ATTACHMENT D

MINIMUM TECHNICAL REQUIREMENTS

1. AUTO-TITRATING CONTINUOUS POSITIVE AIRWAY PRESSURE (APAP) MACHINE:

1. Documentation that products meet International Organization for Standardization (ISO) 80601-2-70:2015 : *Particular Requirements for basic safety an essential performance of sleep apnea breathing equipment therapy*, and all ISO collateral and particular standards cited by the previously mentioned ISO/ International Electrotechnical Commission (IEC) standard.

2. Documentation that products meet ISO 80601-2-74:2017: *Particular requirements for basic safety and essential performance of respiratory humidifying equipment* and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

3. Documentation that products meet United States FDA 510K Standard.

4. Documentation that products meet 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.

5. Documentation that products meet IEC 60601-1 General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

6. Documentation that products meet IEC 60601-1-2:2014 Electromagnetic Compatibility and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

7. 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. Supportive 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.

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

9. 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.

10. Prescribed Parameter Set-Up: Must be possible through ALL 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

11. 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 cmH20 in increments of 1 cmH20 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).

12. 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.
(g) A secure digital (SD) card must be supplied with each device. It also must be available for purchase as a replacement item for lost/damaged SD cards.
    a. Capacity of 2GB or more
    b. Full Size SD
    c. Class 6 or higher
    d. Conform to IEC 60601-1 requirements

13. 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).

14. 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) Steady-state ("typical") power consumption without humidifier on 120 V AC power must be ≤75 watts. Maximum power consumption with humidifier on 120 V AC power must be ≤100 watts.
    (c) Machine must have double insulated, 2-prong AC plugs for home use. Three prong is not acceptable.
    (d) The power supply unit and power cord must be available for purchase for replacement of lost or damaged power supply and/or power cord.

15. 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 types of tubing manufactured by companies other than the manufacturer, unless utilizing heated-wire circuits.

(e) Humidifier water chamber must be available for purchase as a replacement item for a lost/damaged humidifier water chamber.

16. 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.

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

18. Warranty: All APAP machines shall be covered by at least a standard commercial warranty of a minimum of two (2) years for the device and 90 days on any accessories. If the manufacturer/vendor standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply for all associated parts including humidifier, power supply, and APAP generator.

2. BILEVEL POSITIVE AIRWAY PRESSURE (BPAP) MACHINES:

1. Documentation that products meet International Organization for Standardization (ISO) 80601-2-70:2015 : *Particular Requirements for basic safety an essential performance of sleep apnoea breathing equipment therapy*, and all ISO collateral and particular standards cited by the previously mentioned ISO/ International Electrotechnical Commission (IEC) standard.

2. Documentation that products meet ISO 80601-2-74:2017 : *Particular requirements for basic safety and essential performance of respiratory humidifying equipment* and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

3. Documentation that products meet United States FDA 510K Standard.

4. Documentation that products meet 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

5. Documentation that products meet IEC 60601-1 General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

   Documentation that products meet IEC 60601-1-2:2014 Electromagnetic Compatibility and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

6. 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. Supportive 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.

7. 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.

8. Operational Modes: There must be two modes of operation as detailed below:
    (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.

9. 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

10. 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.

11. 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) Useage date 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.
(g) A secure digital (SD) card must be supplied with each device. It also must be available for purchase as a replacement item for lost/damaged SD cards.
    a. Capacity of 2GB or more
    b. Full Size SD
    c. Class 6 or higher
    d. Conform to IEC 60601-1 requirements

12. 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).

13. 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) Steady-state ("typical") power consumption without humidifier on 120 V AC power must be ≤75 watts. Maximum power consumption with humidifier on 120 V AC power must be ≤100 watts.
    (c) Machine must have double insulated, 2-prong AC plugs for home use. Three prong is not acceptable.
    (d) The power supply unit and power cord must be available for purchase for replacement of lost or damaged power supply and/or power cord.

14. 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 types of tubing manufactured by companies other than the manufacturer, except those utilizing heated-wire circuits.
(e) Humidifier water chamber must be available for purchase as a replacement item for a lost/damaged humidifier water chamber.

