## **MASTER THESIS**

Thesis submitted in partial fulfilment of the requirements for the degree of Master of Science in Engineering at the University of Applied Sciences Technikum Wien Degree Program Healthcare- and Rehabilitation Technology

# Heart Rate Variability analysis and data quality evaluation in non-invasive wearable biosensors

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### Kurzfassung

Das aktuelle Wachstum im Gesundheitsmarkt führt zu einer hohen Anzahl von verfügbaren Sensoren zur Messung von Biosignalen. Diese Arbeit konzentriert sich auf eine Analyse der Datenqualität von Biosensoren zur Messung der Herzratenvariabilität (HRV), da mit dieser Methode die Prozesse des vegetativen Nervensystems erfasst werden können. In der Regel ist keine wissenschaftliche Validierung der PPG- und EKG-basierten Geräte vorhanden. Einige technische und strukturelle Anforderungen, wie eine ausreichend hohe Datenerfassungszeit (> fünf Minuten) und die richtige Abtastfrequenz (> 250 Hz), sind für eine qualitativ hochwertige Messung notwendig. Die HRV wird häufig in der Kardiologie, im Sport und für die Überwachung des Lebensstils und der persönlichen Gesundheit ermittelt. In einer Online-Literaturrecherche wurden verschiedene themenbezogene Publikationen gesammelt. Fast alle Wissenschaftler konzentrierten sich nur auf HRV-Kurzzeitmessungen in Ruhe und nicht während einer Trainingsphase. Das Internet wurde nach Wearables durchsucht und eine Liste von 21 Sensoren, die eine HRV-Messung ermöglichen, erstellt. Ein Zugriff auf die Rohdaten der Sensoren ist bei den meisten Geräte unmöglich. Ziel der Probandenmessungen war es, sieben verschiedene Fitness-Tracker und ein medizinisches EKG-System (klinischer Standard) zu vergleichen. Insgesamt 17 Teilnehmer führten einen fünfminütigen Test in Ruhe und einen fünfminütigen Test auf einem Ergometer durch, während sie mit den Sensoren und dem klinischen Standard ausgestattet waren. Anschließend wurden die Daten verarbeitet und analysiert. Die HRV Parameter wurden mit der Kubios-HRV-Standard Software (Kubios Oy, Kuopio, Finnland) berechnet. Die Ergebnisse zeigen große Unterschiede in der Datengualität zwischen EKG- und PPG-basierten Biosensoren. Alle berechneten Pearson-Korrelationskoeffizienten (> 0,9171) zeigen eine sehr starke positive Beziehung zwischen dem klinischen Standard (Biopac MP35) und den einzelnen Biosensoren. Die EKG-basierten Sensoren lieferten hochwertige Daten (z.B. beträgt der absolute Fehler der mittleren RR-Intervalle 0,25 ms) während der Ruhe- und der Bewegungsmessung. Es wurden geringe Standardabweichungen (< 0,22 ms) und eine geringe Anzahl von Artefakten (< 0,9 %) ermittelt sowie eine einfache und robuste Bedienbarkeit gefunden. Schlussfolgend kann gesagt werden, dass EKG-basierte Sensoren für bestimmte medizinische Anwendungen eingesetzt werden könnten, wie z.B. für eine genaue Messung der Herzrate (HR) oder der HRV. Die PPG-basierten Geräte lieferten geringe absolute Fehler für die mittlere HR (< 0,29 ms) und die mittlere RR (< 3,61 ms), aber hohe absolute Fehler (bis zu 26,01 ms) für alle anderen HRV-Parameter. Darüber hinaus waren die Standardabweichungen (< 7,38 ms) und die Anzahl der ausgefallenen R-Zacken (< 9,57 %) deutlich höher als jene von EKG-basierten Geräten. Aufgrund dieser Ergebnisse, der mangelnden Bedienerfreundlichkeit und regelmäßiger Probleme während der Probandenmessungen sind diese für den medizinischen Gebrauch nicht zu empfehlen. Die private Verwendung von PPG-basierten Sensoren zur Herzfrequenzmessung kann jedoch empfohlen werden.

**Schlagwörter:** Herzratenvariabilität, nicht-invasive Sensoren, Wearables, Elektrokardiographie, Photoplethysmographie, Fitnesstracker, autonomes Nervensystem

### Abstract

The current growth in the healthcare market is leading to a high number of wearables available for measuring biosignals. This thesis focuses on an analysis of the data quality of biosensors for Heart Rate Variability (HRV) measurement, because with this method the processes of the autonomic nervous system can be detected. Usually there is a lack of scientific validation of the PPG (Photoplethysmography) -based and ECG (Electrocardiography) -based devices. In the home-care sector it would be a great improvement if vital signs like the heart rate (HR) or the HRV could be measured with common available wearables. Some technical and structural requirements, like a time of data collection high enough (> five minutes) and the right sampling frequency (> 250 Hz), are necessary for a high-quality measurement. The HRV is frequently determined in cardiology, in sports and as a tool for surveillance of the lifestyle and the personal health status. Different publications which are topic-related were gathered in an online literature research. All publications investigate the possibility of measuring the HRV with wearable fitness trackers. Nearly all scientists focused on HRV short-term testing during rest but not during an exercise phase. The internet was screened for wearables and a list of 21 sensors, designed for an HRV measurement was created. The access to the raw data of the sensors is impossible for most of the devices. The aim of the subject testing was to compare seven different fitness trackers and a medical ECG-system (clinical standard). Seventeen participants in total performed a five-minute test at rest and a five-minute test on an ergometer while the biosensors and the clinical standard were equipped. After this, the data were processed and analysed. The parameters of interest were calculated with the Kubios HRV Standard software (Kubios Oy, Kuopio, Finland). The results indicate big differences in data quality between ECGbased and PPG-based biosensors. All calculated Pearson's Correlation Coefficients (> 0.9171) show a very strong positive relation between the clinical standard (Biopac MP35) and each biosensor. The ECG-based biosensors delivered high-quality data (e.g. the absolute error of the Mean RR-intervals is 0.25 ms) at rest and at exercise. They showed small standard deviations (< 0.22 ms) and a low number of artefacts (< 0.9 %). A simple and robust usability and a good peak detection were found. It can be concluded, that ECG-based sensors could be used for some medical applications, like an accurate measurement of the HR or the HRV. The PPG-based devices delivered low absolute errors for the Mean HR (< 0.29 ms) and the Mean RR (< 3.61 ms) but high absolute errors (up to 26.01 ms) for all other HRV parameters. Furthermore, the standard deviations (< 7.38 ms) and the number of failed R-peaks (< 9.57 %) were significantly higher than the parameters from ECG-based devices. Due to these results, a bad usability and regular problems during the subject tests they are not recommendable for medical use. However, a private use of PPG-based sensors for heart rate detection can be recommended.

**Keywords:** heart rate variability, non-invasive sensors, wearables, Electrocardiography, Photoplethysmography, fitness trackers, autonomic nervous system

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### 1 Introduction & background

In the last decade there has been an exponential growth in the market for health-related wearables. The current fitness trend is leading to a high number of wearables available for measuring biosignals [1]. 28 percent of the population in Germany track or monitor their health via a mobile application, a fitness band or a smartwatch [2]. In particular, the watch-like devices, which provide an average heart rate measurement, are accepted and popular in the public health sector [3] [4]. Furthermore, a wide range of gadgets for step counter measurement are available on the market. Most devices are positioned on the wrist or the chest of a person, but more and more manufacturers are developing sensor systems for use on the upper arm, finger and the ear lobe [1] [4].

This thesis focuses on an analysis of the data quality of wearable biosensors. The main parameter of interest is the heart rate variability (HRV). The project behind this thesis was realised in cooperation with the company Autonom Health GmbH in Vienna. The subject testing was done in the lab of UAS Technikum Wien. The author declares that no conflict of interest exists.

### 1.1 Scientific question & motivation

# "Can biosensors integrated in wearables measure the heart rate variability with an accuracy high enough for use in medical diagnostics?"

Due to a constant improvement of sensor technology the measurement of the autonomic nervous system (ANS) is arousing interest in the field of medicine and sports [5]. Usually there is a lack of scientific validation of the devices available on the market [3] [6]. Most of the studies only validate the heart rate estimation. The developers of the products explicitly point out that it is not a medical device, so there is no time consuming and expensive validation necessary [7] [8]. Nearly all gadgets are based on the photoplethysmography (PPG) or electrocardiography (ECG) principle [1] [8]. In particular, for long-term surveillance and in the home-care sector it would be a great improvement if vital signs like the heart frequency or the HRV could be measured with common available wearables [9]. In the last ten years the scientific publications on wearable devices or fitness trackers has increased rapidly. Nicole Chudy [10], for example, described, that under special conditions a measurement of the HRV is possible with the Microsoft Band 2. Plews et al. [11] compared a chest belt and a smartphone application with a medical electrocardiogram. In 2018, Hernando et al. [12] focused on the comparison of heart beat intervals derived from a H7 Polar chest belt and the Apple Watch. A good match and reliability of the results in a Relax and Mild Cognitive stress test without any movement of the arm was found. However, there were some missing heart beats (about 10%) in the Apple Watch detection.

#### 1.2 Background of the HRV

The physiological process of the human heartbeat is based on a conduction system. Special cardiac muscle cells provide an electrical activity in the tissue which leads to a contraction of the heart muscle. The system consists of five main components, the sinoatrial (SA) node, the atrioventricular (AV) node, the bundle of His, the bundle of branches and the Purkinje fibres [13]. The electrical potential travels through these components beginning with the anatomical pacemaker (SA node). This process leads to a rhythmic contraction of the heart and the electrical activity can be measured on the surface of the body with electrodes [14]. The HRV is a reaction of the physiological system to changing physiological processes in the human body. This dynamic regulates important vital functions like the heartbeat, the breathing, the physiological water balance, the metabolism and the blood pressure [15]. The inter-beat-intervals (in milliseconds) of the heart change permanently due to these developments. The parasympathetic (see chapter 1.3.2) and the sympathetic (see chapter 1.3.1) are the main inputs for variability [15]. The heart frequency increases during activity and decreases during rest or sleep. In general, it can be said that a high HRV is a sign for a good adaptability and a low one for a weak adaptability of the physiological body system [16]. With a mathematical algorithm, health correlating parameters, like the performance in sport, sleep quality, the reaction to physical and psychological stress or the recovery after exercises can be calculated [15] [17]. In Figure 1 three intervals are illustrated and show the changes in milliseconds. To detect always the same peak of the ECG-signal the RR intervals were taken to measure the time. The R-peak can be detected with an amplitude of about 1-20 mV and is therefore the easiest and the most efficient way to find the inter-beat-intervals of the heart [18]. Inter-beat-intervals are mostly named as RR intervals.



