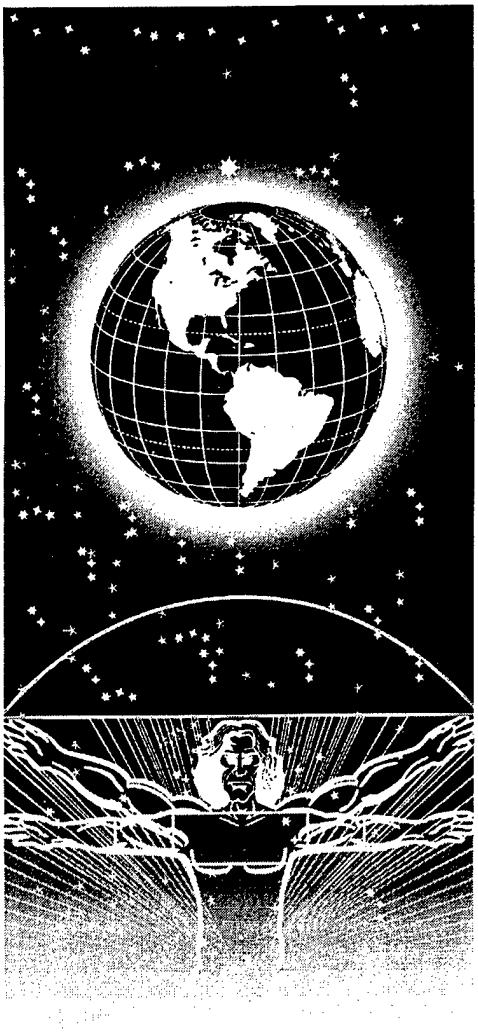
AFRL-HE-BR-TR-2000-0030



UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE VITAL SIGNS, INC., MODELS: VITAL BLUE (ADULT) & CODE BLUE (ADULT), PEDI BLUE (CHILD), AND BABY BLUE (INFANT) MANUAL RESUSCITATORS

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February 2000

NOTICES

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	February 2000	Final, March 1999

4. TITLE AND SUBTITLE

Testing and Evaluation of the Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators.

5.FUNDING NUMBERS

PE: 62202F
PR: 7184
TA: 56
WU: 01

6. AUTHOR(S)

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8. PERFORMING ORGANIZATION REPORT NUMBER

AFRL-HE-BR-TR-2000-0030

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release; distribution unlimited.

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 words)

The Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators are hand held lightweight, manual resuscitators. The units provide clinicians a way to maintain ventilatory support for patients with life-threatening airway disorders. The units operate by manually squeezing the plastic reservoir bag to create a positive airflow to expand the patient's lungs.

14. SUBJECT TERMS

Vital Signs	manual	resuscitator
Ambu	aeromedical	
Airworthy	aircraft	

15. NUMBER OF PAGES

12

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	UL

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TESTING AND EVALUATION OF THE VITAL SIGNS, INC., MODELS VITAL BLUE (ADULT) & CODE BLUE (ADULT), PEDI BLUE (CHILD), AND BABY BLUE (INFANT) MANUAL RESUSCITATORS

BACKGROUND

Headquarters Air Mobility Command (AMC) requested the Air Force Medical Equipment Development Laboratory's (AFMEDL) participation in evaluating and approving the Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators for use on board USAF aeromedical evacuation aircraft. Specific components of the manual resuscitators that under went the evaluation process included the oxygen tubing, reservoir tubing, bag, pressure relief cap, pressure relief valve, valve assembly, swivel flange/ elbow, duck bill valve, sensing pressure port and cap, deflector cap or expiratory port option-peep valve and mask (optional). Throughout this report, the term Equipment Under Test (EUT's) refers to all models of manual resuscitators.

DESCRIPTION

The EUT's are hand held lightweight, manual resuscitators. The EUT's provide clinicians a way to maintain ventilatory support for patients with life-threatening airway disorders. The EUT's operate by manually squeezing the plastic reservoir bag to create a positive airflow to expand the patient's lungs (Figure 1).

