Why The Upper Arm? Factors Contributing to the Design of an Accurate and Comfortable, Wearable Body Monitor

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*Abstract*¾*Wearable and ambulatory body monitors hold many obvious benefits for the future of public health. At the heart of the healthcare industry lies the unmet need for consumers, researchers and clinicians to continuously and accurately monitor physiological states of the body. This paper discusses in-depth the challenges and reasoning for the specific positioning and design of the SenseWear™ Armband and how the important and contradictory requirements of comfort and accuracy were reconciled in order to create a product that can collect continuous and accurate data for extended periods of time, outside of labs and hospitals.*

*Index Terms*¾*Ambulatory body monitors, SenseWear Armband, sensor array, energy expenditure, sleep state, physical activity level, physiological data, galvanic skin response, GSR, heat flux, near body ambient temperature, accelerometer, derived data, free-living environment, accuracy and reliability, wearable computer.*

1. INTRODUCTION

Whether a sleep researcher is trying to understand the nocturnal patterns of insomnia patients, a pharmaceutical company is running clinical trials for an antidepressant drug, or an individual is trying to lose weight, continuous and accurate recording of what the body is doing and how it responds to treatment in the context of everyday life is crucial to the success of most healthcare initiatives.

There are many products that monitor physiological parameters. Most of these, however, like metabolic oxygen uptake carts and polysymnography devices, are too cumbersome and costly to be used outside the lab environment.

Wearable monitors, such as pedometers and actigraphs, help solve the portability and cost problem but are ultimately too inaccurate for determining derived measures like caloric burn and sleep states because they are limited, single sensor solutions [1][2]. Somewhere between the expensive but unwieldy high-end solutions, and the mobile but inaccurate solutions, lies an enormous opportunity for improving how the body is monitored and elevating the state of health assessment.

2. THE PROBLEM

Dr. John Jakacic, Associate Professor at Brown Medical School and Director of the Physical Activity and Weight Management Research Center at the University of Pittsburgh states, "With regard to wearable body monitors, it all comes down to accuracy, ease of use, and participant willingness to wear the device over a specific period of time." If a wearable body monitor is to be useful to the people who depend on them, it has to be, above all, accurate and comfortable. Accurate recording and interpretation of relevant physiological and lifestyle data affords users trustworthy and useful results. Comfort assures that the user will wear the product for enough time to collect a meaningful amount of data without altering the wearer's natural behavior. The challenge is that these two criteria are often at odds with one another. Medical-grade accuracy has historically been synonymous with discomfort due to the size, shape, materials, and methods for attaching and wearing body monitors and sensors. Our goal was to build a device that could be worn for long periods of time, much like a person wears a watch or pair of glasses, without sacrificing accuracy.

Our position is that such a product will allow health professionals and consumers with a variety of health concerns to know more about the status and performance of the body outside of the lab or hospital environment. Access to such free-living data has the potential to transform the areas of clinical research, health assessment, and self care.

3. THE SOLUTION

Years of research and design iteration have culminated in the SenseWear Armband. Worn on the back of the upper arm, the Armband is a multi-sensor device consisting of a body-contoured monitor surrounded by soft flexible "wings" and an adjustable strap that keeps the sensors in contact with the arm during a variety of activities and conditions. While worn, the Armband continuously collects physiological data, such as motion, heat flux, skin temperature, and galvanic skin response data. From this data, BodyMedia's customized algorithms derive energy expenditure (caloric burn), level of activity, and sleep state. The physiological data can be retrieved from the armband to a user's PC then derived and graphed by using BodyMedia's InnerView™ Software.

4. WHAT DO WE NEED TO SENSE?

While there are many medical monitors that provide doctors and patients with glimpses into the body's physiological states, few collect data in the context of a patient's or wearer's natural environment. Of the leading products that do, there are notable limitations resulting from single sensor solutions and long-term comfort issues.

