Revision History

Date	Revision	Pages	Changes
June 2003	Α	All	Release
May 2004	В	All	Release manual in VIASYS Healthcare template using VIASYS Healthcare Critical Care nomenclature.

Contact and Ordering Information

United States, Latin America, Asia Pacific:

Sales, Service and Clinical Support: VIASYS Healthcare Critical Care Division 22705 Savi Ranch Parkway Yorba Linda, CA 92887 Phone: (714) 283-8444

none: (714) 283-8444 (800) 381-3552

Fax: (714) 283-8493 **www.VIASYShc.com**

United Kingdom:

Sales, Service and Clinical Support: VIASYS Healthcare 3 Welton Rd. Warwick, CV34 5PZ

Phone: 01926 490888 Fax: 01926 402262

Europe

Sales and Customer Service Technical Service

VIASYS Healthcare Critical Care Division 22705 Savi Ranch Parkway Yorba Linda, CA 92887

Phone: (714) 283-8444

(800) 381-3552

VIASYS Healthcare Leibnizstrasse 7 D-97204 Hoechburg Germany

Phone +49 (0) 931 4972 – 0 Fax:+49 (0) 931 4972 –423

e-mail: Support.CC.EU@VIASYShc.com

website: www.VIASYShc.com

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

CAUTION

Not suitable for use in the presence of flammable anesthetics.

CAUTION

Service and/or repair of this instrument is restricted to VIASYS Healthcare authorized or VIASYS Healthcare Trained Personnel only.

Warranty

The Bear Cub 750PSV is warranted to be free from defects in material and workmanship and to meet the published specifications for One (1) year from date of shipminent.

The liability of VIASYS Healthcare, Critical Care Division, (referred to as the Company) under this warranty is limited to replacing, repairing or issuing credit, at the discretion of the Company, for parts that become defective or fail to meet published specifications during the warranty period; the Company will not be liable under this warranty unless (A) the Company 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 the Company, transportation charges prepaid by Buyer; (C) the defective unit or part is received by the Company for adjustment no later than four weeks following the last day of the warranty period; and (D) the Company'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 the Company for repair or alteration by the Buyer must be in writing to prevent voiding the warranty. In no event shall the Company 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.

The Company 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 the Company or its agents in connection with the Buyer's order of the products furnished hereunder.

Limitation 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 the Company or authorized for use in writing by the Company or if the equipment is not maintained in accordance with the prescribed schedule of maintenance.

The warranty stated above shall extend for a period of One (1) year from date of shipment, 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 the Company has no control, are warranted for sixty (60) days from date of receipt.
- 3. Internal batteries are warranted for ninety (90) days from the 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 the Company.

Contents

Revision History	2
Contact and Ordering Information	3
Warranty	5
Limitation of Liabilities	5
Contents	7
List of Figures	9
List of Tables	11
Chapter 1: Specifications	13
Modes	13
Controls	13
Alarms	15
Monitors	17
Preset Values	19
Emissions/Susceptibility	19
Outputs	19
Inputs	20
Physical Dimension and Shipping Information	20
Environmental Specifications	21
Method of Sterilization/Disinfection	
Cleaning	22
Sterilization	22
Chapter 2: Theory of Operation	23
Overview	
Ventilator pneumatics - General description	
Gas Inlet Conditioning	
Blender	
Flow Control Valve	
AOPR Valve/Sub-Ambient Valve/ Dump Solenoid	
Auxiliary Gas Outlet	
Pressure Control System	
Exhalation Valve	
Flow Sensor	
Ventilator Electronics	
Power Supply	
Ventilator Software	

Chapter 3 OVP Recommended Service	29
Operational Verification	29
Equipment Required	29
Test Procedures	32
Exterior Inspection and Cleaning	34
Exterior Cleaning	
Plugs and Cables	
OVP Checklist	
Verification Steps	
Chapter 4 Calibration (for software releases 2 and 3 only)	
Introduction	
Pressure Transducers and Flow Control Valve Calibration	
Air and O ₂ Regulator Balance	
Objective Equipment	
Requirements	
Chapter 5 Schematics and Assemblies	
Chapter 6 Troubleshooting	81
Chapter 7 Removal & Replacement	85
Interior Access	85
Flow Valve Assembly Removal	85
Control PCB Removal	85
Display PCB Removal	86
Air/O ₂ Regulator Removal	86
Blender Removal	86
Exhalation Valve Removal	86
Chapter 8 Preventive Maintenance	87
Replacement Parts	
Recommended Service Procedure	
Exterior Inspection	
Interior Inspection	
Specifications	
Calibration and Verification Procedure	
Ground Resistance Test	
Current Leakage Test	
Operational Verification Procedure	
Chapter 9 RS-232 Protocol	
•	93 93
ULUUT	

Hardware Definition	93
Pin Assignment	
Software Protocol	95
Continuous Output (Default Mode)	
Data Upon Request Data Format	
Chapter 10 Parts List	105
Chapter 11 Repackaging Instructions	107
General	
Packaging Instructions	107
Procedure	107
Addendum A: Release 4 Software	109
Addendum B: Bear Cub 750 PSV Infant Pediatric	Ventilator System111
Index	113
List of Figures	
Figure 2-1: Top Level Block Diagram	23
Figure 2-2: Pneumatics System Schematic	24
Figure 3-1: Bear Cub 750 US with Patient Circuit	33
Figure 5-2:	46
Figure 5-3:	47
Figure 5-4:	48
Figure 5-5:	49
Figure 5-6:	50
Figure 5-7:	51
Figure 5-8:	52
Figure 5-9:	53
Figure 5-10:	54
Figure 5-11:	55
Figure 5-12:	56
Figure 5-13:	57
Figure 5-14:	58

Figure 5-15:	59
Figure 5-16:	60
Figure 5-17:	61
Figure 5-18:	62
Figure 5-19:	63
Figure 5-20:	64
Figure 5-21:	65
Figure 5-22:	66
Figure 5-23:	67
Figure 5-24:	68
Figure 5-25:	69
Figure 5-26:	70
Figure 5-27:	71
Figure 5-28:	72
Figure 5-29:	73
Figure 5-30:	74
Figure 5-31:	75
Figure 5-32:	76
Figure 5-33:	77
Figure 5-34:	78
Figure 5-35	79
Figure 6-1: Troubleshotting Decision Tree	81
Figure 8-1: Ventilator Back Panel	90
Figure 11-1: Packaging System Diagram	108

List of Tables

Table 3-1: Standard Settings	30
Table 3-2: Rate	30
Table 3-3: Exhalation Time and I/E Ratio Table	30
Table 4-1: Control PCB Transducer Calibration	38
Table 4-2: Calibration	39
Table 4-3: Diagnostic Function	40
Table 4-4: Inspiratory Flow Calibration	41
Table 4-5: Regulator Balance	42
Table 4-6: Standard Test Settings	43
Table 6-2: Troubleshooting	82
Table 9-1: Pin Assignment	94
Table 9-2: Alternate Pin Assignment	94
Table 9-3: Valid Requests Received by the Ventilator	96
Table 9-4: Valid Message Transmitted by the Ventilator	96
Table 9-5: Real Time Data	97
Table 9-6: Adult Ventilator Control Settings	98
Table 9-7: Adult Ventilator Alarm Settings / Status	99
Table 9-8: Adult Ventilator Monitor Status	100
Table 9-9: Infant Ventilator Control Settings	101
Table 9-10: Infant Ventilator Alarm Settings/Status	102
Table 9-11: Infant Ventilator Monitor Status	

Chapter 1: Specifications

Modes

A/C

In the Assist/Control 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. 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 is available. Mechanical breaths, either assisted or controlled, are delivered at the set ventilator rate while all other breaths are spontaneous. Disabling the assist sensitivity mechanism. or removing the flow sensor from the ventilator, will cause the equivalent of IMV mode of ventilation to exist.

CPAP

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

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.

Controls

Rate

Range: 1 to 150 BPM

Resolution: 1 from 1 to 100BPM

2 from 100 to 150 BPM

Tolerance: Greater of \pm 1 BPM or 0.02 seconds applied to the Breath

Interval

Inspiratory Time

Range: 0.10 to 3.0 seconds

Resolution: 0.01 from 0.10 to 0.50 seconds

0.02 from 0.50 to 1.70 seconds 0.05 from 1.70 to 3.00 seconds

Accuracy: \pm 0.02 seconds from 0.10 to 0.50 seconds

± 0.025 seconds from 0.50 to 3.00 seconds

Inspiratory Flow

Range: 1 to 30 L/min

Resolution: 0.5 L/min from 1 to 10 L/min

1.0 L/min from 10 to 30 L/min

Accuracy: Pressures 0 to 60 cmH2O: ± 0.5 L/min or ± 10% of setting,

whichever is greater.

Pressure 60 to 72 cmH2O: ± 0.5 L/min or + 10%/- 15% of

setting, whichever is greater.

Baseline Flow

Range: 1 to 30 L/min

Resolution: 0.5 L/min from 1 to 10 L/min

1.0 L/min from 10 to 30 L/min

Accuracy:Pressures 0 to 60 cmH2O: ± 0.5 L/min or ± 10% of setting, whichever is

greater.

Pressure 60 to 72 cmH2O: ± 0.5 L/min or + 10%/- 15% of

setting. Whichever is greater

Volume Limit™

Range: 5 to 300 ML

Resolution: 1 ML from 5 to 50 ML

2 ML from 50 to 150 ML 5 ML from 150 to 300 ML

Accuracy: ± 2 ML or $\pm 10\%$ of setting, whichever is greater

PEEP

Range: 0 to 30 cmH2O

Resolution: 1 cmH2O

Repeatability: $\pm 1 \text{ cmH2O or } \pm 5\%$, whichever is greater

Inspiratory Pressure

Range: 0 to 72 cmH2O

Resolution: 1 cmH2O from 0 to 30 cmH2O

2 cmH2O from 30 to 72 cmH2O

Repeatability: $\pm 1 \text{ cmH2O or } \pm 5\% \text{ whichever is greater. Breath to breath}$

Manual Breath

Range: X1

Assist Sensitivity

Range: 0.2 to 5.0 L/min

Resolution: 0.2 at 0.2 L/min increasing to 0.5 at 5.0 L/min

Accuracy: Not a calibrated scale, minimum setting accuracy is ± 0.1 L/min

Over Pressure Relief

Range: (Pressure at the patient wye): 15

to 75 cmH2O

Resolution: 2 cmH2O stability (repeatability) ±4 cmH2O

%0₂ Blending

Range: 21 to 100% Oxygen concentration

Resolution: 1%

Accuracy: ± 3% oxygen

APNEA Interval

Range: 5, 10, 20, or 30 seconds

Accuracy: ± 1 second

Alarms

Alarm Loudness

Range: Min. to Max. 60 to 75 db(A)

High Breath Rate

Range: 3 to 255 BPM

Low PEEP/CPAP

Range: -5 to 30 cmH2O

Low Inspiratory Pressure

Range: 1 to 65 cmH2O

Patient Circuit

LED On/Off

Failed to Cycle

LEd On/Off

Low Gas Supply

LED On/Off

Apnea

LED On/Off

Settings Incompatible

LED On/Off

Pressure Settings Incompatible

LED On/Off

Prolonged Inspiratory Pressure

LED On/Off

Flow Sensor

LED On/Off

Low Battery

LED On/Off

Alarm Silence

60 seconds

Visual Reset

Push Button

High Pressure Limit

Range: 10 to 75 cmH2O

Line Power

Green/Red LED

Monitors

Total Breath Rate

Range: 0 to 255 BPM

Resolution: 1 BPM from 0 to 100 BPM

2 BPM from 100 to 150 BPM 3 BPM from 150 to 255 BPM

Exhalation Minute Volume

Range: 0 to 30.0 L/min

resolution: 0.01 L/min from o to 1.00 L/min

0.02 L/min from 1 to 2.00 L/min 0.05 L/min from 2 to 5.0 L/min 0.10 L/min from 5 to 10.0 L/min 0.20 L/min from 10 to 30.0 L/min

Accuracy: Accuracy of the exhaled minute volume is a function of both

volume and breath rate. To evaluate the performance of this monitor the accuracy of both tidal volume and breath rate must

be combined

Exhaled Tidal Volume

Range: 0 to 500 ML

Resolution: 0.1 ML from 0.0 to 99.9 ML

1.0 ML from 100 to 500 ML

Accuracy: ± 1 ML or $\pm 10\%$, whichever is greater

% of Tubing Leakage

Range: 0 to 100%

Resolution: 1%

Accuracy: $\pm 2\%$ or ± 1 ML

Inspiratory Time

Range: 0 to 3.10 seconds

Resolution: 0.01 seconds
Accuracy: ± 0.02 seconds

Expiratory Time

Range: 0 to 99.9 seconds

Resolution: 0.01 seconds from 0 to 99.9 seconds

0.10 seconds from 10.0 to 99.9 seconds

Accuracy: ± 0.02 seconds

I:E Ratio

Range: 9.9:1 to 1:9.9

Accuracy: ± 0.1 or ± 20 mseconds, whichever is greater

Peak Inspiratory Pressure

Range: 0 to 99 cmH2O

Resolution: 1 cmH2O

Accuracy: $\pm 2 \text{ cmH2O or } \pm 5\% \text{ of reading, whichever is greater}$

Mean Airway Pressure

Range: 0 to 75 cmH2O Resolution: 0.5 cmH2O

Accuracy: $\pm 2 \text{ cmH2O or } \pm 3\% \text{ of reading, whichever is greater}$

Inlet O₂ Pressure

Range: 0 to 100 PSIG

Resolution: 1 PSIG
Accuracy: ± 5 PSIG

Proximal Airway Pressure

Range: -10 to 100 cmH2O

Resolution: 1 cmH2O

Accuracy: ± 1 cmH2O from -10 to 20 cmH2O

± 2 cmH2O from 20 to 65 cmH2O ± 3 cmH2O from 65 to 100 cmH2O

Hourmeter

Range: 0 to 99,999 hours

Resolution: 0.1 hour

Accuracy: ± 2% of reading

Breath Type (Patient Initiated)

LED

Test

Push Button

Battery

LED On/Off

Preset Values

Minimum Expiratory Time 150 milliseconds

Maximum Inspiratory Time 3.10 seconds

Maximum settable I:E Ratio 4:1

Model 9300

Classification Class 1

Degree of Protection

Electric Shock Type B

Harmful Ingress of Water None (Ordinary Equipment)

Degree of Safety of Application

in Presence of Flammable Anesthetics None

Mode of Operation Continuous

Emissions/Susceptibility

This 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 1000-4-5:1994, 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.

Outputs

Digital

(see Section 10, Page 1) RS-232 Bi-Directional

Analog

Proximal Pressure -10 to 100 cmH2O, 1 cmH2O/25 mv

Proximal Inspiratory/Expiratory Flow -40 (expiratory) to 40 (inspiratory) L/min, 1

L/min/50 mv

Breath Phase 1 "Logic" signal; 0, 5V

Remote Nurse Call 0.5 amps max at 24 vdc max

Pneumatic

Auxiliary Blended Gas Outlet 7 to 17 psig, 0 to 8 L/min

Inputs

Electrical

Supply Ratings

Voltage:	100V	80 to 110 VAC
	120V	96 to 132 VAC
	220V*	176 to 242 VAC
	240V	192 to 264 VAC
Current:	100V	1.0 A maximum
	120V	1.0 A maximum
	220V	0.5 A maximum
	240V	0.5 A maximum
Frequency:	100V	50/60 Hz
	120V	50/60 Hz
	220V	50/60 Hz
	240V	50/60 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 L/min Supply Ratings

Physical Dimension and Shipping Information

Ventilator Weight 27 lbs., 12 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" x 40.5" H

Compressor Dimensions 22"W x 21.5"D x 36" H

Shipping Weight Including Ventilator 38 lbs.

