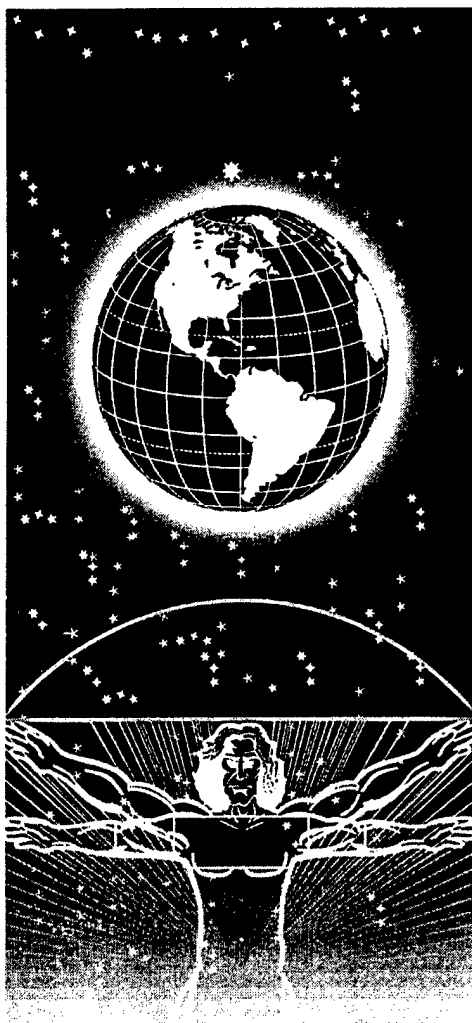




UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE SPACELABS MEDICAL, INC., ULTRAVIEW MODELS 1030 & 1050 PATIENT MONITORS

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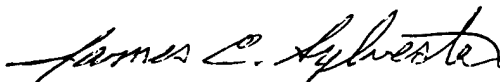
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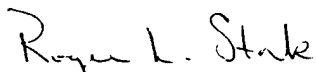
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TESTING AND EVALUATION OF THE SPACELABS MEDICAL, INC., ULTRAVIEW MODELS 1030 & 1050, PATIENT MONITORS

BACKGROUND

Spacelabs Medical requested the Air Force Medical Equipment Development Laboratory's (AFMEDL) participation in evaluating and approving the Spacelabs Medical, Inc., Ultraview, Models 1030 & 1050, Patient Monitors for use on board USAF aeromedical evacuation aircraft. Specific components of the Spacelabs Medical, Inc., Ultraview, Models 1030 & 1050, Patient Monitors that underwent the evaluation process included: the Spacelabs Medical basic units 1030 (P/N: 90367Z) & 1050 (P/N: 90369Z); model 1050 Command Module (P/N: 90469Z-1AHRVS, S/N: Par 1 020); software versions 0.09.09 & 1.00.06EN; 10-lead ECG patient cable (P/N: 700-0008-00); 24 inch snap-style ECG lead wires (P/N: 700-0007-16); Nellcor adult oxygen finger sensor (P/N: DS-100A); SL invasive pressure cable (P/N: 700-0028-01); SL temperature adapter cable (P/N: 700-0031-01); SL SPO₂ adapter cable (P/N: 700-0030-01); power supply, model 100-DOD (P/N: 119-0251-02, S/N: 0623-003); batteries (P/N: 146-0018-00); and aircraft mounting kit AF1 (P/N: 016-0519-00). All components of the models 1030 & 1050 were tested for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the models 1030 & 1050.

DESCRIPTION

The EUT is a lightweight, compact, portable patient care monitoring system. The EUT provides diagnostic data in the form of 10-Lead ECG, SPO₂, invasive & noninvasive B/P, temperature, and cardiac output (not tested). The EUT integrates functional controls by way of touch-screen technology. All input diagnostic data is stored internally for up to 24 hours or printed directly. The unit operates off of 115 VAC/60 Hz and internal rechargeable battery. The unit weighs approximately 13.56 lbs. with internal batteries and 10.76 without internal batteries. Its dimensions are 11.75 in. W. X 8.36 in. H. X 6.12 in. D. The power supply is 4.5 in. W. X 2.95 in. H. X 9.36 in. D. and weighs 2.88 lbs. (Figure 1).

