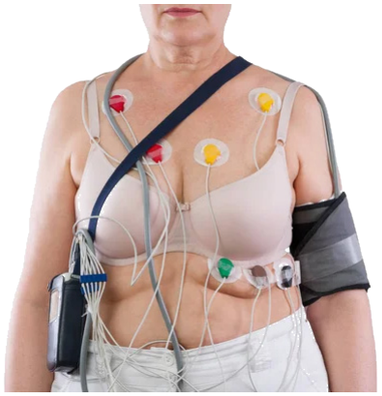


FIGURE 1: DRAWING OF A HOLTER DEVICE (HOPKINS MEDICINE, 2025)

1.1.2 TELEMONITORING IN HEALTHCARE

The practice of ECG monitoring has become increasingly prevalent, not just in hospitals, but also in home settings. Some wearable ECG devices and smart technologies now allow for continuous heart monitoring over days or even weeks, providing real-time data to healthcare providers remotely. This shift from hospital-based to home-based monitoring is called tele-monitoring and allows patients to monitor different types of medical information from home (Heart Failure Matters, 2022). It has become especially relevant in today's healthcare environment, where hospitals and clinics are often overburdened due to rising patient numbers and limited resources (Van de Poel, 2024). By allowing patients to wear these devices at home, healthcare professionals can track symptoms over time and make informed decisions based on real-world data, reducing the need for frequent in-person visits.

A heart attack, for example, can be diagnosed prematurely with an ECG, allowing for prompt medical intervention that can save heart muscle and, ultimately, the patient's life. Similarly, atrial fibrillation (AF), a common yet often asymptomatic arrhythmia, can be identified through routine or prolonged ECG monitoring. Left untreated, AF significantly increases the risk of a stroke, making early detection critical for preventing serious complications.

Telemonitoring, and therefore wearable ECG technologies, provide an innovative way to optimise patient care without overwhelming hospital resources. Also, many cardiovascular conditions, particularly arrhythmias, may not present with consistent or obvious symptoms, making them difficult to detect in a single ECG reading taken during a doctor's visit. By allowing continuous or intermittent monitoring over extended periods, at-home ECG devices can capture data on longer episodes that would otherwise go unnoticed. This data can be transmitted directly to healthcare providers, enabling them to make more informed decisions about a patient's care and potentially reducing the risk of severe events, such as strokes or sudden cardiac arrest.

1.1.3 BARRIERS FOR E-HEALTH ADAPTATION

However, the adaptation of telemonitoring, by the use of technology-facilitated healthcare (e-health), and allowing doctors to remotely analyse their patients, is not going as swiftly as one might hope.

As for the research of Herrera et al. (2022), several barriers to the implementation of e-health were identified. The users' age in combination with their technological knowledge level formed a first barrier. Depending on their limitations in technology access and usability, interaction with smart health devices could be troublesome. Considering this knowledge gap, Herrera et al. established that aids are needed, in the form of digital education and support from significant others. These limitations were also identified in another research, done by Wilson et al in 2021. Here, Wilson et al. identified active engagement of the users in the design and delivery of e-health programs, support for overcoming concerns and enhancing self-efficacy in the use of technology as potential solutions.

E-health was also often associated with high costs. Costs patients could not see as valuable investments in their health (Wilson et al., 2021).

SANNE RUIGROK (2024)

'PATIENTS WANT TO BE HEARD AND SEEN'

They also feared depersonalization in attention, meaning they perceived the remote care as a disinterest of their doctors. This was also confirmed in an interview with Sanne Ruigrok, policy advisor of Harteraad (Personal communication, 2024). In this interview, performed by Diplora's co-worker Jetske Brummer, Ms Ruigrok states that patients value 'the humane approach'. They expect human tips and feedback, in the form of calling, visiting or online chatting. 'Patients want to be heard and seen' Sanne states.

1.1.4 GENDER GAP IN CARDIOVASCULAR DISEASES

Early detection of heart conditions remains a significant challenge, particularly for women. Due to differences in symptom presentation and a lack of gender-specific medical devices, women are often diagnosed later than men. For example, in a standard exercise ECG conducted in hospitals, 72% of men receive conclusive results, while this figure drops to only 43% for women (Wittekoek, 2017). This discrepancy has severe consequences: 54% of women receive a diagnosis too late, compared to 33% of men (Wittekoek, 2017). A saddening number, but even more worrying is that 7% more women than men suffer from cardiovascular diseases, as can be seen in Figure 2.

Fortunately, awareness of the differences in cardiovascular diseases between men and women has grown in recent years. However, as research into female heart diseases began much later, there remains a significant knowledge

gap (Hartstichting Nederland, 2024). This historical delay has not only limited understanding but has also affected the design and effectiveness of medical devices.

Many medical devices, including those for cardiac care, were traditionally designed and tested primarily on men, operating under the outdated assumption that *"the heart functions the same way for everyone."* Pacemakers are a clear example. Initially developed with men in mind – who have larger hearts and different pacing thresholds – these devices caused significant complications for women (Nowak et al., 2009).

It is therefore critical that a telemonitoring device is not only effective for men but also, and maybe even more importantly, optimised for women. Addressing this inequality is essential to improve early detection and treatment outcomes for female patients.

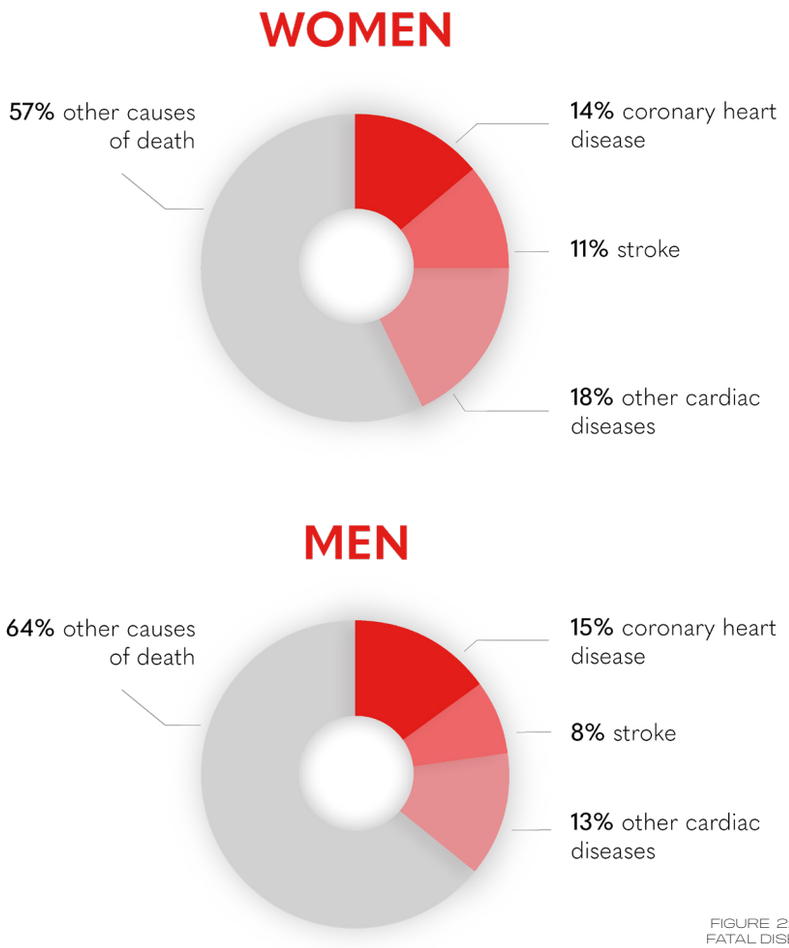


FIGURE 2: PERCENTAGES OF FATAL DISEASES IN MEN AND WOMEN (WITTEKOEK, 2017)

CHAPTER 1.2

THE PROBLEM

When zooming in on this interaction with telemonitoring devices, such as a Holter, several problems arise. These problems are not only located at the GP's office or at the cardiologist, but also during the patient's interaction with the device.

1.2.1 PAIN POINTS IN THE PATIENT JOURNEY

As already described in chapter 1.1, when a GP suspects something is wrong with the patient's heart, the wear of a Holter monitor can be prescribed to check for any anomalies.

This process can be cumbersome, as the patient has to revisit the cardiologist to have the device fitted. The traditional Holter monitor, while effective, comes with limitations: it is worn for only 24 - 72 hours, during which patients are often restricted from activities like exercise and even showering due to the device's wires. Given the short monitoring period, there is a significant chance that the arrhythmia or condition remains undetected, leaving patients without answers and having to repeat the entire process.

A deeper look into the current patient journey, as illustrated in Figure 3, reveals several key challenges that patients face when undergoing testing for arrhythmias. These obstacles not only hinder the diagnostic process but also significantly impact the patient experience, often causing frustration and discomfort.

●○○

Repeated visits to the cardiologist or their assistants for the placement of a traditional 24-hour Holter monitor. Patients often find themselves returning to the hospital multiple times, either because the initial ECG failed to capture any irregularities or because further testing is needed. These repeated appointments are inconvenient, especially for those with busy schedules, and can add unnecessary stress to an already anxious situation.

○●○

The Holter monitor itself is bulky, with multiple wires connecting to adhesive patches placed on the body. These wires often get in the way of everyday activities, while the patches can cause skin irritation. More restrictive still is the fact that patients are unable to shower or exercise while wearing the device, further disrupting their normal routines. Many patients report feeling limited and uncomfortable during the monitoring period, as the device serves as a constant reminder that their health is being examined.

○○●

When the monitoring period is over and patients return to the cardiologist for their results, patients are often left in the dark, unsure of whether the test successfully captured any abnormalities. The uncertainty surrounding whether they will receive meaningful answers or face another round of testing creates additional stress. When patients are informed that the 24-hour monitoring failed to detect anything conclusive and are asked to repeat the entire process, the prospect of wearing the cumbersome device again is met with dread.

These pain points highlight significant areas for improvement in the patient journey. From the inconvenience of repeated visits, to the discomfort of wearing the device and the emotional burden of waiting for results, the current process is far from patient-friendly.

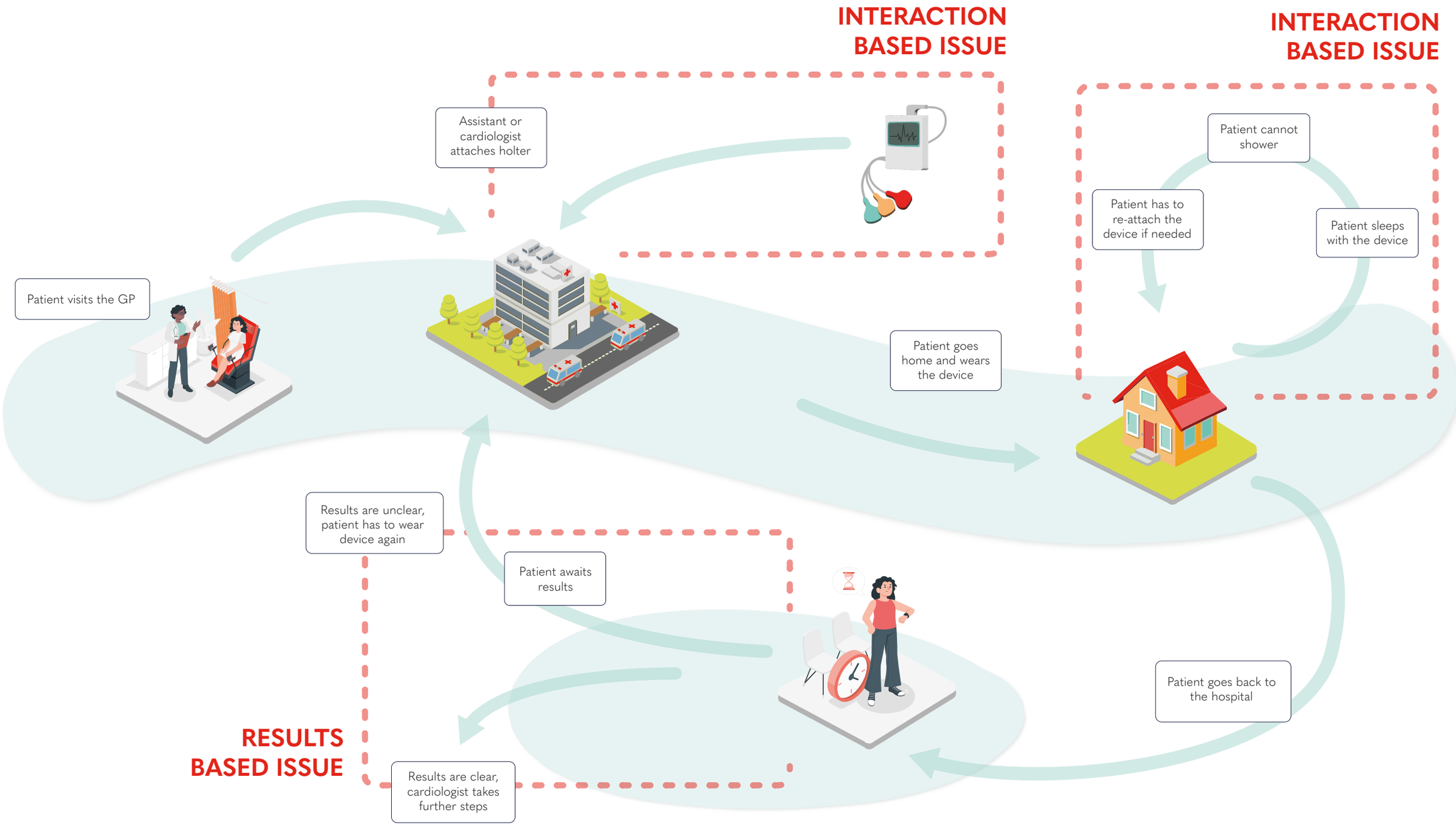


FIGURE 3: CURRENT PATIENT JOURNEY

CHAPTER 1.3

THE COMPANY

This is where Diplora steps in. Founded in 2023, Diplora is a young and ambitious start-up founded in 2023, setting out to reshape the future of cardiological diagnostics. By innovating within this evolving field of telemonitoring and e-health, Diplora creates relevance in recognising the urgency and complexity of heart health.

The company specialises in creating a Diplora Holter, an innovative ECG analysis device designed to deliver precision and thoroughness. With this device, Diplora wishes to provide faster, more affordable services compared to traditional systems, ensuring that high-quality heart diagnostics are accessible to every healthcare provider. They are striving to provide a service that not only improves the speed and affordability of heart diagnostics but also reduces the strain on the healthcare system.

1.3.1 DIPLORA'S EXPERTISE

By creating and optimising digital learning systems and artificial intelligence, Diplora aims to transform the input of a 3-lead ECG, into a full-fledged 12-lead ECG output. The system works by continuously collecting ECG data through the sensor, which is securely stored and processed through the platform. Using an AI-driven approach, the system performs artifact rejection and reconstructs a full 12-lead ECG, providing deeper clinical insights. Additionally, the integrated IMU (inertial measurement unit) records physical activity data, allowing for correlation between movement and heart rhythm patterns.

The AI engine analyses the data in real time, detecting arrhythmias such as atrial fibrillation, bradycardia, and tachycardia. A comprehensive report is generated, highlighting critical findings and their relationship to activity levels. This report is then reviewed by the GP, who can adjust treatment plans or refer patients to secondary care if needed.

The cardiac diseases focused on, are those that are not detectable with short-term ECGs. This includes arrhythmias such as atrial fibrillation, bradycardia, supraventricular tachycardia, ventricular tachycardia or second- or third-degree atrioventricular block, based on symptoms like palpitations, dizziness, or fatigue.

However, as for the scope set at the beginning of this project, September 2024, the primary focus shall initially be on the recognition of Atrial Fibrillation (AF), as this is the most common arrhythmia (Wyndham, 2000). From there, they will expand their field of detection to the other mentioned arrhythmias.

INTENDED USE

To understand their intended use, it is important to note that there are three types of diagnosing, as can be seen in Table 1.

MONITORING	Here, people that are ***already diagnosed*** with a certain disease, will be monitored to check their current health, evaluate changed prescriptions or monitor their progress over time.
DETECTING	Detecting will be done by people who are ***not ready diagnosed, but suspect a medical condition***. These people often receive a monitoring device from their doctor to either validate or disprove their complaints.
SCREENING	When screening, everyone, already sick or ***still unknowing***, is monitored. Here, also patients that do not suspect something to be wrong, will be checked.

TABLE 1: DIFFERENCE BETWEEN MONITORING, DETECTING & SCREENING

Diplora will focus on all of these groups by offering decision support for clinicians in the screening, monitoring, diagnosing and/or treatment of cardiac rhythm patterns. As the device is intended for long term ambulatory use, typically up to 14 days, it is prescribed for patients in home care settings who have known or suspected intermittent arrhythmias, as well as asymptomatic individuals undergoing screening. The device is meant to empower not only the patient but also the medical personnel, rather than competing against their expertise. Therefore, all findings must be assessed by a qualified healthcare professional before any medical decisions are made.

Through their innovative approach, Diplora hopes to redefine how cardiological diagnostics are delivered, ensuring that both healthcare professionals and patients benefit from advanced, yet easy-to-access, solutions. This ensures informed decision-making, facilitates early intervention, and ultimately enhances patient outcomes.

1.3.2 GOALS FOR THIS PROJECT

While the interior of the device (electronics and intelligence) is currently being optimised by Diplora, there is also a need to improve the exterior design and user interaction of the device. The current design still uses inconvenient wires, used for electrode attachment, whereas the new design shall focus on two main wireless components: a patch or several patches, which attaches to the chest and contains the electrodes, and a casing that houses the device and its functional components (Figure 4). To improve usability, the form, shape, and weight of the device must be refined, with an emphasis on a comfortable and intuitive interaction.

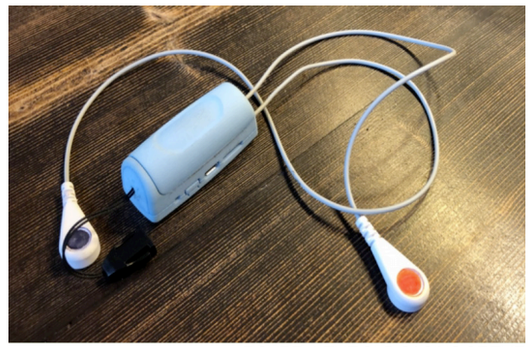


FIGURE 4: THE OLD CASING OF THE DIPLORA DEVICE

Referring back to the pain points in the patient journey, as can be seen in chapter 1.2.1, improvements in the interaction will be made. See Figure 5.

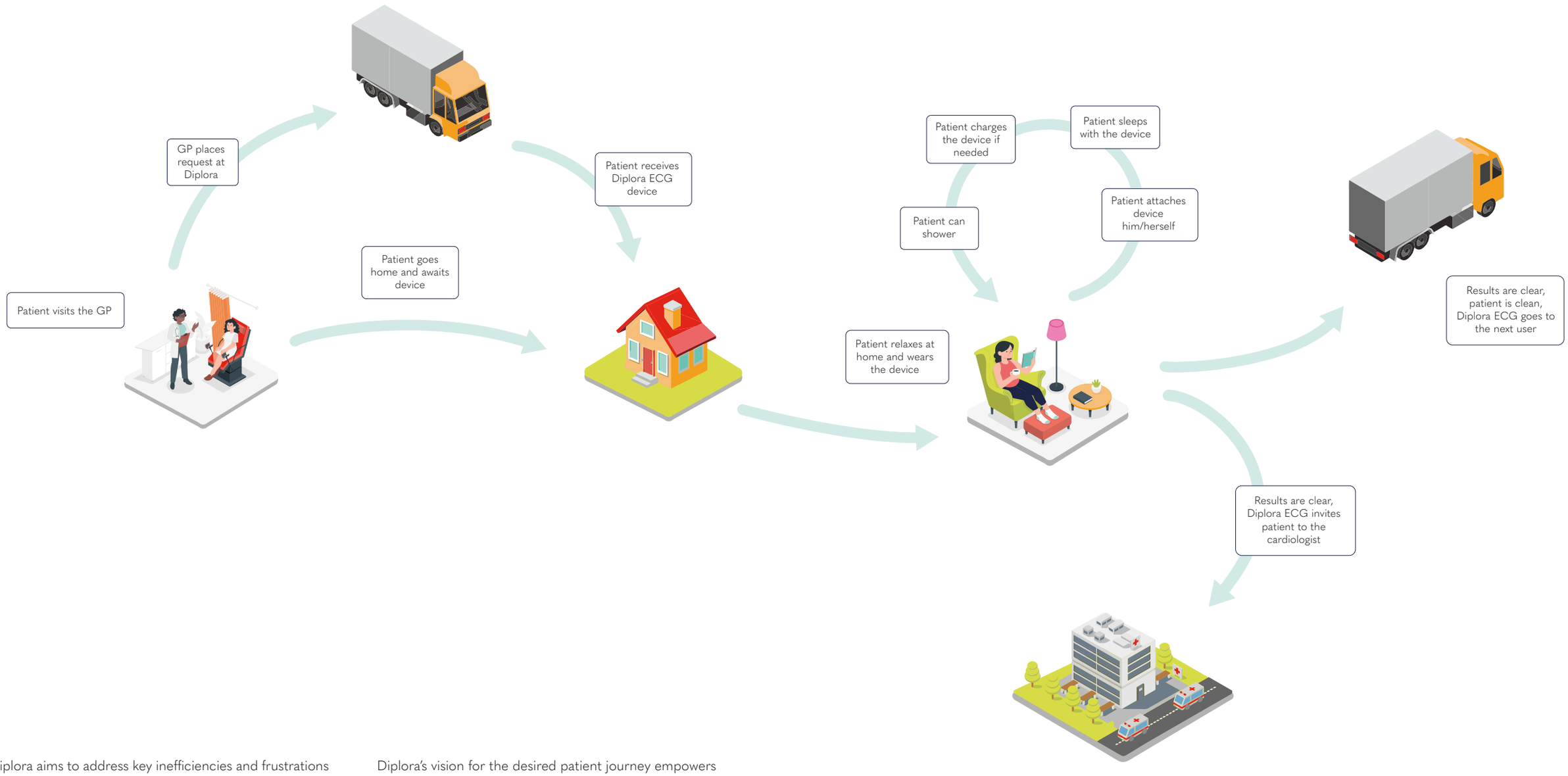


FIGURE 5: THE DESIRED PATIENT JOURNEY

Diplora aims to address key inefficiencies and frustrations in the current patient journey by designing a more patient-centric and sustainable ECG monitoring system. The current journey is full of interaction-based and results-based issues, such as dependence on medical staff for device setup, difficulties in managing detaching sensors, and delays caused by unclear results requiring repeated monitoring.

Diplora's vision for the desired patient journey empowers patients by enabling them to attach the ECG device themselves, simplifying the process of receiving a device – enabling the GP to hand out the device directly to the patient without interference of cardiologist – and improving usability. With features such as easy sensor reattachment, rechargeable batteries, and clear result communication, Diplora seeks to enhance the patient experience while promoting sustainability through device reusability. These improvements not only streamline the diagnostic process but also prioritise patient autonomy and satisfaction.

1.3.3 WHAT SETS THEM APART IN THE MARKET

This new view on the patient-product interaction is not all Dipora wishes to improve.

Figure 6 shows the SWOT analysis performed on the company Diplora, when compared to the other ECG wearable devices on the market. The full analysis can be found in Appendix A.

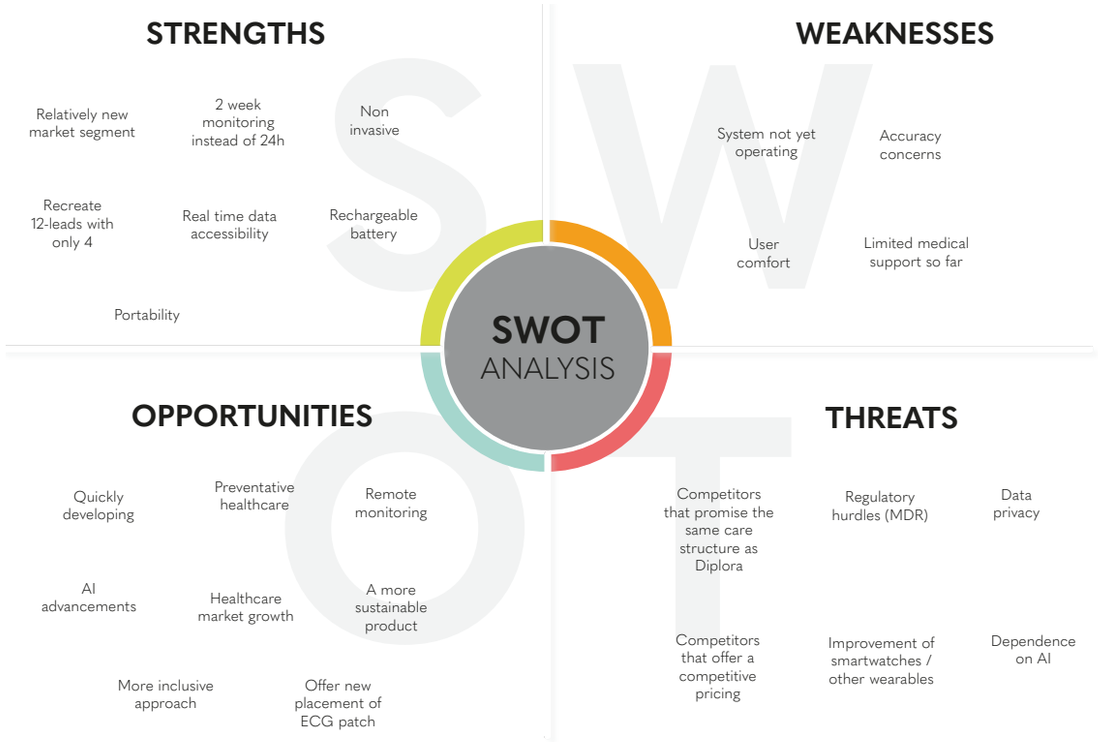


FIGURE 6: SWOT ANALYSIS ON DIPLORA

While the market for ECG wearables is relatively young, competitors are quickly on a rise. It is important for Diplora to set themselves apart from these competitors, to secure their own market share. This can be done by focussing on their sustainable approach; creating a product that is not to be thrown away, but can rather be passed onto the next user, repaired or eventually recycled.

FIGURE 7: SUSTAINABLE DESIGN (DOLCE, 2019

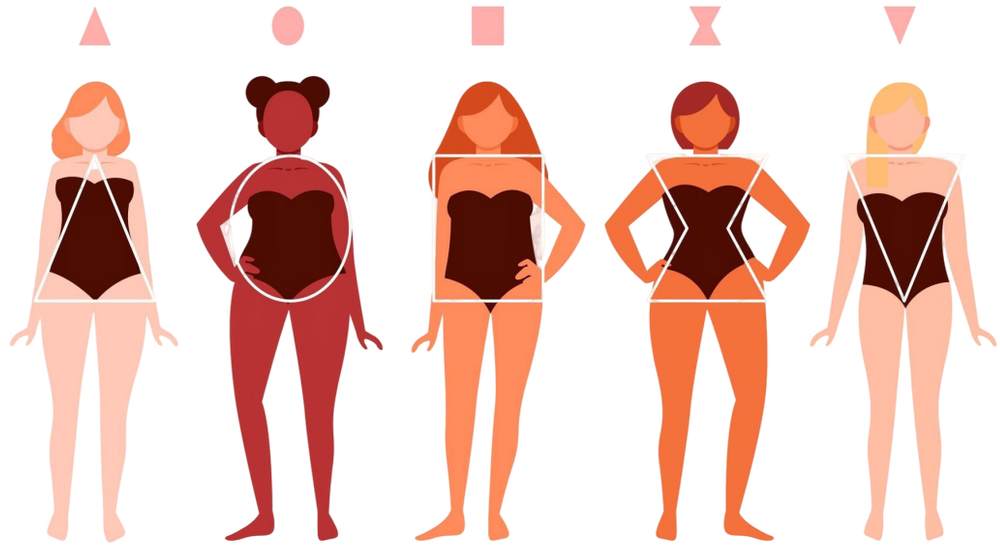


FIGURE 8: DIFFERENT FEMALE BODY SHAPES (FREEPIK, 2025)

Another opportunity to diversify from their competitors is by using a more inclusive approach. By designing the device for all different types of (female) body shapes, considering comfort as well as appearance, a new group of potential users could be reached. As mentioned before, many medical devices, including wearables, have been designed with men as the primary reference point, often resulting in a poor fit or discomfort for women. This can lead to inaccurate readings, reduced usability, or even non-compliance in wearing the device over longer periods (Wisbey, 2024).

The female body does present its distinct challenges — such as variations in chest anatomy and body proportions — which must be carefully considered during the design process. By prioritising a design that fits women comfortably and effectively, Diplora can ensure the device works well across all users.

Therefore, it is important to note that focusing on women's specific needs doesn't mean excluding men. In fact, designing a device that can accommodate the complexities of the female body will likely result in a product that also fits the different body types of men. A design that works well for women is typically more adaptable, to accommodate all different body types, eventually ensuring that the Diplora Holter is both functional and comfortable for everyone.

Another factor is of course to remain relevant by delivering accurate and reliable ECG analysis data, to both the doctor as well as the patients, and to also offer a competitive pricing.

Something else to consider is their approach towards medical staff and potential new users. It is important to gain trust from both parties at the same time. Users need to be persuaded that the Diplora device is the best fit for them, and medical professionals need to be convinced that this device not only provides reliable results, but also doesn't undermine their professional opinion.

CHAPTER 1.4

DESIGN GOAL & RESEARCH QUESTIONS

The analysis of the current Patient Journey, combined with the factors that will diversify Diplora from the rest of the market has identified three objectives for improvement that will be discussed in this chapter.

First, the interaction with the Holter device itself needs to be redesigned and optimised, ensuring a more comfortable and user-friendly experience for patients. Second, the way patients engage with the results must be enhanced, whether it involves understanding if the device is correctly placed, receiving real-time feedback from the device, or accessing results through a connected app. This will provide patients with clearer insights into their health and the progress of their monitoring.

Finally, considerations for the device's lifecycle must be addressed. If the Holter is intended to be reused by the next patient, it is essential to explore strategies for repair, reuse, and recycling, ensuring sustainability and minimizing waste.

This results in the following Design Goal and side objectives, as can be seen in Figure 9:

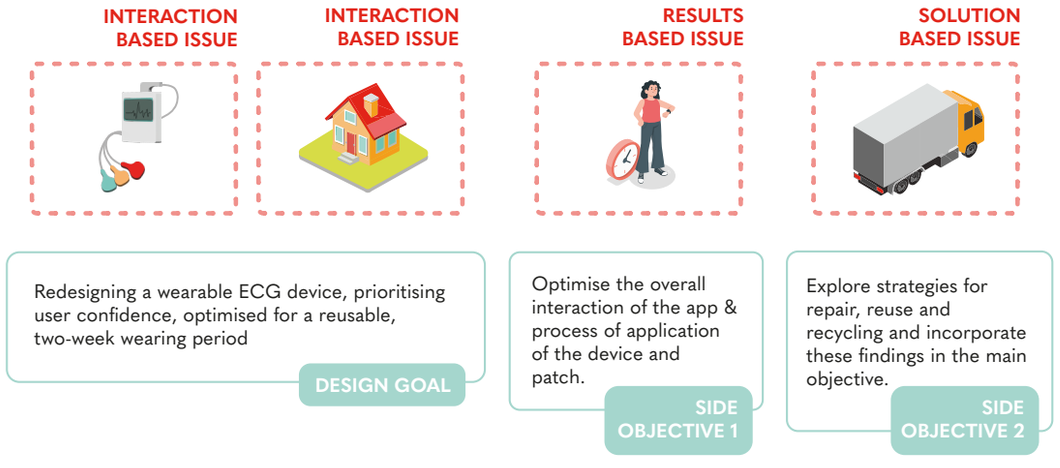


FIGURE 9: DESIGN GOAL AND RESEARCH QUESTIONS

CHAPTER 1.5

METHOD & STRUCTURE

The structure of this report will mirror the process of the project: it follows the journey from research and insights to thematic development, testing, and design, concluding with recommendations and a roadmap for the future. See Figure 10.

The design goal raised a variety of questions. These were categorised into four key pillars: product device requirements, optimal placement of the device, user needs, and sustainability. These questions were addressed through a combination of desk research, literature reviews, and interviews with both users and medical professionals. The findings from this process provided key insights that formed the foundation for the design process.

These insights translated into a list of requirements, such as waterproofness and ease of use. However, to make this list more actionable and manageable – considering that development cannot focus on technical aspects like waterproofing before defining the broader concept – these requirements were distilled into themes. Each theme was carefully chosen to contribute to the overarching goal of building user confidence.

Using these themes as a framework, tests were developed, ideation sessions were conducted and co-creation workshops were organised. This iterative design cycle allowed me to gradually refine the product towards its final form.

This final concept will be proven by a final validation, which will conclude in the suggested steps for the future of this product.

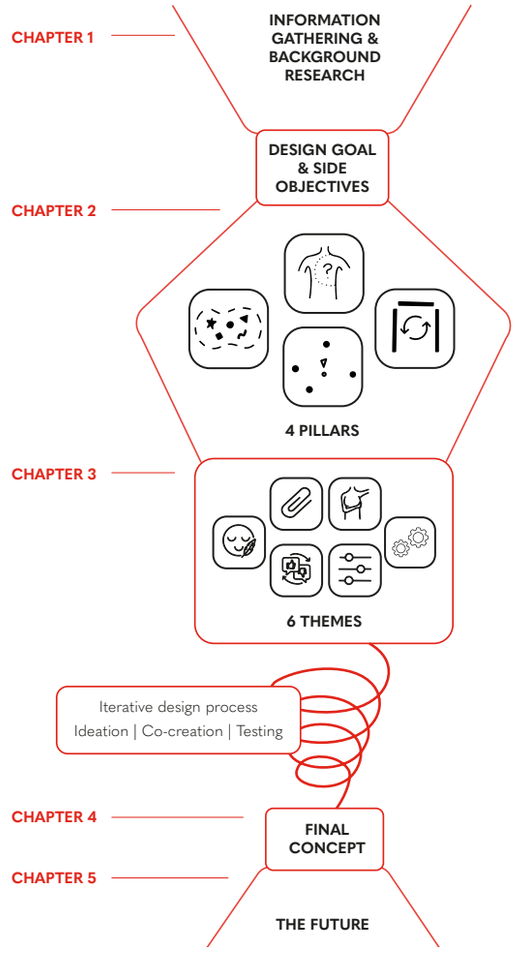
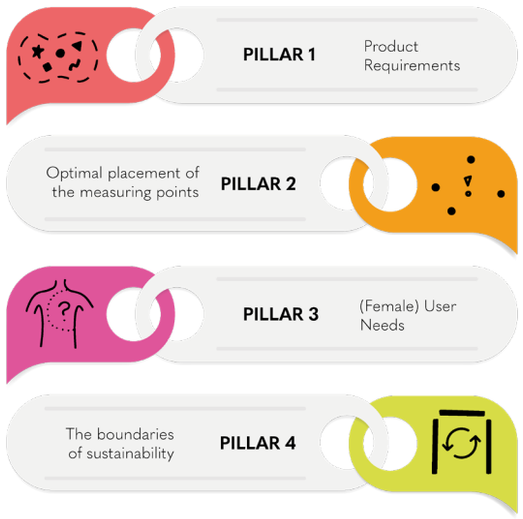


FIGURE 10: METHOD AND REPORT STRUCTURE

02 THE FOUR PILLARS

From the 3 objectives mentioned in chapter 1.4 several questions arise. These questions are divided into four pillars, where every pillar will elaborate on an important part of what will define the boundaries of the design. All pillars will start with an investigation into the topic, and end with a list of key insights.



CHAPTER 2.1 // PILLAR 1

PRODUCT FUNCTIO-NALITIES

This pillar will explore the practical functionalities of the product. What does it need to include on the inside or outside, and what key properties must not be forgotten?

2.1.1 FUNCTION ANALYSIS

To understand what is necessary to include in the redesign it is important to understand what components are located in the device and what function they serve. In Figure 12 the internals of the ECG device can be seen. A big part of the functional components in the device merely serve the purpose of making sure the ECG acquired data is recorded and sent to the cloud for further analysis.

When consulting with Diplora about what types of functions were desired to be active whilst wearing, it became apparent that the more 'real-time' feedback you want to give the user, the more 'full-time connected' the device needs to be. To give an example; for a light signal that indicates if the sensors are placed correctly, an active connection to the cloud or a device needs to be established to confirm whether or not a correct signal is being obtained. If that process has to be performed inside of the device, extra components accompanied with extra size, weight and costs have to be implemented. This trade-off is momentarily under debate in the company.

