

Instructions for Healthcare Personnel (HCP): Use of the NRS AVR-100 device.

The U.S. Food and Drug Administration (FDA) has authorized an Emergency Use Authorization (EUA) for the emergency use of the Negative-pressure Respiratory System with Advanced Ventilation Return (hereafter referred to as the “NRS AVR-100”), to be used by HCP as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP exposure to pathogenic biological airborne particulates by providing isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing medical procedures, or during transport of such patients during the COVID-19 pandemic. Authorized non-transport use of NRS AVR-100 is only for airway management (e.g., intubation, extubation and suctioning airways), or when performing any aerosol generating medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or CPAP/BiPAP (continuous positive airway pressure /bi-level positive airway pressure) mask use, airway suctioning, percussion and postural drainage).

HCP should follow these instructions, as well as procedures at their healthcare facility, to use the NRS AVR-100 device.

The NRS AVR-100 is authorized for use by HCP as an extra layer of barrier protection to prevent HCP exposure to pathogenic biological airborne particulates; it is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE. The NRS AVR-100 has not been FDA-approved or cleared for this use; FDA authorized it for emergency use for the duration of the COVID-19 public health emergency (unless it is otherwise terminated or revoked sooner).

The NRS AVR-100 is a negative pressure, clear, rigid chamber that attaches to standard hospital or surgical beds around the head, neck, and shoulders of the patient. Access holes, sealed by rubber shrouds, built into the chamber allow for isolated patient access. The negative pressure environment is generated via a portable suction or negative pressure pumps equipped with an in-line high-efficiency particulate air (HEPA) filter suction device or via the healthcare facility wall-mounted suction.

The NRS AVR-100 can be used during patient transport within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. To transport patients on ventilators, all valves and ports are closed. To transport patients who are not on ventilators, the NRS AVR-100 would maintain negative pressure via portable self-contained, suction or negative pressure pumps equipped with HEPA filters. A registered nurse or physician should be in constant attendance during this time. Adequate oxygen flow and maintenance of negative pressure with adequate air flow should be assured. Patients should have continuous monitoring of SAT-O₂ levels, vital signs, and End-tidal CO₂ if available during transport.



The instructions below are to assist in using the NRS AVR-100. The NRS AVR-100 is an adjunctive protective barrier designed to mitigate risk to HCP. The NRS AVR-100 is not meant to be a stand-alone unit of PPE. The NRS AVR-100 should always be used with appropriate PPE and pursuant to the guidance of your institution.

Inspect NRS AVR-100 prior to use. Any wear/tear of the chamber or other signs of degradation on the NRS AVR-100 must promptly be reported to Oceanetics, Inc.; the healthcare facility must not use on patients and must dispose of such NRS AVR-100.

All connections should be tightly secured and checked frequently. Anytime anyone is within the NRS AVR-100, direct observation is required.

Rx Only

WARNINGS:

- Flammability of the NRS AVR-100 has not been tested. No interventions that could create a spark or be a flammable source should be used within the NRS AVR-100.
- Remove the NRS AVR-100 and use standard of care if there is difficulty visualizing or identifying anatomic land marks or inability to intubate after the first try.
- Prolonged use of the NRS AVR-100 may induce hypercarbia in a spontaneously breathing patient. The NRS AVR-100 should only be used with a spontaneously breathing patient with medical air flow and suction both on and working, under direct observation, and with end-tidal CO₂ monitoring if available. If end-tidal CO₂ monitoring is not available, then the use of the NRS AVR-100 should be limited to no more than a short duration of time, with medical air flow and suction both on and under direct observation.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety.
- Patient transport must only occur within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. Maintenance of negative pressure with adequate air flow must be assured. All patients should be on supplemental oxygen. Patients must have continuous monitoring of pulse oxygen saturation (Sp-O₂), vital signs, EKG, and End-tidal CO₂ if available during transport.

CONTRAINDICATIONS:

- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On individuals with communication disorders that might interfere with clinical care
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes
- Children under 45 pounds (lbs.)

