



**Test and Evaluation Report
of the
Medical Technology Products Peristaltic Infusion Pump
Model 1001**

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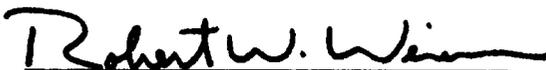
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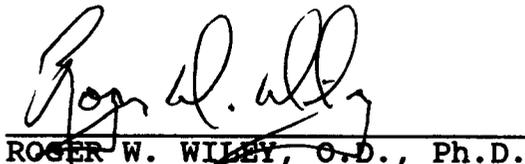
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Section 1. Executive digest

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

1.1 TEST OBJECTIVES

- 1.1.1 To determine if the medical equipment is complete and operational per the manufacturer's operating instructions.
- 1.1.2 To ensure the electrical safety of the medical equipment.
- 1.1.3 To ensure the equipment will function as designed throughout the rated battery operation time.
- 1.1.4 To ensure the safety of the operator, the patient, and the aircrew.
- 1.1.5 To assess design considerations which could potentially contribute to an operator error.
- 1.1.6 To determine if the medical equipment can function as designed in a low pressure environment.
- 1.1.7 To determine the ability of the medical equipment to withstand the vibrational stresses expected in a rotary-wing flight environment without degradation or malfunction.
- 1.1.8 To determine the ability of the medical equipment to be stored and operated in a high temperature environment.
- 1.1.9 To determine the ability of the medical equipment to be stored and operated in a low temperature environment.
- 1.1.10 To determine the ability of the medical equipment to operate satisfactorily for short periods during exposure to high humidity conditions.

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

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

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

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

1.2 TESTING AUTHORITY

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

1.3 SCOPE

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

1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was configured with the Medical Technology Products Peristaltic Infusion Pump*, model 1001 and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 3.3 flight hours.

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

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

1.3.5 An airworthiness release (AWR) dated 24 Feb 1992 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the MTP Infusion Pump, Model 1001.

* See list of manufacturers

1.4 MATERIAL DESCRIPTION

The Medical Technology Products Model 1001 is a peristaltic infusion pump designed to deliver intravenous fluids on an automatic basis. A "Standby/On" control switch on the front panel turns the infusion pump on. The unit conducts an internal self test when it is energized. During the self test, the unit emits a tone and displays "TEST", "OK", and then "SET" on the red light emitting diode (LED) display. Pushbutton switches labeled "+" and "-" on the front panel allow the operator to set the rate and volume of fluid to be administered. The rate can be adjusted from 0 to 499 mL/h in 1 mL/h increments and the volume to be infused can be set from 0 to 9999 mL in 1 mL increments. After the rate and volume have been set, the operator presses the "Start/Stop" button to begin delivery of fluid. When the selected volume has been delivered, an audio alarm sounds and the pump reverts to a delivery rate of 5 mL/h. A door on the front of the unit protects the infusion set. A pole clamp, ac power receptacle, and nurse call are located on the back panel.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery Life Evaluation: The unit averaged 7 hours and 10 minutes of operation at a delivery rate of 70 mL/h from a fully charged battery. The manufacturer specifies a battery life of 8 hours with a fully charged battery.

1.5.1.2 Electrical Safety Evaluation: Grounding conductor resistance was 1000 milliohms which exceeds the limit of 150 milliohms specified in TB-38-750-2, April 1987. The maximum case leakage current was 1.9 microamperes.

1.5.1.3 Human Factors Evaluation: The Medical Technology Products 1001 was found to be satisfactory in all categories of the evaluation except that it lacks external fuses or circuit breakers.

1.5.1.4 Environmental Tests: The Medical Technology Products 1001 can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of the environmental testing, except the high temperature and low temperature operation tests. The requirements for environmental tests are established in MIL-STD-810D, Methods 500.2 (altitude), 514.3 (vibration), 501.2 (high temperature), 502.2 (low temperature), and 507.2 (humidity).

1.5.1.5 Radiated Emissions Tests (RE02): The Medical Technology Products Model 1001 may be unsatisfactory for use in certain EMI sensitive environments. Broadband (BB) and Narrowband (NB)

radiated emissions that exceed the specification limits were detected in the test frequency range. Emission limits are set forth in MIL-STD-461A, Notice 4.

1.5.1.6 Radiated Susceptibility Test (RS03): The Medical Technology Products Model 1001 was not 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): A narrowband emission over specification was detected.

