

EC SERVICE, INC. PROTOCOL 605.019
EC Service, Inc. 915 South Frontage Road, Centerville, UT 84014

Protocol No.: 605.019

Revision No. 3

TITLE: Effect of the Kalogon AF Prototype Smart Cushion on B52 Pilot Fatigue and Comfort

Date: 31 August 2023

Supersedes: 22 August 2023

APPROVED

Approvals:

Author:  Date: 05 Sep 2023

Technician: _____ Date: _____

QA:  Date: 05 Sep 2023

Revision History

Rev #	Date	Description
0	15 August 2023	New
1	18 August 2023	Remove all references to vibration.
2	22 August 2023	Removed exclusion criteria of > 170 lbs.; added Appendix III with the height/weight requirements for the Air Force and included the source in the references section (3.8). Changed all references of “test rig” to “test seat”.
3	31 August 2023	Changed cushion name, removed V2.0

1. PURPOSE:

1.1. This study is designed to demonstrate that the AF Prototype Cushion (AF Proto) can reduce seating fatigue and improve human performance in aircraft seating.

2. SCOPE:

2.1. For testing of the AF Proto and its ability to increase comfort in a pilot’s seat in a B52 bomber, by combating seating fatigue and improving human performance for flights up to 12 hours in duration.

3. REFERENCES:

- 3.1. ISO Guide to Expression of Uncertainty in Measurement
- 3.2. EC Service SOP 807.001 Human Subject Research
- 3.3. Arsintescu, L., Kato, K. H., Cravalho, P. F., Feick, N. H., Stone, L. S., & Flynn-Evans, E. E. (2019). Validation of a touchscreen psychomotor vigilance task. *Accident Analysis & Prevention*, 126, 173-176.

- 3.4. Shen, W., & Parsons, K. C. (1997). Validity and reliability of rating scales for seated pressure discomfort. *International journal of industrial ergonomics*, 20(6), 441-461.
- 3.5. Vanacore, A., Lanzotti, A., Percuoco, C., Capasso, A., & Vitolo, B. (2019). Design and analysis of comparative experiments to assess the (dis-) comfort of aircraft seating. *Applied ergonomics*, 76, 155-163.
- 3.6. FAA Medications List.
https://www.faa.gov/ame_guide/media/DNI_DNF_tables.pdf
- 3.7. Air Force Medical Disqualifications.
<https://www.academyadmissions.com/requirements/medical/disqualifications/>
- 3.8. Air Force Weight Requirements. <https://www.military.com/military-fitness/air-force-fitness-requirements/air-force-height-and-weight-charts>

4. EXPERIMENTAL DESIGN:

4.1. Subjects

- 4.1.1. This study will be conducted with 22 healthy subjects.
- 4.1.2. Inclusion criteria for healthy subjects:
 - 4.1.2.1. Signed informed consent
 - 4.1.2.2. 18 – 35 years old
 - 4.1.2.3. Ambulatory
 - 4.1.2.4. Able to sit for up to 12 hours with minimal breaks
 - 4.1.2.5. Able to follow instructions in English
- 4.1.3. Exclusion criteria:
 - 4.1.3.1. Weight < 91 lbs. and > 250 lbs.
 - 4.1.3.1.1. Priority will be given to those who are within the ranges found in Appendix III.
 - 4.1.3.2. Pregnant
 - 4.1.3.3. Travel across time zones in the last 7 days
 - 4.1.3.4. Chronic pain
 - 4.1.3.5. Taking any of the medications not allowed by the FAA including:
 - 4.1.3.5.1. Opiates
 - 4.1.3.5.2. Muscle relaxants
 - 4.1.3.5.3. Anticholinergics
 - 4.1.3.5.4. Sedating antihistamines
 - 4.1.3.5.5. Anti-psychotics
 - 4.1.3.6. Any of the following conditions:
 - 4.1.3.6.1. Asthma or other bronchospasm diagnoses
 - 4.1.3.6.2. Abnormalities of the heart valves, major vessels, heart rate or rhythm, any condition leading to poor circulation, increased risk of blood clots
 - 4.1.3.6.3. Chronic disease of abdominal organs including: hepatitis and inflammatory bowel disease
 - 4.1.3.6.4. Un-united fractures, instability of a major joint, retained orthopedic fixation devices, severe scoliosis, or disorder of the skeletal muscles
 - 4.1.3.6.5. Psoriasis

