Redesign of the HeartEye portable ECG for Home use

by Lucas Habets

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Faculty of Industrial Design Engineering
Delft University of Technology

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Author
Lucas Habets

Graduation committee
Prof. dr. ir. Jan-Carel Diehl | Chair
Department of Sustainable Design Engineering
Faculty of Industrial Design Engineering
Delft University of Technology

Prof. dr. ir. Maaike Kleinsmann | Mentor
Department of Design, Organization and Strategy
Faculty of Industrial Design Engineering
Delft University of Technology

In collaboration with
Heleen Willemsen and Tjebbe Tauber from HeartEye
Jos Oberdorf and Martin Steffner from NPK Design BV.

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ABSTRACT

This Master's thesis describes the redesign of the HeartEye portable Electrocardiogram (ECG) device to enable home use for patients with coronary artery disease (CAD). The initiative aimed to transition the medical-grade 12-lead ECG from a clinical setting to a user-friendly, home-based application, maintaining the device's diagnostic integrity while enhancing accessibility for non-expert users.

The project was done in collaboration with HeartEye, TU Delft, and NPK Design, applying the double diamond design framework that works with four key phases: Discover, Define, Develop, and Deliver.

Discover Phase: The redesign began with an examination of the existing HeartEye ECG device, assessing its design and functionality. Following research explored the opportunities in E-Health, highlighting trends and innovations that could inform HeartEye's integration into telemonitoring service centres. In-depth user group research was conducted to understand the specific needs, behaviours, and experiences of CAD patients, guiding the development of user personas. This phase also looked at the regulatory landscape to ensure that the redesigned device would comply with the most important medical device standards and to address potential future regulations related to AI and sustainability in healthcare. A quick dive into machine learning interpretability was completed. Additionally, market strategies were evaluated to discover if they would have an impact on the to be designed device. Gender-specific issues of heart disease and care were addressed as well. Lastly, a qualitative study enriched by direct patient feedback provided deeper insights into the personal impact of CAD.

Define Phase: Using the knowledge from the Discover phase, a start was made to discover potential use scenarios. A well evaluated choice was made to choose for the rehabilitation to rehabilitation period as the use scenario to be designed for. Once this was defined, we scoped down the design space to only encompass the physical design considerations and set up some boundaries to help make design decisions later on in the project. Lastly, we defined four determinants that determine what makes a good measurement based on expert feedback and research.

Develop Phase: Factors influencing measurement quality were developed, allowing for the exploration of a broad range of directions. Ideas were iteratively conceptualized, prototyped, and refined, with three main directions chosen for further development: housing geometry, feedback methods, and electrode material. These were prototyped and tested in a structured user test, consisting of four parts: quantitative evaluation of device geometries, qualitative interviews about user experiences, a card game to discuss feedback needs and methods, and an internal test on electrode material effects on contact resistance. The results informed design guidelines for the redesign.

Deliver Phase: This phase explored the practical implications of the developed design guidelines, by designing, optimizing, and evaluating a concept design. Moreover, some recommendations are given for the future implementation of the insights generated over the course of this project.

The resulting redesigned HeartEye portable ECG device could empower patients to monitor their cardiac health effectively at home, combining clinical-grade monitoring capabilities with an accessible, user-centric design to potentially reduce CAD-related mortality through timely and frequent monitoring.

INTRODUCTION

Background

Cardiac health complications are the number one cause of death globally, according to the global burden of disease study (IHME, 2020). Coronary artery disease (CAD), in particular, presents a considerable healthcare burden, for example in the United States accounting for a third of the deaths of people older than 35 (Ralapanawa & Sivakanesan, 2021). A majority of cardiac arrest incidents occur outside the hospital environment, where immediate medical intervention is often not available (Vervueren et al., 2012; Norris, 1998). The early stages of CAD normally go a-symptomatic, making pre-symptomatic check-ups an invaluable tool that can result in timely interventions preventing further development of the disease (Tan et al., 2018).

Electrocardiography (ECG) has stood at the forefront of cardiac diagnostic methods for over a hundred years (Barold, 2003), providing essential data for detecting and assessing the risk of CAD (Mayo Clinic staff, 2022). The clinical standard 12-lead ECG systems are the benchmark tool, offering a possibility for the detection of CAD symptoms (McDonagh et al., 2021). While these systems are proven to be robust and reliable, their application is largely confined to the hospital due to their size, complexity, and the need for trained personnel. Consequently, this restricts the potential for frequent pre-hospitalization ECGs which have been shown to decrease time-to-treatment and mortality (Diercks et al., 2009).

Existing portable ECG devices offer a measure of convenience and accessibility. However, they are typically limited by a reduced number of leads, which in turn limits their accuracy and diagnostic capabilities (Bansal & Joshi, 2018). This compromise on medical-grade monitoring capability reveals a notable gap in cardiac care that is yet to be filled. Specifically, the need for an at-home ECG monitoring solution that combines the comprehensive diagnostics of a 12-lead ECG with the accessibility and user-friendliness suited for non-expert users.

This project aims to address this gap by redesigning the HeartEye for home use. The objective is to develop a concept product-service system that empowers individuals to take control of their cardiac health outside of clinical settings. The hope is that this project will contribute to the ultimate goal of reducing CAD-related mortality by providing people with easy, portable, and cheaper medical-grade cardiac monitoring.

Figure 0: Current design of the HeartEye ECG device

Project goal

HeartEye has developed the first iteration of its product service system. The current design is intended to be used in hospitals by medical professionals. However they have grander plans, in the future, they aim to make the system more widely available by making it usable for home use by cardiac patients. For this to become a reality a lot of work is still to be done and this is where this graduation project comes into the picture.

This project aims to propose a concept product that empowers patients to make ECGs by themselves with the HeartEye technology.

However, the whole product service system will not be taken into account (device, digital interaction, possible service, and e-health aspect) as this would not fit within the timeframe of this graduation project. Thus, to create the necessary and grounded focus, different interesting directions will be explored at each step of the way and subsequently the most relevant will be selected and continued with.

Project structure

The project is structed according to the double diamond design framework (Design Council, n.d.)(see figure 1). It consist of diverging and then converging on more specific and relevant areas, and to make it a double diamond we do that twice. That makes four phases in total which are defined as follows:

Discover. The first diamond helps us understand, rather than simply assume, what the problem is. It involves speaking to people who are affected by the issues and experts in the field. For this project we will delve deep into all the facets of the problem during the discovery phase, trying to find interesting areas to further explore and to get a complete overview of what is needed to take on designing a portable handheld ECG for home use.

Define. With the insights gathered from the discovery phase, we can define the design challenge better and develop the specific use scenario. For example, we will define who we are going to design for, when they might use the product, how they should use it, and where they might use it.

Develop. In the first half of the second diamond, we try to explore different answers to the defined scenario. We take the defined design space and try to come up with interesting directions to explore based on all the previously gained knowledge and expertise.

Deliver. Delivery involves testing out different directions at a small-scale, rejecting those that will not work, and improving the ones that will. The goal is for the resulting findings to guide future designs to improve the device for home use. As an initial exploration, these findings will be used to create a novel concept of the HeartEye ECG intended for home use.

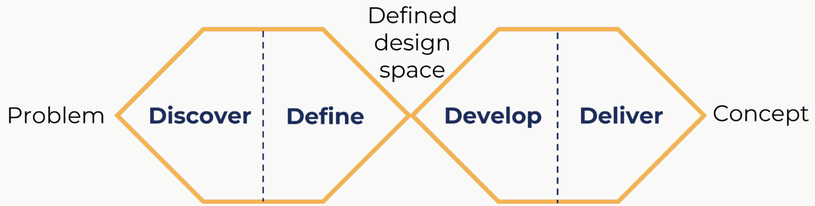


Figure 1: Schematic overview of the double diamond deisgn framework

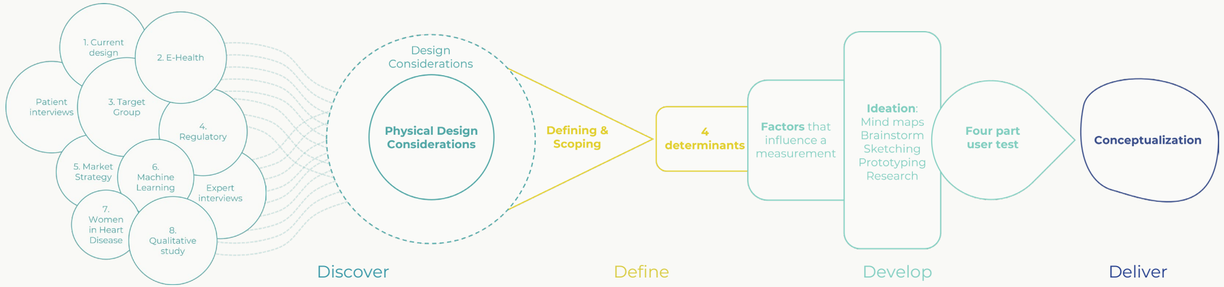


Figure 2: Detailed overview of the project

Project team

This project involves three main parties besides myself; HeartEye, TU Delft, and NPK Design. They have all provided guidance and support throughout the project ensuring a meaningful result. In the following section, each party and their role is explained in short. In this report, I will refer to these stakeholders as the project team.

HeartEye
HeartEye, the client for this project, provides a blend of medical expertise, medical product development experience, and business insights. The involvement of Rien van der Zee, the company's founder and former cardiologist, brings easy access to invaluable medical knowledge that guided the development process from the start. Furthermore, Heleen Willemsen (CTO) and Tjebbe Tauber (CEO) provided fundamental knowledge and experience of the product and its technology in combination with offering business and regulation perspectives crucial for aligning the project with market demands and healthcare industry standards.

TU Delft
As part of the Master's Integrated Product Design program at TU Delft, this graduation project benefits from the expert guidance of two university professors, prof. Jan-Carel Diehl is the chair of this project and Prof. Maaike Kleinsmann is the mentor. They both have a truly expert understanding of various areas of this project and provided guidance and direction to this project, as well as their wide connections in the academic field. This support was vital for maintaining the project's academic goals and aligning it with current research in healthcare technology.

NPK Design
From NPK Design, the design studio responsible for the current physical design of the HeartEye device, Jos Oberdorf and Martin Steffner offered their technical and design expertise. Their role was to provide feedback and guidance to ensure the resulting design is not only functionally effective but also user-friendly, manufacturable and suitable for its intended environment. Their extensive expertise in product development helped avoid common pitfalls and maintain a clear goal and vision.

Reading Help

Throughout this report we will be talking about the HeartEye team, their device, technology and system a lot. Therefore it is wise to define what is meant with each of these:

- **HeartEye:** is the company itself, including their team.
- **The HeartEye ECG:** is the physical device
- **The HeartEye system:** is the whole product service system that device is included in (for example, the app / platform or e-health system)
- **The current or original design:** Is the current physical design as designed by NPK design and meant for use in hospitals and GP offices.

Next to this, also the major abbreviations and technical terms, which are explained in the report itself, are also listed her, if you ever get confused:

- CAD: Coronary Artery Disease is a prevalent condition where the coronary arteries become damaged or blocked, usually due to the build-up of cholesterol-containing plaques.
- ECG: Electrocardiogram, is a medical test that records the electrical activity of the heart over a period of time using electrodes placed on the skin.
- MDR: Medical Device Regulations refers to the European Union Medical Device Regulations, which provide guidelines and standards for medical devices to ensure their safety, performance, and quality.
- EHR: Electronic Health Record is a digital version of a patient's medical records.
- IP: Ingress Protection is a standard that indicates how well a device or product is protected against solids (like dust) and liquids (like water).
- ABS: Acrylonitrile Butadiene Styrene is a type of plastic
- AI: Artificial Intelligence is an algorithm that performs complex tasks by optimizing itself based on example data.
- USP: Unique Selling Point is a distict feature of a product/service that sets it apart from other products/services.
- PCB: Printed Circuit Boards is a, often green, thin board for connecting and carrying smaller electronic components.
- 12-Lead ECG: is a ECG that provides 12 different views (or leads) of the heart's electrical activity. These 12 leads correspond to 12 separate derivations or graphs, not the amount of physical electrodes.
- Electrodes: Electrodes are conductive, low contact resistant pads placed on the skin that act as an interface between the skin or electrical activity of the heart and the ECG device.

Lastly, it is important to keep the accompanying **appendix** to this report nearby as many more in-depth explanations or analysis are located there.

DISCOVER

Understanding the Problem

This part of the thesis explores broad set subjects in order to gain a deep understanding of what is needed for a feasible, desirable and viable design. In the eight chapters that follow, seven subjects will be explored, these were selected as interesting to explore through discussions with the project team during the first meetings and personal interest.

First, the current design of the HeartEye device is analysed, assessing its features and capabilities. The next chapter evaluates potential target groups for the HeartEye device, followed by a detailed look into the basic regulatory requirements. Then, we examine the growing trend in E-health. Subsequently, we explore the market strategies, focusing on possible distribution channels and the possibility to be covered by insurance. This is followed by an investigation into the integration of machine learning in to the HeartEye system. Finally, we include a qualitative analysis based on forum posts among heart patients and insights gathered from two interviews with individuals suffering from heart conditions.

Each chapter of this phase concludes with a list of design considerations synthesised from the analysis in the chapter. In the body of each chapter the origin of the design considerations is marked with DC and then the corresponding number in parentheses, like this: "(DC 1)". These considerations will be clustered in the conclusion chapter of this phase into eleven design considerations. Together, they form a comprehensive understanding of the (problem) context and of what needs to be taken into account when designing the HeartEye system for home use. In the next phase of this report - define - we will narrow the focus on the physical design considerations, limiting our scope. Ultimately leading to a design that is focussed on the physical requirements, while being grounded in a broad understanding of the context.

Therefore, this chapter shows a extensive exploration of multiple facets related to the context, laying a solid foundation for focussed and informed design decisions.

Figure 2: Overview of the chapters in the discover phase

CURRENT DESIGN OF THE HEARTEYE ECG

As this project encompasses the redesign of the HeartEye ECG device it is important to do a short analysis of the current design (see figure 3).

First, it's use is explained, followed by the rationale for the need for a rapid and portable 12-lead ECG within this context. Then the ergonomics of the device are looked into. Followed by an overview of the different interfaces incorporated into the system. Next, a quick summary of the hardware that makes up the device is given and finally how the device is meant to be used is illustrated.

Figure 3: Current design of the HeartEye ECG device

Target use

The HeartEye portable ECG is designed to cater to healthcare professionals who use the device for fast and portable cardiac assessment within hospitals and GP offices.
Designed specifically for medical practitioners, the HeartEye can be used as a faster and cheaper alternative to the standard large 12-lead ECG currently used, which makes it suitable for a variety of scenarios ranging from routine check-ups to emergency diagnoses.

Why a 12-lead portable ECG

The 12-lead ECG has been the cornerstone of cardiac diagnostics for over a hundred years (Barold, 2003), offering a multidimensional view of the heart's activity.
HeartEye's capacity to provide a clinically proven (De Vries, 2023; Zepeda-Echavarria et al., 2024) medical-grade 12-lead recording makes its diagnostic capabilities beyond what was possible with typical portable devices, which are often restricted to fewer leads. The information that can be gathered by the 12-lead ECG is indispensable for many diagnoses in the hospital or GP office, making the current HeartEye design useful in scenarios where a slow, large, and expensive machine and specialized on-site knowledge are not available.

The Technology

Where HeartEye innovates is the ability to make a clinical grade 12-lead ECG from only four dry electrodes positioned on the chest for no more than one minute. The electrodes need to be positioned from each other by a fixed distance and the four electrodes need to be positioned within 4 cm of the specified area. The placement of the device should be in the middle with the bottom electrodes on the same height as the bottom of sternum, in figure 4 you can see the a visualization of this placement and in figure 5 you can see where the sternum is located. These requirements for number of electrodes, distance between electrodes and placement location on the chest cannot be altered and thus will form the base for any future design.

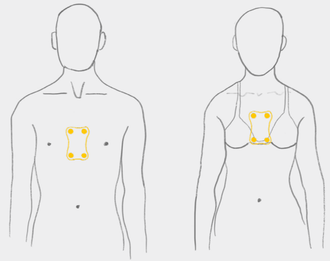


Figure 4: Schematic of the correct placement location of the HeartEye ECG device

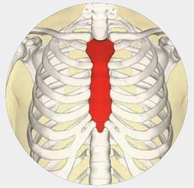


Figure 5 Location of the sternum (Rohit, 2023)

Ergonomics

The current design is designed to be used by a medical professional administering care to the patient. This means that it was never intended to be used on the users themselves. The design reflects this, with its slanted top and button position being ideal for holding the device away from the user whilst leaving room for the fingers to grip the device steadily under the top ledge without coming in contact with the patient's skin.
Although this grip was well tested by NPK design for the current scenario, it was not yet tested for taking self-measurements.

Interface

The current HeartEye system has two main interfaces: The physical device itself and the accompanying phone application.

Physical Interface

The HeartEye ECG is outfitted with two LED indicators that communicate operational statuses. The first indicator communicates the connectivity status with the phone (either connected or searching state). The second one indicates battery level and power status. There also is a semi-circle of LEDs that communicate the progress of the measurement during use and the battery level during charging.
There are also two buttons on the device. One power button can be used to turn the device on by pressing it once and to turn off the device by holding the button for five seconds. The second button is the record button. The device starts a recording once this button is pressed and the device is set up correctly.

Phone Interface

HeartEye has developed its mobile application together with Q42. This interface facilitates interaction with the device and wrangles the incoming data into an ECG. Below an overview is of the various capabilities of the current application:

- It links the device and the resulting ECG data to the user.
- It instructs the user on how to use the device, e.g. where to place the device.
- It converts the sensor data into the 12 ECG derivations with algorithms and filters.
- It sends the data to the cloud storage or somewhere else like a local printer or email.
- It shows a real-time single lead ECG preview during measurement to ascertain if the measurement is going okay.
- It facilitates the viewing of the ECG reports it generates.
- The app is also capable of exporting the ECG report as a PDF file in order to fit with the established practice of handling ECG reports.
- The application can also be set up to send the ECG data to a cloud server for further integration into healthcare systems

Hardware

In this section an overview is given of the hardware components, by defining their function and features (see figure 6):

1. **Construction**
The HeartEye is designed with intense use in a hospital environment in mind. Its construction is watertight and alcohol-proof in order to withstand thorough sterilization practices.
Furthermore, the device is made to endure physical stress, including accidental falls, something regular ECG devices are not equipped for. The main material of the housing is a medical grade ABS and PP mixture, this was chosen to comply with medical device regulations.

2. **PCB**
The device features a PCB that handles the sensor input, initial filtering of the signal, power management, and the hardware control interfaces of the device. It also features Bluetooth connectivity used to make contact with the user's phone. The rough dimensions of the PCB are 90 mm x 40 mm.

3. **Battery**
The HeartEye portable ECG is designed to be able to record 50 ECG measurements within a span of 24 hours without the need to recharge the battery. The rough dimensions of the battery are 35 mm x 45 mm x 5 mm.

4. **Electrodes**
The electrodes are positioned to make simultaneous contact with the patient's skin, on a variety of chest sizes and shapes. The device's electrodes are designed to meet safety regulations, by being made from medical-grade stainless steel.

5. **Charging Dock**
The system features a charging dock which is connected via a USB type-C cable. The device can simply be put into this dock and it will snap into place with magnets. The dock is designed so that there is no way to incorrectly place the device into the charging dock, decreasing the chance of users picking up a device with an empty battery.

HeartEye chose to include a proprietary charging dock to lower the chance of users charging the device wrong, reducing the risk of malfunctioning. Furthermore, it is detrimental that there is no way that the device would be charged while the device is placed on a patient.

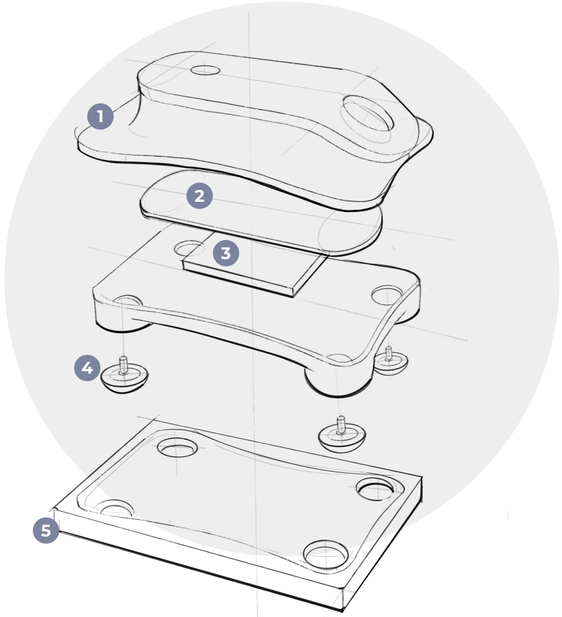


Figure 6: Simplified exploded view of the current HeartEye Device

Curernt Use Scenario

The current use scenario is illustrated in figure 7, in order to gain a better understanding of how the device is intended to be used.

1. A patient comes into the ward and the doctor decides an ECG is needed to help diagnose the patient.
2. A medical professional picks up the HeartEye and accompanying phone from a central location in the ward.
3. The medical professional connects the phone to the HeartEye device by scanning the QR code on the back.
4. The medical professional puts the device in the correct position on the patient's chest. Once the medical professional deems the ECG preview on the phone to be good. They press record on the ECG device or the phone and the HeartEye device starts the measurement.
5. The measurement takes approximately 45 seconds to complete.
6. The phone creates the 12 derivations and shows them as an ECG report which can be printed on a local printer, read directly from the device, or exported to a cloud service.
7. The device is returned to the dock and starts charging again.

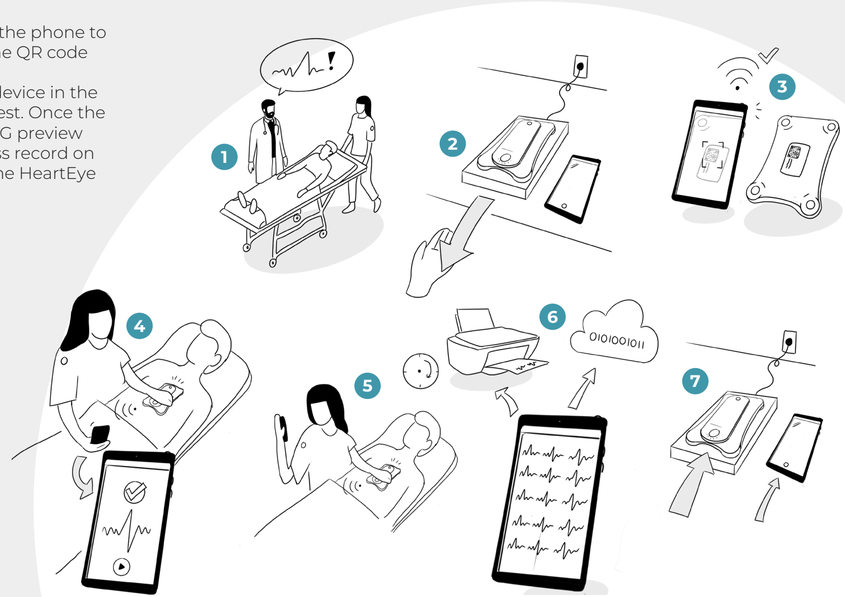


Figure 7: Use scenario of the current HeartEye system

Design considerations

Concluding, there already has been done extensive development into the current design of the HeartEye device. It would be a shame to not incorporate some of the findings from this excellent work into this project. The following design considerations were found to be the most relevant findings to take on board:

- **Medical-grade material**: The material choice of medical-grade ABS and stainless steel, were carefully made decisions to optimize price, form freedom, and structural integrity, whilst complying with regulations. As the material requirements will be similar in the future version, it is possible to take on this material choice for this project.
- **Waterproof**: The current design is waterproof (IP68) to: reduce the risk of malfunctioning due to water damage, regulatory reasons, and to be able to clean the device effectively. This should be taken on in this project as well.
- **PCB components**: The size of the current PCB can be used as a starting point for internal dimensional requirements for the redesigned device.
- **Charging dock:** The charging dock mitigates several risks for misuse and malfunctions. Therefore, it is preferable to also take on this aspect of the current device to not have to deal with mitigating the risks in another way.
- **Battery size**: The battery size in the current design can be used as a starting point for the internal dimensional requirement for the redesigned device.
- **Technology requirements**: There are fixed requirements for the number of electrodes, the distance between electrodes, and placement location on the chest and thus cannot be altered.

THE OPPORTUNITIES IN E-HEALTH

The trending field of E-Health presents significant opportunities to address the escalating challenges in healthcare, particularly in managing heart failure, a condition that makes up 1 - 2 % of the worldwide healthcare budgets (Ski & Rocca, 2020; Lesyuk et al., 2018). With the prevalence of heart failure on the rise, exacerbated by increasing comorbidities like diabetes and obesity and an aging population (Savarese, 2020), the strain on healthcare systems intensifies. However, it has been long known that many hospital admissions for heart failure can be preventable (Michalsen et al., 1998). This suggests a new way to provide care might be needed.

E-health – defined as: "the application of both digital information and communication to support and/or improve health and healthcare." (Van Lettow & Wouters, 2019) - can be a part of the solution. It is a rapidly growing field that utilizes digital technologies to revolutionize healthcare delivery. With the advancements in these digital technology and their adoption, E-Health has gained significant attention as a promising solution for improving patient care, increasing access to healthcare services, and reducing healthcare costs.

This chapter will explore the current state of E-Health in cardiovascular care, mainly in the Netherlands. First, a look at examples of other ECG telemonitoring devices currently on the market. Followed by an exploration of the services that connect telemonitoring devices with healthcare providers. The next section looks at considerations to be taken into account when developing an e-health system. Finally, a conclusion and discussion on what the implications for the project are.

Exploration of ECG telemonitoring devices

A thorough exploration of the currently available or currently in development ECG devices was done and a surprising amount of already available ECG devices to facilitate cardiac health monitoring outside the clinical were uncovered. In appendix K a full description of all the researched products is listed and in table 1 an overview and comparison of the products can be found.

These devices, which range from wearable to implantable, share a common goal of empowering patients with the tools for self-monitoring, while also ensuring seamless integration with healthcare systems for efficient data management. Despite their common objectives, these products differ significantly in other areas such as the methods of data collection, with some offering continuous monitoring capabilities and others designed for episodic use. Additionally, the number of health parameters tracked, the interface through which the user interacts with the device, and the specific technologies employed to capture cardiac data, all varied between the researched devices. This variation can be seen as a reflection of the still-evolving landscape of e-health technologies and signals the ongoing innovation required to meet a wide range of patient needs and preferences for personalized cardiac care.

Table 1: overview of analysed ECG telemonitoring devices

Company or product	HeartEye	QardioCore	MyDiagnostick	HappiTech	Alivecor / Kardia	OMRON healthcare	Zio	Phillips	Medtronic	Commwell PhysioGlove	Praxa Sense / Afi	Savvy ECG	Corsano band	Spengler Cardiomate	Welch Allyn CP 150
Number of leads	12	6	1	1	1	1	1	12	1	12	1	1	12	3, 6 or 12	3, 6 or 12
Continuous VS episodic	Episodic	Continuous	Episodic	Episodic	Episodic	Episodic	Continuous	Continuous	Continuous	Episodic	Continuous	Continuous	Continuous	Episodic	Episodic
Clinically proven	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Connection to healthcare system	Via patients' phone connected to a virtual care platform	Via patients' phone connected to a virtual care platform	Stores 140 measurement on the device which can be retrieved by a doctor via USB	SDK to be used in other E-health services	Via patients' phone connected to a virtual care platform	Via patients' phone connected to a virtual care platform	The patch is sent back after 2 weeks, then the data is physically retrieved	Via patients' phone connected to a virtual care platform	Connected to the healthcare provider via a separate device next to the user's bed	Via patients' phone connected to a virtual care platform	Via patients' phone connected to a virtual care platform	Via patients' phone connected to a virtual care platform	Via patients' phone connected to a virtual care platform	Features a printer to print the ECG report	Features a printer to print the ECG report
Measures other vitals	No	raspatory rate, temperature	No	No	No	blood pressure	No	No	No	No	heart rate, oxygen saturation, respiratory rate, movement, temperature	No	blood pressure, skin temp, SPO2, sleep, activity, breathing rate	No	No
Note				Hardware free heartrate monitoring tool			Non-reusable heart monitoring patch	Holter for use in decentralized clinical trials	Non-reuseable implantable heart rate monitor for three years	Holter	Non reusable patch	Reusable patch	Research platform	An actual professional ECG system	An actual professional ECG system

From this wide range of systems, we can see that the HeartEye system does have its little niche, with none of the other home monitoring devices being able to make 12-lead ECGs, except the two Phillips Holters, but those are aimed at detecting arrhythmias and not CAD. Thus from this analysis, we learn that HeartEye's unique selling point is being able to make 12-lead ECGs in a home monitoring context (DC 11).

