

Accuracy and Reliability of the SenseWear™ Armband as an Energy Expenditure Assessment Device

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Abstract -- Consumers and researchers lack an easy-to-use, reliable and cost efficient way to accurately assess physical activity and energy expenditure, a critical component of successful weight management. BodyMedia has addressed this need by developing the SenseWear® Armband which utilizes a 2 axis-accelerometer, heat flux sensor, galvanic skin response sensor, skin temperature sensor and a near-body ambient temperature sensor to gather data leading to the calculation of energy expenditure. This paper outlines the studies that show how the SenseWear Armband provides very low energy expenditure error rates relative to equipment that is more costly, limiting and difficult to use and how it is a cost efficient and simple solution that can be applied outside the laboratory to track and explore energy expenditure.

Index Terms -- SenseWear Armband, energy balance, sensor array, energy expenditure, TEE, AEE, REE, expenditure assessment physical activity assessments, contextual detection, free-living environment, accuracy and reliability, wearable computer.

INTRODUCTION

Increased physical activity, along with the achievement and maintenance of energy balance, has emerged as important personal health goals for the 21st century. It is well understood by health professionals that many leading health problems are caused or aggravated by physical inactivity and the consequences of consuming more calories than we burn. The obesity epidemic and its associated problems including hypertension, type II diabetes, coronary artery disease, arthritis and chronic back pain are testimony to the fact that a sedentary lifestyle and being overweight contribute to a poor quality of life, and in many cases, premature death.

While health professionals, as well as, individuals with weight problems acknowledge the need to improve and sustain their exercise and eating behaviors, they lack the tools needed to accurately measure energy expenditure, an important body measurement for determining if a person is burning more energy than they are consuming. In order to lose weight, a person must first be able to accurately quantify levels of activity and energy expenditure. Only then can they begin to implement the proper changes necessary to daily routines that will help them increase activity levels and modify caloric intake.

To date, there is not an easy-to-use, reliable and accurate way to routinely assess physical activity and energy expenditure outside the lab environment. This has significant ramifications for weight

management success. From the behavior change literature (Delley 1998, Khem 2000, Schnool 2001, and Wierenga 1990), it is well recognized that regular and accurate self-monitoring in the free-living environment can provide important feedback which increases self-awareness – the prerequisite for healthy decision-making and long-term lifestyle change.

As microprocessors, wireless technology, software, and the Internet, have advanced, so have the opportunities to develop personalized body monitoring devices that allow individuals to accurately track and analyze their daily activities. BodyMedia has responded to this opportunity by developing a wearable device, the SenseWear Armband, which accurately measures a number of physiologic parameters that allow health researchers, professionals, as well as individuals to continuously and more accurately track physical activity and energy expenditure. The SenseWear Armband gives health professionals and the weight conscious the opportunity to see how changes in daily activities affect changes in energy expended, energy balance and ultimately weight loss. The remainder of this paper will provide validation data that supports the use of BodyMedia's SenseWear Armband for the monitoring of physical activity and energy expenditure.

I. DESCRIPTION OF THE SENSEWEAR ARMBAND

The BodyMedia SenseWear Armband utilizes a 2-axis accelerometer, heat flux sensor, galvanic skin response sensor (GSR), skin temperature sensor, and a near-body ambient temperature sensor to capture data leading to the calculation of energy expenditure. The SenseWear Armband also offers the option of heart rate detection through the use of the Polar Chest Strap. The following is a brief description of each sensor and its function in the device. More detailed specification can be found in the paper "Characterization and Implications of the Sensors Incorporated into the SenseWear Armband for Energy Expenditure and Activity Detection".

1) The accelerometer in the SenseWear Armband is a 2-axis micro-electro-mechanical sensor (MEMS) device that measures motion. The motion can be mapped to forces exerted on the body and hence energy expenditure. By taking into account gravity, our algorithms can also predict the context in which the armband is being worn.

2) The proprietary heat flux sensor in the armband is a robust and reliable device that measures the amount of heat being dissipated by the body. The sensor uses very low thermally resistant materials and extremely sensitive thermocouple arrays. It is placed in a thermally conductive path between the skin and the side of the armband exposed to the environment. A high gain internal amplifier is used to

bring the signal to a level that can be sampled by the microprocessor located in the SenseWear Armband.

3) Skin temperature is measured using a highly accurate thermistor-based sensor located on the backside of the armband near its edges and in contact with the skin. Continuously measured skin temperature is linearly reflective of the body's core temperature activities.

4) The near-body ambient temperature sensor measures the air temperature immediately around the wearer's armband. This sensor also uses a highly accurate thermistor-based sensor and directly reflects the change in environmental conditions around the armband; for example, walking out of an air-conditioned building on a hot day.

5) Galvanic skin response (GSR) represents electrical conductivity between two points on the wearer's arm. The SenseWear Armband GSR sensor includes two hypoallergenic stainless steel electrodes integrated into the underside of the armband connected to a circuit that measures the skin's conductivity between these two electrodes. Skin conductivity is affected by the sweat from physical activity and by emotional stimuli. GSR can be used as an indicator of evaporative heat loss by identifying the onset, peak, and recovery of maximal sweat rates.

6) The SenseWear Armband houses a custom receiver board to receive the pulses transmitted by a heart beat detection chest strap. The receiver board includes a free-running 8kHz timer derived from the crystal controlled microprocessor clock that is accurate to 50 beats per minute. Heart rate and energy expenditure exhibit a linear relationship, particularly between a heart rate of 110 and 150 beats per minute. Heart rate can also be used as an aid in distinguishing frequency, intensity, and duration of activity.

II. SUMMARY OF ENERGY EXPENDITURE STUDIES

We have embarked on a series of studies to help us develop, refine and validate a set of algorithms that approximate several aspects of energy expenditure including Total Energy Expenditure (TEE), Resting Energy Expenditure (REE), and Active Energy Expenditure (AEE).

TEE is the total number of calories a person burns over a period of time. REE is TEE during a period(s) of rest, essentially the slowest rate at which a person burns calories while awake. This second parameter is sometimes referred to as Resting Metabolic Rate (RMR) or Basal Metabolic Rate (BMR). AEE is the number of calories a person burns over a period of time due to physical activity during periods of non-rest. The best practical gold standard for measuring energy expenditure is the metabolic cart or VO2 machine. All studies conducted for the purpose of building or evaluating algorithms have used a MedGraphics CPX Express Metabolic Cart to provide an accurate view at the true value of the parameters TEE, REE, and AEE. The following is a description of the studies conducted to date.

III. THE INITIAL ENERGY EXPENDITURE STUDY

For approximately one year we conducted a series of in-house experiments to explore and refine the capabilities of each of the sensors that were to become a part of the SenseWear Armband. Data gathered during these preliminary investigations suggested that measuring heat loss from the arm as recorded by calibrated heat flux sensors is an accurate indicator of total body kilocalories burned, especially during low activity states such as office work, reading, standing or talking. In addition, both preliminary and published data (Wong 1995, Usaj, 2000) suggest that high activity level states could be measured with an accelerometer and correlated with VO2 measurements for medium to high ambulating activities. Encouraged by the results of these preliminary studies, we built a set of prototype armbands and began more formal studies.

The initial energy expenditure study conducted by BodyMedia, entitled "The relationship of accelerometer and heat flux data collected by the SenseWear Armband to kilocalories burned as measured by VO2 metabolic analysis: Implications for algorithm development," was designed to explore the following hypotheses:

1. The algorithm for the accelerometer in the SenseWear Armband will have a linear relationship to kilocalories burned under controlled circumstances and will be consistent across the sample population and ranges of activities performed.
2. The algorithm for the heat sensing components of the SenseWear Armband will also show a linear relationship to kilocalories burned under controlled circumstances and will be consistent across the sample population and ranges of activities performed.
3. Other parameters will be identified in the course of researching the above-mentioned objectives that will contribute to future algorithm development.

