Validation of the SenseWear HR Armband for Measuring Heart Rate and Energy Expenditure

Manuella Barbosa Crawley
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VALIDATION OF THE SENSEWEAR HR ARMBAND FOR MEASURING HEART RATE AND ENERGY EXPENDITURE

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Bachelor of Science in Kinesiology
The Pennsylvania State University
August 2003

Submitted in partial fulfillment of requirements for the degree
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at
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MAY 2008
This thesis has been approved for the Department of HEALTH, PHYSICAL EDUCATION, RECREATION AND DANCE and the College of Graduate Studies by

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VALIDATION OF THE SENSEWEAR HR ARMBAND FOR MEASURING HEART RATE AND ENERGY EXPENDITURE

MANUELLA BARBOSA CRAWLEY

ABSTRACT

The purpose of this study was to determine the validity of the SenseWear HR Armband in measuring heart rate and energy expenditure. The SenseWear HR Armband was compared to an electrocardiogram (ECG), the Actiheart Mini Mitter and the Polar Heart Rate Monitor. Energy expenditure estimations were compared to indirect calorimetry (Cosmed’s K4 b) measurement and the Actiheart Mini Mitter’s estimations. Thirty healthy adults (18-59 years old) participated in the study. The protocol consisted of 5-minute stages, starting with two resting stages (sitting and standing), followed by four walking stages (1.5, 2.0, 2.5 and 3.0 mph) and ending with a standing recovery stage. The SenseWear HR Armband consistently recorded higher heart rate when (2-8 bpm) compared to the ECG, the Actiheart Mini Mitter (1-3 bpm) and the Polar Heart Rate Monitor (4-8 bpm). The SenseWear Armband overestimated energy expenditure by approximately 0.5-1.0 kcal/min during the exercise stages of the protocol when compared to the indirect calorimetry measurements, while the Actiheart Mini Mitter consistently underestimated (0.5kcal.min) energy expenditure. The SenseWear HR Armband was found to be a valid device for measuring heart rate; however, it consistently overestimated energy expenditure by about 10% during the exercise stages of the protocol.
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CHAPTER I
INTRODUCTION

Background

According to the Centers for Disease Control and Prevention, the United States is experiencing a major increase in obesity among its population. In 1999, 61% of adults in the country were considered overweight or obese. As of 2006, twenty-two states have an incidence of obesity at or above 25%.\(^1\) According to the Surgeon General, overweight and obesity have been linked to heart disease, some types of cancer, type II diabetes, and even psychological problems such as depression.\(^2\)

The American Heart Association (AHA) indicates that physical inactivity is a main risk factor for the development of heart disease. Exercising regularly can help maintain a healthy blood lipid profile, blood sugar level, blood pressure and weight.\(^3\) However, a difficult part of maintaining an exercise program is motivation. There are various tools available such as pedometers, accelerometers and heart rate monitors.\(^4\) Pedometers measure steps taken and some use a simple equation to calculate general energy expenditure. Furthermore, pedometers are affordable and readily available.\(^5\) Conversely, accelerometers measure change in movement. Algorithms estimate energy expenditure via monitoring acceleration and deceleration in one direction (uni-axial) or two or three...
dimensions (bi-, tri-axial). However, these motivational tools give little information regarding the intensity of the exercise being performed, and the energy expenditure is not specific to the exercise or to the individual. Therefore, a motivational tool able to monitor heart rate for exercise intensity and energy expenditure for calories expended such as the SenseWear HR Armband may be a very useful tool in fighting the obesity epidemic in the sedentary and fitness population.

The SenseWear HR Armband (Figure 1) is a device based on the SenseWear Pro3 Armband. The SenseWear Pro3 Armband is a device designed to monitor physiological variables for the purpose of determining energy expenditure. This device is worn on the back of the right arm and continuously monitors physiological data such as physical activity, steps per minute, and energy expenditure.

The SenseWear Pro3 Armband uses four sensors including: 1) two-axis accelerometer which tracks movement and body position, 2) heat-flux sensor determining heat dissipated from the body by the measurement of heat loss between the skin and a vent on the side of armband, 3) sensitive thermistors which measure skin temperature and, 4) sensor that measures galvanic skin response (GSR) which varies due to sweating and emotional stimuli. The data collected by the armband is stored in the device for later
transfer to a computer, where it can be analyzed and interpreted by a comprehensive set of algorithms.\textsuperscript{6}

The SenseWear HR Armband is a heart rate-enabled version of the SenseWear Pro3 Armband. It uses two standard electrocardiogram (ECG) monitoring electrodes to receive pulse waves and uses them to calculate heart rate without the aid of a chest strap. The heart rate and heart rate variability measurements add another dimension to the armband’s assessment of metabolism, due to the well established link between heart rate and metabolism.\textsuperscript{7} The SenseWear HR Armband contains a radio for both wireless and wired communication, and meets the requirements for a Non-Significant Risk Device as defined by Institutional Review Board (IRB) guidelines.

**Statement of the Problem**

A study is needed to determine if the SenseWear HR Armband is accurate in measuring heart rate and energy expenditure. If this product is proven to be accurate, it may have a major impact on the technology used today for determining heart rate and energy expenditure and lead to a new tool available for fighting the increasing obesity epidemic.

**Purpose of the Study**

The purpose of this study was to validate the accuracy of the SenseWear HR Armband for measuring heart rate and energy expenditure in ambulatory subjects.

**Research Question**

Is the SenseWear HR Armband an accurate device for measuring heart rate and energy expenditure?
**Hypothesis**

It was hypothesized that the SenseWear HR Armband is an accurate device for measuring heart rate when compared to Respironics’ Actiheart Mini Mitter heart rate monitor, Polar’s heart rate monitor and standard electrocardiography.

It was also hypothesized that the SenseWear HR Armband is an accurate device for measuring energy expenditure when compared to indirect calorimetry using Cosmed’s K4 b\(^2\) open circuit method and to Respironics’ Actiheart Mini Mitter monitor.
CHAPTER II
LITERATURE REVIEW

The purpose of this study was to investigate the validity of the SenseWear HR Armband in measuring heart rate and estimating energy expenditure. A summary of the literature relevant to this study is discussed in the following sections: heart rate monitors; energy expenditure estimation and measurement; relationship between heart rate and energy expenditure; and validation of similar systems.

