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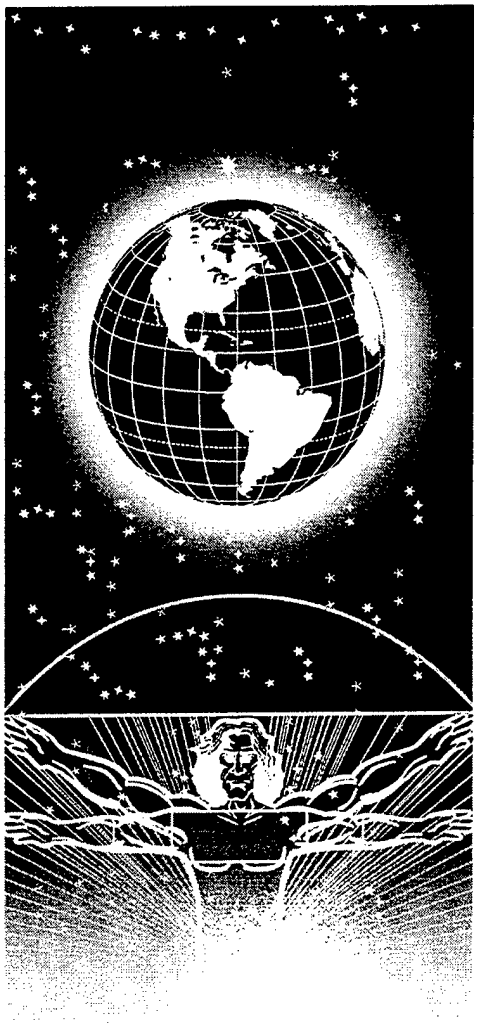

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE PHYSIO-CONTROL, INC., LIFEPAK 500 AUTOMATED EXTERNAL DEFIBRILLATOR

James C. Sylvester, Major, USAF, NC

HUMAN EFFECTIVENESS DIRECTORATE
FLIGHT STRESS PROTECTION DIVISION
SYSTEMS RESEARCH BRANCH
2504 Gillingham Drive, Suite 25
Brooks AFB, Texas 78235-5104

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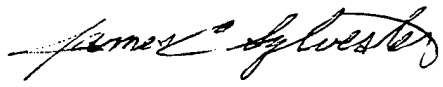

JAMES C. SYLVESTER, Major, USAF, NC
Chief, Aeromedical Research

ROGER L. STORK, Colonel, USAF, BSC
Chief, Crew Technology Division

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James C. Sylvester, Major

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Air Force Research Laboratory (AFMC)
Human Effectiveness Directorate
Flight Stress Protection Division
2504 Gillingham Dr. STE 25
Brooks AFB TX 78235-5104

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Physio-Control, Inc. model LP500, automatic external defibrillator is a portable, battery-powered device that provides defibrillation therapy to patients in cardiac crisis. Specific components of the model LP500, automatic external defibrillator include: model LP500, automatic external defibrillator basic unit, Quick-Combo pacing/defibrillation/ECG electrodes with REDI-PAK pre-connect system (P/N 3008497), LP500 rechargeable sealed lead-acid (SLA) battery pack (P/N 3005379), LP500 battery charger (P/N 3006535), and LP500 carrying case (P/N 3005343). The unit operates on a rechargeable SLA battery pack. The unit weighs approximately 2.76 Kg or 6.1 lb. and is 10.5 in. W. X 4.0 in. H. X 11.6 in. D. The battery charger weighs approximately 0.9 Kg or 1.9 lb.

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TESTING AND EVALUATION OF THE PHYSIO-CONTROL, INC., LIFEPAK 500 AUTOMATED EXTERNAL DEFIBRILLATOR

BACKGROUND

The Physio-Control company requested Aeromedical Research's participation in evaluating and approving their model LP500, automatic external defibrillator for use on board USAF aeromedical evacuation aircraft. Specific components of the model LP500, automatic external defibrillator evaluated included; model LP500, automatic external defibrillator basic unit, Quick-Combo pacing/defibrillation/ECG electrodes with REDI-PAK pre-connect system (P/N 3008497), LP500 rechargeable sealed lead-acid (SLA) battery pack (P/N 3005379), LP500 battery charger (P/N 3006535), and LP500 carrying case (P/N 3005343). All components of the model LP500, automatic external defibrillator were tested for air worthiness. Throughout this report the term Equipment Under Test (EUT) refers to the model LP500, automatic external defibrillator.

