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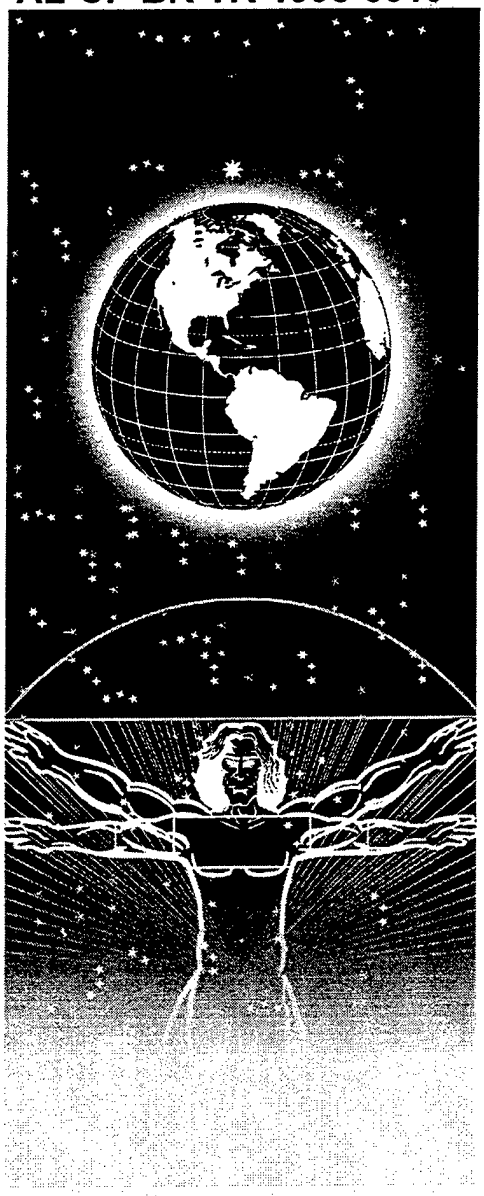

UNITED STATES AIR FORCE
ARMSTRONG LABORATORY

TESTING AND EVALUATION OF THE IMPACT INSTRUMENTATION, INC. 308ME13 CONTINUOUS OROPHARYNGEAL/ TRACHEAL SUCTION APPARATUS

Butch O. Blake

CREW SYSTEMS DIRECTORATE
CREW TECHNOLOGY DIVISION
2504 Gillingham Drive, Suite 25
Brooks Air Force Base TX 78235-5104

May 1998

NOTICES

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Butch Blake

BLAKE, BUTCH O., MSgt, USAF
Aeromedical Research Technician

James C. Sylvester

JAMES C. SYLVESTER, Major, USAF, NC
Chief, Aeromedical Research

Roger L. Stork

ROGER L. STORK, Colonel, USAF, BSC
Chief, Crew Technology Division

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Brooks AFB TX 78235-5104

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The IMPACT Instrumentation, Inc., Continous Oropharyngeal Tracheal Suction, model 308ME13 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/60-400 Hz, external 12 VDC, and an internal rechargable battery pack. The unit weighs approximately 11 lbs and is 13.5 in. W. X 10 in. H. X 6.65 in. D.

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TESTING AND EVALUATION OF THE IMPACT INSTRUMENTATION, INC. 308ME13 CONTINOUS OROPHARYNGEAL/ TRACHEAL SUCTION APPARATUS

BACKGROUND

The Defense Personnel Support Center requested Aeromedical Research to evaluate the IMPACT 308ME13 Continuous Oropharyngeal/Tracheal Suction Apparatus for use onboard USAF aeromedical evacuation aircraft and for use in the Department of Defense Deployable Medical Systems. Specific components of the IMPACT 308ME13 that underwent evaluation included the IMPACT 308ME13 basic unit, reusable collection canister, water container, bio-filter, securing straps (x2), and 12 VDC Power Cord. All components listed above were evaluated for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the IMPACT 308ME13 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 12 VDC, and an internal rechargeable battery pack (Figure 1). The unit weighs approximately 11 lb and is 13.5 in. W. x 10 in. H. x 6.65 in. D.