Heart Rate Monitoring

A study by Terbizan et al.\textsuperscript{8} tested the validity of seven heart rate monitors, including two Polar heart rate monitors, by comparing the measurements given by the monitors to an electrocardiogram (ECG) measurement. In this study, the heart rates of 14 men (19.6±2.3 years) were simultaneously measured by the heart rate monitors and an ECG for 10 seconds during rest or during treadmill exercise at 85.7 m/min, 107.3 m/min and 160.8 m/min. The heart rate monitors were considered valid if the correlation between the heart rate and the ECG was found to be ≥0.90, with a standard error of estimate at ≤5 beats/min. Both Polar heart rate monitors tested as well as the Accurex II, Cardiochamp, and the Cateye-PL 6000 monitors, which were found to be accurate during both rest and
exercise as defined above. However, it was also found that as the speed increased, the accuracy decreased leading to the need for further studies on the accuracy of heart rate monitors at higher speeds.\(^8\)

Another heart rate monitor validation study determined that a Polar heart rate monitor could accurately measure heart rate of 30 participants age 18–48 years during rest as well as during two stressful tasks.\(^9\) The participants were simultaneously measured by the Polar heart rate monitor and an ECG. It was found that the Polar monitor produced heart rate values that were valid as compared to the ECG values. However, the Polar heart rate monitor provided slightly higher absolute heart rate measurements. The average difference between the Polar and the ECG was 0.4bpm, and therefore this difference was deemed insignificant. This difference was attributed to the different methods by which the heart rate is calculated with the Polar heart rate monitor and the ECG. In the ECG, heart rate is calculated by counting the number of R-wave deflections continuously for one minute, while the Polar heart rate monitor calculates heart rate by averaging 5 second interval samples for each minute.\(^9\)

**Energy Expenditure**

There are numerous methods for measuring energy expenditure (EE), and each method has its advantages and disadvantages. Measurement of energy expenditure can be done through direct or indirect calorimetry. Direct calorimetry, the “gold standard” measures the actual heat lost by the body during activity or rest, while indirect calorimetry measures oxygen consumption, which is directly related to heat produced by the body during activity or rest. Direct calorimetry is a less practical way of measuring energy expenditure and requires expensive and cumbersome equipment.\(^6\) Conversely,
indirect calorimetry has become a much more affordable and portable way of measuring energy expenditure.\textsuperscript{10} The Cosmed K4 b\textsuperscript{2} used in this study is a portable indirect calorimetry system. It measures O\textsubscript{2} consumption, CO\textsubscript{2} production and pulmonary utilization.\textsuperscript{24} The K4 b\textsuperscript{2} has been validated and is found to provide accurate and reliable measurements both at rest and during light exercise.\textsuperscript{10}

A study by McLaughlin et al.\textsuperscript{11} determined the accuracy of the COSMED K4 b\textsuperscript{2} portable metabolic system in measuring energy expenditure as compared to the Douglas Bag (DB) method. Ten healthy male subjects (ages 27.6±6.4 years) participated in the study. They were asked to perform 2 trials on a cycle ergometer, on consecutive days at similar times of day. Measurements were obtained for Oxygen consumption (VO\textsubscript{2}), carbon dioxide production (VCO\textsubscript{2}), minute ventilation (Ve) and respiratory exchange ratio (R) at rest and during outputs of 50, 100, 150, 200 and 250 Watts for both the K4 b\textsuperscript{2} and the Douglas Bag methods. No significant differences were found in VO\textsubscript{2} at rest or at the peak intensity; however the K4 b\textsuperscript{2} overestimated VO\textsubscript{2} during the workloads between rest and max (50-200W). The authors concluded that the results indicated that the VO\textsubscript{2} produced by the K4 b\textsuperscript{2} were acceptable through the range of activities tested.\textsuperscript{11}

A similar study by Duffield et al.\textsuperscript{12} examined the validity and reliability of the Cosmed K4 b\textsuperscript{2} portable gas analysis system. Twelve male subjects (23.3±3.2 years) participated in four testing sessions with one day between each session. During each testing session the subjects participated in a series of treadmill runs (easy 10 min run, hard 3 min run, and 1 min sprint with 10 minute rest between each run). The subjects repeated each session four times, with the exception of a different measuring device. In two sessions, the K4 b\textsuperscript{2} was used, in one session, a metabolic cart (non-portable indirect calorimetry)
was used, and one session used the K4 b² and the metabolic cart simultaneously. The authors of the study concluded that the Cosmed K4 b² system was reliable, especially during steady state and sustained maximal exercise.¹²

St-Onge and colleagues⁴ evaluated the portable Armband when compared to the Doubly Labeled Water method of measuring energy expenditure. Forty-five subjects ages 18-85 participated in the study. Energy expenditure was recorded simultaneously by both methods for a 10-day period. The study found that the Armband significantly underestimated daily energy expenditure when compared to the Doubly Labeled Water method of energy expenditure.⁴

A study by Cristofaro et al¹³ examined the accuracy and validity of the SenseWear HR Armband when estimating energy expenditure of morbidly obese subjects. 228 morbidly obese subjects participated in the study. Energy expenditure estimated by the SenseWear HR Armband was compared to indirect calorimetry (SensorMedics Vmax 29N metabolic cart) measurement and Harris Benedict equation. This study found not significant difference between in total energy expenditure between the SenseWear Armband and the Harris Benedict equation; however, significant differences were found when the Armband was compared for the indirect calorimetry measurement. Despite those findings, the authors concluded that the SenseWear HR Armband can be an acceptable device to measure total energy expenditure in morbidly obese subjects.¹³

**Heart Rate Monitoring and Energy Expenditure**

A study by Keytel et al.¹⁴ attempted to determine the effects of the mode of exercise, body composition and training on heart rate and energy expenditure during exercise.
Additionally, they aimed to develop prediction equations of energy expenditure from heart rate. In this study, 115 subjects, 18-45 years were first tested for max VO$_2$. Next they completed a steady state exercise on either a treadmill or cycle ergometer. Heart rate and respiratory exchange ratio were measured. A mixed model analysis showed gender, heart rate, weight, VO$_2$max and age to be factors influencing the relationship between heart rate and energy expenditure. It was concluded that energy expenditure can be accurately estimated during exercise by heart rate after adjusting for age, gender, body mass and fitness.$^{14}$

