

# iVent™ 201

## Technical Reference Manual



iVent™ 201 Technical Manual

VersaMed Part Number SM-01-04

GE Part Number M1162065

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CE 0473

## Owner's Record

The model number and serial number of your iVent™201 are on the rear panel of your ventilator. Record the serial number in the space provided below to have this information should you need to call for service or support.

Model Number:

Serial Number:

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## Important

The information contained in this Technical Reference manual pertains only to those models of products which are marketed by VersaMed as of the effective date of this manual or the latest revision thereof. This Technical Reference manual was prepared for exclusive use by VersaMed service personnel in light of their training and experience as well as the availability to them of parts, proper tools and test equipment. Consequently, VersaMed provides this Technical Reference manual to its customers purely as a business convenience and for the customer's general information only without warranty of the results with respect to any application of such information. Furthermore, because of the wide variety of circumstances under which maintenance and repair activities may be performed and the unique nature of each individual's own experience, capacity, and qualifications, the fact that customer has received such information from VersaMed does not imply in any way that VersaMed deems said individual to be qualified to perform any such maintenance or repair service. Moreover, it should not be assumed that every acceptable test and safety procedure or method, precaution, tool, equipment or device is referred to within, or that abnormal or unusual circumstances, may not warrant or suggest different or additional procedures or requirements.

This manual is subject to periodic review, update and revision. Customers are cautioned to obtain and consult the latest revision before undertaking any service of the equipment. Comments and suggestions on this manual are invited from our customers. Send your comments and suggestions to the Manager of Technical Communications, Datex-Ohmeda, Ohmeda Drive, PO Box 7550, Madison, Wisconsin 53707.

## CAUTION

Servicing of this product in accordance with this Technical Reference manual should never be undertaken in the absence of proper tools, test equipment and the most recent revision to this service manual which is clearly and thoroughly understood.

## Technical Competence

The procedures described in this Technical Reference manual should be performed by trained and authorized personnel only. Maintenance should only be undertaken by competent individuals who have a general knowledge of and experience with devices of this nature. No repairs should ever be undertaken or attempted by anyone not having such qualifications.

VersaMed strongly recommends using only genuine replacement parts, manufactured or sold by VersaMed for all repair parts replacements.

Read completely through each step in every procedure before starting the procedure; any exceptions may result in a failure to properly and safely complete the attempted procedure.

<p><b>WARNING</b> (EN)</p>	<p>This service manual is available in English only.</p> <ul style="list-style-type: none"> <li>• If a customer's service provider requires a language other than english, it is the customer's responsibility to provide translation services.</li> <li>• Do not attempt to service the equipment unless this service manual has been consulted and is understood.</li> <li>• Failure to heed this warning may result in injury to the service provider, operator or patient from electric shock, mechanical or other hazards.</li> </ul>
<p><b>ПРЕДУПРЕЖДЕНИЕ</b> (BG)</p>	<p>Това упътване за работа е налично само на английски език.</p> <ul style="list-style-type: none"> <li>• Ако доставчикът на услугата на клиента изиска друг език, задължение на клиента е да осигури превод.</li> <li>• Не използвайте оборудването, преди да сте се консултирали и разбрали упътването за работа.</li> <li>• Неспазването на това предупреждение може да доведе до нараняване на доставчика на услугата, оператора или пациента в резултат на токов удар, механична или друга опасност.</li> </ul>
<p><b>VÝSTRAHA</b> (CS)</p>	<p>Tento provozní návod existuje pouze v anglickém jazyce.</p> <ul style="list-style-type: none"> <li>• V případě, že externí služba zákazníkům potřebuje návod v jiném jazyce, je zajištění překladu do odpovídajícího jazyka úkolem zákazníka.</li> <li>• Nesnažte se o údržbu tohoto zařízení, aniž byste si přečetli tento provozní návod a pochopili jeho obsah.</li> <li>• V případě nedodržování této výstrahy může dojít k poranění pracovníka prodejního servisu, obslužného personálu nebo pacientů vlivem elektrického proudu, respektive vlivem mechanických či jiných rizik.</li> </ul>
<p><b>ADVARSEL</b> (DA)</p>	<p>Denne servicemanual findes kun på engelsk.</p> <ul style="list-style-type: none"> <li>• Hvis en kundes tekniker har brug for et andet sprog end engelsk, er det kundens ansvar at sørge for oversættelse.</li> <li>• Forsøg ikke at servicere udstyret uden at læse og forstå denne servicemanual.</li> <li>• Manglende overholdelse af denne advarsel kan medføre skade på grund af elektrisk stød, mekanisk eller anden fare for teknikeren, operatøren eller patienten.</li> </ul>
<p><b>WARNUNG</b> (DE)</p>	<p>Diese Serviceanleitung existiert nur in englischer Sprache.</p> <ul style="list-style-type: none"> <li>• Falls ein fremder Kundendienst eine andere Sprache benötigt, ist es Aufgabe des Kunden für eine entsprechende Übersetzung zu sorgen.</li> <li>• Versuchen Sie nicht diese Anlage zu warten, ohne diese Serviceanleitung gelesen und verstanden zu haben.</li> <li>• Wird diese Warnung nicht beachtet, so kann es zu Verletzungen des Kundendiensttechnikers, des Bedieners oder des Patienten durch Stromschläge, mechanische oder sonstige Gefahren kommen.</li> </ul>

<p><b>UPOZORENJE</b> (HR)</p>	<p>Ovaj servisni priručnik dostupan je na engleskom jeziku.</p> <ul style="list-style-type: none"> <li>• Ako davatelj usluge klijenta treba neki drugi jezik, klijent je dužan osigurati prijevod.</li> <li>• Ne pokušavajte servisirati opremu ako niste u potpunosti pročitali i razumjeli ovaj servisni priručnik.</li> <li>• Zanimarite li ovo upozorenje, može doći do ozljede davatelja usluge, operatera ili pacijenta uslijed strujnog udara, mehaničkih ili drugih rizika.</li> </ul>
<p><b>ΠΡΟΕΙΔΟΠΟΙΗΣΗ</b> (EL)</p>	<p>Το παρόν εγχειρίδιο σέρβις διατίθεται μόνο στα αγγλικά.</p> <ul style="list-style-type: none"> <li>• Εάν ο τεχνικός σέρβις ενός πελάτη απαιτεί το παρόν εγχειρίδιο σε γλώσσα εκτός των αγγλικών, αποτελεί ευθύνη του πελάτη να παρέχει τις υπηρεσίες μετάφρασης.</li> <li>• Μην επιχειρήσετε την εκτέλεση εργασιών σέρβις στον εξοπλισμό αν δεν έχετε συμβουλευτεί και κατανοήσει το παρόν εγχειρίδιο σέρβις.</li> <li>• Αν δεν προσέξετε την προειδοποίηση αυτή, ενδέχεται να προκληθεί τραυματισμός στον τεχνικό σέρβις, στο χειριστή ή στον ασθενή από ηλεκτροπληξία, μηχανικούς ή άλλους κινδύνους.</li> </ul>
<p><b>ATENCIÓN</b> (ES)</p>	<p>Este manual de servicio sólo existe en inglés.</p> <ul style="list-style-type: none"> <li>• Si el encargado de mantenimiento de un cliente necesita un idioma que no sea el inglés, el cliente deberá encargarse de la traducción del manual.</li> <li>• No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio.</li> <li>• La no observancia del presente aviso puede dar lugar a que el proveedor de servicios, el operador o el paciente sufran lesiones provocadas por causas eléctricas, mecánicas o de otra naturaleza.</li> </ul>
<p><b>HOIATUS</b> (ET)</p>	<p>See teenindusjuhend on saadaval ainult inglise keeles</p> <ul style="list-style-type: none"> <li>• Kui klienditeeninduse osutaja nõuab juhendit inglise keelest erinevas keeles, vastutab klient tööteenuse osutamise eest.</li> <li>• Ärge üritage seadmeid teenindada enne eelnevalt käesoleva teenindusjuhendiga tutvumist ja sellest aru saamist.</li> <li>• Käesoleva hoiatuse eiramine võib põhjustada teenuseosutaja, operaatori või patsiendi vigastamist elektrilöögi, mehaanilise või muu ohu tagajärjel.</li> </ul>
<p><b>VAROITUS</b> (FI)</p>	<p>Tämä huolto-ohje on saatavilla vain englanniksi.</p> <ul style="list-style-type: none"> <li>• Jos asiakkaan huoltohenkilöstö vaatii muuta kuin englanninkielistä materiaalia, tarvittavan käänöksen hankkiminen on asiakkaan vastuulla.</li> <li>• Älä yritä korjata laitteistoa ennen kuin olet varmasti lukenut ja ymmärtänyt tämän huolto-ohjeen.</li> <li>• Mikäli tätä varoitusta ei noudateta, seurauksena voi olla huoltohenkilöstön, laitteiston käyttäjän tai potilaan vahingoittuminen sähköiskun, mekaanisen vian tai muun vaaratilanteen vuoksi.</li> </ul>

<p><b>ATTENTION</b> (FR)</p>	<p>Ce manuel d'installation et de maintenance est disponible uniquement en anglais.</p> <ul style="list-style-type: none"> <li>• Si le technicien d'un client a besoin de ce manuel dans une langue autre que l'anglais, il incombe au client de le faire traduire.</li> <li>• Ne pas tenter d'intervenir sur les équipements tant que ce manuel d'installation et de maintenance n'a pas été consulté et compris.</li> <li>• Le non-respect de cet avertissement peut entraîner chez le technicien, l'opérateur ou le patient des blessures dues à des dangers électriques, mécaniques ou autres.</li> </ul>
<p><b>FIGYELMEZTETÉS</b> (HU)</p>	<p>Ezen karbantartási kézikönyv kizárólag angol nyelven érhető el.</p> <ul style="list-style-type: none"> <li>• Ha a vevő szolgáltatója angoltól eltérő nyelvre tart igényt, akkor a vevő felelőssége a fordítás elkészítése.</li> <li>• Ne próbálja elkezdni használni a berendezést, amíg a karbantartási kézikönyvben leírtakat nem értelmezték.</li> <li>• Ezen figyelmeztetés figyelmen kívül hagyása a szolgáltató, működtető vagy a beteg áramütés, mechanikai vagy egyéb veszélyhelyzet miatti sérülését eredményezheti.</li> </ul>
<p><b>AÐVÖRUN</b> (IS)</p>	<p>Þessi þjónustuhandbók er aðeins fánleg á ensku.</p> <ul style="list-style-type: none"> <li>• Ef að þjónustuveitandi viðskiptamanns þarfnast annas tungumáls en ensku, er það skylda viðskiptamanns að skaffa tungumálþjónustu.</li> <li>• Reynið ekki að afgreiða tækið nema að þessi þjónustuhandbók hefur verið skoðuð og skilin.</li> <li>• Brot á sinna þessari aðvörun getur leitt til meiðsla á þjónustuveitanda, stjórnanda eða sjúklingi frá raflosti, vélrænu eða öðrum áhættum.</li> </ul>
<p><b>AVVERTENZA</b> (IT)</p>	<p>Il presente manuale di manutenzione è disponibile soltanto in lingua inglese.</p> <ul style="list-style-type: none"> <li>• Se un addetto alla manutenzione richiede il manuale in una lingua diversa, il cliente è tenuto a provvedere direttamente alla traduzione.</li> <li>• Procedere alla manutenzione dell'apparecchiatura solo dopo aver consultato il presente manuale ed averne compreso il contenuto.</li> <li>• Il mancato rispetto della presente avvertenza potrebbe causare lesioni all'addetto alla manutenzione, all'operatore o ai pazienti provocate da scosse elettriche, urti meccanici o altri rischi.</li> </ul>
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# Section 1: Introduction

## 1.1 Intended Use

The information within this Manual describes the service, maintenance and test procedures for the iVent™201 ventilator system. It is intended to assist in maintaining the optimal functional operation and safety of the device.

This Service Manual should only be used by authorized, VersaMed certified, technicians. Should you require further information on becoming a VersaMed certified technician please contact your local VersaMed representative.

The information within this manual is not intended as a sole source of reference and has been intended for use in conjunction with the iVent 201 Operators Manual (OM-01-04). Both manuals should be referenced when performing any maintenance to the system.

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. Some earlier hardware or software versions may not be fully supported by this manual.

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

**IMPORTANT: THE TECHNICAL INFORMATION WHICH IS SUPPLIED IN THIS MANUAL 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 IVENT™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 iVent™201 is a compact, portable, fully featured, microprocessor-controlled ventilator offering the versatility and capability of larger and costlier ventilators. A turbine-powered air source and a rechargeable internal battery provide freedom from wall air and power outlets. An intuitive turn-and-click control knob, quick-choice pushbuttons, and a bright, well-organized, easy-to-read screen allow rapid control and continuous real-time monitoring of patient ventilation. Alarm settings are fully adjustable. Optional Waveform and Diagnostic Software package displays pressure and flow waveform data, loops, trends, and logged totals in a full array of graphical and numerical modes.

The iVent™201 supports many modes:

- Assist/Control
  - Volume Controlled A/C
  - Pressure Controlled A/C
- Synchronized Intermittent Mandatory Ventilation (SIMV)
  - Volume Controlled SIMV (Vctrl SIMV)
  - Pressure Controlled SIMV (Pctrl SIMV)
- Continuous Positive Airway Pressure (CPAP)
- Pressure Support Ventilation (PSV)

(Note: Certain modes are optional features and may not be operational in some iVent™201 models.)

In addition, the iVent™201 has these advanced features:

- Rise time is adjustable
- Preset Parameters by Patient Weight enables quick setup
- Adaptive Peak Flow™ can determine and deliver Inspiratory Peak Flow Rate according to a target mandatory tidal volume, maintaining a 1:2 I:E ratio
- Adaptive I-Time™ allows the ventilator to determine and deliver a respiratory cycle time to sustain a 1:2 I:E ratio
- The iVent™201's Adaptive Bi-Level feature enables leak-tolerance for facemask ventilation or other specialized high-leak tube ventilation
- Easy Exhale™ is an advanced PEEP mode designed to reduce expiratory work of breathing
- Firmware is upgradeable via a PC connection

- The iVent™201 is designed to operate according to specifications in any physical orientation – such as during transport use

### 1.2.1 Looking At The iVent™201



Figure 1-1 Front View of the iVent™201

Table 1-1 Front View of the iVent™201

Item Number	Description
1	Display
2	Keypad

Vent™201 Technical Reference Manual

3	Control knob
4	Exhalation valve luer inlet
5	Ventilator outlet
6	Sensor line luer inlets
7	Nebulizer outlet

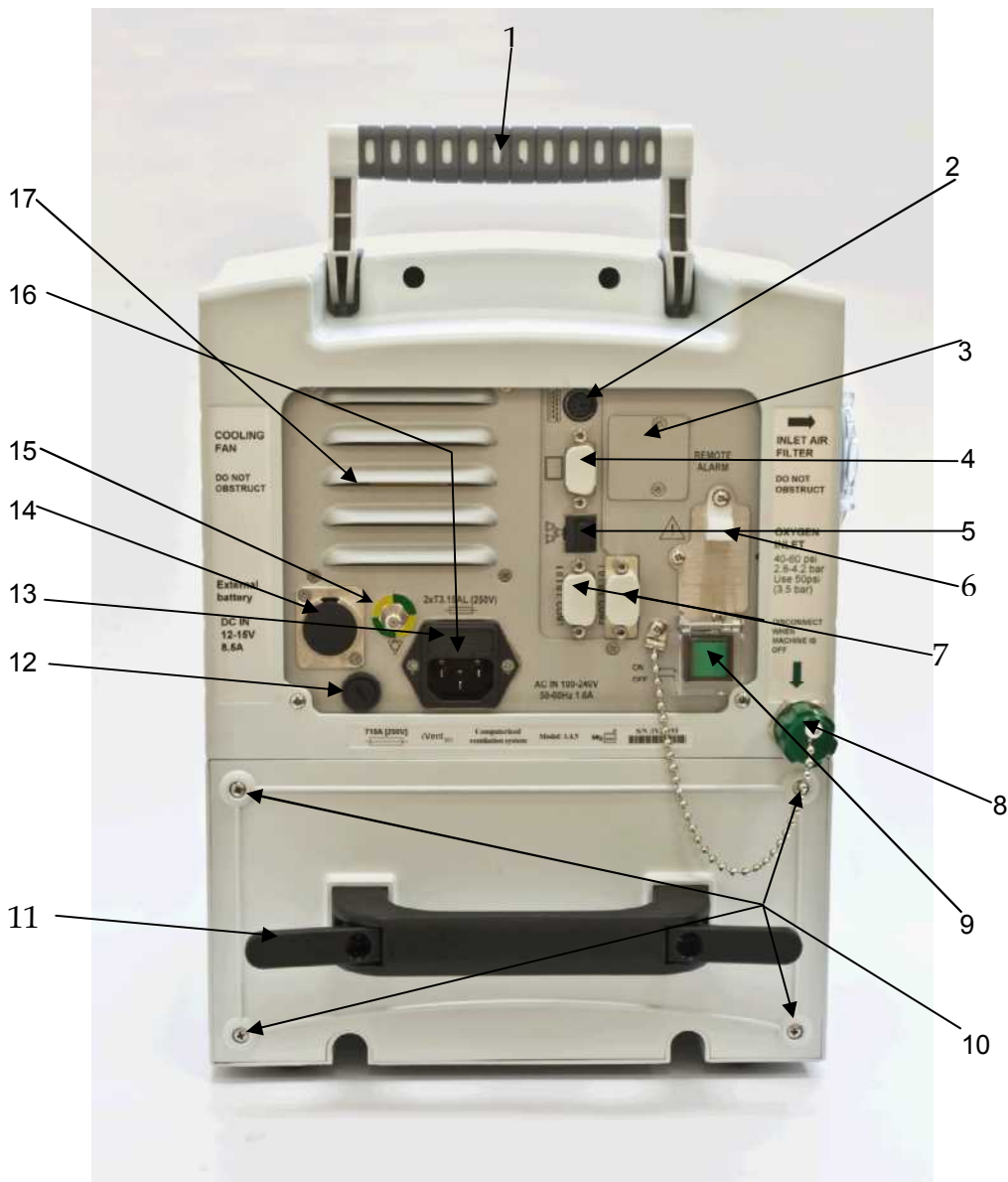


Figure 1-2 Rear View of the iVent™201

Released



**Table 1-2 Rear View of the iVent™201**

<b>Item Number</b>	<b>Description</b>
1	Carrying handle
2	Keyboard connector
3	Remote alarm connector
4	External screen connector
5	LAN connector
6	AC cable clip
7	RS 232 connectors (COM1 and COM2)
8	High pressure oxygen inlet connector
9	On/off switch (with cover)
10	4 x Battery pack screws
11	Internal battery handle
12	DC fuse
13	AC fuses
14	DC cord connector
15	Grounding pin
16	AC cord connector
17	Cooling fan

## 1.2.2 Product Versions

This manual is intended to be generic to all recent hardware versions of the iVent™201 ventilator system. You will see the following product versions referred to throughout this manual:

Between iV12000 and iV14999	Denotes in general all devices with Stepper Motor based pneumatic system.
Between iv15000 and iv19999 or greater than 30000	Denotes all devices in with standard color configuration which are equipped with the PSV based pneumatic system.
Between iV20000 and iV29,999	Denotes all devices in with the HHS color and hardware configuration.

### 1.2.3 Safety Information

- US federal law restricts this device to sale by or on the order of a physician.
- Only medically pure oxygen should be used for operation of the device. Anaesthetics and potentially explosive gases may not be used.
- To avoid any potential fire hazard, keep all matches, lighted cigarettes and other sources of ignition away from the device.
- An alternative source of ventilation should always be available when using the iVent™201 ventilator.
- Do not replace any accessories or other parts of the iVent™201 while a patient is being ventilated.
- Insert a bacteria filter between the iVent™201's patient connector port and the ventilator breathing circuit to prevent any contamination of the device.
- If you notice that the iVent™201 is damaged in any way its life supporting function can no longer be guaranteed. Stop ventilation with the defective device immediately and use an alternate form of ventilation.
- Do not use the iVent™201 unless an internal battery with at least a minimal charge is installed. If the iVent™201 has been stored for an extended period of time it is recommended that the internal battery be recharged prior to use. It is recommended that the devices internal battery be replaced every year.
- Maintenance work must always be carried out in compliance with all relevant safety regulations. Repairs, assembly and use should only be carried out by VersaMed certified personnel.
- To ensure that your device continues to perform to specification all manufacturer-prescribed planned maintenance guidelines should be followed and the device should be checked by trained personnel on a minimum of an annual basis.
- To avoid electrical shock while servicing the ventilator, be sure to disconnect the device from all AC and DC power sources prior to undertaking maintenance.
- A high voltage of 1800 Vrms exists on the DC-AC inverter unit. Do not touch this unit for a minimum of 5 minutes after the ventilator is powered off.
- Only genuine VersaMed replacement parts should be used for service. Failure to comply may seriously impair the ventilators performance, safety or reliability.
- When the iVent™201 is connected to another device via the serial port, the power cord should be in place to ensure adequate grounding.
- 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.
- Alteration or repair of the iVent™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.
- During reassembly of the iVent™201 or any of its subcomponents take care to inspect and reconnect all electrical grounds that have been previously disconnected.
- On completion of any servicing or planned maintenance always perform calibration, ventilator verification test and full functional testing prior to returning the device to use. Failure to do so may result in the device not performing to specification.

## 1.2.4 Safety Regulations

**The following medical electrical equipment safety standards have been met:**

ISO 10651-1	Lung Ventilators for medical use
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 60601-1	Medical Electrical Equipment, part1: General Requirements for Safety
ASTM F1246-96	Standard Specification for Electrically Powered Home Care Ventilation.
Mil-STD-810E	Environmental consideration and testing
IEC-68-34	Environmental consideration and testing /Vibration/Shock
IEC-68-2-27	









## 1.2.5 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.
- Full details regarding the appropriate level of ESD precautions to use are included in the service and repair section of this manual.

## 1.3 Labels and Symbols

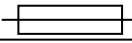
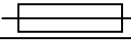

### 1.3.1 Symbols

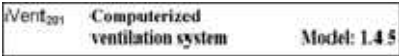
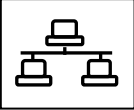



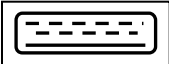
The following IEC 601-1 symbols appear on the ventilator:

Symbol	Meaning
	Indicates that you should “Refer to documentation for further information.” Refer to manual per IEC 601-1
	Potential equalization (Ground) point
	Direct Current ( DC) and Alternating Current (AC)
	Type BF equipment, per IEC 601-1
	MR conditional per ASTM 2503-05
	Nebulizer
	Sensor line luer inlets
	Ventilator outlet





	Exhalation valve luer inlet
---	-----------------------------

### 1.3.2 Labels

Location	Label
AC Connector	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p><b>AC IN 100-240V</b> <b>50-60Hz 1.6A</b></p> </div>
AC Fuses	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p><b>2xT3.15AL (250V)</b></p>  </div>
Air Inlet	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p style="text-align: center;"><b>➔</b></p> <p><b>INLET AIR FILTER</b></p> <p>DO NOT OBSTRUCT</p> </div>
Cooling Fan Vent	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p><b>COOLING FAN</b></p> <p>DO NOT OBSTRUCT</p> </div>
Connector	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p><b>DC IN</b> 12-15V 8.5A</p> </div>
DC Fuse	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p><b>T15A (250V)</b></p>  </div>
Device ID	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p>Mfg: 2006  S/N :IV12576</p> </div>

Location	Label
Device Product	
Ethernet Connector (not on all units)	
External Display Connector	
High Pressure Oxygen Inlet	<div style="display: flex; justify-content: space-around;"> <div style="background-color: #cccccc; padding: 10px; width: 45%;"> <p style="text-align: center;"><b>COOLING FAN</b></p> <p style="text-align: center;">DO NOT OBSTRUCT</p> <p style="text-align: center;"><b>External battery</b></p> <p style="text-align: center;"><b>DC IN</b> <b>12-15V</b> <b>8.5A</b></p> </div> <div style="background-color: #cccccc; padding: 10px; width: 45%;"> <p style="text-align: center;"> <b>INLET AIR FILTER</b></p> <p style="text-align: center;">DO NOT OBSTRUCT</p> <p style="text-align: center;"><b>OXYGEN INLET</b> 40-75 psi 2.8-5.1 bar Use 50 psi (3.5 bar)</p> <p style="text-align: center;">DISCONNECT WHEN MACHINE IS OFF</p> <p style="text-align: center;"></p> </div> </div>
Keyboard Connector	



Location	Label
Power Pack Fuse	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>T15A (250V)</b> </div>
Power Switch	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>ON</b>   <b>OFF</b>  </div>
Remote Alarm Connector	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>REMOTE ALARM</b> </div>
Serial Communication Connector	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>RS-232</b> </div>
Power Pack (inside)	<div style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;"><b>POWER PACK</b></p> <p style="text-align: center;">P/N : 503A0012</p> <p><b>Caution:</b> This Power Pack contains a sealed Lead - Acid Battery. Disposal of this unit should be according to Environmental Safety Requirements for Lead-Acid batteries.</p> </div>
VersaMed	<div style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;">VersaMed Medical Systems Ltd.</p> <hr/> <p><b>CAUTION</b>          US Federal Law restricts this device to sale by or on the order of physician</p> <div style="display: flex; align-items: center;">  </div> <p><b>WARNING</b>          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.</p> <div style="display: flex; justify-content: space-between;"> <div style="font-size: small;">             Versamed Medical Systems Ltd              P.O.B. 5011, Ornat Bldg.              Hasheron Ind Park, Kadima              60820              Israel <a href="http://www.versamed.com">http://www.versamed.com</a> </div> <div style="text-align: center;">  <p>3130058 0473</p> </div> </div> </div>



## Section 2: System Specifications

### 2.1 Ventilation Modes

Assist/Control (A/C)

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

Synchronized Intermittent Mandatory Ventilation (SIMV)

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

Continuous Positive Airway Pressure (CPAP)

Pressure Support Ventilation (PSV)

Adaptive Bi-Level (A. BI-LEVEL)

### 2.2 Ventilation Performance and Controlled Parameters

Ventilation Component	P Parameter s/ Range	Unit of Measure	Accuracy	Set	Display
Respiratory Rate	1-12 12-80	bpm	±1 ±2	Y	Y
Inspired Tidal Volume	50-2000	mL	±10%	Y	Y
Exhaled Tidal Volume	50-300 300-2000	mL	±10 mL or ±15% ±10%	N	Y
Inspiratory Pressure Limit	5 to 80	cmH <sub>2</sub> O	±5	Y	Y
Inspiratory Time	0.2 to 3 or Adaptive I-Time™	sec.	±10%	Y	Y
Peak Flow	up to 120 or	L/min	±10%	Y	Y

Ventilation Component	P Parameter s/ Range	Unit of Measure	Accuracy	Set	Display
	Adaptive Flow™				
Peak Flow (Spontaneous)	up to 180	L/min	±10%	Y	Y
Oxygen Mix (FiO <sub>2</sub> )	21 to 100%		±5%	Y	Y
PEEP	0 to 40	cmH <sub>2</sub> O	±1 or ±10%, whichever is greater	Y	Y
Trigger sensitivity	1 to 20, off -0.5 to -20, off	L/minmH <sub>2</sub> O		Y	Y
PSV	0 to 60	cmH <sub>2</sub> O	±10%	Y	Y
Positive Pressure relief valve	80	cmH <sub>2</sub> O		N	N
Controlled Pressure	5 to 80	cmH <sub>2</sub> O	±5	Y	Y
FiO <sub>2</sub> at power up	21%, 40%, 60%, 100% (selectable)			Y	Y
Purging cycle	1, 2, 5, 10, off	minutes		Y	N
Flow Termination	10-90	%	±10%	Y	Y
Rise Time	Mid, High, Max, Auto		NA	Y	Y

## 2.3 Monitored Data

Parameter	Range, resolution, accuracy
Breath type	<b>Range:</b> Type: - Control, assist, spontaneous, sigh <b>Resolution:</b> N/A <b>Accuracy:</b> N/A
Respiratory Rate	<b>Range:</b> 0 to 150/min <b>Resolution:</b> 1/min <b>Accuracy:</b> ±1 for 1 to 12/min ±2 for 12 to 150/min
Exhale tidal volume	<b>Range:</b> 0 to 5000 mL <b>Resolution:</b> 1 mL <b>Accuracy:</b> ±10 mL or ±15% (whichever is greater) for 0 to 300 mL ±10% for 300 to 5000 mL
Exhaled Minute Volume	<b>Range:</b> 0 to 99.9L <b>Resolution:</b> 0.1 L <b>Accuracy:</b> ±10%
Peak flow	<b>Range:</b> 0 to 140 L/min <b>Resolution:</b> 1 L/min <b>Accuracy:</b> ±10%
PIP (Peak Inspiratory Pressure)	<b>Range:</b> 0 to 99 cmH <sub>2</sub> O <b>Resolution:</b> 1 cmH <sub>2</sub> O <b>Accuracy:</b> ± 2 (+ 5 % of reading) cmH <sub>2</sub> O
Inspiratory time	<b>Range:</b> 0 to 3.0 sec <b>Resolution:</b> 0.1 sec <b>Accuracy:</b> ±10%
I:E ratio	<b>Range:</b> 1:11 to 3:1 <b>Resolution:</b> 0.1 for 1:1 to 1:5 1 for 1:5 to 1:11 and 3:1 to 1:1 <b>Accuracy:</b> ±0.1

<b>Parameter</b>	<b>Range, resolution, accuracy</b>
Delivered O2%	<b>Range:</b> 21 to 100% <b>Resolution:</b> 1% <b>Accuracy:</b> ±5%
Flow Leak	<b>Range:</b> 0 to 100% <b>Resolution:</b> 1% <b>Accuracy:</b> ±15%
Mean Airway Pressure	<b>Range:</b> 0 to 99 cmH <sub>2</sub> O <b>Resolution:</b> 1 cmH <sub>2</sub> O <b>Accuracy:</b> ± 2 (+ 5 % of reading) cmH <sub>2</sub> O
Resistance (dynamic)	<b>Range:</b> 0 to 99.9 cmH <sub>2</sub> O/L/s <b>Resolution:</b> 0.1 cmH <sub>2</sub> O/L/s <b>Accuracy:</b> ± (2 + 20% of actual value) cmH <sub>2</sub> O/L/s
Compliance (dynamic)	<b>Range:</b> 0 to 99.9 ml/cmH <sub>2</sub> O <b>Resolution:</b> 0.1 ml/cmH <sub>2</sub> O <b>Accuracy:</b> ± (2 + 20 % of actual value) ml/cmH <sub>2</sub> O
RR/Vt-Rapid Shallow Breathing Index (RSBI)	<b>Range:</b> 0 –200 /min*L <b>Resolution:</b> 1 /min*L <b>Accuracy:</b> ± (5 + 20% of actual value). /min*L
Static compliance	<b>Range:</b> 0 to 99 ml/cmH <sub>2</sub> O <b>Resolution:</b> 1 ml/cmH <sub>2</sub> O <b>Accuracy:</b> ± (2 + 20% of actual value) ml/cmH <sub>2</sub> O
Auto PEEP	<b>Range:</b> 0 to 99 cmH <sub>2</sub> O <b>Resolution:</b> 1 cmH <sub>2</sub> O <b>Accuracy:</b> ± 2 (+ 5 % of reading) cmH <sub>2</sub> O
Time Constant	<b>Range:</b> 0.0 to 9.9 sec <b>Resolution:</b> 0.1 sec <b>Accuracy:</b> ±20%
Plateau Pressure	<b>Range:</b> 0 to 99 cmH <sub>2</sub> O <b>Resolution:</b> 1 cmH <sub>2</sub> O <b>Accuracy:</b> ±2(+5% of reading) cmH <sub>2</sub> O



## 2.4 Monitoring and Displayed Parameters

The following table lists specifications for all parameters the iVent™201 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 Limit (Vt limit)	ML		●		●			●	●	
Tidal Volume (estimated)	mL						●			●
Leak (estimated)	L/min						●			●
Rate	bpm	●	●	●	●	S	●	●	●	●
Inspiratory Pressure (above PEEP)	cmH <sub>2</sub> O		●		●	●		●	●	
Alarm Pressure/ Limit Pressure	cmH <sub>2</sub> O	●		●			●	●	●	
Oxygen Concentration	FiO <sub>2</sub>	●	●	●	●	●	●	●	●	L
Inspiration to Expiration time ratio (I:E)	I:E	●	●	●	●	●	●			●
Inspiratory time (I.Time)	sec	●	●	●	●	●	●	●	M	A
Peak Inspiratory Flow (Vpeak)	L/min	●	v	●	●	●		●	M	A
Flow Termination	%	●	●			●	●	●	●	
Trigger Sensitivity (Flow)	L/min	●	●	●	●	●	●	●	●	
Trigger Sensitivity (Pressure)	cmH <sub>2</sub> O	●	●	●	●	●	●	●	●	
Rise Time	sec	●	●	●	●	●	●	●	●	



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
Pressure Support Ventilation (PSV)	cmH <sub>2</sub> O	●	●	●		●		●	●	
Positive End Expiratory Pressure (PEEP)	cmH <sub>2</sub> O	●	●	●	●	●		●	●	
Exhaled Minute Volume (M.Vol)	L	●	●	●	●	●	●			●
Peak Inspiratory Pressure (PIP)	cmH <sub>2</sub> O	●	●	●	●	●	●			●
IPAP (Inspiratory Pressure)	cmH <sub>2</sub> O						●	●	●	
EPAP (Expiratory Pressure)	cmH <sub>2</sub> O						●	●	●	
Pressure Waveform	cmH <sub>2</sub> O	●	●	●	●	●	●			●
Flow Waveform	L/min	●	●	●	●	●	●			●
Breath type	Icon symbol	●	●	●	●	●	●			●
Power Source	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<sub>2</sub> Pressure mode only V=measured value only (not settable)

## 2.5 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

## 2.6 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 <sub>2</sub> O)	High (4 - 80)	Low (1 - 77)
FiO <sub>2</sub> (%)	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	

## 2.7 Additional Alarms

Low O <sub>2</sub> 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	SpO <sub>2</sub> Sensor disconnect from the patient
SpO <sub>2</sub> Sensor disconnect from the iVent	SpO <sub>2</sub> Sensor not found
SpO <sub>2</sub> Reading Failed	

## 2.8 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	17.6 lb / 8 kg (without battery)
Battery Weight	6 lb / 3 kg (standard battery) 10.1 lb / 4.6 kg (extended battery)
Overall Weight	24/6 lb / 11 kg (standard battery) 27.6 lb / 12.6kg (extended battery)

## 2.9 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
<i>Standard Battery:</i>	
Battery Type	Sealed Lead-Acid, 12V, 7.2-9 Ah (rechargeable)
Operating Time	Up to 2 hours (varies with ventilation parameters)
Recharge Time	8 to 10 hours
<i>Extended Battery:</i>	
Battery Type	Sealed Lead-Acid, 12V, 12.0 Ah (rechargeable)
Operating Time	Up to 4 hours (varies with ventilation parameters)
Recharge Time	16 to 20 hours

## 2.10 Oxygen Supply

Medical Grade High Pressure Oxygen	40 to 60 psi (2.8 to 4.1 bar) or 40 to 73.5 psi (2.8 – 5 bar)
------------------------------------	---

Low Pressure

Maximum flow 15 L/min or 0.5 psi

## 2.11 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

## 2.12 Standards and Safety Requirements

The iVent™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

## 2.13 Indicators and Icons

Power Source

Internal Battery Charge Level

Alarm Silence and Countdown Timer

Date and Time

LEDs: On, Charge, Alarm

Work Hour Counter

Breath Type

Zeroing

Purging

100% O<sub>2</sub> Suction Mode

External DC

## Section 3: Installation and Setup

### 3.1 Introduction

This section of the manual has been formulated in order to provide a reference of the steps required to ready the product for its first usage following delivery. This section describes in full the unpacking, assembly and set up procedure.

**Note** A checklist of the installation procedures is included in Appendix C: Installation Check list, on page 214. Use this checklist to verify that all the needed steps for the installation have been performed.

### 3.2 Unpacking the Ventilator

Prior to unpacking the device inspect the shipping carton thoroughly for any signs of mishandling or damage. On opening the shipping carton firstly retrieve the packing list. Referring to the packing list unpack and check off all of the carton contents. In the event of finding any shortages please contact your local VersaMed representative.

### 3.3 Connection of Power Sources

The device may be operated with either mains AC power, external DC power or from its own internal DC supply. Application of all three types is described here below. Electrical safety testing requirements are also covered.

#### 3.3.1 External Power Sources

The iVent™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.

**CAUTION:** *BEFORE CONNECTING THE VENTILATOR TO AN AC OR DC OUTLET, VERIFY THAT THE EXTERNAL POWER SUPPLY IS THE CORRECT VOLTAGE AND FREQUENCY.*

**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** Power connections to iVent™201

When setting the ventilator up for the first time insert the power cord into the devices power inlet module. Using a Philips screwdriver remove the screw securing the cable clamp (and O2 dust cover) to the device. Allowing a suitable length of cord for strain relief, install the cable clamp over the cord and secure back in position.

When the device is switched on and connected to AC power, the 3-prong (AC plug) symbol is displayed on the lower part of the screen. When disconnected from AC power, the symbol is displayed crossed out with a red X.

If the device is to be operated from an external DC power source connect the appropriate cable to the external DC receptacle on the rear panel. 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.**

### 3.3.2 Internal Power Pack

The iVent™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 failure is detected.

**CAUTION: THE IVENT™ 201 MUST BE USED AT ALL TIMES WITH A PROPERLY FUNCTIONING BATTERY IN ORDER TO ENSURE THE CORRECT OPERATION OF THE VENTILATOR.**

#### 3.3.2.1 Internal Power Pack 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 CHARGE. IT IS STRONGLY RECOMMENDED THAT THE DEVICE STILL BE ALLOWED TO CHARGE FOR TEN HOURS.**

#### 3.3.2.2 Internal Battery Power 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 word EMPTY is displayed inside the indicator. The table below shows all of the charge status' which may be displayed in this area at any given time.