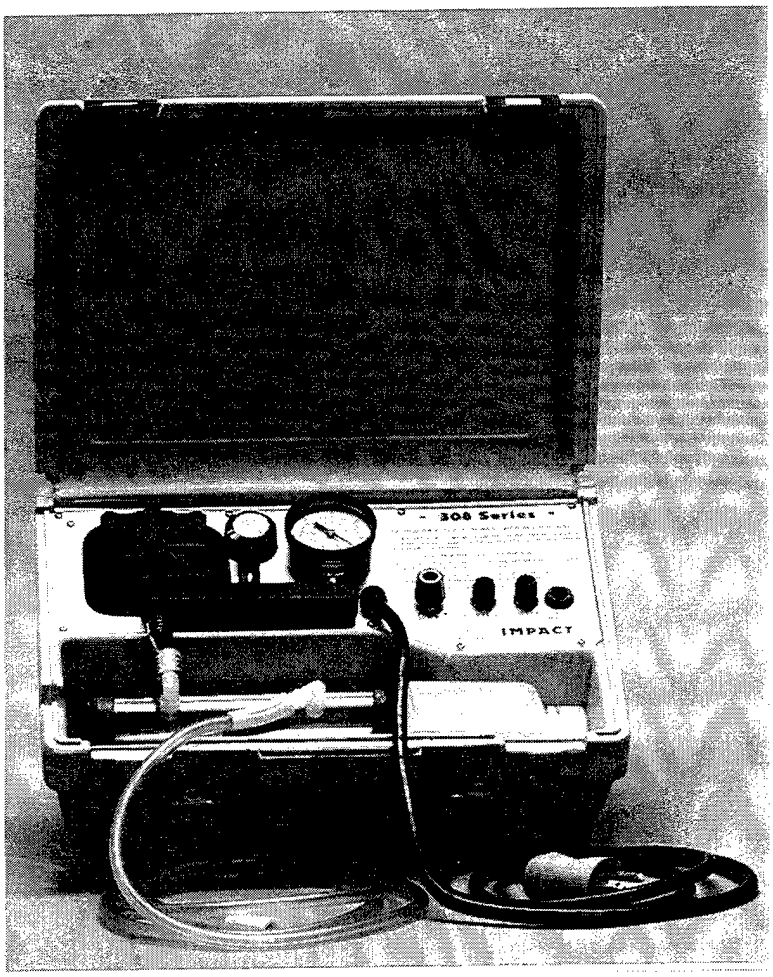


Figure 1. IMPACT 308ME13

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. Unless otherwise noted, all testing is conducted and monitored by Aeromedical Research personnel assigned to the Systems Research Branch (HEPR), Flight Stress Protection, Air Force Research Laboratory, Brooks AFB, TX.

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.

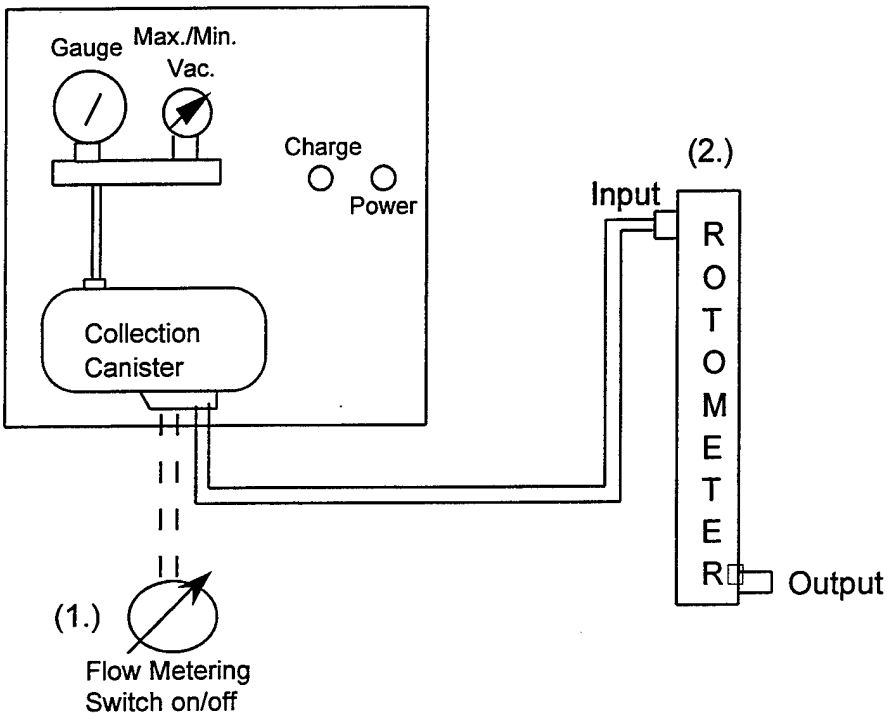
b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1), Electrical Shock Hazards, AFI 41-203 (2), and Equipment Management in Hospitals, AFI 41-201 (3). Ground resistance and leakage current measurements were 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 placed on a level surface, the power switch was set to AC, the vacuum regulator was set to maximum (MAX.) flow position and a wye was placed at the output end of the collection tubing which was connected to a flow metering switch (on/off). The other output of the wye was connected to a rotometer to measure system flow.



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 worst case results. Then connect a rotometer to the collection tubing to measure unit's free airflow, record results. Check unit in both AC 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 worst case results. Check unit in both AC 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 24 hours. A fully charged battery lasts approximately 20 minutes while operating under maximum vacuum.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. The EUT's components were mounted on a NATO litter segment on the vibration table as it would be secured in the aircraft. 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 3).

