# MAXO$_2$Vent
# Operators Manual


**CAUTION**
**Federal Law Restricts this device to be used by or on the order of a physician.**

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maxtec

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**GENERAL DESCRIPTION**

The Maxtec Ventilator is pneumatically powered, single-circuit, volume-constant, time-cycled and inspiratory flow variable.

The Maxtec Ventilator utilizes a high-pressure drive with regulated, high internal resistance to control pressure and is considered a non-constant pressure generator. Simultaneously, the Maxtec Ventilator produces a flow pattern that is constant in spite of changes in lung mechanics (inspiratory square-wave).

Originally designed, tested and utilized for military field work, the Maxtec Ventilator is able to be used in virtually any demanding environment such as In-Hospital Transport, Air-Mobile Operations, Special Treatment Areas, Operating and Recovery Rooms, Animal Laboratories and Veterinary Medicine.

The Maxtec Ventilator is designed with internal simplicity for operations and maintenance. Quick connect features allow the operator to provide for all necessary clinical situations: controlled ventilation, continuous-flow intermittent mandatory ventilation, constant positive airway pressure, as well as being adjustable to inspiratory/expiratory ratios that are infinitely variable. A wide-range pressure relief valve allows for both the prevention of barotrauma and time-cycled, pressure-relieved ventilation.

In standard use, the Maxtec Ventilator may be used in conjunction with a variety of face masks, cricothyroid tubes, endotracheal and tracheostomy tubes.

Humidifiers and air/oxygen blenders of various types may be used, as the operator desires.

**FACTORY QUALITY ASSURANCE TESTING**

Every Maxtec Ventilator is tested several times during the manufacturing process. Final testing and calibration procedures utilize the Bio-Tek Lung Analyzer, model VT-2. A copy of the final test is sent with each ventilator as it is shipped from the Factory.

**DEFINITION OF STATEMENTS**

The following terminology and definitions are important for the operator to understand before proceeding with the manual or operation of the device:

**WARNINGS:** mean there is a possibility of injury to the operator or others.

**CAUTIONS:** mean there is a possibility of damage to the equipment.

**NOTES:** mean particular points of interest for professional operation of the equipment

**GENERAL WARNINGS**

1. Patients requiring life-support equipment should be under the constant surveillance of competent medical practitioners. There is always the possibility of machine and alarm failure and some malfunctions require immediate corrective, action.

2. The Maxtec Ventilator should always have the **Pressure Relief Valve** adjusted in order that barotrauma cannot occur.

3. The **Maxtec, Inc. Patient Tubing Circuit and Exhalation Valve Assembly (P/N Oceanic-15.0)** is the only tubing/valve system authorized for use with the Maxtec Series ventilators. Other systems may not work properly.

**SPECIFICATIONS**

| | |
|---|---|
| Dimensions | 8 x 5.5 x 5.5 inches |
| Weight | 5.0 LBS |
| Case Material | aluminum |
| All other Materials | aluminum, brass and plastic |
| Gas Inlet Pressure Range | 30 to 150 PSI |
| Breaths Per Minute Range | 0 to 60 BPM |
| Inspiratory Time Range | 0.2 to 3.0 seconds |
| Inspiratory Flow Range | 0 to 100 LPM |
| Tidal Volume Range | 0 - 2.0 L's |
| Pressure Relief Range | 0 to 120 $CmH_2O$ |
| IMV/CPAP Continuous Flow Range | 0 to 60 LPM |
| PEEP/CPAP Range | +1 to +50 $CmH_2O$ |
| Internal Compliance | 0 $CmH_2O$ |
| Air/Oxygen Blenders | any capable of producing from 30 to 60 PSI |
| Exhalation Valves | Oceanic-P/N 15.0 reusable |
| MRI Capable | to 4.7 Tesla |

**FUNCTIONAL AND OPERATIONAL PROCEDURES**

The following procedures should be performed between the time the Maxtec Ventilator is assembled and before it is placed into clinical service to ensure proper assembly.

**Assembly of Components**
Attach the Patient Tubing Circuit and desired accessories to the ventilator, as shown in the photograph below.


**A.** Exhalation tubing attach point
**B.** Pressure gauge tubing attach point
**C.** IMV/CPAP tubing attach point

**A. Inlet Gas Pressure Hose**
Attach a high pressure hose to the Gas Inlet connector, which is located at the right-rear position of the box container. Screw on the hose connector securely, with the opposite end of the hose attached to the gas source. Ensure that the gas source is ready to be used when the on/off switch is turned on.

**B. Breath Per Minute and Expiratory Control Knob**
Turn the pointer of the inner knob to the 10 BPM position as indicated on the label (or higher/lower position as desired). Confirmation of the actual time may be made with a suitable watch or monitoring system.

**C. Inspiratory Time Control Knob**
Turn the pointer of the inner knob to the 1.0-second position on the label (or higher/lower position as desired). Confirmation of the actual inspiratory time may be made with a suitable watch or monitor.

**D. Tidal Volume Control Knob**
Turn the pointer to the 1.0 L position on the label. Confirmation of the Tidal Volume may be made with a
hand-held spirometer or other volume montior.

**NOTE:** Tidal Volume markings are accurate when the inspiratory time is set at 1.0 seconds.

**E. Pressure Relief Valve**
The pressure relief valve may now be adjusted to relieve any undesired, excess pressure that may be generated due to the other control settings. Observe the working pressure (assuming that the tubing circuit is attached to a test lung) and turn the pressure relief Control Knob until the desired maximum pressure is reached. It may be necessary to completely occlude the outlet port of the tubing circuit in order to generate the pressure level that the operator desires to use as the maximum value.

**NOTE:** It is recommended that as the ventilator is placed in use with an actual patient, the maximum relief pressure be re-adjusted to approximately +5cmH20 above the actual working pressure.

**NOTE:** Re-confirm the delivered Tidal Volume whenever a pressure relief value has been changed. If the relief pressure is set too low, the desired Tidal Volume may not be achieved.

**F. On/Off Switch**
The on/off switch may be turned from either the “on” or “off” position by turning the control knob 90 degrees in either direction. The pointer on the knob will indicate that the knob is positioned to allow gas flow to begin to the internal, working components of the machine.

**G. Intermittent Mandatory Ventilation (IMV)**
Gas flow may be employed by turning the IMV control knob anti-clockwise and observing the gas reservoir bag. As the bag is inflated and with the patient inhaling spontaneously ftom the bag between mechanical breaths (or without any mechanical breaths as during CPAP) the Operator should adjust the gas flow to the reservoir bag in order that the bag is not deflated during the patients inspiratory efforts. IMV gas flow may also be utilized during the administration of PEEP in order to keep the PEEP level at a precise value.

**CAUTION:** High IMV gas flows may cause the ventilator to diminish in total gas flow functions for Controlled Ventilation procedures and the Control Knobs may have to be re-adjusted to compensate during the IMV procedure.

**NOTE:** Source gas consumption using the IMV system (for IMV or CPAP) is increased over gas utilization during controlled Ventilation. Measure the continuous flow with a hand held spirometer and add this value to any controlled minute volume for accurate calculation of total gas consumption.

**NOTE:** The On/Off Switch must be in the "ON" position for the IMV continuous gas flow bleed valve to operate.

**CLINICAL TECHNIQUES**

The following techniques may be utilized with the proper setting of the Maxtec Ventilator controls:

**Controlled Ventilation (CV)**

For the apneic patient, CV is accomplished by using the Maxtec Ventilator with the Patient Tubing Circuit only. Adjustment of the Breath Per Minute, Inspiratory Times as well as the Tidal Volume Controls and Pressure Relief Valve will provide the minute volume and other parameters as the Operator deems necessary. PEEP valves and other accessories can be employed as needed.

**Intermittent Mandatory Ventilation (IMV)**

For use with the patient that may desire to spontaneously breathe between CV breaths, the IMV kit should be attached to the outlet port of the ventilator. Using the continuous flow method, adjust the IMV gas flow to the reservoir bag using the IMV control knob on the front panel. Adjust the Breaths Per Minute, Inspiratory Time, Tidal Volume and Pressure Relief Valve settings to those desired by using a suitable timepiece, a hand-held spirometer or other monitoring system.

**Pressure Controlled Ventilation**

When the Operator desires to provide an inspiratory pressure plateau to occur during the inspiratory phase and to control the inspiratory time simultaneously, this system can provide the needed support. Establish either CV or IMV parameters; observe the working pressure on the pressure gauge, then set the Pressure Relief Valve setting to a pressure slightly less than the original working pressure. Tidal Volume delivery can be manipulated by adjusting the Tidal Volume Control until the desired Volume is approximated.

**NOTE:** It is possible to not be able to deliver a high level of Tidal Volume, depending on the settings of all of the controls.

**Pressure Control-Inverse Ratio Ventilation (PC-E:I)**

Inverse ratio ventilation can be established by using the Breaths Per Minute and Inspiratory Time Controls and observing the pressure gauge and using a watch and hand-held spirometer, until the desired parameters are met. Then adjust the Pressure Relief Valve setting to the

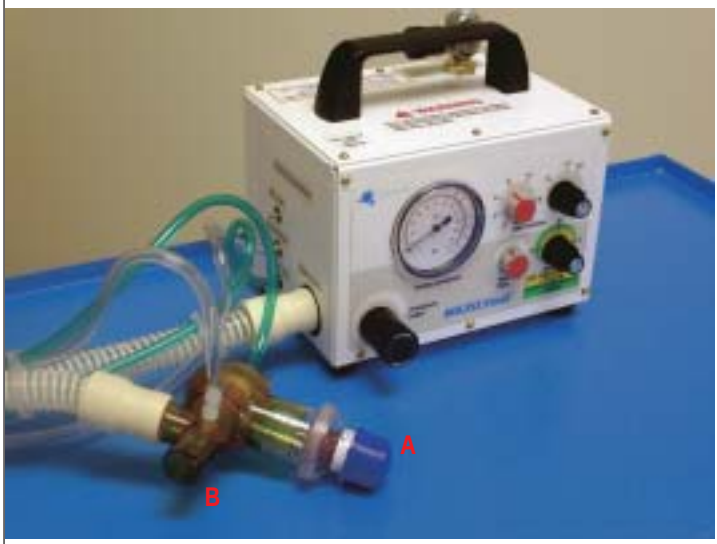
value below the working pressure observed on the Monitor to that pressure limit desired. Manipulation of the other controls will allow the Operator to adjust the ventilator to the level of support desired.

**NOTE:** The IMV system may also be employed with this maneuver in order to provide the greatest amount of instantaneous gas volume during the initial phases of the Inspiratory Time.

**Positive End Expiratory Pressure (PEEP)**
PEEP may be employed at any time the Operator desires by attaching a PEEP valve to the outlet port of the Patient Tubing Circuit and adjusting the end-expiratory pressure to that value desired by observing the pressure gauge.

**NOTE:** As PEEP pressure is increased, the inspiratory Pressure will also increase, therefore, it may be necessary to re-adjust the Pressure Relief Valve setting to compensate for this increased pressure.

"A" is the PEEP Valve. "B" is the Exhalation Valve.




**Continuous Positive Airway Pressure (CPAP)**
CPAP is provided by attaching the same accessories as in PEEP and IMV, then:

1. Turn the On/Off Switch to the "on" position.
2. Turn the Breaths Per Minute Control Knob to the longest time position (fully clock-wise).
3. Turn the Inspiratory Time and Tidal Volume to the lowest position (fully anti-clock-wise).

4. Adjust the IMV Flow Control to a position wherein the IMV reservoir bag is fully inflated.
5. Adjust the PEEP valve until the desired CPAP value is achieved.
6. Adjust the Pressure Relief Valve to a setting slightly above the CPAP level to prevent inadvertent barotraurna.

**NOTE:** It may be necessary to "fine-tune" the adjustments of various controls until the desired parameters are achieved.

**NOTE:** The regular Patient Tubing Circuit and other accessories may be used as desired.

**GENERAL ACCESSORY SYSTEMS**

**Humidifiers**

Heated Molecular Humidifiers of any type may be used with the Maxtec Ventilators. Follow the manufacturers recommendations for tubing attachment and use.

"Artificial Nose" humidifiers of any type may also be used by placing the device at the distal end of the Patient Tubing Circuit, between the exhalation valve assembly and the patient interface. Follow manufacturers instructions for use.

**Air/Oxygen Blenders**

All air/oxygen blenders may be used with the Maxtec Ventilators. Follow the manufacturers instructions for use.

**CAUTION:** Some blenders are limited in their gas pressure/volume output, which could affect the performance of the Maxtec Ventilator. Refer to the manufacturers specifications for more information.

**Cylinder Gas**

Cylinder gas sources from size "E" through "H" may be used with the Maxtec Ventilator, by attaching a suitable pressure-reducing regulator to the cylinder and sending the gas through a high pressure hose to the ventilator gas inlet port. The cylinder should be changed when the pressure is 1/4 fullor less.

**Pressure Reducing Regulators**

Pressure reducing regulators of various descriptions may be utilized. Pressure adjustable, dual-stage regulators give the Operator the ability to know the actual outlet pressure during operations.

**WARNINGS:**

1. Regulators with flowgauges or flowmeters cannot be utilized unless there is a 50 PSI gas outlet available that is not otherwise used. Using a regular flowmeter outlet port will cause the ventilator to not function properly or at all.

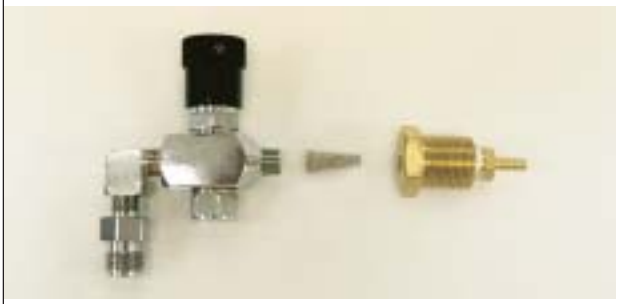
3. Regulators should be maintained according to the manufacturers

recommendations; do not use a regulator that has not been maintained properly as gas outlet pressures may not be adequate to power a ventilator properly.

**FUNCTIONAL TESTING**

Attach the Patient Tubing Circuit, along with any accessories desired, to a mechanical test lung. Adjust the Control Knobs to the settings desired, then turn the On/Off Switch to the "ON" position and observe the results on the test lung, Turn on the Monitor and observe the results, comparing them to those of the mechanical test lung. Minor variations may occur depending on the equipment used. Several Control Knob positions should be used to compare full range of ventilator output.

**NOTE:** If a rubber test lung is used, keep in mind that the compliance and resistance factors in this type of product are not constant, which may result in a variance in delivered parameters.



**RECOMMENDED MAINTENANCE AND PROCEDURES**

**Inlet Filter**

The Inlet Filter should be inspected (and replaced if necessary) at least annually. Refer to the Service Manual for this device for complete inspection/replacement instructions.

**Control Knob Calibration Procedures**

In order to calibrate the Breaths Per Minute, Inspiratory Time and Tidal Volume controls to coincide with Bio Tek Test Lung Displays, the following procedure should be used:

1. Attach the Maxtec Ventilator to the test lung with the patient tubing circuit and any accessories desired.
2. Remove the Breaths Per Minute, Inspiratory Time and Tidal Volume Control Knobs, by using a 1/ 16" Allen wrench to loosen the two Allen screws located on the sides of each knob.
3. Attach a high-pressure hose from a gas source to the gas inlet adapter.

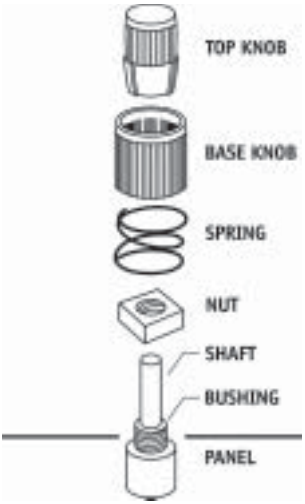
4. Turn the On/Off Switch Control Knob to the “ON” position and allow the ventilator to cycle several times.
5. Activate the test lung and scroll up to the appropriate display window.
6. Adjust the Inspiratory Time Control Knob Shaft until a reading of “1.0 seconds” is displayed.
7. Simultaneously, adjust the Tidal Volume Control Knob Shaft until a reading of “1.0 Liters” is displayed.
8. Adjust the Breaths Per Minute Control Knob Shaft until a reading of 10 BPM is displayed.

While the machine is operating at these settings, carefully re-install the Control Knobs, ensuring that those knobs with pointer-indicators are pointing to the proper reference positions.

**CAUTION:** The BPM and Inspiratory Time Control Knobs are semi-locking and a position stop system is molded into the plastic of both parts of the knob assembly. Care should be taken to re-install these knobs according to the instructions and diagram, following:

**CAUTION:** While calibration procedures are taking place, ensure that the IMV/CPAP Flow Control is in the OFF position.

**Locking-Knob Re-Assembly Instructions:**




1. Ensure that the brass holding nut is secure and cannot move with finger tension.
2. Place the spring over the brass nut.
3. Place the base knob over the spring and brass nut.

**NOTE:** The base knob has a single "rib" that should be placed at the 3 o' clock position when placing the base knob over the brass nut. If this position is not available when installing the base knob over the brass nut, use a wrench to rotate the brass nut, clock-wise, to a position that will allow the base knob to seat properly and position the "rib" at the proper position.

4. Place the Top Knob into the Base Knob opening, with the indicator pointing to the proper indicator on the label (Breaths Per Minute at 10 BPM and Inspiratory Time at 1.0 seconds).

5. Tighten the Top Knob into place with the Allen wrench.
The test lung display should now read the same as the indicated values on the ventilator label.


**Tidal Volume Control Knob**
This Control knob may now be re-installed by placing the knob over the shaft, reading the test lung display which should still indicate "0.8 L", and ensuring that the indicator is pointing to 1.0 L on the label display. Tighten the two Allen screws into place.

The Calibration Procedure is now complete. The unit may now be placed back into service.

**CLEANING AND DISINFECTION**

**Cleaning**
The ventilator may have the entire exterior cleaned with a mild solution of soap and water and thoroughtly dried off.

**Disinfection**
The ventilator may have the entire exterior disinfected using standard cold disinfection materials, rinsed with a wet cloth and thoroughly dried off.

The patient tubing circuit and exhalation valve may be totally immersed in a cold disinfection solution or pasteurized, thoroughly rinsed and dried.

**Sterilization**
The ventilator may be gas sterilized with ethylene oxide and

purged with pure oxygen for 24-hours.

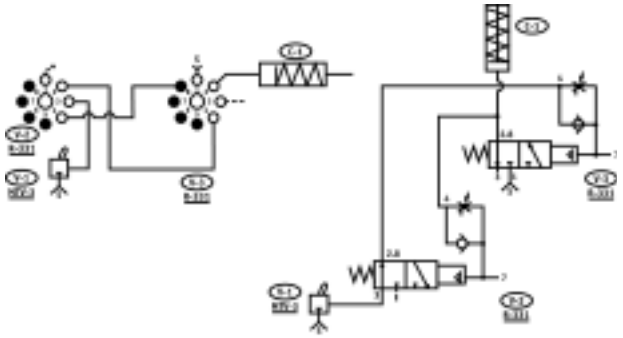
The patient tubing curcuit and exhalation valve may be gas sterilized with ethylene oxide according to the institutions guidelines for plastic materials.

**WARNING:** if the exhalation valve is disassembled, care must be taken to ensure that the spring is re-installed before any clinical use.

**APPLICATION CIRCUIT DIAGRAM**

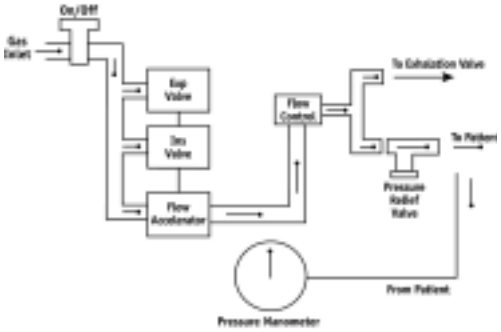
**Automatic Cycler**

Turning the On/Off Switch to the “on” position V-1 sends a signal through V-2 and to the flow control of V-3 where it is delayed before piloting the 3-way (normally open) valve V-3. The output of V-3 goes to the flow control of V-2 where it is delayed before piloting the 3-way (normally closed) valve V-2. When V-2 shifts, it shuts off the original signal from V-1 and exhausts the pressure that has piloted V-3, allowing the spring to sift the valve. This action exhausts the pressure that has piloted V-2, allowing the spring to shift the valve. This allows the signal from V-1 to start the cycle over again. The adjustment on V-3 controls the “on” duration, and the adjustment on V-2 controls the “off” duration at C-, patient tubing circuit outlet port.



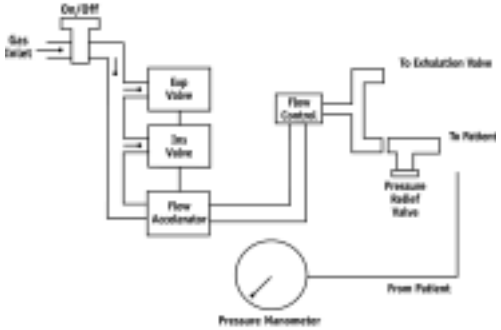
## GAS FLOW DIAGRAMS

### Inspiratory Phase




Source gas is introduced through a filter in the gas inlet assembly, then gas flows to the pneumatic valve supply inlet. The gas flows to the flow control then to the “tee” assembly, which directs gas simultaneously to the exhalation valve, pressure relief valve and to the patient As gas pressure/ volume is transmitted from the patient, it is transmitted to the pressure gauge and displayed.

### Expiratory Phase

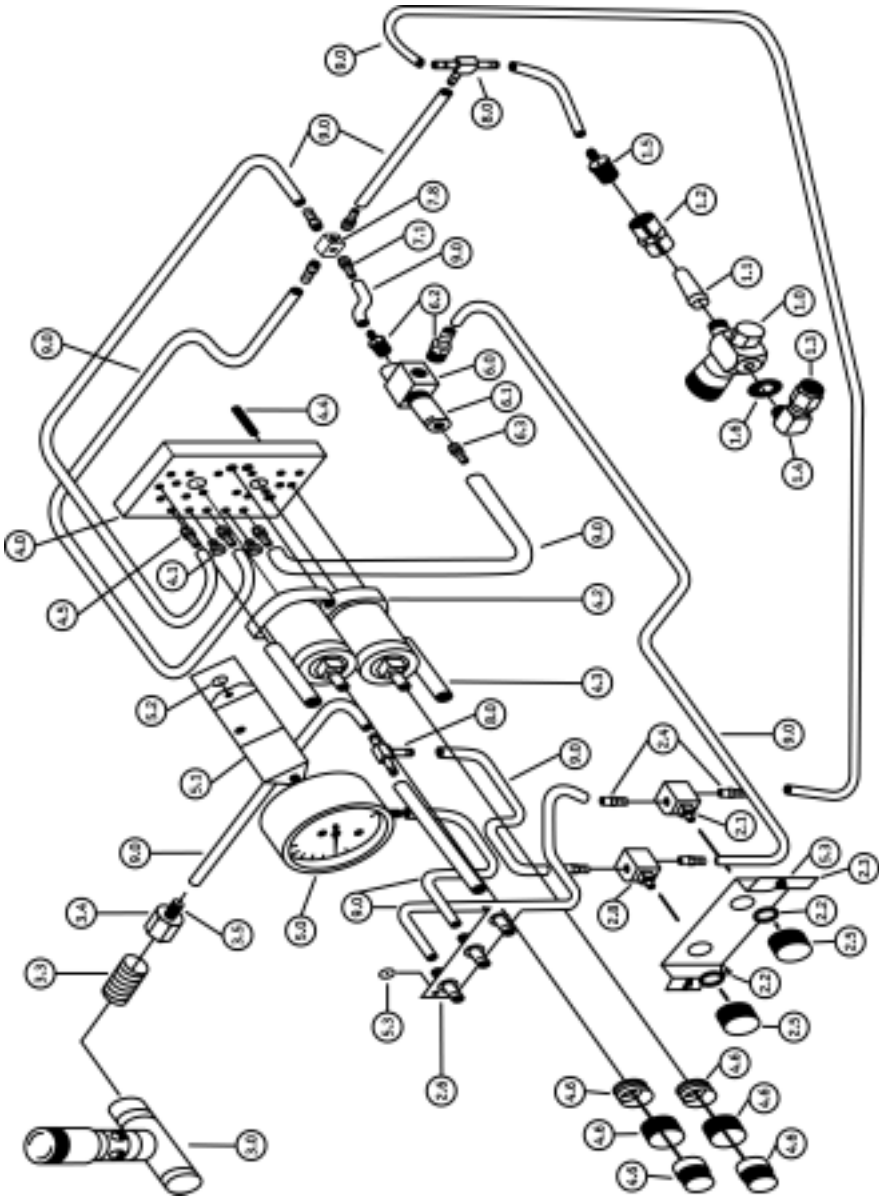



Source gas follows the identical path of the inspiratory phase to the pneumatic valves and is then held until the inspiratory phase begins the cycle.

## PROBLEM SOLVING

| Problem | Solution |
|---|---|
| Failure for Ventilator to cycle | Check on/off switch for proper position<br>Check gas source available<br>Check Expiratory Time Control Position<br>Check inlet filter for foreign debris |
| Tidal Volume too low | Check Pressure Relief Valve Setting<br>Check patient's artificial airway<br>Check for leaks in the system<br>Adjust Control Knob to full open position and re-calibrate if necessary<br>Check inlet pressure at 30 to 50 PSI<br>Check external pressure reducing regulators, if using<br>Check inlet filter for debris |

