Smart Detection of Atrial Fibrillation

Usability and Acceptance of a Commercially Available Smartwatch in a Clinical Setting

Master Thesis

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Declaration

I declare that I have developed and written the enclosed Master Thesis completely by myself, and have not used sources or means without declaration in the text. Any thoughts from others or literal quotations are clearly marked. This work was not used in the same or in a similar version to achieve an academic grading or is being published elsewhere.

Wartmannstetten, 9.5.2019

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Place, Date Signature

Preface

This thesis is dedicated to

my beloved **Mum**

who has supported and encouraged me all of my life.

I would like to acknowledge and thank my advisor

Dipl.-Sporting. Dr. Mario Heller

for his expert advice, support and motivation throughout the process of writing this thesis.

Special thanks also go to my **family**, my **husband-to-be**, my **friends** and **colleagues** who supported me throughout the whole study.

This thesis would never have been possible without the participation of **patients** with atrial fibrillation and **physicians** of the Internal Medicine, Cardiology and Nephrology department at Landesklinikum Wiener Neustadt. I would therefore like to express my sincere gratitude to all participating patients and physicians for their valued contribution to this thesis. Thanks also to the **Study Nurse** of this department for her support during conducting my pilot study.

Many thanks to my **fellow students**, who made the last two years fly by.

Abstract

Smartwatches have the potential to support patients and physicians in the detection and treatment of atrial fibrillation as they provide an opportunity for continuous rhythm monitoring. Frequently, atrial fibrillation is only detected when a complication of the disease occurs, such as stroke or heart failure. Physicians visits or short-term monitoring only provide a small insight into the disease's presence and burden. Several studies have already proven the accuracy of the smartwatches within the detection of atrial fibrillation. However, for a successful implementation of the smartwatch in the healthcare system not only the accuracy of atrial fibrillation detection is important. The device must also be perceived as easy to use and be accepted by patients as well as physicians.

In order to investigate the usability and acceptance of a smartwatch in the detection of atrial fibrillation, a pilot study was conducted in a cardiology department. For this purpose, 30 subjects who have already been diagnosed with atrial fibrillation as well as five physicians from the clinical field were recruited. The subjects tested a smartwatch within the framework of a usability test. Afterwards they were asked to evaluate them based on a usability and acceptance questionnaire. Expert interviews were conducted with the physicians.

Overall, the smartwatch is perceived as an easy to use and useful tool within the detection of atrial fibrillation by both patients and physicians. Patients rated the usability of the tested smartwatch with an average System Usability Scale of 83 (SD ±11.9). Physicians were impressed by the simple functionality of the device. Even though patients showed some anxiety towards technologies in general (medium agreement: 20%; high agreement: 26.6%) they were hardly sceptical about the use of the smartwatch (low agreement: 82.3%). They stated that a smartwatch would support them in dealing with their disease and increase the feeling of security in everyday situations. 67% of the patients said that they would use the smartwatch. Physicians consider the smartwatch as a useful additional diagnostic tool, but in their opinion a verification of the diagnosis via 12-channel ECG will always be necessary.

The findings indicate that if smartwatches provide meaningful results in a way it is compatible with the workflow of physicians there is a chance of implementing them in the healthcare system. However, further studies are necessary to define use cases and the ideal population for the smartwatch system. Additionally, data privacy and data security of the smartwatch recordings must be ensured.

Kurzfassung

Smartwatches haben das Potenzial, PatientInnen und ÄrztInnen bei der Erkennung und Behandlung von Vorhofflimmern zu unterstützen, da sie eine Möglichkeit zur kontinuierlichen Rhythmusüberwachung bieten. Im Rahmen von einigen Studien konnte bereits bewiesen werden, dass Smartwatches erfolgreich Vorhofflimmern detektieren können. Aufgrund ihrer Funktionen im Bereich der Arrhythmieerkennung haben Smartwatches das Potential sich als unterstützendes Monitoring-Tool im Gesundheitssystem zu etablieren. Dies hängt allerdings sehr stark von der Akzeptanz dieser Methode durch ÄrztInnen und PatientInnen ab. Auch die Benutzerfreundlichkeit der bisher am Markt befindlichen Geräte hat Einfluss auf die Breite der Umsetzung in der Bevölkerung.

Um die Benutzerfreundlichkeit und Akzeptanz der Smartwatch in der Erkennung von Vorhofflimmern zu untersuchen wurde eine Pilotstudie an einer Fachabteilung für Kardiologie durchgeführt. Hierfür wurden 30 ProbandInnen, welche bereits die Diagnose Vorhofflimmern erhalten haben, ebenso wie fünf ÄrztInnen aus dem klinischen Bereich rekrutiert. Die ProbandInnen hatten im Rahmen eines Usability Testes die Möglichkeit die Funktionen der Smartwatch zu testen und beurteilten diese anschließend anhand eines Benutzerfreundlichkeits- und Akzeptanzfragebogens. Mit den ÄrztInnen wurden Experteninterviews geführt.

Die Ergebnisse zeigen, dass sowohl ÄrztInnen als auch PatientInnen die Smartwatch als ein einfach zu bedienendes und nützliches Gerät in der Erkennung von Vorhofflimmern beurteilen. Die Benutzerfreundlichkeit des Gerätes wurde von den PatientInnen mit einem durchschnittlichen System Usability Scale von 83 (SD ±11.9) bewertet. Die ÄrztInnen waren beeindruckt von der einfachen Bedienung der Smartwatch. Obwohl die PatientInnen eine gewisse Ängstlichkeit gegenüber Technologien im Allgemeinen angaben, waren sie kaum skeptisch gegen über der Verwendung der Smartwatch. Diese würde sie im Umgang mit ihrer Erkrankung unterstützen und zu einem erhöhten Sicherheitsgefühl im Alltag beitragen. 67% der Patienten gab an, dass sie die Smartwatch nutzen wollen. Die ÄrztInnen empfanden die Smartwatch als nützliches, zusätzliches Diagnose Tool.

Die Resultate weisen darauf hin, dass eine Einbindung von Smartwatches in das Gesundheitssystem für möglich gehalten wird. Es bedarf allerdings weiterer Studien, um konkrete Anwendungsfälle und die richtige Population für die Verwendung der Smartwatch zu definieren. Außerdem muss eine sichere Übertragung und Speicherung der Smartwatch-Daten gewährleistet werden.

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1 Introduction

Atrial fibrillation is the most common persistent heart rhythm disorder. It occurs in about 1-2% percent of the population. In Europe alone, over 6 million people suffer from this cardiac arrhythmia. The number of people affected worldwide is estimated between 30 and 100 million. During the next decade, prevalence of this arrhythmia is expected to increase because of the ageing populations and an increase in risk factors (Mairesse et al., 2017). It is estimated that 14-17 million people in the European Union will suffer from atrial fibrillation in 2030. Approximately 120,000–215,000 initial diagnoses are expected each year (Kirchhof et al., 2016).

1.1 Problem

The detection and management of this disease is quite challenging because it often appears paroxysmal or asymptomatic. Sometimes atrial fibrillation remains undetected until a thrombotic event or a heart failure occur which are caused by the untreated arrhythmia. The classic model with doctor visits or short-term monitoring are not a solution due to the often-unpredictable occurrence of atrial fibrillation episodes. These conventional methods offer only a small insight into the disease's presence and burden (McConnell, Turakhia, Harrington, King, & Ashley, 2018).

Wearables have the potential to change this traditional way of atrial fibrillation treatment, as they provide a way for continuous rhythm monitoring. Smartwatches have been successfully tested in several studies, proving their ability to detect atrial fibrillation accurately (Bumgarner et al., 2018; Tison et al., 2018).

There is a chance that these devices can be implemented in the health care system, either as assisting diagnostic tool or for follow-up reasons. For example, patients suffering from atrial fibrillation can purchase a smartwatch approved to detect arrhythmias. It gives them the chance to monitor their rhythm disorder themselves. Patients can check whether their palpitations or their dizziness are caused by an atrial fibrillation episode or not. If the device recognises atrial

fibrillation, they can make an appointment with their physician and even show them the recording of their arrhythmia episode.

To successfully integrate a smartwatch arrhythmia detection system into the healthcare system, the acceptance of this method by doctors and patients must be ensured. In addition, it must be guaranteed that the usability of the device meets the requirements of both parties.

This leads to the research questions stated in the following chapter.

1.2 Research Questions

- How is the acceptance and usability of a commercially available smartwatch rated by patients and physicians for detecting atrial fibrillation?
- Can doctors and patients imagine to use smartwatches as an assisting diagnostic tool?
- Do they think that the Austrian healthcare system can benefit from smartwatch use in the context of atrial fibrillation detection and follow-up?

1.3 Structure and Method

This master thesis consists of two main parts, a theoretical and an empirical part. The theoretical part is based on a thorough literature research. The empirical part answers the research questions mentioned above. In addition, a pilot study will be carried out. Within this study, 30 people diagnosed with atrial fibrillation are performing a usability test with a commercially available smartwatch. After completing the test-scenario, the participants will be asked to answer a questionnaire concerning the usability and acceptance of the smartwatch tested. To capture the doctors' opinions on this technology, physicians from the clinical field will be consulted about their attitudes towards smartwatch use for arrhythmia detection and follow-up.

The chapter "Medical Background" aims to provide background information for a better understanding of the atrial fibrillation disease anatomy and the physiology of the human heart. The impulse formation and conduction system are also described in this context. Furthermore, an overview about atrial fibrillation disease including its symptoms, diagnosis and treatment is provided. The two heart rate sensing techniques electrocardiography and photoplethysmography, as well as their function within detecting atrial fibrillation are also explained.

The following chapter provides an overview about current applications of smartwatches in healthcare based on recent studies. Those papers that deal with the use of this technology in the detection of atrial fibrillation are explained in more detail. Furthermore, previous work on the acceptance of smartwatches is presented. Finally, the limitations of smartwatch use in healthcare are mentioned.

In the chapter “Methodology,” the approach of the pilot study is explained in detail. Afterwards the results of the study are presented.

Finally, the results are discussed and a conclusion is presented.

1.4 Goals

The aim of this master thesis is to evaluate how patients rate the usability of a commercially available smartwatch for the detection of atrial fibrillation. In addition, the acceptance of this technology by doctors and patients will be investigated. At the end, it will answer the question whether it is conceivable to use smartwatches within a clinical setting for the detection of atrial fibrillation.

2 Medical Background

For a better understanding of atrial fibrillation, basic knowledge about the structure and functioning of the heart is important. This chapter provides information about heart anatomy and physiology, as well as basic explanations of the development and conduction of excitation. Subsequently, the cardiac arrhythmia atrial fibrillation is described. Dysfunctions in the formation or conduction of the excitation can be identified using an electrocardiogram, short ECG, which is also explained. Finally, the method of photoplethysmography used by smartwatches to detect irregular heartbeats is explained in the subchapter Heart Rate Sensing Techniques.

2.1 The Heart

2.1.1 Anatomy and Physiology

The heart is a hollow muscular organ. As can be seen in Figure 1 it is located in the chest between the lungs in the so-called mediastinum. Embedded in the pericardium, it borders the breastbone (sternum) at the front, and the oesophagus and the trachea at the back. At the top, the aorta and truncus pulmonalis branch off (Bley, Centgraf, Cieslik, Hack, & Hohloch, 2015, p. 108). It has a conical form and lies diagonally in the chest. The heart weighs about 300 to 500 grams and has a filling capacity of between 250 to 400 millilitres of blood (Schneider, 2005, p. 5).

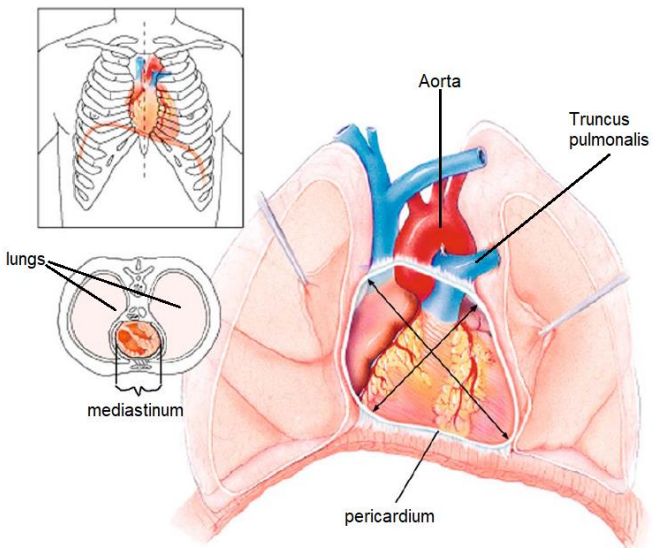

Figure 1 Location of the heart (Iaizzo, 2009) modified

Inside, the heart consists of four chambers formed of cardiac muscle the so-called myocardium. The four chambers are divided into a left and a right side, both containing an atrium and ventricle. In the upper chambers the atria collect blood, whereas the lower chambers the ventricles are more powerful and pump blood. These structures are essential for the general function of the heart as muscular pump for the blood circulation system. The heart ensures that blood is enriched with oxygen before it reaches the organs. For this purpose, the blood is pumped in two different circulation systems which are connected in series: the systemic and the pulmonary circuit. The right side of the heart serves the pulmonary circulation system. It collects oxygen-poor blood from the tissues of the body and pumps it to the lungs. There, carbon dioxide is released and oxygen is absorbed. The oxygen-rich blood is collected from the lungs by the left side of the heart, the systemic circuit, and then pumped into all tissues of the body. Four valves maintain that there is a one-way blood flow through the heart (Aumüller, 2007, p. 566ff; Bley et al., 2015, p. 108). Figure 2 depicts the pathway of blood flow through the heart.

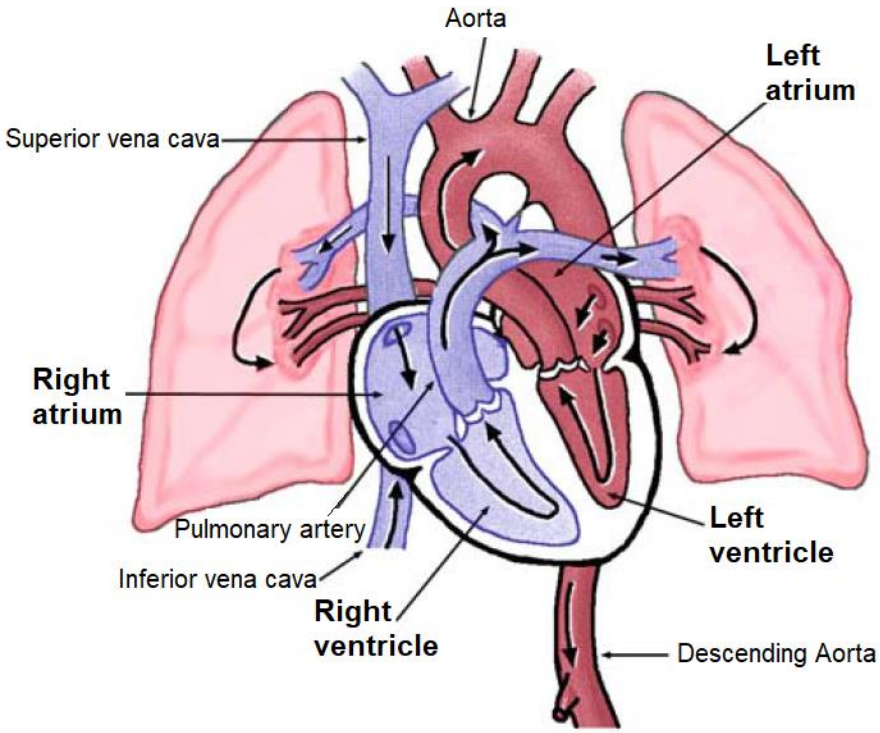

Figure 2 Pathway of blood flow (Iaizzo, 2009) modified

In order to pump effectively the coordination of the heart's contractions must be precise. This is done via the excitation formation and conduction system of the heart.

2.1.2 Impulse Formation and Conduction System

The heart beats in a basic rhythm without being influenced by the nervous system. It has its own excitation system in which electrical impulses are generated. These impulses are then transmitted through the heart's conduction system. Both systems are formed by specialised heart muscle cells, no stimuli from outside the heart are required.

However, the basic rhythm of the heart is not suitable for all life situations. For example, the heart must beat faster during physical activity. In these situations, the vegetative nervous system adapts the activity of the heart to current needs.

The impulse formation and the conduction system are hierarchically ordered and consist of the following centres, which are depicted in Figure 3:

- Sinoatrial node
- Atrioventricular node
- His Bundle
- Left and Right Bundle Branch
- Purkinje Fibres

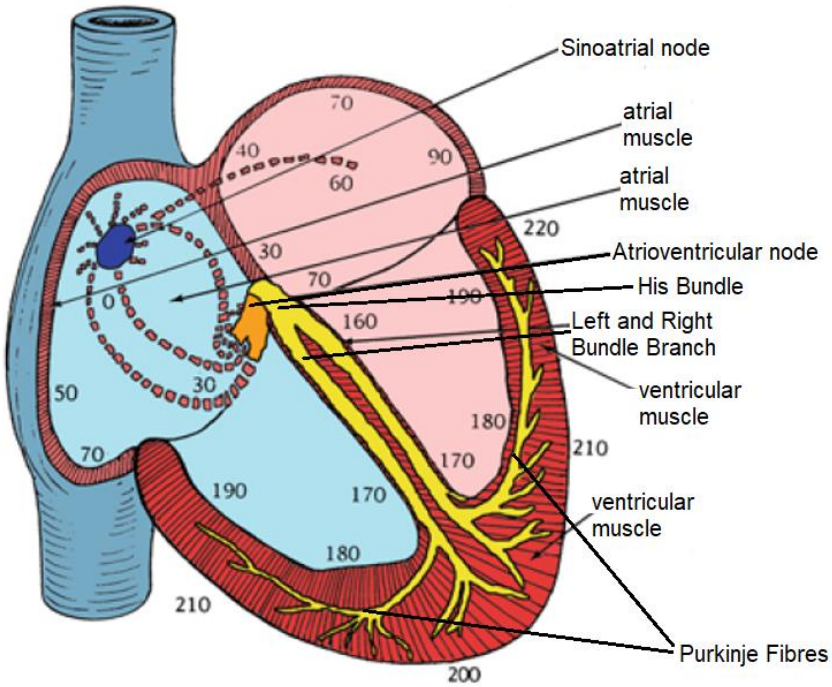

Figure 3 Impulse formation and conduction system (Iaizzo, 2009) modified

The rhythm of the heart is produced by pacemaker cells. Mainly the sinoatrial node and the atrioventricular node are responsible for the impulse formation.

The **sinoatrial node** is the superordinate centre of the excitation formation and conduction system. It is often referred to as natural pacemaker of heart action. The sinoatrial node is located in the upper right atrium directly next to the junction of the upper vena cava and generates the impulses in a healthy heart. Here, about 60 to 80 excitations per minute are produced. These impulses spread via the muscle cells of the atria to the atrioventricular node during atrial contraction.

The **atrioventricular node** is the second station of the cardiac conduction system. It is located at the bottom of the right atrium and ensures the delayed excitation from the atrium to the chambers. This ensures that a complete contraction of the atria occurs before the excitation reaches the chambers. Following atrioventricular nodal excitation, the impulses conduct to the His Bundle.
If the sinoatrial node fails or the transmission of the impulses is blocked, the atrioventricular node can take over the pacemaker function. However, the natural frequency is lower than that of the sinus node, with only around 40 to 60 excitations per minute.

The **His bundle** is responsible for the excitation of the ventricle musculature. Its conduction fibres go from the AV node through the heart skeleton. It forms a muscle fibre bridge between the myocardium of the atria and the ventricles.

The **left** and **right bundle branch** are created by dividing the His bundle. The right chamber leg runs on the right side of the chamber septum to the apex of the heart, the left chamber leg on the left side. They branch to Purkinje fibres.

Purkinje fibres are the end branches of the excitation conduction system and run inside the chamber myocardium. They transfer the excitation to the muscle cells of the ventricles which causes the contraction of the working myocardium.

The excitation conduction system ensures that the impulses generated by the pacemaker cells are transmitted and eventually spread through all cells of the working myocardium. Its defined orbits ensure that each area of the heart is activated at the right time and that an ordered contraction occurs.

Errors in the formation of excitation lead to cardiac arrhythmia. Depending on where the excitation disorder is located, different forms can be distinguished. One of these arrhythmias is atrial fibrillation. (Aumüller, 2007; Bley et al., 2015)

2.2 Atrial fibrillation

Atrial fibrillation is the most common cardiac arrhythmia, representing a major challenge for healthcare systems worldwide (Zulkifly, Lip, & Lane, 2018).

In atrial fibrillation, a chaotic, circling excitation with constantly changing excitation waves occur in both atria. This results in a frequency of more than 350 pulses per minute in the atria. The chaotic impulses prevent rhythmic contraction of the atrial myocardium. Only the smallest flickering movements occur. Therefore, the chambers receive very irregular stimuli from the atria via the AV node and are also arrhythmic. Very irregular chamber frequencies occur, varying between 60 and 130 impulses per minute. Atrial fibrillation makes the heart go out of beat and losing its synchronous activity (Schneider, 2005, p. 91; Schönfelder, Rupp, & Zern, 2006).

