Mechanical Ventilation Basics (CPG ID: 92)

This CPG provides an overview of prehospital and interfacility mechanical ventilation of a patient for point of injury to en route care up to Role 2 levels of care in a standardized approach.

Contributors

<table>
<thead>
<tr>
<th>CAPT Michael Tripp, MC, USN</th>
<th>HM1 Steve Brooks, ATP, FP-C, USN</th>
</tr>
</thead>
<tbody>
<tr>
<td>HMC Wayne Papalski, FP-C, USN</td>
<td>HMCS Tyler Scarborough, ATP, USN</td>
</tr>
<tr>
<td>MSG Michael Remley, NRP, SO-ATP, USA</td>
<td>1LT Jamie Eastman, RN, FP-C, USA</td>
</tr>
<tr>
<td>SFC Sam Patrick, ATP, FP-C, USA</td>
<td>CDR Joshua Tobin, MC, USA</td>
</tr>
<tr>
<td>SFC Paul Loos, ATP, USA</td>
<td>Jonathan Friedman, RN, FP-C (Civ)</td>
</tr>
<tr>
<td>MAJ Seth Assar, MC, USA</td>
<td>HM2 John Siedler, FP-C</td>
</tr>
<tr>
<td>CAPT Benjamin Walrath, MC, MPH, USN</td>
<td>Andrew Rowley, FP-C, TP-C (Civ)</td>
</tr>
<tr>
<td>SFC James Johnson, FP-C, NRP, USA</td>
<td>LCDR (Ret) Nikki Selby, RN, USN</td>
</tr>
<tr>
<td>SFC Phillip Hogsed, ATP, FP-C, USA</td>
<td>1SG Branden Coughlin, NRP, FP-C, USA</td>
</tr>
<tr>
<td>HMC Ryan Honnoll, NR-P, USN</td>
<td>SGT (Ret) Ricky M Ditzel Jr, MC, ATP, FP-C, USA</td>
</tr>
<tr>
<td>LTC Cord Cunningham, MC, USA</td>
<td>SMSgt Brit Adams, USAF, NRP, FP-C</td>
</tr>
<tr>
<td></td>
<td>Col Stacy A Shackelford, USAF, MC</td>
</tr>
</tbody>
</table>

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Opinions, interpretations, conclusions, and recommendations are those of the authors and are not necessarily endorsed by the Services or DoD.

Safety statement, Nov 2022

CAUTION: The Hamilton T1 as fielded by the Department of Defense DOES NOT support noninvasive ventilation (NIV). In environments where there is a risk of patients requiring NIV, a different ventilator should be fielded.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background</td>
<td>3</td>
</tr>
<tr>
<td>Definitions</td>
<td>3</td>
</tr>
<tr>
<td>Mechanics/Physiology of Breathing</td>
<td>3</td>
</tr>
<tr>
<td>Ventilation</td>
<td>4</td>
</tr>
<tr>
<td>ABG Definitions</td>
<td>5</td>
</tr>
<tr>
<td>Ventilator Terms</td>
<td>6</td>
</tr>
<tr>
<td>Ventilator Modes</td>
<td>6</td>
</tr>
<tr>
<td>Volume-targeted Modes</td>
<td>7</td>
</tr>
<tr>
<td>Ventilator Adjustable Settings</td>
<td>7</td>
</tr>
<tr>
<td>Assessment</td>
<td>8</td>
</tr>
<tr>
<td>Application of Mechanical Ventilation</td>
<td>9</td>
</tr>
<tr>
<td>Initial Ventilator Settings</td>
<td>9</td>
</tr>
<tr>
<td>Troubleshooting</td>
<td>10</td>
</tr>
<tr>
<td>Changes in Respiratory Status</td>
<td>12</td>
</tr>
<tr>
<td>Performance Improvement (PI) Monitoring</td>
<td>15</td>
</tr>
<tr>
<td>Population of Interest</td>
<td>15</td>
</tr>
<tr>
<td>Intent (Expected Outcomes)</td>
<td>15</td>
</tr>
<tr>
<td>Performance/Adherence Measures</td>
<td>15</td>
</tr>
<tr>
<td>Data Sources</td>
<td>16</td>
</tr>
<tr>
<td>System Reporting &amp; Frequency</td>
<td>16</td>
</tr>
<tr>
<td>Responsibilities</td>
<td>16</td>
</tr>
<tr>
<td>References</td>
<td>16</td>
</tr>
<tr>
<td>Appendix A: Predicted Body Weight and Tidal Volume</td>
<td>18</td>
</tr>
<tr>
<td>Appendix B: IMPACT 754</td>
<td>19</td>
</tr>
<tr>
<td>Appendix C: Zoll EMV+ (731 Series)</td>
<td>23</td>
</tr>
<tr>
<td>Appendix D: Hamilton T1</td>
<td>24</td>
</tr>
<tr>
<td>Appendix E: SAVe II</td>
<td>27</td>
</tr>
<tr>
<td>Appendix F: Information Regarding Off-label Uses in CPGs</td>
<td>28</td>
</tr>
</tbody>
</table>
BACKGROUND

Appropriate consideration must be taken when placing a patient on a mechanical ventilator. Ventilator management is resource intensive and demanding which might not make it appropriate for all tactical situations. It is not without risk. The benefits should outweigh the attributable cost and risk of managing the mechanically ventilated patient, especially within the austere/ battlefield setting. Pathology associated with failure to oxygenate and failure to ventilate will most often require definitive airway interventions and appropriate mechanical ventilator support. At times, it may only serve as a temporizing measure while seeking definitive critical care. Institution of mechanical ventilation must be guided by clinical suspicion of underlying pathophysiology and clear criteria. Definitive airway management and sedation are often required for effective mechanical ventilation. See JTS CPGs Airway Management of Traumatic Injuries and Analgesia and Sedation Management during Prolonged Field Care. The intent of this CPG is to provide the non-critical care trained/proficient medical personnel with guidance on basic ventilator management until the appropriate level of care can be reached physically or via telemedicine in the operational environment while supporting ventilation, oxygenation, and reduce labored breathing while ensuring patient comfort. Additional JTS CPGs with ventilatory support considerations are Acute Respiratory Failure and Wartime Thoracic Injury.