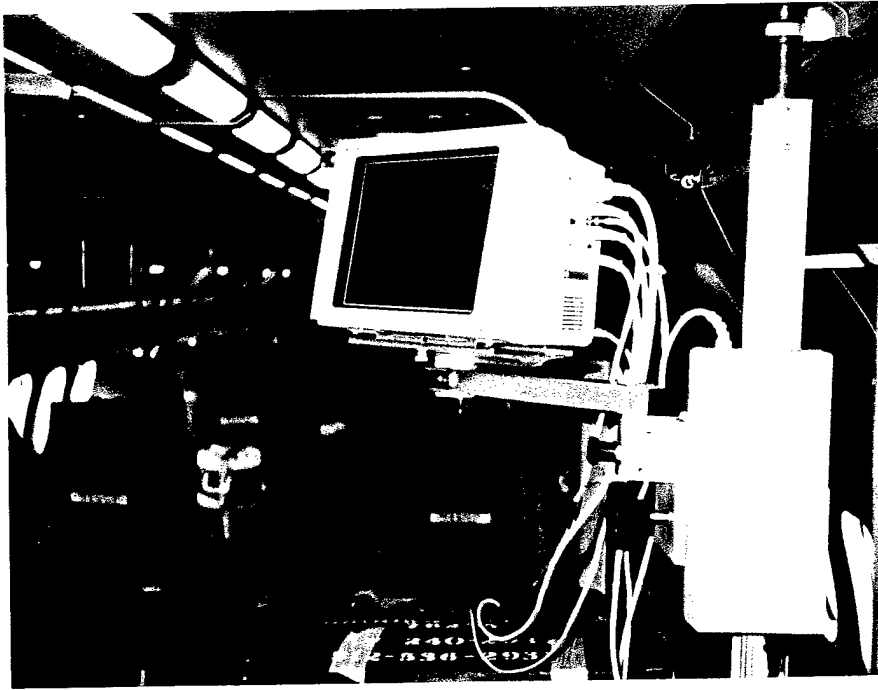


Figure 1. Spacelabs Medical, Inc., Ultraview, Models 1030 & 1050, Patient Monitors

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-8), and manufacturer's literature (9). The AFMEDL Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check was developed specific to this EUT to verify its proper functioning under various testing conditions. All tests were conducted by (AFMEDL) personnel assigned to the Systems Research Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas unless otherwise noted.

The EUT was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Electromagnetic Interference (EMI)

4. Thermal/ Humidity Environmental Conditions, encompassing:

- a. Hot Operation
- b. Cold Operation
- c. Humidity Operation
- d. Hot Temperature Storage
- e. Cold Temperature Storage

5. Hypobaric Conditions

- a. Cabin Pressure/Altitude
- b. Rapid Decompression to simulated flight level

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (3); AFI 41-201, Equipment Management in Hospitals (4). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.

c. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472 (5).

d. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The EUT was prepared for tests as follows:

- 1. Placed EUT on a level surface
- 2. Insert expansion module
- 3. Connect ECG, SPO₂, invasive & non-invasive B/P, and temperature cables to labeled ports on expansion module

4. Inserted batteries into battery compartment
5. Plug EUT into 115VAC/60 Hz power
6. Connect other ends of ECG, SPO₂, invasive & non-invasive B/P, and temperature cables to their respected analyzers/patient simulators
7. Turn EUT on by pushing in the on/off button located at the lower left corner of EUT and waited for EUT to perform a self-test
8. Self-test complete turn on all analyzers/patient simulators
9. Input the following patient parameters: ECG at 80 bpm, SPO₂ at 98%, invasive at 30/10, non-invasive B/P at 120/80, and temperature probe indicating ambient temperature. The display screen on EUT will verify the input parameters.

