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To the Graduate Council:

I am submitting herewith a thesis written by Susan Park entitled "Validity of Step Counting Methods over One Day in a Free-Living Environment." I have examined the final electronic copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Kinesiology.

David R. Bassett Jr., Major Professor

We have read this thesis and recommend its acceptance:

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Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

Validity of Step Counting Methods over One Day in a Free-Living Environment

A Thesis Presented for the

Master of Science

Degree

The University of Tennessee, Knoxville

Susan Park

August 2018

DEDICATION

To my beloved family and friends. You have showered me with unconditional love and brought me so much joy. I cannot thank you enough for all that you do to help me achieve my dreams. To Perry. I miss you and you are forever in my heart.

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ABSTRACT

This thesis was designed in two parts to determine the step count accuracy of activity monitors in a free-living environment. The aims of the first and second part of the study were to (1) critically evaluate the effects on step counts using the study methodology of wearing multiple monitors on the same area of the body and to (2) determine the step count accuracy of numerous consumer- and research-grade activity monitors worn on various locations of the body across all hours of a day in a free-living environment, respectively. For both parts of the study, the same hip- and wrist-worn monitor brands were examined. Wrist monitors included the ActiGraph GT9X (GT9X), Fitbit Alta (FA), Garmin Vivofit 3 (GV), and Apple Watch Series 2 (ApW). Hip monitors included the ActiGraph GT9X (GT9X), Fitbit Zip (FZ), Omron HJ-325 (OM), Yamax Digiwalker SW-200 (YX). In the second part of the study, a thigh-worn monitor, activPAL (AP), was also examined.

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CHAPTER I: INTRODUCTION

The past decade was marked by exponential growth in the use of activity monitors to track physical activity (PA) (20, 178). The popularity of activity monitors can be attributed to the "Quantified Self", a movement that embodies the quantification and assessment of human behavior (e.g., PA, sleep, food and water consumption) (14). With the widespread availability of monitors on the market today, PA measurement has become practical and easily accessible for the ordinary person. In many consumer-grade monitors, additional features (e.g., cellular updates, music, GPS) allow for diverse application and incorporation into one's daily routine (178). Similar trends in monitor usage are observed in research and clinical settings.

The use of activity monitors in research has drastically changed in recent years (178). Previously, monitors have been utilized to determine the relationship of PA and health (26, 49, 86), elicit behavior change (29, 105, 153), and classify populations by PA level (120, 142). In addition to the prior uses, monitors are adapted to track PA in longitudinal studies (20), predict health outcomes in clinical trials (25), and validate medical procedures (12, 69). Recently, there has been growing interest in the incorporation of activity monitors in electronic medical records (20, 150, 178).

Amongst researchers and consumers, a commonly used output of activity monitors to quantify ambulatory PA is steps (27, 178). Steps are a useful metric for quantifying human locomotion (166) and have shown to be associated with cardio-metabolic health (136, 142). The step is based on physical anthropometry (rather than fixed *Scientific Internationale* units, such as the meter or kJoule), thus simplifying comparisons across individuals of different height or body mass index (BMI) (20). Moreover, steps are intuitive, objective, and they can be a motivational tool to promote PA (150). For these reasons, step estimates from activity monitors may be utilized for a variety of purposes (20, 28, 94).

A major concern regarding the use of activity monitors is the accuracy of these monitors (20, 51, 177, 178). Thus, regulations have been implemented to regulate monitor accuracy. In Japan, the Japanese Ministry of Economy Trade and Industry has set standards for pedometers in which monitor estimates must be within $\pm 3\%$ of actual steps (75). The criteria may likely be in reference to steps completed during treadmill walking at an average walking speed (e.g., 80.4 m/min or 3 mph). It was not until late 2016 the standards for step count accuracy for consumergrade monitors were established in the United States (U.S.) by the Consumer Technology Association (CTA) (151). The CTA requires consumer monitors be tested during separate walking (i.e., 67-107 m/min) and running (i.e., 134-322 m/min) treadmill trials and yield a mean absolute percent error within 10% of actual steps for both trials (151). Although both standards require monitors to be accurate, they have limitations since they do not reflect the step count accuracy of monitors in free-living environments, across a waking day. The steps taken throughout the course of a day are accumulated within a wide range of human behaviors (e.g., cooking, cleaning, playing sports) that extend beyond continuous treadmill ambulation, thereby substantiating the need to determine the step count accuracy across numerous activities.

Previous research has validated activity monitors in laboratory settings. Typically, researchers have examined step count accuracy at various treadmill speeds and for different types of activities (41, 73, 81, 122, 138). Numerous sources of error (i.e., wear location, body mass, slow walking, irregular gait, intermittent walking) were found to affect step estimate accuracy (22, 53, 141, 149). Although these studies provide insight into the specific characteristics of movement and activities that increase step count error, it is difficult to apply these findings to step counts that encompass an entire day. Thus, in order to enhance ecological

validity, it would be better to conduct step count validations that monitor performance across an entire day under free-living conditions.

The validation of monitors in a free-living environment is accompanied by challenges not encountered with laboratory-based studies. Most laboratory-based studies use visual observation by a trained investigator as the criterion for step counting. However, this method can be difficult to apply when validating activity monitors in a free-living environment over prolonged time periods. Some studies have used another monitor as a criterion for step count (38, 56, 133), although these monitors were not validated against the gold-standard in the free-living environment. Furthermore, differences in the criterion monitor across studies make it nearly impossible to compare results across studies. Despite these challenges, a recent study conducted in our laboratory was able to validate numerous research- and consumer-grade monitors against the gold-standard in a free-living environment across a waking day.

Toth and colleagues (162) were able to utilize the gold-standard of hand-counted steps by video-recording steps taken throughout an entire day. This study implemented rigorous testing to ensure the most accurate measure of steps per day was established. Hand-counted step estimates from 10-minute video segments were counted independently by two trained researchers. If the values differed by more than ±5% or 6 steps over 10 minutes, a third researcher counted the video and steps per day. The number of steps in a 10-minute segment was then determined by taking the average of the two closest values. Findings showed that the StepWatch (OrthoCare Innovations; Mountlake Terrace, WA) captured the greatest percentage of hand-counted steps taken during a waking day compared to other step counting methods. This monitor allows the researcher to initialize it by entering various settings for cadence and sensitivity. Across multiple settings, the StepWatch yielded 95.3-102.8% of hand-counted steps. Laboratory-based studies

have found similar results across a wide range of speeds and activities (34, 52, 114, 141, 149, 160, 162). These findings substantiate the use of the StepWatch as a valid criterion measure in place of hand-counted steps in a free-living environment.

The StepWatch has previously been used as a criterion measure for free-living validation studies (52, 54, 77, 91, 141, 173). However, these studies did not assess wrist-worn monitors or hip-worn consumer monitors (except for the Omron HJ series and Yamax SW-200). It is critical to establish the step count accuracy of consumer monitors since they are the most popular wearable monitors on the market today (144, 150). Additionally, large-scale research studies such as the All of Us Research Program (76) and over 175 randomized clinical trials are now using consumer monitors (178). It is important to include the validation of consumer-grade activity monitors in a free-living environment, and to use a rigorous methodology for determining monitor step count accuracy.

A common method used in many step count validation studies involves wearing multiple monitors during the same trial (e.g., four wrist monitors worn on a participant's wrist/forearm) (15, 37, 95, 112, 133). Wearing multiple activity monitors allows for more monitors to be investigated with less participant burden. However, this study design may conflict with the manufacturers' instructions. In instances of wearing multiple activity monitors, only one monitor can be worn at the manufacturer's suggested location (e.g., one monitor can be worn at the wrist while the subsequent monitors must be worn further up the forearm). Compromised monitor performance due to wear location could be mistaken for step count inaccuracy of that specific monitor. Thus, if step count accuracy is going to be tested using this method (simultaneously wearing four monitors on the wrist/forearm and hip), it is critical that monitor performance not be impacted by placement.

Statement of the Problem

There is a need to establish the accuracy of consumer- and research-grade activity monitors in a free-living environment. Although the gold-standard for step counting is direct observation of steps, this method is difficult to perform outside of a laboratory setting and over extended time periods. The StepWatch is an activity monitor that can be used as a criterion in place of direct observation (162). Although a commonly used method in many step count validation studies is to simultaneously wear multiple monitors, it is not known if wearing these monitors at varied locations will produce equivalent step counts. To date, limited studies exist that validate both consumer-grade activity monitors and numerous step counting algorithms for research activity monitors against the StepWatch in a free-living environment. Additionally, no study has examined the effect of monitor placement on step counts of multiple monitors, worn simultaneously.

Statement of Purpose

This thesis will be carried out in two parts. The purpose of part one is to examine the effect of monitor placement on daily step counts of activity monitors worn at different positions on the wrist/forearm and hip. The purpose of part two is to examine the daily step count accuracy of multiple consumer- and research-grade activity monitors, using the StepWatch as a criterion measure.

Research Questions

Part 1: Will step count estimates of the same research- and consumer-grade monitors worn at different locations on the wrist/forearm and hip yield different step counts across waking hours of one day?

Hypothesis 1: It is hypothesized that step estimates of consumer monitors will yield different step counts when worn at different locations on the wrist/forearm and hip.

Hypothesis 2: It is hypothesized that step estimates of research monitors will yield different step counts when worn at different locations on the wrist/forearm and hip.

Part 2: Are step estimates from consumer- and research-grade activity monitors significantly different from steps compared to a valid criterion (i.e., StepWatch) across all waking hours of one day?

Hypothesis 1: It is hypothesized that consumer monitors will yield significant different step count estimates compared to the StepWatch.

Hypothesis 2: It is hypothesized that research monitors will yield significant different step count estimates compared to the StepWatch.

Delimitations

- 1. Participants shall be between 18 and 60 years of age.
- Participants must answer "No" to all questions on the Physical Activity Readiness
 Questionnaire (PAR-Q).
- 3. Participants will be excluded if they have any heart conditions, are pregnant, or are unwilling to refrain from riding a bicycle or stationary exercise cycle during the study.

Limitations

- 1. Participants may experience some skin irritation from wearing monitors.
- 2. Although monitors will not be directly touching each other and strapped tightly, excessive physical movement may temporarily misplace the monitors.

CHAPTER II: REVIEW OF LITERATURE

Ambulatory Physical Activity

Physical activity (PA) is defined as body movements, produced via recruitment of skeletal muscles, that results in expenditure of energy (126). There are many types of PA (e.g., aerobic PA, muscle strengthening) but this thesis will only focus on the associations of health and ambulatory PA, specifically with walking and running. With regular quantities, walking has been shown to decrease the risk of cardiovascular disease (7), declining cognitive function (143), hypertension (87), and other complications leading to premature morbidity and mortality (21). Current PA guidelines issued by Department of Health and Human Services recommend that adults avoid inactivity and obtain at least 150 minutes per week of moderate-intensity activity (e.g., brisk walking), 75 minutes per week of vigorous-intensity activity, or a combination of both (2). Despite this, based on self-report, it is estimated that less than a third of U.S. adults meet the PA guidelines (32, 167). As a result, the prevalence of inactivity in society is contributing to increased health care expenditure (33), decreased life expectancy (99), and health of future generations (61, 113).

Step Counting

One method of measuring ambulatory PA is step counting. Steps are a unit of human locomotion (84). A step is usually defined as the act of lifting one's foot off the ground and setting it down in order to move to a new position (6). However, some researchers maintain that steps also include unweighting the foot so that it supports less than 50% of body weight and moving it to a new location; this definition could include shuffling steps taken by older adults. In addition, Hickey et al. (77) defined a step as lifting the foot up off the ground and putting it back down again; this definition could include situations where a person is stepping in place. Steps have numerous advantages as an objective metric (20). Regardless of educational status or

professional capabilities, the average person can easily comprehend steps and step counting. Unlike other units of measurement (i.e., SI units) that are based upon physical quantities (e.g., seconds, meters, calories), steps are not quantifiable by absolute units. Instead, steps are an individually-based anthropometric unit that is related to a person's height and age. For these reasons, steps can provide a common ground for researchers to translate findings into public health messages.

Associations Between Steps and Health Variables

An important reason for the popularity of step counting among consumers is because of the associations between steps and health variables. Steps can be measured by visual observation or estimated through activity monitors (i.e., pedometers, accelerometers, fitness trackers). The use of activity monitors to estimate steps has given researchers the ability to determine total steps per day which is often used in studying the associations of health variables. This section will further delve into the types of studies that use activity monitors to estimate steps and the potential for using new, technologically advanced activity monitors.

Surveillance Studies

Across the world, activity monitors have been utilized to estimate steps per day in surveillance studies (70, 85, 86, 108, 109, 140, 170). In Switzerland, 493 adults wore a pedometer at work and during leisure time for one week. Steps per day from the pedometer were compared to the outputs of a questionnaire (140). On average, steps were found to be lower in woman than men and also for those that were older compared to younger age groups. These relationships seem to be consistent in other countries (85, 86, 109, 170) using different activity monitors. Additionally, for women, engagement in leisure time PA (e.g., fitness training,

walking, gardening) more than once a week was associated with significantly higher number of steps (p<0.003) (140).

Using the U.S. National Health and Nutrition Examination Survey (NHANES) from 2005-2006, Tudor-Locke et al. (170) utilized data from the ActiGraph 7164 to determine how many steps/day were taken by U.S. adults. ActiGraph 7164 data was censored to adjust the step counts to make the step counts more closely resemble those of the Yamax Digi-walker, a pedometer that was often used in surveillance studies. Censoring of steps was accomplished by eliminating any steps taken during a minute on the ActiGraph clock in which less than 500 ActiGraph "activity counts" were recorded. This procedure resulted in a reduction in steps taken during slow walking and intermittent activity, causing a decrease in daily step counts for men (10,578 to 7,431 steps/day) and women (8,882 to 5,756 steps/day). Tudor-Locke and Bassett (169) have outlined a classification system to group populations according to their PA level, as measured by steps/day. The differences in steps/day resulting from the differences in processing data can influence the classification of a population.

Cross-sectional Studies

The output of steps per day is of great interest to researchers seeking to understand the relationship of ambulatory PA and chronic diseases. Although insight on the dose-response relationship can be attained with a prospective-cohort study design, there are currently no studies that have been done (20). Despite this, cross-sectional studies have been conducted around the world and have shown that steps per day is associated with decreases in metabolic syndrome and cardiometabolic risk factors (e.g., obesity, hypertension) (71, 86, 142). Unlike previous studies, recent NHANES (2011-2014) cycles have utilized the ActiGraph GT3X worn on the wrist. The decision to change the wear location from the hip was due mainly from the low compliance and

wanting to capture sleep data in previous cycles (165). Compliance with wearing the activity monitor has increased from 40-70% of participants wearing it for at least ten hours per day for at least six days to 70-80% of participants wearing it for at least eighteen hours per day for at least six days. Unfortunately, no daily step counts have been reported with NHANES (2011-2014) data and there is still a need for a validated step algorithm for the ActiGraph on the wrist.

Intervention Studies

Another common use of step counters in research is as a motivational tool to increase PA in behavioral interventions. Several reviews have outlined intervention studies (27, 90, 130) that aim to increase daily step counts with walking interventions in individuals with musculoskeletal disease (107), post-pregnancy (118), cardiovascular disease (157), diabetes mellitus (40), and the general population (117, 127, 155, 156). Most studies show that pedometers are useful as an intervention tool to increase PA (155, 156, 158), leading to decreased body weight and improvements in other cardiometabolic measures (e.g., systolic blood pressure, glucose handling) (154, 180).

Recently, several studies have assessed the use of newer consumer monitors and their applications beyond typical uses in intervention studies (20, 78, 150, 178). Since most consumer monitors come with mobile phone/computer interfaces that allow users to track, store, and share PA data; the usefulness of monitors has been expanded in intervention studies to include social support, extrinsic rewards, and other behavior modification techniques (178). The feedback that participants receive on their activity monitor, smartphone, or webpage has been shown to encourage PA, compared to wearing a traditional monitor (30, 92, 105)

Unique Applications

The use of activity monitors in research has branched into various applications in medical practice, pharmaceuticals, and clinical trials.

The ActiGraph GT3X-BT is being used in a randomized crossover pilot clinical trial (NCT02835937) to observe the effects of ambulatory red blood cell transfusions in patients with chemotherapy-induced anemia on functional status (115). Although the primary outcome measure is energy expenditure, step counts will also be measured. In addition to validating the efficacy of this costly practice, this trial will also provide information on the feasibility of using activity monitors to assess functional status in patients with red blood cell transfusions.

Activity monitors are also used to evaluate postoperative recovery after surgical procedures (174). Previously, postoperative recovery has been measured via self-report questionnaires. Van der meij et al. (174) determined the feasibility of activity monitors when assessing postoperative recovery after laparoscopic abdominal surgery in patients (N=30). Patients were instructed to wear the ActiGraph GT3X-BT one week before surgery, and during the first, third, and fifth week post-surgery. Additionally, patients were asked to self-report their recovery process which included a written list of several activities that were completed before surgery and the date in which the patient was able to complete them post-surgery. Patients who had a minor surgery were able to reach baseline step count three weeks after surgery, while those who had major surgery did not meet their baseline step counts at five weeks. Overall, the activity monitor was well-accepted by the patients and there was a fair agreement between accelerometer and self-report data (Cohens Kappa range: 0.273-0.391).

History of Step Counting

Leonardo da Vinci designed the first step counter that was worn on the waist (65). This mechanical pedometer counted steps from the movement of a lever arm attached to the thigh during walking. As early as the 1800s, pedometers have been used for mapmaking and measuring distance (18, 63, 116). Gell records in the topography of Troy, "the number of paces we walk affords a tolerably good measure of distance passed over, but the value of this is much enhanced by possessing a pedometer, which will count for us the number of steps" (63)..

Throughout the next century, a variety of pedometers (e.g., self-winding (68), spring-levered pedometers (89)) with unique mechanisms for counting steps were invented to provide a better measure of distance to improve maps of the world (66, 110).