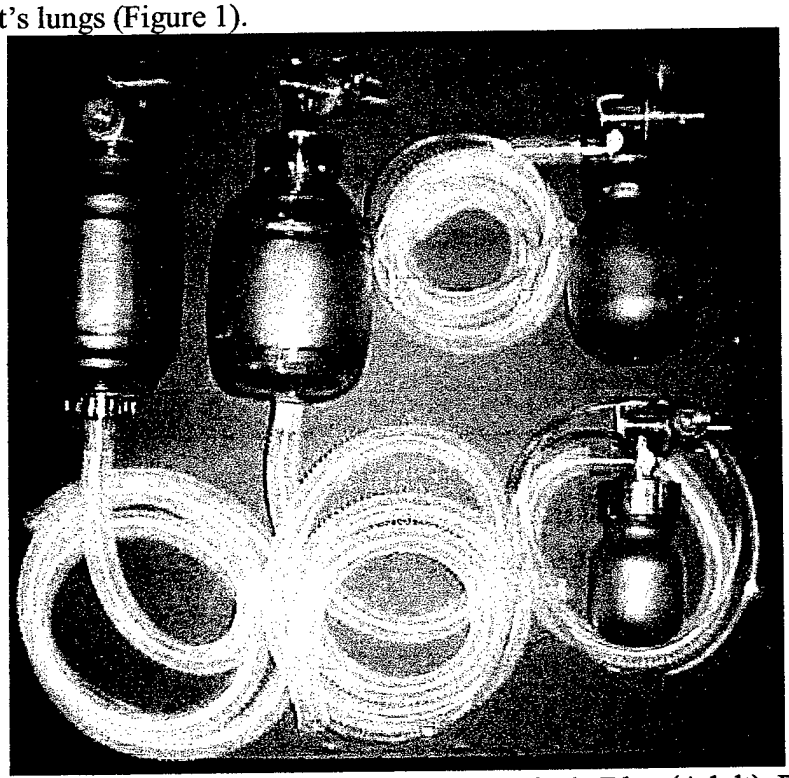

Figure 1. Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-5), and manufacturer's literature (6). The AFMEDL Flight Performance Evaluation Procedure Guide and Testing Standards describes additional safety and human interface issues to be considered during equipment testing (7). A test setup and performance check were developed specific to these EUT's to verify their proper functioning under various test conditions. All tests were conducted by AFMEDL personnel assigned to the Protective Systems Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas unless otherwise noted.

The EUT's were subjected to various laboratory and in-flight tests to observe and evaluate their performance under anticipated operational conditions.

1. Initial Inspection

2. Thermal/ Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Temperature Storage

    e. Cold Temperature Storage

3. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to simulated flight level

4. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

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

b. The EUT's were checked to ensure they met safety requirements and operating Characteristics established in National Fire Protection Agency (NFPA) 99 (1), and AFI 41-201,

Equipment Management in Hospitals (3).

c. The EUT's were examined to ensure they met basic requirements for human factor design as outlined in MIL-STD 1472E (4).

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

TEST SETUP

The EUT's were prepared for tests as follows:

1. Connect EUT's output to Michigan Instruments lung simulator's input port
2. Connect EUT's oxygen tubing to 100% oxygen
3. Squeeze adult manual resuscitators at a rate of 5:1 (one breath every 5 seconds)
4. Squeeze child and infant manual resuscitators at a rate of 3:1 (one breath every 3 seconds)