DEFINITIONS

MECHANICS/PHYSIOLOGY OF BREATHING

1. **Respiratory drive**: The normal respiratory rate is 12-20 bpm. Respiratory drive is controlled by the hydrogen ion concentration in the cerebrospinal fluid and modified by receptors throughout the body. Increased intracranial pressure, administration of opioids and other medications may cause a decreased respiratory drive causing ventilation insufficient to maintain an adequate level of oxygenation and clearance of carbon dioxide (CO₂).¹⁻³

2. **Work of breathing**: Work of breathing is the mechanical work needed to maintain oxygenation and ventilation. Pain, acidosis, and hypermetabolic states will cause an increased work of breathing. This is not necessarily pathologic, but may indicate that the patient has increased CO₂ production and that respiratory support may be needed. Tachypnea secondary to shock could lead to inspiratory muscle fatigue which could eventually require mechanical ventilator support.¹⁻³

3. **Lung compliance**: The tendency for the lungs to recoil from an inflated state is a good conceptual representation of compliance. Lung compliance impacts all functions of the respiratory system. Changes in lung compliance may be caused by both intrinsic and extrinsic causes. Atelectasis or fluid/blood in the alveoli can cause an intrinsic decrease in lung compliance. Examples of extrinsic causes of decreased compliance include obesity, pregnancy, burns, and chest wall injury. A decrease in lung compliance from any cause can lead to hypoxemia and hypercapnia. Fentanyl may also cause chest wall rigidity, leading to poor lung compliance.¹⁻³

4. **Tidal volume (TV or Vt)**: Is the volume of air that is exchanged in one breath. Decreases in tidal volume can result from external pressure (i.e. Pneumothorax, hemothorax, tension pneumothorax) by effectively reducing lung volume. Dynamic hyperinflation also known as “breath stacking” is caused by the inability to completely exhale and can lead to “auto-positive end expiratory pressure (auto-PEEP).” This may be due to inadequate exhalation time, airflow obstruction, or both. This condition leads to decreasing tidal volumes and can cause hemodynamic compromise.¹⁻³
5. **Oxygenation**: The successful binding of oxygen to hemoglobin at the cellular level in the alveoli, drives $\text{SaO}_2$ (arterial oxygen saturation) and $\text{SpO}_2$ (oxygen saturation) values. Successful alveolar gas exchange enables efficient aerobic respiration at the cellular level in all perfused body tissues.\(^1\)\(^-\)\(^3\)

6. **Diffusion/exchange**: The process where oxygen ($O_2$) is exchanged with $CO_2$ on red blood cells in the alveoli/pulmonary capillaries for transport to body tissues. Pathologic conditions such as pulmonary edema, pneumonia, and acute respiratory distress syndrome (ARDS) can impair diffusion of oxygen across the alveolar membrane leading to reduced oxygen saturation of hemoglobin.\(^1\)\(^-\)\(^3\)

7. **Fraction of Inspired Oxygen ($FIO_2$)**: Normal atmospheric air contains 21% oxygen or an $FIO_2$ of 0.21. By increasing the percentage of oxygen delivered to the patient (supplemental oxygen), you can potentially increase the arterial oxygen saturation and oxygen content of the bloodstream.\(^1\)\(^-\)\(^3\)

8. **Dead Space**: Any part of the airway where gas exchange does not occur, pharynx, larynx, trachea, bronchi, and ventilator tubing are examples.

9. **Hypoxia**: A state of $O_2$ deficiency in the tissue significant enough to cause impairment of function. There are four types of hypoxia that exist that must be accounted for during ventilator support:\(^1\)\(^-\)\(^3\)

   - **Hypoxic Hypoxia**: Occurs when there is not enough available $O_2$ in the surrounding environment or when decreasing atmospheric pressure prevents diffusion of $O_2$ from the lungs to the bloodstream. Most commonly occurs during unpressurized transport at high altitude (>10,000 ft). This is correctable with supplemental oxygen.

   - **Hypemic Hypoxia**: Reduction of the blood's oxygen carrying capacity due to inadequate red blood cells (RBCs) (e.g., hemorrhage, anemia) or impairment to RBCs, carbon monoxide ($CO$) poisoning, etc.). Correction of the causal factor is required.

   - **Stagnant Hypoxia**: Occurs at the circulatory level. Blood's $O_2$-carrying capacity is adequate but circulation is inadequate (e.g., high-gravitational (G) forces, heart failure, blood vessel occlusion). Correction of underlying causal factor is required.

   - **Histotoxic Hypoxia**: Results from an interference with the use of $O_2$ by body tissues. Alcohol, narcotics, or a poison such as cyanide (blue) is inhaled (or can be ingested) and is delivered to the tissues by the blood where it poisons the tissues, preventing use of available $O_2$. Correction of underlying causal factor is required to positively change.\(^1\)\(^-\)\(^3\)

**VENTILATION**

1. **Minute ventilation ($V_t$)**: Tidal volume multiplied by the respiratory rate (normal is 60cc/kg/min), usually expressed in liters. The body regulates carbon dioxide through changes in minute ventilation. Increases in carbon dioxide leads to increased respiratory rate and/or tidal volume and increased minute ventilation (amount of air exchanged during one minute of ventilation).\(^1\)\(^-\)\(^3\)

2. **Peak Inspiratory Pressure (PIP)**: The greatest pressure within the lungs during inspiration. Pressures above 35mmHg have been shown to cause pressure-related lung injury (barotrauma). Ideally, pressures should remain at 30 mmHg and below. Increased peak pressures are usually due to increases in resistance within the respiratory system (e.g., tension pneumothorax, inability for adequate exhalation, edema).\(^1\)\(^-\)\(^3\)
3. **Arterial Blood Gas (ABG):** This is the gold standard for evaluating acid-base status, oxygenation, ventilation and adjusting ventilation settings. If a point of care blood gas analyzer is available, this will enable targeted ventilator settings. Knowing these values will greatly improve critical care guidance via telemedicine resources. Consider placement of an arterial cannula for continuous blood pressure and ABG sampling if it is appropriate for the operational setting and training level of the care provider.

**Normal ABG values:**
- pH (7.35-7.45)
- PaO₂ (75-100 mmHg)
- PaCO₂ (35-45 mmHg)
- HCO₃ (22-26 meq/L)
- Base excess/deficit (-4 to +2)
- SaO₂ (95-100%)

**ABG Definitions**

1. **pH:** Measure of hydrogen ion concentration (i.e. acid-base status). Acidosis (low pH) leads to coagulopathic states in trauma patients as well as development of potentially fatal cardiac arrhythmias.

2. **PaO₂:** Measurement of dissolved oxygen in blood, also a measurement of adequacy of gas exchange at the cellular level.

3. **PaCO₂:** Measurement of dissolved carbon dioxide in blood, also a measurement of adequacy of gas exchange at the cellular level.

4. **HCO₃:** Measurement of bicarbonate in the blood, serves as a buffer against acid.

5. **Base excess:** Gives indication of metabolic component of blood gas results, most likely will not change field ventilator management but can provide information for telemedicine consultation regarding adequacy of resuscitation.

6. **SaO₂:** Percentage of oxygen bound to hemoglobin in arterial blood, correlates closely with SpO₂ values.

7. **End Tidal CO₂ (ETCO₂):** Measurement of carbon dioxide on end tidal expiration. Normal values are 35mmHg-45mmHg. Exhaled gasses are analyzed by either vital signs monitor or portable ETCO₂ devices (e.g., EMMA) a quantitative capnograph or capnometer is the clinical standard of care with invasively ventilated patients.

