Application of Mobile Phone-Based ECG, Heart-Rate and Physical Activity Monitor for Heart Failure Management

by

Romina Forouzanfar

A thesis submitted in conformity with the requirements for the degree of Masters of Health Science, Clinical Engineering

Institute of Biomaterials and Biomedical Engineering
University of Toronto

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2016

Abstract

Heart failure (HF) is the main cause of mortality in North America with a significant social and economic cost. Recent studies indicate there is a relationship between discharge heart rate and mortality and hospitalization in HF patients. Hence, heart rate could be monitored as another clinical indicator in HF patients transitioning from hospital to ambulatory care. Current heart rate monitors either lack the user-friendly interface, or designed to be used as wellness devices and not validated against clinical gold standard systems. This work describes the design, development and evaluation of a wearable heart rate, ECG and physical activity monitoring system called BeatHR that is able to capture and stream ECG and heart rate values in real-time via using a chest patch and a smartphone application. BeatHR was compared to a clinical gold standard, Holter monitor, and was found to generate comparable result with Intra-class correlation coefficients as high as 0.954.
Dedication

I dedicate this work to my family without whom this would not have been possible. To my mom, for her endless and unconditional love. To my dad, for his great support and always teaching me to put my best for my work. To my sister, who is the best gift God has ever given me.
Acknowledgments

This work was only possible with the support and help of many people whom I will always be grateful to. I would like to first express my gratitude to my supervisor Dr. Joseph A. Cafazzo. Joe, it has been an extreme privilege to work with you for my masters. Thank you for having given me this amazing opportunity. Your vision and guidance throughout this project has been incredible. I would also like to thank my committee members Dr. Heather Ross, Dr. Babak Taati and Dr. Douglas Lee for their valuable support and guidance throughout this work.

I would also like to express my sincere gratitude to Nathaniel Hamming for his incredible patience, great recommendations and unlimited support throughout the application-programming phase of the project. Thanks for everything you have taught me about iOS programming. I am truly grateful to other members of the project team, Kevin Tellavi for his contributions and support in design and development of the wearable sensor and smartphone application, Damon Pfaff, for his great efforts on industrial design of the wearable chest patch.

I would also like to thank Akib Uddin for sharing all of his valuable experience through his thesis experience and other colleagues at Centre for Global eHealth Innovation, Plinio Morita, Melanie Yeung, Lily Alexander, Shivani Goyal, Raghad Abdulmajeed and Harry Qiu for all of their time, support and attention in different stages of this project. I would like to thank all my participants for having the taken the time to participate in my study and provide me with valuable data.

I am also grateful for my great friend Ali Parahoo, who has been a great support throughout this project and his recommendations on how to approach various challenges in my project. Also, thanks a lot for helping me with thesis editing.

Finally, I would like to thank my family for their emotional and financial support throughout my studies. I am more than blessed to have you in my life.
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1 Introduction

Heart Failure (HF) is a clinical syndrome that is caused by structural or functional impairment of ventricular filling or ejection of blood. HF is known as the main cause of morbidity and mortality in North America [1]. While, American over the age of 40, have 20% risk of developing HF [2], incidence of HF has continued to remain stable over the past several decades. There have been over 650,000 new HF patients diagnosed annually [3], [4]. The 2014 update of the American Heart Association shows that based on National Health and Nutrition Examination Survey data over 5.1 million adult Americans aged over 20 suffer from HF. In addition, HF occurrence will increase at rate of 46% from 2012 to 2030 and result in more than 8 million HF cases among adults over 18 years old [1].

Despite improvements in HF survival, the absolute mortality rates is still approximately 50% within 5 years of diagnosis [4], [5]. In the ARIC (Atherosclerosis Risk in Communities) study, the HF mortality rates after hospitalization for 30-day, 1-year and 5-year time periods were shown to be 10.4%, 22%, and 42.3% respectively [6]. Furthermore, for over one million hospitalizations annually, HF is the primary diagnosis [3]. These patients are also at high risk for all-cause re-hospitalization, with 25% readmission rate in one month following the discharge time [7].

While HF is mentioned in one out nine death certificates in Unites States, the number of deaths caused by HF has remained the same between 1995 and 2006 [3]. In addition, HF has a significant economic and social cost. It was estimated that in 2012, HF cost in US was $30.7 billion dollars, which includes costs of healthcare services, medications and lost productivity. Furthermore, projections indicate this rate to increase by approximately 120% to an estimated cost of $70 billion dollars by 2030 [1]. Higher number of HF patients would result in a growing population suffering from heart failure leading to an increase in financial expenditures required for these patients.

Due to the high risk of developing HF during one’s remaining lifetime, also termed as lifetime risk; it remains important to focus on the primary prevention of HF. Modifiable lifestyle factors, such as maintaining health weight, quitting smoking, exercising on regular basis, and having a healthy diet have shown to have a positive impact on HF risk factors which including: coronary
artery disease [8] - [12], diabetes mellitus [13] – [16], and hypertension [17], [18]. Moreover, according to a study conducted in [2], adherence to a healthy lifestyle is linked with a lower lifetime risk of heart failure.

When a patient is diagnosed with HF, they will receive an adjusted treatment to minimize risks of polypharmacy and drug interactions [12]. Diuretic therapy with titration is also applied to treat symptoms of fluid retention. Additional treatments include using ACE inhibitors, β-blockade, spironolactone or digoxin [15]. Although numerous therapeutic advances in medical and pharmacological interventions for HF, along with improvements in healthcare practice, have transformed many HF patients’ experience [19], HF still has a great economic and social burden on the community [20].

Furthermore, chronic care management programs often integrate with providing people with HF continuous care. For instance, one HF management program is associated with deployment of HF nurses, which enhances care delivery and coordination for HF patients [14]. Despite the variation of these programs in their structure, scope and delivery, they all aim to improve the well-being of these patients and reduce avoidable hospital admissions. The factors that these HF management programs aim to study are patients’ service utilization patterns along with government and healthcare system costs [21]. Based on an examination of 129 systematic reviews of patient-centered interventions by Coulter and Ellins [22], [23], it has been shown that engaging patients in their healthcare decision making is effective in improving health literacy, experiences with care resources and provide better health behaviors along with improved health.

A number of different studies have reported significant benefits of multidisciplinary HF management for reducing hospital utilization, improved quality of life, functional capacity, patient satisfaction, and compliance with diet and medications [24], though these programs are not available for all HF patients. Moreover, high hospitalization and readmission rates of HF patients prove that there is still a great demand for new approaches.

In despite of high HF readmission rates, there is little known about patient factors associated with hospital readmission. A literature review by O’Connor et al. [25] was conducted to recognize patient characteristics measured before discharge and their contribution to hospital readmission rates. It was shown that there is a relationship between patient characteristic and all-
causes of HF-related readmission within 7 to 180 days leading to hospital discharge. One of the studies by Habal et al. demonstrated an association of higher discharge heart rate with not only a greater risk of re-hospitalizations for HF and cardiovascular diseases, but also a higher risk of all-cause mortality and cardiovascular death, in patients who were discharged after a HF hospitalization. This study indicates that heart rate could be a significant modifiable prognostic indicator in hospital to ambulatory care transition [26].

Currently heart rate measurement and monitoring is being performed in clinical setting. However, Wireless Body Area Networks (WBANs) facilitate unobtrusive ambulatory health monitoring for extended periods of time while providing real-time feedback to the user and healthcare personnel [27]. The recent advancements in sensors, low-power integrated circuits, and wireless communications technologies led to the design of low-cost, miniature, lightweight, intelligent physiological sensor platforms which could be included into a body area network for health monitoring [28].

Considering the numerous advantages suggested by WBAN and the importance of monitoring heart rate in an ambulatory setting for HF patients, the goal of this project was to design, develop and evaluate a system that is composed of a wearable hardware and a smartphone application, which facilitate monitoring heart rate changes in real-time in an ambulatory setting.

However, since increase in physical activity level could also lead to increase in heart rate, it is crucial to monitor physical activity along with heart rate measurements as a function of time. This allows for the identification of unhealthy heart rate increases, which are not due to the higher level of physical activity.
2 Background and Review of Literature

2.1 Heart Rate

Heart rate is defined as the number of heartbeats per unit of time and mostly stated in beats per minute (bpm). Human's heart beats to pump oxygen and nutrient-rich blood to body muscles and also move cell waste products away from tissues [29]. Heart rate fluctuates according to muscle demands for absorbing oxygen and excreting carbon dioxide [30]. It also varies based on factors such as individuals’ fitness, age and genetics. Normal resting heart rate is about 70bpm for male adults and 75bpm for female adults [31]. HF is a chronic condition in which the heart muscle is unable to pump enough blood to supply the body with enough oxygen-rich blood. As a result, the heart becomes enlarged through the development of more muscle mass to pump faster and keep up with the workload [32].

There are different methods available for heart rate measurements including: Phonocardiogram (PCG), Electrocardiogram (ECG), Photoplethysmogram (PPG) and blood pressure waveform [33]. There are also two approaches for extracting the heart rate from body signals: 1) Real-time approach, which analyzes the time and feature variations on the two abrupt signals for each input heartbeat signal, applies various algorithms to identify the heartbeats and then compute the heart rate [34]-[36], 2) The Non-real-time approach, which collects a longer-period of waveform and uses software to break the long signal down into different segments before making use of a software to compute the heart rate [37]-[40].

2.2 Current Heart Rate Monitors

Current real-time heart rate monitors that are designed for ambulatory setting use either PPG or ECG waveforms.

2.2.1 PPG and Pulse Rate Monitoring

PPG waveform is composed of two components. The first component is attributable to the pulsatile component in the vessels, arterial pulse. This is the fluctuating part (AC component) of the signal and is caused by the heartbeat, and the second component of the steady signal that is due to the blood volume and its changes in the skin. This component of the signal only changes
slowly (DC component) and catches large artifacts due to motion. Only the AC component of the signal could be distinguished through the application of a band-pass filter [41].

In order to measure PPG, it is required to illuminate a tissue bed with LEDs and measure the amount of light absorbed by the tissue using a light-sensitive photodiode. As a result, the oxygen concentration in the arterial blood, heart rate, and blood flow could be estimated. PPG signal could be measured through transmittance and reflectance mode optical sensors. In transmittance mode sensors, which are commonly used in finger clips, a photo-sensor is placed on the opposite side of a tissue bed to measure the amount of light passing through the tissue. These optical sensors could be used on body parts such as fingers and earlobes. In reflectance operating mode, the photo-sensor is positioned adjacent to the LEDs to measure the amount of reflected light. This class of optical sensors could detect the PPG signals in any part of human body where there is a reasonable concentration of blood vessels, such as wrists [42]. The figure below demonstrates an optical sensor mounted on the fingertip. A photo detector records the infrared rays passing through the finger and converts it to a voltage or frequency:

![Figure 1. Infrared LED and detector on terminal phalanx on finger [43]](image-url)

There are a number of recently developed wristbands and smart watches, such as Apple Watch [44], that use PPG reflectance operating mode to monitor heart rate in real-time. A number of different studies, such as the one conducted by Kornowski et al. [45] have compared data generated by one of these wristband heart rate monitors against heart rate extracted from ECG signal, as the conventional clinically accepted method. This study looks at a wireless wristwatch-like sensor that is developed by Telecare system, known as Medic4All and conducts evaluation against the standard system on participants while they rest on a chair. While this study shows a significant correlation between the measured heart rates of the two monitoring methods, there are other more recent studies that show that most of these recent wrist-band based heart rate
monitors are accurate in normal resting heart rate range, which is 70 – 80 bpm. These wristbands require the user to hold still and do not provide acceptable heart rate readings at higher ranges of heart rate (160 – 170 bpm) [46].

