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**Test and Evaluation Report
of the
IMED 927 Infusion Pump**

By

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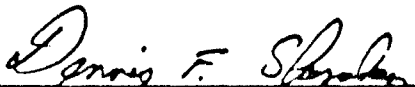
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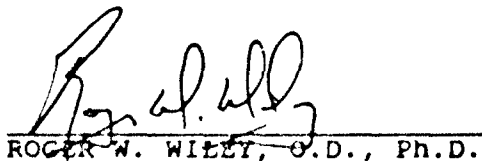
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Section 1. Executive digest

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards 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 the possibility of risks due to: (1) Interference by the medical equipment with aircraft's 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 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 Aeromedical Equipment.

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 IMED 927 Infusion Pump*, model 927 (IMED 927) and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 2.7 flight hours.

1.3.3 Laboratory testing was accomplished at USAARL using government furnished equipment (GFE) by Universal Energy Systems (UES), Inc., 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 14 December 1989 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the IMED 927.

* See manufacturer's list

1.4 MATERIAL DESCRIPTION

The IMED 927 Volumetric Infusion Pump* is electrically driven and designed to administer intravenous (IV) fluids on a semiautomatic basis. Thumbwheel controls, under a clear plastic cover on the front of the IMED 927, allow the user to set the rate and volume of fluid to be administered. The rate adjustment range is from 1 to 299 mL/hr and the volume may be adjusted from 1 to 999 milliliters. When the selected volume has been delivered, an "INFUSION COMPLETE" audio alarm and message is activated, and the IMED 927 reverts to a "keep vein open" delivery rate of 1 mL/hr. A clear plastic locking door protects the administration set and an air-in-line detector. A pole clamp is located on the side of the IMED 927. An audible alarm and silence switch, a nurse call receptacle, and an AC power receptacle are located on the back panel.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery life evaluation: The battery in the IMED 927 provided power for an average of 27 hours and 43 minutes of operation at a delivery rate of 299 mL/hr at room temperature. This exceeds the manufacturer's specification of 15 hours.

1.5.1.2 Electrical safety evaluation: All measurements were within acceptable limits. No unsafe qualities were noted in the IMED 927. The limits for currents and resistances were in accordance with (IAW) the National Fire Prevention Association (NFPA) standards.

1.5.1.3 Human factors evaluation: The flashing red pilot light, which indicates normal operation, is difficult to see in ambient lighting conditions and IAW MIL-STD-1472D, flashing red lights are to indicate emergency conditions rather than normal operation. Second, the IMED 927 has no externally accessible fuses or circuit breakers. All other evaluation criteria were met satisfactorily. Standards referenced include MIL-STD-1472D, AAMI Human Factors Engineering Guidelines, and UL-544.

1.5.1.4 Environmental tests: The IMED 927 can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of environmental testing. The requirements for environmental tests are established in Military Standards 810D, Methods 500.2 (altitude), 501.2 (high temperature), 502.2 (low temperature), 514.3 (vibration), and 507.2 (humidity).

1.5.1.5 Radiated emissions tests (RE02): The IMED 927 may be unsatisfactory for use in certain EMI sensitive environments. Narrowband and broadband 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-461A, Notice 4.

1.5.1.6 Radiated susceptibility test (RS03): The IMED 927 was not found to be susceptible to radio frequency interference in the testing range and magnitude.

1.5.2 In-flight testing

1.5.2.1 During the in-flight human factors evaluation, the IMED 927 was found to be satisfactory in all categories of the evaluation criteria with two exceptions. The red operations light was not visible in ambient light and there were no externally accessible fuses, circuit breakers, or calibration points.

1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the IMED 927 in any of the prescribed flight test modes.

1.5.2.3 The IMED 927 was not affected by the aircraft and its subsystems during the in-flight testing.

1.6 CONCLUSIONS

Based on the results of laboratory and in-flight testing, the IMED 927 was found to be compatible with U.S. Army medical evacuation UH-60A Blackhawk with the subsystems listed in paragraph 3.2.2. However, this device must be restricted to the use of nonvented, collapsible IV solution bags (paragraph 2.4.4.2) to adequately control a category IA hazard.

Section 2. Subtests

2.1 INITIAL INSPECTION

2.1.1 Objective

To determine if the IMED 927 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 IMED 927 will accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the IMED 927 was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the IMED 927 was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

2.1.4 Test findings

2.1.4.1 The IMED 927 was inventoried and found to be complete. Criterion met.

2.1.4.2 The IMED 927 operated as prescribed in the manufacturer's operating manual. Criterion 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 15 hours at a delivery rate of 299 mL/hr.

2.2.3 Test procedure

2.2.3.1 Charging and operation cycles were conducted in ambient room conditions of 23°C, 40-60 percent relative humidity (RH).

2.2.3.2 The battery was charged to full capacity according to the manufacturer's instructions. The battery then was discharged by operating the unit at a 299 mL/hr delivery rate until a low battery indication light illuminated on the front panel and the audio alarm was engaged. Depletion time was noted (recorded to the nearest minute), and the battery was allowed 24 hours to recharge.

