SUBSALVE OXYGEN TREATMENT HOOD

FDA Authorized for Emergency Use (EUA) for Covid-19

The Subsalve Oxygen Treatment Hood is a patient interface intended for helmet based Non Invasive Positive Pressure Ventilation (NIPPV) according to clinician established protocols to treat Acute Respiratory Distress Symptoms (ARDS) resulting from COVID-19. The device is for adults only and intended for use in Intensive Care Unit (ICU) settings.

Benefits:

- Raise patient airway pressure
- Elevate FiO2 for treatment
- Protect healthcare workers from virus

Features:

- One-piece design, no assembly required
- All soft materials for patient comfort
- Includes two 22mm ports for standard ventilator and respiratory circuit hoses
- Raised interior port stem to reduce backflow of fluids
- An additional pluggable service port is included.
- Latex and Silicone neck seal options available
- Shoulder straps to restrain when inflated
- Single patient use

For sales & technical inquiries, please contact:

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LOMBARDI

manufactured in the USA

SUBSALVE
A Performance Inflatables Company

Specifications

Dimensions	12” diameter x 12” tall internal volume ~22.23 liters, deadspace varies pending head size
Weight	1.1 lbs
Materials	PVC film white & clear (hood) Molded PVC (22mm ports) Molded PVC (service port) Latex (neck seal option #1) Silicone (neck seal option #2)
Gas Connections	22mm respiratory circuit connections, non-directional Complies with ISO5356 and ISO5367
Service Port	friction fit plug
Under Arm Straps	reinforced white vinyl with tri-glide buckles for adjustment

Neck Seal Options users may select silicone or latex at time of purchase. The neck seal may not be changed by the end-user.

Minimum Working Flow and Pressure

Minimum flow of 60 LPM required. Minimum operating pressure is 3 cm H2O (no PEEP valve, or PEEP full open)

Maximum Working Flow and Pressure

Maximum flow tested was 125 LPM. Maximum pressure tested was 35 cm H2O

Therapy pressures

Therapy may be implemented from 3 to 25 cm H2O according to clinician prescribed treatment

Anti-asphyxia Valve (AAV) none present

Regulatory Notice

Effective August 4th, 2020, the US FDA has authorized the Subsalve Oxygen Treatment Hood for emergency use in healthcare settings to treat patients during the COVID-19 pandemic, and has been added to Appendix B of the FDA’s Emergency Use Authorization (EUA).

The Subsalve Oxygen Treatment Hood is a patient interface intended for helmet based Non Invasive Positive Pressure Ventilation (NIPPV) according to clinician established protocols.

- This device has not been FDA cleared or approved
- This device has been authorized by FDA under an EUA
- This device is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of ventilators, ventilator tubing connectors, and ventilator accessories under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.