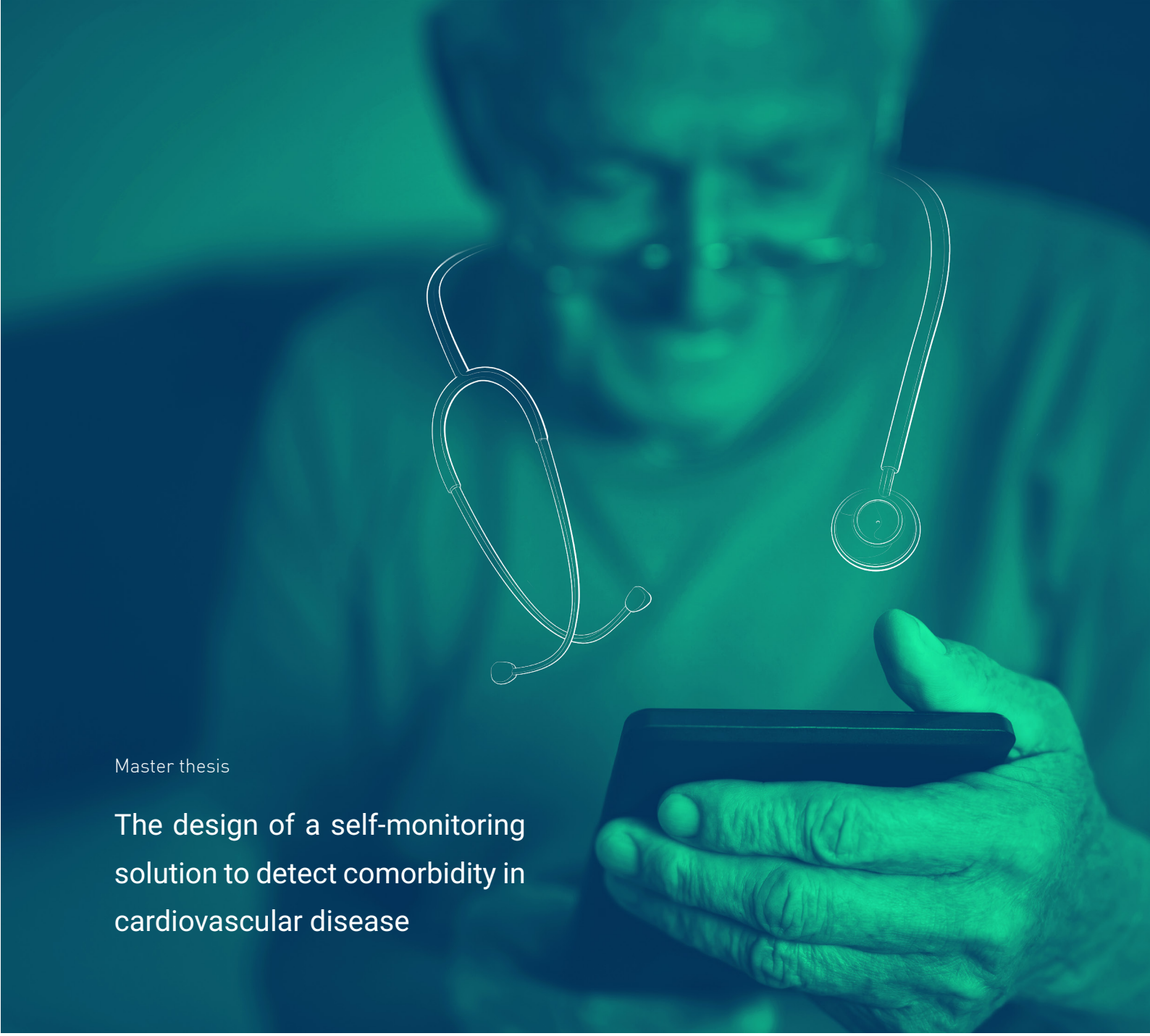

Master thesis

The design of a self-monitoring solution to detect comorbidity in cardiovascular disease

Saskia mosterman | Faculty Industrial Design Engineering | Master Integrated Product Design
Delft Design Labs | CardioLab | Delft, January 2018

TU Delft
Maaike Kleinsmann
Armağan Albayrak

PHILIPS
Marleen van Leengoed
Floor Borgonjen

Hartstichting
Ellen Janssens
Raymond Wimmers

This master thesis is written in context of the master Integrated Product Design at the Delft University of Technology.

January 2018

Author

Saskia Mosterman

Delft University of Technology

Faculty of Industrial Design Engineering
Delft, The Netherlands

Project chair
Dr. ir. Maaike Kleinsmann

Project mentor
Dr. ir. Armağan Albayrak

Philips Electronics Nederland B.V.

Eindhoven, The Netherlands

Project mentors
Marleen van Leengoed
Floor Borgonjen

The Dutch Heart Foundation

Ypenburg, the Netherlands

Project mentors
Ellen Janssens
Raymond Wimmers

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Executive Summary

Chronic diseases often come together. Having one disease increases the risk of having another different disease. A coexisting disease, also known as a comorbidity, drastically decreases the quality of life and can result in further health decline, as they come unnoticed and untreated. Detection of the first disease signs gives rise to timely seeking help and intervention. Therefore, screening for other diseases than the one diagnosed is essential for the health and well-being of patients.

This graduation project aims to improve secondary prevention of cardiovascular disease by design. It focused on opportunities to encourage people with established cardiovascular disease to act on cardiovascular risk and decline, using data derived from self-monitoring. The project aim was to develop a solution which helps patients at home with the interpretation of clinical signs indicative of cardiovascular decline and undetected co-occurring diseases.

The project is carried out for the CardioLab, a research consortium between Philips Healthcare, the Dutch Heart Foundation and the faculty Industrial Design Engineering. The common goal of the three partners is to "join forces in research and design to decrease the large number of heart patients and casualties due to heart failure with the use of data-driven technologies".

Problem

The prevalence and detection of comorbidities bring along various problems. The actual prevalence of comorbidities is underestimated due to underdiagnosis of the primary disease and the comorbidity. It may that the comorbidity is confounded by shared risk factors or that the features of the comorbidity overlap with features used to define the primary disease. The first signs of the comorbidity are often undetected or unacknowledged as checkups at the specialist are just isolated samples. Complaints and clinical signs do not always present or are not actively sought during these samples. Also, the timing can be just unfortunate. The presence of the comorbidity causes many complaints and can result in contradictory treatments. Needless to say, new strategies for comorbidity detection and care are necessary.

Research

Longitudinal screening through self-monitoring could pick up on the first signs of disease. Literature and field research showed that certain health variables, such as heart rhythm and blood pressure, are indicative of multiple diseases. Combinations of these variables can be suggestive towards specific diseases. Therefore, integrating these variables in a home-use screening device enables patients to monitor the risk of various diseases continuously.

Design proposal

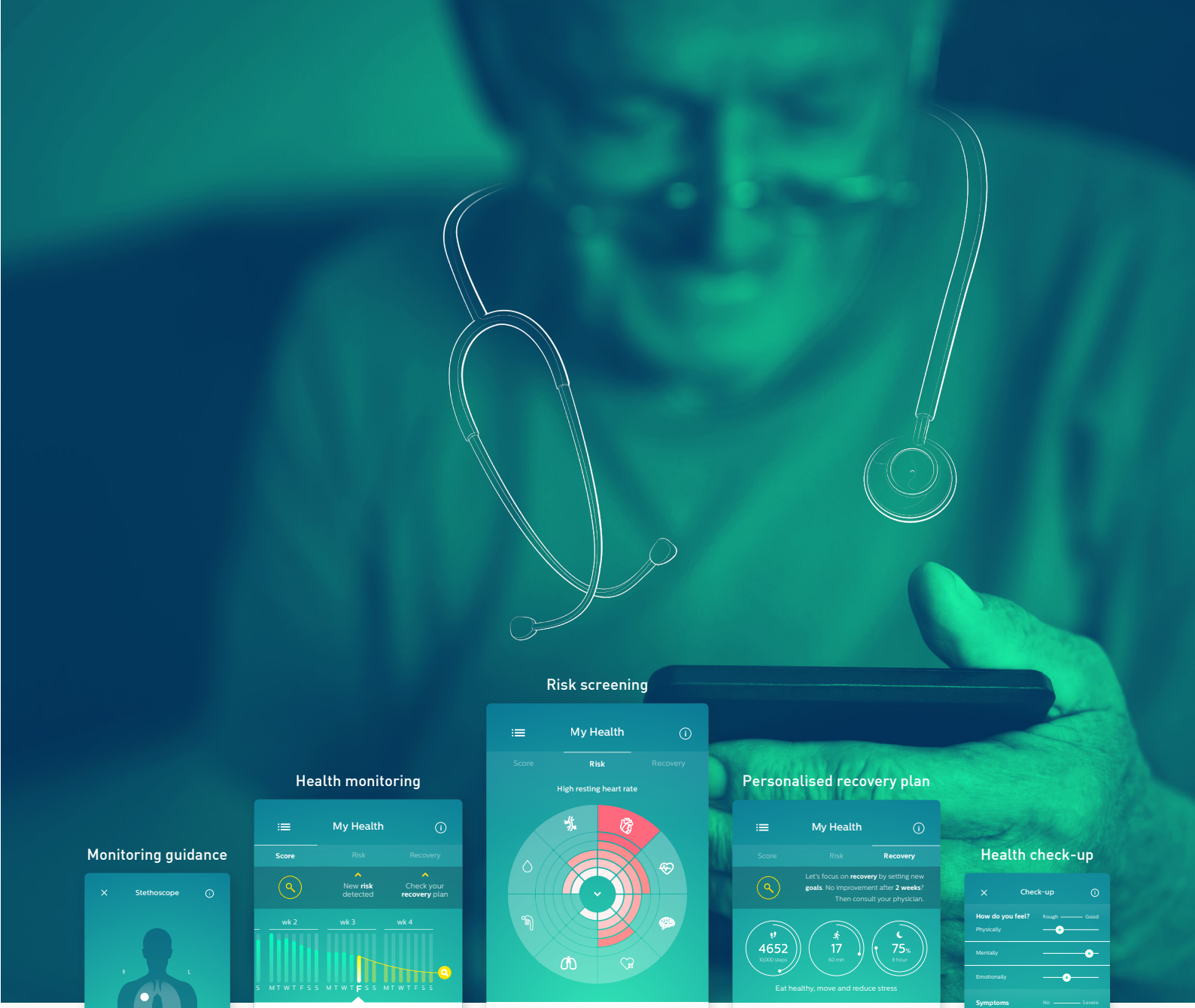
The project proposes a self-monitoring solution which enables patients to monitor their risk of complications and comorbidity by using a **home-use stethoscope** and a **smartphone application**. The smartphone application visually demonstrates the near future risk of complications and gives patient-tailored action points to reduce this risk.

The proactive feedback intent to evoke a well-considered patient response, ranging from encouraging healthy lifestyle habits, to the reassurance of seeking help. It aims to engage and empower patients in the ambiguity of risk management by providing insights on the whys and hows of preventative self-management strategies which apply to their situation.

Evaluation

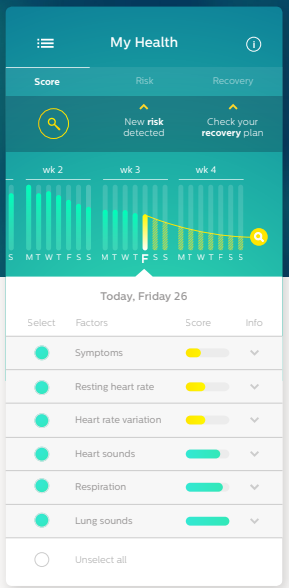
The user evaluation demonstrated that most participants, with and without a cardiovascular disease, perceive the design proposal as helpful and motivating. However, the experience of stress due to an increased risk level for disease was perceived as a concern by many. Some saw the risk insights as a necessary evil to come in action to reduce their risk; others wouldn't want to know about it. This assumes that the platform would not be suitable for all personality types. Further research needs to assess the role of stress in these risk scenarios.

The project explored a new strategy to improve secondary prevention of cardiovascular disease. Further research and development are needed to substantiate the true effectiveness of the proposal.

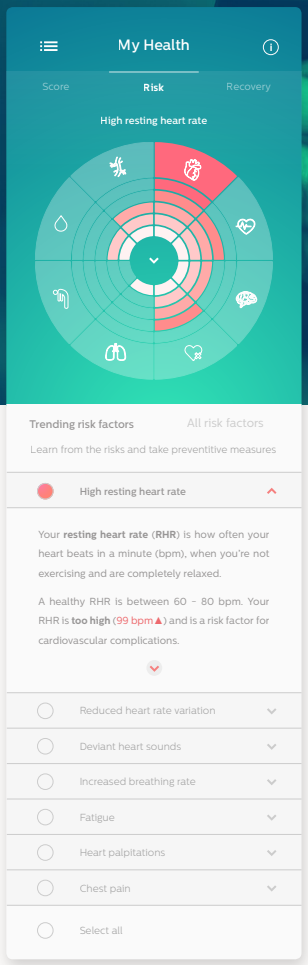


Monitoring guidance

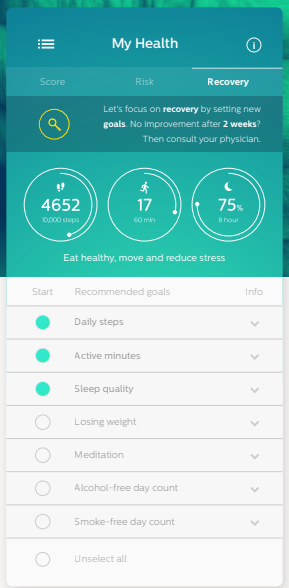
Health monitoring



Risk screening



Personalised recovery plan



Health check-up

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Part IV. Validate

Introduction

CardioLab

The project is carried out for the CardioLab, a research consortium between Philips Healthcare, the Dutch Heart Foundation and the faculty Industrial Design Engineering. The common goal of the three partners is to "join forces in research and design to decrease the large number of heart patients and casualties due to heart failure with the use of data-driven technologies".[1] The parties value the research and design outcomes in different ways but mainly benefit from the insight in opportunities on the intersection of people, technology and business in cardiovascular care.

TU Delft

The faculty of Industrial Design Engineering has an increasing number of design projects carried out in the medical field. The CardioLab is an initiative to align student projects to create state-of-the-art knowledge on cardiovascular care and to cultivate inventiveness with cross-disciplinary teamwork.[1] The collaboration with Philips and the Dutch Heart Foundation boosts the level of knowledge and resources needed for the design explorations.

Philips Healthcare

Philips Healthcare is one of the leading companies in healthcare, focusing on the complete cycle of care, both in professional healthcare and in personal health. Philips has various home monitoring products in its portfolio. The Philips HealthSuite connects these monitoring products via a cloud-based service and digital platform.

The Dutch Heart

The Dutch Heart Foundation is a non-profit organisation with a mission to cure cardiovascular diseases. It has a network of patients and their close relations, researchers and health professionals. The efforts of the Foundation mainly focus on research, societal interventions and promoting awareness to reduce the incidence of cardiovascular disease and to improve the quality of life of cardiovascular patients.

Secondary prevention

Cardiovascular diseases (CVD) are globally the leading cause of death.[2] Besides the importance of primary prevention, there is a lot to gain in secondary prevention which comprises early detection of disease process and application of interventions to prevent progression of disease.[3] Prevention of disease progression and CV events are vital since damage of the cardiovascular system is irreversible.

Put briefly, secondary prevention aims to:

- stop/delay CVD disease progress;
- reduce the risk of disease recurrence;
- improve functional capacity;
- and restore quality of life.[4]

The recommended secondary prevention approach comprises:

- patient assessment;
- physical activity counselling and exercise training prescription;
- nutritional counselling;
- risk factor control;
- psychosocial management;
- vocational support;
- therapy adherence;
- and patient education.[4]

Problem definition

In patients with established CVD, small interventions like altering medication can have a significant impact in preventing further progression of the disease and acute cardiovascular events [5]. However, the presence of an undetected underlying disease, called a comorbidity, interferes with adequate treatment and can even cause life-threatening events such as a stroke. Early detection of the first signs of comorbidity can be vital in seeking help and timely intervention. However, the first signs of the comorbidity are often

undetected or unacknowledged as checkups at the specialist are just isolated samples. Complaints and clinical signs do not always present or are not actively sought during these samples, or the timing of presentation can be just unfortunate.

The under recognition and severe nature of comorbidity demand for new screening strategies. The gap in the detection of complaints and clinical signs between specialist check-ups presents an opportunity for longitudinal screening using self-monitoring of multiple diseases at once.

Graduation assignment

The goal is to develop a solution which encourages people with an established cardiovascular disease to act on cardiovascular risk and decline, using data derived from self-monitoring. The intended solution helps patients at home with the interpretation of clinical signs indicative of cardiovascular decline and undetected co-occurring diseases.

Method and report

The problem definition describes a "wicked problem" since both the problem and the solution were unknown at the start of the project.[6] In contrast to a conventional design approach, the project started without a clear design brief. Hence, design research was used to come up with a point of view which frames the real design challenge and design brief.

The project was executed and reported in 4 phases which represent the solution-based design approach. Although the process was predominantly linear, a lot of iterations modified the preceding steps and made the process more cyclical. The report describes the 4 phases in a result-based style:

Understand

These chapters help to get acquainted with disease prevention and management of cardiovascular diseases and associated comorbidities.

Discover

This part entails the research and analyses of the project. It starts with a rationale and strategy to come up with promising opportunities for comorbidity screening. The next chapters discover and weight the user, clinical and technological aspects, useful to consider in a self-monitoring. The part ends with a synthesis, which translates insights to a final design brief.

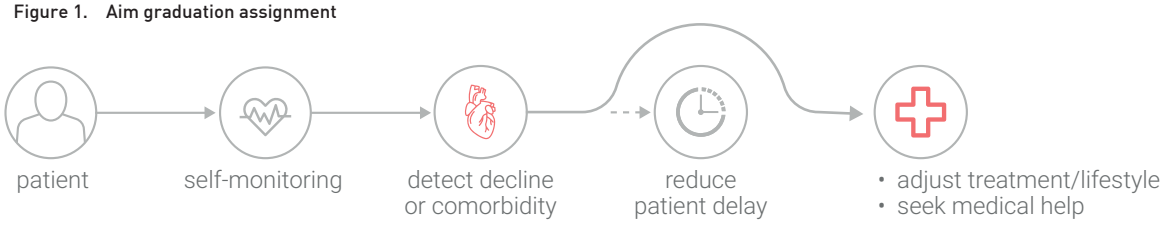
Design

This section entails the ideation and concept development. This part displays the system and digital design of the proposed product-service system.

Validate

These chapters evaluate the feasibility and acceptance of the design proposal. This part concludes the project and describes recommendations for further research and development.

Figure 1. Aim graduation assignment



1

Understand

1. Cardiovascular Diseases

Cardiovascular diseases (CVDs) are disorders of the heart and blood vessels.[7] Different types can be identified by their location and cause as illustrated on the next page. Among these, commonly known are heart attacks and strokes as they are acute and severe by nature. Both are the result of a blockage in a vessel preventing blood flowing towards the heart or brain. The most common reason for this blockage is atherosclerosis. Atherosclerosis is an inflammatory process that builds up fatty plaques in arteries over a period of several years.[8] These plaques clog the arteries and therefore reduce the blood flow and oxygen supply to cells. Other mechanisms leading to CVD can be the result of a damaged heart structure or alterations in the heart's electrical system. Chapter 3 goes into more detail about the different CVDs.

1.1 Epidemiology

CVDs are globally the leading cause of death as more people die annually from CVD than from any other cause.[9] In 2015 alone, an estimated 17.7 million people died from CVDs. This amount accounts for 31% of all global deaths of which 7.4 million were due to coronary heart disease and 6.7 million due to stroke.

Over three-quarters of the number of global CVD deaths take place in low- to middle-income countries. Compared to high-income countries, often there is no such thing as integrated primary health care programme leaving people with risk factors undetected and untreated. Also, people who suffer from CVDs have less access to adequate and equitable health care services and are therefore detected in a late stage of disease and die younger from CVDs.

Internationally, the Netherlands has a relatively low mortality of CVD, over 39.000 people died of CVD in 2015.[10] The reason for the relatively low rate in the Netherlands and other high-income countries are the investments in prevention, management and monitoring of cardiovascular disease.[11,12] High-income countries implement strategies to:

- reduce CVD risk factors and their determinants;
- make CVD management accessible and equitable;
- improve treatment and monitoring of CVD and their risk factors, which contributed to the reduction in CVD mortality.

Due to these strategies, the mortality rate in the Netherlands reduced by half in the last 50 years.[13]

However, the reduction in CVD mortality increased the chronic morbidity, meaning that more people become chronic CVD patient. The Netherlands alone has about 1 million people with a CVD.[14] The growing group of chronic patients requires long-term and costly care which forms an enormous burden on healthcare and society. To reduce this burden, early detection of people with an increased risk of disease or disease decline is essential.[15]

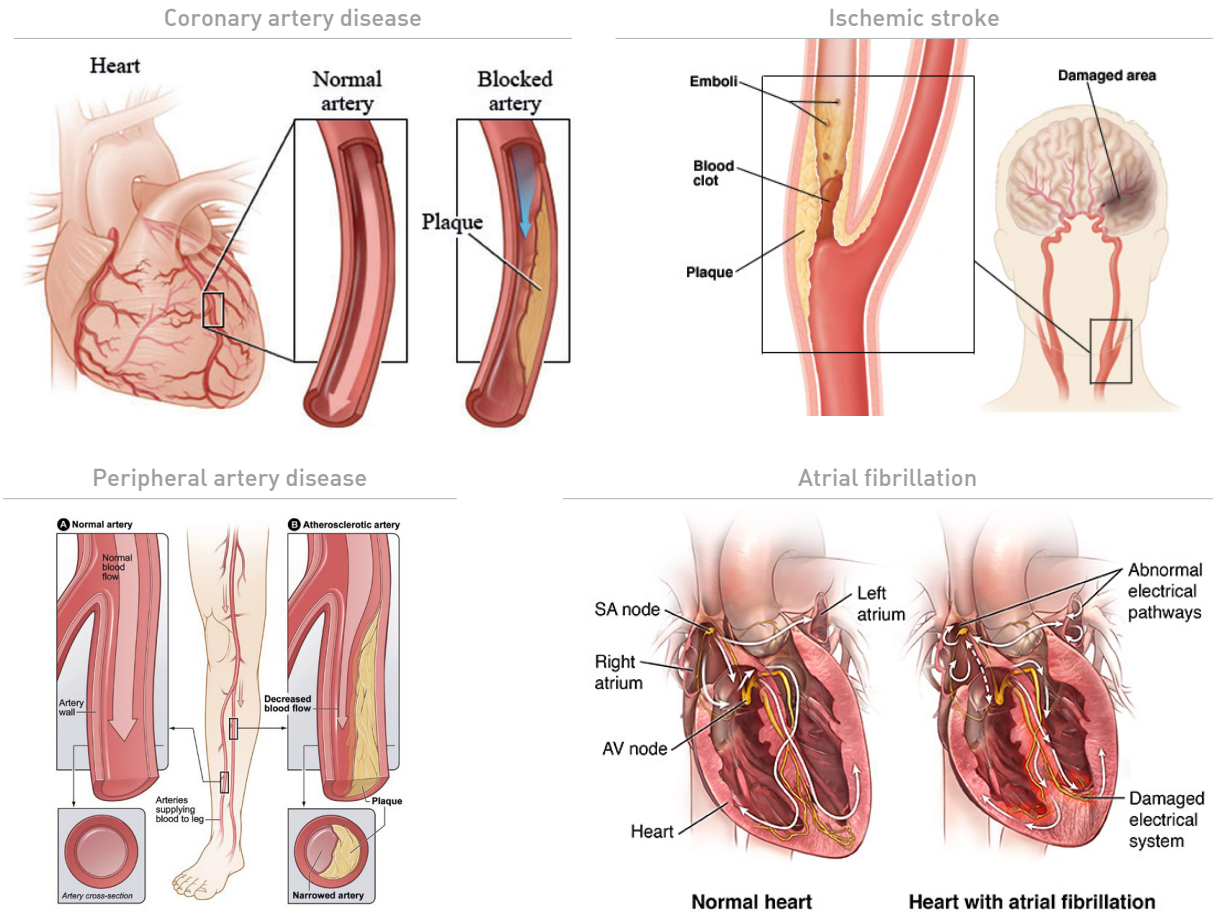
1.2 Traditional risk factors

There are many risk factors associated with CVD, including immutable and modifiable factors as illustrated in figure 2.[16] Having one risk factor does not necessarily lead to CVD but having multiple risk factors increases the likelihood it will. For every individual, it is essential to prevent and modify risk factors that could compromise cardiovascular health.

Risk factors, such as age, gender and family history/genetic predisposition cannot be changed. Unfortunately, age is by far the most important risk factor, since it triples the risk of CVD with each decade of life.[17] Also, being male or having a first-degree relative with CVD increases the risks of developing CVD considerably.[18]

However, many important cardiovascular risk factors are modifiable by behavioural change and drug treatment. The most important behavioural risk factors of CVDs include tobacco use, physical inactivity, unhealthy diet, stress and harmful use of alcohol.[19] The effects of behavioural risk factors may show up as "intermediate risks factors" such as raised blood pressure (hypertension), overweight and obesity, and the chronic disease diabetes mellitus type 2. Cessation of tobacco use, regular physical activity, consuming

Figure 1. Overview of cardiovascular diseases. [35]



Unhealthy lifestyle
Smoking
Physical inactivity
High fat diet

High risk diseases
Hypertension
Diabetes
Hyperlipidemia
Obesity

End organ damage
Heart disease
Stroke
Peripheral artery disease

Non-modifiable factors
Age
Family history

Figure 2. Traditional risk factors of CVD.[36]

fruits and vegetables, reducing salt intake and avoiding harmful use of alcohol have shown to reduce the risk of CVD. In case of hypertension, high blood lipids and diabetes, drug treatment may be necessary to reduce the CV risk.

1.3 Non-traditional risk factors

In the last decade, research found novel risk factors and markers due to improved understanding of the pathophysiology of CVD.[20] A risk marker, sometimes referred as a biomarker, is a non-causal factor of a normal or pathogenic processes, or an indicator of a pharmacologic response to a therapeutic intervention .[21] These novel risk indicators serve as a tool to better identify high-risk individuals, to diagnose conditions more accurately, and to effectively treat patients.[20] A number of novel factors and markers are associated with cardiovascular risk.[21] However, the clinical applicability of many are still investigated or optimized.

1.4 Risk prediction

Multimarker risk prediction models and risk scores are often used for CVD risk prediction, and significantly improve risk prediction.[22] These strategies combine markers or factors to provide more incremental information about the risk. Table 1 illustrates a few well known scores. Noteworthy are the similarities in the used traditional factors, although some disagreement exists between the scores over conditions and novel factors. However, the risk scores presented in the table seem to be barely useful in secondary prevention.[23] This is serious since the European guidelines state that patients with established CVD have, on average, a very high-risk of recurrent CV events and mortality.[24] Nonetheless, not all patients are alike. Substantial variations in the 10-year risk exists in individual patients, even if all the treatment targets are reached.

The SMART risk score is an example that can be used for all individual patients with clinical manifest atherosclerotic vascular disease, including: coronary artery disease, stroke and peripheral artery disease. It estimates individual 10-year risk for myocardial infarction, stroke or vascular death if standard care is provided. Identified high-risk individuals can benefit from preventive treatment, more intensive follow-up, high-cost therapies and patient education and motivation.

1.5 Cardiovascular disease continuum

CVD complications take years to develop and are found to develop along a chain of events called the cardiovascular disease continuum (CVDC). The CVDC is a complex disease cascade towards end-stage heart disease.[25] It entails a sequence of events initiated by a myriad of risk factors such as diabetes mellitus, dyslipidemia (often an elevated cholesterol), hypertension, smoking and visceral obesity (excessive fat around the organs).[26] Without intervention, it inexorably progresses to atherosclerosis, coronary artery disease, myocardial infarction, cardiac remodelling and dysfunction and eventually end-stage heart failure and death. Intervention at any stage of the cascade can arrest or delay its progress, and for this reason, early prevention and treatment are crucial.

Several clinical trials and epidemiological studies validated the CVDC and provided insights into the underlying pathophysiology and possible ways to intervene the progression. It all starts with traditional risk factors, such as smoking, elevated cholesterol, hypertension, and diabetes mellitus, that promote oxidative stress. Oxidative stress is the toxic effect of an imbalanced oxygen metabolism and causes inflammation and blood vessel dysfunction, which in turn initiate more inflammatory processes and damage; starting the array of CVD complications. Mounting evidence suggests that managing the risk factors is more important than treating the CVD itself.

To better identify both these risk indicators and the intermediate disease stages, novel biomarkers continue to be studied and elucidated. An increased resting heart rate, for example, is an emerging marker for CVD as it interferes at all stages of the CVDC.[27] It is a marker of disease severity and is closely related to CVD outcomes.[28] Reduction of heart rate is directly associated with event reduction and is, therefore, a therapeutic target. Monitoring biomarkers, such as resting heart rate, potentially identify the stages of the CVDC more accurately from which treatment intervention can prevent or delay severe conditions like CAD, arrhythmias and HF.[29]

The concept of the CVDC demonstrates the interrelations between the CVD. It supports the idea that screening for other CVD diseases than the one diagnosed is crucial in preventing CVD complications.

Table 1. A selection of variables used in cardiovascular disease risk scores [37]

		variables used							
		FRS	ARIC	ARIC-IMT	PROCAM	SCORE	Raynolds	Qrisk	SMART
fixed risk factors	age	x	x	x	x	x	x	x	x
	gender	-	x	-	-	x	-	x	x
	population	x	-	-	x	-	x	x	-
	family history	x	x	x	x	x	x	x	-
modifiable risk factors	smoking	x	x	x	x	x	x	x	x
	systolic blood pressure	x	x	x	x	x	x	x	x
	HDL cholesterol	x	x	x	x	x	x	x	x
	total cholesterol	x	x	x	x	x	x	x	x
	BMI	-	-	-	-	-	-	-	-
	triglyceriden		-	-	x	-	-	-	-
ongoing conditions	hypertension treatment	x	x	x	x	x	-	x	-
	diabetes	x	x	x	x	x	-	x	x
	rheumatoid arthiritis	-	-	-	-	-	-	x	
	kidsney disease	-	-	-	-	-	-	x	
	atrial fibrillation	-	-	-	-	-	-	x	
emerging risk factors	hsCRP level	-	-	-	-	-	x	-	x

Framingham Risk Score (FRS), Atherosclerosis in communities (ARIC), Atherosclerosis in communities with c IMT measurement (ARIC IMT), HeartSCORE (SCORE), Reynolds Risk Score (RSS), QRisk2, Prospective Cardiovascular Munster study (PROCAM). The Second Manifestations of Arterial disease score (SMART) uses more variables.

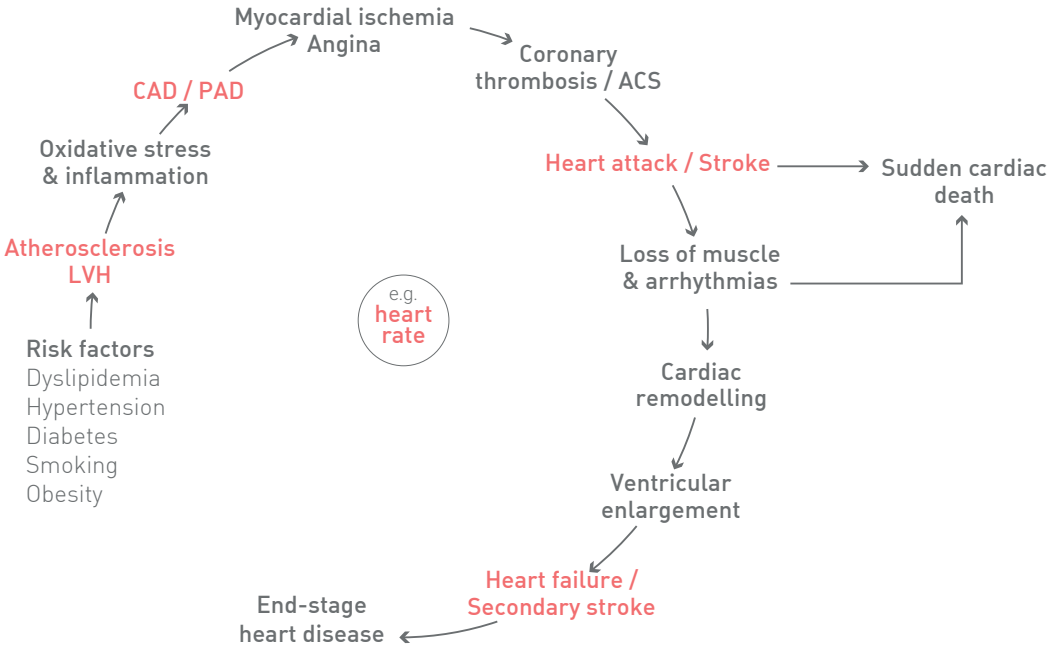


Figure 3. Cardiovascular Disease Continuum. CAD = coronary artery disease, PAD = peripheral artery disease, ACS = Acute Coronary Syndrome.[26]

1.6 Comorbidities

Individuals with multiple coexisting CVD and non-CVD are nowadays the norm rather than the exception.[30] More disease interrelationships exist beside the CVDC since all kinds of disease combinations occur. A comorbidity is each additional disease or disorder and can be both physical or mental. Consider for example someone with both diabetes mellitus, hypertension, and depression. There are several mechanisms towards comorbidity. Besides the genetic predisposition of an individual, disease co-occurrence merely happens by chance or by causal association . Figure 4 explains the different associations. The presence and detection of comorbidity bring along various problems.

Prevalence

Comorbidity is a global problem, and the number of patients with comorbidities is growing as a result of ageing and improved survival.[31] In the Netherlands alone, 13% of the total population and 37% of people aged over 55 have 2 or more chronic diseases. 70% of the people with a chronic disease has 1 or more extra chronic diseases. Figure 5 shows the prevalence of 10 chronic diseases and their associated comorbidities in the Netherlands.

However, the actual prevalence of comorbidities is underestimated due to underdiagnosis of the primary disease and the comorbidity.[32] It may that the comorbidity is confounded by shared risk factors or that the features of the comorbidity overlap with features used to define the primary disease. The first signs of the comorbidity are often undetected or unacknowledged as checkups at the specialist are just isolated samples. Complaints and clinical signs do not always present or are not actively sought during these samples. Also, the timing can be just unfortunate. New strategies for comorbidity detection and care are necessary.

Patient burden

Patients with (undetected) comorbidity have a fragile health and are susceptible for disease.[33] They have many complaints and have a significantly reduced quality of life. Many are restricted in daily functioning and cannot fully participate in society, which has many social and financial implications. Unsurprisingly, this group has a relatively high rate of depression. Alleviation of these burdens and care improvement should aim at desired future scenarios, including:

- Patients with one or more chronic diseases feel healthy as possible.
- Patients feel in control over own life and health. The need for control over own life and health and self-management is great among patients with comorbidity. However, patients need coaching in self-management, and they need a level of self-management tailored to the disease stage and their wish.
- More primary prevention aiming at health promotion; healthy diet and physical activity.
- More preventive secondary care to prevent and delay the complications of comorbidity.
- Early detection of patients with complex comorbidity (case finding) and systematic problem analyses. Early detection and (secondary) intervention contributes to prolonging health and reduces the amount of care.

Healthcare burden

Having comorbidities is associated with worse health outcomes, together with more complex and expensive health care management.[30] It requires the involvement of more disciplines, which drives up treatment costs, care complexity and the chance of contradictory advice and treatments. In the US, about 80% of the Medicare costs are devoted to patients with 4 or more chronic conditions.[34] The health care costs increase exponentially as the number of chronic conditions increases. Strangely enough, healthcare is not organised to provide care to patients with comorbidities. Nowadays, the available amount for care is based on the average care needed to treat a particular disease, while patients with comorbidities need expensive tailored care compared to this standard care.

1.7 Conclusion

CVDs are globally the leading cause of death and impose a significant burden on people and health care. Due to increased survival, more people become chronic patient and require long-term and costly care. The growing group of chronic patients are at higher risk of (recurrent) cardiovascular events and comorbidity. For this group particularly, it is essential to prevent and modify risk factors that could compromise their cardiovascular health. Many important cardiovascular risk factors are modifiable by behavioural change and drug treatment. Risk management could arrest or delay the array of CVD complications.

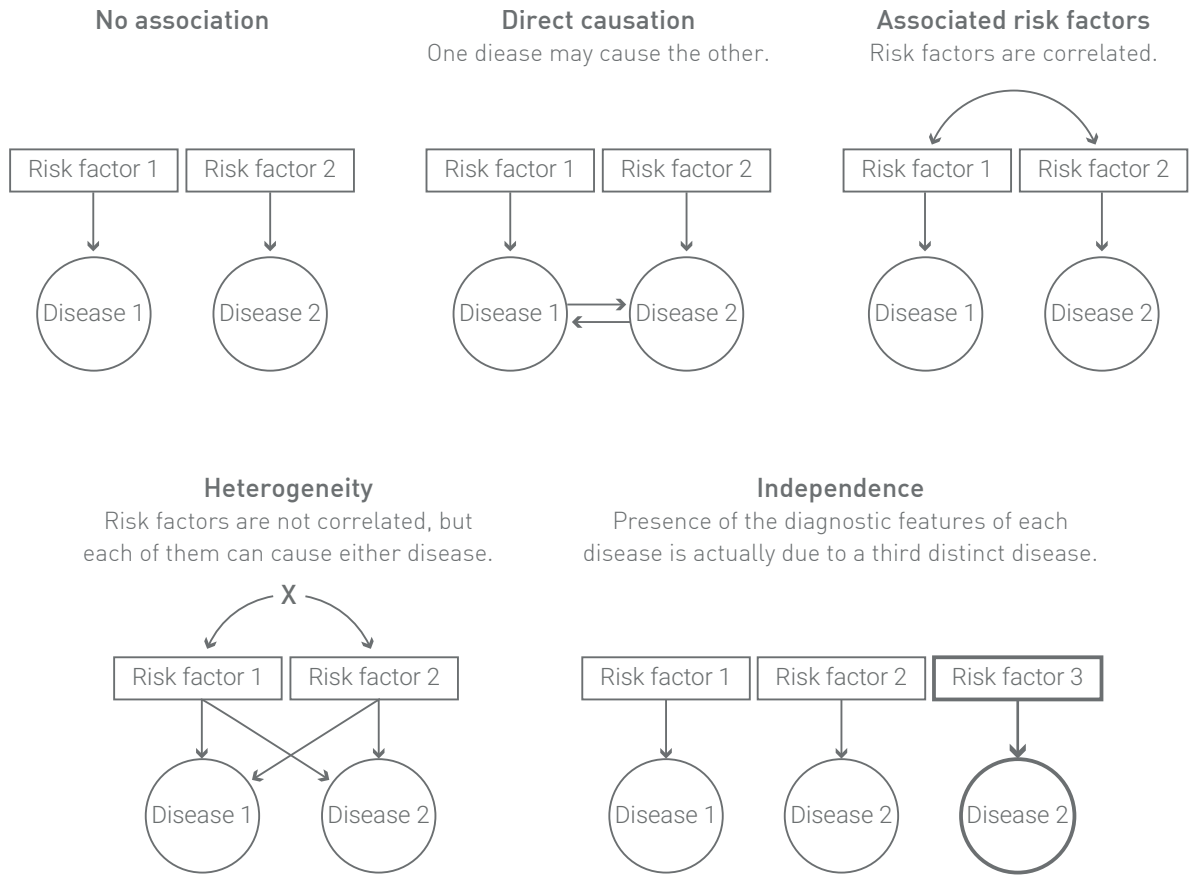
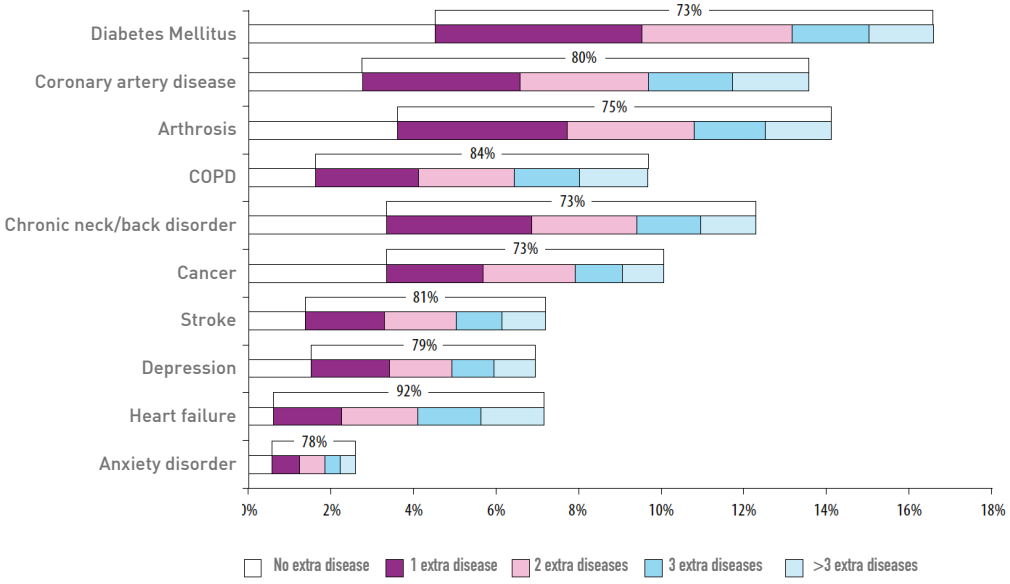


Figure 4. Etiological models of comorbid diseases [30]. For simplicity, the illustration only demonstrates 2 different diseases and 2 corresponding risk factors. Each model relies on the interaction between either diseases or risk factors. All models proved empirically valid but are not necessarily mutually exclusive.

