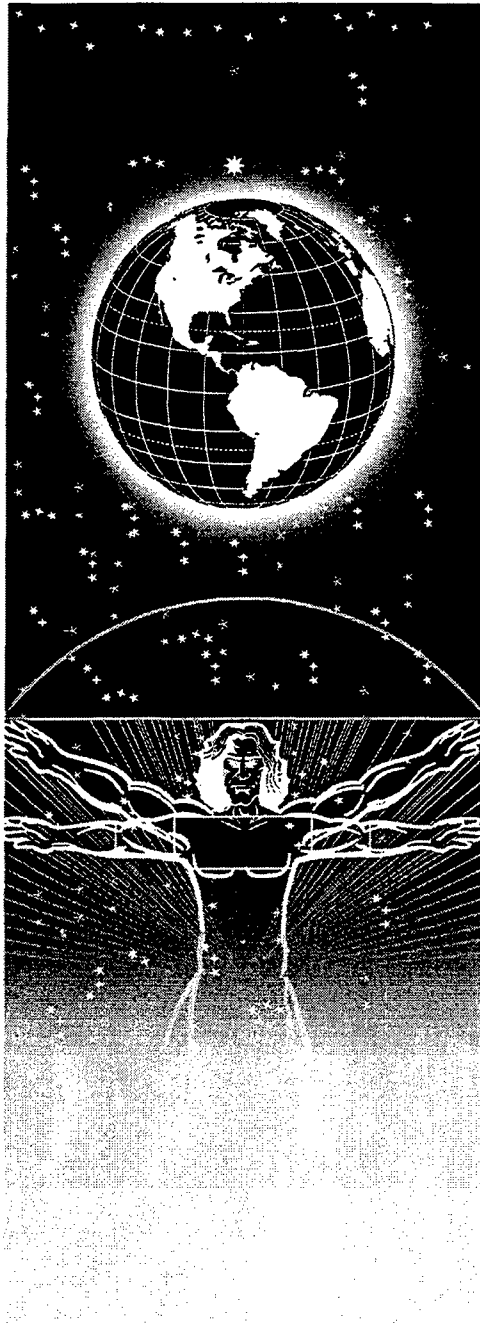




UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE IMPACT INSTRUMENTATION, INC. 326M INTERMITTENT/ CONTINUOUS OROPHARYNGEAL/ TRACHEAL SUCTION APPARATUS

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**TESTING AND EVALUATION OF THE
IMPACT INSTRUMENTATION, INC.
326M INTERMITTENT/CONTINUOUS
OROPHARYNGEAL/TRACHEAL SUCTION APPARATUS**

BACKGROUND

The Aeromedical Systems Division, Human Systems Program Office, Brooks AFB requested Aeromedical Research to evaluate and approve the IMPACT 326M Intermittent/Continuous, Oropharyngeal/Tracheal Suction Apparatus for use on board USAF aeromedical evacuation aircraft. Specific components of the IMPACT 326M that underwent the evaluation process included the IMPACT 326M base unit, two reusable collection canister, water container, bio-filter, securing brackets for both unit and collection canisters, and 12 VDC Power Cord. All components of the IMPACT 326M were tested for air worthiness. Throughout this report, the term equipment under test (EUT) refers to the IMPACT 326M Intermittent/Continuous, Oropharyngeal/Tracheal Suction Apparatus.

DESCRIPTION

The EUT is a portable, self-contained, general purpose, medical suction apparatus designed for removing secretions from the upper airway during oropharyngeal and/or tracheal suctioning. The unit operates on 115 VAC / 50-400 Hz, external 11-30 VDC, and an internal rechargeable battery pack (Figure 1). The unit weighs approximately 5.5 Kg or 12 lb and is 9.5 in. W. X 11.5 in. H. X 4.33 in. D.

