Comparison of Dual- and Tri-Axial Accelerometer Accuracy

Lindsay Powell Toth
Western Michigan University, lindsay.p.toth@gmail.com

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COMPARISON OF DUAL- AND TRI-AXIAL ACCELEROMETER ACCURACY

by

Lindsay Powell Toth

A thesis submitted to the Graduate College
in partial fulfillment of the requirements
for the Degree of Master of Science in Exercise Physiology
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Thesis Committee:

Timothy Michael, Ph.D., Chair
Carol Weideman, Ph.D.
Michael Miller, Ph.D.
The purpose of this study was to investigate the accuracy of the Omron HJ-720ITC and the Fitbit Zip activity monitors with regard to step count, energy expenditure, and distance traveled measurements. The importance of this research rests in the success rates of pedometer-based physical activity interventions which have been shown to increase physical activity while also enabling weight loss and lowering blood pressure in the adult population. Activity monitors available for retail sale must be found accurate for proper participation in exercise interventions especially low-cost devices as used in this study.

In order to test the accuracy of the Omron and Fitbit, participants walked on a treadmill at four randomized speeds (67, 80, 93, and 107 m·min⁻¹) while wearing the activity monitors on opposing hips. The device outputs of step count, energy expenditure, and distance ambulated were compared with criterion measurements.

The results of this study show both devices are accurate with regard to step count and could be used interchangeably. Energy expenditure data revealed a large discrepancy between both devices and the criterion measurement with the most accuracy occurring with the Omron at 67 and 80 m·min⁻¹. Finally, both devices shared the trend of overestimating distance ambulated at speeds below 80 m·min⁻¹ and underestimating distance at speeds above 94 m·min⁻¹ with better accuracy between 80 and 90 m·min⁻¹.
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INTRODUCTION

Physical activity has been shown to positively influence cognitive function, mental health status, and physical health and well-being. Current and regular participation in exercise reduces the risk of cardiovascular disease, type II diabetes, obesity, stroke, multiple types of cancer, and all-cause mortality (Pescatello, Arena, Riebe, and Thompson, 2014). Although the complete list of benefits continues, data from surveys administered by the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, shows only 64.5% of adults are physically active and 25.4% reported no leisure time physical activity (Centers for Disease Control and Prevention, 2010) with further information revealing only 48% of adults meet the physical activity guidelines published by the American College of Sports Medicine (ACSM) and the American Heart Association (AHA) (Centers for Disease Control and Prevention, 2014).

The ACSM/AHA guidelines state 30 minutes of moderate intensity cardiovascular exercise on five or more days per week positively influences overall health; additional exercise time or increased intensity provides supplementary health related benefits. These guidelines cite walking as a moderate intensity, functional exercise which is commonly accessible and cost-friendly for most adults. It can satisfy the minimum level of suggested physical activity and has been shown to be an effective tool for combating physical inactivity especially when paired with pedometer based exercise interventions (Owen et al, 2011; Tudor-Locke and Lutes, 2009; U.S. Department of Health and Human Services, 2008). The benefits of walking and tracking steps is not a newly developed concept but has a rich history which has evolved over time to offer substantiated walking goals with valid measurement devices.
Measurement of walking has been the main focus of pedometers and activity monitors since their invention by Leonardo DaVinci. Although the purpose for the pedometer was measuring distance walked for creating maps, this invention has since transformed into a step-counting, health promotion device. The first health promotion use of the pedometer was the Manpo-Kei thought of 10,000 steps per day, and currently has blossomed into more specific areas of personal health tracking such as energy expenditure, total distance traveled, sleep quality, grams of fat expended, flights of stairs climbed, and so on while retaining accuracy of step count (Tudor-Locke, 2003).

The history of steps per day recommendations began in the mid-1960’s with Manpo-Kei, a Japanese pedometer model and walking theory, which swept Japan and was met with an overwhelming response so much as to instill a walking tradition. Manpo-Kei, itself, means ten-thousand steps meter, thus, beginning the 10,000 steps per day recommendation (Tudor-Locke, 2003). As the pedometer and walking recommendation spread beyond Japan, research seeking the optimum steps per day proliferated, leaving the classic step recommendation as a building block which has been augmented to fit the needs of special populations such as children, older adults, and those with chronic disease (Adams, et al, 2009; Tudor-Locke and Bassett, 2004; Tudor-Locke, Lutes, et al, 2011; Tudor-Locke, Mutrie, et al, 2011; Tudor-Locke, Raustrop, et al, 2011). Although the physical activity recommendations of today are predominately time and intensity based, the drive to use pedometers remains. Not only have researchers developed translations of intensity based physical activity guidelines into step per time period goals (Adams et al, 2013; Marshall et al, 2009) but developers have also updated
and enhanced pedometer technology to monitor and record additional physical activity data.

Due to the spread of information on the importance of regular physical activity and the push to quantify more aspects of personal health, consumers demand for higher performing activity monitors has influenced the technological advancement of pedometers beyond basic step count. Pedometers have evolved from basic spring-lever devices capable only of counting steps to tri-axial accelerometers able to detect movement in three dimensions, estimate energy expenditure, and distance traveled while improving accuracy for step count (Bouten et al, 1994; Crouter et al, 2003). The classic spring-lever pedometer is worn on the waistband and counts steps when the spring-suspended horizontal lever arm is displaced from its resting position due to the force of the user’s foot as it strikes the ground. The lever swings above and below the resting angle which opens and closes an electronic circuit, thereby, counting steps. Because the horizontal lever arm only responds to the vertical displacement of the hips, this device is considered uni-axial.

The uni-axial nature of classic pedometers creates several limitations. In the event the pedometer rotationally shifts beyond its vertical placement on the waistband, step count data will be inaccurately recorded because the device is unable to read motion when in any other position. This limitation invites user error as the pedometer must be secured to the waistband vertically and placed on the correct area of the hip. It must also be fixed securely to a tight waistband to prevent rotation of the device during ambulation (Crouter et al, 2003; Giannakidou et al, 2012). Also, according to Melanson et al (2004), a major downfall of spring-lever pedometers lies in step count inaccuracy during walking...
speeds below 80.47 m·min\(^{-1}\). Slower walking speeds exhibited by the elderly, obese, and chronic disease populations do not impart sufficient force on the lever-arm with each step, therefore, the device does not display an accurate step count. The use of piezoelectric accelerometers is suggested for increased accuracy in slower walking individuals due to their heightened sensitivity to movement.