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

1.5.2 In-flight testing

1.5.2.1 During the in-flight human factors evaluation, the Medical Technology Products Model 1001 was found to be satisfactory in all categories of the evaluation criteria. However, audio alarms are not detected with the high ambient noise level in the aircraft. Errors were detected by monitoring the LED display.

1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the Medical Technology Products Model 1001 in any of the prescribed flight test modes.

1.5.2.3 The Medical Technology Products Model 1001 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 Medical Technology Products Peristaltic Infusion Pump, Model 1001 was found to be compatible with U.S. Army MEDEVAC UH-60A Black Hawk with the subsystems listed in paragraph 3.2.2.

Section 2. Subtests

2.1 INITIAL INSPECTION

2.1.1 Objective

To determine if the MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 will display consistent and accurate performance as an acceptable performance test.

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the MTP Infusion Pump Model 1001 was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the MTP Infusion Pump Model 1001 was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

2.1.4 Test findings

2.1.4.1 The MTP Infusion Pump Model 1001 was inventoried and found to be complete.

2.1.4.2 The MTP Infusion Pump Model 1001 operated as prescribed in the manufacturer's operating manual.

2.2 BATTERY LIFE EVALUATION (Laboratory)

2.2.1 Objective

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

2.2.2 Criterion

Verify manufacturer's specified full power internal battery life expectancy of 8 hours operation.

2.2.3 Test procedure

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

2.2.4 Test findings

The unit operated for an average of 7 hours and 10 minutes on a fully charged battery at 70 mL/h infusion rate. This is less than the manufacturer's specified life expectancy, but exceed the duration of a typical medical evacuation mission. Criterion partially 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 MTP Infusion Pump Model 1001.

2.3.2 Criterion

The MTP Infusion Pump Model 1001 shall meet the standards established in TB-38-750-2 and NFPA 99 for electrical safety of medical equipment.

2.3.3 Test procedure

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

2.3.4 Test findings

Grounding conductor resistance was 1000 milliohms and maximum case leakage current was 1.9 microamperes. The conductor resistance exceeds the limits specified in TB-38-750-2. Criterion partially 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 MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 was operated according to prescribed instructions through its full range of functions.

2.4.4 Test finding

The MTP Infusion Pump Model 1001 was found to be satisfactory in all of the evaluation criteria except fuses and circuit breakers. There were no fuses or circuit breakers accessible to the operator. Criterion partially met.

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

2.5.1 Objective

To determine if the MTP Infusion Pump Model 1001 can function as designed in a low pressure environment.

2.5.2 Criterion

The MTP Infusion Pump Model 1001 will perform as designed while exposed to an altitude equivalency of 15,000 feet above sea level.

2.5.3 Test procedure

2.5.3.1 A pretest performance check was conducted to ensure proper operation of the MTP Infusion Pump Model 1001.

2.5.3.2 The altitude test was performed in a Tenney Engineering model 64S altitude chamber*. This test is based on MIL-STD-810D, Method 500.2. The MTP Infusion Pump Model 1001 was operated on the floor of the chamber. Chamber pressure was decreased to 420 mmHg (15,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to

ambient conditions (760 mmHg) over a 10-minute period. There are no provisions for the control of temperature or humidity inside this chamber.

2.5.3.3 A posttest performance check was conducted to ensure proper operation of the MTP Infusion Pump Model 1001 after the exposure to low pressure.

2.5.4 Test findings

2.5.4.1 The pretest performance check met criterion 2.1.2.2.

2.5.4.2 No failures in the performance of the MTP Infusion Pump Model 1001 were noted before, during, or after the altitude test. Criterion met.

2.5.4.3 The posttest performance check met criterion 2.1.2.2.

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

2.6.1 Objective

To determine the ability of the MTP Infusion Pump Model 1001 to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

The MTP Infusion Pump Model 1001 will remain operational and be able to display consistent and accurate performance while exposed to vibrational stresses.

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the MTP Infusion Pump Model 1001.

2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TA115-40/CSTA vibration test system*. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are derived from performance taken on the floor under the copilot's seat in a UH-1 helicopter traveling at 120 knots. The reference spectrum breakpoints are from MIL-STD-810D, Method 514.3; reference spectrum levels are based on field performance with a conservatism factor of 1.5. Independent tests were conducted in the X, Y, and Z axes.

