Instructions for Healthcare Facilities: Assembly, Disassembly and Disinfection of the NRSAVR-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 "NRSAVR-100"), to be used by healthcare providers (HCPs) 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 NRSAVR-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 NRSAVR-100 device.

The NRSAVR-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 NRSAVR-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 NRSAVR-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 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.

Authorized use of the NRSAVR-100 during patient transport is within a hospital setting for temporary transfer with direct admission within the hospital in the presence of a registered nurse or physician. The patient should have constant monitoring of EKG, Pulse Oxygen Saturation (SpO2), End tidal CO2 if available throughout transport and patient should always have supplement oxygen during use of the NRSAVR-100. At this time, NRSAVR-100 should only be used in airway management, intubation, extubation and respiratory treatments.

To transport patients on ventilators, all valves and ports are closed. To transport patients who are not on ventilators, the NRSAVR-100 would maintain negative pressure via portable self-contained, suction or negative pressure pumps equipped with HEPA filters.

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

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

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

Rx Only

WARNING:

- **Flammability of the NRSAVR-100 has not been tested. No interventions that could create a spark or be a flammable source should be used within the NRSAVR-100.**
- **Remove the NRSAVR-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 NRSAVR-100 may induce hypercarbia in a spontaneously breathing patient. The NRSAVR-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 CO_2 monitoring if available. If end-tidal CO_2 monitoring is not available, then the use of the NRSAVR-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 receiving supplemental oxygen. Patients must have continuous monitoring of pulse oxygen saturation (SpO_2), vital signs, EKG, and End-tidal CO_2 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.)**

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1. Declarations of Conformity

The NRSAVR-100 is a novel product; therefore, the product is manufactured in conformance with the design in NRSAVR-100 Drawing number 8020-000.