Activity monitors such as the Omron HJ-720ITC collect data via two piezoelectric accelerometers; one in the vertical and one in the horizontal plane. This form of accelerometer functions when force from foot strike and acceleration of the body places strain on the piezoelectric crystals that lie within the accelerometers. Data from the movement of the crystals is interpreted into step count, energy expenditure, and distance traveled using algorithms in the small processing unit of the device. Because piezoelectric activity monitors are more sensitive to force than spring lever devices, they are able to more accurately count steps for speeds of 80.47 m·min\(^{-1}\) and below, which in spring lever pedometers has been shown to produce inaccurate readings. Finally, the dual-axis accelerometer can read motion in two planes providing more options for affixing the device to the body and allows for rotation of the device without a loss in accuracy (Crouter et al, 2003; Le Masurier and Tudor-Locke, 2003).

One of the most recent technological advances in accelerometers has been the application of micro-electro-mechanical (MEMS) accelerometers to analyze movement. MEMS accelerometers, as seen in the Fitbit Zip, have the ability to track strain or acceleration in three dimensions, potentially providing increased sensitivity (Mannion, 2012). Data collected by the tri-axial Fitbit is meshed with proprietary algorithms in the device’s small central processing unit to produce step count, resting energy expenditure,
energy expenditure during exercise, aerobic step count, and distance traveled. Takacs et al (2013) concluded the tri-axial accelerometer used in the Fitbit One, a similar product to the Fitibit Zip, to be valid and reliable device for measuring step count, but not accurate, for distance estimation at all walking speeds utilized in the study (90, 112, 133, 154, and 178 m·min⁻¹). The accuracy of the Fitbit algorithm for energy expenditure is questionable as recent studies have reported the Fitbit Tracker and the Fitbit Ultra underestimate energy expenditure during physical activity (Dannecker et al, 2013; Gusmer et al, 2014).

Previous pedometer and activity monitor research shows uni-, dual-, and tri-axial devices, to most accurately measure step count, less accurately estimate distance traveled, and least accurately estimate energy expenditure (Crouter et al, 2003; Dannecker et al, 2013; Giannakidou et al, 2012; Gusmer et al, 2014; Hasson et al, 2009; Melanson et al, 2004; Swartz et al, 2009). As mentioned earlier, dual- and tri-axial piezoelectric activity monitors are most accurate for step count because they are more sensitive to smaller amounts of force. The increased sensitivity is important when monitoring steps of an individual who walks slowly or has a shuffling gait (Melanson et al, 2004). Accurately monitoring steps is not only important for research goals of tracking physical activity, but also plays a key role in meeting steps-per-day goals, participating in walking exercise interventions, or simply to assist individuals in satisfying the ACSM/AHA physical activity recommendations.

The importance of accuracy is magnified when activity monitors are used in weight loss interventions and in physical activity research. Those who use the energy expenditure output from an activity monitor must be able to trust its validity and accuracy
in order to either create the energy deficit necessary to cause weight loss or accurately track caloric expenditure of exercise interventions. Kashiwazaki et al (1986) studied the correlations of energy expenditure in activity monitors during free-living activities of clerical and assembly workers. The results of this study show the highest correlation of net energy expenditure and activity monitor estimated expenditure to be clerical workers while at work and clerical and assembly workers while commuting to and from work. This finding highlights the accuracy of activity monitors’ estimation of energy expenditure for walking activities only.

The measured net energy expenditure of the assembly line workers was greater than the sedentary clerical workers was suggested to be because the assembly individuals performed more movement throughout the day. Movements involved with assembly are much more diverse than clerical workers in that assembly workers lift objects, move their arms, and walk with unusual gait as necessary for their job while clerical workers mainly sit at a desk and walk short distances in the office. Researchers concluded the disparity between measured and activity monitor estimated energy expenditure was a result of the inability of the activity monitor to record upper and lower body movements which did not create a sufficient amount of force on the device and these movements usually did not include normal walking gait. The high correlation of measured and device estimated energy expenditure of the clerical workers was related to their steady walking gait and speed such as walking to meetings, offices, and the like during regular office work. As there were minimal kilocalories expended from other movements, the device estimate showed higher correlation to the actual measurement for energy expenditure. Finally, the accuracy of the device also is evident from the high correlation of measured and devices
estimated expenditure during commuting to and from work which for both groups involved walking.

Recent research compared uni-axial and piezoelectric accelerometers energy expenditure estimation capabilities over a varied list of activities. The results show similar responses in that the devices are most accurate for moderate walking and jogging activities, but vigorous running and other endeavors (basketball, filing papers, mopping) all exhibit varying counts of less accurate estimations. Crouter et al (2006) concluded the accuracy of specific accelerometers lies within the manufacturer’s equation choice which is commonly based on accurately predicting energy expenditure for moderate intensity walking.

Although activity monitors are becoming more technologically advanced, research reveals their highest accuracy in step count, energy expenditure, and distance traveled remains in the original type of physical activity which these devices were used: walking. Walking is a very common, easily accessed, and virtually cost free exercise for most adults, it has been deemed a sufficient activity to satisfy physical activity recommendations and combat obesity, and, finally, has been a very successful activity in exercise interventions especially those that are pedometer based (Owen et al, 2011; Tudor-Locke and Lutes, 2009). Because individuals rely on activity monitors for varying reasons, these devices must be accurate and reliable as to allow users to properly track personal activity status and to fulfill personal activity goals.

