GE Healthcare

iVent™201

User's Reference Manual

Revision: 13

VersaMed, a General Electric Company, doing business as GE Healthcare.

Calling for Help

Owner's Record

The model number and serial number of your iVent™201 are located on the rear panel of your ventilator. Record the serial number in the space below in case service or support is necessary.
Model Number:
Serial Number:

Customer Service

If you have a ventilator problem you cannot solve **and you purchased your ventilator directly from GE**, call:
US number 800-345-2700 - Customer Service
If you have a ventilator problem that you cannot solve **and you purchased your ventilator from an authorized GE distributor**, please contact your distributor directly to report the problem.

TABLE OF CONTENTS

1 INTRODUCTION

This chapter contains the following sections:

INTRODUCTION

The iVent™201 is a compact, portable, multi-featured, microprocessor-controlled ventilator, which has the versatility and capability of larger and more costly 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 for 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 variety of graphical and numerical modes.

The iVent™201 supports the following modes:

- Assist/Control (A/C)
  - 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 the following advanced features:

- Quick setup enabled by Preset Parameters according to Patient Weight
- Adaptive Peak Flow™ and Adaptive I-Time to adapt to patient flow demand during volume control breath delivery or to maintain a 1:2 I:E ratio in the event of no patient flow demand.
- Rise time is adjustable
- 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 feature when PEEP>0 is selected, designed to shorten expiratory time and reduce risk of auto-PEEP.
- 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

HOW TO USE THIS MANUAL

The iVent™201 must only be operated by authorized medical personnel certified trained in the use of this product. It must be operated according to the instructions provided in the Operator's Manual.

The manual is primarily organized according to available screens, menus, options and settings and begins with a look at the hardware, including power considerations and patient circuit setup.

Study the manual with the iVent™201 in close proximity, along with a patient circuit (preferably with a test lung and Rp20 resistor). Become comfortable with the Control Knob and the front panel buttons.

The user interface consists of three primary screens/menus:

- The **Main** Screen
- The **Main** Menu
- The **Mode** Menu

Almost every function or operation of the iVent™201 is accessible through one of the Main screen menus. Be aware of the notes, warnings, and cautions marked in bold print.

Refer to the index and the Table of Contents to assist you in finding information.

For more information about the Adaptive Bi-Level feature see About Adaptive Bi-Level, page 131.

LOOKING AT THE IVENT™201

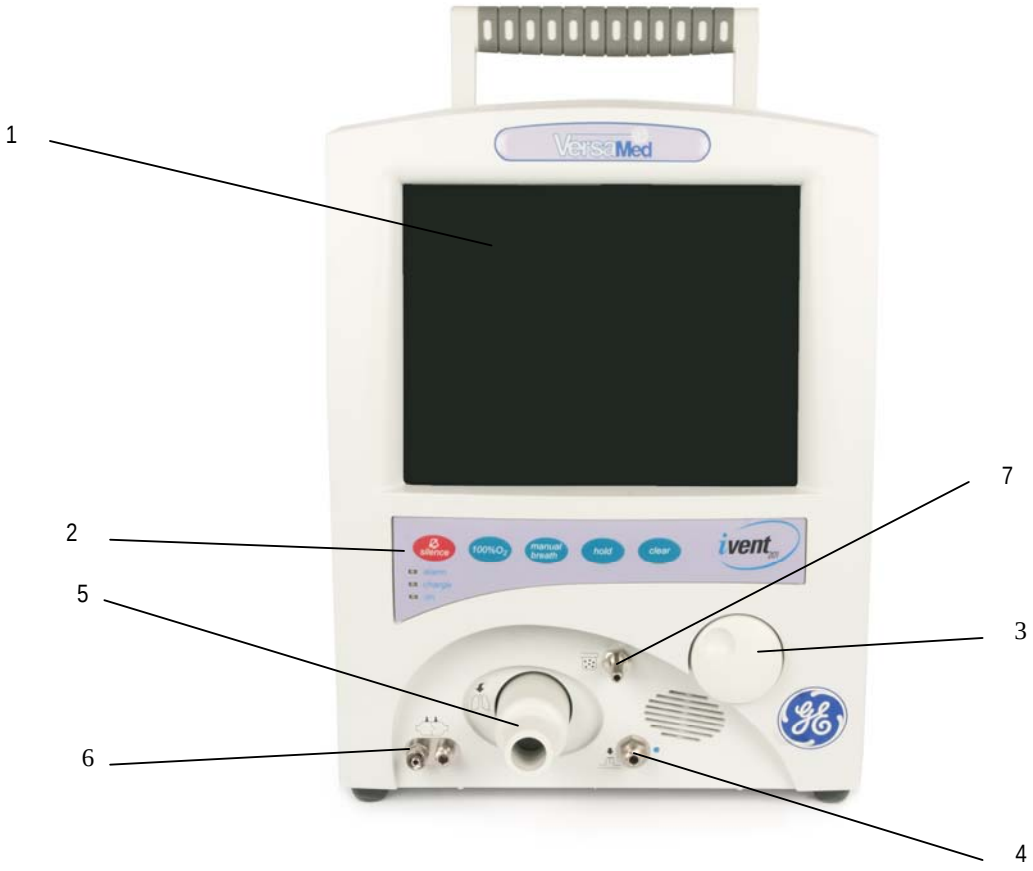


Figure 1: Front View of the **iVent™201**

Item Number	Description
1	Display
2	Keypad
3	Control Knob
4	Exhalation valve luer inlet
5	Ventilator outlet
6	Sensor line luer inlets
7	Nebulizer outlet

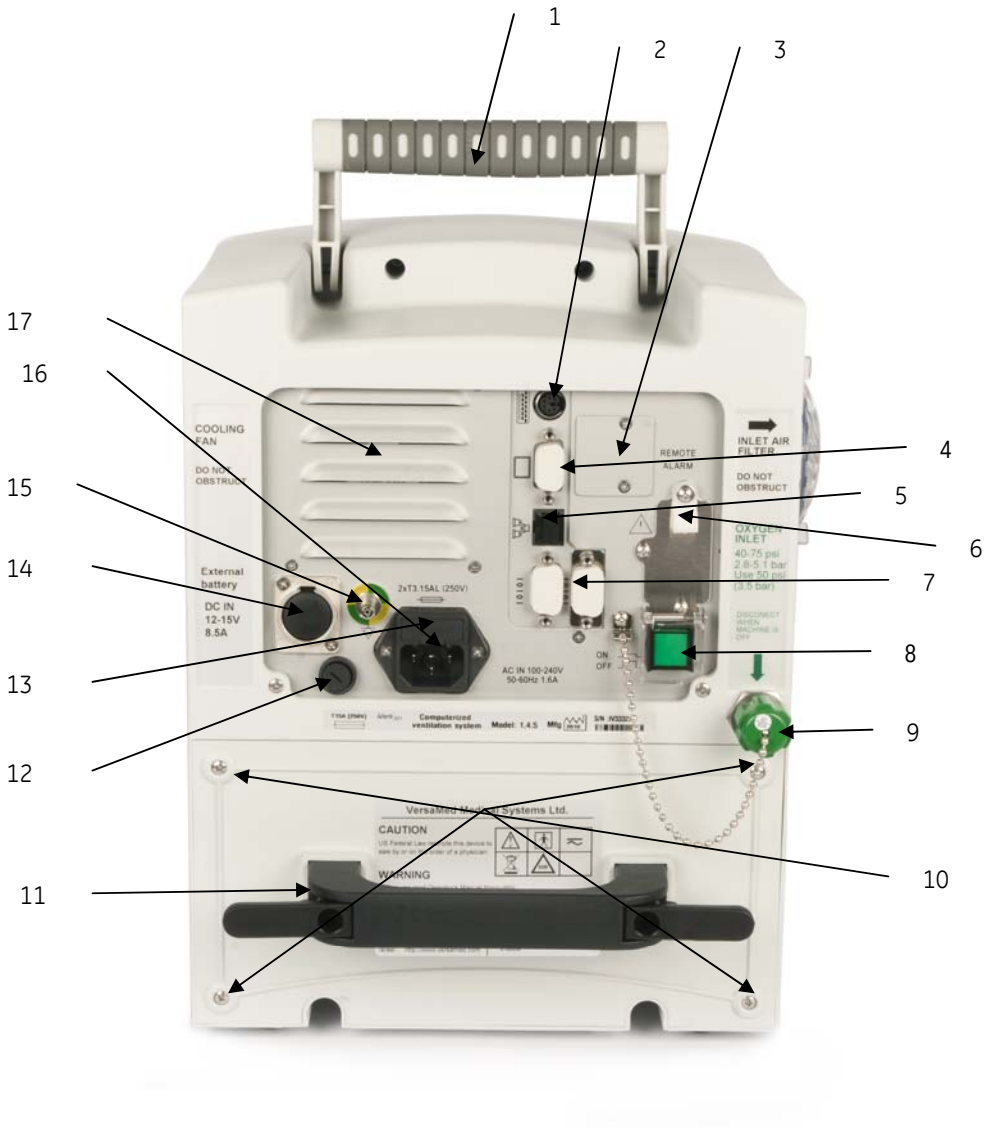


Figure 2: Back View of the iVent™201

Item Number	Description
1	Carrying handle
2	Keyboard connector
3	Remote alarm connector
4	External screen connector
5	LAN connector* Do not remove connector cap. This connection port is not in use
6	AC cable clip
7	RS 232 connectors (COM1 and COM2)
8	On/off switch (with cover)
9	High pressure oxygen inlet connector

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

CAUTIONS AND WARNINGS

CAUTION

The iVent™201 is a restricted medical device to be operated by qualified medical personnel under the direction of a qualified medical practitioner

Always perform a complete Operation Verification Test (O.V.T.) when connecting a new patient circuit to the ventilator, and before using it on a patient. Standard facility policy should be followed.

Using the iVent™201 in combination with devices such as humidifiers or filters can increase the pressure gradient across the breathing system. Make sure that such devices do not produce excessive resistance to the airflow provided by the iVent™201.

The iVent™201 must not be operated immediately following storage or transport outside the recommended operation condition

The iVent™201 internal battery contains lead and must be disposed of in accordance with local ordinances and environmental regulations.

Do not connect the O2 supply when equipment is not in use.

The remote alarm should be considered secondary to the ventilator's primary alarm system.

Verify the remote alarm device functionality before use

The remote alarm connector should be connected to a nurse station device on a low voltage less than 24Vdc and compliant with IEC 60601-1.

The factory default setting for Leak Alarm is set to Off. Users must manually set the leak alarm to enable it.

WARNING

The iVent™201 is a life-sustaining device. Do not rely solely on the ventilator performance: always make sure an alternative source of ventilation is available. Clinical supervision of the patient is

mandatory.

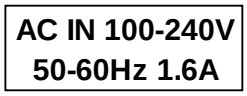
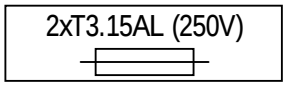
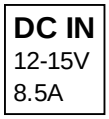
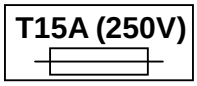
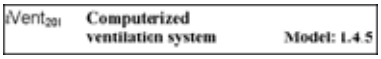
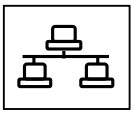
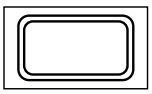
Qualified medical personnel should visually monitor patients on life-support ventilation. Life-threatening conditions may arise that might not activate alarms,

To prevent explosion hazard, do not use the ventilator in the presence of flammable anesthetics.

Do not cover the iVent™201 while it is in use. Make sure that the iVent™201 is positioned so that its inlet ports and cooling vents are open to freely circulating air.

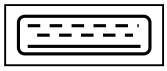
SYMBOLS AND LABELS

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

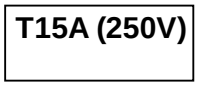
Location	Label
AC Connector	
AC Fuses	
Air Inlet	
Cooling Fan	
Connector	
DC Fuse	
Device ID	
Device Product	
Ethernet Connector (not on all units)	
External Display Connector	

High Pressure Oxygen Inlet

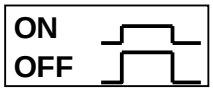
Keyboard Connector



Power Pack Fuse

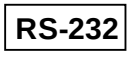


Power Switch



Remote Alarm Connector

Serial Communication Connector



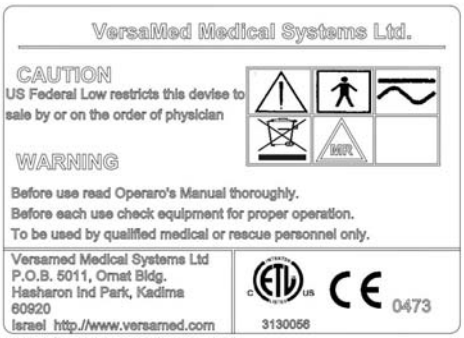
Power Pack (inside)

POWER PACK

P/N : 503A0012

Caution: This Power Pack contains a sealed Lead - Acid Battery. Disposal of this unit should be according to Environmental Safety Requirements for Lead-Acid batteries.

VersaMed



PERFORMANCE PARAMETERS

Ventilation Component	Parameters/ Range	Unit of Measure	Accuracy	Set	Displayed	Page
Respiratory rate	1-12 12-80	bpm	±1 ±2	Y	Y	67
Inspired Tidal Volume Measurement	50-2000	mL	±10%	Y	N	69
Exhaled Tidal Volume Measurement	50-300 300-2000	mL	±10 mL or +15% whichever is greater +10%	N	Y	NA
Inspiratory Pressure Limit	5 to 80	cmH2O	±5	Y	Y	71
Inspiratory Time	0.2 to 3 or Adaptive I-Time™	sec.	±10%	Y	Y	80
Peak Flow	up to 120 or Adaptive Flow™	L/min	±10%	Y	Y	74
Peak Flow (Spontaneous)	up to 180	L/min	±10%	Y	Y	74
Oxygen Mix (FiO2)	21 to 100%		±10% of the set value or ±3% absolute whichever is greater	Y	Y	73
PEEP	0 to 40	cmH2O	±1 or ±10%, whichever is greater	Y	Y	78
Trigger sensitivity	1 to 20, off -0.5 to –20, off	L/min cmH2O		Y	Y	79
PSV	0 to 60	cmH_2O	±10%	Y	Y	76
Positive Pressure relief valve	80	cmH_2O		N	N	NA
Controlled Pressure	5 to 80	cmH_2O	±5	Y	Y	NA
Flow Termination	10-90	%	±10%	Y	Y	84
Rise Time	Mid, High, Max, Auto		NA	Y	Y	82
FiO_2 at power up	21%, 40%, 60%, 100% (selectable)			Y	Y	185

SPECIFICATIONS

MONITORED DATA RANGE, RESOLUTION AND ACCURACY

The following section describes the various specifications and parameters of the iVent™201.