15. 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.

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

17. Warranty: All BPAP machines shall be covered by at least a standard commercial warranty of a minimum of two (2) years for the device and 90 days on any accessories. If the manufacturer/vendor standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply for all associated parts including humidifier, power supply, and BPAP generator.

3. VOLUME ASSURED PRESSURE SUPPORT (VAPS) MACHINES:

1. Documentation that products meet International Organization for Standardization (ISO) 80601-2-70:2015 : *Particular Requirements for basic safety an essential performance of sleep apnea breathing equipment therapy*, and all ISO collateral and particular standards cited by the previously mentioned ISO/ International Electrotechnical Commission (IEC) standard.

2. Documentation that products meet ISO 80601-2-74:2017: *Particular requirements for basic safety and essential performance of respiratory humidifying equipment* and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

3. Documentation that products meet United States FDA 510K Standard.

4. Documentation that products meet 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

5. Documentation that products meet IEC 60601-1 General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

6. Documentation that products meet IEC 60601-1-2:2014 Electromagnetic Compatibility and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

7. 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 VAPS machines must have integrated humidifier.
   (d) VAP machine (with empty humidifier) must weigh 7lbs or less.
   (e) When operating and producing 10 cmH2O pressures, machine noise must be below 40 dB. Supportive 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.

8. 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.

9. Operational Modes: There must be two modes of operation as detailed below:
   (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.

10. Prescribed Parameter Set-Up: Must be possible through ALL of the following methods.
   (a) Directly from operation keys on the VAPS device
   (b) Remotely using PC/Mac software via USB drive/data card application
   (c) Remotely using secure wireless, cloud-based technology

11. VAPS Parameter Settings:
   (a) Inspiratory and expiratory pressures must be independently adjustable.
   (b) Tidal Volume must be independently adjustable.
   (c) Inspiratory time periods must be independently adjustable.
   (d) Respiratory rate must be independently adjustable

(e) Machine must have selectable back-up breathing rates between an inclusive lower limit of 6 breaths per minute and an inclusive upper limit of at least 30 breaths per minute.

12. 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 date 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) A secure digital (SD) card must be supplied with each device. It also must be available for purchase as a replacement item for lost/damaged SD cards.
        a. Capacity of 2GB or more
        b. Full Size SD
        c. Class 6 or higher
        d. Conform to IEC 60601-1 requirements

13. Maintenance, Cleaning, and Infection Control:
    (a) VAPS 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).

14. Power Supply Specifications:
    (a) The VAPS 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) Steady-state ("typical") power consumption without humidifier on 120 V AC power must be ≤75 watts. Maximum power consumption with humidifier on 120 V AC power must be ≤100 watts.
    (c) Machine must have double insulated, 2-prong AC plugs for home use. Three prongs is not acceptable.

(d) The power supply unit and power cord must be available for purchase for replacement of lost or damaged power supply and/or power cord.

15. 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 VAPS machine is used with humidification, it must be compatible with at least 2 types of tubing manufactured by companies other than the manufacturer, except those utilizing heated-wire circuits.
    (e) Humidifier water chamber must be available for purchase as a replacement item for a lost/damaged humidifier water chamber.

16. 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.

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

18. Warranty: All VAPS machines shall be covered by at least a standard commercial warranty of a minimum of two (2) years for the device and 90 days on any accessories. If the manufacturer/vendor standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply for all associated parts including humidifier, power supply, and VAPS generator.

4. **ADAPTIVE SERVO-VENTILATION (ASV) MACHINE:**

1. Documentation that products meet International Organization for Standardization (ISO) 80601-2-70:2015 : *Particular Requirements for basic safety an essential performance of sleep apnea breathing equipment therapy*, and all ISO collateral and particular standards cited by the previously mentioned ISO/ International Electrotechnical Commission (IEC) standard.

