

USAARL Report No. 93-18



**Test and Evaluation Report  
of the  
Medical Data Electronics Escort Patient Monitor  
Model E300A**

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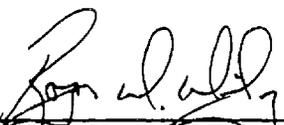
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19. ABSTRACT (Continue on reverse if necessary and identify by block number) The Medical Data Electronics escort patient monitor, model E300A, was tested for environmental and electromagnetic interference/compatibility in the UH-60A helicopter under 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 Medical Data Electronics escort patient monitor, model E300A, did not perform properly in the vibration test, high temperature operation test, and low temperature operation test. Excess electromagnetic emissions and electromagnetic susceptibility make it ineligible for an airworthiness release. The unit is not considered compatible with the U.S. Army Medical Evacuation UH-60A 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 systems' 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 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 potentially could 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) at Fort Rucker, Alabama.

1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was available for flight test of the MDE® patient monitor\*, model E300A. The unit was not approved for flight testing.

1.3.3 The following tests were accomplished: Acceptance inspection, equipment training, electromagnetic compatibility, human factors and safety, and environmental compatibility.

## 1.4 MATERIAL DESCRIPTION

The MDE® model E300A patient monitor is electrically driven and designed to measure and monitor a patient's electrocardiograph (ECG), noninvasive blood pressure (NIBP), respiration (RESP) and temperature (TEMP). Six soft keys (membrane switches) on the bottom front panel of the patient monitor allow the operator to select the desired function. Each function's membrane switch has menu driven screens for adjustments and selections which are displayed on the bottom of the backlight liquid crystal display (LCD). Each menu and submenu screen allows the operator to select parameters and other menus ("NEXT PAGE") or

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\* See list of manufacturers

return to the original menu ("PAGE HOME"). Parameter measurements and corresponding wave forms, if selected, are displayed on the LCD. Each measured parameter has a separate alarm indicator and warning setting which are selected via the front panel membrane switches. If activated, an "ALARM SUSPEND" button on the front panel will suspend all alarms for 180 seconds in the adult mode and 90 seconds in the neonatal mode. The side panel of the E300A houses the patient input connectors for the ECG leads, NIBP, SAO2, BP, and TEMP. The rear of the patient monitor incorporates the ac receptacle, on/off ac line switch, ac voltage select switch, fuse holder, auxiliary output, two rechargeable batteries, and a defibrillator interface.

## 1.5 SUMMARY

### 1.5.1 Laboratory testing

1.5.1.1 Battery life evaluation: The MDE model E300A was operated on a fully-charged battery and connected to a Valmedix ECG simulator, at room temperature (75° F and 51% RH). The fully-charged MDE® model E300A averaged 2 hours and 39 minutes of operation. The battery is rated for up to a maximum of 3 hours of operation.

1.5.1.2 Electrical safety evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the MDE® model E300A. The limits for currents and resistances were in accordance with (IAW) the limits specified in TB-38-750-2, April 1987.

1.5.1.3 Human factors evaluation: The MDE® model E300A was found to be satisfactory in all major categories of the evaluation criteria with one exception.

1.5.1.4 Environmental tests: The MDE® model E300A may be unsatisfactory for use in certain environmental conditions. Its performance was found to be unsatisfactory in stages of the environmental testing. The MDE® E300A patient monitor performance was found to be unsatisfactory during the vibration, high temperature operation, and low temperature operation tests. During vibration on the Z-axis, the patient monitor malfunctioned internally and would not operate. During the high temperature operation test, the unit's backlight LCD screen failed. The unit was sent back to the manufacturer for repairs on both occasions. At the manufacturer's request, the low temperature operation test was not performed. The unit will not operate in an environment below 5°C . The requirements for environmental tests are established in MIL-STD-810E, 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 MDE® model E300A may be unsatisfactory for use in certain EMI sensitive environments. Narrowband (NB) and broadband (BB) radiated emissions were detected in the test frequency ranges. Some narrowband and broadband emissions exceeded the test limits. Emission limits are set forth in MIL-STD-461C, Notice 5.

1.5.1.6 Radiated susceptibility test (RS03): The MDE® model E300A 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 specification limits were detected.

1.5.1.8 Conducted susceptibility test (CS02 and CS06): The MDE model E300A was not found to be susceptible to the test-generated signals and spikes on its power lines.