Parameter	Range, resolution, accuracy
Breath type	**Range:** Type: - Control, assist, patient, sigh Resolution: N/A Accuracy: N/A
Respiratory Rate	**Range:** 0 to 150/min Resolution: 1/min **Accuracy:** ±1 for 1 to 12/min ±2 for 12 to 150/min
Exhale tidal volume	**Range:** 0 to 5000 mL Resolution: 1 mL **Accuracy:** ±10 mL or ±15% (whichever is greater) for 0 to 300 mL ±10% for 300 to 5000 mL
Exhaled Minute Volume	**Range:** 0 to 99.9L Resolution: 0.1 L Accuracy: ±10%
Peak flow	**Range:** 0 to 140 L/min Resolution: 1 L/min Accuracy: ±10%
PIP (Peak Inspiratory Pressure)	**Range:** 0 to 99 cmH_2O Resolution: 1 cmH_2O **Accuracy:** ± 2 (+ 5 % of reading) cm H2O
Inspiratory time	**Range:** 0 to 3.0 sec Resolution: 0.1 sec Accuracy: ±10%
I:E ratio	**Range:** 1:11 to 3:1 **Resolution:** 0.1 for 1:1 to 1:5 1 for 1:5 to 1:11 and 3:1 to 1:1 Accuracy: ±0.1
Delivered O2%	**Range:** 21 to 100%

	Resolution: 1% Accuracy: ±5%
Flow Leak	**Range:** 0 to 100% Resolution: 1% Accuracy: ±15%
Mean Airway Pressure	**Range:** 0 to 99 cmH_2O Resolution: 1 cmH_2O **Accuracy:** ± 2 (+ 5 % of reading) cmH_2O
Resistance (dynamic)	**Range:** 0 to 99.9 $cmH_2O/L/s$ **Resolution:** 0.1 $cmH_2O/L/s$ **Accuracy:** ± (2 + 20% of actual value) $cmH_2O/L/s$
Compliance (dynamic)	**Range:** 0 to 99.9 ml/cmH_2O **Resolution:** 0.1 ml/cmH_2O **Accuracy:** ± (2 +20% of actual value) ml/cmH_2O
RR/Vt-Rapid Shallow Breathing Index (RSBI)	**Range:** 0 –200 /min*L Resolution: 1 /min*L **Accuracy:** ± (5 + 20% of actual value). /min*L
Static compliance	**Range:** 0 to 99 ml/cmH_2O **Resolution**: 1 ml/cmH_2O **Accuracy:** ± (2 + 20 % of actual value). ml/cmH2O
Auto PEEP	**Range:** 0 to 99 cmH_2O Resolution: 1 cmH_2O **Accuracy:** ± 2 (+ 5 % of reading) cmH_2O
Plateau Pressure	**Range:** 0 to 99 cmH_20 Resolution: 1 cmH_20 **Accuracy:** ±2(+5% of reading) cmH_20
Time Constant	**Range:** 0.0 to 9.9 sec Resolution: 0.1 sec Accuracy: ±20%

SIZE AND WEIGHT

Parameter	
Height:	13” / 33 cm
Width:	9.5” / 24 cm
Depth:	10.3” / 26 cm
Screen:	8.4” / 21.3 cm diagonal
Weight	18.3 lb/8.3 kg (without battery)
Battery Weight	6.2lb/2.8kg
Extended Battery Weight	10.1 lb / 4.6 kg
Overall Weight	24.5 lb/11.1 kg
Overall Weight (with extended Battery)	27.8 lb/12.6 kg

VENTILATION MODES

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

NOTE Certain modes are optional and might not be operational in all iVent™201 models

ENVIRONMENTAL SPECIFICATIONS

Parameter	
Operating Temperature	0 to +50 °C / +32 to +122 °F
Storage Temperature	Without battery: -15 to +70 °C / +5 to +158 °F
	With battery: -15 to +30 °C / +5 to +86 °F
Relative Humidity	15 to 95% @ 30 °C / 86 °F
Water and Dust Resistance	IP-54 (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 (100 g)
	MIL-STD-810E
Total External Sound Level	40 – 45 dBa at one meter

POWER SUPPLY

Parameter	
External AC	100 to 240 V, 50-60 Hz, max 1.6 A.
External DC Battery	12 to 15 V max 8.5 A.
Internal Battery	Sealed Lead-Acid, 12 V 8 Ah (rechargeable)
Recharge Time	Over 8 hours, <1 Ampere
Operating Time (internal battery)	Up to 2 hours (varies with ventilation parameters)
Extended Battery	Sealed Lead-Acid, 12 V, 12 Ah (rechargeable)
Extended Battery recharge time:	Over 24 hours, <1 Ampere
Operating Time (extended battery)	Up to 4 hours (varies with ventilation parameters)
Operating Time (external battery)	Up to 8 hours (varies with ventilation parameters)

O2 SUPPLY SPECIFICATIONS

Parameter	
High Pressure	Pressure Range 40 –75psi (2.8-5.1 bar). Warning: The exact oxygen pressure which the iVent™201 uses depends on the version you have. Check the back label (shown in Figure 11) for the pressure levels of your unit.
Low Pressure	Maximum flow 15L/min or 0.5 psi

VENTILATION PERFORMANCE AND CONTROLLED PARAMETERS

Parameter	
Respiratory Rate	1 – 12 ±1, 12 – 80 ± 2 bpm
Tidal Volume	50-2000 mL
Accuracy of Tidal Volume Delivery	±10% or ±10 mL whichever is greater
Accuracy of Exhale Tidal volume Measurement	±15% above 100 mL from actual reading or ±10 cc below 100 mL
Inspiratory Pressure Limit	5 to 80 ±5 cmH_2O
Inspiratory Time	Adaptive Time™ or 0.2 to 3 ±10% sec
Peak Flow (PIF)	Adaptive Flow™ or to 120 ±10% L/min Spontaneous to 180 ±10% L/min
Oxygen Mix (FiO_2)	21% to 100% ±10% of the set value or ±3% absolute, whichever is greater
PEEP	0 to 40 ±1 cmH_2O or ±10%, whichever is greater
Trigger Sensitivity	1 to 20 L/min Flow, Off - 0.5 to – 20 cmH_2O Pressure, Off
PSV	0 to 60 ±10% cmH_2O
Positive Pressure Relief Valve	80 cmH_2O
Pneumatic Nebulizer	5 to 240 minutes
Controlled Pressure	5 to 80 cmH_2O ±5 cmH_2O
FiO_2 at Power up	21%, 40%, 60%, 100% (configurable)
Configurable Humidifier Setting (Purging Cycle)	HME (10 minute), Heated (1 minutes), Off

PULSE OXIMETRY SPECIFICATIONS

Oxygen Saturation Range:	0 to 100%	
Pulse Rate Range:	18-300 pulse par a minute	
Measurement Wavelengths:	Red- 660 nanometers at 3m W nominal Infrared – 910 nanometers at 3m W nominal	
SpO2 Accuracy: (70-100%)(+1SD)	No motion (adult, pediatrics) Motion (adult, pediatrics) Low Perfusion (adult, pediatrics)	+ 2 digits + 2 digits + 2 digits
Heart Rate Accuracy:	No motion (18-300 BPM): - adult, pediatrics Motion (40-240 BPM): - adult, pediatrics: Low Perfusion (40-240 BPM) - adult, pediatrics:	+ 3 digits + 3 digit + 3 digits
Operating Temperature:	0°C to 50°C (32°F to 122°F)	
Storage Temperature:	-20°C to +50°C (-4°F to 122°F)	
Power Consumption	60mW – typical operation	
Dimensions:	2.1'' x 0.8'' x 0.6'' (53 x 201 x 15mm)	
Weight:	75g (including 6' and connector)	
Shock Ruggedness Immersion:	Per IEC 86-2-27	
Vibration Ruggedness Immersion:	Mil-STD-810C, method 514-2	
Sensors:	Disposable and reusable sensors (8000 series) manufactured by Nonin and labels for Patients ranging from pediatrics to adults.	

STANDARDS AND SAFETY REQUIREMENTS

The iVent™201 meets or exceeds the following international standards:

EN/IEC 60601-1	Medical Electrical Equipment – General requirements for safety
EN/IEC 60601-1-2	Medical Electrical Equipment - Part 1: General requirements for safety 2. collateral standard: Electromagnetic Compatibility - requirements and tests
EN/ IEC 60601-1-6	General requirements for basic safety and essential performance - Collateral standard: Usability
EN/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	Standard Specification for Electrically Powered Home Care Ventilation.
ISO 10651-2	Lung Ventilators for medical use – Particular requirements for Home Care Ventilators

DISPLAYED PARAMETERS

The following table presents the displayed parameters and indicates whether the displayed values are set, measured or both.

Parameter	Unit of Measure	Set	Displayed
Rate	bpm	+	+
Ventilation Mode		+	+
Oxygen Concentration	FiO_2	+	+
Inspiration to Expiration time ratio I:E ratio			+
Inspiratory Time (I_{time})	sec	+	+
Sensitivity Values (Triggers): Pressure and Flow	cmH_2O/LPM	+	+
Pressure Support Ventilation (PSV)	cmH_2O	+	
Flow termination (Esens)	%	+	
Rise time (drive)		+	+
Alarm Pressure / Limit Pressure	cmH_2O	+	+
Positive End Expiratory Pressure (PEEP)	cmH_2O	+	+
Exhaled Minute Volume	L		+
Peak Inspiratory Pressure	cmH_2O		+
Pressure/Flow Wave Forms			+
Electrical Power Source (Ext./Int.)			+
SpO2	%		+
Heart rate	Bmp		+
In Adaptive Bi-Level Mode:			
IPAP (Ins Pressure)	cmH_2O	+	+
EPAP (Exp. Pressure)	cmH_2O	+	+
Tidal Volume (estimated)	mL		+
Leak (estimated)*	LPM		+
Rise Time Setting	sec	+	
Non-Displayed Additional Parameters			

Parameter	Unit of Measure	Set	Displayed
Sigh Breath Setting		+	
Humidifier Setting (purge cycle)		+	
Nebulizer Settings (time)	Hr: min	+	+

* In SW version 19.18.01 estimated leak in adaptive Bi-Level mode is presented in %

USER ADJUSTABLE ALARMS

Value	Range
Respiratory rate	High: 4-80 bpm Low: 1-77 bpm
Minute volume	High: 1-99 L/min; off Low: 0-60 L/min
Inspiratory pressure	High: 4-80 cmH_2O Low: 1-77 cmH_2O
Apnea	5-120 seconds
FiO_2	High: 22-100% Low: 21-99%
Leak	0-100%
Low Tidal Volume Delivered	Off or 15%-85%
Volume Limit Reached	100-2000 mL
Inverse I:E Ratio	ON/OFF
Patient Circuit Disconnect (AB-Level mode, for other modes – optional)	ON/OFF
Alarm Volume	1-10
SpO2	High: 60-100 Low: 59-99
Heart Rate	High: 50-175 Low: 40-150

ADDITIONAL ALARMS AND INDICATORS

The following table shows Additional Alarms.

Alarms
Low O2 Pressure
AC Power Disconnect
Low Battery
Empty Battery
Battery Disconnect or Damaged
Over Temperature
Check Sensor
Tube Disconnect
Sensor Disconnect
Patient Disconnect
Service Notice
High PEEP
Need Cal (Calibration)
Patient Circuit Failed
SpO2 Patient Disconnect
SpO2 Sensor Disconnect
SpO2 Reading Failed

The following table shows additional Indicators and Icons.

Indicators
Battery Charge
Alarm Silence Icon & Timer
Work Hour Counter
Date and Time
LEDs: ON, Charge, Alarm
Power Source Icon
Breath Type: Mandatory, Spontaneous, Assist, Hold, or Sigh
Zeroing
Purging
100% O2 suction mode
External DC

WAVEFORMS AND DIAGNOSTICS PACKAGES

Pressure, Flow, and Volume Waveforms Software Package includes the following:

- Real Time Pressure and, Flow Waveforms
- Waveform History Browsing
- Trending of Monitored Data
- Respiratory Diagnostics Software Package
- Pressure, Flow and Volume Loops
- Lung Mechanics (Compliance-static and dynamic, Resistance, Mean Airway and Plateau Pressure)

INTENDED USE

The iVent™201 MR Conditional is a portable, computer controlled, electrically powered intensive care ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for use with adult through pediatric patients, who require invasive or non-invasive assistance via the following general modes of ventilatory support, as prescribed by an attending physician:

- Assist/Control (Pressure Controlled or Volume Controlled)
- SIMV (Pressure Controlled or Volume Controlled)
- CPAP/PSV

The iVent™201 MR Conditional ventilator is suitable for use in the ICU and all other hospital areas, including Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field, in all hospital-type facilities, alternate care sites, transport, emergency and in the home environment. The iVent™201 MR Conditional ventilator is MR conditional.

The optional non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate and is suitable for use in all above mentioned areas, excluding MR environments.

The iVent™201 MR Conditional ventilator is a restricted medical device intended for use by qualified, trained personnel under the direct supervision of a physician.

USE OF THE IVENT™201 WITH MRI

The iVent™201 ventilator (serial number 15 000 and higher) is classified as MR conditional for 1.5T and 3T MR scanners. This means that the iVent™201 is safe to use in the MR environment if the operation conditions specified in this section are met.

For the MRI conditional specifications refer to MRI Conditional Tests Specifications, on page 29 of this document.

CAUTION The *iVent™201* ventilator should not be subjected to field strength greater than 100 Gauss and must be kept outside of 100 Gauss perimeter.

NOTE The iVent™201 MR Conditional has been demonstrated to pose no known hazards in MR Environment under specified conditions of use. However, MR image quality may degrade when working with the ventilator in a specific MR suite. It is recommended to perform a pre-qualification image quality test to ensure an acceptable level of image quality. For more details contact your local sales representative

The facility must map and permanently mark the 100 Gauss strength line on the floor with a durable tape. VersaMed Gauss line warning floor label (Versamed P/N 350C0323-01, GE P/N M1218236), shown in Figure 3 below can be used to emphasize the location of the 100 Gauss line.

Figure 3: 100 Gauss Line Warning Floor Label

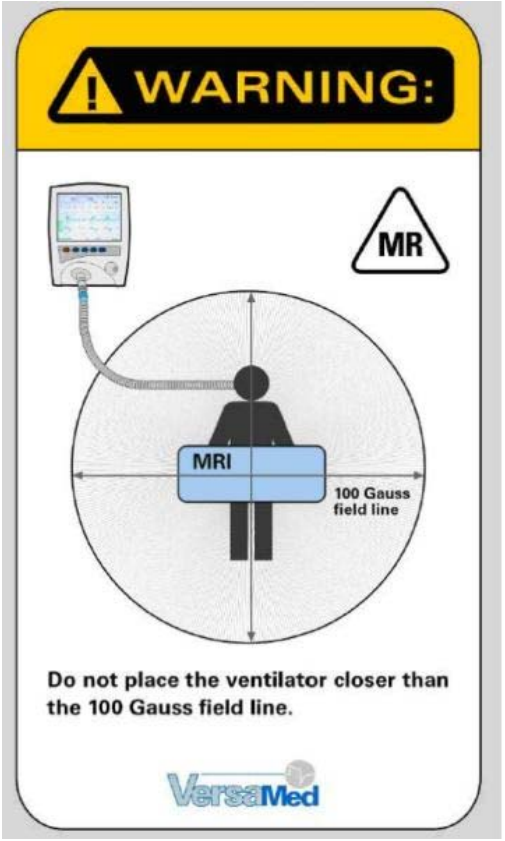


Figure 4: MRI Warning Card

MR Class

MR conditional per ASTM 2503-05

WARNING **Use of the ventilator other than as instructed may result in injury to the patient or personnel.**

CAUTION *Connect the potential equalization pin on the back of the ventilator to the ground during battery (DC power) operation*

Before using the MR suite, remove the green cover and the attached metal chain from the high-pressure oxygen fitting.