Figure 1: illustration of the inter-beat-intervals of four consecutive R-peaks of a human ECG-signal. sec.=seconds; BPM=beats per minute [19].

#### 1.3 The autonomic nervous system

The autonomic nervous system (ANS) controls the physiological processes of organs like the heart, the lungs, the urinary bladder, the blood vessels for oxygen supply of the organs or the digestive organs. Autonomic control is important to adjust the activities of the organs in a way that the best function for the human body is the result. The control of these organs is based on either reflexes or in the cortical control centres [20]. The most common definition of the ANS is to divide it into the sympathetic, the parasympathetic and the enteric divisions [21]. However, it is a misunderstanding that sympathetic and parasympathetic are the opposite players in the nervous system. Both cooperate at the same time and adjust instantly like a loop control system at the most physiological processes. Only in the deep sleep there exists nearly no sympathetic activity [15]. The last division of the autonomic nervous system is called enteric division. The nerve fibres in the digestive organs like the intestine and the autonomic ganglia are the components of this part. The enteric division still works if there is no connection to the central nervous system. Reasons for this are complex reflex circuits and a high number of neurons [17] [20].

#### 1.3.1 The sympathetic nervous system

The sympathetic nervous system (SNS) stimulates the whole ergotropic functions of the body structure. These nerves are associated with the so called "fight or flight" reaction [15]. It is a preparation to react in injury or stress situations, like danger. A postganglionic transmitter for the sympathetic activity is noradrenaline, which leads to an increased blood pressure [22]. Stress hormones like cortisol are produced to put all the energy together in dangerous situations [23]. A permanent high cortisol level can have lasting effects on the health status. The effect of the sympathetic division on the human body is illustrated in *Figure 2*. It leads e.g. to a dilatation of the pupils and the bronchi, and to an inhabitation of the urinal system [14]. The heart accelerates to be prepared for body exercises. The HRV decreases during high sympathetic activity [17] [23]. The stomach, the pancreas and the intestines are inhibited to reduce the oxygen consumption in these organs. The saliva production is inhibited. On the body's surface the sympathetic supports the activity of the perspiratory glands, the sebaceous glands and the olfactory glands. The muscle tension in core, neck and the lower jaw increases to avoid injuries [15] [20].

#### 1.3.2 The parasympathetic nervous system

The parasympathetic nervous system (PNS) is responsible for the control of processes which are highly active during rest. The human body digests during parasympathetic activity but rarely at a moment of high sympathetic activation [17] [14]. Acetylcholine (ACh) and nitric oxide (NO) are the primary transmitters of the post-ganglionic neurons in the nervous system [22]. PNS also uses peptides as a neurotransmitter. The effect of the parasympathetic nervous system can be seen in *Figure 2*. It leads to a pupillary constriction and a physiological

bronchoconstriction [24]. Furthermore, the saliva production and the urination is stimulated [22] [15]. The stomach, pancreas and intestines are stimulated for an improved digestion. Other features are an increased peristalsis and an activation of digestive enzymes. The vagus activity supports the production of glycogen [15] in the liver. The heart frequency slows down during rest. This modulation is regulated through a sinoatrial node response of the vagus nerve [17]. An increased vagal tone leads to a higher HRV in general [21]. The rhythmical change of the heart rate during respiration (increases during inspiration, decreases during expiration) is called Respiratory Sinus Arrhythmia (RSA) and is an indication for parasympathetic activity [20] [15].



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Figure 2: The Illustration describes the effect of sympathetic (brown column) and parasympathetic (red column) activity on the different organs of the human body. The schematic display of the spinal cord shows the locations of the responsible nerves [24].

### 1.4 HRV measurement

Some technical and structural requirements are necessary for a high-quality measurement of the HRV. The time of data collection during a subject testing is as important as the sampling frequency, the type of data processing and the filtering process. Furthermore, the method of ECG-measurement influences the result of the HRV parameters [9] [15]. A non-invasive measurement of the variability is a standard for nearly all the available testing systems. Invasive methods deliver a higher accuracy of the electrical heart activity in some physiological areas, but they are not necessary for the HRV measurement and not adaptable in home care applications [15] [25]. The mechanical robustness is important, especially for long-term testing and during activity. Subjects with a high number of extrasystole beats (>1%) should be excluded due to a resulting high, but incorrect variability of the heart [9] [17]. Portable sensor systems with a wireless transfer standard (Bluetooth, ANT+) are sensitive to nearby electromagnetic fields and other devices with a similar standard.

#### 1.4.1 Recording of the Electrocardiogram

The calculation of the HRV is based on the recording of an electrocardiogram. The electrical activity of the heart can be detected with electrodes on the human body surface. The well-known PQRST-complex is the result of such a measurement [14] [15]. Depending on the position of the electrodes the results are changing. There are different recording methods of the ECG common in the medical use:

- Einthoven's lead system
- Goldberger's lead system
- Wilson's lead system
- Frank's lead system
- Nehb's lead system

The lead systems of Einthoven, Goldberger and Wilson are used in every hospital in diagnostic of different cardiological diseases, but they are not usable for HRV measurement during exercise or long-term testing because of the electrode positions on the extremities [15] [17] [26]. Nehb's bipolar lead system, which is measured on the chest, provides a stable signal during activity. Though the medical use of an 1-lead ECG is limited, it is a simple and efficient method for measuring the HRV [26].

#### 1.4.2 Sampling frequency

The sampling frequency is one of the main parameters for a high quality HRV measurement. According to the Shannon theorem the sampling rate must be at least two times the maximum existing frequency in the signal [27]. In light of this, no loss of information can be guaranteed [25] [9]. *Figure 3* shows the difference between a sampling rate which is high enough and a sampling rate which is too low. The sampling frequency of the signal (yellow curve) in the upper illustration is high enough to avoid information loss. If using the same sampling

rate for a signal with a higher frequency, it is detected incorrectly. This so-called aliasing effect must be considered during biosignals-processing and can be seen in the lower illustration of *Figure 3*.



Figure 3: The blue vertical lines show the sampling rate of the system. The red circles mark the data points measured of the signal. The yellow curve in the upper illustration shows the signal detected with a sampling rate, which is high enough to avoid an aliasing effect. The blue curve in the lower illustration shows an aliasing effect due to a low sampling frequency. The signal detected (blue curve) does not match the real signal (yellow curve) [28].

The American Heart Association recommends a minimum sampling frequency of 500 Hz for resting ECG and 250 Hz for long-term ECG. Low values can lead to detecting the R-peaks imprecisely and to incorrect results in the HRV parameters calculated. Especially during exercise (increased heart rate) a sampling rate of e.g. 100 Hz leads to a loss of information because of decreasing variability [15] [17]. On the other hand, a detection with extremely high rates (4000 Hz) is not recommendable because of the big amount of data storage needed. Furthermore, common-mode interference due to outer conditions increases with higher frequency [25]. Modern ECG systems provide a sampling rate of about 1000 Hz, which is the recommended frequency for peak detection [29], [9], [15].

#### 1.4.3 Electrodes

A pair of electrodes is necessary to measure the electric potential difference between two locations. A differentiation into unipolar and bipolar leads is usually made. A unipolar lead has a single electrode on the tip and a bipolar lead is an electrode with two isolated and separated conductors [30]. Gel electrodes with a decentral connection of the cable are common for one-time use in cardiology. This reduces the risk of slipping if external forces stresses the disposable electrode [15]. Reusable electrodes should be moistened with water before attaching it. The position should be cleaned with diluted alcohol to reduce contact-resistance between electrode and skin [9].

#### 1.4.4 Artefact detection

The data set of detected RR intervals are the basis for all the following calculations in timedomain and frequency-domain. A data processing with filtering and artefact detection is necessary [31]. With this, incorrect results of the HRV measurement can be excluded [15]. Furthermore, the raw signal is shortened during data processing. This is called artefact limitation. If the length of the raw signal stays equal due to interpolation, the method is called artefact replacement [25]. Wrong beats or not detected beats lead to a significant increase of the variability calculated. In *Figure 4* an ECG-signal with movement artefacts can be seen. Many parameters of the frequency-domain are sensitive to outliners, though time-domain parameters are less sensitive [17].

Scientists gave different definitions for the characteristics of outliners. Outliners are all values, which fell outside the 95% bound of the confidence interval, stated Ward Dobbs et al. [7]. A visual inspection of the raw data for artefact detection is recommended. Furthermore, absolute and relative filtering of the signals is necessary in many cases [25].



Figure 4: ECG-signal with movement artefacts (red circle) after four consecutive beats. Modified illustration from [32].

### 1.5 Sensor principles

Clinicians show increasing interest in using HRV as an indicator for cardiovascular diseases and in determining the activity of the autonomic nervous system [33]. It is common to use non-invasive sensors for detecting the heart beats. An accurate determination of the heartbeat interval is required. Two different sensor principles are usually used for testing the HRV [34]. The most common method is the Electrocardiography (ECG). The second one is the Photoplethysmography (PPG). Both can provide raw data (inter-pulse-intervals) for use in further calculation of HRV parameters. There are differences in usability and data processing [35].

#### 1.5.1 Electrocardiography

The HRV measurement through ECG is described in chapter 1.4.1. This method shows high accuracy and is state of the art in many applications. The depolarization of the ventricular myocardium delivers a signal without any phase delay. The electric potential of the heart can be detected on different locations on the human body surface [14]. Physiological processes can generate noises in the signal like a respiration induced baseline drift, interferences of signals and a contamination through electromyographic activity [35] [34]. Non-physiological processes like a power line interference, body movement artefacts and a movement of electrode contact are responsible for artefacts as well. Right now, mainly ECG-based measurements are used in clinical environment.