The study was conducted over a three-month period utilizing the hand built beta SenseWear Armband units. An additional goal of this study was to evaluate the performance of the hand built units for the purpose of ongoing product development and refinement prior to entering into further studies and/or mass production. One hundred sixty separate studies of 2.5 hours each utilizing the beta SenseWear Armbands were conducted using the following protocol:

Subjects were combined into 4 groups. Each group was comprised of 10 subjects recruited from the general population and chosen based on an even distribution of (1) Sex (2) Height (3) Body Mass Index and (4) Age. A breakdown of each group is provided in the following tables.

Groups 1 and 3 had the following characteristics

Sex	Height			BMI	Age				
M / F	5'9"	'9" to '11"	5'11"	24	24-26	>26	20-32	32-38	38-50
M	X			X			X		
M			X			X	X		
M		X			X			X	
M			X	X					X
M	X					X			X
F	X			X			X		
F			X			X	X		
F		X		X				X	
F			X	X					X
F	X					X			X

Groups 2 and 4 had the these characteristics

Sex	Height			BMI	Age				
M / F	5'9"	'9" to '11"	5'11"	24	24-26	>26	20-32	32-38	38-50
M			X	X			X		
M	X					X	X		
M		X			X			X	
M			X			X			X
M	X			X					X
F	X			X			X		
F			X			X	X		
F		X			X			X	
F			X	X					X
F	X					X			X

Exclusions and conditions

- Healthy individuals were selected via a medical screening. Test subjects with any of the following were excluded:
Hypertension, heart disease, pregnancy, certain medications, (decided case-by-case by Dr. Liden), eating disorders, asthma, chronic or acute bronchitis, diabetes, exercise-induced wheezing, missing or irregular periods, pneumonia, pulmonary diseases (COPD, etc.), seizure disorders, major surgery within the past year.
- No subject was allowed to start a new exercise routine during the time they were participating in the study.
- Subjects were asked to fast at least 4 hours before each test.

Materials and/or instruments used

Calibrated SenseWear Armbands	BodyMedia, Inc.
Heart Monitor Strap	Acumen
CPX Express Metabolic Analyzer	MedGraphics
Quantum II Bioelectrical Body Composition Analyzer	RJL Systems
Electro-therm Temperature Gauge and Hygrometer	Cooper Instrument Corp
Digital Weight Scale	Tanita Corp
OMEGASCOPE Surface Temperature Thermometer	Omega Corp
Digital Camera	AGFA
Video Camera and Accessories	Sony
Stationary Bicycle with Digital Feedback	Diamondback 1100R
Motorized Treadmill with Digital Feedback	SportsArt 3100HR
First Aid and Lab Supplies	Miscellaneous

VO2 Metabolic Analyzer Calibration

The metabolic cart chosen for use in this study was the MedGraphics CPX Express. The CPX Express™ is a compact, portable cardio-respiratory testing system. It provides measurement of VO2, METs, AT, and complete spirometry. It can be interfaced with existing 12-lead ECG systems, or measure HR via radio transmission (POLAR® HR transmitter/receiver). In accordance with the manufacturer's instructions, the CPX Express™ was calibrated to reference gases before each test session. Gas analyzer calibration required two gases:

- Calibration Gas: 5% CO2, 12% O2, Balance N2
- Reference Gas (similar to room air, no CO2): 21% O2, Balance N2

Calibration and reference gases were pre-mixed from pure gases to a blend tolerance of 1% of reading. After the system has warmed up for at least 45 minutes and the pump had been turned on, airflow was allowed to stabilize for 10 minutes. Gas cylinders were adjusted to 500 psi. The device's calibration program was then initiated. The device first purged the gas lines, and then took multiple samples of reference and calibration gases. The CPX Express™ prompted the user if calibration had been successful, or unsuccessful. If successful, the test began. If unsuccessful the device prompted the user to try various remedies. The device also provided a calibration report that displayed the measured and acceptable ranges, the barometric pressure, relative humidity and ambient temperature.

Procedures

The purpose of this study was to collect physiologic data from study participants who were wearing a SenseWear Armband during differing periods of physical activity. The procedure involved:

1. A telephone interview to determine eligibility for participation.
2. A face-to-face interview with a BodyMedia staff member to gather baseline health information and make certain body measurements including height, weight, skin temperature, blood pressure, heart rate, upper arm measurements, body-fat percentage.
3. Completion of an on-line health and wellness questionnaire (TRANSACT Profile), which surveyed the participants' current and past health and various behavioral characteristics.
4. Participation in a three-hour physical activity testing protocol.

The activity testing protocol began after basic physiologic information (height, weight, etc.) was recorded and the SenseWear Armband was strapped on and activated. Subjects were shown how to use the treadmill and stationary bicycle and were shown how to breathe into the VO2 mouthpiece. Subjects underwent a short training period while using the VO2 machine and the treadmill to acquaint them with the sensations involved and to alleviate anxiety. After the training period, subjects were instructed to:

Rest	15 minutes	
Walk	2.5 minutes	at 2.4 mph
Walk	5 minutes	at 3.6 mph
Walk	2.5 minutes	at 3.6 mph
Rest,	15 minutes	
Sit	10 minutes	
Walk	5 minutes	at 2.4 mph
Sit	10 minutes	
Break		
Rest	15 minutes	
Bike	5 minutes	at 16 mph
Stand	10 minutes	
Rest	15 minutes	
Walk	2.5 minutes	at 2.4 mph
Walk	5 minutes	at 3.6 mph
Walk	2.5 minutes	at 3.6 mph
Rest	15 minutes	

At this point, the VO2 machine was stopped and the data downloaded. The armbands were removed and data downloaded. The subject was paid and dismissed. When the same subject returned for the second test, the same conditions were used, however, the test activities were slightly different as follows:

Rest	15 minutes	
Walk	2.5 minutes	at 2.4 mph
Walk	5 minutes	at 3.6 mph
Walk	2.5 minutes	at 3.6 mph
Rest,	15 minutes	
Stand	10 minutes	
Bike	5 minutes	at 16 mph
Rest	10 minutes	
Break		
Stand	10 minutes	
Walk	5 minutes	at 2.4 mph
Stand	10 minutes	
Rest	15 minutes	
Walk	2.5 minutes	at 2.4 mph
Walk	5 minutes	at 3.6 mph
Walk	2.5 minutes	at 3.6 mph
Rest	15 minutes	

The metabolic behavior over this 2.5-hour protocol has a higher variation than most individuals experience on a daily basis. This was done so that results from this trial, though short in comparison to a full day, could safely be seen as an upper bound on the errors that our algorithms are likely to produce across days or weeks of normal use. This study's 40 participants also varied widely in age, sex, height and weight. This variation again allowed for the generalization that the

results of our algorithms were likely to be a good estimate of the error on a person whose demographics fall within our study range.

Summary of Data Collection and Analysis Procedure

Data collected from the CPX machine and the SenseWear armband was downloaded to our database along with each subject's demographic information. Data from each test was time aligned and joined. All test data was concatenated and formatted to be compatible with Matlab.

Analysis proceeded in two phases. First, data from individual SenseWear sensors were assessed for quality and potential use as a predictor of energy expenditure. If needed, smoothing filters and/or transforms were applied to condition the data. The second stage was to search for the subset of variables which taken together most accurately predicted energy expenditure. We focused primarily on the use of multivariate linear models.

