Portable and Transport Ventilators

REQUEST FOR INFORMATION

1.0 INTRODUCTION

1.1 General. This Request for Information (RFI) is an invitation to submit to DLA Troop Support the following: Technical information, quotes, and all related support documentation for all components and accessories that you have for portable and transport ventilators. This request is a **market research effort** undertaken by the Government to be used for information gathering purposes. The information received will be used for Acquisition Planning purposes and will help define future requirements.

1.2 Submission Package. The submission package should consist of submittal of a compliance spreadsheet (**attachment A**) **and section 7 of this document, Feedback Questions** with appropriate compliance codes for both tabs on the spreadsheet, technical literature addressing compliance with the functional requirements, along with product pricing, which includes the ventilator device itself, consumables, maintenance services, repair parts, and any other elements required to use and maintain the portable ventilators. Respondents are requested to provide all operator and service manuals, parts list, training CDs, and schematics for review of completeness and clarity. Additionally, the government may request at a future date an on-site demonstration of the functional packing and the system's ability to meet the required functionality and interoperability requirements stated here-in. Portable ventilators may be reviewed, tested, and validated by government equipment specialists and clinical staff.

1.3 Test and evaluation: The government may also test offered systems to requirements of this RFI as part of its evaluation of proposals. Test and evaluation will include, but is not limited to, temperature, drop, and other environmental resistance requirements, usability (to include clinical review), and maintainability requirements. Prior environmental testing conducted by Government or other laboratories may be accepted in lieu of new testing.

2.0 SCOPE

The United States Government requires portable and transport ventilators capable of performing to the objectives described within the RFI to meet the specifications for use within a wide variety of clinical and environmental conditions. The required device is a lightweight, compact, portable, self-contained ventilator for use in the management of infants through adult patients who weigh equal or greater than 11 lbs. with acute or chronic respiratory failure, or during resuscitation, by providing continuous positive-pressure ventilation.

3.0 FUNCTIONAL REQUIREMENTS.

The current requirements are for advanced models (with Pressure Support) of portable and transport ventilators. The following abbreviations will be used if there are both required and/or desirable values for the essential characteristics:

(T): Threshold value representing a required value.
(O): Objective value representing a desirable value.
T=O: If Threshold and Objective values are the same.

3.1.1 Item description. The advanced model ventilator shall be a portable and transport ventilator for air and ground movement of patients. The equipment shall be capable of sustaining the ventilation requirements of acutely ill or injured patients during extended transport. The ventilator

shall be a self-contained system which shall be capable of supplying 21% to 100% oxygen when provided with a 50 psi +/- 5psi oxygen source. The breathing circuit shall be capable of using a standard disposable universal 22 mm tubing set. Unit shall operate from battery and/or various electrical sources. The unit shall function in an **Assist/Control, Synchronized Intermittent Mandatory Ventilation (SIMV), Continuous Positive Airway Pressure (CPAP) with/ without pressure support, and positive end expiratory pressure (PEEP) mode**.

3.1.2 FDA requirements. Manufacturers shall be properly registered and listed with FDA and comply with general GMP (Good Manufacturing Practice) and shall have the appropriate 510K clearance for the device.

3.1.3 The ventilator shall be used on a variety of patient populations (Adult, Pediatric, and Normal and Injured Lungs).

3.1.4 The integral compressor may be detachable from the ventilator, but shall be attached in a secure manner to avoid any change of accidental detachment during transport. Compressor shall be capable of supplying a minute ventilation of 1-20 liters per minute through all setting combinations. Compressor output shall not drop below 50-55 psi at cabin altitudes of 10,000 feet (3048) meters).

3.1.5 Compressed air and oxygen supply connections shall comply with CGA STD V-1 and V-5.

3.1.6 Ventilator shall function, without using the internal compressor, when supplied with a 50 psi +/- 5 psi compressed gas (air or oxygen) source (T). It is desirable that the unit be able to function with less than 50 psi +/- 5 psi compressed gas (O).