#### 1.5.2 In-flight testing

In-flight testing of the MDE® model E300A patient monitor could not be accomplished. As a result of excessive failures in laboratory environmental (vibration, high temperature, and low temperature) and electromagnetic compatibility (RE02 and RS03) a request for airworthiness release from the U.S. Army Aviation Systems Command will not be pursued.

#### 1.6 CONCLUSION

The MDE® model E300A did not perform properly in the vibration test, high temperature operation test, and low temperature operation test. This, combined with excess electromagnetic emissions and electromagnetic susceptibility, make it ineligible for an airworthiness release. The unit is not considered compatible with the U.S. Army medical evacuation 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 MDE® model E300A 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 MDE® model E300A 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 MDE® model E300A was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the MDE® model E300A was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

#### 2.1.4 Test findings

2.1.4.1 The MDE® model E300A was inventoried and found to be complete.

2.1.4.2 The MDE® model E300A 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 battery life expectancy of up to 3 hours operation.

### 2.2.3 Test procedure

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

2.2.3.2 The MDE® model E300A was operated continuously using its fully-charged battery until a low battery indication occurred. The depletion time was noted and the battery was recharged. This procedure was repeated three times.

### 2.2.4 Test findings

The test was conducted using the fully-charged battery. The average operating time in testing was 2 hours and 39 minutes at room temperature. Criterion met.

## 2.3 ELECTRICAL SAFETY EVALUATION

### 2.3.1 Objective

To ensure the electrical safety of the MDE® model E300A by evaluation of case-to-ground resistance and case-to-ground current leakage.

### 2.3.2 Criterion

The MDE® model E300A shall meet the standards established in Technical Bulletin Number 38-750-2, April 1987 for electrical safety of medical equipment.

### 2.3.3 Test procedure

Measurements 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. 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 80.2 milliohms and maximum case leakage current was 28.5 microamperes. These measurements are below the limits specified in TB 38-750-2 and NAFF 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 MDE® model E300A 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 MDE® model E300A was operated according to prescribed instructions through its full range of functions.

### 2.4.4 Test finding

The MDE® model E300A was found to be satisfactory in all of the evaluation criteria Criterion met.

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

### 2.5.1 Objective

To determine if the MDE® model E300A can function as designed in a low-pressure environment.

### 2.5.2 Criterion

The MDE® model E300A will display consistent and accurate measurements 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 MDE® model E300A.

2.5.3.2 The altitude test was performed in a Tenney Engineering model 64S altitude chamber\*. This test is based on MIL-STD-810E, Method 500.2. The MDE® model E300A was operating and placed 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 were 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 MDE® model E300A 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 The posttest performance check met criterion 2.1.2.2.

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

#### 2.6.1 Objective

To determine the ability of the MDE® model E300A to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

#### 2.6.2 Criterion

The MDE® model E300A will remain operational and be able to display consistent and accurate measurements 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 MDE® model E300A.

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 measurements 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-810E, Method 514.3; Independent tests were conducted in the X-, Y-, and Z-axes.

### X-, Y-, and Z-axes

duration: 60 minutes  
broadband intensity: 2.116  $G_{rms}$   
random vibration: initial slope : 99.00 dB/oct  
5 Hz level: 0.00007  $G_{sqr/Hz}$   
100 Hz level: 0.0007  $G_{sqr/Hz}$   
300 Hz level: 0.0007  $G_{sqr/Hz}$   
500 Hz level: 0.00007  $G_{sqr/Hz}$   
final slope: -99.00 dB/oct

#### sinusoidal vibration:

0.9500  $G_{pk}$  at 17.00 Hz  
1.4000  $G_{pk}$  at 34.00 Hz  
0.9000  $G_{pk}$  at 51.00 Hz  
0.9000  $G_{pk}$  at 68.01 Hz

The MDE® model E300A 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 MDE® model E300A.

#### 2.6.4 Test findings

2.6.4.1 The pretest performance check met criterion 2.1.2.2.

2.6.4.2 Failures in the performance of the MDE® model E300A occurred during exposure to vibration. The E300A internally malfunctioned and would not operate. The unit was sent back to the manufacturer for repairs. Criterion not met.

2.6.4.3 The posttest performance check met criterion 2.1.2.2.

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

##### 2.7.1 Objective

To determine the ability of the MDE® model E300A to be stored and operated in a high-temperature environment.

