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Test and Evaluation Report of the Physio Control Vital Signs Monitor Model VSM 2

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The Physio Control Vital Signs Monitor, Model VSM 2, was tested for environmental and electromagnetic interference/compatibility in the UH-60A helicopter under the U.S. Army Program for Testing and Evaluation of Equipment for Aeromedical Operations. The tests were conducted using current military and industrial standards and procedures for environmental tests and electromagnetic interference/compatibility and human factors. The Physio Control Vital Signs Monitor, Model VSM 2, was found to be compatible with the U.S. Army MEDEVAC UH-60 Black Hawk.

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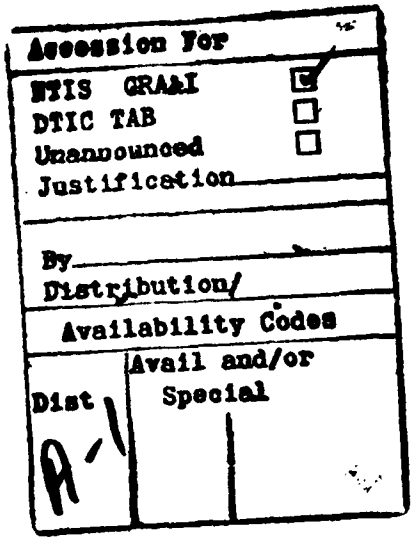

Section 1. Executive digest

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.

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 Vital Signs Monitor*, model VSM 2 and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 2.3 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 24 Feb 1992 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the Physio Control Vital Signs Monitor.

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* See list of manufacturers

1.4 MATERIAL DESCRIPTION

The Physio Control Vital Signs Monitor, model VSM 2, is designed to noninvasively monitor a patient's electrocardiogram (ECG), blood pressure, and temperature. A 5-inch cathode ray tube (CRT) provides a visual display of the ECG and numeric light emitting diodes (LED) display the heart rate, blood pressure, temperature, and alarm condition. The ECG can also be printed on an integral strip chart recorder. A square pushbutton labeled "POWER" energizes the VSM 2. A lead select switch is provided to select display of Lead I, II, III, or STD. Two rotary switches are provided to allow the user to select high and low alarm conditions for heart rate. In addition, rotary switches are provided to adjust QRS volume, alarm silence, and ECG size.

The systolic, diastolic, and mean blood pressure are shown on individual LED displays. A fourth LED display is used to show the elapsed time between blood pressure measurements. When a temperature probe is connected to the unit, this display alternates between the elapsed time and temperature display.

ECG data is obtained from the patient using standard ECG electrodes and lead wires. Blood pressure is obtained from a standard blood pressure cuff. The VSM 2 uses the oscillometric technique, where expansion of the cuff due to blood vessel filling, is monitored rather than auscultation of Kortokoff sounds at the brachial artery.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery Life Evaluation: The VSM 2 operated for 1 hour and 17 minutes from a fully charged battery. The manufacturer specifies a battery life up to 20 minutes.

1.5.1.2 Electrical Safety Evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the Physio Control VSM 2. 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 VSM 2 was found to be satisfactory in all categories of the evaluation except visual displays, controls, and labels and coding. Although there is a battery level indicator, there are no audio or visual alarms to warn that monitoring has stopped due to low battery power. The spacing between several controls are less than the recommended distance. When the LED display shows temperature, labels showing "ELAPSED TIME" and "TEMP" are visible which may cause user confusion.

1.5.1.4 Environmental Tests: The Physio Control VSM 2 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 VSM 2 may be unsatisfactory for use in certain EMI sensitive environments. Narrowband and broadband 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 VSM 2 was found to be susceptible to radio frequency interference in the testing range and magnitude.

1.5.1.7 Conducted Emissions Test (CE01, CE02, and CE04): Narrowband and broadband emissions exceeding standard were detected from the VSM 2 during this test.

1.5.1.8 Conducted Susceptibility Test (CS02 and CS06): No susceptibility to the test power line spikes was noted in the VSM 2.

