Product-Service Design to Improve Self-Monitoring after Myocardial Infarction at the LUMC

Kevin Mamaqi Kapllani

MSc Integrated Product Design
Specialisation Medisign

Chair
Ruud van Heur

Mentors
Kaspar Jansen
Roderick Scherptong

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Project Description

In the Netherlands alone, an estimated 730,000 persons are currently diagnosed with coronary heart disease (CHD), 120,000 with heart failure, and 260,000 with atrial fibrillation. As of 2014, cardiovascular disease accounted for 27% of all deaths[1]. The cardiology department of the Leiden University Medical Centre (LUMC) has a regional role in treating patients with different cardiovascular diseases, ranging from myocardial infarction, heart failure and infectious cardiac diseases to life support with left ventricular assist devices (LVAD) in severe heart failure patients. Coronary artery disease (CAD) affects a big proportion of these patients. Forty myocardial infarction (MI) patients are seen on a weekly basis in the outpatient clinic (MISSION!-clinic) at set times after the infarction event; 1 month, 3 months, 6 months or 12 months.

In an attempt to improve patient outcome, provide a better service and reduce the workload at the outpatient clinic, the LUMC launched a novel project called "the BOX". The BOX allows patients to self-monitor their vitals after a myocardial infarction (MI) or heart surgery, thus reducing visits to the hospital.

Patients are given a Wi-Fi scale, a watch with a pedometer, a Wi-Fi blood pressure meter (BPM) and a one-lead EKG/ECG monitor. The devices are produced by two different companies (Nokia/Withings and Alivecor) and are connected to the mobile phone of the patients. Patients have to measure their vitals on a daily basis and are instructed to contact a professional in case of emergency. Preliminary results show a good acceptance from the patients and high willingness to self-monitor their disease. This new product-service reduces the number of regular visits to the outpatient clinic by 40%, which are replaced by video conference[2].

In this context, the cardiology department plans to take the next steps to expand this service and provide effective and quality care using e-Health medical devices. Nevertheless, they are dependent on different stakeholders to do so. On the one hand, the companies that sell the medical devices (like the ones included in the BOX) control the patient data, and grant access to the hospital. A change in their business model can affect patient safety, privacy and the systems that the hospital has to put into place. On the other hand the patient must use the devices. Self-monitoring is an important behaviour for self-management, required for various chronic illnesses such as diabetes, hypertension, and heart diseases[3]. But, having a plethora of devices and applications is not accessible for all the patients, which is a critical requirement for the LUMC as a part of a public institution that focuses on providing healthcare services to the general population. Moreover, a hospital requires stability for the long-term in order to implement technological solutions that directly affect patients.

The described situation is an interesting opportunity to look at product/services through different lenses (public sector) and design within the institution. Although, it also has the constraint/limitation that doctors are not engineers/producers. In addition, it is a vast problem to tackle, thus the necessity to focus on one area as the research is done.

Planning and Approach

A Gantt chart (Appendix A. Gantt Chart) is created according to the faculty guidelines. To better illustrate the design process –which is not well captured in the Gantt chart format– a Double Diamond model is created (Figure 1). The Double Diamond model represents the number of possible ideas that are generated ("divergent thinking"), as well as the refining and narrowing down to the best idea ("convergent thinking").

In addition several analysis are planned to integrate the faculty three pillars of research expertise; people, technology, business. Moreover, the research is projected towards the future, to make the subject relevant to the mission of the Industrial Design Engineering (IDE) faculty: Design for Our Future (Figure 2).

The aforehead indications are taken from the IDE graduation guidelines.

Moreover, to properly guide and evaluate the project each chapter has conclusions to "Effectively collect, analyse, integrate and generate knowledge required for the project", thus justify the choices made.

Finally, this information and documents are used to properly communicate with the chair and mentors on each stage what is relevant, leaving room for improvements and modifications if necessary.

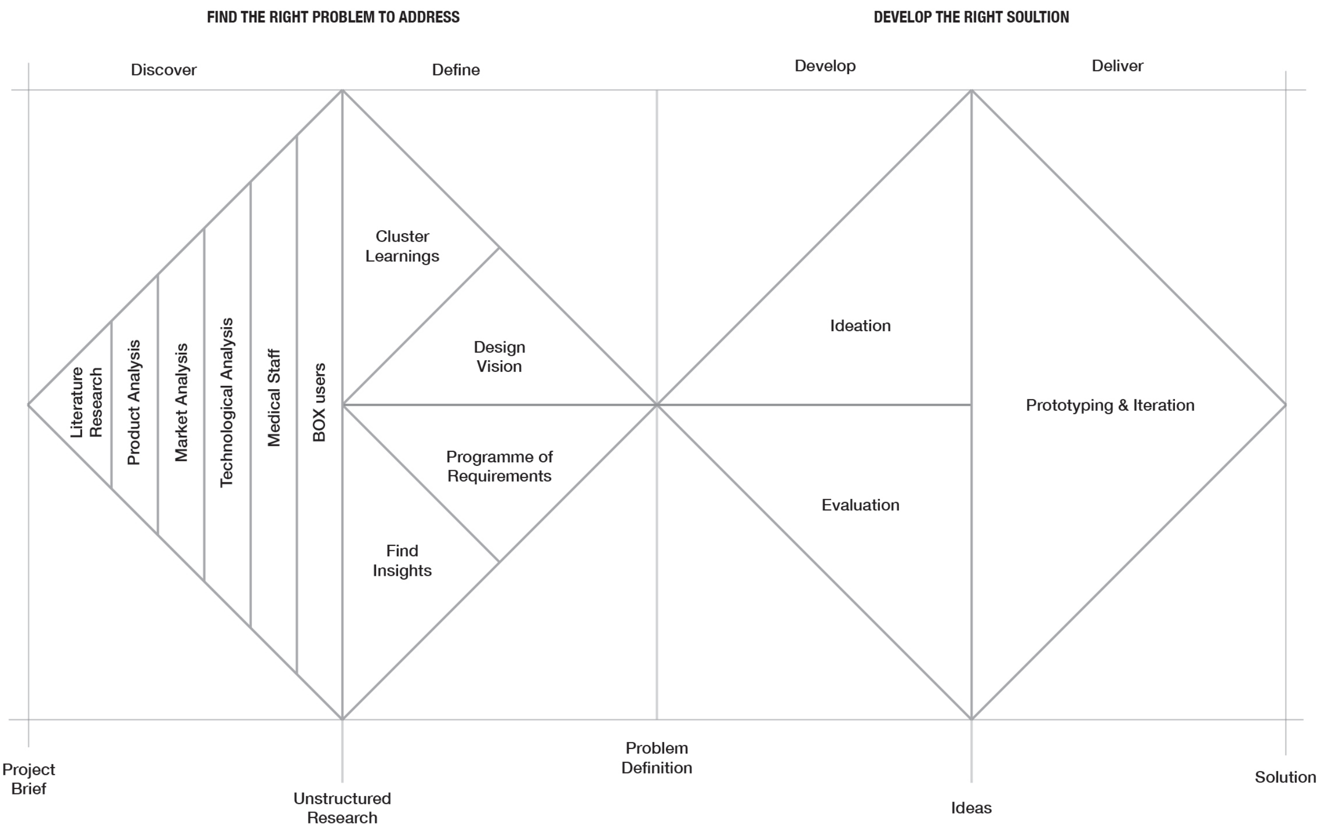
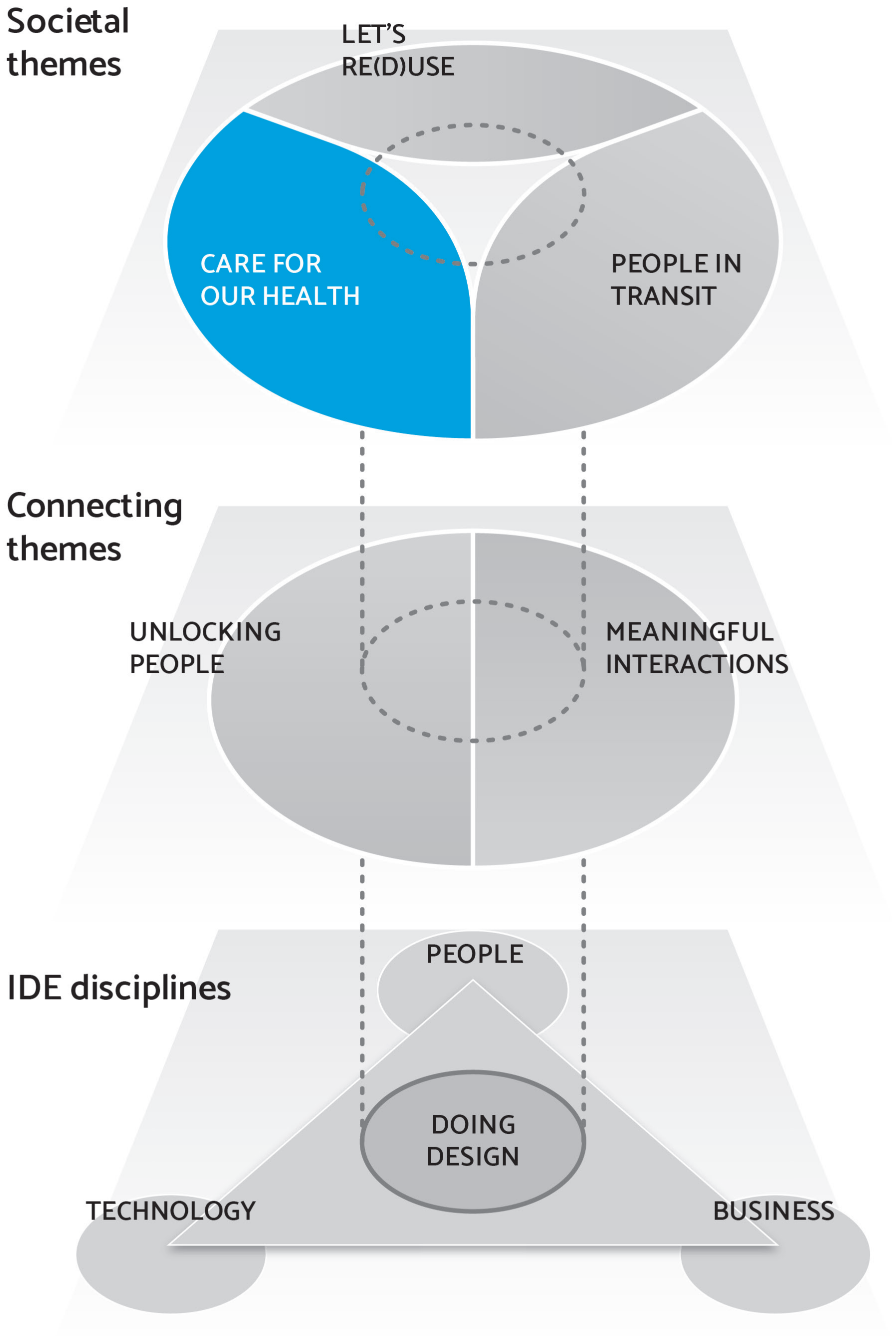


Figure 1. Double Diamond used for the planning.

Research - expertise



The focus of the present thesis is on CARE FOR OUR HEALTH.

Connecting themes:

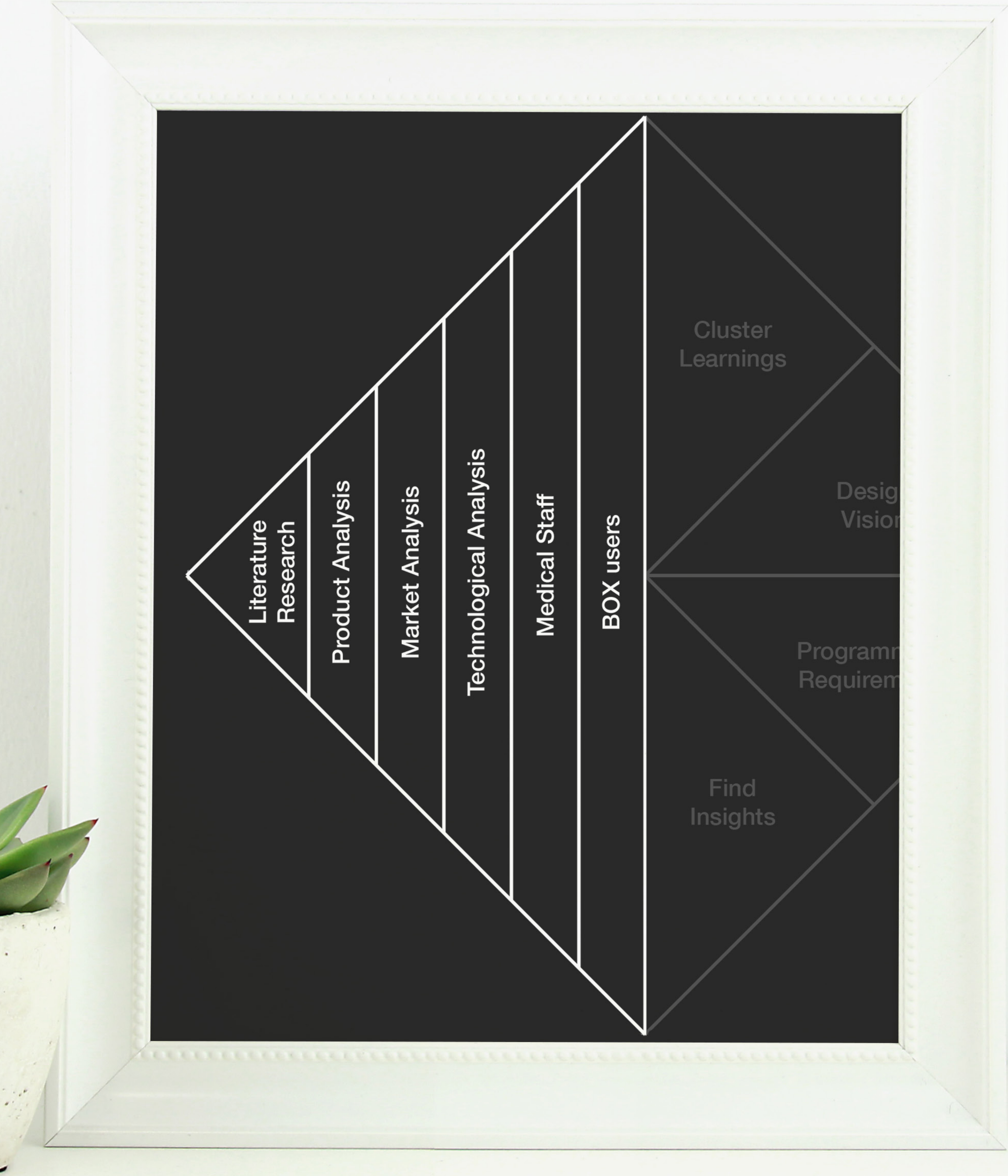
- Prospective design, to look into the future.
- Technological evaluation, to select technologies that bring value.
- Literature review on behaviour, focus on patient outcome.

Analysis conducted to generate knowledge withing the three pilars of IDE:

- Product Analysis (structure and function).
- Market Analysis (competition, features, components, materials and cost, ...).
- Technological Analysis (alternatives, and future technologies).
- Patient and hospital staff interviews to understand the stakeholder needs and interactions.

Figure 2. Accommodation of the planned analysis to the IDE faculty mission.

stage 1 **DISCOVER**



Chapter 1

Introduction

The purpose of this chapter is to provide a solid base in terms of practices, methods and experiences related to MI, the healthcare sector and the world of wearables. To have a global view and the detailed description of the process that leads a patient to have a heart attack and its recovery process. It serves as a comprehensive understanding to further evaluate the products and system of the Box, the patient experience, identify bottlenecks in the system and other key factors that could provide insights.

1.1 Myocardial Infarction (MI)

MI, commonly known as a heart attack, occurs when the flow of blood to the heart is blocked. There are various causes for the blockage, such as spasms, embolism and thrombosis, but the most common cause of MI is atherosclerosis[4].

Atherosclerosis is the building up of cholesterol in the wall of the heart arteries, generally as a plaque. These plaques can break and spill cholesterol and other substances into the bloodstream, which triggers the formation of a blood clot. A blood clot is a clump of blood that has changed from liquid to gel-like or semi-solid state[5]. If it is large enough, the clot can block the flow of blood through the coronary artery, causing a MI.

1.1.1 Clinical Classification of MI

MI is a type of acute coronary syndrome (ACS), which happens when the arteries that provide blood to the muscles of the heart get blocked (ischemia)[6].

The three classifications of MI are[7]:

- **ST segment elevation myocardial infarction (STEMI)**: Occurs when thrombus formation results in complete occlusion of a major epicardial coronary vessel. It is the most serious of ACS. It is a time-sensitive emergency that requires immediate diagnosis and treatment[8].

- **non-ST segment elevation myocardial infarction (NSTEMI)**: Occurs when thrombus formation results in partial occlusion of a major epicardial coronary vessel. It causes enough myocardial damage leading to detectable quantities of myocardial injury biomarkers (elevated troponins)[9].

- **Unstable angina (UA)**: Occurs when thrombus formation results in partial occlusion of a major epicardial coronary vessel. It does not cause enough myocardial damage to lead to detectable quantities of myocardial injury biomarkers (elevated troponins). The level of troponins is the main difference between UA and NSTEMI.

1.1.2 Diagnosis of MI

The three ACS mentioned above are primarily diagnosed by the patient symptoms and history, an electrocardiogram and a blood test to determine elevated troponins in the blood.

MI symptoms and severity can vary depending on the class of heart attack and patient. Generally, when a possible MI is reported by the patient, the emergency care team will ask about the symptoms and the history, while proceeding with the tests immediately, especially the Electrocardiogram (ECG).

The ECG records the electrical activity of the heart over a period of time. The wave of a heart in normal sinus rhythm can be seen in Figure 3. The blood test is performed in order to find cardiac troponins, the most sensitive and specific biomarkers to diagnose NSTEMI and UA (NSTE-ACS).

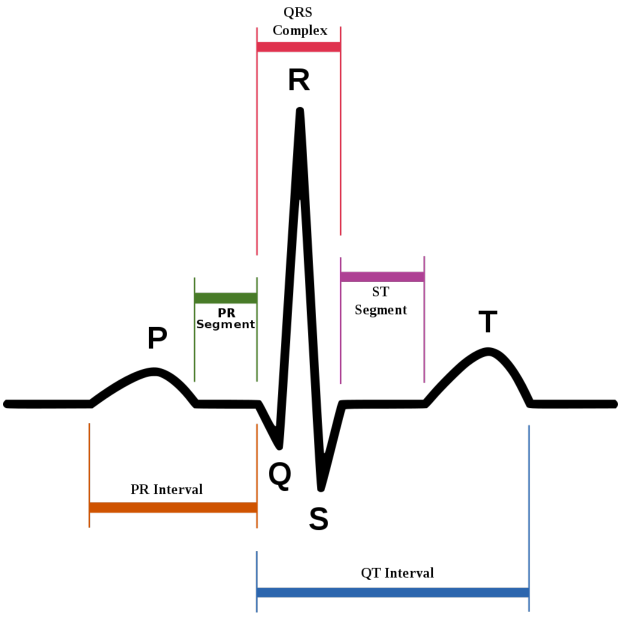


Figure 3. ECG of a heart in normal sinus rhythm.

Most patients that present elevation on the ST segment will have a STEMI. Patients with abnormalities on the ECG, such as ST depression, transient ST-elevation, and/or prominent T-wave inversions may have a NSTE-ACS, the distinction is made on cardiac biomakers (troponins)[9].

1.1.3 Types of MI

The types of MI are based on pathological, clinical and prognostic differences, along with different treatment strategies. The types differ from the clinical classification mentioned in point 1.1.1, because the clinical classification serves as a tool to classify and apply immediate treatments in case of a MI[7].

- **Type 1**: MI caused by atherothrombotic coronary artery disease (CAD) and usually precipitated by atherosclerotic plaque disruption (rupture or erosion).
- **Type 2**: Pathophysiological mechanism leading to ischaemic myocardial injury in the context of a mismatch between oxygen supply and demand.
- **Type 3**: When suspicion for an acute myocardial ischaemic event is high, even when cardiac biomarker evidence of MI is lacking.

1.1.4 Signs of MI

The symptoms can vary from patients, depending on the type of MI, age and/or gender among other factors.

According to the American Heart Association (AHA), the main signs are:

- Pain or discomfort in the chest.
- Lightheadedness, nausea or vomiting.
- Jaw, neck or back pain.
- Discomfort or pain in arm or shoulder.
- Shortness of breath.

1.1.5 Causes of MI

The causes that increase the risk of having a MI are the same as for CVD, which are generally classified in two big groups: non-modifiable risk factors and modifiable risk factors[10].

Non-modifiable risk factors:

- **Family history**: Having direct family member(s) who suffered a MI increases the risk of heart disease. If both parents suffered from heart disease before the age of 55, your risk can rise up to 50% compared with the general population.
- **Diabetes**: Having diabetes increases two to four times the chances of developing CVD.
- **Age**: The risk of stroke doubles with each decade after the age of 55.
- **Gender**: Men are more at risk than pre-menopausal women.
- **Ethnicity**: Being of African or Asian ancestry increases your risk of developing CVD.
- **Socioeconomic status**: Being poor increases the risk of developing CVD. Chronic stress, isolation, anxiety and depression also increase the risk.

Modifiable risk factors:

- **Physical activity**: Doing more than 150 minutes of moderate activity (walking fast, cycling, ...) every week or one hour of vigorous exercise everyday can reduce the risk of coronary heart disease by 30%.
- **Tobacco**: Quitting smoking is the most effective strategy to prevent CVD. It is the single most important preventable cause of premature mortality and disability-adjusted live years DALYs[11].
- **Diet**: It is crucial in the development and prevention of heart disease. Comparing two people, the first following an unhealthy diet and the second having a healthy diet, the latter has a 73% reduction in the risk of new major cardiac events. Unhealthy diet is generally defined by low intake of fresh fruit, vegetables, wholegrain flour combined with high intakes of refined grains, saturated fats and sodium.
- **Unhealthy fats**: Saturated and trans fats raise the blood cholesterol level, which develops in atherosclerosis, increasing the risk of MI.
- **Hypertension**: It is the most important risk factor for stroke. Hypertension stresses the body's blood vessels, causing them to clog or weaken. Hypertension can lead to atherosclerosis and narrowing of the blood vessels making them more likely to block from blood clots or bits of fatty material breaking off from the lining of the blood vessel wall.
- **Obesity**: Being overweight may lead to the development of hypertension, diabetes and atherosclerosis. Statistics show that 58% cases of diabetes and 21% of ischemic heart disease are attributable to a BMI above 21.

The data has been obtained from the World Heart Federation and was published in 2017 [10]. Other studies and organizations use different classifications, such as the AHA[12] or clinical studies like the INTERHEART study[13]. Moreover, research based on large populations is conducted and published constantly, updating the risk factors effects. Nonetheless, there is consistency in the affirmation that smoking, diet and exercise, altogether with hypertension control and medication (if necessary), improves the quality of life and reduces the risk of MI.

The knowledge on modifiable risk factors also raises some questions. If they are well known, studied and effective; Why is it difficult for patients to adhere to them? and when do the prevention should start? This will be discussed in section 1.5 Behavioural change.

1.1.6 Treatment of MI

Immediate treatment: Having a STEMI, NSTEMI or UA are important causes for the use of emergency medical care and hospitalization. A quick assessment of patients history, symptoms combined with electrocardiogram and blood test will help to make the best assessment for treatment. The treatment can be surgical (revascularization, angioplasty, ...) combined with aggressive medication (anti-ischemic, antiplatelet, anticoagulant, and lipid-lowering drugs)[14].

Mid-term and long term treatment: Patients are prescribed several medicines that might include; atorvastatin, ACE inhibitor and angiotensin-ii inhibitor, anticoagulants, beta-blockers, stomach protector (for the anticoagulants). This medicines are combined with numerous lifestyle changes (diet, moderate exercise, tobacco, ...) which are related with the modifiable risk factors mentioned in section 1.1.5.

1.1.7 Consequences of MI

The physiological and psychological consequences of MI are highly dependent on the damage caused to the heart. During a MI, the heart tissue deteriorates or dies (necrosis) which can lead to death, deteriorated pump function, arrhythmias and increased risk of having another MI or sudden death among others. Moreover, a MI is a traumatic event for patients, after which approximately 40% of them have either major or minor depression[15]. Apart from depression itself, patients question their capabilities and have to gradually return to their normal activities while making lifestyle changes. Intimate lifestyle aspect - sexuality - is also affected.

1.1.8 Historic overview of MI treatment

MI treatment history can be classified in three main categories or periods since 1912 with the publication of "Certain clinical features of sudden obstruction of the coronary arteries" [16].

- 1912–1961: The bed rest and 'expectant' treatment. During this period the only treatment offered to patients after a MI was to rest and wait. There was a lack of knowledge, tools and procedures. The specialists considered MI to be 'wounds' of the heart.
- 1961–1974: the coronary care unit. The second category of MI treatment was the coronary care unit, in which; 1) patients with acute MI were delivered to a separated and specialized area in the hospital; 2) they were continuously monitored; 3) staff was trained in resuscitation; 4) staff had the authority to perform resuscitation without the presence of a physician.
- 1975–present: myocardial re-perfusion. This period is characterized by the percutaneous coronary intervention (PCI), use of aspirin and antiplatelet agents, the addition of stents, and other procedures/logistics. Altogether, this advances reduced the hospital mortality caused by MI from 15% to 3.5% nowadays.
- Present-future: Prevention of lethal myocardial re-perfusion injury. Re-perfusion is often called as a double-edge sword, as it restores blood circulation, but also cause damage to the heart. Regenerative medicine, new drugs and methods are being studied to avoid it to further reduce the in hospital MI mortality.

Nowadays, treatment has expanded to prevention and early detection of heart failure. For the purpose of this thesis, the Present-future category will be explored. The Box project and the devices given within it are very much aligned with future trends in healthcare, discussed in Chapter 1. Section 1.2.

Information on the historical overview of heart treatment can be found in the references[16].

1.1.9 Successes and failures

CVD treatment and prevention have constantly improved in outcomes. In the Netherlands MI-associated mortality declined significantly by more than 70% over time in both men and women. Age-standardised mortality declined even further[1]. This is due to improved treatments, the introduction of stents and better orchestration in cardiology, using standardized procedures from diagnosis, emergency care to hospitalization and intervention.

Outside the clinical realm, patient actionable prevention has been reported continuously to improve/reduce or postpone the incidence of cardiovascular disease in the general population. Nevertheless, change in behaviour remains a failure in the system, up to 98% in the United States of America[4]. This failure is due to multiple factors such as lack of focus until recent years on this area and the complexities of behavioural change, which is becoming an area of interest. This is further discussed in section 1.5.

1.2 Healthcare trends

Driven by the aging population, prevention as a cost-effective treatment and new technologies, several governments around the world have taken action and are introducing modifications in their healthcare systems accordingly. Some of these plans are:

- **USA**: From quantity care to value based healthcare thanks with the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[17].
- **Mexico**: Prevention supported by community outreach through CASALUD programme.
- **Canada**: Connecting to Care Programme, invest in community care to prevent hospitalization.
- **United Kingdom (UK)**: NHS empowers patients to have a more active role in their own healthcare.
- **Singapore**: The 3 Beyonds Programme: Moving from hospital to community. From quality to value. From healthcare to health.
- **China**: Healthy China 2030: working towards the national goal of reaching a health standard on par with developed countries by 2030. The focus is on prevention, aging and accessible healthcare services among others.
- **Japan**: Integrated Community Care System: healthcare, long-term care, housing and livelihood support for elderly in their communities.
- **The Netherlands**: The Netherlands is moving towards the Electronic Health Record to facilitate exchange of information between patient, cure and care professionals. Some of the goals are[18]:
  1. 80% have access to their own medical records by 2019.
  2. 75% elderly or vulnerable chronically ill patients monitor somehow aspects of their health.
  3. Online contact with the healthcare provider.

The trends overview with the leading new drivers are summarized in Figure 4[19].

The trends are highly dependent on technology and require the usage of new devices and methods to measure the outcomes of the treatments, collect data, free caregivers from repetitive tasks to provide custom treatment, etc.

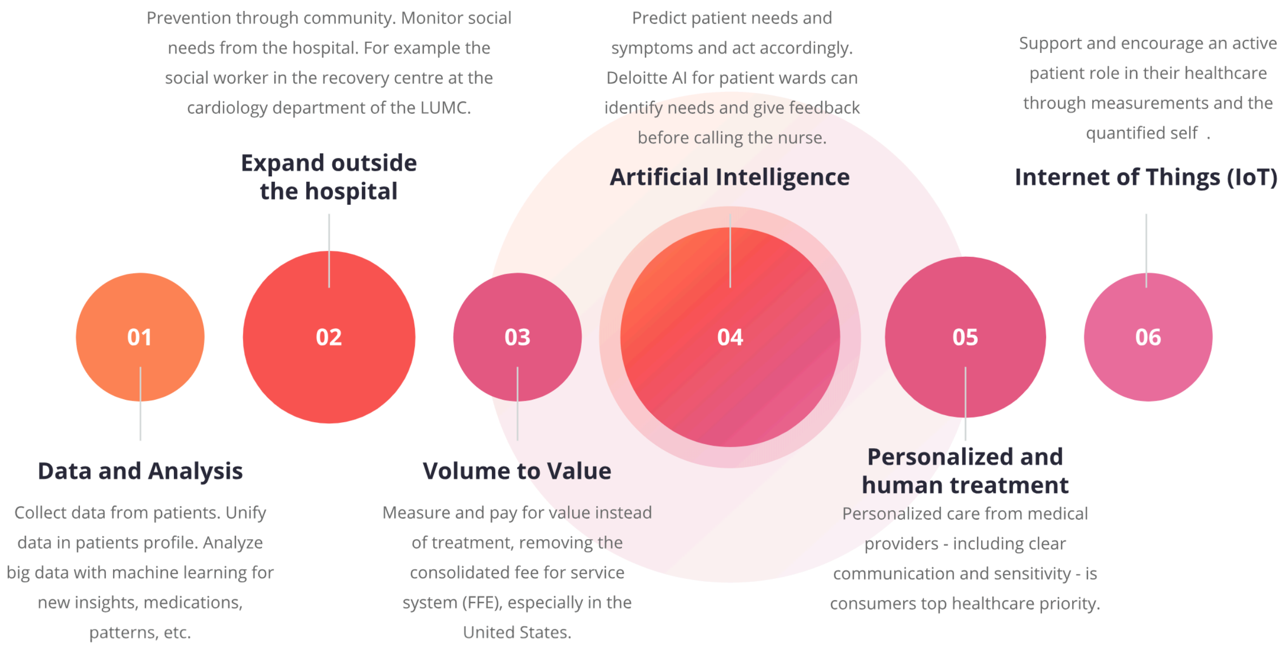


Figure 4. Overview of new technologies and practices in the healthcare domain.

1.2.1 Trends in cardiology

CVD is the first cause of death in the world[20, 21] as well as in The Netherlands[22]. For this reason huge efforts are being made from institutions and companies to reduce CVD mortality, as increase in the research output and research quality shows[23].

This efforts are leading to several solutions[24] to combat different aspects of the disease. Some are purely technological, such as new sensors while others are methods to better diagnose and treat patients. To mention a few of the main:

- New drugs for the treatment of ACS, oral anticoagulants, antyarrhythmics, etc.
- New methods for interventions such as percutaneous coronary interventions (PCI) using fractional flow reserve (FFR) in addition to angiography to guide the placement of the stent.
- Progress in stem cell therapy.
- Improvements in cardiac imaging for education and intervention.
- Biosensor-based devices. To identify C-reactive protein in a fast and cheap way[25].
- Machine learning to process big data and find new insights, for instance, to identify arrhythmias with one lead ECG input[26], or estimate blood pressure with photoplethysmography[27].

The aforementioned advances are being explored in the clinical and intervention domain, helping doctors to better diagnose, intervene and treat patients. In the meantime, an increase in the awareness of the general population, altogether with new and cheap sensors and software platforms have lead to the availability of a plethora of consumer devices. These devices can help to measure movement, burnt calories, heart rate and other vitals or body measures. Currently, they cover the necessities that conventional healthcare programmes are not covering, offering customized feedback and continuous monitoring to the patients. These devices are also the enablers or necessary tools of the Quantified Self [28, 29], a new field of study.

The usage of consumer devices in the domain of healthcare has interesting opportunities and risks, both derived from the exchange of private data.

1.3 Data Privacy

Data privacy is a difficult and important matter. On the one hand, attitudes towards data privacy greatly differ among the population as they are based on personal preferences and experiences. Moreover, there is a huge disparity in what consumers want, say and do, for example, with the privacy settings of websites. On the other hand, we rely on personal data in order to make important decision about our lives, therefore it can also be used to influence our decisions to obtain better outcomes. But, it can also be used as a tool to exercise control over people or cause harm.

In the healthcare sector, the use, collection and storage of personally identifiable information or other sensitive information are cause for concern. It can empower patients towards positive change, but also generate conflicts if the information is leaked. For the purpose of this report the main threats and opportunities will be listed in order to evaluate the products of the Box. The guidelines of the Personal Data Empowerment report[30] from the citizens advice bureau will be used, from which can be subtracted the following elements:

Problems with data privacy:

- Lack of trust in the consent model.
- Disparity in what users want and do.
- Low awareness of tools and methods to control personal data from the consumer's side.
- Complex and different attitudes towards data sharing.

As the LUMC wants to expand the Box usage to cover more patients, concerns and threats towards patient privacy will rise. The devices are produced by different companies with their own product-service systems which require login and/or identification (trade-off on data) to offer the full functionality.

Opportunities:

- Empower consumers towards better outcomes individually.
- Empower consumers towards better outcomes collectively.
- Low awareness of tools and methods to control personal data from the consumer's side.

Ideal situation:

- Implement a model of atomic sharing of data instead of sharing all at once. Generally users have to accept wide-spectrum terms and conditions that involves the sharing of too much data beforehand. Patient data should be shared when necessary and in relation to the usage of the application or product.
- Respect user privacy, making the service user -centric.
- Products should store data in HL7 compatible format and/or offer APIs to allow third parties to use them.
- Offer full functionality without data trade-offs.

The products given in the Box require important trade-offs of the patient personal data in order to be used, which will be analysed in depth in Chapter 2. Product Analysis.

1.4 The LUMC Patient Journey

The patient journey is part of an ongoing study done at the LUMC. It was done by the author of the thesis between March and June of 2018. For this purpose 12 patients were interviewed altogether with 6 clinicians, 2 cardiologist, 2 nurses and 1 psychologists and 1 sexologist, all of them treating directly with patients of MI. The patient journey can be found in Appendix A.

1.4.1 Patient Journey

Once a patient is admitted at the LUMC after reporting a possible MI, the patient receives an immediate treatment to restore circulation and is put under observation in the ward. After 24 hours, if no complications appear, the patient receives a booklet containing relevant information about the MI and has a meeting with a cardiologist or specialized nurse, after which, is discharged. The appointments for the next visits are set at 1 month, 3 months, 6 months and 12 months as represented in Figure 5. Each of the meetings lasts 15 minutes and generally is conducted by a specialised nurse. During the visit, the nurse asks the patient about the treatment, the test results are discussed and vitals are taken. There is not much time for further discussion.

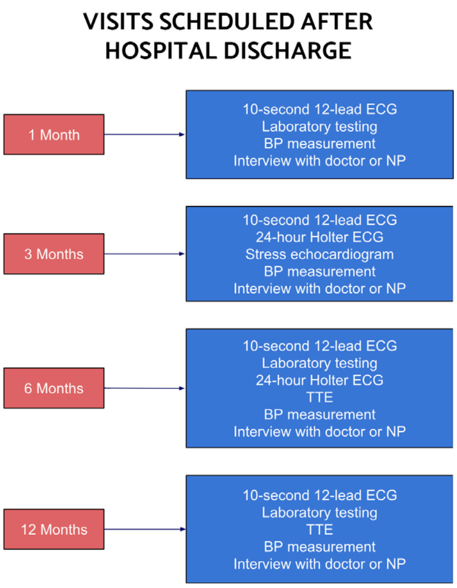


Figure 5. Outpatient clinic visits scheduled after the hospital discharge.

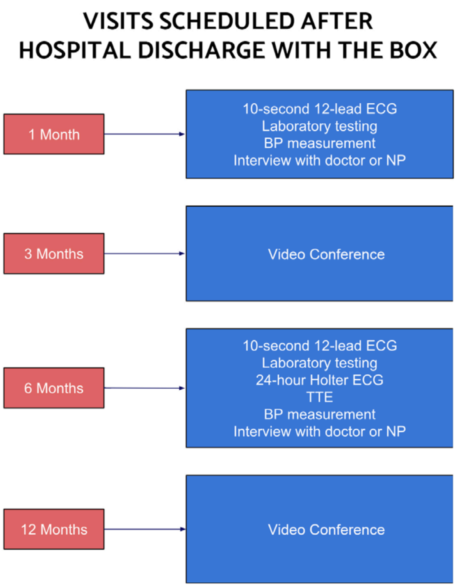


Figure 6. Outpatient clinic visits scheduled after the hospital discharge.

In addition to the set visits, most of the patients go to the rehabilitation centre, starting two weeks after the discharge. In the rehabilitation centre they do a self report survey for depression and physical tests. They are assessed by a cardiologist, a physician, a psychologist, a dietician and a social worker. The specialists prepare a recovery plan that includes exercises and assists the patients that require further help with diet, organizational matters or psychology. Apart from the aforementioned specialists, patients can also see a psychologist and a sexologist along the recovery process. The different groups of specialists that patients see are presented in Figure 7.

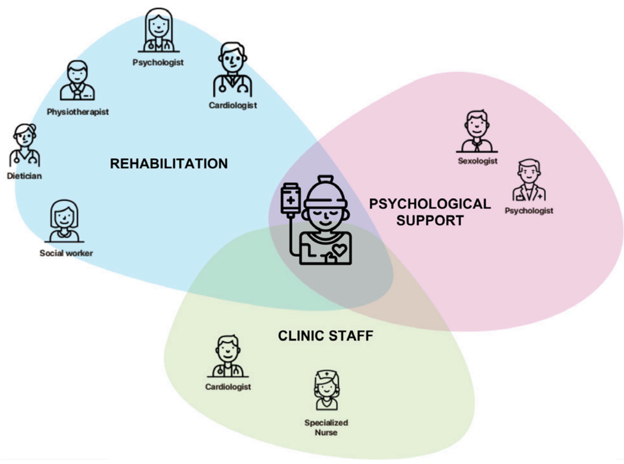


Figure 7. Different specialists at the LUMC.

