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**Test and Evaluation Report
of the Physio Control Defibrillator/Monitor
Model Lifepak® 6s**

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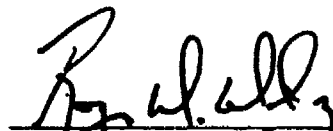
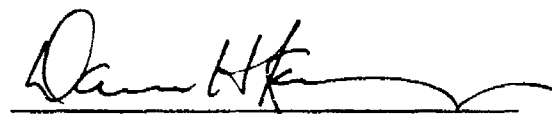
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Section 1. Executive digest

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards (MIL-STD) and collective professional expertise to test and evaluate selected medical equipment proposed for use aboard Army aircraft. Equipment meeting these standards ensures the safety of the crew, patients, and aircraft by eliminating risks due to: (1) Interference by the medical equipment with aircraft systems/subsystems operation, (2) the aircraft system's interference with the operation of the medical equipment, (3) the medical equipment's susceptibility to environmental exposure, or (4) physical and/or functional incompatibility while in use on board selected rotary-wing aircraft. This program tests both developmental and nondevelopmental (off the shelf) medical equipment destined for use aboard Army medical evacuation (MEDEVAC) aircraft.

1.1 TEST OBJECTIVES

1.1.1 To determine if the medical equipment is complete and operational per the manufacturer's operating instructions.

1.1.2 To ensure the electrical safety of the medical equipment.

1.1.3 To ensure the equipment will function as designed throughout the rated battery operation time.

1.1.4 To ensure the safety of the operator, the patient, and the aircrew.

1.1.5 To assess design considerations which could potentially contribute to an operator error.

1.1.6 To determine if the medical equipment can function as designed in a low pressure environment.

1.1.7 To determine the ability of the medical equipment to withstand the vibrational stresses expected in a rotary-wing flight environment without degradation or malfunction.

1.1.8 To determine the ability of the medical equipment to be stored and operated in a high temperature environment.

1.1.9 To determine the ability of the medical equipment to be stored and operated in a low temperature environment.

1.1.10 To determine the ability of the medical equipment to operate satisfactorily for short periods during exposure to high humidity conditions.

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1.1.11 To assess the levels of electromagnetic emissions produced by the medical equipment within selected frequency ranges.

1.1.12 To assess the minimum electromagnetic susceptibility levels of the medical equipment within selected frequency ranges.

1.1.13 To assess the physical and/or functional compatibility of the medical equipment while in use on board the aircraft.

1.1.14 To assess the electromagnetic interference (EMI) and electromagnetic compatibility (EMC) characteristics of the medical equipment with the host aircraft and its installed systems.

1.2 TESTING AUTHORITY

Research and Technology Work Unit Summary, dated 5 October 1989. Project number 3M463807D836, titled, Army Program for Testing and Evaluation of Equipment for Aeromedical Operations.

1.3 SCOPE

1.3.1 This test was conducted at the United States Army Aeromedical Research Laboratory (USAARL), Cairns Army Airfield (CAAF), and designated test flight areas in and around Fort Rucker, Alabama.

1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was configured with the Physio Control Defibrillator/Monitor*, model Lifepak® 6s and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 3.0 flight hours.

1.3.3 Laboratory testing was accomplished at USAARL using government furnished equipment (GFE) by Universal Energy Systems, Inc. (UES), under contract No. DAMD 17-86-C-6215.

1.3.4 Prior to flight testing, the following tests were accomplished: Acceptance inspection, equipment training, electromagnetic compatibility, human factors and safety, environmental compatibility, and in-flight compatibility.

1.3.5 An airworthiness release (AWR) dated 5 Mar 1992 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the Physio Control Defibrillator/Monitor, model Lifepak® 6s.

* See list of manufacturers

1.4 MATERIAL DESCRIPTION

The Physio Control Lifepak® 6s is a portable monitor and defibrillator system. The monitor and defibrillator are separate modules and may be used independently or as a single unit. When used together, the monitor slides over the defibrillator and locks in place. When synchronized defibrillation is selected, the defibrillator receives the QRS signal from the monitor module.

The electrocardiogram (ECG) monitor displays the ECG signal on a 3 x 4 inch cathode ray tube (CRT) in real time. A red light emitting diode (LED) digital display shows the heart rate. Rotary switches are used to set high and low heart rate alarms, ECG size, beep volume, freeze the ECG signal, or select the integral strip chart recorder. The patient connection is made through a 6-pin Physio Control patient cable connector. The unit operates from an internal battery or line voltage. Battery charging is indicated by an LED and the charge is shown on a charge level meter.

The defibrillator delivers energy with the integral paddles or internal paddles in a synchronized or non-synchronized mode. The defibrillation charge is selected as 5, 10, 20, 30, 50, 100, 150, 200, 300, or 360 joules. Push buttons turn power on, initiate the charge cycle, discharge the paddles internally, or select synchronized discharge mode. A digital readout displays the available energy when energized and the energy delivered.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery Life Evaluation: The Lifepak® 6s is rated by the manufacturer for 3 hours continuous ECG monitoring and 25 360-joule discharge cycles. Three tests were conducted with the monitor operating continuously and the defibrillator discharged 10 times at the beginning of each hour. The average operating time in testing was 3 hours and 30 minutes and the defibrillator averaged 28 discharge cycles on a battery charge. This exceeds the manufacturer's specification.

1.5.1.2 Electrical Safety Evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the Physio Control Lifepak® 6s. The limits for currents and resistances were in accordance with (IAW) the limits specified in TB-38-750-2, April 1987, and National Fire Prevention Association (NFPA) standards.

1.5.1.3 Human Factors Evaluation: The Physio Control Lifepak® 6s was found to be satisfactory in all categories of the evaluation except Controls. The rotary controls for alarm limits, ECG size, QRS volume, and power are spaced closer than recommended by the referenced guides. The power switch for the monitor does not illuminate when activated, but the power switch for the defibrillator does illuminate. This difference in display may confuse the operator.

1.5.1.4 Environmental Tests: The Physio Control Lifepak® 6s can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of the environmental testing. The requirements for environmental tests are established in MIL-STD-810D, Methods 500.2 (altitude), 514.3 (vibration), 501.2 (high temperature), 502.2 (low temperature), and 507.2 (humidity).

1.5.1.5 Radiated Emissions Tests (RE02): The Physio Control Lifepak® 6s may be unsatisfactory for use in certain EMI sensitive environments. Broadband (BB) and narrowband (NB) radiated emissions were detected in the test frequency ranges. Some emissions exceeded the test limits. Emission limits are set forth in MIL-STD-461A, Notice 4.

1.5.1.6 Radiated Susceptibility Test (RS03): The Physio Control Lifepak® 6s was susceptible to radio frequency interference in the testing range and magnitude. It may be unsuitable for use in EMI intensive environments.

1.5.1.7 Conducted Emissions Test (CE01, CE02, and CE04): Narrowband and broadband signals were detected on the power lines of the Lifepak® 6s during this test. Some emissions exceeded the test limits.