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 -40 to 158 °F (-40 to 70 °C)

Checkout and Operating 50 to 104 °F (10 to 40 °C)

Altitude

Checkout, Operating,

Transport and Storage 0 to 9,000 feet (14.7 to 10.5 PSIA/760 to 543 mm Hg)

Humidity

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

Method of Sterilization/Disinfection

NOTE

See also the BEAR CUB™ 750vs Infant Ventilator Instruction Manual Cleaning and Maintenance (section 7)

Cleaning

External Surfaces

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

A. Isopropyl Alcohol

B. Chlorine Compounds Maximum Concentration: 1:10
 C. Quaternary Ammonium Compounds Maximum Concentration: 1:500

NOTE

These compounds are diluted by volume in water.

Sterilization

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

Methods of Sterilization

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

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

Liquid Sterilization

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 6 months Liquid Sterilization 6 months

Pasteurization (using mesh bag) 6 months

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

Chapter 2: Theory of Operation

Overview

This section describes the operating theory of the BEAR CUB™ 750vs Infant Ventilator. The BEAR CUB™ 750vs ventilator can be classified as a microprocessor 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 2-1) graphically illustrates the overall structure of the ventilator.

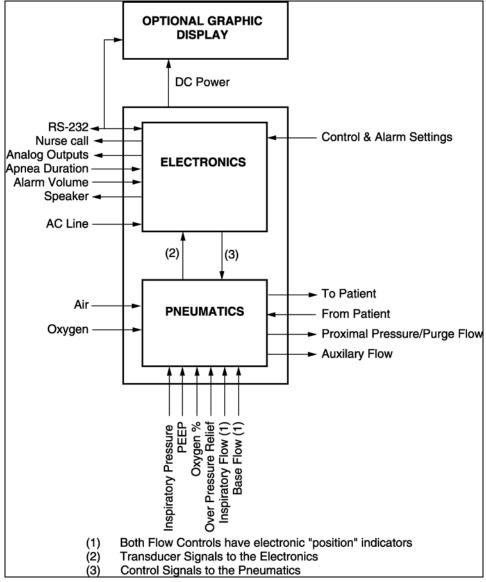


Figure 2-1: Top Level Block Diagram

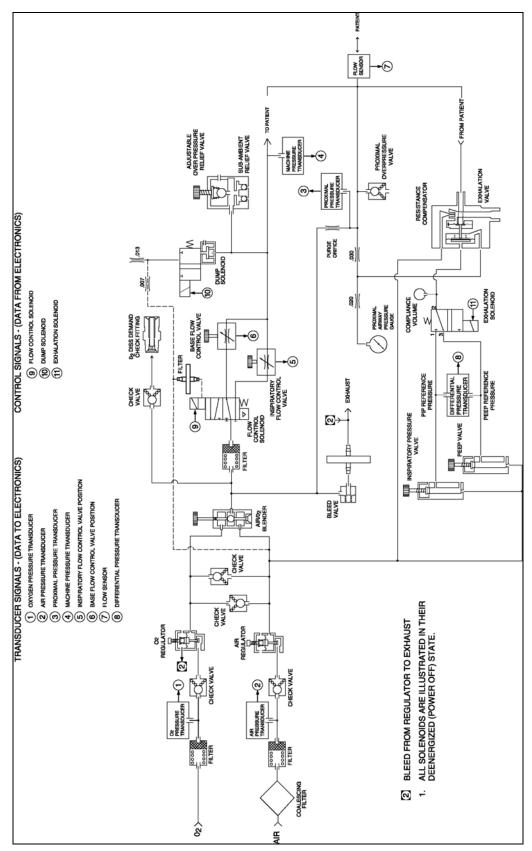


Figure 2-2: Pneumatics System Schematic

Ventilator pneumatics - General description

Figure 2-2 shows the schematic diagram of the BEAR CUB™ 750vs 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 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 O2, 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.

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 L/min. 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.

AOPR Valve/Sub-Ambient Valve/ Dump Solenoid

Maximum pressure to the patient can be limited using the Adjustable/Over Pressure Relief valve. The mechanical, user adjustable, pressure relieving valve can be set from 15 cmH₂O to 75 cmH₂O. A patient effort of -3 cmH₂O 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 $_2$ O 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 L/min. 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™ 750vs Infant Ventilator ventilates the patient between two pressure levels: Positive End Expiratory Pressure (PEEP) and Peak Inspiratory Pressure (PIP). 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 cmH₂O (measured at the patient wye). The PEEP valve can be set from 0 to 30 cmH₂O. 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 cmH₂O PEEP setting at up to 10 L/min of Base Flow (to less than 4 cmH₂O at 20 L/min). 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 proximal airway line 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™ 750vs Infant Ventilator flow sensor reads gas flow while sensing flow direction. The flow is calibrated to 37 °C, ambient pressure, and assumes 100% humidity. Inhaled flows, 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 L/min) required to initiate a breath can be adjusted (.2 to 5 L/min) 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 inhaled and exhaled volume measurements.

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 inhaled and exhaled volumes.

The flow sensor reads from 0.2 to 40 L/min, calibrated from 0.2 to 25 L/min, and indicates to 40 L/min. Each Flow Sensor Cable Assembly contains an electronic memory circuit (an E2PROM) which stores calibration data for the unit. Therefore, the sensor will function with the electronic circuit of any BEAR CUB™ 750vs 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 Graphic Display in order to chart ventilator data. 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 the 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™ 750vs 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 m-sec 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 on pressure transducer, and flow sensor data read on its own 8 bit Analog to Digital (A/D) 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, (4) receives performance data back from the Controller, and (5) transmits display data and annunciator status to the front panel.

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 alarms. These systems, among others, are provided to reduce the possibility of a software/hardware error leading to an undetected hazardous condition.

Chapter 3 OVP Recommended Service

Operational Verification

Operational Verification should be performed between patient use or a minimum of once each month. Verification may be done by a qualified operator, Allied Healthcare Trained Hospital Service Technician or Allied Healthcare Technician. Verification is intended to be done in the hospital. If done by an Allied Healthcare Technician, there will be a charge.

Certain procedures such as a verification of the alarm circuits should be performed at least once every 24 hours that the unit is in clinical use. Refer to the BEAR CUB™ 750vs Infant Ventilator instruction manual for details.

Do not use the ventilator unless it passes all the steps in the Operational Verification Procedure.

Equipment Required

Infant Test Lung P/N 52000-40027

Patient Circuit P/N 50000-01147

Oxygen Analyzer

Rubber Stopper

Stop Watch

CAUTION

If any of the following procedures fail to producer the results as outlined in this document, disconnect the ventilator and contact your authorized VIASYS Healthcare service technician.

Table 3-1: Standard Settings

Mode	SIMV
Rate	30 BPM
Inspiratory Pressure	40 cmH2O
Inspiratory Flow	15 L/min
PEEP/CPAP	0 cmH2O
Inspiratory Time	0.8 seconds
Base Flow	5 L/min
Assist Sensitivity	MAX
O2%	21%
Apnea	10 seconds
Low PEEP/CPAP Alarm	-3 cmH2O
Volume Limit™	300 ml
High Pressure Limit	50 cmH2O
Low Inspiratory Pressure Alarm	30 cmH2O
High Breath Rate Alarm	40 BPM

Table 3-2: Rate

Set Rate	Inspiratory Time	Using stop watch verify Breath Rate
10 BPM	3 seconds	10 ± 2 BPM
40 BPM	1 second	40 ± 3 BPM
80 BPM	0.4 seconds	80 ± 4 BPM
120 BPM	0.1 seconds	120 ± 6 BPM

Table 3-3: Exhalation Time and I/E Ratio Table

Rate	Set Inspiratory time	Verify Exhalation Time	Verify I/E Ratio
10 BPM	3.00 seconds	3.0 ± 0.4 sec	1:1.0 ± 0.3
75 BPM	0.40 seconds		1:1.0 ± 0.3
150 BPM	0.10 seconds		1:3.0 ± 0.4

WARNINGS

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

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

- Liquid spilled or dripped into the unit may cause damage to the unit or result in an electrical shock hazard.
- Oxygen vigorously accelerates combustion. To avoid violent ignition, do not use any gauges, valves, or other equipment that has been exposed to oil or grease contamination.
- Do not release this medical device if any alarm/alert function is inoperative. To do so could result in a malfunction without warning, possibly resulting in personal injury, including death or property damage. Refer the unit to a Allied Healthcare Authorized Service Technician or a Allied Healthcare Trained Hospital Service Technician.
- All tubing and fittings used to connect high pressure gas (air and oxygen) from
 the source to the test equipment and from the test equipment to the device being
 tested must be capable of withstanding a minimum supply pressure of 100 psi
 (7.03 kg/cm2). The use of tubing and fittings not capable of withstanding this
 pressure could cause the tubing to rupture, resulting in personal injury or
 property damage.
- When verifying the operation of this medical device, do not breathe directly from the machine. Always use a fresh bacterial filter and test circuit. A hazard to the health of the service person may result.
- If any of the following procedures cannot be verified as outlined in this document, do not use this device on a patient and refer it to Allied Healthcare or a Allied Healthcare Authorized Service Facility or a Allied Healthcare Trained Hospital Service Technician.

CAUTIONS

- Do not sterilize the ventilator. The internal materials are not compatible with sterilization techniques.
- Do not use MEK or Trichloroethylene, as damage to surface may result. Do not allow any liquid to spill or drip into the ventilator.
- Circuit boards are subject to damage by static electricity. Do not touch components, circuit, or connector fingers with hands. Handle only by edges.

Before using any test equipment [electronic or pneumatic] for calibration procedures [other than operational verification], the accuracy of the instruments must be verified by a testing laboratory. The laboratory master test instruments must be traceable to the NIST (National Institute of Standards Technology) or equivalent. When variances exist between the indicated and actual values, the calibration curves [provided for each instrument by the testing laboratory] must be used to establish the actual

correct values. This certification procedure should be performed at least once every six months. More frequent certification may be required based on usage and....???

Test Procedures

- 1. Set up the ventilator with a standard infant test circuit. Plug the end of circuit with rubber stopper.
- 2. Set the ventilator to standard settings per Table A. Ensure overpressure relief valve is set to maximum pressure. Connect air, oxygen, and AC power to ventilator.
- 3. Press the TEST button, verify all indicators and digits illuminate.
- 4. Verify rates per Table B. While doing rate verification you will get a rate alarm. Press the alarm silence button. Verify that the audible alarm is silenced and the silence is canceled after 60 seconds ± 10%. Return to standard settings. Set mode to Assist Control.
- 5. Verify Exhalation Time and I:E Ratio per Table C. Return to standard settings.
- 6. Adjust Inspiratory Pressure to 25 cmH₂O. Verify activation of Low Pressure alarm.
- 7. Increase Inspiratory Pressure to 50 cmH₂O. Verify High Pressure alarm and limit.
- 8. Return Inspiratory Pressure to 40 cmH₂O. Push the Visual Reset button and verify that the Low Pressure and High Pressure LEDs are canceled.
- 9. Occlude patient circuit limb going to the exhalation valve. Verify that a prolonged inspiratory alarm occurs.
- 10. Increase ventilator rate to 45 BPM. Verify that the High Rate alarm activates.
- 11. Decrease rate to 4 BPM. Verify that the apnea alarm activates.
- 12. Set ventilator rate to 70 BPM. Verify that the Incompatible Setting alarm activates. Return rate to 30 BPM.
- 13. Push the Pressure Selector button to read air pressure. Verify reading is within 5 PSI of input pressure.
- 14. Push the Pressure Selector button to read O₂ Pressure. Verify reading is within 5 PSI of O₂ supply pressure.
- 15. Disconnect air supply. Verify that the Low Gas Supply alarm activates. Reconnect air supply.
- 16. Disconnect O₂ supply. Verify that the Low Gas Supply alarm activates.
- 17. Disconnect the air supply. Verify that the fail to cycle alarm activates. Reconnect the air and O₂ supplies.
- 18. Connect an O_2 analyzer inline. Verify that the FIO_2 is within \pm 3% at the following settings: 21%, 60%, 100%. Remove O_2 analyzer.
- 19. Adjust the rate to 10 BPM. Turn the Low PEEP/CPAP alarm to 5 cmH₂O. Verify that the Low PEEP/CPAP alarm activates. Return the Low PEEP/CPAP alarm to -3 cmH₂O.
- 20. Disconnect the AC power. Verify that the audible alarm activates and the line power LED illuminates red within 10 seconds. Push the Visual Reset button.

- Verify that the audible alarm is canceled and the unit continues to function. Reconnect the AC power.
- 21. Connect the circuit to the infant test lung. Set the Volume Limit to 25ml. Verify That the tidal Volume readout is 25 ml ± 20%.
- 22. Disconnect the Flow Sensor cable from the ventilator. Verify that the flow sensor alarm activates, assist sensitivity window is blank, and that the monitored volume and volume limit displays show dashes. Reconnect the flow sensor cable, verify audible alarm cancels, assist sensitivity window illuminates, and volume digits return.
- 23. Turn Assist Sensitivity to MIN. Squeeze and release the patient circuit. Verify that the unit will assist and that Patient Initiated LED is illuminating.
- 24. Disconnect the patient circuit from the test lung. Verify that both audible and visual Low Inspiratory Pressure alarms are activated. Verify that the Alarm Loudness can be varied from minimum to maximum, but the alarm cannot be turned off.

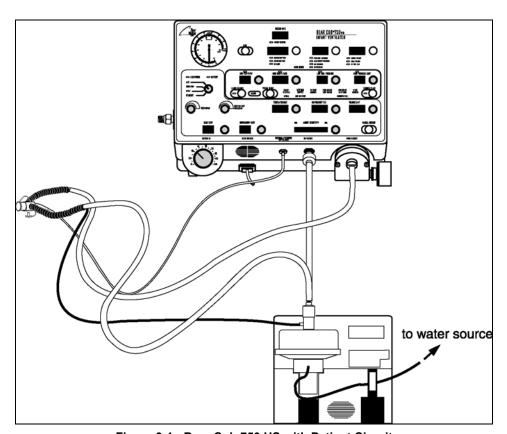


Figure 3-1: Bear Cub 750 US with Patient Circuit

Exterior Inspection and Cleaning

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

Exterior Cleaning

- 1. Before any cleaning of the ventilator, disconnect WALL AC.
- 2. Clean the exterior of the ventilator with an appropriate bactericidal or germicidal agent. Care should be exercised not to allow any liquid to penetrate the inside of the ventilator.

CAUTION

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

Plugs and Cables

Plugs and cables may be wiped down with an appropriate bactericidal or germicidal agent.

L2342 Revision B November 2004

OVP Checklist

This checklist is for use during the Serial Number I						
Service Location		Serv	rice Organization			
AddressAddress						
City/State/ZipCity/State/Zip						
Contact Contact Phone () Phone ()						
rione (<u>)</u>		F1101	ne (<u>)</u>			
Verification Step	S					
STEP	PASS	FAIL	STEP	PASS	FAIL	
Indicator Verification			O2 Pressure Reading Verification			
Breath Rate Verification			Low Gas Supply Verification(Air)			
Alarm Silence, Reset Verification			Low Gas Supply Verification (O2)			
Exhalation Time, I:E Ratio Verification			Fail to Cycle alarm verification			
Low Pressure alarm Verification			FIO2 verification (21%, 60%, 100%)			
High Pressure alarm/Limit Verification			Low PEEP/CPAP alarm verification			
Pressure LED reset			AC power loss verification			
Prolonged Inspiratory alarm verification			Tidal Volume Limit verification			
High Rate alarm verification			Flow Sensor alarm verification			
Apnea alarm verification			Patient Triggering verification			
Incompatible setting alarm verification			Alarm loudness verification			
Air Pressure reading verification						
ADD Warning ????? Signature PROCEDURE COMPLETE						

Chapter 4 Calibration (for software releases 2 and 3 only)

Introduction

The information in this section is intended for use by a factory trained service technician. Before opening the console or removing assemblies to perform calibration, a reference should be made to the Instruction Manual and Sections 1, 2, 3, and 7 of this Manual to assure that the ventilator is being properly utilized.

