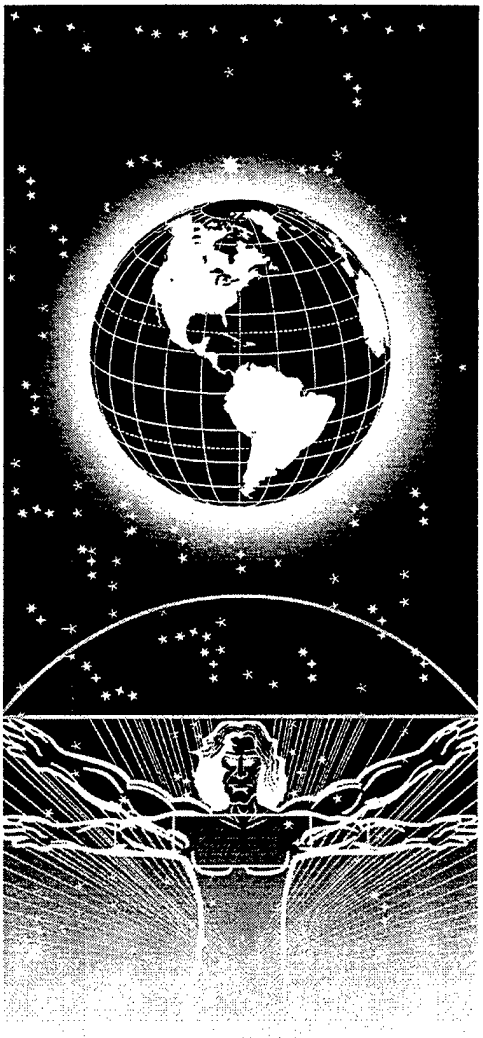
AFRL-HE-BR-TR-1998-0121



UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE HEARTSTREAM, INC., MODEL EM SEMI-AUTOMATIC EXTERNAL DEFIBRILLATOR

James C. Sylvester, USAF, NC

HUMAN EFFECTIVENESS DIRECTORATE
BIODYNAMICS PROTECTION DIVISION
2504 Gillingham Drive, Suite 25
Brooks Air Force Base TX 78235-5104

December 1998

NOTICES

This final technical report was submitted by personnel of the Systems Research Branch, Biodynamics Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, nor any of their contractors, subcontractors, or their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency, contractor, or subcontractor thereof. The views and opinions of the authors expressed herein do not necessarily state or reflect those of the United States Government or any agency, contractor, or subcontractor thereof.

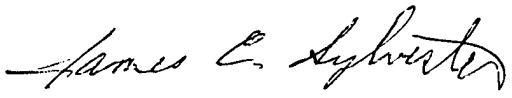
When Government drawings, specifications, or other data are used for any purpose other than in connection with a definitely Government-related procurement, the United States Government incurs no responsibility or any obligation whatsoever. The fact that the Government may have formulated or in any way supplied the said drawings, specifications, or other data, is not to be regarded by implication, or otherwise in any manner construed, as licensing the holder or any other person or corporation; or as conveying any rights or permission to manufacture, use or sell any patented invention that may in any way be related thereto.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

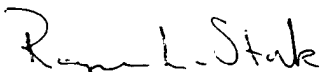
This report has been reviewed and is approved for publication.

Government agencies and their contractors registered with Defense Technical Information Center (DTIC) should direct requests for copies to: Defense Technical Information Center, 8725 John J. Kingman Rd., STE 0944, Ft. Belvoir, VA 22060-6218.

Non-Government agencies may purchase copies of this report from: National Technical Information Services (NTIS), 5285 Port Royal Road, Springfield, VA 22161-2103.