A study by Hilloskorpi et al.$^{15}$ evaluated the use of heart rate and oxygen uptake as a means to estimate energy expenditure during exercise. In this study, 43 women and 45 men (38.1±9.8 years) performed a total of 4 tests including an incremental cycle ergometer, a treadmill test, and a 10 minute steady state exercise during cycling and walking. Indirect calorimetry was used to measure energy expenditure during the tests and to later compare to the estimated results. The tests showed that gender, body weight, age and heart rate are all needed to accurately estimate energy expenditure during physical activity.$^{15}$

An important and often overlooked variable in heart rate measurement and energy expenditure estimation is the placement of monitors. Brage et al.$^{16}$ examined how the placement of the Actiheart Mini Mitter heart rate and movement sensor influence the heart rate measurement and energy expenditure estimation. Twelve males and twelve females (20-39 years) participated in the study. The subjects participated in a treadmill test and a free-living test while wearing two Actiheart Mini Mitter units. One unit was at the level of the third intercostal space (upper position) and the other was below the apex
of the sternum (lower position). It was found that the heart rate data was of better quality when the Actiheart Mini Mitter was placed in the lower position in men, but the difference was not as clear in women. However, no significant differences between the two positions when compared to each other were found for energy expenditure.

**Validation of Similar Systems**

A recent study by Arvidsson et al. examined the validity of the SenseWear Pro2 Armband (a device produced by the same company as the SenseWear HR Armband) in estimating energy expenditure in children. Twenty children between the ages of 11-13 years participated in the study. Energy expenditure was assessed while the subjects were lying down, sitting, playing games on mobile phones, stepping up and down on a step board, biking on a stationary bike, jumping on a trampoline, playing basketball, as well as walking/running on a treadmill at 2, 3, 4, 5, 6, 7, 8 and 10 km/h. Simultaneous measurements were made by a portable metabolic cart (Oxycon Mobile) and the SenseWear Pro2 Armband. The SenseWear Pro2 Armband was shown to underestimate energy expenditure (up to 51% underestimation) during most activities and this underestimation increased with an increase in intensity.

Jakicic et al. conducted a validation study of the SenseWear Pro Armband, another device produced by the same company as the SenseWear HR Armband. This study attempted to determine the validity of the SenseWear Pro Armband’s energy expenditure estimation through a range of exercises when compared to a metabolic cart. Forty subjects (20 males and 20 females), ages 23.2±2.8 years, were subjected to 4, 20-30 minute duration exercises (walking, cycling, stepping and arm ergometry) in random
order, with the workload for each exercise increased every 10 minutes. Energy expenditure was measured by the SenseWear Pro Armband and the metabolic cart simultaneously. This study found the SenseWear Pro Armband to be accurate in measuring EE, but only when exercise-specific algorithms were applied to each exercise protocol.  

A similar study by Mealey and colleagues \(^\text{18}\) examined the accuracy of the SenseWear Pro Armband in measuring energy expenditure during testing simulating common daily activities. Fourteen subjects were a part of the study. Each subject participated in a total of 60 minutes of activities designed to simulate daily activities including multiple series of sitting, standing and walking. No significant differences were found between the SenseWear Pro Armband and the indirect calorimetry. The authors concluded that the SenseWear Pro Armband was an accurate estimate of energy expenditure when assessing a simulation of common daily activities. \(^\text{18}\)

Brage et al. \(^\text{19}\) performed a validation study of the Actiheart Mini Mitter monitor. The purpose of the study was to investigate the reliability and validity of the monitor during walking and running. Electrocardiogram readings and indirect calorimetry measurements were used as the “gold standards” for the study. Eleven men and nine women (26-50 years) participated in the study. The protocol consisted of a four minute resting period followed by treadmill walking at speeds at 3.2, 4.5 and 5.8 km/h and running at 8.5, 10.3 and 12.1 km/h or until exhaustion. The Actiheart Mini Mitter was found to be reliable and valid during walking and running as per the study’s protocol. \(^\text{19}\)

Brehm et al. \(^\text{20}\) aimed to validate the accuracy of the Sensormedics VmaxST portable oxygen uptake system. In this study, the Vmax ST was compared to the Douglas Bag
method. Ten adults (5 males and 5 females, 24-37 years) participated in the study, which consisted of two trials of 5 minutes and 5 minute cycling at 80Watts. Minute ventilation (Ve), oxygen uptake (VO\textsubscript{2}) and carbon dioxide production (VCO\textsubscript{2}) were measured or estimated for both systems. The study found no significant differences between the VmaxST and the Douglas Bag method for net EE or net oxygen uptake. A significant, but small difference was found for resting and exercise values between the systems. The VmaxST yielded slightly higher values for these conditions. However, the VmaxST was found to be valid for gait studies in determining EE during walking.\textsuperscript{20}

A study by Nieman et al.\textsuperscript{21} sought to determine the validity and reliability of Cosmed’s FITMATE\textsuperscript{TM} metabolic analyzer in measuring VO\textsubscript{2} and EE during rest and exercise by comparing the system to the Douglas Bag method. The study enrolled 60 subjects (30 males and 30 females) aged 19-65 years. Ten minute resting metabolic rates (RMR) were measured simultaneously by the FITMATE\textsuperscript{TM} and the Douglas Bag. The study found no significant differences between the FITMATE\textsuperscript{TM} and the Douglas Bag measurements and therefore concluded that the FITMATE\textsuperscript{TM} is a reliable and valid method of measuring energy expenditure.\textsuperscript{21}

King et al\textsuperscript{6} evaluated the validity of 5 activity monitors, including the SenseWear HR Armband. The study consisted of simultaneous measurements of body motion and metabolic cart by the 5 monitors (CSA, Tri-Trac-R3D, SenseWear Armband and Biotraner-Pro) during a walking (54, 80 and 107m.min\textsuperscript{-1}) and a running (134, 161, 188 and 214 m.min\textsuperscript{-1}) protocol. Ten males and 11 females participated in the study. It was found that in general, all devices overestimated energy expenditure (2-3 kcal/min) at most speeds when compared to indirect calorimetry. More specifically, the SenseWear
Armband was found to produce the best estimate of total energy expenditure at most speeds.\textsuperscript{6}

Davis and colleagues\textsuperscript{22} examined the affect of clothing on the accuracy of the SenseWear Pro Armband’s estimation of energy expenditure. Fourteen subjects participated in two 20-minute walking sessions (short-sleeved shirt vs. long-sleeved shirt), while equipped with the SenseWear Pro Armband and indirect calorimetry (Viasys Vmax Spectra). No significant differences in energy expenditure were found between the devices while wearing a short-sleeved or a long-sleeved shirt. The SenseWear Pro Armband was therefore found to be accurate in estimating energy expenditure.\textsuperscript{22}
CHAPTER III

METHODS

An experimental design was used for this study. The independent variables were the mode of measurement (4 different devices) and the dependent variables were heart rate and energy expenditure.