Z-axis

duration: 60 minutes
broadband intensity: 0.4506 G_{rms}
random vibration: initial slope : 99.00 dB/oct
5 Hz level: 0.00006210 G_{sqr/Hz}
100 Hz level: 0.0006210 G_{sqr/Hz}
300 Hz level: 0.0006210 G_{sqr/Hz}
500 Hz level: 0.00006210 G_{sqr/Hz}
final slope: -99.00 dB/oct
sinusoidal vibration: .5450 G_{pk} at 11.25 Hz
.1690 G_{pk} at 22.50 Hz
.1200 G_{pk} at 33.75 Hz
.0310 G_{pk} at 45.00 Hz
.0530 G_{pk} at 56.25 Hz

X and Y axes

duration: 60 minutes each
broadband intensity: 0.3099 G_{rms}
random vibration: initial slope: 99.00 dB/oct
5 Hz level: 0.00002920 G_{sqr/Hz}
100 Hz level: 0.0002920 G_{sqr/Hz}
300 Hz level: 0.0002920 G_{sqr/Hz}
500 Hz level: 0.00002920 G_{sqr/Hz}
final slope: -99.00 dB/oct
sinusoidal vibration: .3200 G_{pk} at 11.25 Hz
.0670 G_{pk} at 22.50 Hz
.0950 G_{pk} at 33.75 Hz
.0350 G_{pk} at 45.00 Hz
.0770 G_{pk} at 56.25 Hz

The MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001.

2.6.4 Test findings

2.6.4.1 The pretest performance check met criterion 2.1.2.2.

2.6.4.2 No failures in the performance of the MTP Infusion Pump Model 1001 occurred before, during, or after exposure to vibration. Criterion met.

2.6.4.3 The posttest performance check met criterion 2.1.2.2.

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

2.7.1 Objective

To determine the ability of the MTP Infusion Pump Model 1001 to be stored and operated in a high temperature environment.

2.7.2 Criteria

2.7.2.1 The MTP Infusion Pump Model 1001 will demonstrate consistent and accurate operation during the high temperature operation check.

2.7.2.2 The MTP Infusion Pump Model 1001 will demonstrate consistent and accurate operation after the high temperature storage cycle.

2.7.3 Test procedure

2.7.3.1 A pretest performance check was conducted to ensure proper operation of the MTP Infusion Pump Model 1001.

2.7.3.2 The high temperature test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 501.2. For the high temperature operation test, the MTP Infusion Pump Model 1001 was turned on and placed on the floor of the environmental chamber. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent relative humidity (RH) within 15 minutes. The environmental control system is capable of regulating temperature within $\pm 2^\circ\text{C}$ and humidity within ± 5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001.

2.7.3.4 The MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001.

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 MTP Infusion Pump Model 1001 functioned properly after the high temperature storage test. Criterion met.

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

2.8.1 Objective

To determine the ability of the MTP Infusion Pump Model 1001 to be stored and operated in a low temperature environment.

2.8.2 Criteria

2.8.2.1 The MTP Infusion Pump Model 1001 will demonstrate consistent and accurate operation during the low temperature operation check.

2.8.2.2 The MTP Infusion Pump Model 1001 will demonstrate consistent and accurate operation after the low temperature storage cycle.

2.8.3 Test procedure

2.8.3.1 A pretest performance check was conducted to ensure proper operation of the MTP Infusion Pump Model 1001.

2.8.3.2 The MTP Infusion Pump Model 1001 was placed on the floor of the environmental chamber and the temperature was lowered to 0°C within 25 minutes. The environmental control system is capable of regulating temperature within 2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant for 2 hours. The chamber door was opened briefly every 30 minutes to minimize the change in chamber conditions, and a performance check was conducted. The chamber temperature then was raised to ambient temperature within a 30-minute period.

2.8.3.3 A posttest performance check was conducted to ensure proper operation of the MTP Infusion Pump Model 1001.

2.8.3.4 The MTP Infusion Pump Model 1001 was "stored" in a nonoperational mode. The MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001.

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. The MTP infusion pump could not maintain the set temperature (90°F). With an ambient temperature of 32°F, the unit maintained an internal temperature of 73°F. Criterion partially met.

2.8.4.3 The posttest performance check met criterion 2.1.2.2.

2.8.4.4 The MTP Infusion Pump Model 1001 functioned properly after the low temperature storage test. Criterion met.

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

2.9.1 Objective

To determine the ability of the MTP Infusion Pump Model 1001 to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

The MTP Infusion Pump Model 1001 will demonstrate consistent and accurate operation while exposed to a high humidity environment.

