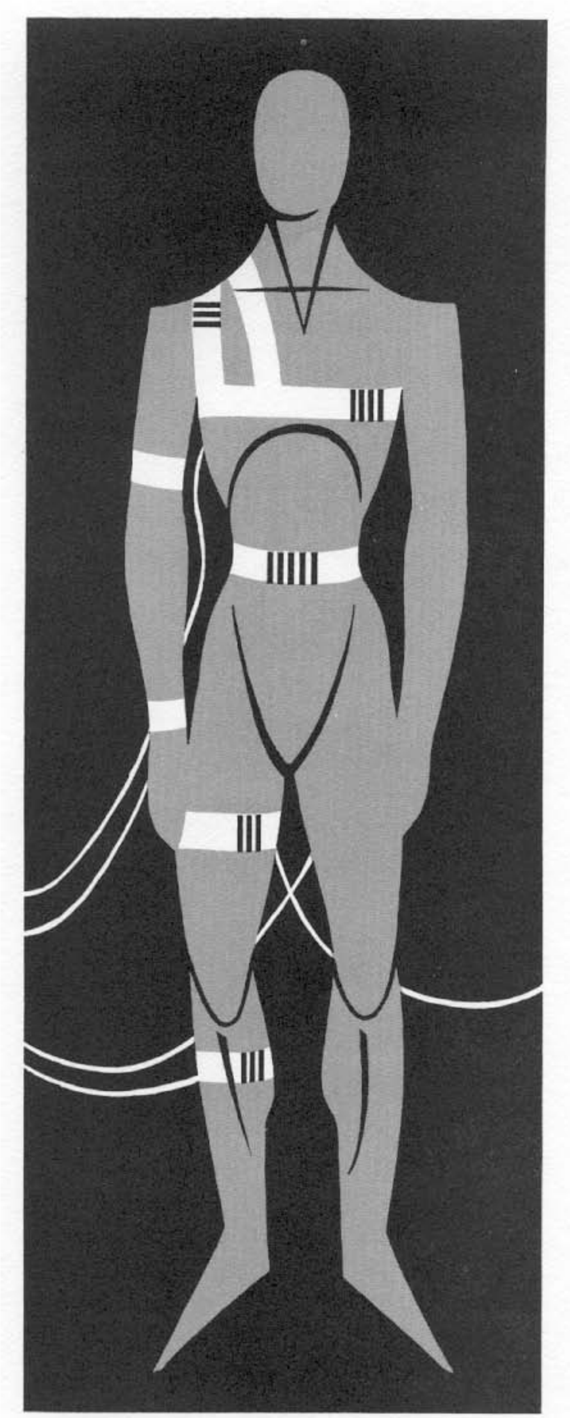

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Human Subject Evaluation of Personal Cooling Systems for Soldiers

Data for Steele PCS Only

Project: Evaluation of Personal Cooling Systems (PCS) for Soldiers

Contract #W91CRB-10-C-0005

submitted to

Project Manager Soldier and Equipment

by

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TR-03

Introduction to Overall Project

There is an immediate need for personal cooling systems (PCS) that can mitigate heat stress for Soldiers deployed in the Middle East – particularly during the summer months when the high air temperatures and radiant load from the sun and hot surfaces can cause the body to gain heat. These environmental conditions, combined with the use of heavy protective clothing and carrying a load of supplies and equipment, can put a thermal strain on Soldiers – especially when they are working and their metabolic heat production increases.

In extremely hot environments and/or at high activity levels, the only way the body can lose excess heat is by the evaporation of sweat from the body surface. The rate of evaporative cooling is dependent upon the vapor pressure gradient between the skin surface and the environment and the rate of air movement around the body and between clothing layers. Unfortunately, protective clothing such as body armor and helmets can inhibit the evaporation of sweat. In addition, the weight, rigidness, and design of protective garments may increase the energy cost associated with wearing them during activity. Consequently, Soldiers operating in hot environments often experience heat stress symptoms that affect performance on extended operations.

To overcome these limitations, the Army has been searching for new technological advances in personal cooling systems (PCS) that have been developed by manufacturers and evaluating their effectiveness for military use. These systems are designed to enhance the performance and comfort of people working in hot environments, and include the following general types:

Cold Boundary

- Refrigeration Systems
- Ice Bath
- Phase Change Materials
- Thermoelectric Coolers
- Compressed Air Systems
- Evaporative Cooling Systems

Enhanced Self Regulation

- Passive Spacer Technology
- Air Circulation Systems

Methodology for Human Subject Trials

Purpose

The purpose of this study was to evaluate the cooling effectiveness of selected personal cooling systems using Soldiers walking on treadmills in an environmental chamber under hot desert conditions. The basic procedures in ASTM F 2300, Standard Test Method for Measuring the Performance of Personal Cooling Systems Using Physiological Testing (ASTM, 2010) were followed except that the environmental conditions were hotter (i.e., to simulate a desert climate in the summer).

Project Design

Groups of four subjects evaluated two personal cooling systems and the baseline condition without a PCS over a six-day period (including days for heat familiarization). Each subject wore all three PCS treatments in a different order. The design of the experiment was a 3 x 3 Latin square design where four subjects evaluated three PCS treatments on three different days. A fourth subject repeated the test sequence of the first. This design was repeated two more times for a total of three weeks of testing on 12 subjects. (See Table 1.)

Personal Cooling Systems and Clothing

A list of personal cooling systems has been compiled by military scientists (***Microclimate Cooling Database*** by Walter Teal and Brad Laprise, 2005) and by university researchers (***KSU PCS Database 2007*** by Elizabeth McCullough and Steve Eckels, 2007 and ***KSU PCS Database 2010*** by Elizabeth McCullough, Steve Eckels, and John Elson, 2010). However, the range of potential products is so broad and diverse that it is difficult to identify the specific personal cooling systems that would work for different military applications. Therefore, we developed a model that evaluated each PCS for three different levels of logistical support and the Army's four levels of metabolic activity for a total of 12 end-use scenarios.

Logistical Support Levels

- Fixed Support (FS) = 60 min
- Mobile Support (MS) = 120 min
- No Support (NS) = 240 min

Activity Levels

- Very Light (VL) = 125 W
- Light (L) = 175 W
- Moderate (M) = 325 W
- Heavy (H) = 500 W

PCS that scored over 80 out of 100 for the worst case scenario (no logistical support/heavy work load) were selected for evaluation with a sweating manikin. (See TR-02 manikin report.) Based on these results, several PCS were selected for evaluation with human subjects. The two PCS evaluated in this phase of the project are described below.

PCS #12. Steele Cool-UnderVest by Steele Inc. This is a ***phase change system*** that contains gel packets that are frozen and placed inside a vest next to the body; heat is absorbed by the phase change material causing it to change phase and melt, cooling the body; the cooling capacity of the material is exhausted when the material has completely changed phase and must be frozen to work again. (See Appendix B.) This PCS weighed 3.501 kg (7.72 lb.). According to the manikin evaluation (TR PCS-12), the vest provided 113 W of cooling during a 2-hour test.

PCS #00. Army Combat Base Ensemble. Each PCS was tested with the following base ensemble which weighed 13.63 – 16. 72 kg (30.04 – 36.86 lb.) depending upon garment sizes. This ensemble had an intrinsic insulation value of 1.00 clo and an intrinsic evaporative resistance of 26.2 $m^2 \cdot Pa/W$. (See KSU TR-01 for manikin test results.)

- ACH Advanced Combat Helmet (with cover, suspension system, and pads)
- Hanes Premium boxer briefs (75% cotton 25% polyester knit, fitted style)
- Gold Toe Ultra Tec crew socks (cushioned, antimicrobial, 79% cotton, 14% nylon, 6% polyester, 1% spandex)

- ACS Army Combat Shirt – Fire Resistant (knit portion on torso replaces T-shirt) shirt tucked into pants
- ACP Army Combat Pants – Fire Resistant (use the drawstrings at the bottom of the trousers to blouse around boots; when bloused, the trousers should not extend below the third eyelet from the top of the boot)
- Belt
- External Knee Protectors
- ACG Army Combat Gloves (worn under sleeve cuffs)
- Athletic shoes (subjects wear their own)
- SPCS Soldier Plate Carrier System (lighter body armor with plates in place)
- ESAPI Enhanced Small Arms Protective Inserts (front and rear hard armor plates)
- ESBI Enhanced Side Ballistic Inserts (small side hard armor plates)

The Army provided us with a number of combat ensembles and sets of body armor in different sizes to use throughout the study. We purchased new underwear and socks for each subject in addition to the cooling systems. Subjects wore their own athletic shoes instead of boots because 1) there was a lesser chance that blisters would form on their feet during the treadmill trials, 2) the Army Research Institute of Environmental Medicine in Natick, MA routinely has the Soldiers wear athletic shoes during treadmill experiments, and 3) athletic shoes are required by the ASTM standard. The three ensembles are shown in Figures 1, 2, and 3. The weights for the PCS ensembles are given in Table 2.

Three PCS treatments were used (#00, #12, and X). Data for X have been removed from this report.

Volunteer Subjects

The target population for this study was male and female Soldiers on patrol in a hot desert environment. According to Demographics Chief of the Office of the Deputy Chief of Staff, G1, there are more males (85%) than females (15%) in the Army. Therefore, we attempted to recruit ten males and two females to evaluate each PCS. Volunteers were recruited from Ft. Riley, a major Army base about 10 miles from Manhattan, Kansas. PM Soldier Protection and Individual Equipment tasked Ft. Riley to provide subjects for the study – including the medical screening.

Criteria for Inclusion/Exclusion of Volunteers. The Soldiers had to meet the following criteria in order to participate:

1. Be an adult between 19-40 years of age.
2. Weigh between 65-100 kg (143-220 lb.) for males and between 55-90 kg (121-198 lb.) for females.
3. Have a height between 1.70-1.95 m (67-77 in.) for males and between 1.60-1.85 m (63-73 in.) for females.
4. Be free of chronic disease and generally in good health.
5. Have passed their most recent Army Physical Fitness Test.
6. Have no history of heat-related illness/injury (heat exhaustion, heat stroke, etc.)
7. Have no recent history of respiratory illness.

