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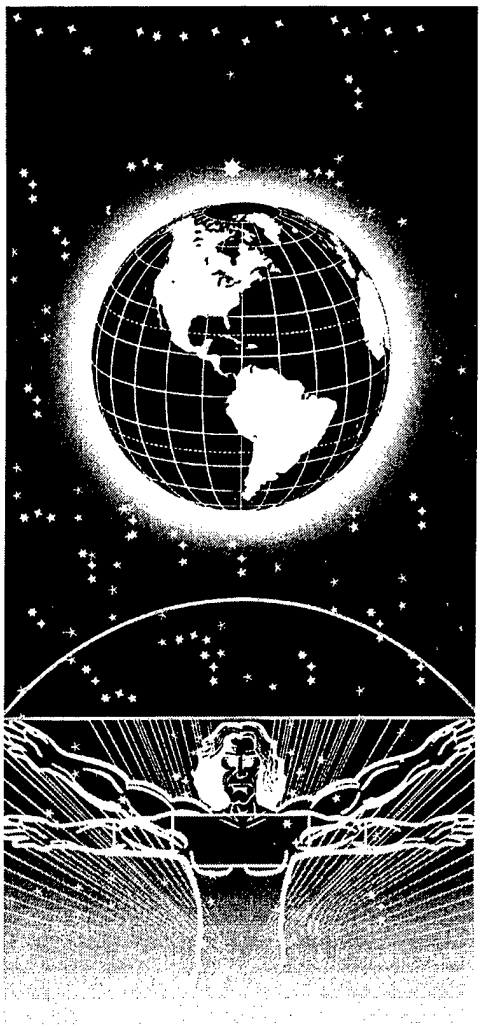

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE BAXTER, INC., MODEL AS50 SYRINGE PUMP

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NOTICES

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The Baxter, Inc., Model AS50 Syringe Pump is a portable, syringe type infusion pump. It provides accurate, continuous or intermittent infusion of intravenous solutions, drug solutions, whole-blood and packed red blood cells. The AS50 can be piggybacked into an ongoing infusion line to delivery a secondary solution. The AS50 can be programmed to set rates of infusion from 0.01 to 438 ml/hr. The AS50 accepts standard disposable syringes from 1 ml to 60 ml. The unit operates off of 115 VAC/60 Hz and internal rechargeable battery. The unit weighs approximately 3 lbs. Its dimensions are 3.5 in. W. X 10.12 in. H. X 2.6 in. D. The power supply weighs 0.72 lbs.

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TESTING AND EVALUATION OF THE BAXTER, INC., MODEL AS50, SYRINGE PUMP

BACKGROUND

The Air Force Medical Logistics Office requested the Air Force Medical Equipment Development Laboratory (AFMEDL) participation in evaluating and approving Baxter, Inc., Model AS50, Syringe Pump for use on board USAF aeromedical evacuation aircraft. Specific components of the Baxter, Inc., Model AS50, Syringe Pump that underwent the evaluation process included: the Baxter model AS50 basic unit: (S/N: 805041AB) and the power supply 900 series, Model C AS40-01-900. All components of the model AS50 were tested for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the model AS50.

DESCRIPTION

The EUT is a portable, syringe type infusion pump. It provides accurate, continuous or intermittent infusion of intravenous solutions, drug solutions, whole blood and packed red blood cells. The EUT can be piggybacked into an ongoing infusion line to delivery a secondary solution. The EUT can be programmed to set rates of infusion from 0.01 to 438 ml/hr. The EUT accepts standard disposable syringes from 1 ml to 60 ml. The unit operates off of 115 VAC/60 Hz and internal rechargeable battery. The unit weighs approximately 3 lbs. Its dimensions are 3.5 in. W. X 10.12 in. H. X 2.6 in. D. The power supply weighs 0.72 lbs.

Figure 1. Baxter, Inc., Model AS50 Syringe Pump

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-8), and manufacturer's literature (9). The AFMEDL Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check was developed specific to this EUT to verify its proper functioning under various testing conditions. All tests were conducted by AFMEDL personnel assigned to the Systems Research Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas unless otherwise noted.

