The Development of the SenseWear® armband, a Revolutionary Energy Assessment Device to Assess Physical Activity and Lifestyle

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Abstract

Consumers, clinicians, and researchers lack an easy-to-use, reliable and cost efficient way to accurately assess metabolic physical activity and energy expenditure, critical components of a variety of behavioral modification programs, including disease- and weight-management. BodyMedia has addressed this need by developing the SenseWear® Pro$_2$ Armband which utilizes a heat flux sensor, galvanic skin response sensor, skin temperature sensor, nearbody temperature sensor, and a two axis-accelerometer to gather data leading to the measurement of energy expenditure. This paper outlines the studies that show how the SenseWear® Pro$_2$[1] provides high energy expenditure accuracy rates relative to equipment that is far more expensive, limiting, and difficult to use and how it is a cost efficient and simple solution that can be applied outside the laboratory in a free-living environment to track energy expenditure, physical activity durations and levels, and lifestyle information.

Introduction

Increased physical activity, along with the achievement and maintenance of energy balance, has emerged as an important personal health goal 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 are expended. The obesity epidemic and its associated problems including hypertension, type II diabetes, cardio-vascular diseases, 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. For many diseases and medical conditions, increasing physical activity can improve recovery rates, delay recurrence rates, and generally improve outcomes.

Healthcare professionals, overweight individuals, and physically inactive individuals all acknowledge the need to improve and sustain exercise and eating behaviors. These individuals, however, have noted the lack of tools to assist in the accurate and objective measurement of total energy expenditure and physical activity durations. Both as an outcome measure for medical treatments (e.g. rehabilitation) and as a treatment itself (e.g. for diabetes and obesity), the accurate and objective measurement of physical activity and energy expenditure is now widely recognized as tremendously important for health care. For example, in order to lose weight, a person must first be able to accurately quantify levels of activity, total energy expenditure and daily caloric intake. Only then can they begin to implement the proper changes necessary to their daily routines that will

[1] The SenseWear® Pro2 Armband has also been marketed as the bodybugg™ system by Apex Fitness and as the HealthWear™ system by Roche Diagnostics.

help them increase activity levels and manage their caloric intake. As an outcome measure, accurate and objective physical activity durations can inform the health care professional about the success of therapy, treatments, and counseling.

To date, there is not an easy-to-use, reliable and accurate way to routinely assess metabolic physical activity and energy expenditure outside the laboratory in a free living environment. This has significant ramifications for the subjects' weight management success. From the behavior change literature (Dilley 1998, Klem 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 series of wearable devices, including the SenseWear® Pro$_2$ armband and the Apex bodybugg™, that utilize an underlying hardware platform that measures and records a number of physiologic parameters that allow health researchers, clinicians, and individuals to continuously and more accurately track physical activity and total energy expenditure. The SenseWear® Pro$_2$ armband gives health professionals 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 review the measurement of total energy expenditure and metabolic physical activity, describe the SenseWear® Pro$_2$ armband and the energy expenditure algorithms it utilizes, review independently performed validation studies of the armband's accuracy, and provide internal validation data that supports the use of BodyMedia's SenseWear® Pro$_2$ armband for the monitoring of metabolic physical activity and total energy expenditure.

I. Measurement of Energy Expenditure

The number of calories a person expends is a very important and actionable parameter for a variety of applications and disease conditions. These include weight control (loss, gain or maintenance), sports performance, and body composition changes. True Total Energy Expenditure (TEE) is very difficult to measure, and nearly all techniques make use of approximations of one kind or another, as discussed below.

Metabolic carts analyze indirect calorimetry. These metabolic carts measure the oxygen and carbon dioxide that a person inhales and exhales and from this, indirectly compute the calories burned during the period of measurement. The calories expended for the time during which the subject is not being measured with the metabolic cart are estimates based on the very short period of the measurement. This technique of measurement is currently very widely accepted in the research community as a gold standard. Based on a survey of the litera-

ture, devices of this category differ from one another by 5-10% and differ even on repeated measurements of the same activity by around 5-10% (Yates 2004, Wells 1998, Gore 2003, and Webster 1999). Most metabolic carts are rather large and bulky and are not suited for monitoring outside the laboratory setting. A few of these monitors are called "portable" – these devices require wearing analyzer modules strapped on the chest or on the back and breathing through a mouthpiece or mask and are able to monitor a wider set of activities for a reasonably short period of time. The portable devices have even higher error rates than the stationary metabolic carts (Twaddle 2005, Kautza 2004, Yeo 2003, Keller 2002 and Wideman 1996).

