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Adopting Modern Fitness Sensors to Improve Patient Care

Master's Thesis at Ulm University

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Abstract

Technology found in modern fitness sensor devices advances at a very fast pace and current smartwatches are on the verge of closing the gap between being an everyday object and a medically reliable monitoring device.

In this thesis, the possibility of adopting fitness sensor devices in medical environments is explored and use cases in which sensor devices can be deployed are examined. Their successful transfer from the area of sports to medical analyses and treatments may help patients to deal with their illnesses and to improve the level of patient care found today.

Privacy and security issues as well as social concerns associated with such a disruptive evolution are discussed and practical tests of a pulse oximeter in various activities of daily living are conducted. The collected health data depicts a close representation of the performed activities. Furthermore, three types of fitness sensor devices were used in different real-life scenarios and the resulting data is compared. The results show that the recorded vital signs may differ significantly, depending on the scenario.

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1 Introduction

In recent years, public awareness of the importance of fitness and health has increased. People try to live healthier and exercise more. However, that often lasts only for a short period of time and most people fall back into bad habits. As a way to stay motivated longer, many people start keeping track of their sport activities and the resulting progress. *Fitness sensor devices* can be a helpful tool in this difficult mission. They record *vital signs* and other measurable characteristic values during the activities and provide ways for their users to later analyze the data and share results with friends, which gives them additional motivation due to peer recognition. Companies have recognized this demand and the need for technological progress in this area to help their customers *quantifying* themselves.

As a result, the range of available fitness sensor devices has widened considerably. Advancements were made not only regarding the size of the devices and their connectivity via wireless communication technologies such as *Bluetooth*, *Bluetooth Smart* and *Near Field Communication*, but also regarding their measuring capabilities. What once were single purpose sensor devices, has now advanced into devices carrying multiple sensors combined. Current fitness sensor devices can track, among other data, the user's *pulse rate*, *blood oxygen saturation*, *skin temperature* and his *physical activity*. Some of these features can also be found in *smartwatches* which are another up and coming trend in mobile devices. Nowadays, smartwatches mainly take over some of the displaying functionality from smartphones but they also support measurement techniques such as *pulse oximetry* that determines pulse rate and blood oxygen saturation.

Many of the vital signs and characteristic values that can be measured by fitness sensor devices are equally relevant to the medical field, in particular to examinations, diagnostics and treatments. When combining this functionality with the wearing comfort and discretion of the form factor of a watch, it can be assumed that fitness sensors are well suited to complement current medical equipment. The potentially resulting benefits regarding patient

1 Introduction

care would not only be an improvement for the patients themselves but also for the medical personnel treating them. Well-known technology companies seem to have already identified this gap in monitoring equipment, such as Google, who announced that it is planning to release a sensor wristband meant to be used in professional medical contexts rather than for simple fitness tracking [9].

Even though fitness sensor devices may be able to provide medical information that has been missing thus far, one has to recognize that this type of information, namely health data, is considered very private. If the devices are worn constantly over a prolonged period of time, what they are meant to be, the analysis of the recorded data poses a substantial risk to the users' *privacy*. As health is also a very personal topic, there are *social* and *ethical* issues that have to be considered very carefully.

This thesis aims to show that fitness sensor devices are suitable and advanced enough to be adopted as medical equipment. It examines the usability and informative value of a fitness sensor in a set of diverse real-life scenarios. It further analyzes the accuracy of the recorded vital signs compared to fitness devices that deploy different methods of measuring. Interviews with doctors and medical personnel were conducted to find fitting use cases in medicine that can benefit from the introduction of such sensor devices. Technical, medical and social aspects as well as limitations that may occur are discussed.

The remainder of this thesis is structured the following way. First, an overview of related research is given in Chapter 2. Chapter 3 then lays out basic information about vital signs and describes methods of measuring these different vital signs. Chapter 4 first gives a listing of current fitness sensor devices. It goes on to present wireless communication technologies commonly used in these devices and in smartphones. Following that, the fitness sensor device is introduced which was used in real-life scenarios. Recorded health data is analyzed in regard to its capability to reflect activities performed during the performance of tests. Statistical tests are conducted to compare the resulting data of three fitness sensor devices to determine their deviations. In Chapter 5, additional medical concepts relevant to this thesis are explained, after which use cases are discussed in which sensor devices are deployed. Chapter 6 discusses privacy and security issues as well as social challenges that such application brings with it, while Chapter 7 summarizes the findings and discusses future areas of research.

2 Related Work

Automating certain aspects of patient care will be one of the many advantages of the adoption of sensor devices into health care and it will not only help reduce the work load of medical personnel but also improve existing processes. In [40], Marschollek et al. identify fall events as a major problem in regards to mortality, morbidity and financial costs, especially among the elderly. As a result, it is important to make an accurate *risk assessment* about which patients are most likely to fall in order to be able to take precautions.

In a study Marschollek et al. conducted, they examine the fall risk of 119 inpatients. They use conventional assessment tests, assessments done by an interdisciplinary care team, a newly developed logistic regression model and a newly developed sensor-based system. The regression model is based on basic clinical data such as *sex*, *body mass index*, *age* and also includes results from assessment tests such as the *Timed Up and Go test (TUG)*. The sensor-based assessment is based on gait and motion parameters such as *kinetic energy*, *pelvic sway*, *step length* and others that were recorded during a TUG and a 20 meter walk. The sensor equipment used is a wireless *triaxial accelerometer* that is attached to a belt worn around the waist. After one year, they revisit and interview 46 patients (mean age 81.3 years) about possible falls they had experienced. 73 of the initial 119 patients could not be included due to death, progressed illness, withdrawn consent or corrupted data. The results show their two proposed methods of basing the decision on logistic regression models and sensor data (accuracy of 72% and 70%) to be slightly better than the three existing methods (accuracy of 48%, 50% and 55%). However, they concede that the moderate performance of the existing methods may be due to the small sample size.

In [54], Schobel et al. present *XFitXtreme*, a proof-of-concept implementation of a mobile business application that integrates multiple sensor devices. Besides the fitness training scenario, they suggest three other possible use cases: A mobile health care business application may support physician in their daily *medical rounds* and supply additional health

2 Related Work

data in *unforeseen alarming* situations. It may enable rescue services to *faster determine* what kind of help a patient they encounter needs and it may also give *additional information* about a patient filling out a psychological questionnaire. After laying out the different ways that can be used in development, they chose to make XFitXtreme a *native* application over a *web-based* or *hybrid* application. Only that method provides them access to all the needed components like the Bluetooth communication stack which the other types do not expose or not to the extent necessary for the designed application. During the development process, the authors use two sensor devices: a *heart rate monitor* and a *pulse oximeter*. They encounter problems caused by *discrepancies* between these devices when it comes to establishing a Bluetooth connection, by *lacking documentation* of Bluetooth packet formats and by *interference* on the used frequencies.

Another approach to monitoring in health care similar to the one discussed in this work is the use of *wireless sensor networks (WSNs)*. WSNs consist of a number of very small autonomous sensor devices called sensor nodes or *motes* which can communicate wirelessly and usually relay their gathered information through a *gateway node* to an application. *CodeBlue* [39], developed in 2004 by Harvard researcher Malan et al., is the first WSN that was designed for a medical environment. As this was an early design of a sensor network for medical environments and mass casualty events, the authors concentrate mainly on the basic challenges such as setting up an *ad hoc* network without a preexisting wireless infrastructure and motes that have to be programmed via very *low-level* software.

In [32], Kargl et al. discuss security and privacy issues on the basis of the WSN-based *ReMoteCare*, a Pervasive eHealth Monitoring System (PEMS) they developed. They define the three distinct environments in which WSNs can be deployed: *individual home monitoring*, *hospital monitoring* and *large-scale monitoring*. The authors further list different types of attacks and derive corresponding types of attackers for them. An *external passive* attacker is not part of the sensor system and thus can not control it but can gather medical data by eavesdropping. Even with encryption in place he may still use the encrypted traffic to track users' locations or activities. An *external active* attacker can try to interact with the sensor system by modifying or forging genuine traffic. He can also try to overload the system using a denial-of-service (DoS) attack, temporarily rendering it unusable. Attackers that have control over system components, like employees or users, are named internal attackers. The *internal passive* attacker can also only listen to the wireless communication, however, he might circumvent encryption mechanisms. The *internal active* attacker can do

the most damage as he controls part of the system and can easily modify or forge data. The authors then specify different parts of the system that could be attacked and propose the countermeasures *encryption*, *authentication*, *integrity checks* and prevention of DoS attacks by *redundancy*. These security measures also take care of some of the privacy issues because only authorized medical staff has access to the recorded files. Issues regarding location privacy could be further lessened if location data is exclusively generated by the local sensor device and only revealed in emergency situations.

Security and privacy issues of health care information technology in general are discussed in [41]. Meingast et al. use the scenarios of *electronic patient records* and *in-home remote patient monitoring* to raise the questions of who owns health data, what should be stored and where and who has access to this data. They further discuss the possibilities of mining such medical data. Their solution, once more, is the use of encryption, authentication and access controls and also the development of *rules* and *policies* that regulate the access to patient data.

Igual et al. [26] present a review of recent studies about fall detection systems, a topic that is discussed in Section 5.4.2 of this thesis. They identify two categories in which all existing studies can be divided: context-aware systems (151 papers) and wearable devices (197 papers). 21 studies are included in both categories as they use a mixture of these two methods. Context-aware systems use stationary sensors that were previously distributed in the target area. Such sensors can be video cameras, floor sensors, pressure sensors, infrared sensors and microphones. Then, relevant features are extracted in order to distinguish falls from ordinary activities of daily living (ADL). A big advantage of contextaware systems is that there is no need for the user to constantly wear a sensory device on his body. At the same time, this also poses a disadvantage as the fall detection system is thereby limited to the area in which the sensors were placed beforehand. The opposite holds true for systems that use wearable sensor devices. Falls can be detected everywhere, inside and outside, but only if the users wears the sensor device. The wearable sensor device used in this kind of systems can be a stand-alone accelerometer or gyroscope, or they are sensors integrated into smartphones. Wearable sensor systems can use simple threshold-based methods for fall detection or machine-based methods. The latter are more sophisticated but require a higher level of mathematical understanding. Many studies report high accuracy, sensitivity and specificity levels between 90% and 100%, however a major flaw in nearly all studies is the absence of elderly test subjects, the overall low number of

2 Related Work

test subjects, the lack of long-term observations and the lack of tests conducted in real-life situations.

Important points of criticism regarding *single-purpose* fall detection systems are *cost* and *acceptance* of the application specific sensor devices and equipment they depend on. In [56], Sposaro et al. propose the deployment of a fall detection system that uses built-in sensors of smartphones for the detection. Due to the widespread use of smartphones, even among the elderly, there often are no additional costs and the users are already familiar with the interface to operate the system. They are also more discrete than dedicated devices. The authors present *iFall* as their solution, a fall detection application for Android — not to be mistaken for iFall developed by Salomon et al. [51], which uses a dedicated hardware device. Besides the actual detection of falls using the internal sensors, they focus on preventing situations in which a fall is *wrongly* detected and emergency services are requested by mistake. They implement several *safeguards* to reduce the number of false positives. Two of them are a screen shown to the user after a detected fall on which he can abort any further actions and the fact that the starting position of the smartphone before an assumed fall is taken into account.

A slightly different approach is taken by Majumder et al. [38], in which they use built-in smartphone sensors and try to *prevent* falls before they happen. In their implementation *iPrevention*, an iOS application for iPhones, they record and analyze the *gait* of the user. They use the gait and its patterns found in the way people normally walk to establish a baseline. If certain *abnormalities* occur in the gait, a visible and audible alarm is triggered that informs the user about his increased risk of falling so he can take appropriate measures to prevent a fall from happening.

This chapter covers the medical basics that are needed throughout the remainder of this work. It describes the vital signs that modern sensor devices are capable of recording and gives details about different methods of how these vital signs can be measured manually and digitally with sensors. Invasive methods are generally excluded because they can only be performed in a medical environment and are not relevant to the everyday use of fitness sensor devices by medical laymen. One exception is made for *blood glucose* in Section 3.1.4 as the accuracy of currently available non-invasive methods is too low.

Even though some of these characteristic signs such as *blood glucose* and *blood pressure* are not built into *multi-sensor* fitness devices because of the particular way they have to be measured, there are *stand-alone* sensor devices that support them. If needed, these stand-alone devices can be used in conjunction with other fitness sensor devices for the time being, until new ways are found that allow them to be integrated with other sensors.

3.1 Vital Signs

To get a basic understanding of what each vital sign represents, this section gives a short explanation for each of the vital signs relevant to this work. Although not vital signs in a strict clinical sense, the characteristics *physical activity* and *skin temperature* are also listed here. Especially physical activity is a feature that is included in a large number of consumer sensory devices. Even if these two characteristics may not be significant enough to draw conclusions about possible medical conditions of a patient, they may be used as a *supplementary* source of information to interpret other recorded vital signs more reliably and to make more accurate medical diagnoses.

3.1.1 Blood Oxygen

The human body needs *oxygen* (O_2) in order for it to survive. Oxygen is inhaled with every breath and is transported to the lungs where it is transferred to the blood by diffusion. A very small amount of oxygen is dissolved in the blood (only about 1%) while most of it is chemically bound to the so called *hemoglobin* (*Hb*), a protein that is a component of red blood cells. Each hemoglobin molecule can bind up to four O_2 -molecules. The *oxygenated* blood is used to distribute oxygen throughout the body where it gives off some of the oxygen. The then *deoxygenated* blood takes on *carbon dioxide* (CO_2), an element that is produced when nutrients and oxygen are converted into energy to sustain the human body. Carbon dioxide has to be released from the body so some of it is dissolved in the blood and some of it bound to hemoglobin and other molecules and then transported back to the lungs where the carbon dioxide is diffused into the lungs and exhaled [24]. Section 3.2.1 describes ways to measure the amount of oxygen contained in blood, called the *oxygen saturation*.

3.1.2 Heartbeat

In order for the steps mentioned in Section 3.1.1 to work, the blood somehow has to be transported through the body. This function is carried out by the heart and the beating of the heart. One heartbeat, also called one cardiac cycle, consists of the two major phases systole and diastole. In the systole, the heart is contracted by the heart muscle, builds up pressure and pumps oxygenated blood out into the aorta, the main artery, and deoxygenated blood out into the blood vessels in the lungs. Artery is the medical term for a blood vessel that carries blood away from the heart. Arteries carry deoxygenated blood when leading towards the lungs and oxygenated blood when going into the rest of the body. Blood vessels that carry blood towards the heart are called veins which also carry both kinds of blood. Oxygenated blood from the lungs to the heart and deoxygenated blood from the rest of the body towards the heart (cf. Figure 3.1). In the second phase, the diastole, the heart muscle relaxes and the heart is filled with blood again. Even without taking diseases into account, there are many factors that can influence how frequent a heart has to beat: age, sex, physical fitness, psychological state, weather and more. Since the heart is such a crucial organ (it pumps around 8,600 liters of blood per day), it is essential that it functions correctly [53]. Different methods of measuring the heartbeat are discussed in Section 3.2.2.

3.1 Vital Signs

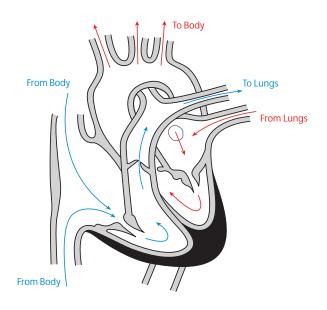


Figure 3.1: Simplified blood flow through the human heart. Red arrows stand for oxygenated blood, blue arrows represent deoxygenated blood [47].