DESCRIPTION

The EUT is a portable, battery-powered device that provides defibrillation therapy to patients in cardiac crisis. The unit operates on a rechargeable SLA battery pack. The unit weighs approximately 2.76 Kg or 6.1 lb. and is 10.5 in. W. X 4.0 in. H. X 11.6 in. D. The battery charger weighs approximately 0.9 Kg or 1.9 lb.

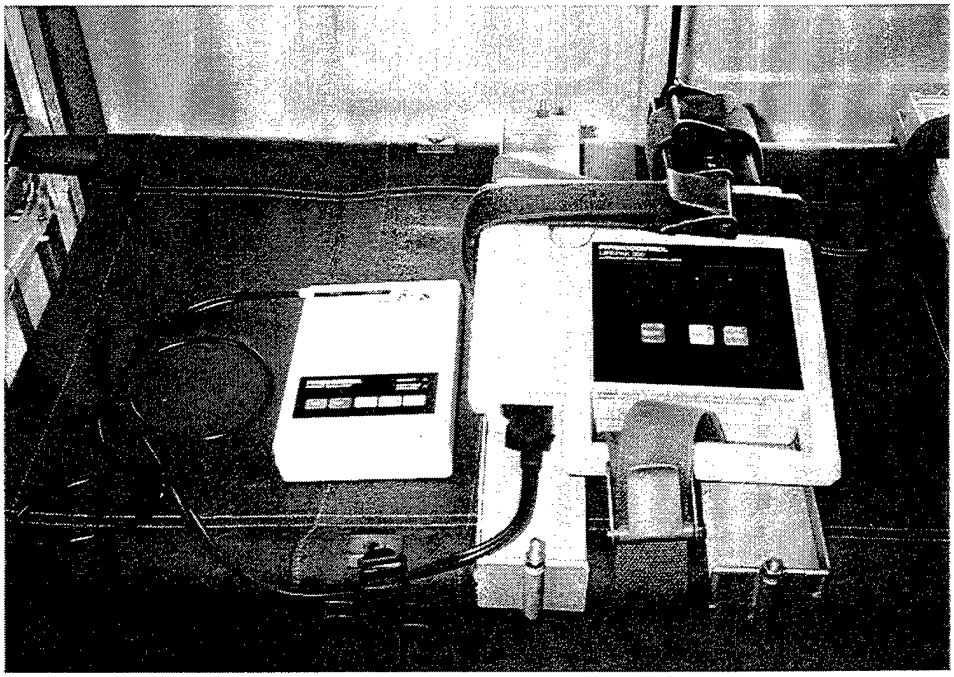


Figure 1. LifePak 500 Automated External Defibrillator

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 5), various military standards (2-4 & 6-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check were developed specific to this EUT to verify its proper functioning under various testing conditions. All tests are conducted by Aeromedical Research personnel assigned to the Systems Research Branch (CFTS), Crew Technology Division, Armstrong Laboratory, Brooks AFB, TX, unless otherwise noted.

The EUT was subjected to various laboratory and inflight 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 Ambient Pressure

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, (2); AFI 41-201, and Equipment Management in Hospitals, (3). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz and 115 VAC/400 Hz.

c. The EUT was examined to ensure it met basic requirements for human factors design as outlined in MIL-STD 1472 (4).

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

TEST SETUP

The EUT was placed on a level surface. Attach the EUT's test electrode (s) snaps to their appropriate [connector/extended] and insert into the center of the respective pad on a Impulse 4,000 Defibrillator/Pacer analyzer. Attach the two electrode leads to the corresponding color coded) receptacles on the EUT and select analyzer setting codes: Dif; energy; high; vfib.

Insert battery into EUT. Turn unit on by pressing the green "on" button. The Advisory function will instruct you to either connect the electrodes or press the yellow "analyze" button.

