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TECHNICAL FEASIBILITY TESTING OF MEDICAL MATERIEL:

EVALUATION OF DRAWOVER VAPORIZERS

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To satisfy the need in field medicine for a small, safe, reliable inhalational anesthesia apparatus that does not require compressed gases for operation, two commercially available drawover anesthesia machines are being considered. In the present study, the durability of these machines was evaluated by studying the effects on vaporizer performance of high and low storage temperatures, shock, and vibration, in accordance with procedures in MIL-STD-810D, Environmental Test Methods and Engineering Guidelines. The results indicated that all parts of both vaporizers remained fully functional following exposure to these stresses. Bench tests revealed that the vaporizers' output was within manufacturers' specifications for the operating conditions studied. The absence of damage following exposure to field-simulated environmental stresses indicates that both vaporizers should be sufficiently durable for deployment by field medical units.

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TABLE OF CONTENTS

PREFACE

Investigation into the possible use of drawover anesthesia machines by U.S. Armed Forces was initiated by a 1985 Trip Report on "Medical Lessons from the Falkland Islands Campaign." The Combat Developer requested testing and review of the units in a fixed facility by the Anesthesiology Consultant to the Surgeon General and other appropriate personnel regarding characteristics required for field use. Pre-clinical testing was conducted at the Uniformed Services University of Health Sciences to obtain basic physiologic data relevant to drawover anesthesia. Clinical testing is planned at Brooke Army Medical Center pending approval of an Investigational Device Exemption by the Food and Drug Administration. The purpose of the study reported herein was to evaluate the durability of drawover vaporizers, by identifying any performance degradation associated with exposure to simulated field environmental stresses.

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ABSTRACT

To satisfy the need in field medicine for a small, safe, reliable inhalational anesthesia apparatus that does not require compressed gases for operation, two commercially available drawover anesthesia machines are being considered. In the present study, the durability of these machines was evaluated by studying the effects on vaporizer performance of high and low storage temperatures, shock, and vibration, in accordance with procedures in MIL-STD-810D, Environmental Test Methods and Engineering Guidelines. The results indicated that all parts of both vaporizers remained fully functional following exposure to these stresses. Bench tests revealed that the vaporizers' output was within manufacturers' specifications for the operating conditions studied. The absence of damage following exposure to field-simulated environmental stresses indicates that both vaporizers should be sufficiently durable for deployment by field medical units.

INTRODUCTION

Inhalational anesthesia is required for the surgical management of combat casualties because intravenous and local anesthetics are not adequate for all types of trauma. The current Anesthesia Apparatus, Gas (NSN 6515-01-003-4133) functions satisfactorily in most field medical scenarios, but is less suitable for use in far forward areas where compressed gases are not readily available. Therefore, a need exists for a small, safe, reliable and versatile gas anesthesia apparatus that does not require compressed gases for operation. Drawover vaporizers, which have been used successfully by various armed forces and underdeveloped countries, are a potential solution to this problem.

The desirable features of drawover anesthesia machines include portability, simplicity, low cost, and operational independence of compressed gases, except to provide oxygen enrichment to hypoxic patients. The devices differ considerably in design from conventional anesthesia machines, in which carrier gases from compressed gas sources are passed over or bubbled through liquid anesthetic agent in a highly controlled manner, yielding very consistent output of anesthetic agent concentration. In drawovers, however, ambient air is drawn over the liquid agent by the negative force of a patient's inspiration, making vaporizer output a function of ventilatory characteristics. In spite of this dependence on ventilation, drawover vaporizer output does not deviate significantly from the control setting for the range of minute volumes normally encountered in anesthesia. This versatility, coupled with the austerity of the technique, makes drawover anesthesia very appropriate for highly mobile surgical units or as a backup to

the current field anesthesia machine during compressed gas shortages.

Although much work has been done to define the performance characteristics of drawover vaporizers for various operating conditions (e.g., temperature, ventilation, attitude), no studies have been conducted to evaluate their durability. This report documents the performance of two commercial drawover vaporizers exposed to environmental stresses in accordance with appropriate military standards.

MATERIALS AND METHODS

The two drawover vaporizers evaluated were the Portable, Accurate Complete vaporizer, ("PAC," Ohmeda, Madison, Wisconsin) and the Oxford Miniature Vaporizer, ("OMV," Penlon, Ltd., Oxon, England). These vaporizers each weigh less than 3 kg and have volumes under 3000 cm^3. Testing of the vaporizers was conducted to assess their susceptibility to high and low storage temperatures, vibration, and shock, in accordance with MIL-STD-810D, Methods 501.2 (I), 502.2 (I), 514.3 (I), and 516.3 (IV). During these tests, the vaporizers were subjected to temperature extremes from 70°C to -54°C, the vibration spectrum of a tracked vehicle, and repeated drops from a height of 122 cm.

Following exposure to these stresses, bench tests were conducted to establish whether the vaporizers performance deviated from manufacturers' specifications. For each vaporizer, a Harvard Apparatus Respiration Pump (Harvard Apparatus Company, Inc., South Natick, MA) was attached to a standard drawover breathing circuit in the position that would be adopted by a

spontaneously breathing patient. The breathing circuit consisted of an Ambu bag, a T-tube, and an Ambu-E unidirectional valve system (Ambu Intl., Copenhagen, Denmark) attached to a length of corrugated rubber breathing tube, as described in the PAC product literature. Vaporizer output was directed into a Chain Compensated Gasometer (Warren E. Collins, Inc.). Anesthetic concentration was measured with a Servo Gas Monitor 120 (Siemens-Elema, Solna, Sweden).