WARNINGS

- The calibration procedures contained in this section must be completed when any part/assembly has been removed and/or replaced. Failure to do so could result in ventilator malfunction and injury or death to the patient.
- After calibration and/or replacement of any assembly(ies), always perform the Operational Verification Procedure (Section 3), then allow a "BURN-IN" period and repeat the Operational Verification Procedure.
- Oxygen vigorously accelerates combustion. DO NOT use any gauges, valves or other equipment that has been exposed to oil or grease contamination to avoid violent ignition.
- Hazardous voltages exist within the ventilator. Always observe appropriate safety precautions when working on the ventilator while the machine is connected to an electrical power source to prevent possible accidental injurious electrical shock.
- When high pressure gas sources are connected to the ventilator, always use
 extreme caution when attempting to measure internal pressures. Abnormal
 conditions may exist where measured pressures exceed the burst pressure of
 the gauge, resulting in possible injury.

NOTE

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

CAUTION

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

NOTE

If problems are incurred in obtaining the calibration performance, refer to Troubleshooting (Section 7) or contact your dealer or VIASYS Healthcare Service Facility.

Pressure Transducers and Flow Control Valve Calibration

Turn OFF the ventilator and disconnect tubing to the Pressure Transducers on the Control PCB. Press and hold the diagnostic switch on the Control PCB while turning the ventilator ON to enter Transducers and Flow Calibration routines. Throughout calibration, the TEST key is for advancing the calibration number; VISUAL RESET is for backing to previous calibration, and the MANUAL BREATH key is for recording calibration data. The calibration number and message are displayed in the Breath Rate and Monitored Time/I:E Ratio windows respectively. Data (when applicable) is displayed in the Monitored Pressure window. Refer to the following (See table 4-1) to calibrate the transducers on the Control PCB:

Table 4-1:	Control PCB	Transducer	Calibration
------------	--------------------	------------	-------------

Transducer	Calibration Number	Message	Input Static Pressure
Machine (port B)	d00	nP00	0 cmH2O
	d01	nP40	40 ± 0.2 cmH2O
Differential (port B)	d02	dP00	0 cmH2O
	d03	dP40	40 ± 0.2 cmH2O
Proximal (port B)	d04	pP00	0 cmH2O
	d05	pP40	40 ± 0.2 cmH2O
O2 (A2)	d06	0P00	0 PSIG
	d07	0P40	40 ± 0.2 PSIG
AIR (A1)	d08	AP00	0 PSIG
	d09	AP40	40 ± 0.2 PSIG

NOTE

The 40 cm/psi settings were 70 cm/psi prior to monitor firmware 511-02803-00. When calibrating the pressure transducers, both pressure points (i.e. 0 and 40 cm/psi) must be read and the 0 cm/psi reading must be obtained first.

- 1. Check the accuracy of the five pressure transducers per table 4.2. The window shows the pressure readings monitor pressure.
- 2. Press the TEST key to advance the calibration number to the Display Set Altitude Test, then press the MANUAL BREATH key until the number in the PRESSURE window indicates the altitude at which the Flow Control valve calibration is to be performed (expressed in units of 100 ft). Then advance to the next test number and power down.
- 3. Re-connect tubing to the transducers on the Control PCB; apply Air and O2 (approximately 50 psi) to UUT. Use an RT-200 to measure flow at the TO

PATIENT port. To calibrate the Flow Control Valve, press the TEST key to advance the calibration number; then set flow as specified and press the MANUAL BREATH key to record data. Calibrate Base Flow, then Calibrate Inspiratory Flow.

Table 4-2: Calibration

Transducer	Calibration Number	Message	Input Static Pressure
Differential (port I	B) d10	0 ± 1	0 cmH2O
	d10	50 ± 1	50 ± 0.5 cmH2O
Machine (port B)	d11	0 ± 1	0 cmH2O
	d11	50 ± 1	50 ± 0.5 cmH2O
Proximal (port B)	d12	0 ± 1	0 cmH2O
	d12	50 ± 1	50 ± 0.5 cmH2O
AIR (A1)	d13	50 ± 2	50 ± 0.2 PSI
O2 (A2)	d14	50 ± 2	50 ± 0.2 PSI

NOTE

The pressure display occasionally flickering 1 digit beyond the tolerance is acceptable.

Table 4-3: Diagnostic Function

NUMBER	FUNCTION
00	Calibrate pmach @ 0 cmH₂O
01	Calibrate pmach @ 40 cmH₂O
02	Calibrate pdelta @ 0 cmH ₂ O
03	Calibrate pdelta @ 40 cmH₂O
04	Calibrate proxp @ 0 cmH₂O
05	Calibrate proxp @ 40 cmH₂O
06	Calibrate O2p @ 0 cmH ₂ O
07	Calibrate O2p @ 40 cmH ₂ O
08	Calibrate airp @ 0 cmH ₂ O
09	Calibrate airp @ 40 cmH ₂ O
10	Display pdelta
11	Display pmach
12	Display proxp
13	Display airp
14	Display O ₂ p
15	Display/Set Altitude
16	Calibrate Base Flow @ 1 L/min*
17	Calibrate Base Flow @ 2 L/min*
18	Calibrate Base Flow @ 5 L/min*
19	Calibrate Base Flow @ 15 L/min*
20	Calibrate Base Flow @ 25 L/min*
21	Calibrate Base Flow @ 30 L/min*
22	Calibrate Insp Flow @ 1 L/min*
23	Calibrate Insp Flow @ 2 L/min*
24	Calibrate Insp Flow @ 5 L/min*
25	Calibrate Insp Flow @ 15 L/min*
26	Calibrate Insp Flow @ 25 L/min*
27	Calibrate Insp Flow @ 30 L/min*

*±0.5 L/min

NOTE

Diagnostic numbers can only be accessed by depressing the diagnostic switch on the Control PCB while turning the Ventilator ON.

Table 4-4: Inspiratory Flow Calibration

| Flow |
|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Sea Level | 500 feet | 1000 feet | 1500 feet | 2000 feet | 2500 feet | 3000 feet | 3500 feet | 4000 feet |
| 2.00± .02 | 2.02± .02 | 2.04± .02 | 2.05± .02 | 2.08± .02 | 2.10± .02 | 2.12± .02 | 2.14± .02 | 2.16± .02 |
| 5.00± .03 | 5.05± .03 | 5.10± .03 | 5.14± .03 | 5.19± .03 | 5.24± .03 | 5.29± .03 | 5.33± .03 | 5.38± .03 |
| 15.00± .1 | 15.1± .1 | 15.3± .1 | 15.4± .1 | 15.5± .1 | 15.7± .1 | 15.8± .1 | 15.9± .1 | 16.1± .1 |
| 25.00± .2 | 25.2± .2 | 25.4± .2 | 25.6± .2 | 25.8± .2 | 26.0± .2 | 26.2± .2 | 26.4± .2 | 26.6± .2 |
| 30.00± .2 | 30.2± .2 | 30.5± .2 | 30.7± .2 | 30.9± .2 | 31.2± .2 | 31.4± .2 | 31.6± .2 | 31.9± .2 |

| Flow |
|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Sea Level | 4500 feet | 5000 feet | 5500 feet | 6000 feet | 6500 feet | 7000 feet | 7500 feet | 8000 feet |
| 2.00± .02 | 2.18± .02 | 2.20± .02 | 2.23± .02 | 2.26± .02 | 2.29± .02 | 2.31± .02 | 2.34± .02 | 2.37± .02 |
| 5.00± .03 | 5.44± .03 | 5.5± .1 | 5.6± .1 | 5.6± .1 | 5.7± .1 | 5.8± .1 | 5.8± .1 | 5.9± .1 |
| 15.00± .1 | 16.2± .1 | 16.4± .1 | 16.6± .1 | 16.7± .1 | 16.9± .1 | 17.1± .1 | 17.3± .1 | 17.5± .1 |
| 25.00± .2 | 26.9± .2 | 27.1±.2 | 27.4± .2 | 27.7± .2 | 28.0± .2 | 28.3± .2 | 28.6± .2 | 28.9± .2 |
| 30.00± .2 | 32.1± .2 | 32.4± .2 | 32.7± .2 | 33.0± .2 | 33.4± .2 | 33.8± .2 | 34.1± .2 | 34.5± .2 |

Air and O₂ Regulator Balance

Objective

To define the calibration requirements for balancing the Air and O₂ Regulators.

Equipment

Pressure gauge, 0 - 30 psig, ± 1/4% F.S.

Differential pressure gauge, 2 - 0 - 2 cm H_2O , \pm 5% F.S. Flow meter, 0 - 10 L/min, \pm 3% F.S.

Requirements

Regulator and Bleed Valve Adjustment:

Set up per Standard Test Settings except set MODE to STANDBY

Set O₂ Blender as noted (Table 4-5)

Set O₂ supply pressure to 50 psi

Patient circuit may be omitted

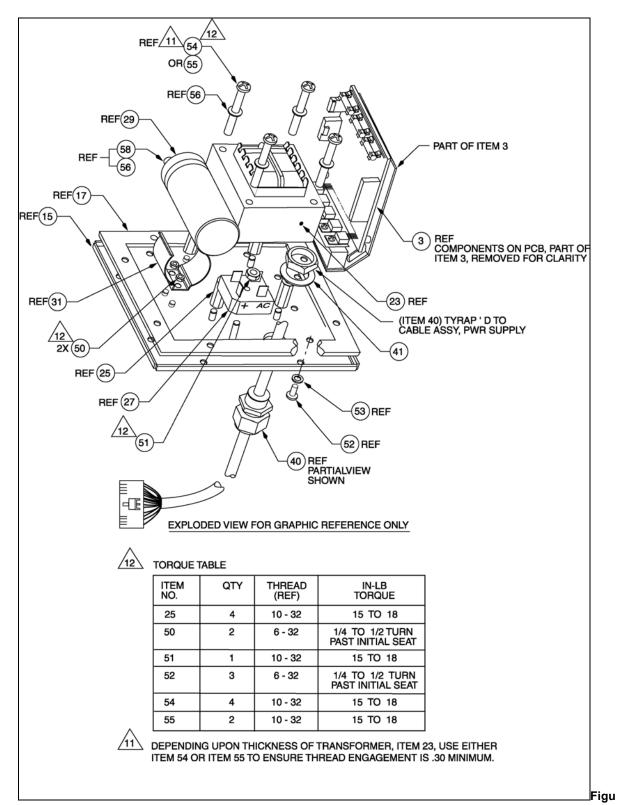
Table 4-5: Regulator Balance

Component	O₂ Blender Setting	Requirement
Air Regulator	100%	17.0 ± 1 psig
O ₂ Regulator	60%	Adjust O ₂ regulator to obtain a pressure balance with the air regulator within 2 cmH ₂ O.
Bleed Valve	60%	With Base Flow Control Valve set to minimum, Bleed Valve exhaust shall equal 3.5 - 5.5 L/min.
Air Regulator	60%	Increase Base Flow rate to maximum.
O ₂ Regulator		Regulators shall remain balanced within 2 cmH ₂ O.
Bleed Valve		Bleed Valve Flow drops to less than .25 L/min.

Table 4-6: Standard Test Settings

CONTROLS			
Mode	Assist/Control		
PEEP/CPAP Pressure	0 cmH2O		
Inspiratory Pressure (PIP)	20 cmH2O		
Ventilator Rate	30 BPM		
Inspiratory Time	1.00 second		
Volume Limit	300 mL		
Base Flow	5 L/min		
Inspiratory Flow	15 L/min		
Assist Sensitivity	Mid Range		
ALARMS			
Low PEEP/CPAP Alarm	-5 cmH2O		
High Breath Rate Alarm	255 BPM		
Low Inspiratory Pressure Alarm	5 cmH2O		
High Pressure Limit Alarm	75 cmH2O		
FRONT OF VENTILATOR			
Humidifier	VH-820 chamber, no water		
Patient Circuit	Standard Allied Infant Circuit		
Patient Resistance	Rp 20		
Patient Compliance	C3		
Endotracheal Tube	None		
Auxiliary Pressure Relief	Fully closed (CW)		
REAR OF VENTILATOR			
Alarm Loudness Control	Minimum		
RS-232 Interface	Open		
Analog Output	Open		
Remote Nurses call	Open		
APNEA Alarm	30 seconds		
Display Power Outlet	Open		
AC Line Voltage	120 VAC		
O2 Supply	>35 PSI		
Air Supply	>35 PSI		

Chapter 5 Schematics and Assemblies



re 5-1:

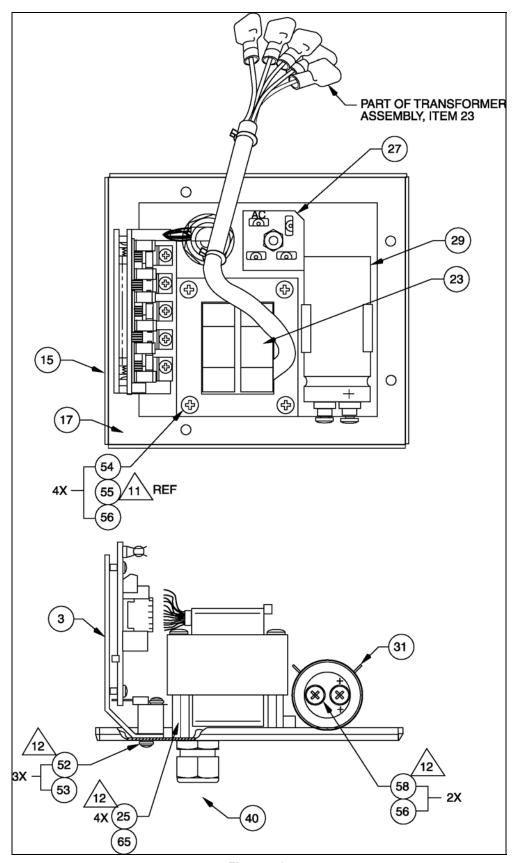


Figure 5-2:

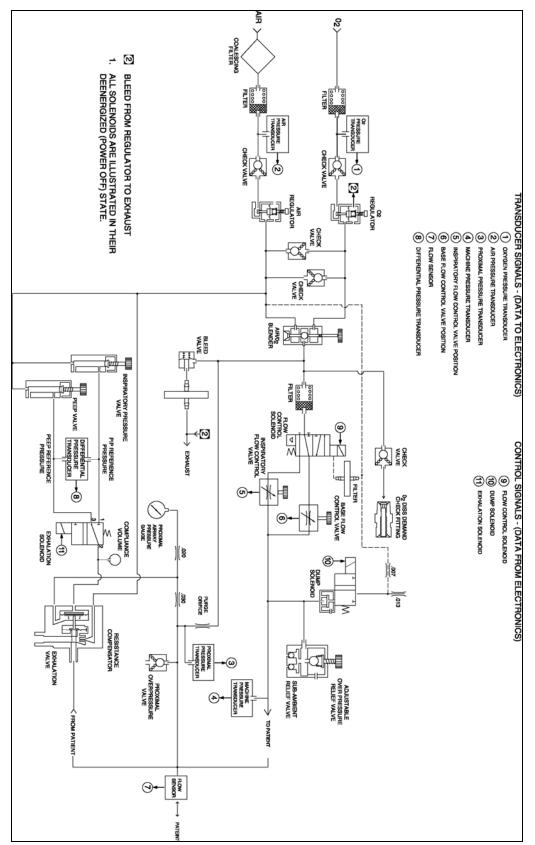


Figure 5-3:

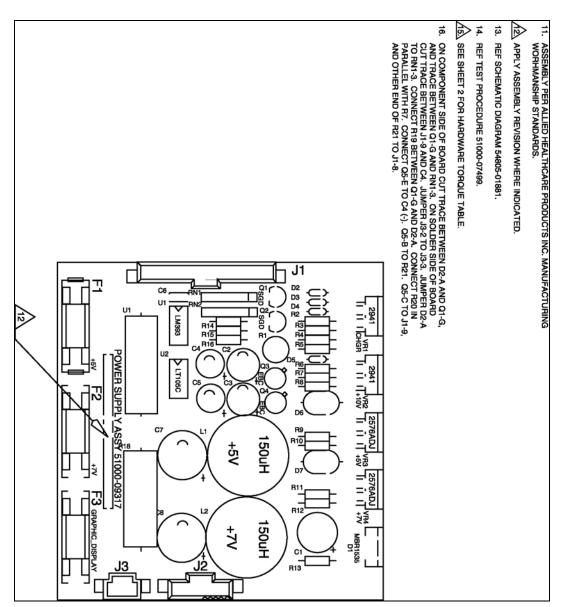


Figure 5-4:

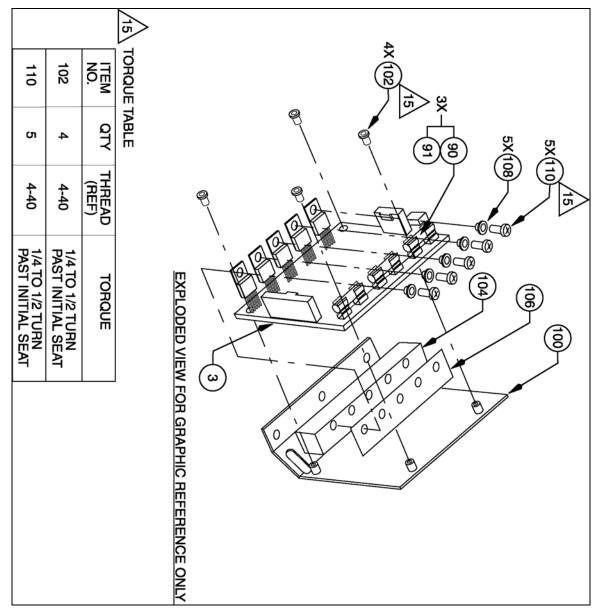


Figure 5-5:

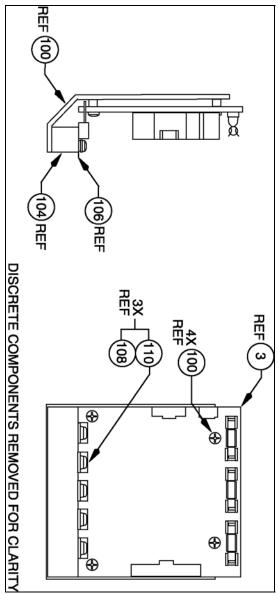


Figure 5-6:

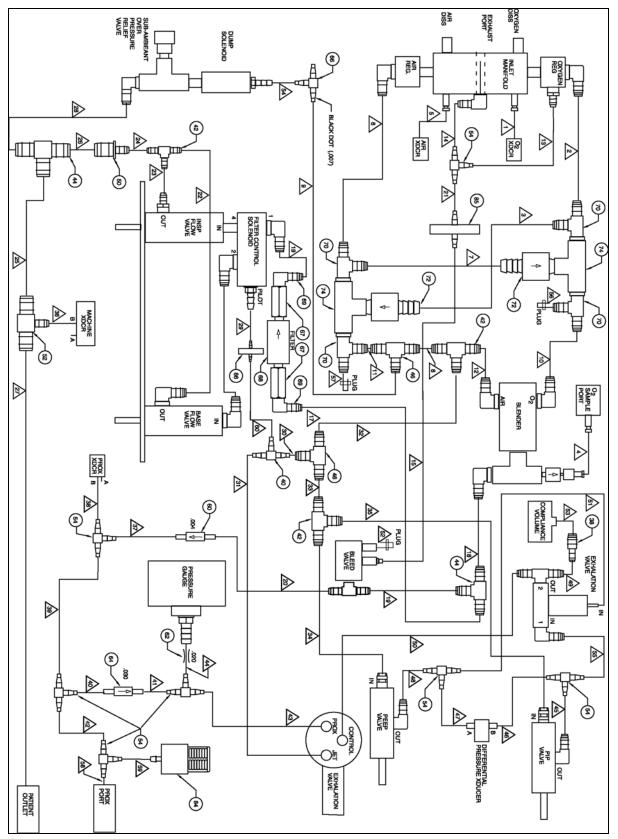


Figure 5-7:

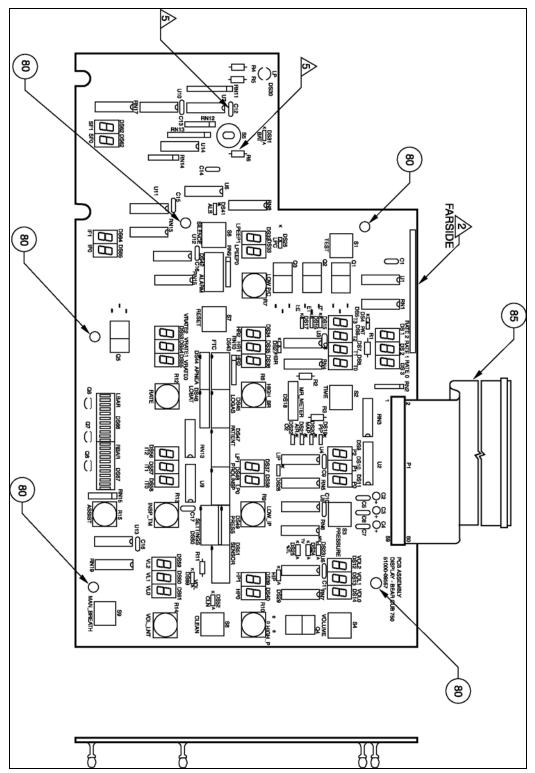


Figure 5-8:

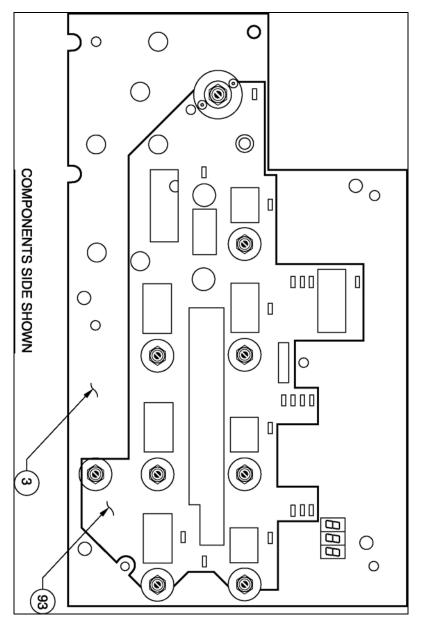


Figure 5-9:

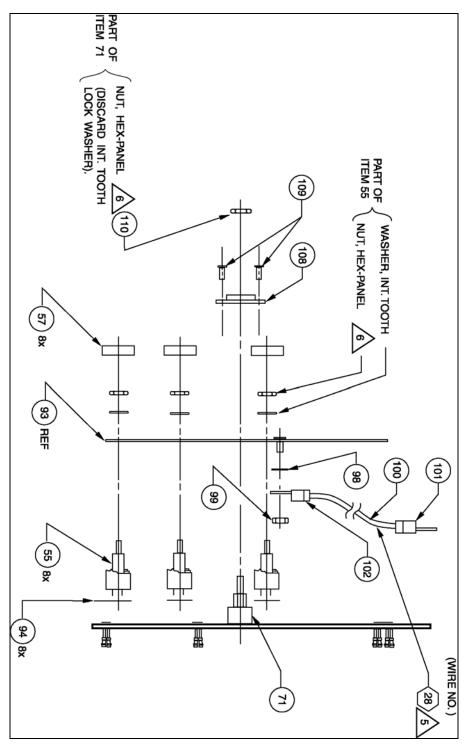


Figure 5-10:

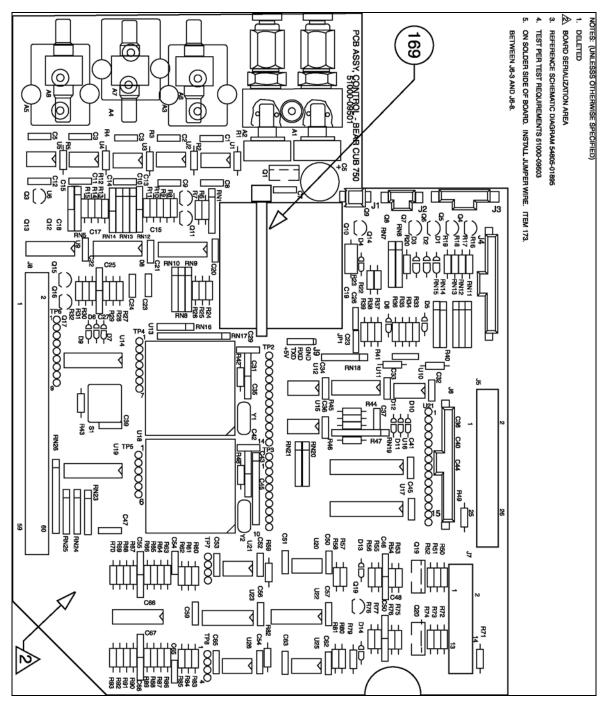


Figure 5-11:

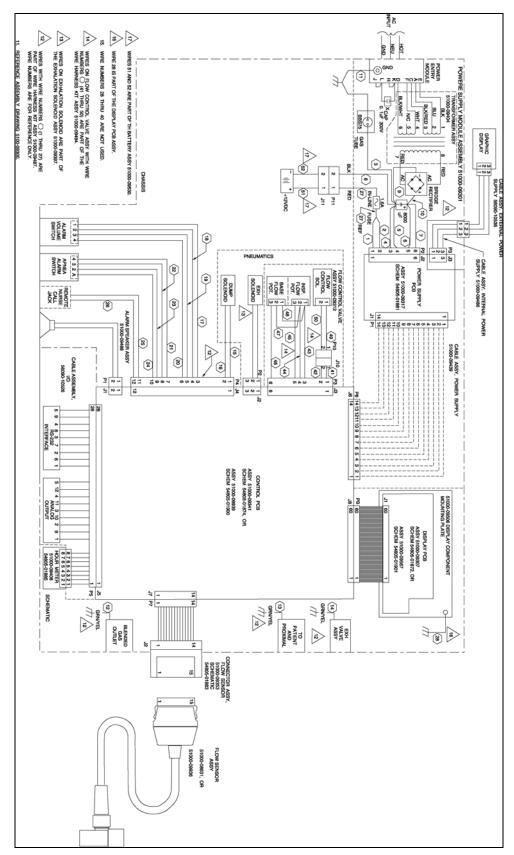


Figure 5-12:

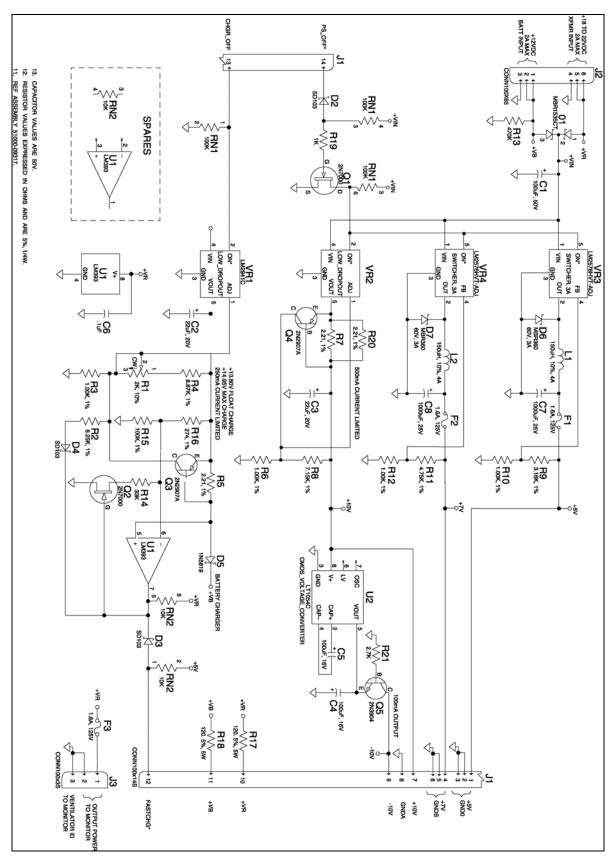


Figure 5-13:

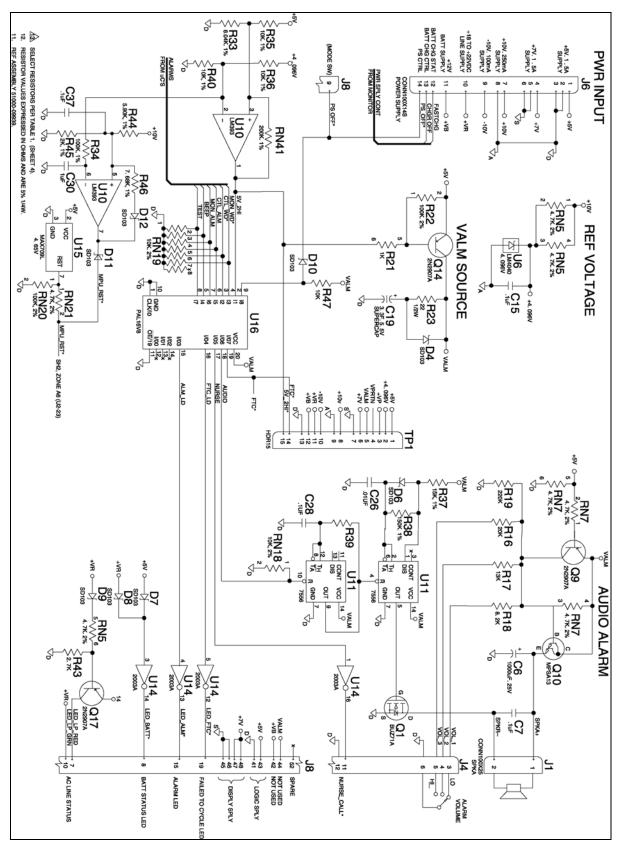


Figure 5-14:

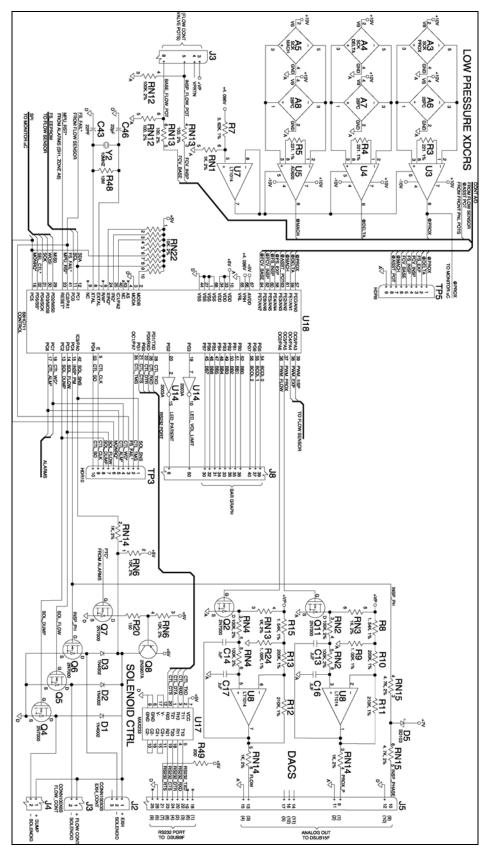


Figure 5-15:

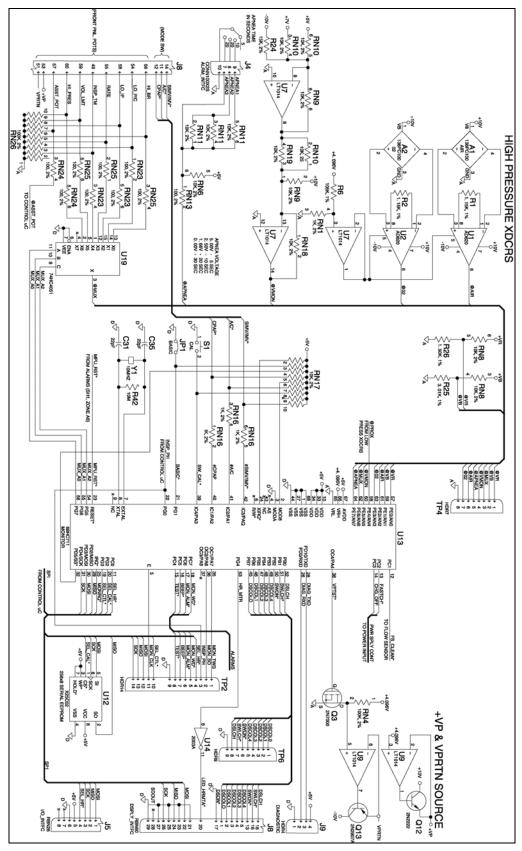


Figure 5-16:

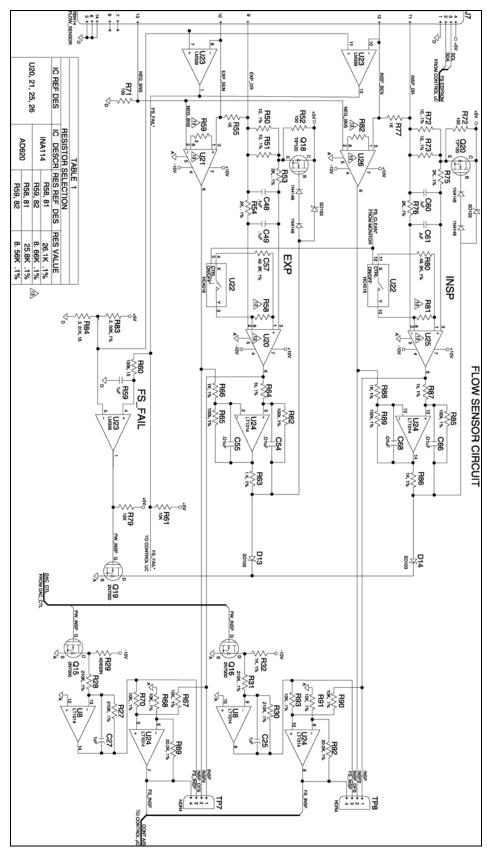


Figure 5-17:

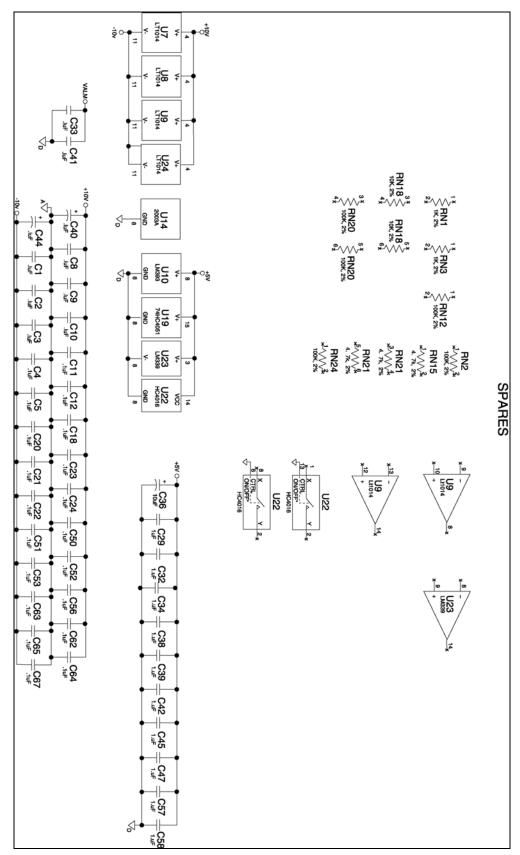


Figure 5-18:

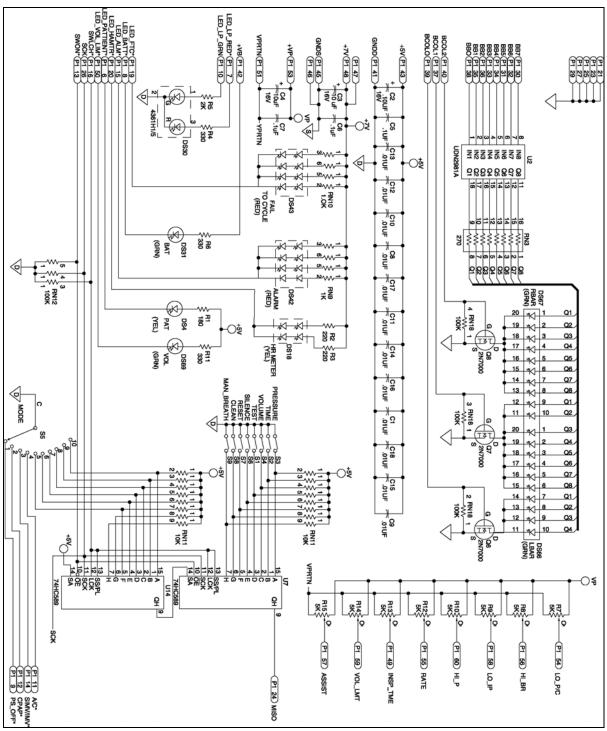


Figure 5-19:

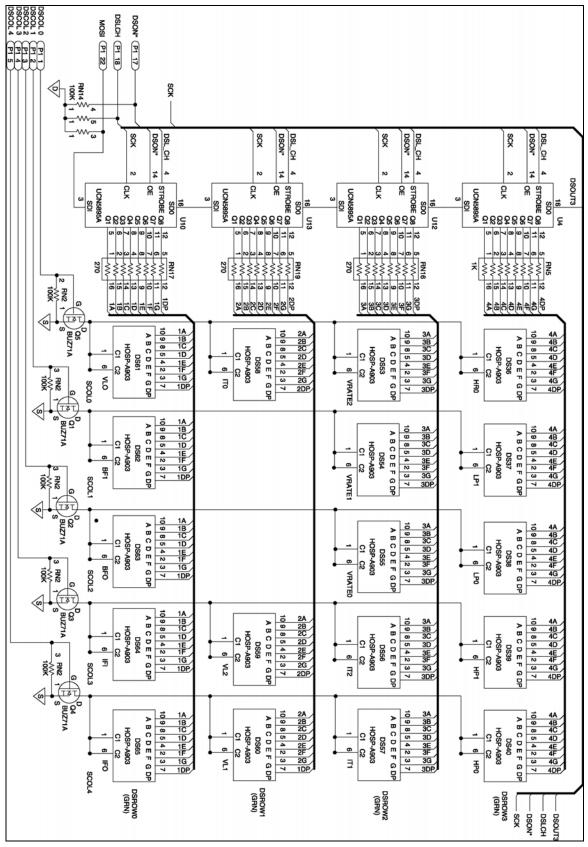


Figure 5-20:

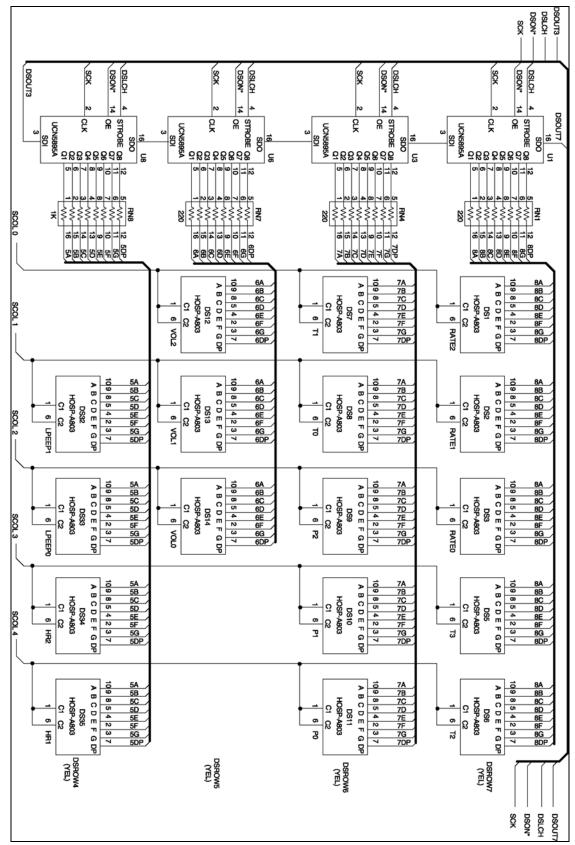


Figure 5-21:

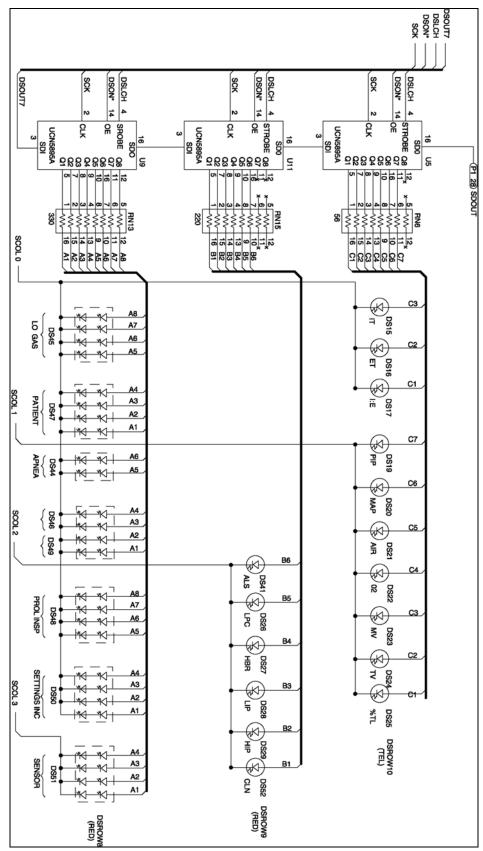


Figure 5-22:

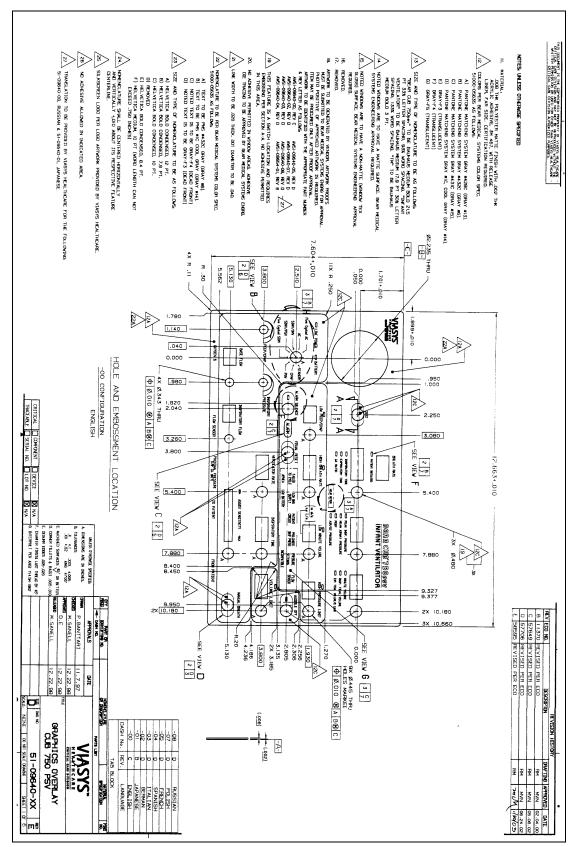


Figure 5-23:

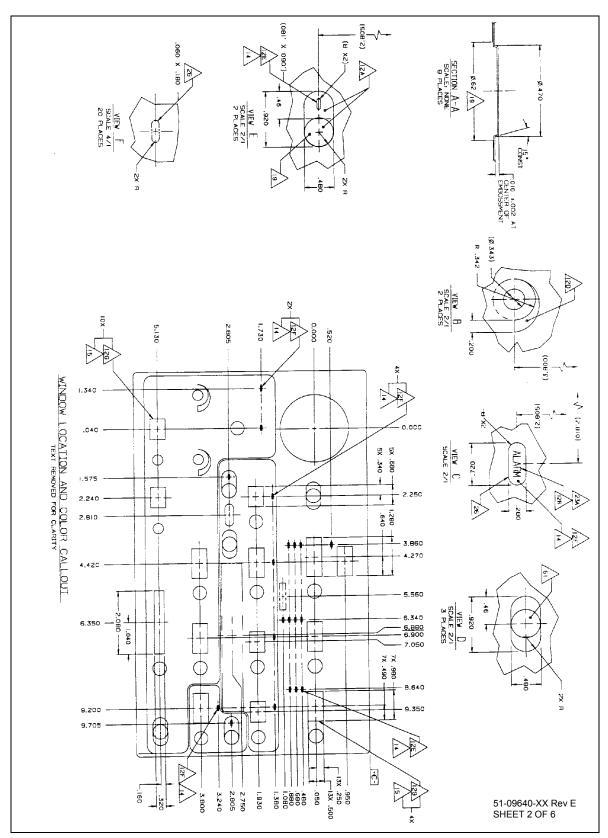


Figure 5-24:

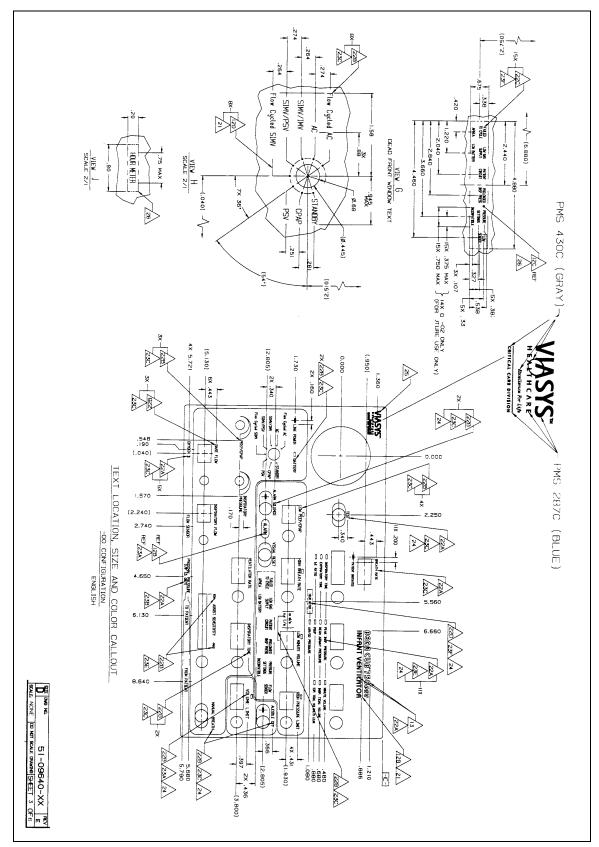


Figure 5-25:

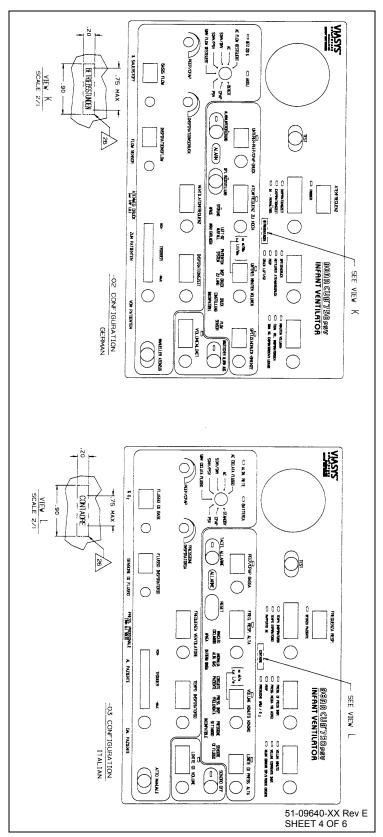


Figure 5-26:

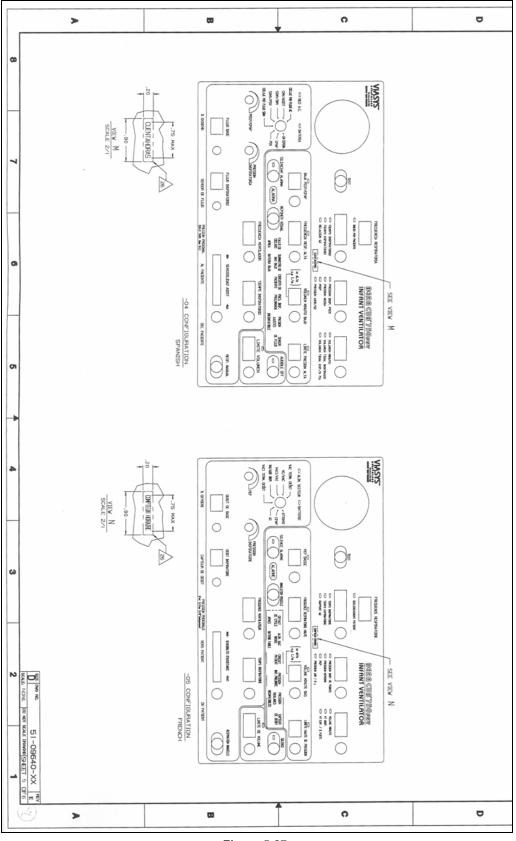


Figure 5-27:

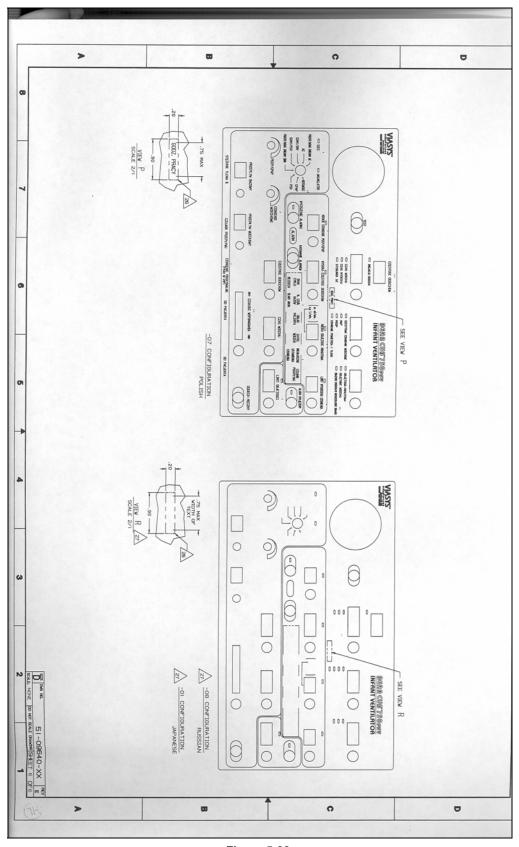


Figure 5-28:

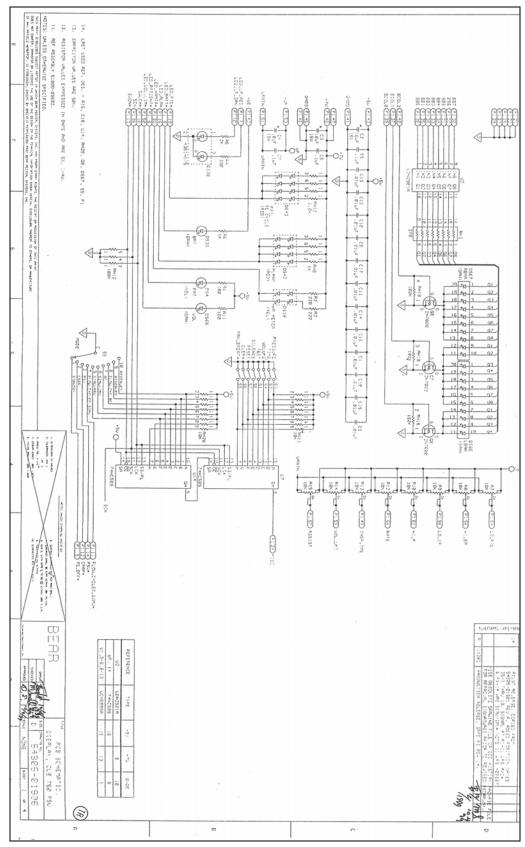


Figure 5-29:

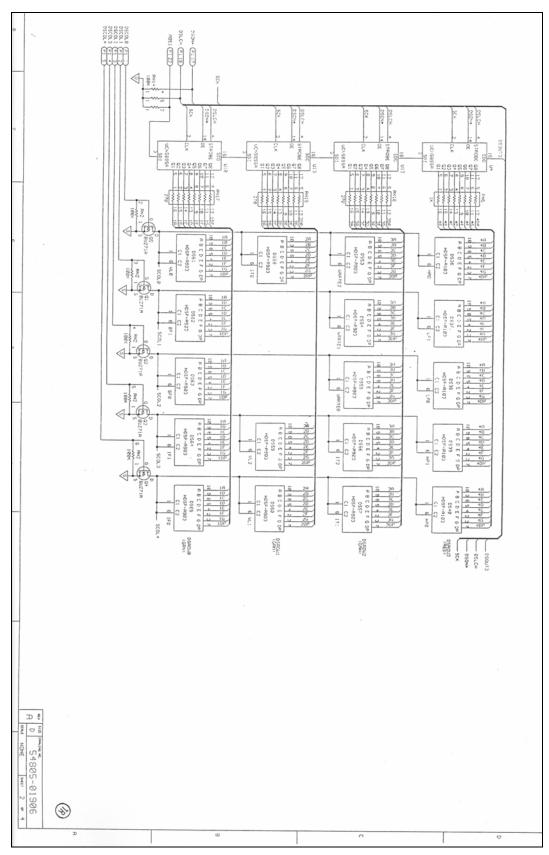


Figure 5-30:

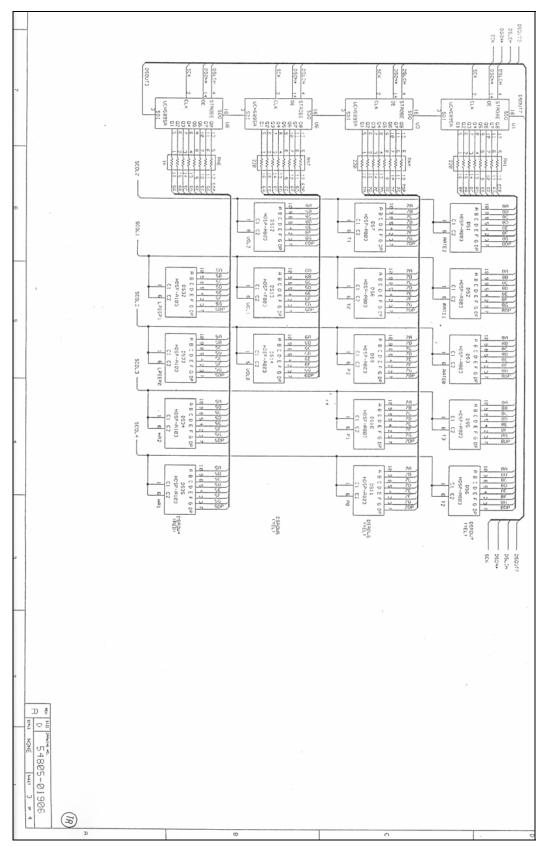


Figure 5-31:

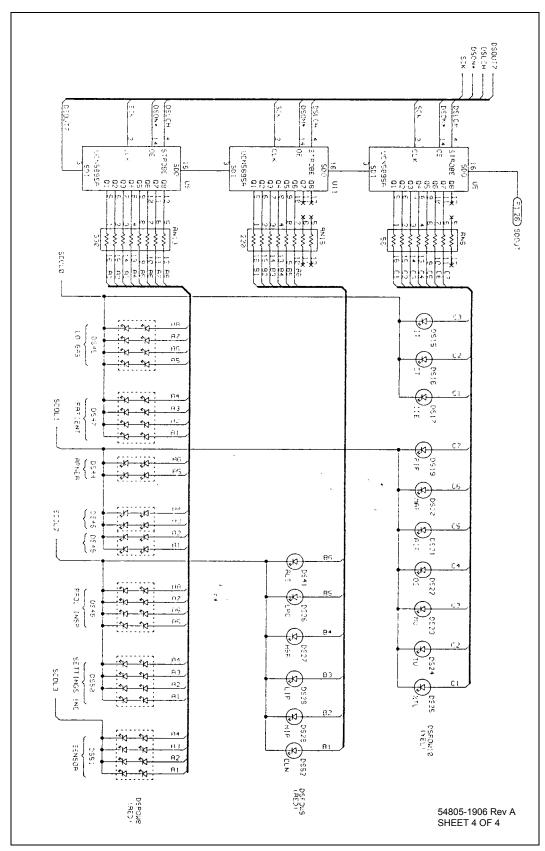


Figure 5-32:

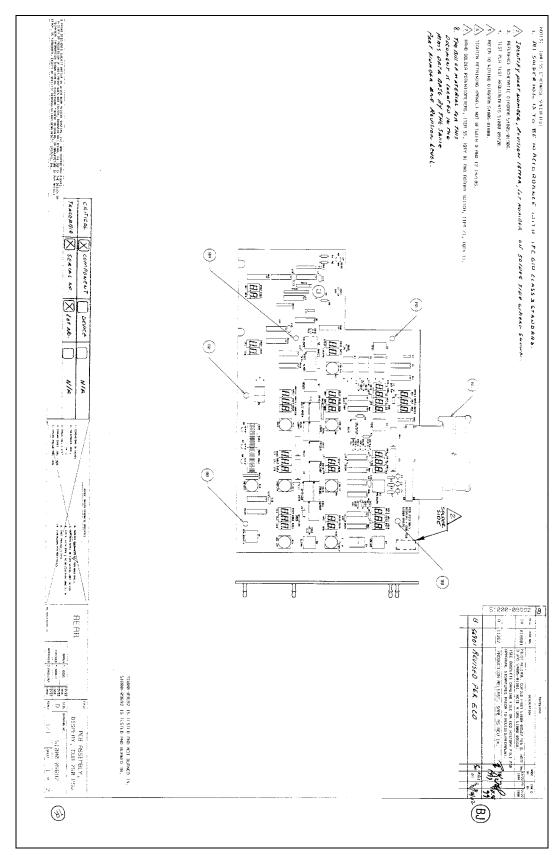


Figure 5-33:

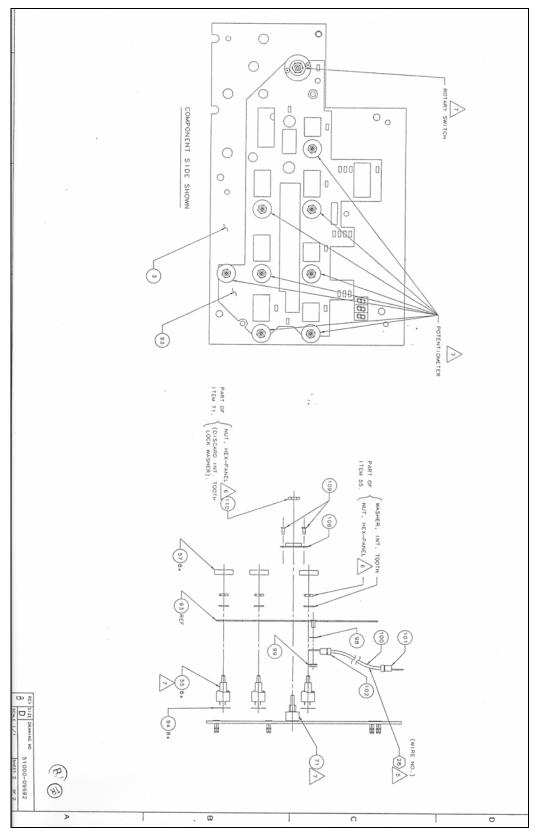


Figure 5-34:

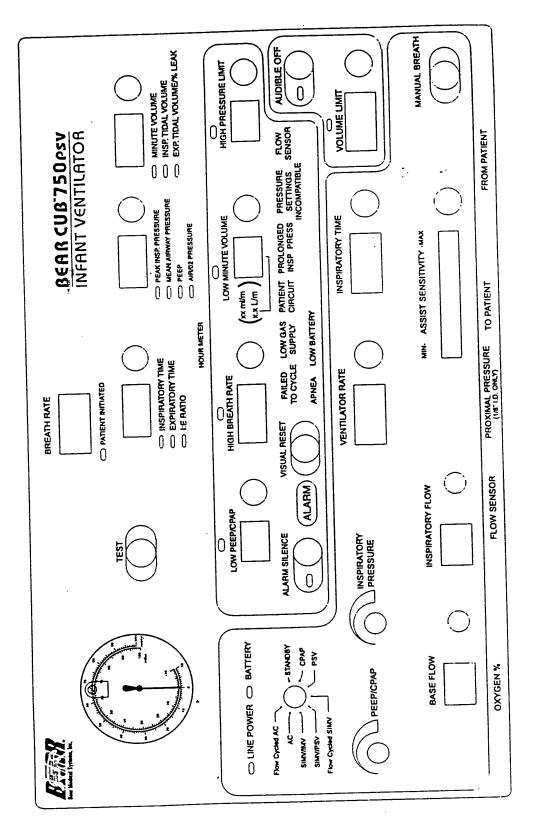


Figure 5-35

Chapter 6 Troubleshooting

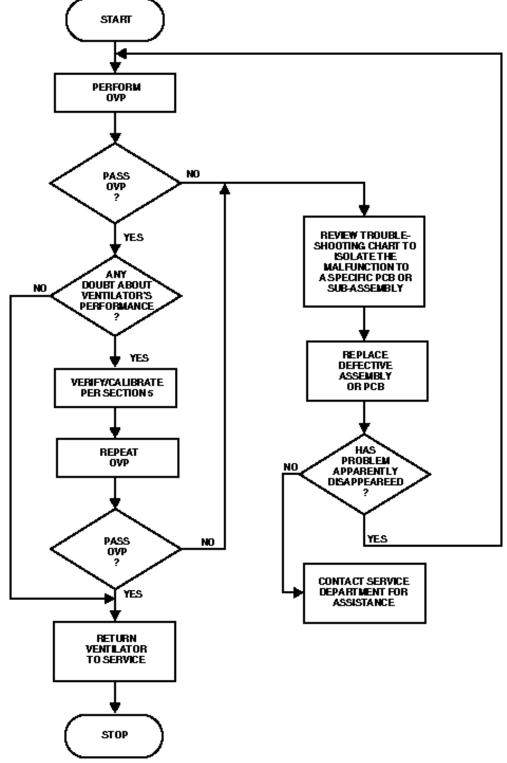


Figure 6-1: Troubleshotting Decision Tree

Table 6-2: Troubleshooting

Symptom	Possible Causes	Corrective Action
Failed To Cycle Alarm	 Air and Oxygen Pressure Have Decreased Below 24 ± 2 PSIG. Power Supply Failure. System Supply Failure. System Software Failure. 	 Verify Inlet Air and O₂ Pressure Entering The Ventilator. Verify Calibration of Air and Pressure Transducers On Control PCB. Verify Power Supply Voltages At The 15 Pin Header Connection Labeled Tp1 On The Control PCB Per The Table Below. If Out of Specification, Replace Power Supply.
		Voltage Test Pt Ground Pt
		+5.0 VDC TP1-1 T1P-13 ± 5% (4.75-5.25) VDC +7.0 VDC TP1-6 TP1-7
		± 5% (6.65-7.35) VDC +10.0 VDC TP1-8 TP1-9 ± 5% (9.5-10.5) VDC -10.0 VDC TP1-10 TP1-9
		± 5% (10.5) VDC -15% (8.5) VDC
		 Remove and Replace Control PCB. Remove and Replace System EEPROM (U-18 On Control PCB)
Low PEEP/CPAP and Low Inspiratory Pressure Alarms Faulty or Out of Specification.	Calibration Pressure Transducer. Defective Pressure Transducer.	 Calibrate Pressure Transducer Per Section 5 of This Manual. Remove and Replace Control PCB.
Pressure Limit Control Does Not Function Correctly. Pressure Limit Not Within	 Calibration Pressure Transducer. Defective Control PCB. Defective Pressure Limit Valve. 	 Calibrate Pressure Transducer Per Section 5 of This Manual. Remove and Replace Control PCB. Remove and Replace Pressure Valve.
Specifications. No Delivered Inspiratory Flow.	Defective Flow Control Solenoid Valve. Defective Control PCB.	Remove and Replace Flow Control Valve Assembly Remove and Replace Control PCB.
Base and/or Inspiratory Digital Flow Readings Do Not Agree With Actual Measured Flow.	Flow Valve Calibration.	Perform Flow Valve Calibration Per Section 5 of This Manual.
PEEP/CPAP Levels Will Not Adjust.	Defective PEEP Valve. Air/O Differential	Remove and Replace PEEP Valve Assembly. Perform Differential Pressure
Oxygen Percentages Are Not Within Specification.	 Air/O₂ Differential Pressure Greater Than ± 2 CmH₂O. Air and/or O₂ 	Calibration Per Section 5 of This Manual. Replace Air and/or Oxygen