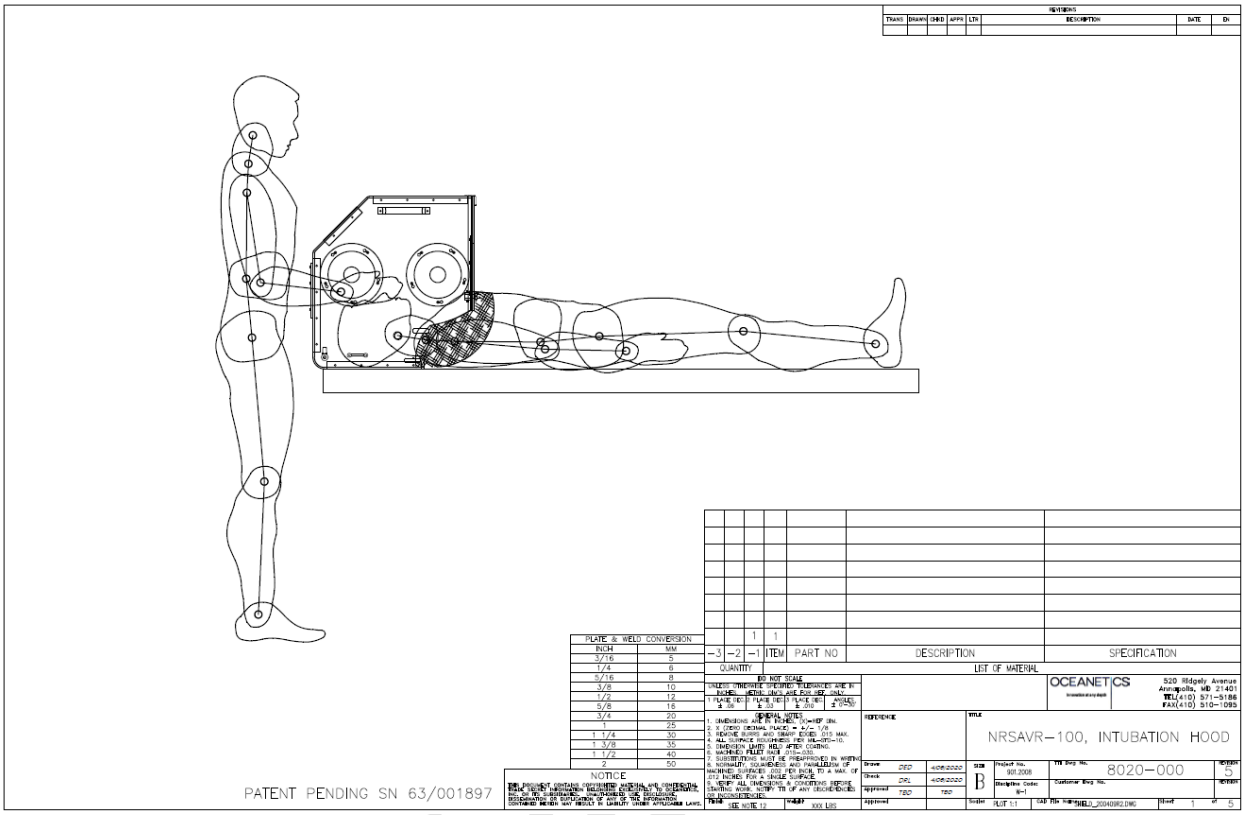

Figure 1 NRSAVR-100 General Assembly Drawing Number 8020-000.

2. Facility Requirements (as applicable)

Gas input connection type: DISS Suction 5/16" barb.
Gas type: Suction, Typical 0-200 mmHg @80L/min each. One or two suctions are permissible.
Gas source: wall mounted suction or equivalent portable unit equipped with HEPA or ultra-low particulate air (ULPA) filtration.
Environmental controls to reduce transmission: Device provides negative pressure cephalic environment and containment.

3. Protocol for Cleaning NRSAVR-100

*** DO NOT AUTOCLAVE ***

1. **Put on clean gloves and appropriate PPE before** beginning the cleaning and disinfection procedure.
2. Remove patient and suction hoses from the device.

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3. To move device for cleaning:
    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.
    e. Continue cleaning procedure.
4. Establish checklist to account for and track the cleaning of each assembly.

Table 1 Assembly list to track cleaning

NRSAVR-100 Assembly List

Assembly	Description	Quantity	Material
1	NSAVR-100 Base Form Assembly	1	Various, See Break-Out
2	Thumb Screws 5/16"	51	Stainless Steel
3	Exterior Arm Shroud Plate	6	PETG (Polyethylene Terephthalate Glycol-modified)*
4	Interior Flap Plate	6	PETG (Polyethylene Terephthalate Glycol-modified)*
5	Interior Body Shroud Plate	1	PETG (Polyethylene Terephthalate Glycol-modified)*
6	Exterior Arm Shroud	6	Rubber **
7	Interior Flap	6	Rubber **
8	Body Shroud	1	Rubber **
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5. Unscrew the exterior and interior arm shroud and plate. Remove the thumb screws, plates, shrouds and plates.
6. Unscrew the interior body shroud plate and remove the thumb screws, plate, and body shroud.
7. For cleaning, dispense a towelette of Cavicide wipe or other hospital approved EPA-registered quaternary ammonium compound/isopropyl alcohol-based hospital disinfectant wipe and wipe clean the inner and outer surfaces of the Base Form Assembly and its attached parts including the suction valve and barbs, handles, clips, strap hooks, handle, corner stiffeners, hardware, and door gasket seal to remove any soil.
8. If visible soil remains, repeat the procedure. Let all parts sit visibly wet for at least 2 minutes. Allow all parts to air dry. Remove and discard gloves.
9. For disinfection, spray all disassembled parts with a hospital approved EPA-registered isopropyl alcohol-based disinfectant, such as Cavicide. Let all parts sit visibly wet for at least the contact time indicated in the labeling (2 minutes for Cavicide) before allowing all parts to air dry. See List N: Disinfectants for Use Against SARS-CoV-2 https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.
10. Do not use harsh chemicals or abrasives to clean. Do not apply heat. Do not use high concentrations of ammonium in excess of 20% as this may degrade components.
11. Store device at room temperature and a relative humidity between 40-60%. Store in a container, if possible, to avoid dust and grease build up on the device.