Subjects

Thirty healthy adults (males and females 18-59 years of age) from the Cleveland State University community volunteered as participants in this study. Each participant completed an informed consent (Appendix A) and took the American Heart Association/American College of Sports Medicine Pre-participation Screening Questionnaire (Appendix B) and completed an IRB approved consent form. High risk subjects and pregnant women were eliminated from participation.

Measurement of Energy Expenditure

Indirect calorimetry using the Cosmed K4 B² was used to measure energy expenditure. Continuous measurement of oxygen consumption (VO₂) and carbon dioxide (VCO₂) was
used to calculate energy expenditure. Expired gasses were analyzed breath-by-breath and stored for averaging one minute intervals.\textsuperscript{23} Calculation of energy expenditure was completed using caloric equivalents for oxygen at different non-protein respiratory exchange ratios (RER).\textsuperscript{23}

**Specific Procedures**

Continuous measurement of heart rate and oxygen consumption were recorded throughout the test. Heart rates were obtained using standard telemetry ECG equipment (ScottCare Advantage System, Cleveland, OH) as well as the SenseWear HR Armband, a Polar heart rate monitor with a chest strap, and the Respironics’ Actiheart Mini Mitter (Figures 2 and 3). Energy expenditure was measured using the COSMED K4 b\textsuperscript{2} portable indirect calorimetry system, and estimated by the SenseWear HR Armband and the Actiheart Mini Mitter. The Actiheart Mini Mitter device does not estimate energy expenditure during rest. Therefore, in order to compare this device to the others in the study, the resting value measured by the K4 b\textsuperscript{2} during the sitting stage (kcal per minute) was added to the Actiheart data.

Following instrumentation, each subject was tested while sitting, standing and walking on a motor driven treadmill at speeds of 1.5, 2.0, 2.5 and 3.0 miles per hour (Table 1). The test was terminated if the subject reached intensity equal to or greater than 85% of
their age predicted maximum heart rate (220-age). The exercise testing was consistent with American College of Sports Medicine standards.\textsuperscript{24}

<table>
<thead>
<tr>
<th>STAGE</th>
<th>TIME (min.)</th>
<th>WORKLOAD</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>Sitting</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>Standing</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>1.5 mph</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>2.0 mph</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>2.5 mph</td>
</tr>
<tr>
<td>6</td>
<td>5</td>
<td>3.0 mph</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
<td>Recovery (standing)</td>
</tr>
</tbody>
</table>

**The SenseWear HR Armband monitor**

The armband was placed on the subjects’ upper left arm. The electrodes were placed on the top of the subjects’ left shoulder above the mid-clavicular line (Figure 4) and on the back of the upper arm just above the armband (Figure 5). Electrode wires were attached to the SenseWear HR armband system (Figure 6), for continuous monitoring of heart rate.

Figure 4: SenseWear 1st electrode placement

Figure 5: SenseWear 2nd electrode placement
The SenseWear HR Armband estimates energy expenditure by the use of a two-axis accelerometer which is used to track movement and body position. Sensors determining dissipated heat, skin temperature and galvanic skin response due to sweating and emotional stimuli complement the algorithm used to estimate energy expenditure by the device.\(^7\)

**The Actiheart Mini Mitter Heart Rate Monitor**

The Actiheart Mini Mitter heart rate monitor was connected to the subject’s chest as seen in Figure 7. The main sensor (RA) electrode was placed near the center of the sternum, and the left lead (LA) was placed in the length of the connecting wire, along with the mid-clavicular line.
The Actiheart Mini Mitter also estimates energy expenditure during activity only through an accelerometer and sensors that measure body movement. Since the Actiheart Mini Mitter does not estimate resting energy expenditure resting values were calculated from the indirect calorimetry obtained from the K4. By adding the resting values to the energy cost estimated during activity, it allowed for comparisons between the Actiheart Mini Mitter, the SenseWear HR Armband and the K4 measurements taken during the activity. Therefore, the comparison at rest was the same for Actiheart Mini Mitter and the K4 measurements.

**Polar Heart Rate Monitor**

The Polar heart rate monitor strap was adjusted to fit snugly around the subject’s chest, just below the sternum (Figure 8).
**ECG Telemetry Heart Rate Monitoring**

Electrodes were placed to monitor a clinical standard two-lead ECG (Lead II). Continuous monitoring and storage of ECG data was done using the ScottCare Advantage telemetry system (Figure 9). R-waves were manually counted for each minute of the protocol for the true minute heart rate measurement.

![Figure 9: ECG electrode placement](image)

**Data Analysis**

Data was compared at each minute for heart rate as measured by the SenseWear Hr Armband, Actiheart Mini Mitter monitor, Polar Hr monitor, and the ECG, with the ECG acting as the “Gold Standard”. A gold standard is a device that has already been determined to be accurate and reliable, and therefore, the devices being tested are compared to it in a validation study. Energy expenditure was compared between the “Gold Standard” Cosmed K4 b² and estimates from the SenseWear HR Armband and Respironic’s Actiheart Mini Mitter.

An analysis of variance (ANOVA) was performed on all dependant variables using SPSS (version 14.0). If the ANOVA demonstrated a significant difference (p<.05) between the devices, paired t-tests were performed to determine which devices
specifically showed significant differences. In order to control for Type I error inflation, a “protected” t-test was run, in which the probability value of .05 is adjusted for the number of comparisons (05/6=0.008, rounded to 0.01 for heart rate and .05/3=0.17, rounded to 0.02 for energy expenditure).

Although 30 subjects were tested in this study, the n values may vary due to the analysis system. SPSS automatically eliminates any incomplete date when running the analysis.
CHAPTER IV

RESULTS AND DISCUSSION OF DATA

Thirty healthy adults (8 males and 22 females) participated in the study (Table 2). Participants recruited from the Cleveland State University community signed an IRB approved subject consent form (Appendix A) and were screened prior to taking part in the study using the American Heart Association/American College of Sports Medicine Pre-participation Screening Questionnaire (Appendix B). Only low and moderate risk subjects were allowed to participate in the study.