2.2.2 ECG and Heart Rate Monitors

ECG signal measures the electrical activity of the heart over some time period. It records the strength and timing of electrical signals while they travel through the heart. Each electrical signal begins in a group of cells called sinoatrial (SA) node, which is located in the right atrium. Then, the signal travels through the right and left atria that result in the atria contraction and blood moving to ventricles. The electrical signal moving through the atria is recorded as the P wave on the ECG recording.

Afterwards, the electrical signal passes between the atria and ventricles through a group of cells called the atrioventricular (AV) node, while it slows down. The slower traveling signal gives ventricles enough time to be filled by blood. This part is represented as a flat line between the end of the P wave and the beginning of the Q wave in ECG signal.

After the AV node, the electrical signal travels along a pathway called the bundle of His that branches into the right and left sides of the heart. The signal spreads quickly across ventricles and causes them to contract and pump blood to the rest of body parts. This process is recorded as the QRS waves on the ECG signal. Following the QRS wave, ventricles recover back to their normal electrical state, which is noted as T wave on the ECG signal. Then, muscle contraction is stopped to let the heart be refilled with blood [47]. Figure 2 shows a normal ECG signal and its associated P, QRS and T wave:

Figure 2. Electrical signal pathway in heart [48]
The ECG could be measured through electrodes attached on the body surface. The ECG signal demonstrates a comparison between voltages collected by two electrodes that they are placed at different points on the body. These pairs are also termed as a leads. Standard ECG configuration applies 1, 3, 5 or 12 leads [50]. The following figure indicates the standard 12-lead ECG electrode placement:
The Holter monitor is a clinically accepted tool to measure heart rate obtained from ECG signal in ambulatory setting [52]. The Holter monitor records the ECG signal continuously for an adjustable time period, usually for several hours. This system is capable of sending the recorded data to the user or the healthcare center when the alert ECG signal is detected or the recording period is completed [53]. Although the Holter monitor is highly accurate, it is not appropriate to be used in field setting due its cost and size [52]. While Holter monitors also lack the user-friendly interface to communicate captured data to the user, there are other heart rate monitoring devices such as Polar S810 that could be paired with a wrist receiver that displays the captured data. A study conducted by Gamelin, et al. [54], compared R-R intervals detected by the Polar S810 heart rate monitor and the standard ECG monitoring system. Subsequent analysis of heart rate variability between the two systems indicates a good correlation between the results. However, wearing a Polar S810 chest strap for extended time periods could be uncomfortable for the user.

In addition to Polar S810, there are several other heart rate monitoring devices that are already available in the market. Nevertheless, there are a number of issues associated with using them. While some of these devices are proven to be accurate like the iRhythm and Zio Patch system, it lacks the user interface to communicate the captured data with its user. The associated chest patch was designed to be a substitute for the Holter monitor and despite recording an ECG signal for up to 14 days [55], it is not a sufficient tool for long-term usage.

For the purpose of this project, heart rate monitoring is based on ECG signal processing as it is shown to be more clinically acceptable. However, a different approach through the use of WBANs was applied to provide a more unobtrusive and comfortable user interface. This is highly desirable since according to a study completed by Bergmann and McGregor [56], it is highly important to consider user preferences when designing a wearable sensor system. Furthermore, in a comprehensive study by Baig et al [57], over 120 different wireless, wearable and mobile ECG monitoring systems were reviewed to identify the most important factors that need to be addressed for developing ECG monitoring systems. Results of this assessment identified the following shortcomings associated with the ECG monitoring systems: low signal quality, imposed limitations on patients, short battery life, lack of user acceptability and medical professional’s feedback, lack of security and privacy of essential data.
2.2.2.1 Signal Quality and System Reliability

It is essential to consider the importance of the following parameters for a clinically acceptable monitoring system: early detection of unhealthy conditions, reliable decision support, along with high quality and real-time patient data acquisition. In addition, the designed system should be user-friendly, easy to wear and understand, as well as being highly acceptable to patients and clinicians [58].

2.2.2.2 User Acceptability and Medical Professional’s Feedback

Recently there has been an increase in the number of available ECG monitoring systems. More researchers are considering feedbacks from patients and healthcare providers to study the effect of wireless wearable ECG monitoring system on patients’ health [59]. It is essential to incorporate user perceptions through the product development process to guarantee a user-centered design.

It is also crucial to consider lower energy consumption of the monitoring system to extend its battery life. Although high quality and real-time data transmission is shown to be crucial, it is shown to consume more battery than processing data [60].

2.2.2.3 Security and Privacy

As these monitoring devices are wireless, security and privacy considerations are among the major areas of concern. In addition, direct human involvement in the system also increases the sensitivity. Hence, it should be considered to obtain consent of human objects before data collection. It is possible not to be able to take full advantage of the capabilities of the system due to privacy concerns and possible misuse [61].

During the design phase of the WBAN system, potential shortcomings were identified. And based on findings from [59] – [61], relevant solutions were adopted in the design process.
3 Research Question, Hypothesis and Objective

Research question:
Can a continuous heart rate monitoring system be beneficial to patients and their clinicians when heart rate is used as another clinical indicator in ambulatory setting?

Hypothesis:
It is hypothesized that this monitoring system would provide patients and clinicians access to another clinical indicator as heart failure patients are discharged from hospital.

Objectives:
Based on the research question, this study aims to design, develop and evaluate a heart rate and ECG monitoring system in an ambulatory setting. This system, which is named BeatHR, is composed of a wearable chest patch and a smartphone application that communicate through Bluetooth Low Energy (BLE). Three main objectives of this study are:

1. Design and develop a wearable chest patch that enables real-time and continuous:
   a. Capturing of ECG signal
   b. Calculation of the associated heart rate
   c. Streaming of ECG signal or calculated heart rate based on user’s request

2. Design and develop a smartphone application that enables real-time and continuous:
   a. Capture of wirelessly streamed data from the wearable chest patch
   b. Save and display the received data from the wearable hardware
   c. Extract, save and display the number of steps taken from the iOS HealthKit

3. To clinically validate the developed BeatHR system, against a clinically accepted ECG and heart rate monitoring system.

Based on these three objectives, this project is composed of three main phases. While the first two phases approach the design and development of the wearable chest patch and the smartphone application, the last phase is dedicated to evaluation of the developed system against a clinically accepted ECG and heart rate monitoring system, the Holter monitor.
4 Methodology

4.1 Phase 1: Hardware Development

4.1.1 Goals and Requirements

The main objective of the first phase of the project is design and development of a wearable chest patch to continuously capture user’s ECG signal, calculate associated heart rate and based on user’s request, transmit the ECG signal and heart rate wirelessly in ambulatory setting. This wearable sensor is classified as a Class II Medical Device based on evaluation by the Medical Device Assessment Committee at the University Health Network. Based on the findings from the literature review covered in section 2, the BeatHR system is required to:

1. Transmit proper signal quality
2. Be comfortable to be worn continuously
3. Have a small footprint
4. Be lightweight
5. Have an extended battery life
6. Ensure acceptable user safety levels

It is essential to develop a device with a small footprint to make the device unobtrusive. In addition, this wearable is designed to be worn continuously. Hence, it is required for it to be lightweight and comfortable. Since heart rate measurement is based on detection of R-peaks on captured ECG signal, high signal quality is essential for accurate heart rate measurements, which could be comparable to clinically accepted heart rate monitors. Furthermore, extended battery life is crucial for continuous usage of the device. Longer battery life also enables the system to monitor and store ECG signal and heart rate changes for extended time periods with little disruptions, which results in more comprehensive assessment of the user’s measurements. Finally, as this system is designed for ambulatory setting usage, all safety aspects should be taken into consideration, to enable the user to safely operate the device without any assistance from the healthcare provider.

To allow for an optimal and efficient design and development approach of the wearable hardware component, a modular design was adopted. This allowed for greater interchangeability between the different modules that make up the wearable hardware. It is required for each
module to have independent components and processes from other modules [62]. This allows for easy debugging, optimization, system service and upgrade.

4.1.2 Design and Development Approach

ISO 13485 was used to approach the product development phases of this project. As this standard identifies the requirements for a quality management system, it could be applied for design, development, production, installation and also servicing of medical devices [63]. Based on objectives of the project, the following ISO deliverables were used to approach the product design and development phase:

2. Design Outputs: the actual product, functional diagrams and schematics
3. Product Verification and Validation Plan

For development of the wearable patch, a standard iterative development process was used. This approach requires rapid iterations of the development cycle that makes use of the features defined in test cases. Test cases were planned based on Product Requirements and Specification documents and fed into the Verification Plan.

Kevin Tallevi, who is a hardware developer at the Centre for Global eHealth Innovation, assisted in the design and development of the electronics to meet the product specifications. Damon Pfaff, who is an industrial designer at center, assisted in the electronics enclosure and the patch design.

4.1.2.1 Product Requirements and Specifications

As a part of the ISO documentation, the product requirements section document defined objectives and expected features of the device. It provides detailed description of both user and non-user requirements. Those requirements were planned to satisfy the project objectives and were based upon the findings from the literature review as well as discussions with Dr. Heather Ross and Dr. Douglas S. Lee, clinicians at UHN.

In addition, Product Specifications document was generated for specifications that satisfy the
non-functional requirements. Specifications indicate how the function, which is defined by the requirements, would be implemented. Appendix A gives a more comprehensive overview of the specifications along with their functions and requirements.

4.1.2.2 Final Design of Wearable Chest Patch

As mentioned above, a modular design was adopted for the development of the wearable chest patch. As the following figure indicates, the final modular design consists of the following modules and parts:

1. Electronic module, that is the enclosure made of a lightweight rigid material (VeroBlack). Its main function is to hold and protect the electronics board and lithium ion battery. The electronic module is connected to the patch module through press-fit board-to-board connectors.

2. Patch module is the soft wearable patch made of a rubber-like material (TangoBlack FLX973). It is used to position the electrodes in the correct orientation and distance, which is a minimum of 5cm for ECG signal collection. It also holds the electronics module in place.

3. Electrodes that are attached to the patch module are intended to collect signal and adhere to the user’s chest.

![Figure 5. Final wearable chest patch design](image)

The following table outlines the specifications of the wearable chest sensor:

<table>
<thead>
<tr>
<th>Table 1. Final product specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
</tr>
<tr>
<td>Weight</td>
</tr>
<tr>
<td>Battery Life</td>
</tr>
<tr>
<td>ECG Sampling Rate</td>
</tr>
</tbody>
</table>
The design presented above provides several advantages to the user. Firstly, it can be placed on different areas of the chest to guarantee that the highest signal quality is being captured. Secondly, if multiple locations show high signal quality, the user could choose their preferred one. Thirdly, the low profile design allows the user to wear it comfortably without any fear of stigmatization.