For longer term measurement, full room chambers can be constructed that carefully measure the consumption of oxygen within a single room (or, in some cases, several carefully constructed and connected rooms). In these systems, a closed system is constructed where air is continuously pulled through the room(s) by a vacuum pump with the rate of flow continuously measured by a mass flow meter. A sample of the extracted air is then pulled through a condenser to remove moisture before measurement of percent O_2 and CO-3 pt by oxygen and carbon dioxide analyzers. These systems result in very high accuracies, but are suitable only for laboratory use due to size and expense (Schoffelen et al, 1997). A related method instead measures heat emissions; some rooms combine heat emissions and gas measurement (Seal and Rumpler, 1997). Some effort has been made to explore suit calorimetry chambers that allow some portability (Hambraeus et al, 1994) but these are bulky, expensive, and rather unsuited for most activities.

Douglas bags are another accepted technique for measuring energy expenditure. Douglas bags are awkward to use and have the same limitations as metabolic carts. Devices such as the MedGem® and BodyGem® from Healthetech are essentially small metabolic carts that measure resting energy expenditure. As such, they share the downside of metabolic carts of only measuring expenditure for a short period of time in the laboratory. Furthermore, because these devices are only useful for resting energy expenditure, they capture very little of the variation caused by changes in a person's behavior and do not provide the feedback essential for behavior and life style changes.

Currently the doubly labeled water (DLW) stable isotope method is considered the gold standard for measuring TEE of free-living individuals. This technique is very expensive (~$1,500/person) and involves the consumption of two stable isotopes. It is based on indirect calorimetry assumptions and on the differential elimination of deuterium (2H) and 18oxygen (18O) from body water following a loading dose of two stable isotopes. Energy expenditure is then calculated from carbon dioxide production by classical indirect calorimetric equations. Energy expenditure is also accurately measured in total over weeks of time – not minute by minute or even day by day. Doubly labeled water has an error rate of about 5% over a 2-week period due to starting and ending conditions (Schoeller et al, 1986).

On the other side of the spectrum from metabolic carts or chambers are devices

such as pedometers, accelerometers, and heart rate monitors. These devices, when used for measuring energy expenditure, are consumer friendly products with limited accuracy because they measure only a single modality and attempt to correlate it with energy expenditure. Pedometers only measure footfalls and are not accurate when used for activities that do not involve footfalls (e.g., weightlifting, biking, household activities). Similar limitations apply to waist-worn accelerometers. Heart rate is affected by stress, medication, disease, and other physiological factors, and the correlation to energy expenditure is only good for a narrow range of moderate intensity exercise. Furthermore, due to individual variations in the HR to VO_2 relationship, individual calibration is required. Some attempts have been made to combine heart-rate and accelerometry using a technique called Flex-HR. Furthermore, many current systems for continuously measuring heart rate and motion can be uncomfortable to wear for long periods of time given that accurate placement using a chest strap (such as the Polar chest strap) or a leg strap (such as the Dynastream system) can be required. The most accurate single-modality systems may be multi-accelerometer systems where accelerometers are taped to the body at many different locations and connected to a processing unit with wires; these systems can distinguish between many different activities and types of motion although is reasonably uncomfortable to wear.

BodyMedia, Inc. was founded around the idea that the combination of multi-sensor, wearable body monitoring devices and sophisticated machine learning algorithms can provide accurate, objective, and actionable data about the health and behaviors of people outside a traditional clinical setting. Through a comprehensive study of the wearability and utility of sensors at different locations on the body, the upperarm was chosen as the best location. The Sense-Wear® series of armbands is the outcome of this work.

The SenseWear® Pro Armband

1 Acceleromoter *(inside)*
2 Heart Beat Receiver Board *(inside)*
3 Skin Temperature sensor
4 GSR sensor
5 GSR sensor
6 Heat Flux sensor
7 Near-body Ambient Temerpature sensor

Figure 1 The SenseWear® Pro armband (2000 – 2003).

The SenseWear® armband is a sleek, wireless, and accurate wearable body monitor that enables continuous physiological monitoring outside the laboratory. The armband is worn on the back of the upper right arm and utilizes a unique combination of sensors. A proprietary heat-flux sensor measures the amount of heat being dissipated by the body by measuring the heat loss along a thermally conductive path between the skin and a vent on the side of the armband. Skin temperature and near-armband temperature are also measured by sensitive thermistors. The armband also measures galvanic skin response (GSR – the conductivity of the wearer's skin) which varies due to physical and emotional stimuli. A twoaxis accelerometer tracks the movement of the upper arm and provides information about body position. The armband also contains a radio and a data port, allowing both wireless transmission and communication as well as wired downloading of data. This version of the armband also had a Polar heart-rate receiver board that could receive heart beat information from a Polar strap. The battery in this version was rechargeable, lasting approximately 3 days before needing a charge. The SenseWear® Pro was sold from approximately 2001 until 2003.