Downfalls of previous activity monitors include inaccuracies in step count at slow speeds, error related to improper placement of the device, and variable accuracy of energy expenditure output, therefore, the purpose of this study was to compare
measurements of the dual-axial Omron HJ-720ITC, tri-axial Fitbit Zip, metabolic cart measured energy expenditure, hand counted steps, and calculated distance traveled to assess device performance. Very little information and research about the Fitbit Zip is available, therefore, emphasizing the importance of this study. Generally, the Fitbit is a comparable device to the Omron with regard to its basic capabilities of providing step count, energy expenditure, and distance traveled information. The Fitbit offers updated accelerometer technology, more options for social media interaction, and a smaller size, but the accuracy remains unknown, therefore, the Fitbit must be assessed against the previously researched Omron. The Omron has been deemed accurate for step count but, like many other activity monitors, has been found to underestimate energy expenditure during walking (Giannakidou et al, 2012). In this study devices were worn on opposing hips of subjects while walking on a treadmill at four speeds (67, 80, 94, and 107 m·min⁻¹) for a duration of 5 minutes at each speed. Other data collection included resting and activity energy expenditure and hand tallied steps; distance walked on the treadmill was calculated using the equation speed multiplied by walking time.
METHODS

Subjects

Twenty four recreationally active individuals (13 male; 11 female) recruited from the Western Michigan University Student Recreation Center (SRC) participated in this study approved by the Human Subject Institutional Review Board at Western Michigan University. All participants provided informed consent and completed both the AHA/ACSM Health Fitness Facility Pre-participation screening questionnaire and the Lower Leg Injury Questionnaire (appendix A, B, C) before being accepted into the study. The AHA/ACSM Health Fitness Facility Pre-participation screening questionnaire was used to ensure the participant fell in the low risk range for cardiovascular disease and was not physically inactive. The lower body injury assessment questionnaire precluded participants who had lower body abnormalities or injury which would confound treadmill walking safety.

Participation was limited to individuals classified as low risk for cardiovascular disease according to the American College of Sports Medicine. Men from 18 to 45 years of age and women 18 to 55 years of age (Pescatello et al, 2014) with no: 1) lower body musculoskeletal/orthopedic injury within the past 6 months or a condition which would prevent treadmill walking, 2) were free of cardiovascular, respiratory, and metabolic diseases, and 3) were within the normal or overweight BMI ranges based on height and weight (Pi-Sunyer et al, 1998). Descriptive characteristics of subjects are located in Table 1.
Table 1. Descriptive Characteristics of Subjects (N=24)

<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>22.92 ± 4.58</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>172.98 ± 10.42</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>72.32 ± 12.65</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24.10 ± 3.19</td>
</tr>
</tbody>
</table>

Abbreviation: BMI, body mass index

Study Design

Each subject attended a total of three meetings: an informational meeting; assessment of resting metabolic rate; and walking trials. All height, weight, resting metabolic rate, and walking trial measurements were performed in the Western Michigan University Human Performance Laboratory.

Informational Meeting

The informational meeting included a detailed description of the study, expectations of voluntary participation, an opportunity to address questions, measurement of height and weight, and completion of an informed consent document and two questionnaires. Following the verbal description of the study and participant expectations, informed consent was verbally explained during which ample time was provided for potential participant questions. If the individual agreed to the terms of the study, he or she then signed the informed consent document. The session concluded with the potential participants completing the AHA/ACSM Health Fitness Facility Pre-participation screening questionnaire, the Lower Leg Injury Questionnaire, and measurement of height (cm) with a standard standiometer and weight (kg) with an electric scale.
Following the first meeting, the student investigator reviewed the completed questionnaires. Participants who fell within the predetermined cardiovascular risk, recreational activity, and body mass index ranges were accepted into the study and contacted to schedule the resting metabolic rate assessment.

*Resting Metabolic Rate Assessment*

Resting metabolic rate (RMR) and stride length were both measured during the second meeting. RMR was determined via indirect calorimetry using the SensorMedics (Vmax 229, SensorMedics, Yorba Linda, CA) metabolic cart. This measurement occurred between the hours of 6am and 9am following an overnight fast with the request that participants refrain from stimulants (coffee, nicotine, etc.) and exercise the morning of the assessment.

When the participants arrived at the lab they were immediately fitted with headgear for breath-by-breath analysis and then asked to lie supine on a padded lab table. The participants were directed to relax (without sleeping) and remain still for the following 45 minutes. During the RMR assessment the lab was general room temperature, lights were dimmed, and no extraneous noises were present. The subjects were not permitted to listen to any music or other audio materials once their assessment began.

For data collection purposes, the 45 minute rest was divided into two segments. The first 30 minutes was to allow participants to adapt to the environment and headgear and provide time for his or her body to return to resting metabolic rate. During this time no data was collected. Oxygen consumption data was collected during the last 15 minutes and averaged for output in 20 second intervals. The metabolic cart converted gas exchange data to resting energy expenditure (kilocalories) which was later averaged
every 60 seconds to determine measured RMR for later comparison to the Fitbit RMR prediction equation.

The Fitbit is programmed to use the MD Mifflin-St. Jeor equation for estimating basal metabolic rate (BMR). The user must create a Fitbit account by inputing height, weight, and age to the web-based system, then must sync the device to the account to enable the personalized energy expenditure output. When an individual performs physical activity, the device is programmed to add physical activity energy expenditure to the resting energy expenditure. The algorithm for energy expenditure during physical activity remains unknown (Fitbit, nd). Because this study is concerned with exercise energy expenditure, the Mifflin-St. Jeor equation was used to determine BMR for each 5 minute trial for later data analysis.

Following the RMR assessment, stride length was measured using the method suggested by the Omron users manual. On a large, flat, obstacle free, indoor floor, the participants were instructed to place the most distal part of their shoe’s toe box on a taped line then walk forward at a comfortable pace until instructed to stop. The student investigator counted 10 continuous strides then placed a second marker on the floor, again, near the subject’s most distal part of the toe box. The distance between the two markers was measured and divided by 10 to determine stride length. This information was recorded and later programmed into the subjects corresponding Omron.

Upon completion of the RMR session, one Fitbit and one Omron were prepared for the subject’s subsequent walking trial. The Fitbit was programmed with the subject’s date of birth, height, weight, and gender via the Fitbit web-based software (www.fitbit.com/start). Weight and stride length were manually entered into the Omron.
The information entered allowed the devices to provide personalized estimated outputs of distance traveled and energy expended. Each participant was provided with a new device to prevent any data error or cross-over from previous use. To prevent errors, each device was labeled with a subject specific four character code which was also used in place of the subjects name on the metabolic cart and in the Fitbit web-based software to maintain confidentiality.

**Fitbit Zip**

The Fitbit Zip (San Francisco, CA) is a clip-on activity monitor. It measures 35.5mm in height, 28mm in width, 9.65mm in depth and has a weigh of 8 grams. This small device uses a MEMS tri-axial accelerometer that detects motion in three orthogonal planes and processes data using a 16 bit microcontroller and proprietary algorithms to provide step count, distance traveled, and calories burned. The Zip has a memory allowing it to hold 7 days of minute-by-minute activity data with the previous 23 days of averaged step, calorie, and distance information. Finally, activity information can be wirelessly synced to the Fitbit web interface by Bluetooth directly to a mobile device or via the wireless dongle for use with a PC. The Fitbit web interface allows for social interaction, goal setting, as well as private data collection and viewing.