In the late 1800s, Charteris (35) outlines in his manual specific activities and behaviors involved to maintain a healthy lifestyle. Specifically, the author suggests exercising daily; specifically recommending walking two miles before breakfast, three miles before lunch, three miles before dinner, and two before sleeping. In order to keep track of the distance traveled to achieve ten miles a day, he encourages readers to use a pedometer.

In 1965, the Yamasa company in Japan initiated a '10,000 steps per day' campaign (75), because it was believed to be the minimum amount of ambulatory PA that would sufficiently decrease the risk of coronary heart disease. In 1987, the company produced a pedometer with a mechanism to prevent double-counting of steps- an issue common with mechanical step counters (75). Soon after, Yamasa introduced a pedometer with a mechanical and electrical mechanism to count steps that included a digital display. Since then, step counting monitors have become more advanced and are now used for more than just measuring steps and tracking ambulatory PA. The advancements in monitors and examples of specific monitors used in the thesis study will be presented in the current literature review.

Sources of Error in Step Counters

Activity monitors can be categorized based on their internal mechanisms, wear locations, and data storage capabilities. This section will explore various types of step counters and the sources of error associated with each type. It is critical to understand the potential sources of error in various step counters, as they may contribute to understanding step count accuracy in a free-living environment. This section will also discuss the study designs frequently used to assess step count accuracy.

Internal Mechanism

Traditional step counters (e.g., Yamax Digiwalker) utilize a spring-levered mechanism, in which a horizontal lever arm moves up and down with vertical accelerations of the body during walking or running. The movement of the arm opens and closes an electrical circuit causing the monitor to count steps; however, in order to count steps, a minimum vertical acceleration to displace the lever arm must be met. In a recent study, John et al (88) found that the Yamax Digiwalker SW200 required a total acceleration amplitude of at least 1.21 g to count a step, though a vertical acceleration threshold of 0.35 g to count step was determined previously (170). This minimum acceleration threshold yields a potential source of error during slow-walking (<80 m/min). Slow-walking does not create sufficient vertical acceleration to move the lever arm to count a step, thus resulting in an underestimation of steps. An additional issue is found with individuals who have a large waist circumference (41, 173). An increased waist circumference causes the monitor to tilt away from the vertical axis, which decreases the amplitude of acceleration and results in an underestimation of steps. For these reasons, spring levered monitors are not recommended for use in individuals with increased waist circumference or older adults who walk slowly.

Piezoelectric or piezo-resistive accelerometers (e.g., some models of the Omron, Fitbit Zip) utilize proprietary criteria involving acceleration-signal features to record steps. During walking and running, the acceleration versus time recording generates a sinusoidal pattern caused by the repetitive ambulatory cycle. Some criteria involve counting the number of zero crossings or vertical acceleration peaks detected in a given time window to determine steps. Unlike spring-levered pedometers, these monitors are not affected by waist circumference, though some monitors may display decreased accuracy for slow-walking (134). In order to prevent the recording of extraneous, non-ambulatory movements, some monitors utilize a step-based time filter. The Omron's step-based time filter requires four seconds of continuous stepping to register a step. Steps taken in short bouts (i.e., less than four seconds) will not contribute to the total steps displayed on the screen of the monitor. These filter constraints may contribute to reduced step count accuracy during activities that consist of intermittent stepping (e.g., household activities) (77, 161).

Wear Location

Although some activity monitors are designed to be worn on the ankle (e.g., StepWatch, AMP 331), most step counters were only designed to be worn on the waist and respond to upand-down movements of the torso that occur in walking and running. However, in recent years, the wear location of step counters shifted to the wrist. The wrist is now the most popular wear location for PA monitors, and it has been shown to be increase wear time compliance (165). Additionally, monitors can be designed to be worn on the thigh, pocket, or clipped to a clothing piece (e.g., bra). With these new wear locations come new sources of error (13, 183), such as recording erroneous steps resulting from extraneous arm movements (161).

Consumer- and Research-Grade Monitors

Consumer-grade monitors are categorized as step counters that are marketed to the general public. Traditional step counters (e.g., Omron, Yamax) fall under that category of consumer-grade monitors and display total steps on the screen. These monitors are easy to use but do not have the capability to store large amounts of data. On the other hand, advanced monitors (e.g., Fitbit, Garmin, Apple Watch) come with associated mobile applications that allow users to upload, save, and store large amount of fine-grained data including raw data. Some consumer monitors are marketed to researchers and provide open source applications that allow access to activity data. Despite the increased use of consumer-grade monitors, a disadvantage of these monitors is that the manufacturers do not explicitly share their step algorithms. In addition, determining the step count accuracy of consumer-grade monitors is challenging due to the fact that manufacturers can alter their step-counting algorithms at any time, unbeknownst to the user (51). Therefore, the same monitor may yield different step estimates depending on the update version.

Research-grade monitors (e.g., ActiGraph) can store raw, time-stamped acceleration data but also allow users to access this information. This allows researchers to study the ability to accurately count steps and improve previous step counting methods. By providing access to the raw data output, research-grade monitors allow researchers to develop new step counting algorithms.

Step Count Validation Studies

Step count accuracy can be determined by using different protocols performed in the laboratory and free-living settings. Laboratory-based studies can identify confounders that affect a monitor's step count accuracy. The most common type of laboratory study consists of treadmill

walking or running. Secondly, structured bouts of activities (e.g., over-ground walking, activities of daily living) can inform researchers on the specific movement patterns that may affect monitor performance. Laboratory studies are useful because they can help researchers understand the sources of error contributing to step count differences throughout the day, which is what users are primarily interested in. Since most laboratory studies are structured and activities are performed for set periods of time, researchers are able to utilize a gold-standard of hand-counted steps by visual observation. Monitors yielding acceptable step count accuracy in laboratory-based studies are often used as a criterion measure in free-living studies.

Free-living studies are characterized by studying monitor performance in an unstructured setting across several hours or days. Since it is difficult to apply the hand-counted steps in free-living studies, surrogate monitors are often used to assess step count accuracy. This practice is problematic since researchers are determining the accuracy of other monitors against a monitor that has not been validated in a free-living setting. It was not until recently that several research and consumer monitors were validated against hand-counted steps in a free-living setting across one waking day (162). In this study, researchers manually counted steps from video recordings of each participant's steps and determined the StepWatch to be a highly accurate monitor (i.e., within 5% of hand-counted steps). This suggests that researchers can use the StepWatch as a criterion for validating other monitors under free-living conditions, without repeating the process of video recording and manually counting each step, as was done in the former study.

Research Monitors

Unlike consumer monitors, research monitors are not marketed to the general public and are usually (although not always) more expensive than consumer monitors. Along with having to purchase the monitor, a docking station for charging and initializing the monitor is also

necessary. Additionally, some companies require the user to purchase a license for the corresponding monitor software. Unlike consumer monitors, research monitors typically do not come with diverse feature options. The main difference between these two groups of monitors is the step algorithms that are used to process raw data. Research-grade monitors that will be covered in this literature review are the ActiGraph, activPAL, and StepWatch. Specifications of the particular model of monitor and findings of the step count accuracy will be presented for the studies conducted under laboratory-based and free-living conditions.

ActiGraph

ActiGraph (ActiGraph, LLC, Pensacola, FL) is a manufacturer of research-grade activity monitors. In addition to activity monitors, ActiGraph also provides a platform (i.e., Centrepoint) that can transfer data (e.g., activity bouts, raw data, steps, sleep score) from a mobile device, computer, and activity monitor in real-time (10) for innovative research. Additionally, ActiGraph monitors have been used in one of the largest cross-sectional studies in the U.S., the National Health and Nutrition Examination Survey (NHANES).

ActiLife is a program designed to initialize ActiGraph monitors, download data, and analyze data. Users can use ActiLife's step counting algorithm to process counts to estimate steps. Prior to being processed with the ActiLife algorithm, ActiGraph GT3X+ acceleration data from the Y-axis are put through a bandpass filter in order to attenuate accelerations that are outside the range of normal human movements. The filtered data are then processed through the algorithm, which identifies the zero crossings to estimate steps. However, due to its use of a single axis, the ActiLife step-counting algorithm is only optimal for counting steps when the ActiGraph is worn on the hip.

ActiLife also allows users to process data with the low frequency extension (LFE) filter option. The LFE filter was designed to make count values of the ActiGraph GT3X comparable to the ActiGraph 7164 (31). Enabling the LFE will reduce the attenuation of acceleration signals from low frequency movements (e.g., slower walking, light-intensity activity). This is done by extending the lower end of the filter's frequency range, thus allowing the amplitude of the low-frequency acceleration signals to be retained (9). Due to the fact that these movements are now more likely to exceed the acceleration threshold needed to record a step, turning on the LFE roughly doubles the number of steps per day recorded (54).

In order to create a step algorithm that could be applied to multiple wear locations, a preliminary (beta) version of the Moving Average Vector Magnitude (MAVM) algorithm was created by ActiGraph. Unlike the ActiLife step algorithm, MAVM uses raw data from the X, Y, and Z-axes or vector magnitude. The MAVM algorithm analyzes raw data in 4-sec timewindows. In addition, ActiGraph claims to use a time-based stepping filter. In other words, continuous stepping, for 10 seconds (on the wrist) and 2 seconds (on the hip), is required in order for steps to be recorded. These time-based filters are applied in order to prevent extraneous movements that are unrelated to ambulation being counted as steps.

ActiGraph GT9X Link

The ActiGraph GT9X Link is a 3-axis accelerometer that stores raw acceleration data to produce step counts. It is (3.5 cm x 3.5 cm x 1 cm) and weighs 14 g. The ActiGraph costs \$275 and cannot be purchased in stores. The GT9X Link has high-resolution liquid crystal display (LCD) window and Bluetooth capabilities, as well as the inclusion of an integrated measurement unit (IMU) including a gyroscope, magnetometer, and second accelerometer. Additionally, users must also purchase ActiLife software (\$1,250) in order to utilize the monitor. The monitor can

last up to 14 days on a full charged battery and can store up to 180 days of data. A 6-port docking station is \$175, and the belt clip is \$12, and the watch band is \$22.

Laboratory Studies

Numerous models of the ActiGraph with several step counting algorithms have been validated in laboratory settings (8, 37, 50, 55, 77, 79, 97, 112).

Hickey et al. (77) examined the step count accuracy of the ActiGraph GT3X across a range of ambulation speeds. Participants (N=15) wore two GT3X monitors in line with the anterior axillary line of either the right or left hip while completing a treadmill protocol. The protocol consisted of ambulating at speeds of 40, 80, 120, and 162 m/min for 5-min at each speed with 2-3 minutes of rest between speeds. The monitors were initialized using ActiLife with LFE (AGL) and without LFE (AG). Hand-counted steps served as the criterion for the study. At 40 m/min, AG significantly underestimated by 25 steps/min (p<0.05). At the remaining speeds, AG and AGL underestimated steps by up to 1 step/min. The greatest step count errors for AG and AGL were exhibited at slower speeds. Höchsmann et al. (79) found similar results with the AG having the greatest underestimation of steps at slower speeds by underestimating by 60 steps/min at 27 m/min and underestimated by 2 steps over 5 minutes at 100 m/min.

Chow et al. (37) determined the accuracy of the ActiGraph GT3X (GT3X) initialized with ActiLife (though no stepping algorithm is mentioned) at speeds 83, 108, 133, 167, and 200 m/min. Participants (N=31) wore the monitors on the hip and wrist and were asked to walk or run at 83, 108, 133, 167, and 200 m/min for 3 minutes. A two-way ANOVA was used to assess the effect of placement site (i.e., hip vs wrist) and speed on step count error. There was no significant interaction between wear location on speed (p=0.796), though significant main effects of wear location were found (p<0.001). Across all speeds, the wrist-worn GT3X underestimated

steps by $41.7\% \pm 13.5\%$ (mean % error \pm SD) compared to hand-counted steps. With increasing speeds, the GT3X on the wrist underestimated more steps (-29% at 83 m/min to -50% at 200 m/min). On the other hand, the hip-worn GT3X had a percent error ranging from -2% to 1% across all speeds. The wrist-worn GT3X decreased in accuracy with increasing speed. Overall, the wrist-worn AG seems to produce inaccurate step estimates while the hip-worn GT3X shows increasing accuracy with speed. The enabling of LFE was not mentioned in the study.

Few studies have examined the step count accuracy for activities of daily living. In a study by Toth et al. (161), participants (N=21) wore an ActiGraph GT3X on the right hip, in-line with the anterior axillary line, and non-dominant wrist while completing a series of activities. Activities included brushing teeth, brushing hair, eating a snack, cooking an egg, folding laundry, and sweeping a room. Each activity was performed for 2 minutes followed by a 30 second break. ActiGraph data were processed with the normal filter (AG), LFE (AGL), and MAVM algorithm (AGM). Hand-counted steps served as the criterion measure and $\pm 10\%$ of mean hand-counted steps were distinguished as the equivalence zones. Unlike the other step methods, the hip-worn AGL was statistically equivalent to hand-counted steps (p=0.02) across all activities while the AG and AGL on the wrist overestimated up to 17 steps/min and AGM on the wrist underestimated by 4 steps/min. AG and AGM on the hip underestimated up to 11 steps/min. In a similar study, Hickey et al. (77) found that during activities of daily living (i.e., cleaning, vacuuming, dusting, sitting, filing) the hip-worn AG processed with ActiLife without LFE significantly underestimated by up to 34% of hand-counted steps while the AGL overestimated by 70% of hand-counted steps (p<0.05).

Free-living Studies

Several studies have examined the accuracy of the ActiGraph in a free-living environment (38, 52, 77, 102, 162).

Toth et al. (162) determined the step count accuracy of the ActiGraph GT9X across an entire day in a free-living environment compared to hand-counted steps by video recording. Healthy adults (N=12) wore a GoPro video camera on their chest to record steps taken throughout the day. Additionally, three ActiGraph GT9X monitors were worn simultaneously on the left and right wrists and right hip in line with the anterior axillary line. ActiGraph data were processed in ActiLife and with AGM. Across all methods, step-count accuracy ranged between 69% to 220% of hand-counted steps. By enabling LFE, both the hip and wrist monitors greatly overestimated steps, recording 128%-220% of hand-counted steps (p<0.05). AGM on the hip underestimated steps, recording 70% of hand-counted steps (p<0.05). AGM on the non-dominant wrist recorded 84% of hand-counted steps, while AGM on the dominant wrist produced step estimates within 10% of hand-counted steps. Findings of this study display the major overestimation from enabling the LFE and the step counting accuracy of ActiGraph's MAVM algorithm (compared to the ActiLife algorithm) when the monitor is worn on the wrist.

Hickey et al. (77) examined the step accuracy of the hip-worn ActiGraph GT3X with ActiLife compared to the StepWatch (SW) in adults (N=15, Male = 7) across one, waking day. AGL steps were significantly greater than SW (9,597 steps/day mean) by 4,000 steps/day. Although AG steps were not significantly different from SW, there was still a 1,300-step underestimation. A similar study by Feito et al. (52) investigated the accuracy of the ActiGraph GT3X (using ActiLife) placed on the hip in line with the right anterior axillary line and the SW across one waking day. AG recorded 74% ± 13% (percent ± SD) of SW steps. Pearson

correlation coefficients showed a strong correlation (r = 0.95) between AG and SW (p<0.001).

<u>ActivPAL</u>

The activPALTM (PAL Technologies Ltd, Glasgow, Scotland) is a research-grade activity monitor that can measure steps, instantaneous cadence for a period of walking, time periods spent ambulating, postural allocation, and energy expenditure. It was initially designed to identify time spent lying/sitting, standing, and walking for stroke populations but is primarily used to measure time spent in sedentary time. The monitor contains a uniaxial accelerometer (although the most recent model is triaxial) that records gravitational acceleration and segmental movement. It also has the capacity to process data and store memory for up to seven days.

activPAL

The activPAL (AP) is small (5 x 3.5 x 0.7 cm) and lightweight (20 g). It is worn on the midline of the anterior thigh between the inguinal and patella crease, and affixed with Palstickies, double-sided hypoallergenic hydrogel adhesive pads. The monitor itself costs \$1,450 USD and the docking station costs \$950 USD. The software is provided online at no cost to the user.

Laboratory Studies

Numerous laboratory-based studies have examined the step accuracy of the AP (28, 43, 52, 72, 77, 106, 134). The first study to validate the step count accuracy of the AP across various walking speeds was conducted by Ryan et al. (134). Participants (N=20) walked on a treadmill at 54, 67, 80, 92, and 107 m/min for 5 minutes at each speed. Additionally, each participant walked at a self-selected slow, normal, and fast walking speed on a 500-m outdoor track, with mean speeds of 83, 99, and 110 m/min, respectively. Across all speeds for treadmill and over-ground walking, the absolute percent error was less than 1% of hand-counted steps.

Dahlgreen et al. (43) established the intra-monitor reliability of the AP to measure steps during ambulatory activities. Participants (N=24) performed the same procedure on two separate occasions a week from each other. The procedure consisted of walking at a self-selected speed, 53, 75, 75 m/min with incline, and running at 133 m/min. Participants also were asked to stair walk and cycle at 45, 60, 75 rpm. Each activity was performed for 2 minutes for each trial. Intraclass Correlation Coefficient (ICC) with two-way mixed model was used to calculate relative reliability of steps. Test retest relative reliability was very high for treadmill walking at 75 m/min and 75 m/min with incline (ICC= 0.94 and 0.95, respectively). High correlation was found for 53 and 133 m/min and stair walking (ICC = 0.88, 0.81, and 0.70, respectively). Finally, moderate correlations were found for self-paced walking and cycling (ICC= 0.69 and 0.55, respectively). It is interesting to note that during running at 133 m/min, the AP overestimated steps by 15 and 23 steps/min for the first and second trial, respectively.