Exploration of E-health services

Next to the devices, the already existing or in development E-health services were also explored (see figure 8). This investigation into E-health services revealed a wide range of diverse platforms all aimed at enhancing cardiac care through digital connectivity between patients and healthcare providers. In appendix K a full description of each researched platform can be found. The platforms cannot easily be compared directly to each other because these services fulfill different functions in the home monitoring ecosystem from simple messaging platforms to facilitating the analysis of data of various home monitoring devices. This large variation again illustrates a still-evolving field and a significant variety in patient needs and preferences across the field.

From this analysis, we learned that not only patients but also medical professionals are users of such a platform. Furthermore, inspiration can be taken from these services as a basis to innovate further (DC 7 - 10).

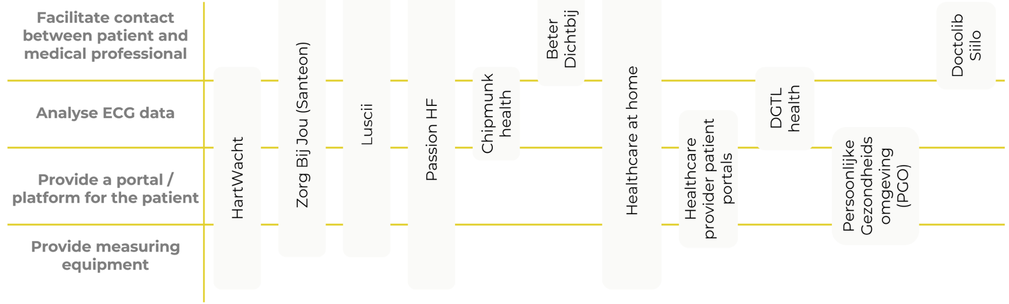


Figure 8: Overview of the analysed e-health services compared on four features

Use of tele-monitoring in healthcare

In 2021, 111.195 telemonitoring insurance declarations were made by GPs and medical specialists in the Netherlands, in comparison to 84.416 in 2020 and 57.896 in 2019 (Nederlandse vereniging ziekenhuizen, 2022). The largest portion of which is for cardiological diseases (van der Vaart et al., 2022). van der Vaart et al. (2022) also found that 30% of the GPs and medical specialists in the Netherlands want to intensify the use of telemonitoring. Thus it can be concluded that there is a clear trend in telemonitoring visible.

Tele-monitoring centres

As seen in the section on e-health services, telemonitoring centers already exist and many more are in development. Experts agree that these centers will become a key part of the transition to hybrid care (Deloitte Netherlands, 2023; Zorgverzekeraars Nederland, 2022) A tele-monitoring center provides services that enable patients to receive care with digital support as much as possible in their living environment (Nederlandse Vereninging Ziekenhuizen, 2022). The service they provide that is most relevant for HeartEye is that they analyze and interpret medical data gathered by home monitoring devices.
In an interview, the quartermaster medical service center of Santeon explained how they plan to operate their telemonitoring center, Zorg Bij Jou, in the future (see figure 9):
Incoming signals are routed through several platforms from different companies, like Luscii or the Philips home monitoring platform.

1. They first get routed automatically based on their importance. Meaning, that signals that are within expected values set by medical professionals are not further analyzed, but incoming signals like questions and deviating vitals are sent further into the system.

2. Then the data gets into the telemonitoring center, where there are three distinct layers, with each layer increasing the need for expertise. This means the first layer (digital reception) is for answering basic questions on the health data or for connecting people to the right resources. The second layer, the home monitoring assistants, are there to analyze basic health data and verify if deviating values are real and require further intervention, and the third layer, the home monitoring medical professionals, can connect multiple health data sources like the electronic patient dossier to analyze and interpret the incoming signal in depth.

3. There are protocols in place that the telemonitoring team can set in motion when needed, based on an incoming signal. These could be, contacting the patient, calling emergency services, or sending the signal further to the supervision layer, which are the doctors in hospitals.

4. In this way, Santeon aims to efficiently and effectively handle large amounts of incoming health data generated by home monitoring devices.

HeartEye could collaborate with a telemonitoring center such as the Zorg Bij Jou platform, as they are open for external services to join. This would significantly reduce the investment cost, time-to-market, and expertise required to operate an effective, safe, and scalable home-monitoring ECG service (DC 1).

Effectiveness of telemonitoring in cardiovascular care

The effects of telemonitoring in cardiovascular care are already well-studied in clinical trials. In appendix L, several studies on the subject are explored. Based on these studies, we can conclude that telemonitoring in general has been shown to have a high potential in improving cardiovascular care in a multitude of ways such as: reducing anxiety and depression, reducing cost, reducing the number of hospital admissions and days spent in the hospital, improve health outcomes and more.

Figure 9: Schematic overview of the workings of a telemonitoring service centre

Barriers for e-health adoption

E-health implementations offer the potential to revolutionize healthcare service delivery. Yet, certain barriers exist for patients and healthcare providers. The HeartEye system should overcome these barriers to become successful.

Patient-related barriers

Patients have expressed an overall positive attitude towards e-health systems (Thomas et al., 2021; Carla Plymen, 2023; Ajčević et al., 2021). Citing, among other positive impacts, an improvement in quality of life and quality of care (Huygens et al., 2021). However, there are also several obstacles and considerations to take into account when designing an e-health system:

1. Low personal motivation
2. Scared of change in patient-doctor relationship
3. Fear of diminished care quality
4. Lack of support from outside
5. Preference for a hybrid model
6. Limited health literacy
7. Type of digital technology and trustworthiness of the provider
8. Missing patient-Centric design

These barriers are further substantiated and explained in appendix M. All of these barriers should be taken into account when designing the new HeartEye system and therefore are included in the design considerations 2 to 6

Healthcare provider-related barriers

According to the E-Healthmonitor 2022 (van der Vaart et al., 2022), medical specialists and GPs are generally positive about the use of telemonitoring:

- More then 80% noticed an increase in the quality of care
- 90% was either neutral or saw an increase in work pleasure
- 90% were either neutral or saw an decrease in healthcare cost due to telemonitoring
- 95% were either neutral or saw an increase in self-sufficiency of patients due to telemonitoring
- 90% of the GPs and medical specialist think they are digitally literacy is sufficient.

However, there are also still several obstacles to take into account:

1. Perception of added burden
2. Inadequate infrastructure and training
3. Navigating the change

These barriers are further substantiated and explained in appendix N. These barriers are represented in design DC 1 and 12.

Other barriers

Government organisations and patient- and medical organisations are actively campaigning for the adoption of e-health solutions (Ministerie van Volksgezondheid, Welzijn en Sport, n.d.; Landelijke Huisartsen Vereniging, n.d.; European Heart Journal - Digital Health, n.d.). Developing guidelines, infrastructure and much more. However, some general industry-wide obstacles should still be taken into account:

1. Lack of national guidelines and standards
2. Reimbursement
3. ICT infrastructure
4. Interoperability
5. Privacy, security, and quality concerns

These barriers are further substantiated and explained in appendix O. We are not listing these in the design considerations because they are not related to the HeartEye system specifically but rather to the E-health market as a whole and HeartEye lacks the resources to have a substantial impact. They are mentioned here for context and completeness.

Guidelines on the development of E-Health

It is helpful to look into already established guidelines for the development of e-health solutions, to not fall into any already discovered pitfalls. Breeman et al. (2021), from the Dutch BENEFIT for All Cardiovascular e-health consortium, identified 10 values that should guide e-health-based programs aimed at promoting healthy living, in the realm of prevention and rehabilitation of cardiovascular diseases.

1. Providing continuous care (DC 9)
2. Reduce burden on healthcare professionals (DC 1)
3. Providing a human-centred approach (DC 3)
4. Supporting the patients' autonomy (DC 6)
5. Providing means for patients to stay healthy, feel safe, and help prevent new cardiovascular disease incidences (DC 8)
6. Inclusion of patients' social environment, improving social support (DC 13)
7. Simplicity and guidance (DC 2)
8. Personal contact (DC 14)
9. Trustworthy (DC 5)
10. Financially self-supporting (DC 4)

These guidelines made by leading experts are used in the design considerations noted in brackets after each guideline.

Design considerations

Concluding, e-health has shown to be a clear trend, which the HeartEye system is poised to benefit from by learning from existing devices and services and being guided by patient and medical professional experiences with those devices. The following design considerations were synthesised from the analysis in this chapter.

1. **Integration with healthcare systems**: The system should be integrated into healthcare systems and a telemonitoring service centre. This mainly entails collaborating with a telemonitoring service centre to have them interpret the ECG data but also includes providing compatibility with existing electronic health records and patient portals, ensuring that the data can be easily accessed and utilized by healthcare providers.
2. **User-friendliness and accessibility:** The system should be intuitive and straightforward to use for individuals without medical training. This includes simple instructions, ease of setup, and clear interpretation of results, ensuring that patients can use the system correctly and effectively in their own homes.
3. **Patient-centric design**: The design should focus on patient needs and expectations. This involves not just technical aspects but also considering the emotional and psychological comfort of the users. The system should foster trust and confidence among users, making them feel secure and supported in their health monitoring journey.
4. **Low cost to patient:** To ensure broad accessibility, the system should be low cost or no-cost for the patient. This is particularly important to make the technology available to diverse socioeconomic groups, ensuring that no patient is left behind due to financial constraints.
5. **Adress patient fears:** Patients have shown to be hesitant about adopting e-health systems because of being unfamiliar with e-health or having a bad experience with another system. These fears should be addressed by the HeartEye system to increase adoption chances.

6. **Support for patient autonomy through data:** The system should support and encourage patient autonomy by providing understandable insights into their health status. This could contribute to enabling patients to make more informed decisions about their health.
7. **Patient Education and Engagement Features**: Incorporate features for patient education and engagement, such as those seen in Lucii's monitoring programs. This can include interactive tutorials, progress tracking, and personalized health tips based on ECG readings.
8. **Adaptability for Remote Rehabilitation Programs:** Design the device to be compatible with remote rehabilitation programs, offering functionalities that support patients' recovery and ongoing health management, similar to the approach in telemonitoring centres.
9. **Real-time data transmission:** Incorporate features for real-time data transmission to healthcare providers, similar to services provided by HartWacht and PASSION-HF, Instead of opting for a-synchronous data transmission. This allows for immediate professional analysis and intervention if necessary.
10. **Automated Alert System:** Implement an automated alert system that notifies healthcare providers when abnormal readings are detected, similar to the mechanism used in Heartcare at home. This system can also inform patients if they need to seek immediate medical attention.
11. **Focus on USP:** As there are plenty of other devices in the home monitoring market, the HeartEye system should focus on enhancing the HeartEye's unique capability to perform 12-lead ECGs within a home monitoring context.
12. **Support the Healthcare provider:** Not only the patient but also the healthcare provider should be supported with educational content. Helping them navigate the change and make a system more efficient instead of adding burdens.
13. **Social Support Integration:** Facilitate the inclusion of a patient's social network to support the patient. This could enhance the patient's emotional well-being and provide an additional layer of support.
14. **Provide Personal Support:** Develop a system for contact between patients and healthcare providers. This could include scheduled virtual check-ins or the ability for patients to request consultations. Such features should be designed to build trust and ensure patients feel valued and listened to.

TARGET GROUP RESEARCH

It is essential to understand the diverse group of people who will interact with this technology. This chapter dives deep into the research surrounding the target groups and stakeholders for the HeartEye system, breaking down their unique needs, experiences, and expectations.

First, the initial scope of users is defined. Then the chapter explores their health statuses, lifestyles, and interactions with medical technology. The roles of medical professionals and secondary users, such as family members, are also considered for their impact on the device's usage. Furthermore, an overview of all the identified stakeholders is given and finally, three personas are shown which will be used to test and guide future design decisions on. As a conclusion, design considerations that need to be taken into account when further developing the HeartEye system are summed up.

HeartEye context of target users

HeartEye has specified a three-phase plan for targeting different users with different versions of their ECG devices. Each phase is targeted at a different target audience which is defined below:

1. **Healthcare professionals**, such as cardiologists and GPs, would find the HeartEye ECG device useful for its portability, ease of use, and ability to provide quick ECG readings. It could be used as a much cheaper alternative to the standard 12-lead ECG, particularly in situations where portability and speed are important, for example in emergency rooms or GP offices.
2. H**igh-risk patients** would benefit from the HeartEye ECG device's ability to monitor their heart health at home, allowing them to track changes in their heart rhythm and share their data with their healthcare providers promptly. This could enable early detection of potential heart problems and facilitate timely interventions. Furthermore, it could lead to earlier discharge from hospitals and fewer visits or consultations.
3. **General consumers** who want to self-track their health would appreciate the HeartEye ECG device's potential to provide insights into their overall heart health and well-being, particularly for individuals who are interested in sports performance, stress management, or general health monitoring. The device could also serve as a motivator for maintaining a healthy lifestyle.

The current design of the HeartEye ECG is designed with the first group (healthcare professionals) in mind. To limit the scope of this project it was chosen, together with the project team, that this project should focus on the high-risk patients only.

Exploring the target group

In this section the target group is explored by looking at the three potential users of the system; the patient, the secondary user and the medical professional.

The Patient

In this section, the main target group of high-risk patients is further explored on several important themes.

Coronary Artery Disease

This project will focus on coronary artery disease (CAD). Coronary artery disease is: “the foremost single cause of mortality and loss of Disability Adjusted Life Years worldwide.” (Ralapanawa & Sivakanesan, 2021). Coronary artery disease is a prevalent condition where the coronary arteries become damaged or blocked, usually due to the build-up of cholesterol-containing plaques. When these plaques build up, they can narrow the arteries, reducing blood flow to the heart muscle and potentially leading to serious health implications such as heart failure.

During an interview, Dr Rien van der Zee (ex-cardiologist and founder of HeartEye) highlighted the potential benefits of directing the HeartEye device towards individuals suffering from CAD.

First of all, a relatively large impact can be made here as currently, a lot of patients suffer from the complications of CAD, while it could be treated relatively well if further complications are diagnosed early enough. Furthermore, The incidence of new coronary artery problems is highest among people who have already been diagnosed, making home monitoring of diagnosed patients extra relevant. The HeartEye device could make this possible thanks to the early warning signs that a 12-lead ECG can reveal.
Next to that, postoperative or post-diagnosis monitoring of patients can be vital in managing their condition by keeping track of deterioration and diagnosing possible new issues. Lastly, in a study by Leening et al. (2013), it was estimated that there are 730.000 people diagnosed with coronary artery disease in the Netherlands. This large number further highlights that improving the accessibility of cardiac diagnostic tools has the potential to make a meaningful impact on numerous patients.
These reasons make patients diagnosed with coronary artery disease an impactful scenario and an interesting group to focus on for the further development of the HeartEye system.

Demographics

Coronary artery disease is an age-related disease, making the elderly a significant demographic for heart health monitoring devices. Dr. Rien van der Zee put the age target between 55 and 70 years old However, the scope broadens when considering middle-aged adults, especially those who have known CAD risk factors like family members with CAD. These people are maybe even more interesting to take into account as they have the potential for more healthy years ahead. Such an example underscores the importance of inclusive monitoring solutions catering to a loosely specified and broad demographic.

Patient types

As previously suggested it is important to acknowledge that there are many different types of patients who all have different needs and wants. It is out of the scope of this project to define all the different profiles associated with CAD, but it is still relevant to look at some of the literature-identified profiles and keep these in the back of our minds when developing the future HeartEye system. For example, Tenbult et al. (2023) found a large inter-individual variation in the need for information in cardiovascular patients and Warth (2011) listed 15 patient profiles ranging from the pleasant patient to the depressed. Some interesting profiles are:

- Demanding patients require a lot of attention.
- Anxious patients require a lot of reassurance.
- Non compliant patients do not follow prescription
- Direct patients like to be in control
- All-knowing patients tend to believe that they are very knowledgeable about medical subjects

Although ungrounded, these profiles do showcase a wide range of differing informational demands. As well as highlighting the importance of a personalised patient journey (DC 1 & 3).

Patient needs

Next to a vast range of patient types, there is also a broad range of different needs of patients. It is again out of the scope of this project to delve too deep into the general patient needs, but to illustrate what we are dealing with we show an example of six themes uncovered in a study by Andersen et al. (2017) on the patient experience in cardiac remote monitoring:

- **Consistency**: Confirmation of symptoms creates relief and missing detection of signs creates frustration and despair. (DC 5 & 6)
- **Being informed:** Information and feedback on clinic transmissions help patients understand and relate to their condition, even if there is no news. (DC 4 & 6)
- **Feeling uncertain and anxious:** Waiting produces uncertainty, Information reduces uncertainty. (DC 7 & 14)
- **Dealing with identity change:** The “patient identity” influences behaviour and social interaction. (DC 11)
- **Concerns about new responsibilities:** being monitored makes patients aware that they, themselves, are responsible for making sure that the clinicians have a basis for diagnosing them. (DC 12)
- **Having expectations**: because patients are putting a substantial effort into the monitoring, some also expect the clinicians to show sympathy and take the time to give feedback. (DC 13)

These themes again highlight the importance of catering to a wide range of needs within the target group (DC 1).

Technology affinity
The target audience is a diverse group, united by medical necessity rather than a voluntary interest in health technology. Their experience with and trust in medical devices are influenced by a plethora of factors. For example: performance expectancy, effort expectancy, and perceived privacy and security are direct predictors of the telehealth adoption rate among the elderly (Van Houwelingen et al., 2018; Schomakers et al., 2019). Next to that, older adults in the Netherlands are less likely to adopt new technologies (Vorrink et al., 2017). Factors like these make the adoption of- and trust in the system a vital requirement for a successful product. Thus in the design of the HeartEye system, we should consider supporting these less tech-savvy users (DC 7) and perhaps make the device not overly high-tech in appearance (DC 8), but instead try to convey its medical value to foster greater trust (DC 9).

Health literacy
In addressing health literacy, it is important to recognize its role in the effective use and adherence to telemonitoring systems like the HeartEye system, especially for patients managing chronic conditions such as coronary artery disease (CAD). Health literacy extends beyond the basic understanding of health information; it includes the ability to access, comprehend, and apply health information to make informed decisions on their health (DC 6). Accommodating for lower health literacy is significant as health literacy directly correlates with health outcomes. For instance, patients with lower health literacy levels may find it challenging to perform necessary lifestyle changes (Peltzer et al., 2020), furthermore it potentially leads to decreased adherence to telemonitoring devices and medication regimes, which can negatively affect health outcomes (Hussey & Gilliland, 1989; Oscalices et al., 2019; Van Der Wal & Jaarsma, 2008).
To address these challenges, the HeartEye system's design and patient education materials should be tailored to accommodate a wide spectrum of health literacy levels (DC 1 & 4).

Adherence
Non-adherence to telemonitoring devices has been cited as a major problem in elderly heart failure patients, by Van Der Wal & Jaarsma (2008). In their study, they defined factors contributing to non-adherence. For example: the complexity of the regime, the prevalence of depression or the fact that a necessity for extensive lifestyle changes decreases adherence significantly.

Adherence can be improved in various ways, such as by addressing the patient needs described earlier or by increasing health literacy also previously discussed. These examples illustrate that adherence isn't just a design consideration on its own but instead is the objective, which is why it is not listed as a separate design consideration.

Accessibility
For older people with heart conditions, using health devices like HeartEye can be tough. Several issues commonly observed with heart diseases are physical dexterity, frailty, sensory impairments, cognitive dysfunction and mental health. In appendix Y a more in-depth analysis of these issues and sources can be found.

Accessibility features to cater to these patients are shown to be important to consider (DC 2), but as a starting telemonitoring service, the HeartEye system will always be prescribed to patients through shared decision-making between the doctor and the patient. Meaning, they will both decide if the system is effective and usable for the patient. If the system is not suited for the patient due to a lack of sufficient accessibility features, then that patient will receive regular care instead of telemonitoring. Therefore it is for this project more important that most people can use this first generation system, instead of focussing on including everyone. In future developments, HeartEye should look into specific physical or ergonomic features to improve the accessibility of their systems.

Secondary users
After having taken an in-depth look into the main target group of the system, we will now take a more shallow look at the people around the heart patients who might help the user use the device and thus could be seen as secondary users.

Transitions in the approach to long-term care in the Dutch healthcare system have stimulated older adults to stay at home longer (Schoot, 2014). This caused the responsibility of care to shift from the healthcare system to the elderly themselves and their close contacts and relatives. It is thus to be expected that the people operating the device are in some cases going to be these informal caregivers or let's call them secondary users.
Next to operating the device, these secondary users could also act as motivators for continued use of the device and might be interested to be able to remain informed of any insights the measurements provide.

This behaviour might even be something HeartEye should promote as family involvement in the care can positively improve the anxiety of heart patients (Soleimani et al., 2023). Next to that, lack of social support has been found to be a risk factor for non-adherence to prescribed therapy in elderly heart failures (Artinian et al., 2002). This lack of support also is related to worse health outcomes in patients with heart failure (Tremethick, 2001; Horsten et al. 2000).
Concluding, the system will need to cater to the needs of these secondary users or the possible lack of, them when designing the next-generation system (DC 10).

Medical professionals

The last target group is the medical professionals who prescribe the device and also will need to analyse the data provided by the system. These healthcare professionals have their considerations to ensure the device is desirable for them. According to the E-health monitor 2022 (van der Vaart et al., 2022) and interviews with medical professionals (I1, I4 & I7) several considerations were found:

- **Patient Compliance and Usability**: GPs and cardiologists will want a device that their patients can use without difficulty, thus they will judge the usability of the device when deciding if the device is desirable. (DC 12)
- **Telemonitoring Capabilities:** As the device will be used for telemonitoring, it should include features which support efficient remote management of patients, reducing the need for in-person visits and allowing for efficient use of healthcare resources. For example: A system to flag abnormal readings automatically could be implemented, enabling healthcare professionals to prioritize patients who may require immediate attention. (DC 5 & 13)
- **Ease of Data Interpretation:** The software application should present the ECG data in a clear and concise manner, which is easily accessible and preferably in a format that is familiar to healthcare professionals. They already need to learn many new systems throughout their careers, thus lowering the barrier of adoption is essential for widespread adoption. (DC 6)
- **Integration with Clinical Systems:** The ability to integrate with existing electronic health records or clinical management systems is important for making the change to a telemonitoring system as easy as possible. (DC 13)
- **Cost-effectiveness:** The device should offer value for the healthcare system, balancing the costs with the benefits it brings in terms of improved patient monitoring and outcomes. (DC 15)
- **Clinically verified and trust:** Medical professionals emphasized the importance of being able to trust the resulting ECG reports in order to be able to adopt the system.
- **Training and Support:** Adequate training materials and support for healthcare professionals is needed to help them to understand the full capabilities of the device and how to troubleshoot common issues, making the transition into a new system more seamless. (DC 7)

In conclusion, making an easy-to-use system that medical professionals trust and can easily adapt to their current way of working is essential to make this system desirable for this influential group.

Personas

To narrow down the target audience for this project, three detailed personas were developed (see figure 10). Personas are not real persons, but rather hypothetical archetypes of the envisioned user (Goodwin, 2009) which, in this case, were created through interviews with heart patients, a study of heart patient forums -which will be discussed in a later chapter- and findings of a study on understanding patient experience by Andersen et al. (2017). The embedded quotes you will find for each persona are from the heart forum study and interviews. These personas were deemed useful to make in this project due to the vast range of inter-individual informational needs among heart patients (Tenbult et al., 2023).
The specific personas help convey these differences and show that an overly generalized solution would fail to meet the nuanced demands of a diverse target group (Cooper, 2004). These personas will be used to evaluate designs within later phases of the project.

The personas are described using the persona framework used by Muzus & Lost Lemmon (2018). Which entails nine questions that the persona answers. The quotes included in each question are actual quotes from the previously mentioned interviews or heart forum study.

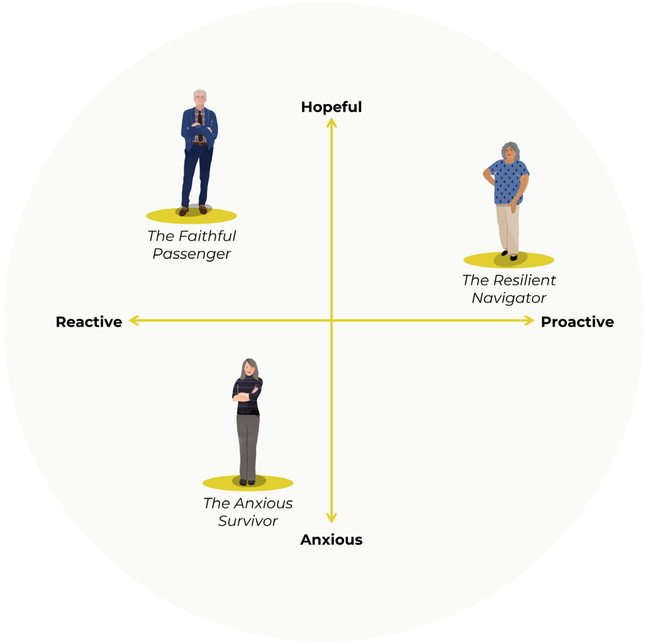


Figure 10: Overview of personas organised on two axis: Hopeful Vs Anxious and Proactive Vs Reactive

THE RESILIENT NAVIGATOR

"Adapting to my new normal with heart disease."

This is me
After experiencing a heart attack at age 62 due to coronary artery disease, I've had to adjust significantly to living with a chronic heart condition. I'm an individual who is actively seeking to understand and manage my health, but I often find it challenging to navigate the complexities of my condition and the healthcare system. I am motivated to take charge of my health, but I need reliable information and support to do so effectively.

"I feel like I'm fighting a losing battle with heart failure. Every day is a struggle, but I'm trying to find happiness where I can."

This is what holds me back
The unpredictability of my heart condition and the fear of recurrence often lead to anxiety. I struggle with the physical limitations imposed by my condition, which affects my daily life and work. Communicating effectively with healthcare providers can be challenging, and I sometimes feel overwhelmed by medical jargon and unclear advice.

“If a doctor sees that the patient does not understand or agree with something they should make an effort to make it more clear for them.”

"I'm getting fed up with telling my cardiologist this is worryingly angina pain... even unstable. It's like my concerns are not being heard."

"I've been to A&E over 10 times now... All readings for HA ok but no one is looking for anything else.”

This is how you seduce me
Show me how the HeartEye can empower me in managing my condition. Provide clear, practical information on how it can help monitor my heart health and alert me to potential issues. Demonstrate its ease of use and reliability, which are crucial for me to trust the technology.

"Take me along in the test and the results. During my heart film, people were very focused on the technique and not on me."

This is my goal
My main goal is to live as normal a life as possible while effectively managing my heart condition. I want to feel confident in my ability to monitor and respond to changes in my health, and to have constructive conversations with healthcare professionals about my care.

"I just want to enjoy life again and am in denial that this might not be the case."

This is how I feel about it
I am cautiously optimistic about using technology like the HeartEye to manage my heart condition. I see its potential to help me live a better life, but I need to trust that it's accurate and user-friendly.

This is what motivates me
I am motivated by the desire to regain control over my life and health. I want to feel confident and secure, knowing that I am doing everything I can to manage my condition effectively.

"I need to know the difference between panic and actual cardiac events."

This is when I disengage
I disengage when faced with overly complex technology or when I feel that my concerns are not being addressed. If the HeartEye appears too technical or if I don't see clear benefits in using it, I may lose interest.

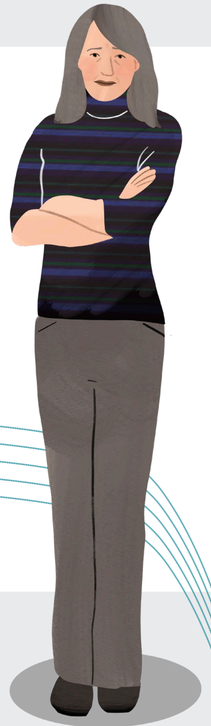
"I have had some results through and am just trying to make sense of them in plain English!”

These are my conditions
I need tools that are straightforward and offer clear, actionable insights. They should facilitate and enhance my own understanding and communication with healthcare professionals, providing me with a greater sense of security and control over my health management.

