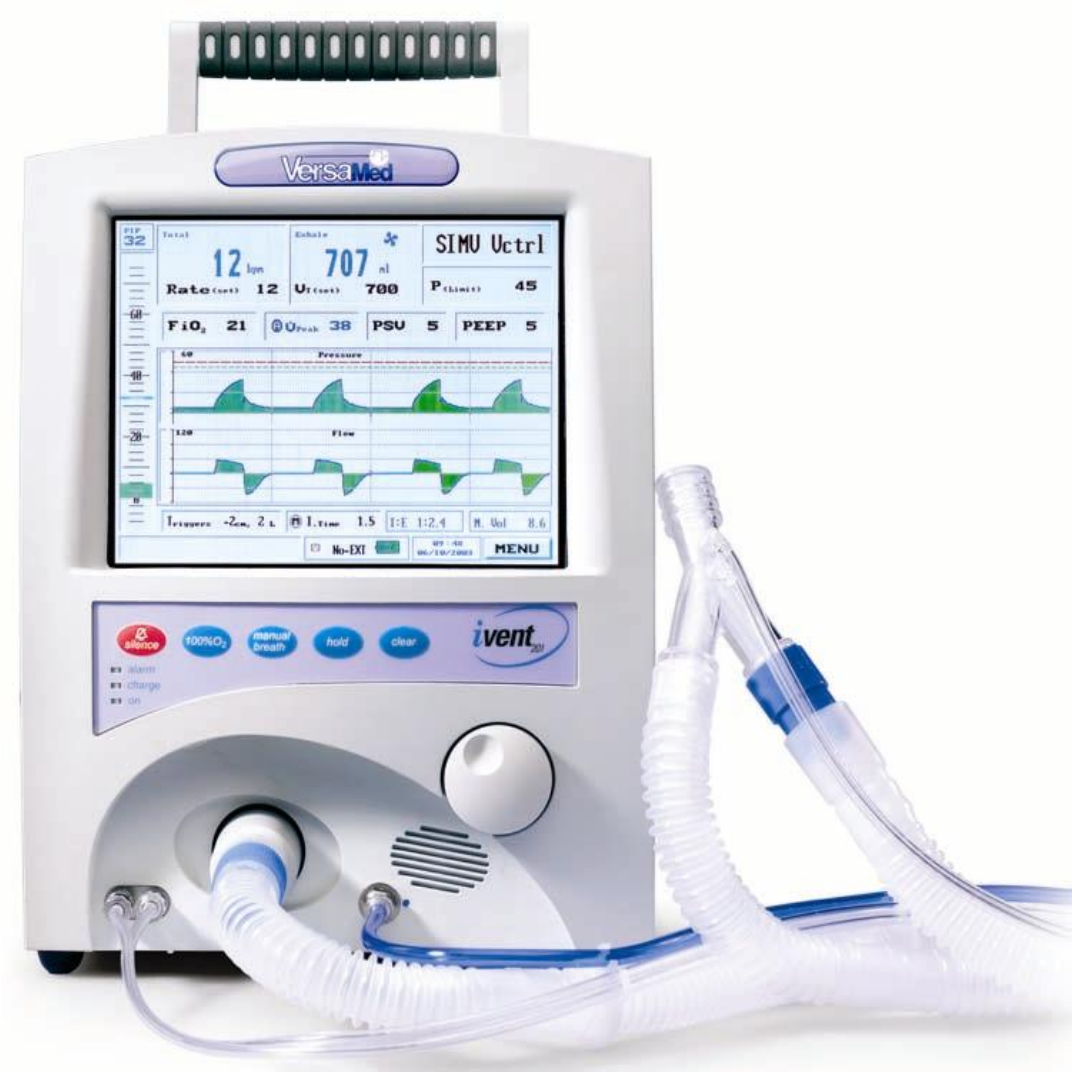
*i*Vent$_{201}$
Service Manual



Part No. SM-01-04 Rev. 4? Revised August 2005

CE 0473

SAFETY Before attempting to service or test the *i*Vent$_{201}$ ventilator please read this manual and the Operator's Manual in their entirety to familiarize yourself with all Cautions and Warnings.

Manufacturer's Address

VersaMed Medical Systems Inc.
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Pearl River, NY 10965
845-770-2840

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B-1040 Brussels
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+32-2-732-59.54
Fax: +32-2-732-60.03

Calling For Help

If you have a ventilator problem that you cannot solve and you purchased your ventilator directly from VersaMed, call:

800-475-9239 Customer Care and Service Assistance Line
or
866-483-6820 (866-iVent201)

If you have a ventilator problem that you cannot solve and you purchased your ventilator from an authorized VersaMed distributor, please contact your distributor directly to report the problem.

NOTE	If this ventilator has not been purchased directly from VersaMed, please ensure that it has been purchased from an authorized distributor of VersaMed. To obtain a list of authorized distributors contact VersaMed at sales@versamed.com.

visit our website: www.versamed.com

Table of Contents

Illustrations

Tables

Section 1 Introduction

1.1 Intended Use

This Service Manual describes the service, maintenance and test procedures for the *i*Vent$_{201}$ (hardware version 1.4). It is intended to ensure optimal functional operation and safety of the device.

This Service Manual should only be used by authorized VersaMed trained technicians.

This Service Manual must be used in conjunction with the Operator's Manual (OM-01-04) and is complementary to it.

The contents of this document are not binding. If any significant difference is found between the product and this document, please contact VersaMed for further information.

VersaMed reserves the right to modify the product without amending this document or advising the user.

IMPORTANT Technical information is supplied in this manual that is intended to facilitate a complete understanding of the ventilator's structure and function. Not every component or subsystem discussed in this manual is accessible or repairable in the field. The *i*Vent$_{201}$ was designed to provide easy access to serviceable areas of the ventilator. Whenever possible, this manual describes the practical (hands-on) aspect of a component or system.

1.2 General Description

The *i*Vent$_{201}$ is a portable, computer controlled, electrically powered ventilator providing continuous or intermittent ventilatory support to patients requiring mechanical ventilation, as prescribed by an attending physician.

The *i*Vent$_{201}$ features advanced software, electronic and mechanical technologies which, along with easy operation, provide effective and reliable ventilation.

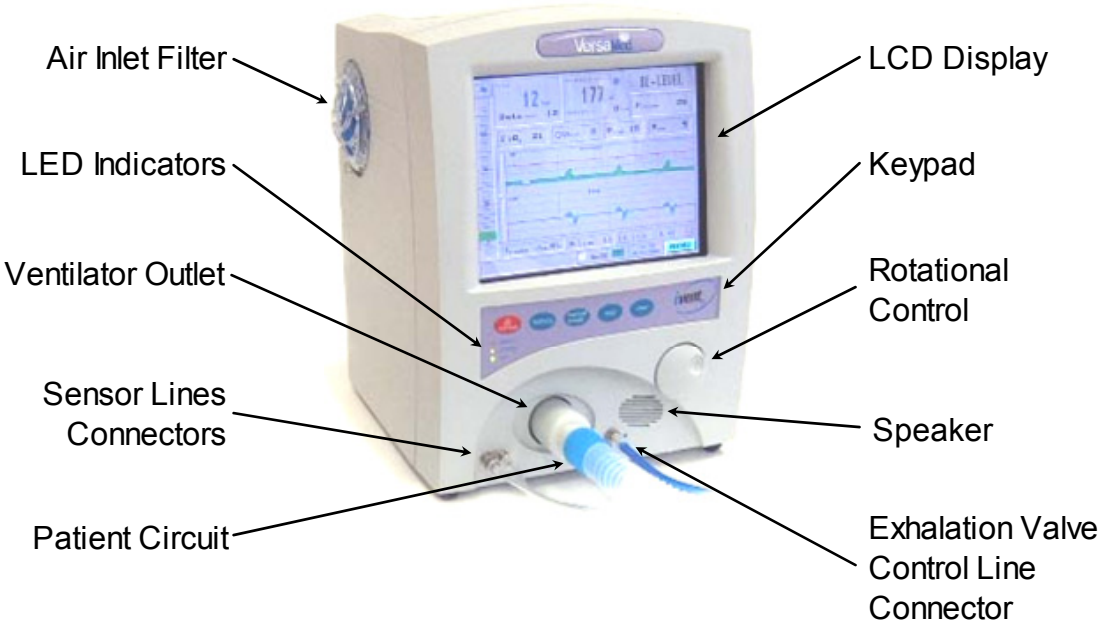


Figure 1-1: The *i*Vent$_{201}$ (front view)

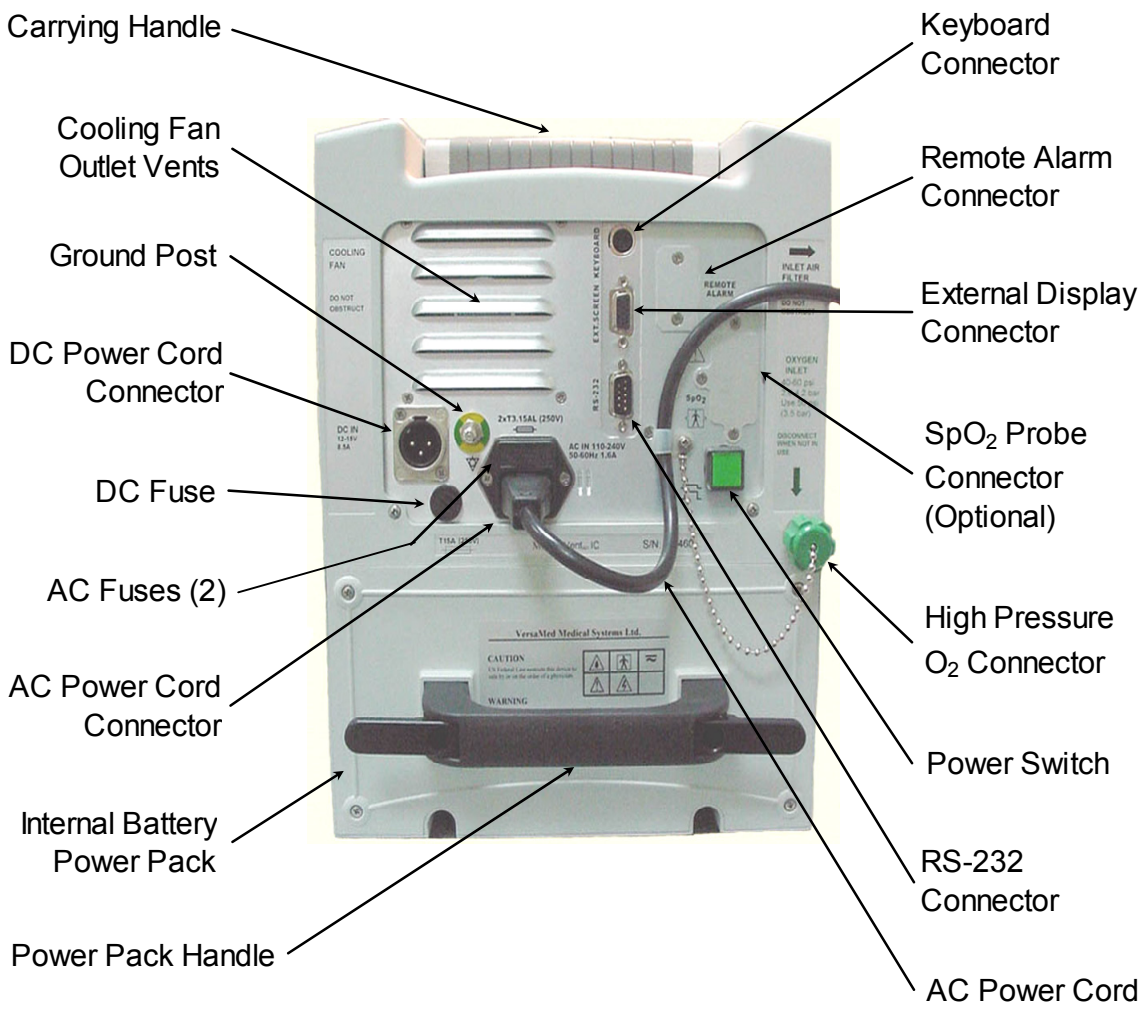


Figure 1-2: The *i*Vent$_{201}$ (rear view)

1.3 Safety Information

In accord with the important information herein, always comply with applicable national and local safety regulations.

Responsibility for the safe function of this equipment reverts to the owner or user in all cases where an unauthorized person performs service or repair and when the equipment is not used for its intended purpose.

1.3.1 Safety Regulations

The following medical electrical equipment safety standards have been met:	
IEC 60601-1-1	Medical Electrical Equipment - Part 1: General requirements for safety 1: Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2	Medical Electrical Equipment - Part 1: General requirements for safety 2: Collateral standard: Electromagnetic Compatibility (EMC)
IEC 60601-1-4	Medical Electrical Equipment - Part 1: General requirements for safety 4: Collateral standard: Programmable Electrical Systems
IEC 60601-2-12	Medical Electrical Equipment - Part 2-12: Particular requirements for the safety of lung ventilators – Critical care ventilators
UL 94 HB	Flammability

1.3.2 Technician Safety

1.3.2.1 Hazard Notices

Before disassembling or assembling the ventilator ensure that:

- The O_2 gas supply is disconnected
- The AC or DC power cords are disconnected
- The power switch is set to OFF

WARNING If the power switch is set to ON, the internal battery will continue to supply power to the PC Boards!

1.3.2.2 Calibration and Verification Test

After any servicing of the *i*Vent$_{201}$ ventilator, perform a Calibration and Verification Test according to the instructions in Section 5 and Section 6.

1.3.2.3 Handling PC Boards

- The PC boards contain components that are highly sensitive to static electricity.
- When coming into contact with circuit boards containing sensitive components, you must take precautions to avoid damaging the components (ESD protection).
- Always use a grounded wristband and grounded work surface when working with ESD sensitive components. Adequate service tools must also be used.
- PC boards (spare or exchanged parts) must always be kept in protective packaging for ESD sensitive devices.
- Remove and insert the PC boards very carefully to avoid damage to the connectors.

1.3.3 Important Safety Considerations

- Specially trained personnel must service the *i*Vent$_{201}$ at the specified periodic intervals described in Section 5. Any service or maintenance must be noted in a log book provided for that purpose in accordance with legal and civic regulations. It is recommended that service be performed as part of a service contract with VersaMed.
- The internal battery must be replaced every every year according to the instructions in this Service Manual. The stated battery backup time, approximately 60 minutes, can be guaranteed only if it is used according to the instructions provided in the Operator's Manual.
- Old or used non-functioning batteries and oxygen sensors must be returned to the place of purchase or to a place where they can be properly disposed of. Batteries and oxygen sensors must not be discarded with ordinary waste.
- A high voltage of 1800 Vrms exists on the DC-AC inverter unit. Do not touch this unit for at least 5 minutes after the ventilator is powered off.
- Only genuine VersaMed replacement parts should be used. Failure to comply may seriously impair the ventilator's performance, safety or reliability.
- Alteration or repair of the *i*Vent$_{201}$ beyond the scope of the service and maintenance instructions or by anyone other than an

authorized VersaMed service person could result in the product's failure to perform as designed.

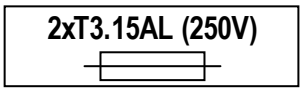
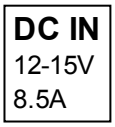
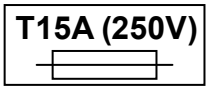
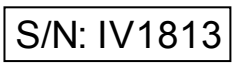
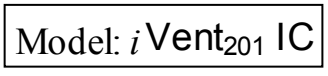
1.4 Labels and Symbols

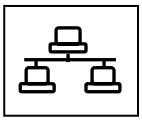
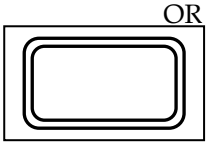
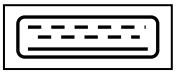
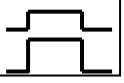
1.4.1 Symbols

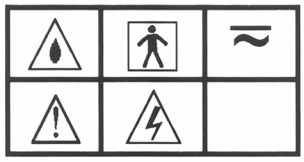
The following IEC 601-1 symbols appear on the ventilator:

Symbol	Definition
	Refer to documentation for further information
	Potential equalization (Ground Point)
	Direct Current (DC) and Alternating Current (AC)
	Dangerous voltage
	Type BF equipment
	Defibrillation proof, Type BF applied part
	IP54 – Degree of protection provided by the enclosure (dust protected and splash proof)

1.4.2 Labels

Location	Label
AC Connector	
AC Fuses	
Air Inlet	
Cooling Fan Vent	
Connector	
DC Fuse	
Device ID	
Device Product	

Location	Label
Ethernet Connector (not on all units}	
External Display Connector	**EXT. SCREEN** OR 
High Pressure Oxygen Inlet	**OXYGEN INLET** 40-60 psi 2.8-4.2 bar Use 50 psi (3.5 bar) **DISCONNECT WHEN NOT IN USE** 
Keyboard Connector	**KEYBOARD** OR 
Power Pack Fuse	**T15A (250V)**
Power Switch	**ON** **OFF** 
Remote Alarm Connector	**REMOTE ALARM**
Serial Communication Connector	**RS-232** **I 0 I 0 I** OR

Location	Label
Power Pack Product (inside)	**POWER PACK** P/N : 503A0012 **Caution:** This Power Pack contains a sealed Lead - Acid Battery. Disposal of this unit should be according to Environmental Safety Requirements for Lead-Acid batteries.
Pulse Oximetry Probe connector (optional; not on all units)	SpO_2
VersaMed	**VersaMed Medical Systems Inc.** **CAUTION** US Federal Law restricts this device to sale by or on the order of a physician.  **WARNING** Before use read Operator's Manual thoroughly. Before each use check equipment for proper operation. To be used by qualified medical or rescue personnel only. Versamed Medical Systems Inc. 2 Blue Hill Plaza Pearl River, NY 10965 USA C US CE 0473

Section 2 System Specifications

2.1 Specifications

2.1.1 Ventilation Modes

Assist/Control (A/C)

- Volume Controlled (A/C Vctrl)
- Pressure Controlled (A/C Pctrl)

Pressure Controlled (A/C Pctrl)

- Volume Controlled (SIMV Vctrl)
- Pressure Controlled (SIMV Pctrl)

Continuous Positive Airway Pressure (CPAP)

Pressure Support Ventilation (PSV)

Adaptive Bi-Level (A. BI-LEVEL)

2.1.2 Ventilation Performance and Controlled Parameters

Respiratory Rate	1 to 12 ±1 bpm , 12 to 50 ±2 bpm
Tidal Volume	100 to 2000 mL
Accuracy of Tidal Volume Delivery from the set value	±10% or ±10 mL (whichever is greater)
Accuracy of (Respiratory) exhale tidal Volume Measurement	±15% above 100 mL from actual reading or ±10 mL below 100 mL
Inspiratory Pressure Limit	5 to 80 ±5 cmH_2O
Inspiratory Time	Adaptive Time™ or 0.3 to 3 ±10% seconds
Peak Flow (PIF)	Adaptive Flow™ or 1 to 120 ±10% L/min Spontaneous to 180 ±10% L/min
Oxygen Mix (FiO_2)	21% to 100% ±5% FiO_2
PEEP	0 to 20 ±1 cmH_2O or ±10% (whichever is greater)

Trigger Sensitivity, Flow	Off or 1 to 20 L/min
Trigger Sensitivity, Pressure	Off or -0.5 to -20 cmH_2O
PSV	(0 to 60) ±10% cmH_2O
Positive Pressure Relief Valve	80 cmH_2O
Controlled Pressure	(5 to 80) ± 5 cmH_2O
FiO_2 at Power up	21%, 40%, 60%, 100% (selectable)
Purging Cycle Interval	1, 2, 5, 10 or off

2.1.3 Power Supply

External AC	100 to 240 V, 50-60 Hz, max. 1.6 A
External DC	12 to 15 V, max. 8.5 A
Internal Battery	Sealed Lead-Acid, 12V, 7.2-9 Ah (rechargeable)
Recharge Time	8 to 10 hours
Operating Time (internal battery)	Up to 2 hours (varies with ventilation parameters)

2.1.4 Oxygen Supply

High Pressure	40 to 60 psi (2.8 to 4.1 bar)

2.1.5 Size and Weight

Height	13 in / 33 cm
Width	9.5 in / 24 cm
Depth	10.3 in / 26 cm
Display	8.4 in / 21.3 cm diagonal
Weight	15.4 lb / 7 kg (without battery)
Battery Weight	6.5 lb / 3 kg
Overall Weight	22 lb / 10 kg

2.1.6 Environmental Specifications

Operating Temperature	-15 to +50 °C / 5 to +122 °F
Storage Temperature	-15 to +70 °C / 5 to +158 °F (without battery)
	-15 to +30 °C / 5 to +86 °F (with battery)
Relative Humidity	15 to 95% @ 30 °C / 86 °F
Water and Dust Resistance	IP54 (splash proof)
Atmospheric Pressure	430 - 825 mmHg (up to 15,000 feet)
Vibration	IEC 68-2-6, IEC 68-2-34, MIL-STD-810E
Shock	IEC 68-2-27 (100G), MIL-STD-810E
Total External Sound Level	40 – 45 dB(A) at one meter

2.2 Standards and Safety Requirements

The *i*Vent$_{201}$ meets or exceeds the following international standards:	
ISO 10651-2	Particular requirements for Home Care Ventilators
ISO 10651-3	Requirements for Emergency and Transport Ventilators
ASTM F1100-90	Standard Specifications for Ventilators intended for use in Critical Care
IEC 60601-1	Electrical Safety
IEC 60601-1-2	Electromagnetic Compatibility (EMC)
IEC 60601-2-12	Medical Electrical Equipment – Particular Requirements for the Safety of Lung Ventilators – Critical Care Ventilators
UL 94 HB	Flammability

2.3 Monitoring and Displayed Parameters

The following table lists specifications for all parameters the *i*Vent201 displays, in each applicable mode, whether set or measured.

Table 2-1: **Displayed Parameters and Indicators During Ventilation**

Parameter	Unit of Measure	Applies to Mode:						Value Is:		
		SIMV Vctrl	SIMV Pctrl	A/C Vctrl	A/C Pctrl	CPAP/PSV	A. Bi-Level	Settable	Displayed	Measured
Ventilation Mode	Name	●	●	●	●	●	●	●	●	
Exhaled Tidal Volume (Exhale)	ml	●	●	●	●	●	●			●
Inspiratory Tidal Volume Set (VT Set)	ml	●		●				●	●	
Inspiratory Tidal Volume Limit (VT Limit)	ml		●		●			●	●	
Tidal Volume (estimated)	ml						●			●
Leak (estimated)	L/min						●			●
Rate	bpm	●	●	●	●	S	●	●	●	●
Inspiratory Pressure (above PEEP)	cmH_2O		●		●	●		●	●	
Alarm Pressure / Limit Pressure	cmH_2O	●		●			●	●	●	
Oxygen Concentration	F_iO_2	●	●	●	●	●	●	●	●	L
Inspiration to Expiration time ratio (I:E)	I:E	●	●	●	●	●	●			●
Inspiratory Time (I.Time)	sec	●	●	●	●		●	●	M	A
Peak Inspiratory Flow (VPeak)	L/min	●	V	●	V	V		●	M	A
Flow Termination (VPeak % Term)	%						●	●		
Trigger Sensitivity (Flow)	L/min	●	●	●	●	●	●	●	●	
Trigger Sensitivity (Pressure)	cmH_2O	●	●	●	●	●	●	●	●	
Rise Time	sec						●	●		
Pressure Support Ventilation (PSV)	cmH_2O	●	●	●		●		●	●	
Positive End Expiratory Pressure (PEEP)	cmH_2O	●	●	●	●	●		●	●	
Exhaled Minute Volume (M. Vol)	L	●	●	●	●	●	●			●
Peak Inspiratory Pressure (PIP)	cmH_2O	●	●	●	●	●	●			●
P-High (Inspiratory Pressure)	cmH_2O						●	●	●	
P-Low (Expiratory Pressure)	cmH_2O						●	●	●	
Pressure Waveform	cmH_2O	●	●	●	●	●	●			●
Flow Waveform	L/min	●	●	●	●	●	●			●
Breath Type	Icon Symbol	●	●	●	●	●	●			●
Power Source (AC/ Battery)	Icon Symbol	●	●	●	●	●	●			●
External Power Source	No-Ext/ Ext	●	●	●	●	●	●			●
Internal Battery Charge Level	Icon Fill	●	●	●	●	●	●			●
Date and Time	Date/ Time	●	●	●	●	●	●	●		●

M= Manual mode only S= Spontaneous breath, measurement only
A= Adaptive mode only L= Low O_2 Pressure mode only V=measured value only (not settable)

2.4 Adjustable Non-Displayed Parameters

Sigh Breath Interval (Breaths)	25, 50, 75, 100, 125, 150, Off
Rise Time (Drive)	Mid, High, Max, Auto
Easy Exhale™	On, Off
Oxygen Supply (Pressure)	High, Low, None
Adaptive Peak Flow	Off, Low, Mid, High
Purge Interval (Minutes)	1, 2, 5, 10, Off

2.5 User Adjustable Alarms

Respiratory Rate (bpm)	High (4 – 80)	Low (1 - 77)
Minute Volume (L/min)	High (1 - 99/Off)	Low (0 - 60)
Inspiratory Pressure (cmH_2O)	High (4 - 80)	Low (1 - 77)
FiO_2 (%)	High (22 - 100)	Low (21 – 99)
Apnea Time (sec)	5 – 120	
Leak (%)	0 – 100	
Low Tidal Volume (%)	15 - 85/Off	
Inverse I:E Ratio	On/Off	
Patient Circuit Disconnect	On/Off (A. Bi-Level only, other modes optional)	
Alarm Volume Level (Loudness)	1 – 10	

2.6 Additional Alarms and Indicators

2.6.1 Alarms

Low O_2 Pressure	Patient Disconnect
AC Power Disconnect	Tube Disconnect

Low Battery	Check Sensor
Empty Battery	High PEEP
Battery Disconnect	Service Notice
Over Temperature	Need Cal
Sensor Disconnect	Auto Start
Patient Circuit Failed	

2.6.2 Indicators and Icons

Power Source	**Breath Type**
Internal Battery Charge Level	Zeroing
Alarm Silence and Countdown Timer	Purging
Date and Time	100% O_2 Suction Mode
LEDs: On, Charge, Alarm	External DC
Work Hour Counter	

Section 3 Installation and Setup

3.1 External Electrical Supply

The *i*Vent$_{201}$ can use either external AC or DC power and is supplied with a hospital grade AC power cord. The AC and DC sockets are located at the back of the ventilator (see Figure 3-1).

CAUTION	Before connecting the ventilator to an AC or DC outlet, verify that the external power supply is the correct voltage and frequency.

When the ventilator is operated from an external power supply, connect the appropriate power cord to the AC or the DC power inlets. Once the ventilator is in operation, icons located at the bottom of the screen indicate the use of an external power source.

When connected to AC power, the 3-prong (AC plug) symbol is displayed. When disconnected from AC power, the symbol is displayed crossed out with a red X.

When connected to an external DC power source, such as a battery, the text EXT appears in blue. When no external power source is detected, the text No-EXT appears in black.

NOTE	If the text EXT flashes in red, the external battery voltage is low and needs to be substituted or recharged.

WARNING	TO PREVENT HAZARD OF ELECTRICAL SHOCK:
●	Connect the ventilator power cord to a properly grounded outlet.
●	Replace the power cord immediately if damaged or frayed.

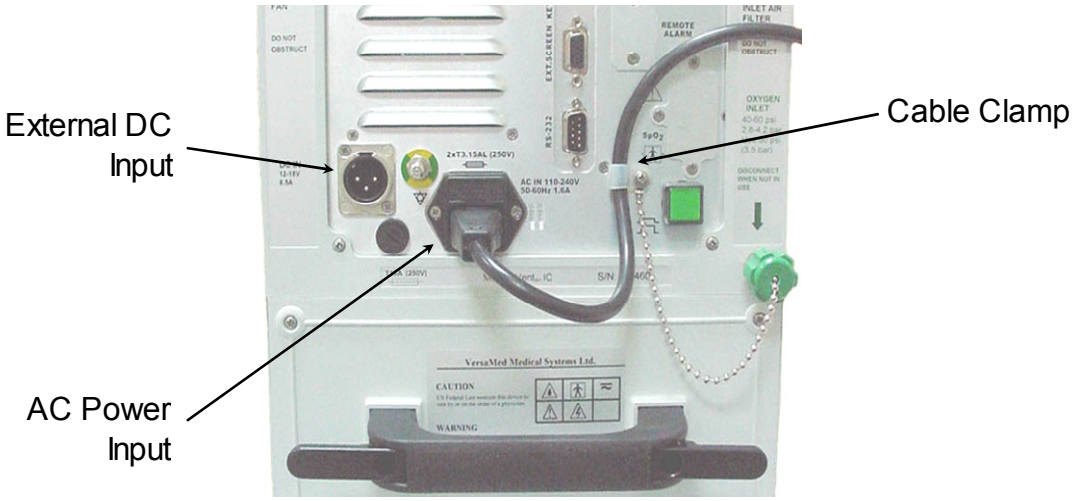


Figure 3-1: External AC and DC Power

NOTE	To prevent accidental disconnection of the AC power card, secure it in place with the cable clamp as shown.

When connected to an external DC and/or AC power supply, the **charge** LED on the front panel is ON. This indicates that the internal battery is being charged.

3.2 Internal Battery

The *i*Vent$_{201}$ contains an internal battery that can supply up to 2 hours of power depending upon the ventilator settings and the initial battery charge level. The ventilator automatically switches to the internal battery when an electrical power supply failure is detected.

CAUTION	The *i*Vent$_{201}$ must be used at all times with a properly functioning battery in order to ensure the correct operation of the ventilator.

3.2.1 Battery Charging

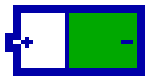
The internal battery is automatically charged when an adequate external power source is connected to the ventilator. Prior to operating the ventilator for the first time, or after prolonged storage of the unit (90 days or more), the battery must be charged by connecting the ventilator to an external power source for a period of at least ten (10) hours.

NOTE After prolonged storage the battery charge level icon may indicate full. The unit should still be charged for ten hours.

3.2.2 Internal Battery Charge Level Indicator

The internal battery indicator (or charge level icon) shows the status of the battery charge and is located at the bottom-center of the display screen. When the battery is fully charged, the message FULL is displayed inside the indicator. When the battery is fully discharged, the work EMPTY is displayed inside the indicator.

Table 3-1: Internal Battery Charge Level Indicator

Indicator	Colors	Description
	Green	Battery is fully charged
	Green/ Clear	Green portion of indicator moves across in 10% increments
	Red/ Clear	Changes to red when the measurement is less than 30%
	Clear	Displays EMPTY when the measurement is less than 7%

3.3 Oxygen Supply

3.3.1 High Pressure Supply

The *i*Vent$_{201}$ can use medical oxygen from a cylinder or from a central supply system at 40-60 psi. When the ventilator is ready for operation, connect the oxygen supply to the male DISS oxygen connector on the back of the ventilator (see Figure 3-2, page 36).

WARNING To prevent hazard of explosion, always make sure the oxygen connector is free from oil.

CAUTION	Before connecting the ventilator to an oxygen supply, verify the oxygen supply has the correct pressure range, as specified above in Section 2.1.4, page 28.

NOTE	Periodic verification of the accuracy of oxygen concentration is highly recommended.

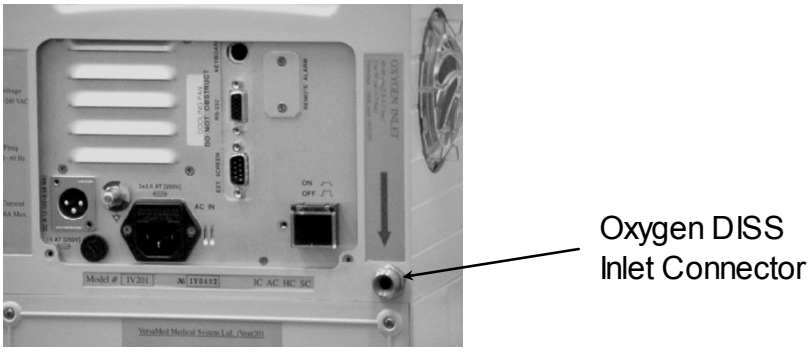


Figure 3-2: Oxygen Inlet Connector

3.3.2 Low Pressure Oxygen Supply

When a high-pressure oxygen source is not available, the *i*Vent$_{201}$ can accept oxygen from a low pressure oxygen source such as an oxygen concentrator or flow meter. This is accomplished by using an optional low pressure oxygen enrichment system that is attached to the ventilator air inlet port through an optional VersaMed adapter (see Figure 3-3: Low Pressure Oxygen Supply System). Adjust the flow of oxygen to reach the desired value of FiO_2. The measured value is displayed in the FiO_2 field in the Main window upon selection of Low Oxygen Supply Pressure option in the Advanced Settings menu. The FiO_2 value can also be measured with a calibrated external oxygen analyzer.

Figure 3-3: Low Pressure Oxygen Supply System

CAUTION	Use of the low pressure oxygen system at concentrations above 60% is NOT recommended, as higher values combined with varying minute volume due to spontaneous breathing of the patient may cause inadvertent PEEP.

NOTE	When using the low pressure oxygen system, “None” may also be selected. This option will disable both the internal O_2 monitoring and alarms. The FiO_2 field will display "0.”