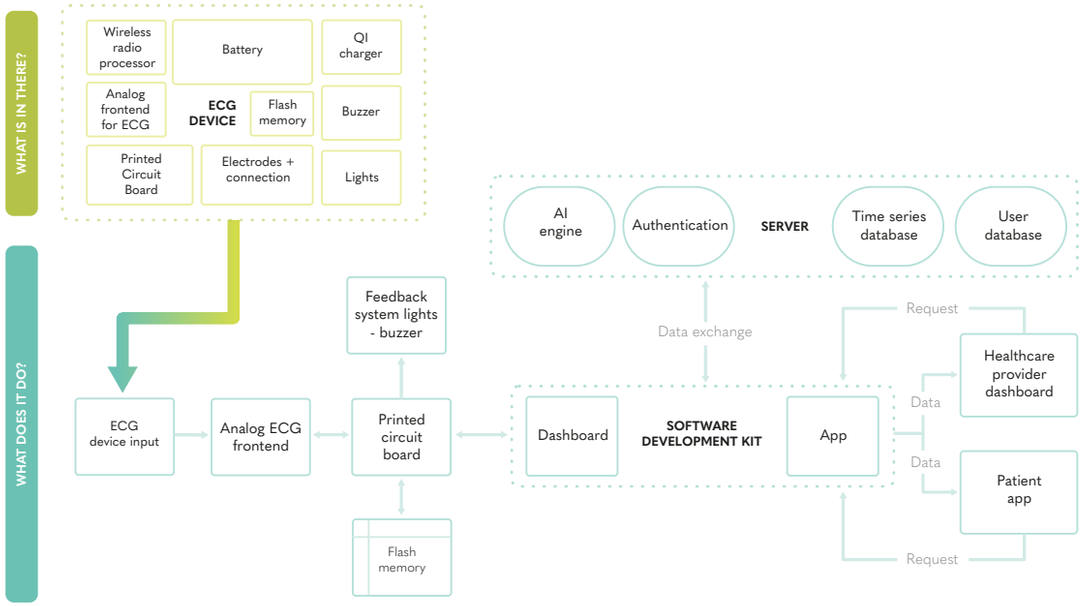
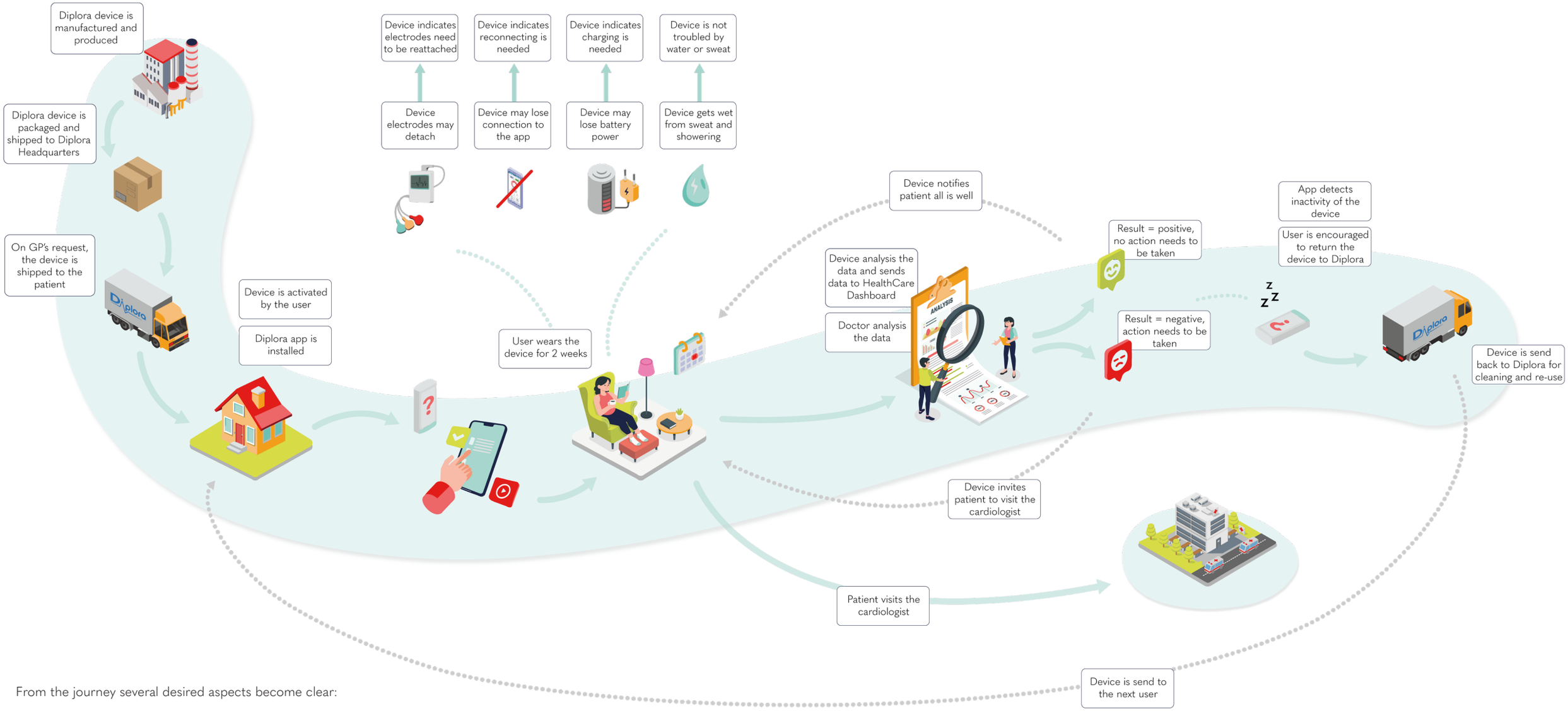


FIGURE 12: FUNCTION ANALYSIS

2.1.2 PRODUCT JOURNEY

To better understand what other functional properties the device should entail, the product journey (next page, Figure 13) is analysed as well. From this different viewpoint, new perspectives or interactions can surface, highlighting other important and necessary product qualities that may not be considered directly.



From the journey several desired aspects become clear:

1. The product needs to be able to withstand shipping and handling
2. The product needs to be water- and sweat-proof
3. It is desirable if the device gives feedback
   A. Feedback about the operability of the device (e.g. battery status, electrode attachment and network connectivity)
   B. Feedback about the recorded heartrhythms (level of detail available for the patient to see is yet to be determined by the company, Diplora)
4. The app needs to work smoothly and intuitively for the user
5. The device needs to be able to last long enough to serve its purpose to multiple users
6. The device needs to be understandable for patient, the doctor, as well as the cardiologist

FIGURE 13: PRODUCT JOURNEY

2.1.3 MEASUREMENT POINTS

For the device to perform as promised, the electrical pulses needed for creating an ECG have to be recorded. This recording is currently being done by traditional ECG patches. These patches detect the electrical activity of the heart and transmit it to the device, allowing it to record and analyse data. Most traditional ECG patches, often foam-based, include a conductive gel to improve signal accuracy and an adhesive backing to secure the patch to the skin. While effective in their function, these patches present several challenges that impact their usability, comfort, and sustainability.

The gel used, often leaves a sticky residue on the skin after removal, which users find unpleasant (Personal communication, 2024). Additionally, the adhesive material can cause irritation or allergic reactions in some individuals, resulting in red marks or discomfort, particularly for those with sensitive skin.

There are two main types of attachment mechanisms for these patches: peg-like and button-like. Peg attachments are prone to being dislodged during daily activities, while button-like attachments require significant pressure to secure, which can be uncomfortable for patients, especially when applied over soft tissue.

Another downside of these conventional patches is their single-use design. They are disposable and cannot be recycled, contributing to environmental waste. Users are often provided with additional strips for reapplication if the patch detaches prematurely, but these are also single-use.

Re-attachment is also often required, as most patches are not waterproof, meaning users must avoid activities like showering or exercising.

Lastly, these patches are required to be connected to the main device in some way. Meaning, that if you wish to measure a certain point on the chest, where the device itself is not located, a wire is required. These wires are not attached to the skin and hang loose, meaning they can easily be pulled loose on accident.

EXPLORING ALTERNATIVES

While this chapter primarily focuses on the challenges and limitations of traditional ECG patches, broader research was conducted into alternative adhesives and attachment methods to address the identified pain points. Inspiration was drawn from related medical products, such as diabetes patches, waterproof bandages, and sports tapes, which offer different approaches to adhesion, durability, and comfort. The extensive research of these topics can be found in Appendix B.

In short, the adhesive patches used in diabetes sensors can remain secure for up to 10 days, even during physical activity or exposure to water. However, interviews with users highlighted potential drawbacks, such as discomfort caused by larger patches pulling on the skin. Additionally, other adhesive technologies, such as synthetic or rubber-based materials commonly used in sports tape or waterproof bandaids offer enhanced water resistance.

Testing these alternative materials and designs could provide valuable insights for improving the usability and reliability of ECG patches while addressing issues such as single-use waste, skin irritation, and waterproofing.

2.1.4 FEEDBACK SYSTEM

Derived from the function analysis and user interviews, it becomes clear that feedback plays a crucial role in ensuring the proper functioning and interacting of the device with the user. As shown in Figure 14, feedback is required for various aspects of the device, such as activation, connectivity, electrode placement, battery status, and recording. Alongside identifying the moments when feedback should be provided, it is equally important to consider the types of feedback, or cues, that are appropriate. While Figure 14 outlines all possible variations of cues, it is important to note that not all of these options are desirable for the user or their surroundings.

According to literature, many medical devices mainly rely on visual and auditory cues for feedback. For instance, in a hospital setting, screens linked to ECG machines display vital information, while the constant beeping of these machines indicates that the device is operational and the patient is still alive (Philips, 2021). In more personal medical devices, such as smartwatches, haptic feedback is commonly used. These devices vibrate to alert users to noteworthy events and, in some cases, use specific vibration patterns to train users in recognising the type of notification they are receiving (Hernandez, 2024).

FIGURE 14: IDENTIFIED POTENTIAL FEEDBACK TYPES AND CUES

When designing feedback mechanisms, it is also crucial to consider the patient's autonomy. Research conducted by Taco Kind from Diplora, highlights a critical example: in a previous project, doctors received direct feedback on patient conditions and would proactively contact patients to discuss their health. However, patients perceived this unrequested contact as intrusive, which eventually led doctors to disregard the notifications and abandon the system. This underlines the importance of designing feedback mechanisms that empower patients to independently engage with their care. Effective feedback design should empower patients to engage independently in their care, fostering self-reliance, which is closely tied to building their confidence.

1 **Connectivity – Real time feedback**
The device needs to constantly check if everything works accordingly

2 **Waterproof**
The device needs to withstand showering or sweat

3 **Durable design**
The device needs to withstand shipping, handling & multiple users

4 **Smooth interaction**
The interaction between user (patient) and device needs to run smoothly

5 **Measuring points**
The current ECG measuring method (patches & cables) need improvement

6 **Feedback system required**
Users need to be able to see or feel if the device works well or not

OPTIMAL PLACEMENT

This chapter discusses the different and vast possibilities for ECG lead placement. Old and new methods are discussed, to eventually determine a design direction for Diplora's ECG device.

2.2.1 LITERATURE REVIEW

The placement of ECG patches is critical for accurately capturing the heart's electrical signals. Different heart conditions may require monitoring from specific areas of the heart (Jacobson, 2000). Therefore, it is very important that the right signals are being retrieved. While traditional 12-lead ECGs use multiple leads to provide comprehensive readings, much research has been conducted to recreate this functionality with only three or four leads, making devices more compact and user-friendly. The question that lasts however, is which three or four leads to pick from those 12.

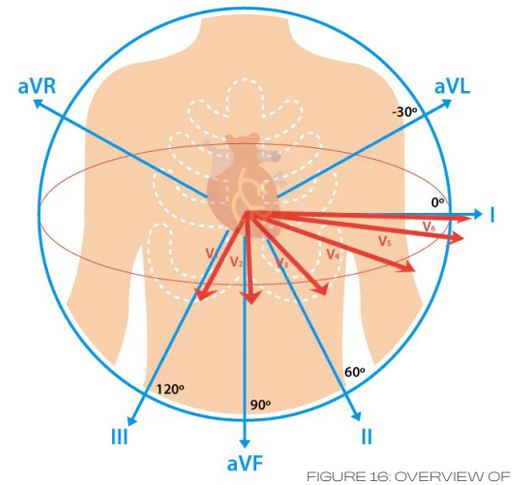


FIGURE 16: OVERVIEW OF LEAD ANGLES (CABLES & SENSORS, N.D.)

See Figure 16 for a comprehensive overview of the different leads.

In general, it is proposed by multiple papers (Nedios et al., 2014 & Sohn et al., 2020) that electrodes should be distanced approximately 5-10 cm from each other. However, the exact locations of these electrodes are still under debate. Nelwan et al. (2004) already suggested that reconstruction of the 12-lead ECG could best be done with the use of lead I, II, V2 and V5. In the research of Wang et al. (2024) they only use lead I, II and V2 to recreate the 12-leads, and V5 then appears the hardest to reconstruct.

This could be caused by the fact that V5 is furthest away from V2. Nevertheless, in a research performed by Jiménez-Serrano et al. (2022), and another research done by Lr et al. (2023), where they also use the 3-lead combination of lead I, II and V2, reconstruction of the 12-lead ECG does not appear to be a problem. In another paper, by Mason et al. (2024), the reconstruction of a 12-lead ECG is tested with leads I, II and V3. Here, they chose V3 for the reason that is located in the middle.

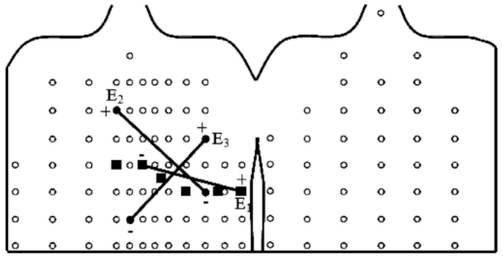


Fig. 1. Schematic of electrode array used to record 117-lead BSPMs with six precordial leads superimposed. Also highlighted are the positions of leads E_1, E_2, and E_3 as dictated by top three eigenvectors.

FIGURE 17: EIGENLEADS AS PROPOSED BY FINLAY ET AL. (2010)

However, besides the debate which of the traditional placements should function best, new locations are also being explored. For instance, in the paper of Finlay et al. (2010), they let go of the original ECG lead placement positions, but discovered their own *'eigenleads'*. These *eigenleads* were tested for the best signal magnitude and best reconstruction of the 12-lead ECG, which resulted in three best-located spots and can be seen in Figure 17.

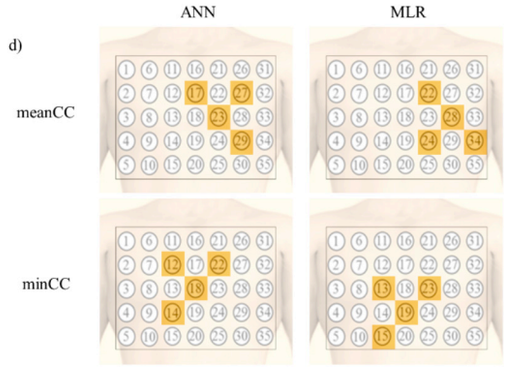


FIGURE 18: RIGHT-ANGLED TRIANGULAR SHAPE COMBINATIONS AS PROPOSED BY LEE ET AL. (2020)

The paper of Lee et al. (2020) also proposes unconventional placement of the ECG electrodes, for designing a patch-type ECG sensor. Here, the results suggested that the bottom of the central area of the chest was most suitable for ECG patch attachment. See Figure 18.

To summarise, the exact placement of the electrodes appears to be less critical, as long as a distance of approximately 5–10 cm between the measurement points is maintained and the signals are captured from different orientations around the heart.

Research from Diplora's data scientist has also been conducted to see whether a consensus could be found between all of these researches. From this research, lead aVR and V4 appeared to be of the most value. Leads V1, V3 and V6 appeared to perform the worst. While this research is still in progress, these preliminary results could already be a valuable indication of the areas to focus on when designing the shape and patch of the device. See Figure 19.

Diplora

Best leads to perform e12

3-lead Combination	R2-Score
II, aVR, V4	0.9890507554696613
aVR, aVF, V4	0.988836247149467
III, aVR, V5	0.987822296957393
III, aVR, V4	0.9877060648833472
I, III, V4	0.9873217223624677
I, aVR, V5	0.9872908894147377
III, aVL, V4	0.9872588575474941
II, aVL, V4	0.9871752346823987
I, aVR, V4	0.9871664531322434
I, II, V4	0.9870643631818473
II, III, V4	0.9869899302180644
aVR, aVL, V4	0.985941165177567
III, aVF, V4	0.9858681366072592
I, aVL, V4	0.9856701328386984
II, aVF, V4	0.98564825300416 2
III, aVR, V3	0.9855797519541246
aVR, aVL, V5	0.9855709466153212
II, aVL, V3	0.9850115437821869
I, aVR, V3	0.9849164090234489

Worst

V4, V5, V6	0.901231129913997
V1, V3, V6	0.8997907641355761
aVR, V2, V3	0.898712043357124
V1, V3, V4	0.8983024739632026
I, V1, V2	0.8970104273991236
V1, V4, V5	0.8958112319969249
V1, V3, V5	0.8935896291755084
aVR, V1, V6	0.8935258818138316
V1, V2, V3	0.8926852999623636
aVR, V3, V6	0.8913185475361954
V2, V3, V6	0.8864548327875393
aVR, V2, V6	0.8832967350937554
V1, V4, V6	0.8790564550504865
V3, V4, V6	0.8741746307496078
aVL, V2, V3	0.8558662512052481
I, V1, V3	0.7314864543314061

FIGURE 19: BEST 3-LEAD COMBINATION RESEARCH BY DIPLORA (2024)

The effectiveness is also heavily depends on how well the software is trained to interpret the signals. In principle, measuring around the heart, preferably near its upper regions, provides reliable results. This is particularly relevant given Diplora's current focus on atrial fibrillation (AF), which is commonly detected using lead I, positioned near the top of the chest.

2.2.1 KEY INSIGHTS

1 **Measuring points distance**
Measuring points need to be at least 5 - 10 cm apart

2 **Location and software**
Software shall have to compensate for slight displacements due to different human physiques, measuring points should be aimed around the heart to optimise ECG readings

3 **Focus on AF**
For detection of AF, lead placement above the heart is required

CHAPTER 2.3 // PILLAR 3

USER NEEDS

In this chapter, the (female) needs are explored. All positive and negative points of wearing a Holter are explored through user interviews and testing. The Rethinking Users Method (Youngblood et al., 2022) helps to investigate who is involved in using such a device, which helps to identify all relevant stakeholders, that need to be considered when designing. Resulting from the analysis, several personas will be identified, which will help shape the design considerations to be made later on in the process.

2.3.1 USER INTERVIEWS & TESTING

Interviews were conducted with six individuals who had previously worn a Holter monitor, five of whom were female and one male. Additionally, a female participant who used an ECG waistband for sports purposes was also interviewed. The aim was to gather their experiences, spanning the entire journey from their initial appointment with a general practitioner (GP) to receiving the final diagnostic results. Six key themes emerged from these interviews, highlighting both the technical and emotional challenges they experienced. Several notable quotes can be found in Figure 21.

TYPES OF HOLTERS

The interviewees reported using different types of Holter monitors, with varying levels of comfort. Many described issues with long, annoying cables connected to a small box, which had to be worn either around their neck or attached to a waistband. The cables, particularly during sleep or movement, were noted as highly inconvenient. Other participants used Holters that were stuck directly to their body with a sticker patch. One interviewee noted that a larger, heavier device caused discomfort, as the weight of the box pulled on the patch and electrodes, eventually resulting in a detached device. Another interviewee had a smaller, more compact Holter device that attached directly to the electrodes, that did not pull on the sticker. However, this smaller device, worn on the chest, was very visible, leading to discomfort and self-consciousness.

ELECTRODE ATTACHMENT TYPES

Two main types of electrode attachments were mentioned: the button-type and peg-type electrodes. Peg-type electrodes, while easy to attach, were prone to falling off with light bumps. In contrast, button electrodes required pressure to secure them, which some found uncomfortable, especially when applied to soft tissue areas such as muscles or fat. The pressure needed to attach these electrodes was a source of discomfort for several participants.

SKIN IRRITATION FROM PATCHES

Skin irritation from the adhesive patches was a common concern among the participants. Many experienced redness and irritation — which although useful for identifying where the electrode had been placed in case re-attachment was necessary — was undesirable and uncomfortable. Participants also found it frustrating when the patches either detached too easily or adhered too strongly, requiring significant force to remove, causing further irritation.

ASSISTANCE AND ATTACHMENT

The interviews revealed varying levels of assistance in attaching the Holter. Some participants received a colour-coded guide along with their device, showing where the electrodes should be placed if they came loose. Others received a booklet, but many expressed uncertainty about proper electrode placement. Doctors often reassured them that precise placement wasn't critical, as the Holter could still function effectively with three out of four signals intact. Nevertheless, participants appreciated when the Holter was attached by a professional, as they felt uneasy about placing it themselves for fear of making an error.

BREAST-RELATED CHALLENGES

All female participants, particularly those with larger breasts, reported difficulties with electrode placement. Wires could become tangled or dislodged, leading them to wear a bra constantly to prevent interference of the breast tissue. Meanwhile, smaller-breasted women also faced challenges as the Holter device, when worn above the breasts, was noticeable and awkward, making them self-conscious about its appearance and potential to be knocked off accidentally.

FEELINGS OF SHAME AND INSECURITY

Emotional discomfort, including feelings of shame and insecurity, was a final big recurring theme. Many participants expressed embarrassment about wearing the Holter in public, particularly when it was visible. Additionally, they felt uncertain about whether they had attached the electrodes correctly or feared that accidental bumps would disrupt the readings. Most Holters had a small indicator light, either red or green, but none of the participants knew what the light signified. This lack of feedback increased feelings of insecurity. However, one elderly participant mentioned that while feedback could be helpful, it should not be too complicated, as it might cause confusion and anxiety about misinterpreting signals.

QUOTES FROM HOLTER USERS

"There was definitely some shame in wearing it, I didn't want anyone to ask about it."

"I just want to sleep well. I think that's what I was most upset about, actually."

"The device had a red light, but I couldn't tell whether it actually meant something or not."

"If you have to do it yourself, I'd still doubt whether I was doing it correctly."

"All those wires, awful! I kept getting tangled up in them the whole time."

"The loose device got in the way when I was jumping, so exercising wasn't really possible."

"The device had to be removed; it wasn't waterproof."

"The device was stuck to my chest but was way too heavy, so it pulled all the patches off."

INTERVIEW WITH PHD CANDIDATE AND DOCTOR

Another interview was held with a PHD candidate in medicine. For his personal research, which is irrelevant to the topic of this report, he checks the vitals of his patient before testing. To do so, he uses a Spaulding ECG device, which is a portable 12-lead ECG, where the 10 wires are attached to a relatively big device, that communicates its measurements with an accompanying app, as can be seen in Figure 22. This app shows all 12-leads from the ECG, and changes in real time when a patient moves, jumps, scratches etc. For this test, I had the opportunity to try the device myself, to understand the process of ECG measurement better and to identify important notions considering the future design. Several things stood out:

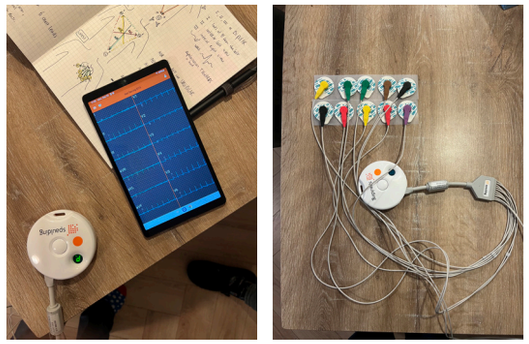


FIGURE 22: THE SPAULDING ECG DEVICE AND ACCOMPANYING APP

The leads that are attached to the patient are colour-coded. Every colour represents a certain place on the body, from where the measurements are to be taken. Interestingly enough, this colour code is not a universal rule, where Europe adheres to a different code than the U.S.A. This sometimes causes confusion, either when doctors work abroad or when a device is developed in a certain country and used in another one.
Despite this inconvenience, doctors and caregivers who sometimes also perform this examination, do think a colour code is clear and easy to use. All electrodes are also labelled with a code, also corresponding to a certain placement on the body, however these codes are often confusing to someone who is not familiar with the terminology.

Another interesting notion was that the chest electrodes, those that are placed under the breast, are not necessarily placed underneath the breast. As I assumed the breast electrodes would only be difficult to attach for females with (significantly) bigger breast sizes, even for smaller breasts the patches have to be attached onto the breast, instead of underneath. Therefore, finding the exact location for some of the electrodes can be relatively tricky as breasts are also quite moveable. For instance, V4 has to be placed on the 5th rib on the middle line of the clavicula, but especially for bigger-breasted ladies or elderly females, who may already experience more hanging of the breasts and creasing of the skin, attachment can be quite tricky. During the interview with the PHD doctor, it was also pointed out that these skinfolds sometimes tend to be unhygienic for some elderly females, as it is a difficult spot to clean.

The electrodes were also easy to disrupt. When you moved over the electrodes with another body part, you could already see a disturbance in the ECG. The same was true when someone else touched you, transferring his/her own electrical charge to you. Also with under-breast placement of the electrodes, disruption could occur when an overhanging breast moves from side to side. Small extra vibrations would enter the output ECG wave, which could be confusing or misleading for whomever has to interpret them. This may not necessarily pose a problem, but it is important to verify with the data scientist from Diplora whether these disturbances can be filtered out.

The patches could only be attached once in the proper location, or the glue would already be satisfied and would not stick properly when applied again. They were relatively well attached to the skin, but because of the size, thickness and sometimes the location of placement, the patches could detach slightly more easily. Especially places where the skin deforms most (creasing, bending, stretching etc).

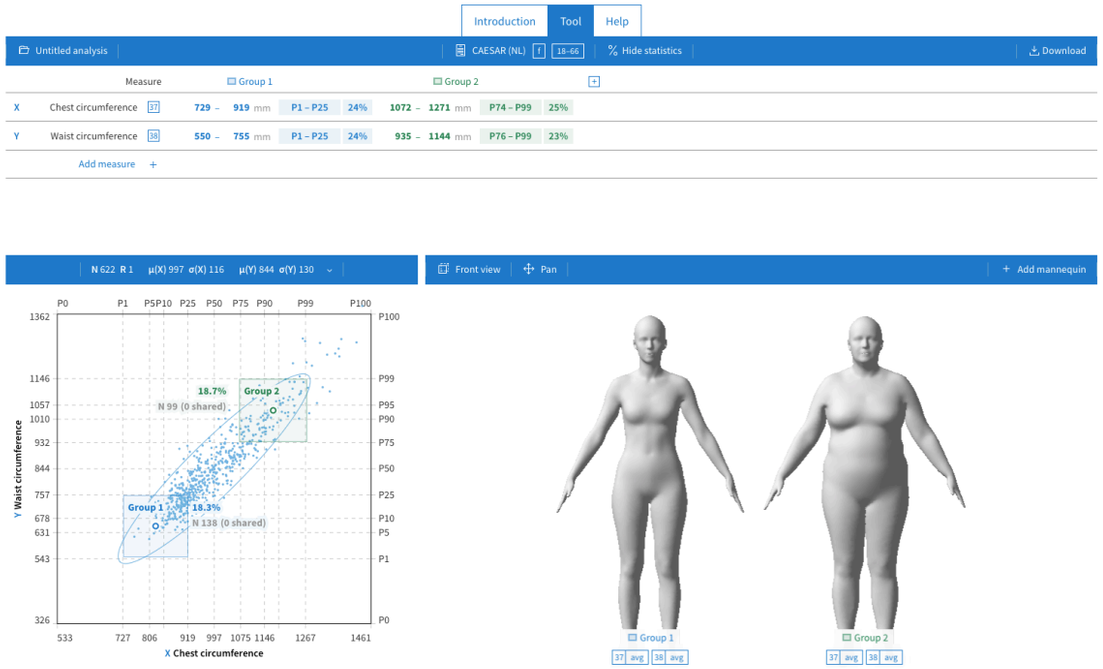


FIGURE 23: BODY INDICATION OF GROUP 1 AND 2 (DINED, 2024)

2.3.2 BODY SHAPES OF USERS

As also observed from the user interviews, there are very many different bodily shapes to take into account. When exploring the distribution ratio of chest circumference to waste circumference in females between 18 and 66 years old, based on TU Delft's Anthropometric Database DINED (Huysmans & Molenbroek, 1980), it becomes even more apparent how diverse these body shapes are. See Figure 23.

However, if the design would fit the P1-P25 group, as well as the P75-P99, it is presumable that it will also fit the P25-P75. These ratios will be important to take into account in further design considerations.

2.3.3 TYPES OF USERS AND STAKEHOLDERS

Not only the body shape of the user varies, but also the way they interact with the device. When investigating the process of wearing and using a Holter through all interviews, it becomes apparent that the patient wearing the ECG device is by far not the only one interacting with this device. To capture all different users that, in some way, interact with the device the *Rethinking Users method* was applied (Youngblood et al., 2022). These can include not only the direct user but also healthcare professionals, friends and family, and even those responsible for recycling or repurposing the device.

The full user type analysis can be viewed in Appendix C.

To conclude: from this analysis, multiple types of relevant users were identified. These 'users' are important to keep in mind when designing. Take, for instance, Friends & Family; When designing the feedback system of the device, lights, buzzing or sounds could appear useful. However, when considering this group and not only the user, it is questionable if audial feedback is desirable as friends and family might also hear the sound. This could perhaps, for the direct user, result in shame or awkwardness.

From this analysis it also became apparent that the Direct User is not as one-dimensional as one might think. The direct user is also the one dependent on the device, the one who needs to become one with the device, the one that wants something from the device and also the one that will hand the device back to the next Direct User.

As described by Youngblood et al. (2022) *'all users are stakeholders, but not all stakeholders are also users'*. Meaning, that although not everyone will actively wear the device, there are many people that will handle it in some way. This could range from the doctor handing out the device, to the person taking the device apart for recycling purposes.

YOUNGBLOOD ET AL. (2022)

'ALL USERS ARE STAKEHOLDERS, BUT NOT ALL STAKEHOLDERS ARE USERS'

For all of these stakeholders, it is important that they know what to do with the device, for the part that they are responsible for. Some stakeholders just need to be informed how the product works or what to do with it, while others need to be accountable for the functioning of the device.

To create a better grasp as to who these stakeholders are, also in relation to each other, the following stakeholder map is created. See Figure 24.

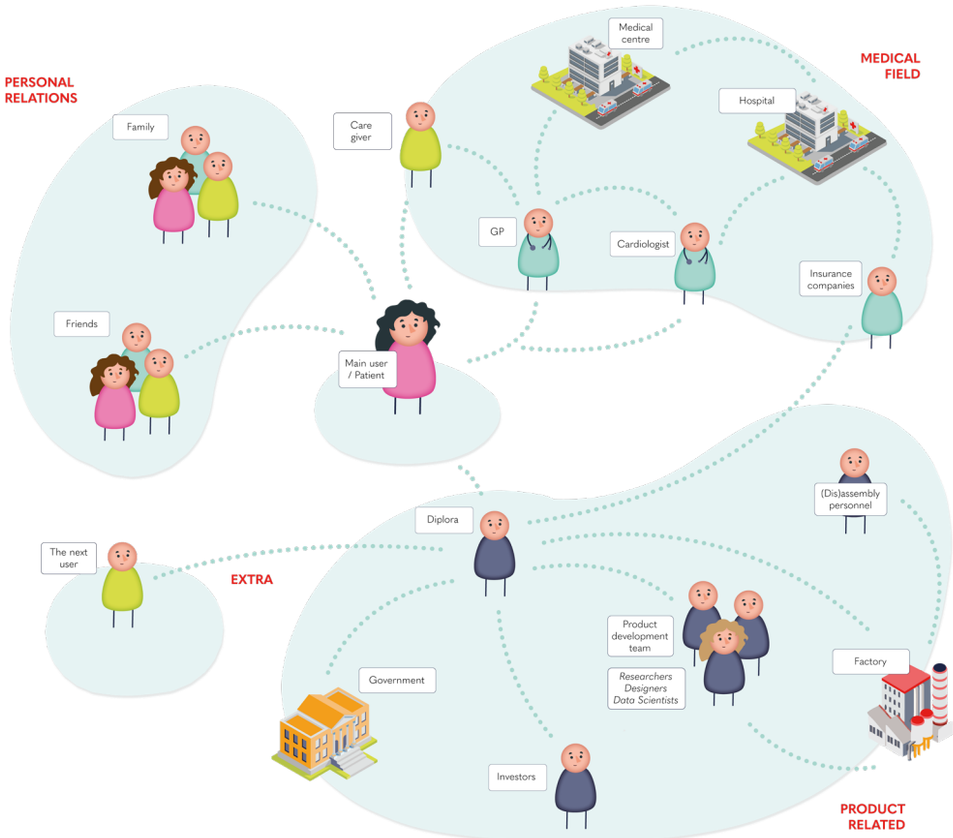


FIGURE 24: STAKEHOLDER MAP

2.3.4 PERSONAS

Based on the findings and perspectives in this chapter, two different personas are created. These personas will help navigate through the design decisions to be made later on, and will also help focus on the different perspectives and skill levels of different people.

To create a fair distribution of the different bodily shapes, each persona represents a different group of the DINED ratio division. Persona 1, Edith, represents the P75-P99 group and persona 2, Emily, represents the P1-P25 group. Further characteristics of the personas can be seen in Figure 25 and Figure 26.

EDITH, 67 | P75 – P99

Edith is 67 years old and a proud grandmother of five. She enjoys going out for a stroll in the park, going over to some friends for tea or playing boardgames with her family. She has a smartphone but uses it for the bare minimum. Calling is fine, but she prefers a personal interaction.

Edith suspects something is wrong with her heart and wants to know if she needs to adjust anything in her current lifestyle. She believes '*Doctor knows best*', so as long as she just follows protocol, everything will be okay, right?

EDITH

'DOCTOR KNOWS BEST, RIGHT?'

EMILY

'I WANT TO BE IN CHARGE OF MY OWN HEALTH'

EMILY, 24 | P1 – P25

Unlike Edith, Emily loves to be out and about. She loves to play football, hang out with friends and go out for dinner. She sees her phone as an extension of herself and is a real tech-savvy.

Emily is strong minded and independent. She suspects something is wrong with her heart, but that will not mean she will give up on her normal way of living. Her motto is '*I want to be in charge of my own health*'.

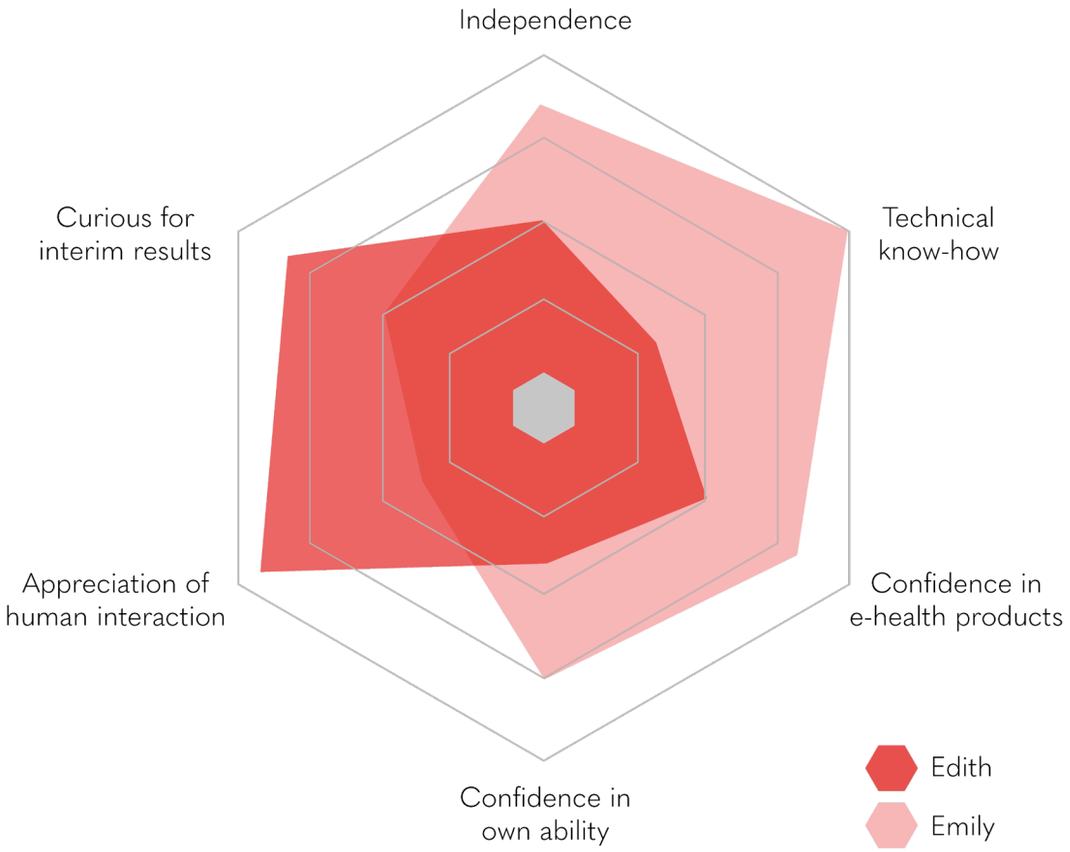


Figure 27 shows the different values of the two personas mapped out against each other. Here it becomes apparent that these two types of women will require different approaches or solutions.

FIGURE 27: PERSONA CHARACTERISTICS MAP

2.3.5 KEY INSIGHTS

1. **Customisable fit**
   The design must account for women with for different breast sizes
2. **Placement and usability**
   Electrodes should be placed in consistent, easy-to-reach areas
3. **Accessible measuring points**
   Attaching the measurement points must be straightforward to understand, ensuring a minimal margin of error
4. **Reducing the margin of error**
   Measuring points should be integrated into a single patch
5. **Electrode attachment**
   Preferably wireless to enhance comfort during use
6. **Skin Compatibility**
   Adhesives should minimise irritation and be hypo-allergenic
7. **Clear instructions**
   A patient/caregiver needs clear guidelines on how to use/apply the device
8. **Ease of use**
   The user must be able to operate the device independently
9. **Confidence is key**
   The user must feel confident in applying, wearing and interacting with the device
10. **Compact and discreet**
    Reducing discomfort and visibility, particularly for (female) users who are sensitive to wearing a visible device in public.
11. **Waterproof**
    The device needs to withstand showering or sweat
12. **Feedback system**
    Clear and simple feedback mechanisms are necessary for intuitive use

CHAPTER 2.4 // PILLAR 4

SUSTAIN-ABILITY

The fourth pillar highlights the importance of a sustainable design, and investigates the possibilities within the medical field and the field of product design.

2.4.1 THE VALUE HILL MODEL & 10 GOLDEN RULES

When designing a sustainable product it is important to consider all aspects of a design. But when a design exists out of several main parts, the focus areas for sustainability can vary significantly. Therefore, it is important to distinguish the device – that processes the incoming ECG signal – and the electrode patches – that acquires the signal.

The Value Hill model (Achterberg, Hinfelaar, & Bocken, 2016), see Figure 29, provides a helpful framework for understanding where sustainability efforts can be applied across a product's lifecycle. This model divides the lifecycle into three phases: pre-use, where value is created through material extraction and manufacturing; use, where the product delivers its function while focusing on maintenance and lifespan extension; and post-use, where strategies like recycling or refurbishing ensure value is preserved.