Table 2: Subject Characteristics

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Range</th>
<th>Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height (cm)</td>
<td>30</td>
<td>152-193.8</td>
<td>171.2±9.7</td>
</tr>
<tr>
<td>Weight(kg)</td>
<td>30</td>
<td>51.8-110.9</td>
<td>69.9±13.3</td>
</tr>
<tr>
<td>Age (years)</td>
<td>30</td>
<td>18-59</td>
<td>25.70±10.0</td>
</tr>
</tbody>
</table>

Data analysis and interpretation was organized as follows: (1) Analysis of heart rate and (2) Analysis of Energy Expenditure.

Heart Rate Data

Continuous heart rate data was obtained from four monitoring devices throughout the stages of the protocol (sit, stand, 1.5 mph, 2.0 mph, 2.5 mph, 3.0 mph and recovery). The devices used were the SenseWear Armband (AB), the Actiheart Mini Mitter monitor...
(AT), Polar heart rate monitor (P), and an Electrocardiogram (ECG). The three devices (AB, AT and P) were compared to each other with the continuous ECG used as the gold standard. Complete results for all devices were collected on 27 subjects. (Figure 10)

![Mean Heart Rate for devices per stage](image)

Figure 10: Mean heart rate per stage of the protocol

**SenseWear HR Armband Compared to ECG (Table 3)**

The SenseWear Armband consistently recorded a higher heart rate (2-8 beats per minute) throughout the protocol when compared to the ECG. However, the only significant differences were during standing and the 1.5 mph walking stage, a difference of approximately 5 beats. No significant differences were found between the devices in the remaining stages (Table 3).

<table>
<thead>
<tr>
<th>Stage of the Protocol</th>
<th>SenseWear Mean±SD</th>
<th>ECG Mean±SD</th>
<th>SenseWear-ECG Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>74±9.13</td>
<td>71±9.46</td>
<td>.014</td>
</tr>
<tr>
<td>Stand</td>
<td>88±10.60</td>
<td>83±10.60</td>
<td>.003*</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>91±10.90</td>
<td>85±11.13</td>
<td>.000*</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>93±10.49</td>
<td>88±10.81</td>
<td>.012</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>98±9.35</td>
<td>92±11.09</td>
<td>.051</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>100±11.70</td>
<td>97±12.11</td>
<td>.591</td>
</tr>
<tr>
<td>Recovery</td>
<td>97±34.04</td>
<td>89±12.97</td>
<td>.216</td>
</tr>
</tbody>
</table>

p=.01 (protected t-test) n= 29
**SenseWear HR Armband Compared to the Actiheart Mini Mitter (Table 4)**

The SenseWear HR Armband consistently recorded a higher heart rate (1-3 bpm) than the Actiheart Mini Mitter monitor throughout the protocol with the exception of the last walking stage at 3.0 mph, which was about 8 bpm lower. However, no significant differences were found between the devices, with exception of the standing stage.

<table>
<thead>
<tr>
<th></th>
<th>SenseWear Mean ± SD</th>
<th>Actiheart Mean HR ±SD</th>
<th>SenseWear-Actiheart Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>74±9.13</td>
<td>71±8.89</td>
<td>.014</td>
</tr>
<tr>
<td>Stand</td>
<td>88±10.21</td>
<td>83±10.60</td>
<td>.005*</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>91±10.90</td>
<td>88±20.91</td>
<td>.51</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>93±10.49</td>
<td>92±21.80</td>
<td>.741</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>98±9.35</td>
<td>97±25.03</td>
<td>.893</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>100±11.70</td>
<td>108±30.62</td>
<td>.157</td>
</tr>
<tr>
<td>Recovery</td>
<td>97±34.04</td>
<td>90±13.13</td>
<td>.0318</td>
</tr>
</tbody>
</table>

*p=.01(protected t-test) n=27

**SenseWear HR Armband Compared to the Polar HR monitor (Table 5)**

The SenseWear HR Armband consistently recorded a high heart rate compared to the Polar HR monitor by 4-8 bpm. However, only the first 3 stages of the protocol showed a significant difference.

<table>
<thead>
<tr>
<th></th>
<th>SenseWear Mean ± SD</th>
<th>Polar Mean HR ±SD</th>
<th>SenseWear-Polar Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>74±9.13</td>
<td>69±7.89</td>
<td>.000*</td>
</tr>
<tr>
<td>Stand</td>
<td>88±10.21</td>
<td>80±11.35</td>
<td>.000*</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>91±10.90</td>
<td>85±12.92</td>
<td>.003*</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>93±10.49</td>
<td>90±20.31</td>
<td>.503</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>98±9.35</td>
<td>92±14.93</td>
<td>.068</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>100±11.70</td>
<td>99±14.06</td>
<td>.764</td>
</tr>
<tr>
<td>Recovery</td>
<td>97±34.04</td>
<td>89±12.65</td>
<td>.221</td>
</tr>
</tbody>
</table>

*p=.01(protected t-test) n=29

**Actiheart Mini Mitter Compared to ECG (Table 6)**

When the Actiheart Mini Mitter was compared to the electrocardiogram, no significant differences were found during any stage of the protocol.
Table 6: Actiheart Mini Mitter and ECG

<table>
<thead>
<tr>
<th></th>
<th>Actiheart Mean ±SD</th>
<th>ECG Mean ±SD</th>
<th>Actiheart – ECG Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>71±8.89</td>
<td>71±9.46</td>
<td>.967</td>
</tr>
<tr>
<td>Stand</td>
<td>83±10.60</td>
<td>83±10.60</td>
<td>.935</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>88±29.91</td>
<td>85±11.13</td>
<td>.607</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>92±21.80</td>
<td>88±10.81</td>
<td>.289</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>97±25.03</td>
<td>92±11.09</td>
<td>.253</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>108±30.62</td>
<td>97±12.11</td>
<td>.070</td>
</tr>
<tr>
<td>Recovery</td>
<td>90±13.13</td>
<td>89±12.97</td>
<td>.172</td>
</tr>
</tbody>
</table>

p= .01 (protected t-test) n= 27

Polar HR Monitor Compared to ECG (Table 7)

When the Polar HR Monitor was compared to the ECG, significant differences were only found for the first two stages of the protocol. The differences were about 3-4 beats per minute.