2.2.1 Epidemiology

According to the Global Burden of Disease Study, atrial fibrillation affected approximately 33.5 million people (20.9 million men and 12.6 million women) worldwide in 2010. In Austria, about 150 000 people suffer from the cardiac arrhythmia. Observational studies in recent years indicate that the number of people affected will continue to increase. In Europe, the current number of about 8 million atrial fibrillation patients is expected to more than double by 2060. In the United States, the number of people affected with the arrhythmia is expected to increase from currently between 3 and 5 million to more than 8 million people. One out of four people will develop atrial fibrillation during their lifetime. Between 120,000 and 215,000 new diagnosed cases of the disease are expected every year (Chugh et al., 2014; Kirchhof et al., 2016; Roithinger, 2013, p. 10).

In the general population, the prevalence of the cardiac arrhythmia is estimated at about 3%. The prevalence of atrial fibrillation rises significantly with age. In patients, older than 75 years, about 6% to 8% are affected. Among the male population, the prevalence of atrial fibrillation is higher in all age groups (Pistoia et al., 2016).

Atrial fibrillation is associated with an increased mortality. While death due to stroke can largely be avoided by anticoagulation, the fatality rate caused by other cardiovascular diseases such as heart failure or sudden death remains common, even in patients treated according to current recommendations. Increased morbidity can also be related to atrial fibrillation. About 20 to 30% of all strokes are caused by cardiac arrhythmia. Cognitive impairments can as well result from the disease. In addition, atrial fibrillation patients often report a decreased quality of

life and a depressed mood. Every year, more than a third of the patients are admitted to hospitals (Kirchhof et al., 2016).

Atrial fibrillation also has a financial impact on health systems. In the UK, the disease already accounts for 1% of the total health expenditure. In the USA, the cost was between 6 and 26 billion dollars in 2008. According to a survey conducted by the Mayo Clinic, one patient with atrial fibrillation increases medical costs by $8,705 a year. The expenditure will continue to rise with the increasing prevalence of atrial fibrillation in the coming years. Therefore, atrial fibrillation is already referred to as an epidemic, with a big financial burden on society (Morin et al., 2016).

2.2.2 Classification

Initially, atrial fibrillation occurs paroxysmal in about three-quarters of all patients. In the course of the disease the type of arrhythmia may change. There may be a change from paroxysmal atrial fibrillation to prolonged episodes of the disease. In the end, a permanent presence of the cardiac arrhythmia is possible. The classification of the disease according to its course over time is important, both for the choice of therapy and for its effect (Kirchhof et al., 2016; Roithinger, 2013, p. 12).

In order to standardise the nomenclature and the classification according to time, the European Society of Cardiology classifies atrial fibrillation according to temporal criteria. This classification is included in the society's guidelines for the management of atrial fibrillation (Kirchhof et al., 2016).

The following types of the cardiac arrhythmia are defined:

- **First diagnosed atrial fibrillation:**
  A patient is diagnosed with atrial fibrillation for the first time. The symptoms and duration of the arrhythmia are ignored here.
- **Paroxysmal atrial fibrillation:**
  This type of atrial fibrillation is characterised by cardiac arrhythmia mostly ending by itself within 48 hours. In individual cases, the episodes can last up to seven days.
- **Persistent atrial fibrillation:**
  The arrhythmia lasts longer than seven days and does not end by itself. A therapeutic intervention is needed to stop it.
- **Long-standing atrial fibrillation:**
  Atrial fibrillation is present continuously for over a year.

- **Permanent atrial fibrillation:**
  Atrial fibrillation is chronic. It is accepted by both the patient and the physician.

Atrial fibrillation can also be classified according to the underlying disease of the rhythm disorder (Kirchhof et al., 2016).

2.2.3 Aetiology

Atrial fibrillation is usually caused by one or more cardiovascular diseases. These diseases cause pathophysiological changes in the atria, which can provoke the development of the arrhythmia. In many cases, mitral valve defects, arterial hypertension, coronary heart disease, cardiac insufficiency or bradycardia after cardiac surgery are the cause of atrial fibrillation.

In addition, non-cardiac diseases can also lead to atrial fibrillation. The most common cause here is hyperthyroidism. Excessive alcohol consumption, taking medication, operations or lung diseases can also be the origin of the arrhythmia.

There is also a genetic predisposition for the disease. If at least one parent suffers from atrial fibrillation, there is a 1. 8 times higher risk of developing this cardiac arrhythmia (Neuzner, 2007, p. 5ff).

Age is described as a main risk factor for the development of atrial fibrillation (Schönfelder et al., 2006).

All the diseases mentioned above can influence the symptoms of atrial fibrillation.

2.2.4 Symptoms

The symptoms of atrial fibrillation are manifold and (in most cases) initially unspecific. The cardiac arrhythmia can be completely asymptomatic but can also lead to cardiac decompensation. At first, many patients suffer from general fatigue, reduction of performance, palpitations, or chest pain. The expression of the symptoms varies depending on the ventricular frequency, heart function, concomitant diseases and individual perception of the patients. Symptomatic patients describe a loss of their quality of life. Patients suffering from paroxysmal atrial fibrillation generally have more complaints (Höhler, 2005; Kirchhof, 2013; Schönfelder et al., 2006)

The PAFAC study leads to the conclusion that there is a poor correlation between occurrence of the rhythm disorder and symptoms. Within this study, patients were telemedically monitored after atrial fibrillation therapy. The patients did not

recognise 70% of recurrences of the cardiac arrhythmia, because they were asymptomatic (Antz & Kuck, 2005).

The European Heart Rate Rhythm Association has compiled a classification of symptoms which, in clinical practice, has established itself as a guideline for symptom-oriented therapy decisions. Table 1 shows the EHRA symptom scale to describe the severity of symptoms in patients suffering from atrial fibrillation.

Table 1 European Heart Rhythm Association Symptom Scale (Kirchhof et al., 2016) modified

EHRA Score	Symptoms	Description
1	None	Atrial fibrillation does not cause any symptoms.
2a	Mild	Normal daily activity is not affected by symptoms related to atrial fibrillation.
2b	Moderate	Normal daily activity is not affected by atrial fibrillation related symptons, but patient troubled by symptoms.
3	Severe	Normal daily activity affected by symptoms related to AF.
4	Disabling	Normal daily activity discontinued.

In 25 to 40% of atrial fibrillation patients, the disease occurs asymptomatically or with minimal symptoms. Only in 15 to 30% of the cases, the patients have severe symptoms that lead to restrictions in their everyday life. The frequent asymptomatic occurrence of the disease makes it difficult to diagnose atrial fibrillation (Kirchhof et al., 2016).

2.2.5 Prognosis

Patients with atrial fibrillation have a more serious prognosis than patients with sinus rhythm. They die earlier from cardiovascular disease and are more likely to develop heart failure and stroke (Neuzner, 2007, p. 10ff).

Atrial fibrillation causes about every fourth stroke, especially severe strokes. Due to the continuous electrical activation of the flickering atria, atrial contraction is lost, and the blood flow is slowed down. This increases the risk of thrombus formation in the atria. If such thrombi are carried along with the arterial bloodstream, an

ischemic stroke occurs. The type and duration of atrial fibrillation has only a negligible influence on the risk of stroke. The risk of developing a stroke is almost equal in patients with paroxysmal and patients with permanent atrial fibrillation. However, from the age of 65 onwards, the risk of thromboembolic consequences increases (Kirchhof, 2013; Neuzner, 2007, p. 10ff).

A timely diagnosis of the disease can improve the prognosis of patients.

2.2.6 Diagnosis

An electrocardiogram (ECG) documentation of the heart rhythm disorder is required for the diagnosis of atrial fibrillation. According to the European Society of Cardiology, the documented episode of the cardiac arrhythmia must be at least 30 seconds long and the irregular ventricle excitation as well as the flickering movements of the atria must be detectable (Kirchhof et al., 2016). Figure 4 depicts how an atrial fibrillation ECG looks like in comparison to a sinus rhythm ECG. The red arrow marks the flickering waves, while the blue arrow marks the regular atrium excitation.

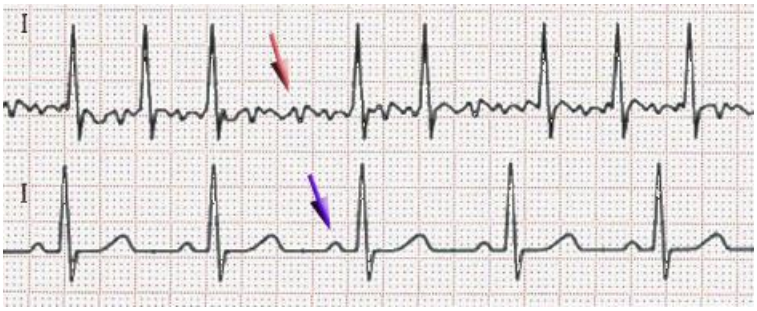

Figure 4 ECG showing atrial fibrillation (top) vs. Sinus rhythm ECG (bottom) (Heuser, 2005)

A survey of a patient's medical history can also be helpful for the diagnosis. If an irregular pulse is detected during the physical examination, this can be an indication of an absolute arrhythmia, the irregular contraction of the atria and chambers.

Due to the disease's manifestation, paroxysmal atrial fibrillation can often only be diagnosed by a long-term ECG or the implantation of a loop recorder (Schönfelder et al., 2006). A loop recorder is a small implantable cardiac device which allows continuous monitoring of the heart's electrical activity. The device can remain implanted for up to one year and helps many patients with paroxysmal atrial fibrillation to receive a diagnosis (Pollet & Levine, 2018).

Even after diagnosis, continuous ECG monitoring can contribute to the management of the disease. Changes in symptoms or the appearance of new symptoms can be better classified. Progression of the disease, such as a change from paroxysmal to persistent atrial fibrillation, can be detected. In addition, the influence of medication on the heart rhythm can be observed. Continuous monitoring could also be used for follow-up reasons during or after therapy.

Asymptomatic or silent atrial fibrillation is a challenge for diagnostics. Especially older people or patients with heart failure are at risk for undiagnosed atrial fibrillation. Therefore, the European Society of Cardiology recommends opportunistic screening for atrial fibrillation in individuals over 65 years of age (Kirchhof et al., 2016). A large randomised controlled trial conducted in Great Britain has shown that this screening method leads to an increase in detection of atrial fibrillation and is also cost-effective (Hobbs et al., 2005).

In patients who suffered from a stroke, an active search for atrial fibrillation is recommended. The European Society of Cardiology advises to check these patients by applying a short-term ECG at first. Afterwards, the performance of a long-term electrocardiogram of at least 72 hours is recommended. Furthermore, additional long-term monitoring with non-invasive or implanted event recorders can be considered to document silent atrial fibrillation.

New patient-operated devices like smartphone cases with electrodes, smartwatches or blood pressure machines with respective algorithms may be very useful to detect paroxysmal or silent atrial fibrillation. However, the accuracy of these devices in comparison to the established methods must still be evaluated. In addition, current studies are also investigating the effects of earlier detection on the management of the atrial fibrillation and whether this improves the outcomes (Kirchhof et al., 2016).

2.2.7 Therapy

The treatment of atrial fibrillation is intended to prevent the disease's complications thromboembolism and heart failure. Furthermore, the quality of life and the performance of the patients should be improved. The long-term aim of atrial fibrillation therapy is to reduce the overall mortality rate (Schönfelder et al., 2006).

Basically, two therapy forms can be distinguished: rate control and rhythm control. In addition, to prevent thromboembolic consequences (especially ischemic strokes), an inhibition of blood coagulation (anticoagulation) is indicated in almost all patients. Anticoagulation is stated to prevent about two thirds of ischemic strokes. A careful treatment of the underlying and concomitant cardiovascular

diseases as well as the risk factors should also be ensured in atrial fibrillation patients.

Rate Control

In most patients with atrial fibrillation, the heart rate is too fast. With rate control, the heart rate is lowered by drugs that slow down the conduction at the AV node. This therapy helps to maintain cardiac performance and relieve symptoms such as shortness of breath and fatigue (Kirchhof, 2015). The target heart rate depends on patient characteristics, symptoms, heart function and haemodynamic (Kirchhof et al., 2016). In his recommendations for practice, Kirchhof states that the goal of rate control is a heart rate at rest of 100 to 110 beats (Kirchhof, 2015). If the heart rate cannot be regulated, it may be necessary to destroy the AV node by catheter ablation and implant a pacemaker.

Within all rate control measures, atrial fibrillation persists.

Rhythm Control

The aim of rhythm control is to restore and preserve the sinus rhythm in patients with atrial fibrillation. This therapy is indicated for patients who are still symptomatic despite rate control measures.

There are several procedures for restoring sinus rhythm:

- **Cardioversion:**
  In cardioversion, an attempt is made to restore the sinus rhythm by emitting an electric shock via a defibrillator. This procedure requires sedation of the patient and monitoring of the vital functions. Furthermore, anticoagulation is necessary as pre-treatment to prevent strokes during the procedure. In almost all patients, this method succeeds in restoring the sinus rhythm at least for a short time. However, atrial fibrillation recurs in almost half of patients within a few weeks or months (Kirchhof, 2015; Kirchhof et al., 2016).
- **Antiarrhythmic drugs:**
  Antiarrhythmic drugs affect the excitation of muscle cells in the heart. By slowing down the cardiac conduction, they rearrange the excitations in the atria so that the sinus node regains its function as pacemaker. Antiarrhythmic drugs are used to restore the sinus rhythm (Kirchhof, 2015). They also prevent the development of recurrent atrial fibrillation following electrical cardioversion and catheter ablation. The use of antiarrhythmic drugs doubles the chance of sinus rhythm maintenance (Kirchhof et al., 2016).

- **Catheter ablation:**
  In the pulmonary veins, there are electrical triggers that can cause atrial fibrillation. In order to prevent the transmission of these disturbing stimuli, catheter ablation isolates irritant structures on the pulmonary veins. During ablation, a special catheter is inserted through the inguinal vein into the heart. With the aid of radiofrequency or cold cryoballon ablation, a cardiologist attempts to isolate heart muscle cells in the transition area between pulmonary veins and the left atrium. The disturbing electrical impulses should be interrupted and the atrial fibrillation stopped (Schneider, 2005, p. 155ff). Catheter ablation is indicated if the patients remain symptomatic despite antiarrhythmic therapy (Kirchhof et al., 2016).

2.3 Heart Rate Sensing Techniques

2.3.1 Electrocardiography (ECG)

The electrocardiography (ECG) is used to measure how the electrical activity of the heart changes over time. During the impulse formation and conduction, which is described in chapter 2.1.2, action potentials within each muscle cell spread throughout the heart, resulting in a weak electrical field. This field propagates throughout the body and can be recorded by placing electrodes on the skin surface. These can be attached either to hands and feet or directly to the chest wall (Bley et al., 2015, p. 120).

The different deflections of the ECG (peaks and waves) are alphabetically named with letters from P to T. Distances between two peaks/waves next to each other are called segments, distances across several peaks/waves are called intervals. Figure 5 schematically depicts an ECG graph with its most common waveforms.

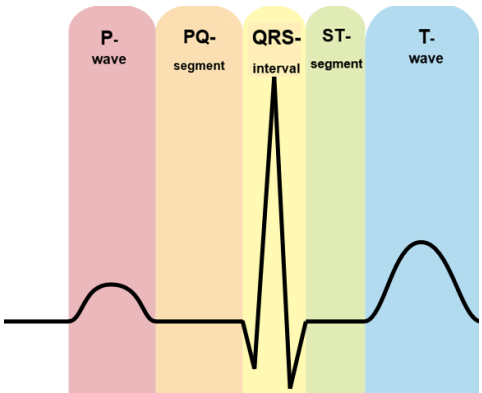

Figure 5 Schematic representation of an ECG graph (Hank van Helvete, 2006) modified

The **P-wave** represents the excitation of the atrial myocardium. The depolarization reaches both atria from the sinoatrial node. When the excitation is completed in the atria and reaches the atrioventricular node, the **PQ-segment** is formed. Due to the delay of conduction into the chambers caused by the atrioventricular node, no electrical field can be measured for a short time. The length of the PQ-segments indicates the extent of the delay. The **QRS-interval** occurs when the excitation reaches the ventricles of the heart. The R-Peak represents the spread of excitation from the valve plane towards the heart apex. It is the largest peak in the ECG. The **ST-segment** is characterised by a straight line because at the end of the QRS interval, the chamber myocardium is in a fully excited state and therefore cannot depolarise again. After the contraction of the ventricles, the excitation recedes. This regression of excitation is represented as **T-wave** in the ECG (Klinge, 2011, p. 42ff).

The electrocardiography has become an indispensable diagnostic tool for heart diseases. It is essential for the detection of arrhythmias, heart attacks or hypertrophy. In cardiology, the use of ECG is standard of care (Iaizzo, 2009, p. 258). The ECG technology is constantly evolving, one of these developments is the KardiaBand of the company Alive Cor, which is used in the context of this work.

2.3.2 Photoplethysmography (PPG)

When light travels through biological tissue, it is absorbed by different substances e.g. blood. In the contraction phase of the heart, blood volume in the arteries is higher than during the relaxation phase, and therefore more light is absorbed. Photoplethysmography (PPG) is an optical technique which can detect these changes in blood volume in microvascular tissue by measurements on the surface of the skin. A PPG system is a simple and inexpensive tool, which requires only two components: a light source to illuminate the tissue and a photodetector, which monitors changes in the light intensity caused by the variations in blood circulation of the tissue. The two parts of a PPG system can either be positioned next to or opposite each other. The light reaches the detector either through transmission or through reflection from the tissue (Tamura, Maeda, Sekine, & Yoshida, 2014). Figure 6 shows the different placements of light source and photodetector.

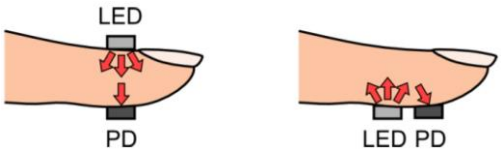

Figure 6 Placement of light source and photodetector (Tamura et al., 2014)

The penetration depth of the light depends on the wavelength and the distance between the two components of the PPG system. Usually, photoplethysmography operates at a red or near infrared wavelength. Tamura et al state that green light is also suitable for measuring superficial blood circulation (Tamura et al., 2014). The changes in reflected green light are greater than in reflected infrared light because it is absorbed better by haemoglobin.

The waveform generated by photoplethysmography consists of two parts. The pulsatile component shows the changes in blood volume during the contraction and relaxation phase of the heart. Their frequency depends on the heart rate. This part is often named the AC component. The static component, which is also called DC, is related to the steady absorption of light by tissue. It changes slowly due to respiration and movements of blood vessels (Alian & Shelley, 2014b). In Figure 7, the AC component of a PPG waveform is demonstrated.

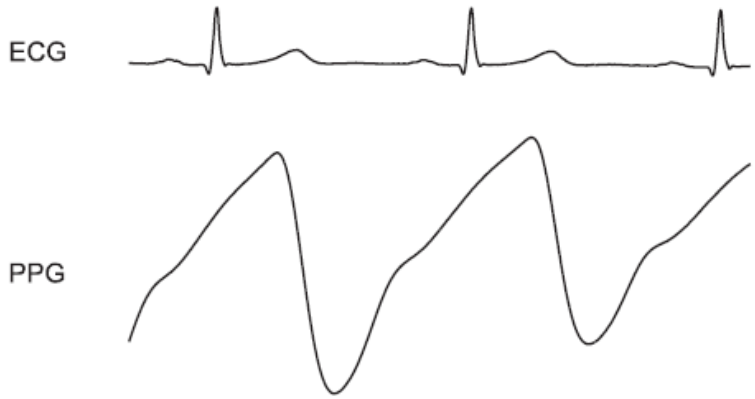

Figure 7 AC component of PPG and corresponding ECG (Allen, 2007)

PPG detects irregularities in the pulse and can therefore as well contribute to the detection of cardiac arrhythmias (Alian & Shelley, 2014a). Figure 8 shows an example of how a cardiac arrhythmia looks like in a PPG waveform.

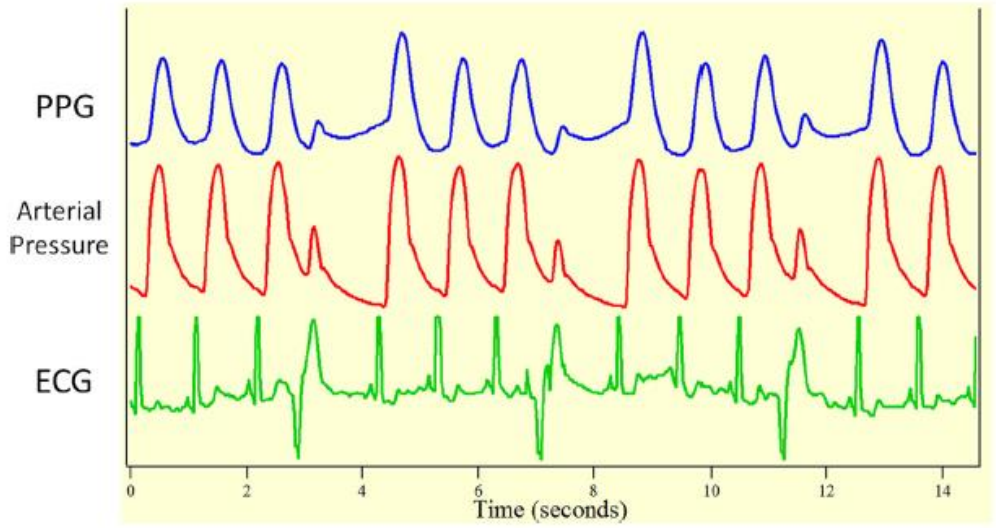

Figure 8 Cardiac arrhythmia on PPG and ECG (Alian & Shelley, 2014a)

In the clinical field, PPG technology is widely used for measurement of oxygen saturation, blood pressure or cardiac output and within the detection of vascular diseases. PPG sensors offer a low-cost, non-invasive pulse measurement solution. Therefore, they are also used in commercially available devices such as smartwatches (Allen, 2007).

