MASTERS THESIS

The Stethoscope as an Improved Pre-Diagnostic Device

In the field of Cardiology

Graduate student
Kolja van der Laan

Supervisory team
Armağan Albayrak
Erik Thomassen
Tobias Bruning

Delft, August 2018

Delft University of Technology
Faculty Industrial Design Engineering
Master Integrated Product Design
Medisign

TU Delft
Delft University of Technology

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Disclaimer
This master thesis is written in the context of the master Integrated Product Design - Specialisation Medisign at the faculty of Industrial Design Engineering at the Delft University of Technology in the Netherlands

Graduate student
N.L. van der Laan (Kolja)
Industrial Design Engineer
Brasserskade, Delft
KoljavdLaan@gmail.com

Supervisory team
Chair: Dr. Ir. A. Albayrak (Armağan)
Mentor: Ir. E.W Thomassen (Erik)
Mentor Maasstad Ziekenhuis: Dr. T.A Bruning (Tobias)

Client
Maasstad Ziekenhuis
Contact: Gona Aziz
Maasstadweg 21
3079 DZ, Rotterdam
T: +31 10 291 1911

Delft University of Technology

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MASTERS THESIS

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Preface

Lectori salutem. Here my master thesis lies, in front of you. Written in the context of my graduation for the Integrated Product Design master at the Faculty of Industrial Design at the Delft University of Technology, with a specialisation in Medisign.

This project really started in October of 2017, when Armağan Albayrak connected me to the likes of Dr. Tobias Bruning and Gona Aziz of Maasstad Hospital. I was provided with the opportunity and liberty to research the paradigms and problems of stethoscope use in the field of cardiology. I decided to go into the project with the aim to create something completely novel and innovative in the context of auscultation.

This project has been a great, but difficult and challenging one; containing many ups and downs. I have lost and found myself again throughout the vastness of the material and disciplines that stretch across the problems and contexts at hand. I have given all I could give and contribute to the project; I hope that one day the end result and the concepts behind it will lead to improving cardiology as well as healthcare in general.

Kolja van der Laan
Delft, June 2018

Acknowledgements

Quite a few people have supported me throughout the course and completion of my graduation project. Without their help, this project would not have been possible. I would like to thank the following people for their presence and involvement during the project.

My parents, Harry and Renate, first and foremost, I would like to thank both of my parents for all of the support they have given me. Not only during this project, but throughout all my years of study. Allowing me to develop myself and always believing in me, even when I didn't believe in myself. I could not wish for a better set of parents.

Armağan, thank you for all of your guidance and positivity during this project and throughout my Master at the TU Delft. I always looked forward to our meetings because you provided new insights when I wasn't sure about the next steps in the project. You were continuously reassuring and I often came out of our meetings with new inspiration and excitement for the project.

Tobias, thank you for making me feel so welcome at Maasstad Hospital and allowing me to follow my own path during the project. Your arrangements allowed me to do a lot of things for the benefit the project. I have no doubt that involvement in the future development of the project will result in a successful product.

Erik, thank you for your genuine realism and support during the project. It really helped me in managing the project in a less stressful manner and put my ambitions in a much more achievable perspective.

Larissa, thank you for the occasional technical support and positive reinforcement. Having a sister who has been in comparable situations helped me in overcoming my doubts and pulling through.

Executive Summary

This report presents a design proposal of a product-service system that is supposed to facilitate cardiologists in their auscultation responsibilities. Auscultation today is usually still performed with an acoustic stethoscope, in which the cardiologist tries to recognize abnormalities concerning the patient's heart through attentive listening.

The efficiency driven practices of modern healthcare have forced cardiologists and other medical professionals to become even more economical with their time. Currently, doctors only have a timeframe of 600 seconds to see a new patient. Since the stethoscope is almost always the first tool used for diagnosis, it can be seen as the first factor that determines if the patient reaches the "further testing threshold". Therefore it is paramount for the general quality of healthcare that auscultation is performed in the best way possible, since this can determine whether further testing is done on the patient, or the patient is sent home. The relevance of this auscultation success is backed up even more by the fact that heart-disease is responsible for 45% of European annual deaths alone.

In connection with its importance, auscultation is a difficult thing to do flawlessly, especially under time constraints. Modern medical education has not succeeded in properly training and teaching doctors how to meticulously auscultate patients. This is due to medical education having a larger focus on the interpretation of imaging technologies, leaving auscultation in the background as a result.

Furthermore, the tools provided to the cardiologists to perform such a difficult task under these suboptimal conditions are also contributing to the problem. Stethoscopes are still mostly acoustic and non-electronic, meaning that the heart-sounds can not be recorded or listened to at a later moment.

The problem, which is a concoction of the efficiency driven practices in healthcare combined by the neglect of auscultation in medical education and the available tools at hand, was attempted to be improved and solved by the design proposal in this report.

Besides the problem stated above, technological, anatomical, literature and user research revealed several opportunities and drivers that established a better view of the problem at hand, and how to come up with a solution.

Design Proposal

Together with doctors, a product-service system was created that makes use of Artificial Intelligence, seamless automation, improved ergonomics and feedback loops in order to facilitate the cardiologist during auscultation.

The design proposal aims to ***increase medical effectiveness*** and ***diagnostic potential***, ***facilitating*** cardiologists in their auscultation responsibilities by creating a ***new and improved diagnostic tool*** in the form of an electronic stethoscope that ***harmonises*** with the efficiency of the auscultation process in an ***unobtrusive*** way; ***benefiting*** both the cardiologist and the patient.

The main part of the design consists of a ***physical product*** in the form of an electronic stethoscope supported by a ***system*** consisting of a simple Bluetooth Forwarding Application and Desktop Application. The essence of the design is described in the following three user benefits.

1. Harmonisation
By automating the task of recording and transferring auscultation recordings, the cardiologist needn't worry about the extra actions and burdens that come with the use of an electronic stethoscope, while still being able to enjoy all of the playback and analytical benefits.

2. Feedback
The design provides the cardiologist with feedback on the completeness of recordings in order to ensure a proper analysis as well as a composed and consistent routine.

3. Facilitation
By *automatically* transferring and analysing the recordings, the cardiologist is substantially facilitated in multiple ways. There is less pressure on in-the-moment analysis, and there is a more reliable and objective way of documentation.

Evaluation

The design proposal was qualitatively evaluated with several cardiologists during a presentation at Maasstad Hospital. It was received with great positive response on the fronts of both appearance and presented functionality. A component-prototype was also created for demonstration purposes. In order to substantiate the promising outlook the design proposal elicits, long term testing with a 0-series product-service system will need to be done.

Glossary

A

Auscultation
Listening for sounds produced within the body. It may be performed with the unaided ear (direct or immediate auscultation) or with a stethoscope

Angina
Angina is pain, discomfort, or pressure localized in the chest that is caused by an insufficient supply of blood (ischemia) to the heart muscle.

Angiogram
An X-ray of one or more blood vessels following the injection of a radiopague substance.

B

Ballistocardiography
The graphic recording of movements of the body imparted by ballistic forces; minute movements are amplified and recorded on moving chart paper after being translated into an electrical potential by a pickup device.

C

Cardiomyopathy
Cardiomyopathy is a chronic disease of the heart muscle (myocardium), in which the muscle is abnormally enlarged, thickened, and/or stiffened.

E

ECG
The record produced by electrocardiography; a tracing representing the heart's electrical action derived by amplification of the minutely small electrical impulses normally generated by the heart.

Echocardiography
Echocardiography is a diagnostic test that uses ultrasound waves to create an image of the heart muscle.

H

Hydrostatic Pressure
The pressure exerted by a fluid at equilibrium at a given point within the fluid, due to the force of gravity.

M

Mediastinum Area
The mediastinum is the space between the two lungs, which is ventrally bounded by the sternum and dorsally bounded by the spinal column.

P

Pacemaker Cells
A small mass of specialized muscle tissue in the heart that sets a rhythm of contraction and relaxation for the other parts of the heart, resulting in the heartbeat.

Pathology
The anatomic or functional manifestations of a disease.

Primary Health Care
The basic first level of contact between individuals and families with the health system. The general practitioners, the family physician, the physiotherapist are the usual primary health care providers.

Pressure Gradient
The change in pressure per unit of distance in the direction in which pressure changes most rapidly.

Pulse-Oximetry
Measurement of oxygen saturation of the blood using an oximeter.

S

Secondary Health Care
An intermediate level of health care that includes diagnosis and treatment, performed in a hospital having specialized equipment and laboratory facilities.

Seismocardiography (SCG)
Seismocardiography (SCG) is the measurement of vibrations produced by the heart’s contraction in the region of the thorax with use of accelerometers placed on the sternum.

Spectrogram
A graphic or photographic representation of a spectrum.

Stroke Volume
The amount of blood pumped by the left ventricle of the heart in one contraction.

Reader‘s Guide

PROCESS STRUCTURE

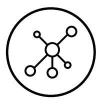
Since this project is an intricate combination of multiple factors, the analysis was split into various parts in order to fully grasp the complexity of the project. The structure is a combination of the Design Thinking Method (Cross et al., 2011), and the iterative design cycle described by Roosenburg et al. (Eekels et al., 1998). The immersive process was divided into four parts, each one being interrelated and playing an important role in coming to a cohesive understanding of the paradigms and subjects at hand. The process is visualized on the right. It is important to to note that a combination of design methods is often more complex than a schematic visualisation can describe. It is an iterative process consisting of proportionally valued methods, and is no way fully linear.

REPORT STRUCTURE

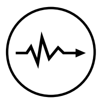
The report is divided in the different phases (such as “The Cardiac Blueprint, and Market & Analysis” on page 27”). Each chapter will start off with an introductory section, explaining what kind of relevance the chapter has for the project as well as its main objective.

Each chapter will be concluded with:

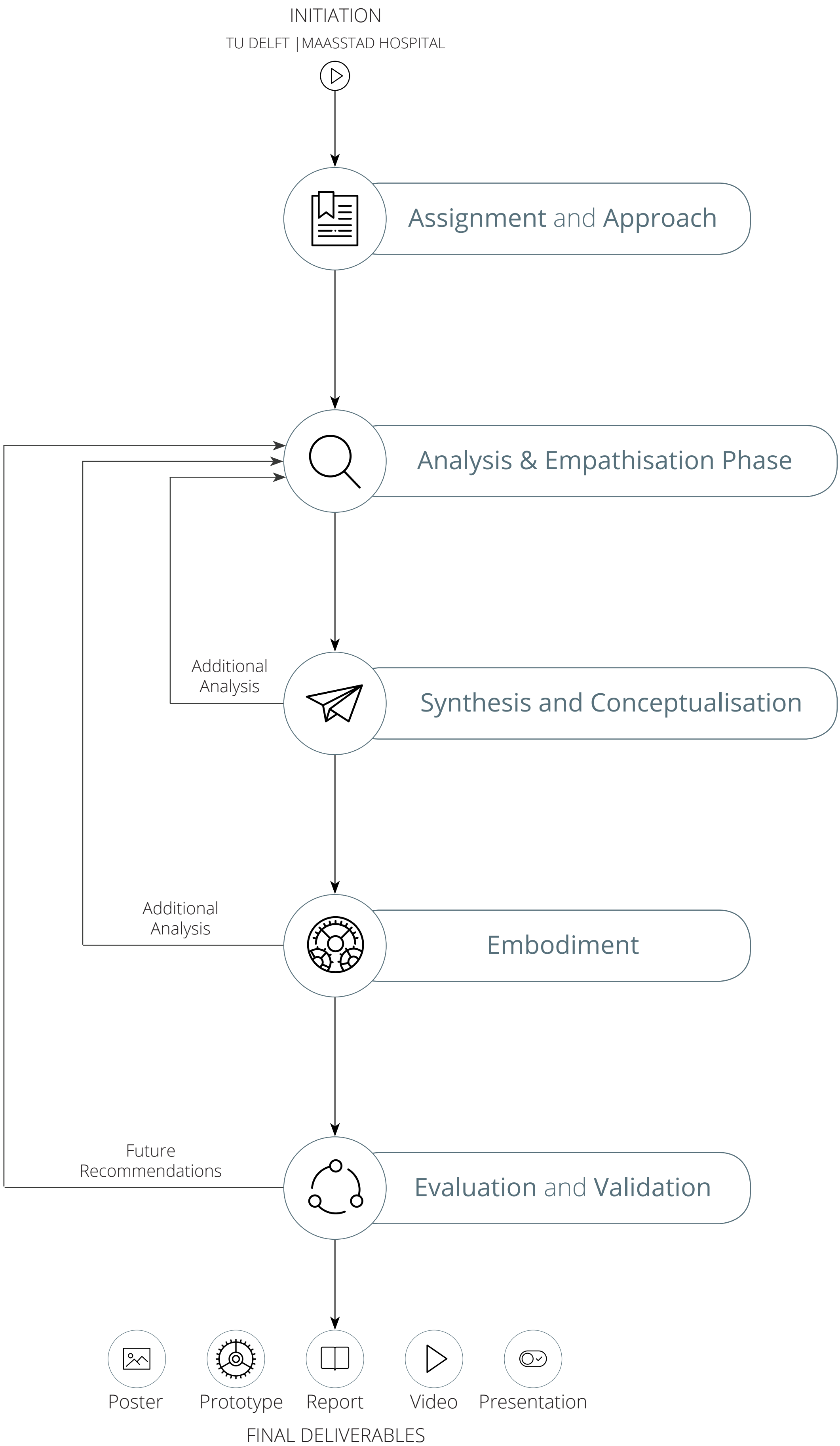
A “**Conclusion**” section represented by:



A “**Design Implication**” section represented by:



In the ‘Conclusion’ the findings will be discussed in relation to the objective(s). The “Design Implications” will go into the effect of the conclusions on the design and further design process. These Design Implications will all contribute to the creation of the list of requirements. The chapter Assignment and Approach contains a more detailed section discussing the design process and the phases individually.


INITIATION
TU DELFT | MAASSTAD HOSPITAL
Assignment and Approach
Analysis & Empathisation Phase
Additional Analysis
Synthesis and Conceptualisation
Additional Analysis
Embodiment
Future Recommendations
Evaluation and Validation
Poster
Prototype
Report
Video
Presentation
FINAL DELIVERABLES

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1 Assignment and Approach

Before the project could be initiated, a preliminary phase occured in order to form the graduation assignment. This chapter entails this preparation, and explains how the project came into existence. It will cover the project scope, problem defition, assignment, and will give a brief introduction into the project. Lastly it will quickly discuss the planned outcome and deliverables.

1.1 Project Partners

Maastad Hostpital
TU Delft

1.2 Surrounding Project Scope

Cardiovascular Disease
Efficiency
Project Definition
Solution Space

1.3 Solution Scope & Assignment

Solution Scope
Project Aim
Assignment

1.4 Project Approach

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Planned Outcome

1.1 Project Partners

The initial inspiration from this project came from Dr. Tobias Bruning, one of the leading cardiologists at Maastad Hospital in Rotterdam. Once a link was established between Maasstad Hospital and the TU Delft, a project brief was formed. This section describes the different stakeholders and their role within this project.

Maastad Hostpital

Maasstad hospital is a clinical training hospital located in the south of Rotterdam. It is one of the largest non-academic hospitals in the Netherlands,. Every year over 450.000 patients visit the policlinics. Maasstad Hospital is a member of the Collaborating Top Clinical Training Hospitals (STZ). The project is done for the Science Department of Maasstad Hospital in collaboration with their Cardiology Department.

Role within the project

Maasstad Hospital is the client and facilitator of the project and is therfore supplying the primary working place of the project at their premises. Close collaboration and guidance from the side of Maasstad Hospital mainly came from the head cadiologist: Dr. Tobias Bruning.

TU Delft

The TU Delft is the educational institute for which this graduation project is executed. To be more specific, the project is carried out within the faculty of Industrial Design Engineering (IDE) in the Master track of Integrated Product Design (IPD) with the specialisation of Medical Design. This project is the second official collaboration between the TU Delft and Maasstad Hospital.

Role within the project

The TU Delft is the academic authority within this project. Their role is to guide and assess the graduation project from an academic perspective, ensuring proper guidance and execution with use of a graduation committee.

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1.2 Project Background & Problem

This chapter describes the situation and problems surrounding the project scope, in order to create an understanding and grasp on the initial inspiration for the project.

Global Cardiovascular Health & Diagnosis

Each year cardiovascular disease (CVD) causes 3.9 million deaths in Europe, accounting for 45% of all European deaths (European Heart Net, 2017). Figure 1.2 shows the annual statistics for Heart Attacks and other prime causes of death. Even though this is one of the leading causes of death in Europe, misdiagnoses and missed diagnoses are definitely not uncommon. A study from the University of Leeds discovered that about a third of people with a heart-attack are initially diagnosed incorrectly (Wu & Gale, 2016). Other than that, the rate of misdiagnosis and delayed diagnosis differ highly between men and women. In fact, as reported in the New England Journal of Medicine, female heart patients in their 50s and younger are seven times more likely to be misdiagnosed than their male counterparts (Wu & Gale, 2016). For multiple cardiovascular diseases, ranging from coronary artery disease to dilated cardiomyopathy, misdiagnosis and delayed diagnosis is still a frequently occuring factor (Bösner et al, 2011) (CardiologyToday, 2013). The fact that the rate of missed diagnoses, or false negatives is so high, is quite problematic. Early treatment of a cardiovascular disease can make a large difference in the development and curing and impeding the developing pathology of said CVD.

The causes for delayed diagnosis and misdiagnosis can vary widely. In some cases it is due to a mix of symptoms that aren't typically associated with heart disease, or that a patient falls widely out of the high-risk group. Pairing one of these factors with the time constraints that a doctor is under can lead to a missed or delayed diagnosis.

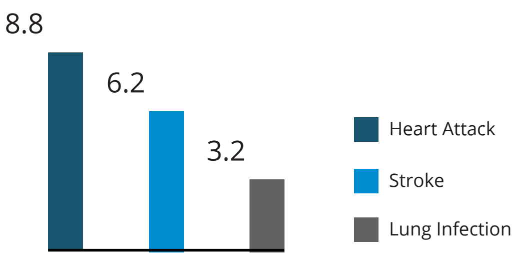

Figure 1.2 Annual Deaths caused by Heart Attacks, Stroke, and Lung infections in millions. (World Health Organization, 2016)

Efficiency in Healthcare & Cardiology

These time constraints are stemming from an increasing need for efficiency in healthcare; it is quite well known that efficiency is one of health care's most important concerns. This is especially the case in secondary/hospital care, which is the region of care that patients find themselves in after a referral from the general practitioner. Analogously, this project has a specific focus on secondary care. The definitions of primary and secondary care can be found in the Glossary.

Hospital logistics are planned into the finest details, patients need to be helped in a timely manner, and a doctor generally only has **600 seconds** to spend on a patient (T Bruning, personal communication 3 December 2017). Such time constraints can cause mistakes and oversight of symptoms and factors pointing towards a cardiac dysfunction. The increased demand for efficiency leads to a high expected throughput of patients, this could mean that the threshold for further testing for certain/'asymptomatic' patients will not be reached as quickly. Of course this is completely understandable, since performing extensive tests on a seemingly healthy patient is a waste of time and resources.

However, it is important to note that this means that there are patients who actually do have a form of CVD that slip through the cracks of the medical system, and become a victim of the efficiency driven practices in the healthcare sector. The question is how to fix this problem. More specifically: How can the rate of diagnostic false negatives within the medical sector be reduced? Specifically within the field of cardiology.

Since the policy concerning efficiency is apparently unchangeable and undeniable, a different approach to the problem should be considered. The reason these patients are sent home with an undiagnosed heart condition is not only due to to time, but it is combined with the tools that are used and the actions performed within that short timeframe of **600 seconds.** A doctor has to ask questions about the patient's history to assess their risk factors as well as perform general diagnostic tasks.

Pre-Diagnostic Tools & Interpretation

In the 600 seconds that the doctor has to spend with the referred patient, the most prominent matter of business is the physical examination, in which blood pressure, cholesterol and blood sugar levels can be measured. As a result of these activities, the tools that are most often used in the physical examination are a blood pressure measuring device (Sphygmomanometer), medical weighing scale, and the stethoscope.

Auscultation of/Listening to the heart sounds is an essential part of the physical examination since it may reveal pathologic cardiac conditions such as arrhythmias, valve disease, heart failure, and more. Heart sounds provide important initial clues in disease evaluation, and serve as a guide for further diagnostic examination, and thus play an important diagnostic role in the physical examination. Since these heart sounds can be of such paramount importance in the diagnostic process, the tool(s) that are used to listen to these sounds should facilitate the doctor as much as possible. Correct interpretation of qualitative factors under time contraints is of utmost importance, since there is usually no possibility to re-evaluate those factors at a later moment.

Modern Medical Education

Therefore due to time constraints, real-time interpretation of complex factors is key, with most of them being qualitative instead of quantitative. Complex training is necessary in order to make an objective decision, even under ambiguous circumstances. However, such a skill takes years to build properly and is often not developed to such a level where gaps of judgement are not present. In the Netherlands, the general medical education is 6 years, with an additional 6 years needed to specialize in a specific field (e.g Cardiology). Doctors are also human of course, and can still make mistakes, even after 6-12 years of medical education.

Medical education in the field of cardiology has been focused more on the use of (imaging) technology such as Echocardiograms and ECG, This shows that the need for broad, non-invasive diagnostic devices is high, preferably one with the least time constraints as possible. The education of interpretation of less obtrusive tools has taken more of a background position in recent years (T Bruning, personal communication 3 December 2017).

The Problem

Since most stethoscopes used in the medical sector are still acoustic, the doctor has no chance to re-listen to a recording, get a second opinion, or let the recording be analyzed by a software system. This means the doctor is under (time-related) pressure to detect anomalies in real time within the expected period. This means that within these 600 seconds, it is possible that the doctor could miss crucial information. This accompanied by the fact that in medical education the quality of teaching medical students to properly use a stethoscope and to interpret/recognize abnormal heart sounds is declining, points to a situation that lacks serious efficacy, in relation to the increasing need for efficiency. This combination of issues shows a strong need for improvement.

There are multiple tools within the spectrum that could be improved. However, the tool with the largest overarching application is undoubtedly the stethoscope. It is not yet designed or utilized for/to its full potential, urgently needing specific enhancements in order to tackle the pressing combination of problems in secondary healthcare with specific regard to cardiology.

To conclude, the cause of the problem is a combination of:

- *Time constraints (600 seconds per patient)*
- *Pre-diagnostic tools with limited functionality*
- *Use of diagnostic tools under time constraints*
- *The necessity of interpreting information in real-time*
- *The inability to reconsider assessment at a later moment*
- *The declining education of using these tools to their ful clinical potential*

Ultimately leading to an increase in false diagnostic negatives

1.3 Solution Scope & Assignment

The development of the graduation assignment was a process in itself, which unfolded in cooperation and accordance with Maasstad Hospital and the interim Graduation Comittee. This chapter sketches the solution scope and elaborates on the Assignment within the graduation project.

Solution Scope

As previously described, the problem consists of multiple factors belonging to the pillars of Policy, Education and Technology; a schematic overview of this problem can be seen in Figure 1.3. Since scope of this project will not be able to focus on directly changing Policy or Education, it can only aim to change the situation through adressing the problem from a technological perspective. Hopefully thus also initiating positive change concerning the pillars of Medical Education and Policy. The solution to the problem would therefore be in the field of Technology, specifically aiming to do the following.

The aim of this project is to:

- *Buy the cardiologist more time and relieve him of pressure*
- *Facilitate interpretation of diagnostic information or allow diagnostic information to be reinterpreted at a later moment if necessary*
- *Unlock a diagnostic tool's full clinical potential by medically trained professionals (e.g cardiologists)*
- *Allow the threshold for further testing to be reached more effectively*
- *Directly or indirectly provide the cardiologist with better diagnostic capibilities*

The Assignment

The primary pre-diagnostic tool in the cardiac diagnostic process is the stethoscope, the information that is gathered and interpreted with the use of this tool has a large influence on the decisions the cardiologist makes. Therefore, a solution which includes improvements to this tool could significantly improve the situation and help (partially) resolve the presented problem.

Therefore, the rest of this report will go more into detail on solving this problem by means of improving the primary cardiac diagnostic tool: **The Stethoscope.**

The presented problem in context has the best chance of finding a solution that will be accepted by everyone, if the context changes as little as possible while an enhanced known factor improves the situation significantly. Since the stethoscope is such an important, known and iconic tool, with a high potential impact, improvement of such a device could yield very substantial results; immediately having a high rate of acceptance in the medical sector. This would make integration of the solution more seamless and (cost)effective. Thus, the formulation of the assignment can be described as follows:

*"Design (of) a diagnostic tool in the form of an electronic stethoscope for cardiologists, that increases **medical effectiveness**, with improved **diagnostic potential**; **facilitating** cardiologists in their auscultation responsibilities."*

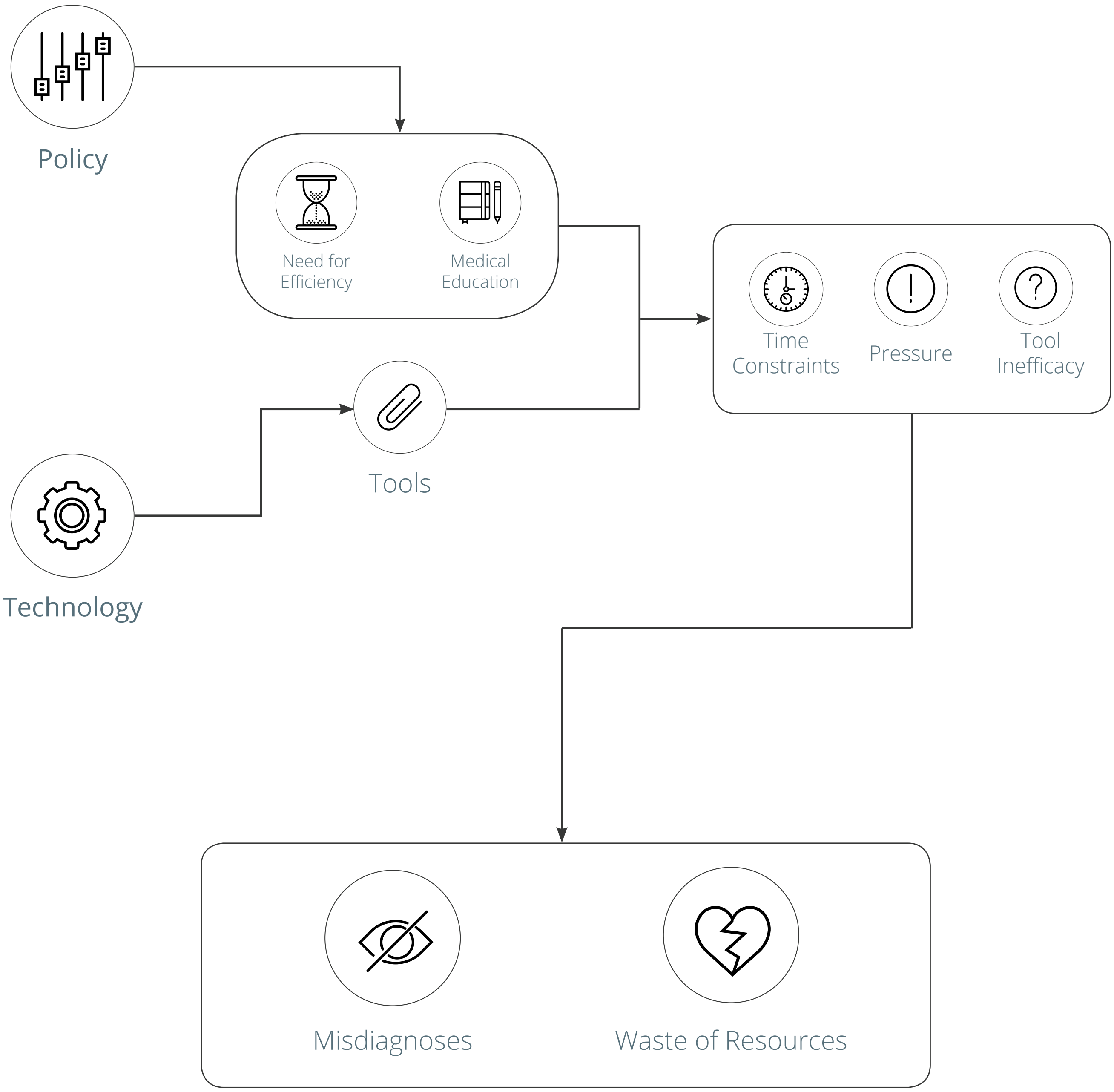

Figure 1.3 Schematic Representation of the problem

1.4 Project Approach

The complexity of this assignment is tackled by combining the iterative design cycle of Roozenburg & Eekels with the Design Thinking Method from Nigel Cross, using a system approach to the project. A structural overview of the project can be viewed in Figure 1.4 on the right. This section is meant to provide an overview and insight of the intended method and structure of the project.

Project Phases

The process as presented in Figure 1.4 shows the design process as a whole. Every phase of the process has its own methods and processes respectively, with the outcomes naturally being interconnected. The different phases do not always follow eachother in a linear fashion, since multiple iterations take place. But for the sake of structural clarity, each of these phases is presented with a clear start- and end point.

Analysis Phase

This phase concerns complete immersion into all of the surrounding aspects of the stethoscope and its use. In order to create a product that increases medical effectiveness and diagnostic efficacy, it is necessary to understand the internal and external factors. In the analysis phase these factors have been divided into four different parts (Figure 1.4). Each part has its own objectives and research questions that are aimed to be answered when starting their analysis.

The phases are interconnected and their outcomes will contribute to the creation of a list of requirements and design vision.

Synthesis and Conceptualisation

The synthesis of the design implications and list of requirements will be input for the development of concepts and solutions in this phase. The concepts will be developed to such an extent that they can be viably assessed. The conceptualisation will consist of the creation of a base concept, which can be supplemented and enriched by additional functions. The base concept in combination with its additional functions will entail the final direction for embodiment.

Embodiment

Once a concept has been chosen, embodiment of the product and system will be done such that its functionality and effectiveness can be evaluated in the next stage. This will be done in the form of a physical prototype and preliminary software system.

Evaluation and Validation

An imporant part of the project is where the embodied hardware-software combination is tested, evaluated and hopefully validated. It is assessed by testing it against the list of requirements that was constructed at the end of the analysis phase. The results from this will be used in order to create a list of recommendations for future development.

Planned Outcome

The planned outcome of this project is a simple prototype that lives to the aforementioned assignment . Other deliverables such as a video and a presentation will naturally be delivered as well.

