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Laboratory Test Report of the Bird Corporation Avian Portable Ventilator, Model 15300, T&E Identification Number 42

by

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19. ABSTRACT (Continue on reverse if necessary and identify by block number)

The Bird Avian portable ventilator, Model 15300, was tested for environmental and electromagnetic interference/compatibility under the U.S. Army Program for Testing and Evaluation of Equipment for Aeromedical Operations. The tests were conducted using current military and industrial standards and procedures. The Bird Avian ventilator was found compatible with the environmental tests after configuration changes. The unit may produce some electromagnetic emissions in excess of the military specification.

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1. Introduction

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards and collective professional expertise to test and evaluate selected medical equipment proposed for use aboard Army aircraft. Equipment meeting these standards ensures the safety of the crew, patients, and aircraft by eliminating risks due to: (1) interference by the medical equipment with aircraft systems, (2) aircraft systems interfering with operation of the medical device, (3) the medical equipment failing due to environmental exposure, and (4) functional incompatibility when used onboard the aircraft. Previous tests of medical devices in this program have shown that 32 percent of the medical devices fail at least one environmental test, 91 percent failed to meet electromagnetic interference standards, and overall 15 percent were unsuitable for use in the UH-60 Medevac helicopter (Bruckart, Licina, and Quattlebaum, 1993).

Test objectives include: (1) determining if the equipment is complete and operational per the manufacturer's operating instructions, (2) ensuring electrical safety of the device, (3) determining the ability of the device to function in low pressure (altitude), cold, hot, humid, or vibration environments, and (4) to evaluate the electromagnetic emissions and susceptibility of the device.

This report describes the results of environmental and electromagnetic characteristics tests of the Bird Avian Model 15300 portable ventilator*. These tests were performed as a reimbursable project at the request of the Defense Procurement Service Center.

2. Description

The Bird Avian portable ventilator is a microprocessor controlled, volume-cycled ventilator. The unit's modes of operating include "CONTROL," "ASSIST/CONTROL," and "SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION" (SIMV). A rotary control knob on the bottom left of the front panel allows the operator to select from the three modes of ventilation or invoke the internal self test. The "CONTROL" mode delivers breaths as set in the ventilator's parameters. The "ASSIST/CONTROL" mode will allow the patient to augment the breath rate but not the flow or tidal volume as set by the operator. The "SIMV" mode can allow the ventilation to be patient controlled or ventilator controlled depending on the control settings. With the patient disconnected from the ventilator and the patient circuit open to ambient conditions, the rotary control switch may be placed in the "CAL" position. Light emitting diodes (LED's), including all segments of the airway pressure bar graph, are illuminated during calibration

* See list of manufacturers

verification. A numerical value indicating the software version (12.01 on the final Avian prototype) followed by "PASS" will be displayed in the 4 digit, 7 segment LED monitor display, if the unit is within calibration. Several "push-to-display" membrane switches on the front panel allow the operator to monitor and adjust the set parameters. Adjustable Parameters are labeled "Flow," "Tidal Volume," "Insp. Time," "Breath Rate," "Low Peak Pressure," and "High Peak Pressure." Parameters are set by depressing the appropriate membrane switch and adjusting the corresponding rotary control knob. Adjustment and current set parameters may be exhibited in the monitor display. This includes ventilator measured "PAW," "PIP," and "MAP." Red LED alarm indicators are labeled and located at the top left of the front panel. Alarm displays include "Peep Not Set," "Apnea," "Battery Low/Fail," "External Power Failure," "Vent Inoperative," and "Disconnect." Alarm activations (flashing red LED) are accompanied by an audible tone. Alarm activations are FLAGGED and the "Silence/Reset" membrane switch must be depressed to halt alarm flashing.