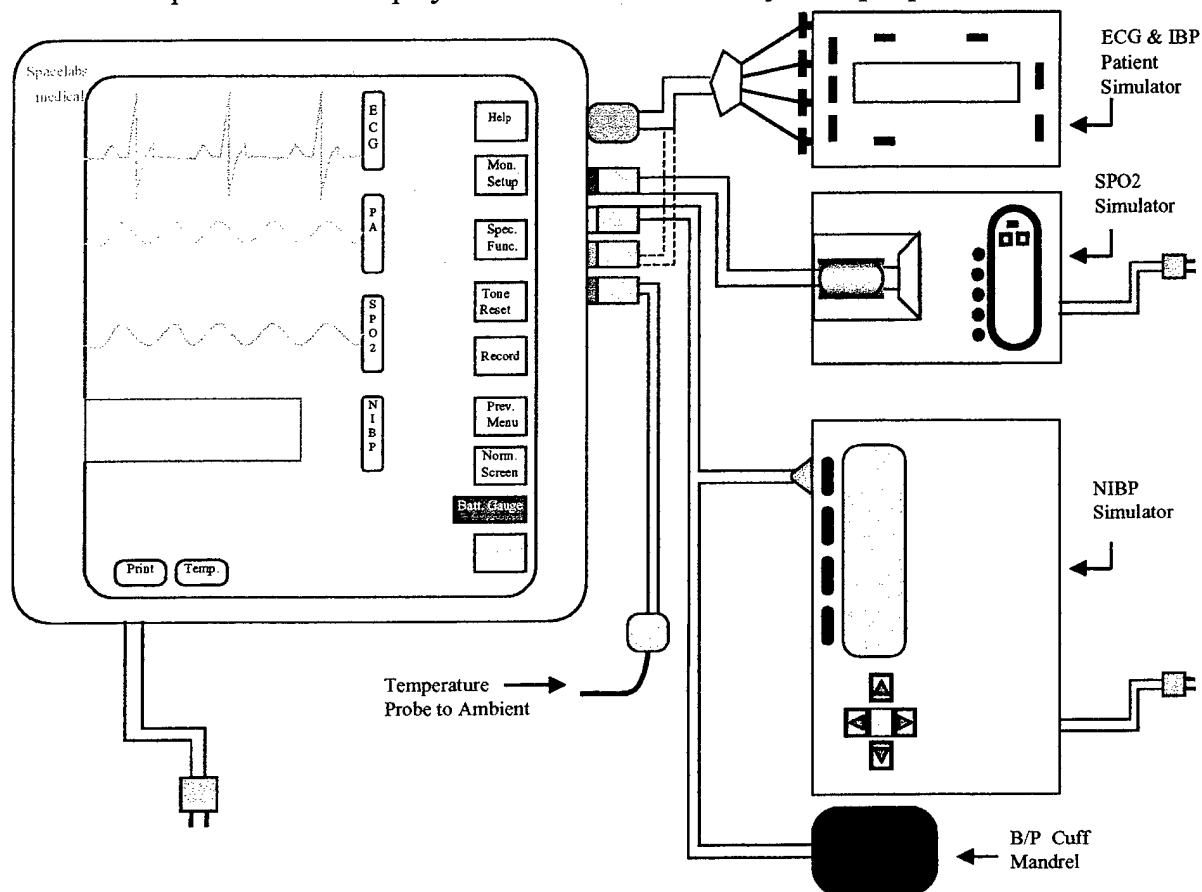


Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions: Connect ECG, SPO₂, invasive & non-invasive B/P, and temperature cables to analyzers/patient simulators and connect other end to outlets on EUT. Configure the EUT and simulators IAW TEST SETUP. Turn the EUT on by pushing in the on/off button located at the lower left corner of EUT. Wait for EUT to perform a self-test. With self-test complete on EUT, turn on all analyzers/patient simulators. The screen will show you

dialled in parameters and EUT operational characteristics. Operational data was recorded three times at one-minute intervals for trend analysis. Battery Operation as outlined in Spacelabs Medical Inc., Operation Manual (9)

VIBRATION

Vibration testing is critical to determine, "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT was secured to an aircraft station pole segment, using a mounting bracket provided by manufacturer. The station pole segment with the EUT was secured to the vibration table as it would be secured in the aircraft. The EUT was subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 3).