For the device, the focus is primarily on the pre-use and use phases. Sustainability can be achieved by designing for maintenance and repair, ensuring that spare parts or upgrades can extend the product's life. Choosing durable materials that can withstand prolonged use and avoiding the use of adhesives in assembly are important, as these choices allow for easier disassembly and recycling. Business models such as leasing, product-as-a-service, or sell-and-buy-back schemes can further contribute to extending the device's lifecycle and reducing waste.

In contrast, the sustainability of the patch is more centred on the post-use phase due to its single-use nature. Reuse is not an option, and refurbishing or remanufacturing is challenging, which shifts the focus to material recyclability. To make recycling viable, careful attention must be paid to material selection, favouring components that can either be recycled or biodegraded after use. Additionally, the patch's design must facilitate the easy separation of materials, such as the adhesive from the electrodes, to optimise the recycling process. Exploring in-house recycling systems, where used patches are collected and processed efficiently, could also significantly reduce environmental impact.

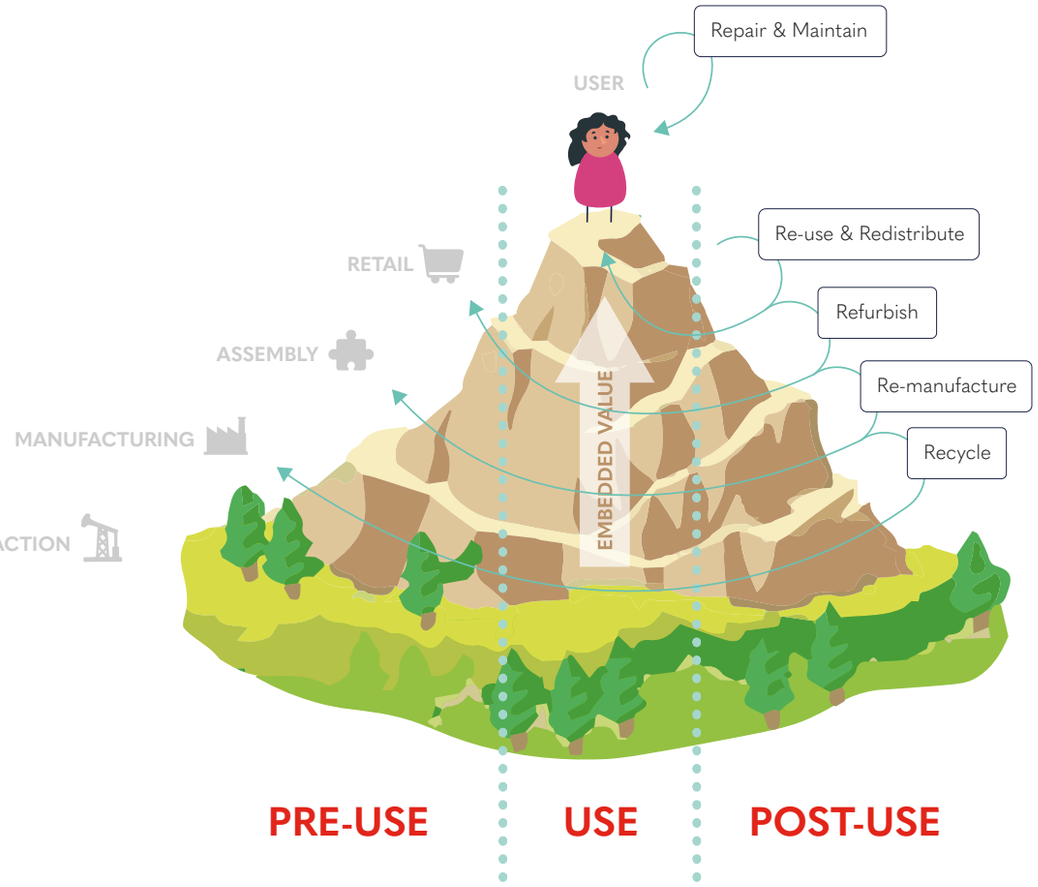
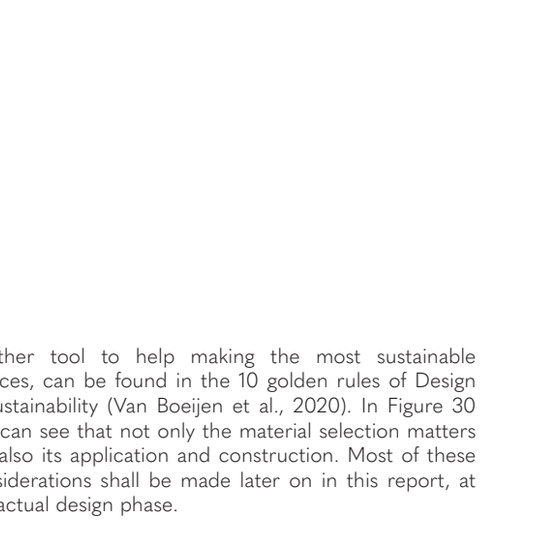


FIGURE 29: THE VALUE HILL MODEL

Another tool to help making the most sustainable choices, can be found in the 10 golden rules of Design 4 Sustainability (Van Boeijen et al., 2020). In Figure 30 you can see that not only the material selection matters but also its application and construction. Most of these considerations shall be made later on in this report, at the actual design phase.

Here you can also see that, by treating the device and the electrode patches as separate entities in the sustainability strategy, it becomes possible to develop targeted solutions. While the device requires a focus on durability, repairability, and longevity, the sustainability of the patches depends on recyclability and reducing waste.

MEANING



CONSTRUCTION - Use as few joint elements as possible, look for intelligent geometric solutions

MIXING MATERIALS - Use as few materials in simple forms

INFORMATION - Prep for repair, recycling, through accessibility, labelling, modularity and manuals

PROTECTION - Invest in durable materials and surface treatments for product protection

LIFETIME - Optimise for intended working life

UPGRADING - Design the product for upgrading and repair

ENERGY - Minimise user's energy

WEIGHT - Minimise weight

HOUSEKEEPING - Review routines to minimise resources

TOXICITY - Limit the use of toxic substances

FIGURE 30: THE 10 GOLDEN RULES OF SUSTAINABLE DESIGN

2.4.2 IMPLICATIONS FOR THE DEVICE

For the device goes, that a balance needs to be created between sustainability and practical requirements. As the device needs to meet a range of certain standards, such as hardness, medical grade certification, resistance to stress points, surface finishing, toxicity et cetera, a trade off must be made.

MATERIAL

Biomaterial

In exploring sustainable materials, biomaterials are often an attractive option. But when speaking about biomaterials, it is important to highlight the distinction between biomaterials and biodegradable materials (Icon Global Supply, 2023). The first one is merely created by renewable sources, like corn, sugarcane and potatoes. However, these biomaterials – bioplastics – are often not recyclable and only contribute to the microplastics on earth. Biodegradable biomaterials are made from starch, algae of cellulose, and can be broken down to their simpler compounds under the right conditions. However, for a medical device that has to perform for a longer time, that requires thorough cleaning in-between users, this characteristic is not very desirable.

Recycling bioplastics is also often challenging. Many are incompatible with current recycling streams, which can lead to contamination. When bioplastics contaminate regular plastic waste, the entire batch often has to be sent to a landfill. This limited recyclability makes bioplastics less eco-friendly, as they can be as harmful as traditional plastics when they cannot be recycled effectively.

Luckily, as written by Medical Plastics News (2024), some bioplastics such as PLGA and bio-based polyamide 11 (PA 11), are already used in medical applications.

In another article, written by Banga (2024), next to PLGA and PA 11, PLA, PHA, PHB, PGA and PHU are mentioned as other biopolymers that are used in medical applications. Not only Banga (2024) but also DeStefano et al. (2020) highlight that especially biodegradable PLA, produced by lactic acid bacteria, shows promising applications in the medical field due to its biocompatibility and biodegradability. As stated by Plavec et al. (2020) PLA is also well suited for recycling, although a mix of PLA and PHB shows even better resistance against degradation.

FIGURE 31: EXAMPLE OF BIOPLASTIC (FREEPIK, 2025)

Regular medical plastics

A trade-off however, must be made whether these bioplastics outperform original plastics, such as PE (HDPE), PP, PEEK, PMMA, TPS, PC or ABS (Allison, 2024), in quality as well as in price. This, because if the product may last for 50 years, application of bioplastics may not add much extra value.

Therefore, when consulting Ansys material database (Granta EduPack, 2023), you can see that already in these well known polymers, there is a vast difference in sense of performance. Figure 32 shows one example where hardness is compared to the CO2 footprint of these plastics. Here you can see that many do not deliver the certain quality that is desired for medical grade products.

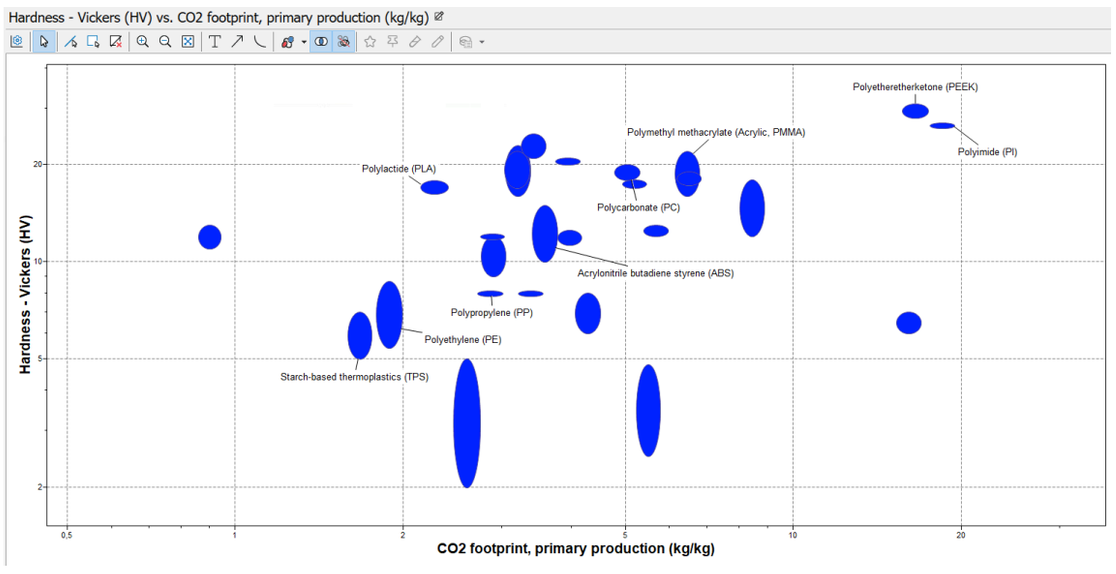


FIGURE 32: COMPARISON OF HARDNESS VS. CO2 FOOTPRINT FOR PLFOR HARD-PLASTICS (GRANTA EDUPACK, 2024)

PEEK	Too expensive and bad CO2 footprint
PMMA	Transparent features are unnecessary
PLA	Is biodegradable but performance is not up to standards
PP	Has potential but degrades easily during use and under UV, so no
TPS	Starch based, yet too soft for medical application
Acrylic Medical Grade	Too expensive for non-invasive use (more meant for implants)
PC	Has potential, tough & impact resistant, Biomedical applications
ABS	Potential, tough & impact resistant, (some) biomedical applications

FIGURE 33: COMPARISON OF SELECTED PLASTICS

Figure 33 shows the trade off of these polymers, based on the different comparisons done in Granta EduPack (2023). Appendix D shows the other comparisons of these polymers.

Recycled medical plastics

There is in terms of sustainability, also potential in not looking at biomaterials, but rather at the recycling of already used medical plastics.

As stated by Simoes et al. (2012b) 'Recycling is undoubtedly a solution to solve the crisis of plastic pollution'. Whilst considering this, it is important to note that in the medical sector of the Netherlands alone, 1.3 million kilograms of plastic waste from polypropylene wrapping paper on surgical instruments is produced annually (Van Straten et al., 2021).

All of this medical waste is categorised as either 'hazardous' or 'non-hazardous' (Kheirabadi & Sheikhi, 2022). 'Hazardous plastics' are plastics that in some way could be contaminated with bacteria, bodily fluids or anything else considered a source of infection. These plastics are either burned, incinerated or disposed of in landfills (Joseph et al., 2021). However, the 85% that is categorised as 'non-hazardous' medical waste is often not recycled properly (Kheirabadi & Sheikhi, 2022). When indeed selected for recycling, a material has to be cleaned anyway, to prevent any type of infection from accidentally happening. The type of cleaning required is often dependent on the type of plastic (Kheirabadi & Sheikhi, 2022), Figure 34. The cleaning process ranges from relatively easy and safe operations, such as autoclaving, to more dangerous processes, using radiation or certain acids.

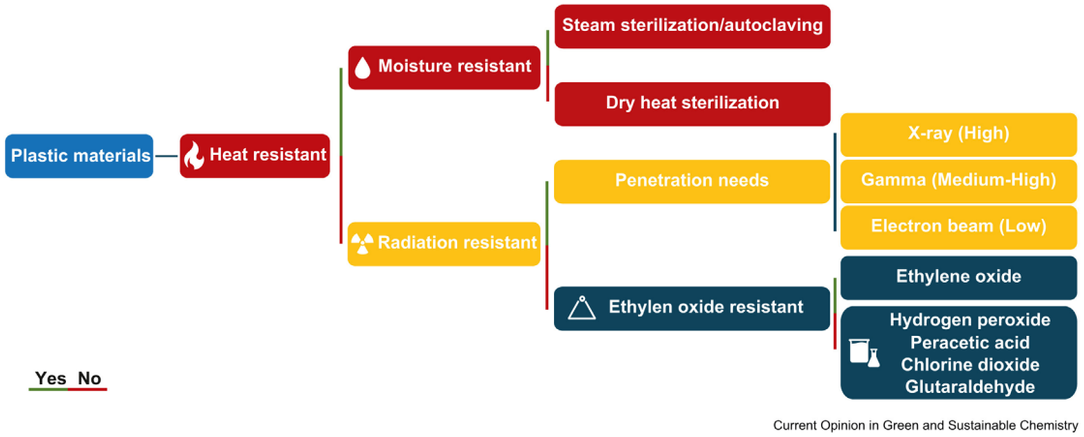


FIGURE 34: REQUIRED METHOD OF CLEANING DEPENDENT ON PLASTIC TYPE FOR MEDICAL PLASTICS (KHEIRABADI & SHEIKHI, 2022)

As can be seen in Figure 35, created by Joseph et al. (2021), plastic that is indeed collected, sorted and cleaned for recycling typically goes through one of these four routes. Unfortunately, the quality of the plastic decreases significantly per chosen route. For route 1, the quality is still fairly high, whilst route 4 generates plastic of a very low quality.

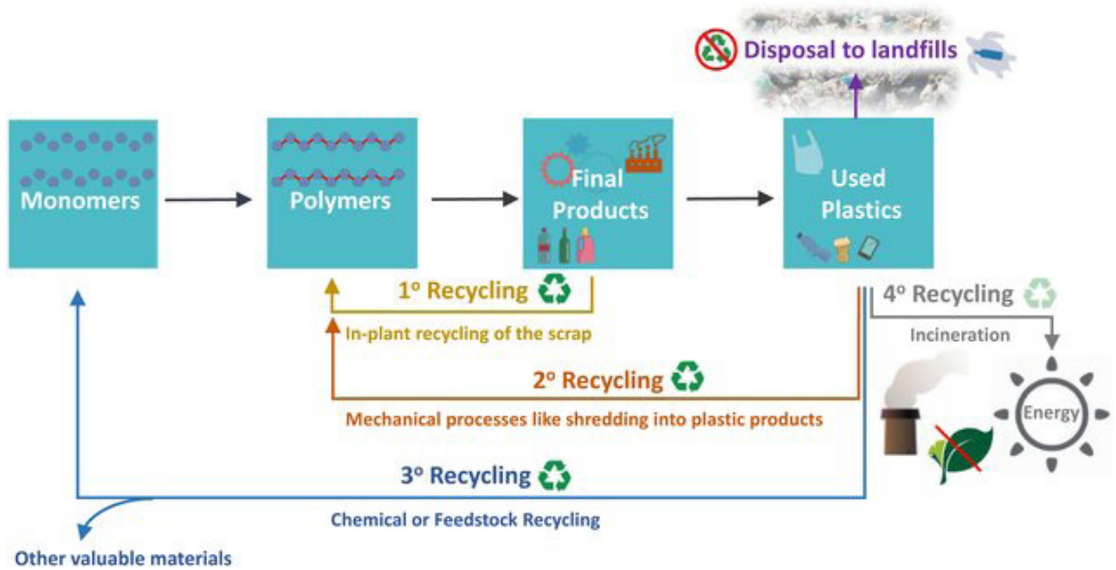


FIGURE 35: DOWNGRADING OF PLASTIC THROUGH DIFFERENT RECYCLE ROUTES (JOSEPH ET AL., 2021)

Despite these steps being relatively costly and cumbersome, there is proof that recycling medical waste is doable and is already being done by several companies. For instance, the PVC Med Alliance in Australia and New Zealand already collects IV bags, face masks and oxygen tubing from 200 hospitals for recycling. The recyclate, which is of high-grade quality, is used to manufacture mats, hoses and other useful products (PVCMed Alliance, 2024). The same company also collects PVC IV bags in South Africa, where they are being recycled into school shoes for disadvantaged children. In this case, only 20 IV bags are needed for a pair of shoes. See Figure 36.

However, whether this type of material is or could be allowed for medical devices, is to be confirmed with the MDR. The MDR does not give a specific list of materials that can or cannot be used, but requires for several clinical tests to be done and safety requirements to be met. A summary of the MDR can be found in Appendix E.

FIGURE 36: IV BAGS COLLECTED FOR RECYCLING (PVCMED ALLIANCE, 2024)

PRODUCTION

The chosen production method also plays an important role in ensuring the sustainability of the device, particularly by enhancing its repairability and recyclability. Avoiding the use of adhesives and permanent connections is essential, as these can make disassembly difficult and prevent the replacement of individual components.

Instead, the use of modular designs with screws or snap-fit connections allows for easy repairs, extending the product's lifespan and reducing waste. However, for snap-fit applications it is important to consider the product's requirement of waterproofness.

Additionally, limiting the variety of materials used in the device simplifies the recycling process. Using as much of the same material as possible ensures that components can be processed together without the need for separation, making end-of-life recycling more efficient.

2.4.2 IMPLICATIONS FOR THE PATCH

Most ECG patches are non recyclable at all. An ECG patch is often composed of a metal (often silver / silver-chloride) electrode, a soft sponge on top, and some gel for conduction. This bundle of elements is then enclosed with a foam sticker.

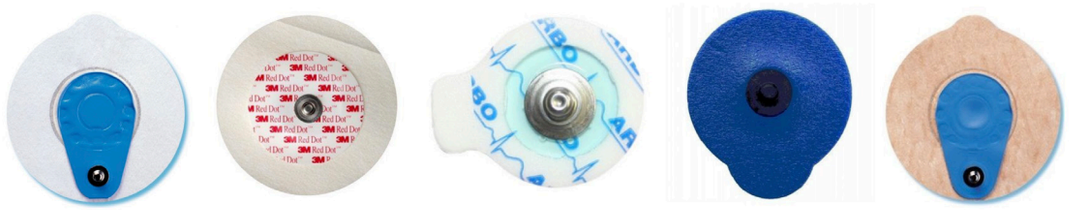


FIGURE 37: DIFFERENT VARIATIONS OF ECG PATCHES (FREEPIK, 2025)

As can be seen in Figure 36, most patches look fairly alike, and can not be taken apart easily for recycling. Therefore, often the whole patch is disregarded as residual waste, and either buried as landfill or incinerated.

MATERIAL

There is however a new type of electrode currently being developed. The VTT — Technical Research Centre of Finland — has developed a sustainable patch that is fully recyclable (Behfar & Jaiswal, 2023), see Figure 38. The patch is made from nanocellulose and both the conductors and ECG electrodes are created with carbon ink. The nanocellulose degrades in soil and repulps in water through a controlled process for easy recycling. As they state themselves, *'the film is strong, flexible, transparent, breathable and has good printability.'* which are very promising qualities for future electrode patches.

BEHFAR & JAISWAL (2023)

'THE FILM IS STRONG, FLEXIBLE, TRANSPARANT, BREATHABLE AND HAS GOOD PRINTABILITY'

FIGURE 38: NANOCELLULOSE PATCH WITH CARBON PRINTED INK (BEHFAR & JAISWAL, 2023)

PRODUCTION

However, as this new material is probably not yet market ready, nor medically qualified, current patches could already improve their sustainability by manner of fabrication. For instance, incorporating 'tear-lines' near the electrodes and cables could make it easier to separate these components from the patch after use. Although this would require manual intervention, enabling such separation could be an important first step towards facilitating recycling. By designing patches with disassembly in mind, manufacturers could pave the way for a more sustainable approach, even within the constraints of existing materials. See Figure 39.

FIGURE 39: TEARLINES IN ECG PATCHES FOR INCREASED RECYCLABILITY

2.4.4 KEY INSIGHTS

1. **Value Hill**
   Device and Patch require different approaches and therefore solutions
2. **Biomaterials or biodegradables**
   Often not of required quality nor approved for medical appliances
3. **Recycled medical waste**
   There is potential but many hurdles to overcome (quality, regulations, costs)
4. **Repairability**
   Minimise different materials and no use of glue
5. **Nano cellulose patch**
   Best option in terms of innovation and sustainable design
6. **Tear-lines**
   Potential interim solution for unsustainable patches

The key insights formed in chapter 2 are the foundation of the full list of requirements. The full list of requirements can be found in Appendix F.

FIGURE 40: "ALL PAWNS PLAYING A PART" - KEY INSIGHTS COMING TOGETHER (FREEPIK, 2025)

03 DESIGN REQUIREMENTS

The design phase of this project was structured around a set of themes derived from the key insights gathered in the four pillars. These themes were established to provide clear focus areas during the design process, ensuring that no critical aspects were overlooked.
They serve as a framework to guide the design, testing, and iteration phases, connecting the insights from research to actionable design strategies. The full list of requirements that came out of this analysis can be seen in Appendix F.

CHAPTER 3.1

DEFINING THE THEMES

The process of clustering resulted in 6 themes; Comfort, Attachment, Application, Adjustability, Feedback and Practicalities. The overview of these themes and how they reflect the research findings can be seen in Figure 41.

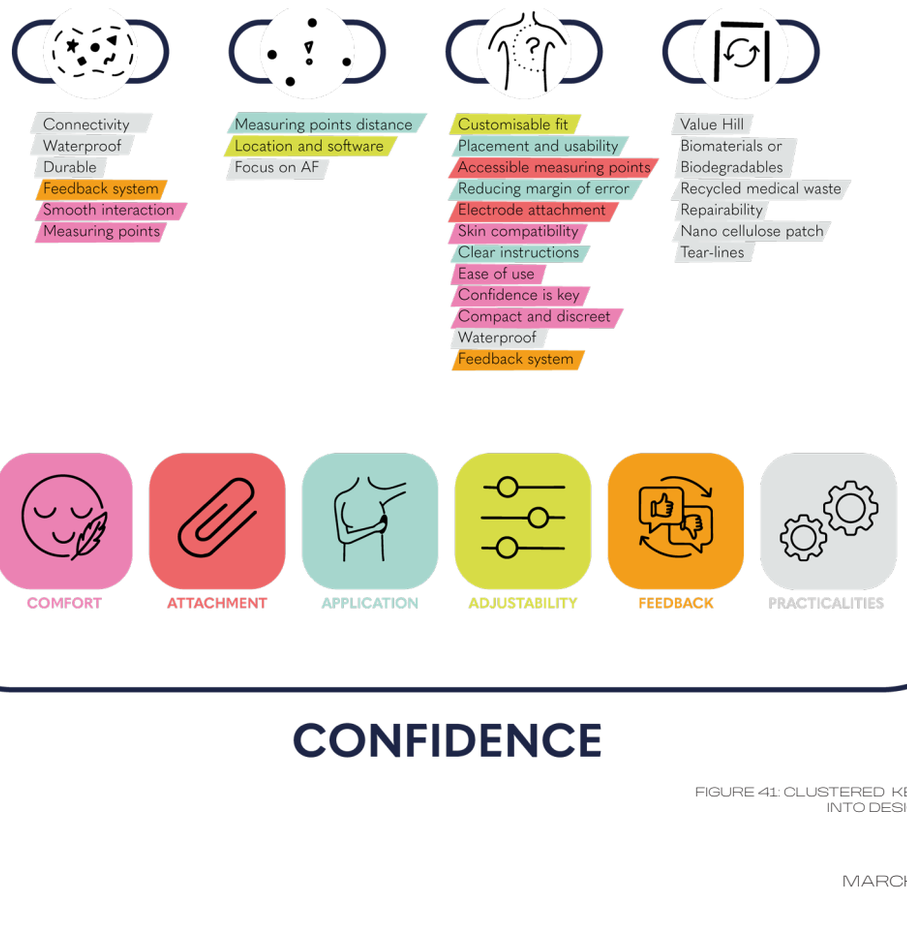


FIGURE 41: CLUSTERED KEY INSIGHTS INTO DESIGN THEMES

COMFORT

This theme is critical for the whole interaction with the device. It needs to be unobtrusive and pleasant to wear throughout daily activities. This includes ensuring the device does not irritate the skin, feels comfortable when worn during sleep or exercise, and does not cause discomfort when applied. Additionally, comfort extends to the ease of applying and removing the device.

ATTACHMENT

The attachment method determines how the electrodes and the device stick to the body. This includes evaluating whether adhesives, alternative mechanisms, or a combination are most effective. The research and tests explored how attachment methods are implemented in other fields, such as diabetes patches, feeding tubes, and medical plasters, see Appendix B. To gain further insight, interviews were held with a dermatologist from the Erasmus MC and a wound care specialist from Mölnlycke. These expert perspectives helped identify options that balance secure attachment with user comfort and skin compatibility. Additionally, the shape in combination with the material were tested to ensure suitability.

APPLICATION

This theme focuses on how the device is activated, put on and removed. This theme is about identifying ways to ensure the user knows exactly where and how to place the device, and what might make the process clearer or more intuitive. Options such as an accompanying app, a physical manual, or a hybrid solution were explored to guide the user effectively. The goal was to create a seamless experience that empowers the user to confidently apply the device independently.

ADJUSTABILITY

Adjustability ensures that the device can fit a wide range of body types and sizes. To address this, testing consistently included women with varying breast sizes to understand the impact of body diversity on the fit and function of the device. Subsequently, these findings were also evaluated on men to ensure inclusivity.

FEEDBACK

Feedback refers to how the device communicates with the user. This includes exploring various forms of feedback, such as vibrations, sounds, or visual signals, and determining what the user wants to feel, hear, or see. It also considers what types of feedback may be undesirable in certain situations, such as auditory signals that could be disruptive or embarrassing. To evaluate these options, "Wizard of Oz" techniques were used to simulate feedback and observe user responses, ensuring the final design aligns with user preferences and needs.

PRACTICALITIES

This theme harnesses all the functional requirements of the device and patch, such as material specifications, waterproofing, and durability. These considerations could only be made once a clearer idea of the device's overall design direction and form language was created. This theme came more into play towards the end of the design iterations to ensure the device would meet its essential performance criteria.

COMMON GOAL

What these themes have in common is that they all share a common purpose. They all contribute to the overarching vision of confidence. Confidence is the driving force behind the design decisions, as the ultimate goal is to enhance people's confidence:
The confidence to wear the device in public, the confidence that the device will function correctly, and confidence in their ability to apply and use it independently. To make them feel assured and self-reliant. This sense of confidence must be reflected consistently across all themes.

CHAPTER 3.2

TEST INSIGHTS

To answer to the specific needs and requirements every theme poses, a set of tests was developed. Each test had its own goal and therefore specific approach. Methods such as the C-Box (Van Boeijen et al., 2020), Hits & Dots (Heijne & Van Der Meer, 2019), Think Aloud Co-Creation set-up (Kerr, 2024) and others, were used to develop these tests.

An overview of these tests, and their individual goal can be seen in Figure 42.

All tests together have led to the following collection of shapes and designs. The results of these intermediate iterations can be seen in Figure 43.

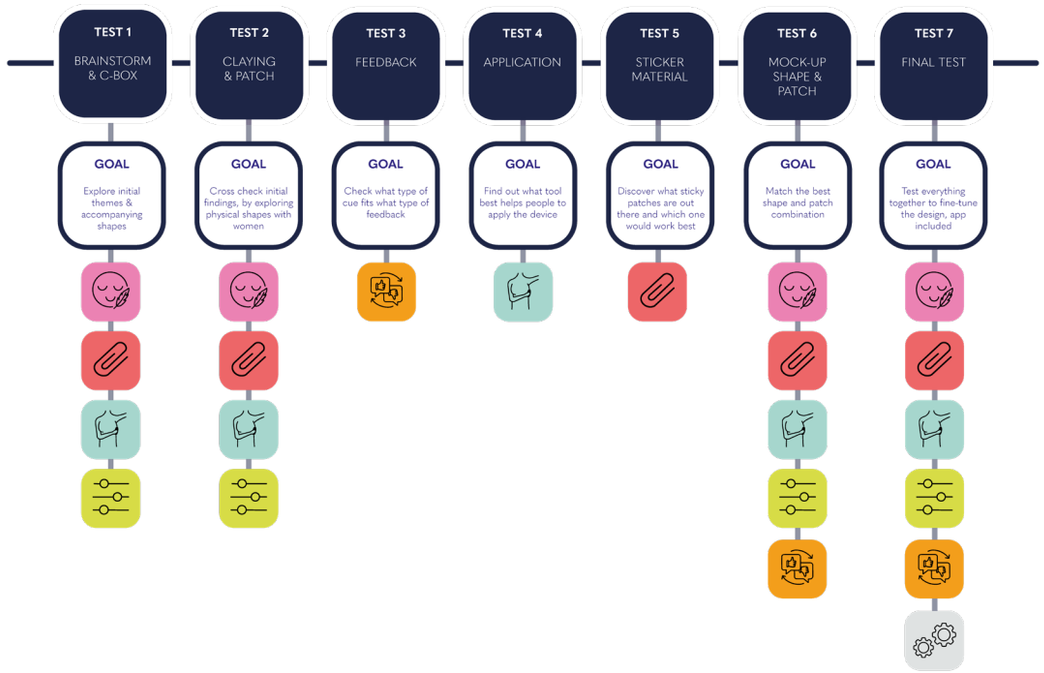


FIGURE 42: TESTS, THEIR GOAL, AND THE INCLUDED DESIGN THEME

FIGURE 43: DESIGN ITERATIONS ALONG THE WAY

Some images from the tests are shown in Figure 44A, 44B and 44C. Thoughts about the final design, ideation or quick ideas were collected throughout the tests as sketches, to make sure all concidered shapes were recorded. A few of these sketches can be seen in Figure 45.

A summary of the findings from the tests is depicted in Figure 46. For a more elaborate description of all the tests, the used methods, approaches and findings, see Appendix G.

FIGURE 44A: PARTICIPANTS CLAYING IN CO-CREATION SESSION DURING TEST 2

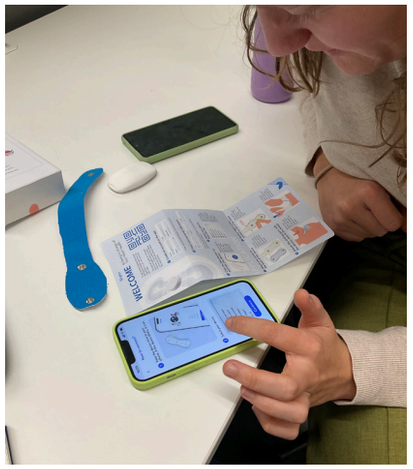


FIGURE 44B: PARTICIPANT INTERACTING WITH MANUAL AND APP DURING TEST 7

FIGURE 44C: PARTICIPANT TRYING OUT THE PATCH DESIGN DURING TEST 6

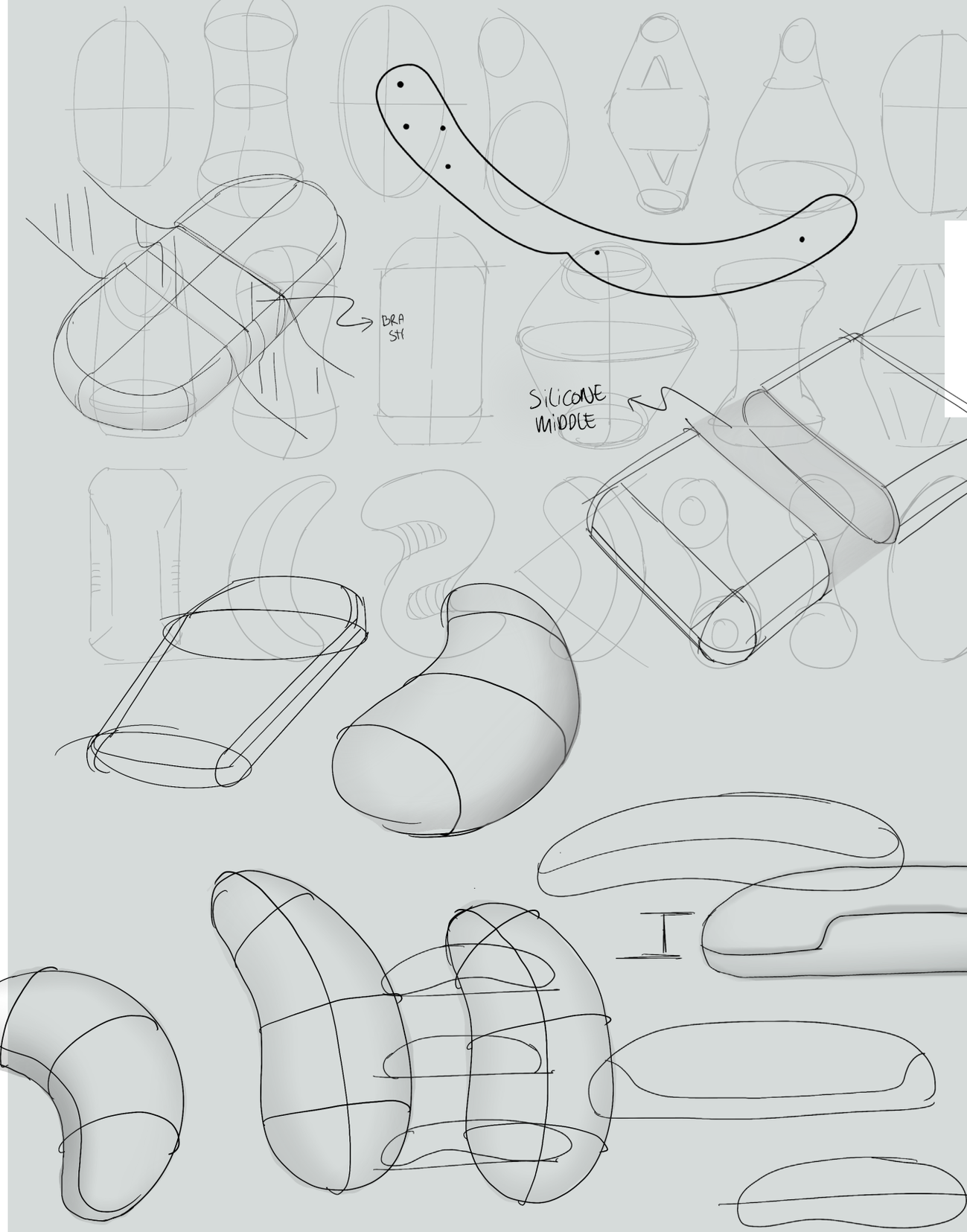


FIGURE 45: SKETCH IDEAS ALONG THE WAY

TEST 1

BRAINSTORM & C-BOX

GOAL

Explore initial themes & accompanying shapes

FINDINGS

Analysis revealed diverse solutions for placement, including positioning the device **under or beside the breast**, rather than on top. Suggestions for application included **magnetism, clip-ons, and bra pockets**, alongside both digital and physical tools. However, ideas varied widely, requiring further exploration.

TEST 2

CLAYING & PATCH

GOAL

Cross check initial findings, by exploring physical shapes with women

FINDINGS

A **compact, flat** patch was preferred over a larger or thicker design, with placement above the breast and under the arm for comfort. A separate clip-on device was rejected due to practicality concerns, as it would require a larger patch and constant bra usage. Silicone casing was deemed unsuitable because it becomes sticky and attracts dirt over time. Application accuracy is crucial - users need either 100% correct placement or **reassurance that slight misalignment is acceptable**, which could be improved with a visual application guide. **Movability** should be considered, ensuring the patch does not restrict daily activities. The measuring tape attachment method was ruled out due to high failure risk. Users emphasised that **application must be intuitive and foolproof**, or there must be clear communication that small errors won't affect performance. Testing different sticker-based patches will help determine the best adhesive for comfort and security.

TEST 3

FEEDBACK

GOAL

Check what type of cue fits what type of feedback

FINDINGS

Participants preferred simple, time-dependent feedback, with **urgent alerts using strong vibrations and medium-priority ones using slow pulses**. Sound was undesirable, and light cues were ineffective as they are only visible in hand. All feedback should be **app-based**, with less urgent updates shown on the home screen or a menu. Vibration rhythms were too confusing, and only the most necessary cues should be on the device. Buttons should be concealed, and notifications should consider **time sensitivity**, as a low battery warning at night is more urgent than during the day.

TEST 4

APPLICATION

GOAL

Find out what tool best helps people to apply the device

FINDINGS

The app is essential for operating the device, and the **manual should clearly direct users to it**, rather than suggest standalone use. Instructions must appear before each step, as delayed guidance caused confusion. **Detailed explanations** boost confidence, especially for older users, who need explicit, step-by-step clarity. **Visual confirmation**, like lights or vibrations, reassures users that actions were completed correctly.