Implicit in our modeling process was the use of cross-validation techniques as a guard against over fitting the data. Candidate models were subject to a series of training-testing cycles. At each cycle, a different subject's data would be removed from the total. The remaining data was used to determine the model's parameters. The model was then applied to the held out data and the error ratio calculated. Error ratios from all cycles were collated and analyzed. The results of this analysis were used to judge model quality.

Discussion and Results

The analysis of our algorithm showed that we could on average estimate each minute's TEE to within 9.4% of its true value. The 95% confidence interval for this error was 9.3% to 9.5%. While this was exciting, the results were even more encouraging on further investigation. The errors of these per minute estimates proved to be normally distributed as well as independent of true TEE. When comparing the sum of our estimates over a longer interval of time to the true TEE for that interval, we observed that the mean error was significantly smaller.

Seen over each 2.5-hour period (one test), our algorithm had a mean absolute error of 5.56% with a standard deviation in the error of 5.69%, giving a 95% confidence interval between 0% and 16.94% error. It was recognized that further investigation was needed to determine why the high end of this range was higher than for the one-minute period, but the average error was significantly lower.

The data used to compile these statistics had one non-optimal feature. The training set used to create the algorithms and test set used to test the algorithms and produce the reported results were distinct, that is, no data point appeared in both sets. However, in order to have the training set and test set have the same distribution of TEE/REE values so the testing of the algorithm was fair, it was necessary to divide up the total data taken such that the training set would have values for minutes X, Y, and Z from person N and the testing set would have values for minutes, A, B, and C from that same person N. A refined energy expenditure study protocol, which will be described later in

this paper allowed us to have no subject overlap between the training and testing sets. It was hoped that this would strengthen the claim that the algorithms being developed will generalize to new people who fall outside the boundaries of the clinical study. This new method (described later in this paper) has clearly shown itself to do a superior job at assessing the generalization accuracy of the algorithm. One result of this methodological improvement is that the accuracy numbers reported above can be seen in retrospect to have been an underestimate of the error generated on new individuals.

The remaining error appeared to be more systematic and the evidence suggested that it would not go down over substantially longer periods of time. However, as noted above, the activity test utilized in this study had higher variation than a person would normally experience over the course of a day. This fact supported the notion that the SenseWear Armband's ability to predict the total number of calories burned over the course of days or weeks for a particular person would be bounded above and below by the error bounds cited above.

At this point, developing these algorithms was viewed as an area of active work for BodyMedia and, as noted above, we had not yet taken advantage of various opportunities to refine them such as using data from previous minutes to help predict the current number of calories burned or collecting data utilizing calibrated production units coming off the line.

BodyMedia also pursued opportunities to characterize the intra-person variability with respect to the sensors and the algorithms. For example, during the 80, 150 minute tests run as part of the initial energy expenditure study, each participant wore a SenseWear Armband on each arm. The supposition was that what the sensors were measuring could be seen as highly repeatable if the two units collected very similar information from different arms and when all other conditions were the same.

For the accelerometer, the correlation coefficient between the right and left arms across these 80 trials was 0.89 establishing that measure as highly repeatable across a range of activities and people. The remaining independence between the values returned by the two units was, in part, ascribed to the fact that nearly all people have a dominant hand which results in different physical characteristics and movements between their limbs. This was borne out by the fact that the correlation coefficient was closer to 1.0 during periods of rhythmic exercise such as walking or jogging where the similarity arm-swings tend to cancel out the effect just cited. In addition, the correlation coefficient was lower during the low active periods such as sitting as might be expected if our assumption about dominance was correct.

For the GSR sensor, the correlation coefficient between the right and left arms across these 80 trials was 0.80 establishing that measure as being somewhat less repeatable than the accelerometer, but still quite repeatable across a range of activities and people. The same "handedness" description given above appeared to apply to the GSR, but to a much smaller extent. There was also some suggestion that the absolute values of GSR which were compared for correlation were

not as valuable as some other channels pulled from the same data stream (e.g., variance from the mean over each minute).

Due to the fact that the SenseWear unit was not perfectly symmetrical, comparisons of the two units was not appropriate with respect to the temperature sensitive sensors. When the unit was placed on the left arm the vent for heat flux is in front of the unit; therefore, it vents faster than the unit on the right arm where the vent is tucked in closer to the armpit; therefore, it shielded to a greater degree. As a result, the same technique for testing repeatability was not able to be used for the heat flux, skin temperature, or near-body ambient temperature sensors.

To further explore repeatability, the question was asked "How different are the values captured for the same person, on the same protocol, on different days (tests)?" Clearly, answering this question was of somewhat limited value since important factors were not accounted for such as how much the person had to eat on the two different days. Despite this limitation, this was viewed as a reasonable mechanism for examining the extent to which the same values would appear under largely the same conditions. This evaluation was conducted by giving to ANOVA, a statistical method for finding statistically significant difference between data sets, pairs of data sets such that for each data set pair, both data sets were drawn from a test with the same person. Each data set has 150 values sets, one for each minute of the trials, with a range of different raw values for each minute. The results were that in 92% of the set pairs, no statistically significant variation was found between the sets. With the limitations cited above, this provided another strong indication that the SenseWear Armband had reliable, repeatable performance characteristics.

Conclusion of this Study

This initial energy expenditure study provided essential information for the creation of initial algorithms, as well as, information that was extremely helpful to the process of ongoing product development. This study also raised a number of software, hardware and usability questions. These questions were subsequently addressed in a number of probative studies which were conducted after this initial study and prior to the initiation of a second energy expenditure study.

IV. PROBATIVE STUDIES INTERIM VALIDATION

A number of probative studies were conducted after the initial energy expenditure study to address various questions raised during that investigation. Three of the more important studies are summarized below:

Probative Study 1: The first of these studies entitled "Validation Tests Using Multiple Heat Flux Set-up" was designed to compare heat flux measurements taken by the SenseWear unit's heat flux sensors with heat flux measurements taken directly from the skin using standard heat flux sensors. The underlying assumption was that the standard heat flux sensor accurately measured heat flux and could serve as a valid tool for further evaluating the characteristics of SenseWear's heat flux sensor. Specifically these comparisons were intended to:

- a) Identify potential time lag between the SenseWear measurements and actual change in the heat flux from the skin.
- b) Compare measurements from the left and right arms simultaneously, using two SenseWear units.
- c) Study the relationship of the heat flux from the skin and skin temperature including both the pattern and magnitude of signals.
- d) Study the relationship between heat flux, VO₂ and VCO₂.
- e) Compare REE data readings from heat flux sensors.

Experimental Protocol

Subjects included five healthy, fit people ranging in age from 20-30 years. Two production SenseWear Armband units were used. Subjects wore one on each arm; the same unit was used on the same side of all subjects. SenseWear Armband units were placed at an upright position, on the outer side of the arm. In addition to the SenseWear Armband, three sets of a standard heat flux sensor and temperature sensor were placed on the lower right arm, the upper right arm and the forehead. A Pulse Oximeter from Nonin Medical was used to collect heart rate and blood oxygen saturation levels. A MedGraphics CPX cart was used to collect VO₂, VCO₂ and estimated REE. The activity protocol was as follows:

- a) Rest: The subjects began by resting for about 30 minutes. The goal was to bring the subject's metabolic rate as close as possible to base level.
- b) Run (treadmill): Each subject then exercised on the treadmill. Initially, the treadmill was operated at a speed of 2.5 miles per hour. At each three-minute mark, the speed was increased by 1 mph until the subject reached 5.5 mph. From this point on, the size of each increase was ½ mph. This was continued until either the subject's heart rate reached 80% of their maximum limit or the subject indicated they wished to stop. The subject was allowed a six-minute recovery period, which consisted of three minutes of 2.5 mph walking, followed by three minutes rest on an examination table. It is important to note that subjects were not allowed to place their hands on the resting bar of the treadmill.
- c) Rest: Finally, subjects rested for 30 minutes while being measured using the MedGraphics REE test.