The Bird Avian portable ventilator is electrically and pneumatically driven. The unit operates from external ac or dc power and an internal rechargeable 6-volt (V) battery. The unit requires an external gas source at 40 to 60 pounds per square inch (PSI). The unit's electronic systems are interfaced with the pneumatic systems through a series of solenoid valves and a pressure transducer. The gas source is connected to the unit via a 1/4-inch flared nipple connector labeled "GAS INLET" and "40 - 60 PSIG." The gas source is internally regulated to 30 psig. The gas source then flows to "MAIN SOLENOID VALVE." The "MAIN SOLENOID VALVE" controls the flow of the gas source depending on the control parameter settings on the front panel ("ASSIST" or "ASSIST CONTROL") of the ventilator. At the beginning of the inspiration, the gas source is adjusted to the appropriate flow using a "FLOW CONTROL VALVE." A "FLOW CONTROL POTENTIOMETER" is attached to the "FLOW CONTROL VALVE." The unit includes a microprocessor which uses these settings and devices to calculate and deliver the tidal volume. The breathing gas continues through a "CHECK VALVE" and on to the patient circuit. During inspiration, there is a pressure reduction at the "CHECK VALVE." An upstream increase in gas source pressure (exhalation balloon drive pressure) results in closure of the "EXHALATION VALVE" during inspiration. After inspiration, the exhalation pressure is vented through an orifice in direct line with the patient circuit and the "CHECK VALVE." During a spontaneous breath (demand breath), a "DEMAND SOLENOID VALVE" is opened and a flow of 60 liters per minute (lpm) is delivered to the patient circuit. When the "DEMAND SOLENOID VALVE" is activated, the flow of gas bypasses the "CHECK VALVE" and does not increase the exhalation balloon pressure. This allows excess breathing gas to bleed off through the exhalation orifice (i.e., the patient inhales the source volume and the nondemanded, remaining gas is

bled off). A "PRESSURE RELIEF VALVE" will vent the breathing gas if airway pressure exceeds the preset value of 100 cmH20. When the inspiration is complete or a ventilator malfunction occurs, the unit will shut off the gas flow to the patient circuit. The patient circuit is equipped with an anti-suffocation valve.

3. Manufacturer specifications

a. Dimensions: Height 10.0 in. (25.4 cm)
Width 12.0 in. (30.5 cm)
Depth 5.0 in. (12.7 cm)

b. Weight: 9.8 lbs (4.45 kg)

c. Power requirements:

(1) External power adapter with switch selectable inputs.
100 - 125 Vac, 50 - 400 Hz
220 - 250 Vac, 50 - 400 Hz

(2) External voltage from 11 - 30 Vdc (positive or negative polarity)

(3) Internal rechargeable 6 Volt battery (11 hours of operation on full charge)

(4) 40 - 60 psi breathing gas source

4. Summary of tests

a. Battery life evaluation

b. Electrical safety evaluation

c. Human factors evaluation

d. Altitude (low pressure) test

e. Vibration test

f. High temperature test (operating and storage)

g. Low temperature test (operating and storage)

h. Humidity test

i. Electromagnetic characteristics tests:

(1) Conducted emissions, [CE01, CE02, and CE04]

(2) Conducted susceptibility, [CS02, CS06]

(3) Radiated emissions, [RE02].

(4) Radiated susceptibility, [RS03].

5. Procedures

a. All tests were conducted in accordance with the procedures in applicable military specifications.

b. Performance test criteria were derived from the military specifications and the Bird Ventilator operator's manual.

c. The Bird Avian ventilator was connected to a BioTek VT-2 ventilator tester*, and operated with settings of 500 ml tidal volume, 14 breaths per minute (bpm), and 30 lpm flow.

d. Electrical safety evaluation: Measurements were taken with a Neurodyne-Dempsey model 431F electrical safety analyzer*, IAW the procedures described in Technical Bulletin (TB) Number 38-750-2. Case-to-ground resistance and various case-to-ground leakage currents were measured. Checks were made for safety concerns such as case integrity, breaks in power cord insulation, and connectors.

e. The human factors evaluation was conducted by reviewing checklist items while operating the ventilator in a laboratory under fluorescent lighting and in ambient conditions. The Avian ventilator was operated according to the operator's manual instructions through its full range of functions.

f. Low pressure (altitude) test: The altitude test was performed in a Tenney Engineering model 64S altitude chamber*. This test is based on MIL-STD-810E, Method 500.2. The Avian ventilator was operating and placed on the floor of the chamber. The unit was connected to a BioTek VT-2 ventilator tester (inside the chamber) for measurement verification. Chamber pressure was decreased to 480 mmHg (11,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to ambient conditions (760 mmHg) over a 10-minute period. There are no provisions for the control of temperature or humidity inside this chamber.

g. Vibration test: The vibration test was performed using an Unholtz-Dickey model TA115-40/CSTA vibration test system*. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are derived from measurements taken on the floor under the copilot's seat in a helicopter. The reference spectrum breakpoints are from MIL-STD-810E, Method 514.3; independent tests were conducted in the X-, Y-, and Z-axes.