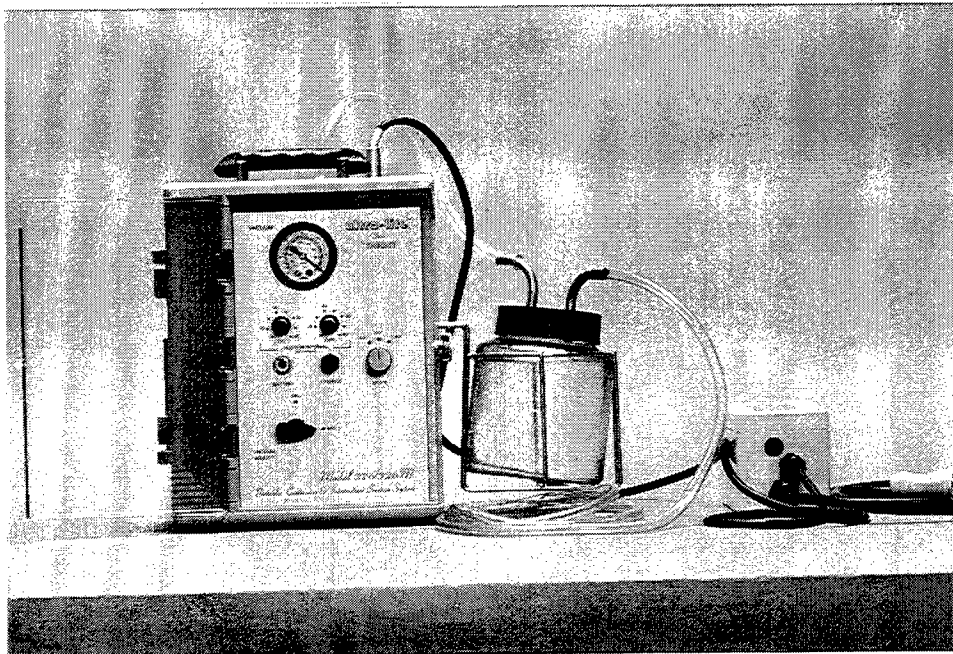


Figure 1. IMPACT 326M

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 5), various military standards (2-4 & 6-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check were developed specific to this EUT to verify its proper functioning of the equipment under various testing conditions. All tests are conducted by Aeromedical Research personnel assigned to the Systems Research Branch (CFTS), Crew Technology Division, Armstrong Laboratory, Brooks AFB, TX., unless otherwise noted.

The EUT was subjected to various laboratory and inflight 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 Ambient Pressure
6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

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

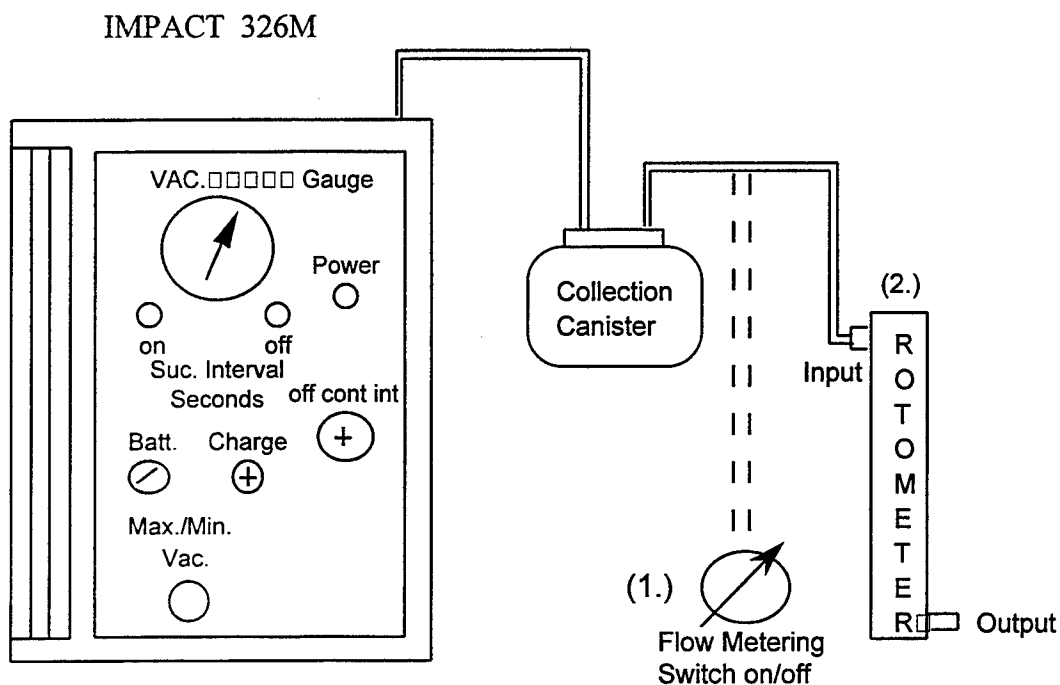
b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1), Electrical Shock Hazards, AFI 41-203 (2), and Equipment Management in Hospitals, AFI 41-201 (3). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz and 115 VAC/400 Hz.