To avoid degrading image quality, do not use the static mechanics function during MRI scanning.

Use of the ventilator other than as instructed may cause damage to the MR scanner

If the ventilator is placed on a roll-stand or a moving cart lock the ventilator cart's wheel to prevent inadvertent movement.

The ventilator is attracted to the magnet if it is brought within 100 Gauss field line of the MR magnet. If there is a risk of personnel moving the ventilator, it should be tethered to the wall, or placed within a retaining box affixed to the floor.

The SpO2 option is not intended for use in the MR environment.

Use of the ventilator other than as instructed may cause the ventilator to malfunction, and may cause permanent damage to the ventilator.

NOTE *To avoid degrading image quality, do not use the static mechanics function during MRI scanning and Connect the potential equalization pin on the back of the ventilator to the ground during battery (DC power) operation*

If the standard patient circuit is not long enough when the ventilator is placed outside the 100 Gauss boundary we offer the following options:

P/N M1173406 3.8m/ 12.5 Ft PATIENT CIRCUIT.

P/N M1173617 MRI PATIENT CIRCUIT

The only metal GEHC accessories that are acceptable for use within the MRI Suite are the following:

P/N M1206572 GCX OXYGEN CYLINDER HOLDER, MRI CONDITIONAL

P/N M1162046 OXYGEN CYLINDER HOLDER, MRI CONDITIONAL

P/N M1206571 GCX iVENT™201 ROLL STAND MRI CONDITIONAL

P/N M1162044 ROLL STAND AND MOUNTING BRACKET, MRI-CONDITIONAL

P/N M1162051 BEDRAIL MOUNTING MECHANISM

The iVent™201 was tested with the Magnetom Trio, a Siemens Medical Solution scanner under 3 Tesla, horizontal static magnetic field. For the test specifications refer to MRI Conditional Tests Specifications below.

The outcomes of the test results were:

- There was no detectable magnetic attraction of the ventilator when placing the iVent™201 close to the 100 Gauss line.
- The operation of the ventilator was not affected when adhering to the instructions as described above.
- The ventilator demonstrated minor visible RF interference (zipper interference) which is detectable in some MR images. This effect varies from site to site due to variation in MR shielding and should be evaluated by the site radiologist.

MRI CONDITIONAL TESTS SPECIFICATIONS

The iVent™201 MR conditional has been performed to demonstrate that there are no known hazards in a specified MR environment with specified conditions.

The specified MR environment was:

Model:	Magnetom Trio, Siemens Medical Solutions, Erlangen, Germany, 3 Tesla, horizontal static magnetic field, active shielded
Image frequency:	123.192952 MHz
Gradient System:	max. 40 mT/m, Slew rate: 200 mT/m/ms
Software:	Numaris/4, syngo MR 2004A 4VA25A
Coil:	Body coil for transmitting & receiving signals
Field Strength:	3 Tesla
Spatial gradient:	0.12 mT/m
dB/dt	200mT/m/ms
RF:	13-231 Watts
SAR:	0.2 – 92.2
Spin echo:	SE 2D
Time of echo (TE):	20 ms
Time of repetition (TR):	1000 ms
Field of view (FoV):	400 x 400mm
Matrix	256 x 256 pixel
FoV phase:	100%
Flip angle	90°
Bandwidth/ Pixel:	100 Hz
Slice thickness:	5 mm
No. of slices:	1
Slice orientation:	Coronal
No. of averages:	1
Phase encoding:	Right –left (RL)

iVent™ 201 configuration during the test:

Ventilation Type:	SIMV Volume Control
Tidal Volume:	500mL
PEEP:	5 cmH20
FiO2:	50
Power source:	AC and battery
Distance from isocenter:	100 Gauss (approximately 3 meters from the isocenter, this field strength must be measured with a gauss meter)

2 SETTING UP

This chapter contains the following sections:

INTRODUCTION

This section shows you how to set up the iVent™201, and includes the following:

- Connecting to external AC or DC power
- Using the internal battery
- Verifying power condition
- Charging the battery, and proper recharging procedure
- Connecting to cylinder, central supply-system, or low-pressure oxygen
- Connecting the breathing circuit
- Installing heated humidification
- Connecting a pneumatic nebulizer
- Connecting a pulse oximeter
- Installing filters at the ventilator's inlet and outlet
- Packing the unit in its optional transportation case

POWER CONNECTION

EXTERNAL POWER

The iVent™201 can use either external alternating current (AC) or direct current (DC) power. Both AC and DC inputs are located on the back panel of the ventilator (see Figure 5). A hospital grade AC power cord is supplied

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

NOTE *When connecting to an external battery use P/N M1162000*

Connect one end of the AC or DC cord to the ventilator and the other to the power outlet

WARNING ***To prevent electrical shock hazards, connect the power cord to a properly grounded power outlet.***

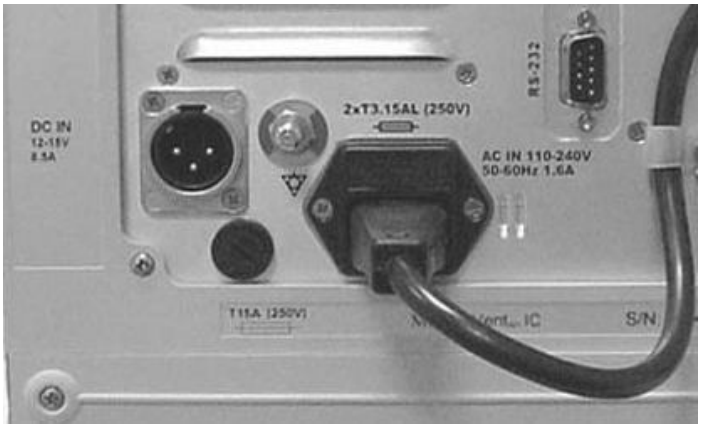


Figure 5: External AC and DC power supply sockets. The AC power cord is connected to the power inlet and fastened with the clip.

NOTE *To prevent accidental disconnection of the AC power cord, secure it with the cable clip*

WARNING ***If the power cord is damaged, worn, or frayed, replace it immediately***

NOTE *Before you turn off the iVent™201 change the mode to Standby mode (Page 61)*

When the ventilator is in operation, icons at the bottom section of the screen indicate the power state (Figure 6).

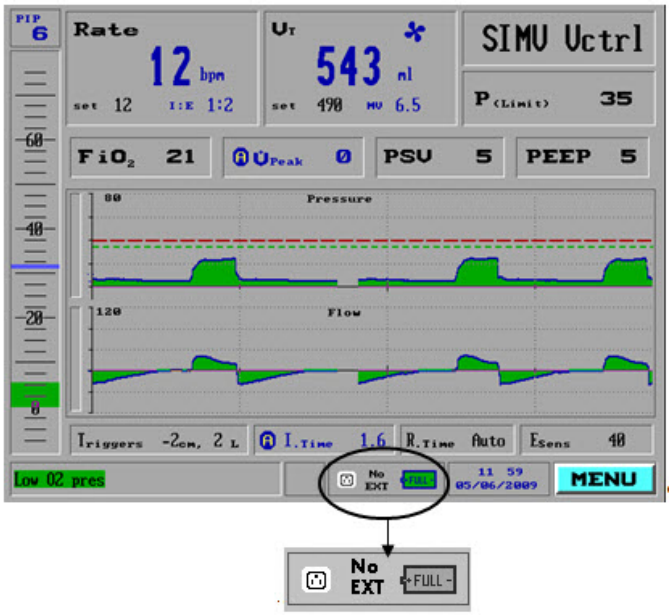


Figure 6: On-Screen Power Status Indicator

Icon	Icon Name	Power State
	Power	When the iVent™201 is connected to an AC power supply, the screen shows a 3-pronged power outlet icon.
	Power disconnect	When disconnected from the AC power supply, the 3-pronged outlet icon is displayed with a red "X" throughout.
	DC power connected and AC power connected.	When connected to an external DC power supply such as a battery, the screen shows "EXT" in blue
	No External battery connected	When disconnected from the DC power supply, the screen shows "No EXT" in black

CAUTION If the screen flashes "EXT" in red, the external battery voltage is low. Replace the battery at once. Ensure adequate power is immediately available

If the external battery connector is removed from the iVent™201 IT MUST REMAIN DISCONNECTED FOR 40 SECONDS before plugging it back in.

NOTE *The* iVent™201 *is designed to switch off the external DC battery if the external battery voltage drops below 10 volts, in order to prevent damage to the external battery. Some batteries may pose a fire hazard if discharged below specified minimum charge levels. Because the ventilator draws variable current while it is operational, the voltages*

provided by external batteries may change. To prevent switch-offs from the external battery due to normal fluctuations in DC voltages, the iVent™201 is programmed to average the external DC voltage reading over time. Therefore, if the user disconnects the external battery, the ventilator interprets this as a dying battery and switches off the external DC source for power. To re-enable input from the external battery source, the user must leave the external battery disconnected for 40 seconds before reconnecting the external battery

INTERNAL BATTERY

The ventilator switches to an internal battery when it detects a loss of external power. When fully charged, the internal battery can supply approximately 1 to 2 hours of power, under typical conditions and settings.

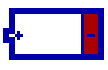
NOTE *The extended internal battery can supply approximately 3 to 4 hours of power under typical conditions and settings*

CAUTION *The iVent™201 should only be used with a properly functioning battery.*

The battery is automatically charged when attached to an external power source, whether the ventilator is operating, in Standby mode, or switched off.

Batteries should undergo a full recharge procedure:

- Prior to initial use
- After prolonged storage
- Every 3 months during normal use
- If after 8 hours charging, the battery indicator fails to indicate a full charge

Indicator	Colors	Description	Remarks
	Green	Battery is fully charged	
	Gray/Green	Battery partly discharged	Indicator moves downward in 10% increments
	Gray / Red	Low battery	At 10%, the indicator changes to red
	Gray	Empty battery	Below 7%, the indicator changes to gray

CAUTION The battery for the iVent™201 is a critical component. It should be replaced only with batteries supplied by VersaMed. If the user has been qualified by VersaMed to service the *iVent™201*, the battery may

be substituted and programmed according to the VersaMed Service Manual and only with the battery specified in those notes

Full Recharge Procedure

CAUTION *'Low Battery" or "Empty Battery" alarm appears, the internal battery must y recharged, as described below*

Continued usage of the battery after the "Empty Battery" alarm appears may disable the battery's charging capability and/or lead to battery failure. Ventilation parameters may not be met in this condition.

NOTE The full recharge procedure first empties the battery of all its charge. Charging it to capacity then allows for proper calibration of the battery gauge.

To perform a full recharge procedure:

1. Plug the AC power cord into the ventilator. Verify that the amber Charge LED is lit.
2. Allow the unit to charge for at least 10 hours.

NOTE If the Extended battery is in use, charge the unit for at least 24 hours

3. Switch on the ventilator. When the Weight Selection window appears, select the 70kg patient weight setting.
4. Set the pressure alarm to 60 (cmH20).
5. Connect the ventilator with a patient circuit to the Rp20 resistor and test lung.
6. Press Start on the ventilator (See page 59) for directions on starting the iVent™201.)
7. Adjust the tidal volume (Vt) so that a PIP (peak inspiratory pressure) of 40 is attained on each breath – for example, a value of 850.
8. Disconnect the power cord. The AC Disconnect alarm sounds and a pop-up window appears. Press the red Silence button on the keypad to remove the pop-up window and silence the alarm.
9. Allow the ventilator to run off the battery continuously. When the Empty Battery alarm sounds, clear it by pressing the red Silence button on the keypad.
10. Place the unit in Standby mode (Page 61), then switch it off. Connect the AC power cord.
11. Let the unit charge for at least 10 hours.

NOTE If Extended battery is in use, charge the unit for at least 24 hours.

If after a full recharge, the battery indicator fails to reach Full, or a Low or Empty Battery alarm displays, then the battery pack must be replaced.

Battery Pack Replacement

The following procedures explain how to replace the battery pack.

1. Disconnect the unit from the external power.
2. With a #1 Phillips-head screwdriver, remove all four screws from the battery pack plate (Figure 7, Figure 8).

Figure 7: Unscrewing the Battery Pack

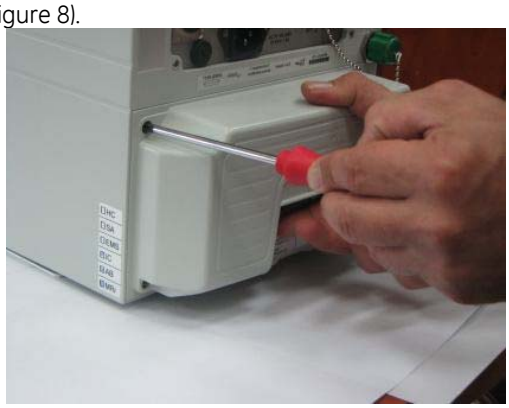


Figure 8: Unscrewing the Extended Battery Pack

3. Using the handle, pull the Battery Pack out

Figure 9: Removing the Battery Pack

Figure 10: Removing the Extended Battery Pack

4. Carefully slide the new battery pack into the chassis. Be sure it is properly aligned.
5. Firmly and carefully push the battery back into place, making certain the female connector at the front end of the pack plugs into the ventilator.
6. Reattach the four screws.

7. Charge the battery by following the instructions in *Full Recharge Procedure*, page 36.

OXYGEN SUPPLY

The iVent™201 can use medical-grade oxygen from either

- A high-pressure source such as a central supply system or cylinder at 40-75 psi (2.8-5.1 bar).

WARNING **The exact oxygen pressure which the iVent™201 requires when connected to medical grade oxygen depends on the version you have. Check the back label (Shown in Figure 11) for the pressure levels of your unit.**

- A low-pressure oxygen source -- oxygen concentrator or flow meter device - using the optional Low Pressure Oxygen Enrichment System (M1161007, M1162020, M1162022)

When connecting the iVent™201 to an oxygen supply, ensure that the correct type of oxygen source is selected in Advanced Settings. [**Main Screen/Menu/Advanced Settings/Oxygen Supply (Pressure**)] (See page 94). The factory default is High pressure.

WARNING **The O2 system must be calibrated every 6 months**

We recommend calibration every 3 months to ensure the O2 system integrity. For instructions for performing the O2 calibration see *O2 Calibration* Page 177.

HIGH PRESSURE OXYGEN SUPPLY

If using pressurized oxygen, connect the oxygen supply to the oxygen O2 inlet connector at the back of the ventilator (Figure 11).

WARNING **To prevent explosion hazard always ensure the oxygen connector is free from oil.**

CAUTION Verify that the oxygen supply is at the correct pressure before connecting to the O2inlet.

When the unit is ventilating the measured concentration of delivered oxygen can be viewed on the **Alarm Settings** screen (See page 145).

