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13. ABSTRACT (Maximum 200 words) The purpose of this study was to evaluate the user acceptability of four design concepts (e.g., textile chest belt, rubber chest belt, vest, and adhesive patch) for a LSDS in four groups of 15 soldiers (i.e., 60 soldiers). During the six days of testing, soldiers participated in a diverse set of military activities as part of their participation in the U.S. Army Expert Infantryman Badge (EIB) course. On the first day of testing, soldiers filled out a demographic survey and were fitted for each LSDS design concept. Over the next four days of testing (Days 2-5), each soldier wore each of the four design concepts for 24 h and completed a user acceptability survey containing yes/no and 9-point hedonic scale questions. On Day 6 of testing, each soldier completed a comparison survey comparing the four design concepts against one another on a 4-point rank order scale, with 1 as the best rank and 4 as the worst rank. A counter-balanced study design was used so that each group wore a different design concept on Days 2-5 of testing. The ambient environmental conditions were recorded each day of testing. In the user acceptability survey, 90% found the textile chest belt acceptable, 83% found the adhesive patch acceptable, 73% found the rubber chest belt acceptable, and 29% found the vest acceptable. The percentage that found the vest acceptable was lower ($P < 0.05$) than all other design concepts. The percentage that found the rubber chest belt acceptable was also lower ($P < 0.05$) than the percentage that found the textile chest belt acceptable. There were no differences between the textile chest belt and adhesive patch in overall user acceptability. In the comparison survey, the textile chest belt (mean $\pm$ SD) (1.7 ± 0.7) and adhesive patch (2.1 ± 1.2) were ranked the best in the overall user acceptability category and the rubber chest belt (2.6 ± 0.7) and vest (3.5 ± 0.9) were ranked the worst. The vest ranked lower ($P < 0.05$) than all other design concepts. The rubber chest belt ranked lower ($P < 0.05$) than the textile chest belt. These results demonstrate that the textile chest belt and adhesive patch were the most user-acceptable design concepts for the soldier.				
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**USER ACCEPTABILITY OF DESIGN CONCEPTS FOR
A LIFE SIGN DETECTION SYSTEM**

Beth A. Beidleman
Reed W. Hoyt
Frederick J. Pearce
Nathaniel M. Sims
Dan T. Ditzler
John Ames
Karen L. Speckman
Laurie A. Blanchard
Alison Garcia
Nhedti L. Colquitt
William P. Gaffney
Beau J. Freund

Biophysics and Biomedical Modeling Division

December 2003

U.S. Army Research Institute of Environmental Medicine
Natick, MA 01760-5007

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Human subjects participated in these studies after giving their free and informed voluntary consent. The investigators have adhered to the policies for protection of human subjects as prescribed in Army Regulation 70-25, and the research was conducted in adherence with the provisions of 45 CFR Part 46.

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BACKGROUND

This research effort supports a milestone under Science and Technology Objective (STO) H, Warfighter Physiological Status Monitoring. The life sign detection system (LSDS) has been identified as a key component for implementation into the Land Warrior (LW) and/or Objective Force Warrior (OFW) systems in order to provide the combat medic with summary data about life sign status of the soldier. The LSDS may ultimately provide rapid access to basic life sign status information, which would help the combat medic make better decisions regarding the early identification, location, and triage priority of casualties. This type of physiological information should lead to reduced morbidity and mortality of soldiers by facilitating appropriate medical response. However, if using the LSDS interferes with the soldier's comfort, performance, other military equipment, and/or causes skin irritations, the soldier may choose not to wear the LSDS despite its potential benefits. Thus, the military needs to identify an acceptable design concept for the LSDS so that the soldier can "wear it and forget it."

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EXECUTIVE SUMMARY

The life sign detection system (LSDS) has been identified as a key component for implementation into the Land Warrior (LW) and/or Objective Force Warrior (OFW) platform in order to provide the combat medic with summary data about life sign status of the soldier. Life sign status may eventually allow the combat medic to optimize triage priority and evacuation of multiple casualties. The purpose of this study was to evaluate the user acceptability of four design concepts (e.g., textile chest belt, rubber chest belt, vest, and adhesive patch) for a LSDS in four groups of 15 soldiers (i.e., 60 soldiers). During the six days of testing, soldiers participated in a diverse set of military activities as part of their participation in the U.S. Army Expert Infantryman Badge (EIB) course. On the first day of testing, soldiers filled out a demographic survey and were fitted for each LSDS design concept. Over the next four days of testing (Days 2-5), each soldier wore each of the four design concepts for 24 h and completed a user acceptability survey containing yes/no and 9-point hedonic scale questions. On Day 6 of testing, each soldier completed a comparison survey comparing the four design concepts against one another on a 4-point rank order scale, with 1 as the best rank and 4 as the worst rank. A counter-balanced study design was used so that each group wore a different design concept on Days 2-5 of testing. The ambient environmental conditions were recorded each day of testing. In the user acceptability survey, 90% found the textile chest belt acceptable, 83% found the adhesive patch acceptable, 73% found the rubber chest belt acceptable, and 29% found the vest acceptable. The percentage that found the vest acceptable was lower ($P<0.05$) than all other design concepts. The percentage that found the rubber chest belt acceptable was also lower ($P<0.05$) than the percentage that found the textile chest belt acceptable. There were no differences between the textile chest belt and adhesive patch in overall user acceptability. In the comparison survey, the textile chest belt (mean $\pm$ SD) (1.7 ± 0.7) and adhesive patch (2.1 ± 1.2) were ranked the best in the overall user acceptability category and the rubber chest belt (2.6 ± 0.7) and vest (3.5 ± 0.9) were ranked the worst. The vest ranked lower ($P<0.05$) than all other design concepts. The rubber chest belt ranked lower ($P<0.05$) than the textile chest belt. These results demonstrate that the textile chest belt and adhesive patch were the most user-acceptable design concepts for the soldier.

INTRODUCTION

It has been shown on numerous occasions that successful implementation of any piece of equipment into the military uniform hinges largely on user acceptability (3,6). If a soldier perceives that his/her comfort, performance, morbidity, mobility, and/or lethality will be affected negatively by a certain piece of equipment, then the soldier will be unlikely to wear it despite its potential benefits. Thus, in order to successfully incorporate a life sign detection system (LSDS) into the Objective Force Warrior (OFW) platform, it is imperative to identify an LSDS design concept that is acceptable to the soldier.

The rubber chest belt design concept for incorporating physiological sensors has been used in the past to collect heart rate information on endurance athletes and individuals trying to lose weight (8,10). However, problems associated with chest belts include the inability to stay in place, poor electrode contact, skin irritation, poor fit, and poor signal quality, especially with high intensity exercise (8). A textile chest belt with an attached shoulder strap may solve some of these problems. A vest/t-shirt form factor for incorporating sensors is practical given that soldiers wear a t-shirt under their Battle Dress Uniform (BDU). Thus, if sensors could be incorporated into a vest/t-shirt, soldiers would not have to add any additional piece of clothing to their uniform. However, whether high signal quality can be achieved in a loose-fitting garment is questionable. An adhesive-based system is one of the most widely used approaches for incorporating sensors because it provides a relatively high signal quality (1). However, adhesive-based sensors have the potential to cause skin irritations and need to be removed after a specified period of time (1,4). Given that all of these design concepts have potential negative and positive aspects associated with them, a user acceptability test conducted under military field conditions would help identify the best LSDS design concept for the soldier.

OBJECTIVE

The objective of this study was to use subjective surveys to evaluate and compare four different design concepts (i.e., textile chest belt, rubber chest belt, vest, and adhesive patch) for the LSDS under a wide range of military field activities (i.e., marksmanship, obstacle course, road march, sleep).

METHODS

SUBJECTS

Sixty-one male soldiers enrolled in the study. One soldier dropped out due to a medical reason, which was not related to the study. Sixty volunteers with a mean ($\pm$ SD) age, body weight, height, chest circumference, waist circumference, and years of active duty military experience of 21 ± 3 yr, 82 ± 11 kg, 178 ± 8 cm, 97 ± 7 cm, 85 ± 7 cm, and 1.6 ± 0.7 yr, respectively, participated. Each gave written and verbal acknowledgment of their informed consent and was made aware of their right to withdraw without prejudice at any time. Investigators adhered to the policies for protection of human subjects as prescribed in Army Regulation 70-25, and the research was conducted in adherence with the provisions of 45 CFR Part 46.

PROTOCOL

Design

Volunteers completed a 6-day military relevant training scenario characterized by activities completed during the Army Expert Infantryman Badge (EIB) course. On the first day of testing, the volunteers were asked to report to a practice session wearing a standard BDU. The body weight (kg), height (cm), and chest (across the nipple) and waist (across the belly button) circumferences (cm) of each volunteer were measured. The volunteers were fitted, briefed and given instructions on how to don and doff each LSDS design concept. Volunteers filled out a demographic survey containing six questions about age, gender, race, rank, and military experience (Appendix A).

In the morning on Days 2-5 of testing, the soldiers wore their standard BDU and combat boots. The 60 soldiers were randomly divided into four groups of 15 soldiers. Each group rotated wearing each of the four LSDS design concepts on Days 2-5 of testing. The study design was counterbalanced so that each group wore a different LSDS design concept on Days 2-5 of testing in order to control for the effects of engaging in different activities on each testing day (Table 1). Volunteers wore other military equipment such as the Kevlar helmet, M16 rifle, pistol belt with suspenders, canteens, and all-purpose load carrying equipment (ALICE), depending on their activities during the EIB course for that day. The ambient environmental conditions were recorded each day of testing.

Table 1. Counterbalanced Experimental Design.

Group/Design Concept	Textile Chest Belt	Rubber Chest Belt	Vest	Adhesive Patch
Group I	Day 1	Day 4	Day 2	Day 3
Group II	Day 2	Day 3	Day 4	Day 1
Group III	Day 3	Day 2	Day 1	Day 4
Group IV	Day 4	Day 1	Day 3	Day 2

The soldiers then underwent a series of military training activities planned for that 24-h day as part of the Army EIB course. These activities included but were not limited to the following: (a) move under direct fire, (b) Army Physical Fitness Test (c) 12-mi road march with rucksack, (d) map reading, (e) marksmanship training, (f) land navigation, (g) hand grenade training, (h) first aid training, and (i) sleep. The soldier reported the next morning to complete the user acceptability survey (Appendix B) for the LSDS design concept worn for the previous 24 h. The 36 subjective questions contained in the user acceptability survey were rated with either a yes/no answer or a rating from the nine-point hedonic scale (9). The questions were derived from previous surveys that evaluated the user acceptability of uniforms, helmets, socks, food, and boots used by the soldier (5,6). The questions were divided into four broad categories related to overall acceptability, interference with performance, ability to stay in place, and likelihood of causing skin irritations. In each of these four broad categories, a place was provided in the survey for soldiers to write individual comments. On Day 6 of testing, each soldier completed a comparison survey (Appendix C) that allowed the soldier to compare each of the four LSDS design concepts against one another in four general areas.

Environmental Conditions

All testing was performed at the Joint Readiness Training Center at Ft. Polk, Louisiana, and conducted in accordance with local standard operating procedures. The mean temperature and relative humidity, respectively, on the four days of testing, collected at three time points during the day (i.e., 0900, 1200, and 1500) was $15\pm 2^{\circ}\text{C}$ and $39\pm 5\%$ on Day 1; $19\pm 2^{\circ}\text{C}$ and $38\pm 5\%$ on Day 2; $20\pm 1^{\circ}\text{C}$ and $50\pm 4\%$ on Day 3; and $24.5\pm 1^{\circ}\text{C}$ and $50\pm 4\%$ on Day 4. Although the environmental conditions differed from day to day, the potential effects of each environmental condition on user acceptability ratings were equally distributed across each LSDS design concept.