3.4 Patient Circuit

The *i*Vent$_{201}$ breathing circuit contains the following components: Tubing, Exhalation Valve and a Wye/Flow Sensor (see

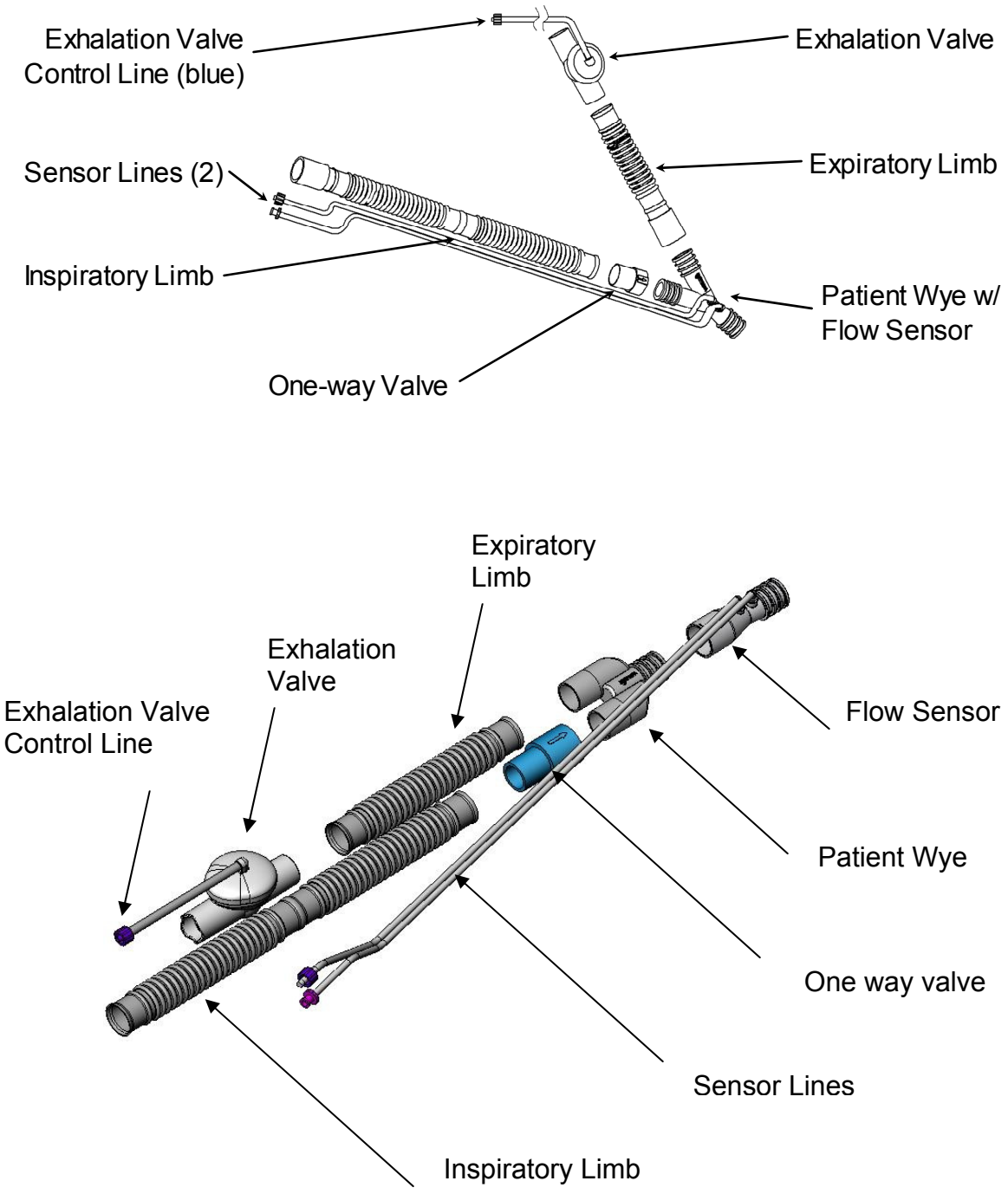


Figure 3-4: Patient Circuit

The ventilator circuit is intended for single-patient-use only and consists entirely of disposable components. A Heat and Moisture Exchanger (HME) should be used and placed between the flow sensor and the

patient connection. An adapter for MDI treatment (user supplied) may be placed between the flow sensor and the patient connection for the temporary administration of medication. If an HME is also being used, place the Metered Dose Inhaler (MDI) adapter between the HME and the patient connection.

CAUTION	Do not use an HME filter that appears to be contaminated or filled with water. Use of a contaminated filter can interfere with the function of the "Patient Disconnect" alarm.

CAUTION	Take care to remove the HME filter and install water-traps on the tubes to prevent penetration of water into the ventilator or circuit valves.

CAUTION	Do not clean or re-use the single-use breathing circuit or its components

NOTE	For correct handling of the Patient Circuit, refer to the User Instructions that are packaged with every circuit.

3.4.1 Patient Circuit Connection

Before operating the system, the following must be connected (see Figure 3-5):

- The inspiratory limb of the patient circuit to the ventilator outlet.
- The sensor lines to the luer connectors on the lower-left side of the front
- The exhalation valve control line (blue) to the single luer connector on the lower-right side of the front. There is a blue dot indicating the proper location.

Figure 3-5: Patient Circuit Connection

WARNING	Always perform an operation verification test (OVT) when connecting a new patient circuit to the ventilator.

CAUTION	Use only breathing circuit accessories approved and/or suppled by VersaMed or authorized VersaMed distributors.

NOTE	When the ventilator is intended to be used clinically (on a patient), a bacterial filter should be placed between the inspiratory limb of the patient circuit and the ventilator outlet

3.5 Filters

The *i*Vent$_{201}$ utilizes the following filters (see Figure 3-6):

- A protective filter at the ventilator air inlet
- A user-supplied bacterial filter at the ventilator outlet
- A user-supplied filter or HME/filter at the patient circuit outlet

3.5.1 Air Inlet Filter

The *i*Vent201 is shipped with the protective air inlet filter in place. This filter should be replaced every 500 hours (or monthly).

There are two other types of filters that may be used at this location:

- A low pressure oxygen filter/adapter (supplied by VersaMed)
- A Chemical/ Biological/ Radiological/ Nuclear Filter

3.5.1.1 Low Pressure Oxygen Adapter and Filter

This filter is used with the low pressure oxygen supply system outlined in Section 3.3.2. It has the same protective media used in the standard filter but terminates in a 22mm female port..

CAUTION	The low pressure oxygen adapter should not be used when entraining ambient air. Unlike the standard air inlet filter, the 22mm port of the low pressure oxygen adapter could be inadvertently blocked.

3.5.1.2 CBRN Filter

In the event of environmental contamination by hazardous or toxic compounds, the air inlet filter may be removed and replaced with a CBRN (Chemical/ Biological/ Radiological/ Nuclear) filter (P/N 620B0012-01) or another active carbon filtration device using a VersaMed supplied adapter (P/N 504A0110-A0).

3.5.1.3 Bacterial Filter

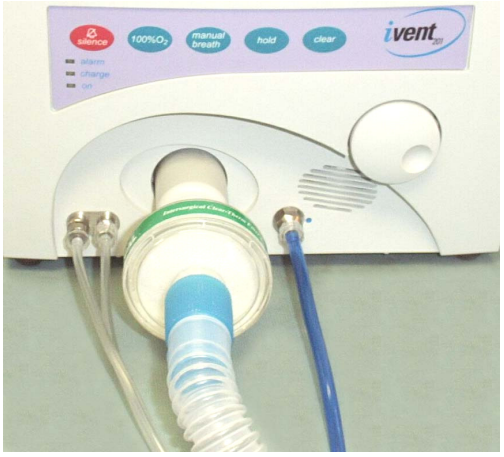
A user supplied bacterial filter must be placed at the ventilator outlet.

WARNING	The bacterial filter is intended to prevent the contamination of the patient circuit components and to prevent the penetration of bacteria, excessive humidity, and liquids into the ventilator. Failure to use an adequate filter may cause severe damage to internal pressure and flow sensors, which may result in ventilator failure.
NOTE	It is recommended that an HME filter be used when connecting to the patient.

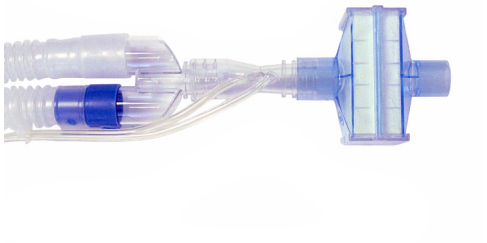
Air Inlet
Filter

Low Pressure O2
Adapter

CBRN
Filter



Bacterial Filter at Ventilator
Outlet



HME/ Filter at Patient
Wye

Figure 3-6: Filters

3.6 Ventilator Controls

The front panel of the *i*Vent$_{201}$ includes the rotational control knob and the keypad (see Figure 3-7).

Figure 3-7: Ventilator Controls

3.6.1 Rotational Control Knob (Encoder)

The rotational control knob is used by rotating the knob in either direction to scroll through and highlight the various fields or values found on the display. The choice is then selected by pushing in the control knob. An audible click can be heard from the speaker.

3.6.2 Keypad

The five push keys on the keypad include:

- Silence - This key is used to mute the alarm sound and minimize pop-up messages. When pressed, a 2-minute countdown timer is activated and temporarily replaces the date/time field at the bottom-right area of the display. Additionally, a "bell" symbol appears with a black "X" crossing it out. A short press on the "silence" key reactivates the timer to 2 minutes. A long press (~1 second) of the silence key cancels the operation.
- 100% O_2 - This key provides 3 minutes of 100% oxygen delivery and 2 minutes of alarm silence during suction procedures. A second press of the key cancels the process. This key is only active during ventilation and will not work in Standby mode.
- Manual Breath - This key enables the operator to deliver a single breath on demand. In CPAP/PSV ventilation mode, where there is no definition for a machine breath, the manual breath will be set according to the default volume control for the specified patient weight.

- Hold - This will invoke an inspiratory or expiratory hold maneuver on an upcoming breath. Pressing the key once will initiate an inspiratory hold maneuver while pressing this key twice will initiate an expiratory hold maneuver. If the hold key is pressed again, the hold maneuver will be canceled. (Some units may not be equipped to support this feature.)
- Clear - This key is used to mute the alarm sound for 30 seconds and minimize the red alarm-warning pop-up message. If this key is pressed again within the 30 seconds, the alarm warning reappears. A long press (1 second) clears all inactive (green) alarm messages at the bottom-left of the display. This key also aborts the last operator action and returns to the previous position. It is similar to the escape key on a computer keyboard.

3.6.3 LED Indicators

The front panel keypad also includes the following LED indicators:

- Alarm - This red LED flashes during an alarm condition. It also lights briefly whenever the rotational control or keypad is pressed or when the audible alarm volume is adjusted.
- Charge - This amber LED lights when the ventilator is connected to an external AC or DC power supply.
- On - This green LED lights whenever the unit is powered up.

3.7 Ventilator Operation

Please refer to the Operator's Manual, Section 3 and 4 for in-depth information.

Section 4 Theory of Operation

The *i*Vent$_{201}$ is a positive pressure mechanical ventilator. This section describes the ventilator's components and shows diagrams of the electro-pneumatic system. The *i*Vent201 ventilator operates by means of continuous interaction between the following modules:

- Pneumatic Unit
- Electronic Module
- LCD Display
- Interface Board
- Power Pack Assembly

4.1 Pneumatic Unit

The pneumatic unit provides the mechanics for ventilation and it is the "heart" of the ventilator. It is the most important component and the key to understanding the entire system.

The pneumatic unit is divided into the following: (see Figure 4-1):

- Blower Assembly (Turbine)
- Oxygen Blending System
- Solenoid Valve System
- Filter and Muffler
- Cooling Fan
- The Patient Circuit

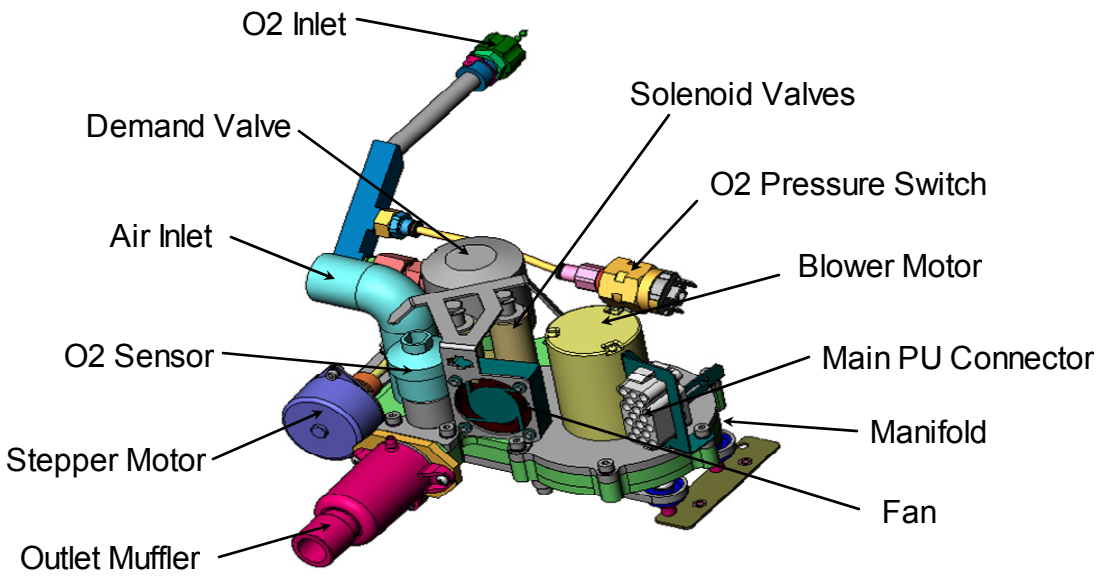


Figure 4-1: Pneumatic Unit

The diagram on the following page shows the basic pneumatic components and their relative positions along the flow path. It is a good idea to reference this diagram when reading the component descriptions.

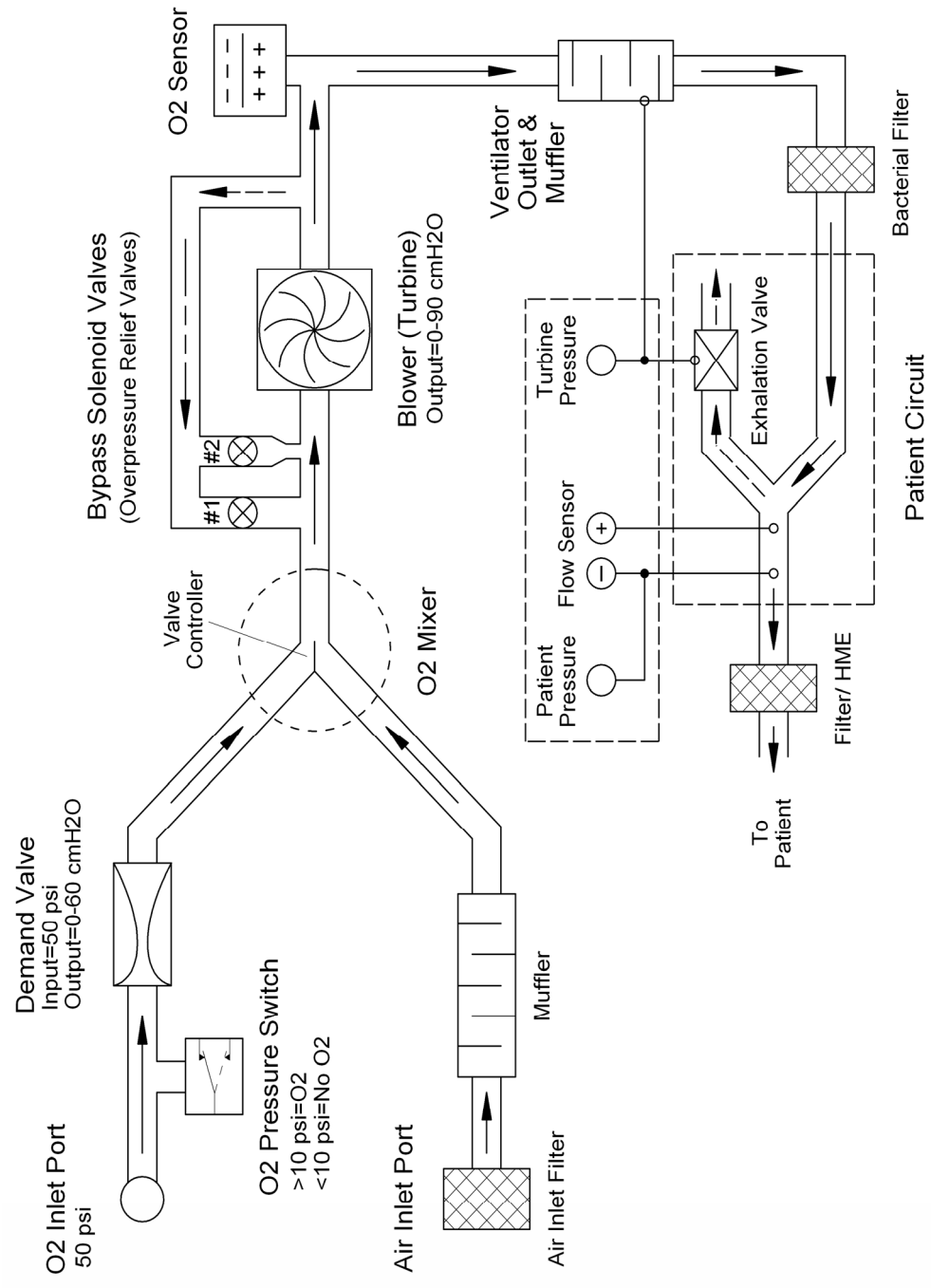


Figure 4-2: Pneumatic Unit Overview

4.1.1 Blower Assembly (Turbine)

The function of the blower assembly is to generate pressure and flow of the gas mixture to be delivered by the ventilator. The blower assembly includes a motor, impeller, blower cover, housing and manifold. The motor is a high speed DC brushless motor with internal commutation. The motor speed is adjusted by changing the voltage of the power input. The voltage is varied by PWM (Pulse Width Modulation) control of the motor driver on the switching board. The motor sets the impeller in motion with variable speeds, which adjusts the pressure and flow parameters. Gas is drawn into the blower from a manifold located at the bottom of the blower assembly.

The blower can reach speeds of 22,000 RPM and generate 80-90 cmH_2O max. It is powered by the 12VDC supply and draws 4 amps maximum. It has a tachometer for monitoring speed and is supervised by a watchdog circuit. A braking function is provided, which connects the motor terminals together via a low resistance power resistor.

It is rated for 15,000 hours and must be replaced periodically.

The blower assembly is carefully balanced inside the pneumatic unit housing by the manufacturer and cannot be serviced in the field.

Replacement of the blower assembly due to failure or scheduled PM requires the replacement of the entire pneumatic unit assembly.

This device is automatically checked during the Ventilator Verification Test (VVT).

4.1.2 Oxygen Blending System

The gas delivered to the patient by the ventilator is a mixture of air and pure oxygen. The oxygen blending system controls the oxygen concentration of the gas mixture.

The oxygen blending system consists of the following components:

- O_2 Pressure Switch
- Demand Valve
- Proportioning Valve
- Controller Valve Limit Switch
- Oxygen Sensor

4.1.2.1 O_2 Pressure Switch

The O_2 pressure switch detects whether or not high pressure (>10 psi) is present at oxygen inlet. The switch is normally open (absence of high pressure O_2) and closes with adequate pressure.

This component is automatically checked during the VVT.

4.1.2.2 Demand Valve

The demand valve's primary function is to reduce the pressure of oxygen from the nominal 50 psi found at its inlet to a 60 cmH_2O potential. The maximum flow of oxygen through this device is 120 lpm.

Its second function is to open only if there is a negative pressure at its outlet.

If the valve were held open by mechanical means, 60 cmH_2O could be measured at the outlet; however by definition, any positive pressure will shut it off. Therefore the 60 cmH_2O of outlet pressure is only theoretical and not a part of normal operation. The actual pressure at the demand valve outlet is approximately 0 cmH_2O or ambient.

This component is automatically checked during the VVT.

4.1.2.3 Proportioning Valve

This is a gate type valve that slides between the O_2 inlet port and ambient port of the pneumatic unit housing (inlet manifold). Each port is 22mm in diameter. When the mixture is equal or 60% oxygen, the valve occludes about one half of each opening.

There is also a one-way valve attached directly to the gate valve that directs flow out through the ambient port when the gate is in the 100% position. This valve has a multiple functions. The first is as a safety device. The second is to further reduce the small amount of pressure from the demand valve down to ambient pressure. This assures that both the O_2 port and the ambient port of the O_2 mixer are exactly equal in potential. The third function is to provide a path back to the air inlet for all of the solenoid bypass functions when the valve is in the 100% O2 position.

This functionality of this component is automatically checked during the VVT.

4.1.2.4 Valve Controller

This system consists of a stepper motor and a mechanical linkage to the proportioning valve. It can turn in either direction and drive the valve to a precise position based upon feedback from the O_2 sensor.

It takes approximately 1000 steps move the valve from one extreme to the other.

It is powered by the 12V DC supply and draws .17 amps.

The mechanical linkage consists of a worm gear, cam, shaft , spring and coupling. It is lubricated with medical grade silicone grease.

The microswitch actuation cam is also attached to the main shaft.

This system is automatically checked during the VVT.

This assembly cannot be serviced because disassembly of the entire pneumatic unit is required. However, this system is historically reliable and seldom is the cause of an oxygen problem.

4.1.2.5 Valve Limit Switch (O_2 Microswitch)

This limit switch detects when the O_2 valve has reached an extreme end of the usable range. It prevents mechanical jamming and prevents the control system from spending time in ineffectual ranges.

It is a short travel, double throw switch with a roller type actuator. It is usually in a closed state actuated by the high area of the cam. When a gate limit point is reached (100 or 21% O_2), the armature "falls" into a low spot on the cam. This sends a signal to the control system. The stepper motor reverses direction ~40 steps, resets the step count and awaits further instruction.

The geometric relationship between the rotating actuating cam and O_2 valve requires precise alignment. It is recommended that VersaMed service perform this task and subsequent verification tests.

This component is automatically checked during the VVT.

4.1.2.6 Oxygen Sensor

The oxygen sensor is a galvanic, partial pressure sensor that is specific to oxygen. It measures the O_2 concentration of the gas mixture at the output of the blower. This value is then used to adjust the O_2 blender to a higher or lower position to match the targeted FiO_2.

The nominal sensor life is rated at 1,000,000 O_2 hours. This means that the sensor is expected to last for a little more than a year exposed to 100% O_2 continuously, or 5 years exposed to ambient O_2.

The voltage output from the sensor changes proportionally with the partial pressure of the O_2 that it is exposed to. At the beginning of the sensor's life the output is approximately 65 mV at 100% O_2 and 15 mV at 21%.

As the sensor degrades the maximum output decreases. When the sensor output at 21% O_2 is less than 7.25 mV, the *i*Vent$_{201}$ will no longer accept the calibration value and the sensor must be replaced.

The output value from the sensor is compensated for pressure and temperature via the internal software. This means that there is usually a slight difference between external O_2 analyzer measurements and the internal O_2 measurement system. The ventilator specification for O_2 control is ±5% FiO_2 but when comparing the values to an external O_2 analyzer, additional tolerance must be added to compensate for the uncertainties presented by the external analyzer. The "rule of thumb" should be an additional ±5%.

This component is automatically checked during the VVT.

The sensor is a perishable component and should be replaced periodically.

CAUTION The oxygen sensor is a sealed device containing a mild acid electrolyte, lead (Pb), and lead acetate. Lead and lead acetate are hazardous waste constituents and require proper disposal.

CAUTION Never use ethylene oxide sterilization, or immerse the sensor in any cleaning solution or autoclave.

4.1.3 Solenoid Valve System

The solenoid valve system performs two primary functions. It provides positive pressure relief (safety valve) and helps to create the desired pressure waveform.

The solenoid valve system includes two identical solenoids with different size conical valves, plungers and springs.

The solenoid valves are normally closed, so that the air under pressure is delivered to the patient during the inhale phase. When open, the solenoid system "short circuits" the blower and helps to achieve a fast pressure drop.

The solenoid valves open and close a pneumatic path between the blower outlet and inlet. Additionally, each solenoid valve is a different diameter and can be controlled separately. Solenoid #1 has a large diameter and solenoid #2 has a small diameter.

There are four possible combinations of solenoid valves states: both closed, both open, only the large valve open and only the small valve open. Manipulation of these valves along with turbine speed can produce a wide variety of pneumatic waveforms.

The desired waveform is created under software control. The valves are opened at the beginning of every exhale, in order to obtain a quick pressure drop to the PEEP level.

The control over the two solenoids also allows for the Easy Exhale™ feature during which the pressure is reduced to a level below PEEP for a short time at the beginning of each exhale.

Both valves are spring loaded to the normally closed position and will begin to open at a nominal pressure of 80 cmH_2O. This provides the over pressure relief function. The safety pressure level is determined by the spring characteristics, which are chosen to match the requirement. Since each valve can "pop-off" independently there are actually two (2) safety relief valves.

This assembly cannot be serviced because disassembly of the entire pneumatic unit is required. However, this system is historically reliable and is seldom the cause of a problem.

This system is automatically checked during the VVT.

4.1.4 Filters and Mufflers

Air is drawn into the manifold through a user replaceable air intake filter, which provides highly efficient filtration of particles exceeding 5 microns. The air passes through a muffler, which reduces the noise level before going to the air intake hose.

The air intake muffler consists of baffling and sound absorbent foam. The air inlet filter is screwed directly to this muffler through a 3.5 inch diameter hole on the left side of the ventilator housing. There is also an O-ring to assure a good seal.

The ventilator outlet port is also a muffler and consists of baffling and sound absorbent foam. It is fastened to the pneumatic unit via a gasket, adapter plate and o-ring.

There is also a small diameter barbed connector for the blower pressure sensing tube.

4.1.5 Cooling Fan

The pneumatic unit cooling fan is directed towards the blower motor and solenoid valves to conduct heat away from these components.

4.1.6 Patient Circuit

Gas is transferred from the ventilator to the patient via the patient circuit. The patient circuit consists of two standard 22mm corrugated hoses, a wye with integral flow sensor and sensing lines, exhalation valve and control line, and a one-way valve (see Figure 3-4).

4.1.6.1 Wye and Flow Sensor

The wye/flow sensor is a proprietary component that connects to patient interfaces such as ET tubes, masks, etc. It has an integrated flow sensing system that connects to the ventilator front panel (see Figure 3-5).

The flow sensor portion of the wye is a differential pneumatic that measures the small difference in pressure at the two ports which are 1/2 inch apart. This differential pressure is then translated to equivalent flow and direction by the electronic module.

The flow sensing lines are connected to the ventilator front panel using medical luer fittings, one male and one female, which are connected to a differential pressure transducer located within the electronic module.

The flow sensor measurement is very dependent upon leak tight seals beginning with the differential ports of the flow sensor and ending at the transducer. The closer a leak point is to the transducer, the greater the error. Thus for a 1 lpm leak at the ET tube, the flow would be measured accurately (1 lpm) but for a 1 lpm leak located directly next to the transducer, the flow measurement would be 140 lpm. The most common location of a flow sensor leak is at the luer connections to the front panel. Of the two luer connections, the left port is more often misconnected, although it can visually appear to be OK.

This system is automatically checked during the VVT.

4.1.6.2 Exhalation Valve

This valve is attached to the expiratory limb of the patient circuit. Its main function is to close off the exhalation path during the inspiratory phase and to open during the expiratory phase (allowing the patient to exhale). It is also used for PEEP control.

The exhalation valve control line is color coded blue and is connected to the bottom-right luer fitting. Internally, it is connected to the ventilator outlet and shares the blower pressure sensing line.

The exhalation valve control line is open to the top of the valve diaphragm. During the exhalation phase of the breath cycle, the patient's lungs are allowed to deflate until they reach the same pressure that is on both sides of the diaphragm. At this point, the exhalation valve closes and holds this PEEP value until something changes the equilibrium (usually the next breath cycle).

This component is automatically checked during the VVT.

4.1.6.3 One-way Valve

This valve is connected between the wye and the inspiratory limb of the circuit. It prevents any flow from going back towards the ventilator and ensures that all inspired gas is exhausted out of the exhalation port. This reduces CO_2 rebreathing characteristics of the circuit while allowing for

faster manipulation with the exhalation valve control line, such as the Easy Exhale™ feature.

CAUTION: When the patient circuit is used with active humidification, the one-way valve needs to be moved to the inlet of the humidifier water chamber to allow for proper drainage.

4.2 Electronic Module

The electronic module of the *i*Vent$_{201}$ ventilator is a computing and control platform with multiple functions enabling the built-in software to operate the ventilator's pneumatic unit. The electronic module senses, monitors and displays the ventilation parameters. It also controls interaction between the user and ventilator through the user interface. The electronic module consists of the following components and sub-systems (see Figure 4-3):

- CPU Board
- Main Board
- Zeroing/ Purge Board
- Switching Board
- Power Supply
- Cooling Fan

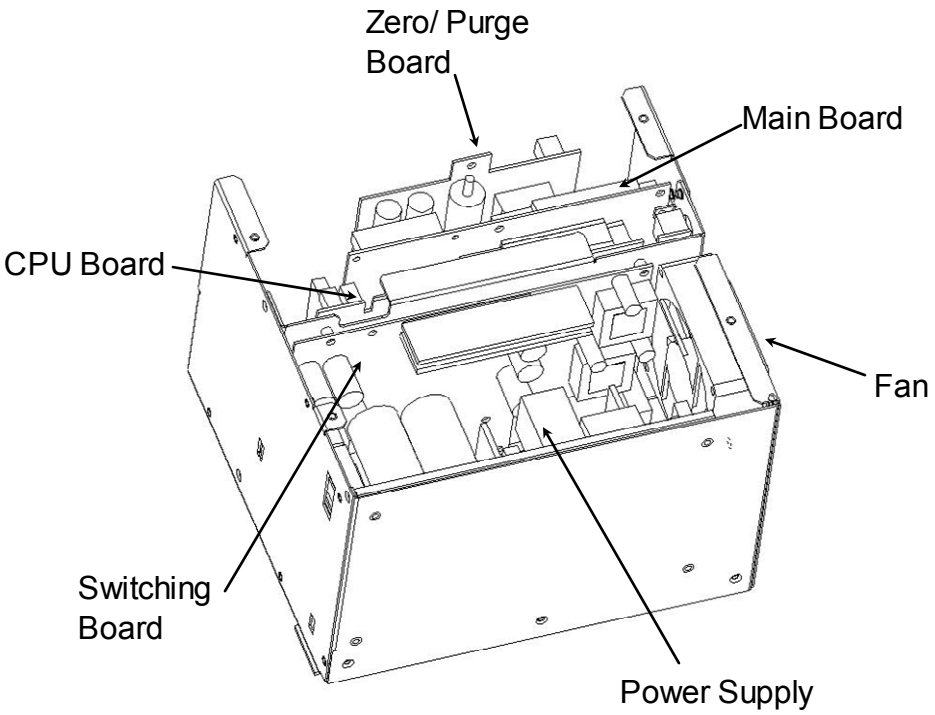


Figure 4-3: Electronic Module

The following diagram shows how the electronic module components interact with each other and with the other components of the *i*Vent$_{201}$:

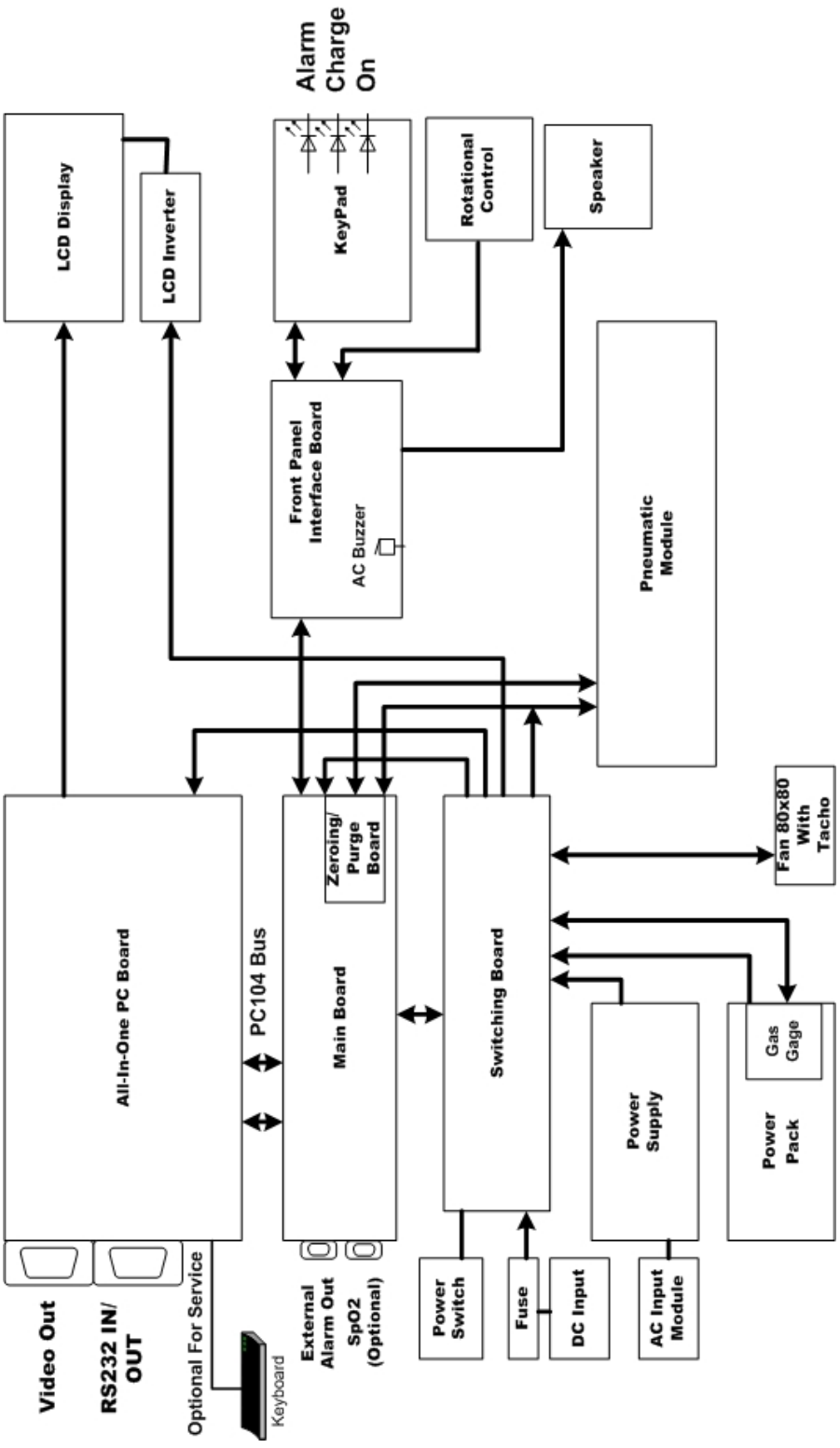


Figure 4-4: Ventilator Overview

4.2.1 Computer

The computation platform of the electronics system is an embedded PC with an AMD 5x86-133 processor. The standard PC components of memory, serial ports, floppy and IDE drive support and VGA support are present. In addition, the CPU board is embedded with such PC specific features as watchdog timer, LCD display support, and PC104 bus. The exposed connectors on the back panel of the ventilator are for a keyboard, RS-232 serial port and a VGA monitor. Other interfaces are only used for debugging. The CPU board interfaces with the main board via the PC104 bus and also receives power through the power connector from the switching board. The CPU board connects directly to the LCD display and is also connected to a buzzer on the front panel.