For example, a Holter monitor, a portable/wearable ECG device, can collect data for up to 48 hours. However, due to its numerous wires, rigid form, and adhesive electrodes, comfort is compromised, particularly while sleeping, making it cumbersome and unnatural for the user to wear continuously. The introduction of such unnatural variables can influence the wearer's natural behavior and skew results. Likewise, heart rate straps, the most prominent wearable body monitor on the market, consist of two carbonized rubber electrodes embedded in a plastic strap worn around the torso below the chest. An adjustable elastic band holds the strap and electrodes in place. In this example, many wearers complain of "constricting discomfort" or "slippage" due to the pressure applied to the diaphragm region after more than a few hours of use. [3] Moreover, these straps do not work during normal sleep activity due to the strap's tendency to "bow" when laid on improperly, lifting the electrodes from the chest and breaking electrical contact. Additionally, heart straps are single sensor systems. While they are very good at monitoring heart rate, they are limited in the diversity of other useful information they can collect.

To improve theses state-of-the-art devices and provide physicians, researchers, and wearers with range of useful health-related indicators, BodyMedia determined the final solution would need to include multiple sensors in its design. Several sensors could more accurately derive and detect multiple physiological states better than any single sensor alone [4].

Through a series of interviews with physicians, researchers, and health-conscious consumers, it was determined that energy expenditure, level of physical activity, sleep quality, heart rate, stress, and contextual awareness (lying down, sitting up, etc.) were the most significant states worth obtaining continuously. These findings were further corroborated by market research, which indicated a need for more acute monitoring due to an increase in healthcare spending as a result of the wave of aging baby boomers with obesity, diabetes, hypertension, and sleep related health problems.

5. SELECTING THE SENSORS AND BODY LOCATIONS

A number of internal studies were conducted to determine which sensors could provide the basis to derive these physiological states. For a sensor to be considered, it had to perform well beyond textbook accuracy and meet the following criteria based on market research:

- Accurately work for up to two weeks under continuous use (24/7) during active athletic and work situations as well as during sleep
- Be manufacturable and robust enough to survive everyday use in low (0° C) and high (45°C) temperature environments
- Be small enough to keep the overall monitor height and footprint unobtrusive beneath clothing
- Consist of only materials or sensors that were non-irritating to the skin and hypoallergenic
- Be designed to be non-invasive
- Be low power consumption and cost effective

Additionally, all external sensors had to function on a part of the body that was within a comprehensive ergonomic guideline for wearable technology [5]. According to Gemperle, et al., the body regions that are optimal for wearing (Figure 1) have the following characteristics:

- Similar size and shape on men and women between the 5% and 95% size range
- Relatively large surface area (at least 2" x 3") to accommodate the required components, including batteries and electronics
- Low mobility (meaning they do not bend or stretch extensively even during high activity)
- Continuous circumference for easy attachment and detachment

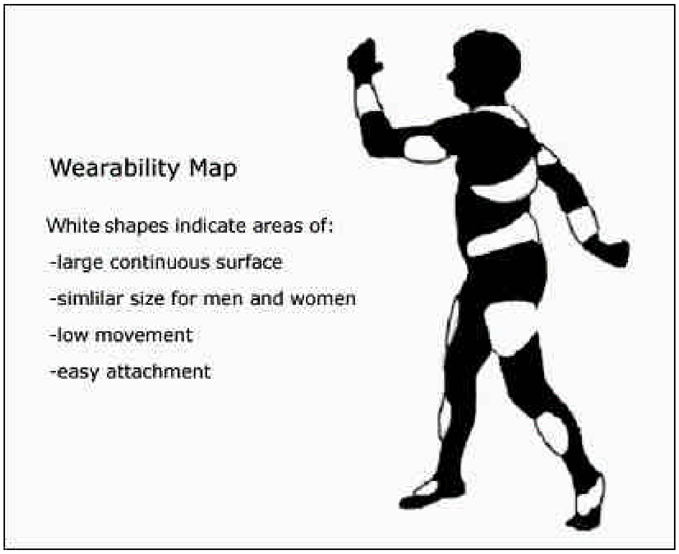

Figure 1

Using these rules and the sensor criteria as a framework for wearability, BodyMedia's team of biomedical, hardware, and mechanical engineers and industrial and clothing designers began testing sensors and materials.