8. **Plateau Pressure (PPLAT):** The pressure applied to small airways and alveoli during positive-pressure mechanical ventilation. It is measured during an inspiratory pause on the mechanical ventilator. A mechanically ventilated patient with a plateau pressure greater than 35cm is at an increased risk for barotrauma.
VENTILATOR TERMS

1. **Volume-targeted modes**: Volume constant, inspiration terminates when preset $V_T$ delivered. Peak airway pressure is variable and increases as needed to deliver prescribed $V_T$. This is generally represented by a constant flow waveform.

2. **Pressure-targeted modes**: Volume variable, terminates when airflow falls below threshold level. Peak airway pressure is fixed, determined by set pressure level. This is generally represented by a decelerating flow waveform.

3. **Tidal volume ($V_T$)**: Is the volume of gas, exchanged during a breath and commonly expressed in milliliters. $V_T$ is generally set between 4-8 ml/kg ideal body weight (IBW), to prevent lung over distension and barotrauma.

4. **Frequency ($f$)**: Is the rate, per minute, of breathing (patient or ventilator). Known as respiratory rate (RR).

5. **Minute Ventilation ($V_e$)**: Is the average volume of gas entering, or leaving, the lungs per minute, commonly expressed in liters per minute. The product of $V_T$ and RR (respiratory rate). Normal $V_e$ is 5 – 10 L/min.

6. **Inspiratory (I) and Expiratory (E) time and I:E ratio**: Is the time period over which the $V_T$ is delivered. Setting a shorter inspiratory time (I) results in a faster inspiratory flow rate in volume cycled ventilation. Average adult inspiratory time is 0.7 to 1 second. I:E ratio is usually 1:2.

7. **Positive end-expiratory pressure (PEEP)**: Is the amount of positive pressure that is maintained at end-expiration. It is expressed in centimeters of water (cmH2O). The purpose of PEEP is to increase end-expiratory lung volume and reduce air-space closure at end-expiration. Normal physiologic PEEP is 5 cmH2O.

8. **Pressure Support (PS)**: Delivers flow at a set pressure, generally to overcome resistance of the airway and ventilator circuit. PS can also be used to support a spontaneously breathing patient, such as with Bi-PAP.

9. **Flow**: Is the velocity at which gas is delivered to the patient, expressed in liters per minute. When the flow rate is set higher, the speed of gas delivery is faster and inspiratory time is shorter.

10. **Peak Inspiratory Pressure (PIP)**: Represents the total pressure that is required to deliver the $V_T$ and depends upon various airway resistance, lung compliance, and chest wall factors. It is expressed in centimeters of water (cmH2O).

11. **Sensitivity or trigger sensitivity**: Effort, or negative pressure, required by the patient to trigger a machine breath, commonly set so that minimal effort (-1 to -2 cmH2O) is required to trigger a breath.1,3

VENTILATOR MODES

VOLUME-TARGETED MODES

1. Volume-targeted modes:
   a. **Volume Assist/Control (V-AC), Assist Control (AC) or Volume Control Ventilation (VCV)**: Delivers a preset number of mandatory breaths per minute. The patient can take their own
breaths in addition to mandatory breaths, with each spontaneous breath receiving the full preset tidal volume. Airway pressures can vary during delivery. 1-3

b. **Volume Synchronized Intermittent Mandatory Ventilation (V-SIMV)** combines mandatory breaths and supported breaths. The ventilator delivers a preset number of mandatory breaths per minute. Any breaths over the set rate will be supported with a fixed amount of pressure support. 1-3

2. **Pressure-targeted modes**:
   
   a. **Pressure Support Ventilation (PSV)** supports every patient breath with a preset amount of pressure support. No mandatory breaths are given, so the patient must be spontaneously breathing.

   b. **Pressure Assist control (P-AC), or Pressure Control Ventilation (PCV)** delivers a set number of mandatory pressure controlled breaths, in which the patient receives a fixed pressure during a preset inspiratory time. Any breaths over the set rate will be pressure controlled with the same amount of pressure. The delivered tidal volume will be based on the amount of pressure applied, the lung compliance and airway resistance of the patient.

3. **Adaptive Support Ventilation (ASV)**: *(Is only available on the Hamilton T1)* ASV provides intelligent ventilation mode that continuously adjusts respiratory rate, tidal volume, and inspiratory time depending on the patient’s lung mechanics and effort. This is similar to “Auto-Flow” or other like settings on different brands of ventilators.

4. **Continuous Positive Airway Pressure (CPAP)**.

5. **Pressure Regulated Volume Control (PRVC)** (may be Impact 731 only).

**VENTILATOR ADJUSTABLE SETTINGS**

1. **Tidal volume (Vt)**: the volume of gas, exchanged during a breath and commonly expressed in milliliters. Vt is generally set between 4-8ml/kg IBW, to prevent lung over distension and barotrauma. 4-8

2. **Ideal IBW**: the weight at which tidal volume is calculated against instead of using actual weight. This enables patients to be ventilated in a lung-protective strategy. A quick reference chart can be found in Appendix A. IBW can be calculated manually as follows:
   
   a. Male: \(((\text{Height in inches-60}) \times 2.2) + 50\) (e.g. 72in-60 = 12; 12 \times 2.2 = 26.4; 26.4 + 50 = IBW of 76.4 kg)
   
   b. Female: \(((\text{Height in inches-60}) \times 2.2) + 45\) (e.g. 65in-60 = 5; 5 \times 2.2 = 11; 11 + 45 = IBW of 56 kg)

3. **Minute Ventilation (V̇)**: The average volume of gas entering, or leaving, the lungs per minute, commonly expressed in liters per minute. Also called minute volume. Minute ventilation is the product of Vt and RR (respiratory rate). Normal V̇ is 5 – 10 L/min. 4-8

4. **I:E Ratio**: See I:E definition. I:E might need to be adjusted for physiology that requires extended exhalation time. 4-8 For example: Asthma patient may require an I:E of 1:3, 1:4, or 1:5 to allow for more exhalation time.

5. **Flow Rate**: Is the velocity at which gas is delivered to the patient, expressed in liters per minute. When the flow rate is set higher, the speed of gas delivery is faster and inspiratory time is shorter. 4-8
4. **Peak Inspiratory Pressure (PIP):** Represents the total pressure that is required to deliver the VT and depends upon various airway resistance, lung compliance, and chest wall factors. It is expressed in centimeters of water (cm H2O).

5. **Sensitivity or trigger sensitivity:** Is the effort, or negative pressure, required by the patient to trigger a machine breath, commonly set so that minimal effort (-1 to -2 cm H2O) triggers a breath.\(^1\) This is usually seen with assist modes of ventilator operation.