- 4.1.3.6.6. Psychosis, schizophrenia, or other severe mental health disorder
- 4.1.3.6.7. Seizure disorders
- 4.1.3.6.8. Sleeping disorders
- 4.2. Metrics of interest
 - 4.2.1. Psychomotor Vigilance Task (PVT)
 - 4.2.1.1. Administered pre- and post-trial
 - 4.2.2. Subjective Fatigue Survey
 - 4.2.2.1. Administered as a start-trial, mid-trial and end-trial
 - 4.2.2.2. Perceived discomfort portion: CR-10 scale with a local discomfort map
 - 4.2.2.3. Perceived comfort portion: Seating Comfort Form
- 5. MATERIALS
 - 5.1. Apparatus:
 - 5.1.1. B52 seat
 - 5.1.1.1. Frame
 - 5.1.1.2. Cushion
 - 5.1.1.3. Harness
 - 5.2. Flight suit
 - 5.3. Devices to administer the PVT
 - 5.4. Flight simulator or other video game equipment
- 6. PROCEDURES:
 - 6.1. The study consists of each subject undergoing 2 trials, one on the Kalogon AF Prototype cushion and the other on the standard B52 cushion, which serves as the control. The order of each trial will be randomized for each subject.
 - 6.2. Each trial will consist of 2 subjects participating at the same time, one on each cushion.
 - 6.3. **Recruitment and Intake:**
 - 6.3.1. Subjects will be recruited as outlined in section 4.1 and will receive information about the study and provide informed consent for participation.
 - 6.3.2. Subjects will be given a time to report for their first trial.
 - 6.4. **Data Collection –**
 - 6.4.1. At the time of their trial, they will be provided a standard flight suit to wear for the study and a place to change.
 - 6.4.2. The subject will be provided with a device and will take the pre-trial PVT.
 - 6.4.3. The subject will be taken to the B52 test seat and be shown what they will need to do during the trial.
 - 6.4.3.1. The subject will be performing tasks meant to maintain their focus and be actively thinking, including video games, flight simulator, puzzles, etc.
 - 6.4.4. The subject will be strapped into the test seat and a timer will be started to begin the trial.

- 6.4.4.1. If the subject experiences any adverse events, harm, or no longer wishes to participate, the trial will be terminated immediately and the subject will receive appropriate care as necessary.
- 6.4.5. The subject will have the start trial Subjective Fatigue Survey administered.
- 6.4.6. The subject will perform the task as described in 6.4.3.1 while strapped into the test seat for up to 12 hours.
 - 6.4.6.1. The subject is allowed minimal short breaks to use the restroom during the trial.
 - 6.4.6.2. The subjects will be instructed to bring a meal and it will be consumed while strapped into the test seat.
- 6.4.7. The mid-trial Subjective Fatigue Survey will be administered in the middle of the trial time.
- 6.4.8. At the end of the trial time, while still strapped into the test seat, the subject will have the end-trial Subjective Fatigue Survey administered.
- 6.4.9. The subject will again be provided with a device to take the post-trial PVT.
- 6.4.10. The subject will be assigned another time to complete their second trial.