##### 2.7.2 Criteria

2.7.2.1 The MDE® model E300A will display consistent and accurate measurements during the high-temperature operation check.

2.7.2.2 The MDE® model E300A will display consistent and accurate measurements 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 MDE® model E300A.

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-810E, Method 501.2. For the high-temperature operation test, the MDE® model E300A was operating and connected to a Valmedix ECG simulator 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 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 MDE® model E300A 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 MDE® model E300A.

2.7.3.4 The MDE® model E300A 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 MDE® model E300A 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 MDE® model E300A.

### 2.7.4 Test findings

2.7.4.1 The pretest performance check met criterion 2.1.2.2.

2.7.4.2 The MDE® model E300A failed to function correctly during the high temperature operation test. The backlight LCD failed and the measured parameters could not be monitored. The unit was sent back to the manufacturer for repairs. Criterion not met.

2.7.4.3 The posttest performance check did not meet criterion 2.1.2.2.

2.7.4.4 The MDE® model E300A functioned properly after the high-temperature storage test. Criterion met.

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

### 2.8.1 Objective

To determine the ability of the MDE® model E300A to be stored and operated in a low-temperature environment.

### 2.8.2 Criteria

2.8.2.1 The MDE® model E300A will display consistent and accurate measurements during the low-temperature operation check.

2.8.2.2 The MDE® model E300A will display consistent and accurate measurements 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 MDE® model E300A.

2.8.3.2 The MDE® model E300A was not evaluated in the low temperature operation test at request from the manufacture. The manufacturer indicates the unit will not operate in an environment below 5°C.

2.8.3.3 A posttest performance check was conducted to ensure proper operation of the MDE® model E300A.

2.8.3.4 The MDE® model E300A was "stored" in a nonoperational mode. The MDE® model E300A 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 MDE® model E300A.

### 2.8.4 Test findings

2.8.4.1 The pretest performance check met criterion 2.1.2.2.

2.8.4.2 The unit was not evaluated in the low temperature operation test at request from the manufacture. Criterion not met.

2.8.4.3 The posttest performance check did not meet criterion 2.1.2.2.

2.8.4.4 The MDE® model E300A functioned properly after the low-temperature storage test. Criterion met.

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

### 2.9.1 Objective

To determine the ability of the MDE® model E300A to operate satisfactorily for short periods of time during exposure to highly humid conditions.

### 2.9.2 Criterion

The MDE® model E300A will display consistent and accurate measurements 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 MDE® model E300A.

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 MDE® model E300A 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  $\pm 5$  percent RH. At 45-minute intervals, the performance of the BP monitor was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the MDE® model E300A 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 MDE® model E300A.

### 2.9.4 Test findings

2.9.4.1 The pretest performance check met criterion 2.1.2.2.

2.9.4.2 The MDE® model E300A was not adversely affected by the high humid 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-461C, Notice 5, 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 MDE® model E300A in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the MDE® model E300A 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 MDE® model E300A in the 10 kHz to 50 MHz frequency range.

2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the MDE® model E300A within the range of 50 kHz to 400 MHz and power spikes.

2.10.2 Criteria

2.10.2.1 The MDE® model E300A will not produce emissions in excess of the limits set forth in MIL-STD-461C, Notice 5, paragraph 6.13.

2.10.2.2 The MDE® model E300A will not malfunction when it is subjected to radiated emissions as specified in MIL-STD-461C, Notice 5, paragraph 6.20.

2.10.2.3 The MDE® model E300A shall not conduct emissions in excess of the limits set forth in MIL-STD-461C, Notice 5, paragraphs 6.1 and 6.2.

2.10.2.4 The MDE® model E300A shall not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461C, Notice 5, 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 MDE® model E300A 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 MDE® model E300A was operating, the frequency spectrum (14 kHz to 12.4 GHz) was scanned for emissions. The MDE® model E300A was operated with both ac and battery power.

2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The MDE® model E300A 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 MDE® model E300A was operating, it was monitored for faulty operation during exposures to fields of 20 V/m from 10 kHz to 10 GHz. The MDE® model E300A 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 MDE® model E300A 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 MDE® model E300A was operating, the frequency range (10 kHz to 50 MHz) was scanned for emissions conducted in the power cable.

