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Neuroergonomics, Human Factors Design, and Special Populations

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CHAPTER 50

Development of a Remote Medical Monitoring System to Meet Soldier Needs

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ABSTRACT

Medical monitoring systems for military use have unique requirements. The purpose of this evaluation was to determine if changes in system designs improved the fit, comfort, durability, impact on military performance, impact on the body, and overall acceptability of the system. This was accomplished though an iterative process of five studies and four versions of the system. Information from soldiers obtained from these evaluations was provided to the materiel developers to improve the form, fit, and function of this system. The resulting system showed progressive improvements in comfort, durability and acceptability through a reduction in size and improvements in design and materials used.

Keywords: Physiological Status Monitoring, Systems Engineering, Human Factors Design, Wearable, Comfort

INTRODUCTION

The use of physiological monitoring systems may reduce the frequency and severity of injuries to soldiers by providing medical situational awareness during training or actual operational activities. This study examined the development of a medical monitoring system for soldiers; the Hidalgo Equivital VSDS EQ-01 (Hidalgo Ltd., Cambridge, UK), a Food and Drug Administration (FDA) 510k certified device. The VSDS EQ-01 reliably measures heart rate and respiration rate (Tharion et al., 2008), but soldiers found it uncomfortable to wear for extended periods (Tharion et al., 2007).

Physiological monitoring systems can provide useful information, but they must also be comfortable, easy to use, and work reliably in the specific environment for which they are intended to be used (Paradiso et al., 2005). Military environments pose unique demands and certainly differ from home health monitoring or other civilian ambulatory monitoring environments. Sensors embedded within clothing have been shown to be comfortable to the user (Paradiso et al., 2005); however, some of these systems increase the risk of thermal strain because of the insulation factor associated with the added clothing. Additionally, some systems may prove comfortable, but the type or quality of the data obtained is not adequate for medical monitoring of military personnel in harsh environments. The system needs to be small, lightweight, unencumbering, and compatible with other military equipment and clothing worn, easy to clean, capable of functioning over many hours, have low power consumption, ensure privacy of the data, and be of reasonable cost (Pantelopoulos and Bourbakis, 2008).

METHODS

This evaluation used experienced military personnel (n=154) in five studies (Table 1). Soldiers had one or more deployments to Iraq or Afghanistan, had regular chemical biological, radiological, nuclear (CBRN) training, or been engaged in elite small unit operations training as Army Rangers or Special Forces soldiers. Prior to the start of each study, participants were briefed on the purpose of the study and the associated risks and benefits. They were informed of their right to withdraw at any time. Participants gave their written informed consent prior to wearing the system or providing any data. These studies were approved by the Scientific and Human Use Review Committees at the U.S. Army Research Institute of Environmental Medicine. All participants were also briefed on the potential for the VSDS to be used more broadly as a medical monitoring device.

Four versions of the VSDS were evaluated during five military training exercises. The first study at Ft. Polk had infantry soldiers wear the VSDS for approximately 8 hours. Training included wearing Interceptor Body Armor (IBA) and load carriage equipment (i.e., rucksack etc.) during simulated combat scenarios. Volunteers slept during the exercise while wearing the VSDS. The second study was at Aberdeen Proving Grounds and used infantry soldiers participating in military operations in an urban terrain (MOUT). They wore the VSDS for over 90 hours, including one 23-hour sustained operation. Activities included an approach march, room clearing,

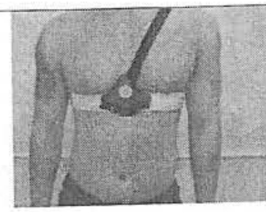
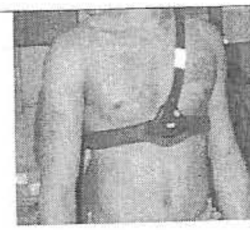
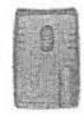
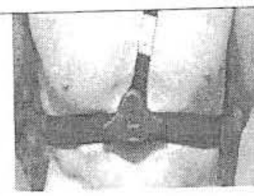
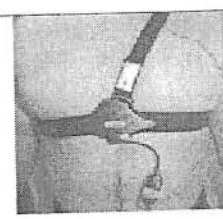
Table 1: Study description