Sine-on-Random Curves

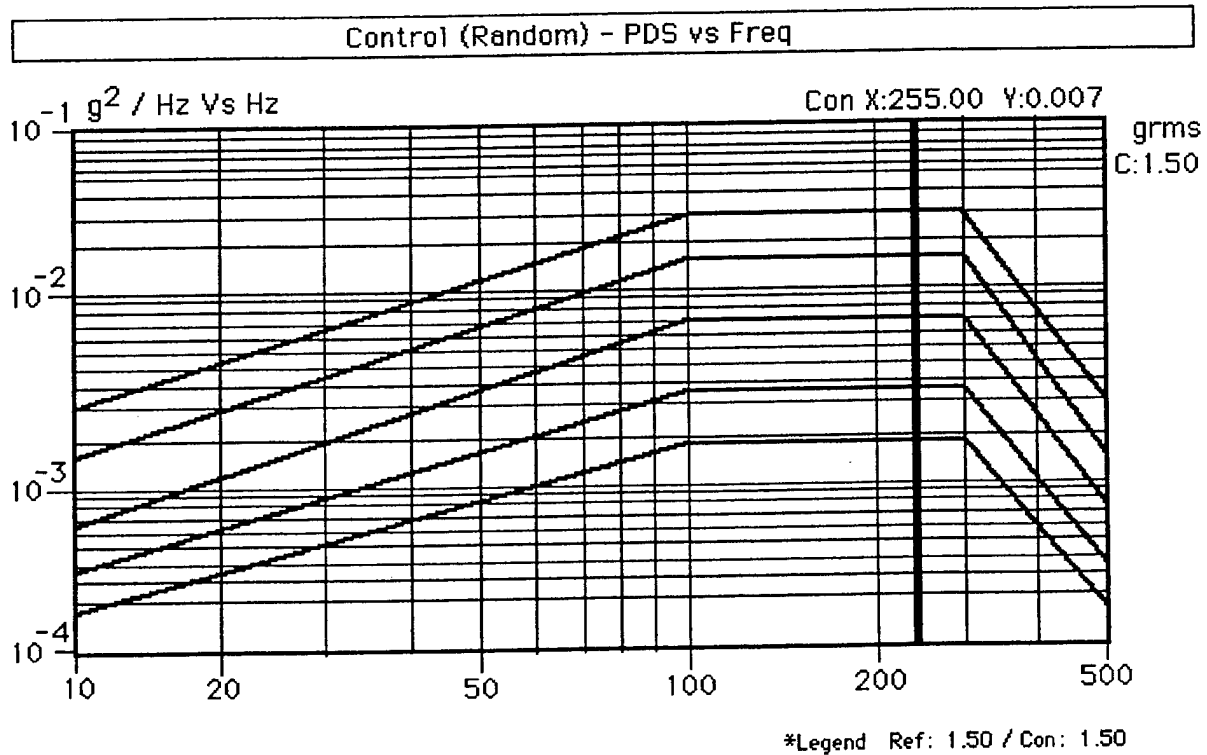
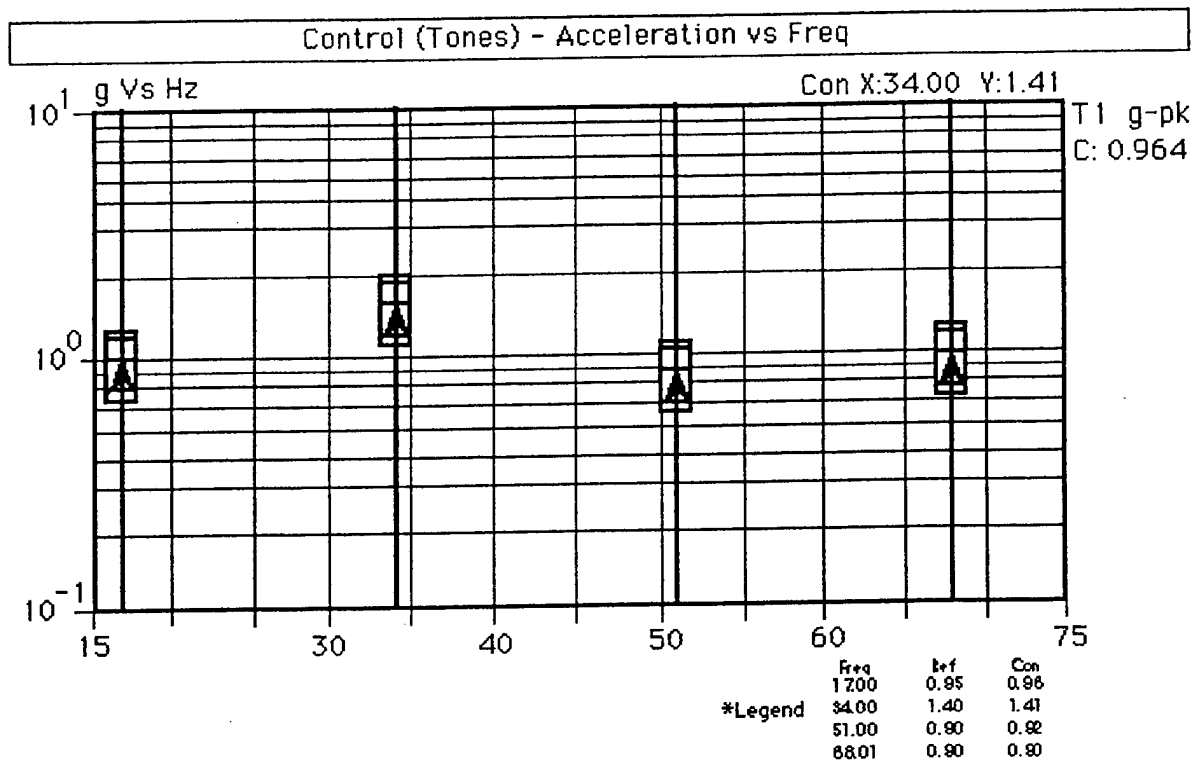