#### 1.5.2 Photoplethysmography

Photoplethysmography is an optical heart rate monitoring technology. The human blood volume changes in the peripheral microvasculature due to the rhythmical contractions of the heart. This effect is monitored to determine the timing of cardiac cycles [34]. An optical source (LED) emits light into the tissue. Modern systems use diodes which emit a nearinfrared light. The photosensor captures the refracted light. A mathematical algorithm calculates the biometric data. This method can be used in the reflection mode and the transmission mode [33]. At the reflection mode, the light source and the detector are placed close to each other on the human skin. The light refracted in the microvascular arteries is detected in the sensor. Wrist-worn wearables are based on this sensor principle. At the transmission mode, the light source (mostly green LED) and the detector are placed on the opposite side of the tissue under review. The light transmitted is compared with the light emitted of the diode [34] [33]. Wearables which are placed on the fingertip or on the ear lobe are based on the transmission mode.

There are some difficulties in using photoplethysmography in medical application. Darker skin tone or inked skin can affect the result of the measurement, because of the change in green light absorption. The so called "optical-noise" influences the reading of the heartbeat.

This effect changes depending on the sensor location. PPG recordings are highly vulnerable to motion artefacts and show a low accuracy during exercise [7], [33], [34]. The oscillations in the blood volume show a phase delay of PPG derived heart frequency compared to an ECG derived heart frequency. This delay can be seen in *Figure 5*. The specific vessel elasticity of each human individual changes this delay [34]. Low surface temperature and low blood flow can falsify the result of the measurement. However, there are many benefits in using photoplethysmography. Parameters like the rate of ventilation and the blood oxygenation can be derived with a simple PPG recording. Patients can record their health parameters at home and transfer it to clinicians. PPG recording prove high convenient for home-care treatment and in clinical institutions, claimed a researcher [34].



Figure 5: The illustration shows a comparison of an ECG-derived signal (black line) and a PPG-derived signal (purple line) of five consecutive heart beats. The red dots mark the peak of the signal detected [36].

#### 1.6 HRV parameters investigated

It is possible to determine many different parameters with an HRV analysing tool. They are divided into Time-Domain, Frequency-Domain and Nonlinear parameters. In this section the parameters of interest for this study are listed and described (Time-Domain and Nonlinear parameters). All of the HRV parameters are standardized and the corresponding mathematical algorithms can be find in the subject-specific literature [25], [29], [37]. The results calculated can be seen in chapter 3.

#### 1.6.1 Mean RR & Mean HR

The Mean RR is the average of all R-peak to R-peak intervals. It is measured in milliseconds (ms). The parameter is calculated from the raw RR series. The Mean RR is higher at rest than at exercise. The Mean HR is the average heart rate over the entire measurement. It is measured in beats per minute. The basis for the calculation is the raw RR series [25].

#### 1.6.2 SDNN & RMSSD

The SDNN is the standard deviation of the N-peak to N-peak intervals. This square root of the variance is measured in milliseconds. It reflects the global variability of the series and indicates the cyclic components [38]. The SDNN is influenced by SNS and PNS and it is higher at rest than at exercise [17]. The RMSSD is the root mean square of successive differences between N-peak to N-peak intervals and it is measured in milliseconds. It is an important HRV parameter, also in short-term measurement. The RMSSD is used to estimate the parasympathetic activity and the regeneration. Long-term measured RMSSD show a strong correlation to pNN50 [37] [39].

#### 1.6.3 pNN50

The pNN50 is the percentage of adjacent N-peak to N-peak intervals with a difference of more than 50 milliseconds to each other. It shows a strong correlation to RMSSD in long-term measurement [37]. This parameter is used to estimate the activity of the PNS. For an evaluation of the RSA the RMSSD should be preferred [25] [37].

#### 1.6.4 SD1 & SD2

A Poincare plot can be analysed by fitting an ellipse to all data points. The SD1 is the standard deviation of the distance (each point) from the y=x axis. It shows a correlation with baroreflex sensitivity [37]. The SD2 is the standard deviation of the distance (each point) from the y=x axis plus the average R-R interval. Both nonlinear parameters are measured in milliseconds [37], [25], [38].

### **1.7 Medical application of the HRV**

K.F. Wenckebach and H. Winterberg described the RSA as an indication for a healthy and physiological function of the heart in 1927 [17]. The heart rate diagnostic with respect to the variability was used first about 50 years ago. Scientists found out, that the analysis of the heart rate variability can provide information about the well-being of an unborn child. This method is called Cardiotocography (CTG). Later, HRV has become a popular method for health education, prevention and for diagnostic of chronical diseases [17]. Many scientific paper confirmed the possible application of the HRV measurement for general mortality

prediction and for cardiac risk stratification [15]. The use of HRV analysis in sports started in the 90<sup>th</sup> of the last century [40]. As a latest trend people show an increased interest in HRV testing to monitor their health status and to improve sleep, nutrition, regeneration and stress resistance [15] [31].

The HRV is frequently determined in cardiology [41]. Modern ECG systems for home-care use are cheap and easy to apply. A myocardial infarction leads to an early decrease of the HRV. The recovery starts after few weeks [42]. There is a mortality increased for patients, who have a low magnitude of HRV in short-term and a standard deviation of all RR intervals (SDNN) reduced (24 h measurement) during 21 months after a myocardial infarction. Furthermore, a low HRV may be an indicator for sudden cardiac death [41]. Clinicians found at, that HRV measurement has the potential to detect rejection episodes after heart transplantation. Frequency domain's parameters can give an information about possible cardiac reinnervation after a time interval of more than one year [42]. Additionally, it has been used in disease detection for Alzheimer, leukaemia, chronic migraines, stroke and renal failure [43]. Insomnia, sleep-related breathing disorders and epilepsy can be detected with an HRV recording during sleep. An analysis shows the different stages of physiological sleep and the control of the autonomic nervous system. The sympathetic is predominate during rapid eye movement (REM) sleep and a high parasympathetic activity can be observed in other sleep stages [41]. A pain detection for people with awareness clouded in palliative care is possible [15]. The autonomic dysfunction is a key characteristic for multiple organ failure, myocardial infarction, brain trauma and sepsis [43]. Moreover, HRV parameters impaired could be a marker for depression. Reduced HRV is an indicator for diabetic autonomic neuropathy [42]. The examination of a human HRV is an efficient tool to make the function of the autonomic nervous system understandable [15]. Factors like gender, age or the individual health status should be considered for a high-quality analysis [43].

An HRV analysis is a commonly used tool in sports [31]. Professional athletes use it to determine the regeneration after a training and to plan the training session's intensity. The results of many publications show time-domain and frequency-domain parameters reduced for a certain time after a high-intensity workout [44]. An HRV-guided training provides a workout adaptation (high or low intensity) based on the daily changes of the parameters [31]. Furthermore, it is an instrument for the identification of overtraining and anaerobic thresholds. Fatigue and nutrition quality can be determined [31] [44].

### 1.8 Topic related papers and scientific publications

Different papers and publications which are topic-related were gathered in an online literature research. All publications investigate the possibility of measuring the HRV with wearable fitness trackers. A selection of relevant sources was made due to the high number of sources. Currently no standard method for the validation of wearable biosensors is available. Therefore, the studies selected vary in study design and data analysis.

Ward C. Dobbs et al. [7] created a matrix of different HRV tests which were generated with wearables. After this, they calculated the separate effect size (ES) and the confidence interval for each testing. The degree of absolute error was modulated through the different use of HRV metric, the biological sex, the position of testing but not the type of portable device. No significant difference was found after outliner removal. The small errors compared to a medical ECG are acceptable when considering the benefits of wearable technology use for medical diagnostics, stated the scientists [7]. K. Georgiou et al. [8] implemented search criteria to present investigations (16 biosensors based on ECG, two biosensors based on PPG) on the accuracy of HRV data recorded with wearables. Nearly all subject tests delivered excellent correlation between the wearable sensor and the clinical standard (stationary ECG device) during rest. The researchers found a progressive decline in correlation at exercise level increased. However, the agreements for RR intervals (derived at the chest) were still high. Studies with higher number of subjects, better data analysis and non-stationary conditions will improve the validation methods in the future [8]. The comparison of data quality in HRV analysis derived from ECG and PPG were implemented in many scientific papers. Nevertheless, the results and conclusions of this studies are often different. For example, G. Lu et al. [34] stated, that PPG provides accurate beat-to-beat intervals for calculating the common HRV parameters (time domain, frequency domain). They used a transmission mode ear-clip (PS-2105, Feedback Instruments Limited, Crowborough UK) for PPG signal recording with a sampling frequency of 100 Hz and an ECG sensor (PS-2111, Feedback Instruments Limited, Crowborough UK) with a sampling frequency of 200 Hz at a subject testing (42 participants). The scientists concluded, that a use of wearables based on the PPG principle can be a practical alternative to stationary ECG for medical diagnostics [34]. V. Jeyhani et al. [45] compared the HRV data derived from a fingertip sensor (PPG sensor with 250 Hz) and from a stationary system (ECG sensor with 500 Hz). They showed, that the error size varies at the different HRV parameters calculated. The SDNN and the root mean-square of successive differences of adjacent RR intervals (RMSSD) revealed relative errors of 2.47% and 5.55%. The percentage of pairs of adjacent RR intervals differing by more than 50 milliseconds (ms), called pNN50, was the parameter most affected with a relative error of 29.89%. The researchers stated, that a calculation of the second derivative of the PPG data delivers no better results [45]. Nicole S. Chudy [10] validated the Microsoft Band 2 (Microsoft Corporation, Redmond USA) as a device for measuring the HRV on the wrist. 49 participants were asked to perform a cognitive task in seating position and without any movement of the arm. A Microsoft Band 2 can be used for a HRV testing during rest and could be an alternative to stationary ECG in the future, concluded the researcher [10]. A validation of the Apple Watch (Apple Inc., Cupertino USA) for HRV measurements conducted David Hernando et al. [12] in 2018. The subjects had to perform a five-minute relax and a mental stress test in seating position. The scientists used a Polar H7 (Polar Electro, Kempele Finland) chest strap as a reference for the RR interval series. Then, the calculated parameters (e.g. Standard

