WARNING

THIS SERVICE MANUAL IS INTENDED FOR USE BY BEAR MEDICAL SYSTEMS, INC. TRAINED AND AUTHORIZED SERVICE PERSONNEL.

BEAR MEDICAL SYSTEMS, INC. DOES NOT CONDONE OR APPROVE OF SERVICE ACTIVITY ON ITS PRODUCTS BY OTHER THAN BEAR MEDICAL SYSTEMS, INC. TRAINED OR AUTHORIZED PERSONNEL; AND, BEAR MEDICAL SYSTEMS, INC. IS NOT RESPONSIBLE FOR ANY UNAUTHORIZED REPAIRS OR MODIFICATIONS, OR ANY REPAIRS OR MODIFICATIONS MADE BY UNAUTHORIZED PROCEDURES.

USE OF THE INCORRECT PART, OR FAILURE TO EXERCISE DUE CARE IN THE INSTALLATION, REMOVAL, SERVICING, CHECKOUT OR CALIBRATION OF PARTS AND EQUIPMENT OR THE USE OF UNAUTHORIZED ACCESSORIES, MAY RESULT IN DAMAGE TO THE EQUIPMENT AND POSSIBLE MALFUNCTION OF THE EQUIPMENT WHICH MAY IN TURN RESULT IN DAMAGE TO PROPERTY AND INJURY (INCLUDING DEATH) TO PERSONS. THE PURCHASER AND INSTALLER OF THESE PARTS SHALL BEAR FULL RESPONSIBILITY AND LIABILITY FOR THE ABOVE.

ALL MAINTENANCE PERFORMED WITHIN THE APPLICABLE WARRANTY PERIOD (SEE WARRANTY CARD) MUST BE AUTHORIZED IN ADVANCE BY A BEAR MEDICAL SYSTEMS, INC. SERVICE REPRESENTATIVE IN ORDER TO RETAIN THE WARRANTY STATUS OF THE SUBJECT UNIT.

WARNINGS AND CAUTIONS

Statement in this manual preceded by the following words are of special significance.

WARNING

means there is the possibility of personal injury or death to yourself and others.

CAUTION

means there is the possibility of damage to the instrument or other property.

NOTE

Indicates points of particular interest for more efficient and convenient operation.

It is recommended that the reader take particular notice of the warnings, cautions, and notes provided throughout this manual.
PREFACE

PROPRIETARY INFORMATION
INFORMATION CONTAINED WITHIN THIS MAINTENANCE MANUAL IS PROPRIETARY TO BEAR MEDICAL SYSTEMS, INC., AND MAY BE USED ONLY FOR THE PURPOSE OF PROVIDING MAINTENANCE. THE PURCHASE, RECEIPT OR POSSESSION OF THIS MAINTENANCE MANUAL DOES NOT CONFER, TRANSFER, OR LICENSE ANY OTHER RIGHTS IN THIS INFORMATION. ANY OTHER USE OR DISCLOSURE AND/OR REPRODUCTION (by any method) OF THE INFORMATION CONTAINED HEREIN IS PROHIBITED UNLESS EXPRESSLY PERMITTED HEREIN.

INTRODUCTION
The BEAR® 1000 Ventilator Maintenance Manual contains electrical and mechanical verification, calibration, troubleshooting and replacement instructions prepared to assist a qualified biomedical technician in the maintenance of the ventilator.

The Maintenance Manual is specifically intended for use by an authorized service person. Any adjustments or procedures that exceed the scope of this manual should be referred to a Bear Medical Systems Factory Service Center. For specific operating instructions and clinical theory of operation, refer to the BEAR® 1000 Ventilator Instruction Manual (50-10613-00). Maintenance personnel should become thoroughly familiar with the Operating and Repair techniques before servicing this equipment.

Page Numbering – The page numbering system used throughout this manual is as follows:

- June 1993

The month/year following the page number indicates the revision level of the individual page. When a page(s) has been revised, the month and year will be updated. Where no change has occurred, the month and year will remain unchanged even though the page may have been reprinted in the revision process.

50000-12029

This indicates the part number of the base manual or component section.

NOTE
Sections 3 and 9 have different part numbers, as they were prepared as individual documents. They do not interrelate to the base maintenance manual.

WARNING
When a GAS SUPPLY FAILURE alarm occurs, the Blender will use the remaining gas supply. This means that the oxygen concentration delivered to the patient may differ from the clinician-selected O2 setting.

WARNING
The Operator Diagnostics must never be performed when the ventilator is connected to a patient. To do so could result in serious injury to the patient.

WARNING
The following warnings must be read and understood before performing the procedures described in this section.

Under no circumstances should this medical device be operated in the presence of flammable anesthetics or other volatile materials due to a possible explosion hazard.

Liquid spilled or dripped into the unit may cause damage to the unit or result in an electrical shock hazard.

Oxygen vigorously accelerates combustion. To avoid violent ignition, do not use any gauges, valves, or other equipment that has been exposed to oil or grease contamination.

Do not release this medical device if any alarm/alert function is inoperative. To do so could result in a malfunction without warning, possibly resulting in personal injury up to including death or property damage. Refer the unit to a Bear Medical Systems Authorized Service Technician or a Bear Medical Systems Trained Hospital Service Technician.
**WARNING**

All tubing and fittings used to connect high pressure gas (air and oxygen) from the source to the test equipment and from the test equipment to the device being tested must be capable of withstanding a minimum supply pressure of 100 psi (7.03 kg/cm²). The use of tubing and fittings not capable of withstanding this pressure could cause the tubing to rupture, resulting in personal injury or property damage.

When verifying the operation of this medical device, do not breathe directly from the machine. Always use a fresh bacterial filter and test circuit. A hazard to the health of the service person may result.

If any of the following procedures cannot be verified as outlined in this document, do not use this device on a patient and refer it to Bear Medical Systems or a Bear Medical Systems Authorized Service Facility or a Bear Medical Systems Trained Hospital Service Technician.

**WARNING**

Do not release the ventilator for use if it does not pass all of the verification procedures specified in the checklist. To do so could result in personal injury including death or property damage. Refer the ventilator to a Bear Medical Service Technician or a Bear Medical Systems trained service technician for appropriate repair and/or calibration.

**WARNING**

When replacing air 02 inlet filters, mark and remove one and only one fitting at a time. Replace the filter and return the fitting to its original location before removing the second fitting. Failure to follow this procedure may result in injury, including death, to the patient.

**BEAR MEDICAL SYSTEMS, INC STANDARD WARRANTY**

Bear Medical Systems, Inc. standard warranty is extended to the original buyer purchasing the equipment directly from Bear Medical Systems, Inc. or through its authorized dealers. All warranty periods, where applicable, commence on the date of first purchase but not more than six months after shipment from Bear Medical Systems, Inc. Bear Medical Systems' sole obligation and liability under this warranty is limited to (at Bear Medical Systems option) the repair or replacement by Bear Medical Systems authorized personnel of any parts or assemblies which, upon test and examination by Bear Medical Systems prove to be defective. This equipment may be returned prepaid to Bear Medical Systems after prior notification has been given and approval obtained for the return.

This warranty does not cover normal maintenance such as cleaning, adjustment, or lubrication and updating of equipment or parts thereof. This warranty shall be void and not apply if the equipment, including any of its parts, is modified without Bear Medical Systems authorization; is attempted to be repaired by personnel not authorized by Bear Medical Systems; is not maintained in accordance with the prescribed schedule; is used with accessories or parts not authorized; or is damaged due to misuse, mishandling, abuse, negligence, accident, fire, or inadequate packaging by owner for shipment. Bear Medical Systems' makes no guarantee of clinical results.

THE WARRANTY STATED ABOVE (INCLUDING ITS LIMITATIONS) IS THE ONLY WARRANTY MADE BY BEAR MEDICAL SYSTEMS AND IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BEAR MEDICAL SYSTEMS SHALL NOT BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND.

Warranty period is one year with the following exceptions:
1. Preventive maintenance (90 day) warranty on all parts and labor included in all procedures.
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## Section 1
### BEAR® 1000 Ventilator Specifications

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M O D E S

Assist CMV (Assist Controlled Mechanical Ventilation).

A volume breath shall be delivered to the patient when a breath interval (as determined by the preset breath rate) elapses or the patient activates the assist trigger. The breath interval shall be reset at the start of every volume breath, thus the patient may trigger every breath if he/she is breathing faster than the preset breath rate. On the other hand, if the patient is not active, he/she shall get breaths at the regular interval of the preset breath rate.

Demand breathing is not allowed in this mode, however, volume breaths may be flow and volume augmented.

SIMV/CPAP (Synchronous Intermittent Mandatory Ventilation/ Continuous Positive Airway Pressure)

SIMV - Preset breath rate is greater than 0

When the breath interval elapses (as determined by the preset breath rate), a mandatory breath window will be opened. A volume breath will be delivered when the patient activates the assist trigger while the window is open. As soon as the volume breath is triggered, the window will be closed and the patient may breathe spontaneous (or pressure supported) breaths until the next breath interval elapses when the cycle starts over.

Note that the breath interval is reset as soon as it elapses, even though a volume breath has not necessarily been delivered.

If a breath interval elapses and the mandatory breath window is still open, then a volume breath will be delivered. The window will remain open until the patient triggers the assist trigger.

CPAP - Preset breath rate equals 0

If the preset breath rate is set to zero, then demand breathing shall be enabled and the patient shall breathe spontaneous or (pressure supported) breaths exclusively except for manual volume breaths.

Press Control (Pressure Control Ventilation) (N/A FOR BASIC UNIT)

A pressure controlled breath shall be delivered to the patient when a breath interval (as determined by the preset breath rate) elapses or the patient activates the assist trigger. The breath interval shall be reset at the start of every pressure controlled breath, thus, the patient may trigger every breath if he/she is breathing faster than the preset breath rate. On the other hand, if the patient is not active, he/she shall get breaths at the regular interval of the preset breath rate.

B R E A T H  R A T E

Normal Breath Rate

Range: 0, 0.5, 1 - 120 bpm

Resolution: 0.5 bpm from 0 to 1 bpm
1 bpm for remainder

Tolerance: 0-60 bpm - ± 1 bpm
61-100 bpm - ± 2% of setting
101-120 bpm - ± 3% of setting

Sigh Breath Rate (N/A FOR BASIC UNIT)

Range: Every 100 breaths

Sigh Interval Assist CMV: 2 x Normal Breath Interval

SIMV/CPAP: Normal Breath Interval

Limitation: Not active in pressure control mode.

Assist Sensitivity (Assist Trigger)

Range: 0.2 to 5.0 cmH2O

Resolution: 0.1 cmH2O
Manual Breath

The manual breath control delivers a single volume breath (in Assist CMV or SIMV/CPAP) or a pressure controlled breath (in Press Control mode) if the ventilator is not in the inspiratory cycle of a breath.

Assist CMV The breath interval will be reset just as if the patient had initiated the breath.

SIMV/CPAP The breath interval will be reset and the mandatory breath window will be opened upon completion of the volume breath. If breath rate is set to 0 (i.e., CPAP), the breath window will not be opened.

Press Control The breath interval will be reset just as if the patient had initiated the breath.

Minimum Minute Volume (MMV) (N/A FOR BASIC UNIT)

MMV will guarantee that the ventilator delivers a minimum minute volume (MMV). If the monitored exhaled minute volume drops below the set MMV level and the set value for MMV is greater than the product of the breath rate and tidal volume control settings, then the breath rate will automatically be increased to MMV divided by tidal volume (MMV breath rate). The breath rate will return to the normal breath rate once the monitored exhaled minute volume exceeds the MMV level by 1 LPM or 10%, whichever is greater.

Range: 0 to 50L.
Resolution: 1.0 L.
Limitation: Only active in SIMV/CPAP Mode

End Expiratory Hold (N/A FOR BASIC UNIT)

Shall not allow the patient to inspire, or exhale any gas. End expiratory hold shall be initiated upon the detection of the next breath.

Limitation: The maximum duration of an end expiratory pause shall be 9.0 ± 0.1 seconds.

GAS DELIVERY SYSTEM

Limitations The maximum minute volume that the ventilator shall be able to deliver is at least 50 L.

If an attempt is made to exceed Maximum Minute Volume, the instantaneous flow capability of the machine will be limited. This will cause peak flow to be limited, which will extend inspiration time. It will in turn be limited by the Max time for inspiration or Max I:E Ratio.

Volume Breath Control

The purpose of a volume breath is to deliver a pre-determined volume of gas to the patient. The preset tidal volume, peak flow and waveform determine how the flow is delivered.

Norm Range 0.10 to 2.00 L.

Sigh Range: 1.5 * Normal (N/A FOR BASIC UNIT)

Tolerance: ± 10% of setting or ± 0.02L., whichever is greater.

Resolution: 0.01L.
Limitation: Volume accuracy assumes a standard temperature of 25°C (77°F) and set barometric pressure.

Peak Flow

Range: 10 to 150 lpm

Tolerance: ± 10% of setting or ±3 lpm, whichever is greater

Resolution: 1 lpm

Waveform

During the delivery of a volume breath, flow shall be delivered in one of the three user selectable waveforms.

Square Wave

Deliver gas at the set peak flow for the duration of the inspiration. However, since flow cannot be changed from zero to the peak flow instantaneously, an ideal square wave will not be delivered.

Sine Wave (N/A FOR BASIC UNIT)

Deliver gas beginning at zero and increasing to the peak flow setting and then decreasing back to zero in a fashion that depicts a sinusoid.

Decelerating Wave (N/A FOR BASIC UNIT)

Deliver gas beginning at the peak flow and continuously decreasing linearly until the flow reaches 50% of the peak flow. However, since flow cannot be changed instantaneously an ideal decelerating wave cannot be delivered.

Inspiratory Pause

Once the preset tidal volume of a volume breath has been delivered, the patient will not be allowed to exhale for a specified amount of inspiratory pause time.

Preset Pause (N/A FOR BASIC UNIT)

A preset inspiratory pause will be delivered with each volume breath.

Range: 0.0 to 2.0 sec

Resolution: 0.1 sec

Manual Pause

A single inspiratory pause shall be delivered, once per actuation of the manual pause control.

Limitation: The maximum duration of an inspiratory pause shall be 2.0 ± 0.1 seconds.

Compliance Compensation (N/A FOR BASIC UNIT)

The volume of gas delivered during a volume breath shall be increased so that it includes the volume intended for the patient plus the volume lost due to the compliance effect of the circuit. During the delivery of all volume breaths, the ventilator will determine the pressure at the end of the inspiration. The volume delivered during the next volume breath will be increased by the difference between the end inspiratory pressure and PEEP times the compliance compensation factor.

Range: 0.0 to 7.5 ml/cmH2O

Resolution: 0.1 ml/cmH2O

Limitation: Not active for sigh volume breaths.

Maximum Flow Acceleration

The maximum rate at which flow can be changed.

Range: 64,000 lpm² (0.1 to 0.25 l) 108,000 lpm² (0.25 to 3.00 l)

Limit: If an attempt is made to exceed Max flow acceleration, then peak flow will not be achieved for a square or decelerating waveform. Tidal volume will be delivered low for a sine wave.
**SPECIFICATIONS**

**Maximum Total Inspiratory Time**

The maximum inspiratory time is 5.0 ± 0.1 seconds plus inspiratory pause time.

Limit: If an attempt is made to exceed Maximum Total Inspiratory Time, the breath will be immediately terminated causing tidal volume to be limited.

**Maximum I:E Ratio (Max I:E)**

The maximum inspiratory to expiratory ratio is 4:1 for the Comprehensive Unit and 1:1 for the Basic Unit.

Limit: If an attempt is made to exceed Max I:E Ratio, the breath will be immediately terminated causing tidal volume to be limited.

**Inspiratory Pressure Control**

The ventilator has the capability to control the inspiratory pressure in the circuit. This includes spontaneous, pressure supported and pressure controlled breaths, as well as flow, volume and pressure augmentation. Except for flow and volume augmentation, the pressure achieved shall be the inspiratory pressure level plus preset PEEP. For flow and volume augmentation, the pressure achieved shall be preset PEEP.

**Inspiratory Pressure Level**

Range: 0 to 80 cmH2O

Tolerance: ±3 cmH2O

Stability: ±3 cmH2O

Min Guaranteed Flow: 150 lpm

**Inspiration Pressure Slope (N/A FOR BASIC UNIT)**

The user shall have the capability to control the slope at which the inspiratory pressure level is achieved. This control shall be a relative control of slow to fast.

Range: (Pediatric) - P9 to P9
       (Adult) - 9 to 9

Resolution: 1

**Demand Breaths**

In those modes where demand breathing is allowed, a demand breath will be triggered by the assist trigger. The patient demand will be met by providing enough flow to achieve the inspiratory pressure level plus PEEP. The pressure will be maintained at this level until the patient stops demanding, at which time the pressure will be returned to the preset PEEP level.

A Spontaneous Breath is a demand breath where the inspiratory pressure level equals zero.

A Pressure Supported Breath is a demand breath where the inspiratory pressure level is greater than zero.

**Pressure Controlled Breaths (N/A FOR BASIC UNIT)**

During the delivery of a pressure controlled breath, pressure in the circuit will be increased to the inspiratory pressure level and maintained for the duration of the breath. The breath shall be terminated when the preset inspiratory time elapses and will not relieve pressure if the patient fights the breath.