Figure 3, A and B. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

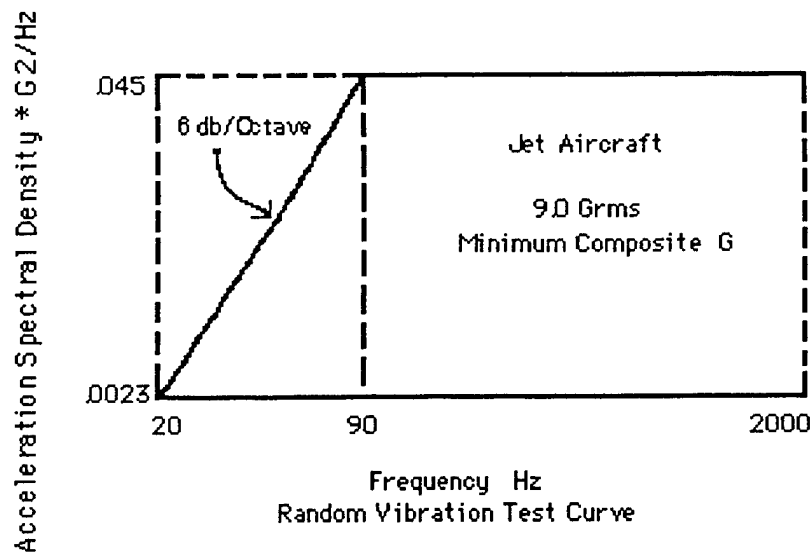


Figure 3, C. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor to assessing the effects of excessive electromagnetic interference (EMI) emissions and potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the EUT along its power supply lines. It was performed to assess the EUT's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category, Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

g. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances."