The EUT was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic Interference (EMI)

4. Thermal/ Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Temperature Storage

    e. Cold Temperature Storage

5. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to simulated flight level

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (3); AFI 41-201, Equipment Management in Hospitals (4). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz and 115 VAC/400 Hz.

c. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472 (5).

d. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The EUT was prepared for tests as follows:

1. Place EUT on a level surface
2. Insert a B-D 60 ml syringe filled with solution into holders on side of EUT
3. Connect one end of I.V. tubing to syringe and the other to 3-way stopcock with a priming syringe attached
4. Connect 3-way stopcock to Bio-Tek, Inc., IDA-4 analyzer
5. Turn IDA-4 on
6. Purge channel on IDA-4 and set to view
7. Connect power supply to EUT and then to 115VAC/60 Hz line power
8. Turn EUT on
9. Configure EUT to deliver 48 mls/hr and press start

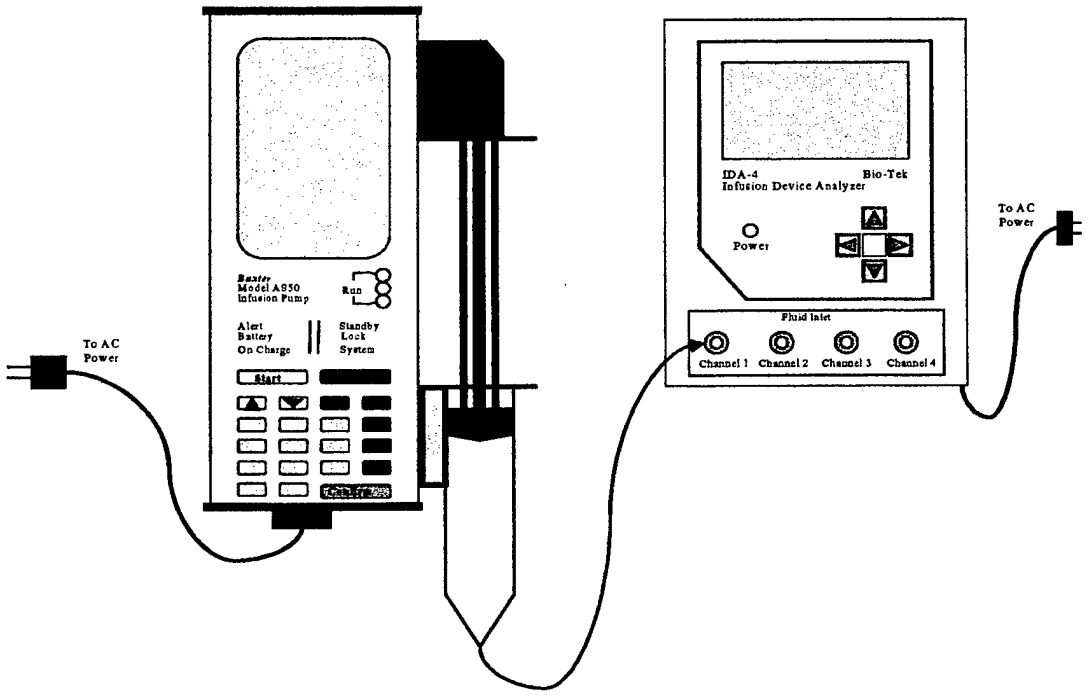

Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions: insert a B-D 60 ml syringe filled with solution into holders on side of EUT; connect power supply to EUT; plugged power supply into 115VAC/60 Hz line power; turned EUT on. Configure the EUT and simulator IAW TEST SETUP. Operational data was recorded three times at one-minute intervals for trend analysis. Battery Operation as outlined in the Baxter, Inc., Operator's Manual (9)

VIBRATION

Vibration testing is critical to determine, "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT was secured to an aircraft stanchion pole segment, using a mounting bracket provided by manufacturer. The stanchion pole segment with the EUT was secured to the vibration table as it would be secured in the aircraft (Figure 3). The EUT was subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figures 4. A, 4. B, and 4. C).