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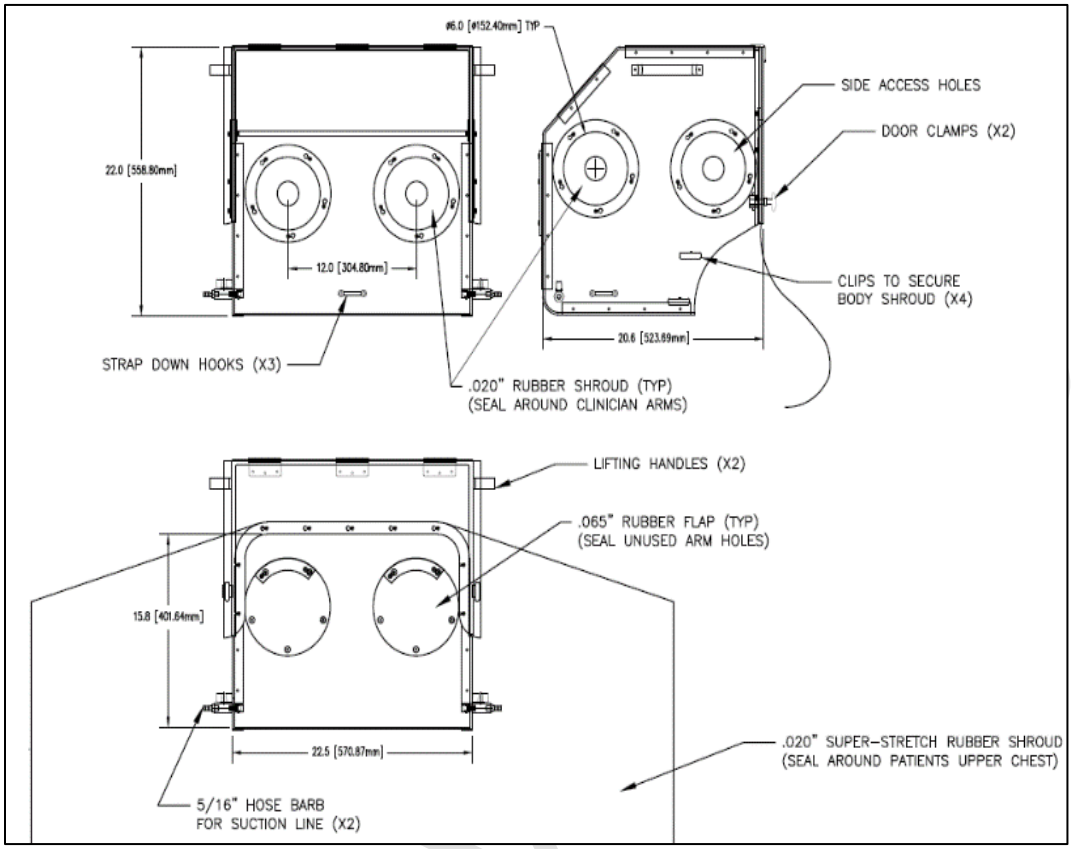

Figure 2 Sketch indicating location of six exterior arm shrouds and plates, six interior arm shrouds and plates, one interior flap and body shroud, suction valves and barbs.