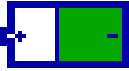


Indicator	Colors	Description
	Green	Battery is fully charged
	Green/ Clear	Green portion of indicator moves across in 10% increments
	Red/ Clear	Changes to red when the measurement is less than 30%
	Clear	Displays EMPTY when the measurement is less than 7%

Table 3-1 Battery indicator

### 3.3.3 Electrical Safety Testing

During first installation of the device and prior to be used clinically it is recommended that an electrical safety test be performed on the device. A typical procedure for performing electrical safety testing is included in the functional testing section of this manual.

## 3.4 Connecting Alternate Power Sources

The device may be used with either high or low pressure oxygen supplies in order to administer supplemental oxygen to the patient. The type of supply (high or low) may be configured through the advanced settings screen. Application of these two types of supply is described here below.

### 3.4.1 High Pressure Oxygen

The iVent™201 can use medical oxygen from a cylinder or from a central supply system at 40-73.5 psi (2.8 to 5 bar), depending on the hardware version. When the ventilator is ready for operation, remove the green dust-cover on the rear panel, and then connect the oxygen supply to the male DISS oxygen connector on the back of the ventilator (see Figure 3-2, page 30).

**WARNING: TO PREVENT RISK OF EXPLOSION AND IMPROPER OPERATION OF THE DEVICE ALWAYS ENSURE THAT YOUR OXYGEN SUPPLY IS OIL, MOISTURE AND PARTICULATE FREE.**

**CAUTION: BEFORE CONNECTING THE DEVICE TO THE OXYGEN SUPPLY, VERIFY THAT THE OXYGEN SUPPLY PRESSURE IS MAINTAINED WITHIN THE CORRECT PRESSURE RANGE AS SPECIFIED IN SECTION 4.2. FAILURE TO DO SO MAY RESULT IN INACCURATE FIO2 MAINTENANCE.**

**NOTE: PERIODIC VERIFICATION OF THE ACCURACY OF THE OXYGEN CONCENTRATION USING AN EXTERNAL MEANS IS HIGHLY RECOMMENDED.**



**Figure 3-2 oxygen DISS inlet connector**

In order to guard against possible ingress of particulate debris, on completion of operation with high pressure oxygen supply always replace the green dust cap on the DISS connector.

### 3.4.2 Low Pressure Oxygen

In the event that high pressure oxygen is not available, but supplemental oxygen is required, the device may be operated using a low pressure oxygen source (e.g. flowmeter, oxygen concentrator or liquid oxygen system). 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 (Versamed PN 620B0009-01, GE PN M1162020)

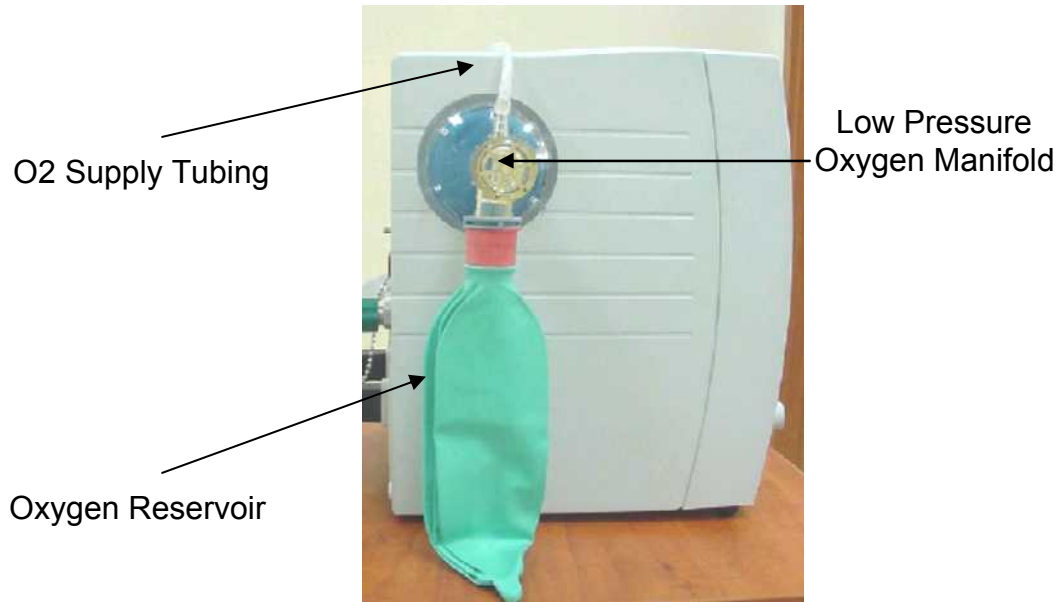


Figure 3-3 Low pressure oxygen connector

To use low pressure oxygen the device must first be configured to oxygen type 'Low' in the advanced settings screen. With the oxygen enrichment system in place and connected to the low pressure oxygen source, manually adjust the flow of oxygen as necessary to achieve the desired FiO<sub>2</sub> level. With oxygen 'Low' selected the measured value may be monitored in the FiO<sub>2</sub> area of the main display. Oxygen may also be monitored using an appropriate external device.

**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<sub>2</sub> MONITORING AND ALARMS. THE FIO<sub>2</sub> FIELD WILL DISPLAY "0."*

## 3.5 Patient Circuit and Accessory Connection

### 3.6 Patient Circuit

There are three ways to connect a patient circuit to the iVent™201: using a disposable patient circuit, a reusable patient circuit, or a dual limb patient circuit.

Consult a physician and an authorized VersaMed dealer for the appropriate patient circuit that suits the patient's needs.

Only patient circuit accessories approved by VersaMed or authorized by VersaMed dealers should be used with the iVent™201.

**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.*

**Warning:** *AN HME OR HME/ FILTER MUST NOT BE USED WITH ACTIVE HUMIDIFICATION. SUBSTITUTE THE HME WITH A BACTERIAL FILTER ONLY.*

**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.



Figure 3-4 Patient Circuit Connection

### 3.6.1 Disposable Patient Circuit

The disposable patient circuit consists of an inspiratory limb with a connector at one end of corrugated tubing, and a one-way valve connected to the Patient Wye at the other end.

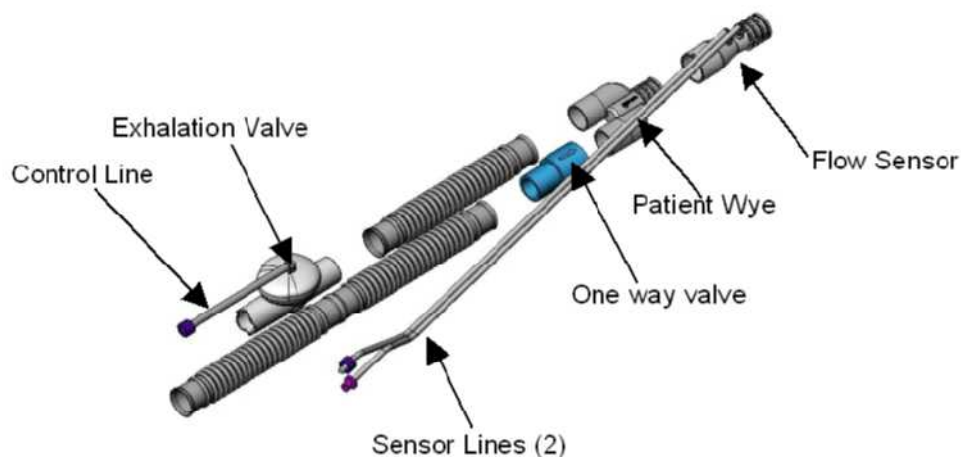


Figure 3-5 Patient Circuit Connections (Breathing Circuit)

The Patient Wye contains a flow sensor which is connected by two sensor tubes to the luer connectors on front of the ventilator.

The Expiratory Limb fastens to the Patient Wye, and leads to the Exhalation Valve, which connects to a blue tube, the Control Line, and leads back to the ventilator front panel. (Figure 3-4).

To connect a disposable patient circuit:

1. Twist the knurled connector of the inspiratory limb onto the ventilator outlet. The connector should fit snugly.
2. Connect the flow sensor tubing (the clear tubes) to their connectors. Male and female luer connectors on the flow sensor tubing ensure correct connection.
3. Connect the external Exhalation Valve control tube (the blue tube) to its connector (marked with a blue dot).
4. Ensure that all connections are secure and airtight. Perform an Operation Verification Test (OVT), as described in Section 6.2, on page 91.

### 3.6.2 Reusable Patient Circuit

The reusable patient circuit contains the same components as the disposable circuit. It should be sterilized by a steam autoclave, up to 40 cycles prior to use.

**CAUTION: Prior to use, examine the patient circuit carefully. Should any damage, discoloration or other abnormality appear on any part of the patient circuit, do not use it. Replace the patient circuit.**

To connect a patient circuit:

1. Twist the knurled connector of the inspiratory limb onto the ventilator outlet. The connector should fit snugly.
2. Connect the flow sensor tubing (the clear tubes) to their connectors. Male and female luer connectors on the flow sensor tubing ensure correct connection.
3. Connect the Exhalation Valve control tube (the blue tube) to its connector (marked with a blue dot).
4. Ensure that all connections are secure and airtight. Perform an Operation Verification Test (OVT), as described in Section 6.2, on page 91.

### 3.6.3 Dual Limb Patient Circuit

The dual limb patient circuit contains two corrugated tubes, which can be used as either inspiratory or expiratory limbs. The expiratory limb is connected to external Exhalation valve, which is then connected to the iVent™201.

To connect the patient circuit:

1. Connect the Exhalation valve and its accessories to the ventilator
2. Connect the tubing.

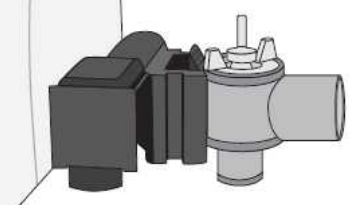
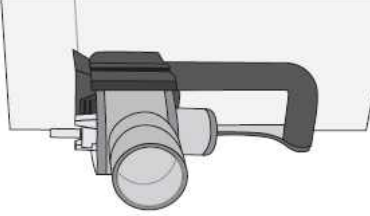
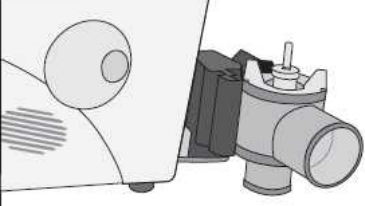
**The instructions provided below only refer to devices in which the Tran port mounting plate (VersaMed P.N. 504A0242-01) is installed. For additional**

**information regarding Transport Mounting plate refer to your local customer support.**

To install the Exhalation valve:

1. Facing the device insert the Exhalation valve adapter into the handle on the right side of the Transport Mounting plate, and guiding the adapter into its place.
2. Insert the Captive screw into the screw-hole on the adapter side, and screwing it with a flat screwdriver.
3. Connect the Exhalation valve holder to the Exhalation Valve adapter. Verify that the Exhalation Valve holder is firmly connected.

There are three ways to connect the adapter:

EXHALATION VALVE POSITION	FIGURE
Side vertically	
Side horizontally	
Front vertically	

**Figure 3-6 Exhalation valve adapter installation**

The Exhalation valve is now connected and ready to use. The next step involves installing the tubing to the ventilator.

To install the patient circuit:

1. Connect the Exhalation Valve control tube to the barb in the Exhalation Valve.

2. Connect the Exhalation Valve control tube to the PEEP outlet.
3. Connect the Patient Flow sensor tubes to the flow sensor luers on the front panel.
4. Connect one limb of the patient circuit into the iVent™201 outlet, marked with a blue dot, by twisting and pushing it until it is firmly in place.
5. Connect the second limb into the Exhalation Valve port by twisting and pushing it until it is firmly in place.
6. Before connecting a patient to the ventilator with a new circuit, you must perform a complete Operational Verification Test (O.V.T.) as described in Section 6.2, on page 91.

### 3.6.4 Circuit Resistance

It is important to check the inspiratory and expiratory resistance specification of the patient circuits used with the iVent™201 ventilator to ensure they do not exceed the following limits when adding attachments or other components or subassemblies to the breathing circuit:

- 0.6 KPA (6cmH<sub>2</sub>O) at 60 L/min for adult patients.
- 0.5 KPA (5cmH<sub>2</sub>O) at 30 L/min for pediatric patients.

**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 SUPPLIED 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.**



## 3.7 Pre Use Testing

Prior to using the ventilator for the first time it is strongly recommended that self-tests be performed. In accordance with the instructions within this manual and the user manual perform Ventilator Verification Test (VVT) and Operator Verification Test (OVT) on the device.

## 3.8 Filters

The iVent™201 utilizes the following filters (see Figure 3-7):

- 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

### 3.8.1 Air Inlet Filter

The iVent™201 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/adaptor (supplied by VersaMed)
- A Chemical/ Biological/ Radiological/ Nuclear Filter

#### 3.8.1.1 Low Pressure Oxygen Adapter and Filter

This filter is used with the low pressure oxygen supply system outlined in Section 3.4.2. 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.*

#### 3.8.1.2 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 M1162023) or another active carbon filtration device using a VersaMed supplied adapter (P/N M1161967).

### 3.8.1.3 Bacterial Filter

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

**Warning:**     **THE BACTERIAL FILTER IS INTENDED TO PREVENT 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.*

*ivent*<sup>™</sup>



Air Inlet Filter



Low Pressure O2 Adapter



CBRN Filter



Bacterial Filter at Ventilator Outlet



HME/ Filter at Patient Wye

Figure 3-7 *ivent*<sup>™</sup> 201 Filters

## 3.9 Ventilator Controls

The front panel of the iVent™201 includes the rotational control knob and the keypad (see Figure 3-8).



Figure 3-8 Ventilator Controls

### 3.9.1 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.

### 3.9.2 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<sub>2</sub>** - 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.

### 3.9.3 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.

## 3.10 Ventilator Operation

Please refer to the Operator's Manual, Section 3: and Section 4: for in-depth information on the operation of the device.

## Section 4: Theory of Operation

This section of the service manual is provided to detail the operational theory of the iVent™201 Ventilator System. This section includes an overview and then goes on to discuss the operational principals of the pneumatic and electronic systems. Finally this section goes on to describe how the devices firmware interacts with the hardware in certain applications.

### 4.1 Overview of System Operation

The iVent™201 is a compact, portable, fully-featured, microprocessor-controlled ventilator offering the versatility and capability of larger and more costly ventilators.

A high performance turbine-powered air source and a rechargeable internal battery provide prolonged autonomy from wall air and power outlets.

An intuitive turn-and-click control knob, quick-choice pushbuttons, and a bright, well-organized, easy-to-read screen allow rapid control and continuous real-time monitoring of patient ventilation. Alarm settings are fully adjustable.

Optional Waveform and Diagnostic Software package displays pressure and flow waveform data, loops, trends, and logged totals in a full array of graphical and numerical modes.

## 4.2 Pneumatic System

The pneumatic system design for the iVent™201 is built around a modular and compact pneumatic engine.

Patient air is drawn into the machine from ambient through the inlet filter and manifold. Supplemental Oxygen may be added, if required, from either a high pressure or low pressure source.

When high pressure oxygen is in use the microprocessor controlled blending system will ensure that patient gas is delivered at the prescribed and operator set FiO<sub>2</sub> level. If low pressure oxygen is selected for use it may be introduced via an accumulator placed at the ventilators air inlet and regulated by the user. The FiO<sub>2</sub> is monitored further downstream by the oxygen sensor.

Inspiratory force is generated by a brushless DC motor turning the impeller of the turbine. The turbine will combine with the bypass solenoids and the flow and pressure sensors to control volume and pressure to ensure ventilation at the set parameters.

The core of the pneumatic system, the blending system, turbine and bypass solenoids are mounted on or within the pneumatic manifold. Patient gas will be conveyed from the pneumatic system, via an outlet manifold, to the patient through the patient tubing system.

The patient tubing system will be a dual limb system incorporating a one way valve, wye, exhalation valve and proximal sensor. The proximal sensor will be used as the reference for regulation of inspiratory volumes and measurement of exhaled volumes.

Should the user wish to make some basic respiratory mechanics measurements more recent devices are equipped with the facility to produce either an inspiratory or expiratory hold. This facility will allow measurement of compliance, auto-PEEP and a number of other values.

The diagrams on the following page show 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 in the following section.

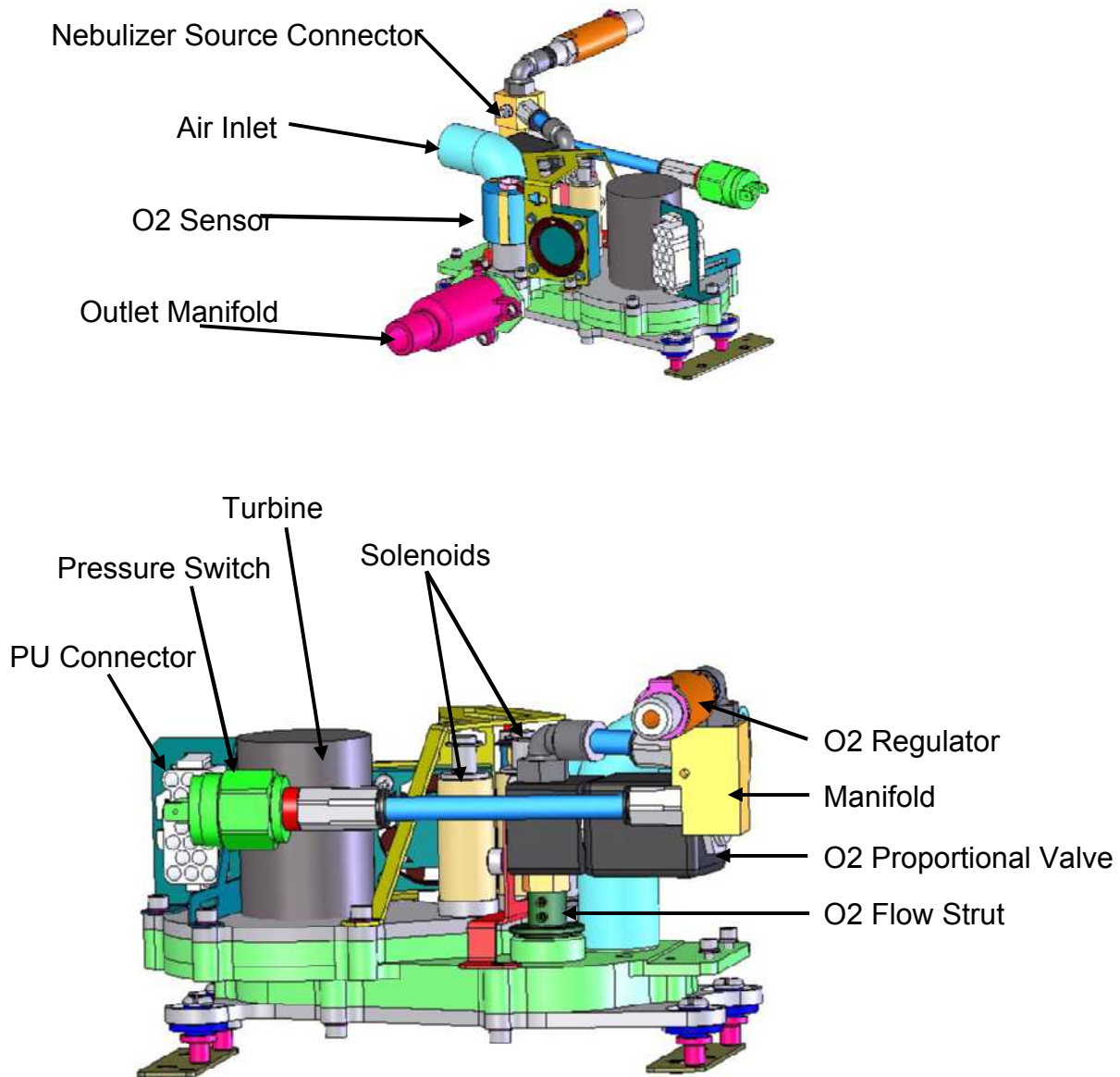
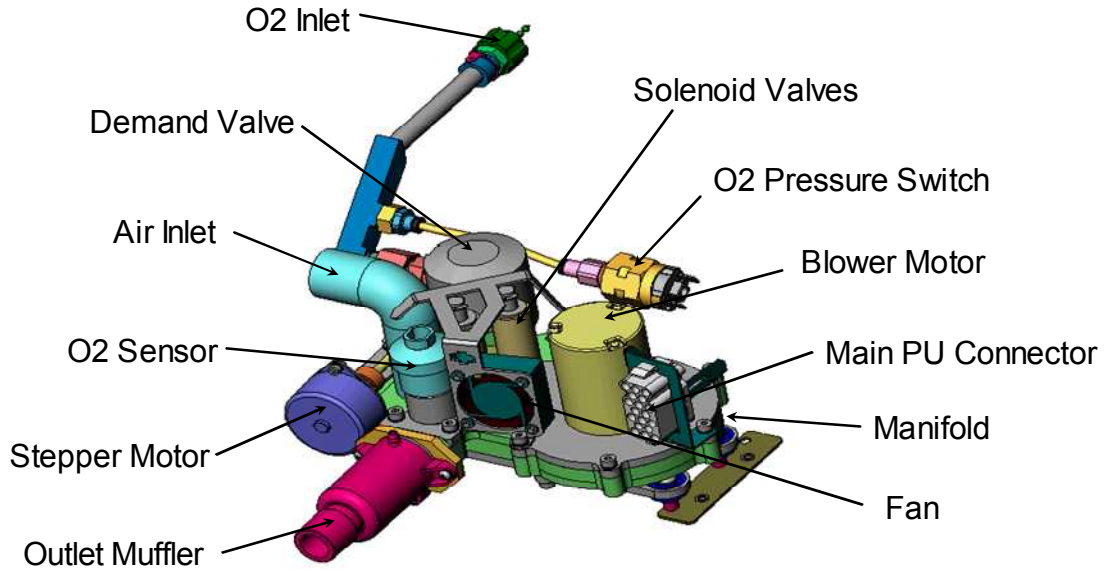


Figure 4-1 Pneumatic Unit – PSV Based System





**Figure 4-2 Pneumatic Unit – Stepper Based System**

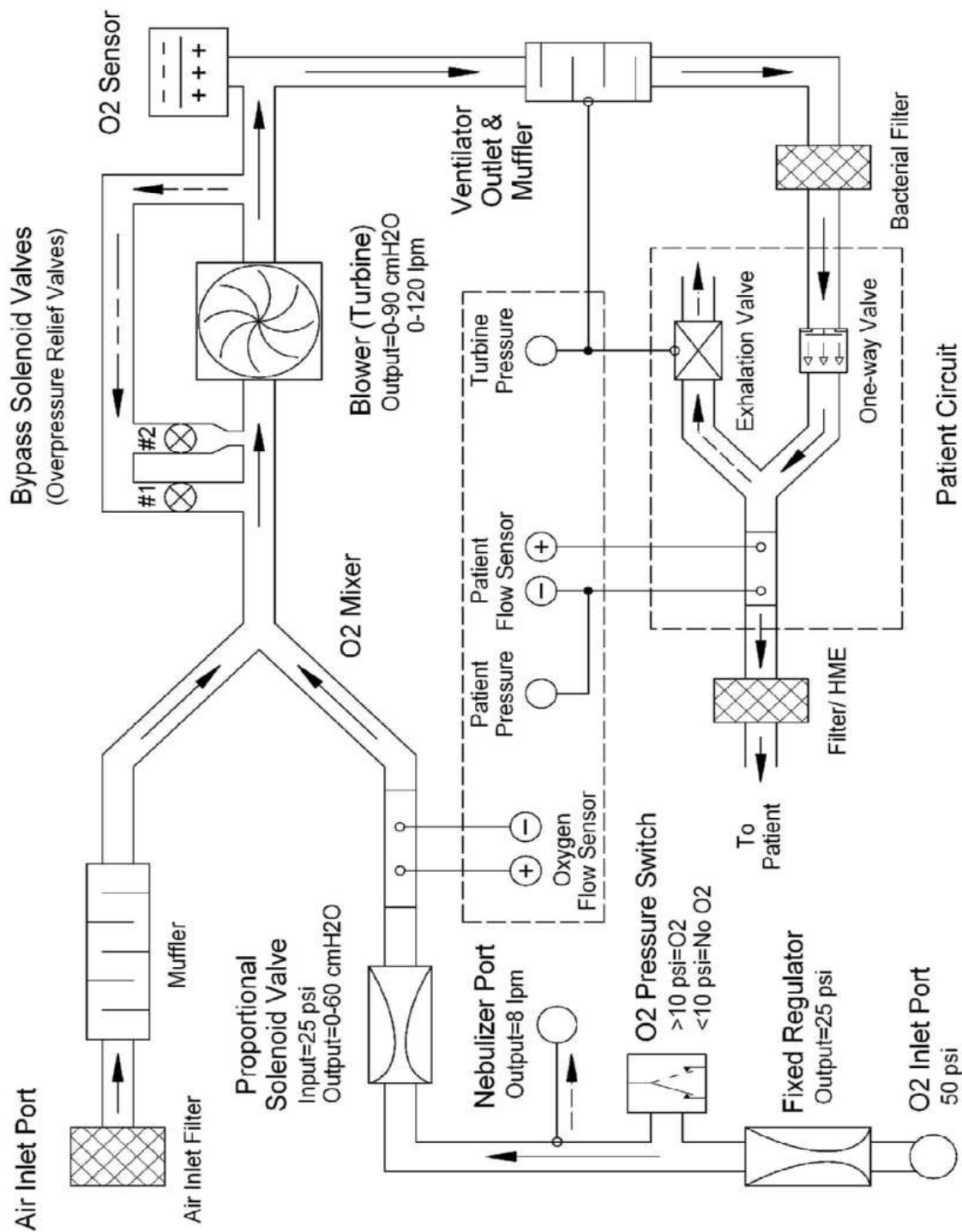


Figure 4-3 Pneumatic System – PSV Based Units

Released

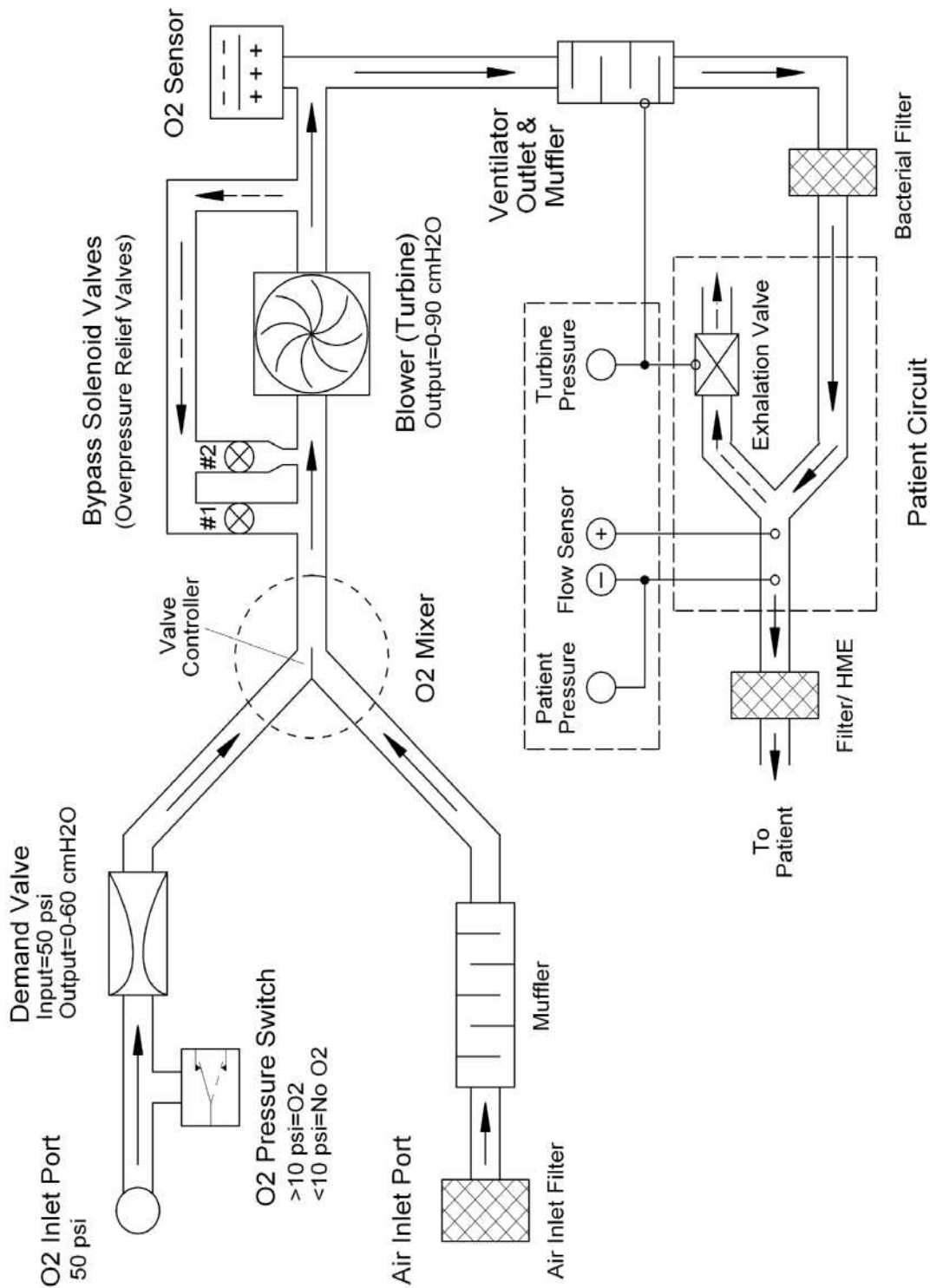


Figure 4-4 Pneumatic System – Stepper Based Units

### 4.2.1 Inlet Filter and Manifold

Ambient air drawn by the turbine will enter the device through the inlet filter. The inlet filter in its basic form includes a media which will allow filtration of particles down to a size of 5 microns. The inlet filter is recommended for replacement every month. A second version of this filter allows connection of an O2 Accumulator (supplied by low pressure O2).

In areas where there is suspected to be high levels of contamination in ambient air it is additionally possible to connect a CBRN type filter, via adapter, in place of the standard filter allowing the device to be operated safely.

Filtered ambient air will pass onwards and into the inlet muffler. 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 between the items.

### 4.2.2 Oxygen Blending System – PSV Units (iV15000>)

The gas delivered to the patient by the ventilator may be a mixture of Air and medically pure oxygen. The oxygen blending system controls the oxygen concentration of the gas mixture passing to the patient.

The oxygen blending system for current versions of the iVent™201 (all units with serial number iV15000>) is based around a proportional solenoid design and incorporates the following component items:

- O2 Regulator
- O2 Pressure Switch
- O2 Proportional Solenoid Valve
- O2 Flow Sensor

#### 4.2.2.1 O2 Regulator

The O2 regulator is included in the system to provide a stable input pressure for the O2 proportional solenoid valve and for the nebulizer system.

High pressure oxygen will be connected directly at the inlet of the oxygen regulator. Oxygen supply pressure should be maintained within the range of 40-73.5 psi  $\pm$  20% (2.4-4.2 bars) and should be medically pure.

If the O<sub>2</sub> supply is known or suspected to carry any level of particulate contamination it is recommended that an external filter be used inline prior to connection to the regulator.

The O<sub>2</sub> pressure regulator will reduce the O<sub>2</sub> system pressure down to a stable 25 psi (1.6 bars) which will provide the input to the O<sub>2</sub> pressure switch, O<sub>2</sub> proportional solenoid valve and the nebulizer system.

#### **4.2.2.2 O<sub>2</sub> Pressure Switch**

The O<sub>2</sub> pressure switch will provide detection of whether or not high pressure oxygen has been connected to the device. The O<sub>2</sub> pressure switch is set for closure at a pressure of 10psi. When the system pressure exceeds 10psi the pressure switch contacts will close completing a circuit and signaling the software that O<sub>2</sub> is connected. When system pressure drops below 10psi the switch contacts will open, breaking a circuit and signaling the software that O<sub>2</sub> is now disconnected.

The operation of the pressure switch will be fully verified during the O<sub>2</sub> tests performed during the ventilator verification test (VVT).

#### **4.2.2.3 O<sub>2</sub> Proportional Solenoid Valve**

The O<sub>2</sub> proportional solenoid valve will be used along with the O<sub>2</sub> flow sensor to control the O<sub>2</sub> flow delivered during breath delivery. The O<sub>2</sub> proportional solenoid valve shall be controlled by software adjustment of the PWM control signal. The higher the duty cycle of the control signal the further the valve will open and the larger the flow which will pass through.

During breath delivery the turbine will be turning at a speed equivalent to the flow requirements and profile of the breath. The proportional solenoid valve shall be controlled to deliver whatever percentage of the total flow is required in order to achieve the correct FiO<sub>2</sub>. The deficit in the total flow requirement shall be drawn through the ambient port.

#### **4.2.2.4 O<sub>2</sub> Flow Sensor**

The O<sub>2</sub> flow sensor is comprised of a strut which is positioned directly at the outlet of the O<sub>2</sub> proportional solenoid valve. The strut is designed to induce a pressure drop proportional to the amount of flow passing through the flow sensor.

Reference pressures are taken before and after strut and routed to the O<sub>2</sub> differential pressure sensor on the Main PCB from which the actual O<sub>2</sub> flow will be

computed. The flow measured at the strut shall be used by the software to control the operation and output of the O2 proportional solenoid valve.

### 4.2.3 Oxygen Blending System - Stepper Units (<iV14999)

The gas delivered to the patient by the ventilator may be a mixture of Air and medically pure oxygen. The oxygen blending system controls the oxygen concentration of the gas mixture passing to the patient.

The oxygen blending system for earlier versions of the iVent™201 (all units with serial number <iV14999) is based around a stepper motor driven mechanical gate design and incorporates the following component items:

- O<sub>2</sub> Pressure Switch - see section 4.2.2.2
- Demand Valve
- Proportioning Valve
- Controller Valve Limit Switch
- Oxygen Sensor

#### 4.2.3.1 Demand Valve

The demand valve's primary function is to reduce the pressure of oxygen from the nominal 40 psi found at its inlet to a 60 cmH<sub>2</sub>O potential. The maximum flow of oxygen through this device is 120 lpm.

Its second function is to open only if there is a demand or negative pressure at its outlet. Negative pressure will displace the valves seat allowing oxygen flow to pass through and into the system.

If the valve were held open by mechanical means, 60 cmH<sub>2</sub>O could be measured at the outlet; however by definition, any positive pressure will shut it off. Therefore the 60 cmH<sub>2</sub>O 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<sub>2</sub>O or ambient.

The operation of the demand valve will be fully verified during the O2 tests performed during the ventilator verification test (VVT).

### 4.2.3.2 Proportioning Valve

This is a gate type valve which is able to slide between the O<sub>2</sub> inlet port and ambient port of the pneumatic unit housing (inlet manifold) under the control of the stepper motor and valve controller. Each port is 22mm in diameter. When the mixture is equal or 60% oxygen, the valve occludes about one half of each opening.

A one-way valve is 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 allowing blow off of excess system pressure. 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<sub>2</sub> port and the ambient port of the O<sub>2</sub> 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% O<sub>2</sub> position.

The function of the proportioning gate valve and the valve controller is fully verified during the O<sub>2</sub> tests performed during ventilator verification test (VVT).

### 4.2.3.3 Valve Controller

The valve controller consists of a stepper motor and a mechanical linkage providing transmission to the proportioning gate valve. It can turn in both direction and drive the valve to a precise position. The valve controller will work under software control with the O<sub>2</sub> sensor further downstream providing feedback to the system.

It takes approximately 1000 steps to 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 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.

### 4.2.3.4 Valve Limit Switch (O<sub>2</sub> Microswitch)

The valve limit switch detects when the proportioning gate valve has reached an extreme at the 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<sub>2</sub>), the armature "falls" into a low spot on the cam), the limit

switch will open sending a signal to the software that the limit has been reached. The stepper motor reverses direction ~40 steps, resets the step count and awaits further instruction from the software.

The geometric relationship between the rotating actuating cam and O<sub>2</sub> valve requires precise alignment. It is recommended that VersaMed service perform this task and subsequent verification tests.

#### 4.2.4 Turbine System

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 23,000 RPM and generate pressures of up to 80-90 cmH<sub>2</sub>O. It is powered by the 12VDC supply and draws a maximum 4 amps when under load. 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.

The turbine assembly 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.

The turbines performance in terms of flow delivery capacity and working pressure will be fully verified during the ventilator verification test (VVT).

#### 4.2.5 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 sized silicon 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 diverting flow and allow the device 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 the 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 programmed 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<sub>2</sub>O. 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.

The operation of the solenoid valve system in all configurations will be full tested during the ventilator verification test (VVT).

#### **4.2.6 O2 Sensor**

The oxygen sensor is a galvanic, partial pressure sensor that is specific to oxygen. It measures the O<sub>2</sub> concentration of the gas mixture at the output of the blower.

In iVent™201 devices which are equipped with the stepper motor based O<sub>2</sub> blending system the O<sub>2</sub> sensor will be used as the primary source of feedback to the software. The O<sub>2</sub> sensor reading will be used for adjustment of the O<sub>2</sub> blender to a higher or lower position as required to match the programmed FiO<sub>2</sub> setting.

In iVent™201 devices which are equipped with the proportional solenoid based O<sub>2</sub> blending system the O<sub>2</sub> sensor reading will be used primarily for monitoring purposes, however in certain error situations it may be used for secondary regulation of the O<sub>2</sub> system.