END OF PROTOCOL

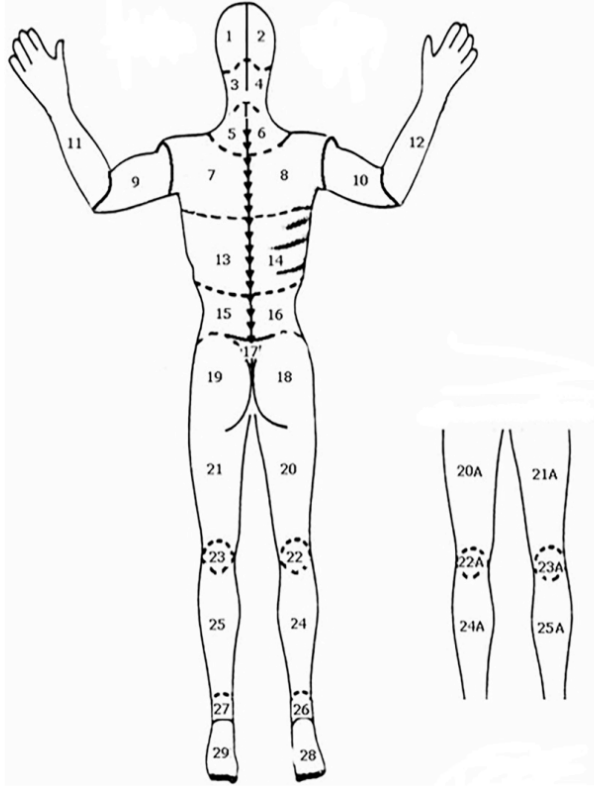
APPENDIX I

Risk Component	Risk Mode	Description of Risk or Outcome to Participant	Preventative Action	Justification/ Notes
1	Sitting on a cushion	Uninterrupted sitting, or getting used to a new cushion	Selection of healthy participants with no vascular or musculoskeletal diagnoses, limited bathroom breaks	Application of study results to target population requires being seated for the duration of the study.
			Participants are able to terminate their participation at any point, for any reason, including experiencing pain and discomfort beyond what they are comfortable with.	Promoting volunteer safety while maintaining the integrity of the study.
2	Volunteer discomfort, toileting avoidance and stiff joints from not moving.	Toileting discomfort and stiff joints from not moving	Provide method of asking volunteer to toilet and prep with bathroom trips in advance, provide breaks periodically to allow toileting.	Providing proper test environment with toileting opportunity before and during tests.
3	Watching a screen	Eye strain from focusing on a screen for up to 12 hours with minimal breaks	Target study population is healthy, the screen will be a safe distance away in a well-lit area and at the proper height. Will be allowed short breaks.	Application of study results requires volunteers to have their mind actively engaged during the study. Screens are an integral part of everyday life. Target study population is also known for their use of technology and gaming.
4	HIPAA violation.	Accidental disclosure of personal information.	Not gather identifying information, only physical description and metrics of interest will be collected from therapist. A release and payment related forms are required, but will not be associated with medical record data.	All information that is gathered to be stored in a secure format and held in secure files on a secure server. All data will be stored in an encrypted folder requiring password entry.
5	Economic.	Economic inducement to be balanced with description of right to end participation at any time.	Data collection personnel and aids are to judge willingness verses inducement to participate. No external pressure may be used to coerce participation.	Financial reward for participation is considered fair compensation for time. No undue inducement is intended. Participants will be informed of their right to end participation in the study at any time before beginning the study.

Table 1. Risk Summary

APPENDIX II

Subjective Fatigue Survey – Discomfort Assessment



Discomfort Intensity	
0	Nothing at all
0.5	Extremely Weak
1	Very Weak
2	Weak (Light)
3	Moderate
4	Strong
5	
6	Very Strong
7	
8	
9	
10	Extremely Strong

Subjective Fatigue Survey – Comfort Assessment

1. The cushion padding is comfortable.
2. The cushion fits comfortably under buttocks.
3. The cushion fits comfortably under thighs.
4. The cushion fits comfortably behind knees.
5. The backrest padding is comfortable.
6. The backrest fits comfortably at shoulders.
7. The backrest fits comfortably at middle back.
8. The backrest fits comfortably at low back.
9. The lumbar support is comfortable.
10. The seat does not make you feel slipping down.
11. The seat does not make you feel forward thrusting.
12. The seat does not make you feel sinking into the cushion.
13. The seat is comfortable.

Figure 1. Subjective Fatigue Survey, Discomfort and Comfort Sections

APPENDIX III

New Air Force Weight Requirements		
Height (Inches)	Min. Weight (Pounds)	Max Weight (Pounds)
58	91	131
59	94	136
60	97	141
61	100	145
62	104	150
63	107	155
64	110	160
65	114	165
66	117	170
67	121	175
68	125	180
69	128	186
70	132	191
71	136	197
72	140	202
73	144	208
74	148	214
75	152	220
76	156	225
77	160	231
78	164	237
79	168	244
80	173	250

Table 2. Air Force Height/Weight Requirements