"I've had it with medics and hospitals... After being discharged, I'm left with a bunch of meds and no clear guidance on what to do next. It feels like I'm just expected to figure it all out on my own."

THE ANXIOUS SURVIVOR

"Living in the Shadow of Uncertainty"



This is Me
I have experienced a significant heart event due to coronary artery disease at age 58. Since then, life has been a rollercoaster of emotions and fears. I constantly worry about my health, particularly about the possibility of another heart event. Simple activities like going for a walk or even just resting can trigger anxiety, as I'm hyper-aware of every sensation in my body.

"Every single twinge I get makes me think I am having another heart attack."

This is what holds me back
My life is dominated by fear and uncertainty. I struggle with the constant worry that my heart might fail me again. This anxiety affects not just my physical activities but also my mental health and relationships. I often feel isolated and misunderstood, even when surrounded by people.

"I'm now frightened...I feel isolated, lonely and frightened, despite having my wife with me who is brilliant and understanding."

This is how you seduce me
Approach me with empathy and understanding. Show me that my fears are valid but also manageable. Help me find strategies to cope with my anxiety, and connect me with others who have successfully navigated similar paths. Provide me with resources that are both reassuring and informative.

"I never realized how much my heart condition affected my mental health until I started talking about it with others who understand."

This is my goal
My primary goal is to regain a sense of normalcy and control over my life. I want to manage my health effectively without being consumed by fear. I also aim to reconnect with the activities and people I love, finding a new balance in my post-heart event life.
"I feel stuck in a cycle of worry and I just can't find a way out."
This is how I feel about it

I oscillate between hope and despair. While I am grateful to have survived a heart event, the lingering fear of recurrence dampens my spirits. I crave stability and peace of mind but often feel that these are just out of reach.

"I'm scared to close my eyes at night. I worry about not waking up in the morning."

This is what motivates me
Hearing success stories of others who have overcome similar challenges gives me hope. Learning practical strategies for managing anxiety and heart health, and seeing tangible improvements in my condition, motivates me to keep pushing forward.

"I just want to get mentally better and stop having my husband wake me in the morning to make sure I'm alive."

This is when I disengage
I tend to withdraw when I feel overwhelmed by health concerns or when my anxieties are dismissed. If the support I receive feels generic and doesn't address my specific fears, I lose interest and become more isolated.

"I feel like I am going nuts... First thing I think of in the morning and last thing on my mind at night."

These are my conditions
I need a compassionate and understanding approach. Information and support tailored to my situation, recognizing the psychological impact of living with a heart condition, are essential for me to stay engaged and hopeful.

"I am frustrated that I cannot link in with a medical person. I feel so darn ill, I sleep away the day, awake to eat and go to the loo."

THE FAITHFUL PASSENGER

"The doctors knows best, right?"

This is Me
My approach to health has always been traditional and conservative, relying heavily on the expertise and advice of medical professionals. I'm not one to chase after the latest health trends or to question the recommendations of my doctors. After being diagnosed with coronary artery disease at 68, I've become more aware of my well-being. While I understand the importance of being an active participant in my health care, I tend to take a backseat, allowing the experts to lead the way. I don't actively seek out health information or tools, I am open to and optimistic about using them.

“They told me I should keep doing that until I visited the cardiologist again to make a echo. That seemed to go well so I kept doing it.“

This is what holds me back
My reactive nature means I often wait for health issues to arise before taking action. I'm hesitant to ask for help and unless it gets unavoidable or my peers push me to look for help, I tend to adopt a 'wait-and-see' approach.

“No, I don’t think I need to go back to the GP, unless it gets really bad of course.”

This is how you seduce me
Win me over with reassurance wrapped in simplicity. Show me how the HeartEye is the compass I didn’t know I needed. I want to be guided towards taking action in my own health journey.

“I needed to be relaxed and careful, as they said I was still a hospital patient.”

This is my goal
I see my health journey as a temporary detour, not a permanent redirection. I believe that by following medical advice, I can navigate through this phase and get back on the familiar track of my life.

"I'm starting to feel a bit down, bit old and vulnerable. I wasn’t before."

This is how I feel about it
I feel confident that I will get through this. This trust is what keeps me together and eases the burden of worry, allowing me to focus more on recovery and less on doubt.

“Those moments it is less pleasant. But well I know that nothing is going to happen. But something can always happen, right?”

This is what motivates me
My motivation is driven by knowing that the steps I'm taking are making a positive difference in my health. Trust in the effectiveness of my treatment and the healthcare system as a whole is fundamental to maintaining my commitment.

"Being able to immerse myself in all things cardio is like having a warm hug."

This is when I disengage
I get doubtful, when I start to feel uncertain or distrustful about the treatment or advice I'm receiving. If I can't see or understand the benefits of a particular health strategy, or if something doesn't feel right, I become hesitant and may start to pull back from participating in my health management.

“Well, personally I don’t have much trouble doing that. I assume that it is well tested, right?”

These are my conditions
I need feedback like signposts, showing me the benefits of my efforts and reassuring me that I am not lost in the woods of my healthcare journey. I need this feedback to be straightforward and goal-oriented, aligning with the advice I receive from my healthcare providers.

“It would be very helpful to be able to show my doctor what I feel at home.”

User-centred relational stakeholder mapping

Stakeholder mapping is a key step in redesigning the HeartEye portable ECG. It helps to understand all the different groups and people who have an interest in this device.

An in-depth investigation was done into each stakeholder connected to the HeartEye ECG system according to the stakeholder analysis method as described by Ashby (2015). For this method, three questions are answered for each stakeholder: A. who they are, B. what they want and C. how they might try to achieve their goals. This analysis can be found in appendix Q.

The stakeholders and their relations were then mapped in a diagram based on the analysis, as can be seen in figure 11.
In this version of a stakeholder map stakeholders are divided into three groups: the main stakeholders like patients and doctors, who are directly in contact with the device, secondary stakeholders like the company making the device or distributors, these have a direct influence on the system, and tertiary stakeholders like regulatory bodies, who only indirectly influence the system.

Furthermore, the connections between stakeholders indicate which stakeholders are in contact with whom. Illustrating the complex network of interactions and dependencies that exist in the development and implementation of the HeartEye portable ECG.

Concluding, through the stakeholder analysis we can convey the intricate web of relationships. Furthermore, this analysis is used as a starting point to ensure that all the stakeholders are taken into account throughout the project.

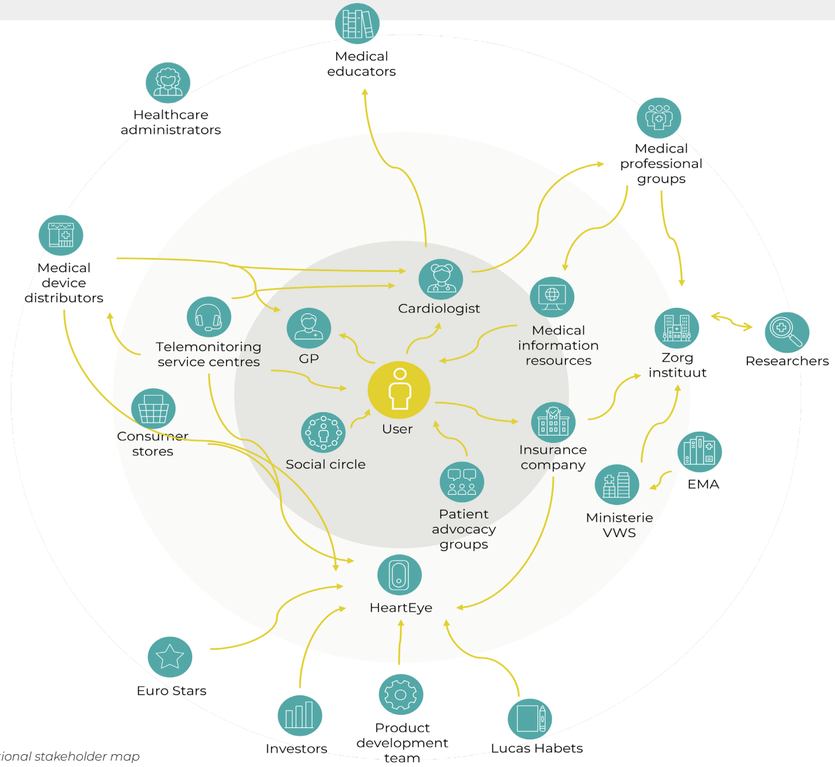


Figure 11: User-centred relational stakeholder map

Design considerations

In conclusion, the target group does not only exist of multiple stakeholders but is also incredibly diverse. Making it important to develop and convey the group's needs and wants in personas and stakeholder maps. However, this diversity also offers an opportunity for identifying unique considerations that may not be apparent in a more homogeneous user group. It allows for the exploration of design modifications that can make the HeartEye more accessible, intuitive, and effective for a wider range of users. The following design considerations were gathered from the analysis in this chapter:

1. **Personalised Patient Experience:** Design a more personalisable experience to accommodate the wide range of patients needs and types.
2. **Accessibility Features:** Catering to users with potential limitations, such as diminished vision, hearing, cognitive challenges, or manual dexterity might provide interesting design directions. This could involve high-contrast screens, large buttons, audio output, and design elements that do not require fine motor skills to operate, e.g. large buttons.
3. **Adaptability to Lifestyle:** Design the device to suit various lifestyles within the demographic, enabling users to continue their routine activities without significant interruption or inconvenience from device use.
4. **Patient education:** Patients must understand how to use the device and interpret the feedback it provides. This could include built-in tutorials, easy-to-understand readouts, or supplemental educational materials.
5. **Real-time feedback:** Functionality that allows the patient to verify the quality of the ECG recording in real-time can help them understand whether they need to adjust the positioning or usage of the device, leading to better outcomes and less frustration.
6. **Convey measurement data:** The device should be able to convey the resulting measurement in an understandable manner, through for example visualizations and comparisons to previous measurements.
7. **Support and Assistance:** Plan for customer service and technical support for users who may require assistance in setting up their ECG device.
8. **Convey medical value**: The device should convey its medical value to foster trust with the target audience. While, still fitting into a home environment.
9. **Evade the high-tech product look**: As technology affinity is found to be a potential obstacle it is important not to get lost in making the design too technology driven. Meaning, features should be limited to the necessities and the design should feel familiar and trustworthy to the user.
10. **Involvement of family and friends**: The social circle has been found to be of immense importance in helping patients use telemonitoring devices.
11. **Minimize stigma:** design to minimize stigma associated with medical devices, making it so patients can use without feeling like they are no more then a patient in constant need of care. Adherence can be enhanced in various ways, such as by addressing the patient needs outlined earlier or by boosting the health literacy also previously discussed. These examples illustrate that adherence isn't just a design consideration on its own but is instead the objective, which is why it's not listed as a separate design consideration.
12. **Ease of Use**: The device should have a user interface that is intuitive and easy to navigate. Clear instructions and prompts can help users to operate the device correctly and confidently, reducing anxiety associated with the use of medical devices.
13. **Integration with healthcare providers**: For seamless healthcare provider interaction, integrating telehealth features that allow for easy sharing of ECG data and virtual consultations could be valuable.
14. **Emotional Support and Encouragement:** Incorporating features that provide emotional support, such as motivational messages or success stories from other users, could help alleviate anxiety and boost user morale.
15. **Cost-effective**: the system should be cost-effective when compared to the current physical care.

REGULATORY REQUIREMENTS

In this chapter, we will survey the current regulatory landscape. This way it is possible to conceptualize ideas that conform with the most important regulatory requirements, even though it is not within the scope of the project to test a final concept against regulatory requirements.

First, the most important set of regulations for the HeartEye system are analysed; the EU Medical Device Regulations (MDR). Then an analysis is done on regulations in the context of algorithmic diagnosis. Finally, the potential impact of future eco-design regulations is taken into account. Then, as per usual, the concluding design considerations are compiled from this regulatory research.

Medical device regulations

The EU Medical Device Regulations (MDR) (European Committee for Electrotechnical Standardization, 2021A) form the cornerstone of regulatory compliance for the HeartEye system. These regulations mandate considerations for environmental operating conditions, usability, safety against hazards, accuracy, and construction robustness to ensure the device's efficacy and safety in home settings. A full analysis of the applicable sections and their considerations can be found in appendix R.

The HeartEye system would be classified as a Class IIa device. This means the MDR emphasizes the need for conformity assessments, clinical evaluations, comprehensive technical documentation, post-market surveillance, risk management, and a robust quality management system for HeartEye as these elements are critical for maintaining the device's required safety, performance, and traceability throughout its lifecycle. However, these aspects are not deemed useful to incorporate into the design considerations, as they are not something this project encompasses.

Algorithmic diagnosis

There is an option to integrate algorithmic diagnosis into the HeartEye system. If that would be implemented, there are some legislative obstacles and unknowns to consider, which are documented in these sections.

The MDR and algorithms

First, there are the EU Medical device regulations to take into account again. Annex 8, Chapter 2, Section 3.7 of the European Medical Device Regulation (2017) defines that: “A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.” Thus according to the MDR, the device needs to be able to provide a full explanation and reasoning on why it diagnosed something. This would mean that if the HeartEye system were to diagnose people it can not do it via deep neural networks, as these are not considered interpretable (see the chapter machine interpretability).

AI regulations

The existing rules for 'normal' medical devices also apply to medical devices based on AI (Ministerie van Volksgezondheid, Welzijn en Sport, 2021).

However, AI systems create a responsibility gap (Geurts & Bergman, 2023): who is responsible for the outcomes that the AI produces? How does this affect the relationship between the patient and the caretaker? This gap challenges existing legislative frameworks, which traditionally hold human practitioners accountable for medical decisions. With AI-driven devices like HeartEye, determining responsibility for diagnostic outcomes becomes complex.

The European Parliament's proposals on AI liability are starting to address these issues by suggesting amendments to the existing Product Liability Directive to include AI systems. According to article 6 of the proposed AI act, a potentially AI-driven diagnosis-support within the HeartEye system would be classified as a: "'High-risk AI system" (EU AI Act Compliance, n.d.). This means that for example, stricter regulations on human oversight, transparency and risk management would apply, a more in-depth analysis of the applicable articles of this act can be found in appendix S.

In conclusion, implementing a diagnosing AI system is very difficult at this point and the future of this field is very uncertain still. Making the involvement of human specialist evaluation still the norm for the coming time (DC 2).

Eco-design regulations

Currently, the rules that govern the design of environmentally friendly products in the European Union, like the HeartEye portable ECG, are mainly based on the Eco-design Directive (2009/125/EC) and the developing Eco-design for Sustainable Products Regulation (ESPR) (Bakker et al., 2023).

The current 2009 directive sets the framework for establishing specific eco-design requirements for various product groups, focusing on energy-related products (The European Parliament & The Council of the European Union, 2009). It doesn't prescribe detailed product-specific design criteria but empowers the EU to develop and enforce regulations that set energy efficiency and other environmental performance standards for these products. Some implemented regulations include the well-known energy labelling (A to G) and the requirements on energy consumption for specific products (European Commission, 2020). But, none of these seem to apply to the HeartEye system.

However, the newly proposed ESPR – which is currently being negotiated- does cover all product categories with only limited exceptions such as food or medicinal products. And just to be clear medicinal products are: "A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action." (European Medicines Agency, n.d.) Thus, making the ESPR requirements are also applicable to medical devices such as the HeartEye system.

The proposed ESPR aims to establish requirements related to product durability, reliability, reusability, upgradability, reparability, maintenance, refurbishment, energy and resource efficiency, recycled content, remanufacturing, recycling, carbon and environmental footprints, and waste generation (European Commission, 2020; Directorate-General for Environment, 2022). Furthermore, the regulation introduces a digital product passport to provide detailed product sustainability information (European Commission, 2020; Directorate-General for Environment, 2022). When these regulations will come into effect is yet unclear, but it is expected to be ratified in late 2023 and then the member states have 24 months to incorporate it into their law (Bakker et al., 2023).

Incorporating these proposed regulations into the design of the new HeartEye system will thus be critical and provide a great opportunity to take a pioneering leap ahead of the competitors (DC 1). Especially aspects like; durability, repairability and recyclability are amazing opportunities to showcase the possibilities of HeartEye's new technology and form factor.

Design considerations

Concluding, while direct compliance testing against regulatory standards is out of the project's scope, we've undertaken a comprehensive exploration of the existing regulatory environment. We found the European regulatory landscape for medical devices to be quite strict and currently a bit of a mess due to upcoming, but not yet final regulations. Therefore it is important to at least try to integrate the proposed regulations into the design process. This sets the new HeartEye system up for success in the regulatory landscape of the future. The following considerations were synthesised from this chapter:

1. **Legislative opportunity:** Compliance with the future regulation of the ESPR and AI act could position HeartEye as a frontrunner in the market, particularly at a time when older products are still adapting to these new standards. This creates an opportunity for HeartEye to fill a market gap with a product that is both technologically advanced and regulatory compliant.

2. **Human Specialist Evaluation:** Human specialist evaluation is the norm for the coming time, making a system that provides human specialist evaluation detrimental to the success of the HeartEye system.

MARKET CONSIDERATIONS

Medical devices are notorious for having a lot of obstacles before being able to deploy to market. It is therefore interesting to look at what different pathways there could be for the HeartEye device and service into the market.

This chapter first looks at the emerging market. Next, the chapter looks into what is needed to be reimbursed by insurance companies. Finally, some possible distribution channels are evaluated. Concluding, with some design considerations that were gathered from this chapter.

A new market

Increasing healthcare costs is an enormous challenge for healthcare providers, stimulating them to focus on improving patient value. (Lee & Porter, 2013). These value-based healthcare principles are starting to be applied in cardiac care, by medical professionals, hospitals and insurance companies (Theunissen et al., 2023). This shift is driving the adoption of technologies that enable patients to monitor their health from home, thus reducing the need for expensive hospital stays. This is one of the reasons that has caused a new market for these monitoring systems to emerge.

This new market can be seen as a double-edged sword. On the one hand is it more difficult to know if a business model will be viable, as reimbursement and distribution systems, are not yet standardized and underdeveloped. But, on the other hand, it also creates opportunities for novel business models to thrive.
Although developing a viable business model for the HeartEye system is out of scope for this project it is useful to open up the possibility for novel business models to be used, which is relevant as that might influence the design of the new HeartEye system.

Reimbursement by insurance companies

From the first of January 2023 onwards, telemonitoring is partially reimbursed by basic health insurance for up to 164,13 euros every three months (De Nederlandse Hartstichting, 2023). Healthcare providers can declare the costs for telemonitoring themselves to health insurers, so patients do not need to do anything for this. This makes 164 euros a cost target to aim for to stay fully covered by basic health insurance (DC 1).

There are however some limitations and requirements that need to be taken into account. They are summarized in appendix CC according to the requirements set by the Dutch healthcare authority (Nederlandse Zorgautoriteit, 2023) and information provided by the Federation of Medical Specialists (Federatie Medische Specialiste, 2022). The most important requirement relevant to the project is that telemonitoring should replace current care to be covered by the insurance (DC 2).
There is a second option for reimbursement, where the HeartEye system gets reimbursed by insurance companies themselves, but this route seems unlikely in the time frame of this project. For example, the Freestyle libre by Abbot (Abbott, n.d.) is a glucose monitoring system, which is currently fully reimbursed for certain patients in the Netherlands (Ministerie van Volksgezondheid, Welzijn en Sport, 2019) and 60 other countries (Abbott, 2023C). Abbott, the multi-billion dollar company (Reuters, n.d.) has achieved this by years of cultivating partnerships (Abbott, 2023A) and talks with insurance companies and government organisations (Abbott, 2023B). Thus, making this route does not look like a viable option for HeartEye as they lack the immense resources required for such a long procedure.

Distribution channels

In order to find out if we need to take the specific distribution channel into account when redesigning the HeartEye system, we are going to explore potential distribution channel strategies from other similar successful products.

Through a e-health service

The Kardia mobile is a six-lead ECG for monitoring Heart rhythm and is fully reimbursed when it is rented with the e-health telemonitoring service Hartwacht (HartWacht, 2022). HartWacht incorporated the Kardia mobile into their e-health service themselves. After the Kardia mobile was already on the market.

Consumer store

As previously mentioned, telemonitoring devices are only reimbursed when it is prescribed by a medical professional. However, even without reimbursement there are several successful non-reimbursed devices such as the single-lead wearable ECG from Qardio (Qardio, 2023). This device is not reimbursed, but sold through several consumer-oriented stores, together with a subscription where a nurse will check the submitted ECGs every 90 days. Because of this it is marketed as a lifestyle product, oriented at people who want to monitor their health status and through that improve their lifestyle.

Distributed by the healthcare institution

Some healthcare institutions - like the Jeroen Bosch Hospital (2023) - have a home monitoring department at their location which takes care of the distribution of the equipment to the patients. These departments currently use off-the-shelf monitoring devices and integrate them into their service.

In conclusion, HeartEye has several options in choosing their distribution channel which do not seem to have large consequences for the compatibility of the design with any one of the channels, as the mentioned examples for each distribution channel were also not developed for that specific distribution channel. We will therefore not take the distribution channel into account during this project.

Design considerations

Concluding, in this stage the market strategy for the HeartEye system might still need to be envisioned as a dynamic blueprint, thus being able to respond to the new and evolving market. By learning from others and focusing on current opportunities, HeartEye might successfully navigate the complexities of the new market. The following design considerations should therefore be taken into account:

1. **Cost target**: Currently aiming for a costs of less than 164,13 euros every three months would mean that the system would be fully covered by its home monitoring use case alone.

2. **Replace current care:** The HeartEye system should be able to replace current care. This could for example be replacing the need to go to the hospital for an ECG check-up or replacing centre based rehabilitation with home-based rehabilitation.

MACHINE LEARNING INTERPRETABILITY

The HeartEye ECG system is planned to have a machine learning algorithm to detect coronary artery disease from the ECGs users are taking. While this has the potential to be revolutionary in terms of preventing heart failures and unburdening the healthcare system, it will be paramount to design a decision system that is interpretable which means “the ability to explain or to present in understandable terms to a human” (Doshi-Velez & Kim, 2017). Most of the current machine learning decision support systems are complex black boxes, which means that their internal logic is hidden which makes it difficult to fully understand the reasoning behind the predictions (Carvalho et al., 2019). Especially because machine learning algorithms can only be as good as the real-world data and thus the biased data it is trained on (Honegger, 2018). All of this makes it a worthwhile subject to explore.

This chapter explores machine learning interpretability in depth. First, discuss the need for interpretable machine learning and then continue by exploring factors that affect model interpretability. Lastly, the chapter introduces various examples of interpretability methods.

Why do we need interpretable machine learning

The need for interpretability in machine learning algorithms stems from an incorrect definition of the task to begin with. For example, the task we give the model is: What is the chance that patient X has of attracting coronary artery disease? The resulting prediction only answers the what. However, because of safety, ethics and the inherent uncertainty of the objective of machine learning models (Doshi-Velez & Kim, 2017) it must also answer the why. So, why does this patient have a certain chance of getting coronary artery disease? This is by no means trivial to implement, as interpretability is a domain-specific problem (Rudin, 2019) and dependent on who is interpreting the results different types of explanations might be more useful in different scenarios (Morik, 2006). For example, the patient with a home-use ECG device might not want to get a full list of how all the intricate deviations in their ECG affect their diagnosis, but a cardiologist might need it as they are obliged to be able to give reasoning on the decisions they make (Freitas, 2014) (DC 2).

Another reason can be found when looking at the way humans and machine learning decision support systems cooperate. Humans excel in intuition and reasoning, an ability machine learning should complement. For machine learning to be effective as a decision-support tool, it cannot only make useful predictions but should also communicate them in a human-understandable manner to tap into our intuition and reasoning (Varshney et al., 2018). Then machine learning can be effectively used to bridge the gap between raw data and our decision-making. Interpretability is thus fundamental for the success of machine learning in these high-stakes decision-making scenarios the HeartEye system would fall under (DC 1).

Lastly, Ribeiro et al. (2016) have argued that “if the users do not trust a model or a prediction, they will not use it”. Consequently, interpretability is crucial for humans to trust and accept the model (DC 1).

Factors that affect interpretability

In appendix T, factors are given that affect the interpretability of machine learning models. Some of the examples are the monoticity of the model, sparsity and size of the model or providing a sense of control over the models.

Examples of interpretable machine learning

Appendix T also provides examples from the literature on how to make machine learning models more interpretable. For example: the SHapley Additive exPlanations (SHAP) method (see figure 12) or a method for generating prototypical parts (see figure 13).

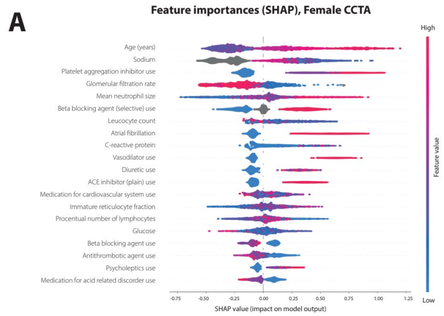


Figure 12: Example of a SHAP visualization of feature imporances for predicting CAD in females (Overmars, 2024)

Figure 13: Visualization of how prototypical parts can be used (Chen et al., 2019)

Design considerations

By understanding that the HeartEye system needs interpretable machine learning models The HeartEye system incorporates interpretability into the core of its system and creates a more convincing design that might have a higher chance of being adopted and approved. The following design considerations were found to be relevant for this project:

1. **Explaining algorithmic predictions:** Design the system to provide clear and understandable explanations for its predictions. This means the algorithm should not only indicate the likelihood of coronary artery disease but also offer insights into why a particular conclusion was reached, by for example using previously described methods to make the predictions more interpretable.

2. **Adaptability to User Needs**: Different users require different levels of detail in explanations. While a cardiologist might need in-depth information, a home user might prefer a simplified overview and a concerned partner might want to delve deeper into understanding their partners risks. The system should cater to these varying needs.

WOMEN IN HEARTDISEASE

In redesigning the HeartEye portable ECG device for home use, understanding the differences in cardiovascular diseases between men and women is worthwhile. As traditionally research has focused predominantly on men, leaving a gap in knowledge about women's heart health. This disparity is an even larger problem than it first appears to be because women experience higher mortality rates from cardiovascular diseases with their symptoms and treatment often being under-recognized. To make a difference here we first need to understand what these differences are and if there are possibilities to change the current state of affairs. Unfortunately, this was found to be largely out of scope for this project which is why you can find the main analysis in appendix U.

Appendix U first delves into the unique cardiovascular risk factors women encounter, emphasizing the negative impact of sex-specific differences in disease processes on women's health. It also addresses the diagnostic challenges presented by the varying symptoms of heart disease in women. Furthermore, it highlights the significant differences in sex for treatment and the underdiagnosis of heart disease for women, highlighting the need for medical diagnostics to account for these differences. Lastly, it underscores the importance of designing medical devices like the HeartEye to meet the specific anatomical and societal needs of women.

From the analysis in appendix U we can conclude that HeartEye's biggest opportunity lies in its unique position to provide large amounts of long-term high-quality 12-lead ECG data to ease the burden of heart disease on women and the healthcare system by enabling higher quality data-driven sex-specific decision support algorithms using machine learning, thus directly addressing the under-diagnosis and treatment gaps. The algorithmic side of the system is something we will not be able to further develop in this project, but the possibilities it provides are still an interesting scenario to remember. While algorithmic developments are beyond the project's scope, HeartEye itself should recognize this pressing opportunity to improve the situation.

Practically, two aspects are essential to consider in this context: differences in disease processes and symptoms between men and women, and differences in physiology. This project can incorporate the latter ergonomic considerations to ensure the HeartEye device is accessible and comfortable for women. This involves designing with women's unique chest ergonomics in mind, such as the presence of breasts and the wearing of bras (DC 1). As well as, considering societal sensitivities around women measuring in a public setting (DC 2).

Design considerations

1. Ergonomics for Women: Tailoring the HeartEye device for a women's chest requires more consideration due to the presence of breasts and the wearing of bras.

2. Socialtal Sensitivity for Women: The process of taking measurements in public settings may present unique challenges for women, given societal sensitivities towards the visibility of women's breasts compared to men's chests.

QUALITATIVE STUDY

A lot of digital healthcare innovations are focused too heavily on clinical and technological advancements and lack the patient perspective. Consequently, they lead to low patient satisfaction, despite their potential (Wildevuur, 2017). The design of the HeartEye is no different.