Table 7: Polar Heart Rate Monitor and ECG heart rate

<table>
<thead>
<tr>
<th></th>
<th>Polar Mean ±SD</th>
<th>ECG Mean±SD</th>
<th>Polar-ECG Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>69±7.89</td>
<td>71±9.46</td>
<td>.003*</td>
</tr>
<tr>
<td>Stand</td>
<td>80±11.35</td>
<td>83±10.60</td>
<td>.006*</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>85±12.92</td>
<td>85±11.13</td>
<td>.772</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>90±20.31</td>
<td>88±10.81</td>
<td>.580</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>92±14.93</td>
<td>92±11.09</td>
<td>.806</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>99±14.06</td>
<td>97±12.11</td>
<td>.181</td>
</tr>
<tr>
<td>Recovery</td>
<td>89±12.65</td>
<td>89±12.97</td>
<td>.689</td>
</tr>
</tbody>
</table>

p= .01 (protected t-test) n=29

Polar HR Monitor Compared to the Actiheart Mini Mitter (Table 8)

The Polar HR Monitor was found to be lower for all stages compared to the Actiheart Mini Mitter (2-8 bpm) but no significant differences were found with the exception of the first sitting stage, a difference of only 2 beats per minute.

Table 8: Polar HR Monitor and Actiheart Mini Mitter

<table>
<thead>
<tr>
<th></th>
<th>Polar Mean ±SD</th>
<th>Actiheart Mean ±SD</th>
<th>Polar – Actiheart Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>69±7.89</td>
<td>71±8.89</td>
<td>.002*</td>
</tr>
<tr>
<td>Stand</td>
<td>80±11.35</td>
<td>83±10.60</td>
<td>.016</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>85±12.92</td>
<td>88±29.91</td>
<td>.567</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>90±20.31</td>
<td>92±21.80</td>
<td>.654</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>92±14.93</td>
<td>97±25.03</td>
<td>.312</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>99±14.06</td>
<td>108±30.62</td>
<td>.142</td>
</tr>
<tr>
<td>Recovery</td>
<td>89±12.65</td>
<td>90±13.13</td>
<td>.185</td>
</tr>
</tbody>
</table>

p=.01 (protected t-test) n= 27
**Heart Rate Summary**

In general, the SenseWear HR Armband consistently recorded higher rates throughout the protocol when compared to the ECG, Actiheart Mini Mitter and Polar Heart Rate Monitor. No significant differences were found during any stage of the protocol between the Actiheart Mini Mitter and the ECG, and when the Polar HR Monitor was compared to the ECG, significant differences were only found for the first two stages of the protocol. Even though differences occur between devices, the differences were only of 1-8 beats per minute. These differences could be considered large in a clinical population, however they may be considered negligible for healthy populations.

**Energy Expenditure Data**

Energy expenditure was measured by indirect calorimetry, using the Cosmed K4 b2 portable CO₂ and O₂ analysis system (K4). Energy expenditure was estimated using an algorithm from the SenseWear Armband (AB) and the Actiheart Mini Mitter (AT). Comparisons were made between each device (Figure 11).

![Figure 11: Mean energy expenditure per stage of the protocol](image)
**SenseWear HR Armband Compared to K4 (Table 9)**

The SenseWear Armband consistently overestimated energy expenditure by approximately 0.5-1.0 kcal/min during the exercise stages of the protocol and it underestimated energy expenditure during the recovery stage by about 0.5 kcal/min when compared to the K4.

Table 9: SenseWear HR Armband and K4

<table>
<thead>
<tr>
<th></th>
<th>SenseWear Mean±SD</th>
<th>K4 Mean±SD</th>
<th>SenseWear – K4 Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>1.18±.192</td>
<td>1.22±.293</td>
<td>.405</td>
</tr>
<tr>
<td>Stand</td>
<td>1.28±.284</td>
<td>1.33±.389</td>
<td>.459</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>3.38±.924</td>
<td>2.72±.669</td>
<td>.000*</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>4.01±.923</td>
<td>3.09±.691</td>
<td>.000*</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>4.57±.910</td>
<td>3.58±.795</td>
<td>.000*</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>4.64±.945</td>
<td>4.27±.919</td>
<td>.041</td>
</tr>
<tr>
<td>Recovery</td>
<td>1.34±.231</td>
<td>1.81±.415</td>
<td>.000*</td>
</tr>
<tr>
<td>Total</td>
<td>101.26±18.73</td>
<td>89.38±19.55</td>
<td>.002*</td>
</tr>
</tbody>
</table>

p=.02 (protected t-test) n= 29

**SenseWear HR Armband Compared to the Actiheart Mini Mitter (Table 10)**

The Actiheart Mini Mitter monitor underestimated the energy expenditure through the exercise protocol with the exception of the resting stages. The values for the resting stages (sit, stand and recovery) were directly calculated from the K4 data because of the Actiheart Mini Mitters’ inability to measure resting energy expenditure.

Table 10: SenseWear HR Armband and Actiheart Mini Mitter

<table>
<thead>
<tr>
<th></th>
<th>SenseWear Mean±SD</th>
<th>Actiheart Mean± SD</th>
<th>SenseWear – Actiheart Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>1.18±.192</td>
<td>1.22±.299</td>
<td>.468</td>
</tr>
<tr>
<td>Stand</td>
<td>1.28±.284</td>
<td>1.23±.297</td>
<td>.332</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>3.38±.924</td>
<td>2.23±.973</td>
<td>.000*</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>4.01±.923</td>
<td>2.64±1.140</td>
<td>.000*</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>4.57±.910</td>
<td>2.98±1.202</td>
<td>.000*</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>4.64±.945</td>
<td>3.34±1.303</td>
<td>.000*</td>
</tr>
<tr>
<td>Recovery</td>
<td>1.34±.231</td>
<td>1.45±.453</td>
<td>.175</td>
</tr>
<tr>
<td>Total</td>
<td>101.26±18.73</td>
<td>72.93±25.93</td>
<td>.000*</td>
</tr>
</tbody>
</table>

p=.02 (protected t-test) n= 29
Actiheart Mini Mitter Compared to Indirect Calorimetry (Table 11)

When the Actiheart Mini Mitter energy expenditure estimations were compared to the K4 measurements, significant underestimations (0.5 kcal/min) were found between all stages with the exception of the first resting stage. The resting numbers for the Actiheart Mini Mitter were taken directly from the K4 measurements for the purpose of this study since the Actiheart Mini Mitter does not estimate resting energy expenditure.