STATISTICS

The user acceptability survey was analyzed using a 4 (group) x 4 (design concept) repeated measures analysis of variance (ANOVA) to assess differences between design concepts on each question answered with the 9-point hedonic scale. The 9-point hedonic scale represents scaled data and the intervals between points may not be equal, but the assumptions violated by using an ANOVA are minimal (7). Tukey post-hoc testing was used to evaluate significant main effects when detected. Because mean scores can be influenced by scores at either end of the spectrum, another criterion of acceptability that may be used is the percentage of individuals who rate the design concept with a 5.0 or higher on the 9-point hedonic scale. Descriptive statistics (mean $\pm$ SD) of this data were calculated. Fifteen subjects per group (i.e., 60 soldiers) were needed to assess a 1.0 meaningful difference on the 9-point hedonic scale with an estimated standard deviation of 1.8 at $\alpha = 0.05$ and $\beta = 0.80$ (2). The meaningful difference and standard deviation have been estimated from previous research assessing user acceptability of soldier clothing systems (5). The yes/no questions contained in the user acceptability survey were analyzed with a Cochran's Q test. The comparison survey data were analyzed with a Friedman's ANOVA for nonparametric rank order data. All data are presented as mean $\pm$ SD.

RESULTS

TEST VOLUNTEERS

Mean age, body weight, height, chest and waist circumference, and years of active duty military experience were not different between groups. The ethnic breakdown of the soldiers was the following: (a) 83% Caucasian; (b) 1.6% African American; (c) 10.6% Hispanic; (d) 1.6% Native American; (e) 1.6% Asian, and (f) 1.6% Other. All soldiers had an infantry military occupational specialty and 96.9% were enlisted while 3.1% were officers.

USER ACCEPTABILITY SURVEY

There were no differences between the four groups of soldiers in any of the user acceptability survey or comparison survey data. Thus, the order in which the four groups of soldiers wore the four different design concepts was not important.

The user acceptability survey contained 36 questions. Five questions were not analyzed due to greater than 25% of the soldiers inquiring about how to answer the question. The remaining 31 questions contained in the user acceptability survey were analyzed. The results from the user acceptability are generally consistent and support the overall comparison survey data with only a few exceptions that are noted in the text. Thus, the soldiers took their role in this study seriously and carefully answered all the questions in a consistent manner. It did not appear that any of the soldiers simply filled in the blanks in order to complete the survey more quickly. The results from the yes/no question, "Was the LSDS initially fitted properly" were encouraging in that 96% found the textile chest was fitted properly, 92% found the rubber chest belt was fitted properly, 93% found the vest was fitted properly, and 97% found the adhesive patch was fitted properly. There were no differences between the four LSDS design concepts for initial fit. These results suggest that any problems observed with the LSDS design concepts were not due to a poor initial fit.

Figures 1 presents the frequency results from four yes/no questions collected from the user acceptability survey. These four questions were most representative of the individual user acceptability questions. The questions were the following: (a) Was the LSDS acceptable to the wearer? (b) Did wearing the LSDS negatively impact on your performance as a soldier for the previous 24 h? (c) Did the LSDS stay in place over the previous 24 h?, and (d) Did wearing the LSDS cause any skin reaction during the previous 24 h?

In the acceptability category, 90% found the textile chest belt acceptable, 73% found the rubber chest belt acceptable, 29% found the vest acceptable, and 83% found the adhesive patch acceptable. The percentage that found the vest acceptable was lower ($P<0.05$) than all other design concepts. The percentage that found the rubber chest belt acceptable was also lower ($P<0.05$) than the percentage that found the textile chest belt acceptable.

In the impact on performance category, the percentage of soldiers that thought the LSDS system might negatively impact their performance was 17% for the textile chest belt, 20% for the rubber chest belt, 53% for the vest, and 3% for the adhesive patch. The percentage that thought the adhesive patch might negatively impact their performance was lower ($P<0.05$) than all other design concepts. The percentage that

thought the vest might negatively impact their performance was higher ($P<0.05$) than all other design concepts. The percentage that thought the textile chest belt and rubber chest belt might negatively impact their performance was similar.

In the ability to stay in place over the previous 24 h category, 80% found the textile chest belt stayed in place, 46% found the rubber chest belt stayed in place, 53% found the vest stayed in place, and 27% found the adhesive patch stayed in place. The percentage that found the textile chest belt stayed in place was higher ($P<0.05$) than all other design concepts. The percentage that found that the adhesive patch stayed in place was lower ($P<0.05$) than all other design concepts.

In the skin reaction severity category, 10% found the textile chest belt caused a skin reaction, 7% found the rubber chest belt caused a skin reaction, 26% found the vest caused a skin reaction, and 7% found the adhesive patch caused a skin reaction. The percentage that found that the vest caused a skin reaction was higher ($P<0.05$) than all other design concepts.

Figure 2 presents the mean ratings on the 9-point hedonic scale for questions contained under the wearer acceptability category that began with the question “please rate, overall, how much you liked or disliked the wearer acceptability of the Life Sign Detection System.” In the wearer acceptability category a rating of 1 was attached to the label “dislike extremely”, a rating of 5 was attached to the label “neither dislike nor like” and a rating of 9 was attached to the label “like extremely.” Thus, a lower rating was considered a worse score.

In the overall user acceptability category, the textile chest belt (6.6 ± 1.9) and adhesive patch (6.6 ± 2.1) were rated more likable ($P<0.05$) than both the rubber chest belt (5.4 ± 2.0) and vest (3.2 ± 1.9). There were no differences in overall user acceptability between the textile chest belt and adhesive patch while the vest was less likeable ($P<0.05$) than the rubber chest belt. These results support the yes/no acceptable to wearer question with the exception that the rubber chest belt was rated significantly less likable than the adhesive patch in the overall user acceptability 9-point scaled question while the rubber chest belt and adhesive patch were rated equally in the yes/no acceptable to wearer question.

In the placement category, the textile chest belt (6.7 ± 1.8) and adhesive patch

(7.2 ± 1.3) were equally liked while the rubber chest belt (5.7 ± 1.8) was rated less likable ($P < 0.05$) than both the textile chest belt and adhesive patch. The placement of the vest (3.9 ± 1.9) was rated less likeable ($P < 0.05$) than all other design concepts. In the ease of donning category, the textile chest belt (7.0 ± 1.4) and adhesive patch (7.6 ± 1.4) were equally liked while the rubber chest belt (5.6 ± 2.0) was rated less likeable ($P < 0.05$) than both the textile chest belt and adhesive patch. The ease of donning the vest (4.2 ± 2.2) was rated less likable ($P < 0.05$) than all other design concepts. In the ease of doffing category the textile chest belt (7.0 ± 1.5), rubber chest belt (6.3 ± 1.8) and adhesive patch (6.3 ± 1.9) were all equally liked while the vest (4.2 ± 2.2) was rated less likable ($P < 0.05$) than all other design concepts. In the comfort category, the adhesive patch (7.2 ± 1.6) was liked more ($P < 0.05$) than all other design concepts. The comfort of the textile chest belt (6.3 ± 2.2) was liked more ($P < 0.05$) than the rubber chest belt (5.3 ± 2.1) and the vest (3.3 ± 2.0) was liked less ($P < 0.05$) than all other design concepts. In the fit category, the textile chest belt (6.7 ± 1.7) and adhesive patch (7.3 ± 1.4) were equally liked while the rubber chest belt (5.6 ± 1.9) was rated less likeable than both the adhesive patch and adhesive patch. The fit of the vest (4.7 ± 2.1) was rated less likeable ($P < 0.05$) than all other design concepts.

Figures 3 and 4 present the mean ratings on the 9-point hedonic scale for questions contained under the impact on performance category that began with the question, "please indicate, overall, how much wearing the Life Sign Detection System would positively or negatively impact the following." In the impact on performance category a rating of 1 was attached to the label "extremely negative impact", a rating of 5 was attached to the label "neutral impact" and a rating of 9 was attached to the label "extremely positive impact." Thus, a lower rating was considered a worse score. If the soldiers did not use the LSDS in a particular condition (i.e., cold weather), the answers to their questions reflect their best guess as to how the LSDS would affect their performance in those conditions.

In the overall impact on performance category, the textile chest belt (5.9 ± 1.5) and adhesive patch (6.0 ± 1.7) had an equally positive impact on performance while the rubber chest belt (5.3 ± 1.3) had a less positive ($P < 0.05$) impact on performance than the adhesive patch. The vest (3.8 ± 1.8) was rated as more likely to have a negative impact on performance than all other design concepts. These results support the yes/no negative impact on performance question with the exception that the textile chest belt and adhesive patch were rated equally in the overall impact on performance 9-point

scaled question while the adhesive patch was rated higher than the textile chest belt in the yes/no negative impact on performance question.

In the comfort in hot weather category, the textile chest belt (5.2 ± 2.0) and adhesive patch (5.9 ± 2.0) were rated equally while the rubber chest belt (4.9 ± 1.9) was rated as more likely to have a negative impact on performance than the adhesive patch. The comfort of the vest in hot weather (2.2 ± 1.6) was rated as more likely to have a negative impact ($P < 0.05$) than all other design concepts. In the comfort in cold weather category, all design concepts rated equally. In the ability to use with a rucksack category, the textile chest belt (6.3 ± 1.7) and adhesive patch (6.6 ± 1.8) rated equally while the rubber chest belt (5.7 ± 1.8) was rated less positively ($P < 0.05$) than the textile chest belt and adhesive patch. The ability to use the vest with a rucksack (4.6 ± 1.9) was rated as more likely ($P < 0.05$) to have a negative impact than all other design concepts. In the ability to use in firing position category, the textile chest belt (6.4 ± 1.6) and adhesive patch (6.6 ± 1.9) rated equally while the rubber chest belt (5.5 ± 1.7) was rated less positively ($P < 0.05$) than both the textile chest belt and adhesive patch. The ability to use the vest in the firing position (4.5 ± 1.9) was rated as more likely to have a negative impact ($P < 0.05$) than all other design concepts. In the range of motion/ease of movement category, the textile chest belt (6.4 ± 1.8) and adhesive patch (6.7 ± 1.7) were rated equally while the rubber chest belt (5.8 ± 1.8) was rated less positively ($P < 0.05$) than the adhesive patch. The range of motion of the vest (4.8 ± 1.8) was rated as more likely to have a negative impact ($P < 0.05$) than all other design concepts. In the overall appearance category the adhesive patch (6.7 ± 1.7) was rated higher ($P < 0.05$) than all other design concepts while the textile chest belt (5.9 ± 1.7) and rubber chest belt (5.4 ± 1.6) rated equally. The appearance of the vest (4.1 ± 2.0) was rated as more likely to have a negative impact ($P < 0.05$) than all other design concepts. In the overall weight category, the textile chest belt (6.7 ± 1.7) and adhesive patch (7.2 ± 1.7) rated equally while the weight of the rubber chest belt (6.2 ± 1.6) was rated less positively ($P < 0.05$) than the adhesive patch. The weight of the vest (5.1 ± 1.9) was rated as more likely to have a negative impact ($P < 0.05$) than all other design concepts. In the overall bulk category, the adhesive patch (7.2 ± 1.6) was rated higher ($P < 0.05$) than all other design concepts. The bulk of the textile chest belt (6.4 ± 1.7) and rubber chest belt (5.9 ± 1.7) were rated equally while the bulk of the vest (4.2 ± 2.0) was rated as more likely to have a negative impact ($P < 0.05$) than all other design concepts. In the ability to use while sleeping category, the adhesive patch (6.4 ± 1.9) was rated higher ($P < 0.05$) than all other design concepts while the textile

chest belt (5.6 ± 2.0) and rubber chest belt (4.8 ± 1.8) were rated equally. The ability to use the vest while sleeping (3.2 ± 1.9) was rated as more likely to have a negative impact on performance than all other design concepts.

