PORTABLE MEASUREMENT OF STEADY-STATE ENERGY EXPENDITURE
AND VO₂ USING THE ZEPHYR™ BIOHARNESS™:
A VALIDATION STUDY
by
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ABSTRACT

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Portable Measurement of Steady-State Energy Expenditure and VO\textsubscript{2} using the Zephyr\textsuperscript{TM} BioHarness\textsuperscript{TM}: A Validation study

Thesis directed by Associate Professor Craig Elder

Previous attempts at portable energy expenditure (EE) calculation have seen limited and variable results, with many devices limited by feasibility, functionality, or validity or a combination of all. Quantification of EE during exertional activities allows practitioners to determine best methods of replenishment and recovery for each individual, allowing optimal human performance to be maintained or repeated. This study aims to test the Zephyr\textsuperscript{TM} BioHarness\textsuperscript{TM}, a portable monitoring device, for its ability to validly predict EE during steady-state exercise, when compared with simultaneous indirect calorimetry. Twenty-one individuals participated in the study (2 males 23 ± 1.4 years, 10.5 ± 3.8 %BF; 19 females 22.3 ± 2.9 years, 19.2 ± 5.1 %BF), however analysis was only run on 18 female participants. Testing protocol was 10-minute step test following YMCA parameters, preceded by a 5-minute resting state. Participants were simultaneously attached to a metabolic cart and BioHarness\textsuperscript{TM} units during entirety of protocol. Data was divided over two time categories, test duration (10-minutes), and possible steady-state (5-minutes). Pearson-Correlation showed EE during 10-minute ($r=-.17$, $n=18$, $p>.05$) demonstrated a weak, negative correlation, while EE during 5-minute ($r=.22$, $n=12$, $p>.05$) demonstrated a weak, positive correlation. Scatterplots and Bland-Altman plots were employed to analyze differences between device scores. Use of the Zephyr\textsuperscript{TM} BioHarness\textsuperscript{TM} to predict EE during steady and non-steady state
stepping exercise does not appear to be a valid method. Choice of performance monitoring device has many options today, but for EE, it appears practitioners would be well served to look at other devices.
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CHAPTER I
INTRODUCTION

To perform, the body utilizes energy, which comes from our food and subsequent physiological processes. Human performance can be boosted with accurate measurement of this energy expenditure.\(^1\)–\(^9\) Total Daily Energy Expenditure (TDEE), encompasses all the energy needs (in kilocalories) one has for the entirety of a day. This includes Resting Metabolic Rate (RMR), which is a measure of how much energy the body needs to sustain its physiological processes at rest. Energy Expenditure (EE), often referred to as Exercise Energy Expenditure (EEE), encompasses all the energy spent during a given exertional bout, or bouts. This value, coupled with the thermic effect of food (measured in kilocalories of heat generated by food consumption), and RMR generates the majority of TDEE.\(^4\),\(^6\),\(^10\)

Numerous factors can influence the amount of energy expended during exercise, most commonly, mode, intensity, duration and type of external load used during the bout or bouts.\(^7\) These factors also influence the amount of energy spent recovering from exercise, and must be understood by the coach and athlete to maintain proper energy balance, which is required to sustain a healthy active lifestyle.\(^2\)–\(^4\),\(^6\),\(^7\),\(^9\),\(^10\) Without balance, performance decrement occurs, and attempts to attain peak athletic and physical performance are likely to fail.\(^2\)

Quantifying energy expenditure under exertion can be challenging, especially anaerobically due to minimal oxygen consumption.\(^7\) Without better quantification of the energy cost of athletics, knowledge of how best to recover and replenish suffers.\(^1\),\(^4\),\(^6\)
Similarly, tactical populations such as firefighters and law-enforcement personnel, face issues with EE quantification. These individuals bring high levels of cardiorespiratory stress and anaerobic exertion to their employment tasks.\textsuperscript{11–14} The ability to quantify the energy they expend in each situation, or in the majority of commonly encountered situations, can provide these individuals with the ability to properly replenish themselves to be at their best for the next crisis.\textsuperscript{1,4,6,7,9,15}

Numerous methods have been utilized to measure TDEE, RMR, and EE, but current gold-standard measurement of EE requires laboratory testing, with an expensive doubly labeled water device, or still expensive indirect calorimeter or portable indirect calorimeter.\textsuperscript{1,4,6,9,16,7,17–19} Additional portable devices have been used to predict EE, but their validity and reliability varies from test to test and situation to situation, and many devices have only one collection based performance variable (stand-alone accelerometers, heart rate strap).\textsuperscript{18,20} Prediction equations can be used, but most have variation that exceeds of the current portable devices, and their applicability is limited due to demographic differences in populations. However, use of equations in conjunction with measurement devices, such as $[\text{EE (kcal/min)}= \text{VO}_2 (\text{L/min}) \times \text{Thermal Equivalents of Oxygen (L/O}_2)]$, where RER is respiratory exchange ratio,\textsuperscript{21} can still provide valuable information. This particular equation can be manipulated so that when EE and RER are known or assumed (such as during steady state exercise) a \text{VO}_2 value can be estimated for the given activity.\textsuperscript{21,22} Determining \text{VO}_2 during activity can be very beneficial in monitoring athletic and tactical performance.

Limitations imposed by previous measures of EE estimation include cost, portability, reliability, and validity. Additionally, with a growing interest in the strength
and conditioning community to track and monitor athlete metabolic functioning, the attempt to establish a reliable, cost effective, portable measure of EE has arisen. One device that attempts to meet this demand is the Zephyr™ BioHarness™ (version 3; Zephyr Systems, Annapolis, MD, USA). This device presents a multi-dimensional platform that measures and transmits heart rate, respiratory rate, posture, activity level, peak acceleration, speed and distance, and an EE prediction measurement. EE prediction is accomplished using a HR-based prediction equation, \( Calories = \sum_{n=1}^{\infty} Cal e \), which is derived in an article by Keytel and colleagues. Previous research has validated the BioHarness™ heart rate, respiratory rate, respiratory breakpoint, and accelerometry monitoring functions.

Previous studies have shown the importance of EE monitoring to athletic and tactical populations, and the benefits that properly tracked energy balance can provide. While there are a variety of methods and devices available to monitor, measure and estimate TDEE, EE and RMR, many options are limited by cost, portability, validity, reliability, or a combination of all four. This study aims to evaluate the current version of the Zephyr™BioHarness™ for prediction of EE values during steady state aerobic work. The purpose is to determine if the EE testing ability of the BioHarness™ is valid for testing and monitoring, and if these values can be used to establish VO\textsubscript{2} during steady-state exercise.

**Delimitations**

The parameters set for this study by the author include:

- Convenient sample of aerobically active participants
- Use of the Training Questionnaire to determine training status of the participants
• Use of the ACSM pre-participation health screen to assess potential risk factors disqualifying potential participants.

• All questionnaires and instructions are given in English.

Limitations

Limitations exist based on the design of the study that may have an impact on overall outcomes.

• There will be limited generalizability of results because participants will only be selected from one specific geographical area.

• Testing will take place at elevation, which will limit generalizability of results.

• VO₂ values will be calculated using assumed RER values, thus VO₂ values may not be true measures

Assumptions

• Participants can read and understand English

• Participants are answering all questionnaires honestly and accurately.