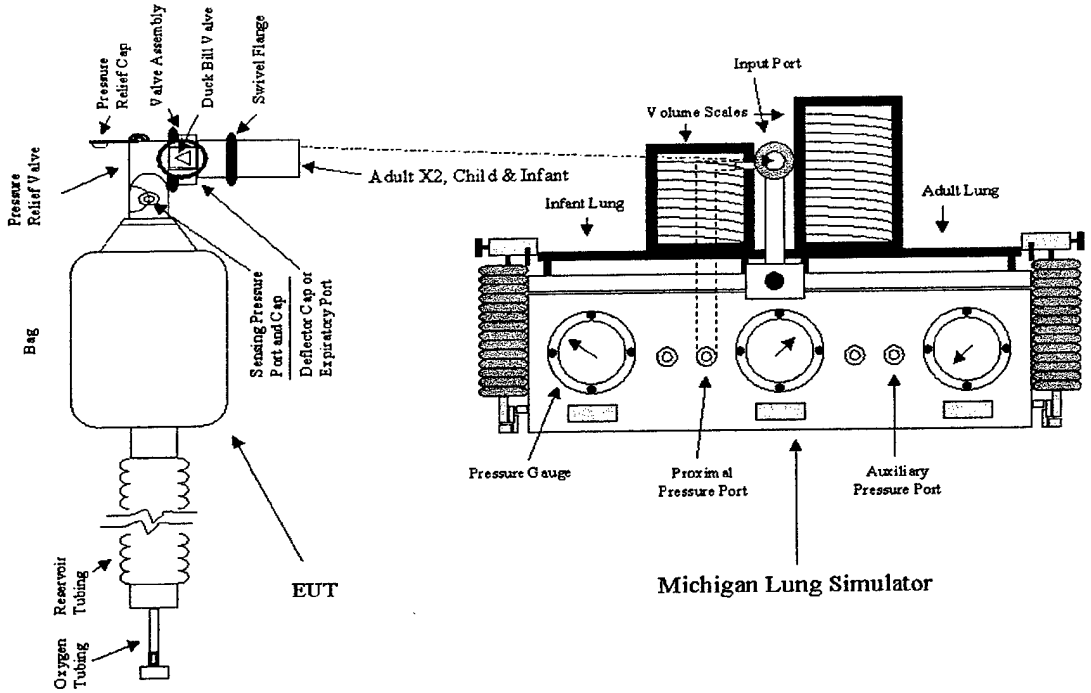

Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT's during each of the test conditions: The EUT's were prepared for test described. After one full minute

data was taken in several modes. Resistance factors were determined by use of appropriate sized Michigan Instruments Pneu-Flow resistors. For the adult resuscitators, O_2 percentage was taken with a compliance of 0.02 l/cmH_2O and 0.05 l/cmH_2O and resistance factors of 20 and 5. For the child resuscitator a compliance of 0.01 l/cmH_2O and a resistance factor of 50, and for the infant resuscitator a compliance of 0.001 and a resistance factor of 200 were used.

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 (5). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, mechanical failures due to rapid water, or frost formation.

Testing was conducted in a calibrated Thermotron Industries, model SM-32 environmental chamber. The EUT's were placed in the center of the environmental chamber. The other components of the test setup remained outside the chamber. For operational tests, the EUT's were monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT's were placed in the chamber and remained non-operational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

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

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

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

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

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 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. The majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation pressurize their cabins to barometric pressures equivalent to 8,000 - 15,000 ft above sea level. The differences in pressure affect the operation of some medical equipment. Altitude testing consisted of operating the EUT's while ascending from ground level to 15,000 ft. Ascent was stopped at 2,000 ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min.

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 performance during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT's were placed inside the rapid decompression test chamber and 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 with a 7-second RD and a 1-second RD. The EUT's were monitored throughout the series of decompressions. Performance checks were assessed each time the EUT's returned to ground level and components examined for damage.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT ability to provide patient care on board USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

Flight qualified AFMEDL aeromedical crewmembers flying on a C-9 aeromedical evacuation mission conducted this phase of testing. The EUT's were taken out of their protective plastic bag and used in various areas of the aircraft. Then human factor characteristics were evaluated, e.g., (securing methods, setup/tear down times and securing locations evaluated.) Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT's human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The units performed to the manufacturer's specification.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT's were evaluated IAW manufacturer's guidelines regarding hot operation, cold operation, and humidity. The EUT's operated according to AFMEDL and manufacturer's guidelines during hot and cold operation, hot and cold storage, and humidity testing.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT's performed in accordance with manufacturer's specifications throughout testing. The EUT's were able to deliver O_2 percentages above 95% when supplied with 100% oxygen at 10 lpm.

2. Rapid Decompression: The EUT's operated satisfactorily following each decompression event.

AIRBORNE PERFORMANCE

The in-flight evaluation of the EUT's was performed on a C-9 aeromedical evacuation mission. It was determined that the EUT's were simple to use and store on the aircraft.

SUMMARY

AFMEDL found the Vital Signs, Inc., Models: Vital Blue (Adult) & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft. Its operation was within expected parameters under environmental extremes and simulated cabin altitudes. It did not produce a hazard to patient or crew during rapid decompression.

Any public announcement of this final report shall be coordinated between Vital Signs, Inc., AFRL, AFMEDL and the Brooks AFB Public Affairs Office. Vital Signs, Inc. shall not use the name of the Air Force Activity or the Government on any product or service, which is directly or indirectly related to this final report. This laboratory or the Government does not directly or indirectly endorse any product or service provided, or to be provided, by Vital Signs, Inc. its successors, assignees, or licensees. Vital Signs, Inc. shall not in any way imply that this technical report is an endorsement of any such product or service.

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code

2. Emergency Care Research Institute (ECRI)

3. AFI 41-201, Equipment Management in Hospitals

4. MIL-STD 1472E, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.

5. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.

6. Vital Signs, Inc., Models Vital Blue & Code Blue (Adult), Pedi Blue (Child), and Baby Blue (Infant) Manual Resuscitators, Operation Instructions.

7. AFMEDL Flight Performance Procedures Guide and Testing Standards, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.