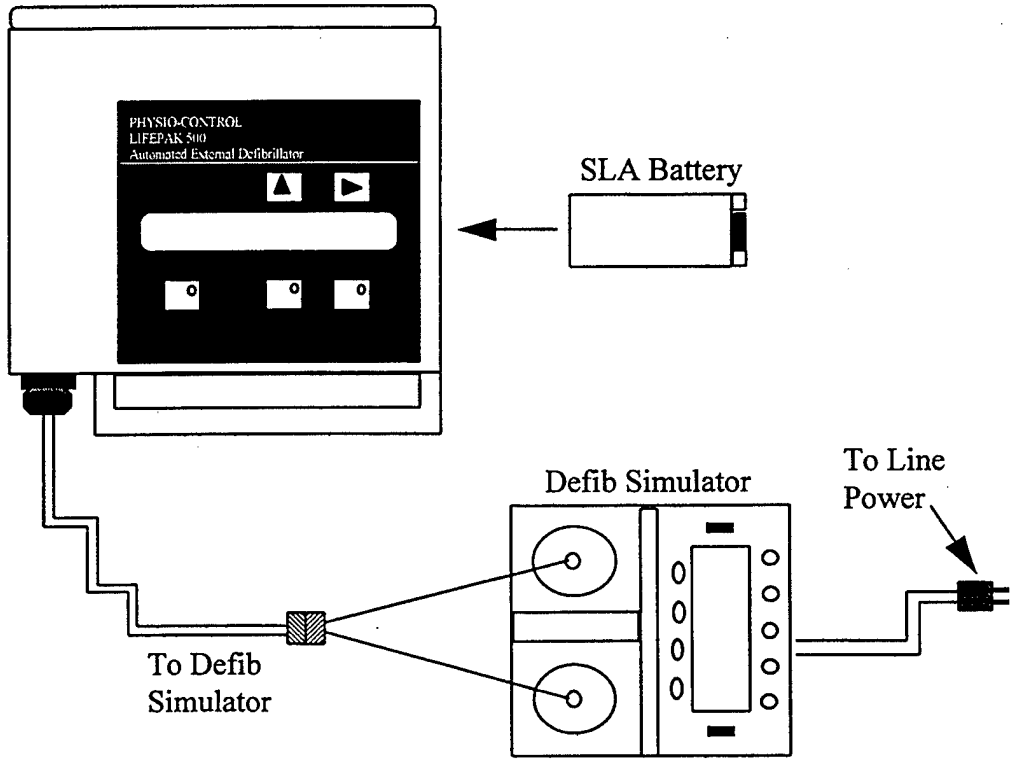


Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions: Insert appropriate end of the EUT simulator test lead (s) into the EUT and connect the other end to each of the defibrillator simulator test points. Configure the EUT and simulator IAW TEST SETUP. Push green "on" button on EUT. Advisory "voice" should instruct the operator to press the yellow "analyze" button. With the simulated arrhythmia (vfib) being sent by the defibrillator simulator, the EUT will cycle through a series of three different shock levels and then instruct the operator to perform cardiopulmonary resuscitation (CPR). Record the energy level read by the defibrillator simulator after each of these three shocks.

Battery Operation as outlined in Phsyio-Control Inc., Operation Instructions (9) - The battery pack can be recharged from the external 115 VAC source in 10 □ 1 hours.

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's components were mounted on a NATO litter segment on the vibration table as it would be secured in the aircraft (Figure 3). They were 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 4).

