

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the AerosolVE Device. This device is authorized for use by healthcare providers (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 temporary isolation of hospitalized patients with suspected or confirmed diagnosis of COVID-19, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

All patients who are treated with the AerosolVE™ Device should receive the Fact Sheet for Patients: Emergency Use of the AerosolVE™ Device.

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). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. 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. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

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.

What do I need to know about the emergency use of the AerosolVE Device?

- The AerosolVE Device is authorized for direct transport of COVID-19 suspected or confirmed patients within the hospital, by HCP donning proper PPE monitoring body temperature, EKG, SpO₂, and end-tidal CO₂, if available, throughout transport.

- The AerosolVE Device is only for use on COVID-19 suspected or confirmed patients after they have been admitted to the hospital. The patient's body temperature, CO₂ level and oxygen levels must be constantly monitored by HCP.
- Authorized non-transport use of the AerosolVE Device is only for airway management procedures, (e.g., intubation, extubation and airway suctioning), or when performing any airway-related procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or continuous positive airway pressure/bi-level positive airway pressure (CPAP/BiPAP) mask use, airway suctioning, percussion and postural drainage). Prior to use, inspect all AerosolVE Device components to ensure they are working properly. Any signs of degradation or wear and tear of the AerosolVE Device must be promptly reported to Inspire Rx, LLC. In such case, the healthcare facility must not use the device on patients, and must properly dispose of the AerosolVE Device.
 - The disposable AerosolVE Device tent kit (P/N IN-200001) with integral HEPA filter is for non-sterile, single patient use only, for intermittent use, as needed, for up to fourteen (14) days.
 - The reusable AerosolVE Device fan (P/N IN-200002) should be cleaned and disinfected per the hospital's infection control protocols, in preparation for its next use.
 - The AerosolVE Device is not intended to replace PPE or room sanitation or disinfection procedures.
 - When using the AerosolVE Device on a patient:
 - Direct observation is required at all times.
 - Patient should be always receiving supplemental oxygen during the use of the device.
 - Use continuous pulse oximetry, body temperature and end-tidal CO₂ monitoring, if available.
 - Position the patient in a temperature-controlled environment to avoid hyperthermia and hypothermia.
 - The AerosolVE Device system should be connected to an uninterruptible power supply (UPS) to mitigate instances of power loss, including during transport.
 - The AerosolVE Device is not to be sealed around the patient and requires airflow into

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- the tent to provide airflow through the HEPA filter.
- Do not exceed eight (8) 406 mm/16 inch long direct patient access slits, or four (4) 100 mm/4 inch holes, per tent.
- The AerosolVE Device fan should be frequently checked, to confirm airflow. When the fan is ON, the fan outlet airflow indicator strips will flutter to provide a visual means to confirm airflow, which indicates the system is under negative pressure, and functioning as intended.
- If loss of negative pressure occurs during use, the AerosolVE™ Device tent should be removed.
- All connections should be secured and checked frequently.

Use appropriate PPE when caring for individuals suspected of having COVID-19, as outlined in the CDC's *"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 HCPs is available at the CDC's webpage, *Information for Healthcare Professionals* (see links provided in *"Where can I go for updates and more information"* section of this Fact Sheet.

What is the AerosolVE Device?

The AerosolVE Device is a portable, negative pressure patient temporary isolation and procedural tent system, to act as an added layer of physical barrier in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates. The AerosolVE Device is comprised of a disposable tent unit that includes a foldable, fire retardant clear vinyl tent enclosure, an integral high-efficiency particulate air (HEPA) filter, exhaust tubing, and a reusable fan. The tent is placed over the head, neck, shoulders, and torso of the patient to isolate airborne particulates. The fan is placed on the floor and the exhaust tubing is connected between it and the HEPA filter, which is located within the tent. The fan is then plugged into a standard 120VAC wall outlet and the flow indicators on the fan outlet indicate when the airflow is sufficient for use with the patient. Once an HCP

dons proper PPE, the HCP can cut slits into the vinyl surface of the tent where needed, to provide full and direct access to the patient (no more than eight (8) each, 406 mm/16 inch long direct patient access slits or four (4) 100 mm/4 inch holes, per tent). When the period of use is complete, the disposable tent unit is disposed of per the hospital's biohazardous waste disposal practice. The fan should be cleaned and disinfected per the hospital's infection control protocols, in preparation for its next use.

