

**BIO-MED DEVICES
MVP-10
NEONATAL/PEDIATRIC
VENTILATOR**

INSTRUCTION MANUAL

**Catalog #2050
Rev. 042916**

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TABLE OF CONTENTS

Addendum	1
MAGNETIC RESONANCE IMAGING ENVIRONMENT	1
SYMBOL EXPLANATION	2
UNPACKING	2
STANDARD MVP-10	2
MVP-10 MRI COMPLETE PACKAGE	2
WARRANTY	4
WARNINGS	5
CAUTIONS	6
I. GENERAL	7
A. INTENDED USE	7
B. MODES OF OPERATION	7
C. FEATURES	7
D. PERFORMANCE CHARACTERISTICS	8
II. DESCRIPTION	9
A. PRINCIPLES OF OPERATION	9
B. CONTROLS, INDICATORS, AND CONNECTIONS	12
C. SPECIFICATIONS	12
III. INSTALLATION CONSIDERATIONS	15
A. EQUIPMENT REQUIRED	15
B. SUPPLY GAS	15
C. MOUNTING BRACKET	15
D. PATIENT CIRCUIT	15
E. OPTIONAL EQUIPMENT	15
IV. VENTILATOR SET-UP	17
A. CONNECTION OF GAS SUPPLY	17
B. CONNECTION OF PATIENT CIRCUIT	17
V. SELECTION OF VENTILATION PARAMETERS AND ADJUSTMENT OF CONTROLS	19
A. TIME-CYCLED OPERATION	19
B. NON-CYCLED OPERATION	23
VI. PRECAUTIONS	30
VII. MAINTENANCE	32
A. NORMAL CARE	32
B. CHECKOUT PROCEDURE	32
C. CALIBRATION	34
D. IF SERVICE IS REQUIRED	35
APPENDIX A	36
AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	36
APPENDIX B	37
MVP-10 VENTILATOR MR INFORMATION	37

Addendum

MAGNETIC RESONANCE IMAGING ENVIRONMENT

WARNING: ONLY AN MVP-10/MRI ORIGINALLY MANUFACTURED BY BIO-MED DEVICES FOR MRI USE OR RECEIVING AN MRI CONVERSION BY BIO-MED DEVICES IS TO BE USED IN AN MRI ENVIRONMENT. THESE UNITS WILL BE FREE-STANDING AND DESIGNATED BY AN MR-CONDITIONAL LABEL AND AN “M” AS A SUFFIX TO THE SERIAL NUMBER.

WHEN USING THE MVP-10/MRI VENTILATOR IN AN MRI ENVIRONMENT, THE FOLLOWING PRECAUTIONS MUST BE TAKEN:

- THE VENTILATOR MUST NOT BE PLACED INSIDE THE MRI BORE (SEE APPENDIX B).
- DO NOT USE ANY ACCESSORIES, INCLUDING OXYGEN AND AIR CYLINDERS, REGULATORS, MOUNTING BRACKETS AND SUPPORT STANDS, THAT ARE MADE OF ANY METAL THAT COULD BE ATTRACTED BY A MAGNET.

SYMBOL EXPLANATION



MR Conditional



MR Unsafe



Follow Instructions for Use



Caution: Consult accompanying documents



Consult Instructions for Use



Product should be kept dry



Warning: Condensed water in air supply can cause malfunction of this device

Rx Only

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.



Date of Manufacture



Manufacturer

SN

Serial Number

REF

Catalog Number



Authorized Representative in the European Community.



The CE mark displayed on this product signifies that this device is in compliance with the European Medical Devices Directive (Council Directive 93/42/EEC). As a prerequisite for the CE mark, Bio-Med Devices operates under an ISO 13485 compliant quality system (covering the design and manufacture of medical devices). The four-digit code underlying the CE mark (0086) pertains to Bio-Med's Notified Body, the British Standards Institute, whose function is to investigate and attest to the validity of CE-mark claims.

UNPACKING

When received, the instrument should be immediately unpacked and checked to see that all component parts have been received, and that there is no apparent damage.

If the MVP-10 was shipped directly to you, and damage due to shipment is found, notify the carrier at once. Only you, the consignee, can make a claim against the carrier for damage in shipment.

If you received the equipment from a BMD dealer, return it to him for adjustment.

The following items are shipped as part of the MVP-10 equipment. Check to assure that all items have been received.

STANDARD MVP-10

- MVP-10 Ventilator
- Two (2) Patient Circuits, Catalog #2030
- Two (2) supply hoses (1/4" ID x 3/8" OD x 10' long) with attached DISS fittings; one hose for air and one for oxygen.
- Bracket (for mounting MVP-10 to column)
- Instruction Manual and Warranty Card
- Infant Test Lung

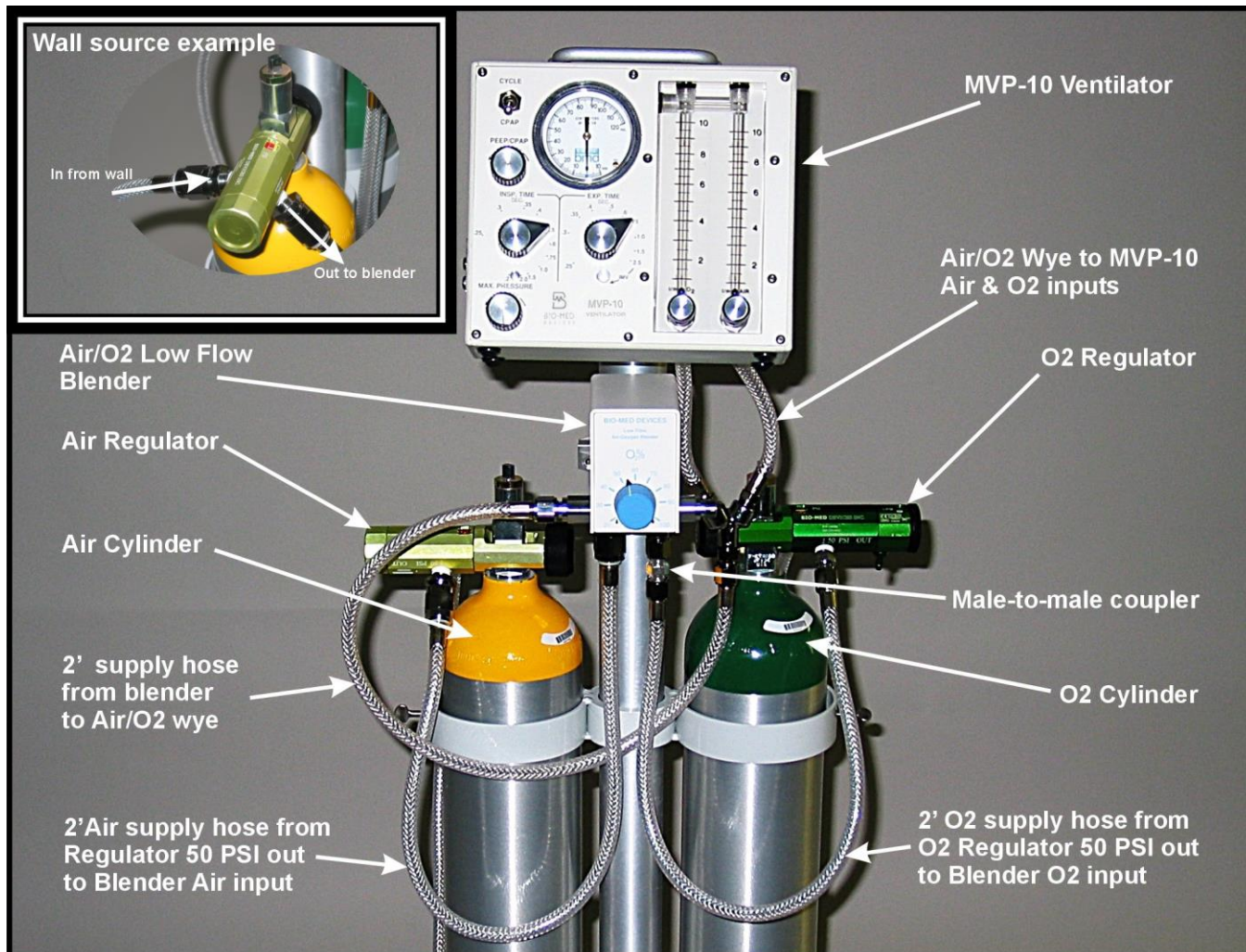
MVP-10 MRI COMPLETE PACKAGE

Note: All components are MR-conditional.

- MVP-10 MRI Ventilator
- Two (2) Patient Circuits, Catalog #2030
- Two (2) supply hoses (1/4" ID x 3/8" OD x 10' long) with attached DISS fittings; one hose for air and one for oxygen.
- Heavy Duty MRI Stand
- Low Flow Air/O2 MRI Blender
- Blender Bracket for 2" pole
- Blender Hose Kit (air/O2 supply wye & coupler & 2' supply hose)
- 2' O2 Supply Hose
- 2' Air Supply Hose
- Cylinder Brackets (upper and lower)
- Deluxe MRI O2 E-cylinder Regulator
- Deluxe MRI Air E-cylinder Regulator
- Instruction Manual and Warranty Card
- Infant Test Lung

See the next page for instructions on assembling this package.