Literature already exists on the experience of heart patients (Jeon et al., 2010; Andersen et al., 2017). However, much of this literature is limited in scope, often focusing on clinical outcomes and the medical aspects of heart disease, rather than on the personal and day-to-day experiences of patients. This gap in understanding the experiences of heart patients can lead to a disconnect between the capabilities of technological solutions like HeartEye and the actual needs and preferences of the end users. To bridge this gap, it is crucial to delve deeper into the real-world experiences and challenges faced by heart patients.

In this chapter, we will discuss the method of used to complete the study and gain the previously mentioned necessary insights. Of course, the resulting insights will be discussed as well. Followed by a discussion of the resulting insights. Then, the ethical considerations of the study are explained in short. Lastly, as usual, will the synthesised design considerations gathered from this chapter be set out.

Method

In the following sections the method of this study is explained.

data collection

An approach to gain the necessary data is through the analysis of discussions and posts on heart-related forums. These forums provide a rich, unfiltered source of patient perspectives, experiences, and needs. By exploring these discussions, a wealth of information about the daily struggles, concerns, and questions that a diverse group of heart patients have can be uncovered. Furthermore, Jamison et al. (2018) state that forum posts are a suitable source of data for a qualitative study on patient experience. Furthermore, the included forums are moderated on quality and keeping the content on-topic. A second approach utilized in this study is to do qualitative semi-structured interviews with heart patients. These two methods of data collection are combined and analysed together. How the data was gathered exactly will be explained in the next sections.

Semi structured interview

Two ex-heart patients were approached through direct connections. During the interview, the interviewee was asked to provide their expert view on the whole patient experience based on a patient journey which was used as a visual aid in the interview (see appendix A). The interview was held online and recorded via Microsoft Teams. The recording was transcribed and anonymised afterwards.

Heart forum analysis

Online forum posts were collected from heart forum posts associated with HealthUnlocked.com, an organisation that provides the technology for creating health forums for over 600 health organisations worldwide. Next to that, the forum posts of Hartpatienten.nl were also included in the data set.
A Python script (appendix B) was created to scrape these data sources. In total 727,881 posts were collected from the HealthUnlocked forums and 9589 posts were collected from the Hartpatienten forum.
The next step was filtering the HealthUnlocked posts based on their relevance to heart disease-related experiences. This filtering was also done using a Python script (appendix B) narrowing down the HealthUnlocked dataset to 16,580 posts.
This means that in total 26,169 posts were analysed, with each post not only containing the original message but also all the replies other users posted under that post.

Data analysis

In this study, AI was extensively used to comb through all the data efficiently. The method used to do this is based on the NLPGPT approach as prescribed by Gamieldien et al. (2023) and is shown to have similar effectiveness compared to a manual thematic analysis.

Step 1: Generating embedding representation

Each forum post was transformed into an embedding representation, using a machine-learning model. This process involves converting the textual data into a numerical form (a 1536-dimensional vector) that can be processed and analysed computationally. Embedding representations are essential for capturing the semantic meaning of the text, allowing for more effective clustering and analysis in subsequent steps.

Step 2: Find optimal N clusters in K-means cluster with elbow method

The elbow method was used to determine the optimal number of clusters for the K-means clustering algorithm (which will be later described), as detailed by Verma (2023). For this method, the Within-Cluster Sum of Squares (WCSS) is calculated for a range of N clusters (0 to 200 in this case). The WCSS is a measure used to evaluate the performance of a K-means clustering algorithm. Then by plotting the WCSS against the number of clusters (see figure 14), you can observe the rate at which the WCSS decreases as the number of clusters increases. The 'elbow point' in this plot typically suggests the optimal number of clusters. This is where the rate of decrease sharply changes, indicating that adding more clusters doesn't significantly improve the fit of the data.

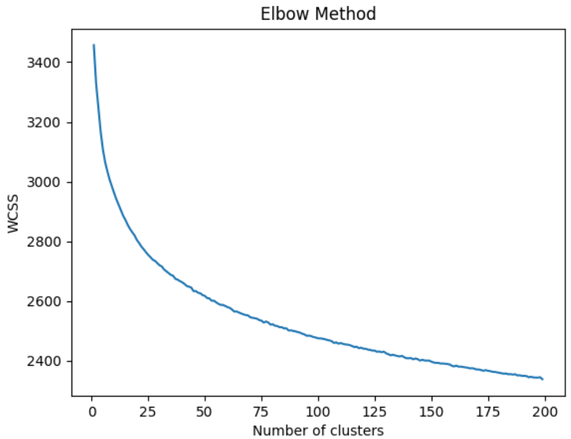


Figure 14: plot that shows the WCSS Vs the number of clusters

Step 3: Cluster embeddings in clusters with K-means clustering

The embedding representations from Step 1 were clustered using the K-means algorithm as described and implemented by Sklearn (n.d.A). This unsupervised learning method partitions the multi-dimensional vector representation of the posts into clusters, with each post belonging to the cluster with the nearest centre. The placement of these centres is optimized over many iterations to optimize for the mean distance of all the posts to their cluster's centre. The number of clusters used was determined from the optimal number identified in Step 2. Appendix D contains the Python script and a more in-depth explanation.
The dimensionality of the embeddings was reduced with the T-distributed Stochastic Neighbour Embedding algorithm (Sklearn, n.d.B) to two to visualize them in a 2-dimensional diagram. In Figure 15, you can see a visualization of the 16580 embeddings colour-coded according to which cluster they belong.

Step 4: Calculate the top 100 most representative posts based on their distance to the cluster centroid

Within each cluster, the top 100 posts that were closest to the cluster's centroid were selected (appendix E). These posts are considered most representative of the themes and topics within each cluster and are used further in analysis. The number of posts was limited because large language models only have a limited context window they can analyse at once. Using more than 100 posts would exceed this limit. Furthermore, analysing all the posts would increase the costs of this study significantly.

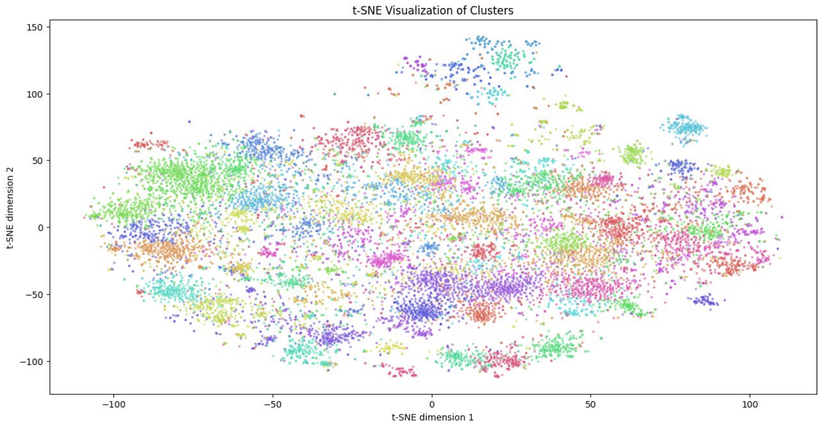


Figure 15: plot of each forum post, colour coded to the cluster they belong

Step 5: Generate cluster summary and extract important quotes

A summary for each cluster was generated using GPT-4 (OpenAI, 2023) to encapsulate the key topics and themes represented in the cluster. Additionally, important quotes were extracted from the representative posts. These quotes provide direct insights and highlight the significant issues and opinions expressed by forum members. This was done by sending a structured query with a carefully created prompt as a system message, the top posts from step 4 as context and a final reference to the system message to increase the model's adherence to the instructions to the GPT-4 API. A more in-depth explanation together with the code can be found in appendix E.

step 6: Manual interpretation of clusters summary and quotes

This step involved a manual, in-depth analysis of each cluster's summary and the extracted quotes from the previous step. The goal was to interpret the underlying meanings, sentiments, and themes from the posts into key insights. During this step, each extracted quote was manually verified with the source data to make sure that no hallucinations ended up in the findings. Lastly, key insights from the interviews were added to the key insights from the forum data during this step as well.

step 7: Construct themes

Based on all the gathered key insights from the manual interpretation in Step 6, overarching themes were constructed by manually clustering the insights together.

> *"I had a heart attack... nearly didn't make it... The past 6 months my breathing has got worse... suspected my CAD has 'progressed'."*

> *"I had a month-long holter that started making noises at me after 2 days... it turned out it hadn't recorded from the beeping onwards."*

> *"I need to know the difference between panic and actual cardiac events."*

> *"I'm just over 4 months from having had a double bypass... still experiencing some discomfort chest wise. Getting mixed messages from GP and hospital... family are telling me I went back to work too soon so need some re-assurance that I am doing the right thing."*

Results

In total 89 key insights (see appendix G) and 102 quotes (see appendix H) were gathered from the 70 clusters. As explained in step 7, these were condensed further into a final 16 overarching themes, which are explained more in depth in appendix II:

1. Abrupt Adjustment to New Realities (DC 1)

> *"I feel completely debilitated. I tried going to the gym, however after 8 minutes on the treadmill, my heart played up and I had to stop... I miss living life normally."*

2. Emotional Journey and Mental Health (DC 1)

> *"Post-op recovery is tough, not just physically but mentally. Some days I feel like I've made progress, other days it's like I'm starting over."*

3. Navigating Healthcare and Communication Challenges (DC 2)

> *"I'm still waiting for a follow-up appointment... Is this what it's come to? No sideways thinking, just sent on your way."*

4. Role of Support Systems in Recovery (DC 3)

> *"[It's nice] to hear other people's views and how the health issues we have affect each of us differently."*

5. Lifestyle Adjustments and Self-Management (DC 4)

> *"I've been told its this, its that causing it. I've watched videos on it. Some say it's not because you don't do enough exercise, it's to do with the meds you take or certain types of food."*

6. Impact on Work and Daily Functioning (DC 5)

> *"I'm not sure when I'll next be able to have the surgery as I go back in October for yet another consultation I can't really afford to keep travelling to!"*

7. Shared Decision Making and Empowerment (DC 6)

> *"I have had some results through and am just trying to make sense of them in plain English!"*

8. Coping with Chronicity and Long-Term Adjustments (DC 7)

> *"I'm terrified the damage is done and my heart is now not going to be able to give me a lifetime of service."*

9 Navigating Uncertainty and Fear of Recurrence (DC 8)

> *I've had no symptoms whatsoever, and it feels like a ticking time bomb.*

10 Technological Integration and Health Monitoring

> *I have a Fitbit Charge 3, which I purchased before my MI, but I'm not convinced about its accuracy.*

11 Physical Recovery and Rehabilitation (DC 9)

> *I thought I was doing everything right with diet and exercise, but my cholesterol still went up. It's frustrating to feel like you're doing all you can and not seeing the results you want.*

12 Emotional Impact of Diagnostic Processes (DC 10)

> *I thought I was going to die before my son graduated university. He graduated over a year ago now. The impact on my mental health at the time of diagnosis was far worse than any physical effects from the heart failure.*

13

> *I'm now frightened...I feel isolated, lonely and frightened, despite having my wife with me who is brilliant and understanding.*

14

> *I've had it with medics and hospitals... I've been discharged with a bucket load of meds and told to get on with it!*

15

> *I'm only 50 and I don't plan anything anymore. I feel I won't see my kids grow up if the chest pain I'm experiencing every day is unstable angina or coronary artery spasm.*

Discussion

The general theme of the resulting clusters showcases the potential of a holistic approach that transcends clinical monitoring. Further strengthening the case that we need to ensure that the HeartEye system is both a sophisticated health monitoring tool and a source of motivation and education, instilling hope and optimism in patients' health journeys.

For example, the findings show patients' struggles with the abrupt adjustments and emotional turmoil following heart disease diagnosis, highlighting the importance of a device that not only tracks health data but also offers emotional support and reassurance. Furthermore, effective communication between patients and healthcare providers is crucial, suggesting the need for features that facilitate easy sharing of ECG data and feedback. Moreover, the results advocate for empowering patients through self-management functionalities and leveraging support systems, indicating the device should enable connections with both healthcare professionals and personal support networks.

In conclusion, the study revealed previously unknown user perspectives and needs, which can be used in this project as another part of a solid foundation to develop the new HeartEye ECG system.

Ethics

The research was conducted according to the code of the Human Research Ethical Committee (HREC) of the Technical University of Delft and the Data Steward of the industrial design engineering faculty. All quotes reported in this study were anonymised and paraphrased to protect individuals' privacy. Furthermore, only publicly available posts were used. Lastly, the forums were verified to allow web scraping and they were emailed to inform them of the use of the data and the possibility to not include their data. For the interviews, special care was taken to ask for permission to make use of the anonymised data and communicate the intent of the research in the form of a written consent form. In this form, interviewees were informed of the risks of participation and the possibility to not answer questions or withdraw their data from the project.

Design Considerations

As mentioned in the discussion, the study revealed another set of design considerations which can be used to create a more patient centred system with. The following design considerations will be used further in the project:

1. **Emotional journey and mental health:** Incorporate features that address the psychological impacts of heart conditions, such as stress and anxiety. This could include calming design elements, motivational messages, or links to mental health resources.

2. **Navigating healthcare and communication challenges**: Ensure the device facilitates clear and effective communication with healthcare professionals. This could involve easy data sharing capabilities, straightforward reporting formats, or features that help articulate patients' experiences and symptoms more clearly.

3. **Role of support systems in recovery**: The device could facilitate connection with support systems, including family, friends, and online communities. Features like shared access to data or integration with online support forums could be beneficial.

4. **Lifestyle adjustments and self-management:** The service should support patients in managing their condition and making lifestyle adjustments. Features could include tracking for diet and exercise, reminders for medication, and personalized health tips.

5. I**mpact on work and daily functioning**: Design the device to be discreet and convenient for use in various settings, including work, to minimize disruption to daily life.

6. **Shared decision making and empowerment:** Empower patients with information and tools to actively participate in their healthcare. This could be through educational content, data visualization that patients can understand and use to make informed decisions, or features that facilitate discussions with healthcare providers.

7. **Coping with chronicity and long-term adjustments:** Acknowledge the long-term nature of living with a heart condition. Features that track progress over time and adapt to changing health conditions could be essential.

8. **Navigating uncertainty and fear of recurrence:** Include features that help manage fear and uncertainty, such as alerts for abnormal readings with actionable advice, or easy access to professional help.

9. **Physical recovery and rehabilitation**: Features supporting physical recovery, like exercise tracking and recovery milestones, can be included.

10. **Emotional impact of diagnostic processes:** The device should be designed to minimize anxiety during the diagnostic process, possibly by providing immediate, easy-to-understand feedback.

11. **Future perspectives and hope:** Features that encourage a positive outlook, such as setting and achieving long-term health goals, could be beneficial.

CONCLUSION DISCOVERY PHASE

Concluding, broad research into various aspects of the future HeartEye system is done, with each chapter yielding a set of design considerations which can be used to redesign the current HeartEye design. These design considerations will now be clustered, based on features for the redesign. This will make it easier to later comprehend what is necessary for each aspect of the redesign.

Digital platform features

Emotional Support

1. Emotional Support and Encouragement: Motivational messages, success stories.
2. Coping with Chronicity and Long-term Adjustments: Tracking progress and adapting to health changes.
3. Navigating Uncertainty and Fear of Recurrence: Managing fears with alerts and accessible professional help.
4. Emotional Journey and Mental Health: Features addressing psychological impacts.
5. Emotional impact of diagnostic processes: The device should be designed to minimize anxiety during the diagnostic process, by providing immediate, easy-to-understand feedback.
6. Future perspectives and hope: Features that encourage a positive outlook, such as setting and achieving long-term health goals, could be beneficial.

Social support

1. Involvement of Family and Friends: Importance in aiding device use.
2. Role of Support Systems in Recovery: Connecting with family, friends, and communities.

Healthcare integration

1. Navigating Healthcare Communication: Easy data sharing capabilities and reporting formats.
2. Integration with Healthcare Providers: Seamless telehealth features for ECG data sharing.
3. Integration with Healthcare Systems: Compatibility with electronic health records and patient portals.
4. Automated Alert System: Notifying healthcare providers and patients about abnormal readings.
5. Real-time Data Transmission: For immediate analysis and intervention.
6. Adaptability for Remote Rehabilitation Programs: Compatibility with remote rehabilitation functionalities.
7. Shared decision making and empowerment: educational content or data visualization that patients can understand and use to make informed decisions and facilitate discussions with healthcare providers.

Supporting lifestyle changes

1. Lifestyle adjustments and self-management: Features could include tracking for diet and exercise, reminders for medication, and personalized health tips.
2. Physical recovery and rehabilitation: Features supporting physical recovery, like exercise tracking and recovery milestones, can be included.

Educational support

1. Support for patient autonomy though health literacy: Providing understandable insights into their health status.
2. Patient Education: Interactive tutorials, progress tracking, and personalized health tips based on ECG readings.

Understanding the measurement data

1. Adaptability to User Needs: Catering to varying levels of detail required by different users.
2. Trust through Compliance: Ensuring compliance to AI act to

enhance user trust.
3. Explaining Algorithmic Predictions: Clear, understandable explanations of algorithmic outcomes.
4. Convey measurement data: Convey the resulting measurement in an understandable manner, through for example visualizations and comparisons to previous measurements.
5. Automated Alert System: Notifying healthcare providers and patients about abnormal readings.
6. Real-time Data Transmission: To telemonitoring centres, for immediate analysis and intervention.

Physical device features

Ensuring a good measurement

1. Patient education: Patient need to be taught what the device does and how it works.
2. Real-time positional feedback: Functionality that allow the patient to verify the quality of the ECG recording in real-time.
3. Support and Assistance: Plan for customer service and technical support for users who may require assistance in setting up their ECG device.

Accessibility / ergonomics

1. Ergonomics for women: Take the female specific ergonomic considerations into account.
2. Accessibility Features: Cater to users with potential limitations.
3. Ease of Use: Ease of use is of the utmost importance. The user interface should be intuitive and easy to navigate.
4. User-friendliness: The system should be intuitive and straightforward to use for individuals without medical training.

Technical specification

1. Medical Grade Material: Optimizing price, form, integrity, and compliance.
2. Water Tight: Ensuring device's safety and cleanliness.
3. PCB components: Use current size as basis for internal dimensional requirements.
4. Battery Size: Use current size as basis for internal dimensional requirements.
5. Charging dock: Incorporate a charging dock to mitigate some important mis-use risks.
6. Technology requirements: Fixed technology specifications for number of electrodes, distance between electrodes and placement location of the users chest.

Form / design

1. Evade High-Tech Product Look: Balancing technology and user comfort.
2. Convey Medical Value: Fostering trust in the device's effectiveness.
3. Fit into home-environment: Making people feel less like a patient and more at ease.
4. Impact on work and daily functioning: Design the device to be discreet and convenient for use in various settings, including work, to minimize disruption to daily life.
5. Adaptability to Lifestyle: The device should suit various lifestyles within the demographic, enabling users to continue their routine activities without significant interruption or inconvenience from device use.
6. Minimize stigma: design to minimize stigma associated with medical devices, making it so patients can use without feeling like they are no more then a patient in constant need of care.

Market considerations

1. Low Cost to patient: Broad socio-economic accessibility.
2. Cost Target: Aligning with market expectations and coverage.
3. Desirability for Patient: Verify desirability for patients, as they need to chose the system compared to other options.
4. Desirability for Medical Professional: Verify the system is an attractive option for them and prescriptible.
5. Legislative opportunities: Compliance with future AI and eco-design regulations
6. Replace current care: The HeartEye system should be able to replace current care.

DEFINE

Defining the Challenge

INTRODUCTION DEFINE PHASE

Now that we have some overarching themes to focus on when developing the next-generation HeartEye system, we could start developing concepts. However, we will first define a specific use scenario for the rest of the project, because the design space is otherwise still too large.

By defining a specific use scenario, ensures that all future design decisions can be made with a clear understanding of whom we are designing for and the specific circumstances under which the device will be used. Taking time for this step ensures that the final concept is not only flashy and innovative but also feasible, viable and desirable.

In this phase, we first find two possible use scenarios, and then we analyse each extensively to find the opportunities and obstacles for each. Finally, one will be selected based on input from the project team and the feasibility, viability and desirability of each use scenario. After selecting one scenario, we further define it by scoping specific design considerations to focus on. Lastly, some boundaries are defined which will help guide the ideation and make design decisions in the future.

DEFINING THE SCENARIO

Based on desk research a rough overview of the care path for coronary artery disease was determined based on several guidelines and online sources (Harteraad, 2023; NHG, 2021; UMC Utrecht, 2023; HartKliniek, 2023; NVVC, n.d.). Through several iterations, it was improved by getting feedback in six (I1 to I6) interviews with experts such as patients, cardiologists and professors. This led to the visualization you can see in figure 15.

Mapping patient journey

The visualization of the care path was made based on the Metro mapping method from I. Griffioen (Metro Mapping, n.d.). Metro mapping is a service design method focused on designing and optimizing care pathways in healthcare. Normally the process of metro mapping takes five steps:

1. Mapping the Existing Care Path
2. Creation of the Metro Map
3. Analysis of Needs
4. Collaborative Improvements
5. Development of Interventions

However in this project only a simplified implementation of steps one and two is done, as it is only used for conveying a rough overview of the existing care path to stimulate discussions with experts and find interesting scenarios to develop further.

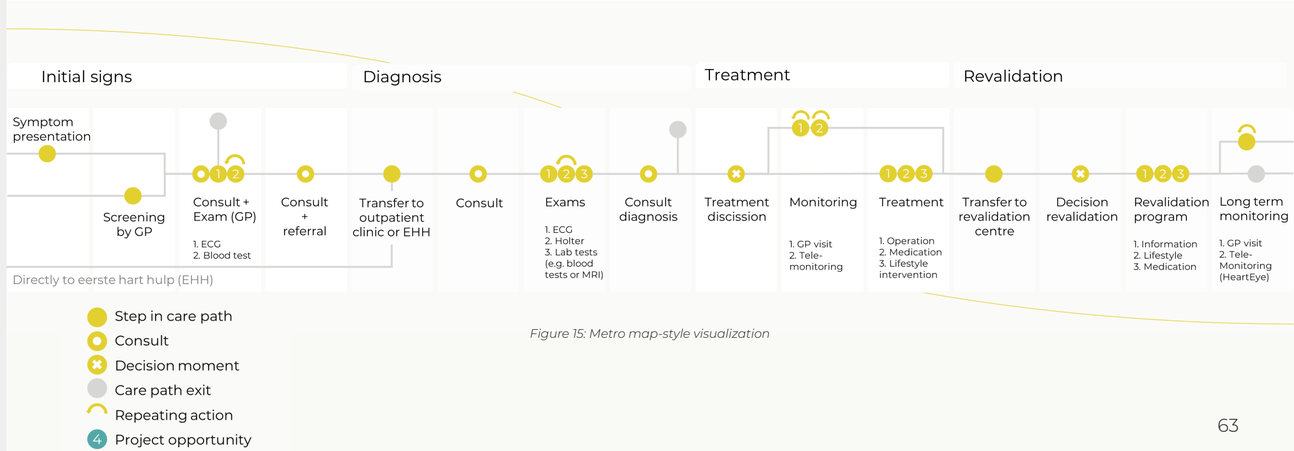


Figure 15: Metro map-style visualization

Scenario selection

During interviews with experts (I1 – I6) in which the basic visualization of the care path was utilized, two scenarios came forward that were deemed interesting enough to warrant further exploration.

The first is screening with a self-check station at for example GP, community homes or sports centres (see 1 in figure 16).

The second scenario is the prehabilitation to rehabilitation monitoring period (see 2 in Figure 16).

In the next sections, the two scenarios and their potential is explored. One of the scenarios will then be selected and further specified.

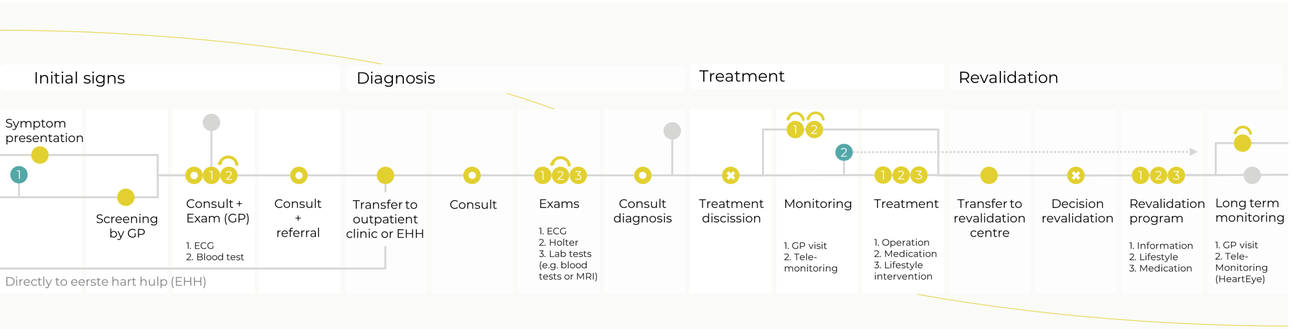


Figure 16: Metro map-style visualization of where the potential scenarios are situated

Scenario 1: Screening

Prevention of cardiovascular disease could benefit significantly from E-health integration according to members of the BENEFIT consortium consisting of researchers, medical professionals and patient representatives (Breeman et al., 2021).

The early stages of CAD normally go a-symptomatic, making pre-symptomatic screening an invaluable tool that can result in timely interventions preventing further development of the disease (Tan et al., 2018). The HeartEye system could be developed into a screening system through which it has the potential to significantly enhance the early detection and management of CAD. By enabling self-measured, accurate 12-lead ECGs for preventative diagnosis outside the hospital. HeartEye can facilitate the early identification of CAD, but also of other cardiovascular diseases such as arrhythmias, ischemic heart disease, and other conditions that may precede serious cardiac events. This approach aligns with the increasing emphasis on preventive healthcare, offering a proactive strategy to mitigate the burden of cardiovascular diseases. It could provide convenient and accessible means for high-risk individuals, as well as the general population, to regularly monitor their heart health, potentially leading to early interventions and improved health outcomes. Therefore it is an interesting scenario to delve deeper into.

Appendix W delves into the current practices of screening for heart disease, highlighting the potential benefits and challenges associated. It explores the effectiveness of traditional screening approaches employed in healthcare settings, such as those used by general practitioners and hospitals. Additionally, it assesses the emerging trends in cardiovascular screening.

Figure 17: Preliminary envisioning of the screening scenario

Scenario 2: Prehabilitation to rehabilitation period

Patient care in cardiac surgery is evolving, due to an increasing understanding of comorbid diseases, frailty, and psychosocial issues connected to cardiac treatment (McCann et al., 2019). Furthermore, many cardiac patients often experience a decline in both physical and psychological health during the waiting period before surgery (Waite et al. 2017).

Pre- and rehabilitation has emerged as a key strategy to overcome these newfound challenges. Rehabilitation has shown its effectiveness in reducing the high readmission rates for older heart patients significantly (Kitzman et al., 2021) and prehabilitation, although relatively new, already is showing positive results in this area as well (Rengo et al., 2010; Drudi et al., 2019).

The HeartEye system could be a useful asset in rehabilitation, as according to studies by Breeman et al. (2021) and Anderson et al. (2017) rehabilitation in the context of cardiovascular disease could benefit significantly from E-health in general. Furthermore, Telemonitoring is also perceived to be a valuable secondary cardiovascular prevention method by the European Association of Preventive Cardiology and the European Society of Cardiology (Frederix et al., 2019; Piepoli et al., 2016). Next to that, maybe the most important raison d'etre of the HeartEye system in this context is that: "The incidence of new coronary artery problems is highest among people who have already been diagnosed, as the underlying problem is atherosclerosis (arteriosclerosis) for which there is no causal therapy." (Dr. R. van der Zee). To illustrate this with numbers: 54,6% of women and 71,1% of men reported a recurring coronary event within 17 years in a recent study by Noordam et al. (2023). Further supported by Michalsen et al. (1998) who showed that 54.2% of hospital admissions for decompensation of chronic heart failure could be regarded as preventable in patients at a district hospital in Berlin with ischaemia being the second most prevalent reason.

In appendix X delves into the current (p)rehabilitation process in The Netherlands. Followed by a more in-depth look into what the new field of prehabilitation is in the context of cardiology. Then, the potential for tele pre- and rehabilitation is discussed followed by a section on the time-period of the period and a section on how (p) rehabilitation affects adherence.

> *"Cardiac rehab was just the service I needed! They are trained and experienced in exercise work for cardiac patients, and will guide you each step of the way, to get back to your best level of fitness, but not taking risks."*

Selection reasoning

Based on a team discussion it was determined that the second scenario (Prehabilitation to rehabilitation) is the most preferred scenario to focus on in this project. This choice will be further substantiated by comparing their feasibility, desirability and viability.