Figure 5. Prevalence of comorbidities in 10 chronic diseases.[31]



1.8 Design implications

Making signs and risks explicit

The disease presentation of cardiovascular diseases and its associated comorbidities are often subtle or unnoticeable. Patients don't have the knowledge or means to pick up or interpret these subtle signs until they impose serious problems. This lack of know-how illustrates the demand for a translation that can help patients to understand and to respond adequately to health changes.

Encouraging healthy behaviour

Mounting evidence suggests that managing the risk factors is more important than treating the CVD itself. The design should explain and encourage how patients can modify their risk by behaviour change drug treatment.

Patient empowerment

The need for control over own life and health and self-management is great among patients with comorbidity. The design should empower patients in their risk and disease management.

Tailored coaching in self-management

Patients need coaching in self-management and need a level of self-management tailored to the disease stage and their wish. The design should provide coaching, tailored to their situation.

2

Discover

2. Research Approach

2.1 Rationale

The previous chapter found that desired future scenarios aim at a prolonged feeling of health, increased self-reliance and self-management. They also aim at improved secondary prevention that prevents, detects and delays complications of CVDs and comorbidity. The prevalence of CVD complications and comorbidities remain high, confirming that (secondary) screening and prevention are still insufficient. The unmet patient needs and the clinical inadequacy to foresee complications, call for new preventive strategies.

Potential of secondary prevention

The potential of secondary prevention is best explained by the commonest cardiovascular events: heart attacks and strokes. Globally, there are 32.4 million attacks and strokes a year.[38] Survivors of a heart attack and stroke are the highest risk group for further CV events. Considerable scientific evidence states that specific interventions reduce the risk of further vascular events in patients with established CVD. If these interventions are implemented appropriately, nearly one-third of the heart attacks and strokes could be prevented. Evidence-based interventions for secondary prevention include a wide range of drug therapies as well as modifying lifestyle-related risk behaviours. Apart from the human suffering it causes, conditions like (recurrent) heart attacks and strokes are costly to treat and indicate the highest potential for cost savings. Cost-effectiveness analyses of secondary prevention measures found that secondary prevention measures are highly cost-effective compared with many other routine medical interventions.

Treatment gap

Despite the benefits and the relatively low treatment costs, less than half of eligible heart attack survivors receive appropriate secondary prevention measures, even in high-income countries.[38] Research concerning the treatment gap in secondary prevention goes into the difference between clinical recommendations and real practice. A significant factor inhibiting the practice of secondary prevention is the inaccurate risk perception of both patients and health practitioners.[39] Both have an optimistic bias and underestimate the risk of future CV events. At first sight, the logical response would be to offer them more support to better understand the risks, so this would potentially encourage the implementation of secondary prevention measures. Notably, an accurate self-perception of the patient in particular was associated with improved secondary preventative behaviours, not the risk perception of the health practitioner. This association illustrates the importance of helping patients to understand and monitor their risk.

Self-monitoring

Patient self-monitoring is an approach to support initiation and long-term adherence to secondary prevention measures.[40] In self-monitoring, patients perform self-measurements to measure potential clinical changes over time objectively. The longitudinal nature of self-monitoring increases the chance to pick up the early signs of disease risk or exacerbation. Some signs are missed during periodic hospital checkups due to the non-constant or sudden nature of disease presentations. For instance, heart failure (HF) patients can home-monitor their weight and adjust their therapy accordingly. Likewise, patients under treatment for atrial fibrillation (AF) can self-measure their coagulation at home. Self-monitoring methods are, therefore, an increasingly recommended method for managing cardiovascular risk.[41]

Scope

Despite the evidence of disease interrelations and increased risk for comorbidity, comprehensive monitoring solutions looking beyond the disease diagnosed are not made for home use. A comprehensive self-monitoring solution could potentially identify patients at risk for a recurrent of new CV event. The fact that such screening solution can detect signs indicative of multiple diseases, also implies that the solution is applicable for multiple disease groups. The confluence of longitudinal monitoring, a broad screening scope and the coverage of multiple disease groups, constitutes sufficient ground to discover various opportunities and to develop novel concepts. Altogether, the project develops within the scope:

Screening for comorbidity through patient self-monitoring.

2.2 Hypothesis

The hypothesis derived from the scope include:

Self-monitoring can empower patients.

- Self-monitoring improves self-management.
- Patients are willing to self-monitor.

Self-monitoring solutions can facilitate complex risk management.

- Longitudinal physiological monitoring can detect signs of CV health decline and comorbidity.
- Smart self-monitoring solution can aid in clinical decision making.

2.3 Research approach

The illustration on the right displays the design approach. The following will describe the content.

Disease selection

This chapter creates an understanding of the different diseases. It addresses the cause of the diseases and both the physical and emotional burden that patients experience.

The patient

This chapter describes the 'typical' person with CVD based on the established risk factors. It gives a general overview of the care journey and how patients experience the adjustment process after the confrontation with the disease.

Clinical opportunities

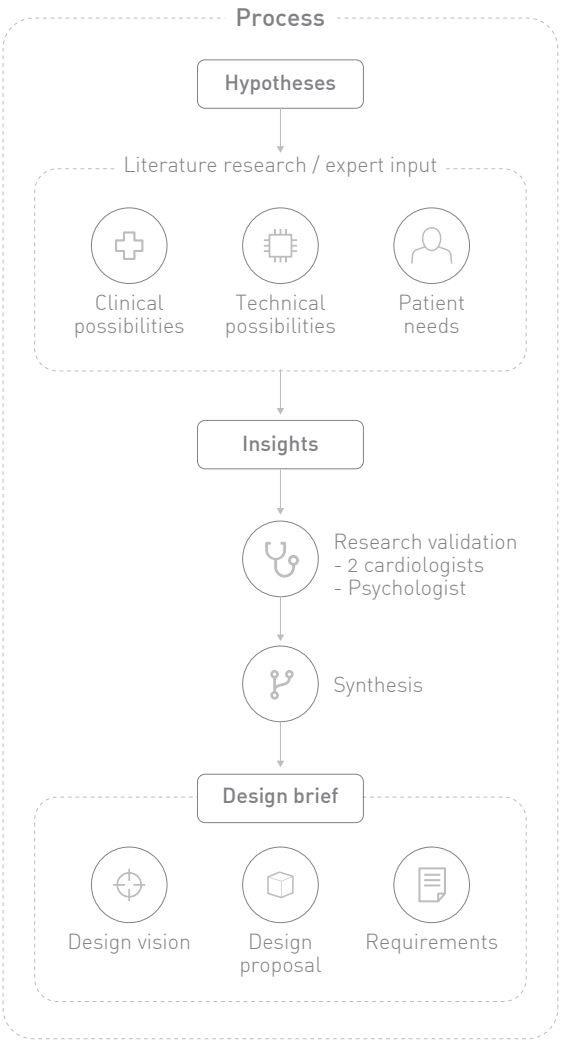
This chapter explores potential variables - measurable changes in the body - useful for health observation. These variables could help patients in noticing signs suggestive for health decline or comorbidity. The section balances the user-friendliness and clinical relevance of the considered variables.

Technologies

This chapter explores technologies that enable self-monitoring and enable patients to interpret the signs of comorbidity. The first part evaluates the monitoring technologies, by weighing the user-friendliness, richness of data, costs and the product complexity. The last part goes into techniques used for data interpretation.

Define

This section synthesises and evaluates the insights found in the previous chapters. The chapter concludes with a design brief which bridges the analyses and the design development. It defines a design vision and draws a clearer picture of the design proposal.



3. Disease Selection

The goal is to screen for comorbidity, and therefore the solution should cover multiple diseases. Turning this around, this also means that the solution may be useful to multiple patients groups. A large target group has advantages, such as a higher price efficiency due to the large target market. However, due to the timeframe of this project, a selection of the disease groups is made to make further research manageable.

3.1 Selection of diseases

The selection includes the most common chronic cardiovascular diseases and their acute conditions, together with a few common associated comorbidities which are non-cardiac. There are other common noncardiac comorbidities, such as arthritis or cancer.[31] However, it makes the solution more effective to focus on diseases that often confound with cardiovascular diseases due to their similar symptoms presentations, such as fatigue and shortness of breath. For that reason, the seemingly disconnected combination of the metabolic disorder diabetes and the lung disease COPD are included.

Another included noncardiac disorder is depression. A clinical depression is a mood disorder causing distressing symptoms affecting feelings, thoughts and daily activities. It is characterised by a persistently low mood and a feeling of sadness and loss of interest.[42] Depression is common among patients with a chronic disease and may come as a result of the emotional burden of this disease. If undetected, the disorder can make physical problems worse as depressed individuals are less likely to take adequate care of themselves, including skipping rehabilitation exercises and taking medication. [43]

Among the chronic cardiovascular diseases and disorders are included:

- heart failure (HF)
- coronary artery disease (CAD)
- atrial fibrillation (AF) and
- peripheral artery disease (PAD).

The acute conditions comprise:

- acute decompensated heart failure (ADHF)
- acute coronary syndrome (ACS)
- stroke and
- cardiac arrest.

The associated non-cardiac comorbidities include:

- diabetes mellitus type 2
- chronic obstructive pulmonary disease (COPD)
- and depression.

The tables on the next page provide an overview of the disease related symptoms.

3.2 Disease burdens

3.2.1 Heart failure

Heart failure is characterised by an impaired heart function and is often the result of coronary heart disease (CAD) or a heart attack. The heart is pumping slow or ineffectively and therefore can't meet the body's needs, resulting in a complex of symptoms and signs which may include fatigue, weakness and shortness of breath. Episodes of acute heart failure (AHF) are characterised by a rapidly worsening symptoms of heart failure that result in hospitalization. The prognosis of heart failure is often poorly. One year after diagnosis 30% of the patients die and after five year this is 65%. Until this day there is no cure for heart failure and there are limited options for treatment.

The majority of HF patients has at least one comorbidity and the number of comorbidities increases with the severity of heart failure.[44] Diabetes, COPD and stroke were among the most common comorbidities. The wide range of comorbidities also include cognitive dysfunction and depression. The presence of comorbidity contributes to HF progression and may alter the response to treatment.[45]

Physical burden

The syndrome brings along many changes and limitations.[46] Among heart failure patients, 43% to 88% experience restrictions within daily life, women more than men. Symptoms such as fatigue and shortness of breath are restricting patients in their work, leisure time and daily activities. Other common

Chronic conditions

Disease	CAD	AF	HF	Post-stroke	PAD
Problem	Insufficent coronary artery circulation	Arrhytmias	Insufficent cardiac output	Insufficient cerebral circulation	Insufficent peripheral circulation
Damage	Cardiac ischemia	Circulatory deficit, systemic ischemia	Circulatory deficit, systemic ischemia	Cerebral damage, neurologic deficits	Chronic limb ischemia
Symptoms	Angina pectoris Shortness of breath Fatigue / faintness Nausea / burning restlessness	Lethargy Palpitations (Exertional) dyspnoea Chest tightness Sleeping difficulties	Breathlessness Orthopnoea (Exertional) dyspnoea Fatigue / tiredness	One-sides weakness Joint pain / rigidity Stiffness / spasms Sensory deficits Apraxia	Claudication Numbness/ weakness Coldness leg/foot Sores that won't heal Change in the color

Acute conditions

Disease	ACS (heart attack)	SCA (heart arrest)	ADHF	Ischemic stroke
Problem	Insufficent/blocked coronary artery circulation	(chaotic / absence) electric heart activity	Insufficent cardiac output	Insufficent cerebral circulation
Damage	Cardiac ischemia, cardiac cell death	Circulatory arrest, systemic ischemia	Circulatory deficit, systemic ischemia	Cerebral ischemia, neurologic deficits
Symptoms	Instable agina pectoris Left arm / neck / jaw Sweating / nausea Abdominal pain Dyspnoea	Sudden collapse No pulse No breathing Loss of consiousness Chest pain	Dyspnea / orthopnea Fatigue / weakness Peripheral edema Exertional dyspnea Palpitations	Facial/Arm weakness Speech problems Blurred vision Confusion / dizziness Severe headache

Comorbidities

Disease	COPD	Diabetes Mellitus II	Depression
Problem	Mucociliary dysfunction	Insulin resistance, hyperglycemia	Mental/chemical imbalance
Damage	Airflow limitation / inflammation	Glucose toxicity, cell damage	Mental/physical heath decline
Symptoms	Shortness of breath Wheezing Chest tightness Coughing / mucus Fatigue	Excessive thirst Increased urination Excessive hunger Fatigue Sudden blurred vision	Depressed mood Decreased energy Difficulty to concentrate Insomnia / hypersomnia Weight change

complaints are nocturnal coughing, fluid retention in the legs and lungs, feeling bloated and a diminished appetite. Cognitive restrictions may occur due to diminished cerebral perfusion or due to the impaired heart function and are resulting in memory problems or problems concentrating.[47]

Living with heart failure implies making changes in your way of life. Patients have to adjust their activity pattern to a new balance of rest and activity, without any peak efforts. It also includes changing dietary habits to healthy food and restricting sodium consumption and fluid intake. If not managed adequately, the latter two cause a fluid overload by which tissues become congested.[48] Congestion is the most common reason for hospital admission and the rehospitalization rates remain high. This may represent an unmet need to improve the way congestion is both recognized and treated in patients after hospital discharge. Besides a lifelong medication prescription, patients are expected to look out for symptoms of decline and fluid retention.

Emotional burden

Patients are often limited in their ability to participate in social activities due to the physical impairment, the treatment and the changed lifestyle rules. Often, the social role of the patient changes the context of his or her family and social circle. Tensions may arise as family members are taking over tasks and the patient may become housebound. Changes or limitations in sexual performance may strain the relationship between partners.[49] The poor prognosis and the experience of life threatening episodes of breathlessness are a cause of fear and anxiety in patients with heart failure. Some patients are scared of death or scared for an extended period of suffering in their final phase of their life.

Depression is common among patient with heart failure. The rate of heart failure patients with clinically significant depression is 2- to 3-times higher than those of the general population.[50] However, it is underrecognized and undertreated. Depression is alarming for patients with heart failure since it creates barriers to successful treatment, leading to more frequent adverse clinical events and hospitalisations plus twice the risk of mortality. Reasons leading to depression may be sought in the fact that physicians don't ask about symptoms or that patient don't share their symptoms, or that mistakenly is believed that depression is a normal response.

3.2.2 Coronary artery disease

Coronary artery disease (CAD) is a disease of the arteries that supply blood to the heart muscle. If the arteries become blocked or severely narrowed, the blood flow to the heart muscle decreases and the heart becomes starved for oxygen and nutrients. In an acute coronary syndrome (ACS), also known as a heart attack, a coronary artery becomes suddenly blocked. This deprives certain areas of the heart muscle from blood, leading to cell death (infarction) and scar tissue. Scar tissue is not able to contract like a normal muscle and therefore the heart muscle doesn't function properly anymore.

In the Netherlands, coronary artery disease accounts for 41% of deaths by cardiovascular diseases. Mortality due to CAD has been cut in half in the last 30 years since more people survive the incident, but this also means that they need long term treatment.

An increasing number of (eldery) patients with CAD have comorbidities such as depression, diabetes mellitus II, rheumatic and joint issues or a history of cancer.[46] This has a major impact on the willingness for both rehabilitation programs and behavioural change programs.

Physical burden

The incidence of functional impairment in many CAD patients is relatively low. When the medical intervention has been successful, the impact on daily life is less severe compared to heart failure or a stroke. People feel generally much better after a bypass operation in which a new artery is placed to circumvent the blocked artery. This reduces their complaints and has a positive effect on their daily activities, work, leisure time, fatigue, mental capacity, family and social life. However, it can be disappointing for about 20% of the patients when physical complaints remain.

Emotional burden

Half of the patients experiences fear during hospital admission. After one year this is reduced to a fifth. The fear is associated with recurrent infarcts and other cardiovascular incidents.[46] Fear is also a risk factor for mortality among patients with CAD. As for the physical complaints, the fear diminishes after a bypass operation. However, again, for 20% this fear remains. Especially elderly patients feel fear and uncertainty due to neuropsychological problems after the bypass operation.

For a few, the recently experienced heart attack or a bypass operation recalls psychic traumas of their past, especially when they are in the eyes of the patient the cause of the prehistory of the cardiac disease. The experience of cardiac arrest and reanimation can cause a panic disorder in both the patients and their witnessing family members. Often this is underrecognized and there underdiagnosed.

About 40% of the patients with CAD have depressive symptoms. This is reduced by half after one year after hospital discharge. However, 10-20% shows in one to three years after the incident clinical levels of fear and depression or a significantly disturbance in quality of life. For those, the problems are persistent and can't be resolved by the patient alone.

Depression is probably underdiagnosed. Reasons for this could be that the depressive symptoms present themselves differently in CAD or perhaps the symptoms are seen as a normal response to the dramatic life event. Fatigue and lack of energy are the most common symptoms instead of a depressive mood.

Depression in CAD has its own range of consequences. This includes increased complaints of angina pectoris (chest pain due to a narrowed coronary artery), a recurrent heart attack, rehospitalizations, revalidation program dropout, treatment nonadherence, social problems and an incapacity for work. Studies have found that treatment compliance is worrying low, causing unnecessary morbidity. Recent studies even suggests that depression any time after a diagnosis of CAD is the strongest predictor of death.[51]

3.2.3 Peripheral artery disease

Peripheral artery disease (PAD) is a disease of the peripheral arteries to the head, organs and limbs, but most commonly the legs.[52] PAD is similar to coronary artery disease (CAD) as both PAD and CAD are caused by atherosclerosis narrowing and blocking arteries. As described in part 1, atherosclerosis is a vascular disease causing plaque build ups in the arteries. These plaques are made up of fat, cholesterol, fibrous tissue, and other substances in the blood. If the blockage remains in the legs, the blockage can cause pain, skin color changes, sores, ulcers and difficulty walking. In case of loss of circulation, the tissue dies and the patient can lose his or her limb.

In 2010, 202 million people were affected by PAD. It affected estimated 27 million individuals in Europe and North America with approximately 413,000 inpatient admissions annually.[53] In most cases, patients have a good prognosis, if well controlled with treatment.[54] Treatment includes lifestyle modifications, regular exercise, medications, and in severe cases, surgery. Uncontrolled risk factors such as diabetes, high blood pressure and high cholesterol, increase the risk for heart attack, stroke and limb amputation.[55]

Physical burden

PAD is a slow and progressive disease, characterised by pain, inability to tolerate normal activity and increased wound infection risk.[56] Left untreated, the pain may become chronic and progress eventually to non-healing wounds, tissue death, and limb loss.[57] Patients with PAD experience great impairment in work and daily activities, and exhibited poorer mental and physical health-related quality of life.

Emotional burden

In advanced states, PAD imposes a hard-to-bear social and emotional burden, and a struggle for pain relief.[58] Pain and sleep disturbances are major features of the disease. Studies found that PAD seriously impairs the quality of life, mainly due to pain, reduced energy, restricted mobility and social isolation.

3.2.4 Stroke

Stroke is a medical condition in which the blood supply to a part of the brain is severely reduced, depriving brain tissue of oxygen and nutrients and results in cell death.[59] [60] This medical emergency is caused by a blocked artery (ischemic stroke) or due to a leaking blood vessel (hemorrhagic stroke). Within minutes, brain cells begin to die. Early intervention is crucial as this minimizes brain damage, potential long-term complications and even prevent death.

It starts by recognising the symptoms and, therefore, awareness campaigns tell us to think "FAST".[61] The presence of either Face drooping or numbness, Arm weakness or numbness and Speech difficulty is reason to call emergency services immediately (Time). Other signs potentially accompanying the F.A.S.T. signs are one sided body numbness, trouble seeing, dizziness or a sudden severe headache. The irreversible brain damage and the chance of death, illustrate the

importance of early detection of stroke risk and direct acting on the first signs.

In the Netherlands, about 41.000 people a year have their first stroke and each year 9.600 die of a stroke.[62] One in three patients die or need lifelong support in daily tasks such as showering and dressing. From hereon, the focus will be on ischemic stroke as it is common and linked to the selected diseases described above. 80% of all strokes are ischemic and are often caused by atherosclerosis. Given the atherosclerotic nature, stroke is independently associated with the selected diseases.[63] The significance of detection plus the shared atherosclerotic presentation presents an opportunity for potential comorbidity detection.

Physical burden

Brain damage due to stroke can cause a range of physical, cognitive and behavioural disorders.
The consequences differ per patient as they are dependant on the size and location of the infarct. It can result in behavioural problems or impaired motor skills, memory, focus, communication or impulse control. 80% experiences loss of strength and motor skills disorders in the acute phase which is reduced by half after six months. 40% to 75% of the patients experience attention and memory problems in the first weeks. The cognitive impairments remain in about 25% of the patients.[46] Loss of energy is another common symptom in affecting the revalidation process. After six months, one third of the patients is still impaired in daily life, in for example grocery shopping, leisure time, work and driving.

Emotional burden

After six months, improvement of physical and cognitive impairments are unlikely. The impairments make patients housebound and less able to participate in social activities. This may result in social isolation and reduction of well-being. One third is socially isolated after a year and a half.

In younger patients, issues arise around family participation and going back to work. 18% of the patients feel that the quality of the relation with their partner is reduced since the stroke. 25% feel that the relationships with family members are deteriorated. One third feels that intimacy and sexuality are negatively affected.

Fear and depression are common consequences of the limitations and changes. Two thirds of the patients experience fear and stress in the first weeks. A fifth is still fearful after five years. Depression is a significant problem with a found incidence of 23% to 39%. The depressive complaints are associated with the severity of physical complaints together with fatigue and loss of mobility, causing restrictions in daily life and reduction of social activities. However, depression can also be the direct result of brain damage. Depression is hereby a psychological response to the arterial damage. Depression seems to be underdiagnosed as only half of the clinical depressed stroke patients are recognised by general practitioners.

3.2.5 Atrial fibrillation

Atrial fibrillation (AF) is a medical condition characterised by an irregular and often rapid heartbeat. It is the most common heart rhythm disorder or arrhythmia. During atrial fibrillation, normal electrical impulses generated by the heart's own pacemaker (the sinus node) are overwhelmed by disorganized electrical impulses. These disorganized impulses are the result of conduction abnormalities caused by scar tissue (fibrosis) in the heart chambers.[64] The chaotic electrical signals travel through the heart's two upper chambers causing the chambers to quiver rather than to contract.[65] This rapid irregularity in itself plus the poor coordination with the lower heart chambers result in a poor pump function and therefore poor blood flow to the body. This leads to symptoms including heart palpitations, shortness of breath and weakness. The episodes can come and go or be permanent.[46]

About 100.000 people in the Netherland have AF and the prevalence is high among elderly, obese people and people with sleep apnea. The main causes are hypertension, obesity, diabetes, obstructive sleep apnea, problems of the heart including valve problems, heart muscle disease (cardiomyopathy) and narrowed coronary arteries (CAD).[66] [67] [68] Atrial fibrillation is thought to be secondary to underlying cardiovascular disease in approximately 70% of patients, illustrating the importance of screening for AF in other cardiovascular diseases.[64]

Although the disorder is not life threatening, it does damage the heart. Over time, this may cause heart failure. Apart from that, it may create blood clots in the heart that can circulate to the rest of the body, forming a big risk of blocking narrower arteries and in particular a stroke.[67] One-fifth of the stroke patients have also AF. Therefore, it is essential to detect and

treat AF. Medications and other treatments can control, not cure, the condition and can prevent other cardiovascular events.

Physical burden

AF can be symptomatic or asymptomatic. Patients are often asymptomatic and therefore experience limited to no complaints. In case of symptomatic AF, the patient experiences symptoms including: heart palpitations, pressure on the chest or chest pain, shortness of breath, dizziness or even fainting, sweating and nausea.[46] The unpredictability of the episodes may bring along limitations to daily activities. However, with appropriate treatment, many people with AF will go on to live normal lives.[69] Physical activities are still possible with AF and regular exercise can even reduce the symptoms.

When AF is detected and treated, the burden of medication may arise.[70] The patient may, for example, experience fatigue as side effect of the beta blocker slowing down the heart rate. This applies also for other disease groups taking medication. This burden is not automatically or temporarily caused by the AF. A similar burden is associated with anticoagulation, commonly referred as blood thinners. Anticoagulation imposes restrictions upon the patient and brings along concerns. Anticoagulation is a nuisance, it interferes with lifestyle and potentially diet, carries a risk and requires monitoring, and carries a cost. None of these effects are desired by patients, though most will accept it because it can prevent something worse, for example a stroke.

Emotional burden

For the symptomatic group, problems in disease adaptation are mainly associated with learning how to deal with fear and stress.[46] Especially the unpredictability of AF is for many patients terrifying. Fear and stress are triggers for arrhythmias which can result in a vicious circle.

3.2.6 Sudden cardiac arrest

Sudden cardiac arrest (SDA) is unexpected death, caused by loss of heart function due to malfunctions in the heart's electrical system.[71] A cardiac arrest is not a heart attack. To clarify, a cardiac arrest is a electrical problem, where a heart attack is a perfusion problem of the heart's arteries. However, the tissue damage of a heart attack can disrupt the electrical system, triggering arrhythmias and therefore causing a SCA. The arrhythmias atrial fibrillation and ventricular (lower chamber) fibrillation are the most common causes of SCA. During a cardiac arrest, the heart beats chaotic and dangerously fast (fibrillation), causing the lower heart chambers to quiver. Due to this quivering, the heart doesn't pump blood anymore. Within minutes, the brain is derived from blood, causing the person to lose consciousness and to stop breathing. Death follows unless emergency treatment is begun immediately. Emergency treatment includes cardiopulmonary resuscitation (CPR) and defibrillation (an electric shock to the chest). SDA is responsible for 20% of all deaths in Europe.[72] The survival rates are just 5–20%.

Physical burden

To most, SCA happens suddenly since there were no clear signs beforehand.[73] About half of the victims was unaware that something was wrong with their heart, others were under CVD treatment, often CAD. Many who survive a SCA have significant disability. This disability is dependant on the duration until resuscitation and the underlying CV problem. Coma and brain damage are common side effects due to the stopped circulation to the brain. Also the CPR itself causes severe bruising or even broken bones, and take time to heal. Preventive treatment aims treat the underlying cause and aims to reduce the risk of another attack. It includes medication, heart damage restoring surgery and lifestyle.

Emotional burden

At first, many survivors experience varying levels of denial when they initially hear about the event. CA survivors and family members present during the event, may develop a panic disorder.[46] However, many survivors say that learning more about the experience helped them to accept and recover.[74] Meeting witnesses and emergency staff helped them to understand what happened and why. Meeting the rescuers was a rewarding and emotional experience to them and their families.

However, SCA survivors may face several challenges after the event. They face changes in health and behavior, and even their ways of thinking about themselves and about life. Depression and anxiety can be the response to the experienced physical and mental problems regarding daily activities. Many survivors receive an Implantable Cardioverter Defibrillator (ICD) soon after the SCA and may experience lasting psychological distress due to the ICD shocks.[75]

3.2.7 Diabetes mellitus type 2

Diabetes mellitus type 2 is a metabolic disorder with raised blood glucose levels due to inadequate functioning of the hormone insulin. Insulin enables glucose uptake into cells to give them energy. Inadequate glucose uptake deprives cells from energy and raises the blood glucose levels to toxic values, which damages blood vessels and nerves in particular.[76] Type 2 diabetes is the most common type in which the body either resists the effects of insulin (insulin resistance) or the insulin production falls short to maintain a normal glucose level.[77] There are approximately 150 million people with diabetes mellitus worldwide, where type 2 diabetes accounts for 90% of all diabetes cases.

Type 2 is inherited during life due to gene mutations and environmental factors, such as obesity and lack of exercise. Treatment of type 2 diabetes entails medication and lifestyle adjustment for glucose control and reduction of risk factors.Good glucose control can delay the onset and progression of CV complications such as atherosclerosis, high blood pressure, CAD, ACS, stroke and limb amputations. Other diabetic complications concern damage to nerves, kidneys, eyes, feet, etc.

Physical burden

Signs and symptoms of type 2 diabetes include: constant hunger, lack of energy, unexplained weight loss, excessive thirst, blurry vision, weakness and fatigue. Diabetes may be diagnosed several years after onset, once complications such as yeast infections and skin problems, already appear. Diabetes is complex and requires burdensome self-management, demanding constant attention to diet, physical activity, blood glucose monitoring and medication adherence.[78]

Emotional burden

The substantial burden of impaired functioning and high demanding self-management contributes to significant emotional stress in diabetes patients. Diabetic complications consistently predict emotional distress and decreased quality of life. Also depression is common individuals with diabetes, affecting 60-100% of the patients.

3.2.8 Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is an umbrella term for progressive and chronic inflammatory lung diseases including: emphysema, chronic bronchitis, asthma, etc.[79] The chronic lung inflammation, caused by long-term exposure to irritating substances like cigarette smoke, obstructs normal ventilation of the lung fields, which in turn results in breathing problems.

Worldwide, about 65 million people have moderate to severe COPD and the disease accounts for 5% of all deaths globally.[80] The prognosis of COPD is poor. The disease worsens over time and there is no cure. Treatment options delay progression and help people breathe easier.[81] COPD treatments include smoking cessation, medication, vaccinations and respiratory rehabilitation.[82] Periods of acute worsening (exacerbation) require increased medication or even hospitalization. Some need long term oxygen therapy and or a lung transplantations.

COPD is commonly associated with comorbidities such as CVD, diabetes mellitus, hypertension and psychological disorders.[83] Although the shared risk factor of tobacco smoking makes it difficult to define the exact relationship between COPD and these comorbidities, recent large epidemiologic studies confirmed the association independent.

Physical burden

COPD imposes a substantial burden on those who have the disease. Symptoms of varying severities include breathlessness, cough, sputum production, wheeze and chest tightness.[84] The disease worsens over time and eventually everyday activities, such as walking or getting dressed, become difficult. Patients report the morning as most troublesome, with symptoms such as coughing and sputum production at its worst. These morning symptoms result in poorer health status, reduction in daily living activities, and increased exacerbation risk.

Emotional burden

Increased COPD symptom burden drastically compromises the patient's ability to function and the quality of life. Studies found that COPD patients experience worse psychological functioning and greater psychological distress than other patients with chronic conditions. Anxiety and depression are important comorbidities and affect quality of life, exacerbation rates, hospitalization duration and

mortality.

3.3 Conclusion

The physical and emotional burden of people with chronic diseases is considerable. Although dependent on the disease stage, the disease impacts daily life, including daily activities, work, leisure time and social life. Many patients have complaints and struggle with lack of energy, immobility, fear and depression. Many need preventive treatment and are requested to monitor their symptoms and risk.

4. The Patient

4.1 The typical patient

Although CVDs can happen to anyone, certain individuals are more prone to CVDs than others. Some have a genetic predisposition to a CVD or are more exposed to risk factors. Taking into account the modifiable and non-modifiable risk factors as mentioned in chapter 1, the stereotypical person with CVD is:

- A man, 45 years of age or older;
- has a sedentary and stressful lifestyle;
- has poor food habits and is overweight;
- smokes and has a high alcohol consumption.

4.1 Patient stories

The following stories are published by the Dutch Heart Foundation and tell real patient experiences. The first story complies somewhat with the typical image of a middle-aged man with a stressful lifestyle having a heart attack. The second story portrays an untypical scenario where a young woman is affected by multiple strokes, demonstrating a more nuanced picture of the patient.

Paul was 50 years old when he was diagnosed with heart failure.[85] In the past, he had one or several myocardial infarctions without noticing. Until the diagnosis, he was unaware of his risk.

In hindsight, he remembered a rough night after a three-day hike in Namibia. That night he was ill, felt terrible and was sweating excessively. That had to be a myocardial infarction, but at the time he thought it was food poisoning. He was in the middle of nowhere, so going to the hospital was difficult anyway.

He isn't the type that goes to the doctor quickly. Therefore, there was quite some time between the incident and his diagnosis. Only when he noticed increasing fatigue, chest tightness and fluid retention he became concerned and consulted his general practitioner. His general practitioner referred him directly to the hospital; there they found narrowed coronary arteries and a leaking heart valve.

After receiving a pacemaker and a heart valve prosthesis, and revalidation in the hospital, he became aware of the long-term consequences. Before, he had a lot of energy which he could use in his busy engineering job of 60 hours a week. He travelled a lot and enjoyed sporting challenges, like scuba diving and rock climbing. Now he has to divide his limited energy. His heart has a pump function of only 30% left. He is not able to work a full-time job or practise endurance sports. Cycling for ten minutes headwind drains already all his energy. Now he only works for a few days in the week and does just things that give him energy, such as photography and going on long walks.

Paul realises that things may have gone differently if he knew he was at risk.

Anoeska had multiple strokes and TIAs (brief episodes of blood flow obstruction without tissue death). Therefore, she has to live without stress and must pay extra attention to body signals.

Anoeska had multiple strokes and TIAs (brief episodes of blood flow obstruction without tissue death). Therefore, she has to live without stress and must pay extra attention to body signals.

She got her first stroke at age 27. She lost consciousness and was admitted to hospital a few hours later. She was in the hospital for three days and had to revalidate for half a year. She was living healthy and had never expected this.

In the following years, she had four more strokes and several TIAs. She needs to avoid stress as this is a major trigger. Therefore, she no longer has a job. When tired, she has trouble remembering things, and speaking becomes difficult.

She tells that it is important to stay positive and to know your body well. She pays close attention to signals so that she can act in time.

4.3 Care journey and adjustment

For all mentioned patient groups, secondary prevention is, in essence, a patient-tailored and uninterrupted lifelong care strategy to encourage and enable them to resume a normal life.[4] The care strategy traditionally consists of three main phases:

- Acute care in the in-hospital phase I;
- Rehabilitation in the early outpatient phase II;
- Chronic care in the long-term maintenance phase III.

Adjustment process

Being confronted with disease is a threat to self-preservation.[86] Once confronted with disease, the way patients think, feel and act is strongly affected by the threatened self-preservation. It does not only concern surviving in physical terms, but it also concerns the preservation of one's self-image, beliefs and social roles. This feeling of self-preservation is an important factor in the adjustment process to the consequences of disease. The adjustment process balances between battling the consequences of the disease and on the other hand the adjusting one's self-image, beliefs and behaviours. During the adjustment process, beliefs of manipulability shifts towards realization and acceptance of vulnerability. This means a shift in disease-management (problem-oriented coping) to disability management (emotion-oriented coping). Figure 6 illustrates the three phases of the adjustment process:

- **Recovery phase**; This phase aims at minimizing the physical consequences of disease. It is the first reflex of self-preservation after disease confrontation, often resulting in a fight response. All available energy goes into surviving. As treatment is just starting, many see various possibilities for recovery, even if the physician sees none. Stress related emotions, such as anger, frustration and fear, are in this phase the result of possible setbacks in their fight against the disease.

- **Acceptance phase**; This phase is about confrontation and acceptance of the permanent consequences of disease and the definitive changes in daily life. Once recovery stagnates and results in

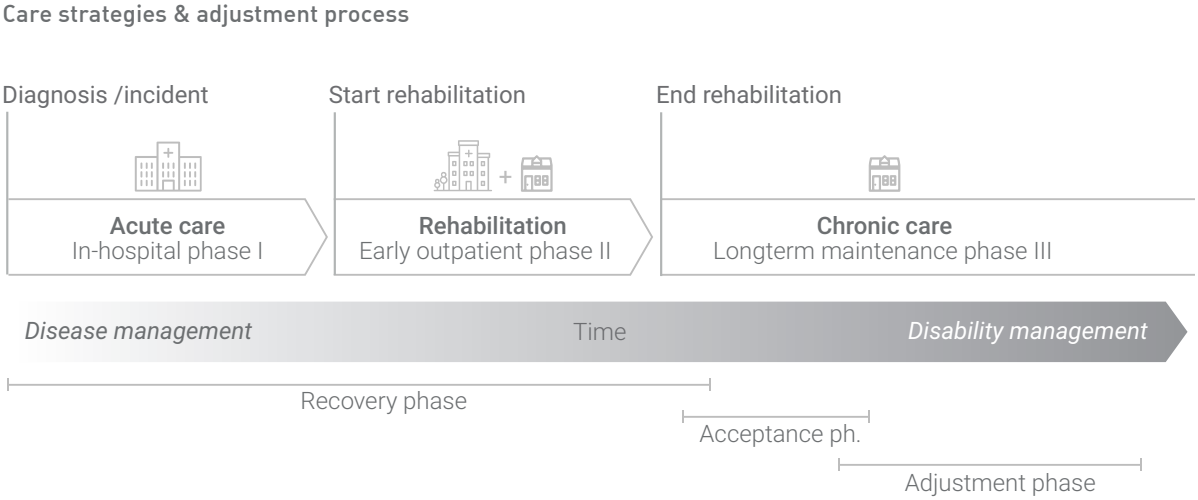


Figure 6. Care phases and adjustment process.[86]

frustration, patients start to let go of the life before disease confrontation.

- **Adjustment phase**; This phase aims at adjustment to the new situation and the search for new opportunities. The patient starts to accept the situation and change his or her self-image. This phase gives rest since no unrealistic goals are pursued.

These phases are not synchronous with the care phases: acute phase, revalidation phase and chronic phase. Most patients focus on recovery during the acute and revalidation phase. Processing and adjustment often occurs in the chronic phase when patients left the medical circuit.

It is important to align care, patient communication and screening interventions with the mental states of the adjustment process. For instance, patients will not register counseling and interventions aiming at awareness and handling of possible future limitations when they are still fighting for physical self-preservation.

Stress related problems

Many patients, and their partners, experience stress after hospital discharge, so after hospital treatment and revalidation when the medical safety net is gone.[87] Stress may be the result of worrying and fretting about recurrent events or disease exacerbation; realising complaints will be permanent; sleep problems; problems with going back to work, or overprotective partners or family members. The impact of the disease and the confrontation with one's own vulnerability is a stressful life event.

Many physical responses of stress are similar to symptoms of CVD, such as an increased heart rate or rapid breathing. This makes dealing with stress difficult since the presentations of stress and disease are hard to distinguish. On top of that, cognitive representations, like thoughts, convictions and mental images, can make things worse by evoking stress when fretting about disasters. One's physiology is partly (and unconsciously) driven by thoughts and mental representations. When disaster scenarios dominate one's thinking, long term disruption of the physiology may occur. Long term stress affects blood pressure, evoking inflammation and eventually damages the cardiovascular system.

Stress is an upsetting and unhealthy experience. Besides the physiology responses, it inhibits the motivation for self-management, especially concerning lifestyle improvement. Therefore, patients need support to adjust their lifestyle and to prevent stress and anxiety. For CV patients, stress management training focuses on learning how to deal with stress and learning about mindfulness. Therefore, preventing or reducing stress by design is essential in the development of the self-monitoring solution.

4.4 Design implications

Preservation of the patient's self-image

Being confronted with a disease is a threat to self-preservation and one's self-image. Therefore, the design should not approach or emphasise the user as a patient.

Aligning communication to adjustment stage

The design should align patient communication and screening interventions with the mental states of the adjustment process.

Preventing or reducing stress

Stress is an upsetting and unhealthy experience. It affects short-term and long-term physiology, which influences variable readings and health in the long term. Therefore, preventing or reducing stress by design is essential for self-monitoring.

5. Clinical Possibilities

This chapter explores potential clinical variables that could help patients in noticing signs suggestive for health decline or comorbidity. Clinical variables are measurable changes in the body, such as heart rate or blood pressure, and are useful for health observation.