Insp Time: 0.1 to 5 sec

Resolution: 0.1 sec

**Flow & Volume Augmentation**

When a patient demands more gas than is being delivered by a volume breath, due to the preset settings, tidal volume and peak flow, additional gas will be delivered in order to maintain the circuit pressure at PEEP. The additional gas will be delivered as long as the patient is demanding, even if the delivered volume exceeds the preset tidal volume. Note, both flow and volume augmentation will be affected by "inspiratory pressure slope".
Pressure Augmentation (N/A FOR BASIC UNIT)

Without pressure augmentation, the ventilator shall deliver a volume breath based on the preset tidal volume, peak flow, waveform and patient demand (i.e., flow & volume augmentation). With pressure augmentation, the minimum pressure level maintained by the ventilator during a volume breath will be raised from PEEP to PEEP plus the inspiratory pressure level. The minimum pressure level will be maintained until the preset tidal volume has been delivered and the patient stops demanding.

PEEP (Positive End Expiratory Pressure)

The pressure that shall be maintained in the patient circuit at the end of exhalation.

Range: 0 to 50 cmH2O
Resolution: 1 cmH2O
Stability: Pressure may not fluctuate by more than ±1 cmH2O within one breath cycle (i.e., including undershoot).

Leaks: Maintain PEEP for leaks up to 25 lpm.

Oxygen Control

Percent Oxygen

The machine shall control the percentage of oxygen in the delivered gas. Normal air is 21% oxygen (O2) and 78% nitrogen (N2).

Range: 21 to 100 percent
Tolerance: ±4% O2 (Full Scale)
Resolution: 1% O2
Stability: ± 1 % O2 within one inspiratory cycle.

100% Oxygen (N/A FOR BASIC UNIT)

Deliver 100% oxygen for 3.0 ± 0.1 minutes regardless percent oxygen setting.

Nebulizer Gas Source

The machine shall provide blended gas, per set O2 percentage, at approximately 10.0 ± 1.5 psig when a nebulizer is attached and the nebulizer gas source is activated. The gas shall only be delivered during the inspiratory cycle of a breath so that the delivery of nebulized gas will be synchronized with the patient’s breathing.

Activation: Once the calculated delivered flow is determined to be greater than or equal to 20 +5, -15 lpm (Active for all breaths).

Limitations: Volume accuracy shall be ± (10 + 200/peak flow)% or ±(2/tidal volume+ 200/peak flow)% for nebulizers that generate between 4 to 8 lpm with a 10 psig gas source.
The maximum duration the nebulizer gas source shall be activated is 30.0 ± 0.1 minutes.

MONITORS

Volume Monitors

Exhaled Tidal Volume

Range: 0 to 9.99 L.
Tolerance: ± 10% of the exhaled volume or ± .03 L., whichever is greater.
Resolution: .01 L.

Exhaled Minute Volume

Range: 0.0 to 99.9L.
Tolerance: ± 10% of the exhaled volume or ± .3 L., whichever is greater.
Resolution: .1L.
Response: The monitored exhaled minute volume will decay to the actual average exhaled minute volume within 30 seconds from the time the actual exhaled minute volume changes.

**Spontaneous Minute Volume (N/A FOR BASIC UNIT)**

- **Range:** 0.0 to 99.9 L.
- **Tolerance:** ±10% of the exhaled volume or ±0.3 L., whichever is greater
- **Resolution:** 0.1 L.
- **Response:** The monitored spontaneous exhaled minute volume will decay to the actual average exhaled minute volume within 30 seconds from the time the actual spontaneous exhaled minute volume changes.

**Percent MMV (% MMV) (N/A FOR BASIC UNIT)**

Monitor the percentage of time, over the last 30 minutes, that the ventilator has been using the MMV breath rate instead of the normal breath rate.

- **Range:** 0 to 100%
- **Tolerance:** ±1%
- **Resolution:** 1%

**Rate/Time Monitors**

**Breath Rate**

Monitor the number of breaths per minute (bpm) that the patient is inspiring. This includes all breath types.

- **Range:** 0 to 155 bpm
- **Tolerance:** ±3% of reading or ±2 bpm, whichever is greater
- **Resolution:** 1 bpm
- **Response:** The monitored breath rate will decay to the actual average breath rate within 30 seconds from the time the actual breath rate changes.

**Spontaneous Breath Rate (N/A FOR BASIC UNIT)**

Monitor the number of breaths per minute (bpm) that the patient is inspiring due exclusively to demand breathing (spontaneous or pressure supported breaths).

- **Range:** 0 to 155 bpm
- **Tolerance:** ±3% of reading or ±2 bpm, whichever is greater
- **Resolution:** 1 bpm
- **Response:** The monitored spontaneous breath rate will decay to the actual average spontaneous breath rate within 30 seconds from the time the actual spontaneous breath rate changes.

**I:E Ratio (N/A FOR BASIC UNIT)**

For all volume and pressure controlled breaths (i.e., not active for demand breathing), measure the inspiratory and expiratory time and calculate the I:E ratio as follows:

- **Range:** 1:0.1 to 1:99.9
- **Resolution:** 0.1

**Pressure Monitors**

**Peak Pressure (N/A FOR BASIC UNIT)**

Monitor the maximum pressure in the patient circuit measured during the inspiratory phase of a breath.

- **Range:** 0 to 140 cmH2O
- **Tolerance:** ±3.5% of reading or ±2 cmH2O, whichever is greater
- **Resolution:** 1 cmH2O
- **Limitation:** Not active for spontaneous breaths
Mean Airway Pressure  (N/A FOR BASIC UNIT)
Monitor the average pressure in the patient circuit for the last 30 second interval.
Range: 0 to 140 cmH2O
Tolerance: ± 3.5% of reading or ± 2 cmH2O, whichever is greater
Resolution: 1 cmH2O
Response: The monitored mean airway pressure will decay to the actual mean airway pressure within 30 seconds from the time the actual mean airway pressure changes.

Plateau Pressure  (N/A FOR BASIC UNIT)
Monitor the circuit pressure during the time that a volume breath is in an inspiratory pause.
Range: 0 to 140 cmH2O
Tolerance: ± 3.5% of reading or ± 2 cmH2O, whichever is greater
Resolution: 1 cmH2O
Limitation: If no plateau occurs, then the displayed plateau pressure shall equal 0.

Proximal Pressure
Continuously monitor the pressure in the patient circuit.
Range: -10 to 120 cmH2O
Tolerance: ± 3 cmH2O or 3%, whichever is greater.
Resolution: 1 cmH2O

Air Inlet Pressure
Continuously monitor the pressure of the inlet air gas supply.
Range: 0 to 100 psig, or 0 to 160 psig
Tolerance: ± 5 psig
Resolution: 5 psig or better

Oxygen Inlet Pressure
Continuously monitor the pressure of the inlet oxygen gas supply.
Range: 0 to 100 psig, or 0 to 160 psi
Tolerance: ± 5 psig
Resolution: 5 psig or better

Inspiration Source/Type
Indicate the type and source of the breath being delivered as well as whether MMV is active, based on the following classification:

Controlled  A normal volume or pressure controlled breath

Sigh  A sigh volume breath (N/A FOR BASIC UNIT)

Patient Effort  A breath is assist triggered, flow or volume augmented, or is a demand breath (spontaneous or pressure supported)

MMV Active Ventilator is using MMV breath rate (N/A FOR BASIC UNIT)

Hour Meter
A non-resettable meter used to measure and display the total amount of time that the ventilator has been on. This shall be independent of whether or not gas is being delivered.
Range: 0 to 99,999 hours
Tolerance: ± 2% of reading
Resolution: 0.1 hour
Alarms/Safety Requirements

Alarm Features

Whenever a monitored value violates its alarm limit, an alarm shall be activated. The following conditions apply to all alarms:

Audible Indicator

An audible indicator shall occur whenever an alarm is activated and it shall continue to occur until the alarm is no longer violated. The audible indicator shall occur for a minimum of 2 seconds once activated.

Limitation: High peak pressure limit shall have a minimum of 1 second.

Alarm Silence

Disables the audible indicator and displays a visual indicator for 60 seconds. It works for all alarms except when the "Failed to Cycle" alarm is active.

Tolerance: ± 1 second

Visual Indicator

Each alarm shall have a red visual indicator that shall occur whenever the alarm is activated. The visual indicator shall continue to occur until the alarm limit is no longer violated and the alarm reset has been activated.

Alarm Reset

Deactivates the visual indicator for all alarms that are no longer violated.

Lamp Test

Activates all audible and visual indicators for approximately 4 seconds.

Volume Alarms

Low Exhaled Minute Volume

Range: 0.0 to 50.0 L.
Tolerance: ± 0.1 L of the monitored exhaled minute volume

Resolution: 0.1 liter

High Exhaled Minute Volume

Range: 0.0 to 80.0 L.
Tolerance: ± 0.1 L of the monitored exhaled minute volume

Resolution: 0.1 L.

Rate/Time Alarms

Low Breath Rate

Range: 3 to 99 bpm
Tolerance: ± 1 bpm of the monitored breath rate

Resolution: 1 bpm

High Breath Rate

Range: 0 to 155 bpm
Tolerance: ± 1 bpm of the monitored breath rate.

Resolution: 1 bpm

Inspiratory Time /I:E Limit

A. Maximum Inspiratory Time

If the inspiratory time of a volume breath exceeds 5 seconds plus inspiratory pause time, or the inspiratory time of a pressure controlled or demand breath exceeds 5 seconds, the ventilator shall alarm and terminate the breath.

Range: 5.0 seconds + inspiratory pause time

Tolerance: ± 0.1 seconds

B. Maximum I:E Ratio

If the inspiratory time for a volume or pressure controlled breath exceeds the maximum I:E Ratio interval, the ventilator shall alarm and terminate the breath.
SPECIFICATIONS

a) I:E Override NOT active.
   I:E Ratio Interval: \((1/f) \times 0.5\) (1:1)
   \(f = \text{Cycles/Second}\)

b) I:E Override active (N/A FOR BASIC UNIT)
   I:E Ratio Interval: \((1/f) \times 0.80\) (4:1)
   \(f = \text{Cycles/Second}\)
   Limitation: Not active for demand breaths (spontaneous and pressure supported).

Pressure Alarms

Low Inspiratory Pressure

Alarm if the peak pressure during an inspiration is less than the low inspiratory pressure limit.

Range: 3 to 99 cmH2O
Tolerance: ±1 cmH2O of monitored peak pressure.
Resolution: 1 cmH2O
Limitation: Not active for spontaneous breaths and pressure supported/pressure control breaths when PEEP + Insp. Press ≤3 cmH2O.

High Peak Pressure Limit

If the high peak pressure limit is violated, the inspiration shall be terminated and circuit pressure shall return to PEEP + 5 ± 1.5 cmH2O before the next PEEP may be delivered.

A. Normal High Peak Pressure Alarm

Alarm if the pressure in the patient circuit exceeds the normal high peak pressure alarm except during sigh breath cycles.

Range: 0 to 120 cmH2O
Tolerance: ±1 cmH2O of monitored peak pressure
Resolution: 1 cmH2O
Limitation: Not active for Sigh Breaths

B. Sigh High Peak Pressure Alarm

Alarm if the pressure in the patient circuit exceeds the sigh high peak pressure alarm during a sigh breath cycle.

Range: 1.5 * (Normal High Peak Pressure) to a maximum of 120 cmH2O.
Tolerance: ±1 cmH2O of the monitored peak pressure.
Limitation: Only active for Sigh Breaths.

Low Baseline Pressure (N/A FOR BASIC UNIT)

Alarm if the baseline pressure (PEEP) is less than the Low Baseline Pressure Limit.

Range: 0 to 50 cmH2O
Tolerance: ±1 cmH2O or 5% of the monitored PEEP, whichever is greater.
Resolution: 1 cmH2O
Limitation: The alarm is off if it is set to zero.

High Baseline Pressure (N/A FOR BASIC UNIT)

Alarm if the baseline pressure (PEEP) is greater than the High Baseline Pressure Limit.

Range: 0 to 55 cmH2O
Tolerance: ±1 cmH2O or 5% of the monitored PEEP, whichever is greater.
Resolution: 1 cmH₂O

**Proximal Disconnect**

If the proximal pressure is below 3 cmH₂O and the Machine Pressure is greater than or equal to the High peak Pressure Alarm plus 10 cmH₂O, the alarm shall be activated and the inspiration shall be terminated. Patient triggered breaths shall not be detected but Breath Rate control and Demand Flow shall remain active.

Tolerance: ± 1 cmH₂O of monitored pressure

Resolution: 1 cmH₂O

**Maximum Circuit Pressure Limit**

An independent mechanism shall exist which shall relieve pressure at the patient wye at a maximum of 175 cmH₂O.

**Failed to Cycle**

If the ventilator fails to cycle for any reason, it shall alarm and allow the patient to breath room air. PEEP shall not be maintained.

**Power Fail**

If power is removed from the unit, an audible indicator shall occur for a minimum of 5 minutes. A “Failed to Cycle” condition shall also occur. The audible indicator shall continue to occur when power is restored until the alarm silence is activated.

**Run Diagnostics**

When the ventilator detects a fault that will allow a certain degree of ventilation to be maintained, the ventilator shall continue to ventilate the patient and the “Run Diagnostics” alarm will be activated to notify the clinician so that he may rectify the condition. This will occur only if it is more effective to continue ventilation than to assert the “Failed to Cycle” condition.

**Cross Contamination of Supply Gases**

The ventilator shall not allow the external source of the supply gases to be cross contaminated.

**Maximum Pressure Differential:** 80 psig

**Maximum Sound Levels**

All sound levels shall be tested per ANSI S12.10-1985.

**Normal Operating:** 50 dBa max.

**Alarms - Adjustable:** 55 dBa min.

75 dBa max.

**Analog Outputs**

The ventilator shall contain 3 analog output signals:

A) **Proximal Pressure**

Range: -60 to 140 cmH₂O

Scale: 1 cmH₂O/25 mV

Tolerance: ± 5% of reading or ± 50 mV, whichever is greater.

Zero Offset: 1.5 Vdc at 0 cmH₂O

B) **Inspiratory/Expiratory Flow**

Range: -300 to 200 lpm

Scale: 1 lpm/10 mV

Tolerance: ± 10% of reading or ± 30 mV, whichever is greater.

Zero Offset: 3 Vdc at 0 lpm

C) **Inspiratory/Expiratory Volume**

Range: 0.00 to 3.00 l

Scale: 0.01 l/25 mV

Tolerance: ± 10% of reading or ± 75 mV, whichever is greater.

Zero Offset: 0 Vdc at 0 l

**RS-232 Port**

The ventilator shall contain an RS-232 port...
for bi-directional communication of data. All control settings, alarm settings and monitor values will be available upon demand. At 19.2 K baud, the system shall continuously output the flow and pressure signal in real time.

Baud Rate: 1200, 2400, 9600 and 19200

Gas Fail

A) Loss of Single Gas Source

Alarm if either gas supply, air or oxygen fails, and ventilate the patient on the remaining gas supply. An alarm shall not occur if the oxygen gas supply fails and the percent oxygen is set to 21%.

B) Loss of Both Gas Sources

Alarm if both gas sources, air and oxygen, fail. A "Failed to cycle" condition shall also occur.

Patient Circuits

The machine shall work with all four foot to six foot adult and pediatric circuits that have resistances and compliances within the range defined below:

Adult:

Compliance: 1.12 - 3.0 ml/cmH2O
Resistance: 0.04 - 0.12 cmH2O/LPS/FOOT @ 50 lpm

Pediatric:

Compliance: 0.215 - 0.322 ml/cmH2O
Resistance: 0.90 - 1.0 cmH2O/LPS/FOOT @ 50 LPM

Endotracheal Tubes (ET Tubes)

This machine shall work with Et tubes of the following size that have corresponding resistances:

Size: 2.5 mm to 9 mm

Resistance: Rp5 to Rp5 (per ASTM F1100)

Nebulizers

The machine will only be guaranteed to work with nebulizers that utilize the machine’s nebulizer gas source. Nebulizers attached to the gas source must perform within the limits specified under Neulizer gas source.

Humidification

The ventilator shall work with the following humidification sources although they may not be used concurrently:

A. Heat and Moisture exchanges (Artificial Nose)

Resistance: 1.5 to 8.0 cmH2O/LPS at 60 lpm
(Dry to fully saturated)

NOTE

Exhaled volume display will be affected if the exhaled gasses are not fully saturated.

Compliance: N/A

B. Humidifier Chamber

Maximum Resistance: 3.5 cmH2O/LPS at 30 LPM

Compliance: 0.2 to 1.5 ml/cmH2O

Pneumatic Supply Requirements

Supply Air

Pressure Range: 30 to 80 psig
Temperature: 10 to 62°C
Humidity: Dew point of gas should be at least 3°F below the ambient temperature.