c. The EUT was examined to ensure it met basic requirements for human factors design as outlined in MIL-STD 1472 (4).

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

TEST SETUP

The EUT was configured as shown in Fig 2.



Legend:

- (1.) Measures 300 mmHg in 4 seconds & Maximum Vacuum
- (2.) Measures flow

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:

Time to Reach 300 mmHg suction as outlined in ECRI (5) - Attach collection tubing to the collection canister, turn unit on, set vacuum adjust to "maximum", use a stopwatch to time an end point of 300 mmHg upon occlusion of collecting tube, repeat test 3 times, record results. Then connect a rotometer to the collection tubing to measure unit's free airflow, record results. Check unit in AC, 28 VDC and battery power modes.

Maximum Vacuum Level as outlined in ECRI (5) - Attach collection canister with collection tubing to unit, select continuous mode, occlude collection tubing, set vacuum adjust to maximum, turn unit on to ascertain maximum vacuum level, record results. Check unit in AC, 28 VDC and battery power modes.

Battery Operation as outlined in IMPACT Instrumentation Inc., Operations & Service Manual (9) - The battery pack can be recharged from the external 115 VAC source in 16 hours.

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's components were mounted on a NATO litter segment on the vibration table as it would be secured in the aircraft (Figure 3). They were 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 (Figure 4).

Figure 3. Vibration Table Mounting

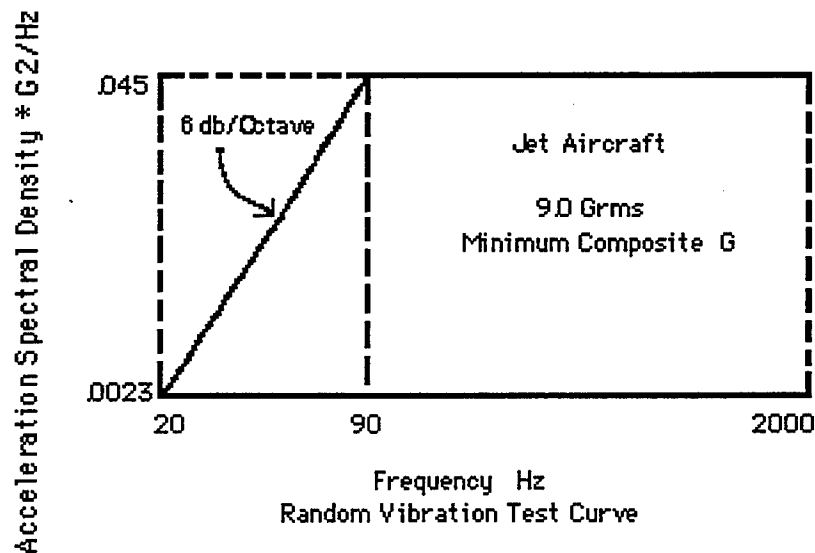
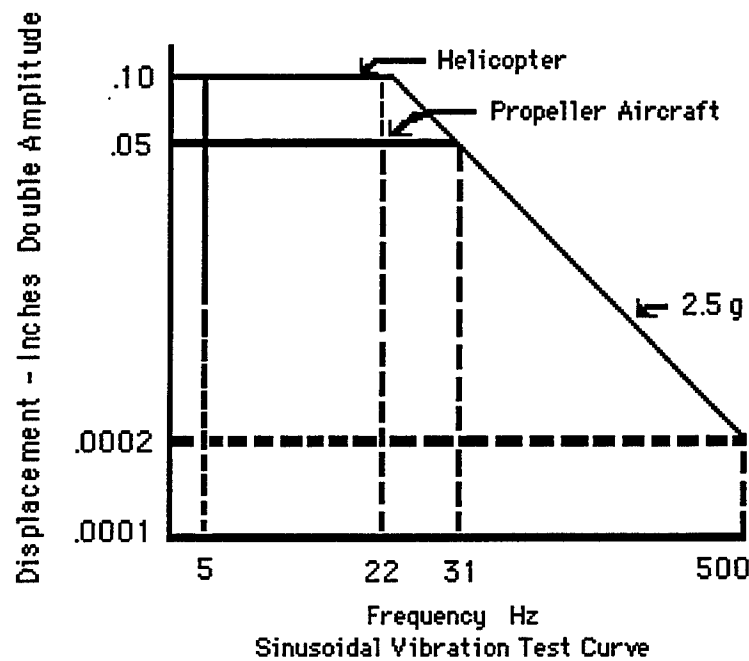


