

STATEMENT OF WORK (SOW)
VA Buffalo
as of March 5, 2018

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| Contract Number: | |
| Task Order Number: | |
| IFCAP Tracking Number: | |
| Follow-on to Contract and Task Order Number: | "Not Applicable" |

1. Contracting Officer's Representative (COR):

| | |
|---------------|---------------------------------------|
| Name: | Wade Sidley |
| Section: | Biomedical Engineering |
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2. Contract Title: Critical Care Ventilator fleet replacement to provide Airway Pressure Release (APRV) mode of ventilation, additional weaning, transport capability, and fully disposable exhalation valves.

3. Background: VA Buffalo Respiratory Therapy department has aging Draeger Evita XL ventilators that need to be upgraded to new Draeger technology that provides APRV mode of ventilation with auto release for our trauma patients with Acute Respiratory Distress Syndrome. Additionally, we need the safety benefits of the gas supply and power supply units that will allow our department to transport critical ventilated patients to radiology and other areas of the hospital. In addition the department is in need of more ventilators to cover the weaning of patients that are outside of the ICU.

- Early implementation of APRV as compared with the other trauma centers represented lower mean Adult Respiratory Distress Syndrome incidence (14% vs. 1.3%) and in-hospital mortality (14.1% vs. 3.9%).
- Reducing alarm fatigue by reducing alarms: The number of airway pressure alarms in the AutoFlow group was less than in the control group (122 vs. 565).
- Increasing Staff Satisfaction
 - Maintaining state licensure without having out of pocket expenses: Draeger's "A Breath Ahead" website provides 6,000 free CEU's annually. In addition, Draeger's partner Intensive Care Online Network provides 24x7 clinical support

as well as free interactive CEU offerings. During 2014's Respiratory Care week ICON provided 3,000 CEU's to Draeger customers

4. **Scope:** This contract will replace the fifteen (15) existing depreciated Draeger Evita XL ventilators with the newest Infinity V500 ventilators and provide for five (5) more Draeger Infinity V500 Ventilators as the budget will allow to give the department the flexibility in out of ICU treatment and transport modality that is urgently needed.

5. **Specific Tasks:**

1. The contractor will provide all necessary labor, parts, transportation and equipment needed for installation of the Draeger Infinity V500 ventilators.
2. The vendor will provide the new Infinity V500 ventilators as required in the PO within 60-90 days after receipt of order and ship to VA Buffalo.
3. Draeger will ship, unbox, assemble and test the ventilators, remove debris and packing material to a place designated by the facility staff.
4. The vendor Technical Support Specialist will coordinate the inventory and unbox and assemble the ventilators at a work site specified with the Biomedical Engineers at the Buffalo VAMC.
5. Draeger Clinical Application Specialist will coordinate the training and go live with the clinical and biomedical staff providing a minimum of 5 days of clinical training onsite.
6. After productive use of the new ventilators, the sales representative will arrange the pickup of the trade-in machines and the TSR will document the start of the 3 year warranty.
7. Trade in of fifteen (15) Evita XL ventilators. Pick up to be coordinated with the biomedical staff and respiratory department.
8. Ventilators shall have APRV-a (Airway Pressure Release Ventilation with Auto-release) mode available for use with patients with ARDS (Acute Respiratory Distress Syndrome).
9. Ventilators shall support the following:
 - Invasive Ventilation
 - Non-invasive Ventilation
 - High Flow (Hi-Flow) Oxygen

- Volumetric Capnography (VCO₂) capabilities that include end-tidal CO₂ (ETCO₂) and VCO₂ with dead space and V_d/V_t ratio values.
10. Ventilators shall support spontaneous breathing modes and weaning parameters (P0.1, RSBI, NIF).
 11. Ventilators shall have integrated pneumatic nebulizers; ventilators shall be able to provide automatic compensation for delivered tidal volume and Fraction of Inspired Oxygen (FIO₂).
 12. Ventilators shall be compatible with fully disposable flow sensors and exhalation systems.
 13. Ventilators shall have batteries with the ability to supply power to the main ventilator unit and compressor for a minimum of two (2) hours.
 14. The offering vendor shall provide the following with procurement of the proposed ventilators:
 - Access to an online support network supported by the Original Equipment Manufacturer (OEM). This support network shall be available at all times throughout the day (24/7). This support network shall provide VAWNYHS staff with clinical/ technical support along with educational support for the proposed ventilators.
 15. Additional Biomedical Engineering Requirements:
 - i. The offering vendor shall provide details of the Evita V500 clinical and technical alarms.
 - ii. Switches and controls of the proposed ventilators should be protected against accidental setting changes (e.g., due to someone brushing against the panel / screen). Device design should prevent misinterpretation of displays and control settings. The controls (i.e., switches, knobs, etc.) should be visible and clearly identified, and their functions should be self-evident.
 - iii. The offering vendor certified that operator safety and system performance should not be adversely affected by fluid spills.
 - iv. The offering vendor certifies that the proposed ventilators shall withstand normal hospital power interruptions, including generator testing, without manual intervention and that normal device operation will be restored

automatically, without loss of data, once power is restored. The offering vendor shall specify and provide power conditioning if required.