Hickey et al. (77) examined the step accuracy in adults (N=15) during running on a treadmill at 120 and 162 m/min, vacuuming, dusting, filing papers, and cleaning a room in a home-setting for 5 minutes each. Participants also sat for 3 minutes. During vacuuming, dusting, and cleaning the AP significantly underestimated steps compared to hand-counted steps by 9, 15, and 13 steps/min, respectively. At 120 and 162 m/min, the AP significantly underestimated steps by 11 and 17 steps/min, respectively (p<0.05). When assessing step accuracy by movement type, the AP significantly underestimated steps during non-rhythmic (e.g., cleaning) and rhythmic (e.g., running) activities, but not during sedentary (e.g., sitting) activities. When assessing step accuracy by movement direction, the AP significantly underestimated steps during forward (e.g., jogging), side-to-side (e.g., dusting) and multidirectional (e.g., vacuuming) movement. The AP

underestimated steps by >5% of hand-counted steps for all activities except for filing papers, in which results were not significantly different (p>0.05).

Free-living Studies

In the same study by Hickey et al. (77) the step count accuracy of the AP was compared to the SW during one, full waking day. The AP significantly underestimated by greater than 1,000 steps/day of SW (9,597 mean steps/day) (p<0.05). Feito et al. (52) found similar results for the AP across one, full waking day compared to the SW. Feito examined participants in different BMI groups (i.e. normal (<24.9 kg/m²), overweight (25.0-29.9 kg/m²), and obese (≥30 kg/m²). The AP recorded only 70% of SW steps (p<0.001). Additionally, no significant effect of BMI was found on step count accuracy.

To determine the step accuracy of the AP across one, full waking day compared to the gold-standard, Toth et al. (162) used a GoPro video camera to film steps taken in one day. Participants (N=12) were outfitted with two AP that were placed in the midline of the anterior aspect of the right and left thighs between the inguinal and patella crease. Similar to previous free-living validation findings (52, 77), the AP recorded 76.9% of hand-counted steps. AP steps were highly correlated with hand-counted steps for the right and left thigh locations (r = 0.969 and 0.973, respectively). The author attributes the 23.1% underestimation of steps to the decreased accuracy of the AP at slower walking speeds. However, based on the present literature review, it appears that the underestimation of steps could also be due to the AP's inability to accurately detect steps during activities of daily living, and at faster ambulatory speeds in healthy adults.

StepWatch

The StepWatchTM (Modus Health, LLC, Washington D.C.) is a research-grade activity monitor specifically designed to measure PA in populations with slow or irregular gait. The StepWatch is regarded as the most accurate monitor for step counting during walking (40-121 m/min) (20, 77, 162). In addition to the activity monitor, the company provides the Modus StepWatch activity monitoring software that is able to initialize the monitor with user characteristics (e.g., height, age, weight) and activity patterns (e.g., engages in both extremes, normal stepping).

The StepWatch uses a step counting method that analyzes the instantaneous acceleration vs. time waveform in order to distinguish specific features of stepping (39, 160). In order to account for varying stepping rates and characteristics of walking, users are able to initialize the monitor with different sensitivity and cadence settings. Sensitivity is defined as the threshold acceleration that must be exceeded in order to record a step. For decreased sensitivity settings, the threshold for step detection is reduced to capture slower walking speeds or light-intensity movements. On the other hand, increased sensitivity will allow for higher step detection for fast walking or for individuals who frequently fidget or produce leg movements that are not steps. Cadence (cadence setting x 0.01 seconds) is defined as the time required before another step is counted to reduce the double counting of steps.

The StepWatch can also be initialized to record steps at different epoch lengths and does not use a stepping filter such as the Omron and ActiGraph MAVM. The StepWatch is worn on the ankle and counts steps using an analog accelerometer which samples at 120 Hz.

StepWatch 3

The StepWatch 3 (SW) is an ankle-worn step counter. The SW costs a total of \$2,000 USD (\$500 for the monitor and \$1,500 for the Modus activity monitoring system and docking station (91)). The monitor does not have a screen and is designed to be strapped to the ankle, above the lateral malleolus. The SW dimensions are 75 x 50 x 20 mm and weighs 38 g. It comes with an elastic strap with Velcro® closures and the battery of a SW can last from 5-7 years. *Laboratory Studies*

Numerous studies have examined the validity of the SW in clinical populations (58, 62, 93, 135, 164) and in healthy adults (53, 60, 91, 160). Karabulut et al. (91) determined the accuracy of the StepWatch 3 (SW) during treadmill walking, heel tapping, leg swinging, driving a motor vehicle, and cycling. The treadmill and cycle protocol consisted of participants (N=20) walking on a treadmill at 27, 40, 54, 67, 80, and 107 m/min, riding a cycle ergometer at 60 rpm, lightly tapping their right and left heels on the floor, and swinging their legs while sitting on a table for 3 minutes for every activity and speed. A subsample of participants (N=10) drove a motor vehicle around a 6.4 km course on a city street. Across all treadmill speeds, the SW was within 1% of hand-counted steps. Unlike other monitors (i.e., AMP 331, New Lifestyles NL-2000, Yamax Digiwalker SW-701) that were studied, modified Bland-Altman plots showed very little variability in individual steps per minute across all speeds. For heel tapping and leg swinging, the SW recorded erroneous steps (zero hand-counted steps) with mean steps 28.7 ± 6.4 and 118.2 \pm 0.75 (p<0.05), respectively. During driving the SW recorded no steps, while for cycling the SW recorded 120.2 \pm 0.41 steps/min. The SW was accurate (recorded \pm 3% of hand-counted steps) during slow to brisk walking. Foster et al. (60) found similar results in which the SW displayed high accuracy (99-100%) and precision [(SD of each test/ hand-count) * 100, with 0 as the highest score] (0.26-0.56%) at 27, 54, 80 m/min during treadmill walking, and at 27 and 48 m/min during over-ground walking. Feito et al. (53) also found similar findings in which the SW recorded 96 to 100% of hand-counted steps across BMI categories at walking speeds ranging from 40 to 94 m/min.

Hickey et al. (77) examined the accuracy of the SW at speeds greater than 100 m/min and during activities of daily living. The SW was initialized with sensitivity and cadence settings at 13 and 67, respectively. Participants ran on a treadmill at 120 and 162 m/min, and performed different activities (i.e., vacuuming, dusting, filing papers, and cleaning a room) for 5 minutes each. Additionally, each participant sat in a chair for 3 minutes. At 120 and 162 m/min, the SW significantly underestimated mean steps by 0.8 and 23 steps/min of hand-counted steps, respectively, compared to hand-counted steps. The SW significantly overestimated steps during vacuuming by 8 steps/min and significantly underestimated during filing by 4 mean steps. No differences in steps were found for the remaining activities. When assessing SW estimates based on movement direction, steps were overestimated (i.e. greater than 5% of hand-counted steps) during activities with multi-directional movements (e.g. cleaning). There was no significant difference between SW estimates and hand-counted steps for activities with side-to-side movements. Since the step counting accuracy of the SW decreases at high ambulation speeds (162 m/min) and certain activities (i.e., vacuuming and filing) and movement direction (i.e., multidirectional), the authors warn the comparison of steps/day using the SW and hand-counted steps as a criterion.

Toth et al. (160) examined the effect of SW initialization settings (i.e., cadence, sensitivity) on step count accuracy across various ambulatory speeds. Participants (N=15) were outfitted with four SW monitors worn above the outer and inner malleolus and performed treadmill

walking/running at ten speeds between 27 to 268 m/min, for 2 minutes at each speed. Treadmill trials were completed twice. During the first trial, the SWs were initialized with the same sensitivity setting (default setting) but different cadence settings (100, 83, 70, and 60% of default setting). For the second trial, monitors were initialized with the same cadence setting (default setting) but different sensitivity settings (18, 16, 14, and 12). The modified setting that yielded the greatest percent of hand-counted steps during treadmill trials (i.e., cadence 70% and sensitivity 16) was examined for the second part of the study. Participants (N=10) wore two SW monitors initialized with the default and modified setting and were asked to clean tables, vacuum, dust, play tennis, and drive a vehicle while wearing both monitors on the right ankle above the medial and lateral malleolus. One-way ANOVA showed significant differences across cadence and sensitivity settings across speeds (p<0.05). The modified setting captured 96- 104% of hand-counted steps. Similar to previous findings, SW recorded no steps during driving. There was a significant underestimation of steps during "singles tennis" when using the default setting (90% of hand-counted steps, p<0.001), and "dusting" when using the modified setting (85% of hand-counted steps, p=0.032). The default setting displayed higher accuracy across activities of daily living, while the modified setting had higher accuracy for singles tennis. To provide step estimates, users who engage in vigorous sports play may consider altering the cadence and sensitivity settings from default settings.

Free-living Studies

In the same study presented earlier (StepWatch: Laboratory Studies), Karabulut et al. (91) compared the step output of monitors (i.e., AMP 331, New Lifestyles NL-2000, Yamax Digiwalker SW-701, StepWatch 3) across one, entire waking day. Significant differences were found across monitors (p<0.01). On average, participants took 12,500 steps/day according to the

SW, while remaining monitors underestimated by a mean of 1,367 to 2,185 steps/day. The AMP 331, a monitor that is also worn on the ankle, significantly underestimated SW steps by 18% (p<0.05). The YX and NL underestimated SW steps BY 15% and 11%, respectively, but were not significantly different from the SW (p>0.05). Although there was no criterion measure of steps, authors conclude that the SW would likely produce the most accurate step estimates because of its accuracy across a wide range of walking speeds. Additionally, authors concluded that although the SW overestimated steps during heel tapping and leg swinging, only a small percentage of time during the day is spent performing these types of activities.

Toth et al. (162) examined the step count accuracy of the SW during one, waking day in a free-living environment compared to hand-counted steps. For each participant (N=12), four SW monitors were randomized to be worn above the lateral or medial malleoli on the right or left ankles. (According to the manufacturer, it makes no difference for step counts whether the monitor is worn on the lateral or medial side of the ankle.) Each SW was initialized with numerous pre-programmed settings (i.e., default, quick stepping, both extremes of walking speed, and quick stepping with dynamic/fidgety leg motion) using Modus software. Compared to hand-counted steps, the SW recorded 95-103% of steps per day (p>0.05). The pre-programmed setting of 'both extremes of walking speed' produced the most accurate step estimate as it recorded 98% of hand-counted steps/day and a MAPE of only 4%,

Consumer Monitors

Consumer monitors can be referred to as a wearable monitor, fitness tracker, and/or consumer-grade activity monitor. These monitors measure a collection of health behavioral data that may track aspects of one's PA, sleep, menstrual cycle, or even water-intake. Over the past decade, the popularity of consumer monitors has increased greatly (144) as the tracking and

monitoring of personal health data has become more prevalent (14). The growing availability, wide price range, and diverse feature options of consumer monitors have increased the affordability and utility for consumers (20, 51, 150, 178). Unlike research-grade monitors, manufacturers of consumer monitors rarely disclose their algorithms or the process of how health data is attained. Additionally, automatic updates to monitors may change the way in which the health data are measured (51). These updates make it difficult to ensure the accuracy of the monitors and comparability of data over time. Despite these limitations, consumer-grade monitors are often user-friendly, as they are accompanied by a free mobile interface that allow users to store data, share and compare data with other users, and track progress over time. Additionally, consumer-grade monitors do not require any further data processing that may need the assistance of a skilled expert. In this review of consumer monitors, manufacturers of the Apple Watch Series Two, Omron HJ-325, Fitbit Alta, and Garmin vivofit 3 will be presented.

Apple Watch

The Apple Watch (Apple Inc., Cupertino, CA) is a series of smartwatches that were introduced by Apple Inc in mid-2015. Smartwatches are starting to take over the wearables market and currently amount to more than \$13 billion USD in annual revenue (145).

Smartwatches offer similar features to fitness trackers but also possess stand-alone phone capabilities (e.g., call and text notifications and response), which may allow for convenience and ease of use in one's daily routine. In 2017, 35% of smartwatch shipments were Apple Watches (131), thus, establishing Apple as a major retailer of smartwatches in the market today. Apple Watches, which are only intended to be worn on the wrist, may be initialized to be worn on either the dominant or non-dominant wrist (16).

Apple Watch Series 2

The Apple Watch Series 2 is small (38.6mm x 33.3mm x 11.4mm) and lightweight (28.2 g). Like most smartwatches, the Apple Watch ranges in price from \$369 to \$1,299 USD, depending on the size (38 and 42mm) and casing material (aluminum, steel, ceramic). The Apple Watch Series 2 contains a heart rate sensor, accelerometer, gyroscope, and a speaker. A major limitation of the Apple Watch is that the monitor is only compatible with an iPhone 5 or later iPhone model (147). Additionally, a single charge will provide only 18 hours of battery life. *Laboratory Studies*

Currently, there are only three step count validations studies of the Apple Watch (19, 59, 112). Of those studies, no free-living validation studies exist.

Bai et al. (19) examined the step count accuracy of the Apple Watch 1 in healthy adult participants (N=41). The criterion measure of steps was the Yamax SW-200 DigiWalker (YX). The entire protocol lasted 80-minutes and was comprised of 20 minutes of sedentary activities (i.e., laptop/phone browsing, reading a book), 25 minutes of aerobic exercise (i.e., walking or jogging on a treadmill at self-selected paces), and 25 minutes of light PA (i.e., folding laundry, and sweeting, moving light boxes, stretching, slow walking). Each activity was separated by 5-min rest breaks. Across activity categories, MAPE ranged vastly: sedentary activity (453%), aerobic exercise (6%), and light PA (161%). Overall, the Apple Watch overestimated YX steps by 12%, with the most overestimation coming from light PA (greater than 200 mean steps). Light activity also had the lowest correlation (r = 0.30) compared to aerobic exercise which had the lowest step error and highest correlation (r = 0.91). The current study showed the Apple Watch displayed less step count error compared to the YX during aerobic exercise, however a

major limitation of the current study was the use of the YX as the criterion measure since slow walking and obesity pose significant threats to validity of the YX spring-levered pedometer.

Modave et al. (112) examined the step count accuracy of the Apple Watch Series 2 during a treadmill protocol. Healthy participants (N=20) between the ages of 18-39 years completed two separate trials, each consisting of a total of 1000 steps, at a self-selected pace between 53.6 and 80.5 m/min. The Apple Watch was worn on the right wrist for the first trial and left wrist for the second trial. The authors do not mention whether the Apple Watch was initialized for specific wrist placement when switching the placement of the monitor between trials, although the dominant wrist was inputted for each participant. Additionally, the exact placement of the Apple Watch in relation to other monitors worn during the same trial was not disclosed; however, it was worn adjacent to the Fitbit Surge and Garmin Vivofit on both wrists. Hand-counted steps served as the criterion measure. Averaging both sessions, the mean step output of the Apple Watch was 964.9 ± 59.0 (mean \pm SD) out of 1,000 steps, though this difference was not found to be statistically significant from hand-counted steps.

Fokkema et al. (59) examined the reliability and validity of the Apple Watch Sport during treadmill walking and running. Healthy adult participants (N=31) walked on a treadmill at slow (53.3 m/min), comfortable (80 m/min), and vigorous (106.7 m/min) speeds for 10 minutes each, on two separate sessions that were separated by a week. The Apple Watch was worn on the left wrist for all trials. Hand-counted steps by visual observation served as the criterion measure of steps per trial. Intraclass correlations (ICC) were calculated to determine test-retest reliability. At the slow, comfortable, and vigorous speeds, the mean average percent error (MAPE) of both sessions was 0.7%, 3.7%, and -0.1%, respectively. ICC for slow, comfortable, and vigorous speeds resulted in 0.38, 0.48 and 0.80, respectively. Although the Apple Watch exhibited low

reliability at slow speeds, it may be valid for counting steps at higher (i.e.- 80-106.7 m/min) speeds where it showed high reliability and low MAPE.

Fitbit

The FitbitTM (Fitbit Inc., San Francisco, CA) is the most popular consumer monitor on the market today and the company holds 72% of the market share in wearable technology (132). Since the release of its first activity monitor in 2011, the company has released a vast number of products, including fitness trackers, fitness watches, headphones, and even smart scales (1).

Fitbit activity monitors range in size and weight, depending on whether the product is classified as a fitness tracker, fitness watch, or clip-on tracker. Fitness trackers are designed to be worn on the wrist or waist and have Bluetooth capabilities in which the user is able to connect the monitor to a mobile platform to store and share activity data. Some fitness trackers are able to receive cellular notifications (i.e., call and text). Also, some fitness trackers have clip-on casing that allow for the monitor to be worn in various locations (i.e., bra, pocket, wrist, waistband). Fitness watches are generally bigger in size and weight and include the features of a fitness tracker in addition to a built-in GPS. Fitbit monitors use a triaxial accelerometer, which capture the accelerations of human movement, to detect steps using proprietary algorithms (3). Additionally, all monitors require the user to create an account to periodically 'sync' or download data using the Fitbit mobile platform and update the monitor firmware.

Fitbit Zip

The Fitbit Zip (Zip) is a small (35.6 x 9.7 x 28 mm) and lightweight (8.5 g) fitness tracker released in 2012. The Zip is inserted into a silicone holder and can be affixed to various parts of the body (e.g., belt, pocket, bra). Based on the Fitbit website, one can purchase the monitor for

\$59.95 USD. The Zip uses a replaceable 3V coin battery, which provides four to six months of battery life.

Fitbit Alta

The Fitbit Alta (Alta) was released in 2016. It is a wrist-worn fitness tracker with an organic light-emitting diode (OLED) display screen. The Alta is listed as \$129.95 USD on the Fitbit website. The Alta is a thin (238.8 x 15.2 x 10.2) and lightweight (31.2 g) fitness tracker. The monitor is rechargeable and uses a lithium-polymer battery that lasts up to 5 days. The Alta also allows the user to initialize the monitor to be worn on the dominant or non-dominant wrist, which is suggested to improve step estimates when counting steps (3).