deviation, SDNN, RMSSD, pNN50) and the agreement and reliability coefficients were analysed. The data derived from the Apple Watch showed good agreement and reliability. However, about 10% of the RR intervals were missing [12]. Daniel J. Plews et al. [11] compared the HRV recorded data of the Polar H7, a smartphone application ("HRV4training") and a Quark T12x ECG system (Cosmed, Rome Italy) in 2017. 29 participants performed a fiveminute test at rest with guided breathing and with normal breathing. The researchers determined only the RMSSD and the technical error of estimate (TEE) for the different biosensors. The agreement of the smartphone application and the chest strap is acceptable regarding the RMSSD and the TEE, stated the scientists. Furthermore, the simple HRV recording via app can be a method which is preferred in home-care and for athletes [11]. Michael R. Esco et al. [46] conducted a study concerning validation of a smartphone pulse sensor (ithlete HRV Fit Ltd, Southampton UK) application for determining the logarithmical transformed RMSSD in 2017. 30 subjects performed an ultra-short-term HRV recording (one minute) in seated, supine and standing position. The data analysis of the PPG based finger pulse sensor showed a strong correlation and good agreement to the Biopac MP100 (Biopac Systems Inc, Goleta USA). Nevertheless, it must be considered, that a validation requires calculation of multiple HRV parameters and that the recording time was short. Furthermore, significant differences were found in the standing and seated position [46]. The Polar V800 smartwatch was validated by David Giles et al. [47] in 2015. They used a Polar H7 chest strap to record the biosignals. The raw RR data was exported from the Polar Flow web page. The Biopac MP36 allocated the reference data (both with a sampling frequency of 1000 Hz). Recordings were performed in the supine (ten minutes) and in the standing (seven minutes) position. The 20 participants were asked to match their breathing frequency to a metronome (0.2 Hz) during data acquisition. The data analysis (executed with the Kubios HRV software) delivered no significant differences in any parameters (e.g. SDNN, RMSSD, pNN50, VLF, LF, HF). The strong Inter-Class-Correlation (ICC) of >0.999 and the small ES (≤0.029) are indicator for a very good agreement between the two data sets. The Polar V800 delivered higher data quality than previous Polar models, stated the researchers [47]. In 2014, the Spanish scientists Marco Romagnoli et al. [40] conducted a study to determine the data quality of a smart textile system for HRV recording. The smart shirt (GOW Weartech, Valencia Spain) has integrated electrodes on the chest to detect the electrical potential of the heart. The biosensor and the Cardiolab 2 plus ECG (Prucka Engineering, Texas USA) deliver data with a sampling rate of 250 Hz and of 1000 Hz. 12 subjects performed a 30 minutes cycling test on an ergometer. Data analysis was executed with the Kubios HRV software. The used Bland-Altman plots showed tight (< 6.1 ms) Limits of Agreement (LoAs). The agreementanalysis delivered high ICC (< 0.948) results. Wide LoAs were found for parameters related to short-term changes (RMSSD, HF, SD). The GOW textile system can be used for measuring the heart rate during sports, but not as a tool for clinical HRV recording, concluded the scientists [40].

## 2 Material and Methods

The aim of the subject testing was to compare different fitness trackers and a medical ECGsystem as a clinical standard [48]. A statement about data quality of the devices investigated followed. Due to a high number of fitness trackers (seven wearables) the project was split into two subject tests. Testing 1 was performed using four wearables (see chapter 2.4.1) in summer 2018. Testing 2 was performed using three wearables in spring 2019. The same testing procedure (see chapter 2.4.4), data recording (see chapter 2.4.3) and data analysis (see chapter 2.5) were used for both investigations.

### 2.1 Search criteria for sensors

A market analysis concerning availability of wearables with appropriate biosensors was carried out online. Google.com was used as a search engine for devices. The following keywords and relevant medical terms delivered results which were screened for commercially available, wearable devices: "hrv tracker wearable" (186 000 hits), "wrist-worn wearables hrv" (111 000 hits), "wearable fitness tracker for hrv" (57 200 hits), "smartwatch hrv test" (120 000 hits), "smartwatch for heart rate variability" (145 000 hits) "tracking hrv with wearable fitness sensor" (171 000 hits), "tracking hrv with smartwatch" (130 000 hits). Due to the high number of devices and the exponential growth of the market for wearable biosensors, a wellstructured selection of the devices is obligatory. Five search criteria were defined to restrict the search results.

#### 2.1.1 Sensor principle

Nearly all commercially available, wearable biosensors are based on the ECG or PPG principles. Almost without exception all chest-worn devices detect the data with an ECG sensor (see explanation in chapter 1.5.1). Devices, worn on the finger, the earlobe or the wrist have an integrated PPG sensor (see explanation in chapter 1.5.2). Invasive use of the wearable device is an exclusion criterion. HRV detections based on other physical sensor principles are not considered in this thesis.

#### 2.1.2 Transfer standard

Most of the commercially available fitness trackers use Bluetooth or ANT+ to transfer the data from the biosensor to the receiving device. When using Bluetooth, the protocol can transmit data faster and over a bigger distance than the ANT+ protocol. It is the most common transfer standard for the connection of fitness trackers. The ANT+ protocol makes it is possible to connect several devices with the same wearable biosensor, whereas this is not possible with Bluetooth [49]. Some devices enable the data transfer via both standards. Other transfer protocols except ANT+ and Bluetooth are not considered in the market

analysis of this thesis. The access to the raw peak-to-peak time intervals is obligatory for subject testing. Many heart frequency sensors which are available on the market do not support the detection of the HRV or a raw data export.

#### 2.1.3 Sampling frequency

The data quality and the reliability of an HRV measurement depends on the sensor's sampling rate. A frequency of at least 250 Hz is recommended for long-term HRV measurements (see explanation in chapter 1.4.2). Devices with a rate of 1- 50 Hz show inaccurate results at the data analysis. A low sampling frequency is an exclusion criterion in this thesis. If the sampling frequency of is unknown, the wearable was not excluded automatically.

#### 2.1.4 Documentation & Market Availability

A proper documentation of the hardware and software of the wearable device is necessary for a scientific comparison. There are numerous fitness trackers commercially available on the big markets for electronic devices, like in China or South Korea. However, some of them lack a user-friendly documentation in English. Wearables without a useful product documentation in English or German were excluded in the thesis. There has been an exponential growth in the market for health-related wearables in the last decade. The current fitness trend is leading to a high number of wearables available for measuring biosignals. The thesis focuses on wearables commercially available on the market. Some future projects which are not realised yet, are described in the discussion. The list of chosen sensors (see chapter 2.3) is only a current selection and could be updated every year.

### 2.1.5 Mobility

The thesis focuses on wearable devices like smartwatches, chest straps, finger sensors, ear clips or similar. They must be portable and adjustable on a certain position on the human body surface. A guaranteed battery supply for at least 24 hours is mandatory. Trackers are excluded if a permanent cable link between the sensor and a receiving device is needed. At the least it must be possible to measure the HRV during the resting phase and preferably during exercise phase on an ergometer. A water-proof cover of the sensor is not required.

### 2.2 Study population & Ethical aspects

The study population consisted of nine participants (mean age: 28.7, SD: 8.1) for the Subject Testing 1 and eight participants (mean age: 22.9, SD: 1.6) for the Subject Testing 2. They had to be free from any injuries or illnesses. All volunteers confirmed to having no cardiac irregularities like arrhythmia and they were not paid for the effort. They were informed about the procedure, the possible risks and the aim of the testing. The subject's anthropometric data (sex, age, weight, height, pulse at rest) can be seen in *Table 1* and *Table 2*.

ID	sex	age	weight [kg]	height [cm]	pulse at rest [bpm]
1	female	45	63	176	57
2	female	22	68	175	85
3	male	27	59	165	44
4	female	41	50	168	71
5	male	26	85	192	65
6	male	28	68	172	64
7	female	24	74	164	65
8	male	22	83	170	84
9	male	22	71	185	65
Ø	-	28.7	69	174.1	66.7

Table 1: Anthropometric data of participants at the Testing 1

ID	sex	age	weight [kg]	height [cm]	pulse at rest [bpm]
10	female	24	53	163	75
11	male	23	72	182	50
12	male	25	74	173	60
13	male	24	70	183	60
14	female	21	66	179	95
15	male	22	68	180	55
16	male	20	60	170	70
17	male	24	55	170	70
Ø	-	22.9	64.8	175	66.9

Table 2: Anthropometric data of participants at the Testing 2

The subject testing of this thesis delivered data for a dissertation with similar subject tests. All the used biosensors are non-invasive and CE certified. Following an ethics committee application (application number: GS1-EK-1/179-2017) the board stated that a vote was not necessary because standard incremental tests were being performed.

#### 2.3 List of sensors for HRV measurement

A list of sensors designed for an HRV measurement can be seen in *Table 3*. The devices gathered are based on the search criteria defined (see at chapter 2.1). All the 21 wearables are based on either the PPG or the ECG principle. If there is no explicit statement regarding the sampling frequency of the sensors on the manufacturer's web pages, it was defined as unknown. The sale price was found in the manufacturer's webshop in April 2019.

Number	Model	Company	Principle	Sensor position	Sampling Frequency	Sale price
1	AIO sleeve	Komodo Tech., USA	ECG	arm	unknown	145 \$
2	Ambiotex Shirt	Ambiotex GmbH, Germany	ECG	chest	1000 Hz	250 €
3	Apple Watch 3	Apple Inc, USA	PPG	wrist	unknown	299€
4	Biostrap	Biostrap LLC, USA	PPG	wrist	unknown	250 \$
5	Bodyguard 2	Firstbeat Tech., Finland	ECG	breastbone + chest	1000 Hz	329€
6	Cor Sense	Elite HRV, USA	PPG	finger	500 Hz	145 \$
7	Cova Necklace	toSense Inc., USA	ECG	neck	unknown	*
8	EQ02+ LifeMonitor	Equivital Ltd., UK	ECG	chest + shoulders	256 Hz	190 €
9	GOW Shirt	Weartech, Spain	ECG	chest	250 Hz	*
10	H10	Polar Electro, Finland	ECG	chest	1000 Hz	90€
11	Hexoskin	Carre Tech., Canada	ECG	chest	256 Hz	499 \$
12	Ithlete finger sensor	HRV Fit Ltd., UK	PPG	finger	unknown	55€
13	Kyto HRM 2935	Kyto Fitness Tech., China	PPG	ear	unknown	22€
14	Microsoft Band 2	Microsoft Corp., USA	PPG	wrist	unknown	120 €
15	Oura Ring 2	Oura Health Ltd., Finland	PPG	finger	250 Hz	315€
16	Qardiocore	Qardio Inc., USA	ECG	chest	600 Hz	499€
17	Suunto smart sensor	Suunto, Finland	ECG	chest	1000 Hz	80 €
18	VIITA Active	Viita Watches GmbH, Austria	PPG	wrist	80 Hz	399€
19	Vitalmonitor	Viita Holding G,bH, Austria	ECG	chest	500 Hz	399€
20	Whoop Strap 2	Whoop, USA	PPG	wrist	100 Hz	500€
21	Zoom HRV	Life Trak Inc., USA	PPG	wrist	unknown	140 \$

Table 3: List of sensors designed for an HRV measurement; all the information was gathered in an online research at the manufacturer's official web pages; unknown = if there is no explicit statement according the sampling frequency, PPG = Photoplethysmography, ECG = Electrocardiography; \* = the device is currently not available or the sale price is unknown; the sale price was found in the manufacturer's official webshop in April 2019

### 2.4 Study design

The study participants performed a five-minute test at a resting phase and a five-minute test while exercising phase on an ergometer (see chapter 2.4.1). The subjects had to read a free selectable text during the rest measurement. The heart frequency at rest was measured at the start of the testing. The heart frequency during the exercise phase had to be twice the frequency at rest if possible. The HRV was measured with different wearables and compared to a clinical standard (ECG-system). A setup for subject testing was generated. The described preparation and the flow chart of the testing procedure had to be followed (see chapter 2.4.4). Variations of the process required a detailed description and explanation. The study design was created for this project.