1.5.2 In-flight testing

1.5.2.1 During the in-flight human factors evaluation, the Physio Control VSM 2 was found to be satisfactory in all categories of the evaluation criteria. Inadequate spacing of controls did not interfere with operation of the monitor in the aircraft.

1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the Physio Control VSM 2 in any of the prescribed flight test modes.

1.5.2.3 The Physio Control VSM 2 was not affected by the aircraft and its subsystems during the in-flight testing.

1.6 CONCLUSION

Based on the results of laboratory and in-flight testing, the Physio Control Vital Signs Monitor, Model VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 will display consistent and accurate measurements as an acceptable performance test.

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the Physio Control VSM 2 was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the Physio Control VSM 2 was conducted per the manufacturer's operating instructions.

2.1.4 Test findings

2.1.4.1 The Physio Control VSM 2 was inventoried and found to be complete.

2.1.4.2 The Physio Control VSM 2 operated as prescribed in the manufacturer's operating manual.

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 20 minutes operation.

2.2.3 Test procedure

2.2.3.1 Charging and operation cycles were conducted in ambient room conditions.

2.2.4 Test findings

The unit operated an average of 1 hour and 17 minutes while monitoring an ECG signal and taking a blood pressure every 5 minutes. 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 Physio Control VSM 2.

2.3.2 Criterion

The Physio Control VSM 2 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 40.3 milliohms and maximum case leakage current was 4.1 microamperes. These measurements are below the limits specified in TB-38-750-2 and NFPA 99. Criterion met.

2.4 HUMAN 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 could potentially contribute to an operator error.

2.4.2 Criterion

The Physio Control VSM 2 must be rated satisfactory in all major categories of the evaluation. The major categories 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 Physio Control VSM 2 was operated according to prescribed instructions through its full range of functions.

2.4.4 Test finding

The Physio Control VSM 2 was found to be satisfactory in all of the evaluation criteria except Visual Displays, Controls, and Labels and Coding. There is no audio or visual alarm to indicate monitoring has stopped when the battery is discharged. Controls on the front panel including the alarm silence button, rotary controls, and alarm limit controls are closer than recommended. The "ELAPSED TIME" label remains in place over the LED display, even when the display is used to show patient temperature ("TEMP"). Criterion partially met.

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

2.5.1 Objective

To determine if the Physio Control VSM 2 can function as designed in a low pressure environment.

2.5.2 Criterion

The Physio Control VSM 2 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 Physio Control VSM 2.

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 Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

The Physio Control VSM 2 will remain operational and be to display consistent and accurate performance while exposed vibrational stresses.

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the Physio Control VSM 2.

2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TA115-40/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 Physio Control VSM 2 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 Physio Control VSM 2.

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 Physio Control VSM 2 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 Physio Control VSM 2 to be stored and operated in a high temperature environment.

2.7.2 Criteria

2.7.2.1 The Physio Control VSM 2 will demonstrate consistent and accurate operation during the high temperature operation check.

2.7.2.2 The Physio Control VSM 2 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 Physio Control VSM 2.

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 Physio Control VSM 2 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 ± 2°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 Physio Control VSM 2 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 Physio Control VSM 2.

2.7.3.4 The Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2.

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 Physio Control VSM 2 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 Physio Control VSM 2 to be stored and operated in a low temperature environment.

2.8.2 Criteria

2.8.2.1 The Physio Control VSM 2 will demonstrate consistent and accurate operation during the low temperature operation check.

2.8.2.2 The Physio Control VSM 2 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 Physio Control VSM 2.

2.8.3.2 The Physio Control VSM 2 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 Physio Control VSM 2.

2.8.3.4 The Physio Control VSM 2 was "stored" in a nonoperational mode. The Physio Control VSM 2 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 Physio Control VSM 2.

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 Physio Control VSM 2 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 Physio Control VSM 2 to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

The Physio Control VSM 2 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 Physio Control VSM 2.

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 Physio Control VSM 2 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 ± 2°C and humidity within ± 5 percent RH. At 45-minute intervals the performance of the Physio Control VSM 2 was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the Physio Control VSM 2 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 Physio Control VSM 2.