For the purpose of the clinical verification of this study, described in section 4.3.1, it was needed to stream the user’s ECG signal continuously. As a result, the firmware is currently setup to stream both the ECG signal and the heart rate values, which requires sampling and streaming of 100 samples per second. However, in the ambulatory setting, only the heart rate values would be streamed continuously and the ECG streaming would be limited to when there is a request from the user. The heart rate monitoring requires a lower streaming rate compared to the ECG and the sampling rate could be set to as low as one sample per second. This would battery life of the chest patch to 25 hours, which is beneficial for the continuous monitoring purpose of the system.

In addition, using the modular design, the device is designed such that the user should take the device off of their body to be able to recharge it. The physical design of the enclosure prevents the user to connect the patch module to the charger. This setting is meant to ensure user safety by preventing the user to get connected directly to the power line.

Besides the various advantages provided by the modular design to the users, it is highly beneficial from a design perspective. Since the electronics module and patch module could be detached, the more costly electronics board could be used with other patch designs that might be designed for different applications and electrode configurations.

4.1.3 Electronics Design

The Electronics module enclosure holds the electronic circuit board with the following main components: microprocessors to collect, process and transmit desired physiological signals, flash memory to store collected signal when the device is not streaming and rechargeable battery for power. There are four different microprocessors included on the electronic circuit board: ECG, accelerometer, gyroscope and pressure sensor. However, for the purpose of this project, the accelerometer, gyroscope and pressure sensor were deactivated.
As the physiological signals are being collected in real-time, they are processed by the Central Processing Unit (CPU) and stored in a buffer to be transferred. When the buffer is filled, data will be sent to the smartphone through radio communication. The three microcontrollers and the CPU are communicating through Serial Protocol Interface (SPI) using master-slave configuration, in which the CPU operates as the master and signal-collecting microcontrollers operate as slaves. To be able to create a log of the user’s heart rate changes, a flash memory is included to store detected heart rate values for a specific time period before data streaming could take place again. The following diagram provides an overview of the circuit board architecture:

![Hardware architecture of electronics circuit board](image)

The following section describes the purpose of each component on the circuit board

**Analog Front End (AFE):** While three 3M Red Dot Repositionable electrodes are placed on user’s skin to capture ECG signal [64], the captured signal is fed to AFE to be processed. Texas Instruments (TI) ADS1293 AFE digitalizes and stores the ECG signal at 24-bit resolution. This AFE is designed for battery-powered, portable ECG sensors with as low power consumption as 300μW per channel. It allows for capture of the ECG signal at different sampling rates. However, for the purpose of this project, the sampling rate is set to 100Hz. It has been shown that for accurate QRS detection, the sampling rate is required to be at least 100Hz [65]. Though, a number of other studies, which target Heart Rate Variability (HRV), consider the optimal sampling rate at 250 to 500Hz [66]. A sampling rate of 100Hz satisfies the requirements of this project and also leads to less processing and power consumptions, that extends the battery life. In addition, the sampling rate could be changed for other applications, such as HRV monitoring. Furthermore, accuracy of the BeatHR system is tested in third phase of the thesis against the
clinically accepted Holter monitor system. Since sampling rate of the Seer Light Holter monitor from GE, which is being used at UHN, is 125Hz, it was aimed to choose the closest sampling rate for BeatHR, which is 100Hz. ADS1293 incorporates a number of circuit components including analog-to-digital converters, instrumentation amplifiers, and analog filters, which simplifies device development [64].

**Accelerometer & Gyroscope:** A tri-axial accelerometer and gyroscope (LSM330DLC) was included on the circuit board to capture user’s linear and rotational motions. It is highly advantageous to monitor user’s motion, which leads to activity tracking, along with body posture to study heart rate changes in different criteria and settings. In addition, collected data from this microcontroller could be used to reduce motion artifact noises of the ECG signal. The microcontroller integrates three independent acceleration and three independent angular rate channels. In addition to its ultra-thin profile, it has a low-power consumption, with the accelerometer consuming 0.5 µA and gyroscope consuming 5µA in their power-down mode [67]. In order to adjust the project scope to available time for the development phase of the project, it was decided to disable this microcontroller and make use of activity data provided by HealthKit from iOS on iPhones. This feature is included in smartphone application, though it is not currently activated. However, this microcontroller could be enabled through PCB reprogramming and be used for future potential projects.

**Pressure Sensor:** LPS331AP is another component of the circuit, which is a Microelectromechanical Systems (MEMS) pressure sensor and could be used as a barometer to measure the altitude changes. A MEMS pressure sensor with 0.1 mbar RMS resolution is capable of detecting an altitude difference of less than one meter, which could be applied for differentiating between floors inside a high-rise building [68]. While this pressure sensor has a high-resolution mode of 0.020 mbar RMS, it could be used to track the number of floors the user has climbed. This data could be used along with monitoring activity data to monitor user’s hear rate changes as a function of user’s different activities. Furthermore, this sensor has low power consumption, which are 5.5 µA for low resolution and 30 µA for high resolution modes [69]. Nevertheless, similar to accelerometer & gyroscope microcontrollers, the pressure sensor is not applied for this project to limit the programming load for the limited allocated time for development. However, it could be enabled and used for future projects.
**Central Processing Unit (CPU):** CPU collects the data generated and processed by the different sensors mentioned above, to be prepared for wireless streaming. For the purpose of this project, collected data by each microcontroller is being processed and then sent to the CPU to reduce complexity and power consumption. EFM32TG was chosen for this project, which could run at up to 32 Mhz. Moreover, it has ultra low power consumption, which is as low as 150 μA/MHz in run mode and as low as 1.0 μA [70].

**Radio Transceiver:** As wireless communication between the wearable hardware and the smartphone consumes the greatest amount of power from the system, it is important to include a radio transceiver that has the lowest power consumption while having the appropriate bandwidth to transmit ECG signal. Therefore, Bluetooth Low Energy was used as compared to classic Bluetooth, since 1) BLE continuously stays in sleep mode until a connection is initialized, 2) BLE connection time lasts a few milliseconds, while Bluetooth connection time is almost 100 ms. This short connection time of BLE is due to its high data transfer rate of 1Mb/s [71]. nRF8001 was selected to be used for this project, which includes three integrated oscillators: 1) low power amplitude regulated 16 MHz crystal oscillator, 2) ultra-low power amplitude regulated 32.768 kHz crystal oscillator, and 3) ultra-low power 32.768 kHz RC oscillator with ± 250 ppm frequency accuracy [72].

**Power Supply:** It is important to include a power supply component that has a long operation time with high energy time, since BeatHR system is designed to operate continuously. Rechargeable lithium polymer battery is commonly being used for body area networks as they have high gravimetric and volumetric energy density [73]. For this design, a 110mAh rechargeable lithium polymer battery was used [74]. It is placed inside the electronics module besides the electronic circuit board. As it was mentioned before, for safety purposes, the electronics module should be detached from the patch module to be connected to the external charging module. This design is intended to prevent the user to be directly connected to the power-line. In addition, as electronics are being charged externally, on-board power isolation would not be required, which saves space and reduces size of the electronics module.

Two figures below demonstrates the schematic of the final electronics circuit board and the final printed circuit board:
As it is mentioned before, the electronics module uses the same set of connectors to attach to both patch board and charger board. The following figure shows a screenshot of the 3D design of electronics circuit board, patch board and charger board:
4.1.3.1 Bluetooth Modes of Operation

The electronics of the wearable hardware operate in three different modes: power off, idle and streaming:

1. Power-off mode: Device is off and electronics and patch modules are disconnected, there is no power consumption.
2. Idle mode: Electronics and patch modules are connected and BLE is in advertising mode to start connection with smartphone. No data is collected or transmitted in this mode.
3. Streaming mode: Electronics and patch modules are connected. As the device and smartphone are connected, the collected data is transmitted to the smartphone in real-time.

Before connecting the electronics and patch module, the device is in power-off mode to avoid power usage while not being used. When the electronics and patch modules are connected, the sensor’s radio (BLE) starts to advertise and upon connecting, streaming mode starts. Data collection and transmission is continuous as long as device is in streaming mode and power.

4.1.4 Enclosure and Patch Design

An earlier masters project titled as “Development of an Ambulatory Wearable Sensor System for
Behavioural Neurocardiac Training” was completed by Akib Amir Uddin at Centre for Global eHealth Innovation. His project attempted to develop a similar hardware system, called Beat. This system was used as the prototype for BeatHR hardware development [75]. The figure below shows the patch and enclosure design of Beat:

![Beat wearable hardware used as prototype for BeatHR hardware development](image)

**Figure 10. Beat wearable hardware used as prototype for BeatHR hardware development [75]**

### 4.1.4.1 Beat Enclosure and Patch Design

The patch for Beat consists of two main components: the cradle and the on-body patch. The main function of the cradle is to act as an attachment site for the electronic module and relay signals from the electrodes to the electronics.

The patch is made of silicone rubber and contains three electrode connector sites, which make use of snap buttons to connect the patch to the electrodes. The electronic module uses a clip mechanism control with two push buttons on either side of the enclosure. These clips latch onto the cradle on the patch and hold the electronic module in place.

Several modifications were implemented to Beat that led to the development of BeatHR. The industrial design and overall aesthetics were improved through the following changes:

1. Replaced the snap buttons with a 3D printed connector button for electrode connection.
2. Removed the initial clip system and associated buttons on both sides of the electronics enclosure through switching to a press-fit instead of piston-load board-to-board connector mechanism with no need for buttons.
3. Modified design of the on-body patch to improve device flexibility to be worn at different locations on user body.

4.1.4.2 Patch and Enclosure Industrial Design

The electronics enclosure holds the circuit board and rechargeable battery. The top part of the enclosure is lightly curved to eliminate the sharp edges. The thickness of the device is kept to a minimum, so it could be inconspicuous underneath clothing while being easily worn. The following two figures indicate screenshots of bottom and top parts of 3D design of electronics enclosure:

![Figure 11. Top and bottom parts of electronics enclosure](image)

The patch module is intended to hold the electronics enclosure on user’s body and keep electrodes in correct positions for signal collection. This part is composed of the cradle and the flexible patch. The figures below demonstrate top and bottom view of the cradle and flexible patch respectively:

![Figure 12. Top and bottom parts of cradle](image)
Three holes on the flexible patch (Figure 13) are designed for the buttons (Figure 14) that facilitate electrode connections. These buttons hold metal clippers that are soldered to the wires that transfer signals to cradle. The following two images show the top and bottom view of button and its cover that is placed on top of the flexible patch:
4.1.4.3 Patch and Enclosure Material Selection

As part of project requirements, it was needed to have a flexible on-body patch, which could easily sit on user’s body. However, for both the electronics module and buttons a more durable and rigid material was needed to protect and hold the electronics and electrodes, respectively.

3D printing was considered to be the most efficient and fastest method of manufacturing for this project. The polyjet process was used to 3D print the following two parts:

1. Flexible patch, manufactured from TangoBlack FLX973, which is a rubber-like PolyJet photopolymer. It offers a number of elastomer characteristics, including: Shore A hardness, elongation at break and tensile strength. It is usually used for medical devices, automotive interiors and consumer electronics [76].