TEST 5

STICKER MATERIAL

GOAL

Discover what sticky patches are out there and which one would work best

FINDINGS

The **silicone sheet** was the most comfortable, while kinesiology tape adhered best but caused slight skin irritation over time. Hydrocolloid patches performed well but were harder to source in larger sizes. Slits improved flexibility but also increased edge curling, which could be mitigated with **rounded corners**. Patch length tests suggested that **1/4 of chest circumference** was ideal, though slightly shorter patches may be preferable for better fit and adjustability.

TEST 6

MOCK-UP SHAPE & PATCH

GOAL

Match the best shape and patch combination

FINDINGS

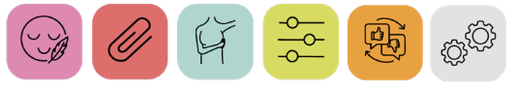
The shape of the device did not hinder users, even during sporting activities, and the placement was well received, as long as it **wasn't under the bra wire**. The patch material was comfortable, but attaching it should be easier, and **clearer tear lines** would help. Stretch-cut patches conformed better than a flat sheet, which was prone to creasing. In terms of application, users needed **bigger fonts**, **clear example images**, and **leading titles** to improve clarity. **Bluetooth activation should be mentioned**, and the app remains essential, though its role should be better **aligned with the manual**.

TEST 7

FINAL TEST

GOAL

Test everything together to fine-tune the design, app included



FINDINGS

Sleeping and showering worked well, with a sports bra improving comfort. Placement instructions should **warn for positioning too close to the armpit**, which led to detachment due to skin movement. **Recessed ECG buttons** improved comfort and adherence, as protruding buttons limited skin contact and caused pressure points. **A smoother backside** design significantly enhanced patch stability. Too many slits in the patch improved flexibility but also weakened adhesion, suggesting that **one well-placed slit may be better than multiple**. The **final electrode area should be slightly extended** to ensure a secure fit.

FIGURE 46: MAIN TEST FINDINGS

04 THE FINAL DESIGN

The insights gathered from the previous tests, has led to every new design iteration, ultimately shaping the final design presented here. This chapter explores the use case scenario from A - Z and provides a comprehensive breakdown of each component of the design. Decisions made throughout the process come together.

FIGURE 47 & 48 WHAT EDITH (LEFT) & EMILY (RIGHT) WOULD LOOK LIKE WEARING THE DIPLORA DEVICE

CHAPTER 4.1

THE DESIGN AND USER SCENARIO

Figure 47 and Figure 48 shows how the device and patch will look on the body. The device is attached next to the breast, behind the bra-wire, with the patch running over the breast. The outer ECG lead is located in line, of the middle, of the clavicula.

The final design consists of three main components: the device, the patch, and the manual. Each of these elements is further detailed in the following chapters, where their specific features, functionality, and design decisions are explained. To provide a comprehensive understanding of how the design comes together, this chapter starts with a user scenario, exploring how the patient uses it, and a use case of the total ecosystem.

Figure 49 and Figure 50 show what the patch and device together would look like.

FIGURE 49: SHAPE AND PATCH COMBINED

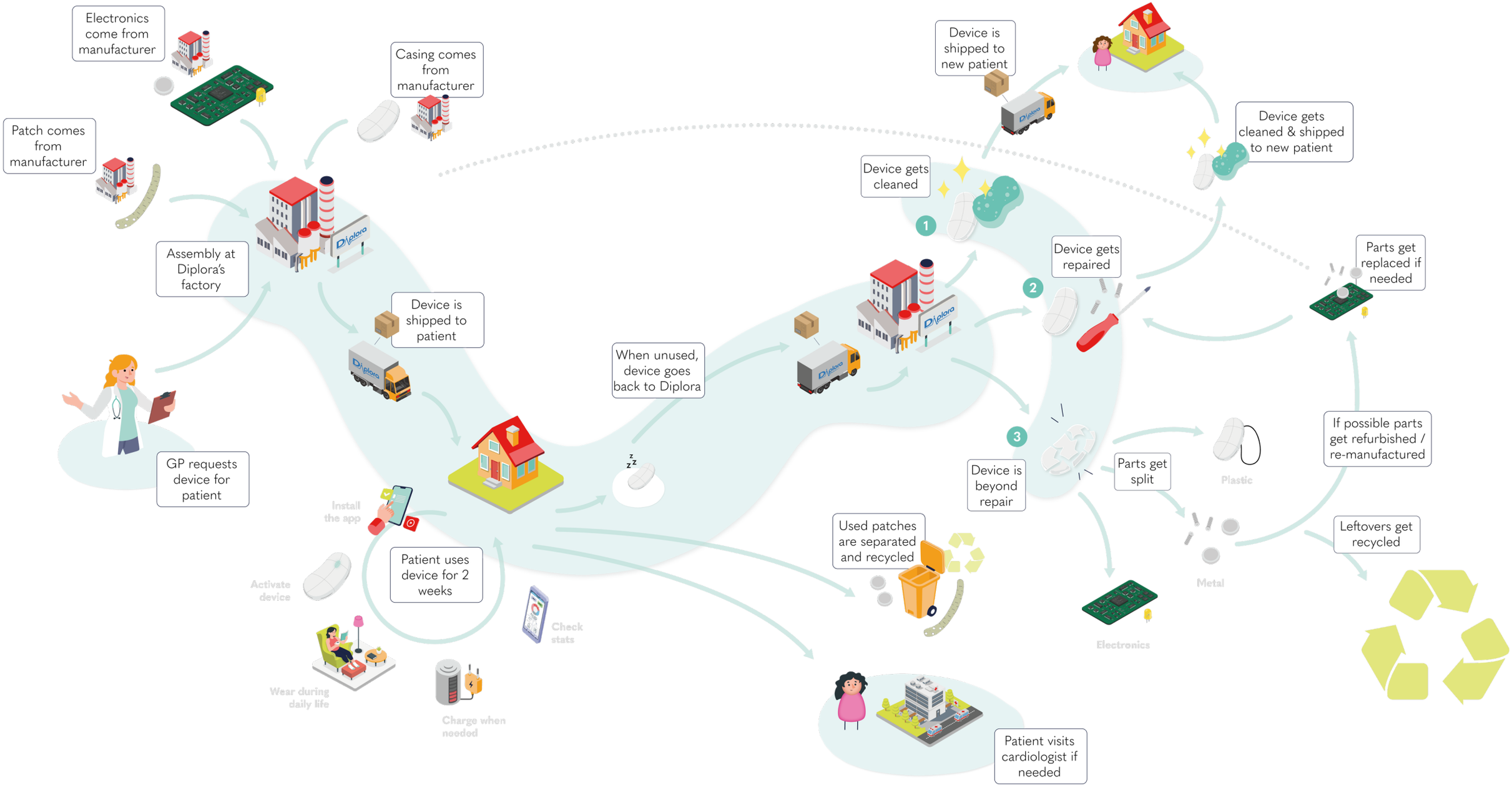
FIGURE 50: SHAPE AND PATCH SEPARATE

USER SCENARIO: HOW DOES SHE USE IT?

The user visits the GP with suspected heart problems. The GP agrees and has a Diplora ECG shipped to the patient's house. At home, the patient receives the package and opens the box. The patient follows the instructions given by the app and manual, and attaches the device on her body. The device is connected properly and alerts the patient if something is wrong. The patient can go sporting, showering and live her daily life, as if not wearing any device. After 2 weeks, she receives a reaction from the doctor that all is well. She doesn't need the device anymore so she sends it back to Diplora for the next patient to be used. The scenario can be seen in Figure 52. Figure 51 shows another indication of where a woman would wear the device.

FIGURE 51: WOMAN WITH LOCATION INDICATION

FIGURE 52: USER SCENARIO



USE CASE, TOTAL ECOSYSTEM

Additionally, a use case scenario is created to illustrate the product's lifecycle and interactions. This scenario shows how the product is assembled, used, and maintained. Scenarios such as repairs, recycling, or repurposing of the device and its components are also highlighted, ensuring a clear understanding of the product's sustainability and user-centred design. See Figure 53.

FIGURE 53: FULL ECOSYSTEM OF THE DEVICE AND PATCH, FROM PRODUCTION TO RECYCLING

CHAPTER 4.2

THE DEVICE

In Figure 56 you can see the top and bottom of the casing, that contains the key parts of the design, including the LED, coil, battery, PCB, IMU, vibration motor, rubber ring for waterproof enclosure, ECG buttons, O-rings for the ECG buttons, M2 screws with their own O-rings and the thread inserts. This visualisation illustrates these components fit together, inside the complete product.

4.2.1 EMBODIMENT

SHAPED FOR COMFORT

As user comfort is one of the most important characteristics, the chosen final shape is drawn from all previous iterations. For enhanced comfort, the upper part of the device has a rounded profile to contour naturally to the body. The bottom part is also rounded but includes a larger flat surface to ensure stable attachment of the ECG measuring points. See Figure 54 and 55.

QI CHARGING

For this design QI wireless charging is favoured over standard USB-C cable charging for several key reasons. A USB-C port is challenging to waterproof properly, requiring an additional O-ring and assembly step. Furthermore, since the device is worn on the body, dust and skin debris can easily collect in the port, affecting its functionality over time.

Another critical concern is moisture. To prevent short circuits, a charging port should ideally dry for several hours before use. However, in practice, most users are unlikely to wait this time period, or will potentially forget, thereby shortening the product's lifespan.
Wireless charging eliminates these risks, offering a more durable, user-friendly, and maintenance-free solution.

FIGURE 54: TOP AND BOTTOM CURVATURE

FIGURE 55: 3D VIEW OF THE DEVICE

FIGURE 56: TOP AND BOTTOM VIEW OF THE CASING

FIGURE 57: EXPLODED VIEW OF THE DEVICE

LOCATION OF EACH ELEMENT

Figure 57 shows the exploded view of the device. Here, the coil, needed for QI wireless charging, is placed in the top part of the device, in its designated enclosure. Here, it can potentially be shielded from the battery, and is furthest away from the ECG leads, to prevent disruption of the signal. This means the device shall have to be charged upside down, but this step shall be made extra clear to the user in the app and manual. See also chapter 4.4.

In the device, the LED is placed in the top part of the device, closest to the top of the casing, to allow the activation light to shine through. Next to the LED is the battery also located in the top section, to maximise space efficiency.

These elements rest on top of the PCB. The PCB consists of 2 parts; the top half regulating the QI charging from the coil to the battery, and the bottom part for storing, processing and sending out the ECG signals to the Diplora server.

Beneath the PCB, the IMU – used to measure the orientation of the device – and the vibration motor are positioned. The vibration motor is deliberately placed on the bottom half of the casing, as this section makes direct contact with the body. This placement ensures that the strongest vibration signal is transmitted to the user.

The ECG leads are located at the bottom, so they can be in contact with the skin, to acquire the electrical signals from the heart.

LED USE

The LED is included for user feedback. As the device will be worn next to the breast, the LED will deactivate whenever the device is in location.

The LED will however be active whenever interaction with the device is needed. When activating the device, the LED will blink blue, searching for bluetooth. When connected to the users app, the LED will shine contiously blue (Figure 58).

When the battery is in serious need of charging, or the electrodes lost connection, the LED will glow red, even when on the body, to allert the user. *(Alerts can also mean vibration and/or app notifications, see also chapter 4.4.1)*

FIGURE 58: DEVICE WITH ACTIVATED LED

FIGURE 59: TOP HALF OF THE CASING

WATERPROOFING

The device is made of a durable and waterproof casing, with the top and bottom part enclosing the electronic components. Waterproofing is achieved through a combination of features, including a double wall, a raised edge, and rubber O-rings. The largest O-ring is not circular but follows the shape of the device, fitting precisely between the top and bottom sections to create a watertight seal. The ECG electrodes are individually sealed with rubber O-rings, as are the screws. The screws not only secure the device but also contribute to its waterproof integrity by clamping the two halves tightly together, preventing water to seep through.

Figure 59 and Figure 61 show what measurements are taken in the design. The triangular raised edge helps to clamp the rubber ring. Figure 60 illustrates how the ECG buttons would be attached.

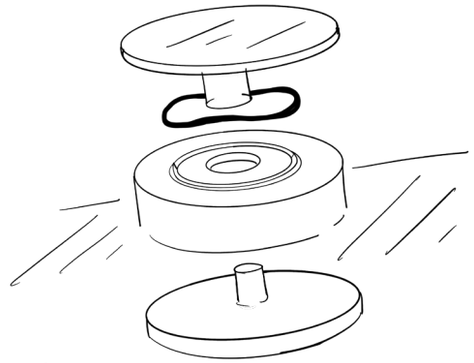


FIGURE 60:
SCHEMATIC DRAWING
OF WATERPROOFING
THE ECG BUTTONS

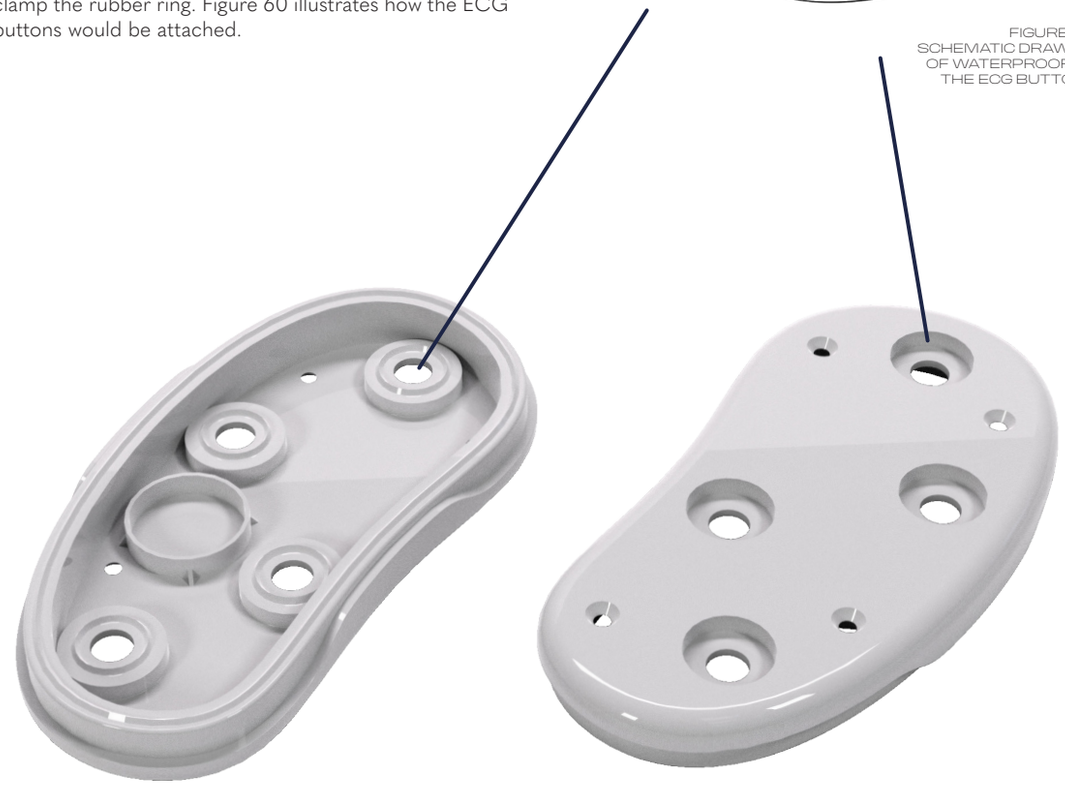


FIGURE 61: BOTTOM HALF OF THE CASING

4.2.2 MATERIAL

The choice for material of the device is based on several considerations, as can be seen in Figure 62.

	Sustainability	Medical Grade	Production	Performance	Price
PC	PC's longevity can make it a better choice for long-term durable products	Better bio-compatibility and sterilisation resistance. High medical grade	More challenging to injection mould, requires more precision	Superior impact resistance, heat resistance and strength. Ideal for long-term use	More expensive, about 3.11 - 3.38 €/kg
ABS	ABS slightly better sustainable wise for production	Some variants are bio-compatible, yet not inherently designed for skin contact	Easier to injection mould, requires less energy to do so	Good impact resistance. Sensitive to UV exposure	Less expensive, about 2.44 - 2.56 €/kg

FIGURE 62: PC VERSUS ABS TRADE-OFFS

Polycarbonate (PC) stands out as the preferred choice due to its high medical grade and proven durability for long-term use. This material is resistant to scratches, retains its glossy finish, does not degrade under UV light, and can be effectively sterilised in an autoclave. These properties make it an excellent option for a device that needs to withstand repeated use and maintain its quality over time.

Although PC is more expensive and requires a more precise manufacturing process, its durability and premium quality justify the higher cost. In the long term, investing in such a high-quality material ensures the creation of a product that can last for many generations, ultimately delivering greater value.

4.2.3 MANUFACTURING TECHNIQUES

The manufacturing process for the device involves a combination of pre-manufactured and custom-made components. The electronic components, such as the battery, LED, and IMU, could be sourced from external suppliers. The same will go for the O-rings, which are standardised and readily available.

The PCB however, will likely need to be custom-made to fit precisely within the casing. A standard rectangular PCB would not maximise the available space, and its dimensions might not align with the ergonomic and functional requirements of the device.

The top and bottom parts of the device are best manufactured using injection moulding, a process that will allow the device to be efficiently produced. The thickness of the top and bottom shall be 1mm PC, to optimise internal space and maintain a lightweight design. Polycarbonate (PC) is a good material for this process due to its versatility and suitability for injection moulding. Although PC requires precise moulding conditions, including tight control over temperature and pressure, the resulting components are of very high quality and durability.

However, to ensure structural integrity and successful injection moulding without defects, several things have to be considered.

UNIFORM WALL THICKNESS

Maintaining a consistent 1 mm wall thickness throughout the design is essential to prevent uneven cooling, warping, and internal stresses during the injection moulding process.

REINFORCEMENT RIBS

Reinforcement ribs will be added in critical areas, such as near the screw insert tubes, to provide additional strength without significantly increasing weight or material usage.

DRAFT ANGLES

Many walls in the current design are perpendicular to the pull direction, which can cause difficulty when removing the part from the mould. Introducing draft angles of 1–3 degrees on these surfaces would benefit the demoulding process, reduce the risk of damage, and extend the life of the mould.

VENTILATION AND VACUUM PREVENTION

In cases where draft angles cannot be applied, additional air vents or ventilation holes in the mould may be necessary to prevent vacuum formation, and to ensure smooth ejection of the part. Proper venting also helps avoid defects caused by trapped air.

FLOW OPTIMISATION

The gate placement in the mould must be strategically designed to ensure smooth and even flow of the molten PC. This minimises the risk of incomplete filling or weld lines, particularly in thin sections.

While the initial cost of producing moulds for injection moulding can be high, this technique is highly efficient for mass production, ensuring consistent quality and cost-effectiveness over large volumes. For a product like this, where precision, durability, and aesthetics are essential, injection moulding offers the optimal balance between functionality and scalability.

4.2.4 ASSEMBLY

The assembly of the device is designed for repairability and water resistance, using four M2 flat-head screws, each 8 mm long, and a custom-shaped rubber O-ring.

The screws ensure that the top and bottom parts of the casing are securely fastened together, while the O-ring provides a watertight seal by fitting precisely between the two halves.

The lower casing features recesses for the ECG buttons, which are secured with individual O-rings to ensure waterproofing around each electrode. The lower part also forms the base plate for the electronic components, including the PCB, battery, vibration motor, IMU and LED. The upper casing contains extended tubes to allow for M2 thread inserts. These inserts allow for a strong and reliable connection between the screws and the casing, making sure that the device can be assembled and disassembled without damaging the plastic material.

The assembly process is as follows:

1. The thread inserts are placed in tubes of the top part.
2. The coil, needed for QI charging is placed in its designated spot in the top half.
3. The ECG buttons are attached to the lower casing, with O-rings positioned to create a waterproof seal around each button.
4. The vibration motor and IMU are placed in their designated areas in the bottom half of the casing.
5. The PCB is secured onto the bottom half, with the battery and LED on top.
6. The upper casing is aligned with the lower casing, ensuring that the components fit securely and that the O-ring is evenly compressed. The assembly is completed by fastening the top and bottom parts together using four M2 screws. Between the M2 screws and thread inserts 4 mini O-rings are also placed.

FIGURE 63: ASSEMBLY OF THE DEVICE

4.2.5 COSTPRICE

Determining the costprice of a product is always challenging, as it depends on a wide range of factors. It is influenced not only by the chosen production or assembly methods, but also by the number of parties involved in the process, and the amount of processes that can be automised or require hand-labour. Some components are purchased off-the-shelf, while others need to be custom-made, which significantly impacts cost.

Each individual part comes with its own cost variables, whether in terms of materials, production complexity, or logistics. Key factors include production volume – as higher quantities generally reduce unit cost – the country of manufacture, where labour costs and regulations play a major role, and the desired quality level. Additionally, there is the question of whether assembly will be handled in-house or outsourced, which further affects the overall cost structure.

Beyond production costs, there are also significant investment costs to consider. These include not just practical expenses such as mould-creation, but also certification, design development, market penetration efforts, and other essential steps. For this reason, the cost of manufacturing a device does not directly reflect the final retail price, as additional percentages for VAT, overhead, distribution, and market competition adjustments must also be factored in. Given the many fluctuating variables, making an exact cost estimate is difficult, and Diplora will need to refine these calculations in collaboration with industry experts.

For now, a set of assumptions is made to provide a cost estimate. It was assumed that an initial production batch of 5,000 units would be a reasonable starting point. Since market penetration is still in its early stages, 5,000 units seemed like a practical first estimate. Another assumption was that final assembly would happen in-house. Additionally, it is assumed production would take place in either Eastern Europe or Asia, both of which influence costs. However, this is of course debatable with an eye on sustainable practices. The full analysis can be viewed in Appendix H.

Based on these assumptions, the estimated cost price per device was calculated as follows:

€3.24 for injection moulding of the top and bottom casing, along with the rubber seal.
€38.55 for the purchase and assembly of all electronic and mechanical components, from the PCB and LED to the M2 screws and their inserts.
When factoring in VAT, overhead costs, distribution, and market pricing adjustments, the estimated final retail price would be **€105.26**.

While these numbers provide a general indication, the final cost structure will require further validation based on actual supplier quotes, logistics costs, market conditions and of course Diplora's preferences.

The set-up of this cost analysis was build upon a lay-out created by Erik Thomassen & Erik Tempelman, both from the department of manufacturing and material science at the TU Delft, IDE faculty. This initial set-up was then supplemented with information derived from various websites (Topworks, 2024), (Bowden, 2025) and personal communication with Erik Tempelman.

FIGURE 64: IMAGINABLE FUTURE. WAREHOUSE (UNSPLAH, 2025)

CHAPTER 4.3

MEASURING POINTS

To transmit ECG measurements from the device, the data first needs to be accurately collected. This is achieved through the patch, which replaces traditional separate electrodes with an all-in-one solution. By integrating multiple electrodes into a single patch, the system enhances both practicality and ease of use for the user. This streamlined approach simplifies application, improves comfort, and ensures reliable signal quality without compromising performance.

4.3.1 EMBODIMENT

So, as the patch has been designed as an important component of the device-system, balancing functionality, comfort, and adaptability is crucial. The patch is constructed using a Mepitel One (Mölnlycke, n.d.) inspired material, chosen for its skin-friendly properties and flexibility. The patch is shaped to fit the contour of the chest, with carefully positioned cut-outs to ensure flexibility and adaptability to the body's natural curves, as can be seen in Figure 65.

At its core, the patch incorporates a conductive wire system that leads signals from the embedded ECG buttons into the device. The wire runs through the patch, connecting the ECG buttons at the following points:

1. Four ECG buttons are located at one end of the patch, designed to click securely into the device. Two of these are ECG buttons used for acquiring a signal. The other two are used as receivers for the buttons mentioned under 2. and 3.
2. One ECG button is positioned at the opposite end of the patch to capture signals from the furthest point, ensuring comprehensive heart monitoring.
3. A central ECG button is added to capture an additional signal.

FIGURE 65: THE PATCH

PROTECTIVE STICKER LAYER

The backing of the sticker, which protects the adhesive side before application, has an intuitive layout that corresponds with both the manual and the app (see also chapter 4.4). As shown in Figure 66, the cover is divided into two sections. The first section covers the part of the sticker positioned beneath the device, allowing the user to attach this part first to the body, without the rest of the sticker being sticky already.

The second section can only be removed after the first, thanks to the double-fold design. The ECG button cutouts are pre-perforated in the protective layer, ensuring they do not remain stuck underneath the buttons when the cover is peeled away. Once the second section is lifted, patients simply need to align the outermost button with the centre of their left clavicle, making the application process both intuitive and precise.

FIGURE 66: PROTECTIVE STICKER LAYER

EXPANDABLE PATCH PACKAGE

The patch's orientation and shape have been carefully designed to run from the side of the chest – where the device is located – curving upwards over the breast, to a position above the heart. This, to acquire the necessary signals for proper measuring of potential AF.

While the current patch has been tailored for this specific AF observation, the design allows for future expansion. Additional patches and shapes could be developed to extend the range of diseases to monitor. Such a patch could, for instance, curve downward beneath the heart for broader coverage. This modularity could allow for adaptability to diverse patient needs and scenarios. See Figure 67.

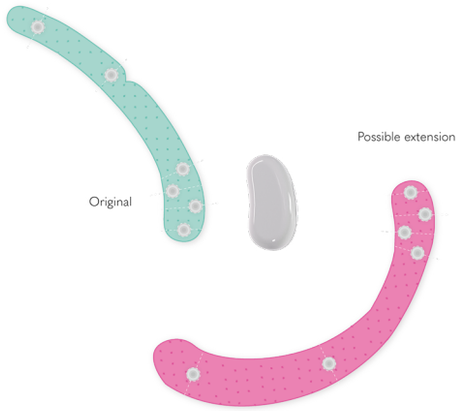


FIGURE 67: EXPANDABLE PATCH PACKAGE

OVER-PATCHES

Additionally, inspired by diabetes sensor patches, an extra 'over-patch' could be provided with the current patch to improve longevity. This over patch is made of a thinner film layer, which can be used to re-attach corners that are coming loose during use. See Figure 68.

FIGURE 68: OVER-PATCHES AS USED FOR DIABETES PATCHES

4.3.2 MATERIAL

The Mepitel One (Figure 69) material offers several advantages that make it well-suited for medical applications, particularly where skin-friendliness and adaptability are key considerations. It uses Safetac technology (Davies & Rippon, 2008), which is a soft silicone adhesive that adheres gently to the skin without causing skin irritation during use or removal (Personal Communication with Dermatologist, 2024). This property makes it ideal for longer term use.

The patch is also highly flexible and conformable, which allows it to adapt very well to body contours. This flexibility makes it particularly suitable for applications on the chest or other areas with significant movement. Furthermore, Mepitel One adheres on one side only, preventing it from unintentionally sticking to clothing and maintaining its position effectively.

Another significant advantage of the material is its somewhat 'reusability'. It can be lifted and reapplied a few times without losing its adhesive properties, allowing for some alterations during the application process. This reduces waste as the patch is not directly unusable, and improves its overall practicality.

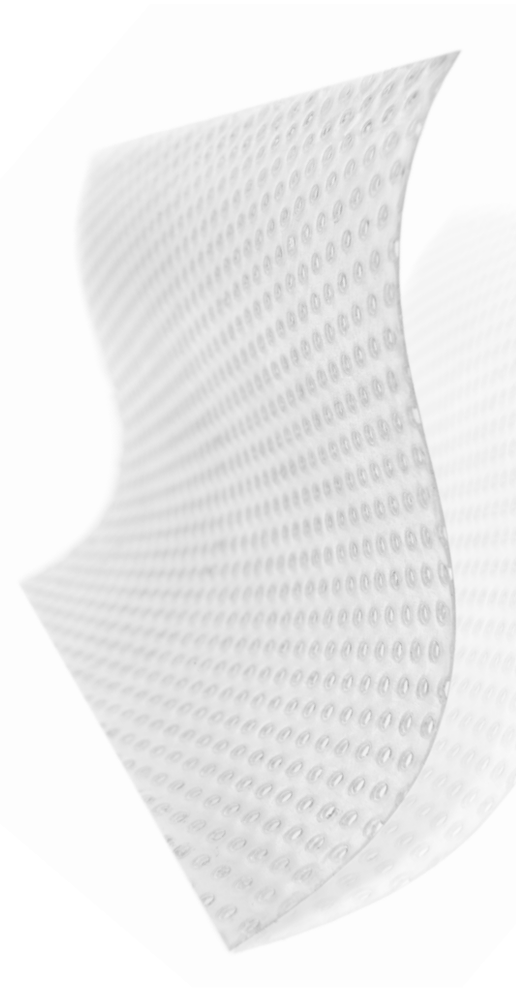


FIGURE 69: MEPITEL ONE SHEET (MOLNLYCKE, N.D.)

4.2.3 MANUFACTURING TECHNIQUES

The manufacturing process for the device involves a combination of pre-manufactured and custom-made components. The electronic components, such as the battery, LED, and IMU, could be sourced from external suppliers. The same will go for the O-rings, which are standardised and readily available.

The PCB however, will likely need to be custom-made to fit precisely within the casing. A standard rectangular PCB would not maximise the available space, and its dimensions might not align with the ergonomic and functional requirements of the device.

The top and bottom parts of the device are best manufactured using injection moulding, a process that will allow the device to be efficiently produced. The thickness of the top and bottom shall be 1mm PC, to optimise internal space and maintain a lightweight design. Polycarbonate (PC) is a good material for this process due to its versatility and suitability for injection moulding. Although PC requires precise moulding conditions, including tight control over temperature and pressure, the resulting components are of very high quality and durability.

However, to ensure structural integrity and successful injection moulding without defects, several things have to be considered.

FIGURE 70: ASSEMBLY OF THE PATCH

4.3.4 ASSEMBLY

For assembly, a multi-step process is used to combine the buttons, wire, and patch material into a single cohesive unit:

1. The patch material is die-cut into the required shape, including slits and attachment points.
2. The conductive wire is laminated or adhered onto the patch, to connect each ECG button to its designated endpoint.
3. The ECG buttons are inserted into pre-cut holes and secured to the wire.

See also Figure 70.

4.3.5 COSTPRICE

The costprice estimate of the patch shall be slightly different from the costprice of the device. This, as the patch will presumably be fully outsourced, and bought from the relevant supplier. Standard ECG patches are currently mass-produced by large corporations such as 3M or major Chinese manufacturers, allowing for very low production costs. However, these low-cost patches are typically made from foam-based materials, which differ significantly from the Mepitel One patch in both composition and functionality.

When purchased at retail price, Mepitel One is relatively expensive, costing approximately **€0.57 per cm^2**. In contrast, low-cost ECG patches can be sourced for as little as **€0.02 - €0.05 per cm^2**, depending on material quality and volume agreements. However, it is important to note that retail prices do not reflect bulk production costs. The surface area of the patch is 171.62 cm^2, and if all VAT, profit margins, and other markups are removed from the €0.57 per cm^2 retail price, the patch would come down to **€35.83**. This is, of course, still a high price for a disposable patch. However, considering that cost optimisations are still possible, fewer of these patches will be needed compared to standard ECG patches, and health insurance providers may potentially contribute if the Diplora ECG will be covered, there is a realistic opportunity to further reduce this price.

To add to that, if a direct collaboration with Mölnlycke's production division were to be established, a more cost-effective and scalable solution could be negotiated. By securing such a strategic supply agreement, pricing could be significantly reduced, making the patch more commercially viable for large-scale deployment.

While the exact cost per unit remains dependent on these – yet to be made – arrangements, volume commitments, and customisation requirements, the outsourced production model ensures that Diplora does not need to invest in in-house manufacturing. This would be an important factor in keeping operational flexibility high and cost efficiency optimised.

CHAPTER 4.4

THE MANUAL

While the device and patch are crucial for functionality – measuring heart activity and detecting potential issues or arrhythmias – there is another key element that ties everything together: the manual. Research quickly revealed that ease of use and building user confidence hinge on clear instructions. Although the app is indispensable for operating the device, the paper manual allows for inclusivity, for those who prefer to read from paper.

Both the app and the manual have been designed to ensure clarity and accessibility for a diverse range of users. Below, the specifications and design considerations for both are outlined. The app officially also interacts with a healthcare dashboard for medical professionals, however this integration fell outside the scope of this project.

4.4.1 THE APP

The Diplora Health app serves not only as a tool for activation and monitoring, but also as a source of guidance, empowering users to use the device confidently. The app's design prioritises clarity and inclusivity, making it suitable for a diverse range of users.

To begin, users must download the Diplora Health app (Figure 71) and either log in or create an account. Once logged in, the app will ask the user to connect their device. A simple tap on the connect button establishes the connection, during which the device's LED begins to pulse blue, providing a visual confirmation of the connection process. When the connection is successfully established, the LED will emit a steady blue light. This synchronisation between the app and the device is there to reassure the user that the system is functioning as intended.

Following the connection process, the app guides the user through the application procedure, offering a step-by-step instruction on how to correctly attach the device and patch. The instructions are designed to be explicit and easy to follow, incorporating visual aids and animations for added clarity. In the future, a video instruction could even be added. Once the device is applied, the LED automatically turns off to ensure it remains discreet when worn underneath clothing. For further optimisation and increased clarity, an instructional video could also be added.

All other screens can be seen in Appendix I.

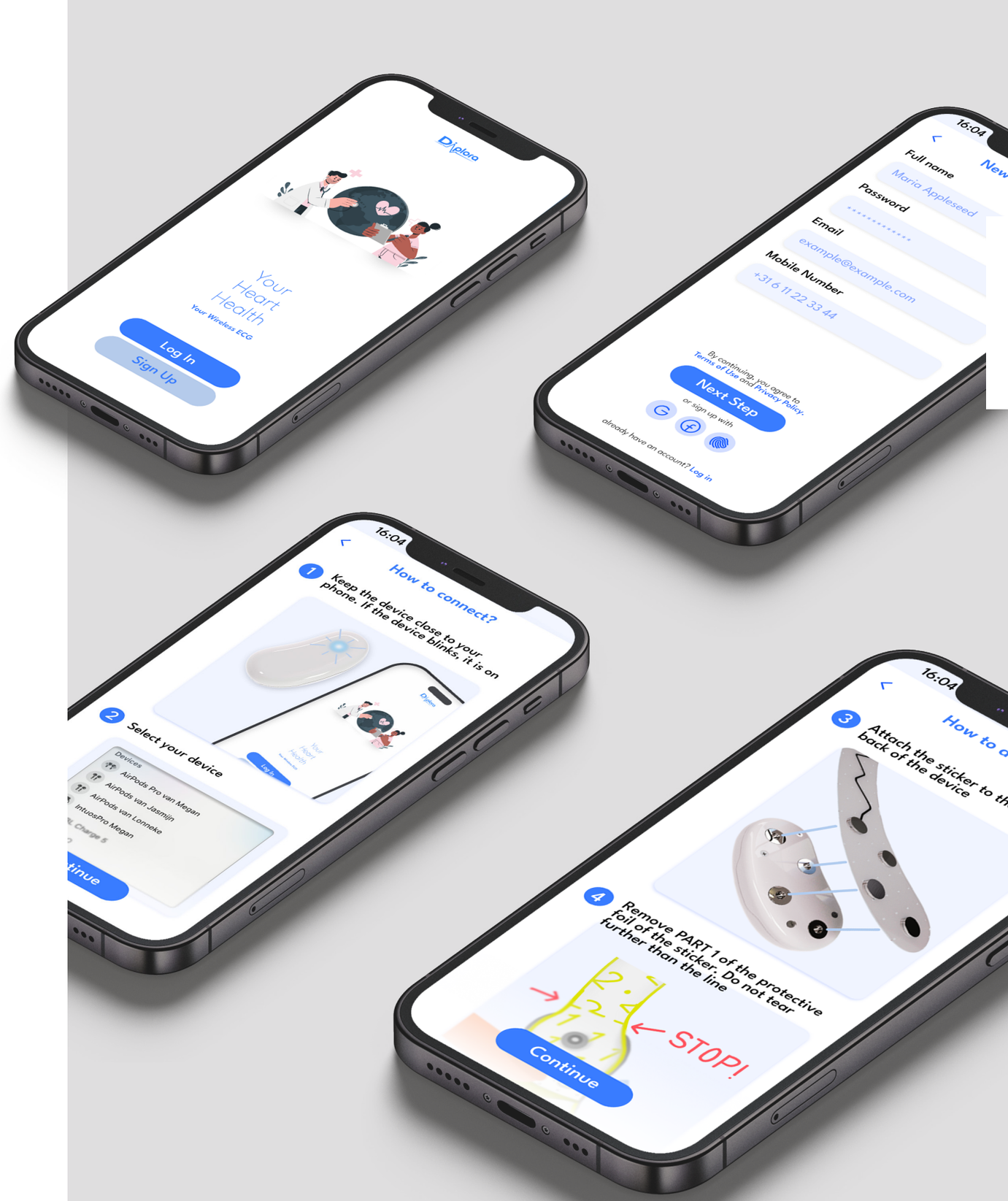


FIGURE 71: SEVERAL SCREENS OF THE APP

FIGURE 72: HOMESCREEN OF THE APP

On the app's homescreen, see Figure 72, the patient can access their personal information, view their heart rate, and see heart rate trends from the past few days. The device's status is also displayed, including its battery level, the connection of the electrodes, and the link to the Diplora server.

Crucial notifications, such as a low battery or electrode detachment, are communicated to the user through push notifications on their phone. For urgent alerts, the device itself may also emit a vibration to even better capture the user's attention and urge for action to be taken. The intensity of the vibration can vary based on the urgency of the alert – such as a near-empty battery before bedtime versus during the day –. Optionally, the LED can also be programmed to glow red for specific alerts, allowing the user to notice issues visually, such as in a mirror.

Also, clear instructions are given as to when, and how, to charge the device. As the QI charging system is located in the top of the device, it has to be flipped over by the user. Although that may be somewhat counter intuitive, clear guidance could help users overcome this issue. See Figure 73.

Another feature of the app – with an eye on sustainability – is its ability to remind users when the device is no longer needed. Once the monitoring period is complete, the app sends a notification requesting the user to return the device to Diplora. This ensures that the device can be reused for the next patient, aligning with the sustainability goals of the project.