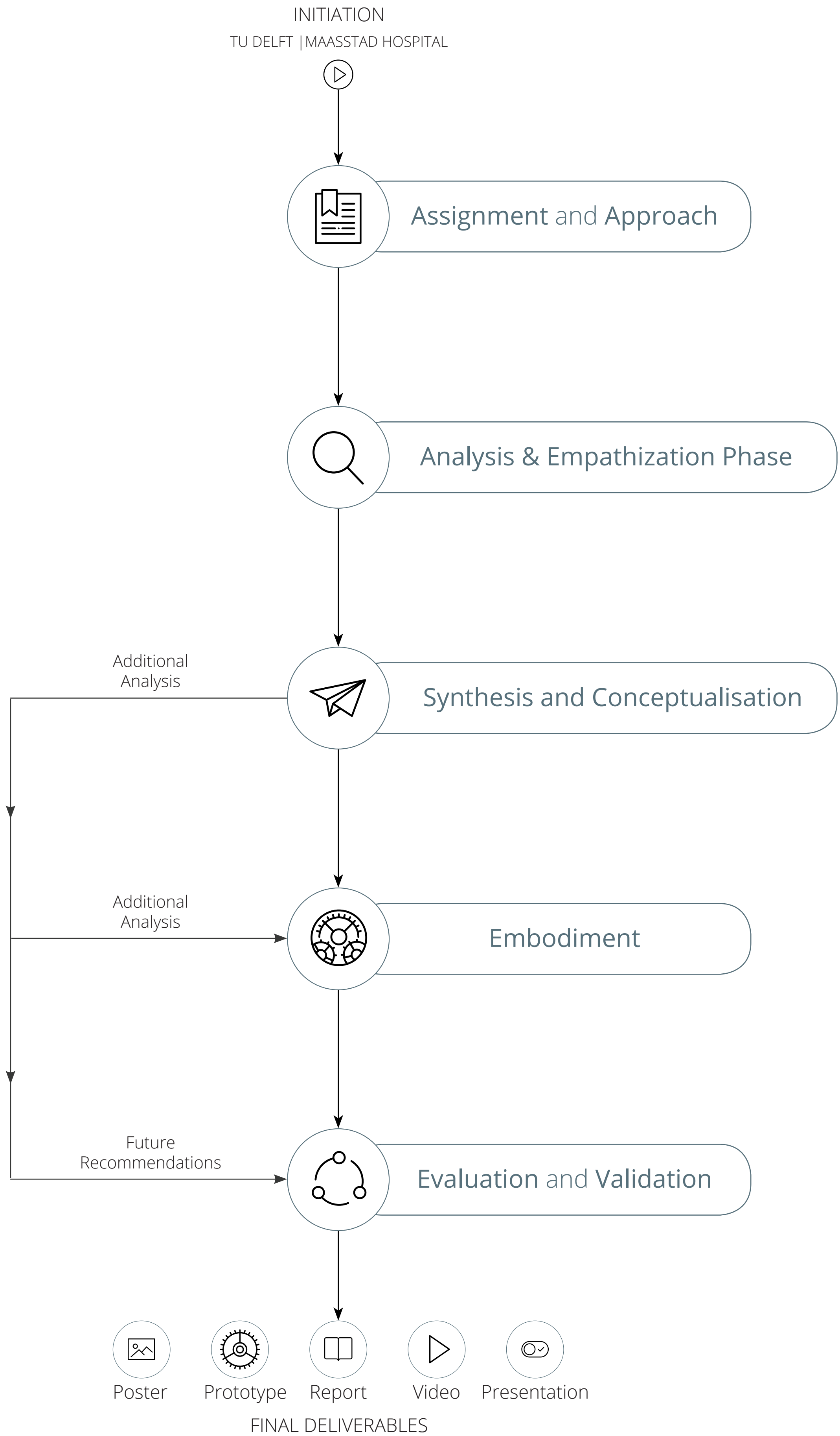

Figure 1.4 Schematic Representation of the Process

2 Analysis & Immersion

Before the project could be initiated, a preliminary phase occured in order to form the graduation assignment. This chapter entails this preparation, and explains how the project came into existence. It will cover the project scope, problem defition, assignment, and will give a brief introduction into the project. Lastly it will quickly discuss the planned outcome and deliverables.

2.1 The Stethoscope: An Introduction

2.2 The Cardiac Blueprint

2.3 Market & Developments

2.4 Technology & Trends

2.5 User Dialogue & Context

2.6 Concluding the Analysis

2.1 The Stethoscope: An Introduction

Since this project is about improving the diagnostic outcome by means of developing a better stethoscope, this chapter will provide a quick introduction to the role of the stethoscope in clinical practice as well as an overview of the cardiac anatomy in relation to the medical purpose of the stethoscope. Entailing this will be some of the stethoscope's history, role in practice and working principle.

History

Hippocrates first mentioned cardiac sounds between 460 and 370 B.C (Fye et al., 2003). However it was not until the early 17th century where René Laennec created a device that would later become one of the most symbolic tools of the physician and practitioner: The Stethoscope. The binaural stethoscope, which is still the standard for acoustic stethoscopes today, was developed in the 1850's by Arthur Leared and perfected by George Phillip Camman (Littman, 2014). The first recording of Heart sounds was made in 1895 by Hurthle, who used resonance to amplify heart sounds and recorded them with a microphone. Around the same time Einthoven was able to record the first phonocardiograms, which are a graphical representation of sounds originating from the heart and its great vessels.

Jumping to the middle of the 20th century, developments were made by Rappaport and Sprague, who designed a two sided stethoscope, of which one side was used to auscultate the cardiovascular system, and the other side for the respiratory system. Important acoustical improvements were made in the 1970's by a Harvard Medical School Professor, David Littman. Littman is still one of the largest stethoscope producers to date (Littmann, 2015).

Role in Practice

The stethoscope is one of the oldest and most symbolic tools for healthcare professionals. It evokes trust and papers have even claimed that when compared to other medical equipment, it has the highest positive impact on the perceived trustworthiness of the practitioner seen with it (Jiwa & Millet, 2012). To this day the stethoscope is still a very important non-invasive screening tool that can detect a wide range of structural, functional and hemodynamic abnormalities in the heart and lungs.

In our present medical context, the stethoscope is used by multiple types of users, seen in Figure 2.2. First of all, the stethoscope is used by family physicians, general practitioners, interns and cardiologists. This project focuses specifically on in-hospital use of the stethoscope, with a specific focus on cardiologists.

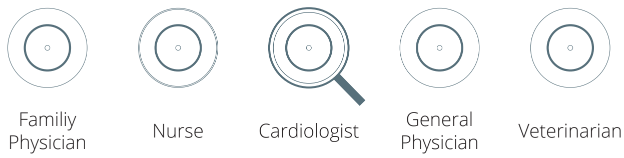

Figure 2.2 Users of the Stethoscope - the Cardiologist being the focus of this project

Figure 2.1 Wooden Monaural Stethoscope from 1890 (Melnick Medical Museum, 2009)

Figure 2.3 Camman's model ca. 1900 (Melnick Medical Museum, 2009)

Working Principle

The working principle behind the stethoscope is the picking up and channeling of sound waves from the body to the listener's eardrums. When the stethoscope is placed on a patient's chest sound waves traveling through the body will cause the flat surface of the diaphragm to vibrate. If it wasn't for the tubing of the stethoscope, the sound waves would disperse. But instead they are channeled in a specific direction. Each wave reflects or bounces off of the inside walls of the latex rubber tube, which is a process called Multiple Reflection. Through this each wave reaches the earpieces of the stethoscope in succession, and finally the listener's eardrums. The funneled sound through the narrow tube amplifies the sound since it is stopping sounds from traveling outward at will.

The functionality of the bell is somewhat different. Instead of picking up the vibrations directly caused by the artery's movement, it picks up the vibrations of the skin. Since the bell is small, its hollow shape contacts the patient with less surface area. Just the thin anti-chill ring is directly touching the patient. Sounds with a lower pitch, which would have a harder time vibrating the larger diaphragm, would still vibrate the skin as they move outward, in turn vibrating the bell. It is common to think that one side of the stethoscope is used to listen to the lungs, and the other for auscultation of the heart. However, both can be used for either purpose, depending on which frequencies one wants, or expects to hear.

The diaphragm, bell, tubing and earpieces are what make up an acoustic stethoscope. The stethoscopes general composition is shown in Figure 2.4, and shown in use in Figure 2.5.

Since this project will focus on the development of an electronic stethoscope, the working principle behind them is also important. The market analysis briefly goes into the working principles per every individual stethoscope.

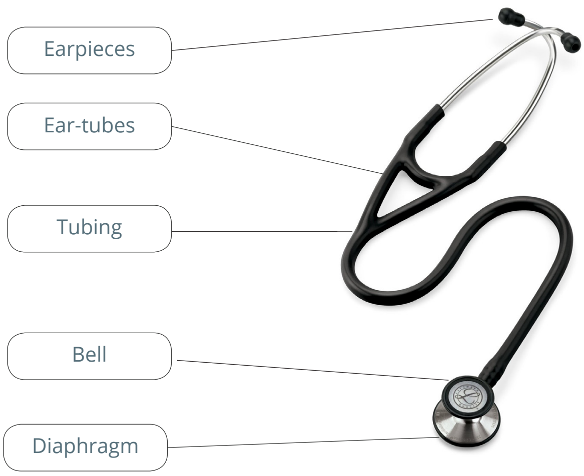

Figure 2.4 Aucoustic Littman Stethoscope (Littmann, 2014)

Figure 2.5 The stethoscope in use (N30, 2014)

2.2 The Cardiac Blueprint

This part will briefly go into the relevant anatomy of the human heart, with regard to the diagnostic functionalities of the stethoscope. It will comprise of the heart's function, general anatomy, physiology, and an overview of its most common pathologies.

Function and Location

The heart is the organ that is responsible for powering the entire circulatory system. Constantly transporting oxygen, nutrients, hormones, waste, immune cells, and heat throughout the body. The most important concern of the heart is the maintenance of pressure. More specifically maintaining an explicit pressure ratio. This means a high hydrostatic pressure is generated such that blood can be pumped out of the heart, as well as creating low pressure such that blood can flow back into the heart. Considering fluids follow and flow from high pressure areas to low pressure areas, this difference in pressure results in blood flow through the body. The heat on average beats around 60 times per minute, resulting in about 35 million heart beats per year and only weighs around 250 to 300 grams. (Mayo Clinic, 2015)

The heart lies in the middle region of the chest. It rests in the mediastinum area between the lungs, and sits at an angle of about 30 degrees, meaning that most of its mass rests to the left of the midsternal line (Weinhaus & Roberts, 2005). The heart is bundled in a two-walled membrane which goes by the name of the pericardium. This membrane has the purpose of protecting the heart from infection and friction as it beats, whilst also having an anchoring purpose at the same time.

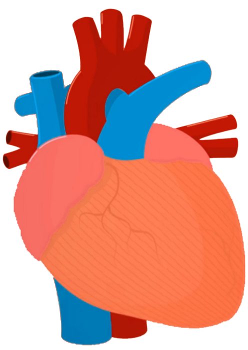

Figure 2.6 Visualisation of the Heart (TCS, 2015)

General Anatomy

The structure of chambers, arteries, valves and veins all collaborate in order to facilitate blood flow throughout the body. The heart's anatomy can be seen in Figure 2.7. The heart is divided vertically into two sides by dividing wall named "the septum". Through this division four chambers are created, consisting of two lower ventricles, which are the high pressure areas, and the upper atria, which are the low pressure areas. Each chamber has its respective valve, which has the main purpose of letting blood flow in at the correct moment, whilst also preventing blood from flowing back out. This closing and opening of the heart valves is what creates the characteristic "Lub - Dub" sound. In a more medically professional sense, these sounds are called "S1" and "S2".

The ventricles are the contracting chambers which are responsible for thrusting the blood outside of the heart. While atria are the chambers which receive blood that is coming after having circulated through the body. Respective to their functions, the atria have relatively thin walls due to the fact that blood flows back into them under low pressure. This means that that the sole task of the atria after this, is to push the blood downward towards the relaxed ventricles.

Logically, the walls of the ventricles have a significantly larger thickness. The ventricles are responsible for the heart's pumping function and need these strong walls such that every contraction results in a thrust of blood throughout the body. The entrance and exit are furnished with a heart valve. This results in four heart valves, aortic, pulmonary, tricuspid and mitral. The heart and circulatory system are connected through arteries and veins. Veins carry blood back to the heart, while arteries carry it away from the heart and throughout the body.

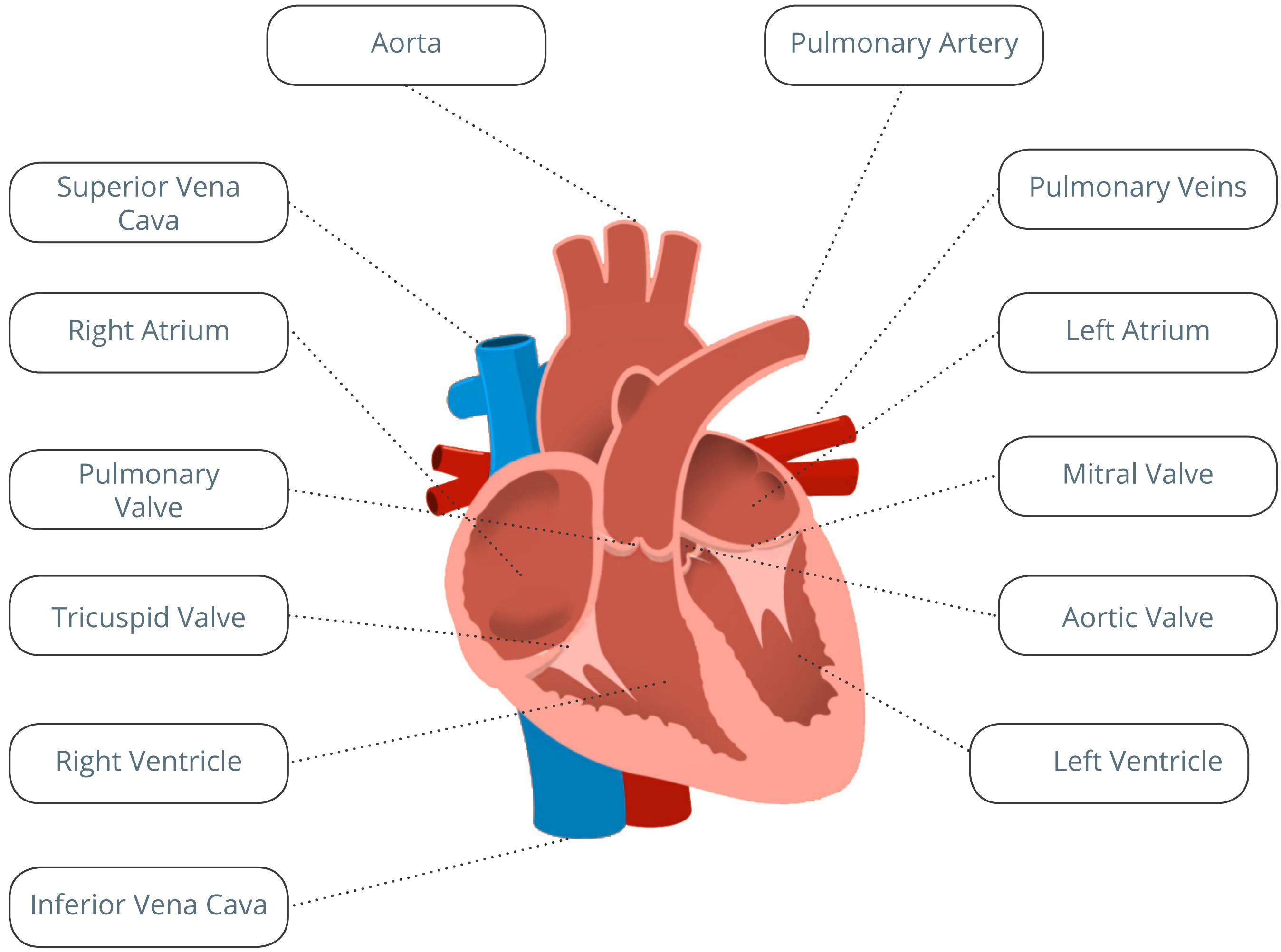

Figure 2.7 Cardiac Anatomy (TCS, 2015)

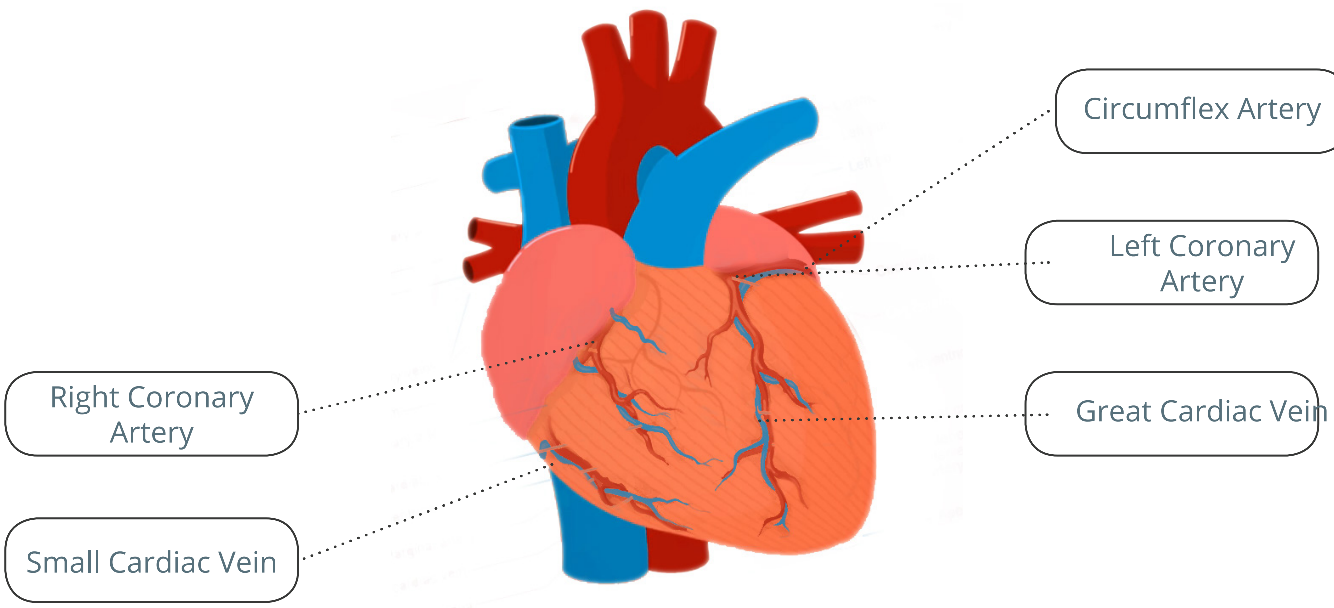

Figure 2.8 Anatomy of the Coronary Heart System (TCS, 2015)

Physiology

The heart's physiology can be divided into two parts; firstly the timespan which is dedicated to filling, also known as diastole, and the time frame in which it is dedicated to pumping blood towards the body, which is known as systole. These 'loops' through which the blood flows in order to go from a state of deoxygenation, to being oxygenated and pumped throughout the body are respectively known as the pulmonary circulation loop, and the systolic loop. Which are described below.

Pulmonary Circulation Loop

The first portion of the heart's cycle goes by the name of the "Pulmonary Circulation Loop". It is visualised in Figure 2.5. Blood is pumped towards the pulmonary trunk through the pulmonary semilunar valve by contraction of the right ventricle. The pulmonary trunk is a large vessel which splits, causing it to form the left and right pulmonary arteries, where oxygen can be picked up. This is the only time an artery carries deoxygenated blood.

The blood then finds it way to capillaries which are extremely thin-walled. These allow materials to dissipate out of and into the bloodstream. In case of the lungs, carbon dioxide moves out of the bloodstream, while oxygen moves in.

Upon this, the blood circles back to the heart through the use of four pulmonary veins. The blood moves to the inside of the relaxed left atrium, which is the area of lowest pressure. Subsequently the left atrium contracts, increasing its pressure, which causes the blood to pass through the mitral valve towards the left ventricle. This sequence of events is how the blood carbon dioxide is unloaded into the lungs, and exchanged for oxygen, called "the pulmonary circulation loop".

Systemic Loop

The systemic loop, which follows and precedes the pulmonary circulation loop, is where oxygenated blood is being pumped and delivered to all the different parts of the body. This loop is initiated in the left ventricle, which contracts in order to increase its internal pressure. Naturally, the blood would attempt to flow back to the low pressure area in the left atrium, however this is prevented by the closure of the mitral valve. Resulting the blood to be forced through the aortic semilunar valve, towards the aorta. After contraction the aortic valve immediately closes such that it is forced towards the rest of the body.

After oxygen has been delivered to the necessary parts of the body, the oxygen-poor blood is looped back towards the heart. It flows through the superior and inferior vena cava veins into the right atrium. From the moment the right atrium contracts, the blood can pass into the relaxed right ventricle by opening of the tricuspid valve. From here blood can once again flow into the pulmonary trunk. From this point the pulmonary circulation loop can be re-initiated.

This dual-looping cycle repeats like an ongoing figure eight. From heart, to lungs, to body, and back to heart again; fueled by the constant low and high pressure differences which are created by (de)contracting ventricles and steered/regulated by the heart valves.

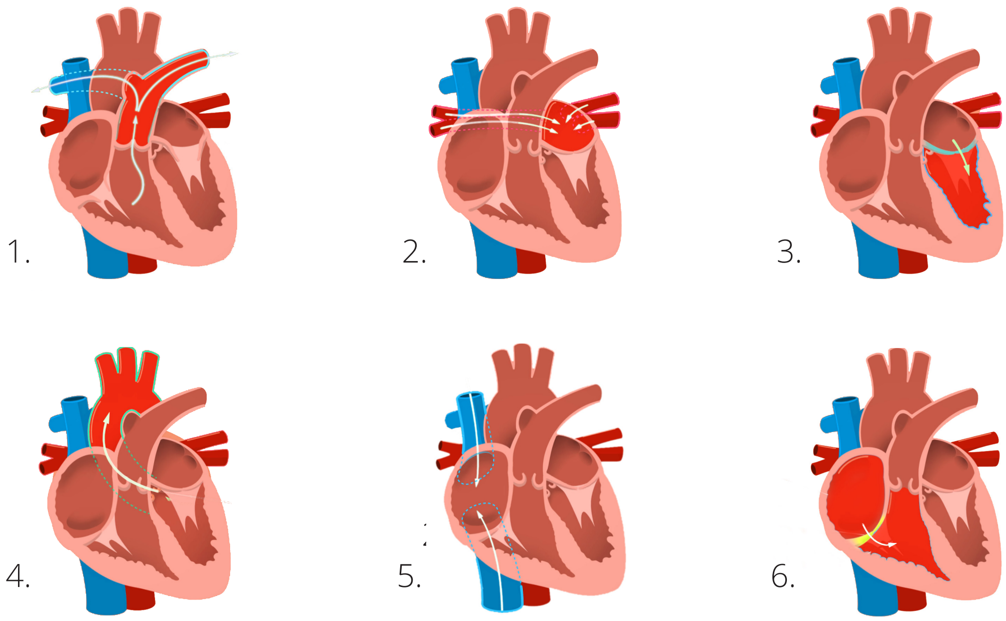

Figure 2.9 Visualisation of the Pulmonary & Systemic Loop (TCS, 2015)

Cardiac Pathologies

Since the heart has a plethora of interdependent mechanisms, naturally there are a lot of things that can malfunction and cause diseases. The most common ones are described below.

Valvular Heart Diseases

The valves in the heart are responsible for letting blood enter and exit from the ventricles smoothly, while making sure that there is no backflow of blood into areas where it just came from. The heart valves can be seen as gates that should only open in one direction, and have three leaflets that can hinge forward in order to let blood flow through. Malfunctions concerning heart valves are classified under valvular heart disease.

Since the heart valves have the two main functions of letting blood through, and preventing backflow, the categories concerning valvular heart disease are directly linked to this. Namely, the two categories that valvular heart disease can be divided into are as follows.

Valvular Stenosis

Valvular Stenosis means that a heart valve isn't opening properly (Figure 2.10), meaning that blood cannot sufficiently flow through. The flaps of the valve could be thickened, stiff or fused together. This creates a smaller opening for the blood to flow through. Due to the fact that the blood cannot flow through sufficiently, the heart has to work harder and as a result the body could receive a reduced supply of oxygen.

Valvular Regurgitation

Instead of having a problem with opening, valvular regurgitation is when a heart valve has trouble closing properly (Figure 2.10). Regurgitation occurs when blood flows back through the valve as the leaflets are in the process of closing, or blood will leak through when the valves should be completely shut. Simply stated, valvular regurgitation means that the heart valves are leaking. This leakage results in a reduced supply of oxygen rich blood the heart can deliver with every contraction. This can result in the heart needing to work harder and/or the body receiving less oxygen.

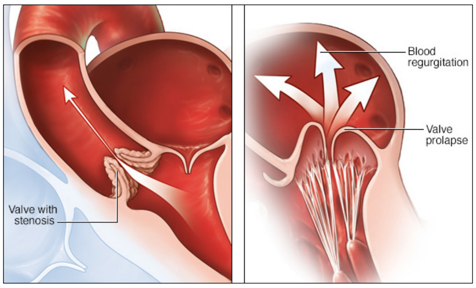

Figure 2.10 Valvular Stenosis & Regurgitation (Mayo Clinic, 2016)

Cardiomyopathy

When the heart muscle is diseased or impaired in a certain way, it is almost always described as a form of cardiomyopathy. The name Cardio - Heart, Myo - Muscle, Pathy - Disease, encompasses what the disease entails. The main things that can go wrong with the heart muscle can be contraction problems, ventricle shape problems and even problems with ventricular stiffness. All of which lead to an obstruction of blood flow and a decreased volume of blood being ejected per heartbeat. These main issues lead to different pathologies, resulting in the three main types of cardiomyopathy. Namely, dilated, hypertrophic and restrictive cardiomyopathy, visualised in Figure 2.11.

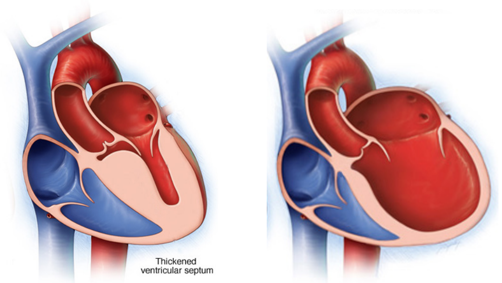

Figure 2.11 Examples of Cardiomyopathy (Mayo Clinic, 2016)

The Stethoscope's Role in Diagnosis

As stated before, valvular heart disease and cardiomyopathy both create problems for the heart's output of oxygenated blood toward the body. This is due to the fact that the irregularities caused by the diseases cause blood flow that is inefficient, obstructed and turbulent. The nature of the stethoscope is to hear irregularities in the heart, while also being able to place them on the correct point in the timeline of the heart contraction. As previously described, the sounds that a healthy heart make (S1 and S2) tell you in which cycle or loop it is at that specific moment in time. Both the regular, and the irregular sounds are caused by blood flow. However, sounds caused by abnormalities in the heart are called murmurs. Therefore, the role of the stethoscope is to listen to and identify murmurs in the heart such that possible problems can be uncovered. All of the valvular heart diseases have their specific murmurs, and most of the cardiomyopathic diseases also display a type of murmur. The Appendix shows all of the different types of heart diseases, as well as their respective murmurs and usual diagnostic procedure.

2.3 Market & Developments

The next step in the development of the stethoscope has been the emergence of the electronic stethoscope. The electronic stethoscope allows the user to digitalize the patient's heart sounds, as well as amplify and filter them. There are different ways to digititalize heart sounds and there are multiple companies that have brought electronic stethoscopes on the market that do this in their own way. A multiple of these stethoscopes was analyzed and compared in order to find gaps for improvement; this chapter will highlight their key commonalities and differences.

Electronic Stethoscope Comparisons

For the comparison the 3 biggest electronic stethoscopes on the market were compared. This was done since these are used the most in the medical context and therefore pose the biggest standard for improvements in this sector. The full analysis of the three stethoscopes can be found in the Appendix .

Litmann 3200

Littmann is the largest stethoscope producer in the world to date (Littmann, 2015), and has been producing electronic stethoscopes since 2009, pushing the auscultation paradigm from purely acoustic to more electronic. In 2015, Littmann released their latest version of the electronic stethoscope: The Littmann 3200 (Figure 2.12)

The Littmann 3200 is a stethoscope that offers a good amount of features in a relatively compact, and classical design. The function that combines bell and diaphragm activation by means of applied pressure is probably the most unique selling point of the stethoscope, a feature that is also integrated in a few of their acoustic stethoscopes. The sound quality has been reviewed as relatively low, and its bluetooth functionality is not great. The fact that it can record 12 audio clips with a maximum length of 30 seconds is noteworthy, but the individual transfer of those files via bluetooth seems very inconvenient. The provided software is not free, and also has not been deemed to be very good. Overall the stethoscope performs relatively adequately, and is one of the best selling electronic stethoscopes, but is definitely lacking in a lot of areas.

Figure 2.12 Littmann 3200 (Littmann, 2015)

Thinklabs One

The Thinklabs One (Figure 2.13) is an electronic stethoscope that falls into the range of more radical innovation. It was primarily invented by an electrical engineer, Clive Smith, who used electric field intensity differences instead of air pressure differences in order to digitize and amplify the heart sounds. It has been deemed to be one of the electronic stethoscopes with the absolute best sound quality on the market (BestStethoscopeReviews, 2016).

The Thinklabs One is an electronic stethoscope that performs relatively well on sound quality (apart from white noise problems), but a lot of improvements can be made on the front of heart-sound recording, software and general user experience. This stethoscope looks very sleek at first, but once it is paired with the additional devices that are needed for recording, the product makes a messy impression. It shows that the Thinklabs One doesn't have product completeness and that there is definitely still a lot to improve in this area.

Figure 2.13 Thinklabs One (Thinklabs, 2014)

EKO Core

The EKO CORE (Figure 2.14) is also one of the electronic stethoscopes with a novel approach to auscultation. It is designed in such a way that it both functions acoustically, as well as electronically. It is also possible to purchase the 'electronic' part separately, and convert any acoustic stethoscope into an electronic one.

The EKO CORE offers a lot of novel features which are unprecedented in other stethoscopes. First of all, it allows you to convert any acoustic stethoscope into an electronic one. The complete EKO Core also looks and functions like a classical stethoscope. This of course means, that all of the disadvantages of a classical stethoscope come into play. It is not possible to record the entire frequency spectrum at once, and one has to switch between the bell and diaphragm when needed. There is also no real time frequency filter, but this is partially done in an analogue way by switching between bell and diaphragm. As for sound quality, there is not much information to be found which objectively assesses the matter. The software for the EKO seems to be very good, both having a HIPAA compliant application and web-based dashboard. It has heart-rate analysis, which allows you to see the patient's heart rate while recording.

The individual transfer of those files via bluetooth seems very inconvenient. The provided software is not free, and also has not been deemed to be very good. Overall the stethoscope performs relatively adequately, and is one of the best selling electronic stethoscopes, but is definitely lacking in a lot of areas.

Figure 2.14 EKO Core with recoding software (EKO, 2015)

Stethoscope Scoring

The previously discussed electronic stethoscopes were scored on their discussed features, with an additional factor regarding the completeness of the design; meaning if the product can be used with all of its expected functionalities without additional attachments. The factors were assessed with a score between 0-2. The results are visualised in Figure 2.15.

Result Elaboration

As can be seen, the Thinklabs One scores high on the front of sound quality due to its novel approach to the digitization of heart sounds. The Littmann 3200 scores the lowest in comparison to the other stethoscopes on amplification due to the fact that it has roughly half of the amplification qualities that the EKO Core has. However it does score high on filtering due to its pressure based filter, as well as digital high and low-pass filter. Nevertheless, it scores very low on software usability, just like the Thinklabs One, since both of their software packages have been met with quite some criticism (Strong Medicine, 2015). The EKO Core scores very high on software since it has been reviewed as very user friendly and usable by multiple sources (Medgadget, 2016) (DocOssareh, 2016). Lastly, since it allows complete functionality without any other necessary attachments, as well as acoustic stethoscope functionality, it gets the full score for product completeness. In contrast to this, the Thinklabs One requires multiple attachments before it can record heart sounds.

