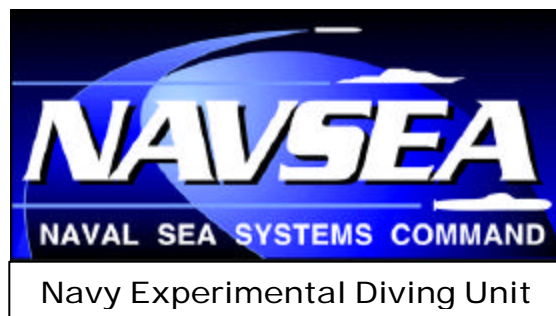


Navy Experimental Diving Unit
321 Bullfinch Rd.
Panama City, FL 32407-7015

NEDU TR 03-18
November 2003

EVALUATION OF RESPIRATORY SUPPORT DEVICES FOR USE IN THE HYPERBARIC CHAMBER



Authors: **D. F. Stanga**
HMC / SCW / DSW
Principal Investigator
G. Beck BA, RRT
Impact Instrumentation, Inc.
Associate Investigator
J. M. Chimiak
CAPT MC USN
Associate Investigator

DISTRIBUTION STATEMENT A:
Approved for public release;
distribution is unlimited.

REPORT DOCUMENTATION PAGE				
1a. REPORT SECURITY CLASSIFICATION Unclassified		1b. RESTRICTIVE MARKINGS		
2a. SECURITY CLASSIFICATION AUTHORITY		3. DISTRIBUTION/AVAILABILITY OF REPORT DISTRIBUTION STATEMENT A: Approved for public release; distribution is unlimited..		
2b. DECLASSIFICATION/DOWNGRADING AUTHORITY				
4. PERFORMING ORGANIZATION REPORT NUMBER (S) NEDU TECHNICAL REPORT No. 03-18		5. MONITORING ORGANIZATION REPORT NUMBER(S)		
6a. NAME OF PERFORMING ORGANIZATION Navy Experimental Diving Unit	6b. OFFICE SYMBOL (If Applicable)	7a. NAME OF MONITORING ORGANIZATION		
6c. ADDRESS (City, State, and ZIP Code) 321 Bullfinch Road, Panama City, FL 32407-7015		7b. ADDRESS (City, State, and Zip Code)		
8a. NAME OF FUNDING SPONSORING ORGANIZATION BUMED	8b. OFFICE SYMBOL (If Applicable) 6.4	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER		
8c. ADDRESS (City, State, and ZIP Code) 2300 E. Street N.W., Washington D.C. 20372-5300		10. SOURCE OF FUNDING NUMBERS		
		PROGRAM ELEMENT NO.	PROJECT NO.	WORK UNIT ACCESSION NO. FT00-10
11. TITLE (Include Security Classification) EVALUATION OF RESPIRATORY SUPPORT DEVICES IN THE HYPERBARIC CHAMBER				
12. PERSONAL AUTHOR(S) D. F. STANGA, HMC / SCW / DSW; G. BECK, J. .M. CHIMIAK, CAPT, MC, USN				
13a. TYPE OF REPORT TECHNICAL REPORT	13b. TIME COVERED FROM 2001-2003	14. DATE OF REPORT (Year, Month, Day) November 2003	15. PAGE COUNT 26	
16. SUPPLEMENTARY NOTATION				
17. COSATI CODES			18. SUBJECT TERMS (Continue on reverse if necessary)	
FIELD	GROUP	SUB-GROUP	hyperbaric medical equipment, ventilators, critical care capability	
19. ABSTRACT: BACKGROUND: The U.S. Navy has identified a need to improve the critical care capability in its hyperbaric chambers. Only the Penlon Oxford ventilator is certified for use in Navy chambers, but it has been out of production since the early 1980s, and its repair parts are increasingly difficult to obtain. METHOD: Performance and evaluation criteria based on military and civilian standards were established. Based on specifications supplied by manufacturers, a search for commercial off-the-shelf (COTS) mechanical ventilators was conducted to identify units that appeared to meet the evaluation requirements. Design schematics and principles of operation were reviewed to identify potential hazards and devices not in compliance with the safety requirements. Ventilators were tested at 0, 33, 66 and 165 feet of seawater (fsw) with a Michigan Instruments (Grand Rapids, MI) Model 5600i test lung with calibrated sensors and PneuView® data collection software. Measurements included peak inspiratory/expiratory flow, respiratory rate, tidal volume, and peak pressure. Oxygen was supplied with a backpressure regulator set to maintain the gas supply pressure at 50 psig greater than that of the ambient chamber. RESULTS: Four ventilators passed the safety requirements and operated at all test depths. At 165 fsw, these ventilators were able to provide a minimum inspiratory flow of 10 L/min. CONCLUSIONS: COTS ventilators can operate safely in Navy hyperbaric chambers, but safe operation is not synonymous with clinical efficacy: increasing pressures cause significant changes in ventilator performance. Ventilation during hyperbaric treatment requires attentive monitoring by personnel trained in ventilator use and respiratory assessment. To assure adequate support, close monitoring and control are particularly critical during depth excursions.				
20. DISTRIBUTION/AVAILABILITY OF ABSTRACT UNCLASSIFIED/UNLIMITED xx SAME AS RPT. DTIC USERS			21. ABSTRACT SECURITY CLASSIFICATION Unclassified	
22a. NAME OF RESPONSIBLE INDIVIDUAL NEDU Librarian	22b. TELEPHONE (Include Area Code) (850) 230-3100	22c. OFFICE SYMBOL		

CONTENTS

	<u>Page</u>
Report Documentation Page	i
Contents	ii
Introduction.....	1
Methods	1
General	1
Experimental Design and Analysis	2
Technical Information/Physical Characteristics Review.....	3
Surface and Chamber Testing	5
Procedures	6
Results	7
Discussion	21
Conclusions	22
References	23

FIGURES

Fig. 1 Chamber Test Configuration	5
Fig. 2 Ambu Matic	7
Fig. 3 AutoVent 3000	8
Fig. 4 Oxylog 2000	8
Fig. 5 Uni-Vent® Eagle Model 754.....	9
Fig. 6 Newport E100M.....	10
Fig. 7 Omni-Vent Series D.....	11
Fig. 8 Oxylator® EM-100	12
Fig. 9 paraPac Medic.....	12
Fig. 10 Multi vent	13
Fig. 11 TXP®	14
Fig. 12 RespirTech.....	15
Fig. 13 Impact Uni-Vent® Eagle Model 754 Graph.....	16
Fig. 14 Newport E100M Graph.....	17
Fig. 15 Omni-Vent Series D Graph	18
Fig. 16 Penlon Multivent Graph	19
Fig. 17 Final Unmanned Testing Graph	20

TABLES

Table 1. Settings Simulating Different Lung Pathologies	4
Table 2. Results Accuracy Validation	4

INTRODUCTION

The U.S. Navy has identified a need to increase the level of patient care and support in the hyperbaric environment; ventilators, cardiac monitors, and other ancillary equipment are being evaluated to meet this need. Two Penlon Oxford ventilators, MK 1 and MK 2 (Penlon Limited; Oxfordshire, UK) are the only devices used in U.S. Navy recompression chambers. The Penlon MK 1 uses a pneumatically driven, mechanically controlled valved bellows — a design that enables the device to be operated in a hyperbaric environment simply by maintaining a pneumatic supply pressure 50–80 pounds per square inch gauge (psig) greater than the bottom pressure. These units have been out of production since the early 1980s, and repair parts are increasingly difficult to obtain.