The SenseWear® Pro$_2$ Armband

Figure 2 The SenseWear® Pro$_2$ armband (2003 – current).

1 Time-stamp Button
2 Two-axis Accelerometer *(inside)*
3 AAA Battery provides 2 weeks of use, USB connector and wireless *(inside)*
4 Skin Temperature sensor
5 GSR sensor
6 GSR sensor
7 Heat Flux sensor
8 Near-body Temerpature sensor

In 2003, Bodymedia released a new version of the armband that has some significant improvements including a replaceable AAA battery and a USB connector. The sensor set remained essentially the same: heat-flux, skin-temperature, near-body temperature, galvanic skin response sensors, and a two-axis accelerometer.

Both versions of the armband sample data at 32-hertz and record compressed channels of data in the armband's memory. The SenseWear® Pro$_2$ has memory for approximately two weeks of wear. The channels recorded are a carefully chosen set of features that capture both basic statistics of the data streams (e.g., averages, variances) as well as more complex features (e.g., peaks, steps). These channels are stored on the armband and are then sent to a PC via either a USB cable or using a proprietary wireless protocol.

Having multiple sensors is very important to the success of the armband and its ability to accurately monitor the physiological states of the wearers. Multiple sensors allow for the disambiguation of contexts that might confuse a single sensor. For example, if a wearer's motion is high, it might be due to exercising or to being in a moving vehicle. However, the signatures of temperature, sweat, and heat flux are typically quite different for exercise and being in a car.

On the computer, activity detection and lifestyle algorithms are executed on the incoming data, producing estimates of each lifestyle algorithm (e.g. energy expenditure, sleep, etc) for each minute of time. The algorithms in BodyMedia's software utilize the physiologic signals from all the sensors to first detect the wearer's context and then apply an appropriate formula to estimate energy expenditure from the sensor values. The armband can recognize many basic activities such as weight-lifting, walking, running, biking, resting, and riding in a car, bus, or train. Other activities are classified into combinations of these basic activities; for example, baseball could be broken down into a combination of mostly nearrestful activity and running. Key to the armband's utility is that it can be worn comfortably during a person's normal life, and does not require any time in the laboratory for uncomfortable measurements.

The Algorithms

The algorithms are created using a proprietary algorithm development process that utilizes a data driven machinelearning approach. Data is first collected during clinical studies with laboratory equipment such as metabolic carts or doubly labeled water. Next, compressed channels are created from this raw data that can be stored on the armband that are useful for determining both the wearer's activity as well as measures such as energy expenditure or sleep state. After this, context detectors are developed that classify the wearer's context. Finally, for each context, a specific algorithm is created using automated machine learning techniques to predict the measure of interest (such as energy expenditure). Knowing the context of the wearer is a unique and very important feature of BodyMedia's algorithms. The wearer's context allows us to apply the appropriate function to predict energy expenditure – this is easy to understand by thinking about the difference in our expected signals for running and for stationary biking. In one case, we expect to see large motion vectors, in the other, we expect to see much smaller motion vectors. In both, the amount of heat and sweat produced should be proportional to the exertion – although in running, sweat will likely evaporate more quickly in the neighborhood of the armband due to arm motion. By knowing the context, all of the sensors can be combined intelligently into an accurate estimate of energy expenditure.

Essentially, the algorithms break down a person's activity into fundamental activities of walking, running, resting, sleeping, resistance activity such as weight-lifting, lower-leg motion such as stationary biking, motion caused by external forces such as driving a car, exercise combined with external motion (road biking), etc. Much in the way that Fourier analysis breaks a sound signal down into its fundamental components during speech processing, BodyMedia's algorithms analyze activities into their fundamental components. For each fundamental component, a different equation is then used to predict the energy expenditure. From this,

physical activity duration and METs levels can be determined. The first version of the armband (the SenseWear® Pro) and the associated software had algorithms that only distinguished between rest and activity. Algorithms for specific activities such as walking, biking, and stair climbing were available, but the user had to choose the context. For the current armband, the SenseWear® Pro$_2$, the algorithms accurately classify many activities automatically and user selection of an appropriate algorithm is no longer required.