This project focuses on self-monitoring and on signs that are easily missed during periodic hospital check-ups due to their non-constant or sudden nature. To catch early disease signs, the patient must measure either continuously, frequently or at the right time. This frequency of monitoring emphasises the need for a user-friendly technology. For this reason, this chapter presents an approach to select variables that are both clinically meaningful for a range of diseases and have the potential to be measured in a patient-friendly way, as this is the starting point of an effective screening tool.

The end of the chapter, outlines the clinical relevance of each variable for each disease. These findings combined form a graphical presentation useful for defining a design strategy for self monitoring. The variable-disease insights are therefore the clinical foundation for concept development.

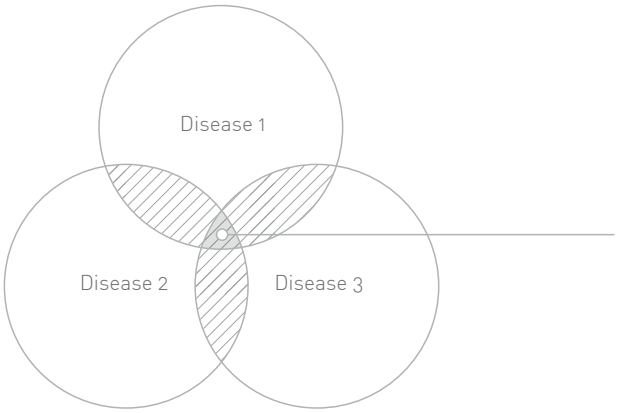
5.1 Approach

The overall approach aimed at finding variables meaningful for multiple diseases, as illustrated in the figure below. The features derived from the variables draw the distinction between the diseases, such as the difference between a high or low blood pressure. A systematic approach identified potential variables that comply with the requirements explained below. Table 2 presents the graphical presentation of the findings, colour-coded on the intersection of the disease on the horizontal axis and the clinical variable on the vertical axis. The cell shading illustrates the importance of the variable-disease combination and the cell itself contains multiple statements plus their reference to scientific literature. Combined they form a heat map, facilitating open assessment and comparison between the multitude of variables and diseases. The following paragraphs describe the steps of the research strategy that have lead to this heat map.

1. It starts with setting requirements for the clinical variables. Clinical effectiveness is key and therefore only scientifically validated variables are included. Also, the overall context imposes requirements in the field of usability, technology and business.

Variables aligned with proposed user requirements are:

- **noninvasive**, meaning not entering or penetrating body tissue. Invasive procedures could bring along discomfort and potential risk to the patient. Traditional blood glucose monitoring, for instance, brings along discomfort as patients need to puncture their skin with a needle. Invasive procedures such as implantation, bring along discomfort of the procedure itself and even risks, such as infection, and are therefore contraindicated for some patients. Traditional blood pressure measurement with a cuff



Overall approach

Determine the shared variables of the diseases
- shared symptoms (e.g. fatigue, breathlessness)
- clinical signs (e.g. heart rate, blood pressure)

Determine the distinctive features of the variables
- differentiating signals (e.g. auscultation sounds)
- quantities (e.g. blood pressure range)

Table 2. Potential comorbidity screening variables.

diagnostic & risk | diagnostic | strong risk | risk | potential risk | x poor variable | - unknown

Variable	ADHF	HF	AF	ACS	CAD	COPD	PAD	C. Arrest	Diabetes	post - stroke	Stroke	Depression
Heart Rate							-					
Heart Rate Variability												
Peripheral Oxygen Saturation									x	-	-	-
Systolic Blood Pressure						comorbidity						
Respiration Rate							-		-			-
Thorax sounds									-	-	-	-
Diastolic Blood Pressure						comorbidity		-				
ECG parameters						-	-		comorbidity	comorbidity	comorbidity	-
Body Mass Index												
Physical Activity												
Hemoglobin | Hematocrit								-				x
Obstructive Sleep Apnea												
Blood pressure variability			x					-		-		-
Pulse pressure								-		x	x	
Pulse Wave Velocity	-							-				-
Sleep Quality Index							-	-				
Sudden weight gain/loss			-	-	-		-	-	-		-	-
Body temperature			-	-	-			-	~		-	
Peripheral edema			-	comorbidity	comorbidity	comorbidity		-	-	-	-	-

is an example of noninvasive measuring.

- **careful**, meaning that the variable is measured by a small and lightweight device which is not causing any physical discomfort.

- **ambulant**, meaning that the patient is still mobile during monitoring and therefore the patient is not fixed to wires or a stationary machine.

- **unobtrusive**, meaning not disrupting daily life or demanding a lot of time and effort of the patient. Self-monitoring should not be a nuisance to the patient. Therefore, easy integration in daily life is essential to make long term use more probable.

- **discreet**, meaning that the device should not draw attention from other people or emphasise that the patient has something.

Variables aligned with technical requirements are:

- **quantitative**, meaning expressed in numbers. This allows devices to detect and compare the physical quantities of body changes.

- **simple**, meaning that the variable is measurable without unnecessary technological difficulty. Reducing complexity and using established technologies positively affect investment time and costs, maintenance and cost price, therefore making the proposal more feasible. On top of that, it allows for modification and the development of successive products.

Variables aligned with economical requirements are:

- **cost-efficient**, meaning that the variable could be detected by non-expensive technologies. Keeping costs low is key in making solutions marketable and accessible for patients.

2. Subsequently, exploratory literature research identified a multitude of variables. Initially, both scientific databases and web search engines were used to get a grip on the potential of health monitoring. Afterwards, more selective research was done solely using scientific search engines to identify significant validated outcomes. Keywords for searching included: *clinical variable, clinical parameter, risk factor, significant risk factor, marker, diagnostic marker, marker, biomarker,* together with disease synonyms and acronyms. For each found variable, potential monitoring technologies were searched. Variables were excluded when the potential technologies seem unlikely to comply with the set requirements. To clarify, some technologies are either too bulky or too costly for home-use. Variables were also excluded if they were not suggestive for multiple diseases. This resulted in the list of variables as can be seen in Table 2.

3. More in depth literature research identified the effectiveness of the variables for each disease. The same keywords were used and preferably systematic reviews were selected. Also the european guidelines for cardiovascular diseases were consulted.[88] For each variable-disease combination, it was attempted to find at least a handful of recently published and significant validated studies or reviews. Concluding sentences of the selected articles were documented in the cell plus the reference to the particular article.

4. Once the matrix was completed, the cells were graded and color-coded to provide a graphical presentation of the insights. The shading of the cell demonstrates the clinical effectivity of the variable-disease combination. Based upon the literature findings, a variable was labeled as:

both a diagnostic marker and a risk marker. Therefore, it can both be an indicator of a current disease (diagnostic) and it can be an associated attribute (risk marker) of an increased probability of a disease occurring.[89] The presence of a risk marker increases probability of a disease occurring, and if absent or removed reduces the probability. However, a risk marker is an association, and not necessarily a causal factor. It is part of a causal chain, or it exposes the host of a causal chain. Once disease occurs, removal of a risk marker may not result in a cure.

a diagnostic marker, an indicator that aid the to diagnosis of a disease.

a strong risk marker, an independently associated attribute of an increased probability of a disease occurring, validated in medical guidelines, systematic reviews or large clinical trials.

a risk marker, a marker of increased disease probability, validated in medical guidelines or scientific articles.

a potential risk marker, a potential new marker of increased disease probability, demonstrated by a single study or a small research population.

\- **unknown** No literature was found.

x **a poor marker** Poor or no indicator of disease.

comorbidity **a comorbidity**. This indicates that the variable is important to measure for the specific disease, but only for sake of a potential underlying comorbidity.

Disclaimer

It must be emphasised, that the grading process is merely a subjective strategy for ranking the clinical relevance. The aim is to mark whether a variable-disease combination has the potential for a design solution, not to find absolute values of effectiveness among the markers.

For the same reason, the sensitivity (the true positive rate), specificity (the true negative rate) and the risk ratios (probability of a disease occurring) are disregarded for now, since they were not found for all combinations. Although these are important, design applications are not solely dependent on these values but are rather a balance of these values together with the aforementioned requirements. An example of this is the Body Mass Index (BMI), a value calculated by a simple formula using weight and height. Although other methods like bioelectrical impedance obtains the exact amount of body fat, BMI is clinically useful enough and easier to measure, in the sense of use, technology and costs. Nonetheless, the process focused on (independently) significant associations to ensure scientific backup. The aforementioned scientific rates are later of interest in choosing a concept direction.

For sake of prevention, it would be interesting to have the predictive and prognostic values of markers. Predictive markers give information about the effect of an intervention, while prognostic markers provide information about the disease outcome regardless of therapy. However, terms such as association, risk and prediction are used interchangeably in research, while this not necessarily correct.[90] Even strong associations do not necessarily indicate increased predictive ability. Because of the ambiguity, the focus is mainly on risk markers. The found prognostic markers are mentioned in the results.

5. Finally, the heatmap was rearranged to have the highest scores concentrated in the top left corner.

5.2 Variable selection

The heat map includes 19 variables. What stands out is that most variables are rather common. Heart rate and blood pressure are known health variables and widely used. This was indeed expected, as scientific literature and proved clinical value were the starting point for the variable selection. The following list describes the importance of the variables briefly:

- **Heart Rate (HR)** is the number of contractions of the heart per minute (bpm). A normal heart rate varies according to the body's need to absorb oxygen and excrete carbon dioxide. However, a high resting heart rate (RHR), an irregular rate or a significant slow or fast rate indicates an anomaly.

- **Heart Rate Variability (HRV)** is the variation in the time interval between heartbeats, also referred as the beat-to-beat variability. Variations between heart rate intervals are normal and caused by nerve stimulation and respiration cycles. A reduced HRV reflect anomalies in the many physiological factors modulating a normal heart rhythm.[91]

- **Systolic Blood Pressure (SBP)** indicates the amount of pressure the blood exerts against the arterial walls during a heartbeat and is therefore the upper limit of the blood pressure.[92] Prolonged high or sudden significant high pressure can indicate risk, acute problems or chronic disease.

- **Diastolic blood pressure (DBP)** indicates the amount of pressure the blood exerts against the arterial walls when the heart is in rest and is therefore the lower limit. Prolonged low blood pressure or sudden significant low pressure can indicate risk, acute problems or chronic disease.

- **Blood pressure variability (BPV)** is the variation in blood pressure over time. Over 24 hours, blood pressure fluctuates due to physical activity, sleep, and emotional stimuli.[93] Blood pressure also fluctuates in the long term, from days to years. However, an increased long term blood pressure variation and a blood pressure drop before sleep are associated with cardiovascular complications and mortality.[94]

- **Pulse pressure (PP)** is the difference between

systolic and diastolic blood pressure. This pressure difference reflects the force of a heart contraction, together with the elastic properties of large arteries. A normal pulse pressure goes up during exercise and goes back to normal in rest. A low or narrow pulse pressure may reflect significant blood loss or heart failure. A high or wide pulse pressure reflects artery stiffness or heart valve malfunctions and is found to be a risk factor for major cardiovascular complications and mortality.[95]

- **Pulse Wave Velocity (PWV)** is the speed of an arterial pulse circulating through the vascular system. It is also a measure of arterial stiffness.[96] Arteries stiffen due to advanced age and hypertension. This stiffness inhibits arteries from expanding during systole and is therefore increasing the wave speed like a pinched hose. The stiffness and increased speed increase the systolic pressure and pulse pressure which both identify cardiovascular risk. PWV is also an independent risk factor.

- **ECG parameters** are characteristics like waves, intervals and segments on the visual line of an electrocardiogram, which reflect the heart's electrical activity over a period of time. Electrocardiography obtains information about the structure and function of the heart, and can detect a range heart conditions. Conventionally, the electrical activity is measured from twelve angles (leads) at once, leading to the characteristic presentation of an ECG. However, ambulant ECG use fewer leads despite of the loss of information.

- **Thorax sounds** include heart sounds and lungs sounds made audible by a stethoscope. The heart sounds reflect the turbulence in blood flow when heart valves close during a heartbeat. The sound characteristics and the presence of additional sounds are indicators of anomaly. Normal breath sounds are present when air travels through the lung fields. The presence of additional sounds such as rales, wheezes and rubs are indicators of disease.

- **Respiration Rate (RR)** is the number of breaths per minute measured during rest. An increased RR may indicate stress, illness or other medical conditions. Also breathing patterns can indicate various disorders. The cyclical episodes of apnea (stopped breathing) and hyperventilation in Cheyne Stokes respiration, for example, are associated with heart failure and stroke.[97]

- **Obstructive Sleep Apnea (OSA)** is a common sleep disorder whereby breathing repeatedly stops and starts during sleep.[98] The throat muscles intermittently relax and block the airway during sleep, which results in snoring. OSA is a risk factor for cardiovascular disease and stroke and is associated to other cardiovascular risk factors such as obesity and insulin resistance.[99] OSA is even implicated in the pathogenesis of congestive cardiac failure, pulmonary hypertension, arrhythmias, and atherosclerosis.

- **Sleep duration and quality** are known influencers of health and quality of life. Inadequate sleep is associated with increased prevalence and incidence of cardiovascular diseases including hypertension, coronary heart disease, and stroke.[100] Long sleep is significantly associated with diabetes mellitus, cardiovascular disease, stroke, coronary heart disease, obesity and with mortality.[101]

- **Peripheral Oxygen Saturation (SpO2)** is an estimated percentage of oxygen in the blood. A low SpO2 percentage signifies that the body is deprived from oxygen and is a severe condition.

- **Hemoglobin (Hb)** is the protein that binds oxygen in a red blood cell.[102] A low level of hemoglobin or red blood cells deprives the body of oxygen and is commonly known as anemia.

- **Body Mass Index (BMI)** is an attempt to quantify the nutritional status and the amount of body fat, in categories of normal weight, underweight, overweight or obese.[103] Both overweight and obesity are associated with an increased risk of cardiovascular diseases, high blood pressure, diabetes and premature death. However, for stroke and heart failure patients, mortality is inversely related to BMI.[104] [105]

- **Unintentional and rapid weight gain or weight loss** of 5% of your normal weight in 6 months may indicate a serious condition.[106] In relation to cardiovascular diseases, rapid weight gain is associated with fluid retention in heart failure.[107] Weight loss is associated with diseases, such as COPD, depression and also heart failure.[108]

- **Peripheral oedema** is swelling due to fluid accumulation in the peripheral tissues, often in the lower limbs.[109] Usually, fluid leakage from capillaries (small blood vessels) is balanced out by lymphatic drainage. However, when this balance is

disturbed, oedema can be mild and temporary, like in pregnancy, or can be severe and a symptom of a serious disease, like heart failure.

- **Body temperature** is a known indicator of disease and disease severity. In relation to cardiovascular diseases, a low body temperature is an independent marker of poor outcomes in patients with worsening HF.[110] Fever develops in half of the stroke patients and the high body temperature is significantly correlated to the stroke severity, lesion size, mortality, and neurologic outcome.[111]

- **Physical activity and exercise** are associated with a decrease in cardiovascular morbidity and mortality. Regular physical activity is a core component and goal in cardiac rehabilitation and positively affects the prognosis of various cardiovascular diseases. Physical activity has, for instance, an U-shaped relationship with the incident AF.

5.3 Overall findings

Table 2 illustrates the colored variable-disease combinations. The extended version is placed in the appendix. The clinical relevance of the 19 variables for 12 diseases count up to 228 variable-disease insights of which 170 have a potential to strong association. This supports the hypothesis that disease signals overlap for the selected diseases.

Cardiovascular diseases

Noticeable is that the diseases of the cardiovascular continuum, CAD, ACS, AF, HF, ADHF, have similar variable results. Likely due to the same underlying mechanisms and shared associated risk factors that build up along the disease cascade. Therefore, it is not surprising that most variables are suggestive for ADHF and HF as these diseases are the end stage of the cardiovascular continuum. Patients with HF often had a longer disease journey and therefore more underlying damage to the cardiovascular system. Hence, the causal chain towards heart failure exposes more measurable factors.

Comorbidities

Variables suggestive for COPD are both the expected COPD presentations and the presentations that overlap with CVDs. The typical measurable presentations are caused by smoking (SpO2, RR and thorax sounds), together with a sedentary and low socioeconomic lifestyle (BMI and PA). The damaging consequences of these risk factors explain the similar variable outcomes with the CVDs and the fact that these diseases often go together (comorbidity). The systemic inflammation and oxidative stress that go with these risk factors are not only damaging the lungs but also the cardiovascular system. [112]

Diabetes shares variables with the CVDs mainly on the field of lifestyle (BMI and PA) and blood pressure. These are credible findings since physical inactivity and obesity are strongly associated with both CVDs and insulin resistance, the cause of diabetes type 2, and insulin resistance is in turn associated with high blood pressure.[113] [114] The outcome for HR is high since a severe low blood sugar (hypoglycaemia) triggers a rapid heart rate.

Unsurprisingly, the variables for the mood disorder depression are less convincing. The cardiovascular consequences of depression are still in investigation but potentially relevant variables include resting heart rate and blood pressure. Evidence shows that BMI has a significant relationship to the severity of depression.[115] [116] Inactivity and sleep disturbance are important contributors to depression.[117] [118]

5.4 Detailed findings

From the graphical presentation alone, the question could arise whether a variable suggestive for multiple diseases says anything at all. It may suggest that this variable is just an indicator of general health decline. However, the characteristics of the variable readings can be more distinctive, like the fact that a heart rate can be high, low or irregular. Table 4 describes some variables along with the characteristic clinical signs that are more suggestive for diseases. Table 3 illustrates what the clinical signs mean for the probability of disease.

5.5 Other findings

The literature findings also illustrate other reasons for comprehensive monitoring rather than just alarming for comorbidity. The same variables could be used to monitor and motivate for treatment adherence. This is interesting since treatment adherence remains low in many patient groups. Also the use of modifiable risk factors and prognostic markers could help patients and healthcare practitioners to tailor treatment. Another reason for comprehensive monitoring is that

certain clinical signs affect biomarker readings in the hospital. The presence of undetected atrial fibrillation or sleep apnea, for instance, affects pro-BNP readings which are used to diagnose heart failure.[119] Knowing these influences could help the diagnostic process. Although interesting, the aforementioned points need more research and are out of the project scope.

5.6 Conclusion

This chapter described the search for variables that are potentially meaningful for self-monitoring. The outcome demonstrates the clinical relevance of the 19 variables which potentially comply with the set requirements. The next step is to determine which variable, or combination of variables, would be effective for a screening solution to detect comorbidity. Detecting comorbidity means bringing together many clinical signs, and therefore variables, to portray a clearer picture of the patients' pathophysiology.
Finding the right combination of variables is a matter of balancing user needs and clinical effectiveness with the use of technology in an inventive manner. For this reason, the next chapter delves into opportunities for self-monitoring from a technical viewpoint.

Table 3. Clinical signs adding up to probability for disease.

Risk	Diagnose		
	ADHF	Acute Decompensated Heart Failure	
	HF	Heart Failure	
	AF	Atrial Fibrillation	
	ACS	Acute Coronary Syndrome	
	CAD	Coronary Artery Disease	
	COPD	Chronic Obstructive Pulmonary Disease	

Risk	Diagnose		
	PAD	Peripheral Artery Disease	
	SCA	Sudden Cardiac Arrest	
	DM II	Diabetes Mellitus II	
	PS	Post-Stroke	
	IS	Ischemic Stroke	
	DEP	Depression	

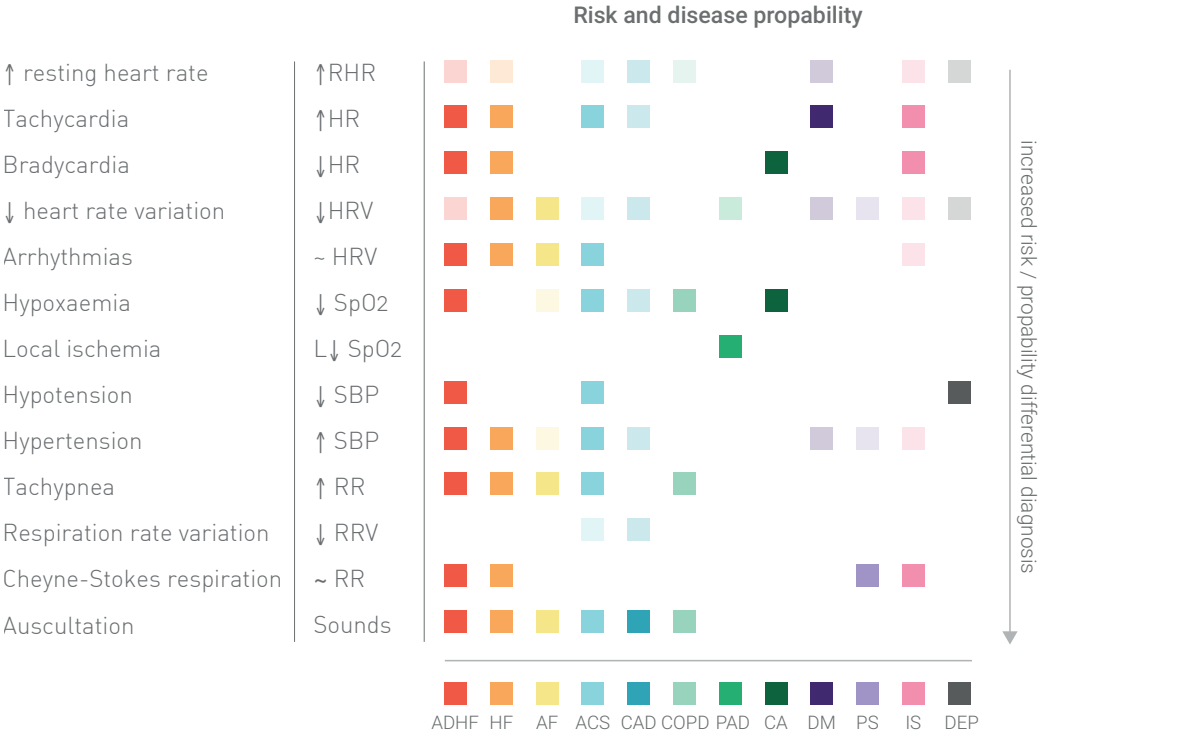


Table 4. Selection of variable-disease findings

	HR + HRV	SpO2	Systolic BP	RR + RRV	HS + LS
ADHF	• ↑ resting HR • tachycardia • bradycardia • brady-arrhythmia	• hypoxaemia • establishing the diagnosis/ severity	• excessive rise in blood pressure • hypoperfusion hypotension.	• breathless-ness • dyspnea • tachypnea • OSA • Cheyne-Stokes respiration	• crackles • rales
HF	• ↑ resting HR • ↓ HRV • brady/ tachy-arrhythmias	-	• hypertension	• tachypnoea • exertional dyspnea • orthopnea • cheyne-stokes respiration	• cardiac murmur • pulmonary crepitations • third heart sound (gallop rhythm)
AF	• arrhythmia by pulse/ECG • ↓ HRV marker recurrent AF	• hypoxemia	• hypertension	• increased RR	• absence S4 • beat-to-beat variations in the intensity of S1
ACS	• ↓ HRV • arrhythmia (NSTEMI) • tachy-arrhythmias	• hypoxemia (only in 10%) • nocturnal hypoxemia (poor prognosis)	• hypertension • hypotension	• dyspnoea • decreased RRV • increased RR (prognosis)	• carotid bruits (doubles risk MI) • abnormal S3+S4 • diastolic heart sounds
CAD	• ↑ resting HR • ↓ HRV	• low baseline saturation?	• elevated SBP	• decreased RRV	• diastolic heart sounds
COPD	• ↑ resting HR	• hypoxaemia	• CV comorbidity	• breathless-ness	• breathless-ness, wheeze, cough
PAD	• altered HRV	• local ischemia	• Hypertension • Local BP?	-	• bruits in arteries?
SCA	• absent HR	• hypoxaemia	• non-readable	• absent RR	• absent heart sounds
DM II	• ↑ resting HR • ↓ HRV • Tachycardia (hypo-glycaemia)	• insufficient sensitivity in DM	• hypertension	-	-
Post-stroke	• ↑ resting HR • ↓ HRV	-	• hypertension	• cheyne-stokes respiration	-
Stroke	• ↑ resting HR • ↓ HRV • Significant tachycardia + bradycardia	-	• hypertension	• cheyne-stokes respiration	-
Depr.	• tachycardia • bradycardia	-	• tachycardia • bradycardia	-	-

6. Technologies

This chapter explores technologies potentially useful in self-monitoring for comorbidity. These technologies enable patients to interpret signs of comorbidity using the clinical variables described in the previous chapter. They must capture physiological data, make meaning of this data and communicate the meaning to the patient. The first paragraphs weight opportunities for obtaining physiological data. It entails the rationalisation of technology use, balancing the richness of data with the costs, complexity and product volume. The last part goes into techniques used for data interpretation. Altogether, the chapter completes the technical view on self-monitoring for comorbidity and weights enabling technologies for concept development.

6.1 Data capturing technologies

The focus is on electronic measuring equipment since the Cardiolab intends to create data-driven solutions. Data-driven solutions enable data analytics to exploit patterns in clinical data to identify risk for disease and to identify opportunities for treatment and healthcare solutions. A data-driven solution complements the aim of the global healthcare industry to become data-driven since they are under significant pressure to reduce costs and manage resources more efficiently while improving patient care.[120]

The solution preferably incorporates a multitude of clinical variables to view the clinical presentation of the patient from different angles. Put briefly, the more you measure, the more you can say. For this reason, an ecosystem of connected monitoring devices would be an answer. A combination of technologies bundles different data signals and therefore covers a multitude of clinical variables. However, in terms of usability, it is preferable to find one instrument capable of tracking multiple variables. This prevents a use scenario in which patients needs to use an abundance of devices. In light of the project scope, the aim is to develop one device for screening multiple variables and diseases.

The search for noninvasive variables, as described in the previous chapter, brought up potential technologies. Variables inclusion required research into enabling technologies that meet the set requirements, as described on page 38. The technologies corresponding with the requirements include:

- **Conventional devices**, thermometer and scale.
- **Actigraphy**, measures movement and activity.
- **Ballistocardiography (BCG)**, measures body movements as result from a heartbeat.
- **Electrocardiography (ECG)**, measures heart's electrical activity.
- **Noninvasive blood pressure (NIBP)**, measures blood pressure with an arm cuff.
- **Bioimpedance spectroscope (BIS)**, measures body composition and fluid distribution
- **PhotoPlethysmogram (PPG)**, measures blood perfusion with optics.
- **Digital auscultation**, measures heart and lung sounds with a digital stethoscope.

Each of these technologies are relevant in specific clinical settings. However, digital auscultation will serve as case study for this project. Auscultation shows potential for comorbidity screening as it includes multiple variables and more potential variables are currently studied. The stethoscope is accepted by physicians and understandable to patients. In the simplest terms, it makes sense to bring the stethoscope to the patient, as auscultation is among the first things physicians use to determine the patient's condition. Regarding comorbidity, it offers the opportunity to extend to other diseases, like conditions of the gastrointestinal system.

Appendix B elaborates on the first seven technologies.

6.2 Digital auscultation

Digital auscultation, or computer-aided auscultation (CAA), obtains digital recordings of heart and lung sounds via an electronic stethoscope.[121] [122] CAA records, visualises, stores and analyses heart or lung sounds and allows sharing of recordings. The graphical presentation of heart sounds is known as a phonocardiogram (PCG).

Philips connected ear **thermometer**

Misfit Beddit sleep monitor (**Ballistocardiography**)

Philips connected body analyses scale (**scale** & **bioimpedance**)

Philips connected wrist blood pressure monitor (**NIBP**)

Pulse oximeter (**PPG**)

Philips health patch (**ECG**)

PPG sensor

Philips health watch (**actigraphy** & **PPG**)

Figure 7. Littmann electronic stethoscope.

Conventional auscultation

Auscultation is often the first screening tool utilized by primary care providers and serves as a quick and inexpensive tool available to detect and manage heart and lung diseases.[123] Although widely accepted by the medical community, conventional auscultation is fraught with error, resulting in missed diagnosis and false alarms. These misdiagnoses result in patient harm and excessive healthcare costs. Reasons for errors are the weak acoustic signals corrupted with noise and the subjective interpretation dependant on skills, experience and hearing ability of the physician. Digital amplification and automated sound analysis remove these errors and make CAA an effective screening tool.

Automation

The automation and improved objective results opens up new opportunities for telemedicine and self-monitoring.[124] It allows for real-time auscultation with specialists at home or at remote places. Once integrated into an intelligent platform, it allows for self-monitoring and health management. The analysed recordings can be documented electronically, possibly included in electronic patient records, and can be retrieved and compared once needed.[125] [126]

Available electronic stethoscopes

Nowadays, most of the commercially available electronic stethoscopes are replicas of the conventional stethoscope. They are targeted at physicians and meant for general auscultation, which includes hearing, recording and transferring the sound data.[127] However, home-use variants recently came to market and received FDA clearance. This means that the Food & Drug Administration determined the medical device as substantially equivalent to another legally marketed device.[128]

Two examples of FDA cleared stethoscopes for home-use are the Eko DUO and TytoCare. These handheld devices are designed for telemedicine and have a selling price around $300. The Eko DUO is a digital stethoscope with one-lead ECG used for cardiac and pulmonary assessment.[129] The TytoCare includes multiple sensors and allows users to examine the ears, throat, skin, heart, lungs and temperature.[130] Although these solutions perform well in guiding users in health assessment, the subsequent patient actions are entirely dependant on the input of a telemonitoring centre or a specialist. The measuring outcomes are not tailored to patients, and the patient receives no direct benefit. In this way, the monitoring solution is suboptimal because of the lack of patient involvement and the costliness of a telemonitoring service.

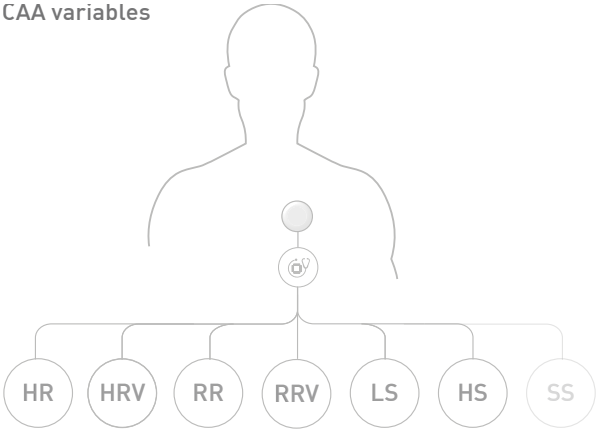
Improved analysing algorithms

Current studies focus on improving algorithms and automated machine learning for analysing digitised recordings. Several studies found promising results in heart sound and murmur detection.[131] [132] One study found an algorithm that could distinguish pathological from healthy sounds in the maturing hearts of newborns with a 92% accuracy.[133] Another study found a direct relationship between the second heart sound and the pulmonary artery pressure and found that the automated speech-recognition-inspired classification algorithms outperformed the diagnostic rate of physicians.[134] Automated lung sound detection and classification is also widely studied. Systematic reviews concluded that computerised respiratory sound analysis are useful in diagnosing and monitoring various lung diseases.[135] [136] The increasing number of studies suggest that automated sound analysis is a promising solution to overcome the limitations of conventional auscultation and to improve disease monitoring.

Comprehensive monitoring

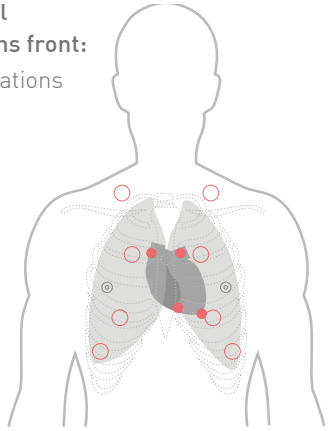
The clinical potential of CAA can be described by the comprehensiveness of heart failure monitoring. Effective heart failure management requires a multitude of variables and symptoms. CAA can extract heart rate and heart rate variability from heart sounds and can detect abnormal heart sounds such as a

CAA variables



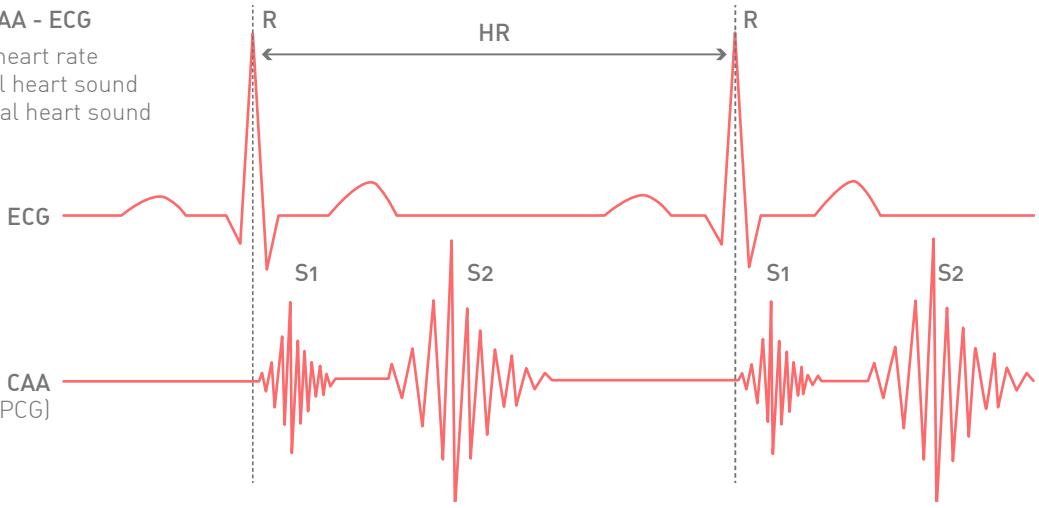
Different individual measuring locations front:

- ○ Lung sound locations
- • Heart sounds



Comparison CAA - ECG

RR-interval = heart rate
S1 = 1st normal heart sound
S2 = 2nd normal heart sound



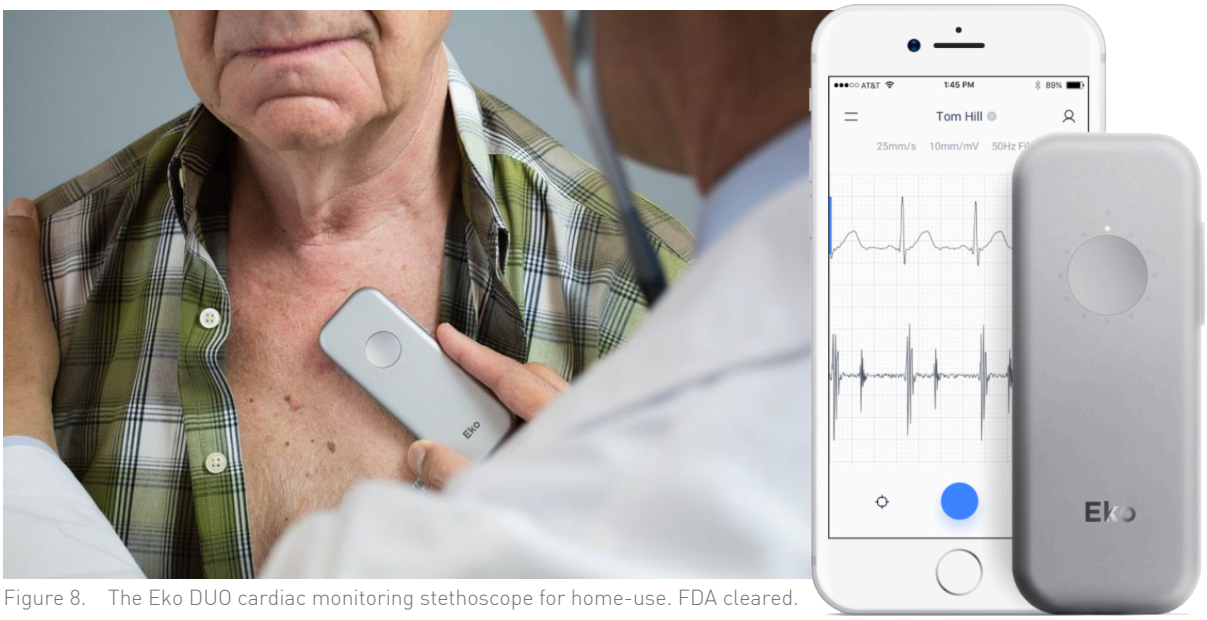


Figure 8. The Eko DUO cardiac monitoring stethoscope for home-use. FDA cleared.

third (S3) and fourth (S4) heart sound and systolic murmurs, providing valuable information concerning the pathological condition of the heart.[137] Even blood pressure can be measured indirectly from heart sounds.[138] [139] The lung sounds give information on pulmonary conditions, such as shortness of breath, rales, dyspnea at rest and night. [140]

6.3 Making meaning of data

The digital stethoscope transforms captured physiological data into actionable insights. First, the acquired data must be processed and analysed. Usually, there are three main modules in digital stethoscopes, namely the data acquisition module, the pre-processing module and the signal processing module as illustrated in figure 9.[141] To get acquainted with the technology of an electronic stethoscope and a CAA-based system, the following describes the modules, along with the electronic components.

1. Data acquisition

The acquisition module creates the digital sound data for further processing. The electronics required for this module include:

- **Stethoscope sensor**, collects sound signals directly from the patient and converts these to analog electrical signals. Commonly used sensors in stethoscopes are microphones or piezoelectric sensors.
- **Filters**, prevent sample artifacts and remove some noises outside the filter range.
- **Amplifier**, increases the amplitude of the signal to a level required by the analog-to-digital converter.
- **Analog-to-digital converter**, converts the amplified and filtered signal to a digital signal by the analog-to-digital converter. A highly set sampling frequency and bit resolution results in greater accuracy but at the cost of more required bandwidth and power consumption.

2. Pre-processing

The signal undergoes noise reduction, normalization and segmentation in the pre-processing module.

- **Signal denoising unit**, extracts the signal within the frequency band of interest from the noisy data.
- **Normalization**, normalises the sound signals to an expected amplitude, so the amplitude is not affected by the data acquisition locations and different samples
- **Segmentation**, segments the normalised data into cycles, ready for sound component detection and features extraction. Algorithms can identify the time interval between high amplitude components, also called peak detection, useful in detecting for instance the intervals between the S1 and S2 heart sounds.[142]

3. Processing and analysing

The sound signal processing module conducts feature extraction and classification.

- **Feature extraction**, converts the raw data to some type of parametric representation, called a feature. These features present properties useful in clinical evaluation.[142] Different (cloud-based) signal processing tools are available and improve classification.[143]
- **Classifier**, categorises data useful for clinical decision making, according to how it is trained with extracted features. Classifiers recently improved due to advancements in machine learning.[144] These machine learning algorithms classify features by analyzing data and recognizing patterns according to the training data set.