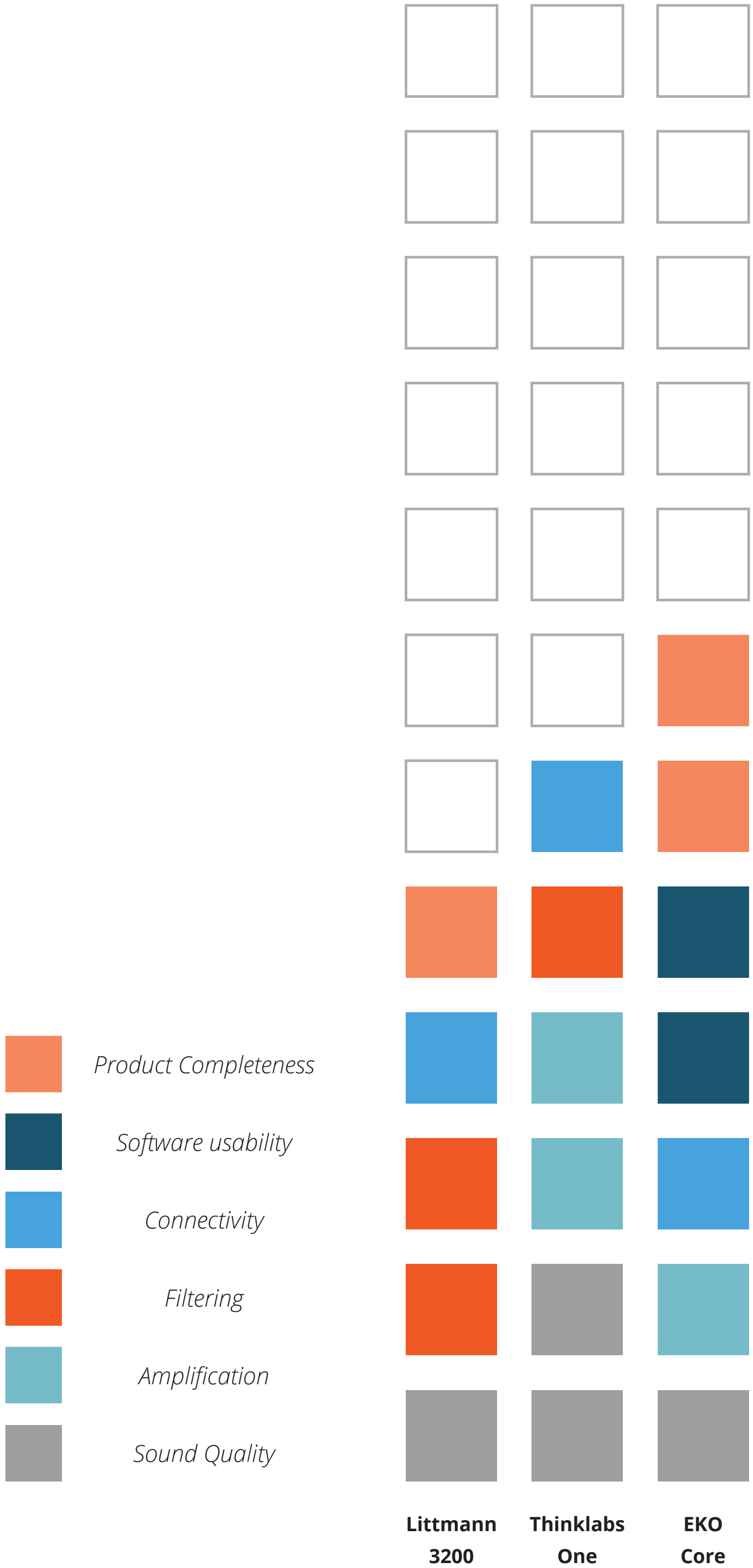

Figure 2.15 Visual Summary of the Market Analysis

Bi-Axial Overview

The overview (Figure 2.16) shows that most of the electronic stethoscopes on the market have some kind of additional functionality. Usually this is on the fronts of real-time sound filtering, switching between modes, or even the addition of a digital thermometer. Clinicloud and Cloudsteth were not mentioned in the more extensive analysis since they are not widely available on the market yet, and do not exhibit novel functionality.

The important thing to note is that the extent to which each of the stethoscopes facilitates assistance with the interpretation of information is still quite low. The EKO Core is the only stethoscope which comes with real-time visualisation capabilities and software that is easy to use.

The gaps on the top and bottom right of the graph show that a stethoscope with facilitated interpretation capabilities, such as software analysis and/or visualisation would be a novel product in the electronic stethoscope market, adding benefit to the medical sector and even the market itself. Additional functionality is quite a given, but it might be beneficial to enable a purely auditory setting, such that the degree of additional functionality can be controlled by the user.

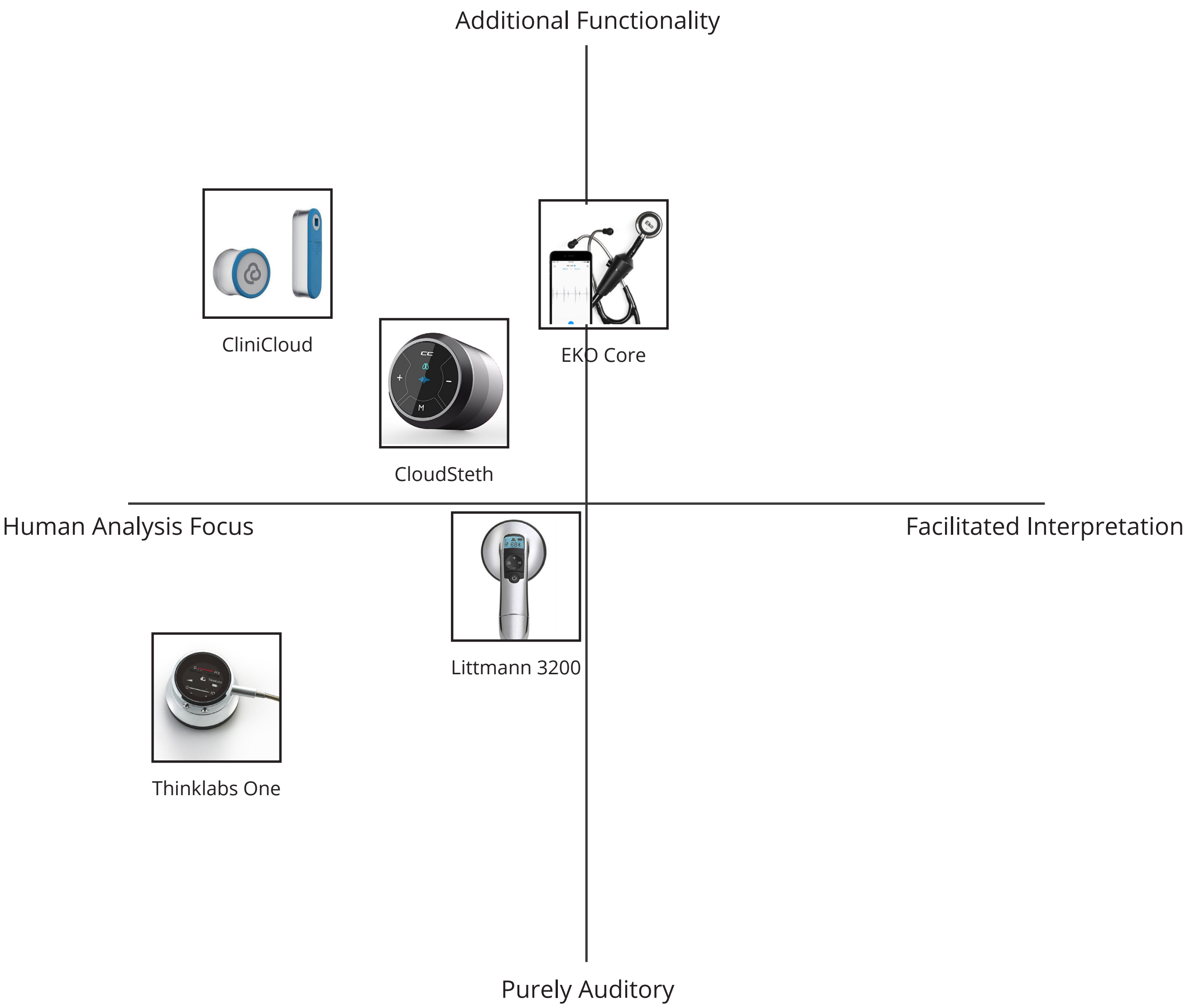

Figure 2.16 Bi-Axial overview of the most prominent commercial stethoscopes

Research Based Stethoscopes

This chapter has the specific aim to analyze and target novel deveopments concerning electronic stethoscopes. Therefore instead of presenting the research oriented stethoscopes separately, the most important features in recently developed stethoscopes are presented and analyzed in the following chapter.

Noise Reduction

An important aspect of noise reduction is the introduction of band-pass filters in order to filter background noise. It is an analog implementation in order to completely cut out certain frequencies from the spectrum, in order to clean up the recording. This seems to be the standard in most research papers (Tang et al, 2010) (Leng et al, 2015). The most common filter being the Butterworth band-pass filter, which is used to filter both low and high frequencies. However, the taken risk is that frequencies important for the classification of cardiovascular diseases are cut out.

Real Time Analysis of Heart Sounds

Research based stethoscopes mainly focus on data analysis of heart sounds while creating their own stethoscope in the process. Shi et al, developed a wireless stethoscope that was able to extract the time-occurence of the heart's most important heart sounds (S1 & and S2), and its oscillation frequencies in real time. Being able to extract those acoustic parameters in real time can be useful for the diagnosis of heart diseases, with specific regard to valvular heart disease. Shi (et al) most of all shows that it is possible to create a wireless stethoscope with adequate data transfer and analysis possibilities (Shi et al., 2016).

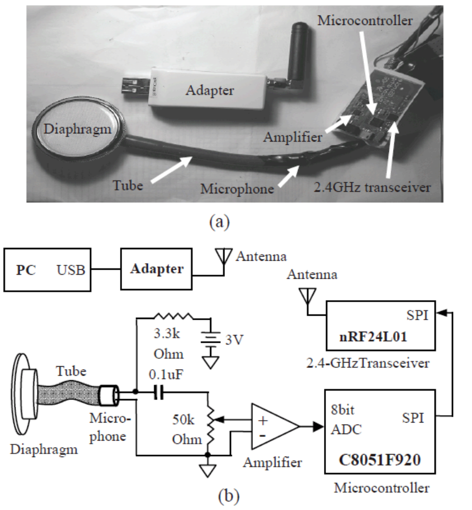

Figure 2.17 Wireless Electronic Stethoscope (Shi et al, 2016)

Electronics

Improvements on the front of electronics is also something which has an important focus in the development of research based stethoscopes. Ou et al, developed a stethoscope with a Micro Electrical Mechanical System (MEMS) Microphone. It has a smaller shape, higher heat resistance, vibration resistance and frequency response. This high-heat resistance apparently also saves money in the manufacturing process, since cooling actions in order to prevent heat damage aren't necessary. Besides this, it uses flexible printed circuit boards in order to reduce noise from vibration (Ou et al., 2016).

Spectrogram Analysis

There is a new movement in the field of cardiological research, namely the analysis of heart sounds with the use of spectrograms. A spectrogram in this context is a visualisation of heart sounds in a new way, showing which frequencies recorded at the highest volume over the course of a certain time period. This results in an image which completely visualizes a snippet of audio footage. This method has been used for years in the field of speech recognition software, but is now also moving toward the analysis of heart sounds using neural networks. Last year there was the PhysioNet / Computing in Cardiology Challenge, which provided a Database of heart sounds and heart sound visualisations, challenging computational scientists to create a classification algorithm to separate normal from abnormal phonocardiograms. Multiple approaches and algorithms were developed in order to differentiate between normal and abnormal heart sounds and their visualisations (phonocardiograms). The algorithm with the highest accuracy was able to classify up to 86% of the heart sounds correctly. With a specificity of 96%, meaning it was able to correctly recognize 96% of the abnormal heart sounds in the testing procedure of the algorithm (Potes et al, 2016). All of these algorithms are open source, and can be implemented if the necessary credit is given (Clifford et al., 2016). More about this topic can be read in the Technological Analysis.

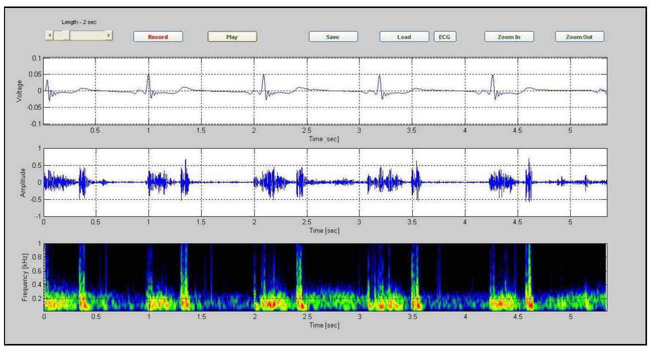

Figure 2.18 Spectrogram (Rogan et al, 2014)

CONCLUSION

The electronic stethoscopes that are currently on the market all offer a certain functionality that add a benefit over the acoustic stethoscope. The key differences between the most successful stethoscopes are their way of registering and digitizing heart sounds, which range from use of a microphone, to measuring differences in electric field intensity. The most important aspects to note, are ease of recording , storage capabilities, and file transfer. It still seems quite time consuming to start recording, stop recording and save files. Other than that, harmonization of the product with the provided software is also very important. The EKO Core does this the best, the communication between the product and the software goes quite seamlessly, and can be used on a wide range of smartphones and tablets. However this is the only stethoscope that has software that is not sub-par.

An important factor that seems to be missing in all of the stethoscopes, is a form of feedback loop between the user and the product. It seems like all of the stethoscopes left the interaction between the doctor and the stethoscope unchanged, whereas there could be a lot of changes and improvements in this area. With an integrated feedback loop the interaction between the doctor and stethoscope could be more seamless, fluent and rewarding.

Other than that, areas that leave room for incremental improvements are in software, compatibility, connectability and overall interaction.

None of them offer a solution which combine: high sound quality, seamless interaction, quick recording and transfer capabilities, effective noise cancelling, useful feedback, and a compact & complete design. Of course, a cost effective solution which also doesn't violate any patent rights is presumably not possible. Therefore the most important factors to focus on in this project are the interaction & feedback aspect, as well as the completeness of the design.

DESIGN IMPLICATIONS

Feedback

In a setting where important information is being gathered, a lack of feedback could cause use errors, misunderstandings or even oversight of crucial information. Therefore the design should integrate a feedback loop that would positively benefit the interaction.

Product Completeness

Handling of electronic stethoscopes can be more cumbersome than aucoustic ones. The design should aim to make recording so seamless that it doesn't take the cardiologist any extra effort or distract him from the patient. The recording and transfer of heart sounds in an unobtrusive manner requires an interaction that is perceived as seamless by both the doctor and the patient.

CONCLUSION

What can be concluded is that there is a lot of potential on the front of research in the area of stethoscope development. There is the aspect of hardware development, which mainly focuses the development of electronics that are less susceptible to noise caused by movement. Besides this, MEMS microphones that can outperform current sound recording technologies are starting to get integrated into electronic stethoscopes.

The software aspect is something that is developing in an even more promising manner. Algorithms are being developed that can distinguish normal heart sounds from abnormal with an accuracy of up to 85% (Xe et al., 2017); of course this is also dependent on the quality of the recording and type of recording technology used. Software development shows promising opportunities for computer aided diagnosis. Of course, it will still take time for completely reliable and real-time analysis, but anticipation and hardware/design facilitation of this is very important.

The analysis of research-based stethoscopes and their development have shown that there is no incentive to broaden the stethoscopes diagnostic abilities yet, which leaves a large space of opportunity. However, the developments on the front of heart sound classification by use of software is very promising. Therefore it is important to design the product in such a way that it can facilitate and function in harmony with such software capabilities when they actually fully break into the medical sector. The developments on the front of electronics and wireless data transfer, presented in (Ou et al., 2016) & (Shi et al., 2016), show that hardware improvements to electronic stethoscopes will only be a matter of time. The question is just: Who will be the one to integrate these promising developments into a product that could take the field of cardiology by storm?

DESIGN IMPLICATIONS

Minimized Electronics

Micro Electrical Mechanical Systems (MEMS) are on the rise and are also starting to be integrated. The design should aim to include MEMS electronics into its configuration in order to keep the design as compact as possible.

Analysis for Facilitation

The analysis of heart sounds with machine learning algorithms is becoming more and more advanced. The hardware and design of the stethoscope needs to anticipate and enable software analysis of heart sounds, possibly combining this with the aforementioned feedback mechanism.

2.4 Technology & Trends

This chapter discusses technologies and trends that come very valuable in the field of cardiology and the project respectively. A nother dope sentence that encopasses this chapter.

Software Developments

Software is becoming an increasingly powerful tool in improving the efficacy of non-invasive tools thanks to the growing amount of accessible clinical information through databases. Because of this, software can transform previously insignificant data into valuable information. Therefore software is one of the most promising trends in cardiology; the following section will go deeper into the most important developments.

The most important development that should be noted is the Computing in Cardiology Challenge of 2016, which is anually organized by Physionet. It is an annual challenge in which computing oriented particpants are invited to tackle clinically interesting problems which are either unsolved, or not well-solved. In 2016 the focus was on the automated classification of normal & abnormal heart sounds; challenging the participants to create an algorithm which was able to distuinguish between abnormal (unhealthy) and normal (healthy) heart sounds with use of machine learning algorithms. Physionet combined as many databases of labeled heart sounds they could find, such that the participants could train their algorithms as extensively as possible.

The participants then had to submit their software, letting Physionet run their algorithm on a previously unknown set of heart sounds, in order to see how well the algorithm would perform in classifying the normal and abnormal heart sounds. The algorithms were scored on sensitivity and specifictity, meaning that they were assessed on the amount of correctly recognized abnormal heart sounds, and the amount of correctly recognized normal heart sounds.

As a result, an extensive paper was written about the algorithms and accuracy of the different algorithms. The participants were also asked to write a paper about how their algorithm worked, such that people could understand how the functionality behind the curtain of the software was structured.

The results of the challenge were quite astonishing, with algorithms reaching up to 94% sensitivity, meaning that is was able to classify 94% of the abnormal heart sounds correctly. (Potes et al, 2016) An overview of the scores can be seen in Figure 2.20. The most valuable thing about this challenge is that the algorithms are **open-source**, meaning that provided with the necessary amount of programming knowledge, one could integrate one of these algorithms into a (well-functioning) cardiac screening tool.

The most interesting thing to note about the paper concerning the different algorithms is the variety of approaches that were taken in order to tackle the problem; each creating algorithms that could be useful in their own way. For instance, Langley and Murray came up with an algorithm which only used 5 seconds of a heart recording, without segmenting it into the classical S1 and S2 segments (Langley & Murray, 2017). That algorithm only reached a sensitivity of 80%, which is still very high in general.

Clifford et al. says:

«Due to the audio processing capabilities, mobile phones have the potential to facilitate the diagnosis of heart disease through automated auscultation. However, such a platform is likely to be used by non-experts, and hence it is essential that such a device is able to automatically differentiate poor quality from diagnostically useful recordings since non-experts are more likely to make poor-quality recordings.»

This shows that integration of one of the top algorithms into a situation where an expert is in the position to make a recording, with use of the proper equipment, could result in a situation which is extremely beneficial to the cardiologist, patient and overall health care.

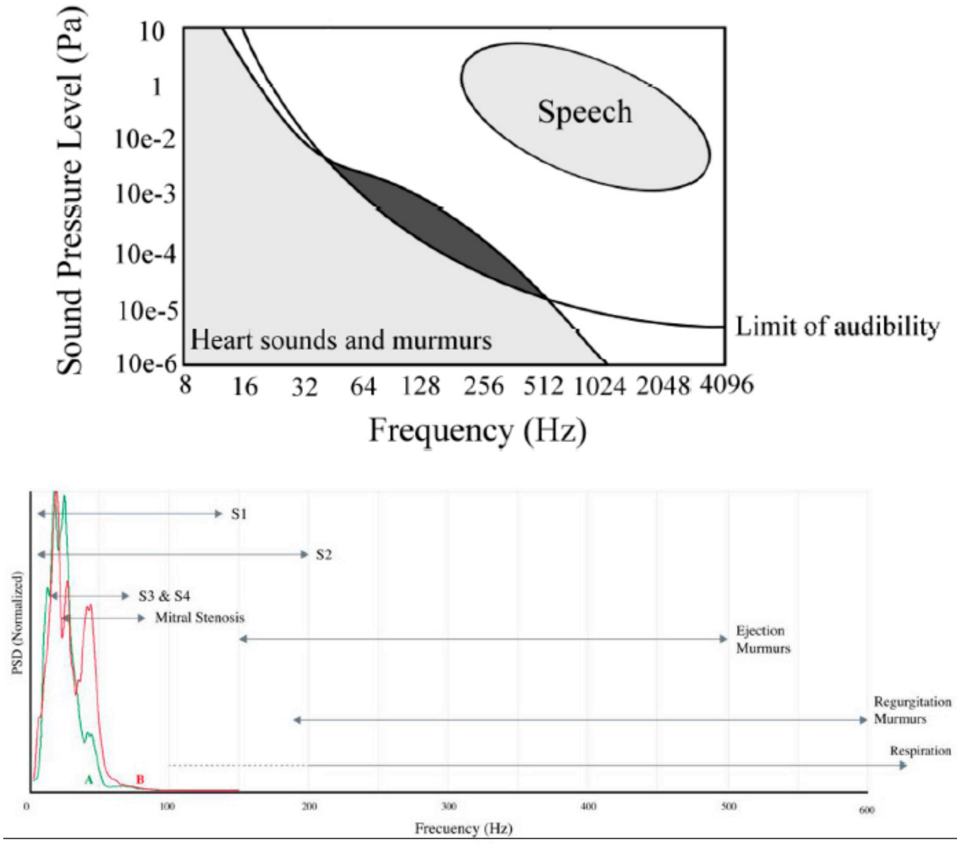

Figure 2.19 Visualisation Explaining Heart Murmur Frequencies and their audibility (Clifford, 2016)

Rank	Entrant	Sensitivity	Specificity	Score	Algorithm Type
1	Potes et al. (2016)	0.9424	0.7781	0.8602	Convolutional Neural Network & Adaboost
2	Zabihi et al. (2016)	0.8691	0.8490	0.8590	Ensemble of Neural Networks
3	Kay et al. (2016)	0.8443	0.8297	0.8520	DropConnected Neural Network
4	Bobillo (2016)	0.8639	0.8269	0.8454	Logistic Regression & Support Vector Machine
5	Plesinger et al. (2016)	0.8848	0.8048	0.8448	Ensemble of Classifiers

Figure 2.20 Overview of the best scoring algorithms from the challenge (Clifford, 2016)

Technology Roadmap

In order to get an overview of the technology that is involved in the sector surrounding electronic stethoscopes, products and technologies with different applications have been plotted into a technology roadmap (Figure 2.23). This analysis provided the possibility to look for opportunity with use of technology as well as to see upcoming trends within the field of cardiology and auscultation in general.

Market

Usually, a technology is first implemented into the consumer market, after which it is used for research and implemented into the healthcare sector. However, this is not the case for products which are specifically designed with a medical purpose (Eg. Echocardiography & ECG). More specifically in the field of cardiac monitoring technology, it is usually after implementation in the medical sector, that products come about which try to commercialize the technology from a consumer perspective.

Novel technologies created for the Health Care & Diagnostics market have an impact on medical education upon being successful, consequentially floating into the cosumer market based on the affordability of the technology. For instance, low-budget electrical stethoscopes for the consumer market are widely available, while consumer oriented echocardiography products are not.

Product

The selection of equipment is a mix of products with diagnostic and monitoring capabilities, mostly consisting of electronic stethoscopes, novel pulse-oximeters and novel diagnostic equipment. The most interesting products that have not been discussed before are noted below.

Cheetah Medical

Cheetah Medical's NICOM® Noninvasive Cardiac Output and Hemodynamic Monitoring System uses the company's proprietary BIOREACTANCE® Technology to deliver continuous, accurate, noninvasive cardiac output (CO) and Stroke Volume monitoring parameters. The system is US FDA cleared and CE Marked. (Cheetah Medical, 2016)

Acarix

Acarix A/S has developed a new non-invasive screening method for detection of Coronary Artery Disease (CAD). The CAD-patch is an acoustic body-mounted sensor designed to identify the turbulent noises from chaotic blood flow in partially blocked coronary arteries. The noise pattern is converted to a score that assesses the patient's likelihood for having CAD. (Acarix, 2017)

Oxitone Pulse Oximeter

Oxitone has developed a wrist-based pulse-oximeter that can pick up pulse rate and SpO2 values with the same accuracy as a traditional fingertip based pulse oximeter.

Figure 2.21 Acarix Acoustics Coronary Heart Disease Stethoscope (Retrieved from Acarix.com)

Technology
The technologies that have been discussed in the previous chapters have been implemented into the technology roadmap alongside other crucial technologies that were needed for the development of electronic stethoscopes. This includes Piezoelectric sensors, which have contributed to the capturing and digitalisation of heart sounds. Other than this the obvious inclusion are Micro Electrical Mechanical Sensors (MEMS) and the Nano Electrical Mechanical Systems (NEMS), which will become more and more embedded into the field of cardiology in the coming years (Ciuti et al., 2015).

Piezoelectric Sensor
A piezoelectric sensor is a device that uses the piezoelectric effect, to measure changes in pressure, acceleration, temperature, strain, or force by converting them to an electrical charge.

Capacitive Sensor
Capacitive sensing is a technology, based on capacitive coupling, that can detect and measure anything that is conductive or has a dielectric different from air.

Trends
There are multiple relevant trends within the healtcare sector that are important for this project. Figure 2.22 shows a comprehensive overview of all trends.

Big Data
The promise and potential of data analytics in healthcare was described by Wang & Kung (2018). With the growth of the amount of data in exorbitant amounts, new possibilities arise in the use of this data. Data analysis can lead to more thorough and insightful diagnoses and treatment leading to a higher quality of care and lower costs (Wang & Kung, 2017).

Machine Learning & Artificial Intelligence
Machine learning and Artificial Intelligence developments are propelling the usefulness of Big Data, since they allow for rapid optimization of processes and real-time analysis of complex factors. They are becoming more and more embedded into the medical industry, concerning the cardiology sector being mostly used for image analysis. However implementation into analysis of other factors such as ECG and Heart sounds is imminent.

Telemedicine/Telehealth
Telehealth is the overlapping term for the provision of healthcare by means of electronic communication devices such as smart phones, mobile wireless devices, video communication devices. Dorsey et. al (2016) emphasized the trend of a rapidly growing market and potential to transform the delivery of healthcare by means of telehealth. The majority of the market of telehealth is based on follow-up of patients. However, Telemedine ould eventually evolve into digital medical consults, creating the trend of remote diagnostics.

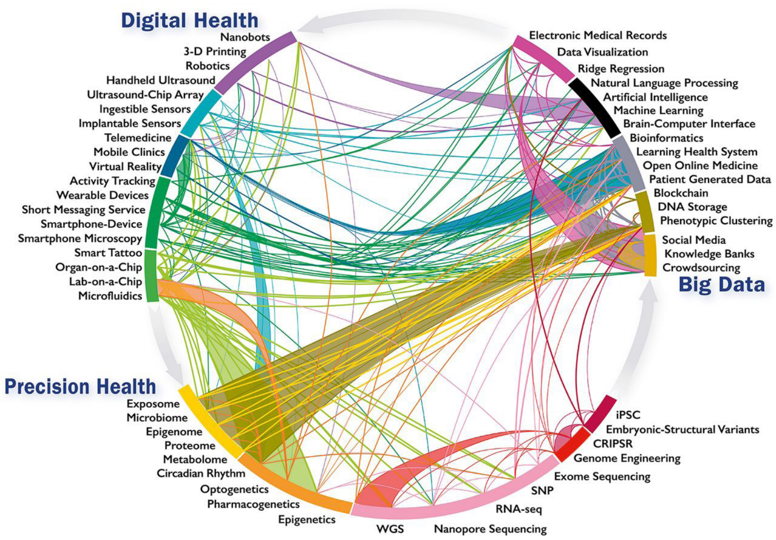

Figure 2.22 2017 Medical Trend Overview (Journal of the American College of Cardiology, 2017)

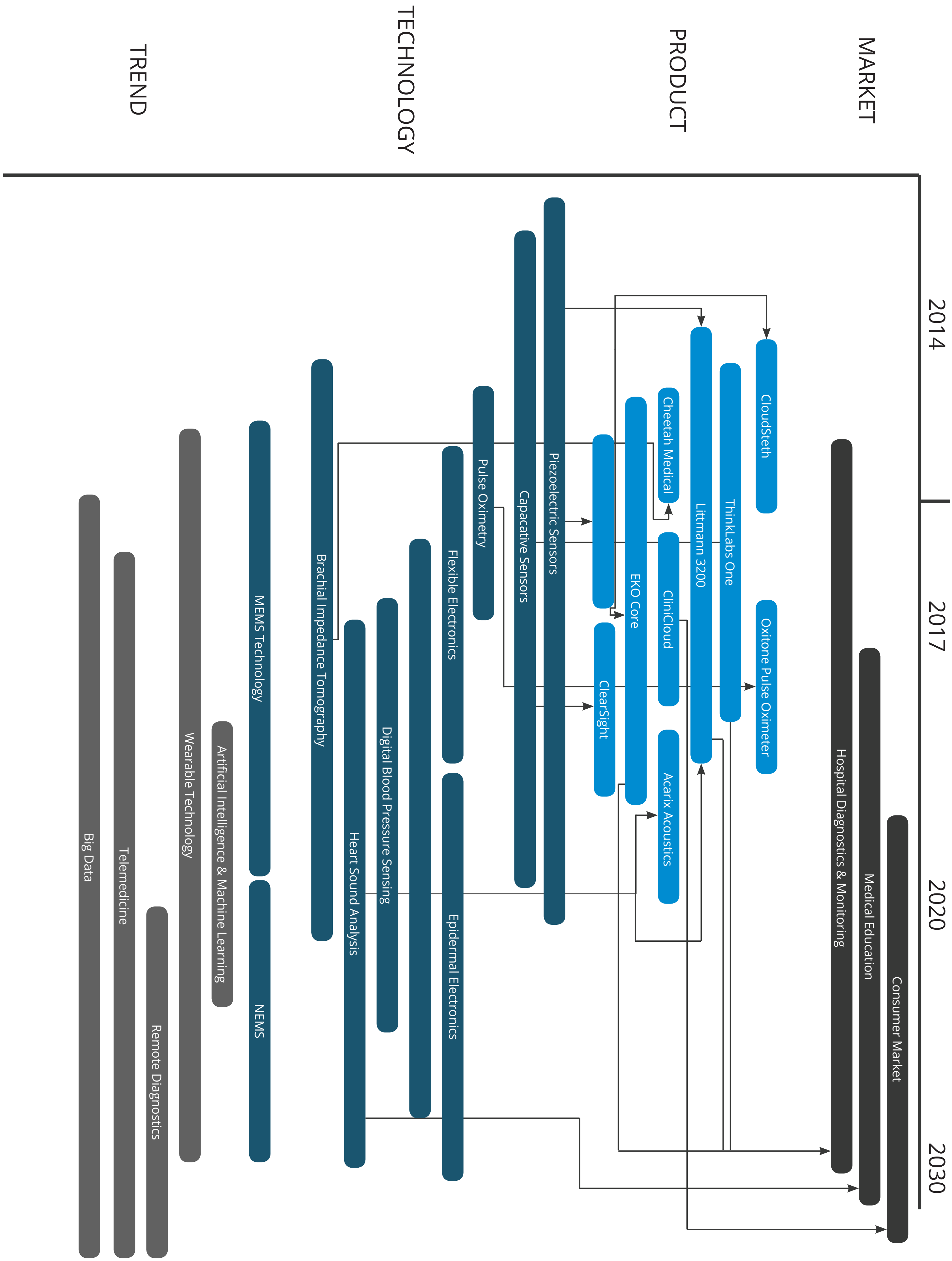

Figure 2.23 Technology Roadmap

CONCLUSION

New technologies that can non-invasively measure important cardiac factors are on the rise, edging their way closer to implementation in the medical sector. Software developments on the front of heart-sound analysis show great potential for diagnostic facilitation in clinical practice. The accuracy is at a point where its value is undeniable; wide spread implementation could have great results.