• Participants are able to continue stepping for up to 10 minutes.

• Participants will provide a maximum effort when testing.

• Heart-Rate measured is accurate

Hypothesis

1. The BioHarness™ heart-rate based prediction equation will be a valid measure of energy expenditure.

2. The BioHarness™ will be a valid measure of VO₂ during steady state exercise.
Research Questions

The following research questions will be addressed in this study.

- Is the Zephyr™ BioHarness™ a valid tool for Energy Expenditure collection, when compared with a metabolic cart?
- Can Energy Expenditure values provided by the BioHarness™, be used to accurately predict steady state VO$_2$, when compared to a criterion measure?
CHAPTER II
LITERATURE REVIEW

Energy Expenditure and Performance

Human performance is comprised of multiple facets, including aerobic and anaerobic capacity, muscular strength and endurance, flexibility, and coordination. In order for any of these abilities to occur, energy must be expended for the duration of the activity. Quantification of the energy cost for this activity can be referred to as energy expenditure (EE). EE is a subsidiary component, which along with basal metabolic rate (RMR), forms the quantifiable amount of energy expended in a given day, known as total daily energy expenditure (TDEE). TDEE encompasses a wide range of bodily energetic processes, and is affected not only by RMR and EE, but also by the thermic effect of food, and the physical activity level (PAL) of the individual. EE will vary depending on the nature of the physical exertion, aerobic versus anaerobic and intermittent versus sustained, as well as the nature of the resistance used in the exertion, bodyweight versus externally loaded. These factors influence both the energy expended during exertion, and the energy expended through excess post-exercise oxygen consumption (EPOC). Knowledge of EE, RMR and subsequently TDEE, is important in order to maintain energy balance, the comparison of energy intake and expenditure. The ability to monitor EE, RMR and TDEE can help to optimize performance in athletic and tactical populations. Athletics Maintenance of energy balance in athletic populations is a critical component of the performance equation. To compete, at any level, the ability to
To perform external work, energy must be expended, and then replenished, both internally (aerobic and anaerobic processes) and externally, via food consumption. Without an adequate fuel balance, the ability to perform external work declines, followed by performance of the athlete. Thus, it can be stated that optimized dietary intake plays a critical role in attaining peak sporting performance.

In soccer athletes, Christensen et al examined the effects of short-term intensified training and short-term training cessation, on performance in repeated high-intensity interval training (HIIT) among 18 Danish professional soccer players. In a similar study, Owen and colleagues examined the effects of a small-sided game (4x4 players; 30x25m pitch) intervention on physical performance in 15 professional European soccer players. Both of these studies were focused on the ability of HIIT training to improve the energy sustainability of athletes, which could lead to improved on-field performance through enhanced ATP replenishment ability, generated by more efficient use of oxygen by the athlete. However, Brown and colleagues have noted that use of HIIT strategies contributes significantly to energy cost, and may lead to underestimation of EE by the athlete, coach or dietician following training. This underestimation may lead to imbalanced nutritional recovery strategies, highlighting the importance of accurate EE measurement during high-intensity training sessions.

High-intensity training, both HIIT and other variants, can also be seen in sports such as basketball, hockey, and rugby, among others. These sports involve many high-intensity stops, starts, and changes of direction, requiring repeated acceleration, deceleration, shuffling and in rugby and hockey, collisions. These
activities generate a high-energy cost during competition and in the training strategies used to prepare the athletes. When training or competition involves a combination of aerobic and anaerobic processes, tracking of this energy cost, or EE, can prove challenging, leading again to underestimation of total EE for the match or training session. Monitoring of long-term energy balance is of critical importance to the endurance athlete for both health and performance variables. Negative energy balance (too little caloric intake) can increase the risk of injuries, infectious diseases, and overtraining, while a positive energy balance (too much caloric intake) may result in excessive weight gain. To safeguard against these risks, accurate assessment of TDEE and its components (RMR and EE), is vitally important for the endurance athlete. Drenowatz et al conducted a study to determine the fluctuations in TDEE, EE, RMR, and non-exercise activity thermogenesis (NEAT) during high- and low-volume endurance training. Results indicated that TDEE increased by 18% during high-volume training, an important revelation when determining nutritional recovery strategies. Interestingly, the TDEE increase could not solely be attributed to an increase in EE during high-volume training; and a non-significant tendency for RMR to be higher during the high-volume training cycle, indicate that understanding of not just TDEE but its components (EE and RMR) is important for the endurance athlete to maintain energy balance. Knowledge of EE may also be helpful in maintaining the performance equation in athletes competing in sports where exertion may not be as apparent. Gillett and colleagues conducted a longitudinal study of 24 major league baseball pitchers comparing estimated VO2max and anaerobic threshold values with pitching results over
seven seasons. While the results of this study indicated that starting pitchers were more physically fit than their reliever counterparts, and that starters with greater aerobic capacity performed better than starters with lower aerobic capacity (p≤0.05), a critical component that could have been tracked was EE during pitching. Starting pitchers may sometimes pitch for two hours or more during a game. Since each pitch is an individual anaerobic effort, followed by aerobic recovery, and then a return to the dugout after each inning; if EE is known the athlete could implement nutritional strategies in-game in order to balance energy stores and maximize performance over the potentially long duration of intermittent exertion.²

**Tactical** Physical fitness plays a crucial role in the tactical field, and can often be the difference between life or death.³³ Fire suppression activities place high cardiorespiratory demands on firefighters, which can lead to high EE for the firefighter.³,⁷,¹¹,¹²,¹⁴ Without a proper understanding of the energy expended during each fire suppression or other lifesaving duty, firefighters may not engage in adequate nutrition replenishment between calls, and may then see diminished mental and physical capability during their next task, which may be life threatening.²–⁴,⁶,⁷,¹⁴,²⁹,⁴⁰

Overexertion on the fire-ground is the leading cause of firefighter injuries.¹¹ In order to track firefighter metabolic exertion (EE), Kesler et al.¹¹ conducted a study to establish a modified self-contained-breathing-apparatus (SCBA), that could be used for future field testing. Results indicated that the modified SCBA was an accurate tool for metabolic measurements, giving potential for future EE measurement during fire suppression activities. The ability to measure EE during fire suppression would provide
more information about the energy cost of firefighting, and subsequently the nutrient replenishment strategies most apt to recovery.

Williams-Bell et al\textsuperscript{15} performed a study on experienced firefighters to analyze their metabolic responses while performing firefighting scenarios using the SCBA. Participants completed simulated high-rise stair climbing and fifth-floor search and rescue scenarios. Results indicated that participants maintained relatively high VO\textsubscript{2} and respiratory exchange ratio (RER) rates, while completing the assigned tasks. This resulted in high aerobic and anaerobic metabolism, which as highlighted by Brown\textsuperscript{3} and Benito,\textsuperscript{7} can have significant impact on the energy expended during exertion.