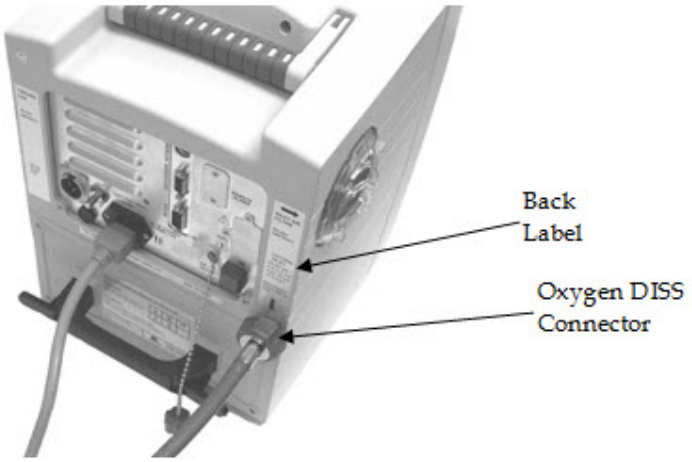


Figure 11: The Oxygen Inlet Connector

CAUTION When using the iVent™201 with a pressurized oxygen supply, the accuracy of the oxygen concentration should be verified periodically with an external calibrated oxygen analyzer

LOW PRESSURE OXYGEN SUPPLY

Connecting a low pressure O2 supply Adapter requires a low pressure O2 filter/adapter, fitted with a 22mm female port.

To connect the low pressure oxygen supply:

1. Remove the air inlet filter by turning it counterclockwise. Then install the Low Pressure O2 filter/adapter with a clockwise turn.
2. You are now ready to connect the Low Pressure O2 Supply Adapter to the air inlet port of the ventilator (Figure 12).

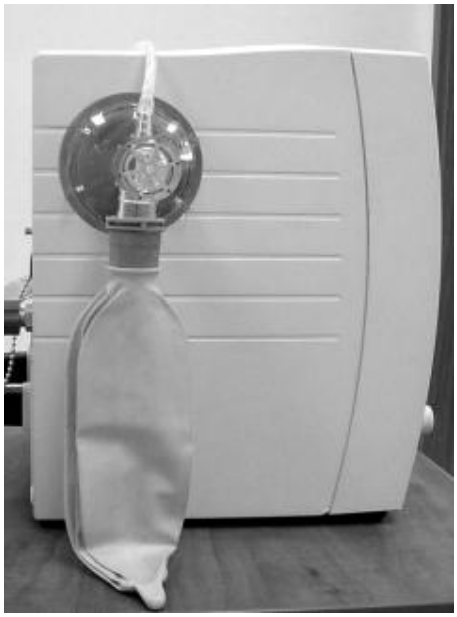


Figure 12: Low Pressure O_2 Supply Adapter and Filter Installed

3. Be sure that the **Low +M or Low option** is selected under **Oxygen Supply** (Pressure) in the **Advanced Settings** menu (See page 91).

CAUTION Do not attempt to use the FiO2 option above 60% when using a low pressure oxygen supply

When not using a low pressure O2 supply, the Low Pressure O2 Filter must NOT be used, as the 22mm port is easily blocked.

When the **Low + M** option is the selected in the **Advanced Settings** window, the measured FiO2 level is displayed in the **Main** window of the screen.

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.

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

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 13).

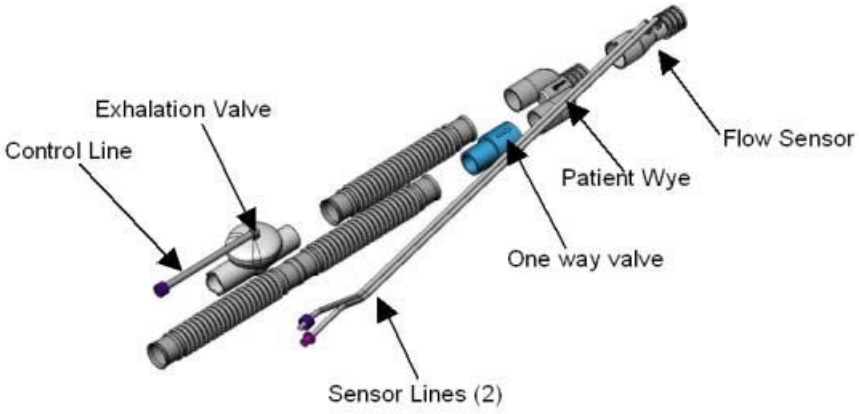


Figure 13: Patient Circuit Connections (Breathing Circuit)

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. (See Figure 1)

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. Ensure correct connection of the Male and Female luer connectors on the flow sensor tubing.
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 (O.V.T.), as described on page 60.

REUSABLE PATIENT CIRCUIT

The reusable patient circuit contains the same components as the disposable circuit. It should be sterilized by a stem autoclave. The Versamed reusable Patient Circuit can be sterilized up to 40 cycles.

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 reusable 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. Ensure correct connection of the Male and Female luer connectors on the flow sensor tubing.
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 (O.V.T.**), as described in on page 60**.**

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 a dual limb patient circuit:

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

NOTE *The instructions provided below only refer to devices in which the Transport Mounting plate (P.N.M1169908) 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 guide the adapter into its place.
2. Insert the Captive screw into the screw-hole on the adapter side, and screw it in 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:

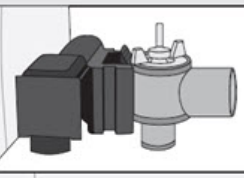
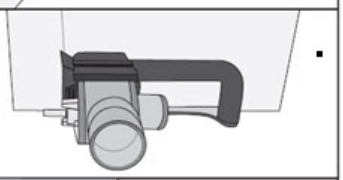
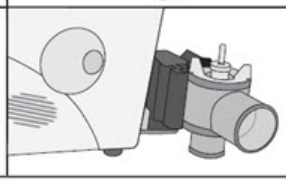
EXHALATION VALVE POSITION	FIGURE
Side vertically	
Side horizontally	
Front vertically	

Figure 14: Exhalation Valve Positions

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. Assemble the PEEP control tube by connecting one end to the barb fitting of the exhalation valve and the other end to the barb fitting of the reusable Luer fitting.
2. Connect the assembled PEEP control tube by securing the luer lock fitting to the Exhalation valve luer inlet, which is marked with a blue dot on the front panel of the ventilator (see figure 1, item number 4).
3. Secure the multi-use one way valve to the ventilator patient outlet (see figure 1, item number 5)
4. Connect the patient circuit inspiratory limb to the one way valve sitting on the ventilator patient outlet and the expiratory limb to the exhalation valve.
5. If appropriate, fit the patient wye to the inspiratory and expiratory patient circuit tubes.
6. Secure the flow sensor to the patient wye and connect the 2 sensor lines to the ventilator sensor line luer inlets (see figure 1, item number 6).
   Note: even though the luer lock fittings at the end of the flow sensor sampling lines are non-interchangeable, it is good practice to verify that the left (while facing the ventilator) male luer connector connects to the fitting on the flow sensor which is closest to the patient

WARNING ***Before connecting a patient to the ventilator with a new circuit, you must perform a complete Operational Verification Test (O.V.T.) as described on page 60***

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:

- O.6 KPA (6cmH2O) at 60 L/min for adult patients.
- O.5 KPA (5cmH2O) at 30 L/min for pediatric patients.

OTHER CONNECTIONS

HME

If required, a Heat and Moisture Exchanger may be placed between the flow sensor and the patient connection.

CAUTION *A contaminated HME filter can impede the ventilator's Patient Disconnect alarm detection. Do not use any filter that appears to be discolored or filled with water.*

NOTE *Adding attachments, components or sub-assemblies to the* iVent™201 *breathing circuit may increase the pressure gradient.*

MDI

To administer medication, install an adapter for MDI treatment between the flow sensor and the patient connection.

USING THE IVENT™201 WITH HEATED HUMIDIFICATION (1.4 STEPPER BASED MODELS ONLY)

The following procedures explain how to connect the iVent™201 to a heated humidifier.

To use the iVent™201 with a heated humidifier:

1. Disconnect the Inspiratory Limb from the ventilator outlet of the iVent201 and reconnect it to the humidifier outlet.
2. Remove the one-way valve from the Patient Wye and reconnect the tube.

3. Connect the one-way valve to one end of a 1-2' length of 22mm corrugated tubing.
4. Connect the other end of the tubing to the ventilator outlet. Fasten the one-way valve to the humidifier inlet. Be sure the directional arrow on the valve is pointing towards the patient end of the circuit.
5. Connect the Male and Female clear sensor tubing connectors to the Male and Female luer inlets on the front of the iVent201 as described above in *Patient Circuit*, page 40.
6. Connect the blue Expiratory Sensor tube to the luer connector marked with a blue dot on the front of the ventilator.

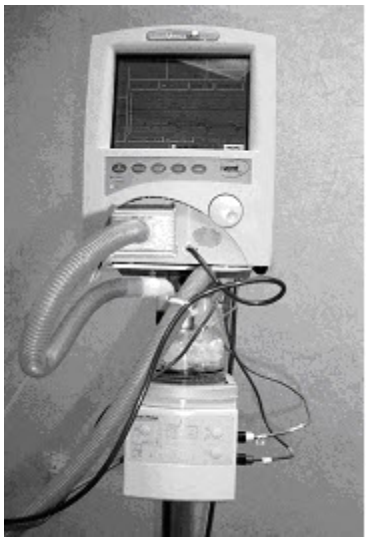


Figure 15: The iVent™201 shown connected to a Fisher and Paykel Heated Humidifier Model MR850

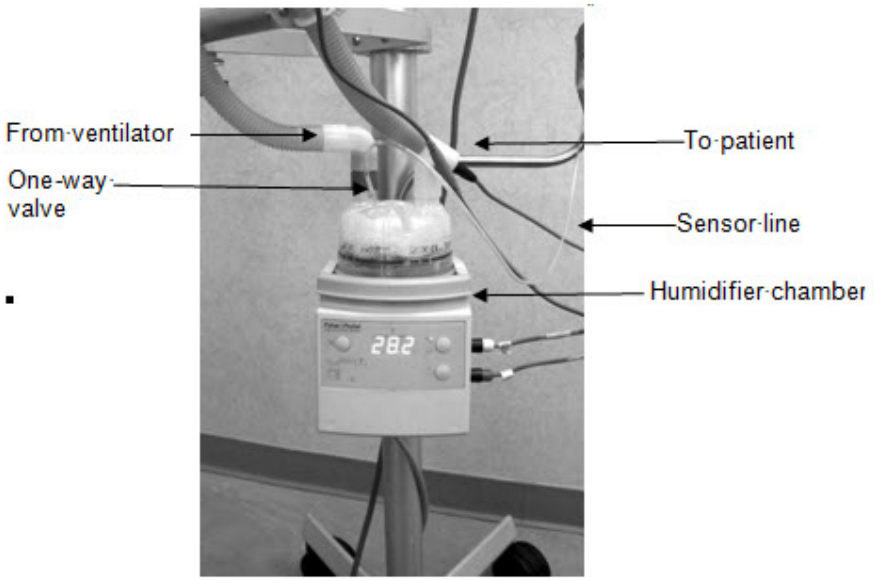


Figure 16: Heated Humidifier Connections

NOTE *If not using a heated wire circuit, placement of a water trap at the*

lowest point of the Inspiratory Limb is highly recommended.

Follow the humidifier manufacturer's instructions for the operation of the humidifier.

If a heated wire circuit is required, use the VersaMed inlet equipment (Patient Wye with one-way valve and exhalation valve. Replace the VersaMed inspiratory tubing with the heated wire tubing.

WARNING ***To prevent water and/or secretions from entering the sensor tubing, always keep the patient sensor tilted upward.***

PNEUMATIC NEBULIZER

If required, a pneumatic nebulizer may be connected to the machine.

NOTE *100% oxygen is used as a driver gas for the nebulizer. Thus an external high-pressure oxygen supply must be connected to the machine to enable the nebulizer operation.*

To activate the nebulizer you need to select the High option under Oxygen Supply in the advance menu (See page 95)

To connect a nebulizer device:

1. Connect the Nebulizer tube to the Nebulizer outlet on the front panel. The Nebulizer icon is still displayed in gray at the lower bar of the display, showing that the nebulizer is connected but not activated (Figure 17).

Figure 17: nebulizer Icon

2. Install the Nebulizer with the required medication to the patient circuit after the Patient Wye and the Flow Sensor.
3. Connect the other side of the Nebulizer tube to the nebulizer.
4. To activate the Nebulizer see page 102.

PULSE OXIMETER

The pulse oximeter and accessories are indicated for continuous non-invasive monitoring of oxygen saturation (SpO2) and pulse rate (measured by the SpO2 sensor). The pulse oximeter and accessories are intended for use with adult and

pediatric patients in hospital, hospital types facilities, mobile/ transport functions, and home environments.

A pulse oximeter can be connected to the iVent™201 ventilator allowing the operator to continuously monitor patient's oxygenation saturation on the iVent™201 screen.

WARNING ***Use only Nonin manufactured pulse oximeter sensors. Using other manufacturer's sensors can result in improper oximeter performance.***

Explosion Hazard: Do not use the pulse oximeter in an explosive atmosphere or in the presence of flammable anesthetics or gasses.

Carefully route cables and connections to reduce the possibility of entanglement and strangulation.

The SpO2 device do not meet defibrillation-proof requirement per IEC 60601-1.

Do not sterilize the SpO2 device. Refer to the cleaning instructions included in the sensor instruction.

Do not use the pulse oximeter in the MRI environment.

To connect the pulse oximeter to the iVent™201 ventilator:

1. Remove the Pulse Oximeter sensor and the unit connector cable from the kit. One end of the unit connector is gray and connects to the sensor. The other end of the unit connector cable has two connectors, a Keyboard connector and an RS-232 connector (Figure 18).

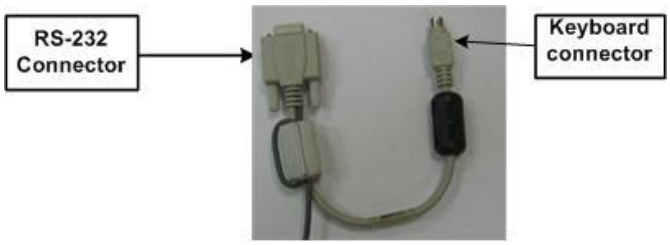


Figure 18: The Pulse Oximeter Connectors

2. Connect the Pulse Oximeter sensor to the gray end of the Unit Connector cable (Figure 19).

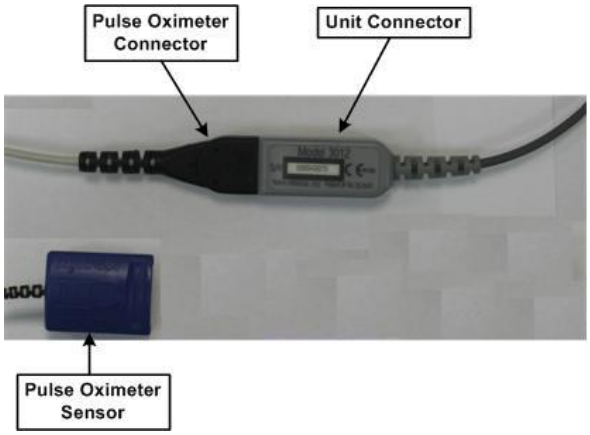


Figure 19: Pulse Oximeter Sensor

3. At the rear panel of the iVent™201 device, connect the following:

- The Keyboard connector to the Keyboard port.
- The RS-232 connector to the RS-232 port (COM1 or COM2), located on the right side of the device. (Figure 20).