To meet the need for mechanical ventilation in U.S. Navy hyperbaric chambers the Navy Experimental Diving Unit (NEDU) tested a series of commercial off-the-shelf (COTS) ventilators between 2000 and 2003. Unmanned testing, including an electrical/mechanical safety evaluation, assessed the functional characteristics of the ventilators. The ventilator controls were then tested in a manned hyperbaric chamber. In addition to meeting design safety requirements, ventilators were required to achieve a minimum flow rate of 10 liters/min (L/min) at a depth of 165 feet of seawater (fsw) under various lung-loading conditions.

All ventilators tested were pneumatically powered, in that pressurized oxygen (O₂) provided the energy to move gas into the lungs. The means of controlling ventilation rate and depth (tidal volume) varied among the units. Some ventilators used mechanical means to control the flow of gas; others used microprocessors to control electromechanical components to regulate gas flow. Any inability to generate sufficient flow as gas density increased at depth eliminated most ventilators from final selection.

METHODS

GENERAL

Units were evaluated in several phases that included reviews of

1. Technical information
2. Physical characteristics
3. Surface functioning at atmospheric pressure
4. Test depth functioning

Test Equipment Requirements

- ◆ Ventilator
- ◆ Michigan Test Lung model 5600i, PneuView[®] data collection software (Grand Rapids, MI)

- ◆ Data collection computer (Dell model PPO1X Latitude)
- ◆ Through-hull penetrator to accept three 9-pin serial connectors
- ◆ NEDU treatment chamber

Training Requirements

As part of the surface testing, familiarization with both the ventilator and the test lung was completed before chamber testing began. Consequently, the test equipment operator was familiar with the ventilators and was proficient in adjusting the controls to achieve proper breathing rate and minute volume required for each test condition.

EXPERIMENTAL DESIGN AND ANALYSIS

A search of military and civilian organizations was conducted to identify standards applicable to the operation of ventilators in a hyperbaric chamber. NAVSEA SS800-AG-MAN-010/P-9290 defines operational standards for U.S. Navy hyperbaric chambers.¹ The National Fire Protection Association's *NFPA 99 Health Care Facilities* provides standards for electronic devices to be used in O₂-enriched environments,² standards that include specific current flow characteristics for operating medical devices in such environments. The test criteria from the NAVSEA SS800-AG-MAN-010/P-9290 sets test criteria for critical care ventilators and provides adult test criteria to benchmark testing and compare performances of the ventilators at various test depths.

A broad search of the market was conducted to identify potential ventilators to meet the needs of the hyperbaric chamber environment. This search included but was not limited to contacts with anesthesiologists and respiratory therapists having hyperbaric experience and knowledge, hyperbaric facilities treating a significant number of critical cases, medical officers and doctors working in the hyperbaric field, and medical equipment manufacturers. These sources were questioned as to ventilators and respiratory support equipment they felt showed promise for hyperbaric application. Areas for consideration included size constraints, since space inside most chambers is very limited and power needs, since all units had to be battery or pneumatically powered. If the units were battery powered, their batteries had to pass safety testing as established by NEDU test procedure 01-23.³

The search identified 11 COTS ventilators that appeared to offer the required clinical functioning and to meet design safety standards needed for hyperbaric operation.

The ventilator manufacturers were contacted and asked to provide technical documentation of products and sample products for review and testing. Most of the units were pneumatically powered; pneumatically or microprocessor controlled; pressure, time, or manually triggered; pressure or time cycled; and pressure, volume, or flow limited, with time-limited demand flow and continuous flow for spontaneous breathing. Most were capable of ventilating infant- through adult-age patients.

TECHNICAL INFORMATION/PHYSICAL CHARACTERISTICS REVIEW

All ventilators were evaluated for safety per Naval Sea Systems Command (NAVSEA) and National Fire Protection Association (NFPA) standards for hyperbaric medical devices. These evaluations included reviews of electrical and mechanical schematics provided by the manufacturer as well as bench reviews of ventilator exteriors and interiors to identify sparking electrical components and systems susceptible to crushing, particularly systems with electrolytic capacitors of a size that makes them susceptible to crushing. Each unit was opened and visually inspected. Any discrepancies between the technical information provided and the physical features examined or any other concerns were directed to the manufacturers, who were afforded opportunities to modify their devices and resubmit them for review and potential chamber testing.

Some of the ventilators contained internal, sealed, jelly-filled lead acid batteries that were tested separately according to NAVSEA SS800-AG-MAN-010/P-9290, NFPA 99, and NEDU Test Plan 01-23 standards.^{1,2,3} A few ventilators were pneumatically powered and controlled and therefore required no additional power source.

Following bench and battery testing, the units were reassembled and pressurized to 220 fsw for one hour. After the exposure, the ventilators were again disassembled and internal components inspected. Ventilators were then operated at the surface to ensure that they still functioned normally.

Once NEDU engineers were satisfied that the ventilators were safe and functional, the devices underwent a series of tests in the NEDU Treatment Chamber at 30, 60, and 165 fsw — the various depths used for hyperbaric treatment with U.S. Navy treatment tables.

TEST LUNG: A Michigan Instruments (Grand Rapids, MI) Model 5600i test lung was used to simulate the patient. Michigan Instruments PneuView[®] software was used to collect, store, and analyze data from the test lung. Various pulmonary resistance and compliance settings were used to simulate patients with different lung pathologies (see Table 1). To assure accurate measurement of volume at depth, a calibration syringe was used to test the accuracy of the test lung/PneuView system, and a U-manometer was used to verify the accuracy of the pressure recording. The proximal air pressure of the test lung, filled with 1.5 liters of gas from a calibrated syringe, was measured with the U-manometer via the proximal airway pressure port, and the readings were compared to those recorded on the data acquisition computer. This procedure was repeated at the surface and at 30, 60, and 165 fsw. Results of the accuracy validation are shown in Table 2.

Table 1. Test conditions

Test	Resistance cm water (L/min)	Compliance L/cm H ₂ O	Frequency range [breaths/min (BPM)]	Minute Volume L/min
1	20	0.05	8–12	6
2	20	0.05	8–12	10
3	50	0.05	8–12	6
4	50	0.05	8–12	10
5	50	0.05	15–20	6
6	50	0.05	15–20	10
7	20	0.05	15–20	6
8	20	0.05	15–20	10

Table 2.