DiVencenzo and colleagues\textsuperscript{41} analyzed the effect that personal protective equipment (PPE) places on a law enforcement officer while performing routine patrol tasks (walking, climbing stairs, chasing a suspect). PPE provided to participants included a nylon duty belt containing a radio holder, magazine holder, gun holster, and flashlight. A protective vest was also worn, with total weight for the belt and small vest at 6.2 kilograms, and total weight for the large vest and belt at 6.7 kilograms. Participants completed two 22-minute exercise sessions. Results indicated that PPE had significant effect on both heart rate (HR) and VO\textsubscript{2}, significantly elevating both during the exercise sessions while wearing PPE. Elevated HR and aerobic capacity (VO\textsubscript{2}) are both indicators of increased EE.\textsuperscript{3,6,7,29} Law enforcement agencies could utilize this information to develop education and training programs that inform officers of the negative effects (mental and physical exhaustion and decreased function) poor energy balance may have on them during their shifts.\textsuperscript{4}
Physiology

Energy expenditure can be quantified in multiple ways; however, the basic process remains the same. Resting metabolic rate (RMR) is used to express the amount of energy an individual requires to maintain metabolic activity and vital functions in the waking condition at rest. This accounts for approximately 60-75% of daily energy expenditure. The remaining 25-40% of energy expenditure comes predominantly from Exercise Energy Expenditure (EEE but also known as EE), which represents the amount of caloric energy expended during a given session of focused exercise or physical activity. Additional factors such as the thermic effect of food and physical activity level (PAL), also contribute to this 25-40%. Thermic effect of food represents the amount of caloric energy expended as heat after food consumption. PAL is a classification system that is used to quantify the level of physical activity of the individual throughout their day, excluding the time spent exercising or training. Total daily energy expenditure (TDEE), represents the total amount of caloric energy expended by an individual in one day, from all activities and bodily functions.

Measurement

Historically, numerous methods have been utilized to measure TDEE, EE and RMR. The gold standard of measurement for all three, is the Doubly Labeled Water technique (DLW). While this technique is extremely accurate, it is limited by cost, as well as lack of portability. As such, it is a test typically only used in research laboratories, and may not be very accessible for athlete usage. Furthermore, DLW, while extremely accurate, does not differentiate between tasks (training vs. competition) and their relative contribution to TDEE. Additional high accuracy measurement can be
provided by indirect calorimetry, however the same limitations of cost and portability apply. Moreover, while indirect calorimetry can provide valuable information about the EE of a specific task, it requires use of a mouthpiece or mask, limiting usage in the field.\textsuperscript{3,7,8}

Recently, a trend toward more portable measuring devices has occurred, with the type and mode of device measurement varying greatly.\textsuperscript{1,3,6} Devices tested include handheld calorimetry, which Madden and colleagues\textsuperscript{31} found to be less accurate than prediction equations, accelerometer, global positioning system (GPS), heart-rate based and, portable indirect calorimetry monitors.\textsuperscript{1,3,5,6,42} Measurement accuracy of these devices varies.

Portable indirect calorimeters, such as the Cosmed K4b\textsuperscript{2} (Cosmed, Rome, Italy), Cortex Metamax II (Cortex, Leipzig, Germany), Cortex Metamax 3B (Cortex Pty Ltd, Leipzig, Germany), and Jaeger Oxycon Mobile (Erich Jaeger, Viasys Healthcare, Germany) have been tested and proven as one of the most accurate portable device options.\textsuperscript{3,7,42} However, it has been shown that with wearable portable indirect calorimeters (gas-analyzers) the potential for increased EE during prolonged use may occur, leading to a potentially inaccurate EE reading for the exertion session.\textsuperscript{17} Furthermore, purchase cost of these devices is high, making them cost prohibited for many practitioners.

Accelerometer based devices quantify body acceleration, and then use algorithms to convert this into energy expenditure estimates.\textsuperscript{5} Numerous accelerometry based devices have been tested, including multi-sensor devices that measure not only acceleration, but also posture, and other physiological and supplementary motion in order
to provide a more complete picture of physical activity.\textsuperscript{5} Research has shown that something as seemingly insignificant as posture differences, can account for up to 477 kilocalories (kcal) of energy expenditure per day in heavier persons.\textsuperscript{5} Correa et al\textsuperscript{5} examined three accelerometry based devices, the Actical physical activity monitor (Philips Respironics, Inc., Bend, Ore., USA), Sensewear armband (BodyMedia Inc., Pittsburgh, Pa., USA), and the Intelligent Device for Energy Expenditure and Activity (IDEEA). Results indicated that the IDEEA produced accurate estimates of both EE and TDEE, while the Sensewear provided accurate estimates of TDEE. The Actical poorly predicted both measures of energy expenditure (TDEE and EE), and the Sensewear underestimated EE with the discrepancy increasing as total kilocalories expended increased.\textsuperscript{5} A previous study, by Brazeau and colleagues\textsuperscript{16} had tested the Sensewear armband and found it to be a reliable tool for EE estimation during multiple activities, noting that previous research had found the Sensewear to be valid as well. The discrepancy of these results with those of Correa et al,\textsuperscript{5} indicate the limitations that portable EE measurement devices encounter when evaluating varying forms of activity.\textsuperscript{5,6,16}

GPS based monitoring devices, such as the SPI HPU (GPSports Pty Ltd, Australia) can be used to track athlete training load and competition performance, as well as predict energy expenditure.\textsuperscript{3,6} Use of GPS devices centers around their ability to collect accelerations and decelerations, and compile them into a metabolic power profile that is then used to predict energy cost.\textsuperscript{3,6} This strategy, known as the metabolic power method, was used in research by Brown and colleagues,\textsuperscript{3} and found to be accurate for use with steady state activities and GPS devices, but unsuitable for field sports in which
numerous accelerations, decelerations and changes of direction occur. Other GPS
devices, such as the MiniMax 4 (Catapult Innovations, Scoresby Australia), use
proprietary technology, like Playerload™ (Catapult Innovations, Scoresby Australia), to
quantify EE of players during matches and training. Walker et al analyzed this system
and found that Playerload™ calculated EE correlated well with previous research results,
as well as the MiniMax metabolic power calculation. However as noted, the metabolic
power calculation may not be accurate for high-intensity activity, potentially indicating
that the Playerload™ calculation may also encounter the same limitation. It was not
indicated whether the MiniMax 4 was previously validated for EE.

Heart-Rate based EE estimation can be calculated by most any device that
measures heart-rate. The validity and reliability of this method comes down to two main
factors. The validity and reliability of the device used, and the fact that HR monitoring
has limitations for EE prediction, based on type of activity undertaken during data
collection. Low levels of activity, such as those in daily living, are harder to predict EE
using HR than those requiring higher physiological effort. Higher intensity activity
reduces the impact of heart rate variability, making its use for EE prediction more
accurate and applicable. Furthermore, a linear relationship between HR and EE can
be observed between approximately 90-150 beats-per-minute during physical activity, which may allow for more accurate EE estimates during submaximal steady-state
exercise within these boundaries. Numerous studies have attempted to quantify the
relationship between HR and EE, with varying results. Keytel et al, research produced a
pair of prediction equations for EE estimation. Both equations correlated well to criterion
values (r = >.85) and account for gender (male or female), weight (kg), age (years), and heart rate, and one considers \( \text{VO}_2\text{max} \) as well.

Prediction equations have long been used as more portable and relatively cost free methods, but are not without their limitations. A single prediction equation cannot be used to adequately capture variations across age, race, gender and body composition. As such, numerous equations with varying degrees of accuracy have been established, with various additions, such as use of a physical activity factor or the Metabolic Equivalents Table (MET’s), have been added to attempt to make prediction equations more accurate, but almost all are fraught with the simple fact that they are predictions, and not actual measurement. Although a study by Juzwiak and colleagues did find that equations by Owen (1987) and Mifflin (1990) were considered acceptable for predicting RMR in Brazilian Track and Field Paralympic athletes, typically when considering multiple forms of physical activity or sport modality, accuracy of the prediction becomes diminished.

