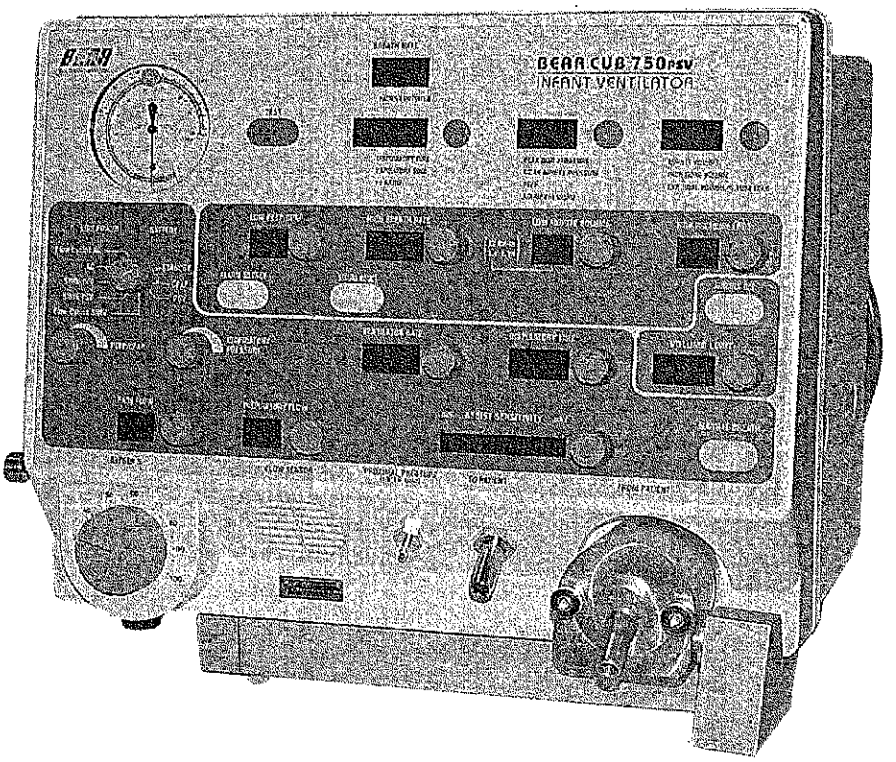
BEAR CUB® 750PSV

INFANT VENTILATOR



Instruction Manual

Thermo Respiratory™ Group
Thermo Electron Companies

BEAR®

P/N 51-10697-00 Rev. A

11/99

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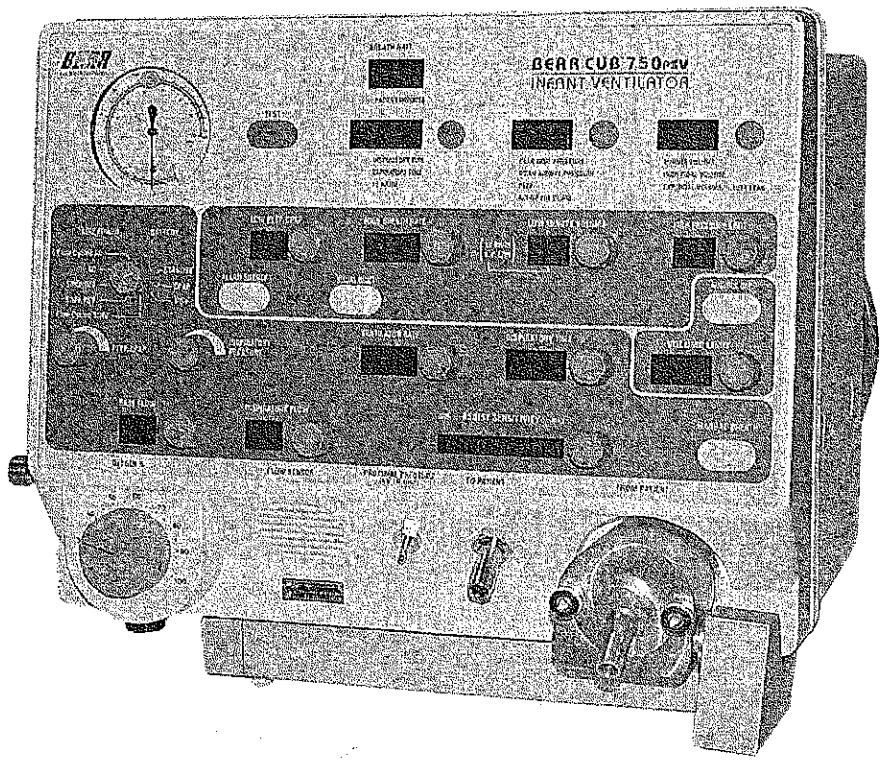

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User/Owner Responsibility

This Bear Medical Systems, Inc. (hereafter referred to as Bear) equipment and the authorized accessories for it are designed to function as specified in the relevant instruction manual only when operated, maintained, and repaired in accordance with supplied manuals and instructions. This equipment must be periodically checked, recalibrated, maintained, and components repaired and replaced when necessary for the equipment to operate reliably. Parts that have failed, in whole or in part, exhibit excessive wear, are contaminated, or are otherwise at the end of their useful life should not be used and should be replaced immediately with parts supplied by Bear or parts which are otherwise approved by Bear. Equipment not functioning correctly or otherwise in need of repair or maintenance must not be used until all necessary repairs and/or maintenance have been completed and a factory authorized service representative has determined that the equipment is fit and ready for use. This equipment and any of its accessories or component parts should not be modified.

The owner/user of this equipment shall have sole responsibility and liability for any damage or injury to persons or property (including the equipment itself) resulting from operation not in accordance with the authorized maintenance instructions, from repair by anyone other than a factory authorized representative, modification of the equipment or accessories, or from the use of components or accessories that have been damaged or not authorized for use with this equipment by the factory.

Warranty

The Bear Cub® 750PSV ventilator system is warranted to be free from defects in material and workmanship and to meet the published specifications for ONE (1) year or 8,000 HOURS, WHICHEVER OCCURS FIRST.

The liability of Bear Medical Systems, Inc. under this warranty is limited to replacing, repairing or issuing credit, at the discretion of Bear Medical Systems, Inc., for parts that become defective or fail to meet published specifications during the warranty period; Bear Medical Systems, Inc. will not be liable under this warranty unless (A) Bear Medical Systems, Inc. is promptly notified in writing by Buyer upon discovery of defects or failure to meet published specifications; (B) the defective unit or part is returned to Bear Medical Systems, Inc., transportation charges prepaid by Buyer; (C) the defective unit or part is received by Bear Medical Systems, Inc. for adjustment no later than four (4) weeks following the last day of the warranty period; and (D) Bear Medical Systems, Inc.'s examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

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

Bear Medical Systems, Inc. warranties as herein and above set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by Bear Medical Systems, Inc. or its agents in connection with the Buyer's order of the products furnished hereunder.

Limitations of Liabilities

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

The warranty stated above shall extend for a period of one (1) year from date of shipment or 8,000 hours of use, whichever occurs first, with the following exceptions:

1. Components for monitoring of physical variables such as temperature, pressure, or flow are warranted for ninety (90) days from date of receipt.
2. Elastomeric components and other parts or components subject to deterioration, over which Bear has no control, are warranted for sixty (60) days from date of receipt.
3. Internal and external batteries are warranted for ninety (90) days from date of receipt.

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

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1. INTRODUCTION

COPYRIGHT NOTICE

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TRADEMARK NOTICES

OVERVIEW

The Bear Cub 750PSV Infant Ventilator is designed to provide ventilatory support for the critical care management of patients ranging from the small neonate (500 grams or larger) to the small pediatric patient (up to 30 kg) with compromised lung function.

The Bear Cub 750PSV Infant Ventilator offers:

- AC
- SIMV/IMV
- CPAP
- Volume Limit*
- Flow Cycled AC
- Flow Cycled SIMV
- SIMV with Pressure Support Ventilation
- Pressure Support Ventilation

*U.S. Patent No. 5, 540, 220

PRODUCT SUPPORT

Bear Medical Systems is committed to product support. The Bear territory manager is a valuable resource for clinical as well as logistical information. For additional support, contact:

Customer Service:

Hours: 7:00 AM to 3:30 PM (PST)
Monday through Friday
Phone: (760) 778-7200
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Bear Medical Systems will make available for purchase, service manuals which include: circuit diagrams, component parts lists, descriptions, calibration instructions, or other information which will assist qualified technical personnel to repair parts of the equipment designated by the manufacturer as repairable.

WARRANTY

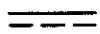
The warranty for your Bear Cub 750PSV Infant Ventilator is provided at the front of this manual, and is also outlined on a card attached to the unit at the time of sale. Please fill out this warranty card and return it. Doing so will ensure that you, as the owner, will receive the full benefit of the warranty period.

The user and owner are responsible to maintain the Bear Cub 750PSV Infant Ventilator in accordance with it's instruction manual. Refer to *Cleaning & Maintenance* (section 7) in this manual.

SYMBOLS

The following symbols are referenced on the ventilator and within this manual:

 Alternating Current

 Direct Current

 Attention, consult ACCOMPANYING DOCUMENTS

 Type B equipment

0086  Medical Device Directive Compliant

WARNINGS, CAUTIONS & NOTES

It is essential that users become familiar with this entire manual and that they devote careful attention to all Warnings and Cautions before using the Bear Cub 750PSV Infant Ventilator on any patient.

WARNING identifies conditions or practices that could result in serious adverse reactions or potential safety hazards.

CAUTION identifies conditions or practices that could result in damage to the ventilator or other equipment.

In general, Warnings and Cautions have been inserted within the manual where they are most meaningful. However, certain Warnings and Cautions are general to the use of the ventilator under all circumstances. Accordingly, these advisories are included in this *Introduction.*

NOTES identify supplemental information to help you better understand how the ventilator works.

WARNINGS

The Bear Cub 750PSV Infant Ventilator is intended for use by a qualified practitioner under the direction of a qualified physician.

When the ventilator is connected to a patient, it is recommended that a health care professional be in attendance at all times to react to an alarm or other indications of a problem.

Always have an alternate means of ventilation available whenever the ventilator is in use.

The operator should not touch the electrical connectors of the ventilator or accessories, and the patient simultaneously.

Under no circumstances should the Bear Cub 750PSV Infant Ventilator be used in the presence of flammable anesthetics due to possible explosion hazard.

An audible alarm indicates an anomalous condition and should never go unheeded.

Antistatic or electrically conductive hoses or tubing should not be used within the patient circuit.

Use only 1/8" I.D. tubing for the proximal airway pressure sensing line. Do not place restrictive adapters in-line as malfunction may result. Use of larger I.D. tubing may cause pressure oscillations under some conditions.

If a mechanical or electrical problem is recognized while running the Circuit Checkout Procedure, or while operating the ventilator, the ventilator must be removed from use and referred to qualified personnel for servicing. Using an inoperative ventilator may result in patient injury.

It is suggested that oxygen concentration be monitored continuously using an oxygen monitor that includes both high and low alarms. If a high or low oxygen percent alarm is activated, an Operational Verification Procedure (OVP) should be performed on both the ventilator and the external oxygen monitor. If the ventilator fails the OVP, it should be referred to a Thermo Respiratory Group service technician.

When a low gas supply alarm occurs, the oxygen concentration to the patient will be different than that set on the O_2 control.

A source gas failure will change the FIO_2 and may result in patient injury.

Failure to appropriately adjust the Over Pressure Relief Valve for each individual patient could result in patient injury.

If the Over Pressure Relief Valve is set to a pressure lower than the High Pressure Limit, the ventilator will not give an audible and visual indication of a high pressure condition that may cause injury to the patient.

To clear a Failed to Cycle alarm condition once the ventilation malfunction has been corrected, the ventilator control knob must be turned to the STANDBY mode prior to the selected mode of operation, with the exception of a Failed to Cycle condition caused by low gas supply.

Should the ventilator Fail to Cycle due to a loss of battery power, the ventilator control knob must be turned to the STANDBY mode prior to the selected mode of operation (once power has been restored to the ventilator).

WARNINGS

The Low PEEP/CPAP alarm must be set within 10 cmH_2O of the PEEP setting, or the Prolonged Inspiratory Pressure alarm will sound and the Patient Circuit alarm and the inspiratory limb dump solenoid may activate.

If the PEEP/CPAP control is incorrectly set, a negative pressure can be applied to the patient circuit. It is recommended that the operator always monitor PEEP levels and adjust appropriately when changing Base Flow.

If the flow sensor is not being used, the Apnea alarm is disabled in CPAP mode, and spontaneous breath rate will not be monitored.

If the Flow Sensor is not installed, the Apnea alarm will be disabled, and the Low PEEP/CPAP alarm will be the only active disconnect alarm when the ventilator has been set to the CPAP mode. In addition, spontaneous breath rate will not be monitored.

When the Flow Sensor is disconnected, or becomes disabled during operation, breath detection is no longer available.

If the Flow Sensor is disconnected or becomes disabled, the Apnea alarm becomes inactive in the CPAP mode.

Removal of the Flow Sensor from the circuit during operation will eliminate the flow trigger, flow cycling and Volume Limiting functions. Failure to detect the absence of the Flow Sensor, and/or respond to the Flow Sensor disconnection alarm, may cause injury to the patient.

When using highly resistant (11mm) dual heated wire circuits and flows above 15 lpm, you must use the Wye flow sensor and set the Low Minute Volume alarm appropriately in order to detect an expiratory limb disconnect at the exhalation valve.

If the Inspiratory Pressure control is set higher than the pressure reached at the Volume Limit condition by more than 30%, the volume delivered to the patient may be significantly greater than the Volume Limit setting.

If the Inspiratory Pressure control is set higher than the pressure reached at the Volume Limit condition, the High Pressure Limit control should be set appropriately to prevent injury to the patient, in the event Volume Limiting is cancelled due to loss of the flow sensor.

Restriction in the proximal line and/or proximal filter will cause the delivered pressure to be less than the monitored values.

Never attempt disassembly of the exhalation valve control chamber assembly, as the control diaphragm may be damaged. Any time the control pin assembly is removed for cleaning, an Operational Verification Procedure (OVP) should be performed in order to verify proper functioning prior to further usage of the unit.

This equipment has been tested to the European EMC directive; however, the functioning of this equipment may be adversely affected by the operation of other equipment nearby, such as high frequency surgical (diathermy) equipment, defribrillators, short-wave therapy equipment, "walkie talkies," or cellular phones.

Electric shock hazard - Do not remove any of the ventilator covers or panels. Refer all servicing to a Thermo Respiratory Group service technician.

WARNINGS

Alarm loudness must be set above ambient sound in order to be heard.

The user should never touch the "RS-232 Interface" or "Analog Output" connectors and the patient simultaneously.

If the Over Pressure Relief Valve is set to a pressure lower than the High Pressure Limit, the ventilator will not give an audible and visual indication of a high pressure condition that may cause injury to the patient.

Do not place restrictive adapters in-line as malfunction may result. Restriction in the proximal line or proximal filter will cause the delivered pressure to be less than the monitored values.

Failure to appropriately adjust the Over Pressure Relief Valve for each individual patient could result in patient injury should the internal pressure relief valve fail.

Do not dispose of the internal battery by incineration as it may explode when exposed to flame.

Do not attempt to charge the internal battery with any other charger than the one built into the ventilator as it may explode or damage the battery.

If the ventilator is not likely to be used for an extended period of time, the battery should be removed or disconnected.

Use only hydrophobic bacteria filters (P/N 51000-01122) in the proximal airway line. Non-hydrophobic filters may become occluded with moisture, causing a ventilator malfunction.

CAUTIONS

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

For ventilator accessories which require sterilization, peak sterilization temperature should not exceed 130° F (54° C) for gas (ETO), and 270° F (132° C) for steam autoclave components.

To ensure proper operation of the ventilator, any components added to the patient circuit should not cause the following parameters to exceed these values: Compliance = .5 ml/cmH_2O (total), and Resistance = 1 cmH_2O at 5 LPM (inspiratory/expiratory limb).

All accessory equipment that is connected to the ventilator shall comply with CSA22.2 No. 601.1/IEC601-1/UL2601.

The O_2 DISS fitting on the Auxiliary Gas Supply is a blended gas outlet. Do not connect an Oxygen Gas supply to this fitting, as damage to the ventilator may occur.

Ensure that the voltage selection and installed fuses on the back panel of the BEAR CUB 750PSV Infant Ventilator are set to match the voltage of the wall outlet, or damage to the Bear Cub 750PSV Infant Ventilator may result.

A battery that is fully drained (i.e. void of any charge) may cause damage to the ventilator and should be replaced.

Any condensate in the water trap is a warning signal that condensate may be entering the ventilator.

Use of the Auxiliary Gas Outlet will affect the accuracy of the delivered Base Flow out of the "TO PATIENT" port when total flow (Base Flow/Inspiratory Flow and Auxiliary Flow) exceeds 25 LPM. Note that total ventilator flow capability is 30 LPM.

Nebulizer medications should not be used when the Flow Sensor is attached to the patient circuit.

Compressed air must be clean and dry to prevent an oxygen blender malfunction, or damage to pneumatic components, which may cause a unit malfunction. Whenever using compressed air, it is recommended that an air inlet water trap be connected to the air inlet port located on the back panel of the ventilator (P/N 50000-01071).

Never attempt to insert cleaning instruments into flow sensor or to dry the internal components with a high-pressure gas source. Doing so will damage the sensor.

2. ASSEMBLY

OVERVIEW

The BEAR CUB 750PSV Infant Ventilator is shipped almost fully assembled. A few unpacking and assembly steps remain, as described below.

UNPACKING

Before unpacking the BEAR CUB 750PSV Infant Ventilator, inspect the shipping container for any sign of damage.

Remove the ventilator and all accessories from the shipping containers. Inspect for damage that may have occurred during shipping.

The BEAR CUB 750PSV Infant Ventilator comes with a Basic Accessory Kit (P/N 50-01187-00, domestic) which includes the following:

1. DISS Air Hose.....P/N 50000-01000
2. DISS O_2 Hose.....P/N 50000-01001
3. Air Inlet Water Trap.....P/N 50000-01071
4. Control Pin Assembly Removal Tool.....P/N 51000-05137
5. Fuse .25amp, 5x20, slow blow.....P/N 56000-20080
6. Voltage Conversion Instructions.....P/N 50000-10656
7. Instruction Manual Kit.....P/N 50-10697-00

NOTE

One Flow Sensor (P/N 51000-08833) is included with the ventilator.

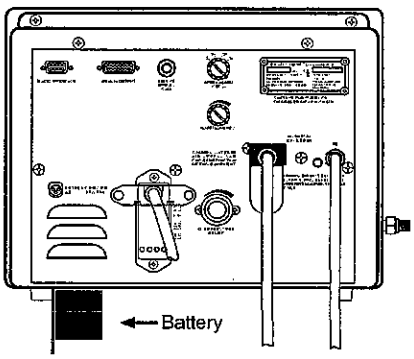
VISUAL INSPECTION

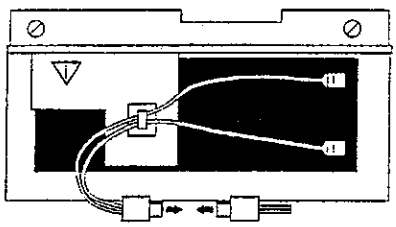
Inspect the exterior for any damage which may have occurred during shipment. In the event that you should find damage, immediately contact the responsible shipping carrier to make a claim. Bear Medical Systems will support you with any information needed.

WARRANTY CARD

Locate the warranty card attached to the ventilator. Complete and return the card to ensure full benefit of the warranty period.

BATTERY CONNECTION





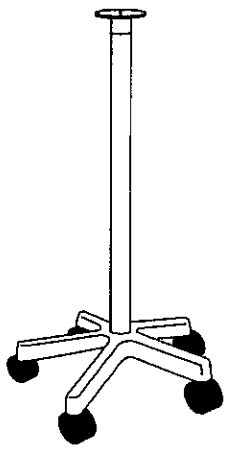
The BEAR CUB 750PSV Infant Ventilator is shipped with the internal battery disconnected. Instructions to connect the battery for operation are as follows:

1. Ensure that the ventilator is not connected to any AC power source.
2. Loosen the two (2) screws holding the battery access door, and gently allow the door to swing downward.
3. Attach the battery assembly connector to the mating connector of the wire harness exiting the battery compartment.
4. Close the compartment door and re-tighten the screws. Battery connection is now complete.

NOTE

Unit can immediately be used on line power; however, if the unit has been stored, a minimum charge is necessary to perform circuit checkout procedures. Ensuring that the ventilator remains plugged into an A/C outlet for four (4) hours will return the battery to full charge.

POLE MOUNT ASSEMBLY



The Pole Mount Assembly Kit (P/N 50000-01160) is used to mount the BEAR CUB 750PSV Ventilator. General pole mount attachment instructions are as follows:

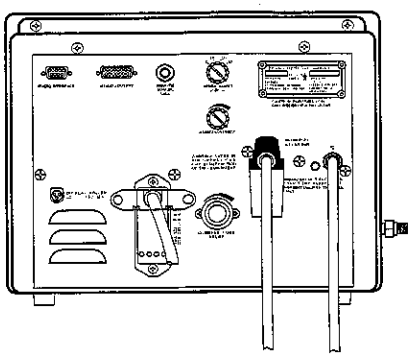
1. Install the pole in the base; install and torque the mounting nut.
2. Install the pole mount base to the ventilator using the pan head screws provided.
3. Lock the two (2) locking wheels to prevent the pole from moving.
4. Place the ventilator on the pole.
5. Secure the ventilator to the pole by using the thumb screws provided. Attachment is now complete.

Additional assembly instructions are included within the Pole Mount Assembly Kit.

The BEAR CUB 750PSV Ventilator may be mounted on a SolidAir Compressor (P/N 51-09659-01 (120v/60hz) or 51-09659-02 (230v/50Hz)). The following mounting kits are required:

1. Compressor mount for use without humidifier (P/N 50000-01163)
2. Compressor mount for use with humidifier (P/N 50000-01174)

AIR & OXYGEN HOSES



Air and Oxygen hoses are provided in the basic accessory kit. Attach the DISS oxygen hose to the oxygen inlet fitting located on the back panel of the ventilator.

Attach the air inlet water trap to the back panel of the ventilator. Connect the DISS air hose directly to the air inlet water trap.

Tighten both air and oxygen hoses securely to prevent leakage.

CAUTION

Compressed air must be clean and dry to prevent an oxygen blender malfunction, or damage to pneumatic components, which may cause a unit malfunction. Whenever using compressed air, it is recommended that an air inlet water trap be connected to the air inlet port located on the back panel of the ventilator (P/N 50000-01071).

ALARM LOUDNESS ADJUSTMENT

The alarm loudness on the BEAR CUB 750PSV Infant Ventilator is adjustable from 60 to 75 dB(A).

The loudness level can be adjusted by following these steps:

1. Start with the ventilator in the STANDBY position, turn ventilator control knob to any mode, and wait for the power-up diagnostics to be completed.
2. Locate the ALARM LOUDNESS knob in the upper center of the back panel of the ventilator.
3. Initiate an audible alarm by pressing and holding the TEST key on the front panel, located in the "monitors group."
4. Adjust alarm to desired level by turning clockwise to increase loudness, and counterclockwise to decrease. Release TEST key.

WARNING

Alarm loudness must be set above ambient sound in order to be heard.

OPTIONAL GRAPHICS DISPLAY

A Ventilator Graphics Monitor (VGM) is available as an upgrade option for the BEAR CUB 750PSV Infant Ventilator. For installation instructions, please refer to the BEAR® Ventilator Graphics Monitor Instruction Manual (P/N 50-10641-00).

OPTIONAL COMPUTER CONNECTION

A computer may be attached to the ventilator. In the absence of a Ventilator Graphics Monitor (VGM), the computer should be attached directly to the RS-232 connector located on the back panel of the ventilator. Subsequently, the appropriate baud rate for communication with the computer should be set on the ventilator.

If a VGM has been installed on the BEAR CUB 750PSV Infant Ventilator, the computer should be attached to the "Digital Out" connector located on the rear of the VGM itself. Subsequently, the appropriate output baud rate should be selected by way of the graphics display menus.

OPTIONAL ANALOG CONNECTION

Three analog signals are available on the BEAR CUB 750PSV Infant Ventilator: pressure, flow and breath phase. Use the 15-pin connector located on the back panel of the ventilator to obtain these voltage signals. Refer to *Panel Details & Specifications* (Section 5) for information regarding the voltage range and scale for each of these signals.

WARNING

The user should never touch the "RS-232 Interface" or "Analog Output" connectors and the patient simultaneously.