JAMES C. SYLVESTER, Major, USAF, NC
Chief, Air Force Medical Equipment & Development Laboratory



ROGER L. STORK, Colonel, USAF, BSC
Chief, Biodynamics Protection Division

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	November 1998	Final, September 1998

4. TITLE AND SUBTITLE

Testing and Evaluation of the Heartstream, Inc., Model EM Semi-Automatic External Defibrillator

5.FUNDING NUMBERS

PE: 62202F
PR: 7184
TA: 56
WU: 01

6. AUTHOR(S)

James C. Sylvester, Major

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Air Force Research Laboratory
Human Effectiveness Directorate
Biodynamics Protection Division
2504 Gillingham Dr. STE 25
Brooks AFB TX 78235-5104

8. PERFORMING ORGANIZATION REPORT NUMBER

AFRL-HE-BR-TR-1998-0121

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release; distribution unlimited.

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 words)

The Heartstream, Inc., Model EM Semi-Automatic External Defibrillator is a portable, battery operated, semi-automatic defibrillator. It performs automatic self-tests and displays the results of these tests on a status indicator. The unit is equipped with a high resolution, liquid crystal display with back light screen that displays text prompts, patient and event information and single-lead electrocardiogram (ECG). The unit operates on a disposable 18 VDC lithium battery. (Figure 1). The unit weighs approximately 4.34 lbs. with battery (5.8 lbs. with battery, case and defib pads) and is 8.75 in. W. (10 in. with case) X 2.5 in. H. (4.75 in. with case) X 8 in. D. (9.25 in. with case).

14. SUBJECT TERMS

Heartstream	Forerunner	medical equipment
Defibrillator	aeromedical	semi automatic
Airworthy	aircraft	

15. NUMBER OF PAGES

17

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	UL

TABLE OF CONTENTS

BACKGROUND 1
DESCRIPTION 1
PROCEDURES 2
INITIAL INSPECTION AND TEST PREPARATION 3
TEST SETUP 3
PERFORMANCE CHECK 4
VIBRATION 4
ELECTROMAGNETIC COMPATIBILITY 6
THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS 7
HYPOBARIC CONDITIONS 8
AIRBORNE PERFORMANCE 8
EVALUATION RESULTS 9
INITIAL INSPECTION 9
VIBRATION 9
ELECTROMAGNETIC COMPATIBILITY 9
THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS 9
HYPOBARIC CONDITIONS 9
AIRBORNE PERFORMANCE 10
SUMMARY 10
REFERENCES 11
APPENDIX 12

LIST OF FIGURES

Figure 1. Heartstream, Inc., Model EM, Semi-automatic External Defibrillator 1
Figure 2. Test Setup 3
Figure 3. Vibration Table Mounting 4
Figure A, B, & C. MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 ..... 5 & 6

ACKNOWLEDGMENTS

I would like to thank those who helped and provided advice during the evaluation of the Heartstream, Inc., model EM, Semi-automatic External Defibrillator. I would especially like to thank:

MSgt Butch Blake:	NCOIC/Aeromedical Research Manager
MSgt Pamela Forest:	Medical Service Journeyman
TSgt Allen Jones:	Aeromedical Research Technician
Mr. Edward Hade:	Electronics Engineer
Mr. Victor Elizondo:	Electronics Technician

TESTING AND EVALUATION OF THE HEARTSTREAM, INC., MODEL EM SEMI-AUTOMATIC EXTERNAL DEFIBRILLATOR

BACKGROUND

The Heartstream Company requested Air Force Medical Equipment and Development Laboratory participation in evaluating and approving their ForeRunner semi-automatic external defibrillator; model EM for use on board USAF aeromedical evacuation. Specific components of the ForeRunner semi-automatic external defibrillator (AED); model EM that under went the evaluation process included the ForeRunner model EM basic unit (P/N: EMO1); disposable 18 VDC lithium battery (P/N: BT1); transport case (P/N: HC) and disposable, self-adhesive defibrillator pads with integrated cable and connector (PN/: DP2 or DP6). All components of the model EM were tested for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the model EM.

