The Use of Continuous Monitoring of Heart Rate as a Prognosticator of Readmission in Heart Failure Patients

By

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A thesis submitted in conformity with the requirements for the degree of Masters of Health Science in Clinical Engineering
Institute of Biomaterials and Biomedical Engineering
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Masters of Health Science in Clinical Engineering, Institute of Biomaterials and Biomedical Engineering, University of Toronto 2016

Abstract

In this study we validated the accuracy of heart rate measurements of two consumer-grade heart rate and activity tracking wearable devices in 8 healthy participants. In a clinical setting and using the Holter monitor as the reference, participants exercised on a stationary bike for 10 minutes with a 10-watts step protocol. The two devices reported better correlation with the Holter monitor at higher workload levels, hence, at higher heart rates with a 90% confidence interval for overall measurement accuracy. We also examined the feasibility of the two devices in remote monitoring 8 heart failure patients (NYHA II-NYHA III) for two weeks. The two devices reported lower daily physical activity, lower total step count and higher resting heart rate for NYHA III patients when compared to NYHA II patients’ data. Therefore, with the wearable devices we differentiated different classes of heart failure based on heart rate and physical activity.
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<td>NYHA</td>
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<td>Heart failure</td>
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<td>ECG</td>
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1 Introduction

In heart failure (HF) patients, the pumping of blood is insufficient to meet bodily needs, resulting in quick fatigue, shortness of breath and fluid retention [1]. This is usually a result of damage to the heart muscle or valves, such as from myocardial infarction, hypertension, or coronary artery disease. The rate of readmission of HF patients is the highest among all other chronic conditions [2], thus affecting the quality of life and introducing many challenges to the healthcare sector. Previous studies reported the effect of monitoring certain critical clinical indicators on reducing readmission rates and identifying early warning signs of decompensation [3]. Prevalence and incidence of HF is rising and will continue to rise due to an aging population and an increased survival rate due to better treatment [4]. Healthcare providers need ways to keep HF patients stable when in ambulatory settings and to identify problems before they become life-threatening emergencies. Often readmissions occur because of a lack of access to healthcare professionals, difficulty recognizing the signs of illness, or a failure to adhere to prescribed medication and lifestyle changes [4].

HF management strategies are categorized into two groups: pre-discharge and post-discharge from the hospital [5]. Pre-discharge from the hospital, patients can meet with an educator to educate them about their symptoms and teach them how to keep an eye on their condition when they are in ambulatory settings. Also, patients get informed about necessary lifestyle changes, such as smoking cessation, weight loss, and avoiding alcohol intake. Post-discharge from the hospital, patients are advised to schedule a follow-up appointment within 7-days of discharge with their primary care physician and to set-up regular telephone follow-up appointments to keep their physician informed about any worsening symptoms. Studies have shown that these strategies are capable of decreasing hospital readmissions and delaying disease progression. Applying HF management strategies pre-discharge and post-discharge from the hospital can reduce readmissions and as a result reduce the associated costs [5]. One of the main challenges with these management strategies is that although readmission rates are declining and costs of rehospitalizations are dropping, there are new costs introduced when applying any of the management strategies. For example, pre-discharge from the hospital, there is a need to hire an educator who is responsible of meeting with patients before they leave the hospital. The educator spends time with patients to
explain their role in self-monitoring their condition and get them engaged in the treatment plan. In addition, another challenge with HF management strategies is that both, pre-discharge and post-discharge from the hospital strategies are limited by time. Also, these management strategies provide snapshots of the patient’s condition at a certain time, rather than giving a continuous and frequent monitoring. For example, during a clinic visit, patients self-report themselves and their symptoms prior to the time of the visit, but not anything else that happened right after the visit. In addition, one of the major concerns is the reliability of information provided by the patients because patients self-reporting their condition can be very subjective.

Clinical indicators that are critical to monitor for HF patients are the heart rate and daily physical activity. Heart rate is one of the key indicators of HF status and prognosis. A study completed by Habal et al was conducted to investigate the relationship between discharge heart rate and the following series of events: all-cause mortality, cardiovascular death and hospitalization within 30-day and 1-year in HF patients [6]. Result of this study indicated that patients with heart rates over 90 beats per minute (bpm) at discharge time have higher risk of all-cause mortality, cardiovascular deaths, successive HF readmission and cardiovascular disease hospitalization within the 30-day and 1-year time periods. Previous studies also reported that lower daily physical activity in HF patients is a significant predictor of rehospitalization and is associated with patients with more severe HF [7]. Activity level provides an explanation behind the variations in heart rate. For example, when the patient is running, it is normal and expected that the heart rate will increase. Heart rate data and activity data recorded by heart rate and activity trackers provide reliable measures for physician to track HF patients’ status.

In this study, these two parameters are monitored synchronously to better understand their association with heart failure condition and severity. The hypothesis of this thesis is that remote monitoring of heart rate and physical activity using wearable devices can identify patients at high risk of readmission by tracking early signs of decompensation and determine the onset, duration and frequency of destabilization in heart failure condition.
2 Background

2.1 Heart Failure Pathology

Heart failure (HF) is a chronic condition where the heart function is impaired, so the heart doesn’t pump enough blood to maintain the body’s needs [8]. The heart muscle becomes too weak or damaged because of certain conditions, such as coronary artery disease or high blood pressure [9]. Cardiac output is the amount of blood the heart pumps through the circulatory system in a minute. The amount of blood put out by the left ventricle of the heart in one contraction is called the Stroke Volume. The stroke volume and the heart rate determine the cardiac output. Ejection fraction (EF) is the percentage of blood that is pumped out of the heart during each beat [10].

The main pumping chambers in the heart are the ventricles. HF can be categorized based on the side of the heart that has the impaired function. Left-sided HF is the most common type of HF, which results in fluid build-up in the lungs, causing shortness of breath and eventually leading to pulmonary edema [11]. Right-sided HF often occurs with left-sided HF, which results in fluid build-up and swelling in the abdomen, legs and feet. In addition, HF can be further categorized based on the type of functional impairment into systolic HF and diastolic HF. Systolic HF is when the left ventricular contraction is abnormal, leading to low left ventricular ejection fraction. Diastolic HF is when the left ventricle fails to relax, resulting in decreased stroke volume and cardiac output.

In HF patients, the heart is not pumping out enough blood each time it beats (low stroke volume). In order to maintain sufficient cardiac output and meet the body’s needs for blood and oxygen, the body follows certain compensation mechanisms to keep up with the body demands. The body compensation mechanisms are categorized mainly into two major contributors: the nervous system and the hormone system.
When the nervous system senses that the brain and vital organs are not getting enough blood, the sympathetic nervous system is stimulated and releases substances called catecholamines into the bloodstream. These substances cause the blood vessels to constrict and speed up the heart rate and at the same time, the arteries supplying the brain and vital organs widen to carry the increased blood flow. When the body thinks it needs more fluid in its blood vessels, the hormone systems release chemicals into the bloodstream (renin, angiotensin and aldosterone) that cause the blood vessels to constrict and cause the body to retain more sodium and water in the circulatory system.

The heart also compensates for the decreasing cardiac output by beating faster, leading to an increase in heart rate. The brain triggers the heart to beat faster by stimulating the adrenal glands to release more adrenaline into the bloodstream; therefore, the heart beats faster than normal to compensate for the decreasing cardiac output. Faster heart rate is a way to compensate for the low cardiac output. However, over time it can weaken the heart muscle.
In addition, as the left ventricle is not pumping out enough blood efficiently at each beat (low stroke volume), the heart will compensate by allowing more blood to fill in the ventricle before it pumps blood out. Thus, leading to an increase in the volume of the ventricle (dilation). As the size of the heart gets bigger and bigger, there is more and more tension on the walls of the heart to pump out the blood inside it, which increases the stress on the heart and overtime, it can worsen the already impaired function of the heart.

The body can utilize these compensation mechanisms to keep up with its demands; however, the duration of compensation is extremely variable and dependent on the cause of HF. When the body is no longer capable of compensating for HF, patients begin to have congestive symptoms that are caused by the backup of blood into the lungs and other organs, including shortness of breath and swelling in the ankles and abdomen. In addition, as the heart is unable to generate enough cardiac output, there is a reduced blood flow into the brain and other vital organs, which can lead to major damage in vital organs, particularly the kidneys. Therefore, if not managed properly, HF can progress rapidly and eventually leads to acute decompensation and require hospitalizations.

2.2 Heart Failure Epidemiology and Cost

Heart failure (HF) affects 23 million people worldwide [12]. HF is the leading cause of hospitalization among adults >65 years of age in the United States [13]. By 2030, more than 8 million people in the United States will have HF [12]. HF affects over 500,000 Canadians and 50,000 new patients are diagnosed each year [14]. Admission rates following HF hospitalization remain high, with 25% of patients readmitted within 30 days of discharge and up to 50% of patients readmitted within 6 months of discharge [15][16]. If HF progresses over time, patients are frequently rehospitalized as a result of the development of HF symptoms. The main costs associated with HF are related to rehospitalizations. Between 2012 and 2030, total medical costs of HF are projected to increase from 21 billion USD to 53 billion USD [17]. The estimated prevalence and cost of care for HF patients is expected to increase more because of aging of the population.
2.3 Heart Failure Diagnosis

Heart failure can present suddenly as the consequence of an acute cardiac event such as myocardial infarction. Most of HF symptoms and signs are non-specific, especially in elderly patients and could be due to other problems.

HF patients suffer from shortness of breath, fatigue, rapid or irregular heart rhythm, reduced ability to exercise, swelling in the legs and sudden weight gain from fluid retention. Clinicians consider a decrease in exercise tolerance with a rapid weight gain as an indicator for deterioration in HF condition [18]. HF is diagnosed based on an assessment of multiple factors such as the patient’s history, physical examination, blood tests and exercise stress test. Echocardiography is also used in diagnosis HF as it demonstrates structural heart disease. Electrocardiography (ECG) is also used as a diagnostic tool to identify the heart rhythm, rate and conduction.

There is no cure for HF. However, it can be managed effectively with diet and lifestyle changes in conjunction with adherence to medication. Lifestyle changes such as exercising, reducing salt intake and losing weight can help in stabilizing the condition. Beta-blockers and angiotensin-converting enzyme (ACE) inhibitors are two of the common medications used for HF patients [19].

2.3.1 NYHA Classification for heart failure patients

The New York Heart Association (NYHA) classification system classifies heart failure patients into four categories based on the severity of their symptoms and the encountered limitations in physical activity [20]. Classifying a patient into a certain class is made based on quantitative and qualitative data collected from the patient. Qualitative data is collected during a clinic visit by asking the patient questions about how they feel when doing different set of activities, such as walking, grocery shopping, climbing stairs, etc. When pairing this qualitative information together with quantitative data from test results; the cardiologist then can make a judgement about the patient’s classification. Functional classification can change from one visit to another, depending on whether or not the patient’s situation is improving, or getting worst. The clinician sets a treatment plan for the patient and monitors the changes in the quantitative test results and the qualitative information gathered directly
from the patient. By monitoring the changes that occur from one visit to another, the clinician can determine the stability of the patient and decide if it is necessary to change the treatment plan or continue with the it.

Raphael et al investigated the measures that clinicians use to assess HF patients. A survey was prepared for 30 cardiologists to ask them about their use of NYHA classification system in assessing patients with HF, their use of specific questions in determining which class a patient belonged to and how they distinguish between class II and class III patients. The 30 cardiologists were interviewed individually over a period of 5 days and they were not allowed to confer with one another. The survey showed no consistent method for assessing NYHA class the assessment and classification can be different from one cardiologist to another. Therefore, it was concluded that the NYHA classification system is subjective and dependent on the way the cardiologist assess and evaluate the patient, as well as on the information provided by the patient when self-reporting their condition. The NYHA classification system categorized patients into classes based on their severity [20], which gave a better understanding of the progression of HF and its impact on daily activities.

The NYHA classification is as follows:

- **Class I (Mild):** Patients with cardiac disease but without resulting in limitation of physical activity.

- **Class II (Mild):** Patients with cardiac disease resulting in slight limitation of physical activity. Ordinary physical activity doesn’t cause fatigue, palpitation, shortness of breath, or chest pain.

- **Class III (Moderate):** Patients with cardiac disease resulting in marked limitation on physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation and shortness of breath.

- **Class III (Severe):** Patients with cardiac disease resulting in the inability to carry on any physical activity without discomfort. Symptoms of HF maybe present even at rest.
When conducting this study in the heart function clinic at Toronto General Hospital, it was noted multiple times that the clinicians classified patients to be falling in between two functional classifications, such as NYHA I/ NYHA II, or NYHA II/ NYHA III, etc. Therefore, one of the challenges encountered in this study was to find HF patients that are eligible to participate in the study based on the inclusion criteria (NYHA II or NYHA III) and also to select patients who do not fall in an ambiguous classification (NYHA I/ NYHA II, NYHA III/ NYHA IV).

2.3.2 Cardiopulmonary Study

The Cardiopulmonary Study (CPS) is an important tool to evaluate exercise capacity and predict outcome in patients with heart failure [21]. It is an exercise test that stresses the body’s systems; making them work harder and faster in order to understand the capabilities and limitations of the patient at various physical activity intensities [21]. Figure 2 shows the cardiopulmonary study setup. The CPS is performed on a stationary bicycle while monitoring the patient’s response to different exercise levels using the following:

- Facemask that is placed over the mouth and nose to monitor the amount of oxygen used, the carbon dioxide produced and the general breathing pattern.
- Pulse oximeter to measure the percentage of oxygen saturation in blood.
- Electrocardiogram (ECG) to monitor heart rate and rhythm
- Blood pressure cuff to take the blood pressure multiple times during the test

![Figure 2: Cardiopulmonary Exercise Test](image)
When it comes to an exercise test, heart failure patients have more limitations compared to healthy adults and that is primarily due to the impaired function of the heart [22]. The CPS helps in assessing the patients by monitoring their performance during the exercise test (heart rate, blood pressure and other important metrics). At the end of the CPS, a summary report is generated for the patient (Appendix F), which have the measurements taken at rest, during exercise, peak activity and recovery.