8. Have no history of orthopedic problems that could be made worse by walking in the combat uniform with body armor and helmet.
9. Have no recent history of skin disorder or disease.
10. Have no known allergy to adhesive tape.
11. Be willing to refrain from the use of any medications (prescription or over-the-counter) or dietary supplements throughout the length of the study, unless approved by both the Principal Investigator and staff providing medical coverage. Volunteers already taking medications or dietary supplements will not be admitted as test volunteers unless approved by both the Principal Investigator and staff providing medical coverage.
12. Refrain from the use of any caffeine or nicotine-containing product for at least 2 hours prior to the start of any test.
13. Refrain from the use of alcohol for at least 24 hours before the start of any test.
14. Have not had a vaccine in the preceding month.
15. Females must not be pregnant, and they must participate during the nine days after their menstrual period (follicular phase) to minimize hormonal effects. (ASTM, 2010)

Mark Lahan, a Senior Operations Specialist at Ft. Riley (civilian), served as the ombudsman to assist Dr. McCullough with the recruiting effort and to ensure that the Soldiers understood that participation was voluntary. Dr. McCullough visited Ft. Riley and explained the protocol with a Power Point presentation, distributed the protocol/consent forms to Soldiers to read, and answered their questions. After the volunteers signed the consent form, they kept a copy and give a copy to Dr. McCullough. Then Mr. Lahan made arrangements for the volunteers to be cleared for participation by an Army physician at Ft. Riley. The physician reviewed the Soldiers' medical records if they were less than 1 year old or gave the Soldiers a new physical exam which included an assessment of their cardio-respiratory status. The physician provided the principal investigator with written documentation regarding the fitness of each volunteer. After the volunteers who met the criteria were identified, TDY orders were issued for one week of testing. Mr. Lahan randomly assigned the volunteers to a week of testing and to a morning session or afternoon session. Mr. Lahan provided the participation schedule to the subjects and Dr. McCullough.

The subjects did not receive any personal benefits for participating in the study. However, they were not expected to return to work during the week they were participating in the study. In addition, Ft. Riley provided the Soldiers who lived on post with van transportation between Ft. Riley and KSU each day.

Test Schedule

The subjects were expected to participate in either six morning sessions or six afternoon sessions held on consecutive days. Two Soldiers of the same gender were tested at one time in the morning, and two different Soldiers were tested in the afternoon. Heat familiarization sessions were scheduled for the first three days (i.e., Sunday, Monday, and Tuesday), and the subjects became familiar with the test procedures and got used to exercising in the heat. The next three days the subjects used two different PCS (or no PCS). The evaluation of each pair of PCS took three weeks (12 subjects). (See Table 3.)

Environmental Conditions

The experimental setup involved the use of two environmental chambers at the Institute for Environmental Research at Kansas State University (FWA 00000865) in Manhattan, Kansas. The primary chamber (18 x 23 x 12.5 ft) was set up with two treadmills, two fans, and solar lights (Figure 4). The second chamber (11.2 x 11.2 x 9 ft) will be used as a preconditioning chamber and contains the dressing rooms and instrumentation stations (Figure 5).

According to NASA Surface Meteorology and Solar Energy Tables, the highest average environmental values for June and July for central Iraq are: air temperature, 42.2°C (108°F); relative humidity, 31%; wind speed, 4.7 m/s; and a high solar radiant load. The ASTM standard requires using an air temperature of 35°C (95°F), a relative humidity of 50%, and still air conditions (0.15 m/s). For this study, we decided to use conditions that would more closely simulate those found in the Middle East.

- Air (dry bulb) temperature = 42.2°C (108°F)
- Dew point temperature = 14.6°C (58.3°F)
- Relative humidity = 20%
- Air velocity = 2 m/s (4.5 mph) average in chamber
- Mean radiant temperature = 54.4°C (130°F)

The small chamber (adjacent to the large one) was held at approximately 28°C and 30% RH in order to expose subjects to slightly warm conditions for 45 minutes prior to the test session while they were getting instrumented and dressed.

Data Acquisition System

An HP VXI bus data acquisition system was used to measure seven skin temperatures on each Soldier, two chamber dry bulb temperatures, and two dew point temperatures. A Labview® interface was developed to read, display, and store each of the instrument readings during testing. Dry bulb temperatures were measured with type K thermocouples; skin temperatures were measured with type T thermocouples. Dew point temperatures were measured with General Eastern hygrometers.

Prior to the beginning of the project, the entire system was calibrated. Each thermocouple was calibrated in a constant temperature bath. The average air speed was set with a vane anemometer positioned at chest level for a person standing on the treadmill. Specifically, the speed of the fan located in front of each treadmill was varied until an average velocity of 2 m/s was obtained. The environmental conditions in the chamber were set by three primary variables: the dry bulb temperature, the wet bulb temperature, and the mean radiant temperature. The dry bulb and relative humidity were actively controlled by the chamber during the experiments. The wattage and number of lights in the solar simulator controlled the mean radiant temperature. The method outlined in the ASHRAE Handbook of Fundamentals (ASHRAE, 2005) was used to measure this temperature. A small black ball with four thermocouples mounted on the surface was placed under the solar lights. The average temperature of the bulb, the dry bulb temperature of the air, and the air speed were then used to calculate the mean radiant temperature. The spectral distribution of the light emitted by the solar simulator was measured by a photo spectrometer. The solar simulator consisted of approximately 40 150 W GE heat lamp bulbs laid out in a square matrix above the treadmills. The dry bulb, wet bulb, and mean radiant temperature were also used to calculate the WBGT Index (ISO, 1982).

Body core temperature and heart rate. Body core temperatures and heart rates were measured with HQ Inc. CorTemp® data recorders attached to each Soldier's belt. We purchased two recorders that use sensors that transmit in 262 kHz and two recorders that transmit in 300 kHz. We scanned the sensors into the computer and prepared cases of six pills for each subject. The cases consisted of holes in a block of insulation board that kept the magnetized pills at least 1.5 inches from one another. (Figure 6.) Different frequencies were swallowed on different days in case two pills were inside the subject at the same time. Subjects were instructed to take their pills 5 hours prior to the experiment so that the pill would be in the intestinal track instead of the stomach at the time of testing. However, we had no control over this. Therefore, subjects were given water at 37ºC during the experiment so that the water temperature would have a minimal effect on the body temperature measurement. The ingestible temperature sensor transmitted the internal body temperature continuously to the subject's recorder. A Polar® heart rate chest strap with electrodes transmitted the heart rate to the same recorder. The recorders then transmitted their data to a base unit and then to our data acquisition system where the skin temperature data and environmental data were being recorded. Backup recorders attached to cables were also used in case there were transmission problems.

Oxygen consumption and metabolic rate were measured with a ParvoMedics True One 2400 Metabolic Measuring System. (See Figure 7.)

Test Procedures

Determining work load. According to the ASTM standard, an energy expenditure between 250-400 W could be selected for the evaluation of PCS (ASTM, 2010). We selected an initial energy expenditure of 350 W for this study. To determine the speed of the treadmill at 1% incline that would generate 350 W of metabolic heat production, the following equation was used (ACSM, 2006). Note: oxygen consumption is directly related to energy expenditure.

$VO_2 = R + H + V$

<u>where</u>

VO_2 = rate of oxygen consumption (ml/kg/min)

R = resting component of energy expenditure (3.5 ml/kg/min)

H = horizontal component of energy expenditure (0.1 × walking speed in m/min × 26.8 to convert to mph = 2.68 mph)

V = vertical component of energy expenditure (1.8 × walking speed in m/min × 26.8 to convert to mph × grade expressed as a decimal) In this study, grade was 1% (0.01), so V = 0.48.

To determine the speed of the treadmill (at a specific grade) that will result in a particular metabolic expenditure, the watts must first be converted to VO_2 in ml/kg/min to solve the equation above. To equate oxygen consumption (VO_2) with energy expenditure (W):

1 W = 0.0143 kcal/min
1 liter O_2/min = 4.825 kcal/min
Therefore: 1 W = 0.00296 liter O_2/min

To determine 350 W: (350 x 0.00296) = 1.036 liter O_2/min.

To convert to correct units for VO2 (ml/kg/min):

$$\frac{\text{1.036 liter O2/min x 1000}}{\text{body + clothing weight (kg)}} = \text{VO2 ml/kg/min}$$

For a 150 lb. subject wearing 50 lb. of protective clothing (total 200 lb. or 90.9 kg):

$$\frac{\text{1.036 liter O2/min x 1000}}{\text{90.9 kg}} = \text{VO2 ml/kg/min} = 11.4$$

Example: The original equation can be turned around to determine the treadmill speed in mph (s) at a 1% incline that would generate 350 W of metabolic heat production for a 200 lb. subject:

$$s = \frac{\text{(desired metabolic rate in W x 0.00296 x 1000 / weight of clothed subject in kg) – 3.5}}{3.16}$$

s = (11.4 – 3.15) / 3.16 = 2.5 mph

Each day of the experiment, the weight of each subject and his clothing and PCS (if worn) were entered into a computer program that calculated the treadmill speed that would produce 350 W of energy expenditure at the beginning of the test period (using the equation above). The energy expenditure was expected to increase to a higher level over the 2-hour test period, however, since the subjects were exercising in the heat. Under real-life conditions, Soldiers' metabolic rates may be even higher when they are carrying heavy loads.