3.1.3 Blood Pressure

Like every liquid that is pumped through pipes, the circulating blood exerts pressure on the pipes it is pumped through. In case of the human body, those pipes are blood vessels like *arteries* and *veins*. How high this *blood pressure* is depends on a variety of factors. Some parameters such as *age*, *sex*, *genetic predisposition* and overall *state of health* have a constant or only slowly changing effect. Others affect the blood pressure rapidly but just for a short time span. These short term effects include *physical activities*, *psychologically stressful* situations and *diseases*. Furthermore, blood pressure shows an *endogenic circa-dian periodic* pattern which means that it adapts to the human 24-hours day and has its minimal values at around 3:00 a.m.¹ and its maximal values at around 3:00 p.m.² local time. Section 3.2.3 gives insights on how to measure the blood pressure level. Low blood pressure, called *hypotension*, and its entailing poor blood flow can result in, for instance, cold hands and feet, headaches and dizziness. If the blood pressure is too high for a longer period of time, a condition called *hypertension*, it can strain blood vessels and cause heart attacks, strokes and kidney damage [44, 24, 53, 1].

¹Latin for ante meridiem; in the morning

²Latin for post meridiem; in the evening

3.1.4 Blood Glucose

Food supplies vital nutrients to the human body that are then converted to energy. A particular kind of essential nutrients are *carbohydrates* which consist of sugar-molecules. Monosaccharides are carbohydrates that consist of only one molecule or sugar. It is also called *glucose* and sometimes just referred to as sugar. As one of the main sources of energy, glucose, is transported through the circulatory system by the blood. The glucose level discussed in Section 3.2.4 is a measurement for the amount of glucose in blood. This level can fluctuate and if it is low, humans become hungry, the signal that new energy is needed. If it sinks too low, it can cause seizures and reduced brain functions. A constantly heightened glucose level in the blood can be the result of *missing insulin* or a built up *insulin resistance* as insulin normally helps to regulate the blood glucose level. The high level can be a symptom of *diabetes mellitus* which is going to be an important issue in the future. Its alarming development is visualized in Figure 3.2. The estimated number of 387 million people (aged 20 to 79 years old) suffering from diabetes in the year 2014 is expected to increase to 592 million by the year 2035 [30, 24, 53].

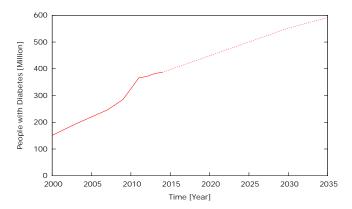


Figure 3.2: Estimated number of people (ages 20 to 79) suffering from diabetes (solid line) and its predicted growth in the near future (dashed line) [29, 30].

3.1.5 Physical Activity

Even though *physical activity* is not a typical vital sign per se, it can give useful information when analyzed together with other vital signs. Collected data about the physical activity of a

patient can include the *position* of his body (or at least of the body part the sensor is placed on) relative to the floor and the positive and negative *acceleration* his body experiences (or, again, the acceleration of the body part where the sensor is placed). More information can be derived using these two sets of data, for example a system for *fall detection* as discussed in Section 5.4.2 or for counting the steps taken in a day. The technical side of measuring these parameters is described in Section 3.2.5.

3.1.6 Skin Temperature

The human body needs a relatively *constant* temperature of $36.5 - 37^{\circ}C$ in its core, where all the important organs are located, to function properly [33]. If it deviates to much from this default value, the body has regulatory mechanisms it can use to bring the temperature back to normal. One way to counteract too low core temperature is the *shivering* of muscles that produces heat. Another is to *reduce* the blood flow to the extremities and the skin which results in a lower *skin temperature* as the heat is kept more to the core of the body. A way to decrease the core temperature in case it is too high is *sweating*. Sweat on the skin evaporates which results in a *cooling effect*. The temperature of the skin is normally slightly lower than the core temperature [36]. Since the skin temperature depends very much on external factors and can vary substantially, it is difficult and not always possible to draw conclusions about the core temperature from it. However, skin temperature can be a helping indicator to prevent false diagnoses when treating patients with chronic pain [37] and in other cases it may be used as an *additional* source of information and help to better interpret the results. Section 3.2.6 gives information on how skin temperature can be measured.

3.2 Methods of Measurement

The previous section established a basic understanding of the different characteristic signs used in medical diagnostic. However, these vital signs have to be measured in order to be used as indicators and parameters of medical conditions. This section describes how these measurements are taken and what sensors can be used to integrate them into sensor

devices. Having that in mind, the main focus is directed to *non-invasive* methods as these are the important ones for long term measurements in everyday situations.

3.2.1 Blood Oxygen Saturation

The standard non-invasive method of measuring the *arterial blood oxygen saturation* is *pulse oximetry*. To be precise, pulse oximetry measures the amount of hemoglobin that carries oxygen in relation to hemoglobin that has no oxygen bound at the time, as detailed in Section 3.1.1. A pulse oximeter has two *light-emitting diodes (LEDs)* of different wavelengths. One with *red* light at a wavelength of 660 *nm* and one with *infrared (IR)* light at a wavelength of 940 *nm*. Placed opposite of the two LEDs is a *photodetector*, normally a photo diode, that can sense these two wavelengths (cf. Figure 3.3). In order to measure the oxygen saturation, the patient's fingertip or earlobe is placed between the LEDs and the detector, usually by clipping the pulse oximeter to either one of them. The device *alternates* between activating the red LED, activating the infrared LED and having both LEDs off and the photodetector takes three measurements of the light that passed through the body part. One measurement when the red LED is on, one when the infrared LED is on, and one when both LEDs are off in order to account for *ambient light* that may otherwise interfere with the result. Then it starts again with the red light and goes through this loop again and again.

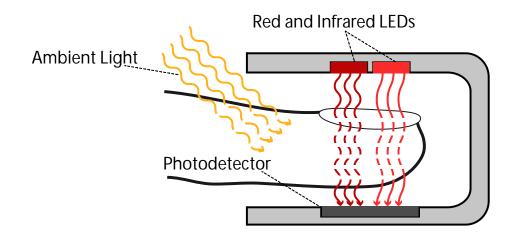


Figure 3.3: Pulse Oximeter placed on a finger with the red and infrared LEDs, interfering ambient light and photodetector.

Some of the red light is *absorbed* while passing through the body part and deoxygenated blood absorbs more of the red light than oxygenated blood. In contrast, more infrared light is being absorbed by oxygenated blood than by deoxygenated blood when passing through the body part. The oximeter further utilizes the *changes* in absorption that happen when the blood circulates after each heartbeat to exclude *static interference* caused by skin, fat and other tissue, for example, so the oxygen saturation of just the arterial blood can be determined [59]. As a byproduct, the pulse rate that is discussed in the next section can be measured.

The general abbreviation for oxygen saturation is SO_2 . To clarify which method was used to determine the oxygen saturation, the terms *peripheral capillary oxygen saturation* (SpO_2) and *arterial oxygen saturation* (SaO_2) are used. SpO₂ refers to the measurement by pulse oximetry and SaO₂ refers to the *invasive* method of arterial blood gas, at which a blood sample is taken from one of the arteries and the oxygen saturation is analyzed in a laboratory. Normal values for SpO₂ are 96 - 100% [53]. Pulse oximetry, especially with fitness sensor devices, is susceptible to *interference* such as nail polish on fingernails. More factors are listed in Section 4.3.1.

3.2.2 Heart Rate and Pulse

Every time the heart beats, it pushes blood through the entire human body as described in Section 3.1.2. The frequency of these beats is called *heart rate* and is measured in *beats per minute (bpm)*. The circulating wave of blood being pumped into the arteries and through the body with each heartbeat results in a sudden and short increase in pressure within the arteries and veins. This spike can be detected in the head and the extremities (i.e. arms and legs) and the pulsating wave is called the *pulse wave*. The rate of these spikes, the *pulse rate*, is measured in beats per minute (bpm) as well. The pulse includes further characteristics to describe the pulsation of blood: Is the pulsation *evenly* spaced or is it *arrhythmic*? Is the pulse *weak* or *strong*? How *quickly* does the *increase* and *decrease* of blood in the artery happen? Average pulse and heart rates for healthy humans when resting are $60 - 100 \ bpm$ [58].

The heart rate can be measured in a non-digital way by the use of a *stethoscope*. It is placed on the upper chest of the patient in the area where the heart is located and it enables

the user to hear the so called *heart sounds*. Normally, two somewhat different sounds can be heard for every beat of the heart. These sounds are caused by *muscular contractions* closing different valves in the heart. The heart rate of a healthy adult is the half the number of sounds heard in 60 seconds. A digital method of measuring the heart rate and the go-to measurement for many health issues is the *electrocardiography (EKG)*. It can give much more detailed information about the condition of a heart than just the heart rate. The EKG uses the fact that the beating of a heart is triggered by small electrical currents and that there is depolarization in heart muscle cells during every heartbeat. This creates electrical fields that can be measured outside the body by electrodes placed on the skin. These fields are then used to derive graphs such as the one in Figure 3.4 called *electrocardiogram* which can then be used for medical diagnoses. For example, the time lapsed from the top of one spike (called R wave) to the next is called *RR-interval* and it can be used to calculate the heart rate for this moment in time [17].



Figure 3.4: Electrocardiogram of a healthy young adult.

The same principles apply for fitness sensor devices that use a *chest belt* to read the user's heart rate. Two electrodes are placed on the inside of the belt with a little gap between them and need direct contact with the skin, like the EKG. Then, the measured heart rate is often displayed on a device that can be worn around the wrist, such as the device in Section 4.3.3. Or it is sent to a smart mobile device. While the EKG and chest belt can be used to continuously record the heart rate over a long period of time, there are also devices like stand-alone watches that have two electrodes on their surface. The user has to touch these two electrodes with two of his fingertips to get a reading of his heart rate. After he removes the fingertips from the electrodes the readings stop, so this solution is not feasible for long term recordings [50].

Manual measurement of the pulse rate is usually done by putting two or three fingertips on a place of the body where an artery can be felt from outside the body and applying slight pressure. Such places are *wrists, ankles, temples, neck* and others. Then, the number of spikes that occur within a 60 second time frame is counted and that number is the pulse rate. Using modern technologies, the pulse rate can also be measured via pulse oximetry as described in Section 3.2.1. Some fitness sensor devices use a slight variation to pulse oximetry with one red and one infrared LED. They have *green* LEDs instead, as does, for example, Apple's *Apple Watch*, which has infrared and green LEDs. The principle stays the same, however oxygen saturation and pulse rate are then measured with visible light.

Under normal circumstances, if the blood flow to the extremities is not obstructed by disease or physical influences from the outside and the heart functions at its full potential, the heart rate and the pulse rate are equal. With this in mind, the terms heart rate and pulse rate are used interchangeably throughout this thesis if not explicitly stated otherwise.

3.2.3 Blood Pressure

The most common non-invasive method of measuring blood pressure in clinics and practices is the Riva-Rocci method, named after the Italian physician Scipione Riva-Rocci (1863-1937) who improved the blood pressure meter that was used at that time and whose principle is still used today (cf. Figure 3.5(a)). The doctor places a *cuff* around the patients upper arm, ideally at heart level to prevent hydrostatic influences, and inflates it while listening to the arterial pulse of the arm with a stethoscope. By inflating the cuff, it applies pressure around the arm until the pressure is high enough to stop the blood flowing through the constriction even when the heart pumps blood into the arteries in its systole phase. No pulse can be heard through the stethoscope at that time. The doctor then slowly releases the air from the cuff, thereby decreasing the pressure on the upper arm, and simultaneously listens for the blood to start flowing again. When this happens and the rushing blood can be heard through the stethoscope, he takes note of the current pressure from a manometer that is attached to the cuff. This pressure is called the systolic blood pressure as it represents the highest blood pressure generated by the systole of the heart. The doctor proceeds to lower the pressure until the sounds of the pulse become dull or fade rapidly. Then, the pressure displayed on the manometer corresponds to the lowest blood pressure, called the diastolic

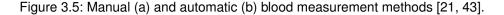
blood pressure, that happens in the diastole phase when the heart expands and refills with blood [63, 53].



(a) Manual Riva-Rocci method.



(b) Automatic blood pressure monitor.



Persistently high blood pressure is called *hypertension* and the opposite, prolonged low blood pressure is call *hypotension*. Hypertension is further categorized by its severity. Table 3.1 shows the three categories of hypertension according to the *World Health Organization (WHO)* [67]. The unit of measurement of blood pressure is *millimeters of mercury (mmHg)* and the blood pressure of a healthy 20 - 40-year-old adult should be at around $120 \ mmHg$ systolic and $80 \ mmHg$ diastolic. A systolic pressure of $100 - 150 \ mmHg$ and a diastolic pressure of $60 - 90 \ mmHg$ are considered normal.

Hypertension	systolic (mmHg)	diastolic (mmHg)		
Grade 1	140 - 159	90 - 99		
Grade 2	160 - 179	100 - 109		
Grade 3	≥ 180	≥ 110		

Table 3.1: The three grades of severity of hypertension according to the WHO.

Digital blood pressure meters (cf. Figure 3.5(b)) that work *autonomously* without a doctor listening with a stethoscope use the *oscillometric* method. The device typically has *piezo-electric* sensors that convert pressure into an electrical signal. When an occluding cuff that has these sensors integrated is placed around an arm and blood flows through the arm, the pulse influences the pressure of the cuff and using the magnitude of the resulting oscillations the pulse can be calculated. The actual measurement takes place in a similar way to the

Riva-Rocci method. The cuff is filled with air until the pressure exerted on the arm completely stops the blood flow. Then, the pressure is slowly reduced until faint oscillations are detected. After continuing to reduce the pressure, these oscillations disappear again [61, 35].

3.2.4 Blood Glucose Level

The blood *glucose level* represents the amount of glucose that is contained in blood and is measured in either *milligrams per deciliter (mg/dl)* or *millimoles per liter (mmol/l)*. Most glucose meters available today take their measurements in a *minimally* invasive way. Nevertheless, the measurements are invasive as they need a small amount of the patient's blood that they then analyze. The blood sample is usually obtained from the finger by pricking the fingertip with a small needle and is then applied on a test strip and inserted into the *glucose meter* (cf. Figure 3.6). Other places can be used to obtain the blood sample but the one from the fingertip shows changes in the glucose level more quickly [53, 64]. This invasive way can cause discomfort, more so because many diabetics have to measure their the glucose level *several* times a day.



Figure 3.6: Measuring the glucose level in a small drop of blood using a glucose meter [52].

In consequence, non-invasive ways of measuring the glucose level are a very pursued area of research. Some approaches try to determine the amount of glucose in other bodily fluids such as *sweat*, *saliva*, *urine* or *tears*. However, the glucose concentration in these

fluids is very low which makes accurate measurements difficult [60]. Nonetheless, Google announced that it is developing a *contact lens*³ that will have the ability to measure the glucose level of tears directly on the eye. They also explore the possibility of embedding LEDs into the lens in order to display information such as warnings of low blood sugar directly into the user's line of sight. In spite of the ingenuity of this idea, a Google developer stated in an interview that the glucose level measured by the contact lens will probably also show *delayed values* compared to the invasive measurements on fingertips⁴. Studies conducted in 2006 and 2012 came to the conclusion that some of the techniques explored for noninvasive glucose monitoring look promising but their *poor accuracy* still poses a problem [62, 55].

3.2.5 Acceleration

Measuring the *physical movement* and position of a sensor device and with it the movement and position of the person wearing it is accomplished in the same way in which the movement and position of smartphones is determined: by the use of *accelerometers*. An accelerometer, as the name suggests, measures acceleration which can manifest itself in *static* forces such as gravity or *dynamic* forces that occur during movement. Their functioning is best illustrated on the basis of a mechanical accelerometer (cf. Figure 3.7(a)). A so called *seismic mass* is suspended by a spring which connects it to the housing of the accelerometer. If the accelerometer is moved, the seismic mass lags behind and the direction and force of its onedimensional movement can be measured by how much the spring is stretched or compressed. Thus, three-dimensional movement can be measured using three accelerometers, one for each axis. The static position of an object such as a sensor device or smartphone can be determined by detecting the *gravitational force* that is exerted by the earth and pulls the seismic mass towards the ground.