### 2.3.3 Ejection Fraction

Ejection fraction (EF) is the percentage of blood by volume that is pumped out of the heart during each beat. Usually EF is measured from the left ventricle because it is the chamber that pumps blood from the heart to the rest of the body. Normal heart has an EF of 50-70%, heart failure has less than 40% EF [10]. EF is an important measurement of heart function and HF diagnosis and monitoring. The most widely used test for measuring EF is echocardiogram (Echo). In an Echo test, a probe is passed over the patient’s chest and produces high frequency ultrasound waves. The ultrasound waves are then bounced off the heart and echo back to the probe. These waves are then transformed into pictures that give information about the heart structure and function. Important information such as the size of the heart, structural thickness, movement of the heart’s walls and heart’s pumping strength can all be identified with an Echocardiogram test.

### 2.3.4 Telemonitoring

Telemonitoring is the process of using audio, video and other telecommunications and electronic information processing technologies to monitor the health status of a patient from a distance. Telemonitoring in healthcare involves the transfer of physiological data from the patient to the clinician, coaching the patient, providing telephone support, video consultations and web-based communications.

Home telemonitoring systems integrate various information technologies for monitoring HF patients at a distance to allow early intervention if there is evidence of clinical deterioration [23]. Telemonitoring systems can be utilized in the circle of care of heart failure patients by giving the patients an opportunity to self-monitor their condition, report symptoms, track key
indicators on daily basis and communicate these reliable records with their healthcare professionals. Remote monitoring is very effective especially for patients with chronic conditions that require attention even when patients leave the hospital.

2.4 Wearable Heart Rate and Activity Tracking Devices

Wearable heart rate and activity tracking devices are widely available now in the market, with a variety of features that can be utilized for health and fitness monitoring. Wearable devices are embedded with different types of sensors and modules that provide information about various metrics that is important for health and fitness tracking. Wearable heart rate tracking devices use optical sensors to detect heart rate based on the Photoplethysmography principle (PPG). Wearable activity tracking devices use microelectromechanical systems (MEMs) inertial sensors to track movement. Movements are detected by measuring the mechanical displacement and converting it into an electrical signal using piezoelectric components. There are many wearable devices in the market that have various capabilities and can be worn in different positions, such as the head, ear, wrist, chest, torso and ankle. The position of the wearable devices is selected so that it has a direct or indirect access to the required measurements.

2.4.1 Photoplethysmography Based Heart Rate Detection

The Apple Watch and the Fitbit Charge HR measure heart rate based on optical detection of blood volume changes using two elements: light emitting diodes (LEDs) and optical sensors. These two elements are embedded in the back of the wearable wristbands. The skin is illuminated with light from the LED and the amount of light reflected back to the optical light sensor is measured. The difference in the intensity of the light emitted and the light reflected is associated with the variations in blood perfusion of the tissue and provides information about the cardiovascular system, in particular, the heart rate [24]. As shown in Figure 3, with each cardiac cycle, the heart pumps blood to the periphery, which results in distending the arteries in the subcutaneous tissue to accept the volume change. Therefore, higher light absorption occurs when the blood is dense; which means on the beat and lower light absorption occurs between beats. The contact force between the sensor and the measurement site can deform the arterial geometry by pressure and as a result affect the
measurement accuracy. Body movements can also introduce motion artifacts that affect the measurement accuracy [24].

In general, PPG wearable tracking devices use green LEDs, Infrared LEDs, or both. Green light wavelength is between 500 and 600 nm. Green LEDs are used in Fitbit Charge HR at all times and used in the Apple Watch for continuous heart rate detection (when the Apple Watch is set to workout mode). The infrared light wavelength is between 800 and 815 nm. Infrared LEDs are used in Apple Watch to detect heart rate in the background when the user is still and not moving.

Previous studies have shown that green LEDs are more accurate for PPG heart rate detection compared to infrared LEDs. It was reported that green light has much greater absorptivity for both oxyhaemoglobin and deoxyhaemoglobin compared to infrared light. Therefore, a better signal-to-noise ratio is achieved with green LEDs. Based on this fact, it is assumed that Apple designed the Apple Watch to work with the two LEDs to improve the accuracy of its heart rate measurements when the user is moving, to reduce errors that might result from the motion artifacts. Another explanation to the lower battery life of the Apple Watch when compared to Fitbit Charge HR can also be related to the use of two different lights (green and infrared light) instead of one option with the Fitbit Charge HR (green light).

![Light source and tissue composition](image)

**Figure 3: Variation in light attenuation by tissue**
3 Literature Review

3.1 Heart Failure Management Strategies

Previous studies found that applying heart failure management strategies have a great impact on improving patient outcomes. One-on-one teaching sessions with a nurse educator prior to discharge time, telephone follow-up, meeting with the physician within 7 days of discharge from the hospital are all interventions that can reduce readmission rates. Krumholz et al conducted a study on 88 heart failure patients over 1 year and 44 patients received the intervention (formal education and support intervention) and 44 patients did not. There was 25% reduction in readmission rates for the patients who received the intervention [25].

Another study by Koelling et al conducted a similar study over 6 months, where 107 patients received the intervention (1-hour one-on-one teaching session with a nurse educator and telephone follow-up at 30, 90 and 180 days) and 116 patients did not. There was a 35% reduction in readmission rates and fewer unplanned hospital visits for the intervention group [26].

3.2 Telemonitoring in Heart Failure

Winkler et al evaluated the feasibility of a new wireless telemonitoring system via a mobile phone network. 30 subjects were enrolled in the study for 26 days. Portable home devices for electrocardiogram, blood pressure, body weight and self-assessment measurements were connected via Bluetooth to a personal digital assistant that performs encrypted transmission via mobile phone. The results showed that 94% of the ECG recordings had sufficient diagnostic quality for rhythm analysis and single beat measurements and as a result, it was suitable for continuous and secure medical data transmission [27].

Schofield et al designed and implemented a care-coordinated, nurse-directed home telehealth management program for HF patients. An in-home telehealth message device was given to 92 patients who received daily heart failure-specific education via the device. The results showed significant improvements in patient outcomes, including systolic blood pressure, diastolic blood pressure and average weight [28].
Seto et al evaluated the feasibility of a mobile phone based telemonitoring system by conducting a randomized control trial for 100 HF patients (50 patients in control group and 50 patients in intervention group) over 6 months. Patients took daily weight and blood pressure readings, as well as weekly ECGs and answered daily questions about symptoms. Cardiologists received alerts through the system and contacted the patient when necessary. The system improved quality of life through improved self-care and clinical management. The use of the mobile phone-based system had high adherence and was feasible for patients, including the elderly and those with no experience with mobile phones [29].

Maeng et al investigated the effect of a new telemonitoring system on 500 HF patients over a period of 5 years. The telemonitoring system has a Bluetooth weight scale with an interactive voice system to collect answers responding to questions about symptoms. The study found that the telemonitoring system contributed significantly to reductions in hospitalizations and achieved 11% cost savings [30].

### 3.3 Heart Rate and Physical Activity in Heart Failure

Discharge heart rate is one of the key indicators of heart failure status and prognosis. Laskey et al conducted a study on 46217 heart failure patients over 1 year, where discharge heart rate was recorded for all patients before they leave the hospital and the frequency of readmission to the hospital is also recorded. The results reported that patients with higher discharge heart rate had a higher rate of readmission within the 1-year study duration [31].

Habal et al conducted a similar study on 9097 heart failure patients over 1 year. Patients were divided into five groups based on discharge heart rate. The first group had a discharge heart rate between 40-60 bpm, the second group had 61-70 bpm, the third group had 71-80 bpm, the fourth group had 81-90 bpm and the fifth group had higher than 90 bpm. It was reported that patients with higher discharge heart rate and specifically between 81 and 90 bpm, or higher than 90 bpm, had a higher risk of all cause-mortality, cardiovascular deaths and readmission rate within 30 days and 1 year of discharge time [6].
Physical activity is another clinical indicator that is used to assess the severity of heart failure. Dontje et al conducted a study on 68 heart failure patients on two consecutive days and used an armband that has an accelerometer to measure physical activity. It was reported that patients with higher NYHA classification had a lower daily physical activity [7]. Melissa Jehn used an accelerometer to measure daily walking performance in patients with heart failure to investigate if this parameter is a determinant of NYHA class and indicative of exercise capacity. 50 heart failure patients (NYHA I, NYHA II and NYHA III) were instructed to wear an accelerometer for 7 consecutive days. It was reported that daily walking performance is an independent predictor in discriminating patients with advanced heart failure [32].

3.4 Photoplethysmography heart rate detection

Lin et al estimated heart rate using rest-acquired Photoplethysmography under different types of daily life motion artifacts and analyzed the influence of motion artifacts on reflective wrist PPG signals. Lin et al proposed a method that consists of adaptive filtering, heart rate selection, and motion identification. The results showed that the proposed method generated reliable heart rate values from wrist PPG signals [36].

Mahdi et al examined heart rate tracking using wrist-type Photoplethysmographic signals during physical exercise with simultaneous accelerometry. Mahdi et al proposed a novel algorithm that consists of two main steps of motion artifacts cancellation and spectral analysis. Results recorded from 12 subjects during fast running at the peak speed of 15 km/hour showed that the proposed algorithm keeps high estimation accuracies even in strong motion artifact conditions during physical exercise [37]. Generally, most of the previous studies that examined the accuracy of heart rate data measured based on Photoplethysmography principle used filtering techniques and developed algorithms to determine the accuracy of the measurements when motion artifacts are removed.

Shi et al investigated the difference between heart rate variability derived from electrocardiogram signals and pulse rate variability derived from Photoplethysmography signals. Ten-minute recordings of finger and ear PPG and ECG were collected in 14 subjects. The results showed a high degree of agreement between pulse rate variability measured by
the finger and the ear with the heart rate variability measured by the ECG. The study suggests using PPG as a simple and robust means to measure heart rate variability [33].

Ahn Jae Mok investigated the statistical validation for the interchangeability of two heart rate detection methods on 6 subjects. Simultaneous ECG and PPG signals were acquired for 5 minutes, using handgrip Lead II type ECG and fingertip PPG. The results suggested that ECG and PPG signal recordings could be interchanged for heart rate variability analysis and the study concluded that the PPG might serve as a surrogate technique for the ECG in all parameter for heart rate variability [34]. Kakub Parak evaluated the accuracy of two PPG based commercially available heart rate monitors, Mio Alpha and Schosche Rhythm. 21 subjects completed an exercise protocol, which included sitting, walking, running and cycling. Embla Titanium wearable recorder was used for measuring the reference ECG signal. Heart rate accuracy of the Mio Alpha was 78%, whereas the heart rate accuracy of the Schosche Rhythm was 76% [35]. These studies provided evidence that the measurements of wearable PPG heart rate tracking devices are comparable to ECG heart rate measurements.

### 4 Heart Rate and Physical Activity Tracking

#### Wearables

**4.1 Fitbit Charge HR**

The Fitbit Charge HR is a heart rate and activity tracker that can record heart rate data continuously and automatically based on PPG principle. The Fitbit Charge HR has a MEMS 3-axis accelerometer that measures motion patterns to determine steps taken, distance travelled, active minutes and calories burned. The Fitbit Charge HR has only one optical heart rate sensor at the back of the wristband, while the Apple Watch has two sensors. The Fitbit Charge HR automatically sync and store all heart rate and activity data in Fitbit Dashboard that is securely linked with the phone and the tracker. All profiles will be anonymous and linked to personal information with unique identifiers. Information about wearing and charging the Fitbit Charge HR is available in Appendix B.
4.2 Apple Watch

Apple watch is a comprehensive smart-watch created by Apple and includes several sensors dedicated to health and fitness tracking. It incorporates heart rate and activity monitoring through multiple embedded sensors. It is compatible with the iPhone 5 or later models running iOS 7.0 or later. Two onboard optical sensors are embedded on the back of the watch and are used to detect users’ heart rate based on PPG principle. Heart rate and step data recorded by the Apple Watch is automatically synced and stored in the Health App, which is available in the iPhone given to the participant. The Apple Watch stores the data it collects in Apple’s Health app using HealthKit. A quick glance into the Health app indicates that it is storing minute-level step data from the Apple Watch.

4.3 Similarities and Differences

Heart rate is detected at every second when the Fitbit Charge HR is set to workout mode and at every 5 seconds at all other times using the green light. The Apple Watch also records heart rate at different intervals depending on the selected mode, just like the Fitbit Charge HR. When the Apple Watch is set in workout mode, it detects heart rate every 5 seconds and it uses green light. When the Apple Watch is not set to workout mode, it uses infrared light and it detects heart rate in the background only when the user is still, therefore, the time between the measurements will vary.