2.2.4 Test findings

The IMED 927 operated continuously for an average of 27 hours and 43 minutes before a low battery indication. This performance exceeds the manufacturer's specification by approximately 12 hours 43 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 IMED 927.

2.3.2 Criterion

The IMED 927 shall meet the standards established in NFPA 99 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) 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 74.1 milliohms and maximum case leakage current was 2.2 microamperes. These measurements are below the limits specified in 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 IMED 927 must be rated satisfactory in all major categories of this 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 IMED 927 was operated according to prescribed instructions through its full range of functions.

2.4.4 Test findings

The IMED 927 was found to be satisfactory in all but two major categories of the evaluation. First, it was difficult to see the flashing red pilot light, which indicates normal operation, in ambient lighting conditions. Furthermore, IAW MIL-STD-1472D, paragraph 5.2.2.1.18, flashing red lights are to indicate emergency conditions rather than normal operation. Second, access to the internal fuses in the IMED 927 requires partial disassembly of the unit. MIL-STD-1472D, paragraph 5.9.17.2.2, requires that all fuses be readily accessible for removal and replacement. Criterion partially met.

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

2.5.1 Objective

To determine if the IMED 927 can function as designed in a low-pressure environment.

2.5.2 Criterion

The IMED 927 will accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured) 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 IMED 927.

2.5.3.2 The IMED 927 was placed in the vertical position in the altitude chamber. The pressure in the chamber was lowered to 420 mmHg (15,000 feet equivalent altitude) over 15 minutes (1000 feet per minute (fpm)), held constant for 60 minutes, then raised to ambient atmospheric conditions (760 mmHg) at 1500 fpm. During the altitude test stage, the IMED 927 was operated in battery mode only due to the lack of a 120 VAC, 60 Hz power supply in the test chamber.

2.5.3.3 A posttest performance check was conducted to ensure proper operation of the IMED 927 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 IMED 927 performance were noted during the altitude test. The test was interrupted to correct problems with IV bottle leakage and "air-in-line" alarms. When chamber pressure was reduced, the plastic IV bottle started to expand, and the higher internal pressure forced the IV set fixture out of the bottle seal before an altitude of 15,000 feet (420 mmHg) could be obtained. This problem was corrected by creating a small vent hole in the bottle to equalize the internal and external pressures. The test was repeated using nonvented, collapsible IV solution bags and the infusion pump performed with no errors. Criterion met.

2.5.4.3 The posttest performance check met criterion 2.1.2.2.

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

2.6.1 Objective

To determine the ability of the IMED 927 to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

While exposed to vibrational stresses the IMED 927 will remain operational and be able to accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the IMED 927.

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-810D, Method 514.3; reference spectrum levels are based on field measurements 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/Hz
 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 IMED 927 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 IMED 927.

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 IMED 927 performance 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 METHOD 501.2, MIL-STD-810D]

2.7.1 Objective

To determine the ability of the IMED 927 to be stored and operated in a high-temperature environment.

2.7.2 Criteria

2.7.2.1 During the high-temperature operation check, the IMED 927 must accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).

2.7.2.2 After the high-temperature storage cycle, the IMED 927 must be able to accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).

2.7.3 Test procedure

2.7.3.1 A pretest performance check was conducted to ensure proper operation of the IMED 927.

2.7.3.2 The high-temperature test was conducted in a Tenney Engineering model 2WUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 501.2. For the high-temperature operation test, the IMED 927 was placed on the floor of the environmental chamber. The chamber temperature then 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 $\pm 2^\circ\text{C}$ and humidity within ± 5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions and a performance check performed. Both AC and battery power operation were assessed. At the end of the operational test, the IMED 927 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 IMED 927.

2.7.3.4 The IMED 927 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 IMED 927 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 IMED 927.

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 IMED 927 functioned properly after the high-temperature storage test. Criterion met.

2.8 LOW TEMPERATURE TEST (IAW METHOD 502.2, MIL-STD-810D)

2.8.1 Objective

To determine the ability of the IMED 927 to be stored and operated in a low-temperature environment.

2.8.2 Criteria

2.8.2.1 During the low-temperature operation check, the IMED 927 must accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).

2.8.2.2 After the low-temperature storage cycle, the IMED 927 must be able to accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).

2.8.3 Test procedure

2.8.3.1 A pretest performance check was conducted to ensure proper operation of the IMED 927.

2.8.3.2 The IMED 927 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. A saline solution, which would not freeze at test temperature, was used in the administration set during this test stage. Both AC and battery operations were checked. 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 IMED 927.

2.8.3.4 The IMED 927 was "stored" in a nonoperational mode with the power cord coiled behind the IMED 927. The IMED 927 was placed on the floor of the environmental test chamber and the temperature was lowered to -18°C for 6 hours. This temperature was used in lieu of -46°C because the chamber normally used for this test was under repair. The chamber then was raised to ambient temperature over a 30-minute period.

