

Salient Characteristics – Positive Air Pressure (PAP) Devices and Supplies

The Department of Veterans Affairs Network Contracting Office (NCO) 18 has a requirement for Positive Air Pressure (PAP) devices and supplies (NAICS 339113).

Continuous Positive Airway Pressure (CPAP) Machines

1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 80601-2-70: Particular Requirements for basic safety and essential performance of sleep apnea breathing therapy equipment. More information on ISO 80601-2-70 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=60049
2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
3. General Device Specifications:
 - (a) Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
 - (b) A power cord and operating instructions brochure must be supplied with the device.
 - (c) All CPAP machines must have integrated humidifier.
 - (d) CPAP machine (with empty humidifier) must weigh 7lbs or less.
 - (e) When operating and producing 10 cmH₂O pressures, machine noise must be below 40 dB. Supporting documentation must be provided.
 - (f) Machine must accept and work properly with facial interfaces from at least three different manufacturers.
 - (g) Machines must have a carrying case that accommodates the machine, facial interface, and tubing.
 - (h) Machine must be able to use standard size tubing: Length 6-12 feet, diameter 22 mm with a female connector.
 - (i) Machine must accommodate tubing with heating coil.
4. Operating Instructions: Must be provided in the English language for both prescriber and user with diagrams, figures, and pictures. User instructions must be written at a 6th grade level for ease of use.
5. Operational Modes: There must be two modes of operation:
 - (a) Prescriber/Clinician Mode - enables settings to be made and adjusted by the prescriber and PAP technicians. Prescribers and PAP technicians must be able to lock the settings made so that the user cannot make adjustments to the parameters set.
 - (b) User Mode - enables a limited range of comfort settings to be made and adjusted by the user.

6. Prescribed Parameter Set-Up: Must be possible through ALL of the following methods.
 - (a) Directly from operation keys on the CPAP device
 - (b) Remotely using PC/Mac software via USB drive/data card application
 - (c) Remotely using secure wireless, cloud-based technology
7. CPAP Parameter Settings:
 - (a) Machines must have selectable pressure between an inclusive lower pressure of 4 and an inclusive upper pressure of at least 20 cmH₂O in increments of 1 cmH₂O or less.
 - (b) Airflow must keep the facial interface pressurized with a positive pressure needed to maintain airway patency.
 - (c) Machines must have continuous PAP (CPAP) capability.
 - (d) The high and low pressure range boundaries must be settable independently by the prescriber and PAP technicians.
8. Data Parameters, Access, and Storage:
 - (a) Machine must store a minimum of 90 days of "time-on-mask" usage data downloadable using a memory-chip AND secure wireless, cloud-based transmission.
 - (b) 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).
 - (c) All data must be made available in structured variable form with HL-7 capability.
 - (d) Summarized data must be provided for 4 weeks or more, and full disclosure data must be provided for 3 nights or more.
 - (e) Memory chip readers, associated software, and updates to that software must be made available to facilities.
 - (f) Wireless data transmission must be available on every CPAP machine.
9. Maintenance, Cleaning, and Infection Control:
 - (a) CPAP units must be able to be cleaned and disinfected with commercially available household cleaning agents.
 - (b) It must be possible to completely dismantle the humidifier and disinfect all parts thermally (machine washable).
 - (c) Machine must use either washable or disposable filters and accept optional pollen, ultra-fine, or HEPA filters.
 - (d) The device must not require any user maintenance other than external cleansing, humidifier cleaning, and changing/cleaning of particulate filters throughout its lifetime.
 - (e) Documentation must be provided with each machine and to the VA facility that specifies the manufacturer's recommendations for routine servicing (including recommended resources for maintenance/servicing).
10. Power Supply Specifications:

- (a) The CPAP device must have an automatic universal power supply that will allow 100 to 240 V AC operation at 50-60Hz with no need for changes to any settings.
- (b) Maximum power consumption without humidifier on 120 V AC power must be <30 watts. Maximum power consumption with humidifier on 120 V AC power must be <80 watts.
- (c) Machine must have double insulated, 2-prong AC plugs for home use. Three-prong plugs are not acceptable.