Figure 5 presents the mean ratings on the 9-point hedonic scale for questions contained under the stay in place category that began with the question, "please indicate, overall, the ability of the Life Sign Detection System to stay in place in the following environments and conditions." In the ability to stay in place category a rating of 1 was attached to the label "extremely negative ability to stay in place", a rating of 5 was attached to the label "neutral reaction to staying in place" and a rating of 9 was attached to the label "extremely positive ability to stay in place." Thus, a lower rating was considered a worse score. If the soldiers did not use the LSDS in a particular condition (i.e., cold weather), the answers to their questions reflect their best guess as to how the LSDS would stay in place in those conditions.

In the overall ability to stay in place category, the textile chest belt (6.7 ± 1.9) was rated higher ($P < 0.05$) than all other design concepts. There were no differences between the rubber chest belt (4.9 ± 2.0), vest (4.7 ± 2.0) and adhesive patch (5.3 ± 2.6) in their overall ability to stay in place. These results support the yes/no ability to stay in place question with the exception that the rubber chest belt, vest, and adhesive patch were rated equally in the overall ability to stay in place 9-point scaled question while the adhesive patch was rated lower than both the rubber chest belt and vest in the yes/no ability to stay in place question.

In the overall ability to stay in place while sweating category, the textile chest belt (6.2 ± 2.0) rated higher ($P < 0.05$) than all other design concepts. There were no differences between the rubber chest belt (4.8 ± 2.1) and adhesive patch (4.2 ± 2.7) but the vest (3.8 ± 2.2) was rated lower ($P < 0.05$) than the rubber chest belt in its ability to stay in place while sweating. In the overall ability to stay in place while relaxing category, the textile chest belt (6.9 ± 1.6) and adhesive patch (6.6 ± 1.7) were rated equally while the rubber chest belt (5.9 ± 1.7) was rated lower ($P < 0.05$) than both the textile chest belt and adhesive patch. The ability of the vest to stay in place while relaxing (4.9 ± 1.9) was rated lower ($P < 0.05$) than all other design concepts. In the ability to stay in place while in motion category, the textile chest belt (6.7 ± 1.8) and adhesive patch (5.9 ± 2.2) rated equally while the rubber chest belt (5.1 ± 1.7) and vest (4.6 ± 1.9) rated lower ($P < 0.05$) than both the textile chest belt and adhesive patch in their ability to

stay in place while in motion. In the ability to stay in place in the cold category, the textile chest belt (6.5 ± 1.8) and adhesive patch (5.8 ± 2.0) were rated equally while the textile chest belt was rated higher ($P < 0.05$) than both the rubber chest belt (5.5 ± 1.6) and vest (5.2 ± 1.6). There were no differences between the rubber chest belt, vest, and adhesive patch in their ability to stay in place in the cold. In the ability to stay in place in the heat category, the textile chest belt (6.1 ± 1.9) rated higher ($P < 0.05$) than all other design concepts. There were no differences between the rubber chest belt (5.2 ± 1.8) and adhesive patch (4.8 ± 2.6) in their ability to stay in place in the heat while the vest (3.9 ± 2.0) was rated lower ($P < 0.05$) than the rubber chest belt in its ability to stay in place in the heat.

Figure 6 presents the mean ratings on the 9-point hedonic scale for questions contained under the skin reaction category that began with the question, "please indicate, overall, the severity or absence of any skin reactions while wearing the Life Sign Detection System." In the skin reaction category a rating of 1 was attached to the label "extremely negative reaction", a rating of 5 was attached to the label "neutral reaction" and a rating of 9 was attached to the label "extremely positive reaction." Thus, a lower rating was considered a worse score. However, there was some confusion on the part of the soldiers in answering these questions because if they did not have a skin reaction, they could have rated the question as either a 5 or 9. Thus, a rating of 5 or above would indicate no skin reaction.

In the overall skin reaction category, the textile chest belt (6.1 ± 2.0), rubber chest belt (6.1 ± 1.9), and adhesive patch (5.9 ± 1.9) rated equally. The vest (5.0 ± 1.6) was rated as more likely to have a skin reaction than all other design concepts. Although you could consider that all ratings 5 and above are equal, the results from the yes/no skin reaction question clearly support the conclusion that the vest caused the most number of skin reactions.

In the skin chafing, skin blisters, and skin irritation categories, the textile chest belt, rubber chest belt and adhesive patch all rated equally while the vest rated below all other design concepts in each category. Again, if all ratings 5 and above are considered equal, then there would be no differences in skin chafing, blisters, and skin irritations between any of the design concepts.

Because mean scores can be influenced by scores at either end of the

spectrum, another criterion of acceptability that may be used is the percentage of individuals who rate the design concept with a 5.0 or higher. Figure 7 presents the percentage of individuals that rated the LSDS acceptable in several categories of wearer acceptability. Figure 8 presents the percentage of individuals that rated the LSDS acceptable on its impact on their performance under various conditions. Figure 9 presents the percentage of individuals that rated the LSDS acceptable in its ability to stay in place under various conditions. Figure 10 presents the percentage of individuals that rated the LSDS acceptable in its reaction with their skin. All of these results were consistent with the results from the four yes/no questions collected from the user acceptability survey and presented in Figure 1.

USER ACCEPTABILITY COMMENTS

Table 2 presents a list of the five most common comments reported for each LSDS design concept. Their frequency of occurrence was calculated as the total number of times the comment was observed for that LSDS design concept divided by the total number of comments made about that LSDS design concept. The total number of comments for the textile chest belt was 109, for the rubber chest belt was 135, for the vest was 150 and for the adhesive patch was 130. The total number of positive compared to negative comments, respectively, made about each of the design concepts was the following: (a) textile chest belt (59/50), rubber chest belt (35/100), vest (14/136), and adhesive patch (55/75). The percentage (%) of positive and negative comments in comparison to the total comments made about each of the design concepts were the following: (a) textile chest belt (55/45), rubber chest belt (26/74), vest (9/91), and adhesive patch (42/58).

COMPARISON SURVEY

Figure 11 presents the results of the comparison survey in four categories: (a) overall user acceptability and (b) overall impact on performance, (c) overall ability to stay in place and (d) overall skin reaction severity. A rank of 1 on the comparison survey was considered the best design concept (e.g., highest ranking) and a rank of 4 was considered the worst design concept (e.g., lowest ranking). Thus, a lower number represents a better score.

In the overall user acceptability category, the textile chest belt (1.7 ± 0.7) and

adhesive patch (2.1 ± 1.2) were ranked the best and the rubber chest belt (2.6 ± 0.7) and vest (3.5 ± 0.9) were ranked the worst. The vest ranked lower ($P < 0.05$) than all other design concepts. The rubber chest belt ranked lower ($P < 0.05$) than the textile chest belt. There were no differences between the textile chest belt and adhesive patch in overall user acceptability.

In the overall impact on performance category, the textile chest belt (2.0 ± 0.9) and adhesive patch (1.8 ± 1.0) ranked the best and the rubber chest belt (2.5 ± 0.7) and vest (3.5 ± 0.8) ranked the worst. The vest ranked lower ($P < 0.05$) than all other design concepts. The rubber chest belt ranked lower ($P < 0.05$) than the adhesive patch. There were no differences between the textile chest belt and adhesive patch on overall impact on performance.

In the overall ability to stay in place category, the textile chest belt (1.9 ± 0.8) ranked higher ($P < 0.05$) than all other design concepts. There were no differences between the rubber chest belt (2.6 ± 0.9), vest (2.8 ± 1.2), and adhesive patch (2.7 ± 1.2) in their ability to stay in place.

In the overall skin reaction severity category, the vest (3.2 ± 1.2) ranked lower ($P < 0.05$) than the textile chest belt (1.9 ± 0.9) and rubber chest belt (2.4 ± 1.1). There were no significant differences between the textile chest belt, rubber chest belt and adhesive patch (2.5 ± 1.2) on overall skin reaction severity.

WEAR TIME

Figure 12 presents the wear time for the four different design concepts. If a design concept was not worn for a full 24-h due to falling off, breakage, or discomfort, the time not worn was recorded. The textile chest belt ($98 \pm 9\%$) and rubber chest belt ($95 \pm 16\%$) were worn for a similar percentage of time. The vest ($78 \pm 33\%$) was worn less ($P < 0.05$) time than both the textile chest belt and rubber chest belt. The adhesive patch ($55 \pm 35\%$) was worn the least ($P < 0.05$) time of all design concepts.

ADVERSE EVENTS

Figure 12 also presents the incidence of adverse events that, in this study, was defined as an observation by the Medical Officer of the Day of any type of skin reaction

that occurred from wearing the different design concepts that was severe enough to report to the USARIEM Human Use Review Committee. All of the adverse events reported in this study were due to skin reactions from wearing the LSDS. Statistical analyses were not done on these data, but it is clear that the vest had the most number of adverse events. Given that the adhesive patch was only worn for ~50% of the 24-h testing day, the number of adverse events associated with it would likely have been more had it stayed on for the full 24-h.

Table 2. Five Most Common Comments and Frequencies Reported for each Life Sign Detection System (LSDS) Design Concept.