VSDS Version #	Personnel and Study Duration	*n*	Location
1	Infantry Soldiers Duration: 8 Hrs	8	Ft. Polk, LA
2	Infantry Soldiers Duration: 95 Hrs	26	Aberdeen Proving Grounds, MD
3	Civil Support Team – Weapons of Mass Destruction Duration: 4 Hrs	12	North Brookfield, MA
3	Ranger Training Brigade Students Duration: 4 Hrs	77	Ft. Benning, GA
4	Special Forces Students Duration: 90 Hrs	31	Camp McCall, NC

combat in close quarters, and decision-making tactics under various enemy threat levels. The third study was with Civil Support Teams – Weapons of Mass Destruction (CST-WMD) Army National Guard personnel. They wore the VSDS while participating in a search and rescue operation in an enclosed space environment. Activities included obtaining samples of simulated CBRN material while wearing personal protective equipment (PPE). They also rescued simulated casualties. The fourth study used Ranger school students at Ft. Benning, GA who wore the VSDS for approximately 4 hours while participating in a timed road march with a weighted backpack. The last study was with students participating in the Special Forces Small Unit Tactics (SUT) course who wore the VSDS for approximately 90 hours over 10 days including one 24-hour sustained operation at Camp McCall, NC. Volunteers wore a variety of military equipment during their combat training including body armor and load carrying equipment.

The four versions of the VSDS tested are shown in Table 2. The belt has electrocardiograph (ECG) sensors to record heart rate, sensors to detect expansion and contraction of the belt to measure respiration rate, and a skin temperature sensor. The sensor electronics module (SEM) is made of hard plastic and snaps onto the belt in the center of the chest and receives data from the belt sensors. It also has accelerometers to detect body motion and body position. An accompanying health hub worn in uniform pockets, backpacks, etc. was used with the first two VSDS versions. Information from the SEM was transmitted to the health hub using a body area network. The health hub weighed approximately 340 g and measured 12 X 8 X 4 cm. Off-system sensors such as an ingestible thermometer pill that records core body temperature transmitted information directly to the health hub. Software to assess thermal, cognitive capability, hydration, and life sign states was housed in the health hub. The health hub was used to turn the system on, begin data collection and provides the radio network

Table 2: Vital sign detection system (VSDS) description

Version Number	Year Used	System	Change from Previous Version
1	2006	 +  Health Hub	
2	2006	 +  Health Hub	1. Change belt fabrics 2. Change in stitching 3. Velcro straps used to hold SEM to belt
3	2007-2008		1. Health hub functions incorporated into SEM 2. Belt-SEM connector made more flexible – negating need for side Velcro straps 3. Softer belt fabrics 4. Change in stitching 5. Plastic belt adjuster replaced with small hook adjusters. 6. Securing bungs to SEM
4	2009		1. Added a prototype heat flux sensor

link for transmission of information to remote computers or other devices. The health hub was rendered obsolete in VSDS Versions 3 and 4 where the functions were assumed by the SEM. Once training was completed while wearing the VSDS, a survey was immediately issued to obtain some basic background information (e.g., time in the military, number of deployments etc.) and responses to questions regarding fit, comfort, durability of the system, impact on military performance, physical impact on the body, and overall acceptability. Five or seven-point Likert rating scales were used. For example when asked about how loose or tight the device was, a scale of very tight = 1, neither tight nor loose = 4, and very loose = 7 was used. Yes/no responses (e.g., would you wear the system if it would help save your life?) and open-ended questions (e.g., was the system acceptable to wear, and if not, why not?) were also used. Analyses of variance (ANOVAs) with Tukey's tests were used to determine differences in ratings between system versions with rating scale questions. Frequencies of open-ended and yes/no questions were analyzed with a chi-square test. All data are presented as means $\pm$ standard deviations.