3 Background and Related Work

This chapter includes an overview of the current applications of smartwatches in the healthcare sector based on recent studies. A major focus is on the use of this technology in the detection of atrial fibrillation. Current studies on this topic are explained in more detail. In addition, an insight into previous work on the acceptance of smartwatches is given. Finally, the limitations of smartwatch use in healthcare are mentioned.

3.1 Smartwatches in Healthcare

A smartwatch is more than a simple timekeeping tool. Ceccinato et al. defined it as *"a wrist-worn device with computational power, that can connect to other devices via short range wireless connectivity; provides alert notifications; collects personal data through a range of sensors and stores them; and has an integrated clock"* (Cecchinato, Cox, & Bird, 2015).

Smartwatches belong to the category of wearable technologies and are part of the smart health systems which started becoming popular in the late 1990s following the "quantified self" movement. The aim of this movement was to place the human at the centre of the healthcare delivery process. The use of wearable devices such as smartwatches enables people to continuously track their health data in daily activities or even during the night. Smartwatches are equipped with numerous sensors (e.g. accelerometers, pedometers, heart rate sensors, GPS and microphones) to monitor the health status of their users (Yetisen, Martinez-Hurtado, Ünal, Khademhosseini, & Butt, 2018). Furthermore, the use of these smart devices allows extended vital sign recordings outside the hospital environment (Dias & Paulo Silva Cunha, 2018). Smartwatches may change the way health data is delivered. They can overcome the daily limitations of healthcare professionals by applying methods that can detect events that occur outside of face-to-face visits (Reeder & David, 2016).

Almost two decades have passed since the first smartwatch, the IBM Linux Watch, was introduced in 2000. Over the past 20 years, smartwatches have evolved considerably (Cecchinato et al., 2015). Nowadays, they represent a popular, multifunctional tool for health monitoring and fitness. In September 2018, the 4th generation of Apple Watch (Apple, Cupertino CA, USA) was presented as a *"Proactive Health Monitor: Part guardian, part guru"*. Dehghani et al. stated that

according to IDC polls, the smartwatch market is expected to grow at an exponential rate and that 373 million shipments are expected in 2020 – almost four times as many as in 2016 (Dehghani, Kim, & Dangelico, 2018). The diagram in Figure 9 shows that market share is shifting from wristbands to smartwatches. In 2020, more people will own a smartwatch than a wristband. Yetisen et al. attribute this to the fact that smartwatches have more sensors and more applications. In addition, the introduction of 5G technology and the associated better and faster connectivity will have a positive impact on the market penetration of smartwatches (Yetisen et al., 2018).

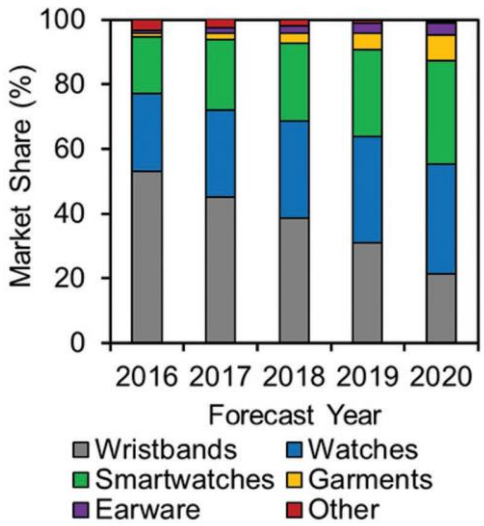

Figure 9 Market Share Wearables (Yetisen et al., 2018)

Previous reviews on smartwatch-based healthcare applications were carried out shortly after the release of the 1st generation of the Apple Watch in April 2015. Between 17 and 27 publications on smartwatches in healthcare were found. None of the reviews mentioned arrhythmia detection using a smartwatch (King & Sarrafzadeh, 2018; Lu, Fu, Ma, Fang, & Turner, 2016; Reeder & David, 2016).

A literature search in the database PubMed on March 3 2019 resulted in 132 hits for the keyword “smartwatch”. As can be seen in Figure 10, the number of publications on this topic has risen steadily in recent years. In 2018, 52 articles were published, more than twice as many than in the previous year. This year there are already 16 articles available.

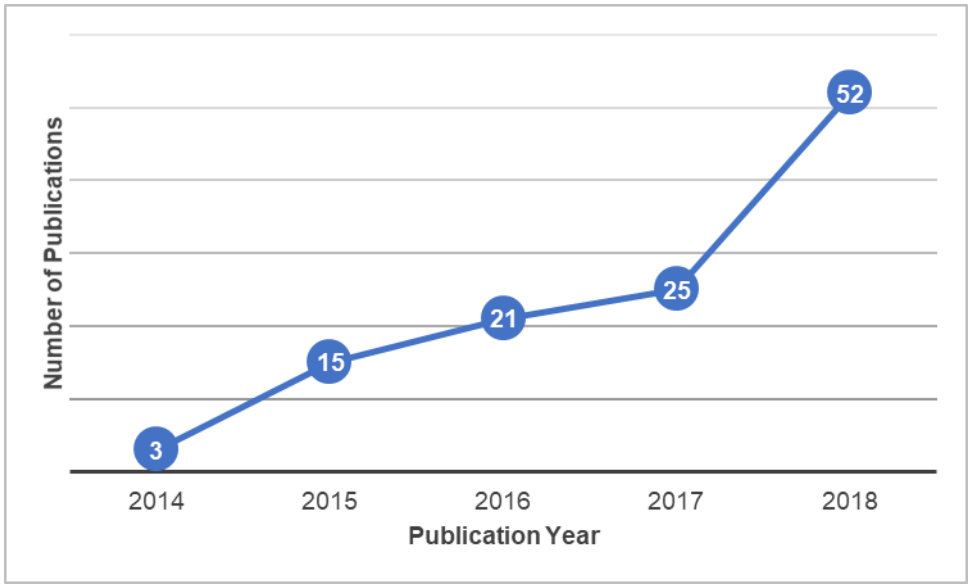

Figure 10 Number of Publications

The results of the literature search reveal several fields of application for smartwatches in healthcare. These are shown in Figure 11.

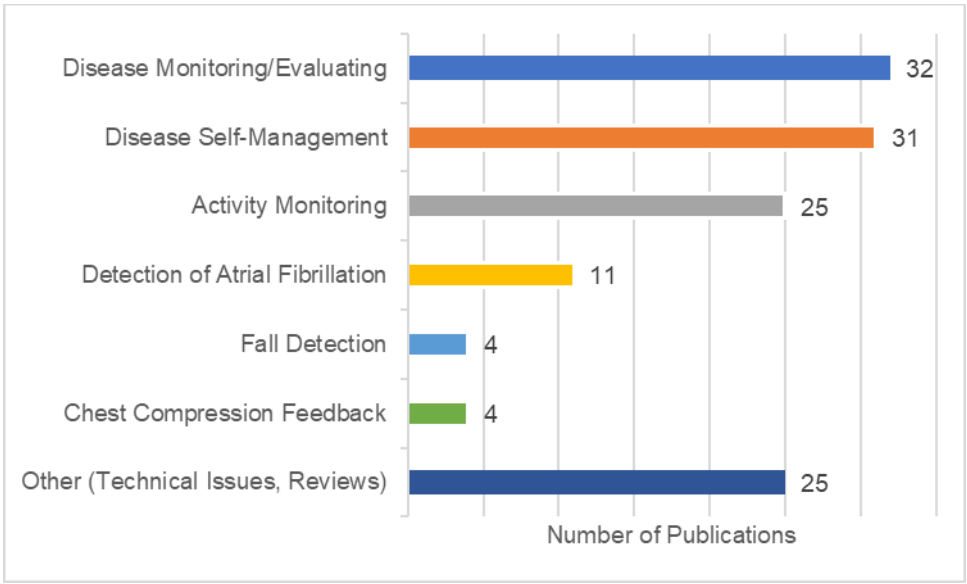

Figure 11 Healthcare Applications of Smartwatches

According to the studies reviewed within the research, smartwatches are mostly used for monitoring various diseases and their symptoms. This leads to a better understanding of the disease and, in addition, therapy can be more precisely adapted. Two further applications of smartwatches are chronic disease self-management and activity monitoring. Some studies evaluate smartwatches in fall

detection and as a feedback device for effective chest compression during resuscitation (for references see King & Sarrafzadeh, 2018; Lu et al., 2016; Reeder & David, 2016). Eleven articles deal with the detection of atrial fibrillation with the aid of a smartwatch.

3.2 Smartwatches and the Detection of Atrial Fibrillation

Smartwatches offer the possibility of continuously monitoring heart rhythm and heart rate. They provide the possibility of prolonged non-invasive arrhythmia monitoring, which is of interest to cardiologists (Carpenter & Frontera, 2016). The results of the literature research, presented in chapter 3.1 indicate that there is a lot of research done in the field of atrial fibrillation detection using a smartwatch. This chapter provides an overview of recent studies on this topic.

In a proof of concept study, Tison et al. developed and validated a deep neural network for detecting atrial fibrillation using data from smartwatches (Tison et al., 2018). The study team assessed heart rate and step count data from the commercially available Apple Watch via the publicly available Cardiogram application (Cardiogram Inc., USA) for building an algorithm to identify atrial fibrillation. The validation of the developed neural network was carried out in two cohort groups. The first group consisted of patients who had already been diagnosed with atrial fibrillation and were about to undergo cardioversion treatment at the University of California, San Francisco. Within this population, the deep neural network was evaluated against the reference standard 12-lead ECG. In the 51 patients in this group, atrial fibrillation was detected with a sensitivity of 98% and a specificity of 90%. In the second cohort, the aim was to find out whether the detection of atrial fibrillation using the developed algorithm is also possible in an ambulatory scenario. The reference standard in this group was self-reported persistent atrial fibrillation. Within a group of 1,617 ambulatory study participants, those with self-reported atrial fibrillation could be identified with moderate accuracy.

Koshy et al. conducted a study to reveal the utility of smartwatches in arrhythmias in Australia (Koshy et al., 2018). For this purpose, 102 hospitalized patients were divided into two cohorts based on their underlying rhythm – either sinus rhythm or atrial arrhythmias. All the patients were evaluated using continuous ECG monitoring as well as by wearing a smartwatch on each wrist. The smartwatches used in this study were Apple Watch Series 1 and Fitbit Blaze (Fitbit Inc., San Francisco, USA). In order to avoid movement artefacts, the evaluation was carried

out at rest. The aim of the study was to examine the accuracy of the heart rate estimation of both smartwatches compared with the reference standard ECG. In the sinus rhythm cohort, there was a strong agreement for both devices, whereas the heart rate in atrial fibrillation was significantly underestimated.

The KardiaBand (AliveCor, Mountain View, CA, USA) is a novel technology to record an ECG rhythm strip which is interpreted by an algorithm – either as atrial fibrillation or sinus rhythm. This ECG watch band can be connected to an Apple Watch. Bumgarner et al. investigated this device to assess its accuracy and clinical utility (Bumgarner et al., 2018). The accuracy of this device in distinguishing sinus rhythm from atrial fibrillation was compared with physician-interpreted 12-lead ECG and KardiaBand recordings. This study included 100 patients with previously diagnosed atrial fibrillation who present for cardioversion. Before the cardioversion procedure, all of them underwent a simultaneous ECG and KardiaBand ECG recording. If the cardioversion was performed, the patients obtained another ECG and KardiaBand ECG. The interpretations from the KardiaBand algorithm were compared to physician-reviewed ECGs. Atrial fibrillation was detected with 93% sensitivity and 84% specificity by the KardiaBand. In those KardiaBand recordings which could not be interpreted by the algorithm, physicians diagnosed atrial fibrillation with 100% sensitivity and 80% specificity. Where KardiaBand and physician readings of the same recording were interpretable, the agreement was excellent.

In the WATCH AF trial, the accuracy of atrial fibrillation detection of a smartwatch-based algorithm which uses PPG signals was compared with physician's diagnosis by ECG (Dörr et al., 2019). In 672 hospitalized patients, a PPG pulse wave recording was obtained with a commercially available smartwatch. Furthermore, a mobile ECG using the KardiaMobile system (AliveCor, USA) was recorded simultaneously in all the subjects. All the PPG recordings were evaluated by a novel algorithm. The cardiologists diagnosed the mobile ECGs, which served as a reference standard. The study reveals a 93.7% sensitivity and a specificity of 98.2% for the detection of atrial fibrillation with the analysis of smartwatch PPG recordings by a novel algorithm. The overall accuracy of the smartwatch-based algorithm was 96.1%.

The Apple Heart Study represents another large-scale study in the field of atrial fibrillation detection using smartwatches (Turakhia et al., 2018). In total, 419,093 participants have been enrolled. A smartwatch-based irregular pulse notification algorithm is being evaluated within this study. Its overall goal is to determine the number of participants who have an irregular pulse as detected by the Apple Watch with a confirmed atrial fibrillation diagnosis in a subsequent ECG. In addition, the

agreement of the algorithm to a simultaneously recorded ECG is examined. The aim is to find out whether it is suitable for real-time analysis of pulse irregularities. Furthermore, Turakhia et al. are attempting to evaluate how many participants contact a health care provider after receiving an irregular pulse notification. No results have been published for the Apple Heart Study as at March 2019.

The results of the studies show that commercially available smartwatches can detect atrial fibrillation with a relatively high sensitivity and specificity. This indicates that smartwatches have a potential for atrial fibrillation screening and monitoring. With the help of this technology, the disease could be diagnosed earlier and strokes could be prevented. Nevertheless, further investigations in larger populations are necessary to determine the acceptance and effectiveness of these devices. The results of the large-scale Apple Heart Study will provide further insights into this topic.

3.3 Acceptance of Smartwatches

As can be seen in the previous chapter, most studies deal with the accuracy of smartwatches. Little research has been done on the acceptance of these devices by physicians and by the general population.

An online survey of 4,109 Canadian adults was conducted to evaluate how many people track themselves using digital technologies (Paré, Leaver, & Bourget, 2018). Within this study, the adoption and use of wearable technologies was investigated. About every fourth respondent owned a wearable device. However, this device was only used regularly by about half of its owners. The main reason given by respondents in this study for using digital technologies was tracking their activity. Only about 13% of self-trackers also monitored their cardiovascular health with the wearable device. Those people who used consumer wearables were very satisfied with them and intended to continue using them in the future. The devices were considered to be very useful and about 70% of the users stated that they have either maintained or improved their state of health by using them. Furthermore, they stated that their health awareness has increased as they felt more confident about taking care of their health themselves. However, feeling less anxious about their health through the use of wearables was not perceived as a major benefit by the subjects in this study. Another result of this study was that only a few people shared their personal health data recorded by the self-tracking devices. If the data was shared, then it was either with family members or friends. Only a small proportion of respondents passed this data on to a health care provider.

As part of a pilot study, the attitude of health care providers towards smart wearable devices was investigated (Holtz, Vasold, Cotten, Mackert, & Zhang, 2019). Nearly 300 primary care physicians and nurses were included in this mailed survey. The results of the survey showed that health care providers consider these technologies helpful. They trust in the accuracy of the data received and are not concerned about data privacy. Providers perceive their patients to be interested in wearable devices. Usability and access to these technologies are stated as possible barriers to the patient using them.

The studies described above show a positive attitude towards wearable technologies. However, both studies were limited by a small study population. In addition, they were not specific to the application of the technology in a particular context, such as the detection of atrial fibrillation, but dealt with the general attitude towards wearables in healthcare. There is no specific study that deals with the acceptance of smartwatches in the detection of atrial fibrillation. For the successful integration of a smartwatch arrhythmia detection system into the healthcare system, the acceptance of this method by doctors and patients must be ensured.

3.4 Limitations of Smartwatches

The review of the literature also revealed several limitations of smartwatch use in healthcare. The use of smartwatches is limited by their battery power. Often, they must be charged daily, usually overnight. This reduces the wearing time and thus also the potential monitoring time. The accuracy of PPG measurements can be affected due to various reasons such as skin colour, erratic movements (e.g. in patients with tremor), extrasystoles or even hairy wrists (Carpenter & Frontera, 2016). In studies, the use of smartwatches takes place under guidance and observation. In an outpatient setting, the performance of these devices may be less accurate due to errors in the application (Bumgarner et al., 2018). Furthermore, most of the current technologies for detection of atrial fibrillation using a smartwatch need the active involvement of the patient (Dörr et al., 2019). For this reason, asymptomatic and short episodes of for e.g. cardiac arrhythmias may not be detected. However, with the Apple Watch 4 and the KardiaBand there are already two devices available which inform their users about changes in heart rhythm by means of smart notifications and recommend them to record an ECG. As smartwatches are relatively new devices, some legal aspects concerning data security still need to be clarified to ensure the privacy of the recorded health data (Ip, 2019).

4 Methodology

This chapter describes the methodology of the pilot study conducted for this master thesis. First, information on the study setting and the study design is provided. Subsequently, the recruitment process of the study subjects is explained. In addition, the procedure of the usability test, the questionnaire and the expert interview designed for this study are described. Finally, it is mentioned how the data is analyzed.

4.1 Study Setting and Study Design

Every year at the Landesklinikum Wiener Neustadt Internal Medicine, Cardiology and Nephrology department, about 200 people undergo a catheter ablation to treat atrial fibrillation. With the permission of the head of the department, a mixed method pilot study was conducted here to evaluate the acceptance and usability of a commercially available smartwatch for the detection of atrial fibrillation and to answer the research questions mentioned in the Introduction. Both a quantitative and a qualitative approach were used to explore the opinions and the attitudes towards this technology. In the quantitative section, people already diagnosed with atrial fibrillation performed a usability test with a smartwatch made available to them. Afterwards they were asked to answer a questionnaire rating the usability and the acceptance of the tested device for the detection of atrial fibrillation. For the qualitative part of the pilot study, physicians were interviewed to examine their opinion on this technology.

The study design is shown schematically for clarification in Figure 12.

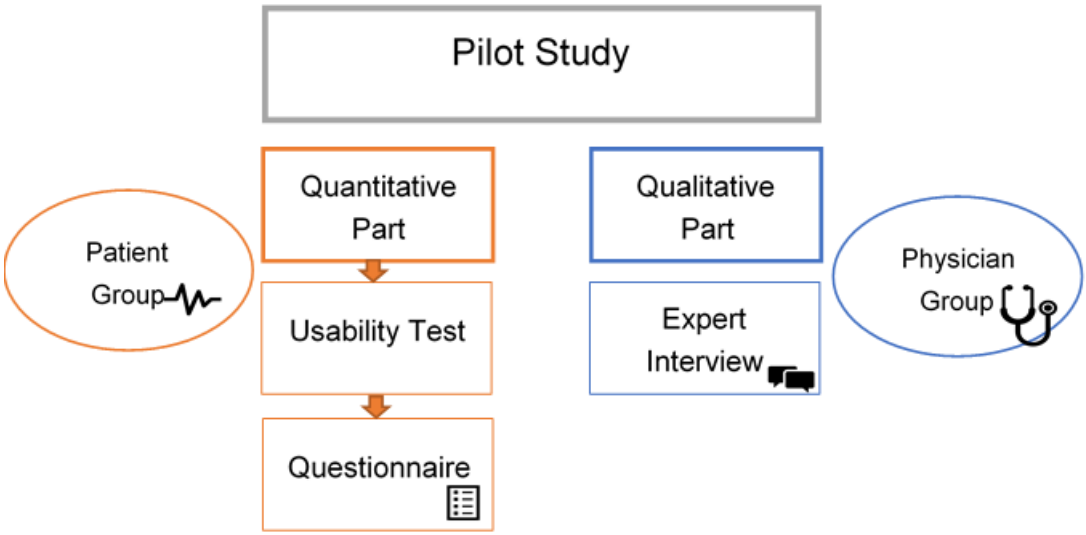

Figure 12 Schematic Representation of the Study Design

The ethics committee of the federal state of Lower Austria stated that there is no obligation for this study to be submitted to an ethics committee.

4.2 Recruitment

All study subjects were recruited at the department for Internal Medicine, Cardiology and Nephrology, Landesklinikum Wiener Neustadt. Due to the mixed method design of the study, two groups of subjects were recruited: people with a confirmed diagnosis of atrial fibrillation (Patient Group) and physicians from the clinical field (Physician Group). All study subjects were asked to provide written informed consent to participate.

Patient Group

After their admission to hospital for the catheter ablation, people were contacted and asked to participate in the pilot study. The study goal and the procedure of the usability test were explained to them and an information sheet was handed to them. If they agreed to participate, they had to sign an informed consent.

All study subjects went through the conventional hospital admission procedure and received the planned treatment. Study participation did not have any influence on the course of treatment.

The following inclusion and exclusion criteria were defined for study participation in the Patient Group:

Inclusion Criteria

- Participants need a confirmed diagnosis of atrial fibrillation.
- Participants need to be able to communicate in English or German.