Individual Comment	LSDS Design Concept	Frequency (%)
1. Stayed in place/good range of motion	Textile Chest Belt	16.5
2. Not irritating/comfortable		11.9
3. Didn't affect performance/able to forget about it		11.9
4. Caused skin irritations		9.2
5. Straps or buckles need improvement		8.3
1. Didn't stay in place/required adjustments	Rubber Chest Belt	17.8
2. Uncomfortable/interfered with certain tasks		14.8
3. Straps or buckles need improvement		12.6
4. Not irritating/comfortable		8.1
5. Caused skin irritations		7.4
1. Too hot/retains heat/heat casualty	Vest	20.7
2. Components cumbersome and dig into skin		14.0
3. Extremely uncomfortable/can't perform job		10.0
4. Stayed in place		7.3
5. Caused skin irritations		5.3
1. Problems with adhesive/fell off/fell apart	Adhesive Patch	42.3
2. Didn't affect performance/able to forget about it		19.2
3. Stayed in place/good range of motion		14.6
4. Not irritating/comfortable		6.9
5. Caused skin irritations		5.4

Figure 1

User Acceptability Yes/No Questions

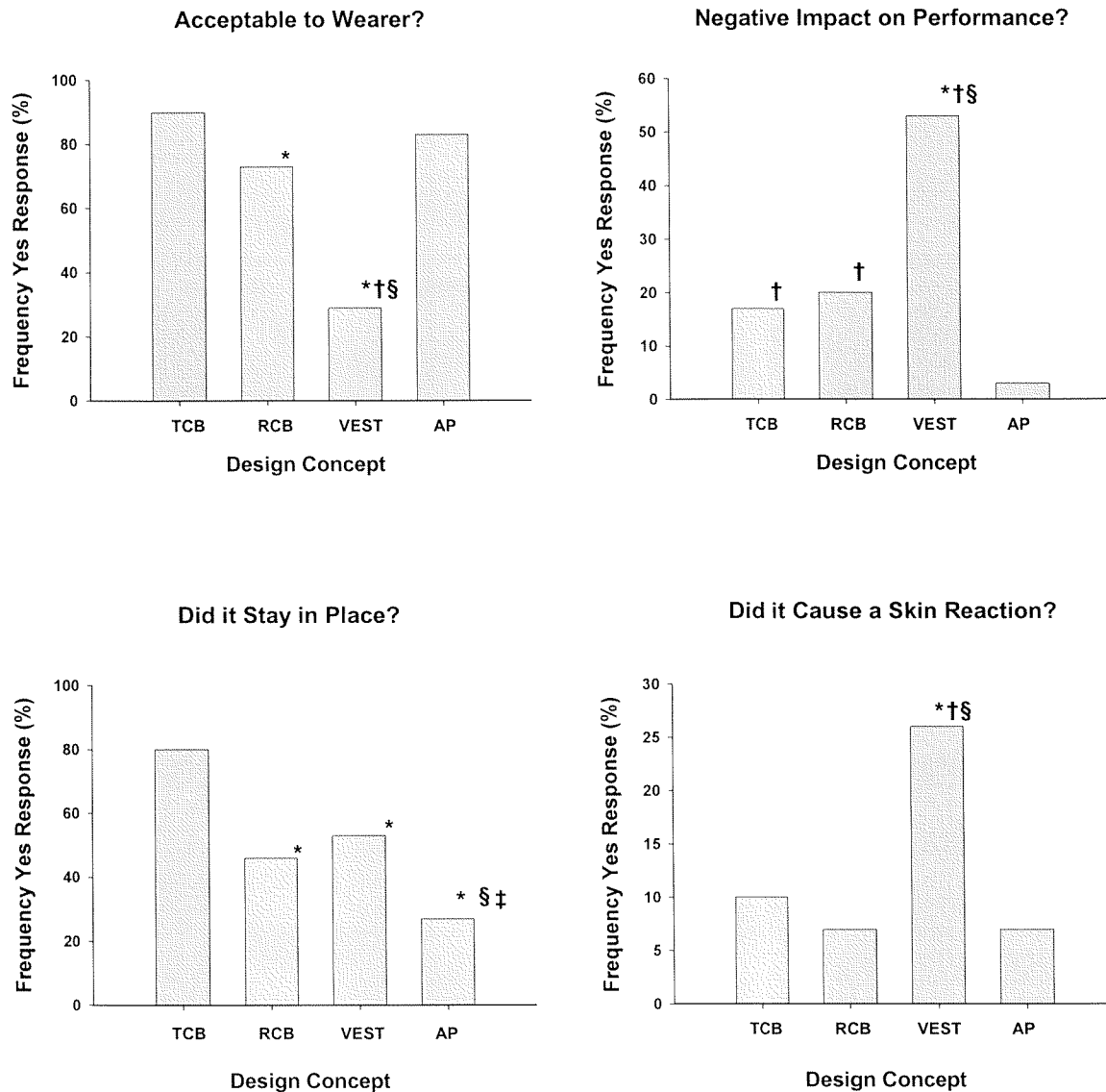


Figure Legend: TCB=Textile chest belt; RCB=Rubber chest belt; Vest=Vest; AP = Adhesive Patch;

*P<0.05 from TCB; †P<0.05 from AP; §P<0.05 from RCB; ‡P<0.05 from Vest

Figure 2

Wearer Acceptability

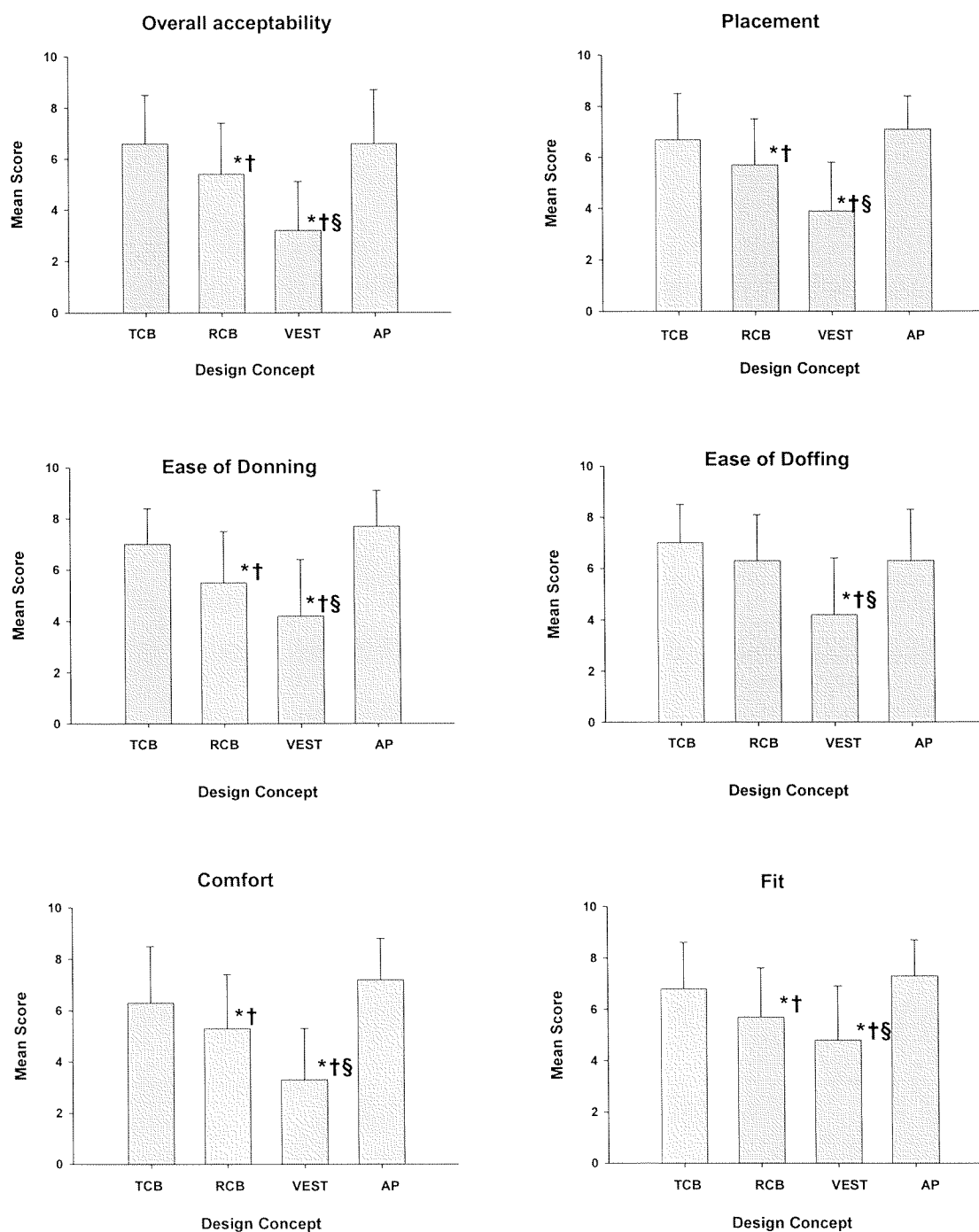


Figure Legend: TCB=Textile chest belt; RCB=Rubber chest belt; Vest=Vest; AP = Adhesive Patch;

*P<0.05 from TCB; †P<0.05 from AP; §P<0.05 from RCB; 1=Worst Score; 9=Best Score.

Figure 3

Impact on Performance (A)

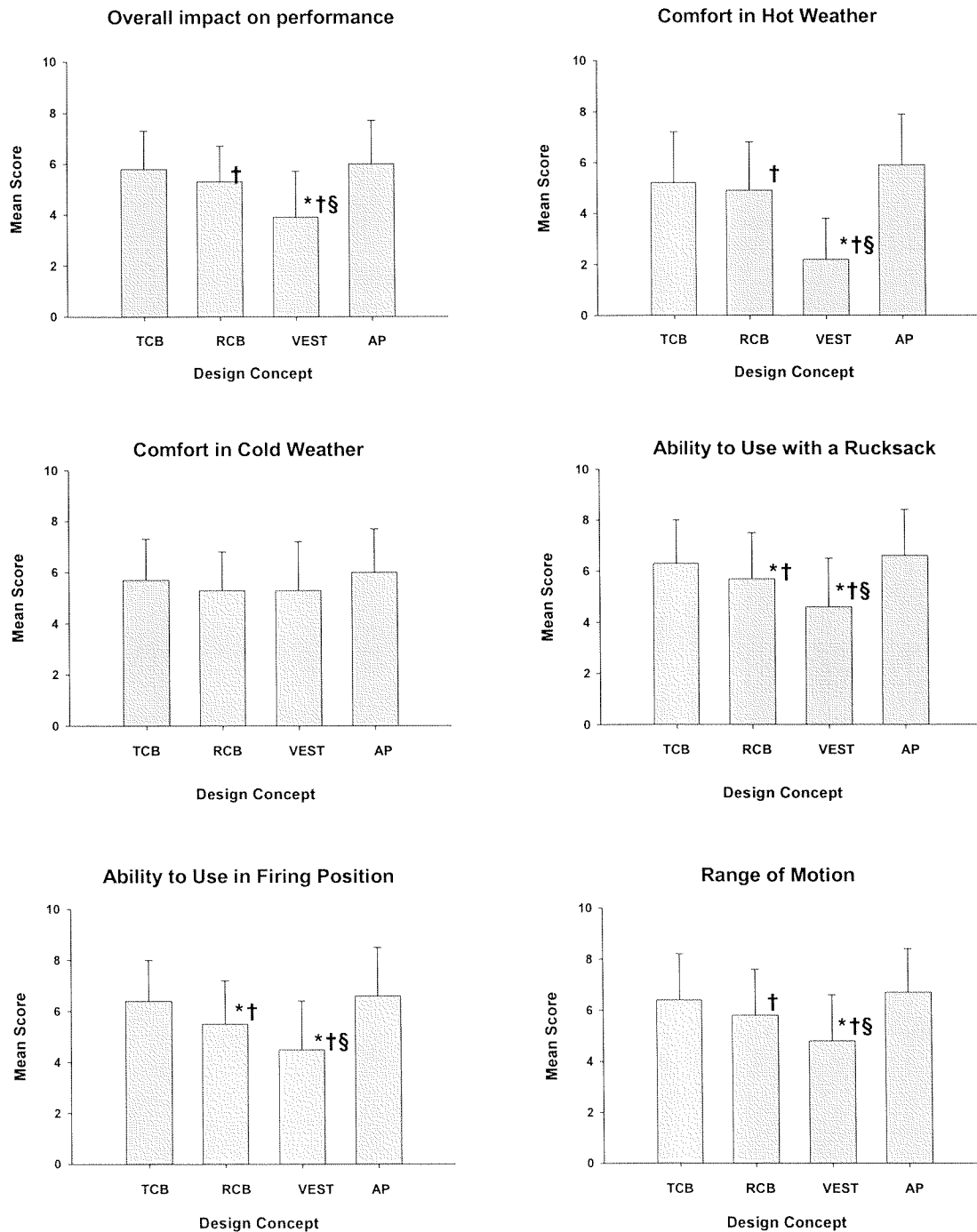


Figure Legend: TCB=Textile chest belt; RCB=Rubber chest belt; Vest=Vest; AP = Adhesive Patch;

*P<0.05 from TCB; †P<0.05 from AP; §P<0.05 from RCB; 1=Worst Score; 9=Best Score.

