Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection 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 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, 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 airborne particles. 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, 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 is designed not to restrict visibility for the patient and HCP while containing pathogenic biological airborne particulates inside the tent and, thus, providing a barrier for 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	✓	

Authorized non-transport use of COVIAGE is only for 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/bi-level positive airway pressure [CPAP/BiPAP] mask use, airway suctioning, percussion and postural drainage).

Authorized use of COVIAGE during patient transport is only within a hospital setting for temporary transfer (less than 40 minutes, at which time the battery may be depleted) with 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), SpO_2% (oxygen saturation), End tidal carbon dioxide ($EtCO_2$), if available, throughout transport.

For all authorized uses, the patient should always have supplemental oxygen via during use of COVIAGE.

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 building, assembling, disassembling and disinfecting COVIAGE. 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 is any tear, puncture or signs of degradation and wear in the tent or bending, dents, or deformation of the frame, the device MUST NOT be used on patients and damaged or degraded components must be disposed. Furthermore, this must promptly be reported to Duke University.

All connections should be tightly secured and checked frequently.

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 the ventilation does not resume, the patient should be removed from COVIAGE.
- If any punctures or tears in the tent are identified, do not use COVIAGE and dispose of the damaged components. 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 CO_2 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.

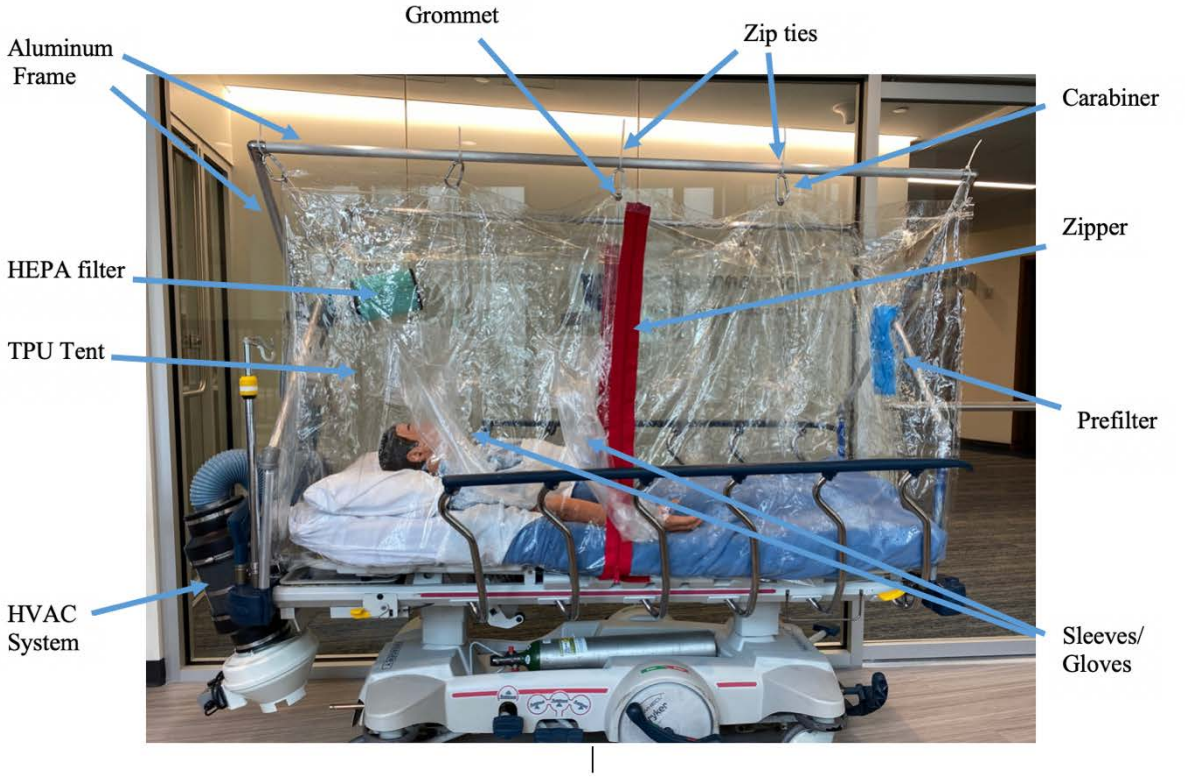
- Patient transport must only occur within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. Maintenance of negative pressure with adequate air flow must be assured.
- Patients must have continuous monitoring of SpO_2, vital signs, EKG, and End-tidal CO_2 if available during transport.
- All patients should be receiving supplemental oxygen.
- 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.)