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 Physio Control VSM 2 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 Physio Control VSM 2 in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the Physio Control VSM 2 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 Physio Control VSM 2 in the 10 kHz to 50 MHz frequency ranges.

2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the Physio Control VSM 2 within the range of 50 kHz to 400 MHz and power spikes.

2.10.2 Criteria

2.10.2.1 The Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 was operating, the frequency spectrum (14 kHz to 12.4 GHz) was scanned for emissions. The Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 was operating, the frequency range (10 kHz to 50 MHz) was scanned for emissions conducted in the power cable from the Physio Control VSM 2.

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 Physio Control VSM 2 was plugged into the other receptacle on the connection box and 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 VSM 2 was placed on a grounded, copper-covered workbench. Radio frequency interference was induced on the power leads and measured at the VSM 2 power cable. The frequency of the interference was incremented

over the 50 kHz to 400 MHz range while the VSM 2 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:

Battery Operation:

Frequency range	Emission exceeding standard
20 kHz - 24.051 MHz	0.1 - 46 dB (NB)
80.146 - 393.174 MHz	0.3 - 33.1 dB (NB)
70 kHz - 93.914 MHz	0.1 - 18.8 dB (BB)
199.996 MHz	8.8 dB (BB)

AC Operation:

Frequency range	Emission exceeding standard
0.28 - 8.345 MHz	4.4 - 44.3 dB (NB)
20.807 - 292.051 MHz	0.9 - 52.2 dB (NB)
0.069 - 1.087 MHz	1.4 - 8.5 dB (BB)
5.5 - 29.204 MHz	0.4 - 21.7 dB (BB)
58.331 MHz	1.0 dB (BB)
92.936 MHz	6.4 dB (BB)
199.996 MHz	6.7 dB (BB)

Criterion partially met.

2.10.4.2 The Physio Control VSM 2 was found to be susceptible to radio frequency interference in the testing range and magnitude. These included:

Battery Operation:

Frequency range	Field strength
19.2 - 23.6 MHz	0.56 - 2.98 V/m
30.0 - 200.0 MHz	0.32 - 8.91 V/m
200.0 - 312.0 MHz	0.45 - 5.01 V/m
352 MHz	6.31 V/m

AC Operation:

Frequency range	Field strength
7.60 - 7.9 MHz	0.42 - 1.67 V/m
10.0 - 12.0 MHz	1.58 - 2.81 V/m
19.6 MHz	2.11 V/m
30.0 - 200.0 MHz	0.56 - 9.44 V/m
200.0 - 312.0 MHz	0.34 - 6.68 V/m

Criterion partially met.

2.10.4.3 Narrowband (NB) and Broadband (BB) emissions that exceeded standards were detected from the VSM 2 during the conducted emissions test. These included:

Frequency	Amount exceeding standard
49.502 - 50.0 kHz	0.8 - 8.0 dB (NB)
50.0 kHz - 45 MHz	0.2 - 22.6 dB (NB)
0.525 - 24.5 MHz	0.1 - 26.5 dB (BB)

Criterion partially met.

2.10.4.4 The VSM 2 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 Physio Control VSM 2 while in use onboard the aircraft.

2.11.2 Criterion

The flight surgeon will be able to operate the Physio Control VSM 2 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 Physio Control VSM 2 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 Physio Control VSM 2 was placed on a seat in the aircraft and secured with cargo straps. The Physio Control VSM 2 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).

2.11.4 Test findings

During the in-flight human factors evaluation, the Physio Control VSM 2 was found to be satisfactory in all categories of the evaluation criteria except as noted in the laboratory evaluation. All controls could be operated with the flight gloves despite the close proximity previously noted. Criterion met.

2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS

2.12.1 Objective

To assess the EMI/EMC characteristics of the Physio Control VSM 2 with the host aircraft and its installed systems.

2.12.2 Criteria

2.12.2.1 The Physio Control VSM 2 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 Physio Control VSM 2's operation.

2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the Physio Control VSM 2 and the aircraft operating as source and victim. The Physio Control VSM 2 and applicable aircraft instruments and systems were monitored for unusual operation, readings, surges, or power anomalies for each checklist item (see pages 3-4 through 3-7).

