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**Laboratory and Flight Tests
of Medical Equipment for Use
in U.S. Army MEDEVAC Helicopters
(Reprint)**

By

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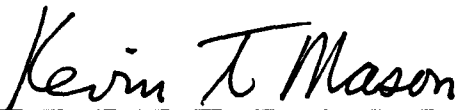
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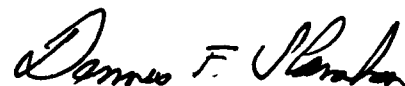
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Laboratory and Flight Tests of Medical Equipment for Use in U.S. Army Medevac Helicopters

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When used in an air medical setting, medical equipment designed for use in hospitals can fail from the stresses of in-flight use, or they interfere with critical rotor-wing aircraft systems. From January 1989 to June 1992, 34 medical devices, including monitor/defibrillators, infusion pumps, vital-signs monitors, ventilators and infant transport incubators, were tested under extreme conditions of temperature, humidity, altitude and vibration (MIL-STD 810D). Electromagnetic emissions and susceptibility were measured (MIL-STD 461C and 462), and human factors were evaluated. The devices were flight tested in a UH-60 MEDEVAC helicopter. Thirty-two percent of the medical devices failed at least one environmental test, and 91% of the devices failed to meet electromagnetic interference standards. Failures included excess conducted and radiated emissions and susceptibility to radiated emissions. Five (15%) of the devices were judged unsuitable for use in the UH-60 MEDEVAC helicopter. Testing is critical to discover the ability of a medical device to perform in the harsh rotor-wing MEDEVAC environment. Failure of a device or interference with aircraft systems can result in loss of a patient or aircrew.

Key Words: medical equipment, MEDEVAC, air medical transport, electromagnetic interference, safety

Modern medical equipment significantly improves the medical team's ability to monitor and treat the critically ill patient in the hospital and during transport. These machines routinely pump fluids, assist respira-

tions, monitor heart beats and blood pressure, or keep an infant warm. The sudden failure of a medical device can endanger the lives of patients. In addition, in air medical transports, if a medical device interferes with an aircraft's systems, the fate of the aircraft and the lives of the crew and patient are threatened.

The U.S. Army operates a fleet of helicopters worldwide. More than 500 of these helicopters are designated for medical evacuation tasks (MEDEVAC) during mobilization. However, even in peacetime, Army

units can perform medical evacuations daily. These include missions to support local disaster plans, military training operations, Military Assistance to Safety and Traffic (MAST) programs, and the general military health care system.

Environmental Hazards

Most medical equipment is designed for use in the hospital environment and is rarely designed to withstand the rigors of transport. In air medical transport, these rigors include extremes of temperature and humidity, vibration and shock, and altitude exposure. The U.S. Army has developed standards to define the extremes of temperature, humidity and vibration that a medical device might be exposed to during its operational life. The Army publication "Environmental Test Methods and Engineering Guidelines" (MIL-STD-810D) details the specific requirements for testing air medical equipment.¹

Electromagnetic Compatibility

More than 50 years ago, the U.S. Army discovered that the ignition system of military vehicles interfered with communications receivers. This instigated the practice of setting standards to measure and

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suppress electromagnetic emissions to prevent electromagnetic interference.²

Electromagnetic interference in aircraft comes from a variety of sources: transmitters of radio frequencies, including those on the aircraft for HF, UHF, or VHF communication and those on the ground for FM radio or VHF television broadcasts; aircraft power line (400 Hz) electrical and magnetic fields; computer and avionics timing and control circuits that generate radio frequencies of 1 MHz or higher; aircraft power regulators; electrical switching transients from turning on and off aircraft lights, fans, or flaps; and electrostatic discharges, including lightning.³ These transients and electromagnetic waves may transfer into wiring and cause electromagnetic interference to other aircraft systems or medical equipment used in the aircraft.