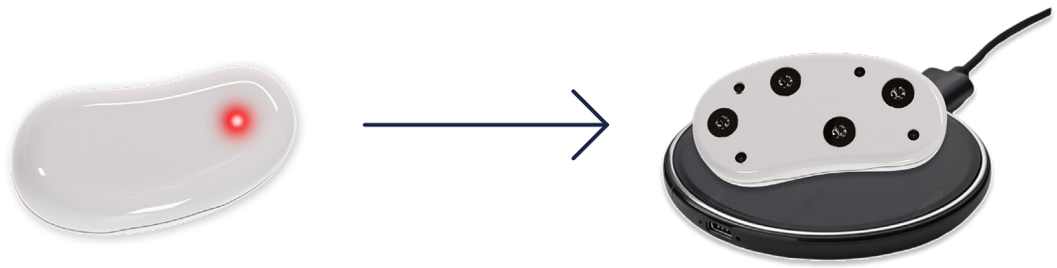


FIGURE 73: CHARGING ORIENTATION

4.4.2 THE PAPER MANUAL

In addition to the app, the paper manual is provided to support users during the setup and use of the device, see Figure 74. The manual is only designed as a supportive resource for the app. The manual itself also highlights that the device cannot function without the app. To reinforce this, the manual includes a download link – QR code – for the Diplora Health app, ensuring users know how to access it.

The manual mirrors the step-by-step guidance from the app, offering the same instructions for attachment and use. This consistency ensures that users who prefer a printed reference or need additional clarity can follow along easily.

Additionally, the manual provides an overview of the app's homescreen, explaining what each element represents – such as heart rate data, historical trends, battery status and electrode connectivity and also elaborates on the importance of 'upside-down charging'.

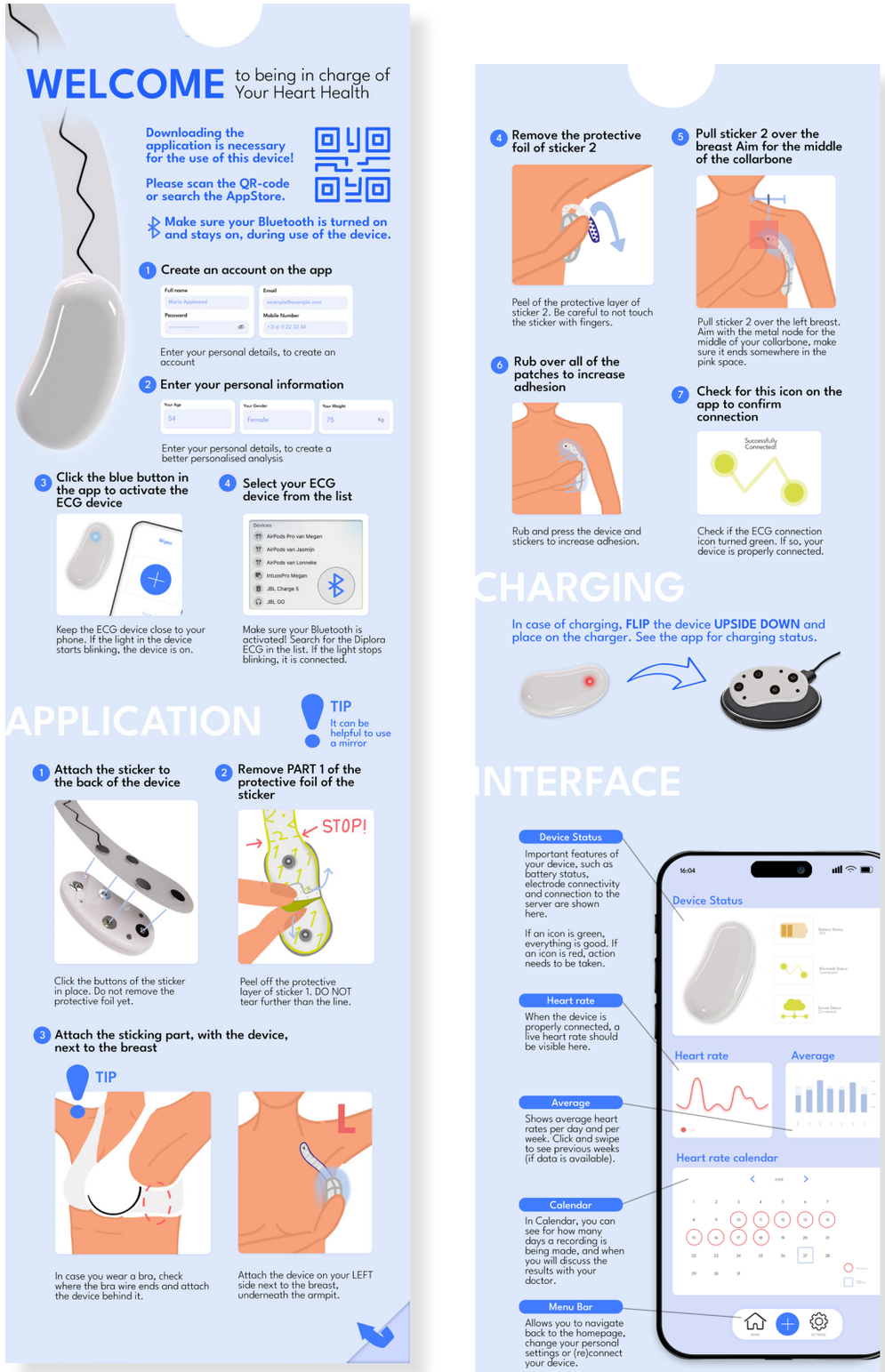


FIGURE 74: FRONT AND BACK OF THE MANUAL

05 THE NEXT STEP

The current design will be validated against the desirability, feasibility, and viability framework to ensure that the product meets user needs, can be successfully manufactured, and is sustainable as a business proposition. Additionally, the design will be evaluated in terms of sustainability and to determine whether it aligns with the established design goal and side objectives set at the beginning of this project. Limitations of the device will be evaluated as well.

To further assess the robustness of the design, an FMEA has been conducted. This identifies potential risks in the current design & highlights opportunities for improvement, ensuring that the product is reliable and fit for use.

CHAPTER 5.1

FINAL VALIDATION

For the final validation, the complete product was presented to users, to recreate a real-world interaction. Therefore, the packaging, wrapper and user manual were optimised and printed, while the patch and device were equipped with buttons and a wire, reflecting how it would likely appear when properly introduced to market.

The test participants were selected to represent the personas Edith and Emily, covering the opposite ends of the P5 - P95 size and age range. Both participants had previously used a traditional Holter monitor, allowing them to provide direct comparisons between the conventional design and the new solution.

To create an authentic test setting, the scenario was structured as follows: participants were first asked to imagine that they had just visited their doctor. The doctor would then say, "You will receive a Diplora ECG, which will be delivered to your home." The participants would then receive the package, as designed for this test, and were simply asked to do whatever felt natural. Unwrapping; reading; assembling; everything was allowed and the intention was to see whether the flow of use was intuitive. Participants were encouraged to think aloud as they interacted with the product. After the test, they completed a questionnaire assessing the Confidence Factors, previously used in earlier tests, for final comparison.

FIGURE 75: EXTERIOR OF THE CREATED WRAPPING

FIGURE 77: REAL MODEL OF HOW THE CONCEPT WAS PRESENTED

FIGURE 78: PICTURES MADE DURING THE FINAL VALIDATION

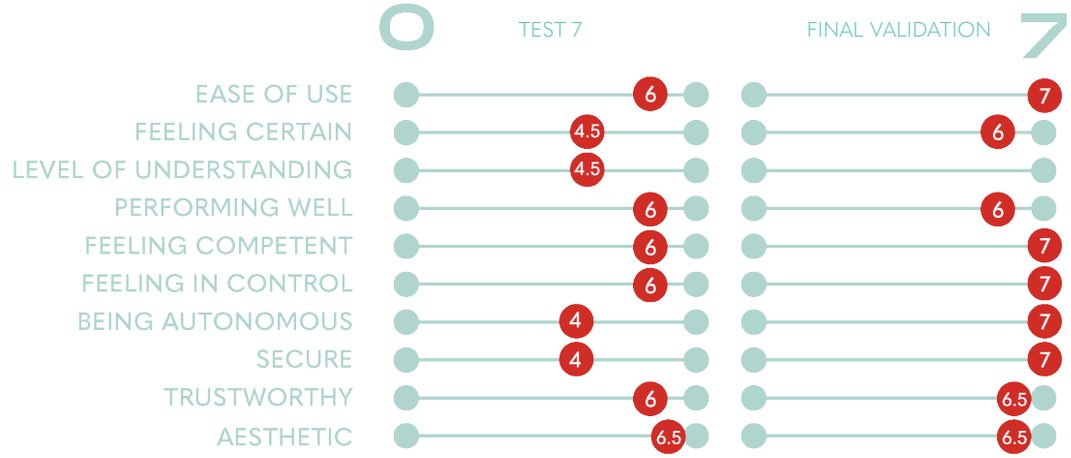


FIGURE 79: CONFIDENCE SCORES OF TEST 7 COMPARED TO THE FINAL VALIDATION

FIRST IMPRESSION

The initial responses were very positive. One user said: *"A huge improvement! My God, what a difference!"* The users instinctively understood how the device and patch should be applied, mainly due to the clear orientation of the buttons and buttonholes, and the instructional image of the mannequin wearing the device on the wrapper. *"The image on the packaging says it all – it's crystal clear"* a user said.

Both users appreciated the smooth design and soft feel of the device and the fact that it sits discreetly under clothing. The placement next to the chest was perceived as ideal, and the users even tested the device in alternative positions, confirming that other placements felt less comfortable.

COMPARISON TO TRADITIONAL HOLTERS

A key finding was the significant improvement compared to traditional Holter monitors, which had previously caused a lot of frustration. One user, for example, had stopped trying to diagnose her condition with a traditional Holter because the wires made it unbearable. Another user noted that traditional Holter wires would get sweaty and uncomfortable, especially during the summer months or while changing clothes, *"however with this one? I wouldn't feel the urge to rip it off – I'd just forget it's even there."* Both participants immediately recognised the advantages of the new design:

- FEWER COMPONENTS
- MORE FREEDOM OF MOVEMENT
- NO LOOSE WIRES
- LESS IRRITATION, ESPECIALLY IN HOT WEATHER

PARTICIPANT (2025)

'A HUGE IMPROVEMENT! MY GOD, WHAT A DIFFERENCE!'

RATING OF THE CONFIDENCE QUALITIES

When comparing the final product to the previous iteration used in test 7 (end of chapter 3.2; test insights), there was already a big improvement, as can be seen in Figure 79. Yet of course, some things are still to be optimised.

So was the feeling of certainty in combination with competence not yet optimally scored. This was for one user caused by the fact that the manual and app instructions were given in English. She highlighted it would be very important to print the instructions in the language of the relevant country. Another user noted that this feeling did not really have anything to do with the design but simply with the fact that a user who is not a cardiologist will never be 100% certain that they are using it flawlessly, simply because of their lack of medical knowledge.

Both users felt confident that they could use the device correctly, thanks to the clear manual and intuitive design. The fact that the patch and device can only be attached in one correct way was very convenient to them. Both participants also trusted the device's reliability, assuming that if it were on the market, it would have passed all necessary regulations. They said the sleek, professional design contributed to this perception. Funnily enough, one user said: *"It looks sleek, but honestly, my first thought was: 'Can it really do the job if it's this small?' But at the same time, I wouldn't want it to be any bigger."* The only thing that didn't fully contribute to the aesthetics was the wire visible in the patch. This made the patch appear very 'medical' in one user's opinion.

PARTICIPANT (2025)

'THE IMAGE ON THE PACKAGE SAYS IT ALL – IT'S CRYSTAL CLEAR'

About the app they mentioned that they now felt more in control. With their old Holters they never knew what was going on, and now, they would have all the information in the palm of their hand.

ADDITIONAL COMMENTS

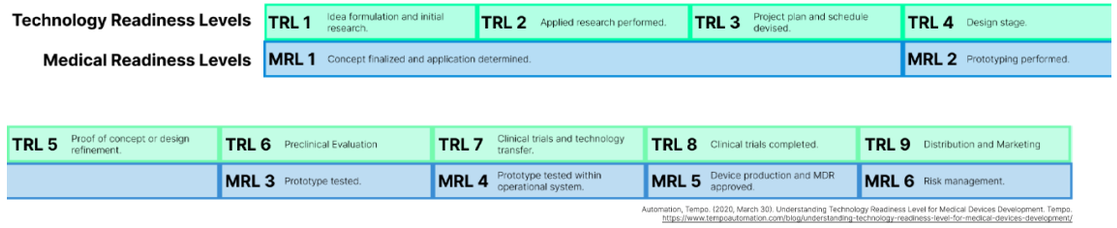
- It was suggested that the packaging insert, where the device rests on, would be closed – instead of a hole –, and be replaced by a recessed layer (somewhat like an eggbox)
- The home delivery model was highly appreciated, as it would reduce the number of visits to the cardiologist or GP.
- Multiple adhesive patches included in the packaging would be preferred.
- The possibility of a brief introduction by a doctor or nurse at the initial appointment was suggested for older or more uncertain patients, on how to use the Diplora device.

All other notes and scoring results can be seen in Appendix J. The creation of the confidence qualities they were asked to rate can be seen in Appendix K.

CHAPTER 5.2

EVALUATION CURRENT DESIGN

To further evaluate the current design to some important aspects this chapter will attend to the desirability, feasibility, viability, sustainability, initial design goals and limitations.



Automation, Tempo. (2020, March 30). Understanding Technology Readiness Level for Medical Devices Development. Tempo. https://www.tempoautomation.com/blog/understanding-technology-readiness-level-for-medical-devices-development/

FIGURE 80: TRL VERSUS MRL LEVELS (AUTOMATION, 2020)

5.2.1 DESIRABILITY // PEOPLE

The design has successfully prioritised user confidence by focusing on the needs and preferences of women. The product has been developed with and for female users, ensuring it is discreet and tailored to their comfort. However, also when tested on men, no signs of discomfort were mentioned. The placement of the device avoids direct interaction with chest hair, minimising discomfort. As this aspect was identified as a concern in traditional ECG devices by men, changing this made the current design more inclusive and comfortable for all users.

The combination of the device, patch, app, and manual have been highlighted by participants as 'a good team', all working well together. Questionnaires revealed that the product was described as "professional" and "trustworthy" in its design, and participants noted they would feel comfortable and confident wearing the device in public.

By improving the user experience and ease-of-use, the Diplora ECG system also redefines the role of long-term ECG monitoring by bridging the gap between primary and specialised care, making advanced cardiac diagnostics accessible at the GP level. It also helps to reduce unnecessary hospital visits, as early detection and monitoring allow treatment to start sooner, improving patient outcomes.

To add to that, shifting from traditional Holter monitors to a smarter, AI-driven system, aligns with the broader trend of digital healthcare solutions.

This way, the system introduces new meaning and value to the field of cardiology and remote patient monitoring, making ECG analysis more effective and accessible to a broader population.

5.2.2 FEASIBILITY // TECHNOLOGY

The device is designed for mass production, using standardised and recyclable materials like polycarbonate (PC) and silicone. The device casing has also been optimised for injection moulding, although some minor adjustments (e.g., draft angles and such) are left to optimise, in order to make the device fully production-ready. The electronic components fit well into the design, but further miniaturisation is of course always desired.

The patch, while promising in its current material and shape, requires further refinement for optimal performance. Improvements to the adhesion and durability are still needed. However, the app and manual have successfully outlined a clear interaction process, which, once fully functional, will complete the product package. Also, as the system is designed to integrate smoothly into the existing GP workflows, the system ensures ease of adoption without requiring major changes in current infrastructures.

From a readiness perspective, the design has advanced from Medical Readiness Level (MRL) 1 to MRL 3, aligning with Technology Readiness Level (TRL) 5, indicating significant progress (Tempo Automation, 2020), Figure 80. Future steps, including MDR validation and clinical testing, remain essential to launch the product. However, when these steps have been successfully taken, this shift from reactive diagnostics to proactive screening, diagnosing and monitoring challenges the existing norms in current cardiology and sets a new standard for the primary care.

5.2.3 VIABILITY // BUSINESS

The product addresses a clear market gap and offers an innovative solution. Especially within the European healthcare market, the direct competition still remains limited. However, the adoption of new technologies in healthcare can be slow due to strict regulations and sometimes resistance to change among healthcare providers.

Nevertheless, as this service-based model enhances affordability by ensuring that patients do not need to purchase the device, advanced ECG monitoring is made more accessible. Especially, when the product would be covered by insurance companies. However, to do so, it is important to invest in the trust and formation of partnerships with healthcare professionals.

To increase this trust from insurance companies, potential funds and healthcare professionals, it is very helpful that the Diplora system delivers a sustainable approach. By shifting from disposable ECG devices to a shared-use system, Diplora redefines sustainability in medical technology, ensuring a meaningful impact on healthcare accessibility and environmental responsibility. This product-service system could show how a sustainable and AI-driven solution can reduce the hospital workload, making cardiac diagnostics more efficient, while lowering overall healthcare costs.

This take on the design of medical products sets a new benchmark for responsible healthcare innovation, making the system not only viable today but adaptable for the future. And with this eye on the future, insurance providers should be able to see the value in this proposition and be keen to support this.

5.2.4 SUSTAINABILITY

OF THE DEVICE

The device has been carefully designed with durability, repairability, and recyclability in mind, ensuring a sustainable approach to its lifecycle. Therefore, the device has no glued components, making it easy to disassemble, repair, and replace parts when necessary. This optimised repairability extends the device's lifespan and significantly reduces electronic waste.

The device is primarily made of polycarbonate (PC), a strong, lightweight, and recyclable material. By minimising the mixing of different materials, the design enhances end-of-life recyclability, making it easier to separate and repurpose its components.

To support responsible use and disposal, clear instructions and guidlines are provided for the user – on how to maintain the device – and for the Diplora employee – on how to assemble and repair the device –. Additionally, its robust and impact-resistant design protects internal components from damage, reducing the likelihood of premature breaking. The elimination of a charging port in favour of wireless charging further improves longevity and durability, as it removes a common failure point and enhances waterproofing without requiring additional materials.

Another key sustainability factor is upgradability. The modular nature of the device allows for future enhancements without requiring a full replacement, aligning with circular economy principles and reducing electronic waste. Moreover, its lightweight construction not only ensures efficient material use but also contributes to lower emissions during transportation and production.

From a user maintenance perspective, the smooth, seamless design prevents dirt and debris build-up, making the device easier to clean without the need for harsh chemicals. In terms of safety and toxicity, the materials used, such as PC, are BPA-free and non-toxic, ensuring they are safe for both users and the environment.

MEANING

CONSTRUCTION - Use as few joint elements as possible, look for intelligent geometric solutions

MIXING MATERIALS - Use as few materials in simple forms

INFORMATION - Prep for repair, recycling, through accessibility, labelling, modularity and manuals

PROTECTION - Invest in durable materials and surface treatments for product protection

LIFETIME - Optimise for intended working life

UPGRADING - Design the product for upgrading and repair

ENERGY - Minimise user's energy

WEIGHT - Minimise weight

HOUSEKEEPING - Review routines to minimise resources

TOXICITY - Limit the use of toxic substances

FIGURE 81: SUSTAINABILITY SCORE FOR THE DEVICE

MEANING

CONSTRUCTION - Use as few joint elements as possible, look for intelligent geometric solutions

MIXING MATERIALS - Use as few materials in simple forms

INFORMATION - Prep for repair, recycling, through accessibility, labelling, modularity and manuals

PROTECTION - Invest in durable materials and surface treatments for product protection

LIFETIME - Optimise for intended working life

UPGRADING - Design the product for upgrading and repair

ENERGY - Minimise user's energy

WEIGHT - Minimise weight

HOUSEKEEPING - Review routines to minimise resources

TOXICITY - Limit the use of toxic substances

FIGURE 82: SUSTAINABILITY SCORE FOR THE PATCH

OF THE PATCH

Although the patch is a disposable component, its design has been carefully considered to make it as sustainable as possible, following the 10 Golden Rules of Sustainable Design (Van Boeijen et al., 2020).

One of the key aspects of sustainability in this design is the construction. While the product does contain mixed materials – including silicone, metal, and wiring – the design encourages partial separation. The patch features pre-perforated lines (Figure 83), allowing the ECG buttons to be easily separated from the silicone, when the patch is removed from the body. This enables users to dispose of materials properly, ensuring that recyclable components like the metal buttons can be processed separately. This can be promoted by clear labelling and instructions in both the app and manual to guide users on how to manage the waste properly.

Also, by creating an intuitive and easy-to-use application method, waste of mis-used patches is also being prevented.

The patch's lightweight design further contributes to sustainability by reducing material needed and improving transport efficiency, helping to lower its footprint.

The non-toxic materials, including silicone and metal, were carefully chosen to be safe for both users and the environment, avoiding hazardous substances wherever possible.

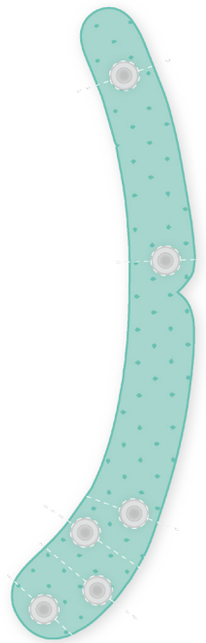


FIGURE 83: TEARLINES IN THE NEW PATCH

OF THE SYSTEM

Beyond the sustainable design of the device and patch itself, the Diplora system also contributes to environmental responsibility through its service-based model. Instead of being a single-use or individually owned product, the system operates on a circular use cycle, ensuring that each device is reused for multiple patients.

Patients receive the device on prescription from their doctor, after which it is sent directly to their home. Once they no longer need it, users are encouraged to return the device to Diplora, where it is made available for the next patient. By following this reuse-and-recycle approach, the system helps to minimise material consumption, reduce electronic waste, prevents unnecessary production of new devices, extends the device's lifespan, and ensures that resources are used as efficiently as possible. This all combined contributes to a more sustainable healthcare solution.

5.2.5 ASSESSING THE DESIGN GOALS & SIDE OBJECTIVES

Redesigning a wearable ECG device, prioritising user confidence, optimised for a reusable, two-week wearing period

DESIGN GOAL

→ The project has met its primary objective of redesigning a wearable ECG device that prioritises user confidence and is optimised for reusability. The combination of app, manual, and the device itself ensure a user-friendly and confidence-building experience. The two-week wearing period still has to be optimised by improvement of the patch.

Optimise the overall interaction of the app & process of application of the device and patch.

SIDE OBJECTIVE 1

→ The interaction between the app, patch, and manual has been optimised, providing clear guidance that supports user confidence during use, as confirmed by test participants and former Holter users.

Explore strategies for repair, reuse and recycling and incorporate these findings in the main objective.

SIDE OBJECTIVE 2

→ With use of the Value Hill Model (Achterberg, Hinfelaar, & Bocken, 2016) and the 10 golden rules of Design 4 Sustainability (Van Boeijen et al., 2020), sustainable strategies for repair, reuse, and recycling have been integrated into the design, particularly in the device casing and the patch material, ensuring alignment with the sustainability goals of the project.

5.2.6 LIMITATIONS

While this project presents a promising step towards a more accessible and efficient ECG system, several limitations must be acknowledged, highlighting areas for further research and development.

HARDWARE & TESTING CONSTRAINTS

Due to ongoing development, the working electronics could not yet be tested within the physical device. A crucial next step would be to validate the chosen electrode placement (on the left of and above the breast) by testing the system with a fully functional ECG and comparing the results against a standard 12-lead ECG in a hospital setting. Additionally, ensuring that the electronics fit, function correctly, and integrate seamlessly within the device remains a key area for improvement.

MANUFACTURING, WATERPROOFING & STRENGTH TESTING

The current prototype was 3D-printed, which was sufficient for this early-stage development and form factor validation. However, a next step would be to transition to injection moulding and incorporate the manufactured rubber sealing, allowing for proper waterproofing verification under real-world conditions. Additionally, it would be recommended to conduct stress and strain testing on the injection-moulded product to simulate long-term use and wear conditions. This would help assess the durability, structural integrity, and material performance over time, ensuring the device remains functional and reliable throughout extended periods of wear.

LIMITED TEST GROUP

The device was evaluated with a relatively small test group, which limits the reliability of the findings. Future studies should involve a larger and more diverse group of users to further refine the design, help assess usability, improve long-term comfort and collect sufficient data for training and validating the AI-driven analysis system.

PATCH EXTENSION & AI DATA ANALYSIS

An additional aspect that remains untested is the potential for an extended patch system. Further research is needed to determine several things. Namely;

User preferences – whether an expanded patch design would be desirable for patients.
Impact on AI analysis – whether this additional electrode placement would improve signal quality and diagnostic accuracy.
Necessity – whether the existing patch already provides sufficient data for reliable AI-driven ECG analysis, or not.

CHAPTER 5.3

FMEA ANALYSIS

No matter how well-designed a product may be, potential risks are always present. For the Diplora ECG system, it is crucial to identify and address these risks to ensure safety, reliability, and user confidence. Below, a detailed Failure Mode and Effects Analysis (FMEA) is conducted for the three main components of the system: the device, the patch, and the system as a whole.

– FMEA is a method used to analyse risks by identifying causes and solutions. It helps prioritise potential failures and assess whether proposed solutions might lead to new risks or errors. Each failure mode is then prioritised based on its Risk Priority Number (RPN), which is calculated by multiplying severity (S), occurrence (O), and detection (D) ratings (1-10) (Lean Six Sigma Groep, 2024). –

By analysing and studying these risks, preventive actions can be taken. This, to minimise these risks before they can occur. An FMEA of the casing, patch and system have been performed and can be seen in Figure 84, 85 & 86. It is advised, as a future step, to create a design and strategy resolving as many failure modes as possible.

CASING							
Failure Mode	**Potential Effect**	**Potential Cause**	**Severity (S)**	**Occurance (O)**	**Detection (D)**	**Risk Priority Number (RPN)**	**Recommended Action**
Device leaks water	Short-circuit of device electronics	Poor waterproofing, O-ring displacement	9	6	5	270	Test waterproofing extensively, improve seal design
Casing cracks	Exposure of electronics, loss of structural integrity	Material fatigue, insufficient wall thickness, production error	7	7	1	49	Increase wall thickness, add more reinforcement ribs
LED not visible	User unaware of device status	Poor positioning, LED broken	4	4	2	32	Adjust LED placement, or renew electronic part
Electronics short-circuit or overload	Electric shock the user	Water damage, poor assembly	9	4	7	252	Improve electronic assemblage, change parts
Overheating of device during use	User discomfort, user burns, device shutdown	Poor heat dissipation from PCB or battery	9	4	3	108	Add mini heatsink, add space in lay-out
Battery leakage	Device damage, user health risk	Faulty battery or over-charging	8	3	7	252	Change battery type to medical grade battery, include safety circuits

FIGURE 84: FMEA OF THE CASING

PATCH							
Failure Mode	**Potential Effect**	**Potential Cause**	**Severity (S)**	**Occurance (O)**	**Detection (D)**	**Risk Priority Number (RPN)**	**Recommended Action**
Patch detaches prematurely	Loss of ECG signal, user discomfort	Poor adhesive, movement of skin, accidentally by user whilst drying	9	6	2	108	Test adhesives under different conditions, refine patch design, increase thickness, use over-patch
Adhesive causes skin irritation	Redness, irritation, skin-damage	Sensitivity to adhesive materials	7	2	5	70	Consult more dermatologists, test adhesive with more users
Wires detach from patch	Incomplete ECG signal transmission	Poor connection design, mechanical stress	9	2	3	54	Improve wire attachment
Electrodes detach from patch	Incomplete ECG signal transmission	Poor connection design, mechanical stress	9	2	3	54	Improve electrode attachment
Patch deforms during wear	Loss of contact with electrodes	Too thin material, lack of structural support	7	7	2	98	Add structural stiffening (ribs) if needed
ECG leads do not conduct signal well enough	Incomplete ECG signal transmission	ECG leads malfunction, user skin type	8	5	3	120	Integrate conductive gel, let user apply gel before application

SYSTEM							
Failure Mode	**Potential Effect**	**Potential Cause**	**Severity (S)**	**Occurance (O)**	**Detection (D)**	**Risk Priority Number (RPN)**	**Recommended Action**
Device loses connection to app	ECG input cannot be monitored, arrhythmia might go undetected	Bluetooth interference, software issues	9	6	8	432	Strengthen Bluetooth stability, improve app feedback loop
App loses connection to server	ECG input cannot be monitored, arrhythmia might go undetected	Bluetooth interference, software issues	9	3	8	216	Strengthen Bluetooth stability, improve app feedback loop
Incorrect placement of the patch	Inaccurate ECG readings, potential misdiagnosis	User error during application	8	6	3	144	Refine app guidance, include tactile cues
Device fails to vibrate for alerts	User unaware of urgent device status	Vibration motor failure, connection failure	7	5	8	280	Strengthen Bluetooth stability, improve vibration motor stability
Inaccurate readings due to noise or interference	Misdiagnosis or delayed medical intervention	Interference from other devices, poor shielding	8	5	9	360	Add shielding, test in combination with other devices
User misunderstand app instructions	Incorrect device placement or application process	Poor app design or unclear instructions	8	7	4	224	Conduct more usability tests, improve instructions, add instruction video
Device not returned after use	Increased costs for device replacement	User forgets or refuses to return device	3	3	2	18	Create incentives for return, improve notification system

FIGURE 86: FMEA OF THE SYSTEM

CHAPTER 5.4

FUTURE ROADMAP

The analysis above highlights several areas for improvement. After all, a product is never truly finished. To address these points and ensure continuous progress, the following roadmap outlines a proposed approach for the coming years, divided into three horizons, as can be seen in Figure 88, on the next page.

These horizons focus on different perspectives. Horizon 1 includes everything that could be achieved in the next year. Horizon two then covers the 2 to 3 years that follow. The third and last horizon describes the broader future. It explores possibilities that are now still far away, but could be achievable in the next 4+ years.

Over the horizons, several themes are identified, and goals are split over these topics. These include objectives across four key areas: design goals, regulatory goals, business goals, and sustainability goals.

Design goals are fairly straightforward; they entail everything that includes the design of the device and patch. The second theme covers all medical relevant regulations and requirements The third topic is about generating business, and the steps that need to be taken in order to make the business viable. The fourth topic covers sustainability, and the actions that could be taken to improve the sustainability of the device, patch and system as a whole.

These goals can of course change over time, but should allow Diplora, at least for the beginning, to focus on certain objectives before others come into play. They can of course also be extended. This roadmap is meant to give a first impression of important considerations to keep in mind, but can of course always be extended or specified.

FIGURE 87: PRINTABLE ELECTRONICS BY MEKOPRINT (2025)

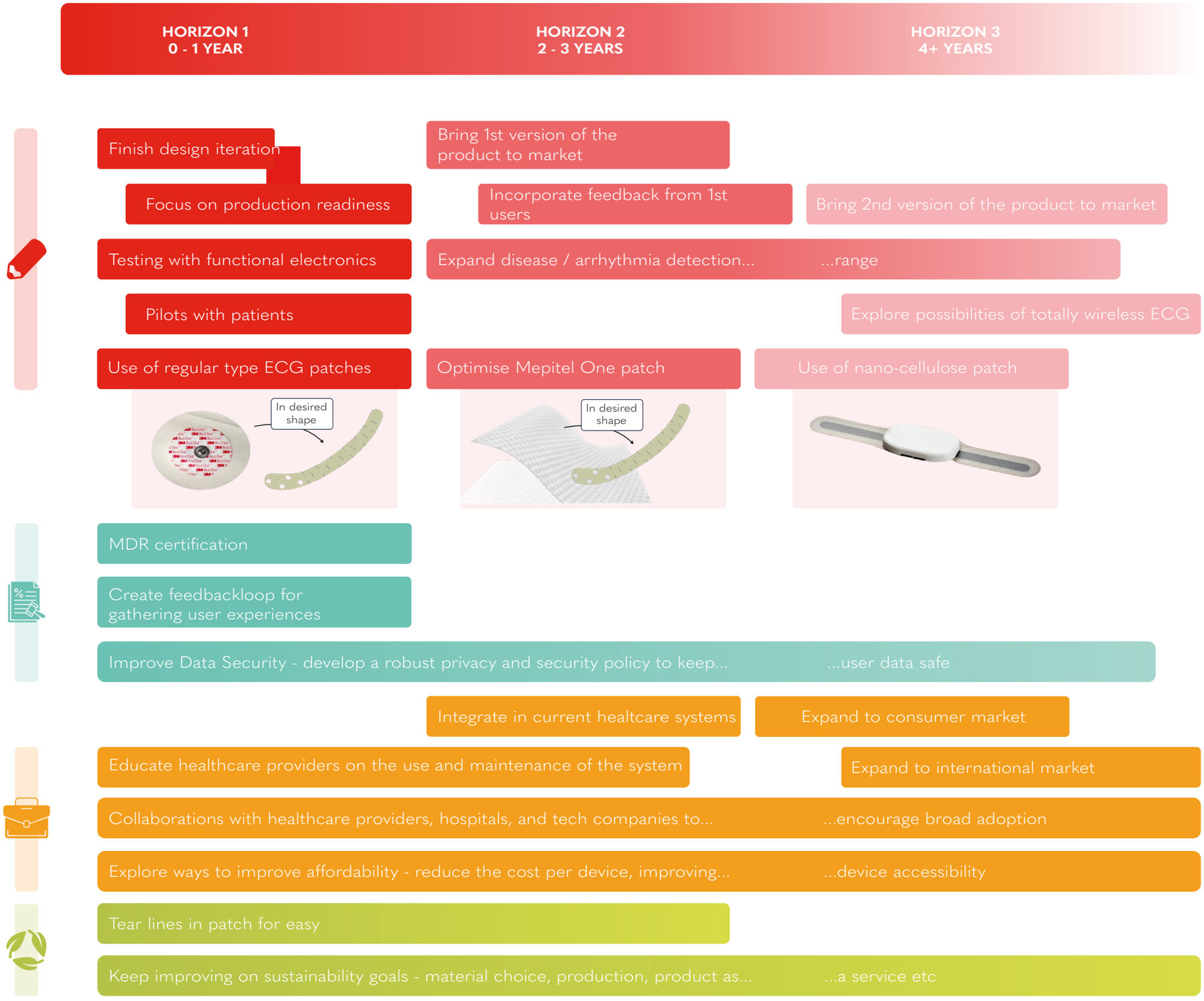


FIGURE 86: ROADMAP

In terms of design, the first horizon shall focus on the first practicalities. Finishing the final design and making sure all electronics are operational and well functioning. On later horizons, the device can be improved, in terms of looks and functionalities, based on first real users' feedback.

Also for the patch, various iteration routes can be considered. A first and practical solution, to quickly be market ready, is to use current existing ECG patches, reshaped to fit the current design. Over time, the Mepitel One patch could be redefined, or other interesting possibilities could be investigated. For instance the company Mekoprint, see Figure 87, specialises in the creation of flexible and printable electronics.

In terms of medical regulations, these should be resolved in the first horizon, in order to get to the market. Passing qualifications is top priority, and once passed, further refinements could be made.

In terms of business it is not only desirable that the product is affordable and convenient to use, it should also be wanted by the market. By educating healthcare providers, GPs, cardiologists et cetera, an interest and notion of importance should be created for the Diplora device. Because no matter how good the product is, if no user wishes to use it, a business case shall be difficult to complete. Over time, the option of expanding to the consumer or international market could be explored.

In terms of sustainability, many improvements can be done. A first one is to create a low boundery for the user, to participate in the recycling of the patch. Sustainability is also an important factor to include in all decisions concerning design, material, manufacturability and even marketing. By continuously designing with sustainability in mind, a good, profitable and sustainable design can penetrate the market.

CHAPTER 5.5

PERSONAL REFLECTION

Six months from September, and here we are; almost touching the finish line. I truly cannot believe that I am finally there. My time in Delft has been wonderful, filled with amazing people, incredible opportunities and spectacular projects. I wouldn't trade it for the world, and to finish off with such a great project is the cherry on top.

As I wrote in my kick-off document, at the start of this project, I really wanted a project with some more depth. I wanted to do a project were I could dive into everything the project would have to offer, and more. And I must say; this project really allowed for me to do so.

I always find the beginning of new projects tricky, as you have no idea where it's going and you're not even sure if you are on the right track to begin with. Lucky for me, IDE is all about TALKING. I think talking to everyone; my fellow graduates, my coaches, my clients, my housemates and sometimes even strangers on the train, always helped me to regain and retain focus. By talking about what I was doing, what I was researching, or where I was stuck, I actually layed out the map of what was sometimes already lingering in the back of my mind for quite a while. It helped me to zoom out, and look at my project from a different angle.

What also really helped me during the project was the hands-on approach. I am not really one to enjoy desk research, and I rather go out and do something. This project also really allowed for me to get out there, test with people, create with people and make the project tangible for everyone.

In hindsights, I think I would have started designing even earlier. Of course all the research was much needed, and background information was important, but all interesting, cool, buzzing or surprising insights came from talking or designing with people.

This realisation also made me more at peace with my study of choice. I started off with DFI, but I always felt like there was missing a layer of depth. I *sort of* switched to IPD, but was sometimes equally surprised by how people totally forgot to think about the bigger picture, of a coherent system, that is (preferably) also contributing to a better world. I used to be biassed as to which one is 'better', but I don't think I am anymore. This project showed me that they are always two sides of the same coin; I couldn't change the material to something indestructible , without considering how it would feel to the user. I couldn't just give the device a fancy shape, without considering its producibility.

I really love how I could combine all of these perspectives into this one project. What started of as the device only, quickly evolved into the redesign of also the patch, app and manual. As I more and more noticed how everything was related, my joy in this project also increased. I just had to make it all come together, to create the best user experience. The *Delft Design Guide*, *The Art of Co-Design* and *Road Map for Creative Problem Solving Techniques* were books that really helped me along the way.