Accelerometers integrated in modern devices range in the magnitude of a few hundred *micrometers* in size and they use *electrical signals* to measure their movement and position. Figure 3.7(b) shows an accelerometer whose parts form a comb-like structure and thereby differential capacitors, with one part that is fixed to the housing and the other part that can slightly move. When the accelerometer is moved, the distance between those plates

³http://googleblog.blogspot.de/2014/01/introducing-our-smart-contact-lens.html

⁴http://www.healthline.com/diabetesmine/newsflash-google-is-developing-glucose-sensing-contact-lenses

changes which results in a change of capacitance from which the strength of the movement that triggered the change can be deducted. Another option is to use a *piezoelectric* crystal such as *quartz* that creates small amounts of voltage when its crystal structures are placed under mechanical stress during acceleration [20, 11].

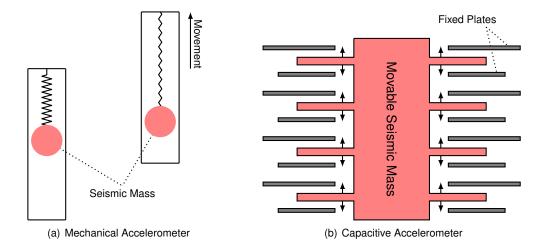


Figure 3.7: Principles of mechanical accelerometers (a) and capacitive accelerometers (b).

3.2.6 Skin Temperature

The *Angel* sensor wristband⁵ is one of only a few fitness sensor devices that offer the option of *skin temperature* as one of the recorded vital signs. If they do offer it, they use the same technology that has been used in electronic clinical thermometers for a long time. There are materials that change their *electrical resistance* depending on their temperature. Once they are calibrated, the skin temperature can be derived from the resistance that the element currently has. With *metals* such as platinum, copper or nickel, they are called *resistance temperature detectors (RTD)* and use the physical principle of positive temperature coefficient (PTC). When the material is *ceramic* or *polymer*, they are called thermistors, a combination of thermal and resistor, and the most common type when measuring temperature is the *NTC thermistor* which stands for negative temperature coefficient (NTC) [42, 57]. In order for this method of measuring temperature to work, the skin has to have direct and proper contact with the sensor.

⁵http://www.angelsensor.com

An alternative method that uses infrared does not need this close contact and allows the temperature to be taken remotely. IR thermometers utilize the fact that all matter with a temperature above *absolute zero* $(-273.15^{\circ}C)$ emits *thermal radiation*. The amount of emitted radiation depends on the temperature of the object. At very high temperatures, the radiation can even be seen by the naked eye, for example the red, orange or white glow of steel at temperatures above $600^{\circ}C$. An IR thermometer collects the radiation of the IR range that is emitted from the circular spot it is pointed at and uses an optical lens to focus it on a detector. The measured temperature is then shown on a display [49, 28]. Big advantages of this remote measuring of patient's temperature is the eliminated risk of *spreading infections* between patients when using the same device on multiple patients and the very short time of less than *one second* needed to take a reading.

4 Fitness Sensor Devices

In this chapter, the focus is on fitness sensor devices and what they are capable of. After a brief overview and comparison of sensor devices that are currently available on the market, there is information given about how they communicate with other devices, in particular about wireless communication technologies such as *Bluetooth*, the newer and more energy-saving *Bluetooth Smart* and *Near Field Communication*. In order to determine how well fitness sensor devices can perform measurements and provide health-related information in real-life situations, the *iHealth Pulse Oximeter PO3* was used in the execution of various test scenarios. Furthermore, the recorded data obtained by three different sensor devices was compared in a statistical analysis to find out if the data differs significantly or if their means can be considered equal.

4.1 Device Overview

The range of available fitness sensor devices has widened considerably in recent years. Once simple *single-purpose* devices that could only detect steps taken, they nowadays usually have *multiple* sensors integrated. Table 4.1 gives an overview of currently available consumer sensor devices and their sensory capabilities. The listing focuses on devices that have two or more different sensors and, where applicable, represent the flagship model of the respective manufacturer. Capabilities that depend on additional equipment such as chest belts for heart rate measurements are excluded. Due to the vast and rapidly evolving market, however, the list is not meant to be exhaustive. Besides *dedicated fitness sensor devices* such as the *Fitbit Surge* and *Angel's Angel*, it also includes *smartwatches* such as *Apple's Apple Watch* or *Motorola's Moto 360*. They may lack some of the features that dedicated fitness that dedicated fitness sensor devices have but still can provide useful health-related information about their owner.

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Device	Pulse	Movement	Skin Temp.	SpO ₂	GPS	Elevation
Amiigo (Amiigo)	\checkmark	\checkmark	\checkmark	\checkmark	_	
Angel (Angel)	\checkmark	\checkmark	\checkmark	\checkmark	_	
Apple Watch (Apple)	\checkmark	\checkmark			_	
Surge (Fitbit)	\checkmark	\checkmark			\checkmark	\checkmark
PO3 (iHealth)	\checkmark			\checkmark	_	
Peak (Intel Basis)	\checkmark	\checkmark	\checkmark		_	
Moto 360 (Motorola)	\checkmark	\checkmark			_	
Gear S (Samsung)	\checkmark	\checkmark			\checkmark	\checkmark
Pulse O _X (Withings)	\checkmark	\checkmark	_	\checkmark		\checkmark

Table 4.1: Overview of modern (fitness) sensor devices and their sensory capabilities.

All the devices in Table 4.1 are worn on the wrist and all but one can take their readings while being attached to it. Only the *Pulse* O_X from *Withings* has to be taken off of its wristband so that a finger can be placed on the back of the device in order to perform *pulse rate* and *blood oxygen saturation* measurements. *Pulse rate* and *physical movement* are characteristics that are quite commonly available in modern fitness sensor devices. Other characteristics, such as *skin temperature* and *blood oxygen saturation*, are not as common, most likely because they may either be not that significant or not cost-efficient enough. Some products such as the Angel wristband are still in an active development phase, are not yet released to the general public and may offer certain measurements only after a firmware update from the manufacturer. However, their features, specifications and design look very well suited to be used in certain areas of patient care.

4.2 Wireless Communication

Early models of sensory devices depended partially on *wired connections* to the device the data should be transferred to. Manufactures used *serial* and *Universal Serial Bus (USB)* connections among others to transfer stored information between devices. A few used *infrared* interfaces which made *wireless communication* somewhat possible, but the need for an unobstructed line of sight between the devices and the very limited range and transmission speed had a negative effect on user acceptance. Today's fitness sensor devices,

4.2 Wireless Communication

however, are always equipped with one or more wireless communication technology which presents the user with a much more convenient way to transfer data. The most commonly used technologies are *Bluetooth*, *Bluetooth* Smart and Near Field Communication. This section gives details about their specifications, their inner workings and their fields of application.

4.2.1 Bluetooth

Bluetooth is an omnipresent wireless communication standard with its origin dating back over 15 years. After being developed by *Ericsson* in 1994, its first official specification was published in 1999 and the *Special Interest Group (SIG)* tasked with creating a uniform standard for short-range wireless communication was created a year earlier [3]. Among the founding members were leading communication technology companies such as Intel, Nokia and the aforementioned Ericsson. The naming process of this SIG is worth mentioning because Bluetooth was only intended to be an *interim* code name until the members could agree on an official name. The name Bluetooth was derived from the Danish *King Harald Gormsson* who fittingly unified tribes of Sweden, Denmark and Norway into Scandinavia and whose nickname was *Blåtand*, meaning Bluetooth. The naming process, after suggestions like "Flirt — getting close, but not touching", resulted in the name *PAN* which stands for *Personal Area Networking*. However, the SIG ultimately was renamed to Bluetooth SIG after concerns about trademark issues arose. The Bluetooth logo is the combination of the two runes for H and B, Harald Blåtand's initials [2, 31].

Bluetooth devices use a frequency spectrum of 2, 400.0 MHz to 2, 483.5 MHz which is further divided into 79 channels with 1 MHz bandwidth each, a guard space of 2 MHz at the bottom and one of 3.5 MHz at the top to avoid interference with other technologies. To further minimize the impact of interference by other devices using the 2, 400 MHz band, Bluetooth performs *adaptive frequency hopping (AFH)*. It splits up the data into packets and uses one the 79 channels to send one packet before it switches to another channel in a predefined sequence at a rate of 1,600 hops per second. If AFH detects interference on one of the channels, it skips that channel in the following transmissions. Combining AFH with the 10 meters transmission range for devices in Bluetooth *Class 2*, the most common among mobile devices, makes Bluetooth very useful for wireless fitness sensor devices. It takes into

4 Fitness Sensor Devices

account that many devices may be used in a certain area such as fitness studios or sport events and it also helps to avoid problems with Wi-Fi networks that also use 2,400 MHz band. The average power consumption of Class 2 devices is 2.5 mW, however the following section will present the advanced Bluetooth Smart which is even more power saving. Classic Bluetooth offers data rates of 1 - 3 Mb/s [8, 6].

4.2.2 Bluetooth Smart

Bluetooth Smart was officially introduced as part of the *Bluetooth 4.0* specification in the year 2010. It is also known as *Bluetooth Low Energy* and *Wibree*. Similar to the classic Bluetooth technology, Bluetooth Smart uses the frequency spectrum 2,400.0 MHz to 2,483.5 MHz but with only 40 channels of 2 MHz bandwidth each instead of 79 channels with 1 MHz. It offers data rates of 1 Mb/s and its main distinction to classic Bluetooth is its low power consumption. According to the Bluetooth SIG, it ranges from 50% to as low as 1% when compared to classic Bluetooth, depending on the use case. A simple beacon device that sends out static information and that can be used as perimeter indicator in location-based services can be powered for one or two years with a single coin cell battery¹. Another advantage is the short amount of time it takes to establish a connection. It can be as low as 3 ms with Bluetooth Smart as compared to 100 ms with classic Bluetooth [7].

One additional feature that makes Bluetooth Smart a fitting communication technology for wireless sensor devices is the principle of *profiles* which it adopted from classic Bluetooth. Bluetooth Smart profiles are based on the *generic attribute profile (GATT)* which is used to define a common data structure between senders and receivers and to discover services that devices are offering. Using GATT as a common starting point, the derived profiles are then fitted for their specific use case. Profiles improve *compatibility* between different device manufactures and application developers and are an important factor as to why Bluetooth is so widely used.

Each profile includes a mandatory *primary service* and may include a secondary *auxiliary service* whose implementation can be optional or mandatory. For each service, *require*-*ments* and *dependencies* on other services can be defined, along with one or multiple *characteristics*. Characteristics ultimately define how a data value is *represented*, its *de*-

¹http://www.aislelabs.com/reports/beacon-guide

scription and properties [8]. Figure 4.1 shows the structure of the heart rate profile. The profile consists of the primary service called heart rate and a secondary service called device information. The service heart rate is then specified with the three characteristics heart rate measurement, body sensor location and heart rate control point. And finally, body sensor location, for example, defines that this information is represented by an 8-bit number and if this number has a value of 1, the sensor is located on the chest, if it has a value of 2, it is located on the wrist, and so on [5].

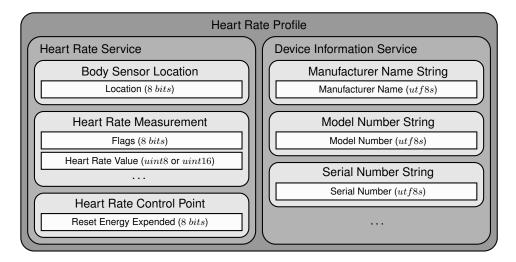


Figure 4.1: Structure of the Bluetooth Smart Heart Rate Profile (uint8 = 8-bit unsigned integer; uint16 = 16-bit unsigned integer; utf8s = UTF-8 encoded string).

The currently available profiles already cover many fitness and health-related values and new profiles are specified every so often. Some of the standardized profiles² relevant to fitness and health care are:

- Blood Pressure Profile
- Cycling Power Profile
- Cycling Speed and Cadence
- Glucose Profile
- Continuous Glucose Monitoring Profile
- Health Thermometer Profile
- Heart Rate Profile

²https://www.bluetooth.org/en-us/specification/adopted-specifications

4 Fitness Sensor Devices

- Pulse Oximeter Profile
- Running Speed and Cadence Profile

This *structured* approach to data transmission helps developers when creating new applications for smart mobile devices. It ensures *interoperability* across vendors and devices. As long as the sensor devices they want to connect with and gather data from adhere to the respective Bluetooth profile, it does not matter from whom the device is manufactured.

4.2.3 Near Field Communication

Near Field Communication (NFC) is a wireless communication technology that was derived from *Radio-frequency Identification (RFID)*. It uses the same physical principles as RFID but while RFID offers different frequency ranges depending on the situation (e.g. Low Frequency 125 - 134 kHz, High Frequency 13.56 MHz, Ultra High Frequency 860 MHz to 960 MHz), NFC only uses a subset of these frequencies (13.56 MHz). It supports two-way communication but can only operate within short distances of less than 4 cm and with transmission speeds of up to 424 kbit/s [16, 45].

Despite its low transmission speed and range compared to Bluetooth and Bluetooth Smart, NFC can be useful when an initial connection between two devices has to be established. A user can indicate which two devices he wants to connect by holding them closely together instead of having to chose the correct device from a listing in an application. NFC is then used to *negotiate* parameters for another connection that uses a different technology, for example Bluetooth. After that, this new and in most cases faster connection can be used to transfer user data. Google uses this approach for *Android Beam*, for example. Two Android devices have to be briefly held together back-to-back to initialize the transfer of data. Android then establishes a Bluetooth connection for the actual transmission and the users benefit from better speed and range from this point forward³. A well-established example that makes use of Android Beam is *Motorola Migrate*⁴, an application marketed by Motorola that helps users to transfer their data to a new smartphone. If both, the old and the new device, support NFC, Motorola Migrate offers the user the options to establish the first connection between the two devices by holding them back-to-back, after which the actual migration takes place

³https://developer.android.com/about/versions/android-4.1.html

⁴https://www.motorola.com/us/motorola-migrate/motorola-migrate.html

and contacts, media files and calendars among other data are transferred via Bluetooth while the devices can be held at a distance of more then a few centimeters.

NFC is a feature that many smartphones running Android, Windows or BlackBerry as their operating system have been supporting for quite some time. Apple has only recently released its first NFC enabled devices, the iPhone 6 and iPhone 6 Plus. NFC is not as common among tablets. No model of Apple's iPad supports it, however, there are some Android and Windows tablets that do⁵. The number of NFC enabled smart mobile devices will certainly grow as new applications are being developed and deployed. Google⁶, as well as Apple⁷, has announced the introduction of payment systems in cooperation with large credit card companies such as MasterCard, Visa and American Express that are based on NFC technology with which users will be able to pay using their smartphones. This will further add to the significance of NFC.

4.3 Hands-on Tests

This section describes the different tests that were conducted with a fitness sensor device. In order to gain *first hand insights* on whether or not such sensor devices present a useful source for health information that can improve medical diagnoses, *everyday situations* are analyzed, such as working a desk job while standing or making a short trip using trains and buses. Considering that the fitness sensor device used is not officially made for long term measurements during physical activity, the data of the sensor device is *compared* to data of other fitness sensor devices as a reference to gather information about the *accuracy* of the recorded data.