Volume measurements of test lung as compared to calibrated syringe

Actual Volume from Calibrated Syringe	0 fsw	30 fsw	60 fsw	165 fsw
500 mL	500 mL	538 mL	516 mL	503 mL
1000 mL	810 mL	1051 mL	1034 mL	1091 mL
1500 mL	1544 mL	1530 mL	1471 mL	1525 mL

Pressure measurements of test lung as compared to U-manometer

Depth (fsw)	0	0	0	30	30	30	60	60	60	165	165	165
Manometer cmH ₂ O	21.5	22.0	21.5	22.0	22.0	22.0	22.5	22.5	22.5	23.0	23.0	23.0
Computer cmH ₂ O	21.5	21.5	21.4	22.5	22.2	22.2	22.9	22.5	22.5	23.4	23.1	24.0

During chamber testing, the test lung was located inside the chamber and attached to the ventilator (Figure 1). Serial data from the test lung was passed through an electrical penetration to the Dell Latitude Pentium 4 Model PBO1X laptop used for data collection. Based on parameters shown in Table 1, resistance and compliance were changed by the inside attendant.

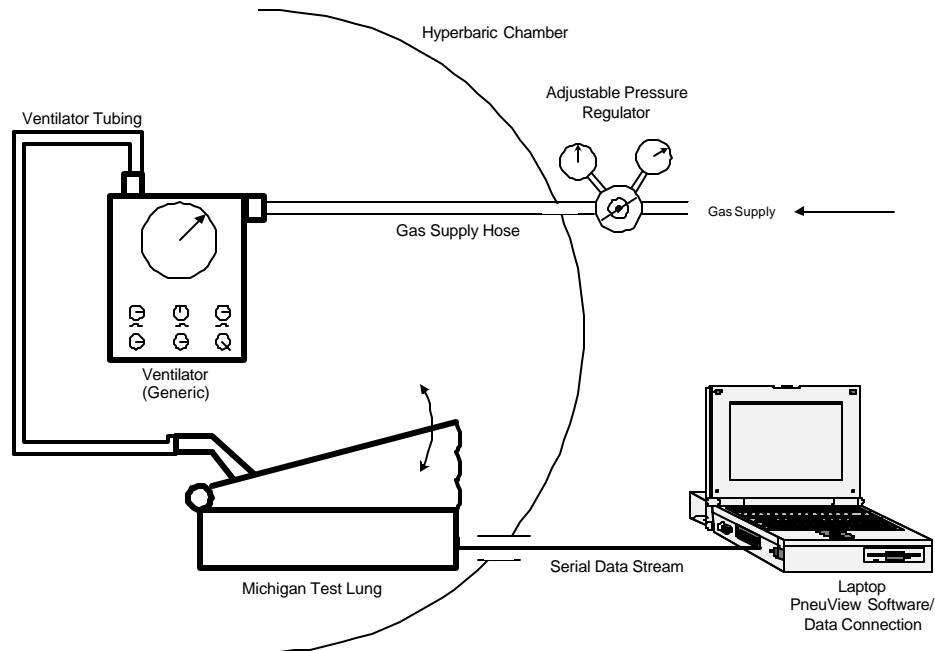


Figure 1. Chamber Test Configuration

SURFACE AND CHAMBER TESTING

Testing was conducted both on the surface and at various depths in NEDU hyperbaric chambers. Attached to a Michigan test lung, the ventilators were operated through the series of tests listed in Table 1. The test lung monitored and recorded the following parameters:

- Baseline pressure
- Average proximal pressure
- Peak proximal pressure
- Average lung pressure
- Peak lung pressure
- Peak tidal volume
- Tidal volume
- Minute volume
- Average inspiratory flow
- Peak inspiratory flow
- Average expiratory flow
- Peak expiratory flow
- Inspiratory time
- Inspiratory hold time
- Expiratory time
- Expiratory ratio
- Breathing rate (br)

For each test condition, the ventilator rate, inspiratory pressure, inspiratory flow, and tidal volume were adjusted to attain the desired breathing frequency and minute ventilation. The ventilator in the test configuration then operated for five minutes, while readings were taken by the PneuView[®] software every 15 seconds. Because not all the ventilators had controls with quantitative scales, approximate ventilator settings required to complete each test condition were noted. This testing time was also used to familiarize the inside tenders with the operational characteristics of each ventilator.

PROCEDURES

Test Procedure

1. On the surface, the ventilator and test lung were configured for one of the test conditions (Table 1).
2. Units were attached to the Michigan test lung and operated on the surface (Figure 1).
3. The NEDU treatment chamber was pressurized to test depths (30, 60, and 165 fsw).
4. At depth, the ventilator was adjusted to achieve the required breathing frequency and minute volume.
5. Ventilator control settings were recorded.
6. Data was collected with the PneuView[®] software for 5 minutes.
7. A data snapshot that shows pressure/volume vs. time tracing was collected.
8. The test lung was then set to the next test condition, and the ventilator was adjusted as required.
9. Steps 4–8 were repeated as required.
10. Descent was made to next test depth or surface.

Unmanned Chamber Testing

Following manned testing to demonstrate the ability of each ventilator, when manipulated by an inside attendant, to deliver the required minute volume and respiratory rate, additional unmanned testing was performed on ventilators that had successfully completed all previous tests. For the unmanned trials, the ventilator and test lung were set up following the ASTM standards for testing critical care ventilators.⁴ These settings included a respiratory rate of 20, a tidal volume of 500 mL, and an inspiratory time of 1.0 seconds. The test lung was set with a compliance of 50 mL/cm H₂O and a resistance of 20 cm of water per liter per second. Each ventilator was configured as shown in Figure 1, and the settings were verified with the PneuView[®] output. Each ventilator was then compressed to 30, 60, 90, and 165 fsw.

RESULTS

Test results from and evaluations of transport ventilators include descriptions of each device. Following these descriptions are sections that provide details about the performance of the four ventilators that met all testing requirements.

Ventilator Overviews

Ambu Matic (Ambu, Inc.; Linthicum, MD)

The Ambu Matic emergency and transport ventilator (Figure 2) is a pneumatically powered, pneumatically controlled, time-cycled volume ventilator designed for automatic ventilation of patients weighing more than 15 kg (33 lb). It requires a breathing gas supply source (usually O₂ at 39 to 94 psig). A single control lever regulates both tidal volume and respiratory rate. Its minimum setting is 4 L/min, with a tidal volume of 200 mL, and its maximum setting is 14 L/min, with a tidal volume of 1200 mL. The Mark III patient valve can be operated with or without an adjustable positive end-expiratory pressure (PEEP) valve. The unit has a built-in pressure-limiting valve set at 60 cm H₂O with an audible pneumatically driven alarm.



Figure 2. Ambu Matic

Test Results. The Ambu Matic ventilator performed satisfactorily at the surface during tests 1–3. Because the breathing rate and tidal volume are set with a single control, the unit could not be adjusted to achieve the other test parameters. The Ambu Matic was operated in the chamber at 30 fsw but was unable to achieve sufficient minute volume at any setting. Its testing was aborted at 30 fsw.