Protocols were developed for each sensor, defining several regions of the body for testing skin contact and reliability of the data collected. In each test, a medical gold-standard sensor was also worn on the body to benchmark and compare results (Figure 2). For each test, participants performed several tasks ranging from mental puzzles to physical treadmill routines. A physiological data collection system collected and stored the results.

Figure 2. Testing galvanic skin response (GSR) on the upper arm and benchmarking against GSR on the fingertip.

As each sensor was tested on the body, it revealed where it could best collect data. For each location, an evaluation was made against the wearability map. Iteratively overlapping these maps, revealed the best areas for both collecting data and continuously wearing the monitor.

The sensors that promised the best results regarding accuracy, reliability, and wearability were:

- Galvanic skin response (GSR)
- Heat flux
- Accelerometer
- Skin Temperature
- Near-body temperature sensors
- Heart rate

Importantly, these sensors, while fulfilling the required criteria, did so on more than one region of the body. Two regions, the back of the upper arm (the triceps) and the upper torso, were areas that could accurately sense all the desired states and accommodate the sensors in a reliable manner. While our initial tests indicated that physiological information off the upper torso was slightly more accurate than the upper arm, it was decided not to just focus on the torso region due to extended wearability and accessibility concerns the team shared at that time.

However, from a business standpoint, it was understood that there was not enough time and resources to pursue two solutions, so a decision between the upper torso region and upper arm was still required. To make this decision, the development team created a range of physical prototypes (Figure 3) for both the torso and upper arm to be evaluated. Several focus groups were conducted around five wearable, non-working prototypes along with computer screen mock-ups, showing the type of feedback the product might provide when the data was uploaded to a computer [6].


Figure 3. Several Prototypes: minimal-torso design, vest-style, and armband.

Participants were asked to wear each prototype and perform a series of activities, including walking, touching their toes, stretching, and sitting. During these activities, each participant was asked the following questions:

– How would you feel wearing this monitor for many days at a time?
– Is it easy to put on and take off?
– What, specifically, would you like the monitor to tell you?
– How would you like this information to be communicated?

The answers to these questions resulted in several important conclusions that further constrained and defined the design space.

1. Participants unanimously agreed that the product should be as small as the technology and usability would allow. While the idea of a shirt was familiar and compelling, there was no interest in wearing something larger, warmer, or more constricting than need be, especially given the daily use requirement, regardless of the fashion appeal.

2. Many participants insisted that the product be no harder to use and no less comfortable than accessories already worn on the body, such as rings, wristwatches, and glasses. With this feedback, we determined the monitor should be as easy to put on and just as comfortable as common body accessories for it to be widely accepted. In fact, an internal goal was to surpass this standard because the monitor would actually be worn longer and under more challenging conditions than most accessories.

With this feedback, the armband design began to emerge as the more compelling solution than the torso-sized products for the following reasons:

1. Noting the sizes of various focus group participants and the importance of a perfect fit to ensure sensor accuracy, it became clear that some degree of sizing would be required if a torso-worn product was selected. At the very least, this would mean a S, M, L solution, which posed a cost problem for manufacturing as well as a fit and accuracy problem for the sensors. We needed perfect fit and something that was personally adjustable.

2. If the monitor took the form of a shirt or vest, it would need to have a large fabric component in which the technology could reside. This meant that some or all of the technology would need to be removed during washing and reinserted for use. Focus group participants pointed out that this could get burdensome and be a potential deterrent to long-tem wearing.