6. **Pressure alarms:** Pressure alarms ensure that providers are alerted to pressures that fall outside of appropriate ranges and have potential to harm the patient via barotrauma (over-pressure) or under-ventilation (circuit disconnect or under-pressure). Pressures will be determined by placing the patient on the vent for ~1-2 minutes and determining intrinsic peak inspiratory pressure. (Labeled as PEAK on 754 Ventilator (top right); Labeled as peak on Hamilton T1 ventilator (top left); Labeled as PIP on ZOLL EMV+ (731) (right center). Standard alarm settings should be:
   a. High pressure alarm: 10 cmH2O above peak airway pressure.
   b. Low pressure alarm: 5 cmH2O below peak airway pressure.

### ASSESSMENT

Determining the need for mechanical ventilation early is critical for the effective application of a mechanical ventilation device. Clinical suspicion is vital to adequately predict a patient who will progress to respiratory compromise. Respiratory compromise requiring ventilator support can be identified early in M-massive hemorrhage, A-airway, R-respiratory, C-circulation, and H-hypothermia (MARCH) assessment. Inability to adequately oxygenate, ventilate, or guard the airway are indications for mechanical ventilatory support. Though it is uncommon for a mechanical ventilator to be applied at point of injury, the treating provider can begin to take steps necessary to prepare for the application of a ventilator (i.e. supplemental O2, positioning, airway interventions).

**NOTE:** Apneic patients with adequate circulation and an open airway require immediate mechanical ventilation (i.e. bag valve mask [BVM]).

Though ABGs are the standard for managing patients with respiratory compromise, they are not often readily available in the operational environment. Utilization of pulse oximetry (SpO2) and capnography/capnometry (ETCO2) can provide a rapid assessment of a patient’s respiratory status (devices to achieve both are readily available in medical logistics systems).

SpO2 values < 90% are indicative of potential oxygenation issues; however, values can be unreliable due to poor perfusion and altitude.

ETCO2 values >45mmHg are indicative of hypoventilation, especially in the absence of tachypnea. Values <35mmHg are indicative of hyperventilation and should be corrected in the least invasive manner. Mental preparation for mechanical respiratory support should be considered.

A high index of suspicion for sepsis or other metabolic acidosis should be maintained in patients with low ETCO2 and hyperventilation.
The inability for a casualty to maintain appropriate SpO2 or ETCO2 values through less invasive measures (airway adjuncts, supplemental O2, etc.) indicates the need for escalating support. For locations with point of care blood analyzers, inadequate blood gas values also indicate the need for respiratory support.

**WARNING:** Prior to the application of mechanical ventilation and/or initiation of invasive airway devices (e.g., Endotracheal Tube (ETT), extraglottic airways), patients must receive adequate sedation (and paralysis as appropriate/required). Detailed guidelines for the initiation and maintenance of this sedation can be found in *Analgesia and Sedation Management during Prolonged Field Care*.

**APPLICATION OF MECHANICAL VENTILATION**

If respiratory insufficiency amenable to respiratory support is identified during the assessment, the initiation of timely mechanical ventilation can improve casualty outcomes. This can be as simple as bag BVM support or as complex as a critical care transport ventilator (e.g. Hamilton T1 or Zoll EMV+).9,15

**CAUTION:** BVM respiratory support should be utilized as a temporary measure until mechanical ventilators can be applied. BVMs deliver irregular Vt and respiratory rates leading to inconsistent blood gas values.

**NOTE:** Many patients may require increased sedation (and paralysis) for effective ventilation. Patients who are not properly sedated may cause issues with high pressure alarms as they breathe over the ventilator increasing their minute volume and intrathoracic pressures.

**INITIAL VENTILATOR SETTINGS**

*Prior to first use, ensure ventilator (as applicable) has been pre-set to utilize parameters of the user’s choice. Some ventilators may be preset to deliver an inspiration time (I-Time) instead of an I:E ratio. Failure to appropriately set up and save these ventilator settings may delay use of the ventilator.

1. **MODE:** AC or ASV (Hamilton T1 only)
2. **BPM/RRate:** 14BPM (10-30 range)
3. **TIDAL VOLUME:** 6ml/kg IBW (4-8ml/kg IBW range)

   Quick Reference (Male): (Detailed reference in Appendix A)
   - 66” = ~380cc [min: 255 / max: 510]
   - 69” = ~420cc [min: 283 / max: 566]
   - 72” = ~465cc [min: 310 / max: 621]
   - 75” = ~505cc [min: 338 / max: 676]
4. **FiO2:** 21 - 100% (0.21-1.0) (low flow O2 @ 3 LPM (liters per minute) = ~ 40% FiO2 [flowrate on Saros oxygen concentrator])
5. **I:E Ratio:** 1:2
6. **PEEP:** 5 [Range 5-20 cmH20]
7. **Pressure Support:** 5 [Range 5-20 cmH20] Consider adding if the patient has airway edema or is being ventilated through a narrower diameter ETT.
INITIAL VENTILATOR SETTINGS

**NOTE:** Initial Ventilator settings are based on the patient’s ideal body weight (IBW) and clinical condition. However, “basic” or standard starting points are necessary to begin treatment.

1. Set the ventilator to Volume Assist/Control.
2. Set driving mechanics by type of ventilation. Tidal Volume at 4-6 mL/kg IBW (Average adult male is 500 mL).
3. Set rate to maintain an appropriate minute ventilation (V_{	ext{e}}) of 4-8 L/min (V_{T} x Rate = V_{E}).
   a. For a MV of 6L and a V_{T} of 500, set the rate at 12.
   b. Continuous capnometry or capnography is the standard for invasive airway management and should be used to monitor ventilations and as a tool to increase or decrease frequency. ETCO2 is especially important for monitoring TBI cases.
4. Set appropriate PEEP. Minimum of 5 cmH2O. Start there and titrate up as needed. In hypoxic patients, consider starting at 10 cmH2O.
5. Set FiO2. Depending on clinical condition the patient may need high FiO2. Start at 100% and titrate down using arterial blood gas and SpO2 data. Do not rely on SpO2 alone (if possible).\(^7\)
6. Set Inspiratory:Expiratory Ratio (I:E) to 1:2 for most patients. Adjust to clinical conditions.
7. Oxygen requirements can be roughly calculated using Minute Ventilation x FiO2 fraction to determine LPM of pure O2 required (e.g., V_{E} of 6 LPM @ 50% FiO2 (0.5) = 3 LPM bottled or generated O2 required.)

**NOTE:** Full D cylinder is ~425 liters O2 at 2200psi (i.e. ~141minutes O2 @ 3 LPM requirement above). Calculations should account for discrepancies in tank fill, leaks, dead space, etc. (consider a planning factor of 1.5X calculated requirement).