Figure 4

Impact on Performance (B)

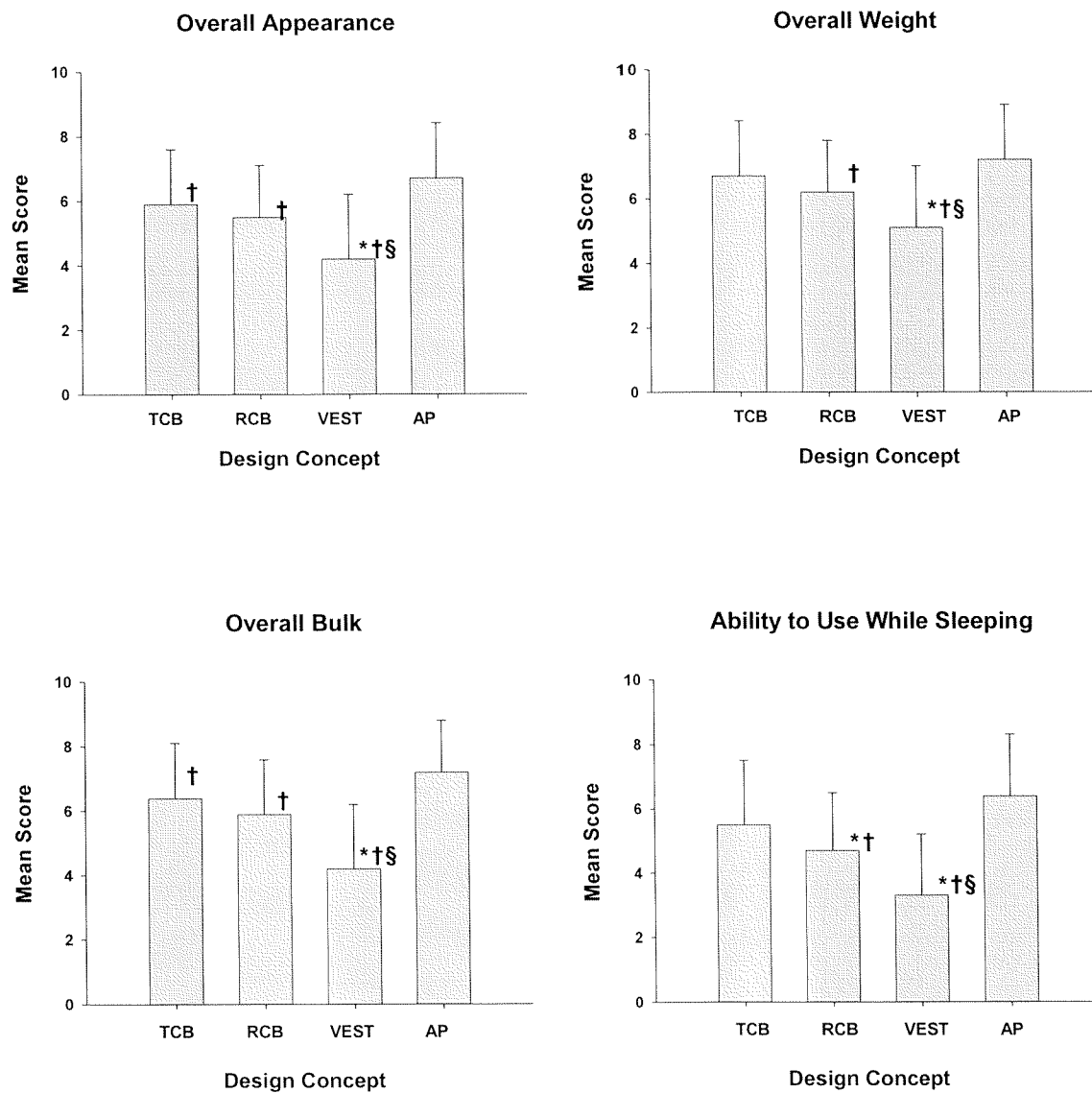


Figure Legend: TCB=Textile chest belt; RCB=Rubber chest belt; Vest=Vest; AP = Adhesive Patch;
 *P<0.05 from TCB; †P<0.05 from AP; §P<0.05 from RCB; 1=Worst Score; 9=Best Score.

Figure 5

Ability to Stay in Place

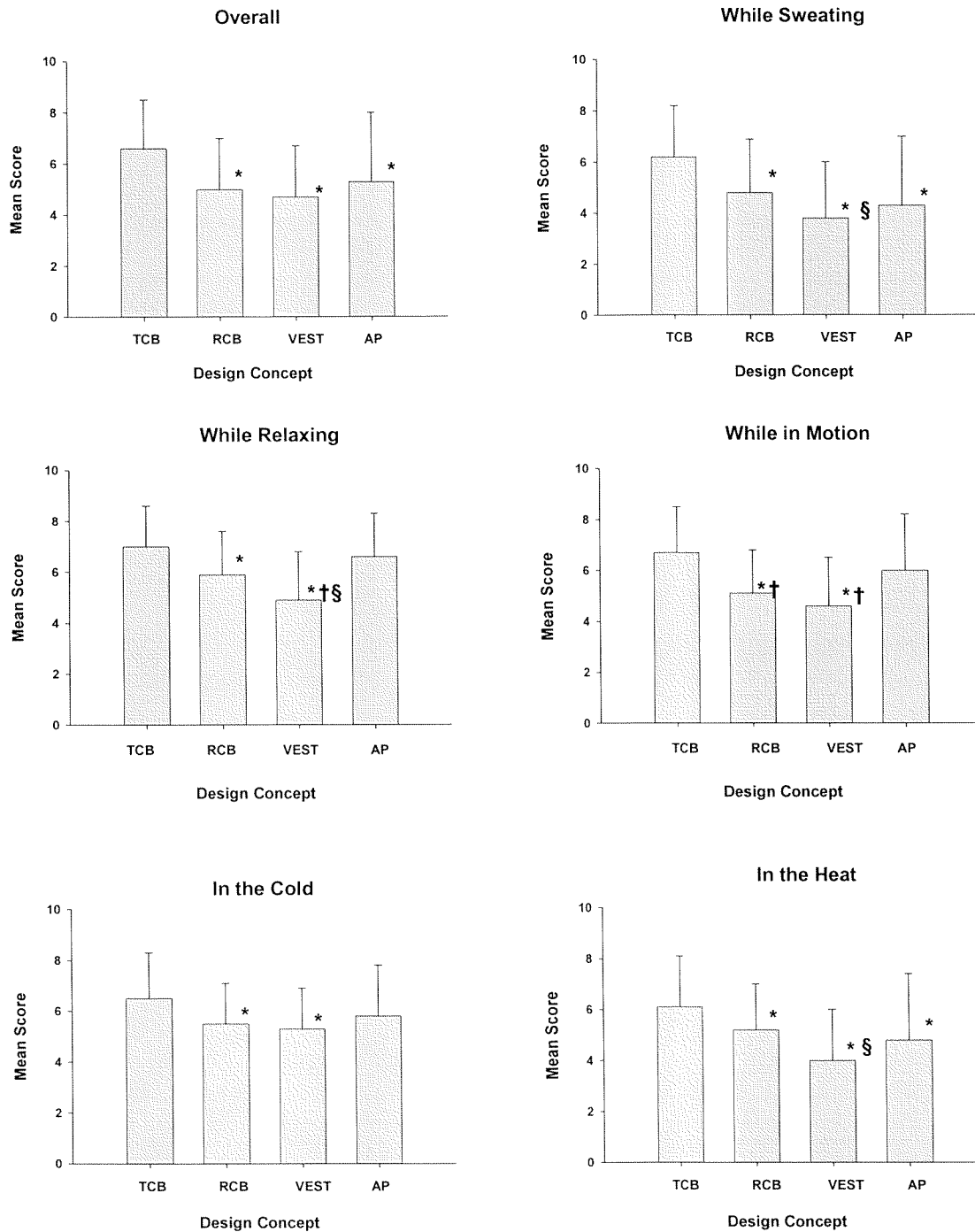


Figure Legend: TCB=Textile chest belt; RCB=Rubber chest belt; Vest=Vest; AP = Adhesive Patch;
 *P<0.05 from TCB; †P<0.05 from AP; §P<0.05 from RCB; 1=Worst Score; 9=Best Score.