Currently, equipment that is being considered for procurement by the U.S. government is tested for electromagnetic compatibility in accordance with standards established by MIL-STD-461C, "Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference," and MIL-STD-462, "EMI Characteristics, Measurement of."^{4,5}

This paper describes the results of medical device environmental and electromagnetic compatibility tests for 34 medical devices examined from January 1989 to June

Table 1

Environmental Tests and Methods*

Altitude Test	Operate device at 15,000-foot altitude equivalent for 1 hour
High-Temperature Test (Operating)	Operate device at 49° C (120° F) for 2 hours
High-Temperature Test (Storage)	Store device at 63° C (145° F) for 1 hour, 71° C (159° F) for 4 hours, and 63° C for 1 hour
Low-Temperature Test (Operating)	Operate device at 0° C (32° F) for 2 hours
Low-Temperature Test (Storage)	Store device at -46° C (-114° F) for 6 hours
Vibration Test	Vibration for 1 hour in each axis with signature equivalent to helicopter seat
Humidity Test	Operate device at 30° C (86° F), 95% relative humidity for 4 hours

**In accordance with MIL-STD-810D¹*

1992. The results of these tests are used by the U.S. Army to determine which medical devices are suitable for use in Army aircraft.

Materials and Methods

The U.S. Army program for testing and evaluating equipment for air medical operations was established for the equipment's use on Army MEDEVAC aircraft. A medical device is tested at the direction of the Army medical department combat developer or materiel developer. First, each candidate medical device is examined to determine how it functions, including examination of electrical safety and battery life. Next, a human factors review is

completed; this includes checks of the visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety of the device.

In the next phase of testing, each medical device is evaluated to determine its compatibility and performance in various temperature, altitude and humidity environments (see Table 1).

Electromagnetic compatibility characteristics are determined by testing each medical device in a computer-controlled electromagnetically shielded test chamber. First, while the device is operated, the electromagnetic field strength around the device is measured to determine the amount of electromagnetic energy conducted and radiated by the device. Next, the medical device is exposed to conducted and radiated electromagnetic fields to see if the device will malfunction when exposed to electromagnetic energy. The minimum field strength that leads to failure of the device is recorded for each narrow frequency band in the electromagnetic spectrum.⁶ The electromagnetic characteristics tests are detailed in Table 2.

Table 2

Electromagnetic Characteristics Tests*

Radiated Emissions (RE)	Assess maximum radiated emissions from 12 kHz to 12.4 GHz
Radiated Susceptibility (RS)	Assess tolerance to radiated electric fields from 10 kHz to 10 GHz
Conducted Emissions (CE)	Assess maximum conducted emissions from 10 kHz to 50 MHz
Conducted Susceptibility (CS)	Assess tolerance to conducted electrical energy from 10 kHz to 400 MHz