11. Humidifier Specifications:

- (a) When used with heated humidification, the device must provide water ingress protection if tilted 90 degrees in any direction.
- (b) Machine must have a humidifier that can be used in both heated and unheated mode.
- (c) The patient must be able to adjust humidifier settings.
- (d) When the APAP machine is used with humidification, it must be compatible with at least 2 breathing circuits manufactured by companies other than the manufacturer, unless utilizing heated-wire circuits.

12. Indication of Fault Conditions:

- (a) The device must indicate conditions which the user can rectify via the device display.
- (b) For all other fault conditions which require expert or manufacturer intervention, the device must indicate via the device display that a fault exists to the user, give a fault code, and advise the user to refer to the provider/manufacturer.

13. Assembly: CPAP machines must leave the manufacturer fully assembled, complete with attachable humidifier. They must be shipped as individual units in standard commercial configuration.

14. Warranty: All CPAP machines must come with at least a standard commercial warranty for all associated parts including humidifier, power supply, and APAP generator.

Auto-Titrating Continuous Positive Airway Pressure (APAP) Machines

- Also known as Auto-Titrating CPAP Machines

15. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 80601-2-70: Particular Requirements for basic safety and essential performance of sleep apnea breathing therapy equipment. More information on ISO 80601-2-70 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=60049

16. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>

17. General Device Specifications:

- (a) Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
- (b) A power cord and operating instructions brochure must be supplied with the device.
- (c) All APAP machines must have integrated humidifier.
- (d) APAP machine (with empty humidifier) must weigh 7lbs or less.
- (e) When operating and producing 10 cmH₂O pressures, machine noise must be below 40 dB. Supporting documentation must be provided.
- (f) Machine must accept and work properly with facial interfaces from at least three different manufacturers.
- (g) Machines must have a carrying case that accommodates the machine, facial interface, and tubing.
- (h) Machine must be able to use standard size tubing: Length 6-12 feet, diameter 22 mm with a female connector.
- (i) Machine must accommodate tubing with heating coil.

18. Operating Instructions: Must be provided in the English language for both prescriber and user with diagrams, figures, and pictures. User instructions must be written at a 6th grade level for ease of use.

19. Operational Modes: There must be two modes of operation:

- (a) Prescriber/Clinician Mode - enables settings to be made and adjusted by the prescriber and PAP technicians. Prescribers and PAP technicians must be able to lock the settings made so that the user cannot make adjustments to the parameters set.
- (b) User Mode - enables a limited range of comfort settings to be made and adjusted by the user.

20. Prescribed Parameter Set-Up: Must be possible through ALL of the following methods.

- (a) Directly from operation keys on the APAP device
- (b) Remotely using PC/Mac software via USB drive/data card application
- (c) Remotely using secure wireless, cloud-based technology

21. APAP Parameter Settings:

- (a) Machines must have selectable pressure between an inclusive lower pressure of 5 and an inclusive upper pressure of at least 20 cmH₂O in increments of 1 cmH₂O or less.
- (b) Airflow must keep the facial interface pressurized with a positive pressure needed to maintain airway patency.
- (c) Machines must have continuous PAP (CPAP) capability in addition to APAP capability.
- (d) Machine auto-adjustment must be based on airflow limitation.
- (e) The high and low pressure range boundaries must be settable independently by the prescriber and PAP technicians.
- (f) 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).

22. Data Parameters, Access, and Storage:

- (a) Machine must store a minimum of 90 days of "time-on-mask" usage data downloadable using a memory-chip AND secure wireless, cloud-based transmission.
- (b) 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).
- (c) All data must be made available in structured variable form with HL-7 capability.
- (d) Summarized data must be provided for 4 weeks or more, and full disclosure data must be provided for 3 nights or more.
- (e) Memory chip readers, associated software, and updates to that software must be made available to facilities.
- (f) Wireless data transmission must be available on every APAP machine.