2. Electronics enclosure and buttons, manufactured from VeroBlack, which is rigid opaque photopolymer. It offers toughness, dimensional stability, high detail visualization, with 83 Shore D hardness. It is a great option for molds and small fine feature parts [77].

The following figure shows the final electronics and patch module design of BeatHR:

![Figure 16. Final implementation of the BeatHR hardware design](image)

4.1.5 Electrodes

Three silver/silver chloride electrodes are used to collect ECG signal from the user’s skin and to
hold the sensor on the user body. 3M Red Dot Repositionable electrodes are used for this project. As their name implies, they could be repositioned without replacement in case they are not placed in right location. In addition, as the figure below shows, they provide larger conductive surface area compared to traditional electrodes, which reduces signal to noise ratio and increases collected signal quality. It also has low impedance, which results in trace quality [79]:

![Comparison between 3M Red Dot Repositionable electrodes and conventional electrodes](image)

**Figure 17. Comparison between 3M Red Dot Repositionable electrodes and conventional electrodes** [79]

4.1.5.1 Wearable Hardware Placement on Body

Standard ECG monitoring makes use of 12 leads, which are ECG vectors indicating differential measurement of the electrical potential at different locations on body surface. However, implementing a similar electrode configuration would make the wearable design bulky and uncomfortable to be worn continuously.

For the purpose of this project, single lead ECG is collected which requires electrode placement on two of the following locations: right arm (RA), left arm (LA), and left leg (LL). Furthermore, right leg (RL) electrode usually acts as the reference electrode to reduce common-mode noise. It is essential to consider the following requirements for electrode configuration: 1) minimize the size of the hardware, and 2) maintain sufficient ECG signal quality to enable accurate R-peak detection required for heart rate monitoring. As a result, it is needed to place the electrodes closer to each other and due to a study conducted by Lim et al, P, R and T wave could be identified as long as electrodes are placed at least 5cm apart from each other [80]. However, as increasing the
distance between electrodes increases signal strength, the flexible patch was designed to balance the RA and LA electrodes spacing to: 1) capture high quality signal, and 2) keep the device size small. In final design, the distance between the RA and LA electrodes is 92.71mm.

Besides electrode configuration on hardware, it is needed to place the hardware in the right position and orientation in order to guarantee the desire ECG signal quality. Although it is shown that different subjects have different ECG signal amplitudes, the overall results show placing electrodes close to the chest electrodes of the standard precordial leads V2, V3, and V4, or above the leads V1 and V2 leads to the capture of high ECG signal quality for R-peak detection [81].

However, it is not possible to define an electrode location and orientation that applied to all subjects. It is considered to design the hardware in a way that could be worn in different locations and orientations while being comfortable. The final device configuration contains two electrodes collecting signal from RA and LA, in addition to the RL electrode that is placed in between and below the two RA and LA electrodes.

After trying different placements and orientations on different subjects, two placements are shown to generate better ECG signal. These positions are:
1. On the upper chest, while electrodes are positioned at the RA and LA of a Lead I ECG.
2. On the central part of chest, around the precordial V1 and V2 ECG leads.

4.2 Phase 2: Software Development

For this phase of the project, it was needed to:

1. Implement a firmware to extract heart rate from collected ECG signal, which is streamed to the smartphone application.
2. Develop a smartphone application to receive the streamed ECG and heart rate data, display the changes and store the data for future reviews.

4.2.1 Firmware Development

4.2.1.1 Goal and Requirements

As part of the project requirements, it is required for the firmware to detect heart rate on the circuit board. As a result, there would be no need to continuously stream the ECG signal, which would lower the power consumption.

4.2.1.2 QRS Detection Algorithm

An open-source software developed by E.P. Limited with support from the National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) was used as the QRS detection algorithm. This software was first released in 2002 and their fifth release was used for this project.

This software contains C functions for implementing ECG analysis, beat detection and classification. However, no beat classification function is being used for the BeatHR firmware. The software implements a modified version of the QRS detection algorithm from Hamilton-Tompkins algorithm [83] as shown below:

![Figure 19. Modified Hamilton-Tompkins QRS detection algorithm used for EP-limited software [84]](image-url)
This algorithm detects QRS complexes by examining the slope, amplitude and width of the ECG signal. While ECG signal is being fed to the algorithm, it outputs QRS locations in real-time.

The signal is filtered through a band-pass filter, which consists of a high-pass, low-pass, and derivative filter combined with each other. The frequency limit of this filter is from 5 to 11Hz, which is where most of the QRS complex energy is. This frequency range also eliminates power-line interference (60 Hz noise), motion artifacts, base-line drift as well as muscle noise. Differentiation is used to spot rapid voltage changes associated with QRS complex. As QRS complex is shown to be gain-sensitive, absolute value is substituted for squaring function in the original algorithm after differentiation. Then, the moving window integral is applied to create a large lump-like time averaged waveform for each QRS complex. On the falling slope of the lump, peaks are detected. Although the averaging window is considered to be 150ms in the original algorithm, narrower 80ms averaging window is shown to result in better output [85].

The following figure shows the effect of each function applied on the ECG signal, though as it was mentioned the software used for this project makes use of a rectification function instead of squaring function:

![ECG signal processing steps](image)

**Figure 20. Outputs after applying filters of the QRS detector:** a) Unfiltered ECG, b) Output of band-pass filter, c) Output after the band-pass, differentiation, and squaring processes, d) Final time-averaged signal, adapted from “A Real-Time QRS Detection Algorithm” by Pan & Tompkins [85].

And finally based on the findings detailed in [83] and [84] a number of detection rules are
employed:

- All peaks preceded or followed by larger peaks in less than 200ms time difference is discarded.
- In case of detecting a peak, the raw signal would be checked to have both negative and positive slope. Otherwise, the detected point represents a baseline shift.
- When a peak is detected within 360 ms time difference from the last detected peak, it is required to check whether the maximum derivative of the raw signal was at least half of the maximum derivative of the previous detection. Otherwise, the peak is a T-wave.
- When a peak is larger than the detection threshold, it represents a QRS complex. Otherwise, it demonstrates noise.
- When no QRS complex is detected in 1.5R-to-R interval, there was a peak that was greater than half of the detection threshold. Therefore, the peak followed the preceding detection by at least 360 ms is noted as a QRS complex.

In order to calculate the detection threshold, it is needed to make use of amplitude estimates of QRS and noise peaks. Two buffers hold eight most recent QRS and non-QRS (noise) detected peaks. The detection threshold is calculated using the following formula, while its value is between the mean and median values of buffered QRS and noise peaks:

\[
Detection \text{ Threshold} = Average \text{ Noise} \text{ Peak} + TH \times (Average \text{ QRS} \text{ Peak} Average \text{ Noise} \text{ Peak})
\]

TH in this formula is the threshold coefficient. Based on suggestions from literature, 0.1825 was selected for the threshold coefficient and is shown to produce good results [84].

When beat detection is started, it is needed to begin with an initial threshold estimate. For this, maximum peaks in the first eight successive 1-second intervals are detected and used to start the QRS peak buffer. Furthermore, the initial eight noise peaks are considered as 0’s.

### 4.2.1.3 QRS Detection Algorithm Evaluation

MIT/BIH arrhythmia database is the standard test data for accessing arrhythmia detectors since 1980 [86]. In order to evaluate the QRS detection software performance, data from the first channel of MIT/BIH database was resampled at 200 samples per second with 5 minutes initialization intervals. Result of this evaluation is as follows:
Table 2. Result of QRS detection evaluation against MIT/BIH arrhythmia database [84]

<table>
<thead>
<tr>
<th>False Positive Detection</th>
<th>False Negative Detection</th>
<th>Sensitivity</th>
<th>Positive Predictivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>235</td>
<td>176</td>
<td>99.74%</td>
<td>99.80%</td>
</tr>
</tbody>
</table>

In addition, software was tested on the AHA ECG database, which is developed for ventricular arrhythmia detectors evaluation during the late 1970s and early 1980s [87]. Result of the beat detector assessment demonstrated a sensitivity of 99.74% and a positive predictivity of 99.76% [84].

4.2.2 Smartphone Application Development

4.2.2.1 Goals and Requirements

The goal of this phase of project was to design and develop a smartphone application to:

1. Communicate wirelessly with the wearable hardware
2. Receive and save the streamed ECG and heart rate data in real-time
3. Display average heart rate changes and ECG based user’s request
4. List average heart rate values that are beyond the set threshold, which could be customized upon each users condition

4.2.2.2 Design and Development Plan

Similar to the hardware design and development, ISO 13485 was used to approach the software development phase of the project. Product requirements and specifications were documented to indicate the desired functions and features in detail. For this phase, the same ISO deliverables were generated: design inputs, design outputs as well as product verification and validation plan.

Agile methodology was used to approach software development of this project. This project management method is shown to be more productive in comparison to the traditional waterfall approach. It relies on adaptive project planning and promotes continuous improvement and rapid response to changes. For this, large features are broken into smaller portions, which are being completed in shorter time periods, called sprints. It is needed to have the associated features planned and verified before start of each sprint. The flowchart below indicates the workflow in this methodology:
Nathaniel Hamming, who is a software developer at the Centre for Global eHealth Innovation, supported the software development process.

4.2.2.3 Platform Development and Programming Language Selection

The software application was developed for iOS 9, which operates iPhone 4s, 5, 5c, 5s, 6 and 6s. This platform supports BLE 4.0, which is essential for this project. Furthermore, the iPhone 6 was the focus of the development as its 4.7” inch screen provides a better presentation of the graphs intended to present the heart rate and ECG signal changes.

The programming language applied for iOS application development was Objective-C, which is a superset of the C programming language that also offers object-oriented capabilities [89].

The following figure presents an overview of smartphone application architecture:
Each part of the software is described in more detail in the following sections:

4.2.2.4 Bluetooth Module

The Bluetooth Module facilitates communication between the wearable hardware electronics and smartphone application. For this project, the Bluetooth library from Centre for Global eHealth Innovation was used to communicate with Bluetooth Low Energy radio of the iPhone. It manages connection and disconnection events between smartphone application and wearable hardware. In addition, it facilitates data capturing once connection is successful.

Currently, for testing purposes, the electronics are programmed to stream BLE packets that contain both ECG samples and detected heart rate values. In this case, the very first streamed ECG packet contains six ECG data points and each sample is three bytes. Whereas, for the next streaming packet, the difference between the initial detected point is calculated and nine of these delta values of two bytes, along with one heart rate data point are streamed in one package. This setup relies on the fact that the delta values are smaller and consume less space of the BLE packet compared to the original voltage values, therefore a greater number of delta points could be allocated and streamed in one ECG packet compared to the voltage values. These delta points are added to the initial baseline value from the first streamed packet and saved into the database of smartphone application, which is discussed in next section.
4.2.2.5 Physical Activity Monitoring

In order to monitor the user’s physical activity, number of steps taken by the user is extracted from the iOS HealthKit where it exists as a sample object type. These objects have a value, start and end date properties [90]. Hence, the number of steps taken by the user while walking or running is extracted from HealthKit along with its properties, and are saved in the smartphone application database. The steps are also plotted along with the average heart rate changes as described in section 4.2.2.7.