Due to the nature of the algorithm development process, the algorithms are constantly being improved as multiple studies continue and the results are analyzed. More diverse activities and activity modes are added to the datasets used to train the algorithms, improving overall performance. At present, the set of activities known to produce accurate results is large and includes the set of activities mentioned above. The algorithms are carefully tested to guarantee that they always improve over previous versions.

The remainder of this paper reviews the validation of the SenseWear® product line as energy expenditure and physical activity devices. Several different types of data are presented. First, data from published articles and abstracts by external researchers is presented. It is important to keep in mind that the hardware, firmware, and algorithms utilized by researchers in each study can be different, depending on what versions they purchased. For the hardware, there are two options, the original SenseWear® Pro (SWP) and the SenseWear® Pro$_2$ (SWP2) armband. Over the years, the set of channels collected in the firmware has increased. Some studies are able to take advantage of these new channels to help both in determining context but also in determining exertion levels. In the summaries that follow, the following configurations are noted: original (those used in the SWP), minimal (those channels minimally used in the SWP2), and algorithm (minimum required for 4.1 algorithms for SWP2). Another configuration, clinical, is also available and is used for the 4.2 version of the algorithms. Table 1 describes the different versions of the algorithms and their rough release dates. The current algorithm version is 4.2.

Table 1
Algorithms tested in the literature.

Armbands	Algorithm	Minimal Configuration Required	Approximate Date of Release
SWP	1.0	Original	Q1, 2002
SWP	2.0	Original	Q1, 2002
SWP	2.2	Original	Q1, 2002
SWP, SWP2	4.0	Minimal	Q4, 2003
SWP2	4.1	Algorithm	Q2, 2004
SWP2	4.2	Clinical	Q1, 2005

II. External Energy Expenditure Studies on Original SenseWear Pro armband

Many studies have investigated the validity of the SenseWear® Pro (SWP) armband as an energy expenditure device. In most of these studies, subjects wear the armband during exercise and rest activities while they are also monitored utilizing indirect calorimetry via a metabolic cart. In all studies on the SWP, the configuration is the original channels. Jakicic et al (2004) examined the energy expenditure of subjects during treadmill exercise, stationary biking, arm ergometry, and stepping exercise. The generalized energy expenditure algorithm (version 1.0) available at the time correlated well with energy expenditure as measured by the cart, but significantly underestimated by 7% during treadmill, 13.5% during biking, 17% during stepping, and overestimated 29% during arm ergometry. If the exercise mode was specified, however, the algorithms (version 2.0) predict values not significantly different from those measured by the cart (with average error around 3% +/-10%). The investigators concluded "When exercise-specific algorithms are used, the SenseWear® Pro armband provides an accurate estimate of energy expenditure when compared to indirect calorimetry during exercise periods examined in this study." This statement reflects the fact that at the time of this study, the algorithms only recognized the contexts of activity and rest rather than more specific activities. As we will see, later algorithms can quite accurately determine the activity and thus apply the appropriate exercise-specific algorithms. As with many validation studies performed on the armbands, after the data was analyzed, the data was included in the training data set to improve later versions of the algorithms.

Fruin and Rankin (2004) report on a comparison of the SenseWear® Pro with indirect calorimetry for rest, stationary biking, and treadmill activity. For rest, the energy expenditure estimates by the algorithms (version 2.0) correlate well and are not significantly different from the metabolic cart. For bike ergometry, no significant differences were found. For treadmill activity, the algorithms' estimates were correlated with speed but not with incline, overestimating on flat walking and underestimating on inclined walking. They concluded that "In summary, this study revealed that the SWA (SenseWear armband), using contextual algorithms from the manufacturer, provided a valid and reliable estimate of energy expenditure."

King et al (2004) report on the validity of four accelerometers (the CSA, the TriTrac-R3D, the RT3, and the BioTrainer-Pro) and the SenseWear® armband (SWP) using algorithms version 2.0. The armband's estimates correlated with those monitored using indirect calorimetry, although overestimated significantly for faster speeds. Overall, "the SenseWear armband was the best estimate of total EE at most speeds." King has continued his investigations on these units in 2005, reporting in a poster at the annual conference of ACSM that this version of the armband (using version 1.0 algorithms) overestimated during outdoor walking and rest although it compared favorably to accelerometers during stair climbing, where significant differences to indirect calorimetry were not found. In 2006, King and his colleagues (Potter, et al, 2006) presented results from this energy expenditure algorithm on children, despite the fact that the algorithm was only designed and tested for adults.