Figure 6

Skin Reaction

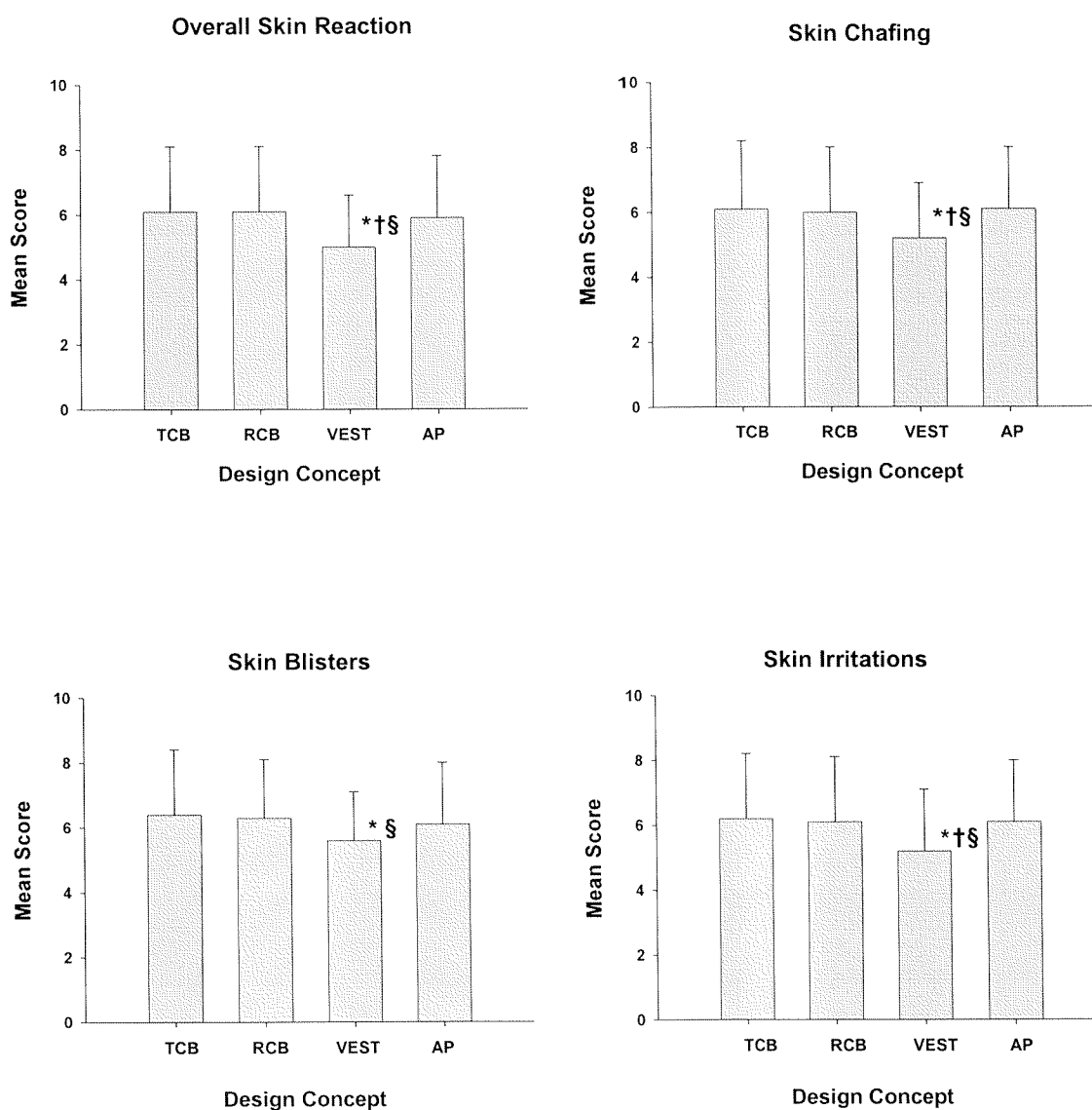
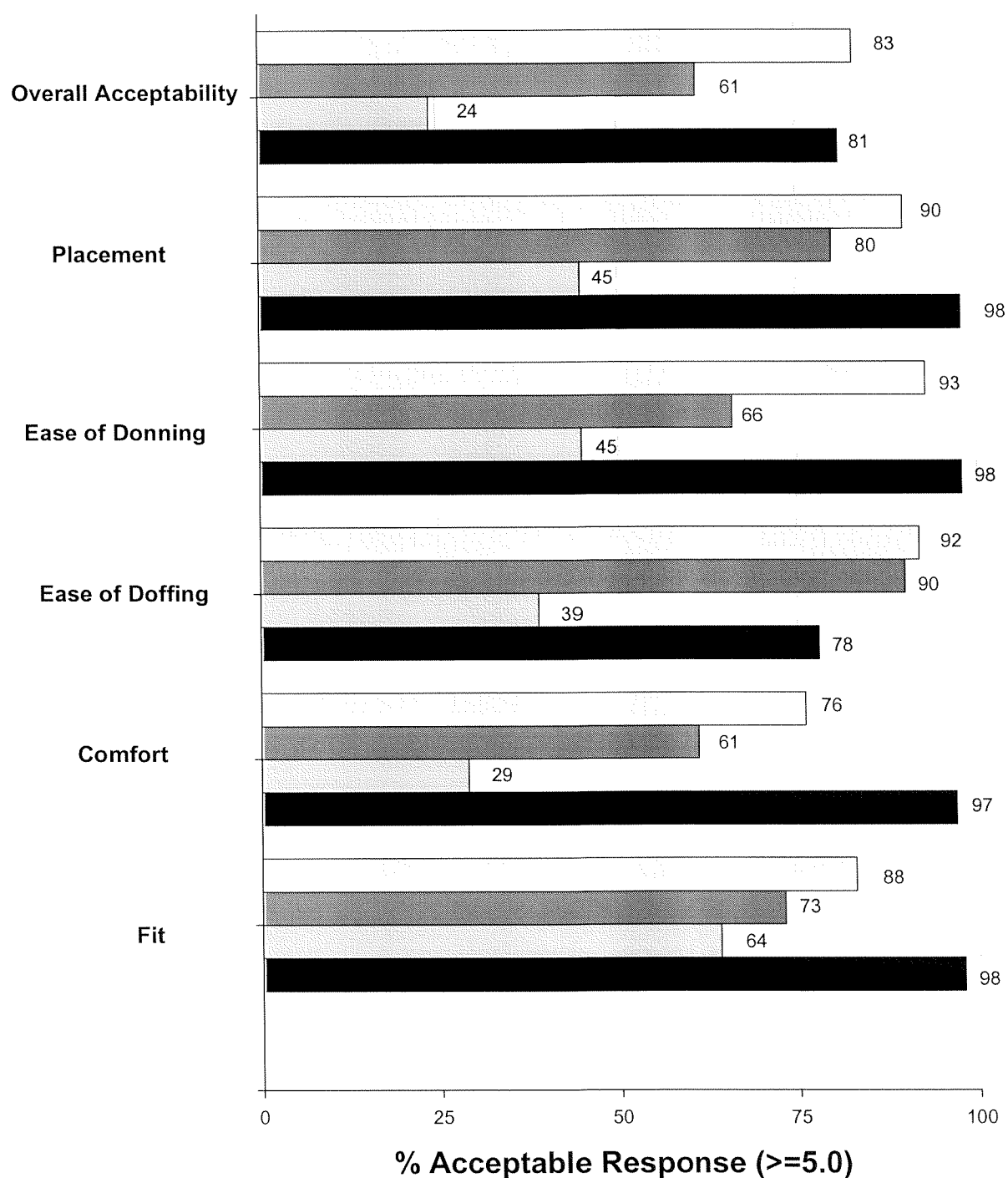


Figure Legend: TCB=Textile chest belt; RCB=Rubber chest belt; Vest=Vest; AP = Adhesive Patch;
 *P<0.05 from TCB; †P<0.05 from AP; §P<0.05 from RCB; 1=Worst Score; 9=Best Score.

- Textile Chest Belt (TCB)
- Rubber Chest Belt (RCB)
- Vest
- Adhesive Patch (AP)

Figure 7

**Please rate how much you liked or disliked
the wearer acceptability of the Life Sign Detection System**



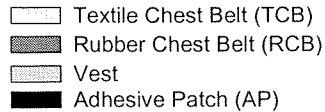


Figure 8

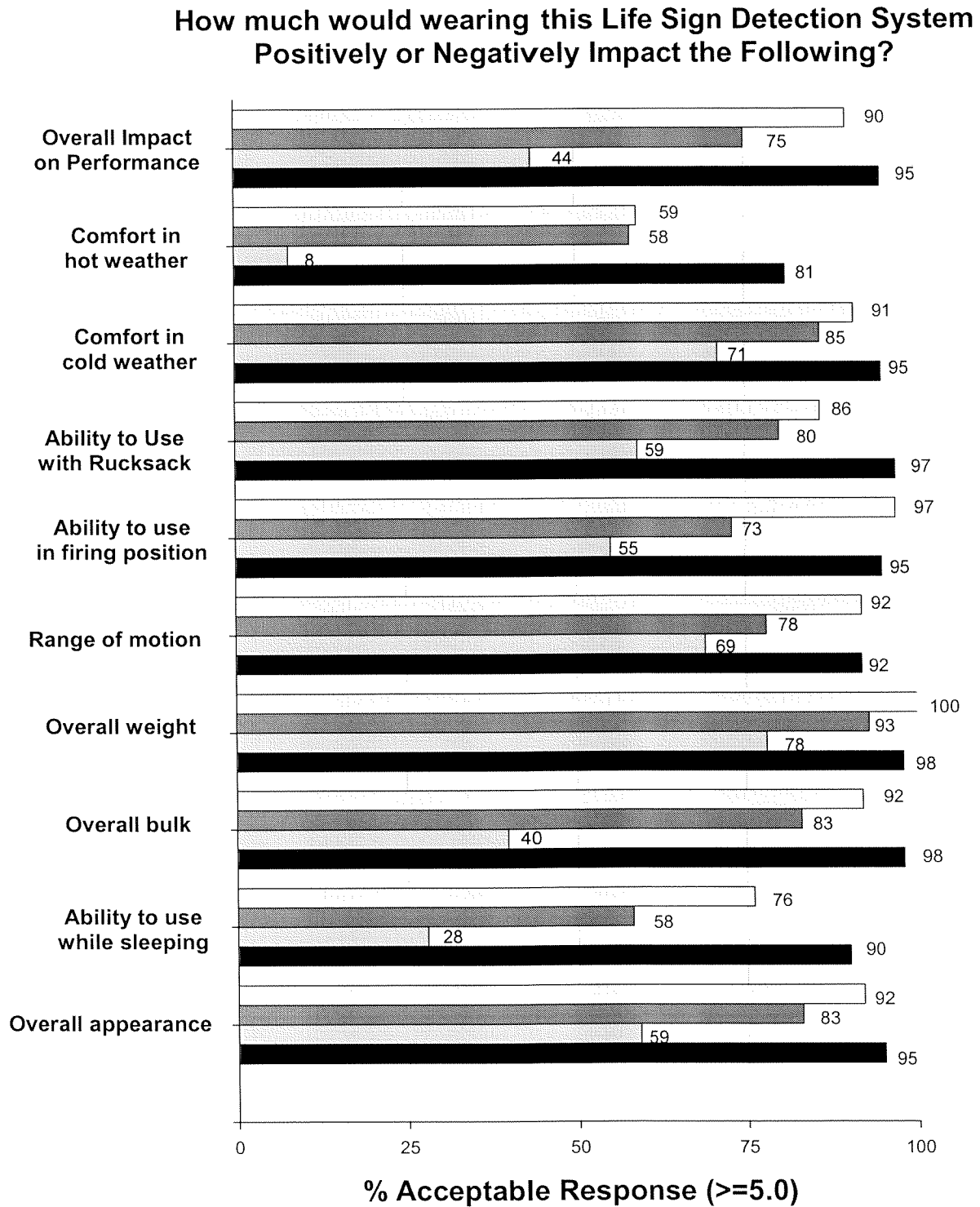


Figure 9

Textile Chest Belt (TCB)
 Rubber Chest Belt (RCB)
 Vest
 Adhesive Patch (AP)

Please indicate the ability of the Life Sign Detection System to stay in place in the following environments and conditions