2.9.3 Test procedure

2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the MTP Infusion Pump Model 1001.

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 MTP Infusion Pump Model 1001 was placed in operation on the floor of the environmental chamber. The chamber temperature was raised to a temperature of 30°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within $\pm 2^\circ\text{C}$ and humidity within ± 5 percent RH. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001.

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 MTP Infusion Pump Model 1001 performance checks conducted during the exposure to the high humidity environment. Criterion met.

2.9.4.3 The posttest performance check met criterion 2.1.2.2.

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

2.10.1 Objectives

2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the MTP Infusion Pump Model 1001 in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 in the 10 kHz to 50 MHz frequency ranges.

2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the MTP Infusion Pump Model 1001 within the range of 50 kHz to 400 MHz and power spikes.

2.10.2 Criteria

2.10.2.1 The MTP Infusion Pump Model 1001 will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.

2.10.2.2 The MTP Infusion Pump Model 1001 will not malfunction when it is subjected to radiated emissions as specified in MIL-STD-461A, Notice 4, paragraph 6.20.

2.10.2.3 The MTP Infusion Pump Model 1001 will not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.

2.10.2.4 The MTP Infusion Pump Model 1001 will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.

2.10.3 Test procedure

2.10.3.1 The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method RE02. The MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 was operating, the frequency spectrum (14 kHz to 12.4 GHz) was scanned for emissions. The MTP Infusion Pump Model 1001 was operated with ac and battery power.

2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 was operating, it was monitored for faulty operation during exposures to fields of 1 V/m from 10 kHz to 2 MHz, and 5 V/m from 2 to 30 MHz, 10 V/m from 30 MHz to 2 GHz, and 5 V/m from 2 to 10 GHz. The MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 was operating, the frequency range (10 kHz to 50 MHz) was scanned for emissions conducted in the power cable from the MTP Infusion Pump Model 1001.

2.10.3.4 The conducted susceptibility spike test was performed on a chemical resistant counter top according to MIL-STD-462, Notice 3, Method CS06. Power was supplied via a customized metal connection box. The connection box has two power receptacles and four banana jacks on its front panel. Connections to the individual power lines were made in series through the banana jacks. Transient spikes of 100 volts, 10 microseconds were generated with a Solar Electronics model 8282-1 transient pulse generator* and induced onto the power leads at the connection box banana jacks. The spikes were monitored with a Tektronix 2235 oscilloscope* connected to a power receptacle on the connection box. The MTP Infusion Pump Model 1001 was plugged into the other receptacle on the connection box, placed in operation. It was

observed visually for correct operation while it was subjected to the power line spikes.

2.10.3.5 The conducted susceptibility test was performed according to MIL-STD-462, Notice 3, Method CS02. The MTP Infusion Pump Model 1001 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 pump was operated. It was observed visually for proper operation while it was subjected to the radio interference on the power leads. Each frequency was held for 15 seconds.

2.10.4 Test findings

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

<u>Frequency range</u>	<u>Emission exceeding standard</u>
Battery Operation:	
18.1 MHz	0.1 dB (NB)
3.168 MHz	3.6 dB (BB)
ac Operation:	
0.023 - 0.982 MHz	14.8 - 32.2 dB (NB)
1.998 - 36.179 MHz	0.2 - 54.9 dB (NB)
50.08 - 155.2 MHz	0.2 - 22.5 dB (NB)
0.044 - 0.844 MHz	0.0 - 17.9 dB (BB)
29.999 MHz	1.8 dB (BB)

Criterion partially met.

2.10.4.2 The MTP Infusion Pump Model 1001 was not found to be susceptible to radio frequency interference in the testing range and magnitude. Criterion met.

2.10.4.3 A narrowband emission of 3.7 dB over specification was detected at 18.118 MHz during the conducted emissions test. Criterion partially met.

2.10.4.4 The MTP Model 1001 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 MTP Infusion Pump Model 1001 while in use onboard the aircraft.

2.11.2 Criterion

The flight surgeon will be able to operate the MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 and the in-flight environment. The flight surgeon conducted the test wearing a flight suit, flight gloves, and an SPH-4B flight helmet. An evaluation of the compatibility with the nuclear, biological, and chemical (NBC) protective equipment was not conducted. Due to restrictions of the AWR, testing was conducted during daylight hours only.