RESULTS

The participants from the five studies had 5.7 $\pm$ 4.7 yrs of service and were 26.8 $\pm$ 5.2 yrs of age. The mean total number of hours the VSDS was worn was 23.8 $\pm$ 40.6 hours. Participants in the Aberdeen study (Study 2) wore the system for the longest period of time, a total of 94.6 $\pm$ 34.6 hours. The CST-WMD and RTB (studies 3 and 4) participants only wore the system for about 4 hours. A summary the total length of time the VSDS was worn in each study is presented in Table 1.

FIT

When participants were asked to rate the fit of the system, significant differences between system versions existed (p<0.001). Table 3 demonstrates the mean ratings of overall fit of the system using a seven point like-dislike Likert scale. The VSDS felt tight on volunteers but three participants mentioned it became loose over time.

Table 3: Overall fit ratings

VSDS Ver. 1 Ft. Polk	VSDS Ver. 2 Aberdeen	VSDS Ver. 3 North Brookfield	VSDS Ver. 3 Ft. Benning	VSDS Ver. 4 Camp McCall
2.9 ± 1.5^a	3.9 ± 1.6^b	5.9 ± 1.0^c	5.7 ± 1.3^c	5.1 ± 1.5^c

Values across the row with different letter superscripts are significantly different from one another as assessed by Tukey's Test at $p \leq 0.05$. 1 = Dislike Very Much 2= Dislike Moderately, 3= Dislike Slightly, 4 = Neither Like nor Dislike, 5 = Like Slightly, 6 = Like Moderately, 7 = Like Very Much.

COMFORT

Significant differences between system versions existed ($p < 0.001$) in overall comfort. Table 4 shows significant differences among VSDS Versions 1, 2, and 3 or 4, but no difference between versions 3 and 4. Only the first two studies had

Table 4: Overall comfort ratings

VSDS Ver. 1 Ft. Polk	VSDS Ver. 2 Aberdeen	VSDS Ver. 3 North Brookfield	VSDS Ver. 3 Ft. Benning	VSDS Ver. 4 Camp McCall
2.0 ± 0.8^a	3.4 ± 1.2^b	5.5 ± 1.2^c	5.5 ± 1.5^c	4.9 ± 1.7^c

Values across the row with different letter superscripts are significantly different from one another as assessed by Tukey's Test at $p \leq 0.05$. 1 = Very Uncomfortable 2= Moderately Uncomfortable, 3= Slightly Uncomfortable, 4 = Neither Comfortable nor Uncomfortable, 5 = Slightly Comfortable, 6 = Moderately Comfortable, 7 = Very Comfortable.

participants sleep while wearing the system. The VSDS in these studies showed slightly more uncomfortable ratings when trying to sleep (VSDS Version 1 (Study 1): 1.8 ± 0.8, VSDS Version 2 (Study 2): 3.0 ± 1.7) compared to the overall ratings VSDS Version 1 (Study 1): 2.0 ± 0.8, VSDS Version 2 (Study 2): 3.3 ± 1.2).

The comfort ratings of the various belt components which included the cloth electrodes, water proof material that surrounds the electrodes, etc., were also assessed. Only Version 1 had components that received ratings lower than slightly uncomfortable. Those components were the adjuster (3.0 ± 1.5), belt fastener (2.9 ± 1.6), belt stitching (1.9 ± 1.1), and belt elastic (1.9 ± 1.1). No component parts in any other versions received ratings of 3.0 or lower. When volunteers were asked what activities were most uncomfortable while wearing the system, the following activities and number of respondents mentioning that activity across all five studies were: doing prone activities such as shooting or low crawling (n = 7), wearing body armor (n = 6), road marching (n = 6), doing land navigation (n=4), rappelling (n = 3), and when sweating (n = 3). A total of 108 different activities or times when the system was most uncomfortable were cited. It should be noted that not all groups did certain activities. For example only 32 individuals slept in the system, whereas 103 individuals participated in a road march while wearing the system.

DURABILITY OF THE SYSTEM

Volunteers and research staff recorded if the system broke or stopped functioning during testing. There were a significantly higher number of failures for VSDS Versions 1 and 2 compared to Versions 3 and 4 (chi-square: $p < 0.001$) (Table 5). Three system failures in VSDS Version 1 were because the SEM became unsnapped from the belt. Most problems concerning durability were with VSDS Version 2. However that study was the longest and most physically demanding evaluation, resulting in the greatest challenge to the systems. The two system failures in Versions 3 and 4 were due to the SEM becoming unsnapped from the belt.