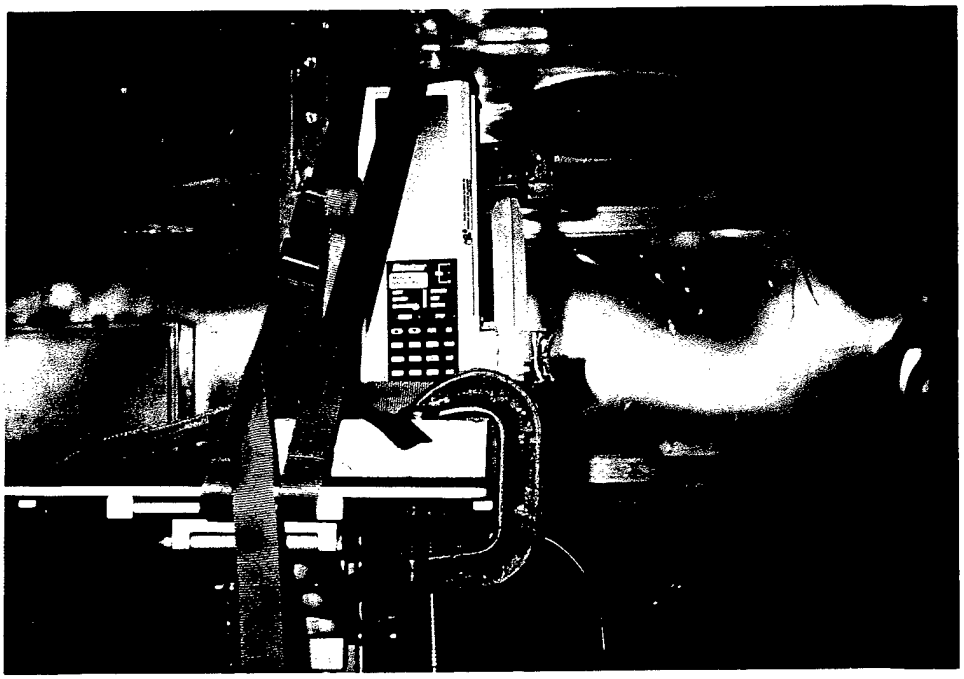

Figure 3. Vibration Table Mounting

Sine-on-Random Curves

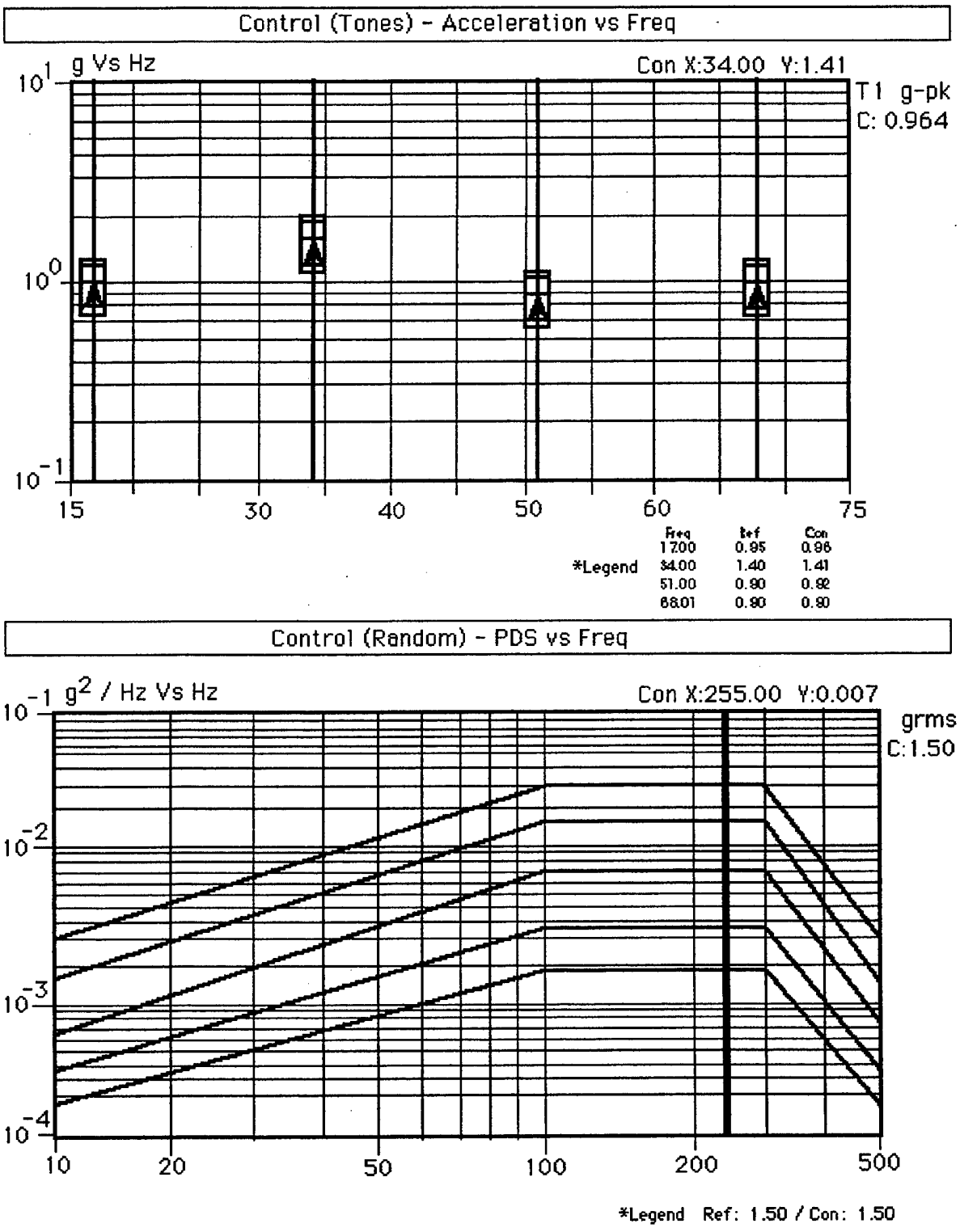

Figure 4. A & Figure 4 B. Mil-Std-810E, Category 10, Figures 514.4-16 and 514.4-17

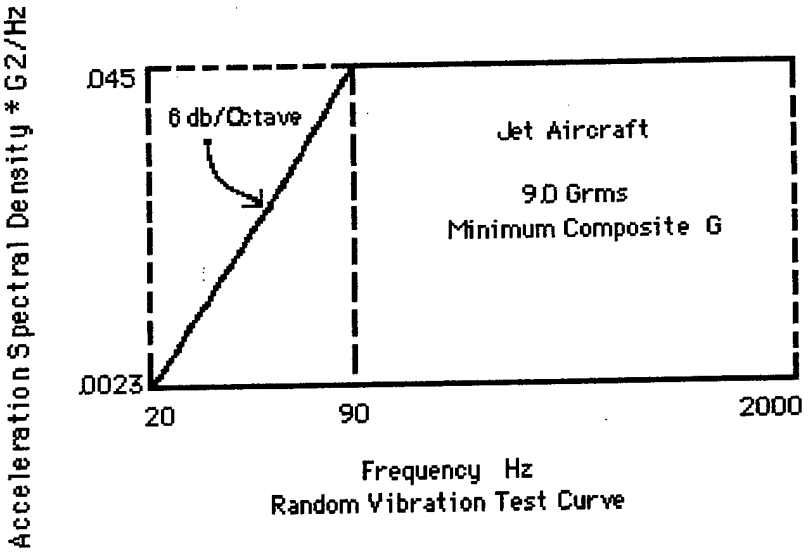

Figure 4. C. Mil-Std-810E, Category 10, Figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility is a primary concern for equipment to be used safely on USAF aeromedical evacuation aircraft. Emissions from medical equipment may cause electromagnetic interference (EMI) with potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to18 GHz.": For Air Force aircraft applications, radiated emissions were measured in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were measured throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the EUT along its power supply lines. It was performed to assess the EUT's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1

GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

g. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances."

During emissions testing, all EUT's electrical components were operating for the duration of the test to create the worst case emissions scenario. In these tests, the EUT was programmed to deliver 48 ml/hr. For both emissions and susceptibility testing, the EUT was tested for operation using 115 VAC/60 Hz and internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, corrosion, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in a calibrated Thermotron Industry, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. All input and output cables, wires, and patient breathing circuit were routed through ports in the chamber wall, which

were subsequently sealed with precut sponge plugs. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained non-operational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hr

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hr

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hr

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hr

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on operation of the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation; pressurize cabin atmosphere to barometric pressures equivalent to 8,000 - 15,000 ft above sea level. Altitude testing consisted of operating the EUT while ascending from ground level to 15,000 ft, stopping at 2,000 ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT operated inside the rapid decompression test chamber as the chamber was depressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000 - 12,000 ft/min. The test was repeated twice more, once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions. Performance checks were assessed each time the EUT returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT's ability to provide patient care on board USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

Flight qualified AFMEDL aeromedical crewmembers flying on C-9 and C-130 aeromedical evacuation missions conducted this phase of testing. The EUT was positioned and secured to an aircraft stanchion pole using the mounting bracket provided by the manufacturer and/or on a NATO litter using litter straps and litter equipment brackets. Then human factor characteristics were evaluated, e.g., securing methods, setup/tear down times and securing locations. Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits. Battery Endurance revealed operation time well within manufacturer's specifications. The battery operated the EUT 9.5 hrs at 100 ml/hr.