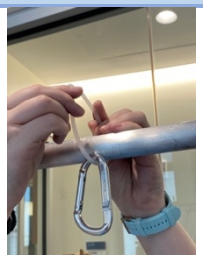
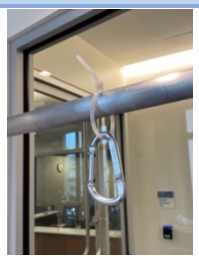
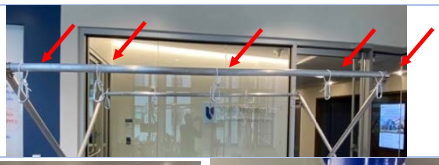
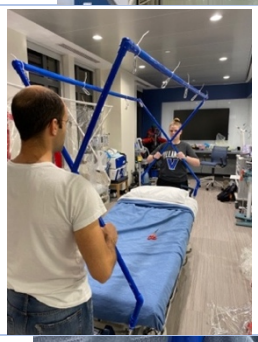
COVIAGE Instructions on Build, Assembly, Disassembly, and Disinfection

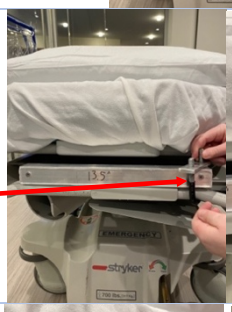
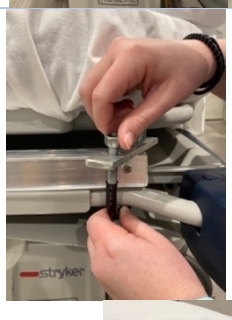
Final assembly of COVIAGE Patient Isolation Tent, with labeled features shown below:



COVIAGE Assembly Instructions:

- Assemble and secure both isolation tent frame and thermoplastic polyurethane (TPU) tent prior to patient use as per instructions detailed below.
- Visually inspect tent frame. If any cracks or significant bends are found in the frame structure, DO NOT USE!
- Ensure locknuts at cross section of frame are fastened completely and unable to be loosened.
- Visually inspect TPU tent. If any rips or significant adhesive/welding errors are found in the tent, DO NOT USE!

Assembly instructions for isolation tent frame	
1. Placement of zip ties and carabiners. a. Insert carabiner through zip tie as shown. Do not fasten zip tie completely yet.	 
2. Place 5 zip ties and carabiners on one side bar and 5 zip ties and carabiners on the other side bar of the frame.	
3. Two people should lift and move the frame so that the marked head and foot are in the correct orientation and align with the bed a. Each person should lift the frame from the cross-section area	 
4. Place the frame in the head and foot holes found at both ends of the bed a. Ensure that the frame is sitting securely in these holes and that the frame supports are as deep as they can go in the holes	 
Assembly instructions for isolation tent Heating, Ventilation and Air Conditioning (HVAC) system	
1. If you are securing the HVAC system on the Emergency Department (ED) stretcher, gather the supplies for the mounting bracket of the HVAC system. A wrench is needed for the assembly. If you are securing to a regular floor or Intensive Care Unit (ICU) bed go to step 6.	

2. Place the square metal bar on the cylinder metal bar of the head frame of the ED stretcher. Place the plastic face towards you.	
3. Place the metal place with the two holes over the U bolt.	U Bolt   Metal Plate
4. Screw the two nuts to the U bolt. Use the wrench to tighten them.	  

5. Place the rubber caps over the U bolt.



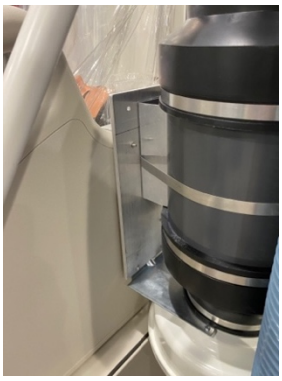
6. Place the fan and hose over the bracket of the bed. Use top two photos for ED stretcher and the bottom two for the regular floor or ICU beds.

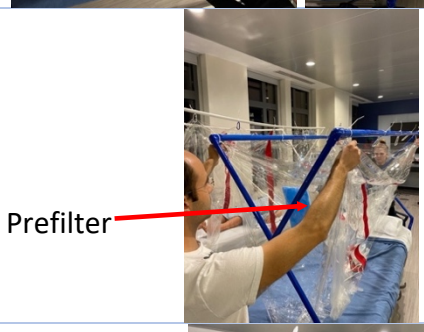
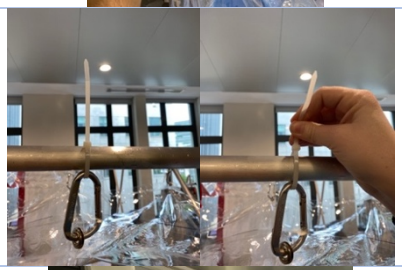
    a. Mount the HVAC system at the center of the headboard of the bed with the hanging channel-shaped mounting part.