The voltage output from the sensor changes proportionally with the partial pressure of the O<sub>2</sub> that it is exposed to. At the beginning of the sensor's life the output is approximately 65 mV at 100% O<sub>2</sub> and 15 mV at 21%.

As the sensor degrades the maximum output decreases. When the sensor output at 21% O<sub>2</sub> is less than 7.25 mV, the iVent™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<sub>2</sub> analyzer measurements and the internal O<sub>2</sub> measurement system. The ventilator specification for O<sub>2</sub> control is  $\pm 5\%$  FiO<sub>2</sub> but when comparing the values to an external O<sub>2</sub> analyzer, additional tolerance must be added to compensate for the uncertainties presented by the external analyzer. The "rule of thumb" should be an additional  $\pm 5\%$ .

The O<sub>2</sub> sensors performance will be checked at maximum (100%) and minimum (21%) settings during the ventilator verification test (VVT).

In order to ensure accurate O<sub>2</sub> monitoring across the full range of FiO<sub>2</sub> settings it is recommended that O<sub>2</sub> system calibration be performed every 3 months. In between full system calibrations the device will periodically perform self-calibrations of the O<sub>2</sub> sensor when set to either 21% or 100%.

The O<sub>2</sub> 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.**

#### 4.2.7 Patient Connector & Outlet Muffler

Gas destined for the patient will exit the system through the ventilator outlet port. 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.

Molded into the outlet muffler's form is also a small diameter barbed connector for taking turbine reference pressure. The turbine pressure will pass into the electronic module and on to the turbine pressure transducer on the Main PCB. A second line tees into this and will be used as a source to drive the closure of the exhalation valve either directly or via the hold system hardware.

## 4.2.8 Cooling Fan

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

## 4.2.9 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).

### 4.2.9.1 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 3-4).

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. For instance; a 1 lpm leak at the ET tube 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.

### 4.2.9.2 Exhalation Valve

The exhalation valve is attached to the distal end of 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). On completion of exhalation the valve will be additionally used for maintenance of PEEP.

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 signal with 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).

When either an inspiratory or expiratory hold is programmed the exhalation valve will be driven fully closed under force of the hold pump. This ensures a closed system for equilibration of the patient lung and patient system.

This component is automatically checked during the VVT.

### 4.2.9.3 One Way Valve

The one way valve may be connected between the wye and the inspiratory limb of the circuit, on the outlet muffler and in the future will be placed internally as part of the outlet muffler.

The one way valves checking action will ensure that all patient exhaled gases travel down the exhalation limb and exit the system through the open exhalation port. This prevents the patient rebreathing exhaled gases. It also allows the exhalation valve control line to quickly manipulate exhalation flow, for the Easy Exhale™ feature.

The device will check to ensure that the one-way valve is present during the operator verification test and during operation using the ventilator's built in diagnostics.

**CAUTION: *WHEN THE PATIENT CIRCUIT IS USED WITH ACTIVE HUMIDIFICATION, IT IS RECOMMENDED THAT THE ONE-WAY VALVE BE MOVED TO THE PATIENT OUTLET CONNECTOR TO ALLOW FOR PROPER DRAINAGE AND TO GUARD AGAINST NUISANCE ALARMS WHICH MAY RESULT.***

#### 4.2.9.4 Inspiratory & Expiratory Hold

The iVent™201 may be configured to allow a number of basic respiratory mechanics measurements to be taken. To make these measurements requires a method for holding the patient system closed allowing the patient lung and tubing system to equilibrate. To achieve closure of the system a hold maneuver will be performed.

In the iVent™201 the hardware which allows the hold maneuver to be achieved is the Hold Solenoid and the Hold Pump which are located on the Mounting PCB within the electronic unit. Under normal conditions exhalation valve inflation pressure is routed from the turbine pressure reference tubing into the electronic unit through the hold solenoid and back down to the exhalation connector.

To achieve an inspiratory hold, at the end of a normal inspiratory phase, the hold solenoid will be energized as will the hold pump. The pressure created by the pump will then pass through the hold solenoid and on to the exhalation valve providing a full closure of the valve. The inspiratory hold will be used to measure the Plateau pressure and static compliance.

To achieve an expiratory hold, at the end of a normal expiratory phase, the hold solenoid will be energized as will the hold pump. The pressure created by the pump will then pass through the hold solenoid and on to the exhalation valve providing a full closure of the valve. The expiratory hold will allow the lung and the patient system to equilibrate, and allow the operator to assess the level of auto peep present.

Although all units are equipped with the hold button on the keypad only units with a serial number of iV12000 or higher are equipped with the necessary internal hardware.

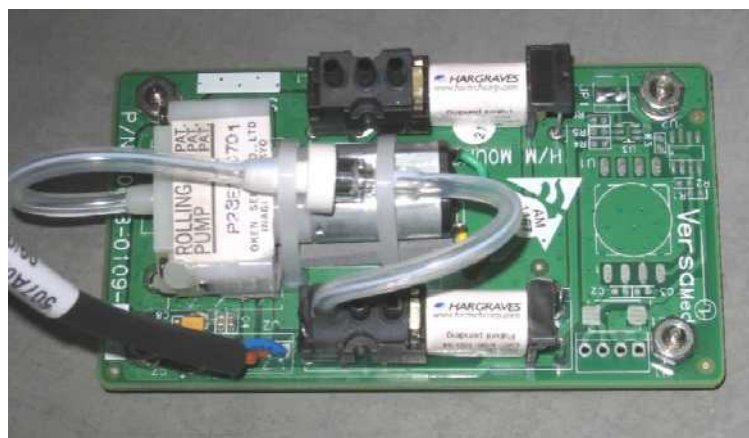


Figure 4-5 Hold/Nebulizer Mounting

### 4.2.9.5 Nebulizer System

Latest generation iV201 ventilators, those with the proportional solenoid valve based blending system, will also be equipped with the means to drive a pneumatic small volume nebulizer.

The nebulizer will be driven from the high pressure O<sub>2</sub> system; therefore in order to use the nebulizer facility, high pressure O<sub>2</sub> must be connected. Regulated O<sub>2</sub> pressure (25psi) will be routed from the O<sub>2</sub> system into the electronic module and on to the nebulizer solenoid located on the Mounting PCB. The output from the nebulizer solenoid is routed down from the electronic module and on to the nebulizer connector at the front panel.

The nebulizer will be programmed by the operator through the advanced settings screen, and will activate only during the inspiratory period. When nebulization is active, during inspiration, the nebulizer solenoid will be energized. With the nebulizer solenoid energized regulated O<sub>2</sub> pressure will be routed through the connector and tubing, and to the nebulizer vial.

When the nebulizer is operating the device will attempt to compensate breath delivery through the main connector in order to ensure that the programmed FiO<sub>2</sub> and other breath parameters reach the patient.

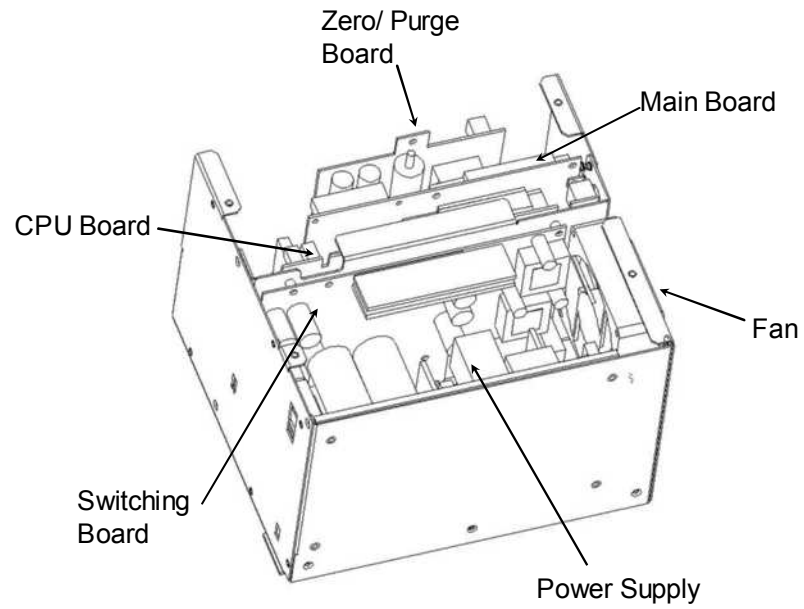
## 4.3 Electronic System

The electronic module of the 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 fig 4-5):

- Power Entry Module
- Power Supply PCB
- Integrated Battery / Gas Gauge
- External DC Supply
- Switching PCB
- CPU Board
- Main Board
- Zeroing/ Purge Board

- Hold PCB
- Hold/Nebulizer Mounting PCB
- LCD Display
- Cooling Fan



**Figure 4-6 Electronic Module**

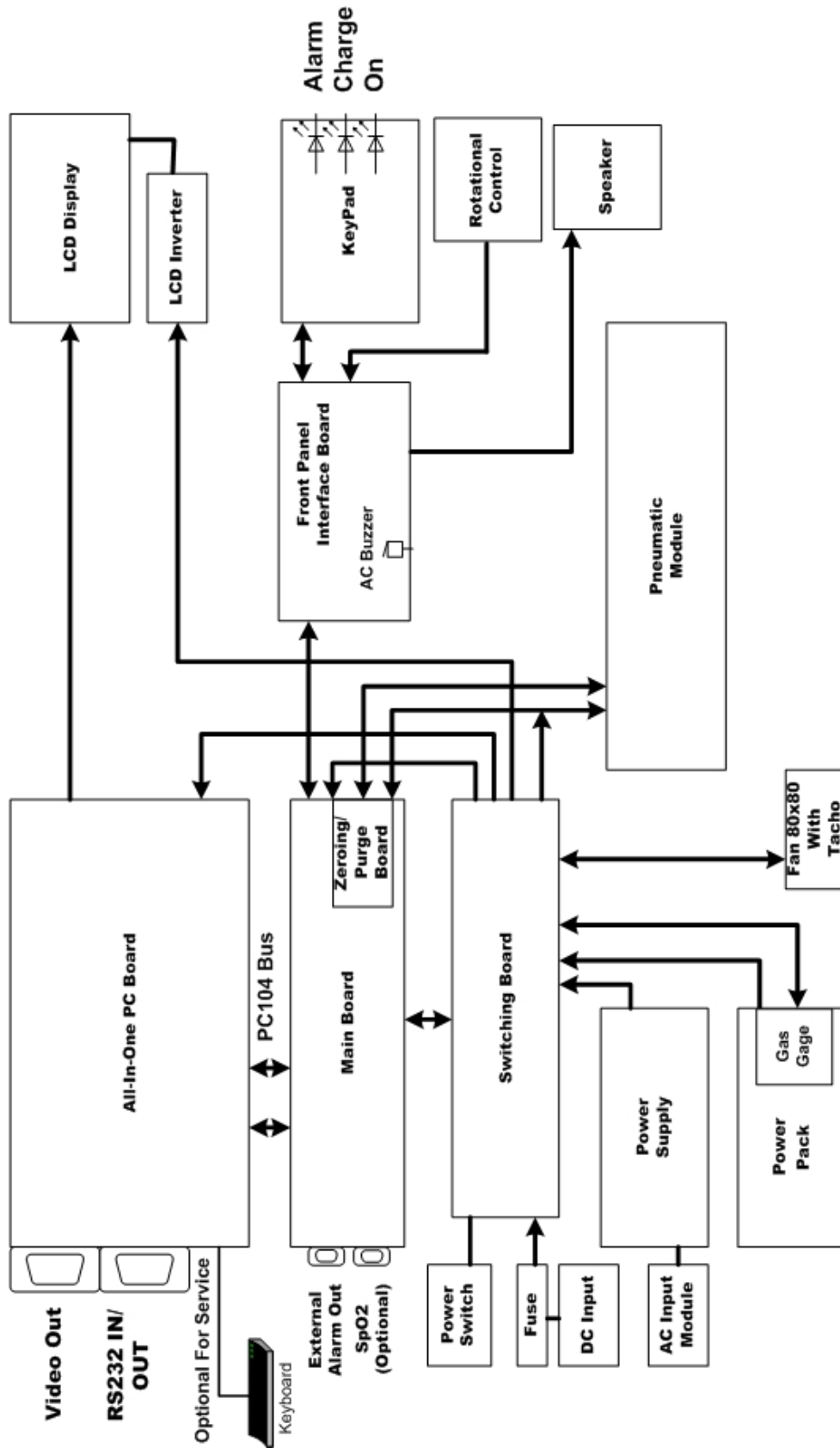


Figure 4-7 Ventilator Overview

Released



### 4.3.1 Power Entry Module

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.

### 4.3.2 Power Supply PCB

The ventilator is equipped with a medical grade power supply module which accepts universal AC input voltages from 85 to 265V, 40-440Hz and outputs a single 14.2VDC supply. The AC input connector also includes a RFI filter and dual 3.15A slow-blow fuses. The DC output voltage of the power supply passes directly on to the switching board.

### 4.3.3 Integrated 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.**

#### 4.3.3.1 Gas Gauge PCB

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 current, 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 7.7, page 126.

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).

#### **4.3.4 External DC Supply**

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

#### **4.3.5 Switching PCB**

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

#### **4.3.5.1 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.

#### **4.3.5.2 RFI Filter Block**

The RFI filter block filters conducted 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.

### 4.3.5.3 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.

### 4.3.5.4 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.

### 4.3.5.5 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.

### 4.3.5.6 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).

### 4.3.5.7 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.

#### **4.3.5.8 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.

#### **4.3.5.9 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.

#### **4.3.5.10 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.

#### **4.3.6 CPU PCB**

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 (2 x RS232 on some units) 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 through to the main alarm speaker on the front panel.

**NOTE: *ALTHOUGH SOME VERSIONS OF THE DEVICE INCLUDE CPU BOARDS WHICH ARE EQUIPPED WITH ETHERNET CONNECTORS, NO ETHERNET FUNCTIONALITY IS SUPPORTED AT THIS TIME.***

#### **4.3.6.1 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.

#### **4.3.6.2 BIOS**

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

#### **4.3.6.3 DiskOnChip®**

M-Systems DiskOnChip® 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).

#### **4.3.6.4 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 iVent™201 uses com 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, OR A PDA SYNC UTILITY (OR ANOTHER VERSAMED APPLICATION).**

#### 4.3.6.5 Display Driver

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.

#### 4.3.6.6 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.

#### 4.3.6.7 Ethernet

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

#### 4.3.6.8 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 IS 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 RE-CERTIFIED.**

### 4.3.6.9 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.

### 4.3.7 Main Board

The main board performs all of the ventilator specific control functions on the device. 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

#### 4.3.7.1 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

##### 4.3.7.1.1 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).

#### 4.3.7.1.2 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.

#### 4.3.7.1.3 Oxygen Sensor

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

#### 4.3.7.1.4 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.**

#### 4.3.7.1.5 Battery Voltage

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

### 4.3.7.2 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.

### **4.3.7.3 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.

### **4.3.7.4 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.

### **4.3.7.5 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.

### **4.3.7.6 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.

#### **4.3.7.7 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.

#### **4.3.7.8 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.

#### **4.3.7.9 Remote Alarm**

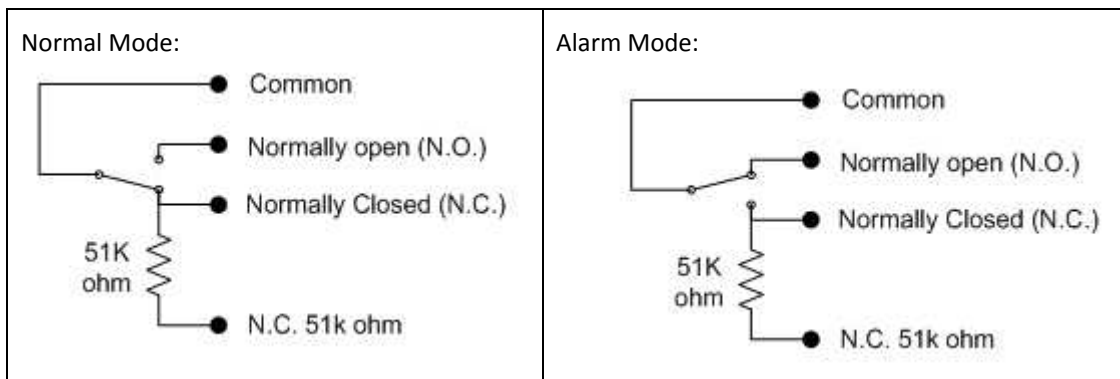
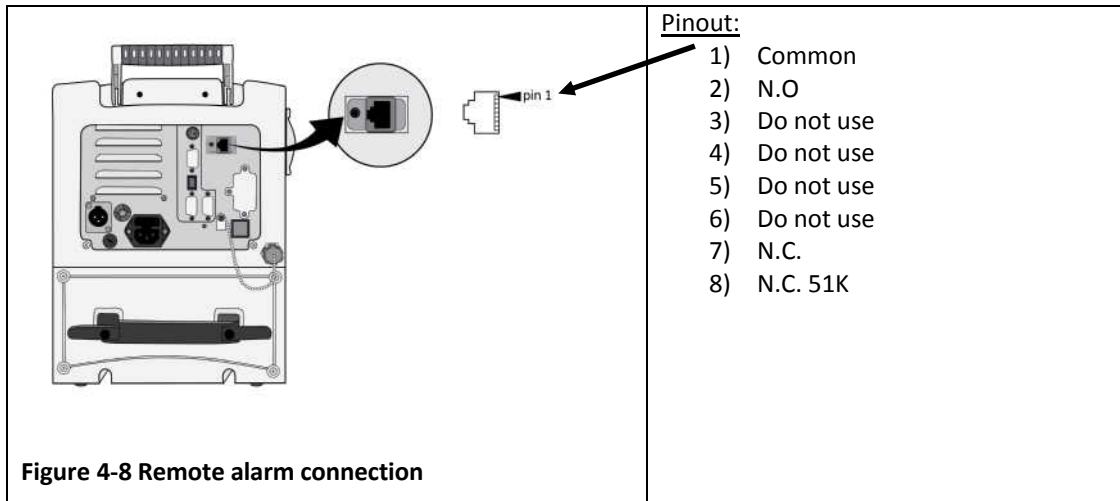
The remote alarm output provides a means of sending the ventilator alarm signal to a remotely located central nurse call station or remote alarm.

The iVent™201 has a female 8 pin RJ45 modular remote alarm connector. The connector must be used with a VersaMed supplied cable of the desired output type.

The following output types are available for remote alarm:

- N.O. - Normally Open Relay Output, switch closure upon alarm.
- N.C. - Normally Closed Relay Output, switch opened upon alarm.
- N.C.51K - Normally Closed Relay Output with 51kOhm resistor in series, switch opens upon alarm.

##### **4.3.7.9.1 Remote Alarm Pinout**



The remote alarm connector provides access to a relay that is normally activated, but deactivates when an alarm status occurs, or the main power is turned off.

In Normal mode, the “N.O.” contact to common is disconnected, while the “N.C.” contact to common is connected. The “N.C. 51K” is connected to common through a 51K ohm resistor required by some alarm systems.

In Alarm mode, the “N.O.” contact to common is connected, while the “N.C.” and “N.C. 51K” contacts to common are disconnected.

### 4.3.8 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.**

### 4.3.9 Hold/Nebulizer Controller PCB

The hold/nebulizer controller PCB, which piggy backs into the Main PCB, is responsible for control of the hold and nebulizer subsystems.

The PCB incorporates all of the hardware necessary to energize the hold solenoid and hold pump (mounted on the mounting PCB) as commanded by the operator by pressing the 'Hold' key on the keypad.

Additionally further hardware will be used to energize the Nebulizer solenoid (mounted on the mounting PCB) as commanded by the operator programming the nebulizer in the advanced settings menu.

### 4.3.10 Mounting PCB

The Mounting PCB, mounted on the side of the electronic unit, houses the pneumatic components needed to perform the hold and nebulizer functions.

The PCB houses the hold solenoid and hold pump, these components will be energized under the control of the Hold/Nebulizer controller PCB, when the operator selects either inspiratory or expiratory hold.

The PCB additionally houses the nebulizer solenoid; this component will be energized under the control of the Hold/Nebulizer controller PCB, when the operator programs the nebulizer in the advanced settings menu. The nebulizer solenoid will be energized in inspiration only.

### 4.3.11 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

### 4.3.11.1 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.

### 4.3.11.2 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.

### 4.3.11.3 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.

### 4.3.11.4 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.

### 4.3.11.5 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.

### 4.3.11.6 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).

### 4.3.11.7 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.

### 4.3.11.8 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.

### 4.3.11.9 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.



### 4.3.11.10 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.

### 4.3.12 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.

#### 4.3.12.1 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.

## 4.4 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 re-securing this connector.

## 4.5 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.

# Section 5: Maintenance Menu

## 5.1 Introduction

The maintenance menu consists of a series of screen options and tests which allow the technician to configure, to test and to calibrate certain attributes on the iVent™201.

## 5.2 Accessing the Maintenance Menu

To access the maintenance menu open the main menu window and select the last of the options 'Maintenance'. On selecting 'Maintenance' a confirmation window will be displayed on the device.



Main Menu



Confirmation Screen

Figure 5-1 Main Menu and Confirmation Screens

**CAUTION:** *THE MAINTENANCE MENU SHOULD ONLY BE ENTERED BY THERAPISTS, TRAINED SERVICE PERSONNEL OR ON INSTRUCTION BY TRAINED SERVICE PERSONNEL. IF YOU DO NOT FALL INTO EITHER OF THESE CATEGORIES DO NOT PROCEED ANY FURTHER.*

To proceed to the maintenance menu select 'Yes' and the full list of maintenance options will be accessible. If 'No' is selected the device will revert to the main display window.

## 5.3 Maintenance Menu

The maintenance menu allows the service technician or therapist to access a series of screens which may be used to configure, calibrate, test and update the device. A full description of each function is provided in the following sections. To access each area use the rotary control knob to highlight and select the desired area.



Figure 5-2 Maintenance Menu Screen

## 5.4 Calibration Screen

By using the calibration screen the trained service technician can perform a range of calibration procedures on the device as may be required periodically and after repair. A complete description of the calibration functions is provided in Section 7: of this manual.

## 5.5 Ventilator Verification Test

Ventilator verification Test (VVT) is a set of ventilator self-tests structured to sequentially check the ventilators operational functionality. A complete description of the ventilator verification test is provided in Section 6: of this manual.

## 5.6 Configuration Screen

The configuration menu allows service technician or therapist to verify certain attributes of the devices configuration and to alter some attributes as may be required by the users.

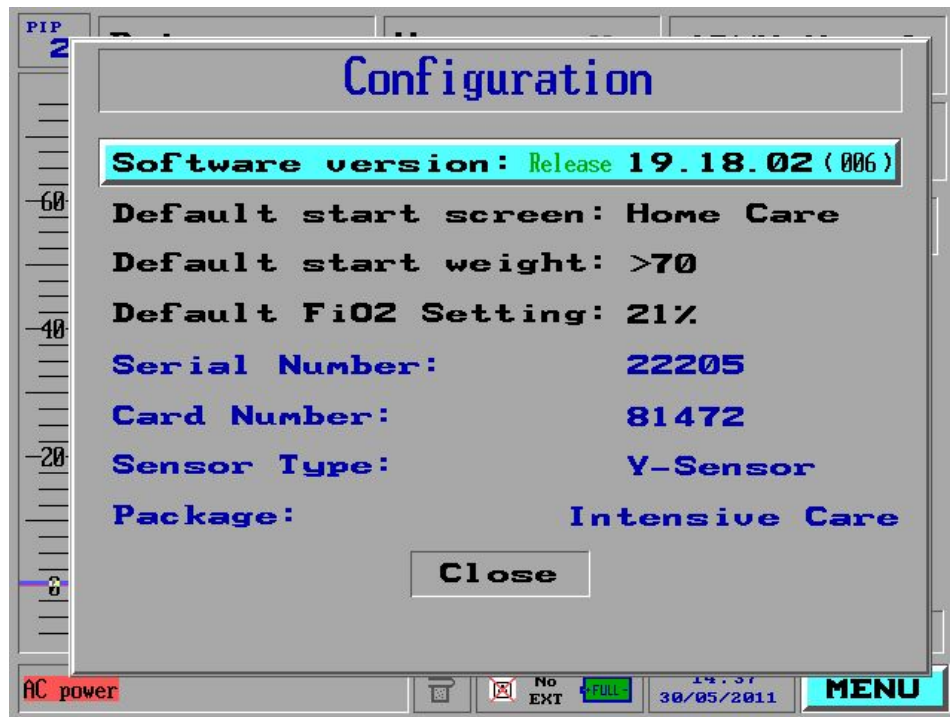


Figure 5-3 Configuration Screen

### 5.6.1 Software Version

Software version allows the current installed software version to be verified. By selecting the software version using the rotary control knob an additional screen will appear displaying 'Version Flag' and 'Version Code'.

### 5.6.2 Default Start Screen

Default start screen allows the service technician or therapist to configure which display screen type will be active each time the device is powered on. The options available are 'Main', 'Monitoring' and 'Homecare'. Please refer to the user manual for a full description on the utility of each screen type.

To change the default start screen:

1. Using the rotary control knob select 'Default Start Screen' on the configuration screen, highlight and then press to confirm.

2. A pop up window will appear showing a range of choices; Main, Monitoring and Homecare. Highlight the desired setting and then press to confirm.

On confirmation the configuration menu will return with the new selection for start screen displayed. On next restart of the ventilator the selected screen type will be displayed.

**NOTE: *DEPENDING ON THE DEVICES CONFIGURATION AND PACKAGE SET UP NOT ALL SCREEN TYPES WILL BE AVAILABLE FOR SELECTION.***

### 5.6.3 Default Start Weight

Default start weight allows the service technician or therapist to configure the patient weight range which will be used as default on start up.

To change the default weight:

1. Using the rotary control knob select 'Default Start Weight' on the configuration screen, highlight and then press to confirm.
2. A pop up window will appear showing a range of choices from 10 to >70kg as well as 'Last'. Highlight the desired setting and then press to confirm.

On confirmation the configuration menu will return with the new selection for start weight displayed.

### 5.6.4 Default FIO2 Setting

Default FiO2 allows the service technician or therapist to configure the FiO2 setting which will be used by default each time the device is switched on.

To change the default FiO2:

1. Using the rotary control knob select 'Default FiO2' on the configuration screen, highlight and then press to confirm.
2. A pop up window will appear showing a range of choices from 21%, 40%, 60% and 100%. Highlight the desired setting and then press to confirm.

On confirmation the configuration menu will return with the new selection for default FiO2 displayed.

### 5.6.5 Serial Number

Serial number allows the service technician of therapist to confirm the device serial number which is programmed to its disk on chip.

### **5.6.6 Card Number**

Card number allows the service technician or therapist to confirm the serial number of the devices electronic unit without the need for opening the device. The card number cannot be adjusted and will only change on replacement of the electronic unit.

### **5.6.7 Sensor Type**

Sensor type allows the service technician or therapist to confirm the type of proximal flow sensor which the device is configured to work with. All device types for which this manual is applicable use the 'Wye' sensor type.

### **5.6.8 Package Type**

Package type allows the service technician or therapist to confirm the feature package enabled on the device. The feature package is defined by the package key which entered on the device (see service screen package update). The package type can only be adjusted by entry of another relevant package key. Should you wish to change the package type on your device please contact your local VersaMed sales and service representative.

## 5.7 Service Screen

The service screen allows the service technician access to two areas which may be used to update the device. To access the service screen use the rotary control knob to select 'service screen' and then press to confirm. The service screen will then be displayed as shown below.

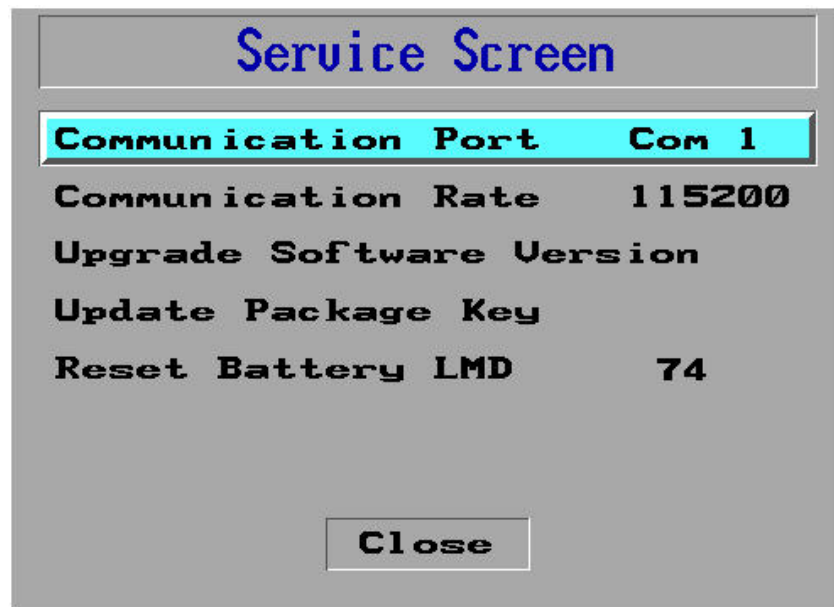


Figure 5-4 Service Screen

### 5.7.1 Communication Port

Communication port allows the service operator to define which of the available Com ports will be used for service applications and general RS232 communications.

### 5.7.2 Communication Rate

Communication Rate may be used by the service technician or therapist to adjust the communication or 'Baud' rate for whichever RS232 Com port has been defined above. The communication rate may be adjusted as needed to allow the ventilator to be connected to external monitoring or other systems.

To adjust the communication rate:

1. Using the rotary control knob select 'Communication Rate' on the service screen, highlight and then press to confirm.



2. A pop up window will appear showing a range of communication rates (1200, 2400, 4800, 9600, 19200, 38400, 57600 and 115200). Highlight the desired setting and then press to confirm.

**Note:** For optimal performance when using the device with VersaMed software utilities it is recommended that the communication rate be set to 115200.

### 5.7.3 Update Software Version

Update software version allows the service technician to place the ventilator in a ready state waiting to receive a new version from a host device. The software update procedure will be covered in full in Section 10: of this manual.

### 5.7.4 Update Package Key

Update package key may be used by the service technician to update the devices current operating configuration. The iVent™201 ventilator contains all of the software which may be needed to run under any configuration so long as the relevant hardware is present.

By manually entering a key code that is unique to each unit, different ventilator features can be enabled or disabled. The package key is provided by VersaMed Technical / Customer support services only. Activation of some features may require special permission since it may effect clinical safety or have local regulatory implications.

To update the devices package key:

1. Contact VersaMed technical/customer support in order to receive the package key appropriate to the required configuration.
2. From the main service screen select the 'Update Package Key' and then press to confirm.
3. The package key screen will now be displayed, as shown below, and will display the devices existing package key. The characters are presented in groups of four, separated by hyphens and are limited to hexadecimal format.

**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 IN SOME CASES IT MAY REQUIRE AS FEW AS ONE CHANGE.*



**Figure 5-5 Package Key Update Screen**

4. Using the rotary control knob scroll through the characters until the first requiring adjustment is highlighted.
5. Press the control knob to select the character and then scroll through until the desired character is displayed. Press the control knob again to confirm the change.
6. Repeat this process for all characters requiring adjustment.
7. When all characters are correct using the rotary control knob highlight 'ok' and press to confirm.
8. A system message will be displayed confirming that 'the package was successfully installed. Restart the iVent for Update'.
9. On completion of the restart it is recommended that you re-enter the update package key screen to verify that the key is correctly entered.

### 5.7.5 Reset Battery LMD

Reset Battery LMD allows the service operator view the last measured discharge of the integrated battery. The number displayed is a representation of the amp hour capacity which was available the last time that the battery was fully discharged. Each LMD unit corresponds with 72.7 mAh of capacity.

In the event that the LMD value drops below 50 (standard or extended battery), the device will respond with a service notice with the message 'battery disconnected or damaged' displayed on screen. Should this happen you need to reset the battery LMD.

To reset the battery LMD:

1. Select 'Reset Battery LMD' using the rotary control knob.
2. On selecting 'Reset Battery LMD' a window will appear (Figure 5-6) allowing the service operator to define whether it is a standard or an extended battery, select as appropriate.



Figure 5-6 Battery type selection

3. On selection of the battery type a final window will appear for confirmation of whether to proceed with the reset, select 'Yes' to proceed or 'No' to return to the battery type window.



Figure 5-7 Confirmation window

4. Selecting 'Yes' will reset the battery LMD to a known value, 66 in the case of the standard battery.
5. On completion of the reset procedure it is necessary to place the device through the battery gas gauge calibration procedure (as defined in iVent™201 service manual). This comprises of a full charge, discharge and recharge of the internal battery. Should the service notice mentioned above persist after completion of these steps it is necessary to replace the battery cell and repeat the process.

## 5.8 Technical Log Book

Allows the service technician or therapist to review any service related events which may have occurred during the current ventilation session. Beginning each time the ventilator is powered up; any time a technical or service related event occurs an entry will be noted in the technical error log.

Up to 300 error events for the current session may be viewed through this screen. Up to 1500 events made up of current and previous sessions are retained in memory and accessible using proprietary software.

Using the rotary control knob, highlight and confirm technical log book and the screen below will be displayed. The errors are date and time stamped and listed in chronological order with most recent at the bottom.



Figure 5-8 Technical Error Log Screen.

## 5.9 Localization

Localization may be used by the service technician or therapist to adjust regional attributes on the device; such as date, time and language. On entering the localisation menu a warning pop up window will be displayed.

The pop window warns that changing the current language will RESTART the device, and requires confirmation by highlighting and selecting 'Yes' in order to proceed.

## 5.9.1 Language

Language allows the service technician or therapist to adjust the ventilator's language set as per regional requirements.

To change the device language:

1. Using the rotary control knob on the localization screen highlight 'language' and then press to confirm.
2. A pop up window will appear listing the available languages (as shown in the diagram below); highlight the desired language and then press to confirm.



Figure 5-9 Localization Screen

## 5.9.2 Date / Interfield Format

Date and Interfield format are two individual selections which allow the service technician or therapist to configure how the date will be displayed on screen and in the event log.

To adjust the date format may be as follows:

1. Using the rotary control knob on the localization screen highlight 'Date Format' and then press to confirm.

2. A pop up window will appear listing the available formats; DMY, MDY, YMD. Highlight the desired format and then press to confirm.

To adjust the date interfield character may be as follows:

1. Using the rotary control knob on the localization screen highlight 'Date Interfield Character' and then press to confirm.
2. A pop up window will appear listing the available characters; '/', ':' and '.'. Highlight the desired character and then press to confirm.

## 5.10 Total Operation Hours

Lastly the maintenance screen allows the service technician or therapist to confirm the total number of hours (stand-by and ventilation time) that the ventilator has been in use.

## Section 6: Self-Tests

### 6.1 Introduction

This section of the service manual provides an overview of the two levels of self-tests available on the iVent™201. A self-test trouble shooting section is also provided to assist diagnosis of any self-test failures.

### 6.2 Operator Verification Test

The Operator Verification Test, referred to from this point onwards as O.V.T., is an automated test designed to check the connections of the patient tubing system to the ventilator. Additionally O.V.T. checks the function of the one-way valve included in the inspiratory tubing limb, and the function of the main audible alarm.

#### 6.2.1 O.V.T. Requirements

O.V.T. requires the use of a complete VersaMed tubing system in any of the available configurations. Additionally O.V.T. requires the use of two 22mm circuit caps to block the circuit ports.

#### 6.2.2 Accessing O.V.T.

O.V.T. may be accessed from the 'Stand-By' screen or from the main menu

**NOTE:** *O.V.T. CANNOT BE INITIATED IF VENTILATION IS IN PROGRESS. IF YOU ATTEMPT TO INITIATE O.V.T. DURING VENTILATION THE DEVICE WILL DISPLAY A WARNING MESSAGE AS FOLLOWS; 'THIS MAINTENANCE OPTION CAN ONLY BE ACCESSED IN THE STAND-BY MODE.'*

#### 6.2.3 O.V.T. Procedure:

1. Using the rotary control knob highlight O.V.T. (from either stand-by screen or main menu) and then press to confirm.
2. On initiating O.V.T. the device will display a window labeled 'O.V.T. Instructions'.
3. Follow the on screen instructions (Fig 6.1) and apply 22mm circuit caps to the patient wye sensor and the exhalation valve port.

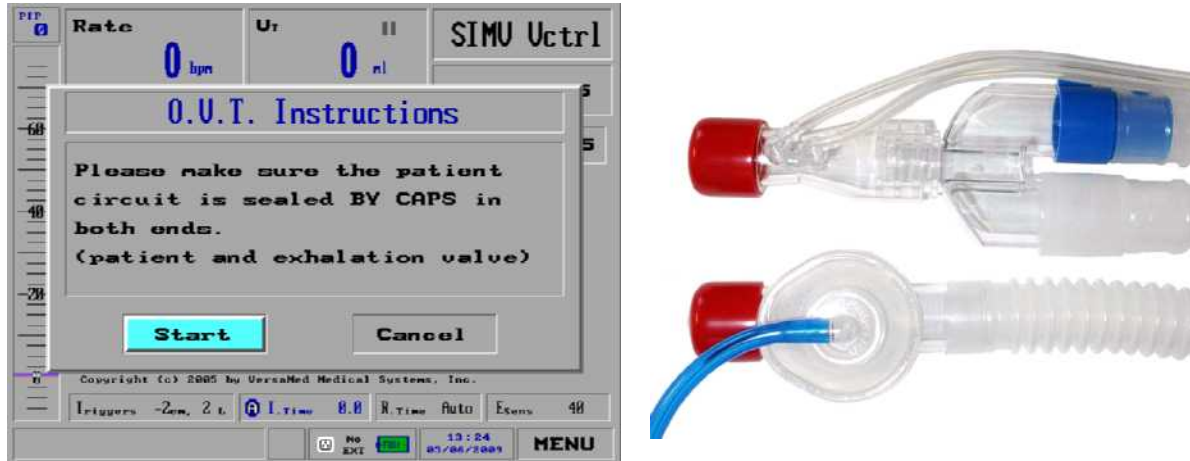


Figure 6-1 O.V.T. part one

4. With the circuit caps applied select 'Start' using the rotary control knob to initiate the test.
5. On initiation the device will pressurize the system to approximately 80cmH<sub>2</sub>O and initiate the various checks.
6. On successful completion of the first stage of O.V.T. a window will appear (Fig 6.2) prompting the operator to remove the circuit cap from the exhalation valve.