NOTE Some CPU boards may have ethernet connectors. This port is not utilized at this time.

4.2.1.1 System Memory

System memory consists of FPM/EDO onboard 8MB SIMM x 1. In addition to the standard locking socket, a bracket is used for increased mechanical security. Newer ventilators (S/N 1900 and higher) use 32 MB SDRAM.

4.2.1.2 BIOS

The flash BIOS (with VersaMed Logo) supports CRT/TFT LCD display, DiskOnChip®, PC Watchdog, etc.

4.2.1.3 DiskOnChip®

M-Systems DiskOnChip(r) is a flash device used to store the *i*Vent$_{201}$ program. The DiskOnChip (DOC) is designed for PC environments. It is a flash disk that is fully compatible with hard disk emulation. The monolithic design of the DiskOnChip ensures high reliability even when subjected to levels of shock, vibration and temperature changes that would destroy a conventional magnetic disk drive. When the ventilator is booted up, the program is read into RAM (volatile memory), from the DiskOnChip. Data that is unique to the specific unit

such as calibration, configuration, last set parameters and the events and error logs are stored on the DOC (non-volatile memory).

4.2.1.4 RS-232

RS-232 is a serial communication interface that conforms to the EIA232 standard. The *i*Vent$_{201}$ uses this interface to download new software from an external PC to the ventilator, to download collected data from the ventilator to external PC, and for real time diagnostics and remote control of the ventilator.

The *i*Vent$_{201}$ uses a male DB-9 connector and communication is enabled by connecting a null modem cable from the ventilator to an RS232 port of the external computer.

The *i*Vent$_{201}$ uses comm port#1 (Com1) while the external PC can be selected for Com1 through Com4. This port selection is a property of the VersaMed software application that is running on the PC.

NOTE The external computer must have a Com1 through Com4 available and unused by any other application such as a mouse, modem, PDA Sync utility (or another VersaMed application).

4.2.1.5 VGA Display

The CPU board supports LCD and CRT displays. The LCD display connects directly to the CPU board, which provides both power and data. A TFT color display is currently in use, but other displays can also be used. The display uses dual compact fluorescent backlights that require a high voltage AC source supplied from an inverter. The inverter is an off the shelf component which receives its input power from a connector on the switching board.

There is a standard DB-15 VGA connector for simultaneous external monitoring.

4.2.1.6 Keyboard

The CPU board supports a keyboard using a PS2 port. It is intended to be used for factory servicing and has no useful purpose for the field. A mouse is not supported.

4.2.1.7 Ethernet

The CPU supports a 10/100 Base-T, RJ45 port. It is not active at this time and is reserved for future applications.

4.2.1.8 PC Watchdog

The PC Watchdog is a circuit that automatically monitors the PC. This is a safety feature that will force the ventilator to resume operation in case of a temporary overwhelming malfunction. In this rare event, the unit will restart within 31 seconds while activating alarms.

WARNING	This is fail safe feature and not a part of normal operation. If this occurs, the unit should be removed from service as soon as possible. You should notify the VersaMed service department to make arrangements to have the unit analyzed, repaired and recertified.

4.2.1.9 Operating System (OS)

The operating system is pSOS+. pSOS stands for "plug-in Silicon Operating System." This real time operating system (RTOS) later evolved to pSOS+. It is an optimal environment for embedded systems.

4.2.2 Main Board

Essentially, the main board is what makes the *i*Vent$_{201}$ a ventilator instead of a PC.

The main board contains all of the sensing, control and interface functions required to operate the ventilator, except for the power

interfaces and the motor driver, which are controlled by the switching board.

The main board is the primary interface between the CPU board and the ventilator pneumatic system. It has the following primary interface functions:

- Sensors Interface
- Digital/Analog Interface
- Control and Status
- Motor Interface
- Bus Interface
- Solenoids Interface
- Stepper Interface
- Watchdog Timer
- Remote Alarm
- SpO_2

4.2.2.1 Sensors Interface

The sensor interface amplifies and filters the low-level signals from the sensors for sampling by the analog to digital converter (ADC).

The following sensors are interfaced:

- Flow Sensor
- Pressure Sensors
- Oxygen Sensor
- Temperature Sensor
- Battery Voltage

4.2.2.1.1 Flow Sensor

The flow sensor in the system presents a low flow and a high flow signal for measurement. A differential pressure applied to the flow transducer is converted to a low-level voltage by the pressure sensor. This voltage is amplified by an instrumentation amplifier and filtered by a 4-pole analog filter. The voltage is sampled by the analog to digital converter (ADC) for measurement of high flow levels. The voltage is then filtered and amplified for measurement

of low flows via a second ADC channel. A reference voltage biases the measured voltages so that at zero flow, the signal is in the center of the ADC input range. Reference voltage may be either fixed or adjusted using a calibration digital to analog converter (DAC).

4.2.2.1.2 Pressure Sensors

The system supports two pressure sensors. Similar to the flow sensor, pressure is converted to a low-level voltage, amplified and filtered. However, only a 2-pole filter is used, and a second level of amplification is not required.

Reference biasing is also similar, but is not at mid-scale, as pressure has a higher positive range than negative range (i.e., the reference pressure would be positive). The channels used are for patient pressure and blower pressure.

4.2.2.1.3 Oxygen Sensor

The oxygen sensor voltage is amplified and filtered in a single stage. The ADC then samples the output voltage.

4.2.2.1.4 Temperature Sensor

An integrated circuit temperature sensor measures temperature, which is presented without amplification or filtering to the ADC. An analog multiplexer selects between the temperature channel and the low flow channel.

NOTE The temperature measurement site is located in the center of the electronic module.

4.2.2.1.5 Battery Voltage

The battery voltage is divided, buffered and presented without amplification or filtering to the ADC.

4.2.2.2 Digital/Analog Interface

The interface between the software operating the system and the physical analog measurements made by the system is through an 8 channel, 12-bit analog to digital converter (ADC). Writing command to the internal registers accesses the ADC, and reading measured results from the internal registers. The ADC voltage reference is a precision,

low noise integrated circuit whose output is buffered and also used by all analog components requiring precise voltage.

A 4-channel, 8-bit DAC provides bias reference voltages to compensate for the offset voltages in the sensor paths.

4.2.2.3 Control and Status

Reading and writing registers access control and status features of the main board. Most writable register locations are also readable. The software recognizes the board as seven, 16-bit registers.

4.2.2.4 Motor Interface

The motor interface consists of control signals to enable, slow down and brake the motor, a register for controlling motor speed, and a register for measuring motor RPM. A Programmable Logic Device (Lattice PLD) primarily controls the motor. The PLD translates the value in the speed control register using PWM (Pulse Width Modulation) to generate the average voltage presented to the motor and thus the speed.

The tachometer output from the motor, after level shifting and filtering, is used to measure RPM. The PLD measures the width of the tachometer pulse and presents this value in the RPM register for use by the software.

When an unexpected signal is detected the motor can be disabled by either the watchdog or by the software. When booting the system, an enable sequence is transmitted from the software to the PLD, which prevents the motor from running freely before the software is active.

4.2.2.5 Bus Interface

The PC104 bus mediates all transactions between the CPU board and the main board. A Lattice programmable logic device (PLD) recognizes accesses to the main board and translates them into control signals to the registers. All bus transfers are 16-bit transfers. Data and address buffers isolate the main board bus from the CPU board bus. The bus is implemented as a stack through a connector. This allows future

expansion boards to be stacked above the main board using the same connector.

4.2.2.6 Solenoids Interface

FET switches drive the solenoids to the 12V supply. The system supports two solenoids. Writing bits to the Lattice PLD activates the solenoids. This either opens the switch continuously to open the valve or presents various PWM levels so that a constant voltage keeps the valves open. The appropriate PWM level is determined by the software as a function of the power supply or the battery voltage.

When a serious system failure is detected the solenoids are disabled either by the watchdog or by the software. Status bits indicate the voltage of the solenoid, which are used to detect a malfunction.

4.2.2.7 Stepper Interface

Setting bits in a register accesses the stepper interface, which sends control signals to a driver device. The stepper can be advanced clockwise or counter-clockwise, in full or half steps, and the driver enabled or switched off. An indication of the voltage on the stepper coils is available at the stepper status register.

4.2.2.8 Watchdog Timer

A watchdog timer monitors that the software is active. If software input is not toggled every 1.6 seconds the watchdog disables the solenoids and the motor and activates an alarm. The watchdog also generates a clean reset pulse and indicates when the analog 5V supply is below normal.

4.2.2.9 Remote Alarm

The remote alarm output provides a means of sending the ventilator alarm signal to a remotely located central nurse call station or remote alarm.

There are two types of remote alarm schemes and connecting accessories depending upon the type of connector present. If the ventilator has a female 4 pin RJ11 modular (handset) connector, a VersaMed supplied interface box is required. When ordering, the output type must be specified.

The Interface Box is used to change the open collector output (connected internally to the buzzer driver) to a relay output (normally open). This output also filters out short pulses such as keypad clicks and latches on for 0.5 sec for filtering pulses from this output. The connector also provides two signal lines and a 5V line.

If a female 8 pin RJ45 modular connector is present, a VersaMed supplied cable of the desired output type must be used.

The following output types are available for both configurations of remote alarm:

- NO Normally Open Relay Output, switch closure upon alarm.
- NC Normally Closed Relay Output, switch closure upon alarm.
- NC51K Normally Closed Relay Output with 51kOhm resistor in series, switch opens upon alarm.

4.2.2.10 SpO2

Provision has been made for a possible future add-on to the main board enabling pulse oximetry measurements and alarms.

4.2.3 Zeroing/Purge Board

The zeroing/purge board is a daughter board of the main board. Its function is to conduct periodic maintenance of the flow sensor lines.

The zeroing function is accomplished by momentarily switching both ports of the differential flow transducer to ambient pressure using two (2) small solenoid valves. The unit recalibrates itself to a new zero value compensating for transducer drifts or changes in barometric pressure. Simultaneously the sensor lines are held closed and no flow measurement is made during this short period (~0.4 sec.).

This can be observed in the flow waveform on the ventilator display. Every three (3) minutes, at the start of exhalation, the flow measures zero (even though there is no change in the pressure graph).

There are also two (2) purge pumps teed off of the flow sensor lines and zeroing solenoids. Their function is to pressurize the flow sensor lines and flush any condensate or obstruction that could interfere with an accurate measurement.

The purge pumps are capable of producing approximately 10 psi and are powered by the 12V supply.

The frequency is selected via the user menu. The purging process is detectable on the front panel pressure waveform.

NOTE Some units are equipped with a zeroing board only.

4.2.4 Switching Board

The switching board is the power conversion and distribution utility board. All power functions occur here, including external DC power management.

The switching board contains all of the power interfaces and the motor driver. The switching board handles the power functions of the system and performs the following functions:

- Switching between different power source
- EMI/RFI Filtering of DC sources
- Protecting against over current and over voltage
- Battery charging
- Converting 10 - 15V Input to 5V Output (DC/DC)
- Power on/off switching
- Determining the status of connected sources
- Motor Drive Circuitry

The primary inputs to the switching board are:

- External power sources and internal battery
- Motor control signals from the main board
- Motor period (tachometer) from the motor

The primary outputs from the switching board are:

- 12V supply to the system

- 5V supply to the system
- Variable voltage to the motor
- Charging current to the battery
- Status signals to the main board
- Miscellaneous control signals to the main board

4.2.4.1 Switching Block

The switching block switches between the three (3) power sources, using Schottky power diodes. The sources are:

- AC/DC power supply (14.2VDC)
- External 12V to 15VDC supply
- Internal 12V battery

All of the external power sources are connected together through signal diodes to indicate that an external source is present (CHEN). The common node of the power diodes is the board main power bus (VSUM). The voltage on VSUM may vary depending on which source is present; nonetheless this is referred to as the 12V supply.

4.2.4.2 RF Filter Block

The RFI filter block filters conduct electromagnetic noise on the DC power supplies. This provides electromagnetic immunity from external noise inwards and prevents conducted emissions from propagating outwards. The filter is an LC filter with a differential stage and a separate common stage. Inductors are formed by common windings on a ferrite core, and capacitors are provided between the source (FIN15V) and the return wire (FGND) and to the chassis ground.

4.2.4.3 Protective Devices

The system is protected against over-current by using fuses and against over-voltage by using transient voltage suppressors (TVS). The fuses are:

- AC power supply - dual fuse inside the power entry unit

- External 12V to 15VDC supply input - an external fuse (15A, 250V)

Internal 12V battery - an internal fuse in the battery pack (15A, 250V)

TVS devices are provided on the VSUM power bus and on the 5V and 12V supplies.

The use of diodes prevents damage resulting from polarity reversal of the sources.

4.2.4.4 Battery Charger Block

The battery charger is a constant-voltage, current-limited linear regulator. The input is VSUM and the output is a constant 13.8V voltage, limited to 1.1A maximum current.

The charger can be disabled under software control.

4.2.4.5 5V Output DC/DC Converter

The 5V power for the CPU and main board is achieved by using a switching regulator that converts the voltage on VSUM (10 to 14 Volts) to a regulated 5V. The layout is provided for either a 3-amp or 5 amp supply, depending on an alternate assembly.

4.2.4.6 Power On/ Off Switching

The main power switch on the back panel is a two-position switch which is operated by the user. The on/off logic is redundant so that if any device fails, the system does not inadvertently switch off. The hard switch directly pulls the 5V enable input low to switch on the system. Releasing the hard switch disables the 5V converter. A bit is also provided for the software to recognize inadvertent reset or user activation of the hard switch. The 12V output is switched whenever the 5V supply is above a threshold. Only the charge circuit is powered whenever AC or external DC is plugged in (using 12V from VSUM).

4.2.4.7 Status Block

The status block provides information to the main board about the external sources that are present. The voltage from the source is compared with a reference voltage to provide a logic bit and a LED indication when the source is present.

4.2.4.8 Motor Driver

The motor driver provides a high current variable voltage to the motor. A PWM signal from the main board controls a driver chip, which switches power MOSFETs, alternately connecting the motor to a 12V source or to the ground. The motor coils are thus presented with a voltage, which is proportional to the duty cycle of the PWM signal, which in turn controls the speed of the motor.

A voltage is provided to power the motor Hall effect sensors. The motor can be halted in case of a malfunction by switching off a power MOSFET between the motor negative terminal and the ground. A brake function is provided, which connects the motor terminals together via a low resistance power resistor. The motor can also be stopped by effectively disconnecting the motor driver whereupon the motor will decelerate passively.

4.2.4.9 External DC/DC Converter and External DC Source

The DC sources are connected to the back panel of the ventilator via a three-pin, XLR male connector with an input for the direct 12V to 15V source or for an external DC/DC converter and a common ground. Both sources have a user accessible fuse on the back panel.

4.2.4.10 Auxiliary Power Supplies

In addition to the 12V and 5V power supplies, auxiliary power supplies are provided for the analog section and for an optional LCD power supply. A precisely regulated "quiet" 5V analog supply powers most of the analog circuits except for a separate adjustable quiet supply for the pressure sensors. A negative analog supply is also provided for the input instrumentation amplifiers in the flow sensor path.

In addition, a digitally controlled voltage source exists for LCD displays, which require a voltage of up to 27V. Assembly wiring determines negative or positive voltages.

4.2.5 Power Supply (AC/DC Converter)

The ventilator has an internal AC/DC converter which accepts universal AC voltages from 85 to 265V, 40-440Hz and outputs a 14.2VDC voltage. The AC input connector also includes a RFI filter and dual 3.15A slow-blow fuses. The DC output of the converter goes directly to the switching board.

4.2.5.1 Cooling Fan

The cooling fan is mounted inside the electronic module and exhausts all of the heat generated inside the entire ventilator.

Air is entrained through the filtered inlet located at the front of the unit and then through the vented slots located at the bottom of the electronic module, to be discharged through the rear of the unit.

4.3 LCD Display

The LCD display is mounted to the front panel but connects directly to the CPU board which provides both power and data. A 640 x 480 TFT color display is currently in use, but other displays can also be used. The display uses dual compact fluorescent backlights that require a high voltage AC source supplied from an inverter. The inverter board is an off the shelf component which receives its 12V input from the switching board.

CAUTION The LCD inverter produces a high voltage. Verify that the system is powered off before attempting to handle the inverter or components close to it.

Connection to the LCD panel is made using a 31 pin Hirose connector. There is an aluminum bracket securing it in place. Most display abnormalities such as reversed screens, mono colors, etc. are remedied by resecuring this connector.

4.4 Interface Board

The interface board receives input signals from the keypad and rotational control and transmits them to the main board.

The interface board also passes the LED signals from the main board through to the keypad, audible alarm buzzer and speaker.

There are two (2) versions of the interface board. One supports a speaker and the other supports a second buzzer.

4.5 Power Pack

The battery power pack is a removable unit which slides into the back of the ventilator and provides power when an external power source is not available. The battery pack connects to the ventilator by means of an internal connector that contains a charging input, a power output, a communication line to the battery gauge and a common ground.

A 12V rechargeable sealed, lead acid battery with a capacity of 7.2 to 9.0 Ah is used.

With a fresh, fully charged battery, 4.8 to 5.6 amp hours are used until the battery voltage reaches 11.0. The ventilator draws approximately 4 amps under typical parameters. Therefore, the unit should run for 1.2 to 1.4 hours.

The battery is a perishable component and should be replaced every year.

CAUTION The power pack contains a sealed lead-acid battery. Disposal of this component should be in accordance with Environmental Safety Requirements for lead-acid batteries.

4.5.1 Gas Gauge

The battery gauge determines battery capacity by monitoring the amount of charge input to or charge output from the rechargeable battery. The gauge measures discharge and charge currents, estimates self-discharge, and monitors the battery for low-battery voltage thresholds. It compensates for temperature and various charge rates. Monitoring the voltage across a small-value series sense resistor

between the battery's negative terminal and ground makes the charge measurable.

The battery gauge monitors the charge and discharge current as voltage across a sense resistor. Monitoring this voltage over time and correcting the measurement for environmental and operating conditions yields the available battery charge.

The current battery charge is displayed as a symbol on the LCD. A low battery message is activated when the measured battery charge has depleted to a remaining 20%, or the battery voltage has depleted to 11.3V.

An empty battery alarm will activate when the battery voltage depletes to 11.0V.

When there are a lot of partial discharges (such as in transport applications) errors will accumulate and the gas gauge must be "re-educated" or allowed it to measure the total battery capacity. This procedure is outlined in Section 7.5, page 136.

Although the gas gauge will track the amount of battery charge, it cannot detect when the battery capacity has deteriorated to an unacceptable value. The best method for determining the battery capacity is to run the unit and measure the total run time under typical parameters.

It is important to distinguish between the low battery message and the empty battery alarm. The low battery message issues a warning. The run time doesn't end until the empty battery alarm activates. Typically, 3-12 minutes of operation remain left after this alarm.

While the battery is automatically checked during VVT to determine if it is severely deteriorated, the VVT cannot measure "adequate" capacity. Only functional testing can determine adequate capacity (run time).

Section 5 Maintenance and Calibration

5.1.1 Cleaning and Routine Maintenance

To ensure correct ventilator operation, perform the following maintenance procedures at the recommended intervals.

The cleaning and routine maintenance for the *i*Vent$_{201}$ is summarized in Table 5-1 below.

Table 5-1: Cleaning and Routine Maintenance

Part	Procedure	Comments
Ventilator	Wipe exterior clean with a damp cloth and mild detergent.	Do not allow liquid to penetrate into the ventilator.
Cooling Vents & Cooling Inlet Filter	Clean every 1500 hours (or 3 months) of use, or as necessary.	Use vacuum device to clean the cooling vent outlet and cooling inlet filter.
	Replace cooling inlet filter annually or as necessary.	
Air Inlet Filter	Replace every 500 hours (or 1 month) of operation, or as necessary.	Do not attempt to clean or reuse the air inlet filter.
Battery Pack	Recharge every 90 days of storage.	Actual life depends on history of use and storage.
	Replace every one year or as necessary.	
O_2 Sensor	Replace as necessary.	Actual life depends on history of use and storage.
Air Inlet Muffler	Replace annually, or as necessary	Actual life depends on history of use and storage
Ventilator Outlet Port (Muffler)	Replace annually, or as necessary	Actual life depends on history of use and storage
Pneumatic Unit	Replace every 15000 hours of operation, or as necessary.	
Other accessories	Follow the manufacturer's instructions.	

5.2 Preventive Maintenance

Table 5-2 summarizes preventive maintenance intervals and procedures.

Table 5-2: Preventive Maintenance Schedule

Interval	Parts Affected	Maintenance
Every 500 hours or 1 Month	Air inlet Filter	Replace the air inlet filter.
	O_2 System	Perform O_2 calibration.
		Perform VVT.
1500 hours or 3 months of use	Power Pack Gas Gauge	Deep discharge and recharge.
	O_2 System	Perform O_2 calibration.
Annually	Air Inlet Muffler	Replace the Air Inlet Muffler
	Ventilator Outlet Port (muffler)	Replace the Outlet Port (muffler)
	Cooling Inlet Filter	Replace the cooling inlet filter.
	Internal Battery	Replace internal battery and reinitialize the gas gage.
		Perform full calibration.
		Perform VVT.
		Perform functional tests.
		Perform safety checks.
Every 15000 hours	Pneumatic unit	Replace pneumatic unit.

CAUTION Remember that the 1500, annual and 15000 hour PM steps also include most of the other PM steps.

NOTE Perform periodic electrical safety checks as mandated by your facility's internal policies as well as local and national regulations.

5.2.1 500 Hour PM

The following steps should be carried out every 500 hours (or monthly):

1. Remove the used air inlet filter by turning it counter-clockwise. Ensure that existing o-ring remains on the side inlet port.
2. Install the new air inlet filter onto the side inlet port.

CAUTION Take care not to over-torque the filter when installing.

CAUTION Do not attempt to clean and/or reuse the air inlet filter.

3. Perform the O_2 calibration.
4. Run the Ventilator Verification Test (VVT) as outlined in Section 6.2, page 90.

5.2.2 1500 Hour PM

The following steps should be carried out every 1500 hours (or every 3 months):

1. Clean the rear cooling vents and the front cooling air inlet using a vacuum device. Tilt the ventilator back to access the front cooling air inlet filter (see Figure 5-1, page 76).
2. Fully discharge, then recharge the internal battery and allow the battery gas gauge to measure the total battery capacity as outlined in Section 7.5, page 136.
3. Perform all 500 hour PM steps.

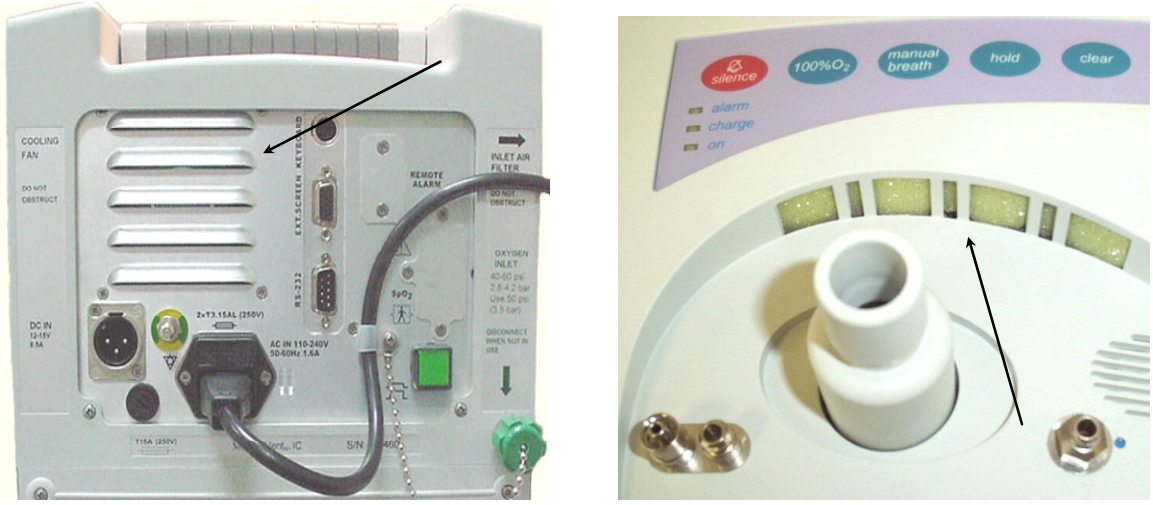


Figure 5-1: Cooling Vent (left) and Cooling Air Inlet Filter (right)

5.2.3 Annual PM

The following steps should be carried out annually:

1. Disassemble the ventilator enclosure as outlined in steps 1-9 of Section 7.4.

TIP Perform steps 1-9 only, since the LCD cable does not need to be detached for this service.

2. Remove the used cooling air inlet filter and install the replacement filter (see Figure 5-1, page 76, and Figure 7-7, page 116). Be sure to examine the installation from the front and verify that there is adequate coverage of the air intake opening.
3. Remove the existing air inlet muffler as outlined in Section 7.4.5.2, steps 3 & 4.
4. Install the replacement air inlet muffler as outlined in Section 7.4.5.3, steps 10-12.
5. Remove the (3) 3mm x 8mm Phillips head screws and washers from the outlet port mounting ears.
6. Remove the existing outlet port and install the replacement port with the 3 screws and washers.
7. Assemble the ventilator enclosure as outlined in Section 7.4.3.3, page 117).

NOTE Perform steps 6-12 only, if the LCD cable was not detached.

8. Remove the power pack assembly, replace the battery and reinitialize the gas gauge as outlined in Sections 7.4.9 through 7.5.

TIP If the entire power pack assembly is to be replaced, perform steps 1-2 only.

9. Perform all 500 hours PM steps.
10. Perform a full calibration as outlined in Section 5.4.
11. Run the Ventilator Verification Test (VVT) as outlined in Section 6.2.

12. Perform the Functional Verification Tests as outlined in Section 6.3.

5.2.4 15000 Hour PM

The 15000 Hour PM requires that the entire pneumatic unit be replaced. This process will replace virtually all moving parts of the ventilator.

The following steps should be carried out every 15000 hours:

1. Disassemble the ventilator enclosure as outlined in Section 7.4.3, Enclosure Disassembly, page 114. Remove the electronic module as outlined in Section 7.4.4.
2. Remove the pneumatic unit as outlined in Section 7.4.5.
3. Install the new pneumatic unit as outlined in Section 7.4.5.3.

CAUTION Remember to position the O_2 microswitch actuation cam to a middle position.

NOTE The new O_2 sensor may be packaged in a sealed can along with the pneumatic unit.

4. Install the electronic module as outlined in Section 7.4.4.3.
5. Assemble the front enclosure to the rear enclosure as outlined in Section 7.4.3.3.
6. Perform a full calibration as outlined in Section 5.4.
7. Run the Ventilator Verification Test (VVT) as outlined in Section 6.2.
8. Perform the Functional Verification Tests as in Section 6.3.

5.3 Storage

When storing the ventilator for three days or more, disconnect the oxygen supply. When the ventilator is stored for a prolonged period of time, the internal battery should be recharged at a minimum interval of every 90 days.

5.4 Calibration Procedure

The Calibration procedure will perform a full calibration of the *i*Vent$_{201}$ by adjusting sensor outputs to match quantitative measurements.

5.4.1 Purpose

The purpose of this procedure is to provide proper calibration of the *i*Vent$_{201}$ ventilator.

5.4.2 Scope

This procedure applies to *i*Vent$_{201}$ Version 1.4 ventilators manufactured by VersaMed and loaded with software version 19.01 or higher. This procedure should be performed after any repair, software upgrade or significant environmental changes (e.g., elevation). Additionally, this procedure should be performed annually or any time that the unit fails the Ventilator Verification Test (VVT).

5.4.3 Tools & Equipment

- Certified manometer (pressure gauge) with 22mm female adapter 0-120 cmH_2O. (Versamed P/N 920C0002-01)
- Certified volume syringe, 500ml. (Versamed P/N 920C0001-01)
- Test lung, 2L. (Versamed P/N 910V0005-01)

5.4.4 Initialization

1. From a power off state: connect the ventilator to AC power.
2. Turn on the ventilator and select the 70+ kg patient weight setting in the opening screen.
3. Set the pressure alarm to 60 (cmH_2O).
4. Connect the ventilator with a patient circuit to the Rp20 resistor and test lung.
5. Press "START" and allow the ventilator to warm up for 15 minutes prior to calibration.

5.4.5 Procedure

The Calibration procedure includes steps for the following:

- Zero Sensors
- Pressure Sensors calibration
- PEEP-RPM calibration
- Flow Sensor calibration
- Volume calibration
- O_2 System calibration

CAUTION	The calibration process described in this procedure should be carried out sequentially and in full each time a calibration is required. Failure to perform all of the steps in sequence can result in an un-calibrated system.

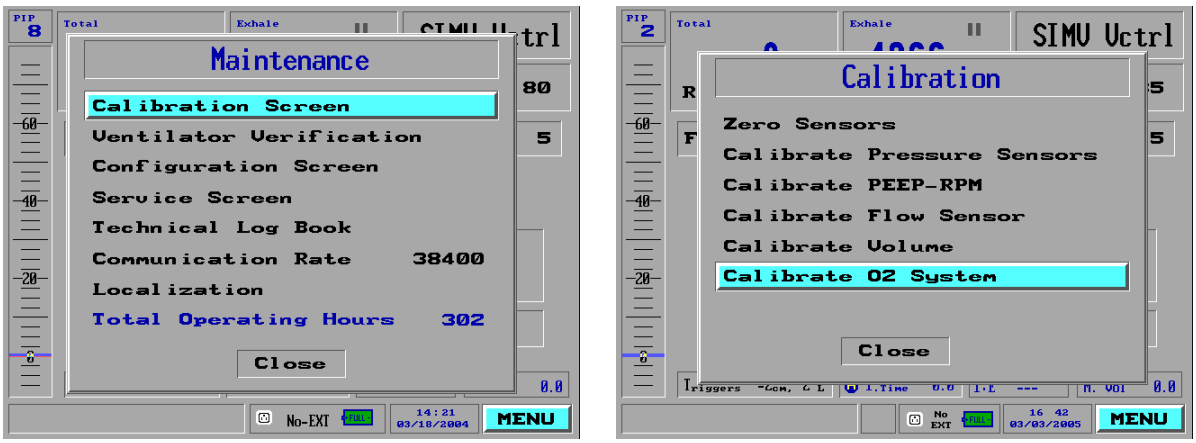
NOTE	Zero Sensors, Volume and O_2 calibrations may be carried out separately.

5.4.5.1 Initialization

1. From the Main Menu select the Maintenance option. A Caution window will appear stating that only trained service personnel should enter the restricted Maintenance area.
2. Select Yes and the Maintenance window appears.
3. Select the Calibration option and the Calibration window will appear listing the calibration steps.

Main Window Caution Window

Figure 5-2: Entering the Maintenance Menu



Maintenance Menu Calibration Menu

Figure 5-3: Entering the Calibration Menu

5.4.5.2 Zero Sensors

1. From the Calibration window select the Zero Sensors option. The Zero Sensors window will appear.
2. Disconnect the test lung and Rp20 resistor from the patient circuit and press start.
3. Wait until the calibration is finished (for about 6 seconds). The message "Working" flashes on the screen during the calibration step.

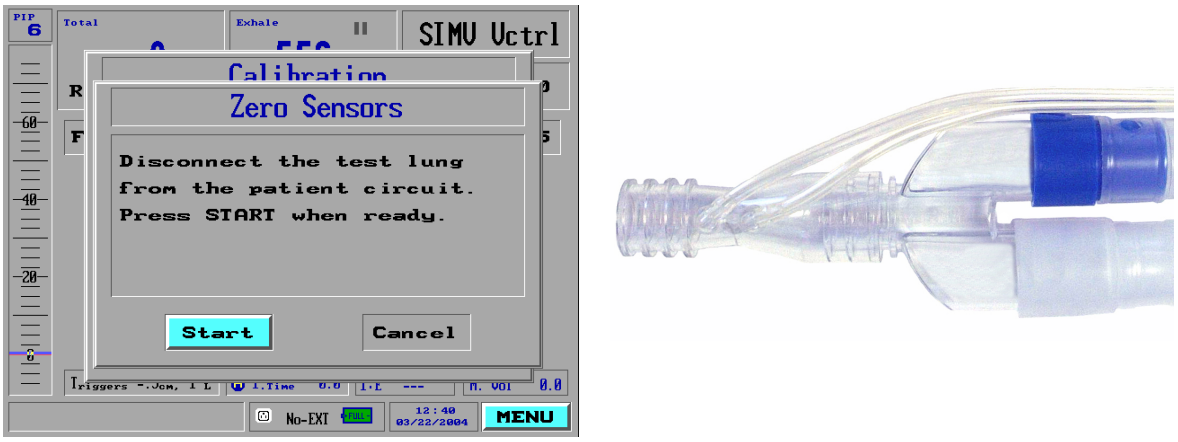
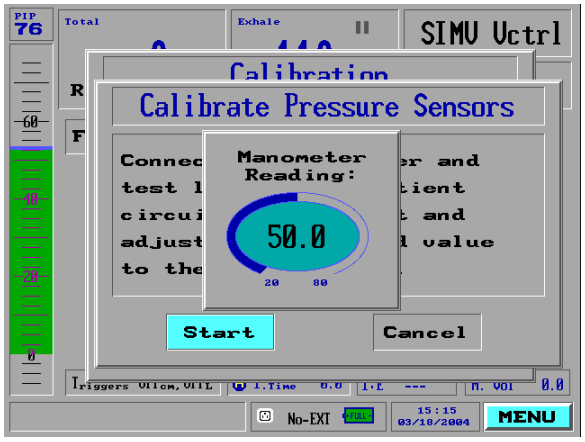


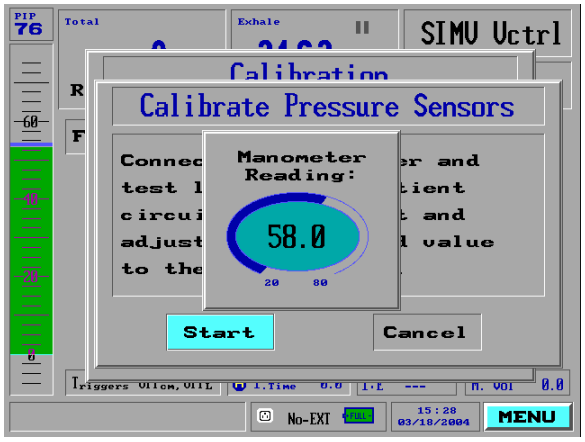
Figure 5-4: Zero Sensors

5.4.5.3 Pressure Sensors

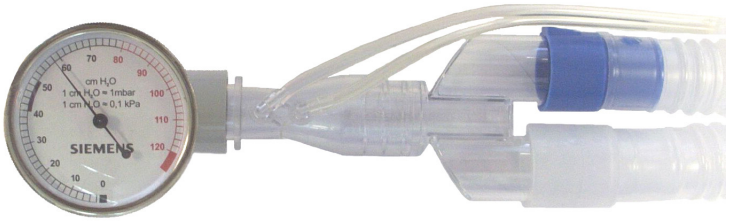
1. Connect the reference manometer to the patient circuit. Be sure that the manometer tee is capped so that there is no flow out of the unit.
2. From the Calibration window select the Calibrate Pressure Sensors option and press Start.
3. Adjust the value in the Manometer Reading field so that it equals the pressure measured by the external manometer and press the control knob to enter the new value.