2.12.4 Test findings

2.12.4.1 There were no adverse instances of EMI/EMC noted with the Physio Control VSM 2 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 Physio Control VSM 2 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 Vistal Signs Monitor, model VSM 2, is designed to noninvasively monitor a patient's electrocardiogram (ECG), blood pressure, and temperature. A 5-inch cathode ray tube (CRT) provides a visual display of the ECG and numeric light emitting diodes (LED) display the heart rate, blood pressure, temperature, and alarm condition. The ECG can also be printed on an integral strip chart recorder. A square pushbutton labeled "POWER" energizes the VSM 2. A lead select switch is provided to select display of Lead I, II, III, or STD. Two rotary switches are provided to allow the user to select high and low alarm conditions for heart rate. In addition, rotary switches adjust QRS volume, alarm silence, and ECG size.

The systolic, diastolic, and mean blood pressure are shown on individual LED displays. A fourth LED display is used to show the elapsed time between blood pressure measurements. When a temperature probe is connected to the unit, this display alternates between the elapsed time and temperature display.

ECG data is obtained from the patient using standard ECG electrodes and lead wires. Blood pressure is obtained from a standard blood pressure cuff. The VSM 2 uses the oscillometric technique, where expansion of the cuff due to blood vessel filling, is monitored rather than auscultation of Kortkoff sounds at the brachial artery.

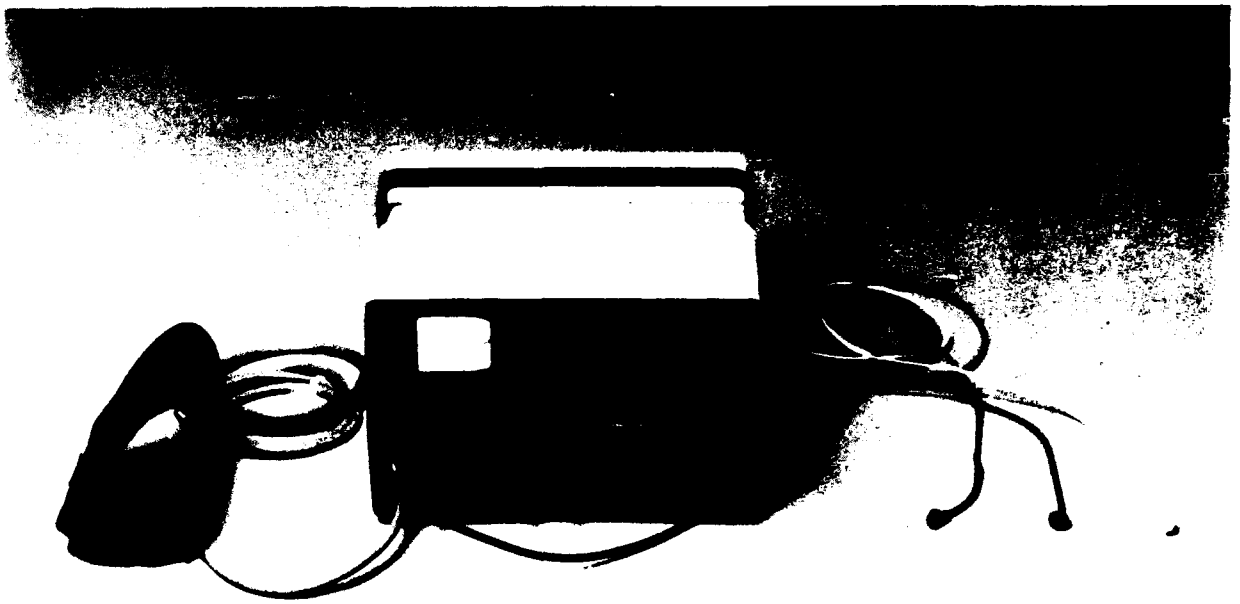
3.1.2.2 Dimensions: 23.2 x 30.5 x 28.6 cm (9.15 x 12 x 11.25 in).

