Operator's Manual

Omni-Vent Ventilators with the Tau Monitoring System

OMNI-TECH MEDICAL, INC.
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General Description

The Omni-Vent Series-D/MRI Ventilator with the built-in Tau Ventilator Monitor is a pneumatically powered, single circuit, volume-constant, time cycled and inspiratory flow variable ventilator that also monitors respiratory rate, i:e ratio, inspiratory time, expiratory time, inspiratory pressure, mean airway pressure, negative inspiratory force and is capable of monitoring high pressure, low pressure and failure to cycle modes, all of which employ default parameters that are re-setable to the users desires.

The Omni-Vent utilizes a high pressure drive with a high internal resistance to control pressure and is considered a non-constant pressure generator. Simultaneously, the Series-D ventilators produce a flow pattern that is constant in spite of changes in lung mechanics (inspiratory square-wave).

Originally designed for military field work, the Omni-Vent ventilators are able to be used in many demanding environments such as Magnetic Resonance Imaging, Hyperbaric Chambers, Airmobile Operations, Emergency Medicine, In-house Transport, Anesthesia, Animal Laboratories and Veterinary Medicine.

The Omni-Vent is designed with internal simplicity in mind and coupled with the Tau Monitoring System, gives the operator a complete system with which to ventilate and monitor the patient. Quick-connecting features allow the operator to provide for all needs: Controlled Ventilation, Continuous-Flow Intermittent Mandatory Ventilation, Constant Positive Airway Pressure, Positive End-Expiratory Pressure, High Frequency and Jet Ventilation, as well as Inspiratory to Expiratory Ratios that are infinitely variable. A wide-range Pressure Relief System allows for both the prevention of barotrauma and Time-Cycled, Pressure Relieved Ventilation.

In standard use, the Omni-Vent may be used in conjunction with a variety of face masks, cricothyroid tubes, endotracheal and tracheostomy tubes, as well as jet tubes and bronchoscopes.

Humidification, air/oxygen blenders may be incorporated as the operator desires.

Testing

Every Omni-Vent is tested numerous times during the manufacturing process. Final testing and calibration procedures utilize Bio-Tek VT-1 and VT-2 lung analyzers. A copy of the final test is included with each delivered Omni-Vent when it is shipped from the factory.

Definition of Statements

The following terminology and definitions are important for the operator to understand before proceeding with this manual:

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. This device should always have the pressure relief valve adjusted in a manner to prevent barotrauma.

3. This device should always have the monitoring system turned on during operations to ensure that the desired parameters and alarms are functioning.

4. The Omni-Vent Reusable Patient Tubing Circuit, P/N OT 2010, is the only tubing/exhalation valve system authorized for use with the Omni-Vent Series-D ventilators. Other systems may not work properly.

5. The Omni-Vent has been designed to be used with the Tau Monitoring System fully functional. If the Monitor is not functional, do not use the machine. Refer to Service Manual for proper instructions.

Specifications

Note

The factory utilizes a 50 psi gas inlet pressure for running, calibrating, manufacturing, and all data and performance specifications in this manual reflect the results of using that pressure. Higher and lower pressures may be used and any unit may be custom calibrated using different pressures. Volumes and rates can differ from settings selected if the inlet pressure is not 50 psi. Recalibration of the device can be made using the data in the Maintenance Section of this manual.

Series-D/MRI-Tau Ventilator

Dimensions	13x7.5x6.5 inches
Weight	8 lbs
Case Material	aluminum
Gas Pressure Range	25 to 140 psi
Patient Population	Neonate through adult
Tidal Volume Range	0 to 2.0 liters
Inspiratory Flow Rate Range	0 to 85 liters per minute
Inspiratory Time Range	0.2 to 3.0 seconds
Expiratory Time Range	0.2 seconds to 5.0 minutes
Breaths Per Minute	0 to 150
PEEP/CPAP Pressure	0 to 20 cm/H_2O (higher if needed)
Continuous Flow Range	1 to 60 liters per minute
Internal Compliance	-0-
Operating Temperature Range	-45° F to +140° F
Pressure Relief Range	0 to 120 cm/H_2O
MRI Capability	with any known magnet to 4.7 Tesla

Monitoring Alarm System

General:

Pressure Transducer Type – Temperature compensated piezo-resistive, differential pressure transducer

Transducer Measurement Range	-120 to +120 cm/H_2O
Accuracy	0.4% FSO
Data Sampling	10ms (20ms below 50 BPM)

Monitoring Alarm System Specifications, cont.

Displayed Information

Displayed Pressure Measurements:	
Pressure Range-Standard Mode	-10 to +120 cm/H_2O
Pressure Range-NIF Mode	0 to -120 cm/H_2O
Respiratory Rate	2 to 300 BPM
Minimum/Maximum Per Cycle	-10 to +120 cm/H_2O
Inspiratory Time	0.01 to 10 seconds
Expiratory Time	0.01 to 60 seconds
I:E Ratio	99:1 to 1:99

User Settable Parameters

Pressure High Limit	-4 to +120 cm/H_2O*
Pressure Low Limit	-10 to +114 cm/H_2O*
Pressure Low Limit Delay	0 to 99 seconds
Pressure Fail-To-Cycle	Enabled/Disabled

* See Limitations outlined in the 'General Description' Section

Other Functions

Pressure Zero Calibration:	User activated
System Self Test:	Automatic upon power-up
Alarm Mute:	15 seconds
Alarm Disable:	60 seconds post power-up

Power Requirements

External Power	Requires 9V dc, 250mA min.
Battery Power	Requires 9V dc
Battery Life	300 continuous hrs. w/ Lithium 170 continuous hrs. w/ Alkaline (below 50 BPM)

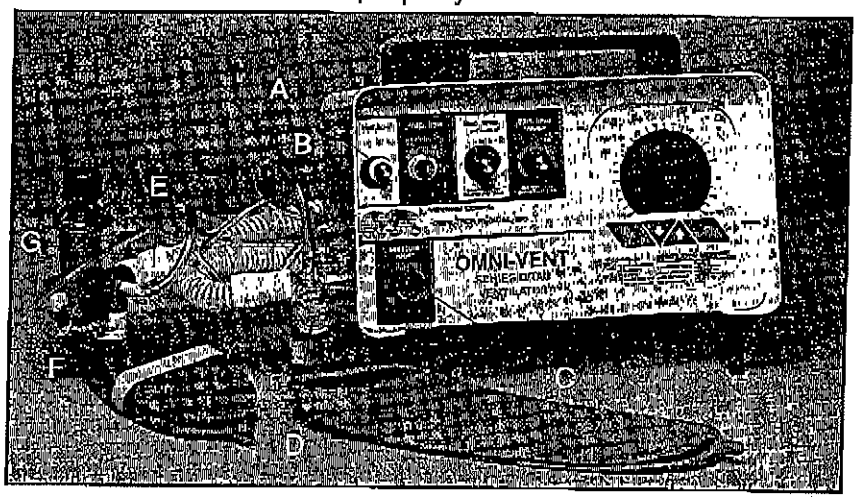
Functional and Operational Procedures

The following procedures should be performed between the time the Omni-Vent is assembled and before it is placed into clinical service to ensure proper assembly and operation.

Assembly of External Components

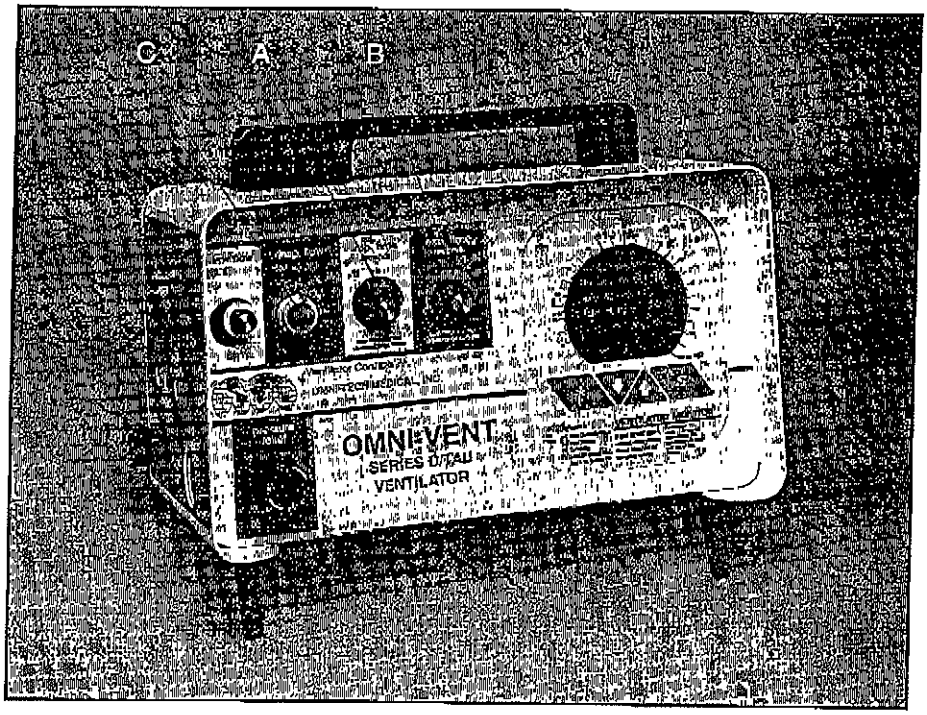
Attach the patient tubing circuit (part number OT 2010) to the left side panel of the machine. There are three tubes to connect; each is size coded to fit the outlet ports as indicated on the label, i.e. patient circuit, exhalation valve and airway pressure. If a functional test is to be performed at this time, attach the distal end of the tubing circuit to an appropriate test lung in order to generate positive pressures that will allow the Monitor to work properly.

large tubing goes to air way pressure small tubing go to exhalation valve



A. Needle Valve-IMV; B. On/Off Switch; C. Pressure Relief Valve
D. IMV Reservoir Assembly; E. Tubing Circuit; F. Exhalation Valve;
G. PEEP Valve

Control Knobs for On/Off Gas Inlet Supply, IMV Flow, Inspiratory Flow, Inspiratory Time, Expiratory Time, and Pressure Relief



A. Inspiratory Time; B. Expiratory Time; C. Inspiratory Flow

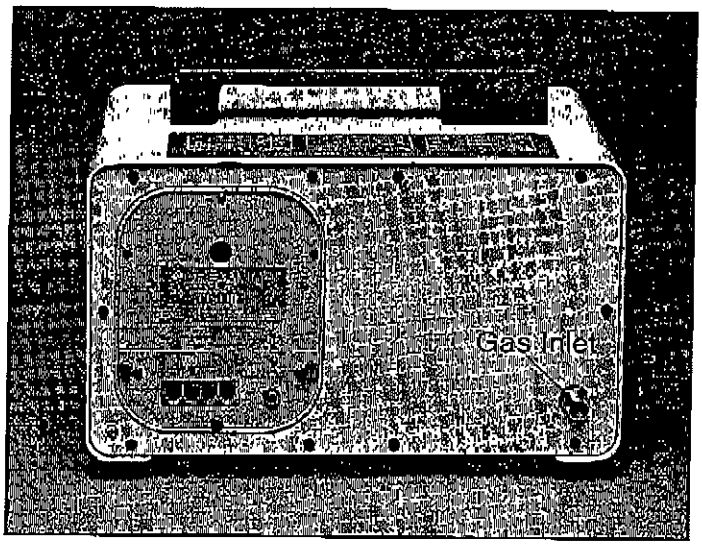
Note

Confirm the volume with a hand-held spirometer or other suitable monitoring device by placing the spirometer at the outermost of the patient tubing circuit before attaching it to the patient's endotracheal tube to check the volume again at the exhalation valve outlet port. Minor corrections in volume may be needed at this time to compensate for gas compression in the external tubing circuit.

Gas Inlet Pressure

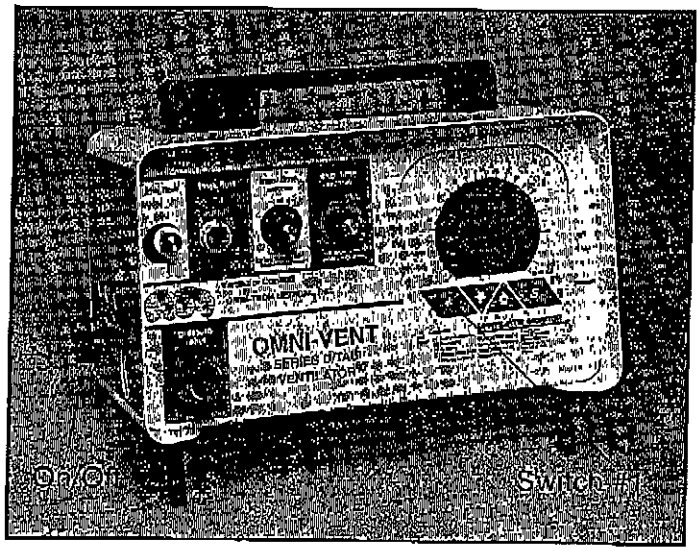
Attach a high pressure hose to the gas inlet adaptor which is located at the lower right rear of the machine, and the other end of the hose to an appropriate pressure-reducing regulator or wall outlet. Inlet pressures from 30 to 140 psi may be utilized, however, 50 psi is optimal for regular performance levels.

Note: The ventilator controls may be re-calibrated, using any inlet pressure specified, refer to the Service Manual for details.



Pneumatics On/Off Switch

The On/Off switch is located on the lower left side of the ventilator and is operated by simply turning the knob 90 degrees in either direction to change the setting from either On or Off.



Tau Monitor On/Off Switch

Depress Switch #1 until numbers are indicated on the window of the Monitor and proceed.

Front Panel Controls

After turning the On/Off Switch to the On position, the front panel controls may now be manipulated.

Tau Quick Operating Guide

Note: Powering up TAU disables all alarm functions for 60 seconds, except in the case of the Pressure High Limit Alarm.

The user can access and/or adjust all of the Tau's functions by using the following switches:

Switch #1:	(*)
Battery operation:	Power On / Back Light
Line-power operation:	Mute
Switch # 2:	(↓) Down Scrolling
Switch #2 and #3:	(Pressure Zero Calibration)
Switch #3:	(↑) Up Scrolling
Switch #4:	(S) Select / Set (Alarm Reset)
	Power Off

Using these four keys, the user may select which parameters / alarm screens they wish to view and/or set a variety of alarm parameters. Upon unit power-up, the system automatically defaults to the Respiratory Rate Window. Thereafter, the user can select which screen they wish to view / adjust by scrolling up or down through the windows.

In order to set an alarm parameter, the user should move to the desired alarm screen and proceed with the following sequence:

1. Momentarily press Switch #4 (S) which changes the function of Switches #2 (↓) and #3 (↑).

2. Utilizing Switches #2 (↓) and #3 (↑), set the alarm to the value desired.

3. Momentarily press Switch #4 (S) which will store the desired setting and revert the function of Switches #2 (↓) and #3 (↑) to their window scrolling functions.

Automatic Shut-off in Battery Mode: In battery mode, the Tau automatically shuts off if it does not detect pressure values greater than 3 cm H_2O for a period of three minutes. Audio alarm silences after one minute.

Departmental policies and/or manufacturer suggested settings of alarm parameters should be adhered to. Never forget the need to adjust these parameters to the individual patient.

The windows (in the following order) appear with the monitoring screens first, followed by the alarm screens.

MONITORING SCREENS	ALARM SCREENS
Rate window (*) Respiratory Rate, Maximum Pressure per breath, Minimum Pressure per breath	Pressure High Limit Alarm Setting
Inspiratory - Expiratory Time I:E Ration (inverse of I/E), Inspiratory Time, Expiratory Time	Pressure Low Limit Alarm Setting
Mean Pressure (*) Continuous readout of mean airway pressure	Pressure Low Limit Delay
Pressure Window (*) Continuous readout of pressure system	Pressure Leak Detect Alarm Setting
Negative Inspiratory Force (NIF) Negative Inspiratory Force (Maximal Inspiratory Pressure [MIP]) per breath, Breath in progress indicator, Maximum Inspiratory Force per session	Pressure Fail-To-Cycle Alarm
* Bar graph displays all pressure alarm settings and continuous pressure reading	
+ Bar Graph displays High and Low pressure limit alarm settings and continuous pressure reading	

Note:
The complete Ventilator Monitor Users Manual should be read and understood before the operator actually uses the machine for patient care.

IMV Flow Control Knob

After attaching the IMV system to the Patient Circuit Outlet, located on the left front position of the machine, and the IMV gas bleed line from the IMV flow outlet, located on the left upper position of the machine, to the IMV reservoir bag, the IMV flow control, located on the left upper position of the front of the machine, may now be utilized. Turn the Control Knob from the full-off position (fully counter clockwise) to whatever continuous gas flow is required to the IMV reservoir bag, by turning the Control Knob clockwise.

Note: This control knob may be turned five (5) full rotations, from full off to maximum flow. The reservoir bag should be inflated only to the degree that the patient will not empty the bag during spontaneous ventilation.

Note:
The Inspiratory Flow control may be used at any time to change the delivered tidal volume. Some users leave the Inspiratory Time control in a fixed position and alter the tidal volume delivery by changing the Inspiratory Flow Rate and measuring the tidal volume with a hand held spirometer.

Inspiratory Control Knob

This control knob may be turned a maximum of 355 degrees, lock to lock, full range of operation. This knob is of the high friction type to prevent accidental movement of the control during operations. The

Note

For utilization of a rubber test lung is necessary. Keep in mind that the compliance and resistance of this device may alter from breath to breath and may not be totally accurate. Inaccurate pressure gauge readings, poor complete accuracy during perio testing of this test lung analyzer or similar device should be employed.

Note

Because the delivered tidal volume is below a pressure relief valve has been set the pressure relief valve is set low the set tidal volume may not be delivered. Correctly the pressure relief valve is set slightly above the actual working pressure (as read on the pressure gauge).

Parameter Estimation Charts for Time-Cycled Ventilators

(For Tidal Volume, Rate, and I:E Ratio)

Approximate Inspiratory/Expiratory Ratio Desired

INSP \ EXP	.2	.5	1.0	2.0
.2	1:1	1:2	1:5	1:10
.5	2:1	1:1	1:2	1:4
1:0	5:1	2:1	1:1	1:2
2.0	10:1	4:1	2:1	1:1

Approximate Tidal Volume Desired (in liters)

LPM \ INSP	.5	1.0	1.5	2.0
20	.2	.3	.5	.7
40	.3	.7	1.0	1.3
60	.5	1.0	1:5	2.0
80	.7	1.3	2.0	2.7

Approximate Rate Desired (in breaths per minute)

INSP \ EXP	.2	.5	1.0	3.0
.2	150	90	50	20
.5	90	60	40	18
1:0	50	40	30	15
2.0	30	25	20	12

label indicates a starting point of 60 LPM and may be manipulated for higher or lower flow conditions as needed.

Note: Once an initial Inspiratory Flow Rate and Inspiratory Time has been selected, Tidal Volume may be changed easiest by turning the Inspiratory Flow Control higher or lower, as needed, thereby keeping the Inspiratory Time Constant (refer to the Monitor for correct times) and altering the Tidal Volume to the value desired.

Inspiratory Time Control Knob

This knob may be turned 355 degrees, lock to lock, and the label indicates an approximate reference point of 1.0 seconds, which should be confirmed on the Monitor. Higher or lower Inspiratory Times may be obtained by turning the control knob in the directions indicated on the label (higher = clockwise, lower = counterclockwise). Confirm the desired times on the Monitor.

Note: Once an Inspiratory Flow Rate and Inspiratory Time have been selected, confirm the desired Tidal Volume with an appropriate volume-measuring device. Minor corrections in Flow Rates and Inspiratory Times may be made at this time.

Expiratory Time Control Knob

This knob also may be turned 355 degrees, lock to lock, and the label indicates an approximate reference point of 5.0 seconds. Desired Expiratory times may be selected, using the Monitor for actual times, by turning the Control Knob to higher or lower positions as indicated on the label.

Note: The term "approximate", in reference to Inspiratory Flow Rate, Inspiratory Time and Expiratory Time, are factory calibrated values obtained with an inlet gas pressure of 50 psi. Other inlet pressures may cause these indicated values to be slightly inaccurate, however the machine may be re-calibrated at other inlet pressures in order that the indications are again accurate. Refer to Service Manual for proper re-calibration procedures.

I:E Ratios

Actual ratios, the result of Inspiratory Flow Rates, Inspiratory and Expiratory Times, are displayed on the second screen of the Monitor. Desired I:E Ratios may be obtained by adjusting the Inspiratory Flow Rate, Inspiratory and Expiratory Time Control Knobs.

Pressure Relief Valve Control Knob

This knob may now be adjusted to control the pressure during the inspiratory phase. When the knob is adjusted fully clockwise, the valve is closed and the inspiratory pressure may rise to higher limits. Conversely, by turning the knob counterclockwise, the pressure may be limited to whatever value that the operator desires.

Note: Be certain to adjust the pressure limit alarm on the Monitor to a position higher than that being used with the pressure relief valve, in order to prevent an unwanted High Pressure Alarm condition.

Clinical Techniques

Controlled Ventilation (CV)

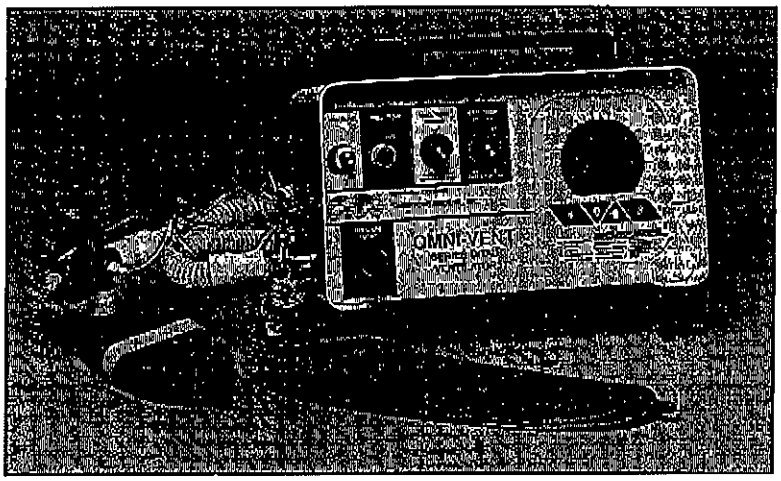
For the apneic patient, CV is accomplished by using the Omni-Vent with the patient tubing circuit only. Adjust the three Control Knobs and Pressure Relief Valve as needed. Monitor the patient as protocol dictates.

Note

Gas consumption using the IMV system is increased total gas consumption during CV. Measure the continuous flow per minute and add this value to the CV volume or cylinder gas calculations.

Intermittent Mandatory Ventilation (IMV)

Using the continuous flow method, attach the IMV Kit to the left-side panel, Patient Circuit Outlet Port, then attach the Patient Tubing Circuit to the outlet port of the IMV Kit, ensuring that the small bore tubing (size coded) are attached to the exhalation valve outlet port, the airway pressure inlet port and the IMV flow outlet port (to the gas inlet stem of the IMV reservoir).



Positive End-Expiratory Pressure (PEEP)

PEEP may be utilized during CV or IMV by attaching a PEEP valve to the outlet port of the expiratory valve on the patient tubing circuit. Adjust the PEEP valve control knob and observe the end-expiratory pressure on the pressure gauge until the desired PEEP value is achieved. As PEEP pressure is increased, the peak airway pressure will increase, therefore, the pressure relief valve may need to be readjusted. (See illustration on page 5.)

Note

The on/off switch must be in the "on" position for the continuous flow bleed valve to work.

Continuous Positive Airway Pressure (CPAP)

CPAP is accomplished by using the same accessories used for IMV and PEEP.

Leave the On/Off switch in the "on" position; turn the Expiratory Time Control to the maximum time position (full clockwise position), and the Inspiratory Flow Control to the lowest position (full counterclockwise). Attach a PEEP valve to the outlet port of the patient tubing circuit exhalation valve; adjust the continuous flow to the IMV reservoir bag as desired; adjust the PEEP valve control to the approximated PEEP level desired and read the PEEP level on the pressure gauge. Adjust the gas flow and PEEP valve as desired.

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

The Omni-Vent is initially set up as in CV, then an inverse ratio may be accomplished by increasing the rate per minute and not allowing as much time for exhalation as for inhalation. The pressure relief valve is set to the desired value. (E:I often produces higher than normal pressures as it does not allow a complete exhalation to occur.) A suitable monitor capable of measuring I:E ratios will allow for precise information.

Pressure Controlled Ventilation (PCV)

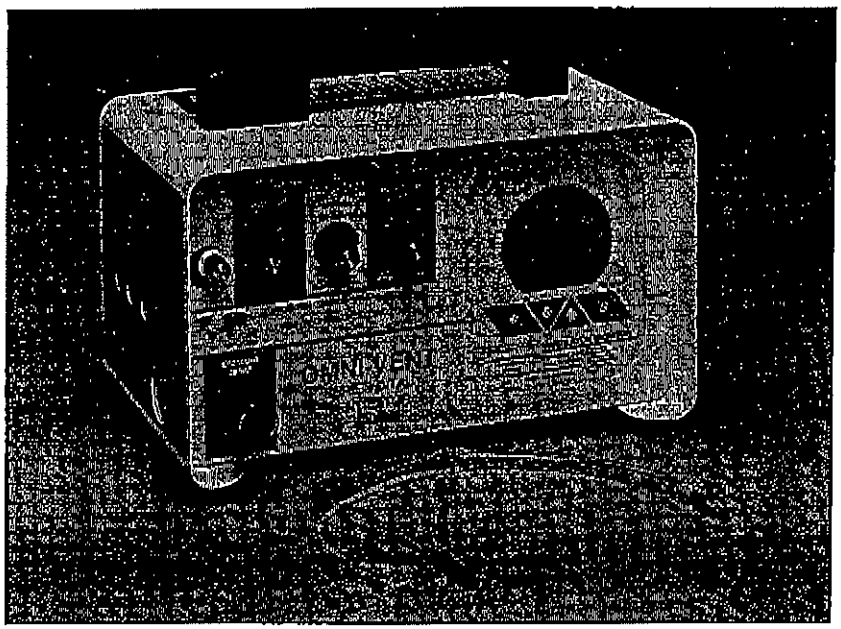
Establish either CV or IMV parameters, observe the working pressure on the pressure gauge, then set the Pressure Relief Valve setting to a pressure slightly less than the working pressure. This allows for an inspiratory pressure plateau to occur during the inspiratory phase. This technique is generally utilized when an absolute pressure limit is mandatory, with the understanding that the initially delivered tidal volume may not continue to be delivered.

Jet Ventilation

The Omni-Vent may be utilized as a jet ventilator by disconnecting the patient tubing circuit, then:

– attach a separate tubing to the outlet port on the front panel labeled "exhalation valve" and the other end to the jet endotracheal tube, cricothyroid tube, or bronchoscope inlet port.

– tidal volume delivery may be adjusted by utilizing the Inspiratory Time and Inspiratory Flow controls, either independently or together. However, the Inspiratory Time control is normally used in the minimal time position for this technique.



Jet Configuration

High Frequency Ventilation – (HFV)

HFV is accomplished by using the standard patient tubing circuit, selecting an appropriate low-level tidal volume, and adjusting the rate per minute above normal levels. (Rates above 60 per minute are considered high frequency in nature.)

Warning–Inadvertent levels of PEEP may occur when using HFV. Carefully observe the Monitor for desired parameters.

Note

There may be a slight drop in tidal volume delivered due to the volume displacement of the humidifier used. Such items as water level in the reservoir and length of tubing, etc. may result in having to increase tidal volume settings from the ventilator to compensate for these probable changes.

Humidifiers

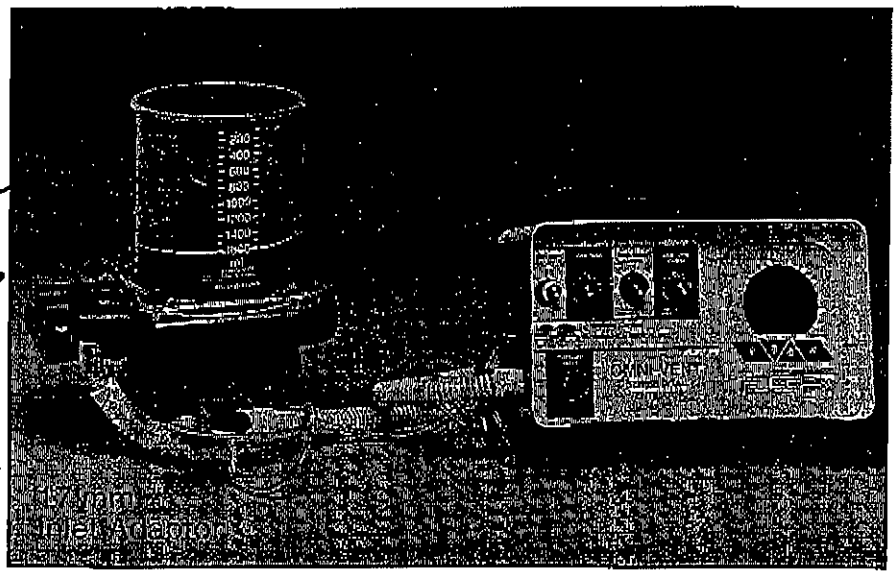
Artificial nose humidifiers, for short term use, are placed between the end of the patient tubing circuit and the endotracheal tube. Heated molecular humidifiers of any type may also be used. Attach a length of tubing between the Omni-Vent patient tubing outlet port on the front panel and the inlet port of the humidifier. Attach the patient circuit to the outlet port of the humidifier and proceed as usual. Follow manufacturer's instructions.

Blenders

Any air/oxygen blender may be utilized for normal operations. Be certain that the blender is approved for MRI utilization if it is to be used for that purpose.

Use of the Omni-Vent with the Ohmeda Excel 210/MRI Anesthesia Machine

The purpose of the Omni-Vent in this configuration is to simply power the bellows of the anesthesia machine. The Omni-Vent is operated in the same manner as during direct patient lung ventilation, however, the Omni-Vent Patient Tubing Circuit is now connected to the 17mm inlet port of the Ohmeda bellows.



start with 2 sec, insp 3 about 6 sec. exp. 7½ RPM to vary tidal volume change flow.

need respirometer to give exhaled tidal volume from Ohmeda about $1200.

Note

During the expiratory phase of the Omni-Vent the gas from the top of the bellows (originally delivered by the Omni-Vent) is released through the exhalation valve and then to the room. As this gas is NOT a part of the anesthetic gas supply, no scavenging is necessary.

Attach the Omni-Vent to the top, right hand portion of the upper shelf of the Excel 210/MRI unit, using the brass, thumb, securing screw, by inserting the screw through the bottom of the shelf and into the hole provided in the bottom of the Omni-Vent. Ensure that the Omni-Vent is securely fastened.

Attach the OT 2010 Patient Tubing Circuit to the Omni-Vent in the normal fashion. Then attach the distal end of the circuit to the bellows inlet, using a 17mm/22mm adaptor. Adjust the fresh gas supply to the bellows from the anesthesia machine to the desired level. Turn on the Omni-Vent and adjust the Inspiratory Time, Expiratory Time and Inspiratory Flow controls until the bellows is ventilated as desired.

Note

The time that the contents of a particular cylinder will last may be accurately estimated by using the following table.

CYLINDER GAS FORMULA

Cylinder Size	E	G	H
Cubic Feet	22	65	244
Factor	0.16	0.28	0.14

1. Pressure 2200 psi in full cylinder
2. Factors illustration for flow: Air, Oxygen
3. Formula: duration of flow (minutes) = cylinder press. x Factor = TOTAL = 60

Cylinders

Cylinder gas sources from size "E" to "H" may be utilized by attaching a suitable pressure reducing regulator to the cylinder, attaching a high pressure hose to the regulator and then to the gas inlet port of the Omni-Vent. The cylinder should be changed when the pressure gauge of the regulator indicates 1/4 pressure remaining or less.

Regulators

Pressure reducing regulators of various types may be utilized. Pressure adjustable, dual-stage regulators give the operator the ability to know the actual outlet pressure during operations (constant pressures of 25 to 140 psi must be available).

Caution – Regulators with flowgauges or flowmeters cannot be utilized to power the Omni-Vent unless there is a high pressure outlet between the regulator and flow metering device.

Caution – Regulators should be returned to the manufacturer annually for preventative maintenance.

Use of the Omni-Vent Series D/MRI for Magnetic Resonance Imaging Procedures

The Omni-Vent ventilators labeled MRI may be utilized in any MRI environment. These machines are nonmagnetic and the recommended accessories have all been tested for use during MRI procedures.

An outstanding attribute of the Omni-Vent Series D/MRI is that the patient requiring mechanical ventilation during this procedure may be ventilated without interruption while being transported from the ICU, etc., during the procedure, and while being returned to the place of origin.

Note

The Omni-Vent Series-D/MRI ventilators have been tested at 4.7 TESLA. At magnetic epicenter, 4 KW ambient current, there is NO increase in temperature during MRI operations. In fact, there is a slight DECREASE in temperature due to the cooling effect of the oxygen and/or air flowing through the machine during ventilation procedures.

Due to the fact that every MRI center is unique in nature and that often oxygen and/or air may or may not be piped into the MRI room, many questions arise before actually beginning these procedures concerning how to best operate a ventilator and associated equipment. Please contact us if you have any questions. If we cannot answer them, we can put you in contact with an expert who can assist you.

Warning – Be absolutely certain that the following equipment, possibly used as accessories with the Omni-Vent, are nonmagnetic:

- medical gas cylinders
- pressure-reducing regulators
- high pressure hose fittings
- air/oxygen blenders
- PEEP valves
- pressure relief valves

It is recommended that someone knowledgeable about mechanical ventilation be in the room, directly observing the patient during the MRI procedure.

Caution – The Omni-Vent Series-D/MRI should be utilized at a distance of one meter or more from magnetic epicenter to prevent artifact from occurring in the MRI imaging process.

Use of the Series-D Labeled "Hyperbaric Chamber Capable"

Warning – The Omni-Vent is designed to be operated **inside air pressurized** hyperbaric chambers and **outside oxygen pressurized** hyperbaric chambers only.

The special Omni-Vent Series-D ventilator incorporates all of the features of the standard Omni-Vent Series-D/MRI with the additional features of:

– special valving in the internal gas circuit

– special pressure-adjustable regulator to enhance ventilator performance, if required

Operational Consideration

Exposure of a mechanical ventilator to the alterations in environment of a hyperbaric chamber (variations in gas density, inlet gas pressure, temperature, as well as other factors) will cause changes in operational characteristics.

Warning – As with any life support device, close monitoring of both patient and equipment is essential, particularly during periods of chamber compression and decompression.

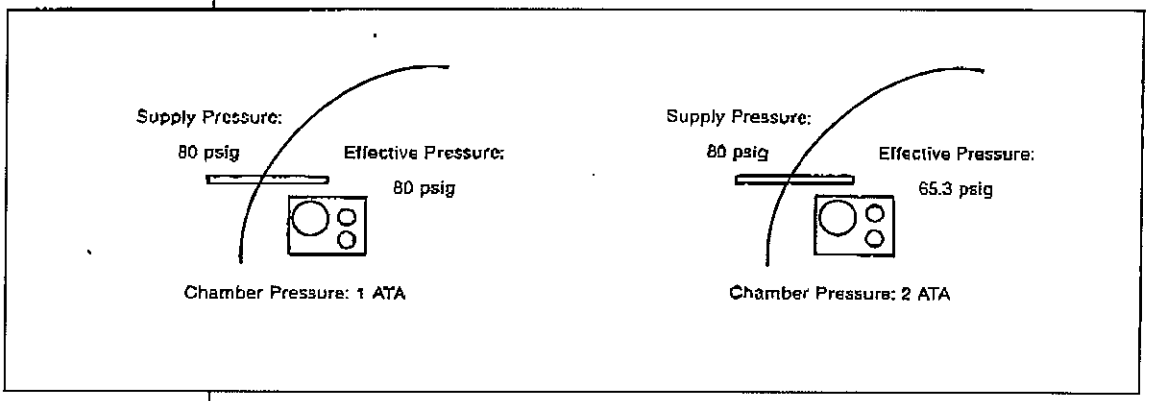


Figure 1:

Delivery Pressure Change Without Internal Regulator

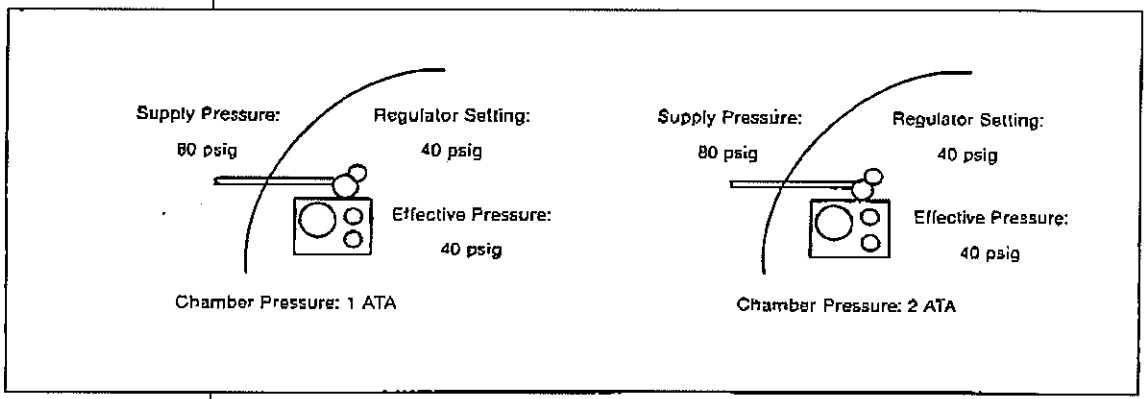


Figure 2:

Delivery Pressure Change With Internal Regulator

Inlet Gas Pressure Changes

Pneumatic ventilators, such as the Omni-Vent, will exhibit some variability of operation when there are changes in the gas supply pressure. When pneumatic ventilators are used in hyperbaric chambers, as the chamber pressures change, the differential between supply gas and chamber pressures change (figure 1), resulting in variations in ventilator performance. The practitioner may wish to incorporate an adjustable high flow regulator which allows the operator to maintain a constant driving pressure to the ventilator (figure 2), resulting in less operational variability during compression/ decompression.

The Omni-Vent HBC is designed to accommodate a wide range of inlet pressures (25-140 psig). The ventilator supply pressure should be no less than the minimum operating pressure for the ventilator **plus** the anticipated treatment pressure **plus** 25 psig.

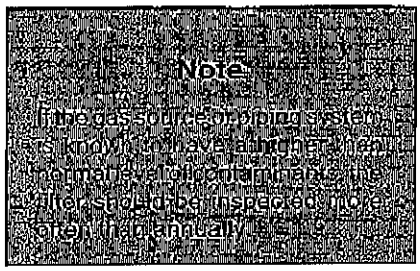
Example: A patient will be treated at 2.5 atmospheres absolute (22 psig). The minimum pressure required to power the Omni-Vent (**outside supply pressure**) is 22 + 50 + 25 = 97 psig. Although the internal high flow regulator will reduce operational variability during compression/decompression, changes in gas density will occur, resulting in some variance from surface settings. During these compression/decompression periods, **close monitoring of ventilator performance is essential.**

Expired Gas/Oxygen Concentration Consideration

To reduce oxygen leakage into the chamber atmosphere, exhaled gases should be routed from the expiratory valve to the off-board-dump system.

Warning – A small volume (10-50 ml) of the driving gas is released into the housing of the Omni-Vent with each inspiratory cycle. If oxygen concentrations above 21% are used to power the ventilator, chamber ventilation should be adjusted to compensate for this additional oxygen load.

Recommended Maintenance



The functional testing procedures (page 6) should be performed between each use. In addition, the following may be performed once a year:

Inlet Filter

The inlet filter should be inspected and replaced, at least annually, using the following procedure:

A. Remove the screws holding the back plate in place.

B. Remove the two screws on the bottom of the machine, located under the on/off switch knob.

C. Pull the on/off switch assembly out of the unit.

D. Unscrew the on/off switch from the aluminum block.

E. Remove the cone-shaped filter and replace same.

F. Screw the on/off switch into the aluminum block, ensuring tightness and correct angle so that the on/off switch control knob aligns correctly with the outlet hole.

G. Place the aluminum block over the screw holes in the bottom plate with the on/off switch control knob in proper position.

H. Replace the screws in the bottom of the base plate into the bottom of the aluminum block, adjusting for proper alignment of the on/off switch control knob, and tighten securely.

I. Place the back cover plate and replace the screws securely.

J. Perform a functional test to ensure that the machine is working according to specifications.

Factory Return

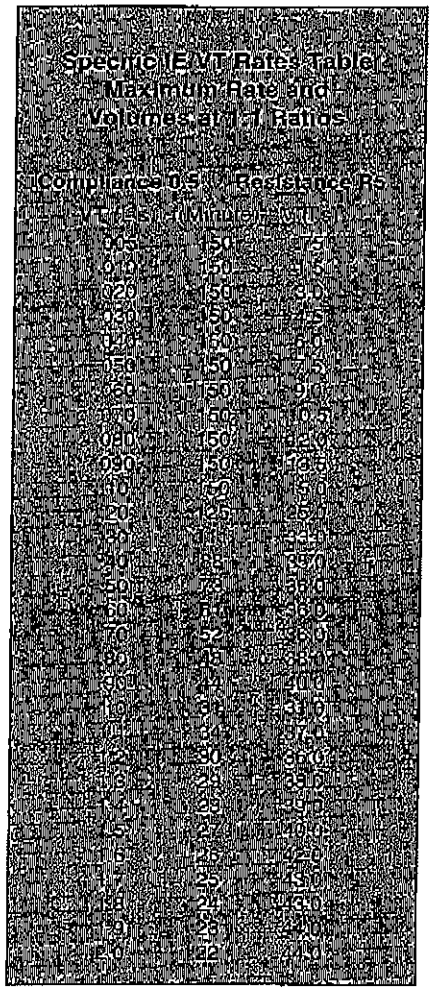
The Omni-Vent may be returned to the factory at any time for thorough maintenance. Please call the factory for a fee quotation, time frame for processing, purchase order, and returned goods authorization number.

Cleaning and Disinfection

The Omni-Vent should be disinfected between uses and during prolonged utilization.

– Using any surface disinfectant will suffice.

Caution – Care must be taken if spray/aerosol driven products are used. Residue may accumulate under the control knobs and cause them to malfunction. **Do not gas sterilize this ventilator.**



Calibration Procedures

In order to calibrate the Inspiratory Flow, Inspiratory Time and Expiratory Time controls, the following procedure should be followed:

A. Attach the Omni-Vent to the usual pressurized gas source that is used. Turn the On/Off switch to the "off" position. Turn on the Tau Monitor and use the Tau for all Knob Calibration.

B. Attach the OT 2010 Patient Tubing Circuit/Exhalation Valve assembly to the Omni-Vent.

C. Attach the Patient Tubing Circuit to a test lung.

D. Remove the three Control Knobs from the Omni-Vent with a 1/16" Allen wrench.

E. Turn the On/Off switch to the "on" position and allow the Omni-Vent to cycle several times.

F. Adjust the controls (by turning the individual shafts) until the following units of measure are obtained:

1. Inspiratory Flow - 60 LPM
2. Inspiratory Time - one second
3. Expiratory Time - five seconds

Whether or not a mechanical test lung is available, use the Tau Monitor to obtain the following calibration setting for the Flow Control:

1. Adjust the Inspiratory Time to One Second indicated on the Tau Monitor.

2. Using a hand held spirometer, adjust the Inspiratory Flow (while measuring the tidal volume at the end of the tubing and obtain the value of one liter with each inspiratory cycle).

When either of the preceding methods has been completed, and with the Omni-Vent still cycling, reinstall the knob assemblies using the following methods:

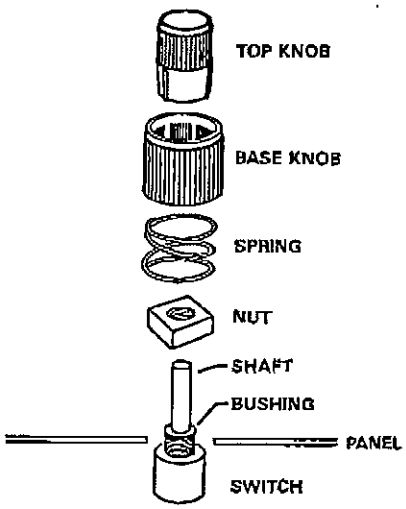
1. Using a wrench, ensure that the square-shaped, brass base nut is firmly secured, then place the brass spring over the nut.

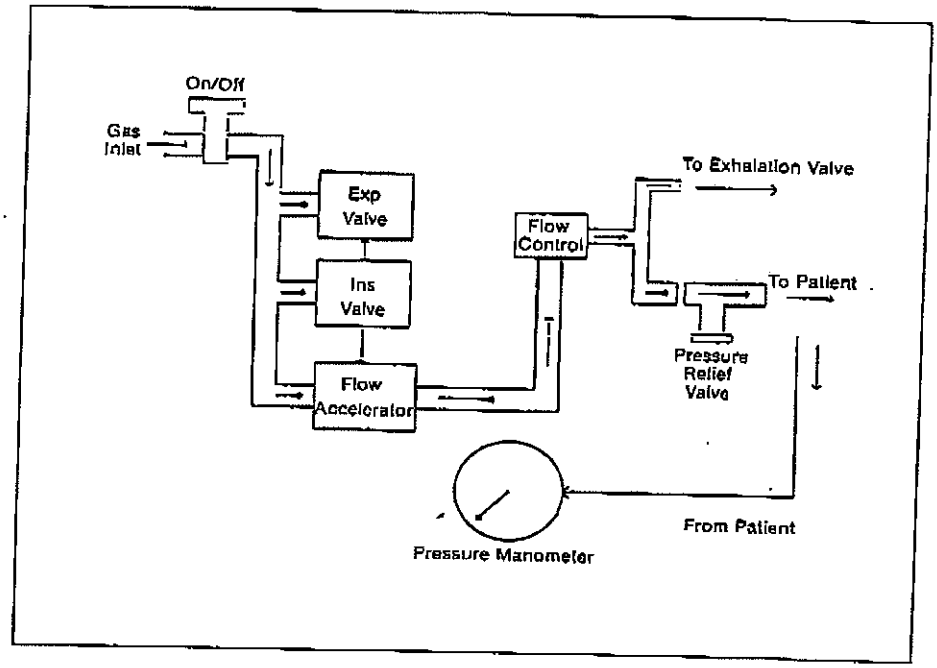
   A. Inspiratory Flow control Knob: The brass base nut must be turned in order that the Base Knob inner stop piece is located at the 2 o'clock position when placed over the brass spring.

   B. Inspiratory Time Control Knob: The brass base nut must be turned in order that the Base Knob inner stop piece is located at the 2 o'clock position when placed over the brass spring.

   C. Expiratory Time Control Knob: The brass base nut must be turned in order that the Base Knob inner stop piece is located at the 5 o'clock position when placed over the brass spring.

2. Place the top knob over the shaft and inside of the base knob; the pointer on the top knob will indicate the value on the front label.
3. Tighten the allen screws with a 1/16" allen wrench.
4. Perform a functional test to ensure that the controls are working properly.