TROUBLESHOOTING

Airway compromise or lost airway: If at any time the patient begins to de-saturate or develop respiratory problems, immediately disconnect the ventilator and manually ventilate the patient with BVM (with PEEP valve if available) and 100% O2 while correcting issues utilizing the following D.O.P.E. algorithm.\(^7\)

- **Displacement:** Verify that ETT is in place, patient not extubated/tube did not move during transfer. If the ETT has advanced – pull back to original length and attempt to bag; if tube has pulled farther out of trachea, DO NOT ATTEMPT TO ADVANCE the ETT without laryngoscopy or placement of bougie to verify tracheal placement. When advancing the bougie, feel for tracheal rings or stop/ resistance at the carina. If in doubt, remove the endotracheal tube and attempt BVM. If air movement is adequate, continue to bag ventilate the patient. Upon stabilization, consider alternative advanced airways (supraglottic airway or cricothyroidotomy).

**If ETT moves freely, access for ETT bulb rupture via cuff manometer.**\(^9\)
Obstructions: Assess for secretions in ETT. Suction if indicated.

Pressure: Ensure that a tension pneumothorax / hemothorax has not developed (if the chest tube is in place, ensure it is properly suctioning, not kinked or clamped). If tension pneumo/hemothorax is suspected, perform immediate needle thoracentesis. Assess the need for escharotomy if circumferentially burned. Consider additional paralysis and sedation if patient does not tolerate ventilation.9

Equipment: Ensure that ventilator did not fail; O2 tank not empty. If ventilator is operational, trace all tubes to the patient connection (airway tube, transducer line, exhalation line) ensuring patency and connections.7

The utilization of concurrent waveform capnography may assist in determining the causative issue while working the D.O.P.E mnemonic.

High pressure alarms / Peak airway pressure alarms (Peak pressure >35 cm H2O): Correct problems causing increased airway resistance and decreased lung compliance, including pneumothorax or pulmonary edema. Check the ventilator to ensure the prescribed tidal volume is being delivered. Check for linked/crushed tubing.

Air leaks causing low pressure alarms / volume loss: Assess, correct air leaks in endotracheal tube, tracheostomy cuff, ventilator system; recheck ventilator to make sure prescribed tidal volume is delivered.9

Ventilator dyssynchrony: Is a clinical entity in which ventilator gas delivery and patient respiratory mechanics are not matched. Agitation and respiratory distress that develop in a patient on a mechanical ventilator who has previously appeared comfortable represents an important clinical circumstance that requires a thorough assessment and an organized approach. The patient should not always be automatically re-sedated, but must instead be evaluated for several potentially life-threatening developments that can present in this fashion.14

Lung hyperinflation (air trapping) and auto-PEEP: Dynamic hyperinflation is associated with positive end-expiratory alveolar pressure, or auto-PEEP. The physiologic effects of air trapping include decreased cardiac preload because of diminished venous return into the chest. This can lead to hypotension and, if severe, to pulseless electrical activity and cardiac arrest. Dynamic hyperinflation can also lead to local alveolar over-distention and rupture. Prevent and manage lung hyperinflation by decreasing tidal volume, changing inspiratory and expiratory phase parameters, switching to another mode, and correcting physiological abnormalities that increase airway resistance.11, 12 In an emergency, auto-PEEP from air trapping can be relieved by simply disconnecting the circuit from the endotracheal tube for 3-5 seconds, and then reconnecting.
CHANGES IN RESPIRATORY STATUS