MVP-10 COMPLETE PACKAGE SETUP INSTRUCTIONS



1. If not already done, assemble the stand per the instructions that came with it.
2. If not already done, install the patient connector (white nylon barb) into the brass tee on the back of the ventilator per the instruction that came with the barb.
3. With the tilt bracket that is on top of the stand facing you, insert an O₂ cylinder into the rings to the right and an air cylinder into the rings to the left. If necessary, loosen the locking knob and adjust the upper set of rings higher or lower to properly support the cylinders. It should be approximately in the position shown above.
4. Install the green, O₂ regulator onto the O₂ cylinder and the yellow air regulator onto the air cylinder. Before finally tightening the regulators on each cylinder, rotate the regulator body so the pressure gauge window is facing up and the 50 PSI OUT fitting is facing front as shown above. Rotate the cylinders in their brackets so the regulators are in the final, desired orientation and tighten the two thumbscrews against the cylinders to hold them in place.
5. Place the ventilator into the tilt bracket at the top of the stand. Its angle may be adjusted, if desired, by loosening the two front screws on top of the stand, adjusting the bracket and then retightening the two screws.
6. Remove the two screws holding the two halves of the blender bracket together and separate the two halves. Wrap the two halves around the pole and loosely secure the bracket to the pole below the ventilator using the two screws. Be sure the two pins in the bracket are towards the bottom so the blender does not fall through the bracket when installed. Hold the blender up in front of, but not engaged with the bracket to aid in where you want the final position of the bracket and blender to be. Once this is determined, secure the bracket in place by alternately tightening one screw and then the other so when done, they have been equally tightened, evidenced by somewhat equal gaps between the front and back halves.
7. Place the blender in the bracket. You may have to temporarily remove the ventilator from its bracket to do this.
8. Install the male-to-male coupler into the O₂ supply fitting on the bottom of the blender. To this coupler, connect one end of a 2' O₂ supply hose and then connect the other end to the OUT fitting on the O₂ regulator.
9. Connect one end of the 2' air supply hose to the air input on the blender and then connect the other end to the OUT fitting on the air regulator.
10. Connect the air/ O₂ wye to one end of the remaining 2' supply hose. Connect the wye to the air and O₂ inputs on the back of the ventilator and the remaining end of the 2' hose to the fitting on the left side of the blender as viewed from the front.
11. The two 10' supply hoses may be connected to their respective regulator input fittings labeled "50 PSI IN". These then are used to connect to air and O₂ wall sources.

WARRANTY

The Model MVP-10 Neonatal Pediatric Ventilator is warranted to be free from defects in workmanship and material for one (1) year from the date of purchase. To insure that its performance is maintained, any necessary repair during the warranty period must be performed by BMD or an authorized agent.

The warranty does not apply to the patient circuit and hoses supplied with the instrument. Nor does the warranty cover abuse or misuse of the instrument, or damage due to unauthorized servicing.

If service is required, the instrument must be properly packed and shipped pre-paid, directly or through your dealer, to:

Bio-Med Devices, Inc.

61 Soundview Road
Guilford, CT 06437

An explanation of the problem should accompany the equipment. Please include your name and telephone number in the paperwork.

There is no oral or implied warranty of the instrument's fitness for a particular purpose other than its intended use.

WARNINGS

Whenever the MVP10 is connected to a patient, a skilled operator should be present at all times at the ventilator or within visual or hearing range of the alarm system used with the MVP10.

High oxygen concentrations may be hazardous to the patient.

If the gas supply fails, the patient may breathe atmospheric gas through the failsafe valve. This is only a temporary emergency measure, which requires elevated inspiratory effort and should be corrected immediately.

A patient filter should always be used in the patient breathing circuit to prevent cross contamination. Breathing through the negative pressure relief valve in a contaminated environment can be hazardous.

Extreme care should be taken to assure that the patient circuit components are connected correctly. Improper connection can cause malfunction.

A test lung should be ventilated prior to each use to ensure that all modes are functioning correctly. An external spirometer should be used to verify correct volumes and flow rates.

Always be certain that the PIP Limit is set correctly and is operative even when volume limiting, to prevent possible inadvertent administration of high pressure. Increased pressure can be caused by blocked tubes, changes in patient compliance or resistance, or system malfunction.

Breathing through the negative pressure relief valve requires a greatly increased work of breathing and only air is provided. A situation in which the patient is breathing through this valve should be rectified immediately in order to prevent possible adverse affects to the patient.

Clean, dry, regulated gas supplies at 50 ± 5 PSI (345 ± 34.5 kPa) must be used at all times or malfunction may result. Note carefully that the logic (power) gas supply should be 100% oxygen at all times to give the greatest accuracy of the control settings and to assure the most trouble-free operation.

If the ventilator is to be used unattended or without remote monitoring, a high/low pressure alarm must be used at all times with the user within visual and/or audible range of this alarm.

A TWO-WAY SAFETY RELIEF VALVE is installed internally. This valve opens when pressure in the hose delivering gas to the patient rises above $70 \text{ cmH}_2\text{O} \pm 10 \text{ cmH}_2\text{O}$ or falls below $-4 \text{ cmH}_2\text{O}$. Its purpose is to limit maximum circuit pressure and to allow patient inspiration in the unlikely event of failure of the gas supply. It is meant to allow spontaneous breathing for a short time only until the operator can respond to the disconnect alarm and rectify the supply malfunction. In such a situation, its use in a contaminated environment could be hazardous. The SAFETY RELIEF VALVE must not be removed; and must be maintained with its screened port up and unobstructed.

Any HUMIDIFIER used with the MVP-10 must be a "flow-through" type having a low pressure drop. Use of a humidifier with a "bubbler" tube or pressure jet will render the SAFETY RELIEF VALVE ineffective.

Do not use in an MRI room unless the MVP-10 has been built by Bio-Med Devices for such an environment. This will be indicated by an MR-conditional label on top of the unit and an "M" at the end of the serial number.

Do not re-use disposable breathing circuits. Re-use of disposable (single-use) breathing circuits can result in contamination (patient infection) or circuit degradation (circuit can fall apart, develop holes, or exhibit polymer decay).

A high / low pressure alarm monitor must be used in conjunction with this ventilator. The high pressure alarm level should never be set above the lowest relief valve setting.

Do not continue using a ventilator which has been significantly impacted or abused.

Volume-limited ventilators should not be used on unattended patients.

CAUTIONS

The BMD MVP-10 Ventilator is intended for use by qualified clinical personnel only. This Instruction Manual should be read before using the equipment.

Because this is a CE marked device, it must never be modified without prior expressed written consent from Bio-Med Devices.

As noted later in the text of this Manual, the MVP-10's time cycle settings are affected by large changes in barometric pressure, flow rates, and gas composition. They are repeatable, however, within 5% under constant conditions. As with any ventilator, periodic blood gas studies should be made to ensure proper levels of ventilation.

Antistatic or electrically conductive hoses or tubing should not be used.

I. GENERAL

A. INTENDED USE

The model MVP-10 Ventilator is for respiratory support of neonatal and pediatric patients both in hospital and during transport. It is intended primarily for use in all applications requiring tidal volumes in the range up to 660 milliliters. It may be used with a wide range of I/E ratios, including inspiratory time greater than expiratory time.

WARNING: Do not use in an MRI room unless the MVP-10 has been built by Bio-Med Devices for such an environment. This will be indicated by an MR-conditional plaque on top of the unit and an "M" at the end of the serial number.

B. MODES OF OPERATION

It is a continuous flow Ventilator which may be used in any of the following operation modes:

- Time cycled, with volume or pressure limitation, with or without Positive End Expiratory Pressure (PEEP).
 - Intermittent Positive Pressure Ventilation (IPPV).
 - Intermittent Mandatory Ventilation (IMV).
- Continuous Positive Airway Pressure (CPAP).
- Continuous Oxygen Administration (COAD) or constant flow.

C. FEATURES

- Portable: compact and light weight
- May be hand carried or attached to incubator; used without interruption during transportation; compatible with masks, tents, and endotracheal tubes.
- Gas Powered: portable pressurized tank or wall outlet, providing 50 PSI oxygen or air.
- Operable in Hazardous Areas: non-electric, no shock hazard, case constantly self-purged.
- High Reliability: controlled by miniature pneumatic logic elements; fail-safe maximum pressure limits; negligible frictional wear.
- Very low compliance and dead space factors.
- Prevention of CO₂ build-up by constant flow wash-out.
- Readily usable with standard accessory humidifier, oxygen blender, oxygen analyzer and pressure alarms.

D. PERFORMANCE CHARACTERISTICS

Direct control is provided for inspiratory and expiratory times, air and oxygen flow rates, and maximum pressure and PEEP or CPAP levels within the patient circuit.

Oxygen concentration, respiratory rate, tidal volume, and I/E ratio may also be controlled.

- Oxygen concentration..... variable, 21% to 100%
- Respiratory rate..... variable, 0 to 120 breaths/min.
- Tidal volume..... variable, 0 to over 660 ml.
- I/E ratio..... variable

Oxygen concentration is determined by the air and oxygen flow rates indicated by two front panel meters. Flow rates corresponding to a desired oxygen concentration can be determined by use of CHART A. At extremely low flow rates accuracy may be reduced; for more accurate determination an auxiliary oxygen analyzer should be used.

Respiratory rate and I/E ratio are determined by INSP. TIME and EXP. TIME control settings. These settings are approximate time reference points which are repeatable within 5%.* For greater accuracy, an external monitoring device may be used.

The tidal volume, when operated in a time-cycled mode is the product of total flow and inspiratory time:

TIDAL VOLUME (ml) = TOTAL FLOW RATE (ml/sec) X INSPIRATORY TIME (sec)

NOTE: Flow rate is not Minute Volume

MINUTE VOLUME = TIDAL VOLUME X RESP. RATE

It should be noted that the PIP and PEEP/CPAP control settings are affected by flow. When flow is increased, the pressure levels set by these controls will increase somewhat. These changes may be noted on the pressure gauge and the settings readjusted.

*At elevations above sea level, the intervals set by the INSP. TIME and EXP. TIME controls are increased due to lower barometric pressure. The difference is about 2½% per 1000' of elevation. With an air supply connected to the POWER OXYGEN inlet fitting, the time intervals are about 10% less than with pure oxygen connected.

II. DESCRIPTION

A. PRINCIPLES OF OPERATION

The MVP-10 Ventilator provides continuous flow that may be time-cycled for automatic ventilation with either volume or pressure limits, and with or without Positive End Expiratory Pressure (PEEP). It may also be used without time cycling to provide continuous flow past the patient at ambient pressure, e.g. Continuous Oxygen Administration (COAD), or at a positive pressure, e.g. Continuous Positive Airway Pressure (CPAP).

1. Time-Cycled Modes:

A constant flow is provided past the patient WYE. The expiration valve is cycled so that it is closed for a pre-set time, (T_I) and opened for a pre-set time, (T_E). When it is opened, gas flows past the WYE at ambient pressure and is vented to atmosphere; when closed, exhaust to atmosphere is prevented and pressure builds up within the circuit, delivering gas to the patient. Gas flow into the system is essentially constant since the source pressure (50 PSI) is much greater than the maximum possible circuit pressure (80 cm H₂O, or 1.1 PSI). An example of this use is for administration of Intermittent Positive Pressure Ventilation (IPPV).

a. Volume-limited:

The pressure developed in the patient's airway depends upon the total system-patient compliance and the tidal volume being administered. When the PIP control is set at a pressure above the pressure developed in the circuit, then the automatic ventilation is volume limited, and a constant flow is delivered to the patient. In this condition the tidal volume (V_t) is the product of the total flow rate (V_i) and inspiratory time (T_I):

$$V_t = T_I \times V_i$$

and minute volume (V) is the product of tidal volume and respiratory rate (f):

$$V = V_t \times f$$

Should the patient compliance become less or resistance increase, then the developed pressure could increase up to the PIP setting. At that point, the pressure in the patient circuit becomes limited and constant. Tidal volume is no longer delivered to the patient; excess gas is vented to atmosphere.

b. Pressure-limited:

With flow rate and inspiratory time set, the pressure developed in the patient's airway depends upon the system and patient compliances. This pressure is limited by the setting of the PIP control. While the expiration valve is closed, pressure within the circuit builds up to the PIP setting. At that point, the valve acts to allow flow past the WYE to atmosphere, while maintaining the airway pressure at the PIP setting. During the expiratory time, the valve is opened.

c. Intermittent Mandatory Ventilation (IMV):

Respiratory rate is set to allow one or more voluntary breaths between machine-controlled breaths. With sufficient flow, the patient's minute volume and the voluntary tidal volumes are not necessarily limited by the machine parameters. The respiratory rate may be set to support the patient, but less than the anticipated voluntary respiration rate. The lower respiratory rate is normally set by increasing the Expiratory Time.

d. Positive End Expiratory Pressure (PEEP):

By use of the PEEP/CPAP control, a pressure may be maintained in the patient's airway during the expiratory time in any of the above time-cycled modes (i.e. PEEP), or during a non-cycled mode with continuous flow-past the patient (i.e. CPAP).

Adjustment of this control places a controlled pressure on the diaphragm of the expiration valve maintaining the patient circuit at this pressure during the expiratory time.

2. Non-Cycled Modes:

A constant flow is provided past the patient WYE, without cycling the expiration valve.

a. Continuous Positive Airway Pressure (CPAP):

A pre-set pressure is maintained across the expiration valve. Continuous flow is provided past the patient WYE, allowing the patient to inhale from this flow while maintaining the airway at the pre-set constant positive pressure.

b. Continuous Flow, or Constant Oxygen Administration (COAD):

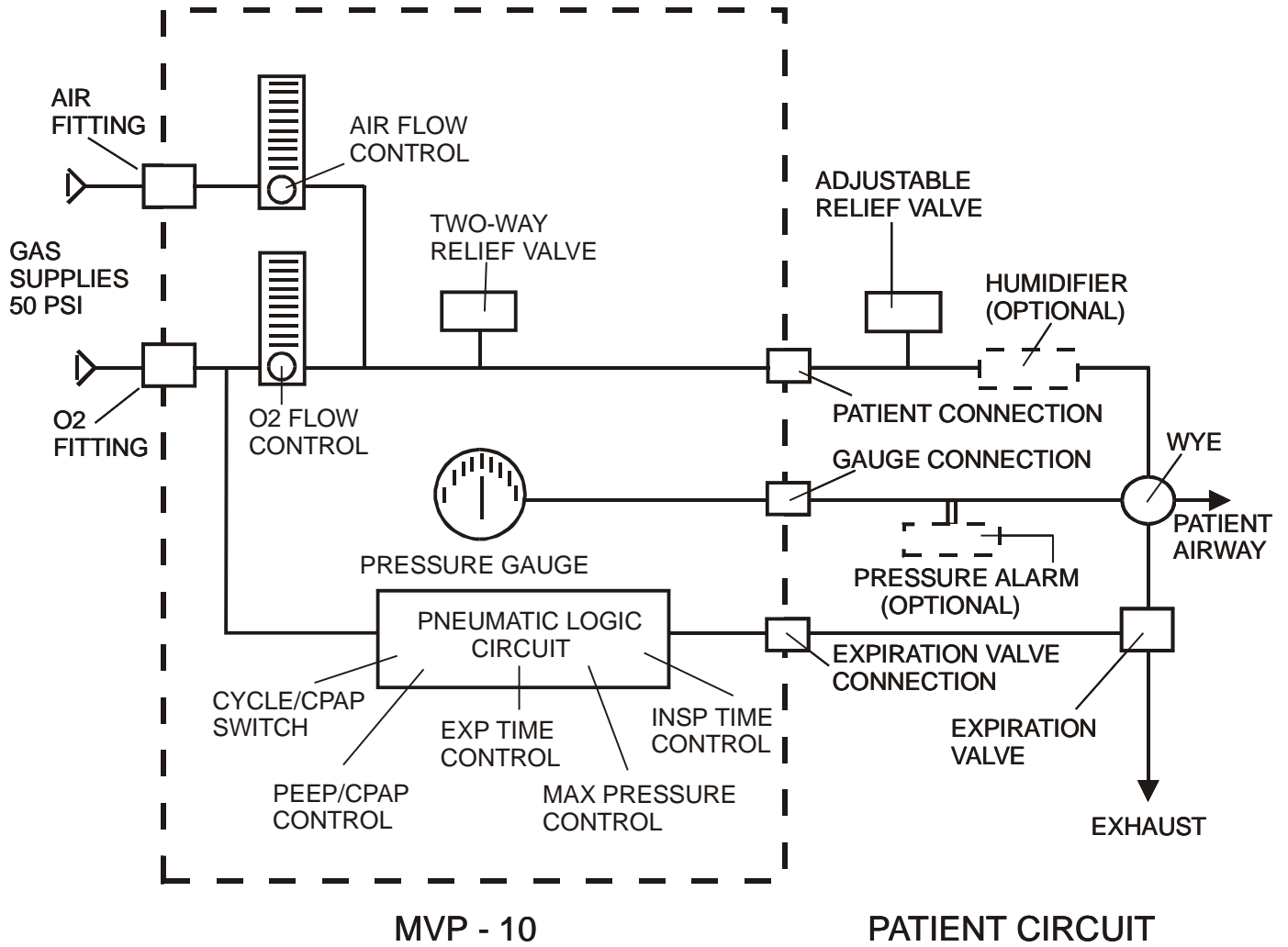
No pressure is maintained across the open expiration valve (PEEP/CPAP control fully clockwise), and a continuous flow is provided past the patient WYE, allowing the patient to inhale from the flow at ambient pressure.

Figure 2 is a flow diagram showing the interconnections within the MVP-10. The expiration valve is controlled by a pneumatic logic circuit which is comprised of four (4) (early models had three (3)) miniature diaphragm devices, four (4) adjustable valves, several fixed flow resistances and a flow accumulator. The diaphragm device is a gas actuated, double-piloted, spring-offset, three-way valve. The entire logic circuit is isolated from the patient circuit by the diaphragm of the expiration valve. Gas flowing into the logic circuit cannot enter the patient circuit, and the exhalation gas cannot enter the logic circuit.

A 40-micron filter is incorporated in the input of the logic circuit. The pneumatic switching elements have a rated life of over one-billion switching operations, at rated supply pressure.

The logic circuit controls the two time intervals for inspiration and expiration and controls the pressure in the patient circuit.

FIGURE 2 - FLOW DIAGRAM



B. CONTROLS, INDICATORS, AND CONNECTIONS

CONTROLS (Front Panel)

- (1) CYCLE/CPAP Switch: Selects non-cycling (CPAP) or time-cycled (CYCLE) modes of operation.
- (2) PEEP/CPAP Control: Sets PEEP level when CYCLE/CPAP switch is set to CYCLE, or CPAP level when set to CPAP.
- (3) EXP. TIME Control: Sets expiratory time in time- cycled modes. Calibrated in seconds from 0.25 to 2.5 (May be set to 30 seconds for IMV).
- (4) INSP. TIME Control: Sets inspiratory time in time- cycled modes. Calibrated in seconds from 0.2 to 2.0.
- (5) PIP Control: Sets maximum pressure limit in patient circuit. Used to establish a pressure- limited mode.
- (6) LPM OXYGEN Control: Sets flow rate of oxygen.
- (7) LPM AIR Control: Sets flow rate of air.

INDICATORS (Front Panel)

- (8) PRESSURE Gauge: Indicates proximal airway pressure (in cm H₂O).
- (9) OXYGEN Flowmeter: Indicates oxygen flow into system (in liters/minute).
- (10) AIR Flowmeter: Indicates airflow into system (in liters/minute).

CONNECTIONS (Rear Panel)

- (11) AIR: Connection to pressurized source of clean, dry, oil-free air (50±5 PSI). Mates with female DISS air fitting.
- (12) POWER OXYGEN: Connection to pressurized source of 100% Oxygen, medical grade (50±5 PSI, 345 ±34.5 kPa). When only one gas supply is used, it must always be connected to POWER OXYGEN connector, since only this line supplies the logic circuit. This mates with female DISS oxygen fitting.
- (13) GAUGE: Connection to patient WYE (for measurement of pressure in patient circuit). Connect 1/8" ID tubing.
- (14) PATIENT: Connection to patient circuit at ADJUSTABLE RELIEF VALVE and through HUMIDIFIER (if used).
- (15) EXP. VALVE: Connection to expiration valve (for control of time-cycling, and CPAP or PEEP or PIP). Connect 1/8" ID tubing.

CAUTION: Antistatic or electrically conductive hoses or tubing should not be used.

NOTE: Filtered and dried, regulated gas supplies must be used to ensure reliable operation.

C. SPECIFICATIONS

Gas Supplies:

Air: Clean, dry, oil-free, 50 ±5 PSI (345 ±34.5 kPa) pressure

Oxygen: Clean, dry, medical grade, 50 ±5 PSI (345 ±34.5 kPa) pressure

Inspiratory Time: variable 0.2 to 2.0 seconds calibrated*

Expiratory Time: variable 0.25 to 2.5 seconds calibrated*; (Variable to 30 seconds, uncalibrated)

I/E Ratio: variable 0.2 / 30 to 2.0 / 0.25 (equals 1/150 to 8/1)

Oxygen Flow Rate: variable 0 to 10.0 liters/minute meter calibration accuracy: $\pm 3\%$ full scale

Air Flow Rate: variable 0 to 10.0 liters/minute, meter calibration accuracy: $\pm 3\%$ full scale

Max. Pressure Setting: variable up to 70 ± 10 cm H₂O

Pressure Gauge: -20 to +120 cm H₂O; $\pm 3\%$ full-scale accuracy (at ATPD- ambient temperature & pressure dry)

Fail-Safe Pressure Limitations:

TWO-WAY SAFETY RELIEF VALVE (installed internally): opens at pressures above 70 ± 10 cm H₂O or below -4 ± 1 cm H₂O

ADJUSTABLE RELIEF VALVE (installed at PATIENT connection): user adjustable to open between a maximum pressure of 80 cm H₂O ± 10 cmH₂O when turned fully clockwise to a minimum of 10 cmH₂O ± 5 cmH₂O when turned fully counterclockwise.

PEEP/CPAP Range: variable up to 18 ± 3 cm H₂O at flow of 6 liters/minute

Breathing Circuit Insp Resistance: 0.03 cm H₂O / lpm, at 5 lpm flow (model 2030)
Breathing Circuit Exp Resistance: 0.06 cm H₂O / lpm, at 5 lpm flow (model 2030)
Dead Space: 0.5 ml maximum

Consumption of gas by Logic Circuits: approximately 4 liters/minute at 50 breaths per minute

Weight: 2.3 kg. (5 lbs. 2 oz.)

Physical Dimensions: 20 x 23 x 7.4 cm (8 x 9 x 3 in.)

Storage Temperature: 32° to 122°F (0° to 50°C)

Operating Temperature: 14° to 122°F (-10° to 50°C)

NOTE: Two safety valves are provided to protect the patient from:

- asphyxiation due to failure, disconnection or depletion of the gas supply
- excessive pressure due to blockage or failure of the expiration valve or hose.

The TWO-WAY SAFETY RELIEF VALVE is installed internally. It vents pressures above $70 \text{ cm H}_2\text{O} \pm 10 \text{ cm H}_2\text{O}$. It also opens at negative pressures below $-4 \text{ cm H}_2\text{O}$ to allow patient inspiration. (If protection at a lower negative pressure is desired, another more sensitive valve should be added.)

The ADJUSTABLE RELIEF VALVE is installed externally and may be adjusted to vent pressures between $70 \text{ cm H}_2\text{O} \pm 10 \text{ cmH}_2\text{O}$ and $10 \text{ cm H}_2\text{O} \pm 5 \text{ cmH}_2\text{O}$.

* INSP. TIME and EXP. TIME control settings are calibrated at sea level and 20°C ., ATPD, using USP oxygen. Large changes of barometric pressure or altitude changes, or use of diluted oxygen will affect time calibration; hence, the settings should be regarded as reference points rather than precise time indicators. However, time settings are repeatable within 5%. Approach time settings in a clockwise direction.

III. INSTALLATION CONSIDERATIONS

A. EQUIPMENT REQUIRED

All equipment required for use of the MVP-10 has been supplied with the instrument, except for the gas supply. No special tools are needed.

It will be convenient to have available a test lung when setting the ventilator parameters before connecting to a patient. If Bio-Med Devices Infant Test Lung (BMD #1021) is not available, a simple finger cot may be attached to the patient WYE or the WYE may be occluded.

B. SUPPLY GAS

The supply gas is normally a pressurized tank(s) or wall source of medical or therapy grade oxygen and/or air. The pressurized tanks should be fitted with regulators adjusted to 50 ±5 PSI (345 ±34.5 kPa).

No flow restricting device (e.g. flowmeter, throttling valve) can be placed in the supply line. A flow restricting device interferes with the operation of the pneumatic logic and may render the time-cycling inoperative.

The MVP-10 will operate with a supply pressure outside of the 50 ±5 PSI (345 ±34.5 kPa) range, but accuracy of settings may be impaired. In no case should a supply pressure less than 35 PSI (242 kPa) or over 100 PSI (690 kPa) be connected to the MVP-10 as it will cause malfunction of the ventilator.

The operating time that may be expected from common tank sizes with different flow rates is given in Table B.

C. MOUNTING BRACKET

The supplied mounting bracket may be installed on a column.

D. PATIENT CIRCUIT

The patient circuit supplied with the MVP-10 incorporates approximate 3-foot lengths of tubing between the MVP-10 and (1) the patient WYE and (2) the expiration valve.

WARNING: Always use a bacterial filter.

WARNING: Do not re-use disposable breathing circuits

E. OPTIONAL EQUIPMENT

Other standard equipment which may be used with the MVP-10 at the option of the user include:

Oxygen Blender --connected in the supply line to the POWER OXYGEN connection, or both POWER OXYGEN and AIR connectors using BMD "Y"

Adapter #2022.

Humidifier --connected on "down-stream" side of SAFETY RELIEF VALVE. Only a flow-through humidifier, having a low pressure drop, may be used; otherwise protection provided by the SAFETY RELIEF VALVE is rendered ineffective. A humidifier with a "bubbler" tube or pressure jet should not be used.

Pressure Alarms (high and/or low) --T-connected to Gauge line.

A Humidifier or Pressure Alarm connection can affect system compliance. Connecting hoses and water level in the Humidifier should be arranged so that system compliance is increased minimally. This means that extra hose lengths should be short, and water level in the Humidifier should be maintained at a high level. Some alarm units affect the volume of gas in the system. The operating characteristics of any auxiliary device should be carefully considered before using it with the MVP-10.

IV. VENTILATOR SET-UP

CAUTION: Antistatic or electrically conductive hoses or tubing should not be used.

A. CONNECTION OF GAS SUPPLY

Using the MVP-10 front-panel flowmeters for mixing:

- a) Connect 50 PSI (345 kPa) oxygen supply to rear-panel fitting marked POWER OXYGEN.
- b) Connect 50 PSI (345 kPa) air supply to rear-panel fitting marked AIR.
- c) If only a single gas supply is used, it must be connected to the POWER OXYGEN fitting.
- d) If using an external Oxygen Blender, connect 50 PSI (345 kPa) Blender output to rear-panel fitting marked POWER OXYGEN, or both POWER OXYGEN and AIR fitting.

In either case, it is essential that:

- The supplies are 50 PSI (345 kPa) sources without flow restricting devices (e.g. flowmeter, valve).
- A 50 PSI (345 kPa) supply must always be connected to the POWER OXYGEN fitting for proper operation of the pneumatic logic controls.
- Hose fittings should be hand tightened to avoid damage to fittings.
- The gas supply should be clean and dry (If gas supply contains moisture, add a moisture trap in the supply line to the MVP-10).
- When a pressurized supply is not connected to the AIR fitting, the air flowmeter valve should be turned off (fully clockwise).

B. CONNECTION OF PATIENT CIRCUIT

- a) Place expiration valve on bracket at side of MVP-10 case.
- b) Connect short length of tubing (approx. 1/8" ID x 12" long) between expiration valve control connection and EXP. VALVE fitting at rear of MVP-10. (Always connect this tubing first to avoid mistakes.)
- c) Connect small diameter line (1/8" ID) in patient circuit, from WYE,

to GAUGE fitting at rear of MVP-10.

d) If a Humidifier is used, connect it to the down-stream side of the SAFETY RELIEF VALVE installed on the PATIENT fitting at the rear of the MVP-10. The large diameter hose of the patient circuit is then connected to the Humidifier outlet. Humidification can be provided by a heated flow-through humidifier or artificial nose. If a Humidifier is not used, connect hose of patient circuit directly to ADJUSTABLE RELIEF VALVE.

e) Connect patient port of WYE to a test lung (Infant Test Lung BMD #1021 or occlude). After selection of parameters and adjustment of controls as described (Sec. V.), observe proper functioning before attaching to the patient.

NOTE: Always be certain that the patient circuit hoses are not pinched or twisted by incubator doors, heavy instruments, etc.

V. SELECTION OF VENTILATION PARAMETERS AND ADJUSTMENT OF CONTROLS

A. TIME-CYCLED OPERATION

(FOR AUTOMATIC VENTILATION (e.g. IPPV, IMV, with or without PEEP))

Determine and note patient requirements for tidal volume, respiratory rate, I/E ratio, and oxygen concentration. Refer to CHART C, to find inspiratory time (T_I), expiratory time (T_E), and MULTIPLICATION FACTOR to compute flow rate for required tidal volume.

STEP 1 Set PIP control fully counterclockwise, PEEP/CPAP control fully clockwise.

STEP 2 Set INSP. TIME and EXP. TIME controls in a clockwise direction to required times.

STEP 3 Determine total flow (V_t) required by multiplying the required tidal volume (V_t) by the approximate MULTIPLICATION FACTOR (from CHART C) or by use of slide rule. Set flow rate controls for this total flow.

STEP 4 Set CYCLE/CPAP switch in CYCLE position.

STEP 5 For oxygen concentration (FIO_2) other than air or 100% oxygen, set by adjusting integral flow rate controls, or by adjusting external oxygen blender:

- a) Using integral flow rate controls, refer to CHART A, which relates oxygen, air, and total flows to oxygen concentration. Set air and oxygen flow for required concentration and total flow determined in Step 3.
- b) Using external oxygen blender, set blender for prescribed concentration, and integral flow rate control for required total flow. NOTE: Output from oxygen blender must be connected to POWER OXYGEN fitting. If required flow exceeds 10 liters/minute, output of blender is connected to both POWER OXYGEN and AIR fittings, using a Y adapter (not supplied). BMD accessory #2022.

EXAMPLE:

Prescribed Parameters:

Tidal Volume	= 10 ml
Respiratory Rate	= 40 breaths/minute
I/E Ratio	= 1:2
Oxygen Concentration	= 60%
Machine Compliance Factor	= 0.5 ml/cm H ₂ O

From CHART C:

Respiratory Cycle	= 1.5 secs.
Inspiratory Time	= 0.5 secs.
Expiratory Time	= 1.0 secs.
Multiplication Factor	= 120

$$\text{Total Flow (V}_i\text{)} = \text{Tidal Volume (V}_t\text{)} \times \text{Mult. Factor}$$

$$10 \text{ ml} \times 120 = 1200 \text{ ml/min (1.2 liters/min)}$$

or

$$\text{Total Flow (V}_i\text{)} = \frac{\text{Tidal Volume (V}_t\text{)}}{\text{Inspiratory Time (T}_i\text{)}}$$

$$\text{Total Flow (V}_i\text{)} = \frac{10 \text{ ml}}{0.5 \text{ sec}}$$

$$\text{Total Flow (V}_i\text{)} = 20 \text{ ml/sec (1.2 liters/min)}$$

From CHART A:

For 60% oxygen concentration

$$\text{Oxygen Flow (V}_{i\text{O}_2}\text{)} = 600 \text{ ml/min (0.6 liters/min)}$$

$$\text{Air Flow (V}_{\text{Air}}\text{)} = 600 \text{ ml/min (0.6 liters/min)}$$

STEP 6 Attach test lung to WYE and observe proper cycling. If operation is normal, remove test lung and determine compliance of system as follows:

- a) Plug WYE port, which connects to patient airway.
- b) With parameters set for prescribed tidal volume, observe maximum reading on pressure gauge during inspiratory time. If gauge reading is over 70 cm H₂O, temporarily reduce tidal volume by lowering flow rate and/or inspiratory time so that

gauge reading is less than 70 cm H₂O.

c) Compliance factor (C_M) of system, without patient connected, is:

$$C_M = \frac{\text{Tidal Volume (V}_t\text{)}}{\text{Pressure Gauge Reading (P)}}$$

Note: V_t = V_I x T_I

The compliance factor of the MVP-10 with patient circuit is approximately 0.12 ml/cm H₂O. With a humidifier connected, it is between 0.2 and 0.5 ml/cm H₂O, depending upon the humidifier, its water level and connecting hoses.

A compliance factor of 0.5 ml/cm H₂O means that 0.5 ml of gas is stored in the patient circuit and humidifier for each cm H₂O of pressure during the respiratory cycle, and does not go to the patient. In the example in STEP 5, assume that the pressure gauge reaches 10 cm H₂O during the cycle. This would mean that 10 x 0.5 or 5 ml is stored in the circuit. The apparent tidal volume is 10 ml, but only a 5 ml tidal volume would be delivered to the patient.

STEP 7 Compensate for the compliance of the system by increasing total flow.

In the previous example, 5 ml must be supplied for the compliance in the system, as well as the prescribed 10 ml tidal volume for the patient. Therefore, adjust flow rate to supply a 15 ml tidal volume:

Adjusted Flow = 15 ml x 120 = 1800 ml/min (1.8 liters/min)

The pressure gauge reading will increase a little, because of the greater volume in the system, to say, 12 cm H₂O. Compliance volume would now be 12 x 0.5, or 6 ml, and a tidal volume of 9 ml would be supplied to the patient.

To more closely obtain the prescribed tidal volume, a second compensatory increase in flow is necessary. With flow increased to 2 liters/min, or about 33 ml/sec., the pressure gauge may indicate 13 cmH₂O. The volume per cycle would now be 33 ml/sec. x 0.5 sec., or 16.5 ml. The compliance volume would be 13 x 0.5, or 6.5 ml, and the prescribed tidal volume of 10 ml would be supplied to the patient.

STEP 8 Volume-limited or pressure-limited operation may be established as follows:

- a) For Volume-limited operation - Set the PIP control fully counterclockwise.

With patient airway connected to WYE, observe maximum pressure during cycle.

Detach patient airway from WYE and block patient port of WYE.

Adjust PIP control so cycle pressure is 5 to 10 cm H₂O higher than PIP with patient connected.

Re-connect the patient airway to WYE.

The MVP-10 will now be limited to the tidal volume determined by the flowmeter and INSP. TIME settings, and will be limited to a maximum pressure in case resistance or compliance characteristics change.

- b) For Pressure-limited operation - Observe maximum pressure during inspiratory time.

Adjust ADJUSTABLE RELIEF VALVE (pre-set at factory to open at 70-80 cmH₂O depending on flow) by occluding patient port of WYE and turning knurled adjusting cap counterclockwise until valve relieves pressure at 5 to 10 cmH₂O above desired pressure limit. Use lock ring to secure adjusting cap.

Adjust PIP control until the desired pressure limit is seen during inspiration. Note that the PIP level is somewhat affected by the flow rate. It should be set with the particular flow rate used.

The MVP-10 will now be limited to the pressure set. When operating in this mode, the exact Tidal Volume is unknown, since gas is vented to the atmosphere as soon as the pre-set pressure limit is reached during each inspiration. Calculation of and compensation for compliance losses are unnecessary.

STEP 9 If PEEP is to be used, set the desired level using the PEEP/CPAP control. Adjust control until the pressure gauge indicates the desired level during the expiratory time. Note that the PEEP level is somewhat sensitive to flow rate. The PEEP control should be set with the flow rate used.

STEP 10 For Intermittent Mandatory Ventilation (IMV) determine prescribed tidal volume, inspiratory time, and rate of automatic cycles. Calculate flow rate:

$$\text{Flow (V}_i\text{)} = \frac{\text{Tidal Volume (V}_t\text{)}}{\text{Inspiratory Time (T}_i\text{)}}$$

Set expiratory time for desired rate of automatic cycles. Rate in respirations/minute is equal to 60 divided by the sum of inspiratory and expiratory times in seconds.

$$\text{Rate (f)} = \frac{60}{\text{Insp. (T}_i\text{)} + \text{Exp. times (T}_E\text{)}}$$

IMV is normally introduced and adjusted by increasing expiratory time.

B. NON-CYCLED OPERATION

(FOR CONTINUOUS FLOW PAST PATIENT WITH OR WITHOUT POSITIVE AIRWAY PRESSURE, e.g. CPAP, COAD).

Determine prescribed oxygen concentration.

STEP 1 Set PEEP/CPAP control fully clockwise.

STEP 2 Set CYCLE/CPAP switch to CPAP position.

STEP 3 Empirically determine total flow required by setting flow so that the pressure gauge reading does not drop during patient inhalation

STEP 4 For oxygen concentration other than air or 100% oxygen, set by adjusting integral flow rate controls according to CHART A, or by adjusting external oxygen blender.

STEP 5 If CPAP is to be used, connect test lung to WYE. Set CPAP level by adjusting PEEP/CPAP control for desired level as indicated by MVP-10 pressure gauge. Disconnect test lung. Note that CPAP level is somewhat sensitive to flow rate. PEEP/CPAP control should be set at the flow rate used.

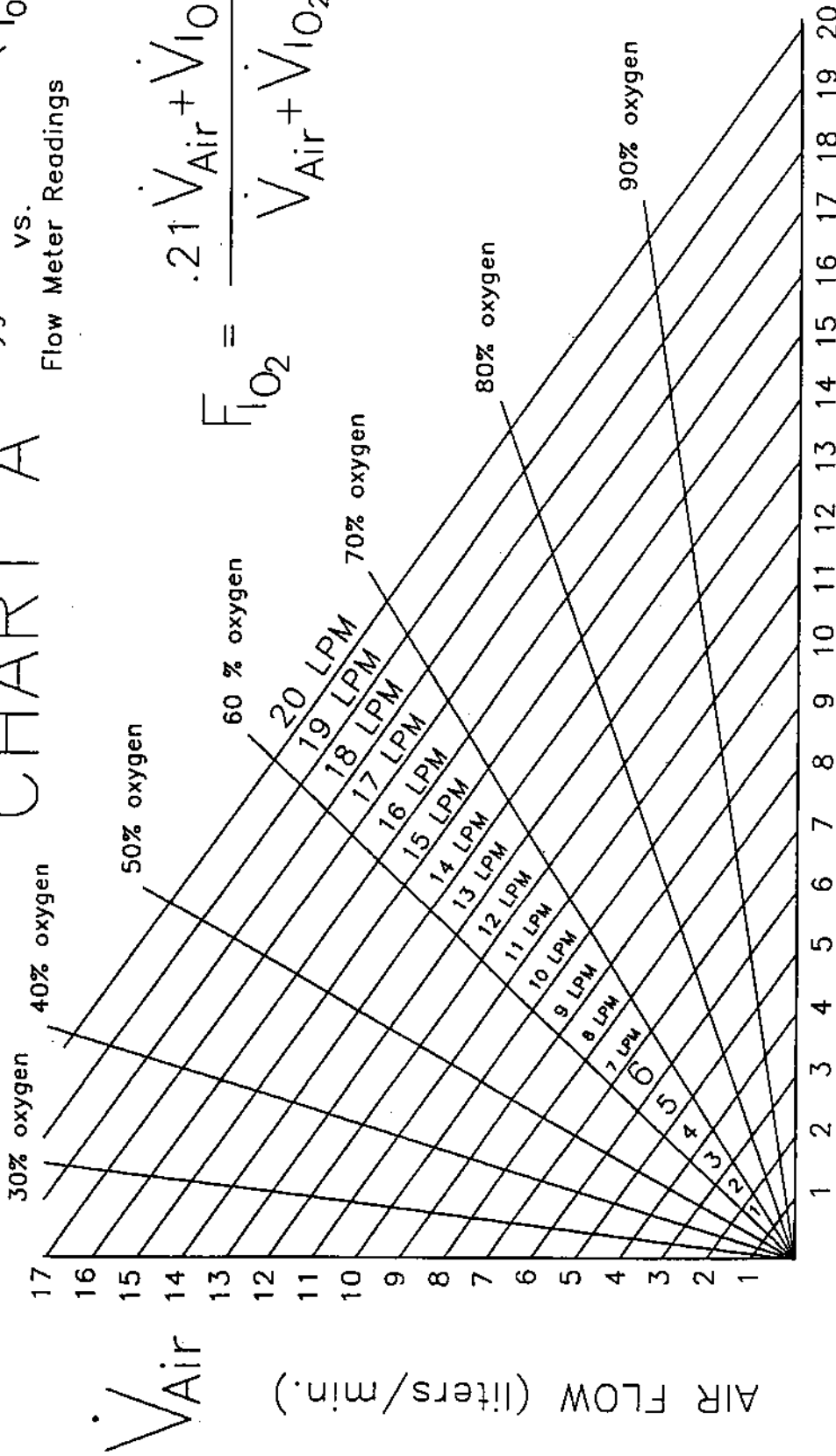
STEP 6 Connect the patient airway to WYE. If CPAP is being used, observe level and adjust if necessary.

NOTE: If MVP-10 pressure gauge reading drops significantly during patient inhalation, the flow rate should be increased.

CHART A

Oxygen concentration (F_{IO_2})
vs.
Flow Meter Readings

$$F_{IO_2} = \frac{.21 \dot{V}_{Air} + \dot{V}_{IO_2}}{\dot{V}_{Air} + \dot{V}_{IO_2}}$$



When using the dual column flowmeter as a blender, the following table may be used to determine flow rates to obtain the FiO2 and Total Flow (T-Flow)

FIO2	T-FLOW	LPM AIR	LPM O2
25%	9	8.5	0.5
25%	9.5	9	0.5
25%	10	9.5	0.5
25%	10.5	10	0.5
26%	7.5	7	0.5
26%	8	7.5	0.5
26%	8.5	8	0.5
27%	6.5	6	0.5
27%	7	6.5	0.5
28%	5.5	5	0.5
28%	6	5.5	0.5
28%	11	10	1
29%	5	4.5	0.5
29%	9.5	8.5	1
29%	10	9	1
29%	10.5	9.5	1
30%	4.5	4	0.5
30%	8.5	7.5	1
30%	9	8	1
31%	4	3.5	0.5
31%	8	7	1
31%	11.5	10	1.5
32%	3.5	3	0.5
32%	7	6	1
32%	7.5	6.5	1
32%	10.5	9	1.5
32%	11	9.5	1.5
33%	6.5	5.5	1
33%	9.5	8	1.5
33%	10	8.5	1.5
34%	3	2.5	0.5
34%	6	5	1
34%	9	7.5	1.5
34%	12	10	2
35%	5.5	4.5	1
35%	8.5	7	1.5
35%	11	9	2
35%	11.5	9.5	2
36%	8	6.5	1.5
36%	10.5	8.5	2
37%	12.5	10	2.5
37%	2.5	2	0.5
37%	5	4	1
37%	7.5	6	1.5
37%	10	8	2
37%	12	9.5	2.5
38%	7	5.5	1.5

FIO2	T-FLOW	LPM AIR	LPM O2
38%	9.5	7.5	2
38%	11.5	9	2.5
39%	4.5	3.5	1
39%	6.5	5	1.5
39%	9	7	2
39%	11	8.5	2.5
39%	13	10	3
40%	12.5	9.5	3
40%	8.5	6.5	2
40%	10.5	8	2.5
41%	12	9	3
41%	4	3	1
41%	6	4.5	1.5
41%	8	6	2
41%	10	7.5	2.5
41%	13.5	10	3.5
42%	11.5	8.5	3
45%	13	9	4
46%	8	5.5	2.5
46%	9.5	6.5	3
46%	11	7.5	3.5
46%	12.5	8.5	4
46%	14	9.5	4.5
46%	14.5	10	4.5
47%	3	2	1
47%	4.5	3	1.5
47%	6	4	2
47%	7.5	5	2.5
47%	9	6	3
47%	10.5	7	3.5
47%	12	8	4
47%	13.5	9	4.5
47%	15	10	5
48%	11.5	7.5	4
48%	13	8.5	4.5
48%	14.5	9.5	5
49%	7	4.5	2.5
49%	8.5	5.5	3
49%	10	6.5	3.5
49%	12.5	8	4.5
49%	14	9	5
49%	15.5	10	5.5
50%	5.5	3.5	2
50%	9.5	6	3.5
50%	11	7	4
50%	13.5	8.5	5
50%	15	9.5	5.5

FIO2	T-FLOW	LPM AIR	LPM O2
51%	4	2.5	1.5
51%	6.5	4	2.5
51%	8	5	3
51%	10.5	6.5	4
51%	12	7.5	4.5
51%	13	8	5
51%	14.5	9	5.5
51%	16	10	6
52%	9	5.5	3.5
52%	11.5	7	4.5
52%	14	8.5	5.5
52%	15.5	9.5	6
52%	16.5	10	6.5
53%	7.5	4.5	3
53%	10	6	4
53%	12.5	7.5	5
53%	2.5	1.5	1
53%	5	3	2
53%	11	6.5	4.5
53%	13.5	8	5.5
53%	15	9	6
53%	16	9.5	6.5
54%	6	3.5	2.5
54%	8.5	5	3.5
54%	9.5	5.5	4
54%	12	7	5
54%	13	7.5	5.5
54%	14.5	8.5	6
54%	15.5	9	6.5
54%	17	10	7
55%	3.5	2	1.5
55%	7	4	3
55%	10.5	6	4.5
55%	11.5	6.5	5
55%	14	8	6
55%	15	8.5	6.5
55%	16.5	9.5	7
55%	17.5	10	7.5
56%	4.5	2.5	2
56%	8	4.5	3.5
56%	9	5	4
56%	12.5	7	5.5
56%	13.5	7.5	6
56%	14.5	8	6.5
56%	16	9	7
56%	17	9.5	7.5
56%	18	10	8

57%	5.5	3	2.5
57%	6.5	3.5	3
57%	10	5.5	4.5
57%	11	6	5
57%	12	6.5	5.5
57%	13	7	6
57%	15.5	8.5	7
57%	16.5	9	7.5
57%	17.5	9.5	8
58%	7.5	4	3.5
58%	8.5	4.5	4
58%	9.5	5	4.5
58%	14	7.5	6.5
58%	15	8	7
58%	16	8.5	7.5
58%	17	9	8
58%	18	9.5	8.5
59%	10.5	5.5	5
59%	11.5	6	5.5
59%	12.5	6.5	6
59%	13.5	7	6.5
59%	14.5	7.5	7
59%	15.5	8	7.5
59%	16.5	8.5	8
59%	17.5	9	8.5
61%	6	3	3
61%	8	4	4
61%	9	4.5	4.5
61%	10	5	5
61%	11	5.5	5.5
61%	12	6	6
61%	13	6.5	6.5
61%	15	7.5	7.5
61%	3	1.5	1.5
61%	4	2	2
61%	5	2.5	2.5
61%	7	3.5	3.5
61%	14	7	7
61%	16	8	8
61%	17	8.5	8.5
61%	18	9	9
62%	10.5	5	5.5
62%	11.5	5.5	6
62%	12.5	6	6.5
62%	13.5	6.5	7
62%	14.5	7	7.5
62%	15.5	7.5	8
62%	16.5	8	8.5
62%	17.5	8.5	9
63%	7.5	3.5	4

63%	8.5	4	4.5
63%	9.5	4.5	5
63%	14	6.5	7.5
63%	15	7	8
63%	16	7.5	8.5
63%	17	8	9
63%	18	8.5	9.5
64%	5.5	2.5	3
64%	6.5	3	3.5
64%	10	4.5	5.5
64%	11	5	6
64%	12	5.5	6.5
64%	13	6	7
64%	15.5	7	8.5
64%	16.5	7.5	9
64%	17.5	8	9.5
65%	4.5	2	2.5
65%	8	3.5	4.5
65%	9	4	5
65%	12.5	5.5	7
65%	13.5	6	7.5
65%	14.5	6.5	8
65%	16	7	9
65%	17	7.5	9.5
65%	18	8	10
66%	3.5	1.5	2
66%	7	3	4
66%	10.5	4.5	6
66%	11.5	5	6.5
66%	14	6	8
66%	15	6.5	8.5
66%	16.5	7	9.5
66%	17.5	7.5	10
67%	6	2.5	3.5
67%	8.5	3.5	5
67%	9.5	4	5.5
67%	12	5	7
67%	13	5.5	7.5
67%	14.5	6	8.5
67%	15.5	6.5	9
67%	17	7	10
68%	2.5	1	1.5
68%	5	2	3
68%	7.5	3	4.5
68%	11	4.5	6.5
68%	13.5	5.5	8
68%	16	6.5	9.5
68%	10	4	6
68%	12.5	5	7.5
68%	15	6	9

69%	9	3.5	5.5
69%	11.5	4.5	7
69%	14	5.5	8.5
69%	15.5	6	9.5
69%	16.5	6.5	10
70%	4	1.5	2.5
70%	6.5	2.5	4
70%	8	3	5
70%	10.5	4	6.5
70%	12	4.5	7.5
70%	13	5	8
70%	14.5	5.5	9
70%	16	6	10
71%	5.5	2	3.5
71%	9.5	3.5	6
71%	11	4	7
71%	13.5	5	8.5
71%	15	5.5	9.5
72%	7	2.5	4.5
72%	8.5	3	5.5
72%	10	3.5	6.5
72%	12.5	4.5	8
72%	14	5	9
72%	15.5	5.5	10
73%	11.5	4	7.5
73%	13	4.5	8.5
73%	14.5	5	9.5
74%	3	1	2
74%	4.5	1.5	3
74%	6	2	4
74%	7.5	2.5	5
74%	9	3	6
74%	10.5	3.5	7
74%	12	4	8
74%	13.5	4.5	9
74%	15	5	10
75%	8	2.5	5.5
75%	9.5	3	6.5
75%	11	3.5	7.5
75%	12.5	4	8.5
75%	14	4.5	9.5
75%	14.5	4.5	10
76%	5	1.5	3.5
76%	6.5	2	4.5
76%	10	3	7
76%	11.5	3.5	8
76%	13	4	9
77%	3.5	1	2.5
77%	7	2	5
77%	8.5	2.5	6

TABLE B

Approximate Number of Hours of Flow with Standard Cylinders Supplying MVP-10 Time-Cycled at a Rate of 50/minute

STANDARD CYLINDER CAPACITY (liters)	D	E	M	H
	360	620	3450	6900
FLOW RATE (lpm)	HOURS			
1.0	1.2	2.1	11.5	23.0
1.5	1.1	1.9	10.5	20.9
2.0	1.0	1.7	9.6	19.2
2.5	.92	1.6	8.8	17.7
3.0	.86	1.5	8.2	16.4
3.5	.80	1.4	7.7	15.3
4.0	.75	1.3	7.2	14.4
4.5	.71	1.2	6.8	13.5
5.0	.67	1.1	6.4	12.8
5.5	.63	1.1	6.1	12.1
6.0	.60	1.0	5.8	11.5
7.0	.55	.94	5.2	10.5
8.0	.50	.86	4.8	9.6
9.0	.46	.79	4.4	8.8
10.0	.43	.74	4.1	8.2
11.0	.40	.69	3.8	7.7
12.0	.38	.65	3.6	7.2
13.0	.35	.61	3.4	6.8
14.0	.33	.58	3.2	6.4
15.0	.31	.55	3.0	6.0
16.0	.30	.52	2.9	5.7
17.0	.28	.49	2.7	5.4
18.0	.27	.47	2.6	5.2
19.0	.26	.45	2.5	5.0
20.0	.25	.43	2.4	4.8

NOTE: Tank life is dependent upon cycling rate, and PEEP/CPAP and PIP settings, as well as flow rate. For higher respiratory rate, the tank life is less; or for lower respiratory rate it is more.

CHART C

INSP. & EXP. Times & Multiplication Factor (to find flow rate) For Various Respiratory Rates and I/E Ratios														
			I/E RATIO											
			3:1	2:1	1½:1	1:1	1:1½	1:2	1:3	1:4	1:5	1:6	1:7	1:8
RESP. RATE (bpm)	RESP. CYCLE (sec.)													
10	6	Insp. Time	4.5	4.0	3.6	3.0	2.4	2.0	1.5	1.2	1.0	.86	.75	.67
		Exp. Time	1.5	2.0	2.4	3.0	3.6	4.0	4.5	4.8	5.0	5.1	5.25	5.33
		Mult. Factor	13.3	15	16.7	20	25	30	40	50	60	70	80	90
15	4	Insp. Time	3.0	2.7	2.4	2.0	1.6	1.33	1.0	0.8	.67	.57	0.5	.44
		Exp. Time	1.0	1.3	1.6	2.0	2.4	2.67	3.0	3.2	3.3	3.4	3.5	3.56
		Mult. Factor	20	22.5	25	30	37.5	45	60	75	90	105	120	135
20	3	Insp. Time	2.25	2.0	1.8	1.5	1.2	1.0	.75	0.6	0.5	.43	.38	.33
		Exp. Time	.75	1.0	1.2	1.5	1.8	2.0	2.25	2.4	2.5	2.57	2.62	2.67
		Mult. Factor	26.7	30	33.3	40	50	60	80	100	120	140	160	180
25	2.4	Insp. Time	1.8	1.6	1.44	1.2	.96	0.8	0.6	.48	0.4	.34	0.3	.27
		Exp. Time	0.6	0.8	.96	1.2	1.44	1.6	1.8	1.92	2.0	2.06	2.1	2.13
		Mult. Factor	33.3	37.5	41.7	50	62.5	75	100	125	150	176	200	225
30	2	Insp. Time	1.5	1.33	1.2	1.0	0.8	.67	0.5	0.4	.33	.29	.25	.22
		Exp. Time	0.5	.67	0.8	1.0	1.2	1.33	1.5	1.6	1.67	1.71	1.75	1.78
		Mult. Factor	40	45	50	60	75	90	120	150	180	210	240	270
40	1.5	Insp. Time	1.12	1.0	0.9	.75	0.6	0.5	.38	0.3	.25	.21	.19	.17
		Exp. Time	.38	0.5	0.6	.75	0.9	1.0	1.12	1.2	1.25	1.29	1.31	1.33
		Mult. Factor	53.3	60	66.7	80	100	120	160	200	240	280	320	360
50	1.2	Insp. Time	0.9	0.8	.72	0.6	.48	0.4	0.3	.24	0.2	.17	.15	.13
		Exp. Time	0.3	0.4	.48	0.6	.72	0.8	0.9	.96	1.0	1.03	1.05	1.07
		Mult. Factor	67	75	83.3	100	125	150	200	250	300	350	400	450
60	1.0	Insp. Time	.75	.67	0.6	0.5	0.4	.33	.25	0.2	.17	.14	.13	.11
		Exp. Time	.25	.33	0.4	0.5	0.6	.67	.75	0.8	.83	.86	.87	.89
		Mult. Factor	80	90	100	120	150	180	240	300	360	420	480	540
70	.86	Insp. Time	.65	.57	.52	.43	.34	.29	.21	.17	.14	.12	.11	.10
		Exp. Time	.21	.29	.34	.43	.52	.57	.65	.69	.72	.74	.75	.76
		Mult. Factor	92.3	105	117	140	175	210	280	350	420	490	560	630

$$\text{Flow Rate Multiplication Factor} = \frac{60}{\text{Inspiratory Time (sec.)}}$$

$$\text{Flow Rate (liters/min)} = \frac{\text{Tidal Volume (ml)} \times \text{Multiplication Factor}}{1000}$$

VI. PRECAUTIONS

To assure that operation will be trouble-free, attention should be given to the following points:

- All tubing should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Gas supplies must be maintained at 50 ± 5 PSI (345 ± 34.5 kPa).
- Flow restrictions (e.g. flow meter, valve, etc.) must not be placed in supply line.
- Gas going to patient should not be supersaturated, as evidenced by excessive rain-out in the tubing. Condensation droplets on the inner walls of the tubing is normal.
- Humidifier, when used, must be placed between PATIENT connection on MVP-10 and hose in patient circuit. **DO NOT PLACE IN SUPPLY LINE.**
- Humidifier must be "flow-through" type having a low pressure drop; otherwise protection provided by SAFETY RELIEF VALVE is ineffective. A pressure jet nebulizer or an unmodified bubbler humidifier may not be used.
- When setting INSP. TIME and EXP. TIME controls, for optimum repeatability, always approach setting by turning knob in a clockwise direction.
- Humidifier should have low compliance, and water maintained at a high level to minimize compliance.
- Expiration Valve must be positioned with diaphragm cap (white section with pilot hose connection) up. Exhaust port, on bottom, should be unimpeded. (White adapter section on exhaust port of valve should be removed.)
- When the Ventilator must be used unattended, always use with an alarm system. Pressure alarms should be T- connected to hose attached to GAUGE fitting at rear of MVP-10.
- System compliance should be compensated when used in a volume-limited, time-cycled mode. (See Step 7 of Section A under SELECTION OF VENTILATION PARAMETERS AND ADJUSTMENT OF CONTROLS.)
- When setting controls, always start with PEEP/CPAP control fully clockwise, and PIP control fully counterclockwise to avoid setting PEEP/CPAP above the maximum pressure limitation.
- Should any control knob come loose for any reason, do not attempt to refasten them. The calibration of these controls depends on the position of the knob on the shaft. If this occurs, the Ventilator must be returned to BMD for recalibration.