X-, Y-, and Z-axes

duration: 60 minutes
broadband intensity: 2.116 G_{rms}
random vibration: initial slope : 99.00 dB/oct
5 Hz level: 0.00007 $G_{sqr/Hz}$
100 Hz level: 0.0007 $G_{sqr/Hz}$
300 Hz level: 0.0007 $G_{sqr/Hz}$
500 Hz level: 0.00007 $G_{sqr/Hz}$
final slope: -99.00 dB/oct

sinusoidal vibration:
0.9500 G_{pk} at 17.00 Hz
1.4000 G_{pk} at 34.00 Hz
0.9000 G_{pk} at 51.00 Hz
0.9000 G_{pk} at 68.01 Hz

The Avian ventilator was strapped to the vibration table fixture, and its performance was evaluated before, during, and after exposure to vibration.

h. High temperature tests: The high-temperature tests were conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810E, Method 501.2. For the high-temperature operation test, the Avian ventilator was operating and connected to a VT-2 ventilator tester and placed on the floor of the environmental chamber. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent RH within 15 minutes. The environmental control system is capable of regulating temperature within ± 2°C and humidity within ± 5 percent. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the Avian ventilator was allowed to return to ambient conditions over a 30-minute period. The Avian ventilator was stored (not operated) at temperatures of 63°C for 1 hour, 71°C for 4 hours, then again at 63°C for 1 hour. The chamber and the EUT then were returned to ambient conditions over a 30-minute period.

i. Low temperature tests: The low temperature tests were conducted in a Tenney Engineering model ZWUL-10107D Walk-in Controlled Environment Chamber. For the low temperature test, the Avian ventilator and placed in operation near the center of the environmental chamber. The chamber temperature was lowered to -25°C within 25 minutes. The environmental control system is capable of regulating temperature within ±2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant at -25°C for 2 hours. At half-hour intervals the chamber door was opened briefly to minimize the change in chamber conditions when performance checks were

conducted. The Avian ventilator also was stored (not operated) at a temperature of -46°C for 6 hours. After each operation and storage test, the Avian ventilator was allowed to return to ambient conditions before a final performance validation check was conducted.

j. Humidity test: The humidity test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber. This test is based on MIL-STD-810E, Method 507.2. For the humidity test, the Avian ventilator was placed in operation on the floor of the environmental chamber. The chamber temperature was raised to a temperature of 29.5°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within ± 2°C and humidity within ± 5 percent RH. At 45-minute intervals, the performance of the Avian ventilator was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the Avian ventilator were returned to ambient conditions before the posttest performance validation check.

k. Conducted emissions test: In the conducted emissions tests (MIL-STD-462, Notice 3, Methods CE01, CE02 and CE04) the Avian ventilator was placed on a grounded, copper-covered workbench. The top of the workbench is 1 meter from floor level, 1.37 meters wide and 0.81 meters long. Power was supplied by a pair of Line Impedance Stabilization Networks (LISN's) with the unit mounted in a test jig. The test jig is a wooden tray with two power receptacles and two slots to hold current probes in place around power supply conductors. While the Avian ventilator was operating, the frequency range (30 Hz to 50 MHz) was scanned for broadband and narrowband emissions conducted in the power cable.

l. Conducted susceptibility tests: The conducted susceptibility test was performed according to MIL-STD-462, Notice 3, Method CS02. The Avian ventilator was placed on a grounded, copper-covered workbench. Radio frequency interference was induced on the power leads and measured at the unit's power cable connector. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the unit was operating. Each frequency was held for at least 10 seconds. The Conducted Susceptibility Spike Test was performed according to MIL-STD-462, Notice 3, Method CS06 on a grounded copper covered workbench. Power was supplied by a custom metal connection box. The connection box has two power receptacles and four banana jacks on its front panel. Connections to the individual power lines are made in series through the banana jacks. Transient spikes of 200 volts for 10 microseconds were generated with a Solar Electronics model 8282-1 transient pulse generator* and induced onto the power leads at the connection box banana jacks. The spikes were

monitored with a Tektronix 2235 oscilloscope* connected to a power receptacle on the connection box.

n. Radiated emissions test: The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method RE02. The Avian ventilator was positioned on a grounded copper-covered workbench inside the electromagnetic interference (EMI) chamber. The unit was directly in line with, and at a horizontal distance of 1 meter from the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to the appropriate EMI receivers. Electrometrics EMC-25 and EMC-50 receivers were used for this test. Their frequency ranges in testing are 14 kHz to 1 GHZ and 1 GHz to 12.4 GHz respectively. Broadband and narrowband detection methods were used from 14 kHz to 1 GHz. Narrowband detection methods were used from 1 GHz to 12.4 GHz.