Additional use of prediction equations can be used to determine \( \text{VO}_2 \) and respiratory exchange ratio (RER), using data provided by a testing or monitoring device. The equation \[ \text{EE(kcals/min)} = \text{VO}_2(L/min) \times \text{Thermal Equivalents of Oxygen (kcal/LO}_2) \] is one of these. Under steady state exercise, this equation can be used to calculate EE using the thermal equivalents of oxygen. Manipulation of this equation (reverse calculation) can be used to establish a \( \text{VO}_2 \) value when EE is provided or known for a given steady state activity. Both versions of the formula require knowledge or assumption of non-protein RER values.
Multi-Dimensional Athlete Monitoring

Multi-dimensional monitoring of athletes and operators in real time, provides the strength and conditioning professional the ability to monitor training loads, and compare them against previous training sessions. The Zephyr™ BioHarness™ (version 3; Annapolis, MD) provides this ability. The BioHarness™ measures, records, and transmits real time data including: heart rate, respiratory rate, posture, activity level, peak acceleration, and speed and distance. Additionally, the BioHarness™ has the ability to track and estimate energy expenditure using the non-VO_{2max} prediction equation derived by Keytel et al.\(^{24}\) ([Calories = \sum_{e=1}^{n} Cal_e] where Cal_e = Gender \* (-55.0969 + 0.6309*HR + 0.1988*weight + 0.2017*age) + (1-gender) \* (-20.4022 + 0.4472*HR – 0.1263*weight + 0.074*age)] in which gender = 1 for males and 0 for females, weight is in kilograms and age in years.

Johnstone et al.\(^{27}\) analyzed the validity and reliability of the BioHarness™ (version 1), including its ability to measure heart rate, breathing frequency, and accelerometry in the field. Each capability was measured against a gold standard of measurement in that area, and then statistically analyzed for agreement. Results indicated that breathing frequency demonstrated measurements too variable in nature to be considered acceptable, but that heart rate and accelerometry both demonstrated reliable and valid measurement capabilities. As such, the authors recommended further refinement in the category of breathing frequency, but current use of the BioHarness™ for heart rate and accelerometry testing in the field is acceptable.

Hailstone and Kilding\(^{25}\) investigated respiratory rate measurement on version 1 of the Zephyr™ BioHarness™, compared to a Metamax3b (Cortex, Leipzig, Germany)
online gas-analysis system while completing an incremental treadmill test to volitional exhaustion. No statistical differences in the measurement of respiratory rate were noted between either device, except at 70% of peak treadmill speed. Results indicated the BioHarness™ to be valid and reliable device for determining respiratory rate and respiratory breakpoint during exercise of varying intensity.

In a similar study, Kim et al²⁶ analyzed the BioHarness™(version 2) for its accuracy of heart rate and respiratory rate during graded exercise, as well as sustained exercise, in heated conditions. The BioHarness™ was tested against either a laboratory metabolic cart (Vmax; BD Carefusion, Franklin Lakes, NJ) or against the previously validated K4b² system from COSMED (Rome, Italy). Participants completed exercise protocols in normal and heated conditions. Data indicated that the BioHarness™ demonstrated comparable data to both the Vmax and K4b² systems, indicating that the BioHarness™ is a comparable solution for measurement of heart rate and respiratory rate during both graded exercise and sustained exercise in heat.

Summary

Various studies have examined and supported the importance of EE measurement for the purpose of maximizing the performance equation, both in athletic and tactical populations. Furthermore, while there are a variety of methods and devices available on the open market to test, measure, and predict EE, many of them are limited by cost, portability, accuracy of measurement, or a combination of the three.¹,²,⁵–⁷,⁹,²⁷,⁴⁵–⁴⁷ Additionally, while some devices, such as the COSMED K4b², Cortex Metamax II, Cortex Metamax 3B, and Jaeger Oxycon Mobile are valid measures of many metabolic functions,³,⁷,⁴² they lack the ability of the Zephyr™ BioHarness™ to measure multiple
performance measures. Therefore, the purpose of this study is to validate the Zephyr™ BioHarness™ EE measurement during steady state exercise. A valid measure of EE in a portable device will allow for VO\textsubscript{2} calculation and provide values for oxygen consumption for field assessment, boosting training strategies.
CHAPTER III

METHODS

Participants

IRB approval was obtained prior to initiation of the study (Appendix A). All subjects completed consent forms for study participation, and an American College of Sports Medicine (ACSM) pre-participation health screen questionnaire for medical history. A convenience sample of local subjects was recruited from Health Science undergraduate and graduate courses, and from University of Colorado Colorado Springs NCAA athletes. Participants were recruited via email and verbal invitation. Subjects were scheduled for 30-minute time blocks to complete the testing protocol. Twenty-One participants completed testing. One additional participant was excluded from testing due to medical disqualification by the ACSM Health Questionnaire (Appendix B).

Procedures

Participants were asked to refrain from eating, smoking or drinking caffeinated beverages or alcohol for at least 2 hours prior to their testing session. Participants were also asked to refrain from exercise for 24 hours prior to testing to ensure a consistent baseline activity level. Upon arrival to the testing lab, participants completed the consent, health history, and training history questionnaires. They were then given a brief synopsis of the testing protocol before completing height (Stadiometer, SECA, Chino, CA), weight (Health O Meter), and skin folds (Slim Guide, Creative Health Products, Plymouth, Michigan). Participants were then seated prior to testing for 5 minutes while wearing the BioHarness™ unit and connected to the Ultima metabolic cart, to establish
baseline values on both devices. Timers were used to mark the time that both testing devices were attached, to differentiate between step-test EE and RMR. The testing protocol consisted of a 10-minute step test. Step height was fixed at 12 inches, and participants repeatedly stepped up and down to a metronome. The metronome (GLP Software, IPhone, Apple, Cupertino, CA) was set at 96 beats-per-minute, such that 24 cycles of up-up-down-down were completed each minute. Tests were initiated with the left foot being the first to step up, with participants being allowed to switch to the right foot first at the 5-minute mark, in-time with the metronome. BioHarness™ units were set to a logging function, such that collected data was stored on the device for later download and analysis. Ultima data was stored on the laboratory computer for later comparison. VO₂ values were calculated using a version of the Indirect Open Circuit Calorimetry equation [\(VO_2(L/min) = EE \frac{(kcal/min)\text{ Thermal Equivalents of Oxygen (kcal/LO₂)}}\)]. The calculation assumed RER values between .82 and 1.0, which provided approximately 5 kilocalories per liter of oxygen consumed.

**Instrumentation**

*Training Questionnaire* The questionnaire was used to evaluate participant demographics, and levels of prior training. Participants indicated if they had previously used any wearable athlete monitoring devices.