**Omron HJ-720ITC**

The Omron HJ720-ITC (Omron Healthcare Co, LTD., Kyoto, Japan) is a clip-on piezoelectric activity monitor. This device uses a dual-axial accelerometer which allows for detection of motion in the horizontal and vertical planes. The small processing unit provides the user with step count, aerobic step count, duration of aerobic walking, energy expenditure, grams of fat burned, and walking distance. The dimensions of the Omron are 47mm in width, 73mm in height, and 16mm in depth and with the battery included, it
weighs 37 grams. Forty-one days worth of activity data can be stored in the device with the most recent 7 days available for viewing. This device offers USB wired connectivity for purposes of downloading data to the Omron healthcare software. The Omron healthcare software allows for tracking of multiple individuals’ physical activity information in one central location which is useful in the healthcare setting. This platform can also be used for personal monitoring, goal setting, and data collection.

**Trial Protocol**

During the final lab meeting participants performed the treadmill walking trials while wearing the devices. When subjects entered the lab, they were first given a brief review of the trial protocol, then the Fitbit and Omron were fixed to the waistband of the subjects clothing. The devices were placed on opposing hips in the area of the anterior superior iliac spine. Crouter et al. (2003) found a high correlation in step count data between accelerometers placed on the right and left hips, therefore, error between devices worn on opposing hips is minimal. The devices were placed on the anterior hip which has been repeatedly shown as a site that produced small step count error (Hasson et al., 2009; Park et al., 2014).

After both devices were affixed, each participant was provided with a six minute treadmill acclimation bout (Quinton Q65 Series 90, Quinton Instrument Company, Seattle, WA) equating to 1.5 to 2 minutes per speed (67, 80, 94, and 107 m·min⁻¹). During the acclimation bout the subjects were also familiarized with stepping onto and off of the moving treadmill belt at each speed. For reasons of consistency between subjects, all acclimation bouts progressed in the following pattern: 67, 80, 94, and 107 m·min⁻¹.
Following the treadmill acclimation, each device was checked to ensure step number increased and the units were functioning properly. The subjects were then fitted with equipment for breath-by-breath analysis after which the walking trials began. Each of the four walking trials lasted five minutes in duration, were randomized for speed, and separated by a three minute rest (Crouter et al, 2003, De Cocker et al, 2012, Giannakidou et al, 2012, Swartz et al, 2009).

*Treadmill Protocol*

To begin each treadmill trial, subjects were directed to straddle the treadmill belt and remain still. Before beginning the actual trials, the student investigator collected step count, energy expenditure, and distance information from both accelerometers and recorded the information on the data collection form under the heading “@ start”. After the primary data collection of the start information, the treadmill was brought to the first of four randomized speeds and upon direction from the investigator the subject stepped onto the belt and began walking. At this time the breath-by-breath analysis and hand count were initiated as well.

Each walking trial lasted five minutes and was ended by the direction to step off, straddle the treadmill belt, and remain still. At this time the breath-by-breath analysis and hand count also stopped. Start and stop directions were necessary as they allowed for an accurate oxygen consumption measurement and step count. The investigator used a hand tally counter (Cosco Industries, Harwood Heights, IL) to measure step count and the SensorMedics metabolic cart was used to measure energy expenditure.

After each 5 minute walking segment, step count, energy expenditure, and distance traveled from each activity monitor as well as hand tally step count were recorded on data collection forms (appendix D). Energy expenditure output from the
metabolic cart was printed and kept for later data analysis. Each trial was separated by a three minute break, thus providing time for data retrieval.

Statistics

Two-way repeated measures analysis of variance (ANOVA) was used to analyze the devices (Fitbit, Omron, actual measurement) across four speed conditions (67, 80, 94, and 107 m·min\(^{-1}\)) for the factors of step count, energy expenditure, and distance traveled. If a significant main effect was found then a post-hoc analysis using a T-Test was conducted with Bonferroni adjustment. Significant interactions were investigated via a Tukey test to seek significantly different means in all pairwise comparisons. An alpha level of \(P \leq 0.05\) denoted statistical significance. The SPSS statistical package V. 19.0.0 (SPSS Inc., Chicago, IL) was used for data analysis.
RESULTS

Step Count

No significant interaction was found between speed and device or main effect for device. However, the main effect of speed was significant, $F(3, 69) = 202.06, p < 0.01$, (Figure 1). Results indicated that regardless of step count method, the number of steps increased per walking speed.

Figure 1. Step count (mean ± SE) per speed during 5 minute treadmill walking trials.
Energy Expenditure

A significant interaction for speed and device on energy expenditure was identified, $F(6, 138) = 21.57, p < 0.01$. At speed 1 (67.07 m·min$^{-1}$), Tukey post hoc test revealed that the Fitbit ($M = 36.5, SE = 1.14$) was significantly different from both the metabolic cart ($M = 17.3, SE = 0.8$) and the Omron ($M = 18.3, SE = 0.8$). At speed 2 (80.47 m·min$^{-1}$), the Fitbit ($M = 39.9, SE = 1.2$) was significantly different from both the metabolic cart ($M = 20.1, SE = 0.8$) and the Omron ($M = 20.9, SE = 1.1$) measurements. Post hoc testing for speed 3 (93.88 m·min$^{-1}$) revealed the Fitbit ($M = 43.1, SE = 1.9$), Omron ($M = 21.8, SE = 1.1$), and metabolic cart ($M = 25.0, SE = 1.1$) were all significantly different. And again at speed 4 (107.29 m·min$^{-1}$) the Fitbit ($M = 44.2, SE = 1.4$), Omron ($M = 23.5, SE = 1.2$), metabolic cart ($M = 31.0, SE = 1.2$) were all significantly different (Figure 2).
Distance Traveled

For the factor of distance, a significant interaction for speed and device was found, $F(6, 138) = 44.06, p < 0.01$. At speed 1 Tukey post hoc test revealed that the Fitbit ($M = 383.6, SE = 6.1$) was significantly different from the actual distance ($M = 338.0, SE = 0.0$) while the Omron ($M = 387.6, SE = 9.7$) showed no difference. At speed 2 the Fitbit ($M = 417.1, SE = 5.3$) was found to be significantly different from the actual distance ($M = 402.3, SE = 0.0$) while the Omron ($M = 417.8, SE = 11.6$) showed no difference. The Omron ($M = 436.5, SE = 10.4$) was significantly difference from the actual distance ($M = 466.7, SE = 0.0$) while the Fitbit ($M = 449.9, SE = 9.3$) showed no
difference at speed 3. Finally, speed 4 post hoc testing revealed that the Fitbit ($M = 498.2, SE = 10.5$); Omron ($M = 462.0, SE = 10.5$); and actual distance ($M = 531.1, SE = 0.0$) were all significantly different (Figure 3).