Laboratory Studies

Numerous Fitbit step count validation studies have been conducted in a laboratory-based environment (11, 13, 24, 37, 45, 81-83, 104, 112, 119, 121, 122, 148, 152). Although a majority of studies use hand-counted steps as the criterion, some studies use the activPAL micro (121), Shimmer 3 (104), and the OPAL sensor (148). Some of these laboratory-based studies have validated newer Fitbit models, such as the Surge (112) and Charge HR (104).

The step count accuracy of Fitbit monitors has been assessed at numerous treadmill speeds. For slow walking speeds (i.e., less than 67 m/min), Diaz et al. (45) assessed the step-estimates from a Fitbit One worn on the hip and upper torso and a Fitbit Flex (Flex) on the wrist during a 6-min treadmill walk at 50.4 m/min compared to hand-counted steps. Percent error was lower for hip- (-1.5 \pm 2.8%) and upper torso-worn Fitbit One (-3.1 \pm 7.8%) compared to the wrist-worn Flex (-15.8 \pm 27.9%). Alina et al. (13) asked participants to walk at a slow speed of 41.4 m/min for five minutes while wearing Fitbit monitors at various locations (i.e., Zip on the upper torso, Fitbit One on the hip, and Flex on the wrist). Similar to previous findings, the hip location had

the lowest error compared to the wrist and the upper torso (i.e., 5.5%, 6.8% 6.7%, respectively) compared to hand-counted steps, though differences were minimal. Both studies also assessed the accuracy at normal walking speeds and found that for all wear locations, percent error decreased (1.4%-3.9%).

Huang et al. (81), determined the step count accuracy of the Fitbit One worn on the waist, Flex worn on the wrist, and the Zip worn on the hip at slow (54 m/min), moderate (80 m/min), and fast walking speeds (107 m/min). Healthy participants (N=10) ambulated on a treadmill for 3 minutes at each speed. Hand-counted steps were used as the criterion measure of steps. Slow walking significantly decreased step count accuracy for the Fitbit One (p=0.04). Percent error was highest in the One at slower walking speeds compared to moderate and fast speeds -3.8%, -1.2%, -1.5%, respectively, though at all speeds the One underestimated steps. The greatest underestimation (step error of -8.9 \pm 13.4% (mean \pm SD)) was exhibited in the Flex at fast speeds, though this was not statistically different than other speeds. Overall, wrist-worn monitors had the highest step count error. Moderate and fast walking speeds did not affect step count error across all monitors, though slow speeds reduced the accuracy of the One.

Chow et al. (37) assessed the step count error of the Fitbit at brisk walking to running speeds. Healthy participants (N=31) wore a Fitbit One on the waist and Flex and Fitbit Charge HR (Charge) on each wrist while ambulating on a treadmill at 83, 108, 133, 167, and 200 m/min for 3 minutes at each speed. Since the wrist-worn monitors were worn on both wrists, this allowed for the comparison of step count error between the dominant and non-dominant wrists. Across all speeds, the One underestimated hand-counted steps (-1.1% to 1.2% error), while the underestimation of the Charge (-10 to 0.3% error) and Flex (-11.9 to 1.8% error) was greater.

The step error was not affected by dominant and non-dominant wrist wear, though further examination of activities of daily living may show significant differences.

Free-living Studies

Several studies have examined the validity and reliability of various Fitbit models in a free-living environment (38, 46, 48, 56, 67, 111, 128, 133, 152, 172). The first published study by Tully et al. (172) examined the Fitbit Zip's step validity compared to the ActiGraph GT3X (GT3X) and the Yamax CW700 (CW700). GT3X was initialized using ActiLife, although no specification on whether the normal filter or LFE was stated. Participants (N=42) wore monitors on the right hip during all waking hours for seven, consecutive days. In addition to wearing the monitors, participants were asked to record their opinions of the monitor as part of the study. Free-living PA was assessed by comparing steps/day from the Zip to the output of steps/day from the GT3X and CW700. There was no statistical difference between steps/day with the Zip (7,477 steps/day) and the CW700 (7532 steps/day), however Zip steps/day were significantly higher than GT3X steps (6,774 steps/day, respectively; p<0.001). In regard to the usability of the Zip, a majority of the participants responded that the Zip was easy to use and did not interfere with their daily routine (88.1% for both categories).

Chu et al. (38) compared steps/day between a wrist worn Flex and waist-worn ActiGraph GT3X (initialized with ActiLife with no mention of enabling LFE) across seven days in 104 adults with a normal walking gait. In addition, daily step counts were used to classify the day by activity level, where greater than 10,000 steps/day were considered as an active day and less than 10,000 steps/day as a non-active day. The median steps/day by the Flex and AG (10,193 and 8,812, respectively) were similar to previous findings in which a wrist-worn Fitbit monitor overestimated steps compared to a waist-worn monitor. There was high correlation in steps

between monitors in both gender and PA categories (Spearman's rho: 0.76-0.91; ICC:0.73-0.87). Mean absolute percent error (MAPE) was 20.4% for inactive days and 9.6% for active days, revealing a discrepancy in the ability of the Flex to count steps in active vs. non-active daily-activity patterns.

Middelweerd et al. (111) assessed PA using numerous time intervals (i.e. minute, hour, day) with the Fitbit One and GT3X (ActiLife algorithm). Healthy adults (N=34) wore monitors on the right hip for seven consecutive days. The absolute mean error was 11.4% steps/day between the GT3X and Fitbit One. When assessing the agreement between steps/day from both monitors, the Fitbit One overestimated steps on all time interval analyses (i.e., minute, hour, and day). Overestimations of steps for the Fitbit One compared to the GT3X were 10.1 vs. 9.3 steps/min, 554.6 vs. 509.5 steps/hour, and 8312.7 vs. 7635.8 steps/day. Bland-Altman analyses were constructed to plot steps/min across each participant and showed a smaller range of differences in steps for those taken at greater than 100 steps/min. There was an excellent association between steps/min, steps/hour, and steps/day (ICC=0.80, 0.97,0.96, respectively). Although step estimates were higher in the One compared to the GT3X across all time intervals, the difference was within the range of 'acceptable error' which was defined as ±10%.

Gomersall et al. (67) compared step estimates of the Fitbit One on two occasions of seven days of wear. Participants (N=14) were the One and the GT3X on the hip. ICC (0.90) was acceptable for the Fitbit One steps/day. Compared to the GT3X, Fitbit One overestimated steps by 1,000 steps/day but was still within the limits of acceptable accuracy (8% of GT3X steps).

Toth et al. (162) examined the error of the Charge and Zip across one waking day in a free-living environment. Compared to hand-counted steps by video recordings, the Charge (i.e., worn on the dominant and non-dominant wrist) and Zip (i.e., worn on the hip) estimated 77-85%

of steps. The correlation of Fitbit monitors to hand-counted steps was high (ranged from r=0.87 to 0.92).

Garmin

The Garmin Ltd. (Garmin, Olathe, KS) is a well-known manufacturer of consumer activity monitors that is geared towards athletes (e.g., runners, cyclists) rather than the general population. Although it is not as popular as Fitbit activity monitors amongst researchers, it is currently being used in numerous clinical trials, including an ongoing study that is using the Garmin Vivosmart to monitor PA and motivate behavior change in patients diagnosed with prostate cancer who are experiencing cancer-related fatigue [NCT2911649]. Garmin specializes in GPS technology and offers a wide-range of products that may serve varying purposes (e.g., marine and aviation utilities). Currently, Garmin provides eight different wrist-worn models of activity monitors and one clip-on monitor that can count steps. Garmin provides a free mobile app that can be used to sync, store, and share daily activity.

Garmin vivofit 3

The Garmin vivofit® 3 (vivofit3) is a wrist-worn activity monitor that comes in a silicone strap. It is small (196.6 x 22.9 x 12.7 mm) and lightweight (45.4 g). The vivofit3 battery life can last up to one year and the monitor can store activity data in memory for up to four weeks. In addition to the step counter, vivofit3 is able to monitor sleep, estimate time spent in moderate intensity activity, calories burned and distance traveled. According to the Garmin website, one can purchase the monitor for \$69.99 USD.

Laboratory Studies

Leth et al. (104) examined the step count accuracy of the Garmin Vivofit 2 (firmware 3.30) for an over-ground walking protocol (121). Healthy participants (N=22) walked on a 100-

m, rectangular track in an asphalt parking lot two times at each speed 33 m/min and 58 m/min. The Shimmer 3 was used as the criterion measure of steps, which was set to process at 64 Hz through an algorithm that detected the swing phases of walking. Since the Shimmer 3 had never been validated, the step output of the Shimmer 3 was inspected and corrected against the gold-standard criterion, hand-counted steps. Garmin underestimated Shimmer 3 steps at 33 m/min and 58 m/min by 5% and less than 1% (mean step difference), respectively. This was the first study to determine the ability of the Garmin to estimate steps at slow walking speeds. Although the percent differences were low, modified Bland-Altman plots show a high individual variability in steps across speeds, especially at 33 m/min.

Several studies have examined the step count of several Garmin Vivofit models on a treadmill at various speeds (15, 104) and over-ground walking. An and colleagues (15), determined the step count accuracy of ten activity monitors, including the Garmin vivofit which was worn on the wrist. Healthy adults (N=35) first walked or ran on a treadmill for 3 minutes at each speed 54, 67, 80, 94, 107, and 134 m/min). Five minutes after the completion of the treadmill protocol, participants proceeded into the over-ground protocol, in which the same monitors were worn. Participants completed three laps around a 200 m track at a self-selected speed at normal, faster than normal, and slower than normal. The distance and time were recorded to calculate speed for each self-selected speed. Both protocols used hand-counted steps by visual observation as the criterion. On the treadmill, walking speeds between 54 and 80 m/min had MAPE ranging from 2.4 - 4.9% while faster speeds showed increasing MAPE 4.0 - 13.6%. A similar tread was observed in the over-ground walking trials where, the MAPE increased from slow walking (2.49 mph), walking (3.2 mph), and fast walking (3.95 mph), 2.7%, 3.3%, 16.5%, respectively. For both protocols, equivalence testing with post-hoc Tukey analysis

showed that the Garmin vivofit (p=0.06) yielded step estimates that were within 10% of hand-counted steps. Overall, the Garmin decreased in MAPE as speeds increased.

Free-living Studies

Only one study has validated the step count of the Garmin in a free-living environment. In the study by An et al. (15), 35 participants wore the Garmin vivofit over the course of one waking day. The reference measure was the New Lifestyle (NL-1000 Series). The Garmin had the highest correlation with the NL-1000 (r = 0.9) compared to any other monitor and had a MAPE of 17.8%. The Garmin also fell within $\pm 10\%$ of the equivalence zone. Additionally, post-hoc Tukey analysis showed no significant differences between steps (p=0.06). However, a limitation in this study was the use of the New Lifestyle as the criterion measure, since this monitor has never been validated in a free-living setting.

Omron

Omron Healthcare Inc. (Kyoto, Japan) is a company commonly associated with their medical equipment such as home blood pressure monitors and electronic scales (125). They manufacture a variety of pedometers and activity trackers that are low-cost in comparison to other consumer activity monitor bands and range from \$16 to \$46 USD. A majority of the Omron pedometers provide users with a limited number of features that can be accessed using on-screen buttons. Most monitors can store memory for up to seven days and provide users with information on steps, aerobic steps, distance, and calories burned. The newest activity tracker (i.e., Omron HJ-327T), is the first Bluetooth compatible monitor and can be synced to view and store data on a mobile interface.

Numerous Omron models have a 4-second filter for counting steps (124). In Omron's 4-second filter, the monitor will not accrue steps from walking bouts less than 4-seconds in duration, which prevents counting erroneous movement as steps.

Omron HJ-325

The Omron HJ-325 (HJ-325) is a pedometer that replaced the Omron HJ-112 (124). The Omron comes with a silicone holder and strap with a clip allowing for it to be worn on the waist, in a pocket, or purse. According to the manufacturer's website, the Omron retails for \$23.99 USD. It is small (12.7x 40.6 x 55.9), lightweight (113 g) and uses "tri-axis technology" that allows for it to be worn in multiple wear locations. The monitor is battery-powered but includes a battery-saving mode in which the screen will shut off after 20-seconds of inactivity.

Laboratory Studies

Crouter et al. (42) conducted one of the first laboratory-based studies on a treadmill across a range of slow and brisk walking speeds. In this study, the step count of the Omron HJ-105 was established across speeds (54, 67, 80, 94, and 107 m/min) using hand-counted steps as the criterion measure. At slow walking speeds (54 and 67 m/min), the Omron estimated 110% of hand-counted steps. As the speed increased, error was within ±1% hand-counted steps. Since the early to mid 2000s, numerous studies have reported similar findings in which numerous models of the Omron were shown to be capture less steps at slower speeds (60, 96, 134) compared to normal walking speeds (80 m/min). There are apparent decreases in error across slow-walking speeds, however, the findings of recent studies show an improvement in this issue.

Most studies conducted in the past decade have determined that step count of numerous models of the Omron was accurate across a wide range of treadmill speeds. Dondzila et al. (47), found no significant differences in steps across speeds (54, 67, 80, 94, and 107 m/min) with

slower speeds (i.e., 54 and 67 m/min) had an error within $\pm 3\%$ of hand-counted steps. Several studies reported similar results at slower speeds (54 m/min) with step estimates within the range of 1% (64), 3% (100), and 5% (175) of hand-counted steps.

In contrast, a recent study conducted by Hickey et al. (77) found that the Omron HJ720-ITC recorded 67% of hand-counted steps at 40 m/min. Although the monitor underestimated steps at this speed, it is important to note that this speed is much slower than most previously studied slow-walking speeds of 54 m/min. Only one study by Foster et al. (60) determined the accuracy of the Omron HF-100at an even slower walking speed (27 m/min) and found that the monitor captured 61% of hand-counted steps. Therefore, caution may be elicited towards the use of the Omron to capture steps at very slow walking speeds.

Ryan et al. (134) examined the ability of the Omron to capture steps during three walking bouts. Each participant walked on a 500-m course at a self-selected slow, normal and fast walking speed, which yielded mean walking speeds of 83, 99, and 110 m/min, respectively. A decrease in error was displayed with increasing speed (11% (slow), 5% (normal), and 3% (fast)). Interestingly, the average slow walking speed that resulted in the largest absolute error is close to the average walking speed of 80 m/min which was examined on a treadmill and shown to have less error (42, 64, 77). Other studies show similar findings, in which increasing speed will yields less error (47, 80).

The ability of the Omron HJ-321 and Omron HJ-303 to capture steps during stair climbing/descending has been assessed in two studies (81, 146) compared to hand-counted steps. Huang et al. (81) assessed stair walking (stair ascending and descending) with two trials, each separated by 3-min of rest. Participants were asked to ascend and descend 16 flights of stairs, each containing 11 stairs (height-15.8 cm, depth-32 cm) at a self-selected pace. During stair

ascend and descend, the Omron HJ-321 underestimated by $3.9 \pm 5.5\%$ and $2.5 \pm 6.5\%$, respectively. The authors state that out of the eight monitors studied, the Omron HJ-321 produced the lowest error as estimates were within 5%. Similarly, Steeves et al. (146) found no significant differences for ascending or descending stairs, although the Omron HJ-303 overestimated steps by 5-10%.

Laboratory-based validations on lifestyle activities are limited across models of the Omron. Although several studies assess the step count error during activities other than treadmill walking/running (44, 81, 146, 175), one study is unique in the incorporation of activities of daily living. Hickey et al. (77), assessed activities that may emulate activities that are commonly performed in a free-living environment and encompass multidirectional movement patterns. Participants were instructed to perform the following activities for 5 minutes: vacuuming, dusting, filing papers, and cleaning a room. Hand-counted steps served as the criterion measure. In this study, the Omron HJ720-ITC (HJ720) underestimated steps in all activities from 8 steps over 5 minutes (filing) to 36 steps/min (cleaning) (p<0.05). The HJ720 was most inaccurate during activities that were comprised of multidirectional movement patterns (i.e., cleaning) and captured only 80% of hand-counted steps. Similar findings were also presented in a study that included multidirectional activities (146), in which the HJ720 captured only 20% of handcounted steps during front-back-side-side and fox trot stepping. Higher error was attributed to the 4-second filter and the nature of lifestyle activities which are typically comprised of shorter bouts.

The reliability of numerous models of the Omron have been assessed (44, 80, 94, 134) across a wide range of activities. Kooiman et al (94), examined the reliability during two, 30-min treadmill walk at 80 m/min that were separated by a week. The Optogait system served as the

criterion for steps for this protocol. Participants wore the Omron (HJ-203) in the front pocket of the pants. To test reliability, Intraclass Correlation Coefficient (ICC) (two-way random, absolute agreement, single measure with 95% CI). The HJ-203 had a low ICC (0.14 ± -0.24-0.47 (ICC, 95%CI)). De Cocker et al. (44), examined the intra-instrument reliability across a range of treadmill speeds (53-107 m/min). ICC ranged from 0.25 to 0.96 with increasing reliability as speed increased. The increase in reliability with increasing speed was found in other studies (134).

In healthy adult populations, the accuracy of the Omron in populations ranging in BMI was assessed (73, 183). Zhu and Lee (183) compared the step output of various wear locations between normal, overweight, and obese BMI categories. Participants were asked to walk two times on a straight, flat sidewalk for 100 steps. There was no interaction between gender and BMI groups with the performance of the monitor to estimate steps (p>0.05). Laboratory-based study findings suggest that variations in BMI may not affect the performance of the Omron to accurately count steps.

Free-living Studies

Free-living validation studies on the Omron have been conducted with a wide array of criterion measures: Yamax SW-200 (44, 101, 137, 141), StepWatch (77, 141), New Lifestyles-1000 (47), ActiGraph CSA accelerometer (96), and activPAL (94).