6.4 AI and machine learning

As mentioned before, machine learning can help disease monitoring in different ways. However, although buzzwords like algorithms, big data, machine learning, deep learning and Artificial Intelligence (AI) are mentioned often, the real definition and breadth of application (in healthcare) remains unclear to most of us. Simply put: AI is human intelligence exhibited by machines and machine learning is an approach to achieve AI.[145] Machine learning uses large datasets (big data) and algorithms to learn complex relationships or patterns needed to perform a task.[146] An established example of machine learning in healthcare is the automated 3D image registration of MR and CT images. Deep learning is a more recent form of machine learning that is inspired by the neural network structure of the human brain and is particularly effective in feature detection as described in the previous paragraph.[147] Studies show that Neural Networks already outperform human physicians at detecting health changes in a range of diseases.[148] These technological advancements open up new opportunities for healthcare. AI systems can help to reduce diagnostic and therapeutic errors that are inevitable in the human clinical practice, and AI can extract insights from large patient populations to

Stethoscope variables	Heart sounds, bruits, lung sounds, HR, HRV, RR, RRV, OSA (BP[152])	**Body locations**	Chest, back, neck (out of scope: stomach)
Indications	HF (pulmonary edema), COPD, AF, CA, OSA, atherosclerosis (bruits), structural heart diseases (out of scope)[153]	**Advantages**	+ Low costs, easy operation + No contraindications + Established clinical variables + Scalable to other conditions (e.g. gastrointestinal system)
Sensor components	Piezo sensor technology, electromagnetic diaphragm, MEMS accelerometers [154 155]	**Disadvantages**	- Sound/placement artifacts - Placement back (need helping hand)
Current applications	Electronic stethoscopes, home-use digital stethoscope (targeted at newborns)	**Accuracy**	Detecting murmurs with a sensitivity of 87%, specificity of 100% and 94% accuracy with an echocardiography as gold standard.[156]

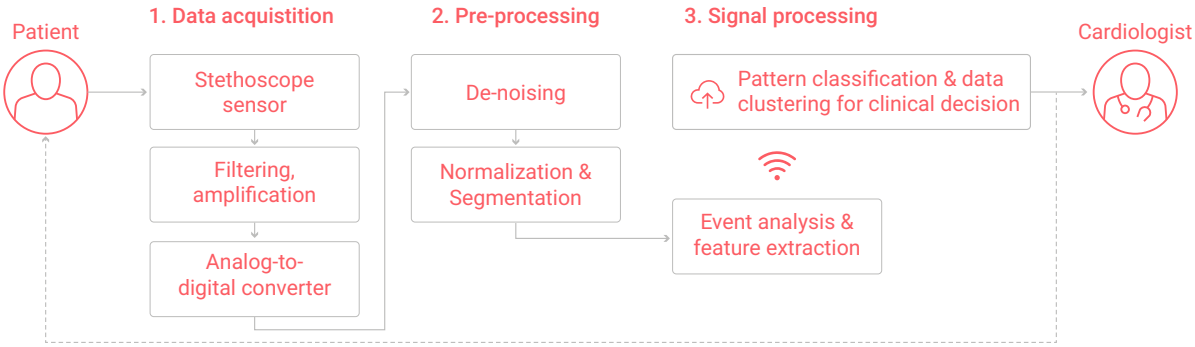


Figure 9. Sound signal acquisition, processing and analysis.[142]

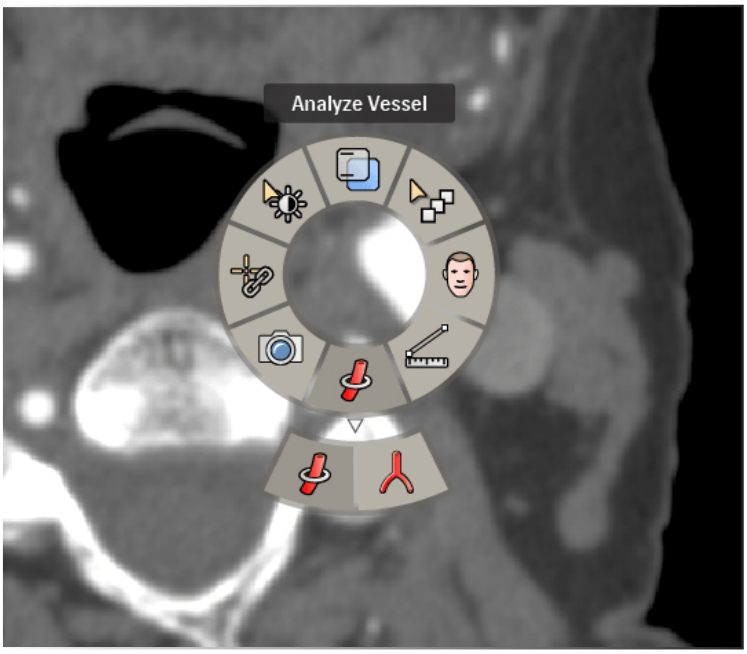


Figure 10. AI example: Philips Illumeo with adaptive intelligence, improving radiology.

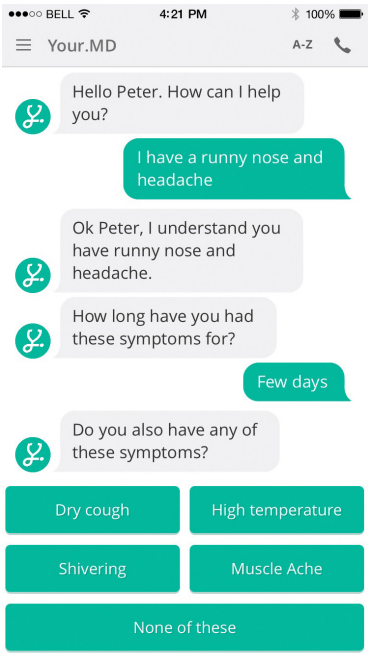


Figure 11. Your.MD, AI personal health assistant app

make real-time inferences for health risk alert and health outcome prediction.[149]

An intriguing example of AI is the use of AI in detecting associations not yet detected by humans.[150] Researchers in the UK, for instance, gave data from 300,000 patient records to machine learning algorithms, to allow them to correlate medical history with rates of CVD and therefore to 'train' itself.[151] Then, these trained algorithms were applied on records from another 82,000 patients -whose subsequent history of CVD events were already known- to predict which ones would have cardiovascular event over 10-years. Compared to the established guidelines, the trained machine-learning algorithms performed better at identifying individuals who will develop CVD and those that will not. This example demonstrates the great potential of machine learning in cardiovascular risk prediction, by identifying those in need of preventive treatment and by avoiding unnecessary treatment for others.

For AI to become accurate, algorithms must 'learn' features from a large volume of data, and receive feedback to learn and self-correct. For this reason, a vast amount of data is essential. Data from electronic patient records would be a start. However, collecting more disease related data can improve the risk assessment as in the example of newly found disease associations. Frequent or continuous self-monitoring could provide this vast amount of data. For this reason, the data derived from continuous monitoring is not only valuable for direct risk prediction for the patient, but it is also valuable for system improvements in disease prevention.

6.5 Conclusion

Computer-aided auscultation by a digital stethoscope shows potential for self-monitoring because of its established clinical variables and the recent technological advances. Software advancements and machine learning show potential for improved clinical feature detection, symptom risk assessment and user-friendliness.

7. Define

This chapter synthesis the insights of the previous chapters together to define a design brief.

7.1 Synopsis

The patient

- Screening for comorbidity, means screening for multiple risk factors indicative for multiple diseases. This broad screening coverage also implies that the solution could be applicable for multiple patients groups.

- Selected cardiovascular diseases: heart failure (HF), coronary artery disease (CAD), atrial fibrillation (AF) and peripheral artery disease (PAD), acute decompensated heart failure (ADHF), acute coronary syndrome (ACS), stroke and sudden cardiac arrest (SCA).

- Selected comorbidities: COPD, Diabetes Mellitus type 2, depression.

- Although varying in severity, CVD and its comorbidities impose substantial physical and emotional burdens on patients. The majority of the patients experience lack of energy, fatigue, pain, immobility or even brain damage. The disease often permanently impacts daily activities, work, leisure time, mental capacity, family and social life. For this reason, depression is common among all mentioned diseases. The potential prospect of recurrent events and worsened morbidity results in fear and anxiety.

- Every patient experiences the adjustment process, in which a shift occurs from battling the consequences of disease towards realization and acceptance of vulnerability, and finally towards adjustment to the new situation and the search for new opportunities. Care, patient communication and screening interventions should be aligned to the mental states of the adjustment process.

- Being confronted with disease is a threat to self-preservation and result in stress and anxiety. The presentations of stress and cardiovascular disease are hard to distinguish, an even fretting about (health-related) disasters evokes stress and presentations similar to cardiovascular disease symptoms. Chronic stress and anxiety could cause long term disruption of the physiology, such as inflammation, high blood pressure and eventually cardiovascular damage.

Clinical opportunities

- Signs of comorbidity are often not detected, recognized or acknowledged.

- Clinical variables are measurable changes in the body, such as heart rate or blood pressure, and are useful for health observation. Included variables had a high potential to be: noninvasive, careful, ambulant, unobtrusive, discreet, quantitative, simple and cost-efficient. The selected variables included: heart rate, heart rate variability, blood pressure variables, pulse wave velocity, thorax sounds, respiration patterns, oxygen saturation, hemoglobin, BMI, weight, peripheral oedema, body temperature and physical activity.

- Diseases of the cardiovascular continuum, CAD, ACS, AF, HF, ADHF, have similar variable results. COPD and diabetes overlap with the CVD, while the variables for depression are less convincing. Although variables can be fairly similar between diseases, the characteristics of each variable reading can be more distinctive, like the fact that a heart rate can be high, low or irregular. These characteristic, called clinical signs, can be more suggestive for particular disease.

- There are other reasons for comprehensive monitoring; variables could be used to monitor and motivate for treatment adherence. This is interesting since treatment adherence remains low in many patient groups. Another reason for comprehensive monitoring is that certain clinical signs affect biomarker readings in the hospital.

Technical opportunities

- The aim is on data-driven solutions, to enable deployment of data analytics to identify risk, treatment opportunities and healthcare solutions. Data-driven solutions complements the aim of the global healthcare industry to reduce costs and manage resources more efficiently while improving patient care.

- In this project, one instrument capable of tracking multiple variables is preferred over an monitoring ecosystem. One instrument prevents a use scenario in which patients needs to use an abundance of devices.

- Considered data capturing technologies: conventional devices (thermometer and scale), actigraphy, ballistocardiography, electrocardiography, noninvasive blood pressure, bioimpedance spectroscope, photoplethysmogram and digital auscultation.

- The chapter selects the digital stethoscope as a promising screening solution for comorbidity. A stethoscope is an established tool of physicians, giving quick and considerable insights into someone's pathological condition. It allows for comprehensive self-monitoring since it includes 6 variables, incorporating numerous risk factors. The act of listening to body sounds, called auscultation, has been digitalized which opens up new opportunities. Computer-aided auscultation (CAA) using a digital stethoscope records, visualises, stores and analyses heart or lung sounds and allows sharing of recordings. Moreover, automated sound detection and classification algorithms already outperform the diagnostic rate of physicians in research setting. An increasing number of studies suggest that automated sound analysis is a promising solution to overcome the limitations of conventional auscultation and to improve disease monitoring.

- The advancements in machine learning open up new opportunities for healthcare. It could, for instance, help to reduce diagnostic and therapeutic errors that are inevitable in the human clinical practice, and extract insights from large patient populations to make real-time inferences for health risk alert and health outcome prediction.

7.2 Research validation

Several experts validated the research. For each part, an expert reviewed the preliminary results and shared their vision concerning the acknowledged findings, current practices and desired future scenario. The following points describe some notable insights briefly:

Patient perspective

A psychologist (who wishes to remain anonymous) specialised in working with patients with cardiovascular disease shared his experience concerning the emotional burdens of disease, which served as input for the patient chapter. He publishes articles and guides sessions concerning stress management and disease acceptance. Fear is common after rehabilitation when patients miss the security of the hospital. Patients need to adjust to the new situation, by learning to recognise and acknowledge the disease and learn to relax. They must overcome fear and rebuild confidence to do stuff. In his opinion, a measuring device may reduce anxiety, but this is a difficult issue. The ideal situation would be that patients know how to feel instead of needing to measure.

Clinical findings

Dr Jaap Deckers is a practising cardiologist in the Erasmus MC and is involved in the education programmes of cardiologists and research concerning risk factors. He reflected and confirmed the findings of the heat map. He added that comorbidities also count as risk factors, particularly AF, diabetes and depression. He is open to the developments of patient self-monitoring, but the technology still has to prove itself. Longitudinal data would be of clinical value to him, but a patient narrative alongside the tracked data would be of limited value in is his opinion. A potential monitoring solution would incorporate the possibility to enter extra data (such as blood parameters) and would include questionnaires such as quality of life and anxiety test to detect depression.

Technical findings

The second cardiologist (who wishes to remain anonymous) also acknowledged the found variables. He validated the potential of digital auscultation but was sceptical concerning the usefulness of certain heart sounds. In case of secondary prevention, these heart sounds would probably already be detected in the hospital. Another reason for concern was his view on the cost-efficiency of the solution. Affordability of healthcare was one of his concerns for the future.

7.3 Validating hypothesis

The research findings enable verification of the hypothesis, drafted at the beginning of part 2. The following paragraphs explain whether the assumptions are true:

Self-monitoring can empower patients.

- *Self-monitoring improves self-management.*

Studies show that the effects of self-monitoring look promising. If implemented well, it has the potential to improve self-management, symptom management and disease regulation and to reduce complications.[157] It offers patients the opportunity to create awareness of symptoms, bodily sensations, cognitive processes and daily activities, and it may provide information for action once needed. Studies found that it could positively affect patient's coping and attitudes toward their disease, realistic goal setting and quality of life.

- *Patients are willing to monitor themselves.*

The willingness to self-monitor varies greatly among patient groups. Literature proposes various disease-specific and patient-specific factors that may influence the willingness. One example of a factor is disease controllability.[157] Disease controllability means the extent to which the disease is controllable by the patient's behaviour, including medication adherence, nutrition and physical activity. Patients are more willing if their disease has a concrete and noticeable behaviour-health relation, like in diabetes. Therefore it is important to offer patients feedback about action and change in disease management to motivate self-management behaviour. The appendix provides an overview of other factors affecting willingness and treatment adherence. Depending on personality and disease, patients are willing to self-monitor.

Self-monitoring solutions can facilitate complex risk management.

- *Longitudinal physiological monitoring can detect signs of CV health decline and comorbidity.*

The heat map includes numerous variable-disease associations, proving that physiological monitoring is sensible to detect risk or decline of CVDs and comorbidities. Monitoring over time is useful to define patient-specific values and detect trends.

- *Smart self-monitoring solutions can aid in clinical decision making.*

Current applications of risk monitoring and risk calculation aid to clinical decision making. Recent studies found novel physiological parameters and machine learning useful in research settings. The integration of all provides an opportunity to improve clinical decision making.

7.4 Design brief

The design brief defines a design vision and draws a clearer picture of the final proposal.

Design vision

The key insights and problems outline a desire for change and improvement. A design vision statement captures the desired improvements into the following sentence:

To improve the well-being and self-care confidence of patients with established cardiovascular disease, by enabling and encouraging them to act on their short-term risk of complications and undetected comorbidities.

Design proposal

The design proposal draws a clearer picture of the intended outcome:

The design of a self-monitoring platform for patients with cardiovascular disease to monitor their own risk of potential complications and comorbidity by use of a digital stethoscope. The focus of the proposal is on patient feedback and feedforward to support patients in their risk management, including treatment adherence, lifestyle changes and seeking help.

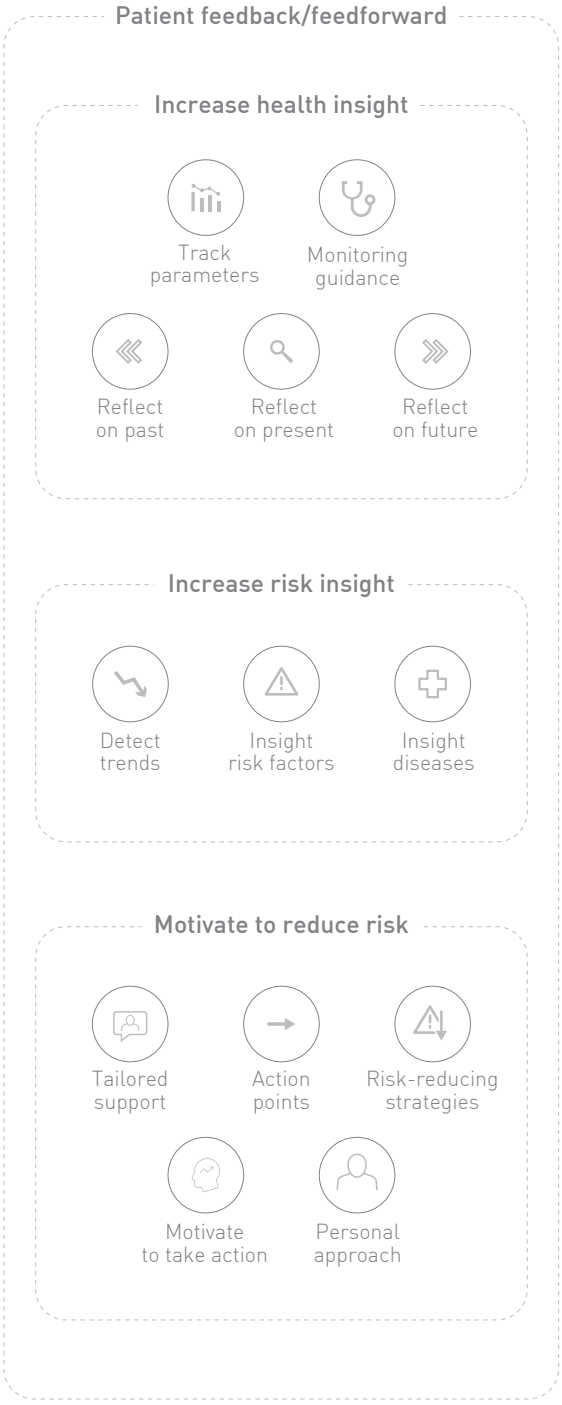
The physiological data derived from the digitised auscultation variables present opportunities to improve risk prediction and promote risk-reducing behaviour, based on risk analyses and medical protocols. The design brief proposes an intelligent monitoring system under the assumption that computer-aided auscultation will advance sufficiently for adequate measuring and will come to the market soon.

Translating risk into insight

The proactive feedback should evoke well-considered patients responses, ranging from encouraging healthy lifestyle habits, to the reassurance of seeking help. However, such patient communication requires delicacy as it may concern stressful situations. The challenge is to engage patients in the ambiguity of long-term risks and to provide insights that help patients to act in a medically sensible way.

Requirements

To realise the design vision, the design must meet the requirements found in the analyses. The illustration below visualises the main requirements concerning patient feedback and feedforward.

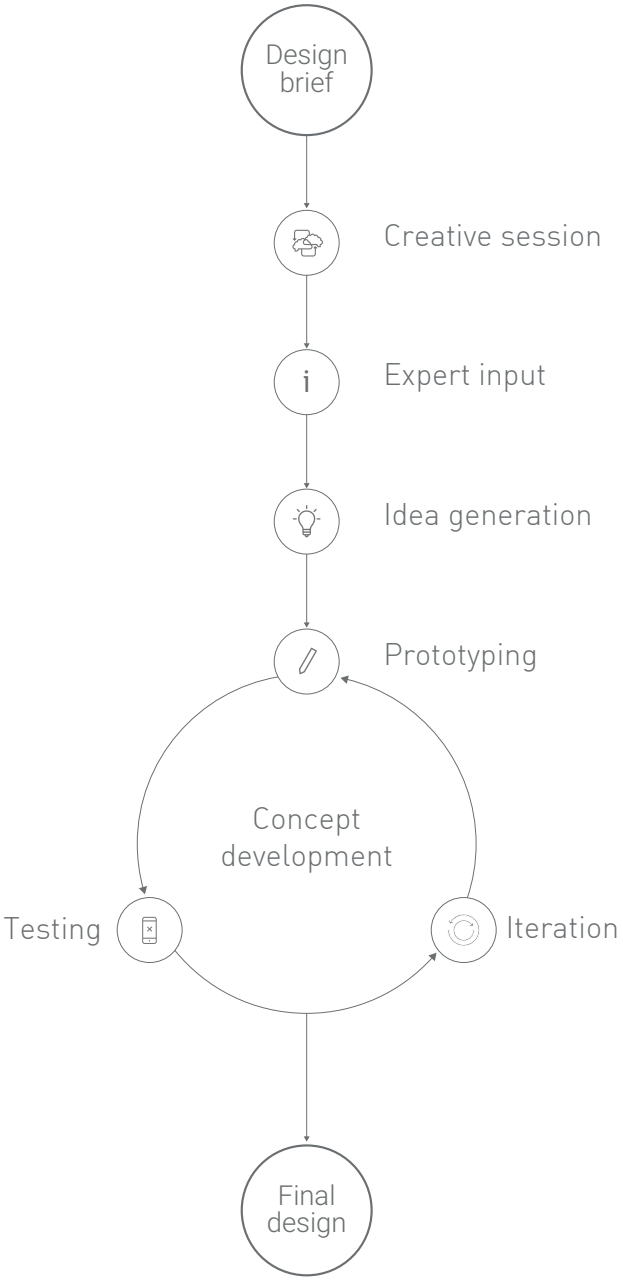


3

Design

8. Design Approach

The design brief was the starting point of the design process which has led to the final design. The illustration below gives an outline of the used design approach.



8.1 Creative session

A creative session was held to explore the design context with others. The main goal of the session was to explore interaction scenarios concerning the patient communication of critical or sensitive information. Another reason for the session was to ventilate the project to new people in order to restore a fresh view. Four Industrial Design Engineering students with different expertise provided their view on the project and generated new insights. The session created ideas for interactions and UI features. However, the main outcome was to rephrase the story with more emphasis on the patient, rather than the clinical aspects.

8.2 Expert input

Discussions with experts provided more input for the idea generation:

Language strategy

Using the language strategy "framing" in the design could persuade patients into action and treatment adherence. Framing is a persuasion technique commonly used in marketing and politics. It is about picking the right words and images to evoke intended emotions and worldviews. The digital design chapter describes the incorporated framing tactics.

UI design rules for an intelligent system

The design comprises a user interface for the proposed intelligent screening-and-respond system. An intelligent UI is like a black box to the user. Therefore, certain design features help to make the interface more transparent to the user. A known example is adding a rationale to functions; like Netflix explains its recommendation with the phrase "because you watched ....". A rationale explains and evokes forgiveness when the recommendations are not quite correct. The right design features can generate enough trust in the system to take the feedback into account, but also evoke forgiveness in case of wrong or inconclusive feedback. The design must stimulate the user to stay critical and to think for themselves.

Figure 11. Brainstorm session.

9. Design proposal

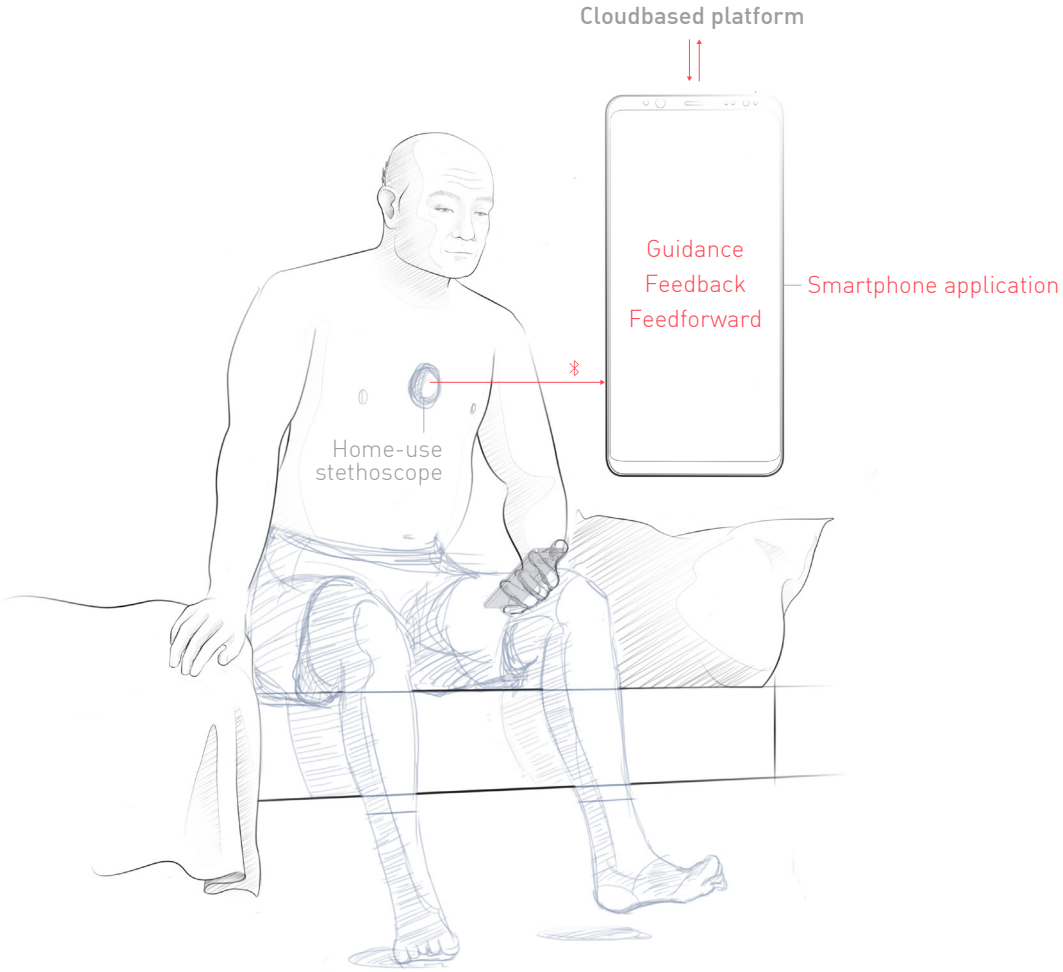
9.1 The value

The design enables patients to monitor their health and encourages them to act on their risk of potential complications and comorbidity. A smartphone application visually demonstrates the near future risk of complications and gives patient-tailored action points to reduce this risk. This proactive feedback intent to evoke a well-considered patient response, ranging from encouraging healthy lifestyle habits, to the reassurance of seeking help. It aims to engage and empower patients in the ambiguity of risk management by providing insights on the whys and hows of preventative self-management strategies which apply to their situation.

9.2 The system

The system consists of a home-use stethoscope, a smartphone application and a cloud-based service. The smartphone provides guidance on the monitoring steps and self-management in general. The home-use stethoscope records chest sounds and sends the recordings to the smartphone. The smartphone connects to a cloud-based service which interprets the health parameters and detects possible anomalies. The smartphone displays the outcomes and meaning to the user.

Due to time constraints, further development will solely focus on the smartphone application and its proactive feedback.



9.3 High level scenario

The following scenario outlines how patients receive and use the service in broad lines. After the confrontation with the disease and acute care (1-3), the patient may receive the self-monitoring solution from his specialist (4-7). The specialist can offer the solution to the patient when the patient:

- is motivated to self-monitor;
- experiences many complaints;
- has many concerns, or;
- is at risk (6).

Then, the patient is onboarded to the system (8) and starts his self-monitoring routine at home (9).

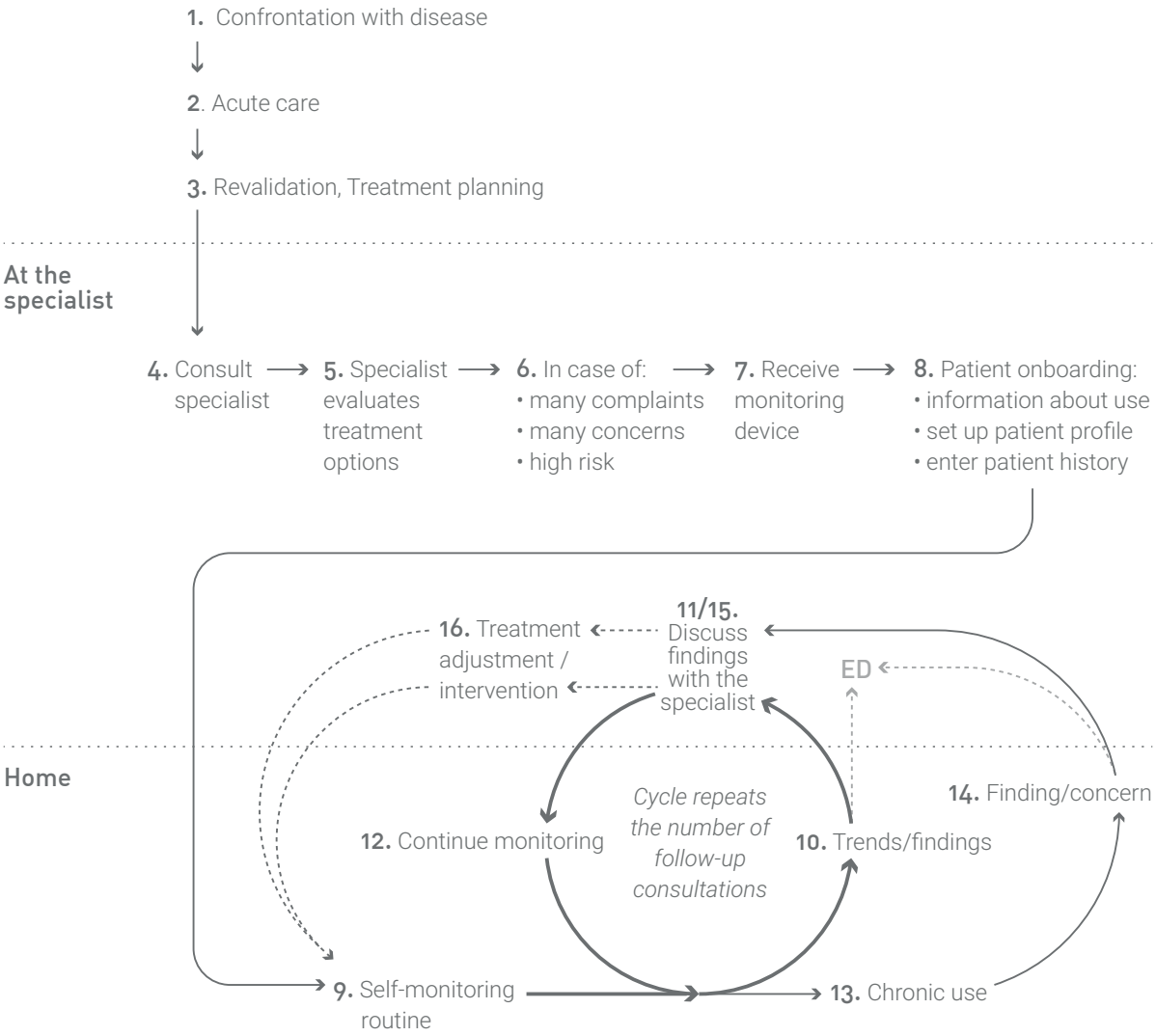
In the first phase, the patient shares his findings (10) with his specialist in the next planned consultation (11).

Here, the specialist will decide whether an intervention or adjustment is necessary (16), or that the patient can continue monitoring without any changes (12). This cycle repeats the number of planned follow-up consultations.

At the last consultation, the specialist and patient agree upon chronic use of the service (13.) Hereafter, the patient must take the initiative, in case of a finding or concern (14), to go to the specialist (15).

In case of severe trends, findings or concerns, the patient could also go to the ED immediately (10/14).

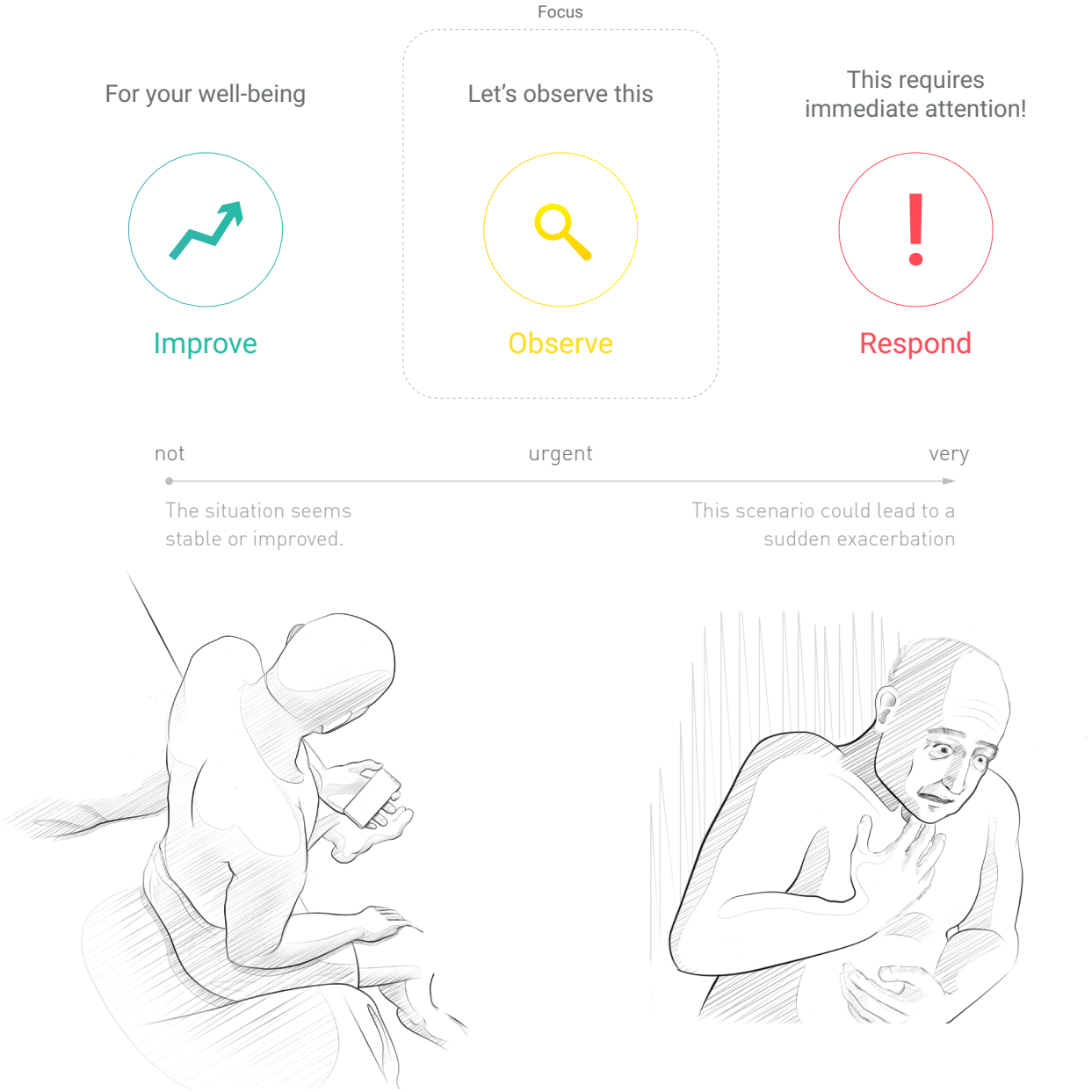
The solution is intended for a home environment since the solution help patients in the long-term disease risk management.



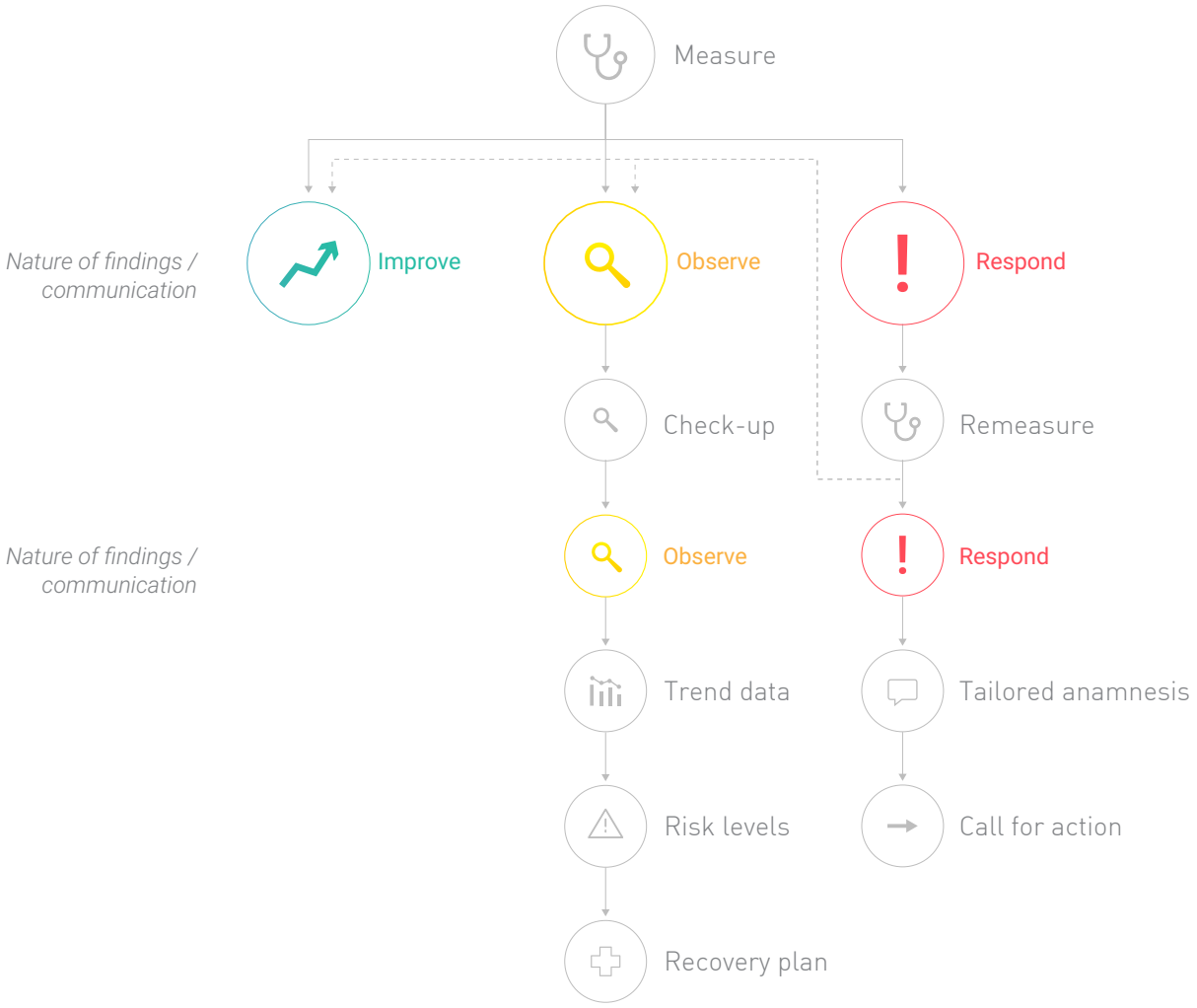
9.4 Communication categories

The application communicates the proactive feedback in three communication categories: Improve, Observe and Respond. These categories instantly express the nature and urgency of the situation. Each category has a visual presentation and language use that fits the nature of the situation. The illustration below demonstrates some characteristics of the categories.

The table on the next page demonstrates some examples of findings, indications and required actions for each category. The illustration below describes the order of information and required actions.
Due to time constraints, further development will solely focus on the 'observe' category. This category communicates the risk levels to the user.

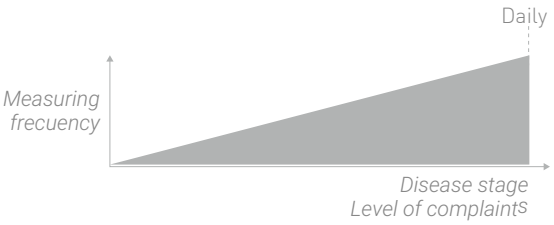


Severity / communication category	Examples of findings	May indicate	Next steps	Examples of required action
RESPOND	↑ Heart rate ↑ Respiration rate Lung sounds	- Exacerbation - Complication	- Remeasure - Anamnesis	- Remove trigger - Medication - Consult - ED
OBSERVE	↓ Heart rate variation ↑ Resting heart rate Arrhythmias Respiration patterns	Increased risk	- Check-up - Check risk - Recovery plan - Set new goal	- Treatment adherence - Lifestyle changes - Stress management - Observation in time frame - Mention next consult
IMPROVE	↓ Resting heart rate ↑ Physical activity	- Situation stable - Improvements		- Continue current habits

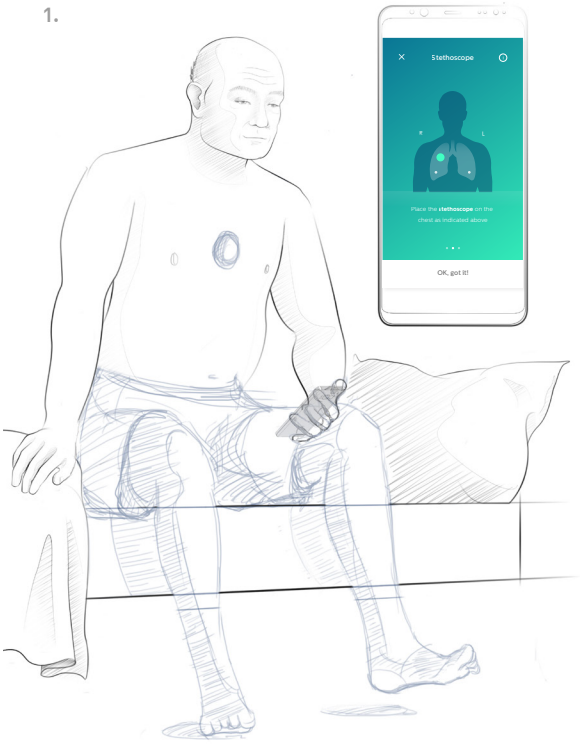


9.5 Monitoring frequency

The monitoring frequency depends on the circumstances of the patient. Patients with a late disease stage or with many complaints will measure more often than someone without these circumstances. The measuring frequency also increases after the finding of a new risk. However, it is important that the patient has a saying in the measuring frequency, and 'signs this agreement' (in a symbolic way). People tend to stick more to their own choices and reminding them of their own choices creates commitment (framing tactic).



1.