2.10.3.4 The conducted susceptibility spike test was performed according to MIL-STD-462, Notice 3, Method CS06, on a chemical resistant counter top. 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 are made in series through the banana jacks. Transient spikes of 200 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 MDE® model E300A was plugged into the other receptacle on the connection box and placed in operation. It was observed for correct operation and visual displays 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 MDE® model E300A was placed on a grounded, copper-covered workbench. Radio frequency interference was induced on the power leads and measured at the power cable. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the MDE® model E300A was operated. It was observed for correct operation and visual displays 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-461C, Notice 5, were detected. These included:

ac operating failure data:

<u>Frequency (MHz)</u>	<u>Amount of failure (dB)</u>
NB: 0.024 - 363.037	0.5 - 34.6
BB: 0.016 - 3.131	0.2 - 20.9
BB: 25.609	9.3
BB: 30.000	11.8

Battery operating failure data:

<u>Frequency (MHz)</u>	<u>Amount of failure (dB)</u>
NB: 0.126 - 425	0.1 - 35.0
BB: 0.016 - 1.688	0.1 - 21.5
BB: 30.0	10.1

Criterion not met.

2.10.4.2 The MDE® model E300A was found to be susceptible to radio frequency interference in the testing range and magnitude.

ac operating failure data:

<u>Frequency (MHz)</u>	<u>Threshold of failure (V/m)</u>
10.0 - 14.2	2.12 - 10.0
29.6 - 38.5	1.89 - 7.10
69.1	6.32
9.7 - 145.6	1.5 - 15.0

Battery operating failure data:

<u>Frequency (MHz)</u>	<u>Threshold of failure (V/m)</u>
10.0 - 14.0	4.75 - 12.6
16.2 - 25.6	6.32 - 15.0
30.0 - 145.6	1.12 - 11.9
174.5	1.68

Criterion partially met.

2.10.4.3 The MDE® model E300A did not produce conducted emissions in excess of the limits. Criterion met.

2.10.4.4 The MDE® model E300A was not susceptible to the test-generated signals or test-generated spikes produced on the power lines. Criterion met.

## 2.11 IN-FLIGHT HUMAN FACTORS EVALUATION

### 2.11.1 Objective

To assess the physical and/or functional compatibility of the MDE® model E300A while in use on board the aircraft.

### 2.11.2 Criterion

The flight surgeon will be able to operate the MDE® model E300A 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

Not applicable since unit not available for in-flight testing.

### 2.11.4 Test findings

Not available since unit not available for in-flight testing. Criterion not evaluated.

## Section 3. Supporting documentation

### 3.1 DETAILED TEST INFORMATION

#### 3.1.1 General information

3.1.1.1 MDE® model E300A 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 MDE® model E300A patient monitor is electrically driven and designed to measure and monitor a patient's electrocardiograph (ECG) noninvasive blood pressure (NIBP), respiration (RESP) and temperature (TEMP). Six soft keys (membrane switches) on the bottom front panel of the patient monitor allow the operator to select the desired function. Each function's membrane switch has menu-driven screens for adjustments and selections which are displayed on the bottom of the backlight liquid crystal display (LCD). Each menu and submenu screen allows the operator to select parameters and other menus ("NEXT PAGE") or return to the original menu ("PAGE HOME"). Parameter measurements and corresponding wave forms, if selected, are displayed on the LCD. Each measured parameter has a separate alarm indicator and warning setting which are selected via the front panel membrane switches. If activated, an "ALARM SUSPEND" button on the front panel will suspend all alarms for 180 seconds in the adult mode and 90 seconds in the neonatal mode. The side panel of the E300A houses the patient input connectors for the ECG leads, NIBP, SAO2, BP, and TEMP. The rear of the patient monitor incorporates the ac receptacle, on/off ac line switch, ac voltage select switch, fuse holder, auxiliary output, two rechargeable batteries, and a defibrillator interface.

3.1.2.2 Dimensions: 7 x 7 x 8.5 in. (17.78 x 17.78 x 21.59 cm.)

3.1.2.3 Weight: 14 lb (6.35 kg).

3.1.2.4 Power requirements: 110 Vac, 60 Hz, 0.5 amp, 3-wire grounded system. External rechargeable batteries provide up to 3 hours of rated operation. Charge time for a low battery to a full charge approximately 14 hours with the unit off. Power cord is 18-3, type SJT, PE CO, of approximately 119 inches in length.