In contrast, a range of compelling arguments that supported the upper arm was discovered. Focus groups and early prototyping revealed:

1. *The upper arm is unoccupied "real estate."* The area is rarely used for jewelry or other functional accessories, unlike the wrist or chest.
2. *The upper arm is gender-neutral.* Because the upper arm is not an area of adornment, neither men nor women have an aversion to wearing something here. In other words, it has not been pre-stereotyped as the lips (lipstick), chest (bra), and ears (earrings) have.
3. *The upper arm, particularly the tricep, is the least obtrusive part of the arm.* It is not prone to the bumps and abrasions that products on the wrist are.
4. *It is a region in which a product can be comfortably worn.* This is because the upper arm is a relatively soft and consistent region of the body with few pronouncements. Moreover, due to the upper arm's structure and strength, even a fairly heavy device could be worn with minimal fatigue.
5. *Concealment.* The upper arm is typically covered by clothing. So in medical, clinical, or perceptually sensitive applications, the product is appropriately private.
6. *One size fits all.* With minor adaptations to the length of an adjustable strap and no changes to the monitor itself, an armband solution can fit a range from small children to professional football players.

For these reasons the upper arm became the preferred development location for the SenseWear body monitor.

6. THE ARMBAND: DESIGN AND KEY INNOVATIONS

With the location of the upper arm (the triceps area) now well understood to be the prime location, new iterations of models were created (Figure 4) to discover the best way to wear such a monitor. This new series of armbands was developed and optimized for fit, comfort, accessibility by the user, and manufacturability. The decision to make the monitor appear mostly soft became a primary investigation, encouraged by participants who wanted the product to feel more like a piece of clothing and less like a medical device.


Figure 4. A selection of mostly hard (left column) v. mostly soft prototypes (right column) shared with potential users.

Continued iterative designs and meetings with users and manufacturers revealed that fabric solutions, while technologically disarming, trendy, and evocative, held many limitations, most notably:

– If the armband gets wet or sweaty, the user will take it off and have to dry the armband, thus interrupting continuous use. In addition, the user would need to remove and re-insert the hardware components each time it is washed, an annoying activity.

– Fabric gets dirty, fades, stretches out, and shows wear more quickly than plastics and metal.

– Fabric does not serve a protective function; it only holds the technology and helps attach the monitor to the body. As a result, it is not a large, value-added material given the additional cost required to make it.

As a result, we focused on the slightly less flexible solution, which required a third round of iterations (Figure 5).

Figure 5. Prototypes exploring the monitor's attachment to the wings and the wings' attachment to the arm.

From these prototypes, a set of key innovations were created that met our initial criteria and also resulted in several patentable design features which include:

– *Symmetrical flexible wings on either side of the monitor.* These wings serve several purposes. They stabilize the monitor, distributing weight evenly across the product, hold the monitor securely to the arm, and create equal pressure on the sensors. The wings also flex open and closed, accommodating virtually all arm sizes and possible movements and exercises.

– *Custom proprietary stretch materials.* A custom elastic strap material was developed to allow the bicep to expand and contract without the armband feeling too tight (constricting) or too loose (slipping)—a fine balance. In addition, this material was designed to be hypoallergenic, non-latex, and integrate a durable hook and loop system for repeated attachment to the arm.

Figure 6. The SenseWear Armband

7. WEARABILITY TESTS

The SenseWear Armband has been worn under many conditions and in diverse environments. It is being used by a wide range of thought-leading institutions and corporations, including Stanford University, University of Pittsburgh Medical Center, University of Louisville, NASA, Sandia National Labs, and PPG Industries. To date, over 50,000 hours of on-body data has been collected. Of that, 11,500 hours have been annotated and compared against 600 hours of lab data for validation. The following are excerpts from several studies conducted, in part, to validate the comfort, wearability, and reliability of the SenseWear Armband.

A. University of Pittsburgh School of Medicine

The University of Pittsburgh's School of Medicine, Department of Psychiatry conducted a sleep disorder study consisting of 23 subjects (both men and women). Each subject was required to wear the SenseWear Armband for approximately 12 hours—before, during, and for a short period of time after they slept. Data collected via the Armband included: heat flux, motion, GSR, and skin temperature. From this, sleep onset, wake, and duration were estimated within 93.5% accuracy compared to the lab's Polysymnography machine. The results from this study (Figure 7) indicate a high acceptance of the Armband and complete reliability of the device during reclined resting and sleep activity. One subject complained of the size of the Armband. BodyMedia is addressing this concern in its next generation of products.