o. Radiated susceptibility test: The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The Avian ventilator was positioned on a wooden test stand 1 meter tall, 0.66 meters wide and 0.56 meters long, inside the EMI chamber. The unit was directly in line with, and at a horizontal distance of 1 meter from, the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to RF transmitters. The Avian ventilator was exposed to fields of 20 V/m from 10 kHz to 10 GHz. All RF carrier waves were 50 percent amplitude modulated with a 1000 Hz tone.

6. Results

a. Battery Life Evaluation: The control mode operating parameters were set at 500 ml tidal volume, 14 bpm, and 30 lpm. The unit was set to indicate (measure) "PIP" on monitor display. Operating time was measured from the initial calibration of the unit until the illumination (flashing) of the "BATTERY LOW/FAIL" alarm. The unit operated for an average battery life (average of three trials) of 10 hours and 11 minutes. The Avian ventilator manual indicates a minimum of 11 hours of battery life under normal conditions. Written clarification of the discrepancy from the manufacturer states the unit will operate for about an hour after the battery low/fail light begins to flash. The manufacturer plans to amend the operator's manual to clarify the warning indications and operation of the unit after the battery low/fail light begins to flash.

b. Electrical safety evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the Avian ventilator. The limits for currents and resistances were in accordance with the limits specified in TB-38-750-2, April 1987.

c. Human Factors Evaluation: The Avian ventilator was found to be deficient in six categories of the evaluation criteria. The categories include: visual displays, controls, maintainability, fuses and circuit breakers, labels and coding, and safety.

d. Altitude Test: Initial evaluation of the test unit in the altitude chamber showed that the peak airway pressure alarm, set prior to the test, activated at a displayed airway pressure lower than the set pressure. Failure analysis by the manufacturer resulted in a new software (EPROM) that displayed the proper pressure when the high pressure alarm activated. After modification, the test was repeated and it was determined that the actual tidal volume delivered by the unit at altitude was greater than the set tidal volume. This discrepancy has been discussed with the manufacturer. Bird Ventilator plans to amend the operator's manual to address operation of the ventilator at conditions other than standard temperature and pressure.

e. Vibration Test: Several days after vibration exposure, the "PAW" (peak airway pressure) membrane switch could not be activated after startup. The manufacturer's failure analysis revealed a "fracture/break" in a wire to the membrane switch assembly. The manufacturer provided a second test unit with "adhesive-backed foam tape" to act as a cushion. The modified unit successfully completed the vibration test regimen without failure before, during, or after vibration exposure.

f. High Temperature Test: During and after operation of the ventilator in the high temperature environment, the ventilator did not acknowledge (illuminate) the "EXTERNAL POWER" light. In addition, the "EXTERNAL POWER FAILURE" indicator was illuminated (flashing with an audible tone). The ventilator would not operate from external power and operated only from internal battery power. The unit was returned to the manufacturer for analysis. Failure analysis indicated a fuse separation which was replaced with a higher amperage fuse. The high temperature operational test was repeated and the unit performed properly before, during, and after operation and storage at high temperature.

g. Low Temperature Test: No failures were noted before, during, or after operation or storage of the Bird Avian ventilator in a low temperature environment.

h. Humidity Test: No failures were noted in the Avian ventilator's performance before, during or after exposure to high humidity.

i. Conducted Emissions: No emissions in excess of current limits were detected from the Avian ventilator during the conducted emissions tests.

j. Conducted Susceptibility (RFI): The Avian ventilator was not susceptible to conducted radio frequency interference on its power lines in this test.

k. Conducted Susceptibility (Spike): The Avian ventilator was not affected by the presence of the test spikes on its power lines.

l. Radiated Emissions: Narrowband and broadband emission exceeding specification limits were detected at the frequencies below.

ac (60 Hz) operating failure data:

Frequency (MHz)	Amount of failure (dB)
NB: 11.797 - 83.757	0.1 - 30.1
NB: 148.2 - 291.382	0.1 - 5.7

ac (400 Hz) operating failure data:

Frequency (MHz)	Amount of failure (dB)
NB: 11.802 - 83.782	0.1 - 29.0
NB: 105.732 - 291.457	0.6 - 5.7

dc (28 V) operating failure data:

Frequency (MHz)	Amount of failure (dB)
NB: 7.080 - 30.182	0.3 - 37.7
NB: 60.147 - 83.827	0.3 - 9.0
NB: 107.828 - 251.846	0.6 - 7.5

Battery operating failure data:

Frequency (MHz)	Amount of failure (dB)
NB: 11.084 - 29.890	0.6 - 11.1
NB: 95.024	0.2
NB: 263.023	3.8
NB: 291.457	1.3

m. Radiated Susceptibility Test: The Bird Avian ventilator was found to be susceptible to the following fields:

ac (60 Hz) operating failure data:

Frequency (MHz)	Threshold of failure (V/m)
183 - 278	8.63 - 20.0
544	20.0

ac (400 Hz) operating failure data:

Frequency (MHz)	Threshold of failure (V/m)
183 - 192	8.93 - 20.0
236 - 262	11.2 - 20.0
278	20.0

dc (28 V) operating failure data:

Frequency (MHz)	Threshold of failure (V/m)
183	13.2
222	11.0
232 - 252	7.96 - 20.0
580	15.9

Battery operating failure data:

Frequency (MHz)	Threshold of failure (V/m)
562	18.2
568	15.2

7. Detailed test data sheets:

Electrical Safety Test
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 2/7/94

Performance: Pass

Grounding conductor resistance (milliohms): na

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity	0.1
unit off, ungrounded, normal polarity	0.1
unit off, ungrounded, reverse polarity	0.2
unit on, grounded, normal polarity	0.1
unit on, ungrounded, normal polarity	0.2
unit on, ungrounded, reverse polarity	0.1

MAXIMUM LIMITS:

ground resistance (milliohms):	150
current (microamperes)	
current (grounded, type A unit):	10
current (ungrounded, type A unit):	100
current (grounded, type B unit):	50
current (ungrounded, type B unit):	500

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

Battery Life Evaluation
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model Number: Avian 15300
Serial Number: 002035
Military Item Number: None

Options Installed: None

Manufacturer battery life specification: 11 hours

Specified battery recharge time: 14 - 16 hours

Specified mode of operation under battery power: 500 ml tidal volume, 14 bpm, 30 lpm flow with the unit indicating "PIP" on the display monitor.

Overall performance: Unit did not meet the manufacturer's specification of 11 hours of operation.

Measurements:

Dates of first test:	1/31/94	2/1/94
Temperature:	23 deg. C	23 deg. C
Humidity:	55% RH	56% RH
Start times:	0855	0740
End times:	1620	1040
Operating times:	7:25	3:00
**********		
TOTAL OPERATING TIME:	10 hours 25 min.	

Dates of second test:	2/2/94
Temperature:	23 deg. C
Humidity:	57% RH
Start times:	0740
End times:	1642
Operating times:	9:02
**********	
TOTAL OPERATING TIME:	9 hours 2 min.

Dates of third test:	2/3/94	2/4/94
Temperature:	23 deg. C	23 deg. C
Humidity:	55%RH	58%RH
Start times:	0743	0740
End times:	1700	0930
Operating times:	9:17	1:50
**********		
TOTAL OPERATING TIME:	11:07	

Comments: The unit was charged for 14 - 16 hours before each battery life evaluation. Battery was considered expired when the "BATTERY LOW/FAIL" LED illuminated and the audible alarm sounded.

Human Factors Evaluation
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 2/7/94

Item configuration during test: Item prepared for normal operation.

Checklist for HFE

RESULTS

VISUAL DISPLAYS: Unsatisfactory

- display type, format, content
- location of displays
- indicator lights
- scalar displays
- color coding
- legends and labels
- cathode ray tubes
- counters
- flags, go-no-go, center-null indicators

Comments: Red colored lights (LED's) on the front panel monitor display and "PAW" bar graph should not be used to indicate proper operation of the unit (MIL-STD-1472D).

CONTROLS: Unsatisfactory

- location
- characteristics of controls
- labeling
- control - display relationships

Comments: Control knobs on the front panel are too close together (MIL-STD-1472D). The "Tidal Volume" and "Insp. Time" membrane switches are located too close to the adjustment control knob.