Table 1: Similarities and Differences of Fitbit Charge HR and Apple Watch

<table>
<thead>
<tr>
<th>Feature</th>
<th>Fitbit Charge HR</th>
<th>Apple Watch</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEDs</td>
<td>2 LEDs</td>
<td>2 LEDs</td>
</tr>
<tr>
<td>Optical Sensors</td>
<td>1 optical sensor</td>
<td>2 optical sensors</td>
</tr>
<tr>
<td>Compatibility</td>
<td>With most of smartphones</td>
<td>Only with iPhone 5 or later</td>
</tr>
<tr>
<td>Heart rate detection</td>
<td>• Every 5 seconds (green light)</td>
<td>• When user is still (infrared light)</td>
</tr>
<tr>
<td></td>
<td>• Every second in workout mode (green light)</td>
<td>• Every 5 seconds in workout mode (green light)</td>
</tr>
<tr>
<td>Battery Life</td>
<td>Up to 5 days</td>
<td>1 day</td>
</tr>
<tr>
<td>Data transfer</td>
<td>Automatic sync to Fitbit Dashboard</td>
<td>Automatic sync to HealthKit</td>
</tr>
<tr>
<td>Price</td>
<td>~ $170</td>
<td>~ $450</td>
</tr>
</tbody>
</table>
5 Objectives and Hypothesis

5.1 Gap in Knowledge

Previous studies reported that high discharge heart rate is associated with greater risk of all-cause mortality and cardiovascular mortality within 1-year and with an elevated risk of 30-day readmission. Previous studies also reported that lower daily physical activity in heart failure patients was associated with higher NYHA classification. Identifying warning signs of decompensation (high heart rate and low physical activity) as early as possible is very critical to reducing readmission rates and improving quality of life. Generally, it is difficult for heart failure patients to recognize these signs and communicate it appropriately to clinicians in a timely manner. Patients have limited access to healthcare professionals and it is based on pre-scheduled visits or telephone follow-ups. Therefore, clinicians depend on patients to self-report the symptoms; which is subjective. Also, the time in which this information is received by the clinician might be too late for them to intervene.

Although many patients come in regularly for check-ups, these visits are rarely reflective of a patient’s condition at home. During the between-clinic-visit time periods, physicians have no access to the patients’ clinical indicators. Therefore, it is difficult to identify patients who are at high risk of readmission. Also, due to limitation in hospital resources patients cannot always be given equal attention.

Previous studies focused on either analyzing heart rate at the time of discharge or physical activity using physical activity trackers. However, no previous studies have been conducted to combine the heart rate and the physical activity together for remote monitoring of heart failure. Moreover, previous studies have been limited to short periods of data collection or daily summaries as opposed to continuous tracking.
5.2 Objectives and Hypothesis

The wearable devices used in this study, the Fitbit Charge HR and the Apple Watch, are consumer-grade products that are available off the shelf. It is important to validate the measurements of these devices and identify its accuracy in clinical settings. Clinical validation of the devices is important considering that the target is to deploy the devices in the circle of care and use it for patients with chronic conditions, such as heart failure.

The two objectives of this study are to:

1. Validate the accuracy of heart rate data measured by the Fitbit Charge HR and the Apple Watch

2. Examine the feasibility of using the Fitbit Charge HR and the Apple Watch heart rate and step data to remotely monitor heart failure patients
6 Methods

SPSS is a statistical program that is used to perform data analysis and a wide variety of statistics. In the two phases of the study, SPSS software was primarily used for analysis. Microsoft Excel was also used to create some of the figures and to organize datasets by averaging them in standardized time intervals.

6.1 Phase I: Clinical Validation of Two Wearable Heart Rate and Activity Trackers Against The Holter Monitor

An Apple Watch, a Fitbit Charge HR and the GE SEER light five-electrodes Holter monitor were used throughout this phase. Participants were asked to wear both, the Apple Watch and the Fitbit Charge HR on their non-dominant wrist and attach the Holter monitor electrodes to the chest in the appropriate orientation. Participants were asked to go on an ergometer exercise bike that was set with a 10-watt step protocol to examine the exercise capacity at different workload levels.

Figure 4: GE SEER Light Holter Monitor
The most critical point before the beginning of the session is the interface between the Holter monitor electrodes and skin. Removal of superficial layer of skin significantly lowers its resistance, thus decreasing the signal-to-noise ratio. The areas for electrodes application were first shaved and then rubbed with alcohol-saturated gauze. At the beginning of the session, participants went on the stationary bike and cycled with 0 watts resistance for one minute. The resistance of the bike was increased by 10 watts every minute, until it reached 100 watts in the 11th minute. The resistance was then decreased back to 10 watts so the participant can recover from exercise.

6.2 Phase II: Feasibility Study of Two Wearable Heart Rate and Activity Trackers for Monitoring Heart Failure Patients Remotely

Six kits were used throughout this phase. Each participant received a study kit containing an iPhone 6 and its charger, Fitbit Charge HR and its charger, an Apple Watch and its charger and a FedEx box with prepaid shipping label to return the materials. Participants were also given study instructions form for proper use of study materials (Appendix B). All phones were connected to a mobile data plan to ensure continuous data synchronization. The phones were locked with a passcode that was shared with the participants to ensure that nobody else uses the devices. The Fitbit Charge HR mobile application was installed on the iPhone and paired with the Fitbit Charge HR and the LubDub mobile applications were installed on the iPhone as well and paired with the Apple Watch. All kits were labelled with numbers to
ensure that the iPhones and the devices were not mixed up. Upon completion of the study, kits were returned back by the participant. Each kit was inspected, cleaned, recharged and re-used for another participant.

Figure 6: Fitbit Charge HR kit (left), Apple Watch kit (right)

Figure 7: iPhone 6 kit
7 Recruitment

7.1 Phase I: Clinical Validation of Two Wearable Heart Rate and Activity Trackers Against The Holter Monitor

Healthy individuals within the age range of 18 to 60 years old were recruited between February and March 2016. The study was conducted in the Heart Function clinic at Toronto General Hospital. Recruitment was conducted using ads that were distributed internally at Toronto General Hospital. The exercise room that has the stationary bike was booked during clinic hours, which is Monday through Wednesday of every week. The recruiter arranged with the clinic staff to use the room on Fridays only. Each session lasted for about 30 minutes, where the recruiter explained to the participant the study design and what to expect during the session. The recruiter had to go over the consent form (Appendix A) with participants and get a signed consent prior to the start of the session. Participants were compensated with $5 Starbucks gift cards.

7.2 Phase II: Feasibility Study of Two Wearable Heart Rate and Activity Trackers for Monitoring Heart Failure Patients Remotely

Heart failure patients were recruited between April and July 2016 from the Heart Function clinic at Toronto General Hospital. The daily recruitment rate ranged from 0 to 2 participants. The recruitment of this phase was challenging as the recruiter was not always available during clinic hours, or not all eligible participants were willing to participate in the study due to certain personal concerns. When patients arrived to the clinic for their CPS appointment, the recruiter first confirmed the eligibility of the patient by asking the clinician or exercise physiologist about the most recent assessment of the patient. It was important to also wait until the CPS session for that day was completed, to confirm that the functional classification of the patient did not change and confirm the eligibility. The recruiter would then approach the participant, introduce the study, go over the consent form (Appendix A), get a signed consent, go over study instructions (Appendix B), study interview form (Appendix C), activity log (Appendix D) and contact information (Appendix E). The recruiter then would demonstrate how to wear and use the study materials. Participants were compensated $50 for successful completion of the study and return of the study materials.
7.2.1 Eligibility Criteria for Participation in Phase II

Heart failure patients were recruited based on the following inclusion and exclusion criteria:

Inclusion Criteria:

- 18 years or older
- Stable NYHA Class II or III
- Left ventricular ejection fraction ≤ 35%
- Normal walking without walking aids
- Capable of understanding instructions in English
- Ability to wear, care for, charge and return the study materials

Exclusion Criteria:

- Congenital heart failure
- HF diagnosis less than 6 months prior to recruitment
- Traveling out of Canada for more than 1 week during the study period
8 Study Design

8.1 Phase I: Clinical Validation of Two Wearable Heart Rate and Activity Trackers Against The Holter Monitor

The purpose of this study is to examine the accuracy of two heart rate tracking wearable devices by conducting a clinical validation of the examined wearable devices. It is important to identify the accuracy of heart rate measurements for many purposes. Mainly, to ensure that consumers are purchasing and using reliable devices that provides accurate measurements. Also, it is useful to understand the possibility of using these technologies as clinically recognized products that can be used to remotely monitor patients with different health conditions.

Sessions were conducted at the heart function clinic at Toronto General Hospital. Each session lasted for about 15 minutes with the participant wearing both the Apple Watch and the Fitbit Charge HR on the non-dominant wrist as shown in Figure 5 and with the Holter monitor electrodes attached. The non-dominant wrist was selected as the testing site in order to minimize the artifact produced by the physical movements as much as possible and thus for better measurement accuracy. During the session, every participant was asked to exercise on a stationary bike, Lode Corival cycle ergometer with a 10-watt step protocol. Participants were asked to exercise in order to determine the performance of the wearable devices at a dynamic range of heart rate. At the first minute of the test, the workload was set to 0 watts, therefore, there was no resistance. The test protocol that was used increased the workload level by 10 watts every minute. The maximum workload level reached was 100 watts in the 11th minute. Afterwards, the workload level was decreased to 10 watts to allow the participant to recover from the exercise.
Figure 8: Holter Monitor Electrodes Placement

Figure 9: Holter Monitor Channels Configuration

Table 2: Study population and exercise data summary

<table>
<thead>
<tr>
<th>Color</th>
<th>Channel</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Red CH1 (+)</td>
</tr>
<tr>
<td>B</td>
<td>White CH1 (-)</td>
</tr>
<tr>
<td>C</td>
<td>Brown CH2 (+)</td>
</tr>
<tr>
<td>D</td>
<td>Black CH2 (-)</td>
</tr>
<tr>
<td>E</td>
<td>Green Ground</td>
</tr>
</tbody>
</table>
The Fitbit Charge HR records heart rate at different intervals depending on the selected mode. Heart rate is detected at every second when the Fitbit Charge HR is set to workout mode and at every 5 seconds at all other times using green light. The Apple Watch also records heart rate at different intervals depending on the selected mode, just like the Fitbit Charge HR. When the Apple Watch is set in workout mode, it detects heart rate every 5 seconds and it uses green light. When the Apple Watch is not set to workout mode, it uses infrared light and it detects heart rate in the background only when the user is still, therefore, the time between the measurements will vary.

For the purposes of this study, the Apple Watch was set to workout mode during the sessions to ensure that the heart rate is measured even if the wrist is not still, when the participant is exercising on the stationary bike. In addition, it was reported in previous studies that green light is more accurate for optical detection compared to infrared light, which is mainly due to the difference in absorptivity of oxyhaemoglobin and deoxyhaemoglobin. Therefore, when the Apple Watch is in workout mode, it will use the green light and thus, better measurement accuracy is acquired.

The Fitbit Charge HR was not set to workout mode for this phase; thus, it was recording heart rate every 5 seconds, similar to the Apple Watch setup. As a result, it was useful for the comparison of heart rate measurements between the Apple Watch and Fitbit Charge HR. In this phase, one Fitbit Charge HR, one Apple Watch and an iPhone 6 that is connected to the two devices were used for all participants. The recruiter recorded the session times in order to identify data from different participants. Upon completion of the study, the Fitbit Charge HR intraday data was downloaded to a Google sheet that was setup with a script that was customized based on open source software that uses Google’s library to connect to the Fitbit API and download data from the Fitbit account used in the study. An application was created on the Fitbit developer website, which provided secure keys to use for authorization.
Apple Watch data was stored in Health App in the iPhone connected to the Apple Watch. Health App dashboard provides summaries and averages for the day, week, month and the year of selected metrics, as shown in Figure 10. The intraday data cannot be exported from the Health App directly in an easy to use format. The Health App provides a list of intraday data that can be viewed, but cannot be exported. In order to export Apple Watch heart rate intraday data, a third-party application, Quantified Self Access (QS Access) was used. QS Access mobile application was downloaded into the iPhone and it was used to export intraday data from the Health App in a table as a .csv file, as shown in Figure 11.

Figure 10: Health App Dashboard
Figure 11: QS Access app
Table 3: Summary of Phase I Study Design

<table>
<thead>
<tr>
<th><strong>Timeline (February-March/2016)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
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<tr>
<td><strong>Duration/Location</strong></td>
</tr>
<tr>
<td><strong>Recruitment</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td><strong>Parameters</strong></td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
</tr>
</tbody>
</table>

8.2 Phase II: Feasibility Study of Two Wearable Heart Rate and Activity Trackers for Monitoring Heart Failure Patients Remotely

After completion of clinical validation phase, it was necessary to conduct a feasibility study to investigate the ability of deploying these wearables as clinical tools to provide clinicians with important information about the patient’s heart rate and activity level when out of the hospital. The goal of this feasibility study was to:

1) To collect heart rate and activity data from heart failure patients using two heart rate and activity trackers and relate heart rate and activity data together to evaluate heart failure condition.

2) To validate the feasibility of using this technology to remotely monitor heart failure progression. Two weeks of minute-by-minute heart rate and step data will be obtained and analyzed.

The study is open label, with one intervention group and no control group. Participants were asked to wear both, the Apple Watch and the Fitbit Charge HR heart rate and activity tracking wristbands for two weeks on their non-dominant wrist.
Participants were asked to keep the devices on the same wrist, without switching them from one wrist to another at different days to ensure consistency. The trackers passively collected heart rate and steps data and periodically synced with a mobile phone that the participants kept in their homes. Participants wore the heart rate and activity trackers throughout their day-to-day activities and removed it only briefly for charging. Participants were also asked to fill in a log describing any major physical activities during the study period.

In this phase, six kits were used for all participants (6 Fitbits, 6 Apple Watches and 6 iPhones). Kits were distributed when an eligible participant was available. Upon completion of the two-weeks study duration, kits are returned back to recruiter. The kits were then inspected, charged, cleaned and re-used for the next available participant.