The tidal volume of the pump was adjusted to 500 ml for all tests. Anesthetic concentration settings of 0, 1, 2, 3, and 4 percent were tested at "breathing" frequencies of 8, 16, and 24 cycles/minute, yielding flow rates of 4, 8, and 12 liters/minute respectively. Anesthetic agent concentration was recorded following stabilization of the output for each test condition. Halothane was studied for the OMV and Isoflurane for the PAC, because those were the agents specified for the vaporizers provided for testing. Room temperature during the bench tests was 23°C.

RESULTS

All parts of the vaporizers remained fully functional following exposure to high and low temperature extremes, shock and vibration. Results of the bench tests for each vaporizer are presented in Tables 1 and 2. As specified by the manufacturers, vaporizer output decreased as flow rate increased for the higher control settings. For a given flow rate, the output was below manufacturers' specifications for room temperature operation; however, the vaporizers had been exposed to freezing temperatures during transport to the

TABLE 1. Halothane output for the Penlon vaporizer (OMV). Tidal volume = 500 ml, f = 8, 16, 24 cycles/min.

Control Setting (% Concentration)	Measured Vaporizer Output (% Concentration)		
	4 LPM	8 LPM	12 LPM
0	0	0	0
1	0.9	0.9	0.9
2	1.9	1.8	1.7
3	2.6	2.5	2.3
4	3.5	3.4	2.6

TABLE 2. Isoflurane output for the Ohmeda vaporizer (PAC). Tidal volume = 500 ml, f = 8, 16, 24 cycles/min.

Control Setting (% Concentration)	Measured Vaporizer Output (% Concentration)		
	4 LPM	8 LPM	12 LPM
0	0	0	0
1	0.9	1.1	1.2
2	1.7	1.8	1.8
3	2.5	2.5	2.2
4	3.3	3.1	2.5

test site and the anesthetics had been refrigerated (5 to 10°C), so that the effective operating temperature was significantly lower than 23°C (estimated 10-15°C). Attempts to warm the vaporizers with the hands were moderately successful for the OMV, but not for the PAC, because the PAC's base frame prevented placement of the hands around the full circumference of the vaporizer.

DISCUSSION

To determine whether the vaporizers performed with expectations, the degree to which low operating temperature affected vaporizer output must be determined. Because anesthetic vapor pressure decreases as temperature decreases, values of concentration well below the control setting are expected at low temperatures. Low temperature data for flow conditions comparable to those studied is only available for the PAC unit, using the agent Halothane. However, since Halothane and Isoflurane have similar values of vapor pressure, heat of vaporization and specific heat throughout the temperature range of interest (Table 3), the temperature effects should be very similar for the two anesthetics.

Table 4 shows the expected values of Halothane (~ Isoflurane) output for reduced versus normal temperature. These values compare closely to the Isoflurane concentrations measured at similar flow rates in this study. The output reduction was even more pronounced at the higher flow rates studied because of the combined effects of reduced vapor pressure due to low temperature, and reduced vaporizer efficiency due to the higher velocities

TABLE 3. Properties of Halothane and Isoflurane related to temperature (Dorsch and Dorsch, 1984).

Property	Halothane	Isoflurane
Vapor pressure at 20°C (torr)	243	238
Heat of Vaporization (cal/ml, 20°C)	65	62 (25°C)

TABLE 4. Low temperature data for Halothane PAC vaporizer (Borland et al., 1983) compared to Isoflurane data from present study.
Tidal volume = 500 ml for both studies.
f = 12 cycles/min, flow rate = 6 LPM, for Halothane study.
f = 8, 16 cycles/min, flow rate = 4, 8 LPM for present study.

Control Setting (% Concentration)	Halothane Output (% Concentration) 6 LPM				Isoflurane Output (% Concentration) 4 LPM/8LPM
	5°C	10°C	15°C	20°C	~10-15°C
1	0.9	0.9	1.2	1.3	0.9/1.1
2	1.5	1.8	2.1	2.2	1.7/1.8
3	2.1	2.3	2.8	3.2	2.5/2.5
4	2.7	3.2	3.5	4.2	3.3/3.1

associated with higher flow rates.

Less temperature-induced reduction in output was evident for the OMV than for the PAC, because of the greater ability to warm the OMV with the hands (an increase of approximately 0.5 percent Halothane was observed). The results of this study compare favorably with the results of low temperature studies by Houghton (1981), once compensation is made for the differences in flow conditions between the two studies. Based on these analyses, the vaporizers performed adequately for the operating circumstances under which they were studied, and were not damaged by the environmental stresses to which they were exposed.

CONCLUSIONS AND RECOMMENDATIONS

The results of this study are not intended to provide a basis for selection of one vaporizer over the other. Since neither of the vaporizers incurred damage as a result of simulated field environmental extremes, both should be sufficiently durable for deployment by U.S. Armed Forces. A determination of which vaporizer most fully satisfies the Army's needs should be made based on physiologic, ergonomic and logistical considerations, pending successful conclusion of the clinical trials.

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ABBREVIATIONS

cal	calorie	LPM	liter per minute
cm	centimeter	min	minute
^{o}C	degrees Centigrade	ml	milliliter
f	frequency	OMV	Oxford Miniature Vaporizer
kg	kilogram	PAC	"portable, accurate, complete"

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