4.2.2.6 Application Database

As it was mentioned in the Bluetooth Module section, the very first received data packet contains 6 sample ECG data points. As captured voltage values are converted to codes in the analogue front end to be streamed, it is needed to have the received data points to undergo the reverse conversion. Afterwards, the resulted voltage values are stored. The very last ECG data point in this packet is used as the baseline for the rest of the packets. When the next data packets are received, they are first added to the baseline values and then converted to the voltage values to be stored in the database.

However, as ECG signal contains considerable amount of noise, a high-pass filter is implemented to eliminate low-frequency noise component of the captured signal. This noise could be due to respiration, muscle motion (contraction) and perspiration, which lead to improper electrode contact. This results in baseline wander and could cause problems in the analysis of lower frequency components of ECG. Therefore, a high-pass filter from E.P. Limited open-source software [84] was included in BeatHR application. This adaptive filter implements the following difference equation:

\[ y[n] = y[n-1] + x[n] - x[n-32] \]
\[ z[n] = x[n-16] - y[n] \]

The filter uses past data samples values and causes a 15.5 samples delay and de-noises the data based on the previously received data points. After de-noising the streamed signal, both raw and filtered ECG signals are stored in the smartphone database. However, as heart rate values do not need to be converted or filtered, they are saved as they are received.
All application data is stored in Realm database, which is a new database available in a number of programming languages, including objective-C; used for this project [91]. Both ECG voltages and heart rate values are saved along with their creation date and also a counter, called ‘key’ to keep track with the order of data saved. In addition, number of steps extracted from HealthKit are saved with their value, start and end times.

In addition, due to the current limitations associated with Realm, date properties could be persisted down to one second [92]. However, as 100 data points are being received in each second, it is needed to save the stored data in another format with a millisecond resolution. Therefore, once data recording is completed, the application makes used of the recording start time to generate two .csv files, one containing ECG data points and the other one containing heart rate values. Each line of the .csv file contains the information associated with one data point.

4.2.2.7 User Interface and Graphing

The purpose of the User Interface of this application is to:

1. Present ECG, average heart rate values and number of steps taken in real-time based on user’s selection.
2. Generate a list of heart rate values, which exceeded the acceptable threshold that could be customized for each user based on their condition.

The core component of the User Interface is real-time graphing of the ECG signal, heart rate and physical activity changes. A graphing library, called iOS Charts [93] is included in this application. For the ECG graph, the last 250 data points are plotted in each frame. At the current sampling rate, this represents over 2 seconds of ECG data. After this, the next frame is substituted. For heart rate data points, average values over five seconds are calculated and plotted in a separate tab. A similar time period of five seconds is used for extracting the number of steps from HealthKit. Therefore, number of steps is plotted in bar chart simultaneously with the average heart rate changes. However, for the testing phase of this study, the activity-monitoring features of the application were not being tested and were deactivated. Furthermore, the most recent streamed heart rate value is displayed on top of the screen. This value is updated each time a new heart rate value is received.
Once the application is opened, the user is led to the Graph Tab, which contains two sub-tabs, for ECG and heart rate displays. First, a message pops up to prompt the user to turn on the phone Bluetooth, if the Bluetooth is off, the Status will show as “Disconnected”.

![Image of the app interface showing a prompt to turn on Bluetooth and options for ECG and heart rate displays.]

*Figure 23. Prompt user to turn on Bluetooth once app is started*

Once Bluetooth is turned on, Status is changed to “Connected” and as data streaming starts, graphing starts. By default, the ECG signal is shown and the user could switch to average heart rate display using the sidebar in the bottom of the graph. The following two wireframes present ECG and average heart rate monitoring respectively:
Moreover, the screen shown below shows the second tab, called Table tab, which lists received heart rate values that exceed a pre-defined value as threshold:
Figure 25. Table tab with list of detected heart rates above the threshold
4.3 Clinical Verification

In order to determine the accuracy of the developed system, it was needed to conduct a clinical verification study against a clinically accepted system. Results of this study will reveal how reliable the generated data is and whether the system requires improvements on the hardware and/or software end to satisfy the expected accuracy levels. The study received ethics approval from the University Health Network Research Ethics Board (Ref # 15-9255-AE).

Initially, it was planned to test BeatHR system against a Cardio-Pulmonary Test (CPT) machine. However, further exploration indicated that the output from the Welch-Allyn CPT machine, which was available for this experiment, was not compatible for the analysis purposes of this project. The exportable CPT output files did not contain the voltage values and their incidence time associated with the ECG signal. Instead, the output file demonstrates the waveform morphology. Therefore, Holter monitor was substituted for CPT system and the amendment approval was received on November 18\textsuperscript{th}, 2015. The following figure shows the electrode placement for Holter monitor:

![Figure 26. Holter monitor electrode placement [94]](image)

4.3.1 Study Design

The purpose of this study is to evaluate the accuracy of the BeatHR system in monitoring user’s ECG signal and estimating heart rate values against a Holter monitor.

In order to access Holter monitor data, Research Utilities section in the MARS system was
needed. The MARS system is the software used for analyzing data recorded by the Holter monitor. This data from the Holter contains ECG voltage values along with their elapsed time from start of recording. The following features from ECG signal was assessed:

1. R-R interval, which is the time in between two consecutive R-waves. By applying the following formula, $60/RR$ interval, the heart rate can be easily obtained. Since the heart rate values are dependent on the RR intervals, validating the time for the RR intervals eliminates the need to evaluate the heart rate values.

2. R-T interval, which is the time between R-peak and end of T-wave.

As R-R interval, which is extracted from QRS detection, leads to heart rate calculation, both QRS complex and/or R-R interval are the most common feature of an ECG signal to be investigated [95] – [98]. In addition to R-R interval, R-T interval was selected to be evaluated, as R-T interval length could be the better approach to determine true end of systole, this is especially useful for lower heart rate ranges where R-T intervals are significantly different from Q-T intervals [99]. In addition, $R_{end}$ and $R_{apex}$ are two intervals that indicate ventricular repolarization [100].

4.3.1.1 Experimental Setup

While participants wore both BeatHR chest patch and Holter monitor, the clinical verification study was conducted for two different scenarios for each participant:

1. In sitting position to monitor resting ECG
2. On stationary bike coupled with CPT machine to increase the resistance of the system and increase participant’s heart rate

The study was conducted in Cardiac Function clinic at Toronto General Hospital. After having the participant sit down for seven minutes (scenario 1), they were instructed to use the stationary bike and cycle for another seven minutes (scenario 2). CardioPerfect software on the workstation that is connected to the stationary bike was set on ECG Exercise Mode. Based on the regular the protocol being used for cardiopulmonary test to evaluate cardiac output for HF patients at the Cardiac Function clinic, the resistance on the stationary bike was set to increase by 10 watts per minute. So, for the six first minutes resistance was increased to a maximum of 50 watts per minute, and in the last minute, the system was put on the Recovery Mode. In this mode, system
resistance is reduced back to 10 watts to get participant’s heart rate back to the normal range. Participants were asked to cycle at an average speed of 60 revolutions per minute. There was no pre-defined target heart rate value that participants were asked to reach. Therefore, the maximum heart rate for participants was different and based on their fitness level.

4.3.1.2 Participants

Different number of participants has been used for clinical validation studies to evaluate ECG signal against clinically accepted monitoring systems. Based on a similar study conducted by Rennie et al. [101], eight healthy participants were recruited for this study. To generate enough data, a total recording time of 14 minutes, which is longer than what has been investigated in similar types of studies, was implemented. Healthy participants were selected for this study and were screened for not having any history of cardiovascular disease in their family.

4.3.1.3 Outcomes Measures

For the purpose of this study, the following statistical outcomes have been generated:

1. Bland-Altman plot to determine the agreement between ECG data captured by BeatHR and Holter monitor
2. Box-plots to demonstrate the dispersion and skeweness of BeatHR data error compared to Holter monitor
3. Intra-class Correlation Coefficient (ICC) with a 95% confidence interval, was applied to calculate the correlation between BeatHR and Holter monitor device. It also indicates the relative reliability of BeatHR compared to Holter Monitor for ECG monitoring. It is shown that once a measurement method is compared to another, it is desirable to have an ICC value over 0.70 [102], and ICC greater than 0.75 indicates excellent reliability of the monitoring system [103].
5 Results

As it was mentioned in section 4.2.2.6, a high-pass filter was added to BeatHR application to eliminate noises from motion and respiration. However, as discussed in section 6.3, the filtered data was not useful for all of the participants and raw ECG signal was post-processed and used for analysis.

In this section, a sample of evaluation results on R-R interval and R-T interval from one of the participants (Participant 2) is presented. Results obtained from the rest of participants are included in Appendix B.

In order to extract the desired features of ECG signal, a MATLAB program was used. The code detects T-wave ends, which requires R-peak detection. This software was evaluated against PhysioNet QT database and shown to outperform the other algorithms available at the time of its development. The algorithm is based on calculating an indicator, which is dependent on the area covered by T-wave. It is shown that once this indicator reaches its maximum value in each cardiac cycle, the T-wave end point is reached [104].

The two tables below indicate the Pearson correlation coefficient and ICC for R-R and R-T intervals in sitting and biking positions for each participant:

<table>
<thead>
<tr>
<th>Participant</th>
<th>R-R Interval</th>
<th>R-T Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sitting Position</td>
<td>Biking Position</td>
</tr>
<tr>
<td>Participant 1</td>
<td>Excluded</td>
<td>Excluded</td>
</tr>
<tr>
<td>Participant 2</td>
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<td>0.8232</td>
</tr>
<tr>
<td>Participant 3</td>
<td>0.8235</td>
<td>0.7575</td>
</tr>
<tr>
<td>Participant 4</td>
<td>0.9584</td>
<td>0.8276</td>
</tr>
<tr>
<td>Participant 5</td>
<td>0.7865</td>
<td>0.7392</td>
</tr>
<tr>
<td>Participant 6</td>
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<td>Excluded</td>
</tr>
<tr>
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<tr>
<td>Participant 8</td>
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Table 4. Summary of ICC values

<table>
<thead>
<tr>
<th></th>
<th>R-R Interval</th>
<th>R-T Interval</th>
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<tbody>
<tr>
<td></td>
<td>Sitting Position</td>
<td>Biking Position</td>
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<tr>
<td>Participant 8</td>
<td>0.954</td>
<td>0.897</td>
</tr>
</tbody>
</table>

As shown in the above tables, four of the total 16 recordings were excluded from this analysis. The reason of this exclusion as well as potential sources of errors of the system will be discussed in section 6.

Further statistical analysis was performed on the results for the RR and RT intervals. Section 5.1 shows the Bland-Altman plots and section 5.2 interprets the error between the two systems as Box-Plots. The Bland-Altman plot would present the agreement between the data generated by Holter monitor with data captured by BeatHR system. It indicates whether there is a systematic difference between these two monitoring systems and if they can be used interchangeably. In addition, the Box-Plot is used to show the statistical distribution of data along with outliers. The upper and lower box edges indicate 25th and 75th percentiles [105].