Figure 3. Distance walked (mean ± SE) during 5 minute trial at each speed. † Omron and Actual significantly different; ‡ Fitbit and Actual significantly different.
DISCUSSION

The purpose of this study was to investigate the accuracy and any potential measurement differences between dual- and tri-axial activity monitors, the Omron HJ-720ITC and Fitbit Zip, respectively. The device outputs of step count, energy expenditure, and distance traveled were compared to criterion measurements of hand tally step count, breath-by-breath metabolic cart analysis, and actual distance traveled during treadmill walking trials for the purpose of seeking device accuracy. Inter-device comparisons were completed to investigate any differences between dual- and tri-axial accelerometer measurement capabilities.

The importance of this study is exemplified by the success of pedometer-based physical activity interventions. Research reviews completed by Tudor-Locke and Lutes (2009) and Kang et. al (2009) both concluded the application of pedometers to physical activity interventions proved to be successful by increasing overall physical activity and enabling other positive health outcomes such as weight loss and decreased blood pressure, all of which are imperative in this time of increasing sedentarism and rising obesity rates.

Tudor-Locke and Lutes (2009) researched the effectiveness of pedometer-based physical activity interventions and developed a list of participant, program design, and device characteristics which foster success in these interventions. Both devices in the current study satisfy several device characteristics such as affordability, ease of use, clarity of information displayed on the device, and ample memory both on the device and on a software or web-based program. It must be noted social support and motivation are additional program characteristics which are provided by the Fitbit Zip used in the
current study. It is the focus of this study to determine the accuracy, arguably the most important device characteristic, of the chosen activity monitors.

Previous researchers have compared the accuracy of research grade activity monitors to commercially available products and have found similarities in step count accuracy, but diverging results for distance traveled with even greater discrepancies in energy expenditure estimation. Research grade devices provide the most accurate and unintrusive form of activity tracking, but remain to be cost prohibitive (Dannecker et. al, 2013; Ginnakidou et. al, 2012; Gusmer et. al, 2014; Noah et. al, 2013). The importance of this study lies in investigating the accuracy of lower cost activity monitoring devices which are available for consumer purchase so as to provide greater access to health promoting tools. Although these devices are equipped with technology which allows them to more accurately assess step count, the energy expenditure and distance traveled estimates have previously been shown to be inaccurate in the Omron HJ-720ITC (Giannakidou et. al, 2012) and remain unknown for the Fitbit Zip.

A study completed by Melanson et. al (2004) compared step count of the basic spring-lever pedometer to that of activity monitors designed with piezoelectric accelerometers. The authors concluded spring-lever pedometers are only accurate at speeds above 80 m·min⁻¹. Walking speeds of 80 m·min⁻¹ and slower do not allow the hips to create sufficient vertical acceleration as to trigger a response from the spring-lever mechanism (Crouter et. al, 2003; Giannakidou et. al, 2012). Increased waist circumference associated with obesity proved to be a secondary source of error as it caused excessive pedometer tilt. When affixed to the waist, the excessive central adiposity tilted the pedometer to such an extent which disabled the spring-lever
mechanism from properly functioning (Crouter et. al, 2005). When these populations were provided with piezoelectric activity monitors, step count accuracy was restored. As the need to track physical activity of the elderly, obese, and chronic disease populations remains, it is known piezoelectric activity monitors have heightened sensitivity and more accurately report step count than the basic spring-lever devices for those who walk 80 m·min$^{-1}$ and slower.

The uni-axial piezoelectric activity monitors were shown to accurately count steps for a wider range of walking speeds and function properly for all body types, but because these devices were limited to a single axis, they had to remain in the vertical position on the waist to accurately count steps. More recent products include a second axis which tracks movement in the horizontal plane. Dual-axial devices enable individuals to mount the device vertically or horizontally on the waistband and also provide additional mounting options such as in the left or right pockets or on the back-pack strap for individuals looking for a more covert activity monitor location. In a study by Holbrook et. al (2009), two piezoelectric Omron pedometers, the uni-axial HJ-151 to the dual-axial HJ-720ITC, were compared. Both devices were found to accurately count steps at all walking speeds and mounting locations investigated in the study except for the dual-axial monitor in the back-pack strap location, which was only slightly outside the industry standard acceptable rage of accuracy. Overall, the dual-axial device has been shown to be an accurate and reliable product, with more mounting options, better memory, and PC connectivity for tracking daily and long term activity data.

The findings of Holbrook et. al (2009), DeCocker et. al (2012), Hasson et. al (2009), Giannakidou et. al (2012), Crouter et. al (2003), and Melanson et. al (2004),
report dual-axial piezoelectric activity monitors to be highly accurate with regard to step count. The previous results parallel that of the current research, which found the Omron HJ-720ITC to accurately count steps as compared to hand count at all walking speeds included in the study. No significant difference was found between the Omron and hand count, and all percent relative error was well within the industry standard of three percent.

Newer products on the market, such as the Fitbit, include tri-axial piezoelectric accelerometers. Tri-axial devices allow motion detection in three orthogonal planes which was thought to more accurately collect more movement data than the previous dual-axial devices and thus provide more precise results. No research is yet available on the Fitbit Zip, the lowest-cost Fitbit model, but findings of Park et. al (2014), Gusmer et. al (2014), Noah et. al (2013), and Takacs et. al (2013) report step count accuracy well above industry standards in other Fitbit devices. The current study also found no significant difference between device and hand count, thereby, supporting the previous findings of accurate step count in tri-axial activity monitors. In fact, when compared to the Omron, the Fitbit resulted in smaller percent relative error at all four speeds. The main effect of speed was significant, showing both devices capability to differentiate between walking speeds.