Minimum Flow: 80 lpm at 30 psig
Inlet Fitting: CGA-Diss body type, No. 1160
**Supply Oxygen**

- **Pressure Range:** 30 to 80 psig
- **Temperature:** 10 to 40°C
- **Humidity:** Dew point of gas should be at least 3°F below the ambient temperature.
- **Minimum Flow:** 80 lpm at 30 psig
- **Inlet Fitting:** CGA-Diss body type, No. 1240

**Altitude/Barometric Pressure**

- **Sea Level to 9,000 ft:**
  - (14.7 psia) to (10.5 psia)
  - (760 mmHg) to (545 mmHg)

**Humidity**

- **Storage:** 0 to 99% Rh (non-condensing)
- **Operating:** 0 to 95% Rh (non-condensing)

**History of Detected Errors**

Except for “gas fail”, the ventilator shall record an error code for all Fail to Cycle and Run Diagnostics alarms. The last 16 error codes shall be retained when power is removed so that the ventilator will maintain a history of its failures.

**Cleaning of External Surfaces**

All external surfaces of the ventilator shall be able to be wiped clean with the following compounds:

- **A)** Isopropyl Alcohol
- **B)** Chlorine Compounds
  - Maximum Concentration: 1:10
- **C)** Quaternary Ammonium Compounds
  - Maximum Concentration: 1:500

*Note: These compounds are diluted by volume in water*
Sterilization

All parts of the ventilator that can come in contact with the patient expiratory gas and all parts of the breathing circuit external to the ventilator shall be sterilizable or disposable.

Methods of Sterilization

Ethylene oxide, maximum temperature 130° F (54° C)

Steam sterilization, maximum temperature 250° F (121° C)

Liquid Sterilization

a) Cidex
b) Sonacide

Minimum sterilization cycles before part replacement

a. Patient Circuit
   Ethylene Oxide  240 cycles
   Steam Sterilization  240 cycles
   Liquid Sterilization  240 cycles

b. All other sterilizable components
   Ethylene Oxide  240 cycles
   Steam Sterilization  240 cycles
   Liquid Sterilization  240 cycles
### APPENDIX 1 - FEATURE MATRIX

#### MODELS

<table>
<thead>
<tr>
<th>MODE</th>
<th>BASIC</th>
<th>COMPREHENSIVE</th>
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</thead>
<tbody>
<tr>
<td>Assist Control</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>SIMV/CPAP</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Press Control</td>
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#### CONTROL

<table>
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<tr>
<th></th>
<th>BASIC</th>
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<tbody>
<tr>
<td>Tidal Volume</td>
<td>0.10 - 2.00</td>
<td>0.10 - 2.00 1</td>
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<tr>
<td>Sigh Volume</td>
<td>N/A</td>
<td>1.5 * Vt</td>
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<tr>
<td>Compliance Comp (ml/cmH2O)</td>
<td>N/A</td>
<td>0 - 7.5</td>
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<td>Breath Rate (bpm)</td>
<td>0, 0.5 - 120</td>
<td>0, 0.5 - 120</td>
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<tr>
<td>Sigh Breath Rate</td>
<td>N/A</td>
<td>100th Breath</td>
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<tr>
<td>Peak Flow (lpm)</td>
<td>10 - 150</td>
<td>10 - 150</td>
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<td>Wave Form</td>
<td>Sqr, Dcl, Sine</td>
<td>Sqr, Dcl, Sine</td>
</tr>
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<td>Inspiratory Time (sec)</td>
<td>N/A</td>
<td>0.1 - 5</td>
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<td>Inspiratory Pause (sec)</td>
<td>N/A</td>
<td>0 - 2</td>
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<td>PEEP (cmH20)</td>
<td>0 - 50</td>
<td>0 - 50</td>
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<td>Assist Sensitivity (cmH20)</td>
<td>0.2 - 5.0</td>
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<td>Inspiratory Pressure (cmH20)</td>
<td>0 - 80</td>
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<td>Pressure Slope</td>
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<td>Pediatric</td>
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<td>Adult</td>
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<td>Min. Minute Volume (lpm)</td>
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<td>100% O2</td>
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<td>Nebulizer</td>
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<td>Man Breath</td>
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<td>Leak MakeUp</td>
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<td>Flow/Volume Augmentation</td>
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<tr>
<td>Pressure Augmentation</td>
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<tr>
<td>End Expiratory Hold</td>
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<tr>
<td>Manual Pause</td>
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#### MONITORS

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<tr>
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<tbody>
<tr>
<td>Tidal Volume (Liters)</td>
<td>0 - 9.99</td>
<td>0 - 9.99</td>
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<tr>
<td>Minute Volume (lpm)</td>
<td>0 - 99.9</td>
<td>0 - 99.9</td>
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<tr>
<td>Spontaneous MV (lpm)</td>
<td>N/A</td>
<td>0 - 99.9</td>
</tr>
<tr>
<td>I/E Ratio</td>
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<td>1.0 - 1.999</td>
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<td>Breath Rate (bpm)</td>
<td>0 - 155</td>
<td>0 - 155</td>
</tr>
<tr>
<td>Spontaneous Breath Rate (bpm)</td>
<td>N/A</td>
<td>0 - 155</td>
</tr>
<tr>
<td>Peak Pressure (cmH20)</td>
<td>N/A</td>
<td>0 - 140</td>
</tr>
<tr>
<td>Mean Pressure (cmH20)</td>
<td>N/A</td>
<td>0 - 140</td>
</tr>
<tr>
<td>Plateau Pressure(cmH20)</td>
<td>N/A</td>
<td>0 - 140</td>
</tr>
<tr>
<td>Proximal Pressure Gauge(cmH20)</td>
<td>-10 - 120</td>
<td>-10 - 120</td>
</tr>
<tr>
<td>Percent MMV (% time/0.5hr)</td>
<td>N/A</td>
<td>0 - 100</td>
</tr>
<tr>
<td>Inspiration Source/Type</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>MMV Active</td>
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### ALARMS/INDICATORS

<table>
<thead>
<tr>
<th>Alarm Silence</th>
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<tbody>
<tr>
<td>Low MV (lpm)</td>
<td>0 - 50</td>
<td>0 - 50</td>
</tr>
<tr>
<td>High MV (lpm)</td>
<td>0 - 80</td>
<td>0 - 80</td>
</tr>
<tr>
<td>Low Rate (bpm)</td>
<td>3 - 99</td>
<td>3 - 99</td>
</tr>
<tr>
<td>High Rate (bpm)</td>
<td>0 - 155</td>
<td>0 - 155</td>
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<tr>
<td>Low InsP Pressure (cmH2O)</td>
<td>3 - 99</td>
<td>3 - 99</td>
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<tr>
<td>High InsP Pressure (cmH2O)</td>
<td>0 - 120</td>
<td>0 - 120</td>
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<tr>
<td>Low Basline Pressure (cmH2O)</td>
<td>N/A</td>
<td>0 - 50</td>
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<tr>
<td>High Basline Pressure (cmH2O)</td>
<td>N/A</td>
<td>0 - 55</td>
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<tr>
<td>Time/I:E Limit</td>
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<td>YES</td>
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<tr>
<td>Gas Failed</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Power Failed (Audible Only)</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Failed To Cycle</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>Run Diagnostics</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>I:E Override</td>
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### ELECTRONIC INTERFACES

<table>
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<tr>
<th>RS-232</th>
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<tbody>
<tr>
<td>Analog Outputs (Flow,Pres,Vol)</td>
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<td>YES</td>
</tr>
<tr>
<td>Humidifier AC Output</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>Graphic Display AC Output</td>
<td>YES</td>
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</tbody>
</table>
Section 2
BEAR® 1000 Ventilator
Theory of Operation

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THEORY OF OPERATION
OVERVIEW

This section provides an in-depth discussion of the operating theory of the BEAR® 1000 Ventilator. Included are descriptions of the:

- ventilator pneumatics,
- electronics (including Monitor PCB, Control PCB and EPI),
- flow delivery logic, and
- RS-232 protocol.

Figure 2-1 shows how these parts of the ventilator interrelate.

VENTILATOR PNEUMATICS

Figure 2-2 depicts the complete pneumatics of the BEAR® 1000 Ventilator.

GAS INLET SYSTEM

Compressed air and oxygen sources, supplied in the pressure range of 30 to 80 psig, are connected to the standard DISS male-threaded fittings on the rear of the ventilator.

Incoming gases pass through coalescing filters housed in the Air and O2 Inlet Water Traps. The filters have a minimum retention efficiency of 95% for 0.7 micron particles and 2 micron droplets.

Figure 2-1
The inlet pressures of the gases are monitored by independent air and oxygen Inlet Pressure Transducers, and are displayed on their respective inlet pressure gauges. A drop in either gas pressure below 27.5 psig activates an audible and visual GAS SUPPLY FAILURE alarm.

From the Inlet Water Traps and Filters, the air and oxygen enter the in-line, one-way Check Valves which prevent gas backflow into the air and oxygen supply systems. To prevent check valve malfunction, compressed gases must be clean and dry.

The Air Regulator and Oxygen Relay create a balance of air and oxygen supply pressures. The Air Regulator reduces the air supply pressure to 18.0 psig and pilots the O2 Relay to track at the same pressure. This balance ensures the accuracy of downstream air and oxygen blending.

In the event air is lost, the Crossover Solenoid opens, delivering high pressure oxygen to the Air Regulator, which in turn regulates the O2 Relay.

**BLENDER**

Air and oxygen enter the Blender and mix to the desired oxygen concentration selected by the O2% control on the ventilator front panel. The Bleed Solenoid bleeds a small constant flow from the blender, to ensure accurate blending at low flow rates.

In the event of a GAS SUPPLY FAILURE alarm, caused by a drop in air or oxygen supply pressure (to below 27.5 psig), the Blender switches over completely to the remaining gas supply. Either 100% oxygen or 100% air (i.e., 21% oxygen) is supplied to the patient.

---

**WARNING**

When a GAS SUPPLY FAILURE alarm occurs, the Blender will use the remaining gas supply. This means that the oxygen concentration delivered to the patient may differ from the clinician-selected O2 setting.

If an error is detected in the Blender during a power-up, a RUN DIAGNOSTICS alarm activates both audibly and visually.

**ACCUMULATOR**

Blended gas leaves the Blender and enters the rigid 3.5 liter Accumulator. Under both low- and no-output-flow conditions, the mixed gas from the Blender fills the accumulator until it reaches system pressure (18.0 psig). In response to an output flow demand, the stored volume in this Accumulator is supplied to the Flow Control Valve, thereby reducing the instantaneous flow demand imposed on the Blender. This minimizes flow-generated pressure transients upstream, and thus maintains stable O2 concentrations at the Blender output.

The Accumulator has two important functions:

- It acts as a mixing chamber for the blended gas, resulting in increased stability of the oxygen concentration.
- It allows for high peak output flows of over 200 LPM while only requiring a relatively low (80 LPM) gas input from the wall.

**FLOW CONTROL VALVE**

Blended gas from the Accumulator enters the Flow Control Valve (FCV) at 10–18 psig of pressure. This inlet pressure varies due to the gas storage function of the Accumulator.

Both ventilator control settings and patient demand together determine the output flow from the FCV.
Figure 2-2
Whatever the output flow established by the flow delivery logic, the temperature sensor built into the FCV enables the ventilator to deliver accurate volumes based upon a standard temperature correction, 77°F, zero saturation and the set barometric pressure.

The FCV delivers peak flows in the range of:

Volume-controlled Breaths: 10 to 150 LPM

Demand or Pressure Breaths: 0 to over 200 LPM

**SOPR VALVE**

From the FCV, the gas flows through the Subambient Overpressure Relief Valve (SOPR) and out of the ventilator through the port labeled "Main Flow to Patient."

During normal operation, the Low Pressure Regulator supplies 140 cmH2O to the SOPR valve diaphragm, thereby closing its relief port. Because this port is closed, gas from the FCV passes directly through the SOPR and out to the patient.

When the Fail State System activates (due to a FAILED TO CYCLE alarm or a power failure), the 140 cmH2O normally supplied to the SOPR valve diaphragm falls to zero, and the SOPR relief port opens. When the relief port opens, the patient can breathe room air.

Beside providing the patient with access to room air, the SOPR has a second function. It acts as an independent relief valve to mechanically limit the maximum pressure the ventilator can deliver. This mechanical limit functions only when ventilator outlet pressure exceeds 175 cmH2O. Such a high pressure on the front side of the SOPR relief port causes the port to open and thereby relieve excess gas through the outlet labeled "Overboard Exhaust."

**LOW PRESSURE CONTROL SYSTEM**

The Low Pressure Control (LPC) System serves three functions:

- It provides 140 cmH2O to the SOPR valve diaphragm, and
- It controls the Exhalation Valve Diaphragm to determine breath phase (inspiration vs. exhalation) and PEEP level,
- It supplies gas to the Proximal Purge.

![Diagram of Low Pressure Control System](image-url)
THEORY OF OPERATION

The LPC System consists of the following components:

- Shut-off Solenoid Valve
- Low Pressure Regulator
- PEEP Needle Valve
- PEEP Jet Pump
- Exhalation Solenoid Valve

After entering the ventilator and passing through the regulator, air is tapped off before entering the Blender. This sidestream of 18 psig gas feeds directly into the Shut-off Solenoid Valve.

During normal operation, the Shut off Solenoid Valve is energized, passing 18 psig gas from the Gas Inlet System to both the Low Pressure Regulator and the PEEP Needle Valve. Under this circumstance, the LPC System functions as follows:

1. SOPR Valve: The 140 cmH2O from the Low Pressure Regulator enters the SOPR valve diaphragm, thereby holding its relief port closed.

2. Exhalation Valve and PEEP Control: The Exhalation Solenoid Valve switches the reference pressure for the Exhalation Valve Diaphragm between:

   - The 140 cmH2O supplied by the Low Pressure Regulator, and
   - The output pressure from the combination of the PEEP Needle Valve and the PEEP Jet Pump.

This allows the Exhalation Valve to close during inspiration and maintain PEEP during exhalation.

By contrast, during Fail State Operation (a FAILED TO CYCLE alarm or a power failure), the LPC System functions as follows:

1. SOPR Valve: The Shut-off Solenoid Valve de-energizes and closes. This cuts off the pneumatic drive to the Low Pressure Regulator which in turn, cuts off gas pressure to the back side of the SOPR Valve, thereby causing its relief port to open, and allowing the patient to inhale room air.

2. Exhalation Valve and PEEP Control: The closing of the Shut-off Solenoid Valve deprives the PEEP Needle Valve of drive pressure. The PEEP Jet Pump consequently exhausts all pressure applied to the Exhalation Valve. Because the Exhalation Valve is also de-energized by the Fail State System, it references this zero PEEP pressure being supplied by the PEEP Needle Valve and Jet Pump. As a consequence the Exhalation Diaphragm opens completely, allowing the patient to exhale, unimpeded.

EXHALATION VALVE

The Exhalation Valve regulates all flow out of the patient circuit. Exhaled patient gases flow through the expiratory leg of the patient circuit, past the Exhalation Valve Diaphragm and Seat, and through the External Flow Sensor. The Exhalation Valve is designed to minimize pressure fluctuations as well as audible noise.

The pressure required to:

- Close the Exhalation Valve during a positive pressure inspiration and
- Control the baseline (PEEP) pressure

The Exhalation Valve also acts as a check valve so the patient cannot rebreathe gas through the expiratory leg of the circuit.

A condensate jar attached to the Exhalation Valve Manifold collects condensed water from the circuit and manifold.

EXTERNAL FLOW SENSOR

The External Flow Sensor, connected to the Exhalation Valve Manifold, measures exhaled
tidal volumes. The flow sensor operates on the principle of hot wire anemometry.

The hot wire flow sensing system is a constant temperature device. The unidirectional operation is achieved with the two platinum wires as follows:

- A reference wire monitors the ambient gas temperature and communicates this temperature to the sensor electronics.
- A hot wire is held at a constant high temperature level based upon the temperature feedback from the reference wire.

The rate of heat loss from the hot wire varies directly with the velocity of the exhaled gases as they pass through the flow sensor. As the gas flow rate increases, the electronic circuitry applies additional electrical current to the wire to maintain a preset temperature. The resulting voltage change can then be translated into a gas flow rate. This measured flow rate is then integrated over time by the ventilator’s microprocessor to yield the measures of exhaled volumes which are displayed on the front panel monitors.

NEBULIZER SYSTEM

When the NEBULIZER key on the ventilator control panel is activated, the Nebulizer Regulator and Nebulizer Solenoid Valve together allow nebulization during the inspiration phase of any breath type so long as flow exceeds approximately 20 LPM. Thus nebulizing is synchronized with patient breathing.

The Nebulizer Regulator reduces the 18 psig pressure from the Accumulator to 10 psig.

While the solenoid valve is open, 6 LPM is assumed to flow through the nebulizer (the actual amount depends upon the specific nebulizer being used.) This 6 LPM is subtracted from the flow delivered by the FCV. In this manner the overall flow (nebulizer plus Main Flow output port) and volume are maintained at the clinician-set levels.

The oxygen concentration of the nebulizing gas is the same as that on the O2% control.

VENTILATOR ELECTRONICS

The five major components: the Monitor PCB, the Control PCB, the Electro-Pneumatic Interface (EPI) PCB, the Flow Sensor PCB, and the Power Supply

ELECTRONICS

Monitor PCB & Control PCB

The user operates the ventilator through the front panel controls and displays.