#### 2.4.1 Equipment

The exercise test was performed on the Ergo Bike Premium i8 (Daum Electronic GmbH, Fürth Germany). The power of the ergometer is adjustable from 20-600 Watt. The Biopac MP35 (Biopac Systems Inc, Goleta USA) was used as well as the Biopac SS2LB Lead Set for the data recording of the subject's ECG. The disposable electrodes Blue Sensor P (Ambu GmbH, Bad Nauheim Germany) were used for both tests. The wearables used for the Subject Testing 1 can be seen in *Table 4*. Every chest strap was moistened before the application to reduce the contact impedance. The Firstbeat Bodyguard's electrodes were placed on the right clavicula and below the left pectoralis major.

Nr.	Model	Company	Position	Principle
1	Polar H10	Polar Electro	chest	ECG
2	HRM Blue	Blue Leza	chest	ECG
3	Firstbeat Bodyguard	Firstbeat Technologies	breastbone + chest	ECG
4	Suunto Smart Sensor	Suunto	chest	ECG

Table 4: wearables used for the Subject Testing 1; ECG = Electrocardiography

The wearables used for the Subject Testing 2 can be seen in *Table 5*. The HRM-2935 biosensor was placed on the subject's right earlobe. The device could not be placed directly on an earlobe piercing. The Zoom HRV smartwatch was positioned about five centimetres below the participant's left wrist. This wearable device enables a maximum HRV recording time of three minutes which had to be considered during data analysis. A data acquisition is only possible during a resting phase. Therefore, no raw data were recorded while exercising. A quick double press of the Zoom Button activated the HRV data recording at rest. The chest strap (Movesense HR) was moistened before the application to reduce the contact impedance. Images of the used biosensors for Subject Testing 1 and 2 can be seen in Appendix C.

Nr.	Model	Company	Position	Principle
1	Zoom HRV	LifeTrak	wrist	PPG
2	Movesense HR	Suunto	chest	ECG
3	HRM-2935	Kyto Technology	ear	PPG

Table 5: wearables used for the Subject Testing 2; ECG = Electrocardiography; PPG = Photoplethysmography

#### 2.4.2 Preparation

The participants were informed about the procedure, the background of the HRV and the goal of the project before the subject testing. Every subject had to sign a declaration of consent (see appendix A) which contained information about risk during the testing and the use of personal data. The subject had to adjust the seat to the preferred position and power of the ergometer. A skin preparation was required to ensure a high-quality ECG-signal. The position for the electrode placement had to be clean, dry and free of body hair to ensure that the electrodes stick properly on the body and to reduce the surface impedance [41]. The first electrode (white cable) was placed on the sternum and the second electrode (red cable) about three centimetres below the left pectoralis major. The reference electrode (black cable) was placed on the right malleolus lateralis (see *Figure 6*) and fixed with a strap to reduce movement artefacts.



Figure 6: The first electrode (white cable) was placed on the sternum. The second electrode (red cable) about three centimetres below the left pectoralis major and the chest belt. The reference electrode (black cable) was placed on the right malleolus lateralis.

The following requirements had to be observed before the subject testing:

- No smoking for one hour
- No exercise for two hours
- No meal immediately before the testing
- No alcohol for two hours
- No relaxation or Yoga immediately before the testing

#### 2.4.3 Data recording

The signal was processed with the Biopac BSL 4.0 MP35 software (Biopac Systems Inc, Goleta USA). The sampling frequency was set to 1000 Hz. The frequency range for detecting the signal was set from 0.05 Hz to 150 Hz. An automatic calculation of the RR-values was processed. The data processing of the ECG signal can be seen in *Figure 7*. The recording was saved as text-file, Matlab-file and as acq-file (data graph for AcqKnowledge).



Figure 7: ECG signal (blue frame) of eight consecutive heart beats with x-axis in seconds and y-axis in millivolt. Calculated RR beat intervals (green frame) of the ECG data with x-axis and y-axis in seconds.

The wearables were connected to the commercially available smartphone application Elite HRV (Elite HRV GmbH, Austin USA) for data recording. An example of the data recording can be seen in Figure 8. Every wearable was connected to a separate smartphone. To avoid automatic data processing and filtering the function "Open Reading" was used.



Figure 8: Zoom HRV smartwatch at Open Reading mode (blue LED is shining) connected to a smartphone, running the Elite HRV application. A preview of the current heart frequency and the variability can be seen on the screen during data recording.

The raw HRV data (RR-values) were exported and saved as text file. Furthermore, all subject data were collected in separated Excel-files. An example of the raw data of Biopac and Polar H10 can be seen in *Figure 9*.

Subject 1		Subject 2		Subject 3		Subject 4	
Biopac	POLAR	Biopac	POLAR	Biopac	POLAR	Biopac	POLAR
1033	1033	684	684	1350	1350	885	886
1067	1067	670	669	1049	1049	887	887
1068	1067	647	647	1023	1023	823	824
1029	1029	652	652	1567	1566	799	800
1067	1067	662	662	1478	1479	814	813
1062	1062	684	684	1345	1345	843	843
1010	1010	649	648	1117	1117	861	861
1078	1078	636	637	1475	1476	875	875
1060	1060	639	640	1443	1442	884	884
1031	1031	656	655	1338	1338	821	821
1085	1085	671	672	1382	1382	772	772
1058	1058	659	658	1456	1457	778	778
1034	1034	636	637	1228	1228	800	800
1077	1077	639	639	995	996	841	841
1027	1026	660	660	1487	1486	883	883
1010	1011	693	692	1411	1411	899	899
1042	1042	703	703	1240	1240	911	911
1000	1000	660	660	1440	1440	898	897

Figure 9: An example of the raw data of Biopac and Polar H10 (Subject 1 - Subject 4), collected in an Excel-file. This data matrix was used for the further analysis.

#### 2.4.4 Testing procedure



### 2.5 Data analysis

The data were processed and analysed with Matlab (MathWorks GmbH Natick USA, R2017a) and with Microsoft Excel (Microsoft Corporation Redmond USA, Excel 2016). The well-known algorithm of Pan and Tompkin [18] was used for the R-peak detection of the ECG data sets, collected from the Biopac MP35 system. It was implemented in a Matlab-file and the data sets were exported as a text-file. These RR intervals of the clinical standard and the wearable were matched for each testing. The changes of inter-beat-intervals caused by breathing allowed a visual synchronisation of the two related data sets. The first 40 pairs of the data columns were observed at a plot and manually matched that the smallest error was found. An example of this synchronisation process can be seen in *Figure 10*. After this, a visual inspection of the data sets was performed in Excel. Data pairs with outliers, artefacts and missing RR-intervals were marked, deleted and counted for further parameter calculation (fail\_c =fail counter). To ensure an equal length of both data sets the longer one was cut in the end.



Figure 10: Plot of the manually synchronised raw data sets (first 40 pairs) for the Biopac (orange line) and the Zoom HRV (blue line).

Data sets with more than 30% missing RR intervals due to connection issues or other problems during subject testing were excluded from the data analysis (see at chapter 3) and noted for each sensor in the results. The further data processing was performed in Matlab. All paired values with a difference bigger than 100 milliseconds were deleted and counted (fail\_c). The numbers of excluded RR intervals during the visual inspection were added to the parameter fail\_c. The data sets of the different subjects were merged to have one data set for each sensor (at rest and at exercise). All parameters necessary for a Bland-Altman plot were calculated in a separate function (e.g. the 2SD confidence limits, the SD of the data set 1+2, the mean value of the data set 1+2). The LoA, the Bias and the percentage of failures (p\_fail) were calculated. Furthermore, the Pearson's Correlation Coefficients for rest and exercise were computed using the Matlab function "corr2". The relative error between the clinical standard and every sensor was calculated. The Bland-Altman plot and the results of the calculation for each sensor can be seen in chapter 3. The x-axes and y-axes were adapted to the scope of the data sets. The scatterplots were computed using the Matlab function "scatter" with a linear fit of the values (see at chapter 4.2). The data processed were uploaded to the Kubios HRV Standard software (Kubios Oy, Kuopio Finland) to calculate the parameters of interest (Mean RR, SDNN, Mean HR, RMSSD, pNN50, SD1, SD2) for each sensor at rest and exercise. Due to the previous data processing in Matlab no further artefact correction was made in Kubios HRV. The user interface of this software tool for HRV analysis during executing an example can be seen in Appendix B.

## 3 Results

The Pearson's Correlation Coefficients for all seven sensors at rest and exercise can be seen in *Table 6*. A Correlation Coefficient of nearly 1 means that the two sensors show a strong linear relation and a Coefficient of nearly 0 means that the two sensors show a weak linear relation. The Zoom HRV smartwatch provides raw data only during rest. Therefore, no results are displayed for this sensor at exercise (see chapter 2.4.1). The number of excluded subjects at the data processing of every wearable is stated in the corresponding section. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. The parameter p\_fail describes the percentage of failed inter-beat-intervals (see description at chapter 2.5). The results are presented in the labelling of every plot.