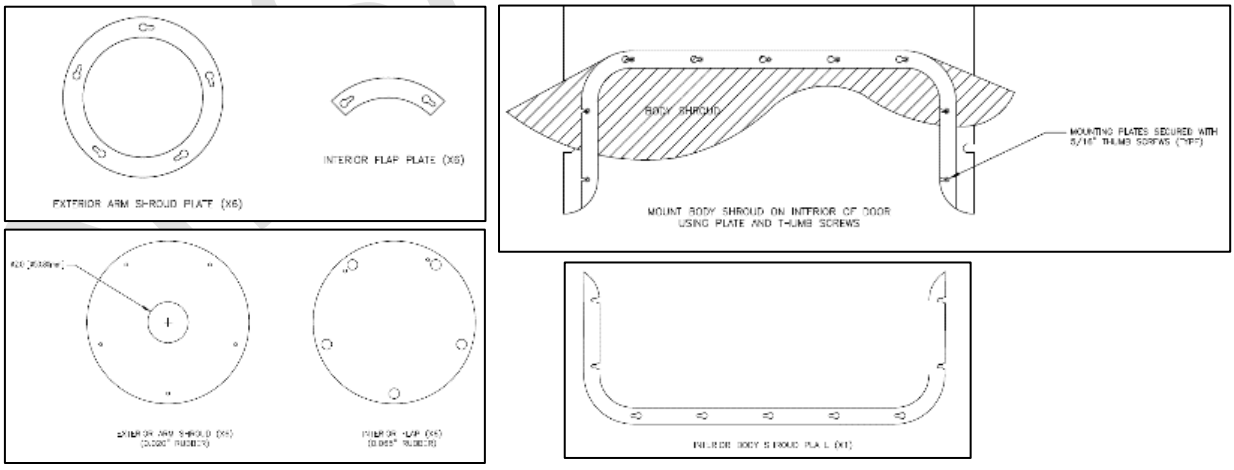

Figure 3 NRSAVR-100 Disassembled Parts

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4. After Reprocessing and Shelf-life Information

a. NRSAVR-100 Parts Assembly

When assembled, the NRSAVR-100 Assembly consists of 78 individual assembled or individual parts. This consists of one assembled Base Form Assembly, one Body Shroud, one interior body shroud plate, six each – exterior arm shroud plates, interior flap plates, exterior arm shrouds, interior flaps, and 51 thumb screws.

Table 2 NRSAVR-100

NRSAVR-100 Assembly List

Assembly	Description	Quantity	Material
1	NSAVR-100 Base Form Assembly	1	Various, See Break-Out
2	Thumb Screws 5/16"	51	Stainless Steel
3	Exterior Arm Shroud Plate	6	PETG (Polyethylene Terephthalate Glycol-modified)*
4	Interior Flap Plate	6	PETG (Polyethylene Terephthalate Glycol-modified)*
5	Interior Body Shroud Plate	1	PETG (Polyethylene Terephthalate Glycol-modified)*
6	Exterior Arm Shroud	6	Rubber **
7	Interior Flap	6	Rubber **
8	Body Shroud	1	Rubber **
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b. NRSAVR-100 Device Base Form Assembly Break-Out

The NRSAVR-100 Base Form Assembly consists of 319 individual parts that are assembled into one Base Form Assembly.

