

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the Negative-pressure Respiratory System with Advanced Ventilation Return (NRS AVR-100)

June 13, 2020

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the **Negative-pressure Respiratory System with Advanced Ventilation Return** (hereafter referred to as the “NRS AVR-100”). This device is authorized for use 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.

All patients who are treated with the NRS AVR-100 will receive the Fact Sheet for Patients: “Emergency Use of the Negative-pressure Respiratory System with Advanced Ventilation Return (NRS AVR-100).”

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the Center for Disease Control and Prevention (CDC) webpage for the most up to date information (<https://www.cdc.gov/COVID19>).

What do I need to know about the emergency use of the NRS AVR-100?

- The NRS AVR-100 is authorized for patient transport within a hospital setting for temporary transfer only for direct admission within the hospital, in the presence of a registered nurse or physician.
- The NRS AVR-100 is not intended to replace PPE.

- 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).
- Inspect NRS AVR-100 upon receipt. 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.
- When using the NRS AVR-100 on a patient, the following is recommended:
 - Direct observation is required at all times
 - Use portable or wall-mounted medical air
 - Use continuous pulse oximetry and end-tidal CO₂ monitoring if available
 - Ensure all connections are tightly secured and checked frequently
 - All patients should have supplemental oxygen in place at all times while NRS AVR-100 is being used.
 - Position the patient in a temperature controlled environment to avoid hyper- and hypothermia.
 - Ensure the suction is connected to vacuum source that has either a High-Efficiency Particulate Air (HEPA) filter or the vacuum is part of a healthcare facility wall suction system that evacuates the vacuumed air safely to the environment per institutions building codes and regulations.

Use appropriate PPE when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*. Current information on COVID-19 for healthcare providers is available at CDC’s webpage, *Information for Healthcare Professionals* (see links provided in “Where can I go for updates and more information” section).

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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What is the NRS AVR-100?

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

When using NRS AVR-100 to transport patients on ventilators, all valves and ports are closed. When using NRS AVR-100 to transport patients who are not on ventilators, the NRS AVR-100 maintains negative pressure via portable self-contained, suction or negative pressure pumps equipped with HEPA filters.

The device is an adjunct to PPE for HCP during the COVID-19 pandemic and does not replace the need for PPE.

The NRS AVR-100 requires the following components which are not included as part of the NRS AVR-100 system:

- Portable suction or negative pressure pump with an in-line HEPA filter or healthcare facility wall-mounted suction; and
- Portable or wall-mounted medical air or oxygen.

Contraindications

The NRS AVR-100 is not authorized for the following uses:

- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients 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
- On children under 45 pounds (lbs.)

Warnings and Cautions

- 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 landmarks 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 medical air or oxygen flow and suction both on and working, under direct observation, and with end-tidal carbon dioxide (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 times 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.
- Use of NRS AVR-100 for patient transport must only occur within a hospital setting for temporary transfer with direct admission within the hospital with a registered nurse or physician in constant attendance during this time. 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) levels, vital signs, EKG, and End-tidal CO₂, if available, during transport.

What are known and potential benefits and risks with the NRS AVR-100

Known and Potential Benefits

- Prevent/minimize risk of HCP exposure to the virus, by providing an extra layer of barrier protection in addition to PPE.
- Allow safer method for HCPs to perform standard, non-invasive respiratory treatments by containing and evacuating pathogenic biological airborne particulates.

Known and Potential Risks

- Device malfunction may lead to hypoxia of the patient, patient injury and possible contamination of HCP, or increased risk of release of pathogenic

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biological airborne particulates to the local environment and possible contamination of personnel.

- Device malfunction may lead to hypercarbia in a spontaneously breathing patient.
- Device may interfere with procedures conducted on the patient.
- Allergic reaction to non-biocompatible materials.
- Inadequate disinfection of the NRS AVR-100 between patient uses may result in increased risk of disease transmission from contamination.

What is an Emergency Use Authorization (EUA)?

The United States Food and Drug Administration (FDA) has made NRS AVR-100 available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The NRS AVR-100, made available under this EUA, has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the NRS AVR-100 may be effective for use by HCP as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates during transport of patients with suspected or confirmed diagnosis of COVID-19 or at the time of definitive airway management and performing medical procedures related to airway management and breathing treatments during the COVID-19 pandemic.

The EUA for this device is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the device may no longer be used).

How can I learn more?

CDC websites:

General: <https://www.cdc.gov/COVID19>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Infection Prevention and Control Recommendations in Healthcare

Settings: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

FAQ on Personal Protective Equipment:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

FDA websites:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Manufacturer Information

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