Heat familiarization sessions. When a person gets acclimated in the heat, his/her heart rate and core temperature under a certain set of conditions will become lower and his/her sweat rate will become higher. Consequently, the physiological strain of exercising in a hot environment lessens as the person conditions his/her body. Ft. Riley could not spare Soldiers on TDY for the two weeks needed for acclimatization. Therefore, we planned several days of heat familiarization sessions for each subject prior to the test sessions. There was still a chance that a subject might feel more comfortable on the last day of the experiment – regardless of what he was wearing – simply because he had become more acclimatized by that time. Therefore, a statistical analysis using "day" as a factor was used to indicate whether any differences between the subjects confounded the results in any way. Note: In our previous studies on PCS for military applications, the effect of "day" was never statistically significant using this protocol; thus, the lack of acclimatization should not affect the results.

During the first three days of each week of testing, the subjects participated in a 2-hour exercise/rest test session under the same environmental conditions used in the study. They followed the exercise/rest protocol given below.

- 0-10 minutes: sitting for 10 minutes
- 10-55 minutes: walking for 45 minutes
- 55-65 minutes: sitting for 10 minutes
- 65-110 minutes: walking for 45 minutes
- 110-120 minutes: sitting for 10 minutes

The purpose of these sessions was to familiarize the subjects with the hot environment, instrumentation, and procedures. The procedures used and measurements taken during the heat familiarization sessions were the same as those described for the experiment ***(see test protocol below)*** except as indicated below. Data collected for the first three days were not used.

Day 1 -- Sunday: On the first day of the experiment, the subjects were assigned a two-digit identification number and asked to provide demographic information (age, gender, race). Their height and weight were measured, and their Body Mass Index was determined. Females had to take a pregnancy test, and the first day of their last menstrual cycle was recorded. The appropriate size garments and PCS were assigned to each subject. (See Appendix C for the Subject Information Sheet.) Then the physiological instrumentation and test protocol were explained to them in detail. They were given a supply of ingestible temperature sensors to swallow at specific times and a wrist band that stated "Warning: No MRI or NMR". They wore the combat ensemble and helmet – without the body armor, gloves, and knee pads. Oxygen consumption and skin temperature were not measured.

Day 2 -- Monday: On the second day, the subjects wore the combat ensemble and helmet – without the body armor. Oxygen consumption and skin temperature were not measured.

Day 3 -- Tuesday: On the third day, the subjects wore the complete base ensemble with the helmet and body armor. The treadmill speed for each subject was adjusted (lowered) to account for the increase in weight due to wearing the body armor. All physiological variables were measured.

Test protocol. When the subjects arrived for an experiment, they were asked to use the toilet. Then they entered a small, warm environmental chamber near the large one. All of the garments and the PCS that each subject was assigned to wear in the test session were placed at a numbered station. Then each subject undressed, put on a pair of briefs, and got weighed. Females wore their own underwear and bra which we used throughout the week.

- **Skin temperature measurement:** The nurse and an experimenter put thermocouples on the subjects' skin with transpore hospital tape. If the subject was excessively hairy in a location where a sensor was to be taped, some of the hair was shaved so that the sensor was securely attached. Skin temperature was measured in seven locations on the body: forehead, right scapula, right upper chest, right upper arm, right lower arm, right anterior thigh, and right calf.
- **Heart rate measurement:** The nurse and experimenter put the Polar® heart rate strap on the subjects.
- **Body core temperature:** The engineer scanned the ingestible temperature sensor

information bar code, verified that the subject swallowed the correct sensor at the correct time (and that it was working), and set up the data recorder.

- **Oxygen consumption and metabolic rate:** The nurse connected each subject to the met cart for the first and last 15 minutes of the experiment.

The nurse and experimenter helped the subjects dress in the appropriate clothing and PCS. Then they entered the chamber and their skin thermocouples were plugged in. The subjects also wore a wrist strap to provide an electrical ground so that they did not build up a static charge and cause electrical interference. They drank 250 ml of water while the experiment set their treadmill speeds. The engineer verified that the data acquisition system was collecting all of the data correctly. When the experiment was ready to start, the PCS was turned on or the experimenter quickly put phase change material packs inside the PCS. Simultaneously, the nurse started a timer, the subjects stepped on the treadmill, and the engineer started the test in the data acquisition system. (See Figure 8.)

The nurse instructed the subjects to drink 250 ml of water every 30 minutes to prevent dehydration (i.e., 30, 60, 90 minutes from the time their treadmill run starts). They were allowed to drink additional water whenever they wanted. Subjects were permitted to listen to the music of their choice or to watch a DVD on a large flat screen television hung between the fans in front of the Soldiers. If the subjects needed to urinate, they did so in a urinal in the chamber. The nurse recorded all fluid intake and excretion on the Case Report Form (Appendix D).

During the experiment, the nurse and experimenter monitored the subjects' core temperature, heart rate, skin temperatures, and environmental conditions on a computer outside the chamber door. The screen could be seen through a window in the door to the chamber. The test session ran for 2 hours for each subject unless one of the following removal criteria was met (ASTM F 2300):

- The subject's body core temperature reached 39.0°C or increased 0.6°C in a 5 minute period (whichever occurred first).
- The subject's heart rate reached 90% of his age predicted maximum.
- The subject's skin temperature at any site reached 38°C.
- The subject experienced heat exhaustion symptoms, including headache, extreme weakness, dizziness, vertigo, "heat sensations" on the head or neck, heat cramps, chills, "goose bumps", vomiting, nausea, and irritability (Hubbard & Armstrong, 1998).
- The subject wanted to quit the experiment.

After a 2-hour test session, the subjects returned to the small chamber, and the nurse or experimenter assisted them in removing their PCS, clothing, recorder, thermocouples, and heart rate strap. Then the subjects were weighed in their underwear. The subjects then put on their own clothes, and they were given cold water or Gatorade® to drink. If the subject's weight after the experiment was not within 1% of his/her initial weight, he/she was asked to stay for observation for about 15 minutes or until his/her target body mass was achieved. The subjects were asked to comment on the characteristics they liked and disliked concerning the PCS they wore that day, and the experimenter recorded their responses on a preference ballot (Appendix E). On the last day of the test sessions, they were asked if they preferred a type PCS or the condition where they did not wear one.

The experimenter laundered the garments and returned them to the small chamber prior to the next day's test. The skin sensors and wires were cleaned with disinfectant wipes to remove perspiration oils, micro-organisms, and tape residue. Any broken sensors were replaced in the bundle.

Medical Precautions, Risks, and Safety

The risks associated with participation in this study on cooling systems were minimal. The probability and magnitude of harm or discomfort associated with this research were no greater than those ordinarily experienced by Soldiers walking and working in hot desert environments.

Risks. Physical exercise can lead to overexertion and/or an accident. In this study, the possibility of cardio-pulmonary overexertion was slight and was minimized by recruiting only young (19-40 year olds), healthy individuals, and abiding by volunteer exclusion criteria. Exercise often carries a risk of injuries like strained and/or sprained muscles although this risk is low with walking. The subjects could have felt fatigued and fallen off the treadmill; however, the treadmills had a hand rail at the front and sides to help prevent this. The nurse watched the subjects during their walk on the treadmill to make sure they maintained a steady pace.

Exercising in the heat may lead to dehydration, fluid/electrolyte imbalance, heat rash, and/or blisters on the feet. Exercise in the heat will increase body core temperature and can induce heat injury/illness, including heat stroke and death, but will more likely cause headache, dizziness, disorientation, and/or nausea. Dehydration can further increase the risk for heat illness. Volunteers were told to be aware of any unusually dark colored urine, and to report this to the Principal Investigator or the nurse immediately for further medical evaluation. Risk of dehydration was minimized by encouraging drinking before, during, and after all tests and monitoring the volunteer's weight daily. The risk from electrical shock is considered to be remote – particularly since all of our equipment and sensors were new and grounded.

The insulation and evaporative resistance of the body armor and helmet in combination with the high ambient temperature during the tests created a situation that could potentially result in some heat strain during the tests – particularly when a PCS was not worn. Dr. McCullough or Dr. Eckels was always present during an experiment along with the engineer who was monitoring the environmental conditions and physiological responses, the nurse who was monitoring the subjects inside the chamber, and the experimenter. Each nurse took an online training course on heat stress and read a copy of Chapter 4, in Section III of the ***OSHA Technical Manual*** on Heat Stress. This document was available during the experiments also.

In the event of a medical emergency, the local Emergency Medical Services would have been contacted immediately. Mercy Hospital is less than 1 mile from IER. The Irwin Army Community Hospital is 15 miles from IER. All volunteers removed from testing due to overheating or fatigue were immediately escorted out of the test chamber, had their helmet, gloves, and body armor removed, were made comfortable (by sitting or lying down on a cot, cooling them with cool wet towels), and were given cold water to drink.

Medical Monitor Requirement. The medical monitor for the project was Dr. Lauren Welch, a retired surgeon in Manhattan, KS. He is currently a site visitor for the Committee on Accreditation of Educational Programs for the Emergency Medical Services Professions. The HRPO requires that the medical monitor review all unanticipated problems involving risk to the subjects, serious adverse events, and all deaths associated with the protocol and provide an unbiased written report of the event within ten calendar days. The medical monitor is supposed to comment on the outcomes of the adverse event and the relationship of the event to the protocol. The medical monitor should also indicate whether he concurs with the details of the report provided by the principal investigator regarding the problem. The services of the medical monitor were not needed.

Data Collection

The subjects' skin temperatures, heart rate, and body core temperature were measured continuously during the exercise protocol using a computerized data acquisition system and data recorder. These data were averaged to produce a data point every minute of the experiment. The oxygen consumption and metabolic rate were measured near the end of the experiment and saved in a summary data file. The whole body sweat rate for each subject was determined by subtracting the subject's weight after the experiment from his weight before the experiment – accounting for the water consumed during the experiment and urination. The environmental conditions were also monitored continuously throughout the experiment. The subjects were asked which PCS they preferred and why, and to provide comments regarding each PCS.

Results

The characteristics of the 12 subjects are given in Table 4. Ten men and two women participated in the experiment. PCS X and PCS #12 – the Steele Cool-Under Vest by Steele (a phase change system) were evaluated in this study.