3. SETUP & CHECKOUT

OVERVIEW

"Setup" and "checkout" procedures are described here.

SETTING UP THE BACK PANEL OF THE VENTILATOR

To set up your BEAR CUB 750PSV Infant Ventilator for use on a patient, perform the following steps:

1. Attach the air and oxygen hoses to the respective wall (or other gas source) fittings. Source gas must be supplied at 30-80 psig with a minimum flow rate of 50 LPM.
2. Inspect the air inlet water trap located on the back panel of the ventilator. No condensate should be in this trap.

CAUTION

Condensate in the water trap warns that condensate may be entering the ventilator. If the compressed air entering the ventilator is not clean and dry, ventilator malfunction may result. Therefore, check the air inlet water trap periodically.

3. Select the Apnea alarm interval that is appropriate for your institution, using the four (4) position switch located on the back panel.
4. Plug the ventilator and humidifier power cords into a properly grounded electrical outlet.

SETTING UP THE FRONT PANEL OF THE VENTILATOR

To prepare the front of the ventilator for use on a patient, you will need to:

- Attach the exhalation valve
- Install the flow sensor
- Attach a patient circuit

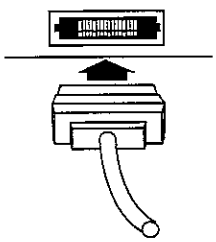
These procedures are described in the following paragraphs.

EXHALATION VALVE

Exhalation Valve Diaphragm

Install the exhalation valve diaphragm convex side down (i.e. button side up) into the exhalation valve manifold. Next, install the exhalation valve manifold onto the base and secure in place with the knurled nuts. Installation is now complete.

FLOW SENSOR



Install the flow sensor connector into the port labeled "Flow Sensor" on the lower left front panel of the ventilator. Insert the large end of the cable into this port with the flat portion of the connector facing down. The cable has been designed to insert only one way. The connector "clicks" and locks when properly installed. The flow sensor end will then be inserted between the patient wye and endotracheal tube following breathing circuit assembly.

NOTE

Both sides of the flow sensor connector must "click" and lock into the ventilator port or information read by the sensor may not be displayed.

PATIENT CIRCUIT

Assembly of the patient breathing circuit is achieved via the following 7 steps:

1. Cut 18 inches of 3/8" I.D. low compliance tubing, and attach one end to the ventilator marked "TO PATIENT," and the other end to the humidifier Inflow Port.
2. Connect three (3) feet of 3/8" I.D. low compliance tubing to the Outflow Port of the humidifier.
3. To the open end of the 3/8" I.D. low compliance tubing, attach a 3/8" O.D. connector.
4. Next, connect a flexible corrugated hose and attach the 4-way (11mm O.D. / 15mm I.D. / 3/8" O.D.) endotracheal connector to the opposite end.
5. Attach an 11mm I.D./4mm O.D. endotracheal adapter to the 4-way endotracheal connector. Then cut five (5) feet of 1/8" tubing. Attach one end to the endotracheal adapter and the other end to the ventilator fitting marked "PROXIMAL AIRWAY PRESSURE."

WARNINGS

Use only 1/8" I.D. tubing for the proximal airway pressure sensing line. Do not place restrictive adapters in-line as malfunction may result. Use of larger I.D. tubing may cause pressure oscillations under some conditions.

Use only hydrophobic bacteria filters (P/N 51000-01122) in the proximal airway line. Non-hydrophobic filters may become occluded with moisture, causing a ventilator malfunction.

6. Attach the other flexible corrugated hose to the 4-way endotracheal connector, insert the other 3/8" O.D. connector and then connect four (4) feet of 3/8" I.D. low compliance tubing between the 3/8" O.D. connector and the exhalation valve fitting of the ventilator, marked "FROM PATIENT."
7. Install flow sensor at patient wye.

CAUTION

To ensure proper operation of the ventilator, any components added to the patient circuit should not cause the following parameters to exceed these values: Compliance = .5 ml/cmH_2O (total), and Resistance = 1 cmH_2O at 5 LPM (inspiratory/expiratory limb).

NOTES

- The factory provides a clean ventilator for initial use. Only clean components should be used when assembling the patient circuit. If there is any question as to the device's cleanliness, please refer to *Cleaning & Maintenance* (section 7) within this manual.
- The Inspiratory and expiratory resistance measured at the patient connection during spontaneous breathing and normal operation should not exceed 6 cmH_2O (.6kPa) at 30L/M (pediatric) and 5/M (infant) when adding attachments or other components to the breathing system.
- Lengths of circuit tubing will be different if operator uses hydrophobic bacteria filters within the patient circuit.

OVER PRESSURE RELIEF VALVE

The BEAR CUB 750_{PSV} Infant Ventilator is equipped with a mechanical, user adjustable, pressure relieving valve (refer to Fig. 3-1) located on the back panel of the ventilator. The ventilator leaves the factory with this valve at a setting of approximately 40 cmH_2O.

To adjust the Over Pressure Relief Valve, loosen the locking ring then occlude the patient wye and the exhalation line. Rotate the Over Pressure Relief Valve control knob counter clockwise to decrease (clockwise to increase) until the peak inspiratory pressure, as shown on the proximal airway pressure gauge, is at the desired setting. It is recommended that the Over Pressure Relief Valve be adjusted to a minimum of 15 cmH_2O above the High Pressure Limit alarm setting. Tighten the locking ring.

WARNING

Failure to appropriately adjust the Over Pressure Relief Valve for each individual patient could result in patient injury.

If the Over Pressure Relief Valve is set to a pressure lower than the High Pressure Limit, the ventilator will not give an audible and visual indication of a high pressure condition that may cause injury to the patient.

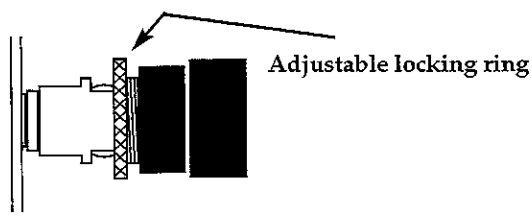


Figure 3-1 • Over Pressure Relief Valve

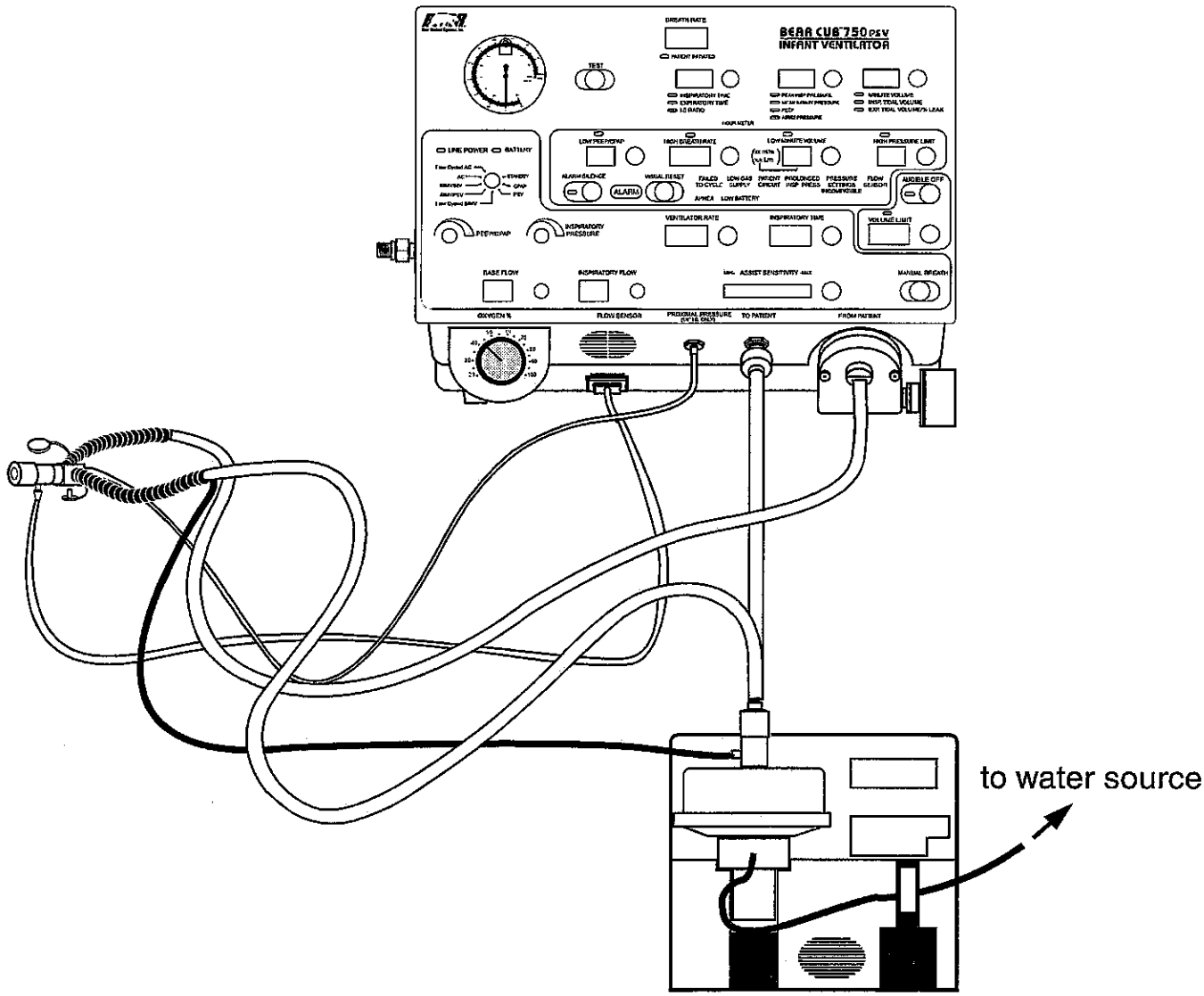


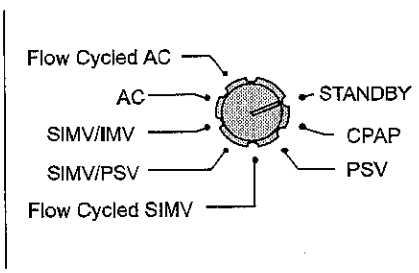
Figure 3-2 • Patient Circuit

CIRCUIT CHECKOUT

Ensure that the internal battery has been connected as described in *Assembly* (section 2), and that the Over Pressure Relief Valve has been adjusted as described in *Setup & Checkout* (section 3) prior to conducting a circuit checkout procedure.

1. Attach an infant test lung (P/N 52000-40027) to the patient circuit.

2. Rotate the mode selector knob to AC, and set the controls and alarms as follows:



Controls	750PSV
Mode	AC
Ventilator Rate	30 BPM
Inspiratory Pressure	40 cmH2O
Inspiratory Time	0.8 sec
Inspiratory Flow	15 LPM
Base Flow	3.0 LPM
PEEP/CPAP	0 cmH2O
Assist Sensitivity	Min.
Volume Limit	300 ml
Over Pressure Relief Valve	60 cmH2O
Alarms	
High Pressure Limit	45 cmH2O
Low PEEP/CPAP	-3 cmH2O
Apnea	10 sec
Low Minute Volume	1 L

After 30 seconds, verify that Peak Inspiratory Pressure display reads 40 cmH2O ± 4 and Mean Airway Pressure display reads 18.0 cmH2O ± 3.

3. Press and hold the TEST button. Observe that all of the displays illuminate and an audible alarm sounds. Upon release of the TEST button, the hour meter will be displayed for approximately 4 seconds.

The ventilator display panel will return to normal operation following test sequence.

4. Disconnect the test lung from the patient circuit and verify that audible and visual notifications for LOW INSP. PRESSURE and the Low Minute Volume Alarm are activated, after one minute. An "LP" should be displayed in the High Pressure Limit Window. Reconnect test lung and allow audible alarm to self cancel. Depress VISUAL RESET to clear LED alarm indicator.

5. Rotate VENTILATOR RATE knob to 1 and verify that the apnea alarm activates at the time interval previously set. Rotate the ventilator rate back to 30 to cancel the audible alarm, then press VISUAL RESET to clear LED alarm indicator.

6. Occlude the expiratory limb of the breathing circuit and verify the following:

   - High Pressure Limit alarm activates (flashing display) and audible alarm sounds.
   - Patient Circuit alarm activates. Internal dump solenoid opens and relieves pressure to less than 5 cmH_2O.
   - Press reset to clear alarms and ventilator will resume cycling.

Remove occlusion and audible alarm should silence, but visual alarm indicators will remain. Press VISUAL RESET to clear LED alarm indicators.

7. Disconnect the proximal pressure line from the patient connector. Note the pressure on the manometer and verify the pressure is zero and that the Low Pressure alarm activates. Reconnect the proximal pressure line. Disconnect the proximal pressure line from the ventilator output. Verify that the pressure is zero and that the Patient Circuit, High Pressure and Low Pressure Alarms activate. Reconnect the proximal line to the ventilator.

8. Disconnect the ventilator power cord from the wall and verify that the BATTERY LED remains green, the LINE POWER LED turns red (within 10 seconds), and the ventilator continues to operate.

An audible alarm will sound to notify the operator that the ventilator is on battery power. This alarm can be silenced once the operator is aware of battery use by pressing VISUAL RESET twice. The internal battery has a capacity to power the ventilator for approximately 30 minutes when at 100% charge.

Plug the ventilator back into the wall. The LINE POWER LED indicator will turn green.

NOTE

With approximately 5 minutes of available battery power remaining, a non-silenceable alarm will activate.

9. To verify that the audible/visual alarms for low gas supply, momentarily shut off or disconnect the air and oxygen gas sources.

10. Disconnect both the air and oxygen supply simultaneously. The low gas supply and fail to cycle alarm should activate and the audible portion should silence when source pressure is reconnected. Press VISUAL RESET to clear LED alarm indicators.

WARNING

A source gas failure will change the FIO_2 and may result in patient injury.

11. The checkout is now complete.

WARNING

If a mechanical or electrical problem is recognized while running the Circuit Checkout Procedure, or while operating the ventilator, the ventilator must be removed from use and referred to qualified personnel for servicing. Using an inoperative ventilator may result in patient injury.

4. OPERATION

OVERVIEW

The following pages describe the general set up and operation of the BEAR CUB 750PSV Infant Ventilator. This section will also discuss ventilator operation in various modes:

Flow Cycled AC	Flow Cycled SIMV
AC	PSV
SIMV/IMV	CPAP
SIMV with PSV	

GENERAL SETUP

1. Prepare the ventilator as described in *Setup and Checkout* (Section 3).
2. Attach infant test lung (P/N 52000-40027) to the flow sensor at the patient wye.
3. Attach the air and oxygen hoses to the appropriate gas sources. Connect the ventilator and humidifier electrical power cords to properly grounded electrical outlets, and turn the humidifier power switch to "ON."

CAUTION

Compressed air must be clean and dry to prevent an oxygen blender malfunction, or damage to pneumatic components, which may cause a unit malfunction. Whenever using compressed air, it is recommended that an air inlet water trap (P/N 50000-01071) be connected to the air inlet port located on the back panel of the ventilator.

4. Select the desired humidifier setting. The proximal airway temperature should be monitored continuously.

NOTE

Refer to the humidifier manufacturer's operator's manual concerning humidifier settings.

WARNING

Under no circumstances should the ventilator be used in the presence of flammable anesthetics due to possible explosion hazard.

5. General set up is now complete.

AC Fundamentals

A time cycled pressure limited (TCPL) breath is delivered when:

- a breath time period elapses, as determined by the VENTILATOR RATE control setting, or
- when the patient activates the assist trigger.

Provided the set ASSIST SENSITIVITY threshold is met, the patient may trigger every breath if demand exceeds the set VENTILATOR RATE, resulting in a synchronization of mechanical breaths with patient effort. If the patient does not trigger a breath before the time period elapses, the ventilator will deliver a mandatory TCPL breath according to the clinician-selected INSPIRATORY PRESSURE, VENTILATOR RATE, INSPIRATORY FLOW and INSPIRATORY TIME as illustrated below.

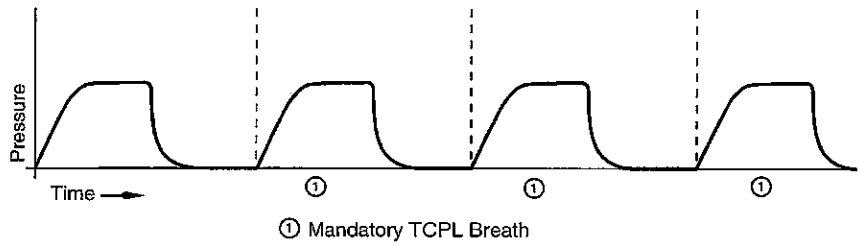


Figure 4-1 • AC Pressure Graphic — No Patient Triggering

FLOW CYCLED AC Fundamentals

In this mode of ventilation, a pressure limited breath is delivered to the patient at the preset INSPIRATORY PRESSURE and is flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or at the preset INSPIRATORY TIME, whichever occurs first.

Provided the set ASSIST SENSITIVITY threshold is met, the patient may trigger every breath if demand exceeds the set VENTILATOR RATE, resulting in a synchronization of mechanical breaths with patient demand. If the patient does not trigger a breath before the time period elapses, a mandatory breath will be delivered at the beginning of the next assist window. As with a synchronized breath, the mandatory breath will be flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or at the preset INSPIRATORY TIME, whichever occurs first.

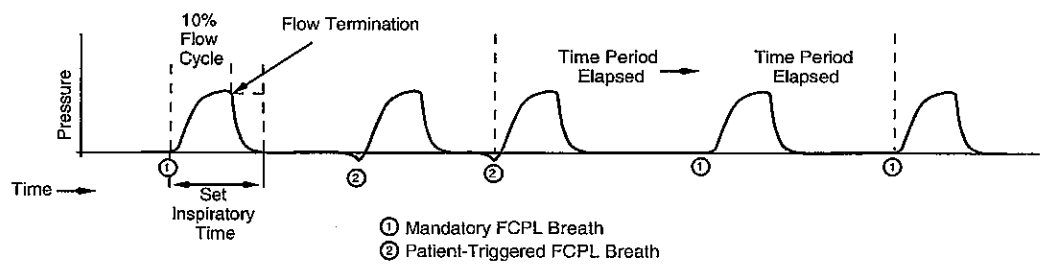
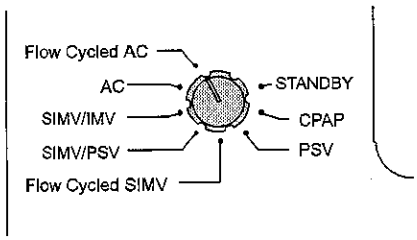


Figure 4-2 • Flow Cycled AC Graphic

AC and FLOW CYCLED AC Setup



1. Rotate the mode selector control from the STANDBY position to AC, or Flow Cycled AC.
2. Adjust the following controls to the appropriate settings, as directed by physicians order:

- Ventilator Rate
- Inspiratory Time
- Inspiratory Pressure
- Base Flow
- Inspiratory Flow
- PEEP/CPAP
- Assist Sensitivity
- Volume Limit
- O2%

NOTES

A SETTINGS INCOMPATIBLE alarm indicates one of the following four (4) conditions:

(a) Operator has attempted to set an Inspiratory Time that is inappropriate for the Ventilator Rate selected (flashing Inspiratory Time and Ventilator Rate displays).

During this condition, the set Inspiratory Time will not be delivered. Ventilator Rate will be maintained.

(b) Operator has attempted to set a Base Flow that is more than 2 times the Set Inspiratory Flow (flashing Base Flow and Inspiratory Flow displays).

During this condition, the flow control solenoid will not cycle and Base Flow will be delivered continually.

(c) Operator has attempted to set a Volume Limit that is incompatible with the Flow or Pressure settings of the ventilator. If the Inspiratory Flow setting is too high, the Volume Limit LED digits will flash, alternating with "E.FL." If the Inspiratory Pressure setting is too high, the Volume Limit LED digits will flash, alternating with "E.PL."

(d) Operator has attempted to set a PEEP/CPAP level that is higher than the Inspiratory Pressure level, or has attempted to set an Inspiratory Pressure level that is lower than the PEEP/CPAP level. This will result in a Pressure Settings Incompatible alarm.

During this condition, the exhalation pressure control solenoid will not cycle and the set PEEP/CPAP level will be delivered continuously.

3. Adjust the Over Pressure Relief Valve on the back panel of the ventilator. It is recommended that the Over Pressure Relief Valve be adjusted to a minimum of 15 cmH_2O above the High Pressure Limit alarm setting. To adjust the Over Pressure Relief Valve, loosen the locking ring, remove the test lung and occlude the patient wye and the exhalation line. Rotate the Over Pressure Relief Valve control knob counterclockwise to decrease (clockwise to increase) until the peak inspiratory pressure, as shown on the proximal airway pressure gauge, is at the desired setting but not less than 15 cmH_2O above where the High Pressure Limit alarm and the INSPIRATORY PRESSURE control will be set. Tighten the locking ring. Reattach test lung.

WARNING

If the Over Pressure Relief Valve is set to a pressure lower than the High Pressure Limit, the ventilator will not give an audible and visual indication of a high pressure condition that may cause injury to the patient.

4. Set the INSPIRATORY PRESSURE control to the desired peak pressure.
5. Set the HIGH PRESSURE LIMIT alarm to the desired level above peak inspiratory pressure shown on the manometer. A maximum margin of 10 cmH_2O is recommended.
6. Set the Low PEEP/CPAP alarm to the appropriate setting below the PEEP/CPAP level.
7. The LOW INSPIRATORY PRESSURE alarm is automatically set by the ventilator accordingly to the following formula:

$$\text{Low Inspiratory Pressure} = 0.25 \times (\text{High Pressure Limit} - \text{Low PEEP/CPAP}) + \text{Low PEEP/CPAP}$$

where Low PEEP/CPAP = 0 if setting is $\leq$ 0.

NOTES

Minimum threshold for the Low Inspiratory Pressure Alarm is 5 cmH_2O.

If High Pressure Limit is set at an excessively high level, a Low Pressure (LP) alarm may flash in the High Pressure Limit window during normal operation.

WARNING

The Low PEEP/CPAP alarm must be set within 10 cmH_2O of the PEEP setting, or the Prolonged Inspiratory Pressure alarm will sound and the Patient Circuit Alarm and inspiratory limb dump solenoid may activate.

NOTE

To verify the Low PEEP/CPAP and Low Inspiratory Pressure alarms, open the proximal airway connection by disconnecting the test lung, and verify that the audible and visual alarms activate. Reconnect the test lung and verify the audible alarm silences. Press VISUAL RESET to clear the LED alarm indicators.

8. Set the High Breath Rate alarm to the appropriate setting above the monitored breath rate.
9. The ventilator is now ready to connect to the patient.

SIMV/IMV Fundamentals

In this mode, both time cycled pressure limited (TCPL) and spontaneous breaths can occur. Between TCPL breaths, spontaneous breaths may occur. Blended gas for these spontaneous breaths is supplied by the base flow setting, which is capable of providing up to 30 LPM of flow.

The concept of an "assist window" is very useful when describing the fundamentals of SIMV operation.

When a TCPL breath is due (as determined by the VENTILATOR RATE control), the assist window opens and waits for the patient's inspiratory effort. Upon sensing the patient's inspiratory effort, the ventilator delivers the preset INSPIRATORY PRESSURE for the preset INSPIRATORY TIME. As soon as the single TCPL breath has been triggered, the assist window closes.

As a consequence, once the TCPL breath has been delivered, subsequent patient effort results only in spontaneous breaths until the next assist window is opened.

If the patient has a period of apnea, and the assist window does not see an inspiratory effort on the part of the patient, a mandatory breath will be delivered at the beginning of the next breath time interval. Mandatory breaths will continue according to the respiratory rate set on the VENTILATOR RATE control until the next inspiratory effort from the patient is sensed.

NOTES

The BEAR CUB 750PSV Ventilator will operate in the IMV mode when the flow sensor is absent or disabled, and the control knob is turned to the SIMV/IMV position.

In this mode of ventilation, mandatory, time cycled, pressure limited breaths are delivered by the ventilator at regular intervals as determined by the VENTILATOR RATE control and are not synchronized with patient effort. Blended gas for spontaneous breaths that occur between the mandatory breaths is supplied by the BASE FLOW.