2.11.3.2 The MTP Infusion Pump Model 1001 was placed on the floor of the aircraft and secured with cargo straps. The MTP Infusion Pump Model 1001 was tested using ac and battery power in all flight scenarios required by the In-Flight Test Operations Procedures (ITOP) (refer to section 3.2).

2.11.4 Test findings

During the in-flight human factors evaluation, the MTP Infusion Pump Model 1001 was found to be satisfactory in all categories of the evaluation criteria. Audio alarms could not be detected in the high ambient noise environment in the aircraft. Problems in the operation of the infusion pump could be detected by monitoring the LED display. Criterion met.

2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS

2.12.1 Objective

To assess the EMI/EMC characteristics of the MTP Infusion Pump Model 1001 with the host aircraft and its installed systems.

2.12.2 Criteria

2.12.2.1 The MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001's operation.

2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the MTP Infusion Pump Model 1001 and the aircraft operating as source and victim. The MTP Infusion Pump Model 1001 and applicable aircraft instruments and systems were monitored for unusual operation, readings, surges, or power anomalies for each checklist item (see pages 3-4 through 3-7).

2.12.4 Test findings

2.12.4.1 There were no adverse instances of EMI/EMC noted with the MTP Infusion Pump Model 1001 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 MTP Infusion Pump Model 1001 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 Medical Technology Products Model 1001 is a peristaltic infusion pump designed to deliver intravenous fluids on an automatic basis. A "Standby/On" control switch on the front panel turns the infusion pump on. The unit conducts an internal self test when it is energized. During the self test, the unit emits a tone and displays "TEST", "OK", and then "SET" on the red light emitting diode (LED) display. Pushbutton switches labeled "+" and "-" on the front panel allow the operator to set the rate and volume of fluid to be administered. The rate can be adjusted from 0 to 499 mL/h in 1 mL/h increments and the volume to be infused can be set from 0 to 9999 mL in 1 mL increments. After the rate and volume have been set, the operator presses the "Start/Stop" button to begin delivery of fluid. When the selected volume has been delivered, an audio alarm sounds and the pump reverts to a delivery rate of 5 mL/h. A door on the front of the unit protects the infusion set. A pole clamp, ac power receptacle, and nurse call are located on the back panel.

3.1.2.2 Dimensions: 11 x 11 x 18 cm (4 x 4 x 7 in).

3.1.2.3 Weight: 2.3 kg (4 lbs)

3.1.2.4 Power requirements: 120 Vac, 60 Hz. An internal rechargeable battery provides up to 8 hours of operation.

3.2 TEST DATA

3.2.1 Photographic description



3.2.2 Aircraft equipment list

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

3.2.3 In-flight test data card

DATA CARD FORMAT

GUIDELINE FOR DATA COLLECTION

IN-FLIGHT SUITABILITY TEST OF MEDICAL ITEMS

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

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

(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 MSL for 20 minutes).

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

(b) Radio communication vs. medical item operation.

- | | | | |
|--------|---|--|--|
| a. FM | X | | |
| b. UHF | X | | |
| c. VHF | X | | |

(2) NOE (20 minutes). compatibility of flight mode and medical item operation.	X		
--	---	--	--

(3) FM homing (10 minutes).	X		
-----------------------------	---	--	--

(4) Doppler navigation vs. medical item operation.

- | | | | |
|--------------------------|---|--|--|
| (a) Initialize function. | X | | |
| (b) Fix function. | X | | |
| (c) Update function. | X | | |

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

3.2.4 EMI switchology checklist

EMI SWITCHOLOGY CHECKLIST UH-60 AIRCRAFT

IN-FLIGHT SUITABILITY OF MEDICAL ITEMS

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

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

3.2.5 Battery life evaluation

Battery Life Evaluation Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Manufacturer battery life specification: Up to 8 hours operation on a fully charged battery. The mode of operation was not specified.

Performance: The unit operated an average of 7 hours 10 minutes while delivering IV fluids at a rate of 70 mL/h.

Comments: None

3.2.6 Electrical safety test

Electrical Safety Test Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: MTP Infusion Pump Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 21 Aug 90

Performance:

Grounding conductor resistance (milliohms): 1000

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity	0.1
unit off, ungrounded, normal polarity	1.8
unit off, ungrounded, reverse polarity	1.8
unit on, grounded, normal polarity	0.2
unit on, ungrounded, normal polarity	1.8
unit on, ungrounded, reverse polarity	1.9

MAXIMUM LIMITS:

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

Comments on item setup or checks: None

Comments on test run (including interruptions): Ground
resistance exceeds limits.