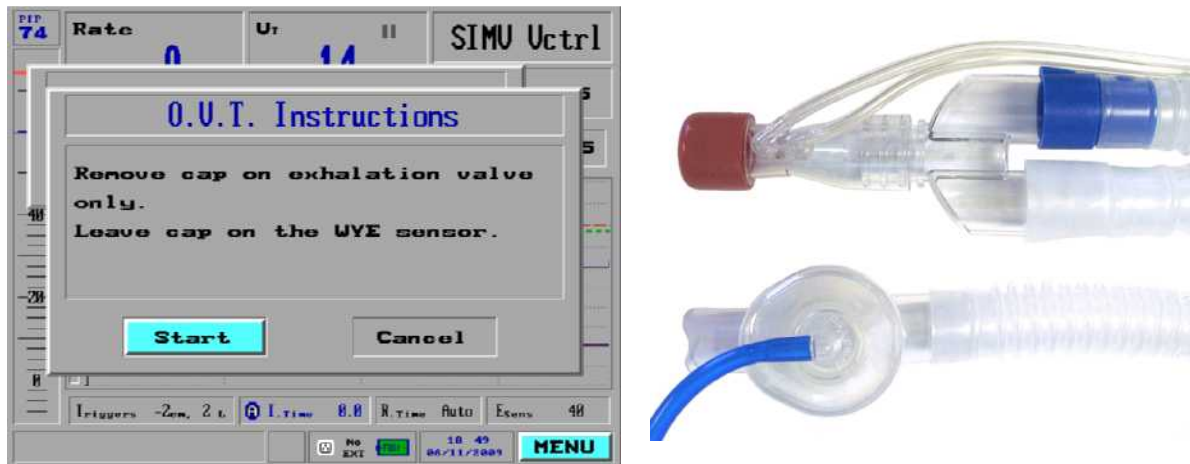


Figure 6-2 O.V.T part two

7. With the cap removed from the exhalation valve select 'Start' using the rotary control knob to proceed.
8. The device will briefly pressurise the system once again and initiate various checks.



9. On successful completion the device will initiate an audible high priority alarm. The operator is prompted to confirm whether the alarm is audible.

**NOTE: IF THE VENTILATOR IS FOUND TO FAIL O.V.T., VERIFY THAT THE CIRCUIT CAPS HAVE BEEN SECURELY PLACED, AND THAT ALL PATIENT TUBING IS SECURELY CONNECTED.**

**NOTE: IF THE VENTILATOR IS FOUND TO FAIL O.V.T. REPEATEDLY PLEASE REFER TO THE SELF TEST TROUBLESHOOTING SECTION 6.5.1, PAGE 106 OF THIS MANUAL.**

### 6.2.4 O.V.T. Technical Description

During the first part of O.V.T., with wye and exhalation valve blocked, the device will firstly perform a zero of the pressure transducers. With a successful zero the turbine motor will be energized with a PWM (pulse width modulated) signal of 120 in order to pressurize the system.

During this first part of O.V.T. the device will check for the following criteria:

- The pressure measurements must be greater than the predefined limit (>60cmH<sub>2</sub>O on AC power, >50cmH<sub>2</sub>O on battery power).
- The measurements for patient pressure and turbine pressure must be within 1.5cmH<sub>2</sub>O of each other.
- The measured flow must be less than 30lpm.

If any of these test criteria are not met then the device will declare a failure of O.V.T. and the test will terminate.

On completion of this first stage the device will test for the presence and correct operation of the one way valve in the patient tubing system. The device will energize Solenoid 1 and Solenoid 2 to relieve the internal pressure. After 200ms the device will check the pressure transducers against the following criteria:

- The turbine pressure should have dropped to a value <20cmH<sub>2</sub>O.
- The turbine pressure should have dropped relative to patient pressure. Patient pressure must be at least 10cmH<sub>2</sub>O greater than turbine pressure.

If any of these test criteria are not met then the device will declare a failure of O.V.T. and the test will terminate.

At the start of the second stage of O.V.T. the operator will be instructed to remove the cap from the exhalation valve and confirm. On confirmation the turbine motor will be energized with a PWM signal of 120 in order to pressurize the system.

The device will energize Solenoid 1 and Solenoid 2 to relieve the internal pressure. After 2ms the device will check the pressure transducers against the following criteria:

- The turbine pressure should be greater than 70cmH<sub>2</sub>O.
- The difference between turbine pressure and patient pressure should be no greater than 8cmH<sub>2</sub>O.

If any of these test criteria are not met then the device will declare a failure of O.V.T. and the test will terminate.

During the final part of O.V.T the device will perform a check of its main audible alarm speaker. The device will initiate a high priority alarm and await user confirmation that the alarm is audible.

**NOTE: IF THE VENTILATOR IS FOUND TO FAIL O.V.T. REPEATEDLY PLEASE REFER TO THE SELF TEST TROUBLESHOOTING SECTION 6.5.1, PAGE 106 OF THIS MANUAL.**

## 6.3 Ventilator Verification Test

The Ventilator Verification Test, referred to from this point onwards as V.V.T., is a semi-automated test which the service technician or therapist may perform to check for correct function of the device.

The test does require operator intervention at certain points throughout, for application/removal of circuit caps, and connection/disconnection of various items. In each case follow the on screen instructions and then confirm using the rotary control knob.

The V.V.T. will check the following area of ventilator function:

- Audible Alarms (Main and Back Up)
- Pressure (Performance, Turbine, Patient, Flow)
- Motor Speed Measurement
- Positive Relief Valves
- Solenoids (Sol1, Sol2, Safety Solenoid)
- Flow Performance
- Flow Zeroing
- O2 System 21% (FiO2, Pressure Switch)
- O2 System 100% (O2 Valve, FiO2, Pressure Switch)
- Battery Status
- Motor Watchdog Safety Device
- CPU Watchdog Safety Device

**NOTE: *IT IS GENERALLY RECOMMENDED THAT THE DEVICE BE ALLOWED TO RUN FOR A PERIOD OF TIME, AT LEAST 15 MINUTES, PRIOR TO RUNNING V.V.T. THIS TIME IS RECOMMENDED TO ALLOW THE DEVICE TO REACH A NORMAL OPERATIONAL TEMPERATURE.***

### 6.3.1 V.V.T. Requirements

To complete V.V.T. fully the following equipment will be required:

- Full Ventilator Tubing System.
- 1 x 22mm Patient Circuit Cap
- High Pressure O2 Supply (40-60psi)
- O2 High Pressure Hose Assembly

### 6.3.2 Accessing V.V.T.

V.V.T. may be accessed through the maintenance menu which is accessible from the main menu (covered in Section 5.2, page 79, of this manual).

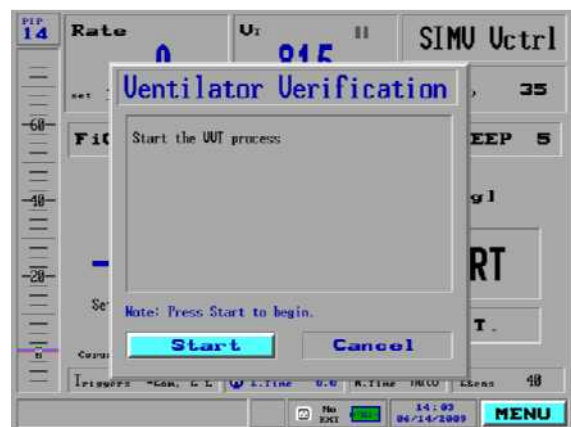
**NOTE: V.V.T. CANNOT BE INITIATED IF VENTILATION IS IN PROGRESS. IF YOU ATTEMPT TO INITIATE V.V.T. DURING VENTILATION THE DEVICE WILL DISPLAY A WARNING MESSAGE AS FOLLOWS; 'THIS MAINTENANCE OPTION CAN ONLY BE ACCESSED IN THE STAND-BY MODE.'**

### 6.4 V.V.T. Procedure:

1. Using the rotary control knob highlight Ventilator Verification Test on the maintenance menu screen, and press to confirm.
2. On initiating the V.V.T. the device will display a window labeled 'V.V.T. Instructions'. Using the rotary control knob highlight and confirm 'Start' in order to initiate the test.



Maintenance Window



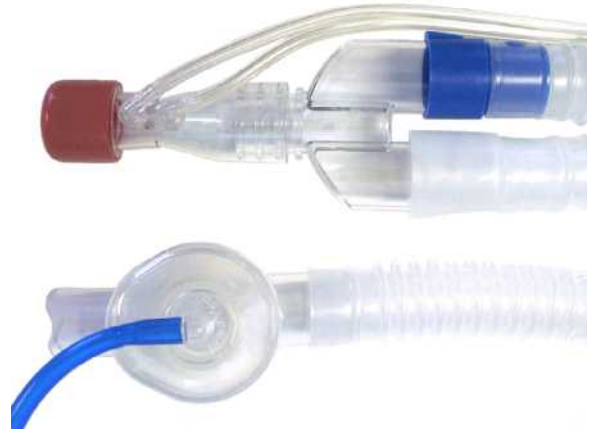
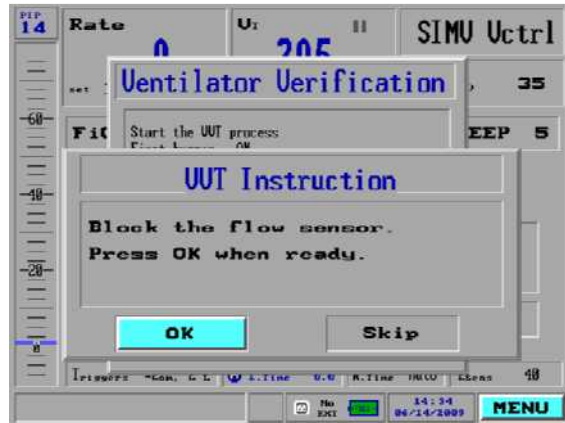
Ventilator Verification

Figure 6-3 Initiating V.V.T.

3. On initiating V.V.T. the device will sound the main audible alarm speaker in a continuous tone.
4. As prompted on screen select and confirm 'Continue' if the alarm is audible, or failed if not.

**NOTE: THE VOLUME OF THE ALARM WHICH IS SOUNDED IN THIS TEST IS DEPENDANT UPON THE CURRENT SETTING IN THE ALARM SETTINGS/OPTIONS MENU. THE DEFAULT VALUE FOR THIS SETTING IS 8.**

5. On selecting 'Continue' the test will proceed and the device will sound the backup alarm in a continuous tone.
6. As prompted on screen select and confirm 'Continue' if the alarm is audible, or failed if not.
7. On selecting 'Continue' the test will proceed and the V.V.T. instruction window (as shown in Fig 6.3) will be displayed.



**Figure 6-4 Pressure Tests**

8. Follow the on screen instructions (Fig 6.3) and apply the 22mm circuit cap to the patient wye sensor.
9. With the circuit cap applied select 'OK' using the rotary control knob to initiate the test.
10. On initiation the device will pressurize the system and run through a sequence of tests which will last approximately 30 seconds. As the device proceeds through each step it will display an 'OK' or 'Failed' flag next to it (Fig 6.4). The results items will continue to accumulate throughout the remainder of the test.

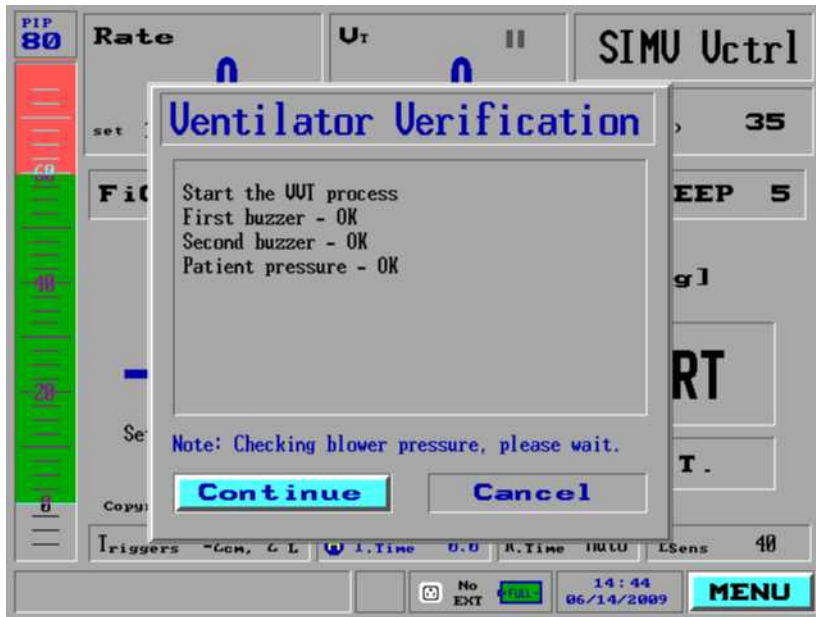


Figure 6-5 Pressure Test Results

**TIP:** *IF A CALIBRATION MANOMETER (SEE PRESSURE CALIBRATION, SECTION 7.6.2, PAGE 115) IS AVAILABLE USE THIS TO CAP THE PATIENT WYE SENSOR DURING THE PRESSURE TESTS. DURING THE TESTS YOU CAN USE MANOMETER TO COMPARE ITS READING AGAINST THE PRESSURE BAR GRAPH READING ON THE DEVICE. IF THE TWO READINGS ARE FOUND TO DIFFER BY GREATER THAN 3CMH2O THEN PRESSURE SENSOR CALIBRATION IS ADVISABLE.*

11. On completion of the pressure based tests the V.V.T. instruction window will be displayed once more.

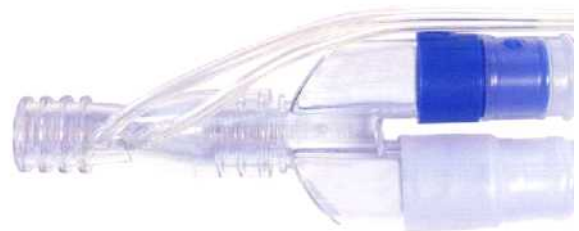
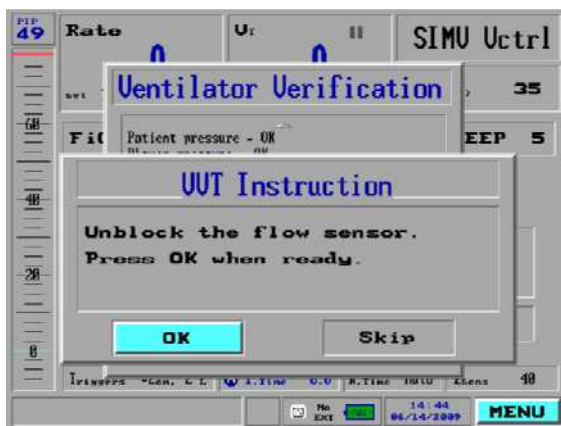


Figure 6-6 Flow Tests

12. Follow the on screen instructions (Fig 6.5) and remove the 22mm circuit cap from the patient wye sensor.
13. With the circuit cap removed select 'OK' using the rotary control knob to proceed to the next test.
14. The device will next initiate a short series of flow tests which will last approximately 6 seconds, after which the V.V.T. instruction window will be displayed.

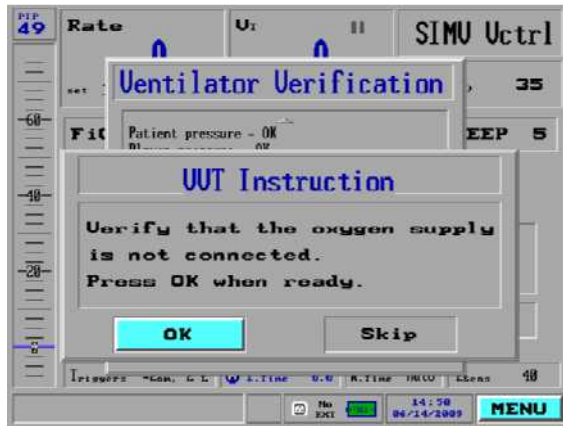


Figure 6-7 O2 Tests (21%)

15. Follow the on screen instructions (Figure 6-7) and verify that high pressure oxygen is not connected to the device.
16. On completion select 'OK' using the rotary control knob to proceed to the next test.
17. The device will next initiate a series of tests on the O2 system at 21% Oxygen which will last approximately 1 minute. During this section of the V.V.T. the device will check the blending system and pressure switch. On completion the V.V.T. instruction window will be displayed.



Figure 6-8 O2 Tests (100%)

18. Follow the on screen instructions (Figure 6-8) and connect a high pressure oxygen supply to the device.
19. On completion select 'OK' using the rotary control knob to proceed to the next test.
20. The device will next initiate a series of tests on the O2 system at 100% Oxygen which will last approximately 2 minutes. During this section of the V.V.T. the device will check the blending system and pressure switch. On completion the V.V.T. instruction window will be displayed.



**Figure 6-9 Disconnect AC Power**

21. Follow the on screen instructions (Figure 6-9) and disconnect the AC power cord from the device. Verify that the amber 'charge' LED on the front panel is no longer illuminated and that the AC plug icon on the display is crossed out.
22. You may also disconnect high pressure oxygen once more as it is no longer required.
23. On completion select 'OK' using the rotary control knob to proceed to the next test.
24. The device will now perform a test on the internal power pack which will last approximately 20 seconds. On completion the V.V.T. instruction window will be displayed.
25. Follow the on screen instructions (Figure 6-9) and reconnect the AC power cord to the device.
26. On completion select 'OK' using the rotary control knob and a further V.V.T. instruction window will be displayed.



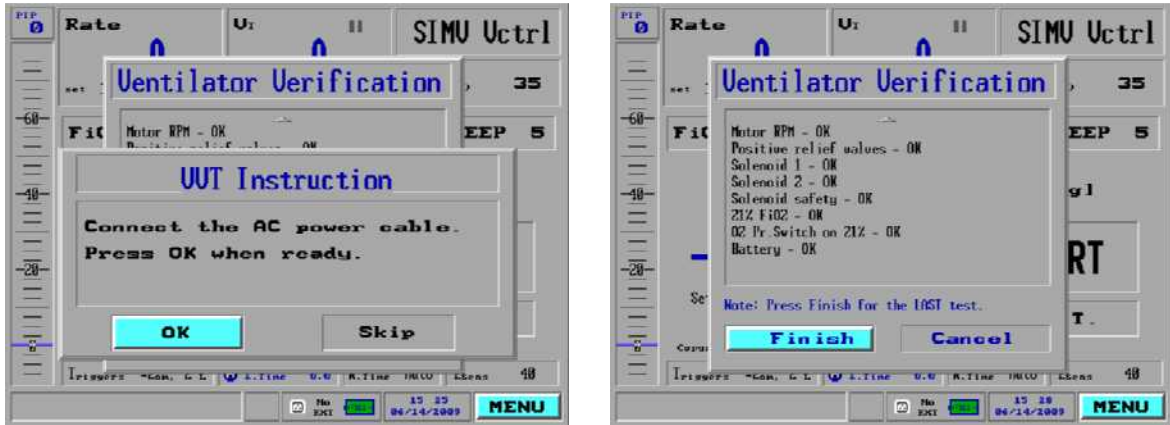


Figure 6-10 AC Reconnect / Watchdog Test

27. Follow the on screen instructions and select and confirm 'Finish' to proceed with the watchdog tests.
28. The device will now perform a series of tests on the device's watchdog system lasting approximately 1 minute, and during which the device will automatically power off and back on once more.
29. When the device has completed powering back on, a system message will appear confirm the completion and the pass or fail status of the V.V.T.



VVT Passed

VVT Failed

Figure 6-11 VVT Test Results

30. On completion of V.V.T. select and confirm 'OK' and the device will return to the weight selection window.

**NOTE:** *IN THE EVENT THAT THE DEVICE DOES NOT PASS V.V.T. VERIFY THAT ALL PATIENT TUBING IS SECURELY CONNECTED AND THEN RE-RUN V.V.T. WHILE RE-RUNNING V.V.T. PAY CLOSE ATTENTION TO THE INDIVIDUAL TEST RESULTS IN ORDER TO DETERMINE WHICH OF THE TESTS, OR NUMBER OF TESTS, MAY HAVE CAUSED THE OVERALL FAILURE. WITH THIS INFORMATION REFER TO SELF TEST TROUBLESHOOTING (SECTION 6.5, PAGE 106).*

**NOTE:** *IN THE EVENT THAT THE DEVICE DOES NOT PASS V.V.T., ALTHOUGH NOT RECOMMENDED, IT WILL STILL BE POSSIBLE TO VENTILATE. IN CASES WHERE THE DEVICE IS BEING USED IN SPITE OF A V.V.T. FAILURE A V.V.T. WARNING MESSAGE WILL BE DISPLAYED AT ALL TIMES UNTIL V.V.T. IS COMPLETED SUCCESSFULLY.*

## 6.4.1 V.V.T. Technical Description

### 6.4.1.1 Audible Alarm Tests

During the first part of V.V.T. the device will perform a verification of the device's audible alarm operation with operator feedback determining the pass or fail status.

Firstly the device main audible alarm speaker will be sounded in continuous tone and the operator will be asked to confirm that it is audible. The volume of the alarm during this test will be determined by the current setting on the 'Alarm Settings/Options' menu.

Next the device back up alarm (PC Speaker) will be sounded in a continuous tone and the operator will be asked to confirm that it is audible.

### 6.4.1.2 Pressure Tests

The pressure tests will perform a functional check on each of the devices pressure transducers and associated measurement circuits. At the initiation of the pressure tests the operator will be prompted to block the patient wye sensor using a 22mm circuit cap (or test manometer for verification purposes).

Upon the tester confirmation the patient wye has been capped, the turbine motor will be energized with a PWM (pulse width modulated) signal of 127 in order to pressurize the system.

The patient pressure transducer will be monitored over a period of 5 seconds and its mean pressure will be calculated. The device will check for the following criteria:

- Mean patient pressure must be within the range  $>60\text{cmH}_2\text{O}$  and  $<100\text{cmH}_2\text{O}$ . If the pressure falls outside of this range 'Fail' will be recorded.

The turbine pressure transducer will be monitored over a period 2 seconds and its mean pressure will be calculated. The device will check for the following criteria:

- Mean turbine pressure must be within the range  $>60\text{cmH}_2\text{O}$  and  $<100\text{cmH}_2\text{O}$ . If the pressure falls outside of this range 'Fail' will be recorded.

The flow sensor leak test will check for leakage from the proximal measurement system by verifying that the output of the flow transducer (DCXL) remains at or close to 0.

During this test the device will firstly perform a zero cycle on the flow transducer and then pause for 2 seconds. The flow transducer will then be sampled every 5 milliseconds over a period of approximately 0.4 seconds and its mean pressure reading will be calculated. The device will check for the following criteria:

- The mean flow transducer reading must be within the range  $>-20\text{lpm}$  and  $<20\text{lpm}$ . If the reading falls outside of this range 'Fail' will be recorded.

### 6.4.1.3 Solenoid System Tests

The solenoid system tests will check that the 2 solenoids within the pneumatic system operate in the correct way in a number of operational scenarios. The first test checks that the mechanical over pressure relief characteristic of the 2 solenoids is correct.

The system will remain pressurized with turbine motor being driven with a P.W.M. of 127. The patient pressure transducer will be monitored over a period of 2 seconds and the mean pressure will be calculated. The device will check for the following criteria:

- Mean patient pressure must be less than  $100\text{cmH}_2\text{O}$ . If the pressure is greater 'Fail' will be recorded.

The next test will check for correct operation of solenoid 1. With both solenoids closed the device will monitor and calculate the mean turbine pressure over a period of 2 seconds.

The device will next open (energize) solenoid 1 in order to open its bypass path and will monitor the turbine pressure while checking for the following criteria:

- Turbine pressure with solenoid 1 open must be less than half the mean turbine pressure recorded with both valves closed. If the pressure falls outside of this range 'Fail' will be recorded.

The next test will check for correct operation of solenoid 2. The device will next open (energize) solenoid 2 in order to open its bypass path and will monitor the turbine pressure while checking for the following criteria:

- Turbine pressure with solenoid 2 open must be less than half the mean turbine pressure recorded with both valves closed. If the pressure falls outside of this range 'Fail' will be recorded.

The last solenoid test checks the solenoid safety system. Initially both of the solenoid valves will be closed and patient pressure will be sampled. The solenoid valves will be opened and patient pressure will be sampled once more. The two measurements will be compared to ensure that the pressure when open is less than the pressure when closed by an appropriate amount.

#### **6.4.1.4 Flow Tests**

The flow tests will check for adequate flow performance from the devices turbine and will perform a zeroing of the flow measurement system.

During the flow performance test the devices turbine motor will be driven with a P.W.M. control signal of 127. After a period of 4 seconds the flow derived from the differential pressure transducer will be sampled and the following criteria checked:

- The measured flow must be > 1.770 l/s (106.2 lpm). If the flow falls outside of this range 'Fail' will be recorded.

The next test will attempt to perform a zero of the devices flow measurement system. The 2 zeroing solenoids, located on the Purge/Zero PCB, will be energized connecting both ports of the differential pressure transducer to ambient pressure. After 2 seconds the flow will be measured.

#### **6.4.1.5 Oxygen Tests at 21%**

The oxygen tests at 21% will be performed using gas flow from the ambient air inlet. The tests will check the performance at 21%, check the O2 sensor at the 21% setting and check the function of the pressure switch in the open condition.

The device will initially attempt to evacuate the high pressure O2 system by opening the PSV and running the turbine. The pressure switch will be checked initially to ensure O2 has been disconnected. If the pressure switch is found to be closed still, the window shown in Figure 6-7 will be displayed once more prompting the user again to disconnect O2.

The device will now verify the ability to deliver flow through the ambient inlet. The turbine motor will be driven with a P.W.M. of 25 driving flow through the system. After 4 seconds the patient and flow transducers will be sampled and the following criteria checked:

- Measured patient pressure should be > 10cmH<sub>2</sub>O. If the pressure falls outside of this range 'Fail' will be recorded.
- Measured patient flow should be < 200lpm. If the flow is greater will be recorded.

To verify the O<sub>2</sub> sensor reading the sensor will be sampled over a 40 second period, 1 sample per second, and the following criteria checked:

- Mean O<sub>2</sub> sensor reading should be >18% and <25%. If the O<sub>2</sub> sensor falls outside of this range 'Fail' will be recorded.

Lastly the condition of the pressure switch will be checked once more. In the event that the pressure switch is in a closed condition the test will fail. If the pressure switch is in an open condition the test will pass.

#### **6.4.1.6 Oxygen Tests at 100%**

The oxygen tests at 100% will be performed using gas flow from the high pressure O<sub>2</sub> supply. The tests will check for leakage from the oxygen delivery valve (PSV or Demand Valve), check the performance at 100%, and check the O<sub>2</sub> sensor at the 100% setting and the function of the pressure switch in the closed condition.

The device will firstly perform a check for leakage of oxygen through the oxygen valve (PSV or Demand valve). With the O<sub>2</sub> valve closed the turbine motor will be run at a slow rate. After 40 seconds the O<sub>2</sub> sensor will be sampled and checked against the following criteria:

- O<sub>2</sub> sensor reading should be <23%. If the O<sub>2</sub> sensor falls outside of this range 'Fail' will be recorded indicating leakage through the valve.

The oxygen valve will next be opened and the turbine motor driven with a P.W.M. of 75 for a period of time before slowing under a P.W.M. of 25. After 40 seconds the O<sub>2</sub> sensor will be sampled and checked against the following criteria:

- O<sub>2</sub> sensor reading should be in the range >80% and <125%. If the O<sub>2</sub> sensor falls outside of this range 'Fail' will be recorded.

Lastly the condition of the pressure switch will be check once more. With the O<sub>2</sub> valve in a closed position the condition of the pressure switch will be checked. The O<sub>2</sub> valve will next be opened for a 5 second period during which the pressure switch will be monitored once more. In both conditions the pressure switch should remain closed.

### 6.4.1.7 Battery Test

The battery test will perform a very simple test on the devices internal power pack.

Once the user has confirmed disconnection of AC and External DC the device will check the power status to ensure this is correct. If it is not the user prompt will be repeated. The turbine motor will be cycled 6 times with a P.W.M. of 127; each cycle will be 2 seconds in duration, with a 1 second pause between cycles. On the sixth cycle the motors tachometer will be checked for the following criteria:

- Motor RPM measured by tachometer must be >17. If the RPM is less 'Fail' will be recorded.

### 6.4.1.8 Watchdog Tests

The watchdog tests will verify the function of both the motor watchdog circuit and the PC watchdog circuit.

During the motor watchdog test the turbine motor will be driven with a P.W.M. of 127. The motor watchdog circuit will be shut down and after 1 second the motors tachometer will be checked for the following criteria:

- Motor RPM measured by the tachometer must be =0. If the RPM falls outside of this range 'Fail' will be recorded.

The motor will next be re-enabled and the error handler activated. After a further 2 seconds the motors tachometer will be checked for the following criteria:

- Motor RPM measured by the tachometer must be >15. If the RPM falls outside of this range 'Fail' will be recorded.

During the PC watchdog test the PC watchdog will be shutdown initiating a warm restart on the ventilator system. The following criteria will be checked:

- The PC system should complete warm restart and recover within 4 seconds. If the system takes too long, then on completion of the warm restart the VVT Error window (see fig 6.10) will be displayed.

## 6.5 Troubleshooting Self-Tests

The following table is provided to assist in the troubleshooting of failures which may have occurred during O.V.T. and V.V.T.

### 6.5.1 OVT Tests

<i>Test Failed:</i>	<i>Description:</i>	<i>Troubleshooting Steps:</i>
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<b>Test Failed:</b>	<b>Description:</b>	<b>Troubleshooting Steps:</b>
OVT Test 1	Unable to create pressure	<ol style="list-style-type: none"> <li>1. Check patient tubing system to ensure no leakage.</li> <li>2. Check tubing system to ensure that the check valve is in place</li> <li>3. Perform VVT</li> <li>4. Perform pressure calibrations</li> </ol>
OVT Test 2	Unable to create pressure	<ol style="list-style-type: none"> <li>1. Check that the exhalation valve drive line is connected to the front panel.</li> <li>2. Check that the exhalation valve is correctly oriented.</li> <li>3. Examine the exhalation valve membrane, replace as necessary.</li> <li>4. Replace exhalation valve.</li> </ol>
Alarm Test	Alarm inaudible	<ol style="list-style-type: none"> <li>1. Adjust alarm volume to maximum and retest.</li> <li>2. Replace alarm speaker</li> </ol>

### 6.5.2 VVT Tests

<b>Test Failed:</b>	<b>Description:</b>	<b>Troubleshooting Steps:</b>
Main Alarm	Main alarm speaker is not audible.	<ol style="list-style-type: none"> <li>1. Adjust alarm volume to maximum &amp; retest.</li> <li>2. Replace alarm speaker.</li> </ol>
Back Up Alarm	Back up alarm is not audible.	<ol style="list-style-type: none"> <li>1. Repeat VVT.</li> <li>2. Verify connection of back up alarm cable between PC and Main PCB</li> </ol>
Patient Pressure	Patient pressure outside of specification - Low	<ol style="list-style-type: none"> <li>1. Check patient tubing system to ensure there is no leakage.</li> <li>2. Recalibrate and repeat VVT.</li> <li>3. Replace Main PCB.</li> </ol>

<b>Test Failed:</b>	<b>Description:</b>	<b>Troubleshooting Steps:</b>
	Patient pressure outside of specification - High	<ol style="list-style-type: none"> <li>1. Check function of over pressure valves, replace as necessary.</li> <li>2. Perform calibration procedures and repeat VVT.</li> <li>3. Replace Main PCB.</li> </ol>
Turbine Pressure	Turbine pressure outside of specification - Low	<ol style="list-style-type: none"> <li>1. Check patient tubing system to ensure there is no leakage.</li> <li>2. Perform calibration procedures and repeat VVT.</li> <li>3. Replace Main PCB</li> </ol>
	Turbine pressure outside of specification - High	<ol style="list-style-type: none"> <li>1. Check function of over pressure valves, replace as necessary.</li> <li>2. Perform calibration procedures and repeat VVT.</li> <li>3. Replace Main PCB.</li> </ol>
Flow Sensor Leak	Pressure offset seen at differential sensor	<ol style="list-style-type: none"> <li>1. Check connection of patient circuit with attention to the luer lines.</li> <li>2. Perform calibration procedures and repeat VVT.</li> <li>3. Check function of the one way valves, replace as necessary.</li> <li>4. Replace Purge/Zero PCB.</li> <li>5. Replace Main PCB.</li> </ol>
Solenoid Relief	System pressure too high	<ol style="list-style-type: none"> <li>1. Verify that the wirings are not interrupting the solenoid work.</li> <li>1. Check function of over pressure valves, replace as necessary.</li> <li>2. Perform calibration procedures and repeat VVT.</li> <li>3. Replace Main PCB.</li> </ol>
Solenoid 1	System pressure too high – valve not opening	<ol style="list-style-type: none"> <li>1. Check operation of solenoid 1.</li> <li>2. Run device for a period of time and</li> </ol>



<b>Test Failed:</b>	<b>Description:</b>	<b>Troubleshooting Steps:</b>
		then retest. 3. Replace Pneumatic Module. 4. Replace Main PCB.
Solenoid 2	System pressure too high – valve not opening	1. Check operation of solenoid 2. 2. Run device for a period of time and then retest. 3. Replace Pneumatic Module. 4. Replace Main PCB.
Solenoid Safety	System pressure too high – valve not opening	1. Check operation of solenoid 1. 2. Run device for a period of time and then retest. 3. Replace Pneumatic Module. 4. Replace Main PCB.
Flow Performance	Delivered flow is too low	1. Check connection of the patient tubing system, ensure luer lines are secure. 2. Perform calibration procedures and repeat VVT. 3. Replace Pneumatic Module. 4. Replace Main PCB.
Flow Sensor Zero	Unable to complete flow sensor zero	1. Check connection of the patient tubing system, ensure luer lines are secure. 2. Perform calibration procedures and repeat VVT. 3. Replace Purge/Zero PCB. 4. Replace the Main PCB.
O2 21%	Measured O2% out of specification	1. Verify that high pressure oxygen is not connected. 2. Perform oxygen system calibration and re-test.

<b>Test Failed:</b>	<b>Description:</b>	<b>Troubleshooting Steps:</b>
		3. Replace O2 sensor.
Pressure SW 21%	Pressure switch in closed position	1. Verify that high pressure oxygen is not connected. 2. Verify operation of the pressure switch, replace as necessary. 3. Replace Main PCB.
O2 Valve Leak	Measured O2% too high	1. Verify that high pressure oxygen is connected. 2. Perform oxygen system calibration and re-test. 3. Replace O2 sensor. 4. Replace O2 proportional valve.
O2 100%	Measured O2% out of specification	1. Verify that high pressure oxygen is connected. 2. Perform oxygen system calibration and re-test. 3. Replace O2 sensor. 4. Replace O2 proportional valve.
Pressure SW 100%	Pressure switch in open position.	1. Verify that high pressure oxygen is not connected. 2. Verify operation of the pressure switch, replace as necessary. 3. Replace Main PCB.
Battery Check	Battery capacity too low	1. Allow integrated battery to recharge and re-test. 2. Replace integrated battery and re-test
Motor Watchdog	Motor speed too high	1. Repeat VVT. 2. Replace Main PCB. 3. Replace pneumatic module
PC Watchdog	Reset takes too long	1. Repeat VVT.

<b><i>Test Failed:</i></b>	<b><i>Description:</i></b>	<b><i>Troubleshooting Steps:</i></b>
		2. Replace CPU PCB.

# Section 7: Calibrations

## 7.1 Introduction

This section of the service manual describes in detail the Calibration operations which may be performed on the device by the service technician or therapist. For convenience a calibration troubleshooting guide is provided at the end of the section.

## 7.2 Calibration Overview

The calibration procedures are for the most part semi-automated procedures which the service technician or therapist may perform at prescribed intervals or as required.

The calibration procedures in some cases require specific test instruments and require operator intervention at certain points throughout. In each case a calibration information window will appear detailing exactly what it required.

When running the calibration procedures, with the exception of the O2 sensor, it is generally good practice to perform all of the calibrations, and perform them in the order they are displayed on screen. The following calibration procedures may be performed from the calibration menu:

- Zero Sensors Calibration
- Pressure Sensor Calibration
- PEEP/RPM Calibration
- Flow Sensor Calibration
- Volume Calibration
- O2 Calibration

**NOTE: *IT IS GENERALLY RECOMMENDED THAT THE DEVICE BE ALLOWED TO RUN FOR A PERIOD OF TIME, AT LEAST 15 MINUTES, PRIOR TO RUNNING THE CALIBRATION PROCEDURES. THIS TIME IS RECOMMENDED TO ALLOW THE DEVICE TO REACH A NORMAL OPERATIONAL TEMPERATURE.***

## 7.3 When to Run Calibration

Calibration procedures are recommended at the following intervals or after performing the following operations:

- Any time the 'Need Calibration' (Cal) alarm or indicator is active.
- Every one year of ventilator operation
- Planned Maintenance, following installation of 1 year and 15K planned maintenance kits.
- Software Installation, after installation of any new software version.
- Service Repair, after completion of any repair.
- Troubleshooting, as a part of the troubleshooting issues

## 7.4 Calibration Requirements

To complete the full set of calibration procedures the following equipment will be required:

- VersaMed Ventilator Tubing System (any configuration)
- 500ml Calibration Syringe (VersaMed Part No. 920C0001-01, M1161170)
- Calibration Manometer (VersaMed Part No. 920C0002-01, M1161184)
- RP20 Resistor Plug (VersaMed Part No. 910V0004-01, M1161188)
- Test Lung 2 liter (VersaMed Part No. 910V0005-01, M1162061)
- Oxygen Calibration Cover (VersaMed Part No. 504A0065-A0, M1161964)
- High Pressure O2 Supply (40-60psi)
- O2 High Pressure Hose Assembly

## 7.5 Accessing Calibration

The calibration menu may be accessed through the maintenance menu which is accessible from the main menu (Section 5.2, page 80).