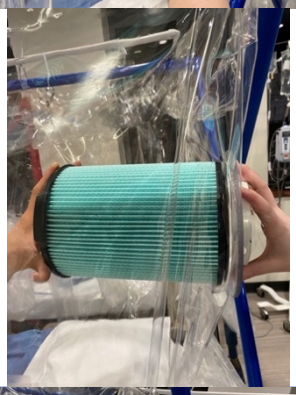
    b. The HVAC system should face outwards.

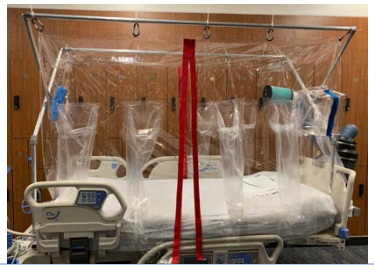
ED Stretcher:

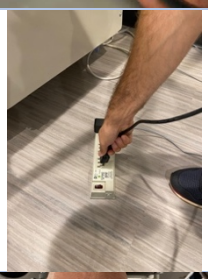
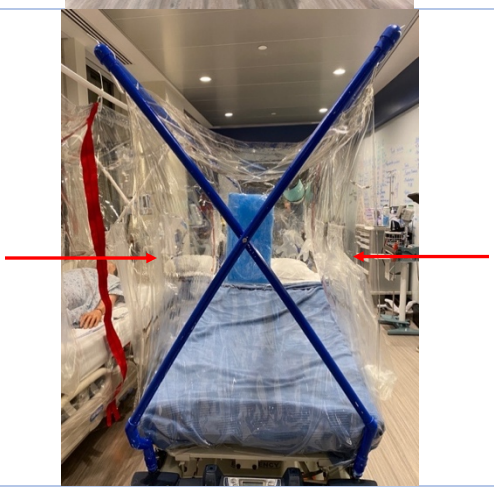

Regular Floor/ICU Beds:

Assembly instructions for isolation tent	
1. Unfold the new, sanitized isolation tent as shown. 2. Visually inspect TPU tent. If any rips or significant adhesive/welding errors are found in the tent, DO NOT USE!	
3. Align the tent in proper orientation. a. Face the blue prefilter at the foot of the bed.	
4. Attach the tent to the carabiners through the grommets. Repeat 10 times for each grommet/carabiner interface.	
5. Tighten the zip ties to secure the carabiners at the desired position on the frame.	
6. Placed tent should be fully expanded and in the desired position.	

7. Place the sleeves on the outside of the tent.	
8. Attach the interior filter by opening the tent and placing the back of the filter (the side with a connection attachment) through the marked hole in the tent above the head of the bed. a. Place the clear Plexiglas attachment around the part of the filter and tent cover on the outside of the tent. b. Avoid touching green part of filter during attachment.	 
9. Attach the hose from the HVAC device onto the outside of the filter. Ensure a tight seal by pushing the filter as close to the hose as possible until it clips into place. a. Make sure holes clip into each other at the connection point.	

	Clipped Holes 
10. Fully close all zippers (sides and two-way access box zippers).	
11. If you are placing the tent over the ED stretcher, contour in the tent completely around and just under the mattress of the bed. The side zippers can be opened to mattress level. For the regular floor and ICU beds, DO NOT TUCK the tent under the mattress. Place the bottom of the tent in between mattress and arm rests/barriers.	ED Stretcher:  Regular Floor/ICU Beds: 
12. Place battery backup box on bottom framework of the bed. See two pictures for the ED stretcher and bottom one for the regular floor and ICU beds. Remove the battery backup box before you drop the head of the bed completely otherwise you may damage the device.	ED Stretcher: 

	Regular Floor/ICU Beds: 
13. Plug the HVAC system into any of the “Battery Backup” outlets of the battery supply box.	
14. Plug the battery backup box into an external outlet.	
15. Turn the fan on by setting the dial at the bottom of the fan to HIGH.	
16. Test the system by letting the fan run for a few minutes and visually inspect the tent for hour-glass shape. (This is the indication for negative pressure.) a. Additionally, check negative pressure indicator	

Disassembly and Disinfection Instructions

The instructions below are to assist in the disassembly and disinfection of the aluminum COVIAGE frame. The large clear plastic tent (polyurethane) is not for reuse.

Disassembly Instructions:
PPE should be donned during the disassembly of COVIAGE.