5.1 R-R Interval Estimation Evaluation

The following six figures indicate: 1) R-R interval values from Holter monitor and BeatHR versus the data points, 2) Correlation and Bland-Altman plots showing agreement between Holter monitor and BeatHR data for R-R interval measurement, and 3) Box-Plot for dispersion and skewness of differences in R-R intervals from two monitoring systems, in sitting and biking positions, respectively:
Figure 27. R-R intervals from Holter monitor and BeatHR in sitting position

Figure 28. Correlation and Bland-Altman plots for R-R interval in sitting position
Figure 29. Box-Plot for R-R interval in sitting position
Figure 30. R-R intervals from Holter monitor and BeatHR in biking position

Figure 31. Correlation and Bland-Altman plots for R-R interval in biking position
5.2 R-T Interval Estimation Evaluation

The following three figures indicate: 1) R-T interval values from Holter monitor and BeatHR versus the data points, 2) Correlation and Bland-Altman plots showing agreement between Holter monitor and BeatHR data for R-T interval measurement, and 3) Box-Plot for dispersion and skewness of differences in R-R intervals from two monitoring systems, in sitting and biking positions, respectively:
Figure 33. R-T intervals from Holter monitor and BeatHR in sitting position

Figure 34. Correlation and Bland-Altman plots for R-T interval in sitting position
Figure 35. Box-Plot for R-T interval in sitting position

Figure 36. R-T intervals from Holter monitor and BeatHR in biking position
The results from above statistical analysis have shown that the BeatHR system does provide an acceptable accuracy level when compared to a clinical gold standard system such as Holter monitor. From table 3 and 4 above, it can be seen that the ICC values obtained for most cases are above 0.75, which indicates an excellent reliability of the developed BeatHR system compared to
Holter monitor [103]. The Bland-Altman plots also indicate that the BeatHR system is a good predictor of the Holter monitor and the two systems can be used interchangeably. However, it is important to note that four of the data sets were excluded in the analysis. The Discussion and Critical Analysis chapter investigates the causes for excluding those four data sets. Furthermore, sources of error along with potential areas of improvement for the BeatHR system are also investigated.
6 Discussion and Critical Analysis

*BeatHR* system is developed to facilitate real-time ECG, heart rate and physical activity monitoring and is composed of a wearable chest patch and a smartphone application. The developed system have two components: 1) chest patch to collect user’s ECG signal, measure heart rate and stream both ECG and heart rate values to the smartphone application, and 2) smartphone application to receive the streamed data from the chest patch, extract number of steps taken from iOS HealthKit, and store both the streamed and the extracted data. *BeatHR* application display the stored data in real-time and generates a summary of heart rate values which were above a pre-defined threshold.

For clinical verification, *BeatHR* system was evaluated against the clinically accepted gold standard, Holter monitor. For this analysis, R-R and R-T intervals were extracted from the ECG signal collected by both of the monitoring systems and compared against each other. Result of the analysis demonstrated that ICC values for both R-R and R-T intervals were greater than 0.75, which represents excellent reliability of *BeatHR* compared to Holter monitor [103]. However, due to very low signal to noise ratio, two of the eight participants were excluded from the study.

In the following sections, observations, lessons learned and challenges overcame in design; development and clinical verification of *BeatHR* are explained. The platform could benefit form future iterations of this system to improve the wearable hardware and smartphone application in terms of accuracy and user experience.

6.1 *BeatHR* Design and Development

6.1.1 *BeatHR* Wearable Chest Patch

As mentioned in section 4.1.4.1, the wearable chest patch designed for *Beat* was used as a prototype for *BeatHR*. A number of modifications were made to improve hardware features. These changes intended to make the product: 1) lighter, 2) more durable, 3) more refined and, and 4) more flexible to be worn at different locations on the user’s body. To implement those changes, the electrode connection mechanism was redesigned by replacing snap buttons with 3D printed connector buttons, and the need for buttons on the electronics enclosure was eliminated.
by using press-fit board-to-board connectors. Furthermore, due to the modifications made in the flexible patch design, it sits better on the user’s body and more comfortable to be worn.

Research shows that HF can increase the risk for Arterial Fibrillation (AF) development [106], which is a condition involving irregular heartbeat, and caused disrupted electrical signaling in the heart [107]. It is shown that the incidence of AF in HF patients increases with the severity of the disease and could be as high as 50% in patients with severe HF [108]. AF causes atrial contraction at 400 to 600 beats per minute. As AV node does not allow many signals to be passed to the ventricles, one or two of every three atrial beats gets to the ventricles. Therefore, ventricles beat are at 110 to 180 beats [109], which is caused by R-R intervals ranging from 333 ms to 545 ms. As it was mentioned in 4.2.1.2, the detection rules are set 200 ms refractory time period between the R-peaks. In addition, if a new peak happens within 360 ms of a previously detected peak, its maximum derivative would be checked to be at least as great as half of the derivative of he previously detected beat. This checking makes sure that a T-wave is not detected instead of a R-peak. Therefore, E.P.Limited software could detect R-peaks as long as they are 200ms apart from each other.

In AF, the atria contract rapidly and irregularly at rates of 400 to 600 beats per minute. Fortunately, the AV node does not allow many signals through to the ventricles; only 1 or 2 out of every 3 atrial beats passes to the ventricles. However, the ventricles would still beat at a rate of 110 to 180 beats per minute. In addition to monitoring heart rate values, it would be clinically beneficial to add beat classification to the future iterations. Beat classification algorithm is already included in E.P.Limited software, however it classifies the detected beats as normal, premature ventricular contraction, which are abnormal heartbeats beginning in the ventricles [110] and unknown beats. This part of the software could be implemented in BeatHR firmware and extended furthermore to classify cardiac arrhythmia, including AF.

Advanced heart failure might cause delay in the right and left ventricles contractions, the heart’s main pumping chambers that normally contract at the same time. A pacemaker could resynchronize passage of the electrical signal between the ventricles. It causes the ventricles to pump together, which is called cardiac resynchronization therapy (CRT). The standard developed by Association for the Advancement of Medical Instrumentation (AAMI) and its Diagnostic Electrocardiograph Subcommittee, specify the pacemaker pulses to have an
amplitude of 2 to 250 mV, duration of 0.1 to 2.0 ms, a rise time of 100 µs, and a frequency of 100 pulses/minute [111]. These narrow pulses could cause beat detection as there is no lower limit on spike width on the original E.P. Limited software [84].

Although the changes above were made to improve the user experience, due to the time limitations of this project, usability testing with HF patients could not be included in the testing phase of the project to receive user feedback on these modifications. However, during the preparation phase of the clinical testing, the connection between the metal clipper and wires, which connect signal to the patch board, were damaged and broken. A more durable wiring option was installed onto the patch to guarantee a secure connection. However, extra care is still needed when electrodes are being mounted on or removed from the patch.

Furthermore, on-board memory was added to the electronics board to prevent data loss once the wearable sensor is disconnected from the smartphone. However, in order to ease the implementation and reduce complexity of the project, it is not currently activated. Making use of the memory would be beneficial for heart rate-only streaming, since data packets could be streamed less frequently and reduce power consumption of the patch sensor. Moreover, this approach extends usability of the wearable patch to an independent device, which could record captured data in absence of the smartphone on the user.

Currently, the application makes use of the physical activity data generated by HealthKit from iOS. However, as was mentioned in section 4.1.3, it is preferred to make use of data generated by the on-board accelerometer to monitor user’s physical activity instead of HealthKit. This is advantageous since the wearable chest patch is worn continuously by the user and that would result in a more consistent database, compared to the activity monitoring on the smartphone. Furthermore, allocating the entire data processing load on the hardware eases smartphone application development in a new platform. In this approach, the smartphone app would be solely used for data monitoring and storing purposes. This would allow for multi-platform smartphone application development. However, it is also necessary to evaluate the algorithm being used for processing the data generated by the on-board accelerometer.
6.1.2 BeatHR Smartphone Application

The smartphone application fulfills the objectives of the study. However, a number of modifications could be used to make it more compatible. Currently, the Bluetooth module is programmed such that data streaming starts as soon as the wearable sensor is connected to the smartphone Bluetooth module. Giving the user the option to initiate data streaming without the need to detach the electronics module from the patch module would make the system more user-friendly. Once the connection phase is started, the “Status” label on the application could be switched to “Data Streaming” to differentiate between connected and data streaming phases.

In addition, alerting the user to when the signal quality is not up to par is an essential feature before patients could use the system. In such a scenario, users could be prompted to detach and re-attach the electronics and patch modules. This adjustment assures that generated data is of appropriate quality for feature extraction.

One of the main challenges of this project was handling the data-streaming rate required for high quality ECG signal monitoring and heart rate measurement. The current sampling rate is lower than the Holter monitor but section 5 indicates that captured data from BeatHR is highly reliable when evaluated against the Holter monitor.

The original application algorithm was making use of Core Data, which is a framework that allows for the usage of model layer objects in your application. It provides automated solutions to common tasks associated with object life cycle, including persistence [112]. Upon receiving each data packet, data was stored and sent to the plotting section of the application. However, this approach was not capable of reaching the proposed sampling and streaming data rate causing the smartphone application to crash randomly. Regardless of the comprehensive set of automated solutions Core Data offered, it was decided to switch the database to Realm to resolve application crashing issues. After substituting Realm for Core Data, major performance improvements were noticed. However, after the data is streamed and recorded for a certain amount of time, an increasing time lag was noticed on the ECG plot on the smartphone app. In order to overcome this issue, the notification token generation and handling mechanism being used by Realm was eliminated. In the original algorithm, the following events happened once new data was received: 1) store data in Realm, 2) generate notification token upon changes in
database, 3) create notification token to make required changes, 4) handle the notification token through sending it to plotting methods. In the modified approach for data plotting, data storing and graphing are independent of each other. Therefore, rather than updating the plots once new data is received, graphing methods request for the new saved data independently. This approach resolved the plotting delay issue and improved the performance of the application.

As a number of important clinical indicators could be extracted from the ECG signal, application capabilities could be extended in terms of monitored features and indicators. For instance, heart rate variability (HRV), which is defined as the variation in beat-to-beat time intervals, is one of the significant clinical indicators that could be added to the list of monitored clinical indicators of the smartphone application. However, research shows that for accurate HRV monitoring, the sampling rate has to be increased from 100 Hz to at least 250 Hz [66]. Higher sampling rates will cause more power consumption. However, the effect of the increased sampling rate on the battery life has to be tested on the current prototype. It is also recommended to conduct a series of interviews with clinicians to distinguish the most advantageous clinical indicators to monitor. Furthermore, it might be desirable for clinicians to be able to activate and deactivate monitoring clinical indicators based on each patient’s condition.

In addition, once the technical modifications are implemented, the user interface of the smartphone application should be tested. It is also needed for the potential users, HF patients to go through testing scenarios and provide their feedback on using the system. Results of such a study could make the system more user-centered.