23. Maintenance, Cleaning, and Infection Control:

- (a) APAP units must be able to be cleaned and disinfected with commercially available household cleaning agents.
- (b) It must be possible to completely dismantle the humidifier and disinfect all parts thermally (machine washable).
- (c) Machine must use either washable or disposable filters and accept optional pollen, ultra-fine, or HEPA filters.
- (d) The device must not require any user maintenance other than external cleansing, humidifier cleaning, and changing/cleaning of particulate filters throughout its lifetime.
- (e) Documentation must be provided with each machine and to the VA facility that specifies the manufacturer's recommendations for routine servicing (including recommended resources for maintenance/servicing).

24. Power Supply Specifications:

- (a) The APAP device must have an automatic universal power supply that will allow 100 to 240 V AC operation at 50-60Hz with no need for changes to any settings.
- (b) Maximum power consumption without humidifier on 120 V AC power must be <30 watts. Maximum power consumption with humidifier on 120 V AC power must be <80 watts.
- (c) Machine must have double insulated, 2-prong AC plugs for home use. Three-prong plugs are not acceptable.

25. Humidifier Specifications:

- (a) When used with heated humidification, the device must provide water ingress protection if tilted 90 degrees in any direction.
- (b) Machine must have a humidifier that can be used in both heated and unheated mode.
- (c) The patient must be able to adjust humidifier settings.
- (d) When the APAP machine is used with humidification, it must be compatible with at least 2 breathing circuits manufactured by companies other than the manufacturer, unless utilizing heated-wire circuits.

26. Indication of Fault Conditions:
- (a) The device must indicate conditions which the user can rectify via the device display.
 - (b) For all other fault conditions which require expert or manufacturer intervention, the device must indicate via the device display that a fault exists to the user, give a fault code, and advise the user to refer to the provider/manufacturer.
27. Assembly: APAP machines must leave the manufacturer fully assembled, complete with attachable humidifier. They must be shipped as individual units in standard commercial configuration.
28. Warranty: All APAP machines must come with at least a standard commercial warranty for all associated parts including humidifier, power supply, and APAP generator.

Auto-Titrating Continuous Positive Airway Pressure (APAP) Machines

29. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 80601-2-70: Particular Requirements for basic safety and essential performance of sleep apnea breathing therapy equipment. More information on ISO 80601-2-70 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=60049
30. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
31. General Device Specifications:
- (a) Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
 - (b) A power cord and operating instructions brochure must be supplied with the device.
 - (c) All APAP machines must have integrated humidifier.
 - (d) APAP machine (with empty humidifier) must weigh 7lbs or less.
 - (e) When operating and producing 10 cmH₂O pressures, machine noise must be below 40 dB. Supporting documentation must be provided.
 - (f) Machine must accept and work properly with facial interfaces from at least three different manufacturers.
 - (g) Machines must have a carrying case that accommodates the machine, facial interface, and tubing.
 - (h) Machine must be able to use standard size tubing: Length 6-12 feet, diameter 22 mm with a female connector.
 - (i) Machine must accommodate tubing with heating coil.
32. Operating Instructions: Must be provided in the English language for both prescriber and user with diagrams, figures, and pictures. User instructions must be written at a 6th grade level for ease of use.
33. Operational Modes: There must be two modes of operation:

- (a) Prescriber/Clinician Mode - enables settings to be made and adjusted by the prescriber and PAP technicians. Prescribers and PAP technicians must be able to lock the settings made so that the user cannot make adjustments to the parameters set.
- (b) User Mode - enables a limited range of comfort settings to be made and adjusted by the user.

34. Prescribed Parameter Set-Up: Must be possible through ALL of the following methods.

- (a) Directly from operation keys on the APAP device
- (b) Remotely using PC/Mac software via USB drive/data card application
- (c) Remotely using secure wireless, cloud-based technology

35. APAP Parameter Settings:

- (a) Machines must have selectable pressure between an inclusive lower pressure of 5 and an inclusive upper pressure of at least 20 cmH2O in increments of 1 cmH2O or less.
- (b) Airflow must keep the facial interface pressurized with a positive pressure needed to maintain airway patency.
- (c) Machines must have continuous PAP (CPAP) capability in addition to APAP capability.
- (d) Machine auto-adjustment must be based on airflow limitation.
- (e) The high and low pressure range boundaries must be settable independently by the prescriber and PAP technicians.
- (f) 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).