Calibration of SenseWear Units and Standard Heat Flux Sensors:

The same two SenseWear units were repeatedly used for all experiments. SenseWear calibration was related only to the offset at thermal insulation conditions. For both devices, a high gain offset of 1723, and a low gain offset of 2097 were found. The two SenseWear units were first tested on a temperature controlled calibration bar and showed similar results. This was done for verification purposes only. Calibration of the three standard heat flux sensors was performed against a fourth similar heat flux sensor, of which a calibration curve was available.

Conclusions of this Study

1. A noticeable difference in heat flux measurements was observed between the left and right arms. Heat flux sensing with the SenseWear Armband is more sensitive on the right arm.

Additional investigation on this point has demonstrated that inversion of the SenseWear Armband on the left arm results in data consistent with that gathered on the right arm. This points to the fact that the vent placement and orientation of the device is an important consideration.

2. The ratio of heat flux data measured by the SenseWear, and the actual heat flux, measured by the standard sensors is significantly subject dependent.
3. The SenseWear's proprietary heat flux sensor acts as a thermal filter. The result of this is that very high frequency changes in heat are smoothed out directly through the thermal properties of the sensor (rather than through software). This filtering is advantageous because these very high frequency heat changes are "physiological noise" and algorithms can be improved through the smoothing of these measurements.
4. The heat flux measurements with the SenseWear show high enough resolution for the purpose of thermal energy calculations.
5. No apparent time lag between the SenseWear and the actual skin heat flux sensors was observed.
6. A warm-up period before the beginning is still recommended, regardless of conclusion # 5.
7. Acceleration and TEE show a linear relationship during physical activity.
8. It is suggested for best results to correlate the energies accumulated in a session, and not the instantaneous values, i.e., the rate of change of energies.

In addition to the conclusions above, the following interesting observations were made:

- Forehead heat flux measurement is not proportionally related to arm heat flux measurement. There is also significant noise in heat flux measurement from the forehead, which is far larger than the noise in heat flux measurements on the upper arm.
- Skin temperature decreases at the beginning of physical activity. Skin temperature increases above its normal level at the beginning of the rest period following physical activity.
- VO₂ and VCO₂ correlate very well with no significant delay in a time scale relevant to the activity protocol. However, VO₂ and VCO₂ respond more quickly to both the beginning and ending of activities than do heat flux measurements. In general, heat flux measurements change more gradually than VO₂ and VCO₂.

Probative Study 2: A second study entitled "Measuring resting metabolic rate by VO₂ metabolic cart and SenseWear: A comparison study" was conducted to determine how accurately the SenseWear Armband measured resting metabolic rate (RMR) by recording heat flow from the arm. Subjects were recruited from a pool of subjects that had participated in the initial energy expenditure study.

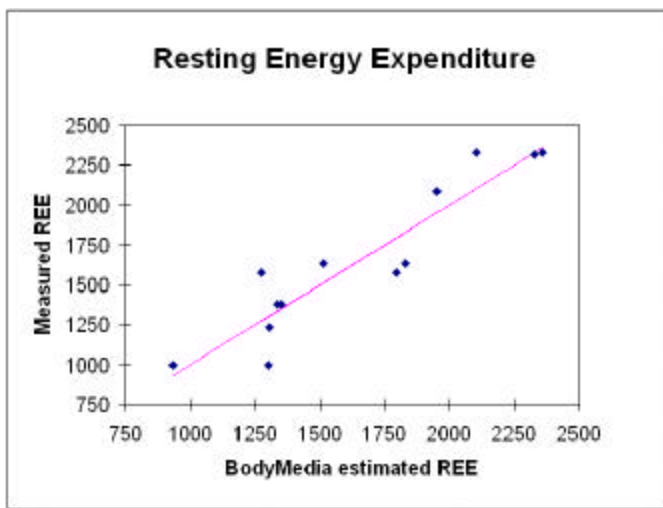
Study Protocol

Former subjects were contacted and asked to participate in this study. Fourteen subjects participated in the study. The subject wore a SenseWear Armband on each arm and an Acumen heart strap. The subject was provided with a sleeveless t-shirt to wear. The room

temperature and humidity were recorded for each test. The VO₂ mouthpiece was inserted and the nose clipped. The subject was then instructed to rest supine and relax as much as possible. The VO₂ analyzer and armbands collected data for 25 minutes. Data was downloaded to a database for analysis.

Results and Discussion

To ensure that VO₂ values were accurately measuring the true REE for each person the first five and last three data points from each 25 data point sets were dropped. The algorithm built for this study was a simple linear weighed combination of sensors including simple body measurements and BMR. In this case “BMR” was the value of the Harris-Benedict formula for approximating the true BMR of an individual based upon the demographic information {Sex, Height, Weight, Age}. The fit to that data is shown below.

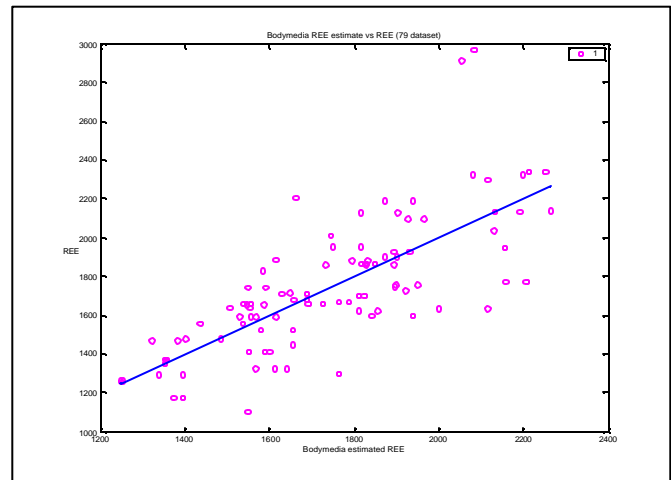


Here is a spreadsheet summary of the comparison of the error rate for this formula relative to using the BMR equation by itself.

REE	Harris-Benedict estimate	Harris-Benedict error ratio	BodyMedia estimate	BodyMedia error ratio
2314.61	1980.95	-0.144155	2329.37	0.00637768
999.389	1841.03	0.842156	935.306	-0.0641225
999.389	1841.03	0.842156	1303.61	0.304403
1378.89	1479.92	0.0732715	1353.76	-0.0182235
1378.89	1479.92	0.0732715	1336.33	-0.0308611
1231.5	1321.63	0.073188	1305.12	0.059779
1231.5	1321.63	0.073188	1305.12	0.059779
2327.05	1977.62	-0.150161	2360.03	0.0141698
2327.05	1977.62	-0.150161	2106.22	-0.0948975
1631.79	1996.17	0.223301	1514.08	-0.0721334
1631.79	1996.17	0.223301	1830.15	0.121559
1579.39	1590.77	0.0072062	1273.58	-0.193623
1579.39	1590.77	0.0072062	1794.51	0.136207
2087.22	1521.86	-0.270868	1950.66	-0.0654274

Mean Absolute % error	20.19		8.87
R2	0.2395		0.8715

Probative Study 3: Following completion of the second study, the same set of variables utilized in that study, again in a linear weighted combination, were run on the resting periods of the initial energy expenditure study as discussed previously. A graph of the results is shown below. Here REE (resting energy expenditure) is the true value as measured by the metabolic cart and it is compared against BodyMedia’s estimate of the same.



This study demonstrated that the algorithms produced for REE reduced, in some cases substantially reduced the error associated with predicting the REE of a particular person during a particular resting period.

