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TractManager

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Conversion and Utilization of Anesthesia Machines as ICU Ventilators

Executive Summary

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Conversion and Utilization of Anesthesia Machines as ICU Ventilators

Situation

The COVID-19 pandemic has resulted in a heightened demand for advanced respiratory care, including ventilatory support, and has been discussed in TractManager COVID-19 reports, *Ventilators: Strategic Sourcing During Coronavirus Pandemic and Non-Invasive Ventilation for the Treatment of COVID-19 Patients*. It is estimated that there are 62,000 high acuity mechanical ventilators in U.S. hospitals (Johns Hopkins, 2020). Due to the public health emergency and overall shortage of mechanical ventilators from COVID-19, the FDA has *temporarily* approved the use of anesthesia gas machines modified for use as ventilators (FDA, 2020).

With the depletion of traditional mechanical ventilators, there is increased attention towards anesthesia gas machines as an alternative method. In March 2020, the FDA issued an Emergency Use Authorization (EUA):

.....authorizing the emergency use of ventilators, anesthesia gas machines modified for use as ventilators.....that FDA determines meet the criteria for safety, performance and labeling set forth in Section II and Appendix A for emergency use in healthcare settings to treat patients during the COVID-19 pandemic, contingent upon submission of a request from the sponsor of a pursuant to the Conditions of Authorization in Section IV of this letter (FDA, 2020).

Problem Statement:

In crisis situations, including the COVID-19 pandemic, what are the best practice considerations for utilizing an anesthesia gas machine modified for use as a ventilator for treating patients with hypoxemic respiratory failure?

Technology Under Evaluation:

- Anesthesia gas machines

Background

Management of severe COVID-19 is not different from management of most viral pneumonia causing respiratory failure. The principal feature of patients with severe disease is the development of acute respiratory distress syndrome (ARDS), a syndrome characterized by acute onset of hypoxemic respiratory failure with bilateral infiltrates. Evidence-based treatment guidelines for ARDS should be followed, including conservative fluid strategies for patients without shock following initial resuscitation, empirical early antibiotics for suspected bacterial co-

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infection until a specific diagnosis is made, **lung-protective ventilation**, prone positioning, and consideration of extracorporeal membrane oxygenation for refractory hypoxemia (JAMA, 2020).

The National Institutes of Health (NIH) COVID-19 Treatment Guidelines address recommendations for Oxygenation and Ventilation of COVID-19 diseased patients. The NIH further conveys treatment rationale:

It is essential that hypoxemic patients with COVID-19 be monitored closely for signs of respiratory decompensation. To ensure the safety of both the patient and health care workers, intubation should be performed in a controlled setting by an experienced practitioner. Early intubation may be particularly appropriate when patients have additional acute organ dysfunction or chronic comorbidities, or when high flow nasal cannula (HFNC) and non-invasive positive pressure ventilation (NIPPV) are not available. NIPPV has a high failure rate in both patients with non-COVID-19 viral pneumonia and patients with ARDS (NIH, 2020).

According to the American Society of Anesthesiologists (ASA), anesthesia machines are equipped with ventilators that in many cases are capable of providing life-sustaining mechanical ventilation to patients with respiratory failure (ASA, 2020). As previously noted, in some healthcare organizations demand for advanced ventilatory support exceeds an adequate supply of traditional mechanical ventilators, resulting in alternative strategies including FDA approval for the use of anesthesia gas machines in crisis situations. Similar to sourcing mechanical ventilators, it is critical to understand the functionality for each anesthesia machine model to safely provide quality patient care.

Technology Description:

Anesthesia machines are designed to deliver and scavenge anesthetic gas to the patient, monitor vital signs, and are equipped with ventilators. Though anesthesia machine ventilators perform the same basic function as traditional mechanical ventilators, they require additional monitoring of the patient. Clinicians must be aware of the limitations of anesthesia machine ventilators used in an ICU setting.

Traditional mechanical ventilators are designed with leak compensation. This allows the system to compensate for air leaks from the lungs and around airway tubing. This helps to limit the amount of false alarms from occurring. Anesthesia machines have a more involved tubing system. These multiple exposed connections increase the potential to disconnect, kink or be obstructed.