## 3.2 TEST DATA

### 3.2.1 Photographic description

Photo not available

### 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 infusion pump -- C-8021E/ASN75
24	Magnetic compass - standby -- MS-17983-4

3.2.3 Battery life evaluation

Battery life evaluation  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Manufacturer battery life specification: Up to 3 hours

Specified battery recharge time: 14 hours (full charge).

Specified mode of operation under battery power: ECG connected to simulator. SA02 and NIBP connected to the test engineer.

Overall performance: Pass

Measurements:

Dates of first test: 9/29/92  
Temperature: 23°C  
Humidity: 51% RH  
Start time: 1226  
End time: 1507  
Operating time: 2 hours 41 minutes  
\*\*\*\*\*  
TOTAL OPERATING TIME: 2 hours 41 minutes  
PERFORMANCE: Pass

Dates of second test: 9/30/92  
Temperature: 24°C  
Humidity: 46% RH  
Start time: 0730  
End time: 1007  
Operating time: 2 hour 37 minutes  
\*\*\*\*\*  
TOTAL OPERATING TIME: 2 hour 37 minutes  
PERFORMANCE: Pass

Dates of third test: 10/1/92  
Temperature: 22°C  
Humidity: 46% RH  
Start time: 0725  
End time: 1005  
Operating time: 2 hours 40 minutes  
\*\*\*\*\*  
TOTAL OPERATING TIME: 2 hours 40 minutes  
PERFORMANCE: Pass

Comments: The unit averaged 2 hours and 39 minutes of operation.

### 3.2.4 Electrical safety test

#### Electrical safety test report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: 9 March 1992

#### Measurements:

Grounding conductor resistance (milliohms): 80.5

Leakage current - case to ground (microamperes):

unit off, grounded, normal polarity	0.1
unit off, ungrounded, normal polarity	0.1
unit off, ungrounded, reverse polarity	28.5
unit on, grounded, normal polarity	0.1
unit on, ungrounded, normal polarity	21.2
unit on, ungrounded, reverse polarity	28.5

#### MAXIMUM LIMITS:

ground resistance (milliohms):	150
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

Additional measurements for equipment with patient leads

EUT always ON, set for Lead I

Current ( $\mu$ A): All leads to ground  
(G, P)0.3 (UG, NP)6.8 (UG, RP)9.1

Current ( $\mu$ A): Right Arm to ground  
(G, NP)2.8 (UG, NP)7.6 (UG, RP)9.4

Current ( $\mu$ A): Left Arm to ground  
(G, NP)2.8 (UG, NP)7.8 (UG, RP)9.8

Current ( $\mu$ A): Right Leg to ground  
(G, NP) NA (UG, NP) NA (UG, RP)NA

Current ( $\mu$ A): Left Leg to ground  
(G, NP)0.3 (UG, NP)6.4 (UG, RP)8.6

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.5 Human factors evaluation

Human factors evaluation  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: 23 November 1992

Item configuration during test: Item prepared for operation,  
sitting on a counter top and connected to simulators.

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:

CONTROLS:

Satisfactory

location  
characteristics of controls  
labeling  
control - display relationships

Comments: None

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: 2.5 to 3 minutes required to prepare for oper-  
ation.

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: There is an internal self-test with each power-up. There is no lubrication or need for internal accessibility.

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: No test points.

TEST EQUIPMENT:

Satisfactory

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

Comments: An internal self-test outputs codes for normal status, leads off, and for failures.

FUSES AND CIRCUIT BREAKERS:

Satisfactory

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

3.2.6 Altitude test

Altitude test  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: 31 March 1992

Item configuration during test: Item operating, sitting on chamber floor connected to ECG simulator.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	76°F
Humidity	65% 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 (battery)
list connections to simulators	Valmedix ECG
list connections to dummy loads	None
list unconnected terminals	ac

IN-TEST DATA

Time of test start: 0935

POSTTEST DATA

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

Time of test end: 1100

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):

Comments on other data:

3.2.7 Vibration test

Vibration test  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: 30 March 1992

Item configuration during test: Item strapped down on vibration table fixture. Unit operating on ac and battery power.

Performance test criteria: Consistent and accurate displays and measurements.

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	80°F
Humidity	63% RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Time at first check:

X: 1320 (3/30/92) Y: 1432 (3/30/92) Z: 1245 (3/30/92)

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Time at second check:

X: 1410                      Y: 1522                      Z: NA

Item functional (based on performance test criteria): No

Deviation from pretest: Unit malfunctioned during the z-axis shake. Unit would not operate and was sent back to the manufacturer for repairs.