3.1.2.3 Weight: 11 kg (25 lbs)

3.1.2.4 Power requirements: 95 - 132 Vac, 60 Hz, 85 Watts. Internal battery: nickel cadmium, 14.4 V, 1.5 Ah.

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 Yes	Suitable No	Comments
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 configuration (functional/stable).	X		

2. Operations and performance.	Suitable Yes	Suitable No	Comments
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	Suitable 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 aircraft hover and medical item operation (EMI switchology checklist).			
(1) Voltage output.	NA		
(2) Radio communication vs. medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		

	Suitable Yes	No	Comments
(3) Navigation equipment operation vs. medical item operation.			
(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 operation.			
a. FM	X		
b. UHF	X		
c. 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	Suitable 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 laboratory 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 conducted 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected 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	EMI Affected Flt	Explanation
Blade deice	Not tested			Ambient temperature was out of test limits.
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 Gnd	EMI Affected Flt	Explanation
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			

3.2.5 Battery life evaluation

Battery Life Evaluation
Report Form

Nomenclature: Patient Monitor
Manufacturer: Physio Control
Model number: VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Manufacturer battery life specification: 20 minutes operation on a fully charged battery

Overall performance: Pass

Performance: Average operating time of 1 hour and 17 minutes operation on a fully charged battery with heart rate display and blood pressure every 5 minutes.

Comments: 16 hours allowed for battery to recharge between tests.

3.2.6 Electrical safety test

Electrical Safety Test
Report Form

Nomenclature: Patient Monitor
Manufacturer: Physio Control
Model number: Physio Control VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 9 Aug 90

Performance:

Grounding conductor resistance (milliohms): 40.3

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity	4.1
unit off, ungrounded, normal polarity	4.1
unit off, ungrounded, reverse polarity	4.1
unit on, grounded, normal polarity	3.9
unit on, ungrounded, normal polarity	3.9
unit on, ungrounded, reverse polarity	3.9

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

Comments on other data: None

3.2.7 Human factors evaluation

Human Factors Evaluation
Report Form

Nomenclature: Patient Monitor
Manufacturer: Physio Control
Model number: VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 6 Sep 90

Item configuration during test: Operating on a counter with the ECG leads attached to a simulator and BP cuff worn by a test engineer. Temperature probe measuring ambient conditions.

Checklist for HFE

RESULTS

VISUAL DISPLAYS: Unsatisfactory

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: No indication of a low battery before the unit shuts off. The battery charge scalar is difficult to see.

CONTROLS: Unsatisfactory

location
characteristics of controls
labeling
control - display relationships

Comments: The alarm silence button is crowded by QRS volume and ECG size rotary switches (ref. MIL-STD-1472D).

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: approximately 6 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: None

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: NA

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: The unit performs an internal self test.

FUSES AND CIRCUIT BREAKERS: Satisfactory

external accessibility
easy replacement or reset by operator

Comments: 1.5 amp fuse, 120 Vac external fuse.

LABELS AND CODING: Unsatisfactory

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: Both temperature and elapsed time alternate on the same LED under the elapsed time label. Temperature could be mistaken for elapsed time.

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: Patient Monitor
Manufacturer: Physio Control
Model number: Physio Control VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 27 Aug 90

Item configuration during test: Item sitting on chamber floor.

Performance test criteria: Correct and accurate measurement of simulated biologic signals.

Ambient conditions outside chamber:

Temperature	77°F
Humidity	68% 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	ECG simulator
list connections to dummy loads	None
list unconnected terminals	None

IN-TEST DATA

Time of test start: 1400

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: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.9 Vibration test

Vibration Test
Report Form

Nomenclature: Patient Monitor
Manufacturer: Physio Control
Model number: Physio Control VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 27 Aug 90

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

Performance test criteria: Correct and accurate measurement of simulated biologic signals.

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	ECG simulator
list connections to dummy loads	None
list unconnected terminals	None

Ambient conditions

Temperature	77°F
Humidity	67% RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Time at first check:
X: 0820 Y: 0930 Z: 1230

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Time at second check:
X: 0840 Y: 0934 Z: 1235

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

POSTTEST DATA

Time at test end:
X: 0920 Y: 1100 Z: 1333

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: Patient Monitor
Manufacturer: Physio Control
Model number: Physio Control VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 24 Aug 90

Item configuration during test: Unit was sitting on wire test stand.