The AerosolVE Device includes the following key components:

AerosolVE Device: Disposable Kit: P/N IN-200001 – For Non-Sterile, Single Patient Use Only

- Tent: Provides a fire retardant, clear vinyl covering over the patient, which allows for direct patient access points and fresh air intake through openings.
- Tent Base: provides tent structure, interfaces to patient bed, and houses the HEPA filter/manifold; includes Patient ID label.
- Exhaust Tubing: carries HEPA filtered air away from the patient
- 2 Tape Strips: to secure exhaust tubing inlet/outlet
- 1 Airflow Indicator Strip: attached to HEPA filter manifold

AerosolVE Device Fan Unit Kit: P/N IN-200002 – Reusable

- Fan with Integral Base and HEPA filter: Creates negative pressure, high volume air flow within the system
- 2 Airflow Indicator Strips: attached to Fan outlet

AerosolVE Device: Instructions for Use (IFU): P/N IN-110001

Contraindications

The AerosolVE Device is contraindicated for use:

- On patients needing emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- On patients with other anatomical abnormalities that might interfere with clinical care including decreased neck mobility from arthritis or other causes

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- On patients with anticipated or known history of claustrophobia
- On patients with communication disorders that might interfere with clinical care
- On patients under the age of 18
- On bariatric patients
- On patients with uncontrolled movements that may prevent the patient from being able to remain enclosed in the tent enclosure
- On patients requiring procedures that involve exceeding the maximum direct access slits or holes as stated in this IFU
- In elderly care centers – it is only for use in a hospital environment
- In ambulance transport
- The system should be connected to an uninterruptible power supply to mitigate instances of power loss.
- The AerosolVE Device is not to be sealed around the patient and requires airflow into the tent to provide airflow through the HEPA filter.
- Do not exceed eight (8) 406 mm/16 inch long direct patient access slits, or four (4) 100 mm/4 inch holes, per tent.
- The AerosolVE Device fan should be frequently checked, to confirm airflow. When the fan is on, the fan outlet airflow indicator strips will flutter to provide a visual means to confirm airflow, which indicates the system is under negative pressure, and functioning as intended.
- If loss of negative pressure occurs during use, the AerosolVE Device tent should be removed.
- After use, the disposable tent kit components should be disposed of following the hospital's biohazardous waste disposal procedures.
- The reusable fan and fan base should be cleaned and disinfected per the hospital's infection control protocols, in preparation reuse.
- Components should not be heated above 130°F.
- Delayed emergency removal of the device may result in patient injury.

Warnings and Cautions

- Patient should always receive supplemental oxygen during the use of the device
- Remove the AerosolVE Device and use standard of care if there is difficulty visualizing or identifying anatomic landmarks or inability to intubate.
- Prolonged use of the AerosolVE Device may induce hypercarbia in a spontaneously breathing patient. The AerosolVE Device should only be used with a spontaneously breathing patient with air flow fan 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 AerosolVE Device should be limited to no longer than 30 minutes with air flow fan on and under direct observation.
- Patient transport must only occur within a hospital setting for temporary transport 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 (SpO₂), vital signs, electrocardiogram (EKG), and end-tidal CO₂, if available throughout transport.
- Patients with diminished hearing may have difficulty understanding the provider while inside the AerosolVE Device tent.
- If the device is accidentally folded, or the airflow inlets are blocked, this may result in patient injury.

What are the known and potential benefits and risks of using the AerosolVE Device?

Potential benefits of using the AerosolVE Device include:

- May prevent or minimize risk of HCP exposure to pathogenic biological airborne particulates.
- May aid as an extra layer of barrier protection in addition to PPE for HCPs.
- May allow for potentially safer method to perform standard, non-invasive respiratory treatments by containing and evacuating pathogenic biological airborne particulates
- Ability to transport suspected/confirmed COVID-19 patient inside a hospital setting without contaminating surroundings and other personnel.

Potential risks of using the AerosolVE Device include:

- 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.
- Inappropriately assembled device may lead to failure of the device to properly isolate patient.
- Accidental device folding or blockage of airflow inlets may result in patient injury.
- Delayed emergency removal of the device may result in patient injury.
- Patient may have an allergic reaction to device materials.

What are the alternatives to the AerosolVE Device during the COVID-19 pandemic?

There are no approved available alternative devices. FDA has issued EUAs for other similar products that can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

What is an Emergency Use Authorization (EUA)?

The United States Food & Drug Administration (FDA) has made the emergency use of the AerosolVE Device available under an emergency access mechanism called an EUA.

The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The authorized use of the AerosolVE Device 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, or available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the device that meets certain criteria for safety, performance, and labeling, and

that it may be effective in treating patients with COVID-19.

The EUA for the AerosolVE 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 products 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>

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