STATEMENT OF WORK (SOW)

Portable Oxygen Generator System (POGS) Prototype Project

Other Transaction Agreement (OTA) Pursuant to 10 U.S.C. § 4022
Agreement Number: [To Be Determined]
Sponsor / Requiring Activity: CPE Ground, Soldier Medical Devices (SMD)
Date: [Award Date]

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1.0 Background & Authority

Executive Summary & Background

The Portable Oxygen Generator System (POGS) is a critical medical device used in deployed field hospitals at Role of Care (ROC) 3. The system provides medical-grade oxygen (93% ± 3% United States Pharmacopeia (USP)) and at 50 Pounds per Square Inch in Gas (PSIG) to support patient care, anesthesia equipment, ventilators, and high-pressure cylinder refilling in austere and remote operational environments.

The currently fielded system, the POGS-33C-HV (first fielded in 2005), presents significant operational and logistics challenges, including excessive weight (790 lbs.), high maintenance burdens, and specific 120/208 VAC, 3-phase power requirements. The continued use of legacy oxygen generation capability without modernization negatively impacts operational medical support effectiveness in austere environments.

To address these limitations, the Government initiated this prototype project to develop a next-generation Portable Oxygen Generator System (POGS) that is lighter, more maintainable, and tactically mobile.

This agreement is executed under the authority of 10 U.S.C. § 4022 for prototype projects. As a non-FAR-based Other Transaction Agreement (OTA), standard Federal Acquisition Regulation (FAR) and Defense Federal Acquisition Regulation Supplement (DFARS) clauses do not apply unless explicitly incorporated by reference or full-text herein.

2.0 Objectives

The primary objective of this effort is to design, develop, deliver, and demonstrate prototype POGS units that meet the Army's operational needs for a rapidly deployable field medical capability. Specific objectives include:

- **Prototype Delivery:** Manufacture and deliver two (2) prototype POGS units capable of oxygen generation at ≥30 Liters Per Minute (LPM) at ≥93% ±3% USP purity under operational and environmental test conditions.
- **Mobility & Power:** Demonstrate system operation within the weight threshold of ≤350 lbs., achieving the desired objective of ≤200 lbs., with single or dual-voltage automatic voltage detection from 110–120 VAC/60 Hz or 220–240 VAC/50 Hz.
- **FDA Clearance:** Achieve Food and Drug Administration (FDA) 510(k) clearance (Class II) or registration (Class I) within 12–24 months of agreement award.
- **Testing Support:** Support Government Operational Testing and Environmental Testing (MIL-STD-810H) to validate system survivability and operational effectiveness.

3.0 Scope of Work

This SOW encompasses the design, manufacture, quality assurance, packaging, and delivery of two (2) prototype POGS units. The Performer is responsible for end-to-end supply chain management, assembly, factory acceptance testing, and providing necessary technical documentation, training, and testing support.

4.0 Tasks & Requirements

4.1 Program and Production Management

The Performer shall manage all technical, schedule, and quality activities required to execute the prototype project.

- **Production Kickoff:** The Performer shall participate in a Kickoff meeting within fourteen (14) days of agreement award.
- **Bi-Weekly Meetings:** The Performer shall participate in bi-weekly meetings commencing fifteen (15) days after award.
- **Risk Reporting:** The Performer shall notify the Agreements Officer Representative (AOR) of any risks or issues that impact the delivery schedule or technical performance within two (2) business days of identification.

4.2 Technical Requirements & Configuration

The Performer shall manufacture and assemble the POGS units in strict accordance with the Critical Operational Device Specifications (CODS) and Critical Logistical Specifications (CLS).

- **Oxygen Flow & Purity:** Generates medical-grade oxygen at ≥30 LPM total oxygen at ≥93% ±3% USP purity at 50 PSI to support simultaneous operation of anesthesia equipment and ventilators.
- **Weight:** Total system weight must be ≤350 lbs.
- **Power:** 110–120 VAC, 60 Hz OR 220–240 VAC, 50 Hz with automatic voltage detection.
- **Alarms:** The system shall include alarms or automated safeguards that detect conditions affecting oxygen purity, system performance, and patient safety.

4.3 Quality Management and FDA Compliance

- **QMS:** The device shall be manufactured under a compliant Quality Management System (QMSR/ISO 13485).
- **FDA Status:** The Performer must submit a regulatory milestone schedule (pre-submission/Q-Sub meeting, testing completion, 510(k)/De Novo submission) projecting a path to clearance within 12–24 months.

4.4 Cybersecurity

The system must be a standalone device that does not require Wi-Fi, internet connectivity, or network connections for functionality. The Performer shall complete the Medical Device and Equipment Risk Assessment (MDERA) supporting cybersecurity compliance and Authority to Operate (ATO) activities within 30 days of award.

4.5 Deliverable Documentation & Data Rights

The Government shall obtain Government Purpose Rights (GPR) to all technical data, operator manuals, training videos, and provisioning data delivered under this Agreement. The following data deliverables shall be provided:

ADRL	Deliverable	Format / Submission Frequency
D-001	Prototype POGS Units (2)	Physical delivery, 120–180 days after award
D-002	User/Operator Manual	1 Physical, 1 Digital per device with unit delivery
D-003	Maintenance/Service Manual	1 Physical, 1 Digital with unit delivery
D-004	Repair Parts List	Electronic Spreadsheet, 15 days after award
D-005	MDERA Questionnaire	Digital PDF, 30 days after award
D-006	TAA Compliance Certificate	Signed Document, At Award
D-009	FDA Clearance Documentation	Official FDA Letter, Within 12–24 months
D-010	Special Tools List	Electronic Document, 15 days after award
D-011	Copyright/Distribution Release	Signed Letter, 60 days after award

4.6 Training & Warranty

- **Training:** The Performer shall provide two (2) on-site CONUS operator training sessions at an agreed-upon date and location for approximately 5–10 people per session. The Performer shall also provide one operational video training or access to a training site per device.
- **Warranty:** The Performer shall provide a minimum one (1) year warranty covering all parts, in-house labor, and technical support.

5.0 Period of Performance & Milestones

The agreement period for this prototype effort is twelve (12) months from the date of award.

- **M-01:** Award / Kickoff Meeting - NLT 14 days after award
- **M-02:** MDERA Submission - NLT 30 days after award
- **M-03:** Prototype Unit Delivery (2 units) - 120–180 days after award
- **M-06 / M-07:** Government Operational Testing (MTEAC) & Environmental Testing (MIL-STD-810H) - Scheduled following prototype delivery
- **M-08:** FDA Clearance / Registration - Per milestone schedule (12–24 months)

6.0 Place of Performance

All manufacturing, assembly, and quality control shall be performed at the Performer's facility. Delivery and testing locations will be designated by the Government (CONUS).

7.0 Security Considerations

This effort is classified Controlled Unclassified Information (CUI). The Performer shall comply with all applicable security requirements, including 48 CFR 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting). An AT/OPSEC review has been completed in accordance with DHA Form 337.

8.0 Travel Requirements

All travel costs (transportation, lodging, per diem) required to support the two (2) CONUS operator training sessions and testing support shall be included in the firm fixed price of the agreement.

9.0 Transition to Follow-On Production

Upon successful completion of prototype testing and validation, the Government may pursue follow-on production of up to approximately 304 POGS units during FY28 through FY32 without further competition, pursuant to 10 U.S.C. § 4022(f). The Performer shall work with DLA Troop Support to add the finalized product to the ECAT contract vehicle, a 3rd party, or Prime Vendor agreement.