1.5.1.8 Conducted Susceptibility Test (CS02 and CS06): No susceptibility to the test power line spikes was noted in the monitor/defibrillator.

1.5.2 In-flight testing

1.5.2.1 During the in-flight human factors evaluation, the Physio Control Lifepak® 6s was found to be satisfactory in all categories of the evaluation criteria. The unit was tested using integral battery power and ac power.

1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the Physio Control Lifepak® 6s in any of the prescribed flight test modes.

1.5.2.3 The Physio Control Lifepak® 6s was not affected by the aircraft and its subsystems during the in-flight testing.

1.6 CONCLUSIONS

Based on the results of laboratory and in-flight testing, the Physio Control Monitor/Defibrillator, Model Lifepak® 6s was found to be compatible with U.S. Army MEDEVAC UH-60A Black Hawk with the subsystems listed in paragraph 3.2.2.

Section 2. Subtests

2.1 INITIAL INSPECTION

2.1.1 Objective

To determine if the Lifepak® 6s is complete and operational for testing per the manufacturer's operating instructions.

2.1.2 Criteria

2.1.2.1 The physical inventory is conducted solely for investigation and documentation.

2.1.2.2 The Lifepak® 6s will display consistent and accurate performance as an acceptable performance test.

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the Lifepak® 6s was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the Lifepak® 6s was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

2.1.4 Test findings

2.1.4.1 The Lifepak® 6s was inventoried and found to be complete. The unit has been in service for several years prior to testing.

2.1.4.2 The Lifepak® 6s operated as prescribed in the manufacturer's operating manual. Criteria met.

2.2 BATTERY LIFE EVALUATION (Laboratory)

2.2.1 Objective

To ensure the equipment will function as designed throughout the rated battery operation time.

2.2.2 Criterion

Verify manufacturer's specified full power internal battery life expectancy of 3 hours operation and 25 360-joule discharges.

2.2.3 Test procedure

2.2.3.1 Charging and operation cycles were conducted in ambient room conditions. The monitor was operated continuously and the defibrillator was charged to 360 joules and discharged 10 times at the beginning of each hour.

2.2.4 Test findings

The monitor operated an average of 3 hours and 30 minutes and the defibrillator averaged 28 cycles on a fully-charged battery. This exceeds the manufacturer's specification. Criterion met.

2.3 ELECTRICAL SAFETY EVALUATION

2.3.1 Objective

To ensure the electrical safety, by evaluation of case-to-ground resistance and case-to-ground current leakage of the Lifepak® 6s.

2.3.2 Criterion

The Lifepak® 6s shall meet the standards established in TB-38-750-2 and NFPA 99 for electrical safety of medical equipment.

2.3.3 Test procedure

Performance in the electrical safety evaluation were made with a Neurodyne-Dempsey model 431F electrical safety analyzer* IAW the procedures described in Technical Bulletin (TB) Number 38-750-2. Case-to-ground resistance and various case-to-ground leakage currents were measured. Leakage currents were measured using a 10 by 20 centimeter (cm) aluminum foil sheet taped flush to the equipment case. Checks were made for safety concerns such as case integrity, breaks in power cord insulation, and connectors.

2.3.4 Test findings

Grounding conductor resistance was 77.8 milliohms and maximum case leakage current was 28.6 microamperes. Maximum lead leakage current was 7.6 microamperes. These measurements are below the limits specified in TB-38-750-2 and NFPA 99. Criterion met.

2.4 HJMAN FACTORS EVALUATION (Laboratory)

2.4.1 Objectives

2.4.1.1 To assure the safety of the operator, the potential patient, and the aircrew.

2.4.1.2 To assess the design considerations which potentially could contribute to an operator error.

2.4.2 Criterion

The Lifepak® 6s must be rated satisfactory in all major categories of the evaluation. These include visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.4.3 Test procedure

2.4.3.1 The evaluation was conducted in a laboratory under fluorescent lighting and ambient room conditions.

2.4.3.2 The Lifepak® 6s was operated according to prescribed instructions through its full range of functions.

2.4.4 Test finding

The first Lifepak® 6s was found to be satisfactory in all of the evaluation criteria except controls. The rotary controls for alarm limits, ECG size, QRS volume, and power are spaced closer than recommended. The power switch on the monitor does not illuminate when activated while the power switch on the defibrillator does illuminate. This difference in displays may confuse the operator. Criterion partially met.

2.5 ALTITUDE (LOW PRESSURE) TEST [IAW MIL-STD-810D, METHOD 500.2]

2.5.1 Objective

To determine if the Lifepak® 6s can function as designed in a low pressure environment.

2.5.2 Criterion

The Lifepak® 6s will perform as designed while exposed to an altitude equivalency of 15,000 feet above sea level.

2.5.3 Test procedure

2.5.3.1 A pretest performance check was conducted to ensure proper operation of the Lifepak® 6s.

2.5.3.2 The altitude test was performed in a Tenney Engineering model 64S altitude chamber*. This test is based on MIL-STD-810D, Method 500.2. The Lifepak® 6s was operated on the floor of the chamber. Chamber pressure was decreased to 420 mmHg (15,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to ambient conditions (760 mmHg) over a 10-minute period. There are no provisions for the control of temperature or humidity inside this chamber.

2.5.3.3 A posttest performance check was conducted to ensure proper operation of the Lifepak® 6s after the exposure to low pressure.

2.5.4 Test findings

2.5.4.1 The pretest performance check met criterion 2.1.2.2.

2.5.4.2 No failures in the performance of the Lifepak® 6s were noted before, during, or after the altitude test. Criterion met.

2.5.4.3 The posttest performance check met criterion 2.1.2.2.

2.6 VIBRATION TEST [IAW MIL-STD-810D, METHOD 514.3]

2.6.1 Objective

To determine the ability of the Lifepak® 6s to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

The Lifepak® 6s will remain operational and be able to display consistent and accurate performance while exposed to vibrational stresses.

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the Lifepak® 6s.

2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TM115-40/CSTA vibration test system*. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are derived from performance taken on the floor under the copilot's

seat in a UH-1 helicopter traveling at 120 knots. The reference spectrum breakpoints are from MIL-STD-810D, Method 514.3; reference spectrum levels are based on field performance with a conservatism factor of 1.5. Independent tests were conducted in the X, Y, and Z axes.