1.4.2 Patient Experience

The patients evaluated the overall experience as very positive, having high confidence in the clinicians, receiving enough information and perceiving the treatment as adapted to their particular case, although they did not perceive being involved in the decisions regarding their treatment.

The main conclusions are summarized in Table 1.

Question	Agree (N, %)
Did the clinician talk to you in a way that was easy to understand?	12 (100%)
Do you have confidence in the clinicians professional skill?	9 (75%)
Did you get sufficient information about your diagnosis?	11 (92%)
Did you perceive the treatment as adapted to your situation?	11 (92%)
Were you involved in decisions regarding your treatment?	3 (25%)
Did you perceive the institution's work well organised?	12 (100%)
Did you have to wait before you were admitted for services at the institution?	12 (100%)
Overall, was the help and treatment you received at the institution satisfactory?	11 (92%)
Did you benefit from the care given at the institution?	11 (92%)
Do you believe that you were in any way given incorrect treatment?	1 (8%)

Table 1. Patient overall experience with the LUMC service.

1.4.3 Patient Journey Themes

Along with the general experience with the service provided at the LUMC 4 themes were found relevant:

1. **Fear of losing control**: After a MI, the most common theme among patients is the loss of control. They question their body and health status, as well as their limitations
2. **Regain of confidence**: patients regain confidence between two to four weeks after the MI. In this phase patients become more critical towards treatment, mainly medication.
3. **Lack of Knowledge**: there is a clear lack of knowledge regarding anatomy and medication. Patients confuse terms and do not know where the infarction happened.
4. **Reassurance by professionals**: patients look for reassurance by staff members, mainly that they are fit enough and can go on with their daily lives.

1.4.4 Key Takeaways from Clinicians

Clinicians stress the fact that more education is positive for patients. The psychologist, sexologist and nurses put emphasis in identifying specific moments to give patients the appropriate information. A key moment is when the patient is starting to recover.

The patient journey is part of an ongoing publication: “Improving patient information and education after myocardial infarction: exploring the opportunities of mixed reality.”

1.5 Behavioural change

Behavioural change in healthcare aims to change personal habits to prevent disease. CVD risks can be greatly reduced with exercise, diet and non-smoking, which also reduces significantly the risk of co-morbidities. Why then does behavioural change remain a failure in clinical practice?

Many models of behavioural change have been developed, focusing on different aspects of individual decisions, attitudes and control over their actions. Due to fragmentation, other models such as the transtheoretical model of health behaviour change[31] (TTMHBC) were developed to integrate several theories into one.

1.5.1 Transtheoretical Model of Health Behaviour Change

The difference between the TTMHBC and other models is the definition of clear stages with specific time frames and processes of change, which are the actions that patients must take in order to go from one stage to another. This stages are summarized in Table 2, and the relation between stages and processes in Figure 8. There are other three characteristics that define TTMHBC, which are:

- **Decision balance**: the individual reflection on the pros and cons of changing.
- **Self-efficacy**: the confidence an individual has to be able to change or cope with a risk situation, without relapsing to the previous habit.
- **Temptation**: the desire or urge to engage in a specific habit when in the midst of difficulties.

The TTMHBC makes it clear that it is extremely important to identify the patient stage and control the feedback/information given to the patient on each stage.

Stage	Time frame	Definition
Pre-contemplation	More than 6 months	Do not intend to start the healthy behaviour in the near future, and may be unaware of the need to change. Patient has difficulties to estimate pros and cons of changing.
Contemplation	In the next 6 months	Patients intend to start the healthy behaviour within 6 months. They know how change may affect positively their lives.
Preparation	In the next month	Ready to make the change in the next 30 days. The patients can take little actions towards behavioural change.
Action	Now	The patient is taking actions and is committed to change. It is important to avoid temptations.
Maintenance	Now	The patient has developed a positive change for more than 6 months. It is important to avoid very stressful situations

Table 2. Stages of change.

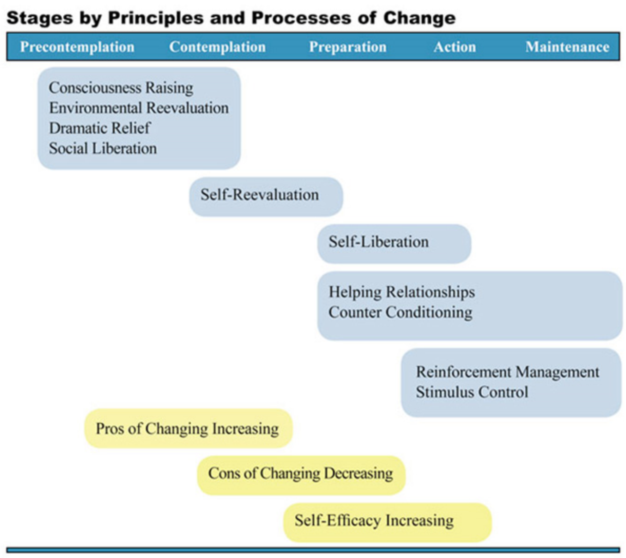


Figure 8. Processes of Change [32]

As can be seen in Figure 8, the pros and cons of changing evolve along the stages, providing a clear indication that the feedback regarding prevention should target pros, cons or encourage self-efficacy in each stage.

How To Apply

The TTMHBC model seems promising, but is it possible to implement it in the current patient journey? There are some difficulties:

- Full change of behaviour from stage one to stage five requires minimum 12 months, which is the full journey at the LUMC.
- It is necessary to identify patient current stage.
- Control the feedback given to the patient on each stage. Update patient stage accordingly.

The University of Rhode Island Change Assessment Scale (URICA)[33] is a self-report test with 32 questions that can be implemented outside the patient journey, similarly to the self-report test for depression that is being used in the Rehabilitation Centre. The URICA self-report could be implemented in the new application being developed for the patients of MI at the LUMC.

1.5.2 Difficulties for Behavioural Change

Behavioural change in patients of MI[34] is difficult because of several reasons:

- The patients are required to have a full behavioural change in big lifestyle areas, such as diet and exercise in a very short time. Information and help is provided, but it is still an overwhelming change for some individuals.
- Information is generic and difficult to apply. For example, to reduce sodium in diet also involves buying the right products, which can be difficult for some patients.
- Wrong weight of cons and pros: Patients have difficulties to evaluate the benefits of changing.
- Lack of vision: The ability and/or conviction to overcome the change and see a different future.

Chapter 1 Conclusions

Many aspects of MI have been analysed to provide tools to properly evaluate the Box products, but also re-design them in future stages of the thesis. The main conclusions of the chapter are listed below.

The focus should be on modifiable risk factors, they can provide as much benefit as drugs, and new devices such as the ones given in the Box can enable patients to better manage them.

According to bibliographic review and the clinicians talks, it is important to identify the specific process of change of the patient. The URICA self-report test is easy to implement and can help professionals to identify patient stage.

A key parameter is the feedback given by the applications. In order to be personal and meaningful it must be tailored to the patient. It is not only important that the feedback is tailored, but also that it has an adequate tone. The process of change requires different This would be studied in future chapters.

The focus should be on reducing and/or integrating the products into simplified versions. One of the main difficulties for a patient to initiate change, such as losing weight, is that they have to deal with too many elements such as exercise, diet, measurement. In addition, these are big areas of the everyday life, which ar difficult to change. Simplicity and focus are key factors for having a successful outcome in such goals.

Privacy is a big topic. It has many trade-offs that may be considered. It is important to know if it is really necessary to have privacy trade-offs:

- To use the product.
- To receive tailored feedback.
- To allow the hospital monitor the patients.

Chapter 2

Product Analysis

In this chapter, the products of the box are analysed in order to identify weak points, strong points and opportunities for improvement. A market analysis is conducted to better assess the products and the current offer.

The Box contains four products given to patients of MI at the LUMC. This products are an activity tracker, a BPM, a WiFi Scale and a one lead mobile EKG for the detection of atrial fibrillation.

An overview can be seen in Table 3.

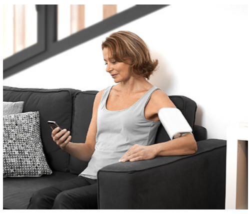
	 Figure 9. Nokia steel[35]	 Figure 10. Nokia BPM[36]	 Figure 11. Nokia Scale[37]	 Figure 12. Kardia Mobile[38]
Name	Nokia health Steel	Nokia health Blood Pressure Monitor (BPM)	Nokia Body - BMI WiFi Scale	KardiaMobile EKG
Price	99€	99€	59€	139€
Weight	37 grams	400 grams	2000 grams	100 grams
Materials	Steel, rubber	Leather, plastic	Glass, plastic	Metal, plastic
Color	Black and white strap band has more options.	White and green.	Black.	Black and silver (metallic).
Feedback	Steps, vibration. Application history and progress.	Blood pressure and heart rate. Application history and progress.	Weight, BMI and weather. Application history and progress.	EKG. Application history and progress with premium plan.
Target users	Young, sports man and woman.	Middle age (40-55) woman and man.	Young and middle age adults. Families.	Older adults that have heart problems.
App Dependency	Yes	Yes	Yes	Yes
Recurring payments	No	No	No	Yes
Certifications		FDA, CE		FDA, CE

Table 3. Product overview.

2.1 Nokia Steel Watch

Figure 13. Nokia Steel Watch[35]

The Nokia Steel Watch is a wearable activity tracker. It measures several activities such as walking (steps), running, swimming and sleeping. It provides the user with visual and haptic feedback (vibration). To set up the device it is necessary to connect it to the Health Mate App application, which is available for Android and iOS devices. The synchronization between the application and the watch is done via blue-tooth. It is a consumer device sold under the sports and outdoors category on Amazon and generally targeted to 30 to 50 years old users, as seen on marketing campaigns.

2.1.1 Measures

- Height: 23cm.
- Display size: 3 inches.
- Width: 4cm.
- Weight: 186 grams.

2.1.2 Nokia Steel Components

Figure 14. External Case[39]

Figure 14 shows the external case of the device, it is sealed because it is waterproof. Once opened the battery is accessible for replacement.

Figure 15. Battery removal and access to the PCB[39]

Once the battery is removed, it is possible to remove the three screws that lead to the PCB as seen in Figure 16.

Figure 16. Removal of PCB and Stepper motors[39]

The PCB features:

- 1 nRF51822 Bluetooth low energy and 2.4GHz proprietary system on a chip (SoC). 1 chip antenna and two crystal oscillators necessary for the Bluetooth.
- 1 ADXL362 Micropower, 3-Axis, ±2 g/±4 g/±8 g Digital Output MEMS Accelerometer.
- 1 Capacitor.
- 3 Stepper motors, one for each hand.
- Other components not recognizable.

2.1.3 Nokia Steel Feedback

Visual feedback: The device provides an extra dial with a hand, situated in the lower right part. The extra dial measures the progress made from 0 to 100%, being 0% no steps and 100% the number of steps set up by the user for each day in the application. This value by default is 10.000 steps. The dial returns to the initial position when the users reaches the goal and at 12pm.

Haptic feedback: The user has the possibility to set up an alarm and the watch vibrates.

2.1.4 Health Mate App connection and feedback

Once the user downloads and installs the application the Nokia Steel Watch can be added as a device. It is a necessary step in order to:

- Set the time.
- Set the amount of daily steps.
- Set the alarm clock.
- Record the daily activity.
- Record the sleeping time.

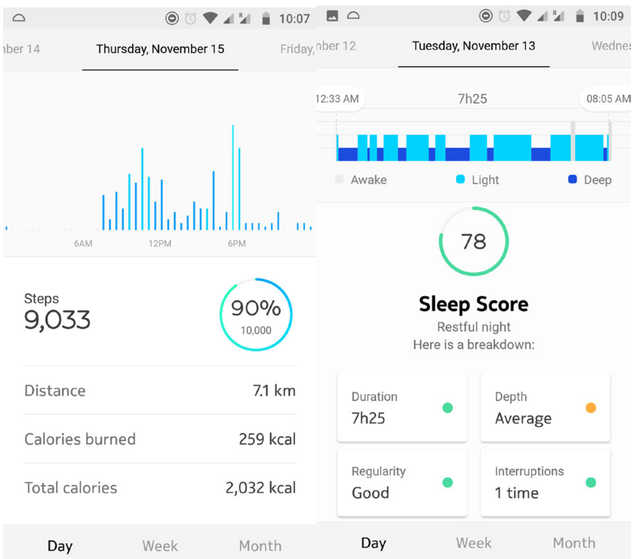


Figure 17. Health Mate App watch feedback. feedback that the user receives on the amount of steps (left). and the feedback regarding sleeping (right).

2.1.5 Nokia Steel Analysis Conclusions

Pros:

- The device has a battery that can last up to 10 months thanks to the analogue display.
- It doesn't look nor feel as a fitness device, the design is unisex and neutral in order to accommodate better to more users and situations, as it is intended to be used for constant monitoring.

Cons:

- The device is difficult to read due to lack of contrast between the hands, the background and the time indicators. In addition it does not have light.
- The feedback is not precise. It is difficult to understand how much progress has been made and how much is required to finish the recommended daily amount of steps.
- The feedback does not encourage the user to move more.
- Bad synchronization, if it is not properly synced on purpose the days appear empty on the phone.
- Does not record cycling, in the Netherlands it is a common activity.

Just using the sensors of the phone and the free application Google Fit, the patient can have better and more precise feedback.

2.2 Nokia Body Scale

Figure 18. Nokia Body Scale[36]

The Nokia Body scale is a WiFi scale that provides immediate on-screen weight measurements to the user. To use all the features it is necessary to connect it to the Health Mate App application, which is available for Android and iOS devices. The synchronization between the application and the scale is done via Wi-Fi. Once it is done, the weight measurements are recorded in the application. In addition, it can calculate the body mass index (BMI) if the user introduces the height.

2.2.1 Nokia Body Scale Measures

- Width and length: 32.75cm (square shape).
- Display size: 45x65mm.
- Height: 2.3cm.
- Weight: 2 kilograms.

2.2.2 Nokia Body Scale Components

The Nokia Body Scale is not meant to be open as it can be used in environments with moister such as the bathroom. It is sealed with double tape glue around the glass.

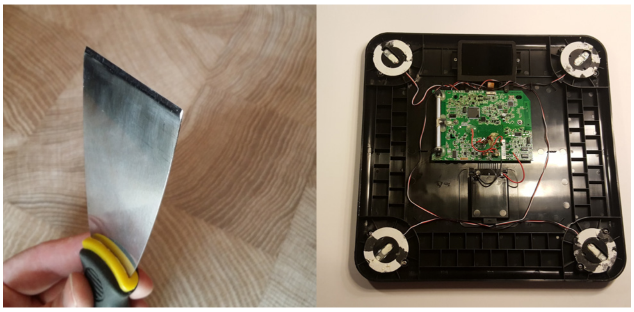


Figure 19. Tools to remove the glass and interior[40].

In order to properly remove the scale it is necessary to use a spatula or any similar tool in order to separate the plastic body from the glass. Once opened, the components are accessible. It features:

- 1 LCD Screen.
- 4 pressure sensors, common practice in scales, one in each corner, where the pads are.
- 1 PCB with CPU, WiFi antenna, flash memory and other components difficult to identify.

2.2.3 Feedback

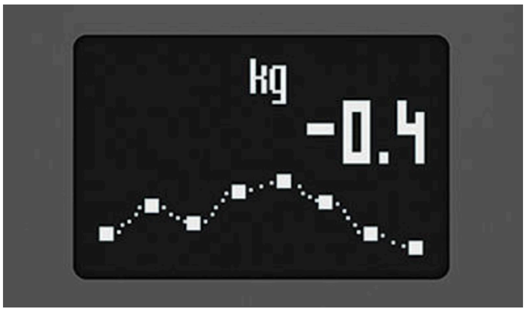


Figure 20. On scale visual feedback

Visual feedback: The device provides immediate feedback on the screen in the following order:

1. The user weight.
2. The BMI index.
3. The weather: including minimum and maximum temperatures, as well as expected rain.
4. The weekly progress and the difference with the last measurement.

2.2.4 Health Mate App connection and feedback

Once the user downloads and installs the application, the Nokia Body scale can be added as a device. It is a necessary step in order to:

- Keep track of the weight progress.
- Set the height in order to receive BMI feedback.
- Invite other members of the family to use the scale.
- Select which visual feedback does the scale provides, and its order. The user can chose between, weight trend, BMI index, weather and also include the steps if the devices are connected.

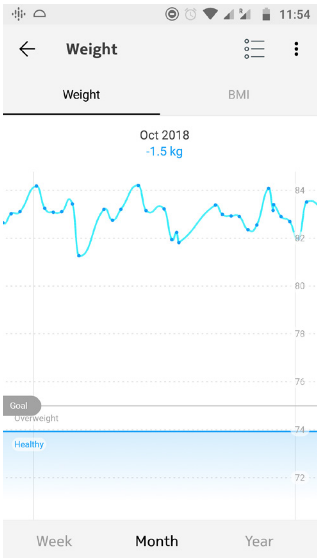


Figure 21. Nokia Scale application feedback.

Figure 21 shows the feedback that the user receives in the application. The weight in kilograms and the BMI index with an indication of what would be a healthy measurement.

2.2.5 Conclusions

Pros:

- It is a prototypical product, which means that the usage is conventional and similar to the rest of the products in the same category.
- The WiFi connections makes it easier to keep records without the Bluetooth sync problems seen in the watch.
- It has family mode, making it more attractive for families.

Cons:

- The product is difficult to open, therefore to repair. As a mass product circular strategies must be taken into account.
- Does not integrate smoothly with other products or feedback of the Nokia Withings ecosystem.
- Although BMI and weight are accurate, it does not adapt well to each user. Fat and muscle, user goals in weight, etc.

2.3 Nokia BPM

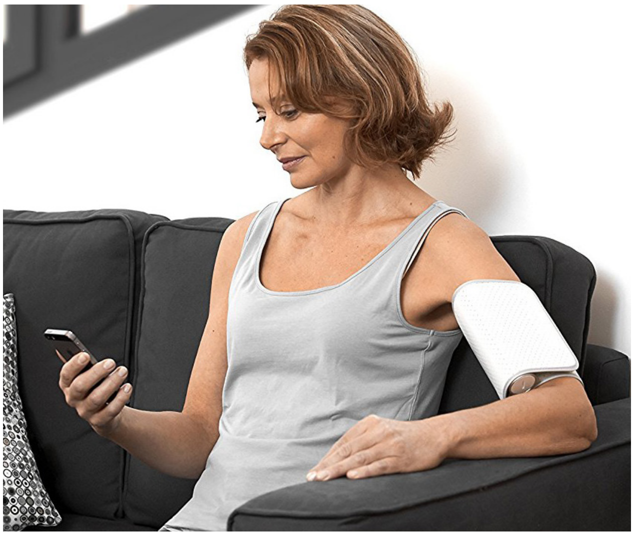


Figure 22. Nokia BPM[37]

The Nokia BPM is a Bluetooth BPM that measures the heart rate and the blood pressure, providing immediate feedback on the mobile device screen. It is necessary to connect it to the Health Mate App application, which is available for Android and iOS devices. The synchronization between the application and the BPM is done via Bluetooth. Once it is done, the blood pressure and heart rate measurements are recorded in the application.

2.3.1 Measures

- Height: 10x14x15 cm.
- Arm circumference: Between 22 and 42 cm.
- Width: 4cm.
- Weight: 400 grams.

2.3.2 Nokia BPM Components

Nokia BPM is not meant to be opened, it is difficult to disassemble and can break in the process. Moreover the screws are not conventional, which makes it difficult for end users. The device has:

- 4 AAA batteries required (included). One year of life.
- Aluminium body, which is heavy.
- Solenoid valves to inflate the device.
- Pressure sensor, to control when the device should deflate.

Figure 23. Nokia BPM Components

2.3.3 Feedback

Visual feedback: The device provides immediate feedback on the mobile phone screen via the APP as seen in Figure 24.

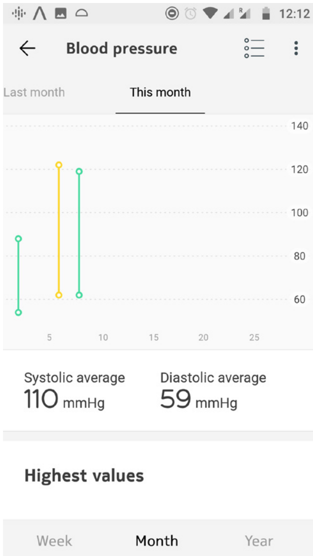


Figure 24. Nokia BPM Feedback

2.3.4 Health Mate App connection and feedback

Once the user downloads and installs the application the Nokia BPM can be added as a device. It is a necessary step to use the device as it does not have a screen.

2.3.5 Conclusions

Pros:

- Nice and modern design.

Cons:

- Requires the mobile phone always.
- It is not a prototypical product, therefore usability may be affected.

2.4 Nokia Health Mate App

Figure 25. Nokial Health Mate App application

The Health Mate App is an application available for iOS8 (or up) and Android 5 (or up) versions. It is a fundamental piece of their healthcare products as it keeps the record of measurements and even gives functionality to some of them, like the Nokia BPM.

It plays an essential role in their business model because at the eyes of the user it is the element that brings value to the platform. Moreover, it can be considered a selling point, as the users see all the products when activating one.

2.4.1 Feedback

The application provides feedback and it records the measurements of the devices. Those measurements and feedback have been mentioned in the previous sections. Moreover, the application has health programmes for the user and it integrates with other applications, such as Google Fit.

The programmes are to track weight, move more or sleep better, they last several weeks and are intended to include healthy habits in daily routines. The applications also gives some feedback when certain goals are reached.

Pros:

- It is fairly simple and visually appealing, making it easier and more acceptable.
- It has community support.

Cons:

- Does not provide precise feedback.
- Does not integrate the parameters to show overall development, especially at the heart level.
- The feedback is generic, like follow Mediterranean diet or walk more, without considering the fitness level or background of the user.

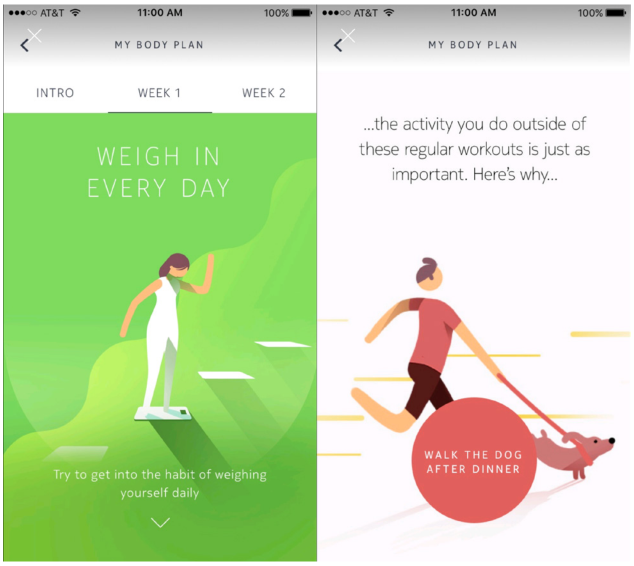


Figure 26. Health Mate App programmes.

2.5 Kardia Mobile (KM)

Figure 27. KM device and application[38].

KM is a portable ECG recorder that works with a compatible mobile device running the KM application. It has two electrodes and it can be attached to the mobile phone with a special plate which is fixed with adhesive. It records single-channel ECG (Lead 1) with the aim to identify paroxysmal atrial fibrillation (AF). It transmits the readings to the application via ultrasound with a patented algorithm.

AF is a condition in which the atria beat irregularly and too fast, disrupting the regular coordination of the heart muscle, and as a consequence, the supply of blood to the rest of the body. The irregular beat increases the risk of stroke and heart failure.[41] AF is difficult to identify as it manifests as an occasional symptom in many cases, therefore, patients do not present the symptoms once they are with the physician. Is in these cases when devices such as KM are useful because they provide mobility and enough accuracy for the specific patient condition.

2.5.1 Application

The KM application interprets the reading, which last 30 seconds and requires the user to place at least two fingers on each electrode as can be seen on Figure 27. Once the reading is finished, the application provides partial feedback and the possibility to save and/or share the ECG in .pdf format.

Alivecor, company owner of KM, offers premium plans in order to allow to store the ECG in the cloud, connect with the patient clinician and/or receive feedback from a trained specialist.

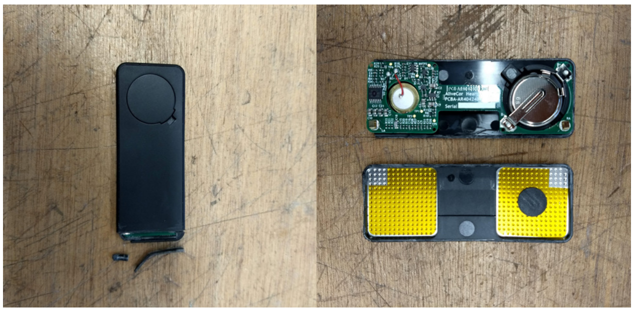


Figure 28. KM components.

2.5.2 Specification

- ECG Channels: Single Channel
- Input Dynamic Range: 10mV
- Frequency Resp.: 0.5Hz to 40 Hz
- A/D Sampling Rate: 300 Hz
- Resolution: 16 bit
- Heart Rate Range: 30 – 300 bpm
- Battery Type: 3V Coin Cell
- Battery life: 12 months typical use

2.5.3 Conclusions

Pros:

- Convenient and easy to use.
- It has been certified by NICE, FDA and has CE marking as a Class IIa medical device.
- It provides enough accuracy for its intended use.
- It uses dry foam electrodes, which makes them last longer.

Cons:

- It requires a premium plan even for on-device storage.
- It is not accurate compared with the 12 lead ECG.
- Once an electrode is broken it is not possible to substitute. The product is not easy to repair and/or open.

Product Analysis Conclusions

The products have been used for two months at the time of this analysis. During the analysis the product applications and the feedback they provide, the components and construction have been reviewed to reveal strong and weak points. This chapter makes clear that the technology is simple, the difficulty relies on the system and the feedback. The products do not provide accurate nor personal feedback.

In the next chapter, the products are compared with the competition, revealing alternatives and insights that enrich this analysis.

Chapter 3

Market Analysis

In this chapter the competition of the products given in the Box are analysed in order to identify viable and valuable alternatives that can improve the current system. It also puts the current products in the market context. The full market analysis can be found in Appendix B. Market Analysis. In the following pages are the main findings presented as conclusions on each product.

3.1 Scales Market Analysis

20 smart scales are chosen for the market analysis. The number is a good representation of the population as the number of results in Google Shopping for the term “body weight scale” is 54 as of November 2018.

The scales are analysed in price, weight, length, surface, height, materials, colours, HL7 compliant, certifications, and other relevant parameters.

Main Findings

It is possible to greatly reduce the price of the scale while offering a better service to the patient. Some scales such as the Renpho Bluetooth[42] have a price of 29€.

It was interesting to find that the scales that were better valued generally had one or many of the following parameters:

- More weight: users comment that a heavy scale makes them feel secure.
- Less height: users comment that a thinner scale can be slipped below the sofa or other furniture.
- More length: users comment that it makes them feel safer. This is an important consideration for elderly.

This features provide great value to design a scale (if necessary) in future stages. Let’s take for instance an old lady with reduced mobility. A heavy, thin and lengthy scale will provide better support thus convey more security. That alone will facilitate the usage and the acceptance of the product.

3.2 Watches Market Analysis

12 products are chosen for the market analysis. The number is a good representation of the population as many of the self-called smart-watches or fitness trackers are the same brand with different colour or completely lack a proper description of their features.

The watches are analysed in price, weight, length, surface, height, materials, colours, HL7 compliant, certifications, and other relevant parameters.

Main Findings

Most of the analyzed watches do not have enough battery lifetime. Actually, the Nokia Steel has the longer lifespan of all and a medium price of 99$. The watches price goes from 29.99$ to 294$.

Many watches have more features, such as continuous heart rate monitoring, GPS, WiFi, etc. Nevertheless, as seen in Chapter 2, Google Fit provides better feedback by just using the phone.

More features does not mean better outcome, but rather the contrary. In Chapter 1. Section 1.5 - Behavioural Change, one of the biggest impediments to change towards a healthier lifestyle for patients is the fact that they are required to modify big areas of their life in short time. Diet, exercise, smoking, stress management, etc.

More products, or products with more features does not mean better outcome.

3.3 BPM Market Analysis

There have been found only 6 BPMs that offer connectivity and have medical grade clearance as consumer products. In addition, BPMs do not vary in functionality and all use the same principle for measurement which is a mercury or mechanical manometer to measure the pressure. Therefore, an analysis as in the previous products will not be conducted.

There is a very relevant difference between Nokia BPM and the other products seen in Figure 29, the possibility to have on-screen feedback. In addition, some of the other products can store the record to synchronize it in other moment. It can reduce the steps during usability.

Figure 29. Nokia BPM[37] (top-left). Philips BPM DL8760/15[43] (top-right). Omron Evolv[44] (centre-left). iHealth Track[45] (centre-right). Beurer BM85[46] (bottom-left). Qardio BPM[47] (bottom-right).

It is worth mentioning the iHealth Track device due to the price and convenience. It costs 34.99$[45], has memory, syncs with the phone, provides on-screen feedback and scans for irregular heartbeats.

Main Findings

iHealth Track has all the characteristics for high usability and acceptance. The only cons is the fact of being perceived as a medical device and not a lifestyle product. The characteristics are:

- It is a prototypical blood pressure, which makes it more familiar and easier to operate the first times.
- It has on screen readings and memory.
- The readings are aided by colours. Using green as good, yellow as worrying and read as bad.
- It costs 34.99$.
- iHealth has a platform for clinicians.

3.4 ECG Market Analysis

There has been found only one ECG/EKG with medical clearance available as a consumer product in major online retailers, the KM device included in the Box. The other one is the Kardia Smartband (KS) for Apple Watch which has the same features, but it is integrated in a band for the Apple Watch. Figure 30 shows its construction.

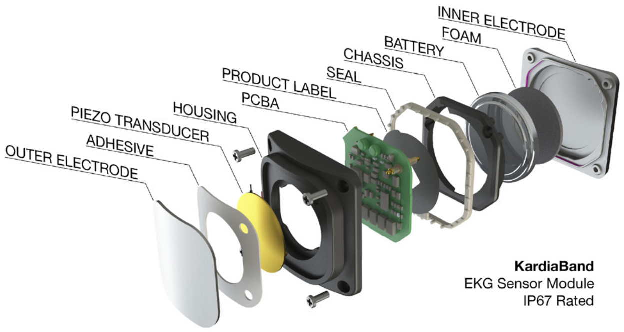


Figure 30. KS construction[48]

Two products worth mentioning are the new Apple Watch Series 4, which features ECG analysis, similar to the KM. It is a complete product that includes continuous heart rhythm monitoring (to help prevent strokes[49]), fall detection, activity tracker and ECG analysis for AF. Moreover, all that information is used for proactive feedback, such as ECG analysis suggestion when the heart rhythm varies abnormally.

Main Findings

It is difficult to describe the ideal ECG, but some features that clinicians demand in the interviews are:

- The ability to record 12 lead ECG.
- A more convenient way to use CardioSecur.
- Access to the system of KM and/or CardioSecur, not only the results but also raw data.

Chapter 4

Technological Analysis

In this chapter current and promising technologies will be discussed. The purpose is to find make the products of the Box more accurate, convenient for the clinicians and easy to use by the patients.

4.1 Working with data

The purpose of all the devices included in the Box is to obtain data in order to increase awareness, gain insights, reduce unnecessary doctor visits and have the tranquillity of continuous monitoring, among others. Therefore it is central to have a basic understanding of the challenges and needs required from these devices in order to properly understand them.

4.1.1 Difficulty in Obtaining Data

The LUMC relies on the products, services and systems of third party companies to gather data from the patient via devices and then from the devices via application programming interfaces (API). The following questions and answers clarify the challenges about data:

- **Is it difficult to obtain data from the devices?** No, there are plenty of devices and the sensors are well known. Moreover there are enough products cleared as medical devices.
- **Is it difficult to obtain data from third party applications?** No, most devices make use off Android and/or iOS and are compatible with HealthKit and Google Fit, the APIs that allow developers to retrieve and store information in the operating system of the mobile phone.
- **Is it difficult to transform this data into HL7 compliant format?** Although none of the devices has HL7 compliance, there are many libraries that could it for the development team of the LUMC.
- **Is it difficult to visualize the obtained data?** No, there are standard libraries to help visualize data for clinicians. Some examples are Open mHealth, Plotlyjs or eChartsjs.
- **Is it difficult to identify patient's physical condition?** No, blood pressure, heart rate and weight are easy to measure and collect.
- **Is it difficult to identify patient's psychological condition?** No, self-test being used at the rehabilitation centre.
- **Is it difficult to give personalized advice to help patient change behaviour?** It - as discussed in section 1.5 behavioural change - requires time and the identification of the current patient situation for each person's lifestyle. It means the information must be given at the right time, reinforcing positive or negative behaviours along the way.

4.2 Measuring Blood Pressure

Medical cleared BPMs are based on mercury or mechanical manometers to measure the pressure of arteries. They are generally composed of an inflatable cuff that is placed in the left arm, one inch above the starting point of the forearm, at the level of the heart.

Once the cuff is placed, it is inflated, either manually or automatically in a controlled manner, until the artery is completely occluded. The pressure is released, blood flow is restored and a sound is heard (in manual operated blood pressure monitors), this is noted as systolic blood pressure. The pressure is continuously released until the sound cannot be heard, which is noted as the diastolic blood pressure.

4.2.1 New Methods for Blood Pressure Monitoring

Blood pressure from PPG

In recent years new methods to obtain blood pressure are being studied. Some of them are based on the usage of PPG.[50,51] These methods are based on the theory that BP can be subtracted from the change of blood volume (BV) and the resistance of vessels. The signal is processed by artificial neural networks (ANN) and compared with the blood pressure reading of the same patient for validation. Although novel and promising, these methods are not ready for production. More importantly, the advantages they present are silent readings and continuous monitoring. The continuous monitoring advantage is not necessary for the patients of the BOX, as they require to monitor the blood pressure a few times per week.

Volume-clamp blood pressure

Volume-clamp is a technique that consist in keeping the blood volume that passes through the arteries constant. It has three parts; a cuff clamp that applies continuous pressure to the arteries of the finger; a light source; a light detector. The signal captured by the light detector changes with the blood flow, during the systole and diastole cardiac cycles. To keep it constant, the cuff clamp pressure increases or decreases accordingly to the heart cycles, thus having a constant blood volume. As blood volume is held constant over time, intra-arterial pressure is equal to the cuff pressure.

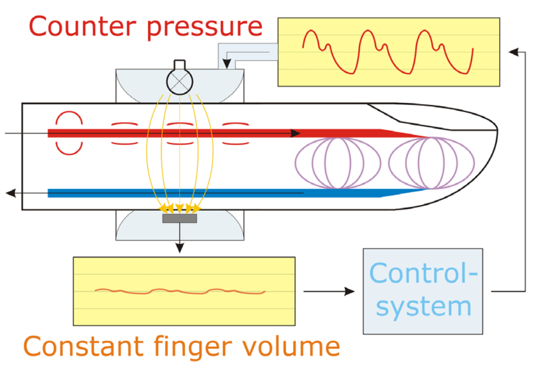


Figure 31. Volume clamp blood pressure schematics.[52]

4.3 ECG/EKG

An electrocardiogram is a test that measures the electrical activity of the heart. It is non invasive, safe, and provides with important information, thus its popularity an extension. The ECG is generally represented in a square millimetre sheet in which X axis is the time and Y the voltage.

On the one hand, the intervals determine how long the electrical wave takes to pass through the heart, the speed can indicate if the electrical activity is normal, slow or fast. On the other hand, looking at the amount of electrical activity passing through the heart muscle indicates size, or parts that are overworked. Both are very important information for cardiologists.[53]

More information on the ECG/EKG can be found on the ABC of clinical electrocardiography[54] and on the Chapter 9. Electrocardiographic Monitoring of Kaplan's Essentials of Cardiac Anesthesia.[55] Both provide an introduction to the practice and in detail interpretation of the signals, respectively.

4.3.1 When to Perform an ECG Test

The ECG is used in conjunction with other tests and always in the context of the symptoms of the patient. It is not recommended for routine checks in patients with low CHD risks and no symptoms as it may lead to errors.[56] In the context of the BOX patients receive an ECG test before being admitted, moreover, other ECG tests are performed as indicated in the section 1.4 Patient Journey.

4.3.2 Why to Perform an ECG Test after MI

The ECG is a useful test to see which parts of the heart have been affected by an MI, which altogether with other tests can provide valuable information. The purpose of an ECG after a MI also depends on the severity of the MI and the patient risk. For instance, patients that undergo surgery require thorough monitoring. At the LUMC they are provided with CardioSecur (Figure 32), a portable ECG device with four leads that can safely be used by patients. It makes use of the EASI method and provides a full 12 lead ECG.

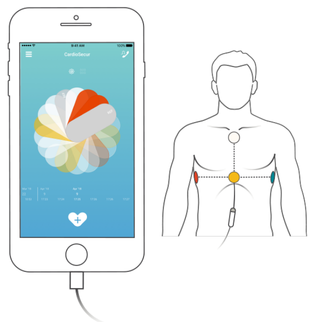


Figure 32. CardioSecur Leads and application.[57]

The rest of the patients that fit into the Box programme are provided with KardiaMobile. It has CE medical device mark and FDA clearance.

Other devices monitor heart rhythm continuously during 7, 10 or even 14 days. A popular solution such as ZIO iRhythm.

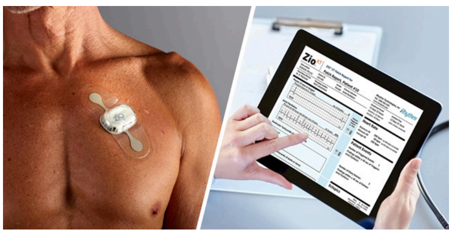


Figure 33. ZIO iRhythm.[58]

4.3.3 How to Perform and Record an ECG Test

There are multiple options to perform and record an ECG test, but the basics remain the same. All the methods require the placement of some leads in specific places of the body, this places may vary according to the method applied. The signals recorded by the leads are processed by an instrumentation amplifier to measure the differences in voltage depolarization and repolarization. This is an essential step because the voltages in the body are in the range of few hundreds of microvolts, and there is also noise that needs to be eliminated for proper representation. Nowadays, the analogue signal is digitalised to be manipulated by digital electronics, which gives stability for further manipulation. Finally, the signal is processed by computer algorithms to represent and pre-identify the result of the test.