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor in assessing the effects of excessive electromagnetic emissions and 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 to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested 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 tested 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 operated in the maximum vacuum mode. For susceptibility testing, the EUT was operated again in the maximum vacuum mode. For both emissions and susceptibility testing, the EUT was tested for operation on 115 VAC/60, 400 Hz, and internal batteries.

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, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory's Thermotron Industries, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. 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 nonoperational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

- a. Humidity Operation: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hr
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hr
- c. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hr
- d. Hot Temp Storage: $140^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($60^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr
- e. Cold Temp Storage: $-40^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($-40^{\circ}\text{C} \pm 2^{\circ}\text{C}$) 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 the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground, at rates of 5,000 ft/min. Descent is stopped at 2,000 ft for performance checks.

Decompression Testing: A decompression 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 decompression so as not endanger a patient, personnel, or the aircraft itself. The EUT operated inside the decompression test chamber as the chamber was pressurized 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 decompression and once for a 1-second decompression. The EUT was monitored throughout the series of decompressions; performance checks were assessed each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research verifies demonstration of all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members from Aeromedical Research on a C-9 aeromedical evacuation mission. The EUT was positioned and secured to the aircraft stantion pole and evaluated. Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from other aeromedical evacuation crew members participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed two problems, first, a power distribution problem located in the main power supply. The problem was a mis-wiring of the main transformer. Second, the power cord connection into the unit would not allow disconnection and reconnection during normal routine use. The manufacturer replaced the power cable and implemented a securing method to maintain the connection during aircraft vibrations. Once the manufacturer corrected these 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 a 2 hour operation time well within manufacturer's specifications.

VIBRATION

The gauge on the EUT became unstable and experienced violent oscillations when the vacuum output was set to maximum (in all three axis). The output flow of EUT was reduced to 20 inHg and the oscillations dampened significantly. This was the only deviation from the vibration testing protocol. The unit then performed according to manufacturers specifications.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft while operating from 115 VAC/60-400 Hz, 28VDC & battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT operated satisfactorily during all five phases of testing. Testing was conducted in the Armstrong Laboratory's Thermotron Industries, model SM-32 environmental chamber.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit was able to deliver 29 lpm flow at 10,000 ft cabin altitude. Reading on EUT gauge was approximately 16 inHg.
2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on a C-9 aeromedical evacuation mission. Evaluation confirmed that the unit would operate successfully during all phases of flight. Analysis of flight data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems. It was noted the power cord length is not sufficient when securing the unit to the stantion pole of the C-9 aircraft.