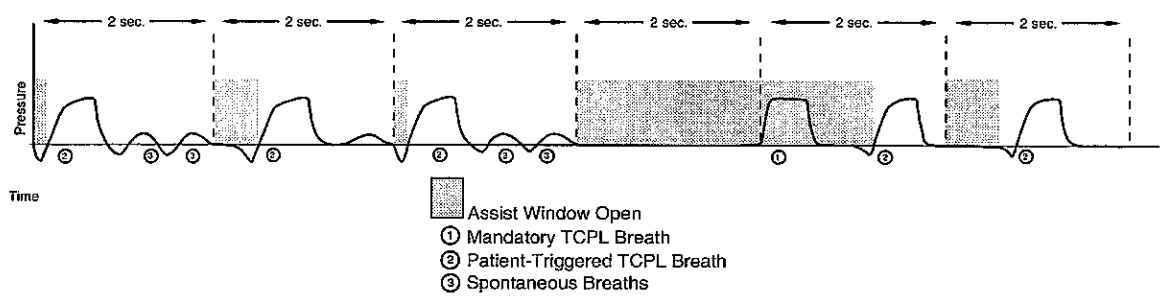


Figure 4-3 • SIMV/IMV Pressure Graphic

Flow Cycled SIMV Fundamentals

In this mode of ventilation, a pressure limited breath is delivered to the patient at the preset INSPIRATORY PRESSURE and is flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or at the preset INSPIRATORY TIME, whichever occurs first. Frequency of mandatory breaths is determined by the ventilator rate control. Blended gas for spontaneous breaths that occur between the mandatory breaths is supplied by the base flow.

When a mandatory breath is due the assist window opens and waits for the patient's inspiratory effort. Upon sensing the patient's effort, the ventilator delivers a pressure limited breath at the preset INSPIRATORY PRESSURE, which is flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or at the preset INSPIRATORY TIME, whichever occurs first. Once the mandatory breath has been delivered the assist window closes until the next mandatory breath is due.

If the patient becomes apneic and the ventilator does not recognize an inspiratory effort by the patient, a mandatory breath will be delivered at the beginning of the next assist window. As with a synchronized breath, the mandatory breath will be flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or at the preset INSPIRATORY TIME, whichever occurs first. Mandatory breaths will continue according to the respiratory rate set on the VENTILATOR RATE control until the next patient effort is recognized.

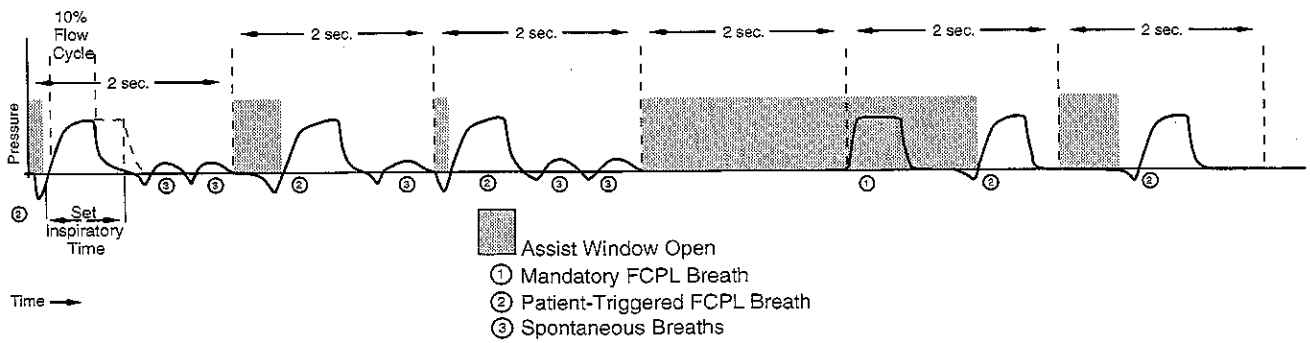


Figure 4-4 • Flow Cycled SIMV Pressure Graphic

SIMV/PSV Fundamentals

In this mode of ventilation, a mandatory pressure limited breath is delivered to the patient at the preset INSPIRATORY PRESSURE and time cycled at the preset INSPIRATORY TIME.

Frequency of the mandatory breaths is determined by the ventilator rate control. Spontaneous inspiratory efforts, recognized by the ventilator, between the mandatory breaths will be supported by the ventilator.

When a mandatory breath is due, the assist window opens and waits for the patient's inspiratory effort. Upon sensing the patient's effort, the ventilator delivers a mandatory breath at the preset INSPIRATORY PRESSURE, which is time cycled at the preset INSPIRATORY TIME. Any spontaneous inspiratory efforts recognized by the ventilator between the mandatory breaths will be supported by the ventilator to preset INSPIRATORY PRESSURE and flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or at the preset INSPIRATORY TIME, whichever occurs first.

If the patient becomes apneic and the assist window does not recognize an inspiratory effort by the patient a mandatory breath will be delivered at the beginning of the next mandatory assist window. The mandatory breath will be pressure limited at the preset INSPIRATORY PRESSURE and time cycled at the preset INSPIRATORY TIME. Mandatory breaths will continue according to the respiratory rate set on the VENTILATOR RATE control until the next patient effort is recognized.

NOTE

Peak inspiratory pressures during both mandatory and pressure support breaths are the same.

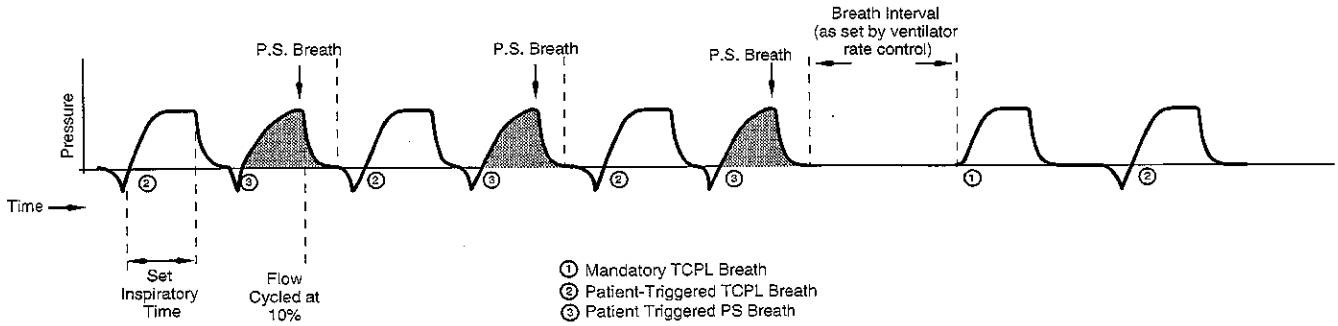
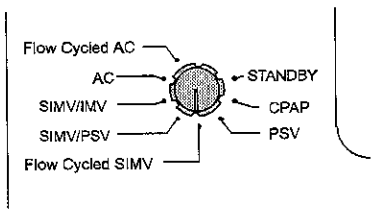
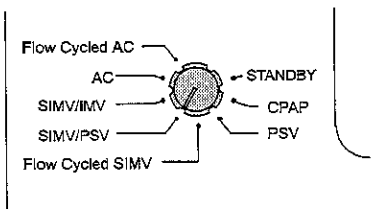


Figure 4-5 • SIMV/PSV Pressure Graphic

SIMV/IMV FLOW CYCLED SIMV, and SIMV/PSV Setup





1. Rotate the mode selector control from the STANDBY position to SIMV/IMV, Flow Cycled SIMV or SIMV/PSV.

WARNING

Removal of the flow sensor from the circuit during operation will disable the flow trigger, flow cycling and volume limiting functions. Failure to respond to the flow sensor disconnection alarm may cause injury to the infant if not corrected.

2. Complete steps 2—9 as outlined in AC Setup page 4-4.

PSV Fundamentals

In this mode of ventilation, all spontaneous inspiratory efforts recognized by the ventilator will be supported to the preset INSPIRATORY PRESSURE and flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or at the preset INSPIRATORY TIME, whichever comes first. There is no mandatory breath rate.

If the patient becomes apneic, following an apnea time-out the ventilator will deliver a backup mandatory breath at the preset INSPIRATORY TIME and INSPIRATORY PRESSURE. If no spontaneous or mandatory breaths occur during a subsequent time-out period, based on the breath interval set by the VENTILATOR RATE or 10 seconds, whichever is less, an additional mandatory breath will be delivered. This sequence will repeat until a spontaneous effort is recognized. An apnea alarm will be reported throughout this sequence.

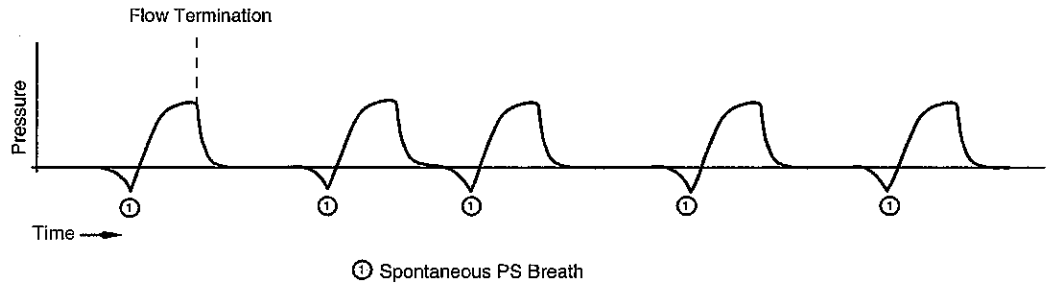
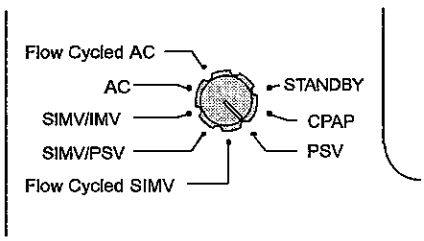


Figure 4-5 • Pressure Support Ventilation Graphic

PSV Setup

1. Rotate the mode selector control from the STANDBY position to PSV.



NOTE

In the event that the flow sensor is disconnected or malfunctions, the ventilator shall revert to CPAP. During this time the ventilator will demonstrate a non-cancelable flow sensor alarm. This condition will continue until the flow sensor is replaced, or the mode switch is turned to a mode that does not rely on flow for breath termination.

2. Complete steps 2 - 9 as outlined in AC Setup Section 4-4 .

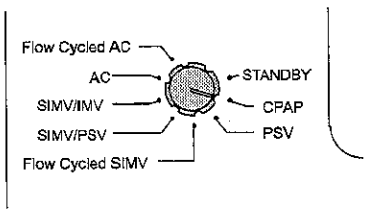
CPAP Fundamentals

In CPAP, the patient breathes spontaneously, and all breaths are counted by the BREATH RATE monitor when patient effort meets or exceeds the ASSIST SENSITIVITY threshold (provided flow sensor is installed). In addition, a constant airway pressure is maintained throughout the breath cycle, as determined by the clinician-selected PEEP level.

If the patient becomes apneic, following an apnea time-out the ventilator will deliver a backup mandatory breath at the preset INSPIRATORY TIME and INSPIRATORY PRESSURE. If no spontaneous or mandatory breaths occur during a subsequent time-out period, based on the breath interval set by the VENTILATOR RATE or 10 seconds, whichever is less, an additional mandatory breath will be delivered. This sequence will repeat until a spontaneous effort is recognized. An apnea alarm will be reported throughout this sequence.

CPAP Setup

The same controls available in AC or SIMV/IMV are also available in CPAP; however, many of them are not used by the ventilator in CPAP unless a Manual Breath is delivered by the operator or Apnea backup is activated.



1. Rotate the mode selector control from the STANDBY position to CPAP.

WARNING

If the flow sensor is not being used, the Apnea alarm is disabled in CPAP mode, and spontaneous breath rate will not be monitored.

2. Adjust the following controls to the appropriate settings:
   - Base Flow
   - PEEP/CPAP
   - O2%

Additionally, other controls should be set and are only active when the manual breath button is pushed or Apnea is activated:
- Inspiratory Time
- Inspiratory Pressure
- Inspiratory Flow
- Volume Limit (active only if flow sensor is installed)

NOTE

Inspiratory Time, Inspiratory Pressure, Inspiratory Flow and Ventilator Rate should be set appropriate to the patient receiving CPAP, as the ventilator will cycle at these settings during apnea backup ventilation.

Additionally, other controls should be set and are only active when the manual breath button is pushed:

3. Adjust the Over Pressure Relief Valve on the back panel of the ventilator. It is recommended that the Over Pressure Relief Valve be adjusted to a minimum of 15 cmH_2O above the High Pressure Limit alarm setting. To adjust the Over Pressure Relief Valve, loosen the locking ring, remove the test lung and occlude the patient wye and the exhalation line. Rotate the Over Pressure Relief Valve control knob counter-clockwise to decrease (clockwise to increase) until the peak inspiratory pressure, as shown on the proximal airway pressure gauge, is at the desired setting but not less than 15 cmH_2O above where the High Pressure Limit alarm and the INSPIRATORY PRESSURE control will be set. Tighten the locking ring. Reattach test lung.

WARNING

If the Over Pressure Relief Valve is set to a pressure lower than the High Pressure Limit, the ventilator will not give an audible and visual indication of a high pressure condition that may cause injury to the patient.

4. Set the INSPIRATORY PRESSURE control to the desired peak pressure.

5. Set the HIGH PRESSURE LIMIT alarm to the desired level above peak inspiratory pressure shown on the manometer. A maximum margin of 10 cmH_2O is recommended.

6. Set the Low PEEP/CPAP alarm to the appropriate setting below the PEEP/CPAP level.

7. The LOW INSPIRATORY PRESSURE alarm is automatically set by the ventilator according to the following formula:

$$\text{Low Inspiratory Pressure} = 0.25 \times (\text{High Pressure Limit} - \text{Low PEEP/CPAP}) + \text{Low PEEP/CPAP},$$

where Low PEEP/CPAP = 0 if setting is $\leq$ 0.

NOTES

Minimum threshold for the Low Inspiratory Pressure Alarm is 5 cmH_2O.

If High Pressure Limit is set at an excessively high level, a Low Pressure (LP) alarm may flash in the High Pressure Limit window during normal operation.

WARNING

If the Flow Sensor is not installed, the Apnea alarm will be disabled, and the Low PEEP/CPAP alarm will be the only active disconnect alarm when the ventilator has been set to the CPAP mode. In addition, spontaneous breath rate will not be monitored.

The Low PEEP/CPAP alarm must be set within 10 cmH_2O of the PEEP setting, or the Prolonged Inspiratory Pressure alarm will sound and the Patient Circuit Alarm and the inspiratory limb dump solenoid may activate.

NOTE

To verify the Low PEEP/CPAP alarm, open the proximal airway connection by disconnecting the proximal tubing and verify that the audible and visual alarms activate. Reconnect the proximal tubing and verify the audible alarm silences. Press VISUAL RESET to clear the LED alarm indicator.

8. Set the High Breath Rate alarm to the appropriate setting.
9. The ventilator is now ready to connect to the patient.

FLOW CYCLING

Ventilation Principles and Guidelines

Flow Cycled Ventilation provides for total breath synchrony, by allowing the infant to initiate and terminate the breath based on flow at the proximal airway. In any of the available flow cycled modes (Flow Cycled AC, Flow Cycled SIMV, SIMV/PSV, and PSV), a mandatory or patient initiated breath may be terminated by flow when the flow decreases to 10% of the peak inspiratory flow. This termination criteria is fixed, not adjustable. In the event that the peak inspiratory flow is not able to decrease to 10%, the breath will be terminated by the set inspiratory time, indicated by a flashing of that display.

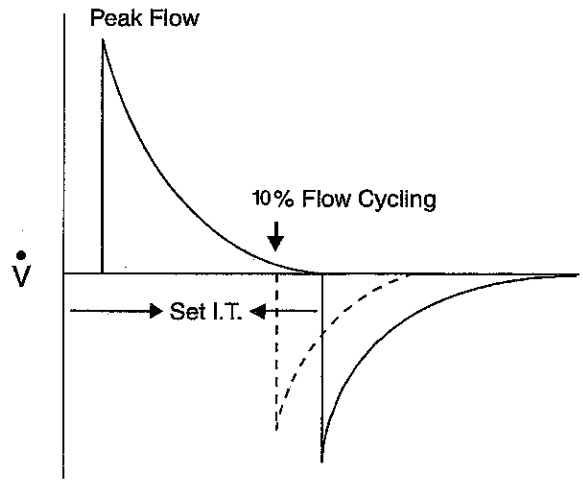
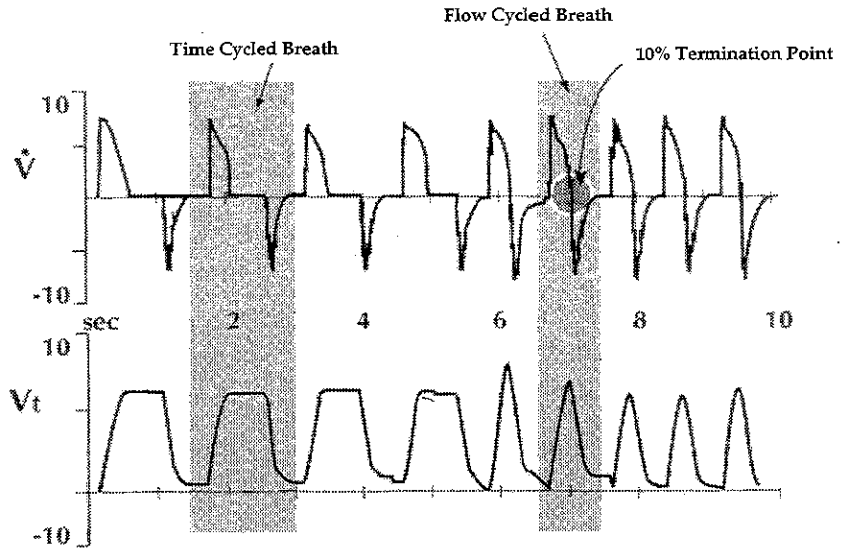


Figure 4-6 • Flow Cycling Criteria

Breaths may not flow cycle in the face of an airway leak or if the set inspiratory time is reached before the flow cycling criteria is met. The advantages of flow cycling are improved synchrony, appropriate inspiratory times that do not exceed what is necessary for complete lung inflation, and lower risk of airtrapping, especially at high respiratory rates. Clinical studies have shown that flow cycling may improve oxygenation, decrease weaning time, and decrease length of time on mechanical ventiation.



Flow Cycled Ventilation on the Bear Cub 750PSV Infant Ventilator can be easily understood by this visual tracing. The first four breaths are delivered with a fixed inspiratory time, without the benefit of flow cycling. The remaining five breaths are delivered in a Flow Cycled AC Mode. With flow cycling, the breath ends by a decrease in inspiratory flow at the airway, rather than a preset inspiratory time. Not that no change in tidal volume is noted, even though the inspiratory time is less.

5. PANEL DETAILS & SPECIFICATIONS

OVERVIEW

The following pages provide an orientation to the front and back panels on the BEAR CUB 750PSV Infant Ventilator. Included is a description of:

- The specifications for the BEAR CUB 750PSV Infant Ventilator ventilator,
- How the rotary controls and touch buttons simplify ventilator operation, and
- How the front panel is arranged into logical groupings (Monitors, Alarms and Controls).

In addition to this general orientation, details are provided for:

- Each user adjustable control, touch button, and LED indicator, and
- All the physical, environmental, pneumatic and electrical specifications.

The BEAR CUB 750PSV Infant Ventilator
Performance Characteristics and Specifications

Controls

Mode.....Flow Cycled AC, AC, SIMV/IMV, SIMV/PSV, Flow Cycled SIMV, PSV, CPAP
PEEP.....0 to 30 cmH2O
Inspiratory Pressure.....0 to 72 cmH2O
Ventilator Rate.....1 to 150 BPM
Inspiratory Time.....0.10 to 3.00 sec
Base Flow.....1 to 30 LPM
Inspiratory Flow.....1 to 30 LPM
Assist Sensitivity.....Min to Max
Volume Limit*.....5 to 300 ml
Audible Off (Volume Limit).....LED On/Off
Manual Breath.....x1
Over Pressure Relief.....15 to 75 cmH2O
% O2.....21 to 100%
Apnea Alarm.....5, 10, 20, 30 sec
Alarm Loudness.....Min. to Max, 60 to 75 db(A)

Alarms

Low PEEP/CPAP.....-5 to 30 cmH2O
High Breath Rate.....3 to 255 BPM
Low Minute Volume.....Off to 9.9 LPM
High Pressure Limit.....10 to 75 cmH2O
Failed to Cycle.....LED On/Off
Low Gas Supply.....LED On/Off
Patient Circuit.....LED On/Off
Prolonged Inspiratory Pressure.....LED On/Off
Apnea.....LED On/Off
Pressure Settings Incompatible.....LED On/Off
Flow Sensor.....LED On/Off
Alarm Silence.....60 sec
Visual Reset.....Push Button
Line Power.....Green/Red LED
Low Battery.....LED On/Off

Monitors

Breath Rate.....0 to 255 BPM
Breath Type (Patient Initiated).....LED
Inspiratory Time.....0.00 to 3.10 sec
Expiratory Time.....0 to 99.9 sec
I:E Ratio.....9.9:1 to 1:9.9
Peak Inspiratory Pressure.....0 to 99 cmH2O
Mean Airway Pressure.....0 to 75 cmH2O
PEEP.....0 to 30 cmH2O
Air Pressure.....0 to 99 psig
O2 Pressure.....0 to 99 psig
Minute Volume.....0 to 30.0 LPM
Tidal Volume (Exhaled).....0 to 500 ml
Tidal Volume (Inspired).....0 to 500 ml
%Leak.....0 to 100%
Proximal Airway Pressure.....-10 to 100 cmH2O
Hourmeter.....0 to 99,999 hours
Test.....Push Button
Battery.....LED On/Off

*U.S. Patent No. 5, 540, 220

The BEAR CUB 750PSV Infant Ventilator
Performance Characteristics and Specifications

Preset Values

Minimum Expiratory Time ..... 150 milliseconds
Minimum Inspiratory Time ..... 0.1 seconds
Maximum Inspiratory Time ..... 3.10 seconds
Maximum settable I:E Ratio 4:1

Tolerances

Monitors:

Breath Rate ..... ± 1 BPM or ± 20 msec, whichever is greater
Inspiratory Time ..... ± 0.02 sec
Expiratory Time ..... ± 0.02 sec
I:E Ratio ..... ± 0.1 or ± 20 msec (on the calculation based on the monitored inspiratory and expiratory times), whichever is greater
Airway Pressure (continuous) ..... ± 1 cmH_2O (-10 to 20 cmH_2O)
± 2 cmH_2O (20 to 65 cmH_2O)
± 3 cmH_2O (65 to 100 cmH_2O)
Peak Inspiratory Pressure ..... ± 2 cmH_2O or ± 5%, whichever is greater
Mean Airway Pressure ..... ± 2 cmH_2O or ± 3%, whichever is greater
PEEP ..... ± 2 cmH_2O or ± 5%, whichever is greater
Air/O_2 Pressure ..... ± 5 psig
Minute Volume ..... Accuracy is based on the Tidal Volume and Breath Rate monitors
Inspiratory Tidal Volume ..... ± 1 mL or ± 10%, whichever is greater
Expiratory Tidal Volume ..... ± 1 mL or ± 10%, whichever is greater
% Leak ..... ± 1 mL or ± 2%, whichever is greater (when compared to the Inspired and Expired Tidal Volume monitors)
Hour Meter ..... ± 2% of reading

Alarms/Limits:

Low PEEP/CPAP ..... ± 2 cmH_2O
High Breath Rate ..... ± 1 BPM
Low Minute Volume ..... ± 10 mL/min (0 to 99 mL/min)
± 0.1 L/min (0.1 to 9.9 L/min)
High Pressure Limit ..... ± 4 cmH_2O
Prolonged Inspiratory Pressure ..... ± 2 cmH_2O
Volume Limit ..... ± 2 mL or ± 10% of setting, whichever is greater
Apnea ..... ± 1 sec
Maximum (Pop-off) Pressure ..... ± 4 cmH_2O

Controls:

Ventilator Rate ..... ± 1 BPM or ± 20 msec (applied to the breath interval), whichever is greater
Inspiratory Time ..... ± 0.020 sec (0.10 to 0.50 sec)
± 0.025 sec (0.50 to 3.00 sec)
Assist Sensitivity ..... Not a calibrated scale
PEEP/CPAP and Inspiratory Pressure (Repeatability) ..... ± 1 cmH_2O or ± 5%, whichever is greater (breath to breath)
Base/Inspiratory Flow ..... ± 0.5 LPM or ± 10% of setting, whichever is greater (0 to 60 cmH_2O)
± 1 LPM or +10/-15% of setting, whichever is greater (60 to 72 cmH_2O)
Oxygen % ..... ± 3%

Emissions/Susceptibility

The ventilator has been tested to conform to the following specifications: MIL-STD-461D:1993, MIL-STD-462D:1993, EN55011:1991, IEC 1000-4-2:1994, IEC 1000-4-3:1994, IEC 1000-4-4:1994, IEC 1000-4-5:1994, QUASI-STATIC:1993

This ventilator is designed and manufactured to comply with the safety requirements of IEC 601-1, IEC 601-2-12, CAN/CSA-C22.2 No. 601.1-M90, and UL 2601-1.