The Fitbit Charge HR intraday data was downloaded to a Google sheet that was setup with a script that was customized based on open source software that uses Google’s library to connect to the Fitbit API and download data from the Fitbit account used in the study. An application was created on the Fitbit developer website, which provided secure keys to use for authorization. Each of the 6 Fitbit accounts was set up to give permission to access data by this application, which resided in the Google Script. The Fitbit data measured from each patient synced to the Fitbit account associated with the given tracker.

The Apple Watch intraday data was stored in HealthKit. It was possible to use QS Access app to export data, but that would be done when the devices are back, after the completion of the study, or by asking patients to export data and send it on daily basis, which is inconvenient. It was important to check that the patients were actually using the devices and data were getting transmitted. Therefore, a mobile app (LubDub) was developed to streamline heart rate and steps data measured by the Apple Watch from HealthKit and send it to a secure server, Fast Healthcare Interoperability Resources (FHIR), where the study coordinator had access to data measured by the devices throughout the study duration.

Participants were asked to sync data on daily basis by launching the LubDub and the Fitbit App once daily, at the end of the day. The LubDub automatically syncs data measured by the Apple Watch to the server everytime it is launched. The Fitbit App syncs data measured by the Fitbit Charge HR as well and store it in the corresponding Fitbit account.
Table 4: Summary of Phase II Study Design

<table>
<thead>
<tr>
<th>Table 4: Summary of Phase II Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Timeline (February-July/ 2016)</strong></td>
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<td><strong>Participants</strong></td>
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<td><strong>Duration/Location</strong></td>
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<td><strong>Recruitment</strong></td>
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<td><strong>Intervention</strong></td>
</tr>
<tr>
<td><strong>Parameters</strong></td>
</tr>
<tr>
<td><strong>Study Design</strong></td>
</tr>
</tbody>
</table>

8.2.1 LubDub Mobile App

On first launch, the user will get a prompt to give LubDub access to HealthKit in order to read heart Rate and steps data. Once access is allowed, the next screen will appear asking for a Patient ID. For the purposes of the trial, ID's 'PATIENTA' to 'PATIENTF' was used. When the main screen appears, LubDub will ask the FHIR server for the date and time of the last reading that was uploaded. This is performed for both Heart Rate and Steps data. LubDub will then query HealthKit for the all data from the current date to the date of the last reading uploaded to the FHIR server.

One reading at a time is uploaded for each data type. If the FHIR server responds with status code 201 (observation created), LubDub will continue to iterate through the data and continue uploading. Data is uploaded to the FHIR server as an observation, the structure of a FHIR observation is detailed in the FHIR section. If the server does not respond, or responds with an error status, LubDub will stop uploading data. The process described above is repeated every time the application is launched.
Figure 12: LubDub Login Screen
Figure 13: Home Screen
Figure 14: Heart rate and Steps detailed data in home screen
9 Results

9.1 Phase I: Clinical Validation of Two Wearable Heart Rate and Activity Trackers Against The Holter Monitor

Heart rate measurements from the Fitbit Charge HR and the Apple Watch were analyzed and compared to the heart rate measured by the Holter monitor. Before starting with data analysis, the differences in the sampling rate of the three devices were taken into consideration. The Holter monitor records heart rate at the milliseconds level, whereas the Apple watch and the Fitbit Charge HR records heart rate at the seconds level, therefore, it was necessary to average the heart rate data into a standardized time interval. Heart rate data of the Holter monitor were averaged and converted from milliseconds into 5 seconds-intervals. The Fitbit Charge HR and the Apple Watch heart rate data was already measured every 5 seconds; therefore, it was ready for analysis.

Heart rate measured from one of the participants during the exercise using the Fitbit Charge HR, the Apple Watch and the Holter monitor were plotted as shown in Figure 15. As expected, heart rate was increasing with increased workload level and decreasing when the resistance is decreased to 10 watts at the end of the session.

The Fitbit Charge HR and Apple Watch heart rate measurements from all participants were compared to the Holter monitor measurements at the different workload levels and a quantitative analysis was conducted to identify the accuracy of the devices at a dynamic range of heart rate zones.
To identify the performance of the devices with respect to one another, it was important to analyze the data based on individual workload levels to ensure the consistency of accuracy among all participants. With increased workload level, the participant puts on more effort to keep up with the increased resistance level and resulting in an increased heart rate.

All participants exercised at 11 workload levels (from 0-100 watts); therefore, the data was separated into 11 datasets based on the corresponding workload level for analysis. The average heart rate measured by each of the three devices was calculated at each workload level as shown in Table 5. For all participants, the average heart rate measured by the Fitbit Charge HR and the Apple Watch was increasing with an increased workload level and in a consistent manner that agreed with the Holter monitor data.

Figure 15: Heart rate data from one of the participants

Heart Rate (bpm)

Recovery

10-watts step protocol
Table 5: Average Heart Rate data measured by Fitbit Charge HR, Apple Watch and Holter Monitor

<table>
<thead>
<tr>
<th>Workload (watts)</th>
<th>Average Heart Rate (bpm)</th>
<th>Holter</th>
<th>Fitbit Charge HR</th>
<th>Apple Watch</th>
</tr>
</thead>
<tbody>
<tr>
<td>0, low</td>
<td>88</td>
<td>83</td>
<td>85</td>
<td></td>
</tr>
<tr>
<td>10, low</td>
<td>90</td>
<td>84</td>
<td>86</td>
<td></td>
</tr>
<tr>
<td>20, low</td>
<td>93</td>
<td>88</td>
<td>87</td>
<td></td>
</tr>
<tr>
<td>30, low</td>
<td>98</td>
<td>91</td>
<td>91</td>
<td></td>
</tr>
<tr>
<td>40, medium</td>
<td>101</td>
<td>92</td>
<td>95</td>
<td></td>
</tr>
<tr>
<td>50, medium</td>
<td>106</td>
<td>98</td>
<td>104</td>
<td></td>
</tr>
<tr>
<td>60, medium</td>
<td>110</td>
<td>106</td>
<td>111</td>
<td></td>
</tr>
<tr>
<td>70, high</td>
<td>116</td>
<td>114</td>
<td>117</td>
<td></td>
</tr>
<tr>
<td>80, high</td>
<td>122</td>
<td>122</td>
<td>123</td>
<td></td>
</tr>
<tr>
<td>90, high</td>
<td>128</td>
<td>128</td>
<td>130</td>
<td></td>
</tr>
<tr>
<td>100, high</td>
<td>136</td>
<td>136</td>
<td>136</td>
<td></td>
</tr>
</tbody>
</table>

As seen in Figure 16, the Apple Watch performed better than the Fitbit Charge HR in detecting heart rate. The Apple Watch heart rate measurements were closer to the Holter monitor measurements throughout all workload levels and for all participants. In addition, the Apple Watch heart rate measurements from all participants had a strong positive correlation to the measurements of the Holter monitor at 60 watts and until the end of exercise. The Fitbit Charge HR heart rate measurements from all participants had a strong positive correlation to the measurements of the Holter monitor at 80 watts and until the end of exercise. The Apple Watch was capable of measuring heart rate values that are as accurate as the Holter monitor measurements at medium and high workload levels (60-100 watts), whereas the Fitbit Charge HR measured heart rate as accurate as the Holter monitor at high workload levels (80-100 watts). Therefore, the measurement accuracy of the Fitbit Charge HR and the Apple Watch is improving at high workload levels, hence, at high heart rate zones and the Apple Watch heart rate measurement accuracy is better at a wider range of heart rate zones when compared to the Fitbit Charge HR.
The performance of the Fitbit Charge HR and the Apple Watch were compared at two workload levels, medium level (50 watts) and high level (100 watts). As shown in Figure 17, at 50 watts workload level, the Fitbit Charge HR and the Apple Watch are both underestimating heart rate when compared to Holter monitor. In Figure 18, the Fitbit Charge HR and the Apple Watch are giving accurate heart rate measurements at 100 watts workload level. Therefore, better heart rate measurement accuracy is achieved at high heart rate zones, or during exercise.
Figure 17: Average Heart Rate at 50 watts workload level

Figure 18: Average Heart Rate at 100 watts workload level
To assess the agreement of heart rate measurements between the Fitbit Charge HR and Holter monitor, the Apple Watch and the Holter monitor, it is important to identify the correlation and regression. Correlation analyzes the relationship between two methods of measurement and demonstrates how the two variables are changing in respect to one another. Regression analyzes the differences in the means of two variables and determine how close are the means of the two variables to one another. The percentage of mean difference can be calculated by taking the percentage of the difference between the means over the average of them.

Based on Figure 16, it is expected that the percentage of mean difference decreases as the workload level increases. In Table 6, the percentage of mean difference was calculated for the Fitbit Charge HR and the Holter monitor, and for the Apple Watch and the Holter monitor, at all workload levels. The results agree with what was mentioned above, the percentage of mean difference is decreasing with an increased workload level, therefore, the Fitbit Charge HR and the Apple Watch are performing as good as the Holter monitor at high workload levels and hence, high heart rate zones.

Table 6: % Mean Difference of heart rate data measured by Fitbit Charge HR, Apple Watch and Holter Monitor

<table>
<thead>
<tr>
<th>Workload (watts)</th>
<th>% Mean Difference</th>
<th>Holter and Fitbit Charge HR</th>
<th>Holter and Apple Watch</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>6.00</td>
<td>3.32</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>6.93</td>
<td>4.56</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>5.41</td>
<td>6.12</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>8.34</td>
<td>7.51</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>8.68</td>
<td>5.49</td>
<td></td>
</tr>
<tr>
<td>50</td>
<td>8.10</td>
<td>2.27</td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>3.69</td>
<td>-0.45</td>
<td></td>
</tr>
<tr>
<td>70</td>
<td>1.63</td>
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<td></td>
</tr>
<tr>
<td>80</td>
<td>-0.20</td>
<td>-0.72</td>
<td></td>
</tr>
<tr>
<td>90</td>
<td>-0.10</td>
<td>-1.64</td>
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</tr>
<tr>
<td>100</td>
<td>0.46</td>
<td>0.37</td>
<td></td>
</tr>
</tbody>
</table>
As shown in Figure 19, the percentage of mean difference between the Fitbit Charge HR and the Holter monitor was within 10% interval, which means that the measurements of the Fitbit Charge HR was within the 90% confidence interval and agreement with the Holter monitor measurements. The percentage of mean difference was approximately zero at 80, 90 and 100 watts, which means that there was no difference between the mean heart rate measured by the Fitbit Charge HR and the Holter monitor at these workload levels.

Figure 19: % Mean Difference for Holter and Fitbit Charge HR Heart Rate Data
In Figure 20, the percentage of mean difference between the Apple Watch and the Holter monitor was within 10% interval, which means that the measurements of the Apple Watch was within the 90% confidence interval and agreement with the Holter monitor measurements. The percentage of mean difference was approximately zero at 60, 70, 80, 90 and 100 watts, which means that there was no difference between the mean heart rate measured by the Apple Watch and the Holter monitor at these workload levels.

Figure 20: % Mean Difference for Holter and Apple Watch Heart Rate Data
Evaluating the accuracy of the Fitbit Charge HR and the Apple Watch cannot be made by only looking at mean differences, simply because a small difference in the mean doesn’t necessarily mean that the Fitbit Charge HR and the Apple Watch are measuring heart rate in the same manner as the Holter monitor. The mean difference doesn’t provide information about how the behaviour seen in one method of measurement is changing with respect to another method of measurement. Therefore, it was important to analyze correlations between measurements as well.

As shown in Table 7, pearson correlation coefficients were calculated based on workload level between the Fitbit Charge HR and the Holter monitor and the Apple Watch and the Holter monitor. Pearson Correlation Coefficient is a measure of the strength of linear relationship between two variables and it can range from -1 to +1. A value of -1 corresponds to perfect negative linear relationship, which means as one variable is increasing, the other variable is decreasing by the exact same amount. A value of +1 corresponds to a perfect positive linear relationship and 0 indicates that there is no linear relationship.

All pearson correlation coefficient values seen in Table 7 are positive, which means there is a linear relationship between the values of the Holter monitor and the Fitbit Charge HR, and the Holter monitor and the Apple Watch. Also, pearson correlation coefficients are improving at high workload levels (approaching 0.9). At 60 watts, the pearson correlation coefficients are ~0.95 for both, Fitbit Charge HR and Holter monitor, as well as the Apple Watch and the Holter monitor, which means that there is a strong agreement between the two methods of measurement.
Table 7: Pearson Correlation Coefficient of heart rate measurements of the Fitbit Charge HR and Holter Monitor, and the Apple Watch and the Holter Monitor

<table>
<thead>
<tr>
<th>Workload (watts)</th>
<th>Pearson Correlation Coefficient</th>
<th>Heart Rate (bpm) measured by Holter Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Holter &amp; Fitbit Charge HR</td>
<td>Holter &amp; Apple Watch</td>
</tr>
<tr>
<td></td>
<td>Minimum</td>
<td>Average</td>
</tr>
<tr>
<td>0</td>
<td>0.406</td>
<td>0.567</td>
</tr>
<tr>
<td>10</td>
<td>0.593</td>
<td>0.305</td>
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<td>0.597</td>
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<tr>
<td>30</td>
<td>0.973</td>
<td>0.61</td>
</tr>
<tr>
<td>40</td>
<td>0.93</td>
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<tr>
<td>50</td>
<td>0.88</td>
<td>0.811</td>
</tr>
<tr>
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<td>0.993</td>
</tr>
<tr>
<td>100</td>
<td>0.992</td>
<td>0.994</td>
</tr>
</tbody>
</table>
9.2 Phase II: Feasibility Study of Two Wearable Heart Rate and Activity Trackers for Monitoring Heart Failure Patients Remotely

One of the major challenges in this phase is the difference in the frequency of heart rate detection between the Fitbit Charge HR and the Apple Watch. The Fitbit Charge HR and the Apple Watch are different not only in design, but also in the logic used for heart rate detection. The Fitbit Charge HR detects heart rate every 5 seconds, therefore, there are 720 heart rate measurements taken per hour. The Apple Watch records heart rate every 5 seconds when the Apple Watch is in workout mode, however, when it is not in workout mode, it doesn’t have a specific time interval that defines when the heart rate will be measured. The Apple Watch detects heart rate when the user is still only, therefore, there are definitely less heart rate measurements for users who are more physically active compared to others with lower physical activity. In this study, the workout mode in the Apple Watch was not used because it consumes a lot of energy and it drains battery very quickly, therefore, the user will need to charge the Apple Watch every 3-4 hours, which is not convenient when conducting a 2-week study.