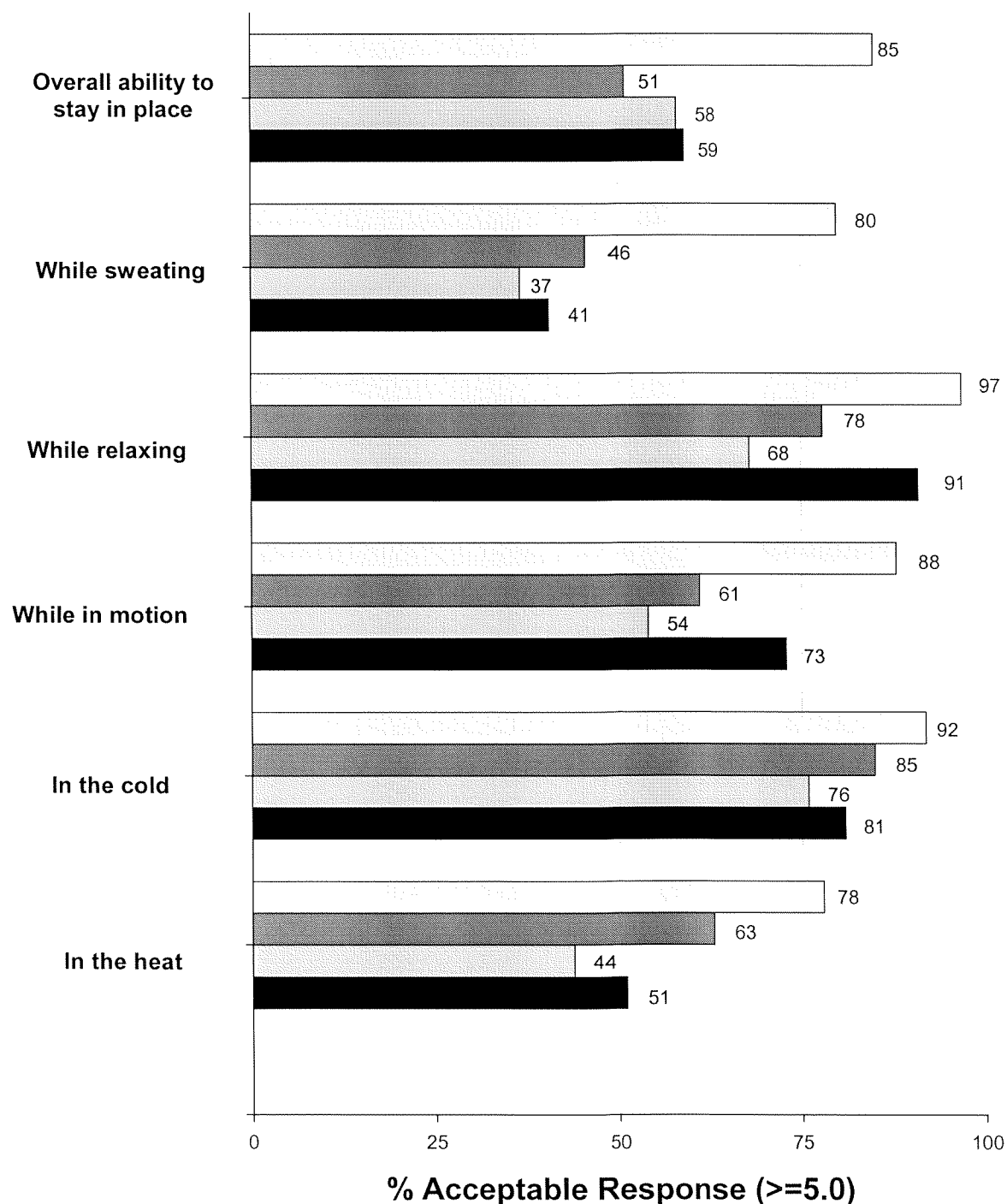


Figure 10

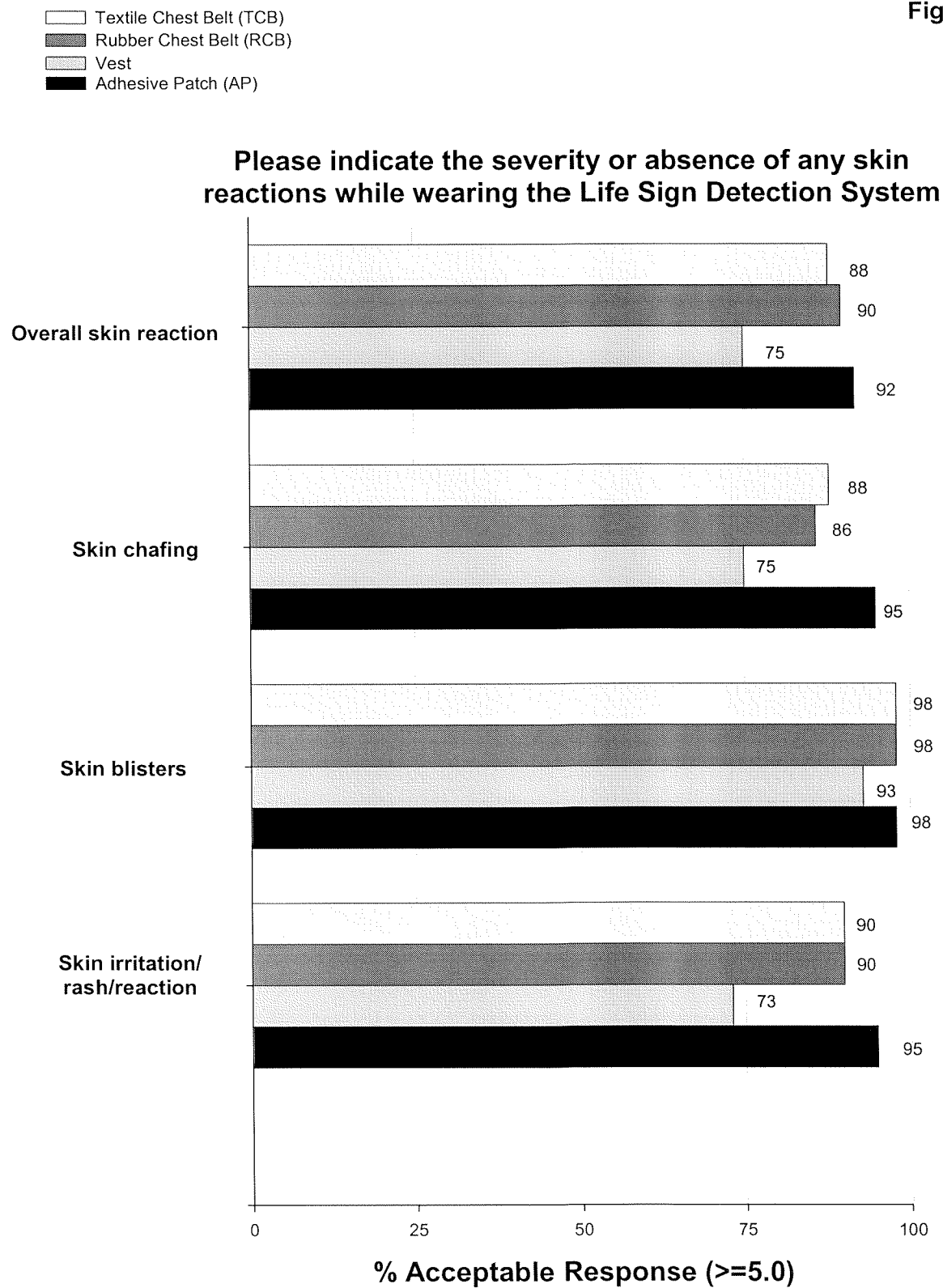


Figure 11

Comparison Survey

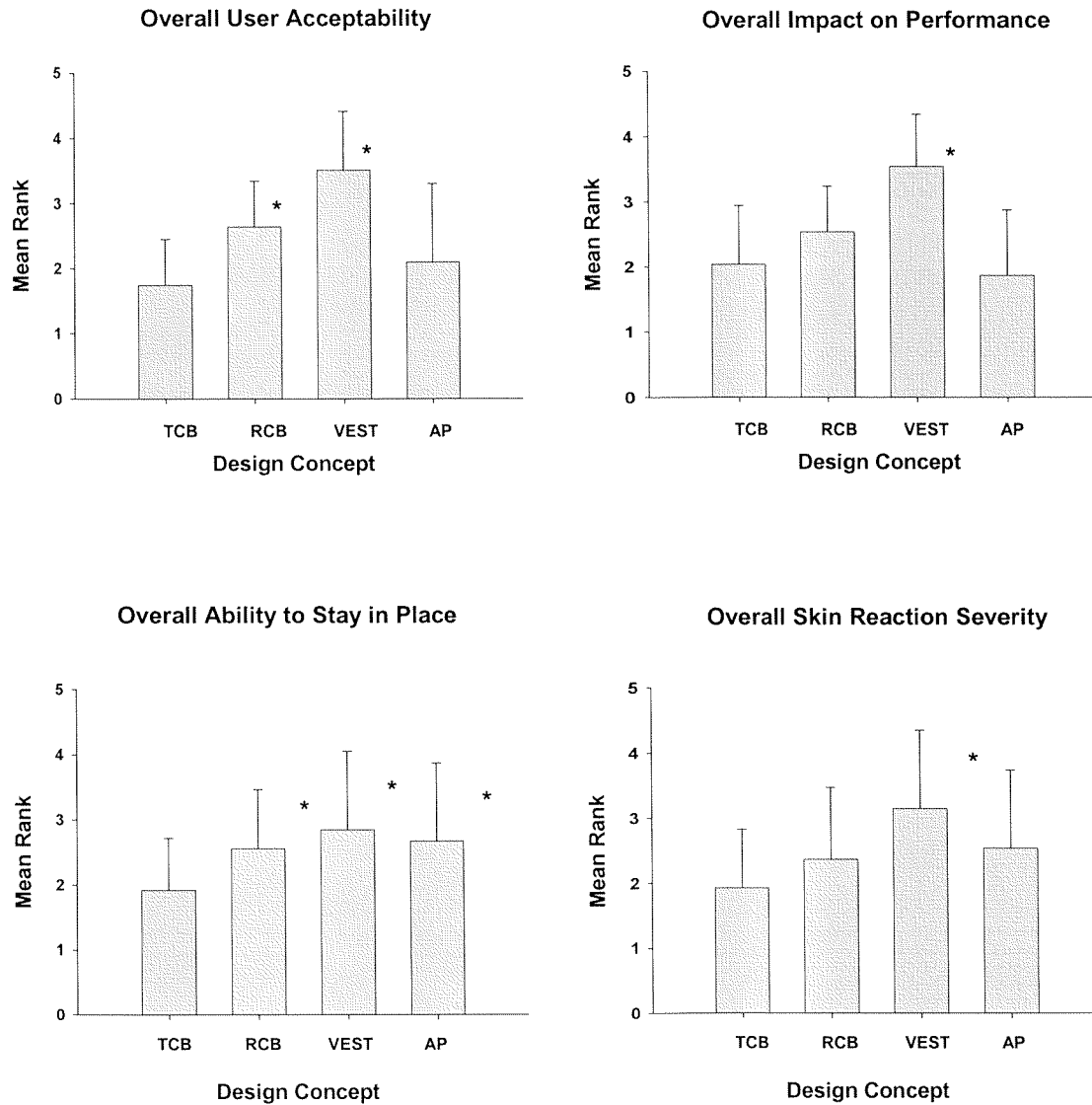


Figure Legend: TCB=Textile chest belt; RCB=Rubber chest belt; Vest=Vest; AP = Adhesive Patch;

*P<0.05 from TCB; †P<0.05 from AP; §P<0.05 from RCB; 1=Best Rank; 4=Worst Rank.