Z-axis

duration: 60 minutes

broadband intensity: 0.4506 G_{rms}

random vibration: initial slope : 99.00 dB/oct

5 Hz level: 0.00006210 $G_{sqr/Hz}$

100 Hz level: 0.0006210 $G_{sqr/Hz}$

300 Hz level: 0.0006210 $G_{sqr/Hz}$

500 Hz level: 0.00006210 $G_{sqr/Hz}$

final slope: -99.00 dB/oct

sinusoidal vibration: .5450 G_{pk} at 11.25 Hz

.1690 G_{pk} at 22.50 Hz

.1200 G_{pk} at 33.75 Hz

.0310 G_{pk} at 45.00 Hz

.0530 G_{pk} at 56.25 Hz

X and Y axes

duration: 60 minutes each

broadband intensity: 0.3099 G_{rms}

random vibration: initial slope: 99.00 dB/oct

5 Hz level: 0.00002920 $G_{sqr/Hz}$

100 Hz level: 0.0002920 $G_{sqr/Hz}$

300 Hz level: 0.0002920 $G_{sqr/Hz}$

500 Hz level: 0.00002920 $G_{sqr/Hz}$

final slope: -99.00 dB/oct

sinusoidal vibration: .3200 G_{pk} at 11.25 Hz

.0670 G_{pk} at 22.50 Hz

.0950 G_{pk} at 33.75 Hz

.0350 G_{pk} at 45.00 Hz

.0770 G_{pk} at 56.25 Hz

The Lifepak® 6s was strapped to the vibration table fixture, and its performance was evaluated before, during, and after exposure to vibration.

2.6.3.3 A posttest performance check was conducted to ensure proper operation of the Lifepak® 6s.

2.6.4 Test findings

2.6.4.1 The pretest performance check met criterion 2.1.2.2.

2.6.4.2 No failures in the performance of the Lifepak® 6s occurred before, during, or after exposure to vibration. Criterion met.

2.6.4.3 The posttest performance check met criterion 2.1.2.2.

2.7 HIGH TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 501.2]

2.7.1 Objective

To determine the ability of the Lifepak® 6s to be stored and operated in a high temperature environment.

2.7.2 Criteria

2.7.2.1 The Lifepak® 6s will demonstrate consistent and accurate operation during the high temperature operation check.

2.7.2.2 The Lifepak® 6s will demonstrate consistent and accurate operation after the high temperature storage cycle.

2.7.3 Test procedure

2.7.3.1 A pretest performance check was conducted to ensure proper operation of the Lifepak® 6s.

2.7.3.2 The high temperature test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 501.2. For the high temperature operation test, the Lifepak® 6s was turned on and placed on the floor of the environmental chamber. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent relative humidity (RH) within 15 minutes. The environmental control system is capable of regulating temperature within $\pm 2^\circ\text{C}$ and humidity within ± 5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the Lifepak® 6s was allowed to return to ambient conditions over a 30-minute period.

2.7.3.3 A posttest performance check was conducted to ensure proper operation of the Lifepak® 6s.

2.7.3.4 The Lifepak® 6s was stored (not operated) at temperatures of 63°C for 1 hour, 71°C for 4 hours, then again at 63°C for 1 hour. The chamber and Lifepak® 6s then were returned to ambient conditions over a 30-minute period.

2.7.3.5 A poststorage performance check was conducted to ensure proper performance of the Lifepak® 6s.

2.7.4 Test findings

2.7.4.1 The pretest performance check met criterion 2.1.2.2.

2.7.4.2 No operational failures occurred during the high temperature test. Criterion met.

2.7.4.3 The posttest performance check met criterion 2.1.2.2.

2.7.4.4 The Lifepak® 6s functioned properly after the high temperature storage test. Criterion met.

2.8 LOW TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 502.2]

2.8.1 Objective

To determine the ability of the Lifepak® 6s to be stored and operated in a low temperature environment.

2.8.2 Criteria

2.8.2.1 The Lifepak® 6s will demonstrate consistent and accurate operation during the low temperature operation check.

2.8.2.2 The Lifepak® 6s will demonstrate consistent and accurate operation after the low temperature storage cycle.

2.8.3 Test procedure

2.8.3.1 A pretest performance check was conducted to ensure proper operation of the Lifepak® 6s.

2.8.3.2 The Lifepak® 6s was placed on the floor of the environmental chamber and the temperature was lowered to 0°C within 25 minutes. The environmental control system is capable of regulating temperature within 2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant for 2 hours. The chamber door was opened briefly every 30 minutes to minimize the change in chamber conditions, and a performance check was conducted. The chamber temperature then was raised to ambient temperature within a 30-minute period.

2.8.3.3 A posttest performance check was conducted to ensure proper operation of the Lifepak® 6s.

2.8.3.4 The Lifepak® 6s was "stored" in a nonoperational mode. The Lifepak® 6s was placed on the floor of the environmental test chamber and the temperature was lowered to -46°C for 6 hours. The chamber then was raised to ambient temperature over a 30-minute period.

2.8.3.5 A poststorage performance check was conducted to ensure proper operation of the Lifepak® 6s.

2.8.4 Test findings

2.8.4.1 The pretest performance check met criterion 2.1.2.2.

2.8.4.2 No operational failures occurred during the low temperature test. Criterion met.

2.8.4.3 The posttest performance check met criterion 2.1.2.2.

2.8.4.4 The Lifepak® 6s functioned properly after the low temperature storage test. Criterion met.

2.9 HUMIDITY TEST [IAW MIL-STD-810D, METHOD 507.2]

2.9.1 Objective

To determine the ability of the Lifepak® 6s to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

The Lifepak® 6s will demonstrate consistent and accurate operation while exposed to a high humidity environment.

2.9.3 Test procedure

2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the Lifepak® 6s.

2.9.3.2 The humidity test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 507.2. For the humidity test, the Lifepak® 6s was placed in operation on the floor of the environmental chamber. The chamber temperature was raised to a temperature of 30°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within $\pm 2^{\circ}\text{C}$ and humidity within ± 5 percent RH. At 45-minute intervals the performance of the blood pressure monitor was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the Lifepak® 6s were returned to ambient conditions before the posttest performance validation check was conducted.

2.9.3.3 A posttest performance check was conducted to ensure the proper operation of the Lifepak® 6s.

2.9.4 Test findings

2.9.4.1 The pretest performance check met criterion 2.1.2.2.

2.9.4.2 No failures were noted in the Lifepak® 6s performance checks conducted during the exposure to the high humidity environment. Criterion met.

2.9.4.3 The posttest performance check met criterion 2.1.2.2.

2.10 ELECTROMAGNETIC CHARACTERISTICS TEST [IAW MIL-STD-461A, Notice 4, AND MIL-STD-462, Notice 3]

2.10.1 Objectives

2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the Lifepak® 6s in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the Lifepak® 6s within the 10 kHz to 10 GHz electric field.

2.10.1.3 To assess the maximum levels of conducted electromagnetic emissions produced by the Lifepak® 6s in the 10 kHz to 50 MHz frequency ranges.

2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the Lifepak® 6s within the range of 50 kHz to 400 MHz and power spikes.

2.10.2 Criteria

2.10.2.1 The Lifepak® 6s will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.

2.10.2.2 The Lifepak® 6s will not malfunction when it is subjected to radiated emissions as specified in MIL-STD-461A, Notice 4, paragraph 6.20.