01	Bassilla C	0
Symptom	Possible Causes	Corrective Action
	Regulator(S) Defective. 3. Defective Oxygen Blender. 4. Defective Cross-Over Check Valve.	Regulator. 3. Replace Oxygen Blender. 4. Replace Defective Check Valve.
Front Panel Control(S) Will Not Adjust.	Defective Front Panel Potentiometer(S).	Remove and Replace Display PCB.
Base and Inspiratory Flow Cycles But No Pressure Building During Inspiration. No Flow Out of TO PATIENT Outlet.	 Defective Dump Solenoid Valve. Defective Control PCB. Adjustable Overpressure Relief Valve Setting. 	 Remove and Replace Dump Solenoid Valve. Remove and Replace Control PCB. Evaluate/Adjust Valve Setting.
Pressure Settings Incompatible Alarm.	Inspiratory Pressure Level Set Below Peep/Cpap Level. Control PCB Has Lost Calibration Data. Defective Control PCB.	 Evaluate Pressure Limit and PEEP/CPAP Level Settings. Calibration Control PCB Per Section 5 of This Manual. Remove and Replace Control PCB.
Ventilator Will Not Turn On.	 Internal Battery Not Connected. Internal Battery Discharged Below Minimum Operating Voltage. Internal Battery Defective. Ventilator Not Plugged In To Wall Ac Power. 	 Connect Internal Battery. Re-Charge Internal Battery Connect Ventilator Power Cord To A Wall AC Outlet. Remove and Replace Internal Battery. Connect Ventilator Power Cord To A Wall AC Outlet.
Audible Alarm Does Not Activate.	Wiring Connection. Defective Alarm Speaker. Defective Control Pcb.	 Verify Connection of P1 of Audible Alarm Cable To J1 of Controller Pcb. Remove and Replace Alarm Speaker Sub-Assembly. Remove and Replace Control Pcb.
	Flow Sensor Not Connected. Flow Sensor Not Installed In Patient Circuit. Occluded Flow Sensor and/or Endotracheal Tube. Defective Flow Sensor.	Connect Flow Sensor To Both Ventilator Connector and 4 Way Patient Connector. Install Flow Sensor. Remove Occlusion. Remove and Replace Flow Sensor.
"Settings Incompatible" Alarm; E.Fl. or E.Pl Flashing.	Incompatible Volume Limit Setting.	Evaluate Volume Limit Setting Versus Flow and Pressure Limit Settings.
Inspiratory Pressure Too Low.	 Control Pin In Exhalation Valve Sticking. Defective Exhalation Valve Diaphragm. Defective Exhalation 	 Clean Control Pin. Verify Freedom of Movement. Remove and Replace Exhalation Valve Diagram. Remove and Replace Exhalation

Symptom	Possible Causes	Corrective Action
	Valve.	Valve.
	4. Adjustable Overpressure	Evaluate/Adjust Valve Setting.
	Relief Valve Setting.	5. Remove and Replace Aopr Valve.
	5. Adjustable Overpressure	
	Relief Valve Leaking	
	(With 1 L/Min Flow	
	Setting).	

Chapter 7 Removal & Replacement

WARNIINGS

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

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

Interior Access

- 1. If connected, remove cables leading to RS-232 and Analog outputs ports of the ventilator.
- 2. Remove the seven screws indicated in Figure 8-1.
- 3. Slide the cover off of the unit applying slight pressure to the outside bottom portion of the cover.
- 4. Remove the two screws indicated in Figure 8-2. The standoff tubes will drop free when the screws are removed.

NOTE

The front portion will swing forward freely when the screws are removed. Take care to ensure that the front swings slowly to avoid damage to the unit.

5. The front portion of the unit will drop forward, stopping when the end of the retaining cord is reached. See Figure 8-3.

Flow Valve Assembly Removal

- 1. Disconnect hoses and connectors to the assembly.
- 2. Remove the four screws from the flow valve bracket, indicated in Figure 8-4.
- 3. Remove the Flow Valve Assembly from the unit.
- 4. To install, reverse removal procedure.

Control PCB Removal

- 1. Disconnect all hoses and connectors from the board.
- 2. Remove screw shown in Figure 8-5.
- 3. Lift board carefully from four retainer points.
- 4. Remove board from unit.
- 5. To install, reverse removal procedure.

Display PCB Removal

- 1. Remove control PCB . See Control PCB Removal Figure 8-5.
- 2. Remove five screws shown in Figure 8-6.
- 3. Disconnect ground wire.
- 4. Remove board from unit.
- 5. To install, reverse removal procedure.

Air/O₂ Regulator Removal

- 1. Remove Air/O₂ fittings from the rear of the ventilator. See Figure 8-7.
- 2. Remove all hoses necessary to free the regulator assembly.
- 3. Remove three screws on rear panel.
- 4. Remove assembly from ventilator. See Figure 8-8

Blender Removal

- 1. Remove all hoses and wiring connected to the blender.
- Loosen allen screws of knob located on the front of the ventilator. Remove knob. See Figure 8-9.
- 3. Remove three screws located behind the knob. See Figures 8-10 and 8-11
- 4. Remove blender from unit.
- 5. To install, reverse order of removal.

Exhalation Valve Removal

- 1. Remove all hoses and wiring connected to the valve.
- 2. Remove three screws located on mounting plate. See Figure 8-12.
- 3. Remove Exhalation Valve from the ventilator.
- 4. To install, reverse removal procedure.

Chapter 8 Preventive Maintenance

Replacement Parts

50000-13040 PM Kit contains the following parts:

Air Inlet Disc Filter (1)	52000-00551
O-ring (1)	53021-01012
O2 Inlet Disc Filter (1)	52000-00552
O-ring (1)	53021-01011
Prox Line Filter (1)	51000-01122
Flow Valve Input Filter (1)	52000-01187
Flow Solenoid Pilot Filter (1)	52000-02097
Air Regulator (1)	52000-00129

Install the following parts using this document and related documents mentioned. Perform Calibration Verification Procedure and Operational Verification Procedure as described

Recommended Service Procedure

Preventive Maintenance on the BEAR CUB™ 750vs Infant Ventilator should be completed at least once per year. Maintenance is intended to be done in the hospital by a Bear Medical Products Authorized Service Technician or a Bear Medical Products Trained Hospital Service Technician.

Ventilator Preventive Maintenance includes:

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

CAUTION

Before using any test equipment (Electronic or Pneumatic) for calibration procedures (other than Operational Verification), the accuracy of the instruments must be certified by a testing laboratory. The laboratory master test instruments must be traceable to the U.S. Bureau of Standards or Equivalent. When variances exist between indication and actual values, the calibration curves provided for each instrument by the testing laboratory must be used to establish the actual correct values. This certification should be performed at least once every six months. More frequent certification may be required based on usage and environment.

Exterior Inspection

- 1. Turn off the ventilator and disconnect from AC power and pressurized gas at the wall sources.
- 2. Clean the exterior of the unit with water or a solution of 70% Isopropyl Alcohol solution only. Wipe all surfaces with a soft cloth or disposable wipe moistened in the cleaning solution.
- Inspect the exterior surfaces of the ventilator for broken or loose knobs. Check
 the display panel for scratches, cracks and alignment of LED indicators.
 Check all front and rear panel fittings, circuit breakers and accessories for
 security. Check the AC electrical cord and plug for damage. Record the
 reading of the hour meter on the maintenance check list.
- 4. Replace the ambient air intake filters at the rear of the ventilator.

CAUTION

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

Interior Inspection

- 1. Open the Ventilator.
- 2. Vacuum all surfaces inside the ventilator. Be sure to reach areas around connectors, circuits boards and pneumatic assemblies.
- Visually inspect for any overheated components, loose connectors, damaged wires or tubing, kinked tubing, loose ribbon cables, loose or missing hardware, signs of water or other residue inside Tygon tubing, loose Tywraps, poor connector crimps or loose fasteners.

Specifications

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

WARNING

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

Calibration and Verification Procedure

Perform Calibration and/or Calibration Verification Procedures as described in chapter 4 of this manual.

CAUTION

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

Ground Resistance Test

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

- 1. Connect a properly functioning leakage and grounding tester between the ground connection and the hospital grade AC plug (middle lug) and the chassis of the ventilator (any unpainted exposed metal part).
- 2. With the tester connected and operating, there should be no more than 0.10 ohms resistance between the plug ground connector, and the ventilator chassis ground.

Current Leakage Test

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

- 1. Connect the ventilator to a properly functioning current leakage tester.
- 2. Turn Mode switch to CPAP and tester on.
- 3. Current leakage should be less than 100 microamps, grounded and ungrounded.

Operational Verification Procedure

After Completing the Preventive Maintenance Procedure, perform the Operational Verification Procedure (OVP) per Section 3, of this Manual. Ensure that the ventilator is functioning properly. Complete an Operational Verification Procedure Checklist form and attach it to the PM Checklist form. See the OVP for specific instructions.

Figure 8-1: Ventilator Back Panel

BEAR CUB™ 750vs Infant VENTILATOR PREVENTIVE MAINTENANCE CHECK LIST

Serial Number	Hour meter reading			ıy's date	
Service Location			Service Organization		
Address			Address		
City, State, Zip			City, State, Zip		
Contact					
Phone ()					
VERIFICATION STEPS					
Step	Pass	Fail	Step	Pass	Fail
Inspection/Clean External			Machine Transducer Calibration		
Inspection/Clean Interior			Differential Transducer Calibration		
Replace Air/O2 Filter			Proximal Transducer Calibration		
Replace O-ring			O2 Transducer Calibration		
Replace Prox Line Filter			Air Transducer Calibration		
Replace Flow Valve Filter			Base Flow Calibration		
Replace Solenoid Filter			Inspiratory Flow Calibration		
Replace Air Regulator			Verify FiO2		
Air-O2 Regulator Calibration			Complete OVP		
specified in the che	cklist.	To do s	f it does not pass all of the p so could result in personal i the ventilator to a Viasys So	injury ir	ncluding

Signature_____

or a Viasys trained Service technician for appropriate repair and/or calibration

Chapter 9 RS-232 Protocol

Scope

This document defines both the hardware and software protocol for the RS-232 communication port on the BEAR® 1000 Adult Ventilator, the BEAR CUB™ 750vs Infant Ventilator, and the BEAR® Graphics Display. Throughout this document the ventilator shall be defined as the SENDING device, that which transmits real time data and responds to requests for data in the form of other parameters. This is true even if the Graphic Display is in place acting as a repeater and providing data to a third device.

Hardware Definition

Connector: Male 9-pin DSub connector (on the Ventilator).

Duplex: Full

Baud Rate: Selectable 1200, 2400, 9600, or 19200

Data: 8-bit character

1 Start bit, 1 Stop bit

No parity bit

Pin Assignment

IBM standard 9-pin version of RS-232-C. The ventilator, is DTE and will interface to any DCE device through a cable wired 1 to 1. (See table 9-1).

Table 9-1: Pin Assignment

DTE Name	DTE Pin	Direction	DCE Pin	Comment
DCD	1	<<	1	Not used by Ventilator
RxD	2	<<	2	
TxD	3	>>	3	
DTR	4	>>	4	
GND	5		5	
DSR	6	<<	6	Not used by ventilator
RTS	7	>>	7	Tied High @ ventilator
CTS	8	<<	8	
RI	9	<<	9	Not used by ventilator

Where: DCD=Data Carrier Detect DSR=Data set ready
RXD=Receive Data RTS=Request to send
T x D=Transmit Data CTS=Clear to send
DTR=Data Terminal Ready RI=Ring indicator
GND=GROUND

Alternatively, the ventilator can be interfaced to a DTE device with the following "null-modem" interface. (See table 9-2).

Table 9-2: Alternate Pin Assignment

DTE Name	DTE Pin	Direction	DTE Pin	DTE NAME
GND	5		5	GND
RxD	2	<<	3	TXD
TxD	3	>>	2	RXD
RTS	7	>>	1	DCD
DTR	4	>>	6 & 8	DSR & CTS
RI	9	Not used	9	RI

Software Protocol

The ventilator's RS-232 port has two modes of communication. The first mode continuously outputs real time data every 10 msec and will provide non-real time data upon request from an external device. This mode requires 19.2 kBaud data rate. This second mode will only provide non-real time data upon request from an external device (all other data rates). The mode of communication is selected by the user upon installation simultaneously with and as a function of the baud rate.

Continuous Output (Default Mode)

The continuous output mode communicates at 19.2 kBaud and sends out the real time data (flow, pressure, breath phase, breath type, and alarm status) every 10 msec. Upon request, non-real time data will also be sent, however it may delay the real time data by up to 25 msec. Note, the real time data is queued by the ventilator so that it is only delayed and not lost.

Data Upon Request

All non-real time data, consisting of control settings, alarm settings and status, and monitor values will be provided upon request from an external device. This data can be requested at any transmitted baud rate. The buffer for requested data will be limited, but will have the capability such that at least three (3) transactions (requests) can be handled (queued) at a time. Any additional data requests prior to completion of a corresponding number of message transmissions may be ignored by the ventilator.

Data Format

The messages are sent and received in variable length data packets. All packets are preceded by a SYN character, and terminated by a check sum.

The purpose of the SYN character is to enable the receiver to detect the start of a message, therefore it is an illegal character within a data packet. If the binary value of SYN (16h) or DLE (10h) appears in the data packet (including the Check Sum, see below) an escape sequence will be used. The illegal character will be preceded by the DLE character and 10h will be subtracted from its original value.

The second character in each packet (both transmitted and received) is defined as the ID character. Valid ID characters are defined in tables 9-3, 9-4 and 9-5.

All other ID's are undefined at this time or are for internal use only. Any request for data using an undefined ID will be responded to by either the transmission of undefined data or will be ignored by the ventilator.

The Check Sum [Check] is defined as the one's complement of the sum of all data contained in the data packet excluding the "SYN" and "CHECK" characters.