	Pearson Cor Rest	Pearson Cor Exercise
Polar H10	0.999993	0.999719
HRM Blue	0.999987	0.999668
Firstbeat Bodyguard	0.999990	0.999923
Suunto Smart Sensor	0.999991	0.999734
Zoom HRV	0.961789	-
Movesense HR	0.999984	0.999639
HR - 2935	0.975603	0.917112

Table 6: Calculated Pearson's Correlation Coefficient for all wearables used for the subject tests (at rest and at exercise). The Zoom HRV smartwatch provides raw data only during rest. A Coefficient of nearly 1 means that the two sensors show a strong linear relation and a Coefficient of nearly 0 means that the two sensors show a weak linear relation.



Figure 11: Bland-Altman plot of the Polar H10 at rest. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = -0.05 ms; LoA = 1.41 to -1.51 ms; p\_fail = 0.17 %

Subject 7 was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in *Figure 11*. The calculated HRV parameters and the relative errors are listed in *Table 7*.

RESI			
	Biopac	Polar	Relative Error [%]
Mean RR (ms)	903.24	903.29	0.01
SDNN (ms)	74.79	74.71	0.11
Mean HR (bpm)	66.43	66.42	0.02
RMSSD (ms)	86.01	85.91	0.12
pNN50 (%)	30.32	30.39	0.23
SD1 (ms)	60.82	60.76	0.10
SD2 (ms)	86.55	86.47	0.09

Table 7: Calculated HRV parameters and the relative errors of the Polar H10 at rest.



Figure 12: Bland-Altman plot of the Polar H10 at exercise. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = 0.06 ms; LoA = 4.12 to -4.2 ms; p\_fail = 0.26 %

Subject 9 was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in Figure 12. The calculated HRV parameters and the relative errors are listed in Table 8.

	Biopac	Polar	Relative Error [%]
Mean RR (ms)	452.69	452.75	0.01
SDNN (ms)	13.73	13.68	0.36
Mean HR (bpm)	132.54	132.52	0.02
RMSSD (ms)	10.13	9.95	1.78
pNN50 (%)	0.38	0.35	7.89
SD1 (ms)	7.16	7.03	1.82
SD2 (ms)	18.06	18.02	0.22

#### EXERCISE

Table 8: Calculated HRV parameters and the relative errors of the Polar H10 at exercise.



Figure 13: Bland-Altman plot of the HRM Blue at rest. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = 0.29 ms; LoA = 5.94 to -5.36 ms; p\_fail = 0.90 %

Subject 7 was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in Figure 13. The calculated HRV parameters and the relative errors are listed in *Table 9*.

RESI			
	Biopac	HRM Blue	Relative Error [%]
Mean RR (ms)	907.99	907.70	0.03
SDNN (ms)	63.62	63.83	0.33
Mean HR (bpm)	66.08	66.10	0.03
RMSSD (ms)	82.52	82.85	0.40
pNN50 (%)	31.38	31.51	0.41
SD1 (ms)	58.36	58.60	0.41
SD2 (ms)	68.50	68.68	0.26

Table 9: Calculated HRV parameters and the relative errors of the HRM Blue at rest.



Figure 14: Bland-Altman plot of the HRM Blue at exercise. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = 0.32 ms; LoA = 5.37 to -4.73 ms; p\_fail = 0.36 %

Subjects 4+7+8 were excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in *Figure 14*. The calculated HRV parameters and the relative errors are listed in *Table 10*.

	Biopac	HRM Blue	Relative Error [%]
Mean RR (ms)	466.55	466.23	0.07
SDNN (ms)	14.11	14.23	0.85
Mean HR (bpm)	128.60	128.69	0.07
RMSSD (ms)	9.63	9.96	3.43
pNN50 (%)	0.19	0.21	10.53
SD1 (ms)	6.81	7.05	3.52
SD2 (ms)	18.76	18.86	0.53

EXERCISE

Table 10: Calculated HRV parameters and the relative errors of the HRM Blue at exercise.

#### 3.3 Firstbeat Bodyguard



Figure 15: Bland-Altman plot of the Firstbeat Bodyguard at rest. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = -0.04 ms; LoA = 3.79 to -3.86 ms; p\_fail = 0.16 %

No subject was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in *Figure 15*. The calculated HRV parameters and the relative errors are listed in *Table 11*.

REST			
	Biopac	Firstbeat	Relative Error [%]
Mean RR (ms)	923.30	923.34	0.004
SDNN (ms)	84.84	84.67	0.20
Mean HR (bpm)	64.98	64.98	0.00
RMSSD (ms)	98.95	98.79	0.16
pNN50 (%)	33.45	33.22	0.69
SD1 (ms)	69.98	69.86	0.17
SD2 (ms)	97.47	97.26	0.22

Table 11: Calculated HRV parameters and the relative errors of the Firstbeat Bodyguard at rest.



Figure 16: Bland-Altman plot of the Firstbeat at exercise. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = -0.02 ms; LoA = 2.83 to -2.87 ms; p\_fail = 0.05 %

Subject 8 was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in *Figure 16*. The calculated HRV parameters and the relative errors are listed in *Table 12*.

	Biopac	Firstbeat	Relative Error [%]
Mean RR (ms)	458.29	458.31	0.004
SDNN (ms)	12.53	12.67	1.12
Mean HR (bpm)	130.92	130.91	0.01
RMSSD (ms)	8.81	9.21	4.54
pNN50 (%)	0.14	0.16	14.29
SD1 (ms)	6.23	6.52	4.65
SD2 (ms)	16.59	16.70	0.66

#### EXERCISE

Table 12: Calculated HRV parameters and the relative errors of the Firstbeat at exercise.

#### 3.4 Suunto Smart Sensor



Figure 17: Bland-Altman plot of the Suunto at rest. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = 0.46 ms; LoA = 2.14 to -1.21 ms; p\_fail = 0 %

No subject was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in *Figure 17*. The calculated HRV parameters and the relative errors are listed in *Table 13*.

RESI			
	Biopac	Suunto	Relative Error [%]
Mean RR (ms)	902.48	902.02	0.05
SDNN (ms)	74.63	74.57	0.08
Mean HR (bpm)	66.48	66.52	0.06
RMSSD (ms)	85.81	85.72	0.10
pNN50 (%)	30.19	30.10	0.30
SD1 (ms)	60.69	60.62	0.12
SD2 (ms)	86.37	86.31	0.07

Table 13: Calculated HRV parameters and the relative errors of the Suunto at rest.



Figure 18: Bland-Altman plot of the Suunto at exercise. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = 0.39 ms; LoA = 4.48 to -3.71 ms; p\_fail = 0 %

Subject 7 was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in *Figure 18*. The calculated HRV parameters and the relative errors are listed in *Table 14*.

	Biopac	Suunto	Relative Error [%]
Mean RR (ms)	454.67	454.38	0.06
SDNN (ms)	13.88	13.76	0.86
Mean HR (bpm)	131.96	132.05	0.07
RMSSD (ms)	10.04	9.45	5.88
pNN50 (%)	0.35	0.29	17.14
SD1 (ms)	7.10	6.68	5.92
SD2 (ms)	18.30	18.28	0.11

#### EXERCISE

Table 14: Calculated HRV parameters and the relative errors of the Suunto at exercise.

#### 3.5 Zoom HRV



Figure 19: Bland-Altman plot of the Zoom HRV at rest. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = 0.57 ms; LoA = 74.48 to -73.34 ms; p\_fail = 9.57 %

Subject 11 was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in *Figure 19*. The calculated HRV parameters and the relative errors are listed in *Table 15*.

REST			
	Biopac	Zoom	Relative Error [%]
Mean RR (ms)	858.04	854.43	0.42
SDNN (ms)	54.74	63.49	15.98
Mean HR (bpm)	69.93	70.22	0.41
RMSSD (ms)	54.48	70.08	28.63
pNN50 (%)	23.85	34.06	42.81
SD1 (ms)	38.54	49.58	28.65
SD2 (ms)	67.17	74.90	11.51

Table 15: Calculated HRV parameters and the relative errors of the Zoom HRV at rest.

#### 3.6 Movesense HR



Figure 20: Bland-Altman plot of the Movesense HR at rest. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = 0.52 ms; LoA = 2.35 to -1.31 ms; p\_fail = 0.05 %

No subject was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in Figure 20. The calculated HRV parameters and the relative errors are listed in Table 16.

RESI			
	Biopac	Movesense	Relative Error [%]
Mean RR (ms)	878.24	877.72	0.06
SDNN (ms)	53.42	53.35	0.13
Mean HR (bpm)	68.32	68.36	0.06
RMSSD (ms)	54.65	54.49	0.29
pNN50 (%)	24.18	23.60	2.40
SD1 (ms)	38.65	38.54	0.28
SD2 (ms)	64.93	64.87	0.09

Table 16: Calculated HRV parameters and the relative errors of the Movesense HR at rest.



Figure 21: Bland-Altman plot of the Movesense HR at exercise. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter  $p_{fail}$  describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = 0.47 ms; LoA = 3.14 to -2.19 ms;  $p_{fail}$  = 0.04 %

Subjects 10 was excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in Figure 21. The calculated HRV parameters and the relative errors are listed in Table 17.

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	Biopac	Movesense	Relative Error [%]
Mean RR (ms)	486.76	486.30	0.09
SDNN (ms)	11.51	11.49	0.17
Mean HR (bpm)	123.26	123.38	0.1
RMSSD (ms)	10.47	10.51	0.38
pNN50 (%)	0.62	0.62	0.00
SD1 (ms)	7.40	7.43	0.41
SD2 (ms)	14.50	14.46	0.28

Table 17: Calculated HRV parameters and the relative errors of the Movesense HR at exercise.

DECT



Figure 22: Bland-Altman plot of the HRM 2935 at rest. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = -4.06 ms; LoA = 62.55 to -70.67 ms; p\_fail = 4.70 %

Subjects 10+13+15 were excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in Figure 22. The calculated HRV parameters and the relative errors are listed in *Table 18*.

NL31			
	Biopac	HRM-2935	Relative Error [%]
Mean RR (ms)	878.81	877.56	0.14
SDNN (ms)	55.57	69.37	24.83
Mean HR (bpm)	68.27	68.37	0.15
RMSSD (ms)	57.29	83.32	45.44
pNN50 (%)	24.50	43.07	75.80
SD1 (ms)	40.52	58.93	45.43
SD2 (ms)	67.23	78.37	16.57

Table 18: Calculated HRV parametesr and the relative errors of the HRM 2935 at rest.