Feasibility

In comparing both scenarios from a feasibility perspective, it was found that although they both are technically possible, the screening scenario faces several significant challenges that make it less feasible within the project's constraints. These challenges occur because this scenario is new and its challenges are yet unexplored. These challenges include uncertainties related to materialization, regulatory compliance, and the development of a viable business model. Given the project's limited resources and tight timeframe, addressing these issues adequately is not feasible.

On the other hand, the prehabilitation to rehabilitation scenario does not have these same issues. In this scenario, HeartEye can look to existing tele-monitoring technologies, which have been shown to improve rehabilitation outcomes and integrate into current care pathways. Moreover, focusing on individuals with a history of coronary artery problems—a group at high risk of developing new issues—presents a clear target demographic that can benefit significantly from this approach. This specificity makes for a more feasible scenario, as it aligns with a well-defined need within the healthcare landscape.

Thus, the prehabilitation to rehabilitation scenario is deemed more feasible due to its clearer path to implementation, better alignment with current healthcare practices, and a focused target demographic. This approach allows for a more straightforward application of HeartEye's capabilities, making it a more practical choice for the project at this stage.

Desirability

To gage the desirability, the two scenarios were presented to experts and representatives of HeartEye. The prehabilitation to rehabilitation scenario also came out on top here, as the screening scenario might not result in improved care or more cost-efficient care.

The desirability of the prehabilitation to rehabilitation scenario emerged as the preferred in comparison to screening, primarily because the screening scenario lacked clear evidence that it would lead to improved or more cost-efficient care. Furthermore, the prehabilitation to rehabilitation scenario could be more easily incorporated into existing care paths making it currently more desirable. This scenario's preference is further shown by significant statistics and healthcare dynamics in the Netherlands:

- The country had 730,000 people living with coronary artery disease as of 2015, indicating a substantial target demographic
- Approximately 40% of heart patients participate in revalidation programs, a figure that is on the rise, highlighting a growing need for supportive services.
- Both monitoring and rehabilitation services are covered by insurance. Making it more accessible for the patients themselves.

These factors combined show that the prehabilitation to rehabilitation scenario's potential to meet a healthcare need, makes it a desirable choice for HeartEye's focus.

Viability

Lastly, in terms of viability, the prehabilitation to rehabilitation would be more viable to achieve for a start-up company like HeartEye, due to lower investment costs, ease of scalability, and a shorter time to market compared to the screening scenario. Although the rest of this report mainly has the purpose of further proving the viability of the chosen scenario. We can already see that it might be a viable scenario, as the HeartEye technology itself is already clinically proven and the openness of telemonitoring centres to integrate third-party monitoring solutions should facilitate access to the necessary diagnostic capabilities.

Conclusion

In conclusion, the prehabilitation to rehabilitation scenario emerges as the clear choice for HeartEye, balancing feasibility, desirability, and viability within project constraints. It leverages existing healthcare practices and targets a well-defined demographic, promising a practical path to implementation. The screening scenario, has too many uncertainties and challenges and thus is deemed as less suitable at this stage. Prioritizing prehabilitation and rehabilitation allows HeartEye to first develop the prehabilitation and rehabilitation scenario and maybe in the future use the findings from its implementation as a proof-of-technology to scale into a general screening scenario. But, for now the prehabilitation and rehabilitation scenario is the preferred choice.

Defining the use scenario

In this section, the chosen scenario is further elaborated and visualized (see figure 18) to better convey the structured journey of a patient from initial diagnosis through to post-treatment rehabilitation, integrating the use of the HeartEye monitoring system.

The first steps in this user journey are similar to the current care path of heart patients. With an intake conversation, exams, diagnosis and treatment discussion all being done within one day.

1. However the HeartEye user journey diverges as instead of going home, the patient can also be prescribed a HeartEye monitoring system, if the cardiologist and patient both decide together that a prehabilitation and/or rehabilitation program with the HeartEye system is effective for the patient.

2. The patient then immediately gets a consult on how to use the system, then and there in the hospital. Their first baseline measurements -which are needed for better diagnostics in the future- will also be taken during this consult.

3. The patient will later receive their own HeartEye device at home, which they will have to register and link with their phone to an online account.

4. From that moment onwards they can take an ECG measurement when prescribed, which is going to be once every week. But, they can also take measurements during their (p) rehabilitation program or when they want to themselves.

5. This ECG data will be reviewed by an analysist and/or cardiologists at a patient monitoring centre, but the actual ECG report itself and light algorithmic feedback could also be provided to the patient immediately after the measurement. What this algorithmic feedback will look like exactly is yet to be defined.

6. Although the platform will not be developed further in this project (see the next chapter for details on why) we can already imagine some features that it might have in the future to illustrate its potential within the scenario. Accessible through the patient's smartphone, the platform could provide access to the users: rehabilitation program, ECG data, educational resources, communities of other patients and easy communication with medical professionals. Next to this, such a platform opens possibilities to create a deeper connection with the user's heart (data) through algorithmic interpretations of the data providing interesting and motivating insights.

7. How long the user will use the system depends greatly on many factors, but as previously found, cardiac prehabilitation should start around 3 months before intervention and rehabilitation commonly lasts around 6 months after the intervention. Therefore 9 months will be our estimation of general usage duration. However, it might be useful to monitor people for a prolonged time, maybe even for the rest of their life as the risk for coronary artery disease only increases with age. In the case that the user is done with the HeartEye system it can be sent back to the manufacturing and refurbished into a new product. It must be noted that refurbishing medical equipment does come with some regulatory hurdles, which need to be overcome first.

Figure 18: Envesioned scenario

SCOPING

The design space that remains after defining the scenario is still too vast, as not everything can be fully developed within the timeframe of this project and thus further scoping was necessary. This was done by making a selection of the discovered design considerations from the discovery phase.

Together with the project team, it was decided that only the physical design considerations are to be further developed, whilst the market- and platform considerations are left for later development during other projects.

Furthermore, it was decided that of the physical design considerations the form/design aspect, thus making the look and feel of the device fit the target group and environment, would not be further researched as well, as this would require extensive and in-depth research of the target group and their preferences for which there was not enough time.

The exclusion of these considerations does not undermine their importance but rather reflects a strategic focus on the effectiveness of the system by implementing physical design interventions.
In figure 19, you can see an overview of the clustered design considerations from the discovery phase and which were selected to continue with.

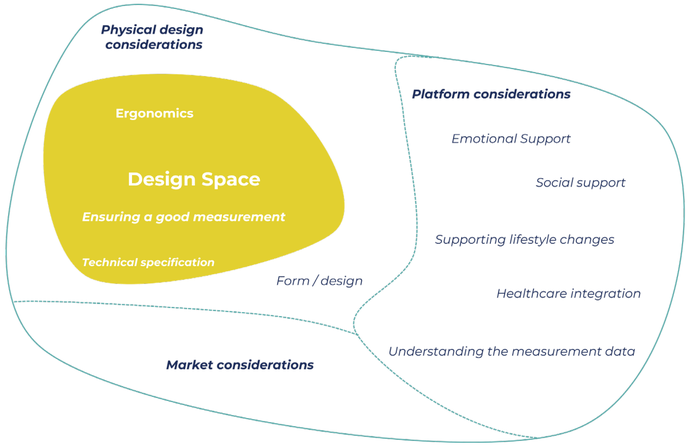


Figure 19: visual of the selected design considerations

BOUNDARIES

In an attempt to refine the vast possibilities inherent in any design space, specific boundaries have been established. These boundaries constrain the scope of the project, enabling a focused approach that is both grounded in research and results in impactful outcomes.

In this context, a boundary defines the limits within which the project will operate, outlining what will be considered and what will be excluded from the design space. These boundaries are meant to help make grounded design decisions later in the process.

In the following section, each defined boundary is listed and substantiated on why it is important to include or exclude in the design space.

Cost Considerations
Although market considerations are not included, it is still valuable to indicate a cost ballpark, if only to be able to limit the unrealistically high-costing directions. HeartEye indicated that a rough price estimation for the envisioned scenario should be around 150 euros. This is in line with the previously suggested cost target of 158 euros from the discovery phase based on the maximum tele-monitoring insurance coverage in the Netherlands.

Size and Portability
As previously defined in the scenario, the device might be used by the user whenever they feel the need to make a measurement. Thus, it is essential that the device is portable. Furthermore, the device will need to fit under the users' clothing, as this is how it is envisioned that users might use the device in a public space. Because of these reasons, the device should be hand sized.

Technology:
The technological boundaries for the HeartEye ECG device are defined by the necessity to leverage HeartEye's existing technology. This includes the use of the 4 electrodes positioned at fixed distances from each other, and the same internal electronics, ensuring consistency with the usage of the old design and the same connectivity, meaning that the device will still need to connect with a phone to communicate the data to external services.

Materials:
This project will not include a material study and thus will aim to use the same material as used by the current design. This is done because this choice in material was thoroughly researched and substantiated by NPK and HeartEye for the current design.

Manufacturing:
A manufacturability study will not be included in this project, but it does help to define that the device needs to be economically mass-producible for at least 1000 pieces. This boundary is only meant to help make design decisions in the future.

Maintenance, repairability and durability
There also will be no study into the maintenance, repairability or durability of possible design interventions. However, as with the previous boundaries, it can help to define that the device needs to be maintainable, repairable and long-lasting to help make design decisions in the future.

HOW TO MAKE A HIGH QUALITY ECG CONSISTENTLY

In the previous sections, we defined that we need to focus on ensuring a high-quality ECG while considering patient-centric ergonomics and the technical specification of the HeartEye technology. This means we need to know what makes a high-quality ECG in this context.

To define this, research was conducted. This exploration included a review of existing literature on the topic (Meziane et al., 2013; Gruetzmann et al., 2007; Goyal & Day, 2023), insights from HeartEye themselves and insights from a biomedical engineer from 2M Engineering (I7), the firm behind the HeartEye's electronics and ECG technology development.

The research resulted in four determinants for producing a high-quality ECG with the HeartEye technology:

1. Device Positioning and Orientation: The accuracy of ECG readings is dependent on the positioning and orientation of the HeartEye device on the user's body. This ensures that the device's electrodes are properly aligned with the heart's electrical axis, and thus with capturing the cardiac activity accurately. HeartEye has done a study in the required precision and they advised it should be within 3 cm of the specified location.

2. Skin Contact: Reliable electrical contact with the and device's electrodes dictates the strength of the signal. A stronger signal ensures that the electrical signals generated by the heart are accurately captured without being affected too much by ever present interference, minimizing the potential for artifacts in the ECG.

3. Consistent Electrode Pressure: Equal pressure must be applied at each electrode to maintain uniform contact quality across the device. This uniformity is crucial for avoiding variations in signal strength that could lead to discrepancies in the ECG interpretation.

4. Minimizing Movement Artifacts: It is essential to minimize any movement of the electrodes across the skin during the ECG recording, as well as the patient's overall body movement. Motion artifacts can significantly degrade the quality of the ECG signal, making it difficult to interpret.

There are other factors which influence the quality of an ECG, for example, the posture of the user or the body fat between the skin and the heart. But these factors are not determinants, but rather factors which affect the four determinants we discussed here. For example, more hair on the user's chest causes worse skin contact, but skin contact remains the factor determining the quality of the measurement.

There are however other determinants like the strength of electrical signals generated by the user's heart. However, these cannot be changed by the physical design of the device and thus were not used as critical determinants in this project.

CONCLUSION DEFINE PHASE

This phase was crucial to ensure that the design efforts would be directed toward a scenario that aligns with the needs of patients and the capabilities of the HeartEye system while remaining in line with the broader requirements of the healthcare industry.

In the define phase of the HeartEye project, an in-depth analysis was done to establish a specific use scenario for the project. Subsequently, the project's scope was refined to concentrate on specific design considerations We also defined boundaries, such as cost limits, size specifications, and material choices, to help guide the ideation in the right direction. Lastly, we defined what is necessary to consistently make a high-quality ECG.

Concluding, in this phase we have broken the brief down to its core. Which means we can start working on the development phase.

DEVELOP

Exploring different anwsers

INTRODUCTION DEVELOP PHASE

We have broken the design brief down to its core in the define phase and thus we can start with coming up with design directions. But where do we even start?

Well, we will be taking a structured and grounded approach to the development phase, by going through steps, which ensure that the defined design space is widely explored.

First, we create ideas by, coming up with factors which affect the previously defined four determinants of a high-quality ECG. We can probe those for interesting directions in order to make sure we do not tunnel vision into one direction.

Next, we will select the three most promising design directions. These will be evaluated through a four-part user test. Based on the insights gained from these tests, we will establish a set of design guidelines. These guidelines will be used in the next phase, where we aim to develop a refined concept.

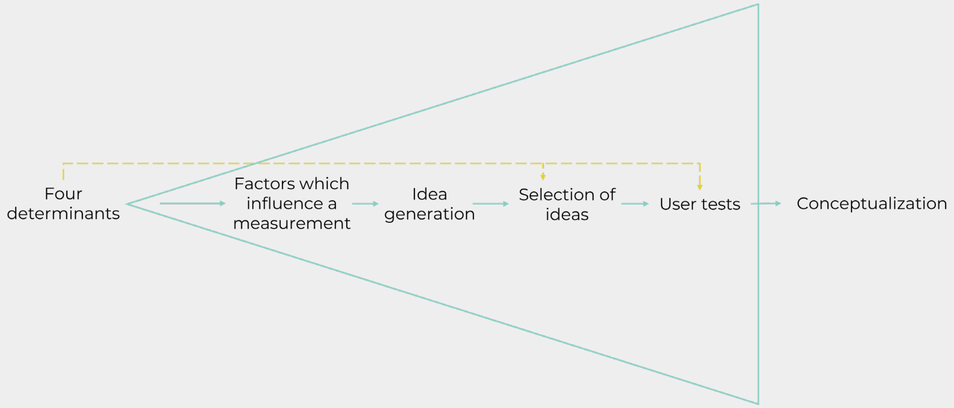


Figure 20: overview of the steps in the develop phase

CREATING IDEAS

To come up with a wide range of idea directions, a structured approach was taken. First, a list of factors which influence an ECG measurement was created. Then based on these factors ideas were generated in several ways, which were evaluated with the most promising directions selected for further development.

Factors that influence the ECG measurement

Various factors that affect ECG readings were identified, such as how the device is held, the user's environment, and the material of the electrodes. These factors were created by brainstorming on what could affect the previously defined four determinants. In table 2 you can see an overview that connects the dots between the factors that influence ECG readings and the four determinants. Every diamond indicates that factor (column) is thought to influence that determinant (row). The factors were evaluated in cooperation with the team at NPK and the team at HeartEye.

In exploring every potential factor, it's clear that some fall outside our project's previously defined scope or scenario. While these factors can still yield valuable ideas during our brainstorming sessions, they are made easy to distinguish by marking them with a specific icon; dotted path for not in the scenario and binoculars for not within scope. This avoids confusion of the goal and helps to concentrate on the factors that truly align with the project's direction. This way, we maintain focus on the project scope and scenario, whilst keeping an open mind for unexpected idea directions.

Within scope / scenario

Not in scenario

Out of scope

Table 2: overview of all 21 factors that influence the four determinants and thus the quality of an ECG measurement

Determinants \ Factors	Users' posture during measurement	Material of electrodes	Ambient temperature / humidity	Electronics factors	Users' clothing	Multi-tasking with phone	Health limitations	Skin condition (e.g. sweat or wounds)	Learning curve / users' understanding of the device	Ease of physical motion / strain on muscles during movement	Environmental influences during measurement	Endurance of strain during use (pushing down + weight)	Body movement during measurement	Health literacy	Hand size	Hair on chest of user	Body contour of user	Physiological state (anxiety / stress) during measurement	Cleanliness / cleanability	Shape / geometry of electrodes	Starting the measurement
1. Device Positioning and Orientation	◆				◆		◆	◆	◆	◆	◆			◆			◆	◆			
2.Skin contact	◆	◆	◆	◆	◆		◆	◆			◆					◆	◆		◆	◆	
3. Consistent Electrode Pressure	◆				◆		◆		◆	◆	◆	◆	◆		◆		◆				
4. Minimizing Movement Artifacts	◆	◆		◆	◆	◆	◆	◆	◆	◆	◆	◆	◆		◆		◆	◆		◆	◆

Ideation

To explore potential design interventions for each identified factor, a multifaceted ideation process was used. This process included:

Mind Maps

For each of the 22 identified factors, a mind map was created to explore potential improvements through design interventions. These design interventions could for example be changes to the geometry of the device, providing specific instructions to users, utilizing novel feedback mechanisms or the addition of certain use cues directly on the device.

NPK and other IDE students aided with the brainstorming of idea directions for the mind maps. This process yielded a diverse set of idea directions which will be used in a later step to make a selection from. In figure 21 you can see an example of a mind map: the mind map on the factor “ease of physical motion”.

Desk Research

As boring as it sounds, desk research was an integral part of the ideation process. Desk research was utilized to verify existing ideas and to generate new ones based on inspiration taken from elsewhere. For instance, researching cutlery designed with special straps to assist those with motor skill challenges sparked the idea of possibly applying similar concepts to the HeartEye device. This could make the device easier to use for everyone, regardless of their physical abilities. Another example is the inspiration taken from computer mice that are made to fit comfortably in the user's hand. This provided insights into how to develop ideas that make HeartEye devices more user-friendly.

Sketching

Sketching was used in parallel to explore possible form factors for the device. It was not just a method of representation, but rather a tool to visually explore a wide array of form factors for the device. What made sketching invaluable in this process was the ability to quickly iterate on ideas and discuss them with others. Moreover, sketching was key in bridging the gap between the abstract text in the mind maps and the physical prototyping done with 3D printing.

In figure 21 you can see how DINED mannequins were used as a plate to quickly and roughly sketch ideas.

Rapid Prototyping

During this process, several physical prototypes were made as well using 3D printing and clay modelling techniques. On the next pages you can see in the figures how clay modeling was used in exploring the ergonomics of different shapes. 3D printing was used to make hypothesised design concepts tangible to test them against the real world, quickly evaluate what works and what does not work and make thoughts that make quick iterations. This was done for example by adding a T-shaped bar to the bottom of the device to make it easier to position the device correctly or making the underside of the device follow the user's body contour to increase stability. In figure 23 you can see an assortment of prototypes made using FDM 3D printing.

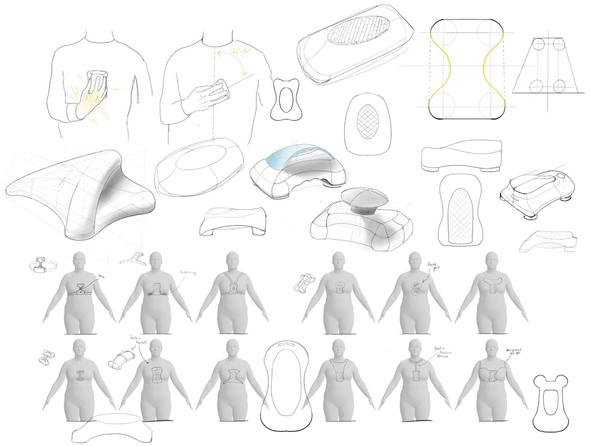


Figure 21: Example of sketches made

Rapid Prototyping

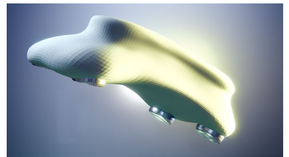
Figure 22 shows examples of prototypes that were created to explore different shapes of the housing. They were 3D-printed out of PLA

Figure 22: Samples of prototypes made







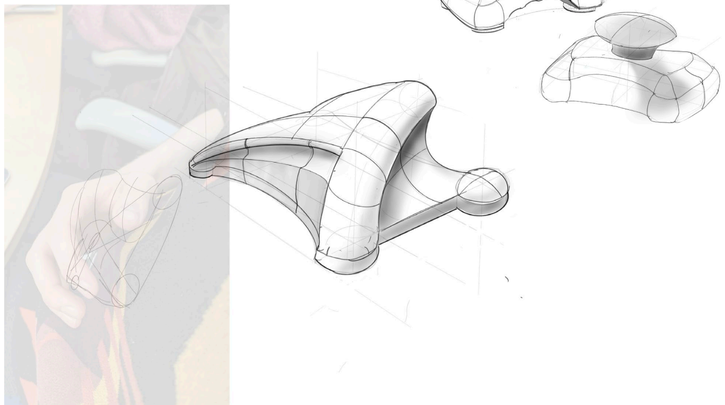



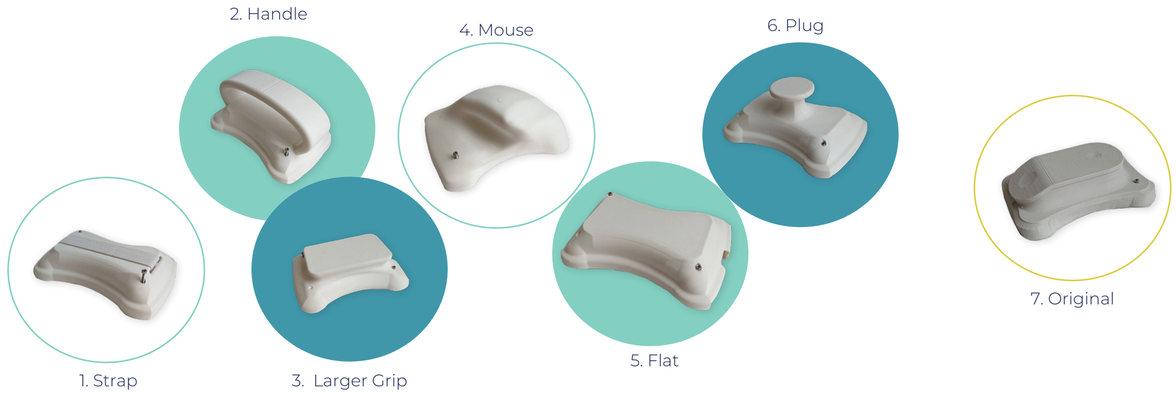
Evaluation and Selection

In the next chapter we will discuss the user test, but for now we need to make a selection on which ideas to test, as not all ideas can be tested within this project. This selection of ideas was done based on the following factors:

- If the direction was considered feasible, desirable and viable.
- Discussions with the team at NPK and HeartEye
- If the directions fit within the previously defined boundaries, scope and scenario.
- Which direction might have the most significant effect on the quality of a measurement within this project.

Through this selection we came to three groups of ideas which were selected as valuable to test, these are the: geometry of the housing, feedback informational need & mechanisms and electrode materials. Figure 23 shows an overview of all the selected ideas. In the following sections, we will go through all the ideas one by one, on how they came to be during the ideation process and why they were selected.





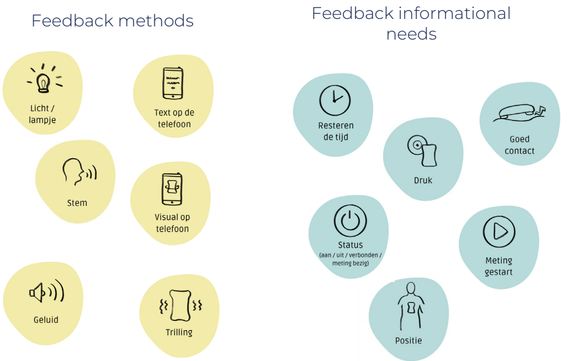


Figure 23: Overview of selected design directions

Substantiation of Selected Ideas

In this section the selected idea directions are substantiated and explained.

Geometry of housing

From the alpha tests done with the original HeartEye design by HeartEye, it became clear that the current geometry of the housing works well for placing the device on someone - as per their scenario - but not when operating the device on yourself. For example, when self-administering, your fingers do not have enough room with the current design another example can be seen in figure 24, which shows how the rotation of the hand causes strain in the wrist with the current design. Thus an improvement to the geometry is desirable to develop.

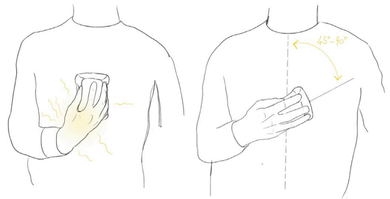


Figure 24: How self-adminstering the with the current design causes strain

Furthermore, designing, prototyping and testing different housing designs is feasible within this project and changing the housing is feasible for HeartEye.

Moreover, alterations to the geometry of the housing are viable and feasible to implement at this stage because the housing can be easily changed without affecting how the technology works. After several iterations through sketching, prototyping and brainstorming, the following ideas were selected.

Figure 25: Prototype of the larger grip variation

Figure 26: Prototype of the flat design variation

Figure 27: Prototype of the lstrap variation

Figure 28: Prototype of the lahandle variation

Larger grip

As one of the noted issues with the current design was that users did not have enough space for their fingers, one option was included in the selection which simply was a larger grip based on the grip of the current design, to see if simply making the grip larger would mitigate this issue. In figure 25 you can see the resulting design.

Flat

One design was made to be as flat as possible. This design was included because having a flat design in the test makes it possible to compare the effect of a handle to having no handle. By including this kind of boring variations we hope to understand better what makes a good design instead of simply testing a limited set of random ideas.

Strap

Limiting the device movement is one of the determinants. A possible reason for movement might be the strength and grip necessary to hold the device in the correct position. To make this easier, inspiration was taken from devices and objects meant for Parkinson's patients, where they added a strap to make it easier to hold.

A strap like this was also incorporated into the design of the HeartEye housing and selected to be tested (see figure 27).

Handle

When sculpting designs in search of improved pressure, stability and comfort the handle design was found to be an interesting direction. In figure 28 you can see the resulting 3D-printed prototype.

Figure 29: Prototype of the plug variation

Figure 30: Prototype of the mouse grip variation

Figure 31: Prototype of the original housing

Plug

When looking at other devices which are held in the same way as the HeartEye would be held, not many devices were found. Maybe the only device which came close to the same grip is a smartphone. Which is also held towards the user with the user's hand on the back. Smartphones themselves do generally not have specific grips, but there is a popular accessory for them which improves this grip from which inspiration can be taken. This is the smartphone plug.

This plug grip was translated into the HeartEye design as one of the ideas to be tested, see figure 29.

Mouse grip

Another device which was found to be similar in grip to the HeartEye device are computer mouse. Some computer mouse designs are also known for their ergonomic qualities making them an intriguing inspiration to look at. For this reason, one of the selected designs is based on the MX Master 3S by Logitech (n.d.), which is a mouse known for its ergonomic qualities (Levin, 2024).
Through several iterations it was found that the grip needed to be turned 50 degrees to be comfortable for the HeartEye use case, which makes sense as that is the angle you would generally hold your arm towards your chest. The final iteration can be seen in figure 30.

Original

The current housing design of the HeartEye device was also included as a control to test against (see figure 31).

Figure 32: Photo of some of the feedback mechanism and informational needs cards

Feedback mechanism

Several feedback mechanisms ideas were developed. For example:

- AR overlay with phone camera to guide user and show where to position the device
- Speech feedback to guide users in performing a good measurement
- Lights on the device indicating the status of the device

However prototyping all the possible options was not feasible, but giving useful feedback during the measurement still looked like an essential part of the design. So instead of making a limited selection of a few ideas, it was decided to take a step back and split the problem into two:

1. **feedback informational need:** What is the informational need of the user during a measurement
2. **feedback mechanism:** How would they want to receive that information.

By trying to answer these questions in the test we can take the first steps in finding out how to provide the user with what they actually need. To do this, seven suggestions for feedback informational needs were created, which will be used in the test to probe the participants to discuss what they would need and prefer:

1. Is the device correctly positioned
2. Is enough pressure applied
3. Do the electrodes make sufficient electrical contact
4. How much time is left of the measurement
5. The measurement has started
6. Status of the device (on / off / connected / measuring)
7. Measurement was successful

Next to these six techniques of providing feedback were selected for the same purpose:

1. Text on the connected phone
2. Visual on the connected phone
3. Voice from the device
4. Sound from the device
5. Haptics on the device
6. Light indicators (LEDs) on the device

Electrode design / material

The current HeartEye prototype needs to be drenched in electrode spray to lower the contact resistance between the electrodes and the skin. Otherwise, the signal is too weak to generate a high-quality ECG. Several studies were found that showed stainless steel electrodes are not the optimal material choice for dry ECG electrodes (Meziane et al., 2013; Gruetzmann et al., 2007; Goyal & Day, 2023). Therefore selecting a more optimal electrode material or design might lead to the electrode spray becoming obsolete. This not only makes the device easier to use but would also make a huge difference in the eco-impact of the system, as found by another master's student in their thesis on improving the sustainability of the HeartEye system.