2.10.2.3 The Lifepak® 6s will not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.

2.10.2.4 The Lifepak® 6s will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.

2.10.3 Test procedure

2.10.3.1 The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method RE02. The Lifepak® 6s was positioned on a wooden test stand inside the EMI chamber, 1 meter away from the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to EMI receivers. While the Lifepak® 6s was operating, the frequency spectrum (14 kHz to 12.4 GHz) was scanned for emissions. The Lifepak® 6s was operated with ac and battery power.

2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The Lifepak® 6s was positioned on a wooden test stand inside the EMI chamber 1 meter away from the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to radio frequency (RF) transmitters. While the Lifepak® 6s was operating, it was monitored for faulty operation during exposures to fields of 1 V/m from 10 kHz to 2 MHz, and 5 V/m from 2 to 30 MHz, 10 V/m from 30 MHz to 2 GHz, and 5 V/m from 2 to 10 GHz. The Lifepak® 6s was operated with ac and battery power.

2.10.3.3 The conducted emissions tests were performed according to MIL-STD-462, Notice 3, Methods CE02 and CE04. The Lifepak® 6s was placed on a grounded, copper-covered workbench. The top of the workbench was 1 meter from floor level, 1.37 meters long and 0.81 meters wide. Power was supplied via a pair of line impedance stabilization networks (LISN) and a test jig. The test jig is a wooden tray with two power receptacles and two slots to hold current probes in place around power supply conductors. While the Lifepak® 6s was operating, the frequency range (10 kHz to 50 MHz) was scanned for emissions conducted in the power cable from the Lifepak® 6s.

2.10.3.4 The conducted susceptibility spike test was performed on a chemical resistant counter top according to MIL-STD-462, Notice 3, Method CS06. Power was supplied via a customized metal connection box. The connection box has two power receptacles and four banana jacks on its front panel. Connections to the individual power lines were made in series through the banana jacks. Transient spikes of 100 volts, 10 microseconds were generated with a Solar Electronics model 8282-1 transient pulse generator* and induced onto the power leads at the connection box banana jacks. The spikes were monitored with a Tektronix 2235 oscilloscope* connected to a power receptacle on the connection box. The Lifepak® 6s was plugged into the other receptacle on the connection box, placed in operation. It was observed visually for correct operation while it was subjected to the power line spikes.

2.10.3.5 The conducted susceptibility test was performed according to MIL-STD-462, Notice 3, Method CS02. The Lifepak® 6s was placed on a grounded, copper-covered workbench. Radio frequency interference was induced on the power leads and measured at the Lifepak® 6s power cable. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the Lifepak® 6s was operated. It was observed visually for proper operation while it was subjected to the radio interference on the power leads. Each frequency was held for 15 seconds.

2.10.4 Test findings

2.10.4.1 During the radiated emissions test, emissions which exceeded specification limits of MIL-STD-461A, Notice 4, were detected. These included:

<u>Frequency range</u>	<u>Emission exceeding standard</u>
88 kHz - 8.43 MHz	1.3 - 41.3 dB (NB)
8.43 - 56.46 MHz	2.2 - 51.8 dB (NB)
35 kHz - 9.20 MHz	0.9 - 35.5 dB (BB)
2.4 MHz	23.2 dB (BB)
9 - 45 MHz	0.4 - 68 dB (BB)
100 - 968.75 MHz	0.1 - 49.3 dB (BB)

Criterion partially met.

2.10.4.2 The Lifepak® 6s was susceptible to radio frequency interference in the testing range and magnitude. These included:

<u>Frequency range</u>	<u>Threshold of susceptibility</u>
10.8 - 12.0 MHz	1.41 - 3.15 V/m
20.8 - 22.4 MHz	0.16 - 2.65 V/m
30.0 - 142.2 MHz	1.68 - 7.94 V/m
166.0 - 196.6 MHz	3.16 - 6.31 V/m
200.0 - 216.0 MHz	1.78 - 5.01 V/m
244.0 - 256.0 MHz	2.66 - 5.96 V/m
304.0 - 316.0 MHz	2.51 - 5.01 V/m

Criterion partially met.

2.10.4.3 Narrowband and broadband signals were detected on the Lifepak® 6s power lines in the following frequency ranges.

<u>Frequency range</u>	<u>Emission exceeding standard</u>
107 - 209 kHz	0.4 - 8.8 dB (NB)
1.31 - 1.79 MHz	0.2 - 2.4 dB (NB)
14.5 - 20.14 MHz	10.7 - 13.4 dB (NB)
250 - 933 kHz	2.4 - 10.4 dB (BB)
1.04 - 2.4 MHz	1.4 - 22.9 dB (BB)
10.75 MHz	13 dB (BB)

Criterion partially met.

2.10.4.4 The Lifepak® 6s was not susceptible to radio frequency interference (RFI) or test spikes during the conducted susceptibility tests. Criterion met.

2.11 IN-FLIGHT HUMAN FACTORS EVALUATION

2.11.1 Objective

To assess the physical and/or functional compatibility of the Lifepak® 6s while in use onboard the aircraft.

2.11.2 Criterion

The flight surgeon will be able to operate the Lifepak® 6s without physical or functional restrictions aboard the aircraft. Major areas of concern include: Proper operation, visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.11.3 Test procedure

2.11.3.1 A human factors evaluation was performed IAW MIL-STD-1472D, AAMI Human factors engineering guidelines, and UL-544 to ensure the compatibility of the Lifepak® 6s and the in-flight environment. The flight surgeon conducted the test wearing a flight suit, flight gloves, and an SPH-4B flight helmet. An evaluation of the compatibility with the nuclear, biological, and chemical (NBC) protective equipment was not conducted. Due to restrictions of the AWR, testing was conducted during daylight hours only.

2.11.3.2 The Lifepak® 6s was placed on a seat in the aircraft and secured with straps. The Lifepak® 6s was tested using ac and battery power in all flight scenarios required by the In-Flight Test Operations Procedures (ITOP) (refer to section 3.2). Synchronized and routine defibrillation was initiated through a

ground at 100 and 360 joules energy setting in each flight scenario.

2.11.4 Test findings

During the in-flight human factors evaluation, the Lifepak® 6s was found to be satisfactory in all categories of the evaluation criteria. There were no problems with energizing or delivering defibrillator energy in a routine or synchronized mode. Criterion met.

2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS

2.12.1 Objective

To assess the EMI/EMC characteristics of the Lifepak® 6s with the host aircraft and its installed systems.

2.12.2 Criteria

2.12.2.1 The Lifepak® 6s will not radiate EMI to disrupt or interfere with other equipment or systems aboard the aircraft.

2.12.2.2 The aircraft will not radiate EMI to disrupt or interfere with the Lifepak® 6s's operation.

2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the Lifepak® 6s and the aircraft operating as source and victim. The Lifepak® 6s and applicable aircraft instruments and systems were monitored for unusual operation, readings, surges, or power anomalies for each checklist item.