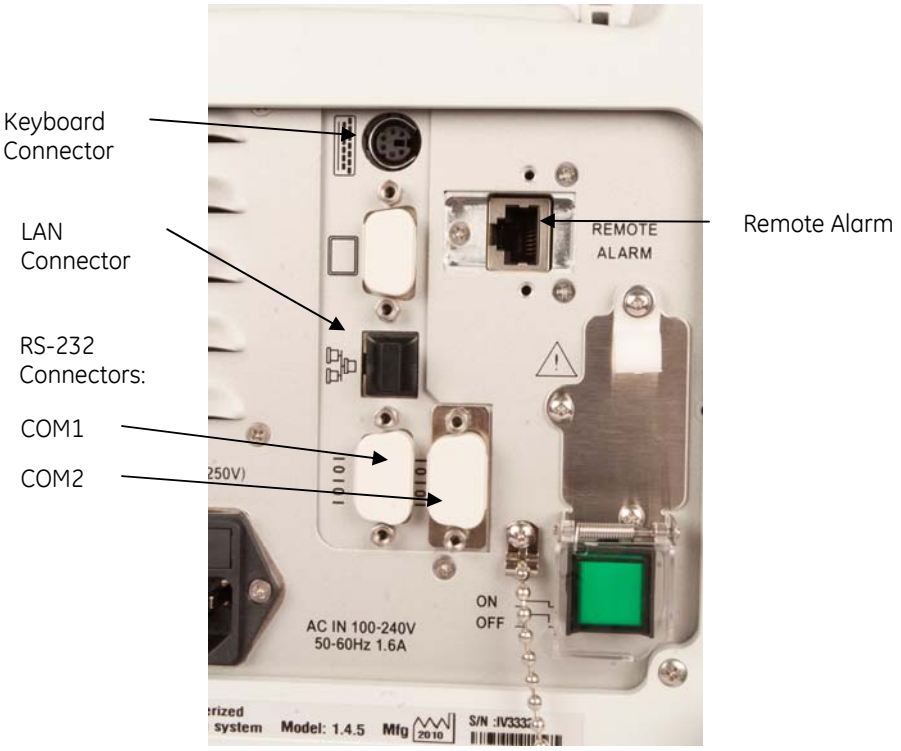


Figure 20: iVent™201 Rear Panel

You can connect the RS-232 to any communication port. The iVent™201 sets the communication automatically. To configure the communication port see page 186.

REMOTE ALARM

The iVent™201 can be connected to a remote alarm system via the Remote Alarm Connection port on the back panel shown in Figure 20.

Using Normally Opened (NO) or Normally Closed (NC) signals, this connection port allows alarm signal activation in locations remote from the ventilator triggered by ventilator alarm conditions. For connector details see Appendix H: Remote Alarm Connector.

WARNING **Connect the Remote Alarm Cable only to its designated port marked accordingly.**

NOTE The iVent™201 is supplied with the Remote Alarm port covered (See Figure 20). Unscrew the cover to connect the Remote Alarm cable.

The LAN port is not in use and should be covered with the plastic cap at all times

SENSOR LINE MAINTENANCE

The iVent™201 monitors the sensor lines and periodically sends pressurized air through the lines to clear them of any accumulated material. It is possible for secretions and/or condensation to accumulate. Should this occur:

1. Do not attempt to clean sensor lines while a patient is connected to the iVent™201.
2. Disconnect the sensor lines from the connectors on the iVent™201.
3. Insert the end of a syringe into one end of the sensor line and discharge air through it until the line is clear of condensation or secretions.
4. Re-attach the sensor lines.

PATIENT CONNECTION

When connecting the patient, make sure the Patient Wye is positioned so that the flow sensor tube connections are on top.

Angle the Patient Wye downward to help prevent fluid accumulation.

FILTERS

WARNING ***Do not use the iVent™201 without the air-inlet filter and a bacterial filter before the patient circuit.***

AIR INLET FILTER

The air inlet filter (part no. M1161007)screens out particulate matter from ambient air (Figure 21).

Figure 21: Air Inlet Filter

WARNING ***Failure to use an air inlet filter may result in severe damage to the internal components of the iVent™201.***

The air inlet filter must be replaced every 500 hours or every thirty days of operation. See page 173 for air filter maintenance procedures.

BACTERIAL FILTER

A user-supplied bacterial filter prevents contamination of the patient circuit components, and prevents bacteria, excessive humidity and liquids from entering the iVent™201.

WARNING ***Failure to use an adequate bacterial filter may cause severe damage to internal pressure and flow sensors, which may result in ventilator failure.***

CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR FILTER

In the event of environmental contamination by hazardous or toxic substances, the air-inlet filter should be replaced with an optional CBRN canister. CBRN canisters are designed for first-response protection against nuclear, toxic, or biological particulate material and chemical vapors, gases, and mists/aerosols and tear gas.

The CBRN filter fits into the iVent™201 via an optional air inlet adapter (item M1161967). Remove the air inlet filter from the iVent™201 by turning it counterclockwise. Then fasten the air inlet adapter to the CBRN filter by twisting it on clockwise. Finally, screw the CBRN canister with the adapter into the air inlet adapter.

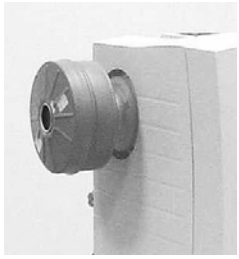


Figure 22: CBRN Filter

OPERATIONAL CASE

With an optional soft case (item M1161883)(Figure 23) the iVent™201 can be operated in bad weather conditions, such as rain or snow. Padding and protected ventilation ports enable full function in a variety of situations.

Figure 23: Soft Case

THE IVENT™201 USER INTERFACE

It is important to invest time to acquaint yourself with the iVent™201 and how the Control Knob is integrated with the screen and the operation of the iVent™201.

Connect a test lung with an Rp20 resistor and patient circuit. Switch on the unit, and navigate through the features discussed in this section. Rotating the Control Knob at the menu level allows for easy, automatic selection of ventilation modes. Choosing the best parameter for a patient is as easy as switching on the iVent™201 and selecting the patient's ideal body weight.

CONTROLS AND POWER UP

THE FRONT PANEL

Located above and to the right of the ventilator outlet, is the rotational Control Knob, which allows control of and access to all the ventilator functions via the LCD screen. Turn the knob to change a value, or navigate through a menu screen or through a list of choices. Press the knob and the iVent™201 responds with a tactile click and with audible feedback – to select or confirm a choice, or to access another menu.

Where a numeric value is required, selection is done by rotating the dial to move a virtual slider bar, spin button, or counter, in increments calibrated precisely along the full range of values. In some settings menus, one press of the knob is enough to instantly select or confirm a value, which thereafter immediately returns you to the previous screen.

Five dedicated keys are positioned below the LCD (Figure 24):

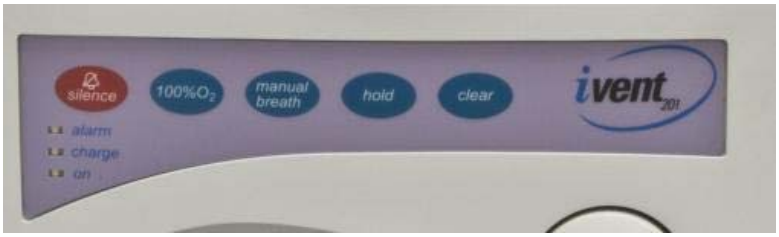


Figure 24: the iVent™201 Front Panel

Silence

Silence is used to immediately mute the audible alarm and minimize the corresponding red message pop-up window. A two-minute timer is activated and displayed in the lower right corner of the display instead of the time-date field, alongside the silenced alarm icon (Figure 25).

One short press on the **Silence** key resets the time to 2 minutes. Press the **Silence** key for one second and it re-activates pending alarms.

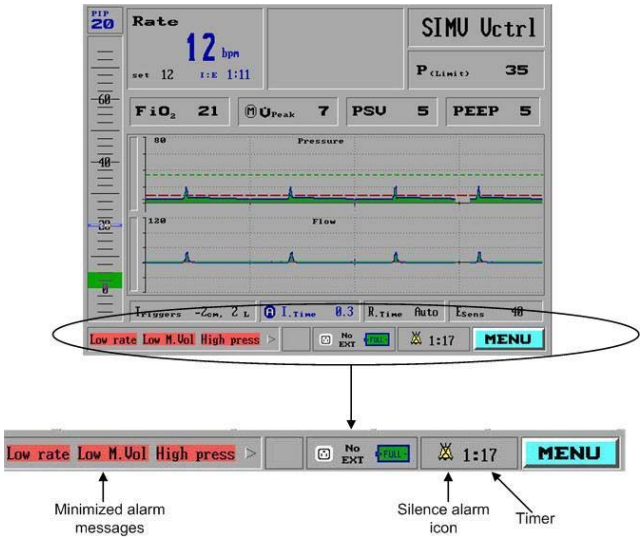


Figure 25: Status Window After Alarm Has Been Silenced

Manual Breath

Manual Breath delivers a single breath at the set tidal volume or pressure. In CPAP/PSV ventilation mode, where there is no definition for machine breath, the **Manual Breath** is set according to the default volume control for the specified patient weight chosen at startup.

Hold

Hold activates and/or cancels the hold maneuver. Press the button once to initiate an inspiratory hold maneuver, which allows the calculation of static compliance. Press it twice to initiate an end to the expiratory hold maneuver, which allows the calculation of intrinsic PEEP. For more details see page 235.

Clear

Clear has several functions. Press it to perform the following:

- Clear the screen of its current selection and return the operator to the previous screen or menu selection – just like the Escape key on a computer keyboard.
- Minimize any red alarm-warning pop-up window and mute the alarm sound for 30 seconds. If clear is pressed again within 30 seconds, an alarm warning pop-up window appears.
- When **Clear** is pressed and held, all corrected alarm messages (displayed in green) are cleared.

LED Indicators

Three LED (light emitting diode) indicators provide a quick indication of power and alarm status:

- The red alarm LED blinks rapidly when the iVent™201 detects an alarm condition.

- The amber charge LED lights to indicate that the iVent™201 is connected to external power.
- The green on LED indicates that the power is switched on.

The Screen

The LCD screen is organized to allow rapid access to the ventilator's functions. The monitoring or control of any critical parameter is performed with ease.

- Baseline indicators and alarms – emergency alerts and alert status indicators, power and battery states, date and time, and the Menu access button -- are all displayed along the bottom of the screen indicators.
- Set values are displayed in black
- Measured and calculated values are displayed in blue -- flashing values indicate that a set value was not obtained.

Here is a quick overview of the most important screens:

The **Main Screen** (Figure 26) is the first screen displayed when the iVent™201 is placed in **Standby** or **Start** Mode.

The slider gauge along the left side of the screen displays the real-time measured Peak Inspiratory Pressure below a digital readout of the last peak inspiratory pressure value.

On the top left of the screen, a large shows the total measured respiratory rate in breaths per minute in large blue numbers. The selected/default respiratory rate is shown in smaller black numbers below. Proceed to the **Respiratory Rate** option to enable and change the number of breaths per minute.

Beside the **Respiratory Rate** option, there is also the **Tidal Volume** option. This displays the exhaled Tidal Volume and allows adjustment to the set Tidal Volume. (See page 69 for more details about the Tidal Volume display**.)**

On the top right of the screen is the **Mode Selection** option, which shows the current ventilation mode. This option allows you to change modes (See page 62).

Selecting and clicking on a mode brings up the appropriate Mode screen for the selected ventilation mode. Use this screen to view or adjust ventilation parameters.

When the ventilator is operating, the middle section of the Main screen displays pressure/flow waveforms. The optional waveforms package permits a host of possible display characteristics. (See page 108 for a guide to the waveform package.)

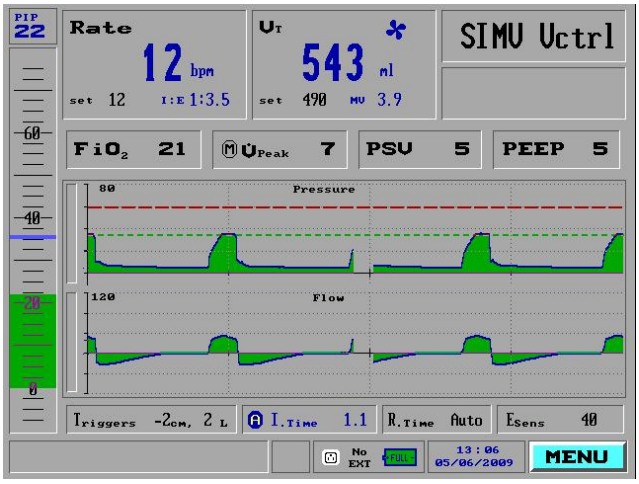


Figure 26: The Main Screen

If a pulse oximeter is connected to the iVent™201 the SpO2 levels and Heart rate are displayed on the lower right side of the screen (Figure 27).

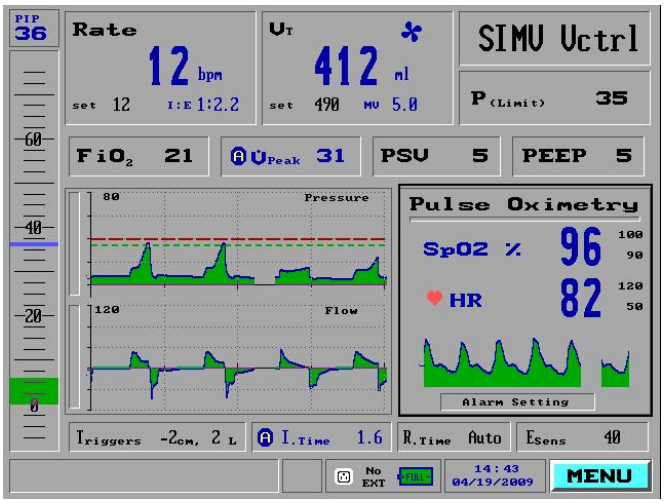


Figure 27: The Main Screen With the Pulse Oximetry Monitoring Window

Notes:

3 OPERATING THE IVENT™201 – SETTING MODES AND PARAMETERS

This chapter contains the following sections:

INTRODUCTION

The iVent™201 offers advanced capabilities for adjusting ventilation parameters for each mode. In this section you learn how to:

- Start the ventilator
- Choosing a patient weight
- Test the patient circuit
- Choose a mode of ventilation
- Use the Mode screen and the Menu screen to change parameters
- Understand breath data returned by the iVent™201
- Reset parameters to default values

OPERATION OF THE IVENT™201

The following section describes the various functions and capabilities for operating the iVent™201.

POWER UP AND WEIGHT SELECTION

If you have installed a patient circuit then you are ready to begin operating the iVent™201. To turn on the power, press the green **ON/OFF** switch on the rear panel.

When power is turned on, the software performs a self-test. Once the boot up process completes (after approximately thirty seconds) you hear a beep and the screen (Figure 28) asks you to select the patient's body weight, which sets the default ventilation parameters.