*ACSM Health Questionnaire* Participants completed a standard ACSM pre-participation health questionnaire prior to any participation. If a participant answered yes to one or more of the questions in Box 1, or two or more in Box 2, they did not participate in the study. Additionally, any participants medically disqualified from the study were encouraged to consult with their physician.
Metabolic Cart A MedGraphics Ultima (MGC Diagnostics, Saint Paul, MN, USA) series metabolic cart was used for gas measurement. The system was calibrated before each test with a 3-liter syringe, and used Calibration gas (12% Oxygen, 5% Carbon Dioxide ± .02%) and Reference gas (21% Oxygen ± .02%) to establish baseline values.

BioHarness\textsuperscript{TM} BioHarness\textsuperscript{TM} units were worn via a chest-strap attached at sternum level. The strap was wetted before attachment to the participant, to ensure good conduction of heart-rate to the BioHarness\textsuperscript{TM} unit. The unit attached on the left-hand side of the torso, via a snap-in port on the strap. Straps and BioHarness\textsuperscript{TM} units were exchanged after each test, and the same BioHarness\textsuperscript{TM} unit was never used for consecutive tests.

Statistical Analysis

Calculations OmniSense\textsuperscript{TM} (v. 3.9.7) software was used to analyze BioHarness data, while Breeze (MGC Diagnostics, Saint Paul, MN, USA) was used to analyze metabolic cart data. Both systems required input of age, height and weight of each participant, prior to use. Data calculations were performed using Excel (Microsoft, Redmond, WA). All pertinent data for each test was input into SPSS (IBM SPSS Statistics Version 24.0, IBM Corp., Armonk, NY) for analysis. Descriptive statistics were computed for demographic and survey items. Participants were entered using a numerical system based on their identification (ID) number (RT01, RT02, et cetera). Training questionnaire answers were entered based on frequency and intensity of workouts. All data analyzed was divided into two time segments. One segment for the totality of the testing protocol (10-minutes), and one segment for the last 5-minutes of the
protocol. The last 5-minutes of testing data was independently analyzed to determine if potential steady-state attainment during this period had occurred, and if this attainment would impact the validity of results. Pearson product-moment correlation coefficients were calculated for the relationships between EE data measured by the metabolic cart and EE data estimated by the BioHarness™, VO₂ data measured by the metabolic cart and VO₂ data calculated from BioHarness™ EE values, and respiratory rate (RR) data measured by the metabolic cart and RR data measured by the BioHarness™. Scatterplots were also used to investigate the possible relationship between metabolic cart EE values and BioHarness™ EE values.
CHAPTER IV
MANUSCRIPT

Introduction

The human body requires energy to survive, which is quantified as Total Daily Energy Expenditure (TDEE), and encompasses all the energy needs (in kilocalories) one has for the entirety of a day. This includes Resting Metabolic Rate (RMR), which is a measure of how much energy the body needs to sustain its physiological processes at rest. In human performance, energy is often expended faster than under normal conditions. This accelerated usage can be quantified as Energy Expenditure (EE), or Exercise Energy Expenditure (EEE), and encompasses all the energy spent during a given exertional bout, or bouts. This value, coupled with the thermic effect of food (measured in kilocalories of heat generated by food consumption), and RMR generates the majority of TDEE. Knowledge of these variables can help to improve replenishment strategies, allowing for optimum performance to occur.

Investigations attempting to quantify TDEE, RMR and EE, have included a variety of methodological approaches including doubly labeled water, direct calorimetry, indirect calorimetry, prediction equations and portable devices such as accelerometers. However, DLW, direct, and indirect calorimetry while valid and reliable, are cost prohibited for most practitioners, and require laboratory testing. Prediction equations while somewhat reliable, have validity issues when compared to DLW and Direct Calorimetry, and must be chosen carefully based on
validity of measurement, can be cost prohibited and can be contraindicated during certain types of activity.\textsuperscript{18,20}

Previous studies have used varying test protocols, however most involve multi-stage intermittent or incremental forms of exercise.\textsuperscript{2,3,27,30,51,52} These tests, while previously validated, are time intensive, may require participant familiarization, and often involve expensive and complicated ergometers. Use of simple, single stage tests, such as the Young Men’s Christian Association (YMCA) step test, may often be a more time and cost effective measure of submaximal fitness levels.\textsuperscript{48} Further, previous research has indicated the test is more time efficient than other protocols, such as the maximal treadmill test, taking over 60\% less time to complete, on average.\textsuperscript{48} This test requires only a timing device, and something 12-inches in height to repeatedly step onto. It has been previously validated for both VO\textsubscript{2peak} prediction, and measurement of cardiovascular fitness,\textsuperscript{48,49} as well as self-administered measures of cardiovascular fitness.\textsuperscript{49}

With growing interest in the human performance community to track and monitor athlete metabolic functioning, the attempt to establish a reliable, cost effective, portable measure of EE has arisen. One device that attempts to meet this demand is the Zephyr\textsuperscript{TM} BioHarness\textsuperscript{TM} (version 3; Zephyr Systems, Annapolis, MD, USA). This device presents a multi-dimensional platform that measures and transmits heart rate, respiratory rate, posture, activity level, peak acceleration, speed and distance, and EE measurement.\textsuperscript{23,25–27} The BioHarness\textsuperscript{TM} uses a heart-rate based prediction equation to estimate EE during activity. This equation uses Heart Rate (HR), weight, age, and gender.\textsuperscript{23,24} HR is an average value collected over the previous 30 seconds, and referred to as HR epoch.\textsuperscript{23} Previous research has validated the heart rate, respiratory rate,
respiratory breakpoint and accelerometry monitoring functions of the BioHarness™. The purpose of this study is to determine if the Zephyr™ BioHarness™ (version 3) is a valid measure of EE during steady state aerobic work, using stepping exercise.

**Methods**

**Participants** IRB approval was obtained prior to initiation of study. A convenience sample of subjects was recruited from a university’s health science undergraduate and graduate courses after obtaining human subject approval. Participants were recruited via email and verbal invitation, with sole inclusion criteria of moderate physical fitness levels. All subjects completed consent forms for study participation and an American College of Sports Medicine (ACSM) pre-participation health screen questionnaire (Appendix B).

**Equipment** Testing equipment included a stadiometer (SECA, Chino, CA), digital scale (Health O Meter), skin fold calipers (Slim Guide, Creative Health Products, Plymouth, Michigan), and a metronome iPhone application (GLP Software). The BioHarness™ is worn on a chest strap affixed at sternum level. The strap was wetted prior to attachment to the subject, and uses the following heart-rate based prediction equation to estimate EE during activity: 

\[
(\text{Calories} = \sum_{e=1}^{n} \text{Cal} e) \text{ where } \text{Cal}_e = \text{Gender} \times (-55.0969 + 0.6309*HR + 0.1988*weight + 0.2017*age) + (1-\text{gender}) \times (-20.4022 + 0.4472*HR - 0.1263*weight + 0.074*age) \].

In this, males = 1, females = 0, age is in years and weight in kilograms. The OmniSense™ BioHarness™ software provides a HR confidence calculation as a percent, which represents how likely the device is directly monitoring HR. Any value less than 100% indicates a percentage of the time where the device was not getting a HR reading and provided an estimated value based on the
previous 5 seconds of recorded data. The Ultima (MedGraphics; MGC Diagnostics, Saint Paul, MN, USA) was calibrated using a 3-liter syringe, and both reference (21% Oxygen ±.02%) and calibration gases (12% Oxygen, 5% Carbon Dioxide ±.02%).