The BEAR CUB 750PSV Infant Ventilator
Performance Characteristics and Specifications

Outputs

Digital ..... RS-232 Bi-Directional
Analog: (see page 5-29)
- Proximal Pressure ..... -10 to 100 cmH2O, 1 cmH2O/25 mv
- Proximal Inspiratory/Expiratory Flow ..... -40 (expiratory) to 40 (inspiratory) LPM, 1 LPM/50 mv
- Machine Delivered Flow ..... 0 to 30 LPM, 1 LPM/50 mv
- Breath Phase ..... 1 "Logic" signal; 0, 5V

Remote Nurse Call ..... 0.5 amps max at 24 vdc
Pneumatic:
- Auxiliary Blended Gas Outlet ..... 7 to 17 psig, 0 to 8 LPM
  kPa (48 to 117)

Inputs

Electrical:
- Supply Ratings

Voltage:	100V	80 to 110 VAC
	120V	95 to 135 VAC
	230V	176 to 264 VAC
	240V	192 to 264 VAC
Current:	100V	1.0 A maximum
	120V	1.0 A maximum
	230V	0.5 A maximum
	240V	0.5 A maximum
Frequency:	100V	47 to 65 Hz
	120V	55 to 65 Hz
	230V	47 to 65 Hz
	240V	47 to 65 Hz
Fuses:	100/120V	T 0.5 A, 5 x 20 mm
	230/240V	T 0.25 A, 5 x 20 mm

** For 220V operation, set the power entry module selector switch to 230V setting.

Pneumatic:
Oxygen and Air ..... 30 to 80 psig, 50 LPM Supply Ratings
kPa (206 to 551)

The BEAR CUB 750PSV Infant Ventilator
Performance Characteristics and Specifications

Physical Dimension and Shipping Information

Ventilator Weight.....30 lbs., 13.6 kg
Graphics Display Weight.....5.5 lbs.
Pedestal Stand Weight .....9 lbs.
Compressor Weight.....110 lbs.

Ventilator Dimensions .....13.5" W x 10" D x 11" H
Graphics Display Dimensions .....13" W x 2.5" D x 9.5" H
Pedestal Stand Dimensions .....24"W x 40.5" H
Compressor Dimensions.....22"W x 21.5"D x 36" H

Shipping Weight Included

Ventilator .....40 lbs., 18.2 kg
Graphics Display.....11 lbs.
Pedestal Stand .....12 lbs.
Compressor.....122 lbs.

Shipping Dimensions

Ventilator .....18" W x 18" D x 19" H
Graphics Display.....16" W x 13" D x 11" H
Pedestal Stand .....25" W x 5" D x 45" H
Compressor.....26" W x 22" D x 40" H

Environmental Specifications

Temperature:
Storage and Shipping .....-31 to 158° F (-40 to 70° C)
Checkout and Operating .....50 to104° F (10 to 40° C)

Altitude:
Checkout, Operating.....0 to 9,000 feet (14.7 to 10.5 PSIA/760 to 543 mm Hg)

kPa (101 to 73)

Humidity:
Storage and Shipping.....0 to 99% Relative Humidity — Non-condensing
Checkout and Operating.....0 to 95% Relative Humidity — Non-condensing

The BEAR CUB 750PSV Infant Ventilator
Performance Characteristics and Specifications

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 Compunds
Maximum concentration: 1:10

C. Quaternary Ammonium Compunds
Maximum Concentration 1:500

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 270° F (132° C)

Liquid Sterilization

1. Cidex

Minimum sterilization cycles before part replacement:

1. Patient Circuit, Exhalation Manifold:

Ethylene Oxide	240 cycles
Steam Sterilization	240 cycles
Liquid Sterilization	240 cycles

2. Flow Sensor:

Ethylene Oxide	50 cycles

3. All other sterilization components:

Ethylene Oxide	120 cycles or 1 year
Steam Sterilization	120 cycles or 1 year
Liquid Sterilization	120 cycles or 1 year

LAYOUT

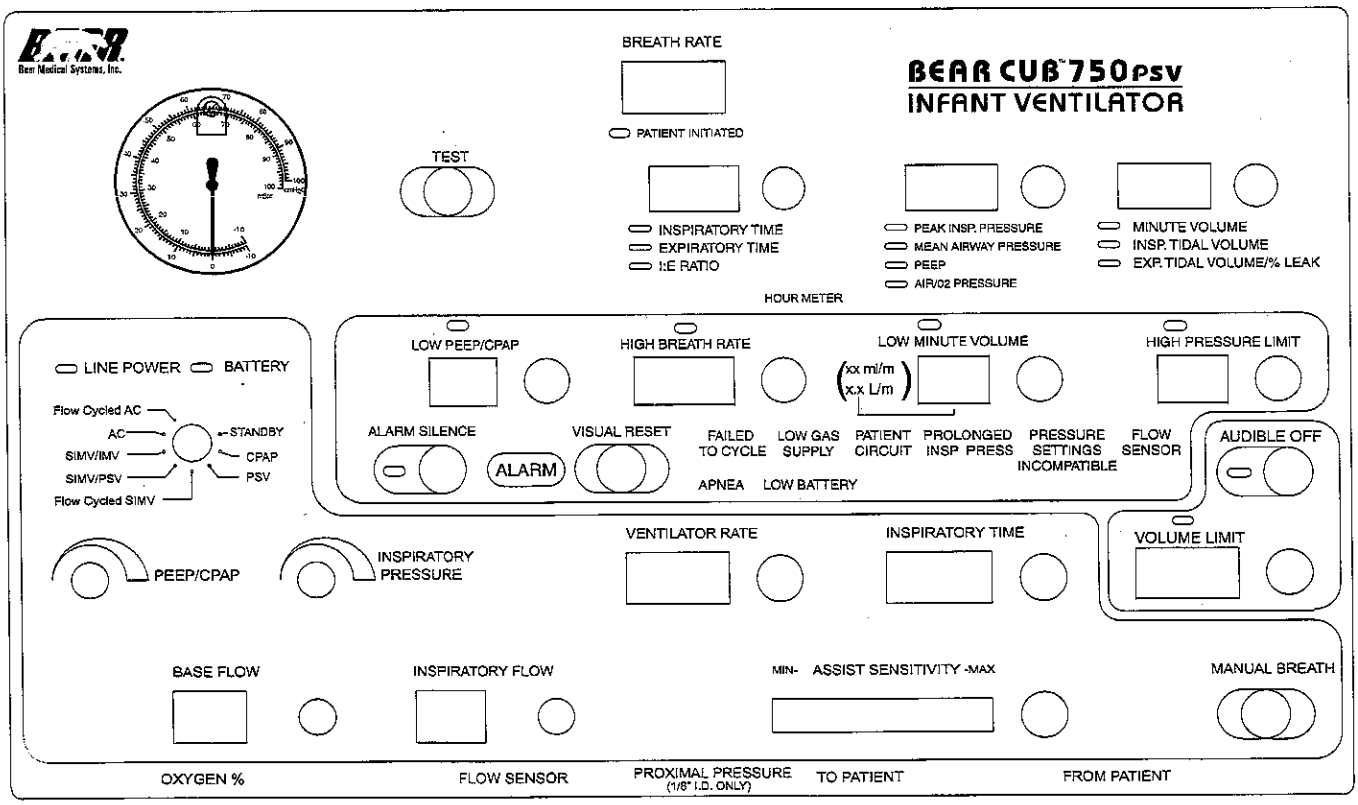
The BEAR CUB 750PSV Infant Ventilator front panel is logically divided into three primary sections

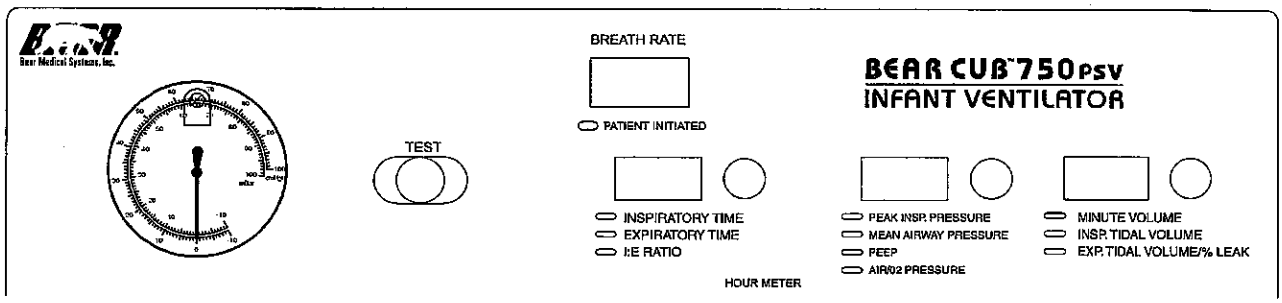
- Monitors (Yellow LEDs)
- Alarms (Red LEDs)
- Controls (Green LEDs).

A fourth area on the front of the ventilator, just below the controls section, houses the blender control, patient circuit, flow sensor connections, and the exhalation manifold.

FUNCTION

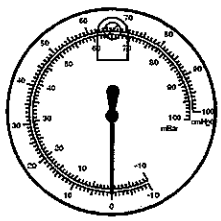
The front panel on the BEAR CUB 750PSV Infant Ventilator uses LED displays with a combination of knobs and touch pads for data entry and/or review.





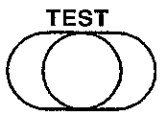
MONITORS

Monitors are located in the upper portion of the front panel. Multiplexing of information reduces display complexity and permits the use of larger, easily read LED displays. To select a monitored parameter, simply press the touch pad until the small LED is illuminated next to the description for the monitored parameter desired, then read the numerical value in the display area. Displays are YELLOW LEDs, indicating monitored data. Some parameters (O_2 Pressure, % Leak) require a second depression of the the touch pad in order to display their value.



Analog Manometer

Panel Group: Monitor
Range: -10 to 100 cmH2O (Outer Scale)
-10 to 100 mBAR (Inner Scale)
The analog manometer provides a continuous display of the proximal pressure as measured at the patient wye.



Test

Panel Group: Monitors
Range: On/Off
Once the TEST button is depressed, all audible and visual indicators are illuminated. Upon release of the TEST button, the Hourmeter will be displayed for approximately four (4) seconds.

NOTE
The ventilator continues to operate during the test sequence.

Breath Rate

Panel Group: Monitors
Range: 0 to 255 BPM
Breath Rate displays the total number of breaths detected by the flow sensor per minute. Breath Rate is updated breath by breath. If no flowsensor is recognized, the set breath rate will be displayed.

Patient Initiated

Panel Group: Monitors
Range: LED On/Off
LED illuminates to indicate that the patient exceeded the assist sensitivity requirement for breath delivery, either triggering a mechanical breath, or taking a spontaneous breath.

Inspiratory Time

Panel Group: Monitors
Range: 0.10 to 3.10 seconds
Inspiratory Time will be displayed for all breath types. For mechanical breaths it is the time from initiation of inspiration to the beginning of exhalation. For spontaneous breaths it is the duration that flow to the patient is positive after the assist sensitivity criteria has been satisfied.

Expiratory Time

Panel Group: Monitors
Range: 0.0 to 99.9 seconds
Expiratory Time is displayed as the duration of time from the initiation of exhalation to the beginning of inspiration for all mechanical breaths.

NOTE

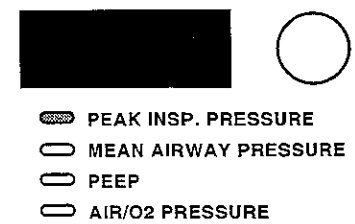
The Expiratory Time LED will display dashes in SIMV/IMV, SIMV/PSV, Flow Cycled SIMV, PSV and CPAP modes.

I:E Ratio

Panel Group: Monitors
Range: 9.9:1 to 1:9.9
I:E Ratio is displayed as the calculated relationship between duration of inspiration to the duration of exhalation for all mechanical breaths.

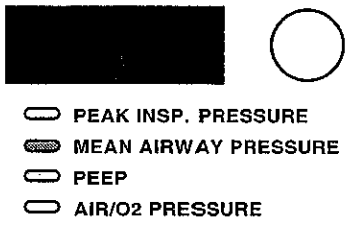
NOTE

The I:E Ratio LED will display dashes in SIMV/IMV, SIMV/PSV, Flow Cycled SIMV, PSV and CPAP modes.



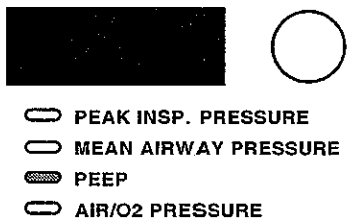
Peak Inspiratory Pressure

Panel Group: Monitors
Range: 0 to 99 cmH2O
The Peak Inspiratory Pressure display shows the maximum pressure reached during each mechanical breath, and is updated breath-by-breath.



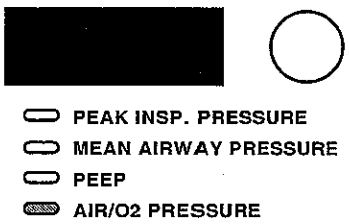
Mean Airway Pressure

Panel Group: Monitors
Range: 0.0 to 75.0 cmH_2O
The Mean Airway Pressure display indicates the average of the pressure measured at the proximal location of the patient circuit. Mean Airway Pressure is updated breath by breath.



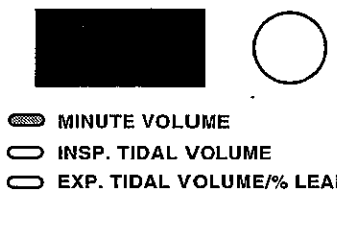
PEEP

Panel Group: Monitors
Range: 0 to 30 cmH_20
Indicates the PEEP/CPAP measured at the proximal location of the patient circuit.



Air/O2 Pressure

Panel Group: Monitors
Range: 0 to 99 psig
The Air Pressure display indicates the air pressure at the inlet to the ventilator. Press again to display the O2 pressure. The O2 Pressure display indicates the oxygen pressure at the inlet to the ventilator.

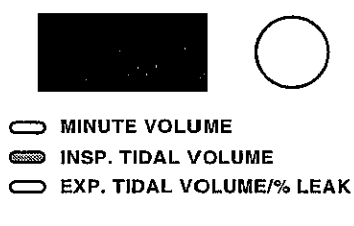


Minute Volume

Panel Group: Monitors
Range: 0 to 30 LPM
The Minute Volume monitor displays measured exhaled minute volume for all breath types, spontaneous and mechanical.

NOTE

The Minute Volume LED will display dashes if the flow sensor is absent or disabled.

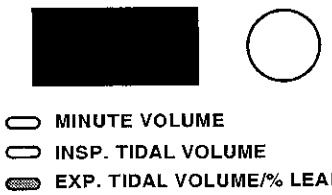


Inspiratory Tidal Volume

Panel Group: Monitors
Range: 0 to 500 ml
The Inspiratory Tidal Volume monitor displays measured inspired tidal volume for all breath types, spontaneous and mechanical. Inspired volume measured by the flow sensor at the patient wye is updated on a breath-by-breath measurement.

NOTE

The Inspiratory Tidal Volume LED will display dashes if the flow sensor is absent or disabled.



Expired Tidal Volume/% Leak

Expired Tidal Volume will be displayed with a single press. Press again to monitor % Leak.

Expired Tidal Volume

Panel Group: Monitors
Range: 0 to 500ml
The Expired Tidal Volume monitor displays Exhaled Tidal Volume for all breath types. Expired volume is measured by the flow sensor at the patient wye and is updated on a breath-by-breath basis.

NOTE

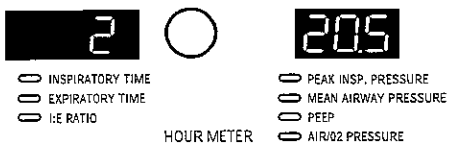
The Expired Tidal Volume LED will display dashes if the flow sensor is absent or disabled.

% Leak

Range: 0 to 99%
The % Leak monitor displays the calculated difference between delivered and exhaled volume, as measured by the flow sensor at the patient wye, in percentage. Information is on a breath-by-breath measurement. The display will indicate the letter "L" followed by the percent leak.

NOTE

The % Leak LED will display dashes if the flow sensor is absent or disabled.

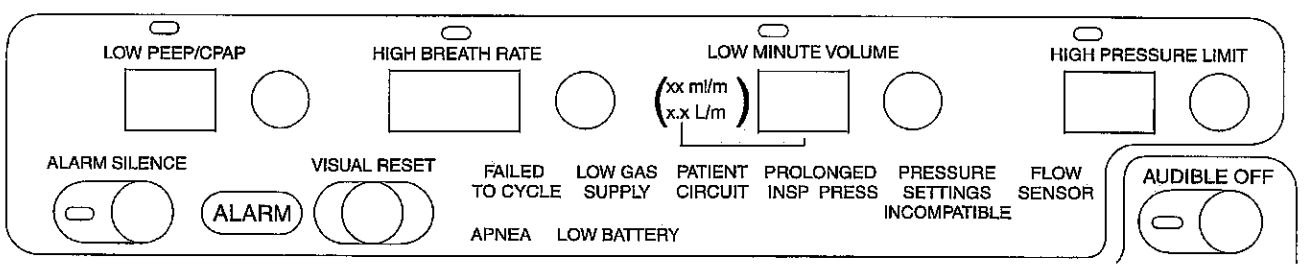


Hour Meter

Panel Group: Monitors
Range: 0 to 99,999 hours
The hour meter is displayed for 4 seconds when the Test Button is pressed and released. The hourmeter displays a running total of ventilator operation hours using a combination of two LED displays. For example, the graphic pictured indicates that the ventilator has been used for a total of 220.5 hours.

NOTE

Hours will not accumulate when the ventilator is in the STANDBY mode.



ALARMS

Alarms are located in the mid portion of the front panel. This section is made up of adjustable and fixed alarms. Displays are RED LEDs indicating alarm data.

Low PEEP/CPAP

Panel Group: Alarms

Range: -5 to 30 cmH_2O

The Low PEEP/CPAP alarm will activate if the measured proximal pressure falls below the set value for a minimum of 250 milliseconds. Restoration of the PEEP/CPAP level will silence the audible alarm, but the visual will remain to notify the clinician that the alarm setting was violated. Press VISUAL RESET to clear the LED indicator.

WARNING

If the Flow Sensor is not installed, the Apnea alarm will be disabled, and the Low PEEP/CPAP alarm will be the only active disconnect alarm when the ventilator has been set to the CPAP mode.

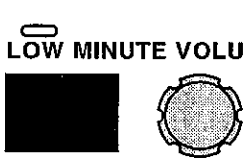
The Low PEEP/CPAP alarm must be set within 10 cmH_2O of the PEEP setting, or the Prolonged Inspiratory Pressure alarm will sound and the patient circuit alarm and the inspiratory limb dump solenoid may activate.

High Breath Rate

Panel Group: Alarms

Range: 3 to 255 BPM

The High Breath Rate alarm will activate whenever the monitored value for breath rate exceeds the alarm setting. A return of the breath rate below the alarm setting will silence the audible alarm, but the visual will remain to notify the clinician that the alarm was violated. Press VISUAL RESET to clear the LED indicator.



Low Minute Volume

Panel Group: Alarms
Range: 0 to 9.9L/min.
The Low Minute Volume alarm will activate when the monitored minute volume falls below the set threshold. If a flow sensor failure or disconnect occurs the ventilator shall display "- -". Setting the Low Minute Volume alarm at zero will disable the alarm.

WARNING

When using highly resistant (11 mm) dual heated wire circuits and flows above 15 lpm, you must use the Wye flow sensor and set the low minute volume alarm appropriately in order to detect an expiratory limb disconnect at the exhalation valve.

LOW INSPIRATORY PRESSURE ALARM

The LOW INSPIRATORY PRESSURE alarm is automatically set by the ventilator according to the following formula:

Low Inspiratory Pressure = 0.25 X (High Pressure Limit - Low PEEP/CPAP) + Low PEEP/CPAP,

where Low PEEP/CPAP = 0 if setting ≤ 0

NOTE

Minumum threshold for the Low Inspiratory Pressure Alarm is 5 cmH_2O.

HIGH PRESSURE LIMIT

High Pressure Limit

Panel Group: Alarms
Range: 10 to 75 cmH_2O
The High Pressure Limit alarm will activate when the proximal pressure exceeds the set threshold. Violation of this alarm will cause both an audible (minimum duration 2 seconds) and visual notification to occur, and will immediately terminate the breath. Alarm will repeat if violation again occurs on subsequent breaths. Once corrected the audible alarm will automatically silence and the visual indicator will remain lit to notify the clinician that the alarm was violated. Press VISUAL RESET to clear the LED indicator.

NOTES

To clear a High Pressure Limit alarm in CPAP mode, press VISUAL RESET.

If High Pressure Limit is set at an excessively high level, a Low Pressure (LP) alarm may flash in the High Pressure Limit window during normal operation.

In addition, High Pressure Limit Alarm may be activated as described in the following two scenarios.

1) Partially Obstructed Inspiratory or Expiratory Limb.
If the alarm occurs, as a result of the partial obstruction, the inspiration will be terminated and cycle into exhalation. Though the breath is terminated, the patient circuit alarm and dump solenoid will **not** be activated. Breaths will continue to be delivered and alarm activated until the occlusion is removed.

2) Proximal Pressure Line Disconnect at the Ventilator.
If the alarm occurs as a result of the proximal disconnect, the patient circuit alarm and inspiratory limb dump solenoid will be activated to dump all circuit pressure. If the pressure is found to be below 5cmH_2O for 3 seconds continuously, the dump solenoid will close. This sequence will repeat until the proximal pressure line is reconnected. Once reconnected the ventilator will resume normal operation.

NOTES

Depressing the Visual Reset switch will close the dump solenoid immediately.

Patient Circuit Alarm and Dump Valve may not activate if settings are too low to generate high circuit pressure. In this case Low Pressure Alarm will be activated and LP will be displayed in the High Pressure Limit window.

ALARM SILENCE

Alarm Silence

Panel Group: Alarms
Range: On/Off
Pressing Alarm Silence cancels the audible portion of an alarm for 60 seconds. All alarms can be silenced except the Failed to Cycle alarm. A lit LED indicator adjacent to the ALARM SILENCE key reminds the clinician that alarms have been silenced until:

- 60 seconds elapse or
- the clinician presses ALARM SILENCE again.

NOTE

The Alarm Silence feature can be used to pre-silence alarms for 60 seconds by pressing the key once prior to any alarm generation.

Alarm
Panel Group: Alarms
Range: On/Off
The Alarm Notification LED will illuminate during all alarm conditions to attract the attention of the operator. Once the alarm condition has been resolved, the LED will extinguish.

VISUAL RESET

Visual Reset
Panel Group: Alarms
Range: On/Off
Pressing Visual Reset causes the ventilator to clear all solidly lit alarm indicators. Note that flashing alarm indicators cannot be cleared by Visual Reset since a "flashing indicator" signals that the underlying alarm condition is still occurring. For momentary alarm conditions (such as High Pressure Limit), the minimum alarm time is 2 seconds. These alarms cannot be reset until the 2 seconds has elapsed.

FAILED TO CYCLE

Failed to Cycle

Panel Group: Alarms

Range: On/Off

The Failed to Cycle alarm will activate if the ventilator detects an internal or external malfunction. During a Failed to Cycle condition, the audible alarm cannot be silenced.

WARNING

To clear a Failed to Cycle alarm condition once the ventilation malfunction has been corrected, the mode switch must be turned to the STANDBY mode prior to the selected mode of operation, with the exception of a Failed to Cycle condition caused by low gas supply.

APNEA

Apnea

Panel Group: Alarms

Range: On/Off

The Apnea alarm will activate if the ventilator detects the lack of breath initiation in excess of the set period of time. This alarm will remain active until breath initiation is detected, at which time the audible will silence, but the visual indicator will remain lit to notify the clinician that the alarm was violated. Press VISUAL RESET to clear LED indicator.