Most of the subjects were able to complete the 2-hour test session walking in the heat. The following subjects were removed because their body temperature reached the 39ºC removal criteria or they asked the nurse if they could quit:

Subject 1: male, wearing no PCS, 102 minutes
Subject 5: female, wearing no PCS, 78 minutes
Subject 6: female, wearing no PCS, 82 minutes
Subject 9: male, wearing no PCS, 95 minutes
Subject 6: female, wearing PCS X, 61 minutes
Subject 6: female, wearing PCS #12 Steele, 84 minutes

Graphic Analysis

The physiological responses of the Soldiers that were measured continuously – core temperature, mean skin temperature, torso skin temperature (average of the back and chest skin temperatures), and heart rate – were averaged and graphed over time for each PCS. (See Figures

9 – 12.) Mean skin temperature (T_s) was area weighted according to ISO 9886 (ISO, 2004) except that the hand temperature was eliminated. The hand's weighting factor (determined by its surface area) was evenly distributed over the other sensors in the equation for determining the mean skin temperature.

Statistical Analysis

The design of the experiment was a 3 x 3 Latin square with three replications where subjects and test days serve as blocks. An extra subject was tested each week to improve the chances of finding statistically significant differences between PCS – particularly if one of the subjects quit the experiment for some reason. PCS and day (order of wearing PCS) were considered to be fixed effects and subject was a random effect in the analysis. The purpose of this design was to remove unwanted variation when looking at the PCS effects that might occur between subjects and over the test days due to acclimatization. There were three replications of the Latin Square, where each replication was run in a different week. The effects of day (ordering of wearing PCS) and week (of the experiment) did not significantly affect the results, so these variables were omitted from the subsequent statistical analyses.

Separate analyses of variance and LSD post hoc comparison tests were used to determine the effect of the type of personal cooling system (including the effect of not wearing one) on the following dependent variables:

- final core temperature (°C)
- change in core temperature (from minute 1 to minute 120 – or the last minute the subject was in the experiment) (°C)
- rate of change in core temperature (from minute 1 to minute 120 – or the last minute the subject was in the experiment divided by time) (°C/hr)
- final mean skin temperature (°C)
- final average temperature of the torso (chest and back) (°C)
- final heart rate (bpm)
- whole body sweat rate (g/hr)
- final metabolic rate (W)
- final oxygen consumption (ml/kg/min)

The final values were taken at 120 minutes or when the subject met one of the removal criteria and the experiment was stopped. The level of statistical significance was set at $p \leq 0.05$. The results of the ANOVAs are shown in Table 5, and the LSD comparisons of means are given in Table 6.

Body core temperature. An increase in core temperature is the most important physiological indicator of heat stress. The LSD post hoc comparison tests indicated that the Soldiers had a significantly lower final core temperature when they were wearing PCS #12 Steele as compared to not wearing a PCS at all (e.g., 0.42ºC difference). In addition, the *change* and *rate of change* in core temperature were also significant. Specifically, the rise in core temperature was smaller for the #12 Steele vest than it was for the baseline condition. These results can be seen in Figure 9.

Skin temperatures. The effect of PCS on final skin temperatures was significant. Specifically, the Soldiers' mean skin temperatures were significantly lower when they were wearing the #12 Steele vest as compared to not wearing a PCS (Figure 10). This is because the mean skin temperature was greatly affected by the skin temperatures under the PCS. When the average chest and back skin temperatures were averaged to get the final torso temperature, the differences between the PCS were very apparent (Figure 11). The final torso skin temperature under the Steele PCS was significantly lower than the baseline condition with no PCS. In addition, the torso temperature dropped rapidly at the beginning of the experiment and stayed about 8-10ºC lower than the torso temperature for the baseline condition for about 40 minutes. This was expected since frozen gel packs were placed against the body when the Steele PCS was worn. As the gel packs started melting, the skin temperature began to rise.

Heart rate. The subjects' heart rates at the end of the test sessions were significantly higher when they were not wearing a PCS as compared to wearing #12. This indicated that the body was not as stressed when exercising in the heat and wearing the PCS. (See Figure 12.)

Sweat rate. The sweat rates were significantly higher when the subjects were not wearing a PCS as compared to wearing #12 Steele vest. The body did not have to produce as much sweat to cool itself when external cooling was provided by the phase change vest.

Metabolic rate and oxygen consumption. The effect of PCS on metabolic rate was not statistically significant. We did not want to find a difference in metabolic heat production because we tried to estimate the speed of the treadmill (based on the weight of each subject fully dressed) so that all subjects would be working at approximately the same rate. Therefore, all of the subjects were producing about the same amount of heat during the test sessions with the different PCS treatments – 385 to 395 W on average. This was a desired result. Oxygen consumption at the end of the test period was statistically significant. Specifically, the Soldiers' oxygen consumption was significantly lower when they were wearing the #12 Steele vest as compared to not wearing a PCS. The magnitude of the difference was not large, however.

Soldier Preferences

The comments of the subjects regarding their opinions about the cooling systems and their preference votes are given in Table 7. The Soldiers liked the cooling provided by #12 Steele, but some commented negatively on the weight. Also, some felt that it was too cold at first.

Conclusions

The #12 Steele Cool-UnderVest uses frozen gel packs to provide cooling. As the packs absorb heat from the body, they change phase and melt. In this study under very hot conditions, they were still cold at the end of the 2-hour test sessions. When the Soldiers were wearing the Steele vest as compared to not wearing a PCS, all of the physiological variables were significantly improved except for metabolic rate (which was controlled to be at about the same level for all tests). In particular, the Soldiers' average final body core temperatures were 0.42ºC lower when they wore the Steele vest as compared to not wearing a PCS. Therefore, the Steele vest has potential for military use in applications where a freezer or an insulated, temporary storage container is available.

Limitations

The goal of this study was to identify the most effective cooling system of those tested using human subjects in a controlled laboratory setting. The metabolic heat production of the Soldier was controlled at a relatively high level (380 ± 25 W). Variables such as the weight of the clothing worn and loads carried (packs, weapons, etc.) and the activity levels of the Soldiers will affect the heat production of the Soldier during military operations. Therefore, the best PCS found in this study may be ineffective in providing enough cooling for Soldiers under some sets of conditions. In addition, the PCS may have other logistical or ergonomic problems that are not being evaluated in this study. Further testing on Soldiers in the field would be necessary to determine the overall effectiveness and durability of a PCS. This study is limited to quantifying the amount of cooling provided by the PCS over a standard 2-hour period, and its effect on the physiological and subjective responses of human subjects under controlled conditions.

Further Research

The test sessions in this study lasted 2 hours. It would be interesting to see how long both types of personal cooling systems would maintain their cooling effectiveness when worn on a sweating manikin and on Soldiers in the field (i.e., determine the duration of cooling).

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Note: A large list of references regarding this topic was provided to the sponsor in a separate document.

Table 1. Design of the Experiment[a]

Week	Day (Order)	Subject Number			
		01	**02**	**03**	**04**
1	**1**	0	A	B	0
	2	A	B	0	A
	3	B	0	A	B
		05	**06**	**07**	**08**
2	**1**	0	B	A	0
	2	B	A	0	B
	3	A	0	B	A
		09	**10**	**11**	**12**
3	**1**	0	A	B	0
	2	A	B	0	A
	3	B	0	A	B

[a] This was a 3 x 3 Latin square with three subjects duplicating one of the treatment sequences for a total of 12 subjects evaluating three PCS treatments.

Table 2. Weights of Army Clothing and Personal Cooling Systems[a]

Ensemble	Weight of Clothing on a Small Subject	Weight of Clothing on a Large Subject
#00. Base ensemble with the Soldier Plate Carrier System body armor (no PCS)	13.626 kg 30.04 lb.	16.719 kg 36.86 lb.
#12. Steele by itself	3.501 kg 7.72 lb.	3.501 kg 7.72 lb.
#12. Base ensemble with the Soldier Plate Carrier System body armor and #12 Steele	17.127 kg 37.76 lb.	20.22 kg 44.58 lb.

[a] Weights vary with the size of the subject and garments.

Table 3. Schedule of Test Sessions for the First Week of Tests[a]

Date	Morning (8:30 a.m. – 12:00 p.m.)	Afternoon (1:00 – 4:30 p.m.)
Day 1 Sunday April 17 Heat familiarization	Subjects wear ACU and helmet – no body armor, knee pads, and gloves; no MET cart; Session 1:00-5:00 p.m. 01 = A1 pill, 02 = B4 pill, 03 = A7 pill, 04 = B10 pill	
Day 2 Monday April 18 Heat familiarization	Subjects wear ACU and helmet – no body armor, knee pads, and gloves; no MET cart; 01 = B1 pill, 02 = A4 pill	Subjects wear ACU and helmet – no body armor, knee pads, and gloves; no MET cart; 03 = B7 pill, 04 = A10 pill
Day 3 Tuesday April 19 Heat familiarization	Subject 01, PCS 00 – None; A2 pill Subject 02, PCS 00 – None; B5 pill	Subject 03, PCS 00 – None; A8 pill Subject 04, PCS 00 – None: B11 pill
Day 4 Wednesday April 20	Subject 01, PCS 00 – None; B2 pill Subject 02, PCS X; A5 pill	Subject 03, PCS 12 – Steele; B8 pill Subject 04, PCS 00 – None; A11 pill
Day 5 Thursday April 21	Subject 01, PCS X; A3 pill Subject 02, PCS 12 – Steele; B6 pill	Subject 03, PCS 00 – None; A9 pill Subject 04, PCS X; B12 pill
Day 6 Friday April 22	Subject 01, PCS 12 – Steele; B3 pill Subject 02, PCS 00 – None; A6 pill	Subject 03, PCS X; B9 pill Subject 04, PCS 12 – Steele; A12 pill

[a] This schedule was repeated on subjects 05 – 08 and 09 – 12.