The mechanical ventilation capabilities also vary among anesthesia machines. New high acuity models are similar to ICU ventilators. These machines have more modes of ventilation, more flexible settings, and specifications similar to ICU ventilators. Anesthesia ventilators with compliance compensation and tidal volume delivery unaffected by fresh gas flow are preferred, as they provide more consistent tidal volume delivery and more accurate monitoring (APSF/ASA, 2020).

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Anesthesia machines obtained from ambulatory surgery centers or office-based practices may be the least suitable for this purpose; however, they might be used to backfill in certain surgical cases for the more capable anesthesia machines that have been moved to the ICU.

Technology Market Segments:

- **High-acuity systems** - These anesthesia delivery systems incorporate patient monitoring and information systems capabilities. These are typically used for high-acuity cases but are often a part of a complete anesthesia management solution.
- **Mid-acuity systems**- These mid-tier anesthesia delivery systems are usually reserved for general to acute surgical cases
 - **MRI Conditional:** have been demonstrated to pose no known hazards in the MRI environment with specified conditions of use.
 - **Non-MRI Conditional:** ventilators that are not designed for use in the MRI environment.
- **Low-acuity systems** - These are anesthesia delivery systems with typical uses in outpatient surgery centers, office-based anesthesia or routine anesthesia cases.

**TractManager Benchmarking Tables indicate which models are available for the adult, pediatric and neonatal patient population. Note in Financial Considerations.*

Assessment

Recommendations and Guidelines:

Evidence-based treatment guidelines for ARDS should be followed, including conservative fluid strategies for patients without shock following initial resuscitation, empirical early antibiotics for suspected bacterial co-infection until a specific diagnosis is made, **lung-protective ventilation**, prone positioning, and consideration of extracorporeal membrane oxygenation for refractory hypoxemia (JAMA, 2020).

In March 2020, the FDA released the Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During Coronavirus Disease 2019 (COVID-19) Public Health Emergency. It is addressed that

wherever possible, health care facilities should use conventional/standard full-featured ventilators to treat patients who develop respiratory failure or respiratory insufficiency. However, for the duration of the public health emergency, in order to help foster the wider availability of devices for patients in need of ventilatory support and to help manufacturers respond to potential device component disruptions in the supply chain, FDA does not intend to object to limited modifications to the FDA-cleared hardware, software, or materials, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the modification does not create an undue risk in light of the public health emergency (FDA, 2020).

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Examples of circumstances where FDA currently believes a modification would not create such undue risk include:

- 1) Modifications to motors, batteries, or other electrical components;
- 2) Material changes to components in the gas pathway or with other patient tissue contact;
- 3) Introduction of filtration to minimize aerosolization.
- 4) Software modifications intended to modify the ventilation parameters including inspiratory pressure, tidal volumes, flow rates, positive end-expiratory pressure (PEEP) in accordance with any applicable device standard;
- 5) Software modifications implementing physiological closed loop (automated) algorithms for oxygen titration where the algorithms/devices are the subject of an FDA-approved Investigational Device Exemption (IDE).
- 6) Hardware and/or software modifications implementing the capability for remote monitoring and remote adjustment of ventilator parameters (i.e., adjustment of parameters by trained health care providers from outside an isolation unit to avoid unnecessary exposures) (FDA, 2020).

Additional guidance regarding breathing circuits and overall guidance can be referenced in the Enforcement Policy: <https://www.fda.gov/media/136318/download> and in Appendix B: Authorized Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories: <https://www.fda.gov/media/136528/download>

The American Society of Anesthesiologists (ASA) and the Anesthesia Patient Safety Foundation (APSF) collaborated on the *APSF/ASA Guidance on Purposing Anesthesia Machines as ICU Ventilators*. The purpose is intended to provide guidance on using anesthesia machines safely and effectively as ICU ventilators. Some notable guidance points:

- Anesthesia ventilators allow for rebreathing of exhaled gas through the ventilator circuit. Consider using anesthesia machines as ICU ventilators on patients who are not COVID-19 positive to reduce the risk of the rebreathing system becoming a COVID-19 vector. Breathing system filters are however recommended for all patients. Anesthesia machines require more monitoring than do ICU ventilators and room access for non-COVID patients is easier.
- **Oxygen utilization** can be a factor when selecting anesthesia machine ventilators and managing the ventilation modes. In general, pneumatically powered ventilators consume more oxygen than electrically powered ones but modifications will be described for conserving oxygen with all ventilator designs.