36. Data Parameters, Access, and Storage:

- (a) Machine must store a minimum of 90 days of "time-on-mask" usage data downloadable using a memory-chip AND secure wireless, cloud-based transmission.
- (b) 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).
- (c) All data must be made available in structured variable form with HL-7 capability.
- (d) Summarized data must be provided for 4 weeks or more, and full disclosure data must be provided for 3 nights or more.
- (e) Memory chip readers, associated software, and updates to that software must be made available to facilities.
- (f) Wireless data transmission must be available on every APAP machine.

37. Maintenance, Cleaning, and Infection Control:

- (a) APAP units must be able to be cleaned and disinfected with commercially available household cleaning agents.
- (b) It must be possible to completely dismantle the humidifier and disinfect all parts thermally (machine washable).
- (c) Machine must use either washable or disposable filters and accept optional pollen, ultra-fine, or HEPA filters.

- (d) The device must not require any user maintenance other than external cleansing, humidifier cleaning, and changing/cleaning of particulate filters throughout its lifetime.
- (e) Documentation must be provided with each machine and to the VA facility that specifies the manufacturer's recommendations for routine servicing (including recommended resources for maintenance/servicing).

38. Power Supply Specifications:

- (a) The APAP device must have an automatic universal power supply that will allow 100 to 240 V AC operation at 50-60Hz with no need for changes to any settings.
- (b) Maximum power consumption without humidifier on 120 V AC power must be <30 watts. Maximum power consumption with humidifier on 120 V AC power must be <80 watts.
- (c) Machine must have double insulated, 2-prong AC plugs for home use. Three-prong plugs are not acceptable.

39. Humidifier Specifications:

- (a) When used with heated humidification, the device must provide water ingress protection if tilted 90 degrees in any direction.
- (b) Machine must have a humidifier that can be used in both heated and unheated mode.
- (c) The patient must be able to adjust humidifier settings.
- (d) When the APAP machine is used with humidification, it must be compatible with at least 2 breathing circuits manufactured by companies other than the manufacturer, unless utilizing heated-wire circuits.

40. Indication of Fault Conditions:

- (a) The device must indicate conditions which the user can rectify via the device display.
- (b) For all other fault conditions which require expert or manufacturer intervention, the device must indicate via the device display that a fault exists to the user, give a fault code, and advise the user to refer to the provider/manufacturer.

41. Assembly: APAP machines must leave the manufacturer fully assembled, complete with attachable humidifier. They must be shipped as individual units in standard commercial configuration.

42. Warranty: All APAP machines must come with at least a standard commercial warranty for all associated parts including humidifier, power supply, and APAP generator.

Bilevel Positive Airway Pressure (BPAP) Machines

1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 80601-2-70: Particular Requirements for basic safety and essential performance of sleep apnea breathing therapy equipment. More information on ISO 80601-2-70 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=60049

2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
3. General Device Specifications:
 - (a) Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
 - (b) A power cord and operating instructions brochure must be supplied with the device.
 - (c) All BPAP machines must have integrated humidifier.
 - (d) BPAP machine (with empty humidifier) must weigh 7lbs or less.
 - (e) When operating and producing 10 cmH₂O pressures, machine noise must be below 40 dB. Supporting documentation must be provided.
 - (f) Machine must accept and work properly with facial interfaces from at least three different manufacturers.
 - (g) Machines must have a carrying case that accommodates the machine, facial interface, and tubing.
 - (h) Machine must be able to use standard size tubing: Length 6-12 feet, diameter 22 mm with a female connector.
 - (i) Machine must accommodate tubing with heating coil.
4. Operating Instructions: Must be provided in the English language for both prescriber and user with diagrams, figures, and pictures. User instructions must be written at a 6th grade level for ease of use.
5. Operational Modes: There must be two modes of operation:
 - (a) Prescriber/Clinician Mode - enables settings to be made and adjusted by the prescriber and PAP technicians. Prescribers and PAP technicians must be able to lock the settings made so that the user cannot make adjustments to the parameters set.
 - (b) User Mode - enables a limited range of comfort settings to be made and adjusted by the user.
6. Prescribed Parameter Set-Up: Must be possible through ALL of the following methods.
 - (a) Directly from operation keys on the BPAP device
 - (b) Remotely using PC/Mac software via USB drive/data card application
 - (c) Remotely using secure wireless, cloud-based technology
7. BPAP Parameter Settings:
 - (a) BPAP machine inspiratory and expiratory pressures must be independently adjustable.
 - (b) BPAP inspiratory and expiratory time periods must be independently adjustable.
 - (c) BPAP with spontaneous-timed (S/T) capability must have selectable back-up breathing rates between an inclusive lower limit of 6 times per minute and an inclusive upper limit of 20 times per minute.
8. Data Parameters, Access, and Storage:

- (a) Machine must store a minimum of 90 days of "time-on-mask" usage data downloadable using a memory-chip AND secure wireless, cloud-based transmission.
- (b) 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).
- (c) Usage data must be made available in structured variable form with HL-7 capability.
- (d) Summarized data must be provided for 4 weeks or more, and full disclosure data must be provided for 3 nights or more.
- (e) Memory chip readers, associated software, and updates to that software must be made available to facilities.
- (f) Wireless data transmission must be available on every BPAP machine.

9. Maintenance, Cleaning, and Infection Control:

- (a) BPAP units must be able to be cleaned and disinfected with commercially available household cleaning agents.
- (b) It must be possible to completely dismantle the humidifier and disinfect all parts thermally (machine washable).
- (c) Machine must use either washable or disposable filters and accept optional pollen, ultra-fine, or HEPA filters.
- (d) The device must not require any user maintenance other than external cleansing, humidifier cleaning, and changing/cleaning of particulate filters throughout its lifetime.
- (e) Documentation must be provided with each machine and to the VA facility that specifies the manufacturer's recommendations for routine servicing (including recommended resources for maintenance/servicing).

10. Power Supply Specifications:

- (a) The BPAP device must have an automatic universal power supply that will allow 100 to 240 V AC operation at 50-60Hz with no need for changes to any settings.
- (b) Maximum power consumption without humidifier on 120 V AC power must be <30 watts. Maximum power consumption with humidifier on 120 V AC power must be <80 watts.
- (c) Machine must have double insulated, 2-prong AC plugs for home use. Three prong is not acceptable.

11. Humidifier:

- (a) When used with heated humidification, the device must provide water ingress protection if tilted 90 degrees in any direction.
- (b) Machine must have a humidifier that can be used in both heated and unheated mode.
- (c) The patient must be able to adjust humidifier settings.
- (d) When the BPAP machine is used with humidification, it must be compatible with at least 2 breathing circuits manufactured by companies other than the manufacturer, except those utilizing heated-wire circuits.

12. Indication of Fault Conditions:
 - (a) The device must indicate conditions which the user can rectify via the device display.
 - (b) For all other fault conditions which require expert or manufacturer intervention, the device must indicate via the device display that a fault exists to the user, give a fault code and advise the user to refer to the provider/manufacturer.
13. Assembly: BPAP machines must leave the manufacturer fully assembled, complete with attachable humidifier. They must be shipped as individual units in standard commercial configuration.
14. Warranty: All BPAP machines must come with at least a standard commercial warranty for all associated parts including humidifier, power cord, and BPAP generator.

Adaptive Servo-Ventilation (ASV) Machines

1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 80601-2-70: Particular Requirements for basic safety and essential performance of sleep apnea breathing therapy equipment. More information on ISO 80601-2-70 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=60049
2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
3. General Device Specifications:
 - (a) Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
 - (b) A power cord and operating instructions brochure must be supplied with the device.
 - (c) All ASVP machines must have integrated humidifier.
 - (d) ASV machine (with empty humidifier) must weigh 7lbs or less.
 - (e) When operating and producing 10 cmH₂O pressures, machine noise must be below 40 dB. Supporting documentation must be provided.
 - (f) Machine must accept and work properly with facial interfaces from at least three different manufacturers.
 - (g) Machines must have a carrying case that accommodates the machine, facial interface, and tubing.
 - (h) Machine must be able to use standard size tubing: Length 6-12 feet, diameter 22 mm with a female connector.
 - (i) Machine must accommodate tubing with heating coil.
4. Operating Instructions: Must be provided in the English language for both prescriber and user with diagrams, figures, and pictures. User instructions must be written at a 6th grade level for ease of use.
5. Operational Modes: There must be two modes of operation:

- (a) Prescriber/Clinician Mode - enables settings to be made and adjusted by the prescriber and PAP technicians. Prescribers and PAP technicians must be able to lock the settings made so that the user cannot make adjustments to the parameters set.
 - (b) User Mode - enables a limited range of comfort settings to be made and adjusted by the user.
- 6. Prescribed Parameter Set-Up: Must be possible through ALL of the following methods.
 - (a) Directly from operation keys on the BPAP device
 - (b) Remotely using PC/Mac software via USB drive/data card application
 - (c) Remotely using secure wireless, cloud-based technology
- 7. ASV Parameter Settings:
 - (a) Airflow must keep the facial interface pressurized with positive pressure needed to maintain airway parameters.
 - (b) Machine auto-adjustment must be based on airflow limitation.
 - (c) The high and low pressure range boundaries must be able to be set independently by the prescriber and PAP technician.
 - (d) ASV machine inspiratory and expiratory pressures must be independently adjustable.
- 8. Data Parameters, Access, and Storage:
 - (a) Machine must store a minimum of 90 days of "time-on-mask" usage data downloadable using a memory-chip AND secure wireless, cloud-based transmission.
 - (b) 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).
 - (c) All data must be made available in structured variable form with HL-7 capability.
 - (d) Summarized data must be provided for 4 weeks or more, and full disclosure data must be provided for 3 nights or more.
 - (e) Memory chip readers, associated software, and updates to that software must be made available to facilities.
 - (f) Wireless data transmission must be available on every ASV machine.
- 9. Maintenance, Cleaning, and Infection Control:
 - (a) ASV units must be able to be cleaned and disinfected with commercially available household cleaning agents.
 - (b) It must be possible to completely dismantle the humidifier and disinfect all parts thermally (machine washable).
 - (c) Machine must use either washable or disposable filters and accept optional pollen, ultra-fine, or HEPA filters.
 - (d) The device must not require any user maintenance other than external cleansing, humidifier cleaning, and changing/cleaning of particulate filters throughout its lifetime.
 - (e) Documentation must be provided with each machine and to the VA facility that specifies the manufacturer's recommendations for routine

servicing (including recommended resources for maintenance/servicing).

10. Power Supply Specifications:

- (a) The ASV device must have an automatic universal power supply that will allow 100 to 240 V AC operation at 50-60Hz with no need for changes to any settings.
- (b) Maximum power consumption without humidifier on 120 V AC power must be <30 watts. Maximum power consumption with humidifier on 120 V AC power must be <80 watts.
- (c) Machine must have double insulated, 2-prong AC plugs for home use. Three-prong plugs are not acceptable.

11. Humidifier Specifications:

- (a) When used with heated humidification, the device must provide water ingress protection if tilted 90 degrees in any direction.
- (b) Machine must have a humidifier that can be used in both heated and unheated mode.
- (c) The patient must be able to adjust humidifier settings.
- (d) When the AVP machine is used with humidification, it must be compatible with at least 2 breathing circuits manufactured by companies other than the manufacturer, except those utilizing heated-wire tubing.

12. Indication of Fault Conditions:

- (a) The device must indicate conditions which the user can rectify via the device display.
- (b) For all other fault conditions which require expert or manufacturer intervention, the device must indicate via the device display that a fault exists to the user, give a fault code and advise the user to refer to the provider/manufacturer.

13. Assembly: ASV machines must leave the manufacturer fully assembled, complete with attachable humidifier. They must be shipped as individual units in standard commercial configuration.

14. Warranty: All ASV machines must come with at least a standard commercial warranty for all associated parts including humidifier, power cord, and ASV generator.