Heart rate and steps data from the Fitbit Charge HR and the Apple Watch was exported and plotted to examine in details the time intervals where heart rate and steps data were both present. For this phase, it was important to understand the changes in heart rate measurements with respect to physical activity. High heart rate is expected when the patient is jogging or running, but not when the patient is at rest. Therefore, steps data was the reference used to identify whether the patient is at rest or active. Simple movements maybe considered as steps by the Fitbit Charge HR or the Apple Watch, depending on how the movements are interpreted by the devices. Therefore, any steps value that is below or equal to 5 was replaced with 0 and any other steps value that is more than 5 was counted as an actual movement and the patient is considered active. It was important to identify not only between being physically active or at rest, but also between the possible errors that might affect and bias the analysis. For example, when the patient is sitting and swinging his arm or reaching for the phone on the table, this swinging might be sensed as a step by the devices. Therefore, with the 5-steps threshold, we eliminated as much as we can from possible errors.
In general, the Apple Watch records heart rate in the background when the user is still, or when it is prompted to take a measurement. In this study, patients were asked to wear the Apple Watch and Fitbit Charge HR and not interact with the devices in anyway other than charging and syncing. Therefore, heart rate measurement was absolutely left to the logic used in the Apple Watch to detect heart rate when at rest.

Heart rate and steps data measured by the Apple Watch from one of the participants over five days were shown in Figure 21. It can be noticed that the heart rate was not recorded when the patient was moving (steps were taken) and many critical heart rate data were not recorded. The Apple Watch provided heart rate measurements approximately 40-50 times per day, when the patient was not active and with significant time gap. The goal of the feasibility study is to evaluate heart rate and steps data together; therefore, it was challenging to do an analysis on Apple Watch data.

Figure 21: Apple Watch Heart Rate and Steps Data measured over 5 days from one of the participants
In Figure 22, heart rate and steps data measured by the Fitbit Charge HR were both available. Whether the patient is moving or not, heart rate was still measured every 5 seconds. The Fitbit Charge HR provided 720 heart rate measurements and 60 steps data measurements per hour.

Figure 22: Fitbit Charge HR Heart Rate and Steps Data measured over a day from one of the participant

Ten heart failure patients participated in the feasibility study. Eight patients were included in the analysis and two patients were excluded because they did not wear the devices during the study period. A summary of the study population is provided in Table 8.
### Table 8: Phase II Study Population

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Gender</th>
<th>Age</th>
<th>NYHA Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>Male</td>
<td>67</td>
<td>NYHA III</td>
</tr>
<tr>
<td>P2</td>
<td>Male</td>
<td>68</td>
<td>NYHA II</td>
</tr>
<tr>
<td>P3</td>
<td>Male</td>
<td>63</td>
<td>NYHA III</td>
</tr>
<tr>
<td>P4</td>
<td>Female</td>
<td>61</td>
<td>NYHA II</td>
</tr>
<tr>
<td>P5</td>
<td>Male</td>
<td>52</td>
<td>NYHA II</td>
</tr>
<tr>
<td>P6</td>
<td>Female</td>
<td>57</td>
<td>NYHA III</td>
</tr>
<tr>
<td>P7</td>
<td>Female</td>
<td>58</td>
<td>NYHA II</td>
</tr>
<tr>
<td>P8</td>
<td>Male</td>
<td>35</td>
<td>NYHA III</td>
</tr>
</tbody>
</table>

| Total      | 5 Males | Average Age: 58 years | 4 NYHA II | 4 NYHA III |

The major goal was to analyze heart rate and steps data measured by the Fitbit Charge HR and the Apple Watch during the 2-weeks study duration and to identify similarities, differences and potential for deploying them as tools for remote monitoring of heart failure patients. Challenges were imposed in analyzing heart rate and steps data measured by the Apple Watch due to the fact that heart rate is not measured when the patient is active and is available only when the patient is still.

One alternative was to compare the Fitbit Charge HR and the Apple Watch in terms of steps data and heart rate at rest. Steps data measured by the Fitbit Charge HR and the Apple Watch were compared for each functional class separately. In this phase, there was no reference that can be used to identify which of the two devices were counting steps accurately. The total step count measured by the Fitbit Charge HR and the Apple Watch over the two-weeks duration for NYHA II patients is shown in Figure 23 and the total step count measured by the Fitbit Charge HR and the Apple Watch over the two-weeks duration for NYHA III patients is shown in Figure 24. NYHA II patients reported higher total step count than NYHA III patients, as NYHA III patients are less physically active. Generally, the total step...
count for NYHA III patients was less than 75000 steps over two weeks as measured by both, the Fitbit Charge HR and the Apple Watch. Whereas the total step count for NYHA II patients was much higher than 75000 steps. The total step count measured by the Fitbit Charge HR and the Apple Watch is shown in Table 9.

**Table 9: Total Step Count for NYHA II and NYHA III patients measured by the Fitbit Charge HR and the Apple Watch**

<table>
<thead>
<tr>
<th>NYHA II</th>
<th>NYHA III</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Fitbit Charge HR</td>
<td>Apple Watch</td>
</tr>
<tr>
<td>133534</td>
<td>114593</td>
</tr>
<tr>
<td>149539</td>
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<tr>
<td>119444</td>
<td>109119</td>
</tr>
<tr>
<td>54455</td>
<td>44627</td>
</tr>
</tbody>
</table>

**Figure 23:** Fitbit Charge HR and Apple Watch Total Step Count for NYHA II patients
Figure 24: Fitbit Charge HR and Apple Watch Total Step Count for NYHA III patients
In Figure 25, the total step count was compared amongst the two functional classes and the two devices, the Fitbit Charge HR and the Apple Watch. The total step count measured by the Fitbit Charge HR for NYHA II patients were 125,000 steps compared to NYHA III patients with 50,000 steps in two weeks. In addition, the total step count measured by the Apple Watch for NYHA II patients were 100,000 steps compared to NYHA III patients with 45,000 steps in two weeks. Despite the differences in total step count reported by the Fitbit Charge HR and the Apple Watch for the same NYHA class, the Fitbit Charge HR and the Apple Watch were still able to differentiate between NYHA II and NYHA III based on total step count.

Figure 25: Fitbit Charge HR and Apple Watch Total Step Count for NYHA II and NYHA III patients
After looking into total step count, the daily step count was also analyzed for the two functional classes. Based on literature review, higher NYHA classification is associated with less daily physical activity. Tudor-Locke and Basset proposed guidelines for healthy adults that less than 5000 steps/day could be considered as a ‘sedentary lifestyle’, from 5000 to 10000 steps/day as a ‘low-somewhat physically active lifestyle’ and more than 10000 steps/day as a ‘physically active lifestyle’. Although these guidelines apply for healthy adults, it can still be used as a reference for heart failure patients. Average daily step count measured by the Fitbit Charge HR and the Apple Watch is shown in Table 10.

<table>
<thead>
<tr>
<th></th>
<th>NYHA II</th>
<th></th>
<th>NYHA III</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Fitbit Charge HR</td>
<td>8902</td>
<td>Apple Watch</td>
<td>6640</td>
<td>Fitbit Charge HR</td>
</tr>
<tr>
<td></td>
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<td>9726</td>
<td>5417</td>
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<td></td>
<td>6051</td>
<td>4736</td>
<td>5901</td>
<td></td>
</tr>
</tbody>
</table>

As shown in Figure 26, the Fitbit Charge HR average daily step count clearly determined a difference between the two functional classes. The Fitbit Charge HR indicated that the majority of NYHA II patients made 5000-10000 steps daily, which means they have somewhat active lifestyle. Whereas the majority of NYHA III patients made less than 5000 steps daily, which means they have sedentary lifestyle.
Figure 26: Average Daily Step Count measured by the Fitbit Charge HR for NYHA II and NYHA III patients
As shown in Figure 27, the Apple Watch data also differentiated the two functional classes based on their average daily step count. The Apple Watch indicated that all NYHA II patients made 5000-10000 steps daily, which means they have somewhat physical active lifestyle. Whereas all NYHA III patients made less than 5000 steps daily, which means they have a sedentary lifestyle.

Figure 27: Average Daily Step Count measured by the Apple Watch for NYHA II and NYHA III patients
In Figure 28, the average daily step count was compared amongst the two functional classes and the two devices, the Fitbit Charge HR and the Apple Watch. The Fitbit Charge HR and the Apple Watch differentiated between NYHA II and NYHA III patients properly. Also, the agreement between the Fitbit Charge HR and the Apple Watch for NYHA III patients is better than the agreement between them in NYHA II patients.

Figure 28: Fitbit Charge HR and Apple Watch Average Daily Step Count for NYHA II and NYHA III patients
Heart rate measurements taken at rest were compared between the Fitbit Charge HR and the Apple Watch; therefore, any heart rate value measured when steps value ≤ 5 was included in the analysis and the rest was excluded. In Figure 29, resting heart rate measured by the Fitbit Charge HR for NYHA II and NYHA III patients were compared. NYHA III patients have slightly higher resting heart rate than NYHA II patients. The mean resting heart rate for NYHA II patients was 67 bpm, whereas for NYHA III patients was 74 bpm, which indicates that resting heart rate can be used to predict prognosis.

Figure 29: Fitbit Charge HR Resting Heart Rate for NYHA II and NYHA III patients
In Figure 30, resting heart rate measured by the Apple Watch for NYHA II and NYHA III patients were compared. NYHA III patients also have slightly higher resting heart rate than NYHA II patients. The mean resting heart rate for NYHA II patients was 72 bpm, whereas for NYHA III patients was 76 bpm.

The resting heart rate measured by the Fitbit Charge HR and the Apple Watch were then compared within the same functional class. In Figure 31 and Figure 32, the differences between the Fitbit Charge HR and Apple Watch resting heart rate for NYHA II patients and for NYHA III are clearly shown. The Apple Watch was measuring higher resting heart rate than the Fitbit Charge HR.
Figure 31: Resting heart rate measured by the Fitbit Charge HR and the Apple Watch for NYHA II patients
Figure 32: Resting heart rate measured by the Fitbit Charge HR and the Apple Watch for NYHA III patients
10 Discussion

10.1 Phase I: Clinical Validation of Two Wearable Heart Rate and Activity Trackers Against The Holter Monitor

Heart rate is elevated during exercise to meet the increased demands of the body for blood and oxygen. How much the heart rate increases depends on the intensity of the exercise and how fit the participant is. If the intensity of the exercise remains constant, then the heart rate will increase until it reaches steady state, where it stays relatively constant as the cardiovascular system meets the demand placed on it by the exercise. If the intensity of the exercise fluctuates, then the heart rate will also fluctuate. In this phase, the workload was dynamic and increasing by 10 watts every minute, as a result, the heart rate was fluctuating according to the corresponding workload intensity.

As shown in Figure 16, the average heart rate measured by the Fitbit Charge HR and the Apple Watch was different from the average heart rate measured by the Holter monitor at low workload levels. The two PPG-based wearables use moving average as a method for optimizing measurements by reducing motion artifacts. The periodic moving average filter segments the PPG signal into periods and resamples each period so that the motion artifacts are removed without degrading the signal. Therefore, the effect of the moving average was more apparent later during the exercise, hence, at higher workload levels. In addition, averaging the measurements might have pulled the data in the direction of the outlying values, making it sensitive to extreme observations and leading to data being skewed.

One of the critical factors to consider in this phase is the time interval between the different workload intensities. In general, protocols for clinical exercise testing include an initial warm-up, progressive uninterrupted exercise with increasing loads and an adequate time interval in each level. The time interval in each level should be 2-3 minutes and the more time is given in each new workload level, the better the body can adjust to its changing demands. In this phase, there was no initial warm-up and there was 1-minute gap between consecutive workload intensities. The low correlation between heart rate measurements of the Fitbit Charge HR and the Apple Watch with the Holter monitor in the beginning of the exercise (0-20 watts) might have been a result of the missed warm-up. When the participant
started to exercise directly without warm-up, the heart rate fluctuations were more significant and as a result, the accuracy of the PPG-based heart rate trackers were not as accurate as the ECG-based Holter monitor. In future studies, it is recommended to follow the protocols of clinical exercise to eliminate possible errors that might result in case of noncompliance with the guidelines.

Another factor that might have affected the overall analysis is the time interval that was selected between workload intensities. In general, as workload intensity increases, the time necessary for the heart rate to stabilize will progressively lengthen. Therefore, the 1-minute gap between workload intensities might be inadequate to get the body adjusted appropriately. In future studies, it is recommended that the time gap between one workload intensity and another increase to 2 or 3 minutes to allow the body and heart to adapt to the new intensity. Another option is also to consider the latter half of the time interval in the analysis. For example, if the time interval between 40 and 50 watts is 2 minutes, then the first minute is considered to be a transition period between 40 and 50 watts and only the latter 1-minute heart rate data is used in the analysis for heart rate at 50 watts.