V. THE SECOND ENERGY EXPENDITURE STUDY

The results from the initial energy expenditure study and the probative studies were instrumental in the design of subsequent energy expenditure study entitled “Energy Expenditure (EE) Measurement via the SenseWear Armband, contribution of multiple sensor array to a novel EE algorithm.” The following changes were integrated into this study:

- The BMI range of the study participants was expanded upwards
- A ramped protocol was employed whereby subjects were run up to a higher speed which allowed us to collect data over a broader range of conditions.
- The number of activities was reduced to two (treadmill and stationary bike) to insure a larger data pool for model construction.
- Treadmill and biking sessions were separated in time to avoid any possible crossover effects.
- A cool down period was incorporated to avoid any possible crossover effect of residual physiological activity.
- Recognizing that a simple linear model would not suffice, the sampling protocol was altered to fully sample each physiological parameter.

The second energy expenditure study was designed to explore the following hypotheses:

- The data from the sensor array in the armband will have a multivariate-linear relationship to kilocalories burned under controlled circumstances and will be consistent across the sample population and ranges of activities performed
- We also expect to identify other parameters driving the above-mentioned objective that would contribute to more refined algorithm development.

Subject Selection and Exclusions

Subjects were recruited from the general population and chosen based on an even distribution of (1) Sex (2) Height (3) Body Mass Index and (4) Age.

The specific demographic characteristics of the 72 subjects, which were recruited, are listed in the following tables:

Males

Age	Height	BMI
18-31	<5'9"	<24
18-31	<5'9"	25-27
18-31	<5'9"	28-30
18-31	<5'9"	31-33
18-31	5'9"-5'11"	<24
18-31	5'9"-5'11"	25-27
18-31	5'9"-5'11"	28-30
18-31	5'9"-5'11"	31-33
18-31	>5'11"	<24
18-31	>5'11"	25-27
18-31	>5'11"	28-30
18-31	>5'11"	31-33
32-43	<5'9"	<24
32-43	<5'9"	25-27
32-43	<5'9"	28-30
32-43	<5'9"	31-33
32-43	5'9"-5'11"	<24
32-43	5'9"-5'11"	25-27
32-43	5'9"-5'11"	28-30
32-43	5'9"-5'11"	31-33
32-43	>5'11"	<24
32-43	>5'11"	25-27
32-43	>5'11"	28-30
32-43	>5'11"	31-33
44-60	<5'9"	<24
44-60	<5'9"	25-27
44-60	<5'9"	28-30
44-60	<5'9"	31-33
44-60	5'9"-5'11"	<24
44-60	5'9"-5'11"	25-27
44-60	5'9"-5'11"	28-30
44-60	5'9"-5'11"	31-33
44-60	>5'11"	<24
44-60	>5'11"	25-27
44-60	>5'11"	28-30
44-60	>5'11"	31-33

Females

Age	Height	BMI
18-31	<5'4"	<24
18-31	<5'4"	25-27
18-31	<5'4"	28-30
18-31	<5'4"	31-33
18-31	5'4"-5'6"	<24
18-31	5'4"-5'6"	25-27
18-31	5'4"-5'6"	28-30
18-31	5'4"-5'6"	31-33
18-31	>5'6"	<24
18-31	>5'6"	25-27
18-31	>5'6"	28-30
18-31	>5'6"	31-33
32-43	<5'4"	<24
32-43	<5'4"	25-27
32-43	<5'4"	28-30
32-43	<5'4"	31-33
32-43	5'4"-5'6"	<24
32-43	5'4"-5'6"	25-27
32-43	5'4"-5'6"	28-30
32-43	5'4"-5'6"	31-33
32-43	>5'6"	<24
32-43	>5'6"	25-27
32-43	>5'6"	28-30
32-43	>5'6"	31-33
44-60	<5'4"	<24
44-60	<5'4"	25-27
44-60	<5'4"	28-30
44-60	<5'4"	31-33
44-60	5'4"-5'6"	<24
44-60	5'4"-5'6"	25-27
44-60	5'4"-5'6"	28-30
44-60	5'4"-5'6"	31-33
44-60	>5'6"	<24
44-60	>5'6"	25-27
44-60	>5'6"	28-30
44-60	>5'6"	31-33

Exclusions and Conditions

Healthy individuals were selected via medical screening. Specifically excluded are test subjects with any of the following:

Hypertension, heart disease, pregnancy, certain medications (decided case-by-case by Dr. Liden), eating disorders, asthma, chronic or acute bronchitis, diabetes, exercise-induced wheezing, missing or irregular periods, pneumonia pulmonary diseases (COPD, etc.) seizure disorders, major surgery within the past year.

No subject started a new exercise routine during the testing period. Subjects fasted at least 4 hours before the test.

Materials and/or Instruments Used

Calibrated SenseWear Armbands	BodyMedia, Inc.
Heart Monitor Strap	Acumen
CPX Express Metabolic Analyzer	MedGraphics
Quantum II Bioelectrical Body Composition Analyzer	RJL Systems
Electro-therm Temperature Gauge and Hygrometer	Cooper Instrument Corp
Digital Weight Scale	Tanita Corp
OMEGASCOPE Surface Temperature Thermometer	Omega Corp
Digital Camera	AGFA
Video Camera and Accessories	Sony
Stationary Bicycle with Digital Feedback	Diamondback 1100R
Motorized Treadmill with Digital Feedback	SportsArt 3100HR
VO2 Metabolic Analyzer Calibration Protocol	
First Aid and Lab Supplies	Miscellaneous

The same calibration protocol used in the initial energy expenditure study was utilized for this study.

Protocol Procedure

A rest/activity protocol was begun after basic physiologic information (height, weight, body fat %, etc.) was recorded, consent and other forms were signed, and the SenseWear Armband was strapped on and activated. Subjects were shown how to use the treadmill and stationary bicycle and how to breathe into the VO2 mouthpiece. The study was divided into three sets of activities, two treadmill sessions and one stationary bicycle session.

A treadmill protocol was conducted first. To begin, the subject was instructed to:

- Rest but not sleep for 30 minutes. At the conclusion of this period, the VO2 machine was stopped and the data downloaded
- Treadmill – the subject started walking at 2.5 mph and this speed was increased 1 mph every 3 minutes until 5 mph was reached or the subject decided to stop. In either case, the treadmill was then slowed to 2.5 mph for a 3-minute recovery period. The subject was then instructed to rest for an additional 3 - minute period. Subsequently, the VO2 machine was stopped and the data downloaded.
- Rest but not sleep for an additional 30 minutes. At the conclusion, the VO2 machine was again stopped and the data downloaded.

- The SenseWear Armbands were removed and downloaded to a database for later analysis.

The Biking Protocol

After completion of the treadmill protocol the subject was allowed to leave and return 1.5 hours later or on another day for completion of the biking protocol. In either case, the subject was instructed not to eat for at least 1-hour before the test. The biking session was performed as follows:

- Rest but not sleep for 30 minutes. At the conclusion of this period the VO2 machine was stopped and the data downloaded
- Bike – the subject pedaled the bicycle at 20 watts for 3 minutes and increased the workload every 3 minutes by 20 watts until the subject reached 80+ watts or the subject wished to begin the recovery phase. The subject was instructed to reduce the workload to 20 watts for 3 minutes and then rest for an additional 3 minutes. At the end of this period the VO2 machine was stopped, and the data downloaded.
- Rest but not sleep for 30 minutes. The VO2 machine was stopped at the conclusion and the data downloaded.
- The SenseWear Armbands were removed and downloaded to a database for later analysis.

The subjects subsequently returned to repeat the treadmill session of the test protocol on a different date.

Summary of Data Collection and Analysis Procedure

Data collected from the CPX machine and the SenseWear armband was again downloaded to our database along with each subject's demographic information. Data from each test was time aligned and joined. All test data was concatenated and formatted to be compatible with Matlab. Subsequently, a data analysis process identical to that described for the first energy expenditure study was employed.