Figure 12

Wear Time & Adverse Events

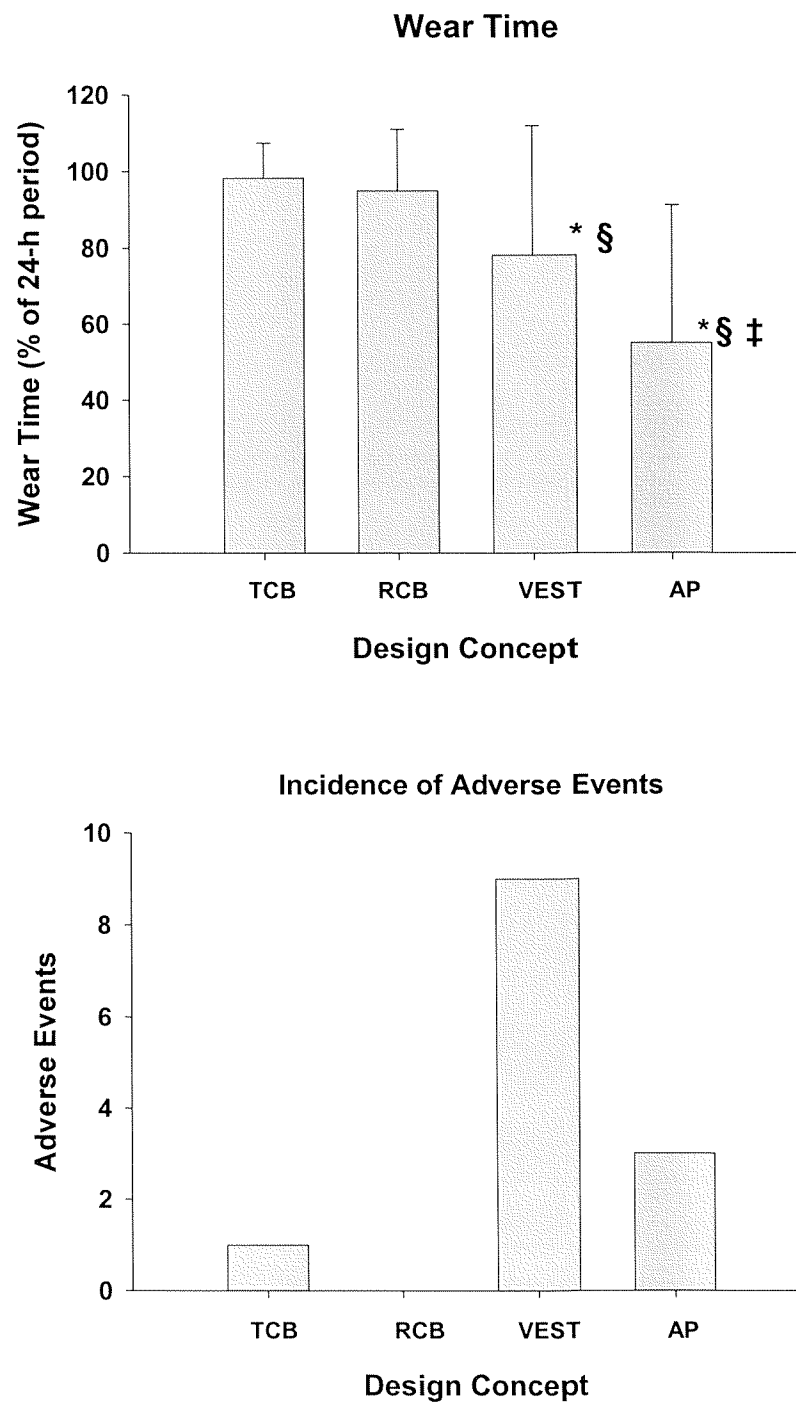


Figure Legend: TCB=Textile chest belt; RCB=Rubber chest belt; Vest=Vest; AP=Adhesive patch; *P<0.05 from TCB; §P<0.05 from RCB; ‡P<0.05 from Vest

DISCUSSION

This study tested the user acceptability of four life sign detection system (LSDS) concepts. Overall, the data presented demonstrate that the textile chest belt was the most acceptable design concept for the soldier. Although the textile chest belt and adhesive patch received similar mean scores in the acceptable to wearer and skin reaction categories, the textile chest belt scored highest in the ability to stay in place category. The percentage of negative comments made about the textile chest belt was lower than all other design concepts. The most frequent negative textile chest belt comments were the following: (a) use a more breathable and less irritating material, and (b) change the metal straps and buckles to plastic.

The adhesive patch was the next most acceptable design concept. It scored higher than all other design concepts in the overall impact on performance category most likely because it was lightweight and unobtrusive. It all scored higher than all other design concepts on overall appearance. However, there were several problems with the adhesive patch. First and foremost, the adhesive patch was only worn 55% of the time due to the fact that it fell off easily, especially when the soldiers performed any physical activity. Clearly, a better adhesive needs to be identified for this design concept to be a viable option. Second, the adhesive patch caused several adverse skin reactions (Figure 12). Given that the soldiers only wore the adhesive patch for ~55% of the 24-h testing period, it is likely that several more adverse events would have occurred had the adhesive patch stayed on. The percentage of negative comments made about the adhesive patch was higher than the textile chest belt but lower than the rubber chest belt and vest. The most frequent negative adhesive patch comments were the following: (a) it fell off/fell apart, and (b) it caused skin irritations.

The next most acceptable design concept was the rubber chest belt. It scored lower than both the textile chest belt and adhesive patch in overall user acceptability and lower than the textile chest belt in its ability to stay in place (Figure 1). Furthermore, on certain soldiers with large chest circumferences, it was hard to adjust the rubber chest belt to position the sensor near the skin in several soldiers, which could have a negative impact on signal quality. The most frequent negative comments were the following: (a) it didn't stay in place and required adjustment and (b) it was uncomfortable and interfered with certain tasks. Since the textile chest belt was rated significantly higher than the rubber chest belt in overall user acceptability, it would make

sense to redesign the rubber chest belt into a textile-based belt that would be more acceptable to the soldier.

The least acceptable design concept was the vest. The vest was rated the worst design concept in all categories of user acceptability by a wide margin. Several other problems with the vest were the following: (a) it caused the most number of adverse events due to skin reactions, (b) it was only worn 78% of the time due to the electrodes falling off or extreme discomfort, (c) the number of negative comments about this design concept exceeded 100, and (d) a full 71% of the soldiers found it totally unacceptable. Several soldiers noted that it was too hot and that they would have become heat casualties if they had not taken it off during exercise. This design concept does not represent a viable option for the infantry soldier in its current configuration.

RECOMMENDATIONS

Based on the user acceptability results of this study, a textile-based solution for future prototypes of the life sign detection system should be considered. However, since the adhesive patch performed equally as well as the textile chest belt in most user acceptability categories, additional research on adhesives that would improve the percentage of wear time and reduce skin reactions is warranted. The rubber chest belt should be redesigned using a textile-based material rather than rubber. This may help eliminate the problems associated with fit and likely improve signal quality. The vest design concept in its current configuration should not be tested further given the results of this study.

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APPENDICES

A: DEMOGRAPHIC SURVEY

Demographics Survey, 2003

Given that a Life Sign Detection System will eventually be placed in the Land Warrior and/or Objective Force Warrior uniform, we want to know from the soldier the most acceptable method to put these systems so that they are comfortable, do not detract from your performance, do not interfere with other equipment you are using, and do not cause skin reactions. These systems will eventually be used to save lives and improve medic response time so the information you provide on this questionnaire is extremely valuable. Thank you very much for your time and cooperation.

MARKING INSTRUCTIONS

- Use a No. 2 pencil only.
- Do not use ink, ballpoint, or felt tip pens.
- Make solid marks that fill the response completely.
- Erase cleanly any marks you wish to change.
- Make no stray marks on this form.

CORRECT: ●

INCORRECT: ○ × ⊗ ⊕ ⊖

Below you will find an example of a question from this booklet. Please note the proper way to record your responses.

Example:

What is your age today?

If your answer is 19 years, then you would write the numbers in the boxes and then darken the corresponding circles. Please make sure that you use leading zeros when needed.

Please write in your response in the blank boxes, then fill in the corresponding circles.

years	1
	9

● ————— ●

Study Title: User Acceptability of Design Concepts for a Life Sign Detection System, 2003
U.S. ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE (USARIEM)
BIOPHYSICS AND BIOMEDICAL MODELING DIVISION
NATICK, MA 01760

User Acceptability Survey

[illegible]

- Flexible Chest Belt
Rubber Chest Belt
Vest
Adhesive Patch

- Yes
No

- Yes
No

- | | | | | | | | | |
|----------------------|----------------------|-----------------------|---------------------|-----------------------------|------------------|--------------------|-------------------|-------------------|
| Dislike
extremely | Dislike
very much | Dislike
moderately | Dislike
slightly | Neither dislike
nor like | Like
slightly | Like
moderately | Like
very much | Like
extremely |
|----------------------|----------------------|-----------------------|---------------------|-----------------------------|------------------|--------------------|-------------------|-------------------|

- A. Overall acceptability
- B. Placement
- C. Ease of Putting on
- D. Ease of Taking off
- E. Comfort
- F. Fit

COMMENTS.

Do not write in this box

q4_comm

- Yes
- No

User Acceptability Survey

6. Using the 9-point scale below, please indicate, overall, how much wearing this Life Sign Detection System would positively or negatively impact the following. If the System was not used in a particular situation, please make your best guess as to how it would impact:

Extremely	Very	Moderately	Slightly	Neutral	Slightly	Moderately	Very	Extremely
negative	negative	negative	negative	impact	positive	positive	positive	positive
impact	impact	impact	impact		impact	impact	impact	impact

- A. Overall impact on performance
- B. Comfort in hot weather
- C. Comfort in cold weather
- D. Ability to use with rucksack
- E. Ability to use in firing position
- F. Overall protection
- G. Range of motion/ease of movement
- H. Overall weight
- I. Overall bulk
- J. Ability to use while sleeping
- K. Overall appearance

COMMENTS: _____

7. Did the Life Sign Detection System stay in place over the previous 24 hours?

Yes (go to question 9)

No

Do not write in this box

Q6_comm

8. If NO, how many times did you have to adjust the Life Sign Detection System stay in place?

number
times

9 or more

9. Did the Life Sign Detection System stay in place after a night of sleep?

Yes

No

User Acceptability Survey

10. Using the scale below, please indicate, overall, the ability of the Life Sign Detection System to stay in place in the following environments and conditions. If the System was not used in a particular situation, please make your best guess as to how it would stay in place:

Extremely	Very	Moderately	Slightly	Neutral	Slightly	Moderately	Very	Extremely
negative	negative	negative	negative	reaction	positive	positive	positive	positive
ability	ability	ability	ability	to staying	ability	ability	ability	ability
to stay	to stay	to stay	to stay		to stay	to stay	to stay	to stay

- A. Overall ability to stay in place
- B. While sweating
- C. While relaxing
- D. While in motion
- E. In the cold
- F. In the heat

COMMENTS: _____

Do not write in this box

Q10_comm

11. Did wearing this Life Sign Detection System cause any skin reaction during the previous 24 hours?

- Yes
- No

12. Using the 9-point scale below, please indicate, overall, the severity or absence of any skin reactions while wearing the Life Sign Detection System:

Extremely	Very	Moderately	Slightly	Neutral	Slightly	Moderately	Very	Extremely
negative	negative	negative	negative	reaction	positive	positive	positive	positive
reaction	reaction	reaction	reaction		reaction	reaction	reaction	reaction

- A. Overall skin reaction
- B. Skin chafing
- C. Skin blisters
- D. Skin open sores
- E. Skin irritation/rash/reaction
- F. Other: (please specify in comments)

COMMENTS: _____

Do not write in this box

Q12_comm

13. Please comment on any suggested improvements for this Life Sign Detection System:

Do not write in this box

Q13_comm

User Acceptability of Design Concepts for a Life Sign Detection System, 2003

C: COMPARISON SURVEY

Comparison Survey

MARKING INSTRUCTIONS	
• Use a No. 2 pencil only. • Do not use ink, ballpoint, or felt tip pens. • Make solid marks that fill the response completely. • Erase cleanly any marks you wish to change. • Make no stray marks on this form.	
CORRECT: ●	INCORRECT: ○ × ⊗ ⊙ ⊖

DATE			SUBJECT
MONTH	DAY	YEAR	Number

Considering the four Life Sign Detection Systems that you have evaluated, please rank them in order from one (1) to four (4), where one equals the best and four equals the worst, for each of the following attributes. Please use each number only once per column:

1 = Best ... 4 = Worst

	OVERALL ACCEPTABILITY	OVERALL IMPACT ON PERFORMANCE	OVERALL HOW WELL IT STAYS IN PLACE	OVERALL SKIN REACTION
Flexible Chest Belt				
Rubber Chest Belt				
Vest				
Adhesive Patch				