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: Approximately 3 minutes

MAINTAINABILITY: Unsatisfactory

component location
component characteristics
rests and stands
covers, cases, access doors
handles
lubrication
component mounting
cord storage provisions
external accessibility
internal accessibility
list special tools required
list realistic inspection requirements
list realistic inspection intervals

Comments: The front panel cover/lid will not stay attached to the ventilator (sn: 002035). Opening the cover/lid only a few times caused the cover/lid to come unhinged. The manufacturer supplied a replacement cover/lid however, the replacement would not stay attached to the ventilator.

CONDUCTORS: Satisfactory

binding and securing
length
protection
routing
conductor coding
fabrication
connectors

Comments: None

FASTENERS: Satisfactory

access through inspection panel covers
enclosure fasteners
device mounting bolts and fasteners

Comments: None

TEST POINTS: NA

general
location and mounting
test point labeling and coding

Comments: None.

TEST EQUIPMENT: Satisfactory

general
equipment self-test
indicators (list in comments)
controls
positive indication of proper operation

Comments: After calibration verification, the unit must be restarted to begin or resume ventilation.

FUSES AND CIRCUIT BREAKERS: Unsatisfactory

external accessibility
easy replacement or reset by operator

Comments: The unit has an internal fuse which is not externally accessible (MIL-STD-1472D).

LABELS AND CODING: Unsatisfactory

placed above controls and displays
near or on the items they identify
not obscured by other equipment components
describe the function of the items they identify
readable from normal operating distance
conspicuous placards adjacent to hazardous items

Comments: Tubing labels for the "EXHALATION DRIVE" and "AIRWAY PRESSURE" ports are obscured from direct view by their location and the location of the "To Patient" port and the "Gas Inlet" port.

SAFETY: Unsatisfactory

manual
materials
fire and explosive protection
operator protection from mechanical hazards
patient protection from mechanical hazards
electrical safety (operator and patient)

Comments: Lack of altitude compensation for operation in varied altitude environments.

Altitude Test
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 1/19/94 (repeat test date)

Item configuration during test:

Operating on the chamber floor and connected to the BioTek VT-2 ventilator tester.

Performance test criteria: The unit's ability to provide continuous and accurate measurements and displays of set parameters.

Ambient conditions outside chamber:

Temperature	75°F
Humidity	66% RH
Barometric pressure	753 mmHg

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria) all OK: Pass

Installation of item in test facility:

list connections to power	None
list connections to simulators	BioTek VT-2
list connections to dummy loads	None
list unconnected terminals	External power

IN-TEST DATA

Time of test start: 1000
The Avian ventilator delivered a higher tidal volume than the set parameter during the high altitude test.

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1100
Item functional (based on performance test criteria): All Ok
Deviation from pretest: None

Comments on item setup or checks: During the first altitude test, the unit sounded and displayed a high peak pressure alarm when an alarm condition did not exist per displayed airway pressure. This condition continued during the post test performance check. When a high pressure peak alarm is present, the ventilator does not deliver the full breath to the patient. The unit was returned to the manufacturer for analysis. It was determined that the unit was improperly displaying airway pressure and an EPROM software change was performed. At the customer's request, the altitude test was repeated with the new software (modification). During the second test, the VT-2 tester showed that the delivered tidal volume at altitude exceeded the set tidal volume. The actual volume being delivered by the unit appeared proportional to the altitude. The manufacturer is aware of this behavior and plans to amend the operator's manual to allow correction of the volume when the unit is operated at various altitudes and tidal volume settings.

Comments on other data: None

Vibration test
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 1/18/94

Item configuration during test: Strapped to vibration table fixture and operating.

Performance test criteria: The unit's ability to provide continuous and accurate measurements and displays of set parameters.

PRETEST DATA

Pretest performance check: All OK: Pass
Item functional (based on performance test criteria)
All OK: Pass

Installation of item in test facility:

list connections to power	120 Vac, 60 & 400 Hz, 28 Vdc
list connections to simulators	VT-2 ventilator tester
list connections to dummy loads	None
list unconnected terminals	None

Ambient conditions

Temperature 77°F
Humidity 65% RH
Barometric pressure 753 mmHg

IN-TEST DATA

Data and performance checks during test:

Times and dates of test start:
X:1/18/94 1340 Y:1/18/94 1447 Z: 1/18/94 0805

Time at first check:
X: 1345 Y: 1455 Z: 0810
Item functional (based on performance test criteria):
All OK: Pass
Deviation from pretest: None

Time at second check:
X: 1435 Y: 1440 Z: 0900
Item functional (based on performance test criteria):
All OK: Pass
Deviation from pretest: None

POSTTEST DATA

Time at test end:
X: 1440 Y: 1557 Z: 0905
Posttest performance check: All OK: Pass
(complete check of item and accessories)
Item functional (based on performance test criteria):
All OK: Pass
Item intact: Yes
Deviation from pretest: None

Comments on item setup or checks: The modified unit's performance was not affected by the vibration test.