DESCRIPTION

The EUT is a portable, battery operated, semi-automatic defibrillator. It performs automatic self-tests and displays the results of these tests on a status indicator. The unit is equipped with a high resolution liquid crystal display with back light screen that displays text prompts, patient and event information and single-lead electrocardiogram (ECG). The unit operates on a disposable 18 VDC lithium battery. (Figure 1). The unit weighs approximately 4.34 lbs. with battery (5.8 lbs. with battery, case and defib pads) and is 8.75 in. W. (10 in. with case) X 2.5 in. H. (4.75 in. with case) X 8 in. D. (9.25 in. with case).

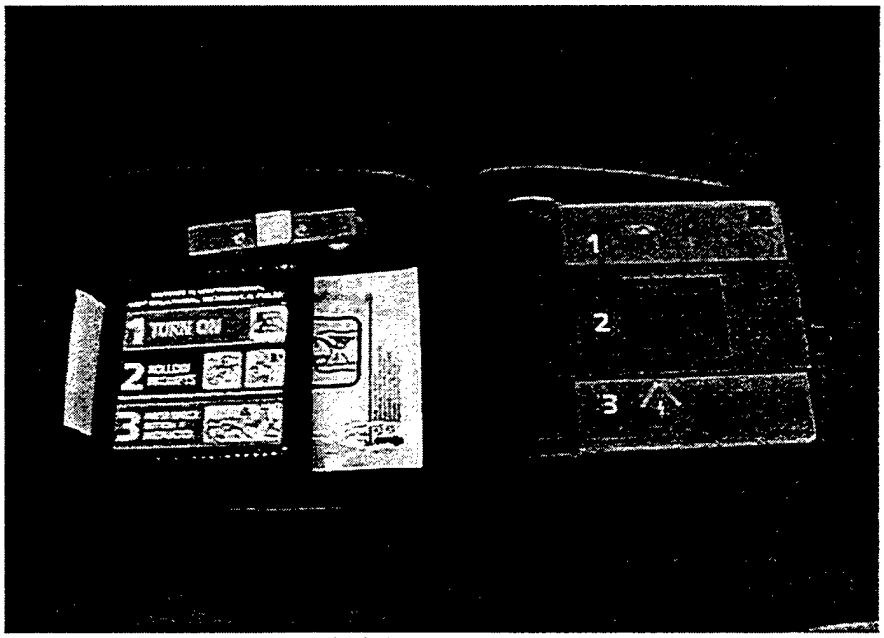


Figure 1. Heartstream, Inc., Model EM, Semi-automatic External Defibrillator

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 Aeromedical Research 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 are conducted by Air Force Medical Equipment and Development Laboratory (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 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 (3); AFI 41-201, Equipment Management in Hospitals (4). 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 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

Placed EUT on a level surface; connected test defibrillator cables to patient cable outlet on EUT; inserted other end of test defibrillator cables to respective pads on the Impulse 4000 Defibrillator/Pacer analyzer; selected analyzer setting codes: Dif; energy; high; vfib; turned defib analyzer on.

Inserted battery into EUT. Allowed EUT to run it's self-test. Turned unit on by pressing the green "on" button. The screen will instruct you on what to do next.