Table 3 NRSAVR-100 Base Form Assembly Break-Out

NSAVR-100 Base Form Assembly Break-Out

Part	Description	Quantity	Material
1	Base	1	PETG (Polyethylene Terephthalate Glycol-modified)*
2	Side walls	2	PETG (Polyethylene Terephthalate Glycol-modified)*
3	Door gasket seal, removable	1	Neoprene
4	Body hinge door	1	PETG (Polyethylene Terephthalate Glycol-modified)*
5	Hinges	3	Plastic, Polyolefin
6	Hinge bolt	18	Stainless Steel
7	Hinge washer	18	Stainless Steel
8	Hinge lock nut	18	Stainless Steel/Nylon
9	Thumb screw expanding threaded insert	51	Stainless Steel
10	Corner stiffener (top, front, base)	6	Acrylic
11	Binding barrel screw	48	Stainless Steel
12	Binding barrel nut	48	Stainless Steel
13	Corner stiffener (front face)	2	Acrylic
14	Binding barrel screw	8	Stainless Steel
15	Binding barrel nut	8	Stainless Steel
16	Strap down hook	3	Stainless Steel
17	Strapdown hook screw	6	Stainless Steel
18	Strapdown hook washer	6	Stainless Steel
19	Strapdown hooklock nut	6	Stainless Steel/Nylon
20	Handle	2	Plastic, Thermoset
21	Handle screw	4	Stainless Steel
22	Handle washer	8	Stainless Steel
23	Handle screw	4	Stainless Steel/Nylon
24	Spring Clamp	4	Stainless Steel
25	Spring clamp Screw	4	Stainless Steel
26	Spring clamp washer	4	Stainless Steel
27	Spring clamp lock nut	4	Stainless Steel/Nylon
28	Interior brass shroud, 1/8" to 1/4"	2	Brass
29	Pipe Nipple, 1/8"	2	Brass
30	Chrome plated ball valve	2	Chrome plated Brass
31	Suction hose barb 5/16"	2	Plastic, Nylon
32	T-handle	2	Rubber **
33	T-frame U-frame	2	Stainless Steel
34	T-handle pin	2	Stainless Steel
35	T-handle washer	2	Stainless Steel
36	T-handle pin keeper e-clip	2	Stainless Steel
37	T-handle to base screws	4	Stainless Steel
38	T-handle to base washers	4	Stainless Steel
39	T-handle to base nuts	4	Stainless Steel
40	Seam Sealant, as required	1	RTV silicone (room-temperature-vulcanizing silicone)
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c. Annual System Maintenance

Preventive maintenance and safety checks should be performed annually by Oceanetics, Inc., a representative or an authorized manufacturer to ensure proper system performance.

d. System Repair

All system repairs should be performed by Oceanetics, Inc., a certified service technician, or by an authorized manufacturer. For training or more information, contact your Oceanetics, Inc., representative or authorized manufacturer.

e. Maintenance by Manufacturer

The device body assembly and rigid polymer parts should be returned bi-annually for reprocessing to an authorized manufacturer. For training or more information, contact your Oceanetics, Inc., representative or authorized manufacturer.

f. Consumable and Replacement Parts

The thumb screws should be replaced immediately if lost or worn. The exterior arm shroud plates, interior flap plates, and interior body shroud plate should be replaced immediately if lost, worn, damaged or warped. These parts should be returned bi-annually with the device Base Form Assembly for inspection to an authorized manufacturer.

The interior flaps, exterior arm shrouds, and body shroud should be replaced if worn, damaged, torn, excessively punctured (where lack of seal may compromise negative pressure environment), or deteriorated. These parts should be replaced annually regardless of condition. For parts, contact your Oceanetics, Inc., representative or authorized manufacturer.

Table 4 NRSAVR-100 Consumable and Replacement

NRSAVR-100 Consumable and Replacement Parts List

Assembly	Description	Quantity	Material
2	Thumb Screws 5/16"	51	Stainless Steel
3	Exterior Arm Shroud Plate	6	PETG (Polyethylene Terephthalate Glycol-modified)*
4	Interior Flap Plate	6	PETG (Polyethylene Terephthalate Glycol-modified)*
5	Interior Body Shroud Plate	1	PETG (Polyethylene Terephthalate Glycol-modified)*
6	Exterior Arm Shroud	6	Rubber **
7	Interior Flap	6	Rubber **
8	Body Shroud	1	Rubber **
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5. 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 device.
- When moving device, close front lid, secure T-handles and place body shroud inside bottom of 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. All patients within the device should be receiving supplemental oxygen. 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 negative pressure environment, ensure air can flow into the device through portholes.
- Close 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 good seal with 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 contaminates 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 contaminates. 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 of 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.

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- 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 device manufacturer. Any used components that are no longer serviceable or damaged should be disinfected and disposed of as a biohazard.

6. Labeling Considerations:

The device does not have any electrically powered components.

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