Figure 23: Bland-Altman plot of the HRM Blue at rest. The red line in the Bland-Altman plot shows the Bias. The two grey lines show the LoA of all datapoints. Every blue dot represents one pair of data points. The parameter p\_fail describes the percentage of failed inter-beat-intervals. Both axes are described in milliseconds. Bias = -0.67 ms; LoA = 44.15 to -45.49 ms; p\_fail = 1.64 %

Subjects 10+13+14 were excluded due to connection issues, a high number of artefacts or because of other problems during subject testing. The Bland-Altman plot is presented in Figure 23. The calculated HRV parameters and the relative errors are listed in Table 19.

EXERCISE			
	Biopac	HRM-2935	Relative Error [%]
Mean RR (ms)	504.71	505.04	0.07
SDNN (ms)	7.94	25.09	215.99
Mean HR (bpm)	118.88	118.80	0.07
RMSSD (ms)	6.51	33.51	414.75
pNN50 (%)	0.21	10.96	5119.05
SD1 (ms)	4.61	23.70	414.10
SD2 (ms)	10.25	26.41	157.66

Table 19: Calculated HRV parameters and the relative errors of the HRM 2935 at exercise.

### 3.8 Absolute Errors:

The Mean Absolute Errors for the parameters of interest of all wearables can be seen in Table 20. It is the mean difference between each parameter of the clinical standard and of the biosensor. Due to the missing data set of the Zoom HRV at exercise the smartwatch was not considered in this calculation. The standard deviations of the results are listed beside in brackets. The selection of the parameters of interest was made by the author before the subject testing.

	Absolute Error - Rest (SD)	Absolute Error - Exercise (SD)
Mean RR (ms)	0.44 (0.45)	0.25 (0.17)
SDNN (ms)	2.40 (5.59)	2.95 (6.96)
Mean HR (bpm)	0.04 (0.04)	0.07 (0.04)
RMSSD (ms)	4.48 (10.56)	4.76 (10.90)
pNN50 (%)	3.28 (7.49)	1.81 (4.38)
SD1 (ms)	3.17 (7.47)	3.37 (7.70)
SD2 (ms)	1.96 (4.50)	2.76 (6.56)

Table 20: Mean Absolute Errors of all wearables at rest and exercise. Due to the missing data set of the Zoom HRV at exercise, the smartwatch was not considered in this calculation. The standard deviations of the results are listed beside in brackets.

## 4 Discussion

Only the most important information is mentioned in the section "The background of the HRV" (see at chapter 1.2). For a deeper insight in HRV analysis, primary literature like "A Review of Heart Rate Variability and its Applications", by C.D. Hoang [43], "Hear Rate Variability: Clinical Applications and Interaction between HRV and Hear Rate", by K. Trimmel [41] or "Herzratenvariabilität: Das HRV-Praxis-Lehrbuch", by A. Lohninger [15] are recommended. It must be considered, that the online market analysis shows only a small section of all wearables available (see at chapter 2.3) and could be updated from time to time. The study design was explicitly created for this project (see at chapter 2.4.4). Therefore, a successful use of the setup in another scientific study cannot be guaranteed. For a better interpretation of the data quality and the usability of PPG-based sensors a higher number of different devices would be necessary.

### 4.1 Market analysis

Due to the growing market for healthcare and fitness, many different wearable biosensors are available. More than 30 percent of the people in the world are tracking their fitness level or their health with a wearable [2].Usually there is a lack of scientific validations of the

devices. Most of the available studies only validate the heart rate estimation or the heart frequency [1] [6]. This fact makes a use of the wearables for medical HRV analysis impossible. The manufacturers explicitly point out that it is not a medical device, so there is no time consuming and expensive validation mandatory [5]. Furthermore, most of them do not publish how they implement data analysis and how they calculate the HRV parameters. For now, there is no mandatory guideline for the calculation of HRV in medicine available [41]. It is usually impossible to gain access to the raw data of the biosensors and the sampling frequency is often unknown. Therefore, it is difficult to interpret the data quality of these biosensors without any scientific data analysis. All PPG-based devices investigated are applicable for short-term use only [8]. The manufacturers of those sensors recommend an HRV measurement during rest [7]. For an extensive HRV analysis a long-term measurement including an exercise period and a period of cognitive work would deliver better results. During the online research occurred, that many manufacturers do not state out the big differences between a heartrate measurement and an HRV measurement. Therefore, costumers may not understand the requirements, conditions and advantages of this method. It can be said that ECG-based sensors are placed on the chest and PPG-based sensors on the wrist or finger [8]. Exceptions are wearables placed on the earlobe, the arm, the neck or the shoulders (see at chapter 2.3).

#### 4.2 Correlation between the sensors

The Pearson's Correlation Coefficient shows how well 2 data sets are linear related. It gives you information about the relationship of the curves but not about the slope [50]. Scientists published a method as a guideline to interpret this correlation coefficient. Furthermore, a visual inspection of a corresponding scatterplot is a helpful tool to analyse the correlation of the data sets [51]. A coefficient of zero means there is no relation between the data sets. If the correlation coefficient is close to minus 1 there is a very strong negative relation. If the correlation coefficient is close to plus 1 there is a very strong positive relation between the data sets [50].

All calculated Pearson's Correlation Coefficients of the subject tests show a very strong positive relation between the clinical standard (Biopac MP35) and each biosensor. They detailed results can be seen at Table 6. The highest correlation was found at the Polar H10 at rest (R=0.999993) and can be seen in a scatterplot in *Figure 24*. The lowest correlation was found at the HR-2935 sensor at exercise (R=0.917112) and can be seen in a scatterplot in *Figure 25*. All ECG-based sensors show an extremely high correlation at rest and exercise. The two PPG-based wearables show a lower correlation. There were no big differences found in the results at rest and at exercise recognizable. The linear fits of all scatterplots are similar with an angle of about 45°.



Figure 24: Scatterplot of the Polar H10 sensor and the clinical standard at rest. R is the Pearson's Correlation Coefficient. The x-axis represents the RR-values of the Biopac MP35 in milliseconds. The y-axis represents the RR-values of the Polar H10 in milliseconds. Every blue dot represents one pair of data points. The red line is the linear fit of all data points.



Figure 25: Scatterplot of the HRM-2935 at and the clinical standard at exercise. R is the Pearson's Correlation Coefficient. The x-axis represents the RR-values of the Biopac MP35 in milliseconds. The y-axis represents the RR-values of the HRM-2935 in milliseconds. Every blue dot represents one pair of data points. The red line is the linear fit of all data points.

#### 4.3 Data quality of the sensors

The Polar H10, the Firstbeat Bodyguard, the Suunto Smart Sensor and the Movesense HR delivered high-quality data at rest and at exercise and are therefore recommended for an HRV recording. A maximum of one subject had to be excluded during data analysis due to connection issues, a high number of artefacts or because of other problems during subject testing. Thus, a high number of data points was used for the calculation of the HRV parameters. Due to the small absolute values of the parameters RMSSD, pNN50, and SD1 during exercise the corresponding relative errors are significantly higher (up to 17.14 %) compared to the other parameters. It must be considered, that pNN50 is not meaningful during a shortterm recording at exercise due to the physiological decrease of the HRV [52]. All the other parameters demonstrate very small relative errors at rest (<0.26%) and at exercise (<1.12%). Furthermore, the results of these four devices show a very low percentage of failed R-peaks at rest (<0.17%) and at exercise (<0.26%). This test results are confirmed with very tight LoA at rest (<3.79 to -3.86 ms) and at exercise (<4.48 to -3.71 ms). The bias in the Bland-Altman plots are close to zero for all chest straps. The maximum aberrance calculated is 0.52 milliseconds. The HRM Blue shows small relative errors at rest and at exercise but several problems at the usability (see at chapter 4.5). Due to problems during testing four participants in total had to be excluded at the data analysis. The percentage of failed R-peaks (<0.9%) is higher than the values of all the other chest straps, but still low. The LoA at rest (5.94 to -5.36 ms) and at exercise (5.37 to -4.73 ms) are acceptable for an HRV measurement. Like all other chest straps, the HRM Blue shows significantly higher relative errors for RMSSD, pNN50 and SD1 at exercise than for the other HRV parameters. The Zoom HRV smartwatch delivers small relative errors for the Mean RR and the Mean HR (<0.42%) at rest. Due to this test result, a heart frequency measurement can be recommended. All other parameters show high relative errors up to 42.81 %. The LoA are considerably high (74.48 to -73.34 ms). Furthermore, the percentage of failed R-peaks is significantly higher (9.57%). Only one subject had to be excluded during data analysis and the bias in the Bland-Altman (0.57 ms) plot is close to zero. However, the use of the Zoom HRV for an extended analysis cannot be recommended. The HRM-2935 earclip shows small relative errors for the Mean RR and the Mean HR at rest (<0.15%) and at exercise (<0.07%). Due to this test result, a heart frequency measurement with a high accuracy is possible. All other parameters show high relative errors (up to 75.8%) at rest and extremely high relative errors (up to 5119%) at exercise. Surprisingly, the LoA at rest (62.55 to -70.67 ms) is higher than the LoA at exercise (44.15 to -45.49 ms). Furthermore, the percentage of failed R-peaks is higher at rest (4.70%) than at exercise (1.64%). It is supposed, that the earclip cannot deliver high-quality data if the variability is increased (at rest). The result shows a bias in the Bland-Altman plot of -4.06 milliseconds at rest and of -0.67 milliseconds at exercise. Summing up, it can be said, that the HRM-2935 earclip measures the Mean HR and the Mean RR with high accuracy but delivers unprecise results for all the other HRV parameters.