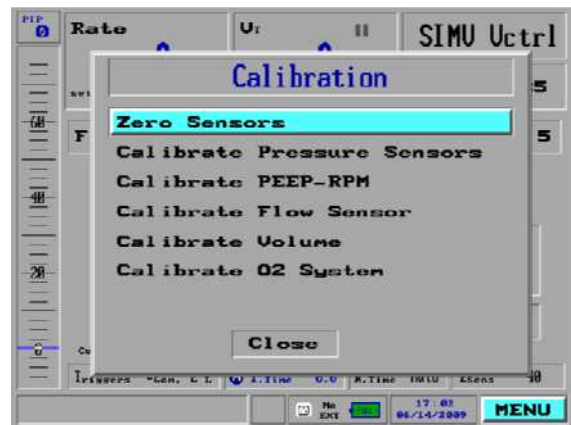
**NOTE:** *CALIBRATION PROCEDURES CANNOT BE INITIATED IF VENTILATION IS IN PROGRESS. IF YOU ATTEMPT TO INITIATE ANY OF THE CALIBRATION PROCEDURES DURING VENTILATION THE DEVICE WILL DISPLAY A WARNING MESSAGE AS FOLLOWS; 'THIS MAINTENANCE OPTION CAN BE ACCESSED ONLY IN THE STANDBY MODE.'*

## 7.6 Calibration Procedures

1. Using the rotary control knob highlight 'Calibrations' on the maintenance menu screen and press to confirm.
2. On selecting 'Calibration' the calibration window will be displayed. Using the rotary control knob highlight the desired calibrations in turn then press to confirm.



Maintenance Menu



Calibration Menu

Figure 7-1 Entering the Calibration Menu

### 7.6.1 Zero Sensors Calibration

During the zero sensors calibration the device will attempt to perform a zero on each of the pressure transducers. The test will be performed with an open wye and under no flow conditions to ensure that each transducer is at ambient conditions.

To perform zero sensors calibration:

1. From the Calibration window select the Zero Sensors option using the rotary control knob.
2. The Zero Sensors window will appear prompting the operator to disconnect the test lung from the wye.
3. If connected disconnect the test lung and Rp20 resistor from the patient circuit and press start to proceed.
4. The calibration procedure will take approximately 6 seconds during which the message 'working' will be displayed on screen.
5. On successful completion of the zero sensors calibration the device will revert back to the calibration main menu.
6. In the event of an unsuccessful outcome of zero sensors calibration, the message 'zero sensors incorrect' will appear on screen.

**NOTE:** ***IN THE EVENT THAT THE DEVICE REPORTS 'ZERO SENSORS INCORRECT' CONFIRM THAT THE WYE IS UNOBSTRUCTED AND THEN RE-RUN THE PROCEDURE. IF THE CALIBRATION IS FOUND TO FAIL PERSISTENTLY REFER TO THE CALIBRATION TROUBLESHOOTING GUIDE (SECTION 7.8, PAGE 127).***

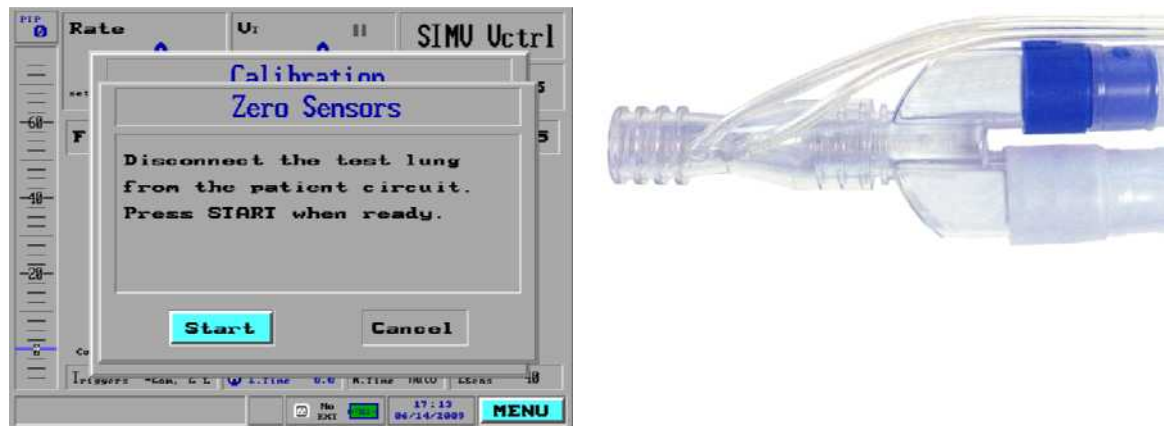


Figure 7-2 Zero Sensors

## 7.6.2 Pressure Sensor Calibration

During the pressure sensor calibration the device will attempt to perform a gain calibration on the patient pressure and turbine pressure transducers. The test will be performed with a reference test manometer placed at the patient wye.

On initiation of the test the turbine motor will be energized with a P.W.M. (Pulse Width Modulated) signal of 90 in order to pressurize the system. A manometer

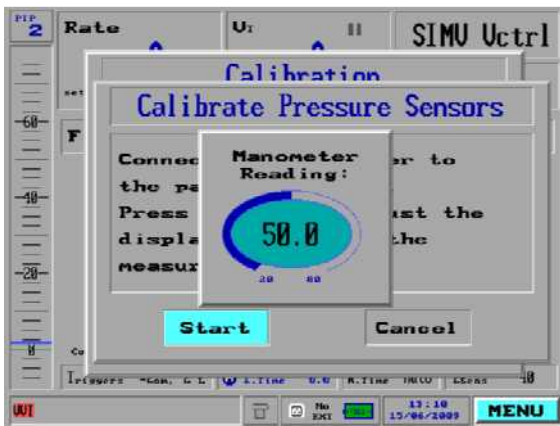
reading window will be displayed on the screen, and the operator will adjust its value to match that of the test manometer.

**NOTE:** *AS THE SYSTEM IS PRESSURIZED THE PRESSURE BAR GRAPH ON THE MAIN SCREEN WILL SHOW A REPRESENTATION OF PRESSURE AND PIP. DURING PRESSURE CALIBRATION THESE VALUES MUST BE DISREGARDED AS THEY ARE DERIVED FROM A DEFAULT GAIN VALUE AND DO NOT ACCURATELY REFLECT THE PRESSURE IN THE SYSTEM.*

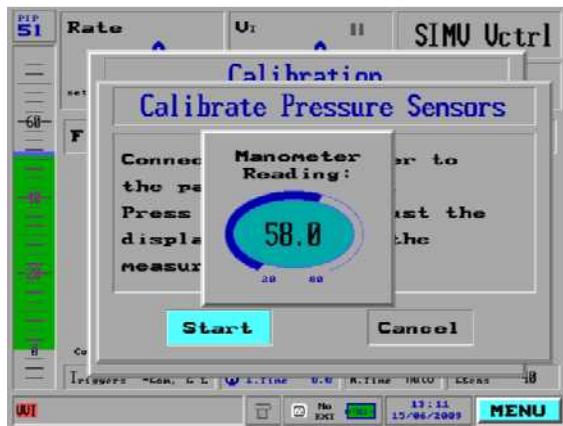
**Note:** *Since the value shown on the pressure bar graph and PIP do not accurately reflect the pressure during calibration it CANNOT be used as a method for verification. The pressure calibration may be verified using the ventilator verification test.*

To perform pressure sensors:

1. From the Calibration window select the Pressure Sensors option using the rotary control knob.
2. The pressure sensors calibration window will appear prompting the operator to connect a manometer at the wye.
3. As prompted connect test manometer (part no 920C0001-01, or equivalent) to the patient wye.
4. Using the rotary control knob select and confirm 'Start' in order to initiate the calibration procedure.



Before Pressure Adjustment



After Pressure Adjustment



Manometer Reading 58 cmH2O

Figure 7-3 Calibrate Pressure Sensors



5. On selecting 'Start' the device will energize the turbine motor in order to pressurize the system.
6. A manometer reading window will appear in the display for adjustment. The pressure bar graph will show a reading but this **MUST** be disregarded.
7. Using the rotary control knob adjust the value in the manometer adjustment window to match that of the manometer placed at the patient wye. Press the rotary control knob to confirm the value entered and the calibration will be verified.
8. On successful completion of the pressure sensor calibration the device will revert back to the calibration main menu.
9. In the event of an unsuccessful outcome of pressure sensors calibration, the message 'pressure sensors incorrect' will appear on screen.

**NOTE:** ***IN THE EVENT THAT THE DEVICE REPORTS 'PRESSURE SENSORS INCORRECT' CONFIRM THAT THE CALIBRATION MONITOR AND ALL PATIENT TUBING CONNECTIONS ARE SECURE. IF THE CALIBRATION IS FOUND TO FAIL PERSISTENTLY REFER TO THE CALIBRATION TROUBLESHOOTING GUIDE (SECTION 7.8, PAGE 127).***

### 7.6.3 PEEP-RPM Calibration

During the PEEP-RPM calibration the device will attempt to perform a calibration of the turbine motor RPM which will be required to establish PEEP. The test will be performed with an RP20 resistor and 2 liter test lung placed at the wye.

**Note:** *Equivalent items to the resistor plug and lung specified may be used but they **MUST** comply with the following requirements; resistance must be equivalent to RP20-RP50, compliance equivalent to 0.001-0.05 L/cmH2O*

The test will be performed under 4 different hardware (solenoid) conditions which can exist during normal operation. These conditions are as follows:

- Condition 1 – Solenoid 1 and Solenoid 2 closed
- Condition 2 – Solenoid 1 open and Solenoid 2 closed
- Condition 3 – Solenoid 1 closed and Solenoid 2 open
- Condition 4 – Solenoid 1 and Solenoid 2 open

The turbine motor will be energized with a P.W.M. (pulse width modulated) signal which will be predetermined for each of the conditions shown above.

At each condition the turbine pressure will be measured, and for reference an assumed RPM will be calculated according defaults in software. The actual mean measured RPM for each condition will be compared against the reference RPM for verification.

If the deviation between the reference RPM and the actual RPM is too large the calibration data will be rejected and 'PEEP RPM incorrect' will result. If the deviation is within acceptable limits the calibration data will be retained.

To perform PEEP RPM calibration:

1. From the Calibration window select the PEEP-RPM option using the rotary control knob.
2. The PEEP-RPM calibration window will appear prompting the operator to connect a test lung at the wye.

**Note** *Although the screen requests connection of test lung alone it is necessary to connect RP20 resistor (910V0004-01) and 2 liter test lung (910V0005-01), or equivalents, to the patient wye.*

3. Using the rotary control knob select and confirm 'Start' in order to initiate the calibration procedure.



Figure 7-4 Calibrate PEEP-RPM

4. The calibration procedure will take approximately 50 seconds during which the message 'working' will be displayed on screen.
5. On successful completion of the PEEP RPM calibration the device will revert back to the calibration main menu.
6. In the event of an unsuccessful outcome of PEEP RPM calibration, the message 'PEEP RPM incorrect' will appear on screen.

**Note:** *In the event that the device reports 'PEEP RPM incorrect' confirm that the appropriate test equipment is attached at the patient wye, and that all of the patient tubing connections are secure and then re-*

*run the procedure. If the calibration is found to fail persistently refer to the calibration troubleshooting guide (section 7.8, page 127)*

## 7.6.4 Flow Sensor Calibration

During the flow sensor calibration the device will attempt to perform a calibration on the differential pressure transducer (DCXL) which is used for flow measurement. The flow sensor calibration requires no equipment other than the patient tubing system.

The differential pressure transducer provides two outputs, high flow via a low gain amplifier, and low flow via a high gain channel. The calibration will attempt to perform a synchronization of the two.

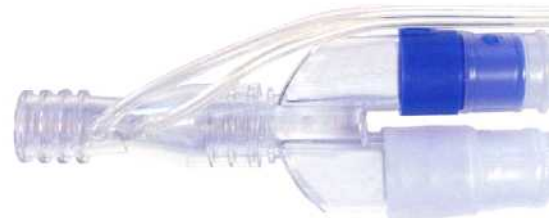
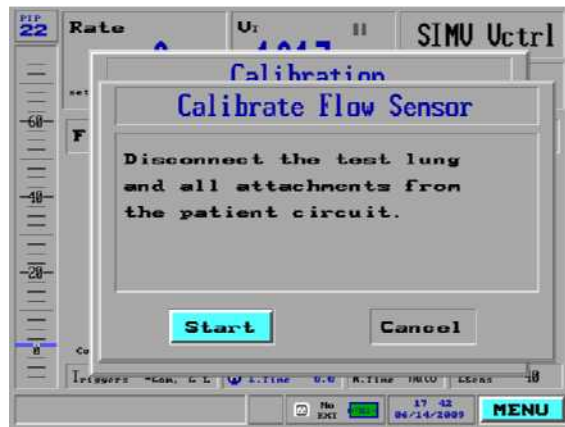


Figure 7-5 Calibrate Flow Sensor

To perform flow sensor calibration:

1. From the Calibration window select the Flow Sensor option using the rotary control knob.
2. The Flow Sensor window will appear prompting the operator to disconnect the test lung from the wye.
3. If connected disconnect the test lung and Rp20 resistor from the patient circuit and press start to proceed.
4. The calibration procedure will take approximately 15 seconds during which the message 'working' will be displayed on screen.
5. On successful completion of the flow sensor calibration the device will revert back to the calibration main menu.
6. In the event of an unsuccessful outcome of flow sensor calibration, the message 'flow sensor incorrect' will appear on screen.

**Note:** *In the event that the device reports 'Flow Sensor incorrect' confirm that the patient wye is open and that all of the patient tubing connections are secure and then re-run the procedure. If the calibration is found to fail persistently refer to the calibration troubleshooting guide (section 7.8, page 127)*

### 7.6.5 Volume Calibration

During the volume calibration the device will attempt to perform a gain calibration on the differential pressure transducer (DCXL) which is used for flow measurement from which volume is derived. The volume calibration requires the use of a 500ml syringe.

On initiation of the calibration the operator will be prompted to connect the syringe to the patient wye and the make 10 strokes backwards and forwards on the syringe. Moving the syringe in the backward direction will represent inspiratory volume, moving the syringe in the forward direction will represent expiratory volume.

Throughout the 10 syringe strokes the device will attempt to balance the two volume readings, and with each stroke the level of error compared to the 500ml reference should be reduced. By the time the 10<sup>th</sup> stroke is reached the displayed inspiratory and expiratory volumes should be within 10% of the 500ml reference.

In the event that the deviation from the reference is too large, or the measured gain value is not acceptable the calibration data will be rejected and 'Volume calibration incorrect' will result. If the deviation is within acceptable limits the calibration data will be retained.

To perform volume sensor calibration:

1. From the Calibration window select the Volume option using the rotary control knob.
2. The Volume calibration window will appear prompting the operator to firstly connect a 500ml syringe (part no. 920C0001-01, M1161170, or equivalent) to the patient wye sensor.



Figure 7-6 Calibrate Volume

3. Connect the calibration syringe to the patient wye sensor and push the plunger in until it reaches a stop, this is the starting position for the syringe.
4. With the calibration syringe connected at the patient wye sensor continue to follow the on screen prompts.
5. Using the rotary control knob select and confirm 'Start' to proceed with the calibration.
6. Using slow and steady strokes pump the calibration syringe 10 times backwards and forwards.
7. While doing so observe the values which are displayed for inspiratory and expiratory volume with each stroke made.
8. On completion of the 10<sup>th</sup> stroke the device will check the validity of the calibration data which has been recorded.
9. On successful completion of the volume calibration the device will revert back to the calibration main menu.
10. In the event of an unsuccessful outcome of volume calibration, the message 'volume calibration incorrect' will appear on screen.

**Note:** *In the event volumes displayed on the 10<sup>th</sup> stroke are found to have an error of greater than 10% against the 500ml reference it is recommended that the calibration be repeated.*

**Note:** *In the event that the device reports 'Volume Calibration Incorrect', verify that all patient tubing connections are secure and that the syringe is correctly set up, then re-run the procedure. If the calibration is found to fail persistently refer to the calibration troubleshooting guide (section 7.8, page 127),*

## 7.6.6 O2 System Calibration

During the O2 system calibration the device will attempt to perform calibration of the oxygen delivery mechanism and the oxygen monitoring system. The calibration procedure will differ slightly according to the hardware type inside O2 system, the two hardware types are as follows:

Type 1: Stepper Motor Based System      Serial No. Up to iV14999

Type 2: Proportional Solenoid System      Serial No. iV15000 onwards

The O2 system calibration requires the use of a high pressure oxygen source and in the case of units equipped with the proportional solenoid based system an O2 calibration cover (504A0065-A0, M1161964).

### 7.6.6.1 Oxygen Calibration on Stepper Units

The oxygen system calibration on units including the stepper motor will be performed at both 100% and 21% with software versions of 19.17.01 and higher. The device will perform a calibration of the stepper motor system and check the backlash within the system.

O2 sensor calibration will be performed at 100% and 21%. The device will firstly wash oxygen through the system, check the O2 sensor reading, and will calibrate if necessary. For 21% the device will wash ambient air through the system and repeat the process.

To perform oxygen calibration on stepper based devices:

1. From the Calibration window select the O2 system calibration option using the rotary control knob.



Calibration at 100% O2



Calibration at 21% O2

Figure 7-7 O2 system calibration screens (Stepper Units)

2. The O2 system calibration window will appear prompting the operator to connect a high pressure oxygen source to the device and to disconnect the test lung from the wye.
3. With high pressure oxygen connected and test lung removed highlight and confirm 'Start' to proceed.
4. From initiation the first part of the calibration procedure will take approximately 30 seconds during which the message 'working' will be displayed on screen.
5. On successful completion of the first part of the calibration the O2 system calibration window will appear prompting the operator to disconnect the O2 supply.
6. With high pressure oxygen now disconnected highlight and confirm 'Start' to proceed.
7. From initiation the second part of the calibration procedure will take approximately 90 seconds during which the message 'working' will be displayed on screen.
8. On successful completion of O2 system calibration the device will revert back to the calibration main menu.
9. In the event of an unsuccessful outcome from either part of the O2 system calibration, the message 'O2 system calibration incorrect' will appear on screen.

#### **7.6.6.2 Oxygen Calibration on Proportional Solenoid Units**

The oxygen system calibration on units including the PSV will be performed at both 100% and 21%. As the PSV system does not include a means for closing off the ambient air path the system requires that the inlet filter port be manually sealed during 100% calibration. O2 calibration cover, 504A0065-A0, M1161964, is required for this purpose.

During the oxygen system calibration on units which include the proportional solenoid valve the device will firstly attempt to create a calibration table plotting the PSV control signal against the flow measured at the oxygen flow sensor. This information will be plotted for 12 incremental PSV levels. Once the calibration table has been plotted the device will proceed with calibration of the O2 sensor.

O2 sensor calibration will be performed at 100% and 21%. The device will firstly wash oxygen through the system, check the O2 sensor reading, and will calibrate if necessary. For 21% the device will wash ambient air through the system and repeat the process.

To perform oxygen sensor calibration on PSV based devices:

1. From the Calibration window select the O2 system calibration option using the rotary control knob.
2. The O2 system calibration window will appear prompting the operator to connect a high pressure oxygen source to the device and to disconnect the test lung from the wye.
3. The operator will additionally be prompted to remove the inlet filter and install the O2 calibration cover.



Figure 7-8 O2 Calibration Cover



O2 Calibration at 100%



O2 Calibration at 21%

Figure 7-9 O2 System Calibration Screens (Proportional Valve Units)

4. With high pressure oxygen connected, test lung removed and cover in place highlight and confirm 'Start' to proceed.
5. From initiation the first part of the calibration procedure will take approximately 30 seconds during which the message 'working' will be displayed on screen.



6. On successful completion of the first part of the calibration the O2 system calibration window will appear prompting the operator to remove the calibration cover and put an inlet filter back in place.
7. With the inlet filter back in position highlight and confirm 'Start' to proceed.
8. From initiation the second part of the calibration procedure will take approximately 90 seconds during which the message 'working' will be displayed on screen.
9. On successful completion of O2 system calibration the device will revert back to the calibration main menu.
10. In the event of an unsuccessful outcome from either part of the O2 system calibration, the message 'O2 system calibration incorrect' will appear on screen.

### 7.6.7 Saving Calibration Data

In order to ensure the retention of new calibration data it is essential that the calibration menu be closed by means of the 'Close' button on the calibration screen. In the event that the calibration screen is closed by means of the 'Clear' key any new calibration data will be lost.

To exit the calibration screen correctly:

1. From the Calibration window select the 'Close' option using the rotary control knob.
2. The 'Save Calibrations' message window will appear prompting the operator whether they wish to save the latest calibrations.
3. Select 'Yes' to save the calibration data and 'No' to reject the new calibration data and revert to previous information. On completion the device will revert to the main screen.

**CAUTION:** *Ventilator Verification Test (V.V.T.) should always be performed on completion of system calibrations in order to verify their validity.*

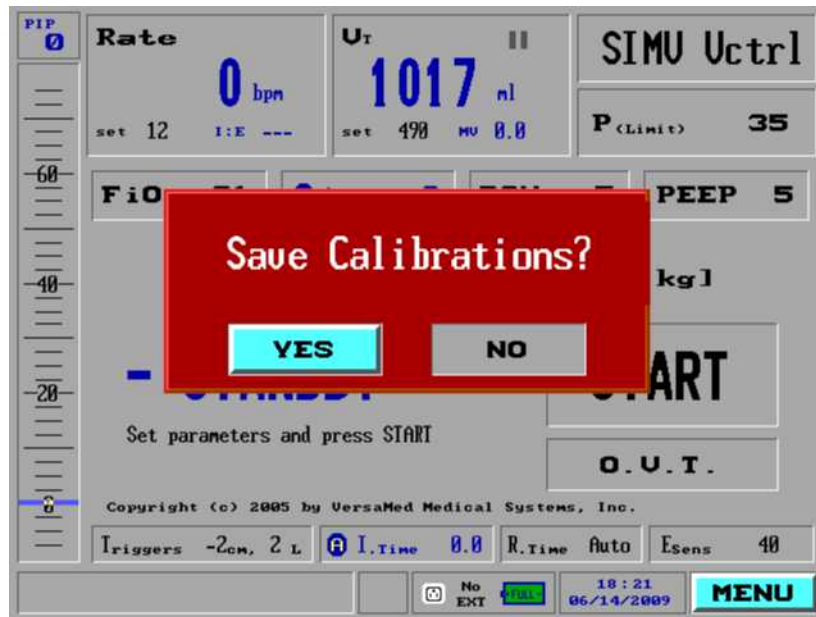


Figure 7-10 Save Calibration

## 7.7 Battery Gas Gauge Initialization Procedure

Whenever the internal battery cell 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 on the display.

In order to achieve this, the device's battery pack must be fully charged and then undergo a controlled discharge and full recharge. Only upon completion the gas gauge should be updated with the battery's current capacity.

The gas gauge initialization procedure requires the use of a standard patient tubing system, RP20 pneumatic resistor (910V0004-A0) and 2 liter test lung (910V0005-01).

To perform battery gas gauge initialization:

1. Plug the AC power cord into the ventilator, verify that the amber charge LED comes on and allow the unit to charge the internal battery for a minimum of 8 hours.
2. Switch the ventilator on 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 high pressure alarm to 60cmH<sub>2</sub>O.

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 to commence ventilation.
6. Adjust the devices tidal volume so that a PIP of at least 40 cmH<sub>2</sub>O is observed on each 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 OPERATING UNTIL THE EMPTY BATTERY ALARM IS OBSERVED.

**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.

## 7.8 Troubleshooting Calibrations

The following table is provided to assist in the troubleshooting of failures which may have occurred during the calibration procedures.

### 7.8.1 Calibration Tests

<i>Test Failed:</i>	<i>Description:</i>	<i>Troubleshooting Steps:</i>
Zero Sensors	Zero sensors incorrect	<ol style="list-style-type: none"> <li>1. Ensure that patient wye is open, nothing connected and retest.</li> <li>2. Probable pressure transducer offset. Replace Sensor PCB.</li> </ol>
Pressure Sensors	Pressure sensors incorrect	<ol style="list-style-type: none"> <li>1. Ensure that tubing system is properly connected and test manometer connected at wye, then</li> </ol>

		<p>retest.</p> <ol style="list-style-type: none"> <li>2. Check the device for any leaks internally, correct and retest.</li> <li>3. Replace Sensor PCB</li> </ol>
PEEP/RPM	PEEP/RPM incorrect	<ol style="list-style-type: none"> <li>1. Ensure that test lung and RP20 are connected at the wye.</li> <li>2. TBA</li> </ol>
Flow Sensor	Flow sensor incorrect	<ol style="list-style-type: none"> <li>1. Ensure that the patient tubing system is securely connected and retest.</li> <li>2. Check for leaks in the flow measurement circuit including one way valves, retest.</li> <li>3. Replace purge/zero PCB</li> <li>4. Replace Main PCB</li> </ol>
Volume	Volume incorrect	<ol style="list-style-type: none"> <li>1. Ensure that the patient tubing system is securely connected and retest.</li> <li>2. Check calibration syringe and ensure it is set for 500ml, retest.</li> <li>3. Check for leaks in the flow measurement circuit including one way valves, retest.</li> <li>4. Replace purge/zero PCB.</li> <li>5. Replace Main PCB</li> </ol>
O2 System	O2 system incorrect during 100%	<ol style="list-style-type: none"> <li>1. Ensure that inlet filter is removed and calibration cover fitted in place, retest.</li> <li>2. Ensure that the patient tubing system is securely connected with wye open, retest.</li> <li>3. Ensure that an adequate high pressure O2 source is connected.</li> <li>4. Replace O2 Sensor.</li> <li>5. Replace Pneumatic System</li> </ol>

	O2 system incorrect during 21%	<ol style="list-style-type: none"><li>1. Ensure that calibration cover has been removed and filter replaced, retest.</li><li>2. Ensure that the patient tubing system is connected with wye open, retest.</li><li>3. Replace O2 Sensor.</li></ol>
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## Section 8: Functional Test Procedure

### 8.1 Introduction

The following section of the manual details the functional test procedure for the iVent™201 ventilator system. The functional test is a series of operational simulations designed to fully validate the critical functions of the ventilator.

### 8.2 Notes

NOTE: The iVent™201 ventilator system is manufactured with accurate pneumatic and electronic test instruments and in a controlled environment. As field conditions vary the accuracy of measurement instruments may become less certain.

NOTE: The following test specifications were established with the test equipment as specified in section 8.4. If the accuracy of your institutions test equipment differs from those listed please make allowances

### 8.3 When to Run Tests

The functional checkout procedure, verification tests (VVT and OVT) and calibration procedures, or parts thereof, should be run periodically or after service has been performed as defined in the table below:

Interval/Service Performed	OVT	VVT	Zero Cal	Pres Cal	Peep Cal	Flw Cal	Vol Cal	O2 Cal	Elec. Sty	O2 Tests	Alarm Tests
Once Per Year	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Patient Tubing Replacement	✓	--	--	--	--	--		--	--	--	--
Exhalation Valve Replacement	✓	--	--	--	--	--		--	--	--	--
Main PCB Replacement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pneumatic System Replacement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Power Pack Replacement	✓	✓	--	--	--	--	--	--	--	--	--

Interval/Service Performed	OVT	VVT	Zero Cal	Pres Cal	Peep Cal	Flw Cal	Vol Cal	O2 Cal	Elec. Sty	O2 Tests	Alarm Tests
Power Supply Replacement	✓	✓	--	--	--	--	--	--	✓	--	--
Disp/Touch Panel Replacement	✓	✓	--	--	--	--	--	--	✓	--	--
Interface PCB Replacement	✓	✓	--	--	--	--	--	--	✓	--	--
Backlight Inverter Replacement	✓	✓	--	--	--	--	--	--	✓	--	--
Hold System Replacement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
O2 Sensor Replacement	✓	✓	--	--	--	--	✓	✓	--	✓	--
Internal Tubing Replacement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

## 8.4 Test Equipment & Materials

- O<sub>2</sub> supply, 40-60 psi.
- O<sub>2</sub> supply hose (VersaMed P/N 620B0001-01 or 620B0002-01)
- Certified external O<sub>2</sub> analyzer (Puritan Bennett 7820 or equivalent).
- Test lung, 2L. (VersaMed P/N 910V0005-01)
- Pneumatic resistor, Rp20. (VersaMed P/N 910V0004-A0)
- Electrical safety test, Biotek 601 Pro or equivalent

## 8.5 Cleaning and Inspection

Clean and inspect the ventilator by the following means:

- Clean the ventilators exterior using an appropriate germicidal or antibacterial agent. Clean all exterior surfaces including gas connections and mains cord.
- Open the ventilator chassis and inspect for cleanliness, if necessary clean its interior using an ESD safe vacuum cleaner.
- Visually inspect the ventilator interior and exterior for any obvious problems such as missing or broken parts, loose assemblies,

disconnected wires, connectors or tubes. Repair as necessary prior to performing the performance verification.

## 8.6 Performance Testing

In order to ensure a systematic performance verification and logical fault diagnosis it is recommended to perform these tests in the order given.

Follow these general guidelines when running the performance verification procedures:

- If you note a problem during performance verification, verify that you have followed all the procedures correctly, and that all required settings are correct, before attempting to perform any repairs on the device.
- When making changes to the ventilator settings beware that because of the interrelationships between some settings, you may not always be able to make changes in the indicated sequence.
- For convenience any operator configurable alarms should be set to their maximum and minimum available ranges. This will reduce the occurrence of nuisance alarms during performance verification.
- Use the alarm silence button as needed during the performance verification procedures in order to mute any alarms should they occur.
- Except for using the silence button do not alter the control settings during these procedures unless specifically instructed to do so.
- If necessary refer to the Service and Repair for repair information, and Parts and Accessories section for identification of the repair parts. When any repairs have been completed repeat the tests in full.
- To locate the cause of any malfunction or failed test procedure you should refer to the troubleshooting section of this manual.
- The procedures described here do not verify the performance of any accessory items (humidifiers, remote alarms, etc.) which may be running with the ventilator system. Verify the performance of any such items using appropriate procedures within the appropriate product manuals.

### 8.6.1 Electrical Safety Test

The electrical safety test is performed in order to verify that ground resistance and earth leakage current are within acceptable safe limits.



This test should be performed whenever the ventilators enclosure has been opened for service, annually or more frequently should national, local or institutional regulations require it.

Figure 8-1 below shows the basic setup for the test along with the appropriate testing points. It is recommended to use Biotek 601 Pro Or equivalent device for electrical safety testing of the ventilator system.

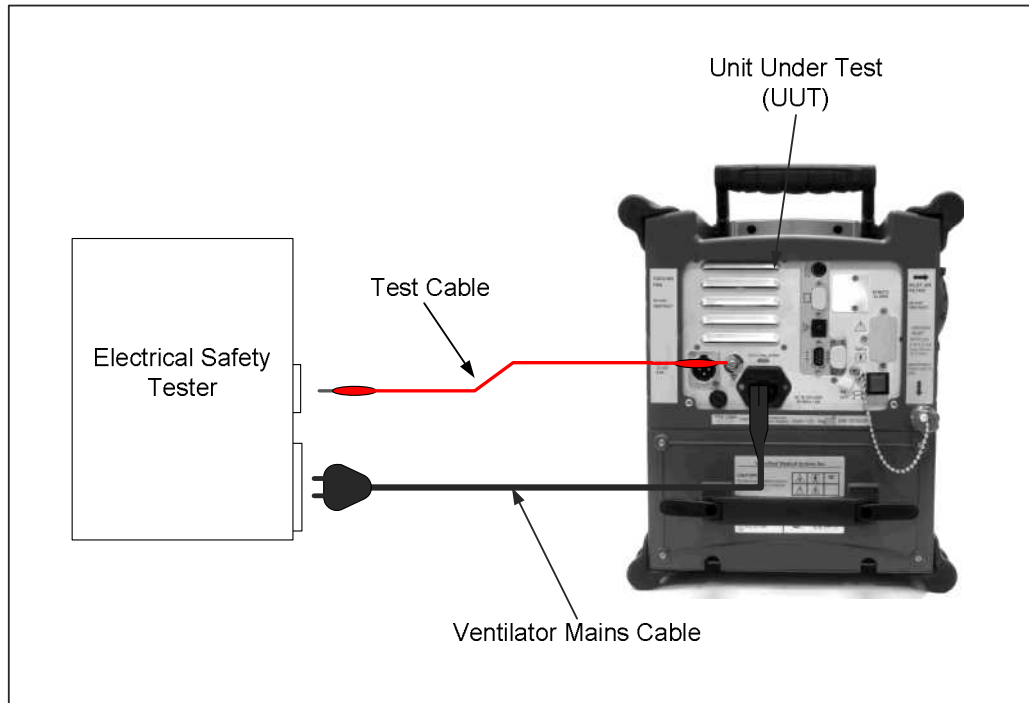


Figure 8-1 Electrical Safety Test Set Up

### 8.6.1.1 Procedure

The electrical safety test procedure includes steps for the following:

1. Connect the mains cable of the unit under test (UUT) to the receptacle on the electrical safety tester.
2. Connect the test cable between the electrical safety tester and grounding post on rear panel of the device.
3. Power on the UUT and set in operation with default settings in use.
4. On the electrical safety tester perform the test for enclosure leakage current in both the forwards and reverse polarity. Measured leakage current must be below 100 $\mu$ A.
5. On the electrical safety tester instigate the single fault condition (no L2) and repeat the enclosure leakage current check with forward and reversed polarity. Measured leakage current must be below 500 $\mu$ A.

## 8.6.2 Oxygen Performance Tests

The oxygen performance tests are performed in order to verify that oxygen delivery accuracy and associated alarms perform to the required specification.

Figure 8-2 below shows the required set up for the oxygen performance testing. It is recommended that a Maxtec MAX-O<sub>2</sub> oxygen monitor or equivalent be used for checking the oxygen accuracy of the ventilator system.



Figure 8-2 Oxygen performance test setup

### 8.6.2.1 Procedure

The Oxygen Performance test procedure includes steps for the following:

1. Adjust the external O<sub>2</sub> analyzer calibration so that it reads 21%.
2. Connect the O<sub>2</sub> supply to the ventilator.
3. Wait for 20 breaths and verify that the external O<sub>2</sub> analyzer measurement is equal to the FiO<sub>2</sub> setting of the ventilator  $\pm 10\%$  (FiO<sub>2</sub>).

**TIP:** BY SELECTING ALARM SETTINGS FROM THE MAIN MENU, YOU CAN VIEW THE O<sub>2</sub> 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.

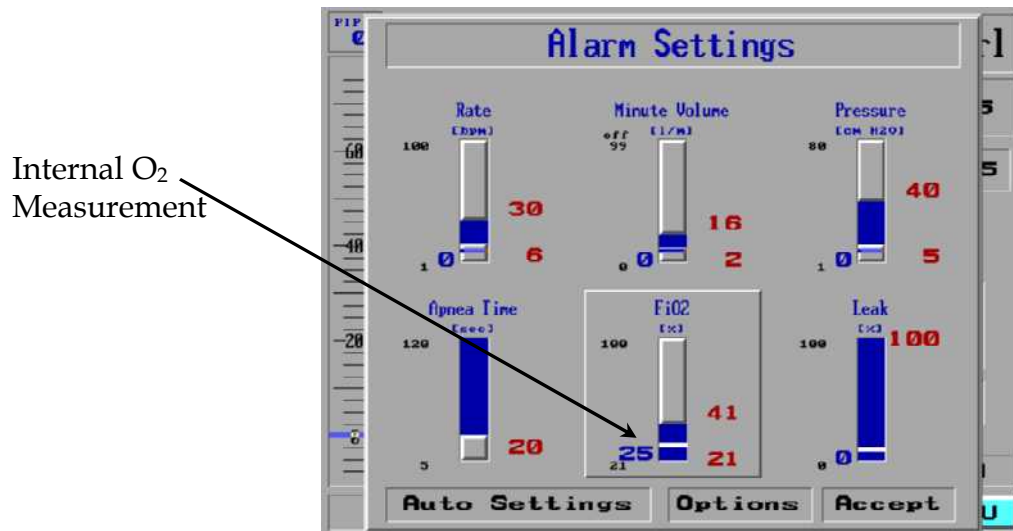


Figure 8-3 Internal O<sub>2</sub> Measurement

4. Set the FiO<sub>2</sub> to 60% and repeat step 3.
5. Set the FiO<sub>2</sub> 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<sub>2</sub>O).

### 8.6.2.2 100% O<sub>2</sub> (Suction) Test

1. Press the 100% O<sub>2</sub> button on the ventilator front panel keypad. Verify that a green pop-up window appears next to the FiO<sub>2</sub> field and the 2 minute alarm silence count-down timer is initiated in the time/date field.
2. Verify that the FiO<sub>2</sub> delivery elevates to 100% nominal.

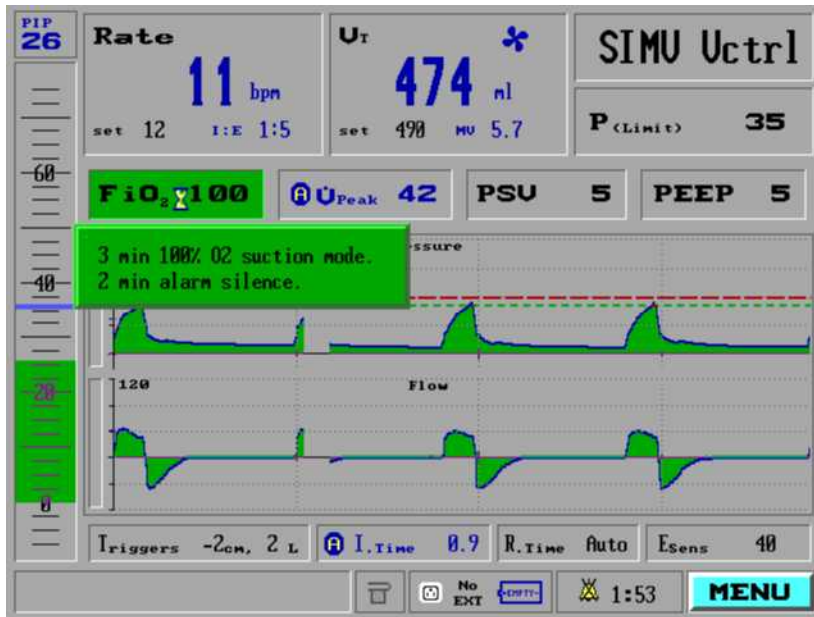


Figure 8-4 100% O<sub>2</sub> (Suction) Mode

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:
  - The audible alarm sounds continuously.
  - A red pop-up "Warnings:" window appears, showing Patient disconnect.
  - 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<sub>2</sub> setting and delivery return to 21% one (1) minute after the count-down timer expires.

### 8.6.3 Alarm Tests

The Alarms test is performed in order to verify that all of the devices critical ventilation alarms work in an appropriate manner. The alarms test will verify the function of each of the following alarms:

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

#### 8.6.3.1 High Pressure Alarm Test

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 cmH2O below the average PIP value (approximately 30 cmH2O). 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 cmH2O.



Figure 8-5 High Pressure Alarm

### 8.6.3.2 Apnea Alarm Test

**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 red pop-up "Warnings:" window appears stating Apnea.
  - The mode field changes to a blinking APNEA.
  - 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.

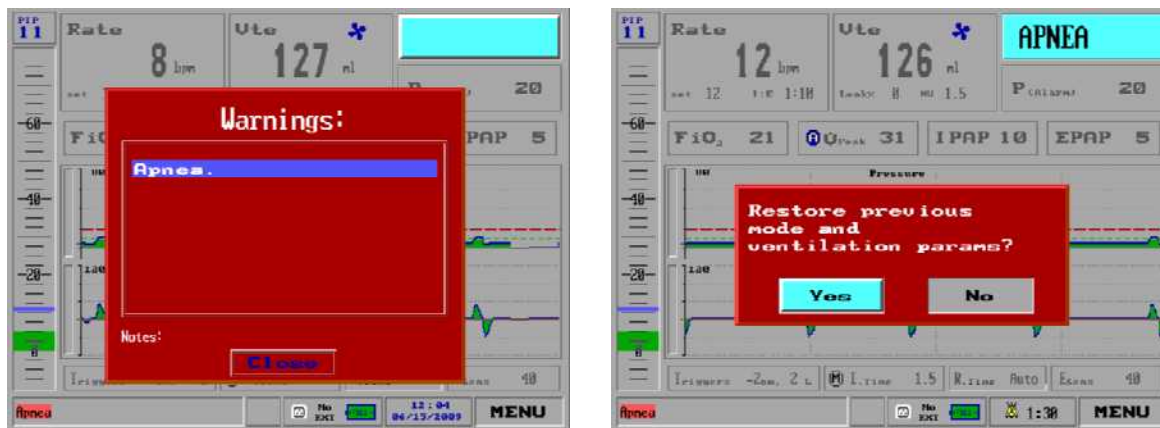


Figure 8-6 Apnea Alarm

4. After another 20 to 25 seconds the unit will go back into APNEA alarm. Simulate patient triggers and Verify that:
  - During the first minute, the unit does not respond to patient triggers.
  - 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.

### 8.6.3.3 Tube Disconnect Alarm

1. Disconnect the external analyzer O2 sensor and patient circuit from the ventilator outlet port.
2. Verify that:
  - The audible alarm sounds continuously.

- A red pop-up "Warnings:" window appears indicating "Tube disconnect."
- A red "Tube disc" indicator appears in the lower left part of the display window.
- The mode field changes to a blinking DISCONNECT.

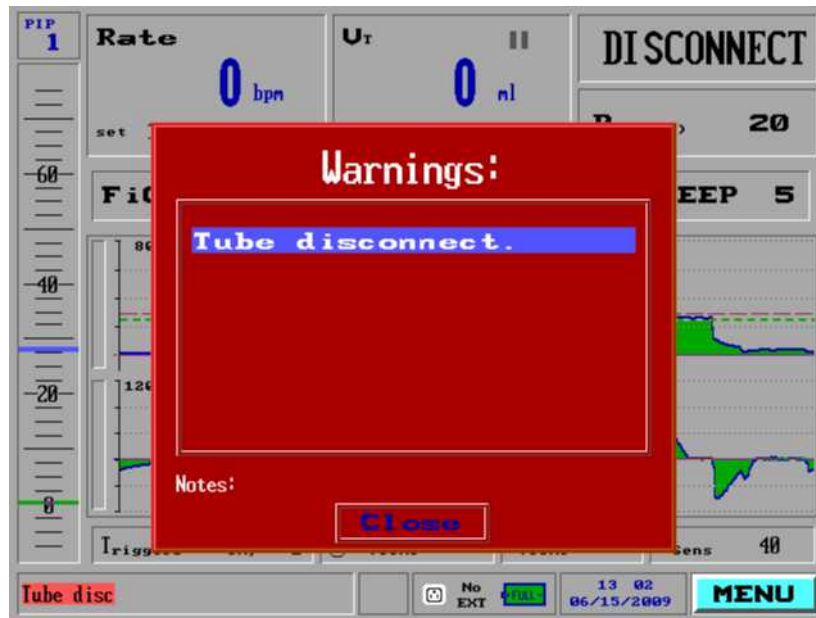


Figure 8-7 Tube Disconnect Alarm

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

#### 8.6.3.4 Patient Disconnect Alarm

1. Disconnect the test lung and Rp20 resistor from the patient circuit.
2. Verify that:
  - The audible alarm sounds continuously.
  - 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:

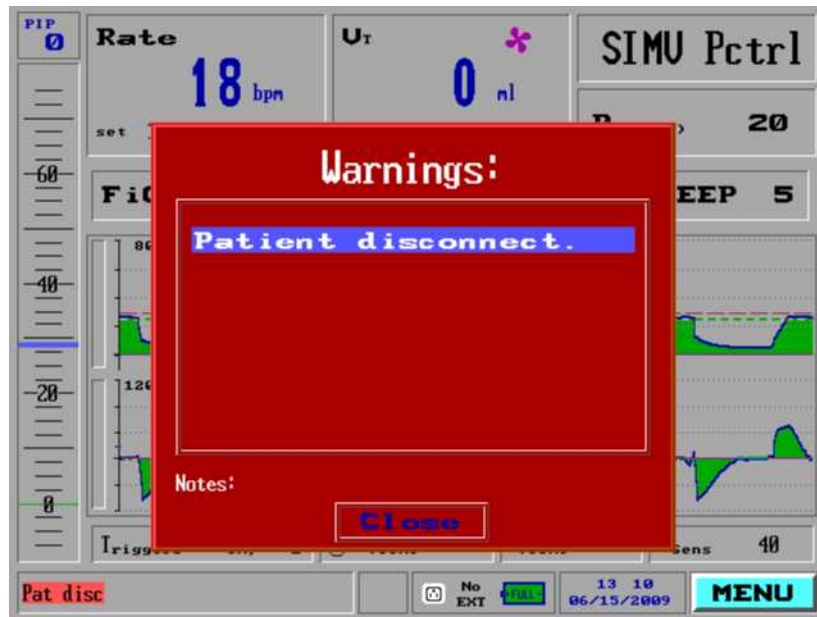


Figure 8-8 Patient Disconnect Alarm

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

### 8.6.3.5 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: The audible alarm sounds continuously.



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# Section 9: Planned Maintenance

## 9.1 Introduction

This section of the manual provides a detailed overview of the recommended cleaning procedures and the planned maintenance which should be performed on the *N*Vent™201.

## 9.2 Cleaning and Routine Planned Maintenance

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

The cleaning and routine maintenance for the *N*Vent™201 is summarized in Table 9-1 below.

**Table 9-1 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 <sub>2</sub> Sensor	Calibrate every 6 months	We recommend calibration every 3 months
	Replace annually, or as necessary	Actual life depends on history of use and storage

Part	Procedure	Comments
Inlet and outlet mufflers	Replace every 5000 hours of operation or annually, as necessary	Actual life depends on history of use and storage
Ventilator Outlet Port (Muffler)	Replace every 15,000 hours of operation	
Pneumatic Unit	Replace every four years or as necessary.	
Other accessories		

### 9.2.1 Cleaning the Ventilator

Clean the exterior of the ventilator when necessary with a soft damp cloth moistened with one of the following cleaning solutions:

- Water
- Mild detergent or soapy water

**Do not allow liquid to penetrate into the ventilator.**

### 9.3 Planned Maintenance

Table 9-2 summarizes planned maintenance intervals and procedures to be carried out on the /Vent™201. The table also specifies the relevance of each requirement according to whether the device is in general use, or whether it is in a prolonged state of storage (more than 3 months of storage, like Homeland Security devices).

**Table 9-2 Planned Maintenance Schedule**

Interval	Parts Affected	Maintenance	General	Prolong Storage
As Necessary	Ventilator Enclosure	Wipe clean the exterior	✓	✓
	Patient Tubing	Replace and perform OVT	✓	
	Cooling Air Filter and Vents	Clean and replace filter as needed.	✓	
	O2 Sensor	Replace the O2 sensor	✓	✓

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Interval	Parts Affected	Maintenance	General	Prolong Storage
Every 500 hours or 1 Month of use, whichever comes first	Air inlet Filter	Replace the air inlet filter.	✓	
1500 hours of operation or 3 months	Power Pack Gas Gauge	Charge the power pack.	✓	✓ <sub>1</sub>
		Perform VVT	✓	
3000 hours or 6 months of use; whichever comes first.	Power Pack Gas Gauge	Deep discharge and recharge.	✓ <sub>3</sub>	✓ <sub>3</sub>
		Perform VVT	✓	✓
Annually Install the annual PM kit, refer to section 9.3.4	Air Inlet and Outlet Muffler assembly	Replace the Air Inlet Muffler	✓	
	Ventilator Outlet Port (muffler)	Replace the Outlet Port (muffler)	✓	
	Cooling Inlet Filter	Replace the cooling inlet filter.	✓	
	Inlet muffler O-ring	Replace the inlet muffler O-ring.	✓	
	On/Off switch cover	Check validity of On/Off switch cover	✓	
	Internal Battery	Replace internal battery and reinitialize the gas gage.	✓	
		Perform full calibration It is recommended to perform O2 calibration every 3 months	✓ <sub>2</sub>	✓ <sub>2</sub>
	Perform safety checks.	✓		
Every 2 years	O2 Sensor	Replace the O2 sensor	✓	✓
Every 15,000 hours, or four (4) years; whichever comes first.  Install the 15,000 kit, refer to section 9.3.6	Pneumatic unit	Replace pneumatic unit.	✓	

Interval	Parts Affected	Maintenance	General	Prolong Storage

**NOTE:** 1. It is recommended that the Power Pack (the battery module) be disconnected (Removed) prior to placing the ventilator in storage. If the Power Pack is disconnected, there is no need to recharge the battery every 3 months.

2. Inspection and replacement if required.

3. Charge – Deep Discharge – Recharge of the internal battery is very time consuming. For that reason it may not be practical to perform during a field service visit.

**NOTE:** *On removing the device from prolonged storage, battery charge and VVT **MUST** be performed to ensure trouble free operation. If VVT fails, a full calibration **must** be performed*

**NOTE:** *In addition to the items of planned maintenance suggested above electrical safety testing should be performed as mandated by national, local or institutional regulations*

### 9.3.1 500 Hour PM Procedure

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

- Remove the used air inlet filter by turning it counter-clockwise. Ensure that the existing O-ring remains on the side inlet port.
- 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.***

### 9.3.2 1500 Hour PM Procedure

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

- Run the Ventilator Verification Test (VVT) as outlined in Section 6.2, page 91.
- Charge the power pack

### 9.3.3 3000 hours PM Procedures

The following steps should be carried out every 3000 hours (or every 6 months):

- Clean the rear cooling vents and the front cooling air inlet using a vacuum cleaner device. Tilt the ventilator back to access the front cooling air inlet filter (see Figure 9-1, below).
- Fully discharge, then recharge the internal battery and allow the battery gas gauge to measure the total battery capacity as outlined in Section 7.7, page 126.
- Perform a full calibration as outlined in Section 7:
- Perform all 1500 hour PM steps.



Figure 9-1 Cooling Vent (left) and Cooling Air Inlet Filter (right)

### 9.3.4 Annual PM Procedure

The following steps should be carried out annually:

- Install annual PM kit (See parts section 13.3.2)  
VersaMed part number - 900K005-01  
GE part number - M1161168:
  - Inlet filter
  - Inlet muffler
  - Outlet muffler
  - Green foam

- Internal Battery
- Perform all 3000 hours PM steps.
- Perform electrical safety test (refer to Section 8.6, on page 132)

### 9.3.5 24 Months

The flowing step should be carried out every 24 months:

- Replace the O<sub>2</sub> sensor

### 9.3.6 15000 Hour PM Procedure

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

- Install the 15000 hours PM kit (See parts section 13.3.2):
  - Pneumatic Unit

15000 PM Kit	VersaMed part number	GE part number
15k Kit H.S	900K0003-03	M1182595
15k Kit QB\L, PSV	900K0003-02	M1177690
15k Kit Stepper	900K0003-01	M1162057



# Section 10: Software Applications

## 10.1 Introduction

This section of the service manual provides a detailed overview of several software utilities which may be used during the servicing of the iVent™201 ventilator system. The section will cover the following software utilities,

- Log Download
- Software Update

## 10.2 Hardware Requirements

To run the VersaMed software utilities the following items will be required:

- Service PC, running windows 95 OS or higher
- Null Modem Cable (VersaMed Part No. 156A0001-01 or equivalent)
- USB>Serial Adapter (may be required)

## 10.3 Software Utilities Set Up

The software utilities in all cases will use the devices RS232 serial communications port Com1. Where the device is equipped with 2 ports (Com1/Com2) Com1 must still be used to interface with these software programs.

All of the software utilities require the use of a Null Modem Serial Cable, VersaMed Part No. 156A0001-01 or equivalent. The null modem cable should be connected between Com1 of the device and one of Com ports 1 to 4 on the service PC.

Many laptops currently available are not equipped with serial communications ports and in such cases it will be necessary to use an appropriate adapter. USB to Serial adapters are the most commonly available and easiest to use of these adapters.



**Figure 10-1 Software utilities cabling setup**

On using the USB to Serial adapter for the first time it will typically be assigned with a high com port number. As VersaMed utilities require the use of Com1 to 4 then some adjustment will be required in order to establish and maintain communications.

Using Control Panel>System>Device Manager you may manually set the Com port number of something within the acceptable range.

## 10.4 Software Utility Availability

Each of the software utilities which will be discussed will be provided to dealers/customers who attend Technical Service Training and who reach the required level of competence.

The software utilities may undergo periodic updates which will be communicated to dealers and customers via technical service bulletins. The updated utility may be distributed upon request.

## 10.5 Technical Error / Event Log Download Utility

During general operation the iVent™201 will record any significant events which may occur on the device. Operational events pertaining to ventilator setting changes, active alarms, resetting alarms, etc.; will be recorded in the Logbook accessed through the main menu. Technical events pertaining to test status, software errors, hardware errors, etc.; will be recorded in the technical log book accessed through the maintenance menu.

These logs have minimal capacity and in each case can only display limit entries of the most recent items with the oldest one is removed as a new entry is made. In addition both of these accessible logs will be cleared each time the device is power cycled.

Although these events are no longer accessible by the user, each type will be retained in two files on the devices disk on chip. These files are available for retrieval using a proprietary download utility named iVDownload.

To retrieve the files using iVDownload:

**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 OR ON DIRECTION OF A QUALIFIED TECHNICIAN.**

1. Connect the null modem serial cable to the RS232 port (Com1) of the ventilator, and to an available serial port (Com1>Com4) of the service PC.
2. On the PC double click on the file named 'ivDownload.exe' or on the desktop icon if a shortcut has been created, to start up the download application.
3. Once the application has started verify that communication has been established. The message 'Connected to Com (number)' should appear at the bottom-left of the application window.
4. The correct device serial number should be retrieved and displayed in the application window.
5. In the download application window, open the file selection pull down menu. Although there are a number of files available the only items with any real troubleshooting value are 'error.log' and 'event.log'. Select the desired item to proceed.

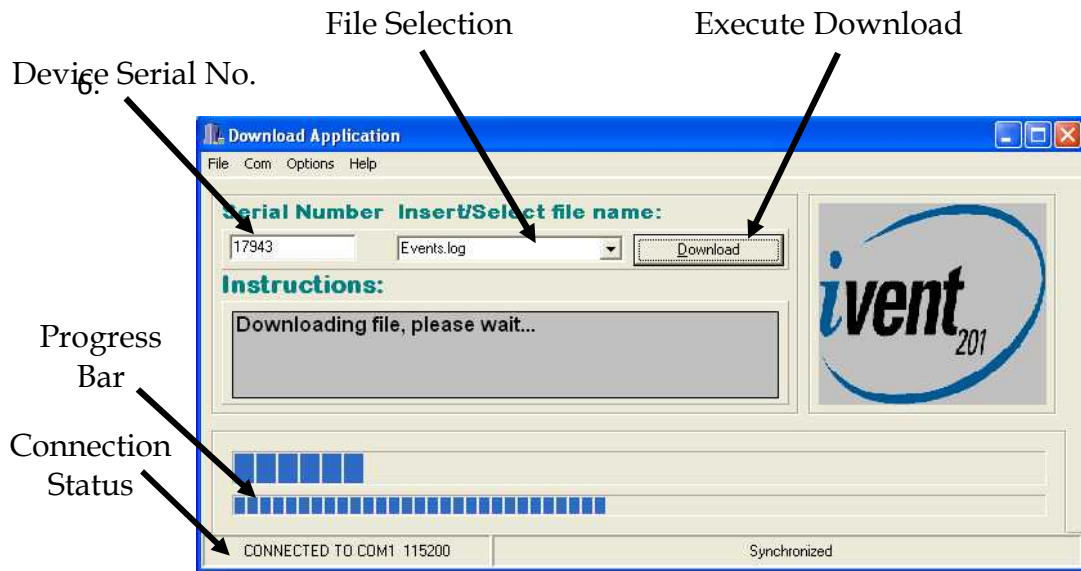


Figure 10-2 iVDownload Application Window

7. When the desired file has been selected click on 'Download' in order to execute the download procedure.
8. During the download the progress bar will indicate the status. The speed of the download will depend upon the number of logs and the connection speed.
9. When complete 'Download Successful' will be displayed in the instructions window.
10. On completion the downloaded file will be placed into the same folder location as the download application. The file will be addressed with the device serial number, file type (error or event log) and the date of the download.

```

4/24 3:21:26- Silenciar Alarma
4/24 3:21:26- Silenciar Alarma
4/24 3:21:26- Silenciar Alarma
4/24 4:01:18- Silenciar Alarma
4/24 4:02:50- Alarma: Presión alta
4/24 4:03:07- Alarma: Presión alta
4/24 4:03:24- Alarma: Vt no Deliverado
4/24 4:48:05- Alarma: Presión alta
4/24 4:48:59- Alarma: Presión alta
4/24 4:49:06- Alarma: Vt no Deliverado
4/24 4:49:23- Alarma: Presión alta
4/24 4:49:35- Alarma: Vt no Deliverado
4/24 4:49:50- Alarma: Presión alta
4/24 4:50:38- Alarma: Presión alta
4/24 4:51:46- Alarma: Presión alta
    
```

Figure 10-3 Event Log

11. To view the downloaded 'event.log' file navigate to the relevant folder and double click.

12. The file will open in a notepad window and will be displayed in the devices local language. All events will be time and date stamped as shown in fig 10.3.
13. To view the downloaded 'error.log' file navigate to the relevant folder and double click.
14. The file will open in a notepad window and will be displayed in English language. All errors will be time and date stamped and will list the current software version and the relevant error message.

```

->19.15.02 b1d 5 - 4/14 12:08:46 - 205109221 - spurious int 1.00 0.00 --
->19.15.02 b1d 5 - 4/14 12:18:37 - 59452 - Calibration Screen entered --
->19.15.02 b1d 5 - 4/14 12:27:12 - 162569 - Calibration has been saved --
->19.15.02 b1d 5 - 4/14 12:28:07 - 173394 - Calibration Screen entered --
->19.15.02 b1d 5 - 4/14 12:28:10 - 174090 - Cal Flow low flow Fail: 2035. 18.00! --
->19.15.02 b1d 5 - 4/14 12:28:29 - 177828 - Calibration has been saved --
->19.15.02 b1d 5 - 4/14 12:33:54 - 242956 - Irregular count 42.00 of 82.00, Module MON --
->19.15.02 b1d 5 - 4/14 12:33:54 - 242956 - Irregular count 42.00 of 82.00, Module MON --
->19.15.02 b1d 5 - 4/14 12:33:54 - 242958 - watchdog has activated : 0.00 ! --
->19.15.02 b1d 5 - 4/23 23:18:11 - 8442770 - O2 system failure: Bad raw flow diff 0.2 ! --
->19.15.02 b1d 5 - 4/23 23:49:05 - 8813462 - O2 system failure: Bad raw flow diff 0.9 ! --
->19.15.02 b1d 5 - 4/24 3:06:59 - 11188326 - O2 system failure: Bad raw flow diff 0.3 ! --
->19.15.02 b1d 5 - 4/24 3:21:12 - 11358950 - O2 system failure: Bad raw flow diff 1.0 ! --
->19.15.02 b1d 5 - 4/24 4:00:54 - 11835370 - O2 system failure: Bad raw flow diff 1.0 ! --
->19.15.02 b1d 5 - 4/24 4:53:14 - 12463314 - O2 system failure: Bad raw flow diff 0.4 ! --
->19.15.02 b1d 5 - 4/24 8:08:49 - 14810242 - O2 system failure: Bad raw flow diff 0.6 ! --
->19.15.02 b1d 5 - 4/24 8:13:01 - 14860620 - O2 system failure: Bad raw flow diff 0.3 ! --
->19.15.02 b1d 5 - 4/24 8:30:22 - 15068886 - Sensors Disc: Vol=-1593, SPr=7.45! --
->19.15.02 b1d 5 - 4/24 8:30:22 - 15068886 - BACKUP-MODE-ACTIVATED!!!! --
->19.15.02 b1d 5 - 4/24 8:31:47 - 15085809 - BACKUP-MODE was restored Manually --
->19.15.02 b1d 5 - 4/24 11:37:39 - 51553 - O2 system failure: Bad raw flow diff 0.3 ! --
->19.15.02 b1d 5 - 4/24 20:07:35 - 6170701 - O2 system failure: Bad raw flow diff 0.9 ! --
->19.15.02 b1d 5 - 4/25 2:19:02 - 10628151 - O2 system failure: Bad raw flow diff 1.0 ! --
->19.15.02 b1d 5 - 4/25 2:41:44 - 10900399 - O2 system failure: Bad raw flow diff 1.0 ! --
->19.15.02 b1d 5 - 4/25 2:54:05 - 11048669 - O2 system failure: Bad raw flow diff 0.6 ! --
->19.15.02 b1d 5 - 4/25 2:57:10 - 11085601 - O2 system failure: Bad raw flow diff 0.2 ! --
->19.15.02 b1d 5 - 4/26 12:26:07 - 3308839 - calibration Screen entered --

```

Figure 10-4 Error Log

15. It is recommended that the Error and Event logs should be downloaded during every ventilator repair and retained on file.
16. When working with the assistance of the VersaMed technical support team it is always highly recommended that both the error and event log be submitted for evaluation.

**NOTE: DURING THE PROCESS OF SOFTWARE UPDATING THE ERROR LOG WILL BE ERASED. IT IS THEREFORE RECOMMENDED THAT THE LOG FILES BE DOWNLOADED PRIOR TO ANY SOFTWARE UPDATE.**

## 10.6 Ventilator Software Upgrade Procedure

Periodically it may be necessary to upgrade the operating system software inside the ventilator system. This may be required to implement new features, and product enhancement or for correction of recognized issues.

To facilitate the installation of new operating software a proprietary installation application must be used. A new application will become available with each new

software release and will be distributed through normal channels with an accompanying Installation instructions document.

**WARNING:** This update must be installed by a GE Authorized representative or by service personnel having experience with this type of equipment.

- Notes:**
- 1. IMPORTANT:** Upgrading iVent™201 Ventilators, which has System SW <19.17.01, will require "Full Calibration", per Section 7: of the iVent™201 Service Manual, after the installation of SW 19.18.02 (reference "Installation Requirements" table below).
  - 2.** Upgrading an iVent™201 Ventilator, which has System SW < 18.05, requires installation of System SW 18.05 (reference TRM Section 10), prior to the installation of System SW 19.18.02. System SW 18.05 is included on the 19.18.02 CD, which is included in this kit.

### 10.6.1 Installation Requirements

SW Version	Pre-Installation		Post Installation		
	Requires installation of SW 18.05 (reference TRM Section 10) before installation of SW 19.18.02	Requires installation of SW 19.18.01 PART1 (reference “19.18.02 Software Update” In This document) before installation of SW 19.18.02	Full Calibration per Service Manual Section 7	OVT per Operator’s Manual Section 7	VVT per Operator’s Manual Section 7
19.18.01	-	-	-	X	X
19.17.01 and 19.17.02	-	X	-	X	X
18.05 to 19.16.02	-	-	X	X	X
< 18.05	X	-	X	X	X

### 10.6.2 Parts List for System Software 19.18.02 upgrade kit

Part Number	Description
M1221264	iVENT 201 SW VERSION 19.18.02

Tools required for updating to SW version 19.18.02

- A PC with Windows 95 or above.
- RS232 cable; Part number M1185020
- 19.18.02 SW Kit (CD); Part number M1221264

### 10.6.3 Software Update

1. Connect the iVent™201 to AC power and turn on the iVent™201. Place the iVent™201 in the “Stand by” mode (Reference URM Section 3)

2. Connect \*RS232 Null Modem Cable (P/N M1185020) to the COM 1 communication ports of the iVent™201 and the COM port of PC. Where the iVent™201 is equipped with 2 ports (Com1/Com2) Com1 must be used for software updates.

\* For local purchase: RS 232 Null Modem Cable DB9 F-F

Many laptops currently available are not equipped with serial communications ports and in such cases it will be necessary to use an appropriate adapter. USB to RS232 Serial adapters are the most commonly available and easiest to use of these adapters.

If you are upgrading from SW version 19.17.01 or 19.17.02 please go to section 3 below; else continue to section 4.

3. Insert the 19.18.02 CD into the PC.

First extract the installation software by opening the "install 19.18.01 PART1" folder.

To install 19.18.01 PART1 on an iVent™201, launch the "iVent v19.18.01 b\_PART1.exe"

Follow instruction in the pop up window and click the install button at the bottom of the window. This will "install" the '19.18.01 b\_PART1' icon on your desktop.

WARNING: You must install PART1 before installing 19.18.02, and complete the

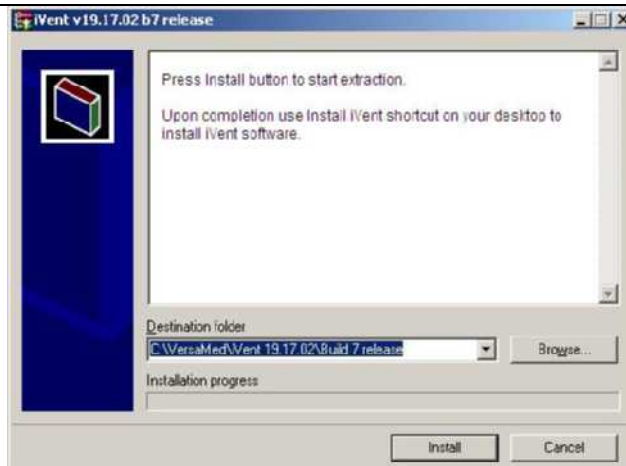
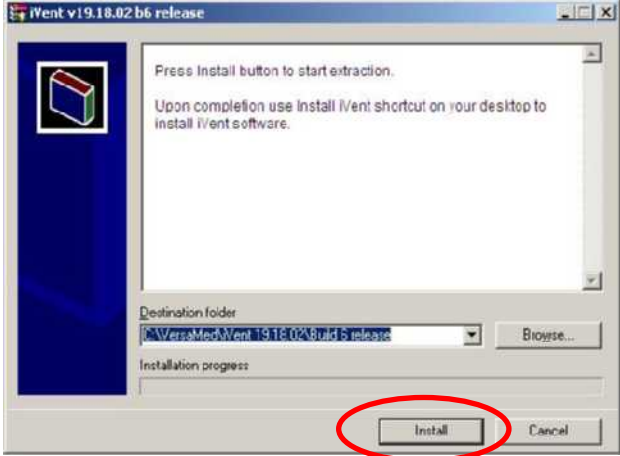


Figure 10-5 Software Installation screen (for SW version 19.17.01 or 19.17.02)



<p>installation of both versions. Failure to perform these actions may result in improper operation of the device and/or the presence of nuisance errors.</p>	
<p>4. Insert the 19.18.02 CD into the PC. Extract the installation software by opening the "Install full 19.18.02" folder. To install 19.18.02 on an iVent™201, launch the "iVent v19.18.02 b6 release.exe" file. Follow instruction in the pop up window and click the install button at the bottom of the window. This will "install" the '19.18.02 b6 release' icon on your desktop.</p>	 <p style="text-align: center;"><b>Figure 10-6 Software Installation Screen</b></p>
<p>5. Repeat the following steps by activating the Install applications (Icons located on your desktop) for "Install iVent v19.18.01 b__PART1" and "Install iVent v19.18.02 b6 release".</p>	

6. The following application window appears after clicking the install Icon on the desktop.

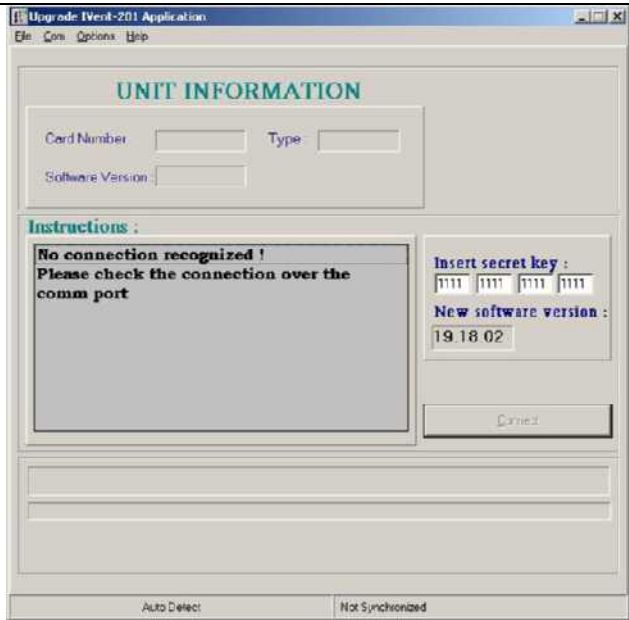


Figure 10-7 Software installation application

7. On the main menu choose menu option "Com". Select PC Com Port and Baud Rate. Typical;  
 Port = Com 1  
 Baud Rate = 115,200  
 Network connection will be established and the following message will appear on the "Instructions box".

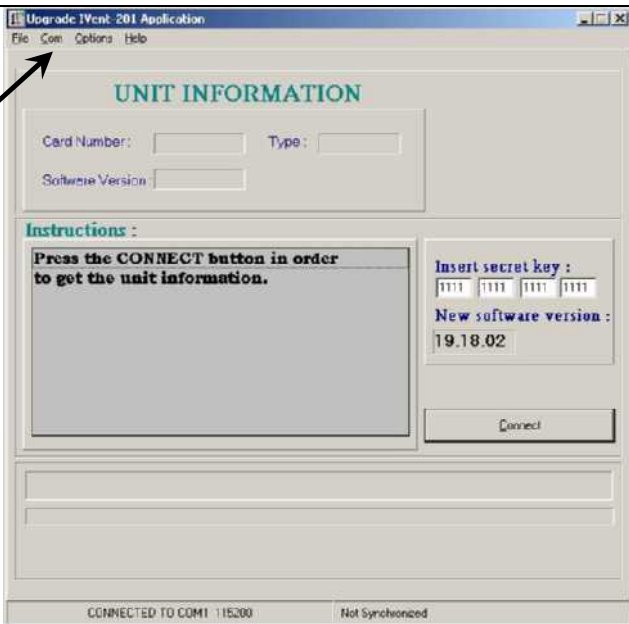


Figure 10-8 Software installation application – establish connection

8. Press the "Connect" button on the software application. The machine information will populate "Unit Information" and instructions for the SW installation will appear in "Instructions" box.
9. Verify the following:  
 For 19.18.02 installation - SW Version is different then 19.17.01 or 19.17.02.  
 For 19.18.01 PART 1 installation - SW Version is 19.17.01 or 19.17.02

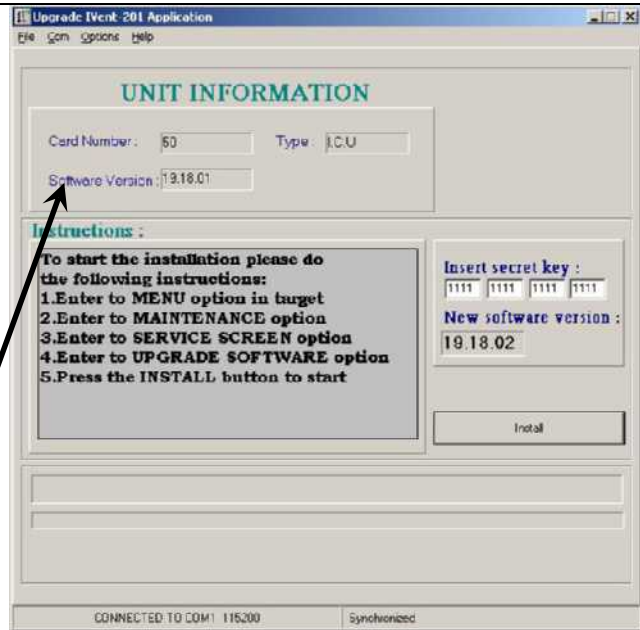


Figure 10-9 Software installation application – Connection established

10. On the iVent™201 screen, select "Menu" and then select the Maintenance option.



Figure 10-10 iVent maintenance menu






<p>11. A message appears that only authorized person can enter the restricted Maintenance area.</p> <p>12. Select " Yes" and the Maintenance window appears.</p>	 <p>The screenshot shows a red warning dialog box with the text: "Caution: Restricted Maintenance Area used by service personnel ONLY. Do you wish to continue?". There are "Yes" and "No" buttons at the bottom of the dialog. The background shows the iVent control panel interface with various parameters like Rate, U, and SIMU Uctrl.</p>
<p>13. Select the "Service Screen" option and the Service Screen window appears.</p> <p>14. Select "Upgrade Software Version". The Upgrade Software Version window will appear.</p>	 <p>The screenshot shows the "Service Screen" window. It lists several options: "Communication Port Com 1", "Communication Rate 115200", "Upgrade Software Version" (which is highlighted), "Update Package Key", and "Reset Battery LMD 66". There is a "Close" button at the bottom.</p>
<p>15. The iVent™201 is ready for upgrading.</p>	 <p>The screenshot shows the "Upgrade Software Version" window. It displays the text "Ready to start installation" and has a "Cancel" button at the bottom.</p>
<p>16. Press the "Install" button on the software</p>	

Figure 10-11 iVent Maintenance warning message

Figure 10-12 iVent Service Screen

Figure 10-13 iVent is ready for upgrading

<p>application. (PC screen) 17. Installation will begin.</p>	
<p>18. When software update is completed, the iVent™201 restarts and a system message appears: "Installation completed successfully". Make sure that a successful installation message appears and press OK. Note: If you installed 19.18.01 PART1, after completing the installation the iVent™201 will display a "Warning" message "NOT FOR CLINICAL USE!" After completing SW version 19.18.02 installation, this message will clear.</p>	 <p style="text-align: center;"><b>Figure 10-14 Installation completed message</b></p>
<p>19. Go to: Menu → Maintenance (Yes) → Configuration Screen → Software version. 20. Verify software version is 19.18.02 21. If 19.18.01 PART1 installation was required</p>	

<p>return to Step 5 and start SW version 19.18.02 installation</p> <p>22. After completing SW version 19.18.02 installation perform the following "Checkout Procedure".</p>	<p><b>Figure 10-15 iVent configuration screen</b></p>
---	---

### 10.6.4 Checkout Procedure

Once system software version 19.18.02 has been successfully installed it is required that the following actions be performed.

1. Enter the advanced settings menu and reset the date and time to reflect the current actual date and time - Reference User's Manual Section 4.

**Note:**

If at a later date, a date or time is entered which precedes the date of last calibration a need calibration ('Need Cal') notice may occur although calibration data will not be corrupted.

Rerunning the calibration procedures will erase this error message.

2. Perform the following tests based on the SW version that was updated.

SW Version	Pre-Installation		Post Installation		
	Requires installation of SW 18.05 (reference TRM Section 10) before installation of SW 19.18.02	Requires installation of SW 19.18.01 PART1 (reference "19.18.02 Software Update" In This document) before installation of SW 19.18.02	Full Calibration per Service Manual Section 7	OVT per Operator's Manual Section 7.4	VVT per Operator's Manual Section 7.5.2
19.18.01	-	-	-	X	X
19.17.01 and 19.17.02	-	X	-	X	X
18.05 to	-	-	X	X	X

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19.16.02					
< 18.05	X	-	X	X	X

Released

# Section 11: Service & Repair Procedures

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.

During reassembly of the iVent™201 or any of its subcomponents take care to inspect and reconnect all electrical grounds that have been previously disconnected.

## 11.1 Introduction

This section of the iVent™201 service manual describes in detail how to repair the ventilators major subassemblies and their major components. These repair procedures will include removal and installation where applicable.

This section does not provide a complete breakdown of all assemblies or complete disassembly, rather disassembly to what the manufacturer deems necessary and reasonable. Repair procedures are provided for all major assemblies and a complete illustrated parts breakdown is included in section Section 13: of this document.

## 11.2 Repair Safety

When servicing the iVent™201 ventilator system, be sure to familiarize yourself with and adhere to all posted and stated safety warning and caution labels on the ventilator and its components. Failure to adhere to such warnings at all times may result in injury or property damage

To prevent patient injury do not use the ventilator if it requires repair.

To prevent personal injury or death, do not attempt any service to ventilator while a patient or other person is connected to it.



To prevent electric shock hazard always ensure that all electrical power has been removed from device prior to commencing service. This statement requires that not only mains power be removed but also the devices internal batteries and any external DC source as applicable. If the device must be serviced with the power on be careful to avoid electrical shock. At all times follow accepted safety practices for electrical equipment when performing any repairs.

To prevent possible personal injury, always ensure that the high pressure oxygen source has been disconnected.

To prevent possible personal injury and equipment damage never attempt to push or pull a ventilator installed on its stand with the brakes set on.

To prevent possible personal injury and equipment damage, if the device is being serviced while on its stand, always ensure that the brakes are set on to prevent inadvertent movement.

## 11.3 Repair Guidelines

The following general guidelines should be considered at all times when performing service to the iVent™201 ventilator system.

Follow repair safety guidelines at all times.

Much of the hardware on the ventilator system is metric sized. Always ensure that only metric tools are used when performing service. Use of non-metric tooling may result in damaged hardware.

To prevent any possible damage caused by electrostatic discharge always ensure that appropriate ESD guidelines are followed when performing service to the equipment.

Use only recommended tools, test equipment, and service materials when servicing the ventilator.

When performing service take precautions to prevent dirt and other particles from entering the ventilator interior, particularly the pneumatic manifold assemblies.

Inspect any removed parts including those removed to gain access to a suspected faulty component. Inspect and clean the exposed area behind removed parts as required. Clean removed parts to facilitate further inspection.

Investigate and determine the cause of any detected abnormality. Repair the unit or consult your local VersaMed technical support location for assistance on unsolved problems.

Replace or repair any parts which are found to be worn, missing, damaged, cracked or otherwise show signs of any physical abnormalities.

## 11.4 Cleaning

If needed, follow these general cleaning guidelines when cleaning the ventilator during servicing. Procedures for periodic cleaning and sterilization of the ventilator and accessories are listed in the iVent™201 ventilator system user manual. Specific procedures for periodic cleaning and inspection done during the ventilators planned maintenance are listed in the relevant section of this manual.

Clean ventilator exterior surfaces before disassembly. Use isopropyl alcohol, a bactericidal agent, or a mild detergent and warm water solution, and a clean, lint-free cotton cloth.

Vacuum ventilator interior using ESD-safe equipment. Do not clean the ventilator interior with high pressure air.

During disassembly, clean parts as necessary with isopropyl alcohol. Any excessively dirty items which cannot be cleaned should be replaced.

## 11.5 Electrical Cables and Pneumatic Connections

To ensure correct reassembly of the device take note of or label wire or tube positions before disconnecting parts. Make sure that all tubes and harnesses are correctly installed and do not interfere with and cannot be damaged by any moving parts.

## 11.6 Electro-Static Discharge (E.S.D) Control

It is important to follow appropriate ESD control procedures whenever the ventilator system is being serviced. The following represents the minimum level of ESD precautions which we would expect to be followed during service to the iVent™201 ventilator system.

### 11.6.1 General Information

ESD can permanently damage ESD-sensitive microelectronic components or assemblies when they are handled and even when no direct contact is made with the component or assembly. ESD damage may not be immediately apparent, however, ESD damage will show up at a later time, either as a premature failure of a component or assembly, or as an intermittent failure, which can be difficult and time consuming to locate.

## 11.6.2 Procedures and Precautions

Follow these minimum procedures and precautions to prevent ESD damage to the ESD sensitive microelectronic components and assemblies of the iVent™201 ventilator system.

*Use a personnel grounding system.* Before opening the ventilator enclosure, ensure that a personnel grounding system (incorporating wrist strap, static-dissipative mat and ground cord) is worn correctly and is properly connected to reliable ground.

*Follow correct procedures for use of static dissipative mat.* Place tools, test equipment and the ESD sensitive device on the mat before starting any repairs. Conduct all work from the mat. Never place nonconductive items on the mat.

*Handle ESD-sensitive components properly.* Do not handle ESD-sensitive component connection points, connector pins, leads or terminals.

*Keep nonconductive materials away from work space.* Static charges from nonconductive material may not be removed by grounding. Items of this nature should be kept well clear of the work space when handling ESD sensitive devices.

*Follow correct procedures for static shielding bags.* Store and transport all ESD sensitive devices in the shielding bags all the time, except when being worked on. Never place more than one ESD sensitive device in a static shielding bag. Never place static generating nonconductive material inside a static shielding bag with an ESD sensitive device. Place any faulty ESD sensitive devices in a static shielding bag immediately after removal to prevent additional damage. Close and seal the bag to ensure that the shield is effective.

## 11.7 Non-Conforming Parts

When investigating reported problems identify the cause of the failure and repair / replace the component as necessary. Any failed, non-conforming parts, should be retained until the subject device has been successfully repaired. Following completion of the repair any non-conforming parts should be returned to the manufacturer to allow failure analysis to be performed.

To arrange for return of non-conforming parts contact your local dealer. The dealer will request and receive a returned material authorization from the manufacturer. Prior to returning non-conforming parts, the parts should be suitably packaged with a copy of any relevant service documentation enclosed.

Any printed circuit boards (PCB's) or similar electronic items MUST be packaged in appropriate electrostatic discharge resistant materials. Also note that any documentation accompanying these types of items must be left outside of the ESD packaging materials.

The return authorization number provided by the manufacturer should be clearly marked on all shipping documentation and on the exterior of the packaging.

## 11.8 Replacement Parts

To order correct parts identify the ventilator version and part, then using section 11 (Parts List) identify the manufacturers part number for the item. Should you find that the specific item is not available as a field replaceable unit (FRU) or that it is not stocked, order the next higher assembly. Retain the part to be replaced until the replacement part is obtained, and compare the two for compatibility, if possible.

## 11.9 Post Repair

After successfully completing any ventilator repair the following should be done prior to returning it to normal operation:

Visually verify that all pneumatic and electrical parts are properly connected and that all parts are properly installed. With a light tug, verify that connections are secure and that parts are securely attached. Listen for any uncharacteristic sounds (pneumatic leaks, vibrations, grinding, etc.). Check for any unusual odors.

Run the appropriate portions of the calibration procedures, VVT and any applicable functional tests (including electrical safety) before placing the ventilator back onto a patient.

Keep a detailed record of all maintenance performed on each device. Make sure that service records and other documentation are completed and maintained for the life of the product.

## 11.10 Repair Documentation

For convenience a service record sheet has been provided as an appendix to this manual. Repairs or any work performed on the device should be recorded on this sheet or similar and retained over the life of the product for future reference. To allow for tracking of product performance and attrition it is also requested that completed service sheets be forwarded to the manufacturer.

## 11.11 Patient System and Accessory Devices

For maintenance of the patient system and accessory items, consult the iVent™201 ventilator system operator's instructions and refer to the applicable accessory manuals.

## 11.12 Recommended Service Tooling and Materials

<i>Hand Tools:</i>	
Hexagonal Drivers, 3mm,	Local Supply
Open End Wrench, 11/16in, 9/16in,	Local Supply
Philips Screwdriver No 1, 2,	Local Supply
Flat Bladed Screwdriver	Local Supply
Socket Driver, 5mm, 7mm, 11mm	Local Supply
Pliers, Needle Nosed	Local Supply
Wire Cutters	Local Supply
Torque Wrench (0-10 Nm)	Local Supply
Static Dissipative Service Kit	Local Supply
Cable Ties, small	VersaMed, 356B2100-01
iVent™201 Wiring Diagram	iVent™201 Service Manual, page 59
iVent™201 Tubing Diagram	iVent™201 Service Manual, page 46 and 47

## 11.13 Service and Repair Procedures

### 11.13.1 Enclosure Disassembly

Front panel, Stepper Unit

VersaMed part number: 503A0213-A1

GE Part Number: M184448

Front panel, PSV unit

VersaMed part number: 503A0213-A2

GE part number: M1173403

Front panel, HSS unit

VersaMed Part number: 503HS213-01

GE part number: M1184449

1. Place the ventilator, face down, on an appropriate protective surface. (The foam inserts from the original iVent™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 11-1, page 171)
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 11-1, page 171).
5. Stand the unit back to an upright position and pull the front enclosure apart from the rear enclosure approximately 4 inches.
6. On all units, disconnect the three tubes (flow sensor (2), exhalation line) from the barbed fittings along the bottom of the inside of the front enclosure. Be sure to note where they were connected. (See Figure 11-3, page 172).
7. On PSV based units only, locate the nebulizer tubing at the front housing, make disconnection at the first union back from the front panel connector.
8. Disconnect the ribbon cable from the interface PC board located in the middle of the front enclosure. (See Figure 11-2 and Figure 11-3, page 172).
9. Disconnect the green ground wire and receptacle from the pneumatic unit (just above the outlet port).
10. Disconnect the inverter cable from the top of the electronic module. (See Figure 11-2 and Figure 11-3, page 172).
11. 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.**

12. 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.
13. Use the nutdriver to remove the (2) 4mm lock nuts from the LCD connector location on the front enclosure (see Figure 11-3, page 172). Remove the aluminum U-shaped bracket from the LCD connector site and pull out the LCD connector and cable.
14. Remove the aluminum U-shaped bracket from the LCD connector site and pull out the LCD connector and cable.

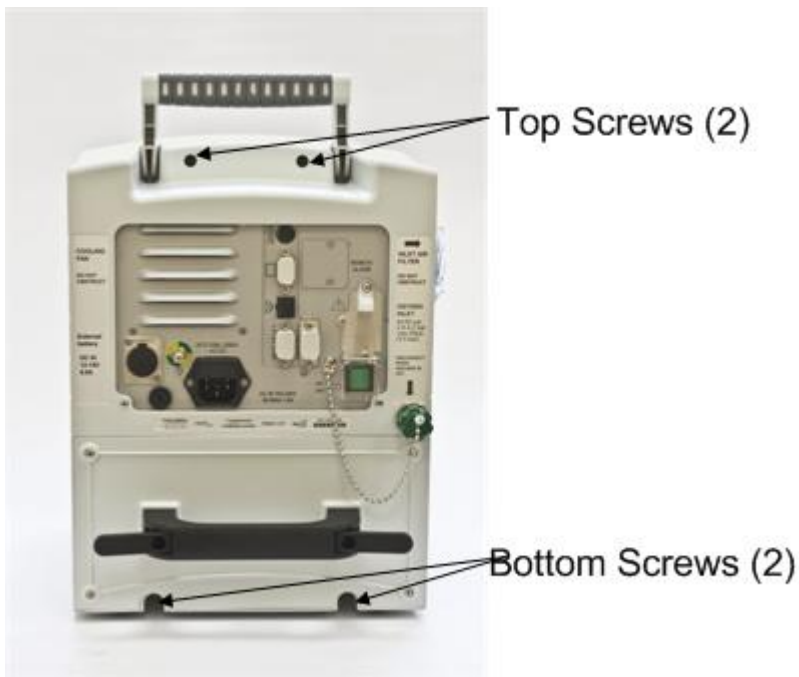


Figure 11-1 Enclosure (Rear View) #1

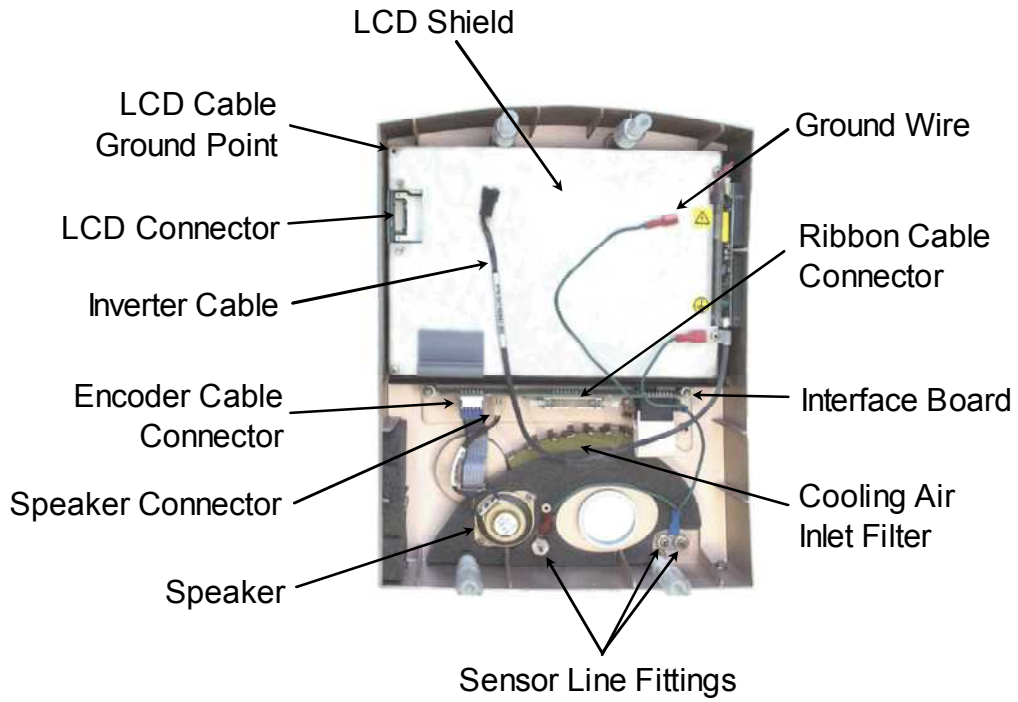


Figure 11-2 Front Enclosure (Inside View) #1

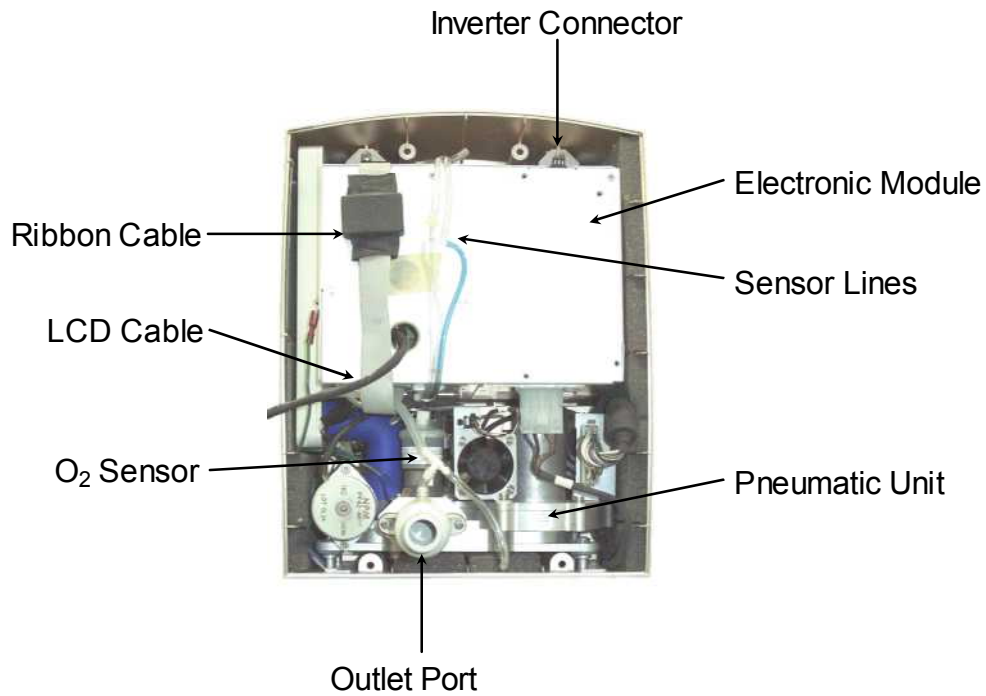


Figure 11-3 Rear Enclosure (Inside View) #1



### 11.13.1.1 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:
11. The tube from the outlet port tee is connected to the left-most fitting (when viewed from the inside).
12. The blue tube (or tube with a blue stripe) is connected to the right-most fitting.
13. The green tube (or tube with a green stripe) is connected to the exhalation line connector.
14. The remaining clear tube is connected to the nebulizer fitting.
15. Bring the front and rear enclosures together. Orient the tubing and cables so that none are kinked or crimped.
16. 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.**

17. Install the (2) 4mm x 30mm screws and lock washers to the bottom-rear of the enclosure.
18. Install the (2) 4mm x 50mm screws and lock washers to the top-rear of the enclosure.
19. 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.

### **11.13.2 Electronic Module Removal and Installation**

Electronic Module (Stepper)

VersaMed part number: 503A0420-C0

GE Part number: M1161024

Electronic Module (PSV)

VersaMed Part number: 503A0430-A0

GE Part number: M1161957

#### **11.13.2.1 Tools & Equipment**

- Screwdriver, Phillips, #2

#### **11.13.2.2 Electronic Module Removal**

1. Disassemble the front enclosure from the rear enclosure as outlined in Enclosure Disassembly, Section 11.13.1, page 169.
2. Unscrew the green O2 inlet cap from the DISS fitting on the rear of the unit (see Figure 11-4, page 175).
3. Facing the inside front of the rear enclosure; disconnect the green ground wire from the left-side of the electronic module (EM) (see Figure 11-5, page 176).
4. Disconnect the blower pressure sensing tube from the port on top of the outlet muffler.
5. On PSV units only, disconnect the two pressure sensing lines for the oxygen flow sensor by disconnecting at the plastic connectors.
6. On PSV units only, disconnect the supply for tubing for the nebulizer system by disconnecting at the plastic elbow.
7. Disconnect the connector from the top of the O2 sensor.

8. 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.
9. Disconnect the power pack connector from the bottom-right of the electronic module (EM).
10. Remove the (2) 4mm x 8mm screws and lock washers from the electronic module mounting plate located at the top of the electronic module.
11. Remove the (2) 3mm x 8mm Phillips head screws from the rear of the enclosure.
12. Pull the entire electronic module out from the front of the unit. Be sure to guide the O<sub>2</sub> 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 11-4 Enclosure (Rear View) #2**

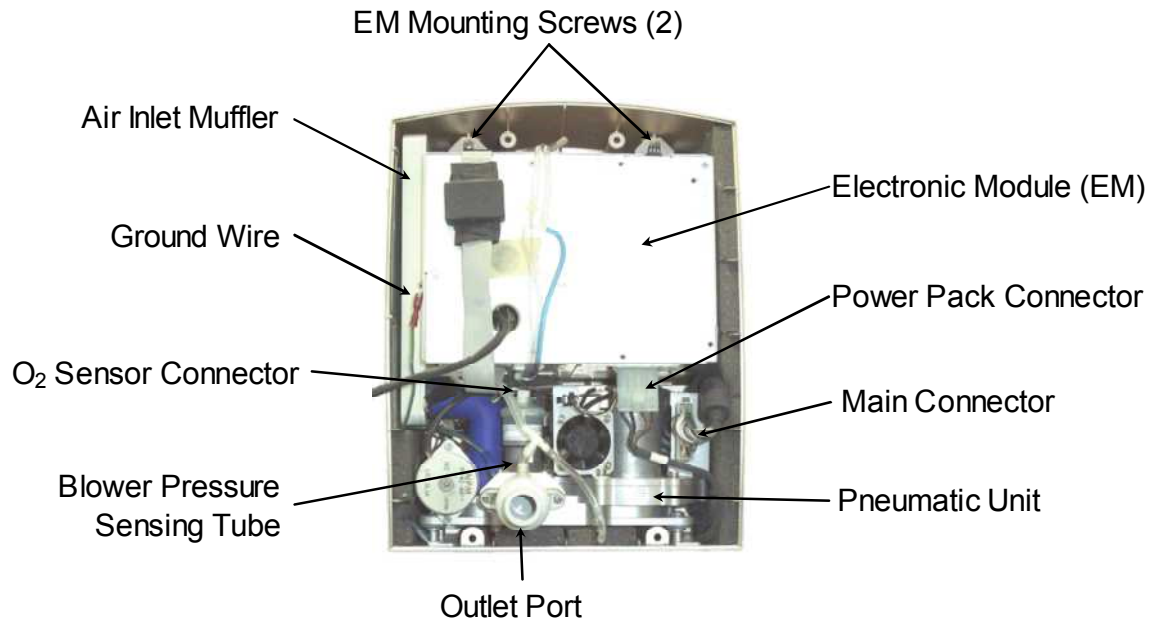


Figure 11-5 Rear Enclosure (Inside View) #2

### 11.13.2.3 Electronic Module Installation

1. Guide the O<sub>2</sub> 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 11-4 , page 175).
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 11-5, page 176).
6. Connect the O<sub>2</sub> sensor connector (marked cable #6) to the top of the O<sub>2</sub> sensor.
7. Connect the blower pressure sensing tube to the top of the outlet port.

8. On PSV units only, connect the two pressure sensing lines for the oxygen flow sensor to the plastic connectors.
9. On PSV units only, connect the nebulizer supply tubing to the plastic elbow connector.
10. Connect the main connector to the right-side of the pneumatic unit.
11. Connect the power pack connector to the bottom-right of the electronic module (EM).
12. Screw the green O<sub>2</sub> inlet cap to the DISS fitting on the rear of the unit.
13. Assemble the front enclosure to the rear enclosure as outlined in Enclosure Assembly, Section 11.13.1.1, steps 4-7 page 173.

### 11.13.3 Pneumatic Unit Removal and Installation

VersaMed part number for Stepper units: 503A0310-G0

GE part number: M1161178

VersaMed part number for PSV units: 503A0320-A0

GE part number: M1161955

#### 11.13.3.1 Tools & Equipment

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

#### 11.13.3.2 Pneumatic Unit Removal

1. Disassemble the front enclosure from the rear enclosure as outlined in Enclosure Disassembly, Section 11.13.1, page 169.
2. Remove the electronic module as outlined in Electronic Module Removal, Section 11.13.2.2, page 174.
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 (see Figure 11-6, page 178).
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. On Stepper units only, use the 11/16 inch and 9/16 inch Open-End wrenches to loosen and detach the DISS collar to the demand valve.
8. On PSV units only, disconnect the proportional solenoid valve from the O<sub>2</sub> manifold by pressing in on the black locking collar and withdrawing the tubing.
9. Identify the O<sub>2</sub> pressure switch type and disconnect the corresponding connector(s):
  10. For the silver colored metal switch which is threaded directly onto the O<sub>2</sub> inlet pipe: Follow the cable assembly coming out of the back of the pressure switch and disconnect the black 3-pin hanging connector.
  11. 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<sub>2</sub> pressure switch.
12. Disconnect the green ground wire assembly from the dual tabs located just above the outlet port.
13. Pull the pneumatic unit straight out of the rear enclosure.

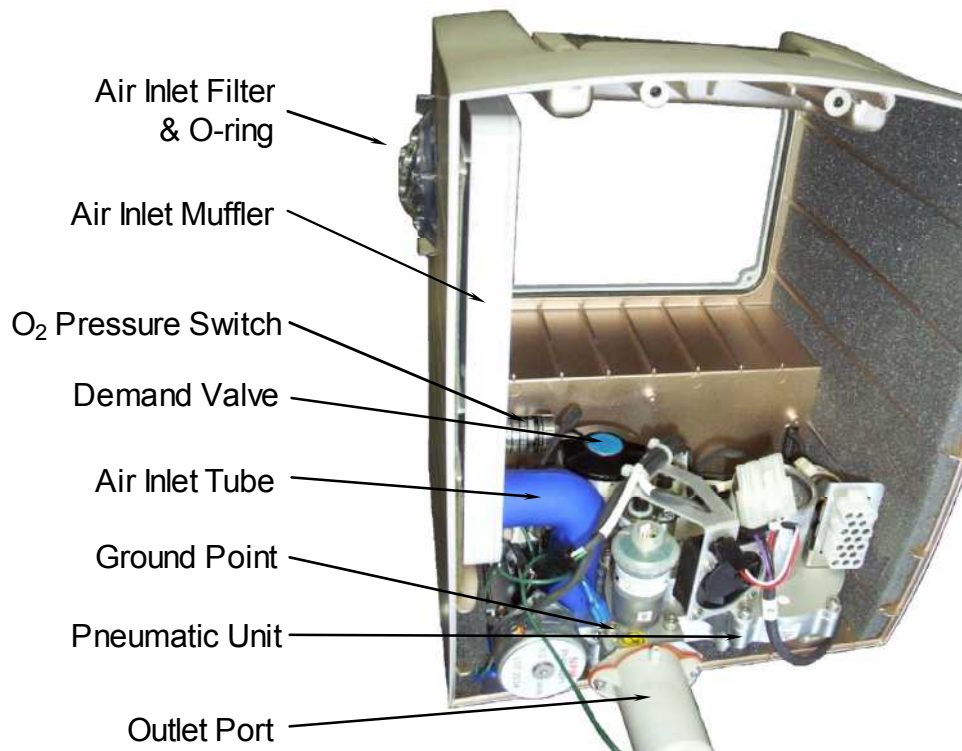


Figure 11-6 Rear Enclosure (Inside View) #3

### 11.13.3.3 Pneumatic Unit Installation

1. Rotate the shaft of the O<sub>2</sub> mixer stepper motor by hand so that the O<sub>2</sub> microswitch actuating arm is in the center of the high area of the cam (see Figure 11-7).



Figure 11-7 O<sub>2</sub> 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<sub>2</sub> 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.
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<sub>2</sub> TO THE REAR DISS INLET AND VERIFY THAT THE DEMAND VALVE SHUTS OFF AND DOES NOT AUDIBLY LEAK. DISENGAGE THE O<sub>2</sub> SUPPLY.**

8. Identify the O<sub>2</sub> pressure switch type and connect the corresponding connector(s):



**Figure 11-8 PU Ground Point Locations**

- Silver colored metal switch which is threaded directly onto the O<sub>2</sub> 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.
  - Brass colored metal body mounted to the back wall of the rear enclosure:
9. Connect the two (2) crimped receptacles coming from the back of pneumatic unit's main connector to the rear of the O<sub>2</sub> pressure switch.
  10. Connect the green ground wire and crimped receptacle onto the dual tabs located just above the outlet port.
  11. 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.
  12. Connect the blue air inlet tube to the outlet of the air inlet muffler.
  13. 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.**



14. Install the electronic module as outlined in Section 11.13.2.3, Electronic Module Installation, page 176.
15. Assemble the front enclosure to the rear enclosure as outlined in Section 11.13.1.1, Enclosure Assembly, page 173.

### 11.13.4 Power Pack Disassembly and Assembly

VersaMed part number: 503A0012-A0

GE Part number: M1161022

VersaMed part number for HS units: 503HS012-01

GE part number: M1161960

#### 11.13.4.1 Tools & Equipment

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

#### 11.13.4.2 Power Pack Disassembly

1. Remove the (4) 3mm x 20mm Phillips head screw from the corners of the power pack (see Figure 11-9).
2. Grasp the black handle of the power pack and pull it straight out from its compartment (see Figure 11-10).
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 11-9 Power Pack (Rear View)****Figure 11-10 Power Pack (Removed)**

### 11.13.4.3 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.

### 11.13.5 O<sub>2</sub> Sensor Removal and Installation

VersaMed part number: 130B0002-03

GE Part number: M1184213

### 11.13.5.1 Tools & Equipment

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

### 11.13.5.2 O<sub>2</sub> Sensor Removal

1. Disassemble the ventilator enclosure as outlined in steps 1-9 of Section 11.13.1.

**TIP:** *PERFORM STEPS 1-9 ONLY, SINCE THE LCD CABLE DOES NOT NEED TO BE DETACHED FOR THIS SERVICE.*



**Figure 11-11** The O<sub>2</sub> sensor location on the pneumatic unit

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<sub>2</sub> sensor.
4. Disconnect the grounding cable from the shield.
5. Remove the existing O<sub>2</sub> sensor by turning it counter-clockwise.
6. Remove the O<sub>2</sub> sensor from the adaptor by turning it counter clockwise.
7. Remove the tie surrounding the shield by pulling it from the O<sub>2</sub> sensor,
8. Turn aside the 3 legs holding the shield and pull the shield out.
9. Remove the sensor from the shielding holder.

### 11.13.5.3 O<sub>2</sub> Sensor Installation

1. Insert the sensor into shielding holder.
2. Insert the shielding into the shielding holder. Verify that the 3 legs of the shielding holder are outside the shield, as shown in Figure 11-12.

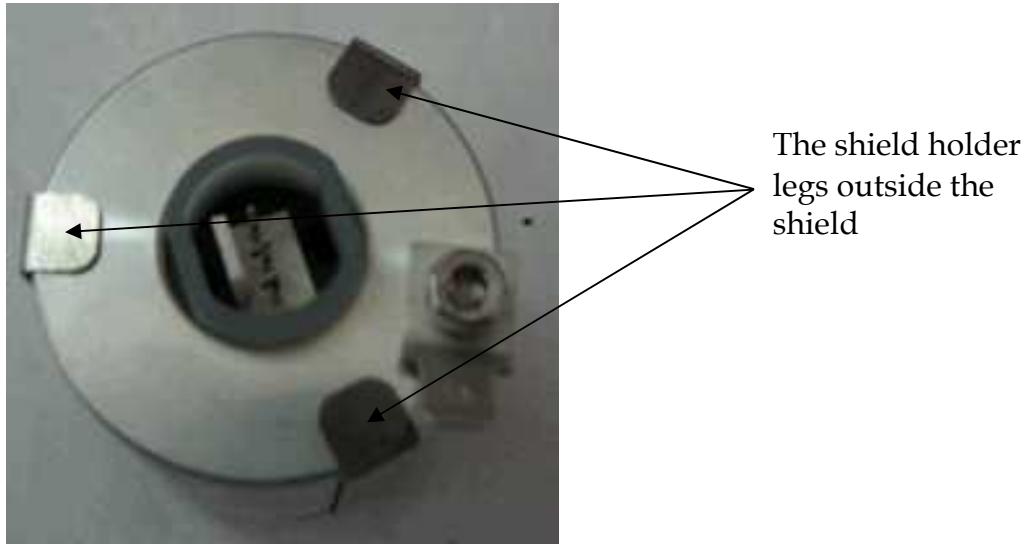


Figure 11-12 The Shield holder 3 legs

3. Install a tie around the legs of shielding holder.
4. Install the o<sub>2</sub> sensor on the adaptor by turning the adaptor clockwise.
5. Place the O-ring on the adaptor.
6. Install the replacement sensor and O-ring by screwing it clockwise into the pneumatic module.
7. Reconnect the gray cable to the O<sub>2</sub> sensor.
8. Reconnect the grounding cable to the shield.
9. Reinstall the blower sensor tubing to the barbed connector on top of the outlet port.
10. Assemble the ventilator enclosure as outlined in Section 11.13.1.1, page 173).

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

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# Section 12: Troubleshooting

## 12.1 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:

- 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.**

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

**NOTE: FILES SHOULD BE E-MAILED TO TECHSUPPORT@VERSAMED.NET**

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

**Table 12-1 Troubleshooting Guide**

Symptom	Observations	Possible Cause	Solution
Unit does not power up on AC power.	No continuity through the power switch terminals.	Defective Electronic Module.	Replace Electronic Module.
Unit powers up but does not boot up.	Green LED lights	Wrong software revision installed or installation was interrupted.	Replace Electronic Module.
		Defective Electronic Module.	Replace Electronic Module.
Unit powers up but restarts over and over again.		Defective Electronic Module.	Replace Electronic Module.
Unit blows AC fuse immediately upon power up.		Defective Electronic Module.	Replace Electronic Module.
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.
	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.
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.
	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.
Battery indicator displays empty after recharge and gas gage reconditioning.	Replacement Power Pack displays empty battery icon.	Defective Electronic Module.	Replace Electronic Module.
Unit displays Call Service/ Battery	Charge LED lights with AC power cord plugged	Power Pack fuse is blown.	Replace Power Pack fuse (15A).

Vent™201 Technical Reference Manual

Symptom	Observations	Possible Cause	Solution
Disconnect or Battery Damaged error.	in.		
Fails VVT, Battery check.		Battery capacity is inadequate.	Replace Power Pack or battery.
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.
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. If problem persist replace Front panel.
Control knob feels loose or worn out.		Encoder mounting shaft nut is loose.	Tighten Encoder mounting shaft nut. If problem persist replace Front panel.
Fails VVT, Solenoid failure.	Solenoid valves able to move mechanically. Error code 330 in technical log.	Defective Pneumatic Unit.	Replace Pneumatic Unit.
Fails VVT, Flow sensor leak.	Patient Circuit connections to the front panel are secure.	Pneumatic leak at sensing tubes connection.	Replace Patient Circuit.
		Defective Electronic Module.	Replace Electronic Module.
Fails VVT, Blower or Patient Pressure.	PIP reaches <65 cmH <sub>2</sub> O during VVT.	Unit out of calibration.	Recalibrate Zero Sensors and Pressure Sensors.
	PIP reaches <65 cmH <sub>2</sub> O during VVT and unit is calibrated.	Outlet Muffler is broken and leaking.	Replace Outlet Muffler. (Ventilator Outlet)
Fails VVT, O <sub>2</sub> Pr. Switch on 100%.	O <sub>2</sub> supply press. is 40 psi and above at all times.	O <sub>2</sub> supply pressure is less than 40 psi.	Raise O <sub>2</sub> supply pressure so that it is 40 psi or greater during the entire test.
Service Notice! Alarm after power up.	Error Code 307 in technical log.	O <sub>2</sub> system out of calibration.	Calibrate O <sub>2</sub> system.
		Defective O <sub>2</sub> sensor.	Replace O <sub>2</sub> sensor and recalibrate.
	Error Code 160 or 161 in technical log.	Inconsistent file size or file not found on reboot.	Device will restart with default parameter. If problem consists replace DOC.
	Error code 321 in technical log.	Analog to Digital converter response time too long	



Symptom	Observations	Possible Cause	Solution
Need Cal alarm after power up.	Error Code 306 in technical log.	O <sub>2</sub> system out of calibration.	Calibrate O <sub>2</sub> system.
Turbine is noisy.	Unit appears to pressurize normally.	Turbine is deteriorating mechanically.	Replace Pneumatic Unit.
No blower pressure or turbine doesn't turn.	Error Codes 345, 347 in technical log.	Defective Turbine	Replace Pneumatic Unit.
		Defective Electronic Module.	Replace Electronic Module
Fails O <sub>2</sub> Calibration.	Error Code 375 in technical log.	O <sub>2</sub> sensor range is inadequate.	Replace O <sub>2</sub> sensor.
Unit won't pass OVT.	Flow offset on graph.	Sensing lines of patient circuit partially contaminated with fluid.	Replace Patient Circuit.
Fails OVT, Patient Circuit Failed		Missing or non-functioning one-way valve	Replace Patient Circuit.
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.

## 12.2 Diagnostics and Repairs

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

### 12.2.1 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<sub>2</sub>O) 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<sub>2</sub> supply to the DISS fitting of the demand valve and apply 50 psi.
2. Initiate a flow through 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<sub>2</sub> intake port.

Earlier versions of the O<sub>2</sub> 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<sub>2</sub> 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:

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

**NOTE: WHEN THE DEMAND VALVE IS PROPERLY INSTALLED ONTO THE O<sub>2</sub> INLET PIPE ASSEMBLY, THERE SHOULD BE A 70MM DISTANCE FROM CENTER TO CENTER. (SEE FIGURE 12-1).**

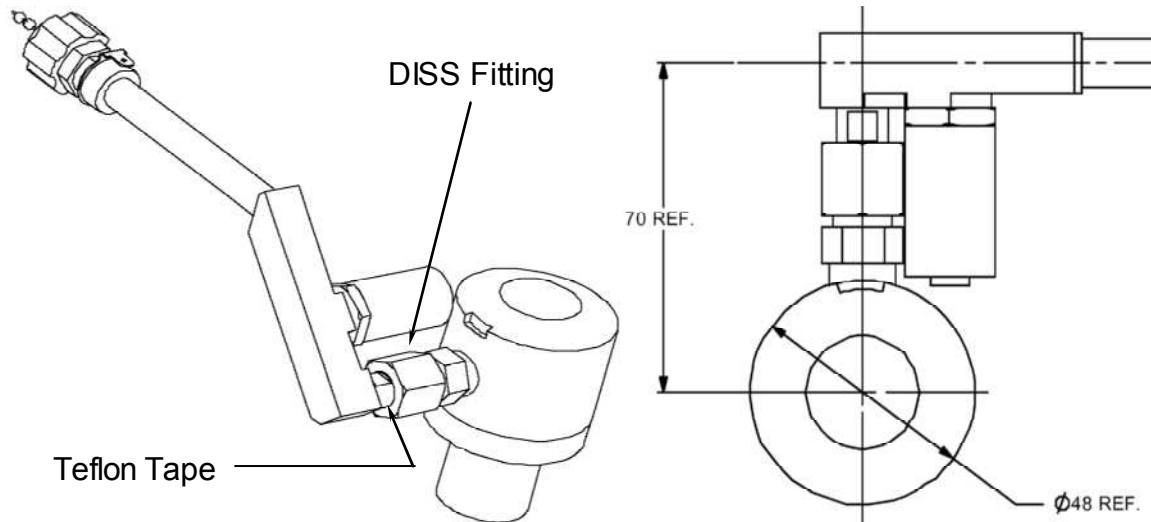


Figure 12-1 O<sub>2</sub> Inlet Pipe and Demand Valve

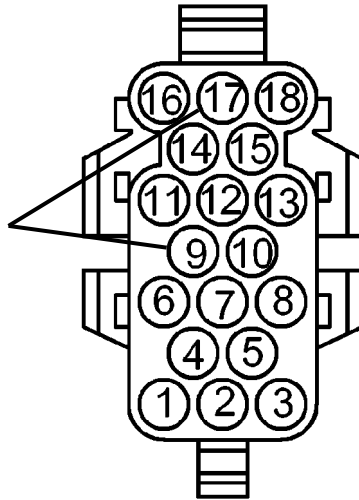
### 12.2.2 Pressure Switch

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<sub>2</sub>) and should close with the presence of high pressure O<sub>2</sub>.