4.3.1 iHealth Wireless Pulse Oximeter PO3

The fitness sensor device used to conduct the following tests was the *iHealth Wireless Pulse Oximeter PO3*. It is manufactured by the 2009 founded California-based company *iHealth*

⁵https://en.wikipedia.org/wiki/List_of_NFC-enabled_mobile_devices

⁶http://officialandroid.blogspot.de/2015/05/pay-your-way-with-android.html

⁷https://www.visa.co.uk/products/visa-contactless/mobile-contactless/apple-pay

4 Fitness Sensor Devices

*Lab Inc.*⁸ which has a variety of different sensor devices in its portfolio. Besides the PO3, iHealth Lab also sells *blood pressure monitors*, *glucose monitors*, *scales*, and *activity and sleep tracker*, all of which are capable of wireless communication and send their data to smartphones and tables using Bluetooth or Wi-Fi connections. According to iHealth Labs, all their products are tested and adhere to the strictest clinical validation protocols⁹.



Figure 4.2: The iHealth Wireless Pulse Oximeter PO3 by iHealth Lab Inc.

The Wireless Pulse Oximeter PO3 (cf. Figure 4.2) is a finger clip sensor that measures the user's pulse rate and blood oxygen saturation. It can display the two measured vital signs on its screen, consisting of green LEDs, and send the data to a smart mobile device via Bluetooth Smart. The PO3 has an internal memory that can store up to 100 measurements which can then be accessed at a later point in time. Its display has further LEDs indicating an active Bluetooth Smart connection, a low or charging battery and whether or not it can detect a pulse rate. Figure 4.3 lists a few of the product specifications and recommendations given in the owner's manual [27] on how to use the device in order to get accurate readings. The manual also contains the disclaimer that "The Pulse Oximeter PO3 is not a medical device and should only be used by healthy individuals who are performing non-medical sports or recreational activities. It is intended to be used for spot monitoring and not for continuous monitoring" [27]. To what extent these two issues influenced the test runs will be addressed in the two following sections.

⁸http://www.ihealthlabs.com

⁹http://www.ihealthlabs.eu/en/content/106-clinically-validated

[...]

- 2. Display System: LED
- 3. Power Source: Lithium-ion battery
- 4. Peak wavelength: 660nm/880nm
- 5. SpO2 Measuring Range: 70-99%

6. Average Root Mean Square (ARMS) of SpO2 Accuracy: 80% \sim 99%: $\pm 2\%,$ 70% \sim 79%: $\pm 3\%,$ <70%: no definition.

- 7. Pulse Rate Measuring Range: 30-250 bpm
- 8. Pulse Rate Accuracy: 30 \sim 99 bpm: ± 2 bpm, 100 \sim 250 bpm: $\pm 2\%.$
- 9. Automatic Shut-off: After 8 seconds of no indication on the sensors
- 10. Operation Environment: 5°C-40°C; Humidity <80%

[...]

2. Limit finger movement as much as possible when using the device. Otherwise, the Pulse Oximeter PO3 might misinterpret excessive movement as good pulse strength.

3. Do not use the Pulse Oximeter PO3 on the same hand/arm when using a blood pressure cuff or monitor.

[...]

5. The Pulse Oximeter must be clean for a proper reading.

6. Your finger must be clean to ensure a proper reading.

7. Any of the following conditions may cause inaccurate measurements of the Pulse Oximeter, including BUT NOT LIMITED TO:

- Flickering or very bright light;
- Poor blood circulation;
- Low hemoglobin;
- Hypotension, severe vasoconstriction, severe anemia or hypothermia;
- Nail polish, and/or artificial nails;
- Any tests recently performed on you that required an injection of intravascular dyes.

8. The Pulse Oximeter PO3 may not work if you have poor circulation. Rub your finger to increase circulation, or place the device on another finger.

[...]

Figure 4.3: Excerpt from the iHealth Pulse Oximeter PO3 owner's manual [27].

4 Fitness Sensor Devices

4.3.2 Measurements

The equipment used during the realization of different test scenarios was the iHealth Pulse Oximeter PO3 and a Google Nexus 4 running Android 4.4.4. The recommended way of collecting and accessing health data recorded by a PO3 device is via the *iHealth Cloud*¹⁰ operated by iHealth Labs. The recorded pulse rate and blood oxygen saturation is uploaded to the iHealth Cloud by the official iHealth app that has to be installed. A developer of an application can then use a provided *application programming interface (API)* to access the data uploaded by the user of the sensor device. In the context of this research, though, this was not an acceptable method, especially the upload to a corporate cloud and storage of personal data on a third party system. There are not only security issues involved but it also poses certain risks to the users' privacy as discussed in Section 6.1.

An alternative method is the use of an *Android software development kit (SDK)* provided by iHealth Labs. This SDK enables the developer to *directly* receive pulse rate and blood oxygen saturation data in his Android application without a detour via their cloud. It keeps the compilation and storage of data locally between the pulse oximeter and the smartphone which not only *improves* performance but also *mitigates* privacy issues. Consequently, this access method was used in the test runs. It delivered about seven measurements for every second but because these seven data sets normally showed the same values and to reduce complexity, only the first measurement of every second was used in the subsequent data analysis.

Before starting with the actual tests, an initial experiment was conducted in order to determine possible alternative locations the iHealth Pulse Oximeter PO3 could be placed on. To this end, the finger clip was placed on a subject's earlobe in order to get a data sample but this did not give any usable results. It was difficult to find a position in which the vital signs were detected at all and the clip tended to slip off when moving even a little bit. However, even if it had been possible to collect data, Haynes showed in [22] that data collected by a pulse oximeter finger clip that is attached to the patient's earlobe is not reliable enough for clinical purposes.

¹⁰ http://developer.ihealthlabs.com/index.htm

Basic Indoor Activities

The first scenario in which vital signs were recorded was kept very simple and basic. The test subject was sitting in a chair and remained seated while keeping movements to a minimum. The duration of this test was 60 minutes and one measurement consisting of heart rate and blood oxygen saturation was recorded for every second. Figure 4.4 visualizes the results. The red graph represents the heart rate, the blue graph represents the oxygen saturation in the blood. The data itself is very inconspicuous, the oxygen saturation only fluctuates between 97% and 98% and has an average level of 97.52% (SE = 0.01)¹¹. The heart rate is also fairly steady with an average of 58.32 *bpm* (SE = 0.11), a maximum of 82 *bpm* and a minimum of 48 *bpm*. In the 30 minutes after marker *A* (cf. Figure 4.4), the subject dozes off which explains the very low heart rate up to marker *B* when he wakes up again. Compared to the readings in the following scenarios, the amplitudes of the heart rate graph are very small due to the lack of movement and relaxing characteristic of this test scenario.

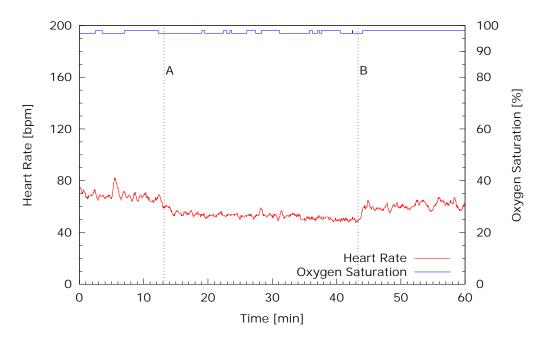


Figure 4.4: Pulse oximetry data of 60 minutes sitting still. After marker *A* there is a period of dozing off until marker *B*.

 $^{^{11}}SE \equiv$ standard error of the mean

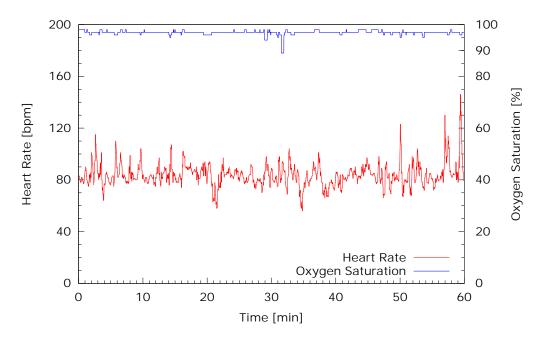


Figure 4.5: Pulse oximetry data of 60 minutes standing at a desk and walking around a few steps, simulating a workplace environment.

The second test scenario simulated an environment similar to an office space. Again, the duration was 60 minutes in which the test subject this time had to stand at a desk and use a computer or write things down. He also walked around several times but only a few meters. Figure 4.5 shows the resulting data points. The oxygen saturation fluctuates a bit more this time and is between 89% and 98% with an average of 96.93% (SE = 0.01). The heart rate has an average of 83.58 *bpm* (SE = 0.14), a maximum of 146 *bpm* and a minimum of 56 *bpm*. However, there are only a few heart rate values in the areas around the minimum and maximum value. The short time span in which the oxygen saturation is at its minimum of 89% is also a singular event which could indicate some *erroneous* readings because no correlation can be made to any special physical activity.

Outdoor Cycling

Having obtained good results in a *controlled* environment in the first two scenarios, further tests were conducted to find out about the *limitations* of the iHealth Pulse Oximeter PO3. Therefore, the device was used during an *outdoor* bicycle ride on a clear sunny day which

is way outside the conditions recommended by the manufacturer. Figure 4.6 shows the recorded data of the first 10 minutes of this trip. As can be seen by the discontinuous graphs, the reading was disturbed again and again and after it was obvious that no useful data could be retrieved this way, the test run was interrupted. However, the PO3 can not be blamed for this poor performance. It is caused by the surrounding environment that is too bright and by the vibrations the finger and the PO3 attached to it were subject to. It is rather a quirk of the pulse oximetry method of measuring and not device specific. As described in Section 3.2.1, pulse oximetry utilizes red and infrared light to detect the oxygen saturation and the pulse rate. If the ambient light is too bright and too much of it reaches the photodetector, the faint light that the two LEDs emit is overpowered by it which makes an accurate measurement impossible.

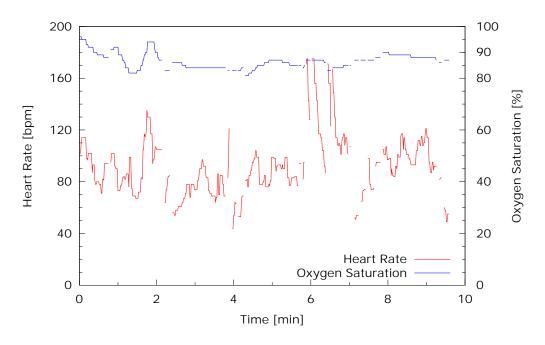


Figure 4.6: Incomplete pulse oximetry data of a 10 minute bicycle ride in for the sensor adverse conditions (sunny, cloudless) and with no supplemental cover used.

After some considerations, a working solution to this problem was found. The PO3 was covered up with a *bandage* which itself was fixated with *tape*. This helped in two ways: it *prevented* the sunlight to interfere with the LEDs of the pulse oximeter and it also *secured* its position on the finger. Furthermore, the test subject tried to separate the hand to which the pulse oximeter was attached as often as possible from the handle bar. The resulting

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heart rate and blood oxygen data is visualized in Figure 4.7. It can be observed that there are no data points missing which illustrates that the actions taken to modify the test setup were sufficient. However, especially the part about avoiding vibrations turned out to be a major *nuisance*, depending on the surface of the ground. If the road was paved and smooth, the vibrations were weak enough so that the handle bar could be grabbed and used as usual. If, on the contrary, the surface was rugged and bumpy like on a dirt track, the vibrations most likely would have interfered with the measurements which effectively meant driving *one-handed* on such tracks. This is not a solution that is practicable for general use, though, but served its purpose well during the test runs.

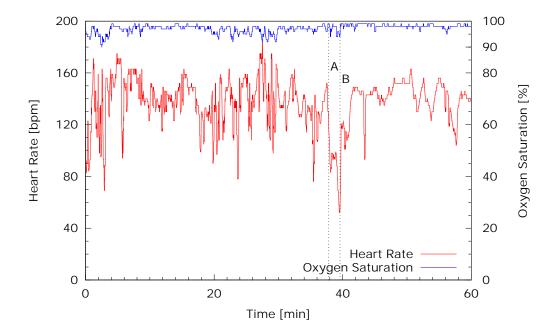


Figure 4.7: Pulse oximetry data of an 60 minute bicycle ride in adverse conditions for the sensor (sunny, cloudless) but with supplemental cover used. The low heart rate between marker A and B was due to a short stop to check the equipment for proper operation.

The resulting data in Figure 4.7 shows an average blood oxygen saturation of 97.18% (SE = 0.03) with a maximum of 99% and a minimum of 90%. The heart rate has a maximum of 184 *bpm*, a minimum of 52 *bpm* and averages at 136.80 *bpm* (SE = 0.32). Naturally, it varies a lot during the course of this test just like the level of physical strain fluctuates a lot, too, always depending on outside influences such as the properties and condition of the route and the direction and speed of the wind. It further is the first scenario in which the

recorded oxygen saturation level varies considerably which is also to be expected during a long-lasting sporting activity with varying physical strain. The low heart rate values between marker A and marker B (cf. Figure 4.7) occurred during a short stop in which the equipment was checked for proper operation.

Outdoor Activities of Daily Living

The first two test scenarios (sitting and standing) were kept simple to get some basic measurements, followed by the more extreme scenario of outdoor cycling which covers more of a fitness-related area. While it is not very hard to imagine that future sensor devices will also function properly under adverse conditions encountered in outdoor sports, it is even more likely that they will be suitable for *activities of everyday living*. The following two scenarios try to represent ordinary activities that one may do outside his home during a day. To prevent any major interference, the same *precautions* regarding ambient light were taken as during the cycling scenario, using bandage and tape.

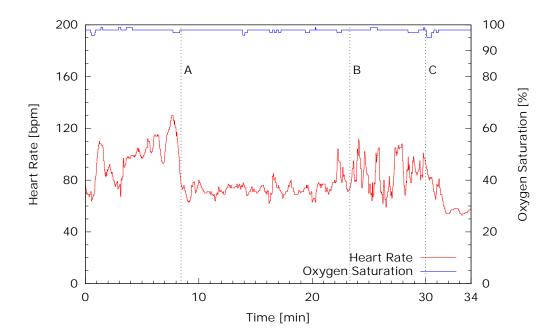


Figure 4.8: Pulse oximetry data of a 34 minute visit to a friend. Point *A* marks the arrival at the friend's house, marker *B* the departure from it and *C* the arrival at home including emptying the postbox.

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The first of these activities of daily living (ADL) scenarios was a visit by foot to a friend. The iHealth PO3 recordings cover 34 minutes of heart rate and oxygen saturation data which represents the time span between leaving the house and returning to it again. The corresponding visualization can be seen in Figure 4.8. The maximum heart rate of 130 *bpm* was reached shortly before arriving at the friends apartment at marking *A* and was caused by taking the stairs to the second floor. The stay itself, the time period between marker *A* and *B*, only consisted of some standing and walking and talking and therefore shows no interesting spikes. The period between *B* and *C* represents the walk home. *C* marks the arrival at home opening the front door and emptying the postbox, during which the minimum heart rate of 53 *bpm* occurred. The average heart rate during this test was 80.37 *bpm* (*SE* = 0.34). The oxygen saturation varied between 95% and 99% with an average level of 97.87% (*SE* = 0.01).

Basically, the activities during this test scenario can be summarized as 9 minutes of walking, followed by 14 minutes of staying in one place which is, again, followed by 7 minutes of walking home. In order to introduce a wider diversity of activities into the recording, the final test scenario was chosen to be a trip to the next major city, Ulm, in order to complete a fictitious task and returning home. The duration of this trip is 120 minutes and includes walking, trains and buses as means of transportation. Figure 4.9 shows the resulting blood oxygen saturation and heart rates. The maximum saturation is 99%, the minimum 87% and the average is 96.83% (SE = 0.03). The saturation level, again, fluctuates considerably. The maximum heart rate is 140 *bpm*, the minimum 53 *bpm* and the average heart rate is 78.19 *bpm* (SE = 0.20).