Table 11: Actiheart Mini Mitter and K4

<table>
<thead>
<tr>
<th></th>
<th>Actiheart Mean ± SD</th>
<th>K4 Mean ± SD</th>
<th>Actiheart – K4 Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit</td>
<td>1.22±.299</td>
<td>1.22±.293</td>
<td>.519</td>
</tr>
<tr>
<td>Stand</td>
<td>1.23±.297</td>
<td>1.33±.389</td>
<td>.004*</td>
</tr>
<tr>
<td>1.5 mph</td>
<td>2.23±.973</td>
<td>2.72±.669</td>
<td>.000*</td>
</tr>
<tr>
<td>2.0 mph</td>
<td>2.64±1.140</td>
<td>3.09±.691</td>
<td>.000*</td>
</tr>
<tr>
<td>2.5 mph</td>
<td>2.98±1.202</td>
<td>3.58±.795</td>
<td>.000*</td>
</tr>
<tr>
<td>3.0 mph</td>
<td>3.34±1.303</td>
<td>4.27±.919</td>
<td>.000*</td>
</tr>
<tr>
<td>Recovery</td>
<td>1.45±.453</td>
<td>1.81±.415</td>
<td>.000*</td>
</tr>
<tr>
<td>Total</td>
<td>72.93±25.93</td>
<td>89.38±19.55</td>
<td>.000*</td>
</tr>
</tbody>
</table>

p=.02 (protected t-test) n= 29

Discussion

The purpose of the study was to determine the validity and accuracy of the SenseWear Armband in measuring heart rate and estimating energy expenditure during a walking treadmill protocol as compared to the Gold Standards, ECG for heart rate, and the K4 for energy expenditure, as well two commercially available devices, the Actiheart Mini Mitter and the Polar heart rate monitor.

Heart Rate Monitors

In general, the SenseWear Armband over calculated heart rate values by 5 beats/min, when compared to the ECG measurement.

Difference heart rate sampling methods and electrode placement can contribute to the difference in heart rate measurements between the devices. Goodie et al’s validation
study of the Polar Heart Rate monitor found that although the monitor is a valid device for measuring heart rate, there is a significant difference between the Polar and the ECG. However, this difference was deemed clinically insignificant. This study suggested that the differences between the devices can be attributed to the different sampling methods used by each device. For example, one difference is in the interval between samplings. The Polar Heart Rate Monitor samples heart rate at 5-second intervals and averages these for each minute, whereas the ECG counted every R-wave.

Brage et al studied the effect of heart rate monitor electrode placement on the precision of the heart rate measurement for the Actiheart Mini Mitter, which may in turn have an effect on the energy expenditure estimations of monitors. However, they found that the electrode position did not change the resulting heart rate and energy expenditure data obtained from the monitor.

In this study, the accuracy of the SenseWear HR Armband and the Actiheart Mini Mitter, decreased with the increase in exercise intensity during the protocol. This finding is supported by a study by Terbizan et al, which investigated the validity of seven other heart rate monitoring devices. In this previous study, it was observed that the validity of all the tested heart rate monitors decreased with the increase of speed, especially when the speed surpassed the 6.0 mph mark.

**Energy Expenditure**

The SenseWear HR Armband consistently overestimated and the Actiheart Mini Mitter underestimated energy expenditure when compared to the K4 (indirect calorimetry) measurements in this study.
Specifically, the overestimation of the SenseWear HR Armband was found during the active stages of the protocol. During the beginning resting stages (sitting and standing), no significant difference was found between the SenseWear HR Armband’s estimation of energy expenditure and the K4’s measurement. This overestimation may be attributed to the sensitivity of the sensors, or the accuracy of the algorithm used to estimate energy expenditure.

A recent validation study by Andreacci et al\textsuperscript{25} of the SenseWear Pro Armband in children 7-10 years of age determined that when child-specific exercise algorithms were used, accurate energy expenditure estimations were made during the treadmill exercise protocol.\textsuperscript{25} This suggests that population and protocol specific algorithms are necessary for an accurate energy expenditure estimation. This study, as well the study by King and colleagues\textsuperscript{6} support the findings of the current study. Both previous studies found that the accuracy of the SenseWear HR Armband decreased with the increase in exercise intensity.

Another variable is the type of exercise being performed. In a validation study of the SenseWear Pro Armband, Jakicic et al\textsuperscript{5} found that it was necessary to apply exercise specific algorithms to the device in order to accurately estimate energy expenditure. It was found that when using a generalized algorithm, the SenseWear Pro Armband underestimated energy expenditure during walking, biking and stepping protocols, and overestimated energy expenditure during an arm ergometer protocol.\textsuperscript{5} In the present study, as the subjects went from rest to walking, and as the speed increased, the accuracy of the energy expenditure estimations decreased. This may be due to the increased arm movement during walking at increased speeds.
Davis and colleagues\textsuperscript{22} examined the effect of short-sleeved versus long-sleeved clothing on the ability of the SenseWear Pro Armband in estimating energy expenditure. Although that study found no significant differences between the measurements, clothing can be a possible variable in the present study.

The Actiheart Mini Mitter consistently underestimated energy expenditure during the active stages of the protocol. This again can be attributed to the algorithm used to estimate energy expenditure.
CHAPTER V
SUMMARY AND CONCLUSION

Summary
The purpose of this study was to validate the accuracy of the SenseWear HR Armband for measuring heart rate and energy expenditure in ambulatory subjects when compared to an electrocardiogram (ECG), indirect calorimetry Cosmed K4 b², the Polar Heart Rate monitor, and the Actiheart Mini Mitter.

The results showed significant differences between the SenseWear HR Armband and the ECG only during the standing and 1.5 mph walking stages, a difference of approximately 5 beats per minute. The results also showed the SenseWear HR Armband to consistently overestimate energy expenditure by approximately 0.5-1.0 kcals/min during the exercise stages of the protocol while it underestimated energy expenditure during the recovery stage by about 0.5 kcals/min when compared to the K4 measurements.

Conclusion
The first hypothesis concerning the accuracy of the SenseWear HR Armband in measuring heart rate when compared to the ECG, Actiheart Mini Mitter and the Polar
Heart Rate Monitor was accepted. Significant differences between the SenseWear HR Armband and the ECG were only found during the standing and 1.5 mph stages of the protocol. The differences were on average 5 beats/min for the SenseWear HR Armband when compared to the ECG, Actiheart Mini Mitter and the Polar Heart Rate Monitor.

