

MEPNN Supplier Scouting Opportunity Synopsis

Section 1: General Information

Scouting Number	2024-025
Item to be Scouted	Various Positive Airway Pressure (PAP) Machines
Days to be scouted	30
Description	<p>The Office of Veteran's Affairs (VA) is seeking market research type information from and availability of domestic accredited medical equipment manufacturers of PAP machines.</p> <p>Types of Machines:</p> <ol style="list-style-type: none"> 1. Auto-Titrating Continuous Positive Airway Pressure (APAP) Machine 2. Bilevel Positive Airway Pressure (BPAP) Machines with and without Spontaneous-Timed (S/T) Capabilities 3. Auto-Titrating Bilevel Positive Airway Pressure (BPAP) Machines 4. Volume Assured Pressure Support (VAPS) Machine 5. Adaptive Servo-Ventilation (ASV) Machine
State item to be used in	Colorado

Section 2: Technical Information

Type of supplier being sought	Manufacturer
Reason	Re-shore
Describe the manufacturing processes (elaborate to provide as much detail as possible)	Electronic/Mechanical Assembly
Provide dimensions / size / tolerances / performance specifications for the item	<p>Technical Standards (as applicable to the different types of machines):</p> <p>See attachment.</p>
List required materials needed to make the product, including materials of product components	Various. Dependent upon the machine, manufacturer, and process.
Are there applicable certification requirements?	Yes
Are there applicable regulations?	Yes
Details	<p>General Standards:</p> <ol style="list-style-type: none"> 1. United States FDA 510K standard (https://www.fda.gov/medical-devices/premarket-notification-510k/510k-frequently-asked-questions). 2. Radio Technical Commission for Aeronautics/ Environmental Conditions and Test Procedures for Airborne Equipment (RTCA/DO-160G) section 21, category M, Emission of Radio Frequency Energy. 3. IEC 60601-1 General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment and all IEC (i.e., IEC 60601-1 and IEC 60601-1-2:2014) standards. 4. IEC 60601-1-2:2014 Electromagnetic Compatibility and all IEC (i.e., IEC 60601-1 and IEC 60601-1-2:2014) standards.
Are there any other standards, requirements, etc.?	No
Additional Technical Comments	See attached minimal requirements document.

Section 3: Business Information

Estimated potential business volume	A total volume estimate is unavailable as VA is seeking information from and availability of domestic accredited medical equipment manufacturers of PAP machines.
Estimated target price / unit cost information (if unavailable explain)	A targeted price estimate is unavailable as VA is seeking information from and availability of domestic accredited medical equipment manufacturers of PAP machines.
When is it needed by?	N/A VA is seeking market research type information.
Describe packaging requirements	Machines must be fully assembled, complete with attachable humidifier, and be shipped as an individual unit in standard commercial configuration including case, tubing, filters, power cord, instructions, etc.
Where will this item be shipped?	Various locations for the Department of Veterans Affairs.

Additional Comments

Is there other information you would like to include?	VA is seeking market research type information from and availability of domestic accredited medical equipment manufacturers of PAP machines.
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