Heart rate at recovery stage (last minute in the exercise, when the workload intensity is dropped from 100 watts to 10 watts) was not used in the analysis of the results. In recovery, it takes about 30 minutes for heart rate and stroke volume to return to normal resting levels. As per the study design, the sessions last up to 30 minutes in total (including introductions, signing forms, preparations and exercising). Therefore, the time was not enough to wait for another 30 minutes for recovery. As a result, the recovery heart rate data was excluded from the analysis.

When comparing the heart rate data from the Fitbit Charge HR and the Apple Watch to the heart rate measured by the Holter monitor, differences between the measurements were expected. This is primarily because the Holter monitor is an ECG-based heart rate detection device, whereas the Fitbit Charge HR and the Apple Watch are both PPG-based heart rate detection devices. The Holter monitor measures the heart activity by tracing the ECG and electrical signals that control the expansion and contraction of the heart chambers. Based on recorded ECG, the heart rate is identified. The Fitbit Charge HR and the Apple Watch uses
light technology for heart rate detection from the surface of the skin when worn on the wrist. In addition to the core difference in the method of measurement, the positioning of the devices also plays a role in the accuracy of the measurements. The Holter monitor electrodes are attached properly to the chest, however, it is possible that during exercise the electrodes fall off or get displaced from their position due to arms and legs movements.

The Fitbit Charge HR and the Apple Watch positioning on the wrist might have also affected the accuracy of its measurements. The Fitbit Charge HR and the Apple Watch are both worn on the non-dominant wrist, with the Fitbit Charge HR worn closer to the wrist bone and the Apple Watch further from the wrist bone. This orientation was selected primarily because of the size and shape of the devices that make it easier to have the Apple Watch worn up, as it has a relatively bigger size than the Fitbit Charge HR and therefore, it would fit properly. As PPG-based heart rate detection trackers, the measurements of the Fitbit Charge HR and the Apple Watch can be easily affected by physical motion artifact that is produced from body movements during exercise. In addition, any geometrical deformation in the measurement site might result in an interruption in the quality and performance of the devices. During exercise, participants were asked to keep their hands still on the handles of the stationary bike to reduce as much as possible from possible motion artifacts.

In addition to the differences in heart rate detection method between the Fitbit Charge HR and the Apple Watch compared to the Holter monitor, there are also differences between the Fitbit Charge HR and Apple Watch. Although they both detect heart rate based on PPG principle, they have different design, logic and algorithm for measuring heart rate. The Fitbit Charge HR has one optical sensor, whereas the Apple Watch has two optical sensors. It doesn’t necessarily mean that the measurement accuracy will improve with more optical sensors. At 20 watts, the Fitbit Charge HR had a 0.95 correlation coefficient, whereas the Apple Watch had a 0.6.

The Apple Watch was running in workout mode to allow heart rate detection every 5 seconds, whereas the Fitbit Charge HR detects heart rate every 5 seconds at all times by default. With two different devices set in different modes, differences in the logic used when measuring heart rate are expected. The workout mode used in the Apple Watch might have
made it more sensitive to fluctuations sensed in blood flow and thus more accurate in its heart rate measurement as seen in the results. The sensitivity of the Apple Watch in workout mode might have improved mainly because it is set to detect heart rate during exercise; therefore, it will be less sensitive to physical movements and hence, less prone to errors. In future studies, it is recommended to set the Fitbit Charge HR and the Apple Watch in the same mode to eliminate differences in algorithm and signal processing techniques.

10.2 Phase II: Feasibility Study of Two Wearable Heart Rate and Activity Trackers for Monitoring Heart Failure Patients Remotely

Higher-than-normal heartbeat means there is an increased demand for oxygen by the heart muscle. Tachycardia refers to an abnormally fast resting heart rate and it is a sign for heart failure. Therefore, it is very important to determine if elevated heart rate is occurring during rest or during physical activity. The threshold of a normal heart rate is generally based on the age and some other factors. Generally, the adult resting heart rate is between 60 and 100 bpm. Some doctors place the healthy limit at 90 bpm and consider any heart rate measured at rest and above 90 bpm to be abnormal.

It is important to understand how the heart rate changes in relation to the physical activity. During physical exertion, the heart normally pumps faster than average to meet the increased oxygen demands and therefore it is normal to have high heart rate during exercise. However, it is abnormal to have high heart rate at rest. In this phase, the Fitbit Charge HR and Apple Watch was given to heart failure patients to determine changes in heart rate with respect to physical activity for two functional classes.

The major challenge was to analyze heart rate and steps data measured from the same patient and identify similarities and differences. The two devices, the Fitbit Charge HR and the Apple Watch are from two completely different manufacturers that are running on different hardware and software, therefore, it is expected that they both have different algorithms for estimating steps from accelerometer data and different logic for interpreting heart rate from the optical sensors. The devices are subject to endless array of software and firmware updates, in which the manufacturers are constantly tweaking and modifying measurements and data collection approaches.
The Fitbit Charge HR provided 720 heart rate measurements and 60 steps measurement per hour. On the other hand, the Apple Watch provided heart rate measurements when the user is still, which is completely dependent on how active the patient is, and provided steps data at an undefined range too. Therefore, there were no heart rate measurements available during physical activity in Apple Watch data; as a result, only resting heart rate measured by the Apple Watch was compared to resting heart rate measured by the Fitbit Charge HR.

The sensitivity of the accelerometers and the logic used to determine movements is different in the two devices. It was noted that in certain patients, the Apple Watch was recording less steps than the Fitbit Charge HR whereas in other patients, the Fitbit Charge HR was recording less steps than the Apple Watch. These differences in step count for the same patient prove that the two devices have different algorithm for steps detection that is set with specific criteria and threshold to interpret movements and count steps. Step count can be highly affected by simple body movements that are made without taking a step. For example, when the patient is turning, or interacting with an object while still stationary, the devices might consider this as a step. The devices can confuse activities like washing the dishes, or lifting weights as steps because they are generally measuring the swing of the arm. Taking into consideration the existing differences between the Fitbit Charge HR and Apple Watch, then what is considered as a step by the Fitbit Charge HR might not be counted as a step by the Apple Watch and vice versa. As a result, there was variability in step count measurements between the Fitbit Charge HR and the Apple Watch.

Another factor that might have contributed to the differences seen in step count data of the Fitbit Charge HR and the Apple Watch is the positioning of the devices. The two devices were worn for two weeks in the non-dominant wrist. Patients were asked to keep the devices worn on the same wrist (non-dominant wrist) and not to switch them to other wrist. The patients were also asked to wear the devices in the same orientation to eliminate errors that might arise from inconsistency. Patients had to wear the Fitbit Charge HR and the Apple Watch and take them off on daily basis for charging and syncing. Therefore, the positioning of the trackers might have been slightly shifted from one day to another, which might have affected steps data. There were two sizes of the wristbands for both, the Fitbit Charge HR and the Apple Watch that was distributed according to the size of the patients’ wrists. The
patients were shown how to appropriately wear the devices without having them very tight, or very loose. The patients were responsible for wearing the devices properly and in case of any noncompliance with the previous instructions; the step count measurement of the Fitbit Charge HR and the Apple Watch will be affected.

During data analysis, it was challenging to distinguish between zero steps and not wearing the devices. Heart rate values at zero steps doesn’t always give an indication to whether or not the devices are worn, because in some cases the devices were reporting odd (very low) heart rate values (very early in the day, very late at night) and this might be due to the fact that the devices don’t turn off and they keep on running. One of the possible improvements in future studies is to use devices that can distinguish whether they are being worn or not. This can be done simply by using an accelerometer sensor that can differentiate whether the device is completely stationary and is placed on a stationary surface, or the device is worn but the user is still.

The Fitbit Charge HR and Apple Watch were given to the patients without calibrating the devices individually for each patient. The Apple Watch calibration technique requires a 2-minute outdoor walk with the iPhone, so that the steps on the Apple Watch are calibrated using the iPhone’s GPS and an individual benchmark is established as for how many of the patient’s steps are in an average mile. It is important to disable the step counter on the iPhone so it doesn’t interact with the step counter measured by the Apple Watch.

Once calibrated, the Apple Watch can then make an educated guess of steps taken and distance travelled based on individual patient information. The Fitbit Charge HR can also be calibrated by setting a custom stride length. In this study the Fitbit Charge HR and the Apple Watch were not calibrated due to time limitation, however, it is recommended to calibrate the devices if used in future studies to improve the accuracy of steps data.

The differences seen in the step count (daily step count and total step count) between the Fitbit Charge HR and the Apple Watch can be better understood if there was a way to measure the steps taken with a third device as a reference. However, such an option was not available and as a result, a judgement cannot be made on whether they are accurately counting steps, or whether any of the two devices is underestimating or overestimating steps.
Similarly, the heart rate measurements of the Fitbit Charge HR and the Apple Watch could have been verified with a reference device such as a loop recorder. The goal of this phase was about evaluating the feasibility of using the Fitbit Charge HR and Apple Watch to remotely monitor clinical indicators such as physical activity rather than focusing on how many steps each of the two devices measured.

The Fitbit Charge HR and Apple Watch showed a good agreement between daily step measurements, as well as total step count for NYHA III patients. For NYHA II patients, the Apple Watch was reporting lower daily steps and total step count than the Fitbit Charge HR. One possibility might be due to the higher physical activity limitation for NYHA III patients and the sedentary lifestyle, therefore, there is less confusion between being active and at rest. NYHA II patients are generally more active; therefore, differences in step detection between the Fitbit Charge HR and the Apple Watch became more visible.

The Fitbit Charge HR and Apple Watch differentiated between NYHA II and NYHA III patients based on daily step count, as well as total step count. NYHA III patients had lower daily step count and total step count compared to NYHA II patients. Being able to identify functional classes using a consumer-grade wearable tracker has a huge advantage in supporting the clinicians in making a variety of decisions that is critical for improving patient outcomes.

As mentioned previously, the Fitbit Charge HR and the Apple Watch have different methods for detecting heart rate; therefore, it is expected to see differences in heart rate measurements between the two devices. The Fitbit Charge HR and the Apple Watch showed an agreement in their resting heart rate for NYHA II and for NYHA III patients. Both devices reported higher resting heart rate in NYHA III patients. When comparing the resting heart rate amongst the same functional class, the Apple Watch was measuring slightly higher resting heart rate than the Fitbit Charge HR in both, NYHA II and NYHA III patients. Based on literature review, higher heart rate at discharge time was associated with higher NYHA classification and an increased risk of readmission. Therefore, higher resting heart rate measured in this study for NYHA III patients might be an indication that they are at high risk of getting readmitted and an intervention is required.
11 Limitations

This study had a small number of participants, with somewhat skewed distributions of traits such as NYHA, age, and sex. Therefore, analyzing the results from all participants as a one group might have affected the quality of the results. Exercise habits and lifestyle varies significantly with age and might be also different among the same age group. In addition, events during the two-weeks study duration might have caused some participants to exercise more or less than they would normally and as a result might have affected the data.

The study provided a general understanding of the usability of the consumer heart rate and physical activity tracking wearables for monitoring HR from the clinician’s end, however, the study did not include a post-study questionnaire. A follow-up questionnaire or interviewing the participants could have been used after the study ended to evaluate key aspects of the usability of the devices from the patients’ perspective. This evaluation would have helped in identifying whether tasks like daily charging, wearing and using the devices were disruptive to the patients’ lifestyle. It is recommended that this evaluation be done in future work to provide evidence that these devices are reliable for both, the clinician and the patient at the same time.

This study had only 10 heart failure patients. Eight of them were included in the analysis and two of them were excluded because they did not wear the devices for enough time. In future studies, it is recommended to recruit more heart failure patients, as a larger sample size is more representative of the population, limiting the influence of outliers or extreme observations.

In the first phase of this study, the heart rate was averaged for all participants to provide a better understanding of the overall performance of the devices generally for any user. Averaging the data might have affected the quality of the results as heart rate data could be skewed towards extreme observations measured for one individual participant. In addition, averaging measurements for the same participant was also necessary to standardize the comparison, taking in consideration the different frequency of heart rate detection among the three devices. Therefore, this might have also impacted the overall quality of the results.
The algorithms used to estimate steps and heart rate in the wearable devices are proprietary and not shared anywhere. The Fitbit Charge HR and the Apple Watch count steps based on repetitive movements of a specific magnitude and threshold, but the sensitivities of the two devices vary and special algorithms maybe used in certain modes. Therefore, the ideal scenario is to have the devices set in the same mode when comparing the two methods of measurements.

In addition, some of the participants were excluded from the study, as they didn’t wear the devices for enough time. Personality and lifestyle are two important factors to consider when it comes to remembering to wear the devices, so a very busy person maybe more likely to forget to wear the devices compared to other participants.
12 Conclusion

Heart failure is characterized by frequent readmissions within 30 days and 6 months of discharge. The goal of this study was to improve quality of life of heart failure patients and reduce rehospitalizations by detecting early warning signs of decompensation. Previous studies found that patients with higher discharge heart rate and lower daily physical activity had a higher NYHA classification and more severe heart failure condition. Decompensation in heart failure condition can occur at anytime in ambulatory settings and the clinicians will not have any information about the time, frequency and duration of the deterioration. Upon readmission to the hospital, clinicians depend on self-reported information provided by the patient, which is very subjective. Clinicians need reliable records of continuously monitored critical clinical indicators that are available in ambulatory settings. Ideally, clinicians would have access to critical clinical indicators after patients are discharged from the hospital, which will give them a better chance of intervention early in the course of deterioration of symptoms before the condition becomes severe and eventually life-threatening.