2.12.4 Test findings

2.12.4.1 There were no adverse instances of EMI/EMC noted with the Lifepak® 6s acting as either the source or victim. Criterion met.

2.12.4.2 There were no adverse instances of EMI/EMC noted with the aircraft acting as either the source or victim. Criterion met.

Section 3. Supporting documentation

3.1 DETAILED TEST INFORMATION

3.1.1 General information

3.1.1.1 Lifepak® 6s testing is not considered a major action significantly affecting the quality of the human environment and, therefore, qualifies for categorical exclusion A-28, appendix A, AR 200-1.

3.1.1.2 A safety pilot will be designated for each flight. Flight operations will be conducted IAW the aircraft operator's manual, appropriate aircrew training manuals, and test item technical data.

3.1.2 Material description

3.1.2.1 The Physio Control Lifepak® 6s is a portable monitor and defibrillator system. The monitor and defibrillator are separate modules and may be used independently or as a single unit. When used together, the monitor slides over the defibrillator and locks in place. When synchronized defibrillation is selected, the defibrillator receives the QRS signal from the monitor module.

The electrocardiogram (ECG) monitor displays the ECG signal on a 3 x 4 inch cathode ray tube (CRT) in real time. A red light emitting diode (LED) digital display shows the heart rate. Rotary switches are used to set high and low heart rate alarms, ECG size, beep volume, freeze the ECG signal, or select the integral strip chart recorder. The patient connection is made through a 6-pin Physio Control patient cable connector. The unit operates from an internal battery or line voltage. Battery charging is indicated by an LED and the charge is shown on a charge level meter.

The defibrillator delivers energy with the integral paddles or internal paddles in a synchronized or non-synchronized mode. The defibrillation charge is selected as 5, 10, 20, 30, 50, 100, 150, 200, 300, or 360 joules. Push buttons turn power on, initiate the charge cycle, discharge the paddles internally, or select synchronized discharge mode. A digital readout displays the available energy when energized and the energy delivered.

3.1.2.2 Dimensions: ECG module: 27.3 x 30.5 x 11.4 cm (10.75 x 12 x 4.5 in. Defibrillator module: 48.9 x 30.5 x 11.4 cm (19.25 x 12 x 4.5 in).

3.1.2.3 Weight: ECG module: 6.70 kg (14.75 lbs)
Defibrillator module: 8.98 kg (19.75 lbs)

3.1.2.4 Power requirements: ECG module: 100, 117, 220, 240, $\pm 10\%$ Vac, 50 or 60 Hz, 30 watts during monitoring, 45 watts during recording. Battery type is nickel-cadmium, 14.4 V, 1.5 Ah, with a typical capacity of 3 hours continuous monitoring or 1 hour continuous recording. Charge time for a depleted battery is 16 hours.

Defibrillator module: 100, 117, 220, 240, $\pm 10\%$ Vac, 50 or 60 Hz, 160 watts during defibrillator charge. Battery type is nickel-cadmium, 12 V, 1 Ah, with typical capacity of 25 360-joule discharges. Charge time for a depleted battery is 16 hours.

3.1.2.5 Environmental considerations: atmospheric pressure, 500 to 775 mmHg; relative humidity, 0 to 95%; operating temperature, 0 to 45°C; storage temperature, -30 to +65°C.

3.1.2.6 Defibrillator charge and synchronization: charge to 360 joules in less than 10 seconds at 25°C with ac power or fully charged battery; charge to 360 joules in less than 12 seconds with battery operation after 15 maximum discharges. Defibrillator will synchronize discharge 20 ms after marker on cardioscope (R-wave).

3.2 TEST DATA

3.2.1 Photographic description



3.2.2 Aircraft equipment list

Item No.	Nomenclature
1	Receiver radio -- R-1496A/ARN-89 (automatic direction finder)
2	Displacement gyro -- CN-1314/A
3	Gyro directional -- CN-998/ASN-43
4	Signal data converter -- CV-3338/ASN-128
5	Receiver -- R-2139/ARN-123 (VOR/LOC/MB/GS)
6	Command instrument system processor -- 70600-01038-101
7	SAS amplifier -- 70901-02908-104 (flight control stability augmentation system)
8	Rate gyro -- TRU-2A/A
9	Amplifier, impedance -- AM-4859A/ARN-89
10	Cargo hook -- FE-7590-145
11	Receiver, radar -- RT-1193/ASN-128 (doppler navigation receiver)
12	Barometric altimeter -- AAU-31/A-1
13	Barometric altimeter -- AAU-32A
14	Receiver/transmitter -- RT-1300/ARC-186 (VHF-AM and/or FM radio)
15	UHF-AM radio set -- RT-1518/ARC-164
16	Interphone control -- C6533/ARC (aircraft intercom control)
17	Receiver/transmitter -- RT-1115D/APN-209 (radar altimeter)
18	Indicator altimeter -- ID-1917C/APN-209 (radar altimeter)
19	Control radio set -- C-7392A/ARN-89 (automatic direction finder)
20	Comparator signal data -- CM-482/ARC-186 (comparator for ARC-186)
21	Receiver/transmitter -- RT-1296A/APX-100 (transponder with IFF)
22	Computer display unit -- CP-1252/ASN-128 (doppler navigation system)
23	Compass set controller -- C-8021E/ASN75
24	Magnetic compass - standby -- MS-17983-4

3.2.3 In-flight test data card

DATA CARD FORMAT

GUIDELINE FOR DATA COLLECTION

IN-FLIGHT SUITABILITY TEST OF MEDICAL ITEMS

1. Installation/removal.	Suitable		Comments
	Yes	No	
a. Weight and balance (DD Form 365-4, Clearance Form F).	X		
b. Space/area allocation.			
(1) Operational requirements.	X		
(2) Storage requirements.	X		
c. Interface connections (safe, positive, secure).	X		
d. Installation/removal (expedient/easily achieved).	X		
e. Mounting/final config- uration (functional/stable).	X		
2. Operations and performance.	Suitable		Comments
	Yes	No	
a. Manufacturer's operating instruction.	X		
b. Medical item operation before aircraft run-up.	X		
c. System interface during aircraft engine run-up and medical item operation (EMI switchology checklist).	X		
(1) Aircraft voltage output.	X		

	Suitable Yes	No	Comments
(2) Flight control function (UH-60).	X		
(3) Stabilator function (UH-60).	X		
(4) Radio communication vs. medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		
(5) Navigation equipment vs. medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) Doppler	X		
(6) Radar altimeter operation vs. medical item operation.	X		
d. System interface during air- craft hover and medical item operation (EMI switchology check- list).			
(1) Voltage output.	NA		
(2) Radio communication vs. medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		