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Financial Considerations

Per TractManager's report, *Ventilators: Strategic Sourcing during Coronavirus Pandemic*, traditional ventilators benchmark pricing runs \$10,600--\$41,000 and portable ventilators can run \$5,900--\$36,500. Per TractManager, anesthesia machine benchmark pricing runs \$22,200--\$35,800. As most Respiratory Therapists and providers are not trained to manage anesthesia machines, it is important to factor the cost of an anesthesia professional available (24/7/365) to manage the use of the anesthesia machine as an ICU ventilator. The labor rate runs an additional \$25-\$90/hour.

The following tables list anesthesia machine technical specifications by market segment, with benchmark pricing. Monitoring supply behavior is suggested and encouraged, particularly in regard to future business relationships.

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Technology: Anesthesia Machine

Market Segment: High Acuity

| OEM | Draeger | Draeger | GE | GE |
|------------------------------|---|--|---|---|
| Product | Perseus A500 | Apollo | Aisys CS2 | Avance CS2 |
| Avg Quoted Price | \$67,188 | \$57,667 | \$64,528 | \$50,142 |
| Tech Specs | | | | |
| Monitor/Display | High resolution TFT 15.3" color flat panel.; Opitonal Infinity Acute Care System (IACS) monitoring system | High resolution TFT 12.1" color flat panel. | Repositionable display. Open architecture with the capability to use any vendor's monitor. | Open architecture with the capability to use any vendor's monitor. |
| Unique Features/Capabilities | TurboVent2 ventilation technology. Options: Mechanically controlled gas mixer or electronically controlled gas mixer. Vapor View w/ Vapor 3000 to transfer settings and agent type to calculate gas concentration, predict effects. | Electronic measurement of gas delivery with export capability to an electronic record system. Electrically driven piston E-vent ventilator. Optimized for low flow with warmed breathing system. Designed to work with Kappa XLT patient monitoring. | INview patient displays. Digital vaporization. Upgradeable. ecoFLOW. Pause Gas. SIMV-PCV-VG. Automated Lung Ventilation Procedures. Small modular breathing system of <3 liters for rapid response in low flow. | Electronic gas mixer with pneumatic back-up control, ecoFLOW, Pause Gas, SIMV-PCV-VG. Automated Lung Ventilation Procedures. Small modular breathing system of <3 liters for rapid reponse in low flow. |
| Patient Population | Neonatal; Pediatric; Adult | Neonatal; Pediatric; Adult | Neonatal; Pediatric; Adult | Neonatal; Pediatric; Adult |
| Ventilation Modes | VC; PC; PC-APRV, volume control; pressure control; synchronized volume and pressure control; pressure support; manual, spontaneous. | Volume control; pressure control; synchronized volume and pressure control. Optional: pressure support. Electronically controlled & driven ventilator with manual, spontaneous. | Digitally controlled flow valve ventilator with standard modes including volume control w/tidal volume compensation. Optional: pressure control, PCV-VG; SIMV, SIMV-PC; SIMV/ PS; PSVPro with apnea back-up. SIMV-PCV-VG, CPAP. | Digitally controlled flow valve ventilator with standard modes, volume control w/tidal volume compensation. Optional: pressure control, PCV-VG, SIMV, SIMV-PC, SIMV/PS, PSVPro with apnea back-up, SIMV-PCV-VG, CPAP. |
| Data Management | Optional Innovian Information System | Optional Innovian Information System | Compatible with Centricity Information System or current data management system. High speed dedicated network connection with HL7. | Compatible with Centricity Information System or current data management system |
| Battery Back-up Time | 30 Minutes | 30 Minutes | 90 Minutes | 90 Minutes |
| Vaporizer | Two or three vaporizer mounts | Two or three vaporizer mounts | One active position: Aladin Cassette. Digital. | Two or three active positions. Selectatec vaporizers: Tec 6 Plus, Tec 850. |
| Monitor/Display | High resolution TFT 15.3" color flat panel.; Opitonal Infinity Acute Care System (IACS) monitoring system | High resolution TFT 12.1" color flat panel. | Repositionable display. Open architecture with the capability to use any vendor's monitor. | Open architecture with the capability to use any vendor's monitor. |

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Technology: Anesthesia Machine