9.6 Scenario

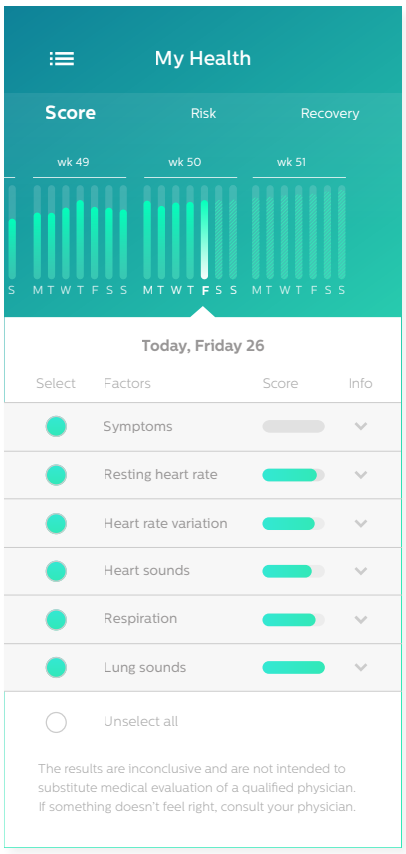
1. Peter is diagnosed with a cardiovascular disease. Besides his normal treatment, his doctor offers him a home-use stethoscope to monitor his health and risk for new disease developments. Peter accepts the offer since he is motivated to reduce his risk of new complications and deterioration of his condition.

At home, Peter gets acquainted with the service and device, and monitors on a routine basis with the clear guidance of the application.

2. After every measurement, Peter looks into the results. On his dashboard, he sees his total health score over time and his predicted health score. He understands that the health score is built up by the results of different measured health parameters.

He sees that he is doing rather well, but some health parameters can be better. He clicks on a lower scoring health parameter to see what he can do to improve the score. Here he finds background information and lifestyle advice to increase the score.

2.



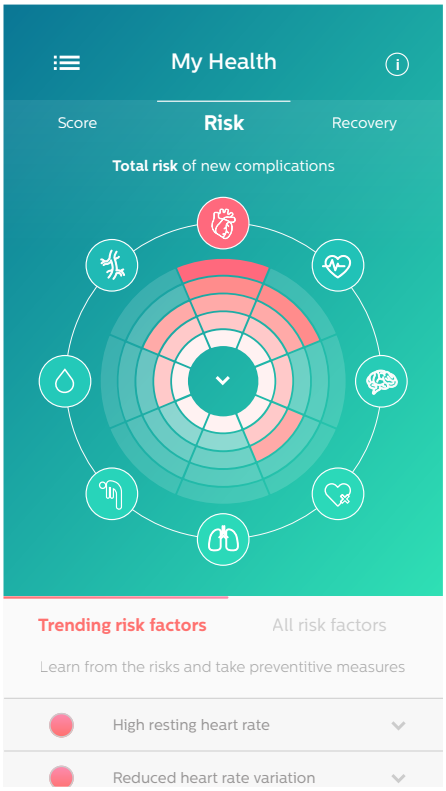
3. A few weeks later, Peter sees that his health scores declined. His dashboard shows a declining trend and a newly found risk. Peter wants to know about the risk and goes to the risk overview.

4. On the risk overview, Peter learns which risk factors influence a probable comorbidity. He sees that some health parameters and symptoms increase the risk of a heart attack. Peter clicks on the risk factors to learn more about them and their relationship to the comorbidities.

5. He clicks on the recovery plan to see what he can do to reduce the risk.

3.

4.



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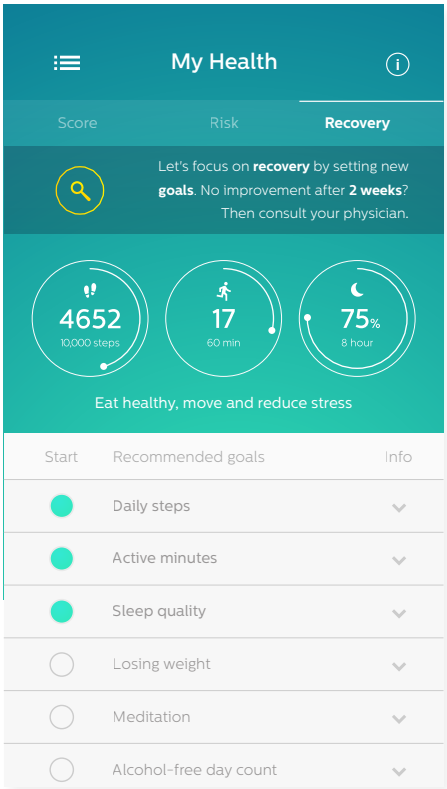


10. Digital Design

10.1 Functions

Based on the proposition, the application should have the following functions:

- Guide users in the monitoring routine.
- Enable users to reflect on past, current and predicted health status.
- Enable users to learn about own risk of new complications and comorbidity.
- Enable users to learn about risk-reducing strategies (risk-management).

10.2 Features

The application requires the following features to operate in the way as proposed:

Provide data-driven feedback by presenting:

- parameter scores and a total health score;
- information on the parameters;
- past measurements;
- measurement trends.

Provide data-driven feedforward by presenting:

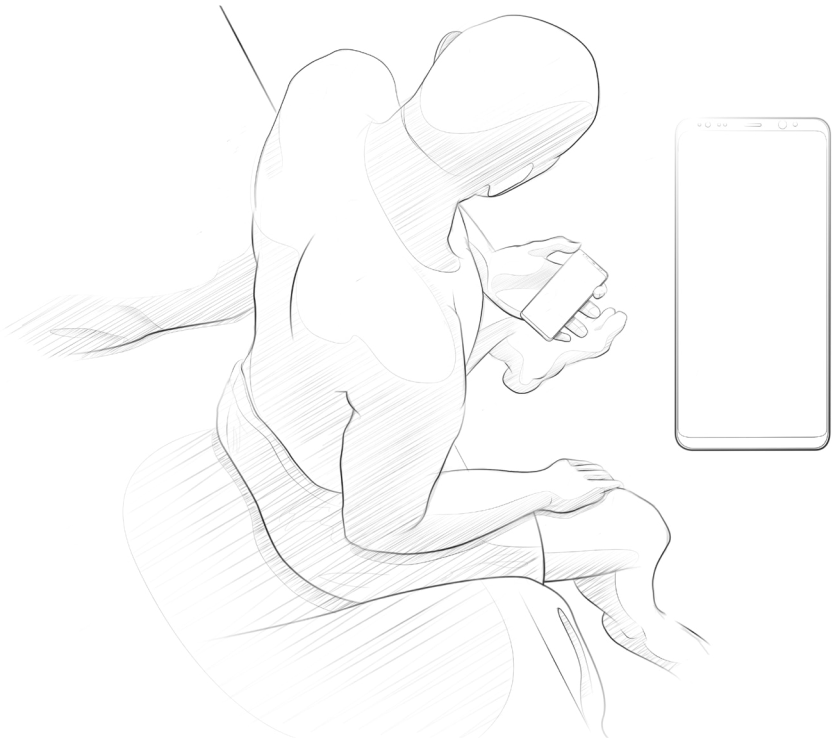
- found risk factors;
- information on found risk factors;
- risk range per disease;
- information on the diseases.

Provide action points derived from risk levels by presenting:

- goals for lifestyle/treatment improvement;
- information on goals.

10.3 'Observe' use flow

The illustration on the next page outlines the use flow of the application. The left side describes the user task flow. The right side provides the UI elements for the corresponding tasks.




Task flow
UI content
Start
1a. Respond to reminder of scheduled measurement
1b. Iniate measurement
Install
2. Pair device with app
3. Follow placement guidance
Measure
4. Follow monitoring instructions
5. Wait till feedback
Focus
Assess
6. Assess scores
7. Assess notification
8. Consider options:
• extra info
• check-up
• close
Assess
6. Display updated dashboard
7. Display 'observe' notification
8. Show:
• information button
• check-up button
• exit button
Check-up
9. Accept check-up
10. Enter condition, symptoms and other measurements
11. Save entry
Check-up
9. Go to 'check-up' screen
10. Show sliders and info button
11. Show save button
Assess
12. Assess scores
13. Assess notification
14. Assess risk overview
15. Assess recovery plan
Assess
12. Display updated dashboard
13. Display 'observe' notification
14. 'Risk' goes to risk overview
14. 'Recovery' goes to recovery plan
Respond
16. Learn more
17. Accept recovery plan goals
18. Do nothing / close
Respond
16. Show 'info' button
17. Show check-box for goals
18. Show 'timeline' + 'exit' button

10.3 Visual design

The visual design should comply with the following interaction qualities.

- **Calm**: Patients need to find acceptance and peace in disease and self-management. It is best for them to stay calm and to reduce stress, especially when receiving a notification of poor prospects. For this reason, the functions and visual appearance of the whole application should support this state of mind. Therefore, the interaction quality should be calm, which can be achieved with clean and simple style elements, calm colours, efficient navigation, and subtle well-though-out microinteractions.
- **Personal**: The application should have a right balance between a friendly and a medical/ professional appearance. The design must feel friendly and familiar, but also professional to evoke trust.

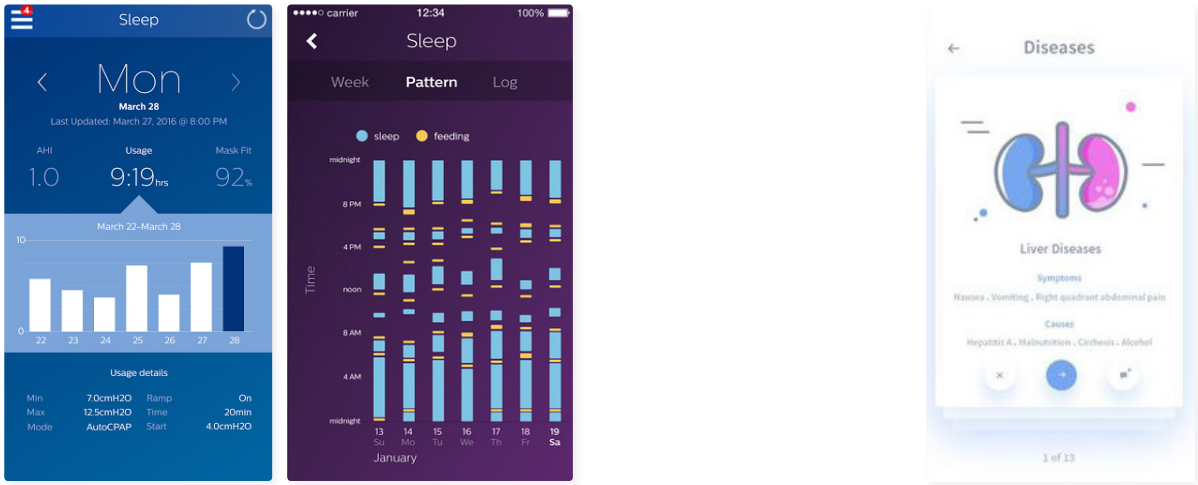
The Philips DreamMapper and Philips uGrow applications served as a starting point for the visual design. However, to achieve a more personal appearance, the design was made with the inspiration screens in mind.

10.4 Screen flow

Monitoring

The following page shows an overview of the first eight screens of the application. These include monitoring guidance and the general health dashboard.

Philips DreamMapper & Philips uGrow

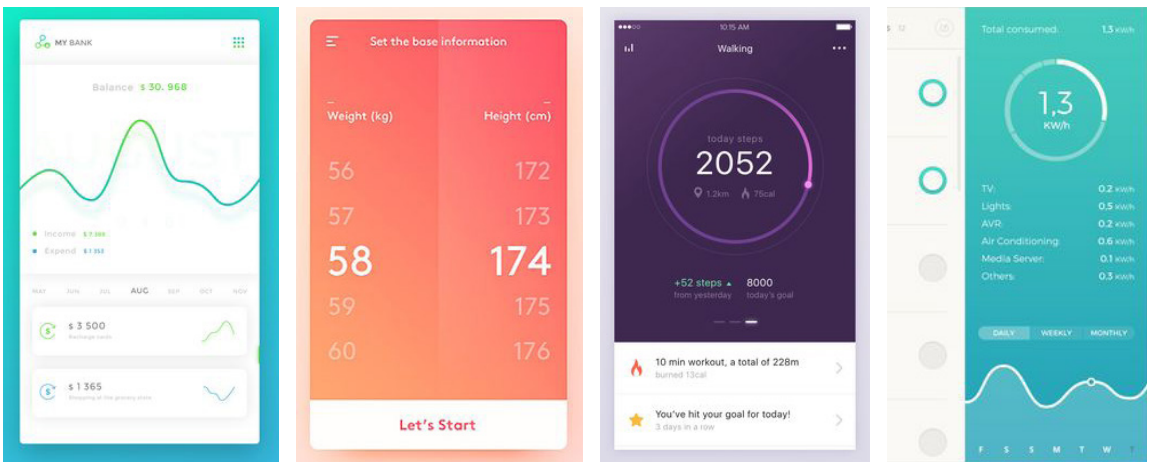


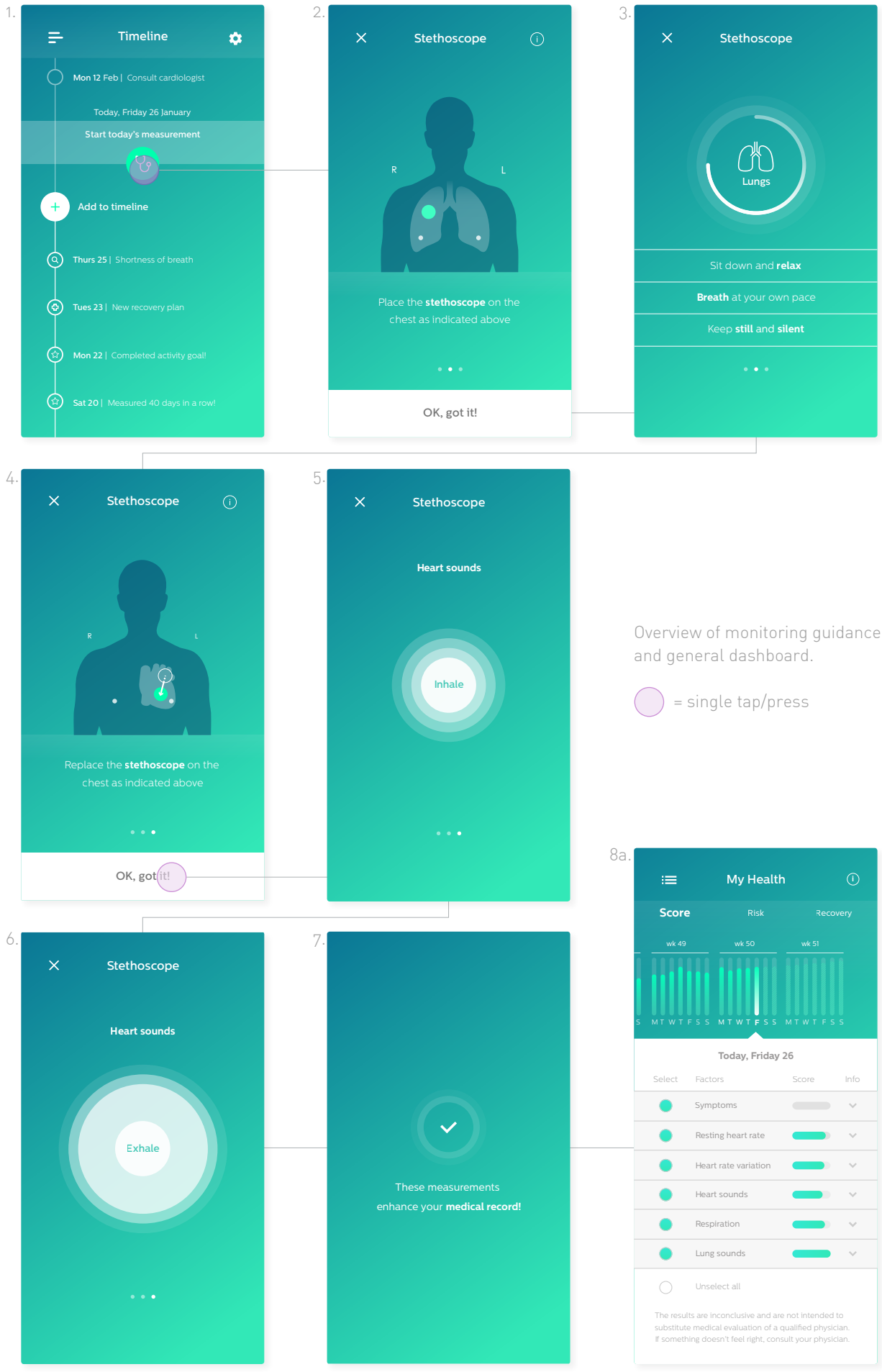
Serious
Formal
Impersonal

Desired level

Inspiration

Playful/friendly
Informal
Personal





Overview of monitoring guidance and general dashboard.

= single tap/press

Feedback I

Screen 8b displays the 'Score' tab of the 'My Health' dashboard. This screen illustrates the feedback from the measurement and previous measurements in a scenario where a negative trend is detected. The bar graphs illustrate the combined day scores, colour coded and arranged per week. Swiping the day scores to the left allows the user to reflect on previous days.

The information card below points and selects a day and lists the measured factors building up that day score. Each factor shows its score on the list. Pressing the arrow on the right opens up the drop-down menu with more information about that factor. The user can select the factors separately to reflect on their scores over time.

In this scenario, the screen has a notification appearing from underneath the main menu (score/risk/recovery). This tells the user that the scores are declining over time and that a check-up is advised. The right side of the day scores visualise the predicted scores, which have in this case a negative trend.

Check-up

Pressing the observe button with the magnifying glass opens up the check-up screen (9). Here, the user enters his condition, symptoms and other measurements to evaluate his condition more thoroughly. The check-up screen shows probable symptoms based on the adverse findings. However, the user can also add symptoms.

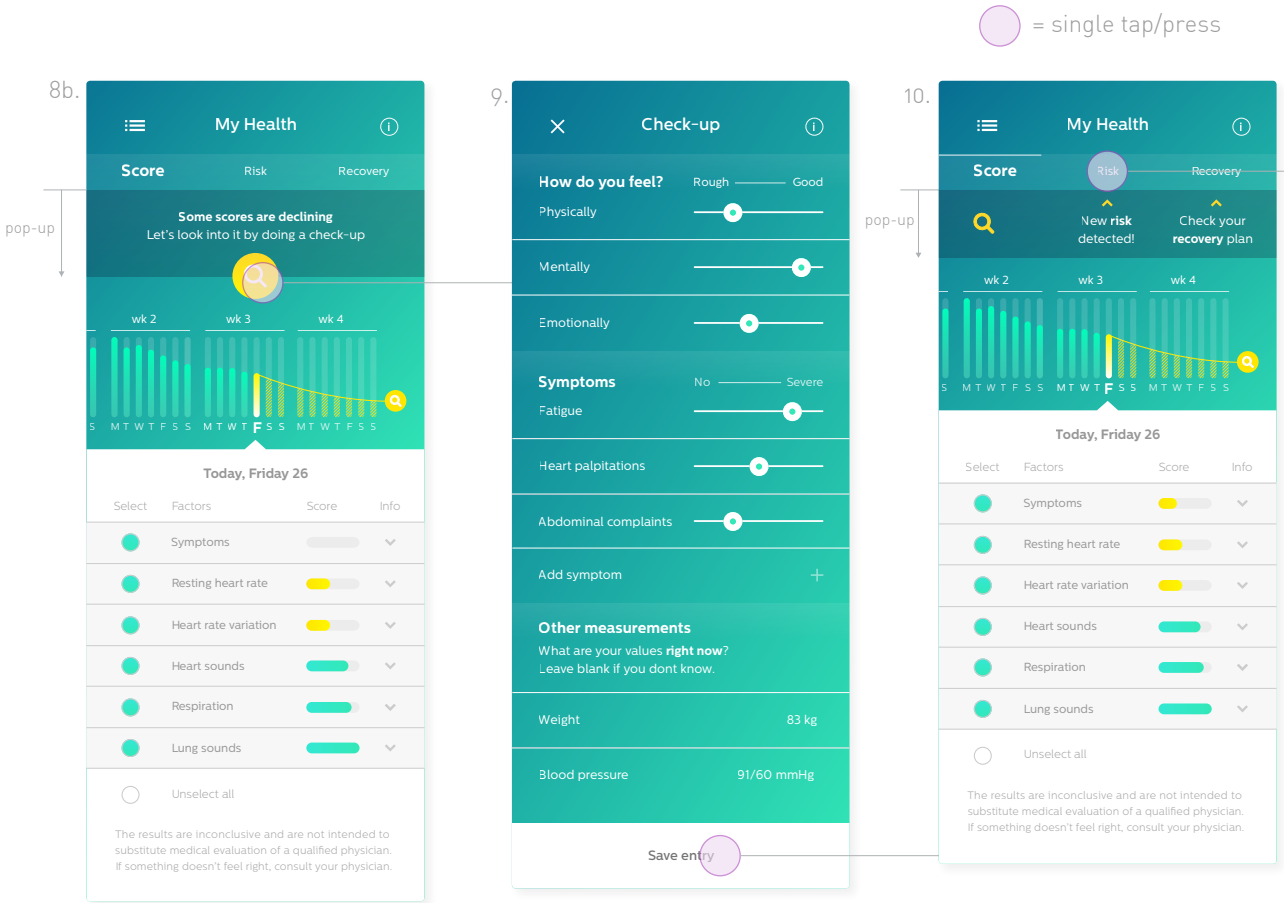
Feedback II

Saving the data closes the check-up screen and show the 'Score' screen again (10). The symptoms shows a score now, and the notification changed. The notification tells that a new risk is detected and refers to the 'Risk' tab. It also tells that the recovery plan changed and then refers to the 'Recovery' tab.

Feedforward

Pressing the 'Risk' tab opens the risk dashboard (11). This screen displays a wheel diagram with the risk levels for the diseases presented in the outer circle.

The buttons in the outer circle represent complications and diseases. Pressing the button opens up more



information about that specific disease (13).

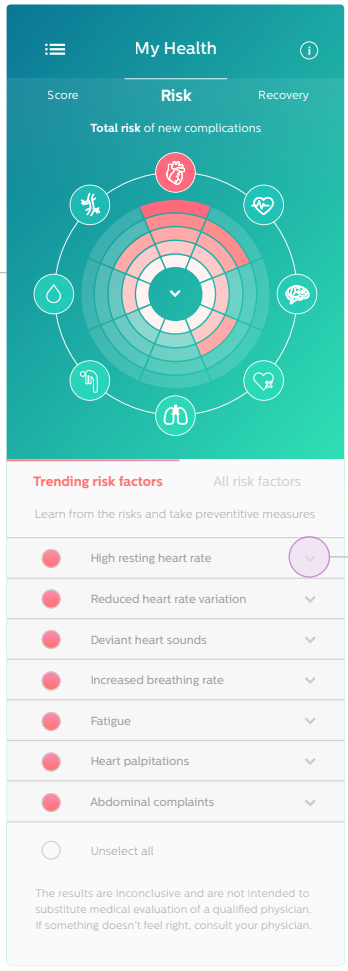
The arrow facing down in the middle of the wheel allows the user to switch between the combined risk score and separate risk factors (12).

The information card at the bottom displays two tabs: 'trending risk factors' and 'all risk factors'. The first tab lists the risk factors which are recent or became worse. Pressing the arrow on the right opens up the drop-down menu with more information about that risk factor. The user can select the factors separately to reflect on the risk of that particular risk factor.

Recovery plan

The 'Recovery' tab shows recommended goals based the on the trending risk factors. The card at the bottom lists the recommended goals and allows the user to start and stop the goal. Each goal has a drop-down menu with more information.
The dashboard with the circles displays the progress of the goals and therefore allows follow-up of the goals.

11.



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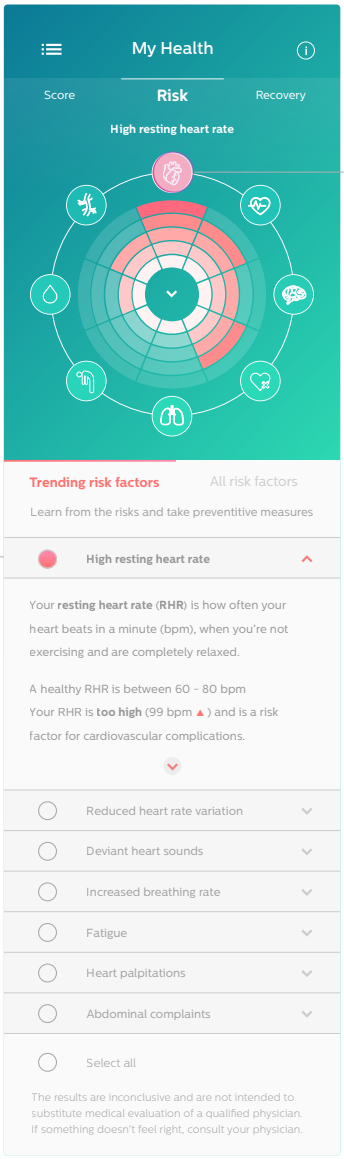

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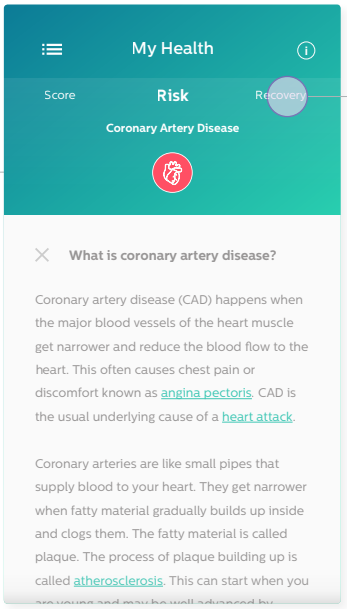
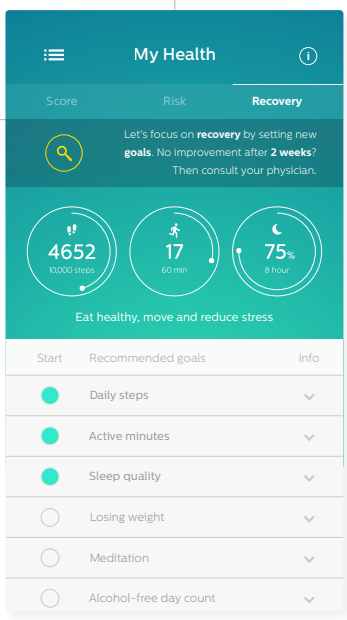


14.

pop-up

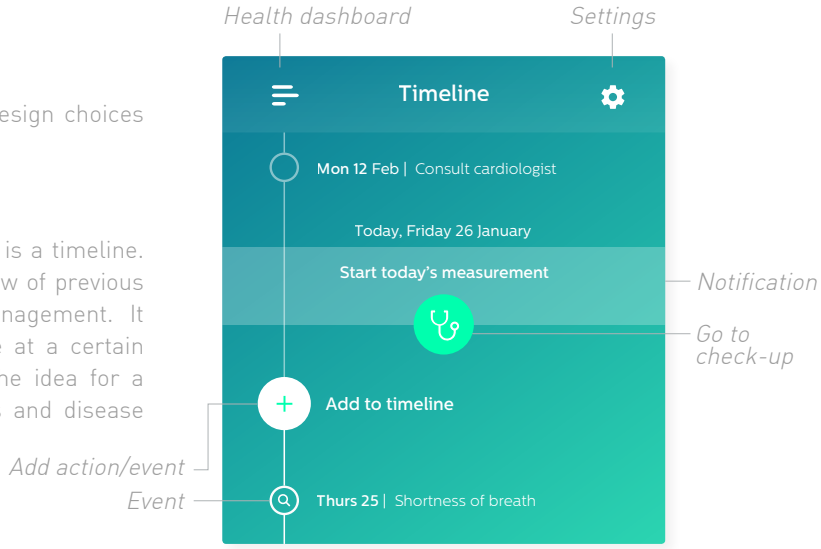


10.5 Design choices

The following pages describe the design choices of the screens.

Timeline

The home screen of the application is a timeline. A timeline gives the user an overview of previous and future events of his self-management. It can indicate that something is due at a certain time, like today's measurement. The idea for a timeline derives from other Philips and disease applications.

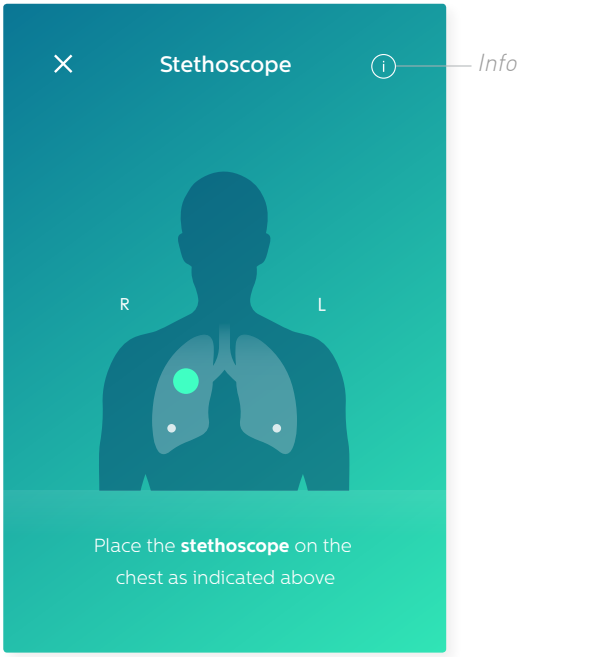


Stethoscope placement

Screen 2 and 4 illustrate the stethoscope placement on the chest. The green dot represents the location of the stethoscope. The R and L above the human silhouette indicate the right and left side.

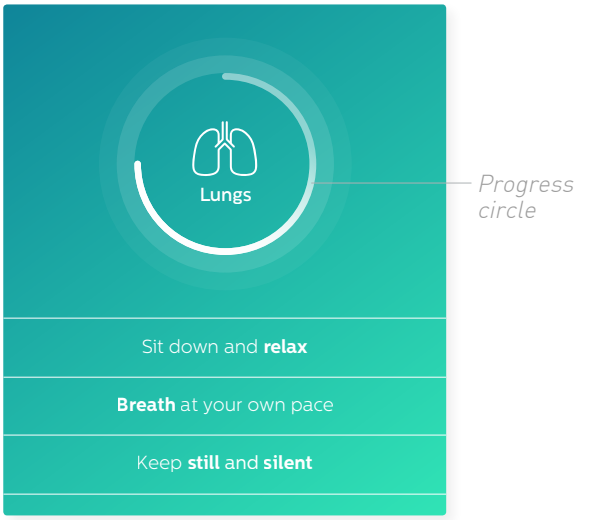
The visible lungs in the silhouette indicate that the placement is for measuring lung sounds.

The information button at the right top provides more information about placement.



Lung sounds

While listening to the lungs, the screen gives advise about the best measuring circumstances and gives a visual time indication through a progress circle. Giving a time indication prevents users from becoming impatient and stopping the measurement.



Heart sounds

The application guides the breathing pace while listening to heart sounds. This is for two reasons:

- Heart parameters are directly influenced by your breathing rate. Therefore, breathing at a steady rate benefits the reading.

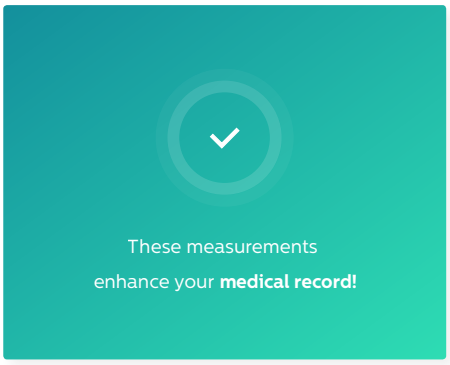
- A deep breathing rate helps people to relax. This benefits the user directly, but also the heart rate readings.

Breathing guide: inflating and deflating spheres

Reward effort

The screen will reward the user for his effort, while the application is processing the stethoscope recording. It was decided to reward effort instead of results since the results can stay the same or be negative.

The screen could show a day streak to motivate people in maintaining their measuring frequency.

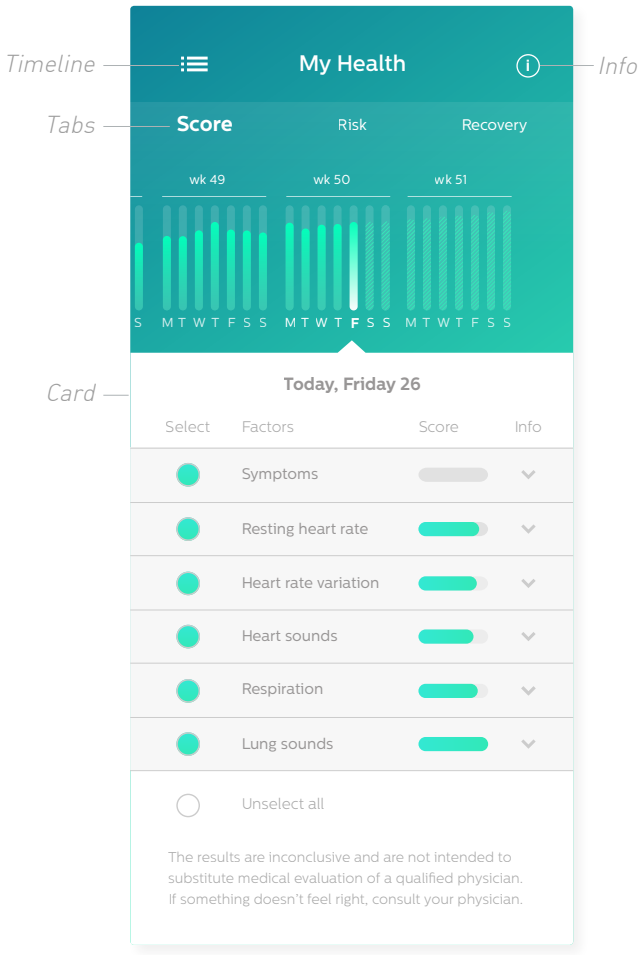


My Health dashboard

The health dashboard contains a lot of information. Therefore, the design splits-the information into different tabs and embeds more details into drop-down menus.

Health scores

The graphs of the predicted scores are hatched to visually indicate that the score is not definitive.



Pop-ups

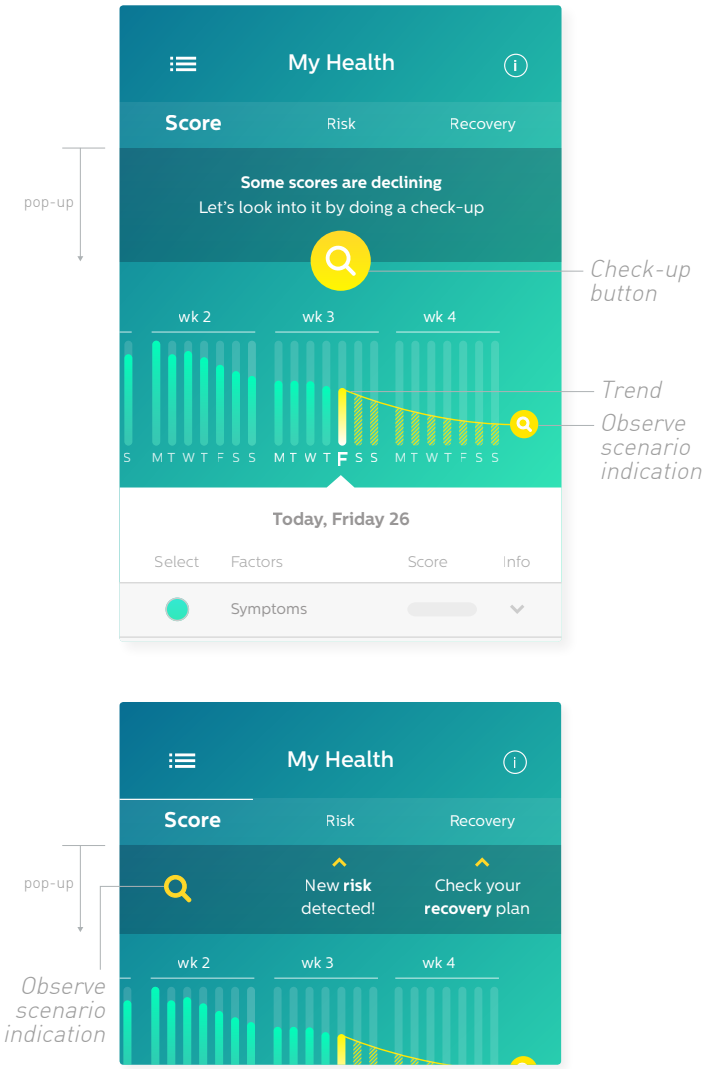
The health dashboard show pop-ups to communicate new findings. A down sliding movement and differentiating colours aim to attract the attention of the user. As a matter of consistency and clarity, the communication scenarios will have their own colour and features. In the case of the 'Observe' scenario, elements will be yellow.

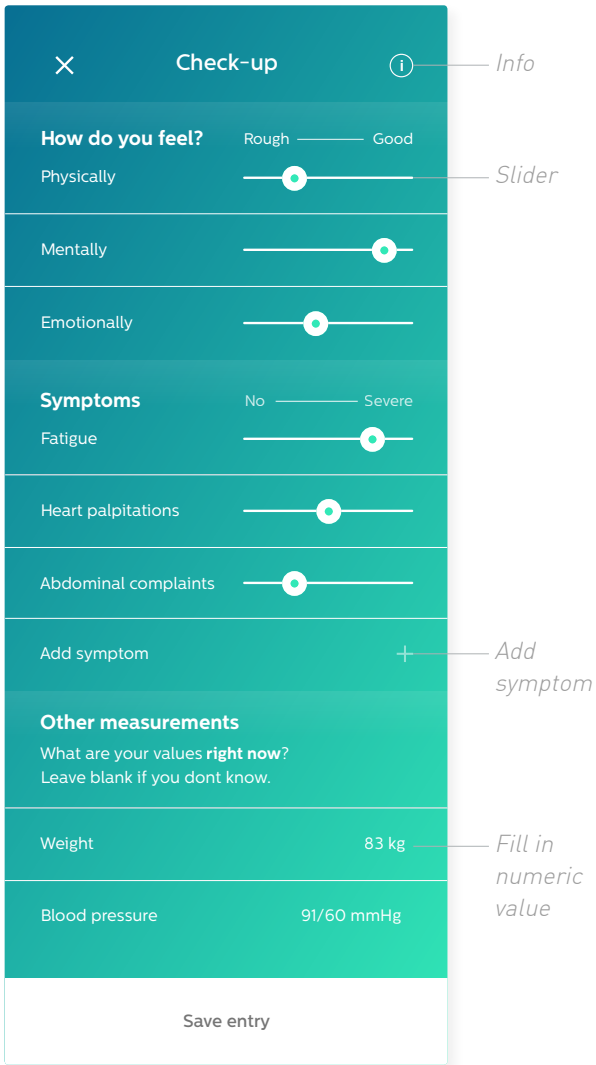
The 'Observe' notification below tells the user what is going on and offers the user the option for a check-up, instead of going immediately to the check-up screen after an adverse finding. Giving users the feeling of choice makes them more willing to cooperate or undertake action (framing tactic).

Check-up

The check-up screen consists of three parts: an experienced health condition check, symptoms and other measurements. The first two parts contain sliders. This enables observation of any changes in the health condition or symptom intensity between check-ups. Pressing the numeric values will trigger the keyboard to appear.

The information button at the right top provides more information about the components.