Comments on other data: None

3.2.7 Human factors evaluation

**Human Factors Evaluation
Report Form**

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 11 Sep 90

Item configuration during test: Item prepared for operation.

Checklist for HFE

RESULTS

VISUAL DISPLAYS:

Satisfactory

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

Comments: None

CONTROLS:

Satisfactory

location
characteristics of controls
labeling
control - display relationships

Comments: None

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: approximately 2 minutes.

MAINTAINABILITY:

Satisfactory

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

Comments: No manuals were provided with the unit.

CONDUCTORS:

Satisfactory

binding and securing
length
protection
routing
conductor coding
fabrication
connectors

Comments: None

FASTENERS:

Satisfactory

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

Comments: None

TEST POINTS: **Satisfactory**

general
location and mounting
test point labeling and coding

Comments: None

TEST EQUIPMENT: **Satisfactory**

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

Comments: None

FUSES AND CIRCUIT BREAKERS: **Unsatisfactory**

external accessibility
easy replacement or reset by operator

Comments: No externally accessible fuses 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: Control labels below each control.

SAFETY: **Satisfactory**

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

Comments: No manual provided with test item.

3.2.8 Altitude test

Altitude Test
Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: MTP Infusion Pump Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 10 Sep 90

Item configuration during test: Item sitting on chamber floor.

Performance test criteria: Correct and accurate fluid delivery.

Ambient conditions outside chamber:

Temperature	20°C
Humidity	73% 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	None

IN-TEST DATA

Time of test start: 0815

POSTTEST DATA

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

Time of test end : 0930

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): Air in line
alarm at 40 minutes.

Comments on other data: None

3.2.9 Vibration test

Vibration Test
Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: MTP Infusion Pump Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 7 Sep 90

Item configuration during test: Item strapped down on vibration
table fixture; ac and battery operation.

Performance test criteria: Accurate delivery of fluid.

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	None
list connections to dummy loads	None
list unconnected terminals	None

Ambient conditions

Temperature	72°F
Humidity	73% RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Time at first check:

X: 0914 Y: 1220 Z: 0745

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Time at second check:

X: 1010

Y: 1315

Z: 0845

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

POSTTEST DATA

Time at test end:

X: 1015

Y: 1315

Z: 0845

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

Item functional (based on performance test criteria): Yes

Item intact: Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

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

3.2.10 High temperature test

High Temperature Test
(Equipment Operating)
Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: MTP Infusion Pump Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 4 Sep 90

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

Performance test criteria: Accurate delivery of correct volume
of fluid at a rate of 70 mL/h (measured).

Ambient conditions outside chamber:
Temperature 26°C
Humidity 56% 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 None
list connections to dummy loads None
list unconnected terminals None
distance from north wall (meters) 0.638
distance from south wall (meters) 0.638
distance from east wall (meters) 1.435
distance from west wall (meters) 1.257
distance from ceiling (meters) 1.422
distance from floor (meters) 0.495

IN-TEST DATA

Time of test start: 0805

Performance checks during test:

First check:

Time: 0835
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
Yes, all ok
Deviation from pretest: None

Second check:

Time: 0905
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
Yes, all ok
Deviation from pretest: None

Third check:

Time: 0935
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
Yes, all ok
Deviation from pretest: None

POSTTEST DATA

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

Time of test end: 1005
Item functional (based on performance test criteria):
Yes, all ok
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.11 High temperature storage test

High Temperature Test
(Equipment in Storage)
Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: MTP Infusion Pump Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 5 Sep 90

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

Performance test criteria: Consistent and accurate operation.

Ambient conditions outside chamber:

Temperature	23C
Humidity	54% 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	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

Time of test start: 0825

POSTTEST DATA

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

Time of test end: 1125
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

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

Comments on test run (including interruptions): None

Comments on other data: None

3.2.12 Low temperature test

Low Temperature Test
(Equipment Operating)
Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: MTP Infusion Pump Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 4 Sep 90

Item configuration during test: Sitting on test stand.

Performance test criteria: Accurate delivery of fluid.