(3) Navigation equipment operation vs. medical item operation.	Suitable Yes No	Comments
(a) Transponder	X	
(b) ADF	X	
(c) VOR	X	
(d) Doppler	X	
 e. Flight mission profile vs. medical item operation (EMI switchology checklist).		
(1) Straight and level (1000 ft MSL for 20 minutes).		
(a) Compatibility of flight mode and medical item operation.	X	
(b) Radio communication vs. medical item opera- tion.		
<u>a.</u> FM	X	
<u>b.</u> UHF	X	
<u>c.</u> VHF	X	
(2) NOE (20 minutes). compatibility of flight mode and medical item operation.	X	
(3) FM homing (10 minutes).	X	
(4) Doppler navigation vs. medical item operation.		
(a) Initialize function.	X	
(b) Fix function.	X	
(c) Update function.	X	

	Suitable Yes No	Comments
(5) VOR navigation 7000 ft MSL for 20 minutes) vs. medical item operation.	X	
(6) ILS approach vs. medical item operation.	X	
f. Medical item operation after engine shutdown (external power source).	X	
g. Restrictions to the medical item's use (i.e., electrical connectors).	X	
h. Deviations from the labor- atory test results.		
(1) Electrical/ electronic.	None	
(2) Mechanical environment.	None	
(3) Human factors (user interface, controls, markings, lighting, egress).	None	
(4) Safety.	None	
3. Deviations from the in-flight test protocol.		
a. The VOR navigation portion of the in-flight test con- ducted at 2000 feet MSL due to air traffic control clearance.		

3.2.4 EMI switchology checklist

EMI SWITCHOLOGY CHECKLIST UH-60 AIRCRAFT

IN-FLIGHT SUITABILITY OF MEDICAL ITEMS

ENG INSTRUMENTS/CDU	No EMI Affect	EMI Affected Gnd Flt	Explanation
Fuel quantity	X		
Fuel indicator test	X		
XMSN oil temperature	X		
XMSN oil pressure	X		
#1 engine oil temperature	X		
#2 engine oil temperature	X		
#1 engine oil pressure	X		
#2 engine oil pressure	X		
#1 TGT	X		
#2 TGT	X		
#1 Ng speed	X		
#2 Ng speed	X		
CDU digits on/off	X		
CDU instruments dim	X		
ENG INSTRUMENTS/PLT PDU	No EMI Affect	EMI Affected Gnd Flt	Explanation
#1 engine RPM	X		
#2 engine RPM	X		
Rotor RPM	X		
#1 torque	X		
#2 torque	X		
ENG INSTRUMENTS/COPLT PDU	No EMI Affect	EMI Affected Gnd Flt	Explanation
#1 engine RPM	X		
#2 engine RPM	X		
Rotor RPM	X		
#1 torque	X		
#2 torque	X		

ENG CONTROLS	No EMI Affect	EMI Affected Gnd Flt	Explanation
#1 overspeed	X		
#2 overspeed	X		
RPM switch	X		
#1 engine anti-ice	X		
#2 engine anti-ice	X		
#1 inlet anti-ice	X		
#2 inlet anti-ice	X		

RADIO EQUIPMENT	No EMI Affect	EMI Affected Gnd Flt	Explanation
ICS, C-6533 ARC	X		
VHF-FM, ARC-186/115	X		
VHF-AM, ARC-186/115	X		
UHF-AM, ARC-164(V)	X		
Crypto, KY-28	Not installed		
Radio retransmissions PLN	Not installed		
Transponder, APX-100(V)	X		
KIT-1A/TSEC IFF computer	Not keyed with code		

MISSION EQUIPMENT	No EMI Affect	EMI Affected Gnd Flt	Explanation
RWR, APR-39(V)	Not installed		
IR CM, ALQ-144	Not installed		
Chaff dispenser, M-130	Not installed		
Cargo hook system	X		

HYDRAULIC CONTROL SYSTEM	No EMI Affect	EMI Affected Gnd Flt	Explanation
Backup hydraulic pump	X		
Servo off 1st stage/PLT	X		
Servo off 2nd stage/PLT	X		
Servo off 1st stage/COPLT	X		
Servo off 2nd stage/COPLT	X		
Hydraulic leak test	X		
Tail servo	X		
Boost servos	X		

FUEL SYSTEM	No EMI Affect	EMI Affected Gnd Flt	Explanation
Fuel pump switch	X		
Fuel boost pump #1	X		
Fuel boost pump #2	X		
Fuel cont panel ESSS	X		

WARNING SYSTEM	No EMI Affect	EMI Affected Gnd Flt	Explanation
Low rotor RPM	X		
Master caution	X		
Caution advisory	X		
Fire warning	X		
AFCS	X		
Stabilator	X		
#1 engine out	X		
#2 engine out	X		

NAVIGATION INSTRUMENTS	No EMI Affect	EMI Affected Gnd Flt	Explanation
ADF	X		
Magnetic compass	X		
CONUS NAV, ARN-123	X		
Doppler, ASN-128	X		
Gyro mag compass (PLT)	X		
Gyro mag compass (COPLT)	X		
Compass cont panel, ASN-75	X		
HSI	X		

FLIGHT INSTRUMENTS	No EMI Affect	EMI Affected Gnd Flt	Explanation
Radar altimeter	X		
Stabilator pos indicator	X		
VSI	X		
CIS mode select	X		
SAS 1	X		
SAS 2	X		
FPS	X		
Trim	X		
Go-around enable	X		
Cyclic trim release	X		
Cyclic stick trim	X		
ALR encoder	X		

FLIGHT INSTRUMENTS (CONT)	No EMI Affect	EMI Affected Gnd Flt	Explanation
HSI/VSI mode select (PLT)			
DPLR	X		
VOR/ILS	X		
BACK CRS	X		
FM HOME	X		
TURN RATE	X		
CRS HDG	X		
VERT GYRO	X		
BRG 2	X		
HSI/VSI Mode Select (COPLT)			
DPLR	X		
VOR/ILS	X		
BACK CRS	X		
FM HOME	X		
TURN RATE	X		
CRS HDG	X		
VERT GYRO	X		
BRG 2	X		
MISCELLANEOUS EQUIPMENT	No EMI Affect	EMI Affected Gnd Flt	Explanation
Blade deice	Not tested		Ambient tempera- ture was out of test lim- its.
Windshield anti-ice	X		
Pitot heat	X		
Vent blower	X		
Windshield wiper	X		
Heater	X		
APU	X		
Generator #1	X		
Generator #2	X		
Generator APU	X		
Air source heat start	X		
Tail wheel lock	X		
Gyro erect	X		

LIGHTING	No EMI Affect	EMI Affected		Explanation
		Gnd	Flt	
Cockpit utility	X			
Cockpit flood	X			
Cabin dome	X			
Search light	X			
Search light control	X			
Landing light	X			
Flt instr lights (PLT)	X			
Flt instr lights (COPLT)	X			
Nonflight instr lights	X			
Console lights, upper	X			
Console lights, lower	X			
Position lights	X			
Formation lights	X			
Anticollision lights	X			
NVG lighting	X			

3.2.6 Electrical safety test

Electrical Safety Test Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Lifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 6 Aug 91

Performance:

Grounding conductor resistance (milliohms): 77.8

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity	4.6
unit off, ungrounded, normal polarity	23.1
unit off, ungrounded, reverse polarity	28.6
unit on, grounded, normal polarity	4.6
unit on, ungrounded, normal polarity	23.0
unit on, ungrounded, reverse polarity	28.6

MAXIMUM LIMITS:

ground resistance (milliohms):	150
current (microamperes)	
current (grounded, type A unit):	10
current (ungrounded, type A unit):	100
current (grounded, type B unit):	50
current (ungrounded, type B unit):	500

Comments on item setup or checks: None

Comments on test run (including interruptions): None

3.2.7 Human factors evaluation

Human Factors Evaluation Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Lifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 11 Sep 91

Item configuration during test: Item prepared for operation.