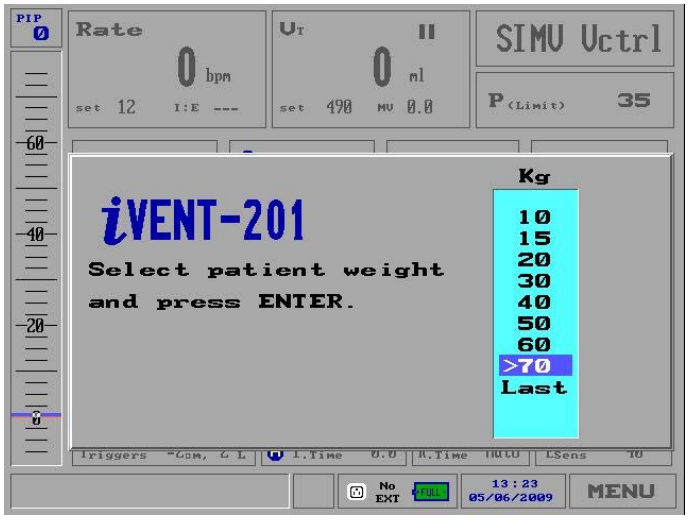


Figure 28: The Patient Weight Selection Pop-Up Window

NOTE *Parameters for all the* iVent™201*'s possible ventilation modes are set when you choose a patient weight upon startup. For a view of the default parameters according to weight, refer to Table 1: Default Start Parameters for Volume Ventilation for 10 kg to 70 kg through Table 4, page 107.*

The default selection for patient weight range for the iVent™201 *is 70+kg. This may be changed using the* ***Configuration*** *utility described on page 185.*

As a safety measure, within a few seconds after the patient weight selection pop-up window appears, the iVent™201 generates airflow to see if resistance is encountered in the patient circuit, which means that the patient is connected.

NOTE *This is an optional feature, not available in all* iVent™201 *units.*

- If the iVent™201 detects resistance, it sounds an alarm and begins ventilating in SIMV pressure control mode at a rate of 15 breaths per minute, P(INSP) 20 and a PEEP of 5.
- If the iVent™201 detects no airway resistance, it enters **Standby** mode. During this state, if flow is detected in the patient circuit the iVent™201 performs an auto-start.

O.V.T

The patient circuit must be tested each time it is connected, so if you are reconnecting a patient circuit or using a new one, you must perform the Operational Verification Test (O.V.T.). This test, which takes less than one minute, checks the integrity of the breathing circuit and audible alarm functionality.

Two plastic caps for covering the ends of the patient circuit are required for the O.V.T. They are included with all patient circuits offered by Versamed.

To perform an O.V.T.:

1. Rotate the Control Knob until the **O.V.T**. option is selected in bright blue.
2. Press the Control Knob until you hear a click. The **O.V.T. Instructions** pop up window appears (Figure 29).

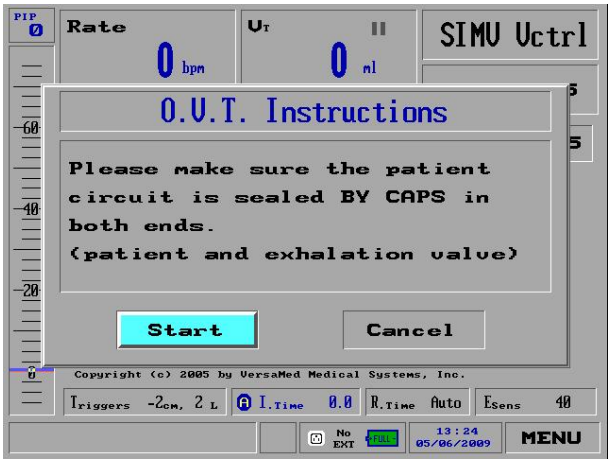


Figure 29: The Initial O.V.T Pop-Up Window

3. Follow the instructions on the screen. Use the plastic caps to seal off the following:
   - The patient Wye sensor, and
   - The exhalation valve
4. Press the knob to begin the test. A pop-up window appears which indicates the test has begun.
5. After several seconds, another pop-up window appears and instructs you to remove the cap on the exhalation valve leaving the cap on the Wye outlet.
6. After the ventilator performs further testing, it sounds an alarm. If you can hear the alarm, press the Control Knob to complete the O.V.T. If remote alarm is connected verify the alarm is activated in remote station.

Once the iVent™201 has successfully completed the O.V.T., the patient circuit and ventilator are ready for use.

If the O.V.T. fails:

1. Verify that both Flow Sensor tubes are properly and snugly connected to the correct luer ports on the front of the iVent™201. (Note: Remember that two lines go to the patient Wye connectors, and the blue line goes to the Expiratory Valve Control connector.) Repeat the test.
2. If the O.V.T. fails once again, then replace the patient circuit.
3. If after replacing the patient circuit, the O.V.T. still fails, try re-calibrating the ventilator. If calibration fails to correct the O.V.T. failure, immediately remove the ventilator from service and contact a Versamed approved technician.

STANDBY AND PATIENT VENTILATION

When you have selected the weight, the iVent™201 enters **Standby**, ready to ventilate the patient with a press of the Control Knob. By default iVent™201 starts up in SIMV Volume control.

To start ventilation from Standby mode:

Return to the **Main** screen, rotate the Control Knob until the **Start** option is selected, then press the Control Knob.

To return the ventilator to **Standby** mode:

1. Return to the **Main** screen, turn the Control Knob to select the **Mode Selection** option on the top right of the LCD display, and press the Control Knob.
2. At the bottom of the drop-down menu is **Standby**. Dial the knob until **Standby** is selected and press. Then select the **Yes** option in the **Confirmation** window and press the knob. The ventilator suspends operation.

NOTE Always return the iVent™201 to **Standby** mode before powering down

CHANGING VENTILATION MODE

The **Mode Selection** option is on the top right side of the LCD display (Figure 30):

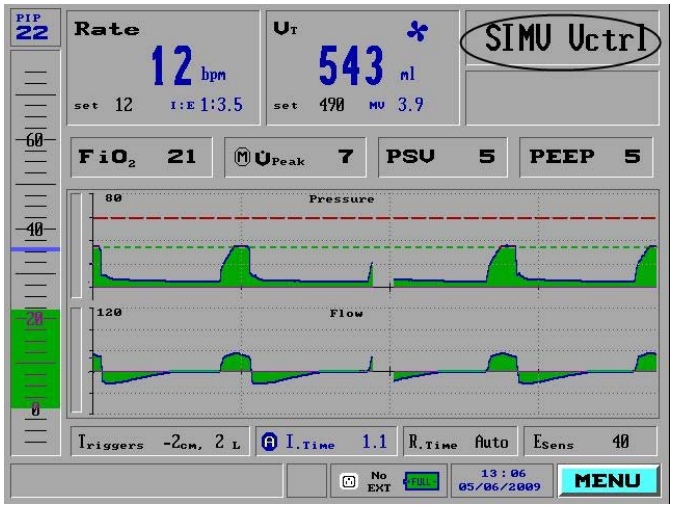


Figure 30: The Mode Selection Menu Selected

To change the mode, turn the Control Knob to select the Mode Selection option, then press. The **Ventilation Modes** menu pop-up window appears (Figure 31) which offers six options including **Standby**:

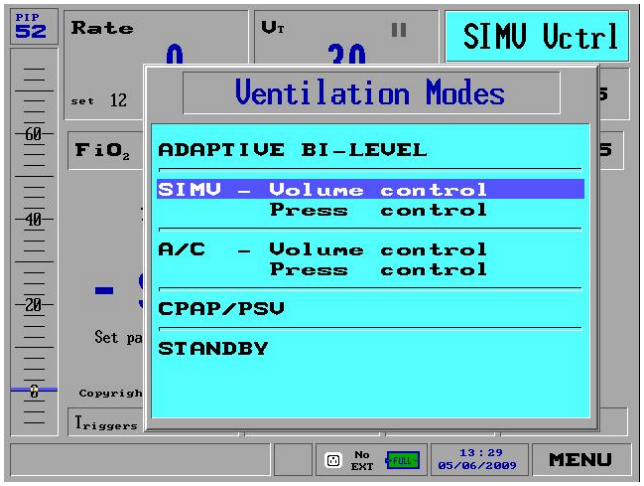


Figure 31: The Ventilation Modes Selection Pop-Up Menu Window

NOTE Depending on which iVent™201 model you have purchased, not every mode may be available.

Turning the Control Knob moves the selected bar through the choices. When the required mode is selected, press the knob to accept it. A parameter screen is displayed where you can either accept the default ventilation parameters or change any of them.

For example, to change to SIMV pressure control mode from SIMV volume control mode:

1. Make sure that you start from the **Main** screen

NOTE *To return to the **Main** screen, press the **clear** key on the keypad below the display. This returns you to all previous screens until you return to the **Main** screen.*

2. From the **Main** screen, turn the Control Knob to select the **Mode Selection** option, as shown in Figure 30. By default, the iVent™201 starts in SIMV Volume Control, abbreviated "**SIMV Vctrl**."
3. Press the Control Knob and the **Parameters** screen appears. Turn the knob clockwise one click to select **Pressure Control** (Figure 32):

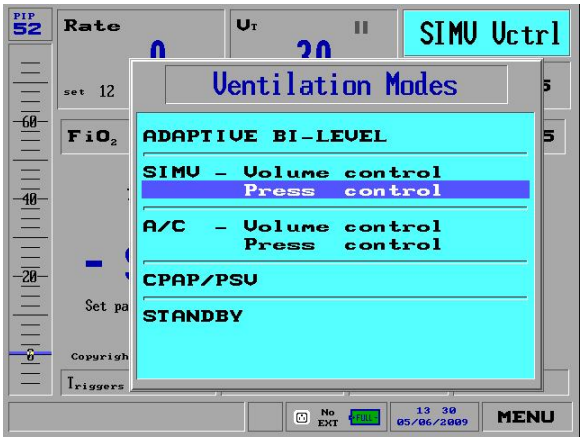


Figure 32: Pressure Control Option Selected

4. Press the knob to accept the selection. The **SIMV Pressure Control Parameters** screen appears (Figure 33).

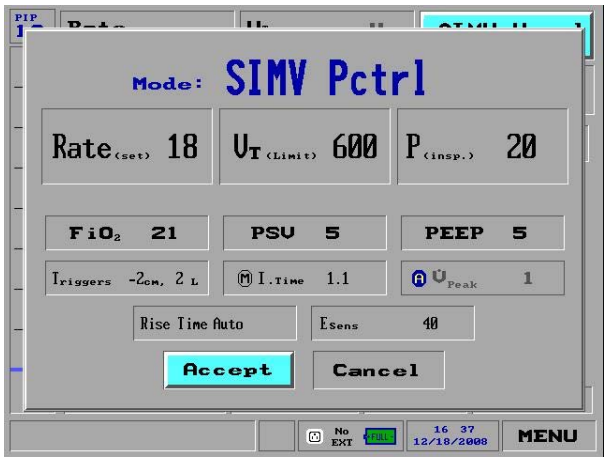


Figure 33: The SIMV Pressure Control Parameters Screen

5. Note that **Accept** is automatically selected, which makes it possible to accept the default parameters immediately and go directly into patient ventilation. This is after you have verified that the patient settings are correct.

NOTE *The user must press **Accept** to change both the mode and the parameters.*

COMMON PARAMETERS

This section details how to change:

- Breath rate

- Tidal volume
- Pressure limit
- Oxygen level
- Peak flow
- Pressure support
- PEEP
- Triggers
- Inspiratory time
- Rise Time
- Flow Termination – Exhale sensitivity (Essens)

CHANGING VENTILATION PARAMTERS – OVERVIEW

CAUTION Only a fully qualified professional should change these settings

The iVent™201 provides two different ways to change ventilation parameters: through the **Main** screen and through the **Mode Parameters** screen.

NOTE *To quickly change an individual parameter setting, the fastest way is through the **Main** screen. If you need to adjust several settings at once, navigate to the **Mode Parameters** screen and make each required adjustment. When you have set each parameter, you can accept all of them at once.*

To change ventilation parameters through the Main Screen:

1. Return to the **Main** screen -- if you are not already there, press the Clear button until you return to it.
2. Turn the Control Knob to select the parameter you want to adjust.
3. Press the Control Knob.
4. Adjust the setting to the required value.
5. Press the Control Knob again to confirm your changes and return to the **Main** screen.

To change ventilation parameters through the Mode Parameter Screen:

1. From the Main window, choose the Mode Selection option and select the required ventilation mode. The Parameters screen appears.
2. Dial the Control Knob to select the particular setting you wish to change.
3. Press the knob to display the setting's control window.
4. Turn the knob until the parameter has been changed to the required level or value.

5. Press the knob again to save the setting. You are returned to the Parameters screen.
6. Continue through the other parameter options, and choose and change until you have set all the values you want. Once you have finished, select Accept at the bottom of the screen. Press the knob and your new selections are saved.

NOTE *To abort the selection process and return the parameter to the previously chosen value, press the **Clear** button*

To change ventilation parameters through the Default Setting Option:

See page 105 *Restore Default Settings*, for instructions

CAUTION Selecting Restore Defaults resets ALL values to their default state, including the Ventilation mode (SIMV Volume Control). For more information about restoring defaults. See page 105 *Restore Default Settings*

THE SELECTION INTERFACE

Most of the quantitative parameters are presented in the form of an oval dial with black numerals – in the iVent™201 black numbers represent Set values – on solid teal. Turning the Control Knob increases or decreases the selected value as indicated by the black numerals inside the oval. A dark blue ribbon indicator moves around the periphery of the oval to show the scale of the selected value.

Recommended ranges are outlined in green, while values outside the recommended ranges are outlined in red. As a precaution, if a setting you are inserting exceeds or fails to meet recommended settings for the patient weight, a bright yellow Caution flag appears, as shown in Figure 34 below.

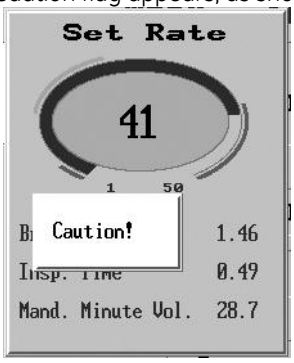


Figure 34: Example of Respiratory Rate exceeding the Recommended Value

Other parameter settings are adjusted on a slider gauge.

The chosen values are not operational until you confirm your selection by pressing the Control Knob, which takes you back to the **Main** screen. The new value(s) you have selected are shown in black.

NOTE *To abort the selection process and return the parameter to the previously chosen value, press the **Clear** button.*

To return the selection of ALL ventilation parameters to their default levels for a given patient weight see page 105.

ADJUSTING THE BREATH RATE

The following procedures explain how to adjust the breath rate, which is measured in breaths per minute.