Exclusion Criteria

- There is no confirmed diagnosis of atrial fibrillation.
- People who have an implanted device (e.g. pacemaker or defibrillator).

In January and February 2019, 33 people were asked to participate in the study. One person refused to participate in the study. Another person could not communicate in either German or English and could therefore not be included in the study. A third person passed the usability test, but did not want to complete the questionnaire and was therefore also excluded. In total, 30 persons completed the usability test and answered the questionnaire and could thus be included in the study.

The recruitment process of the Patient Group is shown in Figure 13.

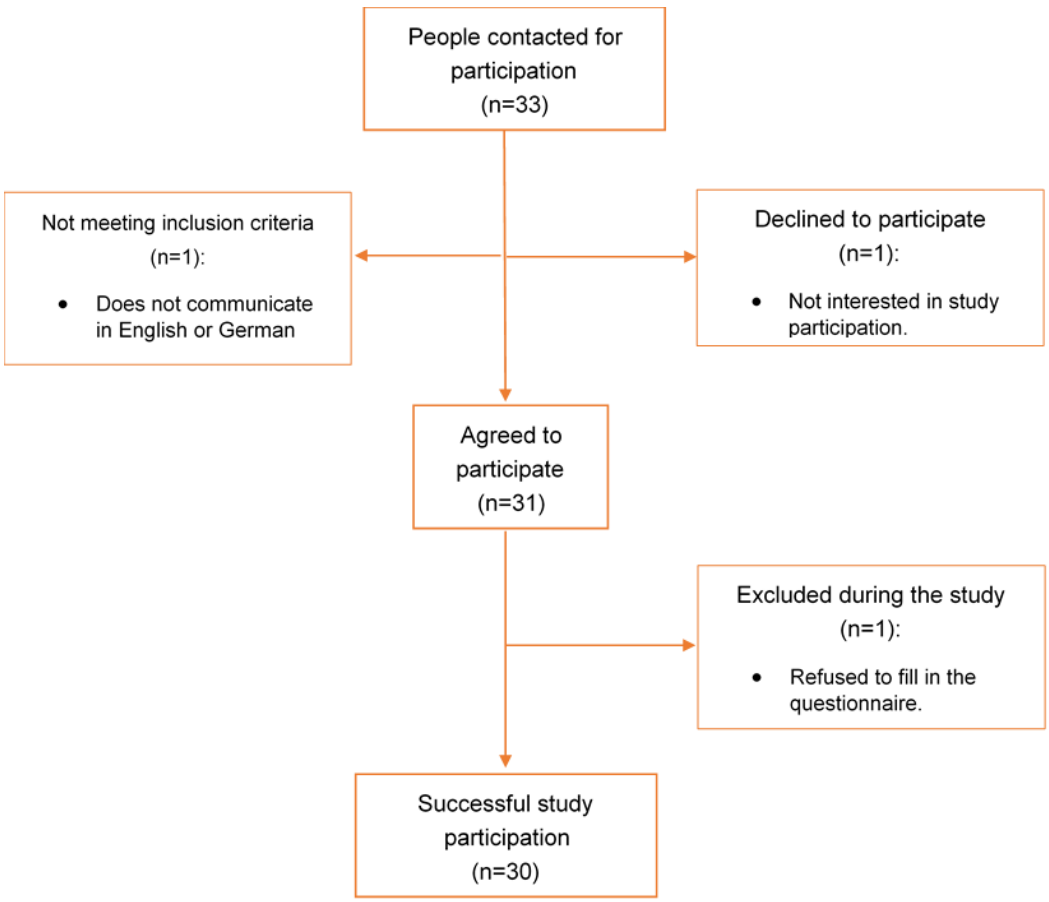

Figure 13 Recruitment Process Patient Group

Physician Group

Cardiologists working in the department were invited to participate in the study. They were contacted either personally, by telephone or by e-mail. Subsequently, an interview appointment was arranged. This group of subjects also received an information sheet and had to give their written consent to participate in the study. They were also asked for permission to record the interviews. To be eligible for the pilot study, the physicians were required to work in the clinical field.

Five cardiologists were contacted and asked to participate in the study. All of them agreed to take part in the study.

4.3 Interventions

This chapter explains the quantitative and qualitative sections of the pilot study in more detail. First, the quantitative section is described which includes a usability test and a questionnaire for the Patient Group. Afterwards, in the qualitative part, the expert interviews with the Physician Group are explained.

4.3.1 Usability Test and Questionnaire – Patient Group

Usability is defined as the extent to which a product can be used by certain users in a certain usage context in order to achieve certain goals effectively, efficiently and satisfactorily (DIN EN ISO 9241-11 quoted from Jordan, 2018). In a usability test, test persons are prompted to solve typical tasks with the test object that they would later perform in a similar way with the same object. In this way, it is possible to evaluate how people use the device and what difficulties may occur during operation.

The usability test that was carried out with the subjects of the patient group within the scope of this pilot study served to determine how they perceived the handling of a commercially available smartwatch. They should be given a realistic impression of the use of a smartwatch in the detection of atrial fibrillation.

The KardiaBand (AliveCor, Mountain View CA, USA) connected to a 3rd generation Apple Watch (Apple, Cupertino CA, USA) and a 4th generation iPad mini (Apple, Cupertino CA, USA) were used for the usability test. The KardiaBand was the first FDA-approved Apple Watch accessory. It is a wristband device which can record, store and transfer single channel ECGs. It also displays ECG rhythms during recording and, with the aid of artificial intelligence, recognizes the occurrence of atrial fibrillation and normal sinus rhythms.

Figure 14 shows the KardiaBand system attached to the Apple Watch and two examples of rhythm analysis.

Figure 14 KardiaBand System and Rhthym Analysis Screenshots (modified) (AliveCor, n.d.; Bumgarner et al., 2018) modified

Furthermore, the KardiaBand offers the possibility of continuous cardiac rhythm monitoring. Its SmartRhythm technology uses artificial intelligence to evaluate the correlation between heart activity and physical activity. If an unusual pattern is detected, it alerts its user to take an ECG. All ECGs are synchronized with the Kardia application installed on a smartphone or tablet. The application can be used to share the recorded ECGs. The ECGs can be converted into PDF format and sent directly from the app by e-mail. Figure 15 shows an extract of an ECG recorded with the KardiaBand. The patient data and the date of admission are specified at the top. In addition, the heart rate and rhythm analysis of the KardiaBand system are also found.

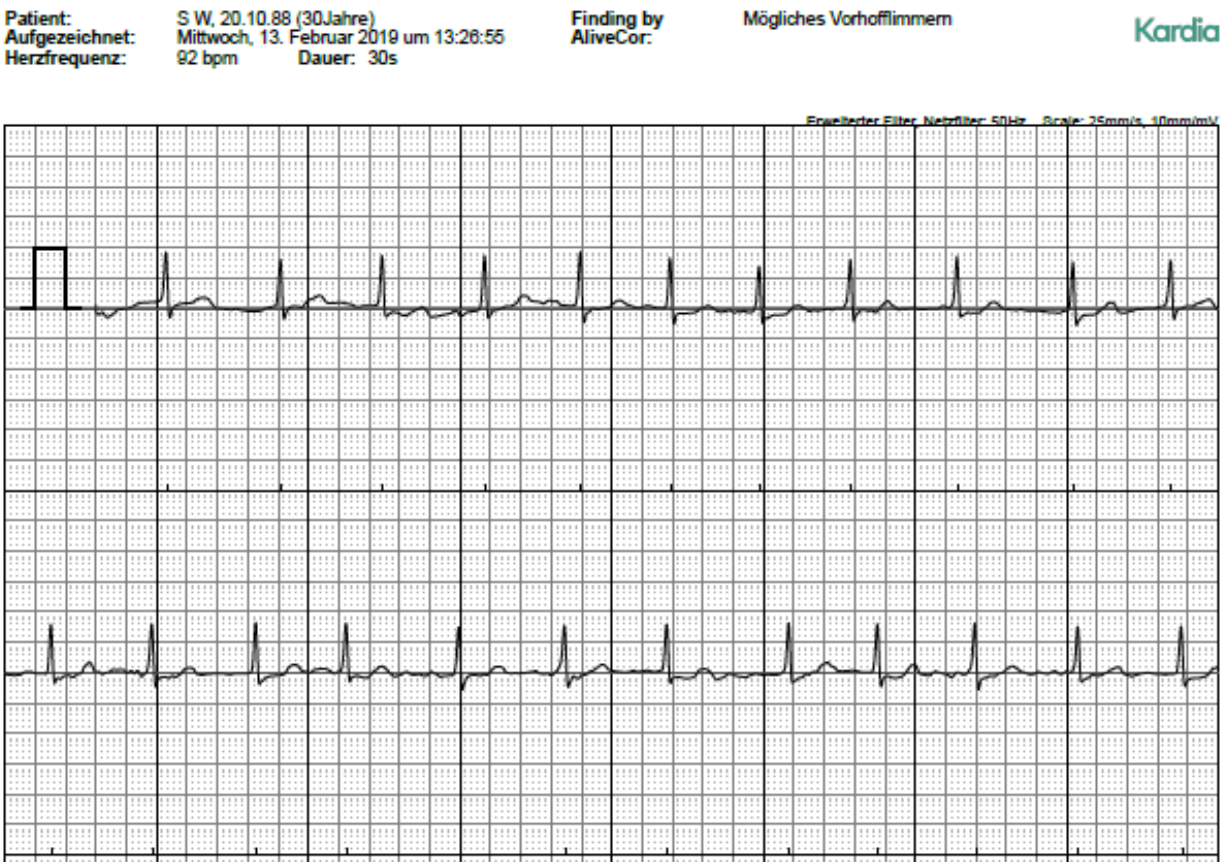

Figure 15 PDF File of a KardiaBand ECG Recording

For the usability test with the KardiaBand system, eight tasks were designed which should give the subject a good insight into the functions of the device. Before the start of the study, the tasks were tested with persons from different age groups for validation. Figure 16 shows the task paper for the usability test. A German translation can be found in the appendix.

Tasks:

1.) Please put the watch on your left wrist.
2.) Call the Kardia application via the menu and open it.
3.) Use the app to record an ECG.
4.) Navigate through your ECG by using the digital crown.
5.) Close the app on the smartwatch.
6.) Now open the Kardia application on the tablet.
7.) Recall your ECG in the chronicle of the application.
8.) Send your ECG as PDF file.

In the test scenario, sending is defined as pressing on the correct symbol. An actual sending of the file is not necessary.

Figure 16 Usability Test Task Page

Before the start of the usability test, subjects received a demonstration and a verbal explanation on all the relevant functions of the KardiaBand System. Afterwards, they had the opportunity to handle and explore the smartwatch and its functions themselves. Following the initial hands-on they were asked to fulfil the tasks of the usability test. During the test the study leader took notes on the subject's performance and comments. After finishing the usability test, the questionnaire, which is described below, was handed to the subjects.

Questionnaire

The questionnaire of the pilot study consists of items regarding usability and technology acceptance. Two already existing questionnaires on these topics were used and adapted. In addition, demographic information about the subjects, such as age, gender and education, as well as their current use of technological devices, such as smartphones, tablets, computers/laptops and smartwatches, were collected.

Usability of the smartwatch was assessed based on the System Usability Scale (SUS). This 10-statement scale is widely used to evaluate the usability of a variety of technological devices (Brooke, n.d.). It consists of five positive and five negative statements which alternate. A five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree) is used for each of the statements. The highest value that can be achieved with the System Usability Scale is 100. Within the pilot study, a German version of the SUS was used. The statements were adapted to the investigation of the smartwatch.

Technology acceptance was evaluated based on the technology usage inventory questionnaire (TUI) (Kothgassner et al., 2013). This survey instrument was developed by the ICARUS research team of the University of Vienna for research purposes in the field of technology acceptance. TUI is used to record technology-specific and psychological factors that contribute to the actual use of a technology. The survey contains the following eight scales: curiosity, anxiety, interest, usability, immersion, usefulness, scepticism and accessibility. Furthermore, there is another scale used to explore the intention to use. For the evaluation of the smartwatch in the usability test setting, the aspects of anxiety, interest, usefulness, scepticism and intention to use were considered. Based on the technology usage inventory questionnaire, three statements were prepared for each item. They were to be evaluated on a 5-point Likert scale with one representing low agreement and five representing high agreement. For evaluating the intention to use, one open-ended question and two questions with predefined answers were created. The scales used are briefly explained and the items are presented in tabular form below.

Anxiety

This scale is used to measure whether the use of technology in general causes anxious or emotional reactions. It is used to determine whether a person generally feels overwhelmed by technical devices of all kinds and is afraid of doing something wrong when using them.

	Items
ANX1	I am often worried that new technical devices might overtax me.
ANX2	If I am to use a new technical device, I am suspicious at first.
ANX3	I find it hard to trust technical equipment.

Interest

This scale captures a person's basic interest in technology. The items do not refer to a specific technology, but rather ask how much technical knowledge a person has in general and to what extent he or she keeps up to date with technological developments.

	Items
INT1	In the course of my life I have acquired a lot of technical knowledge.
INT2	When a new technical device enters the market, I inform myself about it.
INT3	I inform myself about new technological developments.

Usefulness

This scale is used to evaluate the benefit that a person perceives through the use of a smartwatch. It measures whether a person considers the technology to be useful and whether he or she believes that it can in some way support him or her in everyday life.

	Items
USE1	The use of a smartwatch would support me in dealing with my disease.
USE2	A smartwatch would increase my feeling of security in everyday situations.
USE3	The use of a smartwatch would strengthen my health awareness regarding my illness.

Scepticism

This scale measures the level of scepticism or mistrust a person has regarding the use of a smartwatch. The aim is to determine whether a person considers the technology to be risky, dangerous and detrimental to them.

	Items
SCE1	I think that the use of this technology is always associated with a certain risk.
SCE2	A smartwatch would disturb my daily routine.
SCE3	The use of a smartwatch would bring me more disadvantages than advantages.

Intention to use

This scale measures the behavioural intention to actually use the smartwatch.

	Items
ITU1	Would you like to use the tested smartwatch? Please explain briefly in your own words why, or why not?
ITU2	How likely is it that you would buy a smartwatch on the recommendation of your internist?
ITU3	How much money would you be willing to spend on it?

The items on the scales for interest and anxiety were taken directly from the technology usage inventory because they refer to technologies in general. The wording of the items of the other categories was adapted to the technology used in this study, the smartwatch and the study objectives. The questionnaire was created with Microsoft Word for Windows.

The complete German version of the questionnaire can be found in the appendix.

4.3.2 Expert Interview – Physician Group

A questionnaire with nine open-ended questions was prepared for the expert interviews. Questions were used to obtain insights into physicians' perceptions of smartwatches in the detection of atrial fibrillation. Regarding the aim of the study, a discussion guide consisting of four topics and a final question was developed. Table 2 shows the discussion guide for the expert interview.

Table 2 Expert Interview Disscussion Guide

Topics	**Questions**
Usefulness	• Commercially available smartwatches are developing more and more from fitness machines towards health monitors. Some devices can detect cardiac arrhythmias by recording a 1-channel ECG. How do you rate the benefits of these devices?

	• The early detection of atrial fibrillation is crucial for the prognosis. Do you see a potential of smartwatches as a monitoring tool, which helps to detect possible atrial fibrillation and to initiate a further medical clarification? • Smartwatches offer a combination of heart rate monitoring and connectivity. Could continuous pulse monitoring in your opinion be used for long-term monitoring of patients in aftercare after for example catheter ablation, like the loop recorder?
Experiences/Usability	• Are you familiar with the KardiaBand system that is used in the pilot study? Have you already had the opportunity to test it and possibly gain medical experience with this technology? • Have you already been asked by patients about the possibility of rhythm monitoring using asmartwatch?
Scepticism	• There is also some scepticism about smartwatches in the detection of atrial fibrillation. Some doctors fear overcrowded outpatient departments or unsettled patients due to the “self-diagnosis” using smartwatches. How do you feel about that? Where do you see advantages and disadvantages of this technology?
Clinical application	• Do you think that smartwatches can be integrated into clinical care scenarios? • Where do you see possible applications for smartwatches in the context of current diagnostic and treatment strategies?
Final question	• Are there any other important things on this subject, that have not been mentioned yet?

The German version of the questionnaire as received by the participants of the expert interviews is included in the appendix.

The interviews were recorded with an iPhone 7 and a 4th generation iPad mini.

Figure 17 schematically summarizes the course of the pilot study. The inclusion criteria are also listed.

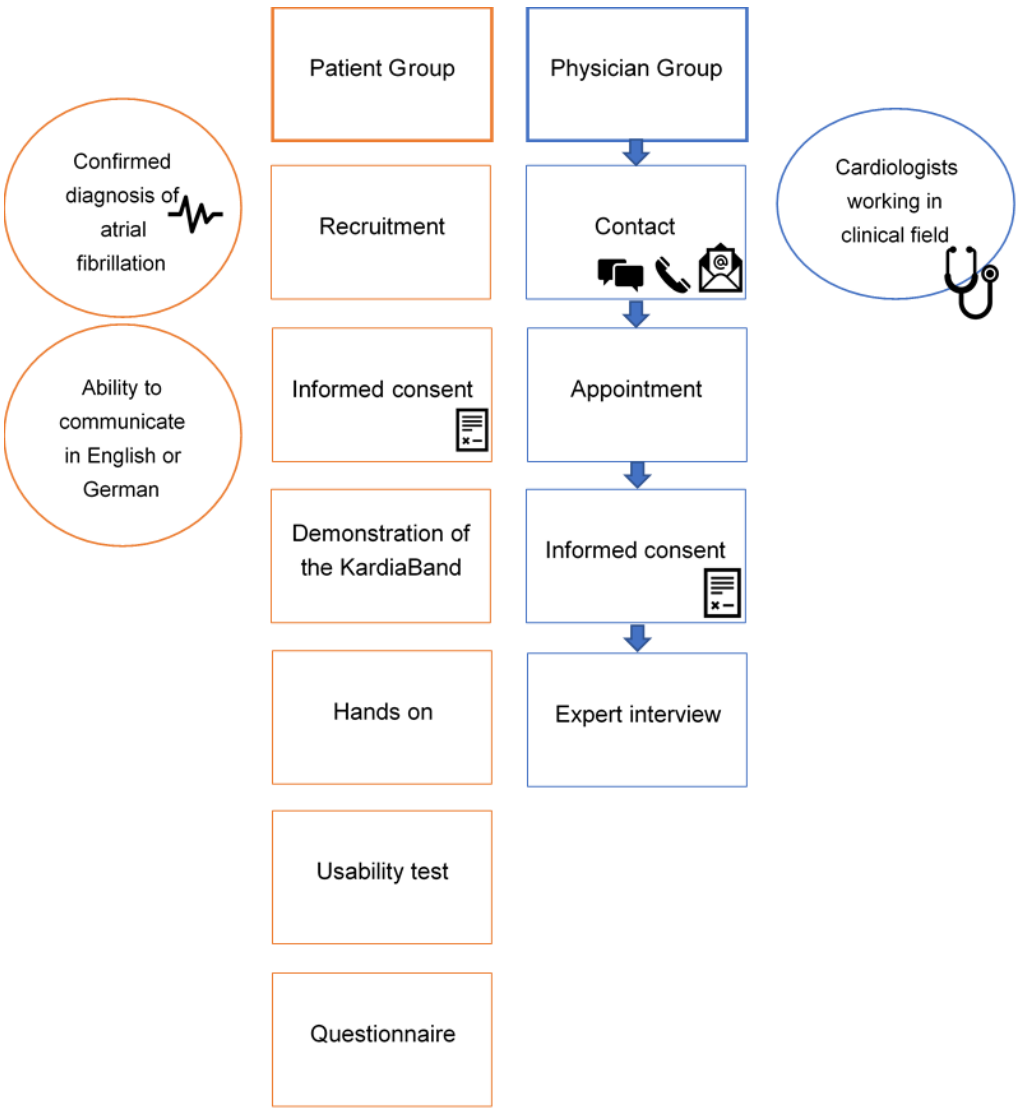

Figure 17 Schematic Representation of the Study Course

4.4 Data Analysis

Patient Group

Data received from questionnaires was entered and analysed in Microsoft Excel (Microsoft Cooperation, Redmond Washington, USA) for Windows. The evaluation and presentation of the collected data was carried out using descriptive statistics. Means, percentages and standard deviation were used to summarize the demographic data of the subjects.

For the evaluation of usability, the System Usability Score was calculated to rate the perceived usability of the smartwatch. The individual score was calculated for each subject and the mean value was then determined for the entire study group. An analysis of whether there were differences in the SUS score according to gender, age or educational level was carried out.

The technology acceptance part of the questionnaire was evaluated according to the individual scales presented in subchapter 0. In order to represent the degree of agreement of individual subjects, the 5-point Likert scale was reduced to three classes. Each value on the 5-point Likert scale was assigned a class for evaluation. Table 3 shows the three classes defined for the evaluation with the corresponding assigned values of the Likert scale as well as the respective description of the scale in German and English.

Table 3 Defined evaluation classes of the Likert scale including the English and German description

Classes for evaluation	Low agreement	Low agreement	Medium agreement	High agreement	High agreement
Scale	1	2	3	4	5
German original	Trifft gar nicht zu	Trifft nicht zu	Neutral	Trifft zu	Trifft völlig zu
English Translation	Not at all true	Not true	Neutral	True	Totally true

The three classes denote the degree of agreement with an item:

- The answers with the values [1] and [2] were assigned to the class “low agreement”.
- The answers with the value [3] were assigned to the “medium agreement” class.
- The answers with the values [4] and [5] were assigned to the class “high agreement”.