The second hypothesis concerned the accuracy of the SenseWear HR Armband in estimating energy expenditure. This hypothesis was rejected due to significant differences between the indirect calorimetry measurements of energy expenditure and the SenseWear HR Armband estimation of energy expenditure. However, the difference between the SenseWear HR Armband and the other devices was only about ±10%.

Limitations

The following limitations may have had an impact on the results:

1. Small sample size (n=30)
2. Low exercise intensity – may not apply to higher intensity
3. No access to the algorithm formula

Future Research

Future research is needed for the validation of the SenseWear HR Armband with higher intensity exercise and other forms of exercise such as cycle ergometers, arm ergometer and running. This study was limited by a small sample size. Therefore a study is needed with a larger sample, including broader representation of the population. Furthermore, this study was performed in a very controlled environment with little fluctuation of temperature or humidity. Studies are needed to determine the validity of the device in hot and cold environments.
BIBLIOGRAPHY

1. [CDC] Center for Disease Control. 2007 May 22. CDC home page.
   


   


INFORMED CONSENT FOR PARTICIPATION

VALIDATION FOR THE SENSEWEAR HR ARMBAND FOR MEASURING
HEART RATE AND ENERGY EXPENDITURE

INTRODUCTION

You have been asked to participate in a research study to be conducted in the Human Performance Laboratory at Cleveland State University. The specific aim of this study is to determine whether the SenseWear heart rate armband can be used as a reliable ambulatory heart rate (HR) monitor. Additionally, the accuracy of the SenseWear HR Armband’s estimation of energy expenditure will be determined.

To determine whether the SenseWear HR Armband can be used as a reliable ambulatory heart rate monitor, comparisons will be made using Respironics’ Actiheart heart rate monitor using a two standard ECG monitoring electrodes attached to the chest. The Sense Wear HR Armband will also be compared to the Polar heart rate monitor, which uses a chest strap and a wrist unit that is capable of downloading continuous heart rate. All three units will be compared to an electrocardiogram recorded continuously via telemetry monitoring.

Estimation of energy expenditure obtained from the SenseWear HR Armband will be compared to calculating energy expenditure by measuring oxygen consumption and carbon dioxide production.

PROCEDURES

Resting and exercise heart rates along with continuous measurement of oxygen consumption will be obtained throughout the test protocol. Heart rates will be obtained
using standard telemetry ECG equipment used in the Human Performance Laboratory at
Cleveland State University. Oxygen consumption will be measured using a Metabolic
cart. Simultaneous heart rates will also be obtained using the SenseWear HR armband
and the Actiheart heart rate monitor using the electrodes attached to the chest, and a Polar
heart rate monitor using a chest strap and a wrist unit.

You will be tested while sitting, standing and walking on a motor driven treadmill
at speeds of 1.5, 2.0, 2.5 and 3.0 miles per hour (Table 1). The test will end if
you develop any symptoms or have any distress or you reach an exercise
intensity equal to or greater than 85% of your age predicted maximum heart rate
(220 – age). The exercise testing will be consistent with American College of
Sports Medicine standards. The total time for the testing should be approximately
one hour.

Table 1. Testing protocol

<table>
<thead>
<tr>
<th>STAGE</th>
<th>TIME (min.)</th>
<th>WORKLOAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>Sitting</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>Standing</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>1.5 mph</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>2.0 mph</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>2.5 mph</td>
</tr>
<tr>
<td>6</td>
<td>5</td>
<td>3.0 mph</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
<td>Recovery (standing)</td>
</tr>
</tbody>
</table>
RISKS AND DISCOMFORTS

The sensor interfaces on the SenseWear HR Armband are made from hypoallergenic grade stainless steel. The probability of risks to you is low other than the possibility of minor skin irritation and/or discomfort that may result when the electrode sites are prepared and electrodes placed. During the exercise testing, there exists the possibility of certain changes occurring; these include abnormal blood pressure, fainting, disorders of the heart rhythm, and rare instances of heart attack, stroke or death (1:20,000 exercise tests). Every effort will be made to minimize these risks through screening provided by the questionnaire.

BENEFITS

There are minimal benefits to be obtained by you other than participating in research to increase scientific knowledge. Risk-benefits status: Based on the precautions to minimize risk previously noted, the investigators view this as a low risk protocol that may provide important data for heart rate determination and for estimation of energy expenditure. You will be compensated a total of $25 for participation in this study.

CONFIDENTIALITY

To protect my privacy and confidentially, my name will not be used in any documentation of the project. The information, however, may be used for statistical or scientific purposes with your right of privacy retained.

Participation

I understand that participation in this project is voluntary and that I have the right to withdraw at any time with no consequences. I understand that if I have any questions
about my rights as a participant, I can contact Cleveland State University’s Review Board at (216) 687-3630.

I attest and verify that I have no known health problems that would prevent me from successfully participating in the exercise test.

Inquiries
Any questions about the procedures used in this project are welcome. If you have any doubts or questions, please ask us for further explanations or call Dr. Kenneth Sparks at (216) 687-4831.

Patient Acknowledgement
The procedures, purposes, known discomforts and risks, possible benefits to me and to others have been explained to me. I have read the consent form or it has been read to me, and I understand it. I agree to participate in this program. I have been given a copy of this consent form.

Signature: _____________________________  Date: _____________

Witness: _____________________________  Date:
AHA/ACSM Preparticipation Screening Questionnaire (AHA/ACSM, 1998)

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

Other health issues:
☐ You have musculoskeletal problems. Specify on back*
☐ You have concerns about the safety of exercise. Specify on back*
☐ You take prescription medication(s). Specify on back*
☐ 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 or you have had a hysterectomy or you are postmenopausal.
☐ You smoke.
☐ Your blood pressure is greater than 140/90 mm Hg.
☐ You don’t know your blood pressure.
☐ You take blood pressure medication.
☐ Your blood cholesterol level is > 240 mg/dl.
☐ You don’t know your cholesterol level.
☐ You have a blood relative who had a heart attack before age 55 (father/brother) or 65 (mother/sister).
☐ You are diabetic or take medicine to control your blood sugar.
☐ You are physically inactive (i.e., you get less than 30 minutes of physical activity on at least 3 days/week).
☐ You are more than 20 pounds overweight.
☐ None of the above is true.

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

If you marked two or more of the statements in this section, you should consult your 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 healthcare provider in almost any facility that meets your exercise program needs.

*RISK STATUS (Low; Moderate; High):