3.1.7 The unit shall be able to ventilate using only the compressor.

3.1.8 The unit shall be compatible with the following regulators:

(a) Pressure Regulator, Oxygen, For D-Cylinders

(b) Pressure Regulator, Oxygen, For H-Cylinders

CONTROLS

3.1.9 All ventilators' controls shall have protection from an inadvertent change or resetting (T). A clear shield for protecting the controls from physical damage is preferred (O). All controls shall be ergonomically designed to allow operator to manipulate them while wearing U.S. Air Force standard issue flight gloves.

3.1.10 Peak Inspiratory Pressure: The ventilator shall provide Peak Inspiratory Pressure (PIP) from 10 to 60 cm H2O.

3.1.11 Tidal volume: User shall be able to set tidal volume from 50 to 1000 ml. A variable flow rate control can be used to adjust the tidal volume, if a direct measurement (not calculated) of exhalation tidal volume is available. Note: Minute ventilation will be 1-20 liters per minute.

3.1.12 Breath rate: The ventilator shall be able to provide a breath rate from 0-60 breaths/min and be directly adjustable to treat the population identified.

3.1.13 The unit shall be able to perform ventilation through the use of a manual breath button as well. (A manual breath is defined as the delivery of one breath at current settings.)

3.1.14 The ventilator shall have Inspiratory time from 0.3 to 2.0 seconds.

3.1.15 The ventilator shall have PEEP adjustable at a minimum from 5-20 cm H2O (T). The objective adjustable range shall be 0-25 cmH20 (O).

3.1.16 The unit shall use an external Positive End Expiratory Pressure (PEEP) valve (T). Internal PEEP is desirable if it can be provided without complicating default settings (O).

3.1.17 Tubing shall be compatible with standard PEEP valves (22 mm).

3.1.18 Unit shall be compatible with both electric and non-electric commercially available humidifiers using 22 mm tubing set.

3.1.19 The ventilator shall have pressure support (measured in reference to PEEP) from 0-30 cm H2O.

3.1.20 The ventilator shall be capable of providing fraction of inspired oxygen (FiO2) from 21 to 100 % (Ventilator shall be capable of blending an external oxygen source with internally compressed air. Unit shall be capable of supplying 21% to 100% oxygen when provided a 50 psi +/-5 psi or low-pressure medical grade oxygen source (99% Oxygen) (T). It is desirable, but not mandatory, that the unit function with less than 50 psi +/- 5psi (O).

3.1.21 The blender shall allow for mixture of 21% through 100% oxygen with maximum of 10% increments.
3.1.22 The ventilator shall have I:E ratio from 1:9 to 4:1.
3.1.23 Default I:E ratio setting of 1:2 with a 2 second maximum inspiratory time. The CPU shall adjust I:E ratio to maintain the 2 second maximum I:E. A control for varying the inspiratory time is allowed provided the default setting is clearly labeled.
3.1.24 The ventilator shall provide a flow rate of 100L/min flow delivery on mechanical breaths.
3.1.25 The ventilator shall be capable of providing flow and time cycle ventilation controls.
3.1.26 The ventilator shall have a trigger mechanism (triggered by patient or pre-set ventilator threshold).
3.1.27 The ventilator shall have an available lock or redundancy to eliminate inadvertent changes.
3.1.28 Shall incorporate a "SIGH ON/OFF" button that would initiate/terminate delivery of three sigh breaths every ten minutes or provide for an alternate recruitment method which allows for changes to the tidal volume to achieve the desired SpO2 levels.
3.1.29 Assist Sensitivity: The sensitivity shall be preset to -2 cmH20. Unit shall change up to +8 cmH20 when internal PEEP mode is used.