2. Documentation that products meet ISO 80601-2-74:2017: *Particular requirements for basic safety and essential performance of respiratory humidifying equipment* and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

3. Documentation that products meet United States FDA 510K Standard.

4. Documentation that products meet 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

5. Documentation that products meet IEC 60601-1 General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

6. Documentation that products meet IEC 60601-1-2:2014 Electromagnetic Compatibility and all ISO collateral and particular standards cited by the previously mentioned ISO/ IEC standard.

7. 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 ASV 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. Supportive 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.

8. 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.

9. 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.

10. Prescribed Parameter Set-Up: Must be possible through ALL the following methods.
   (a) Directly from operation keys on the ASV device
   (b) Remotely using PC/Mac software via USB drive/data card application
   (c) Remotely using secure wireless, cloud-based technology

11. ASV Parameter Settings:
    (a) Airflow must keep the facial interface pressurized with a positive pressure needed to maintain airway patency.
    (b) Machine auto-adjustment must be based on airflow limitation.
    (c) The high and low-pressure range boundaries must be settable independently by the prescriber and PAP technician.
    (d) ASV machine inspiratory and expiratory pressures must be independently adjustable.

12. 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.
    (g) A secure digital (SD) card must be supplied with each device. It also must be available for purchase as a replacement item for lost/damaged SD cards.
        a. Capacity of 2GB or more
        b. Full Size SD
        c. Class 6 or higher
        d. Conform to IEC 60601-1 requirements

13. 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).

14. 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) Steady-state ("typical") power consumption without humidifier on 120 V AC power must be ≤75 watts. Maximum power consumption with humidifier on 120 V AC power must be ≤100 watts.
(c) Machine must have double insulated, 2-prong AC plugs for home use. Three prong is not acceptable.
(d) The power supply unit and power cord must be available for purchase for replacement of lost or damaged power supply and/or power cord.

15. 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 ASV machine is used with humidification, it must be compatible with at least 2 types of tubing manufactured by companies other than the manufacturer, unless using a heated-wire tubing.
    (e) Humidifier water chamber must be available for purchase as a replacement item for a lost/damaged humidifier water chamber.

16. 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.

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

18. Warranty: All ASV machines shall be covered by at least a standard commercial warranty of a minimum of two (2) years for the device and 90 days on any accessories. If the manufacturer/vendor standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply for all associated parts including humidifier, power supply, and ASV generator.

5. FACIAL INTERFACE CHINSTRAPS:

1. All manufactures will submit documentation that products meet International Organization for Standardization 80601-2-70: *Particular Requirements for basic safety an essential performance of sleep apnoea breathing equipment therapy* ("ISO PAP standard")

2. All manufactures will provide documentation that products meet or exceed International Organization for Standardization 17510:2015: *Sleep apnea breathing therapy –Masks and application accessories (*"ISO mask and accessory standard").

3. All manufactures will submit documentation that products meet United States FDA 510K Standard ("FDA Standard").

4. General Specifications:
   Chinstrap must be supplied in individual, standard commercial packaging in standard commercial configuration
   A user's guide must be provided in the English language to both prescriber and user at a 6th grade level.

5. Compatibility: Each chinstrap must be compatible with PAP facial interfaces from at least 3 different manufactures.
6. 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.
   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: Chinstraps must be cleanable with commercially available household cleaning agents.

8. Adjustment: Chinstraps must be adjustable to fit patients' head and face.

9. Warranty: The Chinstraps shall be covered by at least a standard commercial warranty of a minimum of 90 days. If the manufacturer's/vendor's standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply.

6. POSITIVE AIRWAY PRESSURE INTERFACES:

- Commonly known as "masks," including headgear, frame, and cushions where applicable.
- Includes full face masks, nasal masks, nasal pillows, and total face masks.

1. All manufactures will submit documentation that products meet International Organization for Standardization 80601-2-70: *Particular Requirements for basic safety an essential performance of sleep apnoea breathing equipment therapy* ("ISO PAP standard")

2. All manufactures will provide documentation that products meet or exceed International Organization for Standardization 17510:2015 : *Sleep apnea breathing therapy –Masks and application accessories* ("ISO mask and accessory standard").