If the patient becomes apneic, in PSV or CPAP mode, following an apnea time-out the ventilator will deliver a backup breath at the preset INSPIRATORY TIME and INSPIRATORY PRESSURE. If no spontaneous effort is detected during a subsequent time-out period, based on the breath interval set by the VENTILATOR RATE or 10 seconds, whichever is less, an additional backup breath will be delivered. This sequence will repeat until a spontaneous effort is recognized. An apnea alarm will be reported throughout this sequence.This requires a functional flow sensor.

WARNING

When the Flow Sensor is disconnected, or becomes disabled during operation, breath detection is no longer available.
If the Flow Sensor is disconnected or becomes disabled, the Apnea alarm becomes inactive in the CPAP mode.

LOW GAS SUPPLY

Low Gas Supply

Panel Group: Alarms

Range: On/Off

The Low Gas Supply alarm will activate if either gas supply pressure falls below 24(±2) psig. If one gas supply fails, the ventilator continues providing ventilation using the available gas supply. Flow and pressure delivered may decrease by a maximum of 10%. If the supply pressures for both gas supplies fall below 24(±2) psig, then a Failed to Cycle alarm will occur and the ventilator will cease to cycle. Restoration of supply pressure over 30 PSI will allow the ventilator to resume cycling and silence the audible alarm but the visual will remain lit to notify the clinician of the alarm violation. Press VISUAL RESET to clear LED indicator.

WARNING

When a Low Gas Supply alarm occurs, the oxygen concentration to the patient will be different than that set on the O_2 control.

LOW BATTERY

Low Battery

Panel Group: Alarms

Range: On/Off

The Low Battery alarm will activate when the internal battery has approximately 5 minutes of power remaining before full discharge. Restoring AC line power will silence the audible alarm and commence charging of the internal battery, but the visual indicator will remain lit to notify the clinician of the alarm violation. Press VISUAL RESET to clear the LED indicator. The internal battery has a capacity to operate the ventilator for approximately 30 minutes when at 100% charge. Ensuring that the ventilator remains plugged into an AC outlet for 4 hours will return a discharged battery (i.e. the level of charge will not support ventilator operation) to full charge.

WARNING

Should the ventilator Fail to Cycle due to a loss of battery power, the ventilator control knob must be turned to the STANDBY mode prior to the selected mode of operation (once power has been restored to the ventilator).

PATIENT CIRCUIT

Patient Circuit

Panel Group: Alarms

Range: On/Off

The Patient Circuit alarm will activate when the machine pressure is greater than the Low PEEP/CPAP setting plus 11 cmH_2O and a flow offset for 4.0 seconds (as would occur with complete occlusion of the inspiratory or expiratory limb of the breathing circuit).

Following activation of the alarm, the inspiratory limb dump solenoid will open in an attempt to decrease circuit pressure to ambient. Once pressure is restored to ambient (<5 cmH_2O) for 3.0 seconds continuously, the inspiratory limb dump solenoid closes and the ventilator returns to normal operation. If the condition continues, the above sequence will repeat indefinitely. Also, pressing VISUAL RESET will close the dump solenoid and cause a return to normal operation. Resolving the alarm violation will silence the audible alarm but the visual alarm will remain to notify the clinician of the alarm violation. Press VISUAL RESET to clear LED indicator.

PROLONGED INSP PRESS

Prolonged Inspiratory Pressure

Panel Group: Alarms
Range: On/Off
The Prolonged Inspiratory Pressure Alarm will activate if the measured proximal pressure remains above the reference value (Low PEEP/CPAP + 10 cmH_2O) for more than 3.5 seconds. This would occur with an occlusion of the expiratory limb as long as the High Pressure Limit is not activated.

SETTINGS INCOMPATIBLE

Settings Incompatible

Panel Group: Alarms
Range: On/Off
The Settings Incompatible alarm will activate if the operator attempts to set a control setting, or group of settings, that are incompatible with one another. The following can cause a Settings Incompatible alarm:

- Operator has attempted to set an Inspiratory Time that is incompatible for the Ventilator Rate selected (Inspiratory Time and Ventilator Rate displays will flash).

  In this condition, the set Inspiratory Time will not be delivered. Ventilator Rate will be maintained.

- Operator has attempted to set a Base Flow that is more than 2 times the Set Inspiratory Flow setting (Base Flow and Inspiratory Flow displays will flash).

  In this condition, the flow control solenoid will not cycle and Base Flow will be delivered continously.

- Operator has attempted to set a Volume Limit that is incompatible with the Flow or Pressure settings of the ventilator. If the Inspiratory Flow setting is too high, the Volume Limit LED digits will flash, alternating with "E.FL." If the Inspiratory Pressure is too high, the Volume Limit LED digits will flash, alternating with "E.PL."

PRESSURE SETTINGS INCOMPATIBLE

Pressure Settings Incompatible

Panel Group: Alarms
Range: On/Off
The Pressure Settings Incompatible alarm will activate if the operator attempts to set an inspiratory pressure level that is less than the PEEP/CPAP setting, or a PEEP/CPAP level that is more than the inspiratory pressure setting.

NOTE

In this condition, the pressure control solenoid will not cycle, and PEEP/CPAP will be the continuous pressure level.

FLOW SENSOR

Flow Sensor

Panel Group: Alarms
Range: On/Off
The Flow Sensor alarm will activate if a sensor malfunction or disconnect from the ventilator is detected. The ventilator will continue to operate, and the alarm indicators can be extinguished. However, volume monitoring and synchronization capabilities are disabled. The alarm indicators can not be cancelled in any mode that relies on flow for breath termination.

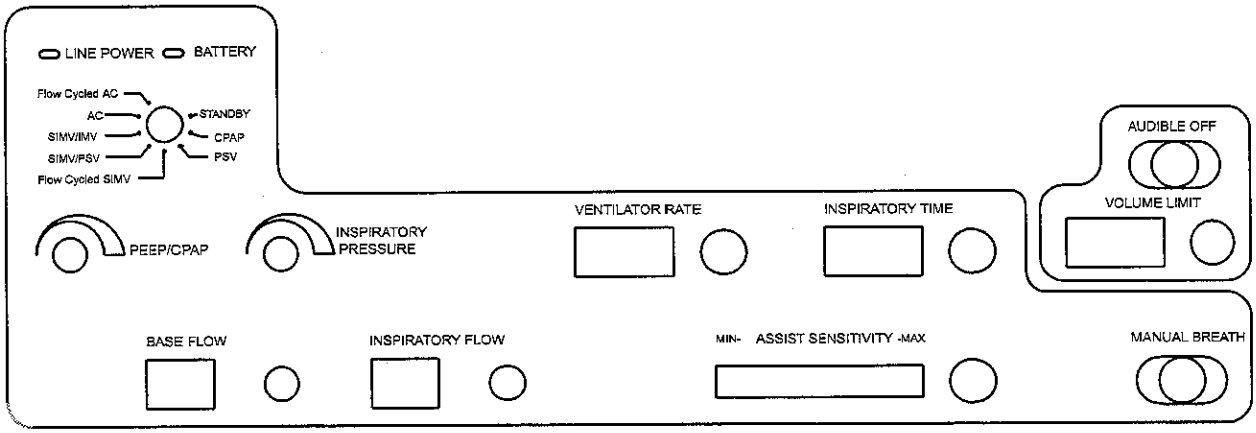
The Flow Sensor alarm will activate if the Flow Sensor is connected to the ventilator but no flow activity is detected in the Apnea period (e.g. the Flow Sensor is not installed in the patient circuit system).

WARNING

Removal of the Flow Sensor from the circuit during operation will eliminate the Assist Trigger and Volume Limiting functions. Failure to detect the absence of the Flow Sensor, and/or respond to the Flow Sensor disconnection alarm, may cause injury to the patient.

CAUTION

Nebulizer medications should not be used when the Flow Sensor is attached to the patient circuit.



CONTROLS

The controls are located in the lower portion of the front panel. Using control knobs and LED displays, data entry is straightforward and always visible. Displays are GREEN LEDs indicating control data.

⊂⊃ LINE POWER

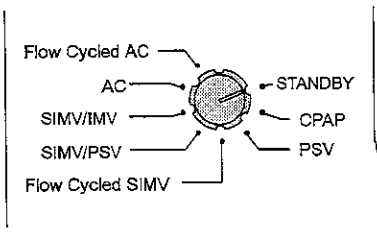
Line Power

Panel Group: Controls
Range: On/Off
The Line Power LED illuminates green when the ventilator is operating on line power. The LED will change to red if line power is lost and the ventilator is operating on battery power. If the ventilator loses all power sources, the LED will extinguish.

⊂⊃ BATTERY

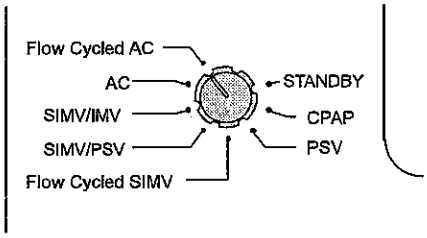
Battery

Panel Group: Controls
Range: On/Off
The Battery LED illuminates green when the ventilator is operating on line power and the battery is charging. The LED also illuminates green if the ventilator is not on line power and the battery charge is sufficient to power the ventilator. If the ventilator is on line power and the battery charge is not sufficient to power the ventilator, the LED will extinguish.

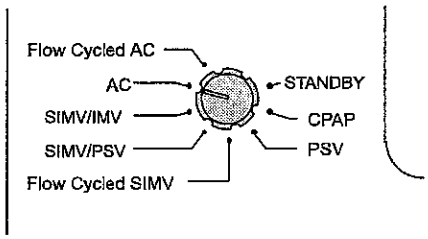


Mode Select

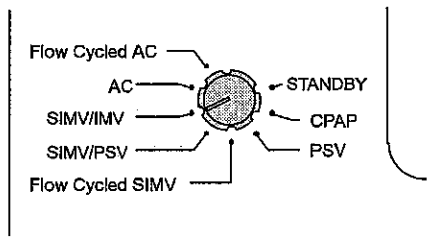
Panel Group: Controls
Range: Flow Cycled AC, AC, SIMV/IMV, SIMV/PSV, Flow Cycled SIMV, Standby, CPAP and PSV
Controls all power to the ventilator and allows selection of the method of operation.



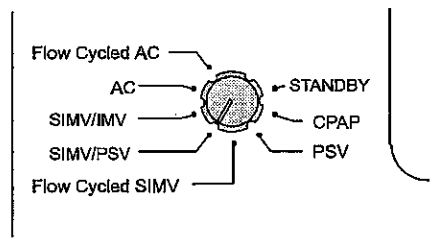
- **Flow Cycled AC**
  In the Flow Cycled AC position, a mechanical breath is delivered with each inspiratory effort, provided the patient satisfies the assist sensitivity criteria. If the patient does not meet the assist sensitivity criteria, the ventilator automatically delivers breaths according to the Ventilator Rate control. All breaths will be flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or time cycled at the preset INSPIRATORY TIME, or volume cycled when the volume limit is reached, whichever occurs first. The Inspiratory Time Display will flash if the breath is terminated based on time rather than flow.



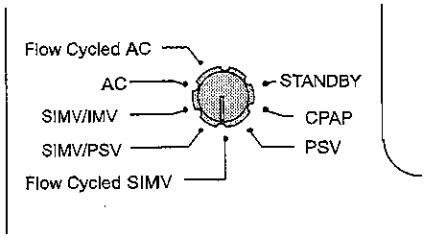
- **AC**
  In the AC position, a mechanical breath is delivered with each inspiratory effort, provided the patient satisfies the assist sensitivity criteria. If the patient does not meet the assist sensitivity criteria, the ventilator automatically delivers breaths according to the Ventilator Rate control. All breaths will be time cycled at the preset INSPIRATORY TIME, or volume cycled when the volume limit is reached, whichever occurs first. Mechanical breaths may then be either patient initiated (assisted) or ventilator initiated (controlled).



- **SIMV/IMV**
  In the SIMV/IMV position, a combination of mechanical and spontaneous breath types are available. Mechanical breaths, either assisted or controlled, are delivered at the set ventilator rate while all other breaths are spontaneous. Ventilator breaths will be time cycled at the preset INSPIRATORY TIME or volume cycled when the volume limit is reached, whichever occurs first.



- **SIMV/PSV**
  In the SIMV/PSV position, a combination of mechanical and spontaneous breath types are available. Mechanical breaths, either assisted or controlled, are delivered at the set ventilator rate while all other breaths are spontaneous. Mechanical breaths will be time cycled at the preset INSPIRATORY TIME or volume cycled when volume limit is reached, whichever occurs first. All spontaneous breaths recognized by the ventilator between the mandatory breaths will be supported by the ventilator to the preset INSPIRATORY PRESSURE and flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or time cycled at the preset INSPIRATORY TIME, or volume cycled when the volume limit is reached, whichever occurs first. The Inspiratory Time Display will flash if the breath is terminated based on time rather than flow.

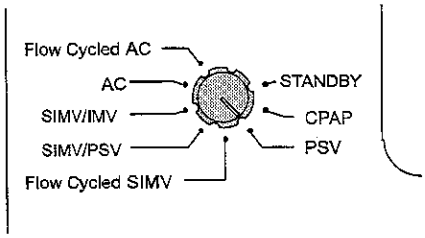


- **Flow Cycled SIMV**

In the Flow Cycled SIMV position, a combination of mechanical and spontaneous breath types are available. Mechanical breaths, either assisted or controlled, are delivered at the set ventilator rate while all other breaths are spontaneous. All pressure limited breaths are delivered to the patient at the preset INSPIRATORY PRESSURE and are flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or time cycled at the preset INSPIRATORY TIME, or volume cycled when the volume limit is reached, whichever occurs first. The Inspiratory Time Display will flash if the breath is terminated based on time rather than flow.

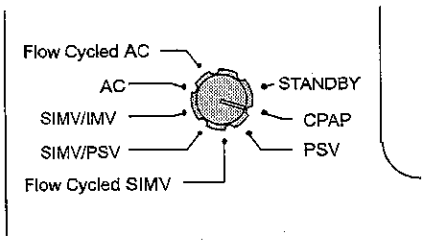
NOTE

Disabling the assist sensitivity mechanism, or removing the flow sensor from the ventilator, will cause the equivalent of IMV mode of ventilation to exist.



- **PSV**

In the PSV position all spontaneous breaths recognized by the ventilator will be supported to the preset INSPIRATORY PRESSURE and flow cycled when the inspiratory flow falls to 10% of the peak inspiratory flow rate, or time cycled at the preset INSPIRATORY TIME, or volume cycled when the volume limit is reached, whichever occurs first. The Inspiratory Time Display will flash if the breath is terminated based on time rather than flow.

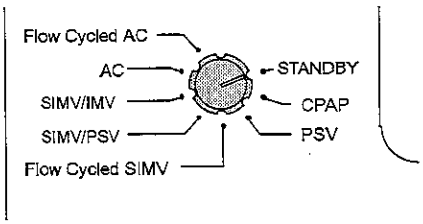


- **CPAP**

In the CPAP position, the Base Flow control establishes the continuous flow available for spontaneous breathing.

NOTE

If the patient becomes apneic, in PSV or CPAP mode, following an apnea time-out the ventilator will deliver a backup breath at the preset INSPIRATORY TIME and INSPIRATORY PRESSURE. If no spontaneous effort is detected during a subsequent time-out period, based on the breath interval set by the VENTILATOR RATE or 10 seconds, whichever is less, an additional backup breath will be delivered. This sequence will repeat until a spontaneous effort is recognized. An apnea alarm will be reported throughout this sequence.This requires a functional flow sensor.



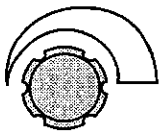
- **STANDBY**

The STANDBY position discontinues all electrical controls and functions with the exception of the charging system for the internal battery.

NOTE

If the ventilator is connected to air and O2 sources, blended gas will circulate while ventilator is in the STANDBY position, making gas available from the Auxiliary Gas Outlet. The amount of gas flow circulating is determined by the Base Flow setting.

PEEP/CPAP

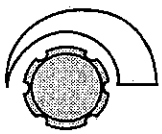


Panel Group: Controls
Range: 0 to 30 cmH2O
The PEEP/CPAP control sets the baseline level of pressure in the breathing circuit. Baseline pressure is set by rotating the PEEP/CPAP control knob (in a clockwise direction to increase), and observing the pressure on the digital display or analog manometer.

WARNING

If the PEEP/CPAP control is incorrectly set, a negative pressure can be applied to the patient circuit. It is recommended that the operator always monitor PEEP levels and adjust appropriately when changing Base Flow.

Inspiratory Pressure



Panel Group: Controls
Range: 0 to 72 cmH2O
The Inspiratory Pressure control sets the inspiratory pressure level delivered during mechanical breaths. The inspiratory pressure level is set by rotating the Inspiratory Pressure control knob (in a clockwise direction to increase) and observing the pressure on the digital display or analog manometer during inspiration.

Ventilator Rate

Panel Group: Controls

Range: 1 to 150 BPM

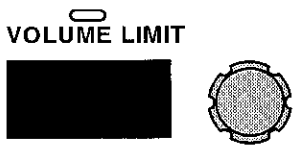
The Ventilator Rate control establishes the minimum number of mechanical breaths delivered in all AC modes, and the number of mechanical breaths in all SIMV modes.

Inspiratory Time

Panel Group: Controls
Range: 0.10 to 3.00 seconds
The Inspiratory Time control sets the duration of the inspiratory portion of the mechanical breath.

NOTE

Inappropriate time selection based on the ventilator rate selected will result in a settings incompatible alarm. During the alarm, the inspiratory time display will flash. Resolving the incompatible control situation will extinguish the audible and visual indicators. During a Ventilator Rate/Time Setting Incompatible condition, the set Inspiratory Time will not be delivered. The ventilator rate will be maintained.



Volume Limit

Panel Group: Controls
Range: 5 to 300 ml
The Volume Limit control establishes an upper boundary for deliverable inspiratory tidal volume during mechanical breaths or supported breaths. When the set threshold is reached, the ventilator will cycle into exhalation, and an LED will be illuminated. An audible indicator will occur only when 5 consecutive mandatory or supported breaths have exceeded the Volume Limit control threshold.

NOTES

If the Inspiratory Flow setting is too high for the Volume Limit Setting, the Volume Limit LED digits will flash, alternating with "E.FL." If the Inspiratory Pressure is too high, the Volume Limit LED digits will flash, alternating with "E.PL."

A "volume limited" breath will result in an inspiratory time and possibly inspiratory pressure which are less than the control settings.

The Volume Limit LED will display dashes if the flow sensor is absent or disabled.

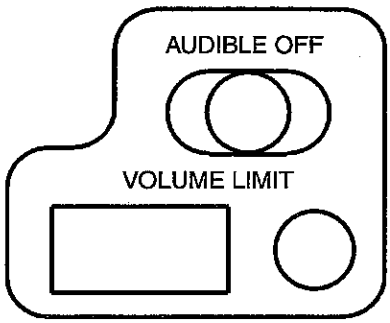
WARNINGS

If the Inspiratory Pressure control is set higher than the pressure reached at the Volume Limit condition by more than 30%, the volume delivered to the patient may be significantly greater than Volume Limit setting.

If the Inspiratory Pressure control is set higher than the pressure reached at the Volume Limit condition, the High Pressure Limit control should be set appropriately to prevent injury to the patient, in the event volume limiting is cancelled due to loss of the flow sensor.

Removal of the flow sensor from the circuit during operation will eliminate the flow trigger, flow cyclings and Volume Limiting functions. Failure to detect the absence of the flow sensor and/or respond to the flow disconnection alarm may cause injury to the patient if not corrected.

Volume Limit Audible Off

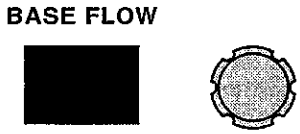


Panel Group: Controls
The Volume Limit Audible Off is activated by depressing the AUDIBLE OFF button for a minimum of 3 seconds. A visual indicator will indicate that this feature has been enabled. The Audible Off feature may be cancelled by depressing the AUDIBLE OFF button while the feature is active.

NOTE

The AUDIBLE OFF feature only cancels the audible volume limit indicator. The Volume Limit Function is not affected.

Base Flow



Panel Group: Controls
Range: 1 to 30 LPM
The Base Flow control sets the background flow available to the patient for spontaneous breathing during the expiratory phase of a mechanical breath.

NOTES

Inappropriate setting of Base Flow will result in an Incompatible Settings alarm. During this alarm, the Inspiratory and Base Flow displays will flash, and Base Flow will be delivered continuously. Resolving the incompatible control situation will extinguish the audible and visual indicators.

Use of the Auxiliary Gas Outlet will affect the accuracy of the delivered Base Flow out of the "TO PATIENT" port when total flow (Base Flow and Auxiliary Flow) exceeds 25 LPM. Note that total ventilator flow capability is 30 LPM.

Inspiratory Flow

Panel Group: Controls
Range: 1 to 30 LPM
The Inspiratory Flow Control sets the flow rate delivered by the ventilator during the inspiratory phase of a mechanical breath.

NOTES

Inappropriate setting of Inspiratory Flow will result in an Incompatible Settings alarm. During this condition, the Inspiratory and Base flow displays will flash, and Base Flow will be delivered continually. Resolving the incompatible control situation will extinguish audible and visual indicators.

Use of the Auxiliary Gas Outlet will affect the accuracy of the delivered Inspiratory Flow out of the "TO PATIENT" port when total flow (Inspiratory Flow and Auxiliary Flow) exceeds 25 LPM. Note that total ventilator flow capability is 30 LPM.

Assist Sensitivity

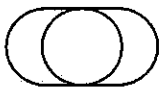
Panel Group: Controls
Range: 0.2 to 5.0 LPM
The Assist Sensitivity control determines the amount of inspiratory effort the patient must exert to trigger an AC breath, SIMV breath, or have spontaneous breaths counted and displayed in the breath rate window. At the most sensitive position, the patient must create a flow demand through the sensor of at least 0.2 LPM to cause any of the above to occur.

To detect a leak at the patient airway, adjust the sensitivity knob to the right and note the presence of a Leak Detection LED bar to the left of the Assist Sensitivity LED. If no LED bar is present, no leak is detected and the Assist Sensitivity LED bar should be positioned at the minimum setting. If a Leak Detection LED bar appears to the left of the Assist Sensitivity, this represents the presence of a leak. Adjust the Assist Sensitivity LED bar one bar position to the right of the Leak Detection LED. This optimizes the sensitivity to prevent auto cycling.

NOTE

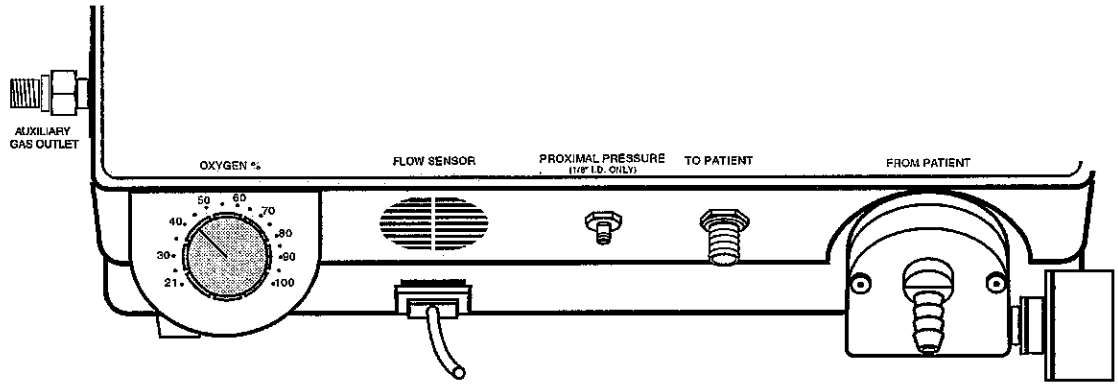
No Assist Sensitivity LED will be displayed if the flow sensor is absent or disabled.

MANUAL BREATH

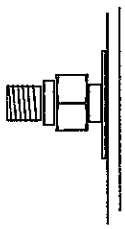


Manual Breath

Panel Group: Controls
Range: On/Off
Once depressed, the Manual Breath button delivers a single mechanical breath at the inspiratory time, flow rate, and inspiratory pressure as set on primary controls.



LOWER/FRONT FACE



Auxiliary Gas Outlet

Location: Left Side of Ventilator
The Auxiliary Gas Outlet provides a source of blended gas for nebulizers at a minimum of 8 PSI for a typical flow of 6 LPM.