Table 4. Characteristics of Subjects[a]

Subject Number	Age (years)	Race	Height	Weight	BMI
01	19	White	1.80 m 5 ft. 11 in.	72.12 kg 159 lbs.	22.2
02	21	Hispanic and Black	1.78 m 5 ft. 10 in.	72.12 kg 159 lbs.	22.8
03	23	Black	1.85 m 6 ft. 1 in.	86.2 kg 190 lbs.	25.1
04	29	White	1.80 m 5 ft. 11 in.	78.47 kg 173 lbs.	24.1
05	27	Black	1.73 m 5 ft. 8 in.	55.34 kg 122 lbs.	18.5
06	19	White	1.60 m 5 ft. 3 in.	58.97 kg 130 lbs.	23.0
07	24	White	1.83 m 6 ft. 0 in.	94.80 kg 209 lbs.	28.3
08	27	Hispanic	1.78 m 5 ft. 10 in.	96.16 kg 212 lbs.	30.4
09	19	Hispanic	1.73 m 5 ft. 8 in.	93.44 kg 206 lbs.	31.3
10	30	Black	1.78 m 5 ft. 10 in.	89.81 kg 198 lbs.	28.4
11	19	Hispanic	1.78 m 5 ft. 10 in.	71.67 kg 158 lbs.	22.7
12	21	White	1.75 m 5 ft. 9 in.	65.77 kg 145 lbs.	21.4

[a] Subjects 05 and 06 were female; the rest were male.

Table 5. Analysis of Variance for the Effect of PCS Type on Different Dependent Variables

The ANOVA results were based on three PCS treatments, but only two – the baseline and the Steele – are being reported. Therefore this table has been omitted.

Table 6. LSD Post Hoc Comparison Tests for Significant Variables

Personal Cooling System	Mean	LSD
Final Core Temperature (ºC)		
PCS #0 Baseline (no PCS)	38.21	A
PCS #12 Steele	37.79	B
Change in Core Temperature (ºC)		
PCS #0 Baseline (no PCS)	1.21	A
PCS #12 Steele	0.50	B
Rate of Change in Core Temperature (ºC/hr)		
PCS #0 Baseline (no PCS)	0.71	A
PCS #12 Steele	0.28	B
Mean Skin Temperature (ºC)		
PCS #0 Baseline (no PCS)	37.25	A
PCS #12 Steele	36.13	B
Average Torso Skin Temperature (ºC)		
PCS #0 Baseline (no PCS)	37.08	A
PCS #12 Steele	33.83	B

***** Means with the same letter designation are not statistically different from one another at the 0.05 level of significance.

--continued--

Table 6 continued

Personal Cooling System	**Mean**	**LSD**
Final Heart Rate (bpm)		
PCS #0 Baseline (no PCS)	139.8	A
PCS #12 Steele	120.5	B
Whole Body Sweat Rate (g/hr)		
PCS #0 Baseline (no PCS)	1130.8	A
PCS #12 Steele	891.7	B
Final Metabolic Rate (W)		
PCS #0 Baseline (no PCS)	394.5	A
PCS #12 Steele	385.2	A
Final Oxygen Consumption VO_2 (ml/kg/min)		
PCS #0 Baseline (no PCS)	13.1	A
PCS #12 Steele	12.5	B

***** Means with the same letter designation are not statistically different from one another at the 0.05 level of significance.

Table 7. Soldier Preferences for PCS

Subject	Preference	Comments
01		**PCS 12 Steele:** Too cold to start, but it felt like it worked better than the fan system. It was also nice to have the front and back of the body cooled.
02		**PCS 12 Steele:** I didn't like the ice, it was too cold, and once the ice melts it is pointless. I would not want ice on me while shooting people. Fans were effective, ice was not.
03		**PCS 12 Steele:** It decreased my sweat. I stayed cool the whole time. I would have to get used to the weight, but it was okay. It kept me cool.
04		**PCS 12 Steele:** Stayed cool the whole time. I sweated less and felt cooler.
05		**PCS 12 Steele:** It kept me cool. The ice packs were hard. I would rather have this cooling system than nothing though.
06		**PCS 12 Steele:** I thought it was too cold at first and felt bulky and heavy. It did keep me cooler longer. It fit well under armor.
07		**PCS 12 Steele:** I liked it better, stayed cool throughout the whole time. Once the strips began to melt I didn't like the extra weight. Would they be disposable? All in general, this one worked better all over my body.
08		**PCS 12 Steele:** It was great but probably wouldn't last over 3-4 hours. Good cooling system. Is it toxic if you were to get shot threw the packs? If it were to catch on fire would it burn off or melt to the skin? It kept me cooler, but still wondering if it would be worth the extra weight in the long run.
09		**PCS 12 Steele:** Very effective. It was very cold at first, but kept me cooler the whole time. It was heavy though.
10		**PCS 12 Steele:** I felt this vest works well, but I feel there should be an additional barrier of material between ice and skin.
11		**PCS 12 Steele:** I liked it. It kept my sweat down. My hands did not hurt as much and they did not swell as bad. I feel that I could have gone another two hours.
12		**PCS 12 Steele:** I loved it. It kept me really cool throughout my whole body.

Preferences and comments on PCS X were omitted.

Figure 1. Subject dressed in PCS #00: Baseline Army combat ensemble with body armor.

Omitted

Figure 2. Subject dressed in Baseline Army combat ensemble with body armor and PCS X.

Figure 3. Subject dressed in Baseline Army combat ensemble and PCS #12: Steele.

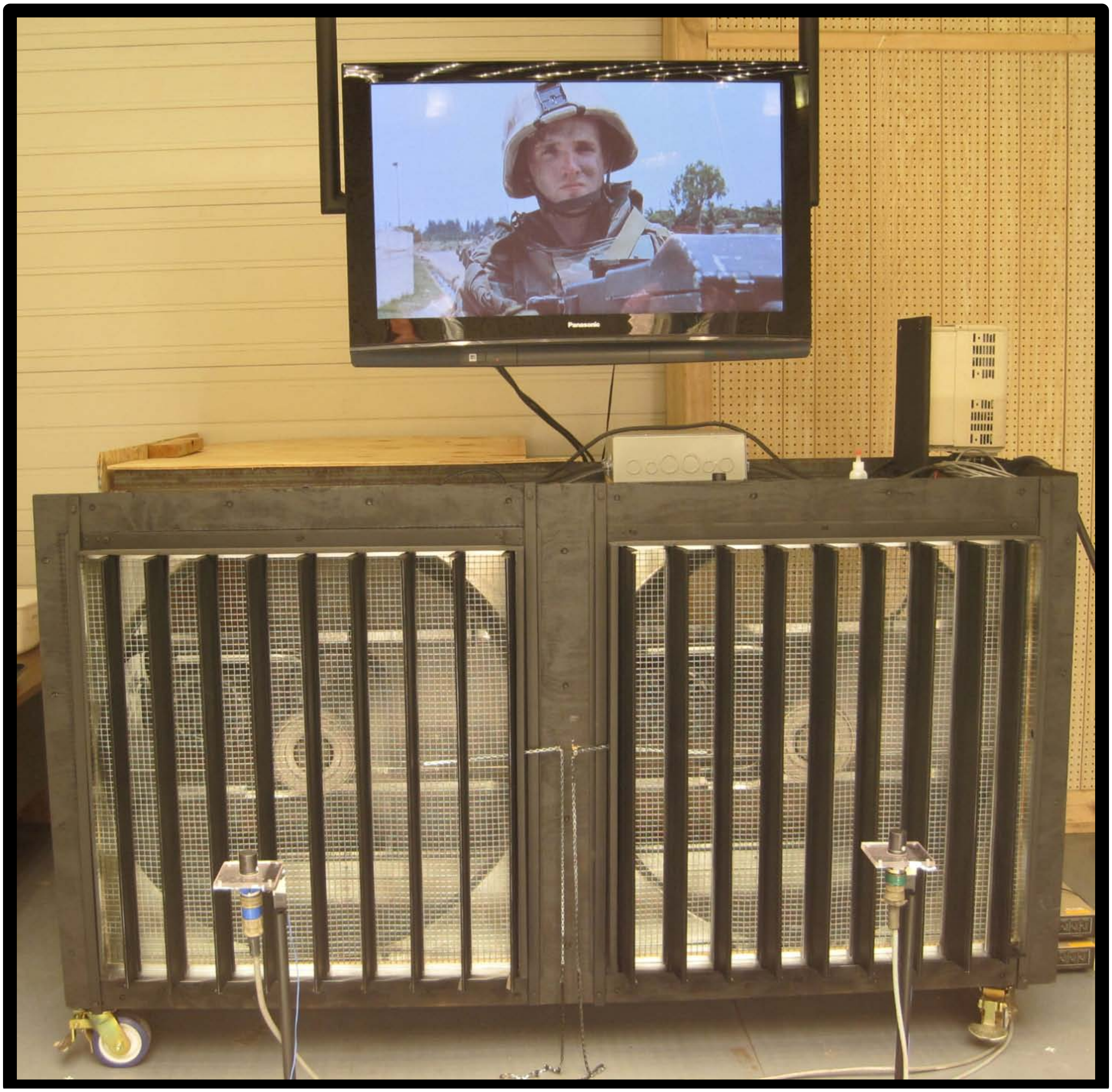

Figure 4. Fans and television in front of the treadmills.