Within the scales, *Usefulness* and *Interest* answers of the class “high agreement” indicate a high usefulness of the smartwatch and a high interest in technologies. Whereas answers of the “low agreement” class in the scales *Anxiety* and *Scepticism* indicate a low technology anxiety and low scepticism towards the smartwatch.

All results of the scales are examined according to gender, age or educational differences.

The scale *Intention to use* consists of an open-ended question and two questions with predefined response options. The answers of the open-ended question are presented in categories according to the intention to use the smartwatch indicated by the subjects. The other questions were evaluated from the chosen response option. In this scale, the focus is on the evaluation of the individual questions, and to a lesser extent on data analysis by gender, age group or educational level.

Physician Group

The recorded interviews were transcribed in Microsoft Word for Windows. The evaluation of the data collected in the interview followed the steps of the qualitative content analysis according to Mayring (2010). The basic concept of this evaluation method is to analyse the interview material systematically using a category system.

5 Results

In this chapter the results of the pilot study are presented. First, the results of the patient group are described and then those of the physician group.

5.1 Patient Group

Between January 3 and February 19 2019, 30 people were successfully included in the patient group. The study group comprised 11 female and 19 male subjects ranging in age from 52 to 79 years, with a mean age of 64.4 years. The largest part (43.3%) of the study group has an apprenticeship as their highest completed education. Six subjects (20%) have completed university studies and five (16.7%) have completed their A levels. Table 4 summarizes the baseline characteristics of the study subjects.

Table 4 Baseline Characteristics of the Study Subjects

Gender, n (%)	Male	19	(63.3%)
	Female	11	(36.7%)
Age, mean ± SD	64.4 ± 7.6		
Education attainment, n (%)	keine abgeschlossene Ausbildung	0	(0%)
	Pflichtschule/Hauptschule	2	(6.7%)
	Fachschule/Handelsschule	4	(13.3%)
	Lehre/Berufsausbildung	13	(43.3%)
	Matura	5	(16.7%)
	Universität/Fachhochschule	6	(20%)

Figure 18 to Figure 21 show how often subjects indicated use of the following devices: computer/laptop, tablet, smartphone and smartwatch. Three subjects (10%) stated that they did not use any of these devices. The device used most often daily is the smartphone with 24 subjects (80%) using it daily. One subject is already using a smartwatch.

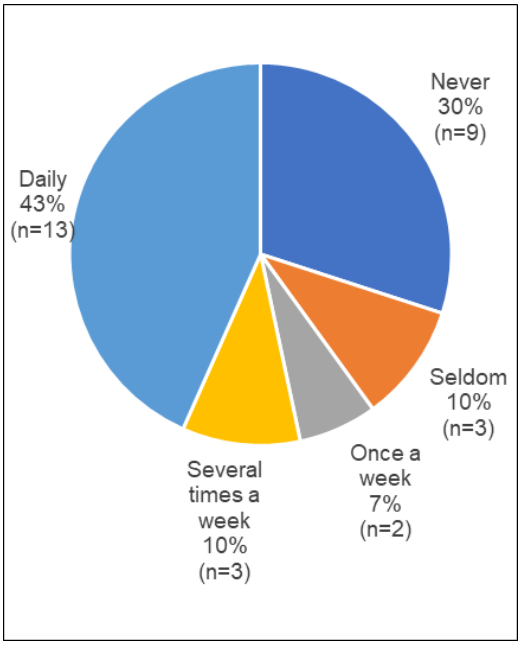

Figure 18 Technology Usage – Computer/Laptop

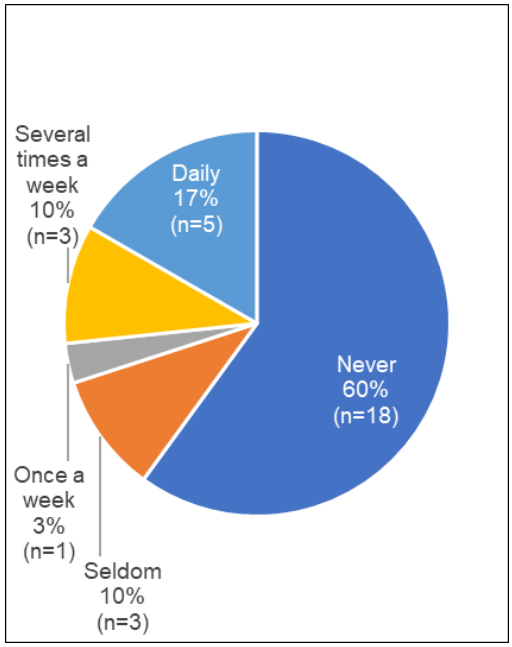

Figure 19 Technology Usage - Tablet

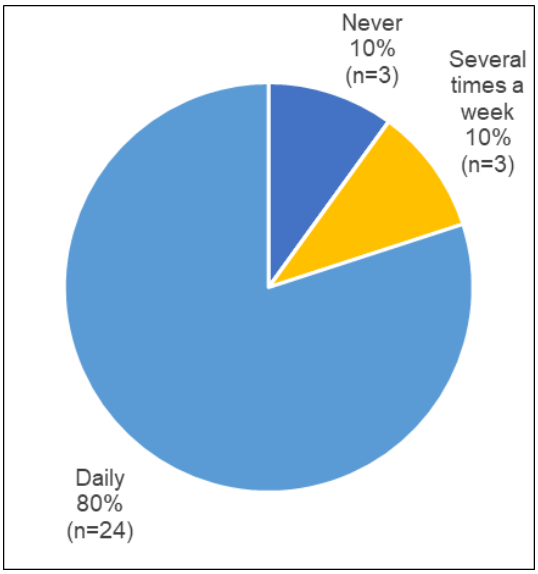

Figure 20 Technology Usage - Smartphone

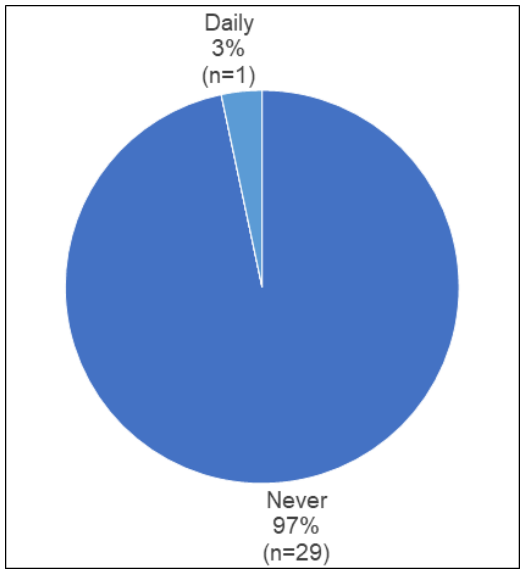

Figure 21 Technology Usage - Smartwatch

5.1.1 Usability

28 subjects passed the usability test on the first attempt. Two people needed several attempts before receiving an ECG measurement using the KardiaBand system.

Usability was rated with an average score of 83 (SD ±11.9). The highest rating was an SUS of 100 points while the worst was a score of 57.5 points. Men (mean 83.2) and women (mean 82.7) awarded almost the same points. Figure 22 shows the mean SUS score mapped onto the acceptability ranges proposed by Bangor, Kortum, & Miller, 2009.

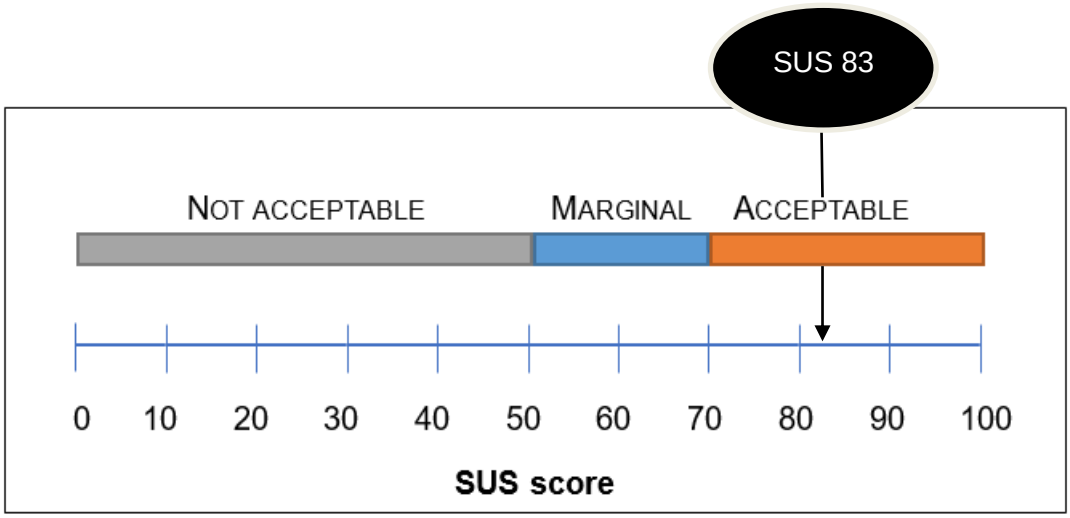

Figure 22 SUS score and acceptability ranges

Subjects younger than 60 years awarded a mean SUS of 88.3. In the age group of subjects over 70 years, the mean SUS was 85. Subjects aged between 60 and 70 years rated usability with a mean score of 77.7. Figure 23 shows the mean SUS and the SD by age group.

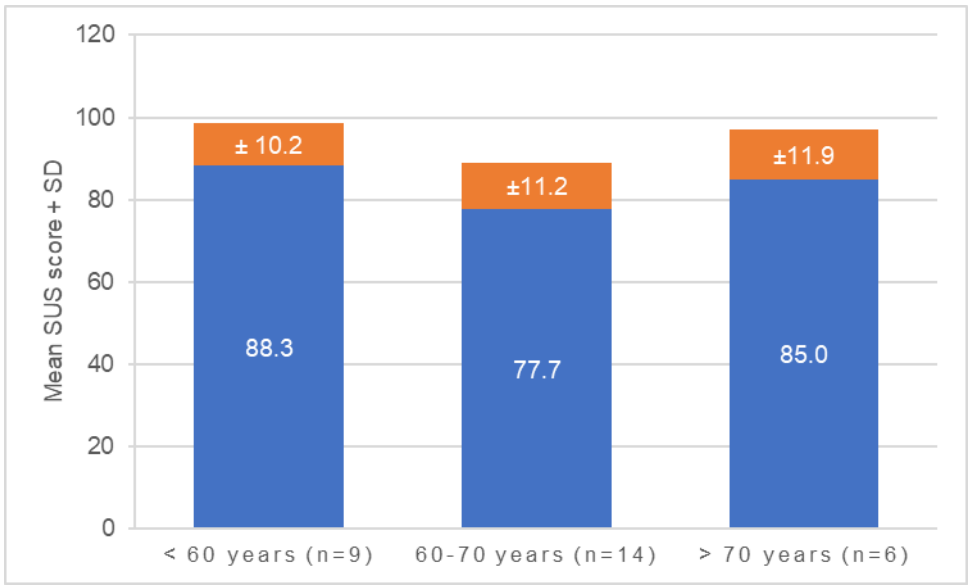

Figure 23 Mean SUS Score by Age Group

Subjects who use at least two technical devices regularly awarded a mean SUS of 86.7. Those subjects who use only one device regularly rate usability with a mean SUS of 77.5.

Figure 24 shows the mean SUS scores according to the level of education. The highest scores were awarded by subjects who have completed their A levels (mean 88). Subjects who have finished either compulsory school or an apprenticeship rated usability with the lowest scores.

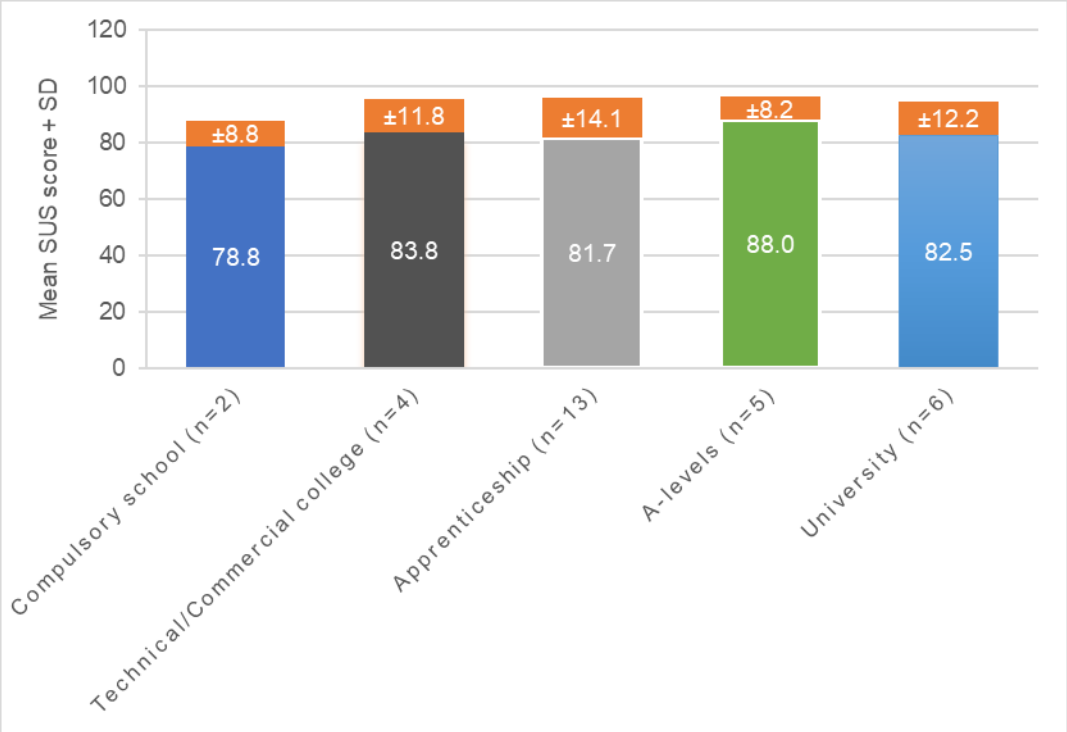

Figure 24 SUS Scores According to Education Attainment

5.1.2 Technology Acceptance

The results for technology acceptance are presented below for each of the five scales of anxiety, interest, usefulness, scepticism and intention to use.

Anxiety

On average, 53.3% (n=16) of the subjects rated the items in the scale for general technology anxiety with the values of 1 and 2. These values suggest low agreement with the respective item statements and indicate a low anxiety towards technologies. Table 5 shows the items of the scale and the percentage frequency of the agreement.

Table 5 Results of the Anxiety Scale

	Low agreement	Medium agreement	High agreement
ANX1	46.7% (n=14)	20.0% (n=6)	33.3% (n=10)
ANX2	56.7% (n=17)	20.0% (n=6)	23.3% (n=7)
ANX3	56.7% (n=17)	23.3% (n=7)	20.0% (n=6)
Mean	53.3% (n=16)	20.0% (n=6)	26.6% (n=8)

An analysis of the data by gender shows that female subjects are more likely to rate the items relating to technology anxiety with high agreement and 40% of women awarded values of the high agreement category. Only 18% of the male subjects gave these values. Men were more likely to rate the items with values of the low agreement category. Figure 25 shows the results of the data analysis by gender.

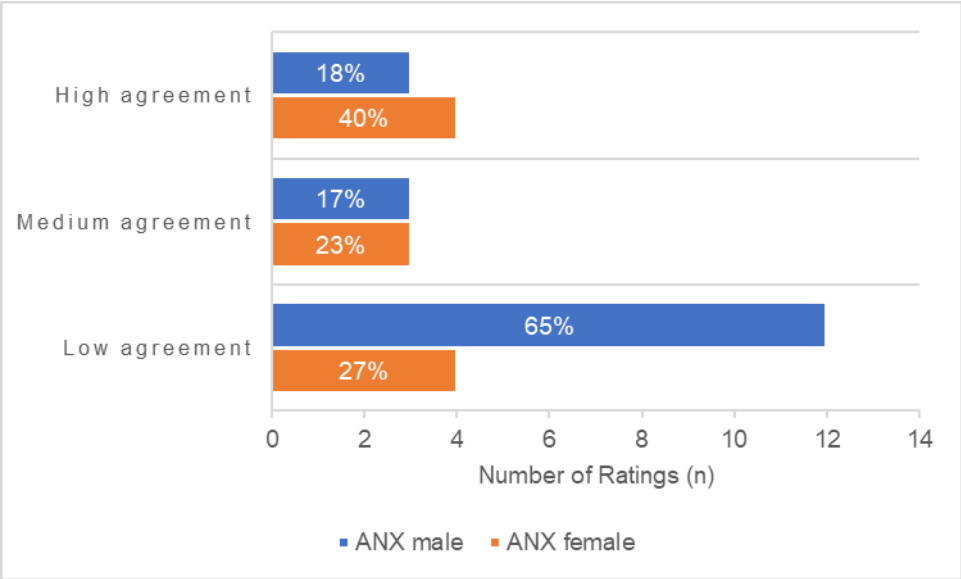

Figure 25 Results of the Anxiety Scale by Gender

For all age groups, subjects rated the items mostly with low agreement (< 60 years: 60%; 60–70 years: 48%; > 70 years: 56%). The categories of medium agreement and high agreement were chosen with almost the same percentage.

Figure 26 to Figure 30 show the results by education level. Subjects from almost all educational groups most often assigned the value low agreement. Only the subjects with a university degree rated most of the statements with high agreement. Two educational groups (compulsory school and A levels) never awarded the high agreement value.

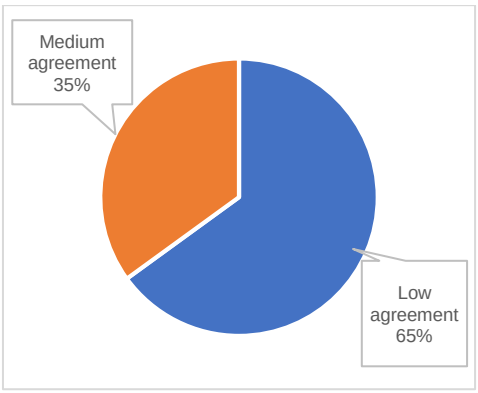

Figure 26 Results Anxiety Scale – Compulsory school

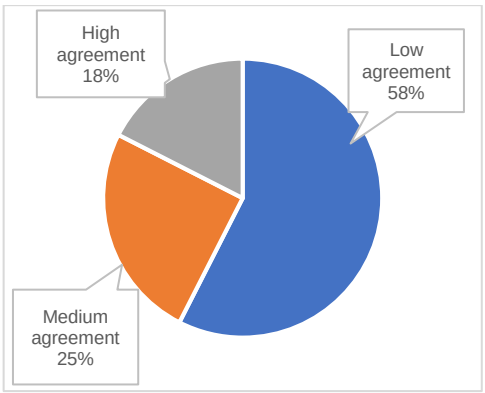

Figure 27 Results Anxiety Scale – Technical/Commercial college

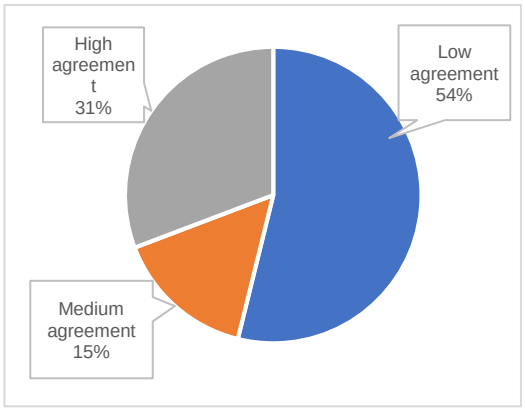

Figure 28 Results Anxiety Scale – Apprenticeship

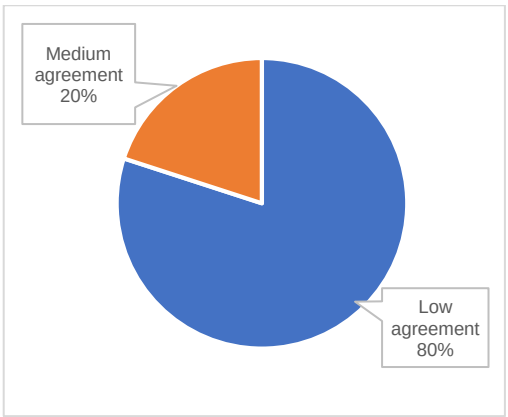

Figure 29 Results Anxiety Scale – A-levels

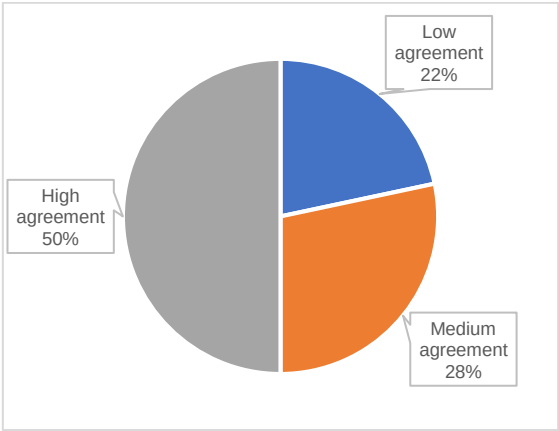

Figure 30 Results Anxiety Scale – University

Interest

The statements of the technology interest scale were rated with high agreement by a mean of 56.6% (n=17) of the subjects. This indicates that they are very interested in technologies in general. On average, seven subjects (23.3%) choose the value of the medium agreement class. One-fifth of study group assigned the low agreement class to the items of this scale. Table 6 shows the results of the interest scale.