POSTTEST DATA

Time at test end:

X: 1420                      Y: 1532                      Z: NA

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

Item functional (based on performance test criteria): No

Item intact: Yes

Deviation from pretest: None

Comments on item setup or checks: The unit would not operate during or after the z-axis shake in each of the three test runs.

Comments on test run (including interruptions): The unit was retested in the z-axis on 23 November and 1 December 1993. During each retest, the unit failed and would not operate correctly. The unit was again sent back to the manufacturer for repairs.

Comments on other data: The unit was not tested after 1 December 1992 for vibration compatibility.

3.2.8 High temperature test

High temperature test  
(equipment operating)  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: 9 March 1992

Item configuration during test: Unit was sitting on the wire test stand, operated on ac and battery power.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:  
Temperature 24°C  
Humidity 53% 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	Temperature probe
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

IN-TEST DATA

Time of test start: 1050  
Performance checks during test:

First check:

Time: 1120  
Temperature: 49°C  
Humidity: 15% RH  
Barometric pressure: 1 atm  
Item functional (based on performance test criteria):  
all OK: Pass  
Deviation from pretest: None

Second check:

Time: 1150  
Temperature: 49°C  
Humidity: 15% RH  
Barometric pressure: 1 atm  
Item functional (based on performance test criteria):  
all OK: Pass  
Deviation from pretest: None

Third check:

Time: 1220  
Temperature: 49°C  
Humidity: 15% RH  
Barometric pressure: 1 atm  
Item functional (based on performance test criteria):  
all OK: Pass  
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:

(complete check of item and accessories)  
Time of test end: 1330  
Item functional (based on performance test criteria):  
Fail  
Deviation from pretest: None

Comments on item setup or checks: The illumination of the LED failed prior to the end of the test. The screen was unreadable.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.9 High temperature storage test

High temperature test  
(equipment in storage)  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: 20 March 1992

Item configuration during test: Sitting on wire test stand in storage, not operating.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	22°C
Humidity	48% 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	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

Time of test start: 0830

POSTTEST DATA

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

Time of test end: 1430

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks:

The unit was allowed to cool overnight, before the posttest performance check was conducted.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.10 Low temperature test

Low temperature test  
(equipment operating)  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE<sup>®</sup> Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: NA

Item configuration during test: NA

Performance test criteria: NA

Ambient conditions outside chamber:

Temperature	NA
Humidity	NA
Barometric pressure	NA

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): The E300A patient monitor was not evaluated at the MIL-STD-810E temperature of -25°C at the manufacturer's request. The unit will not function correctly at a temperature below +5°C. This represents a failure of the low temperature operational test.

Installation of item in test facility:

- list connections to power
- list connections to simulators
- list connections to dummy loads
- list unconnected terminals
- distance from north wall (meters)
- distance from south wall (meters)
- distance from east wall (meters)
- distance from west wall (meters)
- distance from ceiling (meters)
- distance from floor (meters)

Time of test start: NA

Performance checks during test:

First check:

Time: NA  
Temperature: NA  
Humidity: NA  
Barometric pressure: NA  
Item functional (based on performance test criteria): NA  
Deviation from pretest: NA

Second check:

Time: NA  
Temperature: NA  
Humidity: NA  
Barometric pressure: NA  
Item functional (based on performance test criteria): NA  
Deviation from pretest: NA

Third check:

Time: NA  
Temperature: NA  
Humidity: NA  
Barometric pressure: NA  
Item functional (based on performance test criteria): NA  
Deviation from pretest: NA

POSTTEST DATA

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

Time of test end: NA  
Item functional (based on performance test criteria): NA  
Deviation from pretest:

Comments on item setup or checks: NA

Comments on test run (including interruptions): NA

Comments on other data: NA

3.2.11 Low temperature storage test

Low temperature test  
(equipment in storage)  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: 19 March 1992

Item configuration during test: Sitting on the wire test stand,  
not operating, unit is in storage.

Performance test criteria: Consistent and accurate displays and  
measurements

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): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

Time of test start:	0830
Midtest time:	1130
Midtest temperature:	-46°C

POSTTEST DATA

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

Time of test end: 1430

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: The unit was allowed to return to  
ambient conditions overnight before final performance check.