The recording in Figure 4.9 starts with the departure from home and the walk to the train station. The fluctuating vital signs reflect the also varying steepness of the route and even the short waiting period at a pedestrian light at minute 2 is reflected by a local minimum for the heart rate. At marker A, the test subject boards the train and sits down. The heart rate slows down and the oxygen saturation recovers and stays at 99% during the first train ride. Between B and C, the subject has to change trains which results in a rising heart rate and falling oxygen saturation. After marker C, at which point the test subject has boarded a connecting train and sat down, the heart rate falls and the oxygen saturation rises again. D marks the arrival at UIm central station where the test subject gets off the train, exits the station and makes his way to the S-Bahn. The time period between D and F represents the stay in UIm, including in this order: leaving the station, briefly riding on the S-Bahn while

standing up, walking through the city to the target destination, completing a task, walking back to the train station. Marker E is placed in the middle of the execution of the task which included waiting in line for some minutes. This explains the low heart rate and high oxygen saturation compared to the surrounding values. F marks the return to and arrival at Ulm central station where the test subject sits down and waits for his train. At marker G, he boards the train home and sits down. The spike of the heart rate at minute 86 occurred during a ticket inspection. The time after H includes alighting from the train, walking to a connecting bus, boarding it and sitting down at marker I. The bus ride ends at marker K, at which point the test subject gets off the heart rate in the end is caused by going upstairs at home.

All the scenarios, and in particular this last one, show that very detailed and expressive recordings of vital signs can be obtained by the use of sensor devices. Even a fitness sensor device that is only specified for brief spot checks of heart rate and blood oxygen saturation such as the iHealth Pulse Oximeter PO3 gives reasonable results when used for continuous measurements.

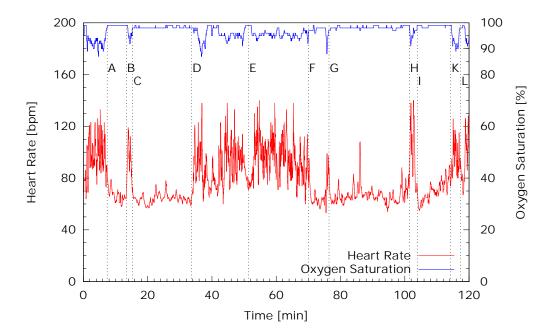


Figure 4.9: Pulse oximetry data of a 120 minute trip to the city of Ulm including the completion of a given fictitious task. See Table 4.2 for explanations for each marker.

4 Fitness Sensor Devices

Marker	Action
A	Having a seat after boarding the train.
В	Exiting train in order to catch a connecting train.
C	Having a seat after boarding the connecting train.
D	Exiting train and leaving Ulm central station towards the S-Bahn.
E	In the middle of completing the given task.
F	Arriving at the train station and waiting for the train home.
G	Having a seat after boarding the train.
Н	Exiting train in order to catch a bus.
Ι	Having a seat on the bus.
K	Getting off the bus and walking home.
L	Arrival at home, getting out the key and opening front door.

Table 4.2: Detailed explanation of the actions taken during the 120 minute recording of a trip to a major city (cf. Figure 4.9).

4.3.3 Comparing Sensor Devices

In three additional test runs, the heart rate displayed by the PO3 finger clip was compared to those displayed by other devices from different manufacturers using different methods of measurement. The second device was a Sigma PC9¹² heart rate monitor which is comprised of a chest belt that gathers the heart rate data and a watch that displays it (cf. Figure 4.10(a)). The third device was a Motorola Moto 360¹³ smartwatch (cf. Figure 4.10(b)) which measures the heart rate using pulse oximetry with two green LEDs as described in Section 3.2.2. All three tests were conducted over a time period of 30 minutes and the heart rate values displayed on each of the devices were recorded manually with a time interval of 30 seconds. The heart rate app Moto Body Heart Rate that is pre-installed on the Moto 360 does not support continuous measurements but only spot checks. Nevertheless, this app and its spot checks are used due to the lack of better alternatives. The measuring process of this app normally took 7-8 seconds so it was possible to time the readings to fit into the 30 second intervals. In some cases, the Moto 360 app was not able to successfully complete a measurement and it displayed the error message "Couldn't get it - Check your watch

¹² http://www.sigmasport.de/en/produkte/pulscomputer/topline/pc_9

¹³ http://moto360.motorola.com

placement and keep your arm still". In these cases, the readings of all three devices were disregarded and the measurement was repeated adhering to the given 30 second interval.



(a) Sigma PC9.

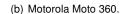


Figure 4.10: The watch component of the Sigma PC9 heart rate monitor showing a heart rate of 98 *bpm* (a) and the Motorola Moto 360 smartwatch showing its Moto Body Heart Rate application currently measuring (b).

Sitting

The first comparison scenario consisted of the test subject calmly sitting in a chair. He did not stand up and kept activities such as arm and head movement to a minimum during the 30 minutes test period. The blue graph in Figure 4.11 visualizes the 61 heart rate values taken with the iHealth PO3 finger clip attached to the left index finger, the red graph represents the data taken with the Sigma PC9 heart rate monitor and the green graph represents the heart rate values displayed by the Motorola Moto 360. The PO3 showed a minimum heart rate of 59 *bpm*, a maximum of 85 *bpm* and the calculated average heart rate is 73.20 *bpm* (SE = 0.76). The Sigma PC9 showed a minimum heart rate of 62 *bpm*, a maximum of 86 *bpm* and the calculated average is 73.28 *bpm* (SE = 0.81). The Motorola Moto 360 showed a minimum heart rate of 54 *bpm*, a maximum of 93 *bpm* and the calculated average is also 73.28 *bpm* (SE = 1.03). A total of 14 readings had to be repeated after the Moto 360 failed to get a heart rate measurement. One possible reason for this poor performance can be a weak pulse when sitting down and resting which makes measurements using pulse oximetry more prone to errors.

4 Fitness Sensor Devices

The interesting characteristics in these comparison tests are the deviations between the measured values of each of the devices. Since they all measure the same vital sign, they should display the same value. This is clearly not the case and Figure 4.12 shows the calculated deviation of all three devices to each of the other two devices. The blue graph represents the number of beats per minute the iHealth PO3 reading deviates from the Sigma PC9 reading. The number is positive if the PO3 displayed a higher value than the PC9, negative if the value was lower than the one on the PC9 and the deviation is 0 if they both showed the identical value. The red graph visualizes the deviation of values displayed by the Motorola Moto 360 to the ones displayed by the Sigma PC9 and the green graph the deviation of the Moto 360 to the PO3. The blue graph and with it the deviation between PO3 and PC9 seem to describe the smallest values compared to the other two graphs. Calculating the average of the deviations is not very meaningful since the values vary between being positive and negative. For example, the mean deviation between PO3 and PC9 is $-0.08 \ bpm$ and the one between Moto 360 and PC9 is $0 \ bpm$. However, it is obvious that the latter varies more than the former. A more significant characteristic in this situation is the standard deviation (SD), for whose calculation each single deviation is squared first so values with opposite signs will not cancel each other out when summing them up. The SD of the difference between PO3 and PC9 is 2.42 bpm and the SD of the difference between Moto 360 and PC9 is 4.56 bpm, nearly two times as high. This corresponds more closely with the graphs in Figure 4.12 and their represented heart rate values. The average deviation of the third pair of devices, the Moto 360 and the PO3, is $0.08 \ bpm$ (SD = 4.93). The maximum absolute deviation of a single pair of values was 16 bpm between Moto 360 and PO3, 13 bpm between Moto 360 and PC9 and only 8 bpm between PO3 and PC9. The heart rate values displayed by the iHealth PO3 and the Sigma PC9 matched in 15 (24.6%) of all 61 cases. There are only 4 (6.6%) matches between the Moto 360 and the PC9 and with 3 (4.9%)even one less match between the Moto 360 and the PO3. In only 2(3.3%) cases was the displayed value identical on all three devices.

Furthermore, statistical analyses were conducted to answer the question if the mean differences between devices vary significantly (H_a) or if they can be considered statistically zero (H_0) . The statistical test used was either the parametric *paired-samples t*-test if the differences between two devices were normally distributed or the non-parametric *Wilcoxon signed-rank* test if the differences were not normally distributed. The tests used to check for normal distribution were the *Kolmogorov-Smirnov* and the *Shapiro-Wilk* test. All statistical

tests were conducted using *IBM SPSS Statistics 21* [25]. If their results were not conclusive or contradictory, additional data such as the corresponding *frequency distribution* and Q-Q *plot* (cf. Appendix A.2) were consulted [14].

In this scenario, the deviation values between Moto 360 and PC9 and between Moto 360 and PO3 are normally distributed, however, the deviation values between PO3 and PC9 are not (cf. Appendix A.1). The reason for this are probably the many times the deviation between the PO3 and PC9 is 0 *bpm* or ± 1 *bpm* which results in a high kurtosis. A Wilcoxon signed-rank test used due to the absence of normal distribution showed that, on average, the displayed values of the PO3 (Mdn. = 71) and the PC9 (Mdn. = 72) do not differ significantly (z = -.593, p > .05). Paired-samples *t*-tests showed that neither is the average difference between PO3 (M = 73.20, SE = 0.76) and Moto 360 (M = 73.28, SE = 1.03) significant (t(60) = -.130, p > .05), nor is, on average, the difference between Moto 360 and PC9 (M = 73.28, SE = 0.80) significant (t(60) = .000, p > .05).

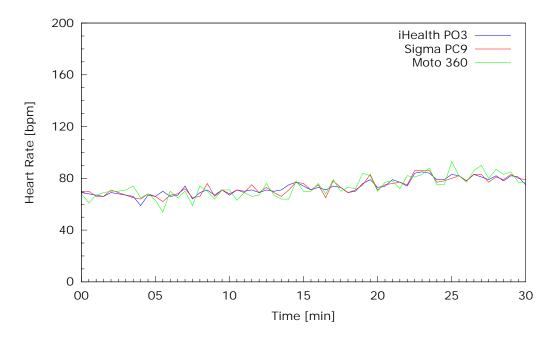


Figure 4.11: Comparison of heart rates gathered from iHealth PO3, Sigma PC9 and Motorola Moto 360 while sitting calmly in a chair.

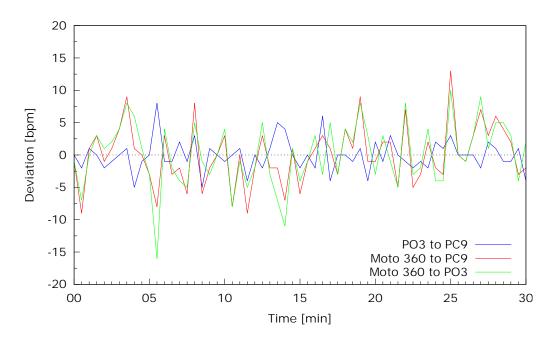


Figure 4.12: The deviations of the displayed values for each pair of devices while sitting.

Standing

The second comparison scenario is similar to the previously used second measurement scenario but it only included standing at a desk, working with a computer and pen and paper. The test subject did not move around other than normal foot movement while standing. Again, the three devices PO3, PC9 and Moto 360 were used to display the heart rate every 30 seconds over a period of 30 minutes. The PO3 showed a minimum heart rate of 68 *bpm*, a maximum of 86 *bpm* and the calculated average heart rate is 77.28 *bpm* (SE = 0.47). The PC9 showed a minimum heart rate of 70 *bpm*, a maximum of 87 *bpm* and the calculated average heart rate is 76.87 *bpm* (SE = 0.51). The Moto 360 showed a minimum heart rate of 68 *bpm*, a maximum heart rate of 93 *bpm* and an average of 77.85 *bpm* (SE = 0.68). The corresponding graphs can be seen in Figure 4.13. This time, the Moto 360 failed to conduct a successful reading only in 4 cases, compared to the 14 times in the previous scenario. Figure 4.14 shows the deviations between each pair of devices. The average deviation from iHealth PO3 to Sigma PC9 is 0.41 *bpm* (SD = 2.67, Max = 6), from PC9 to Moto 360 is 0.98 *bpm* (SD = 4.47, Max = 15) and from PO3 to Moto 360 0.57 *bpm* (SD = 4.44, Max = 14).

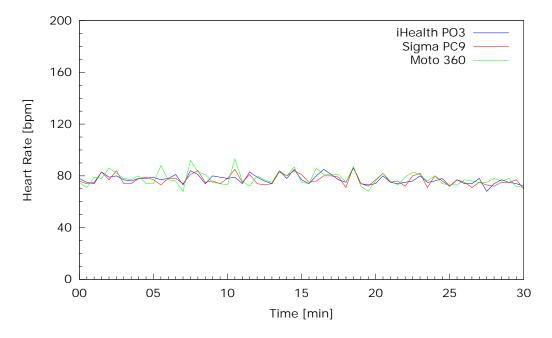


Figure 4.13: Comparison of heart rates gathered from iHealth PO3, Sigma PC9 and Motorola Moto 360 while standing and working at a desk.

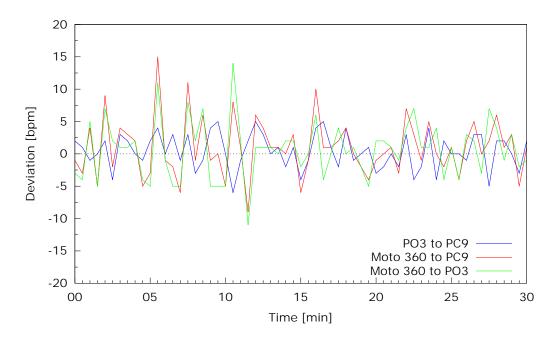


Figure 4.14: The deviations of the displayed values for each pair of devices while standing.

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The values displayed by the PO3 and the PC9 matched in 10 (16.4%) of the total of 61 cases. Only 6 (9.8%) matches occurred between the Moto 360 and the PC9 and with 4 (6.6%) matches between the Moto 360 and the PO3. In 0 readings the three devices showed matching values.

In this scenario, the tests of normality for all three device pairs were inconclusive (cf. Appendix A.1) however a visual inspection of the corresponding frequency distributions and Q–Q plots (cf. Appendix A.2) warrant the assumption of normally distributed deviations. Consequently, a paired-samples *t*-test was done for each pair of devices, however, the mean difference between the Sigma PC9 and the iHealth PO3 is not significant (t(60) = -1.197, p > .05). Nor is the mean difference between PC9 and Motorola Moto 360 significant (t(60) = -1.719, p > .05) and also the mean difference between the PO3 and the Moto 360 is not significantly different from zero (t(60) = -1.010, p > .05).

Cycling

The third test was conducted while cycling on a stationary indoor bicycle with increasing and decreasing intensity. This test run was only conducted with two of the three devices, the iHealth PO3 and the Sigma PC9. The Motorola Moto 360 was not suited for such an intense sporting activity due to its leather wristband. The high intensity during this test, compared to the first two scenarios, is also the reason for the high minimum and maximum values. In light of that, the minimum heart rate according to the iHealth PO3 data was 135 bpm, the maximum $184 \ bpm$ and the calculated average $154.48 \ bpm$ (SE = 1.74), which is represented by the blue graph in Figure 4.15. The Sigma PC9, represented by the red graph, showed a minimum heart rate of 131 bpm, a maximum of 180 bpm and a calculated average heart rate is $153.38 \ bpm$ (SE = 1.65). In 10 (16.4%) out off the 61 cases both devices displayed identical heart rate values and the maximum deviation between them was 5 bpm. All the deviation values between the two devices can be seen in Figure 4.16. They average at $1.10 \ bpm \ (SE = 0.23, SD = 1.79)$ and are not normally distributed. The thereby required Wilcoxon signed-rank test shows that the values displayed on the iHealth PO3 (Mdn. = 156), compared to the values displayed by the Sigma PC9 (Mdn. = 153), are significantly higher (z = -4.195, p < .001).