Comments on test run (including interruptions): After the first vibration test the unit malfunctioned internally. The unit was sent back to the manufacturer. A failure analysis indicated a "fracture/break" in a flex circuit for the membrane switch panel causing a malfunction with the "PAW" switch and display. At the customer's request, the vibration test was repeated with a modified unit. The second test unit had not previously undergone vibration testing.

Comments on other data: None

High Temperature test
(Equipment Operating)
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 1/21/94

Item configuration during test:

Operating on a wire test stand and connected to the BioTek VT-2 ventilator tester via portals in the chamber wall.

Performance test criteria: The unit's ability to provide continuous and accurate measurements and displays of set parameters.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	60% RH
Barometric pressure	759 mmHg

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria):
All OK: Pass

Installation of item in test facility:

list connections to power	120Vac, 60-400Hz, 28 Vdc
list connections to simulators	BioTek VT-2
list connections to dummy loads	none
list unconnected terminals	none
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance form east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

Time of test start: 0900

Performance checks during test:

First check:

Time:	0930
Temperature:	49°C ± 1°C
Humidity:	15% RH ± 1% RH
Barometric pressure:	758 mmHg

Item functional (based on performance criteria):
All OK: Pass
Deviation from pretest: None

Second check:

Time:	1000
Temperature:	49°C ± 1°C
Humidity:	15% RH ± 1% RH
Barometric pressure:	758 mmHg

Item functional (based on performance criteria):
All OK: Pass
Deviation from pretest: None

Third check:

Time:	1030
Temperature:	49°C ± 1°C
Humidity:	15% RH ± 1% RH
Barometric pressure:	758 mmHg

Item functional (based on performance criteria):
All OK: Pass
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1100
Item functional: (based on performance criteria):
All OK: Pass
Deviation from pretest: None

Comments on item setup or checks: During the first test, the unit failed and would not operate on external power. A manufacturer failure analysis indicated a blown main power fuse.

Comments on test run (including interruptions): This test was repeated at the customer's request with a modified unit with a larger amperage fuse installed.

Comments on other data: None

High Temperature test
(Equipment in Storage)
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 1/27/94

Item configuration during test: Sitting on wire test stand, not operating. The unit is in storage.

Performance test criteria: The unit's ability to provide continuous and accurate measurements and displays of set parameters.

Ambient conditions outside chamber:

Temperature	22°C
Humidity	42% RH
Barometric pressure	755 mmHg

PRETEST DATA

Pretest performance check:
Item functional (based on performance criteria):
All OK: Pass

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance form east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

Time of test start: 0730
Mid-test time: 1030
Mid-test temperature: 71°C ± 1°C
Mid-test humidity: 15% RH ± 1% RH

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1430
Item functional (based on performance criteria):
All OK: Pass
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

Low Temperature test
(Equipment Operating)
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 11/17/93

Item configuration during test:

Operating on a wire test stand and connected to the BioTek VT-2 ventilator tester via portals in the chamber wall.

Performance test criteria: The unit's ability to provide continuous and accurate measurements and displays of set parameters.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	59% RH
Barometric pressure	753 mmHg

PRETEST DATA

Pretest performance check:

Item functional (based on performance criteria)

All OK: Pass

Installation of item in test facility:

list connections to power	120 Vac 60-400Hz, 28Vdc
list connections to simulators	BioTek VT-2
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance form east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

Time of test start: 0845

Performance checks during test:

First Check:

Time: 0915
Temperature: - 25°C ± 1°C
Humidity: NA
Barometric pressure: 753 mmHg
Item functional (based on performance criteria)
All OK: Pass
Deviation from pretest: None

Second check:

Time: 0945
Temperature: - 25°C ± 1°C
Humidity: NA
Barometric pressure: 753 mmHg
Item functional (based on performance criteria)
All OK: Pass
Deviation from pretest: None

Third check:

Time: 1015
Temperature: - 25°C ± 1°C
Humidity: NA
Barometric pressure: 753 mmHg
Item functional (based on performance criteria)
All OK: Pass
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1045
Item functional (based on performance criteria)
All OK: Pass
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

Low Temperature test
(Equipment in Storage)
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 1/28/94

Item configuration during test:

Sitting on wire test stand, not operating. The unit is in storage.