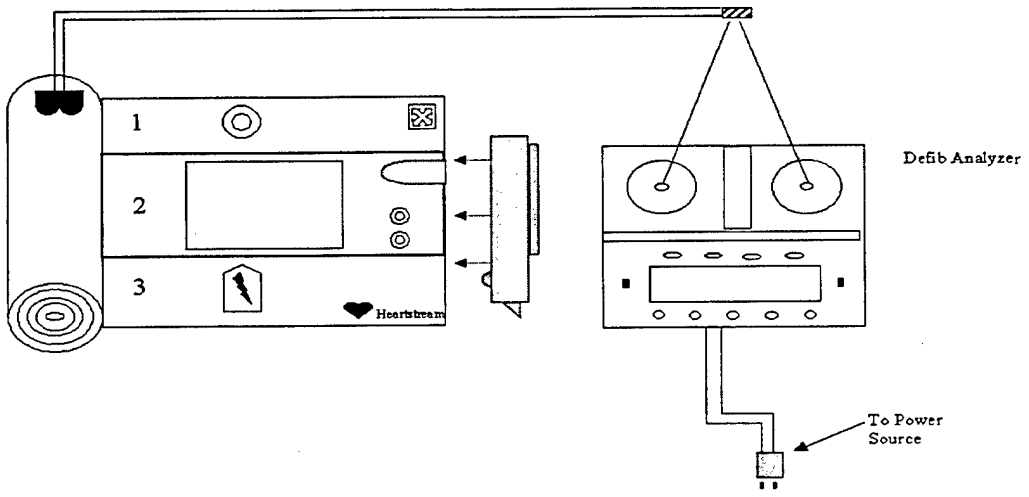


Figure 2. Test Setup

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. The screen will instruct you on what to do next. With the simulated arrhythmia (vfib) being sent by the defibrillator simulator, the EUT will cycle through a series of three different stacked shock levels and then instruct the operator to check airway, breathing, and pulse and begin cardiopulmonary resuscitation (CPR). Record the energy level read by the Impulse 4000 Defibrillator/Pacer analyzer after each of these three shocks.

Battery Operation as outlined in Heartstream Inc., Operations & Service 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 mounted on a NATO litter segment on the vibration table as it would be secured in the aircraft (Figure 3). 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 4).