4.3 Hands-on Tests

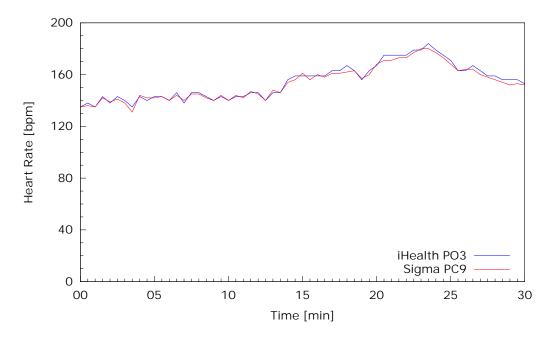


Figure 4.15: Comparison of heart rate values gathered from iHealth PO3 and Sigma PC9 while stationary cycling indoors.

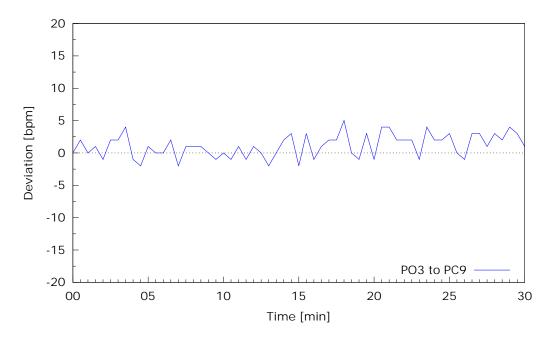


Figure 4.16: The deviations of the values displayed on the iHealth PO3 and the Sigma PC9 while cycling indoors.

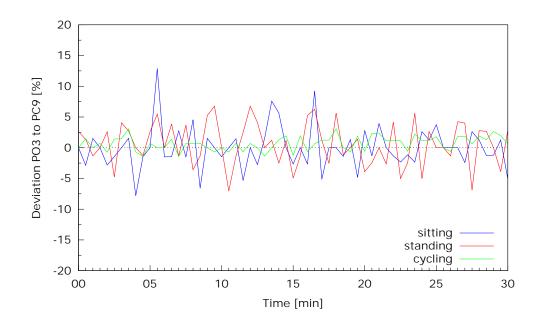


Figure 4.17: Comparison of the percentage deviations between the values displayed by the iHealth PO3 and the Sigma PC9 during the three scenarios.

In conclusion, all three devices report heart rate values that, on average, do not differ significantly from each other in activities of daily living with a relatively low heart rate. At the same time, singular outliers with high deviation can be observed, such as the $15 \ bpm$ (20.5%) deviation from the Motorola Moto 360 to the Sigma PC9 in the second scenario. Depending on the use case in which sensor devices are adopted, the occurrence of outliers has to be factored in to prevent erroneous conclusions that can result in false positives. One possible solution is to always look at series of values and compare each value to the preceding and succeeding mean level.

The cycling scenario showed that there can be a significant mean difference in measured values between different sensor devices. In 37 (60.7%) readings the iHealth PO3 displayed a higher value than the Sigma PC9, compared to 14 (23.0%) cases in which it showed a slightly lower value (cf. Figure 4.16). However, Figure 4.17 shows that even though the deviation is significant in the cycling scenario, the mean percentage deviation (using absolute values) while cycling (M = 1.08, SE = 0.10) is less than while sitting (M = 2.60, SE = 0.27) or standing (M = 2.84, SE = 0.26). That means that in these scenarios and using the iHealth PO3 and the Sigma PC9, the deviation between the devices did not increase proportionally to the increasing recorded heart rates.

Having discussed the basic vital signs and their measurement techniques in Chapter 3 as well as the capabilities and limitations of fitness sensor devices in Chapter 4, this chapter builds on this foundation and explores possible *real-life* medical use cases in which the deployment of sensor devices may improve patient care. This can be beneficial not only for the treated patients but also for the doctors involved in the treatment process. Well-known corporations such as Google are pursuing this area of research with great effort. Google not only plans to integrate a glucose meter in contact lenses as mentioned before but is also currently developing their own sensor wristband for the use in a medical environment¹.

The three scenarios examined here are the improvement of existing *fall detection systems*, an easier *verification* that the prescribed *dosage* of certain *medications* is adequate and an adaptive system for *dynamic oxygen regulation*. Important factors that are crucial for a successful adoption of sensor devices in medical applications are *patient compliance* and the *willingness of doctors* to utilize this technology. Furthermore, the concepts of *sensitivity* and *specificity* of medical testing are briefly introduced as they are relevant when discussing possible problems and challenges of the proposed solutions.

5.1 Sensitivity vs. Specificity

An important aspect of medical diagnostics is the *validity* of tests. A test and its results have to be accurate in order to be useful and valid. Diagnostic tests are called *binary tests* because their results can lead to one of two conclusion: the disease or illness is either *present* or *absent*. The objects of these tests are symptoms of diseases, which can,

¹ http://www.bloomberg.com/news/articles/2015-06-23/google-developing-health-tracking-wristband-for-health-research

however, vary from patient to patient to a certain degree. Their accuracy can be described by the concepts of *sensitivity* and *specificity*.

Sensitivity describes the probability that a test can detect a disease, given that the disease is in fact present in the test subject. Table 5.1 shows the four distinct possible outcomes of a test. On the one hand, there are those test subjects that are in fact diseased and the test will detect it, called *true positives*. In contrast to that, there are *false negatives*. Cases in which the test will not detect the disease, even though the test subject is diseased. The sensitivity of a test is calculated with Equation 5.1.

$$Sensitivity = \frac{\text{True Positives}}{\text{True Positives} + \text{False Negatives}}$$
(5.1)

If a test detects all X diseased as positive and misses none, its sensitivity is $\frac{X}{X+0} = 100\%$ which is the best possible sensitivity. If, however, the test detects X diseased but misses Y, the sensitivity $\frac{X}{X+Y}$ will decrease to a value less than 100%.

	Disease Present	Disease Absent
Test Positive	True Positive	False Positive
Test Negative	False Negative	True Negative

Table 5.1: Possible outcomes of a medical test.

Just like sensitivity characterizes how accurately a test can detect the truly diseased, specificity is used to describe how accurately it can identify the test subjects that are not diseased. The two remaining categories in Table 5.1 of test subjects that are not diseased and are either tested negative (i.e., *true negatives*) or wrongly tested positive (i.e., *false positives*) are now used. Equation 5.2 is used to calculate specificity of a test.

$$Specificity = \frac{\text{True Negatives}}{\text{True Negatives} + \text{False Positives}}$$
(5.2)

Similar to sensitivity, the best specificity a test can have is $\frac{X}{X+0} = 100\%$, in which no test subject is wrongly detected positive. If the number of false positives gets bigger than 0, the level of specificity decreases below 100%.

For the sake of completeness, it should be mentioned that there are two more additional values that can be derived from Table 5.1: the *positive predictive value* and the *negative predictive value*. The positive predictive value is calculated with Equation 5.3.

$$Positive \ Predictive \ Value = \frac{\text{True Positives}}{\text{True Positives} + \text{False Positives}}$$
(5.3)

It represents the likelihood that a test subject really is diseased, given that the test results came back positive. The negative predictive value, in return, is calculated using Equation 5.4.

$$Negative \ Predictive \ Value = \frac{\text{True Negatives}}{\text{True Negatives} + \text{False Negatives}}$$
(5.4)

The negative predictive value and stands for the likelihood that a test subject really is nondiseased, given that the test results were negative. In other words, they stand for how likely it is that a given positive or negative test result is correct [34, 13, 48].

The *ideal* diagnostic test has a sensitivity of 100% and a specificity of 100%, meaning that every single diseased test subject is tested positive and every single non-diseased subject is dismissed. No false positives or false negatives occur. However, this is normally not the case and a *reasonable balance* between sensitivity and specificity values has to be reached. These principles and the need to find the right balance between them also have to be factored in when trying to adopt fitness sensor devices in a medical environment and to create monitoring applications and notification systems around them.

In some of the medical use cases in which sensor devices could be deployed, the initial decision whether the patient is in an urgent emergency situation that needs immediate attention or not is made *programmatically* by an application. Firstly, in order to achieve the best possible test sensitivity and depending on the use case, the recorded data has to be as *accurate* as possible and of high temporal resolution. This reduces the number of false negatives as the necessary information is available to correctly detect disease-relevant characteristics in the data. Secondly, the specificity level has to be increased as high as possible by *safeguarding* the application and its notification system against false positives. This can be accomplished by choosing sensible *thresholds* at which an alarm is triggered, by implementing *grace periods* to allow for temporary interruptions and by ignoring *statistical outliers* in the data. These specific values depend heavily on the intended use and in some cases may even have to be adjusted to the individual patient.

5.2 Patient Compliance

The compliance of patients is a medical term that is used to describe to what extent patients adhere to directions given to them by their doctors. This includes a variety of different aspects of patient care: Does a patient take his medication? Does he take it regularly and at the right time? Is the patient following a recommended diet? Is he doing his physical exercises? A key element of a successful treatment is good compliance. Only if medication is taken as prescribed and exercise is done correctly, they can have their intended positive effects on patients' diseases.

In spite of its importance, good compliance is all but a given. A report published by the WHO states that only about 50% of patients in developed countries that suffer from chronic diseases comply with the instructions for their treatment. Numbers of developing countries are suspected to be even worse. Poor compliance not only has a negative effect on the chances for success of treatments but it can also prolong their duration and reduce their effectiveness. It can result in increased costs for health insurance companies and patients, not to mention the emotional implications. The reasons for poor compliance are diverse. According to the WHO, there are five interacting areas that affect patient compliance. There are social and economic factors such as gender, age and race and especially in developing countries poverty, lack of social support networks and the level of education. Health care team and system-related factors such as poor medication distribution systems and inadequately educated or overworked health care professionals. The third area of factors is referring to the condition such as severity of the disease, its symptoms, rate of progression and whether or not there are treatment options available. In contrast, there are therapy-related factors such as the duration of the treatment and previous failures. The lack of immediate benefits and the appearance of adverse or side effects [19] and also a too complex medication regimen can hinder compliance. The more pills and the more frequently a patient has to take them, the more likely he is to take only a reduced dosage, take is less frequently or stop taking them at all [10]. The fifth and last type of factors are patient-related factors such as the patient's knowledge about the disease, his motivation and confidence to cure or manage it and whether he believes in the diagnosis or not. Forgetfulness is another patient-related factor of great importance in regards to the elderly. They often have multiple chronic diseases and have to take a variety of medication throughout the day, however, their mental ability decreases with age and they have to be reminded to take them.

5.3 Doctor's Acceptance

The WHO further suggests to differentiate between the terms *compliance* and *adherence*, with adherence meaning that patients follow the given instructions, agree with them and are *integrated* in the development and planning of a personalized treatment plan. In contrast, compliance should be used when patients do *obey* the instructions given to them but don't necessarily understand, approve or support them. This distinction may be helpful when it comes to finding methods for improvement because they each represent a different set of problems to solve [66].

Of course, the important role of patient compliance is also applicable to the use of sensor devices in a medical context. Such devices can be looked at as just additional tools for analysis and treatment that have to be used exactly in the way the doctor has suggested. Only then are the results reliable and can have the best possible influence on the patient's recovery. Research shows that in America, over one third of people that own a fitness sensor device *stopped* using it six months after receiving it [12]. There are measures that can be taken to improve compliance in general such as *including* the patient in decisions regarding the treatment and keeping him *informed* about all important aspects of the disease. Besides that, there are also measures that specifically target compliance when using sensor devices. If the patient has to worry about keeping the device *charged*, feels that it is *too heavy*, has his movements *hindered* or is *bothered* by it in any way, he is more likely to dismiss it. These are all points that have to be considered. Furthermore, the patient should be made aware of in what concrete way the sensor device is expediting his recovery.

5.3 Doctor's Acceptance

While the patient compliance as discussed in Section 5.2 will be an important aspect, it is only part of the issues. Another big part will be played by the treating physicians and whether or not they are *willing to participate* in this new development. The patients may be bothered by having to wear the sensor device all the time but the physician has to handle all the accumulated data he receives from it. The amount of data that will be available, even if only a fraction of patients share their personal health information, poses a *serious challenge* in terms of storage and analysis. Furthermore, some of the data may even be wrong due to inaccurate sensors or plain misuse of the sensor device by patients. Will the physician be *liable* [23] if the data for a certain diagnosis was available, but he did not act on it as he

may not have seen it yet? He might delegate some of the analyses to an outside firm or laboratory, however that just intensifies the liability issues. A last and maybe one of the most important issues are the costs. The *initial investment* for the necessary infrastructure and possibly additional employees are going to *discourage* physicians to adopt the technology in their practice. Especially so if they can not be sure whether their patients will embrace the new technology or not. However, the patients can not try it if their physician does not make the upgrade which leads to a typical *chicken-and-egg* problem.

5.4 Use Cases

The remainder of this chapter discusses three scenarios in which the introduction of fitness sensor devices could benefit patients as well as the medical professionals treating them and contribute to an improved patient care as compared to present conditions. These improvements include *saved time, increased flexibility* and *faster response times* in emergency situations. The scenarios were worked out during a course of multiple interviews with doctors and medical students. First, they were presented with the types of information modern fitness sensor devices can provide. Then, the situations in which this additional and more detailed information would be most beneficial were discussed further. The scenarios chosen are the *regulation of supplemental oxygen, fall detection* for the elderly and *dosage adjustment of medication*.

5.4.1 Automatic Oxygen Regulation

There are certain medical conditions that result in lungs which are left with only a reduced capability of processing oxygen. Two examples of such conditions are *cardiac insufficiency* and *chronic obstructive pulmonary disease (COPD)*, which is often caused by smoking tobacco or adverse environmental factors. As of today, COPD can not be cured but there are treatments available to alleviate the patient's symptoms such as shortness of breath and chronic cough. Treatment options include *oxygen therapy* in which the patient is given pure oxygen as a supplement to the existing breathable air around him. And even though the human body depends on oxygen to survive, too much of it can also be harmful. The

exact amount of supplemental oxygen needed, however, is different with every patient. The current approach is to give the patient a certain amount of oxygen using an oxygen cylinder that is connected via a regulator and a thin tube to a nasal cannula or face mask. After a short period of time, his blood oxygen saturation is checked and the flow of oxygen adjusted if necessary. These steps are repeated until the desired saturation level is reached.

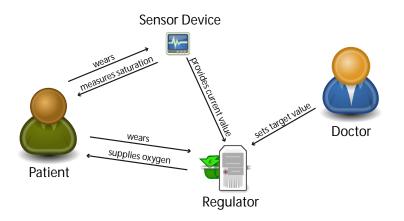


Figure 5.1: Overview of persons and devices taking part in the oxygen regulation scenario and their interactions (Icons [46]).

With the introduction of a sensor device to this scenario, this repetitive task can be automated. The required devices are a sensor device capable of measuring blood oxygen saturation and a regulator device that can communicate wirelessly with the sensor and regulate the flow of oxygen. Figure 5.1 shows all the main parties and devices involved in this scenario and the flowchart in Figure 5.4 visualizes the sequence of events that a program controlling the regulator device would have to go through. After the device is switched on by medical personnel, the target level of blood oxygen saturation that the patient should have is entered and the device tries to establish a connection with the sensor device that is attached to the patient. If it fails, it tries again while showing an error message. If it is successful, it reads the current saturation level and compares it to the previously entered target value. If the values are equal, the device changes nothing and waits for a certain amount of time after which it re-scans the patient's saturation level and compares it again. If the target and the current oxygen saturation are not equal, there are two options. In case the current value is lower than the target value, the patient needs a higher amount of supplemental oxygen and the regulating device *increases* the flow of oxygen. In the opposite case, if the current value is higher than the target value, the regulator device can *decrease* the flow of oxygen to the

patient. Regardless of which case occurs, the next step is to wait a certain amount of time until the changes can take effect and re-scan the current level.