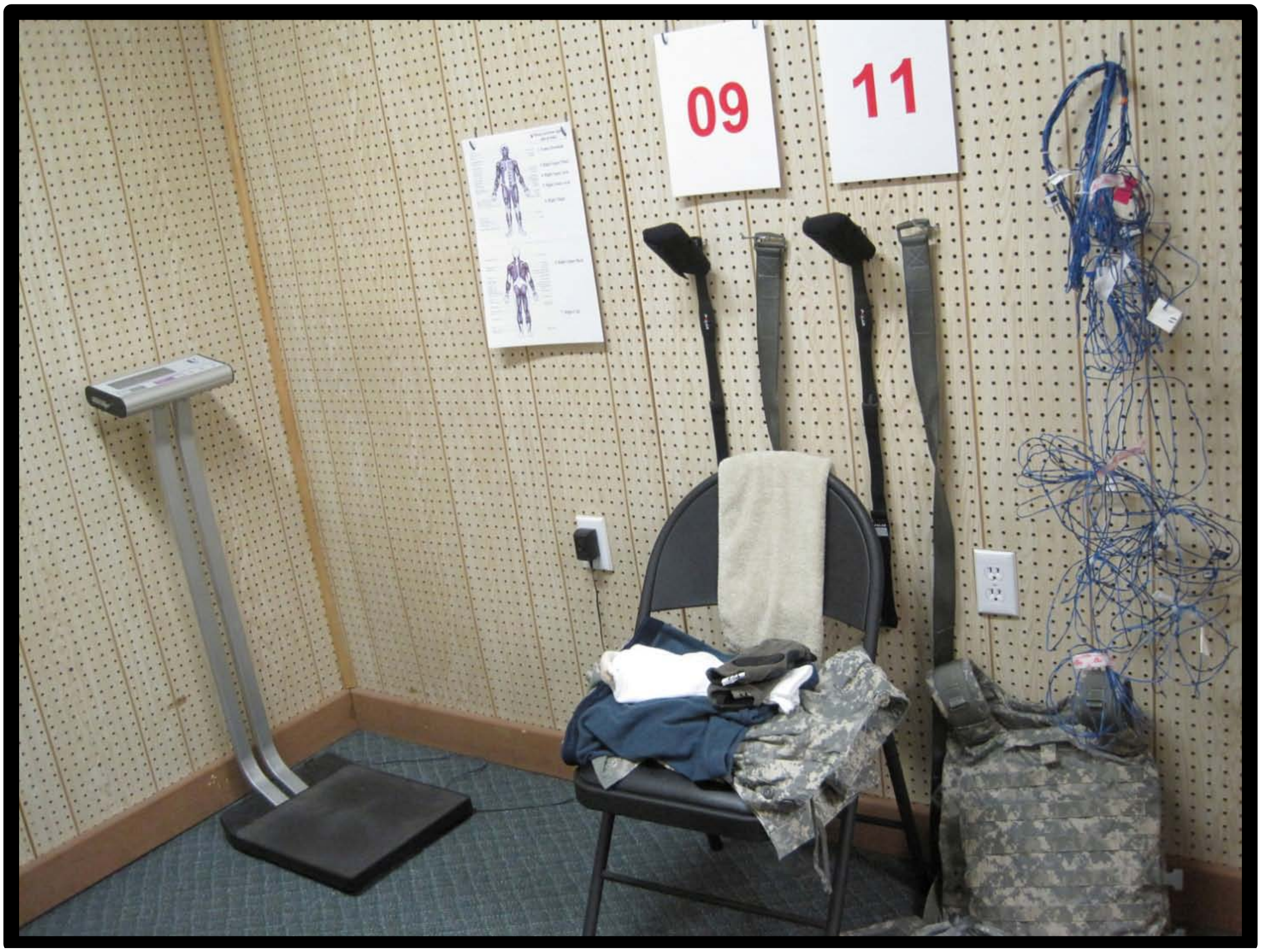

Figure 5. Subject station in the preconditioning chamber; there is one on either side of the room. One number is for the morning subject, the other for the afternoon subject.

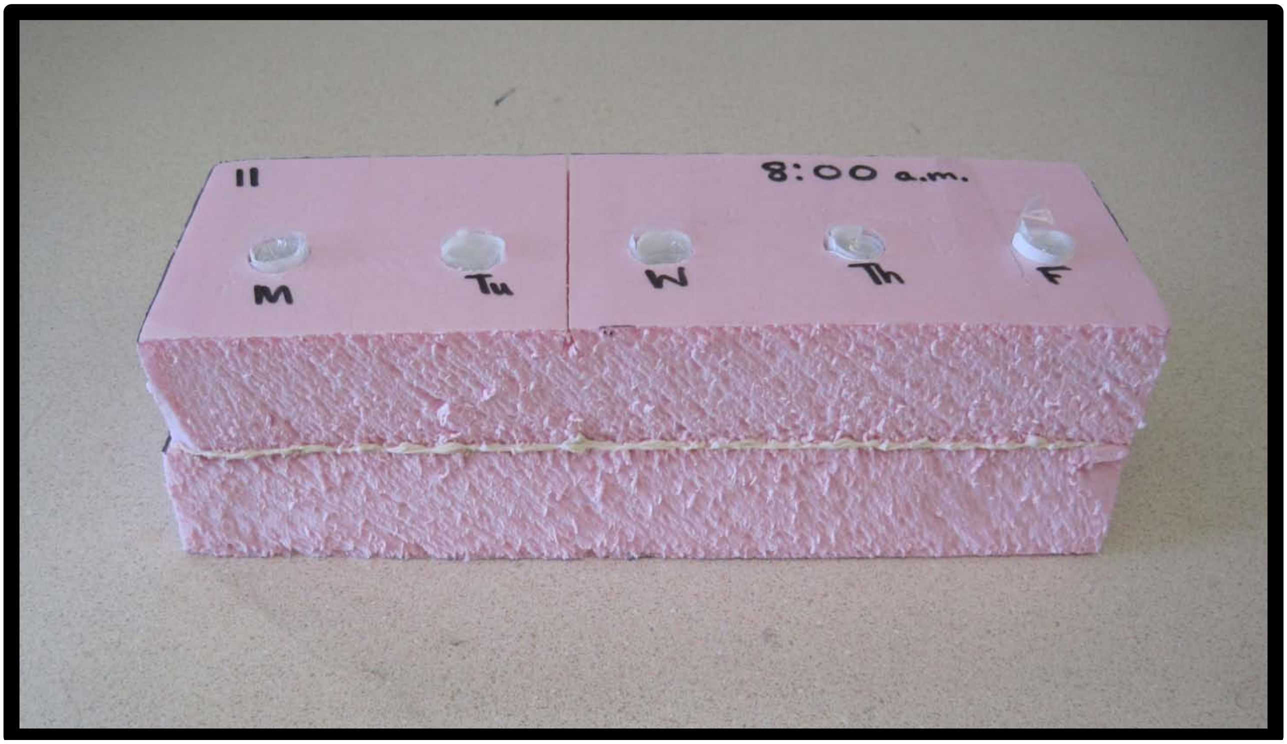

Figure 6. Ingestible core temperature sensor (pill) carrier for Soldiers to take home.

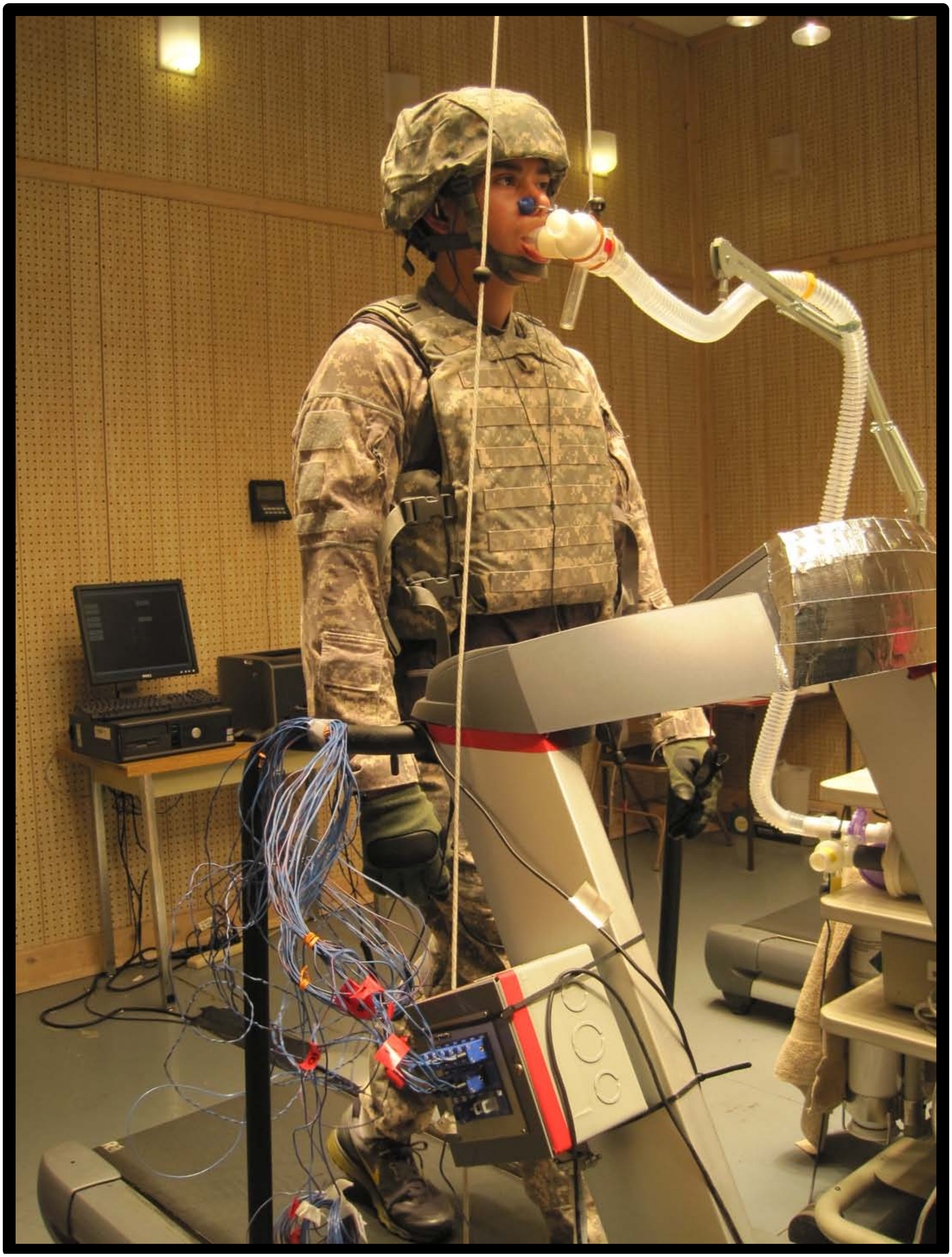

Figure 7. Subject connected to the met cart.