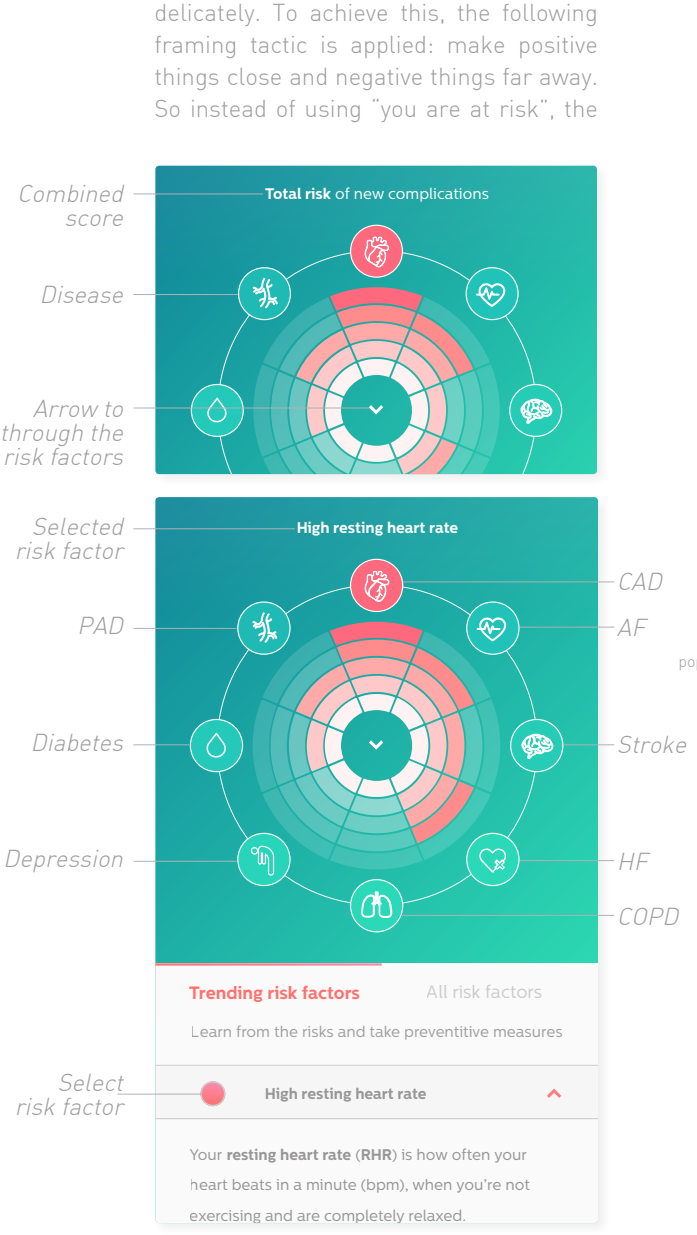
Risk dashboard

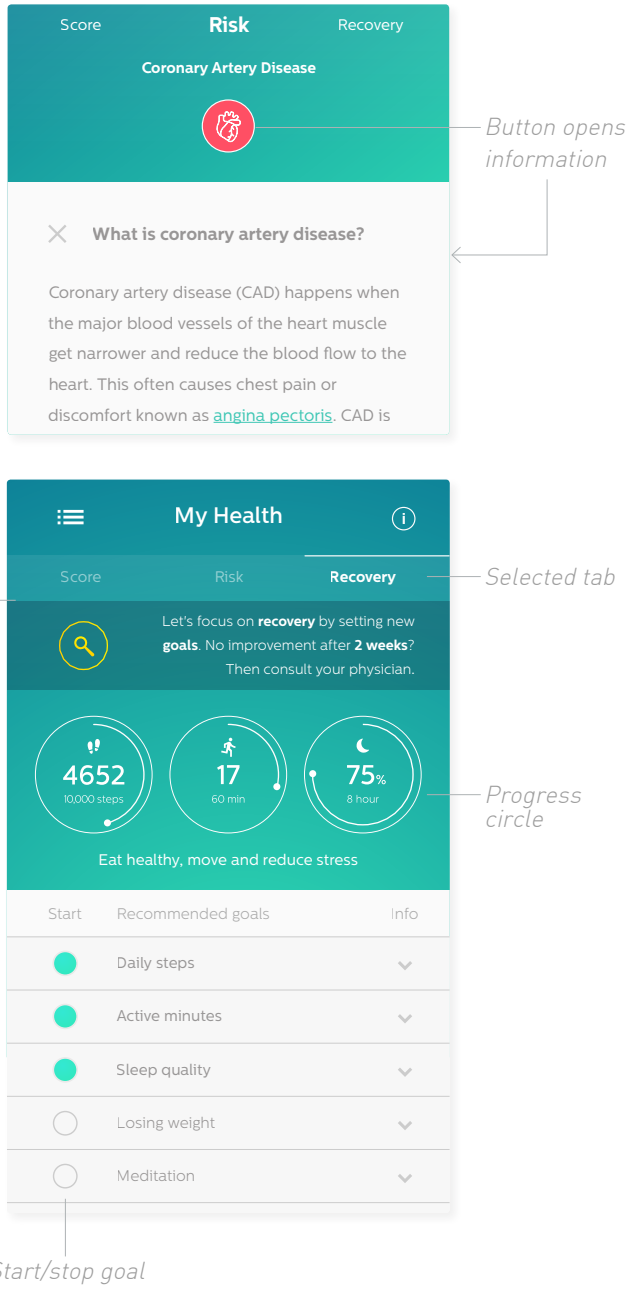
The risk dashboard contains a wheel diagram which communicates the risk of several diseases and conditions. The diagram visualises the risks stepwise to clearly communicate an increased risk (iteration step after user evaluation). The first wheel diagram shows the combined risk score. However, clicking on the arrow in the middle of the wheel allows seeing risk factors separately.

This screen communicates bad news, which could evoke stress. Therefore, the screen must present the insights delicately. To achieve this, the following framing tactic is applied: make positive things close and negative things far away. So instead of using "you are at risk", the screen says "these risk factors increase the risk of disease (let's tackle them)".

Recovery dashboard

The recovery screen has the same bedded structure as the Score and Risk screen. The card at the bottom lists the recommended goals and allows to start or stop a goal. The progress circles track the progress of the set targets. Once a goal starts, it appears in the dashboard in the middle of the screen. The dashboard visualises the progress circles in the same manner as the Philips Health suite application.





11. Design Overview

11.1 Key features

Monitoring guide

- Stethoscope placement guide
- Breathing guide

Health monitoring

- Tracks health parameters and trends
- Health dashboard shows symptoms and health parameters over time
- Health check-up

Health risk screening

- Detects risk factors for disease
- Risk dashboard demonstrates the risk factors/ level for various diseases.

Personalised recovery plan

- Recommends recovery goals based on the trending risk factors.
- Recovery dashboard to track and follow-up goals

11.2 Key benefits

Support

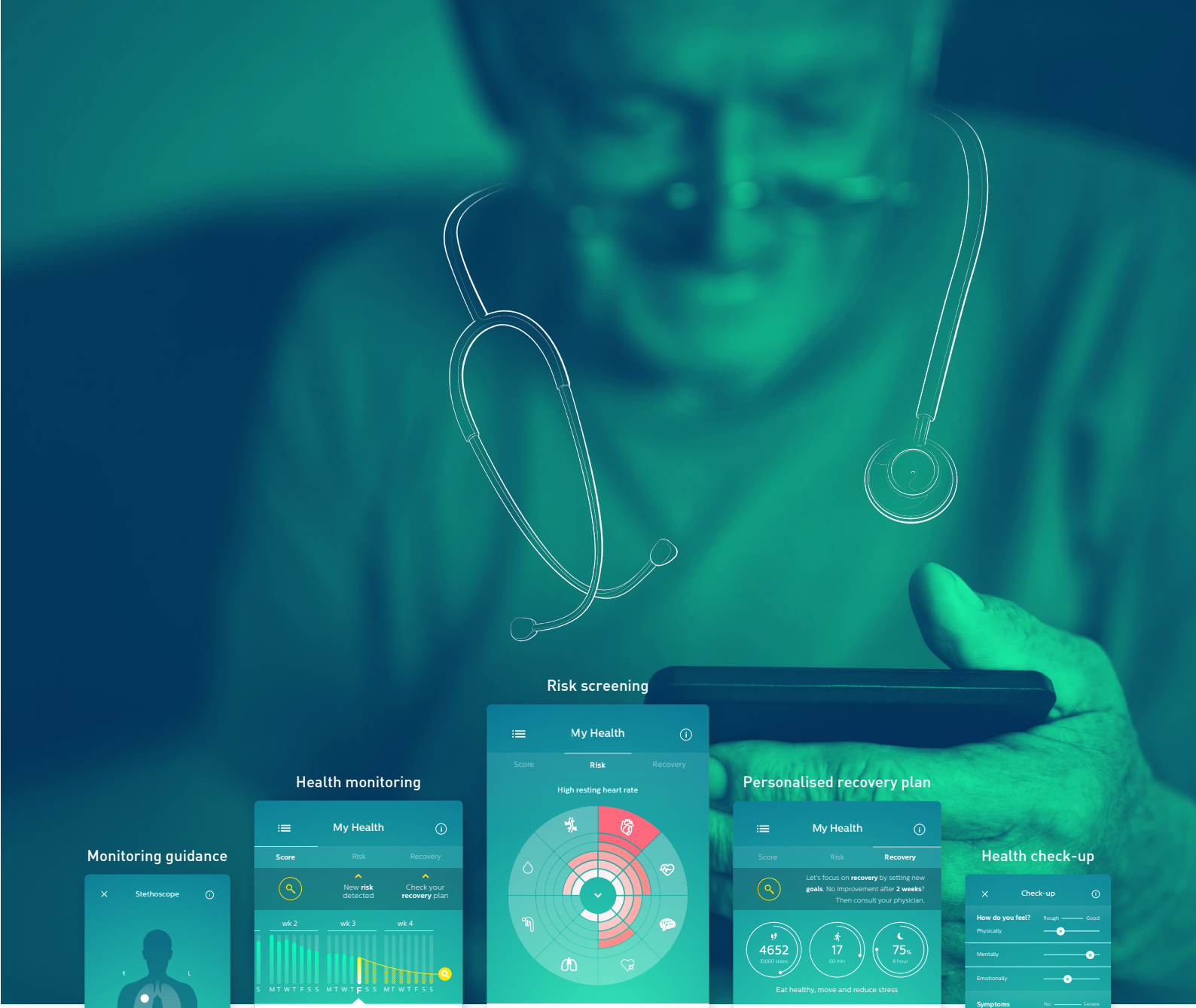
The Philips Self Care supports patients in their disease risk management, by providing action points for self-care based on measured risk levels of disease and complications.

Empowers

The solution empowers patients in the ambiguity of risk management by providing insights on the whys and hows of preventative self-management strategies that apply to their situation, to evoke self-care confidence and a well-considered patient response when the doctor is not around.

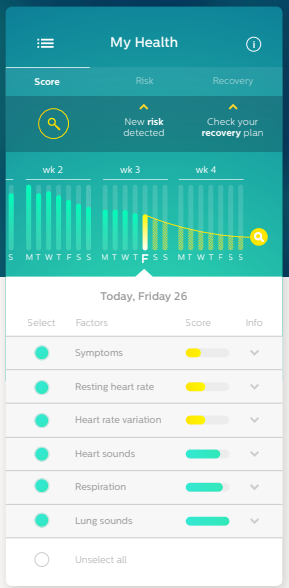
Personal

The design allows patients to set their own goals and pace in pursuing a healthier lifestyle. It enables the patient to do health check-ups at a convenient moment or during the experience of complaints or concerns.

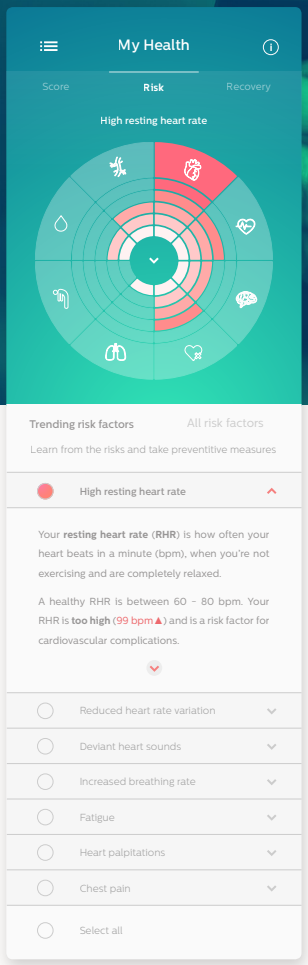


Monitoring guidance

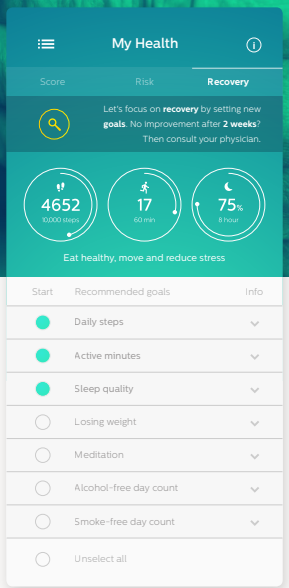
Health monitoring



Risk screening



Personalised recovery plan



Health check-up

4

Validate

12. User Evaluation

12.1 Objective

User research was conducted to evaluate the proposition and design with the user. The research objectives were to understand how users perceive the proposition and how they conceptually interpret and prefer specific functionalities of the application.

Research question

How do patients experience feedforward concerning their short-term risk of cardiovascular events and comorbidity?

Subquestions

Do patients feel encouraged or despondent (stress/fear) by a provided risk level of disease?

Does feedforward improve the patient's understanding of their risks and disease self-management?

12.2 Method

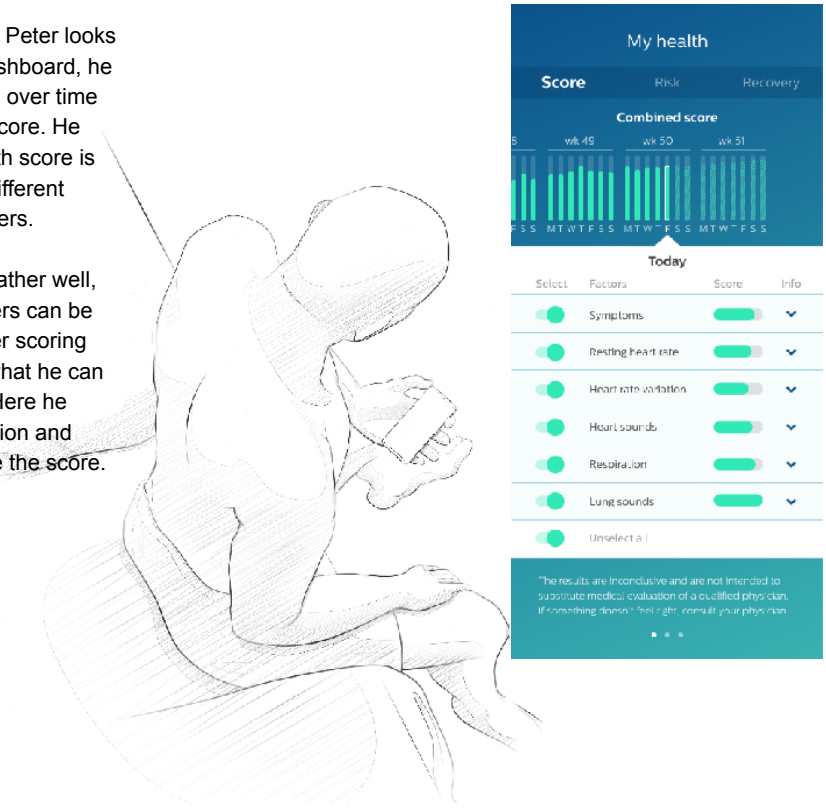
The user test was conducted with an online community from the US. Over three days, the participants replied to questions based on a scenario and different screens. Appendix F contains the scenario and screens displayed to the participants. Each day, a topic was addressed:

- Day 1. Showing the scenario and testing the general understanding of the proposition.
- Day 2. Showing the scenario and testing the experience/value of the proposition.
- Day 3. Showing the risk dashboard and testing the understanding, experience and value of the screens.

The study included people at risk or diagnosed with cardiovascular disease (hypertension, PAD, CAD, AF, HF, or ACS), with or without comorbidities.

After every measurement, Peter looks into the results. On his dashboard, he sees his total health score over time and his predicted health score. He understands that the health score is built up by the results of different measured health parameters.

He sees that he is doing rather well, but some health parameters can be better. He clicks on a lower scoring health parameter to see what he can do to improve the score. Here he finds background information and lifestyle advice to increase the score.



12.3 Results

Appendix F visualises all the questions and answers of the study. The following paragraphs describe the main insights.

Participants

The study started with 18 participants on the first day. 15 participants answered on day 2 and 11 to 15 on day 3.

The research group included 10 participants who can directly relate to the scenario. Most of them have a heart disease or monitor their blood pressure regularly. Participants who could not relate did not have a cardiovascular disease (in the stage of the presented scenario).

" It is not a direct match as I do not currently suffer from cardiovascular disease. However, I do suffer from high-blood pressure and depression. Both are conditions I treat with presciptions, exercise, diet and knowledge. I would welcome the opportunity to try an in-home treatment. Especially if it utilized technology - applications, mobile devices, etc. "

Knowing about risk

Most participants want to know about their risk factors and their risk of complications and comorbidities.

" I want to know about risk factors. There is so much medicine or treatment regimes to fight or delay full-blown complications, why not take advantage of it. "

" Yes, I would like to know about my risk levels, and that is what my doctor is for. "

Some say it depends. They only want to know if they can do something about it.

" Yes, I want to know about risk factors and levels for complications/comorbidity as long as there is something I can due to decrease my risk. If I can take actions to prevent future problems, I want to know, and I want to be able to take those actions. "

" I already know that I am a carrier for Alpha 1 anti trypsin deficiency, which my mom died from and all her siblings. Knowing that I too have that gene is disturbing for me. Sometimes I wish I didn't know."

One person wouldn't want to know about it because it will induce stress.

Proposition

The proposition was understandable to the majority of the participants. 9 out of 11 participants answering the direct question understood the proposition.

" The parameters can tell you the areas where you are improving, and, more importantly, the areas where you need to improve. It finds them via the application and the health data on the device. They inform you of the complications that can arise based on the risk factors."

The majority of the participants described the service as helpful and that the service would improve the user's understanding of disease self-management.

" I have heart disease and have had to have a triple bypass 1 1/2 yrs ago. It would have helped me very much if I had this tool before I got into big trouble with my heart issues. "

" Some sort of device like this would be helpful. As a CHF patient, it is important that I do all to keep my risk factors as low as possible. "

" I think this would be helpful. I am at risk for a stroke my dr told me because I get stroke-like symptoms with my chronic migraine. I also was diagnosed as diabetic, but the last times that I was checked it showed no signs of it, so I'm not on those meds anymore as long as I monitor it. For some of the examples I gave, it would be helpful to know what you could do to improve on it."

However, 3 participants mentioned otherwise. The main reasons for concern were anxiety, misinterpretation and overuse of smartphones.

" No, it would not help me. I see the doctor often

enough and feel the more I check it, the more anxious I would get. ”

“ *I feel you can sometimes misunderstand what you are seeing. I think you should contact your doctor with any questions about the information you are reading.* ”

“ *It would add more stress with knowing that much detail. It would scare me and cause me more stress, but I am sure other folks would want this. [...] Another problem with this is I don't have a cell phone so that it wouldn't work for me at all. I hate seeing everything depending on cell phones [...] To me, it is causing people to think less and try to figure out things and not able to do anything without the cell phone.* ”

Emotional influence

The participants were divided about whether they would feel encouraged or despondent (stressed/fearful) by a provided risk level of disease. The participants who could relate to the scenario were also divided. A small majority answered to be encouraged.

“ *I would feel bad if I thought I was living a healthy lifestyle and had a high risk, but then I could do something about it.* ”

“ *I would go through the seven stages of grief. In the end, I would be encouraged the know what lies in front of me.* ”

Some would experience both encouraged or despondent.

“ *I would feel encouraged by provided risk level of a disease only if there is something I can do to prevent my risk. I would feel stressed if there was nothing I could do to reduce my risk level of disease.*”

“ *It can certainly cause some stress. But for me, it is absolutely a benefit to at least be aware. Knowledge is power. I can now make decisions based on what I know, rather than what I don't.*”

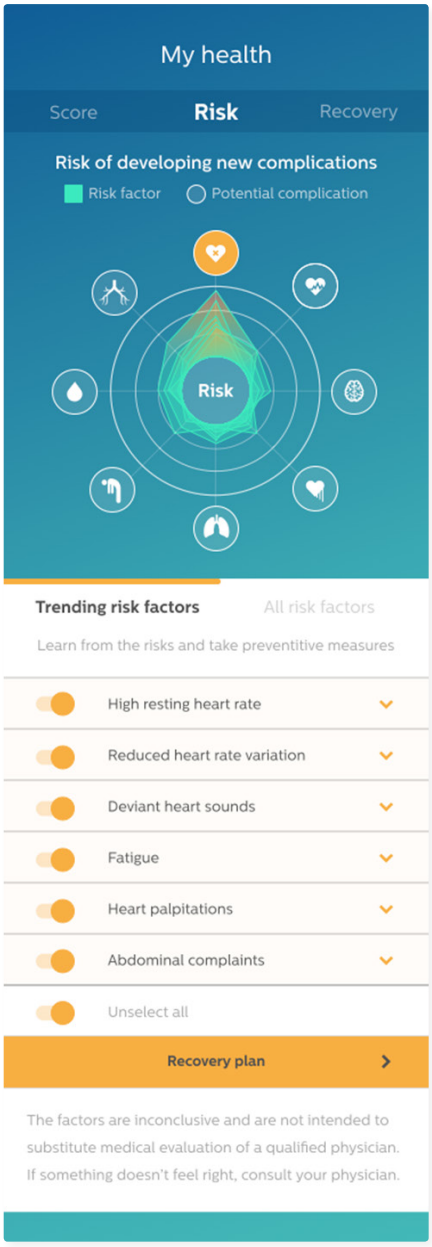
Some would get too stressed.

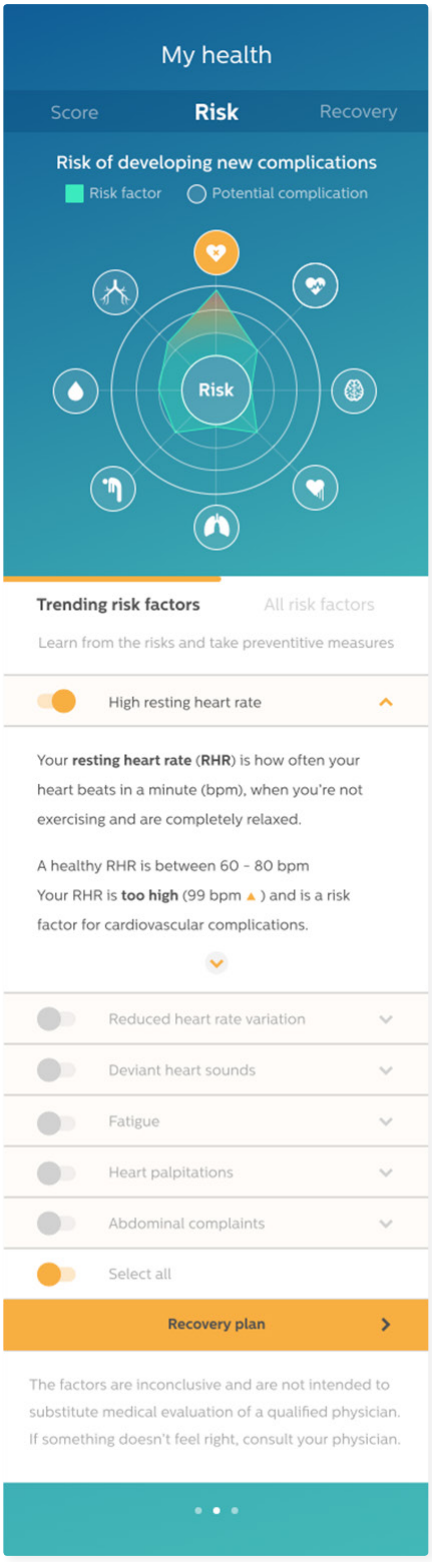
“ *I wouldn't know about it. I think the idea is not for me as it would make me too anxious and mask the real results.*”

“ *I live with a disease and as time goes on it gets worse. I don't want to think about it because it scares me and adds stress, which is not good for your health either. I have plenty of stress in my life, so I try not to add more to it.*”

Risk dashboard

Opinions were mixed about the first screen (the dashboard with the pull-down menu closed). Some understood the screen at once, while the majority understood the concept, but were uncertain about some features. To three participants it was all unclear. The second screen with information on the pull-down menu made things clear to most participants.


My health
Score
Risk
Recovery
Risk of developing new complications
Risk factor
Potential complication
Risk
Trending risk factors
All risk factors
Learn from the risks and take preventitive measures
High resting heart rate
Reduced heart rate variation
Deviant heart sounds
Fatigue
Heart palpitations
Abdominal complaints
Unselect all
Recovery plan
The factors are inconclusive and are not intended to substitute medical evaluation of a qualified physician. If something doesn't feel right, consult your physician.


My health
Score
Risk
Recovery
Risk of developing new complications
Risk factor
Potential complication
Risk
Trending risk factors
All risk factors
Learn from the risks and take preventitive measures
High resting heart rate
Your resting heart rate (RHR) is how often your heart beats in a minute (bpm), when you're not exercising and are completely relaxed.
A healthy RHR is between 60 - 80 bpm
Your RHR is too high (99 bpm ▲) and is a risk factor for cardiovascular complications.
Reduced heart rate variation
Deviant heart sounds
Fatigue
Heart palpitations
Abdominal complaints
Select all
Recovery plan
The factors are inconclusive and are not intended to substitute medical evaluation of a qualified physician. If something doesn't feel right, consult your physician.

“ This screen now tells me detailed information on all of my trending risk factors. For example, for resting heart rate, the screen tells me what a normal resting heart rate is and what my resting heart rate is. It also has information on all risk factors and a recovery plan. I feel most of the information is clear. However, again the icons within the circle are unclear. I am not sure what each one means. ”

Most participants valued the risk dashboard. A few did not for reason of confusion and anxiety.

“ I value this screen much more than the first one because I need to know which factor is the worst and needs to be addressed. I can value everything separately so I know which factor is which, on the graph.”

“ I would truly ask my doctor about this and see if it might help me I would not get stressed but happy this idea is here.”

The second risk dashboard was concidered:

Answer options	Response total	Response percentage
1. Least helpful	0	0%
2. Not so helpful	0	0%
3. Neutral	0	0%
4. Helpful	10	77%
5. Most helpful	3	23%

“ I like how it alerts me to trending risk factors and offers a recovery plan. I also like that it educates me.”

Answer options	Response total	Response percentage
1. Least motivating	0	0%
2. Not so motivating	0	0%
3. Neutral	1	8%
4. Motivating	5	38%
5. Very motivating	7	54%

“ I like that this service offers a recovery plan. A plan to help me is motivating. ”

“ It will always depend on the degree of disease. ”

Answer options	Response total	Response percentage
1. Not at all distressing	3	23%
2. Slightly distressing	4	31%
3. Neutral	2	15%
4. Distressing	3	23%
5. Very distressing	1	8%

“ Heart risks are always distressing ”

“ It should scare you enough to want to do something about it ”

12.4 Conclusion

The participants experienced feedforward concerning risk of various diseases in different ways. Most of them want to know about their risk, but only when they can do something about it. Some would welcome such device, while other would rather consult their doctor.

Most participants were overall positive about the proposition. Most saw value because it could potentially motivate and improve the patient's understanding of risks and disease self-management. However, many saw the downside of the stress that it could evoke in case of bad news. Bad news would be distressing to all, but some see it as a necessary evil whereas others don't want to know about (from a device). Further research needs to assess the role of stress in these risk scenarios.

The participants with cardiovascular disease, who could relate to the scenario had different views concerning the proposition. This assumes that the opinions are more personal instead of disease-related, meaning that the platform would not be suitable for all personality types. The solution may be received well by patients who are analytical, determined and in favour of tracking technology, rather than those prone to stress and having an aversion to smart technology.

Conclusions about the presentation and features of the risk dashboard:

- The visual presentation of the wheel diagram was unclear to many. The colour gradient did not indicate the risk level well enough. A stepwise overview could make the diagram plainer.

- The overlapping values of the risk factors in the wheel diagram were unclear until the second screen showed only one risk factor. The diagram could illustrate a combined risk score instead of all factors mapped at once.

- The information in the pulldown menus from the risk factors make the intention of the dashboard clear to the user.

- The disease buttons are unclear to many as they are not familiar with the icons/diseases. A responsive application would show the disease information after pressing the button.

12.5 Limitations

The user study had some limitations due to the use of an online community. As the topics were divided over three days, the number of participants decreased every day.
Another limitation was that some things were not clear to the participants. To two participants it was unclear that the images were not responsive. Others did answer all questions or did not interpret some questions correctly. Some problems could have been prevented by formulating the questions differently and describing the intention more explicitly.

However, the major advantage of this method was that participants did not shy away from sharing their real opinion since the session is anonymous.

12.6 Iteration

One last iteration followed the user research and included most aspects described above. Chapter 10.5 decribes what design choices have been made to incorporate the feedback.

13. Design Proposal Evaluation

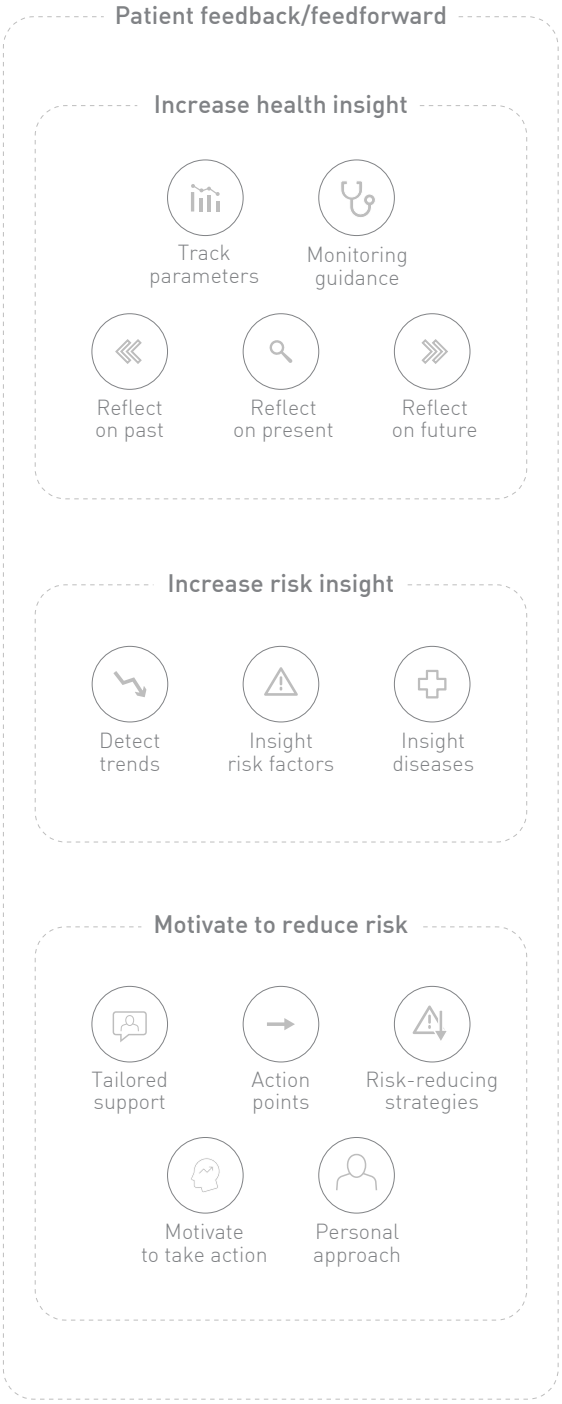
13.1 Design brief

This paragraph evaluates whether the design proposal complies with the intended goal. The design vision statement captured the intent of the design in one sentence:

'To improve the well-being and self-care confidence of patients with established cardiovascular disease, by enabling and encouraging them to act on their short-term risk of complications and undetected comorbidities.'

Theoretically, the solution meets the proposed design vision. The solution provides patients with information concerning risk and lifestyle adjustments on which they could act. However, whether the solution actually motivates and increases the well-being and self-care confidence in the long-term has not been tested. Although, the majority of the participants perceived the design as motivating, the actual effect must be tested with long-term user testing.

The design includes the determined requirements. However, further research must reveal whether this is done effectively.



13.3 Feasibility

Most feasibility-related aspects of the proposal cannot be determined because these require further development and long-term testing. However, the following paragraphs will discuss the found insights and the importance of some key aspects.

User acceptance

User evaluation revealed that most participants want to be informed about their risks, as long as they can do something about it. However, they also shared that in case of bad news, it would evoke stress. Most would still value the bad news, while others wouldn't want to know about it. The question is whether an improved design would reduce the stress response or are most patients not able or not ready yet for this kind of knowledge and responsibility. Further research needs

to assess the role of information and stress in these risk scenarios.

Although not addressed in this report, the user privacy is another critical issue. Who can see the data and who owns the data? Further research and development need to address these questions.

Medical feasibility

A cardiologist confirmed the visible medical aspects of the design proposal and application. However, since the scenario is just a snapshot of the complete system, this input is limited.

An essential aspect of the proposal is the calculation of the risk scores for the diseases. Although risk scores for secondary prevention exist, more elaborate algorithms need to translate medical input into degrees of risk.

Technical feasibility

The design proposal builds upon the assumptions that monitoring technologies and AI classification algorithms advance in the near future. Monitoring technologies should miniaturise and diminish movement and sound artefacts which would distort variable readings. AI classification algorithms for diagnostic usage have proven to be effective in research settings. However, actual implementation requires further advancements.

Healthcare context

The report did not address the health care context. However, successful integration into the healthcare context depends on various factors:

- Alignment with other healthcare systems;
- Acceptance of the medical community;
- Cost-effectiveness and business model, and;
- Regulatory compliance with the platform.

13.4 Project limitations

No user study or patient co-creation

The proposed design was developed without elaborate user study or patient co-creation. Therefore, it is likely that the proposed solution does not meet all user needs.

Limited medical experts involved

The project involved only two cardiologists and one psychologist. The input of only three views does not represent the overall healthcare view and knowledge.

User evaluation participants

The user evaluation had only a small sample (n = 18), which reduced the following two research days. Furthermore, it may be that the participants in the online community do not represent the true population as they joined the online community because of their interest in new healthcare developments.

Incomplete and untested proposal

The final result is nor complete or fully tested. Further development and testing are required to discover the true value and effectiveness of the outcomes.

14. Recommendations

Improving the heat map findings

- Include the predictive and prognostic values of the variables to determine the most effective variables for screening.
- Include sensitivity and specificity of variables to determine the false positives and false negatives rates of the variables.
- Include the different disease classifications to include the distinct disease presentations.
- Define the modifiable risk factors to improve health outcomes and to monitor treatment adherence.

User-centred approach

Further research should focus more on the different user groups:

- Extensive user study and patient co-creation to discover more user needs.
- Testing with more randomised participants.

Design proposal

- Designing, elaborating and long-term testing of the complete system.
- More involvement of medical experts in the platform design.
- Perform an elaborate market analysis.
- Investigate how the platform would align with the healthcare context and rules and regulations.
- Investigate how false positives and false negatives would impact the system.
- Investigate how the effectiveness of the system can be checked.

Design

- Study the role of stress in risk scenarios and how design can influence the stress response.
- Design, elaborate and test the application flow and architecture.
- Refine the visual appearance on the user needs.
- Refine the visual appearance to evoke trust and calm in users.
- Implement an use tutorial to teach patients how to use the application (onboarding explanation and in-screen hints).

15. Conclusions

The project explored a new strategy to improve secondary prevention of CVD by aiming at screening options to detect comorbidity. The design research was initially medical-driven as it focused on measurable disease interrelationships between common CVDs. A composed heat map shows scientifically-backed disease-variable combinations, useful in self-monitoring. Implementing these variables into home-use screening solutions would enable patients to monitor their health and risk for disease and comorbidity.

Based on the analyses, the project proposes a self-monitoring solution with a home-use stethoscope to measure multiple variables and a smartphone application to communicate the risk and patient-tailored action points. It aims to engage and empower patients in the ambiguity of risk management by providing insights on the whys and hows of preventative strategies and why it applies to their situation. Evidence-based interventions for secondary prevention include a wide range of drug therapies as well as modifying lifestyle-related risk behaviours. These preventative measures proved to be highly effective and cost-efficient.

User evaluation demonstrated that most participants perceive the design proposal as helpful and motivating. Most of them want to be informed about their risks, as long as they can do something about it. However, the main concern about the proposal is the experience of stress after being informed about a substantial risk for a disease. Most would still value the bad news, while others wouldn't want to know about it. Further research needs to assess the role of stress in these risk scenarios.

This graduation project should be regarded as exploratory research. It scratched the surface on how self-monitoring can improve secondary prevention in CVD. Further research and development are needed to substantiate the effectiveness and potential of the proposal.

5

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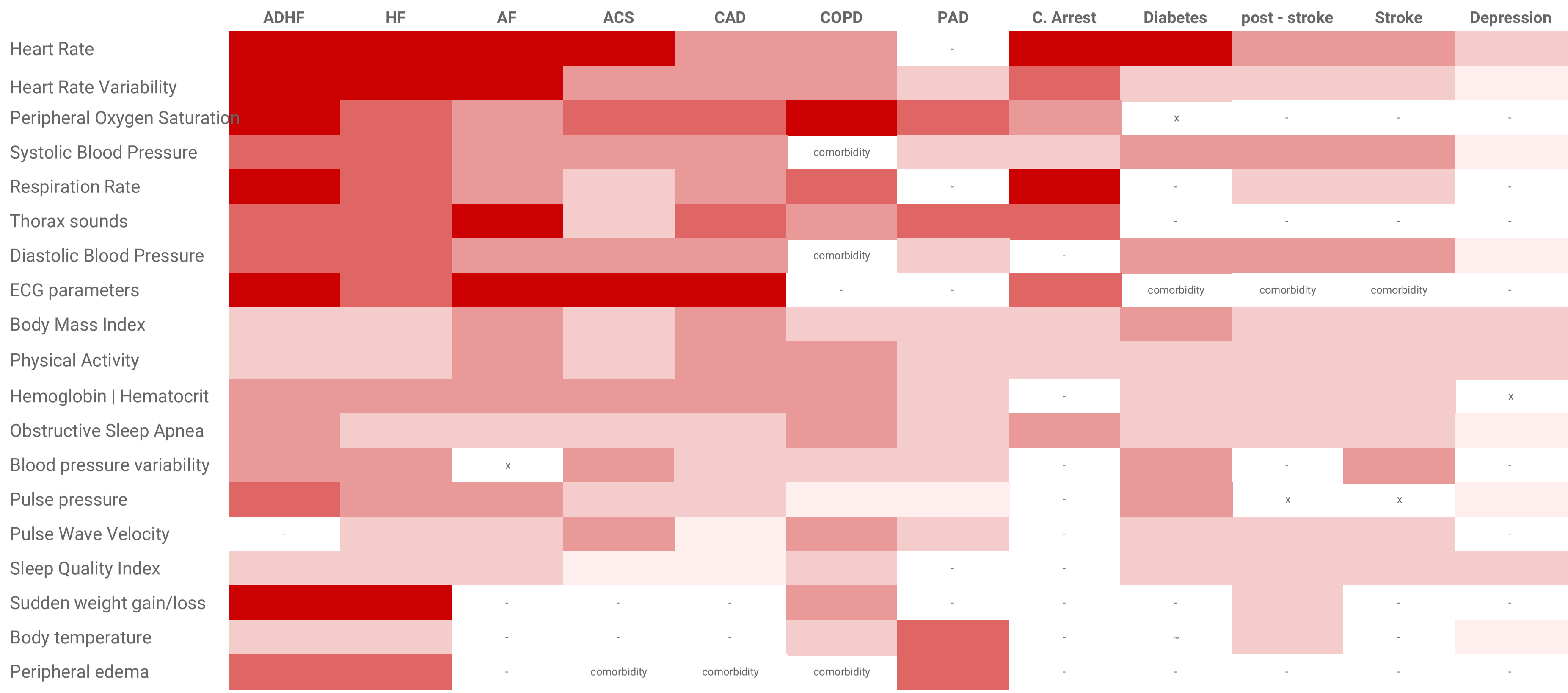
6

Appendix

Appendix A

Heatmap


ADHF
HF
AF
ACS
CAD
COPD
PAD
C. Arrest
Diabetes
post - stroke
Stroke
Depression
Heart Rate
Heart Rate Variability
Peripheral Oxygen Saturation
Systolic Blood Pressure
Respiration Rate
Thorax sounds
Diastolic Blood Pressure
ECG parameters
Body Mass Index
Physical Activity
Hemoglobin | Hematocrit
Obstructive Sleep Apnea
Blood pressure variability
Pulse pressure
Pulse Wave Velocity
Sleep Quality Index
Sudden weight gain/loss
Body temperature
Peripheral edema
comorbidity

Parameter	Abbr	Direct modifiable	Sample	Method (examples)	ADHF	HF	AF	ACS	CAD	CO
Diagnostic + Risk factor/marker	X	Poor/no indicator			**cardiac output**	**cardiac output**	**arrhythmias**	**coronary perfusion**	**coronary perfusion**	**muco dysfu**
Diagnostic marker	-	No literature found			circulatory deficit, systemic ischemia	circulatory deficit, systemic ischemia	circulatory deficit, systemic ischemia	cardiac ischemia	cardiac ischemia	airflow li inflam
Strong risk factor/marker					dyspnea / orthopnea	breathlessness	lethargy	Instable AP	Angina Pectoris	Shortnes
Risk factor/marker					fatigue / weakness	orthopnoea	palpitations	left arm / neck / jaw	shortness of breath	Whe
Could be a risk factor					peripheral edema	dyspnoea	dyspnoea	sweating / nausea	fatigue / faintness	Chest ti
					exertional dyspnea	exertional dyspnea	chest tightness	abdominal pain	nausea / burning	Coughin
					palpitations	fatigue / tiredness	sleeping difficulties	dyspnoea	restlessness	fati
Heart Rate	HR	M + L	Rate	ECG | Bio-Impedance | PPG | etc						
Heart Rate Variability	HRV	M + L	Rate	ECG | Bio-Impedance | PPG | etc						
Peripheral Oxygen Saturatio	SpO2	T	Optics	Pulse oximetry (PPG)						
Systolic Blood Pressure	SBP	M + L	BP	NIBP | ~PPG						como
Respiration Rate	RR	-	Rate	ECG| PPG | accelerometry						
Thorax sounds	Sound	-	Sound	Phonocardiogram | Stethoscope						
Diastolic Blood Pressure	DBP	M + L	BP	NIBP | ~PPG						como
ECG parameters	ECG	M	ECG	ECG 12 lead						
Body Mass Index	BMI	M + L	weight	scale						
Physical Activity	PA	L	Movement	accelerometer | gyro | gps						
Hemoglobin | Hematocrit	Hb/Hgb/Hc	M + L	Optics	NIRS | PPG						
Obstructive Sleep Apnea	OSA	T	Sound	recorder						
Blood pressure variability	BPV	M + L	BP	NIBP | ~PPG						
Pulse pressure	PP	M + L	BP	NIBP | ~PPG						
Pulse Wave Velocity	PWV	M + L	Optics	PPG						
Sleep Quality Index	PSQI	M + L	-	PSG | EEG | accelerometer | sour						
Sudden weight gain/loss	BW	-	Weight	scale				-	-	
Body temperature	Temp	-	Temp	Thermometer | Infrared thermog				-	-	
Peripheral edema	OED	M	Fluid	Bio-Impedance				comorbidity	comorbidity	como

COPD	PAD	C. Arrest	Diabetes	post - stroke	Ischemic Stroke	Depression	Active lifestyle / exercise	Food	Smoking	Stress
ciliary nction	**peripheral perfusion**	**(absence) electic activity**	**insulin resistance Hyperglycemia**	**cerebral perfusion**	**cerebral perfusion**	**mental/chemical imbalance**	**training stress coping responses**	**nutrient + energy intake**	**inhalation poisonous chemicals**	**(perceived) threatened homeostasis**
mitation / mation	chronic limb ischemia	circulatory arrest, systemic ischemia	Glucose toxicity, cell damage	cerebral ischemia, neurologic deficits	cerebral ischemia, neurologic deficits	mental/physical health decline	metabolic+musculo-skeletal adaptations	maintenance homeostasis	cell damage + inflammation	sympathetic nervous output
s of breath	claudication	sudden collapse	excessive thirst	one sided weakness	**F**acial/**A**rm weakness	depressed mood	**aerobic / anaerobic**	**salt / fat / alcohol / (caffeine) intake**	**(passive) cigarette consumption**	**stress response**
eezing	numbness/weakness	no pulse	increased urination	joint pain / rigidity	**S**peech problems	decreased energy	↓↑ CV health	↓↑ BMI		fatigue
ightness	coldness leg/foot	no breathing	excessive hunger	stiffness / spasms	blurred vision	difficulty concentrat.	LDL / HDL ratio			energy
g / mucus	sores that won't heal	loss of consciousness	fatigue	sensory deficits	confusion/dizziness	insomnia/hypersom.	↓↑ BP			↓↑ appetite
igue	change in the color	chest pain	Sudden blurred vision	apraxia	severe headache	weight change	↓ stress			body aches
	-									
										...
			x	-	-	-		-	x	-
rbidity								x!		
	-		-			-		-	-	
			-	-	-	-				...
rbidity		-								
-	-		comorbidity	comorbidity	comorbidity	-		x		...
							x	~	-	-
								-	-	-
		-				x				-
							-	-	-	-
		-		-	3	-	x			
		-		x	x			-		...
		-				-			?	
	-	-						-		
	-	-	-		-	-	x		-	
		-	~		-					
rbidity		-	-	-	-	-	-	-	-	-

Direct measurable effect

Long term measurable effect

Possible measurable effect

Appendix B

Technologies

Noninvasive monitoring technologies

Actigraphy

Actigraphy is used to monitor rest and activity . The actimetry sensor includes an accelerometer which measures movement and therefore steps, activity and sleep.