Performance test criteria: Correct and accurate measurement of simulated biologic signals.

Ambient conditions outside chamber:

Temperature	26°C
Humidity	52% 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	ECG simulator
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

IN-TEST DATA

Time of test start: 1025

Performance checks during test:

First check:

Time: 1055
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: 1125
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: 1155
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: 1225
Item functional (based on performance test criteria): Yes, all ok
Deviation from pretest: None

Comments on item setup or checks: ECG leads and temperature probe extended through chamber portal to simulator and ambient conditions. Unit operated on ac and battery power.

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: Patient Monitor
Manufacturer: Physio Control
Model number: Physio Control VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 28 Aug 90

Item configuration during test: Unit was sitting on wire test stand, temperature probe, BP cuff, ECG leads, and power cord coiled and placed on top the unit.

Performance test criteria: Correct and accurate measurement of simulated biologic signals.

Ambient conditions outside chamber:

Temperature	26C
Humidity	52% 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	ECG simulator
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

Time of test start: 0815

POSTTEST DATA

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

Time of test end: 1415
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: Patient Monitor
Manufacturer: Physio Control
Model number: Physio Control VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 24 Aug 90

Item configuration during test: Unit was sitting on wire test stand.

Performance test criteria: Correct and accurate measurement of simulated biologic signals.

Ambient conditions outside chamber:

Temperature	25°C
Humidity	53% 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	ECG simulator
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

Time of test start: 1325

Performance checks during test:

First check:

Time:	1355
Temperature:	0°C
Humidity:	NA
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Second check:

Time:	1425
Temperature:	0°C
Humidity:	NA
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Third check:

Time:	1455
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:	1525
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: Patient Monitor
Manufacturer: Physio Control
Model number: Physio Control VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 29 Aug 90

Item configuration during test: Unit was sitting on wire test stand, BP cuff, ECG leads, and power cord coiled and placed on the unit.

Performance test criteria: Correct and accurate measurement of simulated biologic signals.

Ambient conditions outside chamber:

Temperature	26°C
Humidity	51% 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	ECG simulator
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

Time of test start:	0815
Midtest time:	1115
Midtest temperature:	-46°C

POSTTEST DATA

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

Time of test end: 1415
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: Patient Monitor
Manufacturer: Physio Control
Model number: Model VSM 2
Serial number: 00003800
Military item number: None

Options installed: None

Date of test: 30 Aug 90

Item configuration during test: Unit was sitting on wire test stand.

Performance test criteria: Correct and accurate measurement of simulated biologic signals.

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	ECG simulator
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

IN-TEST DATA

Time of test start: 0835

Performance checks during test:

First check:

Time:	0920
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:	1005
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:	1050
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:	1135
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:	1220
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: 1235
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: 25 Date: 10 Aug 90

Nomenclature: Patient Monitor
Manufacturer: Physio Control
Model number: VSM 2
Serial number: 00003800
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): Fail

Comments: Emission 0.8 - 8.0 dB from 49.502 - 50.0 kHz

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

Comments: NB and BB emissions in excess of limits were detected. NB: 0.2 - 22.6 dB from 0.05 - 45 MHz. BB: 0.1 - 26.5 dB from 0.525 - 24.5 MHz.

Conducted Susceptibility Tests

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

Comments: Not susceptible to test signals on power conductors.

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, ac power.
Performance (pass/fail): Fail

Comments: Range and emissions:

Battery Operation:

Frequency range	Emission exceeding standard
20 kHz - 24.051 MHz	0.1 - 46 dB (NB)
80.146 - 393.174 MHz	0.3 - 33.1 dB (NB)
70 kHz - 93.914 MHz	0.1 - 18.8 dB (BB)
199.996 MHz	8.8 dB (BB)

AC Operation:

Frequency range	Emission exceeding standard
0.28 - 8.345 MHz	4.4 - 44.3 dB (NB)
20.807 - 292.051 MHz	0.9 - 52.2 dB (NB)
0.069 - 1.087 MHz	1.4 - 8.5 dB (BB)
5.5 - 29.204 MHz	0.4 - 21.7 dB (BB)
58.331 MHz	1.0 dB (BB)
92.936 MHz	6.4 dB (BB)
199.996 MHz	6.7 dB (BB)