Table 5: Percent of system failure

VSDS Ver. 1 Ft. Polk	VSDS Ver. 2 Aberdeen	VSDS Ver. 3 North Brookfield	VSDS Ver. 3 Ft. Benning	VSDS Ver. 4 Camp McCall
37.5%	69.2%	0.0%	1.3%	3.4%

For VSDS Version 2 there was a 50% failure rate with the health hubs. The hub was worn either inside a pocket of the Camelbak drinking system (Camelbak, Petaluma, California) or in a small pouch fastened to the soldier's belt. There was a 26% failure rate with the SEMs. Two common failures were that the units could not be turned on, or that the bungs (a small rubber-plastic device that covers some of the electronic pins and acts as the on/off switch) fell out during the exercise. Thirty-nine percent of SEMs became detached from the belt as the snap at the sides of the SEM unsnapped. Three belts had at least one torn metal snap out of the five that are normally present. The other belt had torn foam (used for padding and comfort) near the center of the belt.

IMPACT ON MILITARY PERFORMANCE

Volunteers were asked to rate the impact of wearing the VSDS on military performance. Table 6 shows the ratings by version and study when wearing the VSDS and Advanced Combat Uniform (ACU) alone. Only two studies with the first two versions of the VSDS evaluated impact on military performance when wearing body armor. These ratings show a slightly negative to moderately negative impact on performance: Version 1 (Ft. Polk) rating 3.9 ± 1.5 and Version 2 (Aberdeen) rating 3.4 ± 1.6 on the 1 to 5 point scale (1 = extreme negative impact; 5 = no negative impact). The only other activity that showed ratings below "slightly negative impact" was for military activities performed in the prone position. No significant differences in the performance of activities in the prone position were evident across the various versions of the system.

PHYSICAL IMPACT ON THE BODY

Impact the system had on the body differed across VSDS versions ($p < 0.001$) (Table 7). No differences between Versions 3 and 4 were seen and impact was negligible. The primary impact was with Versions 1 and 2. Discomfort caused by skin irritation was reported in over 90% of Soldiers wearing these versions of the system. The central belt area and the adjustment buckle were the primary areas of complaint. Complaints included skin irritation, redness, sensitivity, abrasion, acne, prickly heat and extreme sweating near the system. Version 3 used an adjustment fastener with small bra-type hooks instead of the plastic buckle.

Table 6: Impact on overall military performance and while performing activities in the prone position

VSDS Ver. 1 Ft. Polk	VSDS Ver. 2 Aberdeen	VSDS Ver. 3 North Brookfield	VSDS Ver. 3 Ft. Benning	VSDS Ver. 4 Camp McCall
Overall impact on military performance				
4.5 ± 0.6^b	4.1 ± 1.2^a	4.7 ± 0.5^c	4.8 ± 0.6^c	4.8 ± 0.5^c
Impact on military performance while performing activities in the prone position				
3.3 ± 2.6^b	3.2 ± 1.6	3.8 ± 0.5	NA	3.3 ± 2.2

Values across the row with different letter superscripts are significantly different from one another as assessed by Tukey's Test at $p \leq 0.05$. 1 = Extreme Negative Impact, 2= Very Negative Impact, 3= Moderate Negative Impact, 4 = Slight Negative Impact, 5 = No Negative Impact NA = Not Applicable

Table 7: Impact on the body of wearing the system

VSDS Ver. 1 Ft. Polk	VSDS Ver. 2 Aberdeen	VSDS Ver. 3 North Brookfield	VSDS Ver. 3 Ft. Benning	VSDS Ver. 4 Camp McCall
3.0 ± 1.5^a	3.7 ± 1.2^b	4.8 ± 0.4^c	4.9 ± 0.2^c	4.9 ± 0.3^c

Values across the row with different letter superscripts are significantly different from one another as assessed by Tukey's Test at $p \leq 0.05$. 1 = Extreme Negative Impact, 2= Very Negative Impact, 3= Moderate Negative Impact, 4 = Slight Negative Impact, 5 = No Negative Impact

Other changes that occurred between Versions 2 and 3 included changing to a softer belt fabric and changing the stitching material, type, and pattern.