In addition, due to the difficulties experienced with data processing explained in detail in section 6.3, comparison of different electrode placements on the chest is needed to pick the one with the highest signal quality. As one electrode placement does not provide the best signal quality for everyone, a simple short tutorial video could be added to the smartphone application once the user aims to connect the wearable sensor to the smartphone. This tutorial could present all of the possible patch placements to the user and display the associate raw ECG signal with that placement. The user would be able to use their visual judgment and choose the placement with the best signal quality. This tutorial could be shown the very first time the user tries the application and the same placement could be used once the application is used again in the future to avoid redundancy and also make sure they have tried it once to assure each user is applying
the best patch placement.

In addition to enabling users to monitor their heart rate and ECG, it would be beneficial for healthcare providers to remotely monitor their patients. Although monitored data would be recorded and list of alerts could be reviewed later, real-time patient tele-monitoring would be beneficial for patients with more concerning health conditions or in areas where patients could not have frequent visits with their healthcare provider. For this feature, it is needed to send the captured data to a server and enable the clinician to review patient data through a dashboard, such as Medly developed at the Centre for Global eHealth Innovation.

6.2 BeatHR Clinical Verification Testing

In order to make use of Holter monitor data for BeatHR evaluation, it is needed to synchronize data generated by the two monitoring systems. This requires Holter monitor initialization using the controller. Then, to generate an event on the Holter data, the event recorder was used in the beginning and end of each testing session.

For regular clinical usage, patients are hooked up to a Holter monitor and are asked to keep the device on for the following 24 or 48 hours. Once patients bring the device back, it is connected to the MARS system, through which data is post-processed. Clinicians make use of the generated results for their diagnostics. However, in order to process the generated data for clinical verification analysis, it was needed to extract data from the MARS system and make use of the recorded data on a personal computer. The “Research Utilities” section of the MARS system was used to extract MIT-Signal and MIT-Annotation data files. In addition to these data files, the list of recorded events with their location on the ECG signal was documented. This information was used to align the two ECG waveforms from the Holter monitor and the BeatHR to prepare them for feature extraction. The MIT-BIH data files were fed to Cygwin, which creates a Linux-like environment in Windows to convert downloaded data files to .txt or .csv file formats, which could be used for data analysis.
6.3 ECG Signal Post-processing

Recording the ECG signal via use of electrodes results in capture of information from a number of other sources including; respiration and body movements activity [113]. Since physical activity was the main factor to add noise to the recorded signal, the study was designed in such as way to minimize body movements of the participants. The testing setup included two sitting postures: 1) sitting on a chair for seven minutes, and 2) sitting on a stationary bike for another seven minutes and cycling. These seated postures were chosen to reduce motion artifact in the signal. In addition, participants were trained to minimize their motion and talking to avoid potential muscle contractions.

As mentioned earlier, in addition to the filters on the firmware side, which is applied for QRS detection, another high-pass filter was included on the app side to help eliminate motion artifacts. However, both raw and filtered ECG signal data were stored, while filtered ECG signal was displayed on the screen. Upon completion of the testing sessions, it was observed that while filters were efficient for a number of participants, they tend to remove some features, such as the T-wave for some of the participants and in some other cases they were not as efficient. Therefore, it was required to extract the raw signal and post-process the data to obtain a clean ECG signal which could be used for feature extraction and analysis. The following figure presents a short sample of raw and filtered ECG signal using app filters while signal features are preserved:
Figure 39. Application filter used for ECG filtering with signal features well preserved

However, in some cases, the same filter could eliminate important features of ECG signal as shown in the graphs below:

Figure 40. App filter used for ECG filtering with some signal features eliminated
6.3.1.1 Excluded Data

Furthermore, in some cases, despite all the precautions taken during data collection, the captured signal contained considerable noise, and the app filter was not as effective:

![Figure 41. App filter used for ECG filtering could not remove noise effectively](image)

Figure 41 demonstrates a sample from one of the noisiest recordings that was completed during the testing sessions. As different cut-off frequencies could not output a clean signal for feature extraction, this recording along with another four samples were excluded from analysis.

For ECG signal post processing, it was required to eliminate: 1) high frequency spikes, which could be due to digital glitches, and 2) baseline noise, which is mostly due to muscle contraction and respiration, which overlap with ECG signal frequency range.

In order to remove high frequency spikes, low pass filter with different cut-off frequencies was applied. However, in most cases removing the high frequency components leads to some ECG data loss. Therefore, these parts of the signal were mostly removed.

6.3.1.2 Baseline Filtering

After excluding some parts of signal due to the above described exclusion criterion, a baseline filter was applied to remove low frequency noises. The baseline filter used in this part is
applying the sparsity-based solution to de-noise the signal [114]. The figure below shows a sample signal, its detected baseline, and the filtered signal after applying the proposed filter:

![Baseline filter](image)

**Figure 42. Baseline filter used to remove low frequency noise from ECG signal**

As acceptable range of the diagnostic ECG is defined to be in the frequency range of 0.05 Hz, which is required for ST analysis, to 40 or 100Hz [115]. However, for some of the participants the cut-off frequency was set to larger values, as high as 0.15Hz as this was resulting in better performance by providing a cleaner signal for ECG signal feature extraction.

After filtering different recording samples and extracting desired features, R-R and R-T intervals, a uniform sample size was needed for presenting the results. The sizes of the results for each participant varied from 565 to 163, except for one of samples with a size of 35 as it was extracted from a noisy recording. In order to preserve as much data as possible for analysis, a size range of 163 to 250 was considered. Therefore extra data was eliminated and the remaining data was fed to MATLAB and SPSS to generate Bland-Altman, Box-Plot and Intra-Class Coefficients for
both R-R and R-T intervals. The section below looks at potential factors that might have affected the signal.

6.4 Factors Affecting ECG Signal

**Filtering:**

As was mentioned earlier, some of the recorded data contained a considerable amount of noise, which in a few cases prevented the feature extraction software from working properly. This was mostly because the resulting signal did not have the regular ECG signal morphology. Although different filters on both the *BeatHR* application and the signal post-process were applied, these recordings could not be prepared for analysis.

Furthermore, as the *BeatHR* application was programmed to display the filtered signal, it was not possible to distinguish if recordings were noisy. At the same time, as the filtered signal did not have all of the features, e.g. T-waves (as mentioned earlier), the filtered signal was not useful for the analysis purposes.

In addition, although the filter implemented on the *BeatHR* application is adaptive, its threshold could get saturated upon receiving significantly large noises. As a result, it is required to adopt the algorithm and have the filtering threshold be reset after a fixed number of samples to correct the effect of those large noises.

**Large T-waves:**

Recordings from some of the participants did not have the regular ECG signal morphology as they had significantly large T-waves as the figure below shows:
For these cases, after applying the baseline filter to remove the DC offset, another baseline filter with a different cut-off frequency was applied through trial and error to obtain a clean ECG signal.

**Patch Location on chest:**

Participants were guided to wear the patch on the upper part of their chest as: 1) it was easier once they had their clothes on, and 2) the recorded signal was less affected by the abdominal muscle motion and contraction once they were cycling in the second phase of the testing session. However, this electrode placement might not be the best location for all of the participants. In addition, as two electrodes (RA and LA) from the BeatHR hardware are located close to Holter monitor electrodes, the resulting differential voltage might be affected by the interference between the two sets of electrodes.

In addition, the standard practice for using ECG monitoring devices recommends shaving the body area where electrodes are being worn. In addition, prep skin sand is applied on the same area to remove the dead skin off the area. However, those preparations were not conducted for this test, as BeatHR is developed for prolonged and continuous monitoring and such practice would cause additional disruption to patient’s body.
Based on the factors affecting ECG signal mentioned above, it can be said that the BeatHR system would be more valuable for use by the HF patients compared to the healthy individuals. The BeatHR system is able to provide valuable ECG data, from which other features could be extracted that are important for HF patient monitoring. However, healthy individuals do not have the advanced need for these extra ECG features rather than heart rate. Therefore, they could rely on PPG-based heart rate monitoring systems that are available in market.

6.5 Study Limitations

A number of study limitations were experienced during this study. Firstly, due to time limitations, participant recruitment was limited to a sample size of eight. Although similar studies have recruited the same number of participants [101], a number of other studies have had recruited 10 [113], 19 [117] and 25 [97] participants. However, testing sessions for this study were designed to be longer to make sure enough data is captured to guarantee a comprehensive analysis. Furthermore, as testing was conducted on a small sample size, it was not possible to monitor the age and gender demographics of the participants.

Secondly, healthy participants were recruited for this study. However, patients with HF have a reduced aerobic capacity, which is due to insufficient blood flow to the active skeletal muscles. In addition, cardiac output of the HF patients is lower than healthy individuals and might reach to less than half of the healthy individuals’ at peak exercise. Two factors cause HF patients’ inability to increase their cardiac output: 1) minimum stroke volume increase, with 2) lower maximum heart rate for a lower workload. Therefore, HF patients experience higher ranges of heart rate with lower levels of exercise load compared to healthy individuals [116]. If HF patients had participated in the same test as conducted in this study, they would have had experienced higher ranges of heart rate compared to the healthy individuals when stationary bike resistance was increasing.

Thirdly, the test settings were designed to minimize unnecessary participant’s motion and prevent motion artifact captured on ECG signal. As a result, although some of the similar studies included a testing phase for walking on treadmill [117], current performance of the hardware and software filters used in the BeatHR is not ideal for testing while participant is walking.
7 Conclusion

In this project, a real-time heart rate and ECG monitoring system was developed. This system is composed of a wearable chest patch that communicates wirelessly with the second component of the system, a smartphone application. The wearable chest patch is designed to be comfortable and to be worn continuously while collecting a single lead ECG signal. In addition, it extracts heart rate values from captured ECG, and streams both ECG and heart rate data via using Bluetooth Low Energy in real-time to a smart phone app.

The user can view their ECG signal and heart rate changes on a smartphone application designed to work with the wearable chest patch. In addition, the user could review the times when their heart rate was above a set threshold based on their condition.