The second factor investigated in this study was estimation of energy expenditure. Energy expenditure is found by an algorithm which meshes user information, and may include age, sex, height, and weight, with activity data. Caloric feedback greatly benefits individuals who are attempting to lose weight as the on-screen view of caloric expenditure can easily be used to create a daily calorie deficit, thus, facilitating weight
loss (Swartz et. al, 2009). However, previous results of inaccurate caloric expenditure in several activity monitors warrants further investigation.

The Omron monitor provides users with an estimate of kilocalories expended during exercise only. When compared to the criterion measurement of a metabolic cart, older Omron models, the HJ-105 and HJ-700IT, were found to significantly overestimate caloric expenditure in slower treadmill walking speeds, but approached the criterion measure as speed increased (Crouter et. al, 2003; Swartz et. al, 2009). In the current study the opposite was found: results show the Omron to slightly overestimate energy expenditure at 67 and 80 m·min⁻¹, with error of 5.6 and 3.7% respectively, both of which were not significantly different from the criterion measure. Speeds of 94 and 107 m·min⁻¹ resulted in statistically significant, increasingly diverging differences with error soaring from 12.9 to 24.2%, respectively.

The Fitbit results portray differing results than previously published research as well. First, it must be known the Fitbit reports resting metabolic rate (RMR) plus exercise energy expenditure in the caloric expenditure output available to the user. In order to isolate exercise energy expenditure, the investigator subtracted the RMR from total energy expenditure for the length of each walking trial and then divided by five to find minute-by-minute caloric expenditure. The Fitbit Sourcecode API suggested the MD Mifflin-St. Jeor equation to be the RMR equation used in this product (Fitbit, 2014).

After isolating exercise energy expenditure, the results in this study show a significant difference for caloric expenditure at all four walking speeds when compared to the metabolic cart. Percent relative error, when compared to the criterion measure, was high at all speeds with results ranging from 110.5% at 67 m·min⁻¹ to the least error of
42.6% at 107 m·min⁻¹. The overestimation of energy expenditure in this study is vastly different from the underestimation found in Gusmer et. al (2014) and Noah et. al (2013). Although both studies were performed under zero-grade treadmill walking conditions, the differences of Fitbit model and walking trial time may have effected research outcomes.

First, very little research has been performed on the Fitbit line of products and only the Tracker, One, and Ultra were investigated in the cited articles. These devices are higher end, more expensive Fitbit models and, thus, have several other capabilities than the low-cost Zip, which was investigated in the current study. Additionally, the Zip is a newer Fitbit product. As noted by Noah et. al (2013), not only are newer models subject to hardware updates, they also may undergo changes in energy expenditure algorithms, especially when they are expected to increase accuracy of the devices. Because the energy expenditure algorithms are proprietary equations, it remains unknown if the Zip differs from earlier products and must be considered a potential reason for differing results.

In order to provide users with an accurate portrayal of daily energy expenditure, Fitbit products can use one of two algorithms to produce daily caloric expenditure. Under conditions of a non-exercise day or when the device has not been synced to the online-interface, expected energy requirement (EER) may be used to determine total energy expenditure rather than the more common RMR plus exercise energy expenditure equation. The device is said to use EER to predict caloric expenditure when EER exceeds RMR plus exercise caloric expenditure (Fitbit, 2009). In the current study it is possible four walking trials each five minutes in duration (total of 20 active minutes) did not expend enough calories for the Fitbit to use the RMR plus exercise energy
expenditure equation, and instead estimated caloric expenditure via the EER equation. This explanation must also be considered when reviewing the results of this study. Finally, very little research on Fitbit products have been completed and no research was found on the Fitbit Zip throughout the duration of this study. Future research is required to find the cause of overestimation and to determine if the Zip has the capability to accurately estimate energy expenditure under the condition of longer exercise trials.

Distance ambulated is the final factor investigated in this study. As part of the device set-up, the Omron requires the user to input measured stride length. To determine distance traveled, the device multiplies the entered stride length by step count. This device does not account of any changes in stride length due to speed of ambulation, therefore, explaining findings of overestimated distance traveled at speeds of 80 m·min\(^{-1}\) and slower and an underestimated distance at speeds of 94 m·min\(^{-1}\) and higher. Previous studies have found similar results and have determined 80 m·min\(^{-1}\) to be the most accurate walking speed for distance estimation (Crouter et. al, 2003; Giannakidou et. al, 2012) parallelling the results of the current study which found 80 m·min\(^{-1}\) to be the only speed that was not significantly different from the criterion measurement and having the smallest relative error of 3.8%.

The Fitbit works in a similar way to the Omron in that it calculates distance traveled by multiplying step count by stride length, but conversely, this device alters stride length based on the frequency and intensity of steps. The Fitbit estimates walking and running stride length from the height and weight data entered in the user profile. Although this device is capable of making stride length corrections for faster or slower ambulation, it still remains to be significantly different from the criterion measurement.
for 3 out of 4 walking speeds used in this study, with the only non-significantly different speed being 94 m·min\(^{-1}\). Takacs et. al (2013) reported the Fitbit One to have similar trends for distance measurement, but all speeds were shown to be significantly different. The error in distance projection may lie in the estimated stride length produced by the Fitbit or may be related the Fitbit determination at which walking or running occurs. It is possible for users to input an actual measured value for walking and running stride lengths on their online Fitbit profile. This information would allow the user to receive a more personalized distance output, but again, the speed at which the device makes the walking verses running adjustments remains unknown and could to be a source of potential error.
CONCLUSION

In conclusion, the data from this study indicates the dual-axial Omron HJ-720ITC and the tri-axial Fitbit Zip both offer accurate measures of step count for all speeds investigated (67, 80, 94, and 107 m·min$^{-1}$). For this factor, both devices in this study performed equally as well and could be used interchangeably. Energy expenditure data revealed much discrepancy between both devices and the criterion measurement with the only accuracy being the Omron at 67 and 80 m·min$^{-1}$. The Omron findings show accurate caloric expenditure projections for slower walking speeds, but quickly diverging results as speed increased which would provide inaccurate information for users who walk at higher speeds. Based on previous research, the Fitbit was expected to perform with greater accuracy, but the relatively short trial time and unknown methods of estimating energy expenditure may have created error in this study. For this reason and because little research is available on the Fitbit Zip, its accuracy cannot be determined and requires future research. Finally, both devices shared the trend of overestimating distance ambulated at speeds below 80 m·min$^{-1}$ and underestimating distance at speeds above 94 m·min$^{-1}$.