DESIGN IMPLICATIONS

Algorithm Potential

One of the most non-invasive types of technology remains software to be. The development of accurate algorithms for heart-sound classification points towards a great design opportunity for an intelligent diagnostics device. The design should keep this potential in mind.

2.5 Context & User Dialogue

Seeing the use of the stethoscope in real time plays an important role in creating a design that positively impacts the current medical context. This main objective is to get insight in general use, points of improvement, and important design constraints.

Context Analysis Approach: Usage Variety

It is now clear that the stethoscope is used in different parts of the healthcare system, ranging from family physician, to assistant-doctor, to specialized cardiologists. Obviously these medical professionals have a different skill level when it comes to using and interpreting the sounds of the stethoscope. The user(s) and context can strongly affect the usage of any product, also in the case of a stethoscope. Therefore it was decided that within this project, multiple contexts needed to be analysed in order to gain valuable insights on the different usage patterns of the stethoscope. As said earlier, the analyses of these contexts should reveal current shortcomings of the stethoscope in the areas of feedback, effectiveness, and general documentation purposes.

The following contexts were analysed for the context analysis:

- Context Type 1: Pre-Diagnosis - Policlinical Consult
- Context Type 2: Acute Symptoms - First Cardiac Aid
- Context Type 3: Post Diagnosis & Monitoring - Cardiac Care Unit

Note: A patient (usually) does not go through all of these contexts. It it mostly the case that the patient starts with Context 1 or 2, and will continue to Context 3 after being diagnosed.

Context Subdivision

As said earlier, the purpose of the context analysis was to get insights on many different aspects of stethoscope use in the medical contexts. These aspects range from general usage procedure, to key shortcomings, and feedback opportunities. If these aspects are comprehended, it will result in a well-rounded understanding of each context.

Method

The method used to analyse the contexts shown in Figure 2.24 was done through observations and interviews. Observation was done through real-time presence in each of the contexts. Being as close to the context as possible without necessarily affecting it. The interviews were conducted in a semi-structured manner, with a defined set of questions, allowing devations according to the flow of the interview.

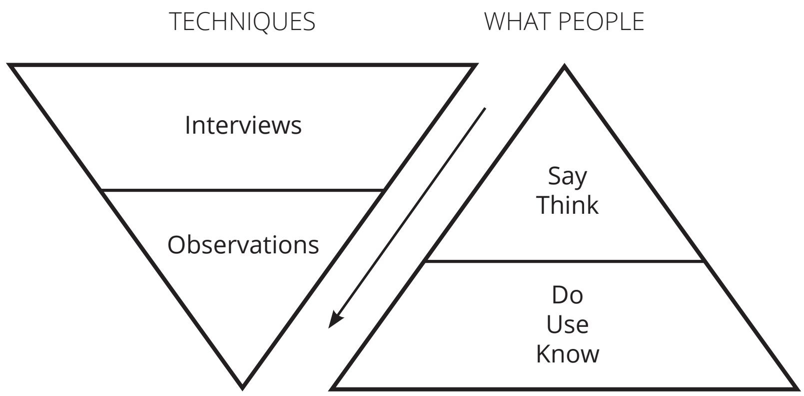

Figure 2.24 Context analysis method simplified from Sleeswijk et al. (2005)

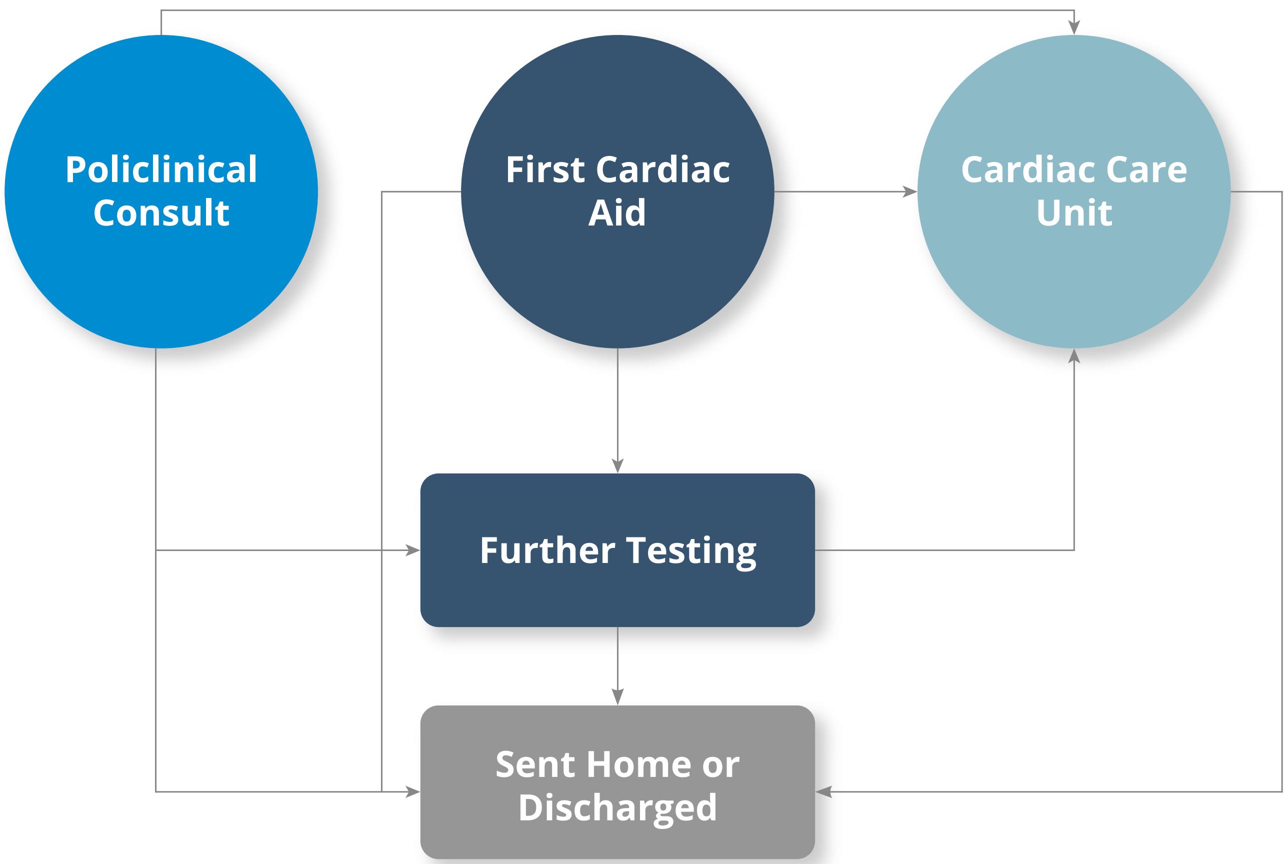

Figure 2.25 Schematical overview of the different analysed contexts

Dialogue with the Users

Within the clinical context the stethoscope is used by many different types of medical professionals, ranging from nurses, to general practitioners, residents and cardiologists. This project focuses specifically on more specialized medical professionals in the field of cardiology. Therefore the target group within this project focuses on cardiologists and cardiologists in training (i.e residents).

The Users

Cardiologists have gone through 6 years of general medical school, with another 6 years of specialized training. Residents are still in this second specialisation segment of 6 years. Figure 2.26 shows this process.

Understanding the Target Group

In order to gain in-depth insight in the users of the stethoscope, user research was conducted in the form of semi-guided interviews. The objective was to understand the use of the stethoscope from the point of view from the user, within their clinical context. Besides this, questions on the front of medical education and shortcomings were also discussed. In order to get more feedback on medical education, interns were also included in the interviews.

The users that were interviewed were experienced cardiologists, as well as residents. Questions were asked about:

- *General procedures surrounding auscultation*
- *Applications of the stethoscope*
- *Difficulties surrounding stethoscope use*
- *Medical Education Concerning auscultation*

The list of questions can be found in Appendix B.
The following pages will discuss these aspects in detail in relation to the conducted interviews.

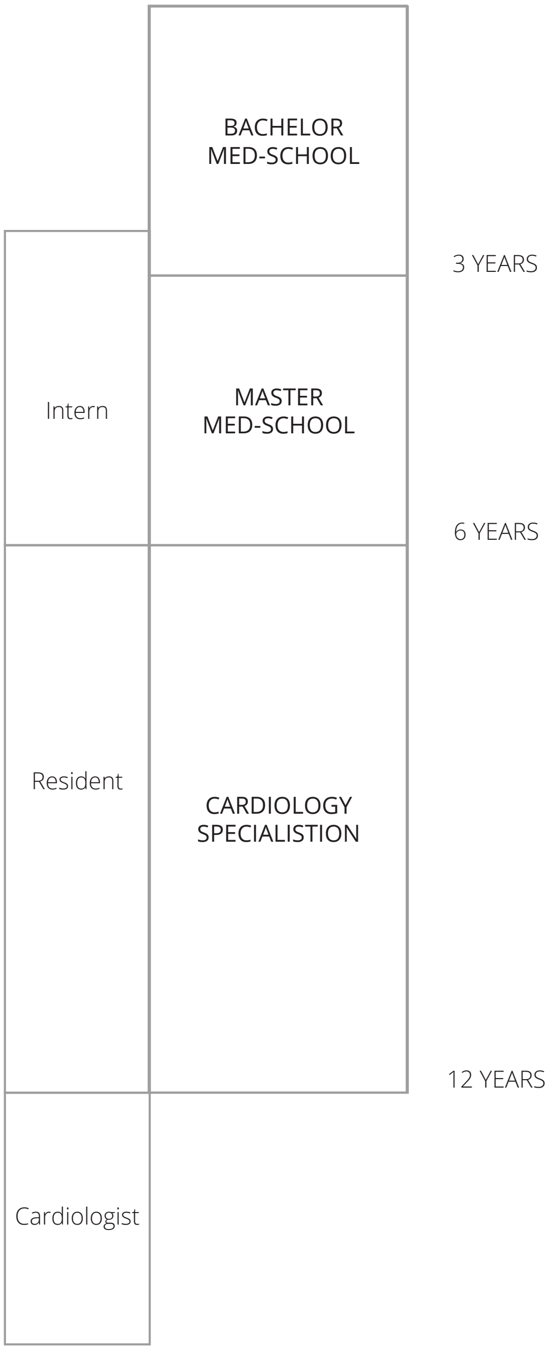

Figure 2.26 Educational Timeline of Cardiologists and Medical students

General Stethoscope Use

An important thing to note is that every doctor has their own routine of auscultating a patient; with the prime task of listening to all of the heart valves. However in most cases the Aortic area is listened to first, since this has the highest anatomical importance and malfunctions in that area mostly present themselves as noticable symptoms immediately. Depending on previous medical conditions certain areas will be listened to more carefully, asking the patient to perform different maneuvers in order to assess the situation more carefully.

Usually findings during the auscultation procedure incite further investigation and more elaborate auscultation; meaning that the presence of a previously unknown murmur can cause far more elaborate auscultation and testing on the patient. Therefore it's imperative that certain clues about a pathology are targeted in order to incite a deeper investigation.

Applications of the Stethoscope

Obviously the stethoscope is mainly used as a diagnostic tool, with which assumptions that the doctor has about a certain pathology are either verified or dismissed. With these verifications and dismissals the image of a patient's state of health becomes more clear, giving the doctor more insight in the action that needs to be taken.

However it is also used as a monitoring tool, in order to assess the development of a patient's pathology over time. If a patient with a previously known pathology (e.g mitral stenosis) is readmitted into the hospital, the auscultating doctor has to assess the previous doctor's notes concerning that specific murmur. The difficult thing is assessing the development of this pathology, purely based on the previous doctor's notes. The notes can be relatively undescriptive and remain a subjective interpretation of sound, which is then converted into a textual description. Naturally this isn't a very effective process.

Other auscultation related monitoring is still mostly done by comparing in-the-moment auscultation sounds with previously heard sounds recalled with the doctor's memory. This method is more effective than converting text into an auditory expectation, but is definitely not optimal.

The interviewees stated that a stethoscope with a recording and monitoring function could definitely benefit clinical processes and streamline the decisions concerning deployment of further invasive testing.

> *"Everyone has their own routine when auscultating a patient.*

> *"Depending on what I hear I can go into a more detailed examination, letting the patient take different positions.*

> *"Sometimes there is more than one thing wrong with the patient, causing your focus to shift more in that direction, causing you to miss other things.*

> *"'The notation of the previous doctor is merely the description of their interpratation of the sound at that time, and everyone's hearing is different.*

> *"Sometimes I think back and ask myself ''how did that sound again, exactly?''*

> *"I think the stethoscope as a monitoring tool could be of value to better assess the necessity for additional invasive testing.*

Difficulties surrounding Stethoscope Use

The interviews presented several perspectives on the downsides and difficulties of stethoscope use. The first one not being able to properly focus on the actual heart sounds due to surrounding noise. Isolating heart sounds from the patient's breathing and external sounds can be difficult to do, especially when trying to locate a murmur in its early stage of development. Other factors negatively impacting sound quality can also come into play, for instance a patient's fat layer or a female patient's bosom blocking certain auscultation areas.

Furthermore, an important difficulty surrounding stethoscope use was the doctor's ability to really take the time to listen critically at every auscultation area. In a context where there is constant movement and turmoil it can be difficult to take this time and listen in the moment. This then also relates back to being able to specifically recall what exactly was heard. This difficulty shows a need for the reproduction of those heart sounds at a later moment in time.

Medical Education regarding auscultation

The medical education regarding cardiology starts quite early in the timeline of medical school. In the second year of the Bachelor's the students are taught to perform the physical examination, with one lesson specifically focusing on the heart, listening to eachother's hearts first. A life-sized doll (Harvey) is used in order to teach the students to learn about murmurs, however a stethoscope is not used for this. Furthermore students ocassionally receive a CD containing heart sounds and murmurs in order to practice with recognition. The interviewees stated that they gained the vast majority of their knowledge on the front of murmur detection and recognition in the field.

At the start of their medical careers the interviewees stated that the most difficult thing was being able to recognize when a heart sound was deviant from the norm; more specifically being able to differentiate between a normal and abnormal heart sound, since some sounds can be completely harmless and other ones can be quite serious.

Overall it seems that certain things in the medical education concerning auscultation can be improved, and that some type of support coming from the technological side could have a positive impact.

"

Taking time to listen critically is not easy in such a busy context.

"

It's never really silent when you're listening.

"

Remembering what you really heard is difficult, especially when there was so much going on.

"

Actually hearing sounds through my stethoscope in the field taught me a lot more, than when I was still a student.

"

The ability to reproduce the sounds at a later moment in time would be very valuable!

Context Observation with Users

This section goes into the different contexts that were observed. Describing the general procedures, auscultation procedure and the user›s tasks, needs and concerns; concluding with the key insights.

Context 1: Policlinic

The Policlinical consult is the first contact a patient will have with another doctor, more specificifally a cardiologist after being referred by the general practitioner. The consult may only last for a maximum of 10 minutes, with 5 minutes of overtime being allowed for new patients. (T Bruning, personal communication 11 January 2017).

General Procedure

The general procedure is that the patient comes into the doctor's office, and sits down. From here the cardiologist will start asking the patient about his complaints. At the same time the cardiologist will be checking the patient's medical history with use of the Electonic Medical Record. At the Maasstad Hospital the platform that is used for this is called HiX. The EMR will contain important information like previous ECG's, X-rays or even old echocardiograms. The medication the patient takes is also an important factor and is not always up to date in the EMR, therefore the cardiologist will always ask a range of questions in order to get the most up to date information.

Usually the cardiologist then commences to auscultate the patient. Once the auscultation procedure is complete the cardiologist discusses the next steps with the patient. These steps range from new medication, to prospective tests that the patient has to undergo. Once this has been discussed the consultation will come to an end.

Key Insights

The most important insights that were gained from this context was the extreme rate of efficiency with which the stethoscope was used. The stethoscope was positioned on the different places on the body for only two heart beats or less; taking up only very little time to auscultate the heart. From an efficiency perspective this is admirable, however such rapid procedures could also be detrimental if a cardiologist is less experienced, possibly missing an important diagnostic clue. This simply underlines the assumption that it could be helpful for cardiologists to re-listen to a certain recording after the opportunity has passed to listen to the patient in a live setting.

Furthermore, seeing that the the cardiologist's knowledge of the patients pathology had impact on the re-listening or skipping of certain auscultation areas was also interesting. However, due to the fact that this mostly happened with patients who had aready undergone more extensive testing such as cardiac ultrasounds this is more understandable.

Context 2: First Cardiac Aid

The First Cardiac Aid (Eerste Hart Hulp) is the place where patients who experience actute and severe heart related complaints are sent to. This can range from coming in with an ambulance, to people who come to the hospital themselves, or even from in the hospital itself. Most of the time these acute complaints relate to chest pain, which can be caused by a (partial) heart attack or arterial constriction.

Key Insights

What stuck out the most in the situation of the First Cardiac Care was that there was less urgency involved concerning the assessment of the patient's health than expected. However the way of operating was in no way complacent and was very professional. The cardiologist and assistent still took time for every patient and during the observation no stressful or hectic situations occurred. However, in the case of an unstable patient this might play out differently.

Concerning stethoscope use the most prevalent insight was once again its efficiency, total auscultation time was usually under 1.5 minutes. The patterns of auscultation that were followed were mostly by the book with the Aortic area being auscultated the longest.

Context 3: Cardiac Care Unit

The Cardiac Care Unit is where patients who have been diagnosed with (relatively) severe cardiac conditions are hospitalized. This could be after a patient had come to the First Cardiac Care station and had been diagnosed with a heart condition that needed monitoring or treatment. Usually patients that have undergone cardiac surgery are also placed here. Patient's are placed in hospital beds and are monitored with use of ECG electrodes, SpO2 sensors, and sometimes real time blood pressure sensors.

Key Insights

The most important insights from the Cardiac Care unit were the reasons for use of the stethoscope. One of the insights was the difference in positioning depending on the patient's pathology., however the stethoscope was still placed on the aortic and pulmonary area for the longest period of time with most patients.

The stethoscope is used more as a monitoring tool in this case, as opposed to a diagnostic tool due to the fact that the patient has been diagnosed. Therefore the stethoscope is more used as a type of checking tool. However, this doesn't mean the stethoscope isn't used to detect any new developments concerning the patient's heart and lung sounds.

Lastly, it was noticable that the cardiologist had to position him/herself in difficult positions due to the length of the eartubes on the stethoscope being (too) short.

General Auscultation Procedure across the contexts

Firstly the patient will be asked to take place on the bed in a sitting position. The patient is asked to remove clothing that would obstruct the stethoscope›s sound transmission capabilities. Usually the cardiologist starts off by listening to the patient's lungs. The generalized auscultation map can be seen in Figure 2.28 at the end of the chapter. As can be seen this is done in an alternating fashion moving downwards.

Once the lungs have been auscultated, the patient is asked to lie on his back, such that the cardiologist can auscultate the chest area. The cardiologist usually starts at the Aortal area quickly moving through the other auscultation areas such as Pulmonary, Mital and Tricuspid. This is in line with the general auscultation order of APTM (Stethographics, 2014). Intermittently the cardiologist will ask the patient to stop breathing, in order to get a clearer sound. However in some cases certain areas are skipped due to the fact that the patient is a returning patient that has already been diagnosed, meaning that auscultation of certain areas is not necessary.

Lastly, the cardiologist can auscultate different areas on the stomach in order to catch abnormalities concerning the intestines; this seems to be done only occasionally.

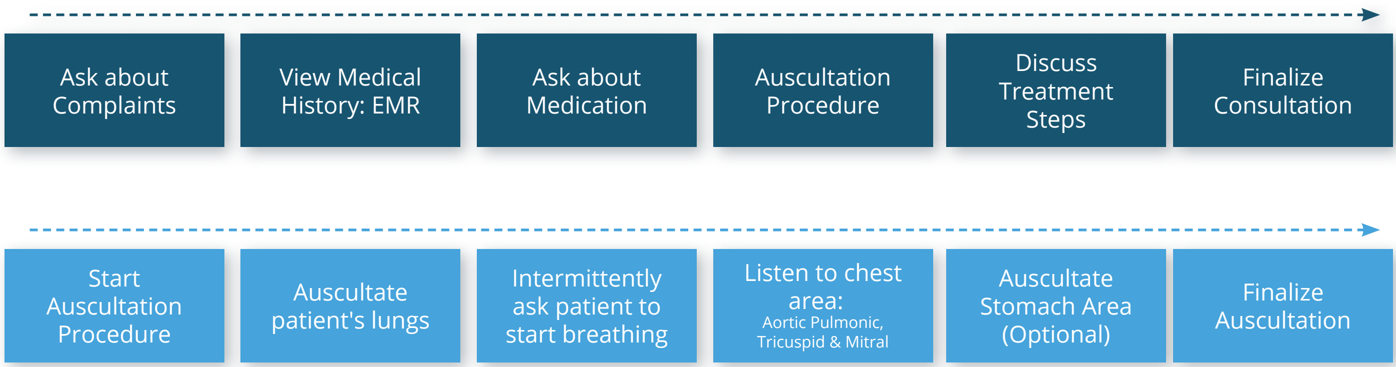

Figure 2.27 Overview of the General Procedures and the Auscultation Procedures throughout the contexts

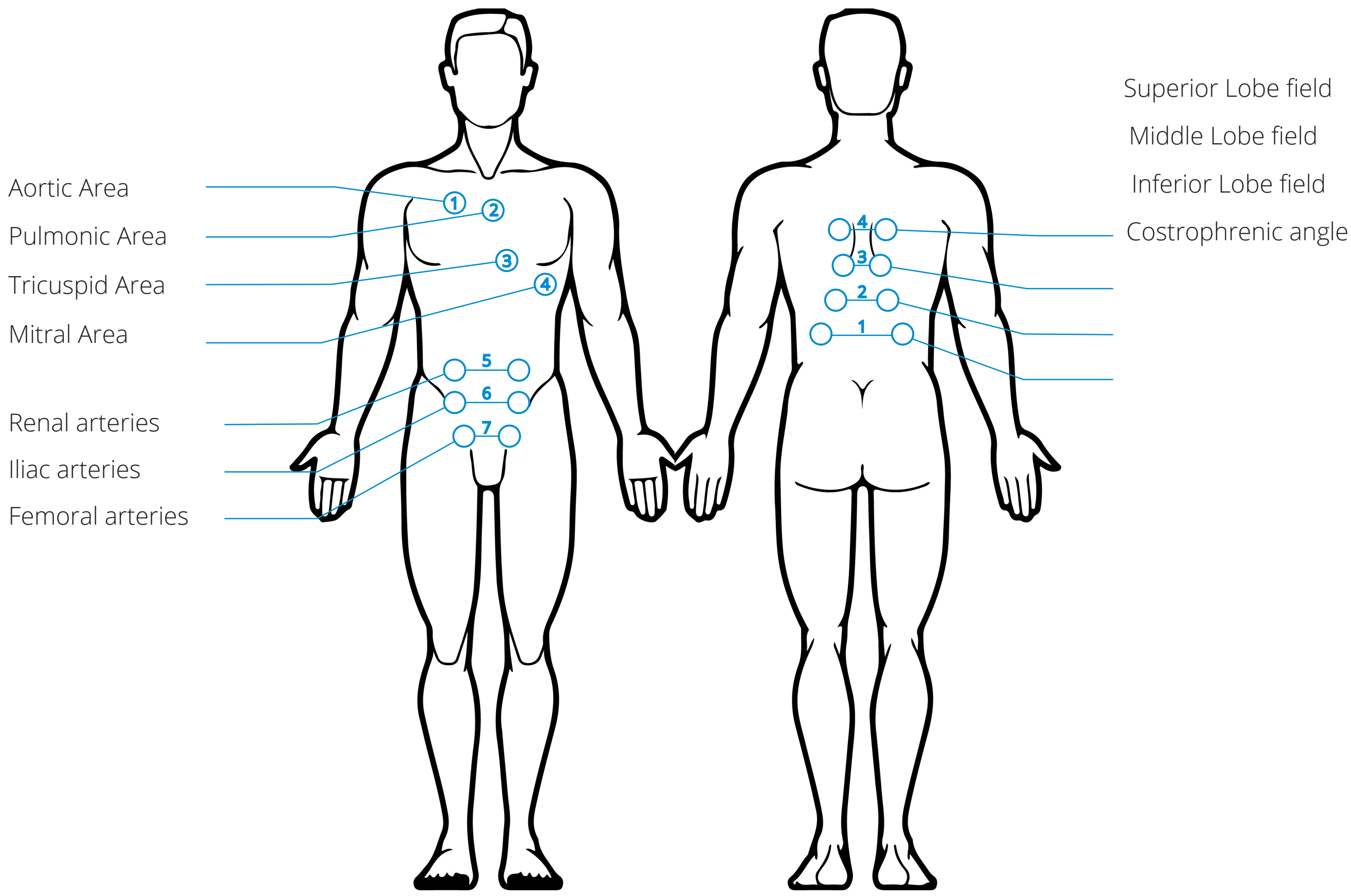

Figure 2.28 The generalized auscultation map from the different contexts

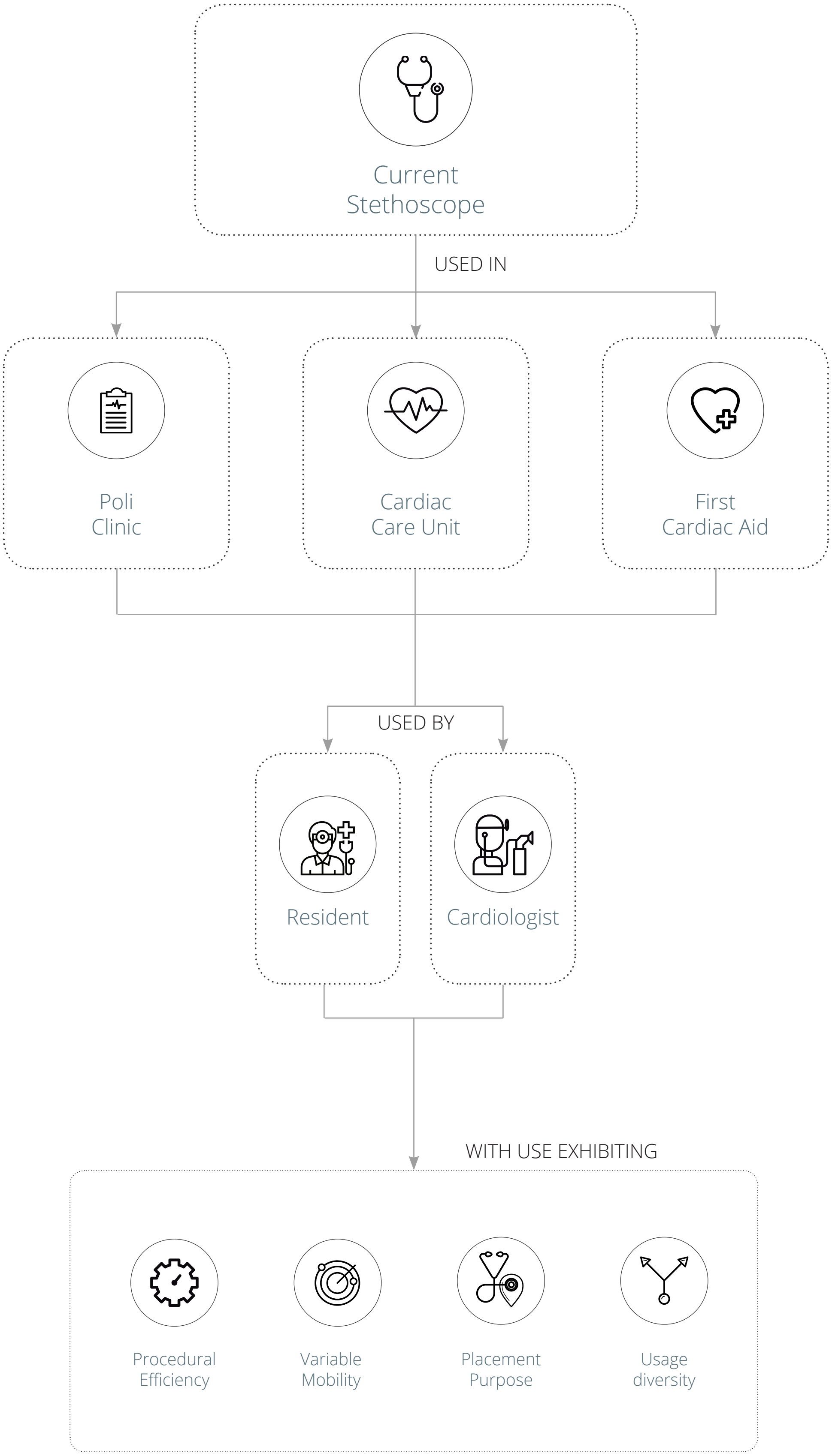

Figure 2.29 Schematical Summary of the Context Analysis

CONCLUSION

From the interviews is became clear that there is a clear need for the facilitation of utilizing the stethoscope as a monitoring tool. Tracking developments of pathologies would be much more consistent if audio records were held throughout the patient's pathological development, dismissing the inconvenience of interpreting a previous doctor's note describing a certain murmur.

Furthermore, listening in real time proves to be a difficult thing, since taking your time in a hectic and sometimes noisy context takes serious composure, and cardiologists sometimes struggle to do so. Reducing this pressure by facilitating later reassessment could greatly impact diagnostic decision making and possibly real-time performance.

The most important and predominant conclusion would be that the stethoscope is used with a very high rate of efficency throughout its different contexts. Auscultation times were always under 1.5 minutes, even when the lungs needed to be auscultated as well. In every context the area auscultated the longest was the aortic area, which was usually also the first place that the cardiologist or assistant auscultated. Other than that the initial auscultation pattern and order was generally correspondent to the well known Aortic, Pulmonary, Tricuspid, Mitral sequence.

However, it showed in Context 2 and 3 that the cardiologist's knowledge about the patient's condition from previous tests or the Electric Medical Record did affect if certain auscultation areas were listened to more carefully or skipped altogether. Also meaning that auscultation of a new patient is usually the most thorough and consistent concerning the auscultation sequence.