3.2.12 Humidity test

Humidity test  
report form

Nomenclature: Patient monitor  
Manufacturer: MDE® Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: None

Options installed: None

Date of test: 10 March 1992

Item configuration during test: Sitting on the wire test  
stand, operating on ac and battery power.

Performance test criteria: Consistent and accurate displays and  
measurements.

Ambient conditions outside chamber:

Temperature	22°C
Humidity	50% 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	Temperature probe
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

IN-TEST DATA

Time of test start: 1000

Performance checks during test:

First check:

Time: 1045  
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: 1130  
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: 1215  
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: 1300  
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: 1345  
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: 1430

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 Electromagnetic characteristics test

\*\*\*\*\*

Electromagnetic characteristics testing  
evaluation of performance

\*\*\*\*\*

T & E item number: 14

Date: 23 March 1992

Nomenclature: Patient monitor  
Manufacturer: MDE<sup>®</sup> Inc.  
Model number: E300A  
Serial number: 1427  
Military item number: NA

\*\*\*\*\*

Conducted emissions tests

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

Comments: NA

CE02      Testing configuration(s): Operating on test bench,  
            connected to ECG simulator.  
            Performance (pass/fail): Pass

Comments: No emissions in excess of limits were  
detected.

CE04      Testing configuration(s): Operating on test bench,  
            connected to ECG simulator.  
            Performance (pass/fail): Pass

Comments: No emissions in excess of limits were  
detected.

Conducted susceptibility tests

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

Comments: Not susceptible to test generated sig-  
nals.

CS06      Testing configuration(s): Operating on counter  
            top, connected to ECG simulator and to test jig.  
            Performance (pass/fail): Pass

Comments: Not susceptible to test spikes

## Radiated emissions tests

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

### Comments:

#### ac operating failure data:

<u>Frequency (MHz)</u>	<u>Amount of failure (dB)</u>
NB: 0.024 - 363.037	0.5 - 34.6
BB: 0.016 - 3.131	0.2 - 20.9
BB: 25.609	9.3
BB: 30.000	11.8

#### Battery operating failure data:

<u>Frequency (MHz)</u>	<u>Amount of failure (dB)</u>
NB: 0.126 - 425	0.1 - 35.0
BB: 0.016 - 1.688	0.1 - 21.5
BB: 30.0	10.1

## Radiated susceptibility tests

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

### Comments:

#### ac operating failure data:

<u>Frequency (MHz)</u>	<u>Threshold of failure (V/m)</u>
10.0 - 14.2	2.12 - 10.0
29.6 - 38.5	1.89 - 7.10
69.1	6.32
99.7 - 145.6	1.5 - 15.0

#### Battery operating failure data:

<u>Frequency (MHz)</u>	<u>Threshold of failure (V/m)</u>
10.0 - 14.0	4.75 - 12.6
16.2 - 25.6	6.32 - 15.0
30.0 - 145.6	1.12 - 11.9
174.5	1.68

### 3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

#### 3.3.1 Criteria

<u>Item</u>			<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 E300A will display consistent and accurate displays and measurements.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 6 hours.	met	2.2.2
4	The E300A will meet the limits established in TB 38-750-2 for electrical safety of medical equipment.	met	2.3.2
5	The E300A 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.	met	2.4.2
6	The E300A will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	The E300A will remain operational and display consistent and accurate measurements while exposed to vibrational stresses.	not met	2.6.2

<u>Item no.</u>	<u>Criteria (source)</u>	<u>Remarks</u>	<u>Applicable subparagraph</u>
8	The E300A will display consistent and accurate measurements during the high temperature operation check.	not met	2.7.2.1
9	The E300A will display consistent and accurate measurements after the high temperature storage.	met	2.7.2.2
10	The E300A will display consistent and accurate measurements during the low temperature operation check.	not met	2.8.2.1
11	The E300A will display consistent and accurate measurements after the low temperature storage.	met	2.8.2.2
12	The E300A will display consistent and accurate measurements while exposed to a high humidity.	met	2.9.2
13	The E300A will not produce emissions in excess of the limits set forth in MIL-STD-461C, Notice 5, paragraph 6.13.	not met	2.10.2.1
14	The E300A will not malfunction when it is subjected to radiated fields as specified in MIL-STD-461C, Notice 5, paragraph 6.20.	partially met	2.10.2.2
15	The E300A will not conduct emissions in excess of the limits set forth in MIL-STD-461C, Notice 5, paragraphs 6.1 and 6.2.	met	2.10.2.3
16	The E300A will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461C, Notice 5, paragraphs 6.7 and 6.10.	met	2.10.2.4