It can be said that the ECG consists of two parts, the hardware (physical elements) and the software (algorithms). Both parts are equally important, but, looking at products such as KM, the algorithm is more relevant, as it is cheaper to develop and scale up. In Figure 34 a schematic of the hardware and software with the relevant functions is represented.

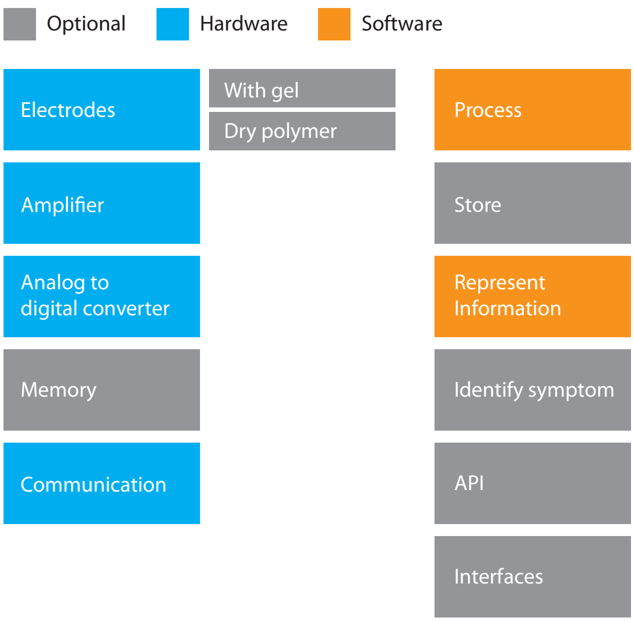


Figure 34. Components/functions of an ECG system.

As it was pointed out by the consulted clinicians at the LUMC, the current problems fall on the API and information storage. From the patient's side the information storage and interface is one of the main problems, as they cannot store more than one reading without paying a premium plan which costs 99€/year. These limitations have been described and revised in the Section 1.3 Data Privacy, in which the necessity of products without information trade-offs is indicated.

4.4 Weight

The conventional method of measuring weight in a bathroom scale, as the one in the Nokia Withings Scale, are load cells (metal parts) with strain gauges glued to them. Other more traditional methods consist in the usage of springs or balances which are out of scope for the present thesis. There have not been found better methods to weight users apart from moving the scale to the bed, although it has more cons than pros.

4.4.1 Weigh-Scale-BPM

This study[59] proposes a weigh-scale like platform with PPG waveforms being measured on the foot to have the pulse transit time (PPT) calculated via larger and more flexible arteries. It provides better results than those made using finger PPG. Applied to the present thesis, having BPM in the weigh-scale is not recommended, as the BPM reading should be taken in a resting position such as sitting.

4.4.2 Weigh-Scale-ECG and Heart Rate

Several studies have explored the possibility of having heart rate monitoring and/or ECG monitoring embedded in a weigh scale[60, 61]. The reason is to save time in the point of care and to record more vitals from the same device. Applied to the present thesis, these combinations are irrelevant as arrhythmias manifest at different moments during the day, so portability is a must.

4.5 Steps/activity

The technology used by activity trackers is based on accelerometers to determine the user position and movement, although most of them have shortcomings. To reduce the risk of heart disease, it is recommended to have 150 minutes of moderate aerobic activity per week[4]. Pedometers, smart watches or fitness trackers which can set goals based on steps, as the Withings Steel Watch, do not provide enough feedback because they are not precise enough for the following reasons:

- The minutes of moderate activity depend on the fitness level of the user, moderate activity is not the same for everyone.
- The steel watch does not recognize biking or climbing stairs as moderate activity.
- A combination of speed and distance is required in order to properly determine minutes of moderate activity, and most of trackers lack GPS.

Moreover, most of the devices have the shortcoming of battery life, being the average of 3.45 days, and the only device that has an extended lifetime is the Nokia Steel Watch, as seen in section 3.2.3.

4.6 Healthcare App Services

This section discusses several projects that can be taken as an example for being innovative or bringing extra value apart from the one that have been seen in the products given in Chapter 3. Market Analysis.

4.6.1 Simple

Simple is a free and open source application that provides a simple tracking system, together with a simple and effective hypertension treatment protocol, to help clinicians to monitor patients' blood pressure.

Highlights

- It is free and offers and easy, free and secure method to track patients hypertension for GP, therefore it focuses on prevention.
- Being free and open source, it reduces the cost and time of development and implementation. It is scalable.

4.6.2 My Signals

My Signals is a centralized development platform for medical devices and eHealth applications.

Highlights

- It is modular and it can be shipped with 1 to 15 sensors as user demands.

4.6.3 Doctrin

Doctrin offers a digital platform to create digital patient records and patient journeys for healthcare providers in order to reduce consultation times, improve engagement and reduce the workload of dealing with digital patient records creation for healthcare providers.

Highlights

- Reduces consultation times up to 10 minutes.

4.6.4 Open mHealth

Open mHealth is an open standard to handle mobile health data. It provides APIs and methods to reduce development costs and time, similar to Simple. It features several libraries not only to treat data, but also to visualize it.

4.6.5 Corrie

Corrie is an application created in the Johns Hopkins clinic to help in the patients discharge. It focuses on the patient's experience to assist the patient who suffered a heart attack in skill-building for diet, exercise, and medication habits.

4.7 Interesting Projects and Research

4.7.1 A label-free fiber optic SPR biosensor for specific detection of C-reactive protein

Wenjia Wang and her team[62] proposed and developed a reusable biosensor to detect C-reactive protein. It is cheap, accurate and disposable, suitable for batch productions. The C-reactive protein (is made by the liver and sent to the blood stream in response to inflammation. If the arteries are inflamed, there is a greater risk of heart disease, heart attack, stroke and peripheral arterial disease. It can be used as another risk factor indicator.

4.7.2 iHealth Gateway

iHealth Gateway is gateway to connect medical devices, encrypt and transmit the data with out previous set-up. It greatly reduces the acceptability from users and development time from developers and system administrators. With a gateway it is possible to drop a ”box” of devices and start collecting data from the initial moment.

Chapter 4 Conclusions

Blood pressure: there are no viable substitute technologies that could provide better measurements compared to the sphygmomanometer, which consist of an inflatable cuff and a mercury or mechanical manometer to measure the pressure. Optical blood pressure is still immature.

Weigh-scale: there are no viable substitute technologies that could provide better measurements, nor better user experience than the common bath scale. Some attempts are made to implement other vital measurements into the weigh scale, such as one lead ECG. This solution is not viable because atrial fibrillation can be asymptomatic (no symptoms available) or happen time to time, therefore making it difficult to detect during a doctor visit.

Portable ECG: there are several alternatives for heart rhythm monitoring. Those make use of continuous monitoring such as patches. Although it could be convenient in conversations with doctors at the LUMC, they question the accuracy of those devices because of not having enough distance to have a proper reading.

Steps activity: It has been previously discussed that most of these devices do not offer enough nor accurate feedback as it is not tailored and lacks accuracy.

Data acquisition and storage: Data acquisition from sensors or third party services (Google Fit or Apple HealthKit) is cheap and affordable.

Overall, two of the most interesting projects are Simple.org and Open mHealth. Both services made use of existing technologies, what varies is how they approach developed the service. Instead of giving access to the results, they provide a tool so the healthcare professional can implement it independently. This model has some challenges, but it solves the dependency on third party companies and improves data security and exchange.

Chapter 5

Medical Staff Interviews

In this chapter medical staff is interviewed in a semi-structured way to obtain more information and different perspectives on the Box. The conversations are recorded with the user consent for further processing.

5.1 Interview Questions

Please, could you describe your Role in The Box project?

According to you, what is the main goal of the project? Why?

- Gather data from patients for research purposes.
- Gather data for telemonitoring.
- Move patients towards behavioural change. Eat healthier, drink less, move more, etc.

Vitals: Currently, the "light" version of the box includes four products:

- A watch with a pedometer. It counts steps.
- A WiFi scale capable of gathering the body mass index (BMI), once the ser introduces his/her data.
- A BP monitor connected to the phone. It also records heart rate once the measurement is done.
- A two leads ECG connected to the phone.

What other vital do you consider relevant? Why?

What are the next steps in the project? Why?

Wearables and technology in general have the purpose of augmenting our capabilities or releasing our mind (memory, problem solving (math), being able to walk with an exoskeleton), but also the risk of distracting us from the main goals.

- How do you think this wearables that we discussed augment the patients?
- How do you think they distract the patients?

5.2 Interview with Prof. dr. D.E. Atsma

His role is to devise new innovative cardiovascular care structures and he is also involved in implementing the strategy of the Box, as well as the dissemination of the findings with other parties. Relevant highlights from the interview:

- The next steps for the Box is to expand the service and the research towards community health.
- There are no absolute lists of non-modifiable risk factors. It is important to consider that genetics have huge influence and the raw data from the meta analysis studies has to be taken into account.
- He emphasises the importance of making the BPM a normal and desirable device. It should be considered as scales, which is sold in shops. Not perceived as a medical device for when you are ill.
- U-prevent.com is an interesting project which enables patients and clinicians to calculate and relate the risk reduction with the patient, both decide a custom plan in which patients are involved.
- It is important to understand if the patients see the Box as a "friend" or as something annoying.
- The patients are overall satisfied with the project.
- Healthy patients are enthusiastic about new projects like the Box, it is important to get to non-healthy ones as well.

5.3 Interview with Roderick Treskes, Ph.D. on the Project

He wrote a Ph.D. thesis focused on a solution for patients to monitor themselves. Some patients are worried and want to be more involved, which is important as involvement implies better adherence to treatment and advice.

- The project improves patient experience, comfort and satisfaction. 50% of the MI patients are still working and many do it as self-employed. For them time is literally money.
- The ultimate goal would be to have a 24/7 service for patients.
- At the beginning, patients had difficulties installing the devices. During the one year treatment provided at the LUMC, the usage drops from once a day to 2-3 days a week, which is a good measurement.
- The value of collecting more data seems not clear, technical possibilities are there, but more research is needed to know if it is relevant.
- It is relevant to have an easy EKG device.
- CardioSecur is a good device, but it is not so convenient.
- There might be an added value to measure sleep.
- The Box has been more focused on monitoring, now there is a shift towards coaching.

5.4 Interview with Tom Biersteker, PhD on the Project

Ph.D. candidate on the Box project. Interview highlights:

- CardioSecur is a very good device and KM has limitations, although it has been cleared as a medical device.
- The Box is more about patient empowerment, as a previous step towards behavioural change.
- We see that older patients can use the technology, and are using it. The biggest issue is that patients do not get feedback on time.
- CardioSecur access is given by the company and we can read the data in the format of 12 lead ECG.

5.5 Interview with Auke de Witte, Software Developer

He wrote a thesis on the project and continued the work that a company started, integrating the Box with Nokia Withings. He explains the process from the point of view of the technical difficulties, which are more related with the system in place. Some highlights:

- Patients have to register in an URL in Withings and allow the LUMC to collect data.
- The LUMC keeps data for 7 days. It is a basic system that generates alerts when blood pressure is too high or in case of similar events.
- There is no API for Alivecor (KM ECG) and it is tedious for the patients and the medical staff.
- Patient measurements slow down.
- The goal of the project is to make people aware, which is a first step for overall motivation. Patients also feel being taken more seriously.
- The scale with heart rate was excluded as not being accurate enough.

5.6 Interview with Marlies Ouwehand, Responsible for the Installation and Setup of the Devices

Marlies is helping the patient to install and setup the devices for the projects. Moreover, she is the contact person for patients in case of doubts. Highlights:

- The acceptance is more difficult than usability.
- The Bluetooth synchronization, battery replacement of the watch and KM are the most problematic parts within usage.
- Some acceptance problems with the watch as a complement.
- After the shock of the infarction patients are enthusiastic to change and use any technology that could help, such as the Box.
- The family is a very important part of the process as they monitor and push patients, but it is not very involved in the system.
- The products can stress patients when a reading is not positive.

Chapter 5 Conclusions

The set-up of the devices remains a big problem for which patients need help. For that reason a technician performs this job at the LUMC.

Patients have not reported serious usability problems with the products.

The main usability problem reported by some patients according to Marlies is the loss of elasticity of the blood pressure cuff.

The biggest usability problem remains with the change of battery of the Nokia Steel or problems caused by product defects.

Another usability problem has to do with the ECG monitoring applications and the restriction it has with the free plan.

50% of the population that goes through the LUMC is less than 63 years old. A big portion is still working and many are working as self-employed. The initial goal of the Box was to provide alternatives for this patients to avoid visits to the hospital. The initial end goal was to provide 24/7 service to patients.

The shift of the project is going from monitoring to coaching.

Chapter 6

Patient Interviews and Usability Evaluation

This chapter contains semi-structured interviews, questionnaires and observations with five patients that have used or are using the Box. The goal is to evaluate the usability of the products. The products are addressed individually and as a whole system. The questions and rationale can be found in Appendix D.

Five patients with different pathologies, age and gender were interviewed. The patients have been using the products of the Box for three months, right after a heart surgery. They are instructed to use the products daily for the first three weeks. Below are the main conclusions and outcomes of the interviews individually. In section 6.2, the answers to the questionnaire can be found. At the end of the chapter the conclusions that summarize the findings.

6.1 Interview highlights

Interesting main findings from the interviews:

Patient 1.

- Age: **46 years**.
- Gender: **Woman**.
- Pathology: **3 leaking valves**.
- Time of usage: **3 months using the BOX products**.
- Previous heart problems: **No**.
- Has family/friends to support her? **Yes**.

Problems with the devices:

- The silicone band of the watch reacts with her skin and the patient does not find it hygienic. No solution was offered from the hospital.
- After the first three weeks the patients finds it difficult to keep engaged with the products, mainly for two reasons. Connectivity problems with the Bluetooth and the need to use the devices together with the phone. As she explains, the phone and the products are not kept together at home, therefore, the patient finds irritating to go for them.

Strong points of the devices:

- The devices give her information when she feels vulnerable, independently of her understanding of the feedback.
- Likes the idea of being connected to the doctors, but when she is asked, the patient misses more interaction with them.

Observation:

- The patient feels reassured, especially when she started to use them, however, the devices are not engaging.
- The devices are perceived as a great service, the patient evaluates them very positively.
- The patient does not think about privacy, the responsibility is in the hospital. The patient is not concerned about this matter.
- The mobility of the KM is questioned. It is not possible for her to use it on the go (street or public space) when she feels something is wrong. Although, she also mentions that in her case she mostly feels arrhythmia at home and in the evening.
- It is important to mention that her husband was present during the interview. He had experience with the devices and mentioned the KM. He is a physical worker with calluses on hands and fingers, therefore the device cannot read properly his signal.

Patient 2.

- Age: **51 years**.
- Gender: **Man**.
- Pathology: **Arrhythmia (AF) and one leaking valve**.
- Time of usage: **3 months using the BOX products**.
- Previous heart problems: **Yes (AF)**.
- Has family/friends to support him? **Yes**.

Problems with the devices:

- There are no problems with the devices. The user is an expert and can sort how the devices work out on his own.

Strong points of the devices:

- The devices give him information which he evaluated as reassuring.
- The user mentions positive and negative aspects about being monitored. Complains that some of his symptoms are known by doctors and integrated on his EPR. Although, sometimes doctors ignore them because there is not an integrated patient profile at the hospital.

Observation:

- The patient is very conscious and controller. He monitors perfectly his vitals and knows very well the symptoms and medications. The tools suit him very well as it allow to exert control and monitor better himself.
- The patient does not have any problem of connectivity and/or irritation because of having the devices scattered. He has a tablet in a fixed space at home, and the products are placed around it. When the times to measures comes he does the measurements at the same point.
- The patient does not mention anything regarding privacy, although when he is asked specifically about it, he considers privacy an important topic.
- He claims that more integration is needed, especially in the database of the hospital to truly improve the service. He evaluates the products very positively.

Patient 3.

- Age: **78 years**.
- Gender: **Man**.
- Pathology: **MI and valve problem**.
- Time of usage: **3 months using the BOX products**.
- Previous heart problems: **Mentions only the MI**.
- Has family/friends to support him? **Yes**.

Problems with the devices:

- The BP monitor is very heavy and long. The connection with the device is bad.
- The scale has problems with connection.
- The KM gave a bad reading and the patient could not contact the doctor from Friday till Monday.

Strong points of the devices:

- The patient mentions that reassurance and control are the main benefits of the devices. The strong point is to avoid going to the hospital.

Observation:

- According to the patient, devices are good, the service is good. The patients considers the devices tools, when they fail they need to be repaired. For the patient it is not a faulty or badly designed device (except from the BPM), it is a defective tool.
- It is important to notice the age of the patient. It might be assumed that the patient is at risk due to technological illiteracy, but it is not the case, which matches the hospital staff comments.
- Despite the bad reading and stress caused by KM, the patient considers the device very safe and very reliable.

Patient 4.

- Age: **65 years**.
- Gender: **Man**.
- Pathology: **Aorta and valve problem**.
- Time of usage: **3 months using the BOX products**.
- Previous heart problems: Does not mention them.
- Has family/friends to support him? **Yes**.

Problems with the devices:

- The BPM seems to be faulty because the readings are too high. Moreover, the readings are not aligned with the ones done at the outpatient clinic.
- The watch does not include biking as an activity.
- The watch band is too small for his wrist.

Strong points of the devices:

- The devices work great without problems (despite the bad readings of the BPM). According to the patient the devices are easy to use.
- The patient does not mention any specific problem about the connection.

Observation:

- The patient reported to feel good using the devices. The patient is looking forward for the version two of the watch to record his biking activity.
- The patient claims that more integration in the application would be good.
- Surprisingly, the patient regarded the BPM as very safe to use and reliable despite the misreadings. This misconception is worrying and more elaborated in the conclusions.

Patient 5.

- Age: **64 years**.
- Gender: **Man**.
- Pathology: **Does not mention**.
- Time of usage: **3 months using the BOX products**.
- Previous heart problems: **Does not mention.**
- Has family/friends to support him? **No**.
- He went to the rehabilitation centre. The experience there was integrated with the devices.

Problems with the devices:

- The connection with the scale had a small problem, which the patient was able to solve.
- KM makes bad readings when it is used near the computer or other electronic devices.

Strong points of the devices:

- The patient controls his activity and recovery through the devices, especially the watch. He is able to set specific activity goals that are adequate with his recovery stage.

Observation:

- The devices give confidence to the patients. It is a common feeling for the patients due to the control feeling it provides (more elaborated on the conclusions).

Alivecor

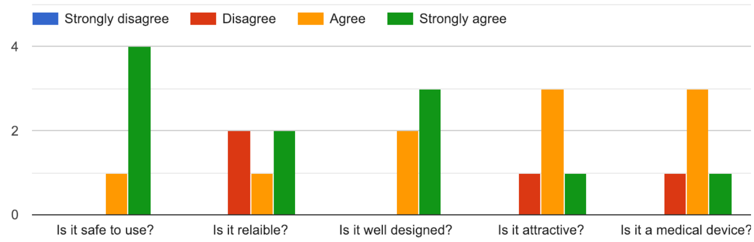


Figure 35. KardiaMobile questionnaire results.

BPM

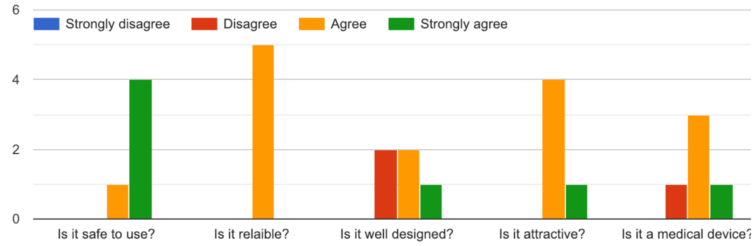


Figure 36. BPM questionnaire results.

Watch

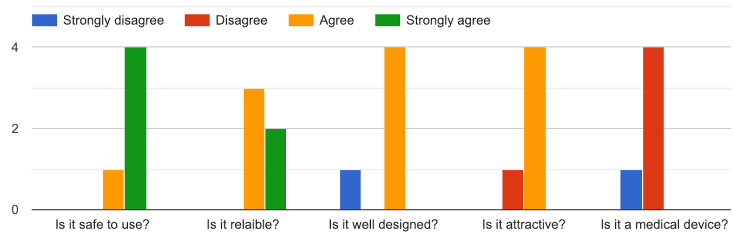


Figure 37. Watch questionnaire results.

Scale

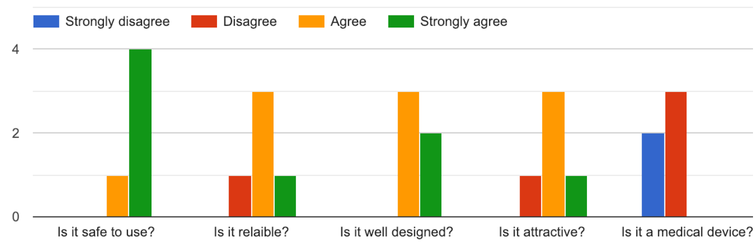


Figure 38. Scale questionnaire results.

Chapter 6 Conclusions

Considerations

The evaluation of the products of the BOX differs from conventional products because of:

- The products of the BOX are given to patients when they are vulnerable, after a heart attack or a heart surgery.
- The products are given and suggested by the same professionals that helped patients to recover and/or even saved their lives.
- The products are given for free. Patients are benevolent with them, meaning that even some bad readings or communication problems are not considered critical problems.

Levels of Interaction

To better assess usability, the interaction of the products has been divided in three levels as seen in Figure 39.

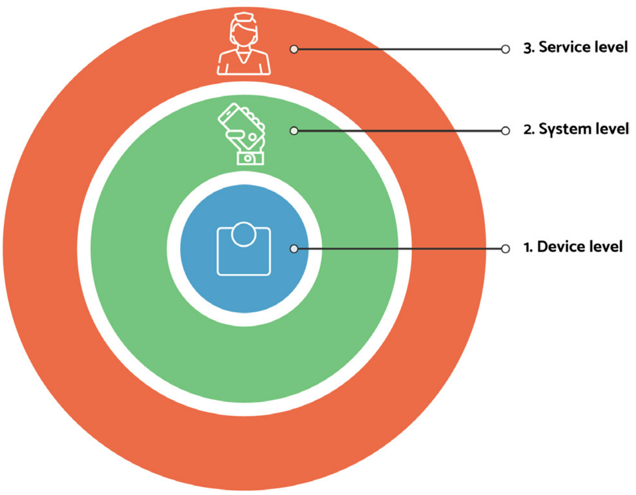


Figure 39. Three levels of usability.

Level 1: User-Device. This is the most basic level and it refers to the physical interaction of the user with the device. Problems at this level are the worst because they can cause problems with readings, with connectivity and at the end with the service.

Level 2: User-System. Refers to the understanding of the user with the system. Is the user capable of connecting the devices? Does the user understands that some problems have to do with interference and not the device itself?

Level 3: User-Service. Refers to the relation between the user and the doctors at the LUMC.

Usability Problems

At User-Device level:

- **Watch**: Two patients reported problems with the watch at this level. One could not use the watch due to skin reaction and other could not fit it around the wrist.
- **Scale**: No problems.
- **BPM**: One patient reported problems with the BPM because of the size and weight.
- **KM**: The husband of one of the interviewed patients was present and mentioned he could not use it due to calluses on his hand.

At User-System level:

- **Watch**: Three patients reported connectivity problems at some point. Were able to solve them.
- **Scale**: Three patients reported connectivity problems at some point. Were able to solve them.
- **BPM**: Two patients reported problems with connectivity. Were able to solve them.
- **KM**: One patient reported interferences. Was able to solve them.

At User-Service level:

- **Watch**: One patient reported that the silicone band of the watch was provoking reactions to the skin and the hospital did not provide an alternative. The patient felt ignored.
- **Scale**: No problems.
- **BPM**: The bad readings of one of the devices provoked the nurse to intervene and have the blood pressure measurement at the hospital.
- **KM**: One patient had a bad reading and could not get in contact with the doctors for three days (it was weekend). It was an unnerving and scary experience. Moreover, KM is not regarded as portable. Patients do not use it outside home for different reasons such as inconvenience and not being used to carry around those devices.

Perception of the whole system

- The service is evaluated as very positive, regardless of numerous mild to severe problems during the usage of the devices.
- The fact of not having to go to the hospital is evaluated very positively.
- Problems of communication with the clinicians are considered the worst experience.

It is interesting that the service is regarded as very good and at the same time many problems are reported.

Why the service is regarded as very positive despite of the many problems?

Firstly, many of the problems are considered mild and some patients are able to find solutions by themselves. The patients that were able to solve the reported problems alone were savvy using technology, which means that this behaviour can not be generalized.

Secondly, the products are given for free and by clinicians that the patient trust.

Finally, there is a big misunderstanding on the patient side. Two patients reported misreadings of the devices, although evaluated them as very safe and reliable.

On product design

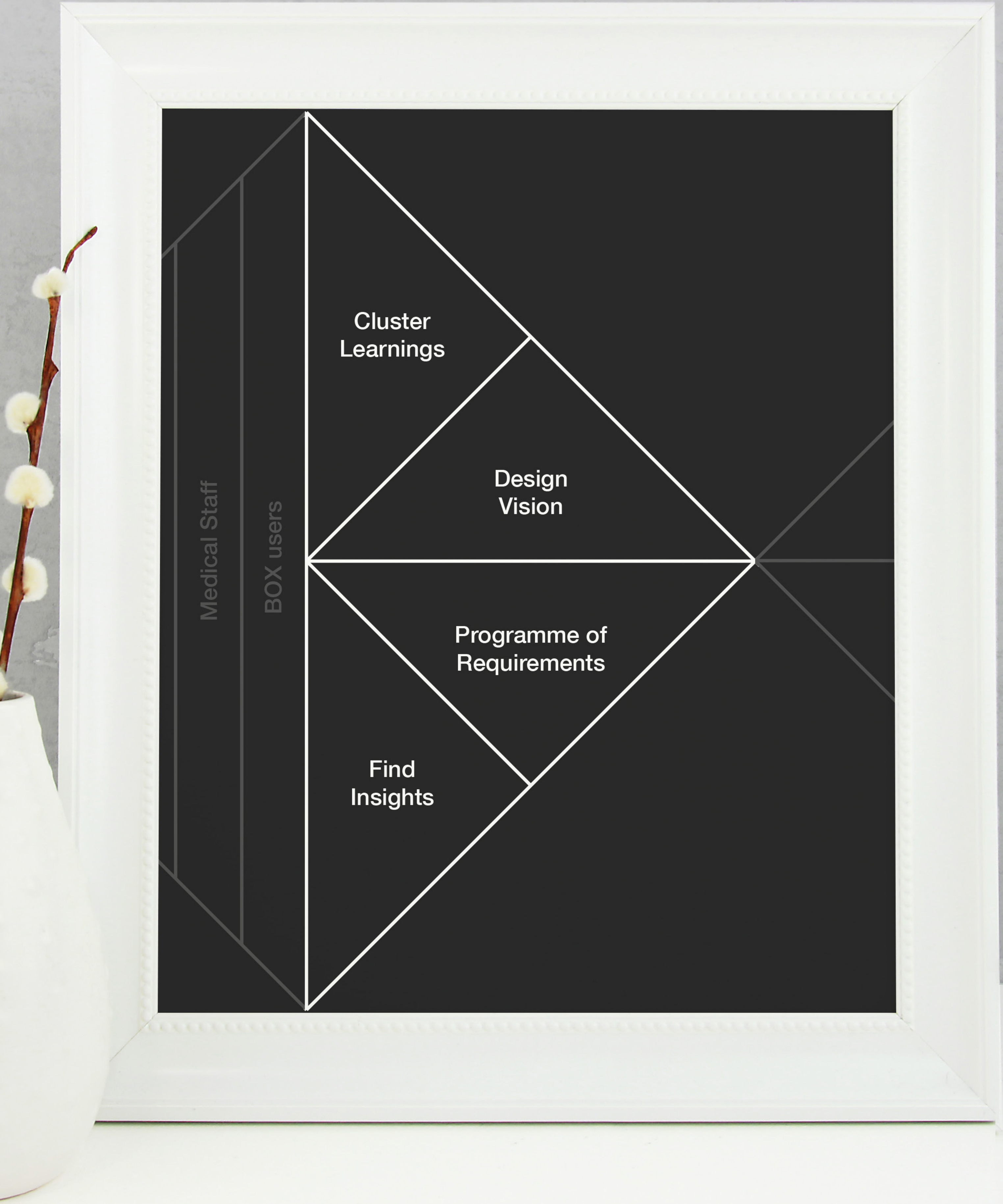
The devices are considered well designed and attractive by most of the patients, which is a success. The same design serves a huge population, patients from 46 to 78 years old, men and women, from different backgrounds evaluated the design as good.

Nevertheless, the design is not visceral, it does not elicit any emotion which is a great mistake and a lost opportunity to truly engage users. Emotions are essential to understand and learn, a positive experience can trigger our curiosity while negative or non-rewarding ones can prevent mistakes.

On product category

As expected, patients associate the BPM and KM as medical devices, while the scale and the watch are not considered medical devices.

stage 2 **DEFINE**



Chapter 7

Definition

In this chapter the findings from the previous research are clustered in order to find insights. The insights are used to develop design visions and concepts are proposed for further selection and development.

SWOT ANALYSIS

	HELPFUL	HARMFUL
INTERNAL	**STRENGTHS** Public institution with constant delivery of patients. Multidisciplinary team: • IT. • Technicians. • Nurses. • Cardiologists. • Psychologists. • Dietitian. • Etc... Simplified and well defined approach. Strong brand name for the project. Aligned with future trends in Healthcare.	**WEAKNESSES** Battery of the devices lead to unnecessary support. Dependency on third party companies. More devices mean more companies. Dependency on companies based on EU soil if the project is used for research purposes and deals with patient data. Not an engineering company. Slow progress and implementation.
EXTERNAL	**OPPORTUNITIES** Move from awareness towards coaching. Better coordination with the GP. Embed patient journey in the upcoming application. Identify user stages. Emerging need for the service -> media coverage.	**THREADS** Privacy concerns with third parties. Multiple stakeholders involved, coordination required for success. Lack of compatibility with similar products already being used by the patient.

SYSTEM MAPPING

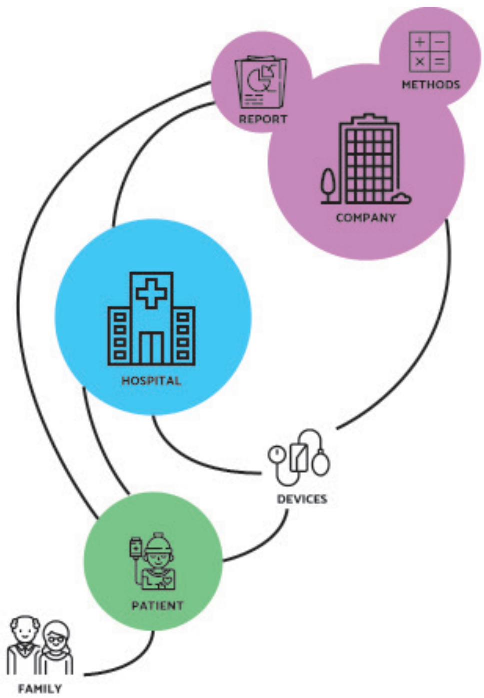


Figure 40. Current system of the Box.

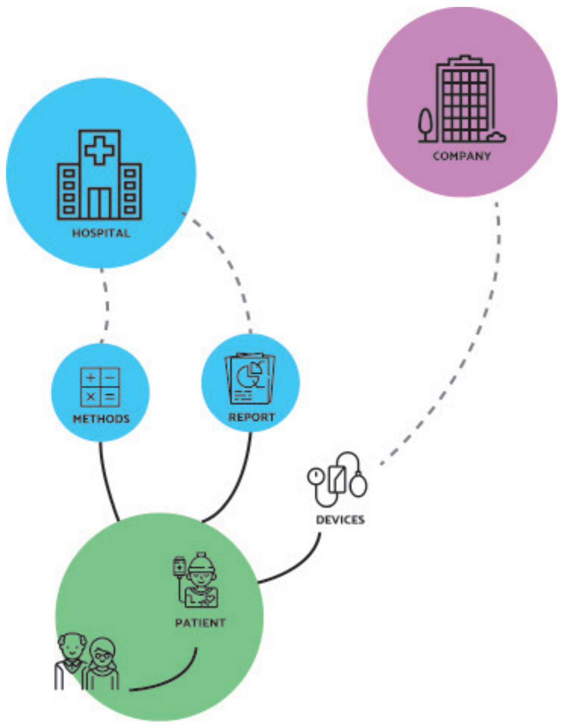


Figure 41. Proposed system of the Box.

Current System

The current system is mapped in Figure 40. The relationship between patient, hospital and devices is illustrated with lines.

The patient communicates with the hospital directly, and indirectly sharing information via the devices. This information is firstly processed and stored by the companies. The hospital has to been granted access by the company to be able to see and store the data.

In the system the family is left out, as the applications provided do not include them in the process.

Proposed System

The proposed system makes the following changes:

Include the family in the applications/devices. As an important part of patient recovery process, the family can play a role in helping to monitor and stabilize the vitals.

Remove company dependency. The acquisition of information and ensuring patient privacy are two cornerstones of the system. The devices and their applications are built in such a way that it is impossible to bypass limitations imposed by the design.

CHANGES IN THE DEVICES

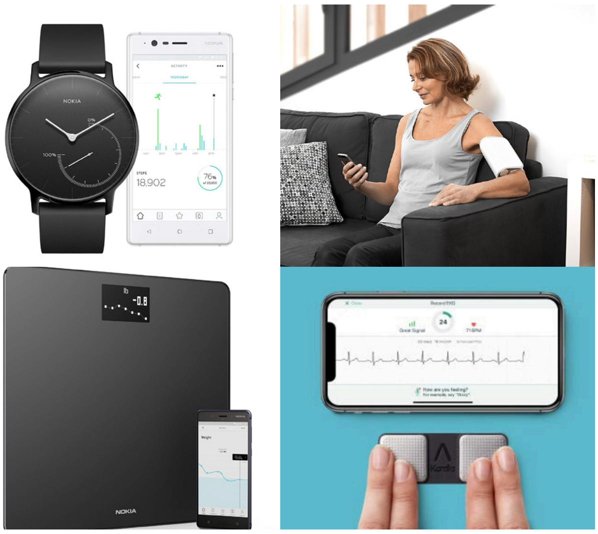


Figure 42. Current devices. Top-left: Nokia steel watch[35]. Top-right: Nokia BPM[36]. Bottom-left: Nokia WiFi Scale[37]. Bottom-Right: KM[38].

Current Devices

Once the market analysis and product analysis are done, and the patients interviews are concluded it can be said that:

- Not all the devices are necessary: The Nokia Steel does not provide any real value that the phone can not bring, it is difficult to read and some patients have complaints about it.
- The Nokia scale can be substituted for a Bluetooth scale, therefore reducing the complexity of the system. Patients will have to deal only with Bluetooth, and not with WiFi.
- The Nokia BPM is expensive and requires the phone to make readings. There are better/cheaper alternatives that will increase patient experience.

Figure 43. Proposed devices. Top: iHealth BPM[45]. Bottom-left: Rempho scale[42]. Bottom-Right: KM[38].

Proposed Changes in the Devices

The proposed changes are:

- **Remove the watch**: It saves 99€.
- **Using the prototypical BP monitor**: The prototypical BP monitor has three parts, the base, the cable and the arm band. Prototypical devices are less challenging and cheaper. The Nokia BP is very expensive (99€) and does not work as a stand alone product. The iHealth BP monitor proposed in Chapter 3 has the same functionality, but it incorporates memory and can work as a standalone device. It costs 34.99$ only.
- **Change the Nokia WiFi scale to a Bluetooth scale**: Using a Bluetooth scale like the Rempho scale could reduce the complexities and the cost to 29€.

The cost is reduced from **397€ to 203€**. It also would improve usability problems.

CRITICAL PROBLEMS AND OPPORTUNITIES

1. The patients are heavily influenced by the doctors and by the free products, which results in biased feedback

MI is a major event in the patients lives which means, above all, lost of control. Lost of control over their bodies and their lives. This results in stress, anxiety and lack of confidence. In this context, the cardiologist and clinical staff perform an intervention (which is simple from the doctors perspective) that saves the patient life. A few hours later, the patients are offered a set of products, for free, that will help them to self monitor.

Patients do see this products as a gift, they are happy and report to re-gain confidence thanks to the BOX programme. However, there is a downside on it, patients do not evaluate the products properly. Two patients reported that the products are very safe and reliable although they were giving bad readings. Other two patients thought that the doctors had access to ECG information which they did not have.

Opportunity

Improving information exchange between the hospital and the user could make patients more conscious about their readings. It is not only important that doctors have the readings, but also that patients are conscious that they have it, and that the readings are positive or negative.

2. KM is not used outside home, does not store the recording and does not provide an API to the hospital

One of the advantages of KM (as the name indicates) is to be mobile, but patients do not use it outside home.

Moreover, the data collected by the device is not stored if the patient does not pay the premium or does not take active action in order to do so. In addition, KM does not provide APIs to access their database to the hospital. This results in lost information which can be relevant in the future. In addition, two patients thought that the hospital got their readings automatically, which is wrong.

Opportunity

Propose a truly mobile device that can store the information and let the hospital access to it.

3. The information management system (users application and doctors applications) creates difficulties in communication

The patient has to use two different applications, which synchronize with the mobile device in different ways (WiFi, Bluetooth, Soundwaves, etc.). This results in difficulties for the patients, for instance, when they change the phone or if the patient is not savvy in the management of the phone.

The applications make use of different interfaces and the patients get confused. This means that

Opportunity

Use the Material Design interface and simplify the amount of options to avoid mistakes. 59% of dutch phone owners are users of Android Devices[63]. Material design is the default set of patterns and interface elements of Android, using the same patterns and elements reduces errors and misunderstandings as it is familiar with the phone interface.

4. The family is not included in the system, despite of being an important part of the recovery process and the patient well being

The family members are an important part of the recovery. They encourage the patients to measure they vitals, take the medicine and accompany them to the doctor. Younger family members, usually the patients children, help them setting up the phone, the applications and the connectivity.

Currently, the applications do not enable family support and access. Making it easy for the family members to review patient measurements can increase engagement and reduce the pressure put on the patient.