AutoVent 3000 (Allied Healthcare Products, Inc.; St. Louis, MO)

The AutoVent 3000 (Figure 3) is a time-cycled, constant-flow, gas-powered emergency and transport ventilator that can deliver between 200 and 1200 mL tidal volume at rates from 8 to 20 breaths per minute (BPM) and with flows up to 36 L/min. Tidal volume and breath rate are controlled independently. Inspiratory time can be set either to an adult level, with a 2-second inspiratory time, or a child level, with a 1-second inspiratory time. The ventilator requires a gas source, usually O₂, from 40 to 60 psig. The patient valve allows for spontaneous breathing with inspiratory efforts of –2 cm H₂O and has an

audible, pneumatically driven alarm to indicate when airway pressure exceeds 60 cm H₂O.



Figure 3. AutoVent 3000

Test Results. The ventilator performed well on the surface but was unable to achieve 10 L/min flow during tests 2 and 4 at 30 fsw. When compressed to 60 fsw, the device achieved a 5.41 L/min maximum flow rate, with a tidal volume of 349 mL. Its testing was aborted at 60 fsw.

Oxylog 2000 (Dräger Medical, Inc.; Telford, PA)

The Oxylog 2000 (Figure 4) is a time-cycled, pneumatically powered, electrically controlled volume constant transport and emergency ventilator. It is capable of controlled mandatory ventilation (CMV), synchronized intermittent mandatory ventilation (SIMV), and continuous positive airway pressure (CPAP), and it has built-in PEEP control. The unit is capable of variable inspiration-expiration (I:E) ratios and can deliver breathing gas at rates between 1 and 40 BPM and tidal volumes from 0.5 to 1.5 liters. The Oxylog contains an internal rechargeable nicad battery that powers the unit for up to 6 hours. A gas supply source, usually O₂ between 38 and 84 psig, is required. A selector switch and air entrainment system can deliver a breathing gas air balance of 100% or 60% O₂.



Figure 4. Oxylog 2000

Test Results. During bench testing the Oxylog was found to have capacitors that posed a risk of failure under pressure. The unit's nicad batteries would have been tested under the same test plan as those lead acid batteries used in other ventilators, but when Dräger, the manufacturer, was informed of this plan, it chose not to develop a modification. No further testing was conducted.

Uni-Vent® Eagle™ Model 754 (Impact Instrumentation, Inc.; West Caldwell, NJ)

The Impact Uni-Vent® Eagle™ Model 754 (Figure 5) is powered either externally by 95–240 volts alternating current (VAC), 50–400 hertz (Hz), or internally by a rechargeable 12-volt, sealed gel lead acid battery. Breathing gas can come from the electrically powered internal compressor, from pneumatically powered external pressurized O₂ and air, or from a combination of external O₂ with air from the compressor. An internal mixer blends O₂ with either air source to provide 21–100% O₂. The internal battery and compressor allows 4 hours of autonomous operation. The microprocessor continuously monitors and displays airway pressures, control settings, alarm parameters, gas mixtures, and power signals. The unit can operate in assist/control ventilation (ACV), SIMV, and CPAP with or without PEEP. Model 754 is certified to MIL-STD 810F for shock, vibration, environmental exposure, and electromagnetic compatibility. It has aeromedical certification for fixed- and rotary-wing aircraft and is part of the Department of Defense (DoD) Patient Movement Items (PMI) system.



Figure 5. Uni-Vent® Eagle™ Model 754

Test Results. Performance of the Eagle Model 754 on the surface was acceptable under all test conditions. The ventilator completed all eight tests at 30, 60, and 165 fsw and was able to deliver the required rates and volumes with only minor adjustments. Very high proximal airway pressures were observed at 165 fsw, particularly on tests 4 and 6. Due to these high pressures, the airway pressure alarms had to be reset to maximum. The Eagle, an electrically controlled ventilator, requires a battery for its operation. Testing determined that a new, fully charged battery provided approximately 6–7 hours of operation when built-in breathing system (BIBS) gas at 75 psig is used. When the onboard compressor was operated to provide gas to the patient, the operating time was cut to 4 hours or less, depending on the patient settings. Though

the compressor was operated while the unit was on the surface. The compressor was not operated in the chamber. The unit was found to be acceptable.

E100M (Newport Medical Instruments; Newport Beach, CA)

The Newport E100M (Figure 6) is a pneumatically powered, microprocessor-controlled, manual-, pressure-, or time-triggered, time-cycled, flow- or pressure-limited ventilator, with time-limited demand flow and continuous flow for spontaneous breathing. It is capable of ventilating infant through adult patients. Power is provided by 110 VAC or an internal, sealed, jelly-filled lead acid battery that powers the ventilator for approximately 6 to 8 hours; to extend this operation time, an external battery can be attached. Two inlet lines supply gases at pressures from 30 to 80 psig to the ventilator. Both air and O₂ are required for the unit to operate. The unit is configured to operate with one hose attached to an oxygen source and one hose attached to an air source, but both hoses may be attached to oxygen if that is necessary. The unit provides ACV and SIMV with or without PEEP.



Figure 6. Newport E100M

Test Results. Performance of the E100M on the surface was acceptable at all test conditions. Since the ventilator requires both pressurized air and O₂ to operate, some initial setup difficulties resulted. Oxygen was supplied to both gas inlets, and the mixing unit on the ventilator's inlet portion was designed with a small (less than 8 L/min) but constant bleed of supply gas into the chamber. Therefore, periodic ventilation of the chamber is required to prevent an unacceptable O₂ concentration/partial pressure. Although the E100M — a large, hospital-based unit — is not well suited for transport, it was found to operate well throughout all tests at all depths, but it required moderate adjustments at the different depths. The unit was found to be acceptable.

Omni-Vent Series D (Allied Health Care Product, Inc.; St. Louis, MO)

The Omni-Vent Series D (Figure 7) — a small, portable, gas-powered, time-cycled, volume-constant ventilator — is capable of continuous flow, intermittent or mandatory ventilation (IMV; controlled breaths not synchronized with patient effort as in SIMV), CPAP, PEEP can be set from 0 to 50 cm H₂O, inverse I:E ratios can be set if required. It can deliver breathing gas at rates from 1 to 150 BPM and at tidal volumes up to 1.5 liters. The Omni-Vent can deliver inspiratory flow rates between 0 and 80 L/min, and it supplies gas, usually 100% O₂, at pressure ranges from 25 to 140 psig. The Omni-Vent is certified to MIL-STD 810F for shock, vibration, and environmental exposure.



Figure 7. Omni-Vent Series D

Test Results. Omni-Vent performance on the surface was acceptable at all test conditions. At 30 and 60 fsw, the unit was able to function at all of the test conditions. It was difficult to adjust, however: small adjustments to the inspiratory or expiratory times produced large changes in breathing rates, but all tests were completed. At 165 fsw, only tests 2 and 8 were completed, because the difficulties in setting breathing rates and the time constraints at depth prevented the ventilator from being set to the desired parameters. The two tests completed were those that required the highest performance from the ventilator. The unit did achieve well over the established minimum flow of 10 L/min at all depths, and its performance was found to be acceptable.