The Monitor and Control PCBs constantly scan the front panel for current settings or for clinician-generated changes. If an appropriate membrane key is selected, the Monitor and Contrc. PCBs couple this parameter to the control knob. An optical encoder senses knob rotation and increases or decreases the currently displayed value accordingly.

The Monitor and Control PCBs receive patient and machine status information from the Electro-Pneumatic Interface (EPI) PCB. Based on clinician-selected control settings and EPI feedback, algorithms within the Control PCB calculate the required delivered gas flow, O2 concentration, and Exhalation Valve state. The Control PCB transmits this information to the EPI PCB, which executes changes to the appropriate electro-mechanical devices.

Another major function of the Monitor and Control PCBs is to monitor and display the ventilator’s clinical data. When monitored parameters deviate beyond clinician-set alarm limits, the Monitor and Control PCBs create audible and visual alarms.
The Control PCB also has an RS-232 9-pin digital communication port to communicate continuous real time control, monitor and alarm data to external devices. The RS-232 communication port transmits data either to the optional BEAR® Graphics Display, or a computer. (For a detailed description of the protocol, refer to the BEAR® 1000 Instruction Manual.) There is also a 15-pin analog port for use in obtaining real time outputs of pressure, flow and volume signals as defined in the Analog Outputs.

ELECTRONICS
EPI & Flow Sensor PCB

The major purpose of the EPI is to provide an interface between the Control PCB and the pneumatic hardware. The EPI receives the desired flow, oxygen concentration, and solenoid valve states every 10 milliseconds from the Control PCB. Based on this information, the EPI commands the individual electromechanical components to move to their correct positions.

The second function of the EPI is to read the various transducer outputs, digitize the data and transmit it to the Control PCB for processing. Six pressure transducers, mounted on the EPI monitor: Proximal Airway Pressure, Machine Pressure, Proximal/PEEP Differential Pressure, Flow Control Valve Pressure, and Air and Oxygen Supply Pressures. The EPI also interfaces with a temperature sensor and the Flow Sensor PCB, to measure delivered gas temperature and exhaled flow, respectively.

In addition to the various transducers, the Autozero Solenoid is also mounted on the EPI. During power up only, the Autozero Solenoid valve is briefly energized (opened). During this time, the solenoid is used to zero the Proximal/PEEP Differential Pressure Transducer.

ELECTRONICS
Fault Detection

The BEAR® 1000 Ventilator, through its own operating hardware and software, continuously monitors itself for subsystem failures. Depending upon the type of failure detected, one of two states will occur:

- Alarm State: an alarm activates to alert the operator of the failure, nevertheless ventilation continues; or
- Fail State: the system activates the “Fail State” system; the ventilator ceases to operate, but the patient is allowed to breathe room air and exhale unimpeded.

If the Fail State activates:

1. All solenoids de-energize. The Shutoff Solenoid removes pneumatic drive pressure to the Sopr Valve diaphragm, PEEP Needle Valve and Exhalation Diaphragm Solenoid Valve, thereby opening the SOPR and Exhalation Valves to atmospheric pressure. The Exhalation Diaphragm Solenoid sets the Exhalation Valve reference pressure to zero. The Nebulizer Solenoid shuts off all nebulizer flow.
2. The EPI closes the Flow Control Valve electronically to prevent additional gas from being delivered to the patient.
3. The patient has access to room air through the SOPR valve.

The BEAR® 1000 Ventilator has three independent mechanisms for detecting these failures in the system:

1. Control PCB Detected Failures
2. EPI PCB Detected Failures
3. Loss of DC Power
ELECTRONICS
Power Supply

The Power Supply converts AC line voltage to DC voltages for the electrical system. If there is a temporary AC line power failure, the Power Supply provides DC power until the voltage in the capacitors drops to below 20.4 VDC. This residual voltage provides more than 300 milliseconds of continuing operation, allowing for alarm-free operation during the most common types of electrical power failure.

Once the voltage in the capacitors reaches 20.4 VDC, the Power Supply causes the ventilator to enter the Fail State, and the following occurs:

1. The alarm sounds for a minimum of 5 minutes.

2. The Flow Control Valve closes and the SOPR valve opens to allow the patient to breathe room air.

NOTE: PEEP is not maintained.

3. The ventilator power shuts off.

Once the Flow Control Valve is closed, +5 VDC is left for the ECS and EPI microprocessors, which continue to run until the +5 VDC is lost. This provides enough power for the microprocessors to store any troubleshooting codes to the EEPROM for later review.

FLOW DELIVERY LOGIC
The logic controlling the flow delivered by the FCV physically resides on the Control PCB. The logic is composed of two parts: Volume Logic and Pressure Logic.

---

Figure 2-4 • Flow Delivery Logic

50000-12131 • NOVEMBER 1993
The Volume Logic determines how much flow should be provided by the FCV to achieve volume-controlled breaths. At the same time, the Pressure Logic determines how much flow should be provided by the FCV to achieve:

- All pressure breaths, including pressure-supported, pressure-controlled, and pressure-augmented;
- All demand breaths, including spontaneous breaths, flow and volume augmentation and leak makeup.

As suggested, the capability called the "Demand System" resides within the Pressure Logic of the BEAR® 1000 Ventilator.

Figure 2-4 shows how two messages (one from the Volume Logic and the other from the Pressure Logic) are compared by the "Comparison" Logic. The "Comparison" Logic then sends the larger of the two messages to the FCV which implements flow delivery.

**VOLUME LOGIC**

When a patient passively receives a volume-controlled breath, the Volume Logic uses the preset TIDAL VOLUME, PEAK FLOW, and WAVEFORM to calculate a flow signal that is sent to the "Comparison" Logic.

Because this is a passively-received breath, the Pressure Logic sends a zero flow signal to the "Comparison" Logic. The "Comparison" Logic then compares these two signals and sends the larger one (which in this case is the Volume flow signal) to the FCV.

The Volume Logic uses feedback information from the FCV regarding actual delivered volume to determine when to switch to sending a "zero flow" signal to the "Comparison" Logic. This occurs when the TIDAL VOLUME and the optional COMPLIANCE COMP volume have been delivered.

**PRESSURE LOGIC**

Demand breaths rely solely upon the Pressure Logic to determine the flow output from the FCV.

When a patient initiates a demand breath, proximal airway pressure drops below baseline. The Pressure Logic (in the Control PCB) sends a signal through the "Comparison" Logic to the FCV instructing it to respond with sufficient flow to maintain proximal airway pressure at either:

- PEEP (for spontaneous breaths), or
- PRES SUP/INSPIR PRES plus PEEP (for pressure-supported breaths).

For spontaneous or pressure-supported breaths the Pressure Logic drops its flow message to zero once delivered flow drops to approximately 30% of the peak inspiratory flow.

**Pressure Control Breaths**

The flow delivery logic for a pressure-controlled breath is similar to that of a pressure-supported breath except that:

- The breath trigger can be machine-controlled, as well as patient controlled, and
- The end of inspiration is determined by the clinician-set INSPIRATORY TIME control rather than by a drop in flow.

**Pressure Slope**

The PRESSURE SLOPE control affects the rate at which the flow signal increases to its peak value. In essence it operates through the Pressure Logic to determine how fast the FCV opens. Thus it affects how slowly or rapidly the preset inspiratory pressure level is achieved at the airway.
Flow and Volume Augmentation

The goals of flow and volume augmentation are to:

1. Ensure that the patient is never starved of flow, and
2. Reduce stacking of volume breaths (auto-cycling).

To achieve these goals, delivered flows must meet or exceed patient demand. To begin with, the Volume Logic begins to deliver a volume-controlled breath according to the clinician-selected PEAK FLOW, WAVEFORM, and TIDAL VOLUME settings. Then, if the patient demands more flow than that delivered by the Volume Logic, proximal airway pressure drops. When pressure drops below baseline, the Pressure Logic sends a signal to increase flow beyond the flow signal from the Volume Logic to maintain airway pressure at baseline.

This increase in flow is termed “flow augmentation.”

If the patient continues to demand flow even after the clinician-set TIDAL VOLUME has been delivered, the Volume Logic will start sending a “zero flow” signal to the “Comparison” Logic. However, the Pressure Logic will continue to request flow to meet patient demand and to maintain pressure at baseline. The “Comparison” Logic, as usual, chooses the larger of these two flow signals (that from the Pressure Logic) and sends the flow signal to the FCV. When patient demand for flow drops to approximately 30% of its peak value, the Pressure Logic switches to a “zero flow” signal, and the FCV stops delivering flow. The patient receives a larger tidal volume than set on the controls because the patient has demanded a larger volume. The increase in tidal volume is termed “volume augmentation.”

Figure 2-6 • Leak Makeup
Pressure Augmentation

Pressure augmentation provides additional pressure support beyond that provided by flow augmentation. Accordingly, with pressure augmentation, the patient is likely to perform even less work during a volume-controlled breath.

The flow delivery logic behind pressure augmentation is similar to flow augmentation except that the Pressure Logic ensures that proximal airway pressure never drops below the sum of:

\[ \text{PEEP} + \text{PRES SUP/INSPIRATION PRES} \]

Accordingly, relative to flow augmentation, pressure augmentation causes the Pressure Logic to increase flow higher, thereby further unloading the active patient's ventilatory muscles.

Leak Makeup

During exhalation, a "leak" in the patient circuit can cause baseline pressures to drop. The Pressure Logic recognizes the drop in proximal airway pressure and sends a signal to the FCV (through the "Comparison" Logic) to increase flow until the proximal airway pressure returns to the PEEP level. This process is termed "leak makeup."
Section 3
BEAR® 1000 Ventilator
Operational Verification Procedure

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OPERATIONAL VERIFICATION PROCEDURE

(Operator Diagnostics)

This procedure is to assist a Qualified Operator, Hospital Service Technician, or Bear Medical Systems Service Technician ensure that the BEAR® 1000 Ventilator is in proper operating condition. A checklist is included and should be completed during each operational verification. A copy of the checklist should be maintained in the hospital file. The attached checklist may be copied, providing forms for future use.

VERIFICATION PROGRAM

The Operational Verification Procedure (OVP) is divided into two parts.

Part 1 consists of an automated series of built-in diagnostics tests and should be performed at least monthly.

Part 2 consists of additional manual verifications and should be performed at least twice a year.

Do not use the ventilator unless it passes the Operational Verification Procedure. For servicing, contact a Bear Medical Systems Service Technician or a Bear Medical Systems Trained Hospital Technician.

OPERATIONAL VERIFICATION PROCEDURE

The following verification procedure should be performed in the hospital by a Qualified Operator, Hospital Service Technician, or a Bear Medical Systems Service Technician. Familiarity with the function, set-up and operation of the BEAR® 1000 Ventilator is assumed. (See BEAR® 1000 Ventilator Instruction Manual.) Perform all tests in the following sequence.

**WARNING**

The Operator Diagnostics must never be performed when the ventilator is connected to a patient. To do so could result in serious injury to the patient.

NOTE

The use of test equipment not specified will introduce variables which may influence test results. Do not assume that a failure has occurred if the specified test equipment or its equivalent is not used.

TEST EQUIPMENT SPECIFIED FOR THE OVP

- Tube, Circle 72” x 3/4 (2 ea.) 51000-02759*
- Patient Wye 51000-01104*
- Chamber, VH-820 51000-02739*
- Filter, Proximal Line 50000-01106*
- Filter, Mainflow 51000-01054*
- Tubing, PVC, 1/4” ID, 72”
- Plug for Patient Wye
- Plug for Humidifier Water Port
- Oxygen Analyzer, 1% Accuracy
- Pressure Gauge, 0–100 psi ±1% F/S or better—Ametek Model 1903, Ashcroft type 1279, or equivalent
- Pressure Gauge, 0–10 cmH₂O ±1% F/S—Marshalltown Model 86F, with scale in cmH₂O,
  Wallace & Tiernan Model FA 14170 or equivalent
- Timeter K1-200 or equivalent
- Test Lung, R5, C10
- Regulated Air/O₂ Source
- Shut Off Valves
- Stopwatch

*(or equivalent)

**WARNING**

The following warnings must be read and understood before performing the procedures described in this section.

Under no circumstances should this medical device be operated in the presence of flammable anesthetics or other volatile materials due to a possible explosion hazard.

Liquid spilled or dripped into the unit may cause damage to the unit or result in an electrical shock hazard.

Oxygen vigorously accelerates combustion. To avoid violent ignition, do not use any gauges, valves, or other equipment that has been exposed to oil or grease contamination.

Do not release this medical device if any alarm/alert function is inoperative. To do so could result in a malfunction without warning, possibly resulting in personal injury up to including death or property damage. Refer the unit to a Bear Medical Systems Authorized Service Technician or a Bear Medical Systems Trained Hospital Service Technician.
WARNING

All tubing and fittings used to connect high pressure gas (air and oxygen) from the source to the test equipment and from the test equipment to the device being tested must be capable of withstanding a minimum supply pressure of 100 psi (7.03 kg/cm²). The use of tubing and fittings not capable of withstanding this pressure could cause the tubing to rupture, resulting in personal injury or property damage.

When verifying the operation of this medical device, do not breathe directly from the machine. Always use a fresh bacterial filter and test circuit. A hazard to the health of the service person may result.

If any of the following procedures cannot be verified as outlined in this document, do not use this device on a patient and refer it to Bear Medical Systems or a Bear Medical Systems Authorized Service Facility or a Bear Medical Systems Trained Hospital Service Technician.

CAUTION

The following cautions must be read and understood before performing the procedures described in this section.

Do not use MEK or Trichloroethylene, as damage to the surface may result. Do not allow any liquid to spill or drip into the ventilator.

Do not gas sterilize the ventilator. The internal materials are not compatible with gas sterilization techniques.

Before using any test equipment [electronic or pneumatic] for calibration procedures (other than operational verification), the accuracy of the instruments must be verified by a testing laboratory. The laboratory master test instruments must be traceable to the NIST (National Institute of Standards Technology) or equivalent. When variances exist between the indicated and actual values, the calibration curves [provided for each instrument by the testing laboratory] must be used to establish the actual correct values. This certification procedure should be performed at least once every six months. More frequent certification may be required based on usage and environment.

EXTERIOR INSPECTION AND CLEANING

Inspect all cords, connectors, and fittings. Inspect the case for any cracks or other damage.

CLEANING

1. Before any cleaning of the ventilator, disconnect WALL A.C.

2. Clean the exterior of the ventilator with an appropriate bactericidal or germicidal agent. Care should be exercised not to allow any liquid to penetrate the inside of the ventilator.

CAUTION

Do not gas sterilize or steam autoclave the ventilator.

FILTERS

The cabinet air inlet filters are easily accessible for removal and cleaning. The filters may be vacuumed or washed in warm soapy water, rinsed, and thoroughly dried.

CAUTION

Do not operate the ventilator without the filters in place.

PLUGS AND CABLES

Plugs and cables may be wiped down with an appropriate bactericidal or germicidal agent.
PART 1
Automated Built-In Diagnostics

Figure 3-1
Patient Circuit Connection
OPERATIONAL VERIFICATION PROCEDURE

TEST SETUP

1. Connect the test circuits to the ventilator as shown in Figures 3-1 and 3-2.

2. Plug the open end of the patient wye and the water inlet port of the humidifier.

3. Record the reading from the Hourmeter on the checklist.

NOTE
While the Operator Diagnostics are in operation, there will be other information displayed in the displays. These are not part of the Operator Diagnostics. For an explanation of these values, see Appendix A.

NOTE
The keyboard is redefined in Diagnostics. See Figure 3-9 for these functions.

NOTE
Turn the Graphics Display OFF when running the Diagnostic tests. If the Graphics Display is on, false d2 failures may occur.

ENTERING THE OPERATOR DIAGNOSTIC MODE

NOTE
PEEP must be turned off completely prior to entering the Diagnostic Mode to avoid test failure. Be sure the PEEP control is set completely counter clockwise.

1. With the ventilator power off, depress and hold the TEST Key.

2. Turn on the ventilator power and hold the TEST Key down until the Power On Testing is complete (approx. 20 seconds).

3. While the Power On tests are running, observe that all digital displays and LEDs light.

4. When the Power On Test is complete, observe and record the Configuration Code shown in two of the displays in the Controls section (See Figure 3-9). Verify that the displayed Code matches the Configuration Code on the rear of the ventilator.
5. Verify that the pressure reading in the "PROXIMAL TRANSUCER" window (see Figure 3-9) is 0.0 cmH2O ± 1.5 cmH2O. If greater than ± 1.5 cmH2O, recalibrate the transducer to zero.

**WARNING**

If Proximal Pressure Transducer reads >3.0 cmH2O, Backup Pressure Alarm will be disabled which may result in injury or death in the event of a Proximal Line Disconnect.

6. Select one of the following tests by pressing the Test Number Key and rotating the SET knob. The selection will appear in the Test Number display window.

   a. All Diagnostic Tests (d 1 through d 7)
   b. d 1 Power Up Diagnostics
      µ Processor Self Check
      ROM Check Sum
      RAM Test
   c. d 2 Flow Control Valve Test
   d. d 3 Blender Control Valve Test
   e. d 4 Leak Test
   f. d 5 Flow Delivery /
      External Flow Testing
   g. d 6 SOPR System Test
   h. d 7 Pressure Delivery /
      Pressure Sensing Test

7. The tests may be run in three different ways by pressing the following keys:

   a. Run Test Once
      Runs the selected test one time.
   b. Cycle Test
      Runs the selected test until it is cancelled or a failure occurs.
   c. Cancel Test
      Halts the running of diagnostics at the end of the current test.