SUMMARY

Aeromedical Research found the IMPACT Instruments, Inc. IMPACT 326M to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60 - 400Hz, 28 VDC or battery power with the recommendations listed below. The EUT operated within expected parameters when subjected to environmental extremes and simulated cabin altitudes, and did not produce a hazard during rapid decompression. The following recommendations apply:

- a. The Specification Sheet, Page 6-1, from the 326M Instruction Manual still reads that the unit can only run for 27 minutes/hour when using 117 VAC External Power. The Specification Sheet should be changed to reflect current model.
- b. Power cord should be at least eight feet long in order to reach power receptacles on the C-9A aircraft when the unit is secured to the aircraft floor.
- c. Velcro securing straps on the soft-sided transport case should be lengthened to allow securing the unit to the litter equipment brackets.
- d. Change the value of Capacitor #C20 (manufacturer's schematic) from 1000 μ fd to 10,000 μ fd.
- e. Add the following components to allow battery meter to read battery charge conditions when operating in continuous suction mode. Regulator #U13, capacitors #C33 and #C34 (manufacturer's schematic.)
- f. Add an External power lamp #LP2 (manufacturer's schematic) to provide visual feedback when connected to live Alternating Current (AC) mains.
- g. Change the external power jack from a connector with a conductive shell and screw-type locking mechanism to P.N.: 708-0750-01 with an aluminum threaded sleeve to secure the AC power supply output plug to the external power jack.
- h. Move the bridge rectifier #BR1 (manufacturer's schematic) from main suction unit to AC power supply.

i. Replace the metal serial number label and replace with a pressure sensitive serial number label. This metal label is used as a heat sink for the bridge rectifier (BR1- manufacturer's schematic).

j. Connect the transformer dual primary windings in parallel for 115 VAC operation.

k. Resize velcro retaining straps that secure battery pack to improve ease by which user can grab, and separate, the battery pack retaining straps.

l. Round edges to the stainless steel collection canister attachment brackets to eliminate sharp, 90° corners.

m. Eliminate protrusions of screws into battery compartment by providing a center channel to stainless steel collection canister attachment brackets.

*NOTE: The EUT was subjected to multiple endurance runs to evaluate the affects of long term use. Tests included: 16 hour continuous free flow and intermittent operation utilizing 115 VAC/60 Hz power and 16 hour continuous free flow utilizing 115 VAC/400 Hz power. The unit functioned in accordance with manufacturer specifications throughout this phase of testing. No degradation in the unit's operability was observed during these tests.

**NOTE: Aeromedical Research identified one additional area for possible improvement. A method to secure the power supply to the base unit will prevent the weight of the power supply from inducing excessive stress and strain on the unit's input power receptacle while also enhancing ease of transporting the power supply and unit.

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. AFI 41-203, Electrical Shock Hazards
3. AFI 41-201, Equipment Management in Hospitals
4. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. Emergency Care Research Institute (ECRI)
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. IMPACT Instrumentation Inc., IMPACT 326M, Operations & Service Manual.
10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF
THE IMPACT Instrumentation, Inc.
IMPACT 326M

SPECIFICATIONS

General

Size	9.5 in. W. X 11.5 in. H. X 4.33 in. D.
Weight	5.5 Kg. (12 lb)
Case	Polycarbonate, color-through, injection-molded
Power	115 VAC 50-400 Hz, 12 VDC, and Sealed GEL cell batteries; 6 V/cell, 2 cells, wired in series.
Air Flow	Minimum 30 Liters Per Minute (lpm)
Vacuum	Continuous: Minimum 0-550 mmHg (0-22 inHg), regulator adjustable. Intermittent: Minimum 0-200 mmHg (0-8 inHg) regulator adjustable.
Patient Safety	All patient connections are electrically isolated.
Environmental	Temperature: -20°C to 49°C (operating). -15°C to 40°C (storage and shipping). Humidity: low