Opportunity

Enable family members participation. Make them aware of the user measurement and current status.

DESIGN DIRECTIONS FOR FURTHER CONCEPT DEVELOPMENT

Design Direction 1: Phone-less ECG

This design direction is an attempt to solve the multiple problems encountered by patients and clinicians using the KM ECG. To summarize them:

- Patients do not use the device outside home, nor place in the back of their mobile phones.
- The device fails in 9% of the cases. This implies more workload for the hospital staff and an increased risk for the patients.
- Some patients do think that the information is sent automatically to the doctors, which ends in a loss of information.
- The information is not stored in the proper format, thus preventing future analysis by the hospital or other healthcare professionals.

Design a phone-less ECG that can be used without the phone, being capable of recording multiple ECG samples and store them in the adequate format. The connection with the phone and the hospital can be done later one, once the synchronization is available.

Design Direction 2: Companion

Based on the importance of the family. The system mapping and the user feedback revealed that the patient family is critical during the recovery process, which is also supported by research[64]. The family is not incorporated into the devices and/or applications they provide.

Design a home device that increases the awareness and participation of the family members during the recovery process and centralises the measurement.

DEVELOP

Chapter 8

Ideation & Conceptualization

The starting point of the ideation and conceptualization will be the design vision. The concepts will be elaborated following the network model illustrated in Figure 44. The model allows to discern between vision, idea and concept.

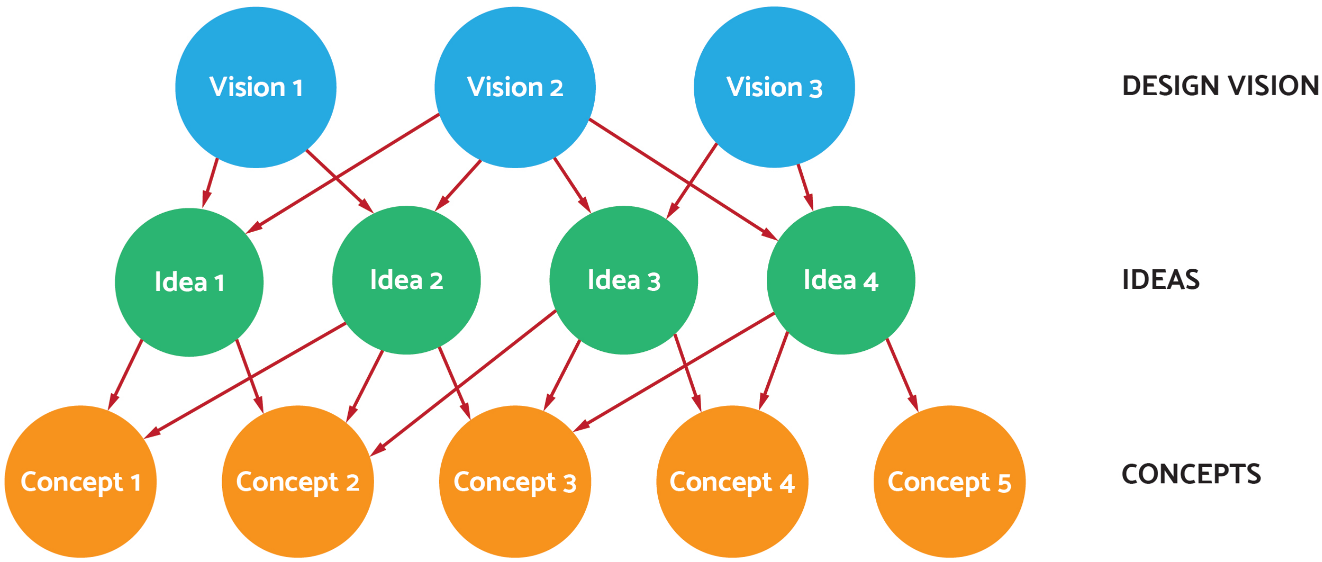


Figure 44. Network model for conceptualization. Illustrates the process of moving from Vision towards Ideas to Concepts.

Approach

The main goals are expressed in the two design visions mentioned in the previous chapter. To move forward and define those visions a series of HOW TO? Questions are formulated in order to achieve them.

1. HOW-TO - Phone-less-ECG

- How to make the product truly portable?
- How to avoid misunderstandings of patients during the exchange of information? For example, when the patients think that the doctor is receiving information when it is not the case.
- How to ensure proper communication between doctors and patients?
- How to make the product store information to synchronize it afterwards with the phone and the hospital servers?
- How to make the product more reliable to reduce bad readings?

How to make the product truly portable?

The most common accessories or devices that people wear everyday are:

- **Fabric**. Shirts, shoes, socks, etc.
- **Key-chain**. It can be a key-chain for home keys or the car keys.
- **Wallet**. With a great variety of models it is a common daily accessory.
- **Mobile phone**: In 2018 there were 14,3 million mobile phone users in the Netherlands[65], which compared to the total population in the same year (17,283,008[66]) results in a coverage of 82.74%.

KM design is based on the mobile phone coverage data, which is statistically relevant, but users do not place the device on the phone.

	Pros	Cons
Fabric	Used everyday, by every user.	The technology is not yet to the level required for implementation. People don't use the same clothes on a daily basis. The monitoring is meant for one year coverage.
Key-chain	Used everyday, by almost everyone.	Some users have a thin wallet, with individual keys (as one of the interviewed users mentioned). They can not fit a device in it.
Wallet	Used everyday, by almost everyone.	Same as above. The amount of wallets and sizes makes it difficult to find a compatibility in shape and size.
Mobile phone	Used everyday, by almost everyone.	Different phone sizes and the periodical change of phones creates problems to attach the device physically to it.

Table 4. Pros and Cons of common accessories and devices which can be used as a hook for the device.

How to avoid misunderstandings of the patients?

Patient does not receive a feedback when the information has been received by the hospital.

The instructions given to the patient indicate that the hospital has access to the information of some devices, nevertheless some patients forget that access is not complete. This leads to loss of information.

Sending a daily or weekly automated message that information has been received will significantly decrease this problem as patient will be aware of it.

How to ensure proper communication between doctors and patients?

In relation with the previous point, doctor and patients do not communicate properly. The outpatient clinic visits ensure exchange of information, but in those visits the main topic is to discuss the results, rather than usage and problems with the system.

Loss of information, misunderstanding of the system and other problems could be solved with in-app communication. When the problem occurs, a message is sent. As most of the problems are common, it means that they can be solved by automatic replies with the same information.

How to make the product store information to synchronize it afterwards with the phone and the hospital servers?

The signal captured by devices such as KM is analogue. They use single lead ECG, generally the LEAD I of the Eindhoven triangle.

To achieve the desired result of storing to post-process the information it is necessary to:

1. Sample the analogue signal to a frequency between 250 and 500Hz as it will allow for an optimal algorithmic post-processing of the data[67]. KM uses 300Hz, while Physionet database generally has 360Hz samples. The second will be used as a reference, but higher frequencies are acceptable.
2. Use a analogue-digital converter to sample the signal.
3. Use a memory to store the signal. The desired amount of readings will be 10, before auto-erasing the previously stored data. The file-size of a 30 second sample of 360Hz with the information required is around 50KB. Therefore 1MB could be enough to store the information.
4. Bluetooth to do the synchronization.
5. An application to store the information in the phone and send it to the hospital.

How to make the product more reliable to reduce bad readings?

To make the product more reliable it is necessary to understand why it is not reliable in first place. KM algorithm correctly interpreted AF versus normal sinus rhythm with 93 percent sensitivity and 84 percent specificity.

In the first clinical study of remote arrhythmia monitoring using KM in The Netherlands[68] the results show that KM cannot be a stand-alone solution for arrhythmia monitoring. When the interpretation of the KM algorithm is compared to the interpretation of a trained cardiologist, the results are:

- 59% of the readings indicated normal sinus rhythm. KM assesses normal sinus rhythm with a 96% of positive predictive result. It is a very good result in order to eliminate AF.
- 22% of the readings indicated possible AF, from which KM failed 20% of times in the interpretation.
- 17% of the readings indicated unclassified, from which the cardiologist team were able to classify 81%.

The device successfully identifies normal sinus rhythm, but it is not accurate enough to classify AF properly. It does not indicate if the normal sinus rhythm is without ectopy, with premature atrial complexes (PACs), premature ventricular contractions (PVCs), etc...

On the one hand, the low accuracy of the algorithm results in more workload for the clinicians. For instance, if the readings are sent periodically, it would be required to review 41% of the readings that are unclassified or possible AF. On the other hand a bad reading is a cause of stress for patients, as revealed in the interviews.

At this moment two problems arise. The first, how to avoid the workload of the clinicians due to bad interpretations:

- **Improve or adjust the algorithm quality**: It is not possible, uses proprietary software, it would be necessary to change the algorithm, which is out of the scope of this thesis and expertise of the author, and MSc. Specialization.
- **Use other algorithm**: Currently it is not possible due to KM limitations. In order to use another algorithm it would be necessary to have access to the raw data. Other algorithms and the process sequence is reviewed in the prototyping stage.
- **Improve patient education** to avoid bad readings, instruct them to double or triple record every time that an unclassified or possible AF are detected.

The second, how to avoid the misreadings to cause stress to patients:

- **Modify the sequence of the interpretation**: Currently, the KM algorithm is in the mobile device and offers an immediate answer. If the answer is delayed to once a week, after the results has been interpreted, it could reduce the stress caused by miss interpretation of the algorithm.

In order to apply any of the above possible solutions, it is necessary to have access to the raw information in a format, which for the ECG signal can be the European Data Format (EDF+), open source and largely to analyse and visualize bio signals. Another acceptable file format is .CSV.

2. HOW-TO - Companion device

- How to establish the required amount of information to share within the family members?
- How to communicate that the patient is taking (or not) measurements periodically to the family members?
- How to communicate positive or negative tendency over the measurements?
- How to incorporate a new the device within the patients home?

How to establish the required amount of information to share within the family members?

The required amount of information varies on each case. In an extreme dependency situation, when the patient has lost physical or cognitive abilities, family members have to monitor the vitals, give the medication and perform many other tasks. In the context of the BOX, patients are able to properly manage themselves and the devices. However, it is reported by clinicians and patients that the family plays an important role by:

- Reminding them to take the measurements.
- Reminding them about the medication.
- Influencing on the behaviour, especially diet, movement and stress.

In order to help family members to better perform those tasks the information shared needs to be:

- Notification when the patient does not measure.
- Notification when the patient does not move enough.

How to communicate that the patient is taking (or not) measurements periodically within the family members?

There are several methods to share the information. The most evident is imitating the hospital method, which is pulling the information from the patient account. This method can carry on some privacy concerns and be very obtrusive.

The purpose of the desired interaction is to:

- Notify family members when the patient is not taking medication and/or not moving enough.
- Reassuring family members that the patient is good. To avoid stress.

A coded communication based on colours, inspired by the Nokia Withings application could be used. The BPM assigns a colour to each reading:

- **Green**: the reading is good. It can be used to indicate that the patient is performing measurements.
- **Orange**: the reading is partially good. It can be used to indicate that the patient is performing some measurements.
- **Red**: the reading is bad. Measurements are missing and/or giving bad results.

The colour code is universal, as it is based on the traffic light.

How to communicate positive or negative tendency over the measurements?

The tendency is related with the measured variables. Some ideas to implement a communication system for tendency is based on blinking lights for the following situations:

- The user gets worse results over time.
- The user measures less times during the recovery process.
- The user improves over time, especially on vitals or measurements that can be compared one to another (like movement and BP).

The blinking light can be adjusted to the previously described colours.

How to incorporate a new device within the patients home?

The purpose of the device is to enable family members to better participate in the recovery process. As the communication method is a light colour code, it makes sense that a lamp and/or an alarm clock based device could be used as an inspiration.

Concept 1

The development of the concept is divided in three parts (IoT architecture, the application and the physical product).

IoT Architecture

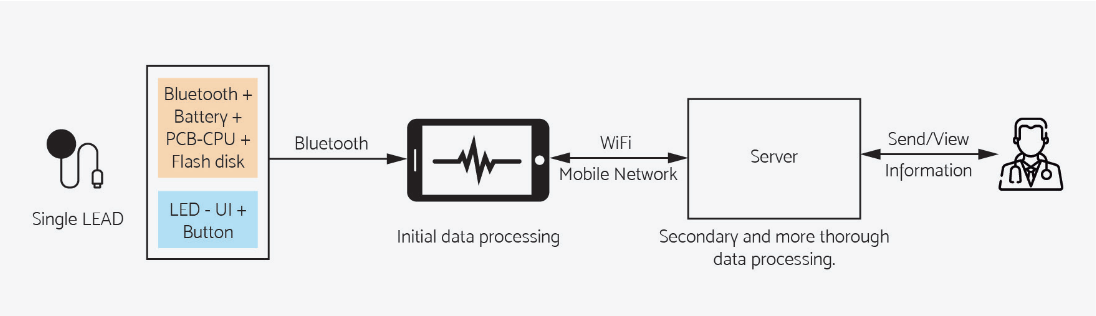


Figure 45. IoT Architecture

The basic PCB requires an operational amplifier (OpAmp) to amplify the body signal, an analogue-to-digital converter (A-to-D) to sample and afterwards store the signal, the disk unit to store multiple readings and the Bluetooth to enable synchronization with the mobile phone.

Application

For the application, Material Design by Google is chosen as the basic interface. It is the default and recommended design for Android applications. Using a familiar and recognizable interface reduces misunderstandings.

The application is designed to reduce complexity from the original KM application.

The focus is on communication with the doctors, history of records, to record a new ECG, the device synchronization and product privacy are the only possible actions.

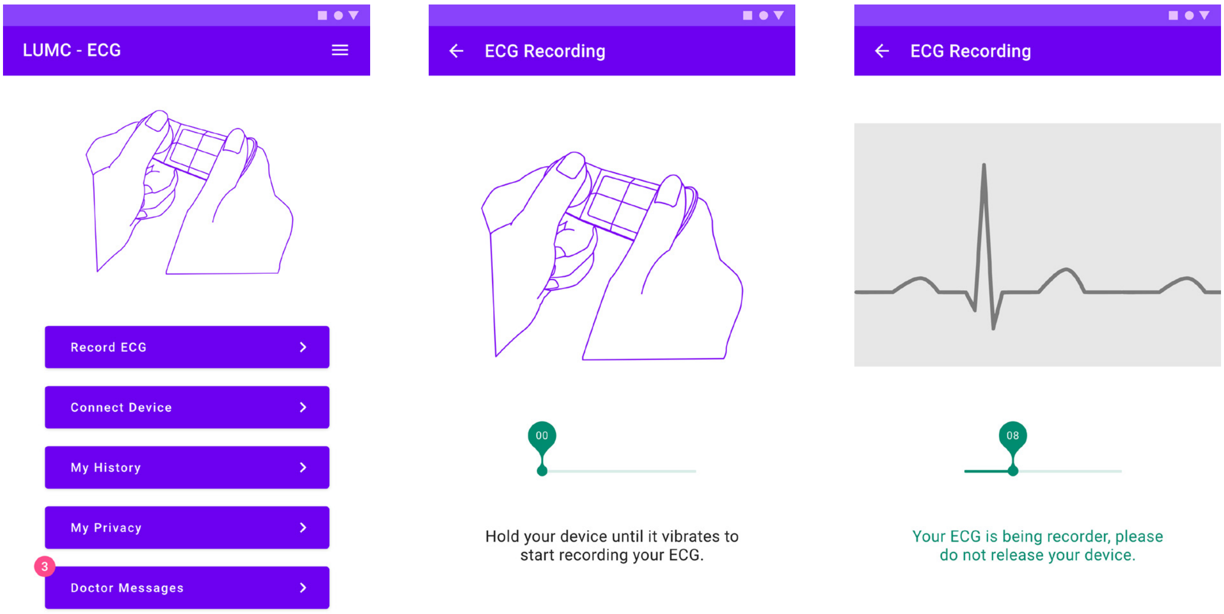


Figure 46. Application design. Home screen (left), Record ECG process (middle and right).

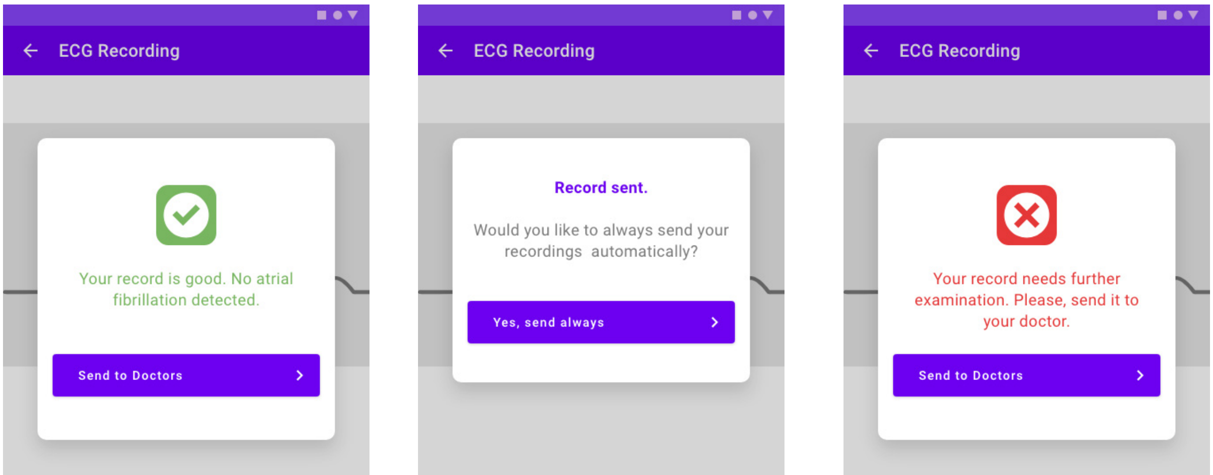


Figure 47. Record ECG possible actions according to the result.

Application home screen (left)

The application home screen is a dashboard with the overview of the actions. It has a visual aid (indication) of how to hold the device, which is lacking in the current product. The way of holding the device has been tested with wood 3D models. Users tend to grab the device intuitively in between their fingers instead of placing them on top of it.

Record ECG (middle and right)

The main purpose of the device itself is to record the ECG, which is the first button.

Once the patients clicks on it, the visual aid and a message indicates to hold the devices in the proper position. When it starts the ECG is being recorded and the timer helps to understand how much time is left.

The only possible action is to send the record to the doctor or save it, regardless of the result. An option to remind the preference is shown in the process.

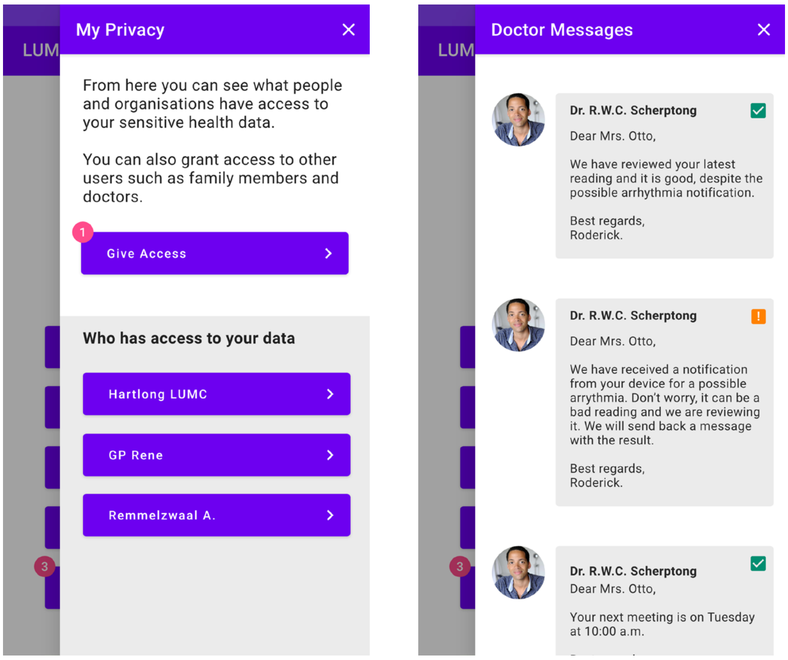


Figure 48. Application design. Privacy (left), Communication (right).

Privacy (left)

Being able to control who and when sees your information empowers patients and ensures safety. The privacy topic is left here and it is not further developed as it is not the main topic of this thesis.

Patients were asked about privacy during the interviews. They were not very concerned or did not think about it until they were asked. In Chapter 1, the importance of having tools to control the data has been exposed. This interface enables patients to view at a glance who and when sees their personal data.

Doctor communication (right)

Being able to properly communicate with doctors is an essential feature demanded by patients. Currently, the EKG is sent by email and no notification if sent that it has been received. Moreover, the communication is done outside the application, via phone or email.

For patients it is very important to receive immediate feedback, especially on bad results.

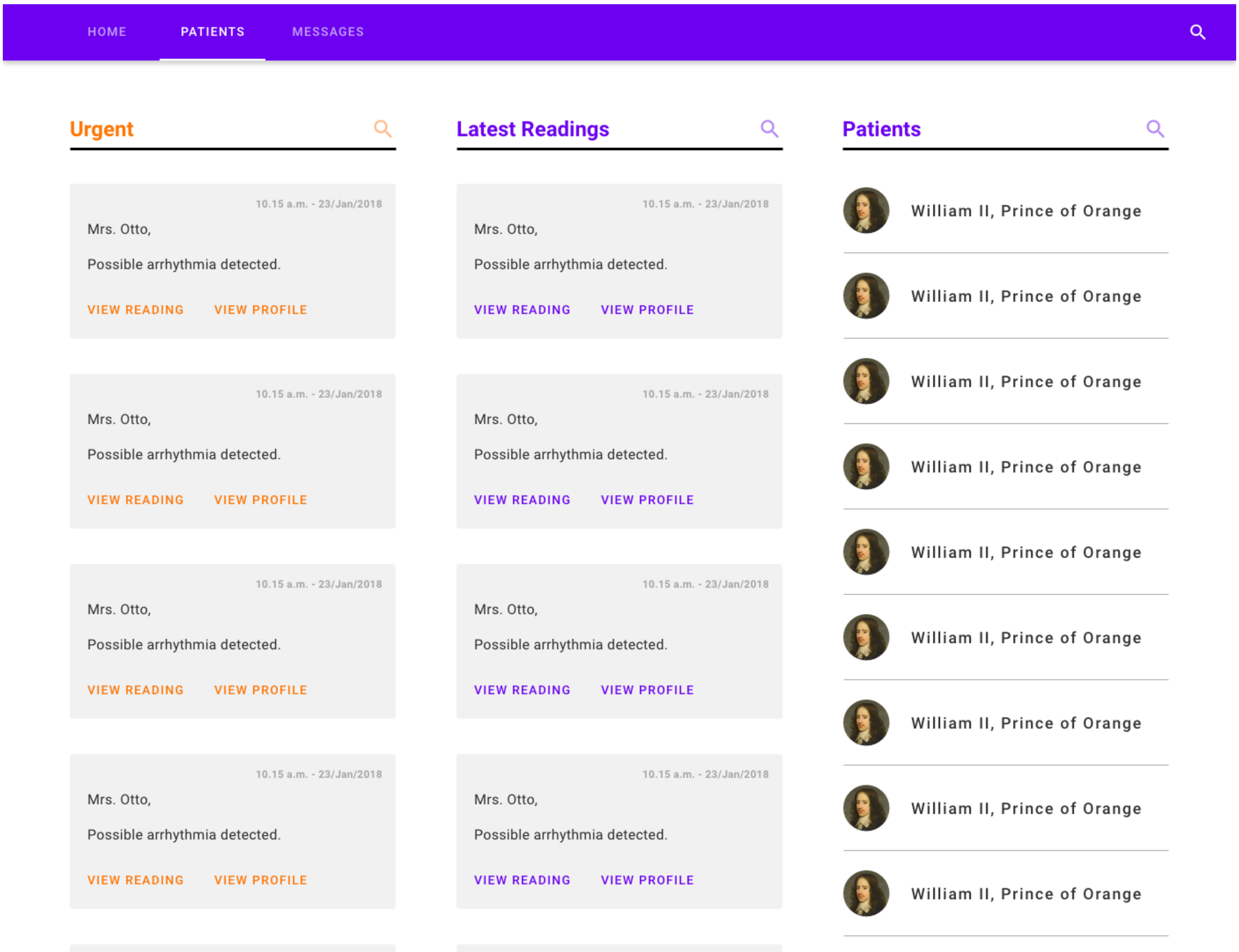


Figure 49. Doctors application - home screen.

Doctors screen

Equally important, if a communication module is enabled for patients, to have it for the doctors. Sharing the same design patterns and elements using Material Design reduces development time and is adequate.

The home screen is an overview of latest messages, readings and possible patients. Doctors can perform search to filter among the different patients.

Bear in mind that the patient profile is a place-holder (fake patient). The focus of the interface is on the functionality and structure, rather than patient details.

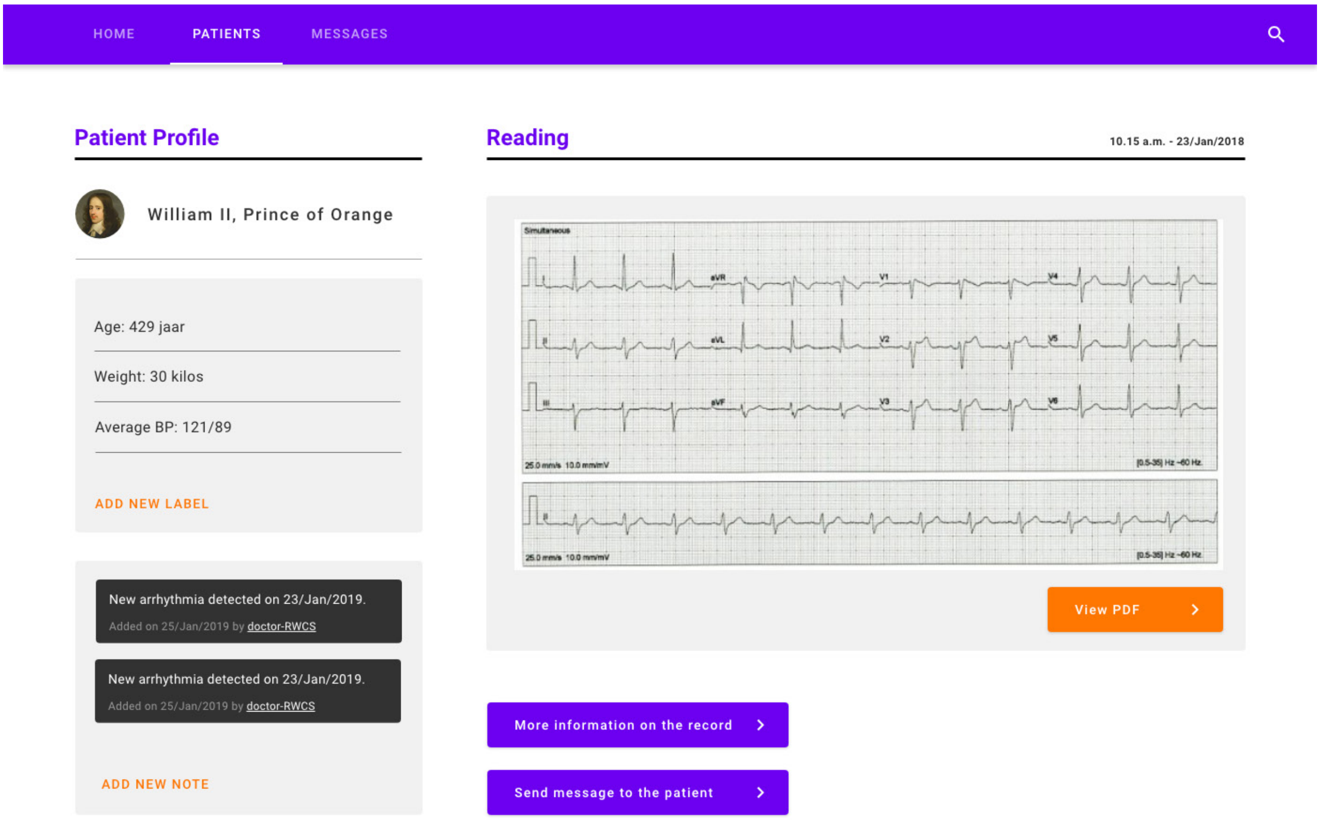


Figure 50. Doctors application - patient profile.

Doctors screen - Patient profile

Once the doctor selects a patients profile, the patient data can be seen altogether with the patient readings.

Big buttons indicate actions.

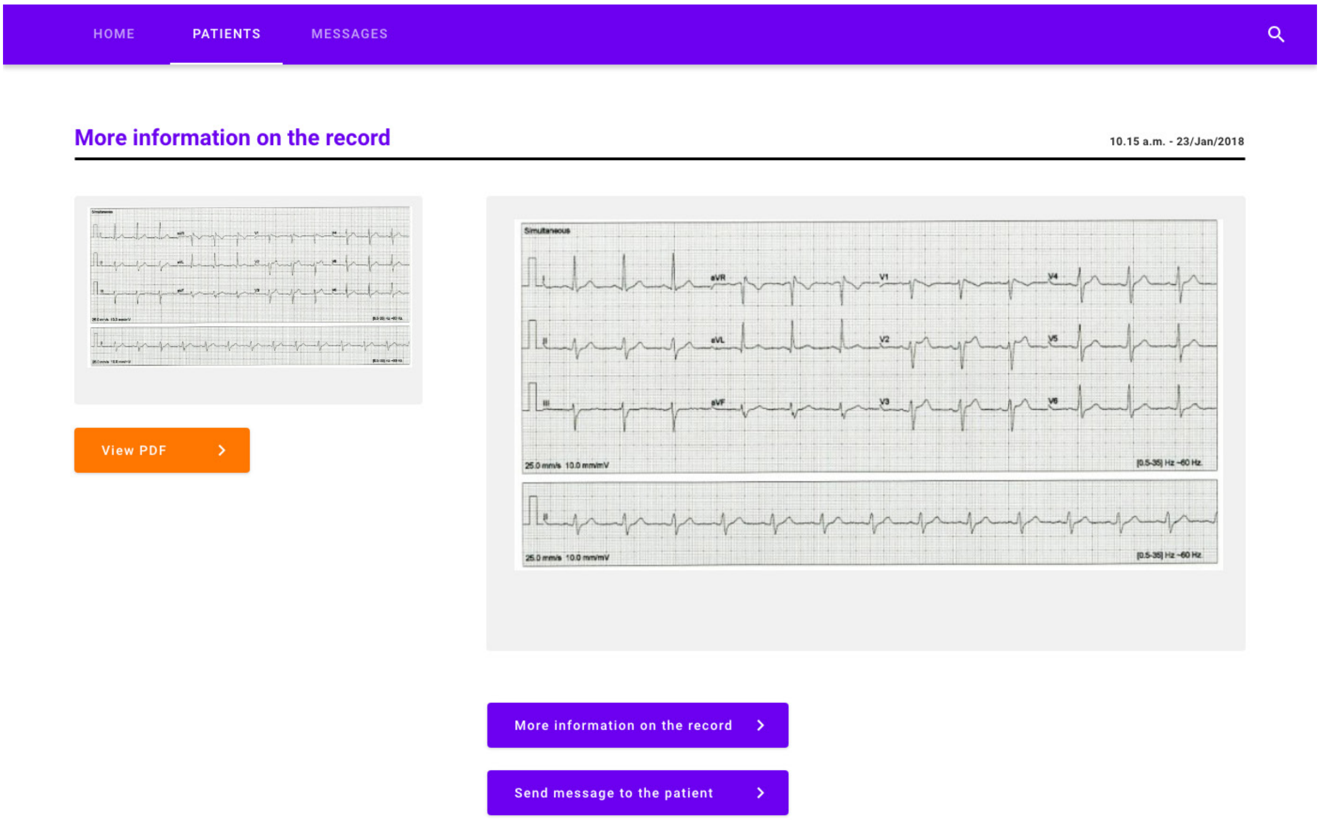


Figure 51. Doctors application - record analysis.

Doctors screen - Record analysis

Once the doctor selects a patients profile, and clicks on review record, the full record can be seen. It is also possible to make annotations and evaluate it, to send the information to the record.

Physical model

Before starting to sketch and build the product, two models are prototyped to explore how users grab and hold the device. It is important as KM interaction is not intuitive, for that reasons it is required education to properly hold the device.

Figure 52. Different 3D models to test how users grab and hold the device.

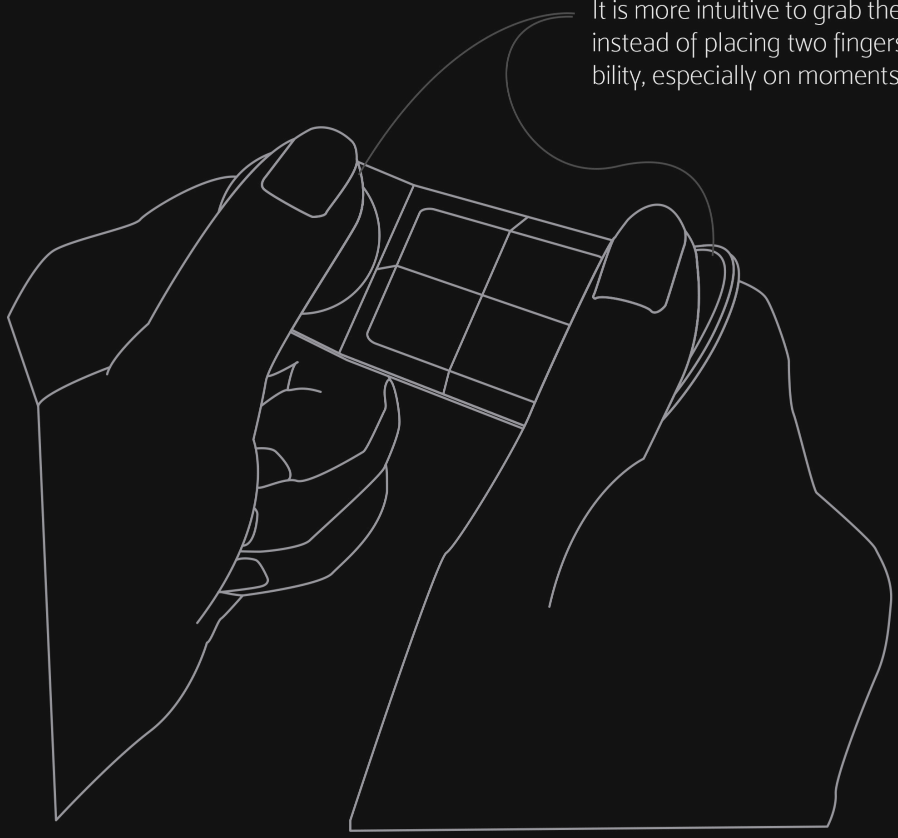
When the product is reduced to a simple physical model, without context, users grab it in a different way than the proposed by KM.

The proposed shape has some advantages:

- It is more intuitive.
- If the product can record without the phone, it would be more easy to use outside home, as it does not require a surface to place it.
- It can have more contact surface using it from top and bottom.

Concept 1. New EKG

The EKG is re-designed with a focus on ergonomics and open design. Business models around medical devices are limiting the capabilities of clinicians and patients to properly process and store information.

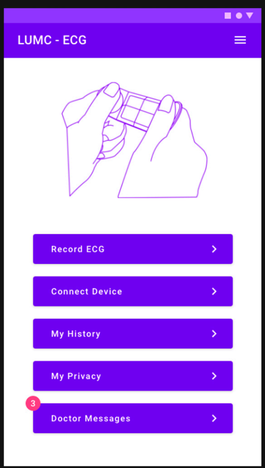


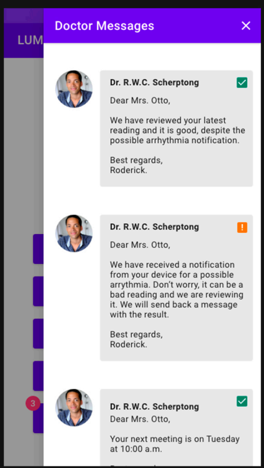
It is more intuitive to grab the product with the fingers on the electrode pads instead of placing two fingers on the surface. It gives more security and stability, especially on moments outside the comfort of a table.

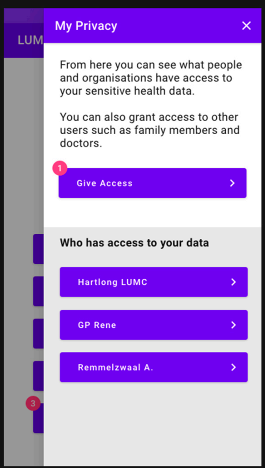
A slightly bigger design enables stand-alone EKG heart rhythm recordings (without the phone) or the app. It enables to use Bluetooth and a flash-memory, similar to the one used in the Nokia Steel watch given with the Box.

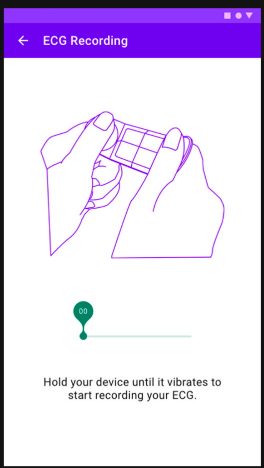
A new approach to patient-hospital-company interaction:

The user has control over who and when gets access to their information and is able to share it with family.









Concept 2

The development of the concept is divided in three parts (IoT architecture, the application and the physical product) and two iterations.

IoT Architecture

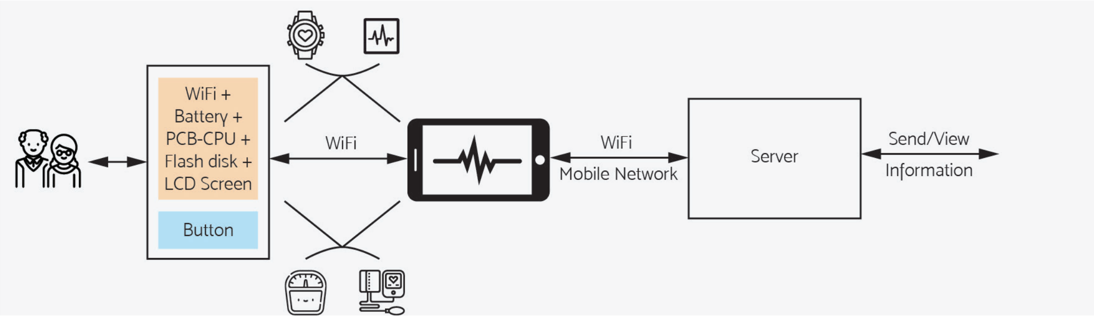


Figure 53. IoT Architecture

The basic PCB requires WiFi module, a battery, a LCD screen and a flash disk to properly work.