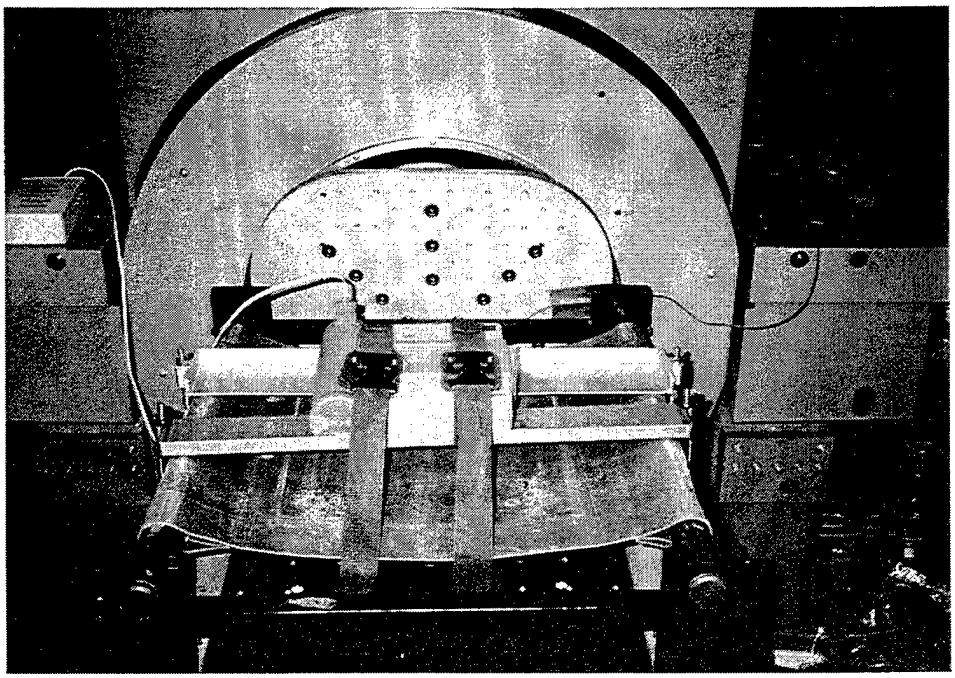
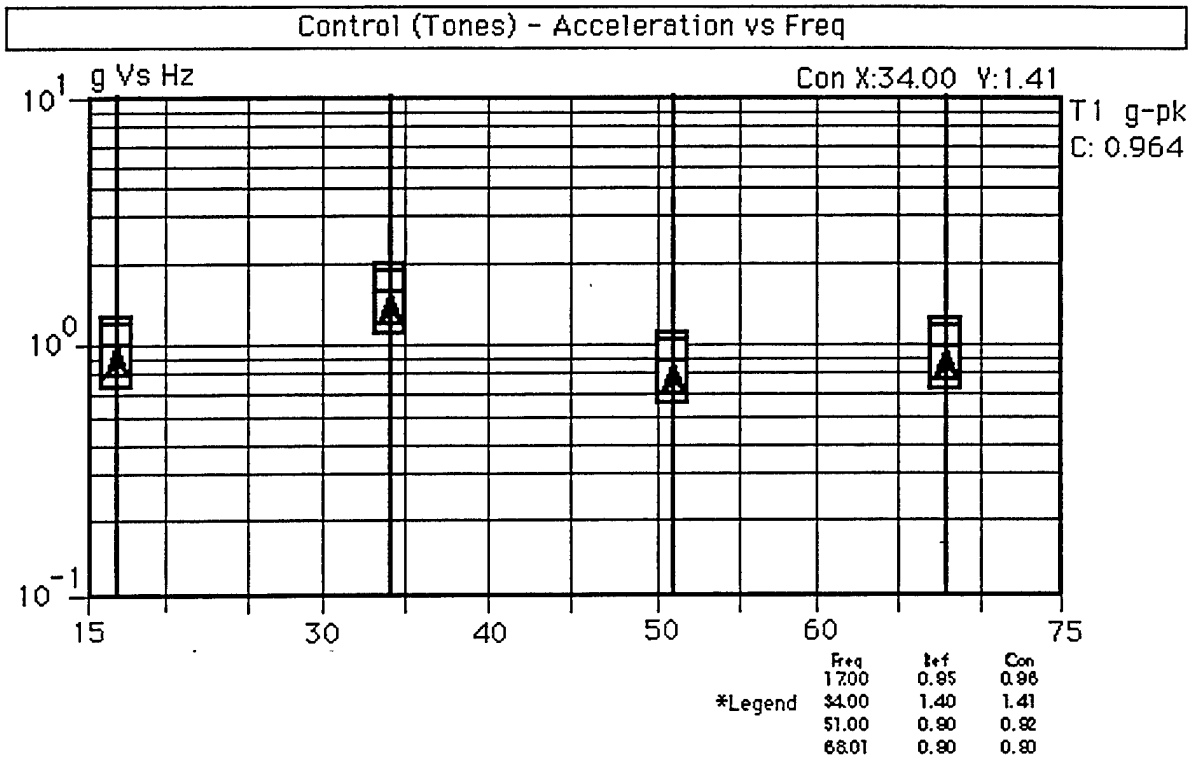