1. With the unit powered off, disassemble the front enclosure as outlined in Enclosure Disassembly, Section 11.13.1, page 169.
2. Identify the O<sub>2</sub> pressure switch type and connect the ohmmeter to the corresponding connector contacts:
3. For the silver colored metal threaded directly onto the O<sub>2</sub> inlet pipe: Pins 1 & 2 (red wire & white wire).
4. 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<sub>2</sub> pressure switch type the switch terminals are connected to pins 9 & 17 in the PU main connector (see Figure 12-2).



**Figure 12-2 PU Main Connector (Front View) - Pressure Switch Pinout**

5. Reassemble the front enclosure to the rear assembly as outlined in Section 11.13.1.1, Enclosure Assembly, page 173.

### 12.2.3 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:

- Set up the ventilator and patient circuit as outlined in Section 6.3, page 95.
- Run the first part of the VVT as outlined in Section 6.4.1.1, Alarm Sound Tests, page 102, and Pressure Tests page 102 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.)
- 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 7.6.1, page 114 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.

### 12.2.3.1 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 11.13.1, Enclosure Disassembly, page 169. Do not disconnect any tubing or cables.

### 12.2.3.2 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 6.3.
2. Block the exhalation valve outlet (22mm male).
3. Run the first part of the VVT as outlined in Alarm Sound Tests page 102 and Pressure Tests page 102.

4. If Flow sensor leak is “Failed”, the cause is not the blower pressure or exhalation valve control tubes.
5. 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.

### 12.2.3.3 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 3.6, page 32.
2. Observe whether the flow offset on the flow graph is above or below the baseline (0 cmH<sub>2</sub>O).

**NOTE: THE FLOW GRAPH RANGE MAY NEED TO BE SET TO 60 TO GAIN ENOUGH RESOLUTION TO VISIBLY DETECT THE FLOW OFFSET.**

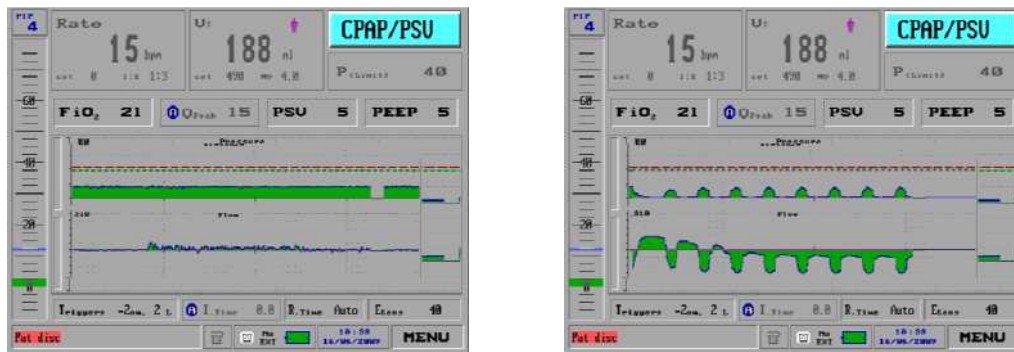
3. If the flow is above the baseline then the leak is along the left-side negative (-) port.
4. If the flow is below the baseline then the leak is along the right-side positive (+) port.

### 12.2.3.4 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 12-3).

If there is a leak in front of the occlusion, the flow graph will go negative or lie in the negative range (see Figure 12-3).



No Leak

Leak

Figure 12-3 Flow Graphs (Occluding the Positive Flow Sensor Port)

## 12.3 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.

### 12.3.1 Inhale VT Accuracy

The iVent™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<sub>2</sub>O. At the 70+ kg default settings the baseline for the tidal volume occurs at the 5 cmH<sub>2</sub>O PEEP value. After injecting another 700 ml into the test lung an additional 29 cmH<sub>2</sub>O is generated above the starting PEEP value. The result is a PIP (peak inspiratory pressure) of 34 cmH<sub>2</sub>O.

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.***

### 12.3.2 Exhale VT Accuracy Interferences

We will assume that the ventilator has been properly 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.

### 12.3.3 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 12.5, the flow graph will show a positive offset.

### 12.3.4 Velocity

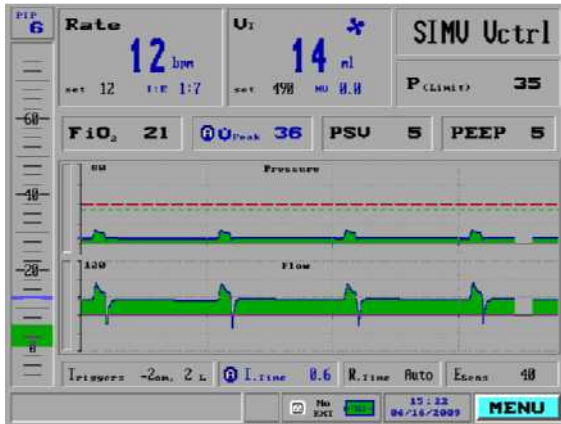
Any test load that can cause a high velocity exhale may create an artificially low exhale tidal volume measurement.

The high velocity flow from the test lung lowers the pressure of the first port (-port) creating an artificial lower exhale volume. The set of iVent™201 screen captures below (Figure 12-5) 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.

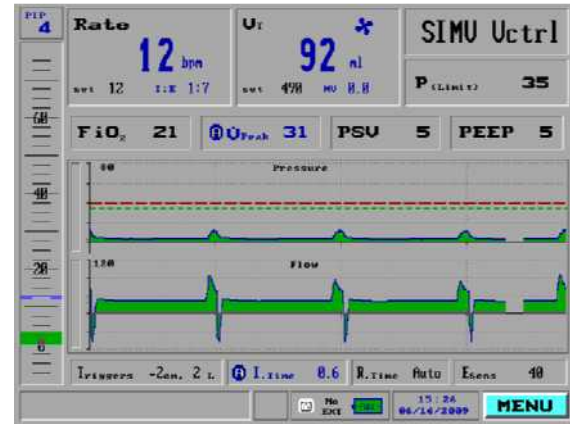


Clinically, this high amplitude, short period exhale waveform is most like a patient cough and is not a common steady state flow pattern.

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.



Test lung with 20Rp Resistor



Test lung without resistor

Figure 12-4 Flow Graphs (High Velocity Exhale)

### 12.3.5 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.

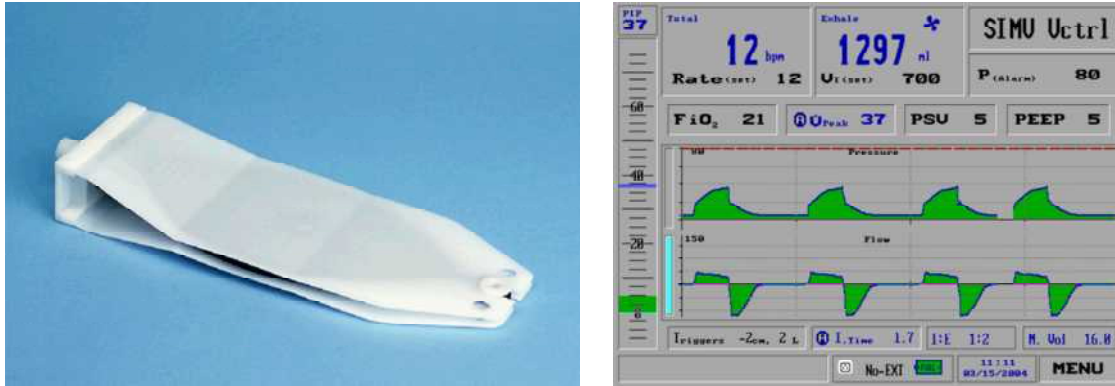


Figure 12-5 Test Lung 190 and iVent™201 Waveforms

## 12.4 Miscellaneous Issues

Some issues cause misleading symptoms, as described below.

### 12.4.1 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.

### 12.4.2 Fails Calibrate Flow Sensor

The unit fails the calibration step “Calibrate Flow Sensor,” but most of the time it is in fact an O<sub>2</sub> problem -- for instance, the O<sub>2</sub> mixer is in the 100% O<sub>2</sub> position and the unit cannot generate the flow that it needs.

### 12.4.3 Erratic O<sub>2</sub> Control

Normally, when a FiO<sub>2</sub> value is set, the unit will seek the targeted O<sub>2</sub> mix and stabilize. If the control or stability of O<sub>2</sub> 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<sub>2</sub> repeatedly becomes unstable, try setting the trigger sensitivities to Off and see if the O<sub>2</sub> control and minute volume stabilize.

#### 12.4.4 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 12.4.3). 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.

#### 12.4.5 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.

### 12.5 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<sub>2</sub>O 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<sub>2</sub>O)

Note: ***IF THE VENTILATOR IS CONFIGURED FOR EXTENDED RANGES THEN YOU CAN ADJUST THE PEEP TO 40 (CMH<sub>2</sub>O).***

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***

.

# Section 13: Spare Parts and Accessories

## 13.1 Introduction

This section of the manual has been provided as a reference for identification and ordering of spare parts primarily. Please read the information and descriptions carefully in order to ensure that you are identifying the correct items.

## 13.2 Hardware Versions

There are a number of hardware versions of the iV201 ventilator system available in the field. As this manual is intended to be generic to all versions of the product the following designations shall be used throughout this spare parts and accessories section:

Between iv12000 and iv14999	Denotes in general all devices with Stepper Motor based pneumatic system.
Between iv15000 and iv19999 or greater than 30000	Denotes all devices in with standard color configuration which are equipped with the PSV based pneumatic system.
Between iv20000 and iv29999	Denotes all devices in with the HHS color and hardware configuration.

**NOTE:** If trying to identify and order parts for units with a serial number of <iV2000, please contact your regional technical support contact for assistance.

## 13.3 Parts Lists

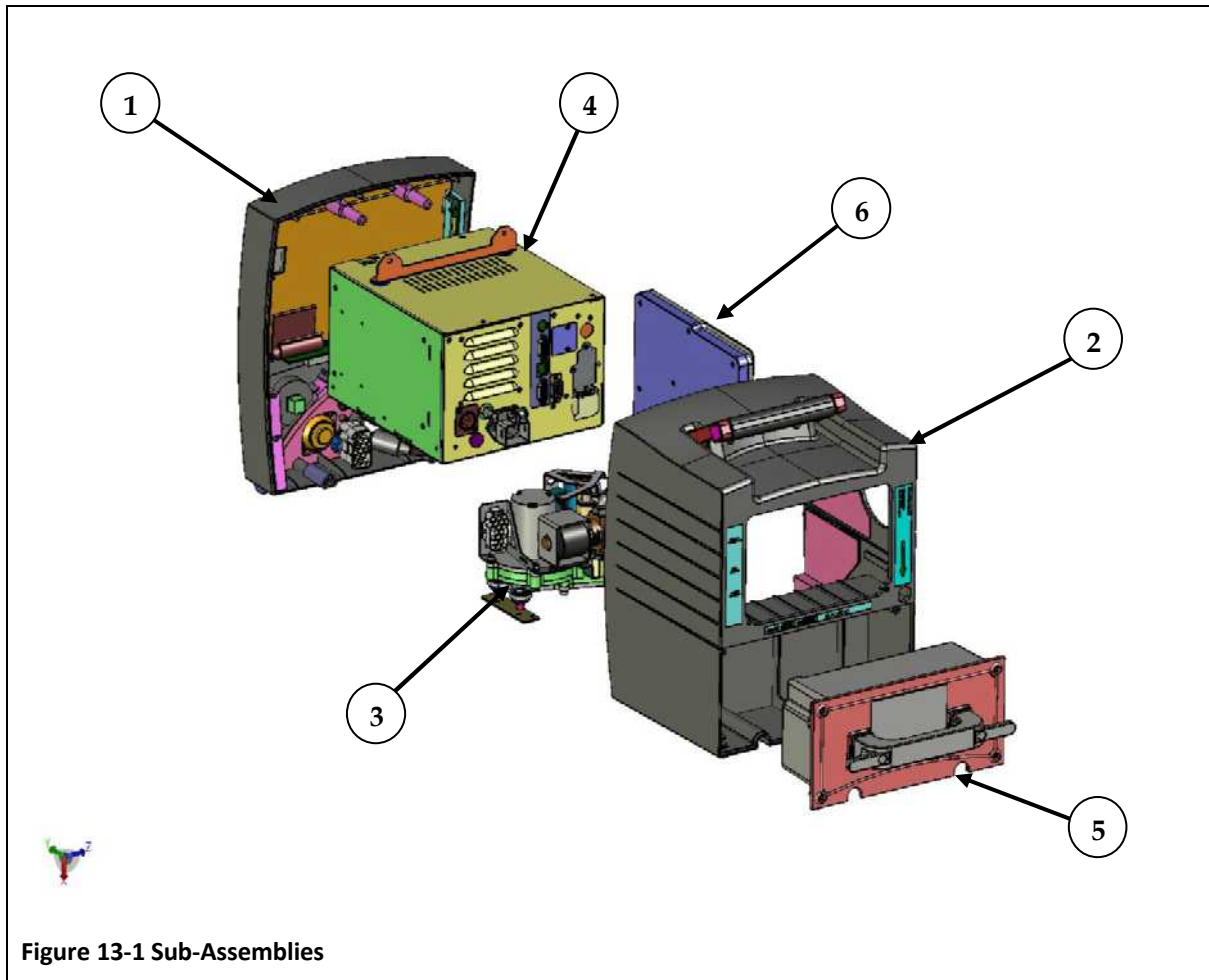
### 13.3.1 Ventilator Accessories

Part Number	GE Part Number	Description
660B0001-24	M1203387	Disposable Breathing Circuit, I type, box of 24
620B0006-20	M1161009	Disposable Breathing Circuit, Y type, box of 20
620B0008-02	M1161145	Multi-use Patient Breathing Circuit, Y type, 1 unit, Polysulfone Sensor and Silicone Tubing
620B0008-20	M1203385	Multi-use Patient Breathing Circuit, Y type, box of 20,
660A0001-12	M1161007	Air filter, inlet, box of 12, disposable
660L0001-12	M1161008	Low Pressure Oxygen Adaptor & Filter, box of 12, disposable
620B0009-01	M1162020	Valve Assembly, Low Pressure Oxygen
620B0010-01	M1162022	Reservoir Bag, 1 Liter, Low Pressure Oxygen
630B0001-02	M1162044	Roll Stand w/ Handle and Mounting Bracket
630B0013-01	M1206571	GCX roll stand
325A0554-01	M1206572	GCX MRI Oxygen Cylinder Holder
510S0005-A0	M1216062	MR-unsafe Basket
371C0010-01	M1212042	GCX MRI LOCKING CASTERS 3IN QTY 5
375A0145-01	M1212038	GCX MRI RAIL SET
146C0004-01	M1212040	GCX MRI HW SET
630B0003-A1	M1162046	GCX MRI TILT PLATE REPLACEMENT SET
630B0004-A1	M1162048	Breathing Circuit Support Arm
620B0001-01	M1162016	Oxygen Supply Hose, six (6) feet, DISS oxygen fittings

Part Number	GE Part Number	Description
620B0002-01	M1162017	Oxygen Supply Hose, fifteen (15) feet, DISS oxygen fittings
900K0004-01	M1162058	Calibration Kit (1 calibration syringe, 1 manometer, 2 test lungs, 2 Rp20 resistors, 1 stopper)
507A0052-C0	M1161989	Remote Alarm Interface for central alarm system (call for details) Normally Closed, 51K
507A0053-C0	M1161990	Remote Alarm Interface for central alarm system (call for details) Normally Closed, Phone Jack
507A0054-C0	M1161991	Remote Alarm Interface for central alarm system (call for details) Normally Open, Phone Jack
507A1020-A0	M1161996	D/C Power Cord – 12 volt vehicle adapter
507A1022-A0	M1161997	D/C Power Cord –12 volt clip-on adapters
910V0004-A0	M1161188	Pneumatic Resistor, 6mm, Rp20
910V0003-B0	M1162059	Pneumatic Resistor, 4mm, Rp50
375B0003-01	M1161882	Rolling Hard Case for Ventilator (NOT FOR SHIPPING)
375B0004-01	M1161883	Soft Case for Ventilator (Not compatible with H.S unit)
504A0110-A1	M1161967	Adaptor for Bio/Chemical Filter
920C0001-01	M1161170	Calibration Syringe – 500ml
920C0002-01	M1161184	Calibration Manometer
910V0005-01	M1162061	Test Lung, 2 Liter
32500004-A0	M1161821	Cap, Red
504A0051-A0	M1161011	External Battery Kit
630B0007-A1	M1162050	External Battery Holder for Roll Stand

Part Number	GE Part Number	Description
SM-01-04	M1162065	iVent™ 201 Service Manual
OM-01-04	M1162064	iVent™ 201 Operator's Manual

### 13.3.2 Sub-Assemblies



Ref	VersaMed Part Numbers	GE part Numbers	Description
01	503A0214-01	M1210301	FRONT PANEL, Stepper Unit
-	503A0213-A2	M1173404	FRONT PANEL, PSV Unit
-	503HS213-01	M1184449	FRONT PANEL, HSS Unit



Ref	VersaMed Part Numbers	GE part Numbers	Description
02	900K0109-01	M1161953	BACK PANEL ASSY (1.4)
-	503HS014-01	M1161961	H.S BACK PANEL ASSY
-	900K0111-01	M1219568	BACK PANEL ASSY (1.4), Stepper
03	503A0310-SP	M1161178	Pneumatic System, (Stepper)
-	503A0320-SP	M1161955	PNEUMATIC MODULE QB\L, PSV (PSV & H.S)
04	503A0430-A0	M1161957	ELECTRONIC MODULE ASSY, PSV
05	503A0012-SP	M1161022	POWER PACK ASSY
-	503HS012-SP	M1161960	H.S POWER PACK ASSY
06	504A0100-B0	M1161965	AIR INLET MUFFLER Q ASSY. (1.4)

**Additional parts (not shown in the figure):**

VersaMed Part Numbers	GE part Numbers	Description
130B0002-03	M1161179	O2 Sensor
900K0001-01	M1161168	1 Year PM KIT
900K0013-01	M1198074	1 Year PM KIT H.S
900K0003-03	M1182595	15k Kit H.S
900K0003-02	M1177690	15k Kit QB\L, PSV
900K0003-01	M1162057	15k Kit Stepper
900K0017-01	M1183858	On/Off Switch Cover Kit

### 13.3.3 Rear Panel Components

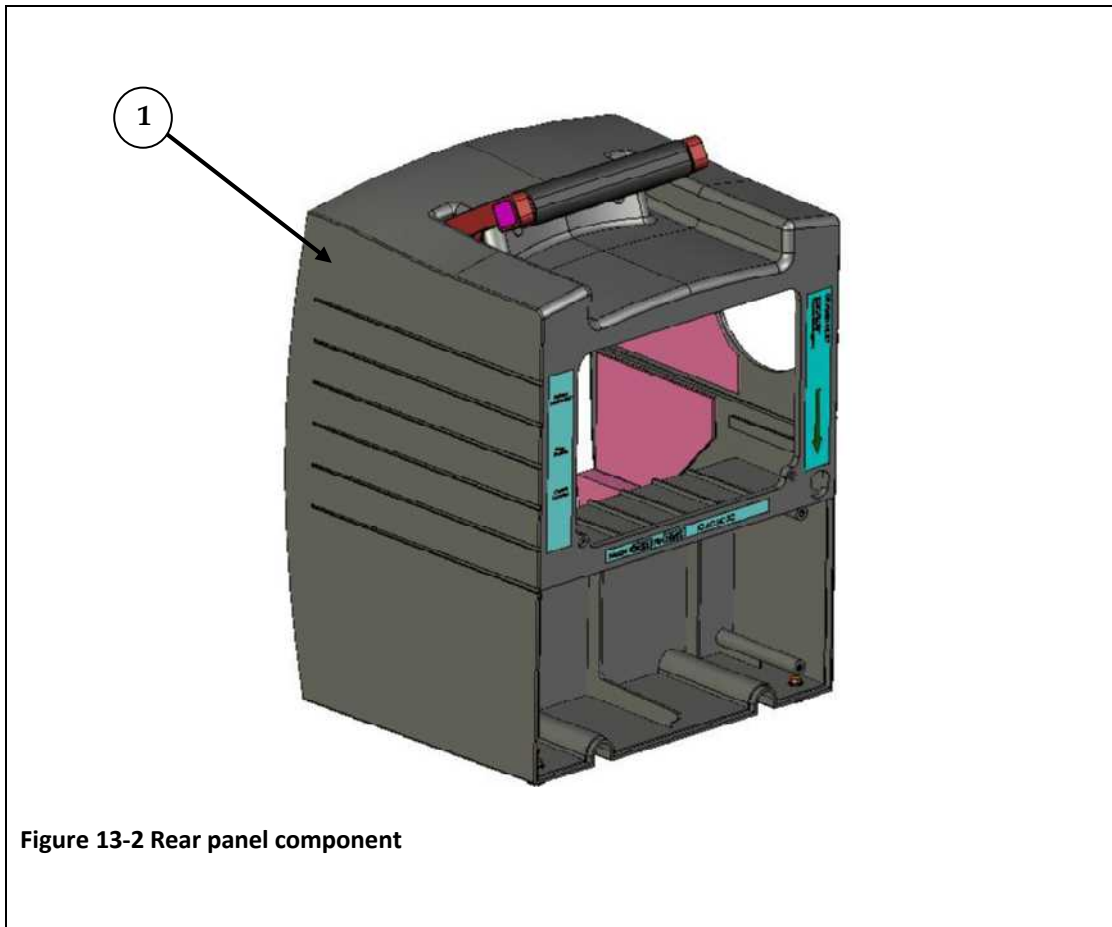


Figure 13-2 Rear panel component

Ref	VersaMed Part numbers	GE Part Numbers	Description
1	900K0109-01	M1161953	BACK PANEL ASSY (1.4)
-	503HS014-01	M1161961	H.S BACK PANEL ASSY
-	900K0111-01	M1219568	BACK PANEL ASSY (1.4), Stepper

### 13.3.4 Integrated Battery Components

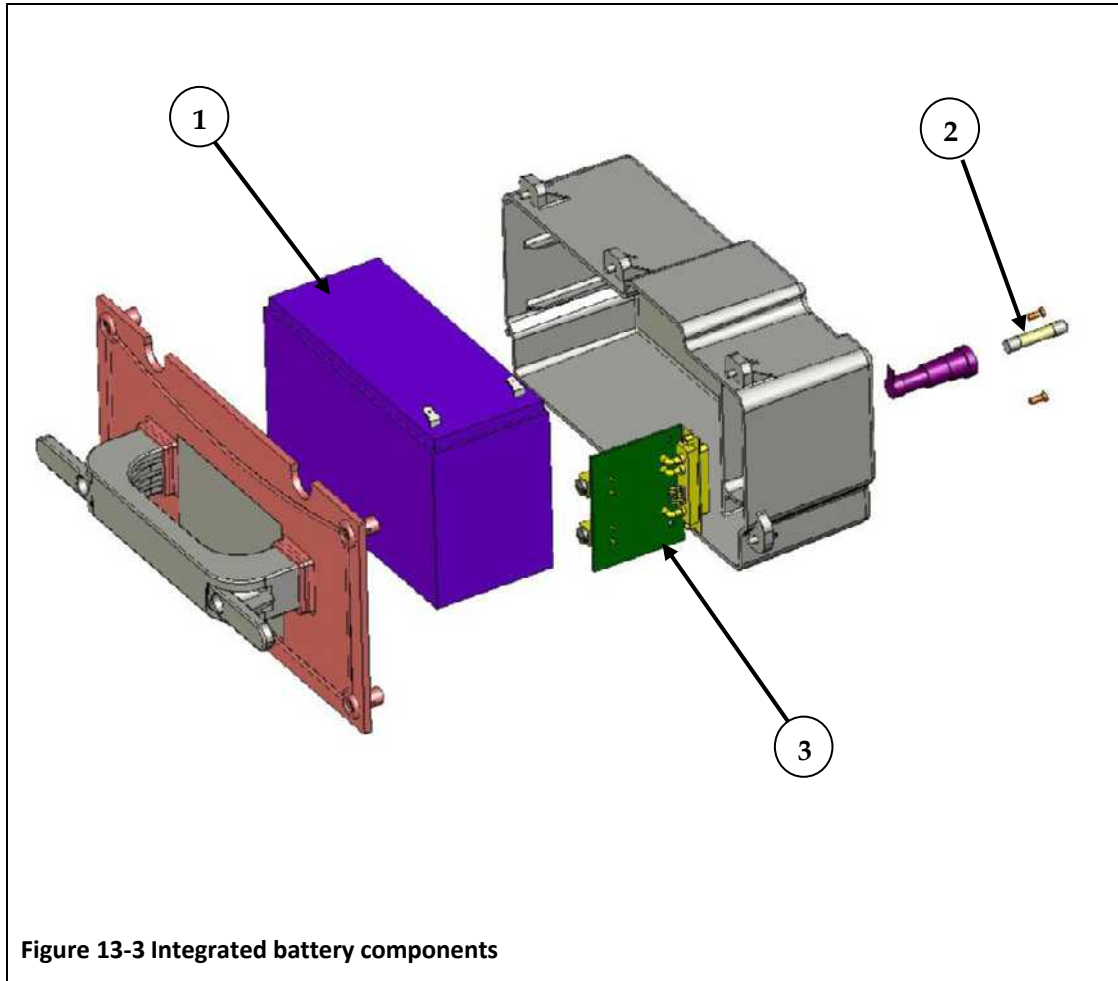


Figure 13-3 Integrated battery components

<i>Ref</i>	<i>VersaMed Part Numbers</i>	<i>GE Part Numbers</i>	<i>Description</i>
1	301B0004-01	M1161722	Battery Cell, Std Integrated
2	137A3150-02	M1161717	FUSE 3.15A 250v S.B
3	900K0023-01	M1202722	Gas Gauge PCB, Std Integrated

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# Appendix A: Ventilator Wiring Diagram

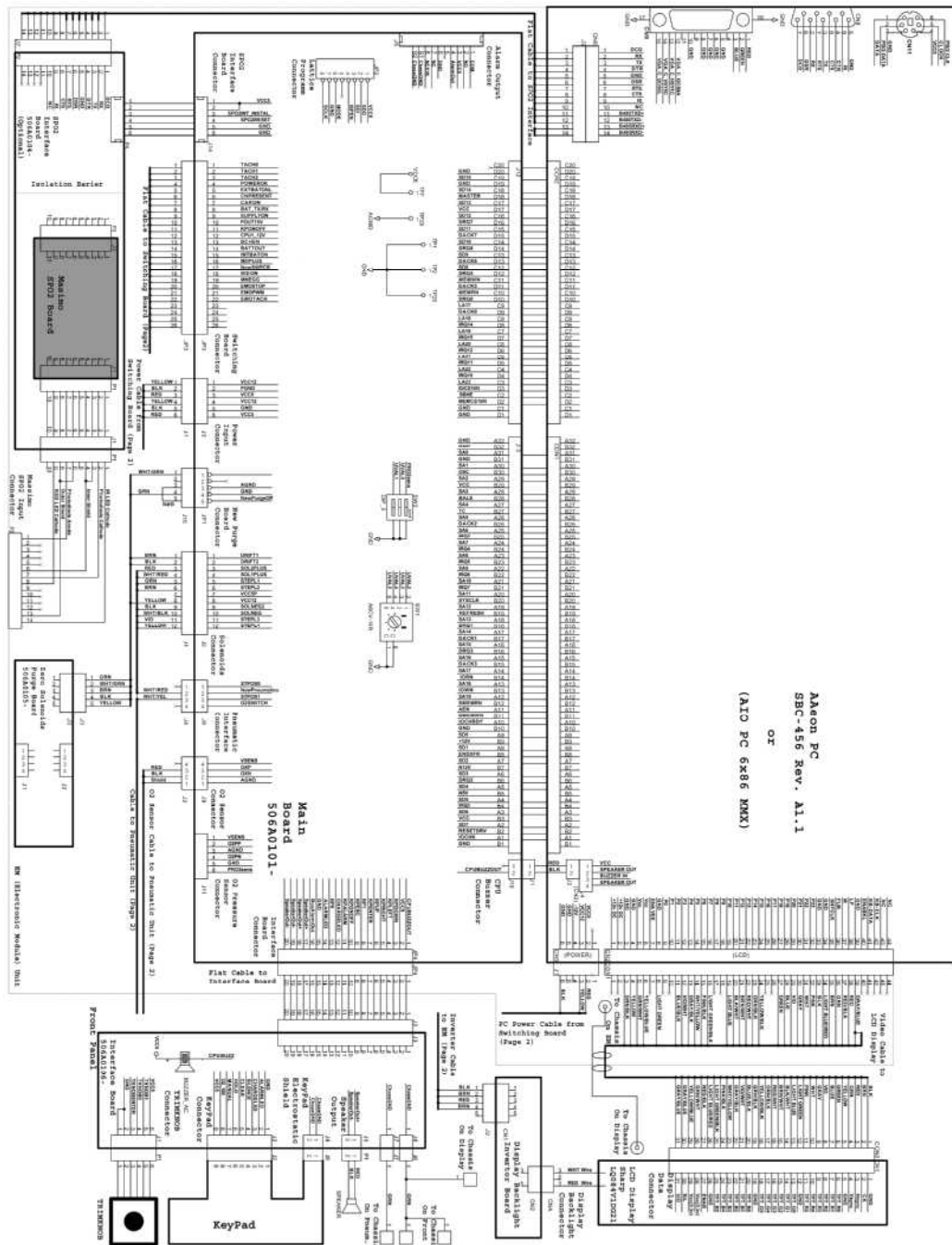


Figure A-1: iVent™201 Wiring Diagram (Page 1)





# Appendix B: Electro Magnetic Declaration

Electro-magnetic emissions		
The iVent™201 is designed to be used in the electro-magnetic environment specified below. The equipment's customer or user must ensure that it is used in such an environment.		
Emission test	Compliance	Recommended electro-magnetic environment
RF emissions CISPR 11	Group 1	The iVent™201 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electro-magnetic immunity			
The iVent™201 is designed to be used in the electro-magnetic environment specified below. The equipment's customer or user must ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Recommended electro-magnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV on power supply lines ± 1 kV on input / output lines	± 2 kV on power supply lines ± 1 kV on input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycles 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles < 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 s	< 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycles 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles < 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the iVent™201 requires continued operation during power mains interruptions, it is recommended that the iVent™201 be powered from an uninterruptible power supply or a battery.  <b>Note:</b> Voltage reduction didn't influence the iVent™201 which is always supplied with the backup battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U <sub>T</sub> is the AC mains voltage prior to application of the test level.			
Electro-magnetic immunity (follows)			

Vent™201 Technical Reference Manual

<p>The Vent™201 is designed to be used in the electro-magnetic environment specified below. The equipment's customer or user must ensure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Recommended electro-magnetic environment
			<p>Portable and mobile RF communications equipment should be used no closer to any part of Vent™201E including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p>
<p>Conducted Radio frequency IEC 61000-4-6</p>	<p>3 V rms 150 kHz to 80 MHz outside ISM bands<sup>a</sup> 10 V rms 150 kHz to 80 MHz within ISM bands<sup>a</sup></p>	<p>10 V 150 kHz to 80 MHz</p>	<p><b>Recommended separation distance:</b>  <math>d = 0.35\sqrt{P}</math> from 150 kHz to 80 MHz outside ISM bands  <math>d = 1.2\sqrt{P}</math> from 150 kHz to 80 MHz within ISM bands where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)<sup>b</sup>.                      Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>c</sup>, should be less than the compliance level in each frequency range<sup>d</sup>.                      Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Radiated Radio frequency IEC 61000-4-3</p>	<p>10 V/m 80 MHz to 2.5 GHz</p>	<p>10V/m 80 MHz to 2.5 GHz</p>	<p><b>Recommended separation distance:</b>  <math>d = 1.2\sqrt{P}</math> from 80 MHz to 800 MHz  <math>d = 2.3\sqrt{P}</math> from 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)<sup>b</sup>.                      Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>c</sup>, should be less than the compliance level in each frequency range<sup>d</sup>.                      Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the highest frequency interval is applied NOTE 2: This guide is not applicable in every situation. The issue of electro-magnetic waves is affected by the absorption and the reflection of structures, objects and people.</p>			
<p>(a) The ISM bands (Industrial, Scientific and Medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 to 40.70 MHz                      (b) Compliance levels in ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are intended to decrease the likelihood that mobile/portable communication equipment could cause interference if it is inadvertently brought into patient areas. This is why an additional 10/3 factor is used in calculating the distance of separation for emitters in these frequency ranges.                      (c) Fields from fixed emitters, such as cordless telephone bases, mobile radios, CB radios, AM and FM radio emissions, TV emissions may not be accurately predicted in theory. In order to evaluate the electro-magnetic environment from fixed emitters, an electro-magnetic surveillance site must be considered. If the force field measured in the environment where the Vent™201 has to be used, exceeds the above applicable RF levels, the Vent™201 must be watched to check if it is working normally. If abnormal performance is observed, extra measures have to be taken such as redirecting or moving the Vent™201.                      (d) Above the 150 kHz to 80 MHz frequency range, force fields should be less than 10 V/m.</p>			

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<b>Recommended distance between portable and mobile RF communications equipment and iVent201</b>				
The iVent™201 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iVent™201 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iVent™201 as recommended below, according to the maximum output power of the communications equipment.				
Maximum power of the emitter (W)	Distance apart in terms of the emitter's frequency (m)			
	150 kHz to 80 MHz outside the ISM bands d = 0.35VP	150 kHz to 80 MHz within the ISM bands d = 1.2VP	80 MHz to 800 MHz d = 1.2VP	800 MHz to 2.5 GHz d = 2.3VP
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23
For checked emitters with a maximum power not listed above, the recommended separation distance « d / in meters (m) may be determined using the equation applicable to the emitter's frequency, where « P / is the maximum power of the emitter in Watts (W) according to the emitter's manufacturer.				
NOTE 1: At 80 MHz and 800 MHz, the separation distance of the highest frequency range is applied.				
NOTE 2: ISM bands (Industrial, Scientific and Medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 to 40.70 MHz				
NOTE 3: An additional factor of 10/3 is used in calculating the separation distance for emitters in the 150 kHz and 80 MHz ISM range as well as the frequency range between 80 MHz and 2.5 GHz in order to reduce the probability that mobile/portable communication equipment causes interference if they are unknowingly taken near the patient.				
NOTE 4: This guide is not applicable in every situation. The issue of electro-magnetic waves is affected by the absorption and the reflection of structures, objects and people.				

## Appendix C: Installation Check list

<b>Serial Number:</b>	<b>Date: (MM/DD/YY)</b> /   /
<b>Hospital:</b>	<b>Performed by:</b>

- Unpack the iVent™201
- Check that you have all the parts in list below
  - iVent™201 device
  - Disposable Wye Breathing Circuit
  - AC Power Cable
  - iVent™201 Operation Manual
  - MRI card
  - GREEN O2 Hose 15 feet+ DISS F Connector
- Place iVent™201 on a solid surface
- Verify that the cooling air can flow through the vents without obstruction.

Refer to the iVent™201 *Operator's manual Section 2: Setting Up* for preparing the iVent™201 for ventilation.

# Appendix D: Planned Maintenance Check List

<b>Serial Number:</b>	<b>Date: (MM/DD/YY)</b> /   /
<b>Hospital:</b>	<b>Performed by:</b>
<input type="checkbox"/> 500 Hours <input type="checkbox"/> 3000 Hours <input type="checkbox"/> 12 Month <input type="checkbox"/> 15000 Hours	

1. **Perform next steps every 500 hours or 1 month of use**
  - Replace the air inlet filter.
  
2. **Perform next steps every 1500 hours or 3 months of use**
  - Replace the air inlet filter.
  - Deep discharge and recharge the battery.
  
3. **Perform next steps every 3000 hours or 6 months of use**
  - Replace the air inlet filter.
  - Perform ALL calibrations
  - Perform VVT
  - Deep discharge and recharge the battery
  
4. **Perform next steps every 12 month (all parts should be replaced before performing checks, tests and calibration)**
  - Replace the Air Inlet Muffler
  - Replace the Air Inlet Muffler O-ring
  - Check validity of On/Off switch cover
  - Replace the Outlet Muffler
  - Replace the cooling inlet filter.
  - Replace internal battery and reinitialize the gas gage.

- Replace the air inlet filter.
  - Perform ALL calibrations
  - Perform VVT
  - Perform functional tests.
  - Perform safety checks.
5. **Perform next steps every 15000 hours of use (all parts should be replaced before performing checks, tests and calibration)**
- Replace pneumatic unit.
  - Perform ALL calibrations
  - Perform VVT
  - Perform functional tests.
  - Perform safety checks.

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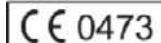
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