A clinical validation study was conducted on eight participants in two different positions: sitting, and cycling on a stationary bike. The objective of this study was to evaluate the accuracy of the BeatHR system by comparing it to a clinically accepted gold standard, the Holter monitor. For this validation, two features of the ECG signal including: R-R and R-T intervals were chosen to be extracted and analyzed. ICC values as high as 0.954 (for R-R intervals) and as low as 0.785 (for R-T intervals) were resulted, which shows good agreement between the two monitoring systems. However, a number of improvements need to be implemented to eliminate the post-processing that was performed for this study.
8 Future Work

Although the system has shown acceptable accuracy levels when compared to a clinically accepted gold standard, there are some areas of improvements, which could be implemented to make the system more efficient. Below is a short overview of those areas:

- Implement an adaptive filtering system, which could customize itself to different signal types from different users to produce a more effective noise reduction mechanism.
- Extract physical activity data from on-board accelerometer instead of iOS HealthKit to guarantee a more comprehensive activity monitoring data.
- Include other clinical indicators, such as heart rate variability, with the data being monitored. It is required to conduct interviews with healthcare providers to evaluate which indicators are more effective to monitor.
- Add beat classification algorithm for AF, as it has a high incidence rate in HF patients and could be as high as 50% in patients with HF.
- Conduct usability testing to receive feedback on areas that require improvement for both the hardware and software.
References


32. About Heart Failure. (2015, June 4). Retrieved October 12, 2015, from http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/About-Heart-Failure_UCM_002044_Article.jsp


44. To wear it is to love it. Retrieved October 12, 2015, from http://www.apple.com/ca/watch/


Appendix A

Functional Requirements:

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<thead>
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<th>REQ. # I.D.</th>
<th>Requirement Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Req 1</td>
<td>User shall be able to start or shutdown the BeatHR Application when requested on their mobile device.</td>
</tr>
<tr>
<td>User Req 2</td>
<td>User shall be able to connect or disconnect the BeatHR Application from BeatHR Hardware when requested.</td>
</tr>
<tr>
<td>User Req 3</td>
<td>User shall be notified of connection issue with the BeatHR Hardware.</td>
</tr>
<tr>
<td>User Req 4</td>
<td>User shall have their ECG signal collected by BeatHR Hardware and streamed in real-time to BeatHR Application when they requested it.</td>
</tr>
<tr>
<td>User Req 5</td>
<td>User shall have their heart rate calculated from collected ECG signal by hardware and streamed in real-time to BeatHR Application.</td>
</tr>
<tr>
<td>User Req 6</td>
<td>User shall have their activity level monitored in real-time.</td>
</tr>
<tr>
<td>User Req 7</td>
<td>User shall be able to view their heart rate, activity level and ECG on the BeatHR Application</td>
</tr>
<tr>
<td>User Req 8</td>
<td>User shall be able to view a dashboard of average heart rate and activity level</td>
</tr>
<tr>
<td>User Req 9</td>
<td>User shall be able to clear off the data from the BeatHR Application</td>
</tr>
<tr>
<td>User Req 10</td>
<td>User shall be able to charge BeatHR Hardware</td>
</tr>
<tr>
<td>User Req 11</td>
<td>User shall be able to connect BeatHR Hardware and BeatHR Application to set it up for use</td>
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Non-functional Requirements:

Hardware Requirements:

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<tbody>
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<td>PRD 1.0</td>
<td>BeatHR Hardware shall prevent patients from attaching the electronics component incorrectly to the patch module</td>
</tr>
<tr>
<td>PRD 1.1</td>
<td>BeatHR Hardware shall have a rechargeable battery</td>
</tr>
<tr>
<td>PRD 1.2</td>
<td>BeatHR Hardware shall prevent patients from recharging the battery while worn on the body</td>
</tr>
<tr>
<td>PRD 1.3</td>
<td>BeatHR Hardware shall have means of acquiring ECG signal from patient</td>
</tr>
<tr>
<td>PRD 1.4</td>
<td>BeatHR Hardware shall use Bluetooth Low Energy to communicate with smartphone</td>
</tr>
<tr>
<td>PRD 1.5</td>
<td>BeatHR Hardware shall be modular with an electronics module that can be detached from the patch module</td>
</tr>
<tr>
<td>PRD 1.6</td>
<td>BeatHR Hardware shall have means of attachment and removal from patient</td>
</tr>
<tr>
<td>PRD 1.7</td>
<td>BeatHR Hardware shall have a microcontroller to run software that calculates heart rate from ECG data and facilitates data transfer</td>
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</table>
Software Requirements:

<table>
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<th>REQ. # I.D.</th>
<th>Requirement Description</th>
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</thead>
<tbody>
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<td>PRD 2.0</td>
<td>BeatHR Application shall operate on mobile devices running the iOS operating system</td>
</tr>
<tr>
<td>PRD 2.1</td>
<td>BeatHR Application shall make use of physical activity data generated by iPhone smartphone</td>
</tr>
<tr>
<td>PRD 2.2</td>
<td>BeatHR Hardware shall have a means to calculate heart rate from the ECG signal</td>
</tr>
</tbody>
</table>
Appendix B

Additional Results - Graphs

Participant 3

- R-R intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
- Correlation and Bland-Altman plots for R-R interval in sitting and biking positions respectively:
- Box-plots for R-R interval in sitting and biking positions respectively:
• R-T intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
- Correlation and Bland-Altman plots for R-T interval in sitting and biking positions respectively:
- Box-plots for R-T interval in sitting and biking positions respectively:
Participant 4

- R-R intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
- Correlation and Bland-Altman plots for R-R interval in sitting and biking positions respectively:
• Box-plots for R-R interval in sitting and biking positions respectively:
• R-T intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
Correlation an Bland-Altman plots for R-T interval in sitting and biking positions respectively:
- Box-plots for R-T interval in sitting and biking positions respectively:
Participant 5

- R-R intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
- Correlation and Bland-Altman plots for R-R interval in sitting and biking positions respectively:
- Box-Plots for R-R interval in sitting and biking positions respectively:
- R-T intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
Correlation and Bland-Altman plots for R-T interval in sitting and biking positions respectively:
Box-plots for R-T interval in sitting and biking positions respectively:
Participant 7

- R-R intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
- Correlation and Bland-Altman plots for R-R interval in sitting and biking positions respectively:
- Box-plots for R-R interval in sitting and biking positions respectively:
• R-T intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
• Correlation and Bland-Altman plots for R-T interval in sitting and biking positions respectively:

![BeatHR vs Holter](image1)

**BeatHR vs Holter**

- n=238
- SSE=0.007 Seconds
- r²=0.9192
- y=0.835x+0.0710

- RPC: 0.010 Seconds (3.4%)
- CV: 1.8%

- 0.0345 (±1.96SD)
- 0.009 (p<0.05)
- 0.025 (±1.96SD)

![BeatHR vs Holter](image2)

**BeatHR vs Holter**

- n=250
- SSE=0.013 Seconds
- r²=0.7145
- y=0.789x+0.084

- RPC: 0.027 Seconds (8%)
- CV: 4.1%

- 0.0411 (±1.96SD)
- 0.013 (p=4.3e-07)
- 0.014 (±1.96SD)
- Box-plots for R-T interval in sitting and biking positions respectively:
Participant 8

- R-R intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
• Correlation and Bland-Altman plot for R-R interval in sitting and biking positions respectively:
- Box-plots for R-R interval in sitting and biking positions respectively:
- R-T intervals from Holter monitor and BeatHR in sitting and biking positions, respectively:
- Correlation and Bland-Altman plots for R-T interval in sitting and biking positions respectively:
- Box-plots for R-T interval in sitting and biking positions respectively:
## Additional Results - ICC

### Participant 2

- Intra-class correlation coefficient for R-R intervals in sitting position:

<table>
<thead>
<tr>
<th>Intraclass Correlation^b</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td></td>
<td>.894^a</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.944^c</td>
<td>-.025</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-R intervals in biking position:

<table>
<thead>
<tr>
<th>Intraclass Correlation^b</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.748^a</td>
<td>-.038</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.856^c</td>
<td>-.080</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in sitting position:

<table>
<thead>
<tr>
<th>Intraclass Correlation^b</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.813^a</td>
<td>.560</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.897^c</td>
<td>.718</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in biking position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.738</td>
<td>.095</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.849</td>
<td>.174</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

**Participant 3**

- Intra-class correlation coefficient for R-R intervals in sitting position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.879a</td>
<td>.762</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.936c</td>
<td>.865</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-R intervals in biking position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.612a</td>
<td>-.086</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.759c</td>
<td>-.188</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in sitting position:

<table>
<thead>
<tr>
<th>Intraclass Correlation \</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.771</td>
<td>.582</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.871</td>
<td>.736</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in biking position:

<table>
<thead>
<tr>
<th>Intraclass Correlation \</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.673</td>
<td>-.009</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.805</td>
<td>-.017</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

**Participant 4**

- Intra-class correlation coefficient for R-R intervals in sitting position:

<table>
<thead>
<tr>
<th>Intraclass Correlation \</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.829</td>
<td>-.033</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.907</td>
<td>-.069</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-R intervals in biking position:

<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation(^b)</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
<td>Value</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.793(^a)</td>
<td>.066</td>
<td>.928</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.885(^c)</td>
<td>.124</td>
<td>.962</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.
a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in sitting position:

<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation(^b)</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
<td>Value</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.861(^a)</td>
<td>.735</td>
<td>.918</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.925(^c)</td>
<td>.847</td>
<td>.957</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.
a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in biking position:

<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation(^b)</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
<td>Value</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.776(^a)</td>
<td>.111</td>
<td>.916</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.874(^c)</td>
<td>.199</td>
<td>.956</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.
a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

**Participant 5**

- Intra-class correlation coefficient for R-R intervals in sitting position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.650a</td>
<td>.079</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.788c</td>
<td>-.173</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-R intervals in biking position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.784a</td>
<td>.420</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.879c</td>
<td>.592</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in sitting position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.646a</td>
<td>.258</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.785c</td>
<td>.410</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in biking position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.674a</td>
<td>.426</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.805c</td>
<td>.598</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

Participant 7

- Intra-class correlation coefficient for R-R intervals in sitting position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.860a</td>
<td>-.030</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.925c</td>
<td>-.063</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.

b. Type A intraclass correlation coefficients using an absolute agreement definition.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-R intervals in biking position:

<table>
<thead>
<tr>
<th>Intraclass Correlation</th>
<th>95% Confidence Interval</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.742a</td>
<td>.196</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.852c</td>
<td>.328</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in sitting position:

<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation(^a)</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.908(^a)</td>
<td>.554</td>
<td>.965</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.952(^c)</td>
<td>.713</td>
<td>.982</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in biking position:

<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation(^b)</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.738(^a)</td>
<td>.213</td>
<td>.885</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.849(^c)</td>
<td>.351</td>
<td>.939</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.

a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

**Participant 8**

- Intra-class correlation coefficient for R-R intervals in sitting position:

<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation(^b)</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.913(^a)</td>
<td>-.012</td>
<td>.979</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.954(^c)</td>
<td>-.024</td>
<td>.990</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.
a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-R intervals in biking position:

<table>
<thead>
<tr>
<th></th>
<th>Intra-class Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.814\textsuperscript{a}</td>
<td>-.041</td>
<td>.946</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.897\textsuperscript{c}</td>
<td>-.086</td>
<td>.972</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.
a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in sitting position:

<table>
<thead>
<tr>
<th></th>
<th>Intra-class Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.873\textsuperscript{a}</td>
<td>.302</td>
<td>.955</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.932\textsuperscript{c}</td>
<td>.464</td>
<td>.977</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.
a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.
c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.

- Intra-class correlation coefficient for R-T intervals in biking position:

<table>
<thead>
<tr>
<th></th>
<th>Intra-class Correlation</th>
<th>95% Confidence Interval</th>
<th>F Test with True Value 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Single Measures</td>
<td>.803\textsuperscript{a}</td>
<td>-.018</td>
<td>.938</td>
</tr>
<tr>
<td>Average Measures</td>
<td>.891\textsuperscript{c}</td>
<td>-.037</td>
<td>.968</td>
</tr>
</tbody>
</table>

Two-way mixed effects model where people effects are random and measures effects are fixed.
a. The estimator is the same, whether the interaction effect is present or not.
b. Type A intraclass correlation coefficients using an absolute agreement definition.

c. This estimate is computed assuming the interaction effect is absent, because it is not estimable otherwise.