**Max$O_2$Vent Exploded View**



## Max$0_2$Vent
## PART NUMBERS FOR EXPLODED VIEW DIAGRAM

| Oceanic Part No. | Repeat of Part No. | Description | No. of Parts |
|---|---|---|---|
| 1.0 | | on/off switch | 001 |
| 1.1 | | inlet gas filter | 001 |
| 1.2 | | 1/4 union | 001 |
| 1.3 | | inlet hose connector | 001 |
| 1.4 | | 90 deg x 1/4npt, female | 001 |
| 1.5 | | 1/8 x 1/8 hose barb | 001 |
| 1.6 | | washer | 001 |
| 1.7 | | “d” washer | 001 |
| 2.0 | | insp flow valve | 001 |
| 2.1 | | imv flow valve | 001 |
| 2.2 | | 15/32 brass holding nut | 004 |
| 2.3 | | bracket, valve mounting | 001 |
| 2.4 | | 10/32 x 1/8 hose barb | 004 |
| 2.5 | | knob, control, rubber | 002 |
| 2.6 | | manifold, in/out barbs | 001 |
| 3.0 | | pressure relief valve | 001 |
| 3.1 | | prv holding bracket | 001 |
| 3.2 | | screws, 8/32 x 1 | 002 |
| 3.3 | | straight pipe, threaded | 001 |
| 3.4 | | pipe cap | 001 |
| 3.5 | 2.4 | 10/32 x 1/8 hose barb | 001 |
| 4.0 | | acrylic base plate | 001 |
| 4.1 | | 10/32 brass plugs | 002 |
| 4.2 | | insp/exp timing valves | 002 |
| 4.3 | | standoffs, aluminum | 002 |
| 4.4 | 3.2 | screws, 8/32 x 1 | 002 |
| 4.5 | 2.4 | 10/32 x 1/8 hose barb | 003 |
| 4.6 | | locking knob assembly | 002 |
| 5.0 | | pressure gauge | 001 |
| 5.1 | | press gauge bracket | 001 |
| 5.2 | | 540 x 1/4brass screw | 002 |
| 5.3 | | 10/32 brass nut | 002 |
| 5.4 | 2.4 | 10/32 x 1/8 hose barb | 001 |
| 6.0 | | flow accelerator A | 001 |
| 6.1 | | flow accelerator B | 001 |
| 6.2 | 1.4 | 1/8 x 1/8 hose barb | 002 |
| 6.3 | 2.4 | 10/32 x 1/8 hose barb | 001 |
| 7.0 | | 10/32 4-way body | 001 |
| 7.1 | 2.4 | 10/32 x 1/8 hose barb | 004 |
| 8.0 | | 1/8 3-way tee piece | 002 |
| 9.0 | | urethane tubing, ft. | 010 |

**WARRANTY**

The products of Maxtec, Inc. (OMPI herein) are warranted to be free from defects in materials and workmanship and to meet the published specifications for a period of five (5) years from date of delivery to the original customer.

The liability of OMPI under this warranty is limited to replacing, repairing or issuing credit, at the discretion of OMPI, for the parts that become defective or fail to meet published specifications during the warrant period; OMPI will not be liable under this warranty unless (a) OMPI is promptly notified in writing by Buyer upon discovery of defects or failure to meet specifications; (b) the defective unit or part is returned to OMPI, with transportation charges prepaid by Buyer; (c) the defective unit or part is received by OMPI for adjustment no later than four weeks following the last day of the warranty period; and (d) OMPI examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair or alteration, or accident.

Any authorization by OMPI for repair or alteration by the buyer must be in writing to prevent voiding warranty. In no event shall OMPI be liable to buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder.

OMPI warranties hereinabove set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of, the rendering of technical advice or service by OMPI or its agents in connection with Buyers order of the products furnished hereunder.

**LIMITATIONS OF LIABILITIES**

This warranty does not cover normal maintenance such as cleaning, adjustment or lubrication and updating of equipment or parts. This warranty shall be void and shall not apply if the equipment is used with accessories or parts not manufactured by OMPI or authorized for use in writing by OMPI, or if the equipment is not maintained in accordance with a prescribed schedule of maintenance.

The warranty stated above shall extend for a period of five years from date of delivery, effective November 15, 2000.

The foregoing is in lieu of any other warranty, expressed or implied, including, without limitation, warranty of merchantabibility, except as to title, and can be amended only in writing by a duly authorized representative of OMPI.

**Returned Goods Policy**

All returns must be authorized by OMPI prior to shipping. Returned goods are subject to a 20% restocking fee. Contact OMPI Customer Service with your request for an authorization number.

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