

Instructions for Healthcare Personnel (HCP): Use of COVIAGE

The U.S. Food and Drug Administration (FDA) has authorized an Emergency Use Authorization (EUA) for the emergency use of the COVID-19 protective barrier enclosure (hereafter referred to as COVIAGE). COVIAGE is authorized to be used by healthcare personnel (HCP) as an extra layer of barrier protection in addition to personal protective equipment (PPE) to prevent HCP from being exposed 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, when performing airway-related medical procedures, or during certain transport of such patients during the COVID-19 pandemic.

COVIAGE is not intended to replace the need for PPE or room sanitation and disinfection procedures. COVIAGE has not been FDA-approved or cleared for marketing in the US. The FDA has authorized COVIAGE for emergency use under an EUA during the COVID-19 public health emergency. COVIAGE has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

COVIAGE is a negative pressure protective barrier enclosure that attaches to hospital beds and stretchers. It utilizes a series of filters to capture and contain pathogenic biological airborne particulates. COVIAGE is comprised of a removable aluminum frame, a plastic tent, and a filtration/ventilation system. The tent contains sleeves with attached gloves, entry zippers, and a two-way access box through which medical supplies, food, and water etc. can be passed into and out of the tent. The aluminum frame is attachable to different types and sizes of hospital unit beds. The transparent plastic tent allows unrestricted visibility for the patient and HCP while containing pathogens inside the tent and, thus, protecting both patients and staff. The ventilation system maintains negative pressure and stable temperature inside the enclosure while keeping pathogenic biological airborne particulates from sneezes, coughs, and talking inside the enclosure. These particles are subsequently filtered at a high-efficiency particulate air (HEPA)-level filtration rate.

COVIAGE is comprised of the following components outlined in Table 1 below:

Component	Reusable	Disposable
Ventilation system with fan and battery for portable operation	✓	
Two in-line filters		✓
Plastic (thermoplastic polyurethane tent)		✓
Sleeves (polyether polyurethane)		✓
Gloves (polyether polyurethane)		✓
Two-way access box (polyether polyurethane)		✓

Zippers		✓
Grommets		✓
Prefilter		✓
Zip ties		✓
Carabiners	✓	
Aluminum frame	✓	

COVIAGE has been authorized for emergency use to isolate patients with suspected or confirmed COVID-19 infections requiring airborne or droplet isolation precautions during transportation and hospitalization in a healthcare setting. However, during the public health emergency, it would not be feasible to require HCP to limit COVIAGE use for patients with suspected or confirmed COVID-19; therefore, the authorization does not restrict use to such patients.



- COVIAGE is intended for use by HCP as an extra layer of barrier protection in addition to PPE to prevent HCP exposure to pathogenic biological airborne particulates by isolating patients with known or suspected COVID-19, at the time of definitive airway management (e.g., intubation, extubation and suctioning airways), when performing any airway-related medical procedures (e.g., high flow nasal cannula oxygen treatments, nebulizer treatments, manipulation of oxygen mask or continuous positive airway pressure (CPAP)/bi-level positive airway pressure (BiPAP) mask use, airway suctioning, percussion and postural drainage).
- COVIAGE is authorized for patient transport within a hospital setting for temporary transfer (less than 40 minutes, at which time the battery will be depleted) for direct admission within the hospital in the presence of a registered nurse or physician. The patient should have constant monitoring of vital signs, electrocardiogram (EKG), SpO₂% (oxygen saturation), End tidal carbon dioxide (EtCO₂), if available, throughout transport.
- COVIAGE is ***not*** intended to replace PPE or room sanitation and disinfection procedures.

Use appropriate PPE when caring for individuals suspected of having COVID-19 as outlined in the Center for Disease Control & Prevention (CDC) *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19), Persons Under Investigation for COVID-19 in Healthcare Settings*, or on the CDC webpage for *Infection Control*. Current information on COVID-19 for HCP is available at the CDC's webpage, *Information for Healthcare Professionals*.

To use COVIAGE, HCP should follow these instructions, in addition to protocols currently in place at their healthcare facility.

The instructions below are to assist in using COVIAGE enclosure. COVIAGE is not meant to be used without PPE. **COVIAGE should always be used with PPE** as recommended by the guidelines of your institution.

Inspect COVIAGE prior to use. **If there are any tears, punctures or signs of degradation and wear in the tent and/or bends, dents, or deformations of the frame, the device MUST NOT be used on patients and degraded or damaged components must be disposed.** Furthermore, this must promptly be reported to Duke University.

All connections should be tightly secured and checked frequently. The vital signs, SpO₂, and end tidal CO₂, if available, of all patients within COVIAGE need to be monitored. All patients to whom COVIAGE is applied should be receiving supplemental oxygen via wall-mounted or portable oxygen.