OPERATING MODES
3.1.30 The ventilator shall be able to provide volume breaths
3.1.31 The ventilator shall be able to provide pressure breaths

SIMV Ventilation Mode
3.1.32 The ventilator shall have Volume breaths
3.1.33 The ventilator shall have Pressure breaths
3.1.34 The ventilator shall have pressure support
3.1.35 The ventilator shall have spontaneous/CPAP
3.1.36 The ventilator shall have apnea-backup ventilation
3.1.37 The ventilator shall have ability to set Apnea parameters
3.1.38 The ventilator shall have leak compensation

Monitored Parameters (Ability to Monitor)

Pressure:
3.1.39 The ventilator shall be able to monitor Peak Inspiratory Pressure (PIP)
3.1.40 The ventilator shall be able to monitor PEEP (Positive End Expiratory Pressure)
3.1.41 The ventilator shall continuously display mean airway pressure
3.1.42 Peak Pressure Relief: The peak pressure shall have a setting range of 20 and 100 cmH20 locked.

Volume:
3.1.43 The ventilator shall be able to monitor Tidal Volume (delivered)
3.1.44 The ventilator shall be able to monitor Minute Volume
3.1.45 The ventilator shall be able to monitor Inspiratory time
3.1.46 The ventilator shall be able to monitor I:E
3.1.47 The ventilator shall be able to monitor respiratory rate
3.1.48 The ventilator shall be able to monitor exhale volume or incorporate a system of alarms that will alert the user in the event of ventilation system leaks or pressure changes such as (incomplete) exhale volume.
3.1.49 The ventilator shall be able to self-adjust tidal volume to compensate for changes in barometric pressure (altitude compensated).

PATIENT ALARMS (Programmable):
3.1.50 The ventilator shall have low/high tidal volume alarm
3.1.51 The ventilator shall have low pressure alarm

3.1.52 The ventilator shall have circuit disconnect alarm
3.1.53 The ventilator shall have high pressure alarm
3.1.54 The ventilator shall have apnea alarm
3.1.55 The ventilator shall have high respiratory rate alarm
3.1.56 The ventilator shall have low PEEP alarm
3.1.57 The ventilator shall have low exhale volume alarm or incorporate a system of alarms that will alert the user in the event of ventilation system leaks or pressure changes such as (incomplete) exhale volume.

EQUIPMENT ALARMS:
3.1.58 The ventilator's display shall be Night Vision Goggle (NVG) Compliant
3.1.59 The ventilator shall be able to provide visual/audio alarming to Health Care Provider compatible with flight platforms/healthcare settings and threat environment despite extremes of light, noise, or vibration.
3.1.60 The ventilator shall have gas supply failure alarm
3.1.61 The ventilator shall have Power failure alarm
3.1.62 The ventilator shall have Ventilator inoperative alarm
3.1.63 The ventilator shall have Low battery alarm
3.1.64 The ventilator shall have Self-diagnostic

PNEUMATIC POWER:
3.1.65 The ventilator shall be capable of operation using compressed gas, internal compressor, oxygen concentrator.
3.1.66 The ventilator shall be capable of providing set minute volume using internal gas delivery mechanism (compressor, turbine, blower, etc.) without need for external gas source.
3.1.67 In the event of CPU failure, the ventilator shall allow manual gas flow control for manual ventilation or provide for a supply of ambient room air into the patients circuit while preventing rebreathing.
3.1.68 The ventilator shall have pressure ranges for appropriate source of oxygen
3.1.69 The ventilator shall be operative with low flow oxygen
3.1.70 The ventilator shall be able to allow the patient to breath with ambient air in the event of ventilator failure.

POWER REQUIREMENTS, VAC:
3.1.71 The ventilator shall operate from alternating current of 110/220 volts at 50/60 /400 Hertz or from direct current of 12-28 volts.

INTERNAL BATTERY:
3.1.72 The ventilator shall have a rechargeable internal battery that will power the ventilator for a minimum of 60 minutes (T) supplying a minute ventilation of 1-20 liters per minute. The desirable/objective operating time using internal battery shall be 120 minutes (O).
3.1.73 Use of rechargeable is mandatory (T). A dual capability of using rechargeable and disposable is desired (O).

EXTERNAL BATTERY:
3.1.74 If an external battery is provided with the unit, it shall have operating time for a minimum of 4 hours and shall be rechargeable.