During emissions testing, all EUT's electrical components were operating for the duration of the test to create the worst case emissions scenario. In these tests, the EUT was programmed to receive input signals simulating patient responses NIBP - 120/80, IBP - 30/10, SPO₂ - 98%, ECG - 60 bpm, and temperature reading ambient conditions. For both emissions and susceptibility testing, the EUT was tested for operation using 115 VAC/60 Hz and internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, corrosion,

changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the calibrated Thermotron Industries, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. All input and output cables, wires, and patient breathing circuit were routed through ports in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained non-operational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hr
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hr
- c. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hr
- d. Hot Temp Storage: $140^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($60^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr
- e. Cold Temp Storage: $-40^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($-40^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabins to barometric pressures equivalent to 8,000 - 15,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 15,000 ft; stopping at 2,000 ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000 - 12,000 ft/min. The test was repeated twice more; once for a 7 second RD and once for a 1 second RD. The EUT was monitored throughout the series of decompressions. Performance checks were assessed each time the EUT returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT's ability to provide patient care onboard USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

Flight qualified AFMEDL aeromedical crewmembers flying on C-9 & C-130 aeromedical evacuation missions conducted this phase of testing. The EUT was positioned and secured to an aircraft stantion pole using the mounting bracket provided by the manufacturer and/or on a NATO litter using litter straps and litter equipment brackets. Then human factor characteristics were evaluated, e.g., securing methods, setup/tear down times and securing locations evaluated. Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits. Battery Endurance revealed operation time well within manufacturer's specifications. The battery operated the EUT for approximately 3.1 hours. The EUT exceeded manufacturer's specifications regarding recharge times. The EUT takes approximately 3 hours to indicate full recharge of the internal batteries, exceeding the 1.5 hours stated in the Owners Manual.

VIBRATION

During evaluation, the EUT was programmed to receive input signals simulating patient responses NIBP - 120/80, IBP - 30/10, SPO₂ - 98%, ECG - 80 bpm, and temperature reading ambient conditions to assess the EUT's ability to function without the possibility of system failure. The unit performed according to manufacturer's specifications and AFMEDL guidelines without any system failure or malfunction.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft (including small and large body, fixed and rotary wing) while operating from 115 VAC/60 Hz and internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT experienced problems during cold storage testing. The EUT's flat-panel, liquid crystal display took 1.5 hours to recover from -40°C exposure. The standard maximum recovery time is one hour following cold storage exposure. The flat-panel display could not display input diagnostic information needed to diagnosis a patient's condition until it had returned to a more liquefied state. AFMEDL engineers suggest refraining from subjecting the EUT to environmental temperatures below those outlined in the manufacturer's literature. The company representative informed AFMEDL staff that the technology used in flat-panel display design could not recover more quickly and opted not to attempt correction. The EUT operated according to AFMEDL and manufacturer's guidelines during hot and cold operation, hot storage, and humidity testing.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit was able to receive and display input signals simulating patient responses. The EUT was programmed with the following data, NIBP - 120/80, IBP - 30/10, SPO₂ - 98%, ECG - 80 bpm, and temperature reading ambient conditions without system failure up to 15,000 ft cabin altitude.
2. Rapid Decompression: The EUT operated satisfactorily following each decompression event.

AIRBORNE PERFORMANCE

The in-flight evaluation of the EUT was performed on a C-9 and two separate C-130 aeromedical evacuation missions. First evaluation the EUT experienced an event with the IBP option. The unit would need to be recalibrated periodically to maintain accuracy of input data to the IBP transducer. After further analysis by AFMEDL staff, it was determined that the need for recalibration was due to barometric pressure changes. AFMEDL recommends implementing a caveat to the owners' manual to remind users the IBP may need frequent, internal recalibration in flight. Simulated patient movement and/or aircraft vibration of the unit caused SpO₂ to be a little erratic; therefore, it should be used for trend analysis. Analysis of performance data indicated this unit was easy to enplane and deplane. The EUT was secured to a NATO litter using litter straps and litter equipment brackets. During evaluation it was determined that manufacturer's mounting system adapts to most stantion poles on board USAF aircraft. An exception was the combination, utility stantion on the C-9A. Some other considerations include limitations on hearing audible alarms with hearing protection. Crewmembers need to rely on visual prompts which could be viewed up to 7 feet away.