**NOTE**

Due to the extensive nature of the RAM test, Diagnostic d1 takes approximately 80 seconds to complete.

---

**NOTE**

While a test is in progress, characters will be seen rapidly flashing in the Test Results display window indicating the test is in progress.

8. When a test has been successfully completed, a "P" will appear in the Test Results window.

9. If a test fails, an "F" will appear in the Test Results window.

10. Turn off ventilator to exit Diagnostic mode.

---

**PART 2**

**MANUAL TESTING**

---

**Table 1—Standard Settings**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>0 cmH2O</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PEEP Pressure</strong></td>
<td></td>
<td>0 cmH2O</td>
</tr>
<tr>
<td><strong>Alarm Settings</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I:E Override</td>
<td></td>
<td>ON</td>
</tr>
<tr>
<td>High Total Minute Volume</td>
<td></td>
<td>80 L</td>
</tr>
<tr>
<td>Low Total Minute Volume</td>
<td></td>
<td>0.0 L</td>
</tr>
<tr>
<td>High Total Breath Rate</td>
<td></td>
<td>155 BPM</td>
</tr>
<tr>
<td>Low Total Breath Rate</td>
<td></td>
<td>3 BPM</td>
</tr>
<tr>
<td>High Peak Insp Pressure</td>
<td></td>
<td>120 cmH2O</td>
</tr>
<tr>
<td>Low Peak Insp Pressure</td>
<td></td>
<td>3 cmH2O</td>
</tr>
<tr>
<td>High Baseline Pressure</td>
<td></td>
<td>55 cmH2O</td>
</tr>
<tr>
<td>Low Baseline Pressure</td>
<td></td>
<td>0 cmH2O</td>
</tr>
</tbody>
</table>

| **Control Settings**     |                                       |         |
| Tidal Volume             |                                       | 0.5 L   |
| Breath Rate              |                                       | 10 BPM  |
| Peak Flow                |                                       | 65 LPM  |
| % Oxygen                 |                                       | 21 %    |
| Pres Sup/Insp Pres       |                                       | 0 cmH2O |
| Assist Sensitivity       |                                       | 5.0 cmH2O|
| Inspiratory Pause        |                                       | 0.0 sec |
| MMV Level                |                                       | 0 LPM   |
| Compliance Comp          |                                       | 0.0 mL/cmH2O|
| Inspiratory Time         |                                       | 1.0 sec |
| Pressure Slope           |                                       | 0       |
| Mode                     | SIMV/CPAP                             |         |
| Waveform                 | Square                               |         |
| 100% Oxygen              | Off                                   |         |
| Sighs                    | Off                                   |         |
| Pressure Augment         | Off                                   |         |
| Nebulizer                | Off                                   |         |

* Not applicable for Bear® 1000 Basic Unit.
Figure 3-3

Figure 3-4
AIR/O2 INLET CHECK VALVE VERIFICATION

1. Connect the ventilator as shown in Figure 3-3.

2. Adjust the controls as shown in Table 1 except change the Oxygen % to 60%.

3. Connect the ventilator as shown in Figure 3-4.


5. Adjust the 100 psi regulator for an indication of approximately 50 psi on the test gauge.

6. Turn ON the ventilator power, ignore any alarms.

7. Open valve No.1.

8. Verify that there is no release of bubbles from hose submerged in beaker of water.

9. Close Valve No.1 and connect the test gauge, regulator and shut-off valve to the air inlet. Connect the hose and beaker to O2 inlet. Repeat Steps 7 and 8.

10. Turn the regulator down to zero and close Valve No.1.

11. Turn the ventilator power OFF, and repeat the procedure with the power turned OFF.

12. Check the appropriate block on the OVP checklist.

Figure 3-5
AIR/O₂ INLET PRESSURE GAUGE VERIFICATION

1. Connect the ventilator as shown in Figure 3-5.
2. Sequentially apply 10, 30, and 50 psig.
3. Verify that at each pressure the inlet gauges indicate ±5 psig of the applied pressure.
4. Change Oxygen % to 21%.
5. Close valve #2.
6. Verify that the Gas Supply failure alarm doesn’t come on.

ALARM LOUDNESS TESTING

1. Set the ventilator as shown in Table 1.
2. Create any condition that will cause a ventilator alarm (i.e. Pressure limit).
3. While the alarm is sounding, adjust the alarm loudness control on the rear of the ventilator.
4. Verify that the alarm loudness can be varied but not turned completely off.
5. Reset alarm to original setting or new setting if desired.

Figure 3-6

BREATH RATE VERIFICATION

1. Set the ventilator as shown in Table 1.
2. Allow the ventilator to cycle and using a stopwatch, verify the following rates ±2 BPM:
   a. 6 BPM
   b. 60 BPM

OXYGEN BLENDING VERIFICATION

1. Refer to Figure 3-2; close valve 2 and disconnect the hose.
2. Connect an O₂ supply and apply pressure.
3. Set the ventilator as shown in Table 1, but set the breath rate at 25 BPM.
4. Connect an oxygen analyzer in line with the patient circuit as shown in Figure 3-6.
5. Vary the ventilator settings as shown in Table 2 and verify that the results agree with the specifications.

NOTE
Due to a 3.5 liter accumulator chamber within the ventilator, oxygen percentage changes will not be immediate. Allow time for stabilization to occur before verifying specifications.
6. Disconnect the oxygen source and reconnect the air source.

7. Return the ventilator to the settings shown in Table 1.

Table 2—Oxygen Blending Settings

<table>
<thead>
<tr>
<th>O2 %</th>
<th>Tidal Volume</th>
<th>Breath Rate</th>
<th>Peak Flow</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>21%</td>
<td>0.50L</td>
<td>25</td>
<td>30</td>
<td>20 to 25%</td>
</tr>
<tr>
<td>40%</td>
<td>0.10</td>
<td>50</td>
<td>30</td>
<td>36 to 44%</td>
</tr>
<tr>
<td>40%</td>
<td>0.50</td>
<td>25</td>
<td>30</td>
<td>36 to 44%</td>
</tr>
<tr>
<td>60%</td>
<td>0.10</td>
<td>50</td>
<td>30</td>
<td>56 to 64%</td>
</tr>
<tr>
<td>60%</td>
<td>0.50</td>
<td>25</td>
<td>100</td>
<td>56 to 64%</td>
</tr>
<tr>
<td>80%</td>
<td>0.10</td>
<td>50</td>
<td>30</td>
<td>76 to 84%</td>
</tr>
<tr>
<td>80%</td>
<td>0.50</td>
<td>25</td>
<td>30</td>
<td>76 to 84%</td>
</tr>
<tr>
<td>100%</td>
<td>0.50</td>
<td>25</td>
<td>30</td>
<td>96 to 100%</td>
</tr>
</tbody>
</table>

**ASSIST SENSITIVITY VERIFICATION**

1. Set the ventilator as shown in Table 1, except set the Rate to 0 BPM

2. Connect the ventilator as shown in Figure 3-7, with the gauge configured to measure negative pressure.

3. Compress the test lung bellows and release while observing the test gauge.

4. Verify that the unit is triggered when the test gauge is deflected to a reading of 5 cmH2O

5. Set the Assist Sensitivity to 1 cmH2O

6. Compress the test lung bellows and release.

7. Verify that the unit is triggered when the test gauge is deflected to a reading of 1 cmH2O.
8. Repeat the preceding test to assure that the ventilator is operating properly.

Delivered/Exhaled Volume Verification

Note
Volume tolerances reflect values without heating or humidification

1. Connect the ventilator and analyzer as shown in Figure 3-8.

Caution
Do not totally occlude the Proximal Airway tube. Doing so may result in Proximal Airway gauge damage.

2. Partially occlude the Proximal Airway tube so that approximately 10 cmH2O is shown on the Proximal Airway gauge.

3. Set the ventilator as shown in Table 1 and vary the Tidal Volumes as shown in Table 3.

4. Verify that the Delivered Volumes are within the specified tolerances.
5. Reconnect expiratory limb and verify that exhaled volume readings at 0.10 and 0.50 liters are within a +0% to -15% or +0.00 to -0.03 Liter (whichever is greater) tolerance range of the delivered volumes measured in step 3.

<table>
<thead>
<tr>
<th>Tidal Volume Setting</th>
<th>Delivered Volume Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.10</td>
<td>0.08 to 0.120 L</td>
</tr>
<tr>
<td>0.50</td>
<td>0.45 to 0.55</td>
</tr>
<tr>
<td>1.00</td>
<td>0.90 to 1.10</td>
</tr>
<tr>
<td>1.50</td>
<td>1.35 to 1.65</td>
</tr>
<tr>
<td>2.00</td>
<td>1.60 to 2.20</td>
</tr>
</tbody>
</table>

APPENDIX A

While the Operator Diagnostics are running, other parameters are displayed in the displays. The following is an explanation of these values. Refer to Figure 3-9.

Monitor Fields

DELIV FLOW

Shows the Delivered Flow in the range of 0 to 278 LPM.

EXT FLOW TRANSDUCER

Shows the Exhaled Flow in the range of 0 to 300 LPM.

GAS TEMP

Shows the Gas Temperature as measured at the Flow Control Valve in the range of 50 to 104 degrees F.

PROXIMAL TRANSDUCER

Shows the pressure seen by the Proximal Pressure Transducer in the range of -60 to 140 cmH₂O.

DELTA TRANSDUCER

Shows the pressure seen by the DELTA (differential) Pressure Transducer in the range of -140 to 60 cmH₂O.

MACHINE TRANSDUCER

Shows the pressure seen by the Machine Pressure Transducer in the range of 0 to 160 cmH₂O.

FCV PRESSURE TRANSDUCER

Shows the Flow Control Valve Pressure Transducer output in the range of 0 to 20 psig.

NOTE

The next displays use each character as a separate indicator and reads from left to right. Each character displays either a 1 (active) or a 0 (inactive) state.

FCV/FAN

Character one will indicate that the Flow Control Valve is at its high end stop (maximum flow).

Character two will indicate that the Flow Control Valve is at its low end stop (zero flow).
Character three will indicate that the Cooling Fan within the ventilator is producing an operating signal.

AIR & O₂ SWITCH

Character one is not used at this time and the position will be blank.

Character two indicates that the Air Inlet Pressure Transducer is sensing sufficient inlet pressure.

Character three indicates that the Oxygen Inlet Pressure Transducer is sensing sufficient inlet pressure.

BLENDER/FLOW TRANSDUCER

Character one indicates that the Blending Control Valve is at its High Stop (100% oxygen).

Character two indicates that the Blending Control Valve is at its Low Stop (21% oxygen).

Character three indicates that the Flow Transducer is drawing an nominal amount of current (neither open/disconnected or shorted).

SOFTWARE REVISION

Shows software revision.

FCV/BLENDER COUNT

Counts from 0 to 120 as Flow Valve moves.
Counts from 0 to 124 as Blender moves.

FCV/BLENDER COUNT

Counts from 0 to 120 as Flow Valve moves.
Counts from 0 to 124 as Blender moves.

Control Fields

BAROMETRIC PRESSURE SET

Displays the current barometric pressure setting in the range of 10.5 to 14.7 psig. When this field is selected the value may be adjusted in increments of 0.1 by rotating the Set Knob.

<table>
<thead>
<tr>
<th>Feet</th>
<th>Meters</th>
<th>Barometric Pressure (psia)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>14.7</td>
</tr>
<tr>
<td>500</td>
<td>152</td>
<td>14.4</td>
</tr>
<tr>
<td>1000</td>
<td>305</td>
<td>14.2</td>
</tr>
<tr>
<td>1500</td>
<td>457</td>
<td>13.9</td>
</tr>
<tr>
<td>2000</td>
<td>610</td>
<td>13.7</td>
</tr>
<tr>
<td>2500</td>
<td>762</td>
<td>13.4</td>
</tr>
<tr>
<td>3000</td>
<td>914</td>
<td>13.2</td>
</tr>
<tr>
<td>3500</td>
<td>1067</td>
<td>12.9</td>
</tr>
<tr>
<td>4000</td>
<td>1219</td>
<td>12.7</td>
</tr>
<tr>
<td>5000</td>
<td>1524</td>
<td>12.2</td>
</tr>
<tr>
<td>6000</td>
<td>1829</td>
<td>11.8</td>
</tr>
<tr>
<td>7000</td>
<td>2133</td>
<td>11.4</td>
</tr>
<tr>
<td>8000</td>
<td>2438</td>
<td>11.0</td>
</tr>
<tr>
<td>9000</td>
<td>2743</td>
<td>10.5</td>
</tr>
</tbody>
</table>

BAUD RATE SET

Displays the four RS-232 Baud rates available as follows:

| 1.2 | = 1200 Baud |
| 2.4 | = 2400 Baud |
| 9.6 | = 9600 Baud |
| 19.2| = 19200 Baud|

When this field is selected, the user may select one of the other three rates using the Set knob.
BEAR® 1000 VENTILATOR
OPERATIONAL VERIFICATION CHECK LIST

This checklist is for use during the BEAR® 1000 Operational Verification

BEAR® 1000 Serial Number_____________ Hour meter reading_____________ Today’s date ______________

Configuration Code ________________

Service Location ________________ Service organization ________________
Address _______________________ Address _______________________
City, State, Zip ________________ City, State, Zip ________________
Contact _______________________ Service Person ________________
Phone (__) ________________ Phone (__) ________________

VERIFICATION STEPS

STEP
Inspection and cleaning performed
Display Panel Verification
Power Up Diagnostics (d1)
Proximal Transducer Verification
Flow Control Valve Test (d2)
Blender Control Valve Test (d3)
Leak Test (d4)
Flow Delivery/External Flow Test (d5)
SOPR System Test (d6)

PASS FAIL

STEP
Pressure Delivery/Pressure Sensing Test (d7)
Air and O₂ Check Valves
Air and O₂ Inlet Pressure Gauges
Alarm Loudness Test
Breath Rate Verification
Oxygen Blending Verification
Assist Sensitivity Verification
Delivered/Monitored Volume Verification
Power Loss Test

PASS FAIL

WARNING

Do not release the ventilator for use if it does not pass all of the verification procedures specified in the checklist. To do so could result in personal injury including death or property damage. Refer the ventilator to a Bear Medical Service Technician or a Bear Medical Systems trained service technician for appropriate repair and/or calibration.

Signature__________________________

PROCEDURE COMPLETE

50-12129-00  •  JULY 1994
FIGURE 3-9
Active Functions and Displays for Operator Diagnostics
Section 4
BEAR® 1000 Ventilator
Updates
Section 5
BEAR® 1000 Ventilator Calibration

Cautions and Warnings .................................. 1
Test Equipment ................................................ 2
Proximal Pressure Transducer .......................... 2
Differential Pressure Transducer ...................... 3
Machine Pressure Transducer .......................... 4
FCV Pressure Transducer ................................ 5
Air & O2 Transducers ...................................... 5
D/A Converter ................................................ 7
Exhalation Valve Regulator .............................. 7
Inlet Check Valves .......................................... 8
Air / O2 Balance ............................................. 8
Nebulizer Calibration ...................................... 8
INTRODUCTION
The information in this section is intended for use by a Bear Medical Systems factory trained service technician. Before opening the console or removing assemblies to perform calibration a reference should be made to the Instruction Manual and Sections 1, 2, 3, and 7 of this Manual to assure that the ventilator is being properly utilized.

WARNING
Oxygen Vigorously accelerates combustion. DO NOT use any gauges, valves or other equipment that has been exposed to oil or grease contamination to avoid violent ignition.

WARNING
Hazardous Voltages exist within the ventilator. Always observe appropriate safety precautions when working on the ventilator while the machine is connected to an electrical power source to prevent possible accidental injurious electrical shock.

NOTE
The Operational Verification Procedure (OVP) is always performed prior to use of this section.

PROCESS
Complete the test or series of calibration verification tests necessary. Make an analysis and judgment as to what assemblies to calibrate and/or replace. If calibration is required, perform the calibration procedures following the calibration verification procedure in this document. If replacement of an assembly is required, refer to the Replacement Section (Section 8) for instructions.

WARNING
When high pressure gas sources are connected to the ventilators, always use extreme caution when attempting to measure internal pressures. Abnormal conditions may exist where measured pressures exceed the burst pressure of the gauge, resulting in possible injury.

WARNING
After calibration and/or replacement of any assembly(ies), always repeat the Operational Verification Procedure (Section 3), then allow a "BURN-IN" period and repeat the Operational Verification Procedure (Section 3).

NOTE
If problems are incurred in obtaining the calibration performance, refer to the Troubleshooting section (Section 7) or contact your dealer or Bear Medical Systems, Inc., Service Facility.

CAUTION
Before using any test equipment (electronic or pneumatic) for calibration procedure (other than operational verification), the accuracy of the instruments must be certified by a testing laboratory. The laboratory master test instruments must be traceable to the US Bureau of Standards or equivalent. When variances exist between the indicated and actual values, the calibration curves (proved by the testing laboratory) must be used to establish the actual correct values. This certification procedure should be performed at least once every six months. More frequent certification may be required based on usage and environment.
TEST EQUIPMENT

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>50000-01000</td>
<td>Hose Assy, DISS Air, 12 ft.</td>
</tr>
<tr>
<td>50000-01001</td>
<td>Hose Assy, DISS O2, 12 ft.</td>
</tr>
<tr>
<td>50000-01210</td>
<td>Assy, Exhalation Valve Water Collector</td>
</tr>
<tr>
<td>51000-20101</td>
<td>Manley Test Lung or equivalent</td>
</tr>
<tr>
<td>52000-01036</td>
<td>O2 Relay Adjustment Tool</td>
</tr>
<tr>
<td></td>
<td>Pressure Gauge 0-200 cmH2O, ± 1% F.S.</td>
</tr>
<tr>
<td></td>
<td>accuracy or digital equivalent</td>
</tr>
<tr>
<td></td>
<td>Pressure Gauge 0-50 psi, ± 1% F.S.</td>
</tr>
<tr>
<td></td>
<td>accuracy or digital equivalent</td>
</tr>
<tr>
<td></td>
<td>Digital Voltmeter</td>
</tr>
<tr>
<td></td>
<td>Patient Circuit (adult)</td>
</tr>
<tr>
<td></td>
<td>Adjustable Pressure Regulator (0-50 PSI).</td>
</tr>
<tr>
<td></td>
<td>Adjustable Pressure Regulator (0-2 PSI).</td>
</tr>
<tr>
<td></td>
<td>Mini Strap Wrench</td>
</tr>
</tbody>
</table>

NOTE
All specification values are nominal. Variance in test equipment must be taken into consideration. Test equipment must be periodically checked to verify conformance to the manufacturer's specifications.

PRELIMINARY

Accessing Inside The Unit

Remove the single screw to the right of the Oxygen Inlet. Tilt the top of the unit up until it remains in an upright position.

Diagnostic Calibration Set Up:

Press and hold the diagnostic push switch while turning on the units power switch. The diagnostic push switch is located on the left side of Monitor board as viewed from the rear (See Figure 5-1).

Refer to Figure 5-3 for the redefined functions of the Control and Monitor Panels to perform the calibrations.

TRANSDUCER CALIBRATION

NOTE
Do not connect external gas sources to the ventilator until instructed to do so.

Proximal Pressure Transducer Calibration:

1. Remove the tubing from the Proximal Pressure Transducer.

2. Select Channel Number 1.
3. Select Calibration Point 0.
4. Adjust R2, if required, to obtain a reading of 307 ±10 in the Current Count window.
5. Select and set 00.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.
6. Press the Set Point key to program the new calibration point.
7. Connect the Proximal Transducer as shown in Figure 5-2 and apply 95 ±.5 cmH2O pressure.
8. Select Calibration Point P.
9. Select and set 95.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.
10. Press the Set Point to program the new calibration point.
11. Connect the Proximal Transducer as shown in Figure 5-2 except to the opposite port (negative) and apply 40 ±.5 cmH2O pressure.
12. Select Calibration Point n.
13. Select and set 40.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.
14. Press the Set Point to program the new calibration point.
15. Connect the tubing back to the Proximal Pressure Transducer.

Differential Pressure Transducer Calibration:
1. Remove the tubing from the Differential Pressure Transducer.
2. Select Channel Number 2.
3. Select Calibration Point 0.

Figure 5-4
Differential Transducer Calibration
4. Select and set 00.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.

5. Adjust R1, if required, to obtain a reading of 716 ±10 in the Current Count window.

6. Press the Set Point key to program the new calibration point.

7. Connect the Differential Transducer as shown in Figure 5-4 and apply 40 ±5 cmH2O pressure.

8. Select Calibration Point P.

9. Select and set 40.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.

10. Press the Set Point to program the new calibration point.

11. Connect the Differential Transducer as shown in Figure 5-4 except to the opposite port (negative) and apply 95 ±5 cmH2O pressure.

12. Select Calibration Point n.

**Machine Pressure Transducer Calibration:**

1. Remove the tubing from the Machine Pressure Transducer.

2. Select Channel Number 3.

3. Select Calibration Point 0.

4. Adjust R3, if required, to obtain a reading of 204 ±10 in the Current Count window.

5. Select and set 00.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.

6. Press the Set Point key to program the new calibration point.

7. Connect the Machine Transducer as shown in Figure 5-5 and apply 120 ±5 cmH2O pressure.

8. Select Calibration Point P.

9. Select and set 120.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.

10. Press the Set Point to program the new calibration point.

**Figure 5-6**

FCV Transducer Calibration

7. Connect the Machine Transducer as shown in Figure 5-5 and apply 120 ±5 cmH2O pressure.

8. Select Calibration Point P.

9. Select and set 120.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.

10. Press the Set Point to program the new calibration point.

**Figure 5-5**

Machine Transducer Calibration

13. Select and set 95.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.

14. Press the Set Point to program the new calibration point.

15. Connect the tubing back to the Differential Pressure Transducer.
11. Connect the tubing back to the Machine Pressure Transducer.

**FCV Pressure Transducer Calibration:**
1. Remove the tubing from the FCV Pressure Transducer.
2. Select Channel Number 4.
3. Select Calibration Point 0.
4. Adjust R4, if required, to obtain a reading of 100 ±10 in the Current Count window.

![Figure 5-7](image)

**Air & O2 Transducer Calibration**
5. Select and set 00.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.
6. Press the Set Point key to program the new calibration point.
7. Connect the FCV Transducer as shown in Figure 5-6 and apply 12 ±5 psig pressure.
8. Select Calibration Point P.
9. Select and set 12.00 psig in the Pressure 3 MSD and Pressure 2 LSD windows.
10. Press the Set Point to program the new calibration point.
11. Connect the tubing back to the FCV Pressure Transducer.

![Figure 5-9](image)

**Figure 5-8**
Interface Pin Locations

**D/A Calibration Potentiometers**

**Air & O2 Pressure Transducers Calibration:**
1. Connect an external gas source and gauge to the ventilator as shown in Figure 5-7.
2. Select Channel Number 5 (Air).
3. Select Calibration Point P.
4. Adjust the external gas source for 28.50 ±.50 psi.
5. Select and set 28.50 psi in the Pressure 3 MSD and Pressure 2 LSD windows.
6. Press the Set Point to program the new calibration point.
7. Select Channel Number 6 (O2).
Figure 5-10
Active Controls in Manual Mode

Figure 5-11
Exhalation Valve Regulator Calibration
8. Select Calibration Point P.
9. Press the Set Point to program the new calibration point.

D/A Converter Calibration

**NOTE**

There have been two designs of the Control PCB. These are interchangeable but the location of the potentiometers and their designations. Refer to Figure 5-9.

1. Select Channel Number 7.
2. Press the Set Point key.
3. Referring to Figure 5-8, measure the voltage between Pin 2 (ground) and Pin 1 of the Analog Output connector (Pressure Channel 0).
4. If this does not measure 5.000± 0.005 Vdc, adjust R5 or R9 on the Control PCB (The pots are on the component side of the PCB in the positions indicated in Figure 9).
5. Measure the voltage between Pin 4 (ground) and Pin 3 (Flow Channel 1).
6. If this does not measure 5.000± 0.005 Vdc, adjust R6 or R10 on the Control PCB.
7. Measure the voltage between Pin 6 (ground) and Pin 5 (Volume Channel 2).
8. If this does not measure 7.500± 0.005 Vdc, adjust R7 or R11 on the Control PCB.

**Exhalation/SOPR Pressure & Over-Pressure Relief**

1. Press the Manual Control key to enter the Service Diagnostics Manual mode (See Figure 5-3).
2. tee in the pressure gauge to the Exhalation Valve Regulator output fitting as shown in Figure 5-11.
3. Press the Exhalation Solenoid key to turn on (display = 1) the Exhalation solenoid See Figure 5-10.
4. Press the Shut Off key to turn on (display = 1) the Shut Off solenoid.
5. Verify that the pressure gauge reads 140 ± 10 cmH2O. Readjust the low pressure regulator if necessary.
6. If required, remove the Adjustment Screw Cover and adjust the Exhalation Valve regulator to achieve 140 ±10 cmH2O.
7. Remove the pressure gauge and turn off (display = 0) both solenoids.
8. Press the FCV POSITION key and turn the SET knob until the Flow Control valve opens to maximum position.
9. Disconnect the Proximal Airway line at the BEAR® 1000 and connect it to the pressure gauge.

![Diagram of Air & O2 Regulator Calibration](image)

**Figure 5-12**

**Air & O2 Regulator Calibration**

10. Press the Exhalation Solenoid key to turn on (display = 1) the Exhalation Solenoid.
11. Press the Shut Off Solenoid key to turn on (display= 1) the Shut Off Solenoid.
12. Verify that the SOPR valve is popped open to relieve the pressure and the maximum pressure in the patient circuit is between 121 to 175 cmH2O as shown on the pressure gauge.
13. Turn off the Shut-Off solenoid, Exhalation solenoid and close the Flow Control valve.
14. Connect a patient circuit to the Manley test lung from the ventilator and set the Manley to C50 and zero resistance.
15. Verify that the gas can flow from the dump port to the patient outlet port by pulling the Manley's bellows.
Nebulizer Calibration

1. Set the Crossover Solenoid to 1 (open).
2. Set the BCV Position to mid range (approximately 60).
3. Apply approximately 50 psi to the air inlet port and verify that there is zero flow (bubble tight) coming out at the O2 inlet port.
4. Apply approximately 50 psi to the O2 inlet port and verify that there is zero flow (bubble tight) coming out at the Air inlet port.
5. Set the Crossover Solenoid to 0 (closed).

Air/O2 Pressure Balance

1. Set the Shut Off & Bleed Solenoids to 1 (open).
2. Connect the ventilator as shown in figure 5-12 and apply 50 psi air and O2.
3. Verify that the air regulator output pressure is 18.0 ± 0.1 PSIG. Readjust the Air regulator if necessary.
4. Air/O2 differential shall be 0 ± 2 cmH2O.
5. If required, remove the plug from the O2 relay and adjust using the O2 Relay adjustment tool.
6. Set the Shut Off & Bleed Solenoids to 0 (closed).

Nebulizer Calibration

1. Connect the test equipment to the ventilator as shown in Figure 5-13.
2. Fully close the needle valve.
3. Turn on the ventilator in Service Diagnostics mode and enter the Manual Control mode.
4. Activate the Nebulizer Solenoid (Ref. Figure 5-10).
5. The gauge should read 10 ± 0.5 psi.
6. If required, adjust the Nebulizer Regulator by pulling up the locking ring and turning the center knob (Ref Figure 5-14).
7. Open the needle valve to obtain a flow of 6 ± 2.0 LPM on the flowmeter.
8. Open the Flow Valve for a position indication of 40.
9. Observe that the gauge reads a minimum of 8.5 psi.
Section 6
BEAR® 1000 Ventilator
Schematics

System Wiring Diagram ........................................1
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Power Supply Module ..........................................3
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Electro-Pneumatic interface ..................................12
External Flow Sensor ..........................................16
Oxygen Blender ..................................................17
<table>
<thead>
<tr>
<th>TPNO</th>
<th>PLNO</th>
<th>TUBE SIZE</th>
<th>TUBE MATERIAL</th>
<th>FROM COMPONENT</th>
<th>TO COMPONENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1/8 X 15.0</td>
<td>NYLON</td>
<td>INLET MANIFOLD</td>
<td>KOUER MANIFOLD</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>1/8 X 10.0</td>
<td>NYLON</td>
<td>INLET MANIFOLD</td>
<td>KOUER MANIFOLD</td>
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<td>3</td>
<td>6</td>
<td>1/8 X 3.5</td>
<td>SILICONE</td>
<td>AIR REG</td>
<td>TEE</td>
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<td>4</td>
<td>6</td>
<td>1/8 X 3.5</td>
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<td>TEE</td>
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<td></td>
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<td>SHUT-OFF VALVE</td>
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<td>ACCUMULATOR</td>
<td>FLOW VALVE</td>
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<td>VINYL</td>
<td>REDUCER</td>
<td>TEE</td>
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<tr>
<td>11</td>
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<td>JET PUMP</td>
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<td>5</td>
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<td>JET PUMP</td>
<td>TEE</td>
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<td>20</td>
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<td>1/8 X 3.5</td>
<td>VINYL</td>
<td>JET PUMP</td>
<td>TEE</td>
</tr>
</tbody>
</table>

16. TUBING THAT IS PART OF THE INLET MANIFOLD ASSY IS NOT SHOWN FOR CLARITY.
15. TUBING AND TEES SHOWN BUT NOT IDENTIFIED ARE PART OF THE EPI PCB ASSEMBLY.
14. TIE-WRAP ALL VINYL TUBING CONNECTIONS.
13. DELETED.
12. SEE TUBE LIST FOR PL ITEMS 1,2,5,7,8 & 11.
11. UNLESS NOTED OTHERWISE, DIAMETERS ARE INSIDE DIAMETERS.
Section 7
BEAR® 1000 Ventilator
Troubleshooting

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INTRODUCTION

The Information in this section is intended for use by a Bear Medical Systems, Inc., factory trained service technician or bio-medical engineer.

**CAUTION**

Thoroughly review the Instruction Manual and Section 3 of this maintenance manual before proceeding with any repair.

This section is NOT intended to replace the skills and knowledge of a trained field engineer, but should only serve to expedite the repair of the ventilator.

This section is to assist in isolating a malfunction from the Error Codes generated by the Bear® 1000.

However in most cases, it is not practical or possible to absolutely determine which assembly may be causing a malfunction in field situations. In these instances, the only reasonable method of repair is the substitution of known good assemblies.

The ventilator is able to store the last 16 Error Codes (numbered 1 thru 16) with the highest number representing the most recent occurrence of the error.

This Error Code history may be viewed by entering the Operator Diagnostic mode. The Peak Flow display will contain the error record number and the Oxygen % display will contain the Error Code itself. Rotating the Control Set knob will allow a review of the Error Codes that have been stored.

**CAUTION**

The error code history may be selectively or completely erased if desired. Prior to doing this, it is strongly recommended that the codes be recorded in the order that they are stored to provide data in the event that there may be some repeat occurrence.

To erase an Error Code, enter the Service Diagnostics mode. Select the Error Number function and using the Control Set knob, display the Error Number to erase. Press the nebulizer key and the Error Number and its corresponding Error Code will be erased from memory. Repeat as required.

**Error codes E1 – E9**

These codes indicate malfunctions with the Control PCB.

1. Check electrical connections for mechanical integrity and proper orientation.
2. Check for complete seating of socketed components.
3. Substitute the Control PCB with a known functional assembly.

**Error codes E10 – E15**

These codes indicate malfunctions with the EPI PCB.

1. Check electrical connections for mechanical integrity and proper orientation.
2. Check for complete seating of socketed components.
3. Substitute the EPI PCB with a known functional assembly.

**Error codes E20 – E23**

These codes indicate malfunctions with the Monitor PCB.

1. Check electrical connections for mechanical integrity and proper orientation.
2. Check for complete seating of socketed components.
3. Substitute the Monitor PCB with a known functional assembly.

**Error codes E24 – E30**

These codes are not in use at this time.

**Error code E31**

This error code is related to the solenoid driving circuitry used within the unit.

1. Substitute the EPI PCB with a known functional assembly.
**Error code E32**

This error code is related to the internal cooling fan.

1. Check to see if the fan is being mechanically jammed by any foreign material.

2. Check the electrical connection between the fan and the EPI PCB.

3. Substitute the fan with a known functional assembly.

**Error code E35**

This error code is related to the External Flow PCB.

1. Substitute the External Flow PCB with a known functional assembly.

**Error code E36**

This error code is related to the Flow Control Valve.

1. Check the electrical connection between the Flow Control Valve and the EPI PCB.

2. Run Operator Diagnostic test d02 to determine if the Flow Control Valve is mechanically jammed.

3. If the error is repeatable, replace the Flow Control Valve with a functional unit.

**Error code E37**

This error code is related to the Flow Control Valve Electronics.

1. Replace the Flow Control Valve with a functional unit.

**Error code E38**

This error code is related to the electronics of the EPI PCB.

1. Replace the EPI PCB with a functional unit.

**Error code E39**

This error code is related to the Power Supply.

1. With the ventilator open and referring to figure 7-1, locate the solder side of the Power Supply Hold Up PCB and the terminal leads of capacitor C2.

2. Check the voltage across these leads. It should be nominally +28 Vdc. If this is not correct, the unit may not be correctly configured for the wall supply voltage or the transformer may be defective.

3. Referring to figure 7-2 and table 7-1, verify the outputs of the power supply. If not within specification, the Power Supply PCB may require replacement.
OPERATOR DIAGNOSTICS CODES

Diagnostic Test d01

This is a test of internal electronic functions. A failure of this test would result from a malfunction of the Control PCB and would also generate error codes E1 – E9 in normal operation.

1. Check electrical connections on the Control PCB for mechanical integrity and proper orientation.

2. Check for complete seating of socketed components.

3. Substitute the Control PCB with a known functional assembly.

Diagnostic Test d02

This is a test of the Flow Control Valve requiring it to reach a fully open and fully closed state within a specific number of step commands.

NOTE

This error may occur if the diagnostics are run with a Graphics Display connected and operating. Repeat test with Graphics Display turned off.