1. Assess patient’s prior interventions.

2. Assess the following patient’s respiratory status:
   - Rate
   - Rhythm
   - Depth
   - Effort

3. Assess monitors:
   - Oxygenation (SpO₂)
   - ETCO₂ (with advanced airway)
   - Cardiac monitoring if available

4. Determine cause of ventilation issue and/or ventilator alarm using DOPE mnemonic.

Table 1. Trouble shooting – DOPE Algorithm

<table>
<thead>
<tr>
<th>Alarm</th>
<th>DOPE</th>
<th>Possible Cause</th>
<th>Troubleshooting</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Pressure</td>
<td>D</td>
<td>Mainstem intubation</td>
<td>If the tube has advanced and unilateral ventilation is confirmed, retract the tube to proper depth using bougie technique to maintain placement.</td>
</tr>
<tr>
<td>High Pressure</td>
<td>D</td>
<td>Esophageal intubation</td>
<td>If the tube is advanced and unilateral ventilation is not present, rule out esophageal intubation. If breath sounds are present over abdomen, or gastric distention noted, remove the ET tube and secure airway by other means and place gastric tube for evacuation of gastric contents.</td>
</tr>
<tr>
<td>High Pressure</td>
<td>O</td>
<td>Obstruction of ET tube</td>
<td>Place patient on FiO₂ 1.0 (100%) and prepare suction equipment. Suction airway using standard technique. If inhalation injury is suspected (burn, agent), saline may be used to facilitate suctioning.</td>
</tr>
<tr>
<td>High Pressure</td>
<td>O/E</td>
<td>Obstruction of ventilator circuit</td>
<td>Ensure circuit connections are attached and not kinked paying particular attention to connections and sharp bends.</td>
</tr>
<tr>
<td>High Pressure</td>
<td>P</td>
<td>Pulmonary circuit</td>
<td>Rule out/treat hemo/pneumothorax.</td>
</tr>
<tr>
<td>High Pressure</td>
<td>P</td>
<td>Pulmonary circuit</td>
<td>Consider Pulmonary Edema. Prolong Inspiratory time if appropriate (i.e. adjust from 1:3 to 1:2 to 1:1).</td>
</tr>
<tr>
<td>High Pressure</td>
<td>P</td>
<td>Pulmonary circuit</td>
<td>Consider airway swelling; may need to add or increase Pressure Support</td>
</tr>
<tr>
<td>High Pressure</td>
<td>P</td>
<td>Pulmonary circuit</td>
<td>Evaluate Tidal Volume. Consider lowering by 1cc/kg (min. 4cc/kg).</td>
</tr>
<tr>
<td>High Pressure</td>
<td>P</td>
<td>Patient arousal</td>
<td>Address analgesia/sedation needs.</td>
</tr>
<tr>
<td>High Pressure</td>
<td>P</td>
<td>Stacked breath/air trapping</td>
<td>Disconnect patient from the circuit and allow full exhale. Address cause (patient triggering, high rate, incomplete exhalation).</td>
</tr>
<tr>
<td>High Pressure</td>
<td>P</td>
<td>Chest tube malfunction</td>
<td>If hemo/pneumothorax are suspected, disconnect all attachments and troubleshoot chest tube and components.</td>
</tr>
<tr>
<td>High Pressure</td>
<td>P</td>
<td>Patient position</td>
<td>If laying supine, elevate head of bed (HOB) to reduce gravitational pressure on the chest.</td>
</tr>
<tr>
<td>Alarm</td>
<td>DOPE</td>
<td>Possible Cause</td>
<td>Troubleshooting</td>
</tr>
<tr>
<td>---------------</td>
<td>------</td>
<td>-------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>High Pressure</strong></td>
<td>E</td>
<td>Alarm setting</td>
<td>After ensuring patient optimization, adjust alarm settings.</td>
</tr>
<tr>
<td><strong>Low Pressure</strong></td>
<td>D</td>
<td>Extubation</td>
<td>If tube has been removed from the trachea, secure the airway using method within scope/skill of the provider.</td>
</tr>
<tr>
<td><strong>Low Pressure</strong></td>
<td>D</td>
<td>Esophageal intubation</td>
<td>If tube is advanced and unilateral ventilation is not present, rule out esophageal intubation. If breath sounds present over abdomen, or gastric distention noted, remove ET tube and secure airway by other means and place gastric tube for evacuation of gastric contents.</td>
</tr>
<tr>
<td><strong>Low Pressure</strong></td>
<td>E</td>
<td>ET tube balloon</td>
<td>Ensure ET Tube cuff is inflated (25-35 cmH2O). If the cuff will not maintain inflation, exchange ET tube using bougie technique.</td>
</tr>
<tr>
<td><strong>Low Pressure</strong></td>
<td>E</td>
<td>Ventilator disconnect/leak</td>
<td>Ensure all connections are attached securely to the appropriate point. Run bare hand along circuit to feel any air escaping during inhalation paying special attention to valves and connections.</td>
</tr>
<tr>
<td><strong>Low SpO2</strong></td>
<td>DOPE</td>
<td>Assess patient</td>
<td>For acute desaturation, place FiO₂ at 1.0 (100%). Check chest rise and fall, ETCO₂, SpO₂ probe placement. Check all conditions from high/low pressure chart to rule out other alarm failures.</td>
</tr>
<tr>
<td><strong>Low SpO2</strong></td>
<td>x</td>
<td>Increase in altitude</td>
<td>Increase FiO₂ to compensate for decrease in pressure.</td>
</tr>
<tr>
<td><strong>Low SpO2</strong></td>
<td>x</td>
<td>Patient deterioration</td>
<td>If desaturation is gradual and presumed to be caused by patient pathology, increase PEEP and FiO₂ in a stepwise fashion according to ARDSNet table.</td>
</tr>
</tbody>
</table>
| **Low SpO2** | x    | Patient deterioration               | Attempt alveolar recruitment maneuvers. Inflation to 30 - 40 cm H₂O for 30 - 40 seconds (difficult with PMI). Recruitment maneuver can be performed with bag-valve manual ventilation.  
1. Set PEEP valve on bag-valve unit to 15 - 20 cm H₂O.  
2. Deliver five sequential breaths, each held for 5 - 8 seconds.  
3. Watch blood pressure closely. Terminate if hypotension develops.  
4. Clamp endotracheal tube while switching between ventilator and bag.  
5. Immediately assess for tension pneumothorax, if applicable. |
| **Low SpO2**  | E    | O2 supply                           | Check O2 PSI and condition of hose/connections.)                                                   |
| **High ETCO₂** | E    | Incorrect vent settings             | V̇E may be too low (Adjust V̇̇/f/I:E for patients IWB).                                             |
| **High ETCO₂** | x    | Hypermetabolic state                | Address pain, shivering, hyperthermia / infection.                                                  |
| **High ETCO₂**  | x    | Respiratory insufficiency           | Increase rate (current ETCO₂ x current rate/40).V̇E may be too high (Ensure proper V̇̇/f/I:E for patients IWB). |
| **Low ETCO₂**  | E    | Incorrect vent settings             | V̇E may be too high (Ensure proper V̇̇/f/I:E for patients IWB).                                     |
| **Low ETCO₂**  |      | Ventilator dyssynchrony             | If on AC and patient is not properly sedated, the patient may be breathing over the ventilator settings, increasing their V̇E. Consider sedation medications followed by paralytics, as needed. |
### Alarm | DOPE | Possible Cause | Troubleshooting
--- | --- | --- | ---
Low ETCO₂ | x | Low perfusion state (hypovolemia or sepsis) | CHECK PATIENT’S PULSE FOLLOWING RAPID DROP. Continue to resuscitate patient within scope and skill.
Low ETCO₂ | x | Decrease in alveolar ventilation | Suction patient if suspected mucus/secretion plug. If associated with high pressure alarm, consider alveolar distention (air trapping/stacked breathing): remove patient from ventilator and allow full exhale.
Low ETCO₂ | x | Respiratory compensation (metabolic acidosis) | DO NOT ATTEMPT TO NORMALIZE patient’s breathing without ABG and expert consultation.

Source: USASAM, Enroute Care Branch Ventilator Guide\(^\text{16}\)

**Figure 1. Recently published USAF EMS protocols**

**Normal Capnogram, Normal ETCO₂: 35-45 mmHg**

![Capnogram Normal ETCO₂](image)

The “normal” capnogram is a waveform which represents the varying CO₂ level throughout the breath cycle.

**Waveform Characteristics:**
- A-B: Baseline
- B-C: Expiratory Upstroke
- C-D: Expiratory Plateau
- D: End-Tidal Concentration
- D-E: Inspiration


**Endotracheal Tube in Esophagus**

![Endotracheal Tube in Esophagus](image)

Possible causes:
- Missed intubation
- A normal capnogram is the best evidence that the ET tube is correctly positioned.
- With ET tube in the esophagus, little or no CO₂ is present.
Inadequate Seal around ET Tube

Possible causes:

- Leaky or deflated endotracheal or tracheostomy cuff
- Artificial airway is too small for the patient.

Obstruction in Airway or Breathing Circuit

Possible causes:

- Partially kinked or occluded artificial airway
- Presence of foreign body in the airway
- Obstruction in expiratory limb of breathing circuit
- Bronchospasm

Source: https://openairway.org/capnography

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All patients with an advanced airway requiring mechanical ventilation during transport.

INTENT (EXPECTED OUTCOMES)

1. Initial tidal volume is based on ideal body weight, targeting 6cc/kg.
2. EtCO₂ is monitored when available, targeting a range between 35-45 mmHg.
3. Adjustments to respiratory rate, tidal volume, FIO₂, and PEEP are based on clinical indicators (i.e. oxygen saturation, peak airway pressure, EtCO₂) and documented on DA 4700 (TACEVAC Patient Care Record).
4. All patients in the population of interest arrive with PaCO₂ 35-45mmHg.

**PERFORMANCE/ADHERENCE MEASURES**

Number and percentage of patients with an advanced airway that arrive with initial PaCO₂ 35-45mmHg.

**DATA SOURCES**

- Patient Record
- Department of Defense Trauma Registry (DoDTR)

**SYSTEM REPORTING & FREQUENCY**

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the JTS Chief and the JTS PI Branch.