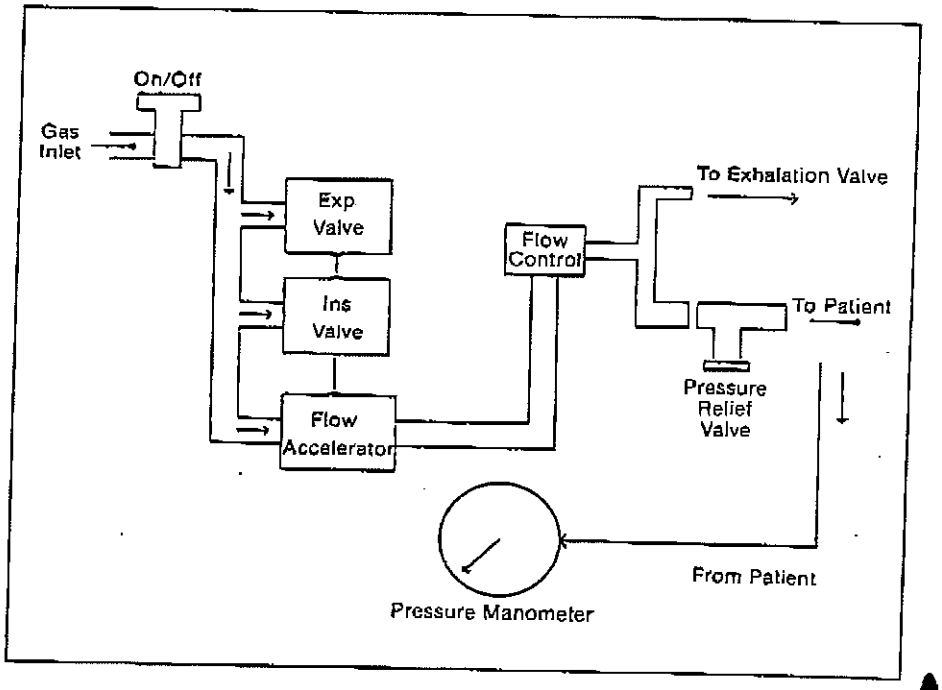




Inspiratory Phase

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 and pressure relief valve and to the patient.

As gas pressure increases in the lung, it is transmitted to the manometer through a tubing independent from the tubing wye connector.



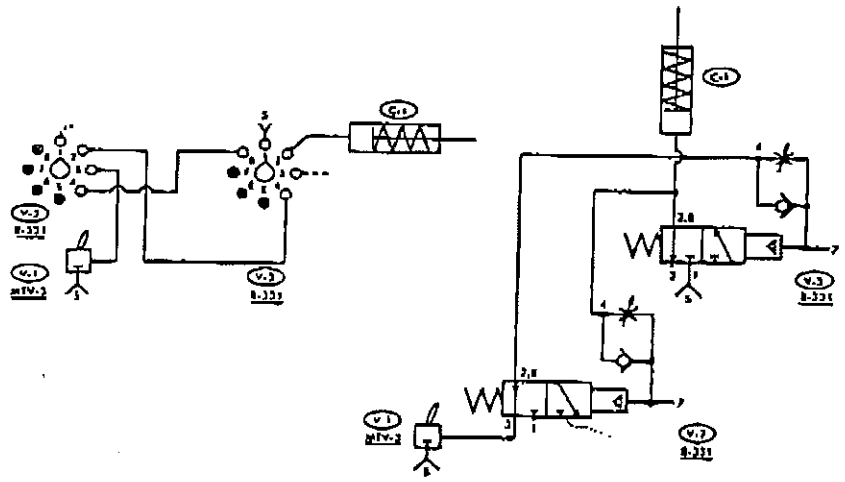
Expiratory Phase

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

Application Circuit Diagram

Automatic Cycler

Turning on the On/Off switch 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 also 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 shift 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-1 (patient circuit outlet port).