Based on the previously mentioned studies, other studies on the performance of dry electrodes (Di Flumeri et al., 2019; Zhang et al., 2020; Gwak et al., 2023) and the interview with the biomedical engineer from 2M (I7), several alternatives to stainless steel were selected to be tested. Almost all of these use an Ag/AgCl coated, this is because silver has the lowest contact resistance when compared to any other metal (Wikipedia, 2024). Next to that, it is the material most commonly used as the interface with the standard gel-based ECG stickers used in hospitals worldwide. Finally, another reason to choose Ag-based electrodes, as explained by Di Flumeri et al. (2019), is: “Because Ag is a slightly soluble salt, AgCl quickly saturates and comes to equilibrium. Therefore, Ag is a good metal for metallic skin-surface electrodes.”

A more practical reason why certain electrodes were selected is the ability to acquire certain materials or electrodes. As the budget and time of this project were limited was not deemed possible to fabricate or acquire micro-needle electrodes or silver-plated stainless steel electrodes for example.

Figure 33: The three original stainless steel electrodes

Stainless steel (Original)

HeartEye provided three different stainless steel geometries to be used in the test (see figure 33). The first two are both an extended circle with the second extending further. The third electrode design has spikes in the middle to penetrate hair on the user's chest. They made these designs in cooperation with the biomedical engineers of 2M.

Figure 34: The front and back of the pads electrodes

Ag/AgCl coated conductive elastomer

Austrian elastomer producer Dätwyler provided two types of SoftPulse electrodes (Datwyler, n.d.)(see figure 34 & 35). What material these are exactly they would not tell. However, they are self-proclaimed state-of-the-art electrodes made from an elastomer coated in Ag/AgCl meant for wearable ECG devices. These were selected for this test, as the previously mentioned papers showed several different Ag/AgCl coated elastomers to be promising improvements over wet electrodes. As Dätwyler does not supply electrodes in the exact size needed for a fair comparison a sheet of the electrode material was made into the correct dimensions and fitted onto a 3D-printed electrode socket (see figure 34). The spider electrode as supplied by Dätwyler was also incorporated into the test (see figure 35), to verify that the DIY approach does not significantly harm the effectiveness of the material.

Figure 35: The spider electrode

Figure 36: The EEG electrode

EEG electrodes

EEG devices need to detect the electrical signals generated by the brain, which are a lot less strong then the signals generated by the heart. Therefore, the electrodes used for EEGs might improve the signal strength for the HeartEye ECG device as well. There a set of EEG electrodes were acquired through HeartEye (see figure 36) and used in the test.

Figure 37: The fabric electrode

Ag/AgCl coated fabric

Statex Produktions- und Vertriebs GmbH (2023) provided samples of their Shieldex Ag/AgCl coated fabric. Which were made into electrodes by wrapping them around conductive low-density foam (see figure 41). These electrodes were hypothesised to make better contact with the skin as they more easily let hair through and deform to fit the body better and thus create a larger contact area, as shown by Gruetzmann, Hansen and Müller (2007) in figure 39.

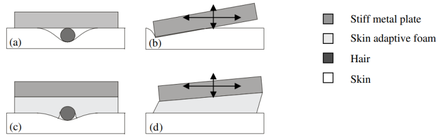


Figure 39: Schematic of how a foam or fabric electrode might improve skin contact (Gruetzmann, Hansen and Müller, 2007)

Figure 38: The spray used to test all the electrodes with spray

Spray

As previously mentioned, currently the HeartEye prototype needs to be sprayed with an electrode spray in order to make good enough contact. Therefore we also include the original HeartEye electrode with this spray as a benchmark for the test.

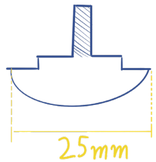


Figure 40: Schematic of the original electrode and the diameter

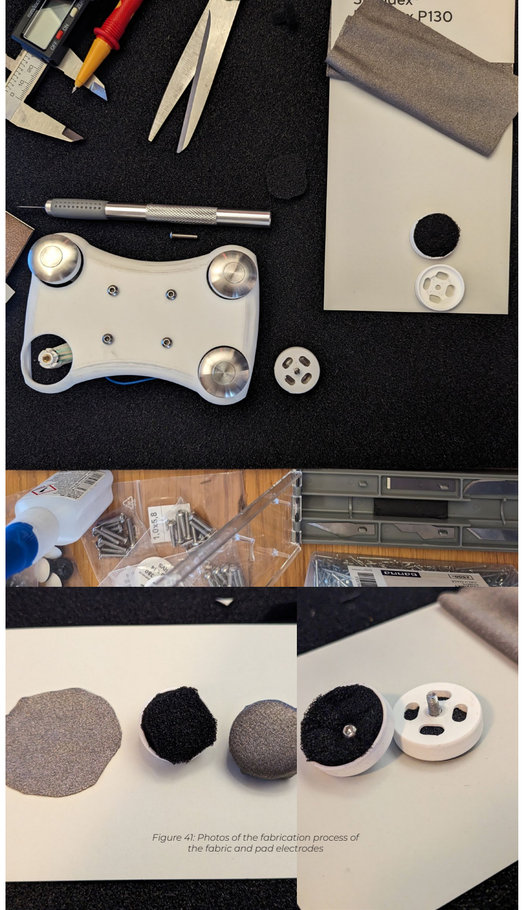


Figure 41: Photos of the fabrication process of the fabric and pad electrodes

FOUR PART USER TEST

This chapter presents a the test designed to explore the impact of the previously developed and selected design interventions. The primary objective is to improve the consistency and quality of a measurements obtained by patient in a home setting. The tests consists of four parts:

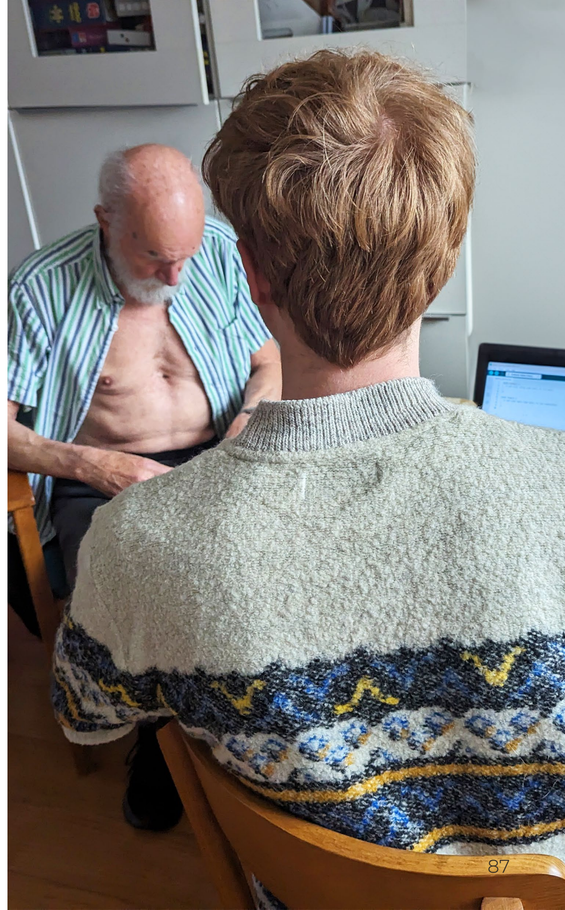
1. A quantitative user test which evaluates the previously selected geometries based on the four determinants.
2. A qualitative interview with the participant on how they experienced the different geometries and how they perceive the envisioned chosen scenario.
3. A card game to guide a discussion on the selected feedback informational needs and feedback methods.
4. A simpler internal quantitative test without external participants on how the material of the electrodes effects the contact resistance.

Throughout this chapter the first four parts will be explained simultaneously, as they use overlapping equipment and the first three parts were done with same participants at the same time.

Research question

To evaluate the efficacy of the selected design interventions, two research questions were developed. These questions are intended to assess whether the interventions represent an improvement within the context of the previously scoped design considerations that this project seeks to address:

1. How do the developed design interventions to the HeartEye handheld ECG affect the consistency and quality of a self-made ECG measurement by non-medical professionals in a home setting?
2. In what ways do individuals within the target group perceive potential barriers and facilitators to adopting the redesigned HeartEye portable ECG in the context of their daily lives and routine.



The first research question can be further split in three sub-research questions:

a. How do the selected housing geometries affect the consistency and quality of a self-made ECG measurement by non-medical professionals in a home setting?
b. How do the selected feedback informational needs and feedback mechanisms affect the consistency and quality of a self-made ECG measurement by non-medical professionals in a home setting
c. How do the selected electrodes affect the consistency and quality of a self-made ECG measurement by non-medical professionals in a home setting

As previously mentioned the test consists of four parts, the first part, the quantitative test aims to answer research question 1a. The second part, the short interview, is mainly meant to answer research question 2. The third part, the feedback card game, was done to try and answer research question 1b. The final fourth part is for answering research question 1c. See figure 42.

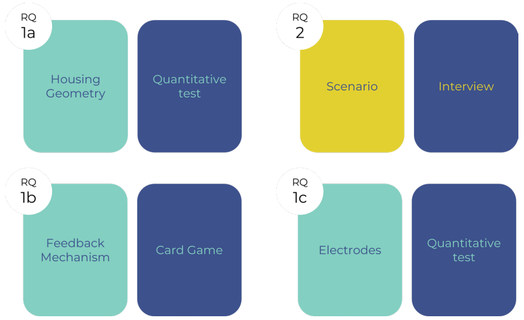


Figure 42: Study overview

The dependent variables or how to evaluate concepts

The previously defined four determinants will be the dependent variable of the first part of the test:

1. Device Positioning and Orientation
2. Skin contact
3. Consistent Electrode Pressure
4. Minimizing Movement Artifacts

How these will be used in the first part of the test is explained in the following sections.

Figure 43: Photo of a test participant engaging in the feedback card game

Device Positioning and Orientation

The four electrodes of the HeartEye device need to be positioned in a specific location on the chest of the patient. The bottom two electrodes need to be positioned on the bottom of the sternum. The positioning can be off by a maximum of 4 centimetres, according to HeartEye. This positioning will be visually asseded by the researcher.

Skin contact

Each electrode needs to make sufficient electrical contact with the skin with an as low as possible contact resistance. This can be measured by measuring the resistance between two electrodes which are in contact with the skin. As the distance between the electrodes is fixed the only variable changing is the contact resistance between the two electrodes and the skin.

By measuring this resistance value we can compare different designs to each other for the same user, but as the resistance of each user is different we cannot compare the resistances directly between users. Therefore we only directly compare the resistance of the same user.

Consistent Electrode Pressure

All four electrodes need to make stable and even contact with the skin. This can be assessed by measuring the pressure placed on each individual electrode during the measurement. An equal pressure on all four electrodes yields the best measurement. This will be measured by using a Force Sensitive Resistor (FSR) sensor on each electrode.

Minimizing Movement Artifacts

Moving the electrodes over the skin during a measurement changes the electrical signal received by the ECG device and thus causes noise and general inconsistencies in the measurement. This can be measured by measuring the variance in the previously discussed contact resistance over time during the measurement. This variance in resistance should be as small as possible. This can be directly compared between participants, as it was hypothesized to vary significantly between participants. Therefore a

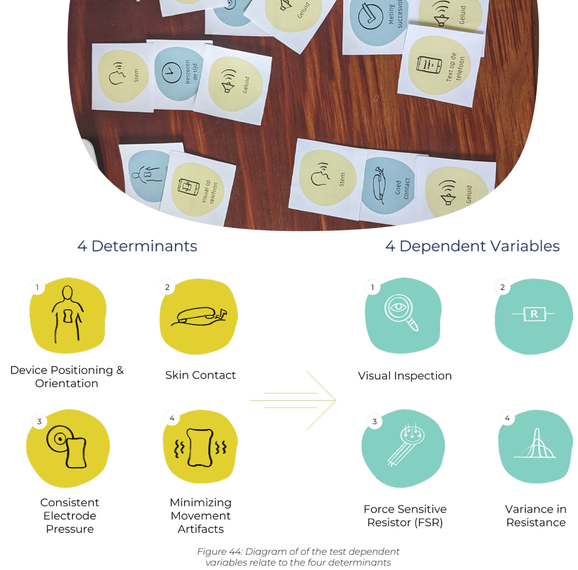


Figure 44: Diagram of of the test dependent variables relate to the four determinants

ranking of all the variations for each participant will be made which then can be used to compare between participants.

Sensor validation

The sensors were tested and calibrated to verify the validity of their measurements, how this was done can be seen in appendix I.

Independent variables

The independent variables are the selected ideas which can be found in figure 23 in the previous chapter. The first part of the test will mainly evaluate the geometry of the housing, feedback informational need, feedback mechanisms and electrode materials.

Test equipment

To conduct this evaluation, several hardware components and software applications were used. The main component however is the test platform, which is a core skeleton with the previously described sensor systems on it and will accommodate the different housing designs and electrodes. This serves as the foundation for conducting the tests, ensuring that each design modification is assessed under consistent conditions to determine its impact on the quality of ECG measurements. The platform also houses an Arduino Every micro controller, which in turn is connected to a laptop. In the following sections all the different hardware and software components are looked into in detail.

Hardware

Test platform skeleton

The core of the test platform is a skeleton made from 3D-printed PLA and is designed to provide fixation points for the to be tested housing shells and the sensors. In figure 45 you can see assembled testplatform and in figure 46 you can see how a housing is meant to encapsulate it.

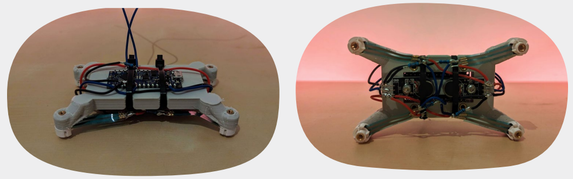


Figure 45: Photos of the assembled test platform

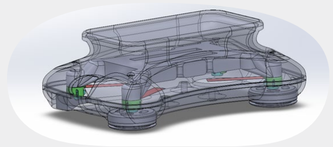


Figure 46: Screenshot of how a housing is meant to encapsulate the testplatform

FSR

A FSR is a sandwich of two flexible substrates, an electrode and a spacer. The resistance of the electrode decreases by compressing the sandwich. This can be measured and converted to an approximate force reading in Newtons, the calculations are done as described by Adafruit Learning System (2012).

For the FSR to work all the force of each electrode needs to pass through the sensor. This means that the electrodes cannot simply be screwed to the test platform, as then the force would go through the screws instead of the FSR. A custom assembly was designed to allow the electrode assembly to move separately from the test platform in the axis which is perpendicular to the chest.

In figure 47 you can see an overview of the FSR assembly.

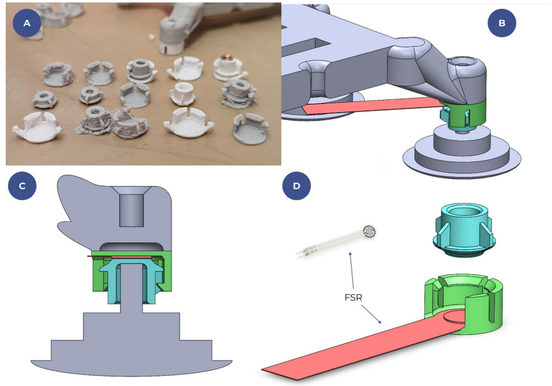


Figure 47: A. shows iterations of prototypes for the FSR assembly, B. shows how the FSR assembly is mounted to the rest of the test platform, C. shows a section view and D. shows the components individually

Skin resistivity sensor

To measure the contact resistance between the electrode and the skin. We can measure the resistance between two electrodes which are in contact with the skin and as the distance between the electrodes is fixed, the only resistance that can change is the contact resistance. Figure 48 shows on the left how the resistance measured consists of two contact resistances between the two connected electrodes and the resistance through the skin. On the right, the figure illustrates which electrodes are used for the measurement.

We can measure this resistance between electrodes using an Arduino microcontroller and known resistors as described by Campbell (2020).

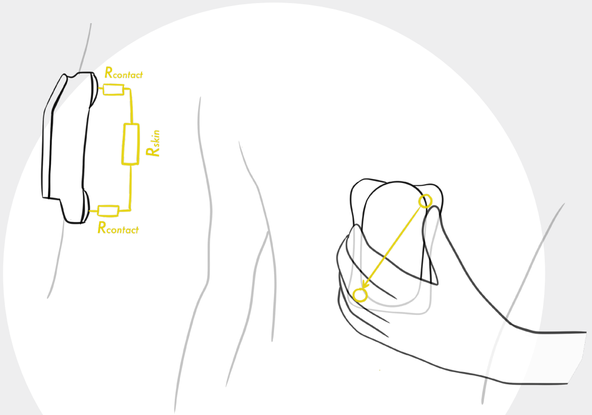


Figure 48: On the left a simple model of the measured resitances is shown and on the right the connected electrodes

Arduino Every

An Arduino Every microcontroller (Arduino, n.d.) is used to process the incoming sensor data and send it to the attached laptop for storage. The Arduino is also responsible for actuating the haptic feedback system.

Laptop

The laptop collects the data the Arduino is sending over serial USB and later provides a rudimental visualization of the live data to the researcher.

Camera

A camera is used (when consented to by the user) to record the position of the device and other noteworthy moments for later review and analysis.

Software

Arduino code

You can find the code that runs on the Arduino Every microcontroller in appendix AA. Its job is to read the incoming signal from the connected sensors, convert the raw sensor data into comprehensive values and send that data over a Universal Serial Bus (USB) to a connected laptop.

Receiving sensor data script

On the connected laptop, a python script receives the data the Arduino every microcontroller sends and averages multiple readings together in 5 ms increments so that the resulting data has a consistent time step. It also is responsible for storing the resulting data into a CSV for later analysis. In appendix BB you can find the code used for this script.

Analysing sensor data script

In appendix CC you can find the python script which calculates the variance in resistance and pressure based on the stored sensor data. It also visualizes the time series data into graphs.

Method

In appendix EE a step-by-step research guide is made that describes how to test is performed in great detail. In this section, a short summary will be given.

First, the user is given an informed consent sheet (appendix DD), notifying them, for example, of the goal of the research and the possibility of stopping the test at any moment.
For this test, we try to follow a normal use scenario as defined in the previous phase. It is assumed that the user would be getting an intake consult with a doctor on the use of the HeartEye. Therefore during the test, the user will first get an explanation of what the device is and how it works.

Then the user will test the first housing, according to the prespecified order. This first test is without an attached cable to not influence the precepted orientation of the device and test how users would position it by themselves. After doing this initial test, the user will be further explained how to use the device with information on position and orientation. Then the user will complete two more tests with the same design before continuing with the other variations. This is done to limit the effect of a learning curve as much as possible.

For each measurement, the researcher will ask some questions on the design of the housing. After all the housings are tested a short open-ended interview is held with the participant. Subsequently, the feedback mechanisms cards are used to discuss the participant's informational need for feedback and how they might want to receive that information.

The different electrodes were only tested on three of the participants as this took quite some extra time, measurements were not deemed necessary as we were only trying to find out which electrode had the lowest resistance.

Finally, all the components used in the test are thoroughly cleaned by the researcher with disinfecting spray and wet wipes.

Participants

In total 10 participants were recruited for the test. Participants were selected on the following criteria:

- Older than 50 years old
- No major physical health limitations

Furthermore, the in order to get a representative group of participant it was decided to get at least 25% of the participants to be left handed and 25% to be female.

In the table 3 the recruited participants sex and age are listed.

Table: 3: list of participants, their age and sex

Participant ID	Sex	Age
0	Female	56
1	Female	52
2	Male	52
3	Male	65
4	Female	64
5	Female	55
6	Male	54
7	Male	60
8	Male	81
9	Female	81

Results

The results will be presented in the four parts of the test. First, we will look at the results from the qualitative interview, as these results yielded the most interesting findings. Subsequently, we will take a look at the results from the quantitative tests of the housing variations. Then, the feedback card game results will be discussed and finally, the results of the electrode test are discussed.

Qualitative open interview

During the interview, the participants were asked to rank all the tested variations from best to worst, as in figure 49. In figure 50 you can see the average ranking the participants gave to each variation, split by sex and a combined ranking.

Figure 49: Example of a user curated ranking

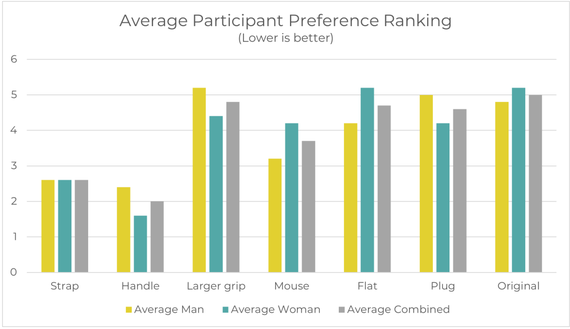


Figure 50: Graph showing the average participant curated ranking

The rest of the interview was manually interpreted by transcribing the interview and gathering insights from them. These insights will be described in the following sections.

Differences between men and women

Women indicated to be helped by their bras in finding the correct placement location for the device. However, one female participant expressed that their bra prevented them from placing the device in the correct position and that it would be necessary to remove the bra to place the device in the correct position.

During the interview, women did express a preference for variations which extended out a bit further from their chest. They stated this was because of the interference of the grip with their breasts for lower profile variations. Men did not seem to express this preference, but as can be seen in the previously shown figure 50, no significant difference between men and women was reported in the average preference ranking.

Women were however observed adopting a different grip when using the lower profile variations, with them gripping the device with their fingers from the top, while men held their hands flat against the device.

The sensor data was analysed for significant differences in performance between men and women, but this was not found to be the case.

These differences suggest the importance of designing for diverse body types and considering how gender-specific anatomy might affect device comfort and usability.

Placement position and orientation

Participants were confident in their ability to find the correct placement and orientation for the device. This confidence is crucial for at-home medical devices, where professional guidance is limited.
There were three participants who always first located the bottom of their sternum with their other hand before placing the device in the correct position.

Furthermore, all participants indicated that they were confident that they would find the correct position if they used the device only once every week.

> *I do think I had it on the correct position, it is a logical placement.*

Button on top with thumb

Participants showed a clear preference for placing the start button on the top of the device where the thumb naturally rests, as drawn in figure 51.

> *I would put it on top, with my thumb as I don't need it.*

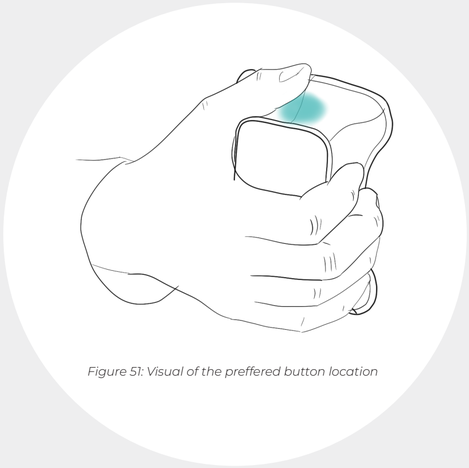


Figure 51: Visual of the preffered button location

Daily routines easily incorporate morning or evening measurements

When asked when they would fit a measurement into their weekly routine, all participants indicated to preferred to do it in the morning or evening, with the morning being the most often preferred.

> *I would do it at home, at a fixed time of day; in the morning or evening. For me a Saturday or Sunday morning would be best.*

Portability is accepted

All participants found all of the variations portable and would carry them around with them if it was prescribed by their doctor. Two participants came up with the idea of a carrying case, as a nice to have, because they were scared of damaging their medical device if they had to carry it around.

Brief use minimizes discomfort

Despite the participants indicating clear differences in perceived comfort between variations, the duration of use (45 seconds) mitigated any significant strain, indicating that the short duration creates flexibility in form factor without negatively impacting user experience due to discomfort.

Grip comfort varies with hand and nail size

Some users with larger hands or longer fingernails reported that the grip ledge -like the original design and larger grip variation- was difficult to hold as the ledge did not provide enough space for their fingers or nails. This underscores the importance of designing and testing for a large variation of physical attributes in design to ensure physical comfort.

Need for Privacy

Users felt comfortable using the device in semi-private spaces like parks, but not in highly public areas like public transport. However, they also indicated that they would be able to find a private location, like a toilet, to measure if necessary. This shows a complex relationship between perceived medical necessity and social comfort.

Furthermore, participants generally would not mind other people seeing that they are measuring if they are friends or family. But, they do not want others like co-workers to know.

> *You don't want to be busy under your clothes where strangers could be looking at you.*

> *You can also do this very easily by going to the toilet. Yes, I would if there was a real reason for it.*

Interest in Data Interpretation

A strong interest in being able to view and understand the ECG data immediately after taking a measurement was indicated. Users are not only interested in knowing their health status but also in understanding the underlying data. When being asked, users did prefer actionable insights over raw data if possible. For example, a system that advises if it is necessary to call a doctor. This suggests a gap in medical knowledge; users are seeking guidance on what to do with the information they receive.

For example, one participant envisioned a use case where they would love to be able to see the effect of certain stressful situations on their heart, empowering them to take action to prevent those situations which cause issues for their heart.

> *I don't know about other people, but I would want to see my report (ECG), interpreting it is not rocket science.*

Immediate Validation vs. Expert Analysis

Waiting a day or even a week for a cardiologist to analyse the ECG report would not be a problem for the participants, but they do show a clear need to know if the measurement they took is correct.

The acceptance of waiting for a cardiologist's analysis contrasts with the need for immediate feedback on the measurement's validity. This suggests users differentiate between technical success (did I do the measurement right?) and medical interpretation (what does my ECG mean?). Indicating a layered approach might be preferred where the technical success is achieved on the spot by the device and the medical interpretation by professionals, which users trust and are willing to wait for.

An indication of what was wrong exactly would be preferred here as well, for example, not enough pressure or incorrect position.

> *I would still want a professional to look at it, always.*

> *It could be that you didn't measure it quite right or that you tensed too much just before or something like that. If it tells me, I would always think it's fine, I will do it again. But, I would get annoyed if that happened hours later.*

Colour preference

Some users expressed a clear preference for the colour of the device. With two people finding the white prototypes ideal and one other participant showing interest in a blue colour scheme.

Secondary users

When asked, users indicated that it would indeed be likely that a secondary user - for example, the partner - might sometimes help in taking the measurement and would be interested in the results as well.

Qualitative sensor test

In Appendix HH you can see an overview of the raw data in graph form. To evaluate the performance of the tested variations in the experiment, we will compare them by each of the four determinants.

1

Device Positioning and Orientation

When the participants were being asked to position the device where they thought it should go only 1 participant placed it in the correct position. All the others placed it too much to the left (from the participant's perspective), presumably because the common idea is that the heart is located on the left. However, after being explained where to place it correctly and being shown figure 52 all of them placed the device in the correct location from there on out. With them expressing no issue in finding or doubting that they found the correct placement.
The mouse grip caused two participants to hold the device upside down as they were unsure how that shape fit into their hand. One participant held the larger grip variations upside down.

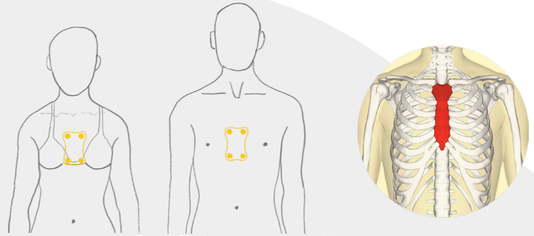


Figure 52: Visual shown to participants to help understand where to place the device

2

Skin contact

The skin contact was measured through the contact resistivity between the electrodes and the skin. In figure 53, you can see an example of what a resulting measurement looks like.

It is not possible to state whether a certain resistance value is “good enough”, as this depends on more variables for example: electrical signal strength generated by the heart of the patient, the electronics used in the HeartEye and the software filtering being done.

What we can do is compare different test variations to each other to see if there are certain design features which significantly improve or worsen skin contact. In figure 54 you can see the average resistance measured for each test variation with the standard deviations noted as error bars.