Cole et al (2004) investigated the accuracy of the SenseWear® armband in cardiac patients using three different versions of the algorithms on four different exercise activities: treadmill, rowing, recumbent stepping, and arm ergometry. Version 2.2 of the generalized energy-expenditure algorithm showed significant correlations on all activities but significantly different estimates as well on treadmill and rowing activities.Version 4.0 of the algorithms (which classifies activities automatically) showed significant correlations and no significant differences for all activities, although the limits of agreement from a Bland-Altman plot indicated some trends to overestimate treadmill activity and underestimate recumbent stepping and arm ergometery. The researchers requested that a special version of the algorithms be created that took into account the fact that the patients had cardiac disease. Data from the study was broken into groups by subject, and crossvalidation was performed.

In cross-validation with N subjects, N versions of the algorithm are created, each trained on all but one of the subjects. The performance of each version of the algorithm is evaluated on the remaining subject. This method has been shown to accurately assess the generalization performance of a classifier or prediction method (Kohavi 1995). In the Cole et al (2004) study, the preliminary cardiac software performed very well when evaluated in this manner. The correlations were significant, ranging from 0.9 to 0.78, the errors were not significantly different from zero, and the limits of agreement were much tighter.

Patel, Slivka, and Sciurba (2004) investigated the accuracy of the original Sense-Wear® armband in the patient population afflicted with Chronic Obstructive Pulmonary Disorder (COPD). These researchers tested patients with the armband and with indirect calorimetry during two six-minute walking tests as well as during two incremental shuttle walking tests. The results, using version 2.2 of the software, were that the armband tracked very well to indirect calorimetry, with very high session correlations (0.93). The armband did underestimate significantly at higher speeds, although the differences were small (on average less than 15%). The testretest reproducibility was high for both types of tests (0.84 and 0.86 intra-class correlation, compared to 0.90 for the indirect calorimetry). Interestingly, the researchers also utilized an accelerometer-only measure – this produced $r2$ values of 0.66 with indirect calorimetry compared to 0.86 for the version 2.2 multi-sensor algorithms.

Across a set of populations and medical conditions, the algorithms for the original SenseWear® Pro armband have correlated well against indirect calorimetry in many laboratory tests. To keep accuracy high, automated recognition of activities was incorporated into the algorithms to avoid the users having to input in their activity type for each period of time.

Mannix et al (2005) examined the HeathWear™ armband, which is a version of the SWP2, using algorithm version 4.0 and the minimal firmware configuration on biking and treadmill tasks in normal, overweight, and obese patients. They found that the armband underestimated expenditure on both timed treadmill exercise and on a stationary biking stress test, although correlations were quite high (0.79). This data was recently presented in poster format and we are wait-

ing for the full paper to better understand these results which were less adequate than those seen in other studies, even with the same channels. This is the first and only study published with results as poor as these.

Many researchers have expressed interest in using the SWP2 with children. The device will record data properly for children; however the early energy expenditure algorithms (1.0 through 4.1) were designed for the age range 18-75. Children younger than 18 have a different physiology and require algorithms specifically tuned to them. BodyMedia has several studies underway collecting data on children, and has very recently developed an algorithm suitable for children – released in the 4.2 version of the Innerview software and in use as part of the bodybugg™ system.

Two studies were performed where the adult energy expenditure algorithm was compared to indirect calorimetry. Dorminy et al (2005) compared the predictions made by the SWP2, minimal channel, version 4.0 algorithm with wholeroom calorimetry for 21 African-American children. The subjects rested, exercised, and slept in the chamber. The algorithms overestimated in general, but the correlations were good for exercise ($R^2 = 0.78$) but fair for rest and sleep ($R^2 < 0.25$). An adjustment based on bodyweight was determined and applied, resulting in considerable improvements: $R^2 = 0.91$ for exercise and $R^2 = 0.984$ for rest.

Crawford et al (2005) also compared the SWP2, 4.0, minimal configuration algorithm with indirect calorimetry for adolescents in a set of biking and walking tests. Using the adult algorithm, it was found that significant differences existed between indirect calorimetry and the adult algorithm applied to adolescents for both treadmill and biking tasks. The estimates from the SWP2 did scale well with effort on both tasks. Adjustments such as those described by Dorminy et al were not described in the poster. In our post-analysis of this data, simple weight-based adjustments greatly improve the results.

At the ACSM conference in Denver, Andreacci et al (2006) presented their results on utilizing a children-specific algorithm with the SWP2 (version 4.2, clinical channel configuration). Thirty-four children aged 6 to 13 were tested on treadmill equipment at three different speeds. No significant differences were found between the estimates made by the algorithm and the values measured by the metabolic carts. This is the first paper to examine the child-specific algorithm (version 4.2).