Oxylator[®] EM-100 (Lifesaving Systems, Inc.; Roswell, GA)

The Oxylator[®] (Figure 8) is an O₂-powered resuscitator/inhalator that requires a gas supply of 45–80 psig to provide respiratory minute volume (RMV) rates up to 15 L/min. The unit can be operated in one of four modes: manual cycling by the operator, manual cycling with PEEP, continuous cycling with PEEP for nonbreathing patients, and spontaneous cycling, which allows spontaneously breathing patients to determine the respiratory pattern. The continuous cycle mode is driven by airway pressure. The manual button initiates the first breath, filling the lungs until the desired airway pressure is reached. Maximum airway pressure is set on the rotating dial on the body of the EM-100. The pressure range is 25 to 50 cm H₂O. When the manual button is released, the patient is allowed to exhale until exhalation pressure drops to 2 to 4 cm H₂O at which

time the next inhalation begins. The unit continues to deliver the next breath until the set airway pressure is achieved.



Figure 8. Oxylator[®] EM-100

Test Result. Because the Oxylator is designed with a single rotating dial to adjust both rate and volume, we were unable to set the unit to any of the test parameters. At the surface, a 10 L/min flow was achieved. At a depth of 30 fsw, 10 L/min was not attained at any setting. No further testing was conducted beyond 30 fsw.

paraPAC Medic (Pneupac; Waukesha, WI)

The Medic (Figure 9) is a pneumatically powered and controlled, time- or hand-triggered, time-cycled, flow- and pressure-limited ventilator with demand flow for spontaneous breathing. It is capable of ventilating infant through adult patients. The unit can operate at rates from 8 to 40 BPM, with inspiratory and expiratory times adjusted automatically with the rates. Tidal volume can be set between 200 and 1500 mL. The maximum airway pressure relief and alarm can be set between 20 and 80 cm H₂O. The unit can deliver 100% O₂ or 50% O₂ by mixing its delivery with entrained ambient air.



Figure 9. paraPAC Medic

Test Results. While the paraPAC Medic was able to achieve acceptable flow rates on the surface, when the ventilator was compressed to 30 fsw it could generate flows of only 8 L/min at any setting. Testing was aborted at 30 fsw.

Multivent (Penlon Limited; Abingdon, Oxfordshire UK)

The Penlon Multivent (Figure 10) is a pneumatically powered, electronically controlled unit designed for mechanical ventilation of patients with body weights greater than 77 pounds. Not readily transportable, it operates with a gas-driven bellows that can be set to deliver tidal volumes between 0.1 and 1.2 liters at rates between 5 and 35 BPM. The driving gas supply requirement is 20–100 psig. The driving and the breathing gas circuits are separate, but exhausted driving gas may be recirculated to the breathing circuit if that is desired. Breathing gas from a pressurized or an ambient source is drawn in through the bellows, which the pneumatic drive circuit controls. This system's advantage in the hyperbaric environment is that it is unaffected by changes in ambient pressure, as long as the driving gas differential is maintained. A sliding weight along the arm above the bellows controls inspiratory pressure to a maximum setting of 50 cm H₂O. The Multivent is capable of variable I:E ratios, and its internal rechargeable battery can operate for up to 100 hours on a single charge.



Figure 10. Multivent

Test Results. The Multivent has a design similar to that of the Penlon Oxford, which has been used in hyperbaric chambers since the 1970s.⁵ The Multivent was able to complete all tests at the surface and at all depths with little to no change in performance. The drawback for the Multivent, as for the Oxford, is that it requires a gas source to drive the ventilator and a gas source for its breathing circuit. In addition, the unit is large, heavy, and therefore difficult to handle in the confines of the chamber. The largest concern is that, because it is not manufactured or used in the United States, the Multivent has not been cleared by the U.S. Food and Drug Administration (FDA) and so cannot be used by hyperbaric facilities in the United States. It is unclear at this time whether the manufacturer will seek FDA approval.

TXP[®] (Percussionaire[®] Corporation; Sandpoint, ID)

The TXP[®] (Figure 11) is a pneumatically powered and controlled, time- or hand-triggered, time-cycled, flow- or pressure-limited ventilator with demand flow and continuous flow for spontaneous breathing. Capable of ventilating infants through adults, the unit provides breathing rates from 6 to 250 cycles per minute, with I:E ratios from 1:1 through 1:5 at low frequencies. Delivered tidal volumes range from 5 to 1500 mL, with peak inspired pressures varying from 5 to 100 cm H₂O. Independent manual

push buttons allow unlimited selection of both inspiratory and expiratory hold functions. The unit is capable of ACV with or without PEEP. The TXP also allows high frequency ventilation.

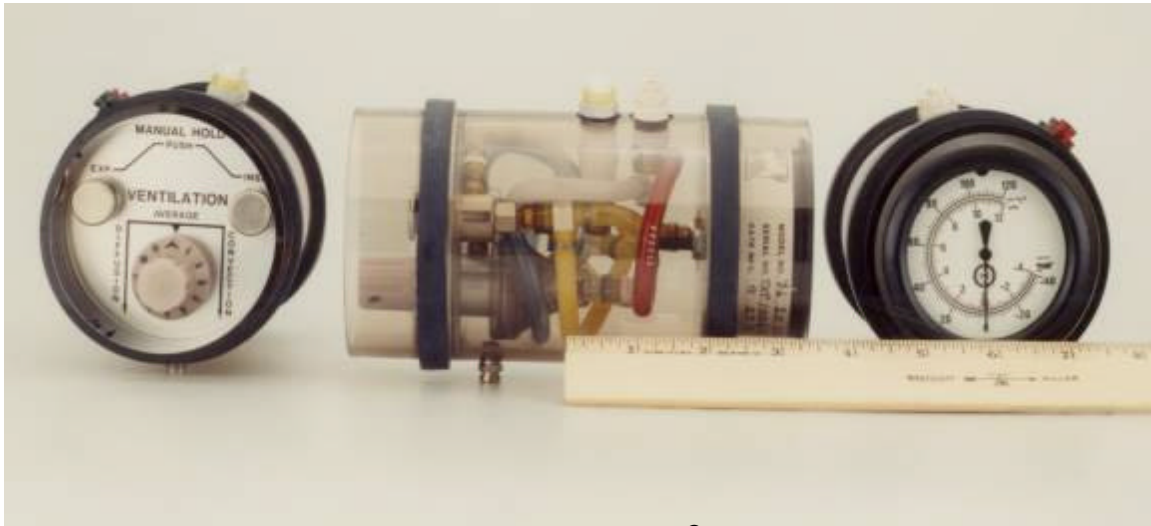


Figure 11. TXP®

Test Results. The manufacturer was unable to provide operating and service manuals for the TXP assembly and operation. Therefore the unit was not evaluated in this series of tests. NEDU still maintains one of these units and hopes to evaluate it in the future.