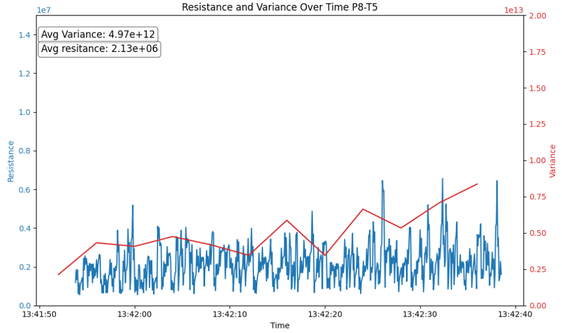


Figure 53: Grarph showing the measured resitance (blue) and the resitance variance (red) for test variation 5 with participant 8 (lower is better)

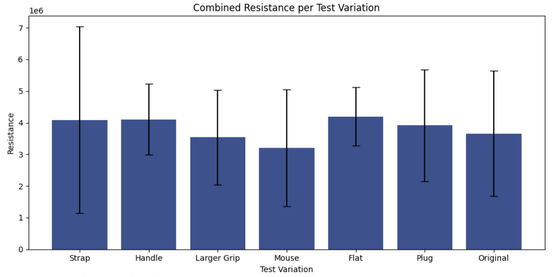


Figure 54: Grarph showing the combined and averaged resitance values of each tested variation (Lower is better)

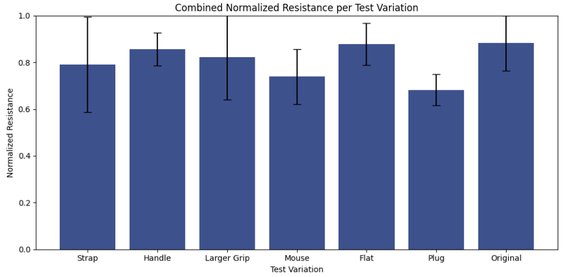


Figure 55: Grarph showing the normalized combined and averaged resitance values of each tested variation (Lower is better)

However, as can be seen, the standard deviation is very large, this is because the resistance is influenced by many factors that differ between individuals including skin type, moisture level, and the presence of hair. Therefore normalization is essential in this context to allow a direct comparison of skin contact performance across the participant pool. This method compensates for individual variances in skin resistance, by scaling resistance values between 0 and 1, with 1 representing the highest resistance measurement.

In figure 55 you can see the seven test variations and the normalized resistance of each test variation averaged over all participants, with the standard deviations noted as error bars.

From the resulting graph we can see the measurements showed no significant improvement or decline in skin contact between variations.

3

Consistent Electrode Pressure

The consistency of the pressure was measured by looking at each pressure graph if, at any one point, the pressure dipped below the threshold, which was determined by testing how much pressure is necessary for the current HeartEye prototype device. If the pressure of any one electrode goes below this threshold, an electrode was not pressured enough to result in a good measurement. In Figure 57 an example is given of a good pressure measurement and in figure 56 one is shown where the pressure goes to 0 for electrode 1 in the first 5 seconds of the measurement, indicating a fail. By checking this for each measurement we can make an overview of each variation's pass percentage, which can be seen in table 4.

We can see from the overview that the strap variant came out on top, with the handle and plug sharing second place. These results provide support for the idea that adding stability-enhancing features such as a strap or handle does increase the stability of the device.
What we can see is that only 76% of the measurements were defined as passing. This number shows that improvements to the instruction and/or ergonomics of the device might be necessary.

Before the measurements the participants were explained not to move the device too much, but not how much pressure to apply. They were also not informed if a measurement failed or passed once they made it. So these results might not accurately reflect actual passing rates, which are probable to be affected by patients learning that pressuring and holding the device still results in better measurements.

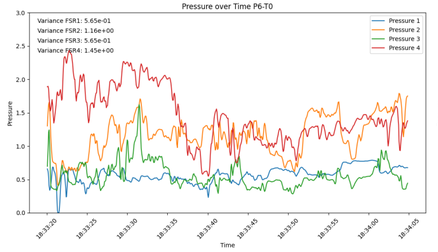


Figure 56: Grarph showing the measured pressure data of test variation 0 with participant 6

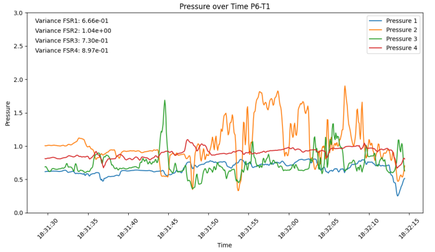


Figure 57: Grarph showing the measured pressure data of test variation 1 with participant 6

Table 4: Overview of percentage of measurements that passed the threshold value for pressure on each electrodes

Variant	Percentage Pass
Strap	90 %
Handle	80 %
Larger Grip	70 %
Mouse	70 %
Flat	70 %
Plug	80 %
Original	70 %
Total	76 %

4

Minimizing Movement Artifacts

The results were analysed in the same manner as previously described for the skin contact results. In figure 58 you can see the resulting graph of the combined and averaged resistance variance for each variation. For these results, it is also the case that lower is better, as a lower variance in the resistance indicates less unwanted movement.

The values were also normalized, as was done with the skin contact results. Figure 59 shows the resulting normalized results. These results show that there is also no significant difference between the variations when looking at their ability to minimize movement artefacts.

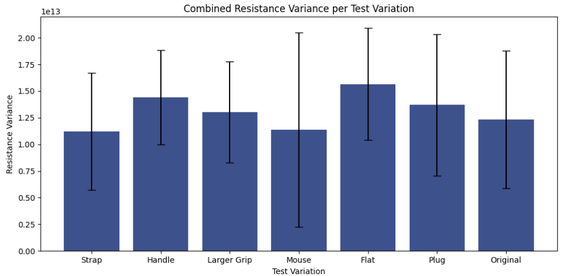


Figure 58: Grarph showing the combined and averaged resitance variance values of each tested variation (Lower is better)

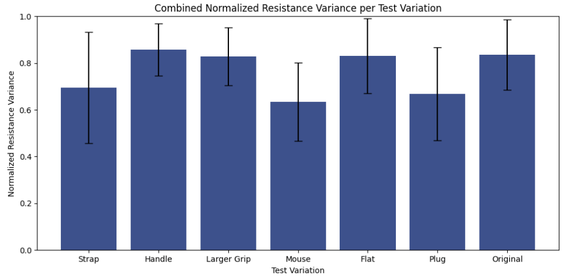


Figure 59: Grarph showing the normalized combined and averaged resitance variance values of each tested variation (Lower is better)

Feedback mechanism result

During the interactive card game activity, participants provided valuable insights into their feedback preferences for the HeartEye ECG device. These insights were combined to form an overview of user preferences for feedback mechanisms, illustrated in table 5. From this overview and other user input during the game, the following insights were gathered:

Preference for Visual Feedback

A preference for light feedback was observed in most of the categories. The light was believed to be discreet, intuitive and non-disruptive of the measurement. However, participants did not unanimously agree on this, with some indicating a dislike for lights, because those would not be observable if they took measurements with the device under their clothes. These people preferred a voice feedback mechanism over any other feedback mechanism.

> *That's (not wanting lights as feedback mechanism) because I would want to use it under my jumper.*

> *Yes a little light, that's just really nice. No one else sees that, but you immediately know. Oh, he's in the right place.*

Remaining Time is Not Necessary

Given the brief nature of the ECG measurement, users felt that information on the remaining time of the measurement was unnecessary.

> *Nahh, it's not that long, I really would not need to know this. Especially if it only is ones a week.*

Essential Feedback Only

Users expressed a preference for minimal feedback, in order to simplify the interaction with the device as much as possible. Users indicated that feedback should primarily alert them to errors or issues requiring attention, minimizing unnecessary distractions.

> *I want it as simple as possible, otherwise I will always wonder: what does this vibration mean again?*

Reduced Reliance on Secondary Devices

Participants expressed a desire to minimize interactions with secondary devices, such as smartphones, during the measurement process.

Table 5: The amount each feedback mechanism was placed at each feedback informational need by all the particiapants combined

	Visual on phone	Text on phone	Light	Voice	Sound	Haptic	Not necessary
Good contact	0	0	4	3	3	2	0
Remaining time	0	3	1	1	2	0	5
Correct pressure	0	0	3	3	2	3	2
Status	1	1	7	0	0	0	1
Measurement succesfull	2	3	3	3	5	1	0
Correct position	3	0	2	3	1	2	1
Measurement started	0	0	3	2	6	2	1
total	6	7	23	15	19	10	10

Physcial prototypes required

Through this simple game with feedback cards, users expressed a clear desire for simple, intuitive and effective feedback. All participants agreed on the necessity of receiving feedback on operational aspects directly from the device itself. However, this test cannot and was not designed to define the optimal feedback method. Therefore it is necessary to perform more in-depth tests with more developed prototypes for the different feedback mechanisms, to gather insights into their preferences, usability challenges, and overall satisfaction with the feedback provided.

Electrode test

An overview of the tested electrodes can be seen in Table 5. Each electrode was tested on four participants, with each electrode applied four times under standard dry conditions and another four times with electrode spray.

The electrode test did show an unexpected result, as shown in the graph in figure 60. Contrary to the assumptions, novel materials from Datwhyler and Shieldex—designed specifically for this application—did not exhibit improved contact resistance when compared to traditional stainless steel electrodes.

Table 5: Overview of tested electrodes

Name	Original Circle	Original Extended Circle	Original Spiked	Fabric	Pad	Spider	EEG	
Photo								
Source	HeartEye	HeartEye	HeartEye	Shieldex	Datwyler	Datwyler	Unknown	Parker
Material	Stainless Steel	Stainless Steel	Stainless Steel	Ag/Cl Coated Fabric	Ag/Cl Coated Conductive PU	Ag/Cl Coated Conductive PU	Ag/Cl Coated ABS	Salt Solution (Electrolyte)

Notably, the EEG electrode significantly improved the contact resistance, being almost 50% lower than the original circle stainless steel electrodes currently used.

Despite these findings, the stainless steel electrodes prepared with electrode spray still outperformed all other tested options. As HeartEye specified that the sprayed Original Circle electrode delivers good enough results for them, we can conclude that the spray will still be a necessary part of the HeartEye system. This indicates that contrary to our initial hopes, the elimination of conductive spray remains elusive.

In figure 61 you can see all the sprayed electrodes. They all came in close with each other and significantly lower than when the electrodes were not sprayed. Thus we can also conclude that other electrodes are probably not necessary as these do not significantly improve the contact resistance (at most with 0,33 Ohm).

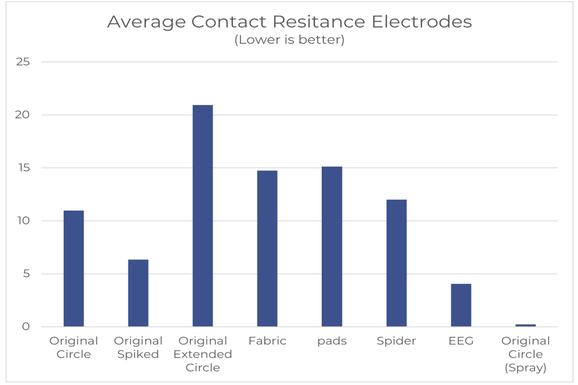


Figure 60: Grarph showing the avarage contact resitance of the electrode test in Ohms

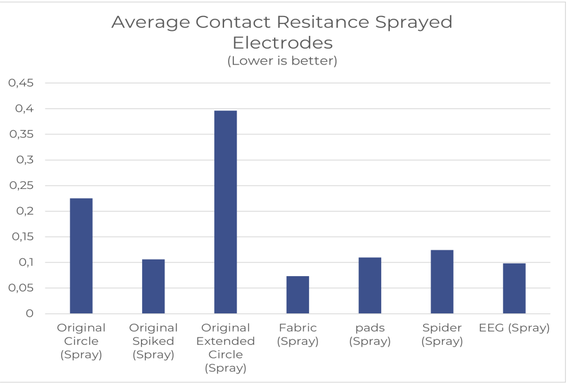


Figure 61: Grarph showing the avarage contact resitance of the sprayed electrodes in Ohms

Insights on Design Guidelines

Although this four-part study is very pragmatic, we can still generate insights from the results, which can be used as design guidelines when designing the new HeartEye ECG device. In this section we will list the design guidelines we will use to design the physical device of the HeartEye system, this means other:

Flexibility in the design of the housing
First of all, the testing showed that there is a certain freedom when it comes to the design of the housing because variations in the device's geometry did not significantly affect the measurements' quality. This finding suggests that HeartEye's design can be made to better accommodate user preferences and their experience without affecting the core functionality. Thus for this project inspiration should be taken from the handle, strap and mouse variations, with those being the top 3 most preferred variations.

Extend the grip from the chest
All participants, but women in particular, did show a preference for geometries that were extended from the chest. This makes sure that the user's body does not interfere where the grip of the device.

Organic yet professional shapes for perceived technology efficacy
The participant's preference for organic or softer designs suggests that the device's perceived efficacy and trustworthiness are influenced by its aesthetic and design elements. Most participants expressed a dislike for sharper edges and a preference for the more organic and softer shapes, citing "sex appeal", "high-tech" and a "trustworthy appearance". Thus, sharper designs should be avoided in favour of softer, more organic shapes.

Obvious Ergonomic design to avoid confusion
The device should have a shape that naturally guides the user's hand to a stable position for easy handling and accurate placement on the chest. To avoid confusion the device orientation should be obvious by the geometry of the housing, as participants did get confused by the orientation of the larger grip variation.

Design for equal pressure
The test showed that design variations using straps or handles to secure the device to the hand or body enhanced stability. This kind of feature should be considered to ensure consistent electrode pressure.

Feedback mechanism should be minimal
While designing feedback mechanisms, consider the users' preference for minimal, non-intrusive feedback that provides essential information only. The feedback mechanism should primarily utilize light signals to convey essential information and status updates due to its discreet and intuitive nature. However, to accommodate diverse user preferences and situations where visual feedback might be obscured (such as under clothing), an option for auditory feedback might be interesting to also integrate. This dual-mode feedback ensures the device can adapt to various environments and user needs, enhancing usability and user experience.

Secondary device should not be necessary during measurement.
Users expressed that the device should be designed to function without the need for interaction with secondary devices, like the smartphone, during the measurement process. This means possible feedback mechanisms or buttons should be on the device instead of in an app. This prioritizes direct interaction between the user and the ECG device, ensuring ease of use and reducing the barriers to obtaining a successful measurement.

Immediate on-device feedback on measurement validity

Users expressed a need for immediate feedback on the success of their ECG measurements. Incorporating simple, intuitive feedback mechanisms, such as lights or auditory signals, can inform users if a measurement was successfully taken or if repositioning is necessary. This feedback would ideally be on the device itself.

Instructional support
Given the fact that users had trouble initially finding the correct position, pressure and orientation. Combined with the importance of correct usage for accurate measurements, provide clear, accessible instructions (possibly integrated into the device design) that guide the user through the correct positioning, orientation, and pressure operation of the device.

Portable and Discreet Design
Make sure that the design is portable and discrete to support privacy and convenience. Users should feel comfortable transporting the device if needed, for discreet usage in semi-private spaces like parks or offices.

Environment consideration
Given that users expressed a preference for conducting ECG measurements during morning or evening routines, the HeartEye device should be designed to integrate seamlessly into these moments. Optimizing the device for use during these times can enhance user adherence. For example, integrating lights in the dock to show the need for a measurement, waterproofing the charging dock for use in bathrooms or optimising charging cable length for the limited number of electrical outlets available in bathrooms.

Customizable aesthetic skins
As some users have clear opinions on the colour of the device, it should be considered to add customization options for the device that users can choose according to their style. This not only personalizes the device to better fit in the environment but also aligns with the finding that the device's appearance can influence perceived efficacy.

Vertical symmetry
To facilitate left and right-handed users, the device requires Vertical symmetry. Although other solutions for left and right-handed compatibility are available, this solution offers the least confusion on orientation and grip.

Horizontal A-symmetry
Some users were confused about the horizontal orientation of the device and although the device can make a successful measurement upside down, it did cause confusion and hesitation when users were uncertain about the orientation. Therefore it is advised to make the device a-symmetrical in the horizontal orientation and communicate the correct orientation clearly through form.

Button on top
When asked for a preference for a possible button location, almost all users expressed a preference for the button to be on the top of the device.

Stainless steel electrodes
Even though the stainless steel electrodes are not good enough by themselves -only with electrode spray-, no other suitable replacement was found in the electrode test. Making stainless steel still the preferred material choice for the electrodes due to its cleanability, durability, price and already proven track record with the current HeartEye prototype.

Secondary user ergonomics
As indicated by the test participants, secondary users might help make measurements in some scenarios, it is important to make the ergonomics of the device in such a way that is comfortably usable for self-measurement and for secondary users making the measurement.

DELIVER

Finding the right anwser

INTRODUCTION
DELIVER PHASE

In the final phase of this project, we will try and deliver a concept based on the insights gathered throughout this report. This includes idiating on a general shape for the device and finalizing key components of the design, including ergonomic and design optimizations, the internal layout and the manufacturability. Additionally, it concludes with recommendations for the next steps.

CONCEPTUALIZATION

In this chapter, we will be designing a concept device derived from the design guidelines established from the four-part test and all the gathered knowledge from the rest of the report.

We will do this by again going through an iterative design process, first by sketching different designs and prototyping several of them, choosing one general shape and developing that as far as possible within the allowed timeframe into a well-rounded concept.

In the next chapter, we will look at how this concept could be implemented in the future.

Finding a shape

The shape will be based on the design guidelines and findings from the four-part test.

The first step was gathering inspiration for the shape and grip of the concept. This was done by gathering inspiration from other handheld and/or medical devices found on the internet (see figure 62).

After being inspired many different shapes were drawn in the initial exploration. Next to sketching by hand also a lot of “digital sketching” was done in the open-source 3D VFX program; Blender. Blender is used as a quick and dirty way to construct 3D geometry and then print it on a 3D printer. Using this technique many novel shapes could printed and tested to find a shape that is both visually appealing and fits the agronomical requirements of this device.

Figure 62: Inspiration gathered for the initial shape exploration

Path to discovery

In this section, we will highlight a few of the initially generated shapes and design directions. Short explanations will be given on some pros and cons of each mentioned design direction, which will later be used to make a selection.

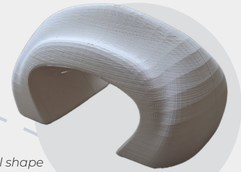


Figure 64: Physical prototype of the novel shape

Novel Shapes

First, to illustrate the extent of the exploration, let's start with the most novel shape which was made. It was an attempt to make a vertically symmetric shape, usable by left and right-handed users while providing support for the palm on the top surface of the device. In figure 63 you can see a photo of how it was intended to be used, and in figure 64 you can see the physical prototype. Although the physical prototype showed promise in being ergonomically viable, it was found that when presenting this design to fellow students they got confused about how to grip the device, making it unintuitive to use and thus not suitable for the HeartEye ECG.

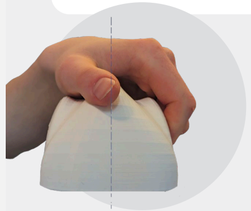


Figure 63: The intended grip

Figure 66: Car inspired closed handle prototypes

Closed Handle

It was noticed at some point that cars closely reassembled the desired shape of the new HeartEye ECG device. Their somewhat organic yet professional structure, four wheels, and central windows suggest a gap for a potential handle. This unexpected similarity led to car contours serving as a novel source of inspiration.

As the resulting designs, together with other closed handle designs, were prototyped and evaluated a key flaw of the design direction became clear: integrating a closed handle required significant horizontal and vertical clearance for the gap of the handle, which the car-like proportions made difficult. Enhancing this clearance, however, led to an overly large housing relative to the spacing of the electrodes. This size issue was further exacerbated by the need to accommodate internal components like electronics and batteries, which are typically square in contrast to the generally organic handle and thus imposed additional constraints on the already challenging design proportions.

On another note, an interesting design element that became apparent from these explorations was that a curving top -similar to the design of cars- ties the lower part of the device and handles it together nicely. Such a slight curvature creates a sort of “tension” in the top surface creating a more interesting shape.

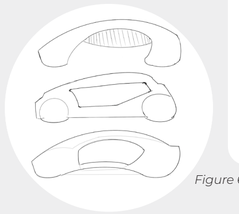


Figure 65: Automotive inspired skecthes

Figure 67: Photo of all the prototyped initially explored shapes

Other shapes were also explored and can be seen in figure 67, but are less relevant for the story.

Open Bottom

Another group of designs were the bottom variations. These variations considerably improved the proportions of the closed handle designs by finding the necessary clearance for the handle at the bottom of the shape instead of elongating the handle upwards.

Nevertheless, these design variations encountered a significant obstacle in integrating the internal components. The electrodes are required to be directly connected to the main PCB to ensure stable, low-resistance electrical contacts, as recommended by 2M Engineering. Such a configuration becomes problematic with an open bottom design as such housing does not facilitate room for a rigid PCB to reach all four electrodes in one plane. Potential workarounds, such as splitting the main PCB into two or four discrete units, introduce new complexities. As the other electronics are also more difficult to fit in the open bottom design, because of a lack of flat space, making it necessary to increase the number of PCBs to fit all the components, which significantly complicates the construction of the device.

Figure 69: Physical prototype of the open handle design

Open Handle

This design was inspired by the concept Braun electronic drill by Jean-Thomas Mayer (Behance, 2021)(see figure 70) and was made mainly to explore the aesthetics. However, once prototyped we found that the open handle design had superior ergonomic qualities over the closed handle designs made thus far. The opening at the back of the handle not only makes the device asymmetrical in the horizontal plane, making the device easier to orientate, but it also leaves more room for larger hands whilst keeping the device relatively slim.

Figure 70: Inspiration for open handle design

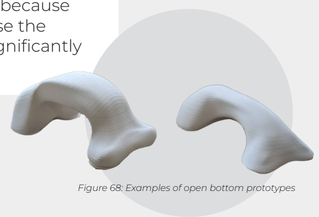


Figure 68: Examples of open bottom prototypes

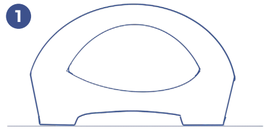


Figure 71: Simple example sketch of a closed handle design

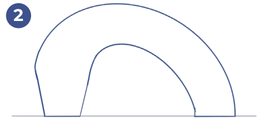


Figure 72: Simple example sketch of a open bottom design

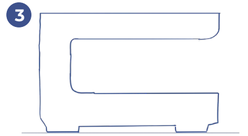


Figure 73: Simple sketch of a open back handle design

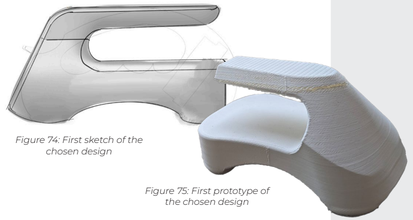


Figure 74: First sketch of the chosen design

Figure 75: First prototype of the chosen design

Selection of general form factor

Based on the initial exploration, it came down to three main variants:

1. Closed handle (see figure 71)
2. Open bottom handle (see figure 72)
3. Open back handle (see figure 73)

The closed handle configuration, while ergonomically sound, requires a large opening to accommodate the hand. This compromises the device's compactness and proportions, leading to a less favourable form factor.

The open-bottom design presented a solution to the proportion issue but at a significant cost to the complexity of the internal layout. Which would complicate the assembly, construction and reparability and potentially also affect the reliability.

Consequently, through a process of elimination and consideration of both aesthetics, ergonomics and functionality, the open-back handle emerged as the leading form factor. It addressed the need for a horizontal a-symmetric, vertical symmetric and ergonomic design, offering a more intuitive orientation and grip for users. While also catering to a wider range of hand sizes without enlarging the device's profile. Moreover, this variant allows for a more straightforward internal organization of components while maintaining the organic yet professional sleek and minimalist form we are looking for.

This open handle shape was then made into a more detailed design through sketching which resulted in the sketch you can see in figure 74. This design was then made into reality by creating a rough CAD model in Solid Works that subsequently was 3D printed, see figure 75.

Of course, we are not there yet, this is only the second iteration of the general shape. In the following sections, we will be optimizing it on several key areas to get to the well-rounded concept we are looking for.

Ergonomics optimizations

The most important considerations are the ergonomic considerations of the new concept. In the following sections, we will be optimizing various parts of the design to improve the ergonomics.

Unwanted moment or unequal pressures on the electrodes
One of the largest potential ergonomic issues with the open handle design is that because the handle is only supported on one side, the pressure over the electrodes might be non-uniformly distributed. Which could cause measurements to fail as explained by the four previously defined determinants for a good measurement.

Therefore a 2D Force Diagram (FBD) was made to calculate this potential moment or unequal force distribution and evaluate whether this would be a significant issue.

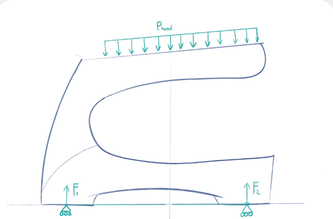


Figure 76: First FBD of the concept

In figure 76 you can see the first FBD. The electrodes are modelled as rolling hinges and the hand as a distributed pressure on the handle. We can simplify this further by making this pressure into a single force and assuming the user will push directly down on their chest (we will also check the scenario when this is not the case later), which you can see in figure 77.

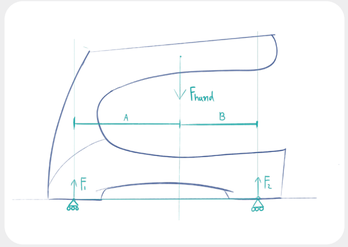


Figure 77: FBD with vertical force of the hand on the handle

This simple FBD is easily solved as the equation only has forces in the Y direction and the hand force is exactly in between the F1 and F2 (distance A = distance B). This means we only have to solve these equations:

$$\sum F_y : F_{hand} - F_1 - F_2 = 0$$
$$\sum M_1 : F_{hand} \cdot A + F_2 \cdot 2A = 0$$
$$\Rightarrow F_1 = F_2$$

Which - as can be seen - can be solved to F1 = F2. Meaning the forces on the electrodes would be equal.

If we look at the scenario where the user pushes down in the direction of the sloped handle we can model the FBD as seen in the figure 78 with an exaggerated angle of the handle to make it easier to understand what is happening.

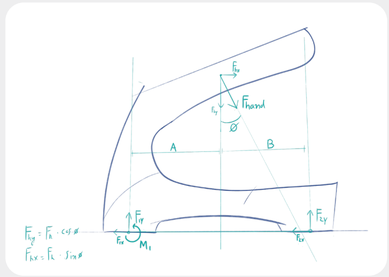


Figure 78: FBD with angled hand force on the hand

To calculate the distributions of forces on the electrodes we need to solve the following equations.

$$\sum F_y : F_{hand} \cdot \cos(\phi) - F_{1x} - F_{2x}$$
$$\sum F_x : F_{hand} \cdot \sin(\phi) - F_{1y} - F_{2y}$$
$$\sum M_1 : F_{2y} \cdot (A+B) - F_{hand} \cdot \cos(\phi) \cdot H$$

Which results in:

$$\frac{F_{1y}}{F_{2y}} = \frac{\sin(\phi) \cdot B - \cos(\phi) \cdot H}{\cos(\phi) \cdot H + \sin(\phi) \cdot H}$$

If the goal is to get an equal force distribution on the electrodes we need to get the fraction F1y / F2y as close to 1 as possible. This expression shows how the ratio of the forces in the y-direction on the electrodes becomes more unequal with a larger angle of the handle (theta). While becoming more equal with a lower height of the handle (H). Making the handle longer and thus shifting the force of the hand further backwards would cause A to increase and B to decrease, this would result in a ratio further from 1 and thus in a more unequal distribution.

We can calculate the fraction between F1y and F2y for the concept design where A = 45 mm, H = 75 mm and theta is 5 degrees. This resulted in a fraction of 0.9 meaning there would be a 10% smaller force in F1y than in F2y. This difference was deemed small enough to cause any worry.

In conclusion, for balanced forces (F2y / F1y ≈ 1), a setup where the force application angle (theta) is as vertical as possible, combined with a minimized height (H) of the handle and the hand being located in the middle of the electrodes where A and B are equal, is optimal. This configuration minimizes the mechanical advantage one side might have over the other due to geometric differences, leading to a more uniform pressure distribution across the electrodes. We will use these findings later on to define the ergonomics of the handle.

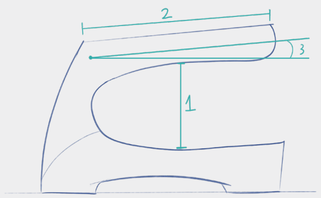


Figure 79: Optimizable dimensions for hand ergonomics

Hand Size Adaptation

Arguably the most crucial ergonomic variable is the hand size and its compatibility with the handle's design. To optimize space for the hand for as many users as possible, we can adjust three main dimensions in this design (see figure 79):

1. Increase the handle gap height either by raising the height of the handle or lowering the bottom part.
2. Widen the handle gap by either extending the handle's length or reducing the thickness of the front section.
3. Modify the angle of the handle upwards to better accommodate different grip styles.