Application

For the patient to use the product, engagement is set as a priority. The companion is a helper meant to integrate family within the recovery, but before that, the patient must use it.

To make the product engaging, the Google Doodles are taken as inspiration. Google Doodle is the team that modifies the Google logo for special events. It is an attraction, a curiosity which also shares relevant information. The process is as follows:

- A relevant graphic or animation is shown instead of the logo.
- Once the user clicks, an animation and fast fact are revealed.
- Finally, if the user has interest there is provided a link with more information.

Based on this pattern, the welcome screen of Cardio Companion is developed.

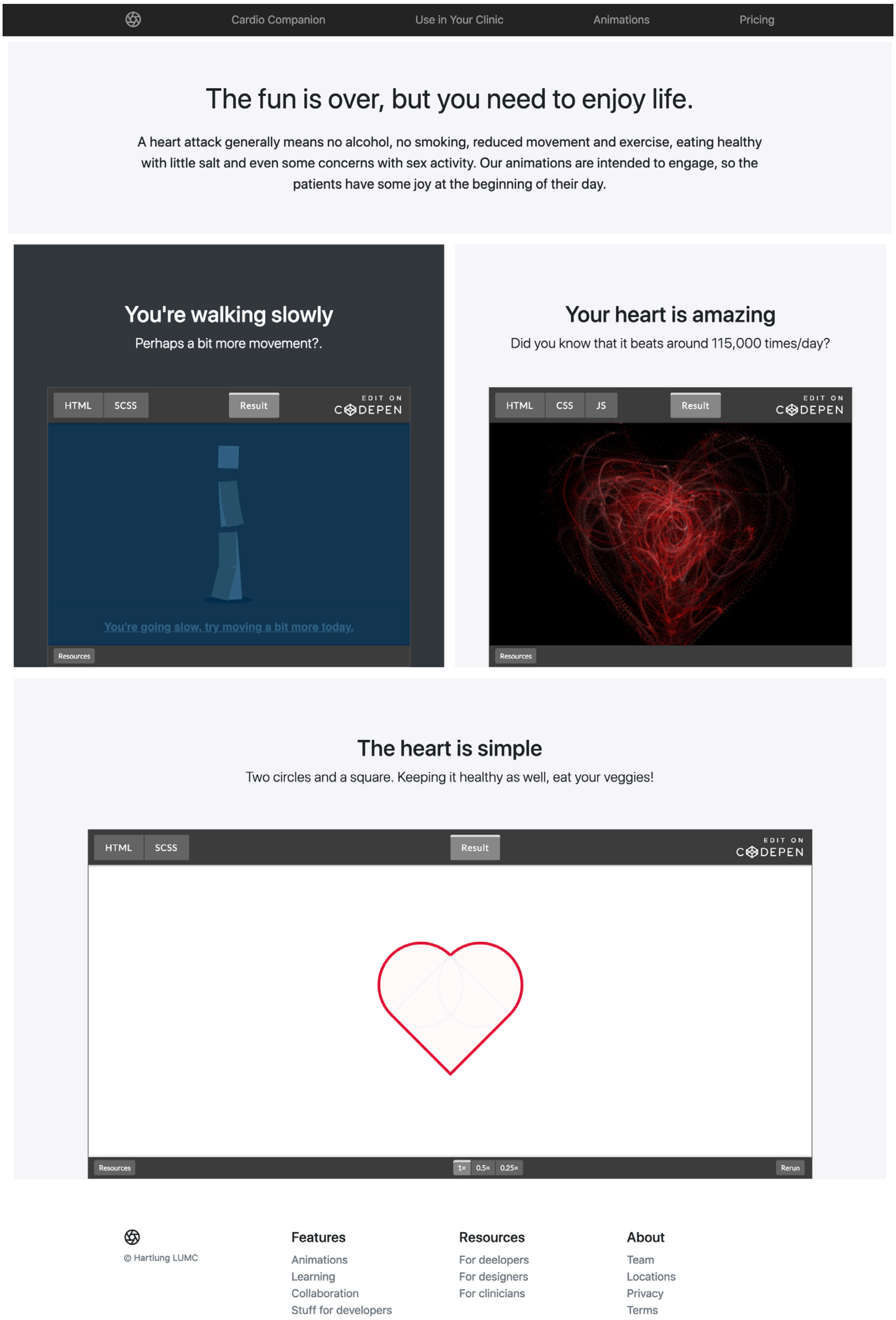


Figure 54. Overview of three animations meant to be used on the Cardio Companion.

The doodle design is represented in Figure 54. Which is also accompanied by a live website (Appendix E. Website). Several animations are prepared to make the experience more engaging.

Physical Device

The physical device is meant to fit within users routine, being a bed-side device that serves as well as an alarm clock. In the next page, the first iteration can be seen.

Users value warm and easy products as the interviews and the research revealed. A map with reference products classified on two scales (easy/difficult - warm/cold) is created. 24 users evaluated the products in a scale from 1 to 7 on being Easy or Difficult and Warm or Cold. The 24 users that took the survey were from the Facebook group "Heart attack families and friends". No age, gender or other personal data were collected.

The result can be seen below.

It is relevant that the materials and textures are perceived as the main driver to classify products as warm or cold. Moreover, being warm and easy to use go hand by hand, except in one of the products. As expected, blue is perceived as cold, while red/orange as warm.

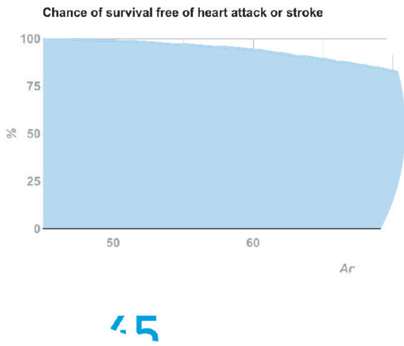
In the next pages can be seen the first and second iteration of the device.

Figure 55. Easy-difficult vs cold-warm.

Concept 2. Companion

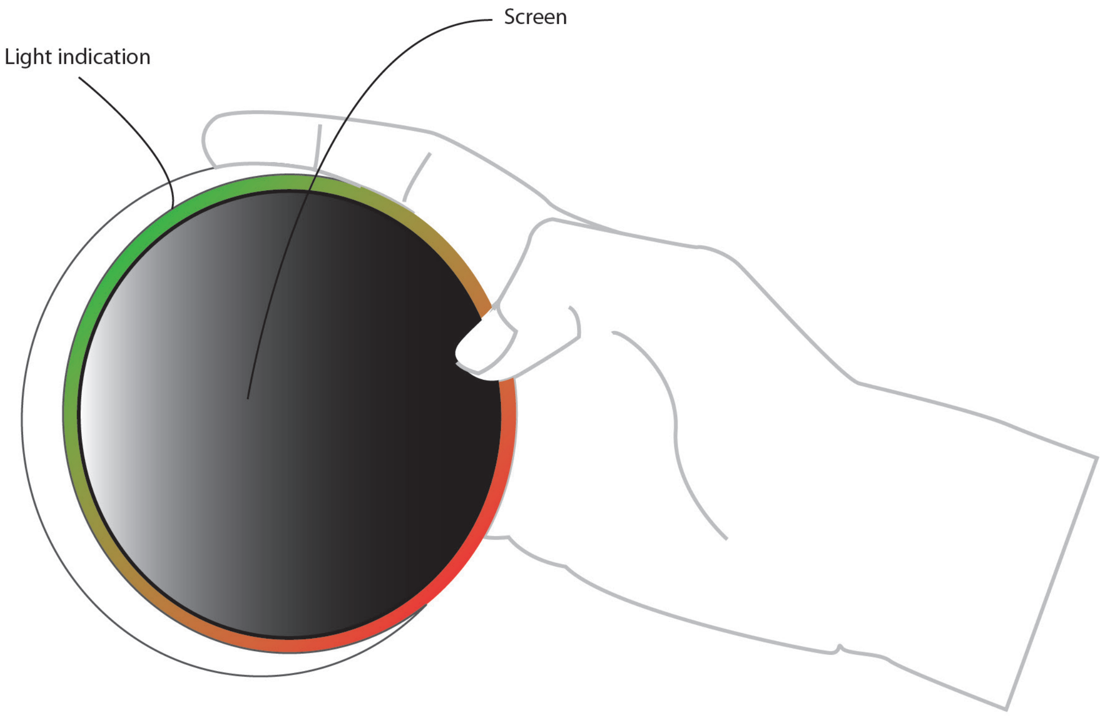
A companion to reinforce progress, or lack of it, and make it available to the rest of the family.

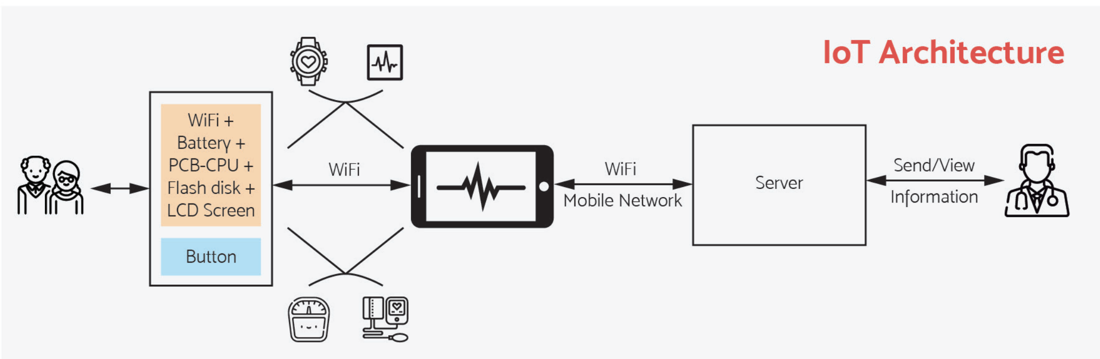
NEST
Simple/Actionable



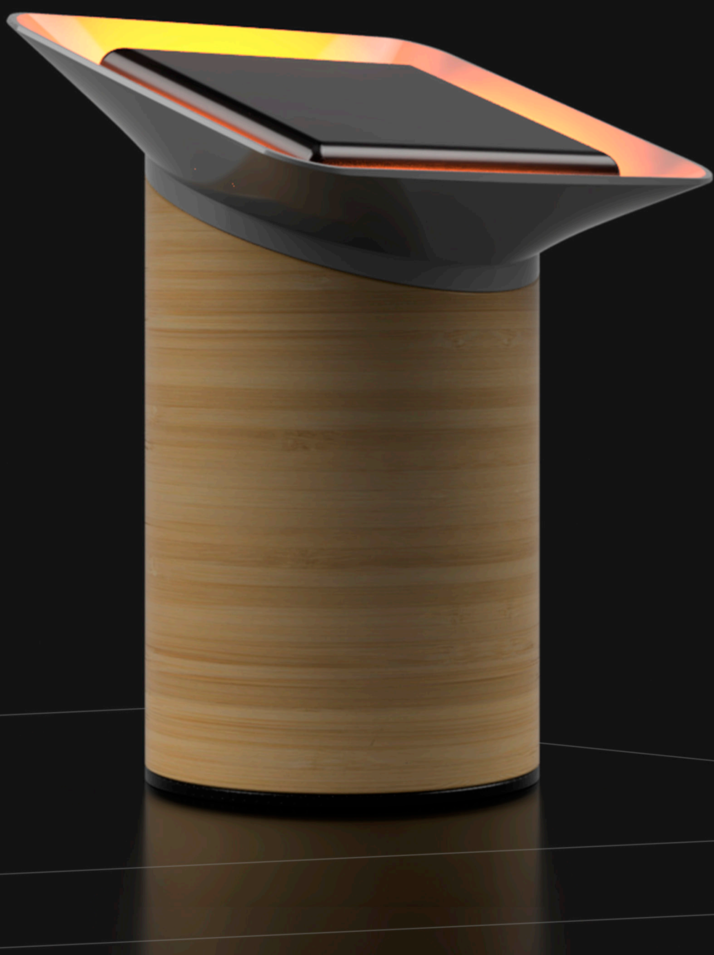
U-Prevent
Personal

MOTI
Friendly/Feedback





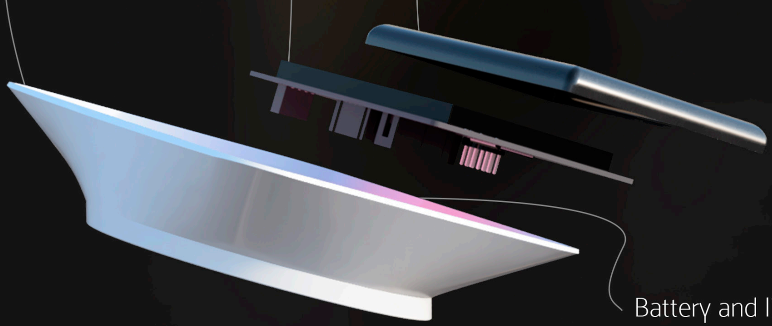
Cardio Companion

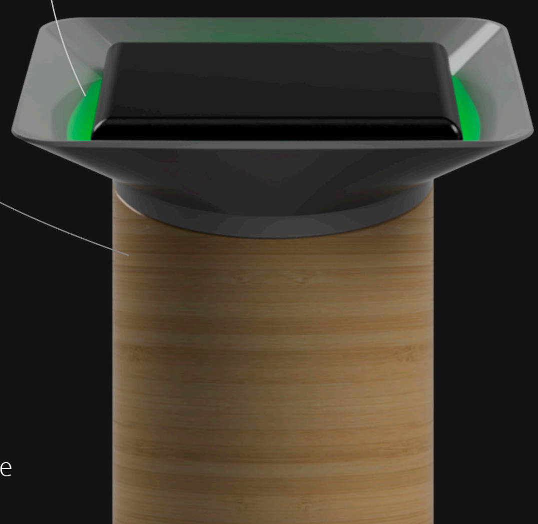


Cardio Companion removes the attention from the phone and displays the progress, risks and advice publicly, so the patient receives help and support from the family.

It provides progress overview rather than data, which the patient can understand.

Cardio Companion is an open platform for designers, clinicians and developers to build and share knowledge, making the platform more engaging.



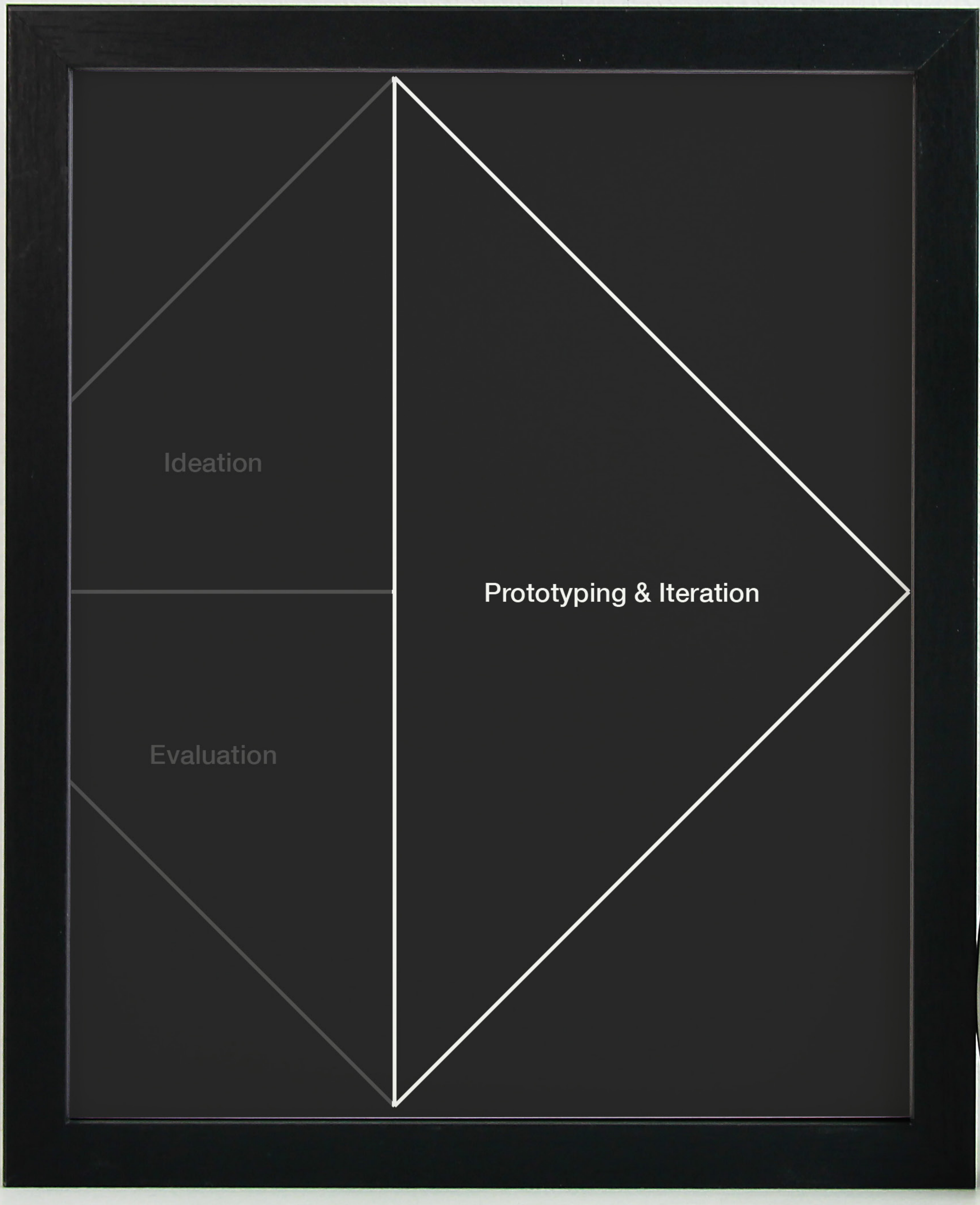


Evaluation

Both concepts are evaluated using the Harris profile. The Phone-less ECG is chosen for further development.

Concept Evaluation	Phoneless ECG				Companion			
	-2	-1	1	2	-2	-1	1	2
Product Usage								
Ergonomics								
No phone dependancy								
Battery life								
Increase the leve of the patient engagement								
Produce or initiate positive behavioural change								
Involve family in the patient journey journey								
Understandable information								
Usage curve								
Product Construction								
Easy to repair								
Easy to substitute								
Easily accepted by the user and the family members								
Reduced waste								
Produced locally								
Software								
Availability of reliable software								
Availability of reliable methods to collect/display the information								
Open API, hospital staff can store and process the information								
Grant full usage to the user (privacy and empowerment)								
Improve staff UI/UX								
Improve user UI/UX								
Maintenance								
Improvement over time								
Information access								
Open source formats to manage the required information								
Available software to collect, manage and store the required information.								
The BOX (as a system)								
Amount of products needed to deliver quality monitoring and care								
Costs								
Acceptability								

stage 4 **DELIVER**



Chapter 9

Prototyping

This chapter focuses on the prototyping of the selected concept.

Preface

Along this thesis many comments on arrhythmias have been made. Nevertheless, it is necessary to group them to set a full list of requirements for the prototyping stage.

What are Arrhythmias

According to the National Heart, Lung and Blood Institute[69]:

"An arrhythmia is a problem with the rate or rhythm of the heartbeat. During an arrhythmia, the heart can beat too fast, too slowly, or with an irregular rhythm. When a heart beats too fast, the condition is called tachycardia. When a heart beats too slowly, the condition is called bradycardia."

Why is it Important to Diagnose Arrhythmias

It is important because of the risks involved with some types of arrhythmias. For example, one of the most common is AF. People with AF are five times more likely to suffer stroke than those without AF.[70] In the Netherlands alone, 260.000 people are diagnosed with AF[1].

How Arrhythmias are Diagnosed

Arrhythmias are difficult to diagnose as some symptoms may last for minutes or days and stop spontaneously, making it difficult for patients and doctors to effectively diagnose them.

It is normally diagnosed based on patient history and symptoms together with an ECG test, either resting, stress test or on an event recorder such as KM.

In the case of AF, the ECG test will show a different waveform characterized by the missing P wave or fluctuation, and/or by irregular ventricular response (irregular heartbeats). The ventricular response is associate with the R of the QRS, as can be seen in Figure 1, page 6.

Those characteristics are easily identified by algorithms, which proliferated dramatically in recent years. Among them, the most accurate are the ones based on the K nearest neighbour (kNN)[71]. The algorithm works in two steps, first it identifies the QRS complex, then it computes the time-domain, frequency-domain and non-linear domain features of the beat-to-beat (RR) to compare it with previous classified records.

The process of the acquired information (ECG) is an important step to determine the viability of the product. The process of acquiring a signal is:

1. Signal acquisition via device. The materials and electronics are the most important part in this step.
2. Signal storage in the device or synchronization with the mobile phone.
3. Signal processing to identify the QRS complex.
4. Signal processing to obtain the relevant features from the RR.
5. Signal is delivered as input for the kNN to be classified.
6. The result is returned to the user.

The signal must be good enough for being processed. This means that it must have between 250 and 500 samples per second[67]. Regarding the frequencies and filters to use literature and regulations are not rigid nor clear[72]. It depends on the purpose and equipment used. For diagnosis purpose the frequency can be between 0.05 to 150Hz in a controlled environment, while for ambulatory use a common practice is to have it between 0.67 to 40Hz.

Requirements

To develop a portable ECG monitor that brings value to the involved stakeholders (clinicians and patients) the product should meet the requirements listed below.

Performance:

- The product can be worn in contact with the human body.
- The product should be able to properly identify activation to increase battery lifetime and avoid fake-readings.
- The product should record real-time electrical activity when it is activated by the user.
- The product should be able to provide feedback.
- The product should remove 50Hz and 60Hz noise interference effectively.
- The product should store at least 10 records without running out of memory.
- The product should use Bluetooth to do the synchronization.
- The product should perform recordings between 250 and 500Hz.

Lifetime:

- The product should be able to work without interruptions for at least one year.

Maintenance:

- The battery unit should be easy to be replaced.

Product cost:

- The product should be affordable and viable without subscription plans.

Aesthetics:

- The product should be attractive.
- The product should look trustworthy and easy to wear.

Materials:

- The materials of the product should be easy to supply.

Ergonomics:

- The product should be easy to grab and adapted to the human body size and shape.

Safety:

- The product should not cause harm, such as abrasion or electric shock for being in contact with the skin.

Wishes:

- The components should be integrated into a PCB to have a full functional prototype.
- The product should provide accurate feedback based on a trained kNN model.

Method

An iterative method based on fast loops is chosen for the prototyping stage. Inspired in the lean start-up methodology, the method aims to fail fast, learn and make decisions based on new data that comes from testing. Figure 56 illustrates the main stages of each loop (iteration).

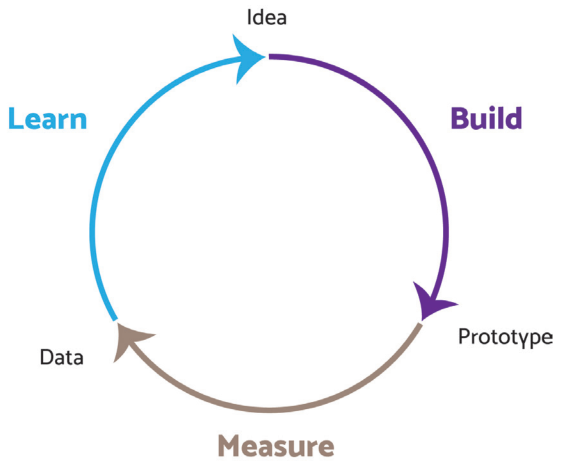


Figure 56. Loops iteration stages

The proposed method is chosen to focus on speed and iteration to build actionable knowledge in order to make decisions.

Sensor Exploration

The available sensors are evaluated. To obtain the ECG signal for an Arduino Board there only available sensors is the SparkFun AD8232[73]. Other sensors are a copy of this.

9.1 First Iteration

The code used in this iteration and the recorded signals can be find in the Folder Prototyping/Iteration 1. The aim of this iteration is to get the basic knowledge about the sensor and gather a set of tools to work with it.

Initial tools

- **Arduino Uno**: Used as the prototyping board. It allows enough flexibility and it is extendible via modules (sensors).
- **SparkFun AD8232 sensor**: The only ECG sensor available. Other sensors are copies of it.
- **Electrodes and electrode leads**: To record the signal.
- **Node.js**: A server written in JavaScript to record the data and control Arduino. It is chosen for the large tools available.
- **Johnny-Five**: A JavaScript Robotics & IoT Platform to control Arduino from the Node.js server.
- **Express.js**: A basic Node.js server rendering module to connect the data with the user interface.
- **Python 3**: To perform signal processing and analysis with Scipy, Numpy and Matplotlib packages.

Test set-up

Following the hook-up guide of the sensor[74] three electrodes are placed in the indicated positions. Figure 57. Left.

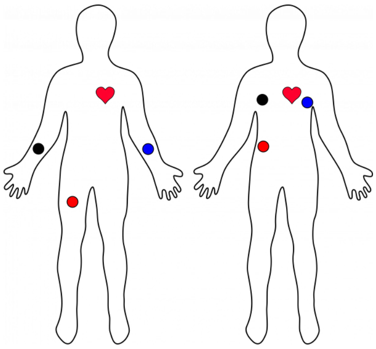


Figure 57. SparkFun 8232 lead placement. Left: placement for measuring from hands/legs. Right: placement for measuring from the body.

The output of the sensor is pinned in one of the Arduino analogue inputs and plotted following the indications[74]. The result can be seen in Figure 58 (bottom). The QRS complex and the T wave are clearly differentiated. The recorded data could provide enough information for an automated HRV analysis if the sampling speed was higher and constant. The frequency varies from 192 to 197 Hz.

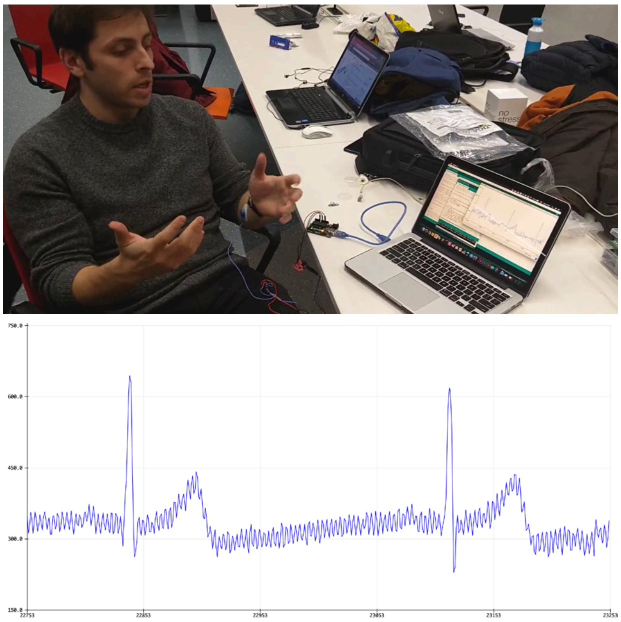


Figure 58. Top: electrodes connected to the arms, live signal being plotted in Arduino Plotter. Bottom: screenshot of the recorded signal.

The frequency domain of the acquired signal is plotted using the fast Fourier transform algorithm (FFT), Figure 59, Top. The signal is shifted due to the DC offset and the noise because of the 50 Hz frequency interference. To process the signal two methods are used. Firstly, a detrend function is used to remove the DC offset. Secondly, to remove the 50Hz signal a notch filter at 50 Hz is applied and filtered with a zero-phase filter. Finally, the result can be seen in Figure 57, bottom.

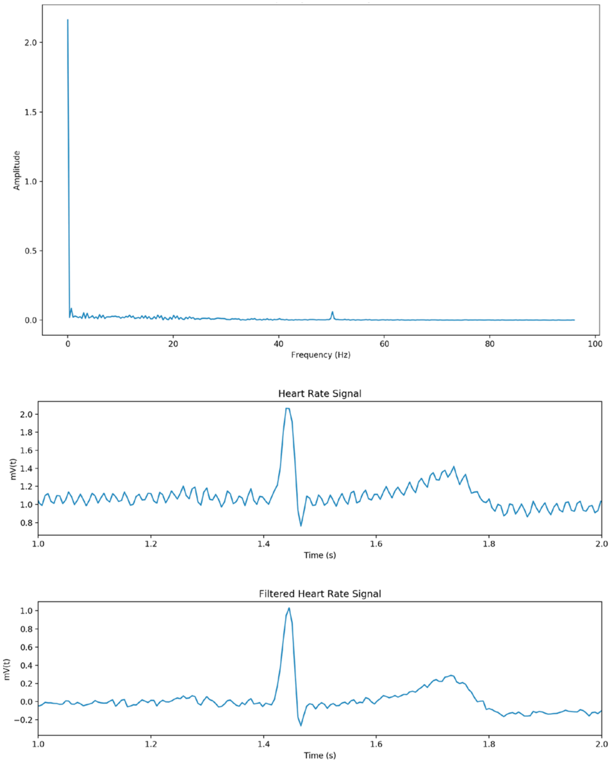


Figure 59. Top: Amplitude/Frequency (Hz) plot. Bottom: there are two graphs, the original recorded signal on top, the processed signal on bottom.

Removing the right-leg electrode (ground)

Once the right-leg electrode (ground) is removed, the sensor works well, although it captures the 50Hz frequency interference. The source of the noise is the computer. The result can be seen in Figure 60. The samples per seconds are between 192-197.

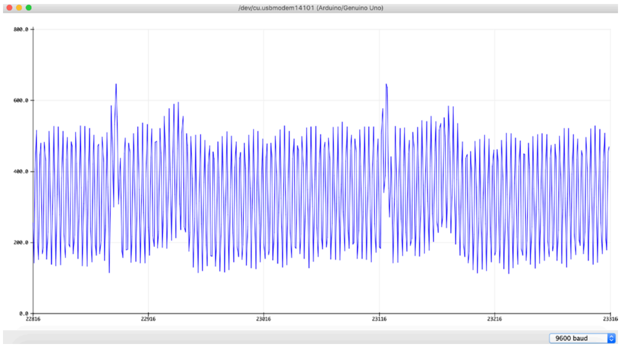


Figure 60. Screenshot of the recorded signal without right-leg electrode.

The signal frequency is plotted using the FFT algorithm, furthermore the DC offset and the 50Hz frequency noise are removed. The result can be seen in Figure 61, the noise around the 50 Hz frequency is more dominant than in the previous example.

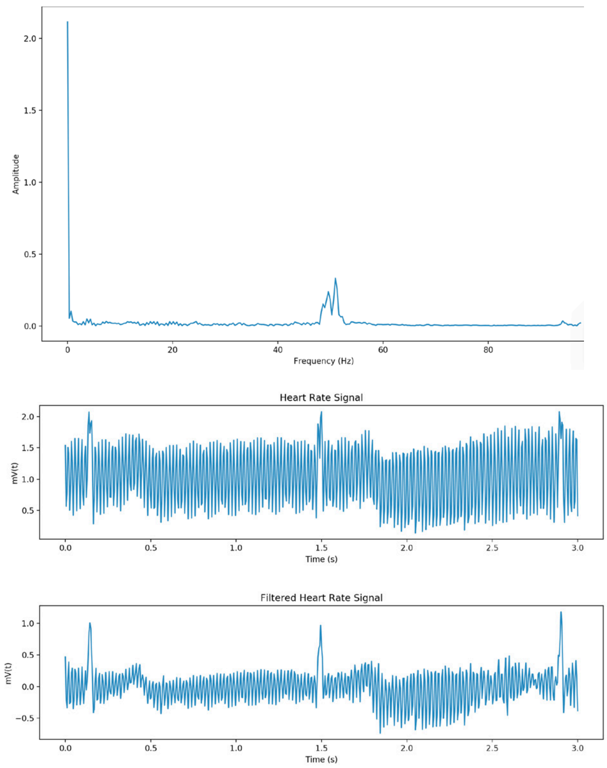


Figure 61. Top: Amplitude/Frequency (Hz) plot. Bottom: there are two graphs, the original recorded signal on top, the processed signal on bottom.

Despite the noise, the QRS complex is visible and enough differentiated to obtain the HRV. Better filter techniques are needed to improve the signal result, especially considering that live plotting is desirable altogether with proper plotting. Those methods together with the HRV extraction will be implemented in the next iteration.

Non-consistent results without right-leg electrode

The results are non-consistent as the sensor is being tested outside a free-noise area. The results vary according to the frequency interference at each moment. For example, if the user removes the right leg (ground) but touches the computer (the source of the noise) the signal is almost perfect, see Figure 62. Other situations is when the computer is connected or other nearby devices reduce the noise, as the computer does in the first example. The three described situations cause different results and will be considered in future iterations to improve signal acquisition and processing.

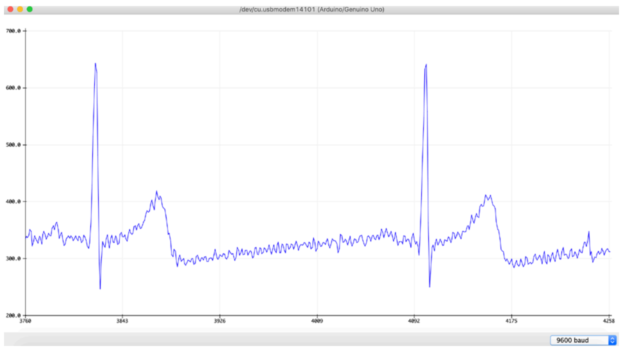


Figure 62. Screenshot of the recorded signal without right-leg electrode and touching the computer. The results present less noise than using the right-leg electrode (ground).

Increasing the baud rate to increase the frequency

The baud rate has been increased to 19.200 and has been recorded immediately after the previous one, without changing/removing the electrodes. The frequency is between 376 and 392 samples/second. The result is more detailed as the signal has less noise, although it is non-related with the frequency, but rather with the non-consistent results mentioned before.

The result can be seen in Figure 63. In this record the P wave is slightly visible. The QRS complex, S-T segment and T wave are clearly represented.

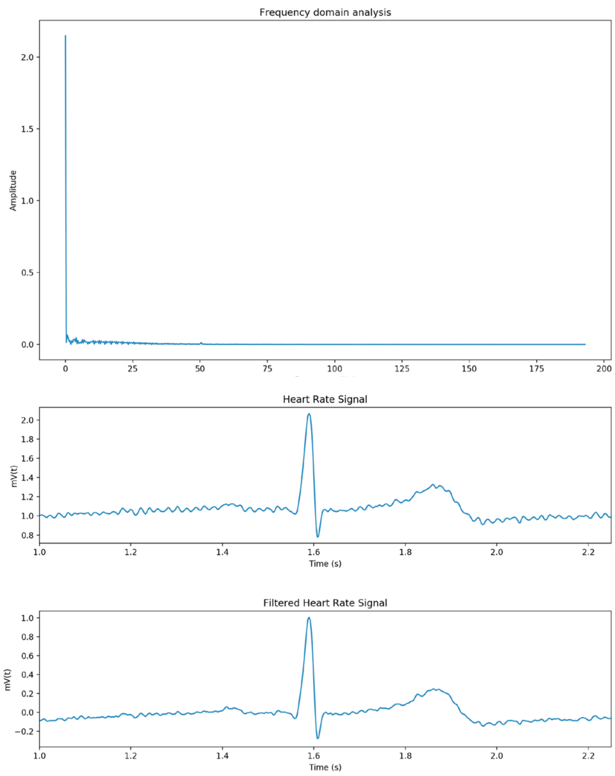


Figure 63. Top: Amplitude/Frequency (Hz) plot. Bottom: there are two graphs, the original recorded signal on top, the processed signal on bottom.

Application Interface

The application is built using Node.js, Express and Socket.io. It allows the user to connect with the phone and interact with it. Moreover, it can read data from Arduino thanks to Socket.io

Next Iteration

For the next iteration the electrodes will be substituted by metallic leads and new solutions to acquire a better sampling rate will be explored. The Table 5 (next page) illustrates the iteration cycle.

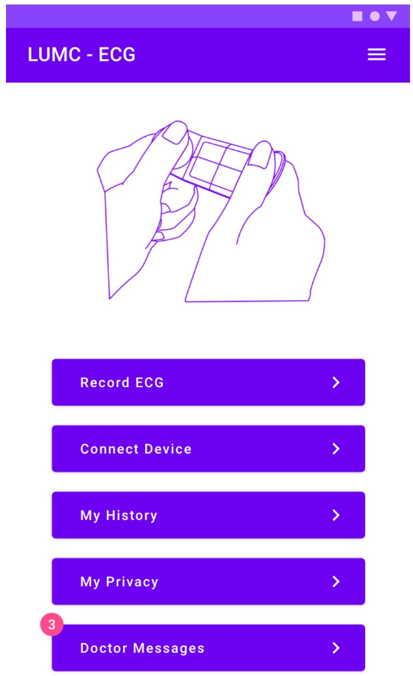


Figure 64. Application prototype.

Build Elements necessary	**Measure** Variables/Parameters to measure and Results			**Learn** Interpret Results
	Variable/Parameter	Result	Reason	
Arduino + Sensor connection.	Sampling rate.	Not constant sampling rate. The signal varies between 95-96 and 192-197 at 9600 baud rate.	Possible causes: 1) Arduino delay function creates Jitter, together with operations used by the code can make it non-consistent. 2) Johnny-five firmata-plus is not designed for higher sampling rates.	In the next iteration find a workaround to access the Arduino clock without using the Delay function. Remove Johnny-five firmata as it is expensive for sampling rates.
	Graph result with three electrodes as indicated in the example.	Very accurate result. See figures 58 and 59.	The sensor is built in analogue filters to remove radio-frequency and 50/60 Hz noise.	Explore the sensor AD8232 chip to modify the input for better signal acquisition.
	Graph result with two electrodes for the desired purpose.	Non accurate result on 50% of the cases. See figures 60 and 61. The result is not consistent as explained.	The right leg ground is an output which "levels artificially the body voltage" to act as a "fake ground". It enables to use only two inputs with the right	Explore the sensor AD8232 chip to modify the input for better signal acquisition.
Interactive Interface to plot the data and enable interaction. The interface is built within JavaScript (functionality) + HTML (structure) + CSS (styles).	Plot data in the user interface. Control Arduino from user interface.	Data plotting is not optimized and non-reliable.	It is due to non-constant sampling speed and the moving of the Y axis while plotting.	Improve the interface to test with users.