Figure 8. Subjects walking on the treadmills during a test session.

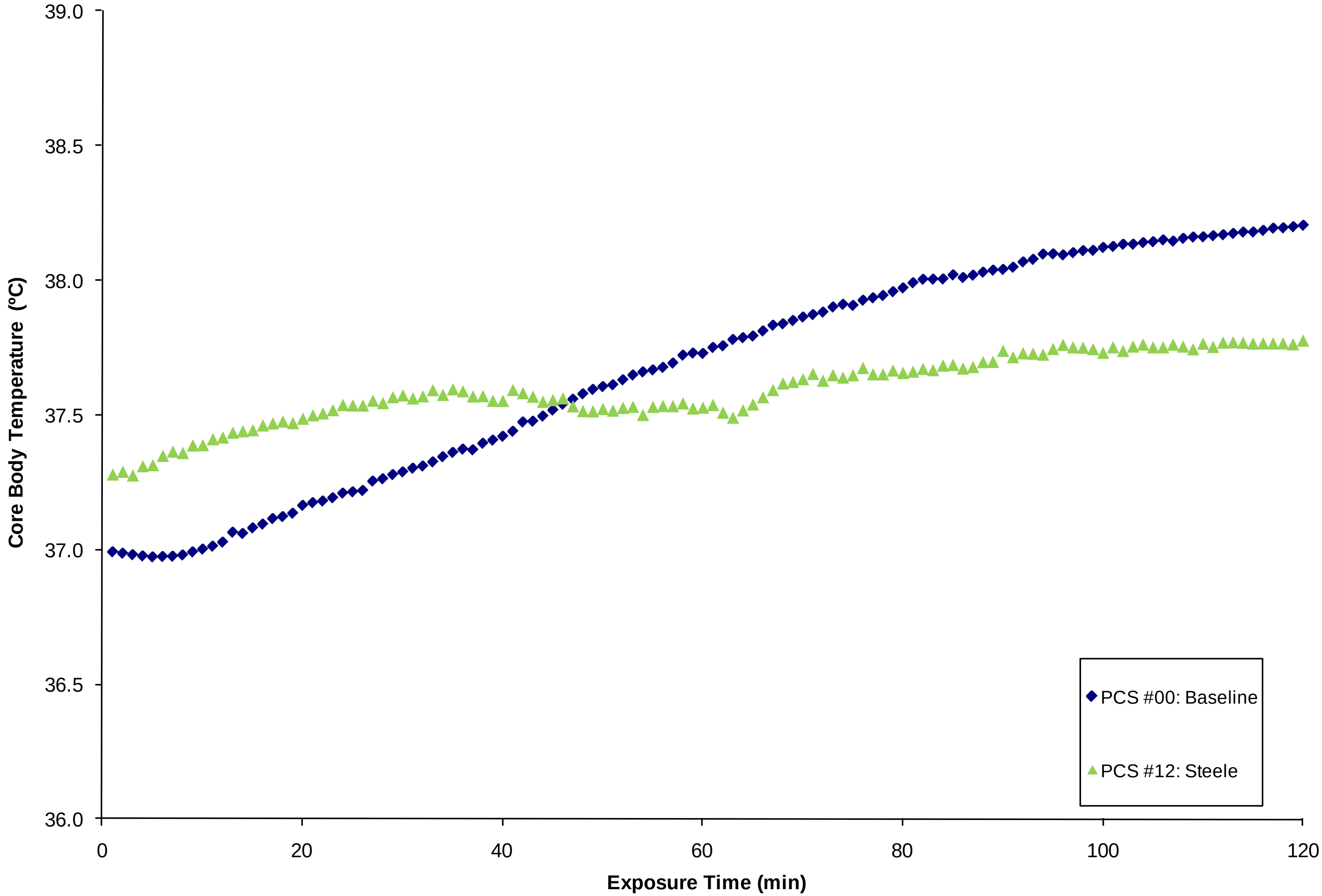

Figure 9. Average core temperatures of Soldiers while wearing different PCS.

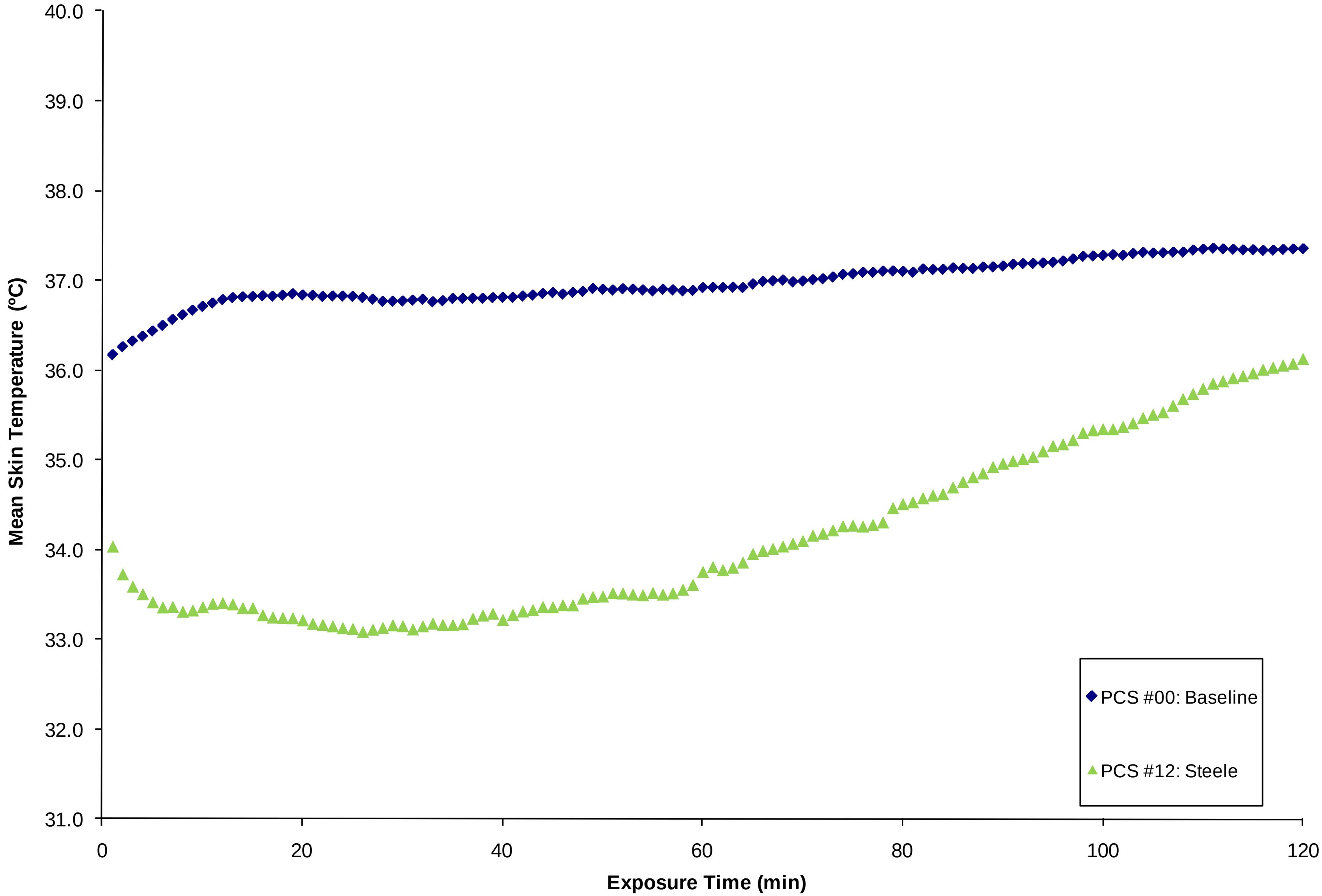

Figure 10. Mean skin temperatures of Soldiers while wearing different PCS.