This study explored the potential of using wearable devices in remote monitoring of heart failure patients. Wearable trackers have a minimal effect on lifestyle, provide reliable records and are capable of monitoring critical indicators continuously.

This study examined the use of wearable trackers for monitoring critical clinical indicators of heart failure patients. Two wearable trackers that record heart rate and physical activity were validated in clinical settings to determine the accuracy of heart rate measurements. The two trackers, the Fitbit Charge HR and Apple Watch reported heart rate measurements that are 90% as accurate as the Holter monitor. The results suggest that the Fitbit Charge HR and Apple Watch can both be used for monitoring heart rate and they would provide clinically relevant measurements.

The study then demonstrated the feasibility of using the Fitbit Charge HR and the Apple Watch for remote monitoring heart failure patients. The two devices were capable of identifying heart failure patients who are at high risk of readmission (NYHA III patients) with higher resting heart rate and lower daily physical activity compared to NYHA II patients.
Both the Fitbit Charge HR and Apple Watch had very close results in terms of their accuracy in clinical validation and in terms of their capability in differentiating between different functional classes of heart failure. However, from a feasibility perspective, the Fitbit Charge HR has some advantages over the Apple Watch. The Fitbit Charge HR records heart rate and steps at a fixed and well-defined interval, independently from any user’s movement. Whether the patient who is wearing the device is moving or not, the Fitbit Charge HR collects heart rate measurements, whereas the Apple Watch does not. In addition, the Fitbit Charge HR is collecting more heart rate and steps measurement every day than the Apple Watch, therefore, it is expected that with more heart rate and steps data there is a higher chance of getting close-to-actual heart rate and steps measurements with the Fitbit Charge HR. One more advantage for the Fitbit Charge HR over the Apple Watch is its battery life. The Fitbit Charge HR can last up to 5 days without charging, whereas the Apple Watch needs to be charged on daily basis. Therefore, the Fitbit Charge HR is more feasible to be used for remote monitoring.

The Fitbit Charge HR and the Apple Watch were both capable of differentiating NYHA III patients from NYHA II patients with higher resting heart rate and lower daily physical activity. Monitoring these critical indicators in ambulatory settings is critical for the condition of heart failure patients and can improve their quality of life if used properly.

This study evaluated modern devices that have not been in the market for a long time. Therefore, there are not any studies that have looked into the accuracy of the Fitbit Charge HR or the Apple Watch and also there are no studies that have explored the use of the Fitbit Charge HR or the Apple Watch in remote monitoring of any chronic condition, including heart failure. In addition, most of the previous studies that evaluated other wearable trackers and their use for heart failure patients, analyzed either the heart rate measurements, or the physical activity measurements separately from one another. This study is new in its approach in analyzing heart rate and physical activity at the same time.
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Appendix A: Consent Form

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Feasibility Study of Wearable Heart rate and Activity Trackers for Monitoring Heart Failure

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Affiliate Scientist Division of Experimental Therapeutics - Cardiovascular Toronto General Research Institute (TGRI)

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Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet.
Do not use e-mail to discuss information you think is sensitive.
Do not use e-mail in an emergency since e-mail may be delayed.
FUNDING
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INTRODUCTION:
You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

BACKGROUND:
You have been invited to participate in this study as you have been previously diagnosed with heart failure and will be doing your cardiopulmonary test today. Research indicates there is a relationship between heart rate at discharge time and rates of mortality and hospitalizations in heart failure patients. It has been shown that higher heart rates at time of discharge were associated with greater risk of: 1) all-cause mortality, 2) cardiovascular deaths, 3) consecutive re-hospitalization due to heart failure, and 4) cardiovascular disease hospitalization within the 30-day and one-year time periods after patient discharge.

Monitoring physical activity and heart rate is a key indicator for evaluating your heart failure condition. The heart rate data itself can’t reflect useful information to the clinician for evaluating your condition. However, analyzing your heart rate data with your activity levels provides an explanation to variations seen in your heart rate. For example, elevated heart rate values are expected if you are running or exercising, however, it maybe an indication that something not right is going on if you are sitting and not performing any intensive physical activity.

As you do your cardiopulmonary test at clinic, your doctor monitors your heart rate changes during the test. However, they do not have access to heart rate changes when you are outside of the clinic and involved with your daily activities. Heart rate and physical activity trackers can be used to keep track of the heart rate as well as the physical activity levels when you are out of the hospital. These wearable heart rate and activity trackers contain electronic sensors that monitor and record users’ heart rate in real-time. Note that these devices are not able to track where you go or
what you do; it only records your step count and measures the associated heart rate. The heart rate and activity data collected by the wristband is sent wirelessly to a mobile phone for analysis.

PURPOSE:
The purpose of this study is to relate heart rate and physical activity as recorded by a wristband tracker to heart failure. This study may lead to a tool that will enable doctors to keep track of their patients’ daily heart rate and activity level remotely, to help with treatment planning and to help alert the doctor if anything is wrong. Currently there is no easy way for doctors to measure and track patient heart rate and activity level outside of the hospital. This study is designed to determine whether heart rate and activity trackers can be used to monitor heart failure, and this will be an important step towards providing clinicians with up-to-date and accessible information about their patient’s recovery. Also, please note the following:

1) You are being asked to participate in this study because you have been previously diagnosed with heart failure.
2) The monitoring technology used in this study should not affect your treatment in any way.
3) Monitoring heart failure through wristband heart rate and activity trackers is experimental, meaning that it is not routinely used in patients’ care.

STUDY DESIGN:
Up to 25 people will be participating in this study at UHN and it will take around 6 months to complete. You will be given two heart rate and activity tracking wristbands: Fitbit Charge HR, and Apple Watch. You will wear the two wristbands on your non-dominant wrist for two weeks. Please be advised that it is important to stay consistent and keep the two wristbands on your non-dominant wrist. This is important to ensure that we are getting comparable results from the two trackers. You can remove the wristbands for short periods when necessary, such as bathing, or recharging purposes. You will also be given a mobile phone with a data plan, charging cables, a log sheet, and a box for mailing the materials back at the end of the study period. You are given the phone to allow wireless syncing of heart rate and activity data from the wristbands to a secure online portal. The phone will be locked, so please do not try to use the phone for any reason. You should plug the phone in a safe place in your home that you access daily and that has a strong cellular signal and leave it there for the duration of the study. You will be asked to return all study materials provided to you at the end of the study period using the packaging provided.
PROCEDURES:
You will be asked a few questions about you and your everyday physical activities. Then you will be shown how to use the two wristbands and the phone. You will be asked to wear both, the Fitbit Charge HR and the Apple Watch on your non-dominant wrist every day during the study, removing it for short periods of time as needed. You will be asked to remember to charge the wristbands in a timely manner to avoid the loss of heart rate and activity data. The two wristbands, mobile phone, and cables will not be available after the study is complete. You will be asked to return all study materials provided to you at the end of the study period using the packaging provided.

Prior to the final day of your study, you will receive a phone call or e-mail from the study coordinator. The study coordinator will remind you to return the study materials via FedEx pickup or drop-off at a time convenient for you. Please try to return the materials within a day or two of the completion of your study. Call FedEx to arrange a pickup time after the final day of the study period that is convenient for you. Call FedEx at 1.800.GoFedEx (1.800.463.3339), and say, “speak to a representative” when prompted or dial 0. Tell them you would like to arrange a pickup and choose a time and location that is convenient for you. If you prefer, you can also drop off the package at an authorized FedEx location, or arrange with the study coordinator to return the package at Toronto General Hospital. If you encounter any problems, please contact the study coordinator. Remove the wristbands, record the date and time on the corresponding spot at the top of the log, seal all of study materials (including all of the materials listed on page 1 of these instructions) in the return package and give it to the FedEx representative when he or she arrives. Please wrap the materials carefully in the provided packaging materials, especially the phone and the trackers.
**RISKS:**
No major risks are associated with wearing the wristband or the mobile phone. If you experience any discomfort or skin irritation due to the wristband, please discontinue wearing the wristband and contact the study coordinator. Heart rate and activity data will be stored separately from personal information and will be linked to this information by a study number. Some potentially sensitive information will be collected in the study recruitment interview form. Potential inconvenience may include wearing and caring for the wristbands (such as remembering to take it off before a shower and putting it back on afterwards), as well as ensuring it is mailed back in a timely fashion. The wristbands are comfortable and should be similar to wearing a wristwatch.

Please call the study coordinator if you have any of the side effects described above.

**BENEFITS:**
You will not receive direct benefit from being in this study. Information learned from this study may help improve remote monitoring of patients with heart failure in the future.
REMINDERS AND RESPONSIBILITIES:
It is important to remember the following things during this study:

- Ask the research team about anything that worries you.
- Tell the research team if you change your mind about being in this study.
- Care for the study materials properly; do not subject them to extreme temperatures or pressures, twist, bend, or cut any part of the wristband. Please avoid dropping the materials. Do avoid getting the mobile phone and cables wet.
- Only you may wear the wristband during the study period. The wristband and other materials must remain in your possession during the study. Your friends and/or family should only interact with the provided materials for the purpose of helping you use them.
- Please leave the phone plugged in at all times in a safe part of your home that you access on a daily basis and where it can receive a good cellular signal.
- The phone that you have been provided with is intentionally locked, and you will not need to use it directly at any point during the study.
- You must return the device and the log as soon as possible on the final date of the study period. You will receive a call to remind you to return the device.
- The study coordinator may contact you during the study if he notices a problem or has any questions. You may be asked to extend or shorten your study period depending on the situation.

Alternatives to being in the study
You do not have to join this study to receive treatment for heart failure. This study should not impact your care. Consult with your physician for the usual standard of care.

CONFIDENTIALITY:
Personal Health Information
If you agree to join this study, the study team will ask you for your personal information relevant to the study. Personal information is any information that could identify you and includes your:

- Name
- Phone number
- Mailing address
- Year of birth
- Sex
- Weight and Height
- Medical history related to your heart failure diagnosis
- Normal activity levels

All devices used in this study will be password protected. In addition, none of the recorded data will be sent outside of UHN, and data collected will not be accessible by any third parties. Your participation in this study will also be recorded in your medical record at this hospital. This is for clinical safety purposes.

Research Information in Shared Clinical Records
If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca).

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines:
- Representatives of the University Health Network (UHN) including the UHN Research Ethics Board

The study team will keep any personal health information about you in a secure and confidential location for 10 years. Only members of the research team will have access to the data.

In case any inappropriate release of personal health information occurs, further release of information will be stopped, any information that can be retrieved will be retrieved, the UHN Privacy Office and REB will be notified, and further actions may be taken according to recommendations from the UHN Privacy Office and REB. These guidelines will be strictly followed in the event of personal health information disclosure to an unauthorized party.

Study Information that Does Not Identify You
Any information about you will have a code and will not show your name or address, or any other information that directly identifies you.
All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or
presentations that may come from this study.

**VOLUNTARY PARTICIPATION:**
Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your care. We will give you new information that is learned during the study that might affect your decision to stay in the study. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying, “pass”.

**WITHDRAWAL FROM STUDY:**
If at any time during your study period you decide you do not want to participate anymore, please contact the study coordinator with the contact information included with your instructions and return all materials using the return package provided. If you leave the study, the information that was collected before you left the study may still be used in order to help answer the research question. No new information will be collected without your permission.

**Costs and Reimbursement:**
There are no costs associated with participation. You will not have to pay for any of the materials used in this study, nor will you have to pay for the postage to return them. You will not incur any expenses as a result of your participation in this study. Upon successful completion of the study and return of the study materials you will receive a cheque via mail for $50 as a thank you for your participation. Note: You will not be held responsible for lost or damaged devices.

**RIGHTS AS A PARTICIPANT:**
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators or involved institutions for compensation, nor does this form relieve the investigators or involved institutions of their legal and professional responsibilities.

**CONFLICT OF INTEREST:**
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

**COMMERCIALIZATION:**
The research team and/or others intend to claim sole ownership of any research results consistent with this consent. You will not receive any financial benefit that might come from the research.

**QUESTIONS ABOUT THE STUDY:**
If you have any questions about the study please email our study coordinator, Raghad Abdulmajeed at raghan.abdulmajeed@uhn.ca.
If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential. You will be given a signed copy of this consent form.

**CONSENT:**

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

___________________________  __________________________
Print Study Participant's Name  Signature  Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

___________________________  __________________________
Print Name of Person  Signature  Date

Obtaining Consent
Appendix B: Study Instructions

Thank you very much for agreeing to participate in this study. Your contribution will be an important part of this project.
Once you have gone over the study instructions, signed the consent forms, and completed the introductory questionnaire you will be provided with the following items:

- 1 Log table sheet
- 1 Prepaid return package for mailing via FedEx
- 1 iPhone 6 and charger

You will be provided with two packages: Fitbit Charge HR package, and Apple Watch package.

The Fitbit Charge HR package includes the following items:
- 1 Fitbit Charge HR wristband
- 1 Fitbit charging cable
- 1 Wireless sync dongle
- 1 Wall charging adapter

The Apple Watch package includes the following items:
- 1 Apple Watch
- 1 Magnetic charging cable
- 1 Wall charging adaptor
**Fitbit Charge HR**
The Fitbit Charge HR is a heart rate and activity tracker wristband that is worn on the wrist and tracks heart rate and steps throughout the day. Wearing it is as safe as wearing a wristwatch and should not affect you in any way. The Fitbit wristband wirelessly communicates via Bluetooth with a mobile application, called the Fitbit App, which is already installed in the iPhone given to you. The Fitbit App will be used to extract heart rate and steps data measured by the Fitbit Charge HR, and upload it automatically into a secure online portal that can be accessed by the study coordinator. The Fitbit Charge HR that is given to you is linked to an account that is created by the study coordinator and can only be accessed by the study coordinator. The collected data will be completely anonymous. The tracker will need to be charged at least every 5 days for up to 3 hours. To avoid missing heart rate and activity data, please charge overnight every 3 days. Charging instructions are attached.