RespirTech (Vortan Medical Technologies 1, Inc.; Sacramento, CA)

The RespirTech (Figure 12) is a single-use, disposable automatic resuscitator that uses constant flow, pressure-cycled ventilatory support in either pressure control or pressure support modes of operation. The device includes a pulmonary modulator (an exhalation valve that opens at peak inspiratory pressure (PIP) and closes at PEEP) and can provide ventilation rates from 8 to 20 BPM. It can achieve an 8-L/min ventilation when it is set to peak flow at 40 L/min. Automatically set at 10% of peak pressure, the unit is pressure cycled between 20 and 50 cm H₂O and can maintain PEEP between 2 and 5 cm H₂O. RespirTech requires a constant supply pressure (usually of O₂) of 50 psig.



Figure 12. RespirTech

Test Results. This small disposable unit was designed to operate by maintaining a constant positive airway pressure: when the patient is not inhaling, breathing gas is vented to the atmosphere. Periodic chamber ventilations are required to avoid increased concentration/partial pressures of O₂ in the chamber atmosphere. Breathing rate and volume are regulated by airway pressure. Although we were unable to set any of the specific test parameters on the unit, we were able to achieve a flow of 10 L/min. At 30 fsw the respirator was unable to produce adequate flow, primarily because of the size of the unit's supply hose. In addition, the airway pressure settings could not be set at depth. Testing was not continued beyond a level of 30 fsw.

Detailed Performance Data

Data from the four commercially available ventilators that met all test requirements are presented along with reviewer comments.

Impact Uni-Vent[®] Eagle[™] Model 754

Since the Eagle[™] measures atmospheric pressure and resets the reference pressure every 5 minutes, the device compensates for increased ambient pressure by maintaining the preset tidal volume. This unit therefore requires less adjustment than other ventilators to maintain a desired tidal volume at different depths. Rate was unaffected by changes in test depth, but flow and tidal volume had to be increased at

the different depths. The unit completed all tests at all depths. Figure 13 illustrates the actual flow rates achieved at the given test setting for each test depth. The values of the flow rates are the average flow based on a 5-minute trend of data collected at a rate of 4 data sets per minute.

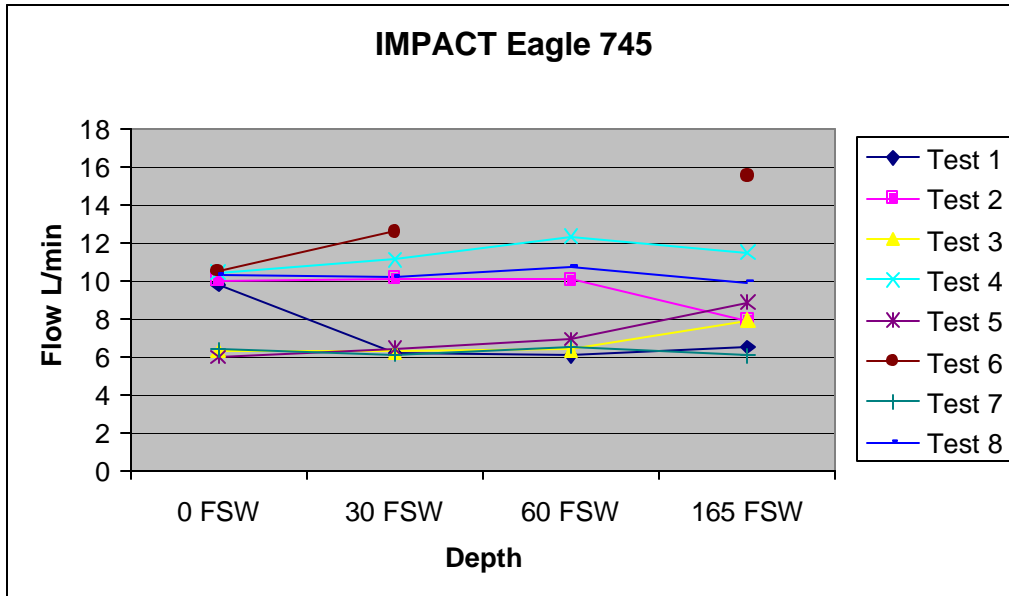


Figure 13. Average flow rate at selected depths for the eight test conditions

Newport E100M

The Newport E100M performed well at all depths. The breathing rate did not need to be adjusted at any test depth; flow needed to be increased slightly at 30 fsw and increased approximately 50% at 60 fsw. At 165 fsw, I:E required adjustment, and flow required a significant increase to maintain test settings. The unit completed all tests at all depths. Figure 14 illustrates actual flow rates achieved at the given test setting for each test depth. The values of the flow rates are the average flow based on a 5-minute trend of data collected at a rate of 4 data sets per minute.

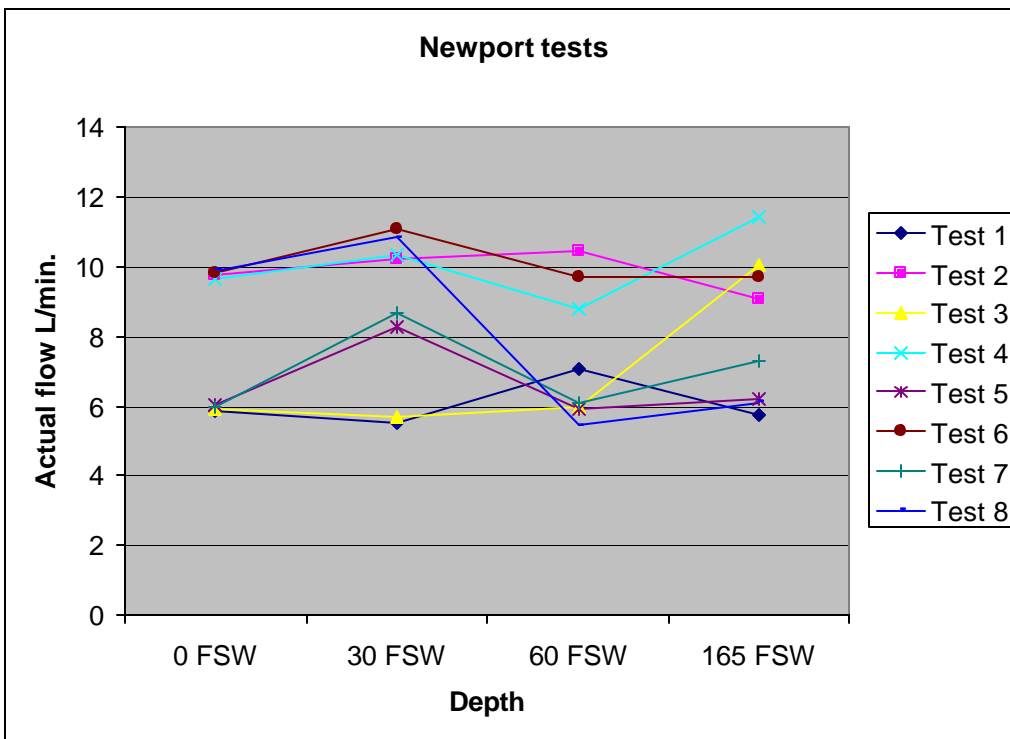


Figure 14. Average flow rate at selected depths for the eight test conditions

Omni-Vent Series D

The Omni-Vent required extensive adjustments at all depths. Its flow setting was increased more than 50% at 30 fsw and was set to maximum at 60 fsw. Flows and rates had to be controlled with the I:E ratio, and such successful control required considerable practice. Controls for inspiratory and expiratory times became very sensitive as depth increased: very small adjustments resulted in large changes in rates and minute volumes. At 165 fsw the Omni-Vent was able to achieve 10 L/min on two tests, 2 and 8. Figure 15 illustrates the actual flow rates achieved at the given test setting for each test depth. The values of the flow rates are the average flow based on a 5-minute trend of data collected at a rate of 4 data sets per minute.