2.8.3.5 A post storage performance check was conducted to ensure proper operation of the IMED 927.

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 IMED 927 functioned properly after the low-temperature storage test. Criterion met.

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

2.9.1 Objective

To determine the ability of the IMED 927 to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

While exposed to a high humidity environment, the IMED 927 must accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).

2.9.3 Test procedure

2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the IMED 927.

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-STD810D, Method 507.2 For the humidity test, the IMED 927 was placed on the floor of the environmental test chamber. The chamber was raised to a temperature of 29.5°C and a humidity of 95 percent within 25 minutes. These conditions were maintained for 4 hours. The environmental control system is

capable of regulating temperature within $\pm 2^{\circ}\text{C}$ and humidity within ± 5 percent RH. At 45-minute intervals, the door was opened briefly, to minimize change in chamber conditions, and an operational check was performed with both AC and battery power. The chamber was returned to ambient conditions over a 45-minute period.

2.9.3.3 A posttest performance check was conducted to ensure the proper operation of the IMED 927.

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 IMED 927 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 Objective

2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the IMED 927 in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the radiated electromagnetic susceptibility of the IMED 927 within the 10 kHz to 10 GHz frequency band.

2.10.1.3 To assess the maximum levels of conducted electromagnetic emissions produced by the IMED 927 in the 10 kHz to 50 MHz frequency ranges.

2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the IMED 927, within the range of 50 kHz to 400 MHz and power spikes.

2.10.2 Criteria

2.10.2.1 The IMED 927 shall not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.

2.10.2.2 The IMED 927 shall 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 IMED 927 shall 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 IMED 927 shall 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 IMED 927 was positioned inside the EMI chamber, on a wooden test stand 1 meter from floor level, 0.18 meters wide and 0.21 meters long, directly in line with, and at a horizontal distance of 1 meter from, the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to the appropriate EMI receivers. Electrometrics EMC-25 and EMC-50 receivers were used for this test. Their frequency ranges in testing are 14 kHz to 1 GHz, and 1 to 12.4 GHz. Broadband and narrowband detection methods were used from 14 kHz to 1 GHz. Narrowband detection methods were used from 1 to 12.4 GHz. The IMED 927 was operated at a delivery rate of 60 mL/hr in 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 IMED 927 was inside the EMI chamber, positioned on a wooden test stand 1 meter from floor level, 0.18 meters wide and 0.21 meters long, 1 meter away from the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to radio frequency (RF) transmitters. The IMED 927 was exposed to fields of 1 V/m from 10 kHz to 2 MHz, 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. All RF carrier waves were 50 percent amplitude modulated with a 1000 Hz tone. The IMED 927 was operated at a delivery rate of 60 mL/hr and was monitored for faulty operation by use of a video camera and monitor. The IMED 927 was operated on battery and AC power during the test.

2.10.3.3 The conducted emissions tests were performed according to MIL-STD-462, Notice 3, Methods CE02 and CE04. The IMED 927 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's) 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 IMED 927 was operating, the frequency range (10 kHz to

50 MHz) was scanned for emissions conducted in the power cable from the IMED 927.

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 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 IMED 927 was plugged into the other receptacle on the connection box, placed in operation, and set for a delivery rate of 60 mL/hr. It was visually observed for correct fluid delivery 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 IMED 927 was placed on a grounded, copper covered workbench. Radio frequency interference was induced on the power leads and measured at the IMED 927 power cable. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the IMED 927 was operated at a delivery rate of 60 mL/hr. It was visually observed for correct fluid delivery 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, narrowband and broadband emissions which exceeded specification limits of MIL-STD-461A, Notice 4, were detected in the frequency ranges below.

<u>Frequency</u>	<u>Amount exceeding specification</u>
16 - 250 kHz	0.2 dB - 4.5 dB (BB)
25.6 - 28.91 MHz	2.4 dB - 6.2 dB (BB)

Criterion partially met.

2.10.4.2 The IMED 927 infusion pump was not susceptible to the radiated test signal while operating on battery or AC power. Criterion met.

2.10.4.3 No signal failures were detected from the IMED 927 during the conducted emissions test. Criterion met.

2.10.4.4 The IMED 927 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 IMED 927 while in use on board the aircraft.

2.11.2 Criterion

The flight surgeon shall be able to operate the IMED 927 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 IMED 927 and the in-flight environment. The flight surgeon conducted the test wearing a flight suit, flight gloves, and an SPH-4 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 IMED 927 was placed on the floor of the aircraft next to the bottom pan of the litter carousel which was configured for four patients. The litter carousel was flown in the "load" position (perpendicular to the long axis of the helicopter). The IMED 927 was tested for accuracy and proper operation when delivering 60 mL/hr IV fluid from an IV bag. The IMED 927 was tested using both AC and battery power in all flight scenarios required by the In-Flight Test Operations Procedures (ITOP).

2.11.4 Test findings

2.11.4.1 With the exception of the red flashing light described in paragraph 2.4.4, the IMED 927 was found to be satisfactory in the in-flight environment. Criterion partially met.

2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS

2.12.1 Objective

To assess the EMI/ELC characteristics of the IMED 927 with the host aircraft and its installed systems.