Energy expenditure and distance outputs of both devices both show very little accuracy suggesting areas for improvement in future devices. Individuals who currently use activity monitors must realize they are a guide and their accuracy, beyond step count, remains to be questionable. Future research must focus on methods for increasing the accuracy of activity monitors currently available for retail sale, such as manually logging bouts of exercise, adding individualized anthropometric information, and creating and managing application program interfaces which enable further personalized outputs and easy to use web-interfaces.
REFERENCES


Appendix A: Informed Consent Document

Western Michigan University
Human Performance and Health Education Department

Principal Investigator: Carol Weideman, PhD
Co-Principal Investigators: Timothy Michael, PhD, Michael Miller, PhD
Student Investigator: Lindsay Toth
Title of Study: Comparison of dual- and tri-axial accelerometer accuracy

You have been invited to participate in a research project titled “Comparison of dual- and tri-axial accelerometer accuracy.” This project will serve as Lindsay Toth’s thesis project for the requirements of the Master of Science in Exercise Physiology. This consent document will explain the purpose of this research project and will go over all of the time commitments, the procedures used in the study, and the risks and benefits of participating in this research project. Please read this consent form carefully and completely and please ask any questions if you need more clarification.

What are we trying to find out in this study?
The purpose of this study is to determine which device, Fitbit or Omron, most accurately measures step count, distance traveled, and energy expended.

Who can participate in this study?
Men between the ages of 18 to 45 and women 18 to 55 years who are considered low risk for cardiovascular disease according to the American College of Sports Medicine can participate in the study. The student investigator will determine risk level after reviewing the completed pre-participation health questionnaires. You cannot have any lower body injuries or conditions which make it challenging to walk on a treadmill. Also you cannot participate if you have been diagnosed with any cardiovascular, respiratory, or metabolic diseases. Finally, you must fall within the normal Body Mass Index range which will be determined by a height and weight comparison completed by the student investigator.

Where will this study take place?
The study will take place in room 1055 of the Student Recreation Center on the campus of Western Michigan University.

What is the time commitment for participating in this study?
In total, you will volunteer a total of approximately 135 minutes over a course of 3 sessions. The information meeting, including informed consent and pre-participation questionnaires, will last 30 minutes; resting energy expenditure assessment will last 55 minutes; and the treadmill trials for data collection will last 50 minutes.

What will you be asked to do if you choose to participate in this study?
You will be asked to sign an informed consent, fill out a health screening and lower leg injury questionnaire, and will have your height and weight measured during the information meeting. The student investigator will review the questionnaires and
determine your eligibility for participation. Those who fall within the predetermined guidelines will be asked to join the study and schedule a resting energy expenditure (REE) measurement.

To measure REE, you will be fitted with headgear and asked to rest on your back on a padded table for 45 minutes. The first 30 minutes of rest allow you to adapt to the new environment. During the remaining 15 minutes, you will remain resting while expired air is assessed to determine REE. After this measurement, you will schedule the third meeting for treadmill walking trials.

When you arrive to the lab for the walking trials, the student investigator will provide you with two accelerometers and directions on how and where to place them on your hips. When the accelerometers are in place, you will be given directions on how to walk on the treadmill followed by a treadmill walking orientation consisting of 1.5 to 2 minutes of walking at each of the four speeds (2.5, 3.0, 3.5, 4.0 miles per hour) used in the study. After the orientation, you will be fitted with a mouthpiece and a noseclip for gas analysis. Finally, you will begin the walking trials. Each trial will last 5 minutes followed by a three minute break. During the break you will stand quietly while the student investigator collects and records data from the accelerometers. You will walk at all four speeds in a randomized order. After you complete the fourth walking trial, the mouthpiece and noseclip will be removed and the student investigator will lead you through static stretching to reduce any muscle soreness.

**What information is being measured during the study?**
Height and weight will be measured before all activity and is used to determine body mass index, a participation criteria. During the second meeting, resting energy expenditure and stride length will be measured. Resting energy expenditure allows the determination of energy or calories expended during rest. Finally, during the walking trials, step count and energy expenditure will be measured and be used for comparison with the output of the accelerometers.

**What are the risks of participating in this study and how will these risks be minimized?**
The risks of participating in this study are minimal due to the low intensity nature of treadmill walking. Slight muscular fatigue or discomfort may occur but to protect against muscle soreness, the student investigator will lead you through post-test low-intensity static stretching. As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or additional treatment will be made available to you except as otherwise stated in this consent form.

**What are the benefits of participating in this study?**
There is no direct benefit to you for participating in this study. The results of this study will benefit consumers who wish to purchase an accelerometer which most accurately tracks movement and energy expenditure. More accuracy will enable users to increase
activity as needed to reduce risk of cardiovascular and metabolic diseases and to live a
more healthy and active lifestyle.

**Are there any costs associated with participating in this study?**
There are no monetary costs for participating in this study, however, it will require
approximately 135 minutes (over a course of three lab visits) of the participants time.

**Is there any compensation for participating in this study?**
There is no compensation for participating in this study.

**Who will have access to the information collected during this study?**
All data will be kept confidential in a secure area. The only individuals who have access
to the data are Principal, Co-Principal, and Student Investigators listed in this document.

**What if you want to stop participating in this study?**
You can choose to stop participating in the study at any time for any reason. You will
not suffer any prejudice or penalty by your decision to stop your participation. You will
experience no consequences either academically or personally if you choose to withdraw
from this study.

The investigator can also decide to stop your participation in the study without your
consent.

Should you have any questions prior to or during the study, you can contact the primary
investigator, Dr. Carol Weideman at (269) 387-3087 or carol.weideman@wmich.edu.
You may also contact the Chair, Human Subjects Institutional Review Board at 269-387-
8293 or the Vice President for Research at 269-387-8298 if questions arise during the
course of the study.

This consent document has been approved for use for one year by the Human Subjects
Institutional Review Board (HSIRB) as indicated by the stamped date and signature of
the board chair in the upper right corner. Do not participate in this study if the stamped
date is older than one year.

I have read this informed consent document. The risks and benefits have been explained
to me. I agree to take part in this study.