**Procedures** Participants were asked to refrain from eating, smoking, drinking caffeinated beverages or alcohol for at least two hours prior to their testing session and exercise for 24 hours prior to testing. Upon arrival to the testing lab, participants were given a brief synopsis of the testing protocol and completed an informed consent, health history, and training history questionnaires. Anthropometric data (height, weight, and skinfolds) were collected and baseline breathing rates and heart rates (HR) were established by having participants rest seated prior to testing for at least 5 minutes while wearing the BioHarness™ unit and connected to the Ultima Metabolic Cart. The testing protocol consisting of a 10-minute step test, set to a 96 beats-per-minute metronome and using a 12-inch step, such that 24 cycles of up-up-down-down were completed each minute was then initiated.⁴⁸,⁴⁹ Participants were given verbal encouragement during protocol. There was no warm up protocol, but participants were given the option of a 5-minute cool down period on a treadmill if desired. Devices were worn for entirety of testing protocol (minimum 15 minutes), and timers were used to mark start of resting period, and start of test protocol. This allowed for differentiation between step-test EE and RMR during analysis.

**Statistical Analysis** OmniSense™ (v. 3.9.7) software was used to analyze BioHarness™ data, while Breeze (MGC Diagnostics, Saint Paul, MN, USA) was used to analyze metabolic cart data. Data calculations were performed using Excel (Microsoft,
Redmond, WA) and statistical analysis was performed using SPSS (IBM SPSS Statistics v. 24.0, IBM Corp., Armonk, NY).

Data was divided into two time categories, 10-min EE, covering the entirety of the test, and 5-min EE, covering only the last 5 minutes of the testing protocol. This was isolated because if participants had achieved steady state during the testing protocol, it would be in the last 5 minutes of the test. Steady state was determined on 4 variables: metabolic cart VO$_2$ with standard deviation (SD) of less than 100ml (with a preference to values closer to 50ml), Respiratory Quotient (RQ) less than 1 and SD less than .02, respiratory rate (RR) with SD less than 3 breaths, and Volume of Expired air (VE BTPS) with SD less than 5 liters.

BioHarness$^{TM}$ and Ultima data was monitored during testing, but logged data was used for retrospective analysis, based on company recommendations. Logged data from the BioHarness$^{TM}$ has higher sampling rate than data monitored live (250+Hz vs. 1Hz), providing more accurate measures for analysis. BioHarness$^{TM}$ EE was given as a caloric value over the total sampling time (15 min). To determine 10-min test EE, a snipping tool was used to isolate the 10 minutes of test time in the OmniSense$^{TM}$ software, which adjusted EE values to represent only 10-min expenditure. The same process was repeated to isolate the 5-min EE values. Ultima sampling was done on a breath by breath basis, with resolution of greater than 8-milliliters-per-second. EE was calculated by exporting raw values to Excel and averaging the Kcal/min column over both the 10 and 5-min time frames. This averaged value was then multiplied by the number of minutes (10 or 5) in that time frame, yielding the final value used.
Results

Demographics: A total of 21 students (2 males; 19 females) completed all study requirements [(\(\bar{x}=22.38 \pm 2.8\) years) Table 1], with one recruited participant excluded because they did not meet the medical requirements. All participants were at least recreationally physically active and engaged in aerobic exercise, all but one participant engaged in resistance training (Table 2). Males were excluded from analysis due to low number and outlier scores. One female subject was excluded due to low (<70%) confidence, leaving 18 female subjects for final analysis.

Table 1. Demographics (gender, age, height, weight, and body fat)

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>18 (100)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>22.3 ± 3.0</td>
</tr>
<tr>
<td>Height (in)</td>
<td>65 ± 2.7</td>
</tr>
<tr>
<td>Weight (lbs.)</td>
<td>142.3 ± 22.6</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>18.8 ± 4.9</td>
</tr>
</tbody>
</table>

Table 2. Training Status (by type, duration and intensity)

<table>
<thead>
<tr>
<th>n (%)</th>
<th>Mean ± SD</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Days</td>
<td>Intensity (RPE*)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Aerobic</td>
<td>18 (100)</td>
<td>3.6 ± 1.5</td>
</tr>
<tr>
<td>Training</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Resistance</td>
<td>17 (94.4)</td>
<td>3.1 ± 1.7</td>
</tr>
<tr>
<td>Training</td>
<td>1 (5.6)</td>
<td></td>
</tr>
</tbody>
</table>

*RPE scale used: Borg Category Ratio 10

Energy Expenditure: Pearson product-moment correlation coefficients were computed to assess the relationships between the BioHarness™ and the Ultima metabolic cart for EE over the 10-minute test and EE during the last 5-minutes of the test. There was a weak, negative correlation, \(r=-.17, n=18, p > .05\), between the 10-minute EE values obtained by the BioHarness™ and Ultima devices. There was also a weak, non-
significant, positive correlation, \( r = .22, n = 12, p > .05 \), between the 5-minute EE values obtained by the two devices (Table 3).

**Table 3. Correlations (energy expenditure and VO\(_2\))**

<table>
<thead>
<tr>
<th></th>
<th>( n )</th>
<th>( r )</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-min EE</td>
<td>18</td>
<td>-.17</td>
<td>.51</td>
</tr>
<tr>
<td>5-min EE</td>
<td>12</td>
<td>.22</td>
<td>.50</td>
</tr>
</tbody>
</table>

*Participants not at steady-state during last 5 minutes excluded from 5-min calculation.

To investigate differences in measured (met cart) and predicted (BioHarness\(^\text{TM}\)) values between individuals, the values were plotted against one another, for both 10 and 5 minute periods (Figure 1 and 2).

Figure 1: Scatterplot; MC10EE is 10-min EE Value provided by Metabolic Cart, BH10EE is 10-min EE value provided by BioHarness
Further, we employed Bland-Altman plots for both time periods, in order to get a rough indication of any systematic or random bias (Figures 3 and 4). The Bland-Altman plot gives a graphic representation of individual subject differences between the tests, plotted against the individual subject means. Limits of agreement were defined as ± 1.96.
standard deviations. Results indicate poor agreement between BioHarness™ and Ultima values in both time frames, with large amounts of variability.

**Discussion**

The present study investigated the validity of the Zephyr™ BioHarness™ EE values compared to a criterion device (metabolic cart). Previous attempts at portable EE calculation have seen limited and variable results, and many devices are limited by feasibility, functionality, validity or reliability or a combination of all. The Zephyr™ BioHarness™ attempts to overcome these prior shortcomings and provide a valid portable device for EE measurement. However, results indicate that during step-testing, the Zephyr™ BioHarness™ had no correlation and poor agreement with the metabolic cart (Table 3, Figures 1-4). The lack of correlation was observed for the duration of both the 10-minute testing protocol, and the isolated last 5-minutes of the protocol (an attempt to examine potential steady state differences). This indicates that the BioHarness™ was inaccurate in measurement, regardless of physiological state during stepping exercise. To the author’s knowledge, this is the first study to examine the EE capabilities of the Zephyr™ BioHarness™. The lack of validity could have been
impacted by various factors, however we believe that mode of measurement may be the main cause.

