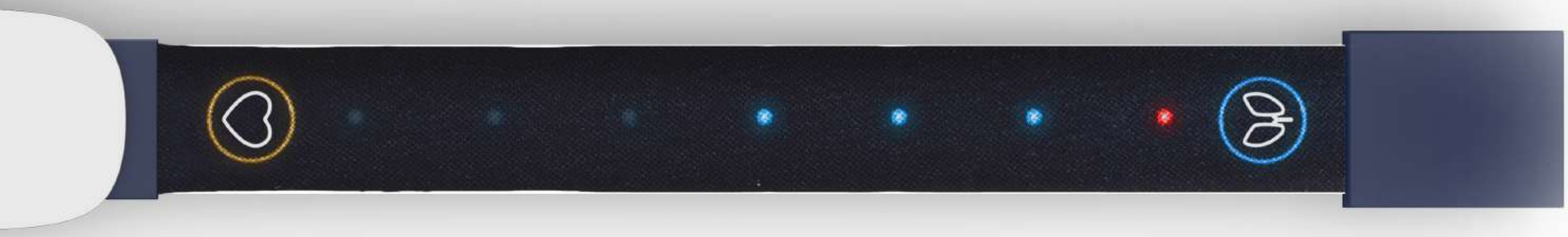

Master thesis

Designing a monitoring device for cardiovascular patients

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Executive Summary

Due to the recent advancements in artificial intelligence based sound analysis, digital stethoscopes soon will be ready to leave behind the clinics of general practitioners, cardiologists, and pulmonologists and move to the homes of patients. But which patients could benefit the most from the technology and how would this step affect the design of stethoscopes? The current project focused on answering these two questions with regards to cardiovascular patients.

Research

The analysis phase of the project focused on exploring the most promising disease – use case combination. The following two scenarios were identified:

Pulmonary edema detection for heart failure patients

Heart failure is a condition where patients' heart is unable to pump enough blood to meet the body's necessities. This can lead to pulmonary edema – fluid retention in the lungs. If pulmonary edema remains undetected, it can lead to severe acute events. Using digital stethoscopes the development of pulmonary edema can be detected in time.

Exacerbation detection for COPD patients

COPD is a progressive disease leading to permanent lung damage. Lung infections pose a great threat to these patients as they speed of the progression of the disease. If lung infections are spotted at an early stage, they can be treated before the acute worsening of the patients' state. However, no current technology can support patients in this early detection. Thereby, digital stethoscopes are highly promising for early detecting lung infections in COPD patients.

Design solution

The developed solution is a strap based self-monitoring device. The device has a double stethoscope set-up, which enables patients to listen to the sounds of both of their lungs at the same time. This halves the measurement time. During the project, the inner structure of the device was elaborated as well. The device is stored on a wall-mounted charger. Hidden lights in the strap help patients to remember measurements and provide feedback about measurement accomplishment. The fabric-based strap design provides a friendlier and more comfortable look and increases the comfort during use. The wall mount is equipped with a holder that supports patients in the easy and accurate placement of the device on their back. The vision on the use integrates breathing exercises to measurements. By conducting the measurements, users can unlock new exercises. This way the use can stay more diverse over time.

Evaluation

The design solution was evaluated with the involvement of COPD and heart failure patients. All participants were highly satisfied with the ease and comfort of the use and the involved measurement reminding features. Participants found the device highly reliable and hygienic looking, friendly and moderately medical looking. Thereby, the aesthetic goal of balancing between a medical and a friendly appearance was met. The opinion of patients greatly varied regarding the envisioned rewarding system. While some participants found it childish, other found it rather interesting. This aspect of the device is recommended to be improved via the integration of various use encouraging features that patients can personalize to their own motivational aspects with ease.

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ANALYSIS
PHASE

1 INTRODUCTION
Starting point of the project

Cardiovascular diseases are the number one cause of death globally. In 2015, approximately 17.7 million people died due to some form of cardiovascular disease, which represents almost third of all global deaths (WHO - Cardiovascular diseases, n.d.). The Cardiolab is a collaborative initiative between the Technical University of Delft, Philips Design and the 'Hartstichting Nederland'. The aim of the initiative is to develop research-based innovations that can support cardiac patients, and that can contribute to decreasing the burden of cardiovascular diseases. The current graduation project is executed within this research initiative.

SASKIA MOSTERMAN'S RESEARCH

The project is based on Sasika Mosterman's – previous graduate student's – research. The goal of her project was to develop a self-monitoring solution to detect comorbidity in patients with an established cardiovascular disease. In order to do that, she aimed to find the most relevant parameters (e.g., blood pressure, ECG parameters) for timely detection of these cardiovascular comorbidities.

She summarized her findings on a heat map. A segment of this heatmap is shown in Figure 1.1 (The full heat map can be found in Appendix A-A). On the image, darker colors are associated with stronger clinical connection between a given disease–parameter combination. Based on this heat map she identified heart rate (HR), heart rate variability (HRV), respiratory rate (RR) and thorax sounds to be indicative for a great number of diseases. She also considered current technologies that for measuring these parameters and found that an electronic stethoscope could measure all the above parameters. This realization directed the CardioLab's interest on exploring the possibilities of using electronic stethoscopes for self-monitoring in a home context and led to the current project. However, it is important to note that the current project is not anymore merely focusing on comorbidity detection using electronic stethoscopes, but expands the use to any self-monitoring activity that supports patients in secondary prevention related self-management.

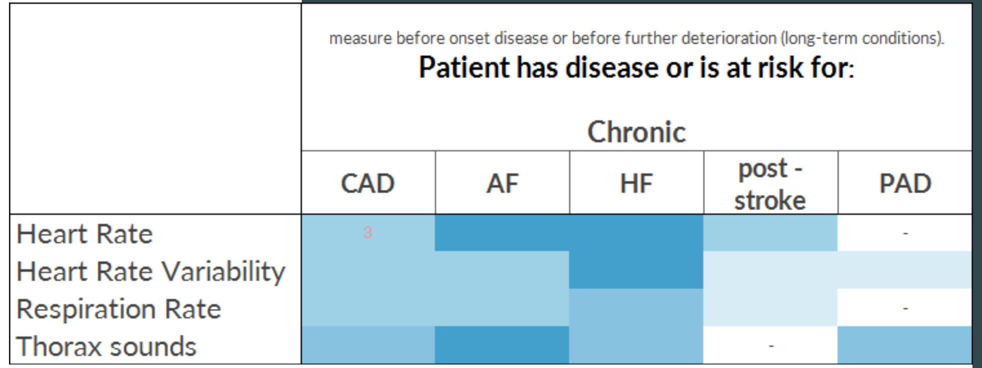


Figure 1.1 A segment of Saskia Mosterman's heat map

DESIGN GOAL

The aim of the project is to design a product service system for cardiac patients that:

- Can be used for self-monitoring and tele-monitoring patients
- Can support patients in self-management
- Is based on the technology of digital stethoscopes
- Can support a broad range of patients

SELECTING THE FOCUS DISEASES

The heatmap of Saskia Mosterman highlights what diseases can HR, HRV, RR and thorax sounds indicate, however, it does not clarify which patient group could be best supported in self-management with an electronic stethoscope and how could they benefit from it. To limit the scope of exploration, the first step of the current project was to filter out a set of cardiovascular diseases to focus on. Identifying the most valuable disease–use case combination started with a preliminary selection of focus diseases where using an electronic stethoscope for self-monitoring could have potential advantages. The first step was defining criteria for the focus diseases.

Criteria

The following criteria were determined to identify the most relevant diseases for the project.

Auscultation has to have an added value to people with the selected disease
As it was explained earlier, an electronic stethoscope can be used to measure HR, HRV, RR and thorax sounds. However, HR, HRV and RR can be measured using more conventional techniques than developing a stethoscope for patients that can be used to monitor these parameters. Thereby, for the selected disease group auscultation – the act of listening to the sounds produced by the human body – has to have an added value.

Patients need to be diagnosed with a disease where the rapid deterioration poses a threat
Supporting self-management via self-monitoring is an overall goal of the project. Regular – daily or weekly – self-measurements have a higher added value for those patients whose condition can worsen quickly.

The selected disease group should affect a considerable amount of people
In order to maximize the impact of the project, only the most prevalent diseases were considered. Apart from maximizing the impact, this criterion also helped to limit the number of diseases to be considered.

Approach

At the start of the project vast amount of information had to be processed about the medical context of the project. The most effective way to speed up the learning curve was to get in touch with medical experts. Two experts were interviewed during a total of three approximately 1-hour sessions. The experts are:

- **Dr. Jan Willem Bech** – Cardiologist at the Reinier de Graaf hospital. His focus area is coronary physiology and cardiology interventions
- **Johan Manshanden** – PhD candidate at the department of Cardiothoracic Surgery of AMC

The interviews were semi-structured interviews focusing on identifying possible diseases that meet the criteria mentioned above and on better understanding cardiovascular diseases and their trajectory, the use of stethoscopes, the parameters they can measure and the healthcare environment. The interviews were conducted over the course of 3 weeks, one each week. Between the interviews, literature research was conducted to further explore topics from the interview and to identify opportunities from a different source as well. A huge advantage of interviewing multiple experts was that they could confirm each other's statements.

Most important interview findings

Here only the most important findings are presented a more elaborate summary of the interviews can be found in Appendix A-B.

First interview – Br. Bech (11.10.2017)

- Dr. Bech was initially intuitively skeptical about the added value of such a device
- Valvular diseases are the most commonly diagnosed diseases using stethoscopes. However, they have a slow, gradual development
- According to Dr. Bech, a stethoscope cannot be used to diagnose coronary artery disease or track its progress
- Dr. Bech saw no added value of stethoscopes for patients with arrhythmias
- Heart failure is the most interesting disease for home monitoring. The S3 heart sound heart failure produces might be useful to be tracked on a long-term to determine if the condition is worsening
- Pacemakers do not need additional monitoring as they already communicate with computers

Second interview – Manshanden (16.10.2017)

- Pulmonary patients could also greatly benefit from such a device (e.g., COPD patients)
- COPD patients could benefit from the device by tracking their disease progress and by detecting lung infections
- Manshanden was not sure how much the S3 sound could tell about the progression of heart failure. However, he agreed that using the device to detect pulmonary edema could be beneficial for them
- The device might be useful for peripheral artery disease patients who could benefit from monitoring blood flow in their legs by auscultating to arterial bruits

Third interview – Dr. Bech (24.10.2017)

- Dr. Bech agreed as well that using the device for pulmonary edema detection could be useful for heart failure patients
- COPD has a strong cardiac relevance, and it leads to many cardiac comorbidities
- The system could be interesting for patients to identify if they have peripheral artery disease related arterial bruits.

Conclusions

The following diseases were considered to be included:

- Valvular diseases
- Coronary artery disease
- Arrhythmias
- Heart failure
- Chronic obstructive pulmonary disease (COPD)
- Peripheral artery disease (PAD)

Valvular diseases are often diagnosed using stethoscopes. However, they have slow and gradual progression, thereby, they were not included in the rest of the project.

Although, the interviewed doctors saw no opportunity for coronary artery disease for the technology, many researches were regarding the non-invasive diagnosis of the disease based on computer-aided analysis of stethoscope acquired auditive information (Azimpour et al., 2016; Chen et al., 2017; Dragomir et al., 2016; Schmidt et al., 2007; Schmidt,et al., 2015). However, these researches focused on the diagnostic value of electronic stethoscopes for coronary artery disease and not for its benefits for patients with an established diagnosis. Thereby, coronary artery disease was not included in the rest of the project.

For patients with arrhythmias, no added value was found of using stethoscopes for self-monitoring purposes. Thus, this disease was not included in the rest of the project either.

Heart failure is one of the most relevant diseases for self-monitoring. Patients could potentially benefit from using an electronic stethoscope for the detection of pulmonary edema (for explanation on pulmonary edema see Chapter 3 - Page 17).

COPD has a strong cardiac relevance leading to many cardiac diseases. A potential benefit for COPD patients would be the tracking of their disease and the detection of lung infections that pose a great threat to these patients. Both seem possible using an electronic stethoscope.

PAD patients' blood flow could be monitored in their legs using an electronic stethoscope.

Thus, heart failure, PAD and COPD were selected as focus disease. The rest of the analysis phase focused on exploring these diseases to confirm if these initial opportunities are truly beneficial for patients.

Doctor interviews were the most important input at the beginning of the project

2 ELECTRONIC STETHOSCOPES

The electronic stethoscope provided the technological starting point for the current project. Before introducing the focus diseases, the use, technology and market of these devices is presented.

THE USE OF STETHOSCOPES

The stethoscope was invented in 1816 by Rene Laënnec (Roguin, 2006). Although in the beginning, many people doubted the usefulness of the device, by today it became one of the most emblematic tools of doctors. It can be used for auscultating all types of body sounds. Most often it is used to auscultate heart and lung sounds. Apart from these sounds auscultation for arterial bruits also has a relevance to this project as these sounds can indicate PAD-related atherosclerosis. This sub-chapter focuses on introducing the use of the stethoscope related to the focus diseases.

Auscultation locations

Different body sounds are auscultated at different locations. The relevant auscultation locations are the following.

Heart sounds

Doctors listen to heart sounds in the frontal part of the chest (Figure 2.1). Five locations are usually auscultated. These auscultation points are related to different valves in the heart. Auscultating to all 5 points could become cumbersome for patients who would use the device on a daily basis. Dr. Bech – cardiologist – said at a personal interview (2017 October 11) that in case only one point is auscultated the most interesting one is the lowest auscultation point which is more lateral than the others.

Lung sounds

Doctors auscultate lung sounds on the frontal part, the dorsal part (back) or the lateral part (side) of the chest. Figure 2.1 and Figure 2.2 show the frontal and dorsal auscultation points. These are the most important ones. Usually, doctors during physical examination listen to the same points on a given height after each other to compare sounds in the left and the right lung. Then, they go to the next pair of auscultation points. In case the number of auscultation points is minimalized for self-monitoring purposes still at least two points need to be auscultated as humans have two lungs. The most effective points are on the back of the patients. The most effective auscultation point varies depending on the purpose of the auscultation. Thereby, it will only be defined after finalizing the use case.

Arterial bruits

Arterial bruits can be auscultated over arteries. PAD mostly affects the arteries that carry blood to the legs. Dr. van t'Sant – vascular surgeon – said at a personal interview (2017 December 04) that auscultating for arterial bruits would only

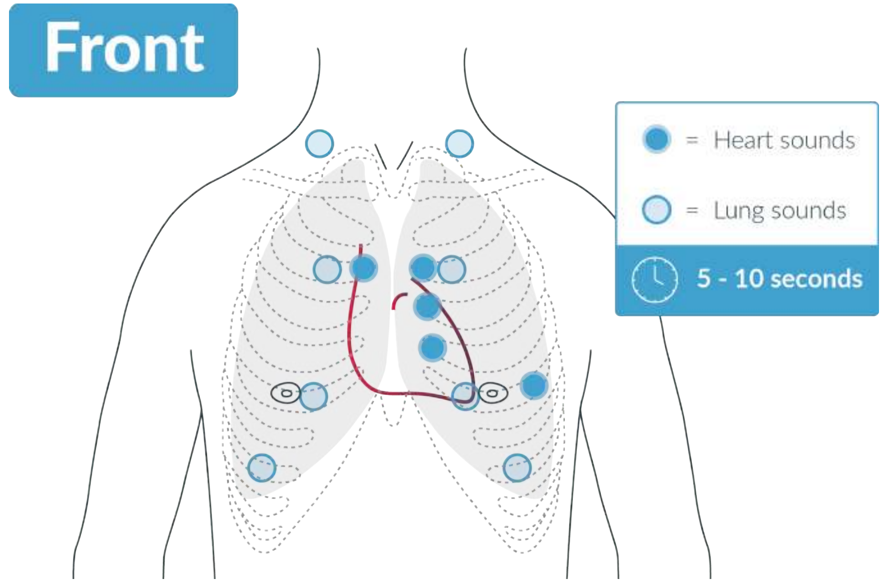


Figure 2.1 Auscultation locations on the front of the chest

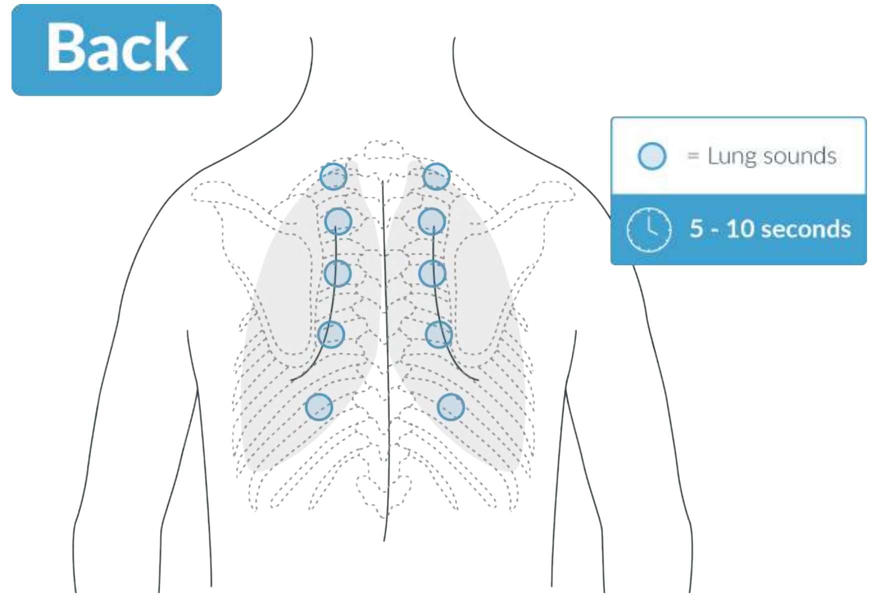


Figure 2.2 Auscultation locations on the back of the chest

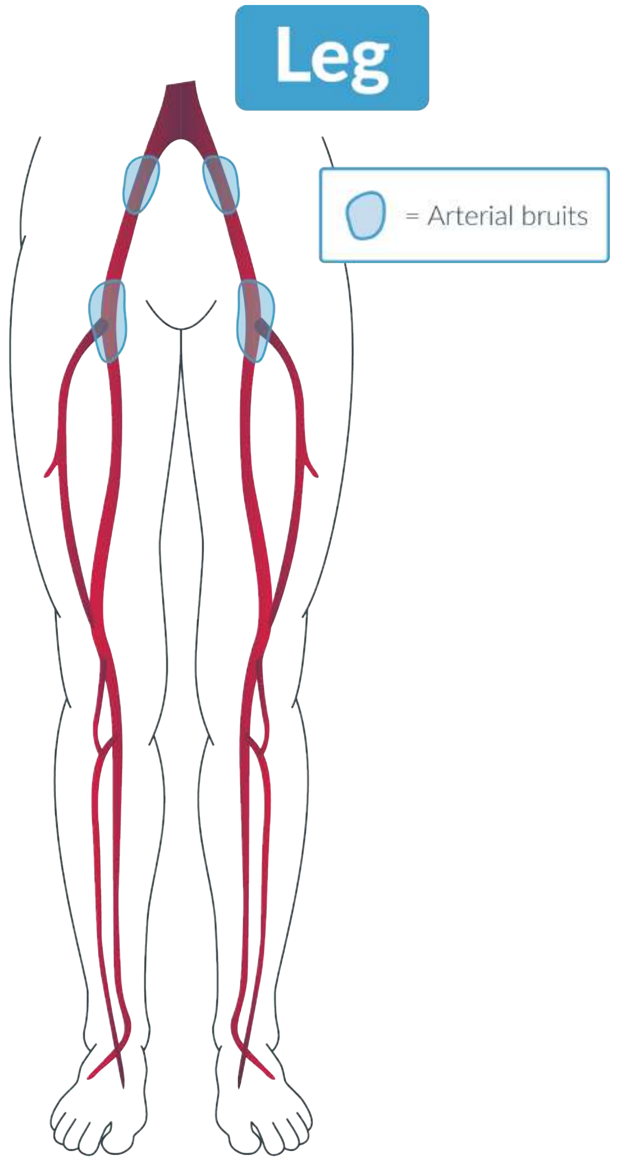


Figure 2.3 Auscultation locations for arterial bruits

make sense over the iliac and the femoral artery (see auscultation points on Figure 2.3) as the arteries lower in the legs are too narrow to produce audible bruits.

Use related challenges and limitations of electronic stethoscopes

There are two major use related challenges of electronic stethoscopes affecting the current project.

Sensitivity to external noise

Electronic stethoscopes enable physicians to interpret audio information gathered from patients. In case noise corrupts the recorded audio, interpretation can become hard or even impossible. Both external noise and vibration can corrupt the signal so badly, that noise cannot be filtered out of it. Thereby, the environment and the way of use is limited. A device based on the technology of electronic stethoscopes can only be used in relatively silent environments – such as homes –, with minimal movements during measurement.

Need for expert interpretation

As it was stated in the Introduction chapter already, the added value of using electronic stethoscopes for determining HR, HRV, RR and recording body sounds is its ability to record body sounds. The other three parameters could be measured using more conventional technologies as well. The problem with these body sound recordings is that it cannot be expected from patients to interpret them. Thereby, the gathered information needs to be interpreted by an expert. Experts, in this case, mean physicians. The need for physician interpretation has a strong limitation on the use of stethoscopes because physicians have very limited time to spend on one patient. As the device is meant to be a self-management supporting tool, the regular recordings would produce a huge amount of information. However, physicians are already overwhelmed in the healthcare system. Thereby, if physicians are expected in the product service system to interpret the gathered information, they should only receive limited and well-selected information.

The other interpretation solution is the use of computer-aided analysis. Currently, there are many breakthroughs regarding this solution. It is a real key technology for the project as it enables the automated analysis of a much bigger data set. In other words, it enables patients to use the stethoscope for self-monitoring purposes on a regular basis without posing any extra burden on the overwhelmed healthcare system. The drawback of deciding for computer-aided analysis, is the fact that the technology at the moment is not readily available – especially considering the long lasting clinical trials that will precede the acceptance of the first algorithms that will provide diagnostic assistance – thereby, firm diagnostic statements from machine learning algorithms are unlikely in the following couple of years. Deciding on this solution places the project in a future context.

Conclusion

The selected focus diseases lead to auscultation on very different locations of the body. These locations have different curvature and different reachability. With the final design, it is important to take this into account.

Electronic stethoscopes are sensitive to movements during use and to environmental noise. Thereby, they are not applicable for continuous monitoring throughout the whole day or in loud environments. The complex audio information obtained with the stethoscope requires expert interpretation. This can either mean a trained physician or – in the near future – smart algorithms.

THE TECHNOLOGY OF ELECTRONIC STETHOSCOPES

This sub-chapter provides an overview of the main components and key technologies of electronic stethoscopes and defines the technological focus point of the project. Where not stated otherwise, the system overview and the key technologies of electronic stethoscopes are presented based on a recent paper written by Leng et al. (2015).

System overview

The stethoscope is technically a highly efficient passive amplifier that helps to amplify the heart and lung sounds of patients and deliver them to the clinicians' ears. Although, it amplifies the human body sounds – due to the very silent nature of these sounds – the most important drawbacks of traditional acoustic stethoscopes are their extremely low sound levels and the lack of possibility to store, share and visualize the recorded audio. These drawbacks led to the development of electronic stethoscopes. Figure 2.4 shows the system overview of electronic stethoscopes. The key technologies are highlighted within the modules.

The data acquisition module (Figure 2.4) is responsible for recording, filtering, buffering and amplifying the audio signal and converting it to a digital signal. The recording itself is one of the key technologies of electronic stethoscopes.

After that, the pre-processing module (Figure 2.4) reduces the noise of the signal, normalizes it and segments it to cardiac or pulmonary cycles. As cardiac and pulmonary diseases produce abnormal sounds that are contained in a single interval, a single cycle can be used for computer-aided analysis. The denoising and the segmentation are other key technologies of electronic stethoscopes.

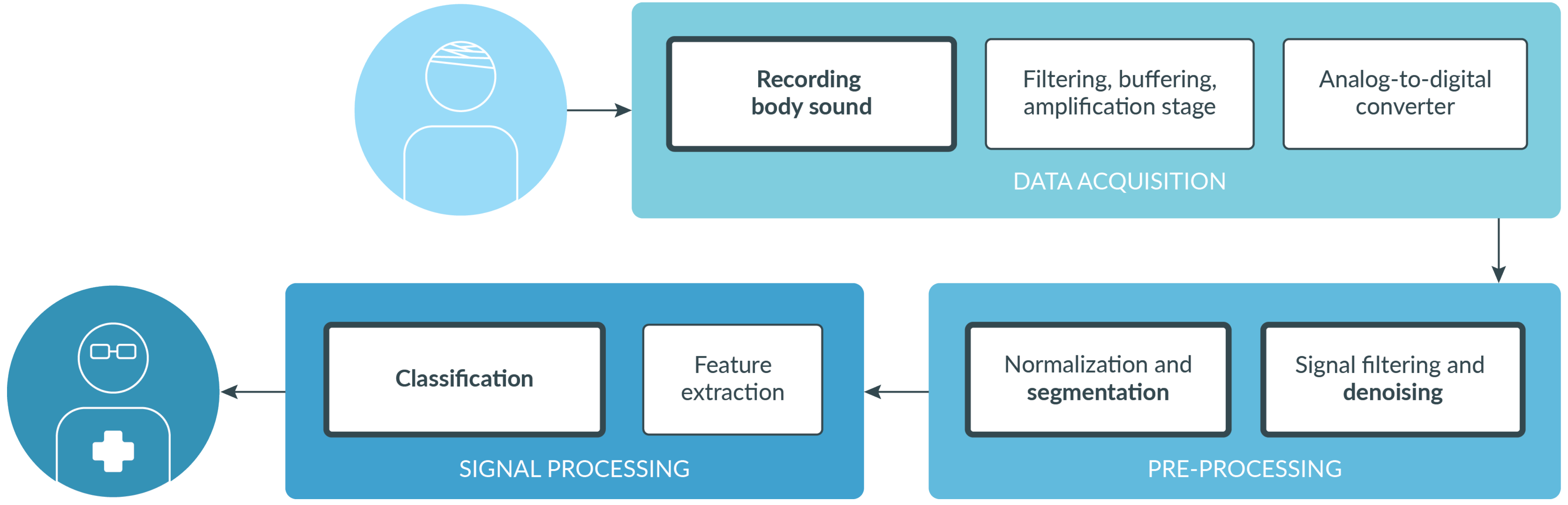


Figure 2.4 The system overview of electronic stethoscopes with key technologies highlighted

The computer-aided analysis of the acquired sounds happens in the signal processing module (Figure 2.4), which transforms the signal to some kind of parametric representation. This representation is used for classifying the signal which means relating it to a known cardiac or pulmonary abnormality. Classification is a key technology of electronic stethoscopes as well. There are many papers written about recent advancements in computer-aided analysis of stethoscope acquired audio signals (Lai et al., 2016; Morillo et al., 2014; Patidar, Pachori & Garg, 2015; Solá et al., 2016; Wang et al., 2016). Not only the number of researches is increasing, but the effectivity of computer-aided analysis as well. Recently, a classification algorithm outperformed clinicians in diagnosing hypertension based on auscultatory information (Kaddoura, 2016). This increased attention and the improved efficiency of computer-aided analysis clearly highlights the possibilities in this technology. However, signal processing is a highly complex procedure done by qualified signal processing engineers and researchers, thereby the development of such a module is outside of the scope of the current project.

The technological focus during the project is on the data acquisition module.

Key technologies

The key technologies of electronic stethoscopes are the recording, the denoising, the segmentation and the classification of the acquired signal. As segmentation and classification are not in the main focus of the project, these topics are only briefly introduced in the report.

Recording

One of the most important technological components of electronic stethoscopes are the sensors used for recording the sounds. Without these components, stethoscopes would not be able to capture sounds. There are multiple technological solutions used for sound detection.

The simplest solution is to mount a microphone behind the diaphragm of the stethoscope. The most important requirements for the microphone are small size – due to the small size of the device –, high sensitivity – due to the low volume of body sounds – and flat frequency response. Frequency response is the quantified output response of a microphone to sounds across a spectrum of frequencies. Microphones with flat frequency response can accurately record input without enhancing certain frequencies in it. Audio accuracy is highly important in electronic stethoscopes. Due to these requirements the most fitting microphones are electret condenser microphones (Figure 2.5). In this set-up, the microphone picks up the sound pressure generated by the diaphragm of the stethoscope and converts it to electrical signal using its own diaphragm (Figure 2.6). The acoustic transmission path compromises of the stethoscope's diaphragm, the air inside the stethoscope housing and the microphone's diaphragm. The drawback of this set up is a relatively high ambient noise pickup and the inefficient acoustic energy transfer due to the two diaphragms present. The advantage is that it's a simple and cheap solution that can be easily developed.

Figure 2.5 Electret condenser microphone

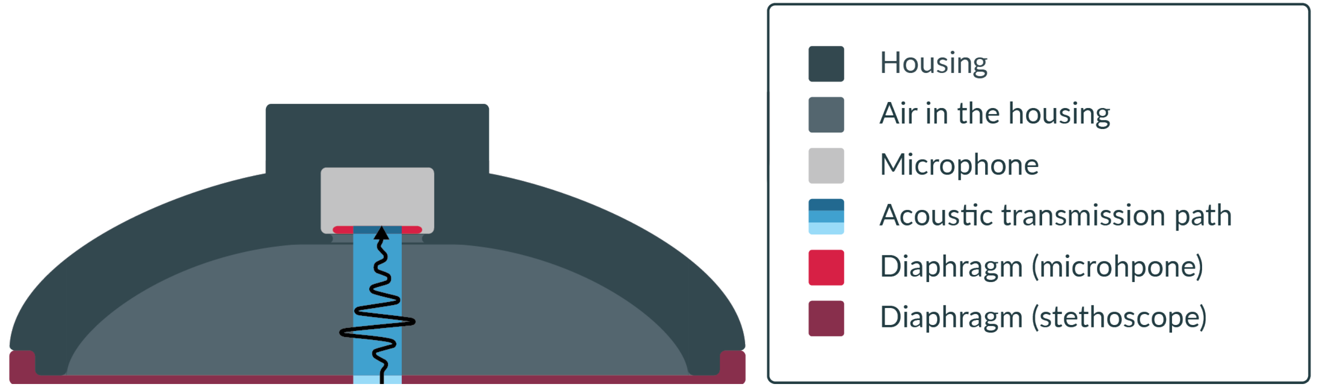


Figure 2.6 Acoustic transmission path for regular microphones

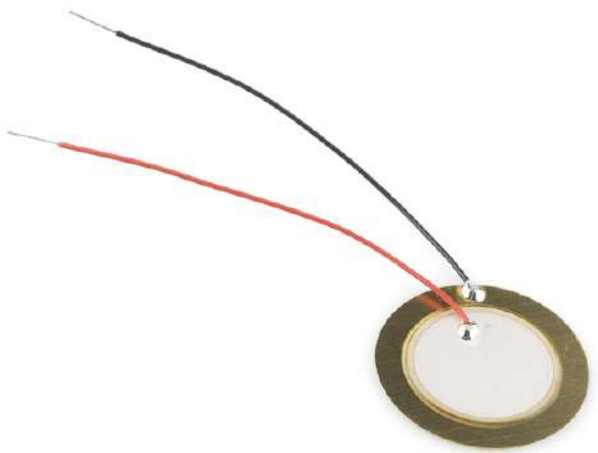


Figure 2.7 Piezoelectric sensor

Another relevant technology for the sound sensing is the use of a piezoelectric sensor (Figure 2.7). These types of sensors generate electrical energy based on the deformation of a crystal substance in them. They are insensitive to air vibrations but sensitive to audio vibrations in solid objects in contact with them. Thereby, they are also called contact microphones. In electronic stethoscopes, the contact with the auscultated surface is solved by mechanically coupling the piezoelectric sensor to the diaphragm of the stethoscope (Figure 2.8). This way, when the diaphragm resonates, it deforms the crystal which results in an electrical signal. The drawback of this solution is that the coupling mechanism between the piezo crystal and the diaphragm results in a slight distortion of the signal. Despite this disadvantage, this is the most commonly used sensing technology in present electronic stethoscopes. The most renown electronic stethoscope – the Littmann 3200 – uses this solution.

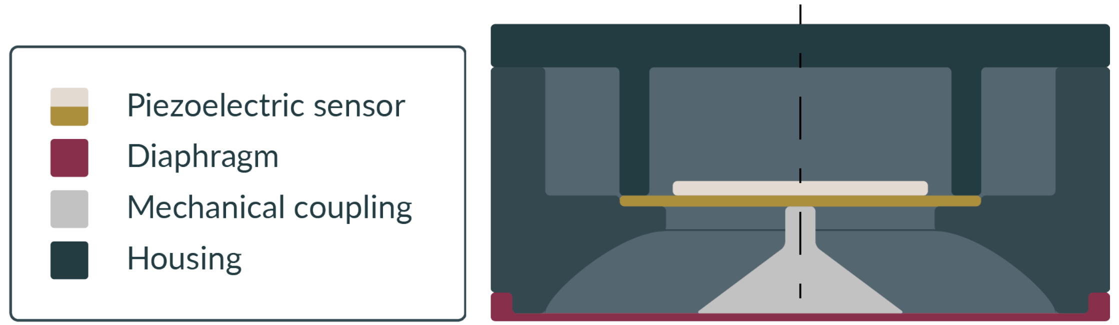


Figure 2.8 Mechanical coupling of a piezoelectric sensor

The third main technology used for recording is the capacitive-type sensor based on Micro-electro-mechanical systems (MEMS). This technology reacts to sound pressure with a change in its nominal capacitance value. From a mechanical perspective, this sensing solution provides same quality signal recording as traditional acoustic stethoscopes. Another advantage is its small size and its suitability for mass production. However, due to its micro size manufacturing requires advanced equipment and expert knowledge. Luckily, the development of the microphone does not have to happen in-house, many ready-made sensors are available on the market.

The selected recording technology has a major impact on the architecture and size of the product. Without that, the design around jt cannot be detailed. Thereby, during the technological elaboration all three technologies were tested for defining the most feasible one.

Denoising

Noise can reduce the utility of auscultated audio signals as it makes it hard for both clinicians and algorithms to recognize features in the signals for diagnosis. Apart of the obvious ambient noises device handling, movements and internal noises such as digestive noises or coughing can also interfere with the recorded audio. The presence of noises makes some components of the lung and heart sounds extremely hard to identify. Thereby, denoising the signal is extremely important for a good result. The most commonly used technological solutions for stethoscope are the following:

Spectral filtering

Lung and heart sounds exist on a well-defined frequency spectrum. The advantage of this is that noises outside of this spectrum can be easily filtered by the circuitry using bandpass filtering. This means that audio signals above approximately 1500 Hz can be filtered out from the recording as it only contains noise (see Figure 2.9). The drawback of this denoising solution is that it is merely a frequency based filtering solution. It does not distinguish noise from the valuable signal, it only enables filtering out those frequencies where no information signal is present. Noises within the spectrum of the information signal cannot be filtered out.

Active noise cancellation (ANC)

ANC technology uses two transducers. The primary transducer picks up the auscultated signal corrupted by the noise, while the reference input only captures noise. After that, the reference input is related to the primary input, and the original signal is estimated by subtracting the pure noise from the primary input (Figure 2.10). Due to the fact that both the signal and the noise are time-varying, relating the two signals to each other requires adaptive algorithms. Examples of such adaptive algorithms are least mean square (LMS) algorithms and recursive least square (RLS) algorithms. Developing these algorithms is not within the scope of this project, thereby, no further elaboration is provided about them. The biggest drawback of ANC is that it requires two input channels for the primary and the reference input.

Transducer isolation

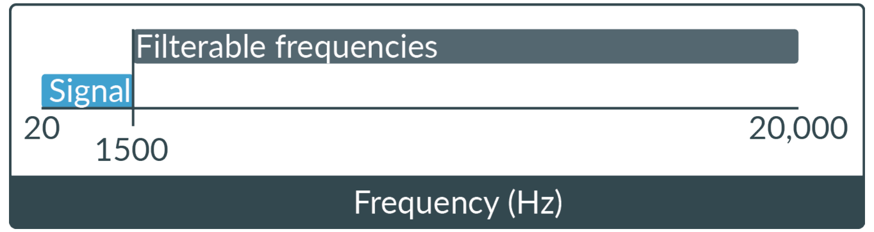


Figure 2.9 Filterable frequencies of electronic stethoscopes

Figure 2.10 The theory behind active noise cancellation

Handling of the device can lead to significant noise due to vibrations that are transferred to the transducer through the housing. Isolation can help to reduce the vibration arriving at the transducer. A relatively simple isolation solution is to sandwich the transducer with two foams that help to reduce the arrival of unwanted vibration to the transducer.

Transform domain denoising

Transform domain noise reduction refers to converting the signal from time domain to another domain to extract characteristic information embedded in the signal that is not observable originally. This way the frequency content of the signal can be identified. As noise has different frequency content than the signal, it can be separated. There are two mathematical bases for such transformations: Fourier transform and wavelet transform. Wavelet transform based solutions are more up to date as they allow both high time and frequency resolution during the analysis. Transform domain noise reduction requires a thorough mathematical and physical understanding of signal processing, thereby the focus of this project is on other denoising solutions. However, as it is the most advanced and effective denoising technology, the development of such an algorithm is recommended in the follow up of the project.

Segmentation

Segmentation refers to segmenting the signal to cardiac or pulmonary cycles. ECG signal and/or carotid pulse are often used as reference signal to define the cardiac cycle length. When no reference signal is used its called direct segmentation. The most commonly used direct segmentation technique is the envelogram based approach. The envelogram is a mathematical representation of the heart sounds that draws a smooth curve on the signals extremities.

Feature extraction and classification

Feature extraction refers to the conversion of the raw data to some kind of parametric representation. This parametric representation is used as an input for the classification. The classification is done by a machine learning algorithm. The machine learning algorithms most often used for auscultatory signal classification are artificial neural networks and support vector machines. These algorithms are becoming better in heart and lung sound classification year by year. However, designing a robust signal classifying algorithm is not within the scope of this project.

Conclusions

The components and underlying key technologies of digital stethoscope have been explored and introduced. During the project, the technological focus is on the selection of the recording technology and on basic denoising of the signal via spectral filtering and transducer isolation.