Number of subjects	Time worn per individual	Activity level during study	Reported discomfort among subjects	Reported unreliability of total data collected due to slippage or sensor malfunction
23	12 hours	Low	5%	none

Figure 7

B. Pittsburgh Steelers

Five professional football players from the Pittsburgh Steelers organization wore SenseWear Armbands for 1.5 days (eight hours one day and four the following day), which included three 90-minute practices during the 2002 pre-season summer training camp. The purpose of this study was to see if the body parameters collected by the Armband yielded any prediction of heat stress. It also gave us an opportunity to test the use of the Armband under extreme conditions and on upper arms with a circumference of 18" to 24". All five players wore full pads and had full practices, including running, hitting, and tackling. The results (Figure 8) indicated that the Armbands remained in contact with the skin for most of the duration of the practice. Some shifting due to intense physical contact caused one Armband to turn off for a total of 23 minutes and another's heat flow sensor to malfunction. The players reported no discomfort or interference from the Armband.

Number of subjects	Time worn per individual	Activity level during study	Reported discomfort among subjects	Reported unreliability of total data collected due to slippage or sensor malfunction
5	12 hours	Moderate to Extreme	None	9%

Figure 8

C. PPG Industries

This study evaluated the usability of the SenseWear Armband as a tool for improving job safety and evaluating the ergonomics and design of PPG's plant equipment. Forty employees split evenly across two PPG fiberglass manufacturing facilities wore the Armband for 20 12-hour sessions, over a six-week period. Activity level and energy expenditure were collected and analyzed for clues pertaining to job-related fatigue and ergonomic problems with the equipment design. In each plant, participants performed repetitive arm-intensive manufacturing tasks within a light-industrial factory floor setting.

Results (Figure 9) concluded that the SenseWear Armband accurately measured the activity and amount of energy expended by the workers throughout their shifts in both plants. The results also indicated that compliance with the devices and overall wearing satisfaction was extremely high. One participant complained of a skin irritation.

Number of subjects	Time worn per individual	Activity level during study	Reported discomfort among subjects	Reported unreliability of total data collected due to slippage or sensor malfunction
40	250 hours	Low to Moderate	2.5%	None

Figure 9

D. Aircraft Rescue and Fire Fighting (ARFF) Training Center

At the Federal Aviation Agency's (FAA) regional Aircraft Rescue and Fire Fighting training center, six firefighters, five male and one female, ranging in age from 19 to 50, wore SenseWear Armbands as they took part in training exercises. Each participant wore the armband for five different scenarios over approximately four hours. The scenarios included:

- *Attacking.* Firefighters enter a burning B757 airplane carrying hoses and extinguish a fire.
- *Rescuing.* Firefighters enter the B757 to locate, unstrap, and carry out dummy passengers.
- *Turret.* Firefighters on a fire truck extinguish a simulated oil spill fire.
- *Backup.* Firefighters carry hoses and approach the airplane but remain on standby outside the plane.
- *Rehab.* Firefighters take off their gear and rest.

Figure 10

All firefighters wore full reflective fire suits, helmets, and oxygen masks when entering or approaching the airplane. Temperatures within the plane reached over 270°F. Study results from this training operation are as follows:

- The firefighters were able to perform all training tasks without interference from the Armbands.
- All six Armbands survived for the entire duration, including multiple entries into the 270+ F heat of the B757.
- Following the exercises, the firefighters' consensus was that they "forgot the Armband was on."

Number of subjects	Time worn per individual *approx.*	Activity level during study	Reported discomfort among subjects	Reported unreliability of total data collected due to slippage or sensor malfunction
6	4 hours	Moderate to High	None	None

Figure 11

8. CONCLUSION

These tests conclude that the SenseWear Armband posed little to no interference with a wearer's usual routine, while collecting reliable data continuously. The decisions made in the design and engineering of the SenseWear Armband deliver on the promise of a wearable body monitor that is both comfortable enough for long-term use and reliable enough to yield accurate results. By ensuring the highest possible rate of user compliance and trustworthy data collection outside the lab and hospital environment, the SenseWear Armband has many useful applications in the future of the healthcare.

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