Market Segment: Mid Acuity >> MRI Conditional

| OEM | Dräger | GE |
|-------------------------------|---|---|
| Product | Fabius MRI | Aestiva/5 MRI |
| Avg Quoted Price | \$65,282 | \$68,192 |
| Tech Specs | | |
| Monitor/Display | Integrated high resolution TFT monochromatic display. | Open architecture with the capability to use any vendor's MRI-compatible monitor |
| Unique Features/ Capabilities | Compatible to 3.0 Tesla. Electronic measurement of gas delivery w/ export capability. Electronically driven piston ventilator. Low, minimal-flow applications. Open architecture. COSY Compact Breathing System. Optional optical alarm displays. | Validated for use in MRI with 300 Gauss, 1.5 Tesla active shielded magnet; Visual and audio Gauss alarm |
| Patient Population | Neonatal; Pediatric; Adult | Neonatal; Pediatric; Adult |
| Ventilation Modes | Volume control, pressure control. Optional: pressure support; SIMV/PS. Electronically controlled, electronically driven ventilator with manual/ spontaneous ventilation. | Digitally controlled flow valve ventilator; volume control, pressure control, tidal volume compensation. Optional: SIMV, pressure support (PSVPro) w/apnea back-up. |
| Data Management | Not available; Method for data transfer: RS232 serial interface port | Not available |
| Battery Back-up Time | 45 Minutes | 30 Minutes |
| Vaporizer | Two vaporizer mounts | Two inline Selectatec vaporizers (Tec 5 vaporizers only) |

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Technology: Anesthesia Machine

Market Segment: Mid Acuity >> Non-MRI Conditional

| OEM | Dräger | GE | GE | Mindray |
|------------------------------|--|---|--|---|
| Product | Fabius GS premium | Carestation 620 | Carestation 650 | A5 Anesthesia System |
| Avg Quoted Price | \$34,971 | \$26,405 | \$35,823 | \$34,496 |
| Tech Specs | | | | |
| Monitor/Display | High resolution color display. Includes ventilation monitoring with airway pressure (numeric), airway pressure wave, expiratory minute volume, expiratory tidal volume, breathing frequency, FiO2, and life of O2 sensor cell. | 15" ventilation display. Open architecture with the capability to use any vendor's monitor. | 15" ventilation display. Open architecture with the capability to use any vendor's monitor. | 15" touch screen, color display; graphic waveforms, numeric and graphic trend data, spirometry loops; direct connection to Mindray patient monitors; open architecture designed for direct integration to EMR. |
| Unique Features/Capabilities | Electronic measurement of gas delivery with export capability; electronically driven piston ventilator with pressure, volume control capabilities; low, minimal-flow applications; open architecture; COST Compact Breathing System. | Slim, compact design for constrained environments. Spirometry. | Slim, compact design for constrained environments. ecoFLOW, Spirometry, Pause Gas, SIMV-PCV-VG. Automated Lung Ventilation Procedures. | Warmed breathing system; automatic compliance compensation to ensure accuracy of delivered volumes; CO2 absorber system uses prepacks or loose fill absorbent; volume, pressure, and SIMV modes standard; blended O2/Air cannula; high pressure O2 port |
| Patient Population | Neonatal; Pediatric; Adult | Pediatric; Adult | Pediatric; Adult | Pediatric; Infant; Adult |
| Ventilation Modes | Volume control; pressure control; optional pressure support and SIMV/PS; electronically controlled; electronically driven ventilator with manual spontaneous ventilation. | Digitally controlled flow valve ventilator with standard modes, volume control w/tidal volume compensation. Optional: pressure control, PCV-VG, SIMV, SIMV-PC, SIMV-VC, PSVPro w/apnea back-up. | Digitally controlled flow valve ventilator with standard modes, volume control w/tidal volume compensation. Optional: pressure control, PCV-VG, SIMV, SIMV-PC, SIMV-VC, PSVPro w/apnea back-up. SIMV-PCV-VG, CPAP. | VCV - volume control, PCV - pressure control, with Volume Guarantee, PS, SIMV in volume and pressure modes, spontaneous and manual assist |
| Data Management | Optional Innovian Information System | Compatible with Centricity Information System or current data management system. | Compatible with Centricity Information System or current data management system. | Not available |
| Battery Back-up Time | 45 Minutes | 90 Minutes | 90 Minutes | 150 Minutes |
| Vaporizer | Two or three vaporizer mounts | Two active positions. Selectatec vaporizers: Tec 6 Plus, Tec 850. | Two active positions. Selectatec vaporizers: Tec 6 Plus, Tec 850. | Two or three vaporizer option, Selectatec manifold |