Optionally, a smart mobile device such as a tablet computer could be used as *intermediary*. It can display information about all the patients that are using this kind of equipment including their current oxygen saturation and what their target level is set to. It can also be used as a *gateway* in cases where the regulator device and sensor device do not share a common wireless communication technology.

5.4.2 Improved Fall Detection

An important issue of elderly people living alone in their homes are falls. Not only can the fall itself cause injuries, if the fallen person is no longer capable of standing up by his own and call for assistance, it also has the potential to result in *psychological trauma* and additional *physiological damage*. A matter of most importance after a fall is to get help as quickly as possible. A system already available in some German cities is called, among other names, *"Heimnotruf"²* which corresponds to *medical alert* or *personal emergency response system* (*PERS*) in English speaking countries. The elderly person carries a device with a single button on it and if that button is pressed, a telephone communication is established between emergency services and a base station that is in the home of the user. If the elderly person is responsive and can communicate, further actions that need to be taken are discussed. If he does not respond, emergency personnel is dispatched immediately to his location. A big problem with this system is the situation in which the elderly person falls and is not able to press the emergency button because he is unconscious or can not reach the button on the device.

As mentioned in Chapter 2, research in this area tries to automatically detect a fall event so that further steps can be initiated without the need of user initiative. This is done either using dedicated sensor devices such as accelerometers or using smartphones. The approach proposed in this thesis uses both types of devices in order to increase sensitivity as well as specificity. The required hardware is a *smartphone* and a *fitness sensor device* that measures acceleration, pulse rate, blood oxygen saturation and blood pressure and can be worn *on the wrist*. Figure 5.2 shows devices and people involved in this scenario. The initial

²http://www.samariterbund.net/pflege-betreuung/notrufsysteme

detection is done via the accelerometer data from the fitness sensor device in which possible falls are identified. If such an identification occurs, it is tested whether or not the smartphone is being worn on the body or not, using the sensor for ambient light in the smartphone. If it is not worn at the time of the fall as detected by the fitness sensor device, the data from the smartphone is dismissed and a decision whether or not to alert emergency services is done solely on the basis of all the different bits of information gathered by the fitness sensor device. If, however, the smartphone was worn on the body, its accelerometer data is also consulted and on the basis of the *combined data*, a *more accurate* decision can be made. The flowchart in Figure 5.5 visualizes the steps involved in this improved fall detection process. A great advantage of this approach is that many people already have a smartphone with them for most of the time in their daily lives so they do not have to remember to take it with them, in contrast to the fitness sensor device which they may have remember to put on every morning.

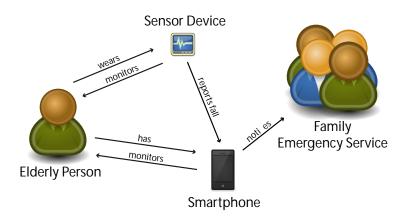


Figure 5.2: Overview of devices interacting with the elderly person and other participants in context of the fall detection scenario.

5.4.3 Dosage of Medication

Overcrowded waiting rooms in hospitals and private practices are an inconvenience for both patients and doctors. The patients are more likely to get irritated due to the time wasted while waiting. Because of that, the doctors then have to work with discontent patients and may feel pressured into completing examinations as fast as possible. A solution that targets the problem of long distances that patients sometimes have to travel to see a necessary

specialist is *telemedicine*³. The term describes a form of examination and treatment in which patient and doctor are not in the same room, sometimes not even in the same country. The patient still has to be in a medical facility that is equipped for this kind of procedure but the doctor can remain in his own office. Their communication and necessary visual examinations are conducted via video conference using cameras and monitors.

The approach proposed in this thesis tries to tackle the problem of overcrowded waiting rooms from a different angle. If the number of times a patient has to visit the doctor's office could be *reduced*, less people would be waiting and the queue for those waiting would be shorter. One process in which the patient could save himself the trip to the doctor is the adjustment of the *dosage* of *newly prescribed medication*. Since finding the right dosage depends on a multitude of factors and it differs with every patient, it is, to a certain extent, a *trial and error* process. The current approach is to estimate the initial dosage, taking into account the doctor's personal experience as well as common reference values. The patient takes the medicine in this initial dose for a certain amount of time, after which he has to return to his doctor, get examined and possibly have the dosage adjusted. This is repeated until an adequate dose is determined.

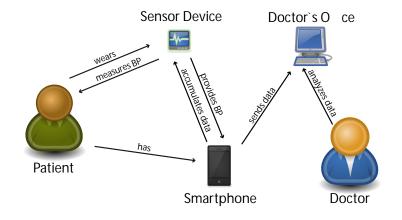


Figure 5.3: Overview of interactions between participants in the medication dosage scenario.

The scenario that was chosen to illustrate the proposed solution is the administration of blood pressure medication. Even though current multi-sensor fitness devices do not support the measurement of blood pressure, there are already stand-alone devices that not only can communicate with smart mobile devices via Bluetooth but also are designed to take the

³http://www.nytimes.com/2012/10/09/health/nantucket-hospital-uses-telemedicine-as-bridge-to-mainland.html

measurement on the wrist⁴. Therefore, it is very likely that future multi-sensor fitness devices will be capable of also measuring blood pressure. The requirements for this scenario are a sensor device that measures blood pressure and a smartphone or tablet. Furthermore, the doctor has to provide the infrastructure necessary to transfer the blood pressure data, store and analyze it. Figure 5.3 gives an overview of the interacting parts in this scenario.

The initial steps stay the same as in the current procedure, up to the point when the patient returns back home for the first time and starts taking the medicine in the initially prescribed dosage. From this point forward, the smart mobile device periodically gathers the patient's blood pressure value from the sensor device and stores it. After a certain amount of time, the patient sends the accumulated data to his doctor who can then analyze the data and decide whether to keep the current medication dosage, increase or decrease it. The flowchart in Figure 5.6 gives a visual summary of all steps involved. This way, the patient saves himself a trip to the doctor's office and the doctor can organize his time in a more efficient way.

5.5 Treat the Patient, Not the Disease

The examples presented above, especially the automatic oxygen regulation and the adjustment of medication doses, describe situations in which it is technologically possible to transfer tasks that are currently performed by doctors to computer systems that depend on information from sensor devices. One aspect that came up on multiple occasions during the conducted interviews of doctors and medical students can be summarized with the saying "*treat the patient, not the disease*". The idea behind this saying is that, when treating a patient diagnosed with a disease, the doctor should not only focus on the symptoms and causes of the disease but also look at the patient as a whole. This includes information such as his *psychological state*, his *social environment* and possible *side-effects* of or *interactions* between medication. This medical premise conflicts with the absence of interpersonal communication and direct contact between doctor and patient in the suggested scenarios. When fitness sensor devices are adopted into medical treatment processes and automate some of the tasks, this limiting factor has to be taken into consideration. If necessary, measures have to be devised to make up for the lack of direct interaction.

⁴http://www.ihealthlabs.com/blood-pressure-monitors/wireless-blood-pressure-wrist-monitor

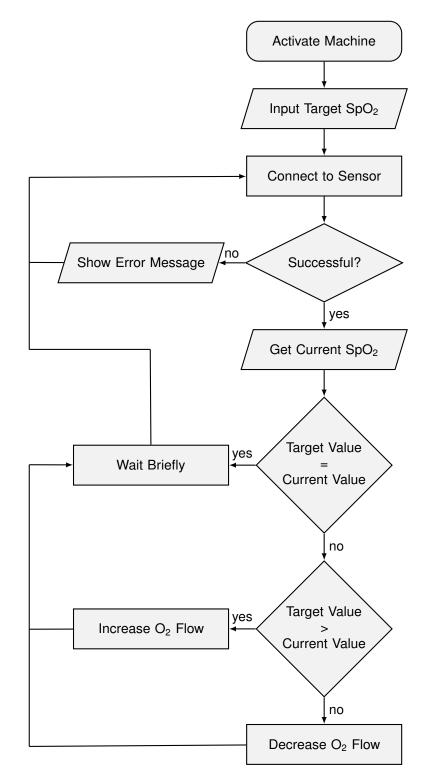
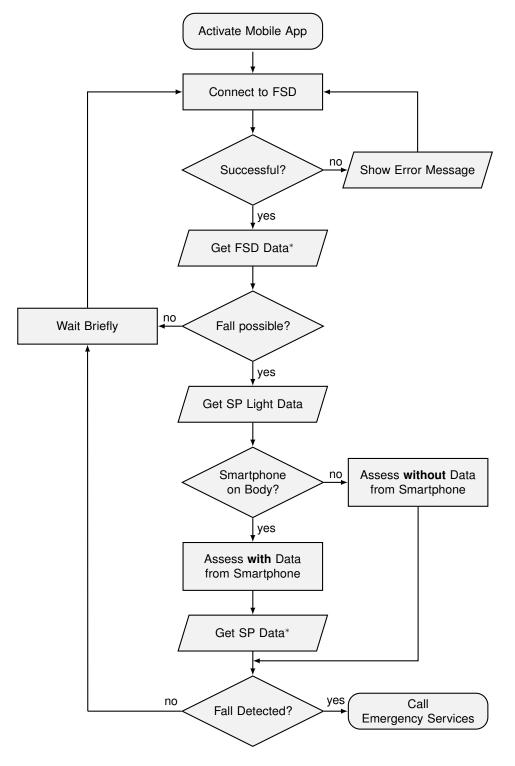


Figure 5.4: Flowchart of the automated oxygen regulation process from the point of view of the regulator device that controls the flow of oxygen.



5.5 Treat the Patient, Not the Disease

Figure 5.5: Flowchart of the improved fall detection system using fitness sensor devices and smartphone in combination (FSD = Fitness Sensor Device; SP = Smartphone; Data* = Data of multiple sensors).

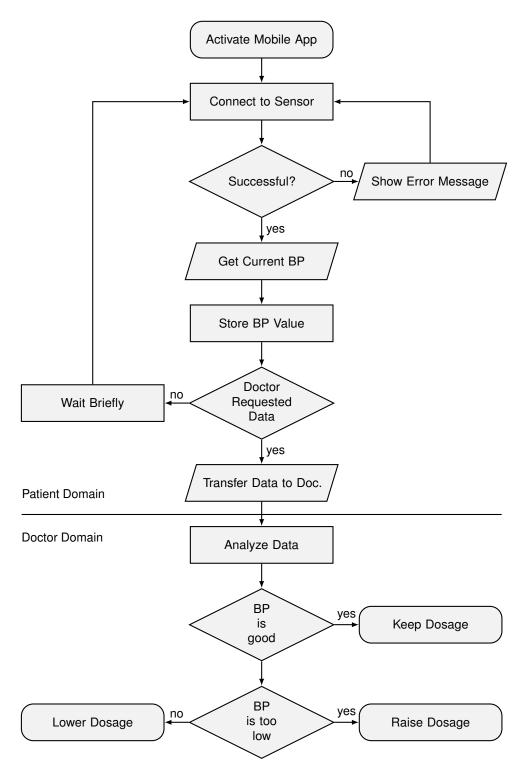


Figure 5.6: Flowchart of the remote examination and adjustment of blood pressure medication (BP = Blood Pressure).

6 Concerns

The growing number of users of fitness sensor devices and their applicability for the medical field and health care brings a multitude of challenges along with it. Besides the inherent technical issues when developing the devices such as battery lifetime and durability, there are social aspects that warrant closer consideration. As a prerequisite for accurate conclusions, the sensor devices have to be worn over a prolonged period of time. Given the context of fitness and health, the data poses risks to people's privacy and everyday living. This chapter discusses *security* and *privacy issues* as well as *social challenges* that may occur.

6.1 Privacy and Security Issues

The best and easiest way to preserve one's privacy is not to collect any sensitive data at all. When no private information is divulged, there is no risk of it ending up in the wrong hands. Alan Westin, a former professor at Columbia University and well-known researcher in this field, defined privacy as "the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others" [65].

Despite the constantly growing need to protect one's privacy against private corporations and federal governments, there are situations where the possible gains outweigh the risks. The medical use cases outlined in Chapter 5 can be considered as such exceptions, provided that there are precautions put in place to minimize the risk of information leaks and to help users to stay in control of their private information. The three main attack vectors that have to be addressed are *acquisition*, *transfer* and *storage* of patient's health data. This section gives a short analysis of these *attack vectors*, following possible countermeasures that can be taken against them.

6 Concerns

6.1.1 Data Gathering

The first possible leak of patient data (i.e. vital signs) occurs at the fitness sensor device *itself* or rather in the immediate *vicinity* around it. Nowadays, devices typically use Bluetooth or Bluetooth Low Energy connections to transmit their data to the user's smart mobile device to be processed and visualized. These transmissions may be *intercepted* by a third party, either by actively *hijacking* the connecting to the fitness device and receiving all data or by passively *listening* to the communication between fitness device and its owner's smart device.

Some sensor devices store measured vital signs on an internal memory and keep it available for a certain amount of time. The next time a smart mobile device is connected, all the collected data can be transferred. In this way, *continuous* measurements are possible even if there is *no connection* established to a smart mobile device at the time of recording. This can pose a privacy problem, however, if the sensor device is lost or gets stolen because the finder or thief has *access* to previously recorded data.

6.1.2 Data Transfer

The same risks hold true for the loss and theft of smart mobile devices that are used in conjunction with sensor devices as even more accumulated measurements and evaluations are stored on it. Considering what else can be found on today's smartphones such as *messages, photos* and other *private* information, the disclosure of health data might be of less importance for the owner in comparison.

The next weak link in the processing of health data appears when patient data is transferred away from the user's smart device. The destination of this transfer can be a dedicated server or cloud storage owned by *private corporations* or a *doctor's office*, or a central data storage operated by the *Federal Department of Health*. If the data is handled carelessly, it will most likely be sent via some kind of *HTTP communication*. In other words, it will be sent *unencrypted* as plain text. There are a number of scenarios in which this method poses a *vulnerability* such as public Wi-Fi access points where unencrypted data traffic can be easily intercepted by anyone inside the area of radio reception.

6.1 Privacy and Security Issues

6.1.3 Data Storage

Significant diagnoses and conclusions about health issues may be based, among other things, on data that has been recorded over a considerable long period of time and stored *persistently*. The comparison of past data with current values allows medically trained professionals to draw conclusions about the *progress of treatments* and about the *course of diseases*. Because it obviously can not be avoided to store recorded patient health information somewhere to be consulted at a later point in time, the huge amount of data that accumulates will be a promising target for attackers. The two basic and most common scenarios to be considered for data management are *centralized* and *decentralized* storage of patient health data.

Centralized data storage could be provided and owned by the Federal Department of Health or by large corporations such as health insurance companies. The number of individuals whose personal health information is stored would be in the *millions* or even *tens of millions*. The risk-reward ratio an attacker is faced with is low because if he can circumvent the security measures put in place to protect the system, the amount of information he gains access to is *enormous*. Even the threat of punishment may not be enough to discourage attempts. Despite that, one big advantage of central data management is that specialized companies can be tasked with the administration of the storage system and that imposed security policies can be monitored and enforced more easily and efficiently.

In contrast, implementation and enforcement of such strict policies would not be feasible with any decentralized solution. For example, if every doctor's office had to store the health data of their patients on their own, they would also be the ones responsible for installation and maintenance of the storage infrastructure, as it is currently the case with existing patient information. They would either handle it themselves or, more likely, delegate it to a local IT company. With *thousands* of those small stand-alone solutions, it would be difficult to enforce *consistent* policies and to ensure an overall high *level of security*. Even though it would result in a higher likelihood for some of those isolated storage infrastructures to be compromised, the impact on the general public would be minimal because each intrusion only affects hundreds or thousands of individual patients. It would still be a bad situation for those affected but less bad compared to the centralized scenario where a system break-in would affect millions.