Other data collected (in addition to VO2/SenseWear):

- Name/Address/SS#
- Gender
- Height & Weight
- BMI
- Race
- Right/Left handedness
- Smoking/Non-smoking
- Blood Pressure/Pulse
- Pre/Post skin temperature
- Waist circumference
- Subject's perception/Estimate of waist size
- Arm circumference (upper, middle, lower)
- Skin-fold thickness
- Impedance/Reactance/Resistance
- Ambient temperature
- Relative humidity
- Reading on waist worn pedometer/accelerometer after test
- Distance on treadmill/bike after use

- Serial number and arm location of SenseWear units
- Digital photographs of subject from 3 angles
- Videotape of entire test

Results

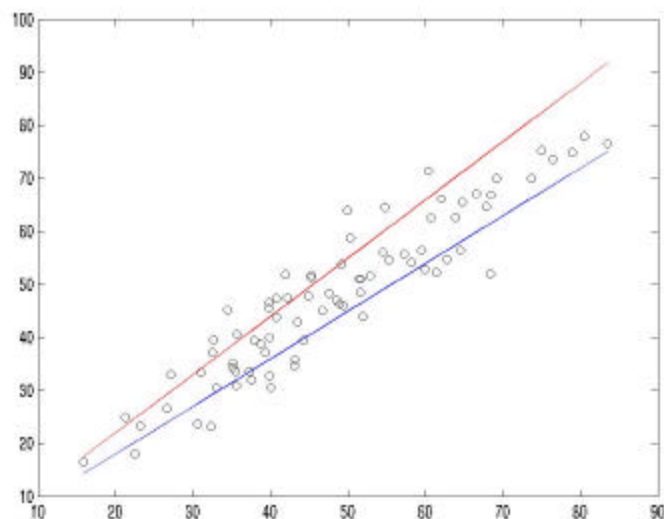
At the time this paper was written, the second energy expenditure study was still in progress. The following section provides a summary of the results after 49 subjects had completed the entire protocol. The data for accuracy and repeatability utilizing our current algorithms is summarized in Table V. Subject repeatability is defined as the absolute difference in accuracy between tests performed on a single subject. Global repeatability is the average of the per subject repeatability measures. Lower measures are better than higher ones with the ideal being a value of zero. In the remainder of this paper, global repeatability will simply be referred to as repeatability.

Table V - Energy Expenditure Detection Accuracy and Repeatability for the SenseWear Armband

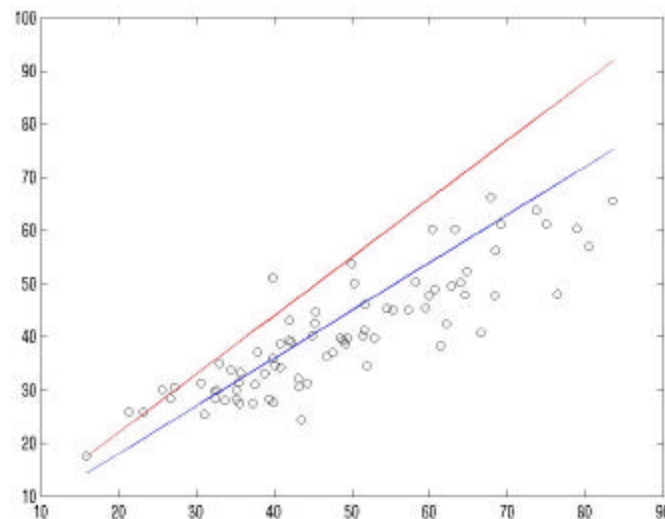
State	Accuracy	Repeatability
Resting Energy Expenditure (REE)	92.0%	93.5%
Active Energy Expenditure (AEE) on treadmill	90.3%	92.0%
Active Energy Expenditure (AEE) on bike	92.46%	98.0%
Active Energy Expenditure (AEE) on treadmill + bike	89.1%	90.1%
Total Energy Expenditure (TEE)	92.1%	94.2%

The following graphs (rest, treadmill, bike, treadmill + bike, and overall) provide visual comparisons of the accuracy of energy expenditure detection the SenseWear Armband to the standard Harris-Benedict equation utilizing the VO2 machine as the standard. (see next page)

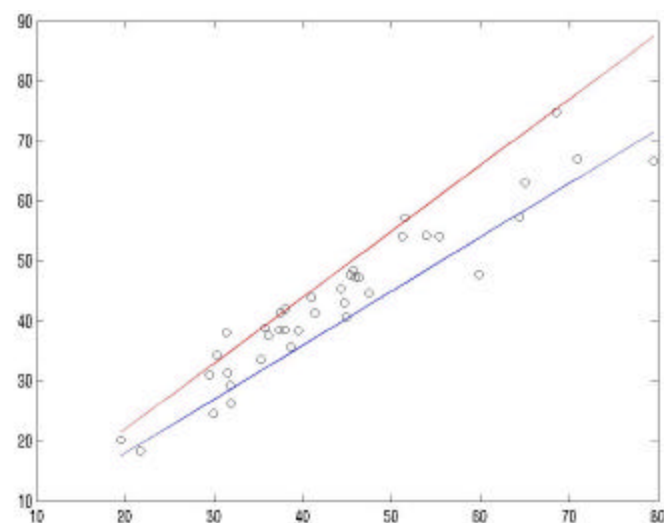
Graph III.a – Treadmill [SenseWear vs. V02] (x-y axes= calories burned/minute)



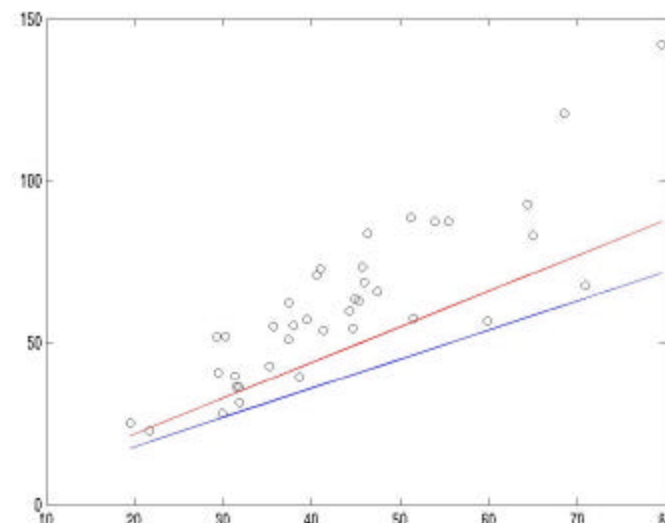
Graph III.b – Treadmill [Harris-Benedict vs. V02]



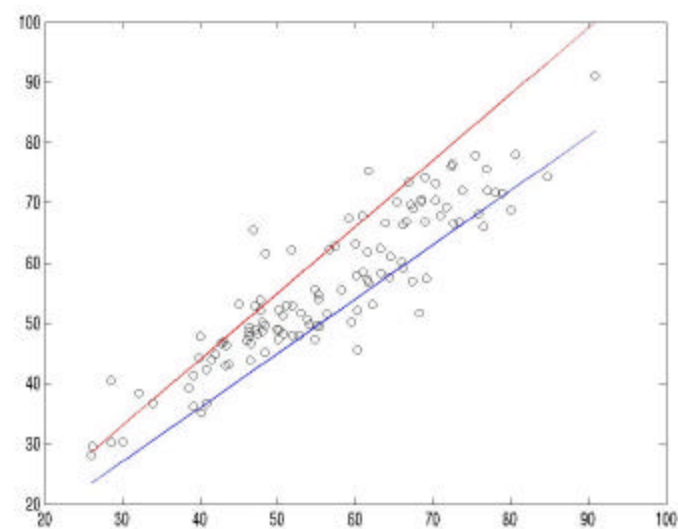
Graph IV.a – Bike [SenseWear vs. V02] (x-y axes= calories burned/minute)