1. Check the electrical connection to the EPI PCB for mechanical integrity and proper orientation.

2. Substitute the Flow Control Valve with a known functional assembly.

Diagnostic Test d03

This is a test of the Blender Control Valve requiring it to reach a fully open and fully closed state within a specific number of step commands.

NOTE

This error may be generated by performing diagnostics with the Blender exposed to high levels of light. Repeat test with upper console closed.

1. Check the electrical connection to the EPI PCB for mechanical integrity and proper orientation.

Table 7-1

<table>
<thead>
<tr>
<th>Connection</th>
<th>Voltage</th>
<th>Acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>P32-1 (GND) - P32-2 (±5 Vdc)</td>
<td>±5%</td>
<td></td>
</tr>
<tr>
<td>P32-3 (GND) - P32-4 (+12 Vdc)</td>
<td>±5%</td>
<td></td>
</tr>
<tr>
<td>P32-5 (GND) - P32-6 (+5 Vdc)</td>
<td>±5%</td>
<td></td>
</tr>
<tr>
<td>P32-8 (GND) - P32-7 (+12 Vdc)</td>
<td>±10%</td>
<td></td>
</tr>
<tr>
<td>P32-3 (GND) - TP1 (+9 Vdc)</td>
<td>±5%</td>
<td></td>
</tr>
<tr>
<td>P32-3 (GND) - TP2 (+5 Vdc)</td>
<td>Precision Reference</td>
<td></td>
</tr>
</tbody>
</table>
2. Substitute the Blender Control Valve with a known functional assembly.

Diagnostic Test d04

This is a test for pneumatic leaks. A specific amount of gas is delivered and the pressure in the patient circuit is recorded. After five seconds the pressure is checked again and must be within ±10 cmH2O of the first reading.

1. Check leaks in the patient circuit.

2. Check for complete seating of the Exhalation Manifold and integrity of the Exhalation Balloon.

3. Check the patient outlet fitting for tightness and the check valve within it.

4. Check for an internal leak along all of the connections on the Proximal Airway pressure line.

5. Check the calibration and stability of the Proximal Pressure Transducer.

Diagnostic Test d05

This is a test of both Flow Delivery and External Flow Sensing.

The internal Accumulator is allowed to charge and its pressure is checked. At this time External Flow is checked to be at normal levels.

The ventilator will then deliver 60 LPM for two seconds and the Accumulator pressure and External Flow is again checked.

This process is repeated for a flow of 150 LPM.

1. Check for internal leaks or occlusions particularly in high pressure lines.

2. Check that the external gas supply is adequate for the ventilator.

3. Repeat test d02 to check for a possible Flow Control Valve Failure.

4. Check the calibration of the Flow Control Valve Transducer.

5. Check the External Flow Sensor as described for error code E34.

Diagnostic Test d06

This is a test of the Sub-Ambient/Over-pressure Relief Valve (SOPR). The valve is opened and its resistance to 60 LPM of flow is measured.

1. Check the calibration of the Proximal Pressure Transducer.

2. Substitute a known functional SOPR Valve.

3. Check for leakage from the Shut Off Solenoid (This would inflate the SOPR balloon).

4. Check the output of the Flow Control Valve (flow too high), Diagnostic Test d02.

Diagnostic Test d07

This is a test of Pressure Delivery and Pressure Sensing.

First the outputs of the Proximal, Delta, and Machine pressure transducers are checked with minimum pressure.

Second, the Proximal and Machine pressure transducers are checked with 60 cmH2O applied and then with 120 cmH2O applied.

NOTE

This error may occur if PEEP is turned on. Make sure that PEEP is completely off and repeat test.

1. Check the calibrations of the Proximal, Delta, and Machine pressure transducers.

2. Check for both external and internal leaks.

3. Check the Exhalation Valve and SOPR Valve for proper assembly and operation.

4. Check the Flow Control Valve for proper operation (Diagnostic Test d02).

5. Substitute a known functional EPI PCB.
MANUAL CONTROL MODE

The Manual Control mode of the Service Diagnostics may be of assistance to the technician. Individual stepper motors, solenoids, and the audible alarms can be activated from the Control Panel.

After entering the Service Diagnostics Mode, refer to figure 7-2 and press the Manual Control button. The functions shown on the Control Panel will then be available.

To actuate the Flow Control Valve (FCV), select it and use the Control Set knob to increment the step count displayed. The same actions will control the Blender Control Valve (BCV).

NOTE

The number of steps indicated will not directly correspond to a particular flow or oxygen setting. Each valve is individually calibrated and correction curves stored on the valve electronics.

Solenoids are activated in a toggle fashion. A "0" in the display window indicates power off and "1" indicates power is applied.

The Audible Alarm toggles between a sounding or non-sounding mode.

Figure 7-2
Manual Control Mode
Section 8

BEAR® 1000 Ventilator

Removal and Replacement

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Air & O2 Inlet Manifold ..........................................2
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Accumulator Assy ....................................................4
External Flow Sensor PCB .......................................4
Fan Assembly ..........................................................4
Shut Off Solenoid ......................................................4
Alarm Loudness Assembly .......................................5
AC Outlet for Graphics Display ..................................5
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**WARNING**

Disconnect all electrical power, air, and oxygen sources before attempting any disassembly. Failure to do so could result in injury to the service technician or damage to equipment.

**WARNING**

After replacement of any assembly(ies), always repeat the Operational Verification Procedure (section 3), then allow a "burn-in" period and repeat the Operational Verification Procedure.

**Interior Access**

1. If connected, remove cables leading to RS-232 and Analog outputs ports of the ventilator.
2. Remove the screw indicated in Figure 8-1.
3. Tilt the console forward to its rest position.

**Figure 8-1**

Console Interior Access

EPI PCB - 51000-08670 or 51000-21XXX

1. Label or mark electrical cables prior to removal to insure proper assembly noting both designation and location of pin 1.

**Figure 8-2**

EPI PCB

50000-12131 • NOVEMBER 1993
2. After marking or labeling, remove the silicone and PVC tubing from the transducers.

3. After marking or labeling, remove the high pressure lines from the Air and O2 pressure transducers by pushing in the collar while pulling on the tubing.

4. Remove the four mounting screws from the EPI PCB (Figure 8-2, Ref. 1).

**NOTE**

If the CFG EPROM, U6, is soldered in place, contact Bear Medical Systems, Inc. for further instructions.

5. Remove the MPU, U8 (Figure 8-2, Ref. 2), and the CFG EPROM, U6, (Figure 8-2, Ref. 3), and place them in the replacement EPI PCB, being sure of proper orientation.

6. To install the replacement PCB, reverse the removal instructions.

7. Perform the transducer calibrations as described in Section 5, and the OVP as described in Section 3.

---

**Air & O2 Blender - 51000-08562 or 51000-21XXX**

1. Remove the ribbon cable (Figure 8-3, Ref. 1) at its connection on the EPI PCB.

---

![Figure 8-3 Air & O2 Blender](image)

---

**WARNING**

Do not interchange a socketed (U6) EPI PCB for non-socketed PCB. It is mandatory to install the same CFG EPROM (U6) into the new PCB.

---

2. Mark or tag the PVC hoses (Figure 8-3, Ref. 2) coming from the Blender and remove.

3. Remove the two mounting screws (Figure 8-3, Ref. 3) and remove the Blender from the ventilator.

4. To install the replacement Blender, reverse the removal instructions replacing any cable ties or tube clamps removed during the process.

5. Perform the OVP as described in Section 3 to verify the proper operation of the Blender.

---

**Air & O2 Inlet Manifold - 51000-08622 or 51000-21XXX**

1. Perform the procedure to remove the Air & O2 Blender.

3. Remove the pneumatic and electrical connections indicated in Figure 8-4 Ref. 1 - 9, marking as required to facilitate re-assembly.

4. Remove the bowls of the water traps on the rear of the unit.

---

![Figure 8-4 Inlet Manifold](image)

---

![Figure 8-5 Inlet Manifold Mounting Screws](image)
5. Remove the four screws (Figure 8-5, Ref. 1) and lift the manifold from the ventilator.

6. Remove the two screws and lift Power supply from the manifold.

7. To install the replacement manifold, reverse the removal instructions replacing any cable ties or tube clamps removed during the process.

8. Perform the regulator calibrations as described in Section 5, and the OVP as described in Section 3.

**Power Supply Module - 51000-08670 or 51000-21XXX**

1. Perform the procedure to remove the Air & O2 Blender.

2. Perform the removal of the Air & O2 Inlet Manifold.

3. Remove the two screws that secure the Power supply to the Inlet Manifold Assembly.

4. To install the replacement PCB, reverse the removal instructions.

**Power Supply Hold Up Capacitor Assy - 51000-08671 or 51000-21XXX**

1. Perform the procedures to remove the following assemblies:

   - EPI PCB
   - Air & O2 Blender.
   - Air & O2 Inlet Manifold.

2. After marking for correct orientation, remove connector J45 from the PCB (Figure 8-6, Ref. 4).

3. Remove the two phillips screws securing the PCB to the ventilator chassis (Figure 8-6, Ref. 5).

4. To install the replacement PCB, reverse the removal instructions.

**Figure 8-6**

Lower Console
Accumulator Assembly - 51000-08623

NOTE
If the ventilator is mounted to a cart or a compressor module, it must be removed prior to removing the Accumulator Assembly.

1. Perform the procedures to remove the following assemblies:
   EPI PCB
   Air & O2 Blender.
   Air & O2 Inlet Manifold.
2. Remove the three pneumatic connections to the Accumulator Assembly (Figure 8-6, Ref. 6).
3. After closing the ventilator, tilt it on its side or back and remove the large phillips screw in the center position on the bottom.
4. Lift the Accumulator Assembly free of the ventilator.

External Flow Sensor PCB - 51000-08625 or 51000-21XXX

NOTE
While it is possible to remove this assembly without involving other assemblies, it will be difficult due to the position of the mounting screws within the chassis. A long, magnetized, phillips screwdriver or holding screwdriver would be required to start and tighten the screws for assembly.

1. Perform the procedures to remove the following assemblies:
   EPI PCB
   Air & O2 Blender.
   Air & O2 Inlet Manifold.
   Accumulator Assembly
2. After marking for correct orientation, remove connector J26 from the EPI PCB.
3. After marking for correct orientation, remove connector J27 from the External Flow Sensor PCB.
4. Remove the mounting brackets for installation on the replacement PCB.

Fan Assembly - 51000-08609

NOTE
There have been three configurations in the way that the fan is mounted. It will require visual inspection to determine the appropriate hardware required for replacement.

The key items are whether the fan is secured by screws and nuts and whether there is a metal shroud between the fan and the ventilator chassis.

If required order:
4 ea. 6-32 x 3/4" screw 53002-16212
Shroud 51000-08871

WARNING
If the fan is of the type with screws and nuts, be certain that none of the nuts are lost within the ventilator.

1. Remove the two foam ambient air intake filters.
2. Remove the 4 fan mounting screws (Figure 8-6, Ref. 8).
3. Install the replacement fan by reversing the removal instructions noting that air flow (indicated by an arrow on the fan body) is into the ventilator.

Shut Off Solenoid- 51000-08720

1. Perform the procedures to remove the following assemblies:
   EPI PCB
   Fan Assembly
2. Remove the two phillips screws (Figure 8-6, Ref. 1) securing the mounting bracket to the chassis of the ventilator.
3. Remove the two screws attaching the mounting bracket to the solenoid.

**Alarm Loudness Assembly - 51000-08717**

1. Perform the procedures to remove the following assemblies:
   - EPI PCB
   - External Flow sensor PCB
2. Remove the Alarm Loudness knob (Figure 8-6, Ref. 2) using an allen wrench.
3. Remove the mounting nut at the rear of the ventila- tor and remove the control from the console.

**AC Outlet for Humidifier - 56090-20385**

1. Perform the procedures to remove the following assemblies:
   - Air & O2 Blender.
   - Air & O2 Inlet Manifold.
2. After marking or labeling the three wires going to the back of the outlet, remove the three retaining screws.

**WARNING**

*Be certain that neither of the mounting nuts are lost within the ventilator.*

3. Remove the two outlet mounting screws (Figure 8-6, Ref. 10) and remove the outlet from the inside of the ventilator.

**AC Outlet for Graphics Display - 56060-20559**

1. Perform the procedures to remove the following assemblies:
   - EPI PCB
   - External Flow sensor PCB
2. Mark or label the three faston connectors to the outlet for proper assembly and remove.
3. Remove the two mounting screws (Figure 8-6, Ref. 3) using an allen wrench.

**Power Entry Module (PEM) - 56090-20558**

**NOTE**

The voltage selector drum is not included as part of this assembly. If required, order separately under part number 56001-00239.

**NOTE**

The fuse receptacles in the Power Entry Module are not used and fuses will probably be absent. It is not necessary to install anything in their locations.

**WARNING**

*Be certain that neither of the mounting nuts are lost within the ventilator.*

1. Perform the procedures to remove the following assemblies:
   - Air & O2 Blender.
   - Air & O2 Inlet Manifold.
2. Mark or label the 6 faston connectors as to position and remove.
3. Mark or label the two wires going to the power switch and remove at the power switch end.
4. Using an allen wrench, remove the power cord retaining bracket.
5. Using an allen wrench, remove the mounting screws and nuts from the Power Entry Module (Figure 8-6, Ref. 9).
6. After removing the heat shrink tubing, unsolder the two lower wires from the Power Entry Module, noting locations.

**WARNING**

*Be certain that neither of the mounting nuts are lost within the ventilator.*

7. Solder the wires to the replacement module, covering the joints with heat shrink tubing.
8. Transfer the voltage selector drum from the original module to the replacement and reinstall.

Main Power Receptacle - 56090-20385

1. Perform the procedures to remove the following assemblies:
   Air & O2 Blender.
   Air & O2 Inlet Manifold.

2. Noting or marking as to orientation, remove the two wires going to the fuses at the fuse end and the ground wire going to the main ground stud.

3. Using an allen wrench, remove the mounting screws and nuts from the receptacle (Figure 8-6, Ref. 10).

4. Transfer the three wires from the old receptacle to the new one.

Fuse Holder (6 ea) - 56001-00245

NOTE
Fuses are not included as part of this assembly. If required, follow the labeling on the rear of the unit to obtain replacement fuses of the proper rating.

NOTE
Removal instructions for each of the 6 fuse holders is the same except that either the Main Power receptacle or the Power Entry Module may have to be removed to get access.

1. Perform the procedures to remove the following assemblies:
   Air & O2 Blender.
   Air & O2 Inlet Manifold.

2. If required, remove either:
   Power Entry Module
   Main Power Receptacle

3. After noting or marking wires as to location, remove them from the Fuse Holder body.

4. Using a wrench, loosen and remove the retaining nut and remove the holder through the back of the unit (Figure 8-6, Ref. 11).

AC Line EMI/RFI Filter - 56001-00175

1. Perform the procedures to remove the following assemblies:
   Air & O2 Blender.
   Air & O2 Inlet Manifold.

2. After noting or marking wires as to location, remove the 5 faston connectors to the filter.

3. After noting orientation, remove the filter by removing the two phillips screws (Figure 8-6, Ref. 12).

Power Switch - 56080-10078

1. Perform the procedures to remove the following assemblies:
   Air & O2 Blender.
   Air & O2 Inlet Manifold.

2. Noting or marking as to connection points, remove the four connectors from the rear of the switch (Figure 8-6, Ref. 13).

3. Using an allen wrench, remove the two screws and nuts from the switch (Figure 8-6, Ref. 14).

4. Pull the switch out through the rear of the ventilator.

Transformer Assembly - 51000 08716

1. Perform the procedures to remove the following assemblies:
   Air & O2 Blender.
   Air & O2 Inlet Manifold.

2. Noting or marking as to connection points, remove the four wires going to the EMI/RFI filter.

3. Remove the one wire going to the Power Entry Module.

4. Unplug the connector going to the Power Supply Assembly.

5. Remove the four screws (Figure 8-6, Ref. 15) from the transformer mounting plate.

6. Remove the two screws and nuts securing the transformer to the mounting plate (Figure 8-6, Ref. 16).
NOTE
The mounting plate is not included as part of this assembly. If required, order separately.

**Flow Control Valve (FCV) - 51000-08520 or 51000-21XXX**

1. Perform the procedures to remove the following assemblies:
   - Air & O2 Blender.
   - Air & O2 Inlet Manifold.
2. Remove the ribbon cable going to the EPI PCB connector P2.
3. Remove the hoses (Figure 8-6, Ref. 17 & 18) from the FCV.
4. Remove the three screws (Figure 8-6, Ref. 19) from the base of the FCV.
5. Remove the FCV from the ventilator.

**Buzzer Assembly - 51000-08608**

1. Unplug the Alarm Buzzer connector from the EPI PCB (Figure 8-2).
2. Unscrew the large holding nut from the inside of the ventilator (Figure 8-6, Ref. 20).
3. Remove the Buzzer from the front of the ventilator.

**Sub-Ambient/Overpressure Relief Valve Assembly (SOPR) - 51000-08540 or 51000-21XXX**

1. After labeling or marking, remove the pneumatic connections from the valve (Figure 8-6, Ref. 21).
2. Remove the screw securing the mounting bracket to the chassis and the screw securing the mounting bracket to the SOPR valve (Figure 8-6, Ref. 22).
3. Unscrew the outlet fitting from the front of the ventilator and remove the valve from the ventilator.