Table 6 Results of the Interest Scale

	Low agreement	Medium agreement	High agreement
INT1	10.0% (n=3)	26.7% (n=8)	63.3% (n=19)
INT2	23.3% (n=7)	16.7% (n=5)	60.0% (n=18)
INT3	26.7% (n=8)	30.0% (n=9)	43.3% (n=13)
Mean	20.0% (n=6)	23.3% (n=7)	56.6% (n=17)

Male subjects were more likely to rate the statements of the technology interest category with values of the high agreement class. The majority of the female subjects chose the low agreement class to evaluate the statements. Figure 31 shows the results of the data analysis by gender.

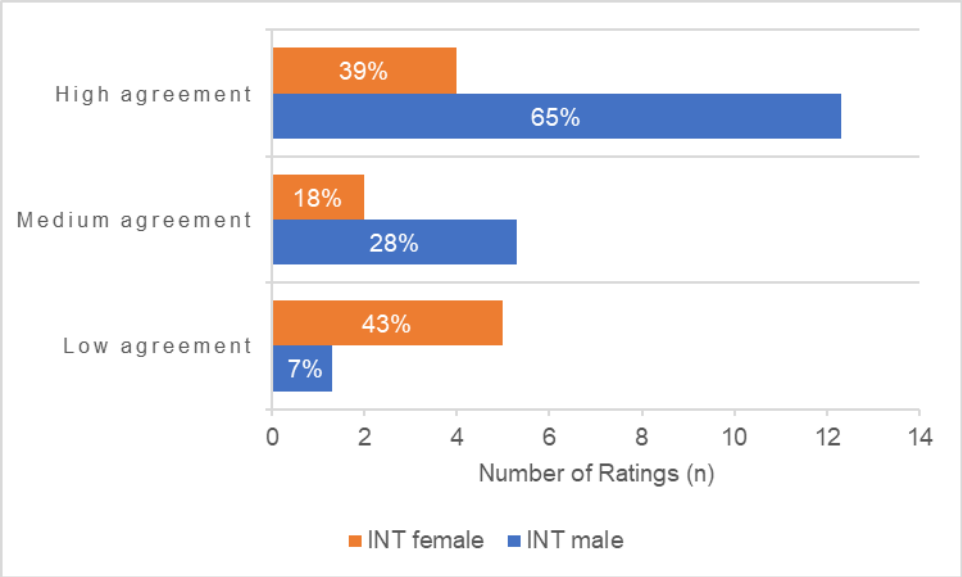

Figure 31 Results of the Interest Scale by Gender

An analysis of the data by age group shows that subjects of all age groups rated most of the statements with values from the high agreement class. Almost three-quarters of the subjects younger than 60 years chose this class. In the age group of subjects older than 70 years, the classes of high agreement and medium agreement were chosen with similar percentages. The rating of low agreement was rarely awarded. Figure 32 shows the distribution of answer classes by age group.

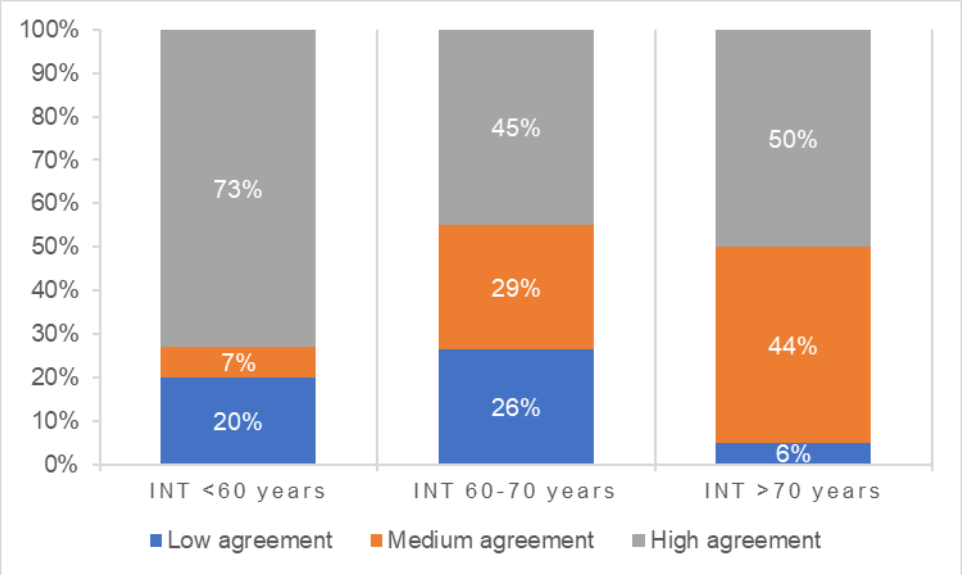

Figure 32 Data Analysis of the Interest scale by Age Group

For all educational groups, the statements concerning technological interest were evaluated with values of the class high agreement most. Subjects with a compulsory school leaving certificate, a technical/commercial college leaving certificate or an apprenticeship chose answers of the medium agreement class second most frequently. Subjects who finished their A levels or have a university degree rated the statements with values of the low agreement class second most frequently.

Usefulness

The results of this scale are intended to give an impression of how the usefulness of smartwatches in the detection of atrial fibrillation is assessed by the subjects. Table 7 shows the results of each item and the mean value of all items. Most of the subjects (mean 71.0%; n=21.3) agreed with the statements with high agreement, which indicates that they believe in the smartwatch's usefulness. The subjects rated the statements that a smartwatch supports them in dealing with their disease and it increases the feeling of security in everyday situations, with higher values than the statement that the smartwatch would strengthen their health awareness regarding atrial fibrillation.

Table 7 Results of the Usefulness scale

	Low agreement	Medium agreement	High agreement
USE1	3.3% (n=1)	13.3% (n=4)	83.3% (n=25)
USE2	3.3% (n=1)	20.0% (n=6)	76.7% (n=23)
USE3	16.7% (n=5)	30.0% (n=9)	53.3% (n=16)
Mean	7.6% (n=2.3)	21.0% (n=6.3)	71.0% (n=21.3)

Male subjects were more likely to rate the statements regarding the usefulness of the smartwatch with values of the high agreement class. Only one male subject chose the low agreement class once. The majority of the female subjects (mean 55%; n=6) also agreed with the statements with values of the high agreement class. The item concerning the strengthening of health awareness by the smartwatch was rated with values of the low or medium agreement class by the female subjects. Figure 33 summarizes the mean results of the data analysis by gender.

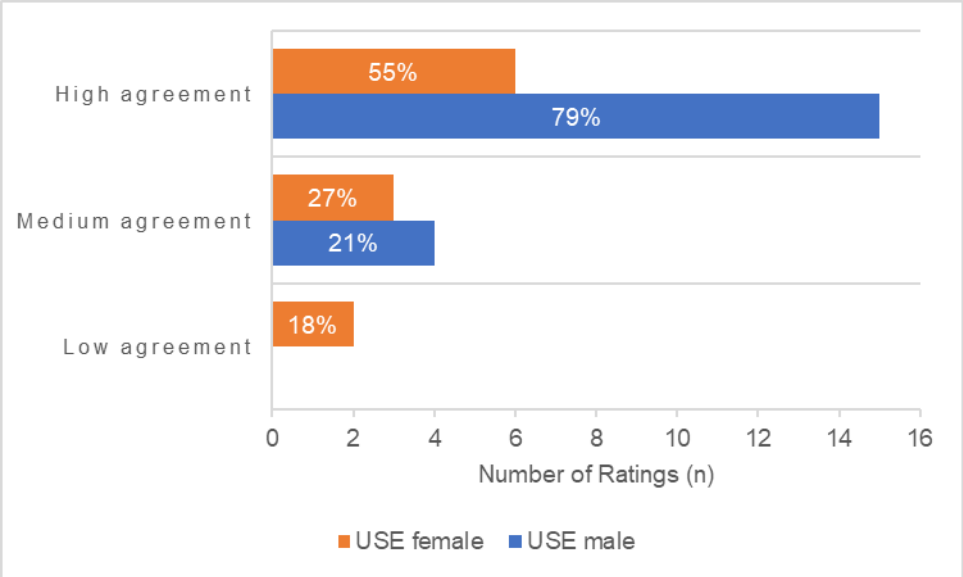

Figure 33 Data Analysis of the Usefulness Scale by Gender

For all age groups, subjects rated the items most with high agreement (< 60 years: 70%; 60–70 years: 74%; > 70 years: 67%). The categories medium agreement and high agreement were rarely chosen.

Data analysis by education level also shows that in each educational group the items were most frequently rated with values from the high agreement class. Subjects who have technical/commercial college leaving certificates or who have finished an apprenticeship never chose the low agreement class for evaluating an item. The group of subjects with a university degree rated an item with the low agreement class most often. Figure 34 presents the results of the usefulness scale by education level.

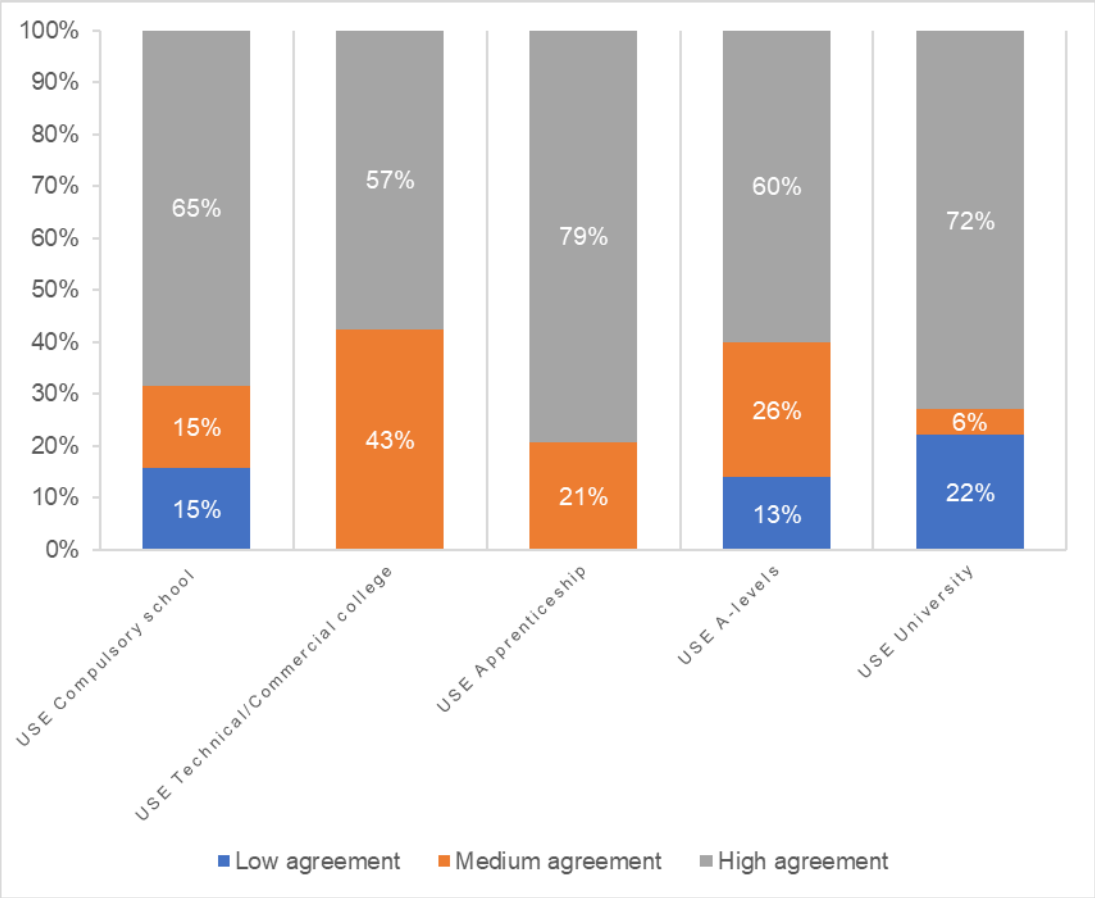

Figure 34 Data Analysis of the Usefulness Scale by Education Attainment Group.

Scepticism

On average, 82.3% (n=24.7) of the subjects rated the scepticism statements towards smartwatches in the detection of atrial fibrillation with values of the low agreement class. Only about one-sixth of the subjects chose values from the other two classes. Table 8 summarizes the results of the scepticism scale.

Table 8 Results of the Scepticism Scale

	Low agreement	Medium agreement	High agreement
SCE1	80.0% (n=24)	13.3% (n=4)	6.7% (n=2)
SCE2	86.7% (n=26)	13.3% (n=4)	0.0% (n=0)
SCE3	80.0% (n=24)	13.3% (n=4)	6.7% (n=2)
Mean	82.3% (n=24.7)	13.3% (n=4)	4.4% (n=1.3)

Data analysis by gender shows that subjects from both sexes most frequently use values from the low agreement class to evaluate the statements. On average, men chose the medium agreement and high agreement classes only once. About a third of female subjects stated medium agreement with the statement that a smartwatch would disturb their daily routine (SCE2). Figure 35 shows the average results of the scepticism scale according to male and female subjects.

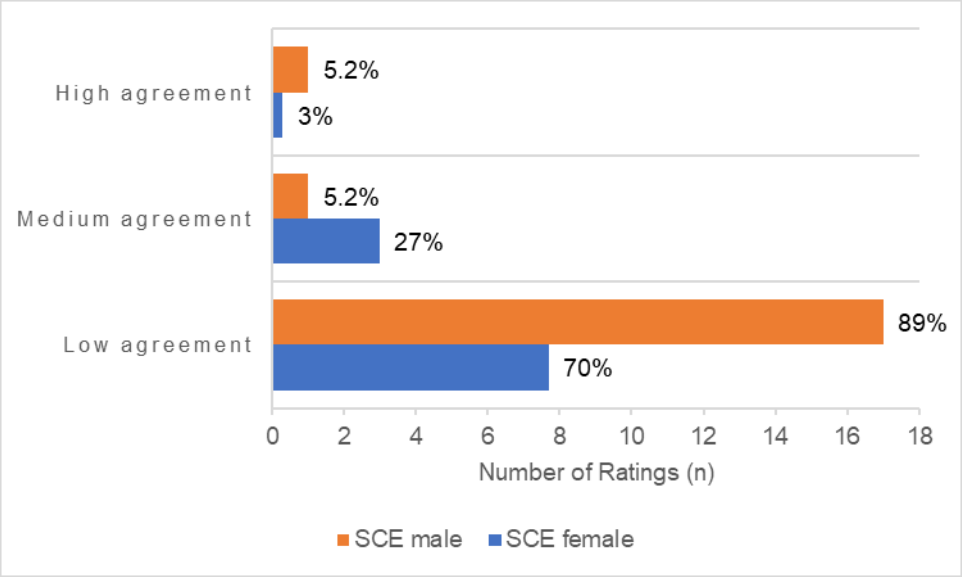

Figure 35 Data Analysis of the Scepticism Scale by Gender

Over three-quarters of the subjects of all age groups rated the scepticism statements with values from the low agreement class. Subjects aged between 60 and 70 years were more likely to choose the medium agreement class for evaluating the statements than subjects from the other age groups. Only one subject from the age group older than 70 years chose another rating class than the low agreement class. Figure 36 shows the results of the data analysis by age group.

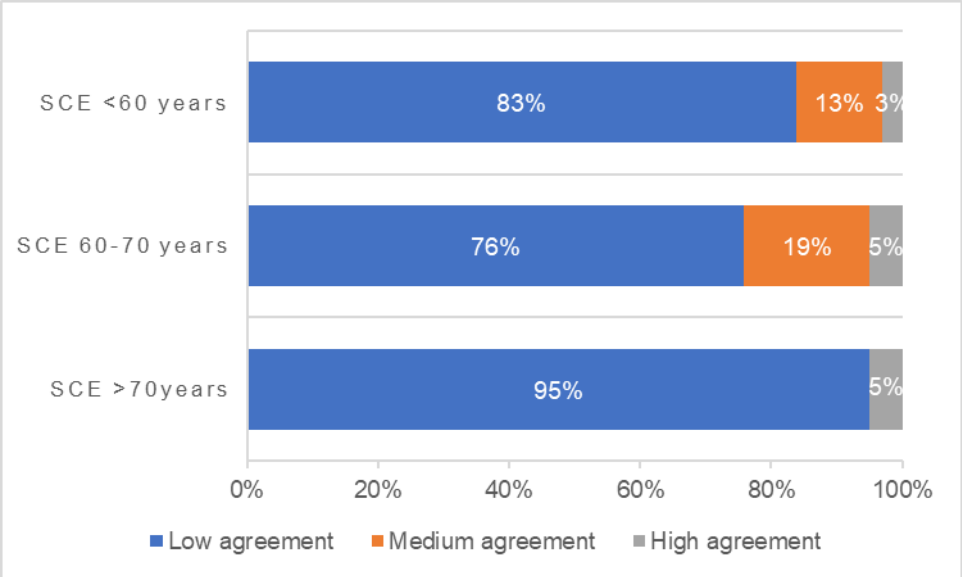

Figure 36 Data Analysis of the Scepticism Scale by Age Group

The majority of subjects from all educational groups evaluated scepticism towards the smartwatch with the low agreement class. Subjects who have a compulsory school leaving certificate, a technical/commercial college leaving certificate or who have completed their A levels showed the slightest scepticism towards the technology. Subjects with an apprenticeship were more sceptical. They evaluated some statements with values of the medium or high agreement class. Most often, subjects with a university degree decided to evaluate the statements with values from these two classes. Figure 37 summarizes the results of the data analysis by education level.

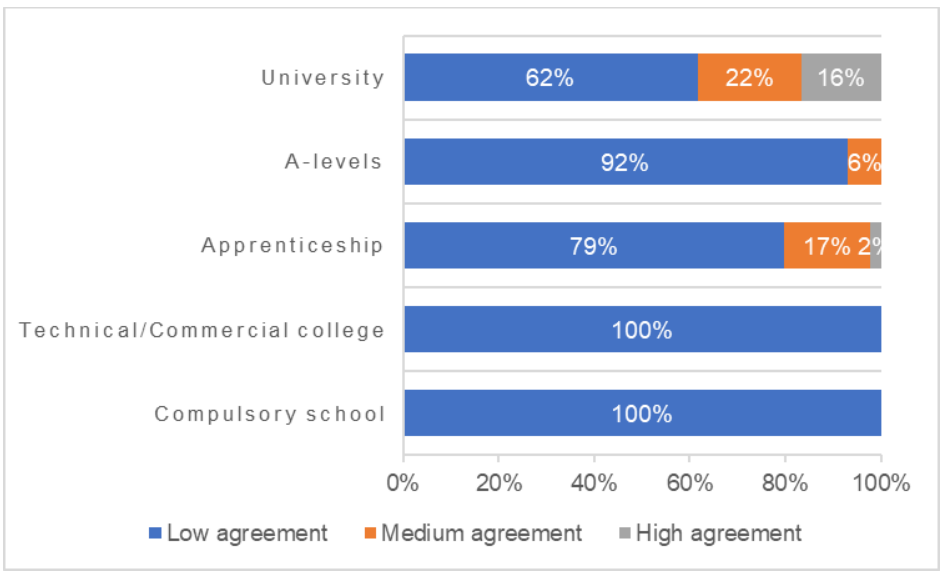

Figure 37 Data Analysis of the Scepticism Scale by Education Level

Intention to use

Of all subjects, 67% (n=20) stated that they would like to use the tested smartwatch. A possible use of this technology was considered by 20% (n=6) of them. This response was most frequently given by subjects from the age group between 60 and 70 years. One female subject indicated that she could not imagine using the smartwatch currently, another stated that she did not want to use it. Two subjects (7%) did not answer this question. Figure 38 depicts the results of the first question of the Intention to use scale.