1. After use, turn off fan.
2. Disconnect tubing of ventilation system from internal filter.
3. Unhook tent from carabiners.
4. Fold tent onto itself, including the internal filter and connection point. Ensure that the inside of the tent is not exposed to prevent contaminants from being released.
5. Dispose of the tent according to biohazardous waste guidelines.
6. Disassembly and replacement instructions for secondary filter are shown below.
7. Clean the aluminum frame and fan thoroughly with a hospital approved disinfectant as described below (e.g., isopropyl alcohol-based wipe or spray) to remove visible soil from all surfaces, paying careful attention to joints.
8. Use established patient room cleaning and disinfection protocols per hospital policy.

Disassembly and replacement instructions for exterior filter

You will need a screwdriver for some steps of the disassembly.

1. Turn off and unplug fan from wall socket or backup battery.

2. Unhook exterior fan and filter unit from bed and place on the floor.

3. Loosen top metal hose clamp screw from around blue connecting hose with a screwdriver to remove hose from the top filter case (black).

4. Remove screw from the hose clamp connecting the black top filter case to the main grey filter case using a screwdriver.	
5. Slide the loosened hose clamp down. Remove top black filter case.	

6. As the top case is lifted, the filter should be visible. Once the filter is free from the filter case, open a biohazard bag, hold the filter inside the bag, and use the bag to grasp the filter. 7. Slide the filter off the white adapter. **Do not touch the filter directly. Do not let the filter come in contact with other surfaces. Dispose the filter in biohazard bag.**	
8. Loosen hose clamp holding white filter adapter and black case together, remove white adapter and dispose of it in biohazard bag.	

9. These are the reusable components.

10. Spray and wipe the interior of the filter case with a hydrogen peroxide-based cleaner before fitting in a new filter.

    Avoid touching the interior of the filter case.

11. These are the disposable components: interior and exterior filters, blue connecting hose, white filter adapters. 12. The interior filter should be disposed of with the tent, do not attempt to remove it from the tent before disposal. These should be disposed of along with the tent in accordance with infectious biohazard waste disposal protocols.	

<u>High-Level Disinfection Instructions:</u>

PPE should be donned during the disinfection of COVIAGE.

1. Transfer COVIAGE frame and fan to the point of disinfection. Prepare a solution of hospital approved EPA-registered isopropyl alcohol-based disinfectant that are compatible with aluminum. See List N: Disinfectants for Use Against SARS-CoV-2 https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2."
    a. Completely spray or wipe the aluminum pipes with the high-level disinfectant.
    b. Spray or wipe the aluminum pipes in the high-level disinfectant solution at the temperature and for the exposure time indicated in the manufacturer's instructions.
    c. Wipe the external surfaces of the fan with the high-level disinfectant wipes.

2. Allow COVIAGE frame and fan to dry for 24 hours in an upright position to ensure complete water drainage.
3. Cover cleaned pieces (frame segments and fan) with sterile drapes, in preparation for next use.

COVIAGE Troubleshooting Instructions

Troubleshooting Guide	
Issue:	**Possible Mitigation:**
Frame will not open	- Check that locknuts are not overly tight - Lubricate screw in between pipe sections
Frame rattles	- Tighten locknuts at cross section of frame
Frame wobbles/is unstable	- Adjust feet of aluminum pipes - Ensure the frame is firmly in the holes and all the way to the top shoulder - Check for cracks, **DO NOT USE if cracks are found**
Tent shifts/moves along frame	- Make sure zip ties are pulled tightly enough to ensure that carabiners don't move - Tie additional zip ties to carabiners
Zipper is stuck	- Check for any articles that may be obstructing the zipper - Apply lubricant to zipper area

HVAC unit rattles/is unstable	- For ED bed:
	  - Ensure that all screws, nuts, and bolts are securely fastened
	  - Ensure that the HVAC is securely in the mount
	- For ICU bed:
	  - Ensure that the HVAC is securely in the mount and that all attachments are tightly fastened
	- Revisit HVAC assembly instructions for further details

Negative pressure issues/ Hourglass shape does not form within the tent	- HVAC does not turn on
	  - Ensure HVAC is connected to power supply
	  - Contact : *Konstantinos Economopoulos at 617-510-4641.*
	- Check the following
	  - The tent is contouring all sides of the bed
	  - All tubing is firmly attached, and no air is escaping
	  - HVAC is turned to HIGH

	- All zippers are closed - Filter is clean - Nothing is obstructing the filter or within the tubing - There should be no rips in the tent. **DO NOT USE if tent is torn** - If mobile, ensure that the backup battery has been charged

If issues persist, disassemble tent/frame setup and reassemble new, sanitized tent/frame setup.