SIZE & WEIGHT:
3.1.75 At a minimum, the ventilator shall have size less than 0.7 cubic feet in volume with battery and weight less than 15 lbs with battery (T). The objective required values are that the ventilator shall have size less than 0.3 cubic feet in volume and less than 10 lbs. with battery (O).

OTHER SPECIFICATIONS. These requirements are for facilities that require additional features (e.g., pressure control, pressure support) to provide continuous care for transporting in-house patients
3.1.76 The ventilator shall have circuit tubing, non-proprietary preferred
3.1.77 The ventilator shall be mountable to transport method, e.g. litter
3.1.78 At a minimum, the ventilator shall operate with noise Level no greater than 70 dB at one meter (T) to allow for necessary conversation without major difficulty in hospitals, aeromedical staging, etc. The desirable value is 65 dB at 1 meter (O).
3.1.79 The unit shall be gas efficient; meaning, all externally supplied oxygen shall be passed to the patient.
3.1.80 When required, the ventilator shall be packable in a reusable transit case (hard case) that shall be decontaminable and shall be designed to protect and prevent damage to the ventilator during non-patient movement/shipping/storage.
3.1.81 The ventilator shall be packable with consumables for the first 72 hours of use
3.1.82 The ventilator shall be operated in any orientation (sideways, vertical, and horizontal)
3.1.83 LED displays are preferred (O).

MAINTENANCE:
3.1.84 The ventilator shall be able to maintain/upgrade software in onsite setting without requiring proprietary Test, Measurement, & Diagnostic Equipment (TMDE).
3.1.85 The ventilator shall have Reliability, Availability, and Maintainability (RAM) Characteristics - indicate meantime between failures. The availability shall be no less than 85% available over 30 days (threshold). The objective value is 90% available over 30 days
3.1.86 Two (2) operators and two (2) maintenance/service manuals shall be provided with the product to the consignee. Both manuals shall comply with the criteria presented in DEPMEDS DIDS.
3.1.87 Offeror shall submit Condition Based Maintenance + (CBM+)
3.1.88 Offeror shall provide maintenance training class
3.1.89 Meantime to Repair (MTTR) shall be no greater than 1.5 hours (T). The desirable MTTR value is 1 hour (O).
3.1.90 Offeror shall provide part list for the ventilator
3.1.91 Offeror shall provide Calibration procedures
3.1.92 The ventilator shall have ability to be maintained onsite
3.1.93 The ventilator shall have an ability to decontaminate

TESTING:
3.1.94 The ventilator shall comply with MIL-STD-810 E/F/G, Department of Defense Test Method Standard for Environmental Engineering Considerations and Laboratory Tests.
3.1.95 The ventilator shall have a Joint (Dual) Airworthiness Certification (JAC) consists of a Safe-to-Fly letter from the U.S. Air Force and a Fleet Airworthiness Release (AWR) and an Aeromedical Certification letter from the U.S. Army. DOCUMENTED PROOF OF THE JAC WILL BE REQUIRED AT TIME OF REQUEST FOR PROPOSAL (RFP) CLOSING. Any equipment upgrades/modifications after the initial certification (JAC) must be reviewed by testing agency for re-certification. The potential PMI shall comply with the following JAC requirements. Military standards shall be interpreted as though all units of PMI could be used aboard military aircraft, and should comply.
3.1.96 Baseline Performance Assessment: When the device first arrives, the test engineers conduct a review validating the device functions as advertised and as expected. Battery test (discharge and recharge) will be repeated three (3) times to obtain a mean value. The assessment familiarizes evaluation personnel with operation and characteristics of the device, noting design weaknesses and potential safety hazards relating to the aeromedical environment and human factors such as man-machine interface and potential for operator error (MIL-STD-1472).
3.1.97 Electrical Safety (ANSI/AAMI ES1-1999) for leakage current, ground resistance, and other medical equipment safety concerns. In addition, power receptacles should have a locking feature to prevent inadvertent disconnects from the power source.