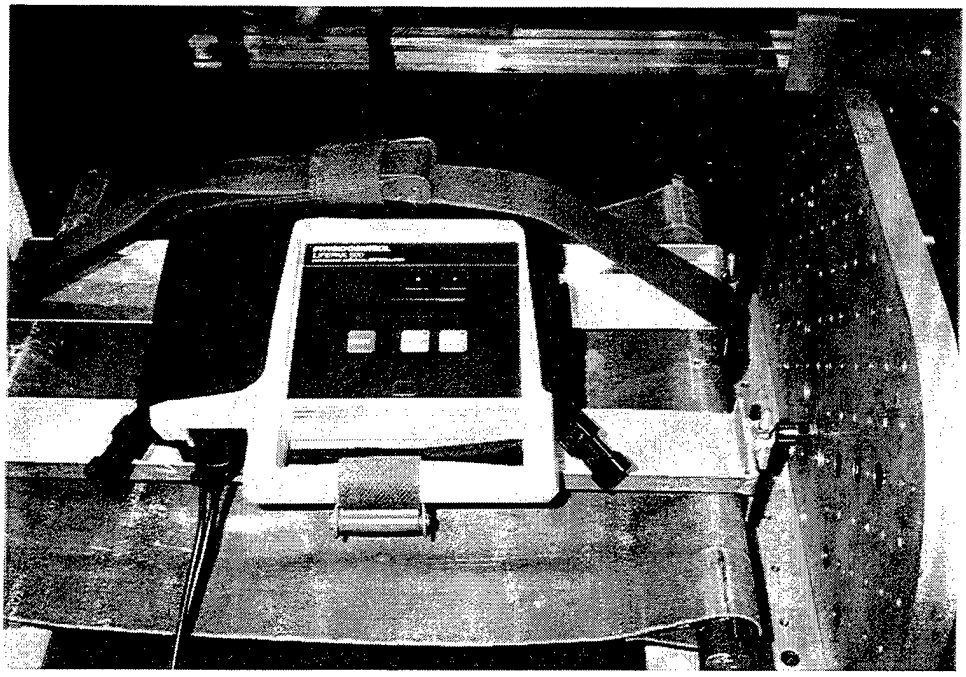
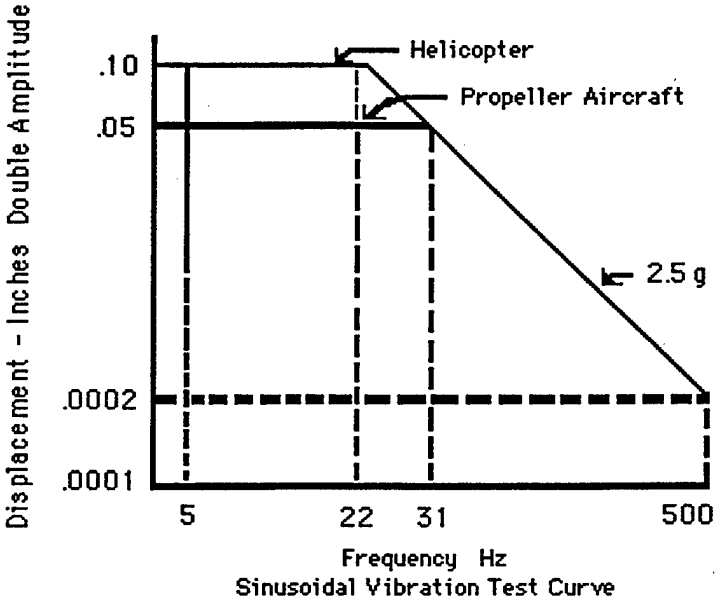


Figure 3. Vibration Table Mounting



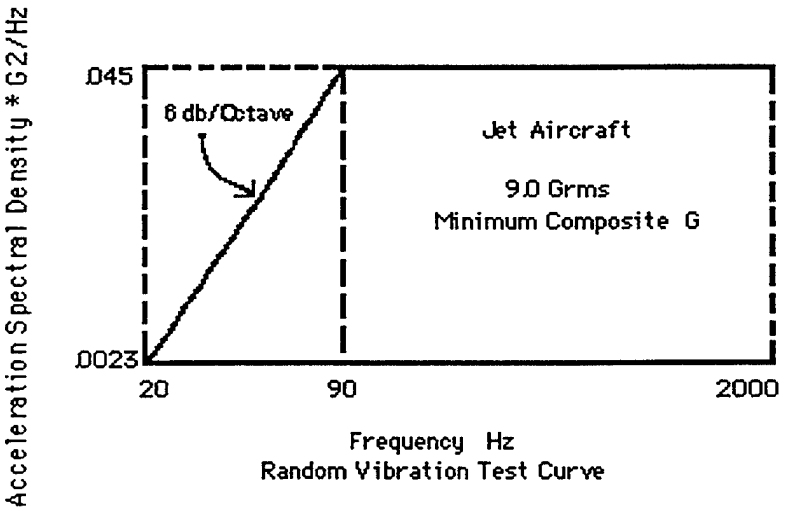


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

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 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 operated in the maximum vacuum mode. For susceptibility testing, the EUT was operated again in the maximum vacuum mode. For both emissions and susceptibility testing, the EUT was tested for operation on 115 VAC / 60, 400 Hz, and internal batteries.