**Apple Watch**
The Apple watch is a heart rate and activity tracker that is worn on the wrist and tracks heart rate and steps throughout the day. Wearing it is safe and should not affect you in any way. The Apple watch attempts to measure your heart rate every 10 minutes, but won't record it when you're in motion or your arm is moving. The Apple Watch wirelessly communicates via Bluetooth with the iPhone given to you. The various parameters measured by the Apple Watch is directly stored in the Health App pre-installed on the iPhone. The two parameters we are specifically interested in analyzing in this study are: heart rate and steps data. In order for us to get access to this information during the study duration, we developed a mobile application that simply streamlines the readings of these two parameters from the Health App in the iPhone, into a secure server that can be only accessed by the study coordinator. This App is called LubDub, and it is already installed in the iPhone. *To get the data to sync from LubDub into the server, we ask you to open the app once daily during the study duration.*

It is important that the study coordinator is able to continuously view the measured data during the two-weeks period to ensure that there are no issues with data syncing and no other problems exist. The collected data will be completely anonymous as every given iPhone and Apple Watch will be assigned a study ID that is not linked directly to your name or personal information.
**Mobile Phone**
You are given an iPhone 6 that connects to the Internet using cellular data. You will not be able to use the phone for anything other than collecting data from the wristbands. Find a place in your home where you will go frequently, such as in your bedroom, where it can be plugged in and left safely throughout the study. Do not turn off the phone at any point during the study. Line of sight is not necessary for syncing. While you do need to wear the wristbands throughout the day, the phone can be left at home, as long as you are within 5 meters of it at least once per day. Make sure that the phone is able to get a cellular signal. You can check whether the signal and that the battery is fully charged by pressing the button on the right side and looking for the symbols shown in the figure below; the top right (battery) and top left (signal) of the phone’s screen.

If the signal strength indicator (left side) has only one or two bars, you may need to find another spot to leave the phone. The electronic devices are designed to withstand normal conditions, but it is important that you be careful not to damage it as you would with a wristwatch. In addition, avoid subjecting it to extreme heat or cold for extended periods of time outside the range of -20° to 45° C.

**Wearing the Wristbands**

You, and only you, will wear the two wristbands for the duration of the study on your non-dominant wrist. You may remove the wristbands for short periods of time. If you must spend over 1 hour without wearing the wristbands, please make a note of that in the log provided. If you are engaged in physical activity significantly outside of your norm, or extended periods of inactivity for any reason, please also record that in the log. Make sure you wear the wristbands loosely enough to allow air circulation. Note that you should wear the wristbands while you sleep. The wristbands will be thoroughly cleaned before and after you use it. If you need to clean them during the study, rinse them with warm water and mild detergent. When cleaning the wristbands, make sure to particularly clean and dry under the band. Although the wristbands are water-resistant, showering or swimming while wearing the wristbands is not recommended. Note that the bands are able to track heart rate...
and steps; and they cannot identify where you are or what you are doing.

Please contact the study coordinator and discontinue wearing the wristbands if the material feels uncomfortable or causes any irritation on your skin.

Important: You should only perform a physical activity within your capabilities and within what you and your physician have agreed is safe for you. We are interested in analyzing your heart rate variations along with the physical activity measurements taken during your normal activity levels, and in no way are we encouraging you to modify your current lifestyle. All of your heart rate and activity data will be kept anonymous.

Upon Completion of the Study
Prior to the final day of your study, you should receive a phone call or e-mail from the study coordinator. The study coordinator will remind you to return the study materials via FedEx pickup or drop-off at a time convenient for you. Please try to return the materials within a day or two of the completion of your study.

Call FedEx to arrange a pickup time after the final day of the study period that is convenient for you. Call FedEx at 1.800.GoFedEx (1.800.463.3339), and say, “speak to a representative” when prompted or dial 0. Tell them you would like to arrange a pickup and choose a time and location that is convenient for you. If you prefer, you can also drop off the package at an authorized FedEx location, or arrange with the study coordinator to return the package at Toronto General Hospital. If you encounter any problems, please contact the study coordinator.

Remove the wristbands, record the date and time on the corresponding spot at the top of the log, seal all of study materials (including all of the materials listed on page 1 of these instructions) in the return package and give it to the FedEx representative when he or she arrives. Please wrap the materials carefully in the provided packaging materials, especially the phone and the trackers.

If you have any questions or concerns please do not hesitate to call or email the study coordinator at 647 938 7531, Raghad.abdulmajeed@uhn.ca
FAQs about the Fitbit Charge HR

1. Can I swim / shower while wearing the Fitbit Charge HR?
   The Fitbit Charge HR is water resistant, however, it should be removed before swimming or showering. Do not wear the Fitbit Charge HR while diving.
   Keep in mind that the wristband may need to be dried.
   Also note that the phone and chargers are not waterproof.

2. Can I switch the Fitbit Charge HR to my other wrist?
   Please try to be consistent with which hand you wear the wristband on, preferably your non-dominant hand.

3. What do I do if there’s something wrong with the wristband / the phone?
   Please contact the study coordinator.

4. How will I know if it’s tracking / monitoring properly?
   We will try and contact you if we think there is a problem with the tracking. To check whether the Fitbit is working properly, press the button on Fitbit Charge HR. If it is working properly, you’ll see the time followed by an icon and your stat will cycle in turn.

5. Why did my Fitbit Charge HR wristband vibrate?
   You may have accidentally activated a mode that is not necessary for the study. To exit this mode, press and hold the button until the Fitbit vibrates again, meaning that its back to the mode required for the study.
Instructions for wearing Fitbit Charge HR

For accurate reading, the Fitbit Charge HR should be worn on your **non-dominant wrist**. Your dominant wrist is the one you use for most day-to-day activities, such as writing or throwing a ball.

1. Put on the wristband so the screen is closest to the outside of your wrist and facing you.
2. Align both ends of the wristband so they are directly overlapping each other with the clasp over the two holes that best fit your wrist.

3. Squeeze both the clasp and the wristband between your thumb and forefinger until you hear a soft click. You'll know your Charge wristband is securely fastened if both pegs on the clasp are fully inserted.
Note that the Fitbit Charge HR should usually rest a finger’s width below your wrist bone and lay flat (as you’d normally wear a watch).

Instructions for charging Fitbit Charge HR

The Fitbit Charge HR comes equipped with a rechargeable lithium-polymer battery. With normal use, your Charge HR should last about 5 days before needing a charge. To charge your Fitbit Charge HR, do the following:

1. Plug the charging cable into the USB port on your computer or an AC charging adapter and plug the other end into the port on the back of the Charge HR. A battery icon on the display will show the charging progress. Charging completely takes between an hour and two hours.
2. Put the wristband back on the wrist you have chosen to wear it on.

Note: When you press the button on your Charge to cycle through your stats, the first screen will show a battery if there is approximately one day or less of battery life remaining.
FAQs about the Apple Watch

1. Can I swim / shower while wearing the Apple watch?
The Apple Watch is water resistant, but not waterproof. You can wear it on a rainy day and have water splashed on it and it'll survive, but you should avoid submerging it in water. Therefore, it is preferred that you take it off when swimming or showering to avoid any damage to the sensors.

2. Can I switch the Apple watch to my other wrist?
Please try to be consistent with which hand you wear the Apple watch on. For the purposes of this study, please continue wearing the Apple Watch on your non-dominant wrist.

3. What do I do if there’s something wrong with the Apple watch/ the phone?
Please contact the study coordinator.

4. How will I know if it’s tracking / monitoring properly?
We will try and contact you if we think there is a problem with the tracking. We will be able to identify that there is a problem if there were missing data points at times other than what you have already specified in the activity log given to you.
Instructions for wearing Apple Watch

For accurate reading, the Apple watch should be worn on your **non-dominant wrist**. Your dominant wrist is the one you use for most day-to-day activities, such as writing or throwing a ball.

**Note that the Apple watch should usually rest a finger’s width below your wrist bone and lay flat (as you’d normally wear a watch).** The Apple Watch must be worn with the right fit, not too tight, not too loose, and with room for your skin to breathe to keep you comfortable and let the sensors do their jobs. Apple Watch should be snug and comfortable.

1. Put on the Apple watch so the screen is closest to the outside of your wrist and facing you.
2. Align both ends of the wristband so they are directly overlapping each other with the clasp over the two holes that best fit your wrist.
3. Squeeze both the clasp and the wristband between your thumb and forefinger until you hear a soft click. You’ll know your Apple watch is securely fastened if both pegs on the clasp are fully inserted.
Instructions for charging the Apple Watch

The Apple watch needs to be charged every night in order to avoid missing heart rate and activity data. Please remember to charge the Apple watch before you go to sleep, and wear it again when you wake up in the morning. To charge the Apple Watch:

1. In a well-ventilated area, place the Apple Watch Magnetic Charging Cable on a flat surface, plug it into the power adapter, and then plug it into a power outlet.
2. Position the back of Apple Watch on the charger. The magnets on the charger should align with the Apple Watch properly, and you'll hear a chime (unless Apple Watch is muted) and see a charging symbol on the watch face.
3. Give the Apple Watch time to charge. The charging symbol is red when Apple Watch needs power and turns green when Apple Watch is charging.
Instructions for checking the battery of the Apple watch

If your battery power is low, you'll see a red charging symbol on the screen of your Apple Watch. If you have enough battery, you will see a green charging symbol.

To check remaining battery percentage, please do the following:

1. Swipe up on the watch face to open Glances.
2. Swipe left or right to find the Glance that shows your remaining charge. Note that if you turned off the Battery Glance, you can turn it on again. Open the Watch app on your iPhone and tap Glances > Battery.

Note: Please **do not** click on power reserve mode, as this will cause the heart rate sensor to stop recording heart rate data to reduce power consumption of the Apple watch.
Appendix C: Study Recruitment Interview Form

This form is to be used as a guideline for the recruitment interview and is to be filled out by the recruiter. This form is not to be given to the participant like a survey.

Study ID: ___________ Date: ____________________
Age: ___________ Weight: ___________ Height: ___________
Sex (circle one): Male Female
Handedness (circle one): Right-handed Left-handed
Wristband preference: Right Wrist Left Wrist
Date of original HF diagnosis: ____________________
Heart Failure Treatment to date: (surgery, medication, diet / lifestyle changes)
Most recent NYHA (New York Heart Association) Classification (circle one):

I    II    III    IV

Regular physical activities undertaken (e.g. daily walks, swimming, bicycling)

Appendix D: Activity Log

Please use these tables to keep a daily log of times when you were not wearing the wristband for extended period of time. Also, any additional information you provide on your physical activity will help the study. Please do not write any identifying information (such as anyone’s name, address, contact information etc.) anywhere on these pages.

Example entries have been provided in the first few rows.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event (e.g. tracker off)</th>
<th>Duration</th>
<th>Reason/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 1, 2014</td>
<td>1, Removed tracker</td>
<td>1 hour</td>
<td>Swimming</td>
</tr>
<tr>
<td>July 2, 2014</td>
<td>Exercise</td>
<td>45 minutes</td>
<td>Bicycle ride</td>
</tr>
<tr>
<td>July 3, 2014</td>
<td>Tracker off</td>
<td>1 hour</td>
<td>Forgot to put on</td>
</tr>
</tbody>
</table>
Appendix E: Contact Information

Date: ________________________________

Recruiter: ________________________________

__________________________________________

Participant

First Name: ________________________________

Last Name: ________________________________

Phone number: ________________________________

Mailing Address: ________________________________

________________________________________

________________________________________

________________________________________

Email: ________________________________
Note: Phone number or regularly checked email is needed to contact participant about syncing issues etc., and will not be used unless necessary. Mailing address needed to send the compensation to the participant.

Appendix F: Cardiopulmonary Study Report
Toronto General Hospital
Heart Function Clinic
Cardiopulmonary Stress Test
Summary Sheet

Date
Age
Height
Weight

REST DATA
SBP 110
DBP 70
HR 52
O2 sat 100
FEV1 2.65
% Pred 74
FVC 3.4
% Pred 73

EXERCISE DATA
SBP 140
DBP 76
Heart rate 133
1 min rec HR 96
Drop in 1 min 37
O2 sat 100
Time 14:03
Watts 140
%predicted 90
Termination leg fatigue
Symptoms Y/N nil

1= leg fatigue
2= dyspnea
3= chest discomfort
4= HR/BP response
5= THR
6= presyncope
7= ECG changes
8= poor motivation

CP DATA
VO2 (ml/kg/min) 22.7
Predicted 31.4
% Predicted 72
VO2 (L/min) 1.534
Predicted 2.12
% Predicted 72
Peak VE 63.1
Peak VO2 (L/min) 1.94
VE/VO2 Peak 33
VE/VO2 @ AT 28
AT (ml/kg/min) 16
% meas. peak VO2 71
% pred. peak VO2 50
Peak RER 1.26

Rest ECG
Rhythm: Sinus
A Fib/flut
APB's
VPb's
Paced
Biventricular

Q-waves: anterior
inferior
later
posterior

Bundle Branch LBBB
RBBB

LVH voltage: no
yes

ST/T abnormalities no
yes
leads: