OVERVIEW

Only properly trained and approved Escambia County Bureau of Public Safety Paramedics are to use the AutoVent 4000 ventilator manufactured by LSP to transport patients already on mechanical ventilators from one facility to another.

The Autovent 4000 is a pneumatically powered portable ventilator and CPAP generator. The Autovent 4000 in Ventilation mode, delivers a time cycled constant flow breath. The inspiratory time is constant and the breath volume is varied by changing the flow rate into the patient. Various breaths per minute are achieved by varying the expiratory time.

The AutoVent CPAP models have all the functionality of the Autovent 4000 plus the added function of CPAP. The CPAP function delivers Continuous Positive Airway Pressure to the spontaneously breathing patient and is used in place of, and not in conjunction with, forced ventilation.

The Autovent 4000 CPAP is intended to be used as a gas powered emergency ventilator which, in ventilation mode, is designed to provide emergency respiratory support by means of a face mask or tube inserted into the patient's airway.

GENERAL GUIDELINES

DO NOT USE WITH THE AUTOPULSE

Assure stable airway and adequate ventilation on the current transferring facility ventilator with either the referring physician, respiratory therapist and/or nurse.

Review the ventilator settings available on the AutoVent 4000 with either the referring physician, respiratory therapist and/or nurse.

With assistance of either the referring facility physician, respiratory therapist and/or nurse, transfer patient to AutoVent 4000 ventilator. Ventilator settings for the AutoVent 4000 should be set by the crew with the assistance of the physician, respiratory therapist and/or nurse.
Patient should be monitored by the paramedic, plus either a physician, respiratory therapist and/or nurse for a minimum of 5-10 minutes to assure compliance to AutoVent 4000. Referring facility physician, respiratory therapist and/or nurse will verify ventilator settings prior to transport.

While in-transit, Paramedic reassess ventilator settings and patient respiratory compliance every 5 minutes.

If during transport an equipment malfunction occurs, and/or the ventilator is not maintaining adequate respiratory compliance, the ventilator will be disconnected from the patient and the Paramedic will Bag (using a bag valve mask-BVM) the patient.

If patient begins to excessively “buck” the ventilator switch to the Manual Breath Button. If ventilations still insufficient either switch to manual ventilation (BVM) or call Medical Control for a sedation order.

Upon arrival of the patient at the receiving facility the receiving physician, respiratory therapist and/or nurse will verify ventilator settings and assist with transfer of patient from AutoVent 4000 ventilator to the facility ventilator.

Operation: (Ventilation)

Warning: Use only as directed. Improper usage or unauthorized modification of this product may result in user or patient injury.

Set the Ventilation Mode switch to "Auto Ventilation" mode.

In the ventilation mode, the three breath control knobs are active and the patient will receive a ventilation cycle based on the setting of the three controls (BPM, Inspiratory Time, Tidal Volume). In addition, the Manual Breath Control is also active.

Connecting to an Oxygen Source:

Located on the left side of the Autovent and marked with an arrow is a diameter index safety system (DISS) fitting. Connect a 50 psi oxygen source with a minimum of 40 LPM flow capacity to this fitting.
Warning: Proper tidal volumes may not be provided with a gas source not meeting the specified requirements below.

Warning: This device operates with medical gases under pressure, including oxygen. Do not use this device while smoking or near open flames. Do not use on this device or operate near flammable materials.

Caution: In order to provide optimal performance, check all gas supplies to assure only clean, dry gas is used, free of contaminants and/or liquids.

The gas source may also be a high flow air/oxygen blender meeting the flow and pressure requirements. Use only the 100% oxygen setting on the Autovent, if using an external blender.

Connecting the patient breathing circuit:

Caution: Due to the dual functionality of the Autovent 4000 CPAP, use only the recommended breathing circuit. The correct ventilator breathing circuit must be used. Using the incorrect breathing circuit may result in the unit not functioning properly.

Located on the right side of the unit is a 22mm connection for a patient breathing circuit and a connection for the patient airway pressure line. Install the corrugated tubing over the 22mm connector so that it is on securely. Install the small airway pressure line over the connecting fitting. Both tubing will not pull off easily when properly installed.

4. Select the proper inspiratory time:

The Autovent™ 4000 CPAP has the options of a 2 second inspiratory time (this is used on adults with tidal volume requirements of more than 600ml) and a 1 second inspiratory time (this is used on children or adults). Turn the Inspiratory time knob to the desired selection. This function operates in the Auto Ventilation mode only.

5. Select the desired Breaths per Minute BPM:

The Autovent™ 4000 CPAP has a BPM range of 8 to 15 with a 2 second inspiratory time
and a BPM range of 8 to 30 with a 1 second inspiratory time.

The American Heart Association Guidelines 2005 recommend a BPM rate of 8 to 12 for an adult and 12 to 20 for a child.

These are recommendations and you should always follow your physicians or medical directors' instructions.

This function operates in the Auto Ventilation mode only.

6. Select the desired Tidal Volume:

The Auto Vent 4000 provides a Tidal Volume range of 200 - 600ml at an inspiratory time of 1.0 sec. and 400 - 1200ml at an inspiratory time of 2.0 sec.

The American Heart Association Guidelines 2005 suggest a tidal volume of 8 - 10 ml/kg will maintain normal oxygenation and elimination of CO2.

7. Verify the Pressure Relief Setting:

This unit has a pressure relief range of 20 to 80 cm H2O. The 60 cmH2O setting is a maximum regardless of vent settings. The pressure relief setting will vary slightly with tidal volume setting. Always verify the pressure relief pressure after the vent settings have been selected. To check the actual relief pressure, block the end of the ventilator breathing circuit and observe the reading on the airway pressure gauge. This will be the maximum airway pressure. You should hear an audible alarm as this maximum pressure is reached.

**Warning:** Preset tidal volumes may not be delivered when the maximum pressure limit is reached. Inspiratory times will remain constant, however no additional tidal volume will be delivered after the pressure limit is reached.

8. Connect the patient breathing circuit to the Patient:

The patient breathing circuit has been design to fit with an oxygen mask (22mm outside diameter) or endotracheal tube (15mm inside diameter). Follow the established guidelines for maintaining the patient's airway.
9. Verify the patient is receiving good ventilation:

Once the patient is connected to the ventilator the patient should be observed to make sure they have adequate chest rise and fall. The chest rise should be even and should return to a normal position. If the patient does not have adequate chest rise check the tidal volume setting, patient connections and examine the patient for a possible obstruction of the airway or other injury. The patient should be monitored to make sure they are receiving proper ventilation.

The airway pressure gauge should be observed to make sure the patient is receiving adequate positive pressure ventilation. If the gauge reading is low during the delivery of a breath and the chest rise is also low, check the tidal volume setting, patient connections and examine the patient for a possible obstruction of the airway or other injury. The gauge reading should also be observed to make sure it is not too high. Common numbers used in practice are a maximum of 20 cm H2O for an unprotected airway and 30 cm H2O for a protected airway. Higher pressures may be required based on the patient's condition and you should always follow the physician's instructions. A high reading with pressure limit alarm may indicate a blocked airway or a stiff lung.

10. Spontaneous Breathing by the Patient:

Should the patient begin to breathe spontaneously the Autovent 4000CPAP will sense this breath and deliver the set tidal volume at the set inspirator/rate. The breath timing will be reset based on the selected BPM rate. For example, if 10-BPM was selected the next breath will be delivered 6 seconds after the start of the spontaneous breath. This function operates in the Auto Ventilation mode only. The gas flow rate to the patient during a spontaneous breath is based on the tidal volume selection as shown in the following table. Should the patient demand exceed the gas flow rate, the addition demand will be supplied by ambient air. Ambient air is pulled in through an anti-suffocation valve located in the breathing circuit connection fitting.
Warning: Should a mechanical problem develop or the patient appears to be experiencing difficulty breathing while connected to the unit, disconnect the unit immediately and ventilate by other means.

Warning: Units that have been stored at temperatures below 32°F (0°C) may have a 20% shift in settings when they are operated at these low temperatures. The readings will return to normal when the unit warms up. Always monitor patients when the unit is used under these conditions.

11. Manual Breaths:

Manual breaths may be delivered using the manual breath button. Each time this button is pushed the ventilator will deliver one breath with the selected inspiratory time and tidal volume. This button can be used to deliver breaths during CPR. If this button is pushed during automatic ventilation, the ventilator will deliver the breath and then continue to deliver automatic breaths based on BPM rate selected.

For example if you were delivering 10 BPM with a 2 second inspiratory time the manual breath button would trigger a breath to be delivered when pushed. This breath would have a 2 second inspiratory time, followed by a 4 second expiratory time. Automatic ventilation would then continue based on the 10 BPM setting.

This button should be pushed and released as soon as the desired breath starts. If the button is held down longer than the inspiratory time the tidal volume will be based on the time the button is held down and will exceed the set value. The pressure relief may trigger if this happens.
Caution:  Holding the manual breath button down for more than 1 second may trigger multiple breaths or increase the delivered tidal volume.

This function operates in the Auto Ventilation mode only.

OPERATION: (CPAP)

Warning:  This device should only be operated by qualified personnel under approved medical direction.

Warning:  Use only as directed. Improper usage or unauthorized modification of this product may result in user or patient injury.

Warning:  The CPAP function delivers Continuous Positive Airway Pressure to the spontaneously breathing patient and is used in place of, and not in conjunction with, forced ventilation.

Switch the Ventilation Mode switch to the "CPAP" mode:

When the Operation Mode switch is set to the CPAP mode, the three breath setting controls , (BPM, Inspiratory Time, Tidal Volume), as well as the Manual Breath and Oxygen Concentration switch are no longer active. Changing these controls will have no effect on the CPAP operation.

2. Connecting to an Oxygen Source:

Located on the left side of the Autovent and marked with an arrow is a diameter index safety system (DISS) fitting. Connect a 50 psi oxygen source with a minimum > of 40 LPM flow capacity to this fitting.

Warning:  This device operates with medical gases under pressure, including oxygen.

Do not use this device while smoking or near open flames.

Do not use on this device or operate near flammable materials.
Caution: In order to provide optimal performance, check all gas supplies to assure only clean, dry gas is used, free of contaminants and/or liquids.

The gas source may also be a high flow air/oxygen blender meeting the flow and pressure requirements. The onboard AutoVent 4000 CPAP blender is inactive when the unit is in the CPAP mode. Changing the oxygen concentration of the onboard blender will have no effect of the oxygen concentration being delivered to the patient during CPAP function.

3. Connecting the patient breathing circuit:

   Caution: Due to the dual functionality of the Autovent 4000 CPAP, use only the recommended breathing circuit.

   The correct ventilator breathing circuit must be used.

   Using the incorrect breathing circuit may result in the unit not functioning properly.

   Located on the right side of the unit is a 22mm connection for a patient breathing circuit and a connection for the patient airway pressure line. Install the corrugated tubing over the 22mm connector so that it on securely. Install the small airway pressure line over the connecting fitting. Both tubing will not pull off easily when properly installed.

4. Airway Pressure Relief Control:

   This unit has a used adjustable main airway pressure relief range of 20 to 80 cm H2O. During CPAP only, the unit also has an active internal 20 cmH2O CPAP pressure relief that will not allow the set CPAP pressure to exceed 20 cmH2O. Due to the high gas flow rates of CPAP, the main airway pressure relief should be set higher than potential CPAP pressures (60 cmH2O).

   Preset the CPAP function prior to patient connection:

   After the patient breathing circuit has been connected to the unit, turn the CPAP control full counter clockwise (lowest setting).
Turn on the inlet supply gas.

Adjust the CPAP control to achieve minimum gas flow.

6. Connect the patient breathing circuit to the Patient:

Once the mask has been fitted to the patient, observe the patient and adjust the CPAP pressure to the desired CPAP pressure. The patient breathing circuit has been design to fit with an oxygen mask (22mm outside diameter) or endotracheal tube (15mm inside diameter). Follow the established guidelines for maintaining the patient's airway.

7. Verify the patient is receiving good ventilation:

Once the patient is connected to the ventilator, the patient should be observed to make sure they have adequate breathing.

**Warning:** The CPAP function delivers Continuous Positive Airway Pressure to the spontaneously breathing patient and is used in place of, and not in conjunction with, forced ventilation.

The airway pressure gauge should be observed to make sure the patient is receiving proper CPAP pressure. Always follow the physician's instructions. A high reading with pressure limit alarm may indicate a blocked airway.

**Warning:** Should a mechanical problem develop or the patient appears to be experiencing difficulty breathing while connected to the unit, disconnect the unit immediately and ventilate by other means.

**Warning:** Units that have been stored at temperatures below 32°F (0°C) may have a 20% shift in settings when they are operated at these low temperatures. The readings will return to normal when the unit warms up. Always monitor patients when the unit is used under these conditions.

8. Pneumatic Alarms:

This ventilator contains several pneumatically operated alarms. These alarms are the pressure relief and low source gas alarms.
The pressure relief alarm is an audible alarm that is actuated when the safety pressure relief setting is reached. This alarm indicates that the maximum pressure setting has been exceeded and that gas has been released to prevent the pressure from reaching levels above this setting.

**Warning:** Preset tidal volumes may not be delivered when the maximum pressure limit is reached. Inspiratory times will remain constant, however no additional tidal volume will be delivered after the pressure limit is reached.

Low source gas alarm is an audible and visual alarm that activates when the source gas pressure drops below 40 to 35 psi. This is an indication that the unit will stop functioning soon and that the unit may not be delivering proper tidal volumes. This alarm will first sound only during breath delivery as a first indication and then sound continuously as the source gas pressure drops.

**Warning:** Preset tidal volumes may not be delivered when the low source gas pressure is reached.

9. Cleaning:

The Autovent 4000CPAP should be cleaned after each use. To clean the Autovent 4000CPAP keep the gas supply hose on the unit to prevent contamination of the oxygen circuit.

**Warning:** Cleaning procedures should be performed in an environment free of oil and petroleum based products.

The Autovent 4000CPAP has been designed to be water resistant but the unit cannot be submerged or sprayed down for cleaning.

Wipe the unit down with a damp rag containing a mild detergent to remove any residue from the surface. Once the residue has been removed the unit should be wiped with isopropyl alcohol or a cold disinfecting solution to kill bacteria. The unit should then be wiped down with water to remove any film left by the cold disinfecting solution. Make sure the unit is dry before putting the unit away.
10. **Maintenance:**

    The Autovent 4000 CPAP contains a dust filter located on the left side of the unit. This filter cleans the ambient air used in the function of the blender. To replace the filter, remove 2 screws from the back cover. Once the cover is removed the filter can be removed and replaced. While the cover is off the audible alarm should be inspected to make sure it is not dirty. If necessary remove the dirt with a vacuum or damp cloth.

    The Autovent 4000 CPAP should be checked for calibration annually.

13. **Oxygen Cylinder Depletion Times:**

    These times are approximate and assume full cylinder capacity and .5 liters per minute usage for the pneumatic module. Always monitor the cylinder pressure and low pressure alarm to make sure you do not run out of oxygen.

    \[
    \begin{array}{|c|c|c|c|c|c|c|c|c|c|c|}
    \hline
    \text{Tidal Volume} & 8 & 9 & 10 & 12 & 14 & 15 & 18 & 20 & 22 & 24 & 26 & 28 & 30 \\
    \hline
    1200 & 41 & 37 & 33 & 28 & 24 & 22 & & & & & & & \\
    1000 & 49 & 44 & 39 & 33 & 29 & 27 & & & & & & & \\
    800 & 60 & 54 & 49 & 41 & 35 & 33 & & & & & & & \\
    600 & 77 & 70 & 63 & 54 & 46 & 44 & 37 & 33 & 30 & 28 & 26 & 24 & 22 \\
    500 & 91 & 82 & 75 & 63 & 55 & 52 & 44 & 39 & 36 & 33 & 31 & 29 & 27 \\
    400 & 109 & 99 & 91 & 77 & 67 & 63 & 54 & 49 & 44 & 41 & 38 & 35 & 33 \\
    300 & 137 & 125 & 115 & 99 & 87 & 82 & 70 & 63 & 58 & 54 & 50 & 46 & 44 \\
    200 & 178 & 166 & 155 & 137 & 122 & 115 & 99 & 91 & 84 & 77 & 72 & 67 & 63 \\
    \hline
    \end{array}
    \]

    \[D \text{ Cylinder } \quad \text{Capacity} = \quad 414.6\]

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Approved by:

[Signature]

Charles Neal, D.O. Medical Director
14. **Explanation of Abbreviations:**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>TV</td>
<td>Tidal Volume</td>
</tr>
<tr>
<td>BPM</td>
<td>Breaths per Minute</td>
</tr>
<tr>
<td>It</td>
<td>Inspiratory Time</td>
</tr>
<tr>
<td>Psi</td>
<td>Pounds per Square Inch</td>
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<tr>
<td>CPAP</td>
<td>Continuous Positive Airway Pressure</td>
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<td>LPM</td>
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<td>Millimeters</td>
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<tr>
<td>LED</td>
<td>Light emitting diode</td>
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<tr>
<td>CPR</td>
<td>Cardio Pulmonary Resuscitation</td>
</tr>
<tr>
<td>LPA</td>
<td>Low pressure alarm</td>
</tr>
<tr>
<td>HPA</td>
<td>High pressure alarm</td>
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</tbody>
</table>

15. **Specifications:**

**Gas Supply Pressure:** 280 kPa (40.6 psi) to 600 kPa (87.0 psi) Oxygen DISS.

**Breaths per Minute (BPM):** Accuracy: ±10%
- BPM Range: 1 sec Inspirator/Time = 8 to 30
- BPM Range: 2 sec Inspiratory Time = 8 to 20

**Tidal Volume (Tv):** Accuracy: ±10% with 100% Oxygen
- Tidal Volume Range 1 Second Inspiratory Time = 200ml to 600ml
- Tidal Volume Range 2 Second Inspiratory Time = 400ml to 1200ml

**Inspiratory Time (Iₜ):** Accuracy: ±10% 1 second or 2 second selection

**Safety Pressure Relief:** Adjustable from 20 to 80 cmH₂O ±10%. The 60cm H₂O mark is a maximum regardless of setting.

**Low Source Gas Alarm:** Activates at 275 to 262kPa (40 to 38 psi) source pressure.
Oxygen Inlet Filter: 65 Micron sintered bronze.

Burst Pressure: 250 psig (1724kPa) minimum.

Leakage: The unit shall be designed so that oxygen is not allowed to leak through any seals or fittings.

Gauge: 0-100 cm H2O (0 - 9.8 kPa) accuracy ±(2% of the full scale reading +8% of the actual reading)

Inspiratory and Expiratory Resistance: 5 cm H2O (.5kPa) maximum Inadvertent PEEP: < 2 cm H2O

Inadvertent Continuing Expiratory Pressure: < 2 cm H2O

Dead Space: 14.8ml

Peak inspiratory Flow: 100 LPM for 2 seconds

Pressure for Initiation of Breath: -2 cm H2O maximum

Oxygen Blending: 65% ±12% oxygen with bender.

CPAP Range: 4 to 20 cm H2O

CPAP Airway Pressure Control: The airway CPAP pressure is controlled to within +/- 2 cmH2O for all treatment CPAP pressures with inhalation / exhalation flows up to 70 lpm. The airway CPAP pressure is controlled to within +/- 3 cmH2O for all treatment CPAP pressures with inhalation / exhalation flows between 70 and 100 lpm.

Operating Conditions: -18 to 50°C (0 to 122°F)
Storage Conditions: -40 to 60°C (-40 to 140°F)

Latex Free: This product does not contain latex.