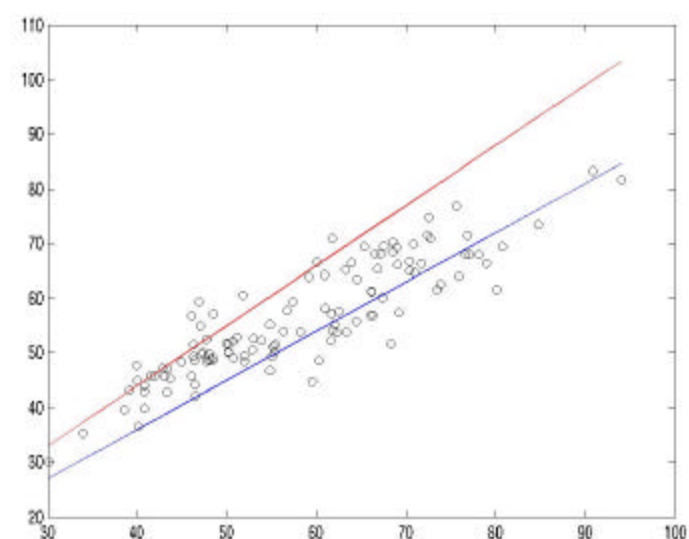
Graph IV.b – Bike [Harris-Benedict vs. V02]



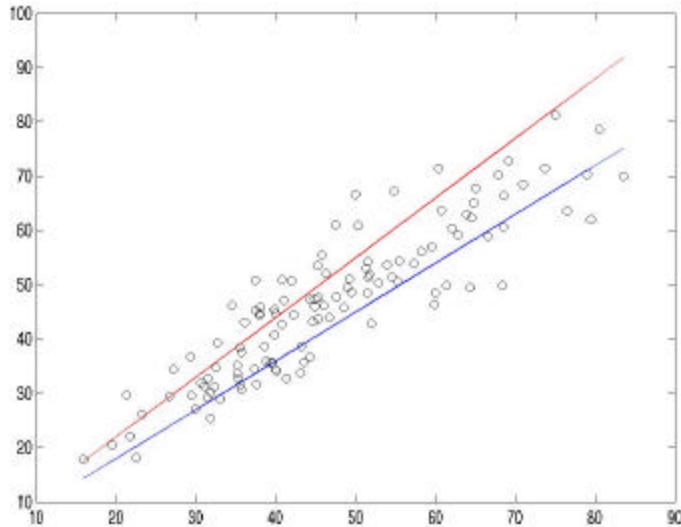
Graph V.a – Rest [SenseWear vs. V02] (x-y axes= calories burned/minute)



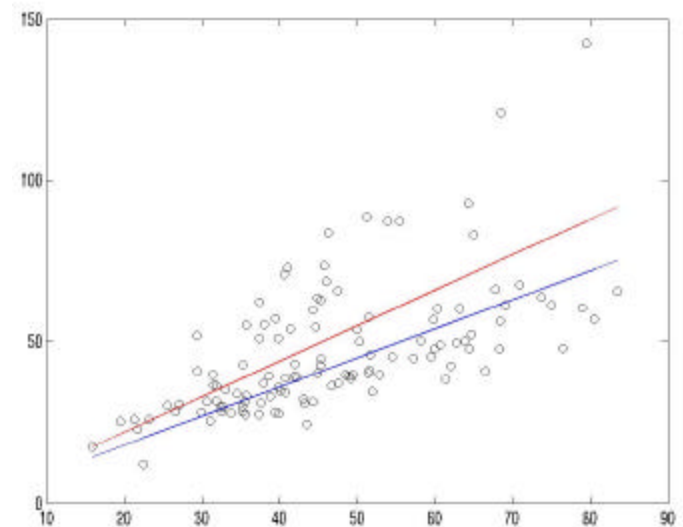
Graph V.b – Rest [Harris-Benedict vs. V02]



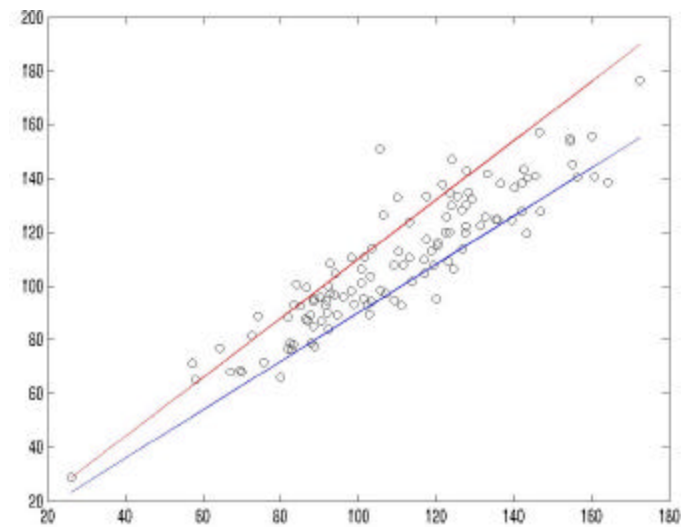
Graph VI.a – Exercise Combo [SenseWear vs. V02] (x-y axes= calories burned/minute)



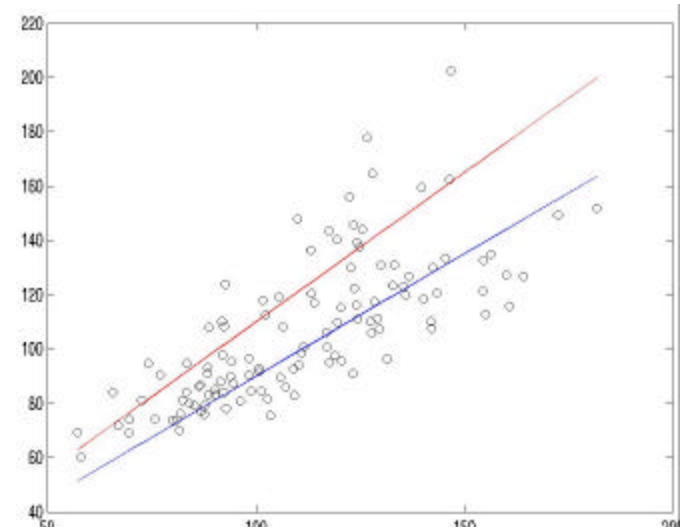
Graph VI.b – Exercise Combo [Harris-Benedict r vs. V02]



Graph VII.a – Overall [SenseWear vs. V02] (x-y axes= calories burned/minute)



Graph VII.b – Overall [Harris-Benedict vs. V02]



Conclusions

To date, in the second energy expenditure study, the SenseWear Armband has demonstrated an accuracy level of 90% or more. Its highest levels of accuracy were found in non-ambulatory biking (92.46%) and total energy expenditure (92.06%).

Repeatability significantly exceeded 90% in all conditions with the highest value being Active Energy Expenditure (AEE) on the bike.

Furthermore, SenseWear vs. VO2 plots show significantly less scatter than Harris-Benedict vs. VO2 plots and clearly demonstrates a strong positive correlation under all conditions.

We feel the data from this study clearly establishes the validity and repeatability of the SenseWear Armband as an energy expenditure detection device. We anticipate that the additional data gathered through completion of this study will only serve to strengthen our algorithms and tighten the bounds on our conclusions.