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

Testing was conducted in the Armstrong Laboratory's Thermotron Industries, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port 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 nonoperational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hr

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hr

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hr

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hr

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°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 cabin atmosphere to barometric pressures equivalent to 8,000-10,000 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 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground, at rates of 5,000 ft/min. Descent is stopped at 2,000 ft for performance checks.

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 endanger a patient, personnel, or the aircraft itself. 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 unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research verifies demonstration of all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members from Aeromedical Research on C-9 & C-141 aeromedical evacuation missions. The EUT was positioned and secured to the aircraft stantion pole and evaluated. Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from other aeromedical evacuation crew members participating in delivery of patient care 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 Performance** revealed 67 operational discharges from a fully charged battery, well within manufacturer's specifications. **Battery Charge Time** revealed a 10 hour & 13 minute recharge time well within manufacturer's specifications.

VIBRATION

The unit performed according to manufacturers specifications. No premature delivery of stored energy to defibrillator simulator or unit degradation noted.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft while operating from the SLA rechargeable battery. The battery recharger is also certified for use in the aeromedical evacuation system on all U.S. Air Force aircraft while operating from 115 VAC / 60 Hz power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT operated satisfactorily during all five phases of testing.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit was able to deliver shocks IAW Advanced Cardiac Life Support directives at 10,000 ft cabin altitude.

2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on C-9 & C-141 aeromedical evacuation missions. Evaluation confirmed that the unit would operate successfully during all phases of flight. Analysis of performance data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems. It was noted the audible alarms could not be heard easily in a high noise environment and visual alarms can be seen up to six feet, but you have to be looking straight at the front of the unit.

SUMMARY

Aeromedical Research found the Physio-Control, Inc., Lifepak 500 Automated External Defibrillator to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating on battery. The battery charger is also acceptable for use on all U.S. Air Force aeromedical evacuation aircraft operating off 115 VAC / 60 Hz power. Its operation was within expected parameters when subjected to environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

a. Inform Aircraft Commander that a defibrillator will be in use on board, and that they will be notified if defibrillation is to occur because of the possibility of electromagnetic interference with aircraft navigation and communication equipment.

b. In certain aircraft such as the C-130/C-141 special training considerations may apply. Considerations include limitations on hearing verbal prompts and the need for auxiliary lighting during periods of low light conditions.

c. On military C-9A aeromedical aircraft the audible cues could be clearly heard and understood if the ear was within 18" of unit without the use of hearing protection.

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code

2. AFI 41-203, Electrical Shock Hazards

3. AFI 41-201, Equipment Management in Hospitals

4. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.

5. Emergency Care Research Institute (ECRI)

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. Physio-Control, Inc., LifePak 500 Automated External Defibrillator, Operation Instructions.

10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF PHYSIO-CONTROL, INC., LIFEPAK 500 AUTOMATED EXTERNAL DEFIBRILLATOR

SPECIFICATIONS

General AED:

Size	4 in. H. x 10.5 in. W. x 11.6 in. D.
Weight	2.76 kg. (6.1 lb.)
Power	Nonrechargeable lithium battery, 12V, 7.5 amp hour or Rechargeable SLA battery, 8V, 2.5 amp hour.
Environmental	Temperature: 0°C to 50°C (operating). -30°C to 65°C (storage and shipping). Humidity: 10 to 95% (non condensing). Atmospheric Pressure: 760 to 429 mmHg (0 to + 15,000 ft above sea level)

General Battery Charger:

Safety Class	Class II, IEC 601-1, 5.1.
Input	100-240V, 0.7-0.4 Amp, 50-60 Hz.
Output	9.9V/9.2V dc.
Output Protection	Current limited, short circuit protected.
Environmental	Operating Temperature: 15° - 35°C.