Another personal goal was to improve my 3D CAD skills. I was super nervous to get on with this, but as I threw myself into the deep end with this project, it actually got more and more fun along the way. I even improved my Keyshot skills, because when you're in, you're in.

All in all, it was an amazing journey. What started off as a scary fuzzy-front end, eventually ended in some wonderfull co-creation sessions, personal skill development and a project I am really proud on.

I'm curious what the future will bring, but for now, I hope you enjoyed the read!

REFERENCES

Abe, M. M., Martins, J. R., Sanvezzo, P. B., Macedo, J. V., Branciforti, M. C., Halley, P., Botaro, V. R., & Michel Brienzo. (2021). Advantages and Disadvantages of Bioplastics Production from Starch and Lignocellulosic Components. *Polymers*, *13*, 2484. https://doi.org/10.3390/polym13152484

Achterberg, E., Hinfelaar, J., & Bocken, N. (2016). Master circular business models with the Value Hill. *Circle Economy*.

Achterberg, E., Hinfelaar, J., Bocken, N., Antoine Heideveld, Johnny Kerkhof, Aglaia Fischer, & Bart Ahsmann. (2016). *MASTER CIRCULAR BUSINESS WITH THE VALUE HILL*. https://www.circonl.nl/resources/uploads/2019/11/value-hill-white-paper.pdf

Allison, K. (2024, May). *A Guide to Injection Molding Material Selection for Medical Devices*. Crescent Industries. https://www.crescentind.com/blog/injection-molding-material-selection-guide-for-medical-devices

Banga, B. (2024, July 4). *The rise of bioplastics in medical devices* (Medical Technology, Ed.). https://medical-technology.nridigital.com/medical_technology_jul24/the_rise_of_bioplastics_in_medical_devices

Behfar, M., & Jaiswal, A. (2023, September 12). VTT develops Sustainable, Biodegradable ECG Patch. *VTT*. https://www.vttresearch.com/en/news-and-ideas/vtt-develops-sustainable-biodegradable-ecg-patch

Bowden, C. (2025, January 6). What Are Cost & Price Analyses and How to Conduct Them. *Preferred CFO*. https://preferredcfo.com/insights/cost-analysis-and-price-analysis

Cables & Sensors. (n.d.). *12-Lead ECG Placement: The Ultimate Guide | Cables and sensors*. Cables and Sensors. https://www.cablesandsensors.com/pages/12-lead-ecg-placement-guide-with-illustrations/

Charlton, P. H., Jr., Kyriacou, P. A., Mant, J., Marozas, V., Chowienczyk, P., & Alastruey, J. (2022). Wearable photoplethysmography for cardiovascular monitoring. *Proceedings of the IEEE*, *110*(3), 355–355. https://doi.org/10.1109/JPROC.2022.3149785

Cosoli, G., Spinsante, S., Scardulla, F., D'Acquisto, L., & Scalise, L. (2021). Wireless ECG and cardiac monitoring systems: State of the art, available commercial devices and useful electronic components. *Measurement*, *177*, 109243. https://doi.org/10.1016/j.measurement.2021.109243

Dattani, S., Samborska, V., Ritchie, H., & Roser, M. (2023, December 14). *Cardiovascular diseases*. Our World in Data. https://ourworldindata.org/cardiovascular-diseases#:~:text=As%20you%20can%20see%2C%20heart,total%20of%20around%2018%20million.

Davies, P., & Rippon, M. (2008, November 1). *Evidence review: the clinical benefits of Safetac technology in wound care*. PubMed. https://pubmed.ncbi.nlm.nih.gov/19252457/

Desmet, P. M. A., A. (2012). Faces of product pleasure: 25 positive emotions in human-product interactions [Emotion-Driven Design]. *International Journal of Design*, *6*(2), 1–29. https://diopd.org/wp-content/uploads/2012/09/faces-of-product-pleasure-published.pdf

DeStefano, V., Khan, S., & Tabada, A. (2020). Applications of PLA in modern medicine. In *Engineered Regeneration* (Vol. 1, pp. 76–87). Science Direct. https://doi.org/10.1016/j.engreg.2020.08.002

Dolce, N. (2019, July 26). Sustainable Design is What the Market Wants. *benefitspro.com*. https://www.globest.com/2019/07/26/sustainable-design-is-what-the-market-wants/?slreturn=20250302104847

Electromechanical solutions for your products | Mekoprint. (n.d.). https://mekoprint.com/

Fayyadh, M. J. A., Hassan, R. A., Tran, Z. K., Kempenich, J. W., Bunegin, L., Dent, D. L., & Willis, R. E. (2017). Immediate Auditory Feedback is Superior to Other Types of Feedback for Basic Surgical Skills Acquisition. *Journal of Surgical Education*, *74*(6), e55–e61. https://doi.org/10.1016/j.jsurg.2017.08.005

Fiesler, C. L., McLaughlin, A. C., Fisk, A. D., & Rogers, W. A. (2003). Conceptual versus Procedural Feedback in the Training of a Home Medical Device. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*, *47*(15), 1810–1814. https://doi.org/10.1177/154193120304701507

Finlay, D. D., Nugent, C. D., Donnelly, M. P., & Lux, R. L. (2010). Eigenleads: ECG leads for maximizing information capture and improving SNR. In IEEE, University of Ulster, & University of Utah, *IEEE TRANSACTIONS ON INFORMATION TECHNOLOGY IN BIOMEDICINE* (Vol. 14, Issue 1, pp. 69–70).

Granta EduPack (By Ansys). (2023). [Dataset; Software].

Hartstichting Nederland. (2024). Hart- en vaatziekten bij vrouwen door de jaren heen. *Vrouw & Hart*, 2.

Heart Failure Matters. (2022, March 1). *Telemonitoring / remote patient monitoring / telemetry*. https://www.heartfailurematters.org/what-your-doctor-can-do/telemonitoring-remote-patient-monitoring-telemetry/#:~:text=Telemonitoring%20uses%20different%20types%20of,or%20body%20weight%20through%20technology.

Heijne, K., & Van Der Meer, H. (2019). *Road Map for Creative Problem Solving Techniques*. Boom.

Hernandez, M. (2024, April 10). *In the ever-evolving world of technology, one term that has been making*. ParallelStaff | Nearshore Software Development Company. https://parallelstaff.com/haptic-feedback-everything-you-need-to-know/

Herrera, S., Salazar, A., & Nazar, G. (2022). Barriers and Supports in eHealth Implementation among People with Chronic Cardiovascular Ailments: Integrative Review. *International Journal of Environmental Research and Public Health*, *19*(14), 8296. https://doi.org/10.3390/ijerph19148296

Hopkins Medicine (By Johns Hopkins Medicine). (2025). Johns Hopkins Medicine. https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/holter-monitor

Horton, J. D., Sherber, H. S., & Lakatta, E. G. (1977). Distance correction for precordial electrocardiographic voltage in estimating left ventricular mass: an echocardiographic study. *Circulation*, *55*(3), 509–512. https://doi.org/10.1161/01.cir.55.3.509

How To Create An Effective RFQ For Plastic Injection Molds -. (2024, November 24). *Topworks plastic mold*. https://myplasticmold.com/how-to-create-an-effective-rfq-for-plastic-injection-molds.html

Huysmans, T., & Molenbroek, J. (1980). DINED [Dataset; Website]. In *Anthropometric Database* (Version 2024). https://dined.io.tudelft.nl/en/about

Icon Global Supply. (2023, March 2). *4 Reasons why bioplastics aren't the answer to our plastic crisis*. https://www.linkedin.com/pulse/4-reasons-why-bioplastics-arent-answer-our-plastic-crisis/

Jacobson, C. (2000). Optimum bedside cardiac monitoring. *Progress in Cardiovascular Nursing*, *15*(4), 134–137. https://doi.org/10.1111/j.0889-7204.2000.080402.x

Jiménez-Serrano, S., Rodrigo, M., Calvo, C. J., Millet, J., & Castells, F. (2022). From 12 to 1 ECG lead: multiple cardiac condition detection mixing a hybrid machine learning approach with a one-versus-rest classification strategy. *Physiological Measurement*, *43*(6), 064003. https://doi.org/10.1088/1361-6579/ac72f5

Joseph, B., James, J., Kalarikkal, N., Thomas, S., International and Inter University Centre for Nanoscience and Nanotechnology, WiTec, & School of Energy Materials. (2021). Recycling of medical plastics. In *Advanced Industrial and Engineering Polymer Research* [Journal-article]. https://doi.org/10.1016/j.aiepr.2021.06.003

Kerr, J. (2024). *The art of Co-Design: Solving Problems Through Creative Collaboration*. Bis Publishers.

Kheirabadi, S., & Sheikhi, A. (2022). Recent advances and challenges in recycling and reusing biomedical materials. *Current Opinion in Green and Sustainable Chemistry*, *38*, 100695. https://doi.org/10.1016/j.cogsc.2022.100695

Kulma, A., Skórkowska-Telichowska, K., Kostyn, K., Szatkowski, M., Skała, J., Drulis-Kawa, Z., Preisner, M., Zuk, M., Szperlik, J., Wang, Y. F., & Szopa, J. (2014). New flax producing bioplastic fibers for medical purposes. *Industrial Crops and Products*, *68*, 80–89. http://dx.doi.org/10.1016/j.indcrop.2014.09.013

Lean Six Sigma Groep. (2024, January 4). *Wat is FMEA?* https://leansixsigmagroep.nl/lean-agile-en-six-sigma/fmea/

Lee, D., Kwon, H., Lee, H., Seo, C., & Park, K. (2020). Optimal Lead Position in Patch-Type Monitoring Sensors for Reconstructing 12-Lead ECG Signals with Universal Transformation Coefficient. *Sensors*, *20*(4), 963. https://doi.org/10.3390/s20040963

Lr, R., Shaiju, A., & Jana, S. (2023, December 14). *3-Lead to 12-Lead ECG Reconstruction:*

A Novel AI-based Spatio-Temporal Method. 20th IEEE 2023, India. https://doi.org/10.1109/indicon59947.2023.10440781

Machaca, S., Ung, G., & Brown, J. D. (2020). Towards an understanding of the utility of Dual-Modality haptic feedback in teleoperated medical devices. *IEEE Transactions on Medical Robotics and Bionics*, *2*(4), 574–577. https://doi.org/10.1109/tmrb.2020.3034254

Mason, F., Pandey, A. C., Gadaleta, M., Topol, E. J., Muse, E. D., & Quer, G. (2024). AI-enhanced reconstruction of the 12-lead electrocardiogram via 3-leads with accurate clinical assessment. *Npj Digital Medicine*, *7*(1). https://doi.org/10.1038/s41746-024-01193-7

Medical Plastics News. (2024, September 17). *Bioplastics in the medical industry: Is a green future a reality?* https://www.medicalplasticsnews.com/medical-plastics-industry-insights/medical-plastics-sustainability-insights/bioplastics-in-the-medical-industry-is-a-green-future-a-real/#:~:text=PLGA%2C%20approved%20by%20the%20FDA,bioplastic%20used%20in%20medical%20applications.

Meek, S., & Morris, F. (2002). ABC of clinical electrocardiography: Introduction. I---Leads, rate, rhythm, and cardiac axis. *BMJ*, *324*(7334), 415–418. https://doi.org/10.1136/bmj.324.7334.415

Mepitel One milde wondcontactlaag | Mölnlycke. (n.d.). https://www.molnlycke.nl/producten-oplossingen/mepitel-one/

Narancic, T., Cerrone, F., Beagan, N., & O'Connor, K. E. (2020). Recent advances in bioplastics: application and biodegradation. In *Polymers* (p. 920) [Journal-article]. https://doi.org/10.3390/polym12040920

Nedios, S., Romero, I., Gerds-Li, J., Fleck, E., & Kriatselis, C. (2014). Precordial electrode placement for optimal ECG monitoring: Implications for ambulatory monitor devices and event recorders. *Journal of Electrocardiology*, *47*(5), 669–676. https://doi.org/10.1016/j.jelectrocard.2014.04.003

Nelwan, S. P., Kors, J. A., Meij, S. H., Van Bemmel, J. H., & Simoons, M. L. (2004). Reconstruction of the 12-lead electrocardiogram from reduced lead sets. *Journal of Electrocardiology*, *37*(1), 11–18. https://doi.org/10.1016/j.jelectrocard.2003.10.004

NICE. (2019, May 8). *Overview | Lead-I ECG devices for detecting symptomatic atrial fibrillation using single time point testing in primary care | Guidance | NICE*. https://www.nice.org.uk/guidance/dg35

Nowak, B., Misselwitz, B., Erdogan, A., Funck, R., Irnich, W., Israel, C., Olbrich, H., Schmidt, H., Sperzel, J., & Zegelman, M. (2009). Do gender differences exist in pacemaker implantation?--results of an obligatory external quality control program. *EP Europace*, *12*(2), 210–215. https://doi.org/10.1093/europace/eup312

Otero Fraiz, S. (2024). *Wearable ECG device* [Report].

Philips. (2021). *Efficia CM Series Patient Monitors* [Technical Data Sheet]. https://www.documents.philips.com/assets/20211004/c4db91a28da84fd58352adb7000d8ea6.pdf

Plavec, R., Hlaváčiková, S., Omaníková, L., Feranc, J., Vanovčanová, Z., Tomanová, K., Bočkaj, J., Kruželák, J., Medlenová, E., Gálisová, I., Danišová, L., Přikryl, R., Figalla, S., Melčová, V., & Alexy, P. (2020). Recycling possibilities of bioplastics based on PLA/PHB blends. *Polymer Testing*, *92*. https://doi.org/10.1016/j.polymertesting.2020.106880

PVCMed Alliance. (2024, October 11). *Medical device recycling*. https://pvcmed.org/sustainability/recycling/

Rautaharju, P. M., MD, PhD, Park, L., MS, Rautaharju, F. S., PhD, & Richard Crow. (1998). A Standardized Procedure for Locating and Documenting ECG Chest Electrode Positions: Consideration of the Effect of Breast Tissue on ECG Amplitudes in Women. In *Journal of Electrocardiology* (Vol. 31, Issue 1).

Rautaharju, P. M., Zhou, S. H., & Calhoun, H. P. (1994). Ethnic differences in ECG amplitudes in North American white, black, and Hispanic men and women. *Journal of Electrocardiology*, *27*, 20–31. https://doi.org/10.1016/s0022-0736(94)80040-5

Rawshani, A., MD PhD. (2023, June 25). *The ECG leads: Electrodes, limb leads, chest (precordial) leads and the 12-Lead ECG*. Cardiovascular Education. https://ecgwaves.com/topic/ekg-ecg-leads-electrodes-systems-limb-chest-precordial/

Roper, A. (2024, March 7). Atrial Fibrillation: A Guide to Wearable ECG Smart Watches. *AFib Institute*. https://afibinstitute.com.au/atrial-fibrillation-a-guide-to-wearable-ecg-smart-watches/

Salari, N., Morddarvanjoghi, F., Abdolmaleki, A., Rasoulpoor, S., Khaleghi, A. A., Hezarkhani, L. A., Shohaimi, S., & Mohammadi, M. (2023). The global prevalence of myocardial infarction: a systematic review and meta-analysis. *BMC Cardiovascular Disorders*, *23*(1). https://doi.org/10.1186/s12872-023-03231-w

Simoes, R., Sousa, J., Nogueira-Silva, C., & Gamboa, H. (2012a). Optimizing Electrode Positioning in 3-lead ECG Chest Devices. In *Proceedings of the 2nd International Living Usability Lab Workshop on AAL Latest Solutions, Trends and Applications (AAL-2012)* (pp. 81–88). https://doi.org/10.5220/0003885800810088

Simoes, R., Sousa, J., Nogueira-Silva, C., & Gamboa, H. (2012b). Optimizing Electrode Positioning in 3-lead ECG Chest Devices. *Proceedings of the 2nd International Living Usability Lab Workshop on AAL Latest Solutions, Trends and Applications (AAL-2012)*, 81–88. https://doi.org/10.5220/0003885800810088

Sohn, J., Yang, S., Lee, J., Ku, Y., & Kim, H. C. (2020). Reconstruction of 12-Lead Electrocardiogram from a Three-Lead Patch-Type Device Using a LSTM Network. *Sensors*, *20*(11), 3278. https://doi.org/10.3390/s20113278

Tempo Automation. (2020, March 30). *Understanding technology readiness level for medical devices development.* https://www.tempoautomation.com/blog/understanding-technology-readiness-level-for-medical-devices-development/

Tomasic, I., Trobec, R., & Lindén, M. (2016). Can the Regression Trees Be Used to Model Relation Between ECG Leads? In *Springer eBooks* (pp. 467–472). https://doi.org/10.1007/978-3-319-47063-4_50

Van Boeijen, A., Daalhuizen, J., & Zijlstra, J. (2020). *Delft Design Guide : Perspectives - Models - Approaches - Methods*. https://research.tudelft.nl/en/publications/delft-design-guide-perspectives-models-approaches-methods

Van De Poel, P. (2024, June 3). *Zorgconsumenten zien wereldwijd zorg overbelast - DutchHealthHub*. DutchHealthHub. https://www.dutchhealthhub.nl/artikelen/drie-van-de-vijf-wereldwijde-zorgconsumenten-noemen-zorg-overbelast

Van Straten, B., Delft University of Technology, Riekwel, C., Maasstad Ziekenhuis, Horeman, T., & Delft University of Technology. (2021). Plastic hospital waste can be recycled into new medical devices. *Journal of Cleaner Production*. https://doi.org/10.13140/RG.2.2.24709.97765

Wang, L., Zhou, W., Xing, Y., Liu, N., Movahedipour, M., & Zhou, X. (2019). A novel method based on convolutional neural networks for deriving standard 12-lead ECG from serial 3-lead ECG. *Frontiers of Information Technology & Electronic Engineering*, *20*(3), 405–413. https://doi.org/10.1631/fitee.1700413

Wang, L., Zou, Y., Xie, C., Yang, T., & Abu, P. a. R. (2024). Feasibility and validity of using deep learning to reconstruct 12-lead ECG from three-lead signals. *Journal of Electrocardiology*, *84*, 27–31. https://doi.org/10.1016/j.jelectrocard.2024.03.004

Wilson, D. G., Cronbach, P. L., Panfilo, D., Greenhut, S. E., Stegemann, B. P., & Morgan, J. M. (2017). Electrode positions, transformation coordinates for ECG reconstruction from S-ICD vectors. *Data in Brief*, *11*, 611–616. https://doi.org/10.1016/j.dib.2017.02.041

Wilson, J., Heinsch, M., Betts, D., Booth, D., & Kay-Lambkin, F. (2021). Barriers and facilitators to the use of e-health by older adults: a scoping review. *BMC Public Health*, *21*(1). https://doi.org/10.1186/s12889-021-11623-w

Wisbey, M. (2024, March 8). *How health system 'designed by men, for men' is failing women*. NewsGP. https://www1.racgp.org.au/newsgp/professional/fixing-a-health-system-designed-by-men-for-men

Wittekoek, J. (2017). *Het vrouwen hart* (2nd ed.). Lucht BV.

World Health Organization: WHO. (2018, February 8). *Health-care waste*. https://www.who.int/news-room/fact-sheets/detail/health-care-waste

World Health Organization: WHO. (2021, June 11). *Cardiovascular diseases (CVDs)*. https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-%28cvds%29?

Wyndham, C. R. (2000). *Atrial fibrillation: the most common arrhythmia*. PubMed. https://pubmed.ncbi.nlm.nih.gov/11093410/#:~:text=Atrial%20fibrillation%20is%20the%20most,very%20individualized%20approaches%20to%20management.

Yano, Y., Greenland, P., Lloyd-Jones, D. M., Daoud, E. G., Koehler, J. L., & Ziegler, P. D. (2016). Simulation of Daily Snapshot Rhythm Monitoring to Identify Atrial Fibrillation in Continuously Monitored Patients with Stroke Risk Factors. *PLoS ONE*, *11*(2), e0148914. https://doi.org/10.1371/journal.pone.0148914

Youngblood, M., Chesluk, B., & Haidary, N. (2022). Rethinking Users Toolkit. In *Rethinking Users*. Bis Publishers. https://www.rethinkingusers.com

APPENDICES

APPENDIX A

FULL SWOT ANALYSIS

ELABORATION ON THE SWOT ANALYSIS PERFORMED ON THE COMPANY, DIPLORA:

On the market, a wide variety of wearable ECG devices are already available. In this chapter, the wearable ECG devices found by Cosoli et al. (2021), Otero Fraiz (2024) and myself will be compared in terms of price, quality, body placement, sustainability, feedback type and current use by GP's in The Netherlands.

COMPETITOR ANALYSIS

Price and quality

The price of many ECG wearables is unfortunately unavailable as most are not for individual sale, or appear to be mere concept products, not available for sale at all.

Nevertheless, when comparing prices that can be found to quality checks (ratings found on Google and other platforms), it becomes quite apparent that the more expensive products are also the more superior ones in terms of functionalities, as can be seen in Figure A1. For instance, the Boxym ECG measurement tool on AliExpress performs far worse than any other device, whilst the QuardioCare and IRythm's ZioMonitor offer more reliable measurements.

Location on the body

Most ECG wearables are located either above the chest, or at the fingertips (fingers are placed on the device). Some are located between the breasts and the QuardioCare is located under the breast, in the shape of a sportsband.

The tools that measure at the fingertips are almost always so called 'snapshot ECG's'. They cannot record 24/7 — as that would mean keeping your hands on the device forever — and therefore are not really a competitor of Diplora's envisioned model.

The ones that are placed in between the breasts often seem to be targeted for men. When considering females with significant breast size, it is doubtful whether they find this comfortable as well.

Also targeted for women, like the ZioMonitor or the Philips ePatch, you see that most patches are located above the breast. Be that as it may, from the user interviews we saw that women find this very flashy. Even with a high-neck shirt, it is hard to hide the obvious bump just below the neck.

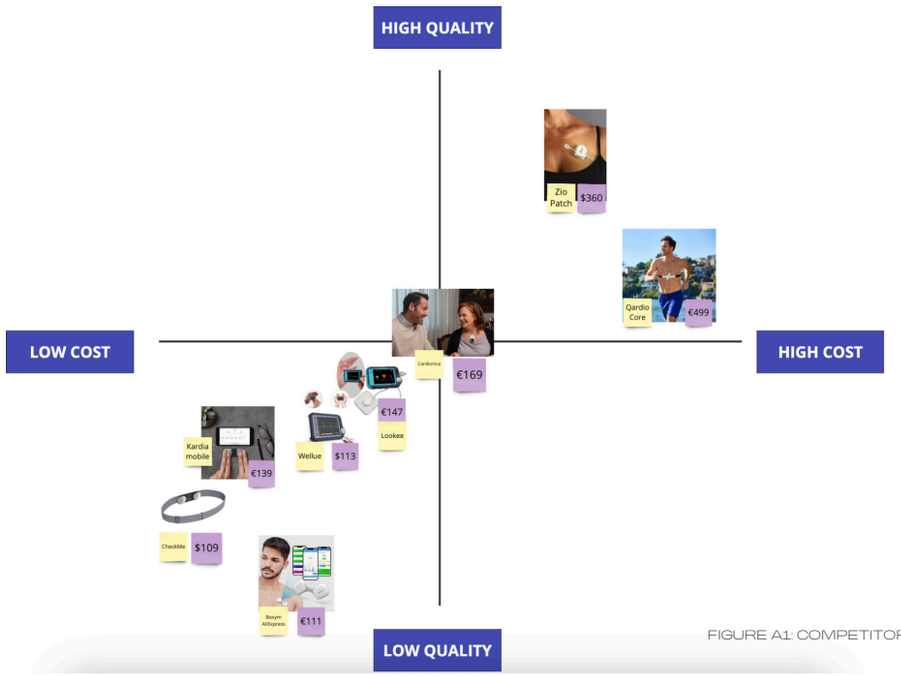


FIGURE A1: COMPETITOR ANALYSIS

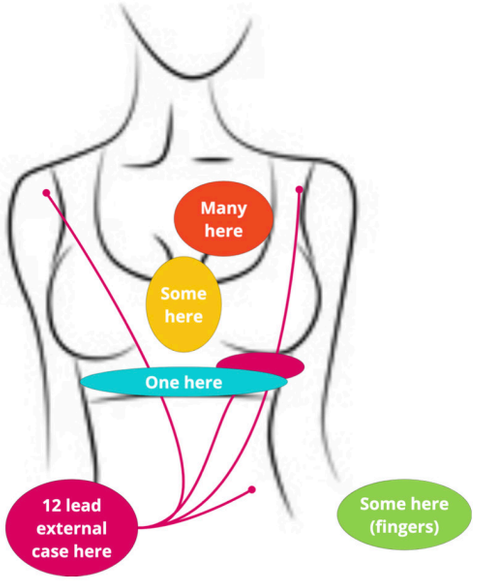


FIGURE A2: LOCATION OF DEVICES

The QuardioCore, which is located under the chest, seems to be usable for women as well. Nevertheless, not only is the use of a band for attachment out of the scope for Diplora's design vision, the QuardioCore appears to be just an incredibly pricey sportsband.

Interesting to note is that for instance the Savvy ECG promotes their device as if it can be placed anywhere on the chest. It is however unclear if this product managed to be viable nor feasible, as it does not seem to be for sale anymore.

The Philips ePatches diversify themselves with their flexibility. One patch can be used on its own, but also implemented in an extra casing, that offers a wider range of electrode placement.

Sustainability

In terms of sustainability, most devices are quite unsustainable. When considering the 'on body' devices (so no fingertip devices) only the devices of QuardioCare and Philips seem to be rechargeable. All other devices either require an entirely new battery, or are to be discarded after the measurement is done.

Also, all of the 'stick-on' devices that require electrode patches, use non recyclable patches. If no patch is used, the device has to either be used on the fingertips (e.g. Kardio Mobile) or strapped to the body with a band (e.g. QuardioCore).

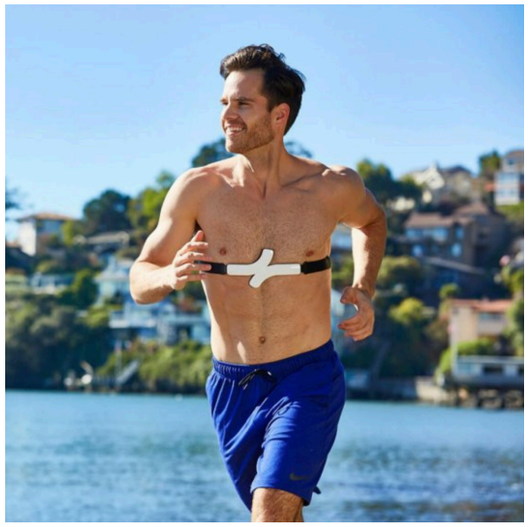


FIGURE A3: QUARDIOCORE

FIGURE A4: SAVVY ECG

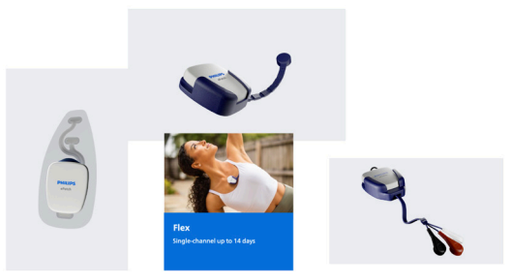


FIGURE A5: PHILIPS E-PATCH

No devices mention anything about their recyclability and none of the devices seem to have a reusable market approach, where a device could be handed in again to the company.

Types of feedback

Most devices do not seem to have any type of feedback, besides through an accompanying application. Through the application, users can view their heart rate and sometimes other specifics.

The device from LifeSignals, Cardionica, Boxym, Biobeat and Philips BioSensor BX100 do have an activation button, often accompanied with a tiny light to indicate the press of the button was successful. The Cardionica device also has a few other buttons, as can be seen in Figure A6. Whether these buttons are clear for the user, and comfortable in use is unknown.

None of the devices mention anything about haptic feedback — in terms of vibrations — or any auditory feedback when interacting with the device.

Currently used In The Netherlands

Although there are already many variants of ECG measurement devices out on the market, the amount of devices used by medical specialists in The Netherlands is still quite small. From the performed interviews for this project it became apparent many patients still received an old school Holter, accompanied with many cumbersome wires, for monitoring purposes.

In another interview, conducted by Diplora's co-worker Jetske Brummer, with a cardiologist, two other devices were mentioned. This was the Kardio Mobile, that is used at the fingertips, and the application FibriCheck. FibriCheck requires the patient to scan their finger with the use of their smartphone camera for one minute, as can be seen in Figure A7.

Both of these technologies rely on a short recording period. Recordings that are only a snapshot ECG may help in the detection of some heart diseases, but fail to detect specific heart deficiencies that accor less often or expected (Yano et al., 2016).

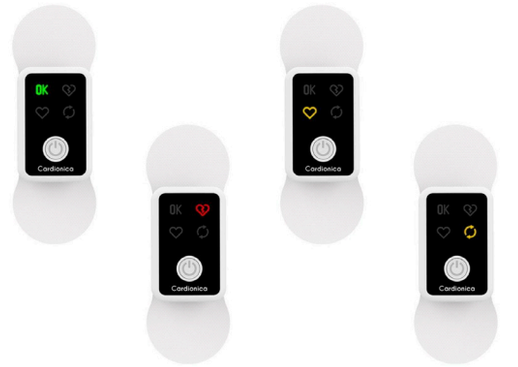


FIGURE A6: CARDIONICA

FIGURE A7: FIBRICHECK

APPENDIX B

ALTERNATIVES TO PATCHES

During interviews with users of ECG devices, several issues with electrode patches were highlighted. One of the primary concerns is that the patches, which have their own adhesive layer, can only be used once. After use, the patches are discarded and never recycled.

The patches are not packed in a sterile manner and users are typically provided with extra strips for reapplication if needed. As mentioned before, there are two main types of attachment mechanisms: button-like and peg-like electrode patches. The downside of peg attachments is that they can easily be dislodged during daily activities. On the other hand, button-like attachments require considerable pressure to secure, which can be uncomfortable for patients, especially when pressing on soft tissue. However, this can be mitigated by attaching the device before applying it to the skin or by using wireless electrodes (Tomasic et al., 2016). The paper of Cosoli et al. (2021) discusses the different types of electrodes, from the disposable wet electrodes many of the interviewees also experienced, to dry-electrodes or non contact electrodes.

Beneath the electrode, a gel is often used to improve conductivity. While this enhances measurement accuracy, it leaves an unpleasant, sticky residue on the skin once removed. In comparison, from the interview with the woman who used a sports-band instead of a Holter, I learned that some sports-bands require the user to apply water to enhance conductivity, which may offer a cleaner alternative to the gel-based method used in medical patches. Additionally, users often complained about the dirt and residue left by the adhesive around the patch, which they found very unclean.

Another significant issue is the adhesive itself, as some people experience allergic reactions to the glue, resulting in red marks on the skin. While this is apparently not uncommon — similar reactions are seen with widely used medical products like orange-red band-aids — this is still a concern that needs addressing.

One other practical limitation with most ECG patches is that they are not waterproof, meaning users are advised against showering or exercising while wearing them. Contact with water often causes the patches to lose adhesion. A possible improvement could be the use of waterproof adhesives similar to those found in waterproof band-aids, ensuring the patches remain secure during activities that involve moisture or sweat.

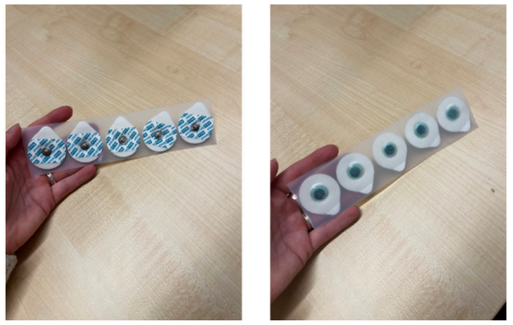


FIGURE B1: REGULAR ECG PATCHES

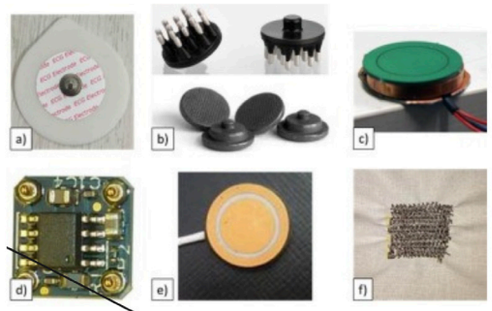


Fig. 2. Electrodes examples: a) disposable wet-electrodes, b) dry electrodes, c) non-contact electrodes, d) PlesseyTM electrodes, e) capacitive electrodes and f) textile electrodes.

FIGURE B2: OTHER TYPES OF ECG PATCHES

ANOTHER PERSPECTIVE ON STICKERS

Another particularly interesting comparison comes from another interview that was performed with a diabetic female interviewee who uses a diabetes sensor attached to her upper arm. While the sensor has an invasive tube for measuring blood glucose, the adhesive patch used for attachment is relevant to this discussion. The patch remains secure for up to 10 days and allows the user to shower and exercise. An "over-patch" is also provided to extend the patch's lifespan for a few extra days. However, the interviewee noted that larger patches tend to pull more on the skin — perhaps by the increase of surface area and movable skin — making them detach quicker. The smaller, more compact sensors she used previously lasted longer, supporting the idea that "the bigger the patch, the more easily it detaches." To address this, she suggested providing users with extra adhesive or glue to reinforce the edges of the patch if it starts to peel.
Regarding additional support, she mentioned the availability of arm bands that can hold the sensor in place, but found them uncomfortable and funny-looking, as they reminded her of wearing a "captain's band". Moreover, the arm band would sometimes cause accidental dislodging of the patch during activities like dressing, which she found painful as the sticker was then also ripped from her skin.

To simplify the application process, the diabetes sensor comes with a specialised device that helps apply the patch in one step, ensuring it doesn't crease or detach prematurely. Each patch and sensor has clear labelling to indicate the order of application steps (e.g. a '1-1-1-1' marked on one side and '2-2-2-2' on the other). While this device ensures a smooth application process, it is a single-use, disposable item, raising concerns about its environmental sustainability. The accompanying app provides further guidance, walking the user through each step, from removing the sticker protector to ensuring proper placement and removing the applicator device afterward.

FIGURE B3: DIABETES SENSOR

FIGURE B4: DEXCOM ONE

OTHER TYPES OF STICKERS

When considering other types of adhesives available on the medical market, a vast scala of sticky materials appear. Most fall under the category of bandaids, but also articles like sporttape, adhesive bandages and blister patches could be a source of inspiration. All of these products are proven to be medically oppropriate, yet all serve a slightly different purpose.

Most of these stickers use either a acrylic-based adhesive or a synthetic rubber based adhesive, with the latter more often used in water-resistant applications.

Testing these different types of bandaids and similar, on factors such as adhesion, skin sensitivity and removability might aid in choosing the right material for the adhesive electrode patch of the device.

FIGURE B5: MEPITEL ONE PATCH

FIGURE B6: TYPES OF STICKERS

APPENDIX C

USER TYPE ANALYSIS

Not only the body shape of the user varies, but also the way they interact with the device. When investigating the process of wearing and using a Holter through all interviews, it becomes apparent that the patient wearing the ECG device is by far not the only one interacting with this device. To capture all different users that, in some way, interact with the device the Rethinking Users method was applied (Youngblood et al., 2022). In this method, multiple types of users are explained, that can all be modified to any project. All proposed types of users can be seen in Figure C1.

From this analysis, nine types of relevant users were identified. These 'users' are important to keep in mind when designing. Take, for instance, Friends & Family; When designing the feedback system of the device, lights, buzzing or sounds could appear useful. However, when considering this group and not only the user, it is questionable if audial feedback is desirable as friends and family might also hear the sound. This could perhaps, for the direct user, result in shame or awkwardness.

From this analysis it also became apparent that the Direct User is not as one-dimensional as one might think. The direct user is also the one dependent on the device, the one who needs to become one with the device, the one that wants something from the device and also the one that will hand the device back to the next Direct User.

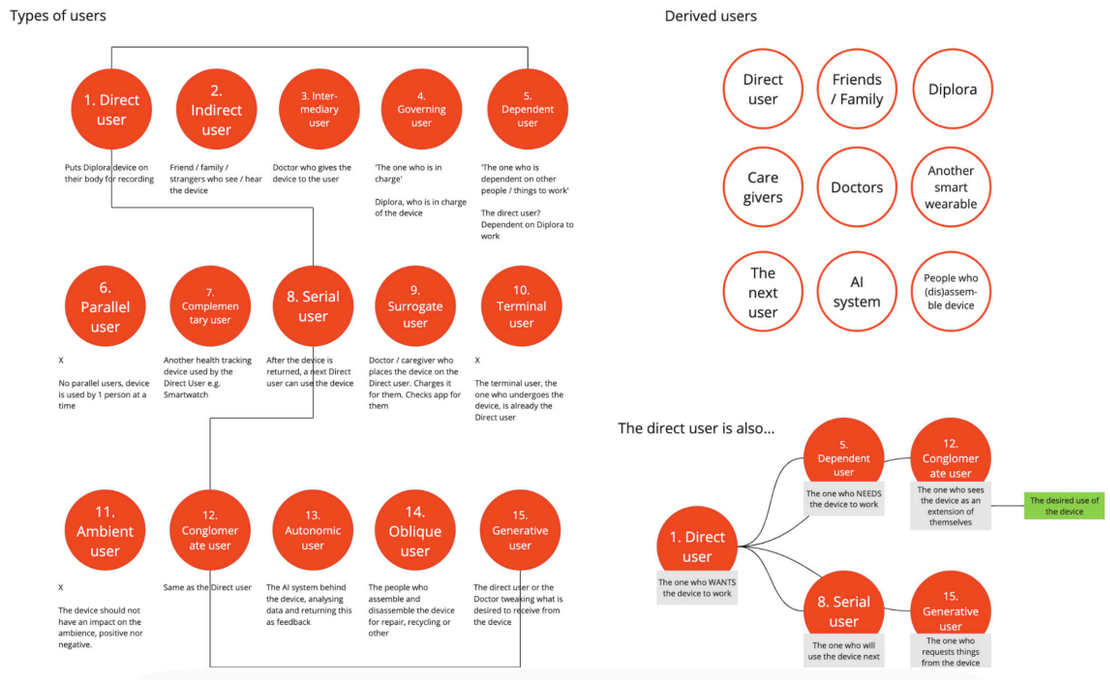


FIGURE C1: USER ANALYSIS

APPENDIX D

GRANTA EDUPACK MATERIAL ANALYSIS

The following figures show all comparisons made in the material analyser of Granta Edupack 2025. In the 'Level 2 database', the category of polymers was explored as this was the most and only suitable group for the medical application of the device.