McClain et al (2005) examined the accuracy of the SWP2, with minimal channels and algorithm version 4.0, on a variety of activities including arm swinging, walking, walking with a backpack, walking up a grade and walking with exaggerated arm swings (as well as combinations). Correlations were quite high (0.77 to 0.88) except for the standing arm swings (0.44). There were no significant differences for walking and walking with load, but exaggerated arm swings and walking up a grade showed significant underestimation. All correlations improve with the addition of heart rate information used in combination with the armband's energy expenditure estimates.

The poor performance of the algorithms on standing arm swings brings up an important question of any measurement technique – what is the range of activities that can be monitored accurately using the device? Due to the fact that the algorithms in the armband are tuned using training data, there is always the possibility that when tested on activities far outside the range of the training data, the algorithms will give incorrect answers. Our goal is to train using a wide spectrum of data and compare that data to vast amounts of free-living data to verify that relatively little data from people's lives is outside the range of our training data. There may be low percentage activities (such as arm swinging without actually walking, or walking with exaggerated arm swings) where the algorithms track slightly less well than on the high probability activities. Compare this to a stationary metabolic cart where activity can only be measured in the proximity of a bulky machine, or to a pedometer where only ambulatory data will be accurately monitored. Our algorithm process allows us to identify such gaps and address them with new data.

Malavolti et al (2005) compared estimates of the SWP2 using algorithms version 4.1 with results from a metabolic cart on both resting and non-resting activities and found very high correlations (0.86) between the two measures. The researchers state "Our results suggested that SenseWear® is an acceptable device to measure TEE".

Wadsworth et al (2005) examined the validity of the SWP2 during resting and walking conditions against indirect calorimetry. Twenty-three subjects rested for 15 minutes, walked on a treadmill for 15 minutes, and rested again for 15 minutes. In all three components of the protocol, estimates from algorithm version 4.0 using the minimal configuration showed high correlations to indirect calorimetry (~0.8 for rest, ~0.94 for walking). The total energy expenditure was highly correlated as well, showing a 0.95 correlation. The researchers concluded that "The armband is a valid method to measure energy expenditure and will allow researchers to validly measure energy expenditure in a free-living environment."

In a sub-study as part of a larger study, Mignault et al (2005) compare the HealthWear armband (a SWP2 configured in the algorithm configuration with algorithm version 4.1) to doubly labeled water over a ten-day period. The subjects were type 2 diabetics examined as part of a larger study and also had their resting metabolic rate measured using indirect calorimetry and the effect of eating on energy expenditure measured in the lab. In these patients, the researchers noticed no significant differences between the doubly labeled water technique and the estimates from the armband. The correlations were extremely high (0.9696), with a technical error of measurement of only 104 kcal/day (less than 5%). The authors conclude: "..Preliminary analyses suggest that the HealthWear Armband is an acceptable device to accurately measure total daily energy expenditure in type 2 diabetic patients over a 10-day period".