Figure 3. Vibration Table Mounting

Sine-on-Random Curves



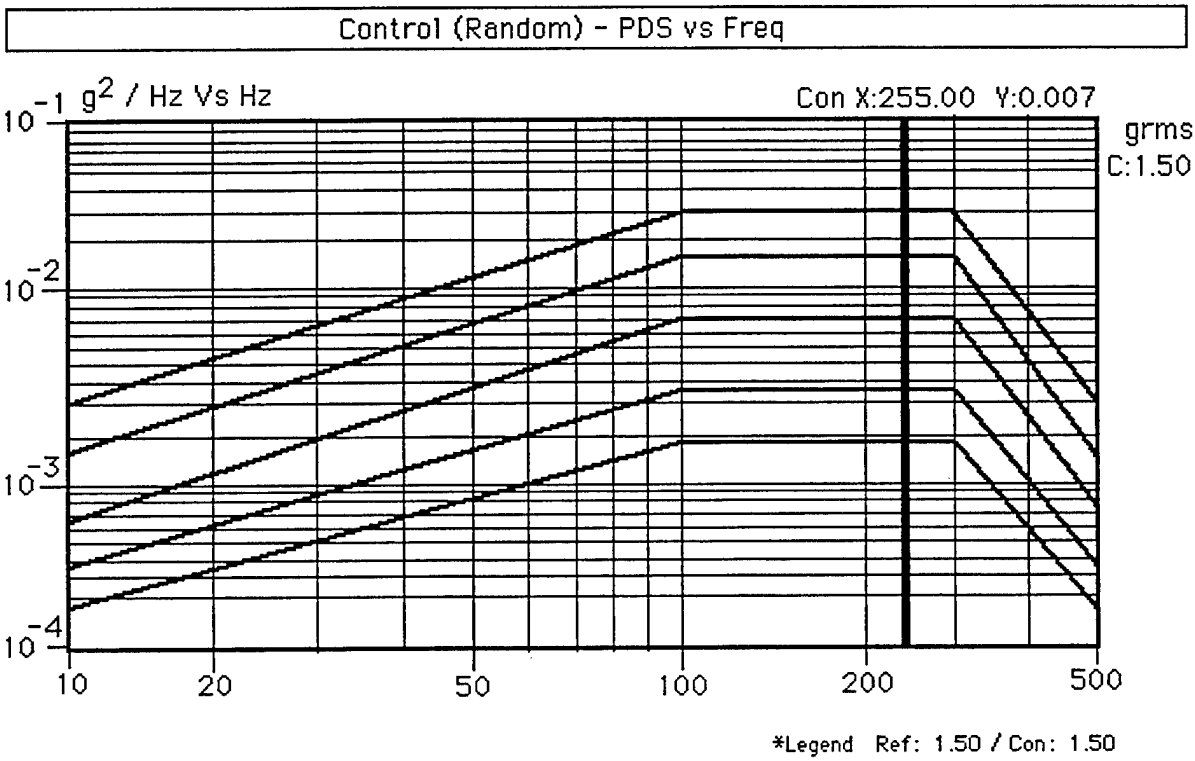


Figure A & B. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

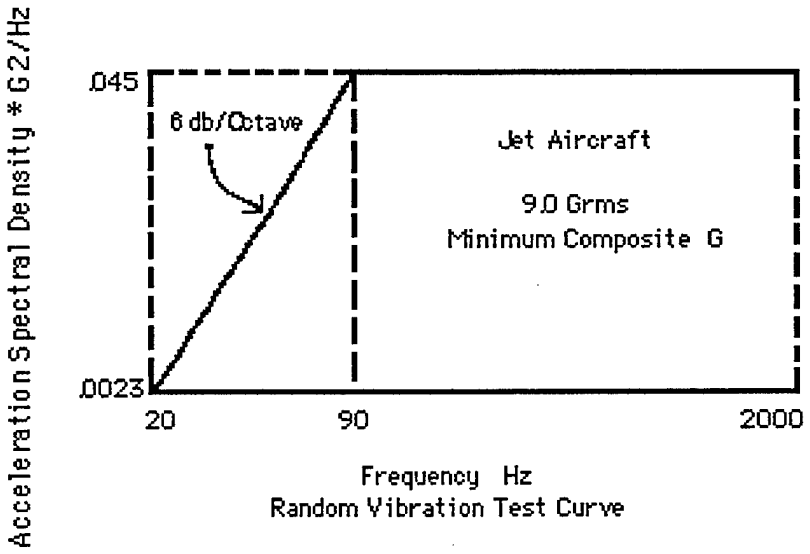


Figure C. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

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 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 to18 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. 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.

c. 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."

d. 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."

e. 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 keep fully charged and ready to deliver shock. For both emissions and susceptibility testing, the EUT was tested for operation using a disposable 18 VDC lithium battery.

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, 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 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 non-operational 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 again 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 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 there proposed operational environment. Inflight 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 inflight evaluation and forms the basis for subsequent recommendations to the users.