2.12.2 Criteria

2.12.2.1 The IMED 927 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 IMED 927's operation.

2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the IMED 927 and the aircraft operating as source and victim. The IMED 927 and applicable aircraft instruments and systems were monitored for unusual operation, readings, surges, or power anomalies for each checklist item (see 3.2.3, Inflight test data card).

2.12.4 Test findings

2.12.4.1 There were no adverse instances of EMI/EMC noted with the IMED 927 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 IMED 927 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 IMED 927 Volumetric Infusion Pump is an electrical-ly driven, piston-type pump that is designed to administer IV fluids on a semiautomatic basis. Thumbwheel controls, under a clear plastic cover on the front of the IMED 927, allow the user to set the rate and volume of fluid to be administered. The rate adjustment range is from 1 to 299 mL/hr and the total volume of the infusion may be adjusted from 1 to 999 milliliters. When the selected volume has been delivered, an "INFUSION COMPLETE" audio alarm and message is activated, and the IMED 927 reverts to a "keep vein open" delivery rate of 1 mL/hr.

Power is supplied as 120 VAC, 60 Hz from a power cord or an internal, rechargeable, lead-acid battery. The manufacturer specifies 15 hours of operation for the infusion pump with a fully charged battery at 299.9 mL/hr. Charge time for a low battery to 80 percent full charge is 24 hours with the pump off.

A locking clear plastic door protects the administration set and an air-in-line detector. A pole clamp is located on the side of the IMED 927. An audible alarm and silence switch, a nurse call receptacle, and an AC power receptacle are located on the back panel.

3.1.2.2 Dimensions: 7 x 7 x 14 in (17.8 x 17.8 x 35.6 cm)

3.1.2.3 Weight: 13 lbs (5.9 Kg)

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/ARN-209 (radar altimeter)
18	Indicator altimeter -- ID-1917C/APN-209 (radar altimeter)
19	Control radio set -- C-7392A/ARN-89 (automatic direction finder)
20	Comparator signal data -- CM-482/ARC-186 (comparator for ARC-186)
21	Receiver/transmitter -- RT-1296A/APX-100 (transponder with IFF)
22	Computer display unit -- CP-1252/ASN-128 (doppler navigation system)
23	Compass set controller -- C-8021E/ASN75
24	Magnetic compass - standby -- MS-17983-4

3.2.3 In-flight test data card

DATA CARD FORMAT

GUIDELINE FOR DATA COLLECTION

IN-FLIGHT SUITABILITY TEST OF MEDICAL ITEMS

1. Installation/removal.	Suitable		Comments
	Yes	No	
a. Weight and balance (DD Form 365-4, Clearance Form F).	X		
b. Space/area allocation.			
(1) Operational requirements.	X		
(2) Storage requirements.	X		
c. Interface connections (safe, positive, secure).	X		
d. Installation/removal (expedient/easily achieved).	X		
e. Mounting/final config- uration (functional/stable).	X		
2. Operations and performance.	Suitable		Comments
	Yes	No	
a. Manufacturer's operating instruction.	X		
b. Medical item operation before aircraft run-up.	X		
c. System interface during aircraft engine run-up and medical item operation (EMI switchology checklist).	X		
(1) Aircraft voltage output.	X		
(2) Flight control function (UH-60).	X		

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

(3) Navigation equipment operation vs medical item operation.	Suitable		Comments
	Yes	No	

(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 m.s.l. for 20 minutes).

(a) Compatibility of flight mode and medical item operation.	X		
--	---	--	--

(b) Radio communication
vs medical item opera-
tion.

(1) FM	X		
--------	---	--	--

(2) UHF	X		
---------	---	--	--

(2) VHF	X		
---------	---	--	--

(2) NOE (20 minutes). Com- patibility 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		
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	Suitable Yes No	Comments
(5) VOR navigation (7000 ft m.s.l. 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 m.s.l. due to air traffic control clearance.		
b. The nap-of-the-earth (NOE) flight mode conducted at Highfalls Stagefield, Fort Rucker, Alabama.		

3.2.4 EMI switchology checklist

EMI SWITCHOLC3Y CHECKLIST UH-60 AIRCRAFT

IN-FLIGHT SUITABILITY OF MEDICAL ITEMS

ENG INSTRUMENTS/CDU	No EMI Affect	EMI Affected		Explanation
		Gnd	Flt	
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		Explanation
		Gnd	Flt	
#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		Explanation
		Gnd	Flt	
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