Furthermore, throughout the contexts the stethoscope was obviously mainly used for diagnostic purposes. However, in the case of the CCU context, the stethoscope was also used with the (side) purpose of monitoring changes concerning the state of patient's heart and lungs. The interviews showed that there is a need for a stethoscope that has kept the monitoring aspect of the stethoscope in mind.

Lastly, something that is not consistent throughout the different contexts of stethoscope use is the orientation and location of the patient. In the policlinical context, the patient will come into the doctors office for a consult, meaning that the cardiologist and the stethoscope are essentially static. Whereas in the contexts of First Cardiac Aid and the Cardiac Care Unit, the cardiologist and stethoscope are used in a dynamic context, meaning that the cardiologist will be going from room to room in order to visit and in turn auscultate patients

The context analysis has revealed many different aspects of stethoscope use in practice; its versatility and efficient embedding into clinical practice being the most prominent. A schematic overview of this can be seen in Figure 2.29.

DESIGN IMPLICATIONS

Efficiency Compliance

The current efficiency of use of the stethoscope within the medical sector implies that the new stethoscope should comply with this efficient use. This means that its functioning and interaction should be tailored to the current use and efficiency rate of the acoustic stethoscope.

Relieving pressure & taking the time

Taking the time to listen critically proves to be a challenge, and recalling murmurs from memory isn't the most optimal method for clinical practice. Therefore the design should aim to encourage doctors to take time to critically listen, while also giving them the opportunity to re-listen to the patient's heart-sounds at a later moment in time for re-assessment. This could improve auscultation, documentation and clinical effectiveness.

Diagnosis & Monitoring

Since the stethoscope is used both for diagnosis and monitoring purposes, the design should facilitate an improvement on the front of monitoring. This could be done with regard to function or interaction.

Mobility

The type of doctor-patient placement concerning the auscultation procedure varies throughout the hospital. The patients come to the cardiologist and vice versa. The design should keep this variability and need for mobility in mind.

Placement

As mentioned earlier, the information the cardiologist wants to acquire about the patient's pathology can impact in which place the cardiologist is listening first. In some cases the cardiologist will assess the diffences in murmur volume depending on the placement of the stethoscope. This means that the location of auscultation on the body is important. The design should keep this importance in mind.

2.6 Concluding the Analysis

The analysis provided insights on a plethora of facets within the context of stethoscope use and cardiology. This section will contain a discussion of the overarching factors from the analysis in relation to the project. These findings are used for the development of the problem definition, ultimately culminating in a design vision for the further development of the project.

DISCUSSION ON ANALYSIS

Neglected stethoscope potential

The prediagnostic role of the stethoscope is an incredibly important one in cardiology for the sake of diagnostic convenience, hospital efficiency, (early) detection of haemodynamic defects, and even patient monitoring. Therefore the fact they are not used to their full potential is very unfortunate. The cardiac analysis shows that murmurs are present in a large percentage of heart defects, meaning that they can be detected and monitored in the most non-invasive way possible: auscultation.

The current stethoscopes do not provide proper performance on the front of auscultation, documentation or analysis. Heart sounds provide incredibly valuable information about a person's cardiac health, however the actual sounds are not recorded, documented or used to look at the patient's pathology over time. This lack of documentation is just one aspect of the technological capacity that is lacking in the current status quo of auscultation. It is therefore clear that to bring the stethoscope's potential to the highest level, improvements must be made on the front of performance, documentation and analysis.

Technology enriching auscultation

The analysis has shown that machine learning and artificial intelligence are becoming huge drivers of healthcare. The ability to use quantifiable analysis capacities on data that is commonly known as subjective can now provide an extra factor of diagnostic support for reinsurance or diagnostic notification in the case of an otherwise imminently missed diagnosis. The analysis of heart sounds through deep learning algorithms is something that could be addition to electronic stethoscope use; if embedded into medical processes it could greatly improve and aid healthcare.

Use (d)efficiency

The context analysis showed the extreme efficiency with which the stethoscope is used in every sub-context of cardiology. The use is integrated to such an extent that auscultation can take even under a single minute of the entire diagnostic process. In some cases this might sound as a good thing, however from the user dialogue it also became apparent that cardiologists admit that they sometimes struggle with really taking their time to listen, and that can even cause doubts concerning the later recollection of what was heard during auscultation. Therefore it is important that cardiologists are facilitated in this efficiency driven use, while also having the opportunity to take their time and being reminded to do so. This in combination with knowing that the sounds can be replayed at a less hectic moment will also provide the cardiologist with reassurance.

CONCLUSION

As can be seen, the design implications can largely be compartmentalized into the aspects of product functionality, technological opportunity and interaction necessities. Firstly, integration of of heart sound classification algorithms could add considerable clinical value to the use of the stethoscope, and would be a conscious anticipation on the artificial intelligence driven developments that are transforming healthcare. Other functionality implications point towards the opportunity of integrated feedback in order to improve the interaction and general clinical outcome.

The design implications on the front of the current stethoscope's extremely efficient use in practice will also have a large effect on the design; integration of the final design into the clinical context is of very high importance. Therefore it is paramount that the efficiency driven design implications will be somehow aligned with the technological implications, such that there is minimal conflict between the two. The upcoming trend of software analysis in the medical sector could be the link in order to bridge this gap.

The design implications concerning usage point to the need for a handsome tool that can be efficiently used for both diagnostic and monitoring purposes; correctly fitting into the efficient clinical process of auscultation and the doctor-patient relationship in general.

Lastly, the design implications concerning reasons for use point toward the greater goal of decreasing the percentage of unnecessary deployment of expensive methods as well as decreasing the amount of false diagnostic negatives.

Refined Problem Definition, Design Vision and List of Requirements

The development of the graduation assignment was a process in itself, which was developed in cooperation and accordance with Maasstad Hospital and the interim Graduation Comittee. This chapter sketches the solution scope and elaborates on the Assignment within the graduation project.

Refined Problem Definition

The problem definition at the start of the project was centered around time constraints, a lack of pre-diagnostic tools with limited functionality and the declining education concerning using these tools to their full clinical potential.

The central tool in this picture was obviously the stethoscope, and the aim remains to create a solution within this scope. The combination of analyses has specified even more that stethoscope use by cardiologists is extremely efficient. However, this does not mean that the stethoscope is used to its full potential, or that its use has high efficacy at the moment. The situation could already be improved by simply allowing the cardiologist to review heart recordings at a later time in order to reduce the time-related pressure (s)he is under. There are already electronic stethoscopes on the market that allow this functionality, however these products are still lacking in many areas, meaning that they are not in line with the efficiency of use that current stethoscopes provide. The recording, transfer, and analysis of heart sounds are all still very inconvenient. Consequentially causing cardiologists to stick with an acoustic stethoscope, since the sound quality is essentially the same.

So the problem is that there is currently no real upgrade or improvement possible concerning the initial problem, due to the fact that an 'upgrade' in one area would mean a step back in different areas. Besides this, the diagnostic capabilities of the stethoscope are currently still limited to diseases that involve heart murmurs, while its non-invasive and mobile nature would be even more valuable if it had a broadened diagnostic horizon.

In essence, current electronic stethoscopes are not able to harmonize with the effiency to which acoustic stethoscopes are currently used. Meaning that the context in which doctors are under time contraints combined with underperforming tools cannot holistically be improved without the introduction of a tool that harmonises with this effiency without neglecting other areas.

Design Vision

From this refined and specified problem definition a design vision was developed. This vision decribes the desired outcome and benefit the design should have on the described situation.

'Creation of a diagnostic tool in the form of an electronic stethoscope that ***harmonises*** *with the efficiency of the auscultation process as* ***seamlessly*** *as possible; acting as a* ***facilitating*** *tool, increasing* ***medical effectiveness*** *through* ***unobtrusiveness*** *and improved* ***diagnostic potential****.'*

The to be designed product will need to fit the current auscultation process at hand as well as possible, ideally adding as much benefit as possible on the fronts of convenience, efficacy and diagnostics capabilities. From this design vision the List of Requirements and List of Wishes were created. Throughout the conceptualisation phase this List of Requirements will be expanded and become more detailed as the specific functions of the design become more clear.

List of Primary Requirements

1. General Use Related performance

1.1 The design should facilitate the cardiologist in the auscultation procedure
1.2 The design should provide the cardiologist with feedback
1.3 The design should improve the diagnostic outcome for the patient
1.4 The design should be capable of logging data
1.5 The design should be clinically unobtrusive
1.6 The design should enable comparisons of data over time
1.7 The design should enable seamless recording with minimal interaction required from the cardiologist
1.8 The design should live up to efficiency standards regarding consultation

2. Physical Design

2.1 The design should be compact, mobile and easily transportable throughout the hospital
2.2 The design should be able to amplify heart sounds
2.3 The design should enable the user to listen to heart and lung sounds
2.4 The design should have automated recording functionalities
2.5 The design should be easiliy sterilizable using alcohol wipes.
2.6 The design should resemble a conventional stethoscope
2.7 The design should be operable with one hand
2.8 The design should have have wireless functionality

3. Context

3.1 The design should be usable within the cardiology-oriented hospital context
3.2 The design should be usable by cardiologists and residents
3.3 The design should be technologically feasible within 3 years
3.4 The design should be perceived as a benefit to the current situation by the stakeholders

4. Constraints

4.1 The design should complement existing healthcare systems
4.2 The design should be in compliance with CE Safety regulations

List of Wishes

1. General

1.1 The use of the design should be time effective
1.2 The design should incite a comparable amount of trust as a stethoscope through its appearance
1.3 The interaction with the design should give the user a rewarding feeling and be enjoyable

2. Performance

2.1 The audio quality should be equivalent to an acoustic stethoscope
2.2 The system should provide the user with visualisations of the recorded heart sounds
2.3 The stethoscope should have an indication of where the recording was made on the body
2.4 The design should have the possibility to gather non-auditive data
2.5 The design shoud decrease unnecessary deployment of follow-up methods/technologies

3. Viability & Feasibility

3.1 The design should be as innovative as possible
3.2 The design should be as cost effective as possible

3 Synthesis and Conceptualisation

This chapter entails the synthesis of the findings from the analysis phase into design direction in a specific context. It consists of ideation, functional analysis, and concept development. The chapter is concluded with the description and presentation of a final concept, together with a complete visualisation and usage scenario.

3.1 Conceptualisation Scope

3.2 Ideation

3.3 Concept Development

3.4 Final Concept

3.1 Conceptualisation Scope

This section entails the definition of the design direction and the design context. The main objective is to delimit the solution space in which ideas and concepts are created.

Design Direction

The deciding factor in particular was the efficiency with which the stethoscope was used and its infusion into surrounding medical processes carried out by everyone involved.

This design direction has two main purposes:

• *Harmonizing with the naturally efficient medical processes at hand; integrating itself seamlessly and intuitively*

• *Adding medical benefit by facilitating the cardiologist and providing enhanced diagnostic potential*

The design direction and vision for the continuation of the project go hand-in-hand, and will be the guideline for elaboration and concretization of the design and functions. The analysis phase has not only shed light on the design direction, but also on technological enablers that support the development of a design that fulfills the requirements and fits the design vision.

Design Context

The context in which the design falls is evidently the secondary healthcare context; meaning that it will be designed for use in every hospital context that currently involves a cardiologist in combination with a stethoscope. The most prominent ones have previously been analyzed in Chapter 2.3. A schematical overview of the design context can be seen in Figure 3.1.

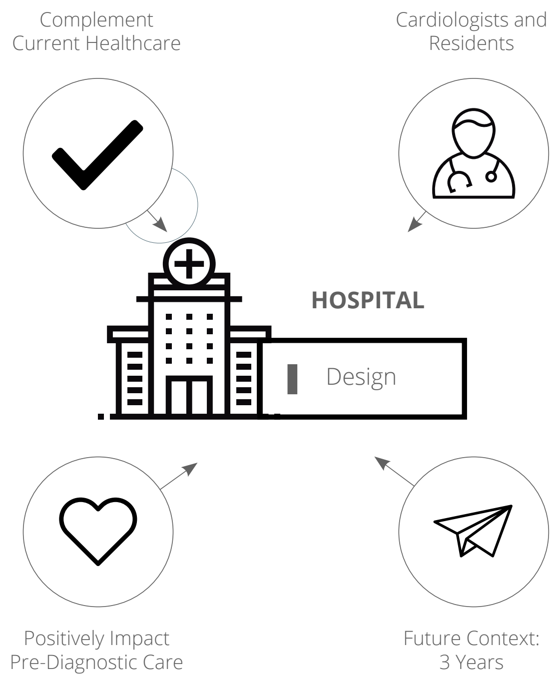

Figure 3.1 Visualisation of the Design Context

3.2 Ideation

This section describes the creation and generation of solutions in relation to the design direction and vision. Initially this was done mainly in regard to function and key components of the design. Subsequently this was followed by the first form generations.

Functional Ideation

Since the vision is foundation for the functions of the design, the key elements were extracted in order to create encompassing functions. By using "How-to" questions multiple functions were created per element; ultimately combined into a mind-map overview. This mind-map can be seen in Figure 3.3.

Besides functional ideation, visual thinking was also used as an ideation tool. This mainly involved the creation of quick sketches in order to visualize sub-solutions. Since the analysis phase had already pointed towards key opportunities such as integrated feedback loops, these were also involved in the (functional) ideation process.

Visual Ideation

Besides functional ideation, visual ideation was also performed using sketching and other visual types of idea generation. Figure 3.2 shows one of the sketches from the ideation process. All of the sketches from the ideation process can be found in the Appendix.

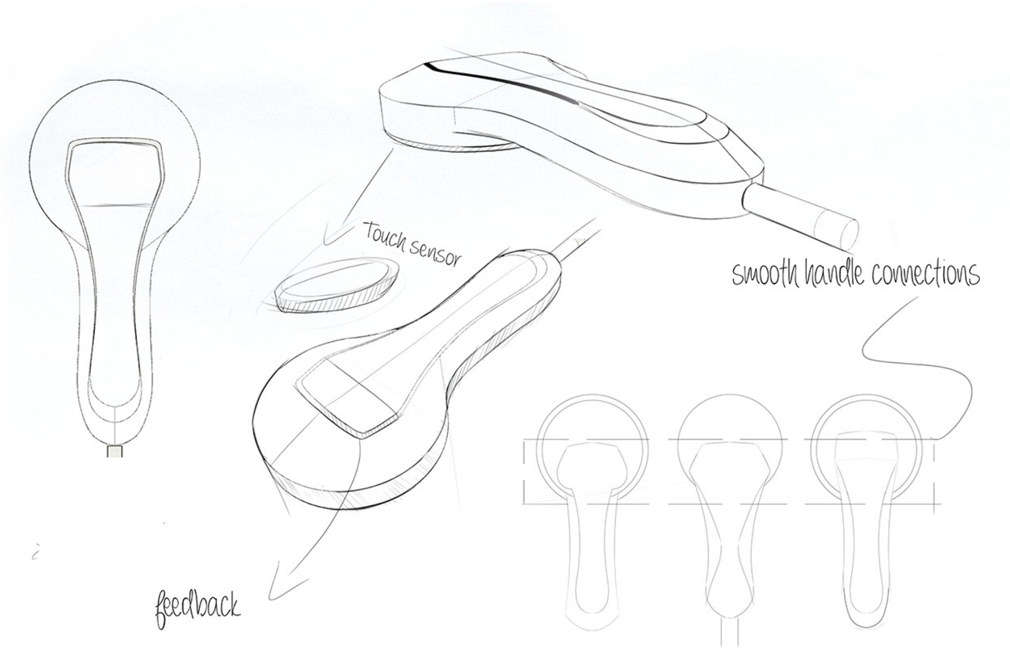

Figure 3.2 Ideation Sketches

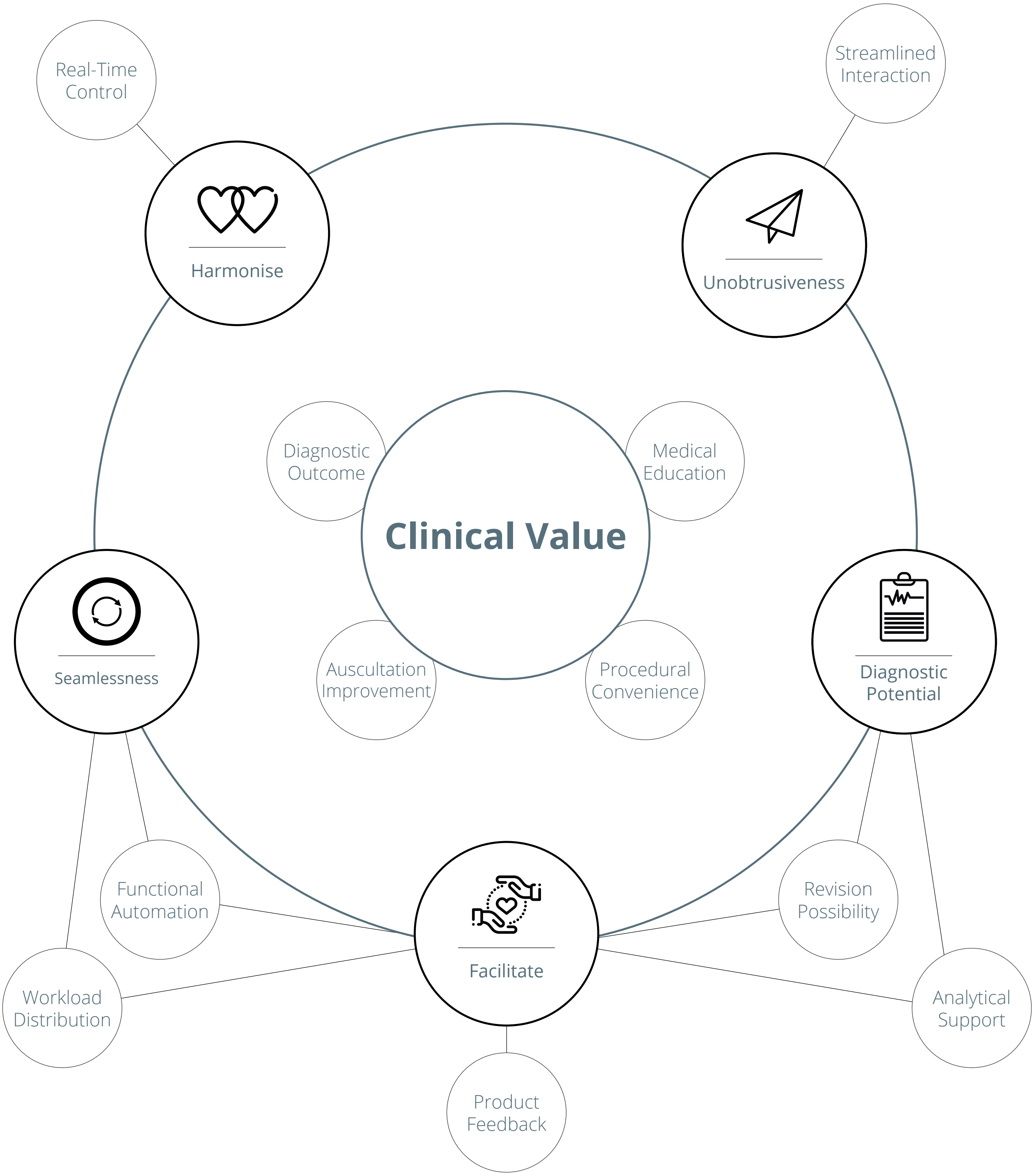

Figure 3.3 Overview of the Functional Analysis and Ideation

3.3 Concept Development

This section describes the conceptual development of the design. As defined in the coming section this was done through functional development, abductive reasoning and the creation of a base concept in combination with additional functions. The main objective of this section is to come to the development of a final concept that can be evaluated on the basis of the list of requirements.

Concept Development Strategy

Since the design and product direction were unequivocally clear, the more logical choice was to develop a base concept with a valuable core functionality on which elements could be added in order to enrich the design. Therefore a base concept was created in combination with additional elements that were eligible for integration in order to form the final concept.

Besides functional ideation, visual thinking was also used as an ideation tool. This mainly involved the creation of quick sketches in order to visualize sub-solutions. Since the analysis phase had already pointed towards key opportunities such as integrated feedback loops, these were also involved in the (functional) ideation process.

Key Vision Values

The ideation phase resulted in a range of functions that had the potential of benefitting the medical context and aiding the design in fulfilling the design vision. The strongest functions and features were combined into a base concept. These functions were created by translating the key values from the problem definition and vision into core aspects of the concept's functionality, features and overall design. This abductive reasoning process from problem, to features and finally to product functions is a method by Roozenburg & Eekels (Eekels et al., 1998), a schematic representation of this process can be found in figure 3.4. Concept development also focused on how the selected functions could be technologically realised, and if this was realistic in relation to the design context or not. An overview of the development from functions to features along with their enablers can be seen in Figure 3.5.

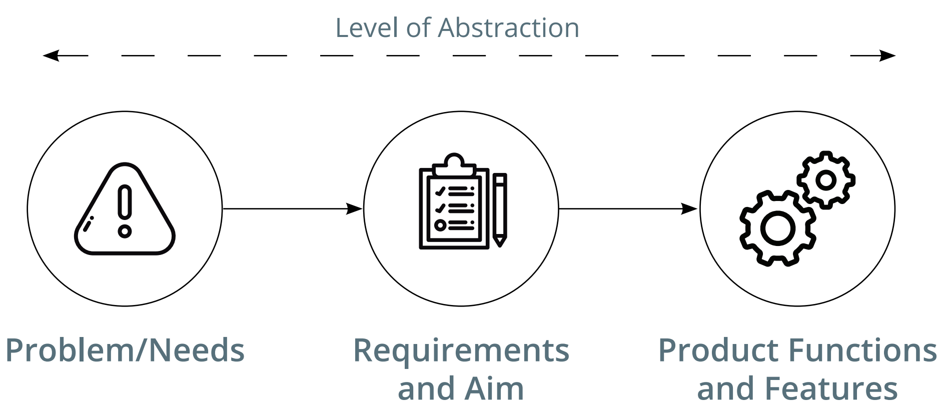

Figure 3.4 Abductive Reasoning Process (Adapted from Eekels et al., 1998)

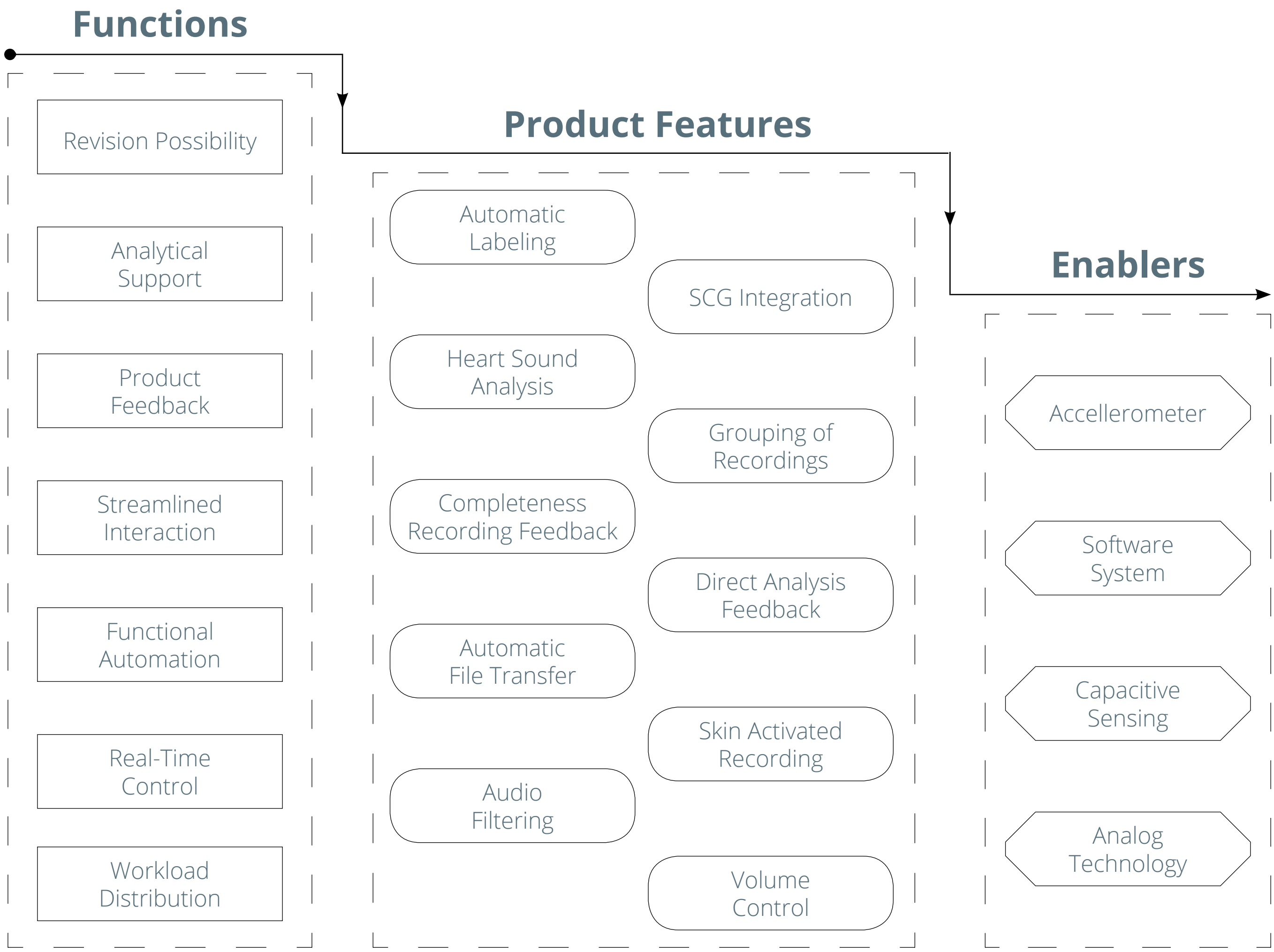

Figure 3.5 Functions - Product Features - Enablers Development Process Visualistion and Overview

BASE CONCEPT ASPECTS & FUNCTIONS

With the list of functions a base concept was created. The aim of this was to have a concept which fundamentally fits the design vision through its functions, and showed the most potential for being the driving solution to the revised problem definition.

Modern & Characteristic Design

Pertaining to the aim of harmonising with the context in which the stethoscope will be used, it is not only important that it does this through function, but also through form and visual impression on the user and surroundings. Therefore the aim is to give the concept a Modern & Characteristic design by remaining familiar whilst also coming across as modern.

Improved Ergonomics

Next to fitting into the context from an aesthetic point of view, it is also important that the design harmonises in a tactile fashion. Therefore the aim of the concept is to have improved ergonomics in comparison to other acoustic and electronic stethoscopes. Seeing as these products haven't seemed to prioritize ergonomics, this is also a novel approach to stethoscope design.

System Connection

The physical product will have a connection to a system which handles and analyzes the recordings. This connection will be established in a wireless fashion through a combination of Bluetooth and WiFi.

Skin Activated Recordings

Familiarity and ease of use plays a large role in the adaptation of a product, especially in the medical sector. A large reason why electronic stethoscopes are not yet as integrated into the medical sector as they could be, is due to the additional actions doctors have to perform in order to use them to their full potential. An important action is the additional interaction and interference that the user has to go through in order to start, stop, and transfer a heart recording. Therefore an important function of the concept is the activation of recording heart sounds upon contact with the patient's skin. In such a way the doctor would not need to perform additional actions in order to use the product, and can focus fully on the patient.

Automatic File Transfer

Not only do the additional actions pertain to the actual recording, but also the transferring of said recordings. In order to completely automate the digitalization and handling of recordings, automatic file transfer is also a key functionality that relates to multiple aspects of the design vision.

System - Heart Sound Analysis

The system will analyse the recorded and documented heart sounds with the newest type of Deep Learning Algorithms in order to provide the cardiologist with diagnostic feedback on the recordings.

System - Grouping Recordings

The system will group and chronologically order the recordings by their timestamps, such that the cardiologist can easily organize and link them to patients.

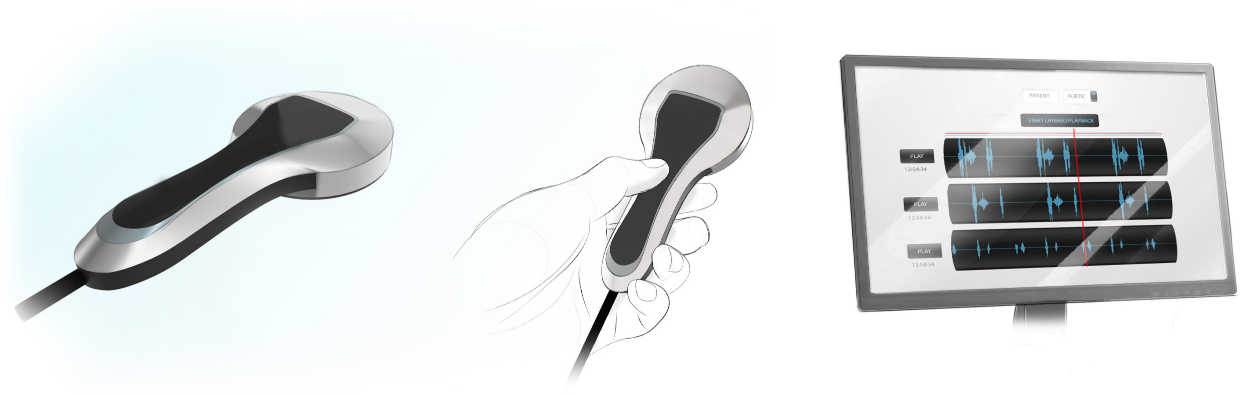

Figure 3.6 Base Concept Visualisation

ADDITIONAL FUNCTIONS

In addition to the core aspects of the base concept, additional functions were defined such that a selection of them could be combined to form the final concept.

Real Time Audio Control

In order to increase the diagnostic potential of the (electronic) stethoscope, giving the doctor more control on the front of acoustics could aid his cognitive and diagnostic abilities. Therefore functions such as volume control could be a helpful additional function.

Accelerometer Labeling

When heart sounds are digitized it is important to know at which point on the body they were made in order to retrace and correlate murmurs that are possibly present. Therefore with integration of an accelerometer it is possible to retrace the pattern of auscultation through analysis of the movements. With use of this the recordings can be automatically labelled, allowing the doctor to have more information about the recording if (s)he wants to replay it at a later moment in time.

Direct Heart Sound Analysis Feedback

As stated in the market analysis, there are currently no stethoscopes in the mainstream medical market that offer a feedback loop between the user and the product. Therefore a possible function of the concept could be the integration of such feedback. The first form of possible feedback could be a direct indication from the stethoscope about the recorded heart sound, indicating whether the analysis noticed anything abnormal.

Recording Completeness Feedback

In the context analysis it was found that a common issue among (learning) cardiologists is that they find it hard to take their time when auscultating a patient, and that they tend to rush through the different positions. This can cause oversight and misdiagnoses. Therefore a feedback indicator could aid the cardiologist in taking his time, e.g through use of a simple progress bar. Furthermore, the algorithms to be used in the concept also need a full recording in order to their analysis optimally, therefore the 'time-taking' feedback could have a double function.

Figure 3.7 Sub-Solution Visualisations

3.4 Final Concept - Function & System

Through combining a selection of additional elements to the base concept, a final concept was formed. The final concept presented has a clear set of functionality and design aspects. At this point in the design process, the form is a mere impression in order to communicate the key functionality. In the coming chapters, the form will be developed in detail on the basis of the intended functions, ergonomics and aesthetic impression.