Positive Airway Pressure (PAP) Facial Interfaces (Full Face Masks)

- Commonly known as “masks”, including headgear, frame and cushions where applicable
 - This section refers to full face masks
1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 17510:2015 Medical Devices – Sleep apnea breathing therapy – masks and application accessories. More information on ISO 17510:2015 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=64910
 2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>

3. General Specifications:
 1. Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
 2. Assembly instructions for headgear, frame, and cushions (where applicable) into a functional interface must be provided in the English language to both the prescriber and user at a 6th grade level for ease of use.
4. Compatibility: Each interface must be compatible with PAP machines and tubing from at least 3 different manufacturers without adaptors.
5. Ordering: Separate ordering for headgear, frames, and cushions must be made available.
6. Materials: All materials used for the construction of interfaces must be independently certified as being medical grade, hypoallergenic substances, free from impurities which may cause allergic reaction. There must be confirmation of biocompatibility and toxicological safety for all product parts which come into contact with the skin or the mucosa by an independent testing institution. All materials must be latex-free.
7. Cleaning: All component parts must be cleanable with commercially available household cleaning agents. Cleaning instructions must be provided in the English language to both prescriber and user at a 6th grade level for ease of use. The interface must dismantle in order to clean each component.
8. Lock/Release Mechanisms: All full face and total face masks must have a quick-release mechanism and must comply with ISO PAP Standards and FDA Standards to avoid risk of asphyxiation if the device fails or there is a power-cut.
9. Sizing: Interfaces must be available in a range of sizes.
10. Adjustment: Interfaces must be adjustable to fit patients' head and face.

Positive Airway Pressure (PAP) Interfaces (Nasal Masks)

- Commonly known as “masks”, including headgear, frame and cushions where applicable
 - This section refers to nasal masks
1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 17510:2015 Medical Devices – Sleep apnea breathing therapy – masks and application accessories. More information on ISO 17510:2015 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=64910
 2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
 3. General Specifications:

1. Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
2. Assembly instructions for headgear, frame, and cushions (where applicable) into a functional interface must be provided in the English language to both the prescriber and user at a 6th grade level for ease of use.
4. Compatibility: Each interface must be compatible with PAP machines and tubing from at least 3 different manufacturers without adaptors.
5. Ordering: Separate ordering for headgear, frames, and cushions must be made available.
6. Materials: All materials used for the construction of interfaces must be independently certified as being medical grade, hypoallergenic substances, free from impurities which may cause allergic reaction. There must be confirmation of biocompatibility and toxicological safety for all product parts which come into contact with the skin or the mucosa by an independent testing institution. All materials must be latex-free.
7. Cleaning: All component parts must be cleanable with commercially available household cleaning agents. Cleaning instructions must be provided in the English language to both prescriber and user at a 6th grade level for ease of use. The interface must dismantle in order to clean each component.
8. Lock/Release Mechanisms: All full face and total face masks must have a quick-release mechanism and must comply with ISO PAP Standards and FDA Standards to avoid risk of asphyxiation if the device fails or there is a power-cut.
9. Sizing: Interfaces must be available in a range of sizes.
10. Adjustment: Interfaces must be adjustable to fit patients' head and face.

Positive Airway Pressure (PAP) Interfaces (Nasal Pillows)

1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 17510:2015 Medical Devices – Sleep apnea breathing therapy – masks and application accessories. More information on ISO 17510:2015 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=64910
2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
3. General Specifications:
 1. Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
 2. Assembly instructions for headgear, frame, and cushions (where applicable) into a functional interface must be provided in the English language to both the prescriber and user at a 6th grade level for ease of use.

4. Compatibility: Each interface must be compatible with PAP machines and tubing from at least 3 different manufacturers without adaptors.
5. Ordering: Separate ordering for headgear, frames, and cushions must be made available.
6. Materials: All materials used for the construction of interfaces must be independently certified as being medical grade, hypoallergenic substances, free from impurities which may cause allergic reaction. There must be confirmation of biocompatibility and toxicological safety for all product parts which come into contact with the skin or the mucosa by an independent testing institution. All materials must be latex-free.
7. Cleaning: All component parts must be cleanable with commercially available household cleaning agents. Cleaning instructions must be provided in the English language to both prescriber and user at a 6th grade level for ease of use. The interface must dismantle in order to clean each component.