6 Concerns

6.1.4 Attackers and Countermeasures

Besides thieves that steal sensor and smart mobile devices and thereby gain access to health data as *coincidental* by-product, there are two different kinds of main adversaries: *government* sanctioned organizations and *private* groups or *foreign* organizations. Whether or not there are ways to protect patient data from local government institutions depends mostly on the country and its respective legislation. In the United States of America, for example, the FBI can subpoena records from companies using so called *National Security Letters*. The companies have to comply and there is little to no leeway for them to oppose it, especially as they are not *allowed* to publicly address the incident. However, National Security Letters only cover *metadata*, not the information itself, so they, in their current form, would not apply to actual health data.

In order to defend against foreign government institutions such as intelligence agencies and private hacker groups that can not use the legal system to access the data, there are technologies and approaches available that can help reduce the previously mentioned vulnerabilities.

The initial bonding between sensor device and smart mobile device could be made more secure. For example, by *supplementing* the bonding process with NFC. The close proximity in which both devices have to be held next to each other in order for NFC to work, makes it very difficult for an attacker to bond with a sensor device *without* the owner noticing it.

Probably the most important security measure in today's world is encryption, meaning that on the one hand, *every single time* any kind of patient health data is being transferred, the communication channel has to be *encrypted*. For HTTP communication, there is *HTTPS* to use instead. The Bluetooth and Bluetooth Smart transmissions between sensor device and smart mobile device also have to happen encrypted. Furthermore, end-to-end encryption such as *Off-the-Record*¹ should be used in order to prevent *information leaks* in cases where vulnerabilities of HTTPS are exploited and the encryption of the communication channel is breached. On the other hand, data also has to always be encrypted *before* it is stored persistently. The key or passphrase used to encrypt and decrypt the data has to be kept secret or in a separate and safe place and only authorized people are allowed to know it or have access to it, otherwise the encryption would be futile.

¹https://otr.cypherpunks.ca

6.2 Ethical Issues

The following part covers ethically very delicate topics. Especially Section 6.2.1 about the adoption of sensory devices for the care of elderly people is difficult to approach. Decisions pertaining to medical and social problems often not only concern the elderly person himself but also *family members, close relatives* and *friends*. Notwithstanding the extreme personal nature of such questions and the fact that there is no universally valid solution, their existence is important enough to warrant mentioning them.

6.2.1 Geriatric Care

As presented in Chapter 5, sensor devices can be deployed in geriatric care. In particular, when elderly people, widowed or single, are *living alone* in their own homes. Considering the increased likelihood of *household accidents* and the scenario of fall detection and assuming that the person fell because of a minor mishap such as stumbling or feeling dizzy. If the person needs assistance but can not call for it himself because of general weakness or broken bones, a sensor device that alarms medical personnel can *minimize* the time the fallen person lies on the ground before help arrives and therefore minimizes possible *physiological* and *psychological* damage. In the depicted scenario, the use of a sensory device is definitely helpful and poses no ethical problems.

Taking the increasing average life expectancy² into account, the term *quality of life* gains more and more importance for the elderly population. For some people, getting as old as possible is not everything. Other aspects of life such as, for example, their level of *independence* from assistance of other people or medical equipment or their own *mobility* have to be taken into account as well. The ethically challenging question is to find the right balance between *living* and being *kept alive* and everyone has to find the best possible answer for themselves.

With previous considerations in mind, there might be scenarios of emergencies in which a person's life is saved by the presence of a sensor device that would have died without it. However, the person never fully recovers and experiences a lower quality of life from this

²http://data.worldbank.org/indicator/SP.DYN.LE00.IN

6 Concerns

point forward or in extreme cases is possibly *dependent* on life support system. The resulting ethical considerations are similar to those of the do-not-resuscitate order in which a patient can explicitly state his wish to *refuse* possibly life-saving measures such as cardiopulmonary resuscitation (mouth-to-mouth and nose ventilation or chest compressions).

The two important item to take away from this discussion are: There are ethical ramifications to be considered in that specific use of sensor devices and the decision whether or not to use them should be left to everybody's own discretion.

6.2.2 Quantified Self and Loss of Liberties

Another ethical problem could arise in a business environment. Obviously, a big objective for many corporations is the need to make profit to return to their shareholders. One way to achieve that objective is to gain the best performance out of their employees. With an increasing amount of specific data about a person's health and current physical condition available, an attempt could be made to *optimize* the relation between time working and time off in favor of work. This may be instigated either by individuals *themselves* who intentionally make that choice or by *corporations* that urge their employees to do so. Fitbit, for example, offers companies a special *Corporate Wellness* program that they advertise for with slogans such as "create culture of well-being", "increase employee productivity", "improve employee health status" and "boot acquisition & retention" [15]. The program also includes statistical analysis and visualization of the gathered data on a *personal, groupwide* and even *company-wide* scale. Well-known companies that take part in this program are IBM³, BP and Adobe. In general, the phenomenon of trying to gather numerical and categorical information about one's own body is termed *quantified self*.

Furthermore, a development that can be currently observed in the car insurance business has the potential to also be applied in the field of health insurance. There are car insurance companies that offer incentives if the insured installs a device in his car that monitors certain aspects of his driving. This data is *sent back* to the insurance company and analyzed. If the manner of driving satisfies a given set of requirements, the insured person then pays a reduced monthly fee.

³http://www-01.ibm.com/services/socomm/shared/pdf/2015beg.pdf

6.2 Ethical Issues

Applying this to health insurance, companies could offer special plans for members that wear sensor devices and share their health data with them. Then again, if the recorded values satisfy certain requirements, the monthly fee would be reduced. The person wearing sensor devices might alter his behavior in some way, which on the one hand can have a positive effect on the individual's health. On the other hand, he might also adopt some changes to his lifestyle only because he feels, and in fact is, constantly *monitored* and *supervised* by his insurance company. Depending on the set of constraints given by the company, the insured might be limited in the liberties he previously enjoyed. This trend is already taking place. The German insurance company Generali, for example, announced the introduction of such an insurance plan. It offers reduced fees if the insured records certain health, fitness and food related information and reports them back to Generali [18].

7 Conclusion and Future Work

Nowadays, technically oriented customers are presented with a wide variety of fitness sensor devices. Most of them offer at least tracking of pulse rate and physical activities, some of them have more uncommon sensors built in, such as for measuring skin temperature or blood oxygen saturation. They can further chose the type and design best suited for their individual needs, such as wristbands, chest belts and clips. Even though blood pressure monitors and glucose meters are only available as stand-alone versions and are not yet integrated in multi-sensor devices, it is only a matter of time until this changes. Assuming that the current technological trend observed in recent years in this area continues, fitness sensor devices are not only going to become smaller, more robust and more precise, they are also going to combine even more different sensors.

The chances of this happening are promising since large technology corporations have recognized the potential that lays in area of research. For example, Google has announced that they are working on their own version of a sensor wristband that is not meant to be used for fitness purposes but rather for tracking the users' health and providing doctors with more information about their patients [9]. Taking the minimization of sensor devices even one step further, first sensors have already been integrated and sewn into clothing to be worn by the user like every other piece of clothing. The trend is further aided by advancements in wireless communication technologies and their more and more widespread use in everyday activities such as in payment methods.

In addition, the number of manufactures that facilitate access to the sensor data recorded by their sensor devices, in contrast to using proprietary protocols, is increasing. This is a prerequisite so that developers and researchers can freely integrate these devices into their own smart mobile applications. This will open up new opportunities to evaluate their applicability in other areas. One of which may be sports medicine, particularly sports in which athletes pilot fast and powerful machinery, such as race cars, airplanes and boats.

7 Conclusion and Future Work

Blackouts or even short dizzy spells can have disastrous consequences and have to be prevented. Sensor devices may help by providing crucial information about the athlete's state of health.

However, the three medical use cases presented in this thesis show that the capabilities of fitness sensor devices are also quite suited for classic medical applications. They can improve patient care not only for the patients undergoing examinations or treatments but also for the doctors and medical personnel treating them. The devices can help save time and increase flexibility by reducing the number of times patients have to go see their doctors which is also an advantage for the doctors. They have more time available for the patients that still have to come in. The devices can help make better decisions regarding treatment options and reduce costs by providing doctors with additional and more complete health data. Further, they can improve quality of life, especially for the elderly living home alone, by providing them with rapid assistance in cases of falls.

There are, however, some limitations. From a medical point of view, automation of patient interaction may not always be the best option when treating patients. There is information the doctor depends on for his decisions that sensor devices can not provide. From a technical point of view, fitness sensor devices still have to be made more resilient against outside interference such as ambient light, movements or vibrations. Only then are they able to collect reliable health data in everyday situations. Nevertheless, as shown during the hands-on tests, current sensor devices such as the iHealth Pulse Oximeter PO3 perform reasonable well, even in situations that go beyond their specifications. But it was also shown that, depending on the situation these devices are used in, their measurements can deviate significantly. Future research of adoption of sensor devices in health and patient care would benefit from close interdisciplinary collaboration between computer scientists, hardware manufactures and medical personnel. Useful solutions can only be found if technical as well as medical aspects are taken into account.

A further technical aspect that needs to be considered are the risks to users' privacy. New sensor devices such as the Angel sensor wristband should be tested in regard to accuracy of the recorded data, and in regard to the privacy implications that may occur by recording health data non-stop. In order to address some of the privacy concerns, further research may be able to derive specific characteristics from the recorded data that is sufficiently anonymized but still allows doctors to draw conclusions about the patient's health. Thereby,

it could be prevented that raw health data has to be divulged. Also, *Bluetooth 4.2* and its feature *LE Privacy 1.2* [4] warrant further investigation whether it can be used to improve the privacy of users of sensor devices.

Finally, an important medical factor that is imperative to improve is patient compliance. Under which conditions are patients willing to wear a sensor device over a prolonged period of time? Are there situations in which the device becomes cumbersome? Can patients be bothered with daily recharging of their device? Do they realize what benefits these devices have for them? A survey among potential users could bring valuable insights about relevant features that are needed for patients' acceptance. Another survey that may give interesting results could be conducted among doctors, asking about how they think sensor devices might help the most when treating their patients, whether they would use them in their patient care and if not, why and how the devices have to be improved to convince them otherwise.

A SPSS Output

A.1 Tests of Normality

	Kolmogorov-Smirnov ^a		Shapiro-Wilk			
	Statistic	df	Sig.	Statistic	df	Sig.
Difference PC9 to PO3	,159	61	,001	,939	61	,005
Difference PC9 to Moto 360	,091	61	,200 [*]	,978	61	,341
Difference PO3 to Moto 360	,084	61	,200 [*]	,973	61	,197

 $^{\ast}\!.$ This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Figure A.1: Test of normality for the differences in the sitting scenario.

	Kolmogorov-Smirnov ^a		Shapiro-Wilk			
	Statistic	df	Sig.	Statistic	df	Sig.
Difference PC9 to PO3	,117	61	,036	,970	61	,141
Difference PC9 to Moto 360	,121	61	,026	,973	61	,196
Difference PO3 to Moto 360	,128	61	,014	,963	61	,062

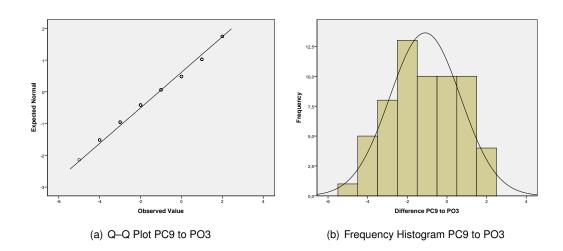
a. Lilliefors Significance Correction

Figure A.2: Test of normality for the differences in the standing scenario.

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Difference PC9 to PO3	,136	61	,007	,953	61	,021

a. Lilliefors Significance Correction

Figure A.3: Test of normality for the differences in the cycling scenario.



A.2 Q–Q Plots and Frequency Histograms

Figure A.4: Q–Q Plots and Frequency Histograms for the cycling comparison scenario.

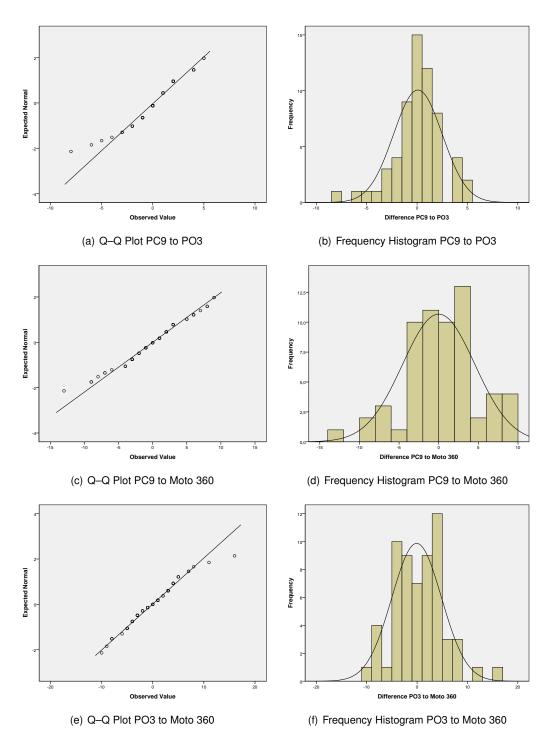


Figure A.5: Q–Q Plots and Frequency Histograms for the sitting comparison scenario.

A SPSS Output

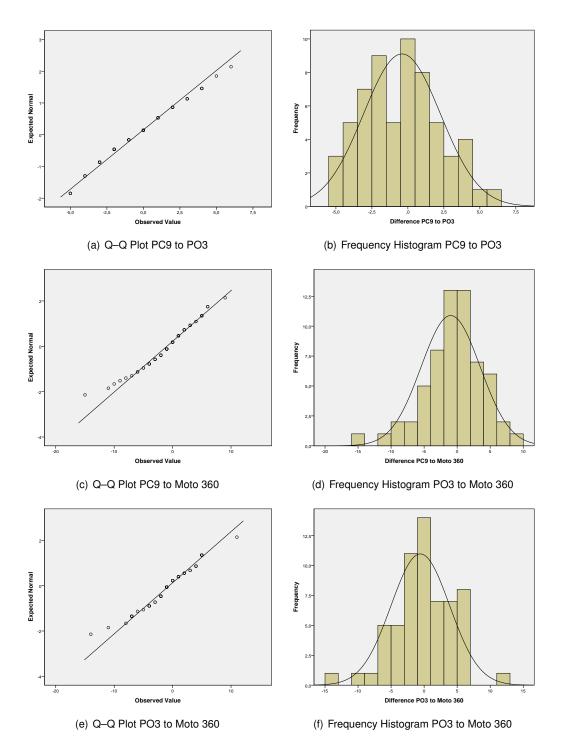


Figure A.6: Q–Q Plots and Frequency Histograms for the standing comparison scenario.

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List of Abbreviations

ADL
AFH
API application programming interface
bpm beats per minute
CO ₂
COPD
DoS
EKG electrocardiography
GATT
Hb hemoglobin
IR
LED
mg/dl
mmHg
mmol/l
NFC Near Field Communication

List of Abbreviations

NTC
O ₂
PERS rersonal emergency response system
PTC positive temperature coefficient
RFID Radio-frequency Identification
RTD resistance temperature detectors
SaO_2 arterial oxygen saturation
SD
SDKkit
SE
SIGSpecial Interest Group
SO ₂
SpO_2 peripheral capillary oxygen saturation
TUG
USB Universal Serial Bus
WHO World Health Organization
WSN

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Erklärung

Ich erkläre, dass ich die Arbeit selbständig verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel verwendet habe.

Ulm, den

Christoph Bachmaier