- v. The offering vendor shall confirm that the performance of the proposed ventilators shall not be affected by EMI radiated or conducted through the power lines from another device.
- vi. The offering vendor shall provide a listing of all Recalls, Safety Alerts and Field Engineering Change notices pertaining to the proposed ventilators over the past 24 months.
- vii. Cleaning and disinfecting protocols for the proposed ventilators shall be provided and demonstrated to staff by the offering vendor. A list of acceptable cleaning and disinfecting chemistries shall be included with the purchase of the proposed ventilators.
- viii. The offering vendor shall provide two copies of all service literature, including any necessary service and maintenance software, keys, and or passwords (in accordance with: 21-CFR 820.170(a), NFPA99 (2012 edition) Chapter 10.5.3, VAAR 852.211-70, and the VA NAC AS3000 clause).
- ix. Technical Training for at least one Biomedical Engineering Support Specialist (BESS) should be included in the proposal.

6. Additional Specific Tasks - Enterprise Management Controls:

6.1.1 Subtask 1 - Integration Management Control Planning:

Training and Service Requirement:

The contract includes training seminar for V series Ventilators:

During this five day course, students will become skilled in identifying assemblies/subassemblies and enhance their knowledge and understanding of device functions. Basic troubleshooting as well as hands-on training will be included. Upon successful completion of this course, students will be able to identify and understand the functions of the pneumatic and electrical systems of the V500 and VN500, including the Human Interface Testing (HIT) software and the optional gas supply unit (GS500). The student will also learn how to perform a scheduled Preventive Maintenance Inspection.

Each course concludes with a timed written or practical exam. Seminar participants must attain a grade of 70% or better to satisfactorily complete each course. Certificates

and Continuing Education Units (CEU's) are only issued following satisfactory completion for the course. A grade transcript will be issued upon request for a nominal fee.

Travel and per diem has not been requested to be included in the cost of the training.

The Elite Care program includes a 5 year subscription to ServiceConnect which provides online access to remote service, manuals, service bulletins and documentation needed to maintain the ventilators

6.1.2 Subtask 2 - Contract Management:

Service: Vendor will supply 24 hr. phone technical support for the duration of ownership of the equipment.

The purchase of Dräger ventilators includes invaluable clinical support from ICON (Intensive Care Online Network) a Dräger exclusive at no charge.

Warranty: The vendor shall provide the Elite Care program for the ventilators. Elite Care is a biomedical partner contract that provides the means for the hospital biomedical staff to completely maintain the Draeger V500 ventilators for 5 years. It includes a 5-year subscription to ServiceConnect, which provides online access to remote service, manuals, service bulletins and documentation needed to maintain the ventilators, a 3-year extended warranty, and 5 years of Preventive Maintenance (PM) kits.

Training: The vendor shall provide a minimum of 5 eight hour days clinical training to Respiratory department on-site staff as determined by the director.

Existing Inventory: Vendor is responsible for removing the ventilators designated for trade-in from VA property

7. Performance Monitoring:

Contact with the vendor will continue after the equipment is purchased and setup to ensure systems are working correctly.

8. Security Requirements:

Vendor will not have access to VA computer systems or sensitive information. Vendor has also filled out the required paperwork to come on grounds to present information/demonstrations when necessary.

9. Government-Furnished Equipment (GFE)/Government-Furnished Information (GFI).

N/A

10. Other Pertinent Information or Special Considerations:

a. Identification of Possible Follow-on Work.

N/A

b. Identification of Potential Conflicts of Interest (COI).

No potential conflicts of interest are known. Draeger Medical is a large company with a sizeable employee base. With the diversified nature of Draeger Medical's business, there are no centralized databases to permit Draeger Medical to access information on a world-wide basis, or even across divisions to determine whether conflicts exist.

c. Identification of Non-Disclosure Requirements:

There will be no access to sensitive or proprietary information by the contractor.

d. Packaging, Packing and Shipping Instructions.

N/A

e. Inspection and Acceptance Criteria.

Inventory of equipment received will be signed off by Draeger Technical Service Specialist and the hospital biomedical staff to assure that everything ordered was received.

Acceptance of the equipment will be confirmed by the clinical and biomedical staff on first productive use. The Draeger Technical Service Specialist will then start the 3 year warranty, 5 years of PM kits and ServiceConnect.

11. Risk Control:

Safety precautions for the V500 ventilator are included in the operator's manual that will be provided electronically on each device. Minimal disruption of the Respiratory department and ICU schedule is anticipated. The set up and exchange of the machines will be coordinated with the COR and Biomedical team.

12. Place of Performance:

The work will be performed at VA Buffalo in Biomed designated area and the ventilators will be installed in designated areas.

13. Period of Performance:

Period of performance is expected 8-12 weeks after contract is awarded for initial installation and 5 years thereafter for annual PM kits.

14. Delivery Schedule:

| SOW Task# | Deliverable Title | Format | Number | Calendar Days After CO Start |
|-----------|-----------------------------------|--|----------------------------|--|
| 1 | Ship Draeger V500 Ventilators | Contractor shipping preferences | 20 ventilators | 8-12 weeks |
| 2 | Unbox, assemble, test ventilators | Draeger Technical Service Representative | 20 Ventilators | Coordinated with RT department and Biomed. |
| 3 | Clinical Training | Clinical Application Specialist | RT staff determined by COR | Timing determined by COR/RT and Biomed |
| 4 | Start of 3 year Warranty | By TSR after first productive use | 20 Ventilators | After first productive use |
| 5 | Biomedical Training | At Draeger HQ Telford, PA | One Biomed | Within two years of award |