FINAL CONCEPT: Steth-Link

The final physical part of the concept, Steth-Link, forms the basis for the elaboration and embodiment phase. Its features comprise:

- *Skin Activated Recording*
- *Automatic File Transfer*
- *Integrated Time-related feedback*
- *Connection to Analytical Software System*
- *Real Time Volume Control*
- *Improved Ergonomics*
- *Modern, recognizable aesthetics*

The digital part, which is the connection to the system has the main function of analyzing the heart recordings in order to facilitate and aid the cardiologist in his diagnostic analysis. The features of the system are:

- *Heart Sound Analysis of Recordings*
- *Automatic Grouping of Recordings*
- *Easy patient-assigning of recordings*
- *Visualisations of Heart Sounds*
- *Convenient Overviews and Monitoring*

The physical and digital part of the concept will work in an intertwined manner, cooperating in order to facilitate the doctor during the auscultation and diagnostic process. The intended usage scenario will show how this will go in practice.

PRODUCT-SYSTEM ARCHITECTURE

In order to automatically get the heart recordings from the Steth-Link to a place they can be analyzed and visualized, a system structure is needed. This structure consists of both bluetooth connections and internet connections in order to make this possible.

First of all, the stethoscope is connected to a smartphone device via bluetooth. In this way, recordings that are made by the Steth-Link are automatically transferred to the smartphone via Bluetooth. From there, the audio files are directly forwarded to a File Transfer Protocol (FTP) server; this is where the audio files will be stored. An external server running the analytical software will be able to access the audio files and analyze them individually. Based on the outcome of the analysis, the server running the analytical software will send a response back to the FTP server, which will link this response to the respective audio file, this is called metadata. Lastly, the visual system (which is also web-based) will group and visualize the individual recordings and show them through an interface. The cardiologist can log into the system with his or her account in order to access the information.

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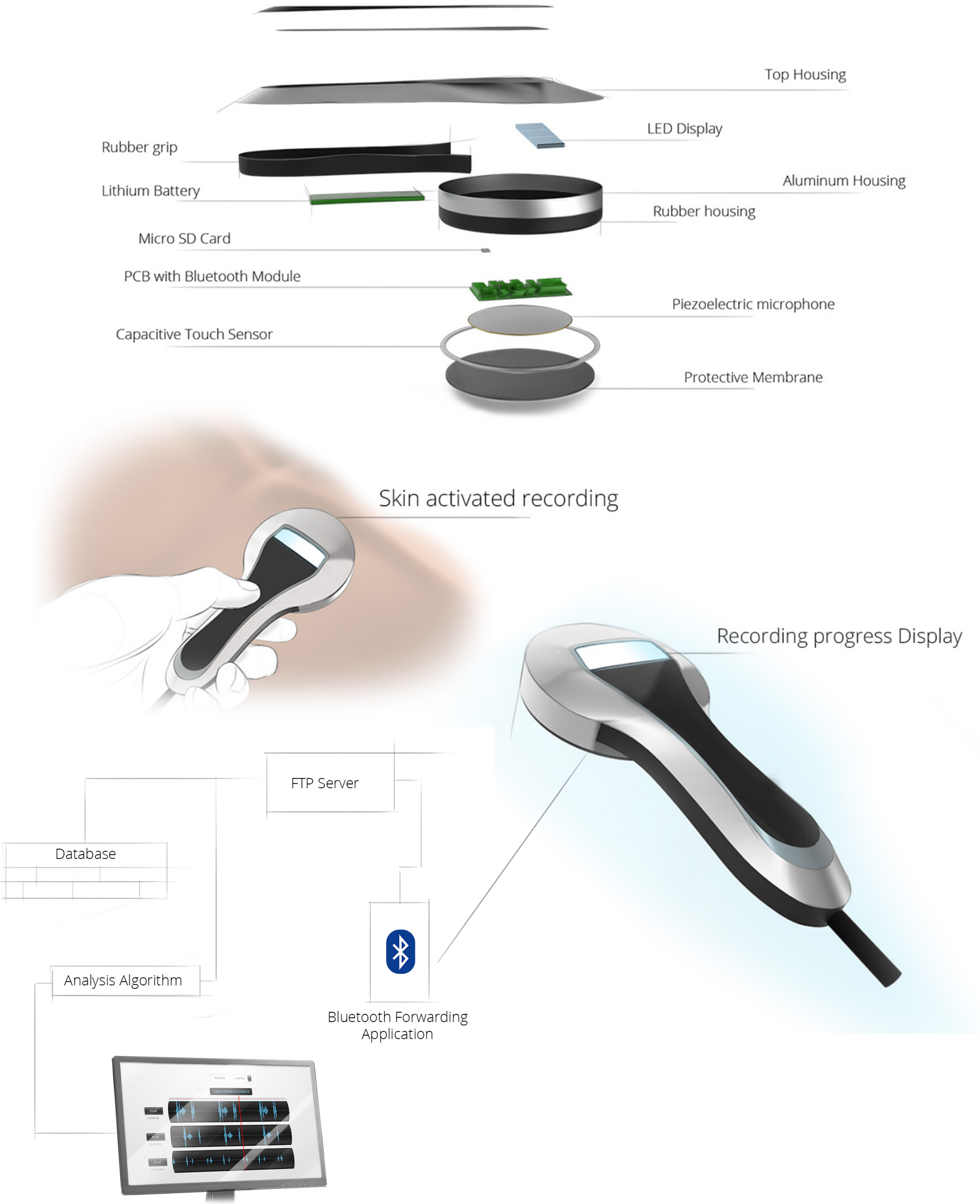
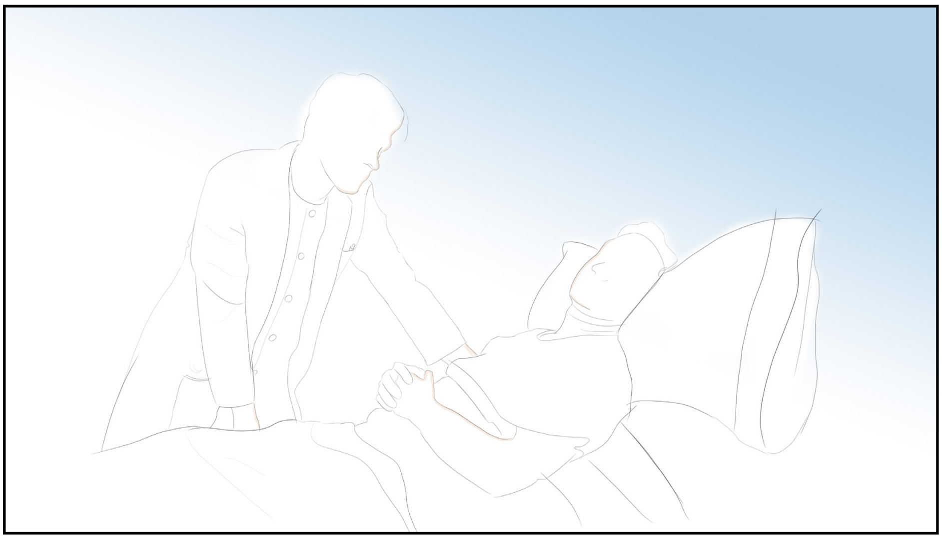


Figure 3.8 Complete Overview of the Final Concept

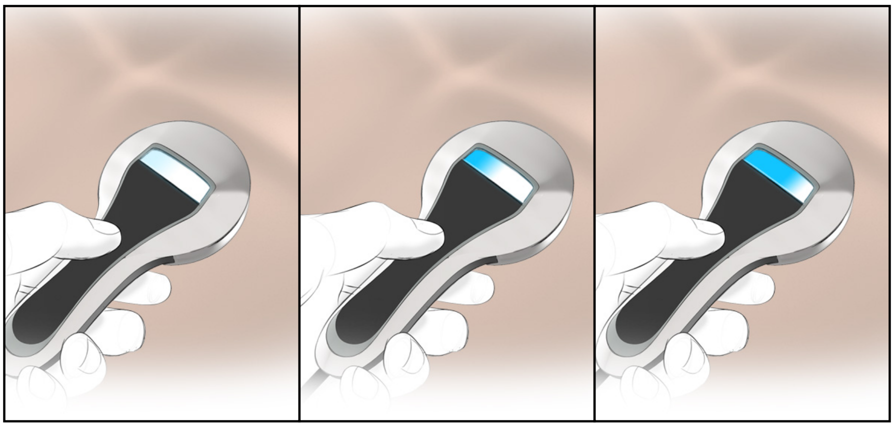
OVERALL USE SCENARIO

The scenario of use from the cardiologists perspective is relatively simple, the features of the concept are integrated in such a way that the user's experience is similar to the usage of an acoustic stethoscope with the intention of enhancing the outcome and solving the problem definition.



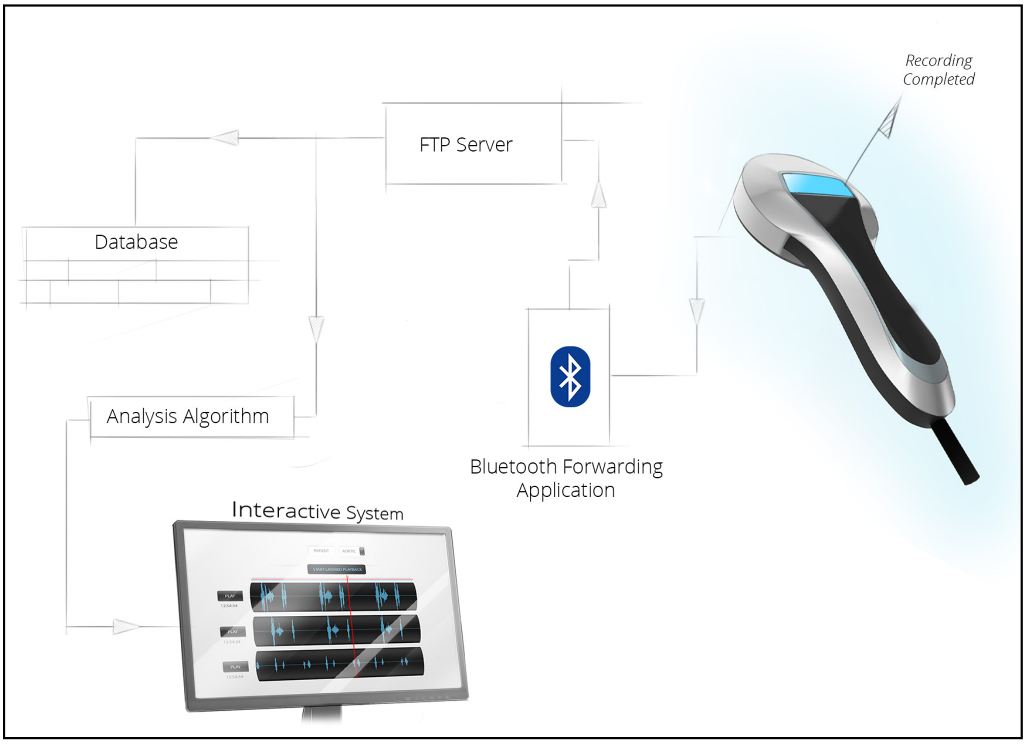
1.

The cardiologist comes into contact with the patient, going through the regular actions performed up to auscultation. Once the auscultation procedure starts, the cardiologist takes the Steth-Link out.



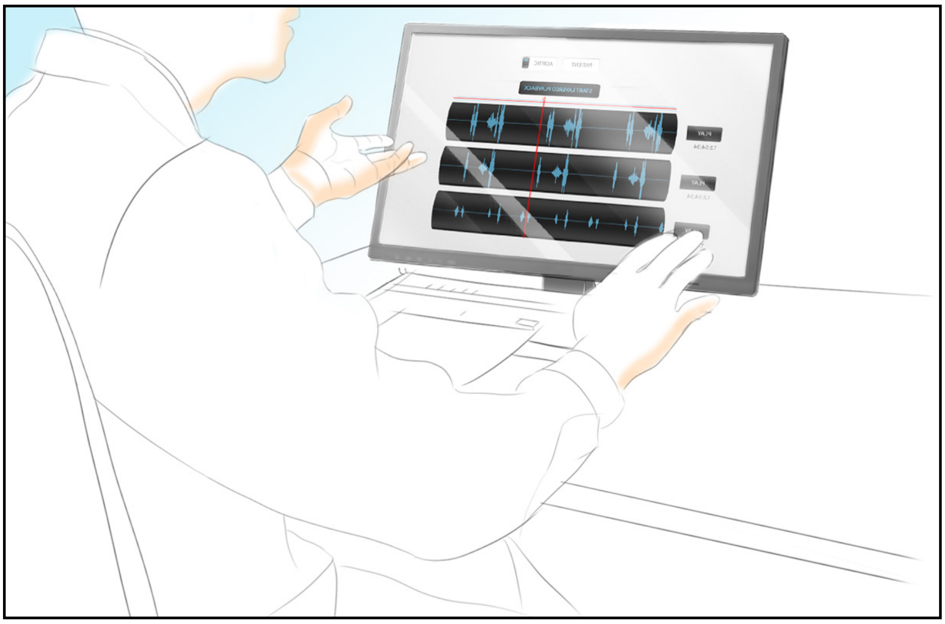
2.

Once the Steth-Link comes into contact with the skin, it automatically starts recording. The Steth-Link provides feedback on the completeness of the recording through a simple progress bar. In this way the cardiologist is reminded to take his time, and can also see if the recording is long enough to be analyzed. Once the stethoscope is taken off the skin, the recording is automatically ended, saved and will start to be transferred to the cardiologists storage device or smartphone via bluetooth.



3.

The cardiologist will go through the most common auscultation order of APTM, the system will label the recordings accordingly. The system will notice the absence of a heartbeat in lung-recordings and will therefore label them as such, removing the possibility of confusion for the cardiologist or analytical system.



4.

Once the cardiologist comes back to the computer for documentation, (s)he can log into the system and link the grouped recordings to his patients. In the system described earlier, the recordings will be analyzed and grouped according to their timestamps. Subsequently (s)he listens to the recordings and views the analysis results. Based on the analysis results and his interpretation of the recordings, he can make notes in the patient's file and decide upon necessary treatment options.

4 Elaboration and Embodiment

The objective of this section is to elaborate and detail the final concept that was described in the previous section. This part of the project was initiated by refining the scope of the project in order to have a clear goal and focus for embodiment. Subsequently, elaboration on the product's form was done based on ergonomic studies and qualitative assessments, continued by further development and detailing of the physical design, followed by the design of the system and its digital design. All of these aspects were integrated, resulting in a final design proposal. This chapter is concluded by giving an overview of the design, its functions, a use scenario, cost estimation as well as implications of the design proposal in relation to medical rules and regulations.

4.1 Scope Refinement

4.2 Ergonomic Development

4.3 Form and Geometry Elaboration

4.4 Physical Design Detailing

4.5 Final Physical Design

4.6 Digital Design

4.7 Final Design Proposal

4.1 Scope Refinement

A general definition of the scope of the project was stated in the "Assignment and Approach" chapter. This section goes into the refinement of the scope in order to define the level of elaboration for the different parts of the concept that was presented in the previous part.

Elaboration Goal

The level of elaboration that is necessary, and most of all possible within this project depends on the final goal of the project. Within this context of the assignment, it would be ideal to test if the concept facilitates the cardiologist to a considerably higher extent than just a regular stethoscope, and if it would generally improve the diagnostic outcome for the patient.

Considering the complexity of the concept in its entirety and the timespan of the project, it is not possible to validate this here. Instead, the aim is to provide a preliminary framework for testing, and evaluate the product in a qualitative manner with cardiologists. Through this a clear assessment of the product can be made at the time of testing, while also generating useful recommendations for the design proposal.

Scope

The concept must be elaborated and embodied up to a point where the previously stated goal can be evaluated and hopefully met. This means that the product must be developed up to a point where the user can interact with the product and also understand its functionalities. Complying with the time constraints of the project, the embodiment and elaboration scope was refined; a visualisation of this can be found in figure 4.1. In this visualisation, the level of detail for the different facets of the design is defined.

	Physical	Digital & System	Overall Design
Out of Scope	Detail Engineering Docking Station Noise Cancelling Production Engineering	Detailed Functionality Detailed Content Prototype Integration Complete Wireframe	System Integration Market Implementation Business Plan
Design	Functionalities (Features) Aesthetics Ergonomics Use & Interation	Functionality Connectivity	Rules & Regulations Product Ecosystem
Detail	Product Architecture Technology Geometry & Dimensions Material	Data Flows Wireframes Data Processing	
Prototype	Feature Validation Feedback Interface (Simplified)	Click-Through Scenario	

Figure 4.1 Scope Refinement Visualisation

4.2 Ergonomic Development

The first part of the elaboration of the concept consisted of the development of the final exterior form. The development of this was in heavy relation to ergonomics and aesthetic impression, ultimately finding a harmonious combination of the two. This section starts off with an ergonomics study in order to uncover the most important form guidelines concerning the product's geometry.

Ergonomics Exploration

Since the Steth-Link enables functions that a regular acoustic stethoscope is not capable of, this also means that it will need to house components that make these functions possible. Therefore it is not possible to maintain the classical, minimalistic design of just bell & diaphragm with its tubing. This means that the housing of said components will (slightly) alter the way in which the product will be held as opposed to the classical stethoscope.

Different grip styles were analyzed in anticipation of the placement of the components. An overview of these grip styles can be seen in Figure 4.3.

The grip style that enables the easiest positioning of the stethoscope while keeping freedom of the most versatile finger (the thumb) is grip style B. This is a grip style that is also used with acoustic stethoscopes. Due to its comfort, familiarity and freedom of the thumb to handle product features, this grip style was the main focus for setting of guidelines for form development.

The different grip styles shown in Figure 4.3 were analysed in relation to their contact points. The most prominent contact points appear to be at the index and middle finger, with a focus on their separation for comfort and grip. This creates a guideline for a grip point in the form of crevice or bump at the bottom of the handle for the index and pointing finger.

Another important contact point is the resting point for the thumb at the top of the grip. The exaggerated forms show a clear contact point and indentation. Shapes with a subtle indentation and arc appeared to have more comfort from a personal perspective. This created a guideline for a slope and indentation for the thumb at the top of the grip.

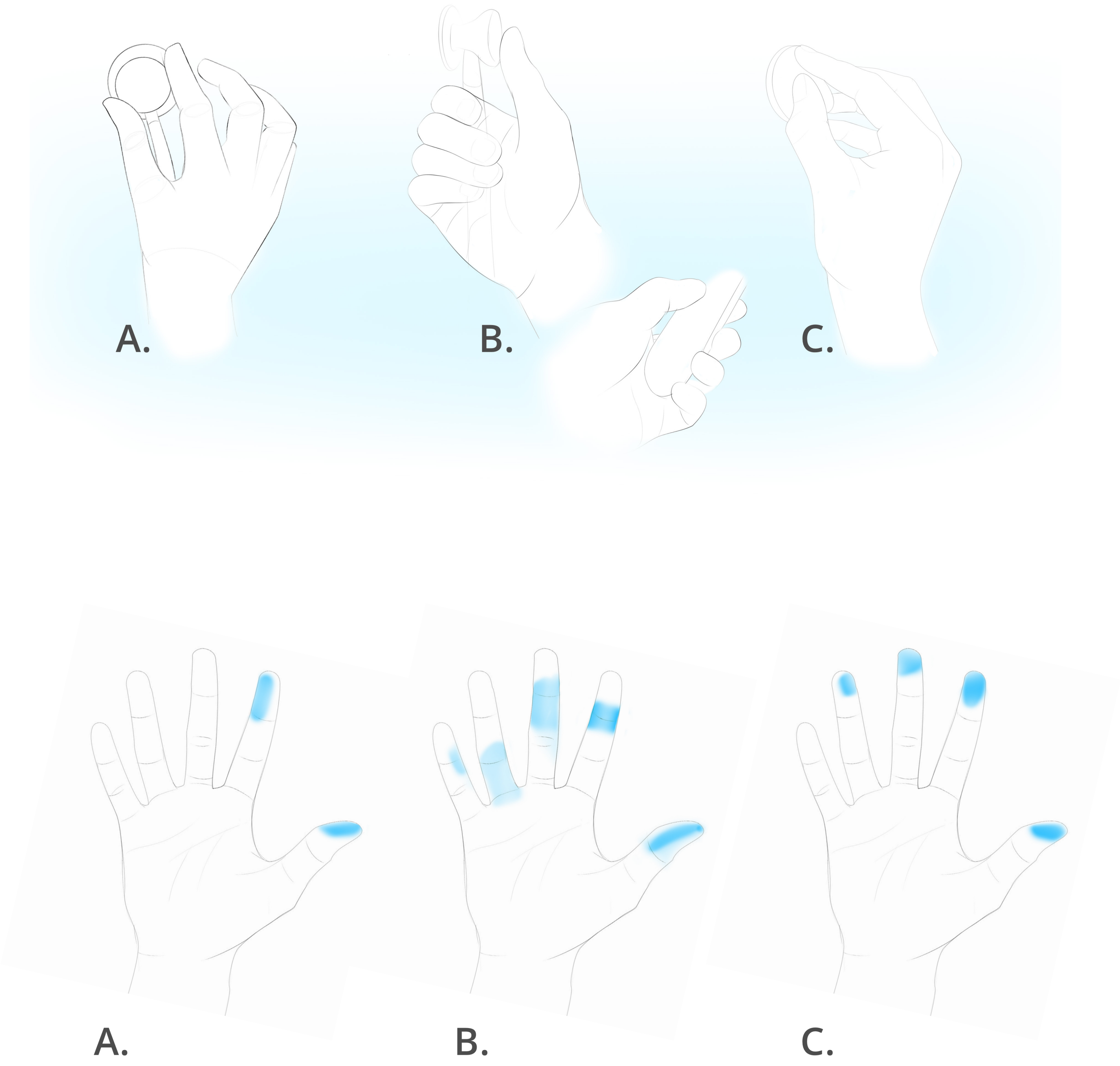


Figure 4.3 Visualisation of the most prominent gripstyles and their contact points on the hand

Size Indications

In order to get an impression and indication of minimal and maximum handle size, the DINED database was consulted in order to get an overview of different percentiles of hand sizes. The most important hand sizes pertained to hand breadth, and grip circumference. The aim of this was to form size guidelines for the final geometry, such that it would be comfortable for the broadest range of percentiles possible. Figure 4.4 shows the relevant measurements that were found in the DINED database.

The indications and implications for the design mainly pointed towards size constraints, the first one being related to circumference of the grip. Since the 5th percentile of the database had a grip circumference of 108 mm, it was chosen to have none of the grips exceed such a circumference at any point. Furthermore the hand witdth and forefinger breadth provided guidelines for experimentation concerning the length of the handle and finger grooves.

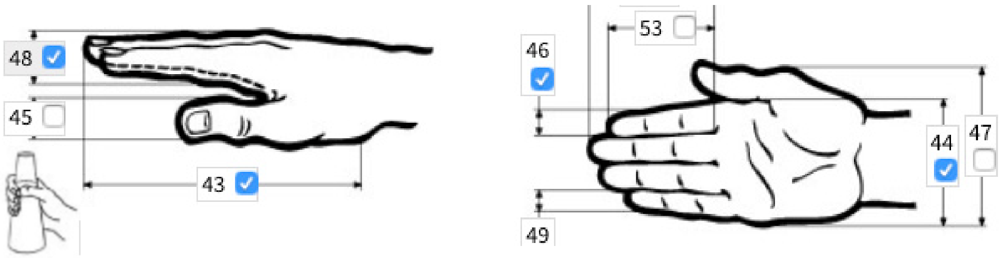
Handle Variation Design

Based on the size indications and ergonomic guidelines, different handle designs were created in order to evaluate and validate different shapes and sizes. In these handle variations, the main point was to integrate and validate the ergonomic guidelines that came from the clay and contact point study while accommodating the main grip style, as well as testing out different combinations of length, thickness and curvature.

The different handle designs were CNC'ed out of foam and qualitatively assessed together with Dr. Bruning. From the findings of these exploratory and qualitative studies. Guidelines were formed for the geometrical design of the stethoscope.

Guidelines

The guidelines coming from the ergonomic study were relatively straightforward, and were aimed to be implemented with a degree of creativity in the following chapter. The most prominent guidelines were an upward slope in the handle, such that the auscultator is not touching the patient while the stethoscope is on the chest. Furthermore the implementation of finger grooves on the bottom of the handle was also a guideline to be taken into account during geometrical elaboration.



populations	Dutch adults 20–30, mixed			Dutch adults 31–60, mixed		
measures	P5	P50	P95	P5	P50	P95
Hand width (without thumb) (mm)	71	84	97	74	86	98
Grip circumference (mm)	108	129	150			
Hand length (mm)	163	186	209	166	186	206
Forefinger breadth (mm)	13	16	19	15	18	21

Figure 4.4 Hand sizes from DINED

Figure 4.5 Handle Grip Explorations

Figure 4.6 CNC'ed grips

4.3 Form & Geometry Elaboration

This section describes the implementation of the ergonomic insights and guidelines into a product geometry that is recognizable and aesthetic while maintaining ergonomics and functionality as much as possible; aiming to find a harmonious combination of the two. This iteration was mainly done through 3D-exploration and sketching.

Implementation of Guidelines

The guidelines and insights from the ergonomic studies were aimed to be implemented in a relatively standard way, while still allowing explorations concerning the product's geometry. The guidelines mainly resulted in a requirement for an upward slope of the handle, as well as finger grooves at the bottom of the grip. Initially the aim was also to integrate geometry that allowed for an additional gripstyle, but this would complicate the addition of controls and features on the design too much.

Geometric Iteration

The combination of ergonomic guidelines and size indications provided a clear direction for the development of the geometry for the exterior design of the product. With use of these guidelines, form explorations were done by form of sketching, as well as 3D-modelling. The aim was to develop a clean, aesthetic form language that matched the ergonomic guidelines while also fulfilling the aims of the concept on the front of aesthetic impression. An overview of the different iterations can be seen on the adjacent page.

Figure 4.7 Overview of the different geometrical variations

Figure 4.8 Top View of the different form variations and iterations

Final Form Language Geometry

A broad range of iterations and shapes ultimately led to the final exterior design for the Steth-Link. It is a wraparound style that fluently connects the handle with the diaphragm without coming across as overly bulky or unnatural. The impression of a stethoscope is maintained and the uniform surfacing allows proper placement for control buttons and a visual display.

The form language incorporates the guidelines from the ergonomic research, with a main focus on the integration of an upward slope in the handle, as well as finger grooves on the bottom of the handle.

Figure 4.9 Final Form Language Geometry

4.4 Physical Design and Detailing

This section delineates the elaboration of the physical design to the level of detail described in the scope refinement section. The aim is to define the physical design to such an extent that a viable design proposal can be made.

Sound Digitization

The digitization of heart sounds into a file that can be transferred and analyzed is an important aspect of the design. An important thing to note is how the vibrations and murmurs coming from the heart will be picked up.

Requirements

- Pick up Heart Sound Vibrations
- Convert into digital signal

Possible Solutions

- Acoustic Stethoscope with Electret Microphone
- Piezoelectric Sensor

Insights

Literature research and testing with Piezoelectric sensors concluded that they are extremely high in noise, and that it is very difficult to get high-quality recordings. Furthermore, the intuitive bell & diaphragm function will no longer be a feature unless it is artificially integrated.

Chosen Solution

The chosen solution is to use a classical acoustic stethoscope piece with a microphone in order to capture heart sounds. This means it is possible to keep the benefits of the bell/diaphragm while being able to amplify, digitize and analyze heart sounds. Furthermore, since there are one-sided acoustic stethoscopes with integrated bell/diaphragm membranes, meaning that the intended design can be maintained.

Figure 4.10 Electret Microphone (Leese Electronics, 2014)

Figure 4.11 Piezoelectric Microphone (Leese Electronics, 2014)

Volume Control Design

Being able to control the volume of heart-sounds in real time gives the cardiologist more control over his auscultation process. Furthermore the design needs a power button as well. Therefore control buttons need to be integrated into the physical design.

Requirements:

- Buttons must be reachable with preferred grip styles
- Buttons shouldn't easily be pressed by accident
- Buttons must fit the design

Insights

From handling the first 3D-prints of the initial model of the final product geometry, as well as the CNC'ed handles, it was found that the power and volume buttons shouldn't be in the same place since the volume buttons will be more frequently used than the power button. Also it became apparent that the most logical placement of the volume buttons should be towards the main body of the Steth-Link

Possible Solutions

There were a wide range of solutions for the volume and power button design. The solutions varied in size, shape, type and placement. An important aspect of the buttons is not to be too dominant in the design, but still be present and obvious enough such that they are intuitively understood.

Chosen Solution

The buttons were integrated into the surface and shape of the design as much as possible, with their icons being embossed on top. The choice was made for the volume buttons to become actual buttons, with a tapered shape making the + button larger than the -, making it intuitive and fitting the designs geometry.

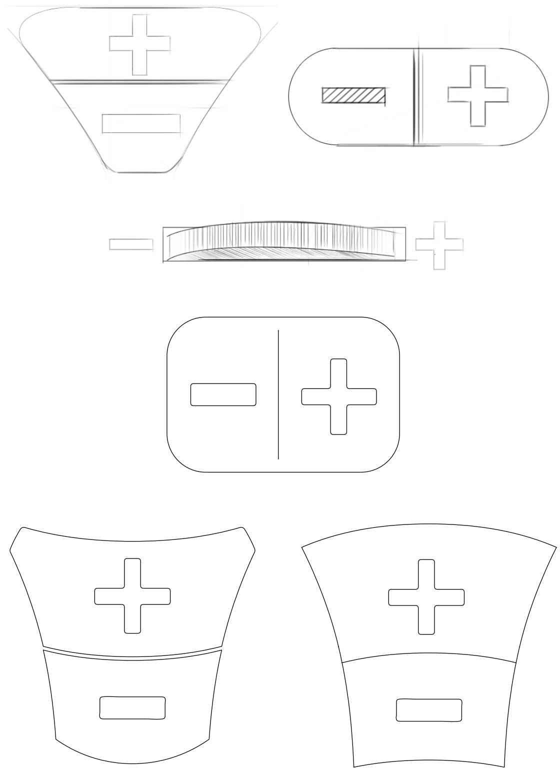


Figure 4.12 Volume Button Iterations/variations

Interface & Feedback

The integrated feedback loop is an important feature and novel aspect of electronic stethoscope use. It is supposed to facilitate the cardiologist and streamline the interaction between them. The type of feedback chosen to be displayed was in relation to the cardiologists taking the time to auscultate, and give them rewarding feedback during the process.

Requirements

- Show information on recording completeness
- Show information of auscultation completeness in relation to each area
- Provide clear, subtle and non-invasive feedback

Insights

Since there will be feedback on more than one single thing, it proved to be important to separate the elements of feedback, such that it is intuitively clear what the feedback means, and which belongs to which. The difference between the completeness of the current recording, and the completeness of the overall auscultation procedure should reflect in the interface of the feedback. Furthermore the actual impression of the progression and completing of a process is very important.

Possible Solutions

There were multiple variations made on the separation information, as well as how the information is communicated. Since both types of information related to completeness and the process towards it, the interface design was geared towards progress-bar oriented designs. The different variations can be seen in Figure 4.13.