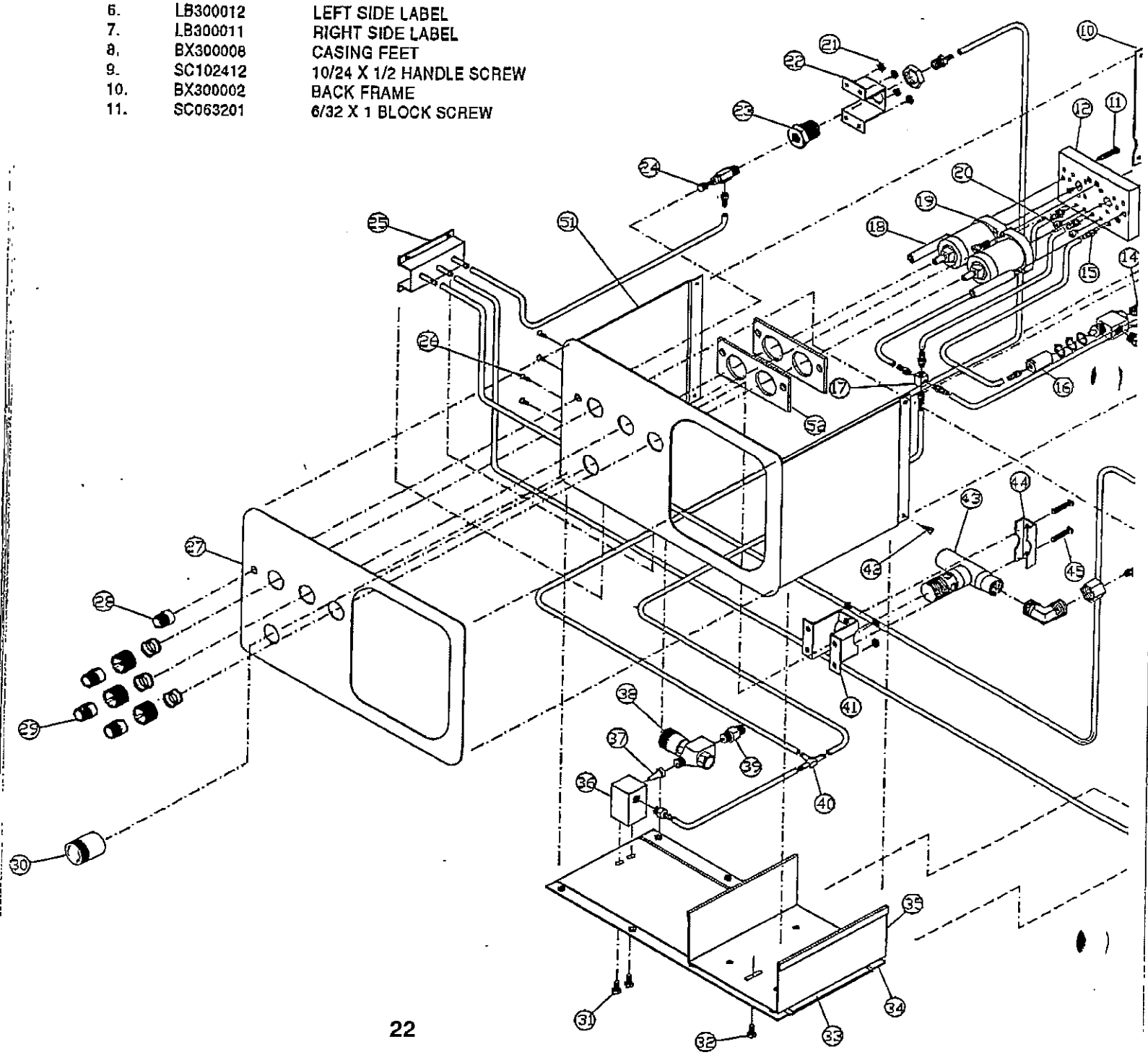
Problem Solving

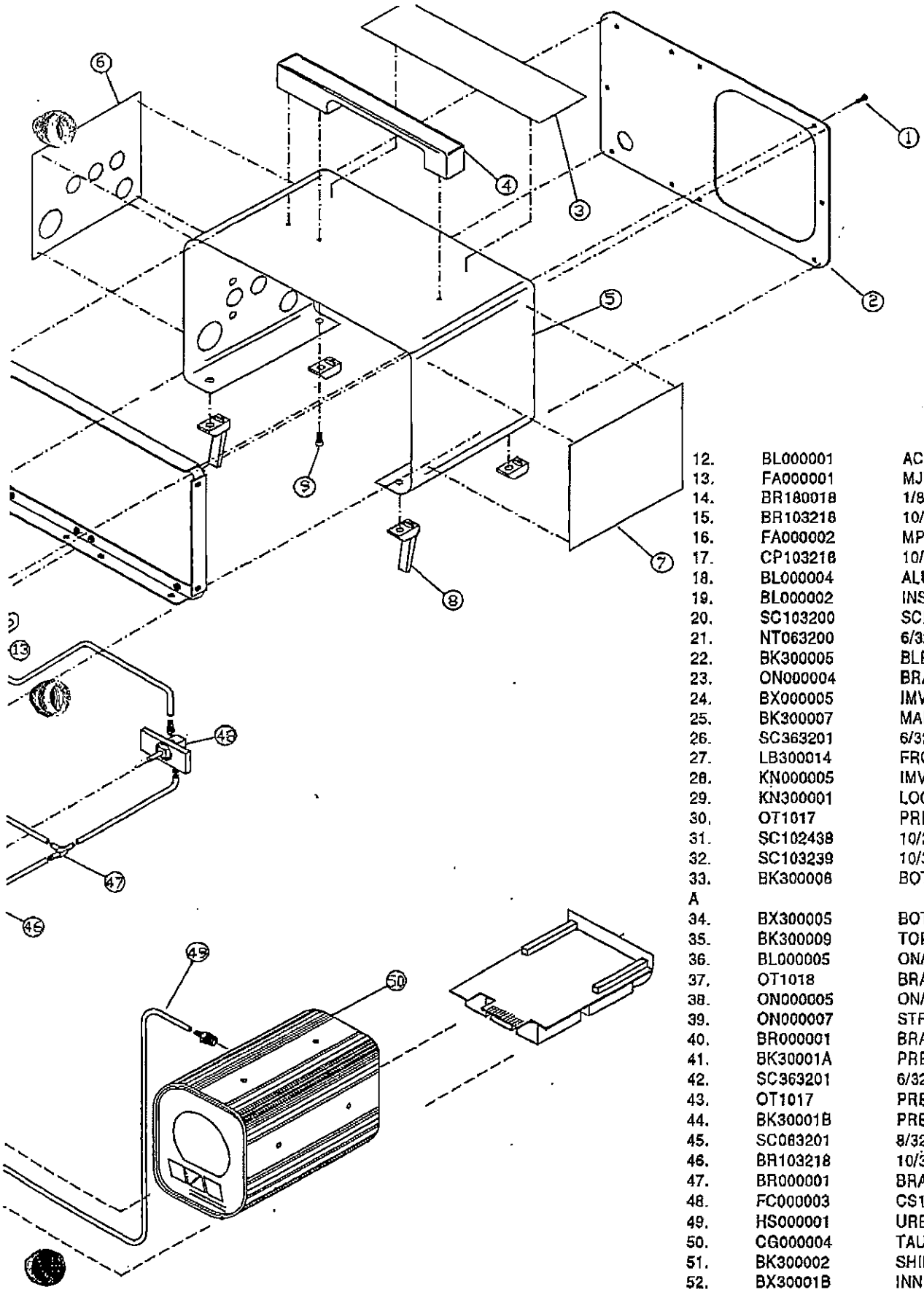
PROBLEM	SOLUTION
–Failure to cycle	–check on/off switch –check gas source for appropriate pressure –check expiratory time
–Tidal Volume too low	–check pressure relief setting –check patient's artificial airway –check flow control –"0" hand-held spirometer between each cycle
–Inspiratory Flow Rate too low (slow)	–adjust flow control to full-open position –ensure inlet pressure is adequate (25-140 psi – 50 psi optimal) –check inlet filter for debris –ensure pressure reducing regulators are in proper working order according to manufacturer's specifications and maintenance schedules

Omni-Vent Ventilators with the Tau Monitoring System

Exploded View Diagram

1.	SC063238	6/32 X 3/8 BLACK SCREW
2.	BX300003	BACK PANEL
3.	LB300009	TOP LABEL
4.	BX300006	HANDLE
5.	BX300004	WRAPPER
6.	LB300012	LEFT SIDE LABEL
7.	LB300011	RIGHT SIDE LABEL
8.	BX300008	CASING FEET
9.	SC102412	10/24 X 1/2 HANDLE SCREW
10.	BX300002	BACK FRAME
11.	SC063201	6/32 X 1 BLOCK SCREW





12.	BL000001	ACRYLIC BLOCK
13.	FA000001	MJV-2 FLOW ACCELERATOR
14.	BR180018	1/8 X 1/8 HOSE BARB
15.	BR103218	10/32 X 1/8 HOSE BARB
16.	FA000002	MPA-3 FLOW ACCELERATOR
17.	CP103218	10/323 X 1/8 COUPLING
18.	BL000004	ALUMINUM STANDOFFS
19.	BL000002	INSP/EXP VALVES
20.	SC103200	SCREW PLUGS
21.	NT063200	6/32 SCREW NUT
22.	BK300005	BLEED VALVE BRACKET
23.	ON000004	BRASS BULKHEAD
24.	BX000005	IMV BLEED VALVE
25.	BK300007	MANIFOLD
26.	SC363201	6/32 X 1/4 SCREWS
27.	LB300014	FRONT LABEL
28.	KN000005	IMV BLACK KNOB
29.	KN300001	LOCKING KNOB
30.	OT1017	PRESSURE RELIEF VALVE
31.	SC102438	10/24 X 3/8 HEX SCREWS
32.	SC103239	10/32 X 3/8 HEX SCREWS
33.	BK300006	BOTTOM SUPPORT BRACKET
A		
34.	BX300005	BOTTOM PLATE
35.	BK300009	TOP SUPPORT BRACKET B
36.	BL000005	ON/OFF BLOCK
37.	OT1018	BRASS INLET FILTER
38.	ON000005	ON/OFF SWITCH
39.	ON000007	STRAIGHT GAS INLET
40.	BR000001	BRASS TEE
41.	BK30001A	PRESSURE RELIEF BRACKET
42.	SC363201	6/32 X 1 SCREWS
43.	OT1017	PRESSURE RELIEF VALVE
44.	BK30001B	PRESSURE RELIEF CLAMP
45.	SC063201	8/32 X 1 SCREWS
46.	BR103218	10/32 X 1/8 HOSE-BARB
47.	BR000001	BRASS TEE
48.	FC000003	CS1808 FLOW CONTROL
49.	HS000001	URETHANE HOSE
50.	CG000004	TAU MONITOR
51.	BK300002	SHIM PLATE
52.	BX30001B	INNER SHELL BOX

Warranty

The products of Omni-Tech Medical, Inc. (OTM herein) are warranted to be free from defects in materials and workmanship and to meet the published specifications.

The liability of OTM under this warranty is limited to replacing, repairing or issuing credit, at the discretion of OTM, for the parts that become defective or fail to meet published specifications during the warranty period; OTM will not be liable under this warranty unless (a) OTM 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 OTM, with transportation charges prepaid by Buyer; (c) the defective unit or part is received by OTM for adjustment no later than four weeks following the last day of the warranty period; and (d) OTM 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 from OTM for repair or alteration by the Buyer must be in writing to prevent voiding warranty. In no event shall OTM 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.

OTM 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 OTM or its agents in connection with Buyer's 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 OTM or authorized for use in writing by OTM, 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 one years from date of delivery, effective April 15, 1991.

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

Returned Goods Policy

All returns must be authorized by Omni-Tech Medical, Inc., prior to shipping. Returned goods are subject to a 20% restocking fee. Contact OTM Customer Service with your request for an authorization number.

The Warranty stated above shall extend for a period of four years from date of delivery, effective, April 15, 1991.