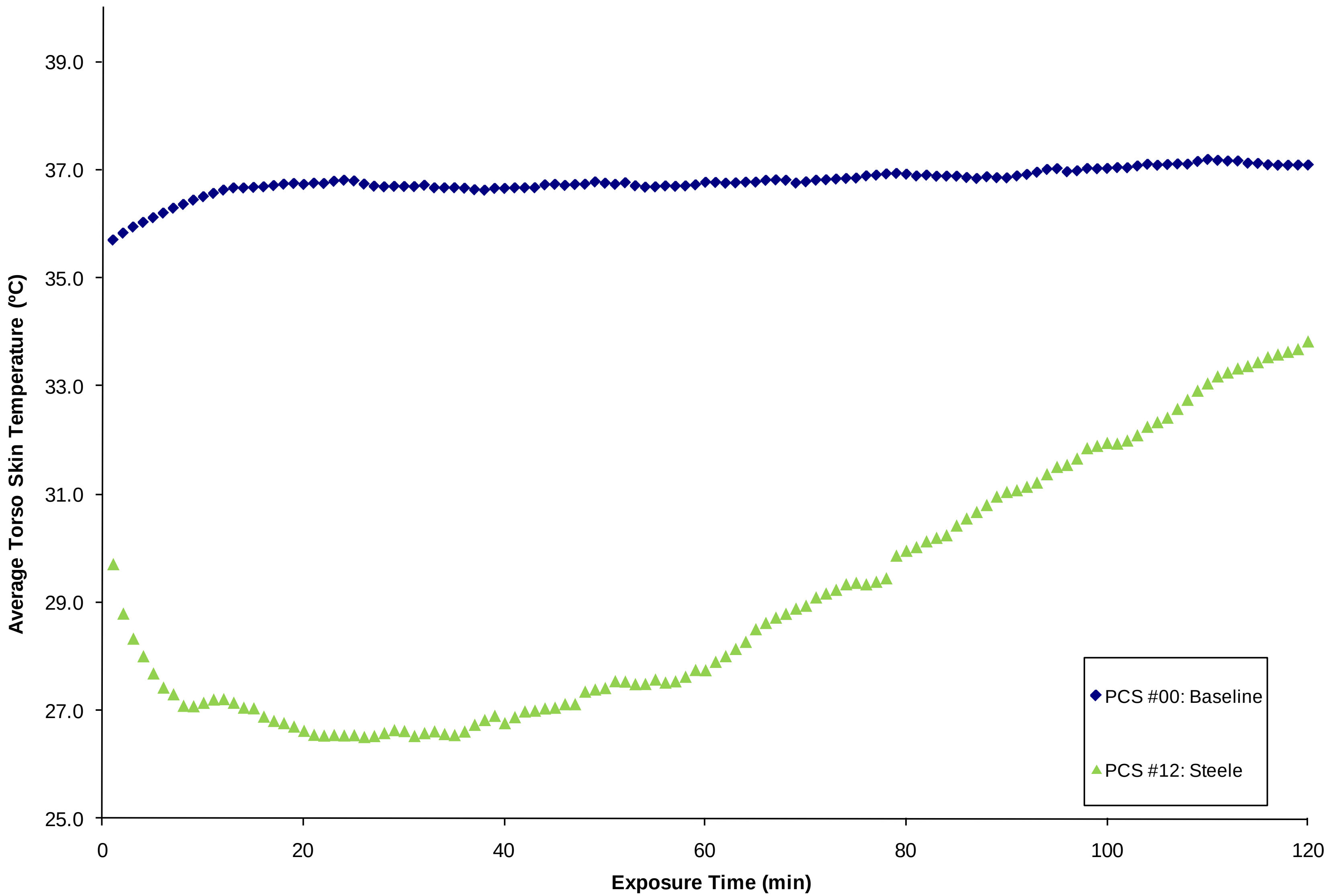

Figure 11. Average torso (back and chest) skin temperatures while wearing different PCS.

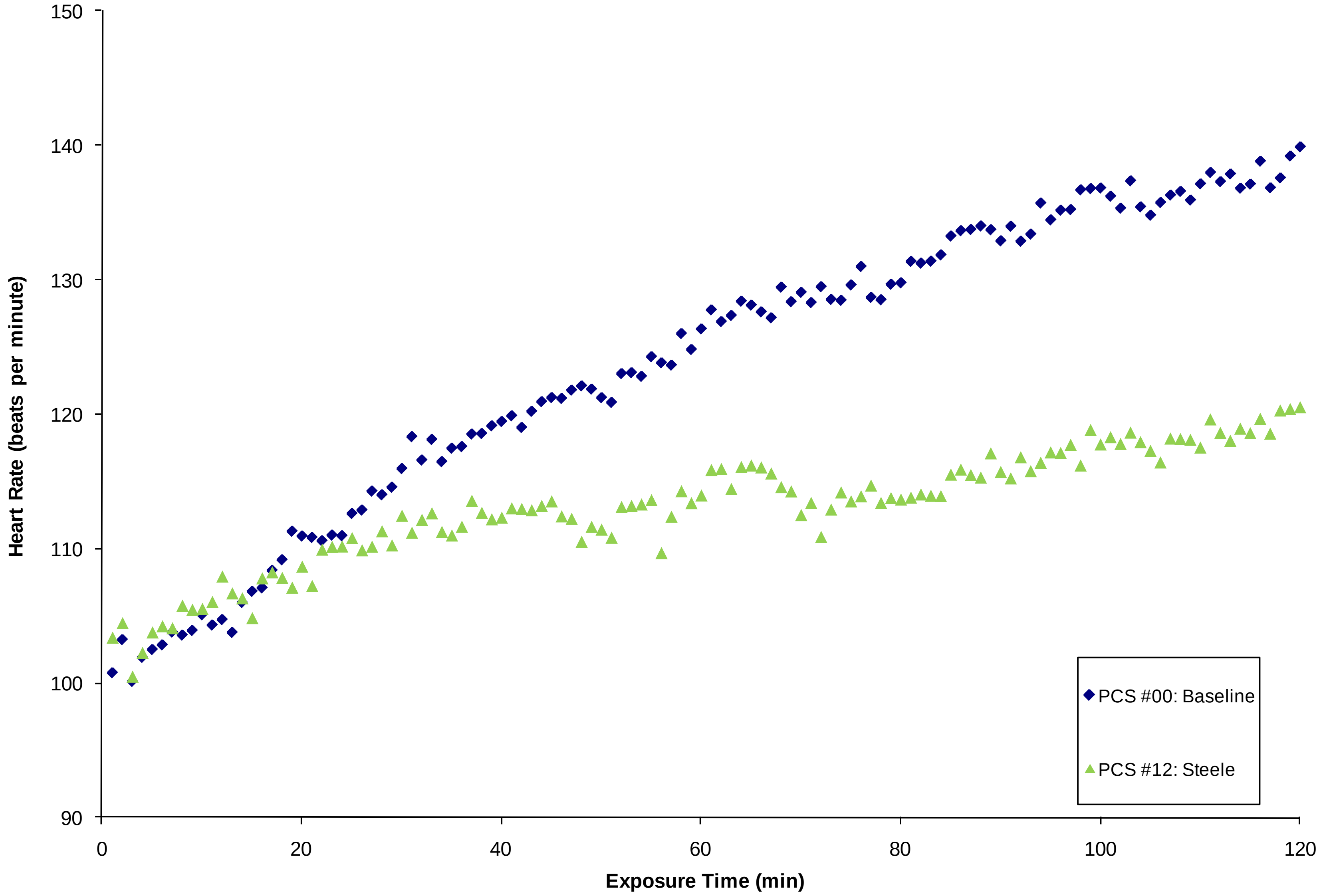

Figure 12. Average heart rates of subjects while wearing different PCS.

Appendix A – PCS X

Omitted

Appendix B – PCS #12 – Steele

Product Name: Steele Cool-UnderVest, P/N SA880

Company Name and Address:
Steele Inc.
P.O. Box 7304
26112 Iowa Ave NE
Kingston, WA 98346

Company Contact: Sandra Steele
Phone: Toll Free 1-888-783-3538
Email: steeleinc@silverlink.net

Web Address: www.steelevest.com

Type of Technology: Phase Change Materials (gel ice passive cooling)

Short Technology Description:
Non-toxic, non-flammable, gel ice absorbs heat and cools body core.

Physical Description:
Insulated vest with adjustable elastic straps holds 4 segmented gel Thermo-strips, two in front and two in back. Loads and unloads packs from top or bottom of zippered pockets without the need to remove armor.

Energy Removal: Approximately 180 Watts/hour

Sizes Available:
One size vest fits XS to XXL.

System Weight: 7.72 lbs.

Estimated Runtime (per Charge/Fill):
2-4 hours

Supplies Required:
Frozen Thermo-strips

Estimated Unit Price:
$250.00 with two sets of Thermo-strips

Appendix C – Subject Information Sheet

Subject Number: ______________________

Age: ______________years

Gender: _____Male _____Female

Race: _____White _____Black _____Hispanic _____Asian ______________Other

Height: ________ft. ________in.

Weight: __________________lbs.

For Experimenter to fill out:

BMI: _____________________

Pregnant? _____yes _____no (test result)

First day of last menstrual period ____

Garment Description	**Size**
Underwear Briefs (S, M, L, XL)	
Army Combat Shirt (S, M, L, XL)	
Army Combat Pants (S-short, S-reg, M-reg, M-long, L-reg, L-long, XL-reg, XL-long)	
Helmet (w/pads) (M, L, XL)	
Body Armor Vest (SPCS) (S, M, L, XL)	
Gloves (M, L, XL)	
PCS #01 (XS, S, M, L, XL)	
PCS #12 (one size fits all)	
Mouthpiece to MET cart (M, L)	

Appendix D – Case Report Form

Subject Number_______________ Week 1 2 3 Morning 1 Afternoon 2
Test Day W4 Th5 F6 PCS #: 00 none 01 12

Measurement	Value
Initial weight: Weight of subject in underwear briefs (lb)	**lb**
Clothed weight: Weight of subject fully dressed in clothing, body armor, PCS – if wearing – and instrumented (lb)	**lb**
Predicted treadmill speed at 1% incline (mph)	**mph**
Maximum heart rate (bpm) predicted from age	**bpm**

hr:min	min	Fluids	√ Done
		Use water bottle #1: Drink 250 ml water when standing on treadmill	
0:00	0	Start walking	
		Nurse puts 2 met cart mouthpieces together	
0:30	30	Drink 250 ml water while walking	
1:00	60	Drink 250 ml water while walking	
1:30	90	Drink 250 ml water while walking Red odd subject on met cart for 10 min.	
1:45	105	Blue even subject on met cart for 10 min.	
2:00	120	Stop experiment; disconnect wires	

Time subject quit experiment if earlier than 120 min.	**min.**
Weight after experiment: Weight of subject in underwear briefs after test session – before drinking any more water (lb)	**lb.**
Amount of water left in 1000 ml water bottle **#1**	**ml**
Amount of water left in 1000 ml water bottle **#2**	**ml**
Amount of water left in 1000 ml water bottle **#3**	**ml**
Amount of urine excreted (ml)	**ml**

Met Cart Information to Enter
Last Name (Subject #):________________ Med Rec # (PCS#):_________________

Age:_______ Sex:_______ Height: _______in. Weight in clothing: ___________lb.

Page 2 (back) of Case Report Form

Elapsed Time (min)	Documentation of Problems (sensor breaking and being replaced, urination, etc.)

Appendix E

Preference Ballot

Subject Number______________________

Please comment on each personal cooling system. What did you like about each system? What did you not like?

PCS 01

PCS 12 Steele – phase change packets in vest

Which personal cooling system did you like the best?

_____PCS 0 (wearing none) _____PCS 01 _____PCS 12

Why?