To adjust the breath rate during the ventilation:

1. From the top most left side of the **Main** screen select the **Respiratory Rate** option (Figure 35).

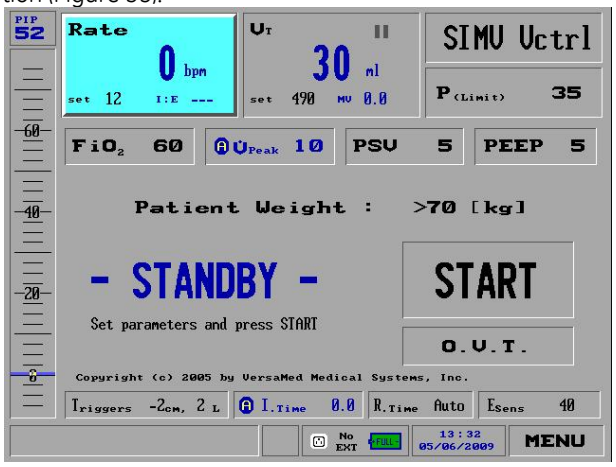


Figure 35: Respiratory Rate Selected

Or select the **Rate** setting option from the **Mode Parameter** screen (Figure 36).

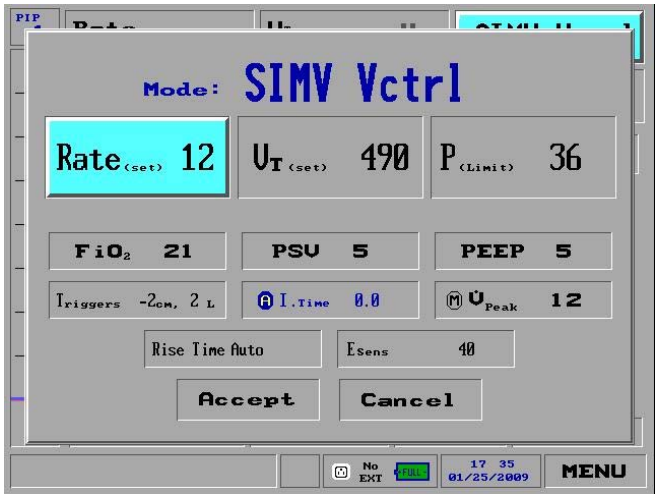


Figure 36: Respiratory Rate Selected on the Mode Parameter Screen

2. Press the Control Knob to display the **Set Rate** pop-up window (Figure 37).

Figure 37: The Set Rate Pop-Up Window

3. Turn the Control Knob to change the rate, measured in breaths per minute. Notice that the calculated values for **Breath Period**, **Inspiratory Time**, and **Mandatory Minute Volume** change automatically.
4. After setting a new value, press the Control Knob to confirm and accept the settings.

NOTE

Certain modes and values described in this section are not operational in all iVent™201 *models.*

When the setting for Inspiratory Time is Adaptive, the value to reach I.E. ratio 1:2 is displayed. Once this value reaches 2 seconds, it does not change since the Adaptive Respiratory algorithm does not allow Tinsp above 2 seconds.

When the setting for Inspiratory Time is Manual, the value is continuously displayed at all breath rate values.

ADJUSTING THE TIDAL VOLUME

The Tidal volume is the amount of air inhaled and exhaled in a breath and can be adjusted during the ventilation.

To adjust the tidal volume:

1. Select the **Tidal Volume** (or in **Pressure Control** select **Volume Limit**) setting from the top middle section of the **Main** screen (Figure 38):

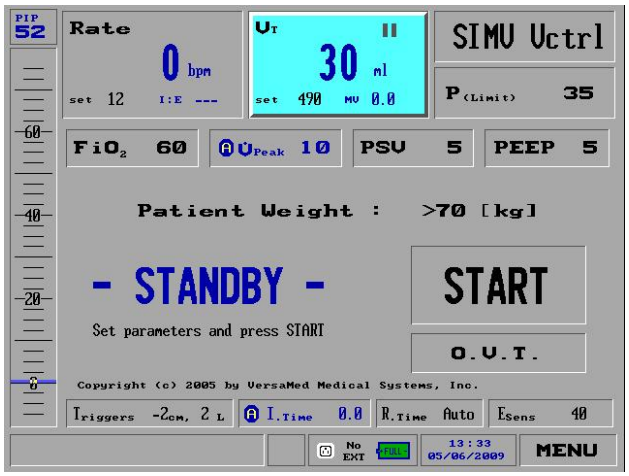


Figure 38: Tidal Volume Selected on the Main Screen

Or select **Tidal Volume** in the **Parameters** screen (Figure 39):

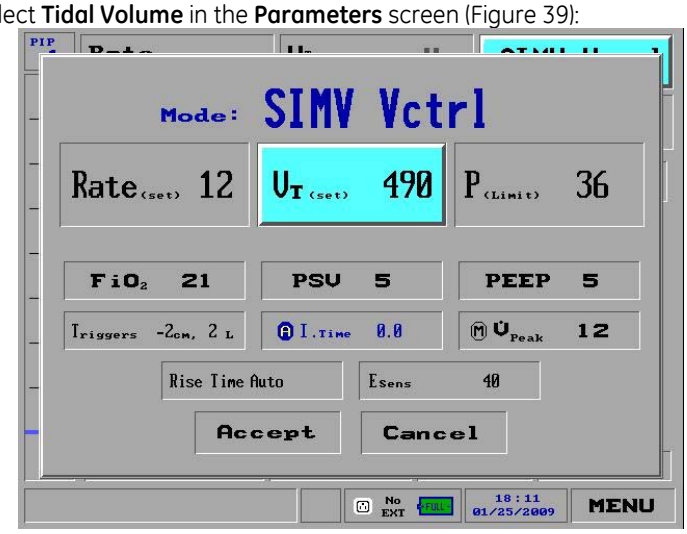


Figure 39: Tidal Volume Selected on the Parameters Screen

2. Press the Control Knob to **display** the **Tidal Volume** pop-up **window** (Figure 40).

Figure 40: The Tidal Volume Pop Up Window

3. Turn the Control Knob to change the **Tidal Volume** settings.
4. After setting a new value press the Control Knob to confirm and accept the settings.

Changing the **Tidal Volume** affects the **Mandatory Minute Volume**. If a **Manual Peak Flow** is set and does not deliver the set volume in the allotted inspiratory time, then the display flashes. During operation of Adaptive Flow, spontaneous and mandatory peak flows are displayed and cannot be changed.

Breath Types

The following section describes the various breath types which are each represented by their own specific icon.

The Tidal Volume portion of the **Main** screen indicates the **Exhale Minute Volume** (MV) on the left side of the window.

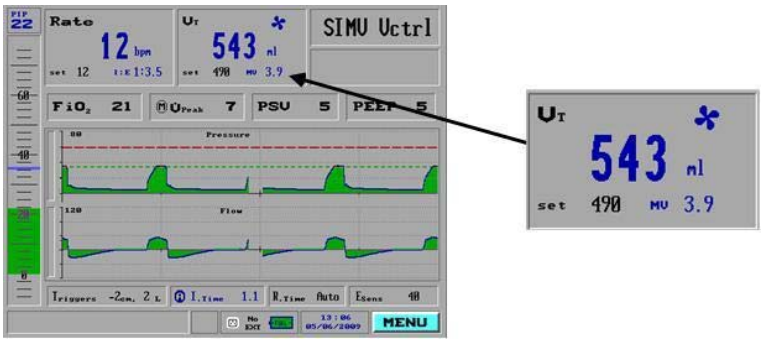


Figure 41: The Tidal Volume Window With the Breath Type Icon Displayed

The upper left corner of the Tidal Volume screen (Figure 41) also indicates the type of breath delivered, by displaying one of several icons beside the exhale volume, which are explained below

Figure	Icon	Description
	Double Bar	No measurement

	Pink Fan	**Mandatory Assist Breath** (patient initiated) - the iVent™201 has responded to patient initiation by delivering a breath.
	Blue Fan	**Mandatory Ventilator Breath** (ventilator initiated) - the iVent™201 has delivered a breath without patient initiation.
	Green Sigh	**Sigh Breath**
	Pink Man	**Pressure Support Breath:** In SIMV and CPAP/PSV modes, the ventilator has delivered a patient breath that has elevated the inspiratory pressure above PEEP.
	Green Z:	**Automatic Zeroing of Sensors:** The iVent™201 has calibrated itself to ensure that the sensors are measuring accurately.
	Blue P	**Purge sensor lines function activated** Periodically, the iVent™201 sends a puff of high-pressure air through the sensor lines to clean them. You can set the purging interval through the Advanced Menu – Humidifier Settings (See page 99). This icon indicates that the Purge System is now activated.

ADJUSTING PRESSURE

The pressure setting depends on the ventilation mode:

- When in a Volume Control ventilation mode you can adjust the maximum acceptable pressure - P(Limit)
- When in Pressure control mode you can adjust the target pressure of the ventilation - P(insp).
- When in Adaptive Bi-Level you can adjust the High pressure alarm – P(Alarm)

To adjust the pressure:

1. Select the option in the top right corner of the **Main** screen, below the **Mode Selection** (Figure 42).

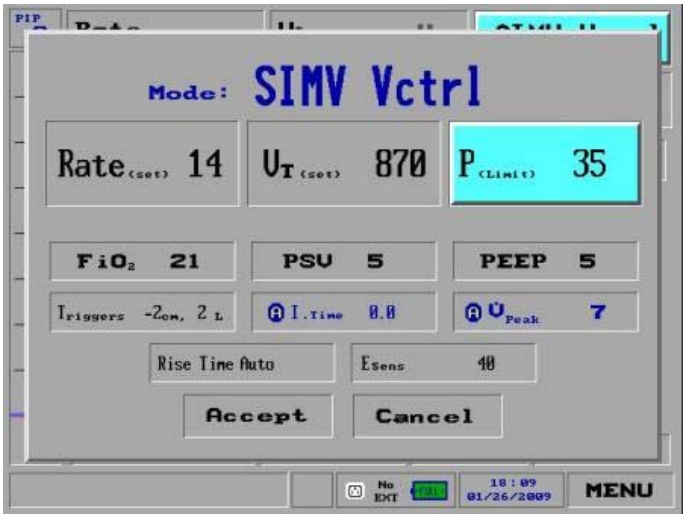


Figure 42: Pressure Limit Selected on the Main Screen

Or select the **Pressure** option in the **Mode Parameters** screen (Figure 43):

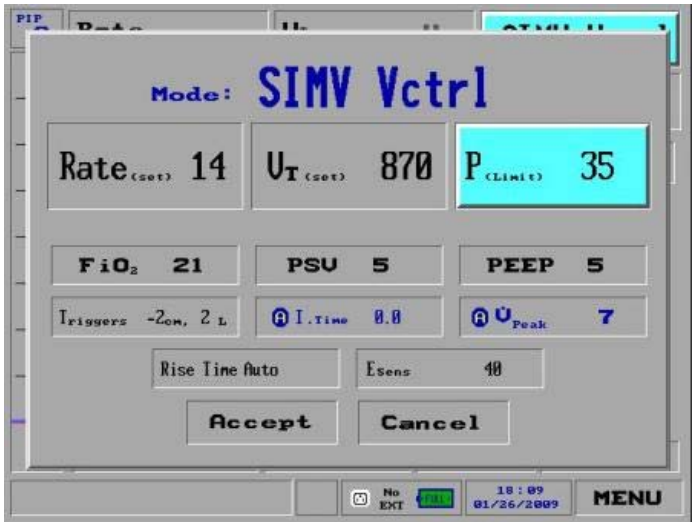


Figure 43: Pressure Limit Selected on the Mode Parameters Screen

2. Press the Control-Knob to display the **Set Pressure** pop-up window (Figure 44).

Figure 44: The Set Pressure Pop Up Window

3. Turn the Control Knob to choose the required numeric pressure value. The high pressure alarm is adjusted automatically to the value PLimit + 5 cmH2O. It can also be set to any required value using the **Alarm** menu. For more information see page 148.)
4. Press the Control Knob to confirm and save the settings.

ADJUSTING FIO2

The O2 percentage delivered to the patient is adjustable.

NOTE *Adjusting FiO2 can be performed only when the Oxygen Supply - High option is selected in the Advanced Setting menu (For more information see page 95)*

To adjust the FiO2:

1. Select the FiO2 setting from the top left of the **Main** screen (Figure 45).

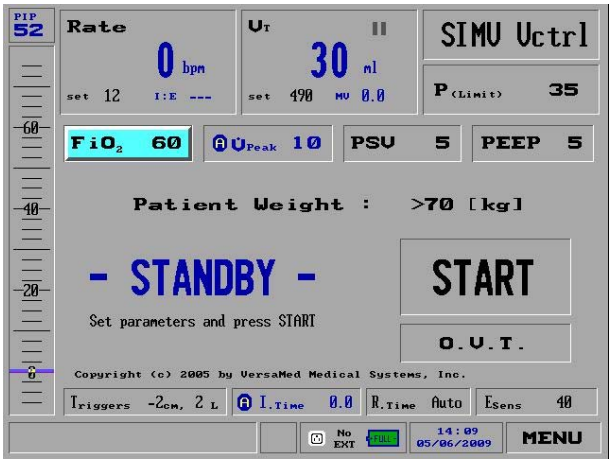


Figure 45: FiO2 Selected on the Main Screen

Or select the FiO2 on the **Mode Parameter** screen (Figure 46):

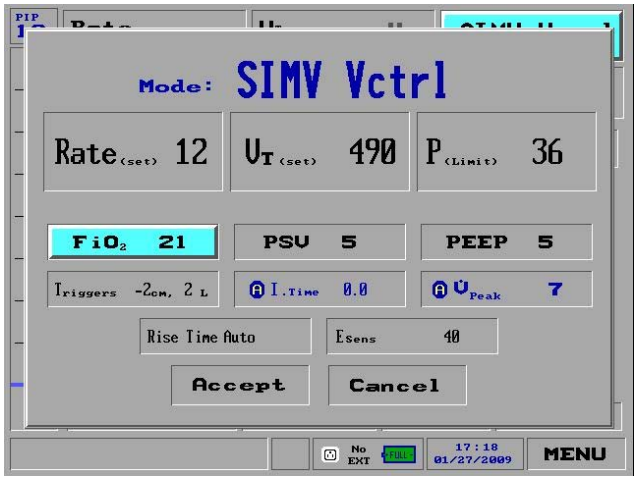


Figure 46: FiO2 Selected on the Mode Screen

2. Press the Control Knob to display the FiO2 pop-up window (Figure 47).

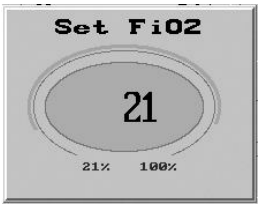


Figure 47: The FiO2 Pop Up Window

3. Turn the Control Knob to adjust the FiO2 level. The range is 21% to 100%.
4. Press the Control Knob to confirm and accept the settings.

Changing the FiO2 percentage automatically changes the O2 alarm based on a default margin of +20%, - 10% O2. The O2 alarm parameters can also be adjusted from the Alarm Settings (See page 150.)

ADJUSTING PEAK FLOW

In volume control ventilation modes you can adjust the peak flow. You can also set the ventilation to adaptive peak flow which matches the flow to the patient spontaneous flow.