3.3.2 Significant problems which require corrective action

3.3.2.1 The unit should function properly in response to the test vibration signature in the Z axis.

3.3.2.2 The unit should not suffer LCD illumination failures while operating in a high temperature environment.

3.3.2.3 The unit should operate correctly in a low temperature environment of  $-25^{\circ}\text{C}$ .

3.3.2.4 Additional shielding will be needed to reduce the electromagnetic emissions produced by the unit. This shielding also may reduce the susceptibility of the device to electromagnetic emissions.

### 3.4 REFERENCES

- 3.4.1 Association for the Advancement of Medical Instruments. Human factors engineering guidelines and preferred practices for the design of medical devices. Arlington, Virginia. AAMI-HE-1988. February.
- 3.4.2 Department of the Army. 1982. Environmental protection and enhancement. Washington, DC. AR 200-1. June.
- 3.4.3 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, DC. TB 38-750-2. April.
- 3.4.4 Department of Defense. 1971. EMI characteristics, measurement of. Washington, DC. MIL-STD-462, Notice 3. February.
- 3.4.5 Department of Defense. 1971. EMI characteristics, requirements for equipment. Washington, DC. MIL-STD-461C, Notice 5. February.
- 3.4.6 Department of Defense. 1983. Environmental test methods and engineering guidelines. Washington, DC. MIL-STD-810D. July.
- 3.4.7 Mitchell, G. W., and Adams, J. E. 1988. Technical test and evaluation of aeromedical equipment. Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory. USAARL Letter Report LR-88-16-1-2.
- 3.4.8 National Fire Protection Association. 1987. Standard for health care facilities. Quincy, Massachusetts. February. NAFF 99.

### 3.5 ABBREVIATIONS

ac	alternating current
AEST	aeromedical equipment suitability test
AVSCOM	U.S. Army Aviation Systems Command
AWR	airworthiness release
BB	broadband
BP	blood pressure
BPM	beats per minute
CAAF	Cairns Army Airfield
CRT	cathode ray tube
dB	decibel
dc	direct current
ECG	electrocardiograph
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
IGE	in-ground effect
MDE® E300A	MDE® Inc. volumetric infusion pump
kg	kilogram
kHz	kilohertz
KIAS	knots indicated airspeed
lb	pound
LCD	liquid crystal display
LED	light emitting diode
LISN	line impedance stabilization network
MAP	mean arterial pressure
MEDEVAC	medical evacuation
MHz	megahertz
MIL-STD	military standard
mL	milliliter
mm	millimeter
mmHg	millimeters of mercury
MSL	mean sea level

NA not applicable  
NAFP National Association of Fire Prevention  
NB narrowband  
NBC nuclear, biological, and chemical  
NiCad nickel cadmium  
NOE nap-of-the-earth  
NVG night vision goggles  
  
RAM random access memory  
RF radio frequency  
RH relative humidity  
ROM read only memory  
  
TB technical bulletin  
TFT technical feasibility testing  
T & E test and evaluation  
  
USAARL U.S. Army Aeromedical Research Laboratory  
  
V/m volts per meter

### 3.6 LIST OF MANUFACTURERS

- 3.6.1 MDE® Corporation  
12720 Wentworth Street  
Arleta, CA 91331-4309
- 3.6.2 Sikorsky Aircraft  
6900 Main Street  
Stratford, CT 06601
- 3.6.3 Neurodyne-Dempsey, Inc.  
200 Arrowhead Drive  
Carson City, NV 89701
- 3.6.4 Tenney Engineering, Inc.  
1090 Springfield Road  
P.O. Box 3142  
Union, NJ 07083
- 3.6.5 Unholtz-Dickey Corporation  
6 Brookside Drive  
Wallingford, CT 06492
- 3.6.6 Solar Electronics Company  
901 North Highland Avenue  
Hollywood, CA 90038
- 3.6.7 Tektronix, Inc.  
P.O. Box 500  
Beaverton, OR 97077
- 3.6.8 Valmedix  
32303 Howard Street  
Madison Heights, MI 48071