Please Print Your Name

___________________________________
Participant’s signature

Date
Appendix B: AHA/ACSM Health Fitness Facility Pre-participation Screening Questionnaire

### AHA/ACSM Health/Fitness Facility Preparticipation Screening Questionnaire

Assess your health needs by marking all true statements.

#### History
- You have had:
  - [ ] A heart attack
  - [ ] Heart surgery
  - [ ] Cardiac catheterization
  - [ ] Coronary angioplasty (PTCA)
  - [ ] Pacemaker/implantable cardiac defibrillator/rhythm disturbance
  - [ ] Heart valve disease
  - [ ] Heart failure
  - [ ] Heart transplantation
  - [ ] Congenital heart disease

| If you marked any of the statements in this section, consult your physician or other appropriate healthcare provider before engaging in exercise. You may need to use a facility with a medically qualified staff. |

#### Other health issues
- [ ] You have diabetes
- [ ] You have or asthma other lung disease.
- [ ] You have burning or cramping in your lower legs when walking short distances.
- [ ] You have musculoskeletal problems that limit your physical activity.
- [ ] You have concerns about the safety of exercise.
- [ ] You take prescription medication(s).
- [ ] You are pregnant.

#### Symptoms
- [ ] You experience chest discomfort with exertion.
- [ ] You experience unreasonable breathlessness.
- [ ] You experience dizziness, fainting, blackouts.
- [ ] You take heart medications.

#### Cardiovascular risk factors
- [ ] You are a man older than 45 years.
- [ ] You are a woman older than 55 years, you have had a hysterectomy, or you are postmenopausal.
- [ ] You smoke, or quite within the previous 6 mo.
- [ ] Your BP is greater than 140/90.
- [ ] You don't know your BP.
- [ ] You take BP medication.
- [ ] Your blood cholesterol level is >200 mg/dL.
- [ ] You don't know your cholesterol level.
- [ ] You have a close blood relative who had a heart attack before age 55 (father or brother) or age 65 (mother or sister).
- [ ] You are physically inactive (i.e., you get less than 30 min. of physical activity on at least 3 days per week).
- [ ] You are more than 20 pounds overweight.

| If you marked two or more of the statements in this section, you should consult your physician or other appropriate healthcare provider before engaging in exercise. You might benefit by using a facility with a professionally qualified exercise staff to guide your exercise program. |

| You should be able to exercise safely without consulting your physician or other healthcare provider in a self-guided program or almost any facility that meets your exercise program needs. |

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Lippincott Williams and Wilkins [http://www.lww.com](http://www.lww.com)

[www.acsm-mesa.org/article/32243](http://www.acsm-mesa.org/article/32243)
Appendix C: Lower Limb Injury Questionnaire

Lower Limb Injury Questionnaire

___ Yes ___ No Have you had any lower leg injuries in the last 6 months? (Explain below)

___ Yes ___ No If you answered yes to the question above, is the injury currently limiting your physical activity?

___ Yes ___ No Have you experienced any pain, numbness, or tingling in the lower leg after exercise?

Explain:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

I, the undersigned, hereby acknowledge, affirm, and represent that all above statements are true and accurate to the best of my knowledge; and that no answers or information have been withheld.

________________________________________________________________________

Signature                                      Date
Appendix D: Data Collection Form

<table>
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<th>Trials</th>
<th>Speed</th>
<th>Omron Steps</th>
<th>Omron kcal</th>
<th>Omron Distance</th>
<th>Fitbit Steps</th>
<th>Fitbit kcal</th>
<th>Fitbit Distance</th>
<th>Step counter</th>
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</table>
Appendix E: Verbal Advertisement for Subject Recruitment

Hello, my name is Lindsay Toth and I’m a student investigator in a study comparing the accuracy of a Fitbit Zip to a standard pedometer. I’m looking for twenty four volunteers to walk on a treadmill at four different speeds while wearing two different pedometers, the Fitbit Zip and Omron HJ-720.

Though participating, you’ll learn your how many calories you use at rest and while walking at four different speeds on a treadmill. Best of all, you’ll get to try out a new Fitbit Zip!

Eligible participants include men between the ages of 18 and 45 and women between 18 and 55 years of age who haven’t had any hip, knee or ankle injuries in the past six months, with no diagnosis of cardiovascular, metabolic, or respiratory disease, and are in the “normal” Body Mass Index range according to their height and weight. Participants will donate two to three hours of their time.

If you are interested or would like additional information, please contact me via email: Lindsay.p.toth@wmich.edu or by phone at (412) 600-4342.
Appendix F: Flyer for Subject Recruitment

What’s the BUZZ about Fitbits??
Research Volunteers Needed!

What?
Comparing the accuracy of a Fitbit Zip to a standard pedometer
- Step count
- Energy expenditure
- Distance walked

Where?
Human Performance Research Laboratory in the Student Recreation Center

Why Participate?
Through three short meetings you’ll learn your how many calories you use at rest and while walking at four different speeds on a treadmill.

BEST of ALL: You get to try out a new Fitbit Zip!!

Eligibility Requirements:
- Individuals with low risk for cardiovascular disease:
  - Men ages 18 to 45
  - Women ages 18 to 55
- Free of cardiovascular, respiratory, and metabolic disease
- No hip, knee, or ankle injury within the past 6 months
- Ability to walk safely on a treadmill
- Within “normal” Body Mass Index range based on height and weight

If you are interested or would like additional information about the study, contact Lindsay Toth, student investigator: Lindsay.p.toth@wmich.edu

Contact Information:
- Lindsayp.toth@wmich.edu
Appendix G: HSIRB Approval Letter

Date: March 26, 2014

To: Carol Weiderman, Principal Investigator
    Lindsay Toth, Student Investigator for thesis
    Timothy Michael Co-Principal Investigator
    Michael Miller, Co-Principal Investigator

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number 14-03-26

This letter will serve as confirmation that your research project titled “Comparison of Dual-and Tri-Axial Accelerometer Accuracy” has been approved under the expedited category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note: This research may only be conducted exactly in the form it was approved. You must seek specific board approval for any changes in this project (e.g., you must request a post approval change to enroll subjects beyond the number stated in your application under “Number of subjects you want to complete the study”). Failure to obtain approval for changes will result in a protocol deviation. In addition, if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

Reapproval of the project is required if it extends beyond the termination date stated below.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: March 25, 2015