NOTE Since repeating the Pressure Sensors calibration step will not display the value that was just entered, it cannot be used to verify the pressure calibration. The pressure calibration may be verified by the Ventilator Verification Test. (See Pressure Tests, page 93).





Before Pressure Adjustment **After Pressure Adjustment**



Manometer Reading 58 cmH_2O

Figure 5-5: Calibrate Pressure Sensors

5.4.5.4 PEEP-RPM

1. Connect the test lung to the patient circuit.
2. From the Calibration window select the Calibrate PEEP-RPM option and press Start.
3. Wait until the calibration is finished (for about 50 seconds). The message “Working" flashes on the screen during the calibration step.

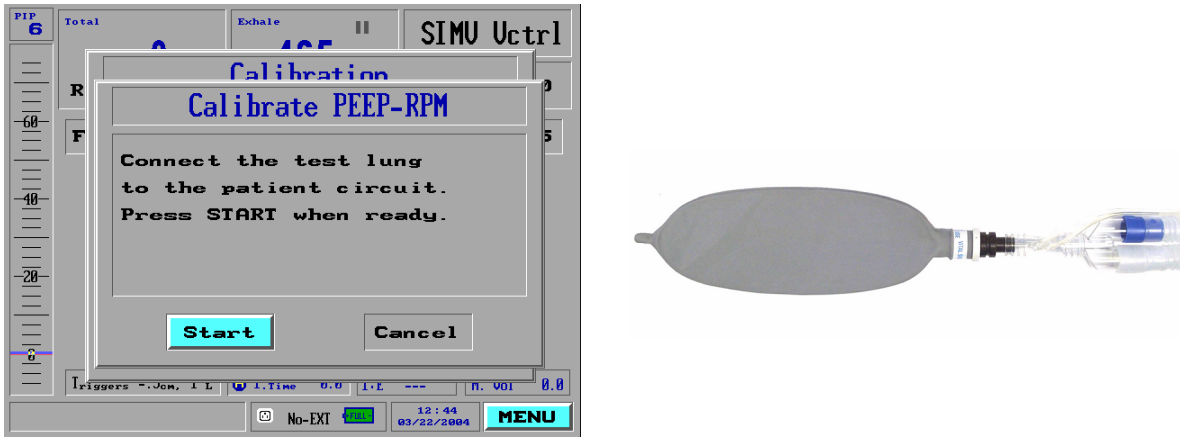


Figure 5-6: Calibrate PEEP-RPM

5.4.5.5 Flow Sensor

1. Disconnect the test lung from the patient circuit.
2. From the Calibration window select the Calibrate Flow Sensor option and press Start.
3. Wait until the calibration is finished (about 15 seconds). The message "Working" flashes on the screen during the calibration step.

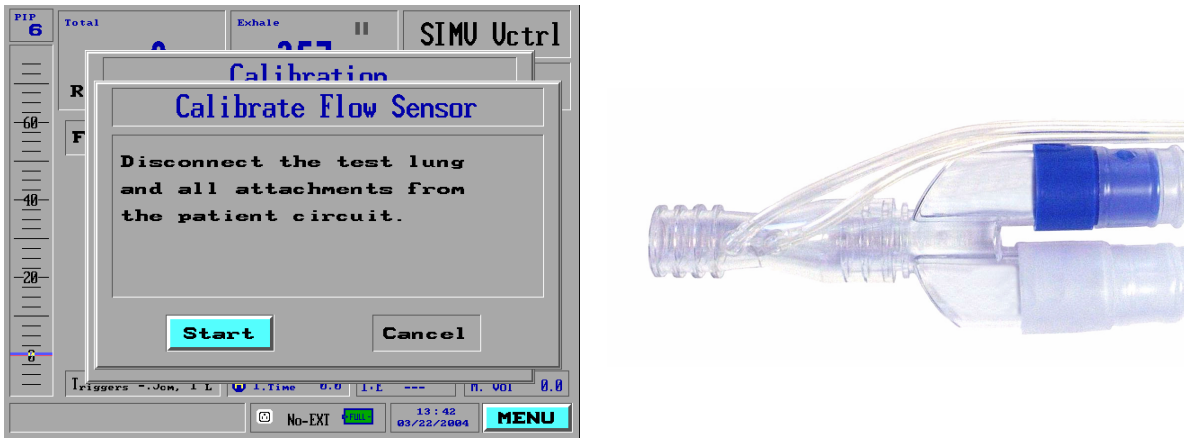


Figure 5-7: Calibrate Flow Sensor

5.4.5.6 Volume

1. Remove the plug from the patient circuit and connect the 500ml calibration syringe.
2. Push the syringe piston all the way in to place it into a starting position.
3. From the Calibration window select the Calibrate Volume option and press Start.
4. Pump the syringe 10 times slowly and steadily (each stroke should last 1.5-2 seconds). The system counts the cycles, displays the final values and then exits automatically.

NOTE At the end of each cycle both the inhale and exhale volume will update. After the 10th count, these values should be 500 ±10. Repeat this calibration step if the values are not satisfactory.

5. Disconnect the calibration syringe from the patient circuit.

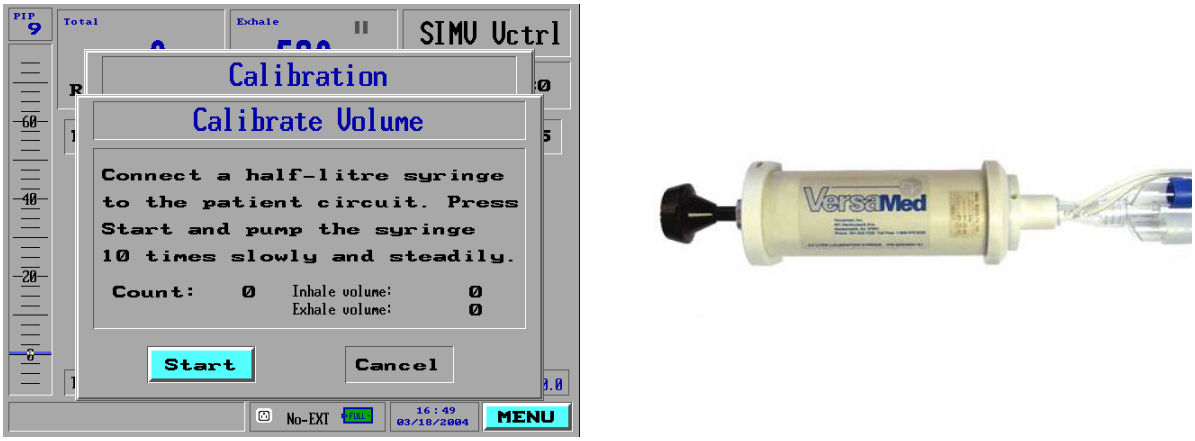


Figure 5-8: Calibrate Volume

5.4.5.7 O_2 System

1. From the Calibration window select the Calibrate O_2 System option and press Start.
2. Wait until the calibration is finished (for about 100 seconds). The message "Working" flashes on the screen during the calibration step.
3. Press Close to return to the Calibration window.

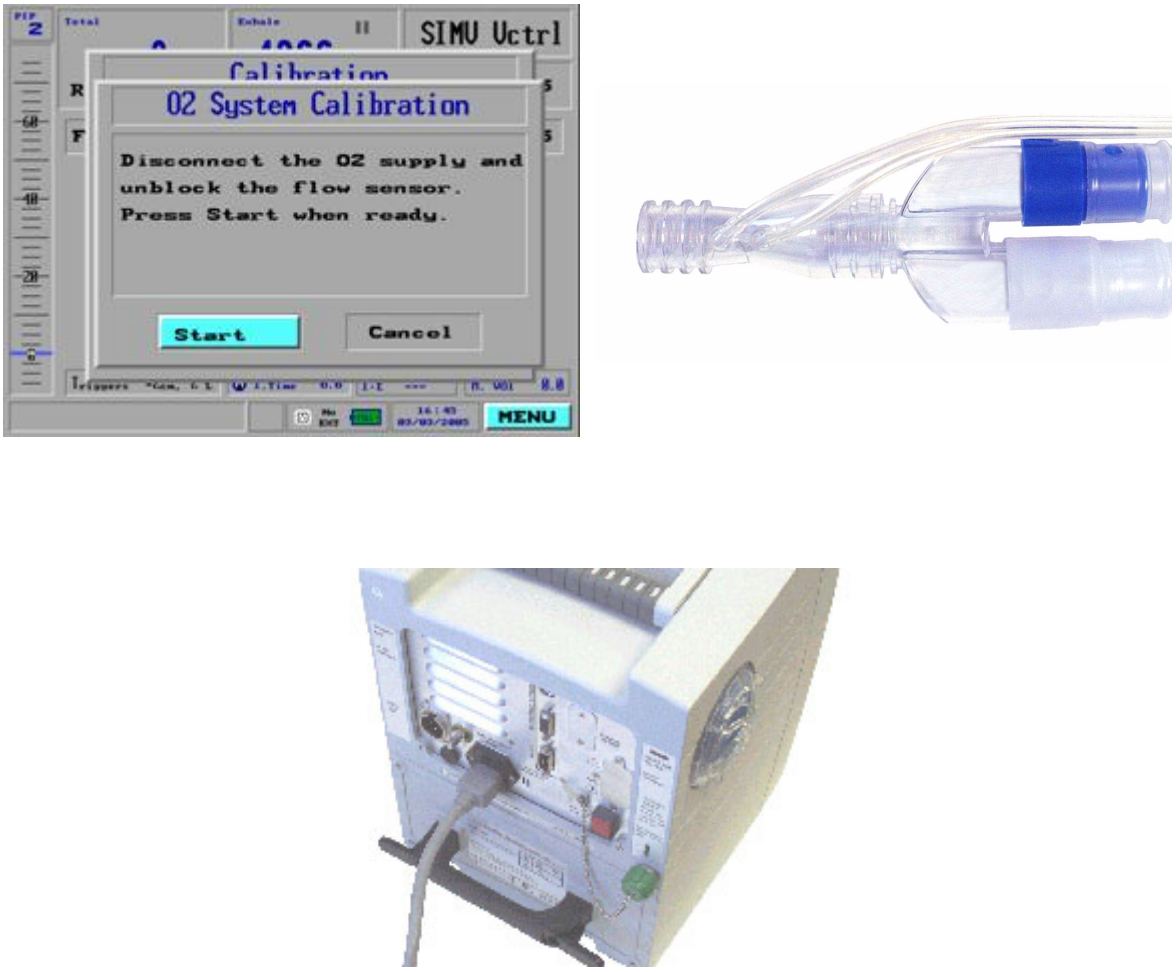


Figure 5-9: Calibrate O_2 System

5.4.5.8 Save New Calibration

1. From the Calibration window press Close.
2. Press YES to save the new calibration factors or NO to discard the calibration and retain the previous values.

CAUTION VVT should always be performed after calibration.

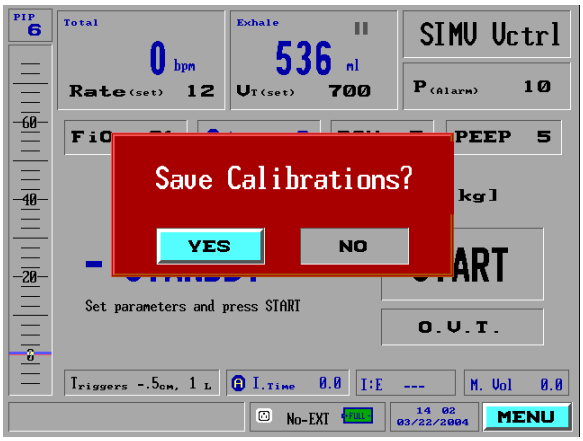


Figure 5-10: Save Calibration

Section 6 Ventilator Test Procedures

6.1 Operational Verification Test

The Operational Verification Test (O.V.T.) is an automated test designed to check the connections of the breathing circuit to the ventilator as well as the function of the one-way valve on the inspiratory limb. The O.V.T. also checks the apnea detection function and audible alarm.

6.1.1 Purpose

The purpose of this procedure is to establish a method of properly verifying the patient circuit connections and functionality.

6.1.2 Scope

This procedure applies to *i*Vent$_{201}$ Version 1.4 ventilators manufactured by VersaMed Medical Systems, Inc. and loaded with software version 19.11 or higher. This procedure should be performed after attaching a new patient circuit to the ventilator.

6.1.3 Tools & Equipment

- Caps, 22mm (supplied with every circuit)

6.1.4 Initialization

1. Connect the patient circuit to the ventilator.
2. Power up the ventilator and select a patient weight setting in the opening screen.

6.1.5 Procedure

1. Highlight and select "O.V.T." from the Standby screen. (O.V.T. can also be selected from the Main Menu.) The O.V.T. Instructions window will appear.
2. Connect the caps to the patient circuit wye and exhalation valve opening and then press Start. The system will pressurize to approximately 80 cmH_2O (for about six (6) seconds).

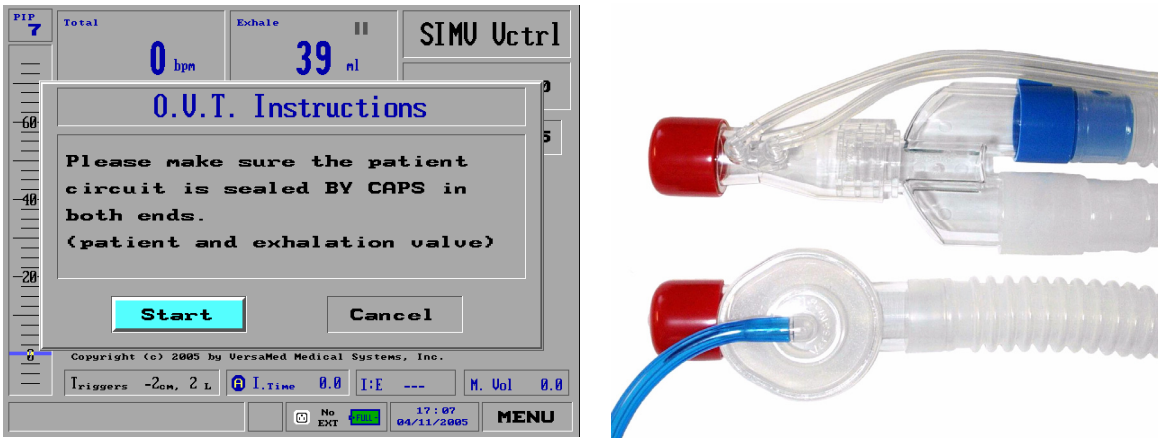


Figure 6-1: OVT #1

3. When prompted, remove the cap **from the exhalation valve only** and press Start. The unit will pressurize briefly and then the alarm will sound while the O.V.T Confirmation window appears.

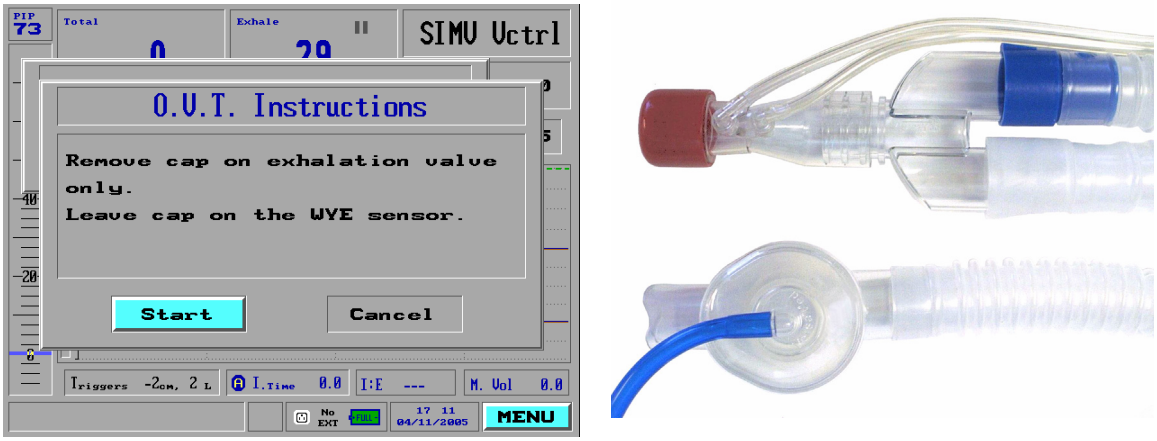


Figure 6-2: OVT #2

4. Press Yes if the alarm is audible. The O.V.T. Results window appears. Press OK and the unit will return to the Standby screen.

NOTE	If the ventilator fails to pass the O.V.T., verify that both caps are pushed onto their respective ports all the way. Also, verify that the flow sensor and exhalation valve control tubes are adequately mated to the front panel luer fittings and repeat the test.

CAUTION If the ventilator repeatedly fails the O.V.T, replace the patient circuit and repeat the test. If the O.V.T. still fails after the circuit exchange, then run the Ventilator Verification Test (V.V.T., described in the next section) to isolate the specific failure mode.

6.2 Ventilator Verification Test (VVT) Procedure

The Ventilator Verification Test (VVT) is a set of simple ventilator self-tests to check the ventilator functionality. User intervention is required to alter various external connections to the ventilator as well as the confirmation of audible alarms.

6.2.1 Purpose

The purpose of this procedure is to establish a method of properly verifying the ventilator functions and performance.

6.2.2 Scope

This procedure applies to *i*Vent$_{201}$ Version 1.4 ventilators manufactured by VersaMed Medical Systems, Inc. and loaded with software version 19.11 or higher. This procedure should be performed after any repair, calibration, upgrade, preventive maintenance or shipment.

6.2.3 Tools & Equipment

- O_2 supply, 40-60 psi.
- O_2 supply hose. (Versamed P/N 620B0001-01 or 620B0002-01)
- Cap, 22mm (supplied with every patient circuit)

6.2.4 Initialization

1. Connect the AC power and patient circuit to the ventilator.
2. Turn on the ventilator and select the 70+ kg patient weight setting in the opening screen.

6.2.5 Procedure

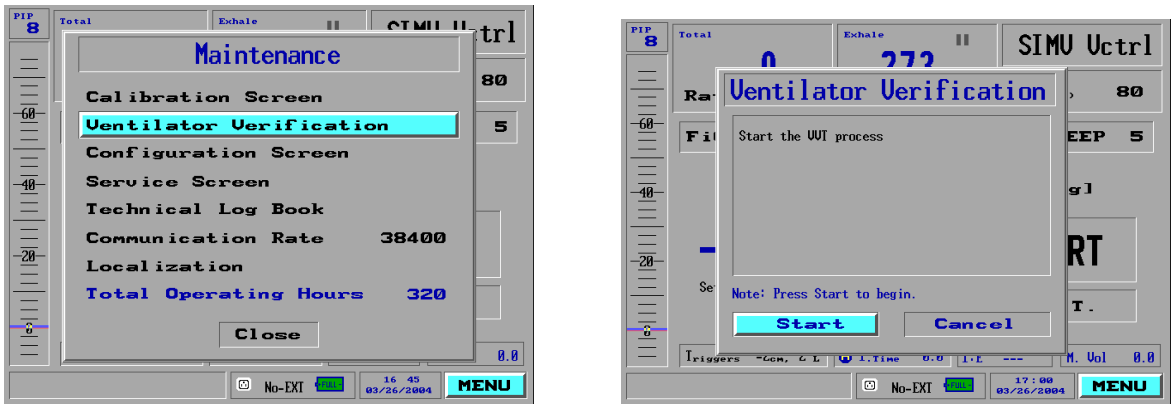
The VVT checks the functionality of the following ventilator components:

- Alarm sounders (two)
- Patient pressure transducer and pressure performance
- Blower pressure transducer
- Transducer tubes leak
- Motor speed measurement
- Positive relief valves
- Solenoid valves (two)
- Solenoid safety release mechanism
- Flow performance
- Flow zeroing function
- 21% FiO_2
- Pressure Switch status at 21%
- Demand Valve Leak
- 100% FiO_2
- Pressure Switch status at 100%
- Battery status
- Motor watchdog safety device
- PC watchdog safety device

6.2.5.1 Alarm Sound Tests

1. From the Main Menu select the Maintenance option. A Caution window appears stating that only trained service personnel should enter the restricted Maintenance area.
2. Select Yes and the Maintenance window will appear.
3. Select the Ventilator Verification option and the Ventilator Verification window appears.

Figure 6-3: Entering the Maintenance Window



Maintenance Window **Ventilator Verification**

Figure 6-4: Entering VVT

4. Press Start and the VVT Confirmation window will appear asking if the first alarm tone is audible.

NOTE The volume of the first alarm is adjustable in the Alarm Settings/ Options menu. The default value is 8.

5. Press Continue if there is an audible tone or Failed if there is none. Another prompt will appear asking if the second alarm tone is audible.
6. Press Continue if there is an audible tone or Failed if there is none. The VVT Instruction window will appear.

6.2.5.2 Pressure Tests

1. Block the patient circuit with the 22mm cap or equivalent.
2. Press OK and the unit will automatically run through a series of tests (for about 30 seconds). As it is goes through each step it will display an OK or Failed next to it. The results items will continue to accumulate throughout the rest of the test.

TIP	If a calibration manometer is available and is known to be free from leaks, block the patient circuit with it instead and compare the pressure reading from the manometer with the pressure reading from the display's left-side bar graph. This is an opportunity to determine full scale accuracy. If the two pressure readings differ by more than 3 cmH_2O, recalibrate the pressure.

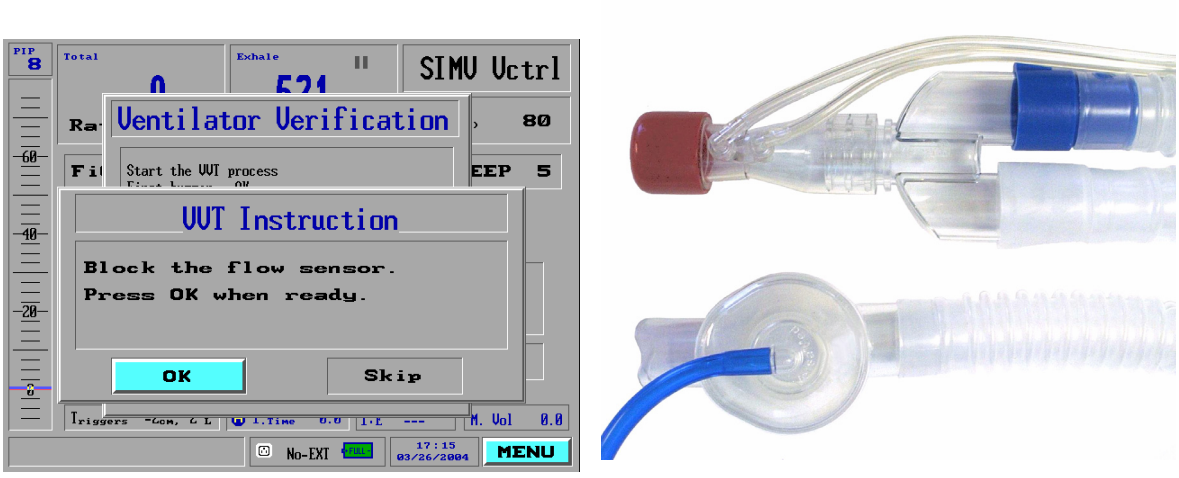


Figure 6-5: Pressure Tests

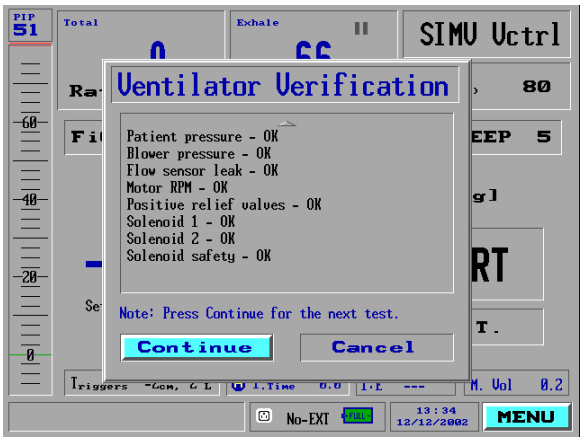
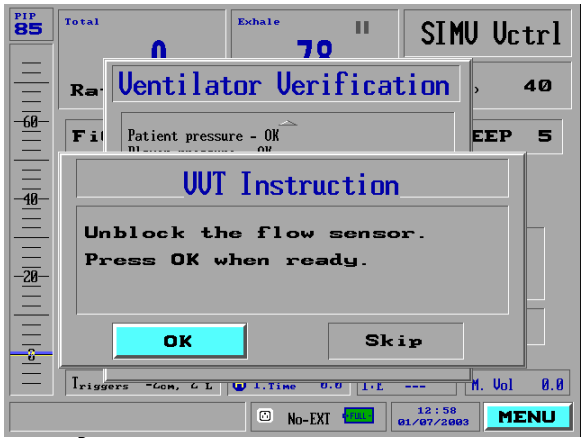


Figure 6-6: Pressure Test Results

6.2.5.3 Flow Tests

1. Remove the plug from the patient circuit and press OK.
2. Wait until the test step is finished (about 6 seconds). The VVT Instruction window will appear.



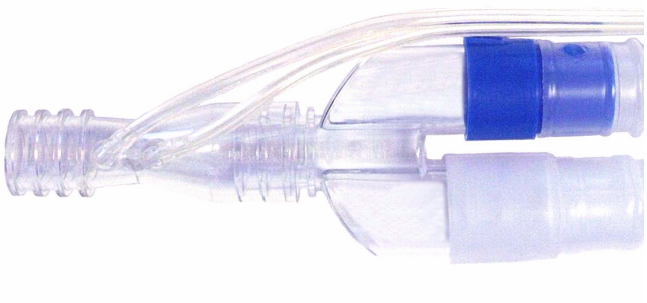


Figure 6-7: Flow Tests

6.2.5.4 O_2 Tests

3. Verify that there is no O_2 supply connected to the ventilator and press OK.
4. Wait until the test step is finished (about one (1) minute). The VVT Instruction window will appear.

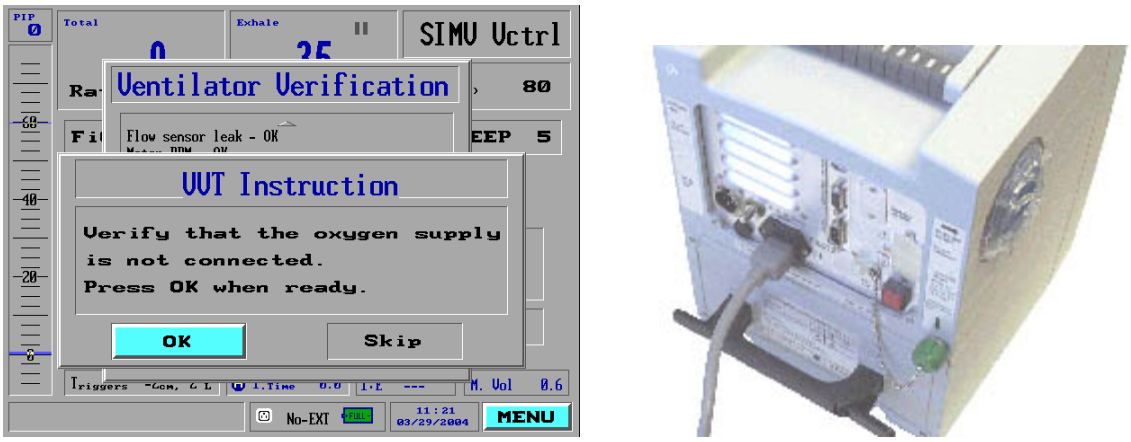


Figure 6-8: O_2 Tests (21%)

5. Connect the O_2 supply to the ventilator and press OK.
6. Wait until the test step is finished (about two (2) minutes). The VVT Instruction window will appear.

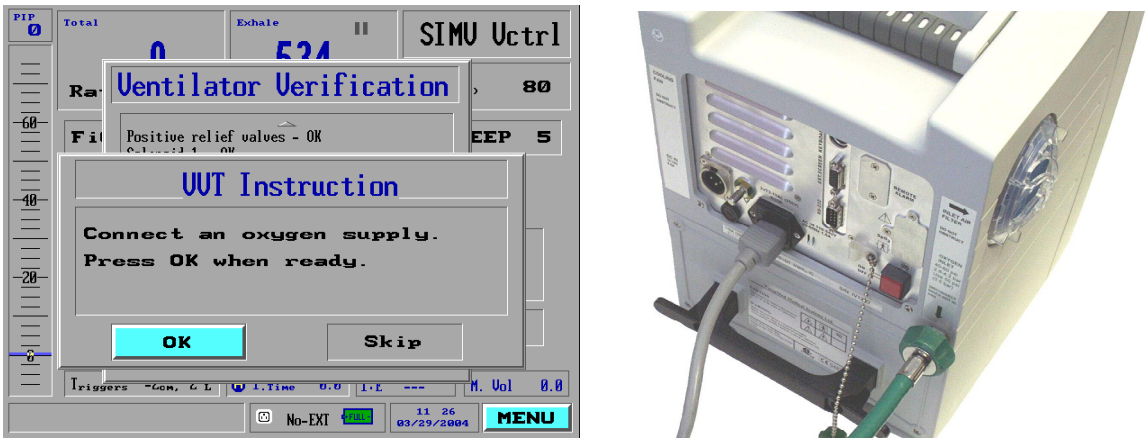


Figure 6-9: O_2 Tests (100%)

6.2.5.5 Battery Test

1. Disconnect the AC power cable from the ventilator and verify that the amber "charge" LED is off and the AC plug icon is crossed out.
2. Press OK and wait until the test step is finished (about 20 seconds). The VVT Instruction window will appear.

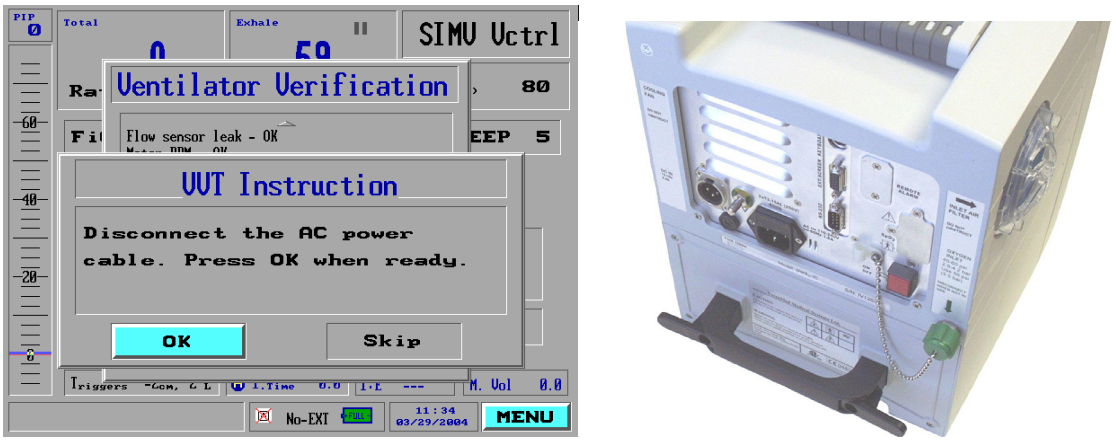


Figure 6-10: Battery Test

6.2.5.6 Watchdog Timer Tests

1. Reconnect the AC power cable to the ventilator and press OK. The Ventilator Verification window will appear.

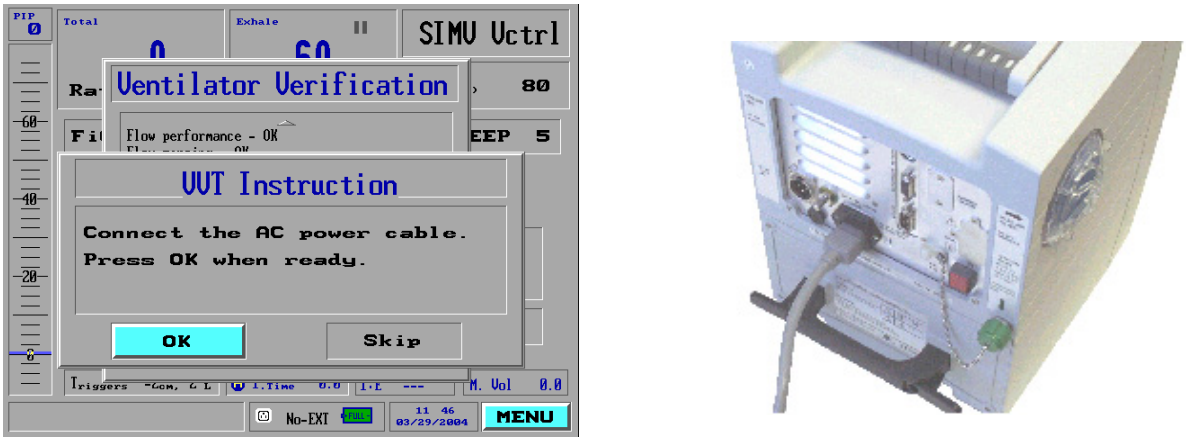


Figure 6-11: Reconnect AC Power

2. Press Finish and wait for the test steps to finish (about 1 minute). During this time the ventilator will restart. The System Message window will appear stating that the Ventilator verification tests were completed successfully or a WARNING window will appear stating that errors were detected during VVT.