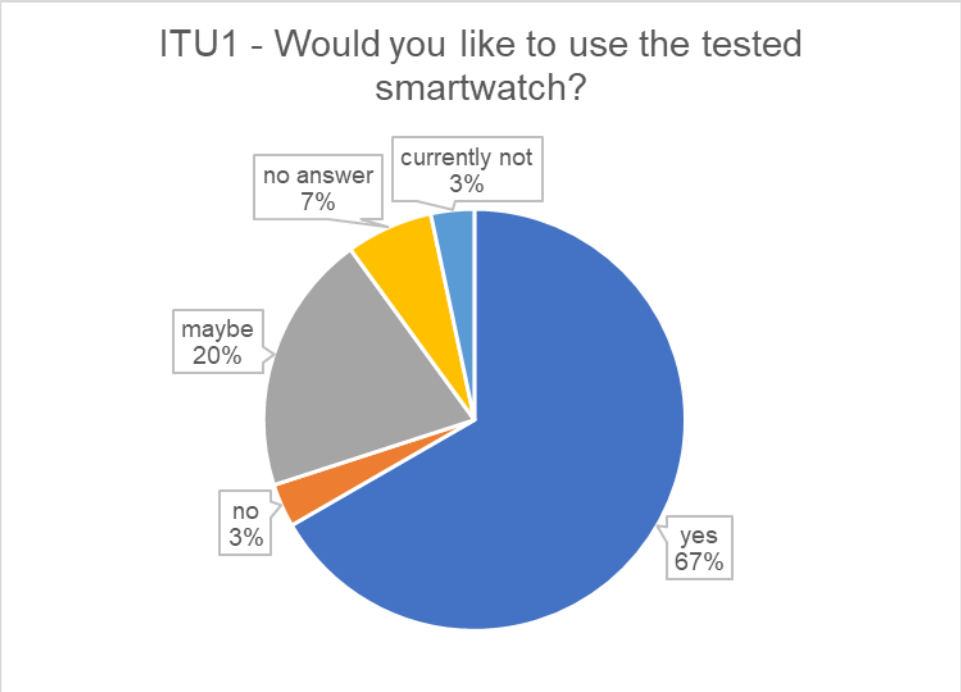

Figure 38 Results of ITU1

Many subjects stated that using a smartwatch would increase their feeling of security in everyday life. The potential for documenting episodes of their cardiac arrhythmia was also perceived as a benefit of this technology. Some subjects highlighted the ease of use of the smartwatch. The use of a smartwatch for the early detection of atrial fibrillation was also mentioned. A subject stated that a smartwatch probably would have helped him to a faster diagnosis, another one explained that he documented his cardiac arrhythmia by means of a 1-channel ECG with a similar technology and finally received a diagnosis of atrial fibrillation after several long-term ECGs without a result.

Subjects who considered a possible use of the smartwatch expressed concerns that the watch could break and thus be wasted money, that it could make them

nervous or that they are satisfied with their current method of monitoring their disease. The woman who did not want to use a smartwatch stated that wearing this device would remind her of her illness on a daily basis.

Half of the subjects reported that they currently monitor their cardiac arrhythmia either by blood pressure monitor or wristband device.

Table 9 describes some of the comments given by the subjects for using or not using the tested smartwatch. The answers are quoted in their original language.

Table 9 Subjects' Comments on the Use of the Smartwatch

Smartwatch Usage – Yes
S01 *„Bin auf der Suche nach einem Gerät mit dem ich mein Vorhofflimmern überwachen kann. Ich verwende aktuell einen Pulsmesser, mit welchem ich aber Speicherprobleme habe. Durch die Möglichkeit einer EKG-Aufzeichnung hätte ich ein verbessertes Sicherheitsgefühl."*
S03 *„Ich würde die Uhr gerne verwenden um Vorhofflimmern/Rhythmusstörungen während meiner sportliche Aktivitäten rechtzeitig zu erkennen. Außerdem hätte ich meine Beschwerden frühzeitig erkennen können, da diese Störungen nicht immer auftreten und damit durch den Facharzt nicht erkannt wurden."*
S04 *„Aufgrund der Tatsache, dass Vorhofflimmern immer dann auftritt, wenn kein EKG in der Nähe ist, ist ein tragbares EKG sinnvoll."*
S06 *„Eine Smartwatch würde für mich mehr Sicherheit und eventuell weniger Einschränkungen im Alltag bedeuten."*
S07 *„Ich würde mich im Alltag sicherer fühlen. Vorbeugung und Früherkennung."*
S09 *„Praktisch durch direkte Anzeige des EKG-Ergebnisses."*
S15 *„Gibt mir Sicherheit, einfache Bedienung."*
S18 *„Smartwatch gäbe mir die bestmögliche Sicherheit im Falle einer Vorhofflimmer-Episode durch die Möglichkeit der augenblicklichen Dokumentation."*
S19 „*Eine hervorragende technologische Weiterentwicklung für den Alltag."*
S20 *„Kann eine auftretende Herzrhythmusstörung sofort dokumentieren und dem Arzt übermitteln."*

S25 *„Eine Uhr kann mittlerweile so viel mehr als nur die Uhrzeit anzeigen.“* **S26** *„Angenehm leicht zu handhaben und man ist ständig informiert, wenn notwendig/gewünscht. Es gibt einem ein Sicherheitsgefühl.“* **S28** *„Würde mir Sicherheit geben.“* **S29** *„Es würde mir helfen, meine Situation richtig einzuschätzen.“*
Smartwatch Usage – No **S13** *„Die Smartwatch würde mich täglich an meine Erkrankung erinnern. Es ist ausreichend, halbjährlich beim Arzt oder beim Krankenhaus Besuch daran erinnert zu werden. Zudem ist mir persönlicher Kontakt zu meinem Arzt wichtig.“c*
Smartwatch Usage – Maybe **S02** *“Ich hätte bei der Verwendung einer Smartwatch Bedenken wegen meiner Arbeit, die teilweise auch sehr schmutzig sein kann. Die Uhr könnte kaputtgehen und wäre somit hinausgeschmissenes Geld“* **S11** *„Ich glaube es würde mich nervös machen. Könnte aber auch sein, dass es mir ein Sicherheitsgefühl gibt. Müsste man ausprobieren.“* **S12** *„Ich hoffe, dass mit dem morgigen Eingriff (Anm. Katheterablation) das Vorhofflimmern behoben ist und dadurch eine Überwachung der Erkrankung nicht mehr notwendig ist.“* **S16** *„Easy to use.“* **S23** *„Bin mit meiner aktuell verwendeten Methode (Anm. Rhythmusüberwachung mit Blutdruckmessgerät) grundsätzlich zufrieden.“*

When asked how likely it is that they would buy a smartwatch on the recommendation of an internist, 33.3% of the subjects (n=10) stated that it is reasonably likely. Another ten subjects (33.3%) stated that it is very likely. Six subjects (20%) considered the purchase of a smartwatch on recommendation of the internist to be highly probable. Four subjects (13.3%) answered that the purchase of the smartwatch is unlikely for them. Figure 39 summarizes the results of the question concerning purchase intention on the recommendation of an internist.

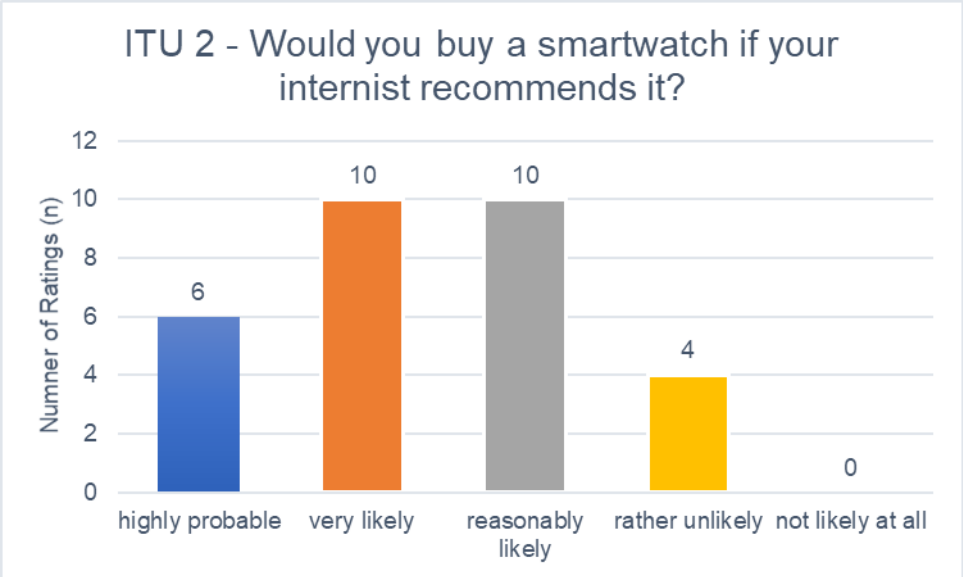

Figure 39 Results of ITU2

The majority of the subjects (43.3%; n=13) stated that they would spend €250 on a smartwatch. Five subjects (16.6%) were willing to invest more than €400 in a smartwatch, while six subjects (20%) would be willing to spend €150 on this technology. One male subject would only spend €50 on a smartwatch while three women would be willing to invest €350 in the purchase. Two subjects did not answer this question. Figure 40 shows the results of the last question of the intention to use scale.

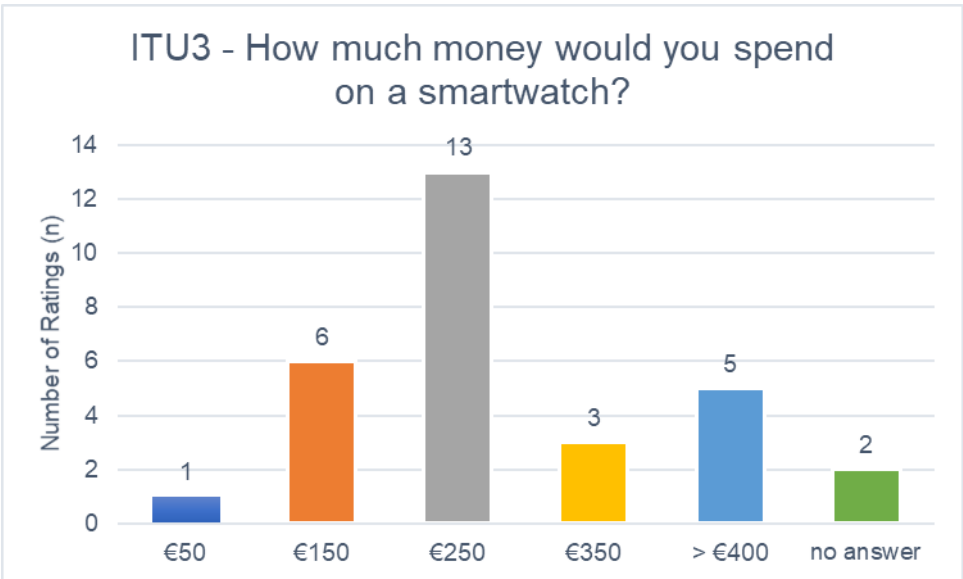

Figure 40 Results of ITU3

5.2 Physician group

Based on the previously defined inclusion criteria, five male cardiologists from the clinical environment were recruited for the expert interviews. Among the interview partners were one primary physician, three senior physicians and one assistant physician. The interviews were conducted between 21 February and 8 March 2019. The average duration of the interviews was 9 minutes. The longest interview lasted 14:30 minutes and the shortest was 7:16 minutes. The expert interviews took place either in the office of the respective physician or in the diagnostic room of the cardiac catheterization laboratory.

The evaluation and presentation of the results followed the categories already developed for the discussion guide for the expert interview. Each category will be presented and illustrated by quotes from the subjects.

Usefulness

The development of commercially available smartwatches from fitness monitors to health monitors was positively evaluated by all experts. The future benefits of these devices in the early detection and aftercare of atrial fibrillation are estimated to be high.

One expert believes that the possibility of a rhythm analysis which can be performed by the user of a smartwatch will lead to an increase in the awareness of atrial fibrillation. This could help to detect the disease earlier and to prevent possible strokes. Another physician also sees a great benefit for the device in the early detection of asymptomatic atrial fibrillation. In his opinion, preventive examinations for the detection of this disease are probably just as important as preventive colonoscopy and mammography.

The ease of use of this technology and the safety that people can achieve by recording and documenting their circulation are also highlighted. Smartwatches could give patients the opportunity to take an ECG if they experience cardiac arrhythmias.

„Ich glaube, dass das etwas sehr Praktisches ist, um genauere Aussagen über die Herzfunktion zu haben, die über tägliche Schrittleistung oder ein regelmäßiges Blutdruck messen hinausgehen.“ – E3

A further advantage is seen in the possibility of being able to send the data directly to a doctor for a second opinion. By interpreting these ECGs, it would also be easy to distinguish between atrial fibrillation and other cardiac arrhythmias such as extra

systoles. Only in the case of fainting would it be difficult to monitor an ECG with the current system.

One cardiologist believes that the smartwatch fills an important gap. The long-term ECG, which is conventionally used for diagnostics, is limited to a period of 24 to 72 hours. If no arrhythmia occurs during this period, no diagnosis is made. Cardiac arrhythmias that only occur every few weeks cannot be detected with this diagnostic method, but with the aid of a smartwatch they may be recognized. The other alternative would be an implanted loop recorder. However, not every patient wants this invasive procedure.

All the experts interviewed agree that a smartwatch is a useful addition to the current diagnostic possibilities. However, it should be noted that the diagnosis should always be verified by a 12-channel ECG and the use of this technology should be subject to some form of medical or nursing control.

"Also prinzipiell ist das auf jeden Fall eine positive Entwicklung und ein guter Nutzen. Nichtsdestotrotz sollte es, wenn der Verdacht da ist, natürlich immer noch verifiziert werden, durch ein „gescheites" EKG." – E1

„Es sollte in gewisser Form einer ärztlich, pflegerischen Kontrolle unterliegen. Das ist sinnvoll." – E4

Experiences/Usability

All five experts are already familiar with the KardiaBand system. Three physicians have experience with KardiaMobile by the company AliveCor, another similar system which detects atrial fibrillation. One expert said that he already occasionally receives ECGs recorded using the KardiaBand from patients. One physician did not have any experience with the KardiaBand.
After testing the device, all experts were impressed by the simple functionality of the device and quality of the recorded ECGs.

Three physicians have been asked by patients about the possibility of rhythm monitoring using a smartwatch. They have all made recommendations.

"Ich habe das durchwegs empfohlen, wenn die Bereitschaft von Patienten oder interessierten Laien, die sich mehr mit ihrem Kreislauf beschäftigen wollen an mich herangetragen wurden." - E3

„Ja vor allem sportliche, junge Patienten verwenden das immer wieder. […] Also ich finde es nützlich, dass die Patienten Smartwatches zur Rhythmusüberwachung verwenden." - E4

Scepticism

One physician is somewhat sceptical about the use of smartwatches in the detection of atrial fibrillation.

“Ich bin sehr skeptisch, dass das funktioniert, weil einfach der Patient den Hintergrund der Erkrankung medizinisch nicht versteht und sagen kann, ich bin mir sicher, das ist Vorhofflimmern und gehe jetzt ins Krankenhaus. Sie werden halt viel kommen und sagen ich habe eine Arrhythmie gesehen. So wie es beim Blutdruckmessgerät oft der Fall ist. Es ist kein eigenständiges Diagnosetool, es braucht jemanden, der dann interpretiert was kann das sein, was kann das bedeuten.“ – E4

He is also concerned about leaving the patient alone with a possible arrhythmia diagnosis made by a smartwatch. Furthermore, he expressed concerns about data protection and is concerned that sensitive health data may not be stored in a sufficiently secure manner.

Four out of the five physicians expressed little scepticism towards smartwatches. They believe that the advantages of this technology outweigh the disadvantages.

„Es gibt auch ohne Smartwatch distanzlose Patienten und es gibt welche die sich an die Regeln halten. Die distanzlosen werden distanzlos bleiben und werden das Tool nützen um noch distanzloser zu sein.“ – E2

It should be emphasised that the appropriate education and training of patients must be provided. Patients must be taught what the rhythm analysis of their smartwatch can indicate and how to deal with it. One physician states that the definition of rules between the people involved contributes to the fact that the use of the smartwatch brings the desired support without burdening any of the sides.

Where patients can already present documentation of the rhythm disorder, this is perceived as an advantage. It is considered simple to distinguish between severe or less severe symptoms with the aid of a smartwatch record,.

„Also für mich ist das eindeutig ein Vorteil, wenn Patienten in die Sprechstunde kommen, nicht weil sie Rhythmusstörungen haben oder Herzstolpern spüren, sondern, weil sie schon einen dokumentierten Befund haben.“ – E4

Two physicians mention that all diagnostic examinations can lead to false positive and false negative results.

“Auch bei Loop-Recordern, ist oft wenn man den Loop-Recorder abfragt, eine falsch detektierte Episode von Vorhofflimmern oder einer anderen

Rhythmusstörung da. Falsch positiv, falsch negativ, vor allem falsch positiv wird es immer geben." – E1

„Aber das ist bei jeder Untersuchung so, dass es Sensitivitäts- und Spezifitätsprobleme gibt. Auch, wenn ich in einer Mammographie was sehe und es ist dann kein Krebs, habe ich die Patientin trotzdem verunsichert." – E5

One expert emphasized that a smartwatch ultimately cannot replace a visit to the doctor.

Clinical Implication/Use Cases

All physicians interviewed believed that smartwatches can be integrated into clinical care scenarios if their accuracy has been validated by studies. In addition, the storage of the recorded data on a secure server would have to be ensured.

Some possible use cases for smartwatches were also mentioned.

According to physicians, smartwatches can be used for screening for atrial fibrillation. Their use in the documentation of cardiac arrhythmias was also considered. The documentation would allow the establishment of a correlation between symptoms and ECG. This would provide the possibility of obtaining a diagnosis or of excluding a disease, especially for patients who have palpitations or other complaints and for whom a long-term ECG has not led to a diagnosis.

„Und gerade bei Patienten, die immer wieder Palpitationen haben, die nicht fassbar sind im EKG, kann das ein Tool sein, welches man den PatientInnen, wenn sie technik-affin sind, empfehlen kann, wenn er/sie es nicht schon hat und das dann zu einer Diagnose führt." - E1

„Andererseits gibt es viele Leute, die anfallsartig Herzrasen haben, das sind dann kurze Herzrhythmusstörungen, die dann nie dokumentiert werden […] Auch, wenn ich die Rhythmusstörung dadurch, dass es nur eine Ableitung ist, nicht einwandfrei diagnostizieren kann […] kann ich zumindest sagen hat der was oder hat er nichts. Eine Aussage Vorhofflimmern ja/nein dürfte von diesen Tracings her funktionieren, zumindest richtungsweisend ist es auf jeden Fall." - E4

The use of smartwatches for monitoring heart rhythm and pulse was noted. They can also be used as a supplement to monitor frequency in patients treated with antiarrhythmic drugs or beta blockers. According to the physicians, this is also a simple way of clarifying non-specific heart complaints.

The use of smartwatches is also considered in patients with atrial fibrillation at risk of stroke.

„Das glaube ich wäre ein Einsatzgebiet um möglicherweise Schlaganfälle zu verhindern, wenn man nur genau genug schaut, wäre das möglich." – E4

The next step in the development of smartwatches is seen by one of the physicians as an algorithm that allows a recording of rhythm changes without active triggering from the patient. He also believes in daily activity monitoring using a smartwatch within primary medical prevention as well as within the treatment of heart failure and claudication.

"Patienten sagen sie gehen schlecht oder haben Schmerzen beim Gehen und wir wissen eigentlich nicht, wie viel sie gehen. Da sehe ich noch viele Möglichkeiten, die Therapie besser anzupassen oder den Therapieerfolg, sei es jetzt konservativ, chirurgisch oder interventionell besser zu objektivieren." – E4

6 Discussion

Past studies have already proven that a smartwatch can detect atrial fibrillation with a high degree of accuracy (Bumgarner et al., 2018; Tison et al., 2018). The results of the present study show that both physicians and patients are convinced of the usability of commercially available smartwatches for the detection of atrial fibrillation. In addition, the smartwatch is regarded by both study groups as a useful tool for the detection of cardiac arrhythmia. The majority of the patient group stated that they would like to use the smartwatch. All physicians can envisage the clinical implications of the technology.

6.1 Usability

After a hands-on trial and after completing a usability test, the subjects of the patient group assessed the usability of the tested smartwatch with an average System Usability Score of 83 out of a possible 100 points. Looking at this result from the acceptability ranges proposed by Bangor et al. (Bangor et al., 2009), the smartwatch falls into the Acceptable range. They also developed a grading scale in which an SUS score of 83 represents a “B”. Lewis and Sauro stated in their work “Item Benchmarks for the System Usability Scale” that it becomes a common industry goal to achieve an SUS of over 80 because this is equated with above average usability (Lewis & Sauro, 2018). The fact that all subjects were able to pass the usability test without any problems and the impressions of the subjects themselves as stated in the questionnaire correspond with these interpretations.

There were no differences in the evaluation of usability according to gender, and male and female subjects gave usability almost the same points. The highest usability rating was achieved in the age group of subjects younger than 60 years. Subjects older than 70 years awarded almost the same System Usability Score. Subjects aged between 60 and 70 years rated usability with the lowest scores. It should be noted, however, that the lower ratings of the respective groups are still within the acceptable range of Bangor. Experience with technical devices and their regular use shows positive effects on the usability ratings within the patient group. It was found that subjects who regularly use more than two technical devices rated usability higher than those who use only one device regularly. Liang and Kortum stated that user experience is an important factor that influences usability (Kortum & Bangor, 2014; Liang et al., 2018). According to their findings, the more

experienced users are with the device to be evaluated, the higher the usability rating. The usability evaluations in the pilot study show that even general user experience with technical devices may also have a positive influence on usability ratings.

In the present study, no subject expressed usability problems due to the small display of the smartwatch. This is in contrast to the results of a study conducted by Chun, where some participants noted usability problems due to small screen size (Chun, Dey, Lee, & Kim, 2018).

All physicians, who took part in the study also praised the usability of the smartwatch. Some have already recommended the use of a smartwatch for rhythm monitoring to their patients, when they have been asked for their opinion.