OVERALL ACCEPTABILITY

Volunteers were asked if the system were acceptable to wear for extended periods of time. There was a significant chi-square ($p < 0.001$) difference among versions (Table 8). Only 50% or less of those wearing Versions 1 and 2 found the system acceptable, whereas over 80% of those wearing Versions 3 and 4 found it acceptable. After explaining the possibility that use of the system may potentially save lives, volunteers were asked if they would wear the present system if it was shown to aid in prevention or treatment of injuries that could be life-threatening. A significant chi-square ($p < 0.005$) showed differences by version in frequency of volunteers who would wear the system for life-saving purposes. Less than 50% of those who wore Versions 1 and 2 said they would wear it, while over 80% of those who wore Versions 3 and 4 said they would wear the system. Those who said they would not wear the system were asked why they wouldn't wear it. The leading reasons were that they did not believe the system would actually help save their life,

Table 8: Percent of system acceptability

VSDS Ver. 1 Ft. Polk	VSDS Ver. 2 Aberdeen	VSDS Ver. 3 North Brookfield	VSDS Ver. 3 Ft. Benning	VSDS Ver. 4 Camp McCall
Overall Acceptability of the System – Acceptable to Wear For Extended Periods of Time?				
50.0%	37.0%	91.7%	92.0%	83.9%
System Acceptable if it Saved Your Life?				
62.%%	85.2%	100%	94.7%	74.2%

or it was too uncomfortable to wear even if it could potentially save their life.

DISCUSSION

These results demonstrate improvements in VSDS product quality achieved by providing feedback to the manufacturer after field testing each version. These tests were varied and some of the response differences between studies could have resulted from differences in the military scenarios volunteers perform, or type of volunteers who wore the system. For example, Version 3 of the system generally had the highest ratings, but participants in those studies wore the system for the shortest amount of time. In addition, Version 4 of the system had a prototype heat flux sensor added as a "dongle" (a heat flux disk attached by a wire to the SEM). Any final VSDS product would eliminate any wires and the heat flux sensor would be embedded in the belt. However, this wire and the length of time wearing the system may explain the overall lower ratings of the Version 4 system compared to Version 3.

The overall ratings in all measures – fit, comfort, durability, impact on military performance, impact on the body, and overall acceptability of the system – improved most substantially from Version 2 to Version 3. The most dramatic change to the VSDS also occurred between these two versions, which incorporated all of the functions from the health hub into the SEM. This reduced the added bulk and eliminated a separate piece of the system that was most susceptible to mechanical failure. At this time, some small removable parts to the SEM were secured and no longer made removable. This eliminated the possibility of them falling out while in use. The center chest piece on the belt where the SEM attached was also made slightly more flexible, which reduced the likelihood of the SEM becoming unsnapped from the belt. Another major improvement was the elimination of the plastic adjustment buckle which caused skin chafing. It was replaced that with an adjustment fastener with small hooks like those used on women's brassieres.

After the first two tests it was known that the SEM needed to be reduced in size, a feasible but expensive proposition. Efforts are currently underway to reduce the size of the SEM and implement various firmware upgrades. A prototype, soon to be tested is shown in Figure 6. These changes were initiated in response to direct feedback from soldiers, thereby demonstrating how human factors research can positively influence the design of a medical monitoring system for soldiers.

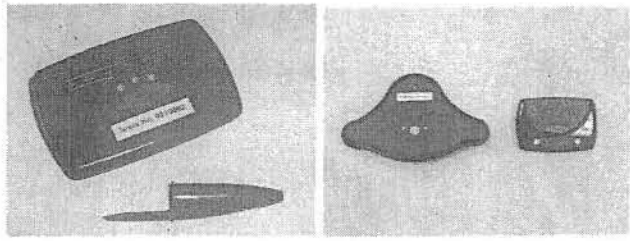


Figure 6. Prototype of the sensor electronics module of the EQ-02.

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