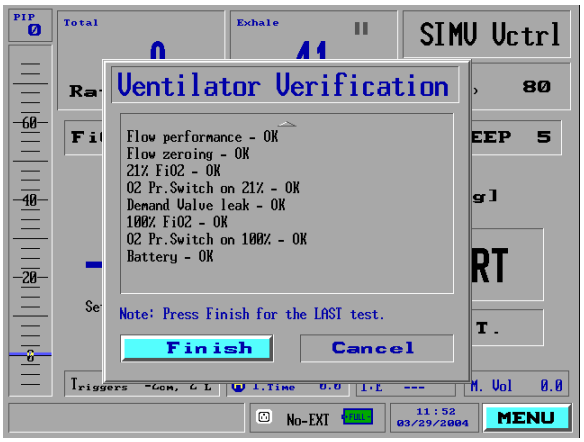
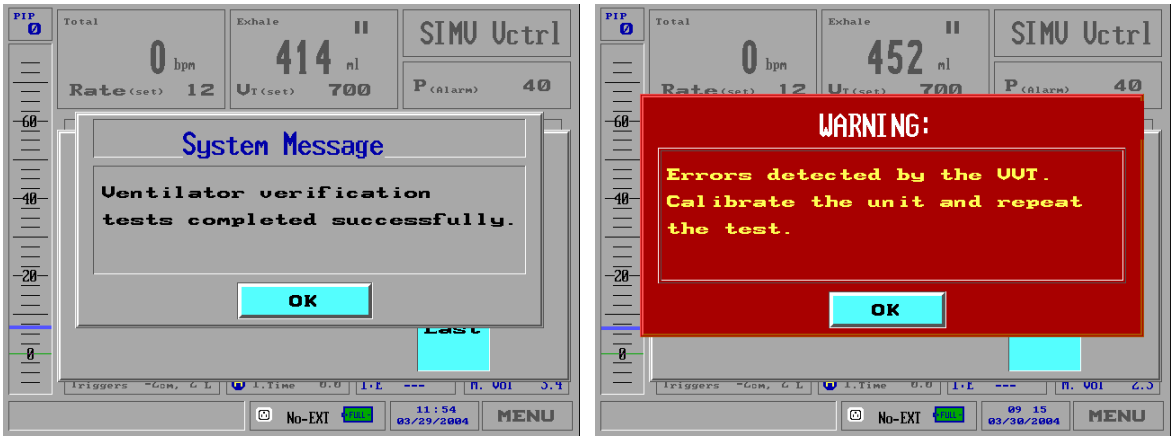


Figure 6-12: Watchdog Timer Tests



VVT Passed **VVT Failed**

Figure 6-13: VVT Test Results

3. Press OK and the weight selection window will appear. Select a weight and the unit will be in the Standby mode.

NOTE	If the ventilator does not pass the VVT, verify that the flow sensor and exhalation valve control tubes are adequately mated to the front panel luer fittings, perform the calibration procedure, and repeat the test.

6.3 Functional Verification Test Procedure

The Functional Verification Test is a series of operational simulations designed to qualify all of the critical functions of the ventilator.

6.3.1 Purpose

This procedure verifies ventilator functions and performance not measured or detectable by the VVT alone.

6.3.2 Scope

This procedure applies to *i*Vent$_{201}$ Version 1.4 ventilators manufactured by VersaMed Medical Systems, Inc. and loaded with software version 19.11 or higher. This procedure should be performed after any repair, software upgrade or annual preventive maintenance.

6.3.3 Tools & Equipment

- O_2 supply, 40-60 psi.
- O_2 supply hose (Versamed P/N 620B0001-01 or 620B0002-01)
- Certified external O_2 analyzer (Puritan Bennett 7820 or equivalent).
- Test lung, 2L. (Versamed P/N 910V0005-01)
- Pneumatic resistor, Rp20. (Versamed P/N 910V0004-A0)

6.3.4 Initialization

1. From a power off state: connect the ventilator to AC power.
2. Turn on the O_2 analyzer and connect its O_2 sensor to the ventilator outlet port and the patient circuit to the O_2 sensor.
3. Connect the Rp20 resistor and test lung to the patient circuit wye.
4. Turn on the ventilator and select the 70+ kg patient weight setting in the opening screen.
5. Set the pressure alarm, "P(Limit) "to 60 (cmH_2O).
6. Press START and allow the ventilator and O_2 analyzer probe to warm up for 15 minutes prior to the test.

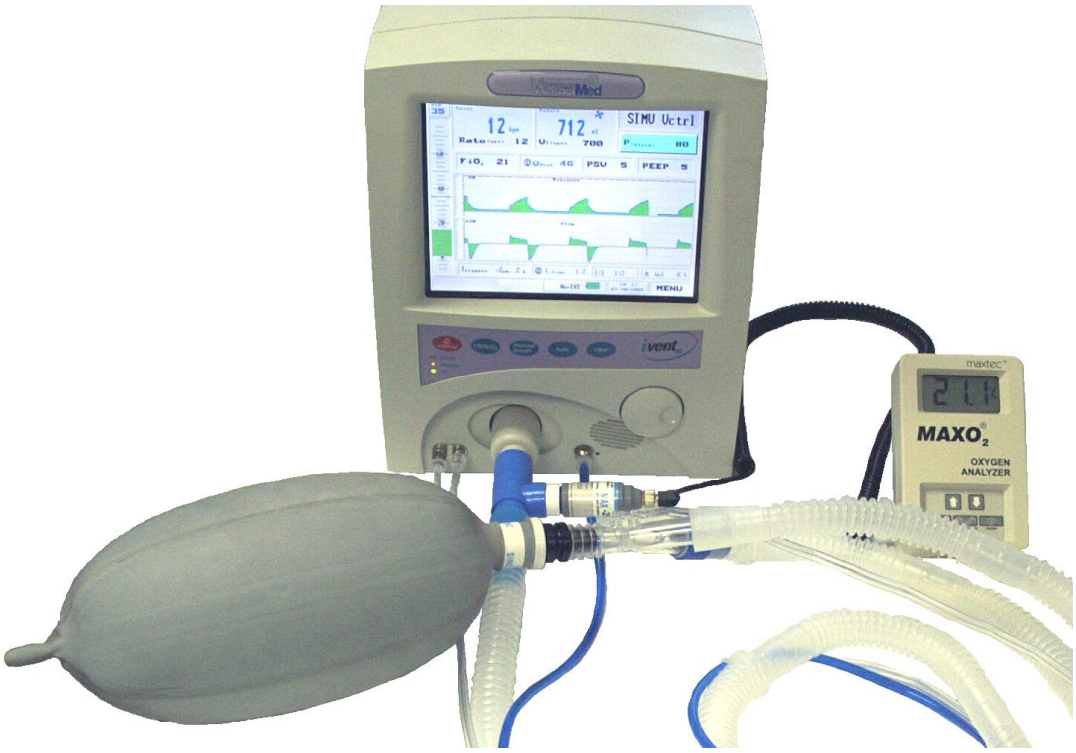


Figure 6-14: External O_2 Analyzer Test Setup

6.3.5 Procedure

The Functional Verification test procedure includes steps for the following:

- O_2 System test
- 100% O_2 (Suction) test
- Safety Alarms test

6.3.5.1 O_2 Delivery and Linearity

1. Adjust the external O_2 analyzer calibration so that it reads 21%.
2. Connect the O_2 supply to the ventilator.
3. Wait for 20 breaths and verify that the external O_2 analyzer measurement is equal to the FiO_2 setting of the ventilator ±10% (FiO_2).

TIP	By selecting Alarm Settings from the Main Menu, you can view the O_2 value that the ventilator is currently measuring. This number is in blue and located to the left of the min/ max alarm bar. Note: If no cursor movement is sensed by the ventilator for one (1) minute, it will timeout and return to the Main Menu.

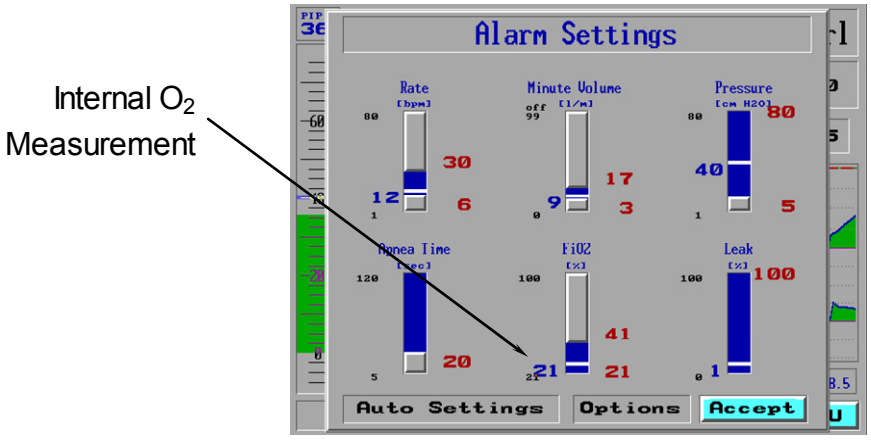


Figure 6-15: Internal O_2 Measurement

4. Set the FiO_2 to 60% and repeat step 3.
5. Set the FiO_2 to 100% and repeat step 3.
6. From the Main Menu select Restore Defaults. A Warning! window will appear stating that this operation will change the mode and all of the current parameters. Select Confirm and then select 40 kg.
7. Repeat steps 3 through 5.
8. From the Main Menu select Restore Defaults. A Warning! window will appear stating that this operation will change the mode and all of the current parameters. Select Confirm, select 70+ kg and set the pressure limit to 60 (cmH_2O).

6.3.5.2 100% O_2 (Suction) Test

1. Press the 100% O_2 button on the ventilator front panel keypad. Verify that a green pop-up window appears next to the FiO_2 field and the 2 minute alarm silence count-down timer is initiated in the time/date field.

2. Verify that the FiO_2 delivery elevates to 100% nominal.

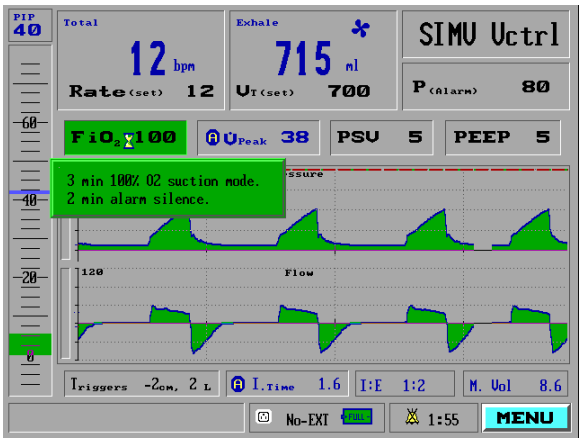


Figure 6-16: 100% O_2 (Suction) Mode

3. During the first 2 minutes, detach the test lung and Rp20 resistor and verify that the audible alarm sounds only once and a red "Pat disc" (Patient disconnect) indicator appears in the lower left part of the display window.

NOTE A "Low press" (Low pressure) indicator may also appear.

4. Reconnect the test lung and Rp20 resistor and verify that the red "Pat disc" indicator changes to green.
5. After the 2-minute alarm silence counts down to zero, detach the test lung and Rp20 resistor. Verify that:
   - **a)** The audible alarm sounds continuously.
   - **b)** A red pop-up **Warning**: window appears, showing **Patient disconnect.**
   - **c)** There is a red "**Pat disc**" indicator in the lower left part of the display window.
6. Reconnect the test lung and Rp20 resistor and clear all alarms by long-pressing the clear or silence button on the keypad.
7. Verify that the FiO_2 setting and delivery return to 21% one (1) minute after the count-down timer expires.

6.3.5.3 Safety Alarms Test

The Safety alarms test checks the following:

- High pressure
- Apnea
- Tube disconnect
- Patient disconnect
- Sensor disconnect

6.3.5.3.1 High Pressure Alarm

1. Enter the Alarm Settings window from the Main Menu and highlight the Pressure group. Reset the high pressure alarm so that it is at least 5 cmH_2O below the average PIP value (approximately 30 cmH_2O). Click on the "Accept" button.
2. Verify that a red pop-up "Warnings:" window appears stating High pressure.
3. Return to the Alarm setting window and reset the high pressure alarm to 60 cmH_2O.

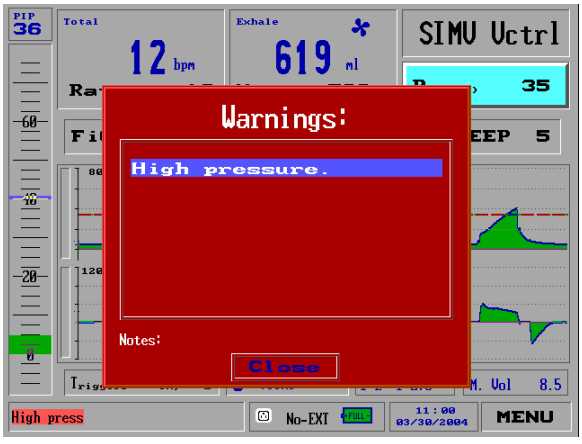


Figure 6-17: High Pressure Alarm

6.3.5.3.2 Apnea Alarm

NOTE The following test requires simulating patient triggers by quickly squeezing and releasing the test lung (in between breaths, while the flow is zero)

1. Set the rate to 2 bpm.
2. After approximately 20 to 25 seconds verify that:
   a) A red pop-up "Warnings:" window appears stating Apnea.
   b) The mode field changes to a blinking APNEA.
   c) The ventilator starts cycling at a higher rate.
3. Press clear on the keypad to remove the pop-up window then select the blinking APNEA and answer Yes to restore the previous mode.

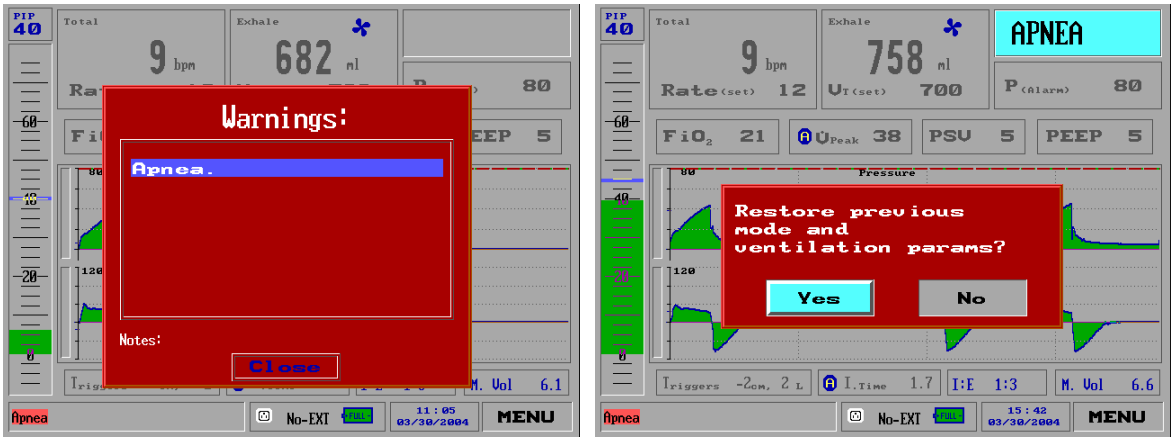


Figure 6-18: Apnea Alarm

4. After another 20 to 25 seconds the unit will go back into APNEA alarm. Simulate patient triggers and Verify that:
   a) During the first minute, the unit does not respond to patient triggers.
   b) After the first minute, the unit does automatically switch back to previous mode after detecting three (3) patient triggers (within a minute).
5. Reset the rate to 12 bpm.

6.3.5.3.3 Tube Disconnect Alarm

1. Disconnect the external analyzer O_2 sensor and patient circuit from the ventilator outlet port.
2. Verify that:
   a) The audible alarm sounds continuously.
   b) A red pop-up "Warnings:" window appears indicating “Tube disconnect. “
   c) A red "Tube disc" indicator appears in the lower left part of the display window.
   d) The mode field changes to a blinking DISCONNECT.

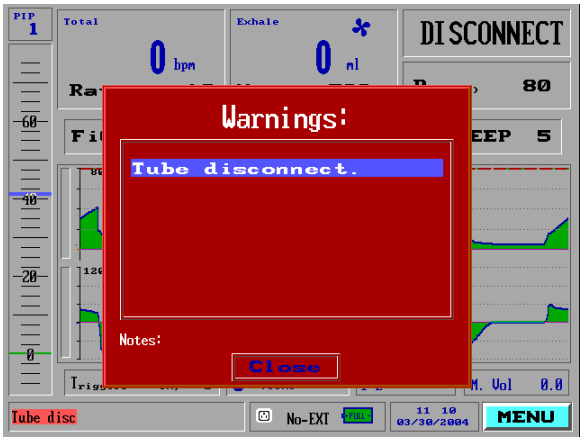


Figure 6-19: Tube Disconnect Alarm

3. Connect the patient circuit to the ventilator outlet port and verify that the alarm automatically recovers.

6.3.5.3.4 Patient Disconnect Alarm

1. Disconnect the test lung and Rp20 resistor from the patient circuit.
2. Verify that:
   a) The audible alarm sounds continuously.
   b) A red pop-up "Warnings:" window appears showing “Patient disconnect” and a red "Pat disc" indicator appears in the lower left part of the display window:

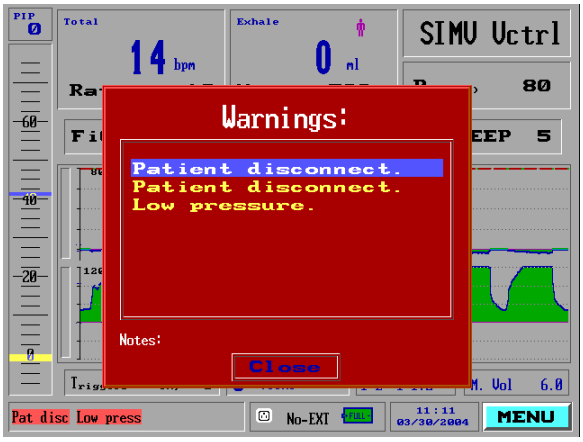


Figure 6-20: Patient Disconnect Alarm

3. Connect the test lung and Rp20 resistor to the patient circuit and verify that the alarm automatically recovers.

6.3.5.3.5 Sensor Disconnect Alarm

1. Disconnect the patient circuit flow sensor connectors (two clear lines at lower left) from the ventilator front panel.
2. Verify that:
   - **a)** The audible alarm sounds continuously.
   - **b)** A red pop-up "Warnings:" window appears stating Sensor disconnect.
   - **c)** There is a red "Sens disc" indicator in the lower left part of the display window.
   - **d)** The mode field changes to a blinking “OPEN LOOP!”

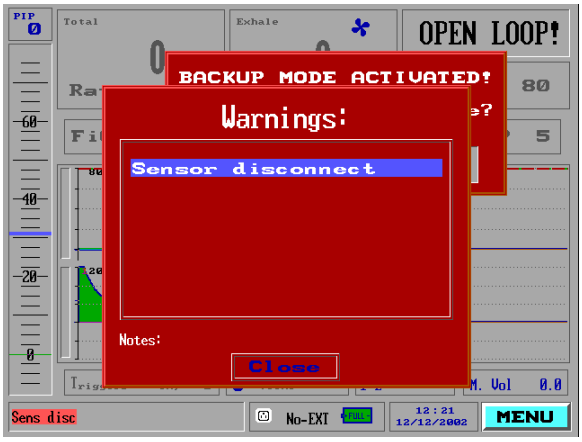


Figure 6-21: Sensor Disconnect Alarm

3. Reconnect the flow sensor lines to the ventilator front panel and verify that the alarm automatically recovers.

Section 7 Service Procedures

The following section provides step by step instructions for upgrading and servicing of the *i*Vent$_{201}$ including the disassembly and reassembly of the unit.

IMPORTANT It is extremely important that Versamed is kept apprised of all servicing activities that affect the final configuration of the unit including traceable components. A form is provided in Appendix B to facilitate this. This form should be copied from the manual, filled-out and remitted to Versamed whenever a PM, upgrade or service is performed on the ventilator. The form can be faxed to: 845-770-2850.

7.1 Software Upgrade Procedure

7.1.1 Purpose

The purpose of this procedure is to provide clear instruction for the upgrade of the ventilator to a new software version.

7.1.2 Scope

This procedure applies to *i*Vent$_{201}$Version 1.4 ventilators manufactured by VersaMed Medical Systems, Inc. and running software version 19.11 or higher.

7.1.3 Tools & Equipment

- PC running Windows 95 OS or higher with the new *i*Vent$_{201}$ software version installed and a free RS-232 port (Com1 to Com4).
- RS-232 communication cable, DB-9, female-female, null modem.

7.1.4 Procedure

1. Turn on the PC, connect the RS-232 port of the PC to the RS-232 port of the ventilator using the null modem serial communication cable.
2. Connect the AC power to the ventilator and switch it on. Select the 70+ kg patient weight in the opening screen.
3. From the Main Menu select the Maintenance option. A Caution window will appear stating that only trained service personnel should enter the restricted Maintenance area.
4. Select Yes and the Maintenance window will appear.
5. Select the SERVICE SCREEN option.
6. Select the UPGRADE SOFTWARE VERSION option.

Figure 7-1: RS-232 Cable to *i*Vent$_{201}$

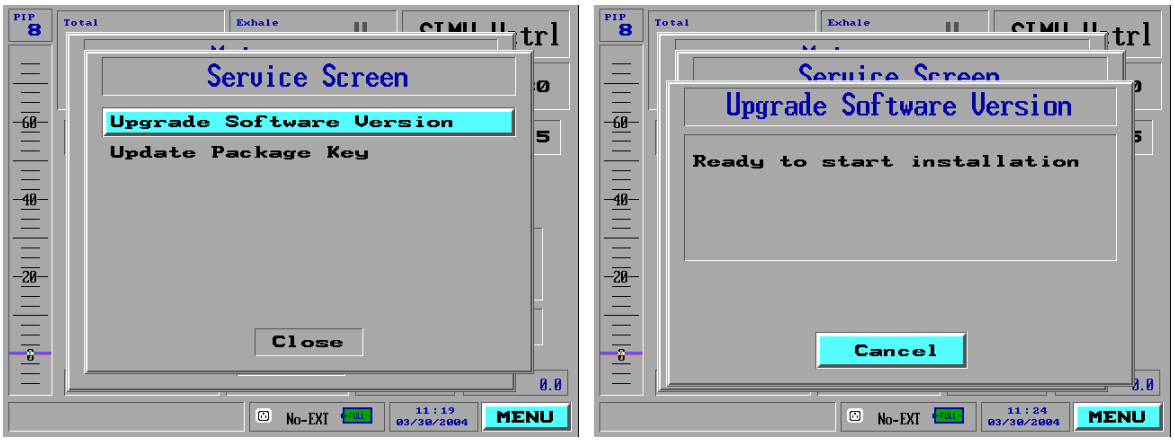


Figure 7-2: Upgrade *i*Vent$_{201}$ Software Screen

7. Double click on the file named "install.exe" on the PC or shortcut placed on the desktop to start up the install application.
8. Verify that communication is established: the message "CONNECTED TO COM (number)" should appear at the bottom-left of the application window. If it does not, check the RS-232 connection and cable. You may also be required to select the appropriate COM port (com1 to com 4) from the Com menu.
9. Press CONNECT on the application screen and wait for a connection. The ventilator card number and the current S/W version will be displayed.

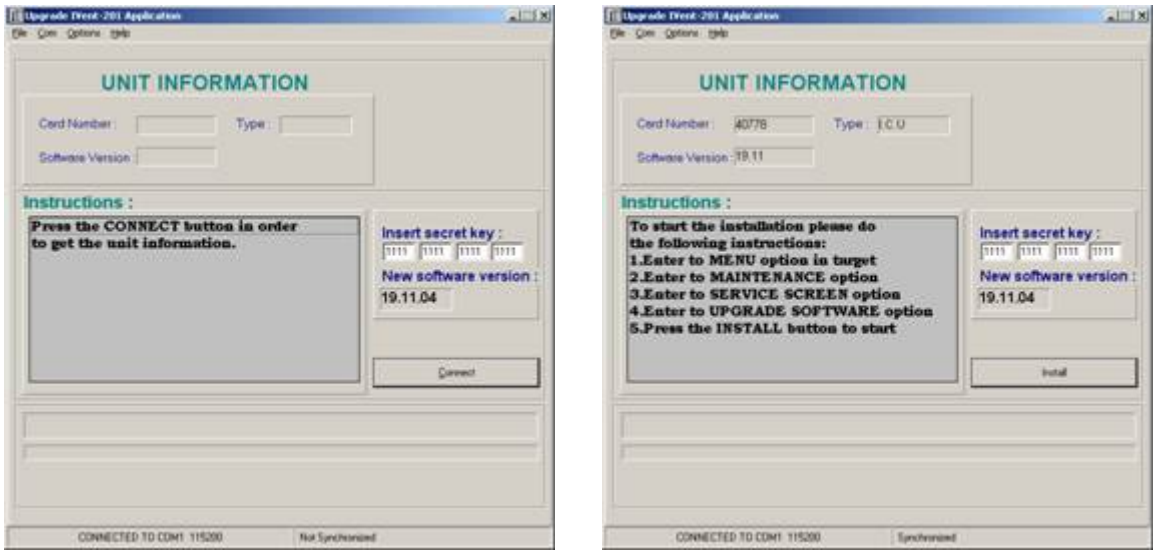


Figure 7-3: Upgrade *i*Vent$_{201}$ PC Application Screens

10. Press the INSTALL button on the application screen and verify that the progress indicator advances at the bottom of the application screen while simultaneously, the loaded percentage increases incrementally on the ventilator screen.
11. At the end of the software installation, the ventilator reboots automatically. After restart, the message INSTALLATION COMPLETED SUCCESSFULLY will appear. Press OK and then select the 70+ kg default.
12. Click OK on the PC screen pop-up window and the install application will automatically close.
13. Select the CONFIGURATION SCREEN option from the maintenance menu.
14. Confirm that the Software version number is updated to the new value.
15. While still in the Configuration screen, select the Default FiO_2 Setting: and change the value to 21% (if desired).

NOTE If no cursor movement is sensed by the ventilator for one (1) minute, it will timeout and return to the Maintenance menu.

16. Press the front panel clear button two (2) times to clear out of the Configuration and Maintenance screen and return to the Standby screen.
17. Calibrate the unit and run the VVT.

7.2 Technical Logs Download

The *i*Vent201 Technical Logs are two (2) non-volatile files contained within the ventilator. The log files contain recorded data of events or errors that occurred during previous usages. The files are accessed using a proprietary download utility named ivDownload. The files are downloaded from the ventilator one at a time and are selected by a specific file name, (either "events.log" or "error.log".) The files must be renamed after they are successfully downloaded from the ventilator onto the PC's hard drive in order to ensure that subsequent downloads can proceed and that no data is overwritten.

NOTE This function can be performed at any time that the ventilator is powered up, including during ventilation. This function should be performed only by a qualified technician.

7.2.1 Purpose

The purpose of this procedure is to provide clear instruction for the retrieval of the *i*Vent$_{201}$ error and event logs.

7.2.2 Scope

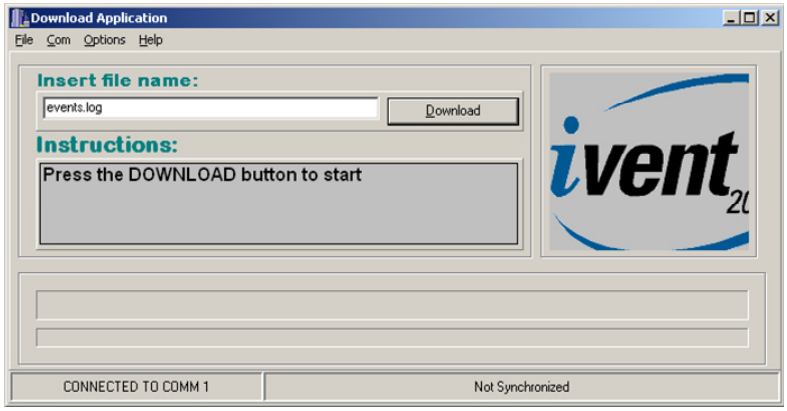
This procedure applies to *i*Vent$_{201}$ Version 1.3 and 1.4 ventilators manufactured by VersaMed Medical Systems, Inc. and running software version 9.xx or higher.

7.2.3 Tools & Equipment

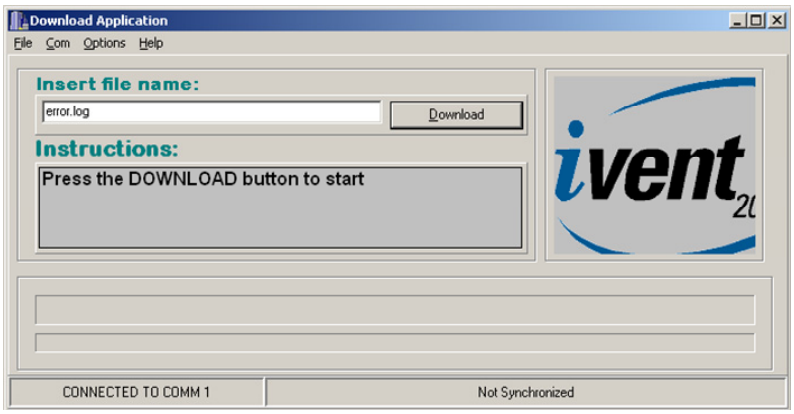
- PC running Windows 95 OS or higher with the new *i*Vent$_{201}$ software version installed and a free RS-232 port (Com1 to Com4).
- RS-232 communication cable, DB-9, female-female, null modem.

7.2.4 Procedure

1. Connect the RS-232 port of the PC to the RS-232 port of the ventilator using the null modem serial communication cable.
2. Double click on the file named "ivDownload.exe" on the PC to start up the download application.
3. Verify that communication is established: the message "CONNECTED TO COM (number)" should appear at the bottom-left of the application window. If it does not, check the RS-232 connection and cable. You may also be required to select the appropriate COM port (com1 to com4) from the Com menu.
4. Type "error.log" or "events.log" into the "Insert file name" box, depending upon which log file you wish to download.



Events Log



Error Log

Figure 7-4: ivDownload PC Application Screens

5. Press the "Download" button to start. The message "Downloading File, please wait" will appear on the PC.
6. When completed, the message "Download ended successfully" will be displayed in a pop-up box on the PC.
7. Press OK and the PC application will automatically close.
8. Locate the file error.log or events.log that you just created in the appropriate PC directory.
9. Right click on the file and select "Rename" from the pop-up window. Rename the file to IVxxx error or IVxxx event where xxx is the serial number of the unit.

CAUTION	The downloaded files will be date/ time stamped with the PC's current date/ time setting. (If the date or time values are incorrect, either adjust the PC clock or include the correct date in the filename.)

10. These file(s) may be sent to technical support (techsupport@versamed.net) for evaluation.

7.3 Option Package Update

The *i*Vent$_{201}$ ventilator contains all of the software needed to run under any configuration as long as the hardware is present. By manually entering a key code that is unique to each unit, different ventilator features can be enabled or disabled. The code is provided by the VersaMed Support Services only. The activation of some features may require special permission since it may affect clinical safety.

7.3.1 Purpose

The purpose of this procedure is to provide clear instruction for reconfiguration of the operational modes and features of the ventilator.

7.3.2 Scope

This procedure applies to *i*Vent$_{201}$ 1.3 and 1.4 ventilators manufactured by VersaMed Medical Systems, Inc. and running software version 9.01 or higher.

7.3.3 Tools & Equipment

- New Package Key Code as generated by Support Services.

7.3.4 Procedure

1. Connect the AC power to the ventilator and switch it on. Select the 70+ kg patient weight in the opening screen.
2. From the Main Menu select the Maintenance option. A Caution window will appear stating that only trained service personnel should enter the restricted Maintenance area.
3. Select Yes and the Maintenance window appears.
4. Select the SERVICE SCREEN option.
5. Select the UPDATE PACKAGE KEY option. The new window will display the old key code. The characters are presented in groups of four, separated by hyphens and are limited to hexadecimal format (0-9, A-F).

NOTE It may not be necessary to re-enter all 16 characters. Typically, less than half of the characters will need to be changed and quite possibly only one may require changing.

6. Using the rotational control knob, highlight and select the first character of the package key that needs to be changed.

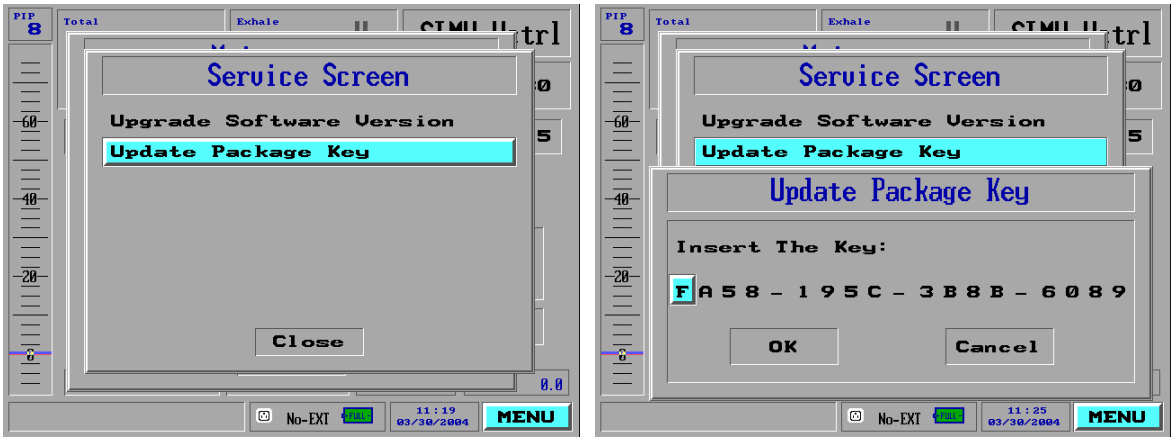


Figure 7-5: Update Package Key

7. Scroll through the values until the desired character appears and press in the control knob.
8. Repeat steps 7 and 8 until all the relevant characters have been changed.
9. Highlight and press OK. A system message appears stating "The package was successfully installed. Restart the iVent for update".
10. Highlight and press OK.
11. Power off the ventilator and then power it up again for the changes to take effect.
12. Select the 70+ kg patient weight in the opening screen.
13. From the Main Menu select the Maintenance option. A Caution window will appear stating that only trained service personnel should enter the restricted Maintenance area.
14. Select Yes and the Maintenance window appears.
15. Select the CONFIGURATION option.
16. View the "Package:" to ensure that it has been changed to the desired option level.
17. Press clear twice to return to the Standby screen.

7.4 Ventilator Disassembly and Assembly

Full or partial disassembly and reassembly of the ventilator will be required for PM component replacement or diagnostics and repair.

The following subsections are organized by sequential stages of disassembly and reassembly. For instance, if you go through all of the disassembly procedures in the order presented, the entire ventilator will have been disassembled down to any replaceable component. If you go through all of the reassembly procedures in the reverse order, the entire unit will have been rebuilt from basic components and modules.

7.4.1 Purpose

The purpose of this procedure is to provide clear instruction for the disassembly and reassembly of the *i*Vent$_{201}$ ventilator.

7.4.2 Scope

This procedure applies to *i*Vent$_{201}$ Version 1.4 ventilators manufactured by VersaMed Medical Systems, Inc.

7.4.3 Enclosure Disassembly & Assembly

7.4.3.1 Tools & Equipment

- Screwdriver, Phillips, #1
- Hex Key, 3mm, 9 inch length
- Pliers, needle-nosed
- Nutdriver, 7mm

7.4.3.2 Enclosure Disassembly

1. Place the ventilator, face down, on an appropriate protective surface. (The foam inserts from the original *i*Vent$_{201}$ shipping carton are well suited for this purpose).
2. Detach the roll stand adapter plate from the bottom of the unit by removing the (4) 3mm x 8mm Phillips head screws and lock washers.

3. Use the hex key to remove the (2) 4mm x 30mm screws and washers from the bottom-rear of the enclosure (see Figure 7-6: Enclosure (Rear View) #1, page 116.)
4. Lift the ventilator carrying handle and use the hex key to remove the (2) 4mm x 50mm screws and washers from the top-rear of the enclosure (see Figure 7-6).
5. Stand the unit back to an upright position and pull the front enclosure apart from the rear enclosure approximately 4 inches.
6. Disconnect the three tubes from the barbed fittings along the bottom of the inside of the front enclosure. Be sure to note where they were connected. (See Figure 7-7, page 116).
7. Disconnect the ribbon cable from the interface PC board located in the middle of the front enclosure. (See Figure 7-7 and Figure 7-8, page 116).
8. Disconnect the green ground wire and receptacle from the pneumatic unit (just above the outlet port).
9. Disconnect the inverter cable from the top of the electronic module. (See Figure 7-7 and Figure 7-8, page 116).
10. With the LCD cable still tethered, lay the front enclosure, face down, on the protective surface.

TIP It is best to orient the front enclosure so that it is facing you, upside down with the tethered LCD cable towards the right.

11. Detach the green LCD cable ground wire from the LCD shield by removing the (1) 3mm x 14mm Phillips head screw and lock washer located in the corner near the LCD connector.
12. Use the nutdriver to remove the (2) 4mm lock nuts from the LCD connector location on the front enclosure (see Figure 7-7, page 116). Remove the aluminum U-shaped bracket from the LCD connector site and pull out the LCD connector and cable.
13. Remove the aluminum U-shaped bracket from the LCD connector site and pull out the LCD connector and cable.

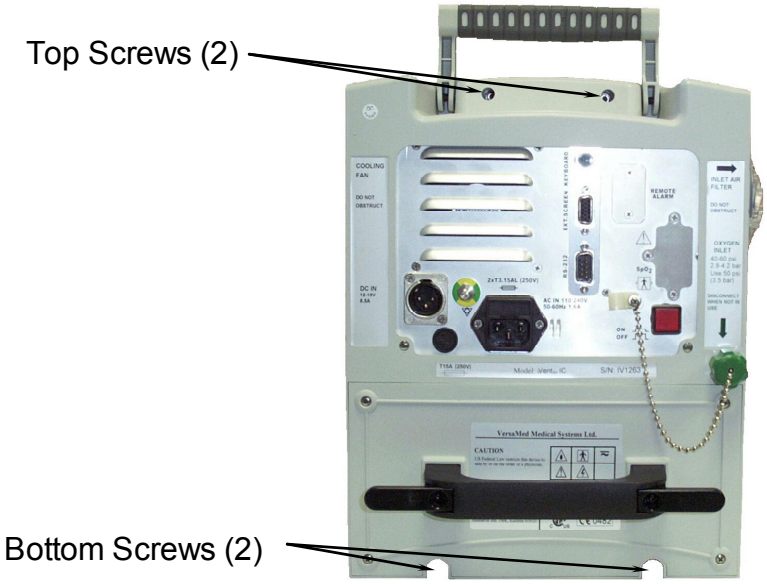


Figure 7-6: Enclosure (Rear View) #1

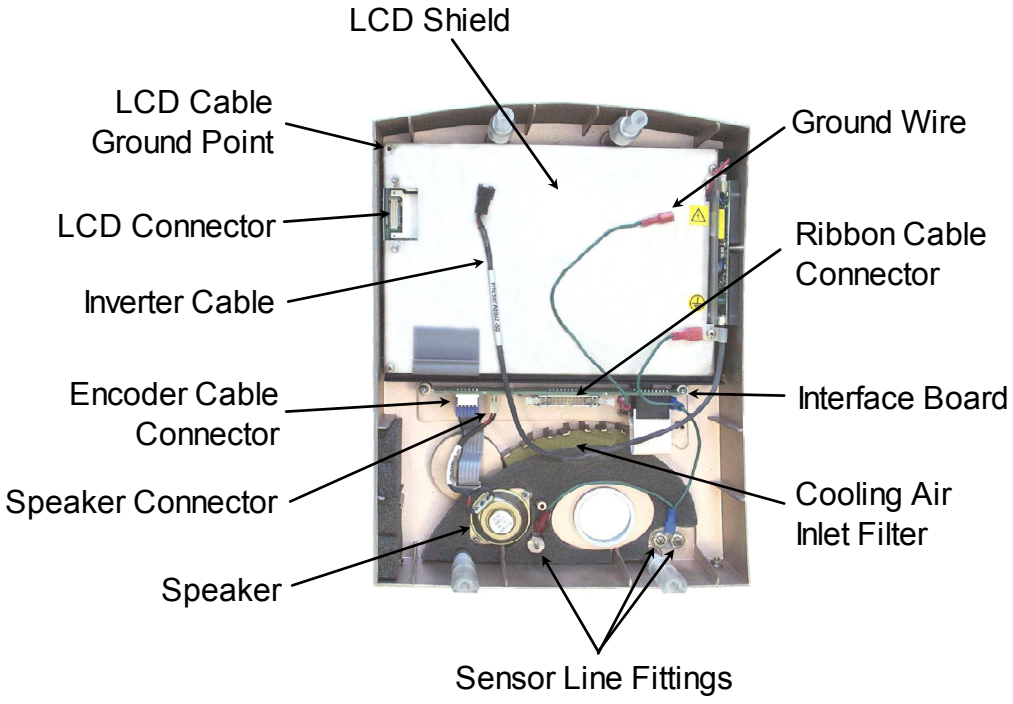


Figure 7-7: Front Enclosure (Inside View) #1

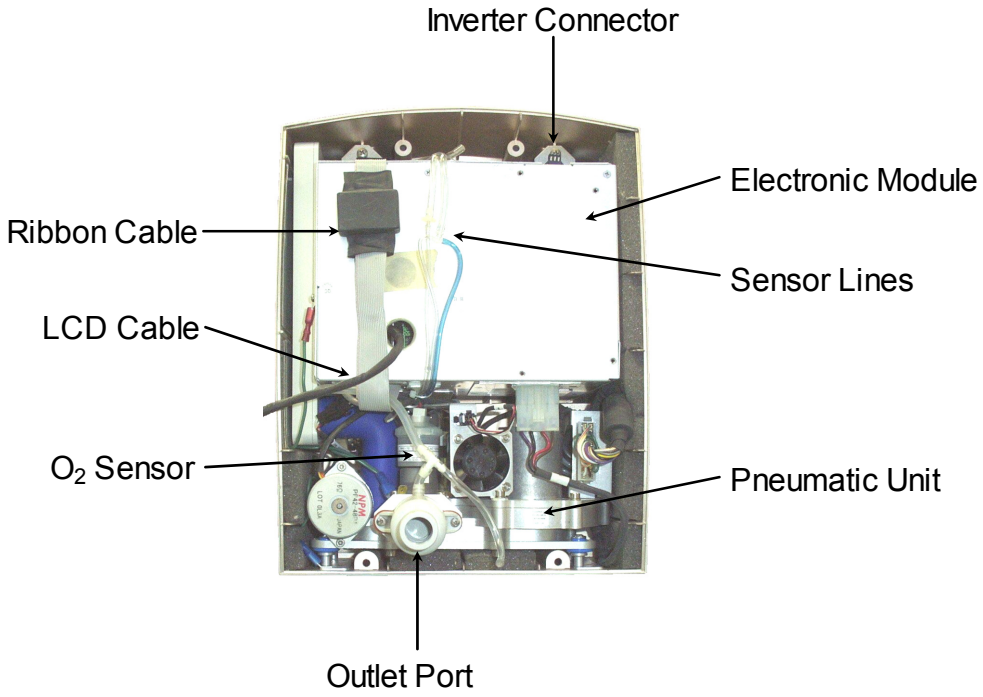


Figure 7-8: Rear Enclosure (Inside View) #1

7.4.3.3 Enclosure Assembly

1. Position the front enclosure face down on a protective surface so that it is upside down and to the left of the rear enclosure assembly.
2. Plug in LCD connector/ cable into the connector located through the LCD shield.
3. Install the U-shaped aluminum bracket oriented foam side down onto the studs protruding from the LCD shield.
4. Thread the (2) 4mm lock nuts onto the studs. While pressing down on the center of the bracket, tighten both lock nuts.
5. Attach the green LCD ground wire to the corner of the LCD shield with the (1) 3mm x 14mm Phillips head screw and lock washer.
6. Position the front enclosure standing up so that it is approximately 4 inches from the rear enclosure.
7. Connect the inverter cable to the top of the electronic module.
8. Connect the ribbon cable (from the bottom of the electronic module) to the interface PC board located in the middle of the front enclosure. Verify that the connector's side retaining clips are snapped into place.

9. Connect the ground cable to the spade terminal located just above the outlet port.
10. Connect the three (3) tubes to the barbed fittings located along the bottom of the inside of the front enclosure. Be sure to reconnect them to the same locations that they were removed from:
    a) The tube from the outlet port tee is connected to the left-most fitting (when viewed from the inside).
    b) The blue tube (or tube with a blue stripe) is connected to the right-most fitting.
    c) The remaining tube is connected to the last remaining fitting.
11. Bring the front and rear enclosures together. Orient the tubing and cables so that none are kinked or crimped.
12. Place the unit, face down, on the protective surface.

TIP Under the weight of the rear enclosure (and assembly), the seam around the entire perimeter of the unit should be closed and even. If it is not, then there is interference from the tubes and/or cables that were just connected.

13. Install the (2) 4mm x 30mm screws and lock washers to the bottom-rear of the enclosure.
14. Install the (2) 4mm x 50mm screws and lock washers to the top-rear of the enclosure.
15. Attach the roll stand adapter plate to the bottom of the unit by installing the (4) 3mm x 8mm Phillips head screws and lock washers. Be sure to orient the plate so that the single middle hole is toward the rear of the unit.

7.4.4 Electronic Module Removal and Installation

7.4.4.1 Tools & Equipment

- Screwdriver, Phillips, #2

7.4.4.2 Electronic Module Removal

1. Disassemble the front enclosure from the rear enclosure as outlined in Enclosure Disassembly, Section 7.4.3.2, page 114.
2. Unscrew the green O_2 inlet cap from the DISS fitting on the rear of the unit (see Figure 7-9, page 120).
3. Remove the (2) 3mm x 8mm Phillips head screws from the rear of the enclosure.
4. From a point of view facing the inside front of the rear enclosure, disconnect the green ground wire from the left-side of the electronic module (EM) (see Figure 7-10, page 120).
5. Disconnect the blower pressure sensing tube from the top of the outlet port.
6. Disconnect the connector from the top of the O_2 sensor.
7. Disconnect the main connector from the right-side of the pneumatic unit by pressing in the side clips of the connector and pulling it out.
8. Disconnect the power pack connector from the bottom-right of the electronic module (EM).
9. Remove the (2) 4mm x 8mm screws and lock washers from the electronic module mounting plate located at the top of the electronic module.
10. Pull the entire electronic module out from the front of the unit. Be sure to guide the O_2 inlet cap and chain through the large opening at the rear of the enclosure.

TIP The rear enclosure assembly can be tilted back so that it rests on the power pack handle.

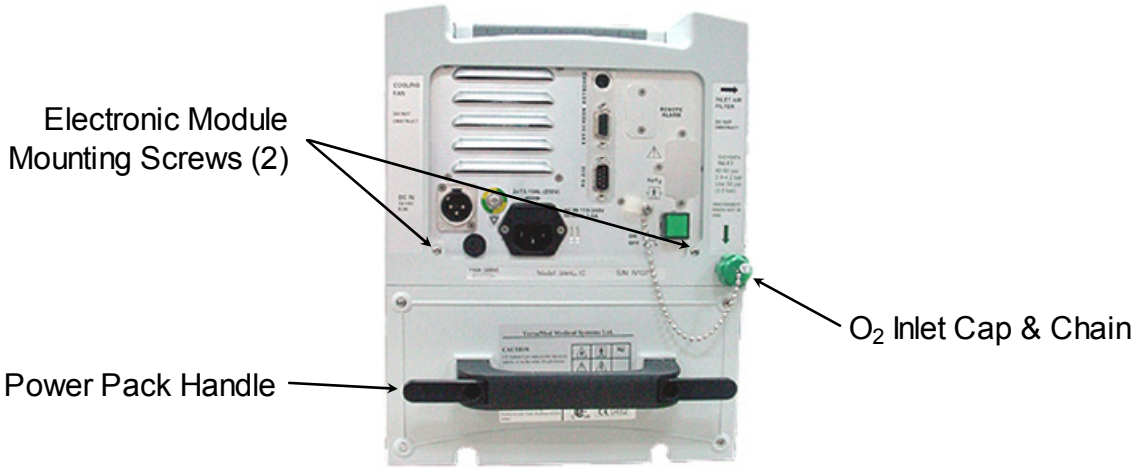


Figure 7-9: Enclosure (Rear View) #2

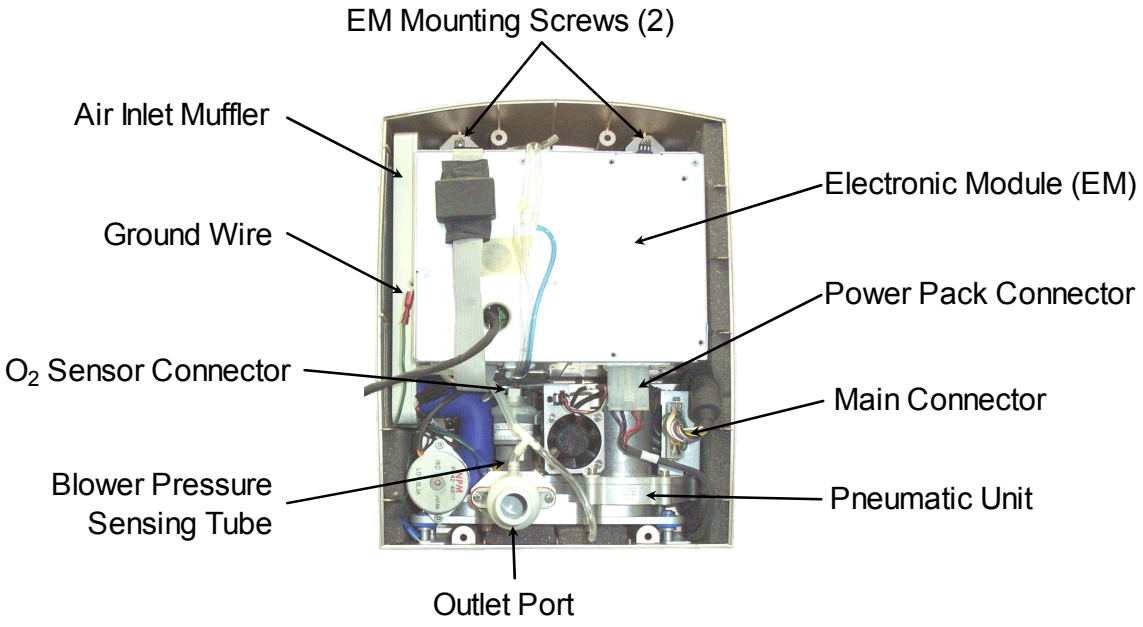


Figure 7-10: Rear Enclosure (Inside View) #2

7.4.4.3 Electronic Module Installation

1. Guide the O_2 cap and chain through the large opening at the rear of the enclosure and slide the electronic module into the top cavity. Be sure that the tubes coming out of the bottom of the electronic module do not kink or bind on the top of the pneumatic unit.

2. Install the (2) 4mm x 8mm screws and lock washers through the electronic module mounting plate located at the top of the electronic module.

NOTE Do not tighten the screws at this time.

3. Install the (2) 3mm x 8mm Phillips head screws to the rear of the enclosure (see Figure 7-9, page 120).
4. Tighten the rear and front mounting screws of the electronic unit.
5. Facing the front of the rear enclosure: connect the green ground wire to the left-side of the electronic module (EM) (see Figure 7-10, page 120).
6. Connect the O_2 sensor connector (marked cable #6) to the top of the O_2 sensor.
7. Connect the blower pressure sensing tube to the top of the outlet port.
8. Connect the main connector to the right-side of the pneumatic unit.
9. Connect the power pack connector to the bottom-right of the electronic module (EM).
10. Screw the green O_2 inlet cap to the DISS fitting on the rear of the unit.
11. Assemble the front enclosure to the rear enclosure as outlined in Enclosure Assembly, Section 7.4.3.3.

7.4.5 Pneumatic Unit Removal and Installation

7.4.5.1 Tools & Equipment

- Screwdriver, Phillips, #2
- Wrench, Open End, 11/16 inch
- Wrench, Open End, 9/16 inch

7.4.5.2 Pneumatic Unit Removal

1. Disassemble the front enclosure from the rear enclosure as outlined in Enclosure Disassembly, Section 7.4.3.2, page 114.

2. Remove the electronic module as outlined in Electronic Module Removal, Section 7.4.4.2, page 119.
3. Remove the air inlet filter from the side of the rear enclosure. Be sure that the O-ring remains on the side inlet port.
4. Slide the air inlet muffler straight out and simultaneously disconnect the blue air inlet tube.
5. Tilt the rear enclosure back onto the power pack handle in order to gain convenient access to the underside of the unit.
6. Remove the (4) 4mm x 10mm Phillips head screws from the bottom of the rear enclosure.
7. Use the 11/16 inch and 9/16 inch Open-End wrenches to loosen and detach the DISS collar to the demand valve.
8. Identify the O_2 pressure switch type and disconnect the corresponding connector(s):
   a) For the Silver colored metal switch which is threaded directly onto the O_2 inlet pipe: Follow the cable assembly coming out of the back of the pressure switch and disconnect the black 3-pin hanging connector.
   b) For the brass colored metal body which mounted to the back wall of the rear enclosure: disconnect the two (2) crimped connectors from the tabs on the rear of the O_2 pressure switch.
9. Disconnect the green ground wire assembly from the dual tabs located just above the outlet port.
10. Pull the pneumatic unit straight out of the rear enclosure.

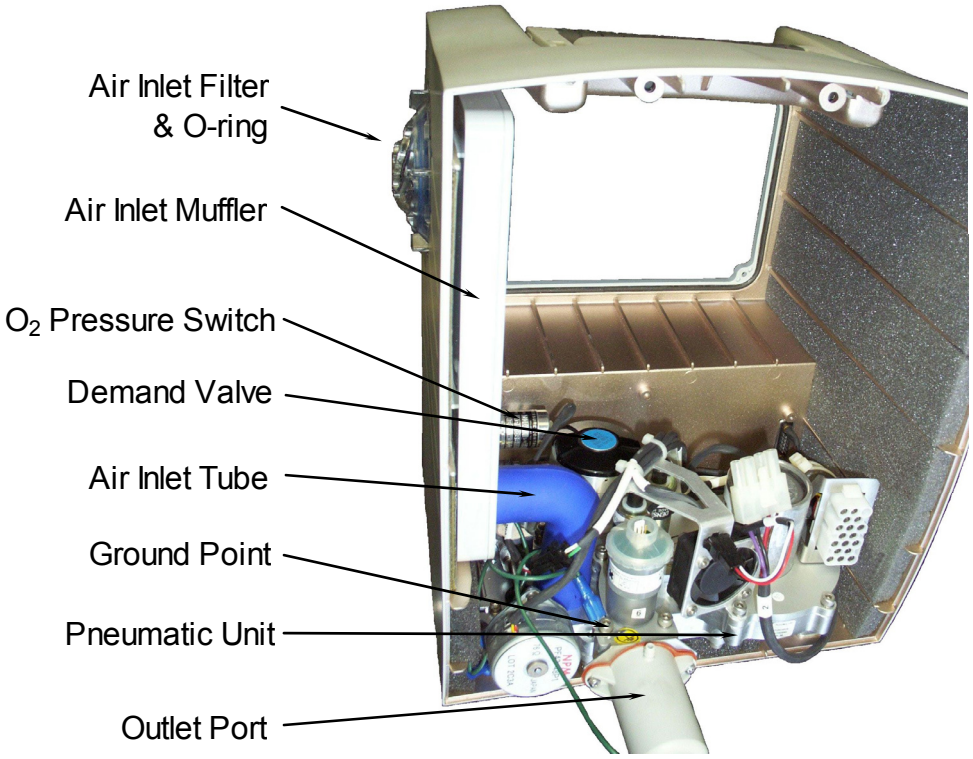


Figure 7-11: Rear Enclosure (Inside View) #3

7.4.5.3 Pneumatic Unit Installation

1. Rotate the shaft of the O_2 mixer stepper motor by hand so that the O_2 microswitch actuating arm is in the center of the high area of the cam (see Figure 7-12).

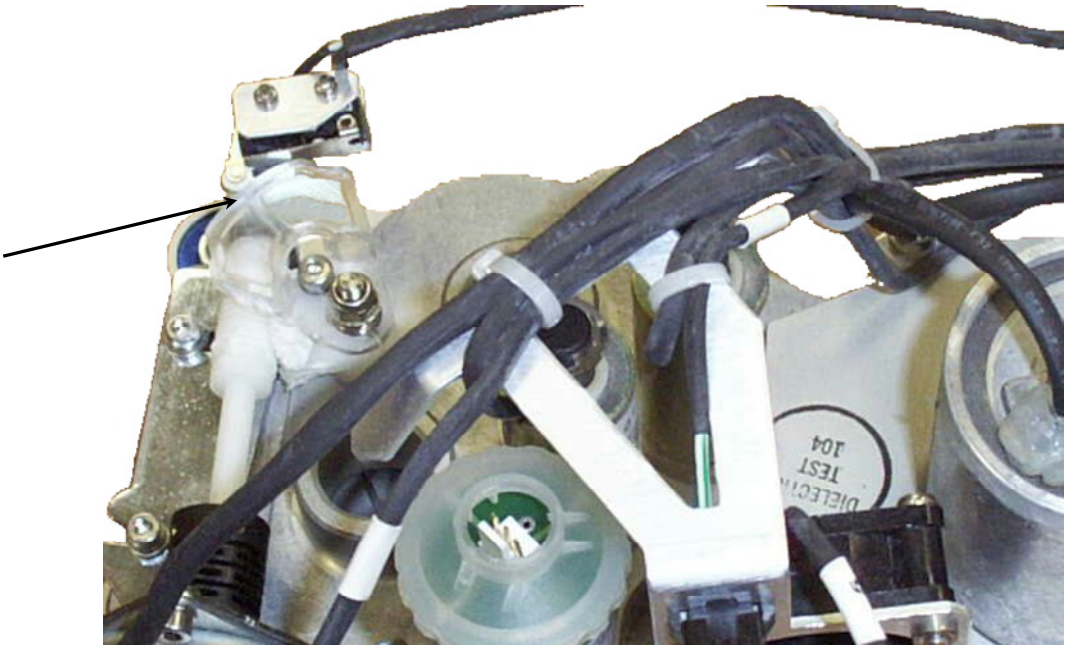


Figure 7-12: O_2 Mixer Cam to Mid Point Position

2. Place the pneumatic unit into the bottom of the rear enclosure.
3. Align the demand valve of the pneumatic unit with the DISS fitting of the O_2 inlet pipe and hand-tighten the collar.
4. Place the green ground wire and tab between the front-left leg of pneumatic unit and the mounting plate.
5. Tilt the rear enclosure back onto the power pack handle in order gain convenient access to the underside of the unit.
6. Beginning with the front-left leg of the pneumatic unit, install the (4) 4mm x 10mm Phillips head screws, lock washers and washers through the bottom of the enclosure, mounting plate and leg. Ensure that the first screw feeds through the ground wire tab of the front-left leg.

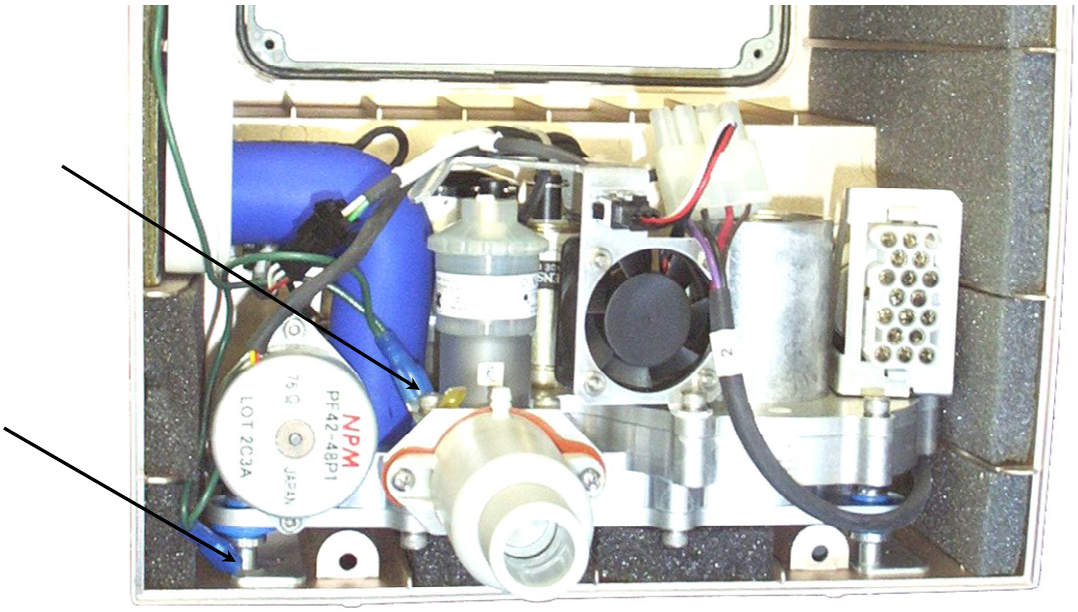


Figure 7-13: PU Ground Point Locations

7. Use the 11/16 inch and 9/16 inch Open-End wrenches to tighten the DISS fitting to the demand valve. Ensure that the demand valve does not twist and remains vertical on the pneumatic unit.

TIP Apply the high pressure O_2 to the rear DISS inlet and verify that the demand valve shuts off and does not audibly leak. Disengage the O_2 supply.

8. Identify the O_2 pressure switch type and connect the corresponding connector(s):
   - **a)** Silver colored metal switch which is threaded directly onto the O_2 inlet pipe:
     - Route the cable assembly coming out of the back of the pressure switch under the blue air inlet tube and connect the black 3-pin hanging connector.
   - **b)** Brass colored metal body mounted to the back wall of the rear enclosure:
     - Connect the two (2) crimped receptacles coming from the back of pneumatic unit's main connector to the rear of the O_2 pressure switch.
9. Connect the green ground wire and crimped receptacle onto the dual tabs located just above the outlet port.

10. Align the air inlet muffler with the tracks found on the left-inside of the rear enclosure and slide the muffler all the way to the back.
11. Connect the blue air inlet tube to the outlet of the air inlet muffler.
12. Install the air inlet filter onto the side air inlet port. Ensure that the O-ring was retained on the port.

NOTE If the air inlet filter does not install easily and without interference then the air inlet muffler was not inserted all the way back.

13. Install the electronic module as outlined in Section 7.4.4.3, Electronic Module Installation, page 120.
14. Assemble the front enclosure to the rear enclosure as outlined in Section 7.4.3.3, Enclosure Assembly, page 117.

7.4.6 LCD Assembly Removal and Installation

7.4.6.1 Tools and Equipment

- Screwdriver, Phillips, #1
- Pliers, needle-nosed

7.4.6.2 LCD Assembly Removal

1. Disassemble the front enclosure from the rear enclosure as outlined in Section 7.4.3.2, Enclosure Disassembly, page 114.
2. Remove the (1) 3mm x 18mm Phillips head screw, lock washer and washer from the LCD shield (located at the inverter cable/ground junction corner) (see Figure 7-14).
3. Remove the remaining (2) 3mm x 14mm Phillips head screws and lock washers from the LCD shield.
4. Disconnect the backlight connector from the inverter board (see Figure 7-14).
5. Lift out the LCD shield and screen as one unit.
6. Remove the (4) 2mm x 8mm Phillips flathead screws from the corners of the black LCD mask and lift it out.
7. Lift out the clear LCD protection window and inverter carrier.

Figure 7-14: Front Enclosure (Inside View #2)

7.4.6.3 LCD Assembly Installation

1. Place the LCD protection window and inverter carrier into the top-inside of the front enclosure. (The assembly is "keyed" so there is only one valid position.)
2. Place the black LCD mask on top of the LCD protection window so that the cutout is to the right and the lip is facing out.
3. Install the (4) 2mm x 8mm Phillips flathead screws into the corners of the black LCD mask.

TIP Now is the best time to dust and clean the inside of the protection window and the LCD screen. A glass cleaner works well for this purpose.

4. Place the LCD shield and screen on top of the black LCD mask so that the shield cutout is facing right and the LCD screen is facing down.
5. Plug in the backlight connector into the inverter board so that the red wire is up.
6. Install the (2) 3mm x 14mm Phillips head screws and lock washers into the upper-right and lower-left holes of the LCD shield.

7. Position the green ground wire and tab between the LCD shield and the inverter cable clamp and install the 3mm x 18mm Phillips head screw, lock washer and washer.
8. Assemble the front enclosure to the rear enclosure as outlined in Section 7.4.3.3, Enclosure Assembly, page 117.

7.4.7 Interface Board Removal and Installation

There are two (2) versions of the interface board.

- The older version has a hard-wired encoder, two (2) sounders, 16 pin main connector and one (1) ground point.
- The newer version has an encoder connector, speaker connector and one (1) sounder, 20 pin main connector and two (2) ground points.

From an assembly viewpoint, the only difference is that the encoder may have to be removed along with the interface board.

7.4.7.1 Tools & Equipment

- Screwdriver, Phillips, #1
- Pliers, needle-nosed
- Nut driver, 11mm (To remove & install encoder)
- Screwdriver, Slotted (To remove & install encoder)

7.4.7.2 Interface Board Removal

1. Disassemble the front enclosure from the rear enclosure as outlined in Section 7.4.3.2, Enclosure Disassembly, page 114.
2. Remove the (2) 3mm x 8mm Phillips head screws and 4mm washers located on each end of the PC Board.
3. Disconnect the green ground cable(s) from the interface board.
4. Disconnect the (front keypad) 9 pin flex cable assembly from the interface board.
5. Disconnect the (front keypad) 2-pin flex cable assembly from the interface board.
6. Identify the interface board type and follow the corresponding steps:

a) Front enclosure has a speaker:

i) Disconnect the blue 6 pin encoder connector and white 2-pin speaker connector from the interface board.

ii) Slide the interface board up vertically to remove it from the front enclosure.

b) Front enclosure has no speaker:

i) Orient the front enclosure so that the front is facing up.

ii) Use the slot bladed screwdriver to pry the rotational control knob off of the encoder shaft.

iii) Use the 11mm nut driver to remove the nut and lock washer from the mounting threads of the encoder.

iv) Orient the front enclosure face down and pull the encoder out of the mounting hole.

v) Slide the interface board up vertically to remove it from the front enclosure.

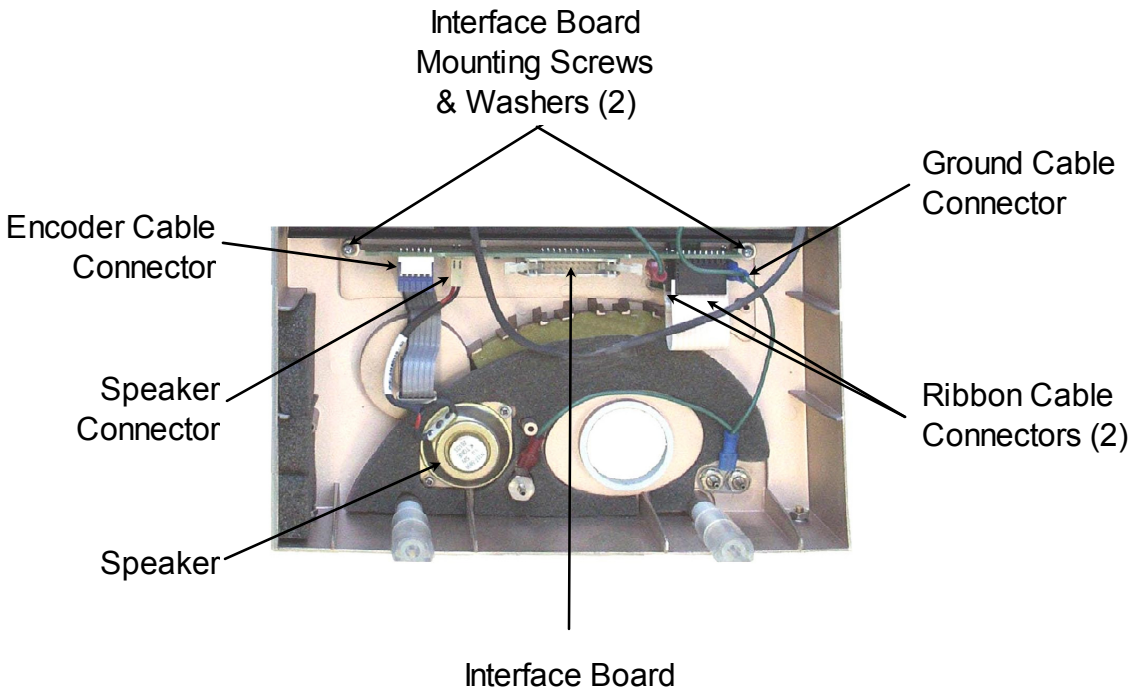


Figure 7-15: Front Enclosure (Inside View) #3

7.4.7.3 Interface Board Installation

7. Route the (front keypad) 2-pin flex cable assembly under the interface board and plug it in to the mating connector.

8. Slide the interface board into the vertical tracks with the component side facing the bottom of the front enclosure. Verify that the interface board has been inserted all the way and that the sides of the board are flush with the mounting holes.
9. Install the (2) 3mm x 8mm Phillips head screws and 4mm washers into the mounting holes located on each end of the PC Board. While tightening the screws, push the washers toward the center so that they hang over the tracks.