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Technology: Anesthesia Machine

Market Segment: Low Acuity

| OEM | Dräger | Mindray |
|------------------------------|---|---|
| Product | Fabius Trio | A4 Advantage Anesthesia System |
| Avg Quoted Price | \$26,036 | \$22,285 |
| Tech Specs | | |
| Monitor/Display | Monochrome LCD display. Ventilation monitoring with airway pressure (numeric), airway pressure wave, expiratory minute volume, expiratory tidal volume, breathing frequency, FiO2, life of O2 sensor cell. | 15" color touchscreen with digital flow meters and customizable settings |
| Unique Features/Capabilities | Electronic measurement of gas delivery w/ export capability. Electronically driven piston ventilator w/ pressure, volume control capabilities. Low, minimal-flow applications. Open architecture. Lightweight, compact. COSY. Optional ceiling or wall mount. | Warmed breathing system; automatic compliance compensation to ensure accuracy of delivered volumes; CO2 absorber system uses prepacks or loose fill absorbant; volume, pressure and SIMV mode standard; blended O2/Air cannula. |
| Patient Population | Neonatal; Pediatric; Adult | Pediatric; Adult; Infant |
| Ventilation Modes | Volume control. Optional: pressure control; pressure support; SIMV/ PS. Electronically controlled electrically driven ventilator with manual/spontaneous ventilation | VCV- volume control, CPAP/PS (optional modes: PCV- pressure control; PS; SIMV in volume mode; spontaneous and manual assist) |
| Data Management | Optional Innovian Information System | Not available |
| Battery Back-up Time | 45 Minutes | 150 Minutes |
| Vaporizer | One vaporizer mount with parking position for second | Two or three vaporizer option; Selectatec manifold |

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Operational Considerations

Utilizing anesthesia ventilators safely and effectively as ICU ventilators warrants proper precautions, education, and planning for hospital facilities.

One of the most critical areas to cover is training and education, including:

The ASA/APSF state that an anesthesia professional should be in the proximity of the anesthesia device at all times to manage the use of the anesthesia machine as an ICU ventilator intensivists, ICU nurses and respiratory therapists are not trained to manage anesthesia machines, and are likely to be overextended and stressed. Consultation with intensivists on the preferred ventilation strategy is desirable (ASA/APSF, 2020). desirable. Respiratory therapists are essential in the management of multiple critically ill patients and long-term ventilation and should be included in discussion and development of hospital policies for placement and replacement of breathing circuit filters and other disposable components. An anesthesia professional needs to be immediately available for consultation, and to “round” on these anesthesia machines at least every hour. Anesthesia machines are not protected against non-authorized users; policy and signs should warn non-authorized users about changing anesthesia machine settings (ASA, 2020).

- Anesthesia machines not currently being used may be located in hospital operating rooms, Non-Operating Room Anesthesia (NORA) locations, at nearby ambulatory surgery centers, nearby office-based surgery practices, and through anesthesia equipment distributors. While **guidance is available from the manufacturers regarding technical specifications and instructions for operation, the guidance may not convey all of the clinical considerations, including those relevant to crisis management.** Anesthesia professionals’ expertise will be required to put these machines into service and to manage them while in use. Safe and effective use requires an understanding of the capabilities of the machines available, the differences between anesthesia machines and ICU ventilators, and how to set anesthesia machine controls to mimic ICU-type ventilation strategies (ASA, 2020).

Logistics and assembly will be another challenge, as anesthesia machines may be located outside of their normal locations and warrant proper setup and considerations:

- **Refer to *Equipment Considerations: Machine Setup in the APSF/ASA Guidance on Purposing Anesthesia Machines as ICU Ventilators*: <https://www.asahq.org/in-the-spotlight/coronavirus-covid-19-information/purposing-anesthesia-machines-for-ventilators>**
- In many hospitals, anesthesia machines are connected to a network to integrate and automate documentation of ventilation parameters to the patient record. If an OR is converted to a COVID unit, continuation of this method of documentation may be possible. However, if moved to another location in the hospital, restoration of a network connection will be required, or manual documentation may be needed. If manual documentation is needed, a template should be used for documentation (ASA, 2020).

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Implement a process to proactively define and predict surge in demand for the actual and anticipated number of COVID-19 patients, the number requiring ICU care, *and the number requiring ventilator support* (CDC, 2020).