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

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

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

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

FUEL SYSTEM	No EMI Affect	EMI Affected Gnd Flt	Explanation
Fuel pump switch	X		
Fuel boost pump #1	X		
Fuel boost pump #2	X		
Fuel cont panel ESSS	Not installed		
WARNING SYSTEM	No EMI Affect	EMI Affected Gnd Flt	Explanation
Low rotor RPM	X		
Master caution	X		
Caution advisory	X		
Fire warning	X		
AFCS	X		
Stabilator	X		
#1 engine out	X		
#2 engine out	X		
NAVIGATION INSTRUMENTS	No EMI Affect	EMI Affected Gnd Flt	Explanation
ADF	X		
Magnetic compass	X		
CONUS NAV, ARN-123	X		
DOPPLER, ASN-128	X		
Gyro mag compass (PLT)	X		
Gyro mag compass (COPLT)	X		
Compass cont panel, ASN-75	X		
HSI	X		
FLIGHT INSTRUMENTS	No EMI Affect	EMI Affected Gnd Flt	Explanation
Radar altimeter	X		
Stabilator pos indicator	X		
VSI	X		
CIS mode select	X		
SAS 1	X		
SAS 2	X		
FPS	X		
Trim	X		
Go-around enable	X		
Cyclic trim release	X		
Cyclic stick trim	X		
ALR encoder	X		

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

LIGHTING	No EMI Affect	EMI Affected		Explanation
		Gnd	Flt	
Cockpit utility	X			
Cockpit flood	X			
Cabin dome	X			
Search light	X			
Search light control	X			
Landing light	X			
Flt instr lights (PLT)	X			
Flt instr lights (COPLT)	X			
Non-flight 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: Volumetric infusion Pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635
Military item number: None

Options installed: None

Manufacturer battery life specification: 15 hrs at 299 mL/hr

Specified battery recharge time: 24 hrs to 80 percent of full
charge (pump off)

Specified mode of operation under battery power: 299 mL/hr

Overall performance: Pass

Measurements: Tested for four charge/discharge cycles to
obtain average performance of 27 hours, 43 minutes operation
on a fully charged battery.

Comments: The IMED 927 averaged 27 hours and 43 minutes of
operation which exceeds the manufacturers specification by
12 hours and 43 minutes.

3.2.6 Electrical safety test

Electrical Safety Test Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635
Military item number: n/a
Line cord identification: 18-3 type SVT E-3462 LL-7874 IJ

Options installed: None

Date of test: 12 Jan 89

Measurements:

Grounding conductor resistance (milliohms): 74.1

Leakage current - Case to ground (microamps):

unit off, grounded, normal polarity	0.0
unit off, ungrounded, normal polarity	1.7
unit off, ungrounded, reverse polarity	2.2
unit on, grounded, normal polarity	0.0
unit on, ungrounded, normal polarity	1.7
unit on, ungrounded, reverse polarity	2.2

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

3.2.7 Human factors evaluation

Human Factors Evaluation Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635
Military item number: n/a

Options installed: None

Date of test: 12 Jan 89

Item configuration during test: Item prepared for operation,
sitting on a countertop.

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: It is difficult to see flashing pilot light
which indicates proper operation in ambient light-
ing conditions. Operational lights should be
green in color. Scalar displays and cathode ray
tubes are not applicable.

CONTROLS:

Satisfactory

location
characteristics of controls
labeling
control - display relationships

Comments: Controls are covered with a clear plastic
door to prevent contact with spilled liquids.

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: It takes 2 to 3 minutes to mount pump
on IV pole, place administration set in pump, and
purge air from set.

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: No provision for storage of power cord.
Performance check completed by unit at start of
each operation.

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:

n/a

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: Internal self-test initiated when device is energized. Failure indicated by an alarm and error message.

FUSES AND CIRCUIT BREAKERS:

Unsatisfactory

external accessibility
easy replacement or reset by operator

Comments: No externally accessible fuse or circuit breakers.

LABELS AND CODING:

Satisfactory

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

Comments: None

SAFETY:

Satisfactory

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

Comments: None

3.2.8 Altitude test

Altitude Test Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635
Military item number: n/a
Options installed: None

Date of test: 10 Jan 89

Item configuration during test: Sitting on chamber floor,
battery power only. IV bottle hanging on a hook above
the pump. Solution delivered into a small reservoir at
a set rate of 60 mL/hr.

Performance test criterion: Accurate delivery of prescribed
volume of solution at a rate of 60 mL/hr.

Ambient conditions outside chamber:

Temperature	19°C (66°F)
Humidity	65%
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check :

Item functional (based on performance test criterion): Yes

Installation of item in test facility:

list connections to power	None (battery)
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	Nurse call, AC power input

IN-TEST DATA

Time of test start: 1040

POSTTEST DATA

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

Time of test end: 1205

Item functional (based on performance test criterion): Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): First test aborted because IV set started leaking before test altitude reached. Second test run aborted because of "air in line" alarm. Observation of the set showed the presence of air in the IV line.

Comments on other data: It was necessary to punch a hole in the semirigid plastic IV bottle to equalize internal and external pressures and prevent leakage. Subsequent tests proceeded without problems. Problems with IV bottles were not seen when tested with bags of IV solution.

3.2.9 Vibration test

Vibration Test Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635
Military item number: n/a
Options installed: None

Date of test: 9 Jan 89

Item configuration during test: Strapped to vibration table
fixture operating in AC and battery power modes.

Performance test criterion: Accurate delivery of prescribed
volume of solution at a rate of 60 mL/hr (measured).