#### 4.4 Absolute errors of the sensors

The Mean Absolute Errors for the parameters of interest of all wearables can be seen in Table 20. It can be said, that the accuracy of the parameters of interest varies. The Mean Absolute Errors of the Mean RR (0.25 to 0.44 ms) and the Mean HR (0.04 to 0.07 bpm) are small with a small standard deviation at rest and at exercise. Therefore, a high accurate measurement of this parameter can be guaranteed. The result shows a difference in SDNN of 2.4 ms at rest and 2.95 ms at exercise. The difference in SD2 is 1.96 ms at rest and 2.76 ms at exercise. The results of both, SDNN and SD2, are acceptable for short-term HRV measurement but they must be considered. The difference in pNN50 is smaller at exercise (1.81 %) than at rest (3.28%) but with a high standard deviation. It can be argued, that the pNN50 is very small at exercise anyway. Therefore, this parameter is not meaningful during a short-term measurement at exercise [52]. The results show a difference in RMSSD of 4.48 ms at rest and 4.76 ms at exercise. The difference in SD1 is 3.17 ms at rest and 3.37 ms at exercise. The results of both show a high standard deviation (up to 10.90 ms). Therefore, the errors of this parameters are not acceptable for an HRV analysis. The data quality of ECG-based sensors is doubtless higher than the data quality of PPG-based sensors (see at chapter 3). To outline the differences between the sensor principles, the mean absolute errors of only the ECG-based wearables were calculated and can be seen in Table 21. All parameters show very small absolute errors at rest and at exercise. The standard deviations are small as well. Therefore, all parameters in Table 21 are acceptable for an interpretation in an HRV analysis.

	Absolute Error - Rest (SD)	Absolute Error - Exercise (SD)
Mean RR (ms)	0.27 (0.22)	0.23 (0.19)
SDNN (ms)	0.12 (0.07)	0.11 (0.08)
Mean HR (bpm)	0.02 (0.02)	0.07 (0.05)
RMSSD (ms)	0.17 (0.10)	0.31 (0.21)
pNN50 (%)	0.22 (0.21)	0.03 (0.02)
SD1 (ms)	0.12 (0.07)	0.22 (0.15)
SD2 (ms)	0.11 (0.08)	0.08 (0.08)

 Table 21: Mean Absolute Errors of ECG-based (n=5) wearables at rest and exercise. The standard deviations of the results are listed beside in brackets.

### 4.5 Usability

All chest straps were equipped with new batteries before the start of the first subject testing. No problems with the power supply were identified during the whole time period of testing. Therefore, a change of battery was not necessary. The usability of the ECG-based devices was excellent. After the application of the sensor and the electrode on the chest it starts

connecting automatically. None of these wearables showed bigger connectivity problems via Bluetooth. The sensors stay in the stand-by mode after disconnection to expand battery life. This easy and reliable structure of the chest straps would be a big advantage for use in medical applications. Some problems with the single wearables occurred during subject testing. The Suunto Smart Sensor delivered high-quality data, showed a reliable usability and only view missed beats during testing. The HRM Blue showed regular connectivity problems. Reliable data were only derived if the strap was really wet and tightly applicated on the chest. The Bluetooth connection interrupted sometimes during the testing and it delivered more missed beats. Therefore, the use of another chest strap for an HRM measurement is recommended. The Polar H10 showed a reliable usability without any connectivity problems. Only view missed beats were recognised during data analysis. The Firstbeat Bodyguard delivered excellent data quality without any missed R-peaks. It is necessary to attach two disposable electrodes on the chest (see at chapter 2.4.1). Therefore, the use of a chest belt for daily measurements is recommended. The PPG-based biosensors delivered many complications regarding usability. The HRM-2935 earclip showed many connectivity problems during testing at rest and exercise. The Bluetooth connection interrupted sometimes at unknown reasons. Furthermore, the device did not show the battery level as expected. The device couldn't be placed directly on an earlobe piercing. It delivered many missed R-peaks, especially during exercise. To avoid wrong measurements a one-minute stabilization period was necessary. A use of the earclip during sports or for long-term measurements cannot be recommended. The Zoom HRV showed many connectivity problems during testing at rest. It does not have a display, so the user must know the meaning of the different blinking diodes. Furthermore, the data acquisition was interrupted immediately if the arm was moved a little bit. Therefore, a measurement during exercise on the ergometer was not possible. To avoid wrong measurements a one-minute stabilization period was necessary. The Zoom HRV only enables three-minutes recording. The wearable delivers many missed R-peaks. Therefore, the use of the smartwatch for a proper HRV analysis cannot be recommended.

### 4.6 Subject Testing

Due to the high number of tested devices at the same time, it was not easy to ensure a highquality recording of the HRV. If one sensor showed connectivity problems, the whole testing procedure had to be restarted. Therefore, the subject testing took a longer time period than expected. For similar, scientific investigations, it is recommended to use less biosensors simultaneously at one recording. More participants for the subject tests would increase the validity of the study. The average age of the participants was only 25.9 years. More subjects in different age groups and with different fitness levels would have improved the expressiveness of the results as well. All the subject tests were conducted by the author of this thesis alone. For a fast and synchronized process of the testing an assistant would have been helpful.

### 4.7 Conclusion & Outlook

The results indicate big differences in data quality between ECG-based and PPG-based biosensors. All wearables show a very strong correlation with the clinical standard. The errors calculated are different at the single HRV parameters. The ECG-based devices delivered very small standard deviations, relative and absolute errors at rest and at exercise. A simple and robust usability and a good peak detection were found. It can be concluded, that ECG-based sensors could be used for some medical applications, like an accurate measurement of the heart rate or the HRV. PPG-based sensors delivered large standard deviations, relative and absolute errors. Due to these results, difficulties at the usability and regular problems during the subject tests they are not recommendable for medical use. However, a private use of PPG-based sensors for heart rate detection can be recommended. The market analysis showed a huge growth of the market for wearable biosensors right now. The access to the raw data of the sensors is impossible for most of the devices. Therefore, a scientific data validation is difficult. Improved or new sensors with higher sampling frequencies, better analyse algorithms and an enhanced usability will be developed in the next years. Therefore, a use of PPG-based sensors like smartwatches, ear clips or finger sensors for an accurate HRV measurement could be possible in the future. In particular, for long-term surveillance and in the home-care sector it would be a great improvement if vital signs like the heart frequency or the HRV could be measured with common available wearables or gadgets of the everyday life.

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## List of Abbreviations

HRV	Heart Rate Variability
UAS	University of Applied Science
ANS	Autonomic Nervous System
PPG	Photoplethysmography
ECG	Electrocardiography
SA	Sinoatrial
AV	Atrioventricular
SNS	Sympathetic Nervous System
PNS	Parasympathetic Nervous System
RSA	Respiratory Sinus Arrhythmia
LED	Light Emitting Diode
CTG	Cardiotocography
REM	Rapid Eye Movement
ES	Effect Size
SDNN	Standard Deviation of all RR Intervals
RMSSD	Root Mean-Square of Successive Differences of adjacent RR intervals
pNN50	Percentage of adjacent RR intervals differing by more than 50 ms
TEE	Technical Error Estimate
ICC	Inter-Class-Correlation
LoA	Limits of Agreement
SD	Standard Deviation
HR	Heart Rate
ms	Milliseconds

## A: Declaration of consent

Die Richtlinien der Grund möchte ich Sie bitten, der vorliegenden Einverständniserklärung zuzustimmen. Zu Ihrer Information sind nachfolgend einige Hinweise aufgeführt.

#### (1) Allgemeines

Die Studie wird am Fachgebiet Gesundheits- und Rehabilitationstechnik der Fachhochschule Technikum Wien mit dem Titel "Ermittlung der Datenqualität und der Usability von in Wearables verbauten Biosensoren, zur Anwendung in der Gesundheitstechnik" durchgeführt und verfolgt rein wissenschaftliche Zwecke. Daraus ergibt sich, dass durch diese Studie gewonnene Messdaten auch im Zuge von wissenschaftlichen Arbeiten in pseudonymisierter bzw. verschlüsselter Form an die Öffentlichkeit gelangen.

#### (2) Teilnahme

Sie befinden Sich körperlich und geistig in einem gesunden Zustand, sodass Sie an der Studie teilnehmen können. Die Teilnahme ist völlig freiwillig, woraus sich folgende Punkte daraus ergeben:

- I. Für Verletzungen und/oder körperliche Schäden, die im Zuge dieser Studie entstehen können, übernimmt der Verantwortliche dieser Studie keine Haftung.
- II. Es steht Ihnen zu jedem Zeitpunkt dieser Studie frei, Ihre Teilnahme abzubrechen, ohne dass Ihnen dadurch Nachteile entstehen.
- III. Es besteht kein Recht auf materielle und/oder immaterielle Entschädigung.

#### (3) Datenschutz

I. <u>Nutzung der Daten:</u>

Ich erkläre mich einverstanden, dass die nachfolgend persönliche Daten erhoben und zu Forschungszwecken verwendet werden dürfen.

II. Einwilligung der Speicherung und Verarbeitung:

Ihre im Rahmen der Studie angegebenen personenbezogenen Daten werden pseudonymisiert gespeichert. Das bedeutet, dass Namen, Geburtsdatum etc. von Ihren Antworten entfernt werden und ein Code verwendet wird, so dass Ihre Angaben in der Studie nicht mit Ihnen persönlich in Verbindung gebracht werden können. Die pseudonymisierten Daten sind nur dem an der Studie beteiligtem Verantwortlichen zugänglich und werden zu keinem Zeitpunkt an Dritte weitergegeben.

#### (4) Offene Fragen

Alle Fragen, die Sie an den Verantwortlichen der Studie im Bezug zu dieser gestellt haben, wurden Ihnen verständlich und genügend beantwortet.

#### **Unterschrift Teilnehmer:**

**Unterschrift Verantwortlicher:** 

#### (5) Optionale Einverständnisse

#### **Zutreffendes bitte Ankreuzen:**

Der Verantwortliche der Studie darf im Zuge der Studie Fotos machen und diese auch in pseudonymisierter bzw. verschlüsselter Form in der wissenschaftlichen Arbeit als Bildmaterial verwenden.

□ JA □ NEIN

#### (6) Persönliche Daten

- Geschlecht: \_\_\_\_\_\_
- Geburtsdatum: \_\_\_\_\_\_
- Größe [cm]: \_\_\_\_\_
- Gewicht [kg]: \_\_\_\_\_
- Ø sportliche Aktivität [Stunden/Woche]: \_\_\_\_\_
- Bevorzugte Sportart: \_\_\_\_\_\_

Ich bestätige hiermit, dass die oben angegebenen persönlichen Daten richtig sind.

## B: Kubios HRV Standard - User interface



## C: Images of the used biosensors



Figure 26: Images of the used biosensors at Subject Testing 1+2; 1=Polar H10 [53]; 2=HRM Blue [54]; 3=Firstbeat Bodyguard [55]; 4=Suunto Smart Sensor [56]; 5=Zoom HRV [57]; 6=Movesense HR [58]; 7=HRM-2935 [59]