Qualified aeromedical crewmembers from AFMEDL on a C-9A, C-130, and C-141 aeromedical evacuation missions conducted this phase of testing. The EUT was positioned and secured on a NATO litter using litter straps and litter equipment brackets and then evaluated. Human factor 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 Endurance** revealed operation time well within manufacturer's specifications. The battery delivered 232 shocks before the battery low indicator came on (flashing red "X"). At 250 shocks, the EUT indicated replace battery and gave a verbal prompt. At 276 shocks, the EUT turned itself off and liquid crystal display (LCD) went blank.

VIBRATION

During evaluation, the EUT was programmed to maintain a continuous shock mode to assess the EUT's ability to hold charge without the possibility of accidental discharge. The unit performed according to manufacturer's specifications and AFMEDL guidelines without any system degradation or accidental discharge due to shock button switch 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 a disposable 18 VDC lithium battery.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT operated satisfactorily during all five phases of testing. Testing was conducted in the Air Force Research Laboratory's Thermotron Industries, model SM-32 Environmental Chamber.

HYPOBARIC CONDITIONS

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

2. Rapid Decompression: The EUT operated satisfactorily following each rapid decompresion event.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on a C-9A, C-130, and C-141 aeromedical evacuation mission. 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. The EUT was secured to a NATO litter using litter straps and litter equipment brackets. During this evaluation it was determined that special training considerations may apply when using EUT in C-130 and C-141 aircraft. Considerations include limitations on hearing verbal prompts and the need for auxiliary lighting during periods of low light conditions and on military C-9A aeromedical aircraft the audible cues could be clearly heard and understood if the ear was within 30 inches of unit without the use of hearing protection.

SUMMARY

Air Force Medical Equipment and Development Laboratory found the Heartstream, Inc., Model Em, Semi-automatic External Defibrillator to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating on a disposable 18 VDC lithium battery with the recommendations listed below. Its operation was within expected parameters when subjected to electromagnetic interference (EMI), environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

a. 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. Although the unit screen is illuminated, incorporation of a brighter screen would enhance reception of visual prompts in low light conditions.

b. On military C-9A aeromedical aircraft the audible cues could be clearly heard and understood if the ear was within 30 inches of unit without the use of hearing protection.

c. The manufacturer's device offers a patient monitoring electrocardiographic liquid crystal display. According to the manufacturer, "The LCD screen is intended only for basic ECG rhythm identification. The frequency response of the monitor screen is not intended to provide the resolution required for diagnostic and ST segment interpretation" [see pg. 20 Heartstream User's Guide.] (9). Thus, interpretations of the ECG tracing should not be used to guide Advanced Cardiac Life Support interventions.

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. Heartstream, Inc., (1996) Models S, E & Em, Semi-automatic External Defibrillator, Operations & Service Manual.
10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF HEARTSTREAM, INC., MODEL EM, SEMI-AUTOMATIC EXTERNAL DEFIBRILLATOR

SPECIFICATIONS

General

Size	8.75 in. W. (10 in. with case) X 2.5 in. H. (4.75 in. with case) X 8 in. D. (9.25 in. with case).
Weight	4.34 lbs. with battery (5.8 lbs. with battery, case and defib pads)
Altitude	-500 to 15,000 ft.
Power	Disposable 18 VDC, 1300 mAH lithium battery.
Environmental	Temperature: 0°C to 50°C (operating). 10°C to 43°C (stand-by temperature). Humidity: 0% TO 95% (non-condensing). 0% to 75% (non-condensing stand-by humidity)
Waveform	Truncated Exponential Biphasic. Waveform parameters are adjusted as a function of patient defibrillation impedance.
Main LCD Screen	A high resolution, backlit LCD screen displays ECG (models E and EM) and informational/instructional text messages on all models.
Event Review Card	Provides the ForeRunner, model EM with Event Review capability and 15 minutes of ECG data collection. This card incorporates a real time clock which provides a means for synchronizing the EMS system time with recorded code events.