Chosen Solution

It was important to consider the realisation of the feedback in the actual product in order to assess the different types of feedback. In relation to simplicity, clarity and realisability, the choice was made to go with the design in Figure 4.13, Middle. The simplicity and intuitiveness of progression bars is something that is naturally understood. Besides this, the separation between recording progression and auscultation progression is also something that is naturally clear. The progress bar will fill with blue light per recording, and the bottom bar will fill per quarter bar per auscultation that is completed. The interface fits naturally with the design and provides subtle but comprehensive feedback.

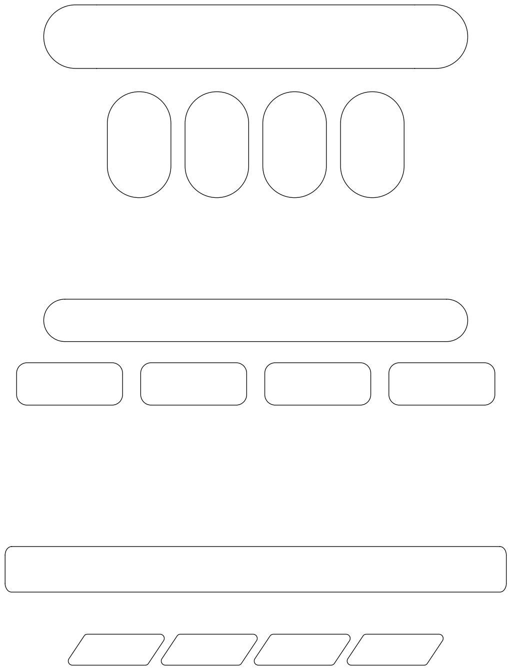


Figure 4.13 Feedback Interface Variations

TECHNOLOGIES

There are multiple implemented technologies into the design in order to realize its functionality. The selection of these technologies is documented in the following passage.

User Feedback

In order to communicate information to the user, a range of different technologies were weighed with respect to the chosen interface design. Since auditory feedback is an inherent function of the stethoscope itself, and haptic feedback would cause interference with this audio, visual feedback was the only possible type. The following possibilities were considered in order to provide feedback.

- LCD Screen (Figure 4.14, Top Left)
- OLED Screen (Figure 4.14, Top Right)
- Standard 5mm LED (Figure 4.14, Bottom Left)
- Surface Mounted Device LED (Figure 4.14, Bottom Right)

Due to size constraints and energy use, it was chosen to use SMD LED's, these LED's can easily be mounted on a PCB and will be luminescent enough to elucidate the interface. They are furthermore the most battery and size conscious decision.

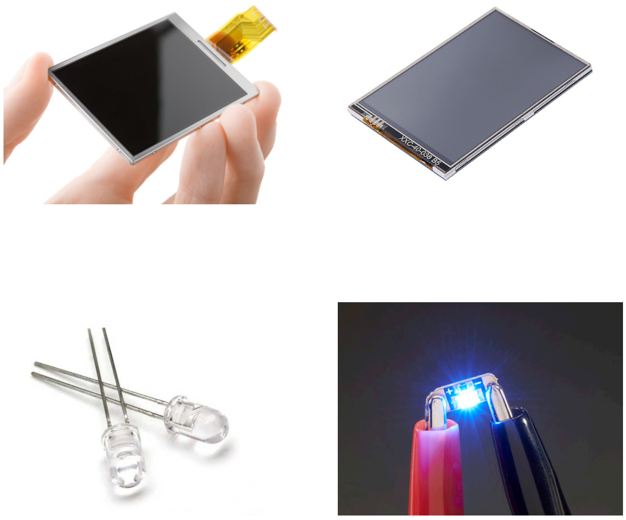


Figure 4.14 User Feedback Technologies

User Input

It is important that the user can interact with the device in order to control audio during auscultation. Besides this it important that the user can switch the device on and off very easily. The possibly usable technologies for this are

- Push button (momentary switch) (Figure 4.15 Top Right)
- Capacitive Sensor (Figure 4.15, Bottom Left)

Since capacitive sensing is usually used to detect touch, this means that when the device is in use it is possible that buttons will be touched, and therefore pressed, by accident. Push buttons have a less ambiguous interact and allow for actual press buttons to be integrated. They are extremely small and thin, and can therefore be nearly mounted flush on top of the PCB.

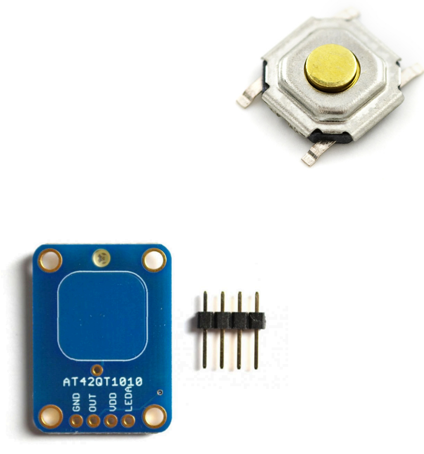


Figure 4.15 User Input Technologies

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Sensing

Since an important functionality of the Steth-Link is to start recording automatically upon contact with the patient's skin. It is important that a technology is integrated that can reliably detect this. Possibilities for this are:

- Force Sensor (Figure 4.16, Top)
- Capacitive Touch Sensor (Figure 4.16, Middle)
- Ultrasonic distance sensor (Figure 4.16, Bottom)

The capacitive touch sensor is chosen to be implemented into the design for the following reasons: it can be placed directly under the area that will come into contact with the skin, causing it to be completely integrated into the design. The capacitive sensor can be calibrated in such a way that it will only react to the capacitance of skin, meaning that it will not react when it is placed inside someone›s pocket, or is lying on a table. Lastly, capacitive sensors are extremely thin, causing them to be integrated easily.

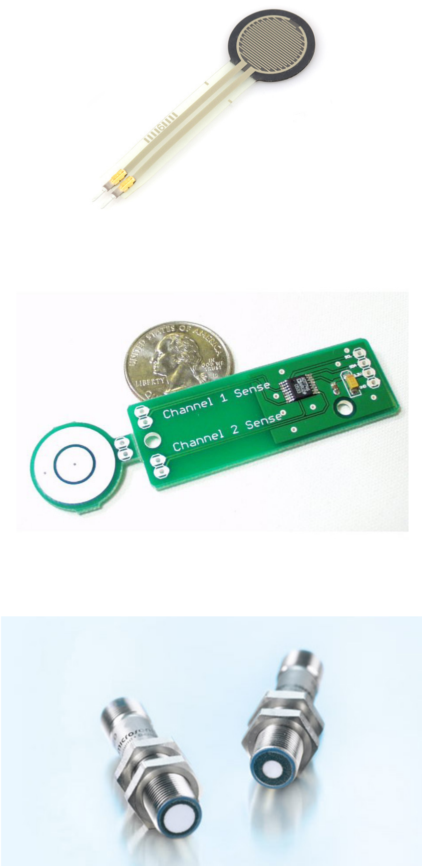


Figure 4.16 Sensing Technologies

Connectivity & File Transfer

The heart sound data will need to be transferred from the stethoscope to the system such that it can be analyzed. There are five possibilities for the transfer of this data:

- Wi-Fi (Figure 4.17, Left)
- Bluetooth (Figure 4.17, Left)
- 4G Network (Figure 4.17, Left)
- USB-Cable
- Audio Jack (Figure 4.17, Right)

Since an important part of the design vision is to be unobtrusive and seamless, the data should be transferred with as little intervention from the cardiologist as possible. Therefore a wireless solution is naturally the best. Since calibration of a device with a public hospital Wi-Fi signal is cumbersome, file transfer over Bluetooth is the best solution. This connection will be between the Cardiologists smartphone, which will automatically forward it to the system. Bluetooth transceivers are easily implemented into a PCB and do not take much power. Furthermore, the distance between the stethoscope and the cardiologists smartphone is easily small enough for rapid file transfer to occur.

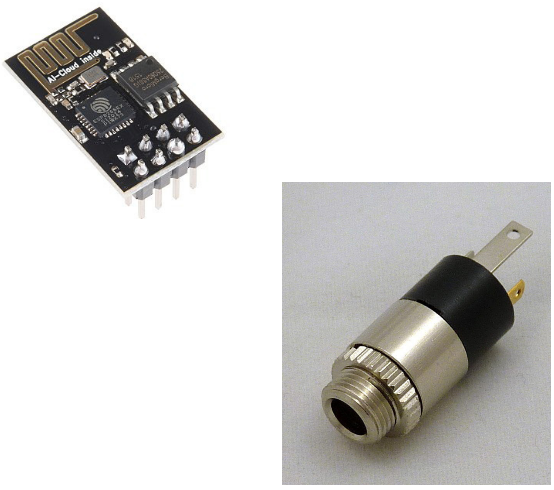


Figure 4.17 Connectivity & Transfer Technology

Power Supply

The stethoscope is an extremely mobile product, and therefore the power source needs to be integrated into the product such that this mobility can be maintained. Considering the relatively small dimensions of the product, there are only three types of suitable power sources.

- Alkaline batteries (Figure 4.18, Top)
- Li-ion batteries (Figure 4.19)
- Coin cell batteries (Figure 4.18, Bottom)

The decision was made to use Li-ion batteries for the following reasons. Li-ion batteries are rechargeable, meaning that the product will never have to be taken apart in order to exchange batteries. Instead a micro-USB port or even the audio-jack port can be used for charging.

Li-ion batteries can be custom made into any size in order to fit inside the product, this means that it can be manufactured in accordance with the PCB in order to fit inside the compact casing of the Steth-Link.

Figure 4.18 Power Suppply Technologies

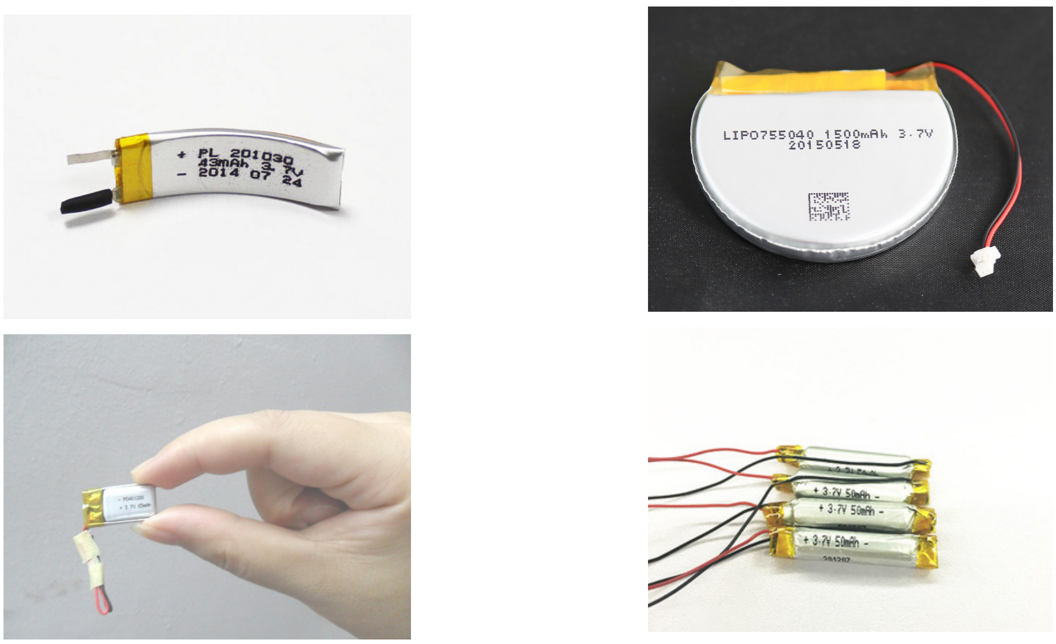


Figure 4.19 Types of Lithium Iron Batteries

4.5 Final Physical Design: Steth-Link

This section presents the outcome of the final physical design to the full extent of its detailed development within the project. It shows the product's functions, features, components, and product architecture.

Form and Features

After an extensive range of shape iterations, the final shape of the physical design was created. It integrates the findings and guidelines from the ergonomic study with the intention of keeping a balance between aesthetics and ergonomics. The handle has a slight upward curve, such that the bell of the Steth-Link can easily be put in alignment with the patient's chest while preventing that the hand holding the stethoscope touches the patient. Furthermore the guidelines from the ergonomic study resulted in the creation of two protrusions on the bottom, creating comfortable grooves for the fingers. Lastly the aim of the final physical design was to create a smooth, tapered form that looks in no way bulky or difficult to handle.

The features of the stethoscope itself were purposely kept relatively simple. As for controls, the design has a simple power button at the end of the handle. It was placed at that particular position on the Steth-Link, such that it is not inadvertently pressed while auscultation is being performed. Furthermore, there are two volume buttons at the beginning of the handle, placed in such a way that the volume can easily be changed during auscultation. Furthermore the Steth-Link is equipped with a LED-powered feedback mechanism that provides the user with feedback on the completeness of the recording. More about this interface can be read on the following pages.

Figure 4.20 Overview of the Final Physical Design's Form & Features

Figure 4.21 Overview of the Final Physical Design's Form & Features

Feedback Interface

The interface was purposely kept as simple as possible in order to avoid confusion as well as to keep a clean look. The interface gives information about the completeness of the individual recording, and makes sure the four most important areas are auscultated for the proper duration. The top bar fills up in order to indicate the completeness of an individual recording. This is to stimulate and remind the cardiologist to take his/her time when auscultatin,. as well as making sure that the recording is long enough to be analyzed. The four bars at the bottom represent the 4 most important cardiac auscultation areas, namely: the Aortic, Pulmonic, Tricuspid and Mitral region. A visualisation and explanation of the feedback interface can be seen in Figure 4.22.

Before recording is commenced, the LEDof the first area will slowly be pulsating until recording is started. Once a valid recording has been made, this LED will stay on, resulting in the first bar to be full. Before the second recording is commenced, the second bar will be pulsating to indicate that the next area is to be recorded. Once the stethoscope is placed on the patient's chest again the recording will start again. The interface will go through this cycle until the 4 areas have been properly auscultated. The advantage of this interface is that keeps a consistent pattern of auscultation. Furthermore, in future developments of the Steth-Link the meaning of the interface could be simply expanded or changed by directly showing the result analysis per area. This was not included in the current design, since the level of two-way communication would be too frequent. However this is definitely an option for the future.

Figure 4.22 Explanation of the design's feedback interface

Figure 4.23 Steth-Link with classical stethoscope earbuds

Product Architecture

The architecture of the different parts in the Steth-Link is relatively simple. It consists of a two-part snap fitted casing, a custom-made acoustic stethoscope and two-part PCB. The top part of the exterior casing snaps on to the acoustic stethoscope, finally letting the bottom part of the exterior casing slide and snap in. The custom-made two part PCB, along with the USB and Audio-Jack port and battery are sandwiched in between. The PCB might seem complicated at first glance, but a single PCB that contains all of the parts for the stethoscope that fits solely in the handle would be a bigger challenge on the front of electronic miniaturization.

Furthermore, this type of architecture allows the Surface Mounted LED's to be easily operated and powered. The PCB consists of a microcontroller that is able to control all of the electric components in the design. Meaning that it can control the LED's for the interface, get readings from the capacitive sensor in order to start and stop recordings, as well as get and split the audio output from the microphone. Lastly the microcontroller can store the recordings and transfer them via the bluetooth module.

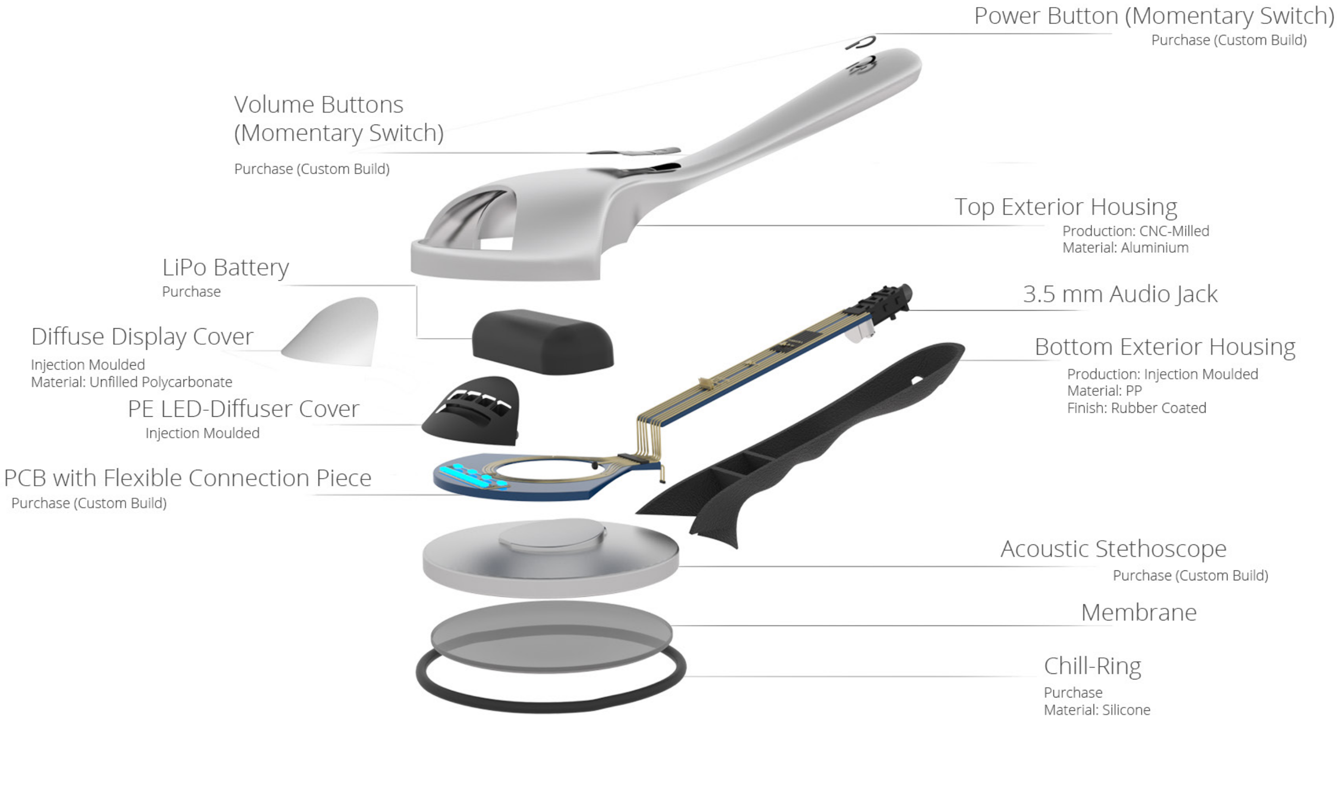


Figure 4.24 Product Components and Architecture

Figure 4.24 Product Architecure Fitting

Capacitive Sensor

The placement of the capacitive sensor is done in such a way that it is placed inside a groove of the chill-ring, calibrated in such a way that a response is triggered once the silicone chill-ring touches someone's skin.

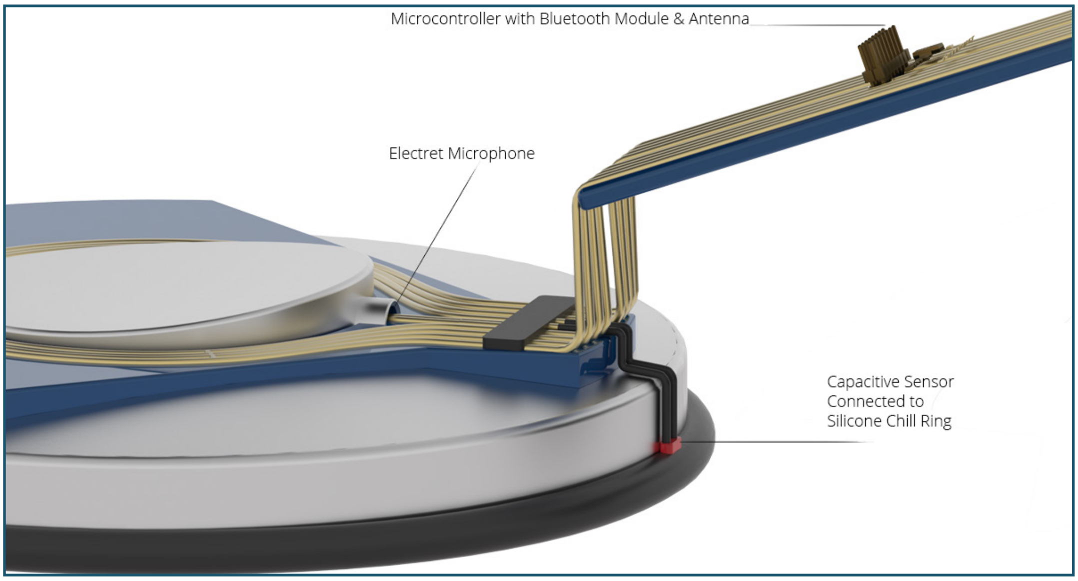


Figure 4.25 Capacitive Sensor Placement

Electret Microphone Placement

The electret microphone, is placed tightly inside the air-cavity of the acoustic stethoscope, such that the vibrations are directly picked up, resulting in a clear sound. The electret microphone will be padded, such that it won't pick up unwanted mechanical vibrations as strongly and stays fixed in place more optimally.

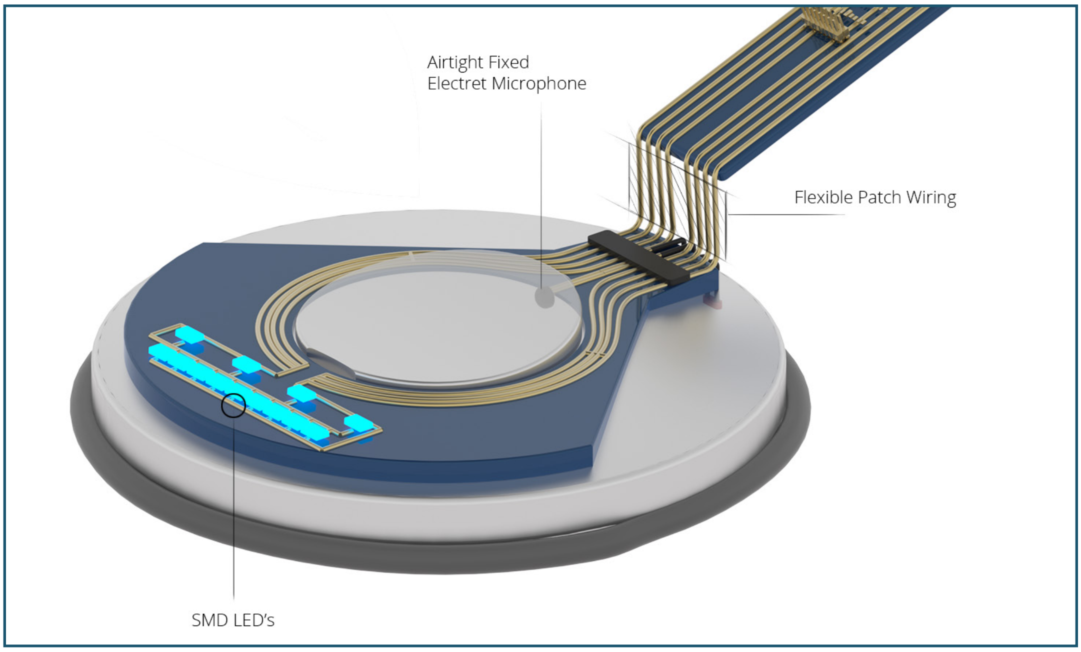


Figure 4.25 Electret Microphone & SMD Led Placement

4.6 Digital Design

This section delineates the digital design of the system applications that support the physical product in its operation. The digital design is meant to provide insight in handling and transferring of data as well as what the cardiologist will interact with once auscultation is complete.

Bluetooth Application

The design of the bluetooth application in mainly reliant on fulfilling the task of transferring the data from the Steth-Link to the server and software system for analysis. The aim was to keep it as simple as possible, while still showing the different functionalities that need to be integrated. First of all from the privacy perspective it is necessary to identify the user and link the cardiologist to an account in the software system, hence the log-in query. Furthermore the fact that Bluetooth is used for data transfer explains the Bluetooth switch and the connection that needs to be established between the Steth-Link and Smartphone. Since an important aspect of the design is that data is transferred automatically this is the default setting. However it is possible that the user prefers to do this transferring him/herself in order to keep better track of the recordings in relation to patients that have been seen.

Desktop Application

The digital design of the desktop application has two main screens. Firstly, it is very important that the cardiologist links the recordings made to the patient he/she has seen. This cannot be done automatically since involves a bit of responsibility and could cause a large amount of problems from the regulations perspective. That being said, the cardiologist needs to drag the made recordings, which are ordered by their timestamps to the patient they were made at. Furthermore, the recordings are already analyzed and can be listened to there if necessary. The second main screen is the Patient Detail page, in which the Cardiologist can listen to the different recordings with more extensive visual reference and editing capabilities. Here the cardiologist can also make notes in the patient's profile and possibly transfer the recordings or ask for a second opinion.

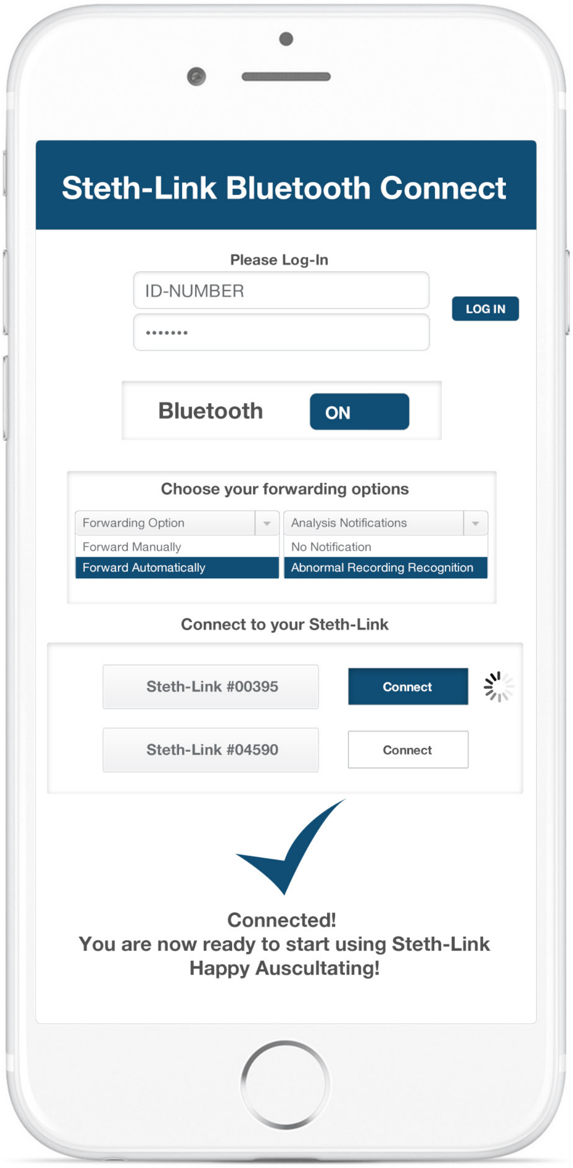
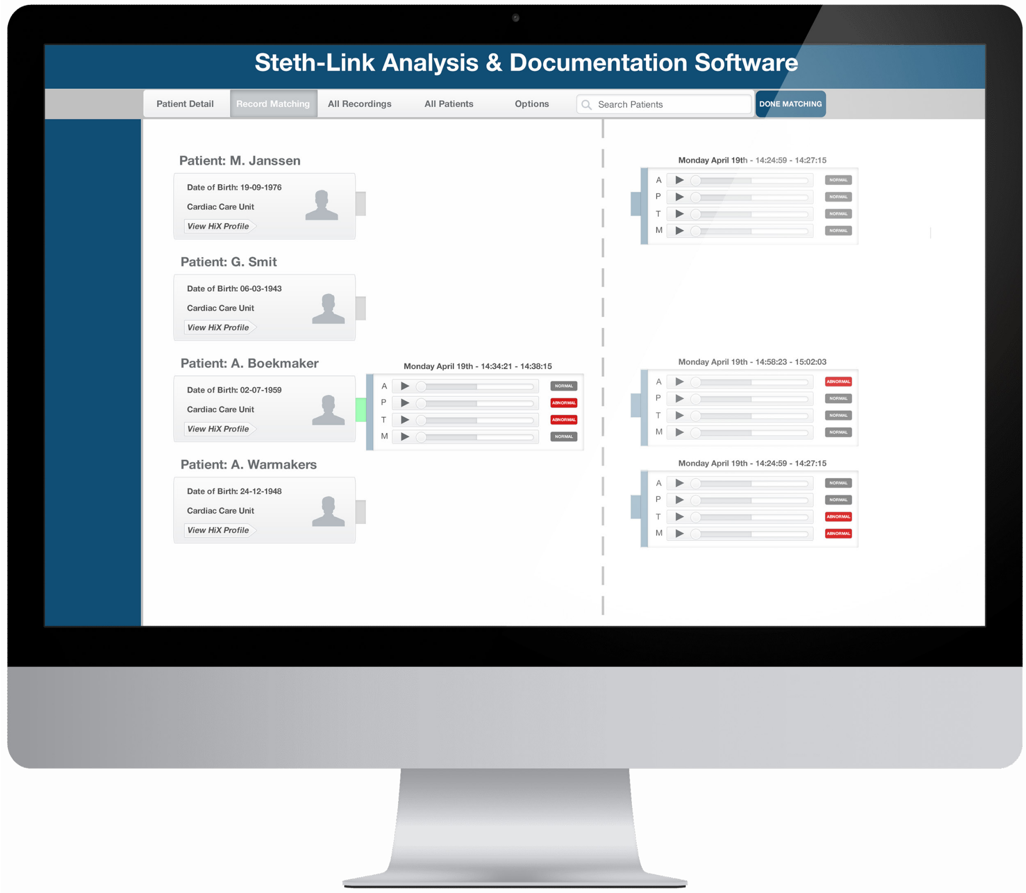


Figure 4.26 Bluetooth Forwarding Application Design



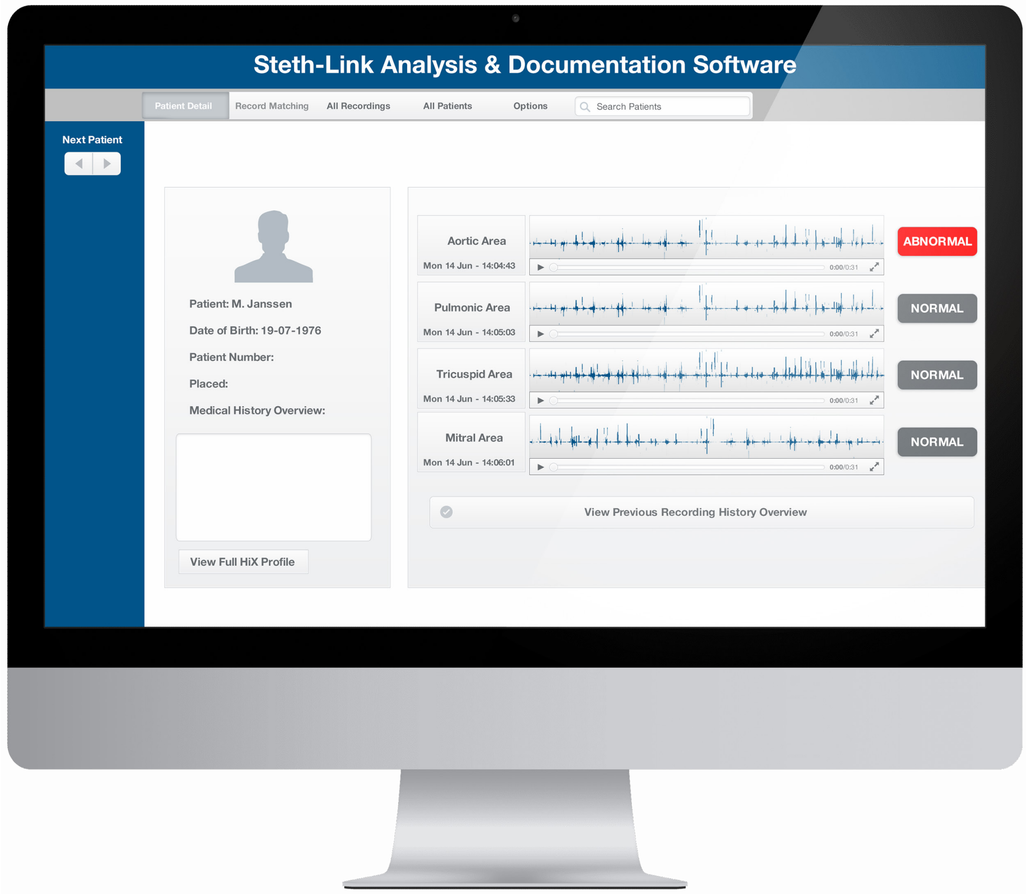


Figure 4.27 Desktop Application Design

4.7 Final Design Proposal

In this section the final design proposal will be presented, beginning with an overview of the design, its key features as well as benefits for all of the stakeholders involved. Furthermore a user scenario is presented, as well as short discussion of the medical rules and regulations and a dimensional overview.

Design Overview

The design is a combination of a physical device and a digital system. The physical device, StethLink, automatically records heart-sounds upon contact with the patient's skin and sends this data to the system through a smartphone. The key part of the digital system is the analysis of the heart-sounds through advanced algorithms. An overview of the product ecosystem and its data flows can be found on the adjacent page.

Key Features

Seamlessness

- Skin contact induced recording/data capture
- Automatic Data transfer
- Seamless integration with the Bluetooth Transfer App and Software System.

Facilitation

- Integration of Product Feedback
- Heart Recording Playback
- Volume Control

Medical Facilitation

- Integrated Heart Sound Analysis
- Easily integratable documentation

Interaction & Use

An overview of the general use of the Steth-Link is visualized in a scenario on page 100 - 102.

Key User Benefits

Unchanged Procedure

The fact that the Steth-Link can be used as a regular stethoscope with no extra needed interactions in the moment is very important. The cardiologist can reap the benefits of the automatic recording and data transfer with help of its capacitive sensor and wireless connection without needing to majorly change the auscultation procedure. The connection between the Steth-Link and smartphone enables the Cardiologist to operate the Steth-Link with maximum mobility.

Support

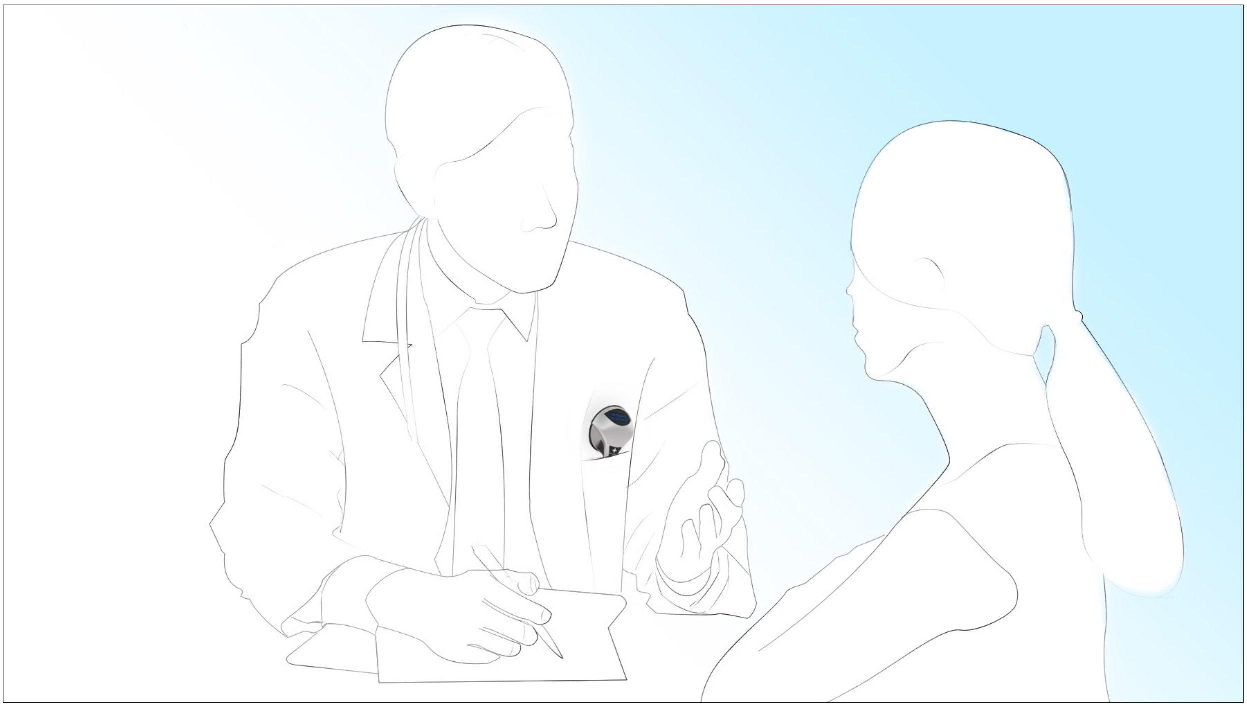
The ability of the system to analyse the heart-sound can act as a facilitating tool for the cardiologist and act as a safeguard in moments of doubt or possible oversight. Furthermore, the fact that the cardiologist can replay the heart-sounds at a later moment in time relieves him/her of some of the time-related pressures that arise during auscultation.
Lastly, the integrated feedback interface requires the cardiologist to listen to each of the areas for a set amount of time, in this way the cardiologist will automatically take his time when auscultating.

Simplify

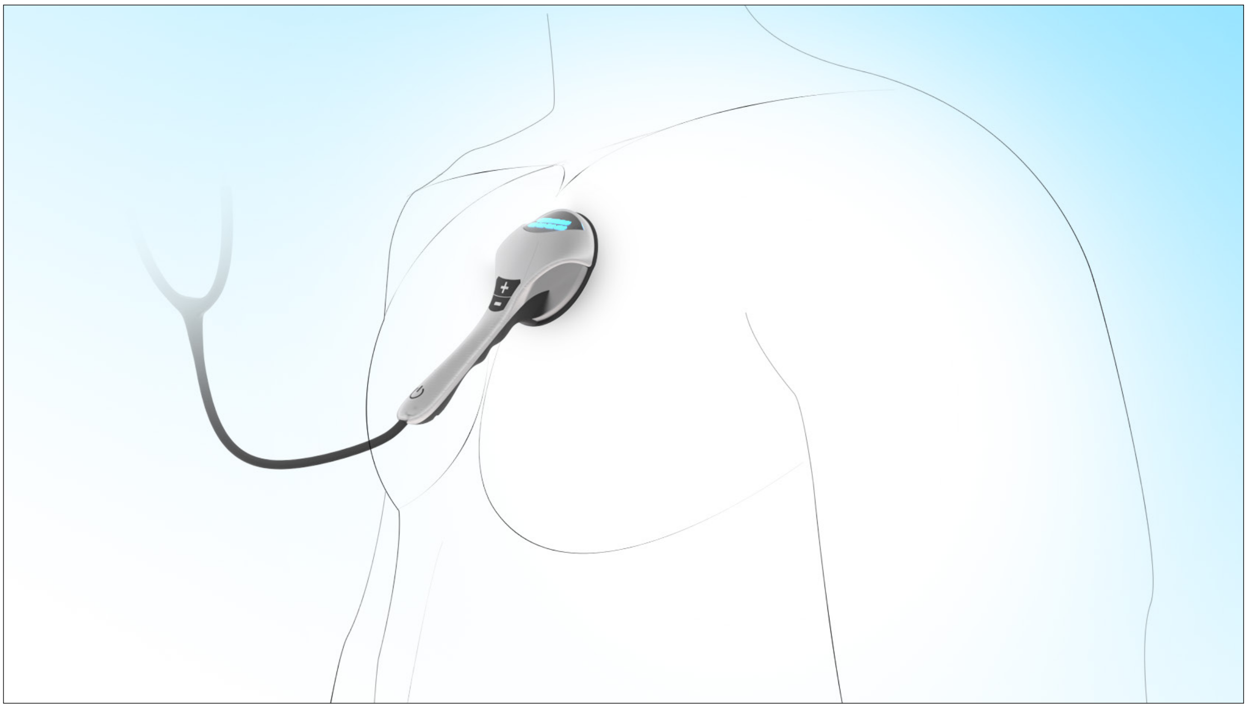
The fact that the nature of the design is so simple and stays close to the actual auscultation procedure could result in the design eventually being used by people other than cardiologists. Furthermore, the simplicity of the interface enables versatility in its meaning, therefore if a different direct analysis feedback function is integrated in the future, this could be easily integrated without changing the interface design.

Figure 4.28 Product Ecosystem Overview

At the beginning of the day, the cardiologist turns on the Steth-Link by pressing the power button on the handle and checking if the Steth-Link is connected by pulling out his/her smartphone. If this is the time using the Steth-Link, the cardiologist will need to set up his/her Steth-Link with forwarding preferences and manually connect it. From there on out the Steth-Link will automatically connect with the smartphone when it is turned on, just like any other regular bluetooth device.



The cardiologist then meets with the patient in order to hear their complaints and ask questions about different health-related factors. Auscultation will commence after this.



The cardiologist will take out the Steth-Link and start auscultating by putting it in the aortic auscultation region on the chest. Upon contact with the chest the stethoscope will automatically start recording.

The interface will show the progress of the current recording in the progress bar. Once the recording is complete and the stethoscope is released from the skin in order to change recording position, the recording is stopped and transferred. If the stethoscope is released far too early the progress bar will reset and the recording will not be transferred.

The recording has already been transferred to the smartphone device during the recording period, and will now be sent to the file transfer protocol server (FTP) such that it can be put into the database. Upon arrival in the database the algorithms will analyse the archived recordings and add the results in their metadata.

Once the cardiologist is back behind the computer in order to update their documentation, they are able to view the analysis results and listen to the transferred heart-recordings. However, the first action the cardiologist must perform when interacting with the system is linking the recordings to their respective patients. Since the recordings are already grouped together in batches, and presented chronologically, the cardiologist should have no trouble doing this.

Sizes and Dimensions

In Figure 4.29 the dimensions of the physical design are shown. The design is built around an acoustic stethoscope that was originally intended to be a part of the prototype. In order to keep a proportionate design, the sizes can be altered in case of a larger acoustic stethoscope integration. This can easily be done, since the overall shape and ergonomic guidelines would also be fully applicable to a design with a proportionally upscaled design.

Medical Rules & Regulations

Due to the fact that the physical design is a non-invasive device that is used in a transient manner, only coming into contact with intact human skin means that the Physical Design is classified as a Class I medical device, meaning that will pass certification barriers most easily. The accompanying software needs to be classified independently as standalone software. This is because it is not embedded into a medical device and is interacted with independently of the physical design.

Considering the fact that the software presents analysis results that could aid with diagnosis, the software has a high chance of falling into the Class IIa category. Diagnosing software can also fall into the Class IIb category if errors or variations could result in immediate danger for the patient. Considering the software acts as a possible reminder for additional testing, a false positive output would not result in immediate danger for the patient. Furthermore, a false negative would also not cause immediate danger, since the software should not be the only variable on which the patient's cardiac health is used.

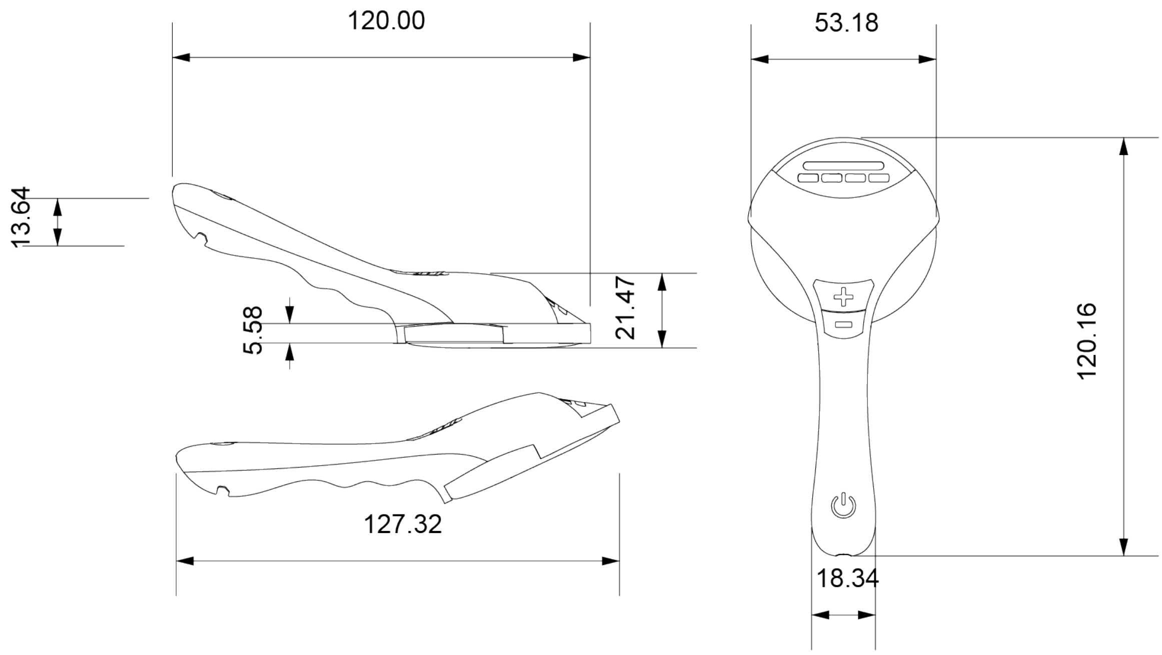


Figure 4.29 Physical Design Dimensions

5 Evaluation and Validation

The main aim of this section is to evaluate the previously presented design proposal on a multitude of factors. The process of this is a combination of a qualitative assessment of the design proposal together with cardiologists, as well as an evaluation of the design proposal against the list of requirements, design vision and problem definition. Ultimately this evaluation will lead to a list of recommendations for future development. This final chapter of the thesis will be concluded with a personal reflection.

5.1 Prototyping

5.2 Design Proposal Evaluation

5.3 Recommendations

5.4 Personal Reflection

5.1 Prototyping

In the final part of the embodiment phase of the project an attempt was made to create a prototype which could be used for qualitative testing in order to have a proof of principle for the project. This consisted of an audio capturing element, as well as a feedback element. Both elements were developed separately and integrated into a preliminary prototype.

Goal

The goal of the prototype was to do a form of testing in order to get feedback on the different features of the design, as well as do tests with the deep learning algorithms. The prototype is meant to be a preliminary proof of concept in order to prove the feasibility of the design proposal.

Process

Throughout the prototyping process many obstacles and hurdles presented themselves, for now resulting in a prototype that is not visually representative of the design proposal. The biggest hurdle was the audio capturing architecture for the prototype. Multiple options were explored, ranging from different microphones, circuits and amplifiers. For the prototype two different audio capturing elements were used, one being an amplifier circuit with an electret microphone, as well as a pre-assembled amplifier circuit with a Lavalier microphone.

Since the feedback aspect of the concept is quite important, an upscaled mock-up of this was created using Sequin LEDs in combination with a capacitive sensor. This consisted of relatively complex soldering in combination with programming.

Ultimately the sound capturing element was integrated together with the upscaled feedback mock-up in order to show the functions and features of the design. The audio was transferred using AUX splitting cables in order to rout the audio to the computer for analysis while also being able to listen at the same time.

The prototyping process and result can be seen in Figure 5.1. The final functional prototype consists of a touch-activated feedback device in combination with a lavalier microphone which picks up sounds from the acoustic stethoscope.

Figure 5.1 Prototyping Process

5.2 Design Proposal Evaluation

This section comprises the overall evaluation of the design proposal that was presented in section 4.7. The design proposal is evaluated in relation to the problem definition following the analysis phase, as well as the design vision and list of requirements.

Problem, Vision & Direction

It was envisioned that cardiologists needed a tool that relieves them of the pressures created by time constraints, a tool which harmonized with their efficient practices while unobtrusively providing them with added clinical value, thereby increasing medical effectiveness. Theoretically, the design proposal provides a solution to this problem by seamlessly adding benefit through automatic recording, transfer and additional analysis in combination with facilitating feedback. Through this, both the cardiologist and the patient should profit from the proposed design.

Even though the design proposal theoretically forms a solution for the problem definition while fulfilling the design vision, the actual success of the design proposal in practice is dependent on a multitude of factors, viz. the combination of final product engineering, software & privacy architecture, procedural implementation and general medical acceptance. Regrettably it was not possible to viably test the design proposal on many of these factors due to the time constraints of this project. However, qualitative evaluations with cardiologists have shown and expressed the pressing need for such a tool, and the development of a preliminary system in combination with a 0-series product would definitely aid in the testing of the design proposal's clinical merits.

Lastly, even though the design proposal could probably add a lot of benefit to the medical sector, it is undeniable that the use of the Steth-Link and its accompanying systems will cause the cardiologist to spend more time on the patient in total. Auscultation with the Steth-Link will take about a little over a minute, while cardiologists sometimes give themselves less than 30 seconds. Furthermore, the biggest time investment comes in the viewing of the analysis results, and linking of recordings to patients. At the moment, cardiologists barely spend time, if any, on the documentation of auscultation, or auscultation in general when they're behind the computer. Therefore, this extra time investment might cause some reluctance with the cardiologist. However, in both cases of auscultation and documentation, the little extra time investment can have great benefits for both the cardiologist and patient. Implementation and clinical trials will have to show how cardiologists perceive this cost-benefit ratio.

‹Creation of a diagnostic tool in the form of an electronic stethoscope that ***harmonises*** *with the efficiency of the auscultation process as* ***seamlessly*** *as possible; acting as a* ***facilitating*** *tool, increasing* ***medical effectiveness*** *through* ***unobtrusiveness*** *and improved* ***diagnostic potential****.›*

- Design Vision

- *Time constraints (600 seconds per patient)*
- *Pre-diagnostic tools with limited functionality*
- *Use of diagnostic tools under time constraints*
- *The necessity of interpreting information in real-time*
- *The inability to reconsider assessment at a later moment*
- *The declining education of using these tools to their ful clinical potential*

- Problem Definition Aspects

Requirements

The design proposal was evaluated against the list of requirements in order to see to what extent the design proposal meets the set of criteria.

Almost all requirements are met within the design proposal, however not all of the requirements could be tested/validated with an adequate prototype due to the limited time scope of the project and thus it currently cannot be substantiated that these requirements are met in practice.

The requirements and issues that are the most relevant are discussed below. The requirements and wishes are represented with a Letter-Number combination: (R-# & W-#, Requirement and Wish number)

Long Term Effects

Various requirements require testing over a long period of time in order to evaluate if they are substantiated within the design. The most important one of these requirements is the improvement of the diagnostic outcome for the patient (R3) . First of all, this is very hard to test since it is unknown what the diagnostic outcome would have been for the patient without the tool, therefore this can only really be substantiated if cardiologists publicly acknowledge a positive impact of intervention of the device in their cases. In the case of W2.5, which states that the design should decrease the unnecessary deployment of follow-up methods/technologies, this is also something that needs to be tested in the long term and compared with data revealing present unnecessary deployment of follow-up methods in cardiology.

Medical Product Acceptance

The medical acceptance of the product in relation to its appearance is related to its physical resemblance to a classical stethoscope (R2.6) . Qualitative evaluation and feedback from cardiologists has shown that it does resemble a stethoscope but is viewed as more aesthetically appealing. Practical implementation of the product needs to be done in order to fully confirm this, but the positive responses from cardiologists to the design lean towards a high probability of medical acceptance on the front of its appearance.

Heart Sound Analysis

Even though the requirements or wishes don't indicate that the design should be able to (accurately) analyze heart sounds, it is still a factor through which other wishes and requirements are fulfilled, i.e. the requirements concerning diagnostic outcome. The preliminary testing with the prototype has confirmed that this is indeed possible and integratable.

Heart Sound Analysis

Even though the requirements or wishes don't indicate that the design should be able to (accurately) analyze heart sounds, it is still a factor through which other wishes and requirements are fulfilled, i.e. the requirements concerning diagnostic outcome. The preliminary testing with the prototype has confirmed that this is indeed possible and integratable.

Time Efficiency and Seamlessness

Since time constraints are a large part of the problem definition, the requirements regarding seamless recording with minimal interaction from the cardiologist (R1.7) as well as that the design should live up to efficiency standards regarding consultation (R1.8) are important evaluation points on the front of this topic. Since the design proposal was created in such a way that the interaction with the product during auscultation does not differ from regular stethoscope interaction validates these requirements to a large extent. However the only part which needs to be seen in practice is the general willingness of cardiologists to listen in each area for a set amount of time.

Medical Regulatory Compliance

Analysis of medical rules and regulations revealed that the physical design is only subject to Class I medical regulations, meaning that it will be in the most easily certifiable category. This means that there are no pressing sterility requirements, even though the design was kept edge- and cranny-free for easy cleaning and pseudo-sterilization using alcohol wipes.

The data aspect of the project means that the software system will be classified on its own as stand alone software, and needs to adhere to General Data Protection Regulations (GDPR). Since only a small amount of time was spent on software development, the issue of data privacy and encryption of data in relation to GDPR compliance is not addressed.

Limitations of the Project

This project, being a time-constrained project executed by a single person who is still in his educational career obviously comes with a set of limitations. First of all, most of the research that was done within this project was done in a qualitative manner, data gathered for ideation and concept creation came from a small user population sample (N=5), of which all were male and worked at the same hospital. Therefore, it has to be said that conclusions could have been made which are not generally representative of cardiologists in the medical sector.

Furthermore, the tests that were performed were not done with a perfect representation of the final design proposal. Therefore the conclusions made from these tests are not necessarily completely representative for the final design proposal as a whole. The tests are merely an indication of the performance of the actual product in practice. Conclusively, extensive testing of a prototype which is fully representative of the design proposal needs to be done in practice before statements can be made about all factors of the design.

Conclusion

The design proposal was evaluated against the project assignment. The final design proposal provides a product-service system that sets out to facilitate the cardiologist by adding benefit through automated recording, integrated feedback, and sound analysis. The foundations of the designs are based on qualitative research and testing with cardiologists, as well as a plethora of scientific literature.

Qualitative testing in the form of interviews, presentations, discussions and user tests has shown positive responses on multiple fronts, and sets a promising tone for future development of the device. Cardiologists indicated that they see the concept as a necessity in the healthcare sector and that it could greatly improve their workflow, and the healthcare sector in general.

Long testing with a professionally produced product in combination with a fully functioning system is necessary to fully validate and substantiate these claims. Therefore the lack of insight in the real practical application of the project in all cardiology related healthcare contexts is the largest limitation of the project. The effects on diagnostic outcome and overall perception of facilitation in practice will need to be verified through long-term practical testing.

In conclusion, the design proposal shows large potential to positively impact auscultation and the procedures around it through adding benefit and facilitating the cardiologist in an unobtrusive manner, expectedly improving the diagnostic outcome for the patient and improving auscultation for the cardiologist. The design proposal has been met with positive response from cardiologists and shows real promise for future development, testing and implementation.

5.3 Recommendations

This section delineates the recommendations for the future development of the design proposal, mostly with regard to the physical design, since the digital design is more of a representation of the system's capabilities.

Improvements & Additions

An important recommendation for the future development of the design proposal is related to sound quality. Sound engineering is a complex thing and it is important that experts improve the sound quality as much as possible. The key improvement would be shielding of the electret microphone of noises that are created by the handling of the stethoscope itself, as well as eliminating sounds that happen around the patient during auscultation. A combination of ambient noise reduction, mic shielding and using a directional microphone that only picks up the vibrations from the diaphragm will radically improve the sound quality.

Cardiologists showed welcoming responses with regard to feedback integration into the stethoscope, but mainly noted that immediate feedback from the stethoscope about the analysis of the heart sound would be even better than feedback about recording completeness. The interface itself would not need be changed, just possibly a colour distinction introduced in order to show if the recording from a certain area has been analysed as a 'normal' or 'abnormal' heart sound recording. The progress bar is something that could remain in the interface, while the four regional parts would be used for the region-specific analysis results. This feature was not included into the final design proposal since it would require a larger amount of communication between the Steth-Link and its accompanying system. However, with optimization of communications between the physical design and its systems it would definitely be an option.

Something that will play a role in the successful implementation and development of the Steth-Link into the healthcare sector is the continuous development of the algorithms that power the analysis of the automatically recorded and transferred heart-sounds. Therefore the recommendation is to keep improving the algorithm through a set test group of cardiologists, which help the algorithm learn by enriching the database with the heart-recordings and their respective diagnoses. Through this the algorithms will eventually be able to directly differentiate between different heart pathologies such as stenotic, regurgitative and restrictive cardiomyopathy murmurs. As this goes on, the algorithms will also become more reliable and most of all valuable in the healthcare sector.

An important discrepancy in the design is the linking of the data to their respective patients. In the final design proposal this still needs to be done by the cardiologist since there is no real way of automatically linking these recordings to patients. However, trends have shown that patient beds will be increasingly equipped with RFID tags, meaning that the cardiologist's phone will know at which bed the recording was made, and thus to which patient the recording belongs. Nevertheless, before this RFID technology is widely implemented, direct feedback from the Steth-Link about the heart analysis results would already address a part of this problem since it directly lets the cardiologist know the heart-sound analysis outcome of the patient (s)he is auscultating.

Even though stethoscopes are mainly used by cardiologists to auscultate cardiac functions, they are also used for auscultation of the lungs. Therefore a recommendation is the integration of a lung auscultation feature, or a special mode in which the lungs can be auscultated. This could be done through the implementation of a simple button or switch in order to let the cardiologist change between cardiac and lung auscultation modes.

Future Development

Lastly, below is a list of other additions and developments that need be made to the product such that the product becomes more competitive and can be brought onto the market.

- Design of a docking & charging station
- Design Transport casing
- Packaging Design
- Long Term, Multi Context testing with cardiologists
- CAD Model optimization for CNC milling and mass production (tolerances, draft angles)
- Geometric optimization with regard to product compactness
- Organization and set-up of cardiologist algorithm development team
- Electronic minimization and PCB development
- Bluetooth forwarding application development
- System architecture development (Privacy, Data Flow, Programming, Upscaling)

5.4 Personal Reflection

This final section comprises the conclusion to the project. The project is evaluated by the graduating student by providing personal insights about the development process of the project as a reflection on the process, outcome and project as a whole.

Project & Scope

This project was initiated through a combination of initiatives, primarily by Dr. Tobias Bruning, who had the initial inspiration for a project which involved the improvement of the stethoscope in order to bring back and improve the nearly lost art of auscultation. The TU-Delft chair of the project, Dr. ir. Armağan Albayrak, suggested I take on the project and connected me with Dr. Bruning and Maasstad Hospital.

The forming of the assignment took a while since the broad scope of the project had to be narrowed down into something that would be doable within the timeframe of the project. Even though at the time it seemed like the scope had been sufficiently narrowed down, the interdisciplinary complexity of the project shows that this scope was still a bit too ambitious in retrospect. Nevertheless, over ten versions of the graduation proposal eventually led to a good starting point of the project.

First Phase

At the beginning of the analysis phase it was my aim to come up with something which could completely revolutionize auscultation and the cardiology sector as a whole. Which was obviously too ambitious an aim to have. It was extremely interesting to dive into cardiac biology and medicine as far as I could, sometimes even going to a cellular level. Something which I thought could be a step towards this revolution was to broaden the diagnostic horizon of the stethoscope in some way, and I was looking for emerging new technologies that could contribute to this. It was exciting to find a few technologies which had great potential to achieve this. Unfortunately it was not justifiable to go with the technology I thought of as most disruptive: too risky in this context, but I still think seismocardiography has huge potential to be integrated into a similar solution and I hope to see it used in homecare situations somewhere in the future. The selection of deep learning algorithms for heart-sound analysis was the best choice given the user group and context.

That being said, the analysis phase was the most interesting part of the project for me; being able to work amongst cardiologists and see what their daily working procedures are like was ever so interesting and helpful for the development of the project. It was humbling to be accepted with such enthusiasm and I greatly appreciate Dr. Bruning's generous attitude for making this possible.

Obstacles and Fruitions

The articulation of the concept and the functions that surround it was something that I really enjoyed. For me it seemed obvious what needed to be created in order to come up with an innovative solution which could contribute to healthcare. Consequently this was something which was done with relative ease.

The most challenging aspects were what followed the functional concept creation phase. Being naturally ambitious, my aim was to come up with a design which would be aesthetically pleasing, functionally convenient, while also having great ergonomics. The requirements I set for myself made it very difficult for me to come up with a design that was acceptable in my eyes. It took a long time to create a final shape, as well as do proper ergonomic development. Integrating the ergonomic insights into the design while keeping an aesthetic proportional design was very difficult, involving more concessions than I had expected. Nevertheless, combining this has taught me a lot and also showed me that it will be a better idea in the future to start from a component level and work up, instead of refitting and adjusting the design in retrofit modes.

Project Management

At the beginning of the project I was very satisfied with my project management because I had a very clear overview and goal of what I wanted to research, as well as where I wanted to end up. However as the project went on, I felt myself slipping deeper into the complexity of the project, sometimes largely losing track of where I was heading. This lead to some severe mental strain at some points, eventually requiring me to take a break from the project for a while in order to regain my perspective. In retrospect I would have structured the last third of the project differently, since it resulted in the rushing of certain aspects, whereas other aspects could have been finished more quickly. The project was not finished anywhere near the deadline I had set for myself, nor was it finished within the academic guideline of 22 weeks. This extra time that was spent on the project did positively contribute to its outcome and insights for further development, but in all honesty I have to say that I expected more of myself working on a project for such a long time.

Result & Takeaway

The largest thing that I have learned during this project: it is impossible to do everything. My aim was to create a beautiful design, a fully functioning prototype with a software system that would be almost ready to go to clinical trials, and I communicated this to my committee with probably too much conviction. If I could go back I would probably tell myself to slow down a bit, and try to streamline the project, setting more modest goals.

Looking back I have to say that this project has revealed my strengths and weaknesses as a designer. Even though it was painful at times, it has taught me more about myself than any other design project ever has. I'm happy to have learned so much and to have gone through these difficulties while I was still a student, in an environment where it is okay to make mistakes, but also choose a road less travelled.

Looking at the project result, I think the design proposal is something that has substance and could really be a big step in improving everything that surrounds auscultation in the field of cardiology. I would have liked to demonstrate my claims that the design proposal has a large chance of success with a fully functioning prototype. Now I think that this is something that has to be done with less stringent time constraints and an experienced multidisciplinary team. All in all, I am happy that this is the graduation project I chose to do. I hope that it will be a building block and trigger the improvement of auscultation in the field of cardiology and healthcare in general.

- *Kolja*

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