III. Internal Validation Studies on SenseWear Pro₂ armband and Current Algorithms

In general, the existing validation on the SWP2 indicates that the algorithms are relatively accurate and suitable for general use in free living environments. However, some valid issues are raised by some of the articles. The SWP2 algorithms prior to 4.2 were not intended for and hence do not do well on children, and there are some issues to be addressed with graded treadmill exercise. Additionally, some may wonder how well the algorithms do across all of the studies. Although we do not have access to the data from every study, we do have approximately 350 hours of indirect calorimetry and SWP2 data. On this data, the most recent algorithm (version 4.2) achieves a correlation of 0.89 for adults. On a session by session basis, the algorithm achieves a correlation of 0.968 and an average absolute error of approximately 11.3% across all activity types (including weight-lifting, arm ergometery, treadmill, stationary-biking, rowing, stepping, arm-swinging, treadmill with load, and rest). The graph below shows a scatter plot of the session totals across this data set. The table below shows classification accuracies and correlations with metabolic cart measurements for biking, ambulatory, weightlifting, and resting activities.
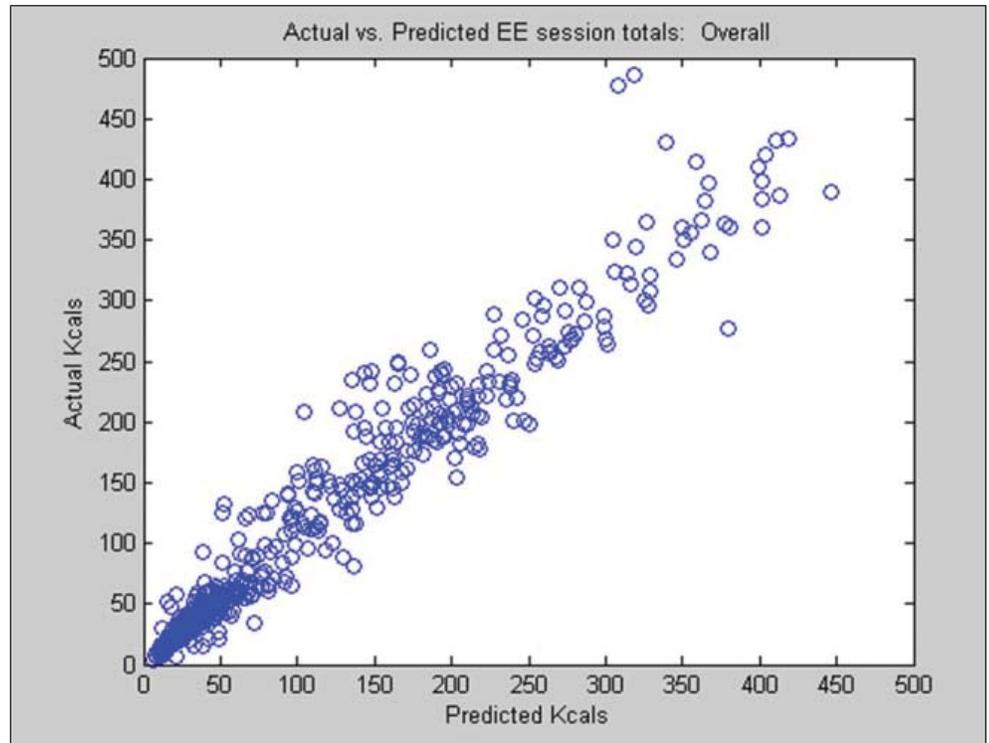
Graph 1
Session total across data set.

Actual vs. Predicted EE session totals: Overall

Table 2
Classifcation accuracies

Activities	Classification Accuracy	Correlation
Ambulatory	99.8%	0.94
Stationary Biking	99.2%	0.88
Resting	99.3%	0.91
Weight lifting	97.6%	0.86

The motoring classifier presently has an accuracy of 96.9%, and the lying-down and sleep detectors are operating at approximately 90%. The metabolic physical activity detector currently has an accuracy of 95% across all exercise types. The road-biking detector has an accuracy of 99.8%. All of these results are for the 4.2 algorithms with clinical configuration.

A child specific algorithm has been created, as mentioned above. This algorithm achieves a correlation of 0.86 on all the data we have (resting, stationary biking, and treadmill), and with an average absolute session error of approximately 11.3%. This algorithm is included in the 4.2 version of the algorithms. In-house algorithms for adults and children that utilize new firmware configurations are presently under construction that will bring the error rate down to approximately 10% across all activities.

IV. Other Relevant Studies and Information

There are several pieces of additional information that attest to the utility and validity of the SenseWear® Pro$_2$ armband as a device for accurately monitoring energy expenditure and metabolic physical activity. These range from successful applications of the technology for clinical weight management to various articles published about other aspects of the armband.

Hanby, Matthews, and Chen (2005) investigated the stepcounting accuracies of four devices: the MTI actigraph, the Digiwalker, the Dynastream AMP, and the SWP2. They compared the results from the four devices and found that the AMP and the SWP2 performed similarly with high correlation to one another. The Digiwalker, in particular, recorded fewer steps than the other three devices. In BodyMedia's internal tests, the step detector counts approximately 99% of all steps.

In a study in Italy, Perini et al (2005) investigated the relationship between metabolic physical activity estimates and energy expenditure estimates with the recovery of a subject with Sydenham's Chorea. Sydenham's Chorea is a childhood disease that causes rapid and frequent involuntary movements but is benign in that spontaneous recovery will occur in a few weeks. This subject was treated with antibiotics, steroids, and antiepileptic therapy. At the outset, the subject was burning 1910 kcals/day as measured by the SWP2, with frequent involuntary muscle movements. In the following few days, the subject burned fewer and fewer calories per day as measured by the SWP2 and additionally scored lower on several indicies (TAS, flogosis) of the progression of the disease. After six days, the subject was nearly back to normal, with only minimal choreic movements in the limbs. Blood tests revealed normal TAS and flogosis levels and the SWP2 showed only 1400 kcals/day expenditure. At day 10, EE as measured by the SWP2 increased in conjunction with some reappearance of symptoms.