CAUTION Be careful not to over tighten the screws.

10. Connect the (front keypad) 9 pin flex cable assembly to the mating connector of the interface board.
11. Connect the green ground cable(s) to the tab(s) on the interface board.
12. Identify the interface board type and follow the corresponding steps:
    - **a)** Front enclosure has a speaker:
      - **i)** Connect the blue 6 pin encoder connector and white 2-pin speaker connector to the mating connector of the interface board.
    - **b)** Front enclosure has no speaker:
      - **i)** Install the encoder into the mounting hole and radially orient it so that the ribbon cable is closest to the bottom. Be sure that it is seated within the raised rectangular area.
      - **ii)** Use the 11mm nut driver to install the nut and tooth washer onto the mounting threads of the encoder.
      - **iii)** Radially orient the rotational control knob so that the indent of the knob is 180° from the flat part of the encoder shaft and push it on.
13. Assemble the front enclosure to the rear enclosure as outlined in Enclosure Assembly, Section 7.4.3.3, page 117.

7.4.8 Electronic Module Cover Removal and Installation

7.4.8.1 Tools & Equipment

- Screwdriver, Phillips, #1

7.4.8.2 Electronic Module Cover Removal

CAUTION Use ESD protection when removing the cover from the electronic module.

1. To expose the edges of all the PC boards and the top-side of the zeroing/purge board:
   - **a)** Remove the electronic module as outlined in Section 7.4.4.2, Electronic Module Removal, page 119.
   - **b)** Remove the (4) #4 Phillips flat head screws from the top of the electronic module (see Figure 7-16).
   - **c)** Remove the (2) #4 Phillips flathead screws from the left-side of the electronic module.
   - **d)** Remove the (1) #4 Phillips head screw, lock washer and ground tab from the left-side of the electronic module and lift off the cover.
2. To gain access to the sensor tubing connections at the transducers:
   - **a)** Remove the (4) #4 Phillips flathead screws from the tubing cover located at the bottom of the electronic module and lift off the cover.
3. To gain access to the power supply and switching board:
   - **a)** Remove the (2) #4 Phillips flathead screws from the front-right-top corner and rear-left-top corner of the electronic module.
   - **b)** Lower the right-side hinged cover of the electronic module.

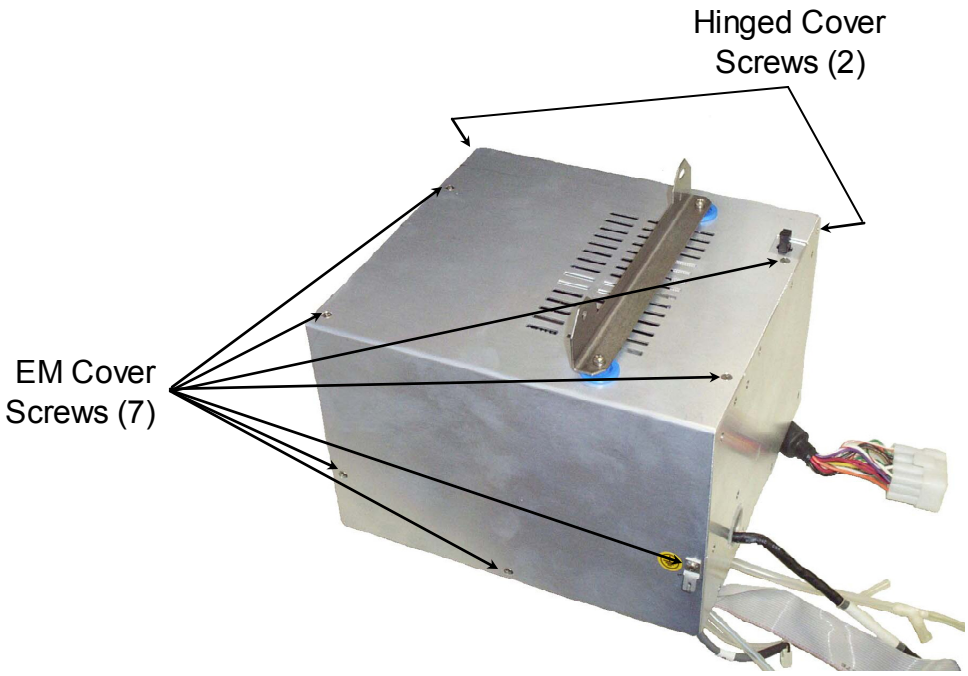


Figure 7-16: EM Cover Screw Locations

7.4.8.3 Electronic Module Cover Installation

1. Raise the right-side hinged cover of the electronic module.
2. Install the (2) #4 Phillips flathead screws to the front-right-top corner and rear-left-top corner of the electronic module.
3. Position the tubing cover over the top of the electronic module and install the (4) #4 Phillips flathead screws.
4. Position the right angled cover over the top of the electronic module and install the (4) #4 Phillips flathead screws.
5. Install the (2) #4 Phillips flathead screws to the left-side of the electronic module.
6. Install the (1) #4 Phillips head screw, lock washer and ground tab to the left-side of the electronic module.
7. Install the electronic module as outlined in Section 7.4.4.3, Electronic Module Installation, page 120.

7.4.9 Power Pack Disassembly and Assembly

7.4.9.1 Tools & Equipment

- Screwdriver, Phillips, #1
- Pliers, needle-nosed

7.4.9.2 Power Pack Disassembly

1. Remove the (4) 3mm x 20mm Phillips head screw from the corners of the power pack (see Figure 7-17).
2. Grasp the black handle of the power pack and pull it straight out from its compartment (see Figure 7-18).
3. Remove the (5) 3mm x 10mm Phillips head screws and lock washers from the back of the power pack assembly and lift off the cover.
4. Turn the battery pack assembly upside-down and slide the battery out of the casing.
5. Using the pliers, remove the two spade connectors from the exposed battery terminals.

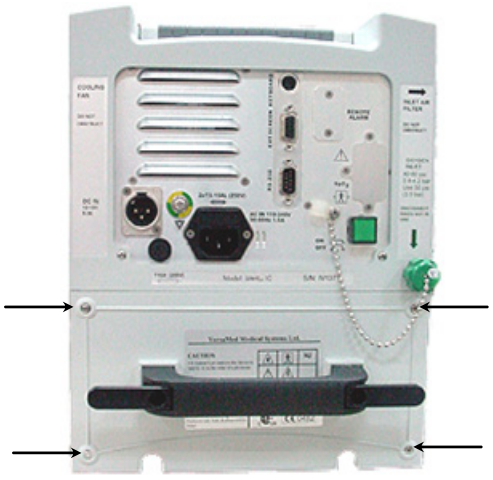


Figure 7-17: Power Pack (Rear View)

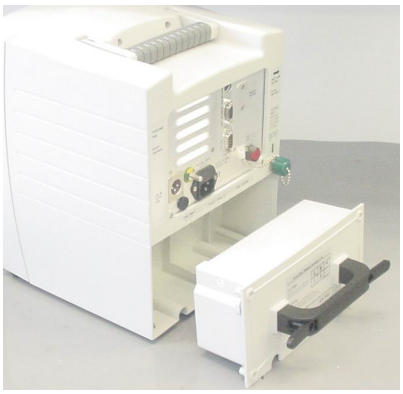


Figure 7-18: Power Pack (Removed)

7.4.9.3 Power Pack Assembly

1. Connect the red wire to the positive terminal of the battery and the black wire to the negative terminal.

CAUTION	Reversing the polarity of the wires will destroy the battery gas gauge located within the power pack.

2. Slide the battery into the casing. Be sure that the red and black wires are located towards the recessed part of the battery cavity.
3. Position the cover into the casing and fasten the (5) 3mm x 10mm Phillips head screws and lock washers to the back of the power pack housing.
4. Slide the assembled power pack into the ventilator compartment until the cover is flush with the back of the unit.

TIP	Power up the unit briefly and verify that the connection was successful by listening for the cooling fan operation.

5. Install the (4) 3mm x 20mm Phillips head screws into the corners of the power pack assembly.

7.4.10 O_2 Sensor Removal and Installation

7.4.10.1 Tools & Equipment

- Screwdriver, Phillips, #1
- Hex Key, 3mm, 9 inch length

7.4.10.2 O_2 Sensor Removal

1. Disassemble the ventilator enclosure as outlined in steps 1-9 of Section 7.4.

TIP	Perform steps 1-9 only, since the LCD cable does not need to be detached for this service.

2. Disconnect the tube from the top of the outlet port to provide clearance.
3. Disconnect the gray cable from the top of the existing O_2 sensor.
4. Remove the existing O_2 sensor and o-ring by turning it counter-clockwise.

NOTE	The translucent adapter and o-ring that connects the **O_2** sensor to the pneumatic unit may also come off. If it does, unscrew the **O_2** sensor and reinstall the adapter and o-ring to the pneumatic unit.

7.4.10.3 O_2 Sensor Installation

1. Install the replacement sensor and o-ring by screwing it into the translucent adapter.
2. Reconnect the cable to the O_2 sensor.
3. Reinstall the blower sensor tubing to the barbed connector on top of the outlet port.
4. Assemble the ventilator enclosure as outlined in Section 7.4.3.3, page 117).

NOTE Perform steps 6-12 only, if the LCD cable was not detached.

7.5 Battery Gas Gauge Initialization Procedure

Whenever the internal battery has been replaced or the gas gauge has accumulated significant error, the gas gauge needs to measure the total battery capacity in order to provide meaningful information (see Section 4.5.1, page 72).

7.5.1 Purpose

The purpose of this procedure is to set the gas gauge to accord properly with initial internal battery measurements.

7.5.2 Scope

This procedure applies to *i*Vent$_{201}$ Version 1.3 and 1.4 ventilators manufactured by VersaMed Medical Systems, Inc. and running software version 10.xx or higher.

7.5.3 Tools & Equipment

- Test lung, 2L. (Versamed P/N 910V0005-01)
- Pneumatic resistor, Rp20. (Versamed P/N 910V0004-A0)

7.5.4 Procedure

1. Plug the AC power cord into the ventilator, verify that the amber charge LED comes on and allow the unit to charge the battery for at least 8 hours.
2. Power up the ventilator and select the 70+ kg patient weight setting in the opening screen.

NOTE Even if the battery icon doesn't show FULL, it should be ignored at this time.

3. Set the pressure alarm to 60 (cmH_2O).

4. Connect the Rp20 resistor and test lung to the patient circuit wye and then connect the patient circuit to the ventilator.
5. Press "START" on the ventilator.
6. Adjust the tidal volume (Vt) so that a PIP of at least 40 cmH_2O is attained on each and every breath. (850 mL is a typical value.)
7. Disconnect the AC power cord and remove the pop-up window by pressing clear.
8. Allow the ventilator to run off the battery continuously until the Empty battery alarm activates.

NOTE If the low battery alarm activates, clear it and allow the unit to continue operation until the empty battery alarm.

TIP The battery run time may be measured during this time by monitoring the time from AC disconnect to the empty battery alarm. These events and their respective time stamps can be reviewed by selecting "Show Log Book" from the Main Menu. (The typical run time under these parameters is approximately one hour.)

9. Reconnect the AC power cord and place the unit into Standby mode.
10. Allow the unit to recharge for at least 10 hours.
11. Operate the unit normally and verify that the battery icon on the display indicates full.

Section 8 Troubleshooting

8.1 Troubleshooting Guide

Prior to utilization of the following troubleshooting table it is assumed that the following basic steps and verifications have been implemented whenever possible:

Verify that:

1. The unit conforms to upgrade changes mandated by Technical Notification (TN) distributed by VersaMed Medical Systems, Inc. including installation of the current released software revision.

NOTE Complete and remit any Field Change Order (FCO) forms supplied by VersaMed Medical Systems, Inc.

2. The periodic maintenance schedule is current and follows the guidelines outlined in Section 5 of this Service Manual and Section 8 of the Operators Manual.
3. All external tubing, cables and connections are properly secured and reliable.
4. The OVT and VVT procedures have been conducted with all failures noted.
5. The unit can be calibrated successfully and re-verified by OVT and VVT.
6. The technical log files (error.log and events.log) have been downloaded and archived.

NOTE Files should be e-mailed to techsupport@versamed.net

7. All internal tubing, cables, connectors and contacts are properly secured, reliable, and routed away from any moving component.
8. Suspected defective component has been temporarily substituted and the unit re-verified by OVT and VVT.

Table 8-1: Troubleshooting Guide

Symptom	Observations	Possible Cause	Solution	Part Number
Unit powers off when the power switch is released.	Power Switch doesn't latch into the "ON" position.	Gasket still present in switch body.	Remove Power Switch gasket. (See Power Switch Sect.)	
		Defective On/Off switch.	Replace On/Off switch.	135D0003
Unit does not power up on AC power.	No continuity through the power switch terminals.	Defective On/Off switch.	Replace On/Off switch.	135D0003
		Defective Electronic Module.	Replace Electronic Module.	Call Service for Part#
Unit powers up but does not boot up.	Green LED lights	Wrong software revision installed or installation was interrupted.	Replace Electronic Module.	Call Service for Part#
		Defective Electronic Module.	Replace Electronic Module.	Call Service for Part#
Unit powers up but restarts over and over again.		Defective Electronic Module.	Replace Electronic Module.	Call Service for Part#
Unit blows AC fuse immediately upon power up.		Defective Electronic Module.	Replace Electronic Module.	Call Service for Part#
Unit powered off without user intervention.	Error Code 1 or Warm restart in technical log.	Power surge, dropout or defective Electronic Module.	Replace Electronic Module.	Call Service for Part#
	Unit was running on battery power. (AC power disconnect in event log.)	AC fuse is blown or discharged battery.	Replace AC fuses or recharge battery.	137A3150
Unit doesn't boot up on battery power.	Charge LED doesn't light with AC power cord plugged in.	AC Fuse blown.	Replace both AC fuses and charge battery for 8 hours.	137A3150

Symptom	Observations	Possible Cause	Solution	Part Number
	Charge LED lights with AC power cord plugged in.	Battery discharged.	Charge battery for 8 hours.	
Battery run time too short or Battery indicator never displays full.	Unit continues to function but displays Low Battery or Empty Battery alarm.	Battery gas gage accumulated too much error or improperly initialized.	Charge battery for 8 hours, discharge battery until empty then recharge battery for 10 hours.	
	Unit goes into functional failure but no Empty Battery Alarm.	Battery capacity is inadequate.	Replace Power Pack.	503A0012
Battery indicator displays empty after recharge and gas gage reconditioning.	Replacement Power Pack displays empty battery icon.	Defective Electronic Module.	Replace Electronic Module.	Call Service for Part#
Unit displays Call Service/ Battery Disconnect or Battery Damaged error.	Charge LED lights with AC power cord plugged in.	Power Pack fuse is blown.	Replace Power Pack fuse (15A).	137A0153
Fails VVT, Battery check.		Battery capacity is inadequate.	Replace Power Pack or battery.	503A0012
Display image is upside-down, reversed, monocolored, fuzzy, etc.	Screen Capture image is correct.	LCD connector is partially dislodged.	Reconnect LCD connector and bend retaining bracket outward.	
Display is dim or flickers.	Display connector is connected adequately.	Defective LCD Display or Inverter Board.	Replace Front Enclosure (w/ LCD).	503A0013
Unit power up sequence is normal but the display is black.	Can see correct image under extremely bright light.	Disconnected Backlight or Inverter Board cable.	Reconnect Backlight or Inverter Board cable.	
Buzzer is audibly too low in volume.	Alarm Volume level is not adequate in options menu.	Defective Interface Board.	Replace Interface Board.	506B0106 or 506B0006

Symptom	Observations	Possible Cause	Solution	Part Number
Front LED doesn't light or is intermittent.		Conductive coating shorting LED leads.	Scrape away coating from inside front enclosure.	
		Defective keypad.	Replace keypad assembly.	155K0003
Cursor moves without touching control knob.		Defective encoder.	Replace Interface Board or Encoder Switch Assembly.	506B0006 or 310C0002
Control knob feels loose or worn out.		Encoder mounting shaft nut is loose.	Tighten Encoder mounting shaft nut.	
Error code 316 found in error log.		User pressed a key on the keypad or control knob for more than 5 seconds.	Instruct users to make momentary selections.	
		Keypad is defective or intermittent.	Replace Keypad Assembly.	155K0003
Unit displays temperature error.	Error Code 304 in technical log.	Cooling fan disconnected or defective connector contact.	Reconnect cooling fan or repair contact.	
		Cabling interfering with cooling fan.	Reroute wires away from cooling fan and secure.	
Fails VVT, Solenoid failure.	Solenoid valves able to move mechanically. Error code 330 in technical log.	Defective contact on Main Pneumatic connector.	Repair contact	
		Defective Pneumatic Unit.	Replace Pneumatic Unit.	Call service for part #
Fails VVT, Flow sensor leak.	Patient Circuit connections to the front panel are secure.	Pneumatic leak at sensing tubes connection.	Replace Patient Circuit.	620B0006
		Pneumatic leak at internal tubing.	Locate internal tubing leak. (See Section 8.2.5)	
		Defective Electronic Module.	Replace Electronic Module.	Call Service for Part#
Fails VVT, Blower or Patient	PIP reaches <65 cmH_2O during VVT.	Unit out of calibration.	Recalibrate Zero Sensors and Pressure Sensors.	

Symptom	Observations	Possible Cause	Solution	Part Number
Pressure.	PIP reaches <65 cmH_2O during VVT and unit is calibrated.	Outlet Muffler is broken and leaking.	Replace Outlet Muffler. (Ventilator Outlet)	504A0111
Fails VVT, O_2 Pr. Switch on 100%.		O_2 supply pressure is less than 40 psi.	Raise O_2 supply pressure so that it is 40 psi or greater during the entire test.	
	O_2 supply press. is 40 psi and above at all times.	O_2 Pressure Switch is out of acceptable range.	Replace O_2 Pressure Switch.	511A0126 or 504A0206
Service Notice! Alarm after power up.	Error Code 359 in technical log.	Mixer was started in extreme 21% position.	Manually turn stepper motor counter-clockwise until microswitch cam is in mid-position.	
	Error Code 307 in technical log.	O_2 system out of calibration.	Calibrate O_2 system.	
		Defective O_2 sensor.	Replace O_2 sensor and recalibrate.	130B0002
	Error Codes 330, 333, 345, 347, 359 in technical log.	Main Pneumatic connector disconnected from Pneumatic Unit.	Reconnect Main Pneumatic Harness.	
Fails VVT, Demand Valve Leak.	O_2% is higher than 21% (at 21% setting) only when high pressure O_2 is supplied.	Leakage at Demand Valve outlet (silicone) connection.	Reinstall Demand Valve fittings closer to O_2 inlet pipe.	
		Demand Valve is entraining O_2.	Replace Demand Valve.	318C0002
	O_2% is higher than 21% (at 21% setting) when high pressure O_2 is <u>not</u> supplied.	O_2 system is out of calibration at 21%.	Calibrate O_2 system.	
Need Cal alarm after power up.	Error Code 306 in technical log.	O_2 system out of calibration.	Calibrate O_2 system.	
Fails VVT, Flow Zeroing (right after Flow Performance).		Zeroing/ Purge Board disconnected.	Plug Zeroing/ Purge Board into Main Board and check retainment.	
Turbine is noisy.	Unit appears to pressurize normally.	Turbine is deteriorating mechanically.	Replace Pneumatic Unit.	Call Service for Part#

Symptom	Observations	Possible Cause	Solution	Part Number
No blower pressure or turbine doesn't turn.	Error Codes 345, 347 in technical log.	Defective Turbine.	Replace Pneumatic Unit.	Call Service for Part#
		Defective Electronic Module.	Replace Electronic Module.	Call Service for Part#
Fails O_2 Calibration.	Error Code 375 in technical log.	O_2 sensor range is inadequate.	Replace O_2 sensor.	130B0002
Slow rise or decay of pressure on graph and PIP bar.	Measurement values are slow to change but actual ventilation sounds normal and fast.	Kinked or pinched internal sensor tubing.	Reroute tubing and recheck.	
Error Code 360 found in technical log.	Unit passes VVT and Functional Tests.	Sensors Disconnect alarm was generated.	Ventilator settings were not optimized for the particular patient or connecting interface.	
Unit won't pass OVT.	Flow offset on graph.	Sensing lines of patient circuit partially contaminated with fluid.	Replace Patient Circuit.	620B0006
	Flow offset on graph with different circuits.	Internal tubing is contaminated with fluid.	Remove fluid with appropriate syringe and hypodermic.	
Fails OVT, Patient Circuit Failed		Missing or non-functioning one-way valve	Install one-way valve or replace Patient Circuit.	620B0006
Unit displays Patient Circuit Failed alarm during normal operation.	Pressure graph waveform is noisy.	Sensing lines of patient circuit partially contaminated with fluid.	Replace Patient Circuit.	620B0006

8.2 Diagnostics and Repairs

The following sections expand on the troubleshooting guide and describe failures requiring more extensive diagnosis and repair.

8.2.1 Power Switch

The power switch connects to the Switching Board via a 3-pin white connector located at J8. When the unit is powered off, there is continuity

between the black and yellow wires. When the unit is powered up, there is continuity between the black and red wires.

Historically, virtually all power switch problems are mechanical in nature and confined to the actuating and hold mechanism of the alternate action.

If a unit will power up only as long as you hold the power switch button in, then check for the following:

1. Use a needlenose or slip joint pliers to pull the power switch button cap straight out from the back of the unit.
2. Visually check that there is no gray ring gasket present. If the gasket is present then remove it.
3. Reinstall the button by lining up the slot on the hollow shaft of the button with the white dot on the recessed collar and pressing straight in.
4. Verify the alternating action of the power switch.

Normally, to change a defective power switch you do not have to desolder wires. The contact assembly will slide out of the back of the switch body (see Figure 8-1).

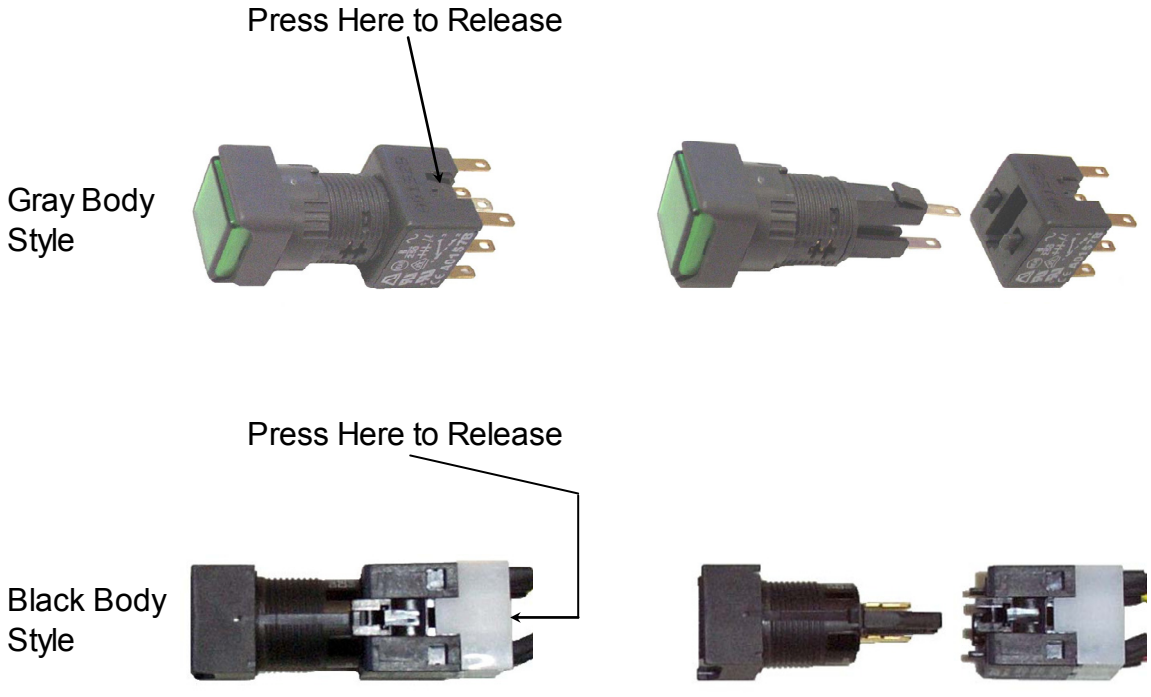


Figure 8-1: Power Switch Assembly

8.2.2 Demand Valve

There are two (2) versions of the demand valve. One has a manual actuation button and the other does not. The unit with the button needs a slight positive pressure (<2 cmH_2O) to shut off the flow while the other version will shut off automatically just from the small amount of back pressure present at its output connector.

This component can be verified for proper function independently:

1. Connect an O_2 supply to the DISS fitting of the demand valve and apply 50 psi.
2. Initiate a flow though the device by actuating the manual button found on top.

NOTE The unit without the button can still be actuated manually by gently pushing a small diameter rod through the center hole on top.

3. Using the palm of your hand, slowly occlude the demand valve outlet and verify that the device shuts off flow with no appreciable buildup of back pressure.
4. Verify that the device remains off and there is no perceptible leakage.

NOTE Some demand valves will shut off as soon as manual actuation is lifted. While this is normal, nevertheless there should be no detectable leakage.

If the demand valve function is verified but still fails VVT when it is reinstalled into the unit, there may be a problem with its position relative to the pneumatic unit's O_2 intake port.

Earlier versions of the O_2 inlet pipe utilized NPT type threads and were sealed with Teflon tape. This could cause the demand valve to be positioned ahead of the intake port of the pneumatic unit. While the flexible silicone tubing used to connect the demand valve to the intake port compensated for variability in distance, over time, as the tubing lost flexibility, the seal would leak, and the demand valve would fail to detect the back pressure necessary to close and shut off O_2 flow.

If the connecting silicone tube is viewed from the side, the offset from the vertical axis should be discernable.

To remedy the problem do the following:

1. Remove the female DISS fitting and nut gland from the O_2 inlet pipe using a 3/8in open end wrench.
2. Remove the existing Teflon tape completely from the threads of the fitting.
3. Cut a 1.5 - 1.75in L x 0.5in W piece of Teflon tape.
4. With the threads-end of the fitting facing you, wrap the tape clockwise around the threads.
5. Install the DISS fitting and nut gland into the O_2 pipe manifold so that 1/8in of threads is visible. (3 or 4 threads)

NOTE When the demand valve is properly installed onto the O_2 inlet pipe assembly, there should be a 70mm distance from center to center. (See Figure 8-2).

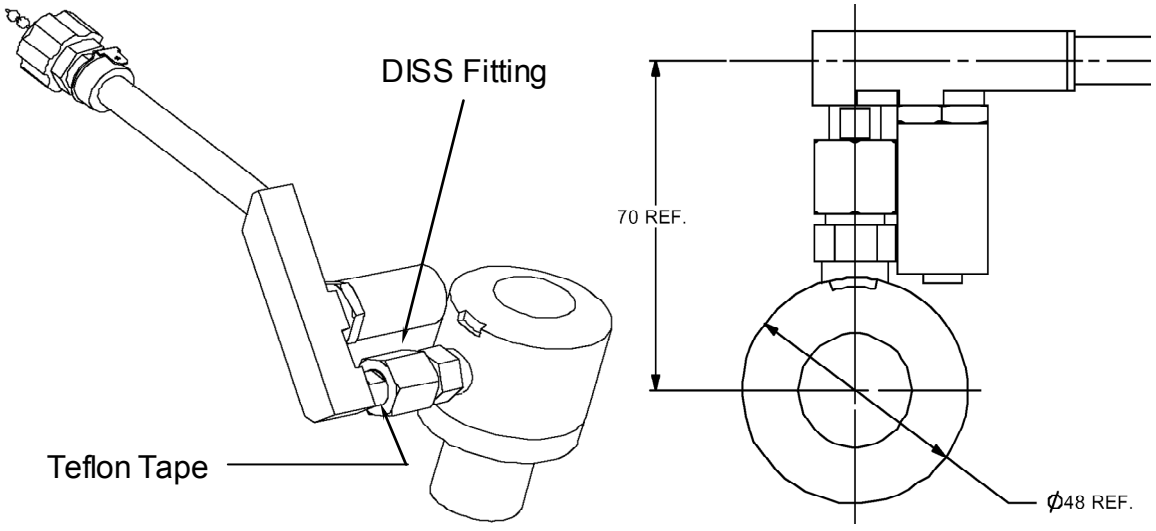


Figure 8-2: O_2 Inlet Pipe and Demand Valve

8.2.3 Pressure Switch

There are two (2) versions of this component and connecting inlet pipe. It is best to call VersaMed service before attempting replacement.

This component can be verified for proper operation independently by connecting an ohmmeter to the terminals and measuring the corresponding switch state. The switch is normally open (no O_2) and should close with the presence of high pressure O_2.

1. With the unit powered off, disassemble the front enclosure as outlined in Enclosure Disassembly, Section 7.4.3.2, page 114.
2. Identify the O_2 pressure switch type and connect the ohmmeter to the corresponding connector contacts:
   a) For silver colored metal which is threaded directly onto the O_2 inlet pipe:
   - Pins 1 & 2 (red wire & white wire).

   b) For the brass colored switch metal body mounted to the back wall of the rear enclosure:
   - The two tabs located on the rear of the switch body.

Regardless of the O_2 pressure switch type the switch terminals are connected to pins 9 & 17 in the PU main connector (see Figure 8-3).

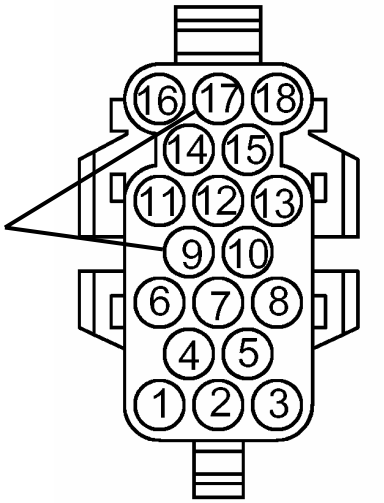


Figure 8-3: PU Main Connector (Front View) - Pressure Switch Pinout

3. Reassemble the front enclosure to the rear assembly as outlined in Section 7.4.3.3, Enclosure Assembly, page 117.

8.2.4 Valve Limit Switch (O_2 Microswitch)

The O_2 microswitch is wired for a normally open configuration but is usually actuated by the "high" area of the cam. The switch goes to an open condition when the actuator "falls" into a low area located on the extreme ends of the cam. This component can be verified for proper function independently:

1. Disassemble the front enclosure from the rear assembly as outlined in Section 7.4.3.2, Enclosure Disassembly, page 114.
2. With the unit powered off, manually rotate the shaft of the stepper motor so that the microswitch actuator is at an end position on the cam (see Figure 8-4).
3. Connect an ohmmeter to pins 7 & 8 in the PU main connector (Figure 8-5) and verify that the switch is in an open state.
4. Manually rotate the shaft of the stepper motor so that the microswitch actuator is at a mid position on the cam and verify that the switch is in a closed state.
5. Reassemble the front enclosure to the rear assembly as outlined in Section 7.4.3.3, Enclosure Assembly, page 117.

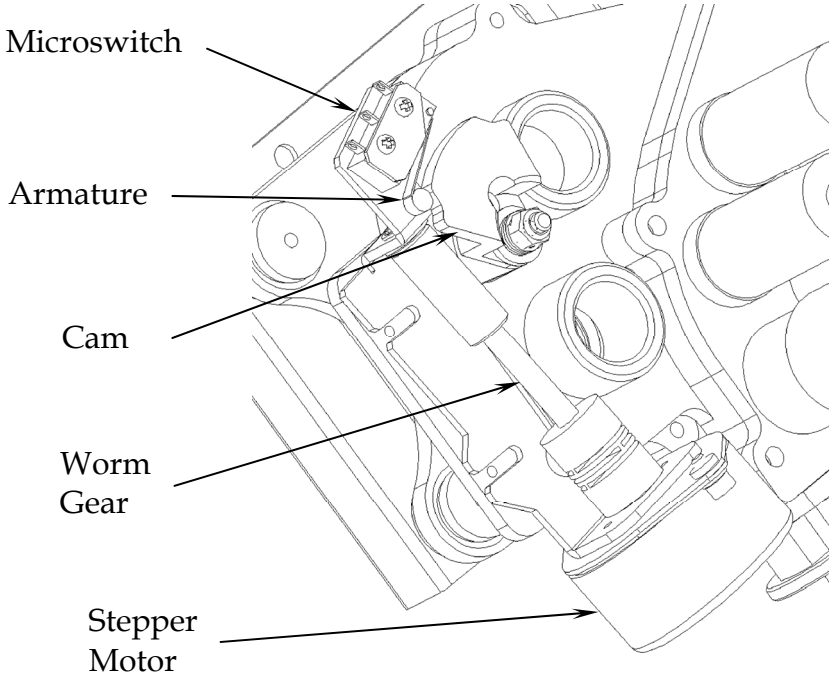


Figure 8-4: O_2 Mixer (Top View)

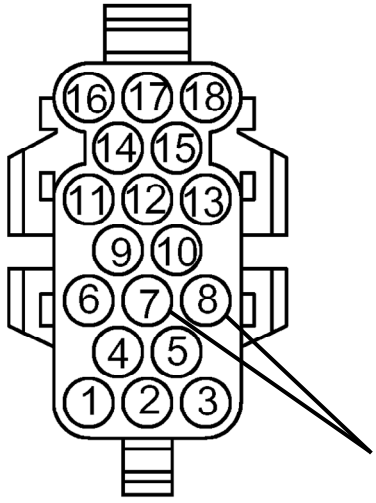


Figure 8-5: Main Connector (Front View) - Microswitch Pinout

8.2.5 Flow Sensor Leak

If you have replaced the patient circuit and verified that the plug, cap or manometer that you are using to occlude the outlet of the patient circuit does not leak:

Most flow leaks occur at a tubing connection point. Occasionally, a connected component -- such as a pressure transducer, check valve or one of the front panel luer connectors -- will develop a leak.

There are approximately 50 possible leak points. Without a method of leak isolation, a single problem can become time consuming and tedious.