One of the first free-living validation studies was conducted by Silcott et al. (141) who compared steps/day of the HJ-720 at multiple wear locations (i.e., pants pocket, neck, waist) during one, waking day. Healthy adults (N=62, Males= 32) were recruited and ranged in BMI (between 22-36.5 kg/m²). They were instructed to wear several HJ-720 monitors on the body: the waist in the midline of the right thigh, the right pants pocket, and around the neck in the center of

the chest. The StepWatch was worn on the ankle and was the criterion measure of steps/day. Across all participants, independent of BMI, the HJ-720 significantly underestimated SW steps in all placement locations (p<0.001). When stratifying the participants by BMI (normal (N=19) or overweight (N=23)), less error was found for the monitor placed on the neck and belt compared to obese (N=20) participants. Across normal BMI participants, the Omron worn on the neck, belt and pocket captured 63%, 64%, and 68% of SW steps. The Omron worn in the pocket was the most accurate across BMI categories compared to other placement locations. There was a wide range in step differences at various placement locations and a significant underestimation of steps/day. This was not observed in laboratory-based studies in which numerous models of the Omron were generally found to show less step error during continuous walking bouts across BMI categories and placement locations. The underestimation of steps may be due to Omron's 4second filter and the context of the free-living environment potentially containing many intermittent walking bouts. Additionally, the discrepancy of the Omron-HJ720 to count steps across BMI groups may be attributed to the tilt angle of the monitor placement. According to the user manual, the manufacturer's warn users that the monitor may not capture steps accurately if the front screen is tilted below 60° (123).

A more recent study conducted by Hickey et al. (77) evaluated the step counts of the HJ-720 using the SW as the criterion measure. Healthy participants (N=15, Male=7) wore the Omron on either hip on the midline of the thigh and the StepWatch was worn on the ankle for one waking day. In this study, the Omron (7460 steps/day) significantly underestimated steps compared to the StepWatch steps (9597 steps/day) (p<0.05). Overall findings suggest that the Omron underestimates total daily steps compared to StepWatch determined steps.

Yamax Digi-walker

The Yamax Digi-walker (Yamasa Corporation, Tokyo, Japan) was perhaps the most popular pedometer used in research studies from 1995 to 2010. In 1965, Yamasa initiated a 10,000 steps per day campaign to sufficiently increase ambulatory PA to decreased the risk of heart disease (75). The YX counts steps using a spring-levered mechanism, in which a vertical acceleration of the body will cause the horizontal lever-arm to move in accordance to a step (20). If the threshold exceeds 0.35 g (42), the movement of the arm will cause an electrical circuit to close, and that will in turn will lead to the counting of a step.

Yamax Digi-walker SW-200

The Yamax Digi-Walker SW-200 (SW-200) is a pedometer that is worn on the waist. According to the manufacturer's website, the SW-200 retails for \$19.50 USD. It is small (50 x 38 x 13 mm) and lightweight (21 g). The pedometer contains a liquid crystal display that can be accessed by opening the cover case to show total steps and a single button that resets steps to zero. SW-200 is powered by a battery that can last up to 3 years.

Laboratory Studies

Many step count validation studies have been conducted with the Yamax (23, 41, 64, 73, 77, 81, 94, 96, 103, 141, 146, 175). One of the earliest laboratory-based studies of the Yamax SW-series pedometers was conducted by Crouter et al. (41). Participants (N=10) wore two Yamax Digiwalker SW-701 (SW-701) monitors on the right and left waist line in the midline of the thigh while ambulating on a treadmill at 54, 67, 80, 94, and 107 m/min for 5-min at each speed. Across all trials, the SW-701 did not significantly differ from hand-counted steps (p>0.05) across a wide range of walking speeds.

Crouter et al. (41) examined the effects of BMI, waist circumference, and tilt angle on step count error of a spring-levered pedometer (i.e., SW-200) and a piezoelectric pedometer (i.e., New Lifestyles NL-2000) in a laboratory setting. Exclusion criteria included those with a BMI < 25 kg/m² or those that could not walk at 107 m/min. Participants wore the pedometers on the left and right sides of the hip in line with the midline of the thigh while walking at 54, 67, 80, 94, and 107 m/min. Each pedometers tilt angle was measured for further analysis. At slow walking speeds (i.e., 54-94 m/min), the SW-200 recorded significantly less steps than the New Lifestyles NL-2000 (p<0.05). Additionally greater step count error was seen for those with larger waist circumferences at slow speeds (54-80 m/min), the group with the largest BMI (>35kg/m²), and for the monitors with a large tilt angle (>15°).

Hickey et al. (77) assessed step count error of the SW-200 in simulated activities of daily living in a laboratory setting. Participants (N=15) wore the SW-200 in line with the midline of the thigh on the hip while performing the following activities: sitting, self-paced walking, vacuuming, dusting, filing papers, and cleaning. In order to further investigate the sources of error with the SW-200, the activities were broken into three categories based on the direction of steps that are taken. Categories consisted of forward (included self-paced walking), side-to-side (included filing, dusting, and sitting), and multidirectional (included vacuuming and cleaning). Compared to hand-counted steps, the SW-200 did not produce significantly different steps for self-paced walking and sitting. However, during the remaining activities, the SW-200 significantly underestimated steps (p<0.05). Although the underestimation of steps was small (less than 1 to 23 steps/min), in activities such as cleaning and vacuuming, the SW-200 recorded only 51% and 58% of hand-counted steps, respectively. When assessing movement patterns, the

percent of hand-counted steps underestimated by greater than 5% in side-to-side, multidirectional, and forward movement.

Free-Living Studies

Due to the acceptable accuracy at normal walking speeds, the Yamax SW series is often used as a criterion measure of steps (19, 44, 137) in free-living studies.

Silcott et al. (141) compared the accuracy of the Omron HJ-720 to the SW-200 in individuals who were normal, overweight, and obese BMI in a free-living environment. The SW was the criterion measure. When comparing the step counts of a piezoelectric monitor (i.e., Omron HJ-720) and a spring-levered pedometer (i.e., SW-200), BMI did not have an effect on error for the Omron HJ-720. With increasing BMI, the SW-200 underestimated SW steps in the normal, overweight, and obese groups by 19%, 21% and 48%, respectively (p<0.05).

Hickey et al. (77), mentioned previously under *Yamax laboratory studies* in this thesis, also assessed the accuracy of the YX under free-living conditions with SW as the criterion measure of steps. Similar to the laboratory conditions, the YX (7,924 steps/day) underestimated SW steps (9,597 steps/day). Toth et al. (162) also found that the YX SW-200 underestimated hand-counted steps by 19.5% of SW steps, across all waking hours of one day.

Standardization

In an effort to ensure step counters achieve a certain level of error, several agencies have issued specific standards.

Ministry of Economy, Trade and Industry

The Ministry of Economy, Trade and Industry (METI) in Japan created industrial standards for pedometers (74). METI states that pedometers must be within ±3% of actual steps

for approval. These standards are most likely in reference to treadmill walking at a normal speed of approximately 3.0 mph or 80.4 m/min.

Consumer Technology Association

In the U.S., the Consumer Technology Association (CTA) created standards for consumer activity monitors and app-based PA monitoring monitors (151). Unlike performance standards created by METI, CTA standards provide detailed procedures in which monitors are tested in order to meet certification requirements. These standards require testing wearable monitors in walking and jogging/running in at least twenty participants that are representative of various body types and sex. Walking is performed at a self-selected pace between 1.11 to 1.81 m/s and jogging/running is performed at a self-selected pace between 2.22 and 5.42 m/s. Testing involves five minutes of treadmill activity at an incline that is no less than 0%. The criterion is hand-counted steps by trained investigator, using video recording. Monitors are considered to meet requirements when step estimates for both ambulatory conditions are within 10% of MAPE.

CHAPTER III: EFFECT OF PLACEMENT ON STEP COUNT

Abstract

PURPOSE: The purpose was to examine the effect of monitor placement on step counts of activity monitors worn at different positions on the wrist/forearm and the hip during waking day. **METHODS:** Each day, participants (N=18) wore four wrist monitors of the exact same model, and four hip monitors of the exact same model. The monitors were worn at designated locations (i.e., positions A-D) during all waking hours on one day. On subsequent days, different models of wrist and hip activity monitors were tested. Apple Watch 2 (ApW), ActiGraph GT9X (GT9X), Garmin vivofit 3 (GV), and Fitbit Alta (FA) were worn on the wrist. Yamax SW-200 (SW200), GT9X, Omron HJ-325 (HJ325), and Fitbit Zip (FZ) were worn on the hip. At the start of each day and before going to bed, participants were instructed to record the current time and step counts displayed on the screens of the monitors. The step counts of each monitor were compared to those of a monitor worn in the reference position (i.e., wrist-just proximal to the ulnar styloid process, hip- in line with the anterior axillary line). For each monitor worn in a specific position, the percentage of reference steps and mean bias were computed. One-way repeated measures ANOVAs were used to determine if there were significant differences in steps between positions for each model (or step counting algorithm). In the case of significant main effects for position, pairwise comparisons with Bonferroni corrections were used to determine which positions were significantly different in terms of steps. **RESULTS:** All wrist step count methods (i.e. consumer monitor or step count algorithm) showed a significant main effect for placement (p<0.05). Steps counts of wrist monitors underestimated steps compared to the monitor worn in the reference position. When expressed as a percent of steps recorded by a monitor in the reference position, steps underestimated by -1% to -16%. All hip step count methods, except for the HJ-325, did not differ across positions (p>0.05). However, the HJ-325 was still within $\pm 3\%$ of steps recorded by a monitor in the reference position. **CONCLUSION:** On the wrist/forearm, step counts decreased the further away the monitor was from the reference position. On the hip, step counts did not differ by more than 5% of steps/day across any of the four positions. For step count validation studies in which multiple monitors are worn simultaneously, researchers should be aware that monitor placement on the wrist may affect the results.

Introduction

The risk of negative health outcomes can be attenuated with ambulatory PA (98, 171). Although a variety of metrics can estimate ambulatory PA, the most intuitive is steps (20). More recently, growth in the popularity of wearable activity monitors has made step counting convenient and accessible even for the layperson (14, 51). Furthermore, researchers are using activity monitors to count steps for population surveillance (109, 181), tracking PA in large prospective cohort studies (139) and changing behavior (129).

With the increased availability and widespread use of activity monitors, there is a need for studies that examine the validity of step counting monitors/methods. The step count accuracy of monitors has been examined using a variety of study designs (37, 42, 112, 172). The most common study designs are laboratory-based studies that involve participants wearing activity monitors while performing structured bouts of activities (e.g., treadmill walking/running, or brief bouts of activities of daily living). Understanding the impacts of locomotor speed or different movement patterns on step accuracy is useful, but a limitation to these study designs is that the results cannot be generalized to free-living settings. Thus, some validation studies have been conducted under free-living conditions (77, 162) in which participants wear monitors for extended periods of time while going about their daily lives. In both types of studies, it is common for researchers to have participants wear multiple monitors at the same time.

Wearing multiple monitors simultaneously allows for more monitors to be investigated with less burden on participants and researchers. However, this method may compromise monitor performance due to the placement of the monitor outside of manufacturer's recommended location. In instances of wearing multiple activity monitors, only one monitor can be worn at the manufacturer's recommended location (e.g., one monitor can be worn at the wrist while subsequent monitors must be worn further up the forearm). If step count accuracy is going

to be tested by this method, it is critical that monitor performance not be affected by improper placement of monitors on the body. Otherwise, compromised monitor performance due to wear location could be mistaken for monitor step count inaccuracy.

Currently, the impact of varied placement sites on step counts is unknown. Therefore, the purpose of this study is to examine the effect of placement on steps per day of four activity monitors worn at different positions on the wrist/forearm, and four activity monitors worn at different positions on the hip.

Methods

Participants

Eighteen healthy adults $(26 \pm 9 \text{ years}, \text{ mean age} \pm \text{SD})$ were recruited by posted flyers and word of mouth at the University of Tennessee, Knoxville and in the surrounding community. Exclusion criteria included contraindications to exercise indicated by the Physical Activity Readiness Questionnaire (PAR-Q) and those who were currently pregnant. In addition, participants were excluded if they participated in bicycling and stationary cycling during the study. The University of Tennessee Institutional Review Board approved the research protocol, and all participants provided a written informed consent prior to participation the study.

Protocol

The study was conducted across five days for each participant. On the first day, each participant's height and weight was measured in light clothing without shoes, using a stadiometer and calibrated scale, respectively. Participants were instructed on how to wear the monitors on the hip and wrist/forearm. They were required to successfully demonstrate the placement of activity monitors before leaving the laboratory and were provided an instruction sheet regarding

the placement of monitors in the case of removal (i.e., swimming, bathing). Additionally, researchers demonstrated how to record step counts and time on/ time off using the step count recording sheet.

For the remaining four days, participants wore four activity monitors on the wrist/forearm and four on the hip. On each day, within a given wear location, participants wore several monitors of the exact same model at four different positions. Each day, participants put on the activity monitors as soon as they got out of bed and recorded the current time and step counts displayed on the screens of activity monitors. Participants were instructed to go about their normal daily routine while wearing the monitors. Before going to bed, participants removed the monitors and recorded the current time and step counts.

Monitors

Wrist-worn activity monitors included the Apple Watch Series 2 (ApW; Apple Inc., Cupertino, CA; firmware version 5.0), Fitbit Alta (FA; Fitbit, San Francisco, CA; firmware version 4.0), Garmin vivofit 3 (GV; Garmin, Olathe, KS; firmware version 4.2.1.1), and ActiGraph GT9X (GT9Xwrist, ActiGraph, LLC, Pensacola, FL; firmware version 1.7.1). Hipworn activity monitors included the Yamax Digi-Walker SW-200 (SW-200; Yamasa Corporation, Tokyo, Japan), Omron HJ-325 (HJ-325; Omron Healthcare, Bannockburn, Illinois), Fitbit Zip (FZ; Fitbit, San Francisco, CA; firmware version 90), and ActiGraph GT9X (GT9Xhip).

<u>Positioning</u>

Wrist positions are displayed in Figure 1a. Position A was defined as the position just proximal to the ulnar styloid process. The subsequent placement positions (i.e., position B-D)

were adjacent to the previous position without directly touching the other monitors. Pre-wrap was worn between each wrist monitor to prevent monitors from directly touching.

Hip positions are displayed in Figure 1b. Position A was located 1 inch to the right of the umbilicus. Position B was defined as the position in line directly below the mid clavicular line. Position C was located directly over the anterior axillary line. Position D was located over the mid-axillary line. Hip monitors were positioned so that they did not directly touch each other.

Data Processing

GT9X monitors worn on the hip and wrist were initialized at 30 Hz using ActiLife 6 software (version 6.13.1) and the wear location (i.e., waist, wrist) was also specified. After monitors were worn, GT9X raw data were downloaded and processed both with and without the low frequency extension (AGL and AG, respectively). Data were exported in 60-second, time-stamped epochs with corresponding step counts. Steps/day were computed by summing the steps from when the monitor was worn, which was indicated on the step count recording sheet.

GT9X data were also processed with a beta version ActiGraph's Moving Average Vector Magnitude Step Algorithm (AGM). AGM step estimates were displayed on the monitor screen. Total daily steps for AGM and all remaining monitors were obtained by subtracting the step counts recorded in the morning from the steps recorded before removal.

Statistical Analysis

Position A was the reference position for the wrist and position B and C were the reference position for the hip, as these are the manufacturers' recommended positions for some monitors and are often cited in literature (42, 52, 57, 77, 141).

For all step count methods in all positions, mean ± standard deviation, mean bias (position steps per day – reference position steps per day), and percent of reference position steps ((position steps per day / reference position steps per day) x 100) were computed. One-way repeated measures ANOVAs were used for each hip and wrist step count method to analyze differences between positions. For step count methods that had a significant main effect of position, pairwise comparisons with Bonferroni corrections were used to determine which positions yielded significantly different steps. All analyses were performed using SPSS Version 24 (SPSS Inc., Chicago, IL) with an alpha of 0.05 to indicate statistical significance.

Results

Participant characteristics are shown in (Table 1). All participants were right-hand dominant and average wear time was 12.2 ± 1.9 hours (mean \pm SD). Since wrist-worn monitors varied in monitor width, placement sites were not consistent across monitors. Table 2 displays each monitor's width and the total width of all four monitors, including three segments of prewrap that were used to separate the monitors.

All wrist methods had a significant main effect of position (p<0.05) (Figure 2). Wrist step count methods in positions B-D underestimated position A steps by a range of 68 to 1,748 steps/day, which represented between 1% and 16% of total steps/day of position A. Expressed as a percentage of position A's steps, the monitors worn in positions B-D captured 84-96% for GT9X wrist step methods (i.e., AG, AGL, AGM) and 94-99% for consumer monitors. For all wrist methods, monitors worn in position C and D recorded significantly fewer steps than monitors worn in position A (p<0.05) (Table 3). For AGM and ApW, position B recorded significantly fewer steps than position A (p<0.05). No significant differences were found between positions B-D for the ApW and GV (p>0.05). In general, GT9X step methods produced

greater step differences relative to position A, compared to consumer devices (i.e., GV, FA, ApW).

With exception of the Omron HJ325, all hip step count methods did not have a significant main effect of position ($p\ge0.05$) (Figure 3). The greatest step difference across positions A-D on the hip was 393 steps/day. Only for the Omron HJ325 was position A significantly different than the reference position C (p<0.05) (Table 4,5), although the step differences were minimal (192 steps). Reference position B was not significantly different from other positions ($p\ge0.05$).

Discussion

To our knowledge, this is the first study to compare the effect of wearing identical activity monitors at various positions on the hip and wrist/forearm. Findings of the current study show that step count estimates for wrist monitors are affected by placement on the wrist/forearm. Hip monitors are generally not affected by placement and yield similar step estimates when worn at various positions (with the exception of the OM).

In general, for wrist methods, step estimates decreased as monitors were positioned more proximally (further up the forearm) than the suggested wrist placement site. During ambulation and activities of daily living, monitors worn on the wrist/forearm move around a joint (e.g., the shoulder and elbow). For monitors worn closer to the wrist (i.e., position A), the radius of gyration around the shoulder or elbow is longer than for a monitor worn at a more proximal location. The closer the monitors are to the hand, the more angular acceleration the monitor will experience. Since all step counting methods use acceleration-based algorithms for counting steps (88), it may explain why monitors worn further up the forearm would detect fewer steps. This was observed in the current study where steps were lower for all monitors worn in positions B, C, and D compared to the monitor worn in the manufacturer's recommended location.