WARNINGS and CAUTIONS:

- Remove COVIAGE and use the standard of care if there is difficulty performing medical care with the device in place.
- Do not place patients inside the enclosure unless the ventilation and filtration system is on and functioning properly.
- If the ventilation and filtration system fails during transport, unplug the battery pack and the fan. Visually inspect the fan, the power cord wires, and battery pack for damage. Check for a dead battery pack by connecting a freshly charged battery and turning on the power.
- If any punctures or tears in the tent are identified, do not use COVIAGE. Clean and disinfect undamaged, reusable components of COVIAGE and obtain new disposable components before proceeding.
- Do not keep patients in COVIAGE in direct sunlight.
- COVIAGE should be operated only in temperature and humidity-controlled environments to prevent temperature and humidity fluctuations that could interfere with patient thermal regulation and function of the filters.
- Monitor patient temperature continuously while the patient is in the unit.
- Use caution prior to use on non-sedated or lightly sedated patients with severe claustrophobia and/or confined space anxiety.
- COVIAGE should be checked for generation of negative pressure continuously (refer to operation instructions).
- COVIAGE includes single use components that must be properly disposed of following use to prevent spread of contamination.
- Inadequate cleaning and disinfection of COVIAGE reusable components between patient use may result in increased risk of transferring contaminants which may lead to infections.
- Inappropriately assembled device may lead to failure of the unit to properly isolate patient.
- This device does not protect against radiation, nor is it intended for use with any imaging modalities that preclude metals (e.g. MRI Use Prohibited).
- The electrical parts of this equipment have not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that may affect the performance of other equipment.

- Patient monitoring, wearable or implanted devices and their cables should be located as far as possible from the device motor; and their performance should be observed periodically to verify that they are operating normally during its operation.
- COVIAGE includes flammable materials. No interventions that could create a spark or be a flammable source should be used within COVIAGE.
- Prolonged use of COVIAGE with a nonfunctioning ventilation system and/or obstructed air intake may induce hypercarbia in a spontaneously breathing patient. Patients should be under direct observation, and with end-tidal CO₂ monitoring if available.
- COVIAGE should be used on spontaneously breathing or intubated patients with the ventilation system on and working, and the air intake unobstructed.
- 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.
- Patients must have continuous monitoring of SpO₂, vital signs, EKG, and End-tidal CO₂ if available during transport.
- All patients should be receiving supplemental oxygen during COVIAGE use.
- Do not use COVIAGE on patients who suffer from noise sensitivity (a.k.a. hyperacusis) or other hearing disorders (e.g. phonophobia).

CONTRAINDICATIONS:

COVIAGE is not authorized for the following uses:

- For emergent endotracheal intubation with severe hypoxemia
- On patients with anticipated or known history of difficult airway
- Combative or non-cooperative patients
- 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.)

COVIAGE Instructions for Use

Final assembly of COVIAGE Patient Isolation Tent, with labeled features shown in Figure 1 below:

Figure 1: Fully assembled COVIAGE enclosure



COVIAGE Instructions:

- Ensure the tent does not have any rips or welding errors and that the heating, ventilation and air conditioning (HVAC) system is on, functioning, and is connected with two in-line filters.
- Ensure placed tent is fully expanded, in desired position and with all zippers (sides and two-way access box zippers) fully closed prior to use.
- Wear appropriate PPE prior to and while using COVIAGE.
- If you are placing the tent over the Emergency Department (ED) stretcher, contour in the tent completely around and just under the mattress of the bed (see Figure 2). The side zippers can be opened to mattress level.

Figure 2: Correct tent configuration for ED stretcher



- For the regular floor and Intensive Care Unit (ICU) beds DO NOT TUCK the tent under the mattress (see Figure 3). Place the bottom of the tent in between the mattress and arm rests/barriers.

Figure 3: Correct tent configuration for regular floor and ICU beds



- Test the system by letting the fan run for a 2-3 minutes and visually inspect the tent for an hour-glass shape (see Figure 4).

Figure 4: Hour-glass tent conformation



Endotracheal intubation using COVIAGE

Endotracheal intubation can be performed while using COVIAGE through the set of sleeves/gloves at the head of the bed (unless noted otherwise). The procedure is outlined below:

1. Prepare equipment (e.g. electrocardiogram (ECG), pulse oximetry, endotracheal tube) by passing tubing between the tent and mattress and through the two-way box or zipper of the tent.
2. Prepare the appropriate medications (e.g. paralytic, opioid, hypnotic etc.) in syringes and insert them into the enclosure through the two-way box or the zipper of the tent.
3. Prepare the patient with preoxygenation and attach both ECG and pulse oximetry for physical monitoring. Pass the oxygen tubing between the tent and the mattress. HCP should hold the oxygen face mask.
4. Pass necessary pretreatment agents through the sleeves/gloves at the side of the tent or through the zipper opening.
5. Administer paralysis with induction through the sleeves/gloves at the side of the tent or through the zipper opening.
6. Position the patient appropriately (i.e. "sniffing" position) using sleeves/gloves at the side of the tent.
7. Place the endotracheal tube in the trachea and confirm correct placement by observing increasing end tidal carbon dioxide or auscultating both lungs. Auscultation of the lungs can be performed through any of the sleeves/gloves. Placement of the endotracheal tube should be done in accordance with institution Standard Operating Procedure.
8. Remove all used equipment through the zipper opening upon completion of the procedure.
9. Postintubation management can be performed by using the sleeves/gloves, or two-way box or zipper openings as needed.