The BioHarness™ uses the previously highlighted HR-based prediction equation to predict EE across all activity or inactivity. As noted previously, use of prediction equations is limited by numerous factors, including gender, ethnicity, and mode of exercise. 28 By utilizing one equation containing only a gender correction, the BioHarness™ ability to accurately predict EE immediately introduces potential error. Additionally, the most important variable in the equation is the HR value, which the BioHarness™ actively collects but is susceptible to error if the device loses connectivity during use. Zephyr™ chooses to use the average heart rate over the previous 30 seconds (epoch) as the input value; however, if the device loses HR monitoring ability (indicated in its HR-Confidence tool), values used to generate the epoch will be estimates, rather than true values, introducing further error into the EE function. As a result of these factors, the original error of the equation (7% for females), 24 is now simultaneously compounded by both the error of a single equation, and the potential error of inaccurate or estimated HR values.

Previous research on other portable systems has also produced varying results. The MiniMax 4.0 (Catapult Innovations, Scoresby Australia), using an algorithm that combines oxygen uptake and accelerometry data, has a moderate correlation ($r = .57$, 90% CI 0.06-0.84) for EE values when compared to PlayerLoad™ during exercise. 6 The COSMED K4b² and Cortex Metamax II, both individually validated against criterion measures, 18,53 were compared against one another during a graded cycle test to exhaustion. 42 All variables except for VCO₂ and RER were found to correlate, however
the discrepancy in VCO\textsubscript{2} and RER led the authors to conclude that EE measures taken by both systems may not be valid, and thus care should be taken when using either device to determine EE.\textsuperscript{42} It is possible the measurement error may be partially due to the carrying effect described by Sparks et al.,\textsuperscript{17} where the effect of carrying a portable respiratory gas analysis system may actually increase EE during submaximal running, leading to higher EE values than those seen when device is non-subject supported. Results of both studies may not be transferable to the current study because devices were compared to one another, instead of a criterion measure.

While results of the study indicate low validity, these results are not completely out of line with previous studies. Correa et al\textsuperscript{5} previously found the Actical physical activity monitor to poorly predict both TDEE and EE, and the Sensewear armband to poorly assess EE. Further, given the limitations posed by other EE calculation methods, cost, portability, and functionality, the additional variables that the BioHarness\textsuperscript{TM} can provide may outweigh its shortcomings on this variable for some.

One feature that was very beneficial in analysis was the Heart Rate Confidence calculation. This was very helpful in determining which participant data the device was most confident in, prior to its entry into SPSS for statistical analysis; and given that the BioHarness\textsuperscript{TM} uses heart rate to compute some of its other tracking information, this tool allows a practitioner to know how confident the device is in what it is reporting. If other portable measurement devices do not have this tool, but use heart rate in the same manner, a practitioner could be using data that is inaccurate. This may be especially important for coaches who use heart rate to monitor the training load of their athletes, such as in soccer and rugby, among others.\textsuperscript{3,9}
Conclusion

Energy expenditure capture by the Zephyr™ BioHarness™ is not a valid method during either non-steady or steady state stepping exercise. Furthermore, use of collected energy expenditure values for calculation of steady-state VO\textsubscript{2} values is not a valid method for stepping exercise. Strengths of the BioHarness™ include its multi-functionality, heart rate confidence tool, and ease of use, however for the measure and manipulation of energy expenditure, it falls short.

Future Research

Results of this study may be limited by many factors, including but not limited to population size, geographic location, participant selection, exercise choice, and researcher error. Future research could focus in many areas. The need for a reliable portable measure of energy expenditure still exists, and is only growing with the increase in popularity of athlete and operator monitoring.

Future research could involve the BioHarness™ in another form of exercise, or in resting situations, but could also involve other devices in the same situations. Some female participants noted that the device location was irritating in nature, so research into other wearable locations or device placement may be a warranted avenue. Additionally, this study was limited in access to metabolic cart attachments, and the use of a mouthpiece and nose clip was a universal complaint. Future research involving a better connection method, such as a mask, may be more prudent.

Practical Applications

Wearable technology is a vastly expanding field. Each new device attempts to create a new category of performance monitoring. The establishment of a device able to
accurately and reliably measure energy expenditure during exercise, would have benefits far beyond tactical or athletic performance. For the average person, the ability to accurately track their energy expenditure, would provide them with the ability to live a healthier active lifestyle. In the performance realm, it could mean improved recovery, less injury potential, and improved long term performance for each individual.

While cost, reliability, and portability remain valid concerns with current wearable tracking monitors, the long-term benefits of such devices may outweigh these limitations. Although the BioHarness™ does not validly measure energy expenditure, it provides other benefits to the user, such as accurate HR and RR monitoring, which may help to develop a more complete wearer profile. For those looking to employ an accurate portable measure of exercise energy expenditure, the BioHarness™ is not a valid device, but other options may still be developed.
REFERENCES


APPENDIX A

University of Colorado
Colorado Springs
Institutional Review Board (IRB) for the Protection of Human Subjects

Date: 12/21/2016

IRB Review

IRB PROTOCOL NO.: 17-077
Protocol Title: Portable Measurement of Steady State Energy Expenditure and VO2 Using the Zephyr™ Bioharness™: A Pilot Study
Principal Investigator: Brandon Robison
Faculty Advisor if Applicable: Craig Elder
Application: New Application
Type of Review: Expedited 7
Risk Level: No more than Minimal Risk
Renewal Review Level (If changed from original approval) if Applicable: N/A No Change
This Protocol involves a Vulnerable Population: N/A (No Vulnerable Population)
Expires: 20 December 2017

*Note: If exempt: If there are no major changes in the research, protocol does not require review on a continuing basis by the IRB. In addition, the protocol may match more than one review category not listed.
Externally funded: □ No □ Yes
OSP #: Sponsor:

Thank you for submitting your Request for IRB Review. The protocol identified above has been reviewed according to the policies of this institution and the provisions of applicable federal regulations. The review category is noted above, along with the expiration date, if applicable.

Once human participant research has been approved, it is the Principal Investigator’s (PI) responsibility to report any changes in research activity related to the project:
• The PI must submit all protocol, recruitment, advertising, and consent form amendments/revisions to the IRB for approval.
  o The IRB must approve these changes prior to implementation.
• If you are a student, please note that it is required to include the IRB approval letter to the library when you submit the dissertation/thesis.
• The PI must promptly inform the IRB of all anticipated serious adverse (within 24 hours). All anticipated adverse events must be reported to the IRB within 1 week (see 45CFR46.169(D)). Failure to comply with these federally mandated responsibilities may result in suspension or termination of the project.
• Renew study with the IRB at least 10 business days prior to expiration.
• Notify the IRB when the study is complete.

If you have any questions, please contact Research Integrity Specialist in the Office of Sponsored Programs and Research Integrity at 719-255-3908 or info@uccs.edu

Thank you for your concern about human subject protection issues, and good luck with your research.

Sincerely yours,

Michele Okun, Ph.D.
IRB Reviewer
www.ucce.edu/osp/

Version 7/1516

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APPENDIX B

PRE-PARTICIPATION SCREENING QUESTIONNAIRE

Answer the following questions to the best of your ability. Only check boxes that apply to you. All your information is kept confidential and will be used for the sole purpose of designing a safe exercise program. This form follows the American College of Sports Medicine (ACSM) guidelines* for risk stratification.