For the GT9X on the wrist, the effect of position was greater for AG than for AGL. This could be due to the low frequency extension (LFE) filter, which extends the lower end of the band-pass filter cutoff, thus increasing the amplitude of acceleration signals in the low-frequency range. Previous studies (31, 54, 162, 168, 176) have assessed the effect of enabling the LFE and found that it results in much higher step counts. Thus, even though the acceleration signal is attenuated as the monitor position becomes more proximal, the LFE allows for more low-amplitude movements to be detected, resulting in less of a drop-off in steps.

In the current study, there was no consistent effect of placement on step estimates for hip methods. Hatano compared the instantaneous vertical acceleration produced during walking at various locations around the hip (75). He showed that peak acceleration for a monitor worn further from the umbilicus was greater than a monitor worn at the center of the body (75). Since step estimates did not vary substantially, it may suggest that regardless of wear location for hip-worn monitors, the accelerations caused by walking will still meet the established thresholds to count a step. Therefore, for most step counting methods (with exception of OM), there was no difference of daily step count when worn in the four locations. Although step estimates from the OM yielded statistically significant differences in step counts across positions, the difference was minimal (less than ±3% of steps) and was not deemed to have any practical significance. The step differences observed in the current study even meet the industry standards set by the Japanese Ministry of Economy Trade and Industry (75). These findings may provide assurance of minimal step differences when the monitor is worn on one side of the hip, though greater step differences may be found when comparing across left and right hips (137).

The present study compared step estimates of the same monitor worn in positions that were close to, but not exactly the same as, the manufacturers' recommended placements, under

free-living conditions. A strength of the study was that steps counts were assessed across all waking hours of one day, under free-living conditions, which may improve ecological validity over laboratory studies. Many previous laboratory (42, 59, 77, 94, 112) and free-living (77, 94, 133, 162) validation studies have utilized the methodology of wearing multiple monitors on either the wrist or the hip. The authors of these studies probably assumed that wearing four different devices on the wrist/forearm in slightly different positions would not impact step counts. Since the current study found that step counts of wrist-worn monitors are affected by placement in the case of wearing multiple monitors, results of previous studies using this methodology to assess step counts across a day may have underestimated total daily steps for some monitors. Researchers should be aware of the effects of placement on step counts when simultaneously assessing the step count accuracy of multiple wrist monitors. Even if one randomizes (or counterbalances) monitor placements, this does not eliminate the position effect; it just spreads it out over the various positions. Rather than having participants simultaneously wear 4-5 wrist monitors for one day, researchers could spread the data collection out over multiple days and then compare each monitor to a criterion. On the other hand, with hip-worn monitors (except for the Omron HJ325), researchers can be reasonably confident that step estimates will be similar when monitors are worn at various locations on the right or left hip.

CHAPTER IV: STEP	COUNT ACCUR	RACY OF 10	WEARABLE	MONITORS IN	I A
	FREE-LIVIN	G ENVIRON	IMENT		

Abstract

PURPOSE: The purpose of this study was to determine the step count accuracy of numerous wrist-, hip-, and thigh-worn activity monitors during all waking hours of one day, under freeliving conditions. **METHODS:** Each participant (N=48) were activity monitors for two days. For one day, the Apple Watch (ApW)/Garmin vivofit (GV) were worn on the wrist with two of the following hip monitors: Omron HJ-325 (HJ325), Fitbit Zip (FZ), Yamax SW-200 (SW-200), ActiGraph GT9X (GT9X). On the second day, the ActiGraph GT9X (GT9X)/Fitbit Alta (FA) were worn on the wrist with the remaining two hip monitors that were not worn on the first day. On one of the two days, the activPAL (AP) was worn on the thigh and on both days, the ankleworn StepWatch (SW) was worn and served as the criterion measure of steps per day. The monitors were affixed to the participants' body soon after they awoke each day, and were removed before going to bed. During placement and removal of monitors, the time of day and step counts displayed on the screens of the monitors were recorded. Participants were instructed to go about their normal daily activities. After the data were collected, the total daily step counts for each method were compared to the SW. Mean absolute percent error, mean bias and Pearson product moment correlations were computed. For all step methods, the percentage of SW steps was used for statistical analysis. One-sample t-tests with Bonferroni adjustments were used to determine if the step method differed significantly from 100%. **Results:** With the exception of the ApW, all step count methods produced step estimates that were significantly different than the SW (p<0.05). The ApW and FA captured within ±10% of SW steps. GT9X processed with low frequency extension (AGL) and GT9X processed with normal filter (AG) on the wrist and AGL on the hip overestimated by 25-102% of SW steps, while the remaining consumer and research step methods underestimated by 13-34% of SW steps. MAPE across all monitors were greater than $\pm 10\%$, with the lowest error coming from FA (14.8%). Conclusion: With exception of some GT9X step methods, most methods underestimated steps when compared to the SW. The FA and ApW showed a mean bias within $\pm 10\%$ of criterion steps. Overall, consumer monitors produce step estimates that are closer to the validated SW than some research step counting methods and could be used to measure steps for healthy adults in free-living settings.

Introduction

Regular physical activity (PA) is widely recognized to reduce the risk of chronic conditions (e.g., cardiovascular disease, cancer, stroke, type II diabetes, hypertension), which currently afflict a large proportion of the world's population (2, 99). Thus, lack of PA is a major public health concern throughout the world, as sedentary occupations are becoming more prevalent with technological advancements (5). New activity monitors provide a unique opportunity to conduct PA surveillance, refine scientific knowledge of the relationships between PA and health, and promote PA to the general public.

In recent years, sales of consumer activity monitors have increased worldwide, reaching revenues of \$16 billion USD in 2016 (163). Unlike research-grade monitors, most consumer monitors have diverse user capabilities (e.g., LCD screen, GPS feature, text/phone messaging) which increases their usefulness in daily life. The use of activity monitors has transformed PA research over the past decade. Currently, the National Institutes of Health is using the Fitbit Charge 2 and the Fitbit Alta HR, two popular consumer monitors, in a large cohort study (76). Additionally, there are over 250 registered clinical studies using the Fitbit (4) and various other consumer monitors (178).

Steps are a commonly used output of activity monitors. Steps are often used as a metric of PA in research and public health, and they are easily understood by the general public. Most importantly, steps are positively associated with cardiometabolic health (20, 179, 182). Due to the increased use of activity monitors, it is important that they are validated to accurately count steps (15, 36, 37, 83). One major advantage of step count validation is that monitors can be easily validated against a gold standard, especially under laboratory conditions (e.g., treadmill walking/running, structured bouts of activities). However, although the findings from these studies are useful in understanding the performance of wearable monitors under different

conditions, they do not capture all the types of activities that are performed throughout the day. Free-living validation studies can provide ecological validity but it is difficult to obtain a valid criterion measure of steps per day.

Unlike laboratory-based studies, it is difficult to use the gold-standard of direct observation and hand-counted steps under free-living conditions. Due to the longer durations of the measurement period and the difficulties of observing individuals outside the laboratory, another monitor is often utilized as a criterion. It was not until recently that a method was developed for validating research and consumer monitors against hand-counted steps, across all waking hours of one day (162). In this study, participants wore a chest-counted video camera pointed at their feet and researchers reviewed the video recordings to count steps. Of all the step count methods examined, only the StepWatch, an ankle-worn research monitor, yielded step counts within 5% of hand-counted steps. This supports its consideration as an alternative measure of steps/day that is similar to direct observation.

Currently, a few studies have assessed the step count accuracy of monitors in a free-living environment, using the StepWatch as the criterion (52, 54, 77, 91, 141, 173). A limitation to prior studies is that they did not examine newer consumer monitors. Although the study of Toth et al. that validated monitors to hand-counted steps included some models of the Fitbit, only one wrist-worn consumer monitor was examined. With the increase in newer wrist-worn consumer monitors, it is important to include them in step count validation studies. Therefore, the purpose of this study is to determine the step count accuracy of multiple consumer and research grade monitors compared to StepWatch across all waking hours of one day, under free-living conditions.

Methods

Participants

A total of 48 healthy adults (mean age \pm SD, 28 ± 12 years) participated in the study. Participants were recruited via word of mouth and flyers at the University of Tennessee, Knoxville and in the surrounding community. Exclusion criteria included contraindications to exercise (determined by administering the PA Readiness Questionnaire (PAR-Q)), pregnancy, and participation in stationary cycling or bicycling. Participants provided a written informed consent and PAR-Q before participating in the study. The study was reviewed and approved by the Institutional Review Board at The University of Tennessee, Knoxville.

Protocol

The study was conducted over three days. During the first day, participants reported to the laboratory on campus for anthropometric measurements and study instructions. Height and weight were measured using a stadiometer and electronic weight scale, respectively, in light clothing with shoes off. Participants were shown how to properly affix activity monitors to the corresponding body locations (i.e. wrist, hip, thigh, and ankle) and were asked to demonstrate proper monitor placement on their own. Participants were also provided a PA diary to record the monitor wear times (on and off) and step counts for monitors with screens. Afterwards, participants were asked if they were comfortable with properly affixing the monitors and completing the PA diary on their own. Those who were confident were given all activity monitors in a bag before leaving the laboratory and instructed to send a picture of the affixed monitors at the beginning of each day to ensure proper placement of the devices. Otherwise, a research assistant met with the participant to help with device placement and PA diary

completion. All participants were given an instruction sheet regarding the proper placement of monitors in the case of removal (i.e., when swimming or bathing).

For the second and third days, participants were instructed to go about their daily routine while wearing monitors. On both days, participants were two wrist-, two hip-, and one anklemonitor. A thigh monitor was worn on only one of the two days. With the exception of the anklemonitor, a different brand of monitor was worn each day.

Wrist Monitors

Each day two wrist-worn activity monitors were worn on the nondominant wrist. Wrist activity monitors included the Apple Watch Series 2 (ApW; Apple Inc., Cupertino, CA; firmware version 5.0), Fitbit Alta (FA; Fitbit, San Francisco, CA; firmware version 4.0), Garmin vivofit 3 (GV; Garmin, Olathe, KS; firmware version 4.2.1.1), and ActiGraph GT9X (GT9Xwrist, ActiGraph, LLC, Pensacola, FL; firmware version 1.7.1). For the GT9Xwrist, monitors were initialized at 30 Hz and specified for wrist placement using ActiLife 6 software (version 6.13.1). For the FA, GW, and ApW, the non-dominant wrist was selected as the preferred wear location using the corresponding mobile application.

Only two monitors were worn each day as a result of previous pilot testing that explored the effect of simultaneously wearing four identical monitors (e.g., 4 ApWs) on the wrist/forearm on steps/day. Across all monitors, there was a significant main effect of position on steps (p<0.05). Step counts were attenuated as the monitor was positioned further away from the reference position (i.e. proximal to the ulnar styloid process). However, step counts were not significantly different between the reference position and the adjacent position for the GV and FA. This indicated that the ApW and GT9Xwrist needed to be worn at the reference position and

the GV and FA could be worn directly adjacent to them. The placement of devices any further up the arm could compromise their validity.

The current study aimed to place monitors as close to the wrist as possible. Thus, monitors worn simultaneously were paired, based on the two monitors that would result in the smallest displacement from the reference position. The ApW and GV were worn on day one while the GT9X and the FA were worn on day two (Table 7).

Hip Monitors

Each day two different hip-worn activity monitors were worn. Hip-worn activity monitors included the Yamax Digi-Walker SW-200 (SW200; Yamasa Corporation, Tokyo, Japan), Omron HJ-325 (HJ325; Omron Healthcare, Bannockburn, Illinois), ActiGraph GT9X (GT9Xhip), and Fitbit Zip (FZ; Fitbit, San Francisco, CA; firmware version 90). The monitors were worn on either the anterior axillary line or mid-clavicular line on the right hip with the exception of the Omron HJ325 which was always worn on the anterior axillary line. For the ActiGraph GT9Xhip, monitors were initialized at 30 Hz and specified for waist placement using ActiLife 6 software (version 6.13.1).

Thigh Monitor

One activPAL (AP; PAL Technologies, Ltd, Glasgow, Scotland) was worn on the anterior midline of the right thigh, midway between the top of the patella and inguinal crease. It was wrapped in parafilm and attached to the body with Tegaderm film (3M Health Care, St. Paul, MN). AP monitors were initialized with activPAL software (version 7.2.28).

Ankle Monitors

One StepWatch (SW; Modus Health, LLC Washington DC) was worn on the right ankle just above the lateral malleolus. It was held on by an elastic strap with Velcro® closures. Monitors were initialized with the Modus software (Modus Health, version 3.4) with each participant's height, weight, and sex. The SW was initialized with a pre-programmed setting called 'both extremes of walking speed' (162). In a previous study, this procedure was shown to yield daily step counts that were 98% of visually observed steps (162).

Data Processing

Total daily steps for monitors with screens were obtained by subtracting the step counts in the morning from the step counts at bed. This was done for all monitors, including ActiGraph's beta version of Moving Average Vector Magnitude Step Algorithm (AGM), which was programmed on the device screen.

For SW, AP, and some GT9X step methods (i.e., AGL, AG), data downloaded for subsequent analysis. For GT9Xhip and GT9Xwrist, raw data were downloaded, processed with and without the low frequency extension (AGL and AG, respectively), and exported in 1-minute, time-stamped epochs with steps. For SW, AP, and some GT9X step methods (i.e., AGL, AG), total daily steps were determined by summing all steps according to participant's wear times indicated from the PA diary.

Statistical Analysis

Mean \pm standard deviation (x \pm SD), mean bias (monitor estimate - SW), and mean absolute percent error (MAPE) were calculated with total daily step counts for each method. Percent of SW steps (monitor estimate / SW x 100%) was used for statistical analysis. To

determine if the percent of SW steps significantly differed from 100%, one-sample t-tests with Bonferroni adjustments were computed. Additional one sample t-tests with Bonferroni adjustments were computed using only step counts from participants with complete data for all wrist pairings. Pearson product-moment correlation coefficients were computed for each step count method. For all comparisons, the α level was set at 0.05. SPSS Version 24 for Windows (SPSS Inc, Chicago, IL) was used to perform statistical analysis.

Results

A total of 48 healthy participants were recruited into the study (Table 7). Forty-seven participants were right-hand dominant, and one was left-hand dominant. The average wear time was 13.2 ± 1.7 hours (mean + SD).

The current study examined the accuracy of 13 step count methods, using the SW as a criterion (Table 8). The ApW (90% of SW steps) was the only method that was not significantly different from the criterion (p<0.05), although the FA recorded a similar percentage of SW steps (91% of SW steps) as the ApW. With the exception of the AG and AGL on the wrist and AGL on the hip that overestimated steps (120% to 202% of SW steps), all step count methods underestimated steps (66% to 91% of SW steps) (Figures 4 and 5). Consumer hip-worn monitors yielded 72%-87% of SW steps while consumer wrist-worn monitors yielded 83%-92% of SW steps. GT9X step algorithms displayed wide variability in step counts and appeared to be influenced by several factors including the placement site, digital band-pass filter, and step counting algorithm used to analyze acceleration data.

When examining just the participants with valid data on both wrist monitors in either pair (GT9X/FA and (ApW/GV), MAPE increased by 2% for AGL and decreased for the AG and FA by less than a percent (Table 4). MAPE did not change for ApW and GV (Table 9).

FZ (r=0.902), AGL (r= 0.930) on the hip, and AP (r=0.910) displayed the highest correlation with SW (Table 10). The consumer wrist monitors displayed correlations that were comparable (r=0.861 to 0.881) to the SW200 and GT9Xhip (r=0.870 and 0.868, respectively) (Figure 6). GT9Xhip step methods displayed stronger correlations with the SW (r= 0.829 to 0.930) than GT9Xwrist step methods (r=0.750 to 0.804).

Discussion

The SW has been used as a criterion measure in previous research on step count accuracy of monitors under free-living conditions. However, these studies were limited primarily to research monitors (i.e., ActiGraph GT3X, AP), and older consumer monitors (i.e. numerous models of the YX and OM) (52, 54, 77, 91, 141, 173). One study (162) validated newer consumer monitors against hand-counted steps, but it only included one wrist-worn monitor (i.e., Fitbit Charge). It is important to include more consumer wrist monitors since they are a major component of the wearable industry market (17), and are now being used in behavioral intervention studies (145, 150), clinical trials (178) and epidemiological research (76).

Out of the thirteen step count methods studied, ApW was the only one that did not show a statistically significant difference from SW (p<0.05). Despite the high cost of an ApW (\$179 to \$1,399 USD), it is the most popular smartwatch on the market today (131). To our knowledge, this is the first study comparing step estimates of the validated SW to the ApW across one day in a free-living condition. Step count validation studies on the ApW are limited and so far have only been conducted in laboratory settings (19, 59, 112). Findings suggest that the ApW displays low MAPE (<5%) at a wide range of ambulation speeds (i.e., 54-107 m/min), with increasing reliability at faster speeds (ICC: 0.38-0.80) (59). Additionally, the ApW displayed less step counting error (MAPE 6%) during aerobic exercise (i.e., walking or jogging) than during light

intensity PA (i.e., folding laundry, sweeping, moving light boxes, stretching, slow walking) (MAPE 161%) (19). Although these studies disclose the sources of error in the ApW during various activities involved in a typical day, they do not quantify the magnitude of error across an entire day of wearing the monitor. Our study shows that the ApW was within 10% of the criterion (SW) over an entire day, in healthy adults.

The FA was the only other monitor that estimated within ±10% of SW steps, in terms of mean bias. Fitbit is the most popular consumer activity monitor and has more than 70% of the market share in fitness trackers (132). Additionally, Fitbit monitors are being used more in NIH-funded research cohort studies and clinical trials (4, 150, 178). The selection of the Fitbit Charge HR and Fitbit Alta HR for use in the 10,000-person pilot study for the "All of Us" program appears to be well-justified, since the FA had the lowest mean bias (compared to the SW) of any step count methods examined in this study. In addition, the FA demonstrated a high correlation with the criterion SW (r=0.861). Despite the ApW and FA capturing more than 90% of SW steps, they still yielded MAPE scores of 18.9% and 14.8%, respectively, showing that there is some individual variability in the step estimates.