**In accordance with MIL-STD-461C and MIL-STD-462^{4,5}*

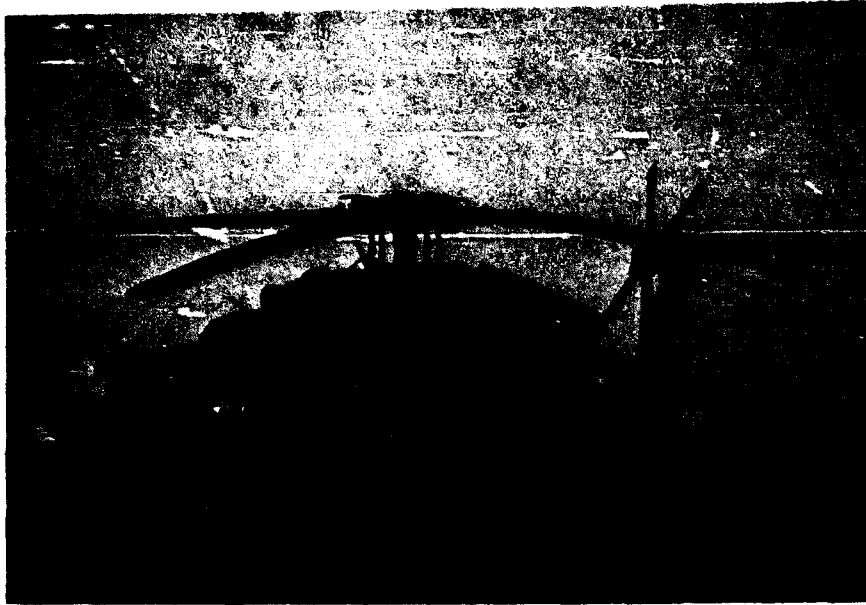


Figure 1. U.S. Army UH-60 Black Hawk helicopter, used for air medical transport.

If the medical device performs properly in laboratory testing and does not produce strong electromagnetic fields within specific frequency bands, the device is approved for limited flight tests. During flight tests, the medical device is operated by a military physician in a UH-60 Black Hawk helicopter (Fig. 1). During these tests, every aircraft system is operated while the device is in service to ensure that it does not interfere with the aircraft's systems or that the aircraft's systems do not interfere with the medical device.

Results

From January 1989 to June 1992, 34 medical devices completed laboratory and flight tests at the U.S. Army Aeromedical Research Laboratory. These included cardiac monitor/defibrillators, infant transport incubators, IV infusion pumps, suction pumps, blood pressure monitors and ventilators.

None of the medical devices failed the electrical safety evaluation. At least one human factor deficiency was noted in 17 (50%) of the medical devices tested. The most common deficiencies were the absence of circuit breakers and the ab-

sence of illumination controls for the display.

Table 3 details the number and percentage of medical devices that failed in environmental tests. Eleven (32%) of the medical devices failed at least one of the environmental tests. This included three failures in the altitude chamber, four failures in each of the high-temperature and low-temperature operation tests, and two failures in the high-humidity environment. As a group, none

of the medical devices failed as a result of exposure to vibration.

Table 4 details the number and percentage of medical devices that failed electromagnetic characteristics tests. Thirty-one (91%) of the medical devices failed at least one of the tests. None of the devices failed the conducted susceptibility tests and the mechanical ventilators passed all electromagnetic characteristic tests.

Among the 34 medical devices tested during the past three years, five devices (15%) were found unfit for use in U.S. Army medical evacuation helicopters: three IV infusion pumps, a suction pump and a blood pressure monitor.

Discussion

Failure of IV infusion pumps in the altitude chamber was typically caused by air bubbles in the administration set. This frequently produced an "air-in-line" alarm and the unit would revert to a keep-vein-open (KVO) infusion rate. High-temperature problems in the transport incubators were caused by improperly calibrated "high temp" alarms; these failed to respond when the incubator temperature exceeded set temperature. One defibrillator model would not synchronize to the

Type of Device	Altitude	High Temp	Low Temp	Humidity	Vibration
Infusion Pump (n=7)	3 (43%)	1 (14%)	0	1 (14%)	0
Monitor/Defibrillator (n=6)	0	1 (17%)	0	1 (17%)	0
Blood Pressure Monitor (n=5)	0	0	0	0	0
Suction Pump (n=3)	0	0	1 (33%)	0	0
Pulse Oximeter (n=3)	0	0	1 (33%)	0	0
Infant Transport Incubator (n=3)	0	2 (67%)	2 (67%)	0	0
Ventilator (n=2)	0	0	0	0	0
Miscellaneous (n=5)	0	0	0	0	0

Table 4

**Number and Percentage of Medical Devices
Failing Electromagnetic Characteristics Tests**

Type of Device	Radiated Emissions	Radiated Susceptibility	Conducted Emissions	Conducted Susceptibility
Infusion Pump (n=7)	7 (100%)	0	4 (57%)	0
Monitor/Defibrillator (n=6)	5 (83%)	4 (67%)	4 (67%)	0
Blood Pressure Monitor (n=5)	5 (100%)	2 (40%)	5 (100%)	0
Suction Pump (n=3)	3 (100%)	1 (33%)	1 (33%)	0
Pulse Oximeter (n=3)	3 (100%)	3 (100%)	2 (67%)	0
Infant Transport Incubator (n=3)	3 (100%)	1 (33%)	2 (67%)	0
Ventilator (n=2)	0	0	0	0
Miscellaneous (n=5)	4 (80%)	3 (60%)	3 (60%)	0

ECG signal when in the humid environment; however, unsynchronized defibrillation was possible. The unit operated normally when returned to ambient conditions.