Radiated Susceptibility Tests

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

Comments: Range and field strength:

Battery Operation:

Frequency range	Field strength
19.2 - 23.6 MHz	0.56 - 2.98 V/m
30.0 - 200.0 MHz	0.32 - 8.91 V/m
200.0 - 312.0 MHz	0.45 - 5.01 V/m
352 MHz	6.31 V/m

AC Operation:

Frequency range	Field strength
7.60 - 7.9 MHz	0.42 - 1.67 V/m
10.0 - 12.0 MHz	1.58 - 2.81 V/m
19.6 MHz	2.11 V/m
30.0 - 200.0 MHz	0.56 - 9.44 V/m
200.0 - 312.0 MHz	0.34 - 6.68 V/m

CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

3.3.1 Criteria

Item No.	Criteria (source)	Remarks	Applicable subparagraph
1	The physical inventory is conducted solely for investigation and documentation.	NA	2.1.2.1
2	The Physio Control VSM 2 will display consistent and accurate performance.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 20 minutes	met	2.2.2
4	The Physio Control VSM 2 will meet the limits established in NFPA 99 for electrical safety of medical equipment.	met	2.3.2
5	The Physio Control VSM 2 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 Physio Control VSM 2 will demonstrate proper operation - while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	The Physio Control VSM 2 will remain operational while exposed to vibrational stresses.	met	2.6.2
8	The Physio Control VSM 2 will remain operational during the high temperature operation check.	met	2.7.2.1

9	The Physio Control VSM 2 will remain operational after the high temperature storage.	met	2.7.2.2
10	The Physio Control VSM 2 will remain operational during the low temperature operation check.	met	2.8.2.1
11	The Physio Control VSM 2 will remain operational after the low temperature storage.	met	2.8.2.2
12	The Physio Control VSM 2 will remain operational while exposed to a high humidity.	met	2.9.2
13	The Physio Control VSM 2 will not produce emissions in excess of the limits set forth in MIL-STD-461A Notice 4, paragraph 6.13.	partially met	2.10.2.1
14	The Physio Control VSM 2 will not malfunction when it is subjected to radiated fields as specified in MIL-STD-461A, Notice 4, paragraph 6.20.	partially met	2.10.2.2
15	The Physio Control VSM 2 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
16	The Physio Control VSM 2 will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.	partially met	2.10.2.4
17	The flight surgeon will be able to operate the Physio Control VSM 2 without physical or functional restrictions aboard the aircraft.	met	2.11.2.1

18	The Physio Control VSM 2 will not radiate EMI to disrupt or interfere with the other equipment or systems aboard the aircraft.	met	2.12.2.2
19	The aircraft will not radiate EMI to disrupt or interfere with the Physio Control VSM 2.	met	2.12.2.3

3.3.2 Significant problems which require corrective action

None

3.3.3 Suggested improvements

None

3.4 REFERENCES

3.4.1 Department of Defense. 1971. EMI characteristics, requirements for equipment. Washington, DC. MIL-STD-461A, Notice 4. February.

3.4.2 Department of Defense. 1971. EMI characteristics, measurement of. Washington, DC. MIL-STD-462, Notice 3. February.

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.

3.4.5 Underwriters Laboratory's, Inc. 1978. Standard for safety, medical and dental equipment. Chicago, Illinois. UL-544.

3.4.6 Department of Defense. 1989. Human engineering design criteria for military systems, equipment, and facilities. Washington, DC. MIL-STD-1472D. March.

3.4.7 Association for the Advancement of Medical Instruments. 1988. Human factors engineering guidelines and preferred practices for the design of medical devices. Arlington, Virginia. AAMI-HE-1988. February.

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
mL	milliliter
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
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

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3.6.3 Tenney Engineering, Inc.
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3.6.4 Unholtz-Dickey Corporation
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3.6.5 Solar Electronics Company
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3.6.6 Tektronix, Inc.
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