Checklist for HFE

RESULTS

VISUAL DISPLAYS:

Satisfactory

display type, format, content
location of displays
indicator lights
scalar displays
color coding
legends and labels
cathode ray tubes
counters
flags, go-no-go, center-null indicators

Comments: Battery charge meters are very small.

CONTROLS:

Unsatisfactory

location
characteristics of controls
labeling
control - display relationships

Comments: Rotary control on front panel are closer than recommended in guidelines. Power button for monitor is unlighted, but power button for defibrillator lights when activated.

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: approximately 2 minutes.

MAINTAINABILITY:

Satisfactory

- component location
- component characteristics
- rests and stands
- covers, cases, access doors
- handles
- lubrication
- component mounting
- cord storage provisions
- external accessibility
- internal accessibility
- list special tools required
- list realistic inspection requirements
- list realistic inspection intervals

Comments: Operational checks should be performed as used and maintenance inspection every 6 months.

CONDUCTORS:

Satisfactory

- binding and securing
- length
- protection
- routing
- conductor coding
- fabrication
- connectors

Comments: None

FASTENERS:

Satisfactory

- access through inspection panel covers
- enclosure fasteners
- device mounting bolts and fasteners

Comments: None

TEST POINTS:

Satisfactory

general
location and mounting
test point labeling and coding

Comments: None

TEST EQUIPMENT:

Satisfactory

general
equipment self-test
indicators (list in comments)
controls
positive indication of proper operation

Comments: None

FUSES AND CIRCUIT BREAKERS:

NA

external accessibility
easy replacement or reset by operator

Comments: None

LABELS AND CODING:

Satisfactory

placed above controls and displays
near or on the items they identify
not obscured by other equipment components
describe the function of the items they identify
readable from normal operating distance
conspicuous placards adjacent to hazardous items

Comments: None

SAFETY:

Satisfactory

manual
materials
fire and explosive protection
operator protection from mechanical hazards
patient protection from mechanical hazards
electrical safety (operator and patient)

Comments: None

3.2.8 Altitude test

Altitude Test Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Lifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 28 Aug 91

Item configuration during test: Item sitting on chamber floor.

Performance test criteria: Accurate display of heart rate and
correct delivery of defibrillator energy.

Ambient conditions outside chamber:

Temperature	20°C
Humidity	87% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	ac power

IN-TEST DATA

Time of test start: 1340

POSTTEST DATA

Posttest performance check (complete check of item and
accessories):

Time of test end : 1510

Item functional (based on performance test criteria): Yes

Deviation from pretest : None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.9 Vibration test

Vibration Test Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Lifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 27 Aug 91

Item configuration during test: Item strapped down on vibration table fixture.

Performance test criteria: Accurate display of heart rate and correct delivery of defibrillator energy.

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	None

Ambient conditions

Temperature	19°C
Humidity	72% RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Time at first check:

X: 1325 Y: 1425 Z: 1435

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Time at second check:

X: 1410

Y: 1510

Z: 1525

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

POSTTEST DATA

Time at test end:

X: 1415

Y: 1520

Z: 1530

Posttest performance check (complete check of item and accessories):

Item functional (based on performance test criteria): Yes

Item intact: Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: Test times for the three axes are on different days.

3.2.10 High temperature test

High Temperature Test (Equipment Operating) Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Lifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 20 Aug 91

Item configuration during test: Unit was sitting on chamber floor, operating on ac power.

Performance test criteria: Accurate display of heart rate and correct delivery of defibrillator energy.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	59% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check :

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance from east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

IN-TEST DATA

Time of test start: 1102

Performance checks during test:

First check:

Time: 1132
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
Yes, all ok
Deviation from pretest: None

Second check:

Time: 1202
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
Yes, all ok
Deviation from pretest: None

Third check:

Time: 1232
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
Yes, all ok
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1400
Item functional (based on performance test criteria):
Yes, all ok
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.11 High temperature storage test

High Temperature Test (Equipment in Storage) Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Lifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 22 Aug 91

Item configuration during test: Sitting on chamber floor, in storage, not operating.

Performance test criteria: Accurate display of heart rate and correct delivery of defibrillator energy.

Ambient conditions outside chamber:

Temperature	24C
Humidity	57% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance from east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

Time of test start: 0830

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1515
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks:
The unit was allowed to cool for 1 hour at ambient conditions before the posttest performance check was completed.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.12 Low temperature test

Low Temperature Test (Equipment Operating) Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Lifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 21 Aug 91

Item configuration during test: Sitting on chamber floor.

Performance test criteria: Accurate display of heart rate and
correct delivery of defibrillator energy.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	52% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Pass

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance from east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

Time of test start: 0800

Performance checks during test:

First check:

Time: 0830
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Second check:

Time: 0900
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Third check:

Time: 0930
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1015
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.13 Low temperature storage test

Low Temperature Test (Equipment in Storage) Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Lifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 23 Aug 91

Item configuration during test: Sitting on chamber floor, not operating, in storage.

Performance test criteria: Accurate display of heart rate and correct delivery of defibrillator energy.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	55% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance from east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

Time of test start: 0930
Midtest time: 1230
Midtest temperature: -46°C

POSTTEST DATA

Posttest performance check:

(complete check of item and accessories)

Time of test end: 1545

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.14 Humidity test

Humidity Test Report Form

Nomenclature: Defibrillator/monitor
Manufacturer: Physio Control
Model number: Modellifepak® 6s
Serial number: 0019726 / 0019957
Military item number: None

Options installed: None

Date of test: 21 Aug 91

Item configuration during test: The unit was sitting on the chamber floor, operating on ac power.

Performance test criteria: Accurate display of heart rate and correct delivery of defibrillator energy.

Ambient conditions outside chamber:

Temperature	25°C
Humidity	57% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance from east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

IN-TEST DATA

Time of test start: 1100

Performance checks during test:

First check:

Time: 1145
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Second check:

Time: 1230
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Third check:

Time: 1315
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Fourth check:

Time: 1400
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Fifth check:

Time: 1445
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:

(complete check of item and accessories)

Time of test end: 1500

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.15 Electromagnetic characteristics test

Electromagnetic Characteristics Testing Evaluation of Performance

T & E Item Number: 31

Date: 5 Aug 91

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control

Model number: Lifepak® 6s

Serial number: 0019726 / 0019957

Military item number: NA

Conducted Emissions Tests

CE01 Testing configuration(s): NA
 Performance (pass/fail): NA

Comments: No dc conductors

CE02 Testing configuration(s): Operating on copper
 work bench.
 Performance (pass/fail): Pass

Comments: No signal failures.