VIBRATION

During evaluation, the EUT was programmed to deliver 48 ml/hr to assess the EUT's ability to function without the possibility of system failure. The unit performed according to manufacturer's specifications and AFMEDL guidelines without any system failure or malfunction.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft (including small and large body, fixed and rotary wing) while operating from 115VAC/60 Hz and internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT could not meet AFMEDL requirements for return to clinical operation following challenge to hot storage (140° F for 6 hours). The EUT may not recover if exposed to this temperature for prolonged periods. The EUT was able to regain operational status within 2 hours following hot storage challenge of 130° F for 6 hours. The EUT operated according to AFMEDL and manufacturer's guidelines for hot operation, cold operation, cold storage, and humidity.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit was able to deliver 48 ml/hr without system failure up to 15,000 ft cabin altitude.

2. Rapid Decompression: The EUT operated satisfactorily following each rapid decompression event.

AIRBORNE PERFORMANCE

The in-flight evaluation of the EUT was performed on two separate C-9 and C-130 aeromedical evacuation missions. Analysis of performance data indicated this unit was easy to enplane and deplane. Evaluations revealed that the battery charger is incompatible with USAF Electrical Cord Assembly System (ECAS). The EUT can be plugged directly into Avionics Instruments, Inc., frequency converter. In certain aircraft such as the C-130/C-141 special training considerations may apply due to aircraft ambient noise affecting audio alarms. The EUT should be positioned to allow visual alarm monitoring throughout all phases of flight. Securing the EUT to NATO litters and aircraft stanchion poles is extremely difficult without impeding EUT function. The EUT requires a securing system/device to overcome this problem. The manufacturer supplied a litter-securing bracket during testing that proved very adaptable and rugged. The EUT was secured using its own mounting clamp to a three-pronged metal bracket provided by the manufacturer. During evaluation it was determined that manufacturer's mounting bracket does work when secured to litter brackets on stanchion poles between litter spaces.

SUMMARY

AFMEDL engineers found the Baxter, Inc., Model AS50 Syringe Pump to be conditionally approved for use on all U.S. Air Force aeromedical evacuation aircraft while operating from 115 VAC/60 Hz and internal battery power. Its operation was within expected parameters when subjected to electromagnetic interference (EMI), environmental extremes, simulated cabin altitudes. It did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

a. Do not expose AS50 to ambient storage temperatures in excess of 130° F.

b. In certain aircraft such as the C-130/C-141 special training considerations may apply. Consider limitations due to aircraft ambient noise affecting audio alarms. AS50 should be positioned to allow visual alarm monitoring throughout all phases of flight.

c. On military C-9A aeromedical aircraft, the audible cues could be clearly heard within 2 feet of the AS50 provided hearing protection was not used.

d. Battery charger is incompatible with USAF Electrical Cord Assembly System (ECAS). AFMEDL suggests using the gray MS III pigtail adapter or similar power-cord extender when using ECAS. AS50 can be plugged directly into Avionics Instruments, Inc. frequency converter.

e. No transport case was evaluated. Care needs to be taken during transport to prevent AS50 damage.

f. Securing the AS50 to NATO litters and aircraft stanchion poles is extremely difficult without impeding AS50 function. AS50 requires a securing system/device to overcome this problem. The manufacturer supplied a litter-securing bracket during testing that proved very adaptable and rugged.

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REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. Emergency Care Research Institute (ECRI)
3. AFI 41-203, Electrical Shock Hazards
4. AFI 41-201, Equipment Management in Hospitals
5. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. Baxter, Inc., Model AS50, Syringe Pump, Operator's Manual.
10. AFMEDL Procedures Guide, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF BAXTER, INC., MODEL AS50, SYRINGE PUMP

SPECIFICATIONS

General

Size:	3.5 in. W. X 10.12 in. H. X 2.6 in. D.
Weight:	
(Syringe Pump)	3 lbs.
(Pwr. Supply)	0.72 lbs.
Flow Rate: Accuracy	±3% of full scale plunger travel (not including syringe tolerance)
Vol. Accuracy:	±3% or 0.007" of travel, which ever is greater (not including syringe tolerance)
Flow Rate Range:	0.01 ml/hr to 438 ml/hr, depending on syringe
Syringes:	B-D 1,3,5,10,20,30 & 60 ml. Sherwood Monojet 1,3,6,12,20,35 & 60 ml. Terumo 1,3,5,10,20,30 & 60 ml.
Deliver Vol.:	Full syringe volume for 1-60 ml syringes
Power Requirements:	115 VAC/60 Hz and internal rechargeable battery.
Operating time:	Internal batteries: 5 hours of operation @ 100 ml/hr or 12 hours of operation @ 2 ml/hr with 60 ml syringe. Recharge time > 16 hrs
Environmental	Temperature: 50°F to 104°F (10°C to 40°C). Delivery of high viscosity fluids at low temperatures is not recommended.