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criterion): Yes

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	None
list connections to dummy loads	N-D IV pump analyzer
list unconnected terminals	nurse call

Ambient conditions:

Temperature: 18°C (65°F)
Humidity: 61%
Barometric pressure: 1 atm

IN-TEST DATA

Data and performance checks during test:

Times and dates of test start:

X:0815 01/09/89 Y:0922 01/09/89 Z:0945 01/10/89

Time at first check:

X:0820 Y:0925 Z:0950

Item functional (based on performance test criterion): Yes

Deviation from pretest: None

Time at second check:

X:0915

Y:1020

Z:1045

Item functional (based on performance test criterion): Yes

Deviation from pretest: None

POSTTEST DATA

Time at test end:

X:0927

Y:1025

Z:1052

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

Item functional (based on performance test criterion): 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: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635
Military item number: None

Options installed: None

Date of test: 30 Jan 89

Item configuration during test: Sitting on chamber floor,
operating on AC and battery power.

Performance test criterion: Accurate delivery of correct volume
of fluid at a rate of 60 mL/hr (measured).

Ambient conditions outside chamber:

Temperature	22°C
Humidity	71%
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criterion): Yes

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	Nurse call
distance from north wall (meters)	0.957
distance from south wall (meters)	0.604
distance from east wall (meters)	1.613
distance from west wall (meters)	1.336
distance from ceiling (meters)	1.865
distance from floor (meters)	0.0

Time of test start: 0800

Performance checks during test:

First check:

Time: 0830
Temperature: 49°C, $\pm 1^\circ\text{C}$
Humidity: 15% $\pm 1\%$ RH
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Second check:

Time: 0900
Temperature: 49°C, $\pm 1^\circ\text{C}$
Humidity: 15% $\pm 1\%$ RH
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Third check:

Time: 0930
Temperature: 49°C, $\pm 1^\circ\text{C}$
Humidity: 15%, $\pm 1\%$ RH
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

POSTTEST DATA

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

Time of test end: 1030
Item functional: (based on performance test criterion): Yes
Deviation from pretest: None

Comments on item setup or checks: IV bottle was hung from a pole during the test. Both AC and battery power were checked during the test.

Comments on test run (including interruptions): Unit was checked at 30-minute intervals.

Comments on other data: Aeromedical test items 9 and 10 were tested with this item (11). The IV pump was allowed to cool for 1 hour, at ambient conditions, before the testing continued.

3.2.11 High temperature storage test

High Temperature Test (Equipment in Storage) Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635

Military item number: None

Options installed: None

Date of test: 31 Jan 89

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

Performance test criterion: Accurate delivery of correct volume of fluid at a rate of 60 mL/hr.

Ambient conditions outside chamber:

Temperature	22°C
Humidity	60 percent
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criterion): 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)	0.957
distance from south wall (meters)	0.604
distance from east wall (meters)	1.613
distance from west wall (meters)	1.336
distance from ceiling (meters)	1.865
distance from floor (meters)	0.0

Time of test start: 0800

Mid-test time: 1130

Mid-test temperature: 71°C, ± 1°C

Mid-test Humidity: 15%, ± 1% RH

POSTTEST DATA

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

Time of test end: 1500

Item functional (based on performance test criterion): Yes

Deviation from pretest: None

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

Comments on test run (including interruptions): None

Comments on other data: Aeromedical test items 9 and 10 were tested with this item (11).

3.2.12 Low temperature test

Low Temperature Test (Equipment Operating) Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635

Military item number: None

Options installed: None

Date of test: 30 Jan 89

Item configuration during test: Sitting on chamber floor,
operating on AC and battery power.

Performance test criterion: Accurate delivery of correct volume
of fluid at a rate of 60 mL/hr (measured).

Ambient conditions outside chamber:

Temperature	23°C
Humidity	38%
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criterion): Yes

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	Nurse call
distance from north wall (meters)	0.957
distance from south wall (meters)	0.604
distance from east wall (meters)	1.613
distance from west wall (meters)	1.336
distance from ceiling (meters)	1.865
distance from floor (meters)	0.0

Time of test start: 1250

Performance checks during test:

First check:

Time: 1320
Temperature: 0.0°C, \pm 1°C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Second check:

Time: 1350
Temperature: 0.0°C, \pm 1°C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Third check:

Time: 1420
Temperature: 0.0°C, \pm 1°C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

POSTTEST DATA

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

Time of test end: 1500
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Comments on item setup or checks: IV bottle was hung from a pole during the test. Both AC and battery power were checked during the test.

Comments on test run (including interruptions): Unit was checked at 30-minute intervals.

Comments on other data: Items 9 and 10 were tested with this item (11). The IV pump was allowed to dry overnight, because condensation accumulated on the unit while returning to ambient conditions.

3.2.13 Low temperature storage test

Low Temperature Test (Equipment in Storage) Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635

Military item number: None

Options installed: None

Date of test: 1 Feb 89

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

Performance test criterion: Accurate delivery of correct volume of fluid at a rate of 60 mL/hr (measured).