Variables: physical activity, sleep duration and quality
Current applications: smartphones and wearables
Advantages: integration in everyday products
Disadvantages: limited accuracy due to movement artifacts

Ballistocardiography

Ballistocardiography (BCG) is a technique for measuring body movements caused by the ballistic forces (recoil and impact) of every heartbeat. The movements are translated into a graphical representation . It is similar to seismocardiography which measures micro-vibrations caused by a heartbeat.

Variables: heart rate, respiration rate and movement
Current applications: bathroom scale, bed-based sleep tracking
Advantages: miniature size and multitude of measurement methods
Disadvantages: a lack of standardization and understanding of the physiological basis, not acceptance by medical community.

Electrocardiography

Electrocardiography (ECG) presents the electrical activity of the heart into a graphical presentation which reflects the structure and function of the heart. Ambulant ECGs often use fewer leads than hospital ECGs and display therefore less information.

Variables: ECG parameters, heart rate, heart rate variability, respiration
Current applications: 24-48 hours holter (2-12 leads), single-lead patch.
Advantages: established technique and accepted by medical community
Disadvantages: expensive, obtrusive due to the number of leads, fewer leads reduces the information.

Noninvasive blood pressure

Noninvasive blood pressure (NIBP) often describes oscillometric monitoring methods using an inflatable arm cuff that constricts and releases, whereby the artery under the cuff collapses and restores in a controlled manner in order to measure the systolic and diastolic pressure.

Variables: systolic and diastolic blood pressure, blood pressure variation, pulse pressure
Current applications: automated home monitor
Advantages: established technique and accepted by medical community
Disadvantages: obtrusive due to constricting arm cuff, errors may occur due to wrong placement, wrong cuff size, movement, a thick fat layer or due to arteriosclerosis and arrhythmias.

Bioimpedance spectroscope

Bioimpedance spectroscope (BIS) is an approach to measure the electrical properties of body tissues and the body composition by running a low-level alternating current into the body. Whole body bioimpedance indicates the nutrition status and thoracic bioimpedance measure alterations in the body's fluid distribution, interesting for pulmonary and cardiac assessment. Novel applications use local bioimpedance around the wrist for heart rate monitoring.

Variables: fat tissue, hydration status, pulmonary edema, cardiac fluid accumulation, respiration rate and galvanic skin response (skin conductance)
Current applications: wrist-ankle whole body BIS, hospital thoracic BIS, wrist worn activity wearable Jawbone.
Advantages: low cost, low battery consumption.
Disadvantages: errors occur due to motion and miss-positioning. Thoracic BIS: high costs, obtrusive, time consuming. Bioimpedance signal is affected by numerous other factors: motion artifacts, electrical interference and other stronger biological signals.

PhotoPlethysmography

PhotoPlethysmography (PPG) optically measures the volumetric changes in blood flow during every pulse by transmitting light through the skin and subsequently measuring the light absorption or reflection. A common example of the light absorption method is the pulse oximeter, an established device that monitors arterial oxygen saturation. The device transmits wavelengths through a thin section of skin, such as a finger or an earlobe, and measures the difference in absorption between red blood cells loaded with oxygen and red blood cells lacking oxygen.

Variables: SpO2, HR, HRV, estimated RR and RRV, (potentially blood pressure)
Indications: AF, CA, COPD, respiration complaints, sleep disorders.Contraindications: dark skin pigment, dyshemoglobinemia, low perfusion level: diabetes, PAD, etc. COPD. Current applications: pulse oximeter, health watches and wearables. Advantages: low cost sensor, miniature size and lightweight, allows long term continuous monitoring. Disadvantages: sensitive to movement and light artifacts. Accuracy: detecting HR and HRV with a sensitivity of 97%, specificity of 94% and 95% accuracy with the single channel electrocardiogram as gold standard.

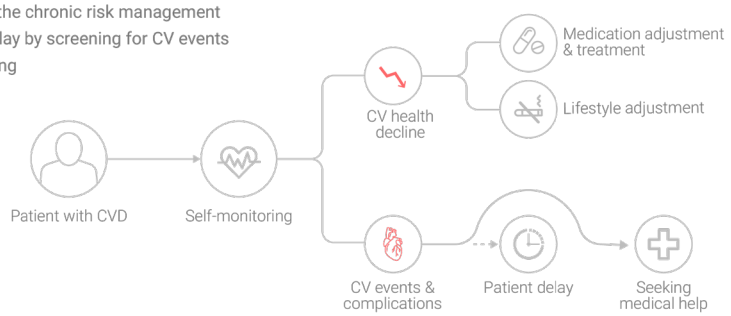
Appendix C

Infographics

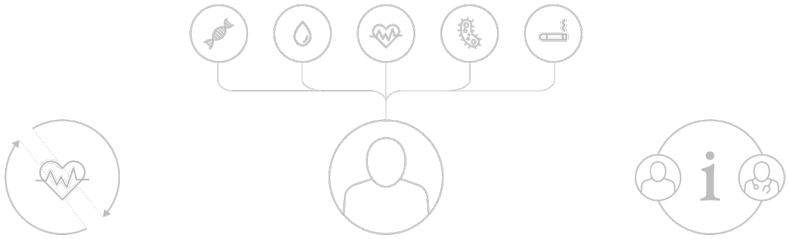
Project goal

Secondary prevention tool for patients with established CVD

- guiding patients in the chronic risk management
- reducing patient delay by screening for CV events through self-monitoring



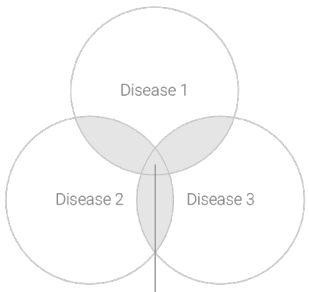
Content interview



1. Clinical value of self-monitoring & non-invasive parameters

Confidential / Draft

Hypotheses



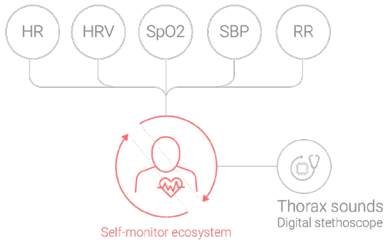
Commonalities
- shared symptoms (e.g. fatigue, breathlessness)
- clinical signs (e.g. HR, BP)

Distinctive features
- differentiating signals (e.g. auscultation sounds)
- quantities (e.g. BP range)

Results

Commonalities **Parameters**	Distinctive features **Clinical signs**
• Heart Rate	bradycardia - tachycardia - high resting HR
• Heart Rate Variability	decreased HR variability - arrhythmias
• Peripheral Oxygen Saturation	(nocturnal) hypoxaemia - local tissue ischemia
• Systolic Blood Pressure	hypotension - normotension - hypertension
• Respiration Rate	tachypnea - hypopnea* - respiration rate variation - Cheyne-Stokes respiration
• Thorax sounds	abnormal S1/2/3/4 - bruits - murmurs - crepitations - rales - wheezing - crackles

Proposal for self-monitoring



2. Interpretation of the patient profile

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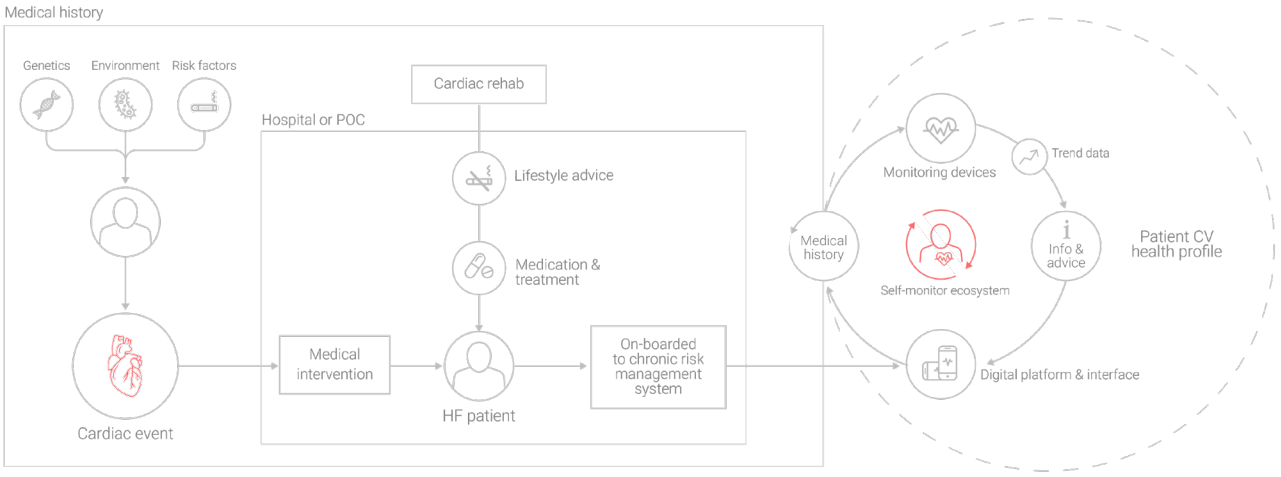
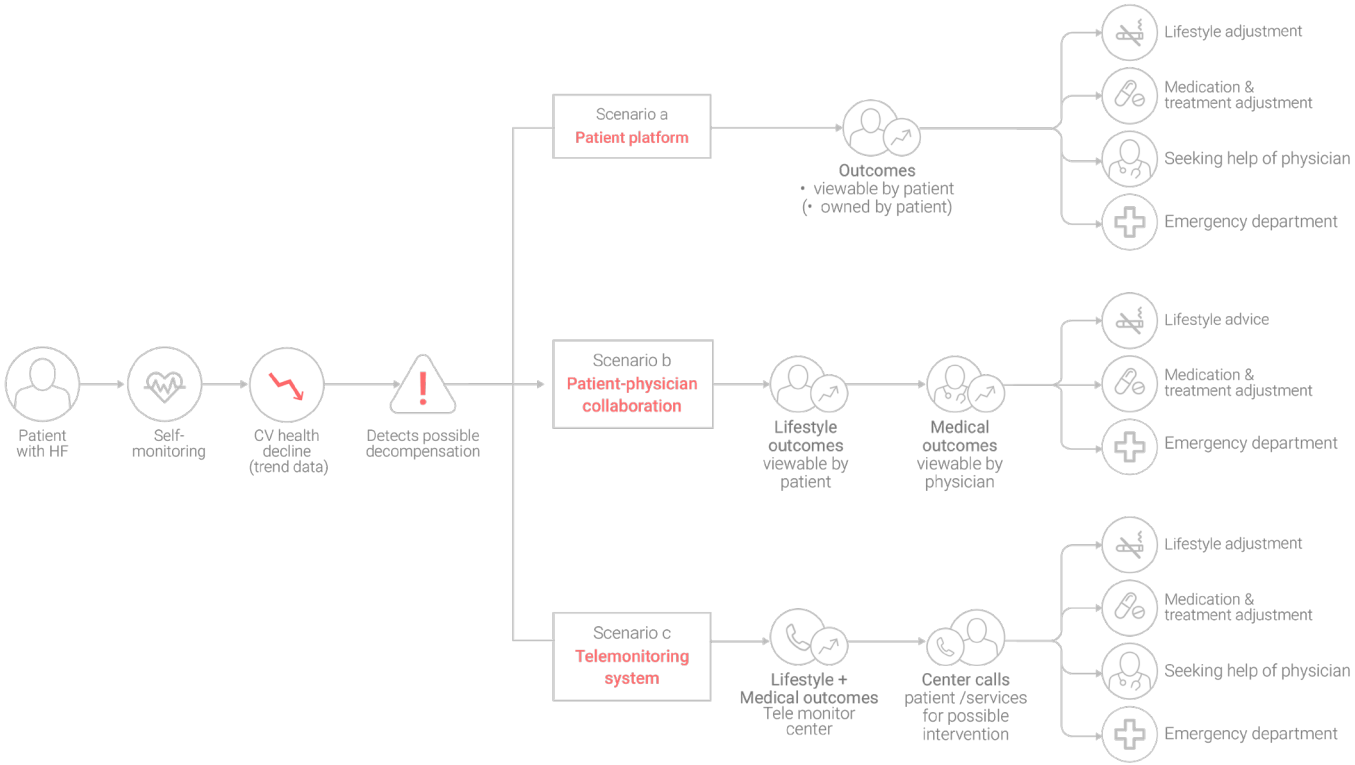
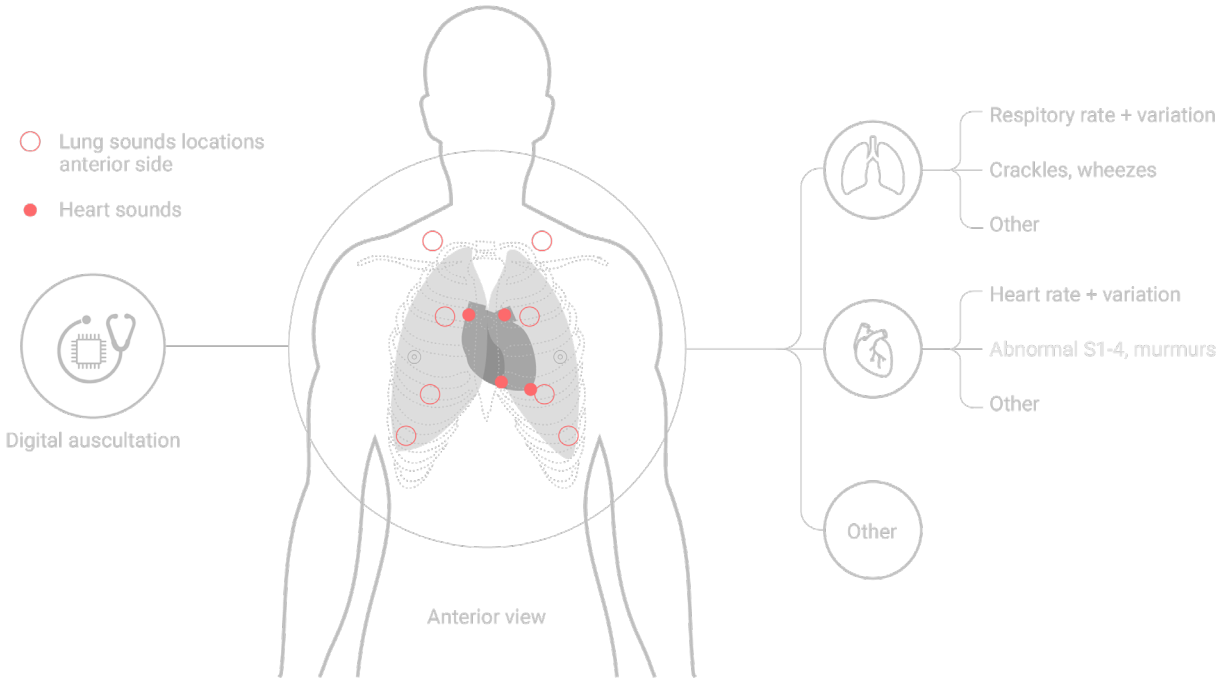
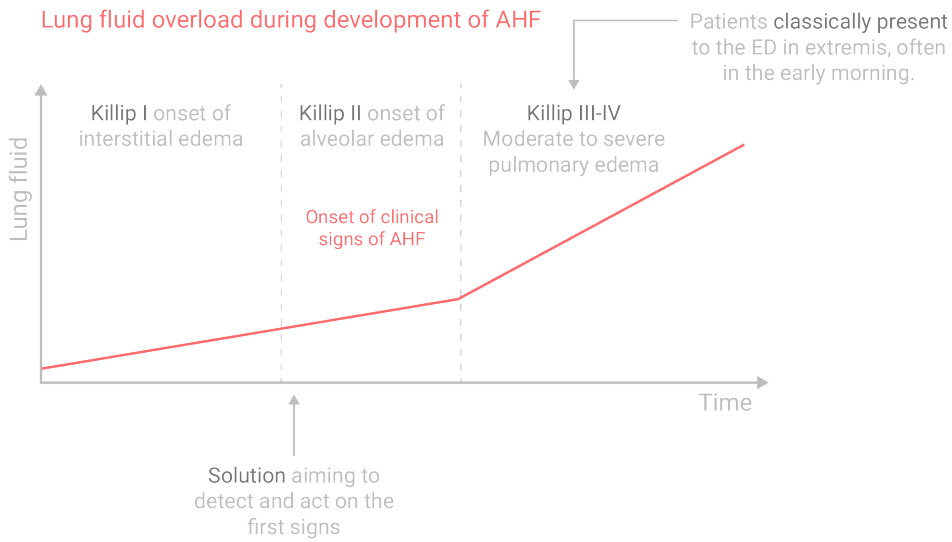


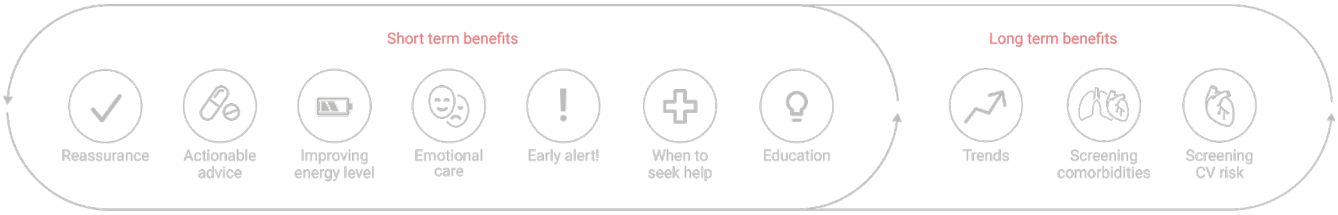
3. The role of the patient & physician

Confidential / Draft




Lung sounds locations
anterior side
Heart sounds
Digital auscultation
Anterior view
Respitory rate + variation
Crackles, wheezes
Other
Heart rate + variation
Abnormal S1-4, murmurs
Other
Other


Lung fluid overload during development of AHF
Patients classically present to the ED in extremis, often in the early morning.
Killip I onset of interstitial edema
Killip II onset of alveolar edema
Killip III-IV Moderate to severe pulmonary edema
Onset of clinical signs of AHF
Lung fluid
Time
Solution aiming to detect and act on the first signs



- situation
- symptoms
- side effects
- treatment
- activities
- emotions
- ...

- medication
- treatment
- extra pillows
- salt intake
- water intake
- ...

- breathing exercises
- walking
- planning
- ...

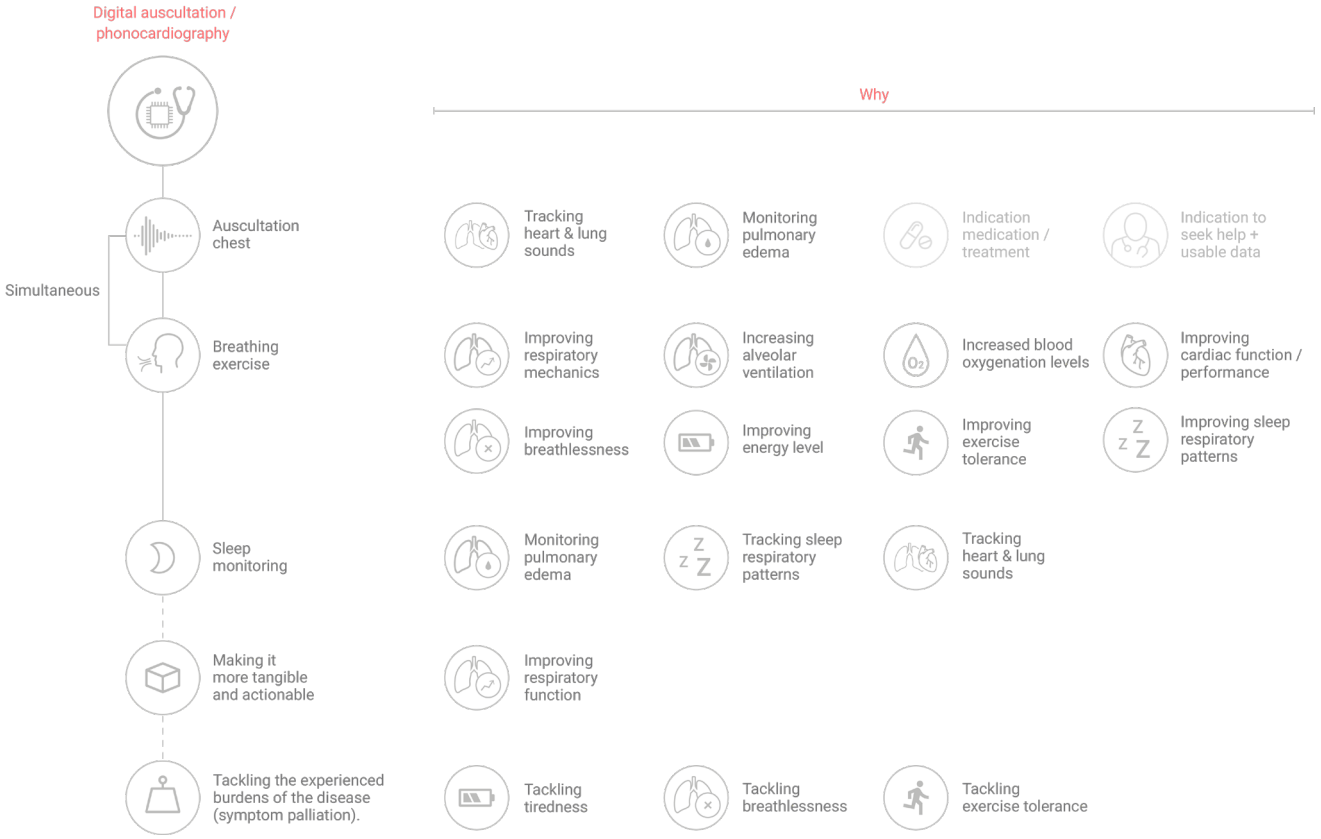
- mood tracking
- healthy insights
- ...

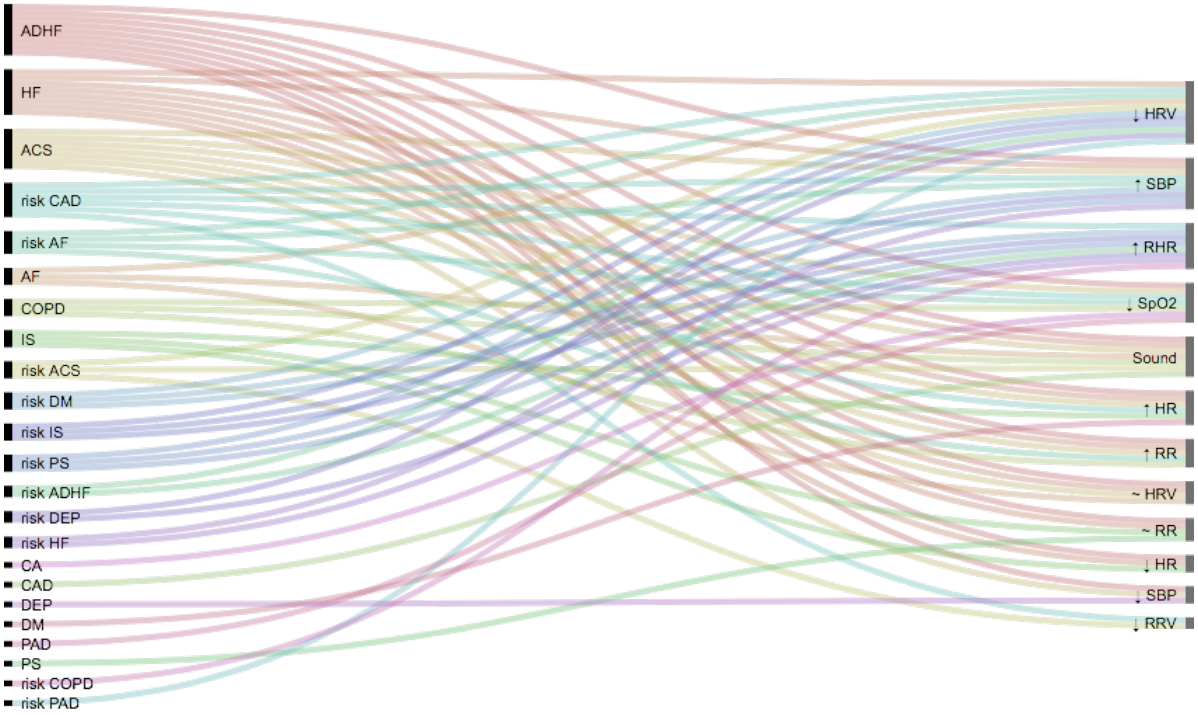
- decompensation
- exacerbation
- potential triggers
- ...

- when to go
- where to go
- prepare

- disease
- risk
- medication
- treatment
- activity
- food
- mental health
- social

- HR / HRV
- RR / RRV
- lung sounds
- apnea
- sleep quality




ADHF
HF
ACS
risk CAD
risk AF
AF
COPD
IS
risk ACS
risk DM
risk IS
risk PS
risk ADHF
risk DEP
risk HF
CA
CAD
DEP
DM
PAD
PS
risk COPD
risk PAD
↓ HRV
↑ SBP
↑ RHR
↓ SpO2
Sound
↑ HR
↑ RR
~ HRV
~ RR
↓ HR
↓ SBP
↓ RRV

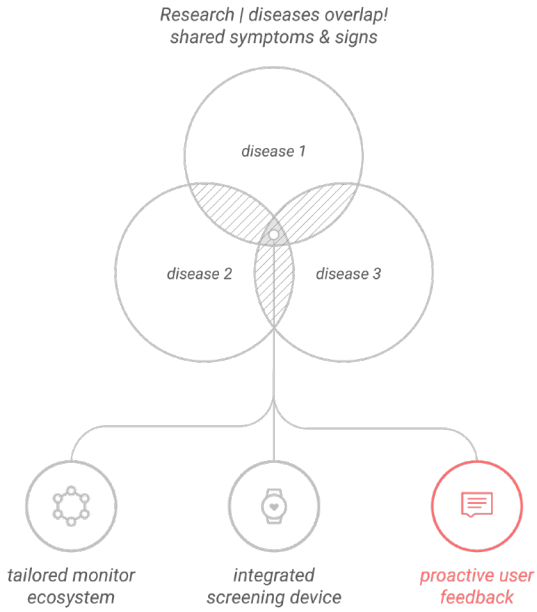
Appendix D

Creative session

Essence graduation

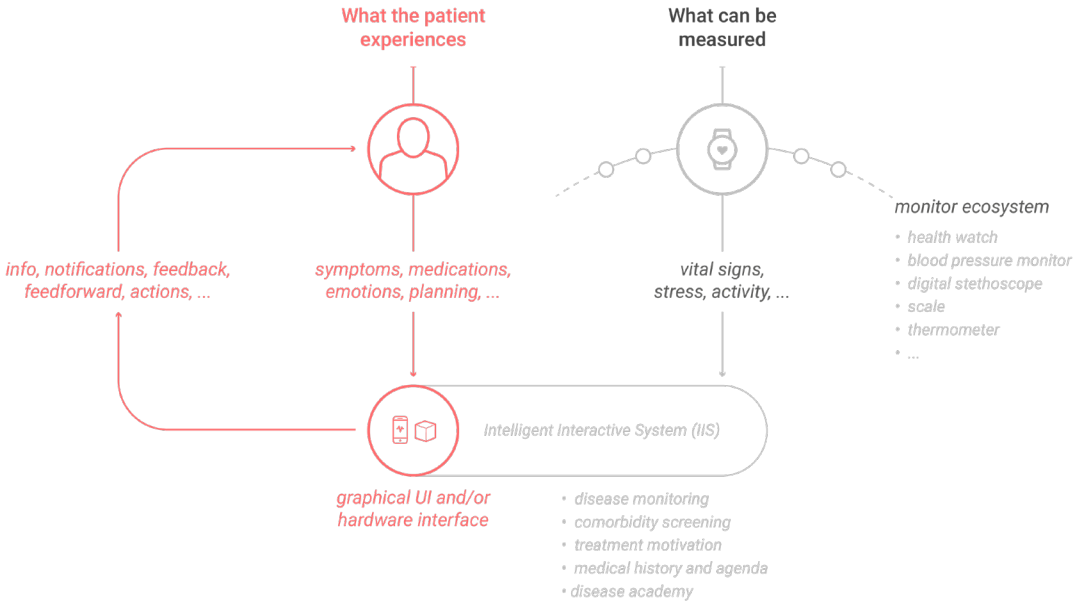
Screening tool for cardiovascular decline and comorbidity

(= multiple diseases at once)

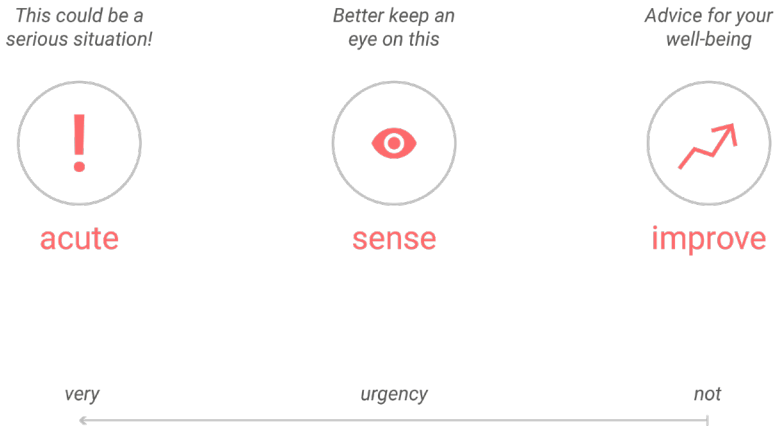


Scope

Patient experience (UX) and communication (UI)



Nature of the situation

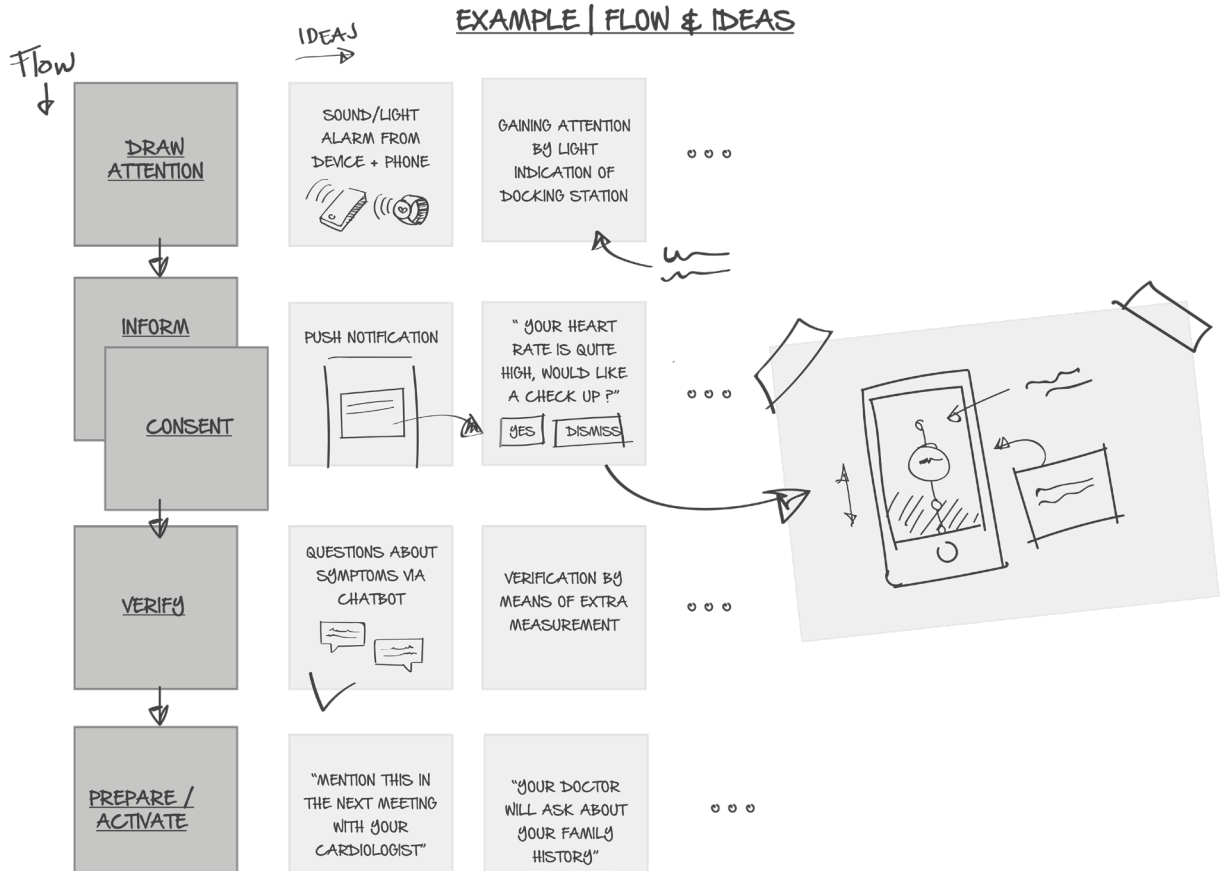


Session flow

EXAMPLE | DEFINE SCENARIO

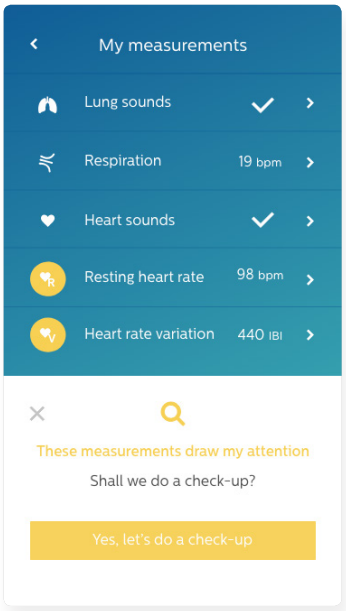
SCENARIO 1 →	DEVICE INITIATES INTERACTION AFTER DETECTION OF A SIGNIFICANT FINDING.	E.G. SMARTWATCH DETECTS HEART RHYTHM DISTURBANCES	ACUTE SITUATION	TIMING AT NIGHT, WHILE SLEEPING	...
POSSIBLE END POINTS	FALSE ALARM	SEEKING HELP / SYSTEM CALLS 112	SEEKING HELP	CONTACT PARTNER/ FAMILY	...
ACTIONS	SYMPTOM CHECK	EXTRA MEASUREMENT	CONNECT TO HELP....		...
USER NEEDS	REASSURANCE	CLARITY (WHAT TO DO)	PRACTICAL / EMOTIONAL SUPPORT (PARTNER OR CAREGIVER)		...