6.2 Technology Acceptance

Most subjects of the patient group stated that a smartwatch could support them in dealing with their cardiac arrhythmia and would lead to an increased feeling of security in everyday situations. In addition, some subjects believe that the use of a smartwatch could strengthen their health awareness regarding atrial fibrillation. Some subjects stated that the use of these devices could contribute to a faster diagnosis of cardiac arrhythmia because it offers the possibility of recording an ECG outside a hospital or a doctor's office. The use of a smartwatch in the detection of atrial fibrillation was met with hardly any scepticism by the patient group. These findings are quite interesting because female subjects, in particular, showed anxiety about technology in general. This could indicate that if a concrete application of a technology is perceived as useful and benefits the user, its advantages outweigh the anxiety towards technology in general. Similar results were obtained in a study investigating the perceptions of individuals over 65 years of age towards smartwatch technology for assessing pain (Manini et al., 2019). They also revealed an interest in the use of a new technology if the perceived usefulness and potential benefits were given.

Rosales et al. explored the expectations and initial experiences of people older than 65 years towards smartwatches (Rosales, Fernández-Ardèvol, Comunello, Mulargia, & Ferran-Ferrer, 2017). Their participants did not plan to use smartwatches for health monitoring and, for heart monitoring in particular, they relied on their specialized devices. The results of the present study deviate to a large extent from these findings. Nevertheless, some subjects have also stated that they rely on their current method of heart monitoring.

The subjects of the Physician Group perceive the smartwatch as a useful addition to current diagnostic options. They believe that by giving patients the opportunity to record an ECG themselves and to receive a rhythm analysis via the smartwatch, the awareness for atrial fibrillation will increase. This may lead to the earlier detection of asymptomatic atrial fibrillation. Furthermore, the ECGs recorded with the aid of a smartwatch would allow an easier distinction between atrial fibrillation and other cardiac arrhythmias. Furthermore, a smartwatch could contribute to the detection of cardiac arrhythmias that occur outside the usual 24 to 72 hours monitoring window of long-term ECGs. However, all physicians stated that a verification of the smartwatch findings by a 12-channel ECG is always necessary. Additionally, appropriate education and training of patients with the smartwatch technology must be ensured.

Interestingly, no subject of the Patient Group raised privacy concerns. The possibility of forwarding data to a physician was seen as an advantage which contributes to an increased feeling of security. Similar findings are noted by Askari et al. in their investigations of drivers and barriers in smartwatch acceptance by senior citizens (Askari, Huldtgren, & IJsselsteijn, 2019). The participants of their study also did not mind sharing their health data with their physicians as it would allow them to monitor their health.

In the present study, one physician expressed concern that the privacy of sensitive personal data should not be ignored and that in the case of the clinical implications of this technology, the storage and transmission of this data should only take place on secure servers.

6.3 Limitations

Although the results of the pilot study point out interesting insights, it has some limitations.

The current study was conducted in the Landesklinikum Wiener Neustadt department for cardiology. Therefore, all physicians interviewed can be considered experts in cardiac arrhythmias. Their attitudes towards the use of smartwatches in the detection of atrial fibrillation may differ from the attitudes of physicians from other disciplines. Furthermore, only people, who have already been diagnosed with atrial fibrillation, were included in the Patient Group. Healthy people may have different opinions towards the use of a smartwatch for the detection of atrial fibrillation. The results may not be generalized for the entire population.

As the study was not conducted in any collaboration with AliveCor and Apple, only one watch was available for the study, which was purchased by the study leader. The smartwatch was provided to the subjects by the study leader. Therefore, they only had the possibility to test the smartwatch within a controlled setting. Also, due to the treatment schedule of the subjects before the catheter ablation, it was not possible for them to test the watch for a longer time.

7 Conclusion

Commercially available smartwatches offer the possibility for screening and monitoring atrial fibrillation. The adoption of these devices by patients and physicians requires that these devices are easy to use and accepted by both groups.

In the pilot study, both patients and physicians were enthusiastic about the usability of the smartwatch provided to them. Patients praised the ease of use of the watch in detecting atrial fibrillation. Physicians were enthusiastic about the simple functioning as well as the quality of the recorded ECGs.

Due to the perceived usefulness of the smartwatch, the patients were hardly sceptical about its use. It would support them in dealing with their disease and lead to an increased feeling of security in everyday life. Physicians also regard the smartwatch as a useful device within the detection of atrial fibrillation. They see the possibility of implementing the smartwatch as an additional diagnostic tool into clinical care scenarios if patients were provided with the necessary education and training in using the smartwatch. Nevertheless, they emphasized that the use of this device should in some way be supervised by physicians or nurses and it should be kept in mind that a smartwatch cannot replace a visit to a physician.

The future benefits of the smartwatch are expected to be high. The majority of patients stated that they would like to use a smartwatch. The fact that a large number of them already survey their cardiac arrhythmia by using a blood pressure or wristband device indicates that there is an interest in monitoring atrial fibrillation. Physicians see potential use cases of the smartwatch in the screening and documentation of atrial fibrillation as well as for the long-term monitoring of patients treated with antiarrhythmic drugs or for those who are at risk of stroke. For all these applications, however, the accuracy of the smartwatch requires further evaluation. Furthermore, the ideal population for the use of the system must be defined. Data forwarding and storage on a secure server must also be guaranteed.

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Appendix

A. Information Sheet and Informed Consent - Patient Group

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ProbandInneninformation und Einwilligungserklärung zur Teilnahme an der Pilotstudie zu der Thematik

„Benutzerfreundlichkeit und Akzeptanz von Smartwatches[1] in der Erkennung von Vorhofflimmern"

Sehr geehrte Teilnehmerin, sehr geehrter Teilnehmer,

Handelsübliche Smartwatches sind längst nicht mehr nur dafür da, um über Neuigkeiten zu informieren und um Aktivitäten aufzuzeichnen. Namhafte Hersteller statten ihre Geräte neuerdings auch mit Funktionen aus, die einen Beitrag zur Gesundheit der TrägerInnen leisten können. So verfügen einige Smartwatches mittlerweile über die Fähigkeit eine Herzrhythmusstörung zu erkennen und ein EKG abzuleiten. Die Erkennung von Vorhofflimmern wurde schon im Rahmen einiger Studien erfolgreich evaluiert.
Einige Geräte, wie auch jenes welches im Rahmen dieser Studie verwendet wird, sind bereits von der US-Zulassungsbehörde FDA als Medizinprodukt zugelassen.

Zweck der Studie

Die Fähigkeit von kommerziellen Smartwatches, Vorhofflimmern zu erkennen wurde bereits in einigen Studien nachgewiesen. Die bisherigen Untersuchungen waren auf die Überprüfung der Erkennung von Vorhofflimmern beschränkt, noch existieren keine Arbeiten über die Einstellung der AnwenderInnen gegenüber dieser Methode.

Die Studie wird als Teil einer Masterarbeit mit dem Titel *„Smart Detection of Atrial Fibrillation: Usability and Acceptance of a commercially availabe Smartwatch in a Clinical Setting"* durchgeführt. Das Ziel der Arbeit ist es herauszufinden, ob Smartwatches als benutzerfreundliches Gerät zur Erkennung von Vorhofflimmern angesehen werden. Außerdem soll die Akzeptanz dieser neuartigen Methode zur Detektion von Herzrhythmusstörungen untersucht werden.

[1] Eine Smartwatch ist eine elektronische Armbanduhr, welche ähnlich wie ein Handy bedient und auch mit diesem verbunden werden kann. Sie kann ebenso wie eine herkömmliche Uhr, Uhrzeit und Datum anzeigen, verfügt aber auch über zusätzliche Funktionen wie Schrittzähler, Pulsmessung etc.

Ablauf der Studie

Die Studie wird am Landesklinikum Wiener Neustadt durchgeführt und es werden insgesamt ungefähr 30 Personen daran teilnehmen. Für Sie würde ein Zeitaufwand von etwa 15 -30 Minuten entstehen.

Die Studienteilnahme setzt sich aus zwei Teilen zusammen: Zunächst werden Sie nach einer kurzen Einschulung und Probephase gebeten, mit einer Ihnen zur Verfügung gestellten Smartwatch einige Aufgaben zu erledigen. Im Anschluss daran erhalten Sie einen Fragebogen, um Ihren Eindruck von dem zuvor getesteten Gerät widerzugeben. Des Weiteren enthält der Fragebogen auch einige Fragen mit denen Sie gebeten werden die Akzeptanz dieser neuen Methode einzuschätzen.

Aus den Ergebnissen, welche durch die Auswertung der Fragebögen erlangt werden, soll ein Eindruck gewonnen werden, wie Personen, welche an Vorhofflimmern erkrankt sind, zum Einsatz von Smartwatches in der Erkennung und Behandlung von dieser Herzrhythmusstörung stehen. So soll das Potential dieser neuen Technologie für eine etwaige Verwendung im klinischen Bereich evaluiert werden.

Datenschutz

Alle in dieser Studie gesammelten Daten werden anonymisiert ausgewertet und dienen ausschließlich der Analyse der in dieser Masterthese behandelten Fragestellung. Sie werden nicht an Dritte weitergegeben. Es erfolgt keine namentliche Verknüpfung oder Nennung mit Ergebnissen der Befragung.

Freiwilligkeit

Ihre Teilnahme an dieser Studie ist freiwillig. Wenn Sie sich für die Teilnahme entscheiden, unterschreiben Sie bitte die Einwilligungserklärung am Ende dieses Dokuments. Sie haben jederzeit die Möglichkeit, die Studie ohne Angabe von Gründen abzubrechen.

Einwilligungserklärung

Name in Druckbuchstaben: .....

Geburtsdatum: .....

Ich erkläre mich bereit an der Studie zur *„Benutzerfreundlichkeit und Akzeptanz von Smartwatches in der Erkennung von Vorhofflimmern"* teilzunehmen.

Ich bin von der Studienverantwortlichen Susanna Weißenböck ausführlich und verständlich über das Ziel und den Ablauf der Studie aufgeklärt worden. Auftretende Fragen wurden mir verständlich und genügend beantwortet. Ich hatte ausreichend Zeit, mich zu entscheiden. Zurzeit habe ich keine weiteren Fragen mehr.

Ich habe den Text dieser ProbandInneninformation und Einwilligungserklärung, welche drei Seiten umfasst, gelesen und verstanden.

Ich weiß, dass ich die Teilnahme an dieser Studie freiwillig erfolgt. Ich kann diese Zustimmungen jederzeit und ohne Angabe von Gründen widerrufen.

Ich bin damit einverstanden, dass meine im Rahmen dieser Befragung ermittelten Angaben aufgezeichnet werden. Die Bestimmungen des Datenschutzgesetzes in der geltenden Fassung werden eingehalten.

Eine Kopie dieser ProbandInneninformation und Einwilligungserklärung, habe ich erhalten. Das Original verbleibt beim Studienverantwortlichen.

.....

Datum und Unterschrift des/der ProbandIn

.....

Datum, Name und Unterschrift der Studienverantwortlichen

B. Information Sheet - Physician Group

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/medien & digitale technologien
/fh///
st. pölten

Sehr geehrte Damen und Herren,

vielen Dank, dass Sie mir die Gelegenheit für dieses Interview geben. Mit Ihrer fachlichen Expertise leisten Sie einen Beitrag zu meiner Masterarbeit über die Thematik „BenutzerInnenfreundlichkeit und Akzeptanz von Smartwatches in der Erkennung von Vorhofflimmern".

Handelsübliche Smartwatches sind längst nicht mehr nur dafür da, um über Neuigkeiten zu informieren und um Aktivitäten aufzuzeichnen. Namhafte Hersteller statten ihre Geräte neuerdings auch mit Funktionen aus, die einen Beitrag zur Gesundheit der TrägerInnen leisten können. So verfügen einige Smartwatches mittlerweile über die Fähigkeit, eine Herzrhythmusstörung zu erkennen und ein EKG abzuleiten. Diese wurde bereits im Rahmen einiger wissenschaftlicher Studien erfolgreich evaluiert (Bumgarner et al., 2018; Chon & McManus, 2018; Tison et al., 2018). Aufgrund ihrer Funktionen im Bereich der Arrhythmieerkennung haben Smartwatches das Potential, sich als unterstützendes Monitoring-Tool im Gesundheitssystem zu etablieren. Dies hängt allerdings sehr stark von der Akzeptanz dieser Methode durch ÄrztInnen und PatientInnen ab. Auch die BenutzerInnenfreundlichkeit der bisher am Markt befindlichen Geräte hat Einfluss auf die Breite der Umsetzung in der Bevölkerung.

Ziel meiner Arbeit ist es, sowohl die Einstellung von PatientInnen als auch ÄrztInnen zu dem Einsatz von Smartwatches in der Erkennung dieser Herzrhythmusstörung zu erforschen. Um die Einschätzung von an Vorhofflimmern erkrankten Personen gegenüber dieser Technologie zu evaluieren, führe ich aktuell eine Pilotstudie durch.
Um meine Arbeit abzurunden, möchte ich nun auch erfahren, wie Sie als ÄrztInnen über den Einsatz von Smartwatches in der Erkennung von Vorhofflimmern denken und Ihnen hierzu einige Fragen stellen.

Das Interview wird etwa 15-30 Minuten in Anspruch nehmen. Allen Befragten werden dieselben Fragen gestellt. Um die Ergebnisse des Gespräches besser dokumentieren zu können, würde ich das Interview gerne mittels Aufnahmegerät aufzeichnen. Ich bitte Sie, mir diesbezüglich Ihr Einverständnis zu geben.

Bumgarner, J. M., Lambert, C. T., Hussein, A. A., Cantillon, D. J., Baranowski, B., Wolski, K., … Tarakji, K. G. (2018). Smartwatch Algorithm for Automated Detection of Atrial Fibrillation. *Journal of the American College of Cardiology*, *71*(21), 2381–2388. https://doi.org/10.1016/j.jacc.2018.03.003

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C. Usability Test Tasks – Patient Group

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Test zur BenutzerInnenfreundlichkeit

Bitte erfüllen Sie die folgenden Aufgaben mit den Ihnen zur Verfügung gestellten Geräten.

Aufgaben:

1.) Bitte legen Sie die Uhr an Ihrem linken Handgelenk an.
2.) Rufen Sie über das Menü die Kardia App auf und öffnen Sie diese.
3.) Zeichnen Sie mit der App ein EKG auf.
4.) Navigieren Sie mit Hilfe der digitalen Krone durch Ihr EKG.
5.) Schließen Sie die App auf der Smartwatch.
6.) Öffnen Sie die Kardia App nun auf dem Tablet.
7.) Rufen Sie Ihr soeben aufgezeichnetes EKG in der Chronik der App auf.
8.) Versenden Sie Ihr EKG als PDF-Datei.
Als Versenden gilt im Test-Szenario der Druck auf das richtige Symbol. Ein tatsächliches Senden der Datei ist nicht notwendig.

D. Questionnaire - Patient Group

Fragebogen zur Pilotstudie

„BenutzerInnenfreundlichkeit und Akzeptanz von Smartwatches in der Erkennung von Vorhofflimmern“

Teil 1 Demographische Daten - Angaben zur Person:

Alter: ..... Jahre

Geschlecht: ☐ weiblich
☐ männlich

Höchste abgeschlossene Ausbildung:

☐ keine abgeschlossene Ausbildung

☐ Pflichtschule/Hauptschule

☐ Lehre/Berufsausbildung

☐ Fachschule/Handelsschule

☐ Matura

☐ Universität/Fachhochschule

Welche technischen Geräte verwenden Sie?

	Nie	Selten	Einmal pro Woche	Mehrmals pro Woche	Täglich
Computer/Laptop	☐	☐	☐	☐	☐
Tablet	☐	☐	☐	☐	☐
Smartphone	☐	☐	☐	☐	☐
Smartwatch	☐	☐	☐	☐	☐

Teil 2 BenutzerInnenfreundlichkeit:

Die folgenden Aussagen beziehen sich auf die BenutzerInnenfreundlichkeit der soeben getesteten Smartwatch in der Erkennung von Vorhofflimmern.
Bitte kreuzen Sie Zutreffendes an.

	Lehne völlig ab	Lehne ab	Neutral	Stimme zu	Stimme völlig zu
Ich kann mir sehr gut vorstellen, regelmäßig eine Smartwatch zu nutzen.					
Ich empfinde die Funktionen der Smartwatch als unnötig komplex.					
Ich empfinde die Smartwatch als einfach zu nutzen.					
Ich denke, dass ich Unterstützung bei der Nutzung der Smartwatch benötigen würde.					
Ich finde, dass die EKG-Funktion gut in die Smartwatch integriert ist.					
Ich finde, dass die Verbindung der Smartwatch mit der zugehörigen App nicht gut funktioniert.					
Ich kann mir vorstellen, dass die Bedienung der Smartwatch für die meisten Personen schnell zu erlernen ist.					
Ich empfinde die Bedienung der Smartwatch als sehr umständlich.					
Ich habe mich bei der Nutzung der Smartwatch sehr sicher gefühlt.					
Ich musste eine Menge Dinge lernen, bevor ich die Smartwatch bedienen konnte.					

Teil 3 Technologieakzeptanz:

Die untenstehenden Aussagen beziehen sich einerseits auf die Akzeptanz der soeben getesteten Smartwatch in der Erkennung von Vorhofflimmern und andererseits auf Ihre Einstellung zu Technologien im Allgemeinen. Bitte kreuzen Sie Zutreffendes an.

	Trifft gar nicht zu	Trifft nicht zu	Neutral	Trifft zu	Trifft völlig zu
Ich mache mir oft Sorgen darüber, dass mich neue technische Geräte überfordern könnten.					
Im Laufe meines Lebens habe ich mir viel technisches Wissen angeeignet.					
Die Verwendung einer Smartwatch würde mich im Umgang mit meiner Erkrankung unterstützen.					
Ich denke, dass die Nutzung dieser Technologie immer mit einem gewissen Risiko verbunden ist.					
Wenn ich ein neues technisches Gerät verwenden soll, bin ich zunächst misstrauisch.					
Wenn ein neues technisches Gerät auf den Markt kommt, informiere ich mich darüber.					
Eine Smartwatch würde mir zu einem verbesserten Sicherheitsgefühl in Alltagssituationen verhelfen.					
Eine Smartwatch würde meine Alltagsroutine stören.					
Mir fällt es schwer technischen Geräten zu vertrauen.					
Ich informiere mich über neue technologische Entwicklungen.					
Die Verwendung einer Smartwatch würde mein Gesundheitsbewusstsein meine Erkrankung betreffend, stärken.					
Die Anwendung einer Smartwatch würde mir mehr Nachteile als Vorteile bringen.					

Würden Sie die von Ihnen getestete Smartwatch gerne nutzen wollen? Erklären Sie bitte kurz in eigenen Worten warum, beziehungsweise warum nicht?

Wie wahrscheinlich ist es, dass Sie sich auf Empfehlung Ihres/Ihrer Internisten/Internistin eine Smartwatch kaufen würden?

- ☐ Äußerst wahrscheinlich
- ☐ Sehr wahrscheinlich
- ☐ Einigermaßen wahrscheinlich
- ☐ Eher nicht wahrscheinlich
- ☐ Überhaupt nicht wahrscheinlich

Wie viel wären Sie bereit, dafür auszugeben?

☐ 50€ ☐ 150€ ☐ 250€ ☐ 350€ ☐ mehr als 400€

E. Questions Expert Inteviews – Physician Group

Masterthesis Project, Susanna Weißenböck BSc
Digital Healthcare, St. Pölten University of Applied Sciences

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1. Handelsübliche Smartwatches entwickeln sich vom Fitnessgerät immer mehr in Richtung Gesundheitsmonitor. Einige Geräte haben die Fähigkeit mittels Aufzeichnung eines 1-Kanal EKGs Herzrhythmusstörungen zu erkennen. Wie schätzen Sie den Nutzen dieser Geräte ein?

2. Ist Ihnen das KardiaBand System, welches von mir im Rahmen meiner Pilotstudie verwendet wird, bekannt? Hatten Sie schon die Möglichkeit, es zu testen und eventuell medizinische Erfahrungswerte mit dieser Technologie zu sammeln?

3. Wurden Sie von PatientInnen schon auf die Möglichkeit der Rhythmusüberwachung mittels Smartwatch angesprochen und um Ihre Meinung dazu gebeten?

4. Das frühzeitige Erkennen von Vorhofflimmern ist ausschlaggebend für die Prognose. Sehen Sie ein Potential von Smartwatches als Monitoring-Tool, welches dabei hilft ein mögliches Vorhofflimmern zu erkennen und eine weiterführende ärztliche Abklärung einzuleiten?

5. Smartwatches bieten eine Kombination aus Herzfrequenzüberwachung und Konnektivität. Könnte die kontinuierliche Pulsüberwachung Ihrer Meinung nach ähnlich wie aktuell beim Loop-Recorder zur Langzeitüberwachung von PatientInnen in der Nachsorge nach beispielsweise einer Pulmonalvenenisolation eingesetzt werden?

6. Denken Sie, dass sich Smartwatches sinnvoll in klinische Versorgungsszenarien integrieren lassen?

7. Wo sehen Sie im Rahmen der aktuellen Diagnostik- und Behandlungsstrategien mögliche Einsatzgebiete für Smartwatches?

8. Es gibt auch einiges an Skepsis gegenüber Smartwatches in der Erkennung von Vorhofflimmern. Manche ÄrztInnen befürchten überfüllte Spitalsambulanzen bzw. verunsicherte PatientInnen aufgrund der „Selbstdiagnose" mittels Smartwatch. Wie ist Ihre Einstellung demgegenüber? Wo sehen Sie Vorteile und Nachteile dieser Technologie?

9. Gibt es Dinge, die Ihnen zu diesem Thema wichtig sind, jedoch bislang in keiner Frage aufgetaucht sind?