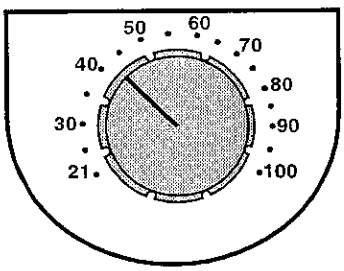
NOTES

Use of the Auxiliary Gas Outlet will affect the accuracy of the delivered Base Flow out of the "TO PATIENT" port when total flow (Base Flow/Inspiratory Flow and Auxiliary Flow) exceeds 25 LPM. Note that total ventilator flow capability is 30 LPM.

If total corrected gas flow (Auxiliary plus Flow Control) is greater than 30 LPM, auxiliary pressure out will be less than 7 PSI and nebulizer may not be effective.

CAUTION

The 0_2 DISS fitting on the Auxiliary Gas Supply is a blended gas outlet. Do not connect an Oxygen Gas supply to this fitting, as damage to the ventilator may occur.



Oxygen %

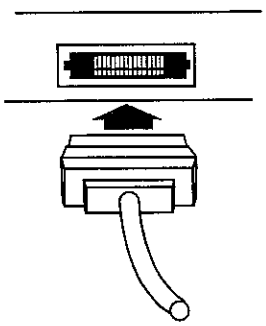
Location: Lower Left Front Face
Range: 21 - 100%
The internal Oxygen Blender provides a variable oxygen concentration from 21 to 100%.

WARNING

It is suggested that oxygen concentration be monitored continuously using an oxygen analyzer that includes both high and low alarms. If a high or low oxygen percent alarm is activated, an Operational Verification Procedure (OVP) should be performed on both the ventilator and the external oxygen monitor. If the ventilator fails the OVP, it should be referred to an Thermo Respiratory Group service technician.

Alarm Speaker

Location: Lower Left Front Face
The Alarm Speaker generates audible alarms. The loudness level for alarms is adjustable within a range of 60 to 75 dB(A).



Flow Sensor

Location: Lower Left Front Face
The Flow Sensor signal is transmitted to the ventilator through this 15 pin connector. If the flow sensor is not connected to the ventilator, a flow sensor alarm will be activated. The alarm may be disarmed by pressing Visual Reset for any mode in which breaths are not flow cycled. The ventilator will operate without the flow sensor but Volume Limit, volume monitoring, flow triggering and Flow Cycling will not be available.

The Flow Sensor is installed at the patient wye between the endotracheal tube and breathing circuit.

WARNING

Removal of the flow sensor from the circuit during operation will eliminate the flow trigger, flow cycling and Volume Limiting functions. Failure to detect the absence of the flow sensor and/or respond to the flow disconnection alarm may cause injury to the patient if not corrected.

If the flow sensor is not being used with the BEAR CUB 750PSV Infant Ventilator, the Apnea alarm is disabled in PSV and CPAP modes.

PROXIMAL PRESSURE (1/8" I.D. ONLY)

Proximal Pressure Port

Location: Lower Front Face
The Proximal Pressure Port (for 1/8" I.D. tubing) receives pressure input from the patient wye via the proximal pressure tubing. A proximal purge flow of 100 ml/min minimizes any moisture or contaminant migration up the proximal line.

WARNING

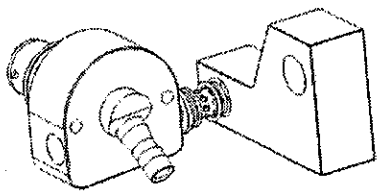
Use only 1/8" I.D. tubing for the proximal airway pressure sensing line. Use of larger I.D. tubing may cause pressure oscillations under some conditions.

Do not place restrictive adapters in-line as malfunction may result. Restriction in the proximal line or proximal filter will cause the delivered pressure to be less than the monitored values.

TO PATIENT

Main Flow "To Patient" Port

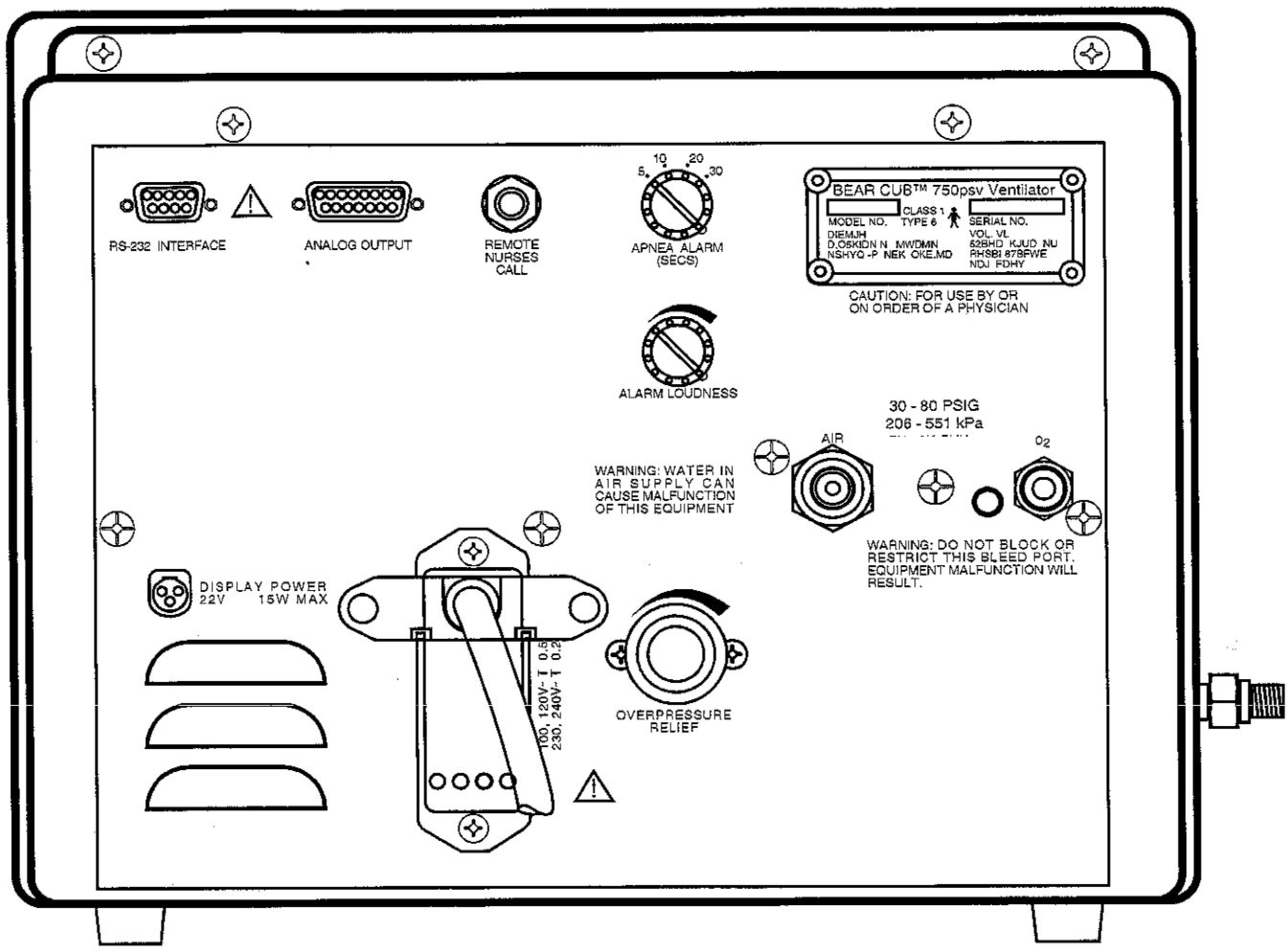
Location: Lower Front Face
The "To Patient" port provides the flow of gas to the patient.

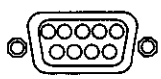


Exhalation Valve Assembly

Location: Lower Right Front Face
The Exhalation Valve Assembly controls the breath phase (inspiration or exhalation) as well as PEEP/CPAP applied during exhalation.

BACK PANEL





RS-232 INTERFACE

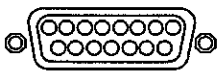
RS-232 Digital Communication Interface

Location: Back Panel

The RS-232 9-pin Female Connector permits the ventilator to digitally communicate with a central monitor, a computer, or the BEAR® VGM.

WARNING

The user should never touch the "RS-232 Interface" or "Analog Output" connectors and the patient simultaneously.



ANALOG OUTPUT

Analog Output

Location: Back Panel

The Analog Output 15-pin Female Connector provides analog signals of pressure, flow and breath phase.

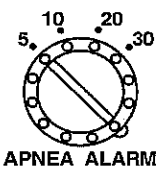
Pressure	(Signal Pin 1, Ground Pin 2)
Pressure Range	-10 to 100 cmH_2O
Scale:	1 cmH_20 / 25mV
Zero:	1.25VDC at 0 cmH_2O
Flow (Insp./Exp.)	(Signal Pin 3, Ground Pin 4)
Flow Range:	-40 to 40 LPM
Scale:	1 LPM / 50mV
Zero:	2.5 VDC at 0 LPM
Flow (Delivered)	(Signal Pin 3, Ground Pin 4)
Flow Range:	0 to 30 LPM
Scale:	1 LPM / 50mV
Zero:	2.5 VDC at 0 LPM
Breath Phase:	(Signal Pin 9, Ground Pin 10)
	0,5 VDC (5 VDC for inspiration phase)

REMOTE NURSE CALL

Remote Nurse Call

Location: Back Panel

The Remote Nurse Call provides a signal (switch indication) for alarm conditions. The switch will be normally closed and will open the circuit when the alarm is active. The contact is rated at up to 0.5 amps at 24 vdc.



APNEA ALARM (SECS)

Apnea Alarm

Location: Back Panel

The Apnea Alarm Control allows the clinician to select from four available time periods for apnea alarm activation. The selections are 5, 10, 20, or 30 second intervals.

ALARM LOUDNESS

Alarm Loudness

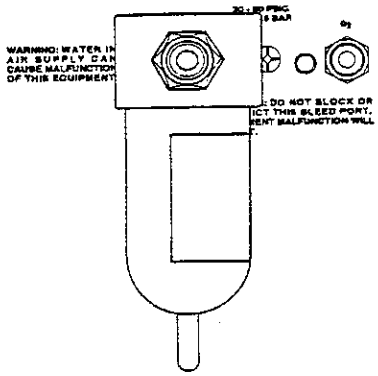
Location: Back Panel

Range: 60 to 75 dB(A)

The alarm loudness knob adjusts the volume of the audible alarms. Turn clockwise to increase volume and counterclockwise to decrease.

WARNING

Alarm loudness must be set above ambient sound in order to be heard.

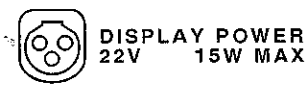


Air Inlet, Water Trap and Oxygen Inlet

Location: Back Panel
Air and O2 Inlet Fittings and the Air Inlet Water Trap provide the connection for the ventilation gas sources. Gases must be supplied at pressures between 30 and 80 psig with a minimum flow capability of 50 LPM.

CAUTION

Any condensate in the water trap is a warning signal that condensate may be entering the ventilator.

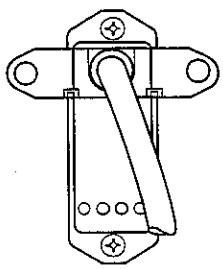


Display Power Outlet
Location: Back Panel

The Display Power Outlet supplies power to the Ventilator Graphics Monitor (VGM). The outlet utilizes a 3-pin connector and provides unfiltered DC (15W maximum) to the display. Output to the VGM is only provided when the ventilator is on and operating off of line power. This power output is EXCLUSIVELY for use with the VGM unit.

NOTE

The VGM will NOT operate when the ventilator is operating solely on battery power.



Power Inlet Module

Location: Back Panel
The Power Inlet Module has an international standard plug (conforming to IEC-320). The BEAR CUB 750PSV Ventilator is configurable to other voltages with voltage conversion kit installation.

Supply Voltage	Fuses
100/120	0.5 amp
230/240	0.25 amps

Set voltage selector switch to 230V for 220V operation.

Over Pressure Relief

Location: Back Panel

The Over Pressure Relief Valve acts as a mechanical back-up limit to the electronic High Pressure Limit alarm. Strictly mechanical in design, it relieves pressure in the inspiratory limb of the patient circuit. Pressure relief is adjustable between 15 to 75 cmH_2O.

It is recommended that the Over Pressure Relief Valve be adjusted to a minimum of 15 cmH_2O above the High Pressure Limit alarm setting. To adjust the Over Pressure Relief Valve, loosen the locking ring and occlude the patient wye and the exhalation line. Rotate the Over Pressure Relief Valve control knob counterclockwise to decrease (clockwise to increase) until the peak inspiratory pressure, as shown on the proximal airway pressure gauge, is at the desired setting but not less than 15 cmH_2O above where the High Pressure Limit alarm and the INSPIRATORY PRESSURE control will be set. Tighten the locking ring.

WARNING

If the Over Pressure Relief Valve is set to a pressure lower than the High Pressure Limit, the ventilator will not give an audible and visual indication of a high pressure condition that may cause injury to the patient.

Failure to appropriately adjust the Over Pressure Relief Valve for each individual patient could result in patient injury should the internal pressure relief valve fail.

6. TROUBLESHOOTING

TROUBLESHOOTING CHART

Symptom	Possible Causes	Corrective Action
Low Gas Supply Alarm	1. Air supply inlet pressure has decreased to below 24 ± 2 PSIG.	1. Check for secure air hose connection to ventilator, compressor and/or wall. Restore air supply pressure. Verify air inlet pressure on front of ventilator in monitor section.
	2. Oxygen supply inlet pressure has decreased to below 24 ± 2 PSIG.	2. Check for secure O_2 hose connection to ventilator, O_2 tank and/or wall. Restore oxygen supply pressure. Verify oxygen inlet pressure on front of ventilator in monitor section.
	3. Air and oxygen supply pressures have decreased to below 24 ± 2 PSIG.	3. Check for secure air and oxygen hose connection to ventilator, compressor, O_2 tank and/or wall. Remove the patient from the ventilator. Provide alternate ventilation. Restore supply pressures.
	4. Clogged air inlet water trap/coalescing filter.	4. Replace inlet filter if clogged.
	5. Inoperative air pressure transducer.	5. Remove the ventilator from service. Contact a Thermo Respiratory Group certified service technician for repair.
	6. Inoperative oxygen pressure transducer.	6. Remove the ventilator from service. Contact a Thermo Respiratory Group certified service technician for repair.
Failed to Cycle Alarm	1. Ventilator hardware or software malfunction.	1. Remove the patient from the ventilator. Provide alternate ventilation and refer to a Thermo Respiratory Group certified service technician for repair.
	2. Air and oxygen supply pressures have decreased below 24 ± 2 PSIG.	2. Check for secure air and oxygen hose connection to ventilator, compressor, O_2 tank and/or wall. Remove the patient from the ventilator. Provide alternate ventilation. Restore supply pressures.

TROUBLESHOOTING CHART

Symptom	Possible Causes	Corrective Action
Flow Sensor Alarm	1. Defective flow sensor.	1. Replace flow sensor.
	2. Flow sensor not connected.	2. Connect flow sensor.
	3. Flow sensor not installed in patient circuit.	3. Install flow sensor.
	4. Occluded flow sensor and/or Endotracheal Tube.	4. Remove occlusion.
	5. Patient has not initiated a breath within the selected apnea time interval.	5a. Evaluate patient status and change level of support as indicated.
		5b. Evaluate Assist/Sensitivity setting.
Low PEEP/CPAP Alarm	1. Leak in patient circuit.	1. Check circuit, including humidifier, for disconnects or leaks.
	2. Patient disconnected.	2. Reconnect patient.
	3. Proximal pressure sensing line disconnect.	3. Reconnect proximal Pressure sensing line.
	4. Improperly set alarm.	4. Re-evaluate alarm setting.
High Breath Rate Alarm	1. Change in patient status causing an increase in breath rate.	1. Re-evaluate patient status.
	2. Improperly set alarm.	2. Re-evaluate alarm setting.
	3. Water in patient circuit causing auto-cycle or false flow trigger.	3. Drain patient circuit.
	4. Autocycling due to Assist Sensitivity setting in conjunction with large endotracheal tube leak.	4. Address endotracheal tube leak and re-evaluate assist sensitivity setting.

If an error code appears in a monitor window, record the error code and contact your Thermo Respiratory Group Certified Service Technician.

TROUBLESHOOTING CHART

Symptom	Possible Causes	Corrective Action
Low Inspiratory Pressure Alarm	1. Leak in patient circuit.	1. Check circuit, including humidifier, for disconnects or leaks.
	2. Change in patient compliance or resistance (⇑ C, ⇓ R).	2. Re-evaluate patient status.
	3. Improperly set High Pressure alarm.	3. Re-evaluate alarm settings.
	4. Volume Limit event with decreased inspiratory time.	4. Re-evaluate patient settings.
High Pressure Limit Alarm	1. Occlusion of the inspiratory or expiratory limb of the breathing circuit.	1. Check patient circuit and remove occlusion. Check for excess water in patient circuit, drain if present.
	2. Improperly set alarm, alarm limit set below observed pressure on manometer.	2. Re-evaluate alarm settings.
Pressure Settings Incompatible Alarm	1. User has attempted to select an Inspiratory Pressure setting lower than PEEP/CPAP setting.	1. Re-evaluate control settings for Inspiratory Pressure and PEEP/CPAP.
Apnea Alarm	1. Patient has not initiated a breath within the selected time interval.	1a. Evaluate patient status and change level of support as indicated. 1b. Evaluate Assist Sensitivity setting.
	2. Occluded Endotracheal Tube.	2. Remove occlusion.
Low Battery Alarm (non-silenceable)	1. Unit operating on internal battery with less than 5 minutes remaining before full discharge.	1. Restore A/C line power source or provide alternate ventilation.
	2. Battery isn't hooked up.	2. Open door and connect battery.

If an error code appears in a monitor window, record the error code and contact your Thermo Respiratory Group Certified Service Technician.

TROUBLESHOOTING CHART

Symptom	Possible Causes	Corrective Action
Patient Circuit Alarm	1. Occlusion or disconnect of the proximal pressure sensing line.	1. Remove occlusion and/or reconnect proximal pressure sensing line.
	2. Occlusion of the inspiratory or expiratory limb of the breathing circuit.	2. Check inspiratory or expiratory limb of breathing circuit and remove occlusion.
Prolonged Inspiratory Pressure Alarm	1. Occlusion of either the expiratory limb or the proximal pressure sensing line of the breathing circuit, not allowing pressure to return to reference level.	1. Check patient circuit and remove occlusion. Check for excess water in patient circuit, drain if present.
	2. User has established a PEEP/CPAP level which is at least 10 cmH2O above the set Low PEEP/CPAP alarm setting.	2. Adjust Low PEEP/CPAP disconnect alarm setting appropriately in consideration of clinician-selected PEEP/CPAP level.
Settings Incompatible Alarm	1. User has selected a Base Flow setting that is more than two times higher than the Inspiratory Flow setting.	1. Re-evaluate control settings for Base Flow and Inspiratory Flow.
	2. User has selected an Inspiratory Time that is inappropriate for the set Ventilator Rate.	2. Re-evaluate control settings for Inspiratory Time and Ventilator Rate.
	3. User has set an Inspiratory Flow rate or Inspiratory Pressure that is inappropriate for the set Volume Limit.	3. Re-evaluate control settings for Flow Rate (E.FL flashing in Volume Limit window) or Inspiratory Pressure (E.PL flashing in Volume Limit window).

If an error code appears in a monitor window, record the error code and contact your Thermo Respiratory Group Certified Service Technician.

ERROR CODES

Error Code	Problem	Action
E01	Power-up ram errors	Call TRG* Technical Support
E02	Power-up rom checksum errors	Call TRG* Technical Support
E03	Pot-disconnect error	Call TRG* Technical Support
E04	Pressure-calibration EEPROM read error	Call TRG* Technical Support
E05	Flowpot calibration EEPROM read error	Call TRG* Technical Support
E06	Altitude setting EEPROM read error	Call TRG* Technical Support
E09	EEPROM hour meter error	Call TRG* Technical Support
E10	Baud-rate setting EEPROM read error	Call TRG* Technical Support
E11	Error-Code setting EEPROM read error	Call TRG* Technical Support
E12	Analog flow output type error	Call TRG* Technical Support
E17	RAM test error	Call TRG* Technical Support
E18	ROM checksum error	Call TRG* Technical Support
E19	Solenoid activation error	Call TRG* Technical Support
E20	Received Flowpot Data error	Call TRG* Technical Support
E25	Failed first ACK test	Call TRG* Technical Support
E26	Failed subsequent ACK test	Call TRG* Technical Support
E27	Not programmed as short wire sensor (Good Wires)	Call TRG* Technical Support
E28	Incorrect checksum	Call TRG* Technical Support
E33	Failed first ACK test	Call TRG* Technical Support
E34	Failed subsequent ACK test	Call TRG* Technical Support
E35	Not programmed as short wire sensor (Bad Wires)	Call TRG* Technical Support
E36	Incorrect checksum	Call TRG* Technical Support
E37	Blown Wire, EEPROM OK	Replace Flow Sensor
E41	A/D error flag	Call TRG* Technical Support
E42	SPI error flag	Call TRG* Technical Support
E45	Loss of AC power	Restore AC Power
E46	Prox P & Rate Mon/Ctrl discrepancy	Call TRG* Technical Support
E49	A/D error	Call TRG* Technical Support
E50	SPI error flag	Call TRG* Technical Support
E51	2.5 ms overrun flag	Call TRG* Technical Support
E52	SCI error flag	Call TRG* Technical Support
E53	Mode Switch Data Error	Call TRG* Technical Support

* TRG = Thermo Respiratory Group

HOW TO IDENTIFY STORED ERROR CODES

1. Enter User Diagnostics mode by depressing MANUAL BREATH switch while turning the ventilator on. The BREATH RATE display shall indicate diagnostic test d22.
2. Repeatedly press TEST until the BREATH RATE display indicates diagnostic test d30. The TIME/RATIO display indicates a number to represent the number in the sequence of 1 to 15 of the circular buffer which stores the error codes in EEPROM. (The ventilator will store a maximum of 15 error codes.) The PRESSURE display indicates the error code stored in the respective buffer location. (refer to error code list) If there are no error codes stored, "E00" will be displayed.
3. If more than one error code has been stored, then press the MANUAL BREATH switch repeatedly to scroll through the list of error codes that have been stored in memory.
4. To clear the error codes stored, press and hold the PRESSURE display switch and simultaneously press the MANUAL BREATH switch.

7. CLEANING & MAINTENANCE

CLEANING INSTRUCTIONS

Following each patient use, or more frequently per hospital protocol, it is important to clean the exterior of the ventilator as well as to disassemble and clean the various components in the patient circuit system, exhalation valve, and air inlet water trap. Before cleaning the exterior of the ventilator, the power cord of the ventilator and humidifier must be unplugged. The ventilator and pedestal stand can be disinfected by wiping the exterior with an appropriate bactericidal or germicidal agent. Care should be taken to not allow any liquid to penetrate the inside of the ventilator.

PATIENT CIRCUIT SYSTEM

The **Patient Circuit System** (with the exception of the bacteria filters) should be cleaned with a warm detergent solution. All parts should then be thoroughly rinsed in warm water and prepared for sterilization. Remove and clean the flexible corrugated hoses, patient circuit tubing, adapters and connectors.

FLOW SENSOR

The **Bear Cub 750** PSV **Flow Sensor** should be cleaned thoroughly at a frequency determined by hospital protocol. The performance of the infant flow sensor can be affected by secretions and particle deposits (i.e. minerals, medications). More frequent cleaning may be necessary when used on patients with heavy secretions. After using a sterilization solution for cleaning, thoroughly rinse in sterile, distilled water before drying and packaging.

CAUTION

Nebulizer medications should not be used when the Flow Sensor is attached to the patient circuit.

The sensor should be cleaned prior to sterilization with an enzymatic cleaner. Ultrasonic cleaning is not recommended.

Immersion Cleaning: Prepare a solution of enzymatic cleaner (ie: Klenzyme) according to the manufacturers recommendations. Add a sufficient amount of the prepared solution to a pan to cover the devices. Allow the device to soak in the solution for a period of ten (10) minutes. Periodic "up and down" agitation may assist with the removal of protein particles from the device.

Remove the sensor from the cleaning solution and rinse in basin of (distilled/de-ionized) water. Agitating "up and down" will assist with the removal of any remaining cleaning solution and will ensure a complete rinse.

CAUTION

Do not rinse sensor with the force of an open faucet. Doing so will damage the sensor.

Dry the device with a soft cloth being careful not to introduce anything into the body of the device.

CAUTION

Never attempt to insert cleaning instruments into flow sensor or to dry the internal components with a high-pressure gas source. Doing so will damage the sensor.

The BEAR Cub 750PSV Flow Sensor can undergo a minimum of 50 (fifty) cleaning cycles.

CLEANING THE EXHALATION MANIFOLD AND MUFFLER ASSEMBLY

The **Exhalation Manifold** and **Muffler Assembly** should be removed and cleaned between patients. Reference the disassembly diagram below.

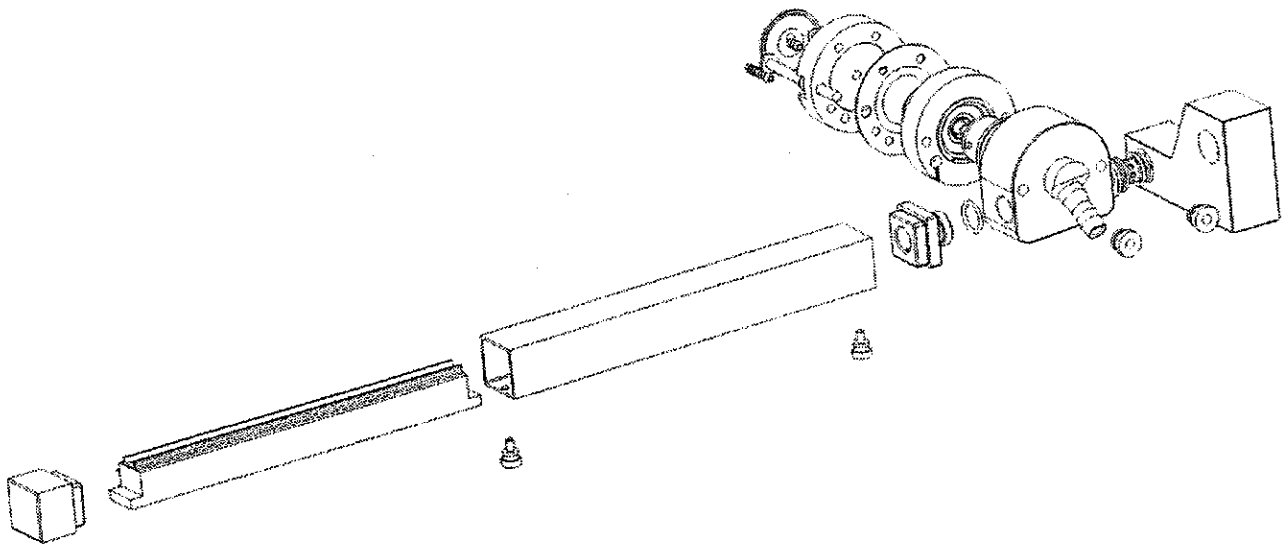


Figure 7-1 • Exhalation Manifold with Muffler Assembly

CLEANING THE EXHALATION MANIFOLD AND MUFFLER ASSEMBLY (continued)

All exhalation manifold and muffler assembly parts (except the exhalation control pin assembly) should be cleaned in a warm detergent solution. Thoroughly rinse all parts cleaned above in warm water, dry, and prepare for sterilization.

The **Control Pin Assembly** need not be removed at each cleaning of the exhalation valve assembly, but it should be disinfected with an alcohol solution and inspected for the presence of contaminents that might interfere with its function. The pin should move freely in its bushing with no sluggishness or sticking. Any question concerning the proper functioning of the pin should be verified by performing an Operational verification Procedure (OVP - P/N 50000-12196).

Periodic removal and cleaning of the control pin assembly is required. The frequency varies depending on use and conditions. Recommendations are as follows:

CONTROL PIN ASSEMBLY CLEANING SCHEDULE

CONDITION	RECOMMENDED CYCLE
1) Where any or all of the below are true: • Any visible fluid at the end of the expiratory leg of the circuit. • Use of nebulized medicants for more than 2 hr./day. • Suspected high contamination in the hospital air supply is present.	Monthly (along with OVP)
2) Where all of the below are true: • No visible fluid at the end of the expiratory leg of the circuit. NOTE: Heated wire circuits have been shown to control end expiratory humidity extremely well. • A 0.8 micron coalescing air inlet water trap is	At every Preventive Maintenance

AIR INLET WATER TRAP

The entire **Air Inlet Water Trap** may be cleaned with a warm detergent solution. All components may then be thoroughly rinsed in warm water. When reassembling the air inlet water trap, be careful to assemble it correctly and not to overtighten the bowl. Overtightening may cause cross threading of the bowl.

STERILIZATION INSTRUCTIONS

The **Bear Cub 750 PSV Flow Sensor** may be sterilized utilizing a Ethylene Oxide (EtO) sterilization process. (50 sterilization cycles maximum).

Ethylene Oxide (EtO)

Sterilize the devices using EtO as follows:

Preconditioning Parameters:

Temperature	54 ± 2°C
Relative Humidity	70% ± 5%
Vacuum	21 ± 1 In Hg
Time	1 hour

Sterilization Parameters:

EtO Carrier	User Specified
Temperature	54 ± 2°C
Relative Humidity	70% ± 5%
Pressure (PSIG)	14 ± 1
EtO Concentrations	600 ± 25mg/l
EtO Exposure Time	4 hours
Aeration Time	12 hours at 55° C

RECOMMENDED GUIDELINES FOR STERILIZATION

COMPONENT	METHOD
Tubing Tygon® 3/8" I.D. and 3/16" I.D.	Gas, liquid, pasteurization, or autoclave
Connector, Endotracheal, 4-way, 11mm O.D./15 mm I.D./3/8" O.D.	Gas, liquid, pasteurization, or autoclave
Connector, 3/8" O.D. — Both Ends	Gas, liquid, pasteurization or autoclave
Adapters, Endotracheal 11mm and 15mm	Gas, liquid, pasteurization or autoclave
Bacteria Filter, Infant 3/8" O.D. — Both Ends and 1/4" O.D. Proximal Bacteria Filter	Steam autoclave only
Hose, Flexible, Corrugated	Gas, liquid, pasteurization or autoclave
Exhalation Valve Assembly (except acoustical foam)	Gas, liquid, pasteurization or autoclave
Acoustical Foam	Gas or liquid
Control Pin Assembly	Ultrasound with alcohol bath

BEAR CUB 750PSV COMPONENTS

CAUTIONS

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

For ventilator accessories which require sterilization, peak sterilization temperature should not exceed 130° F (54° C) for gas (ETO), and 270° F (132° C) for steam autoclave components.

PREVENTIVE MAINTENANCE SCHEDULE

An Operational Verification Procedure (OVP) should be performed a minimum of once per month.

Preventive Maintenance should be completed once every year.

INTERNAL BATTERY CARE

The use of the internal battery to power the BEAR CUB 750PSV Infant Ventilator dramatically improves the ventilator's mobility. However, there are several important facts to know about the care and maintenance of the battery.

The rechargeable internal battery is for emergency use and brief periods of transition from one power source to another. It is recommended that the operator always have the ventilator plugged in when running it. The battery has a capacity to operate the BEAR CUB 750PSV Infant Ventilator for approximately 30 minutes when at 100% charge. However, battery life is affected by ambient temperature during storage and use. The efficiency of the internal battery decreases as the temperature decreases, and increases as the temperature increases above room temperature. High temperatures increase the rate of self discharge.

In addition, batteries typically lose their charge when not used. For this reason, except when unit has been placed into storage, always leave your ventilator plugged into an AC outlet to maintain the internal battery charge. Avoid fully discharging the battery. However, if it is unavoidable, ensure that it remains plugged into an AC outlet for 4 hours to return the full charge.

NOTE

A battery that is fully drained (i.e. void of any charge) will require a longer time to recharge and may be unusable if it remains "drained" over an extended period of time. Further, a fully drained battery must be recharged while the ventilator is in the STANDBY mode of operation until the green battery LED illuminates. Then, the battery will recharge during other modes of ventilator operation.

WARNING

Do not dispose of the internal battery by incineration as it may explode when exposed to flame.

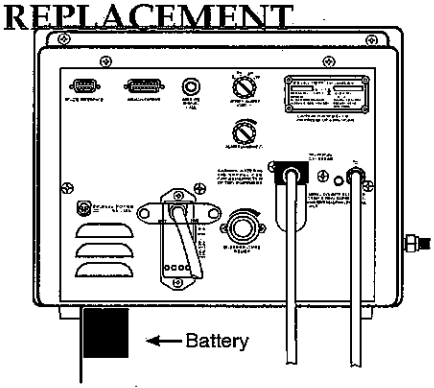
Do not attempt to charge the internal battery with any other charger than the one built into the ventilator as it may explode or damage the battery.

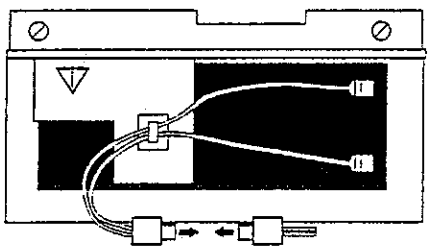
If the ventilator is not likely to be used for an extended period of time, the battery should be removed or disconnected.

CAUTION

A battery that is fully drained (i.e. void of any charge) may cause damage to the ventilator and should be replaced.

INTERNAL BATTERY REPLACEMENT





NOTES

The rechargeable internal battery should only be replaced with the same type as stated on the label inside the battery compartment.

Use only rechargeable battery assembly, (P/N 51000-09530) and fuse type "Slow Blow", 1.6A, 250 VAC (P/N 56000-20078).

1. Disconnect the ventilator AC power cord from the AC power source.
2. Loosen the two screws holding the battery access door and gently allow the door to swing downward.
3. Disconnect the battery assembly connector (see Figure).
4. Slide the battery out of its compartment.
5. Reverse the above sequence to install the battery.
6. Replacement is complete.

8. THEORY OF OPERATION

OVERVIEW

This section describes the operating theory of the BEAR CUB 750PSV Infant Ventilator. The BEAR CUB 750PSV Infant Ventilator can be classified as a micro-processor controlled, time cycled, pressure limited, dual flow, neonatal/pediatric critical care ventilator. Breaths are initiated either by the ventilator (controlled), by patient activity (assisted), or by the operator (manual).

The Top Level Block Diagram (Figure 8-1) graphically illustrates the overall structure of the ventilator.

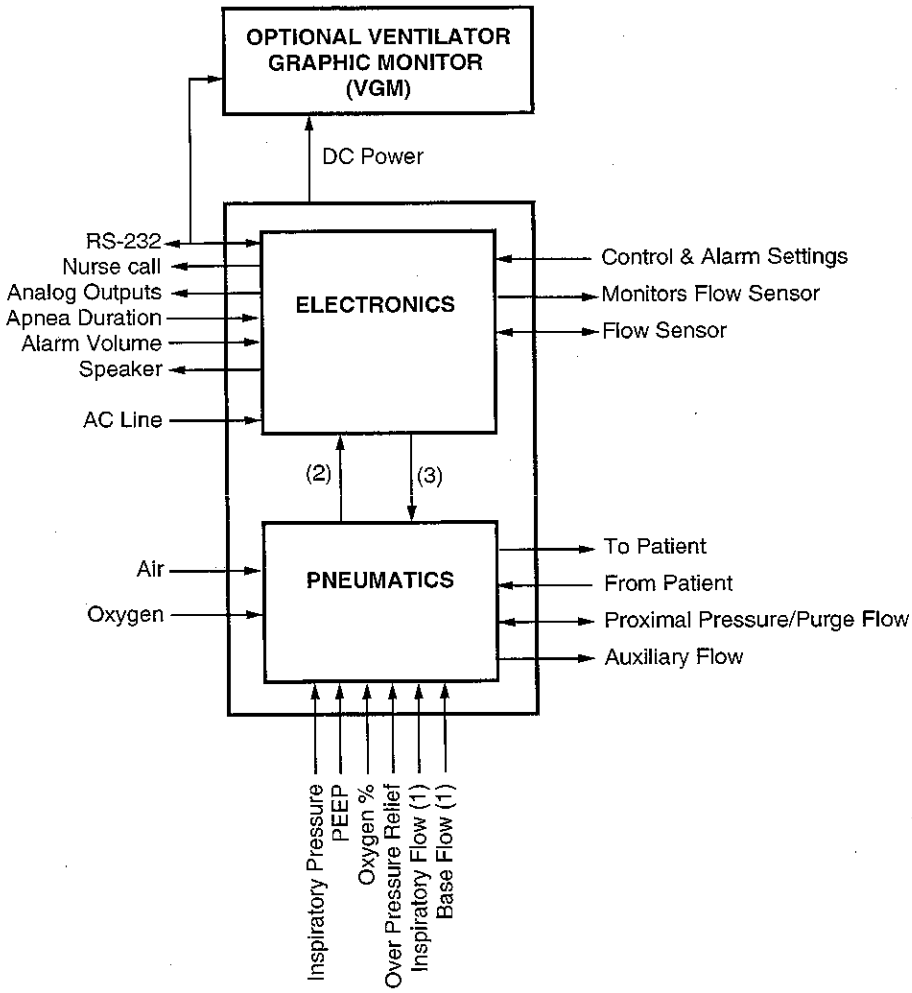


Figure 8-1 • BEAR Cub 750PSV configuration

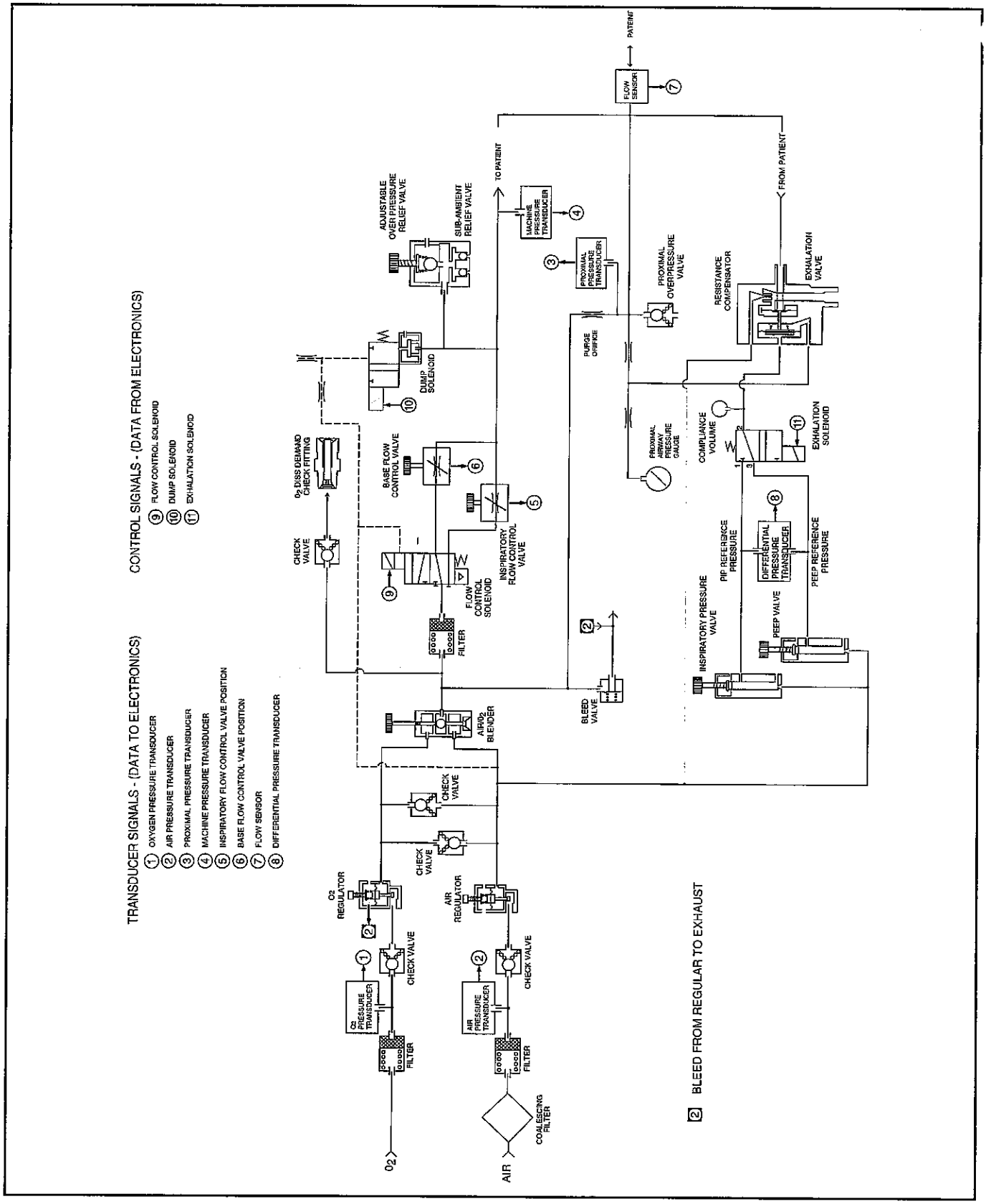


Figure 8-2 • Bear Cub 750PSV Infant Ventilator Pneumatic Schematic

VENTILATOR PNEUMATICS GENERAL DESCRIPTION

Figure 8-2 shows the schematic diagram of the BEAR CUB 750PSV Infant Ventilator Pneumatics System. The pneumatics interface to the electronics is achieved using various actuators (solenoids) and transducers. The Pneumatics System consists of eight (8) main subsystems: Gas Inlet and Conditioning, Oxygen Blender System, Flow Control, Sub-Ambient/Overpressure Relief system, Exhalation Valve/Pressure Control, Pressure Monitoring, the Proximal Airway Purge System, and the Auxiliary Gas Outlet.

GAS INLET AND CONDITIONING

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 back panel of the ventilator.

Incoming air passes through a coalescing filter housed in the Air Inlet Water Trap. Particulate matter down to .3 micron in size, and aerosols down to .75 micron, are trapped. Both gases, air and O_2, pass through sintered metal filters.

Supply pressures are monitored and displayed by the ventilator via pressure transducers and the system electronics. The system will trigger an alarm if either Air or O_2 pressure drops below 24(±2) psig, and the alarm will reset when the pressures are above 30 psig.

From the Air Inlet Water Trap and internal filters, the air and oxygen enter the in-line, one way Check Valves which prevent flow from exiting through an inlet if that source is removed.

BLENDER

Air and O_2 pressure are regulated to 17 psig and are balanced to each other for accurate blending of gases in the O_2 blender.

In the event of a failure of either of the supply gases, one of a pair of crossover check valves will open to permit continued operation. Oxygen blending will not be maintained in this condition, and the patient gas flow and pressure may decrease by less than 10%, depending on settings.

To ensure accurate oxygen blending at low patient flow rates, a bleed valve maintains a minimum flow through the blender of 3.5 -5.5 l/min at a minimum base flow setting of 1 l/min.

FLOW CONTROL VALVE

Two flow control valves are switched by a solenoid valve to create Inspiratory and Base Flow. Each valve controls flow from 1 to 30 LPM. Each flow control valve is geared to a potentiometer. The potentiometer provides an electronic signal to the microprocessor; this flow is then displayed on the front panel corrected to set barometric pressure.

NOTE

The Inspiratory Flow and Base Flow displayed on the front panel are independent of the flow readings taken by the flow sensor.

SOPR VALVE/ SUB-AMBIENT VALVE/ DUMP SOLENOID

Maximum pressure to the patient can be limited using the Sub-Ambient/Over Pressure Relief System (SOPR.) The mechanical, user adjustable, pressure relieving valve can be set from 15 cmH_2O to 75 cmH_2O. A patient effort of -3 cmH_2O allows the patient to breathe air through the Sub-Ambient valve.

A Dump Solenoid is activated upon detection of an obstruction in the expiratory leg of the patient circuit. Activation of the solenoid opens the Dump Valve to the atmosphere. The solenoid is controlled by software which monitors system pressures. Depending upon flow rate, patient circuit pressure will drop to 5 cmH_2O or less.

AUXILIARY GAS OUTLET

The auxiliary gas outlet provides blended gas for use with a nebulizer, or for manual ventilation. The connection of auxiliary gas is achieved via a DISS O_2 fitting. To inhibit overpressure in the system due to a mistaken connection to high pressure oxygen supply, a check valve in line allows only one direction of flow. Auxiliary gas flow levels can range from 0 to 8 LPM. This flow will not be interrupted by a disruption in electrical power (therefore, use of a manual resuscitation bag could be initiated if needed).

PRESSURE CONTROL SYSTEM

The BEAR CUB 750PSV Infant Ventilator ventilates the patient between two pressure levels: Peak Inspiratory Pressure (PIP) and Positive End Expiratory Pressure (PEEP). Inspiratory Pressure must always be above the PEEP pressure for ventilation to occur. The PIP pressure is manually set by the user at a level of 0 to 72 cmH_2O (measured at the patient wye.) The PEEP valve can be set from 0 to 30 cmH_2O. A solenoid valve switches reference pressure to the Exhalation Valve. An exhalation assist jet venturi compensates for flow resistance in the exhalation limb of the patient circuit to allow 0 cmH_2O PEEP setting at up to 10 LPM of Base Flow and to less than 4 cmH_2O at 20 LPM. At low levels of Base Flow, the PEEP control must be set appropriately to prevent negative patient circuit pressures.

The patient circuit has a proximal airway line for monitoring patient pressure. This airway provides a link to the control electronics and software. It also functions as a pneumatic servo control line to the exhalation valve. Only tubing that is 1/8 inch in diameter is to be used in the proximal airway system. Any other diameter tube may cause patient circuit pressure to become less stable.

A purge flow (100ml/min) of blended gas through the proximal airway tube is used to prevent the migration of moisture and patient contamination into the ventilator.

EXHALATION VALVE

The Exhalation Valve regulates 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 out to the atmosphere . The Exhalation Valve is a pneumatic servo controlled regulator. Within the Exhalation Valve, Proximal pressure and Control pressure (which alternates between PIP and PEEP reference pressure depending on the breath phase) are separated by a Control diaphragm. If Control pressure is higher than Proximal pressure, the Control diaphragm will move the control pin to close the Exhalation Valve diaphragm. When proximal pressure equals PIP/PEEP control pressure, the diaphragm will open slightly to maintain the PIP/PEEP level. At exhalation, Control pressure drops to PEEP reference pressure which causes the control diaphragm to retract the control pin opening the Exhalation Valve diaphragm. Proximal pressure then drops to the PEEP level and stabilizes.

FLOW SENSOR

The BEAR CUB 750PSV Infant Ventilator flow sensor reads gas flow while sensing flow direction. The flow is calibrated to 37°C and ambient pressure, inspiratory flow, expiratory flow, exhaled flows, and volumes are monitored with control electronics through the flow sensor. The flow sensor enables the ventilator to trigger a breath based upon inspired flow. The patient effort (in LPM) required to initiate a breath can be adjusted (.2 to 5 LPM) using the assist sensitivity setting. The flow sensor also enables the ventilator to display on the front panel the percentage of endotracheal tube leak based upon inspiratory flow and expiratory flow volume measurements.

EEPROM (Electronic Erasable Programmable Read Only Memory)

.The flow sensor operates on the principle of hot wire anemometry. The hot wire flow sensing system is a constant temperature device. The bidirectional operation is achieved with two platinum wires. The two wires are positioned in the same plane with a pin installed between them. The upstream wire will cool more rapidly than the downstream wire. Therefore more current will be required to maintain a constant preset temperature. The electronics interprets this higher current in the upstream wire to determine both flow and flow direction. This measured flow rate is then integrated over time by the ventilator's microprocessor to yield inspired and expired volumes.

The flow sensor measures flow from 0.2 to 40 LPM, is calibrated from 0.2 to 25 LPM, and measures to 40 LPM. Each Flow Sensor Cable Assembly contains an electronic memory circuit or EEPROM which stores calibration data for the unit. Therefore, the sensor will function with the electronic circuit of any BEAR CUB 750PSV Infant Ventilator without the need for a system calibration.

VENTILATOR ELECTRONICS

The major components of the electronics system include the Display PCB, the Control PCB, and the Power Supply.

The Display circuit board is the user interface for the ventilator electronics. Ventilator controls and alarms are set by the clinician, and monitors feed current ventilator status back to the display.

The Control circuit board includes the Monitor MCU and Control MCU. The Control board drives the system solenoids which control breath phase, flow, and pressure. This is achieved using front-panel settings from the display board, as well as incorporating its own real-time pressure and flow readings. The Control board also enables bidirectional (digital) communication to the optional Ventilator Graphics Monitor (VGM). Also, analog outputs proportional to pressure and flow, plus a breath phase signal are provided to the back panel. The electronics to drive and read the flow sensor are also contained on the Control PCB.