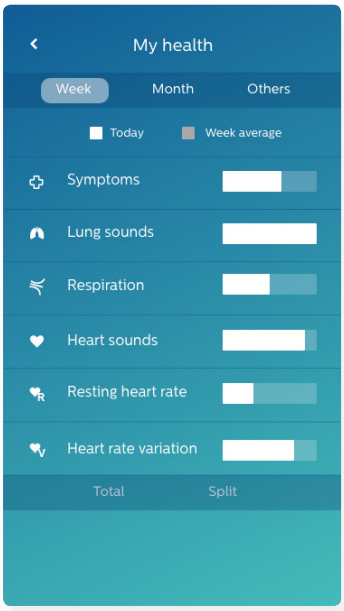
EXAMPLE | FLOW & IDEAS

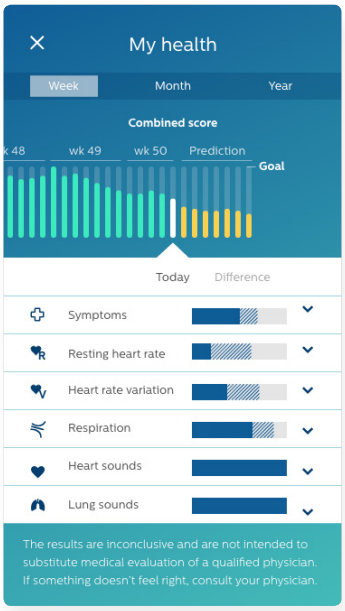


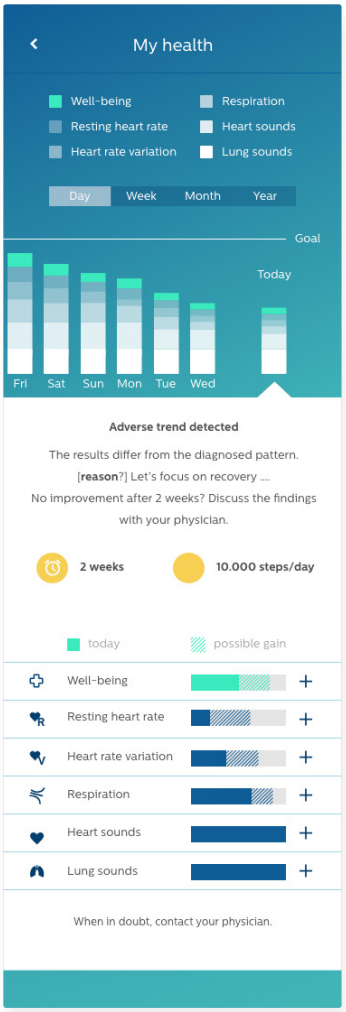
Appendix E

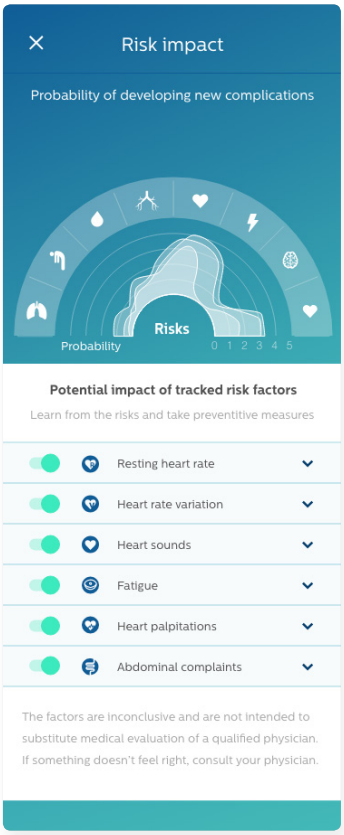
Design iterations

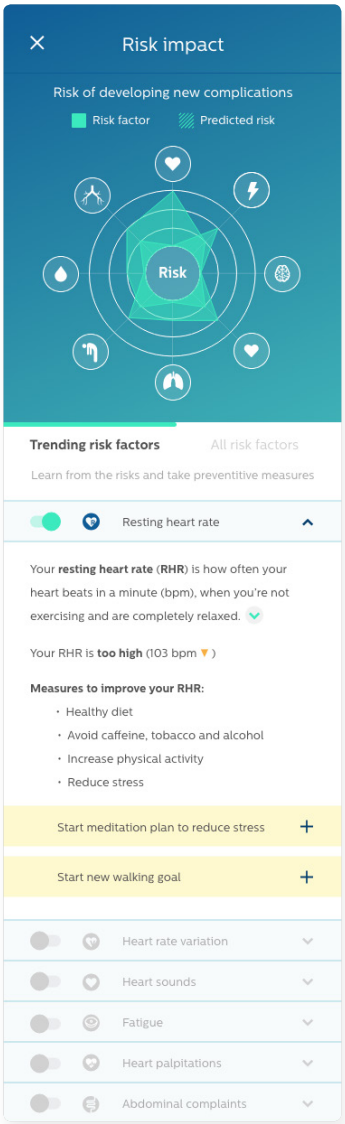

My measurements
Lung sounds
Respiration
19 bpm
Heart sounds
Resting heart rate
98 bpm
Heart rate variation
440 IBI
These measurements draw my attention
Shall we do a check-up?
Yes, let's do a check-up


My health
Week
Month
Others
Today
Week average
Symptoms
Lung sounds
Respiration
Heart sounds
Resting heart rate
Heart rate variation
Total
Split


My health
Week
Month
Year
Combined score
wk 48
wk 49
wk 50
Prediction
Goal
Today
Difference
Symptoms
Resting heart rate
Heart rate variation
Respiration
Heart sounds
Lung sounds
The results are inconclusive and are not intended to substitute medical evaluation of a qualified physician. If something doesn't feel right, consult your physician.


My health
Well-being
Respiration
Resting heart rate
Heart sounds
Heart rate variation
Lung sounds
Day
Week
Month
Year
Goal
Today
Fri
Sat
Sun
Mon
Tue
Wed
Adverse trend detected
The results differ from the diagnosed pattern.
[reason?] Let's focus on recovery ...
No improvement after 2 weeks? Discuss the findings with your physician.
2 weeks
10.000 steps/day
today
possible gain
Well-being
Resting heart rate
Heart rate variation
Respiration
Heart sounds
Lung sounds
When in doubt, contact your physician.


Risk impact
Probability of developing new complications
Risks
Probability
0 1 2 3 4 5
Potential impact of tracked risk factors
Learn from the risks and take preventitive measures
Resting heart rate
Heart rate variation
Heart sounds
Fatigue
Heart palpitations
Abdominal complaints
The factors are inconclusive and are not intended to substitute medical evaluation of a qualified physician. If something doesn't feel right, consult your physician.

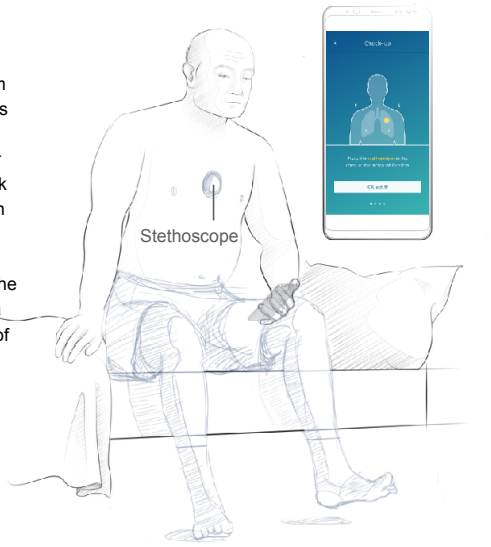

Risk impact
Risk of developing new complications
Risk factor
Predicted risk
Risk
Trending risk factors
All risk factors
Learn from the risks and take preventitive measures
Resting heart rate
Your resting heart rate (RHR) is how often your heart beats in a minute (bpm), when you're not exercising and are completely relaxed.
Your RHR is too high (103 bpm)
Measures to improve your RHR:
Healthy diet
Avoid caffeine, tobacco and alcohol
Increase physical activity
Reduce stress
Start meditation plan to reduce stress
Start new walking goal
Heart rate variation
Heart sounds
Fatigue
Heart palpitations
Abdominal complaints

Appendix F

User research

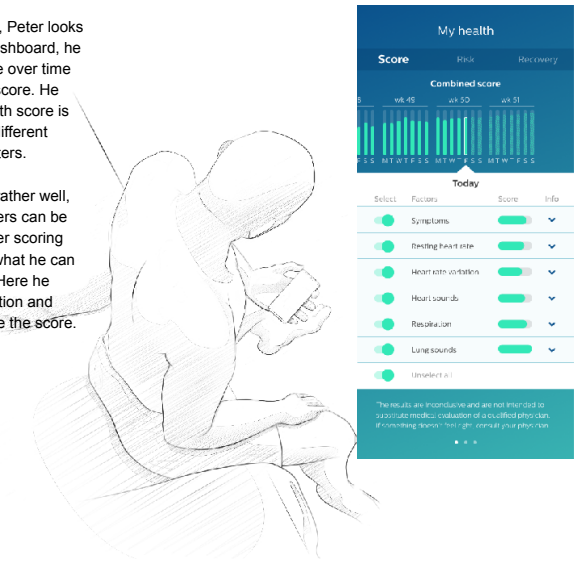
Peter is diagnosed with a cardiovascular disease. Besides his normal treatment, his doctor offers him a home-use stethoscope to monitor his health and risk for new disease developments. Peter accepts the offer since he is motivated to reduce his risk of new complications and deterioration of his condition.

At home, Peter gets acquainted with the service and device, and monitors on a routine basis with the clear guidance of the application.

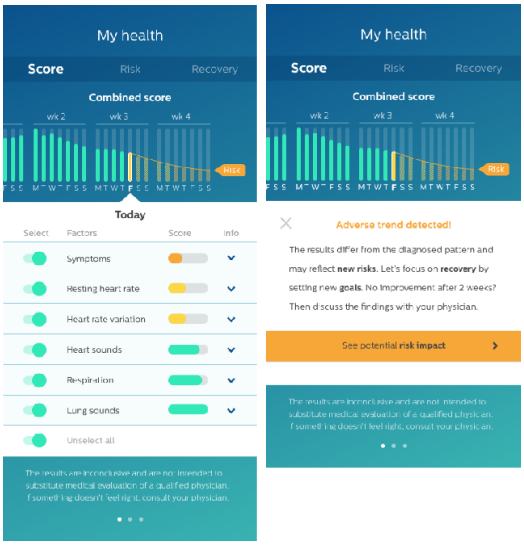


After every measurement, Peter looks into the results. On his dashboard, he sees his total health score over time and his predicted health score. He understands that the health score is built up by the results of different measured health parameters.

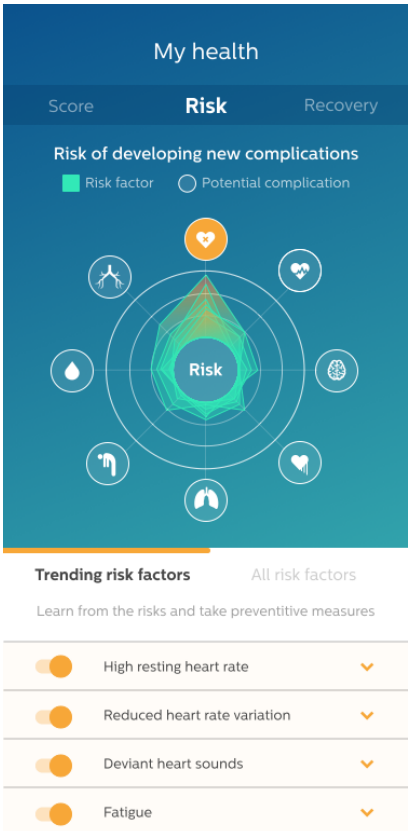
He sees that he is doing rather well, but some health parameters can be better. He clicks on a lower scoring health parameter to see what he can do to improve the score. Here he finds background information and lifestyle advice to increase the score.



A few weeks later, Peter sees that his health scores declined. His dashboard shows a declining trend and a newly found risk. Peter wants to know about the risk and goes to the risk overview.

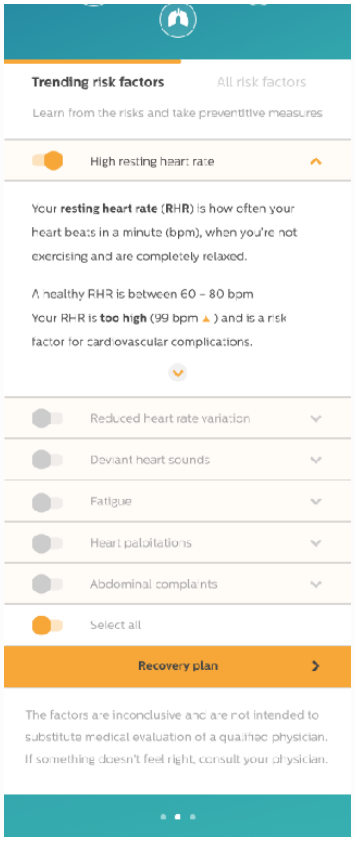


On the risk overview, Peter learns which risk factors influence a probable comorbidity. He sees that some health parameters and symptoms increase the risk of a heart attack.



Peter clicks on the risk factors to learn more about them and their relationship to the comorbidities.

He clicks on the recovery plan to see what he can do to reduce the risk.



Topic 1

1. To what extent does this scenario fit your situation?

Fits — Somewhat — Doesn't fit

[1] It fits with monitoring my blood pressure.

[2] I feel this scenerio fits my situation overall. I also have a heart condition and I would like to be able to monitor my condition at home in between doctor appointments.

[3] I monitor my blood pressure 3 times a week with my own blood pressure kit. I also check my blood sugar an average of three times a day. I record them and then every three months review my results with my doctor when I go for my checkup. He adjusts my situation accordingly and comments on my results and gives me pointers aqs to how to improve my numbers by losing weight.

[4] Fit very well

[5] I do have high blood pressure and if I could have a program like what he has I would love to see what I could do to turn things around in a positive way to make my health better.

[6] I have heart disease and have had to have a triple bypass 1 1/2 yrs ago this would have helped me very much if I had this tool before I got into big trouble with my heart issues.

[7] It fits my health scenario quite well.

[19] Some sort of device like this would be helpful. As a CHF patient it is important that I do all to keep my risk factors as low as possible.

[8] I do take my blood pressure often so I can monitor it. I do not feel like this whole situation is for me but I do think that some of them are relevant and would be helpful for me

[9] It is not a direct match as I do not currently suffer from cardiovascular disease. However, I do suffer from hypertension / high-blood pressure and depression. Both are conditions I treat with presciptions, exercise, diet and knowledge. I would welcome the opportunity to try an in-home treatment. Especially if it utilized technology - applications, mobile devices, etc.

[10] This scenario does not really fit my situation but is a good monitoring toll for anyone that wants to monitor their Cardiovascular health.

[11] It does not fit me.

[12] This scenario does not fit me. My health conditions are not this advanced.

[13] This doesn't fit my situation. I am monitored with a ICD that transmit my information automatically.

[14] I feel like this is something I might have to do in the future but for right now I'm not really following up with a doctor or doing anything in particular for my condition other than trying to eat healthy and exercise.

[15] This does not fit my current situation but if I had a cardiovascular disease I would not hesitate to use it.

The participant can relate his/her own experience to the scenario in some way.

- 16 answers of 18 responses -

Topic 1

Understanding of proposition

2. What do the health parameters tell you?
3. How does the service find risk factors?
4. What do the risk factors tell you about complications?

Understands ◄——————————————► **Doesn't understand**

[1] They would tell me what I was doing well and where I needed improvement. It tells me all the possible outcomes for the different risk factors.

[2] I like that it gives me my total health score and keeps track of other heart information (ex. symptoms, resting heart rate,etc.). The health parameters tell me how I can improve my score. He gives me lifestyle advice to improve my score. The service finds risk factors by monitoring your heart. It evaluates a variety of factors such as resting heart rate and heart rate variation. The risk factors tell me what complications are likely. For example, certain factors might increase my risk for a heart attack.

[4] 2.monitor my conditions 3. by electronic monitoring 4. that situations is serious and she be dealt with

[6] It seems like they can detect what your problem areas are and how you might help correct those issues. by monitoring your heart with the online app and scope it seems. you can help yourself by finding problems earlier.

[9] 2. The parameters can tell you the areas where you are improving, and, more importantly, the areas where you need to improve. 3. It finds them via the application and the health data on the device. 4. They inform you of the complications that can arise based on the risk factors.

[10] 2. The health parameter tell you where you are falling short and over time will tell you if you are on a down swing. 3. The service must have pre programmed risk factors that are monitored through an electronic app. 4, Over time it will show if you are declining or improving.

[12] 2.The health parameters provide you a risk factor for future heart complications. 3, The service finds risks by monitoring and evaluating the input from the stethoscope readings you provide. 4. It tells you if you are a risk for new complications or if your heart is in recovery.

[14] 2. They show if you are getting better or worse over time 3. Using a stethoscope 4. They determine how bad the complications might become

[15] 2. The health parameters tell you what your scores are and how you can improve them. 3. By checking your scores it can tell you how to reduce your risks. 4. That some symptons can increase the risk of a heart attack.

[7] 2. The parameters can be telling me various symptoms that may effect my health. 3. I don't know, based on a stethoscope and app it is hard to determine. 4. The risk factors are not showing much, exceptfor a dependency on this app and possibly anxiety over it.

[11] 2. Wonderful tool, 3. Great way to help be aware of oneself and surroundings, 4. Sometimes your environment can be a factor as well,

- 11 answers of 18 responses -

Topic 1

5. Would this service improve your understanding of your disease self-management?

Improves ◄——————————————————► Doesn't improve

[2] I feel this service would improve my understanding of my disease because it allows me to mintor my symptoms, my resting heart rate, my heart rate variation,etc.

[4] yes and help me lower risks

[5] I do have high blood pressure and if I could have a program like what he has I would love to see what I could do to turn things around in a positive way to make my health better. I love that everything is seen on this program and tips and hints are given.

[6] yes, it would to the 5th question.

[19] Once I was having difficulty with a medication, and if I had this device, it might have shown up before I suffered the consequences. If I had this, I would prefer to have some sort ph pamphlet to explain every part of the program.

[8] I do not feel like this whole situation is for me but I do think that some of them are relevant and would be helpful for me

[9] An in home service would definitely compliment any other methods of treatment. And taking advantage of all the data collected by mobile devices can be so valuable.

[10] I would think that the app would help one's understanding of self management because it provides information on how to improve.

[11] This sounds like a really nice option for a person to assist in taking control of a specific health issue. Would be a great asset to anyone as needed.

[12] This service would provide you a better understanding of how you are managing your heart disease.

[14] Yes because I might see a correlation between the parameters and something I'm doing at home.

[15] I think this service would really help improve my understanding of my disease and how to mange it. It would also help me know what I am doing wrong and what I can do to improve my scores and maybe prevent a heart attack.

[17] Although not specifically for cardiovascular, the monitoring device would work in a number of scenarios. device would not only monitor current conditions, but also show where improvement is necessary Monitor over a time period and gage what could happen if not attended to. A service like this could very well become an important barometer for a disease.

[7] No it would not help me. I see the doctor often enough and feel the more I check it, the more anxious I would get.

[13] I feel you can sometime you can misunderstand what you are seeing. I think you should contact your doctor with any questions about the information you are reading

[16] All of the graphs can be a bit much and hard to maintain but to me it would also add more stress with knowing that much detail and not sure I would really want to know that much b/c it would scare me and cause me more stress but I am sure other folks would want this.Another problem with this is I don't have a cell phone so it wouldn't work for me at all.I hate seeing every thing depending on cell phones and I don't want to depend on a cell phone for all the things they are doing with them.To me it is causing people to think less and try to figure out things and not able to do anything without the cell phone.

- 16 answers of 18 responses -

Topic 2

1. Would you value actionable advice based on the found risk factors?

Value ◄——————————————————► Doesn't value

[1] Yes, because I would be willing to try some of them and see if they work.

[2] Yes, I would value actionable advice based on the found risk factors. I want to learn how to be healthier and to reduce risk factors.

[4] yes

[5] I like the idea of being able to see my results and trying to figure out my problems.

[19] As a CHF patient it is important that I do all to keep my risk factors as low as possible. If it turned out that the risk factor was increasing, I would be depressed, but I would try to find out why & then correct it.

[8] I think this would be helpful. I am at risk for a stroke my dr told me because I get stroke like symptoms with my chronic migraine. I also was diagnosed as diabetic but the last times that I was checked it showed no symptoms of it so I'm not on those meds anymore as long as I monitor it. For some of the examples it gave it would be helpful to know what you could do to improve on it. I already know that I am a carrier for Alpha 1 anti trypsin deficiency, which my mom died from and all her siblings and knowing that I too have that gene is kind of disturbing for me. Sometimes I wish I didn't know.

[9] Absolutely. I started a new job about 5 years ago. And one of the best features has been the onsite wellness center. It provides me with tons of access to health and wellness opportunities that I never had before. Why wouldn't I take advantage of them. This is the same type of thing. It can only benefit me so why not?

[10] I would value advice based on the risk factors found so that I could improve my habits and lifestyle.

[12] I would value actionable advice within certain parameters. Sometimes the phrase "one size fits all does not apply." I would take the advice and vet it with a healthcare professional to ensure I'm not under/over responding to a potential medical condition.

[14] Yes because I want to live

[15] I certainly would because if I had risk factors I could improve, I would want to try if it is possible I could have a heart attack.

[17] Yes, any information is valuable. Being an optimist at heart, I always want to know my risk values. so that I can make an informed decision..Given feedback on values doe change from time to time, maybe not by much, it is always a good idea to stay up to date with what is going o in a disease.

[18] I think this a great idea for his monitoring and he should use it all the time.

[3] I would coordinate with my doctor and let him analyze results. I have a home blood pressure kit and blood sugar monitor, so I regularly do this and see my doctor every 3 months and he gives my risk factors and makes suggestions, like losing weight

[7] I would not take any action because I would not use the home device. I think the idea is not for me as it would make me too anxious and mask the real results.

[16] It has a value to it but it also can cause stress and that is what it would do to me

- 15 answers of 15 responses -

Topic 2

2. Would you feel encouraged or despondent (stressed/fearful) provided risk level of disease?

Encouraged — Both — Stressed

[4] encouraged

[5] If there is a decline, it probably should encourage you to contact your doctor to see what to do.

[10] I would feel bad if I thought I was living a healthy lifestyle and had a high risk but then I could do something about it.

[12] I would go through the 7 stages of grief. In the end I would be encouraged the know what lies in front of me.

[14] I would be encouraged, as long as I can do something to help myself.

[2] I would feel encouraged by provided risk level of a disease only if there is something I can do to prevent my risk. I would feel stressed if there was nothing I could do to reduce my risk level of disease.

[9] It can certainly cause some stress. But for me it is absolutely a benefit to at least be aware. Knowledge is power. I can now make decisions based on what I know, rather than what I don't.

[15] Yes the risk level would definitely make me fill encouraged or despondent. I would be happy if I was doing well. If I had a high level of risk I know it would cause me more stress which is something I would not need.

[7] I wouldn't know about it. I think the idea is not for me as it would make me too anxious and mask the real results.

[16] I would want to know how well I am doing but the bad part would add stress to me and I would worry about not being able to get the bad taken care of. I really couldn't do this on a day by day and keep being reminded of the bad as it would cause me worry and stress and I would be scared to death I couldn't get those problems down so it will add stress.I live with a disease that is bad and as time goes on it gets worse and I don't want to think about it b/c it scares me and adds stress to me which is not good for your health either and I have plenty of stress in my life so I try not to add anymore to it.

- 10 answers of 15 responses -

Topic 2

3. Would this feedback on risk help you or would it have helped you in the past?

[1] Yes, because it could give me the possibilities of different outcomes

[2] I feel this feedback would have helped me in the past and and now in that I could have maybe engaged in specific behaviors in the past or now to decrease my risk.

[4] proactive

[5] I like to think I can help my self but I am no doctor or have no medical training.

[19] Once I was having difficulty with a medication, and if I had this device, it might have shown up before I suffered the consequences.

[8] I think this would be helpful. I am at risk for a stroke my dr told me because I get stroke like symptoms with my chronic migraine. I also was diagnosed as diabetic but the last times that I was checked it showed no symptoms of it so I'm not on those meds anymore as long as I monitor it. For some of the examples it gave it would be helpful to know what you could do to improve on it.

[9] It definitely helps. And would have in the past as well. Just simple changes or adjustments in diet, exercise, etc. can make a huge impact over time.

[10] The feedback on the risk would help as I can make changes in my lifestyle to minimize my risks.

[12] This feedback would have helped me in the past. My current conditions had red flags that showed in my blood work and wasn't picked up by my doctor. While there was no serious complications, the potential was there.

[14] It would help because I could figure out ways to make it better

[15] The feedback on risk would help me know how I am doing and I would want to know that. That way I could read what I could do to improve my risk.

[17] Given feedback on values doe change from time to time, maybe not by much, it is always a good idea to stay up to date with what is going o in a disease. Yes, of course, about risk values , as I stated before any information good or bad contributes to better decision making.

[3] I would coordinate with my doctor and let him analyze results.

[7] The idea is ridiculous, it would cause the patient to be anxious and results would never be proper.

[16] I live with a disease that is bad and as time goes on it gets worse and I don't want to think about it b/c it scares me and adds stress to me which is not good for your health either and I have plenty of stress in my life so I try not to add anymore to it.

- 15 answers of 16 responses

Topic 2

4. Do you want to know about risk factors and risk levels for complications/comorbidity?

Know ◄——————————► Not know

Depends

[1] Yes, facts are always good and helpful and can help me make changes where I need to.

[3] I would coordinate with my doctor and let him analyze results. I have a home blood pressure kit and blood sugar monitor, so I regularly do this and see my doctor every 3 months and he gives my risk factors and makes suggestions, like losing weight.

[4] Yes to be prepared for good or bad.

[5] I want to know what is going on with my body and possibly I can change something to improve my health.

[7] Yes, I would like to know about my risk levels and **that is what my doctor is for.**

[19] Given a choice of whether or not I want to know, I'd much prefer to know if my issues are becoming more difficult.

[9] Absolutely. What I don't know can definitely hurt me. When it comes to health and wellness, knowledge and guidance are critical factors. I can make much better decisions if I know the facts and the options.

[10] I want to know what I can do to minimize my risks and if a don't change my lifestyle what could happen.

[12] I want to know about risk factors. There is so much medicine or treatment regimes to fight or delay full blown complications, why not take advantage of it.

[14] Yes because I want to know how hard I need to try to make things better

[17] Yes, of course, about risk values , as I stated before any information good or bad contributes to better decision making

[2] Yes, I want to know about risk factors and levels for complications/comorbidity as long as there is something I can due to decrease my risk. If I can take actions to prevent future problems I want to know and I want to be able to take those actions.

[8] I am at risk for a stroke my dr told me because I get stroke like symptoms with my chronic migraine. I also was diagnosed as diabetic but the last times that I was checked it showed no symptoms of it so I'm not on those meds anymore as long as I monitor it. For some of the examples it gave it would be helpful to know what you could do to improve on it. I already know that I am a carrier for Alpha 1 anti trypsin deficiency, which my mom died from and all her siblings and knowing that I too have that gene is kind of disturbing for me. Sometimes I wish I didn't know

[15] In some ways I would want to know my risk factors so I can make them better but if they are really bad I would worry about having a heart attack and I don't want to know my chances of dying.

[16] I live with a disease that is bad and as time goes on it gets worse and I don't want to think about it b/c it scares me and adds stress to me which is not good for your health either and I have plenty of stress in my life so I try not to add anymore to it.

- 15 answers of 16 responses -

Topic 2

5. What do you like/dislike about the service?

Like Dislike

[1] I like that it gives factual feedback.

[2] I like that this service monitors my health and that it offers a recover plan to reduce my risk.

[4] nothing all good

[5] I like the idea of being able to see my results and trying to figure out my problems

[9] Again, I really like technology. So any apps, date, etc. that is available easily and readily is a win for me. I am always using my mobile devices so if this takes advantage of that, it is all the better for me.

[10] I like that I can track my progress in reducing my risks.

[12] I like the fact that I am actively involved in my diagnosis which allows me to have a better understanding of what I am facing in the future.

[14] I like being able to do it from home but certain things would probably be better if you were seeing the doctor.

[15] I like that the service tells you what you can do to improve your risk because that is worth knowing. I can see both pros and cons to the service.

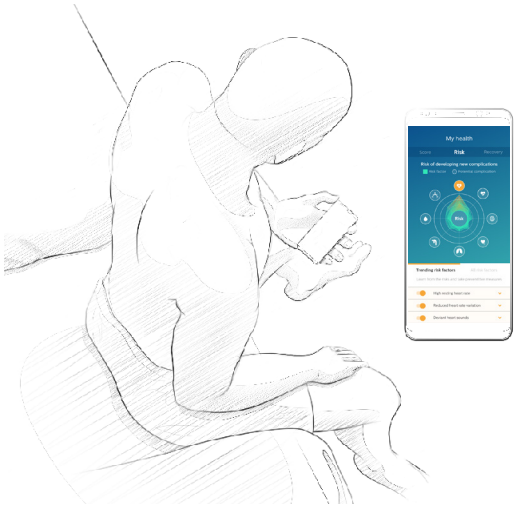
[17] I like the service because it provide information.

[7] I think the idea is not for me as it would make me too anxious and mask the real results.

[15] I dislike knowing I am at terrible risk and my have a heart attack or die. I can see both pros and cons to the service.

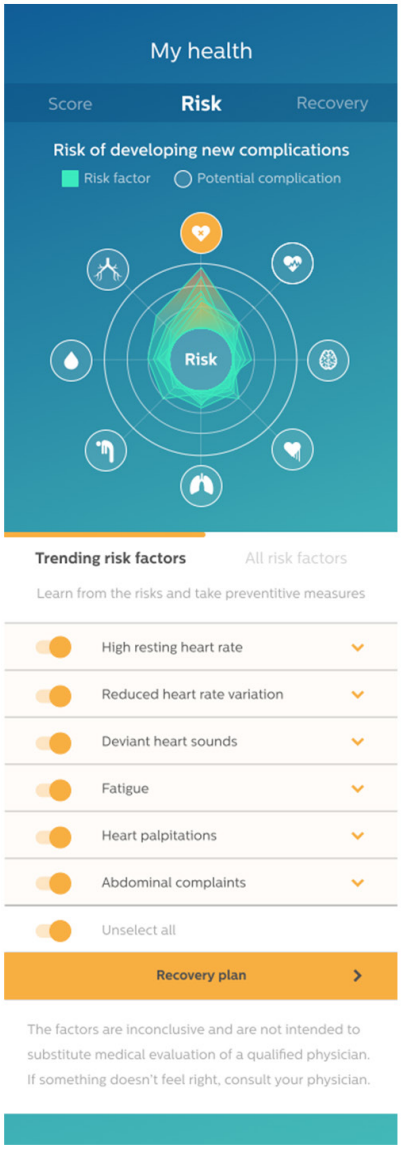
[16] I really couldn't do this on a day by day and keep being reminded of the bad as it would cause me worry and stress and I would be scared to death I couldn't get those problems down so it will add stress.

- 10 answers of 16 responses -



In the story, Peter is learning about a potential risk for a complication.

Let us know what you think about the way this information is presented to him/you.



Topic 3

1. What does the screen tell you now? Are the elements and changes clear to you?

Clear — Not all clear — Unclear

[1] It tells me the risk factors associated with heart disease and seems to offer a link to a plan of things to do to combat the risk factors. Yes, it's clear.

[7] It seems as if the screen is saying that there are heart risks.

[15] The screen tells me what risks I have. I find them to be clear and informative.

[2] This screen tells me information on the risk of developing new complications. It tells me about trending risk factors and all risk factors. I feel the information is not completly clear. It is unclear what each icon within the circle is referring to.

[9] I like the fact that the information is presented visually. However, I must admit that I am somewhat confused by the different symbols. It helps that the bottom has text and drop downs with more details. And the recovery plan section is a plus.

[12] This screen tells me the risk factors for heart related diseases and the potential I have for incurring them. This screen does not help me because if I cannot relate to colors. I prefer numbers and percentages. The elements are clear, the changes are not. Some of the values are straightforward, others are just medical words. I understand how most of the elements impact the heart, but elements like abdominal pains need further explaining.

[14] The factors are all present on the graph at once so you don't know which one might need to be addressed first, but you should be able to separate them and find out. It shows how close you are to developing a complication.

[16] It is some what hard to read and I can't get it any larger but from what I do see it is telling me that the heart is at risk and then gives a list of what else can be a problem.The elements are clear but not sure about what changes are needed or how to fix the risks.

[6] No they were not clear at all to me. I wasnt sure how to read that chart and where any other info would come from. disappointed. it doesnt offer any value to me. feel let down.

[11] This screen is confusing at first glance, possibly would be clearer if I could open into it further. As a whole this continues to look like a valuable tool for self assesement

[19] There was a "risk chart". I did not understand what it was attempting to do. I clicked on various items in the chart, and nothing happened.

- 10 answers of 10 responses -

Topic 3

2. What value has this screen for you? How do you value the different elements?

Value — No value

[1] The value in knowing the risk factors would guide me in knowing the things to avoid and things to do to help the condition. The recovery plan could be helpful in providing concrete solutions to manage the condition.

[2] This screen has some value. It is valuable that I can track my risk factors, learn about trending risk factors and that they offer a recovery plan. However, this screen would be more valuable if I fully understood all of the information. I would suggest labeling the icons so it is more clear what they mean. I value the different elements equally

[7] It is showing me that a doctor is needed to evaluate the situation further.

[9] I like visuals so that is a plus. My hope is that the various symbols can be clicked or rolled-over for better descriptions. The text at the bottom with drop downs for details really helps too. I find value in the different risk factors and the recovery plan sections.

[11] As a whole this continues to look like a valuable tool for self assesement

[14] It's a good value because you can find out which factor needs to be dealt with first. It's hard to value the factors separately though, until you view them separately

[15] It is very valuable because it lists the risks I have and how I can take preventative measures. I think each element is valuable because the more information I have, the more I can do to prevent more risks.

[16] This has no value to me b/c I do not own a cell phone and will not ever have one but for someone who does all this high tech stuff then it would be very helpful for them but for me it would add stress.

- 8 answers of 10 responses -

Topic 3

1. How helpful is this information? Rate on a scale of 1 to 5 with 5 being the most helpful.

Answer options	Response total	Response percentage
1. Least helpful	0	0%
2. Not so helpful	2	13%
3. Neutral	5	33%
4. Helpful	6	40%
5. Most helpful	2	13%

2. How motivating is this information? Rate on a scale of 1 to 5 with 5 being very motivating.

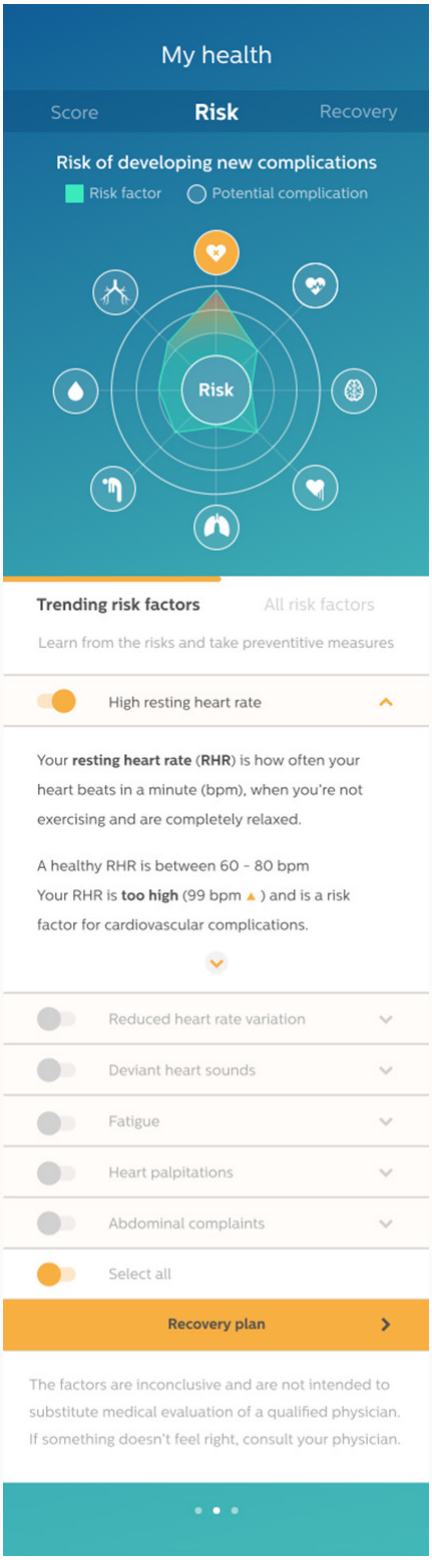
Answer options	Response total	Response percentage
1. Least motivating	0	0%
2. Not so motivating	2	13%
3. Neutral	4	27%
4. Motivating	6	40%
5. Very motivating	3	20%

3. How distressing is this information? Rate on a scale of 1 to 5 with 5 being very distressing.

Answer options	Response total	Response percentage
1. Not at all distressing	2	13%
2. Slightly distressing	2	13%
3. Neutral	6	40%
4. Distressing	4	27%
5. Very distressing	1	7%

4. How patronizing is this information? Rate on a scale of 1 to 5 with 5 being very patronizing.

Answer options	Response total	Response percentage
1. Not at all patronizing	8	53%
2. Slightly patronizing	0	0%
3. Neutral	7	47%
4. Patronizing	0	0%
5. Very patronizing	0	0%


My health
Score
Risk
Recovery
Risk of developing new complications
Risk factor
Potential complication
Risk
Trending risk factors
All risk factors
Learn from the risks and take preventitive measures
High resting heart rate
Your resting heart rate (RHR) is how often your heart beats in a minute (bpm), when you're not exercising and are completely relaxed.
A healthy RHR is between 60 - 80 bpm
Your RHR is too high (99 bpm ▲) and is a risk factor for cardiovascular complications.
Reduced heart rate variation
Deviant heart sounds
Fatigue
Heart palpitations
Abdominal complaints
Select all
Recovery plan
The factors are inconclusive and are not intended to substitute medical evaluation of a qualified physician. If something doesn't feel right, consult your physician.

Topic 4

1. What does the screen tell you now? Are the elements and changes clear to you?

Clear — Not all clear — Unclear

[1] The screen tells me more information about my heart rate and what it should be. This makes the elements much clearer to me because it is explained in more detail.

[2] This screen now tells me detailed information on all of my trending risk factors. For example, for resting heart rate, the screen tells me what a normal resting heart rate is and what my resting heart rate is. It also has information on all risk factors and a recovery plan. I feel most of the information is clear. However, again the icons within the circle are unclear. I am not sure what each one means.

[6] That was much easier to understand. it is clear to me now. i would be interested in this. value is high.

[11] This is much better as compared to element three. It gives me more information how this tool would work.

[12] It explains the risk factors for heart disease and where Peter stands on each. The elements and changes are clear. He is being told his RHR is too high.

[13] This is something I monitor all of the time. It has a direct bearing on my heart condition

[14] Now you'll be able to see each factor separately, which is more helpful because you'll know which one is the most serious for your heart, for example, and address it first.

[15] The screen tells me more information about my heart rate and what it should be. This makes the elements much clearer to me because it is explained in more detail.

[9] It is indicating a potential issue with his RHR. It is too high and should be checked. It is a bit more clear to me than the previous view. However, the symbols are still confusing. And in need of more detail.

[18] I find the risk chart a little bit on the busy side could/should be made a bit easier to use

[16] I don't like this screen at all and it is not the way I'd like to see and to find what I am needing to do.It is really hard for me to see but what I can see it is not really telling me in more details of what is needing to be done.I'd rather have the screen that was shown before this one.

[19] This was much like the other chart, only with a little more explanation. Again, I tried to click on various parts of the chart to get further information, but again nothing happened.

- 15 answers of 11 responses -

Topic 4

1. What value has this screen for you? How do you value the different elements?

Value — No value

[1] This screen is informative and it's value would come from learning something I didn't know. This might be something I would need to contact my doctor about. It's good being brought to my attention.

[2] This screen has value to me overall because I want to learn about my risk factors so I can take action to reduce my risk and be healthier. I value all of the different elements equally.

[9] It is a nice visual that shows there are some risks. The symbols are still a bit unclear, but the detail under the risk factors really helps. It explains the issue and relates it to the norm.

[12] The screen is a useful tool for me because it explains why I am/am not a risk for future heart complications. I have an idea how all the elements play into diagnosing a healthy heart except abdominal pains. I need more info on how this ties in.

[14] I value this screen much more than the first one because I need to know which factor is the worst and needs to be addressed. I can value everything separately so I know which factor is which, on the graph.

[15] This is more valuable because it gives me numbers that I can use. The elements are explained better and I would find it easier to see if I was at risk.

[11] It gives me more information how this tool would work. My only caution is whether it might trigger anxiety. This could certainly be mitigated with education on how to interpret the information provided.

[16] This screen has no value to me at all and the one before it was easier and a lot better.

[18] I would truly ask my doctor of this and see if it might help me I would not get stressed but happy thisidea is here.

- 9 answers of 11 responses -

Topic 4

1. How helpful is this information? Rate on a scale of 1 to 5 with 5 being the most helpful.

Answer options	Response total	Response percentage
1. Least helpful	0	0%
2. Not so helpful	0	0%
3. Neutral	0	0%
4. Helpful	10	77%
5. Most helpful	3	23%

2. How motivating is this information? Rate on a scale of 1 to 5 with 5 being very motivating.

Answer options	Response total	Response percentage
1. Least motivating	0	0%
2. Not so motivating	0	0%
3. Neutral	1	8%
4. Motivating	5	38%
5. Very motivating	7	54%

3. How distressing is this information? Rate on a scale of 1 to 5 with 5 being very distressing.

Answer options	Response total	Response percentage
1. Not at all distressing	3	23%
2. Slightly distressing	4	31%
3. Neutral	2	15%
4. Distressing	3	23%
5. Very distressing	1	8%

4. How patronizing is this information? Rate on a scale of 1 to 5 with 5 being very patronizing.

Answer options	Response total	Response percentage
1. Not at all patronizing	10	77%
2. Slightly patronizing	0	0%
3. Neutral	3	23%
4. Patronizing	0	0%
5. Very patronizing	0	0%