- Leverage the CDC **COVID19 Surge Tool**
 - Spreadsheet-based tool that hospital administrators and public health officials can use to estimate the surge in demand for hospital-based services during the COVID-19 pandemic: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/covidsurge.html>
 - **Spreadsheet:** https://www.cdc.gov/coronavirus/2019ncov/downloads/covid19surge/CoVID19Surge_v1.xlsm
 - **Manual:** <https://www.cdc.gov/coronavirus/2019-ncov/downloads/covid19surge/COVID19Surge-Manual.pdf>

Develop proper protocol with the Respiratory Team for PPE when monitoring patients on an anesthesia ventilator:

- Follow CDC guidelines and adhere to Standard Precautions: use respirator, gown, gloves, and eye protection as noted in Appendix A (CDC, 2020).
 - Employers should select appropriate PPE and provide it to healthcare personnel who are caring for COVID-19 patients.
 - Provide proper training for donning and doffing PPE
 - Reinforce and provide proper hand hygiene supplies, including Alcohol Based Hand Rub (60-95% alcohol) (CDC, 2020).
 - www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

Recommendation

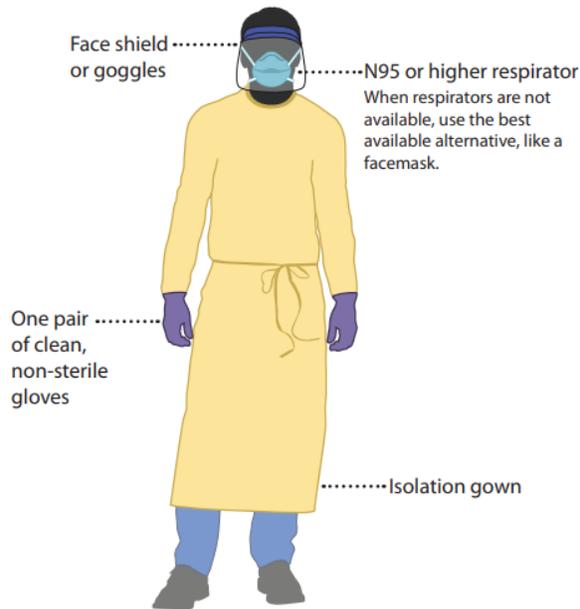
Monitoring the CDC Strategic National Stockpile (SNS) for availability of mechanical ventilators and repurposing anesthesia machines as ventilators are alternative solutions to a depletion of ventilators in the United States. Though these solutions temporarily solve the short-term supply issue, there are increased challenges. Anesthesia machines require attention to new hardware, systems, patient settings, periodic maintenance, and cleaning and disinfecting. A standardized process for return to regular service in the operating room should be developed and implemented to insure for proper operation, cleaning, and safety. The most critical challenge is that the anesthesia machine's technology requires a trained anesthesia professionals and respiratory therapists to manage a patient on a life supporting ventilator. When a facility is planning for staffing during the COVID-19 pandemic, there is an increased demand for these specially trained professionals and should be accounted for.

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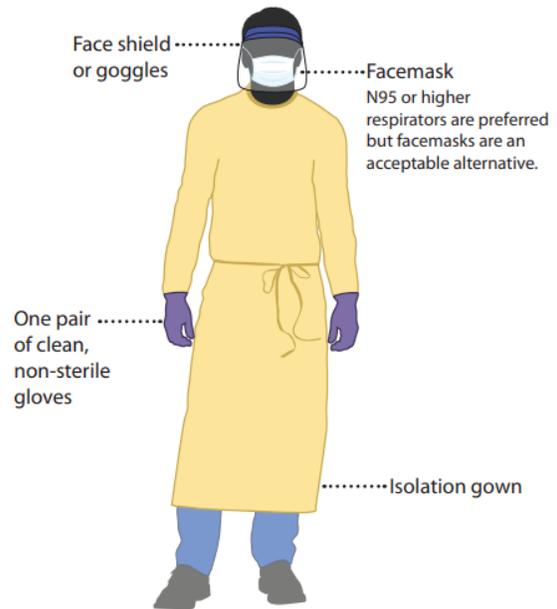
Appendix A

COVID-19 Personal Protective Equipment (PPE) for Healthcare Personnel

Preferred PPE – Use N95 or Higher Respirator



Acceptable Alternative PPE – Use Facemask



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cdc.gov/COVID19

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