1. Emergency Removal Instructions

If the device needs to be opened emergently, the device can be loosened enough to allow removal of the device. The operator and nearby personnel should be wearing appropriate maximal PPE including an appropriately fitting N95 respirator in case of potential airborne exposure or leave the area immediately if without appropriate PPE.

2. NRSAVR-100 Instructions for Use

1. To move device for use:
 - a. Close front lid and secure T-handles.
 - b. Place body shroud inside bottom of device.
 - c. Pick up device with handles on lateral sides.
 - d. Handle device with care. Do not drop, strike or place heavy objects on device.
2. The entire device is reusable. Device should be re-wiped down right before use on a new patient to remove any visible disinfectant residue that can obstruct the view.
3. Place device at the head of the bed and strap device to bed. Strap down hooks are located at the lateral sides and head side of the device. Place the patient head first into the device when ready.

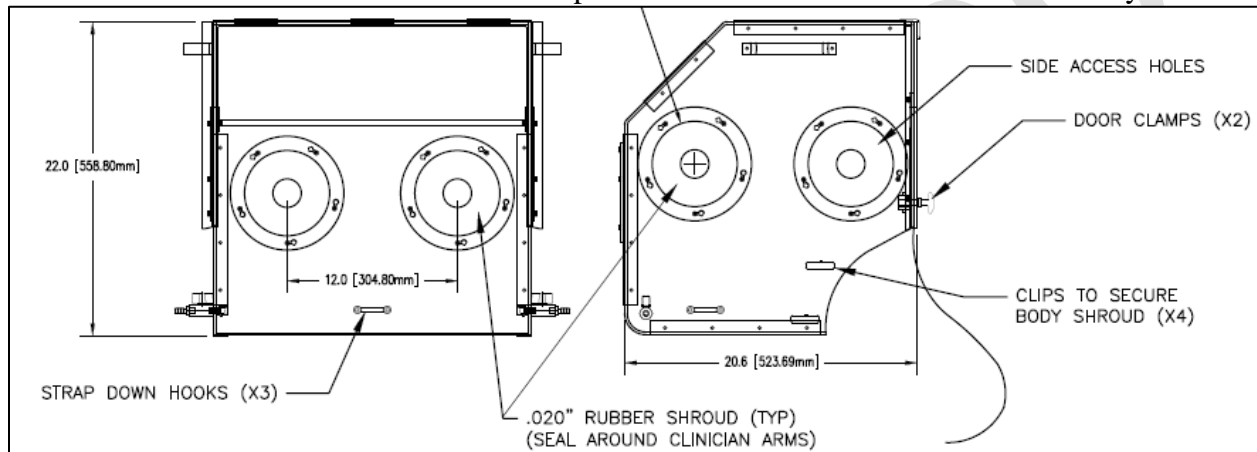


Figure 1 Three Strap Down Hooks are located on the front and lateral faces of the device.

4. Attach existing healthcare facility wall suction hose(s) to one or two of the 5/16" hose barb suction ports on the lateral side(s) of the device. If the device suction port is not connected, it shall remain closed. Verify suction system is equipped with adequate filter system to prevent contaminants or discharges from entering into healthcare facility suction discharge system.