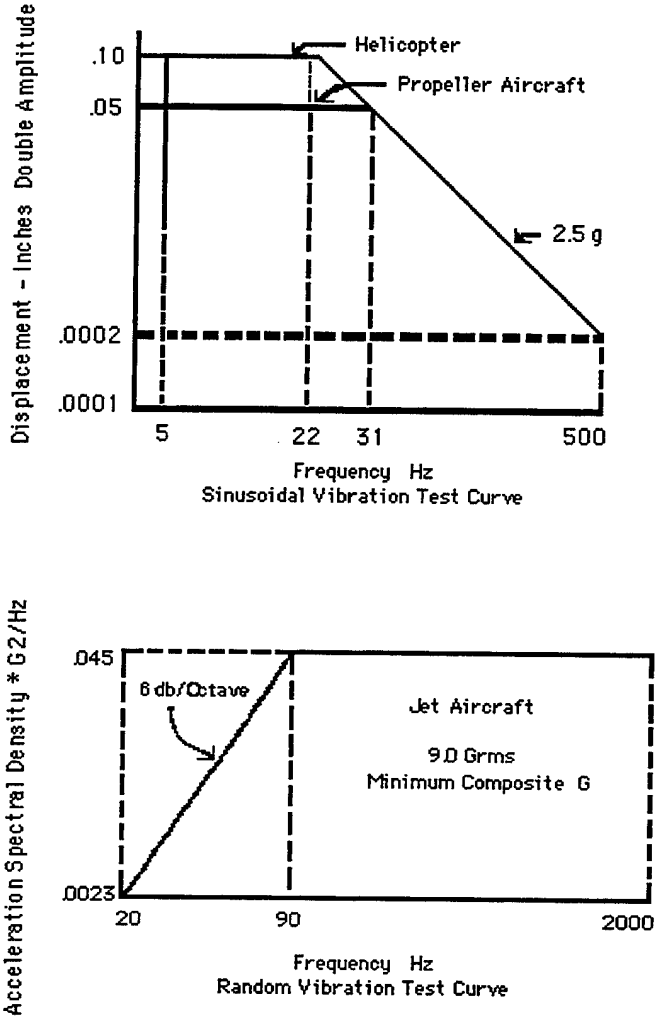


Figure 3. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety of everyone on board is the driving factor to 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 the aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D and 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 (field strength values from MIL-STD-461D Table IV, Category Aircraft Internal). This test evluated 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 EUT."

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 electical current and volatge waveforms occurring in platforms from excitation of natural resonances."

During emissions testing, all EUT 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 calibrated 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 EUT was then allowed to return to ambient temperature and humidity after which a performance check was repeated. The following describes the conditions of the environmental tests performed:

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

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

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

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

e. Cold Temp Storage: -40 ± 3.6°F (-40 ± 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 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 every 2,000 ft for performance checks.

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 a patient, personnel, or the aircraft itself. The EUT operated inside the rapid 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 RD and once for a 1 second RD. 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 NATO litter and evaluated. Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from other aeromedical evacuation crew members was obtained and evaluated concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification for time to reach 300 mmHg suction and obtain maximum vacuum level. Electrical safety test results showed all parameters to be within referenced guideline limits. **Battery Endurance Test** revealed a 50 minute operation time at maximum vacuum, which is beyond manufacturer's specifications and the internal battery was fully recharged within 24 hours.

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 quit. This was the only deviation from the vibration testing protocol. The unit then performed according to manufacturer's 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 & 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 operated and monitored by Aeromedical Research personnel assigned to the Systems Research Branch (CFTS), Crew Technology Division, Armstrong Laboratory, Brooks AFB, TX.

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 airborne performance data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems. EUT was secured using existing velcro straps to the litter equipment brackets, and also using NATO litter straps in conjunction with litter equipment brackets. However, it was noted that the power cord length is not sufficient when securing the unit to the aircraft's floor for inflight use.

SUMMARY

Aeromedical Research found the IMPACT Instruments, Inc. IMPACT 308M to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC/60 - 400 Hz or battery power with the recommendations listed below. Its operation was within expected parameters when it was subjected to environmental extremes and simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

a. The Specification Sheet, Page 6-1, from the 308M 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 models ability to operate continuously inflight without any time constraints.

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. When subjected to our vibration curves the IMPACT 308ME13's gauge experienced violent oscillations when the vacuum output was set to maximum (22 in.Hg). However, oscillations subside, when the units output is set to 20 in.Hg. According to Emergency Care Research Institute (ECRI) guidelines the unit's output must reach a level of at least 400 mmHg (15.75 in.Hg) for oropharyngeal suctioning. Therefore, our office found this unit to be acceptable for use.

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 308ME13, 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 308ME13

SPECIFICATIONS

General

Size	10 in. H. x 13.5 in. W. x 6.65 in. D.
Weight	4.9 kg. (11 lb.)
Case	Polyethylene, double-wall, shatterproof, scuff proof, flame retardant.
Power	115 VAC/50-400 Hz, 12 VDC, and Sealed GEL cell batteries; 6 V/cell, 2 cells, wired in series.
Air Flow	Minimum 31 Liters Per Minute (lpm)
Vacuum	Minimum 0-550 mmHg (0-22 inHg), regulator adjustable.
Patient Safety	All patient connections are electrically isolated.
Environmental	Temperature: -60°C to 60°C (operating). -15°C to 40°C (storage and shipping). Humidity: low