Table 5. Iteration 1 cycle.

9.2 Second Iteration

The code used in this iteration and the recorded signals can be find in the Folder Prototyping/Iteration 2. The aim of this iteration is to:

- Improve the sampling rate of the Sensor/Arduino combination.
- Perform basic HRV analysis to extract the required features from the Signal.
- Build a physical prototype to test with users.
- Prototype different lead connections to enable a electrode-less device using reusable metal electrodes.

Improve the sampling rate

The problems of Arduino with sampling at high speeds or to obtain constant samples from any signal are known[75, 76]. Some of the main reasons are:

- Jitter caused by the delay function.
- The loop functions also has some trade-off in performance.
- Doing operations such as Serial.print, float, etc... could cause some jitter as well.

The chosen strategy to overcome these problems is to use micros function instead of the delay (as it has less jitter) and remove the Johnny-Five Firmata-plus software. The sampling rate will be increased to 400Hz and the baud rate to 115.200.

Perform basic HRV analysis

To perform the HRV analysis, the R-peaks must be identified. For that purpose the detection of the QRS complex is necessary to extract the RR. Many methods are available, from complex to relatively simple. Two of the most accurate and widely used algorithms are the Hamilton-Tompkins[77] algorithm and the Hilbert--transform based algorithm[78] from the first differential. For the purpose of this study the latter will be used as it offers better performance. The algorithm is implemented in python and slightly modified for the purpose of this thesis. It is implemented as follows:

1. The signal is detrended to remove DC offset.
2. A butterworth bandpass filter with 8 to 20Hz is applied to remove noise and reduce the P and T waves.
3. The first derivative is applied.
4. The Hilbert-transform function is applied. It amplifies the QRS complex, facilitating the location of peaks.
5. A moving average is applied to the Hilbert-transform, using a windows size of the equivalent of 120ms, as it is the higher value of a QRS complex.
6. The peaks are detected with the following criteria: 1) the minimum distance between RR is considered 200ms; 2) the width is set to the equivalent of 80ms, as it is the lower value of a QRS complex; 3) A threshold of 20% height is set to remove non-real peaks.
7. The detected peaks are used as a reference to mark them in the original signal to not loose precision in the RR interval.

The algorithm is tested with four records from two different users. It is accurate even with noisy signals, as can be seen in Figure 65. The algorithm will be improved if necessary in future iterations.

Once the RR interval is clearly defined, it is necessary to extract the features that enable machine learning processing. The features will be extracted in future iterations.

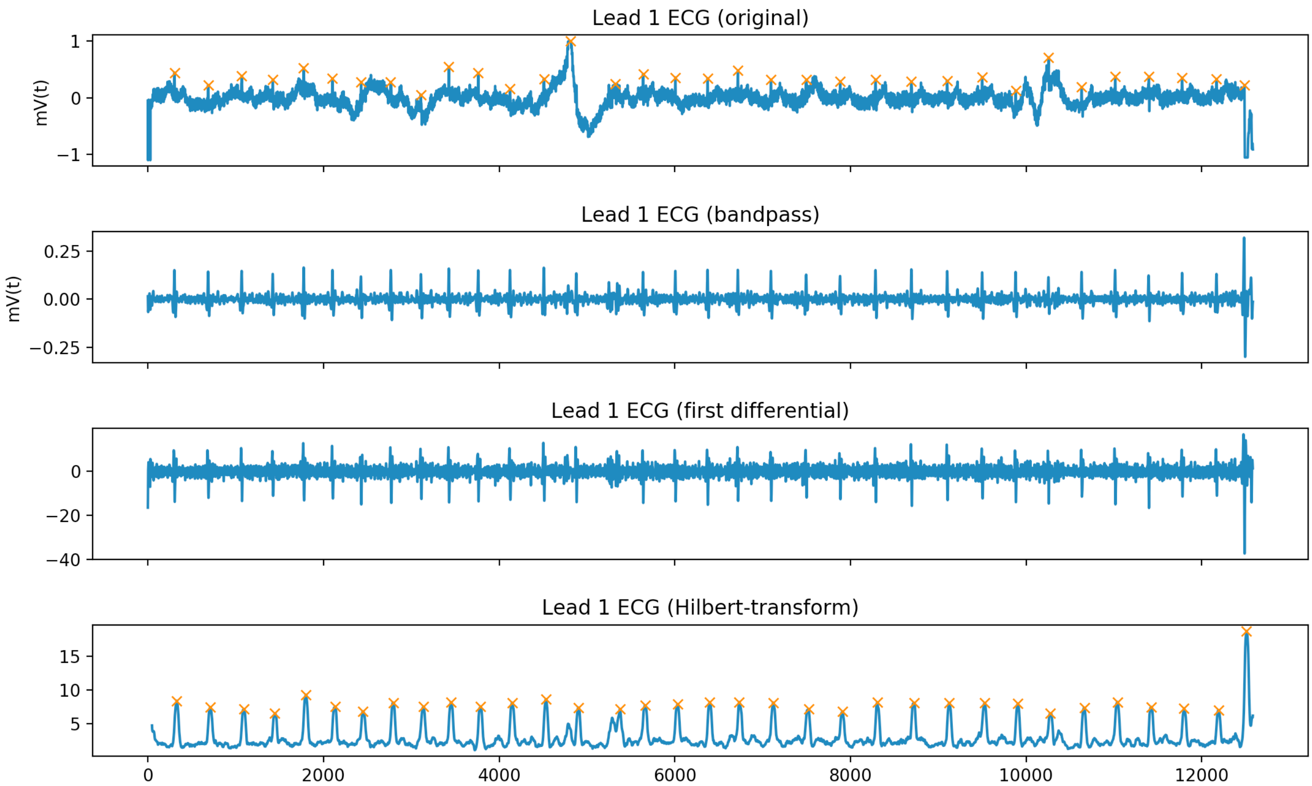


Figure 65. Filtered signal using the Hilbert-transform method.

Prototype Different Leads

Several leads are prototyped to find an alternative to the electrodes. A combination of steel, aluminium and copper electrodes are used to record an ECG with the sensor. The steel and aluminium are connected with copper-tape on which the cables are soldered, as none of those were adhering properly to tin. None of the metal electrodes works as expected, the sensor is incapable of recording a proper signal.

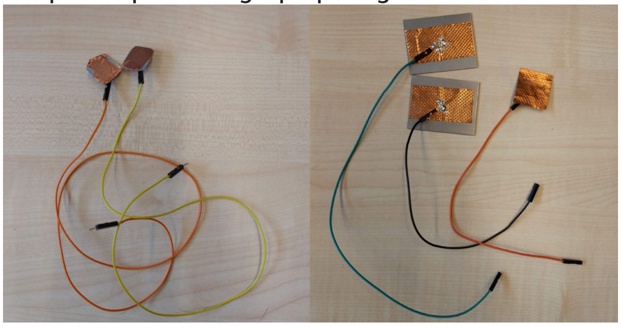


Figure 66. Copper on steel and aluminium, as was not possible to solder with tin on those materials.

The copper-tape alone has enough conductivity to record a noisy signal, although it is very susceptible to changes in impedance caused by pressure. This is an important consideration that affects the results of the physical prototype and how it is intended to be held.

Physical Prototype

The physical prototype is based on the KM design. The design is based in the initial physical models created to understand how users prefer to grab and hold the device.

It includes 5 holes to place 5 LEDs as a visual feedback to indicate the progress of the recording. It also has a placement to include one motor vibrator to indicate the start and end of the recording.

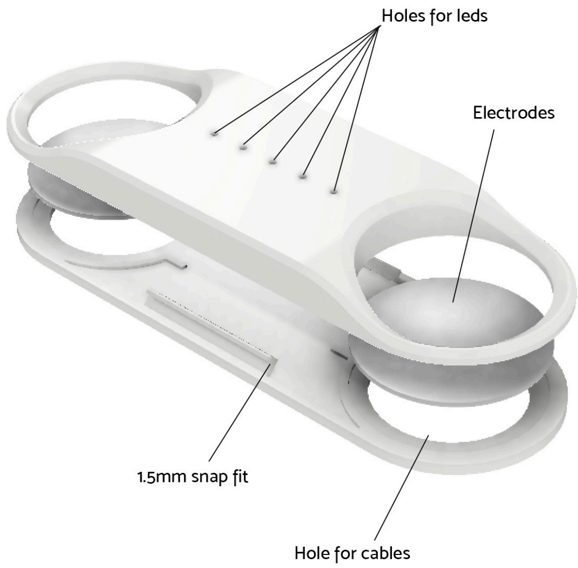
How it works:

1. The user grabs the product placing the thumb finger on the circular electric pads.
2. Second 0: The vibrator is actuated for 0.5 seconds.
3. Second 0: All the LEDs turn on for 0.5 seconds and the first LED starts to vibrate.
4. Second 0: Data starts to be recorded.
5. Each LED toggles for 6 seconds until it is left on. At the end of the recording all should be on. In this way the use has a constant feedback on the time left.
6. Second 30: All LEDs toggle for 0.5 seconds.

Testing the prototype:

The prototype is tested with conventional electrodes as the materials did notprovide enough conductivity for the sensor to work.

The signal is greatly affected by the force applied to the electrodes due to the impedance change. It means that the shape, despite of being more intuitive and easy to grab is not so adequate. A redesign will be proposed for next iteration to reduce impedance caused by applied force, but also differentiate the design from the KM, making it smaller and more portable.



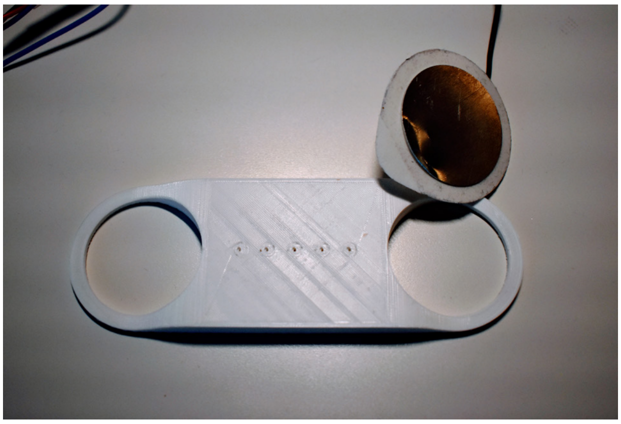


Figure 67. Top: prototype render with indications. 3D printed prototype for test.

Build Elements necessary	**Measure** Variables/Parameters to measure and Results			**Learn** Interpret Results
	Variable/Parameter	Result	Reason	
Better Arduino sampling rate.	Sampling rate.	Constant sampling rate.	Using micros function to read the data from the input and storing the data in a variable outside Arduino.	Use this code in future interactions.
Perform basic HRV analysis.	Peak detector accuracy.	The results are good with stable signals, and even noisy ones.	The algorithm is accurate . The chosen threshold differentiates properly R peaks from other peaks.	Use this algorithm in future interactions.
Build first Physical prototype.	Construction. ECG measurement result. Record results.	How users hold it. ECG Result.	The user applies force to the electrodes while holding the device. It increases the baseline wander and distorts the signal at low frequencies.	Build a different prototype.
Build alternative leads.	ECG measurement result.	Bad ECG result.	Low conductivity of the materials.	Find new materials.

Table 6. Iteration 2 cycle.

9.3 Third Iteration

The code used in this iteration can be find in the Folder Prototyping/Iteration 3. The aim of this iteration is to:

- Improve metallic electrodes
- Build a better physical prototype to test with users
- Test with patients the haptic and light feedback, and the application. It is done at this stage due to time constrains with patients schedule

New electrodes

To improve conductivity cooper-brass foil is used as the material to be in contact with the body. Compared to harder metals such as stainless steel, it does not require a superficial coat to improve conductivity nor machinery for form-giving and polishing, making it suitable for prototyping.

The length and type of cables used are the same as it is recommended to reduce common-mode rejection ratio (CMRR).

The right-leg is also used, but derived from the right hand as the chip AD8232 allows for it. Therefore, three electrodes are used, one at the left hand, two at the right hand. The processed recording can be seen in figures 68 and 70. The result is good for HRV analysis, but not for visual inspection, it is necessary to reduce the noise.

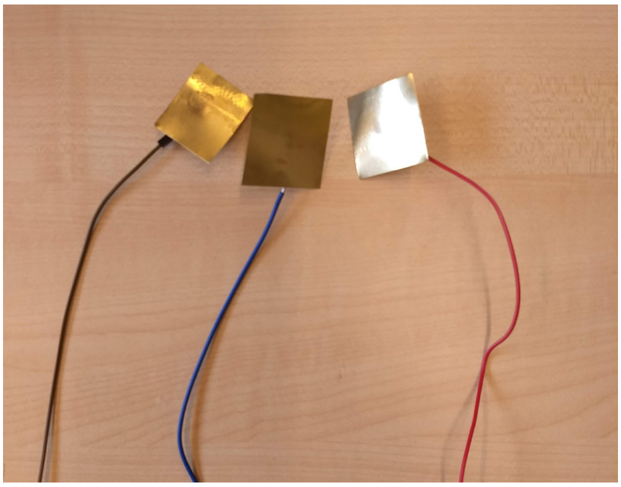


Figure 68. Copper-brass foil leads.

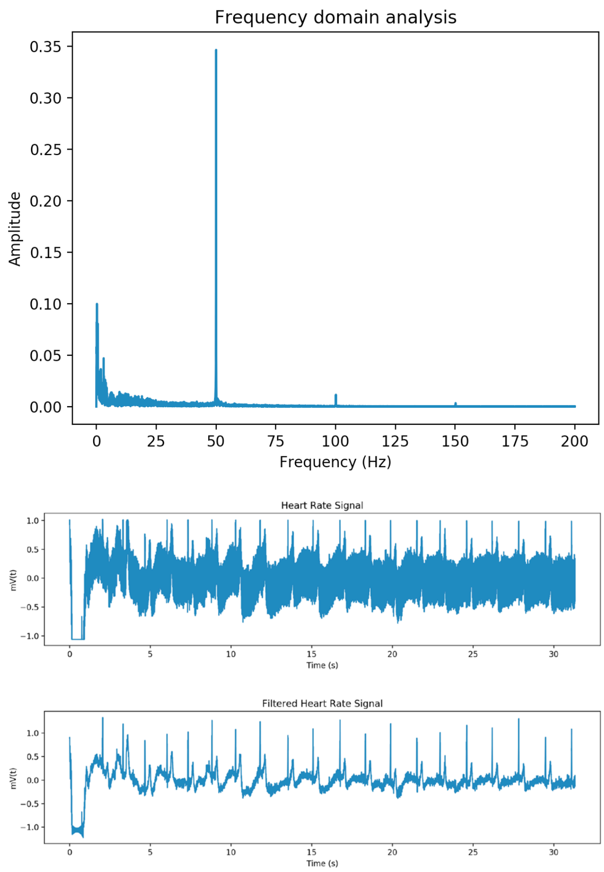


Figure 69. Top: Amplitude/Frequency (Hz) plot. Bottom: there are two graphs, the original recorded signal on top, the processed signal on bottom.

The right leg lead is a reference input to create a "fake ground". It is done using the right leg drive feedback input (RLDFB) current to level the body as a zero reference voltage, as can be seen in Figure 70.[79]

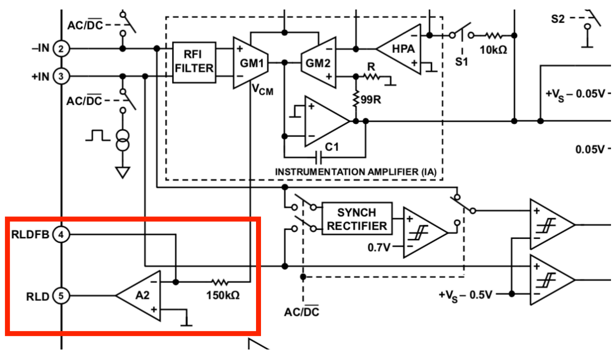


Figure 70. AD8232 Schematics. Image zoomed in the RLDFB area to illustrate the explained behaviour. Full image and data sheet in reference.[79]

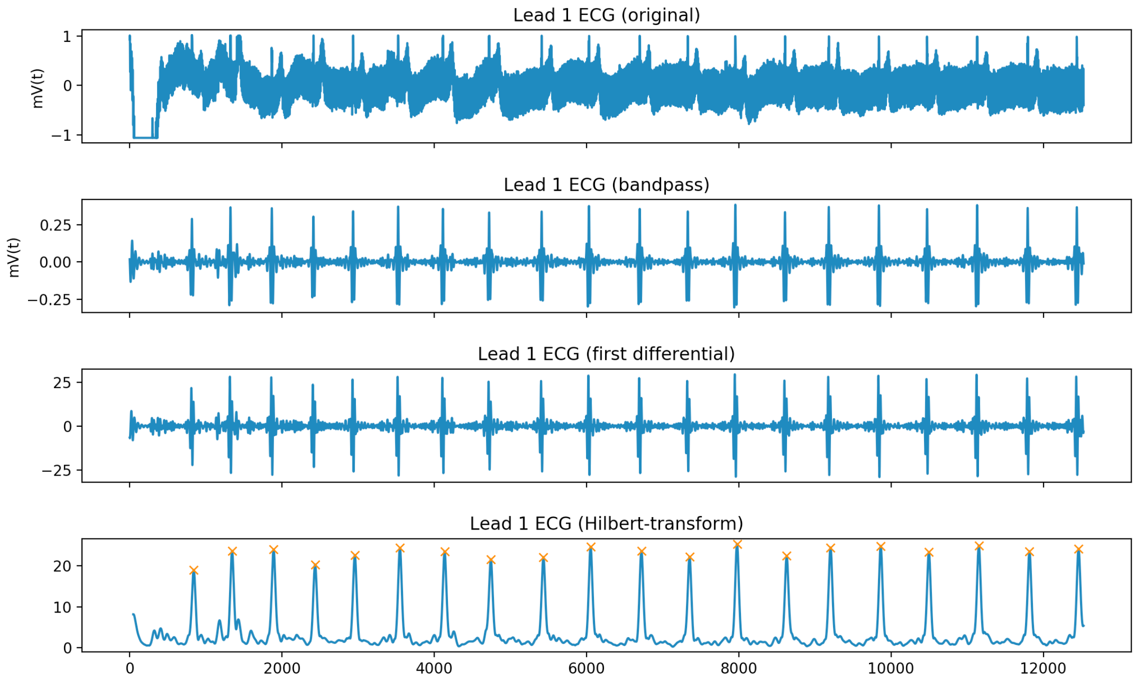


Figure 71. Filtered signal using the Hilbert-transform method.

New physical prototype

The new physical prototype is based on a keychain. The purpose is to have it always portable, being embedded in an everyday object. It can record the ECG by pressing it with one hand against the users wrist, as shown in Figure 72.

The design includes the five LEDs and one motor of the prototype from Iteration 2. It is the same working principle. The prototype is tested with four users to unveil possible usability problems. The main results are listed below, the full user test is in Appendix E.

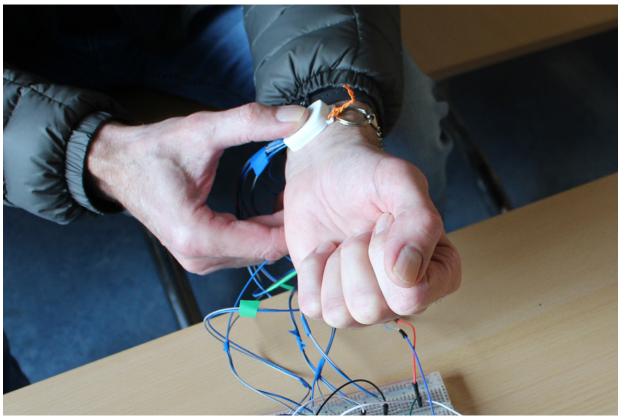


Figure 73. User holding the prototype during the user test.

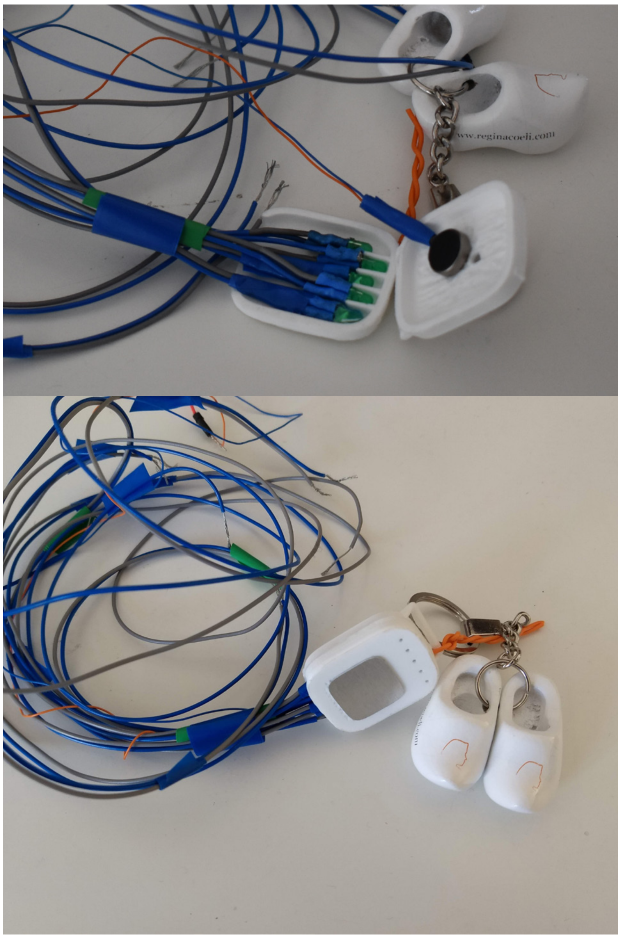


Figure 72. Physical prototype with all the cables required to operate it, the LEDs and the motor.

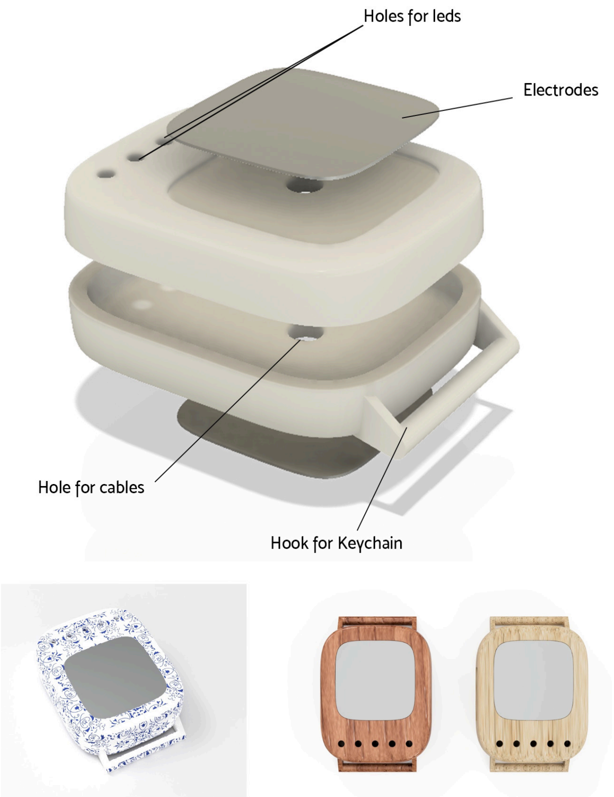


Figure 74. Prototype design and rendering.

Build Elements necessary	**Measure** Variables/Parameters to measure and Results			**Learn** Interpret Results
	Variable/Parameter	Result	Reason	
New electrodes.	Signal quality.	Good signal for detecting ECG features. Even good for visual inspection.	The material has higher conductivity, thus allows for more the impedance.	For the purpose of the prototyping stage copper-brass is good enough. For further development a more conductive material that matches the body and OpAmp impedance will be necessary.
Keychain prototype.	Usability of haptic and visual feedback. Test the application.	Patients ignored the light and understood perfectly the start and end of the recording thank to the haptic feedback. Patients used the application without any problem and valued positively the incorporation of a message system with the clinicians. The keychain is not adequate for everyone.	Patients do not pay attention to light. Probably they compare the proposed experience with KM, therefore they do not expect light. The vibration is impossible to go unnoticed. Some patients do not have keychain.	Although patients ignore light feedback, it is an important feature. During a meeting with chair and mentors it was agreed that the having a double-check system (vibration+light) is necessary to ensure safety. It was also decided to move from keychain to necklace to improve experience.

Table 7. Iteration 3 cycle.

9.4 Forth and Final Iteration

The code used in this iteration can be find in the Folder Prototyping/Iteration 4. The aim of this iteration is to:

- Embody the design into a necklace to test it as discussed in Table 7.
- Modify electronics to improve signal acquisition after expert consultation.
- Develop a final design for the product. It must reflect the conclusions of the report.

Embody the Design into a Necklace

During the last meeting it was discussed with the Chair and Mentors that moving the device from a keychain to a necklace could provide an improved experience to patients. As soon the patient feels that it is necessary to record an ECG, he or she can press the necklace with the right hand against the chest, near the heart. The proximity to the heart makes it convenient and natural.

To test this solution and the quality of the record, a simple prototype is developed. It includes 3 leads, two for the right hand and one for the chest. In previous iterations working with the AD8232 sensor has proven to be better more accurate if the RLD is derived from the right hand instead of being left out.

Figure 75. Necklace prototype to test against the chest. Two electrodes on one side, one on the other.

Testing the prototype in the chest

The prototype is tested two times with two users, a man and a woman. The device is placed as seen in Figure 76. The results are very good because the features can be extracted and the signal is appropriate to differentiate the main waves of the heart. P, QRS and T. The results can be seen in the next page.

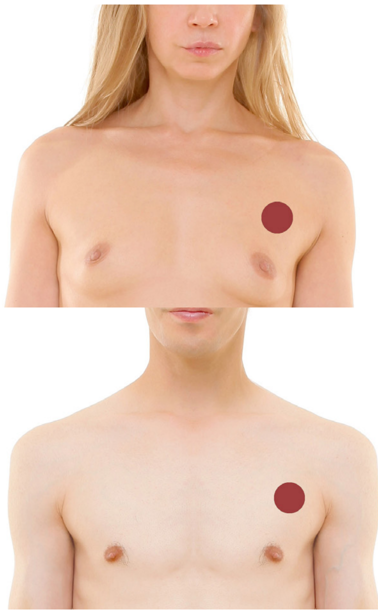


Figure 76. The spot where the device is placed. [Public domain image of Human Body by Mikael Häggström]

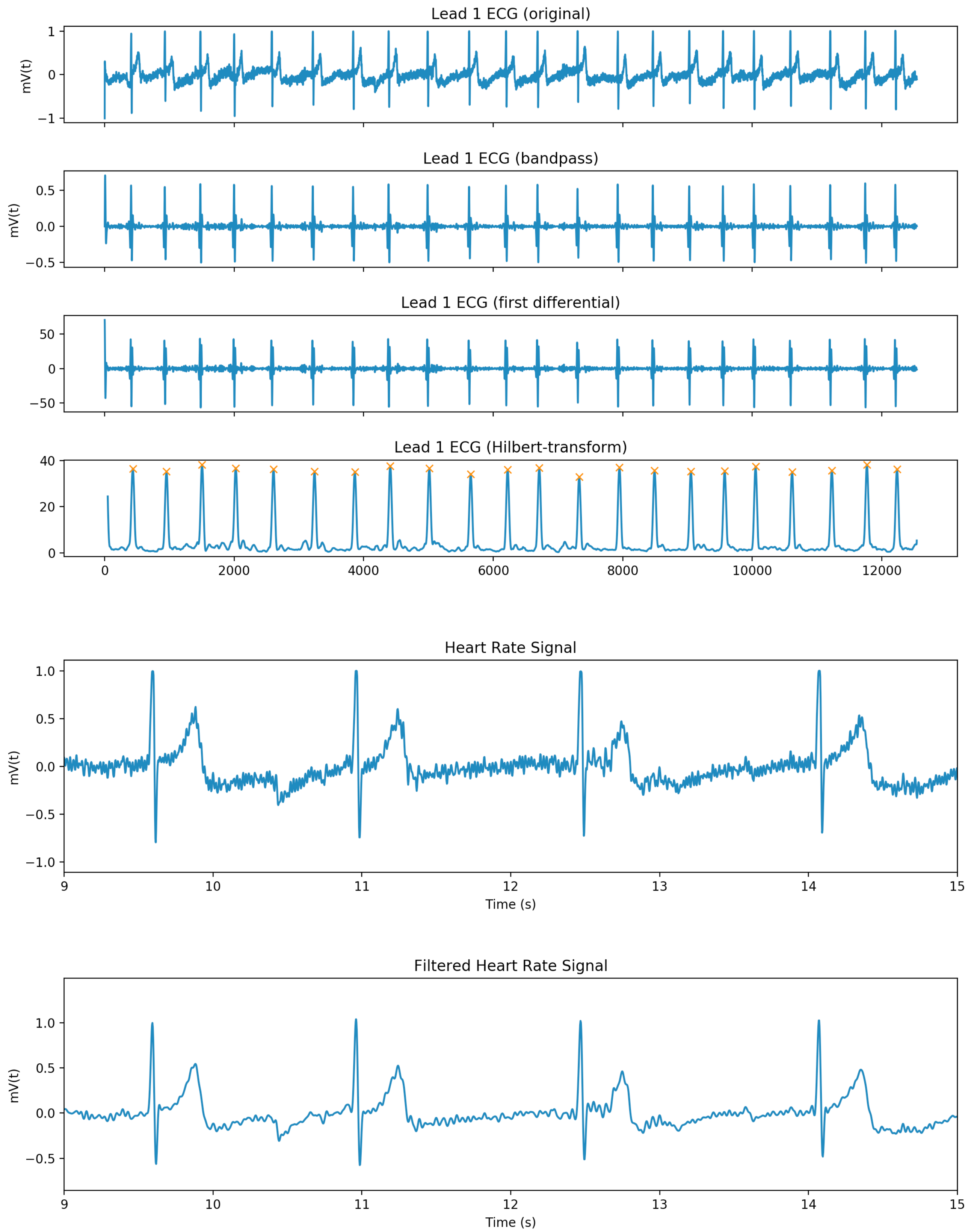


Figure 77. User 1, test 1. Top: Peak detection using the Hilbert-transform method. Bottom: Sample of the signal, from second 9 to 15. The signal is filtered from 0.5 to 40Hz an then a Savgol filter is applied to smooth the curvature with low distortion.

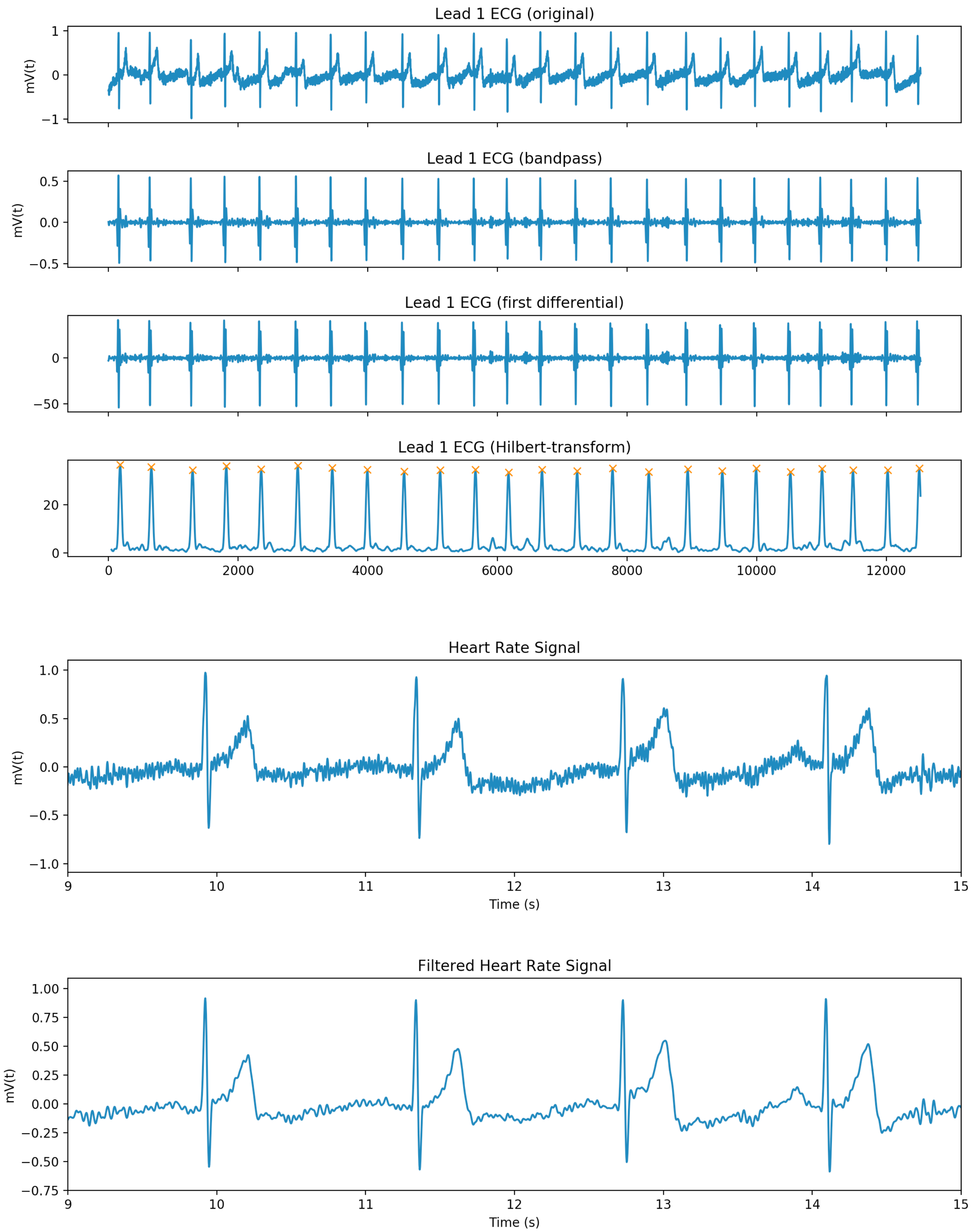


Figure 78. User 1, test 2. Top: Peak detection using the Hilbert-transform method. Bottom: Sample of the signal, from second 9 to 15. The signal is filtered from 0.5 to 40Hz an then a Savgol filter is applied to smooth the curvature with low distortion.

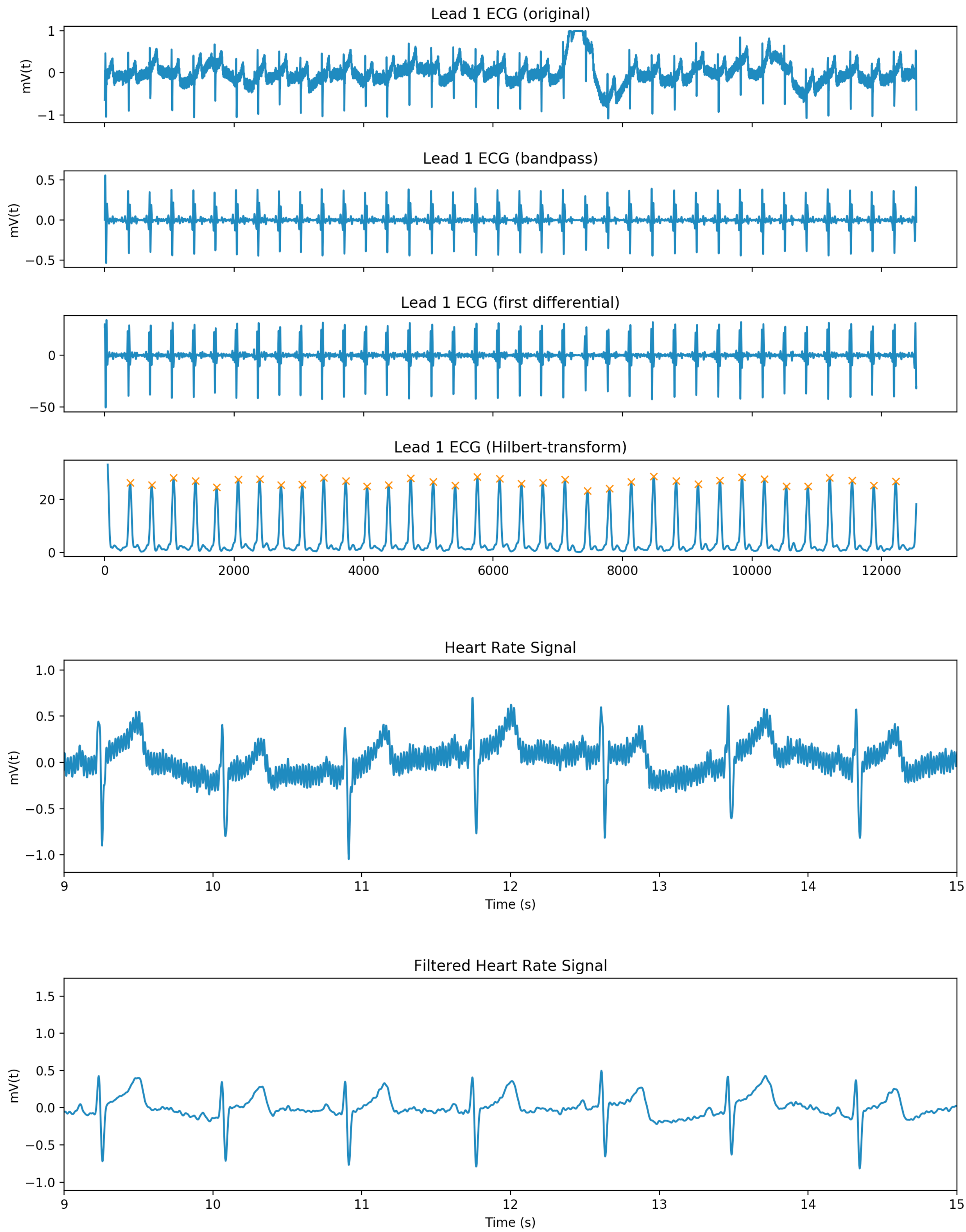


Figure 79. User 2, test 1. Top: Peak detection using the Hilbert-transform method. Bottom: Sample of the signal, from second 9 to 15. The signal is filtered from 0.5 to 40Hz an then a Savgol filter is applied to smooth the curvature with low distortion.