Ambient conditions outside chamber:

Temperature	22°C
Humidity	60%
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criterion): 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)	0.957
distance from south wall (meters)	0.604
distance from east wall (meters)	1.613
distance from west wall (meters)	1.336
distance from ceiling (meters)	1.865
distance from floor (meters)	0.0

Time of test start: 1020

Mid-test time: 1340

Mid-test temperature: -18°C, $\pm 1^\circ\text{C}$

POSTTEST DATA

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

Time of test end: 1700

Item functional (based on performance test criterion): Yes

Deviation from pretest: None

Comments on item setup or checks: Both AC and battery power were checked on the unit.

Comments on test run (including interruptions): Items 9 and 10 were tested with this item (11).

Comments on other data: The unit was allowed to dry overnight, before the posttest performance check, due to condensation accumulation on the unit while returning to ambient conditions.

3.2.14 Humidity test

Humidity Test Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IMED INC.
Model number: 927
Serial number: 927-38635

Military item number: None

Options installed: None

Date of test: 2 Feb 89

Item configuration during test: Sitting on chamber floor,
operating on AC and battery power.

Performance test criterion: Accurate delivery of correct volume
of fluid at a rate of 60 mL/hr (measured).

Ambient conditions outside chamber:

Temperature	25°C
Humidity	58%
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criterion): Yes

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	Nurse call
distance from north wall (meters)	0.957
distance from south wall (meters)	0.604
distance from east wall (meters)	1.613
distance from west wall (meters)	1.336
distance from ceiling (meters)	1.865
distance from floor (meters)	0.0

IN-TEST DATA

Time of test start: 1230

Performance checks during test:

First check:

Time: 1315
Temperature: 29.5°C, $\pm 1^\circ\text{C}$
Humidity: 95%, $\pm 1\%$ RH
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Second check:

Time: 1400
Temperature: 29.5°C, $\pm 1^\circ\text{C}$
Humidity: 95%, $\pm 1\%$ RH
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Third check:

Time: 1445
Temperature: 29.5°C, $\pm 1^\circ\text{C}$
Humidity: 95%, $\pm 1\%$ RH
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Fourth check:

Time: 1530
Temperature: 29.5°C, $\pm 1^\circ\text{C}$
Humidity: 95%, $\pm 1\%$ RH
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Fifth check:

Time: 1615
Temperature: 29.5°C, $\pm 1^\circ\text{C}$
Humidity: 95%, $\pm 1\%$ RH
Barometric pressure: 1 atm
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

POSTTEST DATA

Posttest performance check: (complete check of item and accessories)
Time of test end: 1715
Item functional (based on performance test criterion): Yes
Deviation from pretest: None

Comments on item setup or checks: The unit was operated continuously throughout the test at a rate of 60 mL/hr (measured).

Comments on test run (including interruptions): Aeromedical test items 9 and 10 were tested with this item (11).

Comments on other data: None

3.2.15 Electromagnetic characteristics test

Electromagnetic Characteristics Testing Evaluation of Performance

T & E item number: 11

Date: 23 Jan 89

Nomenclature: IV pump

Manufacturer: IMED INC.

Model number: 927

Serial number: 927-38635

Military item number: n/a

Conducted emissions tests

CE01 Testing configuration(s): n/a
 Performance (pass/fail): n/a
 Comments: No DC power leads

CE02 Testing configuration(s): Operating on copper
 bench
 Performance (pass/fail): Pass
 Comments: No signal failures

CE04 Testing configuration(s): Operating on copper
 bench
 Performance (pass/fail): Pass
 Comments: No signal failures

Conducted susceptibility tests

CS02 Testing configuration(s): Operating on copper
 bench
 Performance (pass/fail): Pass
 Comments: Pump not susceptible to test
 signals

CS06 Testing configuration(s): Operating on counter top

Performance (pass/fail): Pass

Comments: Not susceptible to test voltage spikes

Radiated emissions tests

RE02 Testing configuration(s): Operating on test stand in EMC chamber

Performance (pass/fail): Fail

Comments: BB emissions detected 0.2 to 4.5 dB over spec in range of 16 to 250 kHz, also 2.4 to 6.2 dB over spec between 25.6 to 28.91 MHz.

Radiated susceptibility tests

RS03 Testing configuration(s): Operating on test stand in EMC chamber

Performance (pass/fail): Pass

Comments: Unit was not susceptible to the test signals.

