ITEM OPPORTUNITY SYNOPSIS

Scouting Number:	2024-025
Name of the item to be scouted:	Various Positive Airway Pressure (PAP) Machines
State item to be used in:	Colorado
Describe the Item:	
Please describe the item application/the end use of the item.	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. Types of Machines: 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
Supplier Information:	
Type of Supplier Being Sought (select from the list below):	
Manufacturer	x
Contract Manufacturer	
Distributor	
Other (Please Specify)	
Reason for Scouting Submission (select from the list below)	
2nd Supplier	
Price	
Re-Shore	x
Past supplier no longer available	
New Product Startup	
BABA	
Other (Please Specify)	
Summary of Technical Specifications and Performance Requirements:	
Describe the manufacturing processes (elaborate to provide as much detail as possible)	Electronic/Mechanical Assembly
Provide dimensions / size / tolerances / performance specifications of the item	Technical Standards (as applicable to the different types of machines): See attachment
List required materials needed to make the product, including materials of product components, if applicable	Various. Dependent upon the machine, manufacturer, and process.
Are there applicable certification requirements?	
Yes	x
No	
Please explain:	Other
Are there any applicable regulations that apply to the production of this item?	
Yes	x
No	
Please explain:	General Standards: 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?	
Yes	
No	x
Please explain:	
Additional Comments:	

Additional technical comments:	See attached minimal requirements document.
Volume and Pricing:	
Estimated Potential Business Volume (i.e. #units per day, month, year):	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:	A targeted price estimate is unavailable as VA is seeking information from and availability of domestic accredited medical equipment manufacturers of PAP machines.
Delivery Requirements:	
When is it needed by? (Immediate, 30 days, 6 months, etc.)	N/A VA is seeking market research type information.
Describe packaging requirements (i.e. individually/group packaging, etc.)	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.

MINIMUM TECHNICAL REQUIREMENTS

Types of Machines:

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

General Standards:

1. United States FDA 510K standard.
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.

Technical Standards (as applicable to the different types of machines):

1. Machines must have selectable pressure between an inclusive lower pressure of 5 and an inclusive upper pressure of at least 20 cmH20 in increments of 1 cmH20 or less.
2. The high and low-pressure range boundaries must be settable independently by the prescriber and PAP technicians.
3. Machines must have “ramp” capability that allows positive pressure to gradually increase over time (maximum pressure increments 2 cm H2O, total ramp time must be adjustable between 0 and 15 minutes or more).
4. Airflow must keep the facial interface pressurized with a positive pressure needed to maintain airway patency.
5. Machines must have continuous PAP capability.
6. Noise volume in dB must be below 40 dB at 10 cm H2O pressures.
7. Universal acceptability of facial interfaces from different manufacturers.
8. Standard size tubing.
9. Accommodated tubing with heating coil.
10. Include two modes of operation: (1) Prescriber/Clinician Mode, and (2) User Mode.
11. Remote connectivity using PC/Mac software via USB drive/data card application or secure wireless, cloud-based technology.
12. Machine must store a minimum of 90 days of "time-on-mask" usage data downloadable using a memory-chip/device and secure wireless, cloud-based transmission.
13. Usage data must include “time-on-mask,” pressure(s) delivered, mask leak, and estimation of residual sleep disordered breathing events (AHI and residual event types including obstructive apneas, hypopneas, clear airway apneas).
14. All data must be made available in structured variable form with HL-7 capability.
15. Wireless data transmission must be available on every machine.

16. Units must be able to be cleaned and disinfected with commercially available household cleaning agents.
17. It must be possible to completely remove the humidifier chamber and clean/disinfect all parts through one or more methods: manually wiping, flushing, brushing, mechanical aids e.g., washer-decontaminators; in combination with water and commercially available household detergents cleaning agents.
18. Machine must use either washable or disposable filters and accept optional pollen, ultra-fine, or HEPA filters.
19. The device must not require any user maintenance other than external cleansing, humidifier cleaning, and changing/cleaning of particulate filters throughout its lifetime.
20. Documentation must be provided with each machine that specifies the manufacturer's recommendations for routine servicing (including recommended resources for maintenance/ servicing).
21. The device must have an automatic universal power supply that will allow 100 to 240V AC operation at 50-60Hz with no need for changes to any settings.
22. Steady-state ("typical") power consumption without humidifier on 120V AC power must be ≤75 watts. Maximum power consumption with humidifier on 120V AC power must be ≤100 watts.
23. Machine must have double insulated, 2-prong AC plugs for home use. Three prongs are not acceptable.
24. Include an integrated humidifier.
25. When used with heated humidification, the device must provide water ingress protection if tilted 90 degrees in any direction.
26. Machine must have a humidifier that can be used in both heated and unheated mode.
27. The patient must be able to adjust humidifier settings.
28. When the machine is used with humidification, it must be compatible with at least two types of tubing manufactured by companies other than the manufacturer, unless utilizing heated-wire circuits.
29. 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.
30. All machines shall be covered by at least a standard commercial warranty of a minimum of two years for the device and 90 days for the accessories.