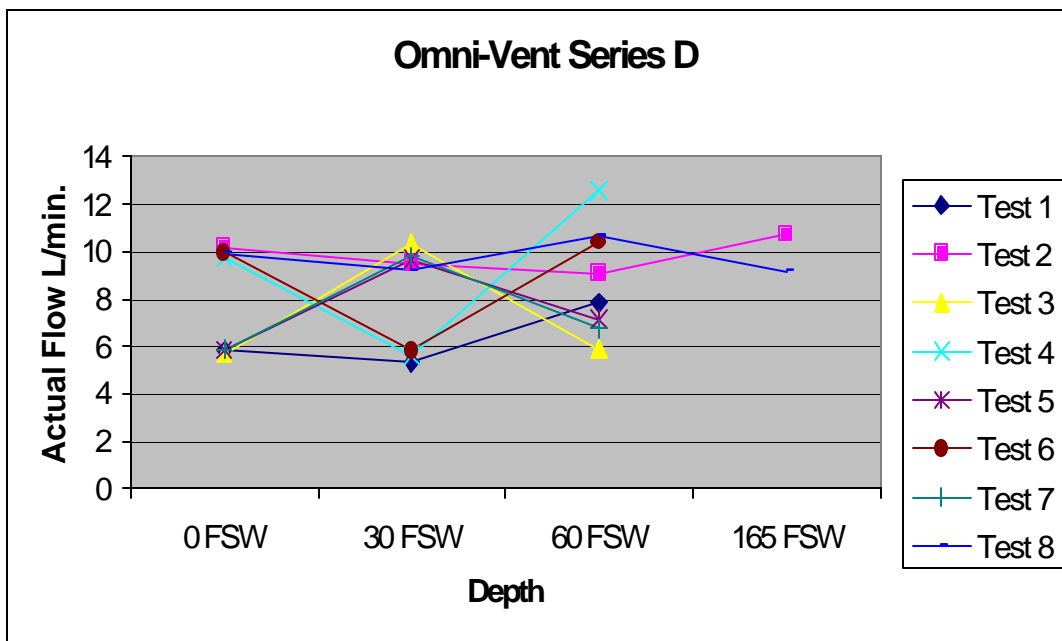


Figure 15. Average flow rate at selected depths for the eight test conditions

Penlon Multivent

The Multivent was virtually unaffected by changes in ambient pressure, provided the supply pressure to the driving gas circuit was maintained. No test data was collected on the surface. Figure 16 illustrates the actual flow rates achieved at the given test setting for each test depth. The values of the flow rates are the average flow based on a 5-minute trend of data collected at a rate of 4 data sets per minute. Due to the manufacturer's time constraints, the unit had to be returned before testing was completed.

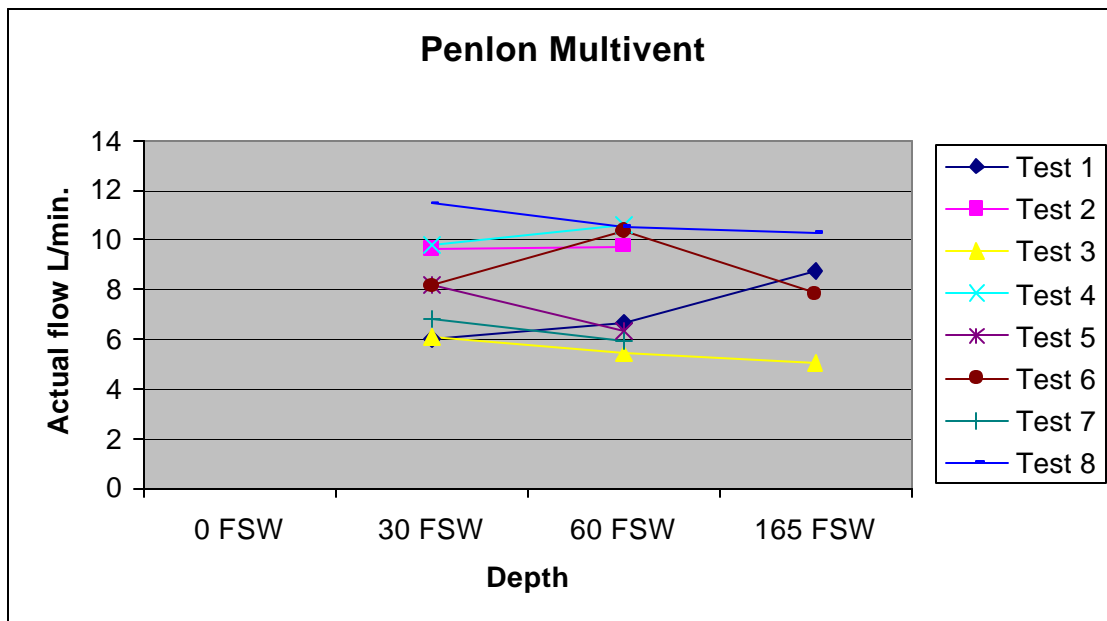


Figure 16. Average flow rate at selected depths for the eight test conditions

Final Unmanned Testing

Each of the four ventilators was configured at the surface and tested at 30, 60, 90, and 165 fsw. Decrements in their resulting tidal volumes in relation to these depths are shown in Figure 17.