All polymers were compaired on several categories deemed relevant for the selection of the material. These categories were; compressive strength, fracture toughness, hardness, price, recyclability and carbon footprint

By compairing all of these graphs, the choice for the final material came down to PC.

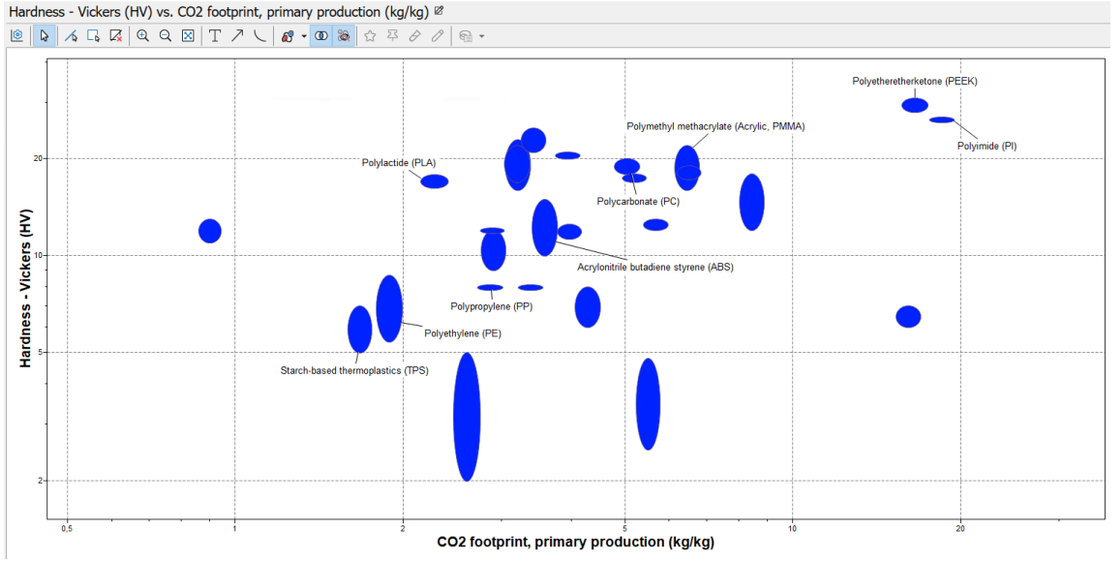


FIGURE D2 ANALYSIS 2

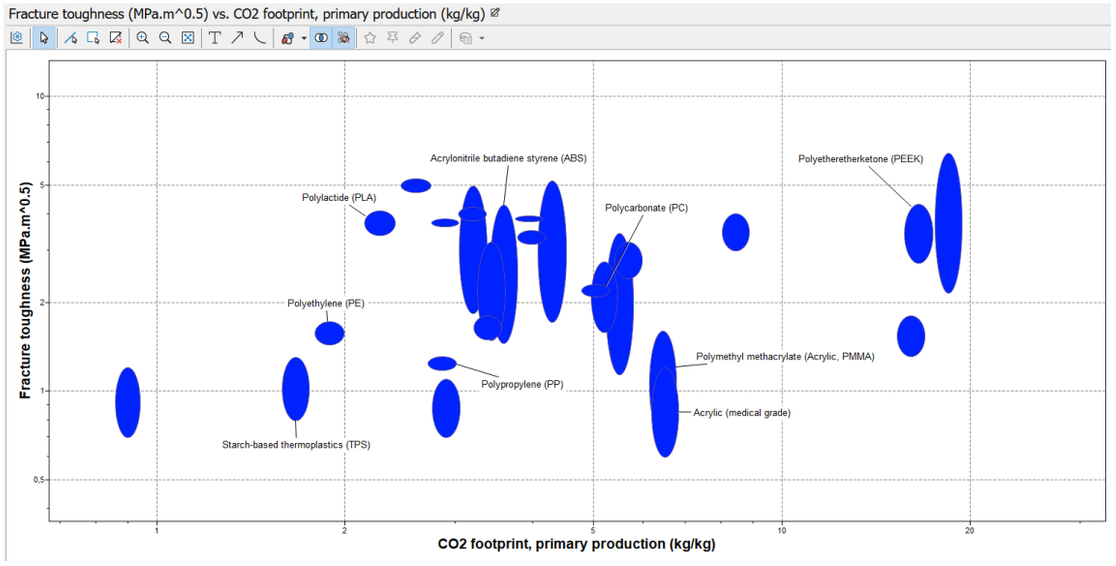


FIGURE D1: ANALYSIS 1

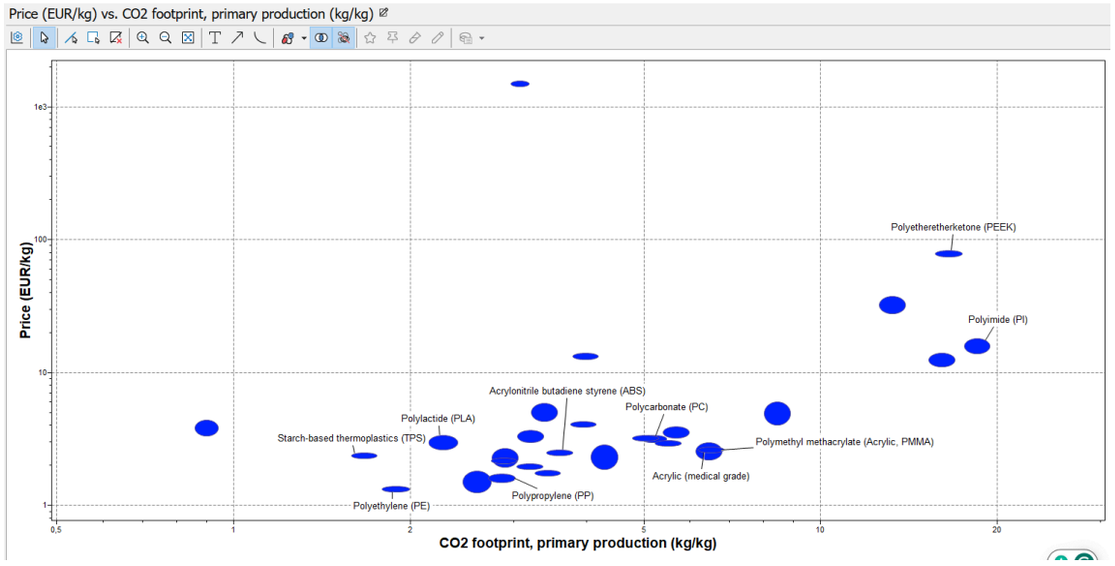


FIGURE D3: ANALYSIS 3

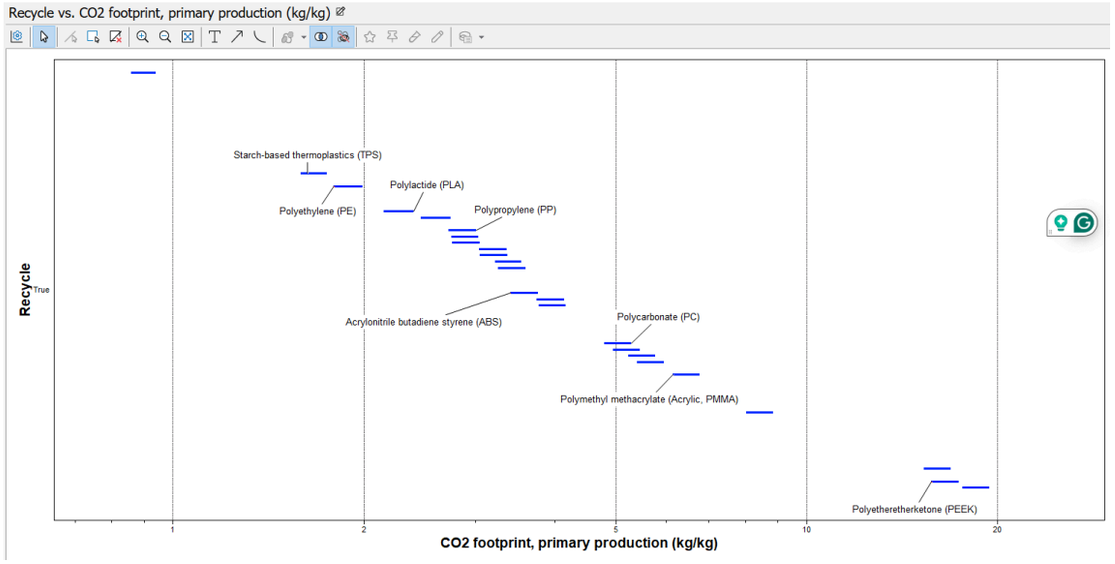


FIGURE D4 ANALYSIS 4

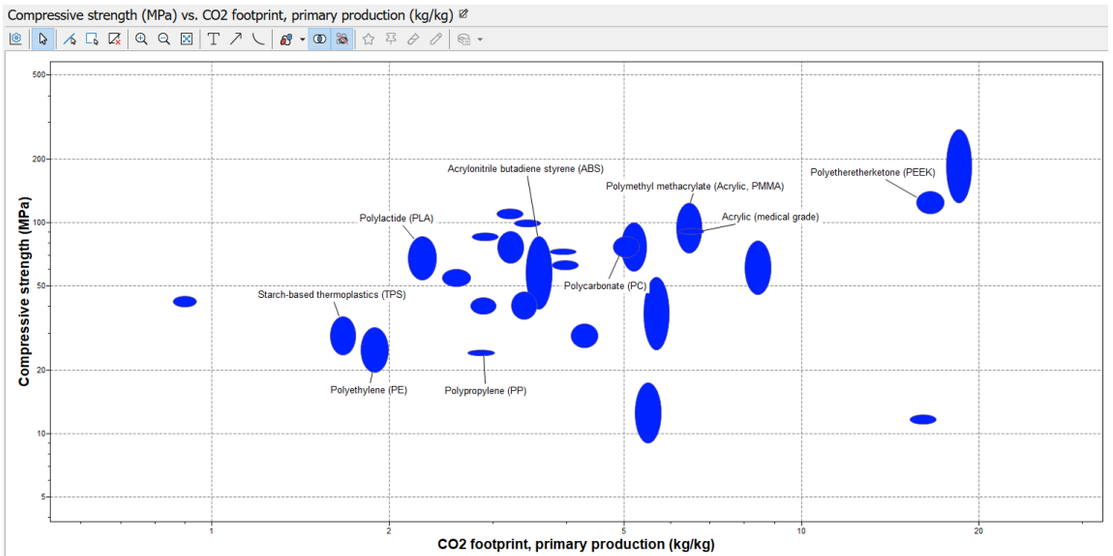


FIGURE D5 ANALYSIS 5

APPENDIX E

SUMMARY OF THE MDR & RELEVANT ISO NORMS

MDCG 2019-11 | GUIDANCE ON QUALIFICATION AND CLASSIFICATION OF SOFTWARE IN REGULATION

This document highlights the requirements and classification of the software used in the ECG device. This software programming is out of scope for this project, and shall be checked by the company, Diplora.

A few highlights of this paper are that the software should not perform any diagnosis itself, as that would qualify the device for a higher risk category, which is accompanied by even stricter rules. The device shall merely record and aid the medical practitioner in making a good diagnosis.

MDCG 2023-4 GUIDANCE ON MEDICAL DEVICE SOFTWARE (MDSW) - HARDWARE COMBINATIONS

Here, it states that if the device uses an external sensor to capture and send physiological data to software, the sensor and software must both meet performance and safety standards. The same goes for the implementation of the app.

MDCG 2021-24 GUIDANCE ON CLASSIFICATION OF MEDICAL DEVICES

Considering the intended function of the device of Diplora, Rule 11 is particularly important, as it applies to software-driven devices monitoring physiological processes. Since the ECG device is meant for detection rather than diagnosis, it would likely fall under Class IIa, subject to the risk level associated with data accuracy and transmission security. However, if the data were used for real-time, critical interventions, it might fall under a higher risk class.

This document also explains which rules apply to the device's hardware + software combination. The relevant rules are the following:

- Rule 1, as the device only touches intact skin.
- Rule 2, as the software is connected to an active device in Class IIa
- Important note: The technical documentation should clarify that the ECG device does not channel or store substances, only data, which aligns it as non-invasive.
- Rule 10, as the device is an 'Active Device' for diagnosis and monitoring
- Rule 11, as the device uses software to monitor physiological processes
- Important note: Emphasis should be put on secure and accurate data transmission to Diplora's server, especially since diagnostic decisions might be informed by the software's interpretations. Ensuring compliance with standards for medical data security, accuracy, and reliability is vital.

REGULATION (EU) 2017/745 ON MEDICAL DEVICES

The software and hardware of the device have to adhere and deliver the following documentations:

- Technical Documentation: This includes detailed specifications, design files, and test reports. It outlines how the device meets essential safety and performance requirements under the MDR. For an ECG monitor, this would cover technical details of components, like electrodes, and their safety and reliability standards.
-
- Clinical Evaluation Report (CER): This document demonstrates the device's clinical performance and safety. It requires a review of existing clinical data or, if necessary, a clinical investigation. The CER verifies that the wearable ECG performs as intended and meets safety standards for patient use.
-
- Risk Management File: This file is part of a comprehensive risk management process as per ISO 14971. It includes risk assessments, mitigation strategies, and procedures for managing risks throughout the product's lifecycle. For a wearable ECG, this might address risks like potential interference with other devices or skin reactions to electrode materials.
-
- Post-Market Surveillance (PMS) Plan and Report: This document details how you'll monitor the device's performance once it's in the market. It includes procedures for gathering user feedback, tracking any adverse events, and ensuring continuous safety. The PMS report is regularly updated to reflect ongoing monitoring.

Regulations that impact the design of the device, and therefore this graduation project, consider the following:

ANNEX I | CHAPTER II | REQUIREMENTS REGARDING DESIGN AND MANUFACTURE

10. Chemical, physical and biological properties

10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and

performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:

A. the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;
B. the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;
C. the compatibility between the different parts of a device which consists of more than one implantable part;
D. the impact of processes on material properties;
E. where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;
F. the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;
G. surface properties; and
H. the confirmation that the device meets any defined chemical and/or physical specifications.

10.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.

10.3. Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.

10.4.1. Design and manufacture of devices
Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

20. Protection against mechanical and thermal risks
20.1. Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

ANNEX I | CHAPTER III | REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE

23.1 Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:

A. The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.
B. The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.
C. Labels shall be provided in a human-readable format and may be supplemented by machine- readable information, such as radio-frequency identification ('RFID') or bar codes.
D. Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section.
E. Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge.
F. Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation.
G. Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer.
H. Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.

23.2. Information on the label

A. The label shall bear all of the following particulars:
B. the name or trade name of the device;
C. the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;
D. the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;
E. if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;
F. N.A.
G. N.A.
H. the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;
I. the UDI carrier referred to in Article 27(4) and Part C of Annex VII;
J. an unambiguous indication of t the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;
K. where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;
L. an indication of any special storage and/or handling condition that applies;
M. N.A.
N. warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;
O. if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;
P. if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;
Q. if the device is custom-made, the words 'custom-made device';
R. an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';
S. N.A.
T. N.A.

23.4. Information in the instructions for use

A. The instructions for use shall contain all of the following particulars:
B. the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2;
C. the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;
D. where applicable, a specification of the clinical benefits to be expected.
E. where applicable, links to the summary of safety and clinical performance referred to in Article 32;
F. the performance characteristics of the device;
G. where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;
H. any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;
I. specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it;
J. details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;
K. any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;
L. the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
M. — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,
N. — identification of any consumable components and how to replace them,
O. — information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and
P. — methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;
Q. N.A.
R. N.A.
S. if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re- sterilisation appropriate to the Member State or Member States

in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;

T. an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;

U. if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request;

V. for devices intended for use together with other devices and/or general purpose equipment:

W. — information to identify such devices or equipment, in order to obtain a safe combination, and/or

X. — information on any known restrictions to combinations of devices and equipment;

Y. N.A.

Z. information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate:

AA. — warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety,

AB. — warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,

AC. — warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment,

AD. — if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered,

AE. — warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and

AF. — precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;

AG. in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose;

AH. N.A.

AI. N.A.

AJ. for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;

AK. for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device;

AL. date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;

AM. a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

AN. information to be supplied to the patient with an implanted device in accordance with Article 18;

AO. for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

ANNEX II | TECHNICAL DOCUMENTATION

1.1. Device description and specification

product or trade name and a general description of the device including its intended purpose and intended users;

3. Design and manufacturing information

information to allow the design stages applied to the device to be understood;

complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;

identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

OVERVIEW OF FURTHER ISO NORMS RELEVANT

1. ISO 13485 - Quality Management Systems for Medical Devices

Design Implications: Implementing a QMS ensures that each stage of your ECG monitor's design and production meets regulatory and quality standards. This system helps in documenting design changes, controlling the manufacturing process, and maintaining consistent quality, which aligns with MDR's requirements.

2. ISO 14971 - Application of Risk Management to Medical Devices

Design Implications: For the ECG device, this standard requires an assessment of potential risks such as signal interference, device malfunction, and skin irritation from materials. Documenting risk mitigation steps, like using secure data transmission or biocompatible materials, is critical for MDR compliance.

3. ISO 14155 - Clinical Investigation of Medical Devices for Human Subjects

Design Implications: If clinical trials are conducted, ISO 14155 ensures the ECG device is tested under ethical, scientifically valid conditions. This standard helps align trials with MDR's safety and effectiveness requirements, ensuring the clinical data supports the device's intended purpose.

4. ISO 10993 - Biological Evaluation of Medical Devices

Design Implications: Since the device makes skin contact, this standard is vital for assessing biocompatibility. Choose materials that avoid allergic reactions or irritation. Following ISO 10993 supports MDR's requirements for safety in materials and reduces the risk of adverse reactions in patients.

5. IEC 60601 Series - Medical Electrical Equipment

Design Implications: This series ensures that the ECG device's electrical components are safe. Key parts include:
IEC 60601-1: General safety, covering insulation, power source protection, and battery safety.
IEC 60601-1-2: Electromagnetic compatibility, which helps prevent interference with other devices.
IEC 60601-2-47: Requirements specific to ECG monitors, ensuring the device's performance meets clinical expectations.

6. ISO 15223 - Symbols for Medical Device Labeling

Design Implications: This standard helps create clear, universally recognized symbols on the ECG monitor's labeling, such as warnings, usage instructions, and device classifications. This improves user understanding, reduces errors, and ensures that the labelling aligns with MDR's clarity and traceability requirements.

7. ISO 62366 - Usability Engineering for Medical Devices
Design Implications: For your ECG monitor, applying usability engineering is crucial, especially since patients and healthcare providers may interact with the device. This involves designing intuitive interfaces, minimizing steps needed to use the device correctly, and reducing risks of misinterpretation. Usability considerations support MDR's safety and effectiveness standards, particularly for patient-operated devices.

**Concrete implications of these MDR terms an ISO norms are to be further optimised and implicated into the design*

APPENDIX F

LIST OF REQUIREMENTS

#	Req. ID	Requirement	Topic	Categorie	Status	Opmerkingen
1		The device should be compact (± 9x4x2cm)	Practicality	Pillar 1	Checked	*Opmerkingen*
2		The device should not be visible when wearing	Confidence	Pillar 1	Checked	*Opmerkingen*
3		The device should not be placed in prominent body areas (above the breast / in the neck)	Confidence	Pillar 1	Checked	*Opmerkingen*
4		The device should feel comfortable when wearing on the body	Comfort	Pillar 1	Checked	*Opmerkingen*
5		The user should feel comfortable wearing the device	Comfort, Confidence	Pillar 1	Checked	*Opmerkingen*
6		The electrodes should be wireless (or hidden wires)	Comfort, Practicality	Pillar 1	Not checked	Was not possible with desired reach in combination with design objectives
7		The attachment of electrodes should be easy (... sec)	Comfort, Confidence	Pillar 1	Checked	*Opmerkingen*
8		The attachment of electrodes should not detach while sleeping	Practicality	Pillar 1	Checked	*Opmerkingen*
9		The attachment of electrodes should be painless	Comfort	Pillar 1	Checked	*Opmerkingen*
10		The detachment of electrodes should be painless	Comfort	Pillar 1	Checked	*Opmerkingen*
11		The electrodes should not detach while engaging in activities	Practicality	Pillar 1	Checked	*Opmerkingen*
12		The device should be suitable for self-application, therefore placed in a consistent, easy to reach area	Comfort, Confidence	Pillar 1	Checked	*Opmerkingen*
13		The device should be suitable for application at someone else	Practicality, Application	Pillar 1	Checked	*Opmerkingen*
14		The device should enable people to feel confident they apply it correctly	Confidence, Application	Pillar 1	Checked	*Opmerkingen*
15		The patches must maintain strong adherence through movements that cause skin deformation, such as bending, stretching, or creasing.	Attachment to body, Sticker	Pillar 1	Checked	*Opmerkingen*
16		The device should be waterproof / sweatproof	Practicality	Pillar 1	Checked	*Opmerkingen*
17		The patches should be waterproof / sweatproof	Practicality	Pillar 1	Checked	*Opmerkingen*
18		Clear and simple feedback mechanisms	Feedback	Pillar 1	Checked	*Opmerkingen*
19		The design must fit big-breasted as well as small-breasted women	Comfort	Pillar 1	Checked	*Opmerkingen*
20		For elderly breasts, the design should consider the challenges of attaching patches around areas with skin folds, ensuring hygiene and a secure fit	Comfort	Pillar 1	Checked	*Opmerkingen*
21		The device should give people a sense of confidence	Confidence	Pillar 1	Checked	*Opmerkingen*
22		Medical professionals should also be encouraged to gain trust in the abilities of the device. The device and doctor should work together, not against each other.	Trustworthy?	Pillar 1	Checked	*Opmerkingen*
23		The device should have real-time feedback	Feedback	Pillar 2	Checked	*Opmerkingen*
24		The device should withstand ... kg/N (for shipping and handling without damage to its sensitive components or adhesive properties.)	Practicality	Pillar 2	Not yet checked	Further testing required with injection moulded device
25		The device must withstand at least .... cycles of use	Practicality	Pillar 2	Not yet checked	Further testing required with injection moulded device
26		The device needs to run for minimal 7 days without charging	Practicality	Pillar 2	In process	Electronics under development at Company
27		The device must give feedback about the battery status	Practicality , Feedback	Pillar 2	Checked	*Opmerkingen*
28		The device should be reparable	Practicality, Sustainability	Pillar 2	Checked	*Opmerkingen*
29		The production of the device is outsourced to other companies	Practicality	Pillar 2	In process	Next step for the Company
30		The production of the patch is outsourced to other companies	Practicality	Pillar 2	In process	Next step for the Company
31		The product should adhere to the MDR	Practicality	Pillar 2	Not yet checked	Further testing required with injection moulded device
32		The product should give reliable results 99% of the time	Trustworthy?, Practicality	Pillar 2	Not yet checked	AI system under development at Company
33		Make sure AF can be properly measured (this would prioritize the use of leads II, III, aVF, and V1)	Location	Pillar 3	Checked	*Opmerkingen*
34		Ensure proper placement of leads that are most critical for detecting common heart conditions, such as lead V5, which is important for detecting left ventricular hypertrophy and myocardial ischemia.	Location	Pillar 3	Checked	*Opmerkingen*
35		The device should correct the potential noise and attenuation of signals caused by breast tissue.	Practicality	Pillar 3	Not yet checked	AI system under development at Company
36		Electrodes should be placed 5-10 cm apart	Practicality	Pillar 3	Checked	*Opmerkingen*
37		The material of the device should be sustainable	Practicality, Sustainability	Pillar 4	Checked	*Opmerkingen*
38		The material of the patch should be sustainable	Practicality , Sustainability	Pillar 4	Checked	*Opmerkingen*
39		All materials should be safe for medical use	Practicality	Pillar 4	Checked	*Opmerkingen*
40		All materials should be recyclable	Sustainability, Practicality	Pillar 4	Checked	*Opmerkingen*
41		Diplora's device must provide accurate and reliable ECG measurements	Practicality	Pillar 5	Not yet checked	Electronics under development at Company
42		The feedback should be user friendly	Comfort, Confidence, Feedback	Pillar 5	Checked	*Opmerkingen*
43		The product should not cost more than 100eu	Practicality	Pillar 5	Not checked	Product is cheaper than this, but considering marketing, overhead, retail, start-up, and regulations costs etc., price will increase
44		After the device is out of use, it should encourage the user to hand it back in for the next user	The app	Pillar 5	Checked	*Opmerkingen*

FIGURE F1: REQUIREMENTS

On the left you can see the list of requirements as created after the initial research fase. The categorisation of pillars is based on the old devision and therefore not exactly the same as in this report. However, every pillar still represents a different category, so therefore these 'pillars' can also be viewed as clusters.

Behind every goal is the status, and whether it was able to be checked during this project. Unchecked boxes have added comments as to why the goal was not yet met.

Below you see the list of things to keep in mind. In Dutch *'wensen'* as this is the list of things that are preferable, yet not fully required for the creation of the product. These are considerations also have a checked or unchecked status, with reasoning behind.

#	Req. ID	To keep in mind	Topic	Categorie	Status	Opmerkingen
1		Adhesives should minimize irritation and be hypoallergenic, considering that some users experience red marks or rashes due to sensitivity. A skin-friendly adhesive must be a priority, especially for long-term wear.	Sticker	Pillar 1	Checked	*Opmerkingen*
2		Testing should confirm the adhesive's reliability in varied skin types and conditions (e.g., oily, sweaty, sensitive skin).	Sticker	Pillar 1	Checked	*Opmerkingen*
3		Explore alternatives to the sticky gel used under electrodes, which leaves residue on the skin. Consider solutions like water-based conductivity from sports bands, which users found cleaner and more comfortable.	Sticker	Pillar 1	Not yet checked	Future recommendation
4		Similar to diabetes sensors, over-patches could be provided to help prolong the lifespan of the patches. These should be designed to avoid adding too much surface area, which might cause premature detachment due to increased tension on the skin	Sticker	Pillar 1	Checked	*Opmerkingen*
5		Users could be provided with additional adhesive or glue strips to reinforce patches that begin to peel at the edges. This would allow for quick fixes, especially for long-term monitoring.	Attachment to body	Pillar 1	Checked	*Opmerkingen*
6		Include an easy-to-use, ergonomic application device (similar to those used for diabetes sensors) that ensures patches are placed properly without creasing or misalignment. This device should be reusable and minimize waste.	Application	Pillar 1	Not checked	Was not necessary anymore
7		The system should educate users about how to handle the device confidently, explaining how to apply patches, check feedback signals, and manage the device on their own. Educational materials could include both written instructions and video tutorials.	Application	Pillar 1	Checked	*Opmerkingen*
8		Implement a universal colour-coded system for electrode placement, reducing confusion for users and healthcare providers, especially in cross-border medical care contexts where systems may vary.	Application	Pillar 1	Not checked	Was not necessary anymore
9		The device should provide feedback for key operations, such as: Activation (whether the device is on). / Proper placement of electrodes. / Connectivity status (whether it is connected to the cloud or phone). / Charging status (e.g., charging and fully charged).	Feedback	Pillar 2	Checked	*Opmerkingen*
10		Explore the possibility of wireless electrodes to reduce the discomfort associated with cables and improve the ease of movement for users.	Attachment to body, Sticker	Pillar 2	Not checked	Impossible with current design in combination with desired reach
11		Provide an over-patch option to extend the life of the adhesive, but ensure it does not add significant bulk or cause discomfort. The over-patch should be designed to minimize pulling on the skin, which was a concern for users of larger patches.	Attachment to body, Sticker, Application	Pillar 2	Checked	*Opmerkingen*
12		The accompanying app should offer a smooth, intuitive user experience, providing real-time updates on device performance, connectivity, and battery life, as well as guidance during the application process.	The app	Pillar 2	Checked	*Opmerkingen*
13		Consider tools like the HeartSquare to simplify the process of determining electrode placement (e.g. for V4). This would ensure correct placement in users with varying body types, minimizing errors in locating the correct thoracic landmarks.	Application	Pillar 3	Not checked	Not deemed relevant anymore
14		Explore the use of biodegradable materials like nanocellulose	Sustainability	Pillar 4	Checked	Longer-term future solution
15		Redesign ECG patches to enable easy disassembly and recycling of components, making them less harmful to the environment.	Sustainability	Pillar 4	Checked	*Opmerkingen*
16		Explore combinations of materials such as PLA mixed with PHB (polyhydroxybutyrate), which provide better resistance to degradation and could extend the life cycle of the device components while maintaining sustainability.	Sustainability	Pillar 4	Not checked	Material analysis concluded PP instead

FIGURE F2: WISHES

APPENDIX G

ELABORATED TEST FINDINGS

TEST 1

The goal of this test was to document creative ideas emerging from the research phase and generate new or initial concepts. Three additional female participants were invited to a brainstorming session structured around the How can you...? method (Van Boeijen et al., 2020). The session focused on four themes: Comfort (e.g., shaping the device for wearability), Attachment (e.g., ensuring secure placement), Application (e.g., intuitive placement methods), and Adjustability (e.g., accommodating different body sizes). Participants shared ideas on post-its, which were later evaluated using the C-Box method (Van Boeijen et al., 2020) to identify high-potential solutions in the "WOW!" quadrant. See Figure G1.

Analysis revealed diverse solutions for placement, including positioning the device under or beside the breast, rather than on top. Suggestions for application included magnetism, clip-ons, and bra pockets, alongside both digital and physical tools. However, ideas varied widely, requiring further exploration.

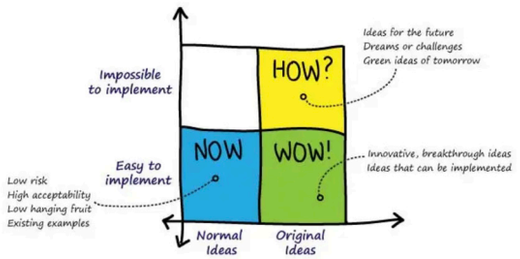


FIGURE G1: C-BOX METHOD

TEST 2

The goal of this test was to cross-check insights from the initial brainstorming session by exploring shapes with female participants. Both the device's shape and patch were investigated. The session began by measuring participants' waist and chest circumferences to ensure diversity, aligning with the personas Edith and Emily. See Figure G2.

Participants were introduced to the Diplora device, its design constraints, and existing examples of Holters and wearable ECGs. Using 3D-printed mock-ups of electronic components and foam clay, participants designed shapes for the device, which were tested under clothing. Exercise like yoga was reenacted to create a more lifelike feel for the device. For the patch, participants explored different shapes and orientations, while adhering to the '5cm distance between electrodes' requirement. The Hits & Dots method (Heijne & Van Der Meer, 2019) was then used to identify the preferred shape, patch, and shape-patch combination. This was followed by a questionnaire to evaluate confidence, and identify areas for refinement.

The main insights from this test can be seen in Figure G3. Interesting to note is that ideas from earlier phases were confirmed or disproved. For instance the idea a separate, clip-on box device, was neglected, as practical reenacted made clear that this would also require a larger patch and continuous wearing of a bra. The idea of using skin-soft silicone also proceeds as faulty, as this material would turn sticky over time and attract dirt. Important to note is also that participants emphasised that confidence in applying the device hinges on two key factors: (1) either ensuring 100% accuracy in placement or (2) providing reassurance that slight inaccuracies are acceptable. Clear communication, such as an image showing the acceptable application range, could significantly improve the user experience.

FIGURE G2: BODY SHAPES OF THE PERSONAS

FIGURE G3: INSIGHTS TEST 1

TEST 3

The third test focused on the interaction between the user and the device, specifically matching different types of feedback with appropriate cues. This, to determine the ideal feedback system. Participants were tested individually using two sets of cards: one featuring feedback types and the other showing potential cues. Participants were asked to mix and match feedback with cues based on their preferences. Combinations were then tested using a mock-up device to ensure their practicality in real-life scenarios, using the Wizard of Oz method (Van Boeijen et al., 2020).

As a result, participants categorised feedback by urgency, agreeing that medium-priority notifications could utilise slow, pulsing vibrations, while urgent ones could involve stronger vibrations. Most participants emphasised that all feedback should be explained and highlighted in an accompanying app. Less urgent notifications, such as status updates, were suggested to be shown within the app, either on the home screen or under a dedicated menu. Some other insides can be seen in Figure G5.

Interesting to note however, is The time of day was identified as a factor influencing the urgency of feedback. For example, a low battery notification would be more critical at bedtime than during the day.

FIGURE G4: FEEDBACK TEST

FIGURE G5: INSIGHTS TEST 3

TEST 4

The fourth test explored the best way to communicate instructions for application of the device. In other words; how to turn it on and attach it to the body. Inspiration was found in the application method used for the Dexcom G7 Diabetes sensor. Here, both an app and a manual provide a step-by-step instruction through text and visuals. Given that the age range of potential users of the Diplora device range from old to young, (Edith to Emily), the test included both a mobile app and a physical paper manual. Early in this test, it became clear that the app is essential for operating the device. Meaning, that it is essential to make clear on the manual that it only serves a supportive role. This insight shaped the testing focus: the manual should direct users to the app and avoid creating the impression that the device can be used without it. Both the app and manual had multiple iterations, with testing revealing several insights.

Participants noted that 'tips' and additional instructions must be provided before the relevant step is taken; otherwise, the guidance comes too late. Detailed instructions are important to give users confidence, as even small gaps in information caused uncertainty. For older users especially, every detail must be explicitly stated, no matter how obvious it may seem. Participants also emphasised the importance of visual confirmation on the device itself, such as a light or vibration, to reassure them that each step was completed correctly.

TEST 5

The fifth test focused on evaluating various patch shapes and materials to determine their performance in terms of comfort, adherence, and suitability for longer use. Materials such as hydrocolloid plasters (similar to blister plasters), silicone-based Mepitel One sheets, and kinesiology tape were compared in a variety of different shapes. It was also tested whether a wire could still be placed in the relevant patch. Patches were worn by both female and male participants, during various activities such as sleeping and sporting.

The silicone sheet was the most comfortable option for users, while the kinesiology tape adhered the best, though it caused slight skin irritation for some after extended wear. The hydrocolloid patch also performed well in terms of comfort and adherence, but was harder to find in larger sizes, and therefore could not be tested in the exact same manner as the other patches. Testing revealed that adding slits to the patch improved flexibility and allowed it to conform better to the curvature of the chest. However, these slits also increased the likelihood of the patch edges curling or detaching prematurely, suggesting the need for rounded corners to potentially mitigate this problem.

The length of the patch was also tested based on average chest circumferences for men and women (Dined, 2024). Considering that the patch extends from the side of the chest to the centre, the ideal patch length was estimated to be approximately 1/4 of the chest circumference. However, this average length proved slightly too long for some users, indicating that a slightly shorter patch is perhaps better than a longer one, as it is easier to extend a patch than to shorten it.

FIGURE G6: PATCHES ALONG THE WAY

TEST 6

The sixth test brought together all the previously tested elements – device shape, patch shape, patch material, feedback type, and instruction method – to evaluate the overall user experience. The aim was to determine user preferences for specific shapes and patch designs, as well as their impressions of the complete product package. Participants were provided with a boxed prototype that included the device, patch, manual, and an app prototype created in Figma. They were asked to unbox the package and follow the instructions as though they had just acquired the device. During this process, participants were encouraged to think aloud (Kerr, 2024), to capture their thoughts and reactions. Participants wore the device for a few hours. After the test ended they were asked to answer a similar questionnaire as used before, to check if the overall feeling of confidence towards – and because of – the device interaction was increasing.

Overall, the integration of all components – device, patch, manual, and app – was well-received, though participants highlighted the importance of refining certain features to optimise the user experience. These notions can be seen in Figure G8.