All of the medical devices tested in the program passed the conducted susceptibility tests. This is probably the result of current isolation design consideration in medical devices to protect patients from inadvertent grounding.

Many devices produced electrical emissions on their power-lines that exceeded the military standard. These emissions could interfere with aircraft power circuits. Most of the medical devices tested in this program exceeded the radiated and conducted emissions standard for use in U.S. Army helicopters. Most of these failures involved weak electrical field strengths or narrow frequency bands that were not used by communication or navigation radios in the air-

craft. In recognition of this, most of these devices obtained airworthiness releases and were successfully test flown in the UH-60 aircraft.

In a test of electromagnetic field strengths produced by the U.S. Army helicopters, a dramatic example of electromagnetic interference was produced.⁷ A monitor/defibrillator was operated with a simulated ECG signal in a UH-1 helicopter on battery power. When the FM radio transmitter in the aircraft was keyed, an interference pattern, similar in appearance to "atrial flutter," was seen on the ECG monitor (Fig. 2).

A suction pump and two infusion pumps were judged to produce sufficient emissions to be a potential hazard in the aircraft. They were not issued airworthiness releases and were not test flown. Another infusion pump was judged unsatisfactory because it always produced an "air-in-line" alarm during alti-

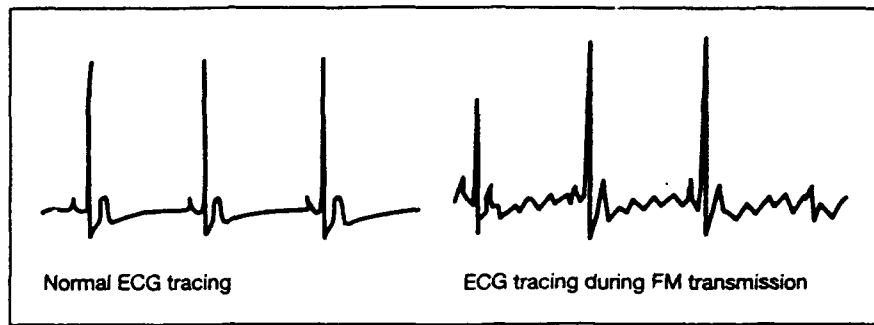


Figure 2. Example of electromagnetic interference in an ECG monitor on board an operating U.S. Army MEDEVAC helicopter.

tude chamber tests. Finally, a non-invasive blood pressure monitor could not differentiate the Kortkoff sounds of the blood pressure in the high ambient background noise produced by the turbine engines of the Black Hawk helicopter.

Conclusions

The lives of patients and the safety of the aircraft depend on the proper

operation of medical devices. This includes operation in the harsh environment produced by extremes of temperature, humidity, altitude and vibration. In addition, the sophisticated electronics of aircraft systems and individual medical devices may not be tolerant of stray electromagnetic signals. Interference can render a medical device or aircraft system unusable or produce more

insidious changes like the "atrial flutter" seen on an ECG monitor.

When a medical device or aircraft system fails unexpectedly, the operating environment and possibility of interference could be the culprit. Laboratory evaluation of the characteristics of each medical device provides useful information to predict the actual performance of the device in air medical transport service. ■

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Editor's Note: The U.S. Army cannot publish a list of manufacturers involved in the tests described in this paper. However, the information on any specific piece of equipment is available to individuals under the Freedom of Information Act. Please write to Dr. Bruckart in care of: U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL, 36362-5292.

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