Extubation using COVIAGE

Extubation can be performed while using COVIAGE through the set of sleeves/gloves at the head of the bed (unless noted otherwise). The procedure is outlined below:

1. Prepare equipment (e.g. nebulizer filled with normal saline, suction catheter, mask, syringe) and pass into the enclosure through the two-way box or the zipper of the tent.
2. Prepare the appropriate medication (e.g. paralytic, opioid, hypnotic etc.) in syringes and insert into the enclosure through the two-way box or the zipper of the tent.
3. Sit patient up to at least 45 degrees.
4. Suction endotracheal tube with bronchial suction catheter.
5. Suction oropharynx with Yankour suction.
6. Deflate endotracheal tube (ETT) cuff with the syringe.

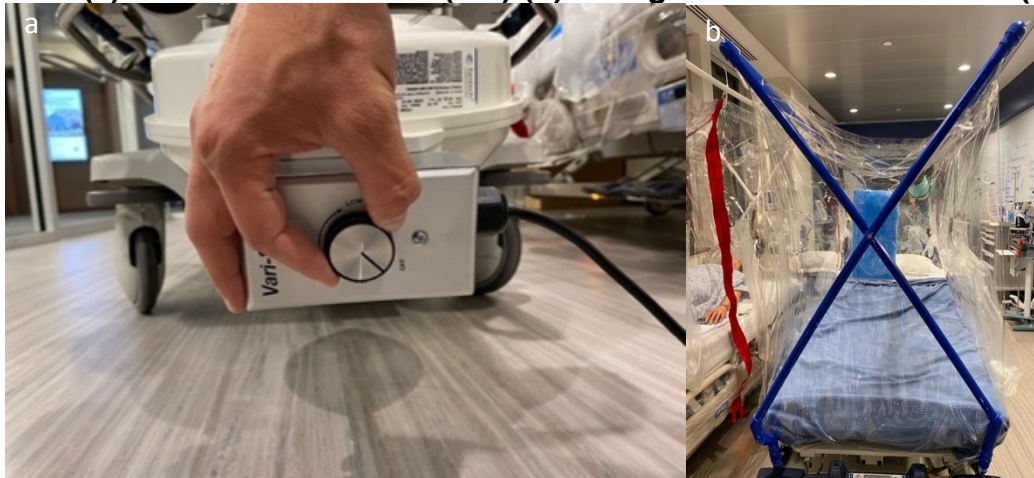
7. Have patient cough; pull the tube during the cough. Extubation should be done in accordance with institution Standard Operating Procedure.
8. Suction the oropharynx again.
9. Encourage the patient to keep coughing up any secretions.
10. Place nebulizer on patient at a rate of 4-6 L/min.
11. Remove all used equipment through the zipper opening upon completion of the procedure.

Patient transport using COVIAGE

During patient transport COVIAGE maintains negative pressure via a portable HVAC system with two in-line filters, and oxygenation is supplied via the inlet prefilter at the foot of the tent enclosure.

- Ensure the HVAC system is connected to a fully charged battery backup prior to disconnecting the HVAC system from the wall AC outlet.
- Ensure that the HVAC system is turned to “HIGH” by turning the knob shown in Figure 5a. Ensure that negative pressure is maintained after the HVAC is disconnected from the wall AC outlet by noting the hourglass shape of the tent shown in Figure 5b.

Figure 5: (a) HVAC Control Knob (left) (b) Hourglass tent conformation (right)



- While transporting the patient on a bed with COVIAGE installed, ensure that you hold and push the bed from the bed hand rails, **NOT the frame**.
- Ensure that the intravenous line tubing (or any other medical tubing) is not overhanging the patient's bed.
- During transport, ensure that the size and height of the frame can clear hospital and elevator doors.
- 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 SpO₂, vital signs, ECG, and End-tidal CO₂ if available during transport.

Emergency Removal Instructions

The instructions below are for the removal of the aluminum COVIAGE frame in the event of an emergency. The large clear plastic tent (polyurethane) is not for reuse and should be discarded according to biohazard guidelines. PPE should be donned during the emergency removal of COVIAGE.

1. Disconnect the ventilation system tubing from the internal filter.
2. Two people should lift and move the frame by holding it close to where the X bars meet as show in Figure 6.

Figure 6: Correct handling of the frame



3. Lift the frame with the tent still attached and place the entire assembly on the floor.
4. The patient is ready to be treated without COVIAGE in place.