FIGURE G7: SHAPES ALONG THE WAY

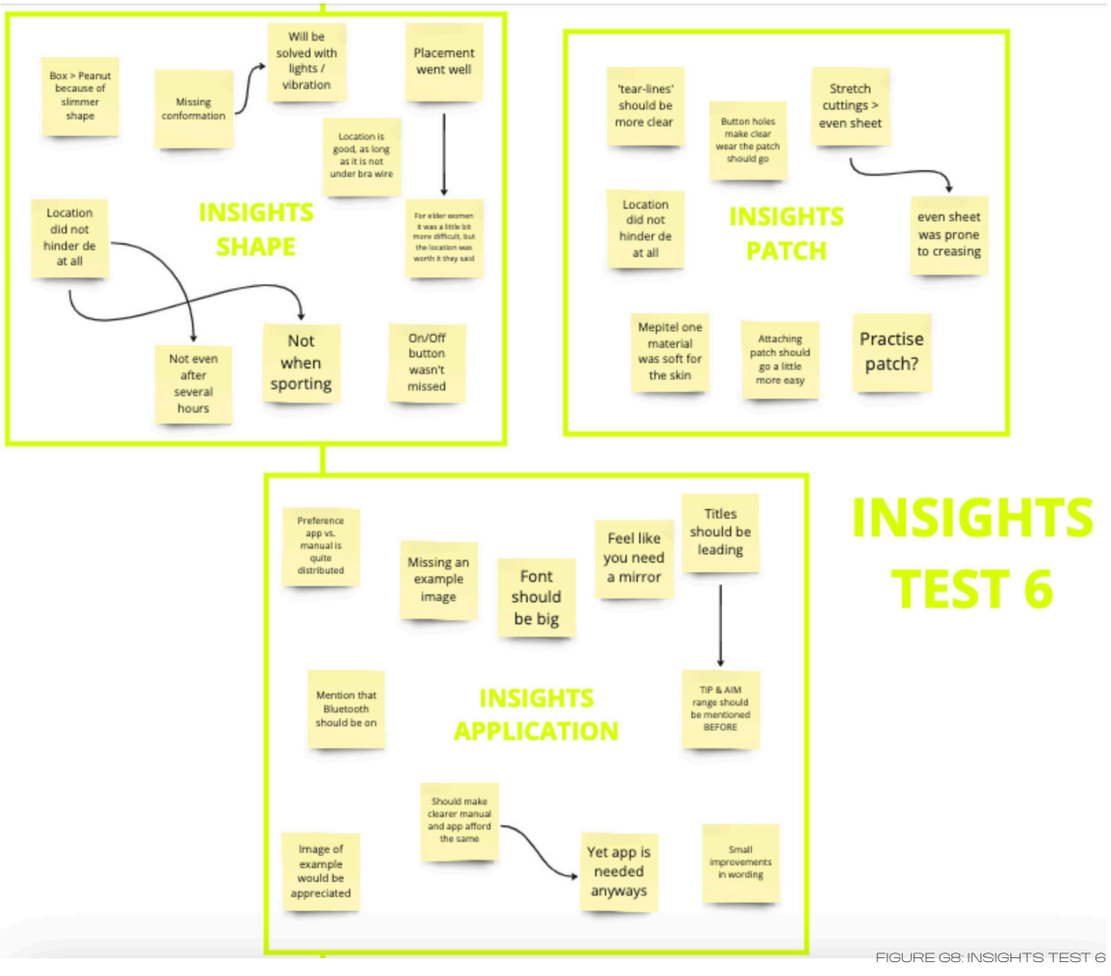


FIGURE G8: INSIGHTS TEST 6

TEST 7

The seventh test was more about optimising the shape, the patch and focussing on long-term usability. For this test, participants were asked to wear the device for several days and maintain a log detailing their experiences, challenges, and adjustments. The goal was to gather insights on how the device performs in the real-world, for prolonged use, and how it interacts with different body types and clothing choices.

Activities such as sleeping and showering generally went well, and participants found that a slightly looser bra or a sports bra improved comfort without requiring significant outfit changes. However, clearer instructions or 'tips' are needed to ensure proper placement of the device, particularly in relation to the bra underwire, and to avoid positioning the patch too close to the armpit. When placed in this area, the patch detached more easily due to increased skin movement.

Care needs to be taken with the device in its current design. The attachment buttons on the underside were still protruding, which caused some discomfort by pressing into the side of the body. These protruding buttons also limited the contact area between the patch and the skin to just the four button points, rather than the entire underside of the patch. Testing an alternative prototype with recessed buttons – a smooth bottom – showed improved adherence. This resulted in better sleep comfort.

While the slits in the patch improved flexibility and allowed for better movement, they also caused certain areas to loosen more quickly. A balance must be found between flexibility and durability. Additionally, the patch's edge near the final electrode needs to be extended to ensure the button remains securely attached and does not detach prematurely.

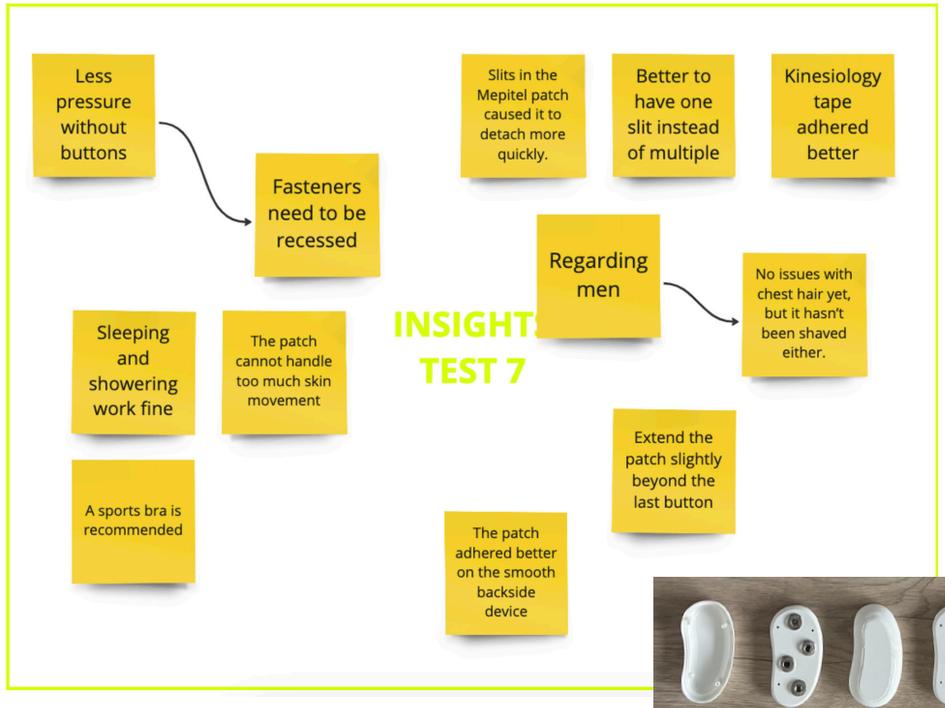


FIGURE G9: INSIGHTS TEST 7

FIGURE G10: SHAPES ALONG THE WAY 2

APPENDIX H

COSTPRICE

Here the estimations for all costs can be viewed. Important to note is that some costs like machine-hour wages, machine costs, human labout costs etc. have all been based on standardised assumptions, derived from earlier performed costs analysis of similar products. For actual costs, the actual factory and employees should be consulted for more accurate pricing.

The set-up of this cost analysis was build upon a lay-out created by Erik Thomassen & Erik Tempelman, a lecturer and a associate professor, both from the department of manufacturing and material science at the TU Delft, IDE faculty. This initial set-up was then supplemented with information derived from various websites (Topworks, 2024), (Bowden, 2025) and personal communication with Erik Tempelman.

Benaming Device			Productieserie	5,000	stuks	per onderdeel
Materiaalkosten	**bruto hoeveelheid/product**		**eenheid**	**prijs/eenheid**	**bedrag**	
Casing top	PC	0.0733	kg	€ 3.00	€ 0.22	
Casing bottom	PC	0.0935	kg	€ 3.00	€ 0.28	
Rubber ring	Rubber	0.0377	kg	€ 5.00	€ 0.19	
				totaal materiaalkosten	**€ 0.69**	**€ 0.69**
Bewerkingskosten	**capaciteit [stuks/u]**	**machineuren**	**machine-uurtarief**	**machine-kosten**		
Casing top	360	13.89	€ 40.00	€ 555.56		
Casing bottom	360	13.89	€ 40.00	€ 555.56		
Rubber ring	960	5.21	€ 30.00	€ 156.25		
nabewerking	1000	5.00	€ 15.00	€ 75.00		
				totaal machinekosten	**€ 1,342.36**	
machines als bovenstaand	**mens/machine-bezetting**	**arbeidsuren**	**mensuurtarief**	**arbeidskosten**		
Casing top	1	13.89	€ 10.00	€ 138.89		
Casing bottom	1	13.89	€ 10.00	€ 138.89		
Rubber ring	1	5.21	€ 10.00	€ 52.08		
nabewerking	1	5.00	€ 10.00	€ 50.00		
				totaal arbeidskosten	**€ 379.86**	
				totaal bewerkingskosten	**€ 1,722.22**	**€ 0.34**
Instelkosten serie	**insteltijd [u]**	**uurtarief insteller**	**mach.uurtarief**	**kosten**	**per product**	
Casing top	8	€ 25.00	€ 40.00	€ 520.00	**€ 0.10**	
Casing bottom	8	€ 25.00	€ 40.00	€ 520.00	**€ 0.10**	
Rubber ring	8	€ 25.00	€ 30.00	€ 440.00	**€ 0.09**	**€ 0.30**
Matrijskosten	**aanschafprijs**	**standtijd [stuks]**		**prijs/eenheid**		
Casing Top Mould €	20,000	250,000		€ 0.08		
Casing Bottom Mould €	20,000	250,000		€ 0.08		
Rubber ring mould €	5,000	500,000		€ 0.01		
subtotalen €	45,000					
				totaal gereedschapskosten	**€ 0.17**	**€ 0.17**
Algemene toeslagen						
uitval-factor*	1.0%	*afgekeurde producten			**subtotaal**	**€ 1.50**
overheadfactor**	15.0%	** algemene toeslag voor productiefaciliteiten				
totaal	**16.0%**					**€ 0.24**
K_{Fi} voor interne calculatie:					**Productiekostprijs Device**	**€ 3.24**

FIGURE H1: PRODUCTIONPRICE DEVICE

Product	Diplora ECG					prijs per product
In-huis te vervaardige	**prijs/stuk**	**stuks/product**	**prijs per product**			
Top, bottom & ring	€ 3.24	1	€ 3.24			
			€ 3.24		**totaal vervaardiging**	**€ 3.24**
Inkopen		**prijs/eenheid**	**eenheid**	**eenheid/product**	**prijs per product**	
PCB	€	5.00	st	2	€ 10.00	
Bluetooth sensor	€	3.67	st	1	€ 3.67	
ECG sensors	€	0.20	st	4	€ 0.80	
LED	€	0.20	st	1	€ 0.20	
Coil	€	3.20	st	1	€ 3.20	
Battery	€	4.20	st	1	€ 4.20	
IMU	€	3.80	st	1	€ 3.80	
Vibration motor	€	1.53	st	1	€ 1.53	
O-rings	€	0.08	st	4	€ 0.32	
M2 screws	€	0.81	st	4	€ 3.24	
M2 screw inserts	€	0.10	st	4	€ 0.40	
					€ 31.36	**totaal inkoop** **€ 31.36**
Assemblagekosten			**assemblageserie**	5,000		
	capaciteit [stuks/u]		**machineuren**	**uurtarief**		
montagestation	80		62.50	€ 40.00	€ 2,500.00	
instellen montagestation	nvt		10.00	€ 40.00	€ 400.00	
handmontageplek	20		250.00	€ 30.00	€ 7,500.00	
verpakken	100		0.10	€ 30.00	€ 3.00	
				totaal machinekosten	**€ 10,403.00**	
machines als bovenstaand	**mens/machine-bezetting**		**arbeidsuren**	**uurtarief**	**arbeidskosten**	
montagestation	1		62.50	€ 25.00	€ 1,562.50	
instellen montagestation	1		10.00	€ 30.00	€ 300.00	
handmontageplek	2		500.00	€ 15.00	€ 7,500.00	
verpakken	1		0.10	€ 10.00	€ 1.00	
				totaal arbeidskosten	**€ 9,363.50**	
				totaal assemblagekosten	**€ 19,766.50**	**€ 3.95**
K_{fi} Productiekostprijs geassembleerd product voor interne calculatie:					**Productiekostprijs Diplora ECG**	**€ 38.55**

FIGURE H2: PRODUCTIONPRICE DEVICE 2

K_{Ft}	Productiekostprijs geassembleerd product voor interne calculatie:	**Diplora ECG**		**€ 38.55**
F_{OB}	Overheadfactor voor algemene bedrijfskosten*		15%	
F_{OV}	Overhead factor voor verkoopkosten		5%	
F_W	Winstfactor (onvoorziene kosten worden a.h.w. uit de winst betaald)		25%	
	Totaalfactor = product van (elk van deze factoren+1) min 1		50.9%	**€ 19.64**
				€ 58.19
	Marge tussenhandel (bijvoorbeeld: importeur, groothandel, leverancier, distributeur)		30.0%	**€ 17.46**
	Groothandelsverkoopprijs			**€ 75.65**
	Marge marktconcurrentie		15.0%	**€ 11.35**
	Netto verkoopprijs (exclusief BTW)			**€ 86.99**
	BTW (= Belasting op de toegevoegde waarde, = omzetbelasting)		21.0%	**€ 18.27**
	Verkoopadviesprijs, normale winkelprijs			**€ 105.26**

*) Voordat iets geproduceerd wordt, moet er doorgaans van alles gedaan zijn: niet alleen het ontwerpproces, maar ook bijvoorbeeld prototyping in meerder stadia, gebruiksonderzoek, marktontwikkeling, certificering, etc. Als dit allemaal in de productprijs meegenomen moet worden, kan deze aardig oplopen.

FIGURE H3: RETAIL PRICE

* Deze investeringen zitten al in de prijs van het product verwerkt, maar worden pok even apart benoemd.

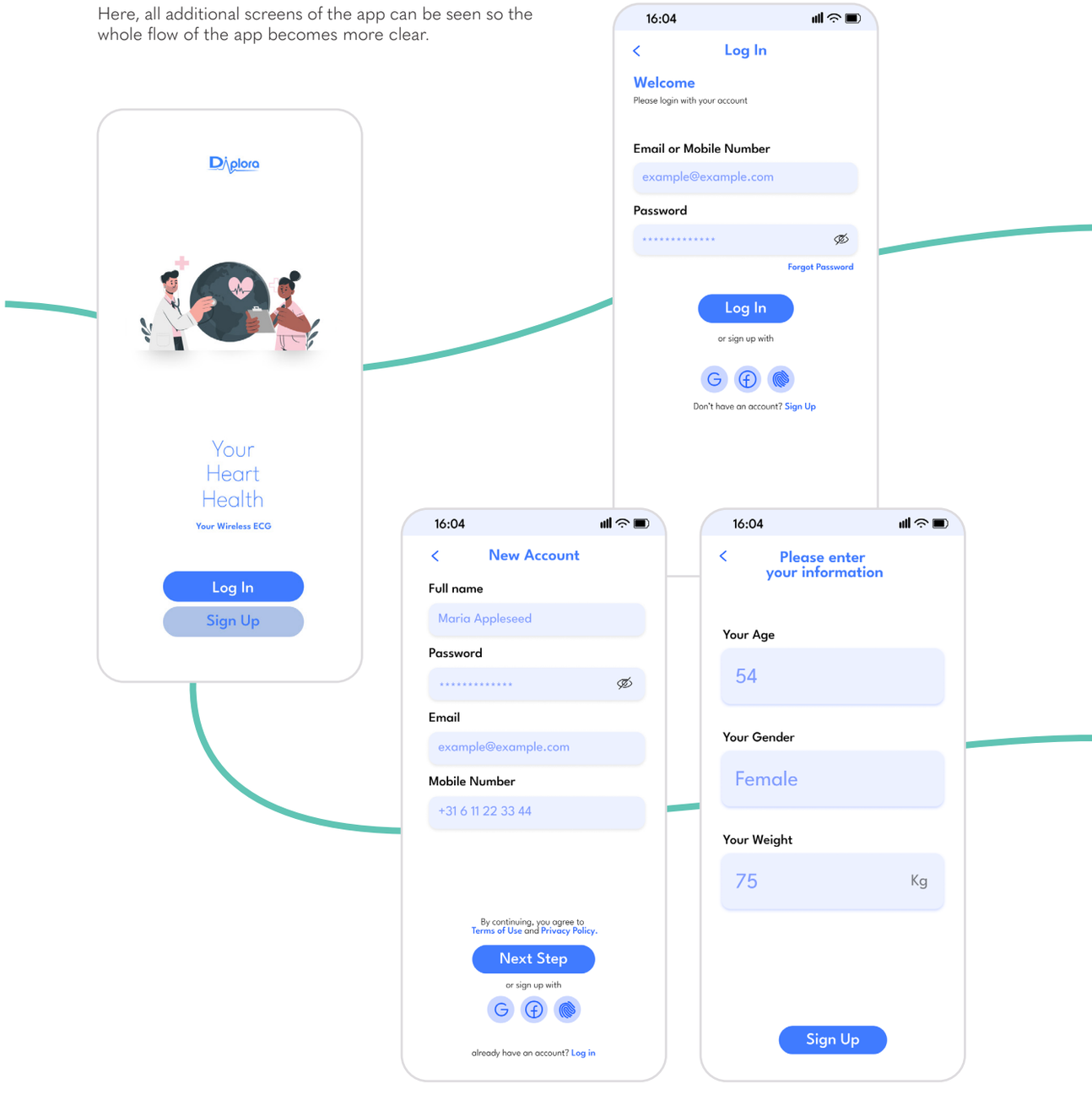
Uitwerken ontwerp / verpakking / ...	**uren**		**tarief euro/u**	**bedrag**
	80		50.00 €	4,000
Ontwikkelen gereedschappen / matrijzen / ...	**uren**		**tarief euro/u**	**bedrag**
	16		40.00 €	640
Aanschaf gereedschappen (per onderdeel, uit sheets)	**Onderdeel**	**gereedschap**	**prijs**	
	Top Casing	matrijs A	€	20,000
	Bottom Casing	matrijs B	€	20,000
	Rubber ring	matrijs C	€	5,000
Eventueel: aanschaf speciale machine	??		€	0
			€	0
Aanpassingen in productieinrichting / assemblage	instellen montagestation	arbeid	€	300
	instellen montagestation	machine	€	400
Werkvoorraad inkopen	??		€	-
			€	-
	Totaal investeringen	Diplora ECG	€	50,340

FIGURE H4: INVESTMENTS

APPENDIX I

ADDITIONAL SCREENS OF THE APP

Here, all additional screens of the app can be seen so the whole flow of the app becomes more clear.



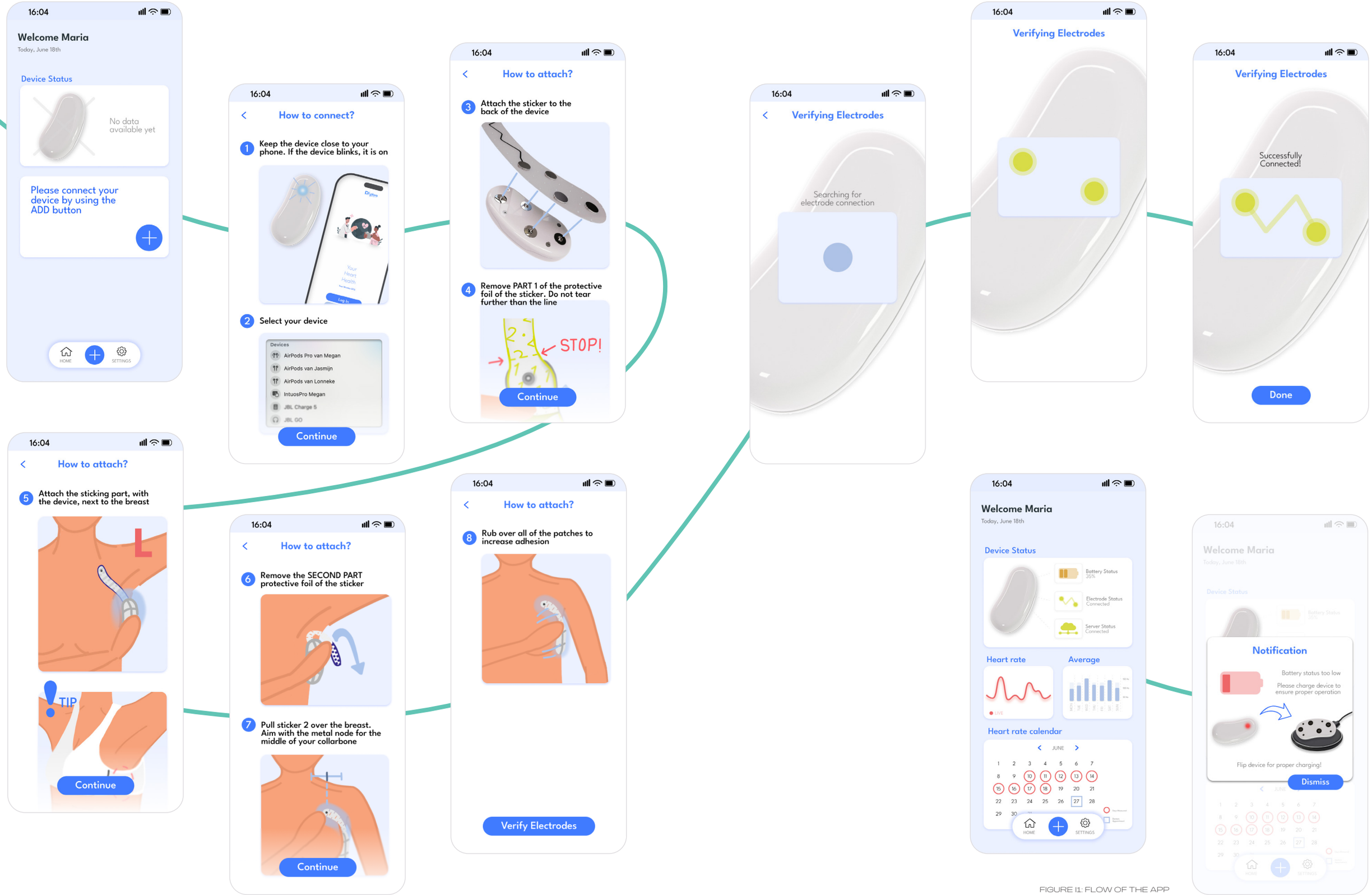


FIGURE I1: FLOW OF THE APP

APPENDIX J

RAW DATA OF FINAL USER TEST

OLDER LADY "EDITH"

Goede eerste indruk

Liever in het NL of in 2 talen

Lettergrootte met bril goed te doen, dikgedrukte goed leesbaar

Drukkers zijn intuitief, je weet waar ze moeten door de oriëntatie

Plaatje vrouw is duidelijk

"Enorme verbetering! Mijn god wat een verschil!"

Voelt licht en zacht, mooi afgerond

Zou zeker niet in de weg zitten op deze locatie

Goed datie zo onzichtbaar is onder kleding

"Dat plaatje zegt alles" heel duidelijk

Edith had ook last van Atrium flutter of boesem fibrilleren

Naast de borst is top! Een andere plek zou ik inderdaad niet prettig vinden (Edith probeert hem nu ook op verschillende plekken)

Hij valt nu ook goed in de bh band

Door het plaatje van de vrouw zie je gelijk dat het product klein is, door de verhouding op het lichaam.

"Ik denk dat iedereen het toejuicht als dit in productie komt!"

Edith was uiteindelijk gestopt met het proberen te vinden van haar probleem met een holter, omdat die draden zo waardeloos waren

! De taal van de manual is erg belangrijk

Over competence: Edith had zelf goed vertrouwen dat zij dit product zelf zou kunnen handelen, maar benoemde wel dat wat meer onzekere oudjes hier misschien wel moeite mee zouden kunnen hebben. Maar, zei ze, die zouden dan wel samen met een kind of verzorger ernaar kunnen kijken, en ik weet zeker dat een kind of verzorger deze instructies ook zou snappen.

Over trustworthiness: Ja ik ga er wel vanuit datie te vertrouwen is anders wassie niet op de markt. Daarnaast is het uiterlijk gewoon betrouwbaar

Wel moeten de schroefjes misschien nog net iets meer verdiept worden (terechte opmerking, de schroefjes gebruikt voor de final prototype waren de platste die er waren, maar niet degene die ik zou kiezen voor een definitief design)

Over de appearance: "Perfect! Ik werd er helemaal blij van! Alleen van het doosje al"

Op de vraag of er nog wat mist: Nee, alleen het 'gat' waar het device in ligt misschien dicht maken, zoals zo'n fluwelen laag in een juwelen doosje (hiermee bedoelde edith een verdiept, dicht gedeelte, waar het device in komt te liggen en niet doorheen valt. Een beetje als een eierdoos zegmaar) Geen gat zou geen probleem zijn, je gaat toch wel zoeken naar die patch, omdat je op de verpakking ziet dat die er ook zou moeten zijn.

Het thuissturen vind ik ook top! Lekker makkelijk en helemaal van deze tijd. Dat scheelt je ook nog eens al die bezoeken aan de cardioloog of de assistent.

De cardioloog of huisarts zou desnoods ook ter plekke 1x het apparaat kunnen uitleggen, met een voorbeeld model, om onzekere ouderen alvast een eerste kennismaking met het product te geven.

"Zonde om dit product te laten schieten, niet alleen voor mensen, maar ook voor cardiologen, assistenten etc, dat scheelt gewoon allemaal onkosten".

YOUNGER LADY "EMILY"

"Je kan de patch enigszins herstellen als je verkeerd plakt en hij irriteert de huid niet; amazing!"

"ik ben zo blij dat het niet allemaal van die kut draadjes heeft"

Nice dat de verpakking aangeeft waar die moet

"Ik denk dat dit heel fijn is want
minder onderdelen
meer bewegingsvrijheid
niks los hangt

Vooral in de zomer waren al die draden goor, met zweten, met omkleden etc

Deze wil je tenminste niet zo snel mogelijk af trekken, en die andere wel. Van deze zou ik gewoon vergeten datie er zit.

Over de looks: ziet er professioneel uit, mooi vorm gegeven en lekker klein.

De app is ook nice, cool dat je meer 'in control' bent omdat je zelf de app in kunt zien. Bij dat kastje had ik geen idee of er nou iets gebeurde of niet.

Over de shape: Dikte is goed, moet niet dikker. Zit niet in de weg.

Over competence: ja 100% de manual is super duidelijk, ik zou er zo mee aan de slag kunnen

Hij is intuïtief met een duidelijke uitleg

Wat daarbij helpt is dat de patch er maar op 1 manier op kan, en het device maar op 1 manier dan logisch om je lichaam past. Dus als je het device goed plakt, hoef je gelukkig verder op niet veel meer te letten (in vergelijking met haar oude apparaat, waarbij je elke losse sensor dan weer op de juiste plek terug moest plakken na douchen)

"Als ik mezelf verplaats in jongere ik van 12 had ik dit ook nog steeds goed begrepen"

Over 'handled the right way': vooral door de app weet je dat je het goed doet. Die feedback is fijn want daardoor zie je of die verbonden is en als je je live hartslag zou zien zou ik dat ook nice en handig vinden.
Of course de enige twijfel die je altijd zult hebben is omdat je zelf geen cardioloog bent / zelf een leek bent, waardoor je nooit 100% zeker bent dat je het goed hebt gedaan

Over trustworthiness: Ik zou zeker denken dat dit apparaat het goed zou doen, mijn enige twijfel zou haast zijn 'hij is zo klein, kan hij het wel?' (omdat ze dus zo'n grote unit gewend was) Maar, voegde ze toe, ik zou hem aan de andere kant ook niet groter willen

Over appearance: de appearance boeit eigenlijk niet want hij moet het gewoon doen, maar ik vind het device wel gewoon sleek. Ja alleen de patch is natuurlijk nog wel wat log, de zichtbare draad maakt het wel meer medisch, maar ik begrijp ook dat dat nou eenmaal nodig is voor een goed meetresultaat.

Op de vraag of er nog wat mist: Meerdere stickers in de doos, maar als dat zo is dan helemaal top.

De lampjes vind ik ook een goede en duidelijk toevoeging (zodat je weet wanneer hij leeg is of verbonden ofzo)

"Soms denk ik als je ergens weer een app voor moet downloaden bleeergh weer een app, maar voor iets als dit is het wel logsich, dus daar zou ik me overheen zetten. Want wat je kan zien in de app is wel echt nice. Daarbij: dit moeten doen voor een laptop had ook niets geweest.

FIGURE J1: TEST PARTICIPANT

APPENDIX K

CREATION OF THE CONFIDENCE QUALITIES

What is confidence?

Different types of confidence

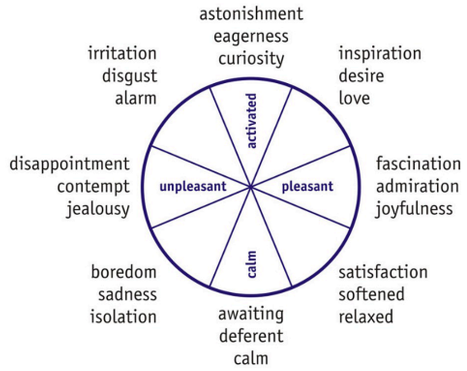


Figure 1. Circumplex model of core affect with product relevant emotions (Desmet, 2008; adapted from Russell, 1980).

Table 1 Summary of the six groups of personality characteristics

Attractive	Aggressive	Bourgeois	Careless	Conspicuous	Aloof
Casual	Dominant	Businesslike	Chaotic	Eccentric	Boring
Charming	Excessive	Calm	Childish	Exuberant	Cheerless
Cheerful	Obtrusive	Consistent	Corny	Funny	Insular
Cute	Showy	Decent	Creepy	Idiosyncratic	Masculine
Easy-going		Honest	Immature	Interesting	Old-fashioned
Energetic		Inconspicuous	Odd	Lively	Reticent
Feminine		Mature	Pathetic	Provocative	Strict
Flexible		Modest	Silly	Tough	Unattractive
Friendly		Precise	Unreliable	Wild	Uninteresting
Happy		Predictable	Untidy		
Informal		Reliable			
Nice		Sensible			
Open		Serious			
Pleasant		Well-groomed			
Popular					
Pretty					
Relaxed					
Romantic					
Sensitive					
Sweet					
Terrific					
Young					
$\alpha = 0.96$	$\alpha = 0.83$	$\alpha = 0.88$	$\alpha = 0.84$	$\alpha = 0.91$	$\alpha = 0.89$

FIG. 20.2 Typology of 25 positive emotions. *Adapted from Desmet, P. M. A. (2012). Faces of product pleasure: 25 positive emotions in human-product interactions.* Int. J. Des. 6*(2), 1–29.*

Figure 1. General typology of 25 positive emotions.

Confidence	• Confidence is the experience of faith in oneself or in one's ability to achieve something or to act in the right way. The related feelings are self-assurance, security and certainty, and the related tendencies are control, competence, resolution, determination, and being free from doubt. • People can feel confident about products that are trustworthy or easy to use. Products can make people confident because they support independence or because they help them look good. Moreover, products that prevent injury or damage and products that support one's expertise or profession also provide confidence.

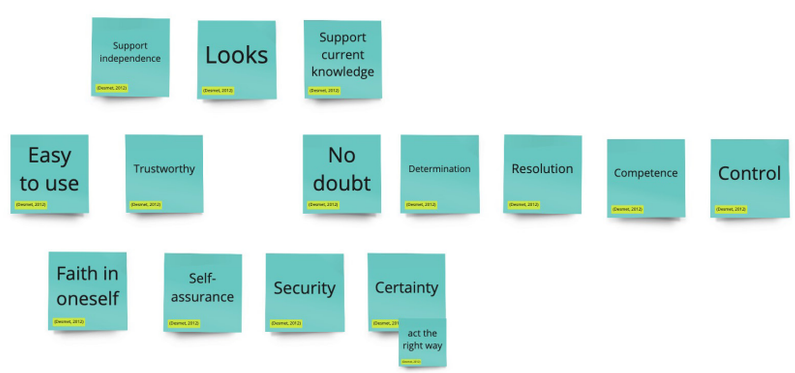


FIGURE K1: COMPETENCE QUALITIES GENERATION

APPENDIX L

INITIAL GRADUATION PROJECT BRIEF

DESIGN FOR our future

TU Delft

Personal Project Brief – IDE Master Graduation Project

Name student Megan Seker **Student number** [redacted]

PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT
Complete all fields, keep information clear, specific and concise

Project title Redesigning a wearable ECG-device to improve early detection of potential heart defects in women for at-home use.

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)

The growing demand for cardiology consultations, driven by the suspicion of heart abnormalities, is contributing to an overburdened (Dutch) healthcare system (Van de Poel, 2024). A significant portion of these referrals could be avoided with more effective at-home monitoring solutions.

Diplora is a company wishing to produce a wearable ECG device, designed for preventative cardiological care. Their ECG device could be used/purchased in three primary contexts: cardiological care in medical centres, as a recommendation from doctor to patient, and by individual consumers seeking to monitor their heart health. The primary function of the device is not to diagnose heart deficiencies, but rather to rule out potential heart issues, making the device more preventative than diagnostic.

While the interior of the device (electronics and intelligence) is currently being optimised, there is a need to improve its exterior design and user interaction. The current design still uses inconvenient wires, used for electrode attachment, whereas the new design shall focus on two main wireless components: the patch, which attaches to the chest and contains the electrodes, and the casing that houses the device and its functional components. To improve usability, the form, shape, and weight of the device must be refined, with an emphasis on a comfortable and intuitive interaction. Although my initial research and graduation project will focus on the optimisation of the design for women, the goal is to create a universally effective solution for both genders.

Furthermore, Diplora aims to explore sustainable materials, such as bioplastics or recycled medical waste, aligning with their commitment to environmentally responsible practices. A significant challenge in the medical device industry, as many products are designed for single use to ensure hygiene and safety, and need to fulfill health requirements.

➔ *space available for images / figures on next page*

introduction (continued): space for images

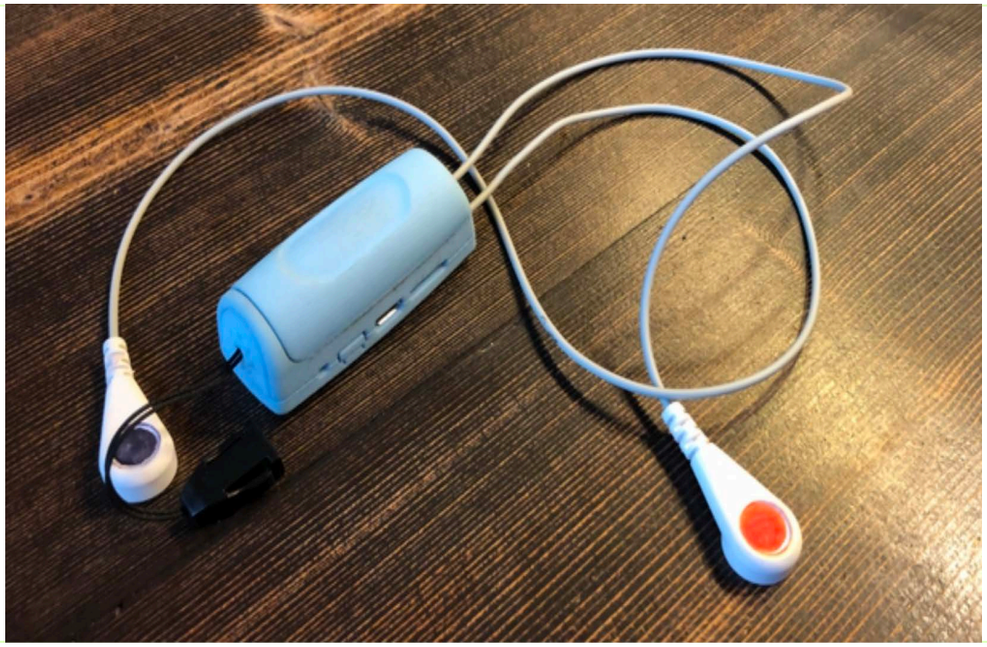


image / figure 1 Current design to be optimised

image / figure 2 Future inspiration image by Diplora

DESIGN FOR our future

TU Delft

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)

In 100 days, I aim to improve the current design of Diplora's ECG device by creating a comfortable, intuitive, and sustainable solution.

The shape and interaction of the device will firstly be orientated for women. As most wearable ECG devices are unisex, resulting in poor fit and comfort for women, usability and the quality of health monitoring can be hindered (Wisbey, 2024). By analysing women's physiological and ergonomic needs, comfort and reliable heart monitoring could be optimised.

Additionally, these devices are often designed for single use, contributing significantly to environmental waste in the healthcare sector (WHO, 2018). The redesigned wearable ECG will also focus on sustainability, considering every step from material selection to manufacturing, as well as disassembly and recycling. However, a balance must be found between sustainability and mandatory requirements for medical devices.

By improving the user experience and sustainability of the wearable ECG device, this project will contribute to better health outcomes and reduce unnecessary strain on healthcare systems, while

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:

Redesign a wearable ECG device to improve early detection of potential heart defects in women for at-home use.

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)

Sustainability and user-friendliness are key priorities in this project and to ensure these elements are thoroughly integrated, they will be incorporated from the very beginning. Tools such as a focus group, user-centred design, co-design, the eco-strategy wheel and the 10 golden rules for sustainable design will ensure that every aspect of the device meets both environmental and user-focused goals.

The project will follow the triple diamond methodology, starting with a strong foundation in the discovery phase. This phase will involve desk research, interviews, context mapping, a competitor analysis, and a stakeholder map.

In the define and ideate phase, a user-centred approach will be implemented, emphasizing co-creation and co-design with female users to ensure the device is both sustainable and tailored to their needs. Methods like brainstorming, a morphological map, and prototyping will be used to generate solutions.
Finally, in the develop and deliver phase, the design will be refined through co-testing and validation.

Project planning and key moments

To make visible how you plan to spend your time, you must make a planning for the full project. You are advised to use a Gantt chart format to show the different phases of your project, deliverables you have in mind, meetings and in-between deadlines. Keep in mind that all activities should fit within the given run time of 100 working days. Your planning should include a ***kick-off meeting***, ***mid-term evaluation meeting***, ***green light meeting*** *and* ***graduation ceremony****. Please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any (for instance because of holidays or parallel course activities).*

Make sure to attach the full plan to this project brief.
The four key moment dates must be filled in below

Kick off meeting	10 Sep 2024
Mid-term evaluation	14 Nov 2024
Green light meeting	30 Jan 2025
Graduation ceremony	10 Mar 2025

In exceptional cases (part of) the Graduation Project may need to be scheduled part-time. Indicate here if such applies to your project

Part of project scheduled part-time	✔
For how many project weeks	14
Number of project days per week	4,0

Comments:
I work every other Wednesday, therfore I cannot work on my graduation on those days. So every 10 working days I cannot work 1.

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)

After my first year at DFI, I felt that the program remained too conceptual and lacked the depth I was seeking in product development. To bridge this gap, I pursued a Joined Master Project in Ghana and selected the IPD package deal in my elective space to gain more concrete experience in product development.

For my graduation project, I aim to merge both perspectives. I want to create a design that is intuitive and user-friendly, empowering women to feel comfortable using the device (DFI perspective), while ensuring it is sustainable in terms of materials, manufacturing, and recyclability (IPD perspective).

On a personal level, I also want to sharpen my 3D CAD design skills, as I believe this technical ability is essential for my future career. I think there is no better way to learn than by diving into a project that demands both creative and technical expertise, which is exactly what I aim to do.