The current study supports the findings of previous laboratory-based and free-living research (141, 162, 173), where ActiGraph step count methods display a wide range of results. The current study found that the AGL on both wear locations overestimated steps (up to 202% of SW steps). These large overestimations in steps that result from enabling the LFE in the ActiGraph GT3X have been documented in previous step count validation studies (54, 77). The LFE was originally designed to make the accelerometer counts of the MEMS accelerometer in the new ActiGraph GT3X align with those of the older, analog ActiGraph 7164. However, an unforeseen consequence of widening the band-pass filter to allow for lower frequency

accelerations to "pass through" was that it reduced the attenuation of low frequency signals, resulting in a large overestimation of steps (31). One possibility is that the AGL algorithm may be recording extraneous non-ambulatory movement as steps. Currently, only one study (162) has examined the most recent ActiGraph accelerometer model (GT9X), and it found similar results to the present study. On the hip, there was an underestimation of steps for the normal filter but an overestimation of steps with the LFE filter. On the wrist, both the normal filter and LFE filter resulted in an overestimation of steps.

The current study also processed raw GT9X data from monitors worn on the non-dominant wrist and hip with the beta version of ActiGraph's Moving Average Vector Magnitude (MAVM). AGM on the hip and wrist recorded 81% and 66% of SW steps, respectively. Only one other study (162) has assessed the step accuracy of the MAVM step algorithm across one day on both wrists and the hip. Interestingly, the findings of that study differed by more than 10% of SW steps at both wear locations. Differences of implementation of the MAVM algorithm from the current study may have contributed to the inconsistencies between the current study and the aforementioned study. In the current study, rather than post processing data, MAVM step counts were obtained directly off the screen of the monitor, similar to how steps were acquired from consumer monitors (The screen display is based on the MAVM algorithm (Wyatt, J. 2018, personal communications, 7 May)).

The other consumer monitors underestimated steps by 72% to 87% of SW steps. Findings of previous studies that utilized the SW as a criterion have found a similar magnitude of undercounting in the YX and OM (52, 77, 91, 141). This could be attributable to the decreased step estimations observed during slow walking (42, 97) and activities of daily living (77). The newer consumer monitors (i.e., GV and FZ) estimated 83% and 80% of SW steps, respectively,

with similar MAPE (22-23%). Although there are limited studies that have validated various models of the Garmin (15, 104, 121) and Fitbit activity monitors worn on the hip and wrist (13, 36, 81, 172), previous studies show that faster ambulation speeds may increase step count error for the Garmin, while slower speeds were found to increase step count error for the Fitbit.

A study conducted in our laboratory assessed step accuracy during brief, intermittent walking bouts and found that for the FZ, steps taken in bouts that were 6 steps (or approximately 3 seconds) did not get added to the total step count (159). This likely contributed to the underestimation of steps that were found in the present study. The underestimation of steps during brief, intermittent walking bouts and sporadic activities of daily living results from the 'continuous stepping requirements' that is designed to prevent extraneous, non-ambulatory movements from being recorded as steps. Most consumer monitors stored the steps in a temporary cache, and require 3-6 seconds of continuous ambulation before those steps are added to the aggregate total step count (i.e., if the person stops walking before that time period, the steps will not be added into the daily step count). In addition, ActiGraph's MAVM algorithm requires more than two seconds of continuous walking when worn on the hip, and ten seconds of continuous stepping when worn on the wrist, in order for steps to be recorded (Wyatt, J. 2017, personal communications, 3 May, (159)). Thus, one of the reasons that many step count methods underestimate the SW is that the SW is designed to capture each and every step, while other methods only count steps taken in continuous stepping bouts of a certain minimum duration.

The current study provides support for the use of consumer monitors in healthy adult populations, though more research needs to be conducted in clinical populations that may have irregular gait patterns and/or slower walking speeds. Our findings add to the step count validation literature by assessing the accuracy of popular consumer and research monitors across

all waking hours of one day, under free-living conditions. This is important because steps per day is a variable of great interest to researchers, and step count monitors are being widely used by researchers, clinicians, and the general public (178).

CHAPTER V: CONCLUSION

This thesis was designed to determine the step count error of activity monitors across all waking hours of one day under free-living conditions. Part one of the thesis aimed to determine the effects of wearing multiple activity monitors on daily step counts when worn in specific positions on the hip and wrist/forearm. The findings of part one (Chapter III) were used to develop the methodology of part two (Chapter IV). The activity monitors examined in these studies included: ActiGraph GT9X (GT9X), Fitbit Alta (FA), Garmin Vivofit 3 (GV), and Apple Watch Series 2 (ApW), Fitbit Zip (FZ), Omron HJ-325 (HJ325), Yamax Digiwalker SW-200 (SW200), and activPAL (AP).

The methodology of simultaneously wearing multiple monitors on the wrist/forearm has been practiced in many step count validation studies (59, 77, 94, 112). Part one showed that this practice can affect step estimates, even when comparing between the same monitor. The results showed that for multiple monitors worn on the wrist/forearm, the monitor is positioned closer to the elbow will record less steps. It is important for researchers to be aware of this issue if they want to obtain valid study results. One way to deal with this position effect is to randomize the placement of monitors. However, this will only spread out the step counting error out across monitors, since the effect of placing monitors in varied positions on the wrist/forearm cannot be prevented. Ideally, even though it requires more time, researchers should ensure multiple wrist monitors are not worn simultaneously. Alternatively, the position effect on the wrist/forearm can be reduced by wearing no more than two monitors as close as possible to the manufacturer's recommended location.

For hip-worn devices (with exception of the Omron HJ325), there were no differences in daily step counts when devices were worn at four different positions on the belt/waistband. Thus,

researchers can feel confident that step counting errors will not be introduced by simultaneously validating up to four waist-worn monitors.

In part two of this thesis, the purpose was to examine the validity of 10 different monitors, and a total of 13 different step counting methods, for step counting over all waking hours of one day. In this study, the ankle-worn StepWatch (SW) was used as the criterion measure of step counting, since this monitor has previously been validated against direct observation of steps both in the laboratory (52, 54, 77, 91, 141, 173) and in a free-living environment (162). Of all step count methods examined, only the ApW produced step estimates not significantly different from the SW. However, the FA also yielded step counts within ±10% of SW steps, which was considered to be an acceptable range of error. In addition, the correlations between consumer monitors and the criterion SW are in the range of r=0.79 to 0.90. This study supports the use of consumer monitors to count daily steps in healthy adults, an important finding given the widespread use of consumer monitors in clinical trials, behavioral studies, and epidemiological research.

With the increasing number of advanced activity monitors that store large amounts of information and provide additional features for increased usability, incorporating daily step counts in clinical practice may soon become feasible. However, prior to including a component of ambulatory PA in clinical practice, it is important that step counters are standardized to produce accurate step estimates not only in laboratory settings but also under free-living conditions. Despite the current study showing consistent step estimates across consumer monitors, there is still an issue of underestimation that must be resolved before activity monitors are adopted into practice. Additionally, there is a need to further improve or develop an accurate step counting algorithm for the GT9X in order to analyze previously acquired data in large

population studies (i.e., NHANES and Women's Health Study). In general, both consumer and research monitors were highly correlated (r=0.75-0.93) with the SW. In conclusion, the thesis was able to improve upon the methodology used in step count validation studies, and directly apply the findings to determine the step count accuracy in many consumer and research monitors in healthy adults, compared to a valid criterion.

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APPENDIX

TABLES

Table 1: Participant descriptive characteristics (mean \pm SD).

	$\mathbf{All}\;(\mathbf{N}=18)$	Female $(n = 9)$	Male (n = 9)
Age (yr)	26 ± 9	25 ± 9	28 ± 10
Height (cm)	169.6 ± 6.2	165.6 ± 4.5	173.6 ± 5.2
Weight (kg)	68.6 ± 13.5	58.8 ± 8.7	78.5 ± 9.6
BMI (kg/m ²)	23.7 ± 3.7	21.4 ± 2.3	26.1 ± 3.3

BMI: body mass index

Table 2: Wrist-worn activity monitor width and total width of four monitors separated by

pre-wrap.

Monitor	Width of single monitor	Total width	
ApW	3.33 cm	16.32 cm	
FA	1.55 cm	9.20 cm	
GV	2.03 cm	11.12 cm	
GT9X	3.50 cm	17.00 cm	

Activity monitors: Apple Watch Series 2 [ApW], Fitbit Alta [FA], Garmin vivofit 3 [GV], ActiGraph GT9X [GT9X]. Total width: ((4 x single monitor width) + (3 cm of pre-wrap)).

Table 3: Mean bias of wrist step count methods worn on positions (B-D) and reference position (A).

P 0 0 1 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
Step Count Method	Total Steps from A	В	C	D
AGL	18,098	-740	-845a	-1,390 ^{a,c}
AGM	7,060	-330a	-486a	-794 ^{a,b,c}
\mathbf{AG}	11,165	-867	$-1,102^{a}$	-1,748 ^{a,b,c}
\mathbf{ApW}	6,774	-288ª	-243a	-199 ^a
FA	9,513	-68	-177a	-366 ^{a,b}
$\mathbf{G}\mathbf{V}$	9,142	-200	-360a	-533a

Mean bias: (position steps – reference steps). Results of pairwise comparisons. Step count methods: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Apple Watch 2 [ApW], Fitbit Alta [FA], Garmin Vivofit 3 [GV]. ^a significantly different than Position A, ^b significantly different than Position B, ^c significantly different than Position C.

Table 4: Mean bias of hip step count methods worn on positions (A, C, D) and reference

position (B).

Step Count Method	Total Steps from B	A	C	D
AGL	10,873	151	-16	204
AGM	6,905	69	-104	-61
\mathbf{AG}	6,481	92	-14	-88
FZ	8,330	-31	43	9
HJ325	7,758	129 ^c	-63	-158a
SW200	8,260	-533	-171	-139

Mean bias: (position steps – reference steps). Results of pairwise comparisons. Step count methods: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Fitbit Zip [FZ], Omron HJ-325 [HJ325], Yamax Digiwalker SW-200 [SW200]. a significantly different than Position A, ^c significantly different than Position C.

Table 5: Mean bias of hip step count methods worn on positions (A, B, D) and reference position (C).

Step Count	Total Steps	<u> </u>		D	
Method	from C A		В	ע	
AGL	10,857	167	16	220	
AGM	6,801	173	104	43	
\mathbf{AG}	6,333	240	148	60	
FZ	8,373	-74	-43	-34	
HJ325	7,695	192°	63	-95 ^a	
SW200	8,589	-362	171	31	

Mean bias: (position steps – reference steps). Results of pairwise comparisons. Step count methods: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Fitbit Zip [FZ], Omron HJ-325 [HJ325], Yamax Digiwalker SW-200 [SW200]. a significantly different than Position A, ^c significantly different than Position C.

Table 6: Total width of wrist-worn activity monitors separated by pre-wrap.

Monitors	Total Width + PreWrap
ApW (3.33 cm) + GV (2.03 cm)	6.36 cm
GT9X (3.50 cm) + FA (1.55 cm)	6.05 cm

Monitors: Apple Watch Series 2 [ApW], Fitbit Alta [FA], Garmin vivofit 3 [GV], ActiGraph GT9X [GT9X]. Width = (width of first monitor + width of second monitor + 1 cm of pre-wrap).

Table 7: Participant Characteristics (mean \pm SD).

	$\mathbf{All}\;(\mathbf{N}=48)$	Female (n = 27)	Male (n = 21)
Age (yr)	28 ± 12	28 ± 12	28 ± 11
Height (cm)	169.8 ± 8.7	164.2 ± 6.1	177.0 ± 5.7
Weight (kg)	72.3 ± 18.3	63.5 ± 16.0	83.6 ± 14.7
BMI (kg/m²)	24.9 ± 5.3	23.6 ± 5.8	26.6 ± 4.0
SW steps/day	$9,634 \pm 3,800$	$9,355 \pm 3,731$	$9,996 \pm 3,869$

BMI: body mass index, SW steps/day: average of both days of wear

Table 8: Total daily steps across all waking hours of one day in a free-living environment as measured by 6 wrist methods, 6 hip methods and 1 thigh method, with the criterion of

StepWatch steps (N=48).

Placement Placement	Step	n	Method	StepWatch	Mean Bias	MAPE (%)
Site	count		$(Mean \pm SD)$	$(Mean \pm SD)$		
	method					
	AGL**	45	$18,630 \pm 5,192$	$9,858 \pm 3,674$	8,772	101.5
	AGM**	42	$6,463 \pm 2,862$	$9,772 \pm 3,539$	-3,309	34.2
	AG**	45	$11,274 \pm 3,414$	$9,858 \pm 3,674$	1,416	24.2
	ApW	45	$8,229 \pm 3,552$	$9,357 \pm 4,093$	-1,128	18.9
Wrist	FA*	45	$9,029 \pm 3,817$	$9,884 \pm 3,653$	-855	14.8
	GV**	46	$7,590 \pm 3,487$	$9,278 \pm 4,126$	-1,664	23.3
	AGL**	46	$12,562 \pm 3,943$	$9,765 \pm 3,779$	2,797	35.1
	AGM**	43	$7,821 \pm 3,618$	$9,674 \pm 3,679$	-1,854	22.5
	AG**	46	$7,506 \pm 3,063$	$9,765 \pm 3,799$	-2,259	23.6
Hip	FZ**	46	$7,623 \pm 3,584$	$9,489 \pm 3,975$	-1,867	23.9
	SW200*	38	$8,004 \pm 4,059$	$9,343 \pm 4,101$	-1,339	20.7
	HJ325**	46	6,652, 2,792	$9,274 \pm 3,627$	-2,623	29.8
Thigh	AP**	37	$8,290 \pm 3,822$	$9,857 \pm 4,147$	-1,567	24.0

Mean: total daily steps. SD: standard deviation. Mean bias: (method estimate – StepWatch estimate). % SW: Percent of StepWatch steps: ((method estimate ÷ StepWatch estimate) • 100). MAPE: mean absolute percent error. Step count method: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Apple Watch Series 2 [ApW], Fitbit Alta [FA], Garmin vivofit 3 [GV]. Fitbit Zip [FZ], Omron HJ-325 [HJ325], Yamax Digiwalker SW-200 [SW200]. *p<0.05. **p<0.01

Table 9: Total daily steps across all waking hours of one waking day in a free-living environment with the criterion of StepWatch steps (N=48). These data only reflect a subset of total participants that had valid data for both monitors; any participants who had

missing data for one monitor or the other were excluded.

Placement	Step	n Method		StepWatch	Mean	% SW	MAPE
Site	Site count		$(Mean \pm SD)$	$(Mean \pm SD)$	Bias		(%)
	method						
	AGL*	42	$18,710 \pm 5,172$	$9,772 \pm 3,539$	8,938	203.9	103.9
Wrist	AGM*	42	$6,463 \pm 2,862$	$9,772 \pm 3,539$	-3,309	65.8	34.2
WTISU	AG*	42	$11,284 \pm 3,399$	$9,772 \pm 3,539$	1,512	120.9	24.9
	FA*	42	$8,888 \pm 3,850$	$9,772 \pm 3,539$	-884	90.3	14.4

Mean: total daily steps. SD: standard deviation. Mean bias: (method estimate – StepWatch estimate). % SW: Percent of StepWatch steps: ((method estimate ÷ StepWatch estimate) • 100). MAPE: mean absolute percent error. Step count methods: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Fitbit Alta [FA]. *p<0.05.

Table 10: Total daily steps across all waking hours of one day in a free-living environment with the criterion of StepWatch steps (N=48). These data only reflect a subset of total participants that had valid data for both monitors; any participants who had missing data for one monitor or the other were excluded.

Placement	Step	n	Method	StepWatch	Mean	% SW	MAPE
Site	e count		$(Mean \pm SD)$	$(Mean \pm SD)$	Bias		(%)
	method						
	ApW*	45	$8,229 \pm 3,552$	$9,357 \pm 4,093$	-1,128	90.1	18.9
Wrist	GV*	45	$7,664 \pm 3,490$	$9,357 \pm 4,093$	-1,693	82.7	23.3

Mean: total daily steps. SD: standard deviation. Mean bias: (method estimate – StepWatch estimate). % SW: Percent of StepWatch steps: ((method estimate ÷ StepWatch estimate) • 100). MAPE: mean absolute percent error. Step count methods: Apple Watch Series 2 [ApW], Garmin vivofit 3 [GV]. *p<0.05. **p<0.01.

Table 11: Pearson Correlation Coefficients for step counting methods during one waking day.

	earson Correi	Non-Dominant Wrist					Hip						Thigh		
		StepWatch	Fitbit Alta	Garmin vivofit 3	Apple Watch2	9V	AGL	AGM	Omron HJ325	Fitbit Zip	Yamax SW200	V	V	AGM	activPAL
Ankle	StepWatch	1	.861	.866	.880	.804	.750	.791	.787	.902	.870	.868	.930	.829	.910
	Fitbit Alta		1			.781	.701	.915	.902	.881	.970	.903	.824	.929	.909
	Garmin vivofit 3			1	.963				.974	.979	.941	.991	.991	.986	.925
Non- Dominant	Apple Watch 2				1				.965	.971	.906	.989	.999	.981	.913
Wrist	AG					1	.950	.629	.980	.818	.721	.741	.866	.631	.897
	AGL						1	.552	.668	.563	.506	.676	.858	.570	.806
	AGM							1	.951	.843	.951	.930	.742	.903	.832
	Omron HJ325								1	.984	.971	.865	.712	.977	.891
	Fitbit Zip									1	.959	.982	.938	.966	.985
IIin	Yamax SW200										1	.971	.880	.993	.885
Hip	AG											1	.866	.924	.883
	AGL												1	.799	.912
	AGM													1	.822
Thigh	activPAL														1

Step counting methods: ActiGraph GT9X Normal Filter [AG], ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM].