Developing denoising, segmentation and classification algorithm is outside of the scope, however, based on the conducted literature research the recommendations are the following:

- In the future of the project the development of wavelet transformation based transform domain denoising algorithms is really promising as it could enhance the audio quality of the recordings without altering the hardware design defined during the project.
- The recommended segmentation algorithm is the envelogram based approach as it doesn't require the obtaining of an additional reference signal (e.g. ECG signal)
- The classification algorithm needs to be developed based on the final purpose of the design. Thereby, no recommendations can be made regarding it at this point of the project.

3 FOCUS DISEASES

The introduction chapter presented the selection of the focus diseases. This chapter is meant to provide an overview of these diseases. The aim during the exploration of these diseases was to verify the added value of using electronic stethoscopes for self-monitoring purposes for these patient groups as self-management supporting tools. The chapter starts with an introduction to the diseases. After that, the diseases are compared based on their actors and the healthcare system perspective is analyzed. Finally, a reflection is provided to evaluate the findings and explain the following steps of the project.

INTRODUCTION TO THE FOCUS DISEASES

The aim of this sub-chapter focuses on providing a basic overview of the selected diseases and to introduce their related vocabulary. The treatment flow of the diseases is presented later in Chapter 4.

Heart failure

Heart failure occurs when the heart is unable to pump enough blood to meet the body's necessities. It is not a disease on its own, but rather a consequence of other underlying conditions ("Heart failure", 2017). In other words, it is the end stage of various cardiac diseases. It is a serious condition, 50% of the people die from it within 5 years after diagnosis (Pelizzari & Bruce Pyenson, 2015). There are many different types it can manifest. Appendix B-A contains a summary of the different types of heart failure, its comorbidities and classification system. The left side of the heart receives the oxygen-rich blood from the lungs and pumps it to the rest of the body (Figure 3.1). Left-sided heart failure refers to inefficiency in this process. When the failure happens backward, there is fluid congestion behind the heart. As the left side of the heart receives oxygenated blood from the lungs (Figure 3.1), this leads to pulmonary edema. As the previously identified advantage of digital stethoscopes for heart failure patients is the detection of lung edema, The focus is on left-sided backwards failure.

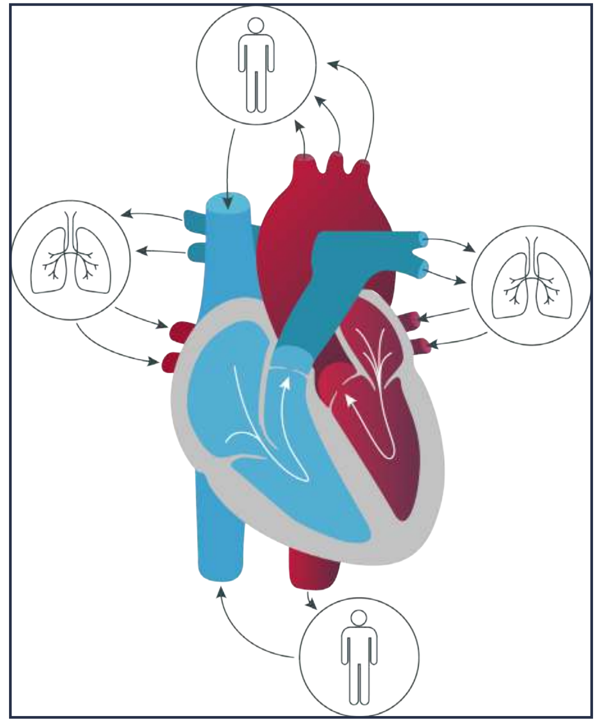


Figure 3.1 Circulation of the heart

Pulmonary edema

Edema refers to abnormal fluid retention in the body. In heart failure, there are two main types of edema: peripheral edema and lung edema. Unlike peripheral edema, pulmonary edema is not visible from the outside as it refers to fluid retention in the lungs. Thereby, currently, there are two ways patients notice the development of it. Via regular measurements of their body weight and via recognizing its symptoms (e.g., breathlessness). However, measuring the total weight of the body is an inefficient way to detect fluid congestion in the lungs and symptoms do not present immediately. When pulmonary edema is not treated, it can lead to an acute decompensated heart failure. Appendix B-A contains more information about pulmonary edema.

Acute decompensated heart failure (ADHF)

ADHF is a rapid, gradual worsening of symptoms due to significantly reduced myocardial function which requires immediate action. It is the most common cause of hospitalization among heart failure patients and 20-30% of patients who experience an ADHF die within 1 year. Every ADHF episode causes damage to the patients' organs, increases the chance on a repeated episode and decreases the chance of surviving another episode ("Heart Failure - Exploring Space and Opportunities for IGT", n.d.).

Affected population

The prevalence of heart failure is 1% in the Netherlands (Leening et al., 2014) and 1.76% in the United States. It is the most common reason for hospitalization for people above the age of 65 in the western world (Rodríguez-Artalejo, Banegas & Guallar-Castillón, 2004), while the most affected age group regarding prevalence are people above 80 years. (Lloyd-Jones, 2010).

Peripheral artery disease (PAD)

PAD is a slowly progressing circulation disorder. Broadly speaking it can involve any disease in any of the arteries outside of the heart, however most commonly it refers to the stenosis (abnormal narrowing) of the arteries in the extremities. Although it can also occur elsewhere, most frequently it occurs in the legs. The stenosis manifests due to atherosclerosis – plaque build-up in the arteries. This plaque consists of cholesterol, fatty substances and other substances in the blood ("Atherosclerosis", 2017). The first symptom of peripheral artery disease is intermittent claudication – muscle pain in the legs induced by exercise or walking due to the poor circulation. At the beginning it only happens during exercising or longer walks, however, if it is not treated walking shorter distances can already cause pain for patients. When the arteries become fully blocked, oxygen and nutrient in the blood cannot arrive in areas of the limb. This condition is called ischemia. When the condition becomes severe it is referred to as critical limb ischemia, and it leads to pain even when the patient is in rest, ulcers – non-healing wounds – and gangrene – the local death of tissue. In severe situations, PAD can also lead to amputation. In case a stenosis raptures a thrombosis is formed that is carried by the blood flow to the narrower vessels until it gets stuck causing an occlusion. These are the acute events of PAD that lead to severe pain and require immediate treatment. Appendix B-B contains further elaboration regarding PAD including its comorbidities and classification system.

Affected population

The prevalence of PAD in the United States is 2.63%. Above 60 years the 12-20% of the population suffers from it ("Peripheral Arterial Disease Fact Sheet", 2016).

COPD

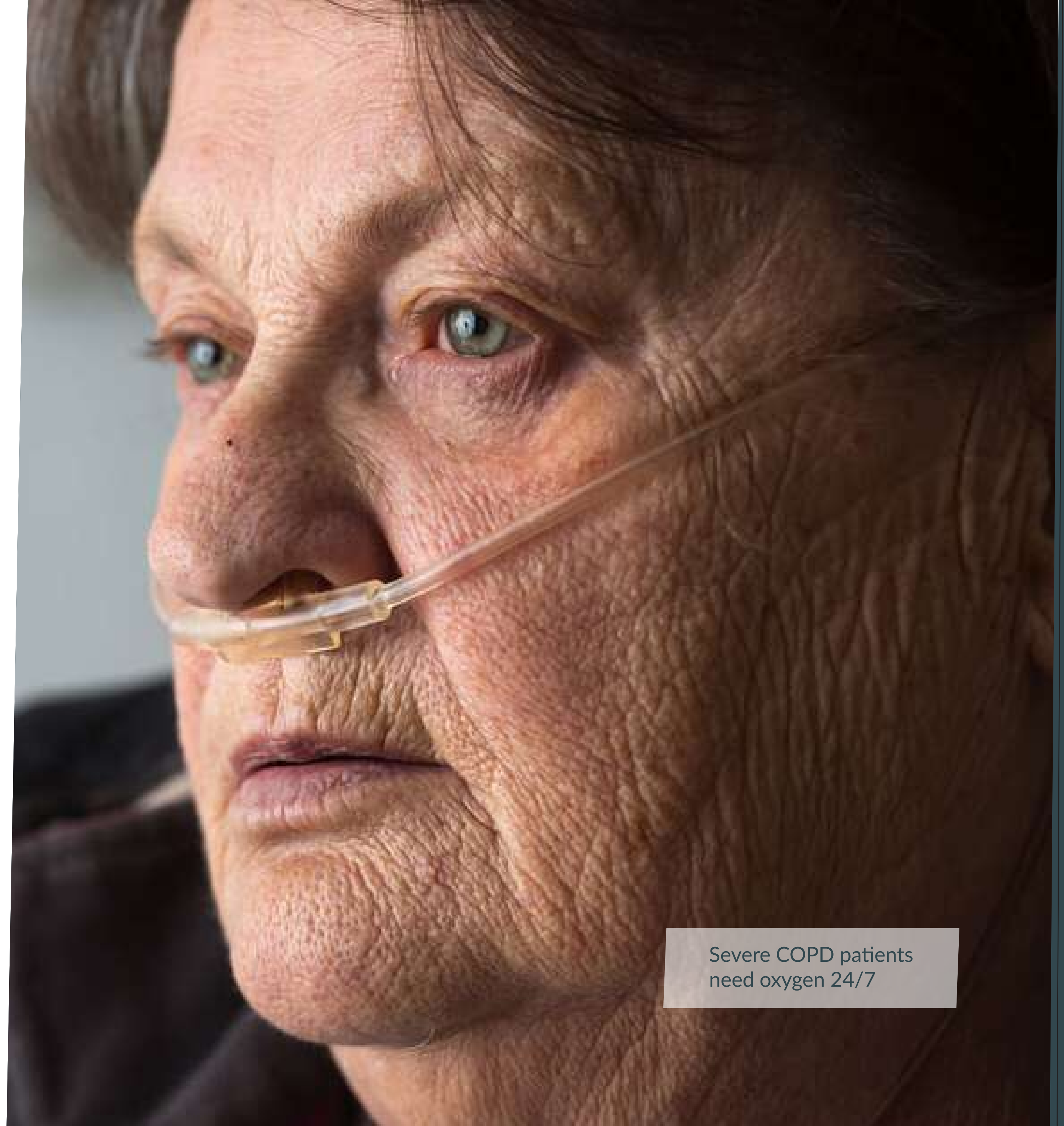
COPD is an umbrella term, referring to a number of diseases that lead to permanent damage of the lungs. This permanent damage causes coughing that produces excessive amounts of mucus and causes shortness of breath, and intolerance to physical activity. It is not a cardiac disease. However, it has a strong cardiac relevance due to the close anatomical relation between the lung and the heart. It can also lead to various cardiac comorbidities (van Rossem, 2017). The term COPD refers to emphysema, chronic bronchitis, refractory (non-reversible) asthma and certain forms of bronchiectasis ("What is COPD?", 2017). Out of these conditions, by far the first two are the most relevant, thereby the focus will be on patients with these conditions. Appendix B-C contains an explanation of these conditions, the classification of the disease stages and COPD's comorbidities.

Exacerbations

The biggest threats for COPD patients leading to hospitalization are lung infections, which rapidly exacerbate their symptoms. It takes longer for them to recover from these diseases and lung infections also lead to permanently decreased lung function for COPD patients which means the progression of the COPD. The progression of the disease leads to many limitations in patients life. Thereby, influenza and pneumococcal vaccination are highly important for these patients, although they do not provide entire protection. Every exacerbation has a gradual increment phase before they arrive to their peak. Thereby, early detection of disease development could lead to significantly milder clinical presentation (Rabe et al., 2007)

Affected population

The prevalence of COPD is 5.45% in the Netherlands (Bischoff et al., 2009), while its 6.4% in the United States (Wheaton et al., 2015). The most affected patient group are people aged 75-85. The prevalence in this age group is 11.2% for men and 9.7% for women (Akinbami & Liu, 2011).



Severe COPD patients need oxygen 24/7

Conclusions

Heart failure

The biggest threats for heart failure patients are ADHF events. By paying attention to their symptoms heart failure patients can react on time in case symptoms are worsening and avoid an ADHF event. Pulmonary edema is a strong indicator of ADHF development for patients with left-sided backwards failure. It is currently tracked with daily weight measurements and paying attention to symptoms such as shortness of breath. A tool that could more efficiently support patients in the timely detection of pulmonary edema would be of great use for them. With the right lifestyle, patients can also have a big impact on slowing down the progression of the disease. Thereby, heart failure patients can greatly contribute to their treatment with self-management.

Peripheral artery disease

Mild PAD has a much smaller effect on patients' life than heart failure and COPD. It also doesn't require patients to pay attention to their symptoms so closely as the other two focus diseases, because the disease does not exacerbate so fast and when it does patients can immediately notice it due to the immense pain. Thereby paying attention to symptoms is not a strong part of self-management of PAD patients. However, lifestyle changes can effectively contribute to preventing the progression of the disease. Motivating these people to lifestyle changes is highly important as the worsening of the disease can lead to repeated operations, amputation and death.

COPD

Although COPD is not a cardiac disease it has a strong cardiac relevance. It can also lead to many cardiac comorbidities. The biggest threats for COPD patients are lung infections that cause exacerbations of symptoms and lead to permanent lung function decrease. Timely detection of exacerbations can result in significantly milder clinical presentation.

The most important lifestyle advice for COPD patients is smoking cessation. Apart from that exercising, and adequate diet can greatly contribute to slowing the progression of the disease. However, these require the active participation of patients. COPD patients can also effectively contribute to their treatment with self-management.

ACTOR ANALYSIS

The current subchapter does not have an additional conclusion as the entire chapter only contains conclusive text. Further insights about the focus diseases are provided by analyzing the actors of the disease. Figure 3.2, Figure 3.3 and Figure 3.4 visualizes the actors of the focus diseases. The visualization is inspired by the stakeholder circle methodology (Bourne & Walker, 2005) but it does not entirely follow it. While the stakeholder circle focuses on visualizing the power and proximity of stakeholders to a project, here the goal is to visualize the proximity of actors to the patient, their contribution to the healing process and their interest in the patient's well-being. The actors of the disease are placed around the patient. The closer they are in the circle, the closer they support the patient. The radial width of the actors' circle segment tells how important is their contribution to the patient's well-being, while the polar length of the actors' segment tells how interested the actor is in the patient's well-being. The actors were evaluated with the help of Dr. Smeekes, general practitioner employed by the Hartstichting

An important similarity between the actor circles is the fact that family and friends are key contributors for all three disease groups. Their support can highly improve the patient's well-being.

Heart failure

For heart failure, the most important physicians are the general practitioner and the cardiologist. Improving their insights about the patients' state and the communication with them is important. The actor circle also illustrates that psychological support is more important for heart failure patients than for peripheral artery disease patients due to the bigger disease burden. Specialized surgeons can be key contributors for certain patients. However, these surgeons mostly treat the underlying disease of heart failure, not the disease itself. Other important actors of the disease are the physiotherapist, the pharmacist (who provides medication) and the dietitian.

Peripheral artery disease

For peripheral artery disease patients, the GP and the specialized surgeon (vascular surgeon) are the most important physicians. The actor circle helps to understand that GPs are less important actors of this disease. This is also related to the fact that this disease needs generally less management and patients generally need less support from most actors. The psychological burden is much lower on the disease as well and patients are less dependent on medication.

However, surgery is a much more common remedy for this disease, that is why the surgeon was placed in the inner circle. Another key contributor of the disease at the early stage is the physiotherapist due to walking therapy that can greatly improve patients' well-being.

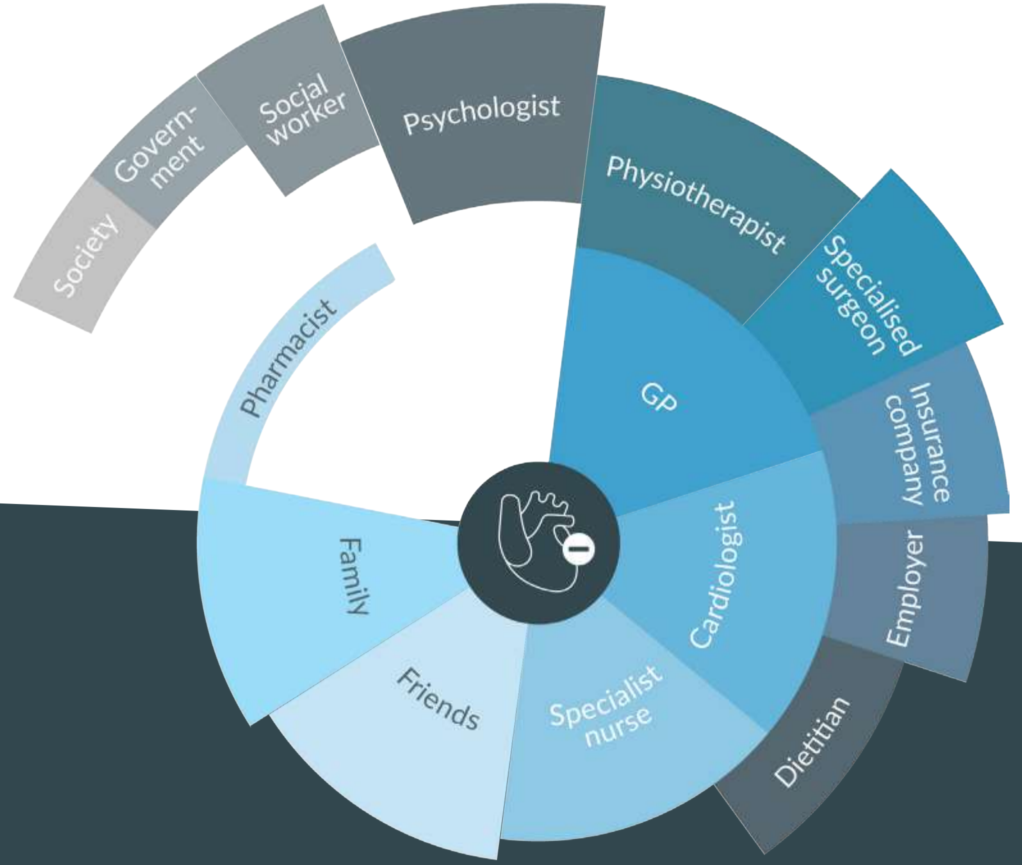


Figure 3.2 Actors of heart failure

COPD

For COPD patients the most important physicians are the GP and the pulmonologist. Improving their insights about the patients' state and the communication with them is important. Figure 3.4 illustrates that the social worker and the specialist nurse are often more important for these patients. It helps to understand that many patients with this disease have a bigger need for support than patients with the other two diseases. The actor circle also shows that psychological support is the most important for these patients. However, surgery is the least common among these patients. Physiotherapy can also be important for these patients, while dietitians are generally less important for them.

Figure 3.3 Actors of peripheral artery disease

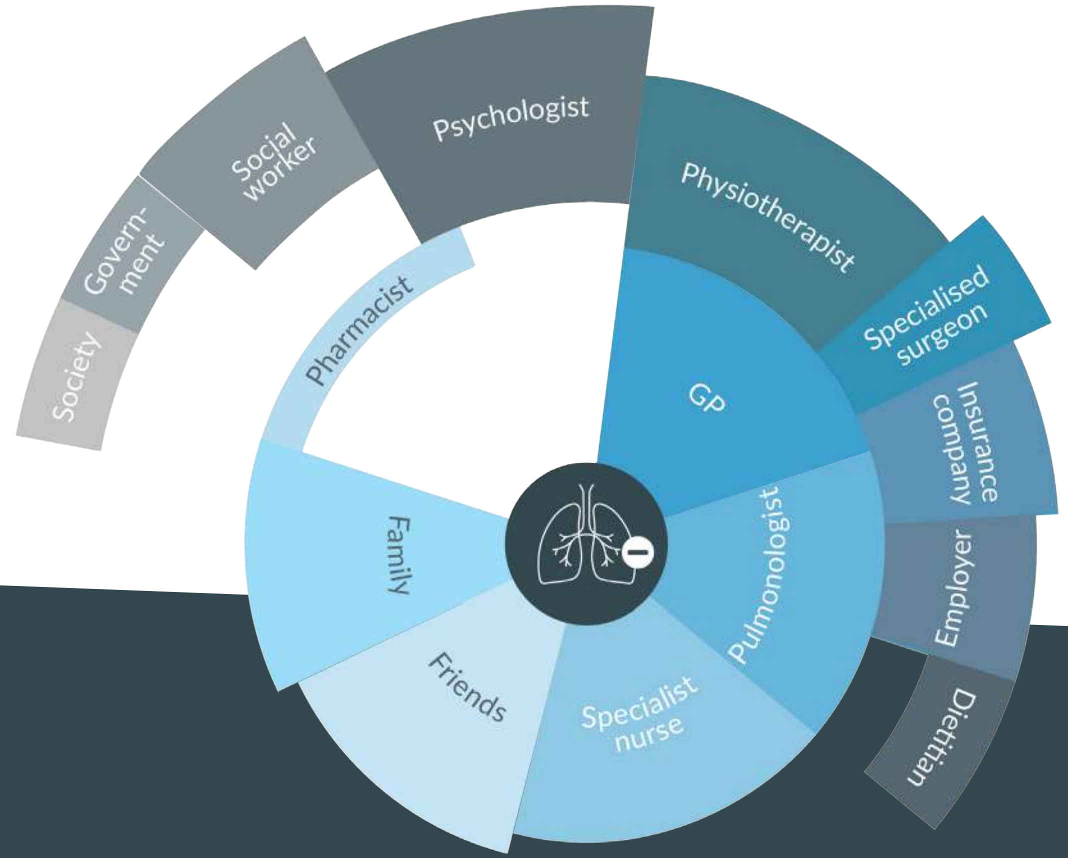


Figure 3.4 Actors of COPD

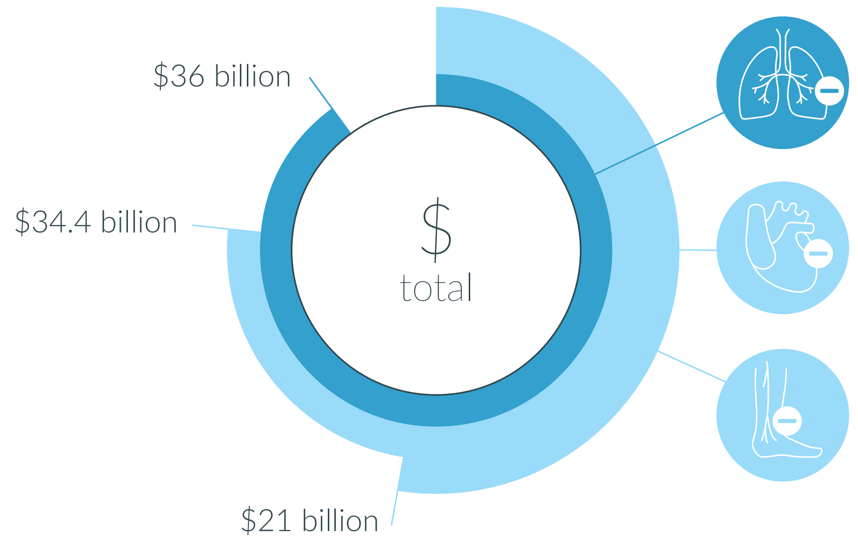


Figure 3.5 Total annual expenditure on the focus diseases in the USA

HEALTHCARE SYSTEM PERSPECTIVE

To understand what are the most crucial problems within the healthcare system regarding these diseases, the healthcare costs of the diseases were analyzed. The current chapter aims to identify strategies that could effectively improve the current healthcare situation. Appendix B-D contains a more elaborate version of this analysis.

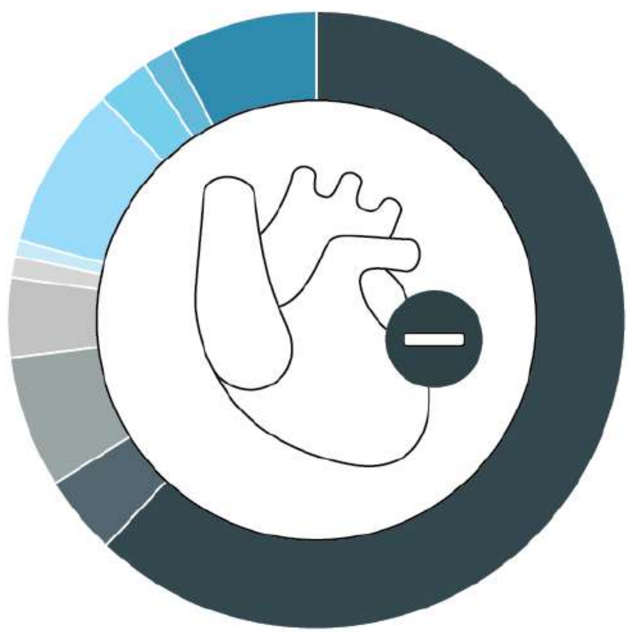
Heart failure

Heidenreich et al. (2010) estimated the total annual expenditure on heart failure in the United States to $34.4 billion (Figure 3.5) – $24.7 billion direct and $9.7 billion indirect costs – and predicted this amount to increase to $95.1 billion – $77.7 billion direct and $17.4 billion indirect costs. Figure 3.6 provides an estimation of the percentage of direct costs spent on certain cost elements (Voigt et al., 2014).

By far the most money is spent on hospitalization of patients. A promising way the current project could contribute to reducing these costs is more effective presymptom identification.

Medication nonadherence is also an important factor leading to hospitalizations (Wu et al., 2008). Thereby, improving medication adherence is another strategy that could contribute to decreasing these costs.

In the United States hospitals have to pay a penalty when a patient is readmitted within 30 days. A significant amount of hospitalization related costs is spent on these readmissions. According to Ziaeian and Fonarow (2016) strategies that involve increased support at discharge, early and close outpatient follow-up and improved communication are often associated with decreased readmission risk.



Inpatient, hospital	62%
Inpatient, clinician services	4.2%
Medication costs	7%
Physician office visits	4.3%
Ambulatory, ED	1%
Ambulatory, hospital outpatient	1%
Nursing home / SNF	8.6%
Home care	2.8%
Hospice care	1.6%
Out-of-packet costs / coinsurance	7.8%

Figure 3.6 Cost elements of heart failure treatment

Peripheral artery disease

Mahoney et al. (2008) estimated the total annual expenditure on PAD to $21 billion in the United States (Figure 3.5). Although this is significantly less money than the money spent on the other two diseases Figure 3.7 helps to understand how much more money is spent annually on a PAD patient in the United States compared to an average Medicare beneficiary (Yost, 2016).

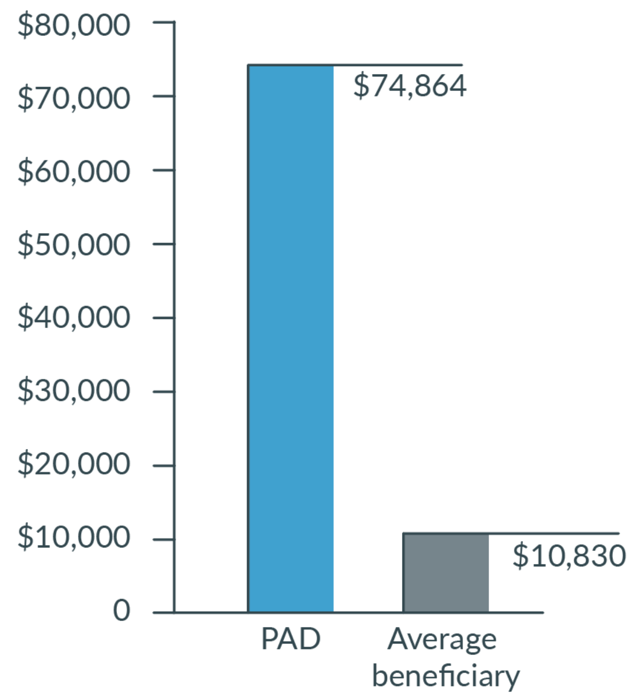


Figure 3.7 Cost of PAD in the USA compared to average Medicair beneficiary

86.8% of total direct costs is spent on hospitalization (Jaff et al., 2010). As PAD progresses, the healthcare costs increase with it as well. On an end-stage patient, more than 230% is spent compared to mild patients (Reinecke et al., 2015).

These insights highlight two strategies the project could contribute to the mitigation of the PAD-related burden on healthcare. By improving the screening for PAD and by supporting already diagnosed patients with mild PAD in their lifestyle changes to avoid the exacerbation of their disease.

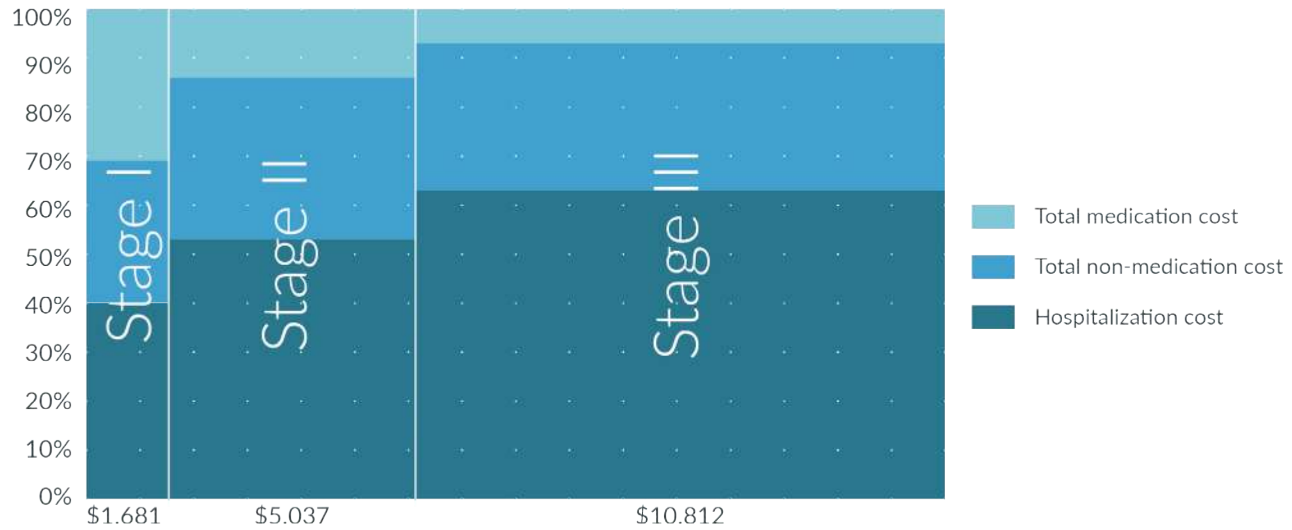


Figure 3.8 The ratio of major cost elements across COPD stages

COPD

Figure 3.5 shows that Ford et al. (2015) estimated the total annual cost of COPD in the United States in 2010 to $36 billion – 32.1 billion direct cost and $3.9 billion indirect cost – and predicted the direct costs to rise to $49 billion by 2020. Figure 3.8 summarizes the major cost elements of COPD related direct expenditures and the direct cost per patient per year in the United States depending on disease severity (Guarascio et al., 2013). The width of the columns is proportionate to the money spent on an average patient within the given progressive stage. It illustrates, for instance, that on average 10.812$ is spent on a stage III patient annually and that less than 10% of these costs is spent on medication. It also shows how drastically the costs increase with disease severity. Hospitalization is the biggest cost element across all three included stages and with each progressive stage its proportion increases. Although patients take more and more medication with the progression of the disease, medication proportionately decreases with severity. Examples of non-medication costs are for instance rehabilitation related costs.

Hospitalizations in COPD are mostly due to exacerbations. Although, these exacerbations do not solely result in hospitalization related costs, according to recent research by Blasi et al. (2014) 70.7% of exacerbation-related costs are related to hospitalization.

The most effective way thereby to reduce the COPD related burden on healthcare would be to prevent these exacerbations. However, the previous chapter explained, not even vaccination provides total protection against lung infections. Thereby a solution that could timely detect the development of such exacerbations could not only have a highly positive effect on patients' quality of life, but it could also save a tremendous amount of money in the healthcare system. Due to the disease severity related increasing costs, the other possible solution is to support patients in slowing down their disease progression. That means helping patients getting adjusted to their disease, supporting them in their lifestyle changes and again, helping patients to react on time to exacerbations.

Conclusions

For heart failure patients, effective presymptom identification and more effective support during the hospital discharge could have the biggest impact on mitigating healthcare expenditures. Apart from that improving medication adherence could also contribute to decreasing heart failure related costs.

For PAD, improving screening and support during the mild stages of the disease are the most important factors to decrease direct costs.

For COPD, timely detection of exacerbation development is the most important strategy that can contribute to the reduction of healthcare expenditures. Apart from that, supporting patients in getting adjusted to their disease and supporting them in their lifestyle changes could also contribute to significant savings for the healthcare system.

CHAPTER REFLECTION

The current chapter helped to better understand the focus diseases and their most relevant issues both from a patient and from a healthcare system perspective. It also clarified that although secondary prevention is an important issue for all three diseases, other issues are also present related to them. Thereby, before selecting a final disease-use case combination, the scope of the project is broadened in the next chapter to identify the opportunity space where the technology of electronic stethoscope could add the biggest value to patients for self-monitoring purposes. Instead of focusing solely on secondary prevention, the following chapter analyses the entire treatment of the diseases along the healthcare pathway.

Hospitalization is the most burdening aspect of all three diseases. Both for the patients and the healthcare system

4 IDENTIFYING
Opportunity spaces

The role of this chapter is to identify the most valuable self-monitoring opportunity spaces of electronic stethoscope for the focus diseases.

Philips supports people in healthier living with services and solutions across what they call the healthcare continuum: from Healthy Living to Disease Prevention, Diagnosis, Treatment and Home Care. Figure 4.1 shows Philip's visualization of the healthcare continuum. With the help of Floor Borgonjen - service designer at Philips and the company mentor of the project - the following steps of the healthcare continuum were selected:

- Initial concerns: supporting diagnosis
- After diagnosis: treatment planning support
- Post discharge: medication setting
- Acute event alarming
- Remote rehabilitation
- Secondary prevention

It is important to add that the aim is not necessarily to identify one opportunity space, a relevant combination of multiple opportunity spaces is also possible.

Insights were gathered from the previous literature review and from interviews with experts. To ensure that no opportunities were missed, experts were selected from the entire healthcare continuum of all three diseases. Due to the time and network limitations of the project not all actors of the diseases could be interviewed (e.g., physiotherapists, patients). To make up for these gaps, experts at Philips were interviewed as well who are aware of the missing actors' perspectives. The interviewed experts were the following:

- Dr. David Smeekes, General practitioner, Hartstichting
- Dr. Boukje van Liempt, General practitioner, Hus en van 't Lindenhout
- Dr. Jan Willem Bech, Cardiologist, Reinier de Graaf
- Dr. Ronald van Rossem, Pulmonologist, Reinier de Graaf
- Dr. Hans Pieter van t'Sant, Vascular surgeon, Reinier de Graaf
- Johan Manshanden, PhD candidate at the department of Cardiothoracic Surgery of AMC
- Jessica van der Kooij, Home nurse
- SeYoung Kim, Senior service designer, Philips
- Hanneke Hoogewerf, Strategic design consultant, Philips
- Alessandra Di Tullio, Strategic design consultant, Philips
- Privender Saini, Senior scientist, Philips
- Jan Tatousek, Innovation strategy director, Home healthcare at Philips
- Wim Stut, Senior scientist, Philips
- Nicolas Foin, Senior Manager - Strategy & Market Development, Philips

These interviews contained questions about the treatment processes of the diseases, the current pain points of these processes, the possible uses of digital stethoscopes and the patient experience througout the disease. Appendix A-B contains the summary of all the interviews.

Build-up

During this chapter first, the treatment of the diseases is presented. Where not stated differently, the treatment reflects on the situation in the Netherlands. After that, opportunities are introduced that could improve the current healthcare situation. Only opportunities that incorporate an electronic stethoscope for self-monitoring purposes were considered. Then, a short reflection is provided on each opportunity regarding its disadvantages or regarding aspects of it that were identified most relevant during the expert interviews. Finally, the opportunities are evaluated based on the defined criteria and the direction for the rest of the project is selected.

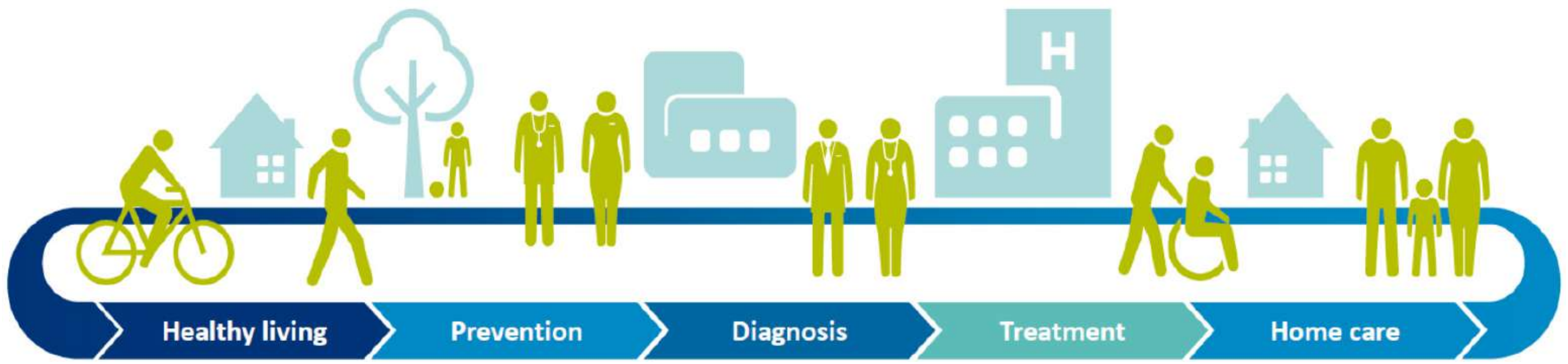


Figure 4.1 The healthcare continuum (visualization made by Philips Design)

HEART FAILURE

Progress

Figure 4.2 shows the limitations and treatments of heart failure in its different stages. The used NYHA classification system is explained in Appendix B-A. The figure helps to understand that limitations become much worse with the progress of the disease. It also shows that ADHF events are becoming more frequent and more severe as the disease progresses. Thereby, lifestyle change coaching is more relevant for milder patients while acute event alarming becomes more important with the progression of the disease

Treatment

Many patients ignore the first symptoms of PAD – pain in the legs induced by exercising or walking – or simply don't experience them (van t'Sant, 2017). As the diagnosis of the disease is mostly induced due to present symptoms, underdiagnosis is one of the greatest problems regarding the disease. The treatment does not need to be as carefully planned as for heart failure and COPD patients. It depends on the severity of the disease.

Only a minimal number of patients are diagnosed when they are asymptomatic (Stage I) and the treatment at that point is only lifestyle change advice.

When patients are diagnosed in Stage II, they have mild intermittent claudication. Their treatment is medication, walking therapy and lifestyle change advices. The medications are blood thinners, blood pressure lowering meds and cholesterol lowering meds. The GP sets these medications. The medication setting is done in a titration process. Rehabilitation can support patients with the walking therapy and education about the disease. If patients change their lifestyle and do the walking therapy, the blockage can be bypassed naturally by developing collateral blood vessels.

In case this does not happen, the pain becomes more severe, and it persists during rest (Stage III). At this point, the stenosis is usually above the knee and ulcers can start to be present. Invasive treatment solutions need to be considered. This can either mean a minimally invasive endovascular therapy (e.g., angioplasty, atherectomy) or an invasive bypass surgery. The exact location and anatomy of the stenosis is only determined here. After the surgery no extensive rehabilitation is needed, patients are mostly treated in primary care. Medications might need to be adjusted.

If the progression of the disease continues the stenosis renews lower in the legs usually at multiple locations. The limited blood flow in the feet leads to more pain, ulcers and gangrenes. Surgical interventions are much harder on the lower legs due to the smaller size of the arteries here. Thus, when the disease arrives to this point, limb salvation can become the main objective. However, at a certain point amputation becomes the only remedy to save the life of patients. After amputation rehabilitation is really important to learn how to cope with the new circumstances.

Main lifestyle advices

- One of the most important lifestyle change advices is smoking cessation
- Heart-healthy diet with low sodium intake, fat and cholesterol
- Moderate exercising is also important as a good condition can help to reduce the demand on the heart

Opportunities

The identified opportunities are presented on the following pages.

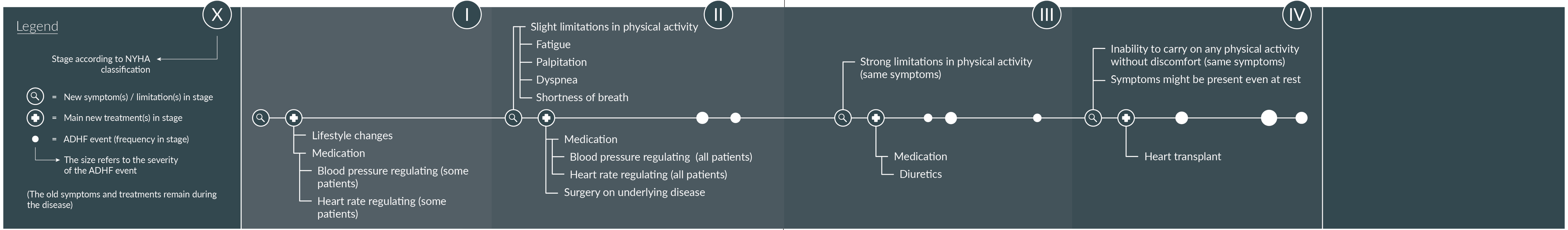


Figure 4.2 Limitations, symptoms and treatments of heart failure as the disease progresses

Initial concerns

Home device for patients to confirm diagnosis

As explained before, GPs have limited equipment for the diagnosis of heart failure. Still, they need to avoid sending too many patients to the cardiologist. Thus, further support in the diagnosis of heart failure could improve the current healthcare situation. A possible solution that also saves time at the GPs office would be a device that GPs can give to patients for short-term home monitoring, and that could reliably support the diagnosis of heart failure.

Reflection

Stethoscopes in the near future might become able to provide diagnosis support for heart failure. Such a system would still require the suspicion of the GP. Patients who present without complaints would still not be diagnosed. The only advantage of providing the stethoscope to patients for self-monitoring would be if the measured parameters would be non-continuous. However, this is not the case with the stethoscope. Thereby, if diagnosis supporting algorithms in electronic stethoscopes will become advanced enough, including them in the GPs' stethoscopes seems to be a more relevant opportunity.

Treatment planning support

Monitoring during the first 30 days

In the United States, treatment planning is especially challenging as hospitals are penalized in case patients are readmitted within 30 days. This legislation is the driver of many healthcare decisions there (Sharon, 2017). An electronic stethoscope that can provide feedback about the state of the patient to the healthcare team during this period could help to timely adjust the treatment depending on the reaction of the patient. Thus, it could contribute to reducing heart failure related costs. Due to the great number of patients, the gathered information needs to be insightful and quickly comprehensible to the healthcare team.

Reflection

During this period many parameters are important regarding the patients' state (e.g., blood pressure, edemas, physical condition). Apart from the heart rate, the only relevant parameter that could be measured with a stethoscope is pulmonary edema. Thereby, a monitoring system would be required that has the stethoscope as one element. Apart of that, continuous monitoring would be important in this period for alarming. However, continuous monitoring is not possible using an electronic stethoscope.

Post discharge

Medication setting

According to Dr. Bech (2017 December 05) – cardiologist – the current self-interpretation of symptoms as feedback for setting the medications works well. However, a system that supports patients in communicating subjective symptoms and completes this feedback with objective, measured parameters could be a valuable addition to current healthcare practice.

Reflection

The only medications where an electronic stethoscope can provide feedback on the effectivity are diuretics. Thereby, an overall solution for adjusting medication for heart failure patients would require other device components as well.

Also, no specific researches have been found where electronic stethoscopes were used for feedback on diuretic effectivity. Moreover, multiple interviewed doctors were insisting that subjective symptom interpretation is much more important than objective data about effectivity.

Acute event alarming

Pulmonary edema detection

ADHF events are preceded with the development of pulmonary edema. It can start to develop a week or more before the ADHF event, but it can also manifest within an hour (Bech, 2017 December 05). A device that could predict such events could greatly contribute to the mitigation of heart failure related healthcare costs – by preventing hospitalizations, the most important costs factor of heart failure care – and to the significant improvement of patients' QoL – as hospitalization and acute events are the most traumatizing experiences of the disease.

Reflection

Acute event prediction and detection are among the biggest current problems in heart failure management. The current low cost, low-specificity alternative overall weight measurement. The only drawbacks of the stethoscope based solution are that it's unclear how early could pulmonary edema be detected using an electronic stethoscope and that there are multiple other promising technologies – such as radar and implantable pressure sensor based solutions – under development that could be used for the same purpose.

Remote rehabilitation

Rehabilitation guide

Remote rehabilitation can be an interesting opportunity for those patients who have trouble visiting hospital or outpatient clinic based sessions. A device that helps the remote assessment of patient's medical state and can provide tailored activity guidance would be of great value for patients who prefer remote rehabilitation.

Reflection

An electronic stethoscope can only measure a limited set of parameters that together do not provide an overview of patients' medical state. Thereby, other equipment (e.g., blood pressure meter, weight scale) would also be important elements of the system. Also, it is not an ideal technology for using while exercising as movements cause noise to the recorded audio.

Secondary prevention

Longitudinal feedback about cardiac and pulmonary state

Using an electronic stethoscope, longitudinal measurement of HR, HRV, RR and thorax sounds could provide insights to heart failure patients about their cardiac and pulmonary state. There are two ways this could contribute to secondary prevention of heart failure. First, according to Mosterman (2018), it could be used to provide insights to patients about the development of various cardiac comorbidities. Second, providing insights to patients about their disease and helping them in understanding it better, could be an effective way to motivate patients in their lifestyle changes.

Reflection

Based on Mosterman's research (2018), HR, HRV, RR and thorax sounds are promising parameters to provide insights about the development of cardiac comorbidities. However, this has not been clinically proven. Thereby, it is rather a strong indication than hard evidence. Also, other technologies – such as PPG sensors or even accelerometers – could be used as well for the same purpose.

PERIPHERAL ARTERY DISEASE

Progress
Figure 4.3 shows the limitations and treatments of PAD in its different stages. Appendix B-B contains the explanation of the used Rutheforf classification system. The figure helps to understand that PAD poses smaller limitations to patients than the other two diseases, especially in its milder stages. The figure also highlights that acute events are much less threatening than for heart failure patients. Thus, patients do not need to pay close attention to symptoms of worsening. This lowers their self-management adherence.

Treatments
Many patients ignore the first symptoms of PAD – pain in the legs induced by exercising or walking – or simply don't experience them (van t'Sant, 2017). As diagnosis of the disease is mostly induced due to present symptoms, underdiagnoses is one of the greatest problems regarding the disease. The treatment doesn't need to be as carefully planned as for heart failure and COPD patients. It depends on the severity of the disease.

Only a minimal number of patients are diagnosed when they are asymptomatic (Stage I) and the treatment at that point is only lifestyle change advice.

When patients are diagnosed in Stage II they have mild intermittent claudication. Their treatment is medication, walking therapy and lifestyle change advices. The medications are blood thinners, blood pressure lowering meds and cholesterol lowering meds. These medications are set by the GP. The medication setting is done in a wait and see manner. Rehabilitation can support patients with the walking therapy and education about the disease. If patients change their lifestyle and do the walking therapy the blockage can be bypassed naturally by developing collateral blood vessels.

In case this doesn't happen, the pain becomes more severe and it persists during rest (Stage III). At this point the stenosis is usually above the knee and ulcers can start to be present. Invasive treatment solutions need to be considered. This can either mean a minimally invasive endovascular therapy (e.g. angioplasty, atherectomy) or an invasive bypass surgery. The exact location and anatomy of the stenosis is only determined here. After the surgery no extensive rehabilitation is needed, patients are mostly treated in primary care. Medications might need to be adjusted.

If the progression of the disease continues the stenosis renews lower in the legs usually at multiple locations. The limited blood flow in the feet leads to more pain, ulcers and gangrenes. Surgical interventions are much harder on the lower legs due to the smaller size of the arteries here. Thus, when the disease arrives to this point, limb salvation can become the main objective. However, at a certain point amputation becomes the only remedy to save the life of patients. After amputation rehabilitation is really important to learn how to cope with the new circumstances.

Main lifestyle advices
- The most important lifestyle change is smoking cessation
- Exercising is important to build collateral blood vessels around the stenosis
- Heart-healthy diet with low sodium intake, fat and cholesterol is also important to prevent further deterioration of the artery's state.

Opportunities
The identified opportunities are presented on the following pages.

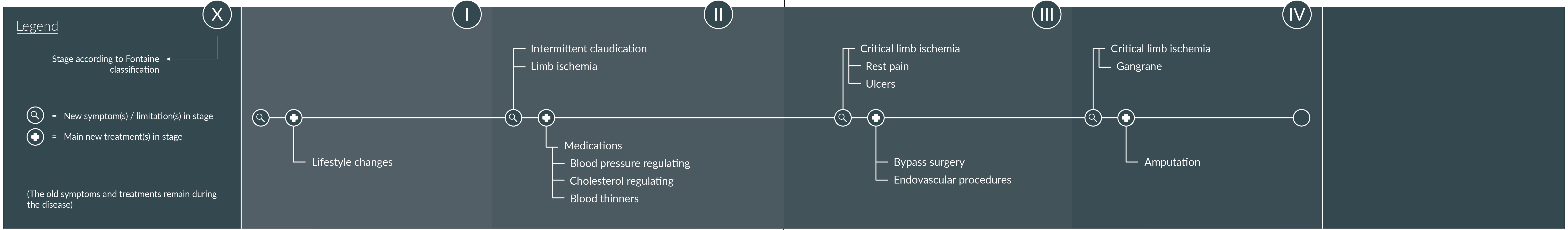


Figure 4.3 Limitations, symptoms and treatments of peripheral artery disease as the disease progresses

Initial concerns
Screening tool

Many patients are currently undiagnosed with PAD. A more effective screening tool that can reliably detect early PAD could contribute to improving timely detection of the disease. This way more patients could be informed on time about the necessary lifestyle changes they need in order to avoid the worsening of their disease. An electronic stethoscope that GPs can give patients for short-term monitoring at home and that could reliably detect PAD could greatly contribute to one of the biggest problems in PAD.

Treatment planning support
No opportunity

Treatment planning for PAD patients is much clearer than for heart failure and COPD patients. The only opportunity found is supporting to plan the surgical treatment. However, due to the high risk of surgeries, doctors are supported with such high-level equipment (e.g., MRI) that an electronic stethoscope cannot compete.

Post discharge: medication setting
No opportunity

Most of the medications for PAD are blood thinners, blood pressure lowering meds and cholesterol lowering meds. An electronic stethoscope would not be suitable to measure parameters related to these medications.

Reflection
Dr. van t'Sant (2017) - vascular surgeon - explained that ankle-brachial index (ABI) measurement is a fairly reliable, cost-effective and non-invasive tool. The electronic stethoscope could only have an added value if it becomes more reliable. However, no clinical suggestion has been found if that is possible. Improving the current situation with new state initiated screening strategies seems more relevant.

Acute event alarming
No opportunity

An acute event in PAD would not remain unnoticed due to the immense pain it causes to patients. Also, these events could not be predicted using an electronic stethoscope, thereby, no opportunities have been found in this direction.

Remote rehabilitation
No opportunity

An electronic stethoscope could contribute to remote rehabilitation by providing feedback on the effectivity of walking therapy. However, according to Dr. van t'Sant (2017) ABI measurement is already being used for this purpose and it provides sufficient feedback. ABI measurement is a cheap, reliable and non-invasive tool. Thus, no added value has been found compared to it. Patients in later stages cannot be supported with an electronic stethoscope as it could most probably only detect bruits in the upper legs and the aorta (van t'Sant, 2017).

Secondary prevention
Longitudinal feedback about overall cardiac state and stenosis progress

Using an electronic stethoscope, longitudinal measurement of HR, HRV, RR and bruits could provide insights to PAD patients about their cardiac state and about their stenosis progression. According to Mosterman (2018), the development of certain cardiac comorbidities could be indicated. Also, in milder stages of the disease patients are not having awfully bad complaints and can easily forget about the severity of their disease and the importance of lifestyle changes for them. Allowing people to keep track of the progression of their disease, could be an effective way to motivate patients in their lifestyle changes.

Reflection
Based on Mosterman's research (2018), HR, HRV, RR and thorax sounds are promising parameters to provide insights about the development of cardiac comorbidities. However, this has not been clinically proven. Thereby, it is rather a strong indication than hard evidence. Moreover, the ABI measurement can already be used for quantifying the progression of the disease. Compared to that the only advantage is cardiac comorbidity indication.

COPD

Progress

Figure 4.4 shows the limitations and treatments of COPD in its different stages. Appendix B-C contains an explanation of the used GOLD classification system. The figure helps to understand that the limitations in COPD are comparable to heart failure's limitations . It also shows that exacerbations are more severe and more frequent as the disease progresses. Thereby, lifestyle change coaching is more relevant for milder patients while exacerbation detection becomes more important with the progression of the disease.

Treatments

Most COPD patients ignore their initial symptoms and only get diagnosed in later stages of their disease (stage II or III). Some of them ignore the symptoms until the point when they are delivered to the emergency department due to an acute exacerbation. However, most of the time they visit their GP due to the complaints before that. After some initial tests, the GP refers the patient to a diagnostic center. After the diagnosis - depending on the severity of the disease and the patient's preferences - the patients either visit a pulmonologist or continue the treatment with the GP.

COPD patients are mostly treated with medications, rehabilitation and lifestyle advices.

The most important medications for them are inhalers. Using these inhalers is a major issue for COPD patients as approximately only 50% of patients use them well (Hoogewerf, 2017). The GP sets these inhalers in a titration process. When people are diagnosed in an early stage (stage I and II), their medication usually starts with short-acting bronchodilators (Smeekes, 2017). These are medications that help patients to get rid of shortness of breath when quick relief is needed. As their disease progresses (stage II, III and IV), patients start to use long-acting bronchodilators as well. These inhalers cannot provide quick relief as their effect builds up gradually. They are made to be used on a daily basis for a long term. Rehabilitation for COPD patients can be a long-term treatment.

The most important aspect of it is exercising. Apart from that patients also learn about breathing exercises and disease management.

Acute events for COPD patients are exacerbations caused by lung infections. They are the main drivers of the progression of the disease. Early detection of them can lead to much milder clinical presentation and consequences. Still, according to Jan Tatousek (2017) –Innovation strategy director at Philips –, currently the 'state-of-the-art' for early detection of these events is subjective symptom interpretation. After an exacerbation is detected patients receive corticosteroid inhalers as well, which helps them to reduce the inflammation in their respiratory system.

During a severe exacerbation or when the exacerbation is untreated patients end up in the emergency department. Recovering can take months for patients, and they might need additional rehabilitation in the meantime. Thus, COPD patients have to pay close attention to symptoms of exacerbations.

As the disease progresses, oxygen therapy can become necessary. Oxygen therapy helps patients whose lungs are diffusing oxygen poorly to deliver enough oxygen in the blood flow. It is used for ideally minimum 15 – but in many cases up to 24 – hours per day (McDonald, 2014). COPD patients only arrive to surgeries in very severe cases.

Main lifestyle advices

- Smoking cessation is the most important aspect of slowing the progression of the disease (van Liempt, 2017; Smeekes, 2017)
- Keeping a good physical condition is also important for COPD patients. There are COPD patient focused physiotherapies, however, exercising shouldn't be limited for to the physiotherapy sessions.
- Keeping a healthy diet can mean both gaining or losing weight depending on the patient's body composition.

Opportunities

The identified opportunities are presented on the following pages.

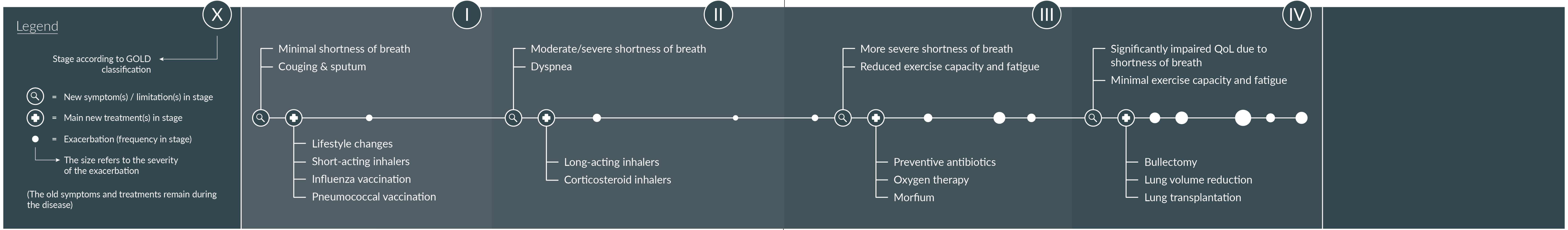


Figure 4.4 Limitations, symptoms and treatments of COPD as the disease progresses

Initial concerns

No opportunity

COPD means permanent damage to the lungs that leads to reduced lung function. Measuring the level of lung function reduction is the main component of COPD diagnosis. However, assessment of lung function is not possible using an electronic stethoscope. Apart from that, doctors can also do an arterial blood gas test or a chest X-ray or CT scan for further signs of COPD. However, an electronic stethoscope could not substitute these tests either. The only somewhat relevant parameter that could be measured is the respiratory rate. However, by itself, it does not provide useful insights to doctors.

Treatment planning support

No opportunity

After COPD patients leave the healthcare environment most of the time physicians do not know anymore about treatment effectivity even though there might be a need for therapy adjustment to adapt to the disease progression and to the needs of the patient (COPD Health Journey Health Continuum, n. d.). A device that could provide meaningful insights to clinicians about treatment effectivity of patients could improve the current situation. However, HR, HRV, RR and thorax sounds are not important measures of treatment effectivity for COPD patients. Thereby, no opportunity was found.

Post discharge

Medication setting

Feedback to users about inhaler use effectivity could have a great added value. Also, COPD medications – just like heart failure medications – are set in a stepwise manner. An electronic stethoscope that could provide feedback to patients about inhaler use and to physicians about inhaler effectivity could improve the current situation.

Reflection

No clinical validation has been found that stethoscopes could be used for assessing inhaler use. Moreover, both of the interviewed GPs insisted that the current system is satisfying in terms of medication feedback. Subjective interpretation is more important than quantification.

Acute event alarming

Exacerbation detector

An electronic stethoscope that patients use on a regular basis and that can early detect the development of lung infections could provide great support for patients.

Reflection

Early detection of exacerbations could lead to significant COPD related cost reduction (see Chapter 3 - Page 29). Experts at Philips were critical regarding the ability of electronic stethoscopes to early detect exacerbations. However, a recent pilot study that used computer-aided analysis of stethoscope acquired sounds achieved 75.8% accuracy of predicting exacerbations an average 5 ± 1.9 day in advance (Fernandez-Granero, Sanchez-Morillo, & Leon-Jimenez, 2015). This is a truly promising result for a first pilot study, especially, as currently there is no effective technology for reliable early detection of exacerbations.

Remote rehabilitation

Breathing exercise guide

For those patients who need to travel too much or have difficulties in incorporating the hospital or outpatient clinic based visits to their daily schedule, remote rehabilitation can be an option. The technology of electronic stethoscopes would not be ideal to be used during physical activity as movements would generate excessive noise in the recordings. However, breathing exercises are also important components of COPD rehabilitation. An electronic stethoscope based solution could be used to guide patients in their breathing exercises and provide feedback to them.

Reflection

Breathing exercises are not valuable without physical exercise (Tatousek, 2017). Thereby, a purely stethoscope based solution would only be a solution to a smaller aspect of remote rehabilitation. Moreover, other technologies could also be used to provide feedback on breathing exercises. Thus, stethoscope is not ideal for a merely breathing exercise focused solution.

Secondary prevention

Longitudinal feedback about overall cardiac state and stenosis progress

Using an electronic stethoscope, longitudinal measurement of HR, HRV, RR and thorax sounds could provide insights to COPD patients about their cardiac and pulmonary state. There are two ways this could contribute to secondary prevention in COPD. First, according to Mosterman (2018), it could be used to provide insights to patients about the development of various cardiac comorbidities. Second, providing insights to patients about their disease and helping them in understanding it better, could be an effective way to motivate patients in their lifestyle changes.

Reflection

Based on Mosterman's research (2018), HR, HRV, RR and thorax sounds are promising parameters to provide insights about the development of cardiac comorbidities. However, this hasn't been clinically proven. Also, other technologies could be used as well for the same purpose.

EVALUATION

Criteria

In order to assess the relevance and potential of these opportunity spaces, criteria were defined. The added weight factors (Table 4.1 and Table 4.2) help to prioritize the criteria.

Technological validity

Technological validity is the measure of how technologically established the given opportunity is. How clear is it that the technology is suitable for the described purpose?

Technological uniqueness

Technological uniqueness tells if the problem can be solved using other technologies as well. A unique technological solution is prioritized over a solution that could be solved with other technologies.

Importance of stethoscope in the solution

Many solutions can be defined where the stethoscope is only a small component of a system. Although these solutions can be highly relevant, due to the scope of the project these solutions are less preferred.

Technological availability

Technological availability evaluates if the required technology is ready available, or long years of research are still required.

Clinical validity of idea

Clinical validity helps to evaluate if there is any clinical evidence that the proposed solution is possible.

Contribution to a relevant healthcare problem

Solutions that can contribute to solving relevant problems in healthcare are preferred. These are either solutions for problems of medical professionals or solutions that save a significant amount of costs.

Solution to an important problem of the patient (positive impact on QoL)

Solutions that have a more positive effect on patients' life are preferred.

Support of self-management activities

Self-management support is one of the key goals of the project. Thereby, the solutions that contribute more to self-management are preferred.

Fits the previously defined scope of the project

Setting an entirely new scope for the project could result in delays. Thereby, projects are preferred that are within the earlier defined scope. This earlier defined scope refers to how closely the given opportunity is related to self-management and secondary prevention.

Personal preference

The personal preference was also taken into account.

Results

The evaluation of the opportunity spaces is shown in Table 4.1 and Table 4.2. The highest scores were achieved by the Acute event alarming and the Secondary prevention opportunity spaces for COPD and heart failure patients. The best opportunity space is early detection of exacerbation for COPD patients. There were fewer opportunity spaces found for PAD and these opportunity spaces performed worse than for the other two diseases.

Reflection

Based on the results the previously defined focus points:

- Acute event alarming and
- Secondary prevention via longitudinal feedback

are confirmed for COPD and heart failure. The results verify that these are the opportunity spaces that fit the functionalities an electronic stethoscope could best fulfill. These functionalities are longitudinal feedback on cardiac and pulmonary state, exacerbation detection for COPD patients and edema detection for heart failure patients.

The mismatch with other opportunity spaces can be explained with the limited set of parameters a stethoscope can measure and the fact that out of these parameters thorax sounds are the only ones that can best be measured using a stethoscope. These thorax sounds have a limited spectrum of usability.

Early detection of exacerbations for COPD patients scored the highest. It is a solution to one of the most relevant COPD related problems both for healthcare and for severe patients. The advantage of it over edema detection for heart failure patients is its technological uniqueness and the fact that a pilot study has been found where the technology was used for this purpose. However, providing a solution for both of these problems would definitely result in a desirable product.

The added value of electronic stethoscopes for PAD patients - tracking the progression of the disease - is unclear compared to current solutions.

Selected direction

In line with the Hartstichting's and Philip's feedback the focus for the rest of the project was on the development of a self-monitoring device for COPD and heart failure patients that can early detect exacerbations and pulmonary edema and that can provide longitudinal feedback on cardiac health and provide insights about cardiac comorbidity development based on that.

Domain	Criteria	Weight	Heart failure: Initial concerns	Heart failure: Treatment planning support	Heart failure: Post discharge	Heart failure: Acute event alarming	Heart failure: Remote rehabilitation	Heart failure: Secondary prevention
Technology	Technological validity	10	6	6	8	8	4	8
	Technological uniqeness	9	6	2	5	5	4	6
	Importance of stethoscope in the solution	7	10	4	4	10	4	10
	Technological availability	4	7	7	7	7	6	6
Healthcare	Clinical validity of idea	10	5	7	6	7	7	6
	Contribution to a relevant healthcare problem	8	8	8	5	10	6	8
Patient	Solution to an important problem of the patient (positive impact on QoL)	10	8	5	6	10	7	10
	Support of self-management activities	6	5	6	9	9	10	10
Other	Fits the previously defined scope of the project	6	6	6	7	10	6	10
	Personal preference	5	4	4	4	9	5	9
Weighted average			6.56	5.47	6.09	8.43	5.83	8.23

Table 4.1 Limitations, symptoms and treatments of COPD as the disease progresses

Domain	Criteria	Weight	PAD: Initial concerns	PAD: Secondary prevention	COPD: Post discharge	COPD: Acute event alarming	COPD: Remote rehabilitation	COPD: Secondary prevention
Technology	Technological validity	10	5	5	6	9	7	8
	Technological uniqeness	9	2	3	5	9	5	6
	Importance of stethoscope in the solution	7	10	10	10	10	10	10
	Technological availability	4	6	6	7	7	7	6
Healthcare	Clinical validity of idea	10	6	6	4	8	6	6
	Contribution to a relevant healthcare problem	8	10	8	8	10	6	8
Patient	Solution to an important problem of the patient (positive impact on QoL)	10	7	8	8	10	6	10
	Support of self-management activities	6	4	10	8	9	10	10
Other	Fits the previously defined scope of the project	6	6	10	8	10	6	10
	Personal preference	5	4	7	5	10	7	9
Weighted average			6.03	7.07	6.77	9.24	6.83	8.23

Table 4.2 Limitations, symptoms and treatments of COPD as the disease progresses

5 LIVING WITH
Heart failure and COPD

After finalizing the focus diseases and before entering the conceptualization phase the human factor – living with these diseases - was further explored. As the direction includes both heart failure and COPD patients, the chapter focuses on the similar patterns in the patient experience.

To better understand how is it live with these conditions Harry Horsman was interviewed. He is a psychologist specialized in chronic diseases, especially HIV, cardiac and pulmonary patients. The interview questions focused on self-management related topics and the psychological burden on these patients. Based on the interview a set of important topics were highlighted. These highlighted topics introduce important problems in the patients' lives and help to better understand them before starting to design for them. Appendix A-B contains the build-up and notes of the interview.

Anxiety and shortness of breath

Shortness of breath can cause a lot of anxiety for both heart failure and COPD patients. Learning to cope with it is a big step in their adjustment phase.

"Patients can have a lot of anxiety. Because they experience shortness of breath and they cannot perform the daily activities as they used to. They have to deal with deterioration of independence."

"As soon as they experience a really bad shortness of breath some people panic because they think 'I'm going to suffocate now, I'm going to die now. I will never make it'. This can be terrifying for them. But the longer a patient has those experiences without actually fainting or dying they will learn that these symptoms come and go and they are associated with activities. They learn to cope with it."

Losing everything

Living with heart failure and COPD leads to many losses in people's life. Losing so many things requires patients to cope with it and adjust to the new situation.

"They lose everything. They lose their social activities, lose your job, their independence. It is a progressive disease as the disease progresses they experience more and more losses in all aspects of life. And they have to cope with it. They have to adjust their expectations in life."

"You have the feeling that you don't control your life anymore, you are dependent on others. You are not living your own life anymore. For us its normal that if you plan a holiday two month ahead you just book your flight and you can expect to be there. But for COPD patients and heart failure patients its not normal to do as they planned. Because the disease is cutting into every aspect of life as well as into the planning aspect. If they are planning to go to a wedding or to a holiday, the sudden deterioration of health can any time come in the way. And as the disease gets more severe this happens more and more. They have to live by the day, by the hour and that's quite hard."

Daily routine

Keeping a daily routine can be really important for these patients.

"These patient's life is greatly affected by the disease. Many of their activities are related to that. In the morning, they have to take their medicine. Then they have to go to rehabilitation, to do exercises. They need to keep a healthy diet so they need to plan with that as well. They can't do too many tasks at a time so they need to break tasks down to smaller tasks. Having the disease controlling so many aspects of their life many patients build up a daily routine. Because if they can do it in a routine, they don't have to think about it. And that helps them."

Learned helplessness

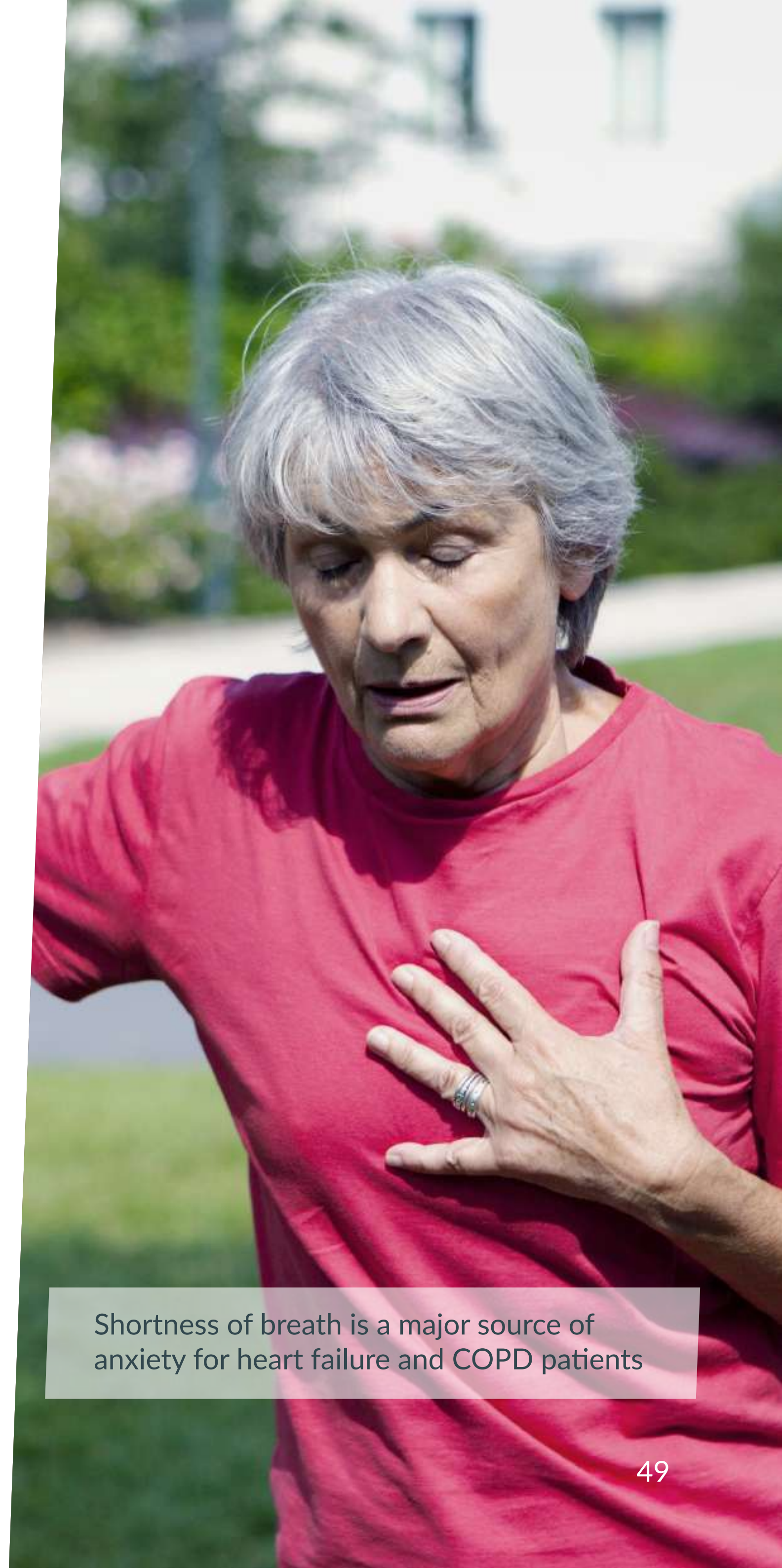
Many patients lose hope and become helpless if they don't experience the positive effects of their efforts for improving their situation

"Chronic patients who feel that they can't have an effect on the progress of their disease will have less and less motivation to change their behavior. Because they learned it doesn't matter what they do. So when they have severe COPD or heart failure and they perform their physical exercise, have a healthy diet, quit smoking, ask for help, break their big task into smaller tasks etcetera but they don't experience any benefits of those behavior changes they think 'Well, why am I changing? Why should I? It's a thing called learned helplessness"

Independence

The independence of patients is a major source of motivation. Supporting patints to keep their independence and have a sense of control over the disease can greatly contribute to keeping them motivated to adhere to medication and therapy.

"I really think independence is an important motivation source for these patients. As humans we are autonomous beings. So its really important for these patients to gain independence. As soon as they loose their independence, they can have the feeling of helplessness. They think 'It doesn't matter what I do, I am dependent on the people around me, the doctors, the nurses, the medication...'. For really motivating people to having an adequate disease management, they have to have a feeling of independence."



Shortness of breath is a major source of anxiety for heart failure and COPD patients

CONCEPTUALIZATION

PHASE

6 SYNTHESIS

The synthesis chapter summarizes the most relevant conclusions of the preceding analysis and to provide a frame for the conceptualization.

DESIGN DIRECTION

The selected design direction is designing a self-monitoring device that can early detect exacerbations for COPD patients and lung edema for heart failure patients. For timely detection regular use is required. This regular use needs to be easily integratable to the patients daily routine. Apart from lung sounds, electronic stethoscopes can also measure HR, HRV, RR and heart sounds. Thereby, due to the regular use many important parameters could be registered over time. This longitudinal information can also be used to provide patients longitudinal feedback about their cardiac health and alarm them on time about signs of cardiac comorbidities.

The regular use can become cumbersome for patients over time. Still, the above-mentioned features can only be delivered if patients use the device and use it correctly. Thus, long-term device adherence is a key aspect of the project. The device needs to encourage patients to the use.

The device adherence can be further improved if patients can emotionally connect to the device and to its use. To achieve that the design needs to become friendly, comfortable, reliable and reassuring in order to empower patients and to help them to gain more control over their own disease.

VISON

Designing a **friendly** self-monitoring solution **for COPD and heart failure patients** that can **encourage patients** to long-term use, and that can be **used alone conveniently, quickly and reliably** in order to support patients in gaining **more confidence and control** over their own disease.

DESIGN CONTEXT

The design context is illustrated in Figure 6.1.

Target group

The primary target group of the design are moderate and severe COPD and heart failure patients who suffer from more severe exacerbations and pulmonary edema, but still are in a sufficient mental state to regularly perform self-management activities. Typically, these patients are between 50 and 80 years old. However, it is important to add that patients in milder condition who are willing to perform daily self-measurement activities could also benefit from the results of this project. Thereby, they are also considered as possible target group.

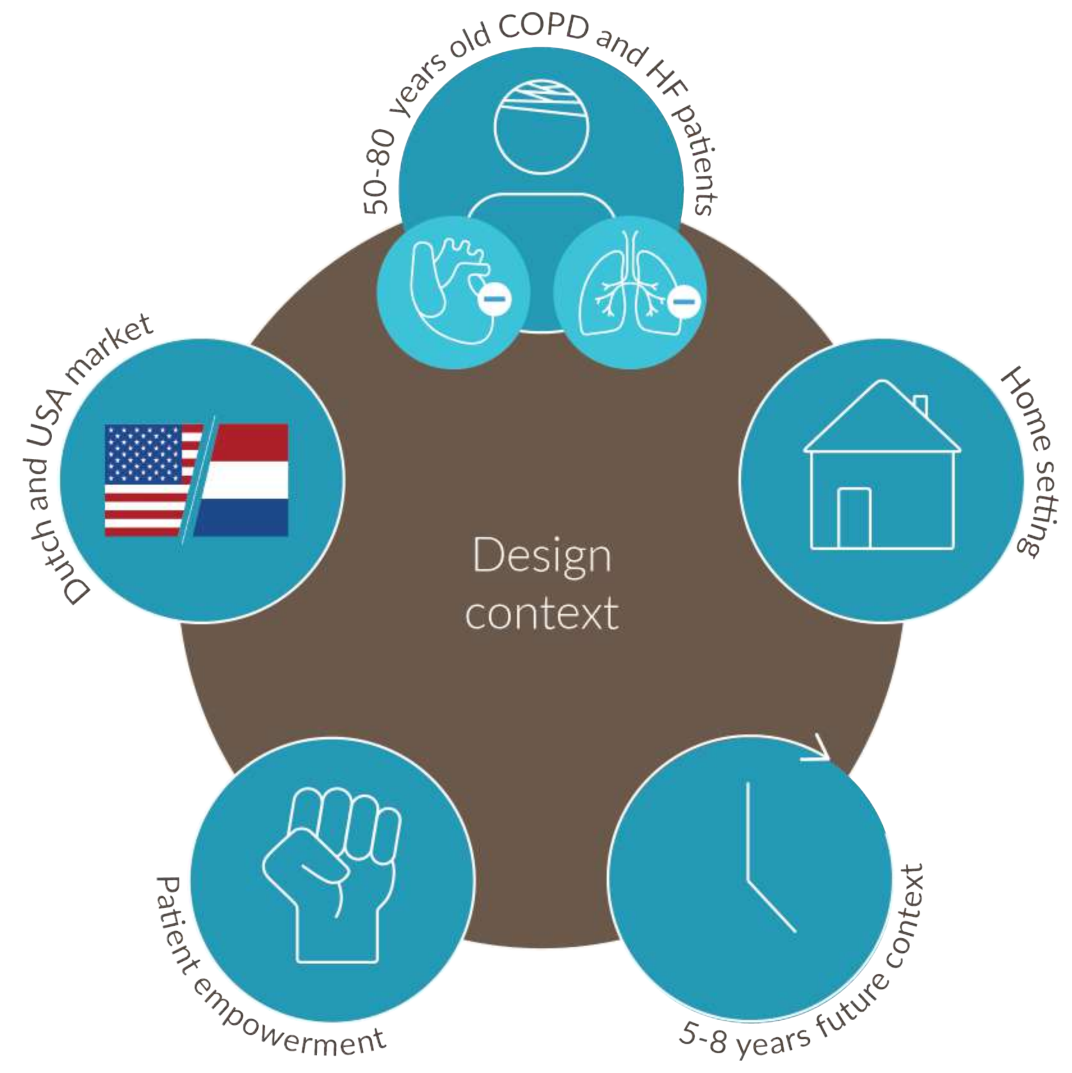


Figure 6.1 Design context

As the target age group is wide, the design needs to take into account the differences between users at the bottom and the top of the target group. 50-year-old people usually work, live a much more active lifestyle and are in a better physical and mental condition. On the other hand, 80-year-old people are in a worse physical and mental condition, live a more passive lifestyle, but are also much less busy. Also, 80-year-old people have more difficulties understanding technology and complicated interfaces.

These patients can be restricted in their shoulder movements due to their age and disease-related physical limitations. As the device is applied on their chest, this insight is important to consider regarding the placement of the device.

Home setting
The device is meant to be used in a home setting. Patients at home are lacking reliable insights about their health and thereby can be worried about their condition. Helping them with insights about exacerbations and cardiac comorbidities in this setting could greatly improve their confidence over their disease. As the device needs to be regularly used and needs to be in direct contact with the patients' skin most probably, it will be used in the bathroom or the bedroom.

Place in healthcare

The design focuses on the acute event alarming and secondary prevention stages of the healthcare continuum. However, the device is not meant to substitute doctors in diagnosis and treatment setting. It rather aims to empower patients and encourage them to act on their own disease.

Future context
Although computer-aided analysis of auscultatory information has improved tremendously in the last few years, there are technological developments required for the project to succeed. Thereby, the project is placed in a 5-8 years future context.

Market
The design is targeted on the Dutch and the United States market with a primary focus on the Dutch market. These are not only important markets of Philips but also the sources of all the gathered information during the analysis serving as an input for the design. In case the design will focus on situations that are fundamentally different on these two markets (e.g., post-discharge care, communication with healthcare professionals, the involvement of GP in the care) either a more defined focus market will be selected, or the differences will be taken into account.

USE FRAMEWORK

Measurement locations
The auscultation locations are shown in Figure 6.2. The location of lung sound measurement varies for COPD and heart failure patients due to the different measurement purpose. Edema accumulates in the bottom of the lungs due to gravity. Thereby, early detection of pulmonary edema in heart failure patients should be performed at the bottom of the lungs. Lung infections can manifest locally in only one segment of a lung. That is why general practitioners usually listen to several auscultation points. However, with a sensitive electronic stethoscope and computer-aided analysis of the recordings, one point is enough per lung. East Lee - senior electrical engineer and respiratory therapist who works at Philips Respironics, who gained experience both in research projects and in clinical check-ups - also confirmed this hypothesis in a personal interview. If only one point is picked for early detection of lung infections the best auscultation point would be in the center of the lungs (Smeekes, 2017 December 14).

Frequency of use

Due to the fact that the design is aiming to early detect acute events, lung sound measurements should be performed on a daily basis. However, cardiac comorbidities do not develop

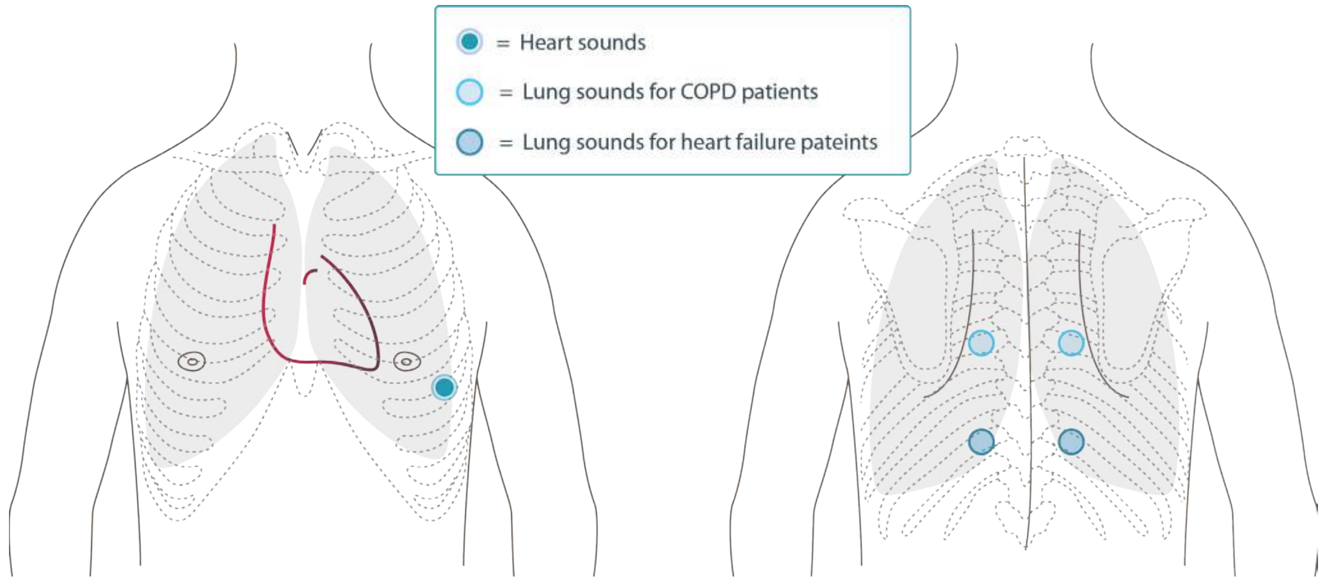


Figure 6.2 Auscultation points of the device

overnight, thereby, there is no need for heart measurements every day. Measuring 2-3 times a week could be enough to determine longitudinal trends and filter out statistical outliers. Still, from a behavior perspective, it might be more efficient to perform both measurements with the same frequency. This aspect needs to be determined further on in the design process.

To ensure the comparability of the measurements, they should be performed under similar circumstances. Otherwise varying factors could affect the measured parameters. For instance, a coffee or even the victory of a favored sports team can increase HR. In current self-monitoring practice of other parameters (e.g., blood pressure, weight), morning measurements are recommended. This practice is also recommended for the future users of the current project.

Category		Name	Requirement/ wish
Placement & Positioning	1	Ease of accurate placement	Requirement
	2	Ease of placement with restricted shoulder movements	Requirement
	3	Fits both scenarios (Lung+Heart measurement)	Requirement
	4	Adaptation to anatomical inter-variabilities	Requirement
	5	Speed of placement	Requirement
	6	Easier use with repetition	Wish
	7	Clarity of use	Requirement
	8	Possiblity of misuse	Requirement
	9	Stability of placement	Requirement
Feedback on measurement	10	Feedback simplicity	Requirement
	11	Feedback clarity	Requirement
	12	Easily noticeable	Requirement
	13	Non-interference with auscultation technology	Requirement
Notification about health and necessary actions	14	Notification simplicity	Requirement
	15	Notification clarity	Requirement
	16	Chance of misinterpretation	Requirement
Product architecture	17	Compactness	Requirement
	18	Easy storage	Requirement
	19	Easy maintenance	Requirement
	20	Easy cleaning	Requirement
Further device adherence contribution	21	Use motivation	Requirement
	22	Effective measurement reminders	Wish
	23	Pleasant interaction	Wish
	24	Patient empowerment	Wish
	25	Additional value	Wish

Table 6.1 List of requirements

Self-use

Patient empowerment and supporting patients in gaining more control over their disease is a fundamental aspect of the defined design direction. Thereby, the design needs to support patients to use the device alone, without help.

Use posture

HR, HRV, RR and thorax sounds should not be measured while standing. Thereby, users need to conduct the measurements either in a seated or in a laying position

LIST OF REQUIREMENTS

The list of requirements was defined that the design needs to meet in order to succeed (Table 6.1). The main requirement categories were selected for the following reasons.

Placement & positioning

Accurate positioning is a key aspect of achieving reliable measurements with the device. Apart from that users will need to place the device on themselves on a daily basis. Thus, the user experience during placement is a major factor in the overall user experience.

Feedback on measurements

The device does not produce any vibration or sound during measurements. Due to the elderly target group who's not so used to using technology providing feedback on the start and finish of measurements is crucial.

Notification about health and necessary actions

The result of the measurements contains sensitive information. The results can either reassure users about their health or alarm them about the development of an acute event.

Product architecture

These are requirements related to the physical design of the device that do not belong to any of the previous groups but highly impact the quality of the final product.

Further device adherence contribution

Device adherence is one of the most important and challanging aspects the design should support.

Further explanation of the requirements is provided in Appendix C-A.

7 CONCEPTUALIZATION

The conceptualization chapter is meant to provide a quick and structured exploration of usability focused concept directions before entering the elaboration phase. The chapter starts by providing a framework for the design. After the ideation three concept directions are presented. The chapter ends by evaluating the concept directions and defining a final direction for the project.

APPROACH

The focus of the conceptualization phase was to find the best solution direction that can support users in using the device alone conveniently and reliably. Other aspects of the vision were also considered during the phase. However, those aspects were only elaborated in the elaboration phase.

Based on the design direction and the list of requirements the key functions of usability were identified. These are the following:

- Placement & positioning of the device
- Operation of the device
- Measurement feedback
- Notification about health and necessary actions

Solutions for these functions were explored in separate ideations. The Placement & positioning and the Measurement feedback topics were explored during a group ideation session. This ideation session is elaborated in w-B. The results of the ideation are summarized in a morphological chart. This chart was analyzed to define the most suitable principal solutions and principal solution combinations. These findings are elaborated in the upcoming chapter. Based on the most promising solutions to the focus areas, three concept directions were defined and elaborated. Finally, the concept directions were evaluated using the list of requirements and the most promising direction was selected.

MORPHOLOGICAL CHART

The morphological chart in Figure 7.1 helps to structure the results of the ideations. After defining the principal solutions, the morphological chart was analyzed the following way. The solutions for the placement & positioning are by far the most defining aspect of the device from a product design perspective as they fundamentally define the product architecture. Thereby, first these principal solutions were analyzed and the three most suitable principal solutions were identified for the three concept directions. After that, the irrelevant principal solutions for feedback, operation and notification functions were filtered out. The remaining principal solutions were used as input during the elaboration of the three concept directions. The main

Figure 7.1 Morphological chart

considerations were the following.

Placement and positioning

The sticker does not support patients to reach their back, and it also doesn't support accurate placement.

The difference between the smart mat and the wall mount solution is that the wall mount solution helps to longitudinally position the stethoscope on the users back (with fixed bottom – stethoscope distance) while positioning is not supported at all in the smart mat solution. Also, the wall mount solution only needs to be placed on the wall once, after that it always stays in place, thereby, it is easily stored during the long-term use.

The back-scratch solution is hard to perform for elderly patients – whose shoulder movements are restricted – and it also doesn't support users in the positioning.

The two-handed back-scratch does not support accurate placement

The forceps solution is hard to place as it requires users to lift their shoulders high.

The strap, the harness and the smart shirt solution all use the patients' chest for fixating and positioning the device on its place. The strap has the added value of quick placement over the harness and the smart shirt solution. Between the chest and the smart shirt, the biggest difference is the placement as the harness can be placed easier. Also, it can be manufactured in fewer sizes – as it can be adjustable unlike T-shirts –, it gets dirty less quick as it does not touch the patients' armpit and finally it uses less material for the same result. The advantage of the smart shirt is that it looks more acceptable to wear among people. However, there is no intention to use the product in public.

Due to these reasons, the most promising principle solutions are the wall mount, the strap, and the harness. It is debatable if the wall mount principal solution is more promising than the smart shirt. However, the strap, the harness and the smart shirt solutions are too similar to each other, thereby, rather an essentially different solution was selected.

Feedback

Measurement feedback means feedback on the start, progress, and validity of the measurements. It is a simple but essential information to users as the device does not provide any feedback when its working as it does not have mechanical components (unlike for instance cars where the engine provides clear feedback if it's running or not). Measurement validity should be communicated as quickly as possible as patients need to stay in place until its confirmed in case they need to repeat the measurement.

Lights are simple and clear principal solutions that are ideal when users can easily see them.

Sounds can corrupt the recording of stethoscopes, producing noise. However, there are two ways to avoid this. First, using earphones. Although this principal solution would not result in added noise, it would require users to have an earphone around every time during use. Second, using spectral filtering on the recordings, sounds outside of the auscultated spectrum could be played loud during measurements to provide feedback to users.

Vibration is another suitable principal solution to provide feedback. It also has the advantage that it does not need to users to look at it. However, it is important to add that vibrations during measurements also cause noise to the recordings. Thereby, vibration can only be used before or after the measurements.

Heat could be another feedback solution. However, it is much less energy efficient to produce, and it cannot be produced immediately. Also, heat feedback could be less clear for elderly users than more conventional solutions.

Finally, smart phones could be used as well. However, it would require users to have their smart phone around every time they use the device.

Operation

There are many ways patients could operate the device. Here, only the filtered principal solutions are elaborated.

Knobs allow gradual operation (e.g., volume adjustment). However, there is no need for gradual adjustment in the device. They can also be used as on/off switches, but thay take much more space than rocker switches.

Touch operation can be a smooth modern alternative of buttons. However, by itself, it does not provide clear mechanical feedback, unlike buttons.

Smart phones were excluded for the same reason as before. Using smart phones for operating the device would always require users to have their phones around when using the device.

Notification

Notification refers to feedback to users about their cardiac health, the risk of developing cardiac comorbidities and the risk of developing acute events. This is more complex information than measurement feedback. However, it does not necessarily have to be as immediate as measurement feedback as users do not need to stay in place until notification.

Lights are not useful for this purpose due to the more complex information to be communicated.

Due to their screens smartphones are ideal for communicating complex information. Moreover, patients do not necessarily need to have their phone around as notifications can also be read sometime later.

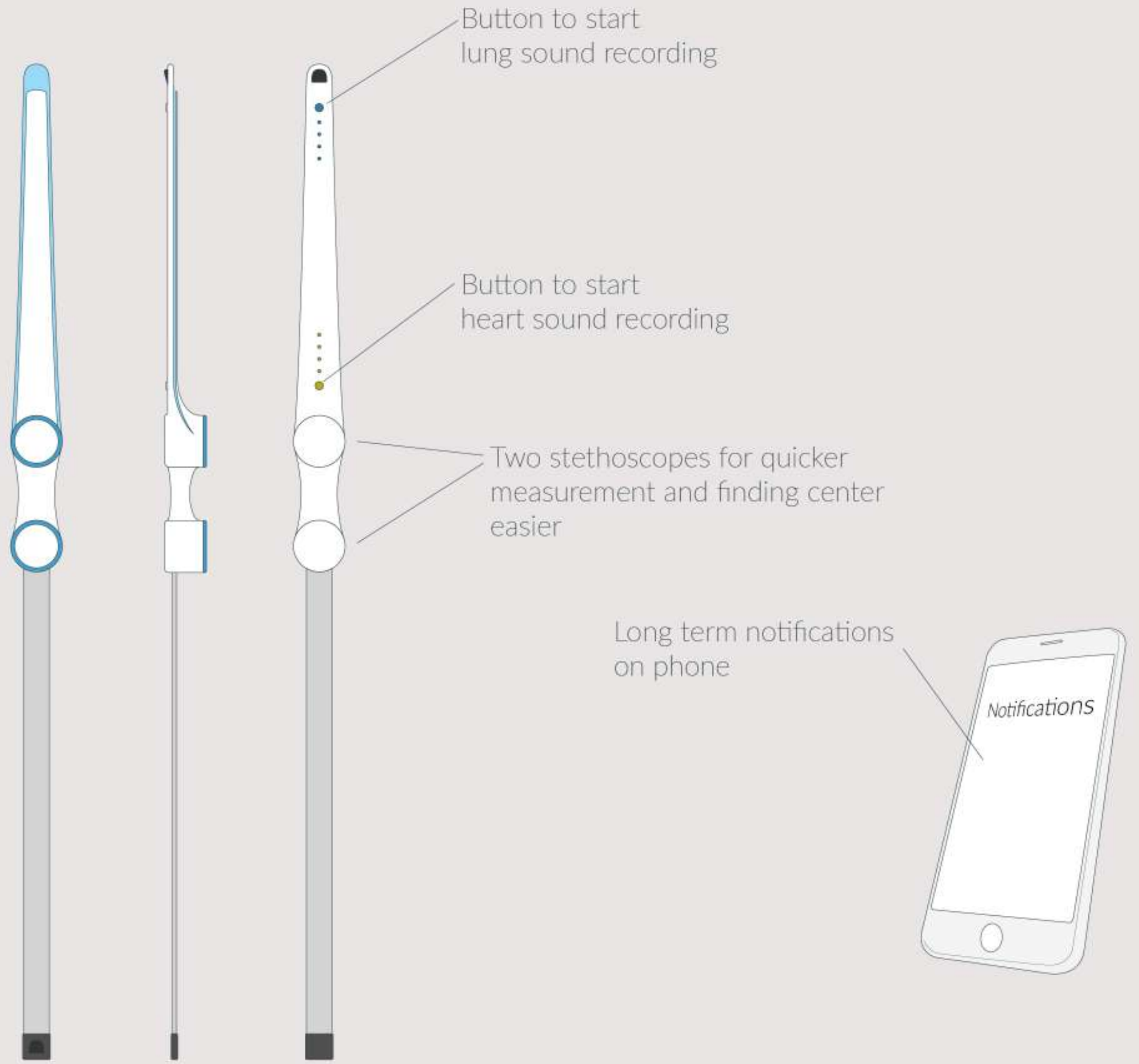
Emails do not have much-added value over smartphones, especially by the time the device will be on the market. However, in case numerous potential users would not have smartphones it can be considered.

The information to be communicated in the notifications can be sensitive to users. Telling this information with a human voice instead of in a written manner could help patients to relate to it better. It could also potentially help them to relate to the device itself more and form an emotional connection with it. This could improve use adherence. However, it is important to add that audio notifications are preferable together with written notifications as written notifications are easier to track back later or to show to doctors at consultations.

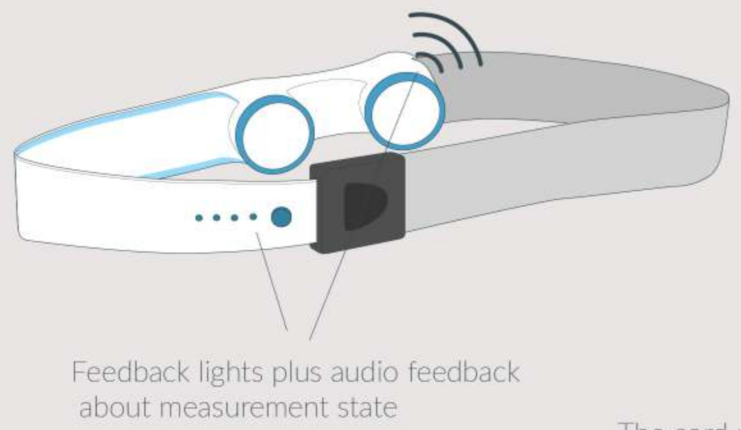
CONCEPT DIRECTIONS

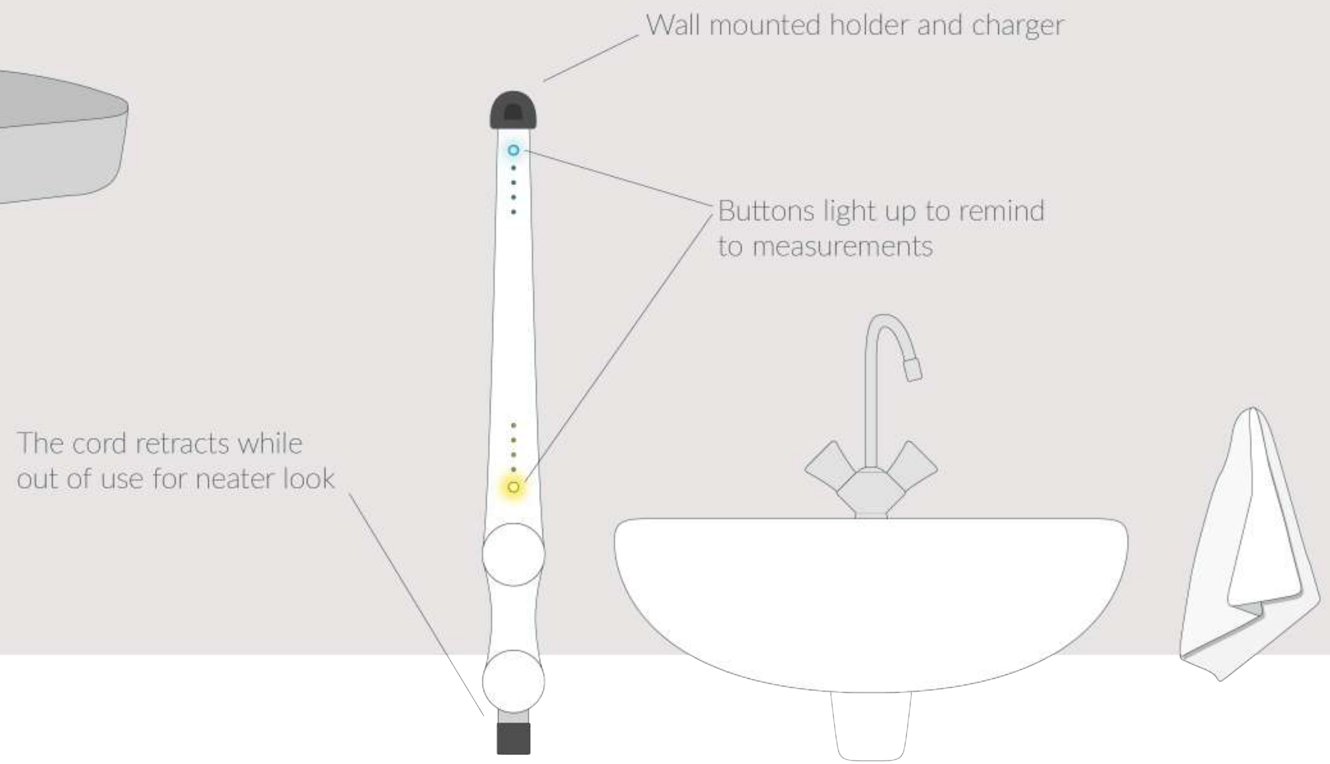
In this sub-chapter the concept directions are presented. The concepts were developed by sketching, digital drawing and using quick mock-ups for testing the product interactions. It is important to note that aesthetic form giving only took place after this stage in the elaboration phase. The presented concepts do not have finalized aesthetics.

Strap



The strap solution allows quick placement for users. Further time can be saved due to the two stethoscopes built in the strap. The two stethoscopes not only save time in this concept but they also potentially allow users to easier position the stethoscopes on the center of their back. The white part of the device should be from a flexible material that allows the integration of electronics in it and can reliably seal them from users (e.g., silicon). This way the operating buttons can be placed next to the clip of the strap and feedback lights can be placed next to it as well. Users can receive visual feedback of use at a visible location. Feedback clarity is decidedly important, thereby, additional audio feedback could be utilized for even more clear, multisensory feedback. The grey part should be from a flexible textile material that can be adjusted in length, to users' own size. This 1-dimensional adjustment enables manufacturing the device only in one or maximum two sizes.





A major advantage of the solution is that it can be easily stored due to its geometry. A wall mounted storage unit could not only be used to charge the device while stored, but it would also allow users to store it at a visible location. This way, the heart and lung sound measurement buttons could light up if a measurement is needed on the given day and stay on until the measurement is conducted. This way users could easily and effectively be reminded to heart measurements that are only necessary a couple of times a week and to daily lung measurements as well.

Another advantage of the strap solution is that it is a compact solution that doesn't require removable components for performing both lung and heart measurements. After conducting the lung measurements, users can simply rotate the strap to position the stethoscope on the heart auscultation point. As heart measurement only require the use of one stethoscope the separate heart sound measurement button allows users to only activate one stethoscope. However, it is important to add that the design needs to emphasize the primary stethoscope for this purpose because patients could position the wrong stethoscope on their heart if its not clear enough which one is the primary.

A challenge of the solution is that the placement of the strap might be hard for patients whose shoulder movements are restricted. Thereby, patients need to be further supported in the placement with the design. Another challenge is that the design allows users to misposition the device on the vertical axis. This also needs to be taken into account if the concept is selected for elaboration.

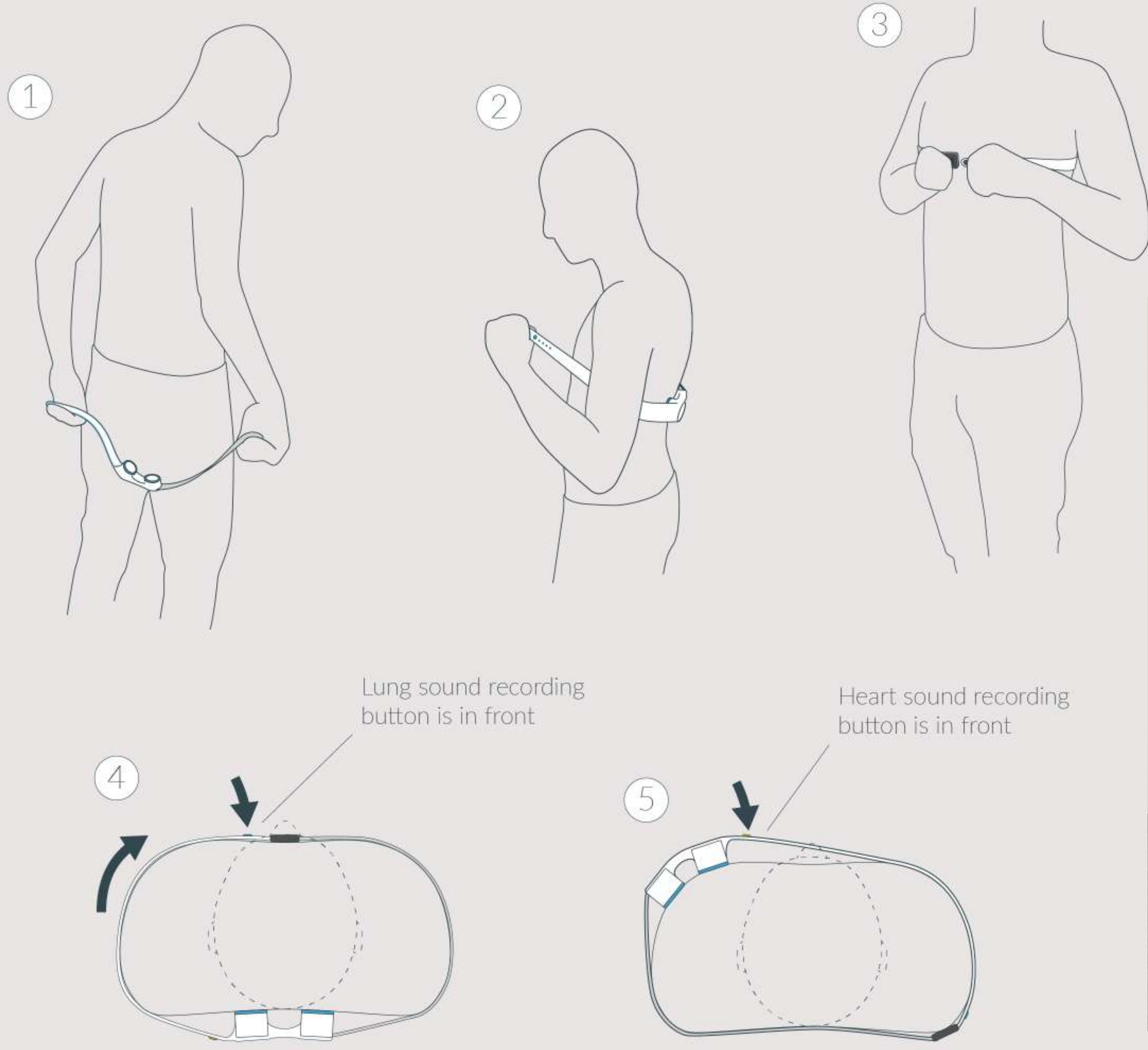
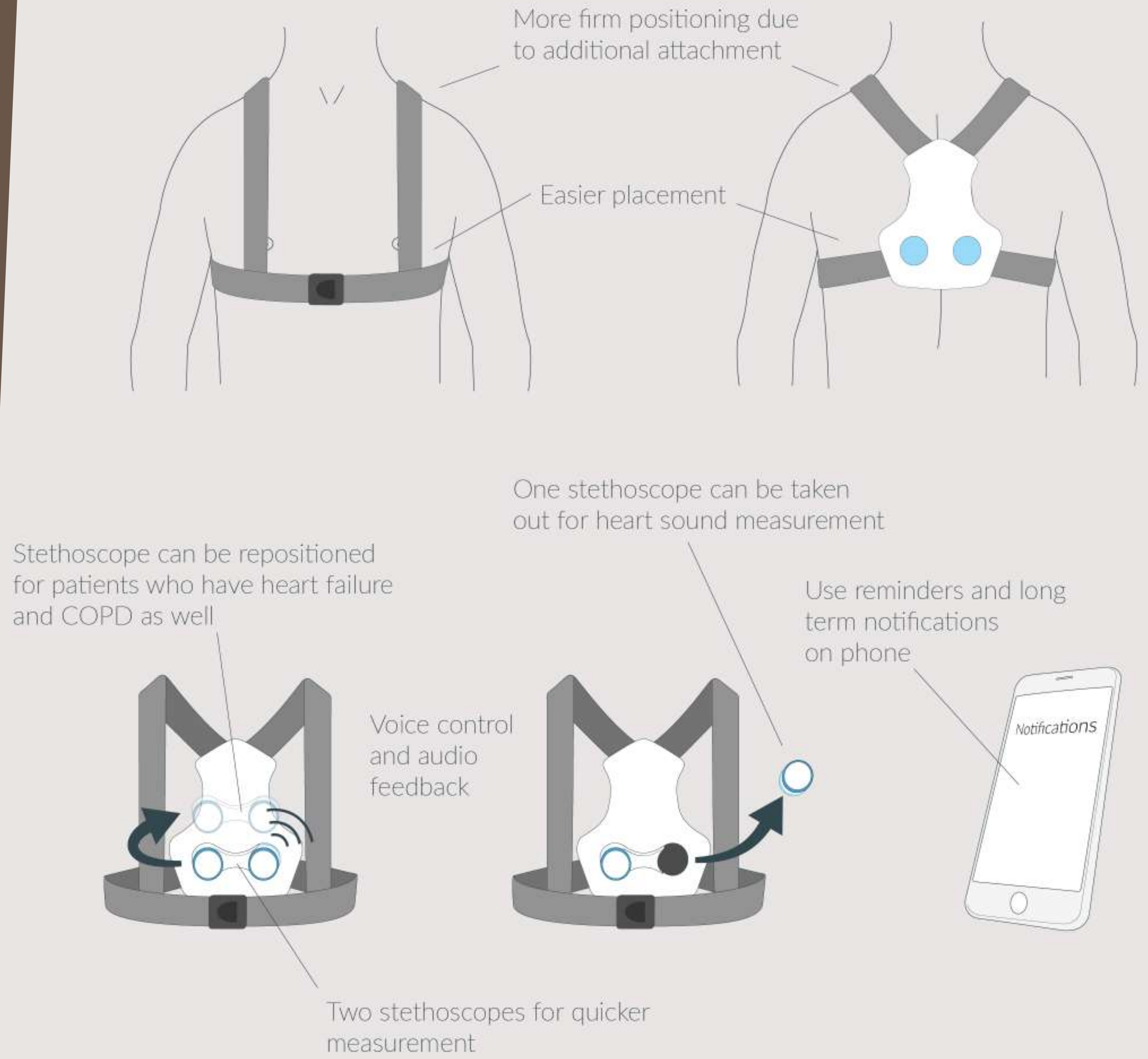


Figure 7.2 Interaction with the Strap mock-up

Harness

The placement and positioning can be further enhanced by using a harness instead of a strap. This way users can place the device on themselves with easier shoulder movements. It can also provide a vertical reference point making the positioning even easier. The stethoscope uses two stethoscopes as well to make measurements quicker. The stethoscope can be easily repositioned in the harness for COPD and heart failure patients. However, it is important that users with both diseases need to place the device on first, conduct the measurements, and then take it off, reposition the stethoscope and put it on again. This is a time-consuming process. For easy cleaning of the harness, no electrical component is placed in it. However, this way patients can only receive audio feedback, no visual feedback. As the harness doesn't contain any electronics patients can operate the device using voice commands.

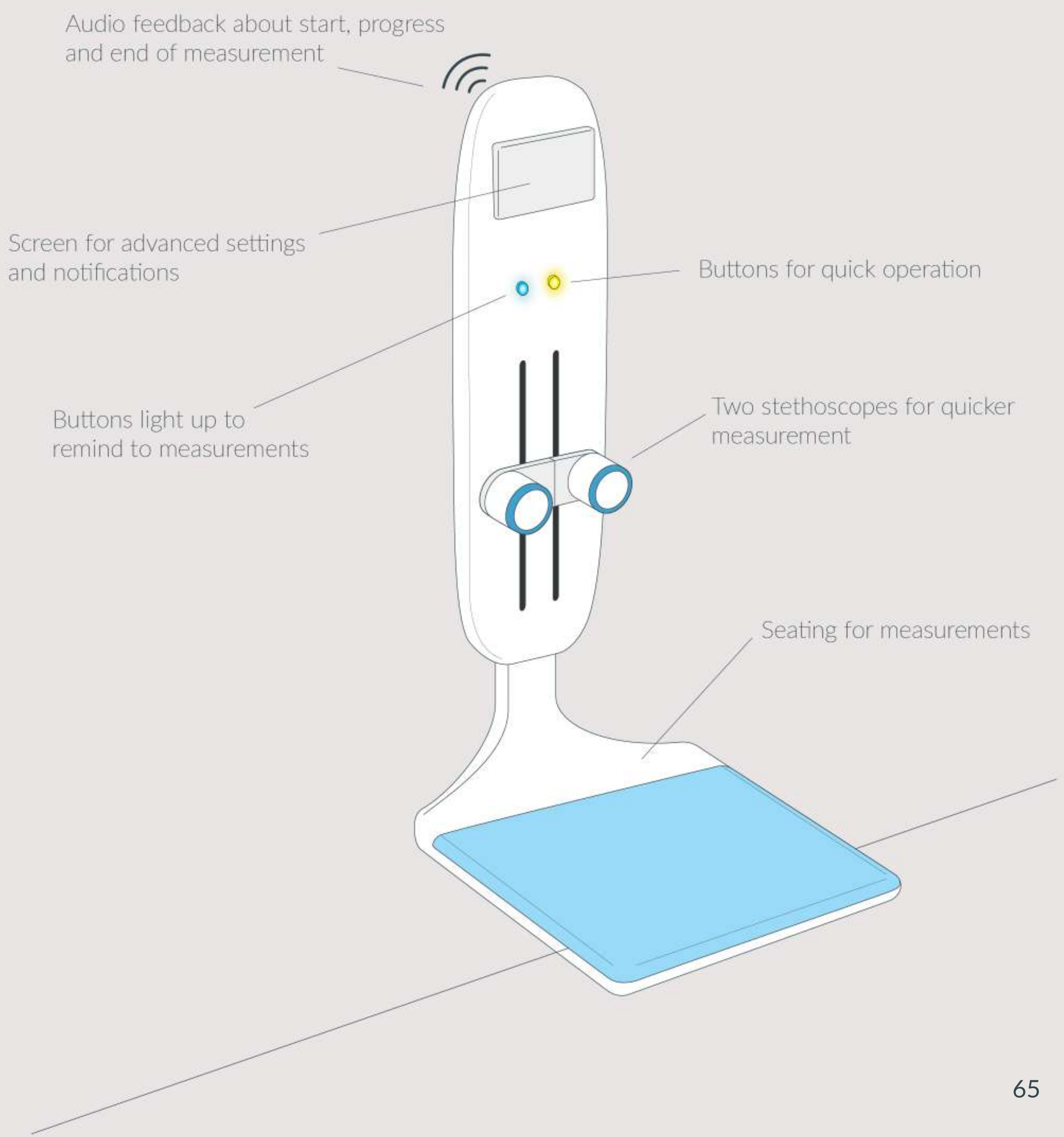


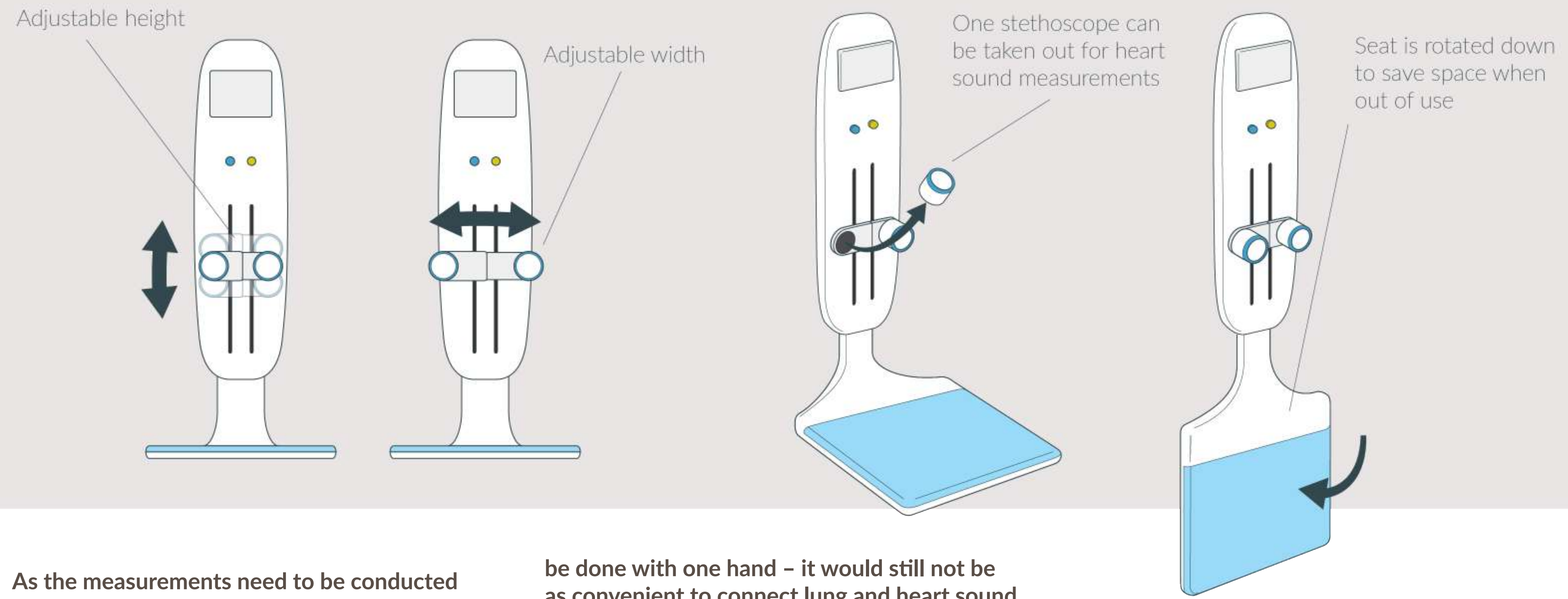
A drawback of the concept is that it needs a separable stethoscope for heart sound measurements as placing three stethoscopes on the harness would be exaggerated cost wise. This means that between heart and lung measurements the harness needs to be taken off, the primary stethoscope needs to be taken out for conducting the measurement and then it needs to be taken back. This can become cumbersome on a long term for users. Another drawback of the concept is that it can't be stored as neatly as the strap solution. As the device will be used on a daily basis for an indefinite period, this drawback is also relevant.

Figure 7.3 Interaction with the Harness mock-up

Mount

The third concept is a wall mounted measuring unit. After calibrating it on the users' anatomy, it can quickly be used, and the correct positioning of the device is also easy with it. Another advantage of the solution is that one user could have saved pulmonary edema and lung infection auscultation points on it, so patients with both diseases could easily use it. Patients could quickly start the measurements with a separate button for heart and lung sound measurement. As the device would be mounted on the wall storage would be easy. Due to this the buttons could light up here as well to remind users to heart and lung measurements. More advanced settings – such as configuring stethoscope position – could be done using the screen on the device. As during use patients are facing away from the device it can only provide patients audio feedback during use.





As the measurements need to be conducted seated, the device needs seating. Patients could also use a separate chair for the measurements, however, by incorporating a seating in the design constant seating-stethoscope distance could be guaranteed. Also, this was patients would not need a separate product to use the device. If the seating would stay in place, it would take a huge space, thereby, when the device is out of use, the seating automatically lowers to save place.

For the heart sound measurements, the primary stethoscope can be removed from the device. This removal would be slightly more convenient than in the harness concept – as it could be done with one hand – it would still not be as convenient to connect lung and heart sound measurements than in the strap concept. The biggest drawback of the solution is its exaggerated size compared to its functionality and the need for integrating a seating in it. These drawbacks together would result in a more expensive solution.

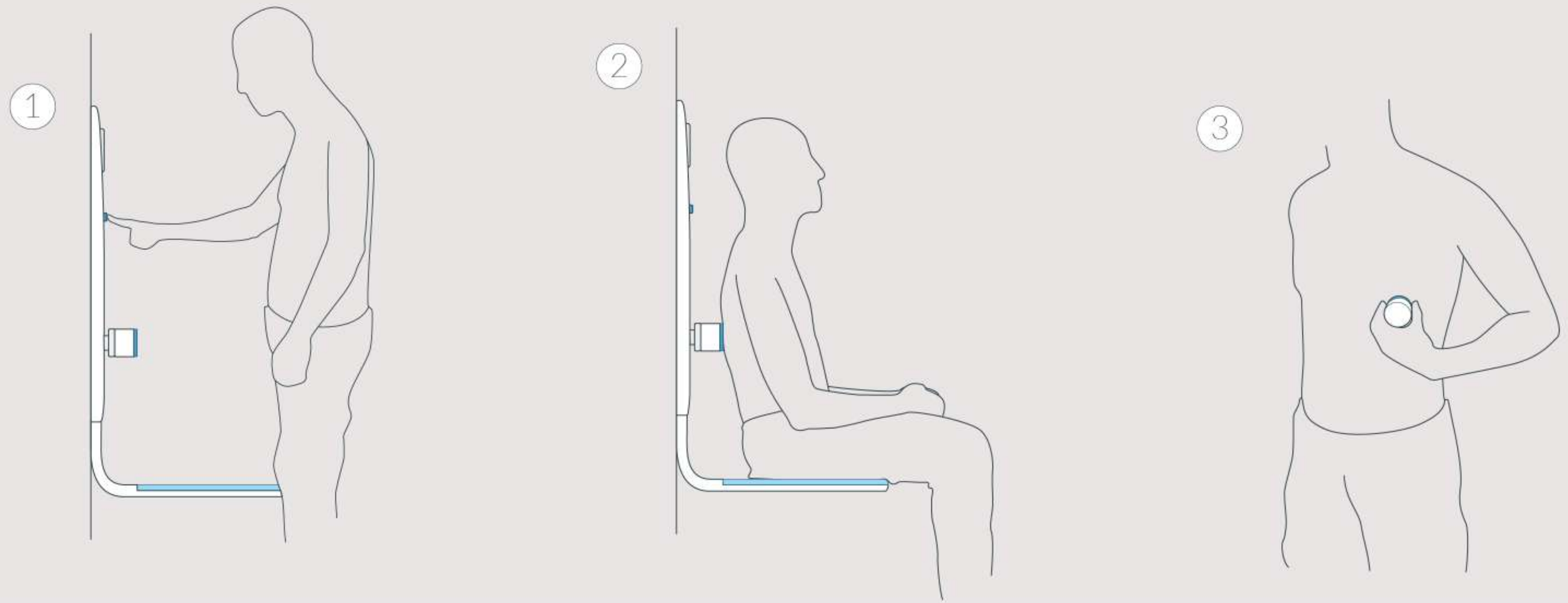


Figure 7.4 Interaction with the Mount mock-up

CONCEPT EVALUATION

which can be effectively used to highlight differences between the concepts. For instance, clarity of use is a very important requirement, however, it could not be used to evaluate differences between the concepts as they do not differ from this aspect. Table 7.1 contains the selected criteria. After defining the criteria their weights were defined. To do that each criterion was compared with all the other criteria in a matrix. When a criterion was more important than the other one it received a 2. When they were equally important it received a 1, while if it was less important it received a 0. Finally, the points of each criterion were summarized and 100 weight points were divided among the criteria based on their score. The defined weights of the criteria are shown in Table 5.2. After the weights were defined each concept was evaluated on each criterion on a scale from 1 to 10. The result of the evaluation is shown in Table 5.2.

Results & reflection

The strap solution scored the highest among the concepts, the mount scored second and the harness third. The strap concept combines quick and easy placement, with neat storage and additional reminder functionality while being stored. It is also the concept that connects lung and heart measurements most conveniently. Thus, the strap concept was selected for elaboration.

Criteria		Weight	Strap	Harness	Mount
Placement & positioning	Ease of accurate placement	14	8	10	9
	Ease of placement with restricted shoulder movements	14	8	10	10
	Fits both scenarios (L+H)	11	10	6	7
	Adaptation to anatomical inter-variabilities	2	10	8	10
	Speed of placement	11	10	6	8
	Easier use with repetition	1	10	8	9
	Possiblity of misuse	11	6	10	10
Feedback	Feedback clarity	9	10	8	8
	Easily noticeable	7	10	8	8
Product architecture	Compactness	6	10	4	4
	Easy storage	4	9	6	10
	Easy cleaning	1	8	10	8
Further device adherence contribution	Measurement reminders	5	10	6	10
	Additional value	4	10	6	6
		Total score	**894**	**786**	**844**

Table 7.1 Concept evaluation

ELABORATION
PHASE

8 Refining the scope

The main objective of the elaboration phase was to detail the selected concept direction and arrive to an embodied concept that can be prototyped and validated with the actual target user group. The current chapter reflects on the vision, defines the focus for the rest of the project and presents the system framework with an emphasis on the features and functions of its components.

REFLECTION ON THE VISION

The conceptualization phase resulted in selecting the strap solution for elaboration. The aim of the elaboration phase was to detail its design having the previously defined vision in mind. As a reminder, the vision for the project is the following:

> Designing a **friendly** self-monitoring solution **for COPD and heart failure patients** that can **encourage patients** to long-term use, and that can be **used alone conveniently, quickly and reliably** in order to support patients in gaining **more confidence and control** over their own disease.

To achieve that the elaboration phase had three focus points:

Usability

The design of the strap needs to enhance quick, easy and accurate placement. This is important to ensure that people do not misuse the product and to achieve a convenient, positive experience during the everyday use. A key focus point of the phase was elaborating on the usability aspect.

Encouraging

The device has a clear benefit for users by alarming them on time about the development of pulmonary edema and lung infections. However, therapy adherence still can be low for many COPD and heart failure patients. Thereby, the design of the device needs to actively contribute to encouraging the patients to the use. Encouraging can consist of both motivating and reminding patients to the use. This is another focus point of the phase.

Friendly and comfortable design

Patients will use the device in their home on a daily basis. Thus, the design of the design needs to become friendlier and more comfortable than the current stethoscope's. However, patients still need to take it seriously as a medical device. This contradiction was in the focus of the form giving during the project.

SYSTEM FRAMEWORK

The key features and functionalities of the product service system were defined before the elaboration. Figure 8.1 visualizes the components and their main features and functionalities.

On a long-term, it can be inconvenient for users to always have their phone with them during measurements. Thereby, they should be able to use the device without having their phone with them. Thus, the device by itself needs to be able to perform measurements and provide feedback about the validity of these measurements. However, uploading the measurements to a central server for processing can take up to a minute depending on the internet connection. Still, it is best to keep the processing centralized for security reasons. Thereby, it is best if users can continue their daily routine and do not need to stay with the device for that period.

The results can be communicated in the application. The application is also suitable for allowing users to monitor their cardiac and pulmonary health based on the measurements and to educate them about the correct use. The design and the detailing of the application related features is not within the scope of the project.

Reminding and motivating patients to use the device are key features that are important to be performed by both the device and the application. Although reminding could easily be done only in the application, due to the partially elderly target group, it is better if the device can also contribute to these aspects.

The holder's main function is storing and charging the device. As the device can be stored on sight with the help of the holder, it also indirectly contributes to helping patients reminding to the use. Finally, the holder can have one useful advantage. It could automatically pull off the measurement data from the device and safely upload it to the cloud for processing. This way, users do not need to keep their phone around the device after use for

Main features and functionalities	Device	Application	Holder
Measurement	●		
Measurement validity feedback	●		
Communicating result		○	
Longterm monitoring cardiac and pulmonary health		○	
Reminding	●	○	●
Motivating patient	●	○	
Educating patient about the use		○	
Charging device			○
Uploading data for analysis			○
Storing device			●

● = Detailed during the project
○ = Detailing is out of the scope of the project

Figure 8.1 Main features and functionalities of the product service system uploading the recordings and the uploading can become safer as well. The idea is not futuristic, the 2net Hub from Qualcomm Life is an already existent solution that can fulfill this feature (“2Net Hub”, 2018). By integrating this feature in the wall mount instead of an additional, system component like Qualcomm’s, the device can become a more compact solution. In case it can connect to the device wirelessly as well, it can pull off the data even when users forget to place it back on the holder. Only the holder’s physical appearance is elaborated during the project. It’s technical details such as its electrical connection to the device or the communicational technology it uses - won’t be detailed during the project.

THE SCOPE OF THE DEVICE DETAILING

Due to the strap-based product architecture, the device has two main components.
The device itself and its straps. During the elaboration phase, both of the components were aesthetically elaborated. However, only the device was detailed to an embodied concept level. This means that the structural build up was detailed for the device but for the straps, this aspect remained on a conceptual level.

9 DESIGN APPROACH

The current chapter provides an overview of the design approach and summarizes the most important findings of the development steps that are not discussed in a separate chapter.

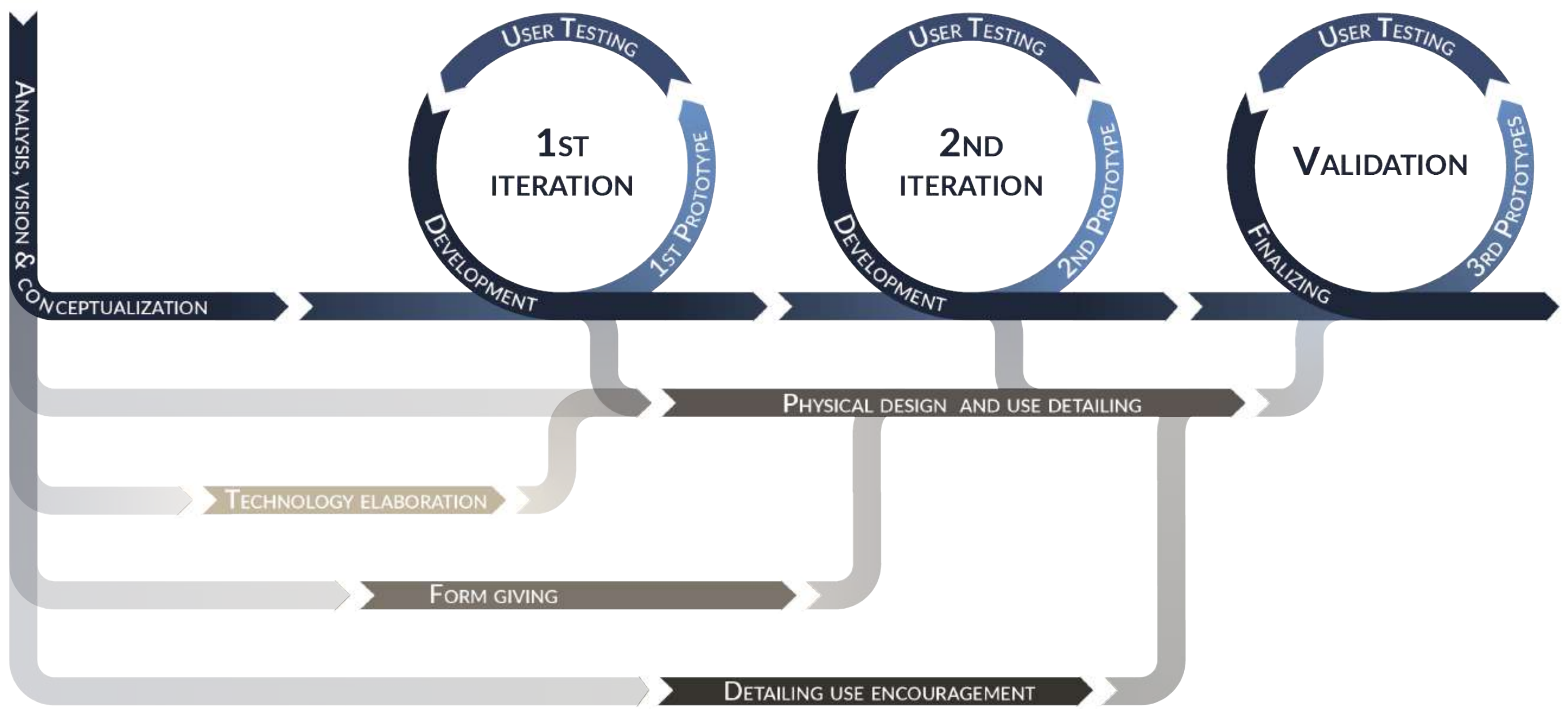


Figure 9.1 Elaboration design approach

Figure 9.1 illustrates the overall design approach of the elaboration phase. The elaboration process was iterative. Continuous mock upping and prototyping served as base for testing and development. In total 3 user tests were conducted. The first two were part of iteration cycles and provided input for the elaboration of the physical design and the use while the third one was a validating test of the design. The technology elaboration, the form giving and the use encouragement detailing was done parallel to these iteration cycles based on the previous chapters conclusions. These all served input for detailing the physical design and the use.

The current chapter summarizes the main findings of the technology elaboration and the first two user tests. The form giving and the use encouragement detailing are discussed in the following chapters.

Figure 9.2 Stethoscope chestpieces designed and manufactured for testing the microphones

TECHNOLOGY ELABORATION

Goal
The technological elaboration aimed to select a recording sensor type for the device. As these sensors have different form factors, the sensor selection affected the possible shape of the design as well.

Method
Three different types of microphones were tested: an electret condenser microphone, a piezoelectric sensor and a MEMS microphone. 2 stethoscope chest pieces were designed that could house the microphones and the diaphragms (See Figure 9.2). These were the first working stethoscopes designed and built during the project. These stethoscopes were tested in the anechoic chamber of the TU Delft to minimize the effect of environmental noise. For further denoising spectral filtering and transducer isolation was utilized. Using each sensor type, 5 heart sound recordings were performed for 10 seconds. The best recordings were selected for each sensor type and these were compared in terms of signal strength, noise too signal ratio and audio quality.

Key findings
The MEMS microphone performed the best during the test. It could capture good quality heart sound signal with high signal to noise ratio compared to the other two slutions. As MEMS is the smallest existing microphone technology, this could contribute to keeping the design as flat as possible. Appendix D-A contains further elaboration on the test.

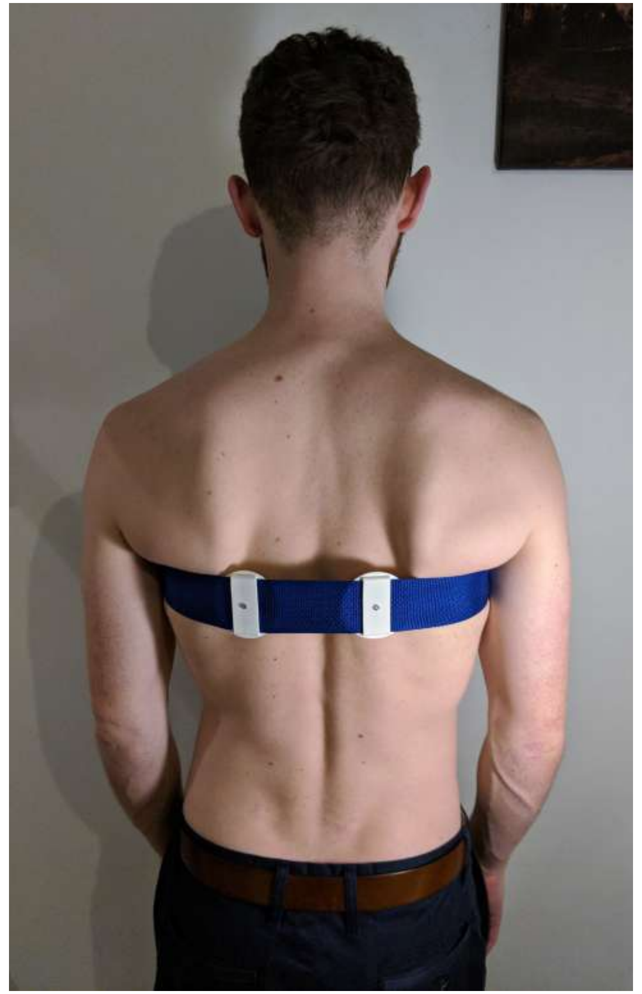


Figure 9.3 First user test - Participant with the prototype

1ST USER TEST

Goal
The primary goal of the test was to verify if the double stethoscope set-up can help users in the horizontal positioning of the device on their back and if so, to what extent. Apart from that, the test was also meant to observe user interactions with the prototype.

Method
The first user test was conducted with young adults because of the unavailability of the target group at this phase of the project. In total 16 people - 10 man and 6 women - participated in the user test with an average age of 24.7. Two separate mock-ups were built for the test. One with single and one with double stethoscope set-up. The participants were first introduced to the project and the test. Then, they had to place the mock-ups on themselves on defined auscultation points. Figure 9.4 shows a participant after the placement. Finally, participants were asked to rate their confidence regarding their positioning accuracy and they were interviewed about their opinion regarding the use of the mock-ups.

Key findings
The majority of the participants felt more confident about their placement accuracy using the double stethoscope set-up. However, it also highlighted that by itself the double stethoscope set-up does not guarantee accurate central positioning. Most participants did not manage to position the mock-up in the center of the back. The test also helped to confirm that the use is not more inconvenient for women and that at least a part of the strap needs to be elastic for comfort, and easy repositioning of the device. Appendix E-A contains further elaboration on the 1st user test and its findings.

2ND USER TEST

Goal
The primary goal of the test was to learn to what extent can people in the target age group comfortably use the design of the device - including the envisioned wall mount interaction and closing mechanism - and to define the most suitable way to support users in the placement and positioning of the device.

Method
6 people participated in the user test - 3 men and 3 women. The average age was 68.3 years. After a brief introduction to the use participants were asked to place the prototype of the device on themselves (see Figure 9.4). In the meantime the interactions with the prototype were observed. After that 3 different placement and positioning scenarios were role-played with the participants. After each scenario participants were asked to rate the comfort and their placement accuracy confidence. In the end, participants were interviewed regarding their general opinion about the use, their likes and dislikes and their preferred placement scenario.

Key findings
All participants were able to comfortably place the mock-up on themselves without pain in their shoulders. Also, all participants were able to touch the device in their back during the positioning, and they all intuitively did so to get feedback on the device position. The main issues regarding the use were the unintentional flipping over of the device during placement and the inadequate closing mechanism design. In the mount holder scenario, the placement of the device is started from an additional holder on the wall mount for the device, which keeps the device on the right height until placement. Participants found this scenario the most comfortable, the most reassuring regarding placement accuracy and it was also the preference of most participants. Thereby, this solution was selected for placement and positioning supporting. The solution is presented in detail later in the report, together with the final design (see Chapter 12). Appendix E-B contains further elaboration on the 2nd user test's setup, the tested placement and positioning supporting solutions and the findings of the test.

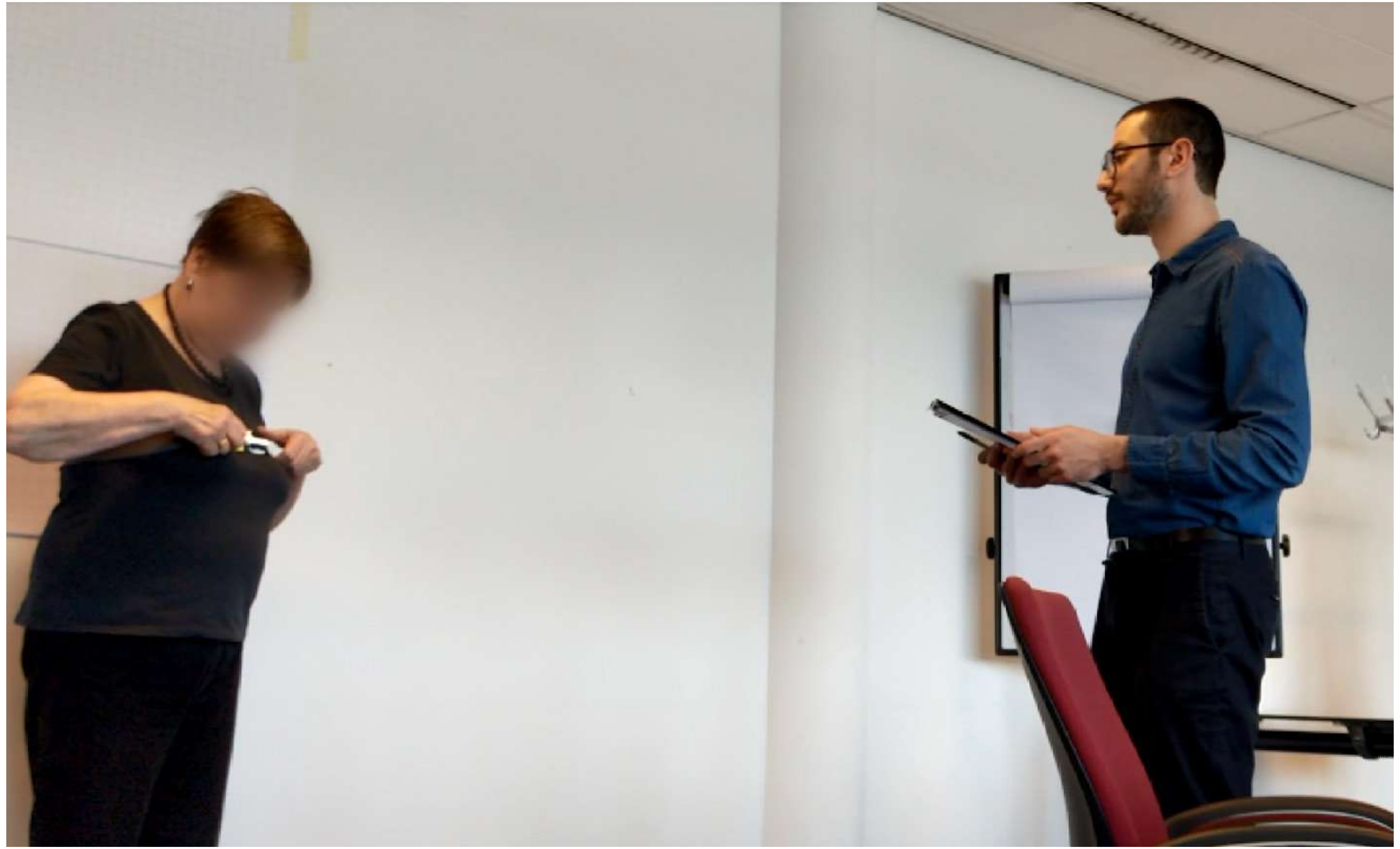


Figure 9.4 Second user test - Participany trying on the prototype

10 ENCOURAGING PATIENTS
To the use

One of the goals defined in the design vision is the development of a device that can encourage people to use it on a long-term. The current chapter introduces the features that are meant to support that and elaborates on the rationale behind these features.

Two main features were incorporated in the design of the device that are meant to encourage users to keep using the device on a long-term:

- Visualizing the accomplishment of measurements
- Making the measurement time more meaningful

These two features were also connected in a rewarding system. Due to the time limitations of the project, the motivational and rewarding features remained on a conceptual level, as proposals. The goal during the project was to explore a conceptual solution for the motivational aspect that can be tested during the validating user tests for gathering insights. Based on the feedback further recommendations are provided regarding the implementation of these features at the end of the report in Chapter 15.

VISUALIZING THE ACCOMPLISHMENT OF MEASUREMENTS

The use of the device can be compared to taking medication. Many times when we need to take medication on a daily basis, we can become uncertain if we have already taken it or not. At these moments, we can look at the packaging if a pill is missing but that only works if we know how many pills should be in the packaging. This can happen even more often with elderly people. A common solution to that are holders that contain seven small departments – one for each day of the week – where people can prepare their weekly medication package in advance. This way users can be surer if they did the measurement or not. These solutions have an additional advantage. When people forget to take the medication, later on, they can see that they missed one dosage. For those patients who have intrinsic motivation to get healthier, this can not only help to remember to take their medication, but it can be frustrating as well to realize that they forgot their medication. This frustration is a good source of motivation which can make people aware that they need to improve their current medication taking strategy. It makes the goal – taking all medicine– and its accomplishment more tangible – emptying all departments.

Inspired by this simple solution the design also incorporates a similar feature. The device has two separate icons for the lung and heart

Figure 10.1 Measurement accomplishment feedback LEDs

measurements. These icons light up when a measurement is needed and turn off after the measurement was performed (See Figure 10.1). The device also contains seven LEDs. After measurement, these LEDs light up and show how many measurements are needed the given week, how many have been accomplished, and how many were missed (see Figure 10.1). To make the feature more motivating for those patients as well who have less intrinsic motivation to improve their health, it was incorporated into a rewarding system.

MAKING THE MEASUREMENT TIME MORE MEANINGFUL

Users need to perform the auscultations seated. During the 1-minute measurements, they need to remain still and silent, otherwise, they corrupt the recordings and they need to take deep breaths meanwhile – just like in the GP's office during auscultation – to improve the audio quality of the recordings. This limits the possible activities that can be performed simultaneously and can make the measurements boring over time. Thereby, enriching this experience could contribute to the long-term device adherence.

Figure 10.2 Making the measurement time more meaningful with a ritual which facilitates the integration of the use to the daily routine

The goal was to define a ritual – an interaction that has a meaning attached to it, which gives it a value that exceeds the primary, technical function (Pasman & Van Der Lelie, 2003) – that can facilitate the integration of the use to the daily routine of patients and that is related to the use (see Figure 10.2).

Many studies have shown the positive effects of breathing exercises. They can improve how well the body uses oxygen and thereby improve dyspnea, strengthen the heart, lower the blood pressure and improve circulation (Felson, 2017), they can improve the left ventricular ejection fraction of heart failure patients (Adamopoulos et al., 2014) and they have been proven to decrease anxiety and depression in COPD patients (Yohannes et al., 2010). Heart failure and COPD patients are familiar with them, many patients include breathing exercises in their daily routine.

Nic van Passen was interviewed about the incorporation of breathing exercises in the concept. He is a physiotherapist at 'Fysiotherapie Delft' - specialized on COPD patient. During the interview, he pointed out that the involvement of learning and practicing breathing exercises during measurements can complete the user experience with an activity that has additional benefits – e.g., improvement of the breathing capacity – that patients can experience in the short term (2018 April 09). Nic van Passen also explained that breathing exercises are easy to learn. Users can easily learn them from instructional videos, which they could access in the application of the device. The digital platform for learning the exercises was not elaborated due to the time constraints of the project.

All in all, breathing exercises were selected as activity during measurement because patients are familiar with them, they help to provide users more immediate and tangible benefits than the measurements alone, they are highly related to the use and contribute to good quality recordings and users can attach their personal meaning to them. For example, for many patients breathing exercises are relaxing remedies that help them to handle their anxiety. These patients can relate these meanings to the use of the device as well. This can enrich the measurement experience for many users.

REWARDING SYSTEM

To make the system more motivating, these two motivational features are connected in a rewarding system. In the system, the visualization of the accomplished measurements can serve as visualized points (see Figure 10.3). If participants do all their measurements, they receive a reward. The breathing exercises can become the reward. A benefit of this is that the breathing exercises can be accessed in a structured way. New breathing exercises can be unlocked over time, and a pace can be set in the system. Another advantage is that this way the use can be more diverse as people do not only need to repeat the same breathing pattern over and over again during the use but they can learn new exercises.

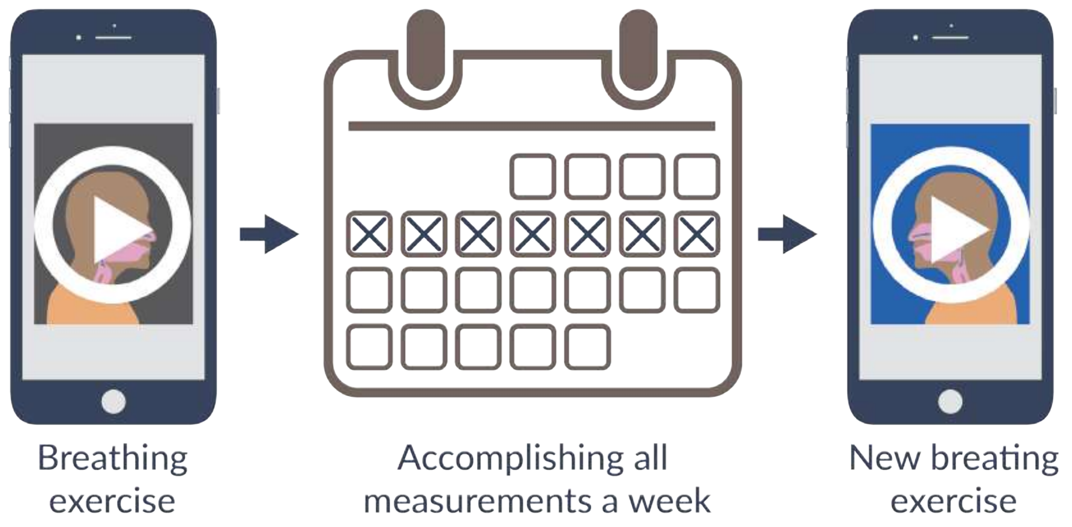


Figure 10.3 Rewarding system vision

11 FORM GIVING

The form giving chapter elaborates on the form giving process during the project. The chapter starts with presenting the aesthetic principles which guided the form giving. This is followed by moodboards and a brief conclusion on how to communicate these aesthetic principles via design. Finally, the form giving strategy is briefly described and the iterative form giving process is illustrated with montages from the process.

AESTHETIC PRINCIPLES

The first step of the form giving was defining what aesthetic principles should the design follow. These principles were based on the previously defined vision. The design should look:

- Medical
- Friendly
- Hygienic
- Intuitive

The medical look is important because people need to trust the device and accept the results of the measurements. People need to take the use seriously and adhere to the use of the device. However, many times medical devices can look sterile and can lack 'personality'. Moreover, hospital visits are often among the worst experiences of chronic patients, thereby it's important that the device shouldn't remind users to the equipment of these facilities. By bringing the stethoscope from a medical context to people's homes, the design needs to become friendlier. As these two principles are contradictory, a good balance between them is one of the main aesthetic challenges.

Hygienic appearance is one of the core aspects of medical look as health and dirt are instinctively opposing. Also, the device needs to be in contact with the bare skin of users. Thereby, clean and hygienic look is essential.

Although intuitiveness is not a mainly aesthetic aspect, design can enhance how intuitive do users perceive a product. As the primary target group includes elderly people, it is important not to scare them away from the use with a complex looking interface but instead guide them in the use to achieve a pleasant user experience.

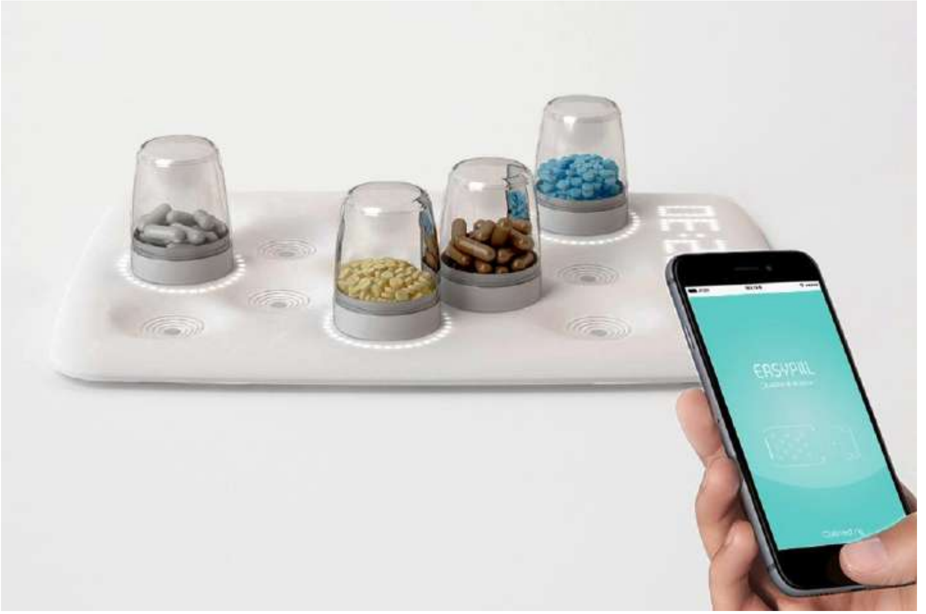
To understand what do these principles mean from a design perspective, existing products were analyzed to define what design features and solutions could help to emphasize these aesthetic principles. The gathered examples are presented with mood boards in the following pages. A short text description also summarizes the main observations based on these designs.


MEDICAL

Medical designs are function oriented. The sterile, professional and reliable appearance can be emphasized with the prominent use of white with additional black, metal or blue features. Smooth, organic shapes help to give a clean, futuristic medical look.


FRIENDLY

There are various ways to communicate friendliness via design. Most often its done with smooth, round shapes and saturated colors. Textiles can also effectively emphasize a comfortable, friendly appearance not only visually but via the tactile experience as well. Silicon straps emphasize a more sporty than friendly and comfortable look, thereby, using fabric for the strap of the device could highly contribute to a friendlier look. Soft, non-cold materials can further improve the tactile experience and can contribute to perceived friendliness. This is especially important for those parts of the design that touch the bare skin of users.



INTUITIVE

Minimalistic and ‘clean’ product designs can provide a great base for an intuitive appearance. The simpler is the overall shape and color of a product the easier it is to highlight parts that are primarily related to the use. Distinct shapes and textures, saturated colors and lights are great ways of highlighting relevant details.

HYGIENIC

Two factors greatly contribute to the hygienic look of products. How hard is it to spot if the product is dirty, and how hard does it seem to clean the product? Thereby, organic shapes, small gaps at parting lines, white color and no hardly reachable surfaces and edges work well for communicating clean, hygienic appearance of products.

FORM GIVING

These observations provided the base for the form giving. The form giving of the device and the wall mount was done in an iterative manner using computer sketching and 3D modeling techniques. Figure 11.3, 11.4 and 11.5 contains montages of the form giving process.

The strap

The strap needs to be manufactured from a material that is flexible can stay in touch with the skin without causing discomfort. Most products that have straps use silicon for them. However, silicon stick to the skin and the use of silicon for the strap would make it look too sporty. On the other hand, fabric can lead to a friendlier and more comfortable look. Thereby, fabric was selected for the material of the strap which embeds the electronic components of the device.

Designing with fabrics requires a hands-on approach as textiles can greatly vary in softness, stiffness, structure and color. Due to that, the strap was designed using a slightly different approach. Thereby, the form giving of the strap started with visiting fabric markets and shops and acquiring textiles that could fit the device (Figure 11.1) and selecting an aesthetically pleasing combination of the available materials. Then, prototypes were sewed with the help of a tailor in an iterative manner. In total 3 iteration cycles were done to improve the shape of design (Figure 11.2).

Figure 11.1 The acquired fabrics

Figure 11.2 Iteration during the form giving of the strap

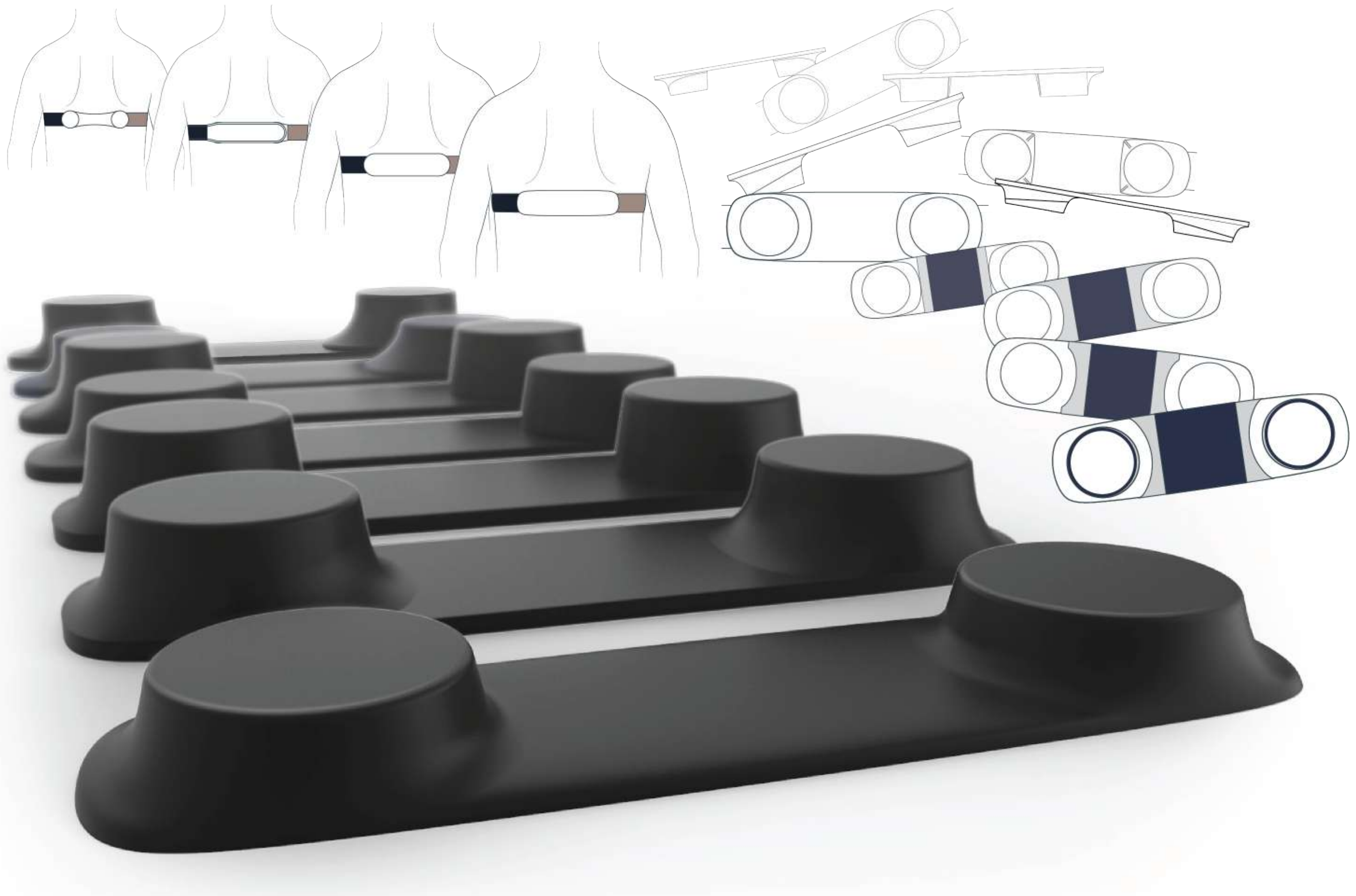


Figure 11.3 Shaping the device

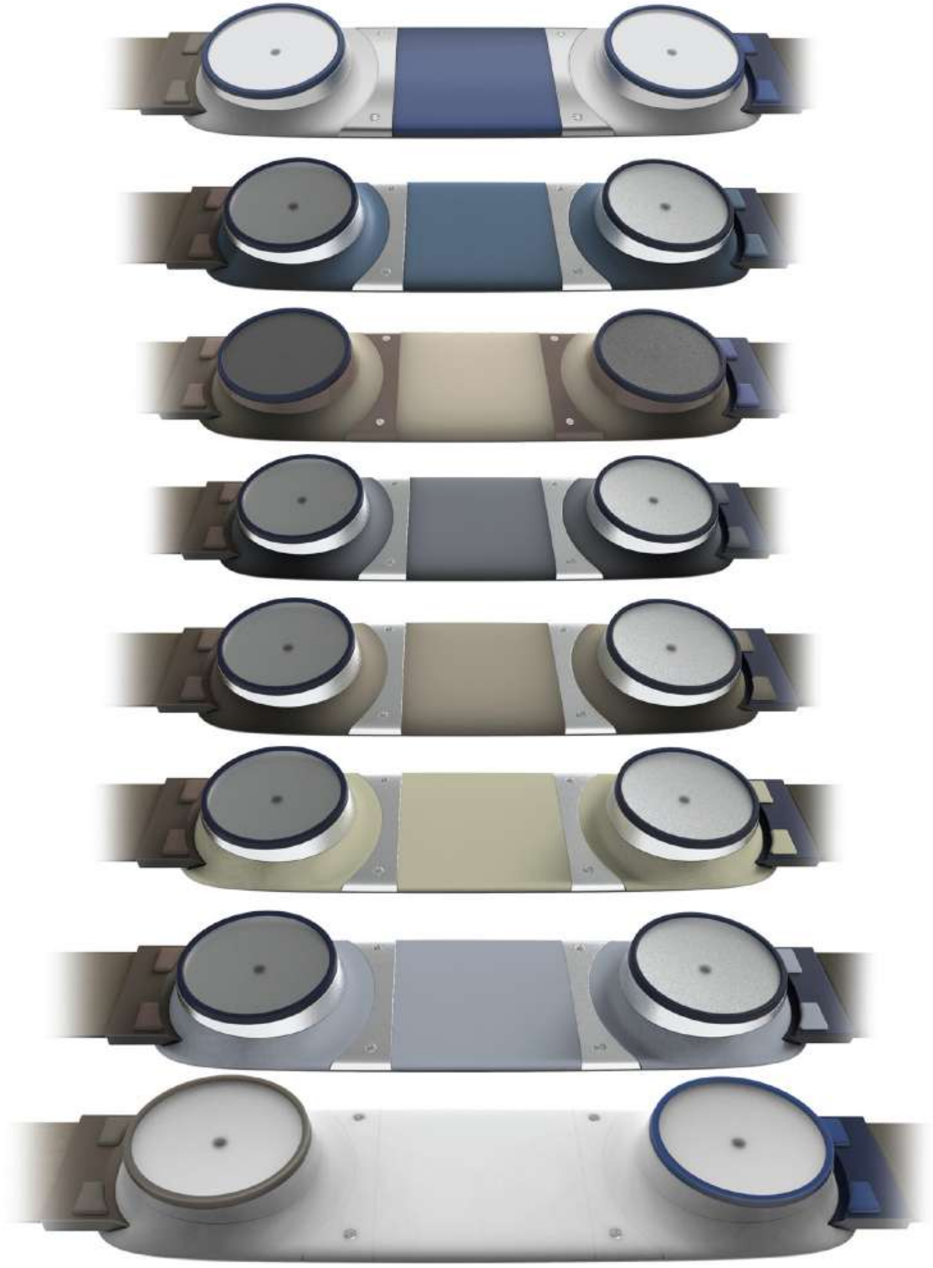
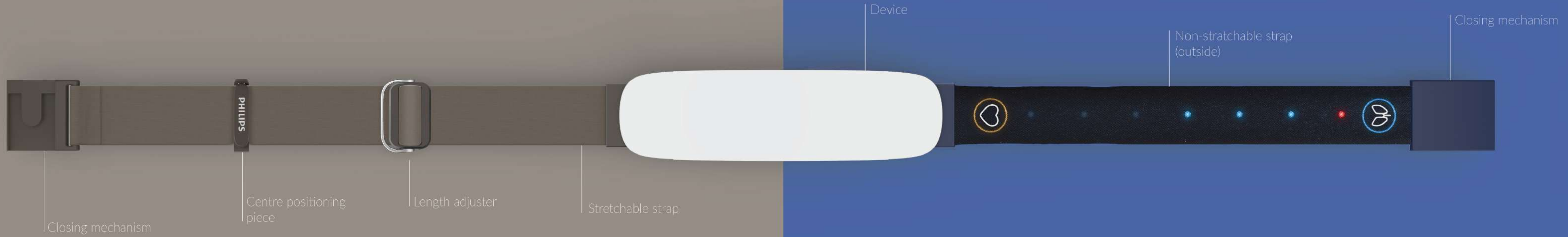


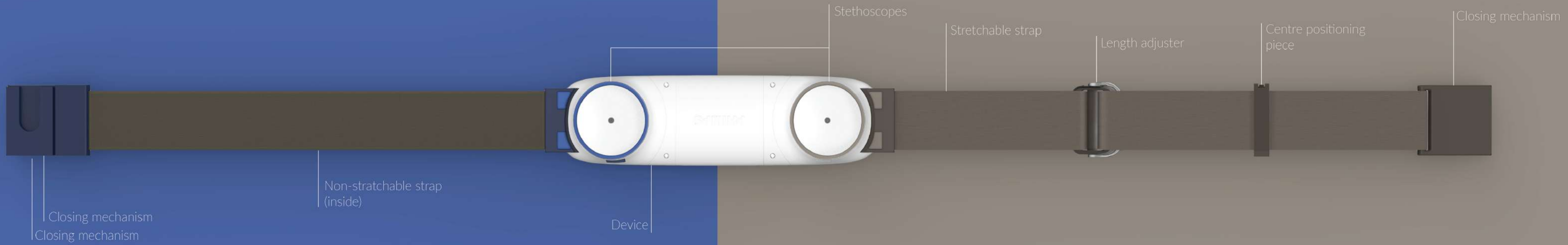
Figure 11.4 Experimenting with the final color of the device

Figure 11.5 Shaping the wall mount

12 FINAL DESIGN



PHILIPS | Serin


Stethoscopes
Stretchable strap
Length adjuster
Centre positioning piece
Closing mechanism
Non-stratchable strap (inside)
Device
Closing mechanism
Closing mechanism

FEATURES

Double stethoscope set-up

The double stethoscope set-up of the device (Philips Serin) supports users in the horizontal positioning of the device and halves the measurement time for the daily lung measurements. The two soft paddings that are in contact with the users' skin during measurements are colored differently. This use cue supports users in orienting the device (left side – right side) during use and provides a friendlier look to the device. The same colors are used for the strap connecting pieces as well.

Flexible center

The center of the device is designed in a way that the device can flexibly follow the users' body curves when worn, but it still provides a reliable and safe electrical connection between the two ends of the device. The design was inspired by the build-up of headphones. Its structural buil-up is presented in the Build-up subchapter (page 96).

Soft materials

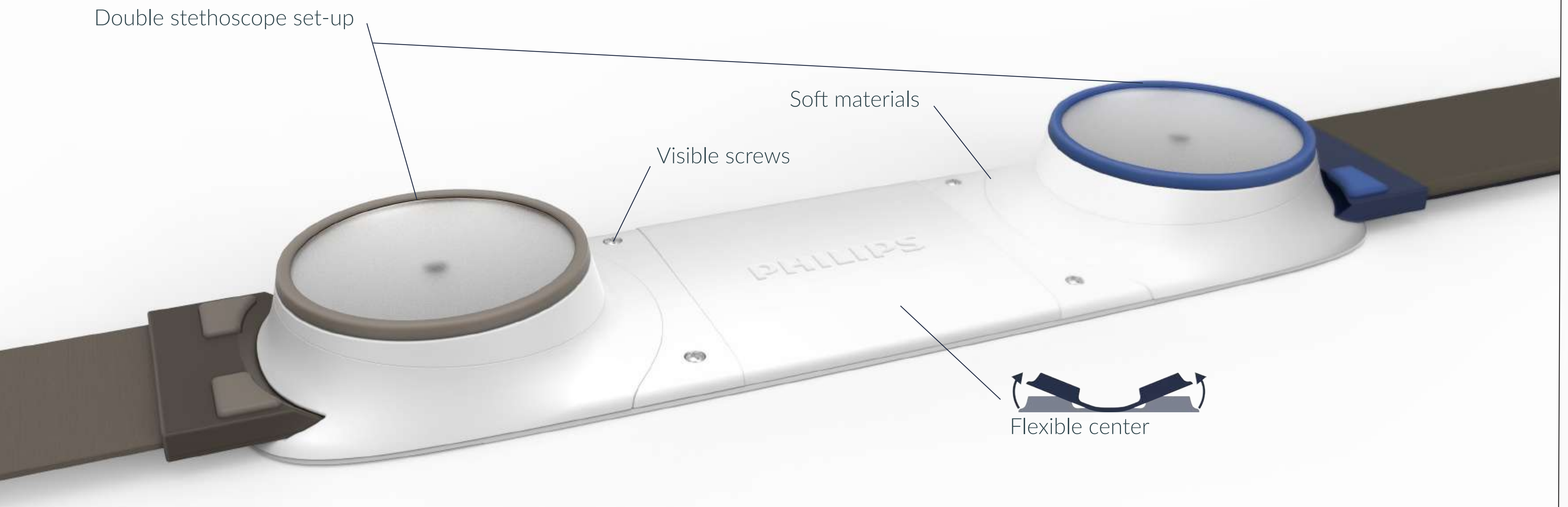
All components of the device are coated with silicone rubber on the inner to provide a softer and friendlier look and feel.

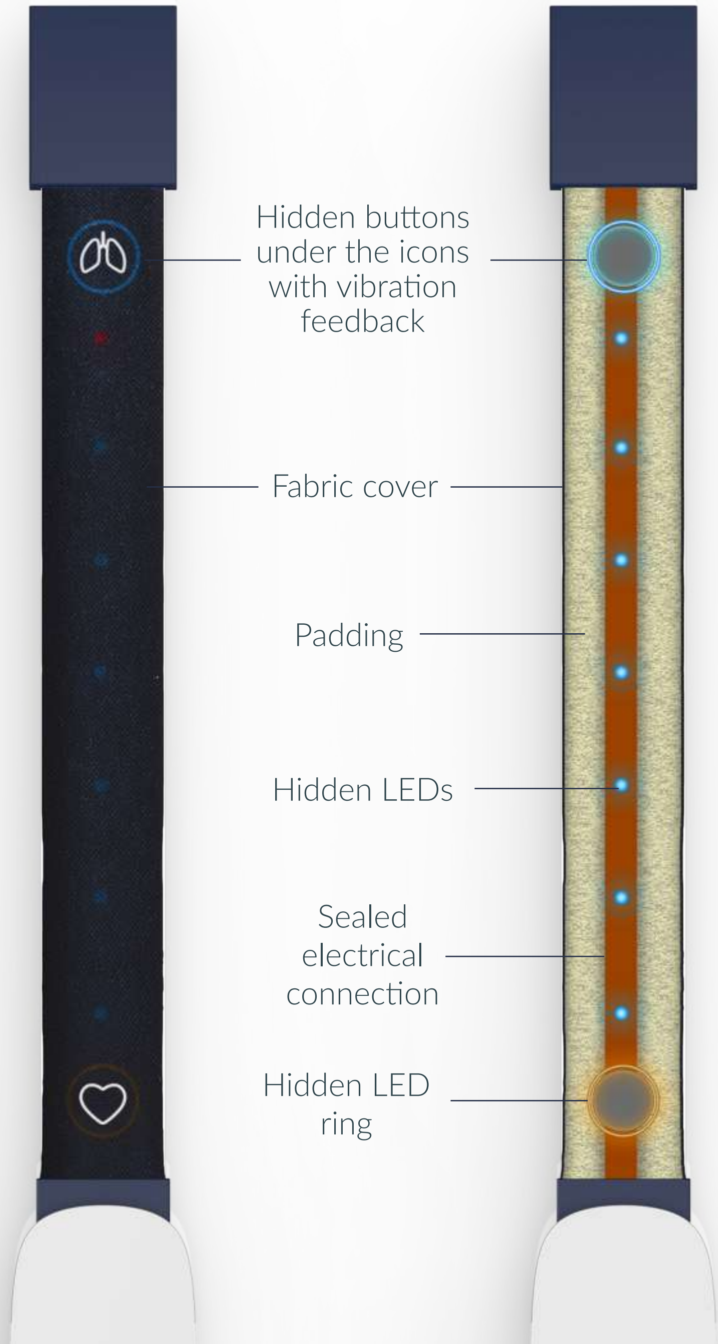
Visible screws

The closing screws of the device are left apparent. These structural components provide the design a more reliable look for the elderly target group.

Hidden LEDs

The strap contains hidden LEDs that can be used to indicate to the users when the device turns on and for feedback on measurement accomplishment. The LEDs inside the strap are silicon coated so the strap can be washed in the machine. By hiding the LEDs and only showing them during feedback, the devicee has a cleaner interface.





Hidden buttons

The measurement starting buttons are hided below the heart and lung icons. The lung and heart measurement starting buttons are separated for easy and clear use and for ensuring that the buttons are on the front of the patient for both lung and heart measurements. The buttons consist of two conductive fabric layers separated by a foam layer with holes on it. This way, when users press on the buttons the two conductive fabric layers touch. The advantage of this button construction is easy integration to the padding of the strap and washability. As the buttons do not provide haptic feedback upon press, small and flat vibrating motors complete them. These motors are sealed with silicone for washability. The hidden LED rings around the buttons remind users of the measurements.

Electrical connection

The device and the charging station are connected with the strap. Thereby, a good conductivity copper wire is embedded in the strap for delivering the current. The wire is sealed with a silicon coating for washability.

Turn on button and feedback light

The turn-on button is on the side of the device. As the device automatically turns on when taken off from the charger and automatically turns off when out of use for 10 minutes, the turn-on button mainly serves as back-up for the occasions when the device is not being stored on the wall mount. A feedback LED is placed next to the turn on button to inform users about the turned-on state. The feedback LED turns orange when the device is being charged and blinks orange when the device is low on battery.

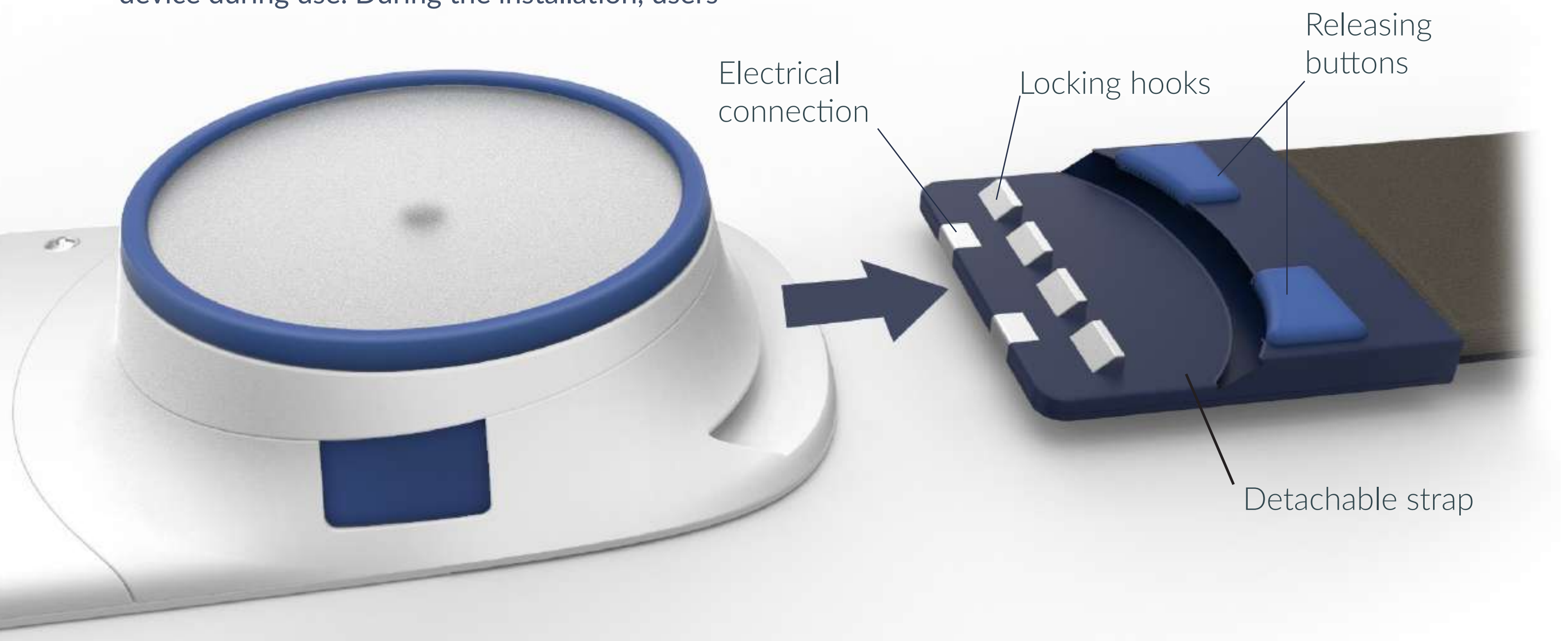
Detachable strap
Users can detach the straps for washing. The non-elastic strap's connection provides electrical connection to the housing. The locking mechanism of the strap is placed on the strap – not the device – to emphasize to the users that the releasing buttons' functionality is related to the straps, not to the operation of the device. To ensure that users don't open the locking mechanism accidentally during use, each strap has two buttons that need to be pressed simultaneously for releasing.

Center positioning piece

The center positioning piece is a use cue that helps patients in the horizontal centering of the device during use. During the installation, users first need to adjust the length of the strap and then clamp the center positioning piece on the elastic strap.

Locking length adjuster
The center positioning piece only remains in the center during use if the length of the strap remains unchanged. To ensure that, the length adjuster is equipped with a locking mechanism.

Easy closing mechanism
The closing mechanism of the strap is an altered version of Fidlock's snap buckle (Figure 12.1). This easy and convenient closing mechanism uses a small magnet for locking. Users can snap it together or on the wall mount from multiple directions while it can only be opened by sliding the buckles sideways. The magnet in the locking mechanism is shielded from the inner side of the buckle, thereby, only marginal magnetic force escapes towards the patient. This magnetic force theoretically shouldn't cause trouble for patients with pacemakers and ICDs. However, this needs to be confirmed by testing before the device arrives at the market. The slight alteration compared to the original Fidlock is that the version for the Philips Serin needs to be able to provide an electrical connection when the device is in the holder. Due to the superior comfortableness of the buckle, a collaboration with Fidlock for the development is strongly recommended to Philips. Before that, the existent version of the snap buckle is user tested during the validating user test.



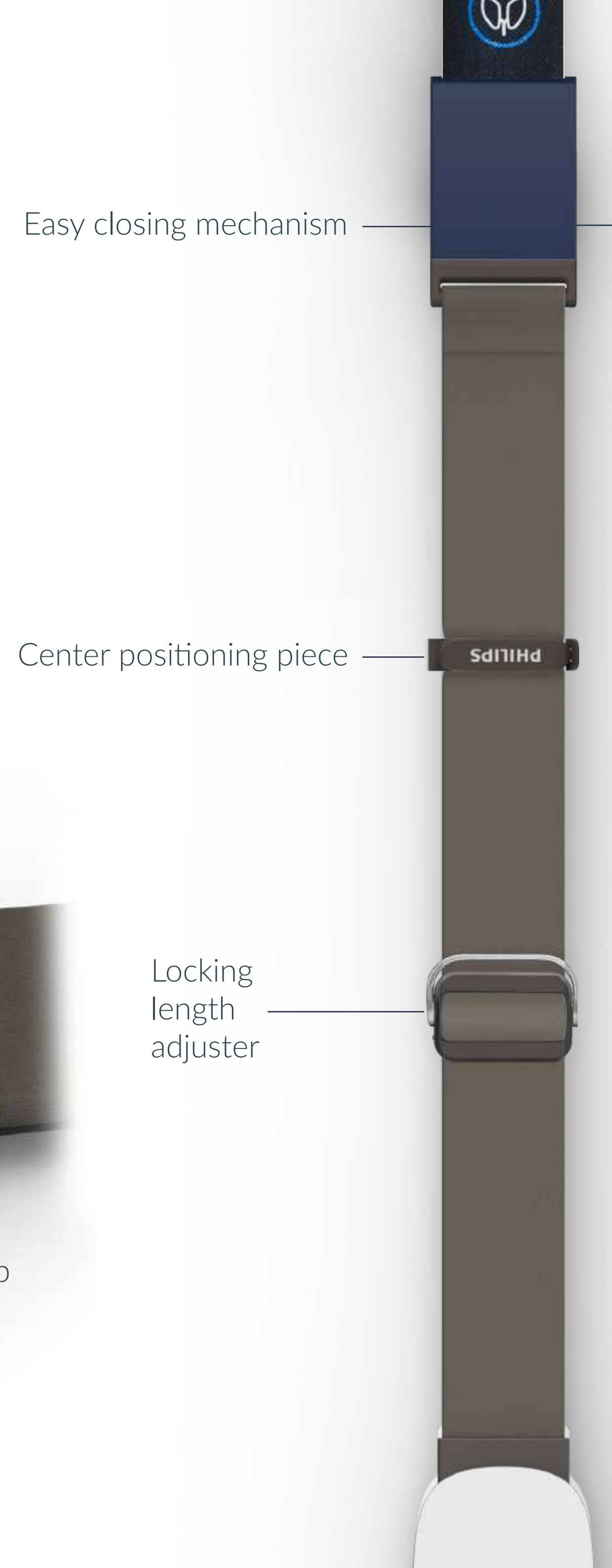


Figure 12.1 Snap buckle from Fidlock ("Snap buckle – Fidlock", 2018))

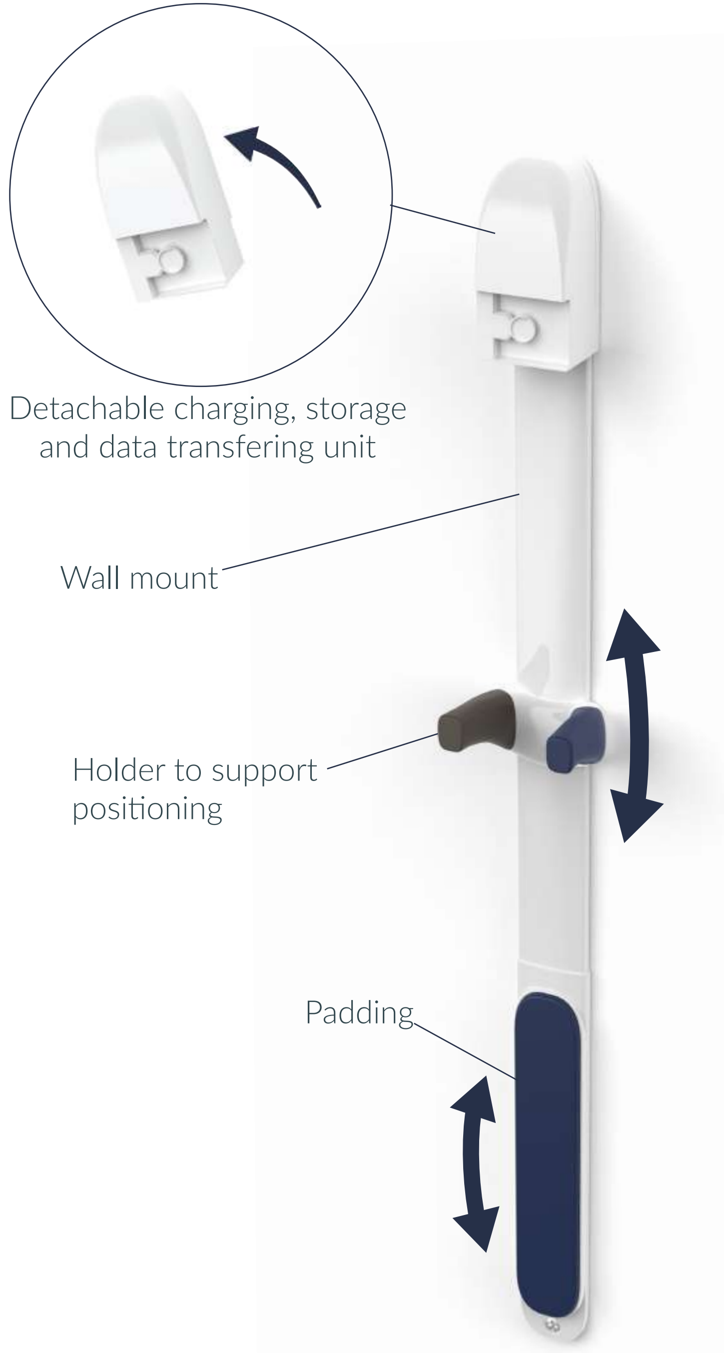
Wall mount
The wall mount needs to be drilled on the wall to a convenient height for the user (with detachable unit slightly below their shoulder).

Detachable charging, storage and data transferring unit

The top piece of the wall mount is where the users can place Philips Serin for storing. For the attachment of the device its equipped with the counter-partner of the closing mechanism of the device. Its other main functionalities are charging and measurement data transferring to the central server for processing (see Chapter 8 - Page 71). Users can detach the unit from the rest of the wall mount. This way, they can bring it with themselves on a trip for charging the device.

Holder to support the positioning
During the placement of the Philips Serin, users can attach the device to a holder on the mount. During installing this holder needs to be positioned to the right height on the central aluminum profile for each user. After that, the holder can support users in accurately placing the device on the right height for them. The device can be attached to the holder via magnets. Just like the soft paddings of the device, the arms of the holder are color-coded to help users orienting the device they attach the device to it.

Padding
The bottom of the wall mount has a padding. This padding protects the device from hitting



against the wall when its placed back on the wall mount. The aluminium profile that connects the padding with the detachable unit’s holder can slide into the padding at the back. This way the wall mount only needs to be manufactured in one size but the padding height can be adjusted to the different device sizes. For the device measurements, see Chapter 15 (page 105).

BUILD UP

During the project, the inner structure of the device was detailed. The current subchapter provides an overview of the components of the device, their function, materials and the assembling of the components. The following requirements were taken into account during the detailing:

- The center of the device needs to be flexible so the device can follow the curvature of users while being worn
- The housings of the stethoscopes cannot be flexible as it needs to protect the technology inside of it
- The two stethoscope heads need to be electrically connected
- The straps need to be electrically connected to the inside of the housing but remain detachable from it
- The device needs to be as flat as possible to make it comfortable for the users to wear it
- The device can be stored in the bathroom, thereby it needs to be waterproof.
- No parting lines should be visible on the back of the device. This is preferable because the back of the device faces outwards during storage. This way the device has neater aesthetics while being stored.

The back plate and the central closing piece (Figure 12.2). of the device are injection molded from POM. POM is an ideal strong but flexible plastic that can enable the back plate to deform and return to its original shape after use. The magnets that attach the device to the mount holder during the placement are inmolded in the back plate. So are the threaded inmolds. The

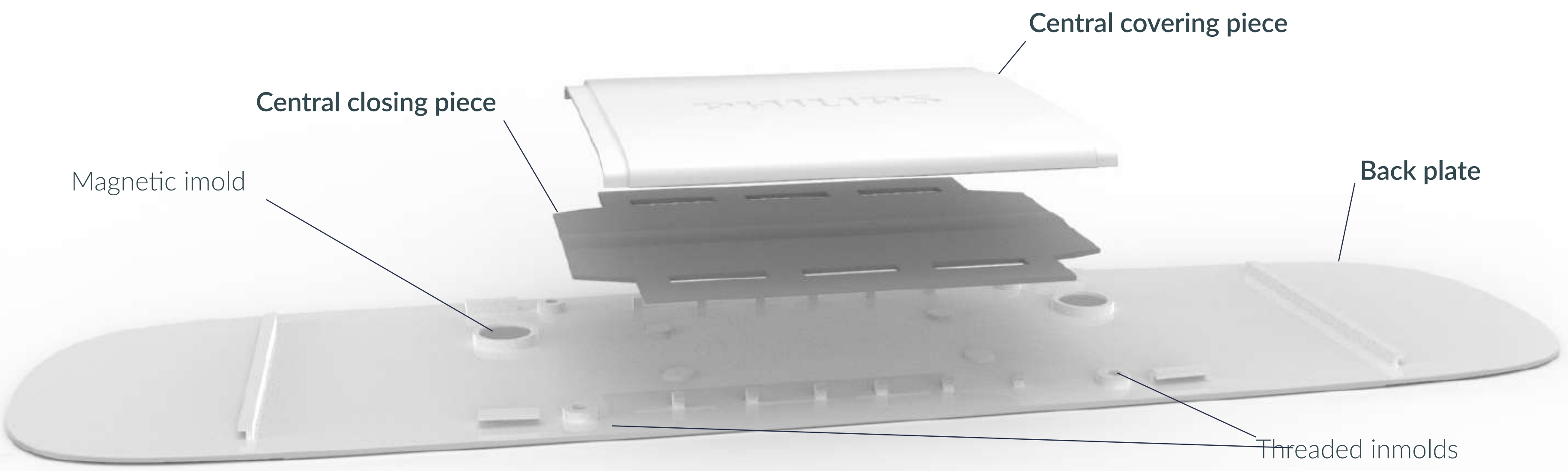


Figure 12.2 Device assembly - Step 1

central covering piece is injection molded from silicone rubber.

During the assembling, the flaps of the silicone piece need to be slid below the central plastic so it can hold the silicone piece down (Figure 12.3). The central plastic is attached to the back plate with a set of snap fits. The snap fits allow the central plastic piece to slide sideways on the back plate during deformation. The other function of the central plastic piece is the protection of the electric cable that connects the two stethoscope heads. The silicone central covering piece seals the housing back plate on the two sides.

There are no additional requirements on the material of the bottom of the stethoscope housing (Figure 12.4), thereby it can be injection molded from polyethylene. Silicone rubber is used for coating its outer surface for a soft touch and a uniform look with the other components. The part contains a set of inmolded screw holes for the attachment of the upper part of the stethoscope housing and a pair of inmolded connecting pads for the electrical connection of the straps with the inner technologies. During the assembling, a sealing silicone ring is placed inside first, which seals the connection between the bottom and the top of the stethoscope housing. Then a sealing plate is placed inside which seals the holes at the strap connection. Finally, an injection molded fastening piece is placed on top of it which holds the sealing plate in place.

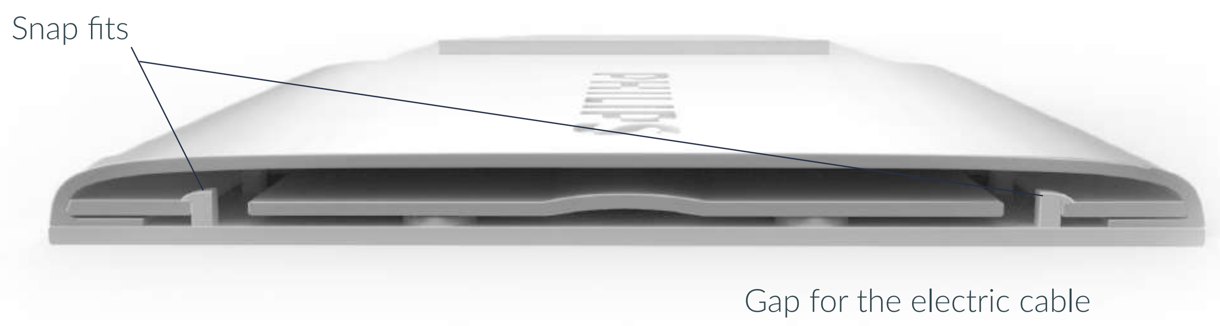


Figure 12.3 Device assembly - Step 2

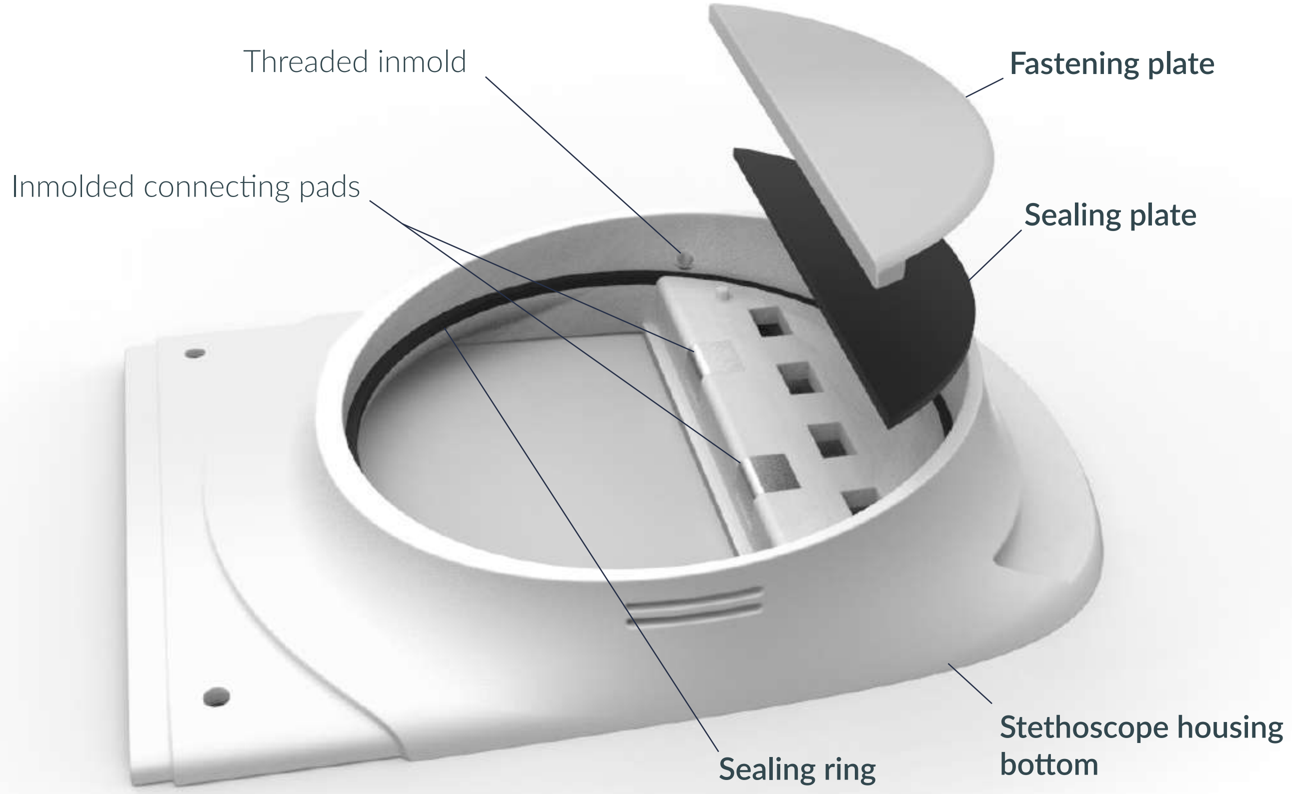


Figure 12.4 Device assembly - Step 3

The top of the stethoscope housing (Figure 12.5) is molded from aluminum. Aluminum was selected because of it's good audio qualities, light weight and low price. The outer surface of the piece is coated with silicone rubber for a soft touch and a uniform look with the other components. The PCB is attached to the housing with a set of screws.

After that, the top of the stethoscope housing is placed on the bottom (Figure 12.6). On Figure 12.7, the microphone sealing between the top of the stethoscope housing and microphone is visible. This sealing is important for closing the air inside of the chest piece, so the sound waves are transferred from the diaphragm to the microphone in a closed volume. This improves the audio quality of the recordings and helps to isolate the microphone from the environmental vibrations. After that, the bottom of the stethoscope housing is screwed to the top from the inside (Figure 12.7). This way, these screws cannot be seen from the outside. Then, the battery is placed inside of the housing and the

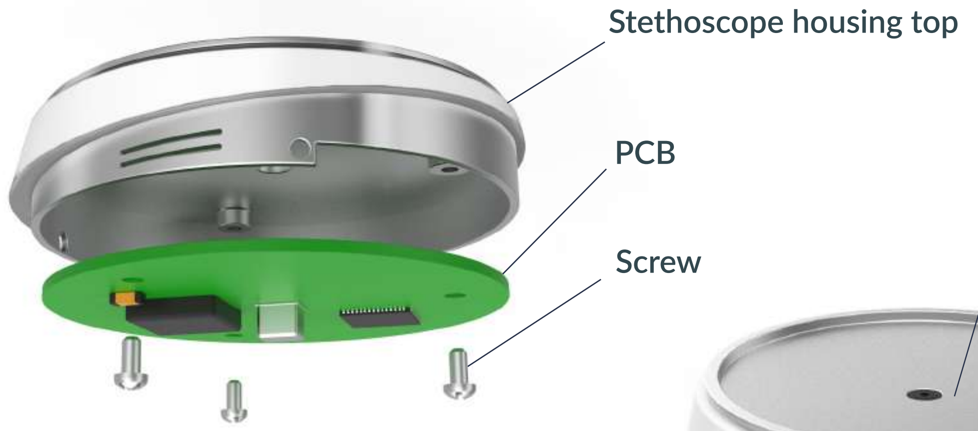


Figure 12.5 Device assembly - Step 4

Figure 12.6 Device assembly - Step 5

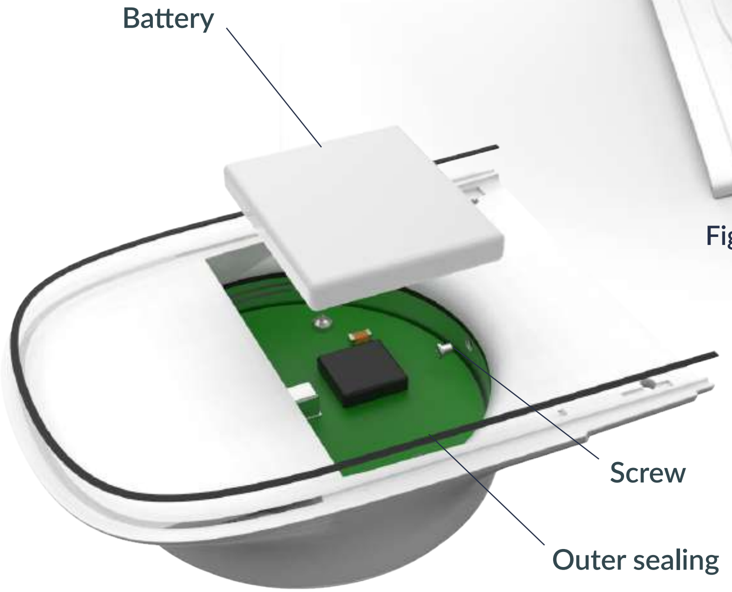


Figure 12.7 Device assembly - Step 6

outer sealing is placed on the bottom of the housing.

The next step is to slide the stethoscope housings on the back plate. The back plate has a set of overhanging features that interlock with the stethoscope housings and hold them down after they are slid to place (Figure 12.8).

After stethoscope housings are slid to place the closing pieces can be placed on top of them (Figure 12.9). These pieces need to hold the housing together, thereby they need to be non-flexible and strong. Thus, they are molded from aluminum. The outer surface of the pieces is coated with silicone rubber for a soft touch and a uniform look with the other components. These pieces are held down with a set of screws. Finally, the diaphragms are placed on the stethoscope. The diaphragm pieces are held in place with two rubber rings. The rubber material makes the touch of the silicone soft and warm, they seal the diaphragm and the flexibility of these components makes the assembling easier.

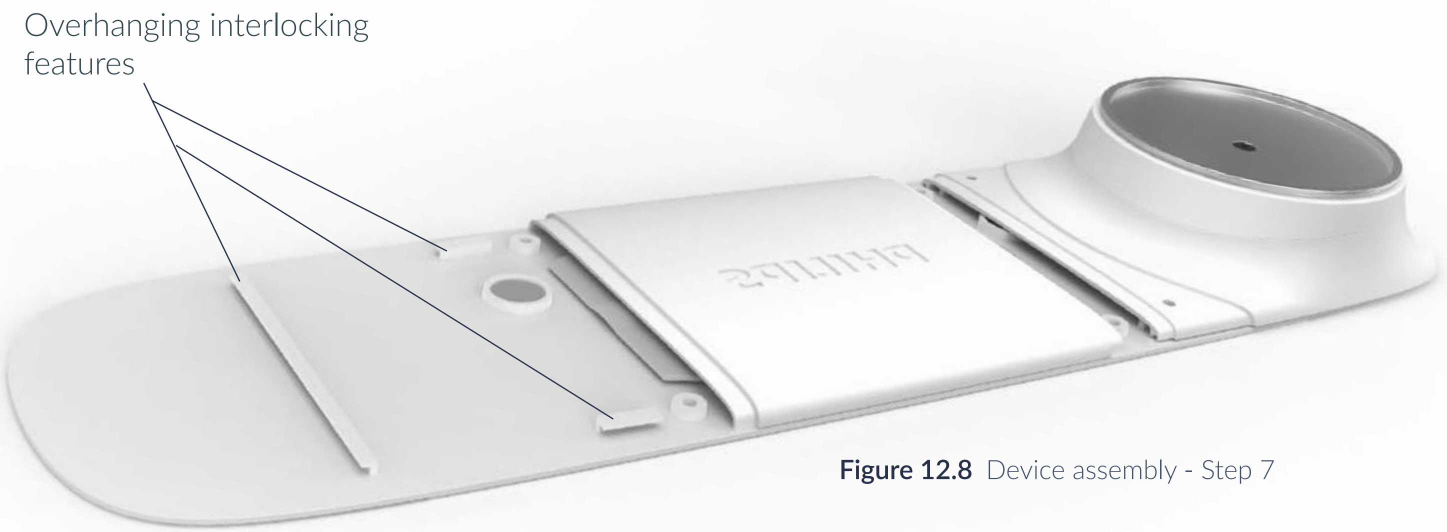


Figure 12.8 Device assembly - Step 7

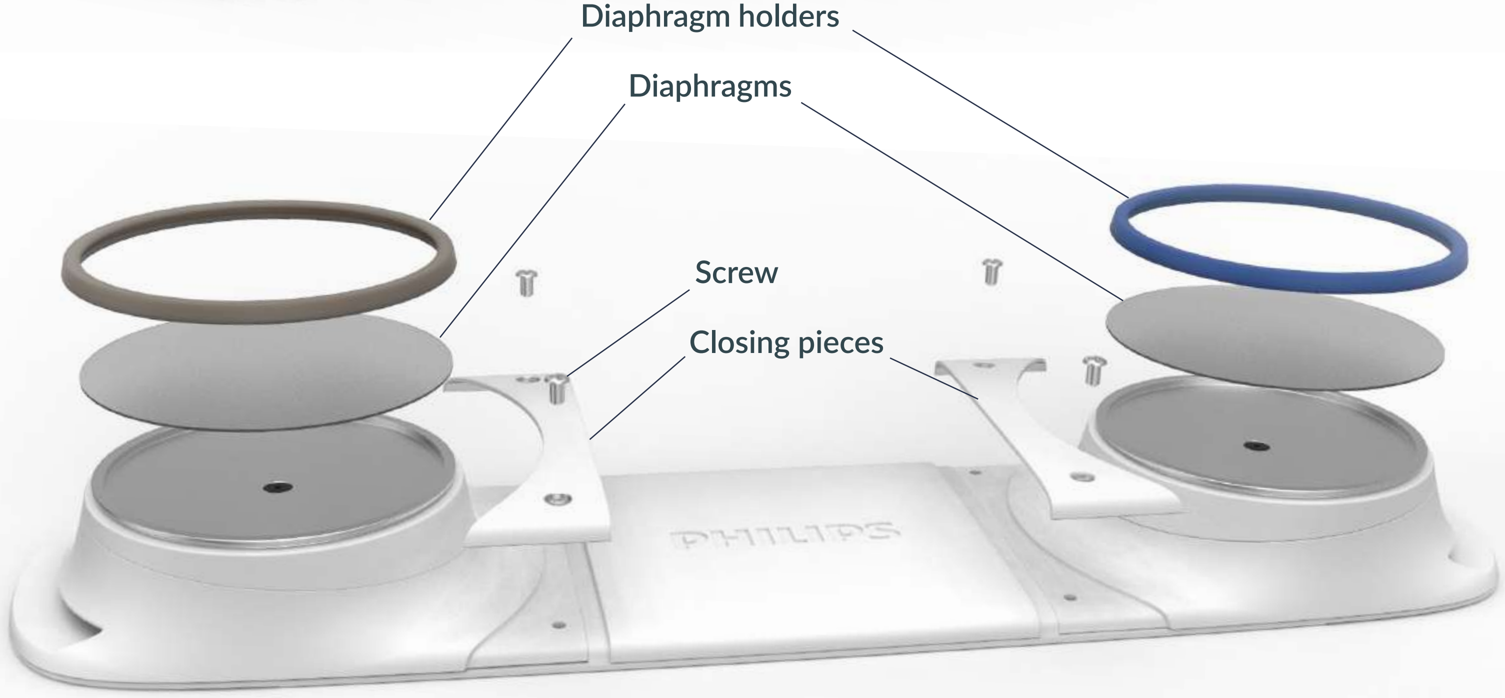
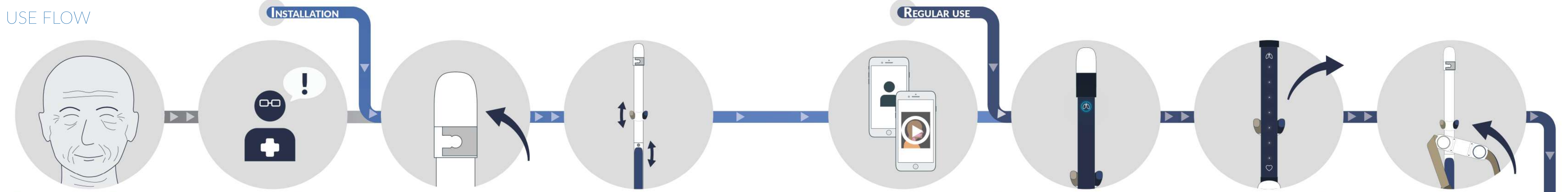


Figure 12.9 Device assembly - Step 8

USE FLOW



This is Kees. Kees is 72 years old and he has stage III COPD. The use flow will be demonstrated via him.

Kees hears about the Philips Serin from his GP.

Afer buying the device Kees's son fixes the wall mount on the wall

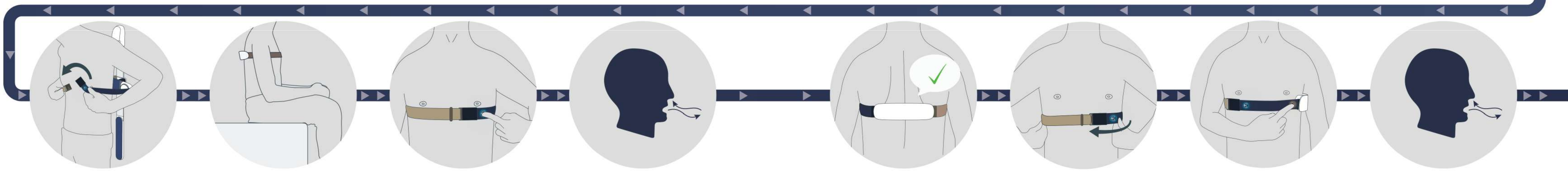
He adjustes the padding height to the device length. He also sets the mount holder to the right height for Kees with the help of the app

Kees sets his profile. When he is ready, he can accesses the first video guided breathing exercise

The reminder lights turn on when a measurement is needed

When Kees takes of the Philips Serin, it turns on automatically. The hidden LEDs light up so Kees is aware that it turned on

Kees places the device on the mount holder. The holder is color coded so he knows how to orient the Serin on the holder



Kees places the device on himself with the help of the wall mount

He learned from the manual of the Serin that he needs to sit and stay silent during the measurements

When he is ready, he presses the button on the strap. During the measurement the button is softly blinking so Kees knows its on

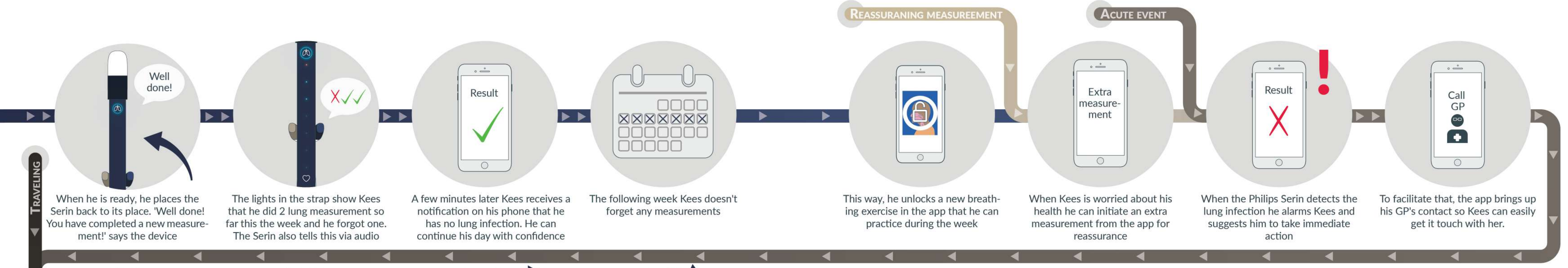
During the measurement he practices the breathing exercise he learned from the video

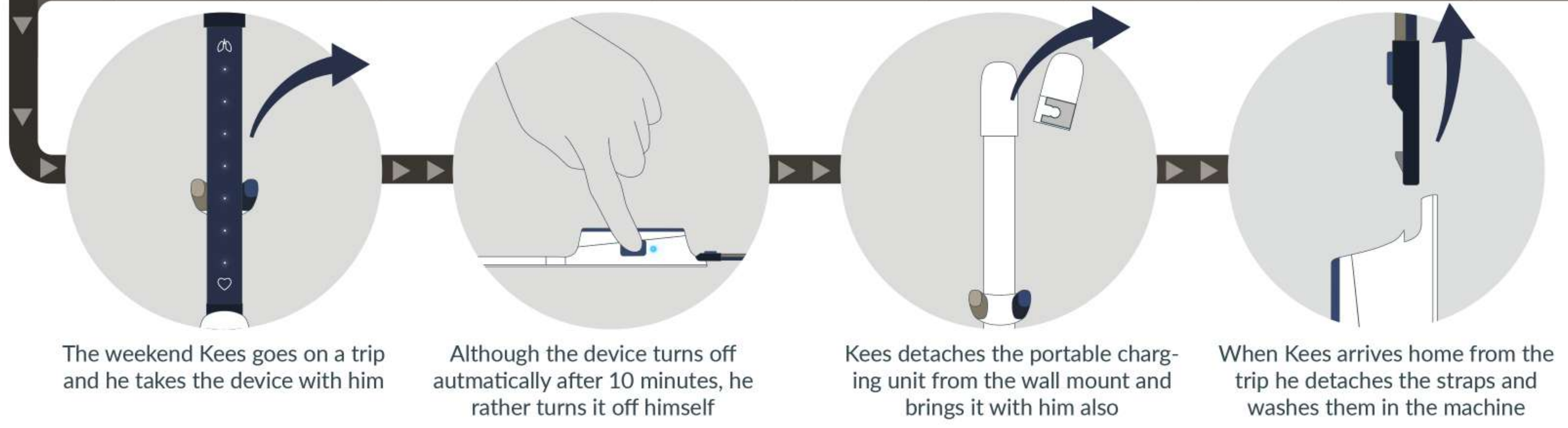
After 1 minute the measurement is ready. The device beeps and confirms in a voice message to Kees that the measurement was valid

Kees rotates the strap around to do the heart sound measurement as well

He presses the button for heart sound measurements. The Philips Serin starts the recording

Heart sound measurements only take half a minute but he still does a couple of cycles of the breathing exercise





PLACE OF USE

The place where the wall mount of the Philips Serin is drilled on the wall has a major impact on where the device is actually being used. The wall mount is intended to be placed in the bathroom of users (Figure 12.10). However, users can make their own decision regarding where to place the wall mount. A couple of recommendations are advised to be taken into account:

- The device uses LED lights to remind users of the measurements. Thereby, it is advised to place the wall mount to a place in the flat where users pass by multiple times during the day
- Placing the wall mount on sight can also contribute to remembering to the use because seeing the device helps to remember the measurements
- The measurements need to be performed half-naked and on a daily basis, preferably at the beginning of the day. Thereby, a location where users are getting cleaning themselves or get dressed is advised.
- The measurements need to be performed seated, at a silent place
- The wall mount needs to be within 1,5m to an electric outlet.
- The wall mount needs to be within reach of a secured wireless network for uploading the measurement results to a central server

Figure 12.10 The device drilled on the wall at the entrance of a bathroom

DEVICE MEASUREMENTS

Figure 12.11 shows the most important measurement of the device. The diameter of the diaphragm and the distance between the two diaphragms fundamentally define the sizes of the device. The diaphragm diameter is 50 mm as that is the recommended diameter for stethoscopes used for cardiac purposes. The distance between the diaphragms was defined with the help of David Smeekes, GP and employee of the Hartstichting. The 16 photos taken from the participants during the first user test were shown to him. Based on these photos and the measurements of the mock-up he could define that 15 cm is certainly wide enough for the wider people as well, while for people with extremely small chest diameter its still not a problem if the device slightly arrives to their sides. According to David Smeekes, these locations are just as good for auscultation. The thickness of the device is kept minimal, but thick enough to encapsulate all the necessary technology. The width of the strap is 40 mm. Narrower straps were also tested, however, the 40mm strap provided more stability during placement. The non-elastic strap is padded, thereby a bit thicker than the elastic one (see Figure 12.11 - Bottom). This way not only the color of the straps is different, but also the shape and feel. This is another use cue that is meant to support users in orienting the device.

Figure 12.11 Device measurements

TECHNOLOGY AND SPACE INSIDE THE HOUSING

Due to the conceptual nature of the project and the 5-8 years of development required before the finalization, no concrete electronic components were selected during the project. The list of major electronic components that need to be incorporated at the further elaboration of the project is the following:

- MEMS microphone
- Amplifying circuit and signal preprocessing unit
- Microprocessor
- Wireless communication unit (the current recommendation is BLE due to its low energy consumption. Low energy consumption is important for saving space on the battery life)
- Push button
- Battery
- Speaker
- LEDs

The necessary space inside the housing was defined based on the specifications of current components. Figure 12.12 shows a cross-section of one of the stethoscope housings. Figure 12.13 contains a top view drawing from the same PCB. The image shows the largest electrical components proportionately. Although the battery is not on the PCB, it is also included on the image. Figure 12.14 visualizes the available space above the PCB. At a consultation, Timothy Nankervits – free lancing electrical engineer who designed the PCB of the functional prototype – evaluated the available space sufficient for the components.

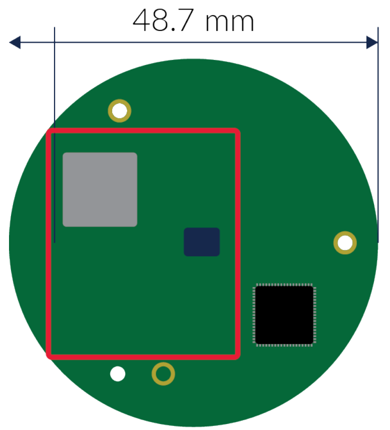


Figure 12.13 Largest components on the PCB

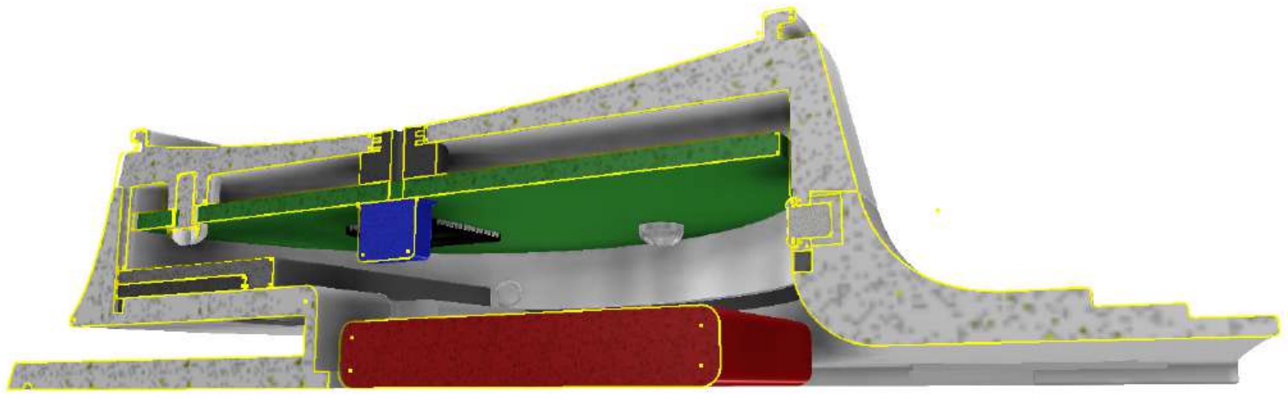


Figure 12.12 Interaction with the Mount mock-up

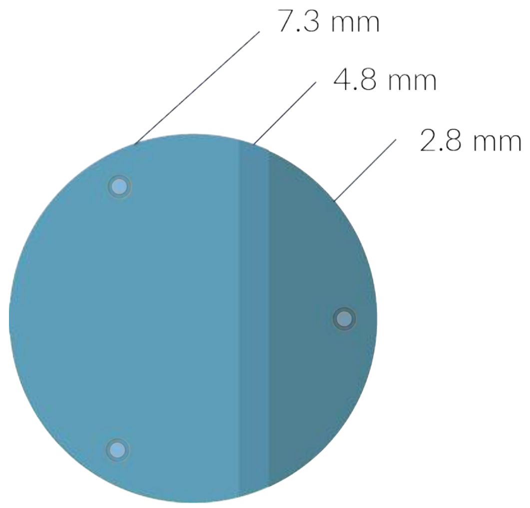


Figure 12.14 Availavle volume above the PCB

STRAP LENGTHS

To define the length of the straps, P5 and P95 chest circumference values of Dutch men and women in the target age group were researched in the database of DINED. The overall smallest (817mm – Female, P5, 30-60 years) and biggest (1352mm – Female, P95, +60 years) value were selected as extremities ("DINED", 2018). Figure 12.15 illustrates, that the strap length needs to be set in a way for all users that the lung measurement button is conveniently reachable, but the buckle does not arrive to the center, in order to allow the users to place the center positioning piece on the elastic strap. This can be achieved by manufacturing the device itself and the elastic strap in one size and manufacturing the non-elastic strap in 3 different lengths (see Figure 12.16).

To verify that these device sizes fit the use the critical situations and measurements were analyzed. Two critical situations can occur. First, the device should not reach the ground for users who are extremely short and wide. Second, the aluminum profile on the wall mount needs to be long enough for users who are extremily tall and slim for placing the positioning supporting mount holder on it to the right height for them. The length of this profile is related to the non-elastic strap's length. P5 and P95 values were used for testing these scenarios and it was confirmed that the selected device sizes fit even the critical users. Appendix F-A contains the details of this analysis. It is important to note that in extreme cases the body ratios of users can affect the minimal and maximal wall mount height. Thereby, it is recommended to Philips to provide personalized guidance for the placement of the wall mount in the application. The guidance could be personalized based on the height and the chest circumference of the user.

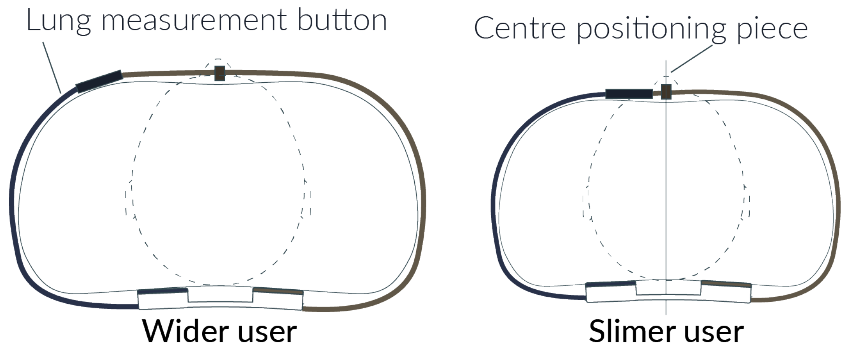


Figure 12.15 The non-elastic strap on wider and slimer users

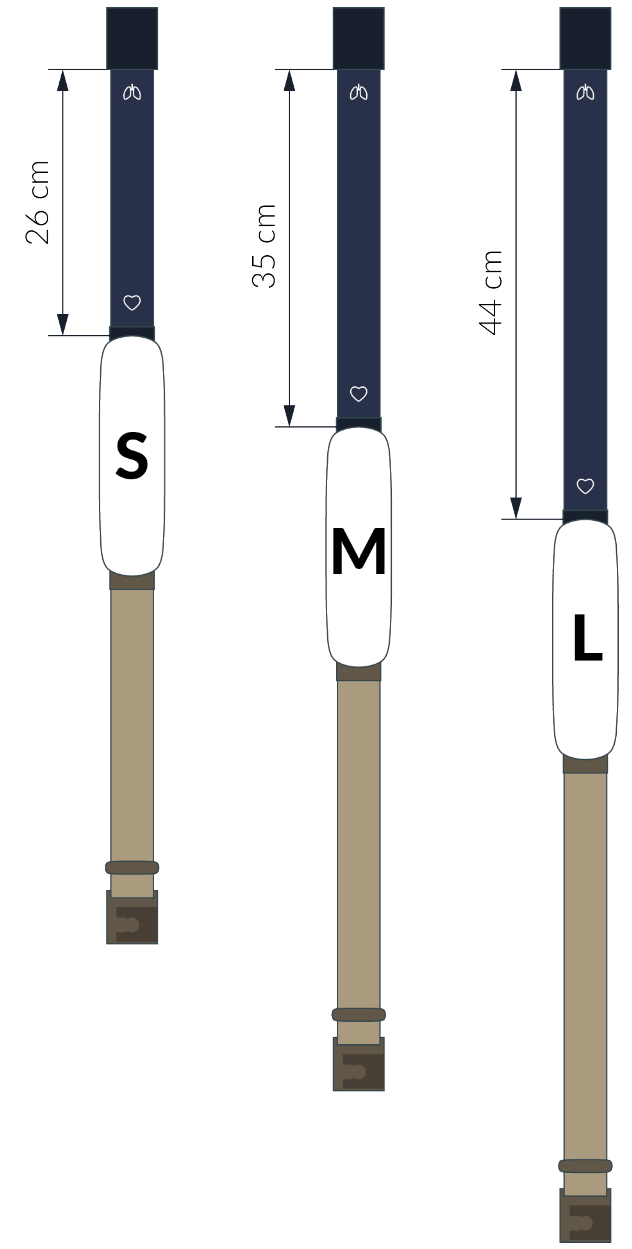


Figure 12.16 The three available device sizes

NAMING THE DEVICE

The name of the device is Philips Serin. Serin is a type of bird closely related to the canary. Canaries are one of the most well-known sentinel species. They were used for alarming the workers in mines about carbon monoxide. Thereby, the name refers one of the oldest early detection technologies people used. However, the name canary is too related to the Canary Islands. A well-known vacation location would be a strange association for a medical, non-wellness device. However, serins were used as well for the same purpose as canaries. These birds have a much more serious sounding name which fits better the medical context. In addition, 'siren' is a similar sounding word to serin, which is a relevant association for the device due to its primary function: alarming people of danger.

PHILIPS | Serin

13 PROTOTYPING

The current chapter briefly illustrates the prototyping process during the project and demonstrates the final prototypes.

As it was explained in the approach chapter, iterative prototyping was a major input for detailing the usability of the final design. It was used as physical input for the form giving, for elaborating on the technological aspects of the project and for testing the usability aspects. Figure 13.2 presents all the prototypes that were done during the project.

Two prototypes were made for the final design. An aesthetic prototype and a usability prototype. Both of these prototypes were done for the validating user test. The aesthetic porotype mimics the materials the shape and the ratios of the final design. The components of the device were manufactured via 3D printing, CNC milling and laser cutting. Figure 13.1 shows these components. After that, they were sanded, rubber coated and glued together. The strap was sewed with the help of a tailor. Figure 13.3 and 13.4 shows the final result.

The usability prototype mimics the general use, the closing mechanism interaction, the wall mount interaction and the interaction with the center positioning piece. The closing mechanism used for the prototype is not the exact same one as selected, but it is from the same company and it opens with the same sliding mechanism. The components were manufactured via 3D printing and laser cutting. After that, the pieces were glued together and the straps were sewed on them. Figure 13.5 and 13.6 shows the final result.

Figure 13.1 Components of the aesthetic prototype before the rubber coating

Figure 13.2 All the prototyping material used during the project


Figure 13.3 The aesthetic prototype - 1


Figure 13.4 The aesthetic prototype - 2


Figure 13.5 The usability prototype - 1

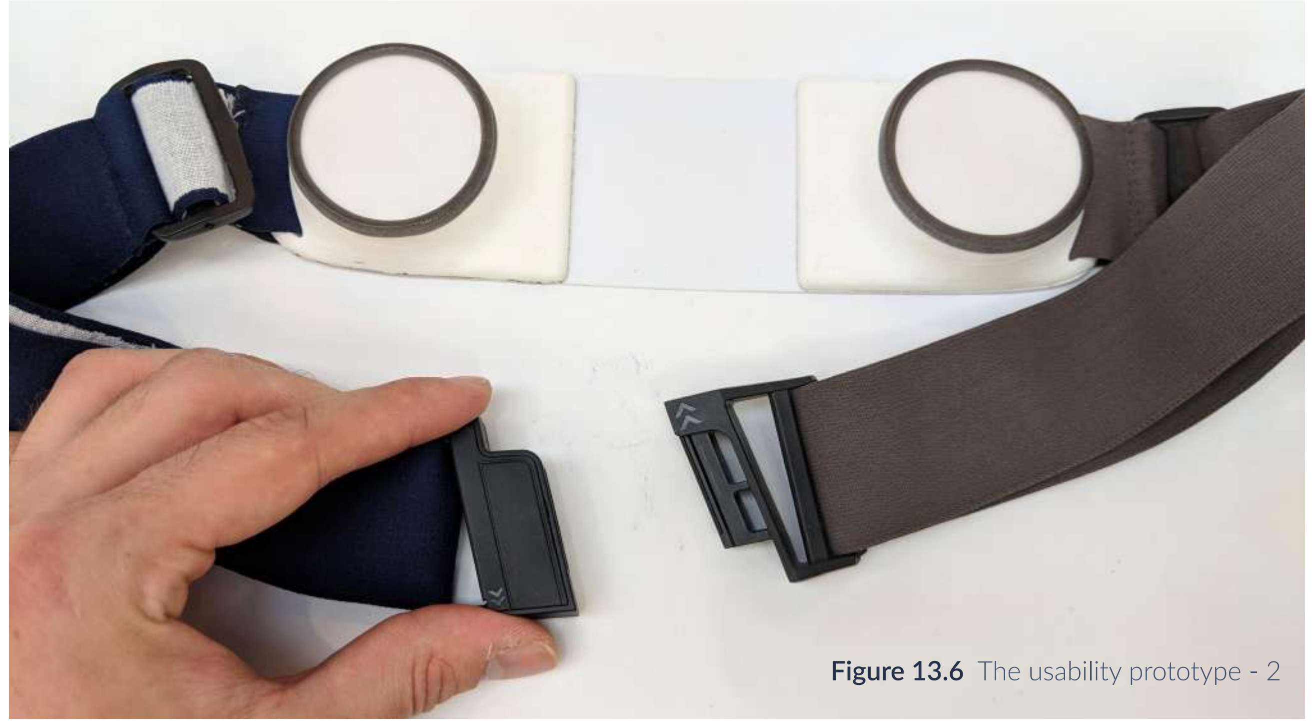


Figure 13.6 The usability prototype - 2

14 USER EVALUATION

Heart failure and COPD patients were in the center of the project. This chapter contains the ealuation of the final design with the involvment of these users. The report only contains a summary and main insights of this test. The elaboration of the test can be found in Appendix G.

GOAL

In order, to better understand the user perspective, the target users (heart failure and COPD patients) were involved in the evaluation of the final design proposal. The users test focused on evaluating the design from three aspects: usability, use encouraging and design aesthetics. The research questions related to these aspects were the following:

Usability

- To what extent can the patients comfortably use the device?

Use encouraging

- How do patients perceive the use encouraging elements of the design?

Subquestions

- How do patients perceive the measurement accomplishment feedback lights?
- How do patients receive the reassuring message?
- What is the patients' opinion regarding the involvement of breathing exercises in the use of the device?
- How do patients perceive the rewarding system of the product?

Design aesthetics

- What do patients think about the aesthetics of the design?

METHOD

5 people participated in the user tests. 3 COPD patients and 2 heart failure patients. The sessions started with the introduction to the use (Figure 14.1), than participants could try the usability prototype first with then without the help of the mount holder (Figure 14.2) and were asked to rate the overall comfort of using the prototype and their confidence about their placement accuracy. After that the use scenario was explained in-depth, including all the use encouraging and reminding features. Meanwhile, participants received 10 positive and 10 negative emotion cards and were asked to use them to express their feelings and opinion about these features (see Figure 14.3). The emotion cards were used to achieve a more profound undersanding about the participants opinion of these features. After that, the

aesthetic prototype and some visuals were shown to the participants. Then, they rated how friendly, reliable, hygienic and medical do they perceive the design and the importance of these design aspects. The user test ended with a semi-structured interview. Appendix G-A contains a more detailed explanation of the build-up. The raw notes of the tests are in Appendix G-B wgile the used materials are in Appendix G-C.

Figure 14.1 Explainging the use of the prototype

RESULTS

Usability

Patients found the device very convenient to use. All participants meantioned ease of use while describing their experiences with the prototype.

Figure 14.2 A heart failure patient's accuracy using the mount holder scenario

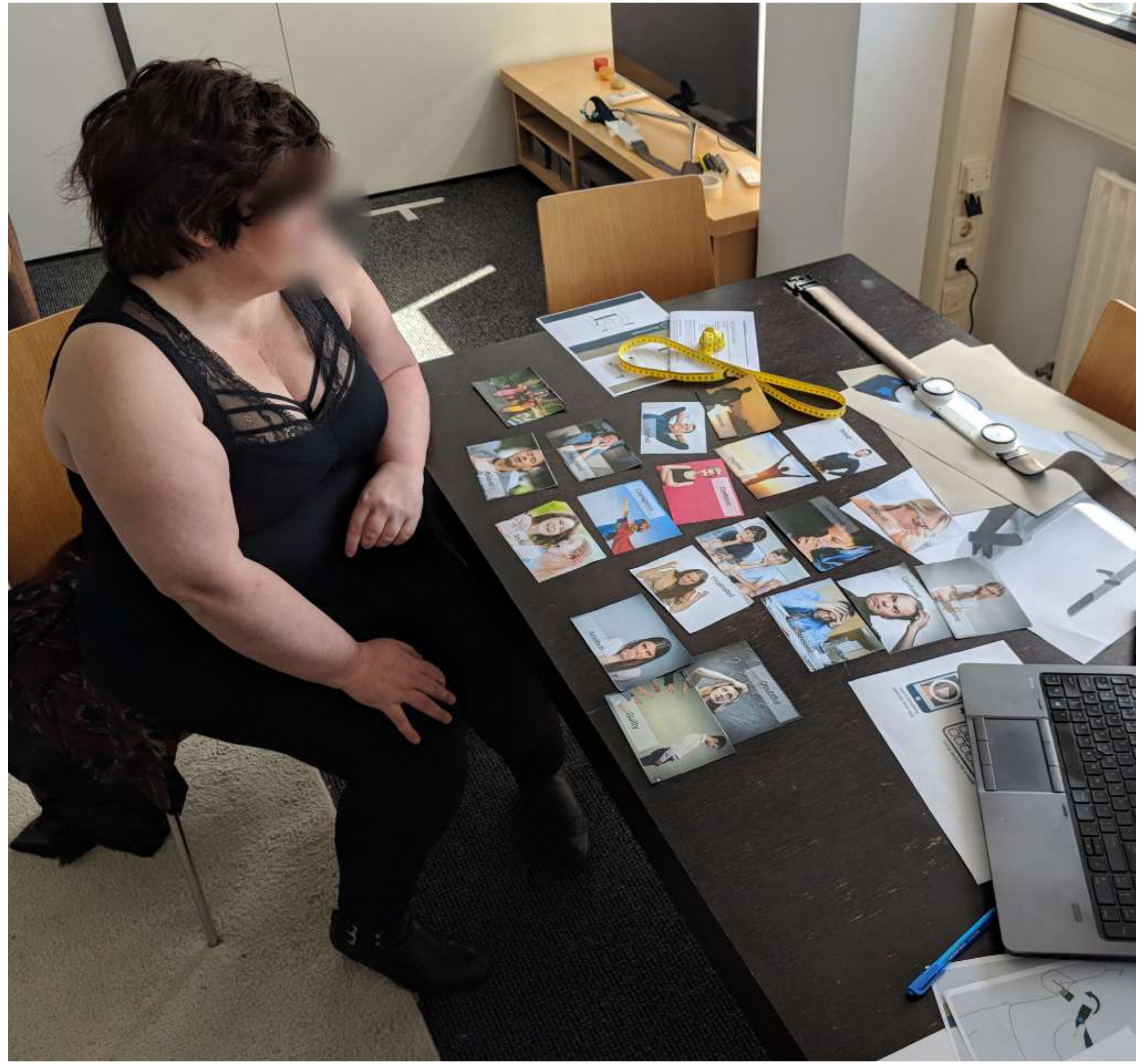


Figure 14.3 A COPD patient with the emotion cards

"This is easy lock [compared to a regular snap fit]!"

"- How would you describe your overall user experience?
- Easy, relaxed.
- Why relaxed?
- Its easy to use, so that's relaxing. So you don't get... insecure... Or how do you say. If its hard to do it can become a mountain. But its easy as it can be. So its relaxing. So I wouldn't care if I have to do it. Or actually I would want to do it if it helps me."

"The most comfortable part was that you don't need another person to use it."

"Its comfortable and easy to put on. Easy to take off."

"Its easy to use so you can easily build it in your daily routine. You don't have to do a lot for it."

"I don't feel it on me,really. It's comfortable to wear. It stretches. It's not like a harness. That is uncomfortable. This is very comfortable I think."

The holder

Most participants found the comfort of using the wall mount the same as doing it without support (See Table 14.1), and on average the only felt slightly more confident about the placement using the wall mount. However, they performed better in terms of actual accuracy. The wall mount also prevented the only flaw that happened multiple times during the measurements: the flipping over of the device during placement. There was one person who emphasized that she liked the wall mount more and one person who didin't because she didn't like standing against the wall.

”I'm working in healthcare (...) I think with older people it would be very helpful to them. But for me it doesn't matter.”

”The hardest part was to put it on the right height. But that piece on the wall [The mount holder] that makes it simpler.”

Use encouraging

Reminder system

Participants found the reminding system of the device necessary and useful.

”The daily measurements are easy to remember to. But for the other measurements its really useful [Referring to the heart measurements].”

”Very useful. You can never forget. I have to put a reminder in my phone everyday. So the lights is really fine. It's very positive.”

”Its good. It sounds less probable that you would forget it. Its very common with heart failure patients that their mind is a mess. So it will be useful.”

Involvement of breathing exercises in the use of the device

Most of the participants are not not doing breathing exercises deliberately, but most participants were interested in the involvement of breathing exercises in the use, even those ones that were not fond of the rewarding system. Most participants also said that they would be interested in learning more about them.

”Learning new breathing exercises is very interesting. And then you can do it anytime.”

”It's a story that helps you and makes sense to do with the device.”

”The breathing exercise I would try it. And if I think its fun and if I can make a routine out of it I would do it. But if I get bored with it I would still use that one [referring to the device] but the breathing exercises no.”

Rewarding system

The rewarding system was the most divisive part of the test. 3 participants had a generally negative opinion about it and 2 of them said that they find it childish to have such a system. The people who disliked the system were claiming that therapy adherence needs to come from an intrinsic source, and that such a system doesn't help in that. On the other hand the other 2 participants were quite positive and found it interesting.

”There is only one thing that helps to stay motivated and that is in your brain. You have to do it and then you do it. You can make it red [referring to the lights when a measurement was not completed] , or say 'hurra' [referring to the reassuring meassage] but that's nonsense. It only depends on the attitude.”

”My opinion is that this device is for your own health. So if you have to take 1 minute

Participant number	Age	Comfort		Placement confidence	
		From hand	From wall	From hand	From wall
1	67	6	6	6	7
2	81	7	7	7	7
3	52	7	6	7	6
4	48	6	7	7	7
5	50	7	7	6	7
Average	59.6	6.6	6.6	6.6	6.8

Table 14.1 Comfort and placement confidence ratings

out of your day to do it and you don't, that's your responsibility. I mean, If I had a device like this in my bathroom, I would do it every morning. Like I take my medicine every morning. Why wouldn't you use a device like that every morning? Maybe I am a little annoyed as well. Because I'm an adult. I'm not... a child.”

”It's like the dog. If you do that you get a pet on the back. (...) Its your health, c'mon! If that isn't important enough to remind yourself to do it, what's the use of apps, or play games or whatever?”

”- Its very interesting stuff.
- What do you find interesting about it?
- Well, how you can use it. Like what you said the breathing exercise is just an extra but it will help. So its also useful. Yeah, that's interesting.”

Measurement accomplishment visualizing lights

Most of the participants found the feature nice, but not so interesting. However, one participant - who disliked the rewarding system the most - found these lights highly encouraging.

”I am a freak with that. I bought a box for my medicine from Monday to Sunday and I never forget. Because I would hate it if I see medicine and not an empty box. So I would never forget because then I wouldn't get a light. So that would stimulate.”

Reassuring message

Although the rewarding system was found childish by some people the reassuring meassage had a better reception. People were either neutral or positive about it.

”It would be nice if you could have your own meassage. You could make fun with it.”

”I would feel reassured that I did good.”

”Its nice. Its always amusing when something sort of talks to you from the wall.”

”That's okay.”

Aesthetics

Table 14.2 summarizes the overall aesthetics ratings. People found reliable and hygienic look the most important design aspects and the design also scored the highest from these aspects. People had a diverse opinion about the importance of medical and friendly look. On average they found these aspects moderately important and on average the device was perceived more friendly than reliable. Interestingly, all participants who rated friendliness more important perceived the device friendlier while participants who rated medical look important rated the device more medical.

Participant number	Friendly		Reliable		Hygienic		Medical	
	Score	Importance	Score	Importance	Score	Importance	Score	Importance
1	4	1	6	6	6	7	6	7
2	5	4	6	5	7	7	4	4
3	7	3	7	6	6	7	4	4
4	7	7	7	7	7	7	6	6
5	6	5	7	7	7	7	2	1
Average	5.8	4	6.6	6.2	6.6	7	4.4	4.4

Table 14.2 Aesthetic ratings

> It's not not important that is looks friendly... Its Important that it looks good. And this looks good and feels good.

> First [before the test] I though it's just a strap. But Its nicer than I thought. I think it's very comfortable. Soft. Easy to use. (...) I think it's a nice thing.

General opinion

All participants were generally positive about the device and all, but one participants claimed they would surely use the device on a daily basis. The person who said she is not sure if she would use it said so because she doesn't regularly suffer from pulmonary edema.

> I don't think I would get bored. Because I need the daily reassurance that my health is okay. And not only me. Loads of people. Because the thing I learned in the Facebook group I moderate– and there are 1700 people on the group – that they are all scared. They want to go to the cardiologist to get reassurance that they are ok. And this device can help. So I'm really inspired. So I don't think that boredom is a problem. Its really reassuring.

> I don't know what would be the benefit for me to use it every day or every week. It would be for the fluid in your lungs, but I always feel it in my hands and in my feet. But it would only take a few minutes so its not very bad to do it.

> - Would you use the device on a daily basis?
> - Yes. I can't wait to have the real one!

CONCLUSIONS

All in all, the participants were highly positive about the device, especially about the usability aspects, which were emphasized by all participants.

The design also performed well on the aesthetic part of the test. People perceived it highly reliable and hygienic looking. People's opinion varied about the friendliness and the medical look of the device, however, all participants who found the medical look important perceived the design medical looking while all participants who found friendliness important perceived the design friendly. Thereby, the aesthetic goal of the project to balance between a medical and friendly look was achieved.

All participants appreciated the reminding features of the design and almost all participants were interested to learn new breathing exercises related to the use. However, the rewarding system related to the breathing exercises had a diverse reception, almost all participants had different opinions about it. While some participants found it boring, childish or even annoying, other participants found it interesting. The measurement accomplishment lights were mostly perceived neutral or positive, however, one person found them really encouraging.

To sum up, motivating people is a complex topic because its highly related to a persons own values. Depending on people's values everybody finds different things motivating or boring. Thereby, based on the user test, the best approach for the improvement of the use encouraging aspects of the design would be to include varius different features in the design that can be motivating for people and allowing users to conveniently personalize which features do they want to use and which features don't.

15 RECOMMENDATIONS

The current chapter contains the main recommendations for the continuation of the project.

Improving the use encouraging features

- The use encouraging features of the design needs to be more personalizable to cover patients with different values. The rewarding system should be optional as it can be a good motivation source for some people, but annoying for others.
- The involvement of breathing exercises in the design needs to be elaborated. Currently no guidance is envisioned, only instructional videos. The involvement of guidance during the exercises could be an optionally accessible feature.

Improving the design

- Multiple participants mentioned during the test that the colors of the straps could be even more different for easy distinguishing for elderly patients
- The fabric materials for the strap need to be selected. Based on a personal conversation with Guy Brown – Philips employee who participated in the Smart Sleep project - the recommended material is a 60% polyester, 30% cotton, 10% rayon.
- Medical grade final materials need to be selected for all components
- The inner structure of the strap needs to be detailed

Testing

- As a next step in the project, a functional prototype needs to be built and tested
- Using the prototype mentioned above, it needs to be tested if one auscultation location is enough per lung for early detecting exacerbations and pulmonary edema
- It should also be tested if patients who suffer from both diseases could monitor both parameters via only one measurement (at the bottom of the lungs)
- Patients highly appreciated the used magnetic clips. However, it needs to be confirmed via testing if these clips are compatible with pacemakers and ICDs
- The flexible central structure of the device needs to be prototyped and tested.

Expansion of the scope

- Other types of patients could also use the current design, not only cardiovascular related patients. The first patient group that should be explored are pulmonary patients

Educating the users

- The educational material for using the device needs to be designed. During the user studies, it was observed that demonstration worked much better than illustrations. Thereby, it is recommended to shoot live action videos for educational purposes

16 Personal Reflection

The personal reflection concludes the report from the perspective of the graduate student and highlights the most important insights gathered during the process.

The graduation project gave me the opportunity to learn and experience many new things. I have never had to realize an entire project all by myself, and this isolation made me appreciate the group working based approach to product design. I realized that discussing your ideas with others is a highly important aspect of designing.

I also learned that planning is really important skill of product designers and that I need to gain more practice in it. Many times, I underestimated the length of certain tasks which resulted in some long nights of work.

A final thing that I would do differently if I would start the project again is defining a more focused scope around the middle of the project. I love the detailing of product design projects, however, detailing is much easier and much more tangible if the boundaries of what to detail are well defined and the scope is focused. During the elaboration phase, I started to work on various aspects of the project that I, unfortunately, couldn't work out due to time limitations.

Apart from these major lessons I have acquired many smaller skills starting from soldering, through communication with medical professionals, to user testing and applying for ethical approvals. I believe the past couple of months truly helped me to become ready to enter the real world of product designers.

17 References

(The references of the appendices are also included in this chapter.)

2Net Hub. (2018). Retrieved 01 May 2018, from https://qualcommlife.com/2net-hub

Abraham, W. T., Adamson, P. B., Bourge, R. C., Aaron, M. F., Costanzo, M. R., Stevenson, L. W., ... & Weiner, S. 2011). Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. The Lancet, 377(9766), 658-666.

Adamopoulos, S., Schmid, J. P., Dendale, P., Poerschke, D., Hansen, D., Dritsas, A., ... & Vartela, V. (2014). Combined aerobic/inspiratory muscle training vs. aerobic training in patients with chronic heart failure. European journal of heart failure, 16(5), 574-582.

Akinbami, L. J., & Liu, X. (2011). Chronic obstructive pulmonary disease among adults aged 18 and over in the United States, 1998–2009. June.

Arenillas, J. F. (2011). Intracranial atherosclerosis. Stroke, 42(1 suppl 1), S20-S23.

Atherosclerosis. (2017). American Heart Association. Retrieved 29 November 2017, from http://www.heart.org/HEARTORG/Conditions/Cholesterol/AboutCholesterol/Atherosclerosis_UCM_305564_Article.jsp#.Wh8VZIWnGpo

AS-¬IS Chronic heart failure care pathway in US (n.d.) Philips.

Azimpour, F., Caldwell, E., Tawfik, P., Duval, S., & Wilson, R. F. (2016). Audible coronary artery stenosis. The American journal of medicine, 129(5), 515-521.

Bech, J. W. (2017 October 11), Personal interview. Reinier de Graaf

Bech, J. W. (2017 December 05), Personal interview. Reinier de Graaf

Bischoff, E. W., Schermer, T. R., Bor, H., Brown, P., Van Weel, C., & van den Bosch, W. J. (2009). Trends in COPD prevalence and exacerbation rates in Dutch primary care. Br J Gen Pract, 59(569), 927-933.

Bourne, L., & Walker, D. H. (2005). Visualising and mapping stakeholder influence. Management decision, 43(5), 649-660.

Bozkurt, B., Aguilar, D., Deswal, A., Dunbar, S. B., Francis, G. S., Horwich, T., ... & Rosendorff, C. (2016). Contributory risk and management of comorbidities of hypertension, obesity, diabetes mellitus, hyperlipidemia, and metabolic syndrome in chronic heart failure: a scientific statement from the American Heart Association. Circulation, 134(23), e535-e578.

Chen, T., Zhao, S., Shao, S., & Zheng, S. (2017). Non-invasive diagnosis methods of coronary disease based on wavelet denoising and sound analyzing. Saudi journal of biological sciences, 24(3), 526-536.

Chronic obstructive pulmonary disease (COPD): Overview. (2017). PubMed Health. Retrieved 19 October 2017, from https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0079014/

Clinicloud Stethoscope. (2017). Clinicloud. Retrieved 12 November 2017, from https://clinicloud.com/store/stethoscope/

Colucci, W., Gottlieb, S. S., Hoekstra, J., & Yeon, S. B. (2012). Treatment of acute decompensated heart failure: Components of therapy. UpToDate. Waltham, MA: UpToDate.

COPD Health Journey Health Continuum (n.d.) Philips.

Di Tullio, A. (2017 November 20), Personal interview. Philips

DINED. (2018). Retrieved from https://dined.io.tudelft.nl/en

DUO Stethoscope + EKG. (2017). Eko devices. Retrieved 12 November 2017, from https://ekodevices.com/duo/

Dragomir, A., Post, A., Akay, Y. M., Jneid, H., Paniagua, D., Denktas, A., ... & Akay, M. (2016). Acoustic detection of coronary occlusions before and after stent placement using an electronic stethoscope. Entropy, 18(8), 281.

Felson, S. (2017). COPD: Exercise and Breathing. WebMD. Retrieved 16 April 2018, from https://www.webmd.com/lung/copd/copd-and-exercise-breathing-and-exercise-programs-for-copd

Fernandez-Granero, M. A., Sanchez-Morillo, D., & Leon-Jimenez, A. (2015). Computerised analysis of telemonitored respiratory sounds for predicting acute exacerbations of COPD. Sensors, 15(10), 26978-26996.

Fokkinga, S., Ozkaramanli, D., Desmet, P., Fischer, A., & Sauter, D. (n.d.). Negative emotion typology. Re-trieved April 25, 2018, from https://emotiontypology.com/

Ford, E. S., Murphy, L. B., Khavjou, O., Giles, W. H., Holt, J. B., & Croft, J. B. (2015). Total and state-specific medical and absenteeism costs of COPD among adults aged≥ 18 years in the United States for 2010 and projections through 2020. Chest Journal, 147(1), 31-45.

Fotoukian, Z., Shahboulaghi, F. M., Khoshknab, M. F., & Mohammadi, E. (2014). Barriers to and factors facilitating empowerment in elderly with COPD. Medical journal of the Islamic Republic of Iran, 28, 155.

Gjoreski et al. (2017). Chronic Heart Failure Detection from Heart Sounds Using a Stack of Machine-Learning Classifiers. Paper presented at IE 2017 : 13th International Conference on Intelligent Environments, Seoul. doi: 10.1109/IE.2017.19

Guarascio, A. J., Ray, S. M., Finch, C. K., & Self, T. H. (2013). The clinical and economic burden of chronic obstructive pulmonary disease in the USA. ClinicoEconomics and outcomes research: CEOR, 5, 235.

Hansen, C., Snyder, S., Qiu, X., Brooks, L., & Moreau, D. (2012). Active control of noise and vibration. CRC press.

Hardman, R. L., Jazaeri, O., Yi, J., Smith, M., & Gupta, R. (2014). Overview of classification systems in peripheral artery disease. In Seminars in interventional radiology (Vol. 31, No. 04, pp. 378-388). Thieme Medical Publishers.

Heart failure. (2017). NHS - UK. Retrieved 28 November 2017, from https://www.nhs.uk/conditions/heart-failure/

Heart Failure - Exploring Space and Opportunities for IGT. (n.d.). Philips.

Heidenreich, P. A., Trogdon, J. G., Khavjou, O. A., Butler, J., Dracup, K., Ezekowitz, M. D., ... & Lloyd-Jones, D. M. (2011). Forecasting the future of cardiovascular disease in the United States. Circulation, 123(8), 933-944.

Hirsch, A. T., Hartman, L., Town, R. J., & Virnig, B. A. (2008). National health care costs of peripheral arterial disease in the Medicare population. Vascular Medicine, 13(3), 209-215.

Hoogewerf, H. (2017 November 20), Personal interview. Philips

Horsman, H. (2017 December 18), Personal interview. Psychologist

Jaff, M. R., Cahill, K. E., Andrew, P. Y., Birnbaum, H. G., & Engelhart, L. M. (2010). Clinical outcomes and medical care costs among medicare beneficiaries receiving therapy for peripheral arterial disease. Annals of vascular surgery, 24(5), 577-587.

Kaddoura, T., Vadlamudi, K., Kumar, S., Bobhate, P., Guo, L., Jain, S., ... & Tymchak, W. (2016). Acoustic diagnosis of pulmonary hypertension: automated speech-recognition-inspired classification algorithm outperforms physicians. Scientific reports, 6.

Kadoglou, N. P., Bracke, F., Simmers, T., Tsiodras, S., & Parissis, J. (2017). Influenza infection and heart failure—vaccination may change heart failure prognosis?. Heart Failure Reviews, 1-8.

Kim, S. (2017 November 23), Personal interview. Philips

Lai, L. S., Redington, A. N., Reinisch, A. J., Unterberger, M. J., & Schriefl, A. J. (2016). Computerized automatic diagnosis of innocent and pathologic murmurs in pediatrics: a pilot study. Congenital heart disease, 11(5), 386-395.

Lee, E. (2018 January 24), Personal interview.

Leening, M. J. G., Siregar, S., Vaartjes, I., Bots, M. L., Versteegh, M. I. M., van Geuns, R. J., ... & Deckers, J. W. (2014). Heart disease in the Netherlands: a quantitative update. Netherlands Heart Journal, 22(1), 3-10.

Leng, S., San Tan, R., Chai, K. T. C., Wang, C., Ghista, D., & Zhong, L. (2015). The electronic stethoscope. Biomedical engineering online, 14(1), 66.

van Liempt, B. (2017 November 16), Personal interview. Huisartsenpraktijk Hus & Van 't Lindenhout

Lloyd-Jones, D., Adams, R. J., Brown, T. M., Carnethon, M., Dai, S., De Simone, G., ... & Go, A. (2010). Heart disease and stroke statistics—2010 update. Circulation, 121(7), e46-e215.

Mahoney, E. M., Wang, K., Cohen, D. J., Hirsch, A. T., Alberts, M. J., Eagle, K., ... & REACH Registry Investigators. (2008). One-year costs in patients with a history of or at risk for atherothrombosis in the United States. Circ Cardiovasc Qual Outcomes, 1(1), 38-45.

Mårtensson, J., Dracup, K., Canary, C., & Fridlund, B. (2003). Living with heart failure: depression and quality of life in patients and spouses. The Journal of heart and lung transplantation, 22(4), 460-467.

McDonald, C. F. (2014). Oxygen therapy for COPD. Journal of thoracic disease, 6(11), 1632.

Morillo, D. S., Granero, M. F., León, A., & Crespo, L. F. (2014). Automatic Classification of Respiratory Sounds Phenotypes in COPD Exacerbations. In XIII Mediterranean Conference on Medical and Biological Engineering and Computing 2013 (pp. 603-606). Springer, Cham.

Moser, D. K., Arslanian-Engoren, C., Biddle, M. J., Chung, M. L., Dekker, R. L., Hammash, M. H., ... & Lennie, T. A. (2016). Psychological aspects of heart failure. Current cardiology reports, 18(12), 119.

Mosterman, S. (2018). Self-monitoring for comorbidity. TU Delft

Müllerova, H., Agusti, A., Erqou, S., & Mapel, D. W. (2013). Cardiovascular comorbidity in COPD: systematic literature review. CHEST Journal, 144(4), 1163-1178.

Norcross, W. A. & Hermann, D. D. (2005). Heart Failure. In R.B. Taylor (Ed.), Taylor's cardiovascular diseases (pp. 140). New York, NY: Springer.

Orten, B. (2003). U.S. Patent No. 6,512,830. Washington, DC: U.S. Patent and Trademark Office

Pasman, G., & Van Der Lelie, C. (2003). Designing Products for Everyday Rituals.

van Passen, W. (2018 April 09), Personal interview.

Patidar, S., Pachori, R. B., & Garg, N. (2015). Automatic diagnosis of septal defects based on tunable-Q wavelet transform of cardiac sound signals. Expert Systems with Applications, 42(7), 3315-3326.

Pauwels, R. A., Buist, A. S., Calverley, P. M., Jenkins, C. R., & Hurd, S. S. (2001). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. American journal of respiratory and critical care medicine, 163(5), 1256-1276.

Pelizzari, P. M., & Bruce Pyenson, F. S. A. (2015). The High Cost of Heart Failure for the Medicare Population: An Actuarial Cost Analysis.

Peripheral Arterial Disease Fact Sheet. (2016). CDC. Retrieved 29 November 2017, from https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_pad.htm

Piotrowicz, E., Piepoli, M. F., Jaarsma, T., Lambrinou, E., Coats, A. J., Schmid, J. P., ... & Adamopoulos, S. (2016). Telerehabilitation in heart failure patients: The evidence and the pitfalls. International journal of cardiology, 220, 408-413.

Rabe, K. F., Hurd, S., Anzueto, A., Barnes, P. J., Buist, S. A., Calverley, P., ... & Zielinski, J. (2007). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: GOLD executive summary. American journal of respiratory and critical care medicine, 176(6), 532-555.

Reinecke, H., Unrath, M., Freisinger, E., Bunzemeier, H., Meyborg, M., Lüders, F., ... & Malyar, N. M. (2015). Peripheral arterial disease and critical limb ischaemia: still poor outcomes and lack of guideline adherence. European heart journal, 36(15), 932-938.

Rodríguez-Artalejo, F., Banegas, J. R. B., & Guallar-Castillón, P. (2004). Epidemiology of heart failure. Revista espanola de cardiologia, 57(2), 163-170.

Roguin, A. (2006). Rene Theophile Hyacinthe Laënnec (1781–1826): the man behind the stethoscope. Clinical medicine & research, 4(3), 230-235.

Roozenburg, N. F., & Eekels, J. (1995). Product design: fundamentals and methods (Vol. 2). John Wiley & Sons Inc.

van Rossem, R. (2017 November 17), Personal interview. Reinier de Graaf

van t'Sant (2017 December 04), Personal interview. Reinier de Graad

Schiffman, G. (2017). What Is Emphysema?. eMedicine Health. Retrieved 28 November 2017, from https://www.emedicinehealth.com/emphysema/article_em.html

Schmidt, S. E., Holst-Hansen, C., Graff, C., Toft, E., & Struijk, J. J. (2007, September). Detection of coronary artery disease with an electronic stethoscope. In Computers in Cardiology, 2007 (pp. 757-760). IEEE.

Schmidt, S., Holst-Hansen, C., Hansen, J., Toft, E., & Struijk, J. J. (2015). Acoustic features for the identification of coronary artery disease. IEEE Transactions on Biomedical Engineering, 62(11), 2611-2619.

Smeekes, D. (2017 November 13), Personal interview. Hartstichting

Smeekes, D. (2017 December 14), Personal interview. Hartstichting

Sobnath, D. D., Philip, N., Kayyali, R., Nabhani-Gebara, S., Pierscionek, B., Vaes, A. W., ... & Kaimakamis, E. (2017). Features of a Mobile Support App for Patients With Chronic Obstructive Pulmonary Disease: Literature Review and Current Applications. JMIR mHealth and uHealth, 5(2).

Snap buckle - Fidlock. (2018). Retrieved 01 May 2018, from http://www.fidlock.com/en/fasteners/snap-buckle.html

Solà, J., Braun, F., Muntané, E., Verjus, C., Bertschi, M., Hugon, F., ... & Gervaix, A. (2016). Towards an unsupervised device for the diagnosis of childhood pneumonia in low resource settings: Automatic segmentation of respiratory sounds. In Engineering in Medicine and Biology Society (EMBC), 2016 IEEE 38th Annual International Conference of the (pp. 283-286). IEEE.

Steth IO - Smartphone Stethoscope. (2017). Steth IO. Retrieved 12 November 2017, from https://stethio.com/

StethoMe - My Home Stethoscope. (2017). Stethome.com. Retrieved 12 November 2017, from http://stethome.com/

Stethoscope. (2017). Wikipedia. Retrieved 30 November 2017, from https://en.wikipedia.org/wiki/Stethoscope

Stut, W. (2017 December 07), Personal interview. Philips

Tatousek, J. (2017 December 08), Personal interview. Philips

Tonkin, A., Barter, P., Best, J., Boyden, A., Furler, J., Hossack, K., ... & Robinson, M. (2005). National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand: position statement on lipid management--2005. Heart, lung & circulation, 14(4), 275.

TytoHome. (2017). TytoCare. Retrieved 12 November 2017, from http://www.tytocare.com/tytohome/

Uhlig, K., Patel, K., Ip, S., Kitsios, G. D., & Balk, E. M. (2013). Self-measured blood pressure monitoring in the management of hypertensiona systematic review and meta-analysis. Annals of internal medicine, 159(3), 185-194.

Upton, L. (2017). Evolution of Stethoscopes – A Patent Analysis. Chicago Heights Patch. Retrieved 12 November 2017, from https://patch.com/illinois/chicagoheights/evolution-stethoscopes-patent-analysis

Voigt, J., Sasha John, M., Taylor, A., Krucoff, M., Reynolds, M. R., & Michael Gibson, C. (2014). A reevaluation of the costs of heart failure and its implications for allocation of health resources in the United States. Clinical cardiology, 37(5), 312-321.

Wang, D., Fang, B., Liang, S., & Wang, S. (2016). The research progress about the intelligent recognition of lung sounds. In Computer and Communications (ICCC), 2016 2nd IEEE International Conference on (pp. 769-772). IEEE.

Weinberg, I. (2010). Rutherford Classification. Angiologist. Retrieved 1 December 2017, from http://www.angiologist.com/arterial-disease/rutherford-classification/

What Is Atherosclerosis? (2016). National Lung Heart and Blood Institute. Retrieved 2 December 2017, from https://www.nhlbi.nih.gov/health/health-topics/topics/atherosclerosis

Wheaton, A. G., Cunningham, T. J., Ford, E. S., & Croft, J. B. (2015). Employment and activity limitations among adults with chronic obstructive pulmonary disease–United States, 2013. MMWR Morb Mortal Wkly Rep, 64(11), 289-95.

WHO - Cardiovascular diseases (n.d.). Retrieved September 21, 2017, from http://www.who.int/mediacentre/factsheets/fs317/en/

Widmer, F. (2011). Herzinsuffizienz und Komorbiditäten. Therapeutische Umschau, 68(2), 103.

Willgoss, T. G., & Yohannes, A. M. (2013). Anxiety disorders in patients with COPD: a systematic review. Respiratory care, 58(5), 858-866.

Williams, S. (2017 December 07), Personal interview. Philips

Wu, J. R., Moser, D. K., Chung, M. L., & Lennie, T. A. (2008). Predictors of medication adherence using a multidimensional adherence model in patients with heart failure. Journal of cardiac failure, 14(7), 603-614.

Yashaswini, B. S., & Satyanarayana, B. S. (2012).

The Design of An Electronic Stethoscope-Review. In International conference on computer science and informatics (ICCSI)–Hyderabad–on 9th march.

Yohannes, A. M., Willgoss, T. G., Baldwin, R. C., & Connolly, M. J. (2010). Depression and anxiety in chronic heart failure and chronic obstructive pulmonary disease: prevalence, relevance, clinical implications and management principles. International journal of geriatric psychiatry, 25(12), 1209-1221.

Yoon, J., Pohlmeyer, A.E., & Desmet, P.M.A. (2015). Positive Emotional Granularity Cards. Delft, Delft Uni-versity of Technology. ISBN: 978-94-6186-440-6

Yost, M. L. (2016). THE ECONOMIC COST OF PAD, CLI & VENOUS DISEASE: HOW BIG IS THE MARKET?. In New Cardiovascular Horizons annual conference (NCVH), New Orleans, LA.

Ziaeian, B., & Fonarow, G. C. (2016). The prevention of hospital readmissions in heart failure. Progress in cardiovascular diseases, 58(4), 379-385.

18 ABBREVIATIONS

ABI - Ankle-brachial index
ACS - Acute coronary syndrome
AF - Atrial fibrillation
ANC - Active noise cancelation
ADHF - Acute decompensated heart failure
CAD - Coronary artery disease
CHF - Chronic heart failure
COPD - Chronic obstructive pulmonary disease
ICD - Implantable Cardioverter Defibrillator
ECG - Electrocardiogram
FEV - Forced expiratory volume
FVC - Forced vital capacity
HF - Heart failure
NYHA - New York Heart Association
PAD - Peripheral artery disease
PVD - Peripheral vascular disease
QoL - Quality of Life
SNF - Skilled nursing facility

19 GLOSSARY

ACE inhibitor – A vasodilator type medication which means widening of the blood vessels. This way it lowers blood pressure and increases blood flow. ACE refers to angiotensin-converting-enzyme.

Angioplasty – In order to open a blocked artery a catheter is inserted through a blood vessel and a balloon is opened at the affected location. A stent might also be placed during the process.

Atherosclerosis – It is a specific form of arteriosclerosis in which an artery wall thickens as a result of invasion and accumulation of white blood cells. These accumulations contain both living, active white blood cells (producing inflammation) and remnants of dead cells, including cholesterol and triglycerides.

Atherectomy – A minimally invasive surgical intervention that helps to remove some of the plaque from the arteries. Often used at treatment for peripheral artery disease

Anemia – A condition that occurs when person's blood lacks enough red blood cells and hemoglobin.

Ankle-brachial index - Ratio between the blood pressure measured at the wrist and at the ankles. It is used to assess the severity of peripheral artery disease

Artery – All blood vessels leading from the heart are known as arteries. All carry oxygenated blood except the pulmonary artery.

Ausculatory semiology – The study of auditory sign.

Auscultation – The act of listening to internal body sounds. Typically, it is performed using a stethoscope

Alveoli – The air sacs of the lung that enable the organ to gaseous exchange.

Bandwidth – In signal processing bandwidth refers to the difference between the highest and lowest frequency in a continuous set of frequencies

Bandpass filter – In analog signal processing bandpass filter is a set circuit elements that passes signals in a given frequency range and rejects signals outside of that range.

Bullae – When the walls of the alveoli get destroyed larger air spaces called bullae form. These bullae do not take part in the oxygen absorbing functioning of the lungs, they only take place.

Bullectomy – The surgical removal of bullae.

Bypass surgery – It is an invasive surgery where a bypass is created around an arterial blockage using a blood vessel harvested from another part of the body or using a synthetic fabric

Cardiac arrest – It is caused when the heart's electrical system malfunctions. In cardiac arrest death results when the heart suddenly stops working properly.

Carotid artery – Major blood vessels in the neck that supply blood to the brain, neck, and face

Carotid pulse – Measuring the pulse of a person at the carotid artery.

Cardiomyopathy – Ìt refers to diseases affecting the muscles of the heart.

Comorbidity – The presence of one or more additional diseases or disorders co-occurring with a primary disease or disorder

Classification (audio signal) – Classification is the term used in literature, for relating a certain type of abnormal heart or lung sound to a cardiac or pulmonary disease.

Diastole – The part of the cardiac cycle when the heart fills with blood

Diaphragm (anatomy) – The diaphragm, located below the lungs, is the major muscle of respiration. It is a large, dome-shaped muscle that contracts rhythmically and continually, and most of the time, involuntarily.

Dyspnea – Shortness of breath, a subjective difficulty or distress in breathing, usually associated with disease of the heart or lungs.

Ejection fraction – The ratio of blood pumped out by the heart at each contraction and the total amount of blood in the heart. It is an overall measure of heart state, thereby, an overall measure of heart failure progression as well.

Envelogram – A commonly used visual representation of the heart sound.

Emphysema – When the inner walls of the alveoli in the lung get destroyed, the active oxygen dissolving surface of the lungs reduces. This progressive chronic disease is called emphysema. Most of the time it is caused by smoking and it leads to shortness of breath due to the decreased lung functions.

Embolism – The blockage of a foreign body in a blood vessel.

Embolus – An unattached mass that is carried along the bloodstream.

FEV test – Refers to forced expiratory volume. It is a measure of overall lung state. It is used for the diagnosis of COPD and it is also referred to as spirometry.

FEV1 – The amount of air exhaled during the first second of a FEV test

FVC – Refers to force vital capacity. It is the total amount of air exhaled during FEV test.

Gain (Audio signal) – Gain means increasing a certain value of an electronic signal (e.g. power, voltage, current). In audio technology gain typically refers to the increase of the signal power. The power of audio signals is expressed in decibel (dB)

Gangrene – Local death of a considerable amount of tissue due to insufficient blood circulation or bacterial infection.

Hypoxemia – Abnormally low concentration of oxygen in the blood.

Hypertension – Medical term for high blood pressure.

Incidence – The number of new cases of a disease over a period of time divided by the population at risk.

Intermittent claudication – A symptom that describes muscle pain on mild exertions, classically in the calf muscle, which occurs during exercise, such as walking, and is relieved by a short period of rest.

Ischemia – Insufficient blood flow to an organ or body part that leads to shortage of oxygen and glucose.

Medicare – Is a federal health insurance program in the United States mostly for people above the age of 65.

Morbidity – It refers to the state of being diseased or unhealthy within a population.

Mortality – The term used for the number of people who died within a population.

Myocardium – Heart muscle.

Necrosis – Cell level death of living tissue.

Normalizing (audio signal) – Normalizing refers to applying a constant amount of gain on an audio recording in order to bring the peak or average signal amplitude to a certain level.

Palpitation –The perceived abnormality of heartbeat. Feeling like the heart is beating too fast or too hard

Percutaneous Coronary Intervention (PCI) – It is a non-surgical procedure that uses a catheter (a thin flexible tube) to place a small structure called a stent to open up blood vessels in the heart that have been narrowed by plaque buildup, a condition known as atherosclerosis. The catheter is inserted into the blood vessels either in the groin or in the arm.

Potentiometer – It is a 3-dimensional resistor. If only two terminals of it are used, it can be used as a variable resistor

Prevalence – The number of existing cases of a disease divided by the total population at a point in time

Sleep apnea – It is a serious sleep disorder, which occurs when there is an interruption is a person's sleeping.

Spirometry –Spirometry is a common pulmonary test for evaluating lung function. It is an essential tool for the diagnosis of COPD. It is also referred to as FEV test.

Systole – The part of the cardiac cycle when the heart ejects the blood.

Stenosis – In the medical field stenosis means the abnormal narrowing of a body channel (e.g. blood vassel)

Skilled nursing facility – A home-like facility equipped with advanced medical resources. Patients can be admitted to skilled nursing facilities after hospitalization for short-term, however, long-term admission is also possible.

Transducer – Is a device that converts energy from one form to another. A microphone, for instance, is a transducer the energy of sounds waves to electrical energy.

Ulcer – An open wound on an external or internal surface that won't heal.

Vasodilator – Widening of the blood vessels.

Veins – The vessels that carry blood from various organs to the heart are know as veins. All carry deoxygenated blood except the pulmonary vein.