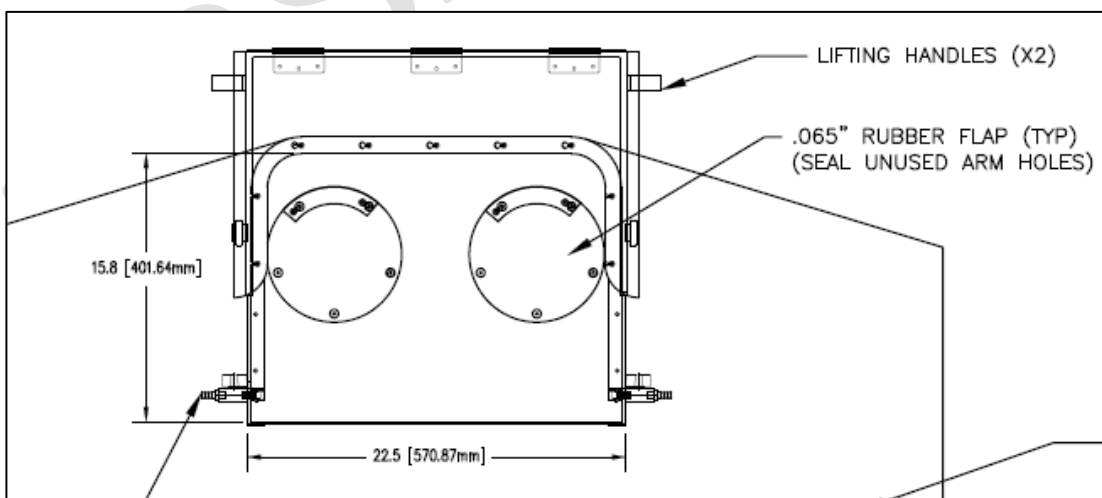


Figure 2 Suction ports equipped with valve handles are located on both lateral sides.

5. Facility regulator capacities may vary. Settings shall be on continuous suction flow. Do not use in intermittent mode. Typical healthcare facility wall mounted suctions provide up to 200 mm Hg at 80 L/min continuous flow.

6. Open suction port valve(s) on device until fully open.

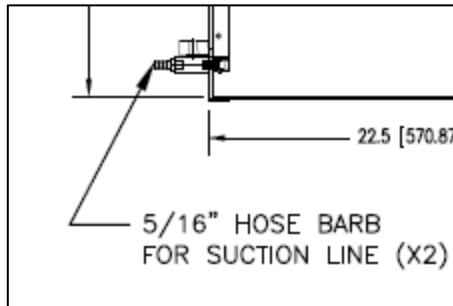


Figure 4 NRS AVR-100 suction port valves.

7. Set wall suction to high continuous setting exceeding 200mm of Hg. If two suctions are available, set the second suction to the same setting.

8. Identify large equipment that will not fit through the portholes intended to be used to provide the desired treatment. Place large equipment into the sides of the box.

Figure 5 Place large items required for procedure inside box prior to closing.



Figure 3 Typical healthcare facility wall suction.



Figure 4 Wall mounted hospital regulator with suction pressure from 0 to 200 mm Hg.



9. Close and secure hatch with rubber T-handles.
10. Wrap rubber shroud around upper body and tuck under shoulders to establish seal.
11. Clamp body shroud to the bilateral edges to secure a good seal.



Figure 6 Close hatch, cover chest with shroud, tuck under shoulders, and secure rubber T-handles.

12. Place arms through the portholes to perform medical procedures
13. Secure patient after performing the procedure and remove equipment through the portholes. Larger equipment can be removed at the appropriate time.
14. Manage any large openings through portholes left by medial hoses and wires with medical tape, while still allowing air flow inside the device to maintain negative pressure. Always ensure there is adequate air flow into the device.

Figure 7 Slip shroud to stainless steel clips on lateral sides of device.



15. While the patient is in the device, monitor the patient's suction supply and device shrouds and flaps to maintain negative pressure environment. The HCP should visually inspect the device for indications of negative pressure. HCP should verify the following:
 - a. Device is connected to one or two suction lines and suctions are opened to full (approximately 200 mm Hg each).
 - b. Verify suction valves on the device are in the open position. Open position is in line with hose barb, closed is perpendicular to hose barb.
 - c. Listen for sounds and look for signs of air flow into the device at arm shroud openings and interior flaps.
 - d. Once connected to the healthcare facility/portable suction device and the device valves are open, verify flow by monitoring the flowmeter or indicators installed on the suction device.



Figure 8 NRS AVR-100 is designed to allow for a patient care procedure while under negative pressure.