Ambient conditions outside chamber:

Temperature	26°C
Humidity	56% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Pass

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

Time of test start: 1200

Performance checks during test:

First check:

Time: 1315
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Second check:

Time: 1415
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Third check:

Time: 1445
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

POSTTEST DATA

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

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

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.13 Low temperature storage test

Low Temperature Test
(Equipment in Storage)
Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: MTP Infusion Pump Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 6 Sep 90

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

Performance test criteria: Accurate delivery of fluid.

Ambient conditions outside chamber:

Temperature	25°C
Humidity	56% 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	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

Time of test start: 0805
Midtest time: 1105
Midtest temperature: -46°C

POSTTEST DATA

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

Time of test end: 1405
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.14 Humidity test

Humidity Test
Report Form

Nomenclature: Infusion Pump
Manufacturer: Medical Technology Products, Inc.
Model number: Model Model 1001
Serial number: 2230
Military item number: None

Options installed: None

Date of test: 10 Sep 90

Item configuration during test: The unit was sitting on test stand, operating on ac and battery power.

Performance test criteria: Accurate maintenance of selected fluid delivery rate.

Ambient conditions outside chamber:

Temperature	23°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	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.638
distance from south wall (meters)	0.638
distance from east wall (meters)	1.435
distance from west wall (meters)	1.257
distance from ceiling (meters)	1.422
distance from floor (meters)	0.495

IN-TEST DATA

Time of test start: 1245

Performance checks during test:

First check:

Time: 1330
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: 1415
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: 1500
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: 1545
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: 1630
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: 1645

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

CS06 Testing configuration(s): Operating on counter top.
Performance (pass/fail): Pass
Comments: not susceptible to test spikes

Radiated Emissions Tests

RE02 Testing configuration(s): Operating on wooden test stand in the EMC chamber, ac and battery power.
Performance (pass/fail): Fail
Comments: Battery: BB failure 3.6 dB over specifications at 3.168 MHz and NB failure of 0.1 dB at 18.1 MHz. ac: BB failures of 0.1 - 17.9 dB at 0.044 - 0.844 MHz and 1.8 dB at 29.99 MHz; NB failures of 14.8 - 32.2 dB at 0.023 - 0.982 MHz, 0.2 - 22.5 dB at 1.998 - 36.179 MHz, and 0.2 - 22.5 dB at 50.08 - 155.2 MHz.

Radiated Susceptibility Tests

RS03 Testing configuration(s): Operating on the wooden test stand in the EMC chamber.
Performance (pass/fail): Pass
Comments: Not susceptible to test signals.

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 MTP Infusion Pump will display consistent and accurate performance.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 10 hours.	partially met	2.2.2
4	The MTP Infusion Pump will meet the limits established in NFPA 99 for electrical safety of medical equipment.	partially met	2.3.2
5	The MTP Infusion Pump will be rated satisfactory in all major categories of the evaluation. These include: Visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.	partially met	2.4.2
6	The MTP Infusion Pump will demonstrate proper operation exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	The MTP Infusion Pump will remain operational while exposed to vibrational stresses.	met	2.6.2
8	The MTP Infusion Pump will remain operational during the high temperature operation check.	partially met	2.7.2.1

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

19 The aircraft will not radiate met 2.12.2.3
EMI to disrupt or interfere with
the MTP Infusion Pump.

3.3.2 Significant problems which require corrective action

None

3.3.3 Suggested improvements

None

3.4 REFERENCES

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- 3.4.4 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, DC. TB 38-750-2. April.
- 3.4.5 Underwriters Laboratory's, Inc. 1978. Standard for safety, medical and dental equipment. Chicago, Illinois. UL-544.
- 3.4.6 Department of Defense. 1989. Human engineering design criteria for military systems, equipment, and facilities. Washington, DC. MIL-STD-1472D. March.
- 3.4.7 Association for the Advancement of Medical Instruments. 1988. Human factors engineering guidelines and preferred practices for the design of medical devices. Arlington, Virginia. AAMI-HE-1988. February.
- 3.4.8 National Fire Protection Association. 1987. Standard for health care facilities. Quincy, Massachusetts. NFPA 99. February.
- 3.4.9 Department of the Army. 1982. Environmental protection and enhancement. Washington, DC. AR 200-1. June.

3.5 ABBREVIATIONS

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

TB
TFT
T & E

technical bulletin
technical feasibility testing
test and evaluation

UES
USAARL

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

V/m

volts per meter

3.6 LIST OF MANUFACTURERS

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