3.1.98 Usability Testing – Device shall be easy to use by appropriate staff. The user shall be able to set up and operate the ventilator given FIO2, breath per minute (BPM), and tidal volume settings by qualified individuals. The given values will have direct correlation to a single adjustment.
3.1.99 Operational Testing – Units shall be made available for operational testing in a field environment
3.1.100 Maintenance Testing - Units shall be made available for maintenance testing in a field environment
3.1.101 Vendor shall provide the lifecycle costs of item
3.1.102 Vendor shall provide the cost of equipment item
3.1.103 Configuration requirements: the ventilator shall be able to be configured into various configurations which includes a standard configuration and optional configuration as described in the following.
3.1.103.1 Standard configuration (for the US Air Force): the ventilator shall come with the following accessories and consumables:
• Universal AC/ DC power supplies and cables
• Battery
• Oxygen and/or air hose(s).
• Disposable patient circuits for Infant, pediatric, and adult.
• Oxygen Reservoir Kit
• A padded case (that shall be able to enclose the ventilator, accessories, and consumables)
3.1.103.2 Optional configuration (for the US Army): the ventilator shall come with the following accessories and consumables:
• Universal AC/ DC power supplies and cables
• Battery
• Oxygen and/or air hose(s).
• Disposable patient circuits for Infant, pediatric, and adult.
• Oxygen Reservoir Kit
• A padded case (that shall be able to enclose the ventilator, accessories, and consumables)
• A reusable transit case (hard case) that meet the 3.1.60 requirement above

OTHER REQUIREMENTS:

3.1.104 The Portable Ventilator unit shall meet other requirements for reliability, maintainability, and supportability as described in section 4.
3.1.105 The Portable Ventilator unit shall meet other requirements for Warranty, Training, and Manuals as described in section 5.
3.1.106 The Portable Ventilator unit shall meet other requirements for Quality and Standards as described in section 6.

4. Reliability, maintainability, and supportability requirements: The Portable Ventilator units shall meet the following reliability, maintainability, and supportability requirements:

- Offerors shall submit user references for the offered systems
- Maintenance support items should be commercially available and not proprietary.
- Ventilator consumables and connections shall be common to all services and levels of care
- The systems shall be field maintainable by military biomedical engineering technicians. This includes unimpeded access to technical literature, parts, schematics, and other information necessary to repair and maintain the devices.
- Offerors shall submit reliability and maintainability data, to include mean time between failures (MTBF) and mean time to repair (MTTR) with any offered system.

5. Warranty, Training, and Manuals:

- Warranty. At a minimum, the device should have one-year manufacturer's warranty. Warranty shall be as specified in the procurement purchase order/contract(site warranty required)
- Operation/user Manual. The unit must contain commercial operations manual which include

preflight/testing procedures and identifies spare parts list- document will be used to develop Army/ Air Force Technical Order manuals.

- Maintenance/service manual to include service schematics and service interval schedule.

- **Parts:** include all parts, carrying cases, disposables, dimensions, and weight of device and all accessories. Note: Spare parts are required to be considered for an award.
- **Power:** include battery type, power requirements for plug-in capacity and use with international electrical standards, as well as total Amperage used during normal function and maximum amperage use. Include minimal length of time for battery to reach full operational capacity from battery empty. Also length of continuous use without replacing or recharging battery and steps to change from battery power to plug in capability. Charge indicator guidance.
- **Pre-Flight**: Steps to prepare device prior to use or transport
- **Positioning/Securing Procedures:** Include recommendations for securing device for transport
- **Performance:** Include specifics on use by Pediatric patients if applicable, training on functionality, safety warnings and cautions.
- **Cleaning:** Product will be easily cleaned and document if reusable in accordance with Air Force (AF) Infection Control Standards. (http://www.epublishing.af.mil/shared/media/epubs/AFI44-108.pdf).
- **Repair:**

- Including tools required and spare parts list. Maintenance manual to include service schematics and service interval schedule.
- Spare parts list to include details and part numbers.
- Repairing the device must not require use of proprietary tools or test equipment.
- Must conform to requirements to be supportable by current BMET kit.
- Vendor must provide initial training (one session) on functionality. Training will take place at U.S. Military bases. For example, the Air Force will provide facility at Scott AFB, IL for training as well as travel (i.e. airfare, hotel, and per diem) on a cost- reimbursable basis in accordance with the Joint Travel Regulations.