**RESPONSIBILITIES**

It is the trauma team leader’s responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

**REFERENCES**


Mechanical Ventilation Basics


15. Fundamental Critical Care Support. 6th ED. Society of Critical Care Medicine. 2017

### APPENDIX A: PREDICTED BODY WEIGHT AND TIDAL VOLUME

#### Predicted Body Weight and Tidal Volume ($V_t$)

<table>
<thead>
<tr>
<th>Height (Ft’’ + inches)</th>
<th>Male</th>
<th>Predicted Body Weight</th>
<th>ml per kg of PBW (total $V_t$)</th>
<th>Female</th>
<th>Predicted Body Weight</th>
<th>ml per kg of PBW (total $V_t$)</th>
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</thead>
<tbody>
<tr>
<td>4’0’’ 48</td>
<td>22.4</td>
<td>90</td>
<td>112</td>
<td>41’’ 48</td>
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<td>4’’ 49</td>
<td>24.7</td>
<td>99</td>
<td>124</td>
<td>41’’ 49</td>
<td>20.2</td>
<td>81</td>
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<td>4’2’’ 50</td>
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<td>135</td>
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<td>41’’ 90</td>
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</tr>
</tbody>
</table>

**Note:**
- PBW Males = 50 + 2.3 [height (inches) - 60]
- ARDSnet, NIH NHLBI ARDS Clinical Network Mechanical Ventilation $V_t$ card

*Guideline Only/Not a Substitute for Clinical Judgment*
NOTE: Some Geographic Combatant Commands (GCC) have placed restrictions on use of Impact 754 Ventilators in U.S. Central Command. Check with the GCC Surgeon cell prior to utilization in theater.

RULE OF 5S (KEEP IT SIMPLE VENT SETTINGS FOR ADULTS)

There are five numbered dials on the front of the Eagle/Impact Vent. Most settings can be set by remembering multiples of five. Do not hook up casualty to the breathing circuit until after the PEEP is set.

1. Dial 1 — Turn on to calibrate. You must calibrate the vent every time you turn it on. Turn the knob to the right. The LED display will show "Cal-Mode" and then "Cal-OK;" turn the knob to the left past Continuous Positive Airway Pressure (CPAP) and to Synchronized Intermittent Mandatory Ventilation (SIMV) or Assist Control.

2. Dial 2 — Ventilatory Rate — set at 10.

3. Dial 3 — I:E ratio of 1:2. Turn the knob all of the way to the left. This setting is generally satisfactory for all adults and pediatrics with trauma related requirements for mechanical ventilation. Medical problems like chronic obstructive pulmonary disease and asthma may require longer ratios, and this should be assessed after the initial settings have been set.

4. Dial 4 — Tidal Volume of 500 ml and adjust as needed. Tidal volume calculation is 4-8 ml/kg, therefore 6 ml/kg is recommended after the initial setting of 500.
5. Dial 5 — Air/oxygen mixer. For room air the knob will be all of the way to the left and for 100% O2 will be all of the way to the right.

**IMPACT 754 VENTILATOR PRE-MISSION CHECKS AND TROUBLESHOOTING**

**Routine Care**

Clean the unit and hose attachments with damp soapy cloth and wipe dry. Remove the inlet filter to check for dirt or debris. Check metal hose couplings for thread wear and debris.

**Duty Inspection**

1. Power Off Checks:
   a. Verify inspection is within the calibration date (6-month maintenance cycle).
   b. Check the air inlet is clear of obstructions and the filter is in place (Right side of vent).
   c. Verify the Gas ("OXYGEN IN" and "AIR IN") and Patient ("EXHALATION VALVE" and "TRANSUDER") connections are clear and tight (Top of ventilator).
   d. Verify the “GAS OUT” clear leaf valve is installed and seated (reseat if loose, replace if missing).
   e. Inspect green high pressure oxygen hose for cracks, dry rot, threads, black O-ring (replace if damaged).

Connect the ventilator to a high-pressure oxygen source, turn on the oxygen tank and ensure no leaks are present. Turn off O2 when complete (conduct in environment conducive to hearing leaks).

2. Power On Checks
   a. Turn “MODE” (knob 1) to desired setting (AC, SIMV, CPAP). The ventilator will run a SELF-TEST upon set up (ventilator circuit should be disconnected). At this point, (CAL) is not required. If SELF-TEST results in a Calibration Failure, place (1) to CAL until CAL OK is displayed. If the calibration fails, the ventilator must be taken out of service.
   b. Check BATT OK
   c. Preset ventilator knobs to:
      - Rate (knob 2) 14
      - Inspiration Time (knob 3) 1:2
      - TIDAL VOLUME: 6ml/kg IBW (4-8ml/kg IBW range)

   *QUICK REFERENCE (Male): (Detailed quick reference in Appendix A)*
     - 66” = ~380cc [min: 255 / max: 510]
     - 69” = ~420cc [min: 283 / max: 566]
     - 72” = ~465cc [min: 310 / max: 621]
     - 75” = ~505cc [min: 338 / max: 676]
      - FiO₂ (knob 5) 100%
      - Set HIGH pressure alarm to 35 cmH2O
      - Set LOW pressure to 15 cmH2O
   d. Turn OFF.
   e. Make sure the air inlet and gas out ports of the ventilator are protected and covered.
EMERGENCY PROCEDURES

These procedures should be practiced before being performed on live patients.

NOTE: Any known malfunction of the ventilator should be addressed prior to utilization. The following are not for routine use, but for emergencies when alternate ventilatory measures are not available and long term BVM is not practical.

*ALL CAUTIONS, WARNINGS, AND NOTIFICATIONS THAT CORRESPOND WITH THE 754 SCREEN WILL BE IN ALL CAPS*

Inability to deliver high pressure O2 when needs exceed 21% FiO2 (i.e. missing/unserviceable green high pressure hose).

Vent will alarm and show O2 Low/Fail-Check Oxygen Source/Connections on screen.

NOTE: First place the patient on BVM with supplemental oxygen. Second, check oxygen tank volume. Third, check the oxygen lines and connections.

Alternative methods to increase delivered oxygen content:


2. Oxygen reservoir fashioned from primary circuit and BVM.
   a. Connect short portion of main circuit tube to the BVM and to the air-inlet port.
   b. Connect BVM oxygen hose to the BVM and regulator.
   c. Set regulator to desired setting (~10LPM, but no lower than total minute volume).

3. Oxygen reservoir fashioned from second ventilator patient circuit.
   a. Cut/disconnect exhalation valve off of second ventilator circuit.
   b. Feed green transducer hose at least ¾ of the way down vent tubing (the goal is to get as close as possible to the air inlet port) and secure in place with tape (do not cover the end of the circuit).
   c. Connect the 90 degree/”L” shape fitting of the green transducer line to the oxygen regulator.
   d. Connect the opposite end of the vent tubing to the air inlet port.
   e. Set regulator on oxygen source to 10 LPM to deliver up to 99% FiO2.

Missing or damaged “Gas Out” leaf valve

Missing Gas Out leaf valve will trigger an alarm, give a DISCONNECT-CHECK CIRCUIT CONNECTIONS, no PEAK value will display, and little to no volume will be delivered to the patient.