3. General Specifications:

Devices must be supplied in individual, standard commercial packaging in standard commercial configuration

Assembly instructions for headgear, frame, and cushions (where applicable) into a functional interface must be provided in the English language to both prescriber and user at a 6th grade level.

4. Compatibility: Each interface must be compatible with PAP machines and tubing from at least 3 different manufactures without adaptors.

5. 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.

6. 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.
   The interface must dismantle in order to clean each component.

7. Lock/Release Mechanisms: All full face and total face masks must have a quick-release mechanism and must comply with ISO PAP Standard and FDA Standard to avoid risk of asphyxiation if the device fails or there is a power-cut.

8. Sizing: Interfaces must be available in a range of sizes.

9. Adjustment: Interfaces must be adjustable to fit patients' head and face.

10. Warranty: The Positive Airway Pressure Interfaces shall be covered by at least a standard commercial warranty of a minimum of 90 days. If the manufacturer's/vendor's standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply.

7. POSITIVE AIRWAY PRESSURE MACHINE FILTERS

1. All manufactures will submit documentation that products meet International Organization for Standardization 80601-2-70: *Particular Requirements for basic safety an essential performance of sleep apnoea breathing equipment therapy* ("ISO PAP standard")

2. All manufactures will provide documentation that products meet or exceed International Organization for Standardization 17510:2015: *Sleep apnea breathing therapy –Masks and application accessories (*"ISO mask and accessory standard").

3. All manufactures must submit documentation that products meet United States FDA 510K Standard ("FDA Standard").

4. Filters must be present with the PAP machine at time of distribution to the user.

5. Filters must be available for both the current and the prior model of PAP machine.

6. Warranty: Filters shall be covered by at least a standard commercial warranty of a minimum of 90 days. If the manufacturer's/vendor's standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply.

8. FACIAL INTERFACE LINERS

1. All manufactures will submit documentation that products meet International Organization for Standardization 80601-2-70: *Particular Requirements for basic safety an essential performance of sleep apnoea breathing equipment therapy* ("ISO PAP standard")

2. All manufactures will provide documentation that products meet or exceed International Organization for Standardization 17510:2015: *Sleep apnea breathing therapy –Masks and application accessories* ("ISO mask and accessory standard").

11. All manufactures will submit documentation that products meet United States FDA 510K Standard ("FDA Standard").

12. General Specifications:
    Liners must be supplied in individual, standard commercial packaging in standard commercial configuration.
    Use instructions must be provided in the English language to both prescriber and user at a 6th grade level.

13. Compatibility: Each liner must be compatible with PAP interfaces from at least 3 different manufactures.
14. 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.

15. Sizing: Liners must be available in a range of sizes for nasal mask and full-face mask interfaces.

16. Warranty: The Facial Interface liners shall be covered by at least a standard commercial warranty of a minimum of 90 days. If the manufacturer's/vendor's standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply.

9. POSITIVE AIR WAY PRESSURE TUBING

1. All manufactures will submit documentation that products meet International Organization for Standardization 80601-2-70: *Particular Requirements for basic safety an essential performance of sleep apnoea breathing equipment therapy* ("ISO PAP standard")

2. All manufactures will provide documentation that products meet or exceed International Organization for Standardization 17510:2015: *Sleep apnea breathing therapy –Masks and application accessories (*"ISO mask and accessory standard").

3. All manufactures must submit documentation that products meet United States FDA 510K Standard ("FDA Standard").

4. All tubing must come in length 6-12 feet.

5. All tubing must have an operating pressure range up to at least 25 cmH_20.

6. All tubing must have a female connector compatible with common commercially available PAP machines and PAP interfaces.

7. All tubing must be compatible with supplemental oxygen connection adapters.

8. 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).

9. All tubing must cleanable using commercially available household cleaning agents, with cleaning instructions provided in the English language to both prescriber and user at a 6^{th} grade level.

10. Warranty: Tubing shall be covered by at least a standard commercial warranty of a minimum of 90 days. If the manufacturer's/vendor's standard warranty exceeds the specified warranty, the manufacturer's/vendor's standard warranty will apply.