6. Regularity, quality, and standard requirements:

- **Federal Food, Drug, and Cosmetic Act.** If the product covered by this document has been determined by the U.S. Food and Drug Administration to be under jurisdiction, the offeror/contractor shall comply, and be responsible for compliance by its subcontracts/ suppliers, with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, and regulations promulgated there under. In addition, the offeror/contractor shall comply and be responsible for compliance by its subcontractors/suppliers, with the requirements of all other applicable Federal, State, and Local regulatory requirements
- Association for the Advancement of Medical Instrumentation (AAMI), Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices (AAMI HE48-1993) and Safe Current Limits for Electro medical Apparatus (ANSI/AAMI ES1-1993).
- **Standards:** Unit shall comply with the following standards.
- Compressed Gas Association, Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections (CGA STD V-1) and Diameter-Index Safety System (DISS CGA STD V-5).
- Department of Defense, Requirements for the Control of Electromagnetic Interference Emissions and Susceptibility (MIL-STD-461D 11 Jan 93), Measurement of Electromagnetic Interference Characteristics (MILSTD-462D),
- Underwriters Laboratories (UL) Standard 544, Standard for Safety of Electrical Medical and Dental Equipment.
- Shall be provisioned in accordance with the DEPMEDS provisioning code "E" to include:

DI-ILSS-80865	Medical Support Kit Lists.
DI-ILSS-80868	Special Equipment Tools and Test Equipment List
DPSC-A	Special Equipment Commercial Service Manual
DPSC-B	Special Equipment Commercial Operating/Instruction Manual
DI-ILSS-80872	Training Materials

DI-V-7000A	Supplementary Provisioning Technical Documentation
DI-V-7009A	Design Change Notice
DI-ILSS-80867	Equipment Consumable/Durable Support Items List

- Comply with the International Organization for Standardization quality standards.
  ISO 9000

(http://www.iso.org/iso/search.htm?qt=9000&sort=rel&type=simple&published=true)

- Comply with the requirements for Emergency, Transport, and Critical Care Ventilators.
  ISO 10651-3:1997
  (http://www.iso.org/iso/iso_catalogue/catalogue tc/catalogue_detail.htm?csnumber=21436)
  ISO 80601-2-12:2011
  (http://www.iso.org/iso/iso catalogue/catalogue tc/catalogue_detail.htm?csnumber=51141)
- Meet the requirements of NFPA 99 Standard for Health Care Facilities
  (http://www.nfpa.org/aboutthecodes/AboutTheCodes.asp?DocNum=99&cookie%5Ftest=1)
- Product will be easily cleaned and reusable lAW AF Infection Control Standards.
  (http://www.e-publishing.af.mil/shared/media/epubs/AFI44-108.pdf)
- Vendor must provide proof of compliance with FDA regulations in accordance with Title 21of the Code of Federal Regulations
  (http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm)
- Selected device will be sent for testing and must be able to obtain joint air worthiness certification for all USAF Mobility Air Forces (MAF) aircraft and rotary wing aircraft as well as work well in fixed facilities.
  Model must be static tested and approved by FAA AWC requirements lAW MIL-STD-810G, Environmental Engineering Considerations and Laboratory Tests, 31 OCT 08; Mil STD 461; AFI10-2909; AFOSHSI91-501.
  (http://www.everyspec.com/MIL-STD/MIL-STD+(0800+-+0899)/MIL-STD-810G_12306/)
  (http://www.everyspec.com/MIL-STD/MIL-STD+(0300+-+0499)/MIL-STD-461F_19035/)
  (http://www.e-publishing.af.mil/shared/media/epubs/AFI10-2909.pdf)
  (http://www.e-publishing.af.mil/shared/media/epubs/AFOSHSTD91-501.pdf)