1. Place the patient on BVM with supplemental oxygen.

2. Perform DOPE (Dislodgment, Obstruction, Pneumothorax, and Equipment) assessment.

3. Check Gas Out clear plastic leaf valve for installation and proper seating.
   - If the valve is folded, use a small object to gently unfold or push the valve back into place.
   - If missing, cover exterior Gas Out side ports with occlusive dressing (replacing Gas Out leaf valve is optimal, but is time consuming.)
**WARNING:** Occluding "Gas Out" side ports will enable the ventilator to provide full respirations, however, this will eliminate the anti-asphyxia function these ports provide. (Ventilator failure will result in increased resistance in spontaneous respiration) and strict surveillance must be kept on ventilator to ensure any further failure is caught immediately. Patients must immediately be transitioned to BVM in the event of any failure.

**Compressor failure/alarms (may show CODE 2).**
1. Place patient on BVM with supplemental O2.
2. Cycle ventilator to OFF.
3. Turn FiO₂ (knob 5) to 100%.
4. Cycle back on and to desired settings. MUST leave FiO₂ at 100%. PEEP will have to be reset when the vent is cycled on.

*NOTE:* This technique will transition the ventilator to using oxygen pressure instead of the compressor to gather drive ventilation and may hasten oxygen usage.

**Battery Failure**
1. Place patient on BVM with supplemental O2.
2. Turn ventilator OFF.
3. Replace ventilator battery with battery from 326M suction apparatus (per the manufacturer, they are the exact same). The 326M battery is in the same location as the 754.
4. Resume normal operations. PEEP will have to be reset.
1. Turn on the ventilator and ensure that the machine is functional and the battery is charged.
2. Attach the ventilator tubing and O2 tubing to the machine.
3. If the patient is a transfer on a vent, maintain ventilator settings from the medical treatment facility.
4. If the patient is “newly” on the ventilator, initial settings should include:
   a. MODE: AC
   b. BPM/RRate: 14BPM (10-30 range)
   c. TIDAL VOLUME: 6ml/kg IBW (4-8ml/kg IBW range)
   QUICK REFERENCE (Male): (Detailed quick reference in Appendix A)
      66” = ~380cc [min: 255 / max: 510]
      69” = ~420cc [min: 283 / max: 566]
      72” = ~465cc [min: 310 / max: 621]
      75” = ~505cc [min: 338 / max: 676]
   d. FiO₂: 21 - 100% (0.21-1.0) (low flow O2 @ 3 LPM = ~ 40% FiO₂ [flowrate on Saros oxygen concentrator])
   e. I:E Ratio: 1:2
   f. PEEP: 5 [Range 5-20]
5. Monitor waveform on the machine and visually inspect the patient to ensure no “breath stacking.” If this occurs, a high-pressure alarm may sound. However, if breath stacking is suspected even in the absence of alarm – disconnect tubing and allow exhalation and decrease the I:E if possible from 1:2 to 1:4.
APPENDIX D: HAMILTON T1

1. **Alarm lamp.** Red = high-priority alarm, yellow = medium- or low-priority alarm.
2. **Touch screen.** Provides access to measurements and controls.
3. **Power/Standyby key.** Turns the ventilator on and off and accesses standby.
4. **Battery charge indicator.** Lit = battery is fully charged. Flashing = battery is charging.
5. **Day/Night key.** Switches between the Day and Night display brightness setting.
6. **Screen lock/unlock key.** Prevents inadvertent change of settings.
7. **Manual breath/inspiratory hold key.** Triggers a mandatory breath when pressed and released during exhalation. Triggers an inspiratory hold when held down during any breath phase. When active, the green indicator is lit.
8. **O2 enrichment key.** Delivers 100% oxygen for 2 min. Press the key a second time to cancel. Press O2 key and disconnect patient to start a suctioning maneuver.
9. **Print screen key.** Save a JPG file of the current ventilator screen to a USB memory drive.
10. **Nebulizer on/off key.** Activates pneumatic nebulizer for 30 minutes or until pressed again during the inspiration phase if high-pressure oxygen (HPO) is connected.
11. **Alarm silence key.** Silences the main ventilator audible alarm for 2 min. Press the key a second time to cancel the alarm silence.
12. **Press-and-turn (P&T) knob.** Use to select and adjust ventilator settings.
13. **Front cover and battery.** The backup batteries are located inside the front cover.
14. **Underside of ventilator.** Expiratory valve bleed port. Do not obstruct.
1. Set up the ventilator.
   a. Install expiratory valve.
   b. Connect coaxial breathing circuit

2. Perform pre-operational checks.
   a. Click PreOp Checks on main page.
   b. Conduct Tightness Test.
   c. Conduct Flow Sensor Test.

   **Do not attach a patient to the ventilator without conducting both tests.**

3. Select modes
   a. Input patient Gender and Height (this calculates all alarm values and “normal” ranges. 
      *Do not bypass this step*)
   b. Touch Modes to change ventilator mode.
   c. Select ASV.

4. Select settings
   a. Set Tidal Volume (4-8 ml/kg IBW) or Pressure Support (not to exceed 30 mmHg).
**NOTE:** This ventilator is “PEEP Compensated” which means when in Pressure Support mode if your Pressure Support is 20 and your PEEP is 10, your settings are actually 30 over 10. If you want 20 over 10, you need to see the Pressure Support at 10 and the PEEP at 10.

**This can get confusing, seek direction from medical control if necessary.**

b. Set appropriate rate for age group.

c. Set FiO2 (21 to 100%).

d. Set PEEP (5 to 20).

e. Adjust I:E Ratio as necessary.

5. Set Flow Trigger (0.5 to 5). Press the start ventilation button prior to connecting patient.

6. **Once the patient is on the ventilator, you may have to adjust alarm parameters**
APPENDIX E: SAVE II

NOTE: The SAVe II is designed for use in place of a Bag Valve Mask (BVM) in the pre-hospital environment. The intended use is to provide ventilator support or Positive Pressure Ventilation (PPV) to adults weighing >45kg (99lbs.).

1. Power on. The device will run through a self-test (all lights will illuminate, and will alarm for a moment).
2. Connect tubing: Tubing will only attach one way. Ensure any patient circuit is being attached on the light grey side of ports, as pictured above. Ensure all connections of the circuit are tight; loose connections may cause low pressure or disconnect alarm.
3. Select height and confirm (failure to select confirm will not change and or set appropriate settings). Any time a change is made, the CONFIRM button must be pressed. The device will default to a PEEP of 0; ensure adjustments are made IAW CPG or protocol.
4. Attach to airway device.
5. Confirm ventilations.
6. Adjust PEEP if needed by setting PEEP and hitting confirm.

NOTE: This device is intended for short term or transport use and is not intended to replace other ventilators available. Consider transitioning the patient to another ventilator (731, 754, or Hamilton T1) as soon as feasible.
APPENDIX F: INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of Department of Defense (DoD) policy and practice regarding inclusion in CPGs of “off-label” uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. “off-label”) uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing “investigational new drugs.” These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion of off-label uses in CPGs is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the “standard of care.” Rather, the inclusion of off-label uses in CPGs is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, the DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.