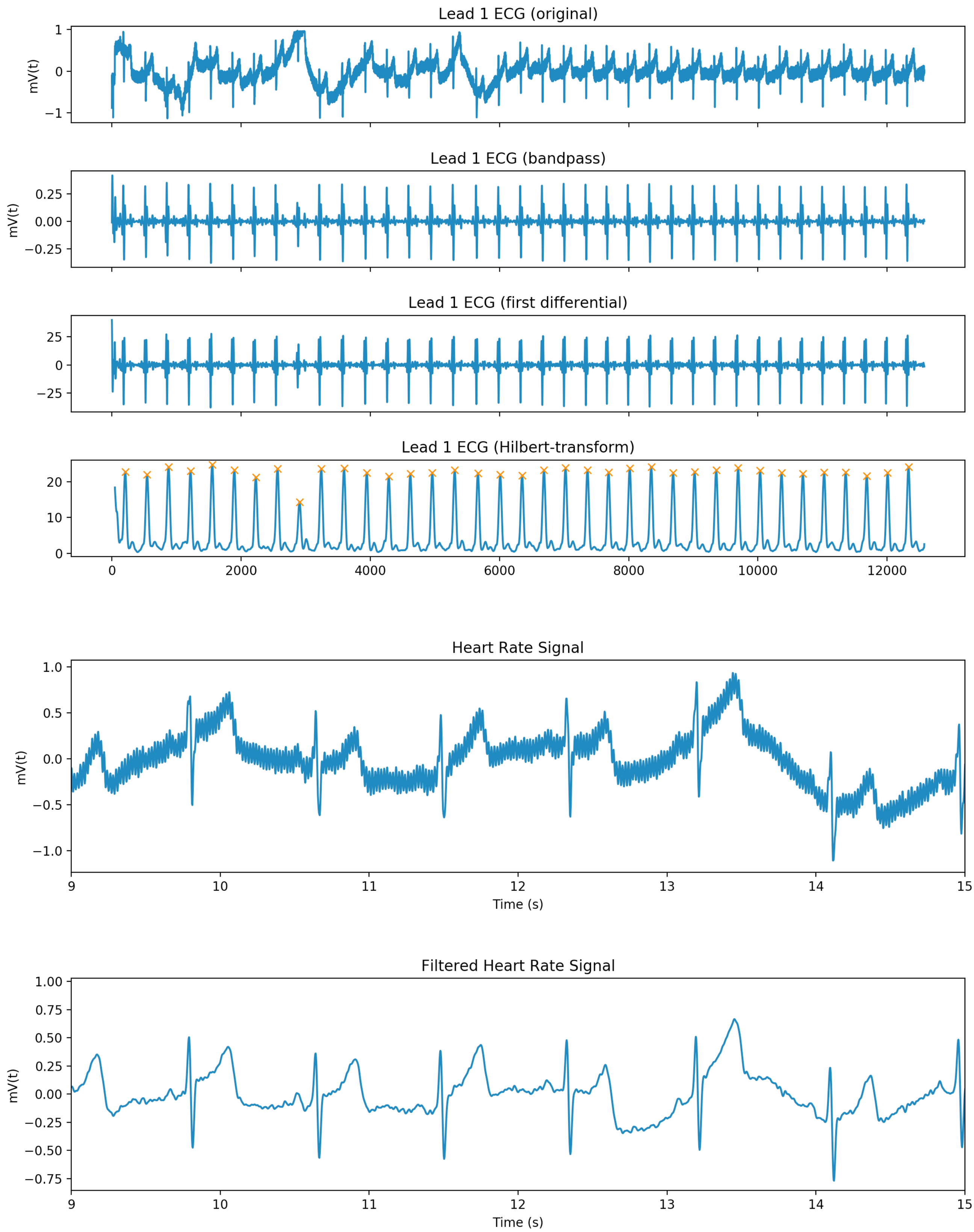


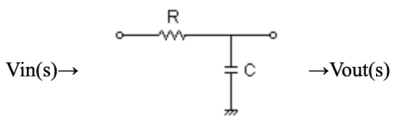
Figure 80. User 2, test 2. Top: Peak detection using the Hilbert-transform method. Bottom: Sample of the signal, from second 9 to 15. The signal is filtered from 0.5 to 40Hz an then a Savgol filter is applied to smooth the curvature with low distortion.

Improve Signal Acquisition

Several circuits are prototyped upon expert consultation in order to reduce the noise and acquire a better signal. Below are the circuits and the results.

1. Filter the signal with an RC lowpass filter

To reduce the noise a RC low-pass filter is placed between the electrodes and the inputs of the sensor. The 3 leads are connected to a resistor of 47kΩ and a capacitor of 68nF as shown in Figure 80. The leads are connected to a breadboard. This circuit should filter frequencies higher than 49.79Hz. The result is more noise and signal distortion.



$$f_c = \frac{1}{2\pi\tau} = \frac{1}{2\pi RC}$$

Figure 81. Low-pass filter design.

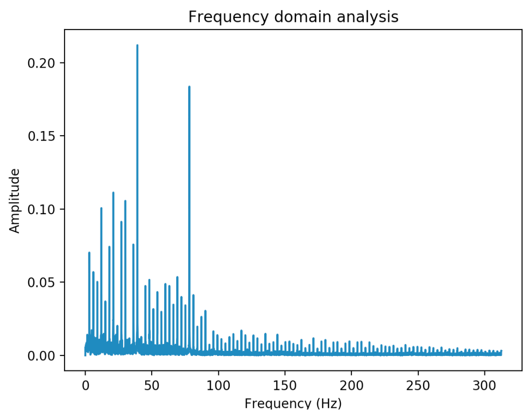


Figure 82. Frequency domain analysis of the acquired signal. Noise peaks can be seen along the whole signal, especially the areas of interest for the ECG analysis (0.5 to 40Hz).

Filter the signal using a simple OpAmp set-up

Another alternative is to use a single OpAmp with a custom circuit to obtain a high frequency signal to be processed later[80]. The chosen OpAmp is the MCP6241. The circuit and the result can be seen in Figure 83.

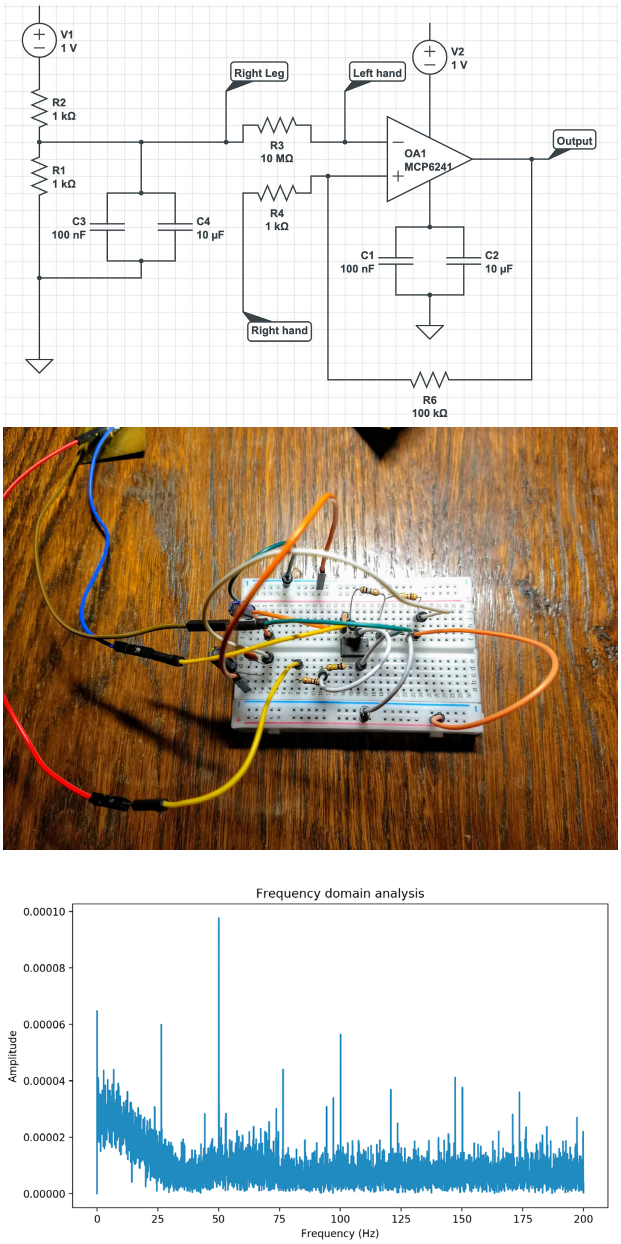


Figure 83. Top: Circuit schematics.
Middle: Circuit implementation. Bottom: Frequency domain analysis result.

AD8232 in a breakout module

The AD8232 chip that powers the sensor is bought separately with a breakout module to modify the values of the resistor capacitors in order to improve noise reduction and enable the usage of two hands without the RLD.

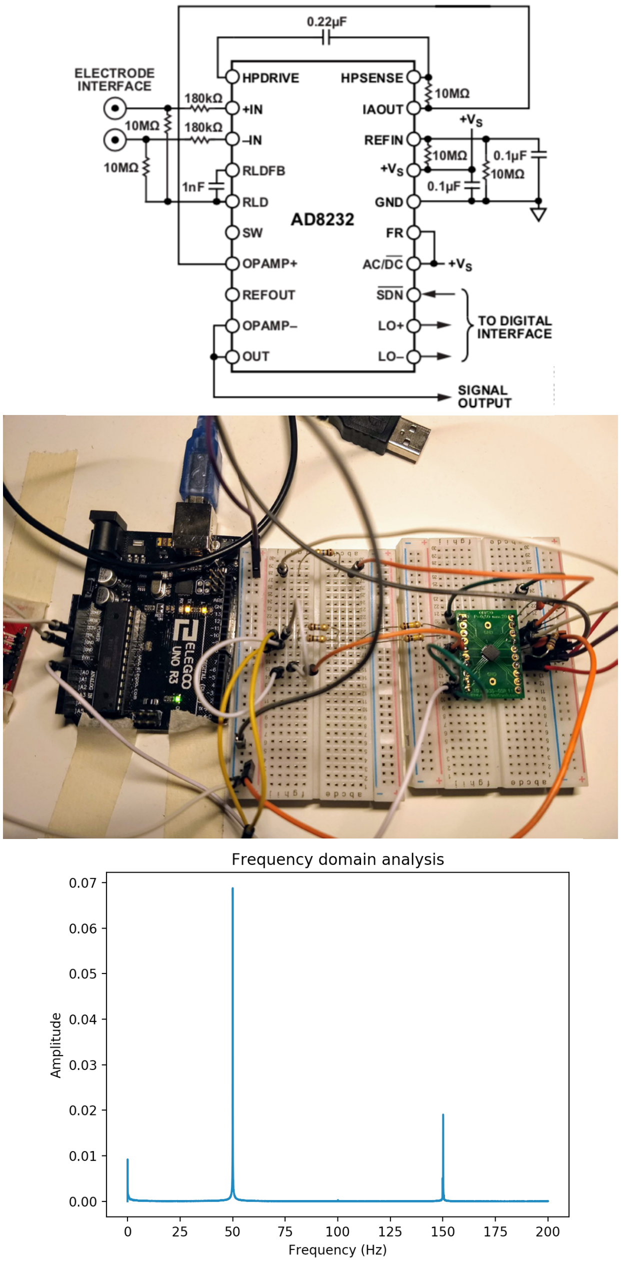


Figure 84.Top: Circuit schematics.
Middle: Circuit implementation. Bottom: Frequency domain analysis results.

Comments on the results

None of the mentioned circuits improves the noise reduction. All of them have been tested several times, placed in a Faraday cage and inspected with an oscilloscope to find failures.

The problems of the circuit are related with:

- The electrodes: A better material is needed to improve conductivity.
- Better isolation: Using metallic electrodes that completely protect the circuit greatly reduces noise.
- Using a PCB: Cables, resistors, capacitors, the breadboard, etc. All of them increase noise, therefore the noise and saturation of the signal.
- Better OpAmp: Using a different OpAmp as the AD620, the gain is 10 times higher.

Final Design

The final design is a necklace, a personal, fashion element and a product that the user may display in public. It is necessary to escape from the medical design.

The users evaluated the products as well designed, but not as exceptional. In conversations with them (see Chapter 6) it is clear that the products are not visceral, are dull, are merely OK. This situation must be changed by design - the product becomes personal if it reflects the user's personality. In addition, in conversations with Prof. dr. D.E. Atsma Ph.D. (Chapter 5), he stresses the need to make medical devices an everyday product, such as the bath scale.

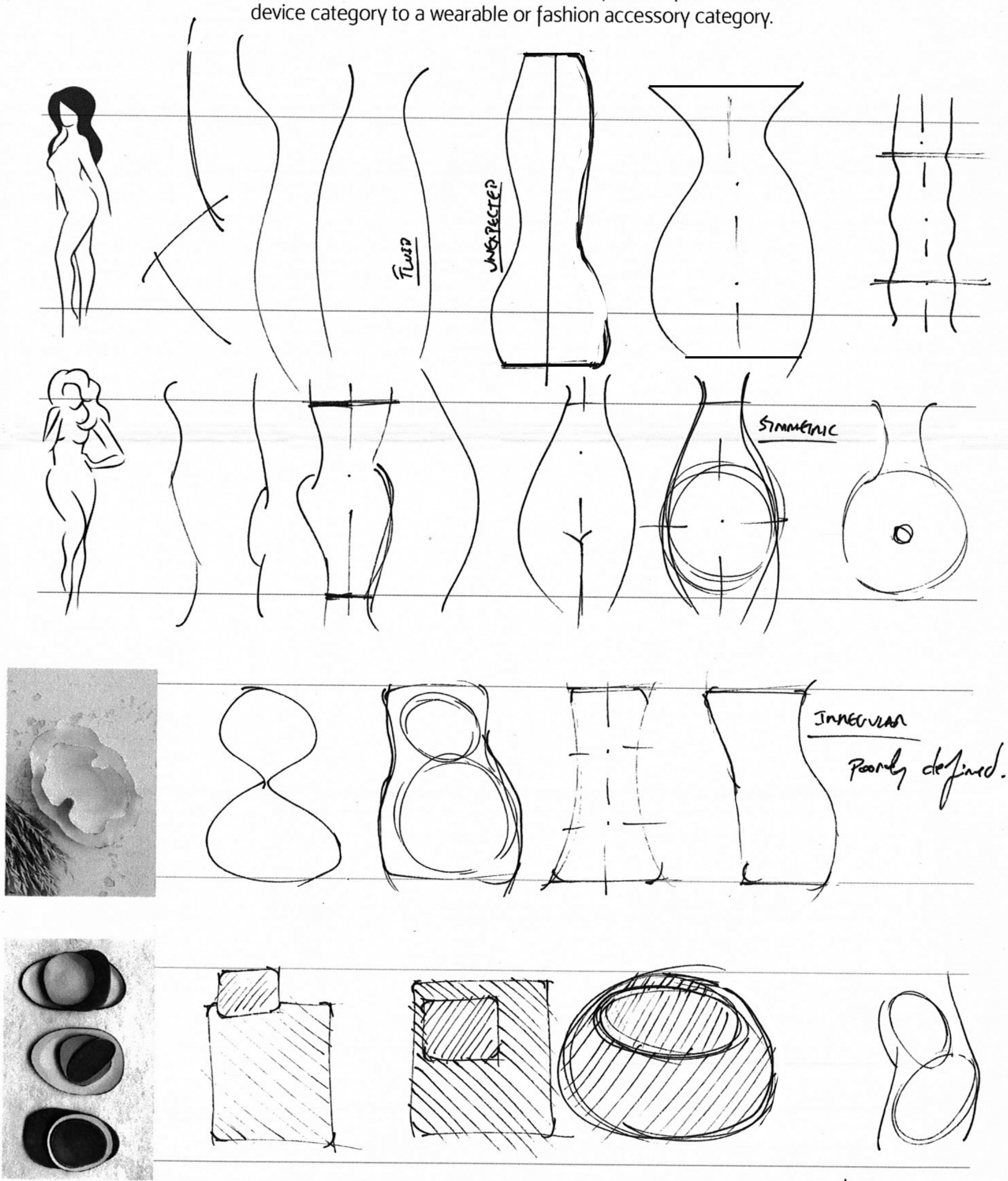
To differentiate the products, the aesthetic features of the medical devices that have been analysed during the thesis are listed below:

- Usage of white, grey and black.
- Usage of metal and plastic.
- Usage of basic shapes.

The new design should be different in these 3 levels. In the next pages the form giving is shown.

Form finding

Use organic shapes and colors to move the product from a medical device category to a wearable or fashion accessory category.

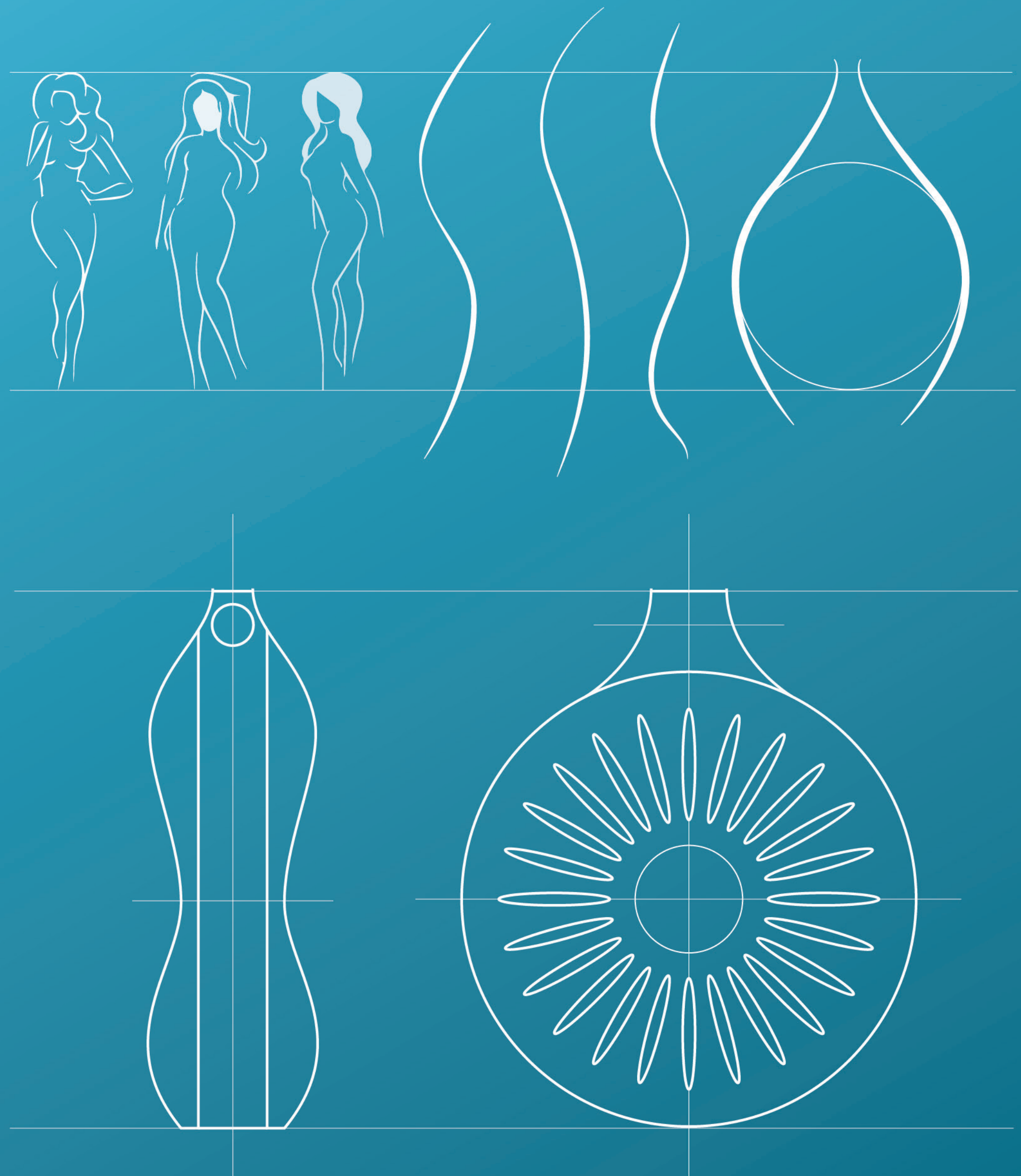


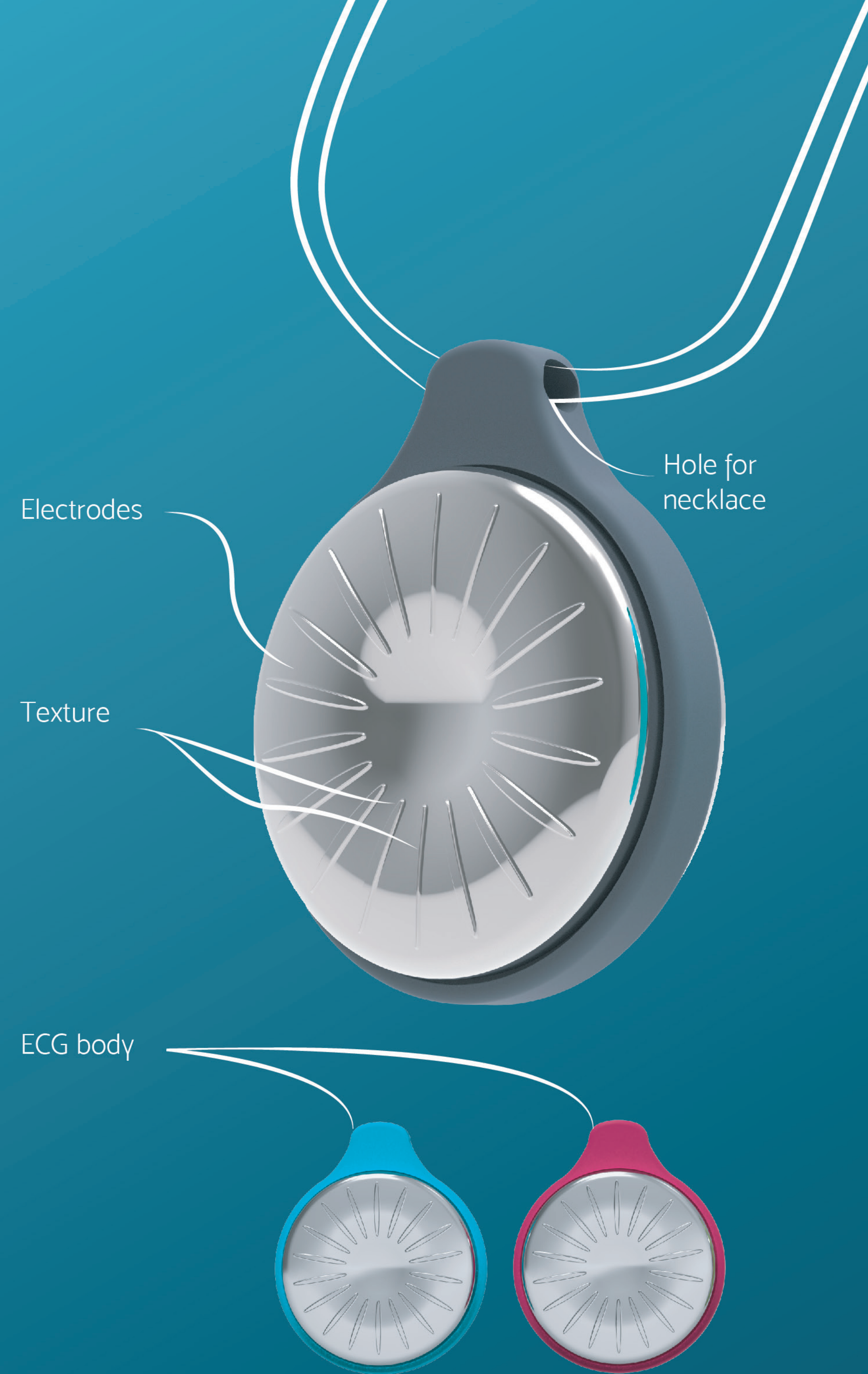
NON-SYMMETRY = BAD

NO BALANCE.

Body Necklace

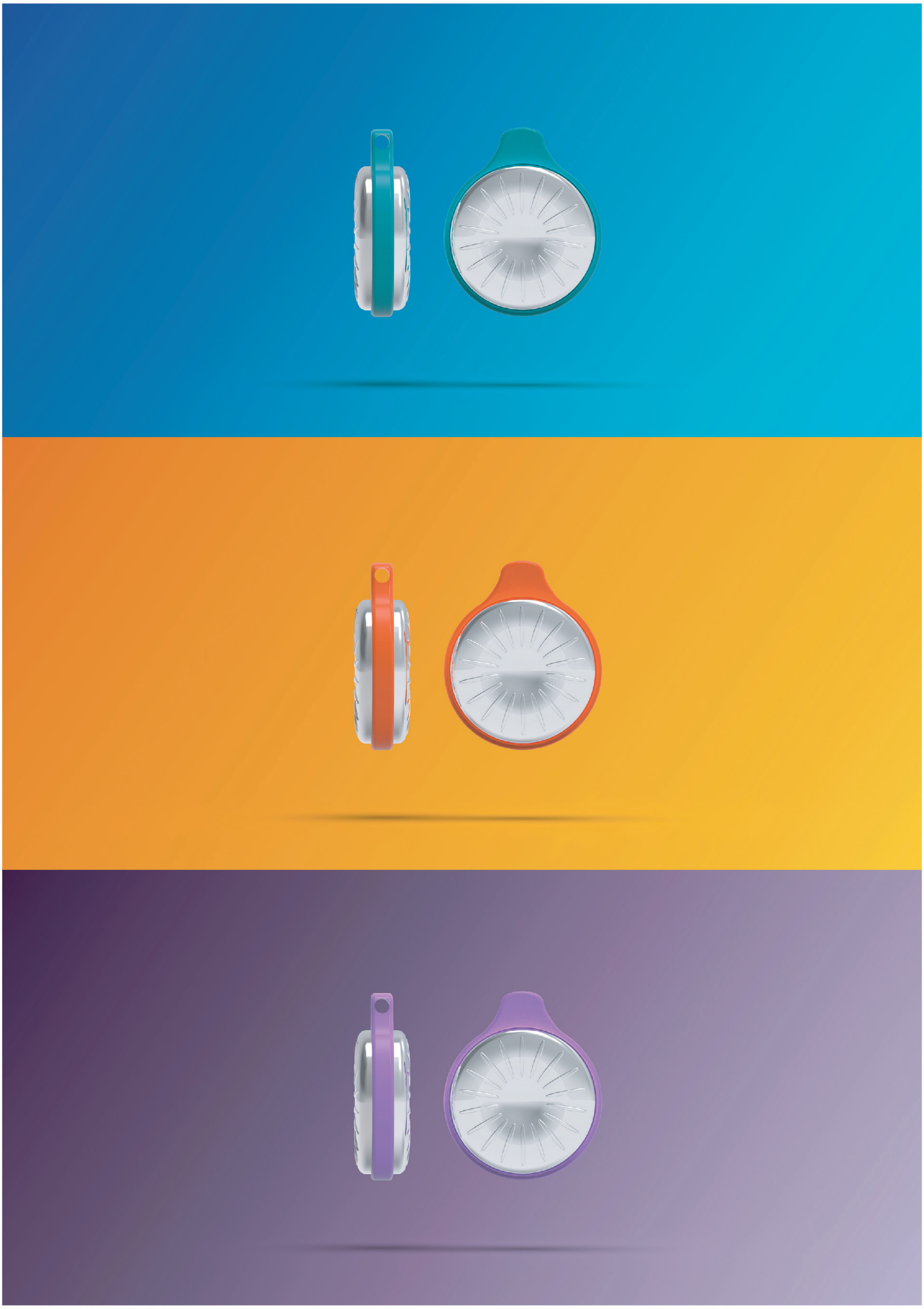
Simple, symmetric and curvy necklace inspired by the human body. The electrodes become the canvas, providing shape and texture, while the body provides a touch of color.





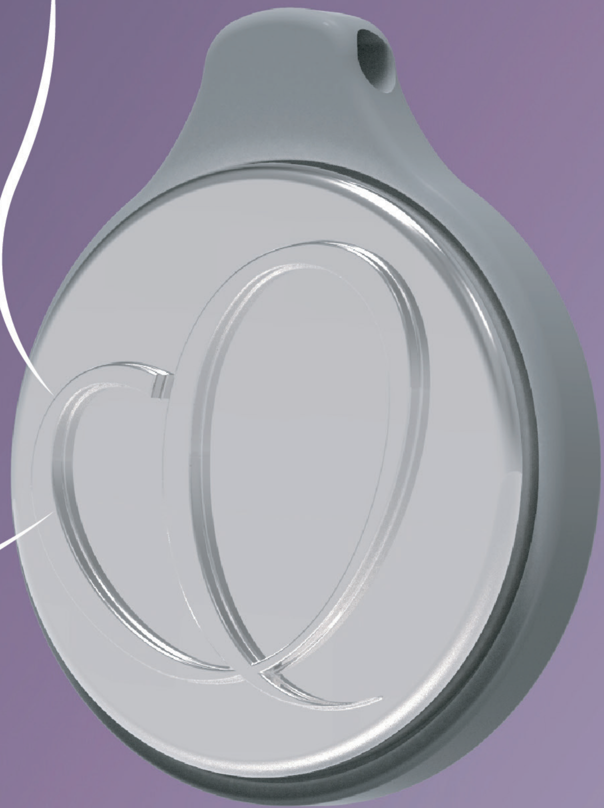
Colours

Colour is attractive and draws the user attention. It is an important feature to shape the user feeling and attachment towards the product because colour association is very personal.



In the new design the electrodes are the canvas. Therefore it can reflect the company, or in this case the Logo of the Hart Long Centrum of the LUMC.

The irregularities, logos or patterns of the surface is functional. They help to get a proper signal in a hairy chest.



Product Construction

This section will explain step by step the product assembly and construction. It is built for the purpose of having a complete prototype to test with users, based on the results of the last iteration. It is a necessary step before the zero-series and mass production.

During this iteration the results provided two key insights. On the one hand, **it is necessary to use a custom PCB to avoid noise and move forward**. The AD8232 chip provides a clear signal when it is used with three fingers. Many circuit alternatives were tested upon expert recommendation and review, but were not capable of suppressing the noise. The source of the noise is mainly caused by the breadboard, the distances between the components and the usage of cables. The result is a noisy signal from which is not possible to subtract HRV features.

On the other hand, it is necessary to build **stainless steel electrodes**. According to literature review stainless steel should perform well compared to Ag/AgCl electrodes[81], which are considered the standard. Moreover, it can be silver plated to improve conductivity and corrosion resistance. Compared to the available materials, stainless steel 316 (common in medical devices) properly machined and polished will increase the accuracy of the readings.

Provided those changes, a complete functional and aesthetic prototype can be produced to test with users.

General view

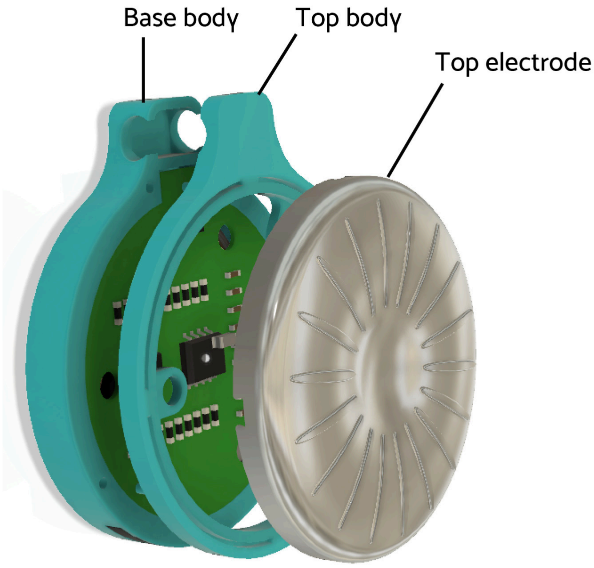


Figure 85. General view 1.

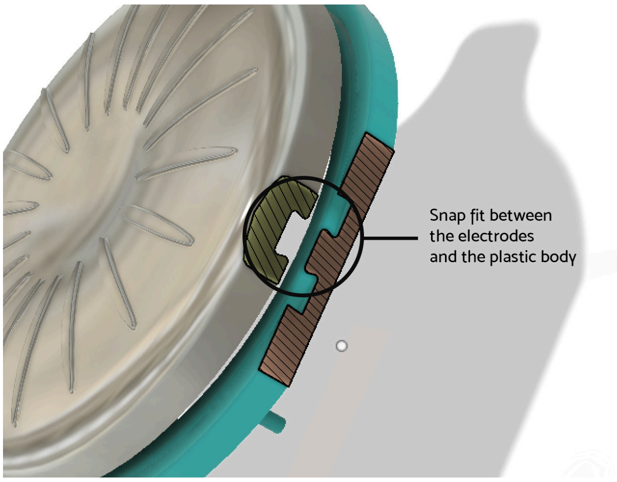


Figure 86. Snap fit between electrodes and body.

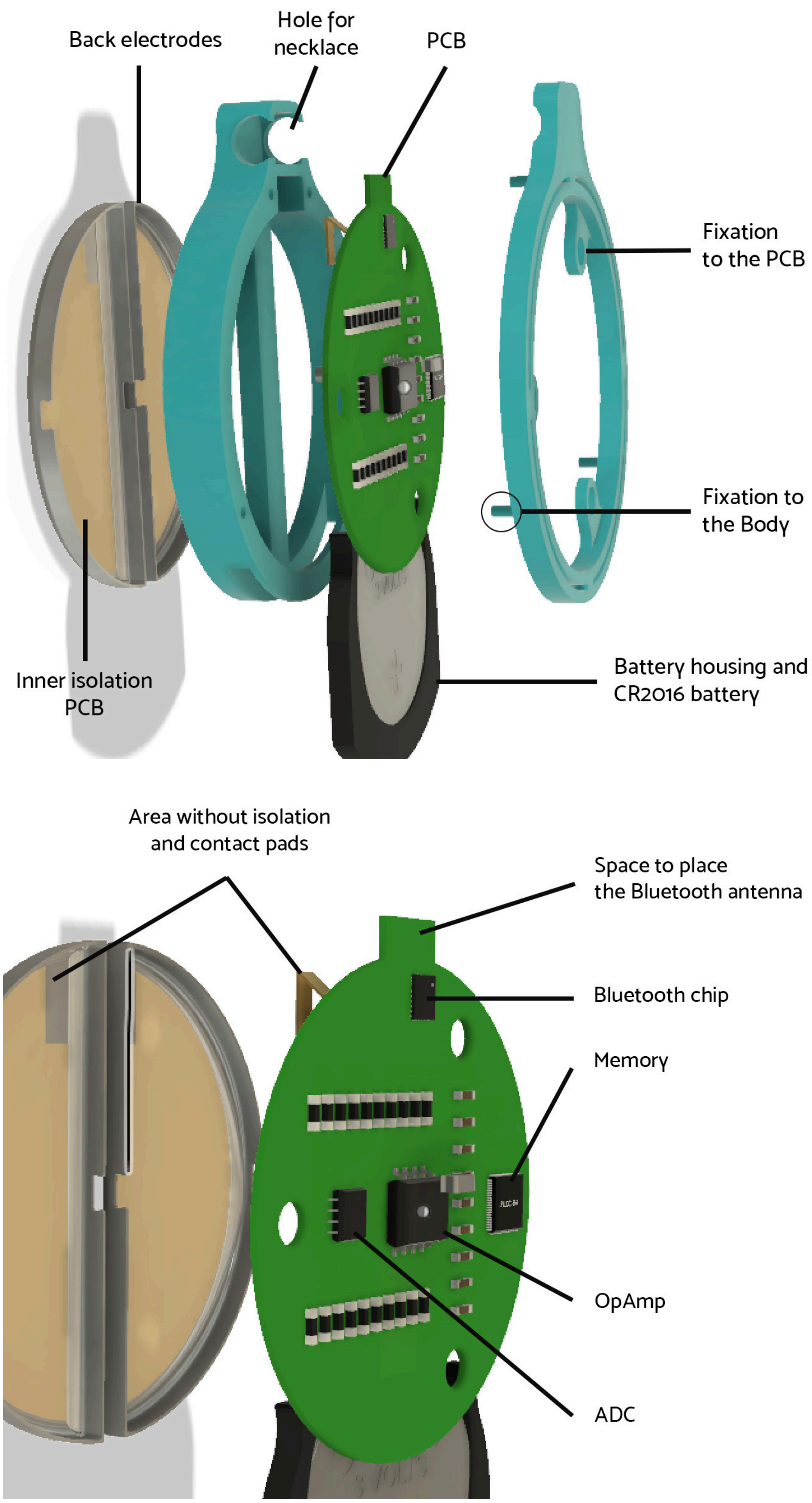


Figure 87. Top: general view 2. Bottom: detailed view of electronic components and contact area with the electrode pads incorporated in the PCB.

The main elements of the construction have been represented in Figures 85, 86 and 87. The full 3D assembly is included in the folder Prototyping/Iteration 4.

Clarifications:

- Max width: 35.2mm.
- Max height: 12mm.
- Max length: 42mm.
- The snap-fit between the electrodes and the body requires the usage of epoxy resin to seal it. As seen in other products such as the Nokia WiFi scale.
- The fixation between the body parts requires the usage of epoxy. The design is intended for 3D printing with the Connex 350 printer. Using snap-fits will require larger space and the product will be less secure.
- The fixation between the body parts and the PCB is done using screw holes on the PCB, as seen in Figure 88. It reduces size.
- The LED goes near the antenna. It is necessary to use two materials in the Connex 350 to have a transparent area.

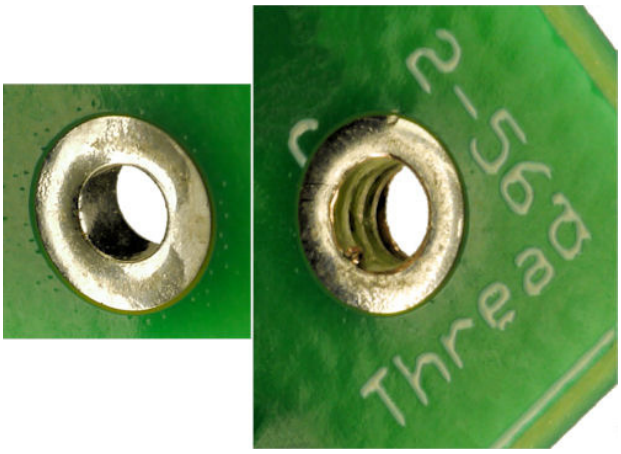


Figure 88. Screw holes.[82]

Final Components

Table 8 summarizes the recommended components process and cost for the next iteration. The cost of the prototype is 208.37€

Although the cost of production may be affected by the results of the next iteration, perhaps components need to be changed, etc. An estimation from online providers (Table 8) and buying units in order of thousands could reduce the cost of metal and PCB drastically. Resulting in a product of 39€ or less.