Selected device will be sent for testing and must be able to obtain joint air worthiness certification for all USAF Mobility Air Forces (MAF) aircraft and rotary wing aircraft as well as work well in fixed facilities.
Model must be static tested and approved by FAA AWC requirements lAW MIL-STD-810G, Environmental Engineering Considerations and Laboratory Tests, 31 OCT 08; Mil STD 461; AFI10-2909; AFOSHSI91-501.

(http://www.everyspec.com/MIL-STD/MIL-STD+(0800+-+0899)/MIL-STD-810G_12306/)
(http://www.everyspec.com/MIL-STD/MIL-STD+(0300+-+0499)/MIL-STD-461F_19035/)
(http://www.e-publishing.af.mil/shared/media/epubs/AFI10-2909.pdf)
(http://www.e-publishing.af.mil/shared/media/epubs/AFOSHSTD91-501.pdf)

Air Worthiness Testing Standards (Note: Testing results will be expressed as Risk Assessment Codes (RAC) according to MIL-STD-882D **Acceleration:** MIL-STD-810G, Method 513.6 and applicable portions of MIL-HDBK-516, MIL-STD- 209K, MIL-HDBK-1791 Procedure III): Verify that items of high mass (objects that can cause injury to occupants) will hold their spatial position relative to the occupants under design crash loads. The inertial design loads should be as following:

fixed-wing (C/KC 135 SPO Specification): 9g forward, 1.5g aft, 4g lateral, 8g down, and 4g up; rotary-wing (SES-700700): 15g forward, 12g aft, 12g lateral, 13g down, and 8g up.
Longitudinal: 9.0g forward, 1.5g aft. Lateral: 4g right/left. Vertical: 8g down, 4g up (Sustained loading for 6 sec duration)
Vibration: MIL-STD-810G Method 514.5
On X, Y, & Z axisJet: 20-2000 Hz for30 mins.@ 4.02 Grms Turboprop: 15-2000 Hz for 60 mins. @ 5.02 Grms Rotary Wing: 10-500 Hz for 60 mins. @ 1.58 Grms
Operational Climate: MIL-STD 810G, Method 501&502 (Note: Repeat two more times at the most extreme temperature at which the medical carry-on equipment passed)
High Temp: 49C, 2h, 1 cycles, <20% R.H.Low Temp: 0C, 2h, 1 cycle
Storage Climate: MIL-STD 810G, Method 501&502
High Temp: 60C, ±2C 6h, 1 cycle, <20% R.H.Low Temp: -40C, ±2C6h, 1 cycle
Humidity: MIL-STD 810G Method 507.4
94 ±4% at 29.5oC ±2oC, 4 h, 1 cycle
Altitude: MIL-STD 810G Method 500.4
2,000, 4,000, 6,000 8,000, 10,000 12,500, 15,000, & 18,000 ft. 2-5 min at each level
(Ascend/descend rate: 2000/5000 fpm)
Rapid Decompression; MIL-STD 810G Method 500.4
Ascend to 8,000 ft., then to 45,000 ft. in 60, 7 and 1 sees.
Explosive Atmosphere: MIL-STD 810G Method 511.4
Exposure to 3.8% volumetric fuel vapor (8.33 AVR by weight) (120oC)
(Change Notice 1): This protocol involves placing the device in a test chamber, decreasing the ambient pressure to 10,000 ft. equivalent, and exposing it to a heated fuel air atmosphere. The device is turned on and off three times. Testing is repeated at ground level.
EMI Testing: MIL-STD-461F
RE102: Electric Field, 10 kHz -18 GHz
RS103: Electric Field, 2-30 MHZ, 20 V/m
RS103: Electric Field, 30 MHz -1GHZ, 20V/m
RS103: Electric Field, 1-40 GHZ, 60 V/m
CE102: Pwr Leads, 10kHz -10 MHz
CS101: Pwr Leads, 30 Hz 150 kHz
CS114: Bulk Cable Injection, 10 kHz -200 MHz
CS115: Bulk Cable Injection, Impulse Excitation
CS116: Dmpd Transients, Cables/Pwr leads, 10 KHz-100 MHz