**BOX 1**

**History**
- You have had:
  - A heart attack
  - Heart surgery
  - Cardiac catheterization
  - Coronary angioplasty (PTCA)
  - Pacer or pacemaker implantation
  - Electrophysiological investigation
  - Rhythm disturbance
  - Heart valve disease
  - Heart failure
  - Heart transplantation
  - Congenital heart disease

**Symptoms**
- You experience chest discomfort with exertion.
- You experience unexplained breathlessness.
- You experience dizziness, fainting, and/or blackouts.
- You take heart medications.

**Other Health Issues**
- You have diabetes.
- You have asthma or other lung disease.
- You have burning or cramping sensation in your lower legs when walking short distances.
- You have musculoskeletal problems that limit your physical activity.
- You take prescription medications that could limit your physical activity.
- You are pregnant.
- You have concerns about the safety of exercise.
- You have had major surgery or hospitalization that could limit your physical activity.
- You have another medical condition or physical limitation that could limit your physical activity.

**BOX 2**

**Cardiovascular Risk Factors**
- You are a man older than 45 years.
- You are a woman older than 55 years or you have had a hysterectomy or you are post-menopausal.
- You smoke or quit smoking within the past six months.
- Your blood pressure is greater than 140/90 mmHg.
- You don't know your blood pressure.
- You take blood pressure medication.
- Your blood cholesterol is greater than 200 mg/dl.
- You do not know your cholesterol level.
- You have a close blood relative who had a heart attack before age 55 (brother or father) or age 65 (sister or mother).
- You are physically inactive (i.e., you get less than 30 minutes of exercise on at least three days per week.)
- You are more than 20 lbs overweight.

If you marked two or more from Box 2...

Physician's consent is required before engaging in exercise.

Staff Initial __________________

Member Initial ____________

I certify my answers to the above questions are correct and truthful to the best of my knowledge. I understand this survey and my responses are not a substitute for a physician's examination. If I experience any changes in my health status during the course of this membership with the Denver Public Schools Sound Body Sound Mind Fitness Centers, I will notify staff immediately with updated information. It is my responsibility to seek medical supervision if any worsening of my health status occurs. A medical clearance by a medical provider is strongly recommended but not required unless results of this questionnaire indicate a need for a medical clearance.

Print Name: ____________________________ Date: ________________________

Signature: ____________________________ Staff Signature: ____________________

Email: ________________________________ Telephone: ______________________

**Title:** PORTABLE MEASUREMENT OF STEADY STATE ENERGY EXPENDITURE AND VO2 USING THE ZEPHYR™ BIOHARNESS™: A PILOT STUDY

**Principal Investigator:** Brandon Robison  
**Co-Principal Investigator:** Craig Elder

**Funding Source:** N/A

**Introduction**
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. A member of the research team will describe this study to you and answer any questions. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:
- Please carefully read this form or have it read to you.
- Please ask questions about anything that is not clear.

Feel free to take your time thinking about whether you would like to participate. By signing this form, you will not give up any legal rights. If you are completing this consent form online, you may want to print a copy of the consent form for your records.

**Study Overview** This study plans to learn more about the ability of the Zephyr Bioharness to accurately assess physiological measures such as heart rate, breathing rate and energy expenditure, which may be used to predict oxygen consumption.

**Procedures** You are being asked to be in this research study because you fit the age range of individuals who commonly engage in aerobic physical activity. Additionally, you will be asked to perform a 10-minute step test at a steady state intensity.

**Other people in this study:** Up to «ID» people will participate in this study.

**Risks and Discomforts** The risks in this study are no greater than the risks you would encounter during aerobic activity using a stepping machine. Therefore the risks you could sustain are musculoskeletal injuries from tripping while stepping and/or other conditions associated with aerobic physical exertion. Data collection will be performed by certified strength and conditioning specialist who will use their expertise to minimize your risk of injury and who is also certified in CPR should you experience situations that necessitate that attention.
Benefits
This study is designed for the researcher to learn more about how collected information may provide a means to capture physiological measures in applied settings, which may predict oxygen consumption.

Compensation
None provided

Confidentiality
Data will be stored in the Principal Investigators office and locked in a file cabinet. Your data sheet will be assigned a random participant number. Only the principal investigator, Co-PI and Additional Personnel will have access to the sheet with the association between subjects’ numbers and names. Any publication of the results of this study will not include your name.

Certain offices and people other than the researchers may have access to study records. Government agencies and UCCS employees overseeing proper study conduct may look at your study records. These offices include the UCCS Institutional Review Board, and the UCCS Office of Sponsored Programs and Research Integrity. UCCS will keep any research records confidential to the extent allowed by law. A study number rather than your name will be used on study records wherever possible. Study records may be subject to disclosure pursuant to a court order, subpoena, law or regulation.

Voluntary Participation and Withdrawal from the Study
Taking part in this study is voluntary. You have the right to leave a study at any time without penalty. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. If you withdraw from the study, you may request that your research information not be used by contacting the Principal Investigator listed above and below.

Contact Information
Contact Brandon Robison: brobiso2@uccs.edu
- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research, or
- if you would like information about the survey results when they are prepared.

Contact the Research Integrity Specialist at 719-255-3903 or via email at irb@uccs.edu:
- if you have questions about your rights as a research participant, or
- if you have questions, concerns or complaints about the research.

Consent
A copy of this consent form will be provided to you.

I understand the above information and voluntarily consent to participate in the research. By signing this consent, I am confirming that I am 18 years of age or older.

Signature of Participant ______________________________ Date ____________
APPENDIX D

Training History

This questionnaire is intended to determine training status and type. You have the right to elect not to answer this questionnaire, or any of the questions within. All information gathered will be used and analyzed as part of this research study. This questionnaire is anonymous and you will not be identified in any manner. Thank you for your participation. **If you have any questions, comments or concerns, please contact Brandon Robison at mailto:brobiso2@uccs.edu.

1. What is your age? (Use whole numbers, example: 22 years)

   ___________ years

2. How do you identify? (circle one)

   Male       Female       Other

3. What is your ethnicity? (circle one)

   White/Non-Hispanic
   Black/Non-Hispanic
   Hispanic
   Asian/Pacific Islander
   Filipino
   American Indian/Alaskan Native
   Other ______________________

4. Do you engage in resistance training? (circle one)

   Yes       No

5. If yes, how many days do you engage in resistance training? (circle one)

   One day
   Two days
   Three days
6. How many days per week do you engage in aerobic exercise? (circle one)

Once per week
Twice per week
Three times per week
Four times per week
Five times per week
Six times per week
Seven times per week

7. What is the average duration of your aerobic session? (circle one)

0-20 minutes
20-40 minutes
40-60 minutes
60-80 minutes
80+ minutes

8. What is the average intensity of your aerobic session? (circle one; based on the scale depicted below)

<table>
<thead>
<tr>
<th>Rating</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Rest</td>
</tr>
<tr>
<td>1</td>
<td>Very, very easy</td>
</tr>
<tr>
<td>2</td>
<td>Easy</td>
</tr>
<tr>
<td>3</td>
<td>Moderate</td>
</tr>
<tr>
<td>4</td>
<td>Somewhat Hard</td>
</tr>
<tr>
<td>5</td>
<td>Hard</td>
</tr>
<tr>
<td>6</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>Very Hard</td>
</tr>
<tr>
<td>8</td>
<td>-</td>
</tr>
</tbody>
</table>
9. What is your most common form of aerobic exercise? (circle one)

Cycling       Running