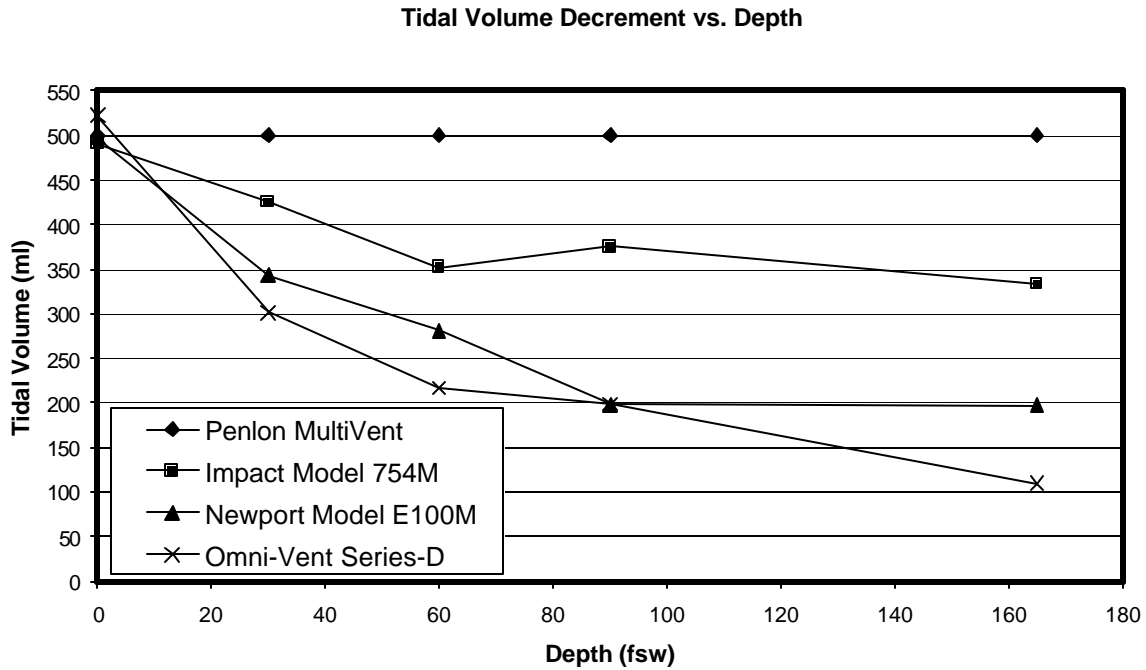


Figure 17. Tidal Volume Decrement at fixed settings through selected depths

DISCUSSION

Using mechanical ventilators in Navy hyperbaric chambers to meet increased needs for critical care support significantly increases the logistic overhead associated with hyperbaric therapy. Using the successful candidate devices to treat casualties at depth remains the responsibility of local medical and command authorities.

Ventilation at depth is fundamentally affected by the increase in ambient pressure and resultant increase in gas density. The flow of gas in and out of the lung is slowed as gas density increases. Similarly, of all the ventilators studied (none of which were designed for hyperbaric use), all but the Penlon Multivent showed some decreases in performance or had designs and components that were found to be incompatible with safe operation at depth.

The pneumatically powered and controlled units — e.g., the AutoVent 3000, Omni-Vent Series D, Newport E100M, paraPAC, TXP[®], and RespirTech — tended to have the most difficulty. All but the Omni-Vent lacked a sufficient inspiratory flow range to meet the test criteria at depths greater than 30–60 fsw. Of additional concern in the transport class ventilator is the lack of alarms, specifically for patient disconnection. While most ventilators do limit peak inspiratory pressure and may provide an audible alarm in the event of excessive airway pressure, the lack of a patient disconnect alarm places a continuous responsibility on the inside attendant to ensure that the ventilator remains connected to the patient and that it is cycling properly.

At depths greater than 60 fsw, the Omni-Vent demonstrated a tendency to increase the respiratory rate. Its operator therefore needed continuous diligence to maintain the breathing rate and minute volume. Blanch et al, who previously described this situation, speculate that the observed changes in breathing rate result from alterations in drive pressure that occur in the expiratory and inspiratory valves.⁶ They add that although an inside attendant might restore tidal volume and other parameters, such readjustments are not always successful — particularly at depths greater than 60 fsw. In addition, continuous monitoring and adjustment of the ventilator may hinder an attendant from performing other duties necessary to manage the patient. A positive feature is the Omni-Vent's small size, which allows it to be readily stowed.

The inherent design of pneumatically powered, electronically controlled ventilators presents an additional safety risk when they are used in hyperbaric chambers. Of the eleven ventilators evaluated, the three electronically controlled units — Dräger Oxylog 2000, Impact Uni-Vent[®] Eagle[™] Model 754, and Newport E100M — contain components that required consultation with the manufacturers. The Dräger had one switch and several capacitors that were of concern. After NEDU investigators contacted the manufacturer, Dräger opted to withdraw the Oxylog 2000 from consideration. The Impact 754 had several capacitors and switches that were of concern, but the manufacturer replaced these components with solid-state capacitors and switches. Following these modifications, testing continued. The Newport was found to have a few capacitors that were close to the maximum physical size. After NEDU investigators

discussed these with the manufacturer, the capacitors in question were determined not to directly affect the function of the ventilator, and testing proceeded.

Both the Impact and Newport units were able to meet all test criteria at all depths. In addition to the quality of their performance, these units provide a range of patient monitoring alarms to alert the attendant to abnormal conditions and thereby enhance the safety of operations at depth.

Except for the Penlon Multi-vent, all of the ventilators tested are time- and/or volume-cycled and thus are significantly affected by pressure changes. Ease of operation is also a major consideration, because Navy personnel charged with actually operating the ventilators will most likely be Diving Medical Technicians with little training in respiratory equipment.

Early in the testing, high peak proximal airway pressure (P_{AW}) on tests requiring high ventilation rates resulted at depths of 60 fsw and greater. Discussions among the investigators, outside experts, and Michigan Instruments technical staff determined that the fixed resistance orifice was generating abnormally high peak proximal P_{AW} secondary to changes in gas density at increased pressure. Several options to address this problem were discussed.

The calibrated orifice represented the resistance of the upper airway. A mechanically ventilated patient would most likely be intubated: an endotracheal tube therefore would be in the upper airway. Accordingly, the calibrated orifice was replaced with a 7.5 mm endotracheal tube. Tests 1, 2, 7, and 8 were then repeated with all the ventilators, and the problems with increased proximal airway pressures were resolved.

CONCLUSIONS

Testing in the recompression chamber at the various depths showed that four ventilators were able to achieve the minimum flow requirement at all the treatment depths. Performance details, along with some of each unit's characteristic features, for all the ventilators tested at various depths can be compared in the charts provided (see **RESULTS**, Ventilator Overviews).

REFERENCES

1. Naval Sea Systems Command, *U.S. Navy Diving and Manned Hyperbaric System Safety Certification Manual*, Publication SS800-AG-MAN-010/P-9290 (Arlington, DC: NAVSEA, 1998).
2. National Fire Protection Association, *NFPA 99 Health Care Facilities* (Quincey, MA: NFPA, 2002).
3. R. R. Lowe, D. F. Stanga, and G. Conley, *Unmanned Evaluation of Batteries for Use in Hyperbaric Chambers*, NEDU TP 01-23, Navy Experimental Diving Unit, November 2001.
4. American Society of Testing Materials, *Annual Book of ASTM Standards*, F1100–90 (West Conshohocken, PA: ASTM International, 1990; reapproved, 1996).
5. A. M. Saywood, R. Howard, R. F. Goad, and C. Scott, "Function of the Oxford Ventilator at High Pressure," *Anesthesia*, Vol. 37 (1982), pp. 740–744.
6. P. B. Blanch, D. A. Desautels, and T. J. Gallagher, "Deviations in Function of Mechanical Ventilators during Hyperbaric Compression," *Respir Care*, Vol. 36 (1991), pp. 803–814.