**Nebulizer Solenoid Valve - 51000-08722**

**NOTE**
A 1/2 " crowfoot style wrench is required for the proper removal and installation of this solenoid.

1. Remove the Nebulizer Electrical connector from the EPI PCB (Figure 2).
2. Remove the screw from the top of the solenoid that secures the two grounding wires.
3. Remove the pneumatic connection from the Nebulizer Solenoid (Figure 8-6, Ref. 23).
4. Using the 1/2 " crowfoot wrench, loosen the chrome nut on the inside of the ventilator that secures the bulkhead fitting to the chassis.
5. From the outside of the ventilator, unscrew the the bulkhead fitting from the Nebulizer solenoid, loosening the inside nut as required.

**Nebulizer Regulator Assembly - 51000-08724**

1. Perform the procedures to remove the following assemblies:
   - EPI PCB.
2. Remove the two pneumatic connections from the Nebulizer Regulator (Figure 8-6, Ref. 25).
3. Unscrew the retaining collar from the Nebulizer Regulator (Figure 8-6, Ref. 25).
4. Slide the regulator from the bracket and remove from the ventilator.
5. After installation, perform the regulator calibration as described in Section 5 of this manual.

**Exhalation Valve Solenoid Assembly - 51000-08721**

1. Perform the procedures to remove the following assemblies:
   - EPI PCB
   - Exhalation Valve Regulator
2. Remove the two pneumatic connections from the solenoid (Figure 8-6, Ref. 27).
Figure 8-7
Upper Console

Figure 8-8
Upper Console (PCB's Removed)
3. Remove the two screws securing the mounting bracket to the ventilator chassis and remove the assembly from the ventilator.

4. Remove the two screws securing the solenoid to the mounting bracket.

**Exhalation Valve Regulator - 51000-08723**

1. Perform the procedures to remove the following assembly:
   - EPI PCB
2. Remove the two pneumatic connections to the regulator (Figure 8-6, Ref. 28).
3. Remove the two screws securing the regulator to the mounting bracket and remove the regulator from the ventilator.
4. After installation, perform the calibration as described in Section 5 of this manual.

**Control PCB - 51000-08674 or 51000-21XXX**

1. Detach the ribbon cables P8, P9, P11 from the Control PCB (Figure 8-7, Ref 1).
2. Detach the ribbon cables P14, P15, P16, from the Control PCB (Figure 8-7, Ref 2).
3. Remove the six screws (Figure 8-7, Ref 3) and insulator (Figure 8-7, Ref. 9).
4. Remove EPROM, U86, and install into replacement PCB taking care as to proper orientation.

**Exhalation Valve Bulkhead Assy - 51000-08635**

1. Perform the procedures to remove the following assembly:
   - EPI PCB
   - Accumulator Assy.
2. Remove the pneumatic connection from the assembly (Figure 8-6, Ref. 30).
3. Remove the two screws from the bulkhead assembly (Figure 8-6, Ref. 31).
4. Pull the assembly out through the front of the ventilator.
5. Unscrew the Diaphragm Mounting Base from the bulkhead assembly.

**Monitor PCB - 51000-08676 or 51000-21XXX**

1. Detach the ribbon cables P9, P11, (Figure 8-7, Ref 1) from the Control PCB.
2. Detach the ribbon cables P6, P13, P18, P20 (Figure 8-7, Ref 4).
3. Remove the four screws (Figure 8-7, Ref 5) from the Monitor PCB.
4. Remove MPU, U9, and install into replacement PCB taking care as to proper orientation.

**External Flow System Internal Cable Assy. - 51000-08632**

1. Perform the procedure to remove the following assembly:
   - EPI PCB
   - Exhalation Valve Regulator
2. Remove the mounting nut from the Hour meter (Figure 8-6, Ref. 32) and slide it forward.
3. Unplug the ribbon cable from the External Flow PCB.
4. Unscrew the mounting nut (Figure 8-6, Ref. 33) from the inside of the ventilator and remove the assembly through the front of the unit.

**Proximal Gauge - 52000-00964**

1. Remove the silicone tubing to the Proximal Pressure Gauge (Figure 8-7, Ref 6).
2. Remove the two nuts (Figure 8-7, Ref 7) from the studs retaining the mounting bracket.
3. Remove the Proximal Gauge through the from of the ventilator.
Control Panel - 51000-08551

NOTE

The inserts that identify the indicators and controls for this panel and not included with this assembly since they are dependent on the configuration of the unit. Contact Bear Medical Systems for the part numbers required.

NOTE

There is a gasket between the Control Panel and the upper Console. It should remain intact when the panel is replaced. If it is damaged, a replacement can be ordered under part number 51000-08657.

1. Perform the procedure to remove the following assembly:
   Control PCB
2. Remove the grounding wire (Figure 8-8, Ref. 1) from the Control Panel.
3. Remove the 8 screws from the Control Panel (Figure 8-8, Ref. 1).
4. Remove the Control Panel through the front of the ventilator.

Monitor Panel - 51000-08550

NOTE

The inserts that identify the indicators and controls for this panel and not included with this assembly since they are dependent on the configuration of the unit. Contact Bear Medical Systems for the part numbers required.

NOTE

There is a gasket between the Monitor Panel and the upper Console. It should remain intact when the panel is replaced. If it is damaged, a replacement can be ordered under part number 51000-08656.

1. Perform the procedure to remove the following assembly:
   Monitor PCB
2. Remove the grounding wire (Figure 8-8, Ref. 3) from the Monitor Panel.
3. Remove the 8 screws from the Monitor Panel (Figure 8-8, Ref. 4).
4. Remove the Monitor through the front of the ventilator.

Needle (PEEP) Valve - 51000-08927

1. Remove the two pneumatic connections from the Needle Valve (Figure 8-7, Ref 8).
2. Remove the knob from the front of the ventilator with an allen wrench.
3. Remove the mounting nut from the front of the ventilator.
4. Remove the Needle Valve from the ventilator from the inside.

Optical Encoder (Control Set) - 56060-30011

1. Perform the procedure to remove the following assembly:
   Control PCB
2. Remove the knob from the control panel using an allen wrench.
3. Remove the mounting nut from the front of the ventilator.
4. Remove the Optical encoder through the inside of the ventilator.
5. Assemble the encoder as shown in Figure 8-9.
Optical Encoder (Monitor Set) - 56060-30011

1. Remove the knob from the Console using an allen wrench.

3. Remove the mounting nut from the front of the ventilator.

4. Remove the Optical encoder through the inside of the ventilator.

5. Assemble the encoder as shown in Figure 8-9.
Section 9
BEAR® 1000 Ventilator
Preventive Maintenance Procedure

Procedures ................................................................. 1
Exterior Inspection ..................................................... 1
Filter Replacement ..................................................... 1
Ground Resistance test .............................................. 2
Current Leakage ....................................................... 2
RECOMMENDED SERVICE PROCEDURE

Preventive Maintenance on the BEAR® 1000 Ventilator should be completed a minimum of once each year. Maintenance is intended to be done in the hospital by a Bear Medical Systems Authorized Service Technician or a Bear Medical Systems Trained Hospital Service Technician.

Ventilator Preventive Maintenance includes:
• Visually inspecting and cleaning of external surfaces, controls, attachments and accessories.
• Opening and cleaning the interior of the unit.
• Visually inspecting all tubing, electrical wiring, connectors, and crimps, screws, nuts and hardware. Checking the general condition of all other internal components or assemblies.
• Replacing the Air and O2 filters.
• Replacing the Air and O2 inlet bowls and seals.
• Replacing the ambient air intake filters.
• Pneumatic and electronic verification and calibrating if required.
• Performing the Operational Verification Procedure.

EQUIPMENT REQUIRED

In addition to the equipment and supplies specified in the Calibration Section of this manual, the following will be required to perform the preventive maintenance:
50000-13001 PM Kit containing the following parts:
Gas Inlet Filters (2 each) 52000-01144
Bowl Kit (2 each w/ seals) 52000-01145
Ambient Air Filter (2 each) 51000-08655

BIO-TEK Digital Safety Analyzer Model 170 or equivalent.

EXTERIOR INSPECTION

1. Turn off the ventilator and disconnect from AC power and pressurized gas at the wall sources.

CAUTION

Do not use Methyl Ethyl Ketone (MEK) or Trichloroethylene, as Damage to surfaces will result. Do not allow any liquid to spill or drip into the Ventilator.

2. Clean the exterior of the unit with water or a solution of 70% Isopropyl Alcohol solution only. Wipe all surfaces with a soft cloth or disposable wipe moistened in the cleaning solution.

3. Inspect the exterior surfaces of the ventilator for broken or loose knobs. Check the display panel for scratches, cracks and alignment of LED indicators. Check all front and rear panel fittings, circuit breakers and accessories for security. Check the AC electrical cord and plug for damage. Record the reading of the hour meter on the maintenance check list.

4. Replace the ambient air intake filters at the rear of the ventilator.

5. Remove the bowl from the Air Water Trap (Figure 9-1).

WARNING

When replacing air/O2 inlet filters, mark and remove one and only one fitting at a time. Replace the filter and return the fitting to its original location before removing the second fitting. Failure to follow this procedure may result in injury, including death, to the patient.
6. Remove the seal from the Water Trap housing using a small pocket screwdriver and discard.

7. Install the new seal from the kit.

8. Turn the filter holder counterclockwise and remove from housing. Discard old filter element (Figure 9-1).

9. Install the new filter element as illustrated on the Water Trap housing and tighten.

10. Install new bowl on the housing of the water Trap.

11. Repeat the procedure for the Oxygen water trap.

**CAUTION**

The circuit boards are subject to damage by static electricity. Do not touch components, circuit, or connector fingers with hands. Handle only by edges.

**INTERIOR INSPECTION**

1. Open the Ventilator by removing the console retaining screw (Figure 9-2).

2. Vacuum all surfaces inside the ventilator. Be sure to reach areas around connectors, circuits boards and pneumatic assemblies.

3. Visually inspect for any overheated components, loose connectors, damaged wires or tubing, kinked tubing, loose ribbon cables, loose or missing hardware, signs of water or other residue inside Tygon tubing, loose Tywraps, poor connector crimps or loose fasteners.

**Specifications**

Current leakage – 100μA maximum (per UL 544)
Ground resistance – 0.1 ohms at 25.0 A (per UL 544)

**CALIBRATION AND VERIFICATION PROCEDURE**

Verify the Power Supply Voltages per Section 7, Page 2, Error code E39.

Perform the following Calibration and / or Calibration Verification Procedures as described in the Calibration Section, Section 5 of the BEAR® 1000 Maintenance Manual.

1. Proximal Pressure Transducer Calibration
2. Differential Pressure Transducer Calibration
3. Machine Pressure Transducer Calibration
4. FCV Pressure Transducer Calibration
5. Air and 02 Transducer Calibration
6. D/A Converter Calibration
7. Exhalation Valve Regulator Calibration
8. Inlet Check Valves and Air/02 Calibration
9. Nebulizer Calibration
GROUND RESISTANCE TEST

Perform a ground resistance check (always follow manufacturer's instructions for test equipment operation).

1. Connect a properly functioning leakage and grounding tester between the ground connection and the hospital grade AC plug (middle lug) and the chassis of the ventilator (any unpainted exposed metal part).

2. With the tester connected and operating, there should be no more than 0.10 ohms resistance between the plug ground connector, and the ventilator chassis ground.

CURRENT LEAKAGE TEST

Perform a current leakage test (always follow manufacturer's instructions for test equipment operation).

1. Connect the ventilator to a properly functioning current leakage tester.

2. Turn Mode switch to CPAP and tester on.

3. Current leakage should be less than 100 microamps, grounded and ungrounded.

OPERATIONAL VERIFICATION PROCEDURE

Perform the Operational Verification Procedure (OVP), Section 3, after the Preventive Maintenance Procedure has been performed to assure that the ventilator is functioning properly. Complete an Operational Verification Procedure Checklist form and attach it to the PM Checklist form. See the OVP for specific instructions.
# BEAR® 1000 VENTILATOR
## PREVENTIVE MAINTENANCE CHECK LIST

**BEAR® 1000 Serial Number** ___________ **Hour meter reading** ___________ **Today's date** ___________

<table>
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<tr>
<th>Service Location</th>
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<td>City, State, Zip</td>
</tr>
<tr>
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<td>Service Person</td>
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## VERIFICATION STEPS

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</tr>
<tr>
<td>Air and O2 Inlet Filters</td>
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<td>☐</td>
</tr>
<tr>
<td>Interior Inspection</td>
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<tr>
<td>Vacuum Interior</td>
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<tr>
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<tr>
<td>Proximal Pressure Transducer Calibration</td>
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<tr>
<td>D/A Converter Calibration</td>
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<td>Exhalation Valve Regulator Calibration</td>
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<td>Inlet Check Valves &amp; Air / O2 Calibration</td>
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<td>Nebulizer Calibration</td>
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<tr>
<td>Perform OVP</td>
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### WARNING

Do not release the ventilator for use if it does not pass all of the procedures specified in the checklist. To do so could result in personal injury including death or property damage. Refer the ventilator to a Bear Medical Service Technician or a Bear Medical Systems trained service technician for appropriate repair and/or calibration.

**Signature______________________**

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*50000-12131 • NOVEMBER 1993*
Section 10
BEAR® 1000 Ventilator
Parts List

Accumulator ........................................ 51000-08623
Alarm Loudness Assembly ...................... 52000-08717
Analog Output Cable Assembly ................. 51000-08609
Auto Zero Solenoid Valve Assembly ............ 51000-08718
Buzzer Assembly .................................... 51000-08608
Cable Assembly Control PCB to EPI ............ 51000-08615
Cable Control to Monitor Assembly ............. 51000-08662
Cable External Flow ................................ 51000-08614
Cable Monitor to Control Assembly ............. 51000-08616
Cable Power Logic .................................. 51000-08611
Cable Power Supply to Caps ..................... 51000-08633
Cable Power Supply to Control PCB ............. 51000-08631
Cable Power Supply to EPI ....................... 51000-08630
Communications Port Assembly ................. 51000-08600
Diaphragm Mounting Base Assembly .......... 51000-08580
Electro-Pneumatic Interface PCB Assembly ..... 51000-08670
EFS Internal Cable assembly ..................... 51000-08632
Exhalation Control Valve Manifold ............. 51000-08591
Exhalation Valve Bulkhead Assembly .......... 51000-08635
Exhalation Valve Diaphragm .................... 51000-08782
Exhalation Valve Regulator Assembly .......... 51000-08723
Fan Assembly ....................................... 51000-08609
Flow Control Valve Assembly ................. 51000-08520
Harness Inlet Power .............................. 51000-08715
Hour, Meter Cable Assembly ..................... 51000-08610
Inlet Manifold Assembly ......................... 51000-08622
Jet Pump Assembly ................................ 51000-08559
Nebulizer Regulator Assembly ................. 51000-08724
Needle Valve ....................................... 51000-08617
Oxygen Blender ..................................... 51000-08562
PCB Assembly Power Supply Module .......... 51000-08671
PCB Control Assembly ............................. 51000-08674
PCB External Flow Sensor Assembly .......... 51000-08625
PCB Monitor Assembly ............................. 51000-08676
PCB Power Supply Hold Up Capacitor Assembly ........................................ 51000-08681
RS232 Output Cable Assembly ..................... 51000-08629
Shut Off Solenoid Valve ......................... 51000-08716
Solenoid, Blender Bleed Valve Assembly ..... 51000-08721
Solenoid, Exhalation Valve Assembly .......... 51000-08721
Solenoid, Nebulizer Valve Assembly .......... 51000-08722
SOPR Valve Assembly ............................. 51000-08540
SOPR Valve Diaphragm ............................ 51000-07475
Transformer ........................................ 51000-08716
Section 11
BEAR® 1000
Repacking and Shipping Instructions

GENERAL:
The packaging system for the BEAR® 1000 Ventilator has been designed to provide a high degree of protection against shipping damage.

All shipments of BEAR® 1000 Ventilators should be made using the packaging system P/N 51000-08896.

Bear Medical Systems, Inc., does not assume any liability whatsoever for any damage incurred in any product returned to our facilities by any means. The shipper and carrier are totally responsible for all damage and costs involved in transporting returned goods. If a package is damaged in shipment, your shipper and/or carrier should be notified within ten days of receipt of the shipment.

PACKAGING INSTRUCTIONS

NOTE
It is advisable that a shipping department or organization perform this procedure. A local freight company will usually pack the product at your facility for a small service charge.

The shipping carton (P/N 51000-08896) consists of:
51000-08899 Accessory Carton
51000-06056 Anti-static Bag 26"x22"x44"
51000-08901 Cavity pack-bottom
51000-08900 Cavity pack-top
51000-08904 Shipping Carton

PROCEDURE:

1. Place a large plastic bag over the ventilator.
2. Attach a shipper to the plastic bag with tape.
3. Place the ventilator in the carton, align the ventilator so it slides into the cavity-pack bottom.
4. Align the cavity-pack top so it slides in place on top of ventilator.
5. Seal the box top flaps with heavy duty packaging tape.

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