CE04 Testing configuration(s): Operating on copper
 work bench.
 Performance (pass/fail): Fail

Comments: NB: 107 - 209 kHz, 0.4 - 8.8 dB;
 1.31 - 1.79 MHz, 0.2 - 2.4 dB;
 14.5 - 20.14 MHz, 10.7 - 13.4 dB;
 BB: 250 - 933 kHz, 2.4 - 10.4 dB;
 1.04 - 2.4 MHz, 1.4 - 22.9 dB;
 10.75 MHz, 13 dB.

Conducted Susceptibility Tests

CS02 Testing configuration(s): Operating on test
 bench, connected to test jig.
 Performance (pass/fail): Pass

Comments: None

CS06 Testing configuration(s): Operating on counter
 top.
 Performance (pass/fail): Pass

 Comments: not susceptible to test spikes

Radiated Emissions Tests

RE02 Testing configuration(s): Operating on wooden
 test stand in the EMC chamber.
 Performance (pass/fail): Fail

 Comments:

<u>Frequency</u>	<u>Failure Level</u>
NB: 88 kHz - 8.43 MHz	1.3 - 41.3 dB
8.43 - 56.46 MHz	2.2 - 51.8 dB
BB: 35 kHz - 9.20 MHz	0.9 - 35.5 dB
2.4 MHz	23.2 dB
9.0 - 45.0 MHz	0.4 - 68.0 dB
100.0 - 968.75 MHz	0.1 - 49.3 dB

Radiated Susceptibility Tests

RS03 Testing configuration(s): Operating on the wooden
 test stand in the EMC chamber.
 Performance (pass/fail): Fail

 Comments: Susceptibility manifested by irregular
 ECG baseline, erratic video display, loss of
 numerical rate display, or erroneous rate display.
 Failure frequency and threshold of susceptibility:

<u>Frequency</u>	<u>Threshold of susceptibility</u>
10.8 - 12.0 MHz	1.41 - 3.15 V/m
20.8 - 22.4 MHz	0.16 - 2.65 V/m
30.0 - 142.2 MHz	1.68 - 7.94 V/m
166.0 - 196.6 MHz	3.16 - 6.31 V/m
200.0 - 216.0 MHz	1.78 - 5.01 V/m
244.0 - 256.0 MHz	2.66 - 5.96 V/m
304.0 - 316.0 MHz	2.51 - 5.01 V/m

3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

3.3.1 Criteria

Item			<u>Applicable</u>
<u>No.</u>	<u>Criteria (source)</u>	<u>Remarks</u>	<u>subparagraph</u>
1	The physical inventory is conducted solely for investigation and documentation.	NA	2.1.2.1
2	The will display consistent and accurate performance.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 3 hours.	met	2.2.2
4	The will meet the limits established in NFPA 99 for electrical safety of medical equipment.	met	2.3.2
5	The will be rated satisfactory in all major categories of the evaluation. These include: Visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.	partially met	2.4.2
6	The will demonstrate proper operation while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	The will remain operational while exposed to vibrational stresses.	met	2.6.2
8	The will remain operational during the high temperature operation check.	met	2.7.2.1

9	The will remain operational after the high temperature storage.	met	2.7.2.2
10	The will remain operational during the low temperature operation check.	met	2.8.2.1
11	The will remain operational after the low temperature storage.	met	2.8.2.2
12	The will remain operational while exposed to a high humidity.	met	2.9.2
13	The will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.	par- tially met	2.10.2.1
14	The will not malfunction when it is subjected to radiated fields as specified in MIL-STD-461A, Notice 4, paragraph 6.20.	par- tially met	2.10.2.2
15	The will not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.2.	met	2.10.2.3
15	The will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraph 6.7 and 6.10.	par- tially met	2.10.2.4
17	The flight surgeon will be able to operate the without physical or functional restrictions aboard the aircraft.	met	2.11.2.1
18	The will not radiate EMT to disrupt or interfere with the other equipment or systems aboard the aircraft.	met	2.12.2.2

19 The aircraft will not radiate met 2.12.2.3
EMI to disrupt or interfere with
the Lifepak® 6s.

3.3.2 Significant problems which require corrective action

None

3.3.3 Suggested improvements

None

3.4 REFERENCES

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3.4.3 Department of Defense. 1983. Environmental test methods and engineering guidelines. Washington, DC. MIL-STD-810D. July.

3.4.4 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, DC. TB 38-750-2. April.

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3.4.8 National Fire Protection Association. 1987. Standard for health care facilities. Quincy, Massachusetts. NFPA 99. February.

3.4.9 Department of the Army. 1982. Environmental protection and enhancement. Washington, DC. AR 200-1. June.

3.5 ABBREVIATIONS

ac	alternate current
AVSCOM	Army Aviation Systems Command
AWR	airworthiness release
BB	broadband
CAAF	Cairns Army Airfield
dc	direct current
EMC	electromagnetic compatibility
EMI	electromagnetic interference
fpm	feet per minute
GFE	government furnished equipment
Gpk	gravity, peak
G(rms)	gravity (root mean square)
Hz	hertz
IAW	in accordance with
ITOP	in-flight test operating procedure
IV	intravenous
kHz	kilohertz
LCD	liquid crystal display
LED	light emitting diode
LISN	line impedance stabilization network
MEDEVAC	medical evacuation
MHz	megahertz
MIL-STD	military standard
mm	millimeter
mmHg	millimeters of Mercury
MSL	mean sea level
NFPA	National Fire Prevention Association
NB	narrowband
NBC	nuclear, biological and chemical
NOE	nap-of-the-earth
NVG	night vision goggle
QRS	largest peak in ECG waveform
RF	radio frequency
RFI	radio frequency interference
RH	relative humidity

TB	technical bulletin
TFT	technical feasibility testing
T & E	test and evaluation
UES	Universal Energy Systems, Inc.
USAARL	U.S. Army Aeromedical Research Laboratory
V/m	volts per meter

3.6 LIST OF MANUFACTURERS

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- 3.6.2 Neurodyne-Dempsey, Inc.
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 Carson City, NV 89701
- 3.6.3 Tenney Engineering, Inc.
 1090 Springfield Road
 P.O. Box 3142
 Union, NJ 07083
- 3.6.4 Unholtz-Dickey Corporation
 6 Brookside Drive
 Wallingford, CT 06492
- 3.6.5 Solar Electronics Company
 901 North Highland Avenue
 Hollywood, CA 90038
- 3.6.6 Tektronix, Inc.
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