The U.S. Army Aviation and Missile Command (AMCOM) and the U.S. Army Aeromedical Research Laboratory (USAARL) need to review and concur with EMI test results per AR 70-62 and AR 40-61.
ASC/ENAE needs to review and concur with EMI test results per AFI 11-202V3.

Flight Testing:

(1) Fixed Wing: The device is evaluated during actual aircraft flights by aeromedical evacuation crewmembers to validate laboratory findings and assess human factors (human factors assessment additionally guided by MIL-STD-1472G) during in-flight operation. USAF in-flight operational test of evaluation performed in cooperation between 311 HSW/Yamland AMC/33FTS.

(2) Rotary Wing for each type of Airframe:
(a) Aircraft EMC (AMCOM - Approved Flight Test Plan): Spectrum Analyzer testing all frequencies as they relate to the aircraft Electro-Explosive Device (Squib Test) for all onboard devices such as fire bottles, etc.
Ground EMC (Aircraft as victim)
Hover EMC (Aircraft as victim)

Altitude EMC (Aircraft as victim)

(b) Performance and Susceptibility Assessments (USAARL - Approved Flight Test Plan) :
Electromagnetic Susceptibility Assessment (PMI as victim)
Ground Human Factors Assessment
Flight Human Factors Assessment
Medical Assessment

7. Feedback Requested

The purpose of this RFI is to assess the commercial industry's ability and or capabilities to provide a lightweight, compact, portable, self-contained ventilator. The response to the structured questions listed below will provide DLA Troop Support with the desired information. Respondents are encouraged to provide any additional information including related topics outside of the specific information requested.

1. Does your firm currently manufacture or have the ability to provide a portable ventilator specifically as specified herein?

2. Would your company be interested in responding to a future solicitation for the ventilator outlined in this RFI?

3. Would any PHI/PII be transferred over any type of network, for example wirelessly or thru network cables?
   -If so, does equipment have Authorization to Operate (ATO), or items for which the Vendor agrees to go through the IA approval process and obtain an RMF ATO?
   -Any offered equipment must meet DoD Cybersecurity/Risk Management Framework (RMF) and the attached Service Information Assurance (IA) requirements. **Vendors are required to provide a statement with their quote that they agree to the Service Cybersecurity/IA Requirements, HIPAA requirements and B2B requirements that are attached to this RFO**
   Vendors are required to provide a completed Joint Medical Device Risk Assessment Questionnaire (v2.0) for the offered system along with their offer.

4. Vendors must provide a plan on how the device will provide data at rest encryption for all PHI/PII stored (temporarily, or permanently) on the system.

5. Is there any information or requirement(s) that you feel is relative to this RFI that is missing?

Any information provided in response to this RFI will be considered and treated as unrestricted information which can be used by the Government in any future planning or acquisitions. DLA Troop Support does not anticipate awarding a contract in response to this RFI. All information comments and suggestions determined to be beneficial to DLA Troop Support may be incorporated into future acquisition documents, including solicitations or contracts, without identifying the source or obtaining prior approval from the source.

The Government shall not be responsible or liable for any costs incurred by any party in the preparation and submission of any response to this RFI.

8. The following documents are provided for as supporting attachments to this RFI:

Attachment A: Portable Ventilator Compliance Spreadsheet

9. Submission Address/Points of Contact. All Submissions, questions, and inquiries regarding this RFI should be directed to the following POC's:
E-mail responses should be no larger than 5 megabytes (MB) in size. If larger attachments are required, additional methods to submit responses include:
Sending documents separately due to size restrictions, as long as each e-mail indicates how many total e-mails are being sent.

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