Performance test criteria: The unit's ability to provide continuous and accurate measurements and displays of set parameters.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	49% RH
Barometric pressure	753 mmHg

PRETEST DATA

Pretest performance check:
Item functional (based on performance criteria):
All OK: Pass

Installation of item in test facility:

list connections to power:	None
list connections to simulators:	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance form east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

Time of test start: 0730
Mid-test time: 1100
Mid-test temperature: -46°C ± 1°C

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1500
Item functional (based on performance criteria):
All OK: Pass
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

Humidity Test
Report Form

Nomenclature: Avian portable ventilator
Manufacturer: Bird Products Corporation
Model number: Avian 15300
Serial number: 002035
Military item number: None

Options installed: None

Date of test: 1/22/94

Item configuration during test: Operating on a wire test stand and connected to the BioTek VT-2 ventilator tester via portals in the chamber wall.

Performance test criteria: The unit's ability to provide continuous and accurate measurements and displays of set parameters.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	66% RH
Barometric pressure	754 mmHg

PRETEST DATA

Pretest performance check:
Item functional (based on performance criteria):
All ok: Pass

Installation of item in test facility:

list connections to power	120 Vac,60-400Hz,28Vdc
list connections to simulators	BioTek VT-2
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.56
distance from south wall (meters)	1.02
distance form east wall (meters)	1.57
distance from west wall (meters)	1.45
distance from ceiling (meters)	1.19
distance from floor (meters)	0.97

IN-TEST DATA

Time of test start: 0815

Performance checks during test:

First check:

Time:	0900
Temperature:	29.5°C ± 1°C
Humidity:	95% RH ± 1% RH
Barometric pressure:	754 mmHg
Item functional (based on performance criteria):	All OK: Pass
Deviation from pretest:	none

Second check:

Time:	0945
Temperature:	29.5°C ± 1°C
Humidity:	95% RH ± 1% RH
Barometric pressure:	754 mmHg
Item functional (based on performance criteria):	All OK: Pass
Deviation from pretest:	None

Third check:

Time:	1030
Temperature:	29.5°C ± 1°C
Humidity:	95% RH ± 1% RH
Barometric pressure:	754 mmHg
Item functional (based on performance criteria):	All OK: Pass
Deviation from pretest:	None

Fourth check:

Time:	1115
Temperature:	29.5°C ± 1°C
Humidity:	95% RH ± 1% RH
Barometric pressure:	754 mmHg
Item functional (based on performance criteria):	All OK: Pass
Deviation from pretest:	None

Fifth check:

Time: 1200
Temperature: 29.5°C ± 1°C
Humidity: 95% RH ± 1% RH
Barometric pressure: 754 mmHg
Item functional (based on performance criteria): All OK: Pass
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1300
Item functional (based on performance criteria): All OK: Pass
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

8. References

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2. Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, DC. TB 38-750-2. April.

3. Department of Defense. 1971. EMI characteristics, requirements for equipment. Washington, DC. MIL-STD-461C, Notice 2.

4. Department of Defense. 1971. EMI characteristics, measurement of. Washington, DC. MIL-STD-462. Notice 3. February.

5. Department of Defense. 1989. Human engineering design criteria for military systems, equipment, and facilities. Washington, DC. MIL-STD-1472D. March.

6. Department of Defense. 1989. Environmental test methods and engineering guidelines. Washington, DC. MIL-STD-810E. July

List of Manufacturers

1. Bird Products Corporation
   1100 Bird Center Drive
   Palm Springs, CA 92262

2. BioTek Instruments, Inc.
   Highland Park, Box 998
   Winooski, VT 05404

3. Neurodyne-Dempsey, Inc.
   200 Arrowhead Drive
   Carson City, NV 89701

4. Unholtz-Dickey Corporation
   6 Brookside Drive
   Wallingford, CT 06492

5. Tenney Engineering, Inc.
   1090 Springfield Road
   P.O. Box 3142
   Union, NJ 07083

6. Solar Electronics Company
   901 North Highland Avenue
   Hollywood, CA 90038

7. Tektronix, Inc.
   P.O. Box 500
   Beaverton, OR 97077

8. Electrometrics, Inc.
   100 Church Street
   Amsterdam, NY 12010