POWER SUPPLY

The Power Supply converts AC line voltage to DC voltages for the electrical system. AC line voltages of 100, 120, 230, and 240 volts (at frequencies from 50 to 60 Hertz) can be used as input power. Five DC voltages are used in the ventilator electronics: 5, 7, 10, -10 and 22 VDC. All power levels that are high enough to pose an ignition hazard in the presence of oxygen concentrations greater than 21% are housed in a separate enclosure from the rest of the system. If input power fails, a 12 volt rechargeable, sealed, lead-acid battery is included to provide a minimum of 30 minutes of ventilator operation. A two-level battery charger circuit is contained on the Power Supply PCB in order to keep the battery on continuous charge whenever the ventilator is plugged into an AC outlet.

VENTILATOR SOFTWARE

The BEAR CUB 750PSV Infant Ventilator is a shared processor system, incorporating two Motorola 68HC11 microcontroller units (MCU), the Monitor and the Controller. Each processor, and thereby its software, have specific and duplicated tasks. Each processor is based on a 2.5 msec timer interrupt, referred to as a 'tick.' The Controller directs basic control of the ventilator based on operational settings communicated from the Monitor MCU, as well as pressure transducer, and flow sensor data read on its own 8 bit Analog to Digital (AD) converter. The monitor has the following functions: (1) reads the front panel switches, back panel switches and potentiometers, (2) monitors ventilator performance as well as the performance of the Controller MCU, (3) transmits front panel status to the Controller, and (4) receives performance data back from the Controller.

During power-up, both processors perform RAM (Random Access Memory), and ROM (Read Only Memory) tests to verify integrity of these two memory systems. Solenoid and Control Potentiometer continuity are also tested during power-up by the Control and Monitor processors respectively. Continuous communication checks between the two processors are used to verify functionality of each sub-system. If an error is detected, either processor has the ability to shutdown the ventilator while enabling the audible and visual Failed to Cycle alarm. These systems, among others, are provided to reduce the possibility of a software/hardware error leading to an undetected hazardous condition.

RS-232 PROTOCOL

INTRODUCTION

This document defines the hardware and software protocols for the RS-232-C communication port for devices produced by Bear Medical Systems, Inc., including the BEAR CUB 750PSV Infant Ventilator, and the Ventilator Graphics Monitor (VGM). Throughout this document the ventilator is defined as the sending device, which transmits real-time data and responds to requests for non-real-time data. Optionally, the VGM may be acting as a repeater and providing data to a third device.

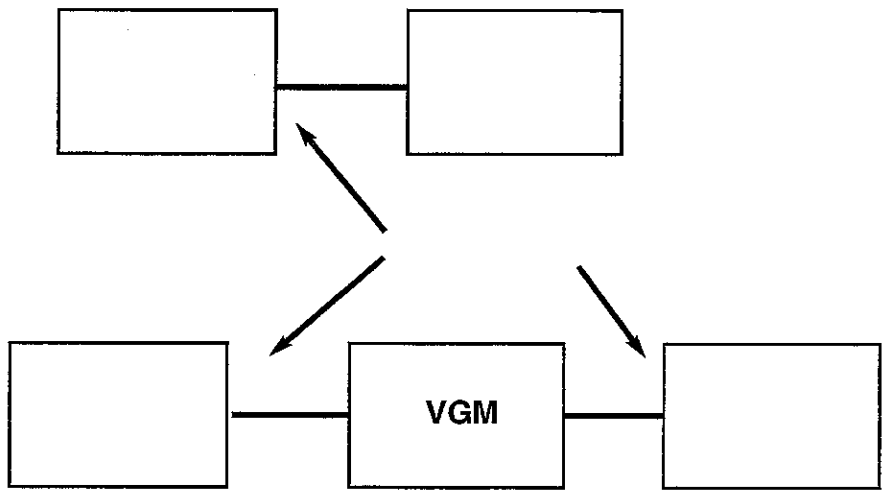


FIGURE 1. RS-232-C VENTILATOR CONNECTION DIAGRAM

HARDWARE DEFINITION

Connector: Male 9-pin DSub connector, Ventilator

Female 9-pin DSub connector, PC-AT serial port

Duplex: Full

Bit Rate: 9600, 19200

Data : 8-bit character

1 Start bit

1 Stop bit

No Parity bit

Pin Assignment: EIA RS-232-C, Ventilator is DTE

The ventilator is DTE and interfaces to any DCE device through a cable wired 1 to 1.

DTE Name	DTE Pin	Direction	DCE Pin	Comment
DCD	1	←	1	Not used by vent
RxD	2	←	2	
TxD	3	→	3	
DTR	4	→	4	
GND	5	←→	5	
DSR	6	←	6	Not used by vent
RTS	7	→	7	Tied high @ v ent
CTS	8	←	8	
RI	9	←	9	Not used by vent

Where: DCD - Data Carrier Detect
RxD - Receive Data
TxD - Transmit Data
DTR - Data Terminal Ready
GND - Ground
DSR - Data Set Ready
RTS - Request To Send
CTS - Clear To Send
RI - Ring Indicator

The ventilator can be interfaced to another DTE device with the following "null-modem" interface:

DTE Name	DTE Pin	Direction	DTE Pin	DTE NAME
GND	5	←→	5	GND
RxD	2	←	3	TxD
TxD	3	→	2	RxD
DCD	1	←	7	RTS
RTS	7	→	1	DCD
DTR	4	→	6 & 8	DSR & CTS
DSR & CTS	6 & 8	←	4	DTR
RI	9	Not Used	9	RI

SOFTWARE PROTOCOL

The ventilator has two modes of communication. The first mode continuously outputs real-time data every 10 msec and provides non-real-time data upon request from an external computer. This mode is activated when a data rate of 19200 bits per second (BPS) is selected.

The second communication mode only provides non-real time data upon request: no real time data is provided. This second mode is activated when a data rate of 9600 BPS is selected.

The communication data rate is selected on the Bear Cub 750PSV Infant Ventilator via the Operator Diagnostic menu.

REAL TIME CONTINUOUS OUTPUT

The continuous output mode communicates at a data rate of 19200 BPS and transmits a real time data message every 10 msec.

DATA UPON REQUEST

Non-real time data is provided in response to requests from an external computer. Non-real-time data can be requested at any communication data rate. The ventilator has the capability to queue at least three requests at a time. Any additional data requests may be ignored by the ventilator.

Requests for non-real-time data during continuous output should be sent to the ventilator at a maximum rate of one request every 150 msec. Real-time data transmission may be delayed by up to 25 msec. while non-real-time requests are being processed. The real-time data is queued by the ventilator so that it is only delayed and not lost.

COMMUNICATION PROTOCOL

COMMAND AND MESSAGE PACKET ORGANIZATION

The ventilator commands and messages are of variable length. All data packets begin with a SYN character, and are terminated with a checksum.

The SYN character (16h) and the DLE character (10h) are control characters within a transmitted data packet. The SYN indicates the start of a data packet and the DLE character indicates that the next character requires special processing. If a SYN or DLE character occurs in the original data packet, excluding the start character and including the checksum, an additional DLE character will be added to the transmitted data packet at the location of the original SYN or DLE character. The original DLE or SYN character will be modified by subtracting 10h from it and will follow the added DLE character. (See Example 1 below.)

The second character in each packet is the ID character. Any request for data using an undefined ID will be ignored by the ventilator.

The checksum [CHECK] is the one's complement of the 8-bit sum of the data bytes in the data packet excluding the SYN and CHECK characters.

EXAMPLE 1.
MESSAGE WITH EMBEDDED "SYN" OR "DLE" CHARACTERS.

ORIGINAL PACKET		TRANSMITTED PACKET	
[SYN]	= 016h	[SYN]	= 016h
[ID]	= 000h	[ID]	= 000h
[Data 1]	= 02Fh	[Data 1]	= 02Fh
[Data 2]	= 016h (embedded SYN char)	[Data 2]	= 010h
[Data 3]	= 0AAh	[Data 3]	= 006h
[CHECK]	= 010h (embedded DLE char)	[Data 4]	= 0AAh
		[Data 5]	= 010h
		[CHECK]	= 00h

16-BIT DATA FORMAT

16-bit data contained within the packet is transmitted as most significant byte (MSB) first followed by the least significant byte (LSB) second. Storing received bytes sequentially in memory results in the MSB being stored in the lower addressed byte and the LSB being stored in the higher addressed byte.

VALID REQUESTS RECEIVED BY THE VENTILATOR

Mode: Upon Request

Length: 3 Bytes

Format: [SYN] [ID] [CHECK]

[ID]:	22h .. 3Fh	(Reserved/Unused)
	41h .. 5Fh	(Reserved/Unused)
	62h .. 9Fh	(Reserved/Unused)
	A0h	Request Infant Control Settings
	A1h .. BFh	(Reserved/Unused)
	C0h	Request Infant Alarm Settings/Status
	C1h	Request Infant Alarm Settings/ Status - Expanded
	C2h .. DFh	(Reserved/Unused)
	E0h	Request Infant Monitor Status
	E1h	Request Infant Monitor Status - Expanded
	E2h .. FFh	(Reserved/Unused)

VALID MESSAGES TRANSMITTED BY THE VENTILATOR

Mode: Continuously every 10 msec or upon request, depending on message type

Length: Variable

Format: [SYN] [ID] [Data 1] ... [Data n] [CHECK]

[ID]:		
	00h..0Fh	Real Time Data, No Alarms
	10h..1Fh	Real Time Data, Alarm Condition
	22h .. 3Fh	(Reserved/Unused)
	41h .. 5Fh	(Reserved/Unused)
	62h .. 9Fh	(Reserved/Unused)
	A0h	Infant Control Settings
	A1h .. BFh	(Reserved/Unused)
	C0h	Infant Alarm Settings/Status
	C1h	Infant Alarm Settings/Status - Expanded
	C2h .. DFh	(Reserved/Unused)
	E0h	Infant Monitor Status
	E1h	Infant Monitor Status - Expanded
	E2h .. FFh	(Reserved/Unused)

REAL TIME DATA AT 19200 BAUD

Mode: Continuously, every 10-msec

Length: Variable, minimum 6 bytes

Format: [SYN] [ID] [Data 1] ... [Data 3] [CHECK]

[ID]: 00h .. 1Fh

Bit 7 - 0

Bit 6 - 0

Bit 5 - 0

Bit 4 - Alarm Condition 0 = No Alarm, 1 = Alarm

Bits 3..1 - Breath Type 000 = Volume

001 = Spontaneous/Demand

010 = Pressure Control

011 = Pressure Support

100 = Time Cycled/ Pressure Relief (Cub 750)

101 = Flow Cycled

110 ..111 = Reserved

Bit 0 - Breath Phase 0 = Inspiration, 1 = Exhalation

[Data 1]	[Data 2]	[Data 3]:
xxxxxxxx	xxxxxyyy	yyyyyyyy
|	| |	|
MSB	LSB\MSB	LSB

x : Net Flow (Insp.-Exhale) - 13 bits

Range: -300 to +300 LPM

Binary Scale: 1 bit = 0.1 LPM

Binary Range: 0 to 6000

Zero Off Set: 3000

y : Proximal Pressure - 11 bits

Range: -60 to +140 cmH_2O

Binary Scale: 1 bit = 0.1 cmH_2O

Binary Range: 0 to 2000

Zero Off Set: 600

INFANT VENTILATOR CONTROL SETTINGS

Mode: Upon Request

Length: Minimum 14 bytes

Format: [SYN] [ID] [Data 1] ... [Data 11] [CHECK]

[ID]: A0h

[Data 1]: Mode & Switches

Bits 7..5 - Mode
- 000 = Assist Control
- 001 = SIMV/IMV
- 010 = CPAP
- 011 = PSV
- 100 = Flow Cycled SIMV
- 101 = SIMV/PSV
- 110 = Flow Cycled A/C
- 111 = Reserved

Bit 4 - Pressure Settings Incompatible 0 = Off, 1 = On

Bit 3 - Flow Settings Incompatible 0 = Off, 1 = On

Bit 2 - Rate/Time Settings Incompatible 0 = Off, 1 = On

Bit 1 - Manual Breath 0 = Off, 1 = On

Bit 0 - Reserved 0

[Data #]	Parameter	Range	Binary Scale	Binary Range
[Data 2]	Breath Rate	0 - 150 bpm	1 bpm	0 - 150
[Data 3,4]	Inspiratory Time	0.10 - 3.00 sec	0.01 sec	10 - 300
[Data 5,6]	Volume Limit	5 - 300 ml	1 ml	5 - 300
[Data 7]	Inspiratory Flow	1 - 30 LPM	0.5 LPM	2 - 60
[Data 8]	Base Flow	1 - 30 LPM	0.5 LPM	2 - 60
[Data 9]	Assist Sensitivity	0.2 - 25.5 LPM	0.1 LPM	2 - 255
[Data 10]	Inspiratory Pressure	Reserved		0
[Data 11]	PEEP/CPAP	Reserved		0

INFANT VENTILATOR ALARM SETTINGS/STATUS - EXPANDED

Mode: Upon Request
Length: Minimum 12 bytes
Format: [SYN] [ID] [Data 1] ... [Data 9] [CHECK]
[ID]: C1h
[Data 1]: Alarm Status Byte 1

Bit 7 - High Breath Rate	0 = Off, 1 = On
Bit 6 - Low PEEP/CPAP	0 = Off, 1 = On
Bit 5 - Low Inspiratory Pressure	0 = Off, 1 = On
Bit 4 - Apnea	0 = Off, 1 = On
Bit 3 - Patient Circuit Fault	0 = Off, 1 = On
Bit 2 - Prolonged Inspiratory Pressure	0 = Off, 1 = On
Bit 1 - High Pressure Limit	0 = Off, 1 = On
Bit 0 - Low Minute Volume	0 = Off, 1 = On

[Data 2]: Alarm Status Byte 2

Bit 7 - Flow Sensor Fault	0 = Off, 1 = On
Bit 6 - Run Diagnostics	0, Not Used
Bit 5 - Low Gas Supply	0 = Off, 1 = On
Bit 4 - Low Battery Supply	0 = Off, 1 = On
Bit 3 - Failed To Cycle	0 = Off, 1 = On
Bits 2..1 - Reserved	00
Bit 0 - Alarm Silence	0 = Off, 1 = On

[Data #]	Parameter	Range	Binary Scale	Binary Range
[Data 3]	High Breath Rate	0 - 255 bpm	1 bpm	0 - 255
[Data 4]	Low PEEP/CPAP	-10 - 50 cmH_2O	1 cmH_2O	0 - 60
[Data 5]	Low Inspiratory Press.	5 - 99 cmH_2O	1 cmH_2O	5 - 99
[Data 6]	High Pressure Limit	10 - 75 cmH_2O	1 cmH_2O	10 - 75
[Data 7]	Apnea Interval	5 - 30 sec	1 sec	5 - 30
[Data 8, 9]	Low Minute Volume	0 - 9.9 L	1 mL	0 - 9900

INFANT VENTILATOR MONITOR STATUS - EXPANDED

Mode: Upon Request

Length: Minimum 23 bytes

Format: [SYN] [ID] [Data 1] ... [Data 20] [CHECK]

[ID]: E1h

[Data 1]: Breath Data

Bit 7 - Control Breath 0 = Off, 1 = On

Bit 6 - Patient Effort 0 = Off, 1 = On

Bits 5..0 - Reserved 000000

[Data #]	Parameter	Range	Binary Scale	Binary Range
[Data 2,3]	Expiratory Tidal Volume	0 - 500 ml	0.1 ml	0 - 5000
[Data 4,5]	Minute Volume	0 - 300.0 L	0.01 L	0 - 3000
[Data 6]	% Leak	0 - 100 %	1 %	0 - 100
[Data 7,8]	Inspiratory Time	0 - 3.10 sec	0.01 sec	0 - 310
[Data 9,10]	Expiratory Time	0 - 99.99 sec	0.01 sec	0 - 9999
[Data 11]	(Bit 7) See Footnote[2]			
	(Bits 6-0) I:E Ratio or E:I Ratio	1.0 - 9.9	0.1	10 - 99
[Data 12]	Breath Rate	0 - 255 bpm	1 bpm	0 - 255
[Data 13]	Peak Inspiratory Press.	0 - 99 cmH_2O	1 cmH_2O	0 - 99
[Data 14,15]	Mean Airway Press.	0 - 99.9 cmH_2O	0.1 cmH_2O	0 - 999
[Data 16]	Air Supply Pressure	0 - 99 psig	1 psig	0 - 99
[Data 17]	O_2 Supply Pressure	0 - 99 psig	1 psig	0 - 99
[Data 18]	PEEP	0 - 50 cmH_2O	1 cmH_2O	0 - 50
[Data 19,20]	Insp. Tidal Vol.	0 - 500 mL	0.1 mL	0 - 5000

2 Bit 7: 1 if Inspiratory Time <= Expiratory Time
0 if Inspiratory Time > Expiratory Time

Bits 6-0: E/I if Bit 7 = 1
I/E if Bit = 0

9. PARTS & ACCESSORIES

PARTS ORDERING

To obtain BEAR CUB 750PSV Infant Ventilator parts contact Thermo Respiratory Group customer service.

VENTILATOR ACCESSORY KIT/STARTER KIT

The domestic BEAR CUB 750PSV Infant Ventilator comes with a Basic Accessory Kit (P/N 50-01187-00) and Starter Kit (P/N 50000-01165).

Accessory Kit (P/N 50-01187-00) ..... Parts

1. DISS Air Hose ..... P/N 50000-01000
2. DISS O2 Hose ..... P/N 50000-01001
3. Air Inlet Water Trap ..... P/N 50000-01071
4. Control Pin Tool, Assembly ..... P/N 51000-05137
5. Fuse .25amp, 5x20mm, slow blow ..... P/N 56000-20080
6. Voltage Conversion Instructions ..... P/N 50000-10656
7. Instruction Manual Kit ..... P/N 50-10697-00
   Instruction Manual Kit includes:
   BEAR CUB 750PSV Instruction Manual .... P/N 51-10697-00
   BEAR CUB 750PSV OVP Manual ..... P/N 50000-12196

NOTE: One Flow Sensor (P/N 51000-08831) is shipped with the BEAR CUB 750PSV Infant Ventilator.

Starter Kit (P/N 50000-01165) ..... Parts

1. Flow Sensor ..... P/N 51000-10027
2. Exhalation Manifold (Block) ..... P/N 51000-09377
3. Muffler Assembly ..... P/N 51000-09712
4. Exhalation Diaphragms (3 each) ..... P/N 51000-04601

AVAILABLE ACCESSORIES

POLE MOUNT

The following upgrade accessories are available for the BEAR CUB 750PSV Infant Ventilator:

The BEAR CUB 750PSV Infant Ventilator can be mounted as follows:

1. BEAR CUB 750PSV Pole Mount Kit ..... P/N 50000-01160

REUSABLE PATIENT CIRCUIT

The BEAR CUB 750PSV Infant Circuit Kit ..... P/N 50000-01147
(provides materials for 3 circuits and includes the following:)

1. Endotracheal Connector,
   11mm O.D./15mm I.D. (3 each) ..... P/N 53012-00109
2. Endotracheal Adapter,
   11mm I.D./4mm O.D. (3 each) ..... P/N 54968-00140
3. Hose Adapter,
   3/8" O.D. both ends (6 each) ..... P/N 53532-01101
4. Tubing 1/8" I.D., 25 feet ..... P/N 54980-01805
5. Tubing 3/8" I.D., 25 feet ..... P/N 54980-01808
6. Hose, Flexible, Corrugated (6 each) ..... P/N 16566-00001

GRAPHICS MONITOR

The following Graphics Ventilator Monitor (VGM) upgrade option is available for the BEAR CUB 750PSV Infant Ventilator:

1. Ventilator Graphics Monitor
   with 750 Mount ..... P/N 50000-20101

COMPRESSOR

The BEAR CUB 750PSV Infant Ventilator can be used in conjunction with, and mounted to, a compressor as follows:

1. SolidAir Compressor (120V 60Hz) ..... P/N 50-01161-01
2. SolidAir Compressor (230V 50Hz) ..... P/N 50-01161-02

HUMIDIFIER

The following humidifiers are available for the BEAR CUB 750PSV Infant Ventilator:

1. LS-460 Humidifier, Infant
   117V, 60 Hz ..... P/N 50000-00460
2. LS-460 Humidifier, Infant
   100V, 50/60 Hz ..... P/N 50000-00461
3. LS-460 Humidifier, Infant
   230V, 50/60Hz ..... P/N 50000-00480
4. VH 820 Humidifier Adult/Infant
   (English) 120V, 60 Hz ..... P/N 50000-00820
5. VH 820 Humidifier, Adult/Infant
   (English) 220V, 50/60 Hz ..... P/N 50000-00826

RAIL MOUNT

The BEAR CUB 750PSV Rail Mount Kit ..... P/N 50000-01148
The Rail Mount Kit includes: Accessory Rail, Strip Reinforcement, Accessory Rail Spacers (2 each), Decorative Insert, Screw 1/4" x 3/4" (2 each), 2-sided Tape.

REPLACEMENT ITEMS

FLOW SENSOR

Flow Sensor . . . . . P/N 51000-10027

EXHALATION VALVE ASSEMBLY and MUFFLER ASSEMBLY

(see Figure 7-1)

1. Exhalation Manifold (Block) . . . . . P/N 51000-09377
2. Exhalation Valve Diaphragm
   (available in multipack of 3 each) . . . . . P/N 50000-03059
3. Nut, Knurled . . . . . P/N 54333-00101
4. Control Pin Assembly . . . . . P/N 51000-04889
5. Muffler Assembly . . . . . P/N 51000-09712
   (includes the following:)
   Adapter, Tube . . . . . P/N 51000-09703
   Tube, Muffler . . . . . P/N 51000-09706
   Foam Assembly, Muffler . . . . . P/N 51000-09715
   Diffuser, Muffler . . . . . P/N 51000-09705
   Screw, Thumb 6-32 X .25 LG SST . . . . . P/N 52000-60073
   O-Ring 1/2 ID x 1/16 THK ETH-P . . . . . P/N 53021-02014

CIRCUIT ACCESSORIES

1. Proximal Line Bacteria Filter . . . . . P/N 51000-01122
2. Infant Bacteria Filter, 3/8" O.D. . . . . P/N 50000-01056

MISCELLANEOUS

1. Air Inlet Water Trap . . . . . P/N 50000-01071
2. Battery Assembly, 12 volts, 1.2 AH . . . . . P/N 51000-09530
3. BEAR CUB 750PSV OVP Instructions . . . . . P/N 50000-12196
4. BEAR CUB 750PSV Instruction Manual . . . . P/N 50-10697-00
5. Bowl, Plastic, with Gasket,
   for Air Water Trap . . . . . P/N 50000-01045
6. Fuse .25amp, 5x20mm,
   slow blow (220/240 volts) . . . . . P/N 56000-20080
7. Fuse .5amp, 5x20mm,
   slow blow (100/120 volts) . . . . . P/N 56000-20079
8. Fuse 1.6amps, 5x20mm, slow blow
   (internal circuit protective fuse) . . . . . P/N 56000-20078
9. Gasket (pkg of 5) . . . . . P/N 50000-01046
10. Infant Test Lung . . . . . P/N 52000-40027
11 O-Ring, Jet Venturi Mount . . . . . P/N 53021-01006
   (1/8" I.D. x 1/16")

10. UPDATES

This section of the BEAR CUB 750PVS Infant Ventilator manual is provided for your convenience to insert instruction sheets for ventilator updates/enhancements and for clinical application bulletins pertaining to this ventilator.

GLOSSARY

GLOSSARY OF ABBREVIATIONS

amp	Ampere
AC	Assist Control or alternating current
BATT	Battery
BPM	Breaths Per Minute
cm	Centimeter
cmH2O	Centimeter of Water Pressure
CPAP	Continuous Positive Airway Pressure
°C	Degrees Centigrade
DISS	Diameter Index Safety System
ETO	Ethylene Oxide
°F	Degrees Fahrenheit
FIO2	Fractional Concentration of Inspired Oxygen
Hz	Hertz
ID	Internal Diameter
I:E	Inspiratory Expiratory Ratio
IMV	Intermittent Mandatory Ventilation
kg	Kilogram
l	Liters. A unit of volume.
lb	Pound
LED	Light Emitting Diode.
LPM	Liters Per Minute
ml	Milliliter
OD	Outer Diameter
O2	Oxygen
% O2	Percent Oxygen
PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure
psi	Pounds per Square Inch
psig	Pounds per Square Inch Gauge
PSV	Pressure Support Ventilation
SIMV	Synchronized Intermittent Mandatory Ventilation
TCPL	See Time Cycled Pressure Limited ventilation.
VAC	Volts Alternating Current
VDC	Volts Direct Current
Vt	Tidal Volume

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