16. To transport patients on ventilators, close suction valves on the device. Then, disconnect from wall suction. Transport patient to ICU or other locations. The closed valves, sealed shroud, and flapper valves will contain the contaminate inside the device for a limited time. Manage any large openings through the portholes left by medial hoses and wires with medical tape. Air flow in the box is not necessary if both suction valves are closed and the patient is on a ventilator. Close the device valves in transport mode if not connected to HEPA or ultra-low particulate air (ULPA) filtered suction. Ensure interior flaps are down and minimize any escaping air. Maintain a good seal with the body shroud.
17. To transport patients not on ventilators, the device should be mated to portable self-contained, suction or negative pressure pumps equipped with HEPA filters. Do not connect to any suction or negative pressure pump that is not integrated with the healthcare facility filtering system or does not contain a HEPA or ULPA filter.
 - a. To transport patients not on a ventilator, the devices flapper valves allow patients to be contained and transported for very short durations without the use of portable suction pumps. Such use of the NRS AVR-100 may induce hypercarbia in a spontaneously breathing patient. The NRS AVR-100 should only be used with a spontaneously breathing patient with medical air flow and suction both on and working under direct observation and with end-tidal CO₂ monitoring, if available. If end-tidal CO₂ monitoring is not available, then the use of the NRS AVR-100 should be limited to no more than a short duration of time, with medical air flow and suction both on and under direct observation. The patient's breathing will bring in new air, and the device containment and flapper valve system will minimize the spread of contaminate during transport.

3. Disassembly

Please refer to “Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection of the NRS AVR-100 Device” for instructions regarding proper disassembly, cleaning and disinfection.

4. CAUTION:

- This Product Contains Natural Rubber that may cause allergic reactions.
- Handle device with care. Do not drop. Do not strike or impact. Do not place heavy objects on the device.

- When moving the device, close front lid, secure T-handles and place body shroud inside the bottom of the device. Wear PPE at all times when handling contaminated device and cleaning device. Wear clean PPE when handling cleaned device.
- The device could be used in the ER and during patient transport within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. Portable medical suction devices with sufficient suction performance, equipped with an in-line HEPA filters should be used in such cases. The suction provides the air flow and filtered exhaust to create the negative pressure environment. The device is equipped with hooks at the base on three sides to facilitate securing the device to hospital beds and gurneys.
- The device could be used for patients over 45 pounds (lbs.) only.
- Patients in the device should be checked regularly to look for potential areas where the device may be providing discomfort, restricting blood flow, or creating an area of irritation. The device body shroud can be placed over clothing, fabric, towels, or sheets to increase comfort to the patient.
- Patients shall be monitored at all times if left in the device to verify air flow into the device, thermoregulation and monitored for discomfort, irritation, or other medical conditions.
- The device is rigid, so it is not able to be folded. The suction hose suction could get blocked, or a valve could get closed. If the suction flow is blocked, the interior flaps do not make an air-tight seal. However, if these flaps are sealed from the interior by some other means, the chamber could become hypoxic.
- When under negative pressure, any surgical barriers may potentially inhibit the flow of air into the device.
- When generating a negative pressure environment, ensure air can flow into the device through the portholes.
- Close the device valves in transport mode if not connected to HEPA or ULPA filtered suction. Ensure interior flaps are down and minimize any escaping air. Maintain a good seal with the body shroud.
- When not under negative pressure, the device arm shrouds may be draped with surgical barriers using medical tape once the patient is intubated or is in a position where they are ready for transport. This further mitigates any contaminants that exit the device when not under negative pressure.
- Do not connect to any suction or negative pressure pump that is not integrated with the healthcare facility filtering system or does not contain a HEPA or ULPA filter.
- The system does not contain filters. The device is connected to external suction provided by the healthcare facility. The suction must be a system provided by the healthcare facility that provides adequate air filtration of the exhausted air. The typical system will be the wall mounted suction system at the hospital facility. Another suction system will be a self-contained portable air suction system equipped with a HEPA or ULPA air filtering system.
- Emergency removal of a patient under negative pressure will potentially expose the area outside of the device to contaminants. HCPs shall use appropriate universal precautions and wear appropriate maximal PPE at all times.

- Do not use harsh chemicals or abrasives to clean. Please use chemicals from the List N: Disinfectants for Use Against SARS-CoV-2 <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>.
- Do not apply heat. Do not autoclave.
- The components provided with the system are all reusable. Spare arm shrouds, interior flaps, thumb screws, and body shroud are provided as required by the healthcare facility. Any used components that are no longer serviceable or damaged should be disinfected and disposed of as a biohazard.

5. Labeling Considerations:

- The device does not have any electrically powered components.

NRSALVR-100