SUMMARY

AFMEDL found the Spacelabs Medical, Inc., Ultraview, Models 1030 & 1050, Patient Monitors to be conditionally acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating from 115 VAC/60 Hz and internal battery power. See recommendations listed below. Its operation was within expected parameters when subjected to electromagnetic interference (EMI), most environmental extremes, simulated cabin altitudes. It did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

- a. The unit was assessed with the following modes operating, NIBP, IBP, SPO₂, Temp and ECG. Cardiac Output mode was not assessed per manufacturer decision.
- b. EUT audible alarms are limited in volume intensity with hearing protection on. Crewmembers must rely on visual prompts, which could be viewed with proper placement up to 7 feet away.
- c. Problems seen during cold storage evaluation were the unit's inability to recover from exposure to - 40°C within the allotted one hour period. The flat-panel display could not display input diagnostic information needed to diagnosis a patient's condition until it had returned to a more liquefied state. AFMEDL engineers suggest refraining from subjecting the EUT to environmental temperatures below those outlined in the manufacturer's literature.
- d. As with any pulse oximeter, patient movement or vibration of the unit may cause pulse rate and SpO₂ to be erratic and unreadable; therefore, it should be used for trend analysis.
- e. Battery endurance revealed operation time well within manufacturer's specifications. The battery operated the EUT for approximately 3.1 hours. The EUT exceeded manufacturer's specifications regarding recharge times. The EUT takes approximately 3 hours to indicate full recharge of the internal batteries, exceeding the 1.5 hours stated in the Owners Manual. Suggest changing manufacturer literature to reflect new recharge times.

Any public announcement of this interim report shall be coordinated between Spacelabs Medical, AFRL, AFMEDL and the Brooks AFB Public Affairs Office. Spacelabs Medical shall not use the name of the Air Force Activity or the Government on any product or service, which is directly or indirectly related to this interim report. This laboratory or the Government does not directly or indirectly endorse any product or service provided, or to be provided, by Spacelabs Medical, its successors, assignees, or licensees. Spacelabs Medical shall not in any way imply that this technical report is an endorsement of any such product or service.

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. Emergency Care Research Institute (ECRI)
3. AFI 41-203, Electrical Shock Hazards
4. AFI 41-201, Equipment Management in Hospitals
5. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. Spacelabs Medical, Inc., Ultraview, Models 1030 & 1050, Patient Monitors, Owners Manual.
10. AFMEDL Procedures Guide, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF
SPACELABS MEDICAL, INC., ULTRAVIEW,
MODELS 1030 & 1050, PATIENT MONITORS

SPECIFICATIONS

General

Size: (Monitor)	11.75 in. W. X 8.36 in. H. X 6.12 in. D.
(Pwr. Supply)	4.5 in. W. X 2.95 in. H. X 9.36 in. D.
Weight: (Monitor)	10.76 lbs. without batteries and 13.56 lbs. with batteries.
(Pwr. Supply)	2.88 lbs.
Operating Modes:	ECG, NIBP, IBP, SPO ₂ , TEMP, CO ₂ , & Cardiac Output (NOT EVALUATED), all print capable and alarm limited.
Display:	Electroluminescent, resolution – 640 X 400 pixels, size 7.5 in. W X 4.69 in. H. With touch screen controls and 3 – 4 waveform capacity
Power: (Monitor)	12-24 VDC
(Pwr. Supply)	115 VAC/60 Hz and internal rechargeable battery.
Operating time:	Removable, Internal batteries: 2 hours (2.3 Ahr, 12VDC sealed lead-acid. External AC: Continuous
Environmental	Temperature: -0°C to 50°C (operating). -40°C to 75°C (storage temperature). Humidity: 10 – 95% (noncondensing). Altitude: 0 – 40,000 ft (storage). 0 – 15,000 ft (operating)