Table 9-3: Valid Requests Received by the Ventilator

Format: [SYN]	[ID]	[Check]
[SYN]:	16h	
[ID]:	20h	Send all Adult Control Settings
	40h	Send all Adult Alarm Settings/Status
	60h	Send all Adult Monitored Data
	A0h	Send all Infant Control Settings
	C0h	Send all Infant Alarm Settings/Status
	E0h	Send all Infant Monitored Data
[Check]:	Check Sum	

Table 9-4: Valid Message Transmitted by the Ventilator

Format: [SYN]	[ID]	[Data #1] [Data #n] [Check]
[SYN]:	16h	
[ID]:	00h0Fh	Real Time Data, No Alarms
	10h 1Fh	Real Time Data, Alarm Condition
	20h	Adult Control Settings
	40h	Adult Alarm Settings
	60h	Adult Monitor Settings
	A0h	Infant Control Settings
	C0h	Infant Alarm Settings
	E0h	Infant Monitor Settings
[Data #X]:	Binary Data	
[Check[:	Check Sum	

Table 9-5: Real Time Data

```
Mode:
         Continuously, every 10-msec
Length: 6 Bytes
Format:
[SYN]
           [ID] [Data #1] [Data #3]
                                      [Check]
         Bit
[ ID ]:
             7 — 0
              6 — 0
         Bit
              5 - 0
         Bit
                               Alarm Condition
         Bit
              4 — X
                                Breath Type
               3 — Y
         Bit
         Bit
               2 - Y_{-}
         Bit
               1 — Y-
                               Breath Phase
         Bit
               0 - Z
Alarm Condition (x):
         0
              — No Alarm
         1
               — Alarm
Breath Type (yyy):
         000 — Volume
001 — Spontaneous
         010 — Pressure Control
         011 — Pressure Support
         100 — Time Cycled/Pressure Relief
         101 — Reserved
         110 — Reserved
         111 — Reserved
Breath Phase (z):
         0
              Inspiration
               Exhalation
[Data #1]
                      [Data #2]
                                       [Data #3]:
XXXXXXX
                      xxxxxyyy
                                       ууууууу
                       MSB
                      LSB\MSB
                                        LSB
x: Net Flow (Insp-Exhale) - 13 bits
                      -300 to +300 lpm
Range:
Binary Scale:
                      1 bit = 0.1 \text{ lpm}
                      0 to 6000
Binary Range:
Zero offset:
                      3000
y: Proximal Pressure - 11 bits
                      -60 to +140 cmH2O
Range:
Binary Scale:
                      1 bit = 0.1 \text{ cmH2O}
Binary Range:
                      0 to 2000
Zero offset:
                      600
```

Table 9-6: Adult Ventilator Control Settings

Mode: Upon Request								
Length:	Length: 16 Bytes							
Format:								
LOVALI UD:								
[SYN][ID]	j įData #	[£] 1] [Data #13]	[Спеск]					
[ID]: 20h	າ							
[Data #1]	Mode/Wave							
	Bit 7 —	X						
	Bit 6 —	X						
	Bit 5 —							
	Bit 4 —							
	Bit 3 —							
		Reserved	(0)					
		Reserved	(0)					
	Bit 0 —	Reserved	(0)					
Mode:								
	000 —	Assist Control						
	001 —	SIMV/CPAP/P	SV					
	010 —	Pressure Cont	rol					
	011 —	Reserved						
	:	:						
	111 —	Reserved						
Wave:		_						
	00 —	Square						
	01 —	Sine						
	10 —	Decelerating						
	11 —	Reserved						
[Data #2]	Switches:	4000/ 00 /4	0 (0)					
		100% O2 (1=c						
		Sigh On (1=c						
		Pres Aug (1=c						
		Nebulizer (1=c	on, υ=οπ)					
		Reserved (0)						
		Reserved (0) Reserved (0)						
		Reserved (0)						
[Doto #n]				Dinami Saala	Pinory Pongo			
[Data #n]	Parameter	Range	;	Binary Scale	Binary Range			
[Data #3]	Tidal Vol	0.03 -	2.00L	0.01 L	3 - 200			
[Data #4]	Rate 0-120 bpm 0.5 bpm 0 - 240							
[Data #5]	Peak Flow 5 - 150 lpm 1 lpm 5 - 150							
[Data #6]	Percent O2 21 - 100% O2 1% O2 21 - 100							
[Data #7]	Assist Sens 0.2 - 5.0 cmH2O 0.1 cmH2O 2 - 50							
[Data #8]	PSV/Insp F		cmH2O	1 cmH2O	0 - 80			
[Data #9]	Insp Pause 0.0 - 2.0 sec 0.1 sec 0 - 20							
[Data #10]	MMV	0 - 50		1 Liter	0 - 50			
[Data #11]	Insp Time	0.0 - 5		0.1 sec	0 - 50			
[Data #12]	cc		.5 ml/cmH2O	0.1 ml/cmH2O	0 - 75			
[Data #13]	Pres Slope							

Table 9-7: Adult Ventilator Alarm Settings / Status

Mode:	Upon Request		***************************************					
Length:	14 Bytes							
Format:	[SYN]	[ID]	[Data #1]	[Data #13]	[Check]			
[ID]: 40h								
[Data #1]	Alarm Status Byte - Bit 7 — High Min Bit 6 — Low Min Bit 5 — High Insp Bit 4 — Low Insp Bit 3 — High Bas Bit 2 — Low Bas Bit 1 — High Rat Bit 0 — Low Rate	Vol Vol Pres Pres e Pres e Pres e	(1=on, 0=off) (1=on, 0=off) (1=on, 0=off) (1=on, 0=off) (1=on, 0=off) (1=on, 0=off) (1=on, 0=off) (1=on, 0=off)					
[Data #2]	[Data #2] Alarm Status Byte - 2 Bit 7 — I:E Limit (1=on, 0=off) Bit 6 — Run Diagnostics (1=on, 0=off) Bit 5 — Gas Fail (1=on, 0=off) Bit 4 — Failed to Cycle (1=on, 0=off) Bit 3 — Reserved (0) Bit 2 — Reserved (0) Bit 1 — Reserved (0) Bit 0 — Alarm Silence (0)							
[Data #n]	Parameter	Range		Binary Scale	Binary Range			
[Data #3] [Data #4] [Data #5] [Data #6] [Data #7] [Data #8] [Data #9] [Data #10] [Data #11]	High Min Vol Low Min Vol High Insp Pres Low Insp Pres High Base Pres Low Base Pres High Rate Low Rate I:E Override	3 - 99 (0 - 55 (L 0 cmH2O cmH2O cmH2O cmH2O 5 bpm	1 L 1 L 1 cmH2O 1 cmH2O 1 cmH2O 1 cmH2O 1 bpm 1 bpm n/a	0 - 80 0 - 50 0 - 120 3 - 99 0 - 55 0 - 50 0 - 155 3 - 99			

Table 9-8: Adult Ventilator Monitor Status

Mode:	Upon Request					
Length:	18 Bytes					
Format: [SYN] [ID]		[Check]				
[ID]:	60h					
Bit 7 Bit 6 Bit 5 Bit 4 Bit 3 Bit 2	Bit 6 — Sigh Breath (1=on, 0=off) Bit 5 — Patient Effort (1=on, 0=off) Bit 4 — MMV Active (1=on, 0=off) Bit 3 — Reserved (0) Bit 2 — Reserved (0) Bit 1 — Reserved (0)					
[Data #n]	Parameter	Range	Binary Scale	Binary Range		
[Data #2] [Data #3]	MSB Tidal Vol LSB " "	0 - 9.99 L	0.01 L	0 - 999		
[Data #4] [Data #5]	MSB Minute Vol LSB " "	0 - 99.9 L	0.1 L	0 - 999		
[Data #6] [Data #7]	MSB Spon Min Vol LSB " "	0 - 99.9 L	0.1 L	0 - 999		
[Data #8] [Data #9]	MSB 1/I:E Ratio LSB " "	0.00 - 4.0	0.01	0 - 400		
Data #10] [Data #11]	Total Rate Spon Rate	0 - 155 bpm 0 - 155 bpm	1 bpm 1 bpm	0 - 155 0 - 155		
[Data #12] [Data #13] [Data #14] [Data #15]	%MMV Mean Pres Peak Pres Plateau Pres	0 - 100 %/hr 0 - 140 cmH2O 0 - 140 cmH2O 0 - 140 cmH2O	1 %/hr 1 cmH2O 1 cmH2O 1 cmH2O	0 - 100 0 - 140 0 - 140 0 - 140		

Table 9-9: Infant Ventilator Control Settings

Mode:	Upon Request			
Length:	14 Bytes			
Format: [SYN] [ID]	[Data #1] [Data #1	1] [Check]		
[ID]: A0h				
[Data #1]	Bit 3 — Flow Settin		1=on, 0=off)	off)
Mode: 000 001 010 011 thru 111	— Assist Control— SIMV/IMV— CPAP— Reserved			
[Data #n]	Parameter	Range	Binary Scale	Binary Range
[Data #2] [Data #3] [Data #4] [Data #5] [Data #6] [Data #7] [Data #8]	Breath Rate Insp Time MSB Insp Time LSB Volume Limit MSB Volume Limit LSB Insp Flow Base Flow	0 - 150 BPM L 0.10 -3.00 sec " 5 - 300 mL " 1 - 30 L/min 1 - 30 L/min	1 BPM 0.01 sec " 1 mL " 0.5 L/min 0.5 L/min	0 - 150 10 - 300 " 5 - 300 " 2 - 60 2 - 60
[Data #9] [Data #10] [Data #11]	Assist Sens Insp Pres PEEP/CPAP	0.2 - 25.5 L/min Reserved Reserved	0.1 L/min	2 - 255 0 0

Table 9-10: Infant Ventilator Alarm Settings/Status

Mode:	Upon Request			
Length:	10 Bytes			
Format: [SYN] [ID]	[Data #1] [Data #7]	[Check]		
[ID]:	C0h			
[Data #1]	Alarm Status Byte-1 Bit 7 — High Breatl Bit 6 — Low Breath Bit 5 — Low Inspira Bit 4 — Apnea Bit 3 — Patient Circ Bit 2 — Prolonged Bit 1 — High Press Bit 0 — Reserved	n/CPAP (1=on atory Pressure (1=on, 0=off) cuit Fault (1=on Insp Pres (1=on	, 0=off) , 0=off) (1=on, 0=off) , 0=off) , 0=off) , 0=off)	
[Data #2]	Alarm Status Byte-2 Bit 7 — Flow Sensor Bit 6 — Run Diagnor Bit 5 — Low Gas S Bit 4 — Low Batter Bit 3 — Failed to C Bit 2 — Reserved Bit 1 — Reserved Bit 0 — Alarm Siler	ostics (1=on (1=on y Supply (1=on ycle (1)) (1) (0)	, 0=off) , 0=off) , 0=off) , 0=off) , 0=off)	
[Data #n]	Parameter	Range	Binary Scale	Binary Range
[Data #3] [Data #4] [Data #5] [Data #6] [Data #7]	High Breath Rate Low PEEP/CPAP Low Insp Pres High Pressure Limit Apnea	0 - 255 BPM -10 - 50 cmH2O 3 - 99 cmH2O 15 - 85 cmH2O 5 - 30 sec	1 BPM 1 cmH2O 1 cmH2O 1 cmH2O 1 sec	0 - 255 0 - 60 3 - 99 15 - 85 5 – 30

Table 9-11: Infant Ventilator Monitor Status

Mode:	Upon Request			
Length:	20 Bytes			
Format:				
[SYN]	[ID] [Data #	#1] [Data #11]	[Check]	
[ID]:	E0h			
[Data #1]	Breath Data			
_		ontrol Breath	(1=on, 0=off)	
		tient Effort	(1=on, 0=off)	
		eserved	(0)	
		eserved	(0)	
		eserved eserved	(0)	
		eserved	(0) (0)	
		eserved	(0)	
[Data #n]	Parameter	Range	Binary Scale	Binary Range
[Data #2]	Tidal Volume MSB	_	1 mL	0 - 500
[Data #3]	Tidal Volume LSB	"	"	"
[Data #4]	Minute Volume MS	SB	0 - 30.0 L	0.1 L 0 -
300			"	,,
[Data #5]	Minute Volume LSI			
[Data #6]	% Tube Leak	0 - 100%	1%	0 - 100
[Data #7] [Data #8]	Insp Time MSB Insp Time LSB	0 - 3.10 sec	0.01sec	0 - 310
[Data #6] [Data #9]	Exp Time LSB	0 - 99.99 sec	0.01 sec	0 - 9999
[Data #10]	Exp Time LSB	"	"	"
[Data #11]	I:E Ratio			
	[Bit 7=Direction]	1 if 1:X.X, 0 if X.X:	1	
[Data #12]	Breath Rate	0 - 255 bpm	1 bpm	0 - 255
[Data #13]	•	0 - 99 cmH20	1 cmH20	0 - 99
[Data #14]		0 - 99.9 cmH20	0.1 cmH20	0 - 999
[Data #15]				
	Air Supply Pres	0 - 99 psig	1 psig	0 - 99
[Data #17]	O2 Supply Press	0 - 99 psig	1 psig	0 – 99

Chapter 10 Parts List

Pneumatic Sub Assembly	
Auxiliary Pressure Relief Valve	51000-04668
Air/O2 inlet Manifold Assembly	51000-09302
Oxygen Blender Assembly	
PEEP Valve Assembly	
Pressure Limit Valve Assembly	51-09308-02
Flow Control Valve	51000-09573
Exhalation Valve Assembly	
Sub-Ambient Over Pressure Relief Valve	51000-40023
Pressure Control Assembly	51000-09484
Proximal Pressure Gauge	52000-00216
Electronic Sub Assemblies	
Power Supply Module	
(Includes Power Supply PCB)	51000-09301
Power Supply PCB	51000-09317
Display PCB	51000-09567
Control PCB	51000-09939
Flow Sensor Connector Assembly	51000-09353
Alarm Speaker Assembly	51000-09488
Battery, Sealed, Lead Acid, 12 VDC	51000-09530
Miscellaneous	
Knob, Front Panel	51000-09461
Knob, Rear Panel,	
Apnea-Alarm Volume	51000-00261
Knob, Mode Select	51000-09514
Knob, Oxygen Blending	56000-00268
Fuse, 0.5A, Slow Blow	56000-20079
AC Power Cord	56090-10540

Chapter 11 Repackaging Instructions

General

The packaging system for the BEAR CUB™ 750vs Infant Ventilator has been designed to provide a high degree of protection against shipping damage.

All shipments of BEAR CUB™ 750vs Infant Ventilators should be made using the complete packaging system.

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

Packaging Instructions

NOTE

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

The packaging carton consists of:

 Accessory Carton
 51000-09505

 Anti-static Bag 26"x22"x44"
 51000-06056

 Cavity pack-bottom
 51-09504-02

 Cavity pack-top
 51-09504-01

 Shipping Carton
 51000-09502

 Shipping Label
 51000-20038

Procedure

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

Figure 11-1: Packaging System Diagram

Addendum A: Release 4 Software

Addendum B: Bear Cub 750 PSV Infant Pediatric Ventilator System

Index

% of Tubing Leakage	17	Hourmeter	18
0 ₂ Blending		Humidity	21
air Regulator	41, 86	I:E Ratio	18
Alarm Loudness	15	Inlet O ₂ Pressure	18
Alarm Silence	16	Inputs	20
Alarms	15	Inspection	34
Altitude	21	Inspiratory Flow	14
Analog output	See	Inspiratory Pressure	15
AOPR Valve	26	Inspiratory Time	14, 17
Apnea	16	Interior	85
APNEA Interval	15	Line Power	17
Assemblies	45	Low Battery	16
Assist Sensitivity	15	Low Gas Supply	16
Assist/Control	13	Low Inspiratory Pressure	16
Auxiliary Gas Outlet	26	Low PEEP/CPAP	15
Battery	19	Maintenance	87
Blender	25, 86	Manual Breath	15
Breath Type	19	Mean Airway Pressure	18
Calibration	37	modes	13
Cleaning	22, 34	Monitors	17
component Removal	85	O ₂ Regulator	41, 86
component Replacement	85	Operational Verification	29
contact information	3	ordering information	
Control PCB	85	Outputs	
Controls	13	Over Pressure Relief	15
CPAP	13	OVP	29, 89
Current Leakage	89	Packaging	107
Digital Output	19	Parts List	105
Disinfection	21	Patient Circuit	16
Display PCB	86	Peak Inspiratory Pressure	18
Dump Solenoid	26	Pediatric Ventilator System	111
Electrical inputs	20	PEEP	14
Emissions/Susceptibility	19	Physical Dimensions	
Environmental Specifications		Pin Assignment	
Exhalation Minute Volume	17	Pneumatic inputs	
Exhalation Valve	27, 86	Pneumatic output	20
Exhaled Tidal Volume	17	pneumatics	
Expiratory Time	18	Power Supply	
Failed to Cycle		Preset Values	19
Flow Control Valve	25	Pressure Control System	26
calibration	38	Pressure Settings Incompatible	16
Flow Sensor	,	Pressure Transducers	
Flow Valve Assembly	85	calibration	
Gas Inlet Conditioning		Prolonged Inspiratory Pressure	16
Ground Resistance		Proximal Airway Pressure	
High Breath Rate		Release 4 Software	109
High Pressure Limit	16	Repackaging	107

Replacement Parts	87	Sub-Ambient Valve	26
RS-232	93	Temperature	21
Schematics	45	Test	19
Service Procedure	87	Theory of Operation	23
Settings Incompatible	16	Total Breath Rate	17
Shipping	20	Troubleshooting	81
SIMV/IMV	13	Ventilator Electronics	27
Software Protocol	95	Ventilator Software	28
specifications	13	Visual Reset	16
STANDBY	13	Volume Limit	14
Sterilization	21	warranty	5
structure	23	·	