- When the Ventilator is used at altitudes significantly above sea level, or in non-pressurized aircraft, the calibration of INSP. TIME and EXP. TIME must be corrected. The actual times will be greater than the panel marking by approximately 2½ % for every 1000' of altitude.
- The pressure levels set by the PIP and PEEP/CPAP controls are somewhat affected by the flow rate. These controls should be set with the flow rate used. If flow rate is changed, the PIP and PEEP/CPAP levels should be checked.
- When a compressor is used as the power source, steps should be taken to filter and dehumidify the room air before introducing it into the MVP-10.
- MOISTURE OR DEBRIS IN THE MVP-10 WILL CAUSE IT TO FUNCTION IMPROPERLY.
- If ventilator internal contamination results from not using a patient filter (as directed herein), do not try to clean the ventilator internally; instead return it to the factory for evaluation.
- Negative pressure (subatmospheric) is not available with this ventilator during the expiratory phase.
- The ADJUSTABLE RELIEF VALVE must not be removed.

VII. MAINTENANCE

A. NORMAL CARE

The MVP-10 Pediatric Ventilator requires very little maintenance. It should be protected from abusive mechanical shock and kept in a clean condition.

The MVP-10 should only be cleaned by wiping the outside surfaces with alcohol applied to a tissue or cloth. It should never be sprayed with or immersed in any other liquid.

The instrument should be returned to BMD for repair.

The supplied expiration valve is disposable and should be replaced for every patient, or during extended periods for a single patient. Any possible use of alternative valves should be discussed with BMD before any patient application.

BMD defers to user facility protocol for recommended time-period of use of patient breathing circuits (tubing sets).

Care should be taken in connecting supply hoses to the POWER OXYGEN and AIR fittings. Hand tightening of these fittings is sufficient. Do not over-tighten with a wrench, as the fittings could be damaged. Never connect a water supply to these fittings. Use only clean, dry, oil-free medical gas.

B. CHECKOUT PROCEDURE

For the following tests, the unit will require supply connections of 50 ±5 PSI (345 ±34.5 kPa) medical grade oxygen and air sources and an infant breathing circuit, Bio-Med Devices part number 2030, with the patient port occluded (test lung not recommended).

1. BLENDER/FLOWMETER

CYCLE/CPAP switch to CPAP

PIP full CW

PEEP PRESSURE full CW

Slowly increase flow in each column of flowmeter until indicators reach stops at tops of columns. Indicator balls should not stick at any point. CLOSE BOTH FLOW VALVES FINGER TIGHT. Occlude patient circuit exhalation valve exhaust outlet and verify that manometer indicates a maximum 1 cm increase in pressure over a two second interval.

2. MANOMETER

Using a variable low pressure source and known standard, verify 3% full scale accuracy and a zero of ±1 cm.

3. RELIEF VALVE

CYCLE/CPAP switch to CPAP
PIP full CCW
PEEP PRESSURE full CW
INSPIRATORY TIME .5 sec
EXPIRATORY TIME 1.0 sec

Occlude patient circuit exhalation valve exhaust port and slowly increase flow to 6 LPM. Manometer should indicate between 65 and 80 cm pressure. Check ADJUSTABLE RELIEF VALVE at patient outlet at rear of unit if pressure is less than 65 cm. Increase flow to a total of 12 LPM and verify pressure is between 65 and 80 cm. Reduce flow to 4 LPM. With exhalation valve exhaust port open to atmosphere, switch CYCLE/CPAP to CYCLE. Manometer should reach a minimum of 65 cm during inspiratory phase.

4. MAXIMUM PRESSURE

CYCLE/CPAP switch to CYCLE
PIP full CCW
PEEP PRESSURE full CW
TOTAL FLOW of 6 LPM
INSPIRATORY TIME 2 sec
EXPIRATORY TIME 1 sec

Manometer should read 70 ± 5 cm during inspiratory. Turn PIP knob clockwise until pressure decreases. Continue turning to OFF position (knob reference line at 6 o'clock position and resistance is felt). Manometer fluctuation should be no more than 1 cm. CAUTION: DO NOT FORCE VALVE.

5. PEEP PRESSURE

CYCLE/CPAP switch to CYCLE
PIP full CCW
PEEP PRESSURE full CCW
TOTAL FLOW of 6 LPM
INSPIRATORY TIME .5 sec
EXPIRATORY TIME 1.0 sec

Manometer should read 18 ± 3 cm during expiratory. Turn PEEP PRESSURE knob clockwise until PEEP PRESSURE decreases. Continue turning to OFF position (knob reference line at 6 o'clock and resistance is felt). During expiratory, manometer should read less than 1 cm above manometer zero reading. CAUTION: DO NOT FORCE VALVE.

6. INSPIRATORY TIMES

CYCLE/CPAP switch to CYCLE
PIP full CCW
PEEP PRESSURE full CW
FLOW OFF
INSPIRATORY TIME - variable
EXPIRATORY TIME 1.0 sec

Using a digital stopwatch set the Expiratory time to an accurate 1 second. Check the Inspiratory times at each setting by measuring the total length of time for ten breaths, then divide that time by 10 and subtract 1. The remainder is the inspiratory time averaged over ten breaths.

7. EXPIRATORY TIMES

CYCLE/CPAP switch to CYCLE
PIP full CCW
PEEP PRESSURE full CW
FLOW OFF
INSPIRATORY TIME - 1 sec
EXPIRATORY TIME - variable

Same as with inspiratory time, but set the Inspiratory to an accurate 1 second and then check each Expiratory setting. With knob against IMV RANGE STOP expiratory time should be 30 ± 3 seconds

C. CALIBRATION

The accuracy of the instrument's indicators and controls should be retained over its life as long as it has not been subject to abuse. The calibration of the pressure gauge, flow meters, and timing controls may be checked with relative ease.

NOTE: The calibration of the two timing controls (INSP. TIME and EXP. TIME) depends on the fixed position of the knobs on their shafts. Should these knobs come loose, do not attempt to refasten. Return the instrument to BMD for repair.

The pressure gauge readings can be compared to a calibrated standard by teeing into the hose connected to the GAUGE fitting at the rear of the MVP-10, and connecting it to the standard gauge.

The timing controls, INSP. TIME and EXP. TIME, may be roughly checked by observing the cycling of the pressure gauge and timing with a stopwatch.

If the calibration of any of the indicators or controls is in error, then the instrument should be returned to BMD for adjustment.

D. IF SERVICE IS REQUIRED

The MVP-10 Pediatric Ventilator should be returned to BMD, directly or through your dealer, for any repair or service that may be required.

Maintenance scheduling of the Bio-Med Devices' MVP-10 Pneumatic Ventilator is dependent upon frequency of use, condition of supply gases, and handling. It is recommended that units operated on a regular basis be factory serviced annually. For units used infrequently, a maximum of 3 years between factory service is recommended. Calibration may be periodically verified by qualified personnel following prescribed checkout procedures. The annual service procedure should be performed by experienced personnel at the factory. Field service beyond minor adjustment is not recommended due to the MVP-10's unique pneumatic logic circuit.

Pack the instrument so that its meters, control knobs, and connections are adequately protected. Ship pre-paid with your name & telephone on the paperwork to:

Bio-Med Devices, Inc.

61 Soundview Road
Guilford, CT 06437

APPENDIX A



AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

Bio-Med Devices' Official Agent in Europe is:

Medical Market I.N.T. AB
Sehlstedtgatan 6
115 28 Stockholm
Sweden

Telephone: +46-08-767 70 00
Fax: +46-08-731 90 09

APPENDIX B

MVP-10 VENTILATOR MR INFORMATION

Non-clinical testing has demonstrated that the MVP-10 infant MRI ventilator is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3-Tesla
- Spatial gradient field of 472-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning.
- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this device.
- Additional requirements:
 - The MVP-10 must be used with the BMD MR-conditional stand, and the stand's wheels that have integral wheel locks must be locked.
 - Do not place the MVP-10 & stand closer than one foot away from the MR bore (do not place the MVP-10 inside the MR bore).
 - If using supply gas cylinders and regulators, use only MR-conditional aluminum gas cylinders and regulators (observe manufacturer's published MR-conditional requirements).