Battaglia et al (2006) utilize the SWP2 as the standard and correlate the energy expenditure and physical activity duration estimates from the 4.2 algorithms with various measures of severity of COPD including distance on 6-minute walk test (r=0.71) and the MRC dyspnea scale (r = -0.71).

Many other studies have utilized the SWP2 in various ways. Holm et al (2004) examined the relationship between pain and energy expenditure in Fibromyalgia patients and found that energy expenditure often increases significantly in the hour before a pain pill is taken. Lisetti at al (2003) utilized the SWP2 to classify subjects' emotions. They found surprisingly good performance, recognizing sadness, anger, surprise, fear, frustration, and amusement with accuracies between 70% and 92%.

All in all, the capabilities of the SWP2 with respect to energy expenditure have sufficient repeatability and reliability to have led to the development of commercial applications and largescale deployments of the SenseWear® Pro armband. Roche Diagnostics launched HealthWear (a private labeling of the BodyMedia technology) to clinicians in the US at the end of 2003. The system monitored and calculated a patient's caloric expenditure on a daily basis. It also provided a tool to estimate caloric intake. This system reported both energy expenditure and energy intake to the patients and their healthcare providers (Roche, 2004). In providing this information, HealthWear was a weight management system that used the continuous monitoring and collecting of physiological data to show the effect that lifestyle has on weight loss. Depicting calories burned, calories consumed, activity duration, and steps per day, the product aimed to increase personal awareness of health and parameters of weight management. Many users reported that this system has allowed them to lose considerable weight. As one example, a user who happened to be a MD/PhD wrote:

> *Since I started using the HealthWear System, I have steadily lost 45 lbs in less than 6 months. As a physician and a scientist, I know that you can't improve what you don't measure. This system gives me the tools to measure and track calories in (consumption) and calories out (expenditure). The difference between in and out is weight.*

The system was used primarily with clinically obese individuals with some focus on patients seeking bariatric surgery or those looking for alternatives to bariatric surgery.

In early 2005, Apex Fitness and BodyMedia announced the launch of the bodybugg™, a SenseWear® enabled web-based fitness and weight management system. The system leverages a branded SWP2 called bodybugg™ and provides fitness professionals and their clients with a highly accurate, easy-to-use solution for establishing and managing fitness and weight loss goals. The system, developed by BodyMedia with Apex Fitness, tracks caloric intake and expenditure automatically, without the need for food logging. The system is supported by other features, such as a state-of-the-art menu generation engine and robust reporting features for both fitness professionals and club members. The system is presently being used by thousands of users across the country – a number that is growing very quickly.

The SenseWear® Pro$_2$ Armband and InnerView Research, Professional, and Wearer software are also commercially available. Hundreds of systems across four continents over 4 years have enabled clinicians and researchers to study

human physiology in real world situations. Applications have included the study of exercise physiology, sleep behaviors, physiological responses, and stress response in car and tank drivers. Groups studied range from professional athletes to the elderly to children. The products have survived intact extreme environments such as Mt Everest, the South Pole, the highest lake in the world, the Pittsburgh Steelers training camp, and National Guard live firefighter training sessions inside burning planes.

V. Future of SenseWear

In the fall of 2004, BodyMedia announced a new, patent pending technology that can accurately monitor the electrical activity of the heart from the upper arm, continuously and for extended periods of time. This latest BodyMedia innovation can record electrocardiogram (ECG) data from the upper arm, as well as other locations on the human body previously considered impractical by conventional standards, without wires, adhesives, or other equipment. BodyMedia has integrated the technology into prototype versions of the SWP2 using two adhesive electrodes. Production of a non-adhesive system is underway. The invention is particularly noteworthy because it challenges conventional wisdom in electrocardiology that ECG can only be observed using electrodes spaced on "either side" of the heart. Al-Ahmad, Homer, and Wang (2004) have presented preliminary results of validating the prototypes, showing that the armband measures heart rate and beat-to-beat variability comparably to a holter monitor. Preliminary results in incorporating heart rate information into the equations for energy expenditure are supporting McClain et al's (2005) finding that adding in heart rate can reduce the error of the SWP2 algorithms for certain activities.

BodyMedia has already started work on the next generation armband. This revolutionary armband will showcase heart rate technology and incorporate innovations including a smaller form factor and a real time display device that receives and displays EE, physical activity duration and steps. We are confident a display device will close the loop in patient motivation and incentive, with direct feedback on his/her physical activity levels and energy expenditure. These features can truly revolutionize monitoring of physical activity in areas such as diabetes, obesity, rehabilitation, and sports. These advances will continue BodyMedia's efforts in bringing accurate physiological monitoring to individuals outside the laboratory.

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