There is usually no audible hiss to help isolate the root cause and visual inspections of suspected areas can escape detection.

Additionally, the flow graph on the display can be very misleading if it is interpreted literally.

Refer back to Figure 4-2: Pneumatic Unit Overview on page 48, and Section 4.1.6.1, Wye and Flow Sensor, on page 54, to familiarize yourself with the patient circuit's role in the pneumatic system.

The following diagram shows the pneumatic sensor’s system components and pneumatic "wiring". All components are shown in their relative sizes and positions:

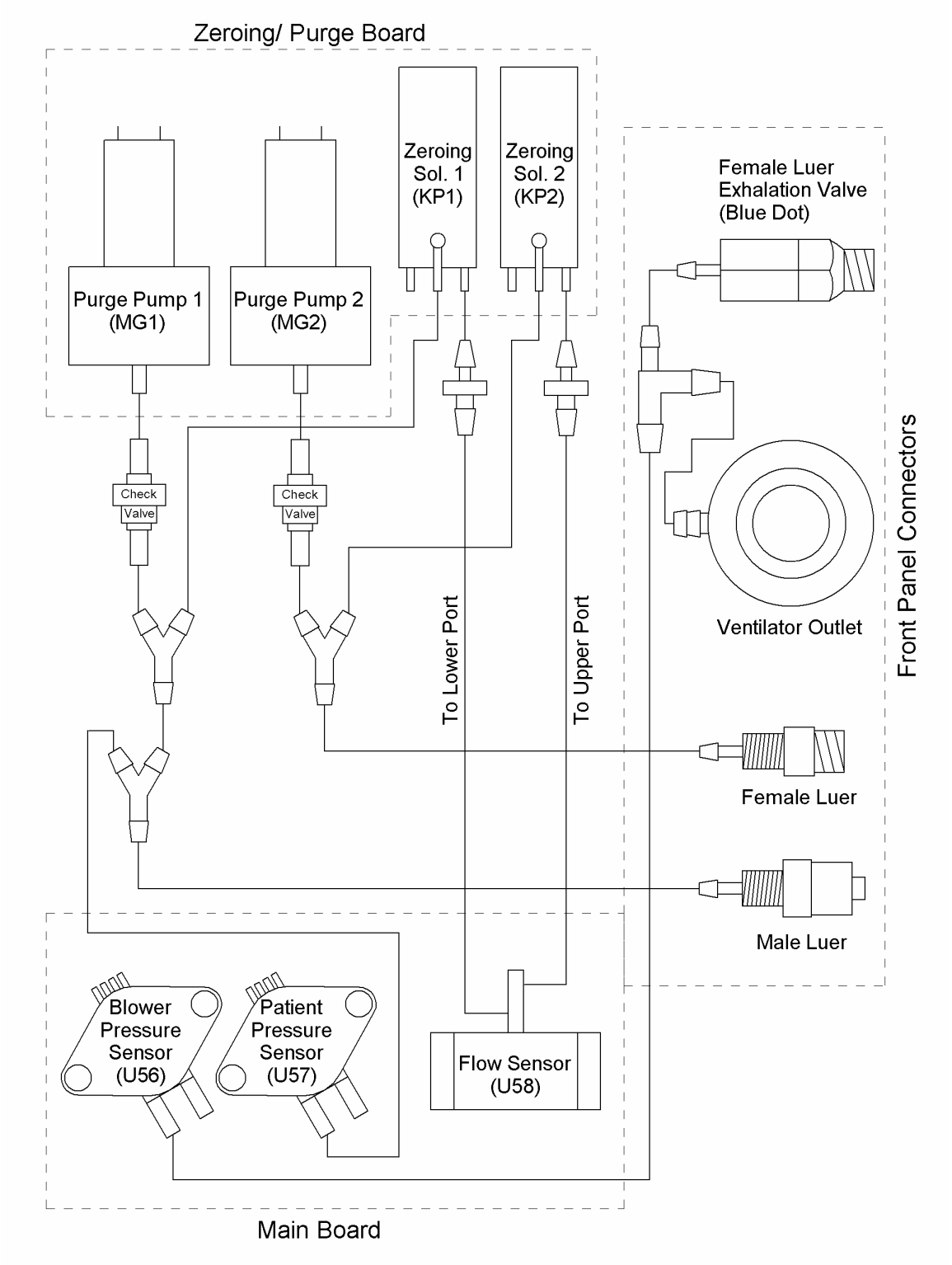


Figure 8-6: Pneumatic Sensors Connections

8.2.5.1 Root Cause - Pneumatic vs. Electronic

The first step of isolating the root cause of a VVT flow sensor leak is to determine whether the problem is pneumatic or electronic. It is possible that there is no actual leak and the unit only "believes" that there is a leak.

If there is no flow signal sent to the flow transducer during the pressurization portion of the VVT, it should fail "everything" *but* flow sensor leak.

Conduct the following experiment:

1. Set up the ventilator and patient circuit as outlined in Section 6.2.4, page 90.
2. Run the first part of the VVT as outlined in Section 6.2.4, Alarm Sound Tests page 91, and Pressure Tests page 93 several times, and determine whether or not flow sensor leak fails each and every time. (This will help you to determine if the failure is borderline and avoid drawing false conclusions.)
3. Disconnect the two flow sensor lines from the left side of the front panel and repeat the test.

Patient pressure, Solenoid 1, Solenoid 2 and Solenoid safety *should* fail due to the lack of a pressure signal.

- If Flow sensor leak is **OK**, the cause of the failure is a pneumatic leak.
- If Flow sensor leak is **Failed**, the cause of the failure is electronic.

If you have determined that the cause of the failure is electronic (failing the VVT for flow sensor leak without the presence of a flow signal), then conduct the Zero Sensors step of the Calibration procedure as outlined in Section 5.4.5.2, page 81 and repeat the VVT (without the patient circuit attached).

If the unit fails VVT for flow sensor leak again, then the electronic module must be replaced.

8.2.5.2 Isolation of Internal Tube Leak

The pneumatic sensing/measurement system consists of three (3) main branches of tubing that are analogous with the three tubes that are connected to the ventilator front panel:

- Blower Pressure & Exhalation Valve Control
- Negative (-) Flow Port & Patient Pressure
- Positive (+) Flow Port

CAUTION Although historically rare, a leak at more than one site is possible.

Although you can isolate the leak to one of these three branches without disassembling the unit, the remedy will require you to at least remove the front panel.

Disassemble the front enclosure from the rear enclosure as outlined in Section 7.4.3.2, Enclosure Disassembly, page 114. Do not disconnect any tubing or cables.

8.2.5.3 Blower Pressure & Exhalation Valve Control

A leak that occurs along the blower pressure sensing tube and exhalation valve control line isn't actually detected by the VVT. If the leak causes the blower pressure to be less than the patient pressure, the exhalation valve will not be held totally closed. The air flow that escapes out of the exhalation valve lowers the pressure at the (+) flow sensing port and creates a small negative flow measurement.

The following steps will determine if the leak is located along this branch:

1. Set up the ventilator and patient circuit as outlined in Section 3.4.1.
2. Block the exhalation valve outlet (22mm male).
3. Run the first part of the VVT as outlined in Alarm Sound Tests page 91 and Pressure Tests page 93.
   - if Flow sensor leak is Failed, the cause is not the blower pressure or exhalation valve control tubes.
   - if Flow sensor leak is OK, the location of the leak is along the blower pressure and exhalation valve control tubes.

A leak that is located anywhere from the blower port tee to the blower pressure transducer will probably fail the Blower pressure part of the VVT but not the Flow sensor leak. This suggests that the probable location of the leak is one of the following:

- the barbed connector just behind the front panel luer of exhalation valve control line, or

- the small barb of the blower pressure connection tee.

8.2.5.4 Negative (-) Flow Port vs. Positive (+) Flow Port

The two bottom-left-side luer connectors on the front panel are the flow sensing ports. The leftmost port is a metal male locking luer: it is the negative (-) flow port. If this port is pressurized or it is at a higher pressure than the right port, the flow graph trace on the display will go below the baseline.

The right port is a female locking luer: it is the positive (+) flow port. If this port is pressurized or it is at a higher pressure than the left, the flow graph trace will go above the baseline.

Again, note that a leak along either branch will have the opposite effect: if there is a leak along the tubing of the negative (-) left-side port, the flow graph will go above the baseline. If there is a leak along the tubing of the positive (+) port, the flow graph will go below the baseline.

The following steps will determine which branch the leak is located:

1. Set up the ventilator and patient circuit as outlined in Section 6.2.4, page 90.
2. Observe whether the flow offset on the flow graph is above or below the baseline (0 cmH_2O).

NOTE The flow graph range may need to be set to 60 to gain enough resolution to visibly detect the flow offset.

3. If the flow is above the baseline then the leak is along the left-side negative (-) port.
4. If the flow is below the baseline then the leak is along the right-side positive (+) port.

8.2.5.5 Negative (-) Flow Port & Patient Pressure

This branch of the pneumatic measurement system has the most connection junctions. This is because it shares the flow signal with the patient pressure.

To isolate the leak location, conduct the following steps:

1. Disassemble the front enclosure from the rear enclosure as outlined in Section 7.4.3.2, Enclosure Disassembly, page 114.
2. Remove the electronic module from the rear enclosure as outlined in Section 7.4.4.2, Electronic Module Removal, page 119.
3. Remove the top cover and tubing cover from the electronic module as outlined in Section 7.4.8, Electronic Module Cover Removal, page 130, steps 1-5.
4. Orient the opened electronic unit on its side so that the zeroing/ purge board is facing up and place it on the right side of the ventilator enclosure (see Figure 8-7, page 156).
5. Position the front enclosure in front of the ventilator enclosure and electronic unit and connect the following:
   - **a)** Connect the main connector from the electronic module to the pneumatic unit.
   - **b)** Connect the power pack connector from the rear enclosure to the electronic module.
   - **c)** Connect the ribbon cable from the electronic module to the front enclosure's interface board.
   - **d)** Connect the LCD cable from the electronic module to the front enclosure.
   - **e)** Connect the inverter cable from the front enclosure to the electronic module.
   - **f)** Connect the tube with the blue stripe to the leftmost fitting (when viewed from the front).
   - **g)** Connect the tube (from the Y adapter) to the right fitting (on the left side).
   - **h)** Connect the remaining tube to the barbed port on top of the ventilator outlet and the right-most front panel fitting.

TIP Try to connect the sensor tubing to alternate external luer fittings if possible (see Figure 8-7, page 156). If no external fittings are available, connect the flow sensor tubes as outlined in steps f) and g) and connect the blower sensor tube to the barbed port of the ventilator outlet, and then insert the remaining tube over the male luer nipple of the patient circuit exhalation valve control line.

TIP Since the O_2 sensor is not connected to the electronic module, a Service Notice! Alarm will sound when the ventilator is powered up. Clear the pop-up window and ignore the alarm. Alternately, you may remove the O_2 Sensor from the pneumatic unit and plug it into the connector coming from the electronic module. Use a #1 stopper to plug off the hole vacated by the sensor.

6. Temporarily disconnect the two check valves from the purge pumps.
7. Adjust the range setting on the flow graph to 210 lpm.
8. Use hemostats or needle-nosed pliers to slowly occlude the diameter of the suspect sensor tube.
9. Observe the flow graph and determine if the flow rate holds or rises.

NOTE If any alarm pop up window appears press the front panel silence button and continue to observe the flow graph.

Normally when there is no leak present if you occlude the negative port sensing tube, the flow graph trace will go in a negative direction or hug close to the baseline (depending upon how fast the tube is occluded). Even if the unit is trying to ventilate, the flow graph trace will spend most of its duration in the negative region (see Figure 8-8, page 156).

If there is a leak in front of the occlusion, the flow graph will go positive or spend most of its duration in the positive range (see Figure 8-8).

Keep in mind that the patient pressure tube/transducer and check valve/purge pump are branches off of the main line which ultimately dead end and are leak tight. Each branch is connected by a Y adapter.

When the patient pressure branch is occluded, the left side pressure bar will rapidly deflate if there is a leak along this line.

When the check valve/purge pump branch is occluded, the flow offset will return to zero if there is a leak along this line. (The flow graph range may have to be reset to 40 lpm to observe the flow offset.)

TIP By continuing to occlude the suspected branch off of the main line and running the first part of the VVT, you can quickly confirm that flow sensor leak now passes.

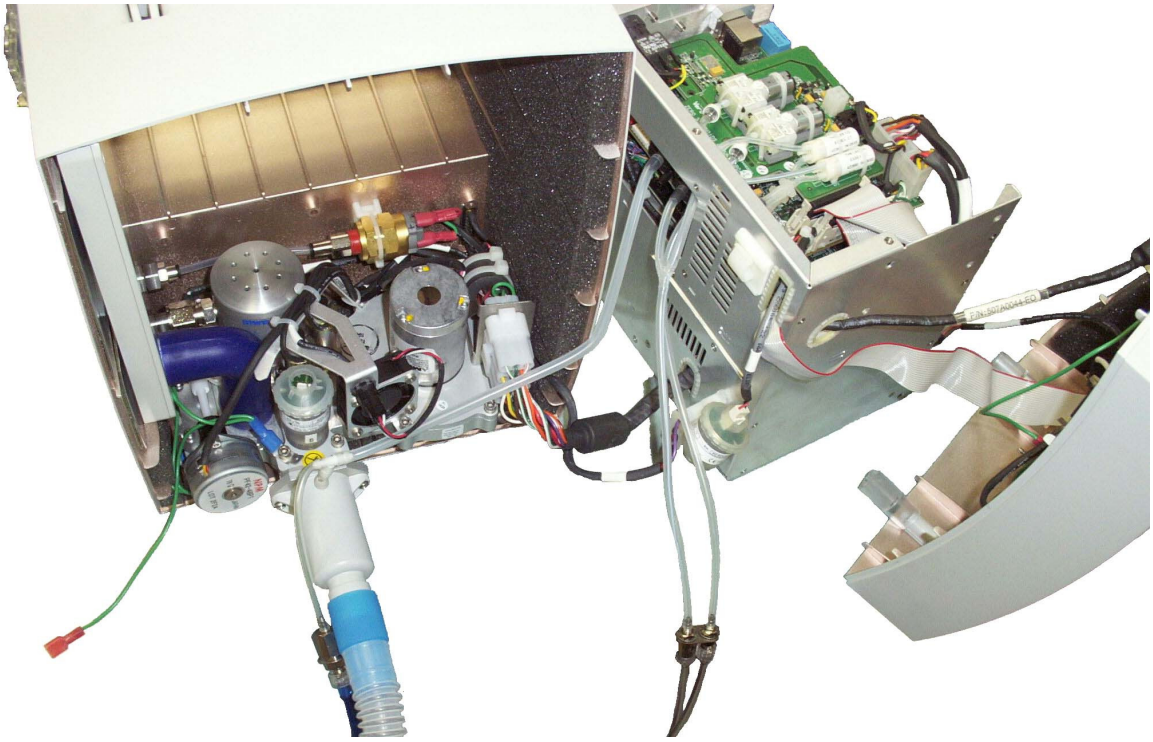


Figure 8-7: Test Setup (Unit Operating Disassembled)

No Leak Leak

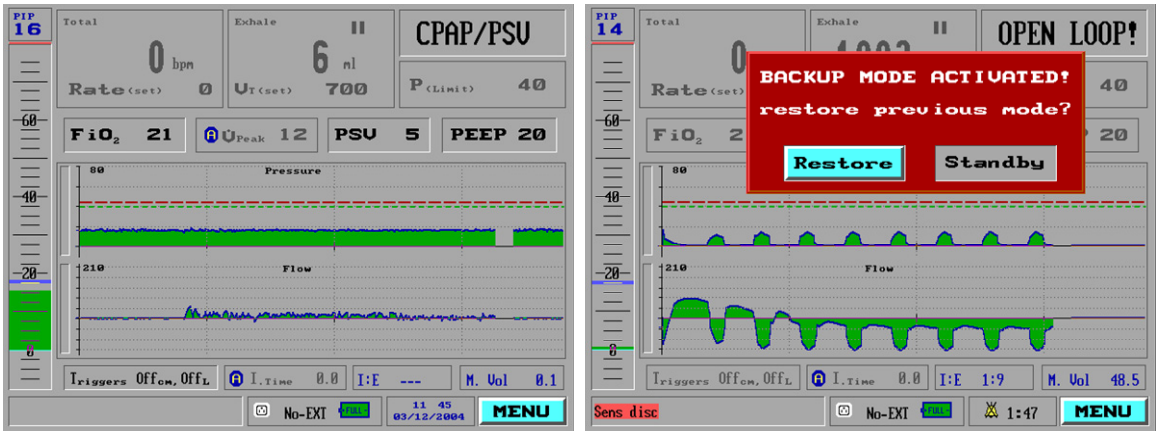
Figure 8-8: Flow Graphs (Occluding the Negative Flow Sensor Port)

8.2.5.6 Positive (+) Flow Port

To isolate a leak that was determined to be along this branch, follow all of the steps and considerations outlined in the previous section. The main difference is that the criteria for determining leak vs. no leak on the flow graph are exactly the opposite.

Normally, when there is no leak present, if you occlude the positive port sensing tube, the flow graph trace will go in a positive direction or hug close to the baseline (depending upon how fast the tube is occluded). Even if the unit is trying to ventilate, the flow graph trace will remain in the positive region (see Figure 8-9).

If there is a leak in front of the occlusion, the flow graph will go negative or lie in the negative range (see Figure 8-9).



No Leak Leak

Figure 8-9: Flow Graphs (Occluding the Positive Flow Sensor Port)

8.3 Exhale VT Accuracy

In general, after performing a calibration and subsequent VVT, there should be a high confidence level in the volume accuracy. The patient circuit would have to be defective and unusable or the strokes during volume calibration would have to be unusually fast to cause a miscalibration.

In clinical applications, there is a wide variety of normal reasons for low exhale tidal volume, such as leakage at the interface, inspiratory time set too low, or pressure limitation set too low. This section will deal with volume inaccuracy issues that can be verified on the test bench under controlled conditions.

8.3.1 Inhale VT Accuracy

The *i*Vent$_{201}$ patient circuit flow sensor measures flow in both directions. The pressure calibration is independent of the flow calibration or the patient circuit that is used. It is also easy to compare the pressure that is generated to a variety of external pressure measurement devices. At the very least, it can be compared and verified by the certified manometer that was used to calibrate the unit.

The VersaMed 2-liter test lung (P/N 910V0005-01) has a consistent compliance of approximately C24. This means that for every 24 ml injected into the test lung, it will generate 1 cmH_2O. At the 70+ kg default settings the baseline for the tidal volume occurs at the 5 cmH_2O PEEP value. After injecting another 700 ml into the test lung an additional 29 cmH_2O is generated above the starting PEEP value. The result is a PIP (peak inspiratory pressure) of 34 cmH_2O.

To summarize: if the ventilator generates a PIP of approximately 34 at the 70+ kg default settings with a VersaMed test lung, the inhale accuracy has been verified.

TIP The test lung compliance measurement can be viewed by selecting Show Mechanics from the main menu. To return to the standard display, select Show Graphs.

8.3.2 Exhale VT Accuracy Interferences

We will assume that the ventilator has been propertly calibrated and verified by the VVT, the accuracy of the inhale volume measurement has been evaluated, the patient circuit has been substituted, and yet you continue to observe a difference of greater than 10% between the set tidal volume and the exhale measurements.

This section will discuss known interferences that can cause inaccurate exhale tidal volume measurements.

8.3.3 Leakage

If the test lung that you are using has a leak, the exhale volume will be smaller than the inhale volume. Moreover, if you set up the ventilator as described in Section 8.5, the flow graph will show a positive offset.

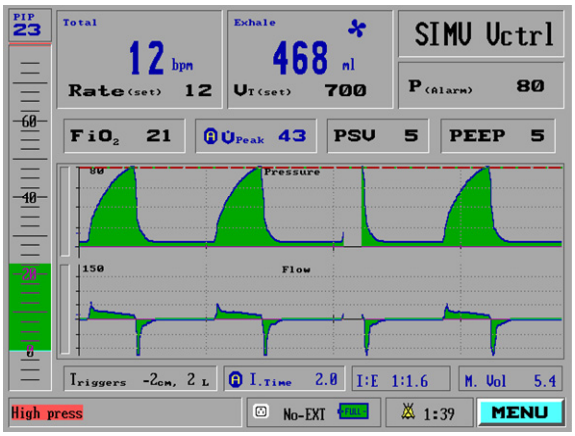
8.3.4 Velocity

Any test load that can cause a high velocity exhale may create an artificially low exhale tidal volume measurement.

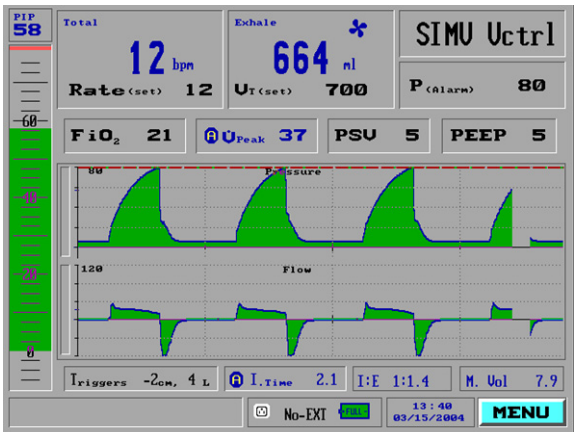
The high velocity flow from the test lung lowers the pressure of the first port (- port) creating an artificial lower exhale volume. The first set of *i*Vent$_{201}$ screen captures below (Figure 8-11) show the effects of an undersized test lung for the application (settings). Note the high inspiratory pressure, as well as the sharply spiking velocity of the exhale flow with a significantly low measured exhale volume.

Clinically, this high amplitude, short period exhale waveform is most like a patient cough and is not a common steady state flow pattern.

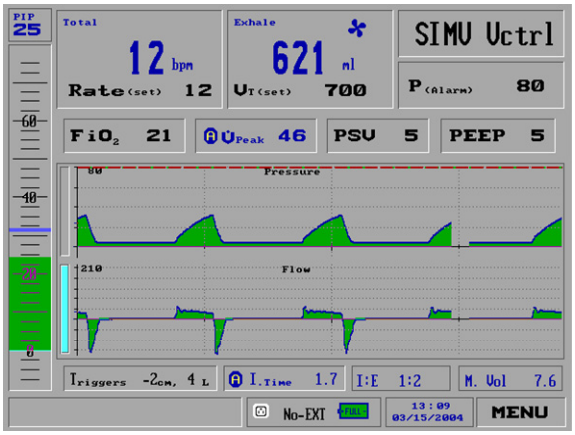
The critical point is that the analysis of the flow graph can lead you to the root cause and corrective action. In this case, the proper remedy for this situation is replacement of the 1-liter test lung with a 2-liter test lung and installation of an Rp20 resistor.



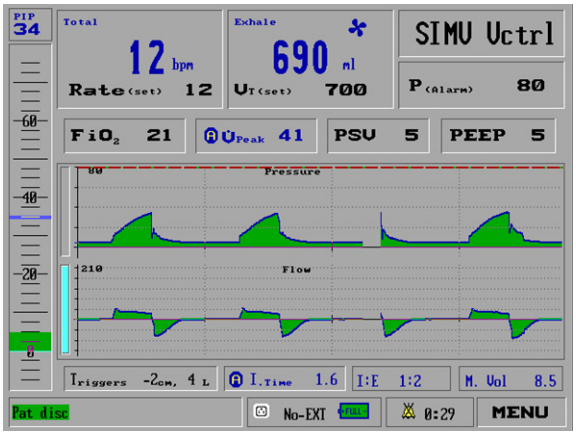
1 Liter Test Lung (no resistor)



1 Liter Test Lung (w/ Rp20 resistor)



2 Liter Test Lung (no resistor)



2 Liter Test Lung (w/ Rp20 resistor)

Figure 8-10: Flow Graphs (High Velocity Exhale)

8.3.5 MAQUET (Siemens 190) Test lung

Two (2) characteristics of this lung interfere with correct tidal volume measurements:

- The test lung has a built-in pneumatic resistor with a value of ~Rp40.
- The connector fits into the 15mm F connector of the patient circuit wye.

The high velocity jet that is emitted from the test lung orifice lowers the pressure of the second port (+ port) creating an artificial higher exhale volume.

This issue is easily resolved by placing a bacterial filter at the outlet of the patient circuit wye.

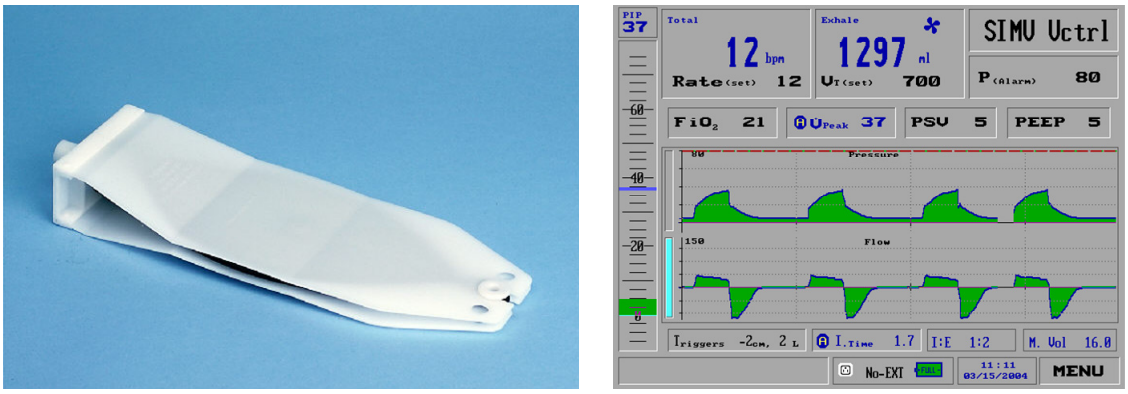


Figure 8-11: Test Lung 190 and *i*Vent$_{201}$ Waveforms

8.4 Miscellaneous Issues

Some issues cause misleading symptoms, as described below.

8.4.1 Black Screen

Sometimes this symptom is reported as "unit doesn't boot up" or "defective display." Most of the time, a black screen is a minor problem with the LCD backlight or inverter. (A disconnected or defective LCD displays an all white screen.) If the screen blacks out, try reflecting a very bright light off of the screen surface and see if you can detect a dim graphical image.

If so, generally the cable is unplugged, or one of the three wires or connector contacts is disconnected or broken.

8.4.2 Fails Calibrate Flow Sensor

The unit fails the calibration step "Calibrate Flow Sensor,": but most of the time it is in fact an O_2 problem -- for instance, the O_2 mixer is in the 100% O_2 position and the unit cannot generate the flow that it needs.

8.4.3 Erratic O_2 Control

Normally, when a FiO_2 value is set, the unit will seek the targeted O_2 mix and stabilize. If the control or stability of O_2 appears to be erratic, the root cause may actually be an unstable minute volume.

Usually the cause of an unstable minute volume is extra breaths being delivered due to auto-triggering. Auto-triggering can occur for the following reasons:

- There is a leak at the patient interface (usually the test lung).
- The test lung is bouncing or hitting against an object.
- There is a flow offset due to calibration error.
- The flow sensitivity is set too low.

If O_2 repeatedly becomes unstable, try setting the trigger sensitivities to Off and see if the O_2 control and minute volume stabilize.

8.4.4 Erratic Exhale Tidal Volumes

"Erratic exhale tidal volumes" means that although the ventilator is set up to deliver consistent breaths, you observe some breaths to be smaller than normal.

This problem is very similar to the previous one (Section 8.4.3). Generally the ventilator is running in a volume control mode and the smaller breaths are extra breaths based on the pressure support settings. You should see a "pink person" breath type icon accompanying these breaths.

Possible root causes are listed in the previous section.

8.4.5 Low Pressure During Calibration or VVT

If during calibration or VVT you observe pressures that are lower than normal, the ventilator may be running on battery power.

Simply plug in the AC power and restart the calibration or VVT process.

8.5 Setting Up the Ventilator for Static Pressure

To aid the technician in the troubleshooting effort, it may become necessary to change the ventilator parameters.

The following procedure will set up the ventilator so that it will hold a 20 cmH_2O static pressure for 2 minutes without attempting to ventilate. It will also deflect any errant signals the technician may create via extensive manipulation of the sensor tubing.

This setup can be especially handy for troubleshooting pneumatic leaks.

1. Connect the AC power and patient circuit to the ventilator.
2. Turn on the ventilator and select the 70+ kg patient weight setting in the opening screen.

3. Highlight the mode field in the upper right-hand corner of the display and select CPAP/PSV. The parameters setting window appears.

NOTE This mode does not require any mandatory breaths and the set rate defaults to zero.

4. Select PEEP and adjust the value to 20 (cmH_2O)

NOTE If the ventilator is configured for Extended Ranges then you can adjust the PEEP to 40 (cmH_2O).

5. Select Triggers and adjust both "Press" and "Flow" to Off.
6. Highlight and select Accept.
7. From the Main Menu select the Alarm Settings option. The Alarm Settings window appears.

NOTE If no cursor movement is sensed by the ventilator for 1 minute, it will timeout and return to the Main Menu.

8. Select Apnea Time and adjust the setting to 120 (sec).
9. Highlight and select Accept in order to keep these settings. The Standby screen appears.
10. From the Main Menu select the Advanced Settings option. The Advanced Settings window appears.
11. Select the "Purge Every" option and set it to Off.
12. Block the patient circuit with the rubber stopper or equivalent.
13. Press START when ready.

NOTE When the Apnea alarm window appears, press Close, then select the blinking Apnea message in the mode field and select Yes to the restore previous mode question. If the Check Sensor alarm window appears, press Close and then Restore.

Appendix A: Parts and Accessories

Ventilators

Part Number	Description
501I2201-IC	*i*Vent201 IC System
501I2201-AB	*i*Vent201 AB System
501I2201-IC/AB	*i*Vent201 IC/AB System
501I2201-HC	*i*Vent201 HC – Home Care System
501I2201-EMS	*i*Vent201 Transport / EMS System
809A0005-A0-AB	Adaptive Bi-Level software option (for IC Systems only)
809A0007-A0-IC	ICU software option (for AB systems only)

Accessories

Part Number	Description
660B0001-12	Disposable Breathing Circuit, I type, box of 12
620B0017-20	Disposable Breathing Circuit, Y type, box of 20
620B0006-20	Disposable Breathing Circuit, Y type, box of 20
620B0008-A0	Multi-use Patient Breathing Circuit, Y type, 1 unit, Polysulfone Sensor and Silicone Tubing
620B0008-10	Multi-use Patient Breathing Circuit, Y type, box of 10, Polysulfone Sensor and Silicone Tubing
660A0001-12	Air filter, inlet, box of 12, disposable
660L0001-12	Low Pressure Oxygen Adaptor & Filter, box of 12, disposable
620B0009-01	Valve Assembly, Low Pressure Oxygen
620B0010-01	Reservoir Bag, 1 Liter, Low Pressure Oxygen

630B0001-01	Roll Stand w/ Handle and Mounting Bracket	
630B0003-A0	Oxygen Cylinder Holder	
630B0004-A0	Breathing Circuit Support Arm	
620B0001-01	Oxygen Supply Hose, six (6) feet, DISS oxygen fittings	
620B0002-01	Oxygen Supply Hose, fifteen (15) feet, DISS oxygen fittings	
900K0004-01	Calibration Kit (1 calibration syringe, 1 manometer, 2 test lungs, 2 Rp20 resistors, 1 stopper)	
507A0052-B0	Remote Alarm Interface for central alarm system (call for details) Normally Closed, 51K	
507A0053-B0	Remote Alarm Interface for central alarm system (call for details) Normally Closed, Phone Jack	
507A0054-B0	Remote Alarm Interface for central alarm system (call for details) Normally Open, Phone Jack	
507A1020-A0	D/C Power Cord – 12 volt vehicle adapter	
507A1022-A0	D/C Power Cord –12 volt clip-on adapters	
910V0004-A0	Pneumatic Resistor, 6mm, Rp20	
910V0003-A0	Pneumatic Resistor, 4mm, Rp50	
375B0003-01	Rolling Hard Case for Ventilator (NOT FOR SHIPPING)	
375B0005-01	Hard Case for Ventilator – Shipping and Transport	
375B0004-01	Soft Case for Ventilator	
504A0110-AO	Adaptor for Bio/Chemical Filter	
920C0001-01	Calibration Syringe – 500ml	
920C0002-01	Calibration Manometer	
910V0005-01	Test Lung, 2 Liter	
504A0050-A0	External Battery Assembly, 110VAC	
	301B0001-01	12V External Battery, 32Ah
	301C0002-01	External Battery Charger, 110VAC

	301D0001-01	External Battery Case
	507A1019-01	External Battery Cable
	630B0007-01	External Battery Holder for Roll Stand
504A0051-A0	External Battery Assembly, 220VAC	
	301B0001-01	12V External Battery, 32Ah
	301C0002-01	External Battery Charger, 220VAC
	301D0001-01	External Battery Case
	507A1019-01	External Battery Cable
	630B0007-01	External Battery Holder for Roll Stand
SM-01-04	*i*Vent201 Service Manual	
OM-01-04	*i*Vent201 Operator's Manual	

Appendix B: Service Report Form

The following 2 pages are the Service Report Form. This form should be copied, utilized and remitted to Versamed whenever a PM, upgrade or service is performed on a ventilator.

SERVICE REPORT

COUNTRY: _____ WARRANTY ☐ CONTRACT ☐

CUSTOMER: _____ NON-WARRANTY ☐ BILLABLE ☐

IV NUMBER: _____ MACHINE HOURS: _____

SOFTWARE VERSION: _____

SERVICE TYPE: REPAIR ☐ UPGRADE ☐ PM ☐ _____

PROBLEM REPORTED / FOUND:

_____

_____

_____

_____

ACTION TAKEN:

_____

_____

_____

_____

PARTS USED:

Part Number	S.N.	Qty	Description

FINAL TESTING:

☐	CALIBRATION	☐	PASS	☐	FAIL
☐	OVT	☐	PASS	☐	FAIL
☐	ENDURANCE TEST (for 2Hrs)	☐	PASS	☐	FAIL
☐	VVT TEST	☐	PASS	☐	FAIL
☐	TRIGGERS (With PEEP 20 and Max)	☐	PASS	☐	FAIL
☐	OXYGEN CHECK (70%, 100%)	☐	PASS	☐	FAIL
☐	BATTERY INDICATION	☐	PASS	☐	FAIL

TECHNICIAN NAME: _____ SIGNATURE: _____

Index