SOCOM254-D002: Operator Portable Oxygen Generation Device

ADDITIONAL INFORMATION
N/A

TECHNOLOGY AREAS:
None

MODERNIZATION PRIORITIES:
Advanced Materials | Biotechnology

KEYWORDS:
O2; Oxygen; Oxygen Therapy; Oxygen Generator; Oxygen Generation; Portable Oxygen; Oxygen Device

OBJECTIVE:
The objective of this topic is to develop applied research toward an innovative capability to improve oxygen therapy at point-of-need in an austere prehospital environment. The goal is to develop a field instrument that is rugged, compact, and able to provide oxygen to patients and oxygen generation capabilities as far-forward as possible to reduce the need for oxygen cylinders.

DESCRIPTION:
The capability to provide oxygen therapy and generation far-forward will incorporate a design that is both durable and small-scale so that it is both portable and able to withstand travel and ground movement while simultaneously providing the necessary oxygen concentration to an adult patient and is able to generate oxygen by separating it from other gases in the atmosphere. As a part of this feasibility study, the proposers shall address the design options with specifications on the key equipment attributes:

- Able to generate and provide oxygen purity of 93% +/- 3%.
- Able to provide 15 liters per minute and capable of supporting multiple patients.
- Device must meet MIL-STD-810H and Environmental – Joint Enroute Care Equipment Test Standards.
- Device must be dual voltage with battery pack capability; capable of running off “shore” power.
- Battery has a run-time of 6 hours.
- Battery charging is compatible with universal USB-C; compatible with external AC/DC (110/240 VAC/12-24 VDC).
- Batteries are swappable without device losing memory or settings; must not require use of hold up battery.
- Battery recharge time is <35 minutes.
- Device has a replace sieve bend and replaceable / cleanable filter(s).
- Device must be able to fit within a standard “D” size oxygen cylinder mount (4.5” diameter x 20” length).
- Device is compatible with standard connectors.
- Device must have a tactical setting that allows audible alarms to be completely disabled or reduced to a level acceptable by the FDA.
- Device must have a tactical setting that changes all light sources or visual screens to the lowest level acceptable by the FDA.
- Device must weight < 5 lbs.
- Device is easily transportable by a single person.

PHASE I:
Conduct a feasibility study to assess what is in the art of the possible that satisfies the requirements specified in the above paragraphs entitled “Objective” and “Description.”
The objective of this USSOCOM Phase I SBIR effort is to conduct and document the results of a thorough feasibility study (“Technology Readiness Level 3”) to investigate what is in the art of the possible within the given trade

space that will satisfy a needed technology. The feasibility study should investigate all options that meet or exceed the minimum performance parameters specified in this write up. It should also address the risks and potential payoffs of the innovative technology options that are investigated and recommend the option that best achieves the objective of this technology pursuit. The funds obligated on the resulting Phase I SBIR contracts are to be used for the sole purpose of conducting a thorough feasibility study using scientific experiments and laboratory studies as necessary. Operational prototypes will not be developed with USSOCOM SBIR funds during Phase I feasibility studies. Operational prototypes developed with other than SBIR funds that are provided at the end of Phase I feasibility studies will not be considered in deciding what firm(s) will be selected for Phase II.

PHASE II:

Develop, install, and demonstrate a prototype system determined to be the most feasible solution during the Phase I feasibility study on an operator portable oxygen generation device that can provide expeditious results to address patient oxygen therapy and oxygen generation as far-forward as possible to reduce the need for multiple oxygen cylinders. During the first year, the prototype(s) will be tested in simulated environments (>40oC, <0oC, humidity > 90%, 10,000 ft elevation) in order to determine practical viability. The second year will involve refinement and more rigorous testing of the chosen design in contractor-arranged laboratory studies to determine purity of the oxygen produced and accuracy of flow rates. Testing and refinement will involve the device's adherence to battlefield constraints; the device must be portable, lightweight (~2 kg), self-contained, have low power requirements (i.e. can operate continuously for 4 hours on a single battery), quiet (<45db), have stacking capability, and perform to all needed parameters concurrently. The phase II commercialization plans should include a regulatory plan for FDA clearance. The contractor would ideally identify appropriate potential commercialization partners (manufacturing, marketing, etc.) to facilitate technology transition.

PHASE III DUAL USE APPLICATIONS:

This system could be used in a broad range of military applications where an operator portable oxygen generation device can provide patients with oxygen therapy and reduce the logistical burden of needing oxygen cylinder replacements. Phase III will consist of finalizing the device design and delivering manufactured devices (in their final form) for military-relevant testing such as airworthiness/performance testing and FDA-related testing (e.g. oxygen purity, accuracy of flow rates, etc.) under design freeze. The device will be functional for use by special operations forces medics, physician assistants, nurses, and physicians in far forward environments. Phase III will also include developing and finalizing training methods and protocols for the new device. In addition, the regulatory package should be in its final form ready for submission to the FDA, including all relevant test data. Other agencies interested in this technology include patient treatment programs, emergency response teams, and other federal directorates.

REFERENCES:

1. Joint Trauma System Clinical Practice Guideline (JTS CPG) Acute Respiratory Failure (CPG ID: 06) CPG 06 - Acute Respiratory Failure
2. MIL-STD-810H – Environmental Engineering Considerations and Laboratory Tests MIL-STD-810H
3. Joint Enroute Care Equipment Test Standard (JECETS) JECETS
4. U.S. Food & Drug Administration FDA - Products and Medical Procedures Landing Page
5. American College of Surgeons, and Committee on Trauma. Advanced Trauma Life Support: Student Course Manual. 2018
6. Douin DJ, Schauer SG, Anderson EL, Jones J, DeSanto K, Cunningham CW, Bebarta VS, Ginde AA. Systematic review of oxygenation and clinical outcomes to inform oxygen targets in critically ill trauma patients. J Trauma Acute Care Surg. 2019 Oct 1, 87(4):961-77
7. McMullan J, Hart KW, Barczak C, Lindsell CJ, Branson R. Supplemental oxygen requirements of critically injured adults: an observational trial. Military medicine. 2016 Aug 1, 181(8):767-72

TOPIC POINT OF CONTACT (TPOC):

None