FIGURES





Figure 1A: Wrist-worn monitors separated by pre-wrap worn on the non-dominant wrist. B: Hip-worn monitors worn on the right side on the waistband. Position A was located two cm right of the umbilicus. Position B was located in the mid-thigh. Position C was located in the anterior axillary line. Position D was located in the middle axillary line.

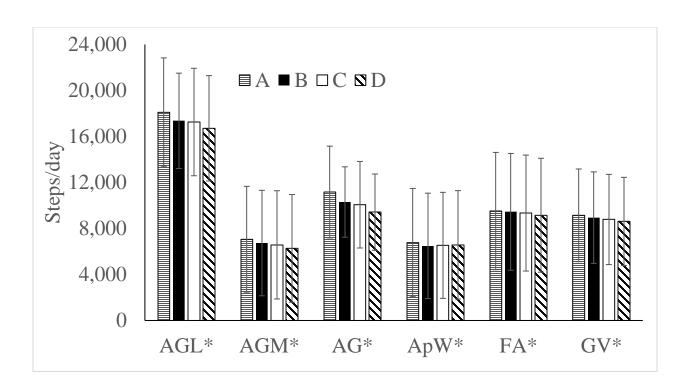


Figure 2: Steps/day from wrist-worn step count monitors worn adjacent to each other on the non-dominant wrist in position A (subsequent to the ulnar styloid process) and positions B-D (adjacent to previous monitors without directly touching). Mean \pm SD; steps/day. Step count methods: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Apple Watch 2 [ApW], Fitbit Alta [FA], Garmin Vivofit 3 [GV]. *p<0.05 denotes main effect for position.

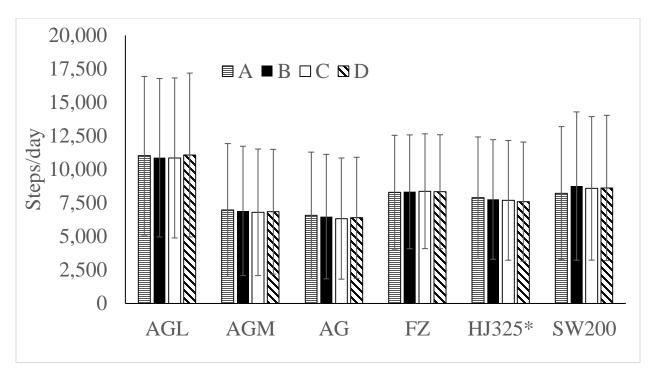


Figure 3: Steps/day from hip-worn step count monitors worn adjacent to each other on the right hip in position A (one inch right of the umbilicus), B (in line with the mid-clavicular line), C (in line with the anterior axillary line), and D (in line with the mid-axillary line). Mean \pm SD; steps/day. Step count methods: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Fitbit Zip [FZ], Omron HJ-325 [HJ325], Yamax Digiwalker [SW200]. *p<0.05 denotes main effect for position.

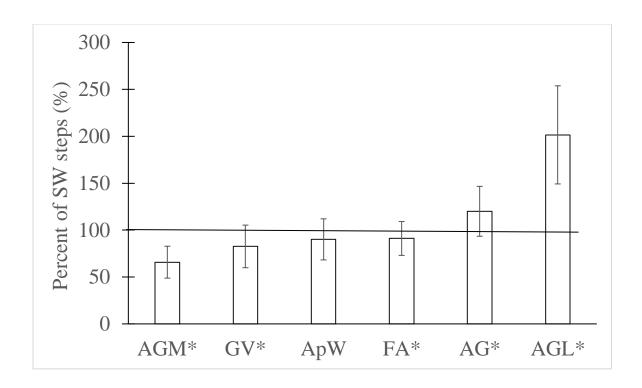


Figure 4: Percent of StepWatch steps: ((estimation method ÷ StepWatch) • 100%) for wrist step counting methods. Abbreviations are as follows: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Apple Watch Series 2 [ApW], Fitbit Alta [FA], Garmin vivofit 3 [GV]. *p<0.05.

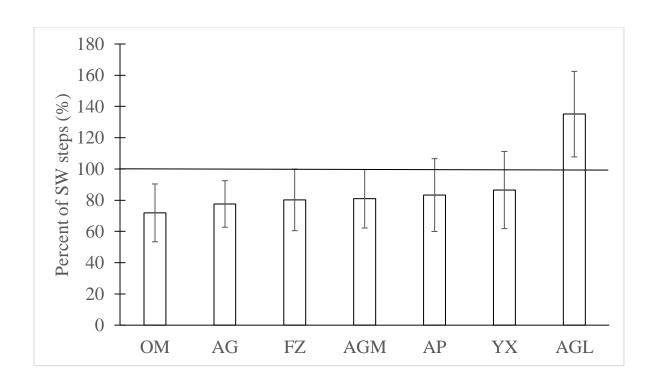


Figure 5: Percent of StepWatch steps: ((estimation method ÷ StepWatch) • 100%) for hip step counting methods. Abbreviations are as follows: ActiGraph GT9X Low Frequency Extension [AGL], ActiGraph GT9X Moving Average Vector Magnitude [AGM], ActiGraph GT9X Normal Filter [AG], Fitbit Zip [FZ], Omron HJ-325 [OM], Yamax Digiwalker [YX]. *p<0.05.

Figure 6: Correlation for wrist (A) and hip/thigh (B) step counting methods and StepWatch across all hours of one day.

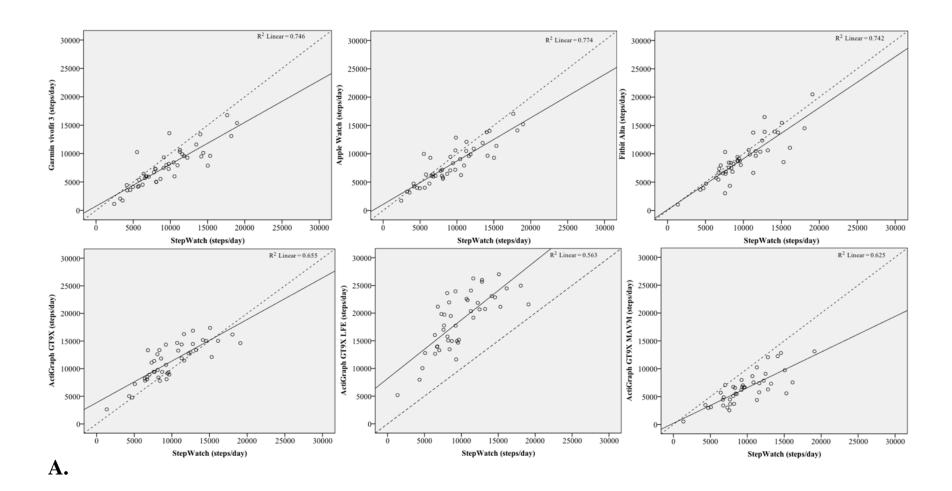
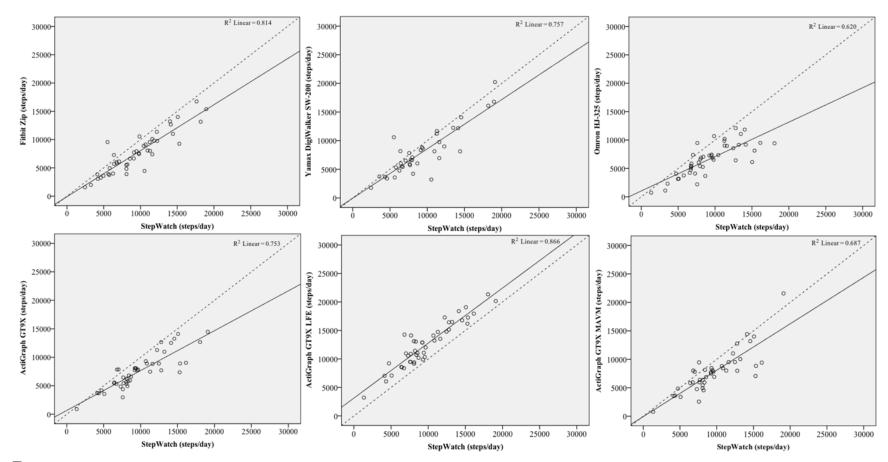


Figure 6 continued



B.

Figure 6 continued

Informed Consent

Project Title: Effects of Device Placement on Total Daily Step Counts

Investigators: Susan Park, BS

David R. Bassett, Jr. PhD

Address: The University of Tennessee; Department of Kinesiology, Recreation and Sports Studies

1914 Andy Holt Ave.; Knoxville, TN 37996

Telephone: (865) 974-5091 (Susan Park)

(865) 974-8766 (Dr. David Bassett)

Purpose

You are invited to participate in a research study at the University of Tennessee that compares total daily step counts obtained by activity monitors. The purpose of this study is to investigate the effects of monitor placement on step count accuracy.

Procedures

You will be asked to fill out the Physical Activity Readiness Questionnaire and Data Sheet. Your height and weight will be measured by a research assistant. Once this is completed, the researcher will show you how to wear several activity monitors, which will be worn for the next four days during waking hours except when showering, swimming, and sleeping. You should go about your normal daily routine while wearing the monitors. You will return all devices and the step counting recording sheet to the lab the day after the last day of wearing the monitors to return all the equipment.

Days 2-5:

- Upon waking, record the current time and step counts of each device in the Step Count Recording Sheet.
- Before going to bed, you will record the current time and step counts of each device in the Step Count Recording Sheet.

Monitors being worn by location:

Right Ankle:

StepWatch

Wrist:

- Garmin Vivofit 3
- ActiGraph GT9X
- Fitbit Alta
- Apple Watch 2

Hip:

- ActiGraph GT9X
- Omron HJ-325
- Yamax Digiwalker
- Fitbit Zip

Date:	
Participant Initials:	

IRB NUMBER: UTK IRB-17-04049-XP IRB EXPIRATION DATE: 11/26/2018

You will be wearing four of the same brand hip monitors and four of the same brand wrist monitors on a given day. On subsequent days, you will switch out to a different brand of hip and wrist monitor, and wear four new hip and wrist monitors. The StepWatch will be worn on all days.

Risks and Benefits

You are not asked to do any activity beyond your daily routine. There are no major risks of wearing activity monitors, but you may experience skin irritation due to prolonged rubbing/pressure from wearing the monitors. To minimize these risks, you will be instructed on how to properly clean the device. There are no direct benefits to you for participating in this study and there is no monetary compensation. Most research involves some risk to confidentiality. Although it is unlikely because of the precautions and procedures we use to protect your information, it is still possible that someone could find out that you were in the study or see information regarding your participation in the study.

Confidentiality

All information collected is considered confidential and no information will be collected or released without your written consent. The information collected from this study will be used in research reports and presentations but your name and other identifies will not be disclosed.

Contact Information

If you have any questions about the study before, during, or after participation, of if you experience any negative effects from participation, please contact Susan Park by phone (865) 974-5091 or by email at spark48@vols.utk.edu or Dr. David Bassett at (865) 974-8766 or by email at dbassett@utk.edu . If you have questions about your rights as a research participant, contact the University of Tennessee's Institutional Review Board at 865-974-7697 or utkirb@utk.edu.

Right to Ask Questions and to Withdraw You can participate in this study or not. You can withdraw from it at any time without penalty. If you decide to withdraw, your data will be destroyed.					
Consent Before you sign this form, please ask questions	about any aspects of the study that are un	clear to you.			
I have read the above information. I have receive	ved a copy of this form. I agree to particip:	ate in this study.			
Name (please print)	Signature	Date			
Investigator's Name (please print)	Signature	Date			

IRB NUMBER: UTK IRB-17-04049-XP IRB EXPIRATION DATE: 11/26/2018

Informed Consent

Project Title: Step Count Accuracy of 10 Wearable Devices in a Free-Living Environment

Investigators: Susan Park

David R. Bassett, Jr. PhD

Address: The University of Tennessee; Department of Kinesiology, Recreation and Sports Studies

1914 Andy Holt Ave.; Knoxville, TN 37996

Telephone: (865) 974-5091 (Susan Park)

(865) 974-8766 (Dr. David Bassett)

Purpose

You are invited to participate in a research study at the University of Tennessee that compares total daily step counts of activity monitors. The purpose of this study is to determine the accuracy of the step counters to measure steps taken over the course of one day.

Procedures

You will be asked to fill out the Physical Activity Readiness Questionnaire and Data Sheet. Your height and weight will be measured by a researcher.

If you are coming to the laboratory:

The researcher will show you how to place the monitors on your non-dominant wrist, right thigh, hip, and ankle. You will wear the monitors the following day during waking hours, except for during showering, sleeping, and swimming. Upon waking, record the current time and step counts of each monitor listed in the *Step Count Recording Sheet*. You should go about your normal daily routine while wearing the monitors. Before going to bed, you will remove all monitors and record the step counts and the current time on the *Step Count Recording Sheet*. You will be given an *Instruction Sheet* to help you put the monitors on.

If the researcher is coming to your home:

The researcher will show you how to place the monitors on your non-dominant wrist, thigh, and hip, in case you need to remove them at any time that day for bathing or swimming. You will also receive an *Instruction Sheet* to help you with putting the monitors on. The researcher will help you put on the activity monitors and then write the step counts for each device and the current time. The researcher will leave your home and you will go about your normal daily routine while wearing the monitors. The researcher will return to your home before you go to bed to record the step counts and the current time. The monitors will be returned to the researcher at this time.

Monitors being worn by location:

- Right Ankle: StepWatch
- o Non-dominant Wrist: Garmin Vivofit 3, ActiGraph GT9X, Fitbit Alta, Apple Watch 2
- Right Thigh: ActivPAL
- Hip: ActiGraph GT9X, Omron HJ-325, Yamax Digiwalker, Fitbit Zip

Initial:	
Date:	/

IRB NUMBER: UTK IRB-17-04161-XP IRB APPROVAL DATE: 01/08/2018 IRB EXPIRATION DATE: 01/07/2019

Risks and Benefits

This study does not require you to do any physical activity beyond your daily routine. There are no known risks of wearing the step-counting devices, however, you may experience possible minor skin irritation due to prolonged rubbing/wear of the devices. In order to minimize these risks, you will be given clean devices and be instructed on how to clean them in case they get wet. Most research involves the risk of loss of confidentiality. We use precautions and procedures to protect your information, however, it is still possible that someone could find out that you were in the study or see information regarding your participation in the study.

No direct benefits or monetary compensation will be gained from participating in the study. The information that is obtained may provide additional insight into improving step count accuracy in the free-living environment.

Confidentiality

All information collected is confidential and no information will be collected or released without your written consent. The information collected from this study will be used in research reports and presentations, but your name and other identifies will not be disclosed.

Contact Information

If you have any questions about the study before, during, or after participation, or if you experience any negative effects from participation, please contact Susan Park by phone (865) 974-5091 or email at spark48@vols.utk.edu or Dr. David Bassett at (865) 974-8766 or email at dbassett@utk.edu. If you have questions about your rights as a research participant, contact the University of Tennessee's Institutional Review Board at 896-974-7697 or utkirb@utk.edu.

You can participate in this study or not. You can withdraw from it at any time without penalty. If you decide

Right to Ask Questions and to Withdraw

to withdraw, your data will be destroyed		
<u>Consent</u> Before you sign this form, please ask quo	estions about any aspects of the stu	dy that are unclear to you.
I have read the above information. I hav	e received a copy of this form. I ag	ree to participate in this study.
Name (please print)	Signature	/
Investigator's Name (please print)	Signature	/

IRB NUMBER: UTK IRB-17-04161-XP IRB APPROVAL DATE: 01/08/2018 IRB EXPIRATION DATE: 01/07/2019 Physical Activity Readiness Questionnaire - PAR-Q (revised 2002)

PAR-Q & YOU

(A Questionnaire for People Aged 15 to 69)

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best quide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES	NO		
		1.	Has your doctor ever said that you have a heart condition <u>and</u> that you should only do physical activity recommended by a doctor?
		2.	Do you feel pain in your chest when you do physical activity?
		3.	In the past month, have you had chest pain when you were not doing physical activity?
		4.	Do you lose your balance because of dizziness or do you ever lose consciousness?
		5.	Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?
		6.	Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?
		7.	Do you know of <u>any other reason</u> why you should not do physical activity?
lf			YES to one or more questions
			Talk with your daster by phone or in parson DECODE you start becoming much more physically active or DECODE, you have a fitness appraisal. Talk

you

answered

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want as long as you start slowly and build up gradually. Or, you may need to restrict your activities to
 those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her advice.
- · Find out which community programs are safe and helpful for you.

NO to all questions

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal this is an excellent way to determine your basic fitness so
 that you can plan the best way for you to live actively. It is also highly recommended that you
 have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor
 before you start becoming much more physically active.

DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever — wait until you feel better; or
- if you are or may be pregnant talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q: The Canadian Society for Exercise Physiology, Health Canada, and their agents assume no liability for persons who undertake physical activity, and if in doubt after completing this questionnaire, consult your doctor prior to physical activity.

No changes permitted. You are encouraged to photocopy the PAR-Q but only if you use the entire form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity program or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

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Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions.





continued on other side...

VITA

Susan Park was born on January 11, 1994 to Jay and Mihi Park. She grew up in several cities throughout Tennessee, but spent most of her life in Brentwood. Susan completed a Bachelor's of Science degree in Education from the University of Tennessee-Knoxville in May 2016 and a Master's of Science degree, with a concentration in Exercise Physiology, in May 2018. She will enroll at The University of Massachusetts-Amherst as a doctoral candidate in - Epidemiology with a concentration in Biostatistics and Physical Activity and Women's Health in August 2018. Susan intends to further her career by applying her foundational knowledge gained from her time at the University of Tennessee to her future research with the application of activity monitors in gestational diabetes research.