Positive Airway Pressure (PAP) Facial Interfaces (Total Face Masks)

- Commonly known as “masks”, including headgear, frame and cushions where applicable
 - This section refers to total face masks
1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 17510:2015 Medical Devices – Sleep apnea breathing therapy – masks and application accessories. More information on ISO 17510:2015 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=64910
 2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
 3. General Specifications:
 1. Devices must be supplied in individual, standard commercial packaging in standard commercial configuration.
 2. Assembly instructions for headgear, frame, and cushions (where applicable) into a functional interface must be provided in the English language to both the prescriber and user at a 6th grade level for ease of use.
 4. Compatibility: Each interface must be compatible with PAP machines and tubing from at least 3 different manufacturers without adaptors.
 5. Ordering: Separate ordering for headgear, frames, and cushions must be made available.
 6. Materials: All materials used for the construction of interfaces must be independently certified as being medical grade, hypoallergenic substances, free from impurities which may cause allergic reaction. There must be confirmation of biocompatibility and toxicological safety for all product parts which come into contact with the skin or the mucosa by an independent testing institution. All materials must be latex-free.

7. Cleaning: All component parts must be cleanable with commercially available household cleaning agents. Cleaning instructions must be provided in the English language to both prescriber and user at a 6th grade level for ease of use. The interface must dismantle in order to clean each component.
8. Lock/Release Mechanisms: All full face and total face masks must have a quick-release mechanism and must comply with ISO PAP Standards and FDA Standards to avoid risk of asphyxiation if the device fails or there is a power-cut.
9. Sizing: Interfaces must be available in a range of sizes.
10. Adjustment: Interfaces must be adjustable to fit patients' head and face.

Positive Airway Pressure (PAP) Tubing

1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 17510:2015 Medical Devices – Sleep apnea breathing therapy – masks and application accessories. More information on ISO 17510:2015 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=64910
2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
3. All tubing must be available in various lengths, from a minimum of 6 feet in length to a maximum of 12 feet in length.
4. All tubing must have an operating pressure range up to at least 25 cmH₂O.
5. All tubing must have a female connector compatible with commonly commercially available PAP machines and PAP interfaces.
6. All tubing must be compatible with supplemental oxygen connection adapters.
7. Heated tubing must offer a temperature range of at least 16°C (60°F) – 30°C (86°F), and have an automatic temperature cut-off at 41°C (106°F).
8. All tubing must be cleanable using commercially available household cleaning agents, with cleaning instructions provided in the English language to both the prescriber and user at a 6th grade level for ease of use.

Positive Airway Pressure (PAP) Facial Interface Chinstraps

1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 17510:2015 Medical Devices – Sleep apnea breathing therapy – masks and application accessories. More information on ISO 17510:2015 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=64910

2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
3. General Specifications:
 1. Chinstrap must be supplied in individual, standard commercial packaging in standard commercial configuration.
 2. A user's guide must be provided in the English language to both the prescriber and user at a 6th grade level for ease of use.
4. Compatibility: Each chinstrap must be compatible with PAP facial interfaces (i.e. masks) from at least 3 different manufacturers.
5. Materials: All materials used for the construction of chinstraps must be independently certified as being medical grade, hypoallergenic substances free from impurities which may cause allergic reaction.
 1. There must be confirmation of biocompatibility and toxicological safety for all parts which come into contact with the skin or the mucosa by an independent testing institution.
 2. All materials must be latex-free.
6. Cleaning: Chinstraps must be cleanable with commercially available household cleaning agents.
7. Adjustment: Chinstraps must be adjustable to fit patients' head and face.

Positive Airway Pressure (PAP) Machine Filters

1. All offerors shall submit the manufacturer's documentation that products meet International Organization for Standardization (ISO) 17510:2015 Medical Devices – Sleep apnea breathing therapy – masks and application accessories. More information on ISO 17510:2015 can be found here: http://www.iso.org/iso/catalogue_detail.htm?csnumber=64910
2. All devices offered must have met the requirement of obtaining U.S. Food and Drug Administration (FDA) 510(k) if applicable. More information on the FDA 510(k) requirements can be found here: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm>
3. Filters must be present with the PAP machine at the time of distribution to the user.
4. Filters must be available for both the current and prior models of the PAP machine being provided.