Component	Description	Process	Price
OpAmp	Current operation amplifier, the AD8232.	Buy from mouser.com	0€, available unit.
Stainless steel 316 electrodes	Good corrosion support and enough conductivity for the electrodes. It will require CNC and good finishing.	Buy from goodfellow.com and/or metalsdepot.com Stamping	100€ for 0.25mm thickness 0.5m surface.
Body.	Body of the prototype.	Print with Connex 350 for accuracy and finishing.	30€
PCB.	To assemble the components.	Buy from eurocircuits.com	43.98€
Resistors and capacitors	To build the circuit.	Multiple providers.	5€
ADC	To sample the signal. Model AD4111.	Buy from mouser.com	13.66€
Bluetooth	Bluetooth low energy Silicon Labs BGX13S22GA-V21R	Buy from mouser.com	8.73€
Memory Flash	Paralllel Flash memory, from 1mb to 64mb.	Buy from mouser.com	2€
Isolation tape	To isolate the electrode body from the electronics.	Buy from kiwielectronics.nl	5€.

Table 8. Final components.

Application

One change is introduced in the application, the main image to indicate how to measure. Moreover it is important to mention that the design, colours, text size and distribution is compliant with the Web Content Accessibility Guidelines (WCAG) 2.1.[83]

From September 2019, it is mandatory to use this regulation in new applications and websites from public institutions.[84]

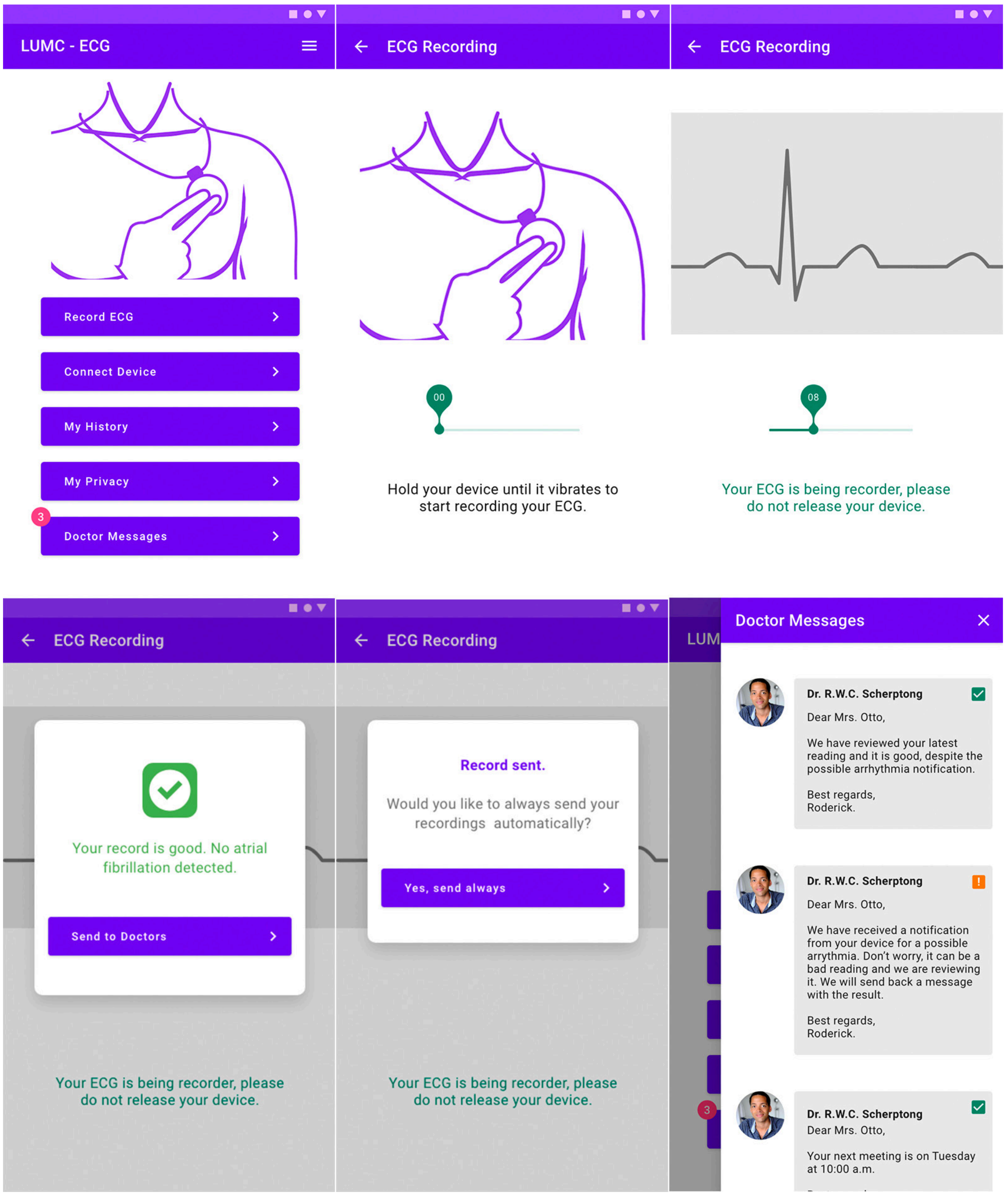


Figure 89. Application screens in order. Left to right, top to bottom. Top left: initial screen. Top middle: initiation of the recording. Top right: recording. Bottom left: result with option to send to the doctors. Bottom middle: reminder to send or not the record. Bottom right: message system with the doctor.

Steps comparison

The steps required to perform a record are compared with KM, in an hypothetical situation. It is done in Table 9. The purpose is to have an overview of the different steps required by both products. It does not involve time though.

It is done comparing the KM steps and the Body Necklace steps (both already described in different sections of the report). Two cases are proposed as examples for the body necklace.

Product	Situation	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
KM.	Winter. The patient is coming back from the office. Waiting for the train in the station. Feels palpitations and fatigue.	The patient finds a place to sit.	Looks for the mobile device.	Looks for KM if not attached (none of the interviewed patients had it attached).	Open the application. Click record.	Place the phone and KM device on a surface.	See the record.
Body Necklace. Case 1: The patient does not a live recording.		The patient finds a place to sit.	Open slightly the jacket/coat.	Press with two fingers the necklace against the left side of the chest. Feel the vibration.	Feel the vibration again.		
Body Necklace. Case 1: The patient does a live recording.		The patient finds a place to sit.	Open slightly the jacket/coat.	Looks for the mobile.	Open the application. Click record.	Press with two fingers the necklace against the left side of the chest. Feel the vibration.	See the record and feel the vibration again.

Table 9. Steps comparison.

HRV Features and k-NN Algorithm

HRV features can be grouped in five categories. Please note that (normal-to-normal beat) NN means normal beats. It is used to indicate that those are processed RR beats.[85]

- Time-domain, based on the beat-to-beat intervals. Some features are the SDNN (standard deviation) and RMSSD (root mean square of successive differences), pNN50, the proportion of NN50 divided by total number of NNs.
- Frequency-domain, which assigns different bands of frequency and count the number of NN. The frequency bands are low frequency (LF), high frequency (HF) and very low frequency (VLF).
- Non-linear methods.
- Long term correlations.
- Geometric methods.

From the five categories, time-domain, frequency-domain and non-linear features are commonly used to develop algorithms that classify arrhythmia. For the purpose of this thesis a basic algorithm based on the RMSSD and pNN50 is developed. It is chosen because RMSSD is higher in people with arrhythmia as the beats are more irregular than in patients with regular heart beat[86]. Moreover, the current prototype has noise contamination in the 0.5-40Hz frequency, which makes frequency-domain analysis not convenient at this stage. The algorithm can be improved in next iterations to include more features.

k-NN algorithm

k-NN is a non-parametric method used for classification and regression. It is one of the simplest algorithms for supervised machine learning, yet one of the most successful in AF detection. The algorithm uses the already classified datasets to compare new data, the new data will be classified according to the most similar datasets.

The implementation for this case will use the normalized RMSSD (nRMSSD) and the pNN50 attributes to classify the four recordings acquired in this iteration.

The algorithm is trained as follows:

- 40 dataset for training the algorithm are used. The data is acquired from PhysioNet/Cinc Challenge 2017. The 20 first AF and the 20 first non AF (NAF) records are taken.[87]
- The data is processed individually using the previously developed RR detector algorithm and parsed to a new dataset that contains the rNMSSD, pNN50 and the type (AF, or NAF)

The code and executable can be found in Prototype/Iteration-4, the table with the results can be found in the next page.

The results are good. The algorithm classifies the user tests done in this iteration as:

- User 1 - Test 1: AF detected with 1, 3 and 5 neighbours. The nearest neighbours on the table are rows 7, 10, 6, 28, 16.
- User 1 - Test 2: AF detected with 1, 3 and 5 neighbours. The nearest neighbours on the table are rows 8, 0, 13, 11 and 9.
- User 2 - Test 1: NAF.
- User 2 - Test 2: NAF.

Record #	nRMSSD	pNN50	Type
1	0.2496161029	0.8214285714	AF
2	0.4907513241	0.6448598131	AF
3	0.2490355312	0.6590909091	AF
4	0.379320949	0.9615384615	AF
5	0.2651933918	0.7857142857	AF
6	0.3657206232	0.8611111111	AF
7	0.1726836562	0.6756756757	AF
8	0.180707638	0.5681818182	AF
9	0.2656078441	0.9183673469	AF
10	0.2753474547	0.8108108108	AF
11	0.2120503996	0.5918367347	AF
12	0.2754463849	0.8461538462	AF
13	0.2241995329	0.2258064516	AF
14	0.2762847585	0.8571428571	AF
15	0.3975087698	0.8	AF
16	0.2892945899	0.75	AF
17	0.0756071147	0.4210526316	AF
18	0.4761090746	0.7288135593	AF
19	0.4266984356	0.84375	AF
20	0.3748986283	0.6444444444	AF
21	0.03075589882	0.02777777778	NAF
22	0.3130276427	0.4242424242	NAF
23	0.1502226789	0.25	NAF
24	0.0414515682	0.1923076923	NAF
25	0.03164585411	0.1111111111	NAF
26	0.01336648226	0	NAF
27	0.1176871711	0.4242424242	NAF
28	0.03056232422	0.06666666667	NAF
29	0.05157575101	0.4285714286	NAF
30	0.1555395106	0.1538461538	NAF
31	0.02608293242	0.04347826087	NAF
32	0.1187883568	0.1333333333	NAF
33	0.03099486605	0	NAF
34	0.01338760285	0	NAF
35	0.009196937574	0	NAF
36	0.01022384837	0	NAF
37	0.01262007086	0	NAF
38	0.04377667294	0.1153846154	NAF
39	0.02616233024	0.03703703704	NAF
40	0.02358042483	0	NAF
User tests from Iteration 4			
User 1 - Test 1	0.07380574216	0.5714285714	AF (with 1, 3 and 5) neighbours
User 1 - Test 2	0.1141833382	0.8947368421	AF (with 1, 3 and 5) neighbours
User 2 - Test 1	0.01948750746	0.0303030303	NAF
User 2 - Test 2	0.02446770645	0.05882352941	NAF

Table 10. Features process and kNN results

Chapter 10

Recommendations

Recommendations for the hospital and other students.

Recommendations for the Hospital

Many insights have been found during this project, below are some general recommendations that summarize them. They are divided in two categories, recommendations to continue the project, and recommendations to improve the Box.

To Continue the Project

The first step is to test the prototype with patients, for which it will be necessary to:

1. Build the body

A quality 3D printing, such as the Connex Object 350, which is available at TU Delft is recommended to build the body. It will provide the desired structure and finish to make it suitable for patient test.

2. Develop the electronics

The general outlines have been drawn, the components named and an approximate price have been given. The code to run and build the application is ready. There is some effort left to put it together and code the low-level C/C++ required for the electronic components. It is also necessary to implement a method to discard bad readings and notify the user to record again.

3. Give it to 12 Users and Perform Interviews

There is nothing better to understand if a product is viable, desired and useful than testing it with users. The proposed test is:

- Instruct the patients to use it for 7 days, doing a record every day.
- Prepare an expected outcome journey in a table fashion way, such as the one included in Appendix E.
- Ask the users to evaluate from 1 to 5 the experience at each point to obtain valuable information.

The steps are a simplified approach to patient experience. I will be glad to continue and prepare a thorough test that will provide more insights if required in the future.

To Improve the Product Service

1. Use less products

It is important that patients are monitored, but the focus should be on the behavioural change. All the patients, healthy and non-healthy face a big change after MI. It is necessary to direct all their energy and attention to that and not to devices or other tasks.

As seen in Chapter 6, one of the patients had problems with a the BP. The nurse had to call him and measure the BP at the hospital, compare with the device if it works properly and look into the device. The attention was shifted from taking care of the patient to taking care of the device. It is not a tragic or huge problem, but with the small amount of time (15 minutes per patient), a few minutes spent on focusing on the devices reduce the quality of the visit.

2. Use the same technology

It will reduce compatibility problems for the patients and workload for the technician and clinicians.

3. Improve communication

Patients seek for reassurance and it is only real when it comes from doctors, not from devices. Automated messages can greatly improve the experience if they feel personal and human, for example, using the face of the doctor that the patient will visit.

4. Identify and group patients with special needs

It was an expressed need from the hospital mentor to attend them, but it was not possible to have access to them. During the elaboration of the thesis there were discussions about elderly people with difficulties, how to design for them. As a designer, I was tempted to try to design for them. Nevertheless, it is bad practice and was not carried out. Without experiencing first-hand what are their difficulties and properly defining the group, it is impossible to design for them.

5. Develop more products

Not necessarily to launch them or produce them, but because it forces the stakeholders to come together around the same problem.

Recommendations for fellow students

There were many difficulties in this project which I want to share in order to save you a great amount of time. Here is a set of resources and thoughts to dive deep and fast into different areas that were crucial in such a project.

The Elderly Understand

During the elaboration of this thesis and previous interviews with patients my view on elderly people changed. The elderly people do not need to be protected from reality, they can learn and evaluate systems and services as well as anyone else. In conversations with other students, experts and in previous Medisign electives we all assumed how the elderly people are. The discourse is that they need easy, pleasant and non-scary products or services. Looking back it was a mistake, some specific elderly groups may have a special need, in any case, no one knows what that need is until they are interviewed and observed in a specific context.

Basics of ECG Biosignals

Nothing better than the Khan Academy to understand the circulatory system and the heart electrical signals. The combination of well structured lessons and videos makes it easier to find and watch the required content for the project.[88]

Electronics

As an expert said to me, working with low-frequency signals is difficult. The introduction to electronics course from Coursera will give you the basics to understand electronics, analogue filtering, OpAmps and other relevant information.[89]

Signal Processing

The Discrete-Time signal processing Edx course from the MIT is an excellent, although advanced resource. [90]

Python and SciPy

The best book to get started with Python and SciPy that I could found was Elegant SciPy, free and well structured.[91]

Work With a Friend

To speed up the process, make it easier and funny work with a friend who is facing the same challenge as you. Working with Filippo and Federico helped to share ideas, knowledge and advance faster.

Chapter 11

Reflections

Reflections on the project, the method and other areas of interest.

On Medical Device Sustainability

This page is built upon request of Roderick and our discussion on sustainability in the medical industry.

The world is going sustainable. Many companies and governments are embracing circular design in order to reduce costs and increase products/services life-time. The end goal is to improve the impact on the triple bottom line (people, planet and profit).[92]

Thus, the question is: Why the medical industry is not embracing it?

Firstly, the question is false. Medical industry is changing and embracing sustainable design especially to reduce costs, although it is very slow. Many examples are a proof of this tendency.[93]

Secondly, innovation on medical devices is difficult and takes time. New products, treatments or services are conceived under the premises of new functionalities with the goal of improving patient outcome, patient experience or provide better care. Sustainability is not a concern at that point as the priority is to bring that new solution to the patients. Moreover, sustainability-first approach is not extended into the design of new products. This is because sustainability-first approach -design to be sustainable- is almost impossible. To prove that a solution is sustainable, or more sustainable than the state of the art, it requires to be compared with an already existing and similar one. Therefore, if the innovation focus is on new technologies, functions and services, sustainability generally comes later.

Thirdly, medical regulations enforce safety above all. In case of materials, the European regulation for medical devices (EU MDR 2017/745) does not impose the use of specific materials, but new products must be proven to be biocompatible if they are to be worn. Companies generally choose materials that have the certifications, regardless of their impact on the planet. The cost of developing new materials that comply with the certificates is very high.

Forth, much of the medical industry problem is on packaging. Too many single use products require a lot of packaging.

Finally, to improve sustainability of medical devices, a new regulation can be applied. Medical devices generally last long and are tested before going into the market and during their lifetime. Products must be tested with 75 different users every year or every two years to behold the CE mark. Moreover, extensive reports on different aspects of the product must be kept updated. The constant monitoring of the devices forces companies to maintain good documentation on the product. Just enforcing a sustainability assessment on the reports can shift the attention to that matter.

Process Reflection

My personal motivation for this thesis as stated in the Graduation Brief was to increase my methodology awareness, my knowledge integration skills and gain knowledge into the medical world (patients, medical staff, medical devices, medical services, etc.). As an Industrial Designer, I was already aware of some of these aspects, nevertheless, the challenge of the medical world surpassed my background experience. It requires deep knowledge on many aspects that range from technology to human emotions such as fear. It is also important to communicate with multiple stakeholders continuously. This thesis gave me the opportunity to see how a public institution innovates to provide better care, what are the user perceptions of this innovation and how design can play a role there.

Not knowing the final result has been the most challenging part. Generally, during my bachelor and my professional experience I have worked with well defined product briefs, concrete products and feasible features. In this thesis the decisions have been made as it advanced, based on results coming from different tests, interviews and literature review.

A combination of the Double Diamond and the Lean Start-up approach was a good fit for the described situation, but it is not a good fit for the medical world. In hospitals processes are slow, meetings take time and getting to patients is not always possible. The fast iteration required by the lean start-up methodology was affected by it.

Final Result Reflection

The final result is not the end product yet, it never is. It must be tested, improved and tested again. It is required by the regulations, but also by common sense. During the elaboration of the thesis many fellow students manifested disappointment in not being able to have a final product. I completely disagree. I am satisfied with the achieved result and full of enthusiasm to pursue it further.

References

[1] Leening, M. J., Siregar, S., Vaartjes, I., Bots, M. L., Versteegh, M. I., Geuns, R. M., . . . Deckers, J. W. (2013, 12). Heart disease in the Netherlands: A quantitative update. Netherlands Heart Journal, 22(1), 3-10. doi:10.1007/s12471-013-0504-x

[2] Treskes, R. W., Winden, L. A., Keulen, N. V., Atsma, D. E., Velde, E. T., Marle, E. V., . . . Schalij, M. J. (2017, 09). Using Smart Technology to Improve Outcomes in Myocardial Infarction Patients: Rationale and Design of a Protocol for a Randomized Controlled Trial, The Box. JMIR Research Protocols, 6(9). doi:10.2196/resprot.8038

[3] Eastwood, C. A., Travis, L., Morgenstern, T. T., & Donaho, E. K. (2007, 09). Weight and Symptom Diary for Self-monitoring in Heart Failure Clinic Patients. The Journal of Cardiovascular Nursing, 22(5), 382-389. doi:10.1097/01.jcn.0000287027.49628.a7

[4] Heart attack. (2018, May 30). Retrieved from https://www.mayoclinic.org/diseases-conditions/heart-attack/symptoms-causes/syc-20373106

[5] Blood Clots: Signs, Symptoms, Risks and More. (n.d.). Retrieved from https://www.healthline.com/health/how-to-tell-if-you-have-a-blood-clot

[6] Types of Heart Attacks: Names, Symptoms, and Treatment. (n.d.). Retrieved from https://www.healthline.com/health/heart-disease/types-of-heart-attacks

[7] Thygesen, K., Alpert, J. S., Jaffe, A. S., Chaitman, B. R., Bax, J. J., Morrow, D. A., & White, H. D. (2018, 12). Fourth Universal Definition of Myocardial Infarction (2018). Global Heart, 13(4), 305-338. doi:10.1016/j.gheart.2018.08.004

[8] Coronary Artery Disease - STEMI Topic Review . (n.d.). Retrieved from https://www.healio.com/cardiology/learn-the-heart/cardiology-review/topic-reviews/coronary-artery-disease-stemi

[9] Amsterdam, E. A., Wenger, N. K., Brindis, R. G., Casey, D. E., Ganiats, T. G., Holmes, D. R., . . . Zieman, S. J. (2014, 12). 2014 AHA/ACC Guideline for the Management of Patients With Non–ST-Elevation Acute Coronary Syndromes. Circulation, 130(25). doi:10.1161/cir.0000000000000134

[10] Risk factors. (n.d.). Retrieved from https://www.world-heart-federation.org/resources/risk-factors/

[11] Prevention of cardiovascular disease: Recent achievements and remaining challenges. (n.d.). Retrieved from https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-15/prevention-of-cardiovascular-disease-recent-achievements-and-remaining-challeng

[12] Understand Your Risks to Prevent a Heart Attack. (n.d.). Retrieved from http://www.heart.org/en/health-topics/heart-attack/understand-your-risks-to-prevent-a-heart-attack

[13] Yusuf, S., Hawken, S., Ôunpuu, S., Dans, T., Avezum, A., Lanas, F., . . . Lisheng, L. (2004, 09). Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): Case-control study. The Lancet, 364(9438), 937-952. doi:10.1016/s0140-6736(04)17018-9

[14] Kumar, A., & Cannon, C. P. (2009, 10). Acute Coronary Syndromes: Diagnosis and Management, Part I. Mayo Clinic Proceedings, 84(10), 917-938. doi:10.4065/84.10.917

[15] Känel, R. V., & Begré, S. (2006, 12). Depression After Myocardial Infarction. Journal of the American College of Cardiology, 48(11), 2215-2217. doi:10.1016/j.jacc.2006.09.007

[16] Braunwald, E. (2012, 04). The treatment of acute myocardial infarction: The Past, the Present, and the Future. European Heart Journal: Acute Cardiovascular Care, 1(1), 9-12. doi:10.1177/2048872612438026

References

[17] What Is MACRA. (n.d.). Retrieved from http://www.nrhi.org/work/what-is-macra/what-is-macra/

[18] Ministerie van Algemene Zaken. (2018, September 14). Government encouraging use of eHealth. Retrieved from https://www.government.nl/topics/ehealth/government-encouraging-use-of-ehealth

[19] Cooper, T. (2018, August 27). 2018 Global health care sector outlook. Retrieved from https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-health-care-sector-outlook.html#

[20] The top 10 causes of death. (n.d.). Retrieved from http://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death

[21] Causes of Death. (n.d.). Retrieved from https://ourworldindata.org/causes-of-death

[22] Netherlands. (2017, September 15). Retrieved from http://www.healthdata.org/netherlands

[23] Kapoor, R. (2015). An Analysis of Global Research Trends in Cardiology Over the Last two Decades. Journal Of Clinical And Diagnostic Research. doi:10.7860/jcdr/2015/11223.5453

[24] Kaul, U., Arora, P. (2012, 09). Recent Advances and Future Trends in Cardiology. JIMSA Vol. 25 No. 3

[25] Guo, L., Yang, Z., Zhi, S., Feng, Z., Lei, C., & Zhou, Y. (2018, 03). A sensitive and innovative detection method for rapid C-reactive proteins analysis based on a micro-fluxgate sensor system. Plos One, 13(3). doi:10.1371/journal.pone.0194631

[26] Easy EKG Interpretation: Zio Cardiac Monitoring. Retrieved from https://www.irhythmtech.com/products-services/zio-xt

[27] Xing, X., & Sun, M. (2016, 07). Optical blood pressure estimation with photoplethysmography and FFT-based neural networks. Biomedical Optics Express, 7(8), 3007. doi:10.1364/boe.7.003007

[28] Ajana, B. (2017, February 01). Digital health and the biopolitics of the Quantified Self. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/29942580

[29] Fernandez-Luque, L., Singh, M., Ofli, F., Mejova, Y. A., Weber, I., Aupetit, M., . . . Ahmedna, M. (2017, 04). Implementing 360° Quantified Self for childhood obesity: Feasibility study and experiences from a weight loss camp in Qatar. BMC Medical Informatics and Decision Making, 17(1). doi:10.1186/s12911-017-0432-6

[30] Personal data empowerment: Time for a fairer data deal. (2015, 04). Retrieved from https://www.citizensadvice.org.uk/about-us/policy/policy-research-topics/consumer-policy-research/consumer-policy-research/personal-data-empowerment-time-for-a-fairer-deal/

[31] Prochaska, J. O., & Velicer, W. F. (1997, 09). The Transtheoretical Model of Health Behavior Change. American Journal of Health Promotion, 12(1), 38-48. doi:10.4278/0890-1171-12.1.38

[32] Processes of Change by Pcbs-wiki2. File is licensed under the Creative Commons Attribution-Share Alike 3.0 Unported license. Retrieved from https://commons.wikimedia.org/wiki/File:Processes_of_Change_3.JPG

[33] Psychotherapy: URICA (university of rhode island change assessment). Retrieved from: https://web.uri.edu/cprc/psychotherapy-urica/

[34] Paul S., Sneed NV. (2004, 07), Strategies for Behavior Change in Patients With Heart Failure. Retrieved from http://ajcc.aacnjournals.org/content/13/4/305.long

References

[35] Withings / Nokia | Steel – Activity Tracker, Sleep Monitor, Water Resistant Smart Watch with 8-month battery life. (n.d.). Retrieved from https://www.amazon.com/Nokia-Steel-Activity-Sleep-Watch/dp/B0716S22WB/

[36] Withings - Blood Pressure Monitor. (n.d.). Retrieved from https://www.amazon.com/Withings-70002601-Blood-Pressure-Monitor/dp/B00C7NKVD4/

[37] Withings / Nokia | Body - Smart Weight & BMI Wi-Fi Digital Scale with smartphone app, Black. (n.d.). Retrieved from https://www.amazon.com/Withings-Nokia-Body-Composition-smartphone/dp/B0728K4371

[38] Alivecor® KardiaMobile EKG Monitor | FDA-Cleared | Wireless Personal EKG | Detects Afib in 30 Seconds. (n.d.). Retrieved from https://www.amazon.com/Alivecor®-KardiaMobile-Wireless-Detection-Smartphones/dp/B01A4W8AUK

[39] Withings Activité Smartwatch Repair. (2016, June 06). Retrieved from https://www.ifixit.com/Device/Withings_Activité_Smartwatch

[40] Withings Smart Body Analyzer Repair. (2017, May 01). Retrieved from https://www.ifixit.com/Device/Withings_Smart_Body_Analyze

[41] Atrial Fibrillation Won't Cause Heart Attack but Can Lead to Other Serious Complications. (n.d.). Retrieved from https://newsnetwork.mayoclinic.org/discussion/atrial-fibrillation-wont-cause-heart-attack-but-can-lead-to-other-serious-complications/

[42] RENPHO Bluetooth Body Fat Scale Smart BMI Scale Digital Bathroom Wireless Weight Scale, Body Composition Analyzer with Smartphone App 396 lbs - Black. (n.d.). Retrieved from https://www.amazon.com/RENPHO-Bluetooth-Body-Fat-Scale/dp/B01N1UX8RW

[43] Buy the Philips Upper arm blood pressure monitor DL8760/15 Upper arm blood pressure monitor. (n.d.). Retrieved from https://www.philips.co.uk/c-p/DL8760_15/upper-arm-blood-pressure-monitor

[44] EVOLV. (n.d.). Retrieved from https://www.omron-healthcare.com/en/evolv

[45] Health Track Wireless Blood Pressure Monitor Bluetooth Blood Pressure Cuff, Digital Upper Arm Cuff, BP Meter with Multi-Color Backlight Large Display, Kit Comes with Batteries (BP Monitor New). (n.d.). Retrieved from https://www.amazon.com/dp/B01C5QS1T8

[46] GmbH, B. (n.d.). BM 85 - Upper arm blood pressure monitor. Retrieved from https://www.beurer.com/web/gb/products/medical/blood-presure/upper-arm-blood-pressure-monitors/bm-85.php

[47] QardioArm Blood Pressure Monitor: FSA-Eligible, Medically Accurate, Wireless & Compact Digital Upper Arm Cuff. App enabled for iOS, Android, Kindle. Works with Apple and Samsung Health. (n.d.). Retrieved from https://www.amazon.com/QardioArm-Wireless-Blood-Pressure-Monitor/dp/B00JM6EBHG

[48] How it works - Alivecor. (n.d.). Retrieved from https://www.alivecor.com/how-it-works/

[49] Archive of all online content. (n.d.). Retrieved from https://www.ahajournals.org/doi/abs/10.1161/01.str.31.12.2925

[50] Xing, X., & Sun, M. (2016, 07). Optical blood pressure estimation with photoplethysmography and FFT-based neural networks. Biomedical Optics Express, 7(8), 3007. doi:10.1364/boe.7.003007

[51] Khalid, S. G., Zhang, J., Chen, F., & Zheng, D. (2018, 10). Blood Pressure Estimation Using Photoplethysmography Only: Comparison between Different Machine Learning Approaches. Journal of Healthcare Engineering, 2018, 1-13. doi:10.1155/2018/1548647

[52] File:Vascaular unloading.png. Retrieved from https://en.wikipedia.org/wiki/File:Vascaular_unloading.png

[53] Electrocardiogram (ECG or EKG). (n.d.). Retrieved from https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/electrocardiogram-ecg-or-ekg

References

[54] Meek S, Morris F. ABC of clinical electrocardiography. Introduction. I-Leads, rate, rhythm, and cardiac axis. BMJ. 2002; 324(7334): 415–418. [PMC free article] [PubMed]

[55] Freudzon, M., Akhtar, S., London, M., Barash, P. Kaplan's Essentials of Cardiac Anesthesia. Chapter 9. Electrocardiographic Monitoring. Introduction. I-Leads, rate, rhythm, and cardiac axis. ISBN: 978-0-323-49798-5

[56] Screening for Coronary Heart Disease With Electrocardiography: U.S. Preventive Services Task Force Recommendation Statement. (2012, 10). Annals of Internal Medicine, 157(7). doi:10.7326/0003-4819-157-7-201210020-00520

[57] ECG device for smartphones - mobile ECG I CardioSecur. Retrieved from https://www.cardiosecur.com/en/product/ecg-device-for-smartphones-mobile-ecg/

[58] Easy EKG Interpretation: Zio Cardiac Monitoring. Retrieved from https://www.irhythmtech.com/products-services/zio-xt

[59] Martin, S. L., Carek, A. M., Kim, C., Ashouri, H., Inan, O. T., Hahn, J., & Mukkamala, R. (2016, 12). Weighing Scale-Based Pulse Transit Time is a Superior Marker of Blood Pressure than Conventional Pulse Arrival Time. Scientific Reports, 6(1). doi:10.1038/srep39273

[60] Bujnowski, A., Osinski, K., Polinski, A., Kocejko, T., Przystup, P., Bogusz, D., Wtorek, J. (2018, 10). Smart Weighing Scale with Feet-Sampled ECG. 10.1109/IECON.2018.8591487

[61] Gonzalez-Landaeta, R., Casa, O., Pallas-Areny, R. (2007, 08). Heart Rate Detection from an Electronic Weighing Scale. 10.1109/IEMBS.2007.4353791

[62] Wang, W., Mai, Z., Chen, Y., Wang, J., Li, L., Su, Q., . . . Hong, X. (2017, 12). A label-free fiber optic SPR biosensor for specific detection of C-reactive protein. Scientific Reports, 7(1). doi:10.1038/s41598-017-17276-3

[63] Mobile Operating System Market Share Netherlands. (n.d.). Retrieved from http://gs.statcounter.com/os-market-share/mobile/netherlands

[64] Kathleen McDowell, J. (2002). Recovery following an acute myocardial infarction: impact on the quality of life of patients and their partners.

[65] Mobile phone users in the Netherlands 2011-2019 I Forecast. (n.d.). Retrieved from https://www.statista.com/statistics/274751/forecast-of-mobile-phone-users-in-the-netherlands/

[66] Demography of the Netherlands. (2019, February 01). Retrieved from https://en.wikipedia.org/wiki/Demography_of_the_Netherlands

[67] Kwon, O., Jeong, J., Kim, H. B., Kwon, I. H., Park, S. Y., Kim, J. E., & Choi, Y. (2018). Electrocardiogram Sampling Frequency Range Acceptable for Heart Rate Variability Analysis. Healthcare Informatics Research, 24(3), 198. doi:10.4258/hir.2018.24.3.198

[68] Selder, J. L., Breukel, L., Blok, S., Rossum, A. C., Tulevski, I. I., & Allaart, C. P. (2018, 12). A mobile one-lead ECG device incorporated in a symptom-driven remote arrhythmia monitoring program. The first 5,982 Hartwacht ECGs. Netherlands Heart Journal, 27(1), 38-45. doi:10.1007/s12471-018-1203-4

[69] Arrhythmia. (n.d.). Retrieved from https://www.nhlbi.nih.gov/health-topics/arrhythmia

[70] Symptoms, Diagnosis and Monitoring of Arrhythmia. (n.d.). Retrieved from https://www.heart.org/en/health-topics/arrhythmia/symptoms-diagnosis--monitoring-of-arrhythmia

[71] Lim, H. W., Hau, Y. W., Lim, C. W., & Othman, M. A. (2016, 10). Artificial intelligence classification methods of atrial fibrillation with implementation technology. Computer Assisted Surgery, 21(Sup1), 154-161. doi:10.1080/24699322.2016.1240303

References

[72] ECG Filters. (n.d.). Retrieved from http://www.medteq.info/med/ECGFilters

[73] SparkFun Single Lead Heart Rate Monitor - AD8232 (n.d.). Retrieved from https://www.sparkfun.com/products/12650

[74] AD8232 Heart Rate Monitor Hookup Guide (n.d.). Retrieved from https://learn.sparkfun.com/tutorials/ad8232-heart-rate-monitor-hookup-guide/all

[75] Arduino Tutorial: Using millis() Instead of delay(). (2017, September 05). Retrieved from https://www.norwegiancreations.com/2017/09/arduino-tutorial-using-millis-instead-of-delay/

[76] Topic: I need a fixed sampling rate of 500Hz (2ms). (2017, April 01). Retrieved from http://forum.arduino.cc/index.php?topic=467144.0

[77] Pan, J., & Tompkins, W. J. (1985, 03). A Real-Time QRS Detection Algorithm. IEEE Transactions on Biomedical Engineering, BME-32(3), 230-236. doi:10.1109/tbme.1985.325532

[78] Benitez, D., Gaydecki, P., Zaidi, A., & Fitzpatrick, A. (2001, 09). The use of the Hilbert transform in ECG signal analysis. Computers in Biology and Medicine, 31(5), 399-406. doi:10.1016/s0010-4825(01)00009-9

[79] AD8232 Datasheet and Product Info - Analog Devices. (n.d.). Retrieved from https://www.analog.com/en/products/ad8232.html

[80] Harden, S. (2016, August 08). DIY ECG - 1 op-amp version. Retrieved from https://www.youtube.com/watch?v=AfirWls9Sys&t=212s

[81] Joutsen, A. S., Kaappa, E. S., Karinsalo, T. J., & Vanhala, J. (2017, 06). Dry electrode sizes in recording ECG and heart rate in wearable applications. EMBEC & NBC 2017 IFMBE Proceedings, 735-738. doi:10.1007/978-981-10-5122-7_184

[82] Electricfuzz, Joan_Sparky, & Dchisholm. (2016, February 02). Screw holes for mounting boards. Retrieved from https://forum.kicad.info/t/screw-holes-for-mounting-boards/2195

[83] Web Content Accessibility Guidelines (WCAG) 2.1. (n.d.). Retrieved from https://www.w3.org/TR/WCAG21/

[84] Web Accessibility. (n.d.). Retrieved from http://ec.europa.eu/ipg/standards/accessibility/index_en.htm

[85] Malik, M., Bigger, J. T., Camm, A. J., Kleiger, R. E., Malliani, A., Moss, A. J., & Schwartz, P. J. (1996, 03). Heart rate variability: Standards of measurement, physiological interpretation, and clinical use. European Heart Journal, 17(3), 354-381. doi:10.1093/oxfordjournals.eurheartj.a014868

[86] Mcmanus, D. D., Lee, J., Maitas, O., Esa, N., Pidikiti, R., Carlucci, A., . . . Chon, K. H. (2013, 03). A novel application for the detection of an irregular pulse using an iPhone 4S in patients with atrial fibrillation. Heart Rhythm, 10(3), 315-319. doi:10.1016/j.hrthm.2012.12.001

[87] Gari Clifford, Chengyu Liu, Benjamin Moody, Li-wei H. Lehman, Ikaro Silva, Qiao Li, Alistair Johnson, Roger G. Mark. AF Classification from a Short Single Lead ECG Recording: the PhysioNet Computing in Cardiology Challenge 2017. Computing in Cardiology (Rennes: IEEE), Vol 44, 2017

[88] Advanced circulatory system physiology | Health and medicine. (n.d.). Retrieved from https://www.khanacademy.org/science/health-and-medicine/circulatory-system

[89] Introduction to Electronics. (n.d.). Retrieved from https://www.coursera.org/learn/electronics

[90] MITx: 6.341x Discrete-Time Signal Processing. (n.d.). Retrieved from https://courses.edx.org/courses/course-v1:MITx 6.341x_2 2T2016/course/

References

[91] Elegant-Scipy. (2019, March 18). Elegant-scipy/elegant-scipy. Retrieved from https://github.com/elegant-scipy/elegant-scipy

[92] Elkington, J. (2018, September 13). 25 Years Ago I Coined the Phrase "Triple Bottom Line." Here's Why It's Time to Rethink It. Retrieved from https://hbr.org/2018/06/25-years-ago-i-coined-the-phrase-triple-bottom-line-heres-why-im-giving-up-on-it

[93] Çolak, M. Y., Çolak, L., & Gürel, E. (2018). The Healthcare Industry and Medical Devices in Environmental Sustainability: Medical Device Industry is Going Green. Lecture Notes in Civil Engineering Proceedings of 3rd International Sustainable Buildings Symposium (ISBS 2017), 280-290. doi:10.1007/978-3-319-64349-6_22