VIII. CONTEXT DETECTION

The accuracy and reliability of the SenseWear Armband as an energy expenditure detection device is greatly enhanced by its ability to accurately detect context. Context refers to a person's activity, location or situation. Examples of such contextual information include driving a car, watching television, or working at the office. We believe that by more accurately characterizing energy expenditure in different contexts, we can optimize the accuracy and reliability of our overall model.

Other devices currently being used for free living energy expenditure monitoring are not able to detect contextual differences, and, therefore, are not able to utilize such information in their calculations. As described previously, motion detectors, pedometers, and accelerometers share the disadvantages of being subject to the detection of false motion and the inability to accurately detect non-ambulatory physical activity. Particularly critical to the accuracy of accelerometer based energy expenditure models are those times when subjects are traveling in motor vehicles. At these times the rapid and continued motion of the accelerometer may equate to high-energy expenditure. While the vehicle is expending high energy, the subject inside the vehicle is not. By incorporating a "motoring" context into an energy expenditure algorithm such false detection can be identified and corrected and, therefore, overall accuracy greatly improved.

There are other significant contexts such as sleeping, resting, and walking, which, if known, can improve the accuracy of energy expenditure calculations. For example, lying down to sleep puts a person in a state of low energy expenditure including some time at their basal metabolic rate. On the other hand, an ambulatory activity such as taking a walk will result in significantly more energy expenditure than resting on the couch watching television. While detection of subtle differences in context may only result in small calorie burned differences for a specific activity, the cumulative effect of this added precision can be significant over the course of a day or week. Such differences could be extremely important to the consumer who is working to maintain appropriate energy balance.

Context detection not only allows for the improved modeling of energy expenditure by detecting activities such as sleeping, resting and ambulatory states throughout the day, it also allows for much more complex situations to be modeled more accurately. This is particularly true for activities where there is a lot of motion but little energy expenditure such as driving a car or, alternatively weight lifting where there is little motion but high-energy expenditure. In these cases, once the context has been identified an energy expenditure calculation can be refined so that its accuracy is significantly enhanced.

Contextual Studies

In order to incorporate such contextual identification into our energy expenditure algorithms, we initiated a series of studies looking at motoring, exercising, resting (e.g. sitting, watching television, reading) and getting in and out of bed. Studies of other contexts are also in progress.

Subjects in these studies were recruited from employees or friends of BodyMedia. Travel that was monitored occurred mainly in the Pittsburgh, PA metropolitan area with some longer distance travel included. Vehicles used included cars and buses. Exercise was defined as any strenuous activity that was sustained for more than ten minutes and included walking, working out at the gym, dancing, and participating in aerobic classes. Resting was restricted to being a sole task. For example cooking while watching television was excluded. The majority of data collection took place in the fall and winter of 2001-2002 during which there was a mix of seasonal weather. Getting in and out of bed data was collected at various times through 2001.

All data was collected in free-living environments, at the discretion and convenience of the subjects as they went about their daily lives and routines. Additionally, each subject kept a journal specifying times when they were definitely not doing the activity they had collected data on. Therefore, it was possible to collect free-living positive and negative examples of the contexts. Algorithms were tuned to give few false positives (i.e. incorrectly predicted events).

Preliminary Results

Results of our modeling to date are presented below. Work is ongoing on re-modeling with larger data sets.

Exercising (N = 14)

Positive data	>90 hours
Negative data	>788 hours
True positive	63.8% (accuracy detecting exercising)
True negatives	98.3% (accuracy detecting non-exercising)

Motoring (N = 16)

Positive data	>122 hours
Negative data	>782 hours
True positive	33.9% (accuracy detecting exercising)
True negatives	92.0% (accuracy detecting non-exercising)

Resting (N = 12)

Positive data	>91 hours
Negative data	>357 hours
True positive	53% (accuracy detecting exercising)
True negatives	97% (accuracy detecting non-exercising)

In and Out of Bed (N = 10) – approximations subject to change

Sleep samples	26 nights
True positive	95.7% (accuracy detecting in bed)
True negatives	88.6% (accuracy detecting out of bed)
Into bed	10.5 (minutes, average error)
Out of bed	09.1 (minutes, average error)

Contextual Studies were also done as part of a larger energy expenditure study. We utilized data from this study to explore the SenseWear Armbands ability to differentiate when subjects were running on a treadmill vs. riding a stationary bike. The results from this analysis are summarized below.

Subjects/Sessions	20
Biking and rest	18 total hours
Treadmill	2.3 total hours

Detecting biking from resting and treadmill:

True positive	0.77
True negative	0.98

Detecting treadmill from resting and biking:

True positive	0.98
True negative	0.97

Conclusions about Context Detection

The results of these preliminary contextual studies clearly support the ability of the SenseWear Armband to accurately detect contexts in free-living situations including exercising, motorizing, watching television and in/out of bed. As a result, the SenseWear Armband has the capability to filter out erroneous sources of movement such as driving which might falsely elevate estimates of energy expenditure. This fact has significant ramifications for the SenseWear Armband's ability to accurately detect energy expenditure in free-living situations and sets the SenseWear Armband apart from other energy detection devices. The contexts that were not accurately identified by the SenseWear Armband, in reality, represent only small fractions of a day's activities and can be expressed in terms of a few minutes. It is doubtful that such errors would significantly alter energy expenditure values in a clinically meaningful way.

Energy Expenditure Algorithms

The results of the studies described in this paper have provided the data used to build and test algorithms for the processing of information gathered by the SenseWear Armband. The following is a discussion of the process used in building and testing these algorithms. The algorithms themselves are the proprietary and confidential property of BodyMedia, Inc. Therefore, the details regarding their structure and design is not included in this document.

We utilized an automated process in building the algorithms. This automatic building process constructs an algorithm to satisfy criteria.

A simple example of this process would be, "I have a distribution of outcomes I would like to predict. I have a set of data points I believe are representative of those outcomes. I will use the formula $y=mx+b$ (a line in two dimensional space) as my representation."

There are an infinite number of algorithms that can be tried but there is a known formula to minimize the mean squared error between the set of data points and the line in question. In this example, the success criterion is the mean squared area and the automated process is the formula for finding the best linear fit to the data points. Success criteria often involve a number of different factors, particularly when building complex algorithms. A criteria important to BodyMedia's building process is Occam's Razor; errors being equal, prefer the less complex algorithms because simpler algorithms we more likely generalize to unseen examples.

In building and testing all of the BodyMedia algorithms the following process was followed. During each study a number of sets of data points were collected, then divided into a training set and a testing set. Typically 60-70% of the total number of sets were put into the training set with the remainder assigned to the testing set. An algorithm was constructed using the chosen representation and success criteria, an automated process for algorithm refinement, and the training set data. The completed algorithm is tested by running it on the data points in the test set and measuring the resulting error produced. The results reported in this paper represent the use of the algorithms on the testing data sets.

IX. CONCLUSION

In summary, this paper has presented work done over an 18 month period in enhancing and documenting the accuracy and reliability of the SenseWear Armband as an energy expenditure assessment device. Detail has been given on the various protocols used to collect data relevant to energy expenditure and results have been presented on the performance of SenseWear and SenseWear's companion algorithms at delivering the same results as those available from medical gold-standard equipment.

The SenseWear Armband provides very low error rates relative to equipment that is qualitatively more expensive, more difficult, and more limiting to use. For many applications, the implications of these results are that the SenseWear Armband provides high quality information in a much lower cost, simple to use solution that can be applied outside of laboratory settings. Other devices on the market within the price range of the SenseWear Armband that offer similar benefits are dramatically less accurate than the results presented here. For more details on these comparisons, see our paper entitled "Explanation of the Benefits of the SenseWear Armband Over Other Physical Activity and Energy Expenditure Measurement Techniques."

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