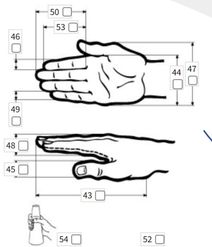


Figure 83: screenshot of the Dined (n.d.) dimensions

By utilizing the DINED (n.d.) databases to gather hand dimension data for our target demographic. However, determining the exact dimensions needed depends on the specific grip style users adopt. Although the device is designed for a particular grip, preliminary testing revealed that some people naturally adopt alternative grips. We identified three grip styles:

1. Thumb on top grip (see figure 80)
2. Thumb below grip (see figure 81)
3. Knuckles below grip, this is primarily observed when the device is used as a secondary user on someone else. (see figure 82)

Figure 80: Photo of the thumb on top grip

Figure 81: Photo of the thumb below grip

Figure 82: Photo of knuckles below grip

Now that we have identified these grip styles, we can define the required handle dimensions to accommodate hand sizes up to the 75th percentile for each grip type. We will then apply the largest value for each dimension. Choosing the largest value ensures the design remains as usable by as many people as possible,

This resulted in the dimensions in table 8. These were used to define the length of the handle and the size of the handle gap.

Table 8: dimensions used for optimization

	Thumb on top	Thumb below	Knuckles below
Handle gap height	Hand thickness (48)	Thumb breadth (45)	Hand thickness (48)
Handle gap Width	Hand width without thumb (44)	Hand width (47)	Hand width without thumb (44)
Handle length	Hand width without thumb (44) + Pink breadth (49)	Hand width (47) + Pink breadth (49)	Hand width without thumb (44) + Pink breadth (49)

Figure 84: Photo of all the itertations prototyped for the final concept

Next to the theoretical ergonomic optimizations also several physical prototypes were made to test how the theory translates to the real world. In figure 84 you can see several prototypes which were made, each to optimize a certain aspect of the design. One of such optimizations was for example to round the underside of the back of the handle, so that when the pink does not fit on the handle -due to a specific grip or larger hand size- it can rest on the soft rounded edge instead of on a hard corner. Other examples of prototyped features are: the handle width, location and strength of certain fillets, length of the handle and handle gap size.

Secondary user ergonomics

One of the key design guidelines stipulated that the device should be operable by a secondary user to perform measurements on someone else. This could be a partner, family member or a healthcare professional. As stated in the previous section on handle ergonomics, the handle is designed to accommodate a grip for this use case. This ensures that the device is accessible and user-friendly for both primary and secondary users.

Button location

From the four-part user preference test, it was found that users generally prefer the placement of the button on the top side of the device. This location aligns well with the natural resting position of the thumb in the proposed design. However, the thumb resting on the button during the measurement could lead to some users being worried they accidentally press the button. Although such an accidental press does not matter, the fact that the user might feel anxiety over it is undesirable. Consequently, an alternative design was explored with the button positioned lower on the same surface, see figure 85. However, this variation was perceived as less comfortable, as it required users with smaller hands to stretch their thumbs too far to reach the button. Therefore, despite the potential for anxiety of accidental activation, the top-side button remained the preferred choice.

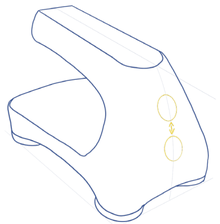


Figure 85: Illustration of the the two options for button location

Figure 86: Photo of how the concept can be used by a secondary user

Lights

The results from the test showed that more research needs to be done to find which feedback method works the best and what feedback informational needs the users might have. This is not feasible to fully develop for this project. Thus to not risk making an ungrounded design decision which might turn out to not work optimally, we will stick with the same feedback mechanism as the current HeartEye device, which is LED lights. Futhermore, we will stick with the same functionality of these lights, like battery level and device status. This choice is also backed up by the limited results from the four-part user test, as it showed lights as the most popular choice for feedback mechanism by the test participants.

Extensions

It might be interesting to further consider how the device can be made more comfortable for more people. This could be done by making the device extendable or customizable. HeartEye found it not feasible to develop the first version of this product, but some example directions were generated to illustrate how this design can be made to be adaptable.

In figure 87 you can see how a hinge could allow for adjustable handle angles to let users choose their preferred angle.

Figure 88 shows how an extension piece could be clicked onto the back to increase the handle length for larger hands and a third option where the rear part of the handle is extendable for adjustability (see figure 89), which would also aid individuals with larger hands in using the design more comfortably.

Another option would be a strap accessory which could allow users with limited control to use the device. Enhancements could make the device more universally accessible but there are future considerations.

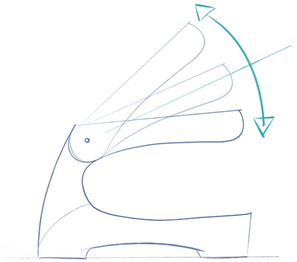


Figure 87: Illustration of how a swivelling handle could be implemented

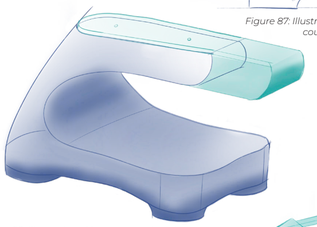


Figure 88: Illustration of how a extension piece could be implemented

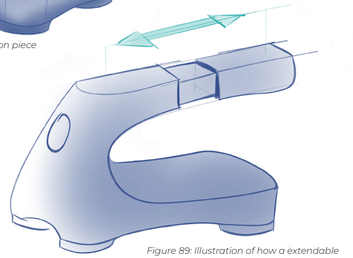


Figure 89: Illustration of how a extendable handle could be implemented

Finally, a more novel option would be to include a T-bar design. The T-Bar was developed by looking at what external body features could help position the device in the correct location. By placing a bar on the bottom of the device the user could position this bar to the underside of their breast and automatically find the correct position, whilst also stabilizing the device more easily. A prototype design was created through several iterations by modelling the bar on top of the p=5, p=50 and p=95 waist and chest circumference mannequin 3D models retrieved from Dined (n.d.), figure 90 of how the design is modelled on top of the mannequin and figure 91 shows a prototype. This concept could be hidden away in the housing by making the T-bar foldable, as was demonstrated in an earlier prototype (see figure 92).

Following body contour

The current design of the HeartEye device is flat on the underside with extending electrodes. This means that the back or front electrodes might not always make good contact when the body contour is too parabolic that the underside of the device becomes a see-saw of sorts as if it was a limousine driving over an Amsterdam canal bridge (see figure 93).

By making the underside of the device follow the body contour more, the electrodes might not only make better contact but the positioning of the device might become easier as well, by notching into the correct position. To roughly test the idea, the geometry was sculpted in the same way as the previously discussed T-bar extension and also went through several iterations. In figure 94 & 95 one of these prototypes can be seen.

Although this idea is untested with real users, it is included in the final concept by curving the underside, as no potential drawbacks were found to unwarranted its inclusion.

Figure 91: Prototype of body contour idea

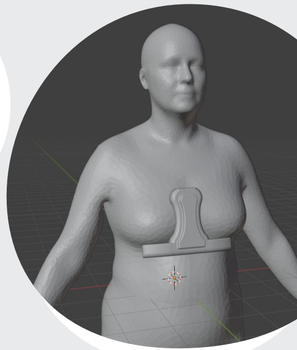


Figure 90: Screen shot of how the first iteration of the body contour idea was modelled on top of a Dined mannequin

Figure 92: Prototype of foldable T-bar

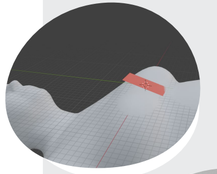


Figure 93: Screen shot illustrating how a flat bottom could cause the electrodes to not make contact on all four electrodes

Figure 94: Photo of a body contour prototype

Figure 95: Photo of the bottom of a body contour prototype

Design optimizations

Next to ergonomic optimizations, also some design optimizations were done to attempt to make the design more aesthetically pleasing. This is important as users of the device will need to store the device in their own homes, which means it needs to be generally pleasing to look at. Furthermore, the four-part test also showed that making the device look the part might also help to make users trust the system more.

Shape

For these reasons, another iteration was made on the shape of the device. With feedback and tips from the team at NPK design an improved version was made through a subtractive approach, where we first find the main archetypical lines to make a basic shape and then make cutouts on that shape to go from one monolithically form with a clean outer shape to a more detailed and interesting, yet visually coherent design.

In Figure 96, 97 and 98, you can see how this process went, with the dark blue lines showing the main shapes from the side-, front- and top view, the smaller dark blue lines showing how the detailing lines relate to each other and the light blue lines showing the final shape. By making the design visually more coherent and simple, the hope is that a larger user group will find the design more trustworthy and unobtrusive.

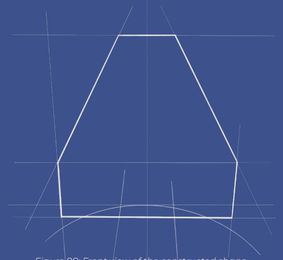


Figure 98: Front view of the constructed shape

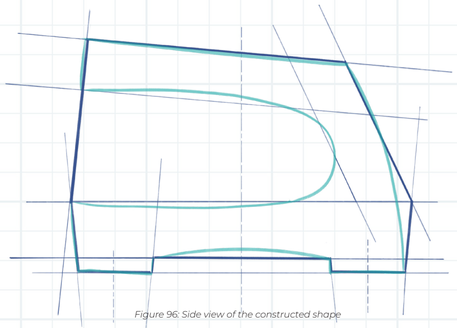


Figure 96: Side view of the constructed shape

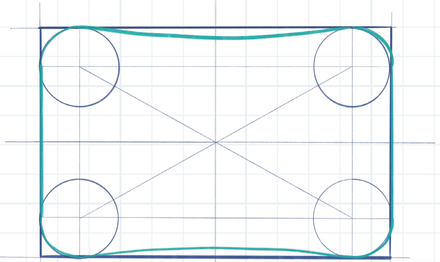


Figure 97: Top view of the constructed shape

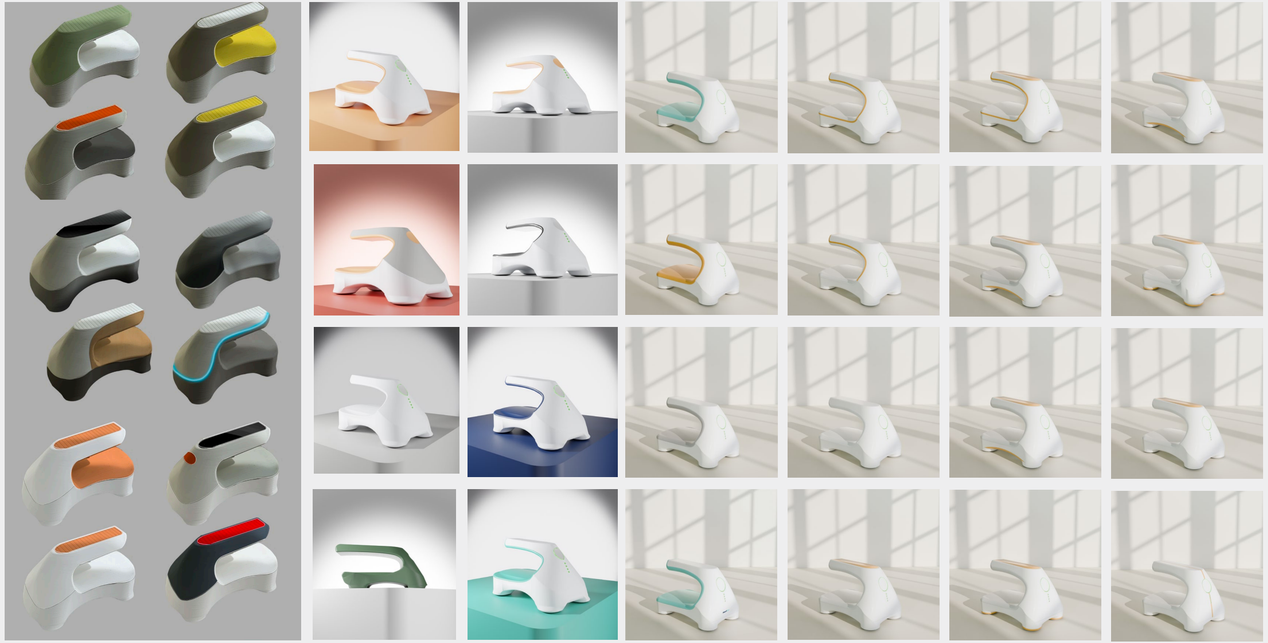


Figure 99: Design evolution of colour exploration

Colour exploration

The colour exploration was a very difficult endeavour. This concept should be a feasible concept that is unobtrusive in any home but also is a boundary object that needs to excite investors and stakeholders. Next to that, it is recommended in the future to perform a colour analysis and gather user feedback on possible colours, which was not done for this project. In figure 99 you can see a design evolution of all the iterations of the colour design. At first, an initial exploration into the colour scheme of the device was conducted by sketching different combinations and divisions. The selection of colours was based on those commonly used in other medical devices.

#FAF9F6

#EBEAE7

#F2B353

Figure 100: Selected colour swatches

Given the intended scenario of home use, it is important to ensure that the device is unobtrusive. It must be able to blend into a variety of homes without clashing or standing out too much. Therefore, eventually, an off-white colour (#FAF9F6) was selected as the main colour of the device. But to make the design more interesting an accent colour needed to be chosen as well and after long consideration the choice was made for the brand colour of HeartEye, a yellow-orange colour (#F3B352). After selecting the colours themselves, the location of the accent still needed to be defined. after many iterations, we ended up with the final result as can be seen in figure 100.

Figure 101: Two renders of the of the concept with the selected colours

Manufacturability

As discussed in the first chapter of this report, the manufacturing method is going to be injection moulding of medical-grade ABS. This means that the design needs to be split up into different sections to make it mouldable. After an initial exploration into different options, it was eventually decided together with the expertise of NPK to split the housing up into three distinct sections: a top part, a bottom part and a middle part, as can be seen in figure 102. These sections can all be made to have a correct draft angle with no undercuts so that the design can be de-moulded when injection moulded.

Internal Components Layout

During the design process, the necessary volume for the internal components and their shape was taken into account based on the dimensions of the original design. But to verify that there is indeed enough space for all the necessary components, a preliminary layout was developed. In figure 102 & 103 you can see the electrodes and main PCB, which also houses all the main electronics. A second PCB is placed slanted in the front of the device to facilitate the LEDs and buttons there. Lastly, the battery module was placed on top of the main PCB as there was plenty of space left there.

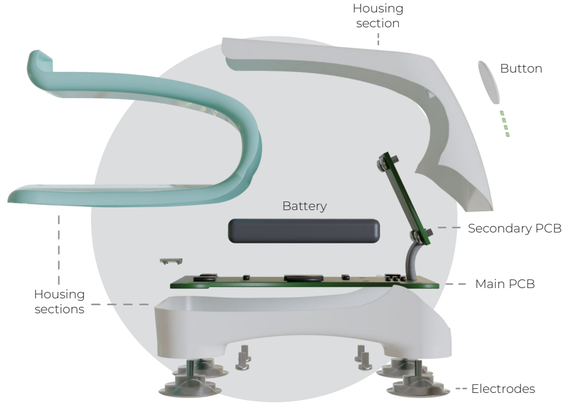


Figure 102: Render of a exploded view of the concept, showing its seperate components

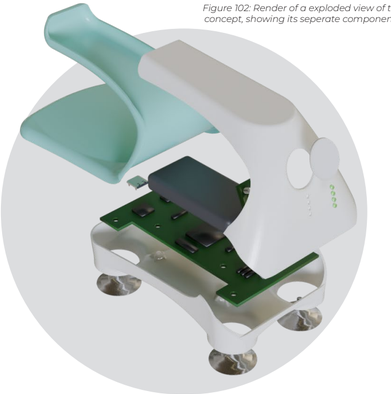


Figure 103: Render of a exploded view of the concept

Dock

The current design of the HeartEye has a proprietary dock, which is well suited for the intended use case for two reasons. First, HeartEye needs to prove for regulatory reasons that the device cannot be used during charging, which the dock guarantees. Secondly, The device needs to be charged and ready to use at all times in an emergency scenario in the hospital, for this reason placing the device in a dock was thought to be more reliable than having to plug a cable into the device every time.

However, in the new scenario where users need to take a measurement only once a week, the dock does not offer this unique advantage. According to Sebastiaan Bakker, who is doing a graduation project on the sustainability of the HeartEye device, does make up a significant part of the eco-cost of the system. For these reasons, the dock was replaced with an ordinary USB-C charging port on the back of the device.

Final Concept

Imagining the product's packaging

FUTURE IMPLEMENTATION

So what work would remain if HeartEye wanted to develop this concept into a manufacturable patient-centric product? To answer that question a simple roadmap was constructed. This roadmap focuses exclusively on the technical or usability aspects of the product development, deliberately excluding operational concerns such as business model development, marketing, and other strategic concerns.

1. Research, prototype and test feedback methods & informational needs

A start has been made on improving the feedback methods and finding the informational needs of the users. However, more focused research is necessary to find out which feedback method works best and what feedback users need before, during and after the measurement. The HeartEye device would benefit greatly from listening to actual users for this to have a lasting impact improving the turbulent times these people are going through.

2. Consider Device Storage

An important but unconsidered aspect of the design is the consideration of how the device will be stored when not in use and during transport. HeartEye could develop a hard case -similar to those used for premium headphones- to safeguard the device from physical damage and improve hygiene when carried in a bag but also provide a more discreet storage solution at home.

3. Improve Sustainability

While sustainability falls outside the scope of this project, HeartEye must consider integrating sustainable practices into its strategy. Strictly linear business models are simply outdated. The transition to circular ones is a necessity, driven by increasing consumer demand for sustainable products and regulatory pressures, such as those from the ESPR, which was discussed in the discovery phase of this report.

The excuse that HeartEye is just a simple start-up is not a valid argument as by designing a device that is not only repairable but also viable for refurbishment, HeartEye can tap into new revenue streams through the sale of certified pre-owned equipment. This practice not only extends the product's lifecycle but also conserves resources and reduces environmental waste, aligning with sustainability targets. Next to that, refurbishment can also ease the burden on healthcare systems by providing more affordable equipment options.

Furthermore, by championing reuse, HeartEye positions itself at the forefront of a movement, fostering customer trust and brand loyalty, with the customers being not only the patients but also the sustainable-minded healthcare professionals as well.

Although on a first glance, the final concept looks feasible to make into a circular product, due to its reversible connections and simple construction. Unfortunately is this project not focussed on fully developing the concept and did not go any deeper into the repairability and the lifecycle of this product. But another student graduation project by Sebastiaan Bakker goes in-depth into this subject for the HeartEye device.

4. Develop the Integration with the wider Product Service System

The HeartEye device needs a companion app to transmit recorded ECGs to a telemonitoring service centre. Next to a role as a messenger, the app will also serve as the primary interface for user interaction. HeartEye should spend great effort in developing an app that simplifies the measurement process and provides clear guidance when the user needs it, to foster trust and minimize anxiety.

The app can be so much more next to these roles as messenger and guide. The app could for example: enhance health literacy by educating users about their condition, integrate motivational features like progress tracking and rewards to encourage lifestyle changes, provide tools for stress management such as guided breathing exercises, and even offer a platform for community support where users can share experiences and advice. These features would make for a more complete health management tool that supports patients beyond just monitoring their cardiac health.

5. Development of training / instructional materials

Based on the earlier findings of the report we found that the development of training and instructional materials is crucial for ensuring the HeartEye system is both feasible and desirable for all users. Comprehensive resources are essential not only for empowering end-users to operate the device confidently but also for convincing healthcare professionals of the system's reliability and effectiveness. Furthermore, training resources could aim to increase the health literacy of the users, which could most definitely improve adherence.

Such resources should be focused on explaining the correct usage of the device, but could also include feedback on how to improve the measurements based on the previous measurements or these materials could extend to cover interpretive guidance that helps users understand their ECG readings, as we found most participants of the four-part test expressed an interest in this.

6. Regulatory compliance

As discussed in an earlier chapter, navigating the regulatory landscape for novel medical devices like the HeartEye can be complex and demanding. To make the process simpler and ensure compliance, some recommendations can be given based on this report.

Firstly, HeartEye should initially avoid incorporating diagnostic AI capabilities. While AI can enhance functionality, it also introduces additional regulatory scrutiny. That does not mean no AI features could be integrated. AI could be used to improve the user experience by for example helping users improve how they take measurements or making the ECG data interpretable.

Additionally, integrating sustainability requirements outlined by the Environmental Sustainability Performance Review (ESPR) from the onset is crucial. This not only ensures compliance with emerging environmental regulations but also positions HeartEye as an eco-friendly option in the medical device market.

A last recommendation is to keep the product within the cost constraints of insurance reimbursements of 163 euros every three months. This makes cost-effective design choices essential. For example, opting for a USB-C charger instead of a more expensive docking station could already reduce manufacturing and retail costs, making the device more accessible.

7. Design for Manufacturing

The current iteration of the HeartEye device's design has been preliminary evaluated for manufacturability by NPK Design, but it remains in an early stage of development. Further development is necessary to ensure the design is suitable for mass production. Key areas include ensuring the device's components are compatible with injection moulding, making the housing IP4X water resistant -as specified by HeartEye- and developing standardised assembly and repair protocols.

In terms of electronics, even though the technology used in the current and new HeartEye designs is the same, updates are still required. Specifically, the device needs redesigned PCBs tailored to the new housing. Next to that, a different battery might be more suitable for the home scenario and the device now needs a USB-C charging port.

8. AI development

It is no new information that Machine learning and AI, in general, can significantly improve healthcare diagnostic capabilities and decrease costs. However to make machine learning models that are accurate enough that we will trust them in making life-altering decisions, we will need lots of data and not just any data, high-quality, labelled, and diverse data. In this context, the HeartEye device presents several unique qualities.

Firstly, the data consistency provided by using the same device technology across all measurements ensures uniformity, unlike datasets gathered from various ECG devices. This would be beneficial for developing robust machine-learning models. Secondly, the data from HeartEye will be expertly labelled, providing accurate annotations. Thirdly, the diversity of the user base and the varied contexts in which the device is used enhance the robustness of the data, making the AI models trained on this data more generalizable across different populations and conditions. Lastly, the long-term usage of the HeartEye by the same individuals offers a unique dataset, allowing for a better understanding of patient-specific trends and outcomes.

However, HeartEye needs to be laying down these groundwork elements now. This way HeartEye can pave the way for future AI integration that could significantly enhance the device’s diagnostic capabilities, ultimately leading to more effective patient care.

9. **Pilot testing with a Large and Diverse User Group**

The most useful insights in this project came from talking directly with users; Heart disease can deeply affect a patient's mental health, highlighting the potential for positive impact in this area. However, many other monitoring devices are too focused on simply gathering medical data efficiently and overlook what patients need. Since telemonitoring devices are often the primary way patients regularly connect with their healthcare, they represent a significant opportunity to positively influence their lives and healthcare experiences. Conversations with users have shown that it's crucial to consider how these devices interact with them and the emotional experience while and after using the product-service system.

Such a patient-centric device requires structured, direct, and frequent user feedback. This could be accomplished through regular meetings with a user panel and consistent pilot testing, possibly involving this same panel.

PROJECT WRAP-UP

Concluding and reflecting

PROJECT CONCLUSION

This project embarked on the ambitious task of redesigning the HeartEye ECG for home use, transforming the device into a practical concept suitable for patients managing coronary artery disease outside the clinical setting. By utilizing the double diamond design framework.

In the initial phase of the project—the Discovery Phase—a comprehensive exploration of seven facets of the problem space was undertaken. This ranged from opportunities in e-health to target group research and market considerations. Together with this analysis, interviews with experts and users, and the analysis of thousands of blog posts on heart conditions, extensive design considerations were formulated.

Once the problem space was sufficiently explored, the scope of the project was further refined in the second phase—the Define Phase. During which significant strides have been made in selecting and developing the prehabilitation to rehabilitation scenario as a desirable, feasible and viable scenario for the HeartEye technology. The scope was further defined to the physical design considerations of the device, leaving the discovered market and platform considerations for future development. Thus the project subsequently aimed to design a concept that would improve the ergonomic design of the device, making it more usable for users to measure themselves, while also ensuring a good measurement.

Over the course of the develop and deliver phase, a much greater understanding has been achieved of what human factors influence a good measurement. This knowledge arms HeartEye with more certainty on what works when designing this self-measurement tool. Furthermore, although the ergonomics of the final concept are not extensively evaluated with the target group, the main shape and ergonomics are based on the user test outcomes and initial evaluation with peers did show promise in that the concept significantly improved the ergonomics of taking a self measurement. Plus, the new shape facilitates not only self-measurement but also the ergonomics of a secondary user taking a measurement.

Perhaps the most significant use for this project is that it has generated a large amount of insights in a wide range of areas. By considering many different facets of the problem space this project aims to enable the design of a user-centric, feasible, viable and desirable product that makes a positive impact on CAD patients. The final concept itself is not the project outcome, but rather a showcase of the gathered insights and should be seen as a starting blueprint.

PERSONAL REFLECTION

If I could do this project again, I would ofcourse do it all differently. But that is a good thing. It shows that I learned a lot during this final stage of my scholarly endeavours. As an extra learning exercise I have written down my main learning points from this project and included them here.

Focus & Goal definition

The initial brief of the project was defined as very ambiguous and because I am new to the world of medical device design I spent a long time trying to soak up as much knowledge on the subject. I went very wide in my initial exploration, as the field is vast and complex. I should have leaned more heavily into the expertise of my guidance team and asked for more direct help to define a more clear goal for the project. So that I could have gone deeper in a specific area instead of going wide.

I think what made this difficult for me in this project was the fact that I started the project with the idea I could fully develop a concept not only on the physical design side of the device but also the business model, sustainability, strategy, AI and more. I truly underestimated the complexity of the problem, the immense size of the problem space and the vast range of possibilities these entail. In the future, I should spend more effort trying to define the goals in manageable chunks on the front end rather than diving headfirst into an oversized problem space.

Feedback

Personally, I am highly convinced design is a team sport, which makes an individual project such as this very hard. This is why I feel very lucky to have had guidance from not only two professors from the TU Delft but also personal guidance from the client company themselves and a renowned design agency. Next to the professional guidance I also had a lot of discussions and talks with fellow IDE students which were pivotal in preventing me from lingering too long on any specific hurdle. However, I wish I would have asked for feedback more often. Each time I received feedback, it significantly sharpened the project's direction.
This is why I am grateful to my chair and mentor for pushing me to find experts in the field to talk to and helping me go to the Healthcare in Shape symposium. The interviews I had with experts because of this helped immensely in creating direction for the project and were more effective in helping me understand the complex field of medical device design than reading any more papers.

User test

I learned a lot from the user test I did. The most important learning is that a quantitative user test can also generate valuable qualitative insights. I got the tip from NPK to record the full user test and I am glad I listened to that advice. The most interesting findings from the test came from random comments participants made, which I sometimes only noticed after listening to the recording again. I also noticed people do not need much in terms of the fidelity of prototypes to give valuable feedback.
Thus what I learned is that talking to the user group is of immense value even without high-fidelity prototypes or quantitative results.

Designing for Ergonomics

I was not very experienced in developing ergonomic products outside the bachelor courses. The most important lesson I learned is that you cannot go only on ergonomic data like you get from DINED. The real world is a lot messier and has way more considerations to take into account like unpredictable user behaviour, deviating user dimensions or physical limitations of users. This made me realise that early and often testing of physical prototypes is very valuable in designing ergonomic designs. What worked for me was rapid prototyping with 3D printing. Using this technique I could go through a lot of iterations in a very short amount of time, which helped in developing an ergonomic design.

Planning

A master graduation project is the first time nobody holds your hand and tells you what you should have finished by the end of each week. Which was a refreshing, but daunting experience. I enjoyed the freedom and found, but often I was unsure if I got enough work done at the end of each day. What I learned from this is to be content with having worked 8 hours a day and that not every hour should be accounted for. A large part of a design project like this is a creative process that you need to work on for some time or talk about with other people. Setting larger and smaller deadlines for yourself is more useful.

Juggling Stakeholders

Working with a client like HeartEye, the requirements of the TU Delft and my own was an interesting experience. This combination of stakeholders is unique because it is my project, but I want to make an impact on the product of HeartEye and I need to do that while following the way of working of the TU Delft. What I learned from this experience was that I need to more clearly make up my mind on what can be done within the available time prioritise the important work and communicate this priority to all the stakeholders to align better on the project which might result in better cooperation and teamwork within the stakeholders.

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