3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

3.3.1 Criteria

Item			<u>Applicable</u>
<u>No.</u>	<u>Criteria (source)</u>	<u>Remarks</u>	<u>subparagraph</u>
1	The physical inventory is conducted solely for investigation and documentation.	n/a	2.1.2.1
2	The IMED 927 will accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).	met	2.1.2.2
3	Verify manufacturer's specified full power battery life expectancy of 15 hours at a delivery rate of 299 mL/hr.	met	2.2.2
4	The IMED 927 shall meet the limits established in NFPA 99 for electrical safety of medical equipment.	met	2.3.2
5	The IMED 927 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.	partially met	2.4.2
6	The IMED 927 will accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured) while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	While exposed to vibrational stresses, the IMED 927 will remain operational and be able to accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).	met	2.6.2

8	During the high temperature operation check, the IMED 927 must accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).	met	2.7.2.1
9	After the high temperature storage cycle, the IMED 927 must be able to accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).	met	2.7.2.2
10	During the low temperature operation check, the IMED 927 must be able to accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).	met	2.8.2.1
11	After the low temperature storage cycle, the IMED 927 must be able to accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).	met	2.8.2.2
12	While exposed to a high humidity environment, the IMED 927 must accurately deliver a correct volume of fluid at a rate of 60 mL/hr (measured).	met	2.9.2
13	The IMED 927 shall not produce emissions in excess of the limits set forth in paragraph 6.13, MIL-STD-461A notice 4.	partially met	2.10.2.1
14	The IMED 927 shall not malfunction when it is subjected to radiated fields as specified in paragraph 6.20, MIL-STD-461A notice 4.	met	2.10.2.2
15	The IMED 927 shall not conduct emissions in excess of the limits set forth in paragraphs 6.1 and 6.2, MIL-STD-461A, notice 4.	met	2.10.2.3
16	The IMED 927 shall not malfunction when it is subjected to conducted emissions as specified in paragraphs 6.7 and 6.10, MIL-STD-461A, notice 4.	met	2.10.2.4

17	The medical tester shall be able to operate the IMED 927 without physical or functional restrictions aboard the aircraft.	partially met	2.11.2.1
18	The IMED 927 shall not radiate EMI to disrupt or interfere with the other equipment or systems aboard the aircraft.	met	2.11.2.2
19	The aircraft shall not radiate EMI to disrupt or interfere with the IMED 927.	met	2.11.2.3

3.3.2 Significant problems which require corrective action

None

3.3.3 Suggested improvements

<u>Suggestion</u>	<u>Applicable subparagraph</u>
1. The red flashing pilot light which indicates normal operation should be changed to a green light, IAW MIL-STD-1472D, paragraph 5.2.2.1.18.	2.4.4 and 2.11.4.1
2. Add an access panel to the IMED 927 case for the removal and replacement of the internal fuses IAW MIL-STD 1472D, paragraph 5.9.17.2.2.	2.4.4

3.4 REFERENCES

- 3.4.1 Department of Defense. 1971. EMI characteristics, requirements for equipment. Washington, D.C. MIL-STD-461A, notice 4. February.
- 3.4.2 Department of Defense. 1971. EMI characteristics, measurement of. Washington, D.C. MIL-STD-462, notice 3. February.
- 3.4.3 Department of Defense. 1983. Environmental test methods and engineering guidelines. Washington, D.C. MIL-STD-810D. July.
- 3.4.4 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, D.C. 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, D.C. MIL-STD-1472D. March.
- 3.4.7 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.
- 3.4.8 Department of the Army. 1978. Operator's manual, UH-60 and EH-60 helicopter, with changes 1-5. Washington, D.C. TM 55-1520-237-10. January.
- 3.4.9 Department of the Army. 1982. Environmental protection and enhancement. Washington, D.C. AR 200-1. June.
- 3.4.10 National Fire Protection Association. 1987. Standard for health care facilities. Quincy, Massachusetts. NFPA 99. February.
- 3.4.11 IMED Corporation. Operating instructions, IMED 927 infusion pump. San Diego, California.

3.5 ABBREVIATIONS

ac	alternating current
AEST	aeromedical equipment suitability test
AGL	above ground level
AVSCOM	Army Aviation Systems Command
AWR	airworthiness release
CAAF	Cairns Army Airfield
cm	centimeter
DAETTEP	Director, Aeromedical Equipment Technical Test and Evaluation Program
dB	decibel
DC	direct current
EMC	electromagnetic compatibility
EMI	electromagnetic interference
fpn	feet per minute
GFE	government furnished equipment
Gpk	gravity, peak
G(rms)	gravity (root mean square)
Hz	hertz
IAW	in accordance with
IMED 927	IMED 927 Infusion Pump
ITOP	in-flight test operations procedures
IV	intravenous
kHz	kilohertz
KIAS	knots indicated airspeed
LISN	line impedance stabilization networks
MEDEVAC	aeromedical evacuation
MHz	mega hertz
MIL-STD	military standard
mL	milliliter
mmHg	millimeters of Mercury
m.s.l.	mean sea level
NBC	nuclear, chemical, and biological
NFPA	National Fire Prevention Association
NOE	nap-of-the-earth
NVG	night vision goggle
RF	radio frequency
RFI	radio frequency interference
RH	relative humidity

TB
TFT
T & E

Technical Bulletin
technical feasibility testing
test and evaluation

UES
USAARL

Universal Energy Systems, Inc.
U.S. Army Aeromedical Research Laboratory

VAC
V/m

volts alternating current
volts per meter

3.6 MANUFACTURERS' LIST

- 3.6.1 IMED Corporation
9925 Carroll Canyon Road
San Diego, CA 92131
- 3.6.2 Sikorsy 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
Post Office 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

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