To adjust the peak flow:

1. Select the **Peak Flow** setting from the second row of options on the **Main** screen (Figure 48):

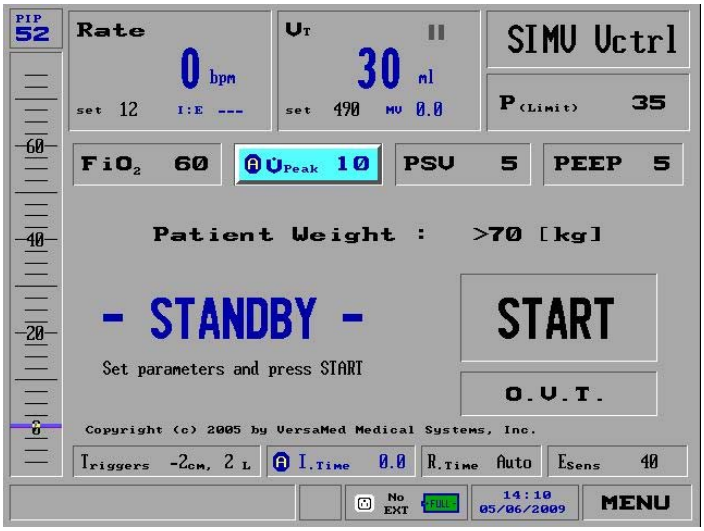


Figure 48: Peak Flow Selected on the Main Screen

Or select the **Peak Flow** on the **Mode Parameters** screen (Figure 49):

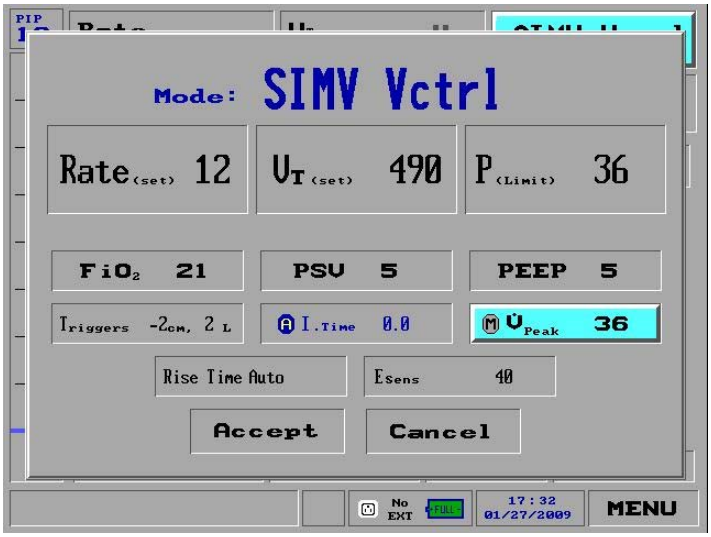


Figure 49: Peak Flow Selected on the Mode Parameters Screen

2. Press the Control Knob to display the **Peak Flow** pop-up window (Figure 50).

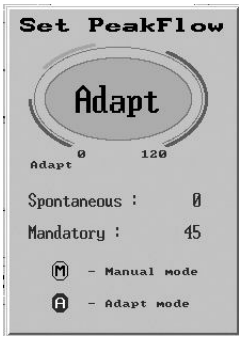


Figure 50: The Set Flow Pop-Up Window

3. Turn the Control Knob to change the peak flow value.
4. To set the flow to Adaptive Flow™, turn the Control Knob counterclockwise until **Adapt** is displayed.
5. Press the Control Knob to confirm and accept the settings.

If Adaptive Flow™ is selected, a blue icon with a black circled A is displayed on the **Main** screen (Figure 51):

Figure 51: Adaptive Flow Icon

If a **Manual Peak Flow** is set, a transparent icon with a black circled M is displayed on the **Main** screen (Figure 52).

Figure 52: Manual Peak Flow Icon

ADJUSTING PRESSURE SUPPORT VENTELATION

The Pressure Support Ventilation (PSV) during the ventilation is adjustable.

To adjust the PSV:

1. Select **PSV** setting from the second row of windows on the **Main** screen (Figure 53):

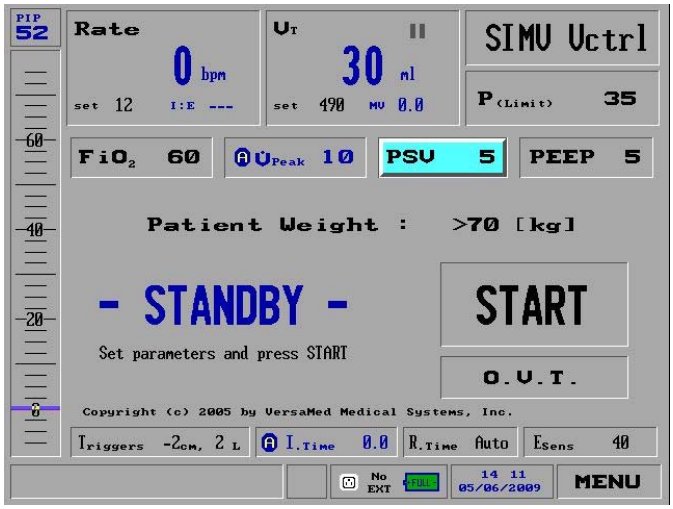


Figure 53: PSV Selected on the Main Screen

Or select the **PSV** option in the **Mode Parameters** screen (Figure 54):

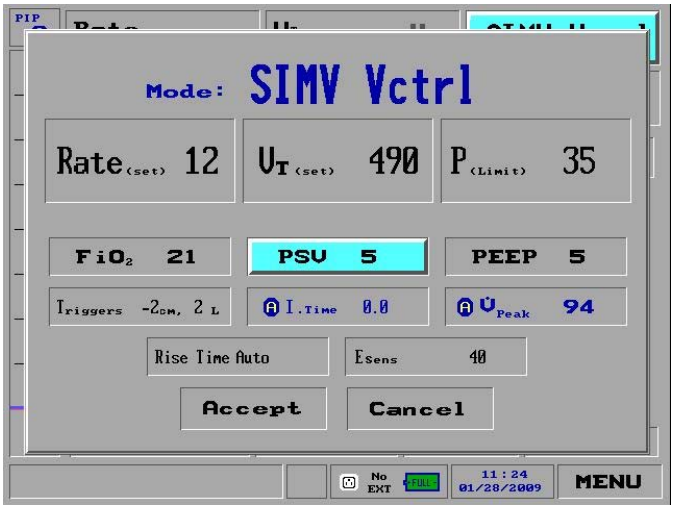


Figure 54: PSV Selected on the Mode Screen

2. Press the **Control Knob**. The **PSV** pop-up window appears:

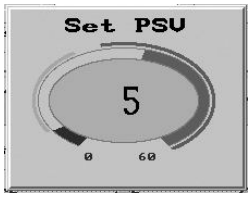


Figure 55: The PSV Pop-up Window

3. Turn the Control Knob to adjust the PSV level.

NOTE *The PSV value cannot be set to a value greater than P(Limit) – PEEP or a maximum value of 60 cmH2O.*

4. Press the Control Knob to confirm and accept the settings

ADJUSTING PEEP

The PEEP level of the patient is adjusted to a set value during the ventilation.

To adjust the PEEP:

1. Select **PEEP** from the second row on the **Main** screen (Figure 56):

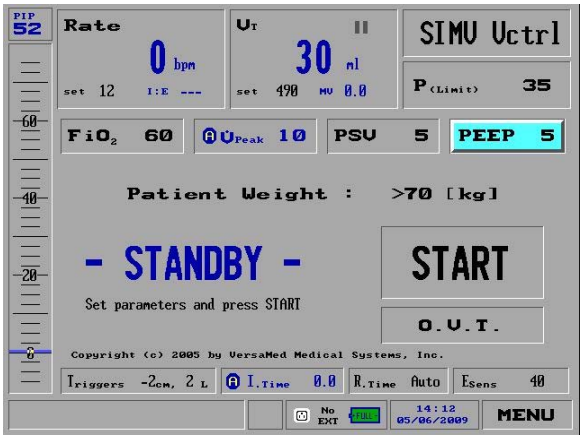


Figure 56: PEEP Selected on the Main Screen

Or select the **PEEP** option in the **Mode Parameters** screen (Figure 57)

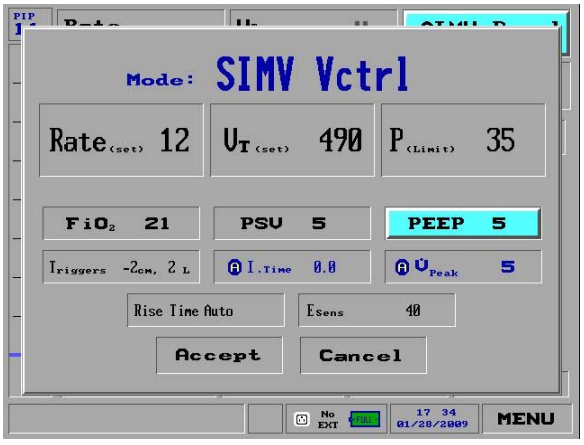


Figure 57: PEEP Selected on the Mode Screen

2. Press the Control Knob. The set **PEEP** pop-up window appears:

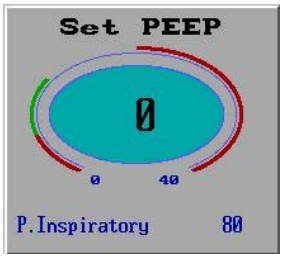


Figure 58: PEEP Pop-Up Window

3. Turn the Control Knob to adjust the **PEEP** level. The **Inspiratory Pressure** limit above **PEEP** is shown at the bottom of the **Setting** pop-up window as adjustments are made.

NOTE *The PEEP value cannot be set higher than P(limit) – PSV or a maximum value of 40 cmH2O.*

4. Press the Control Knob to confirm and accept the settings.

ADJUSTING TRIGGER SENSITIVITY

When the patient's breathing is measured, and above the adjustable value, then it is identified as spontaneous breath.

To adjust the triggers sensitivity:

1. Select the **Triggers** option from the bottom left section of the **Main** screen (Figure 59):

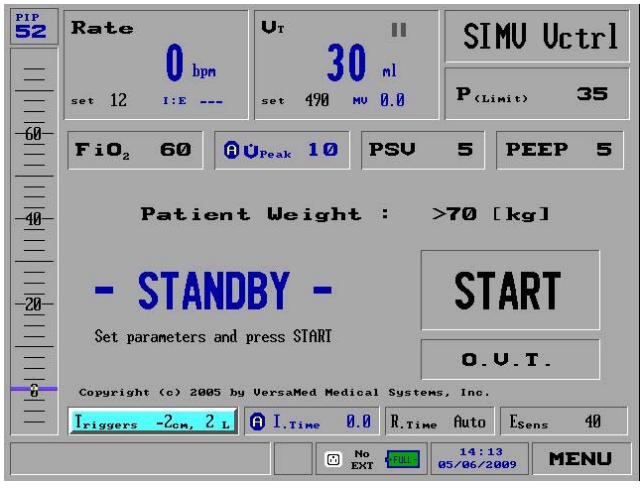


Figure 59: Triggers Selected on the Main Screen

Or select the **Triggers** option in the **Mode Parameters** screen (Figure 60):

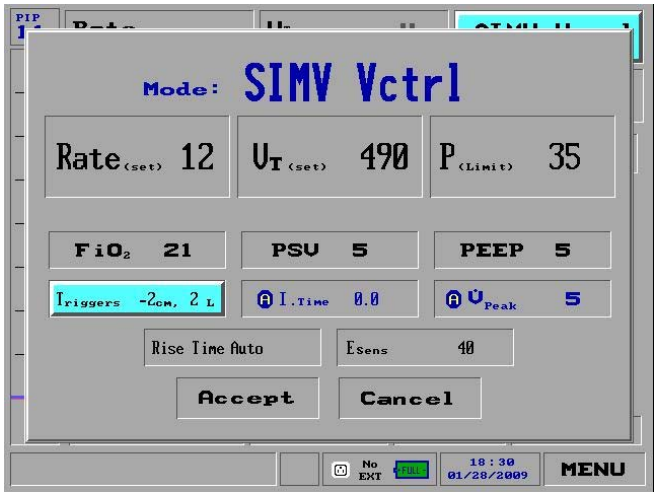


Figure 60: Triggers Selected on the Mode Parameters Screen

2. Press the Control Knob. Two sliding numeric gauges appear (Figure 61)

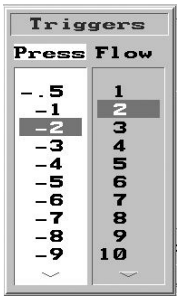


Figure 61: The Triggers Slider Gauges

3. Dial the Control Knob to select the required pressure value.
4. Press the Control Knob to confirm the pressure settings and select the **Flow** gauge.
5. Dial to select the required **Flow** settings.
6. Press the Knob to confirm and accept the settings.

ADJUSTING INSPIRATORY TIME

The inspiration time is the time between the start of the inspiration until the exhalation is started.

To adjust the inspiratory time:

1. Select the Inspiratory Time setting from the middle of the lower portion of the **Main** screen (Figure 62):

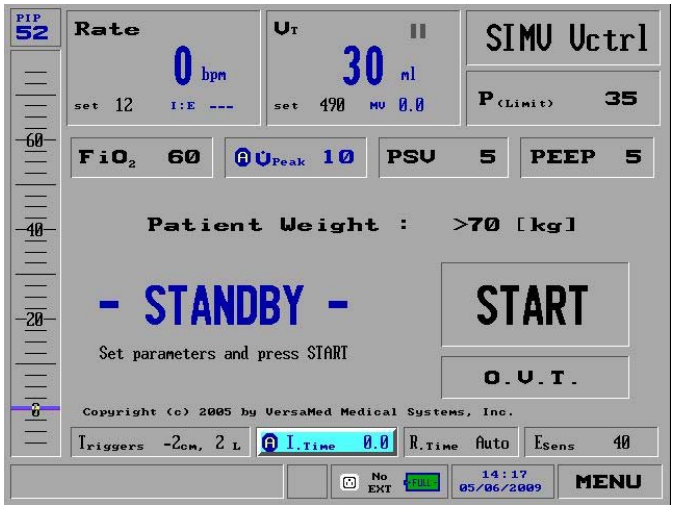


Figure 62: Inspiratory Time Selected on the Main Screen

Or select the **Inspiratory Time** option on the **Mode Parameters** screen (Figure 63):

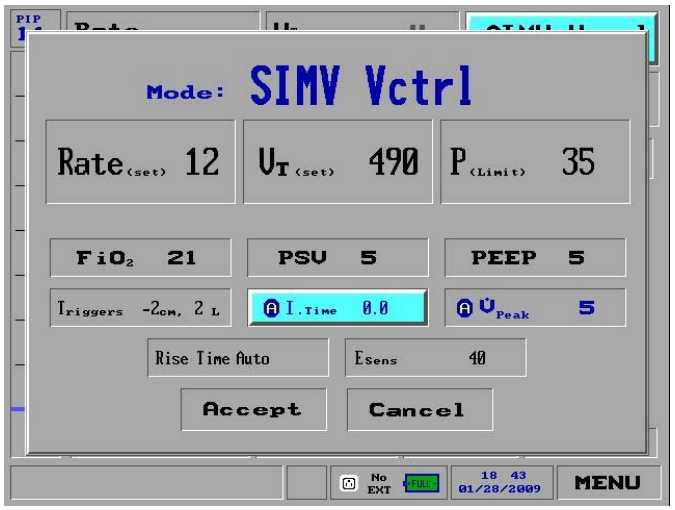


Figure 63: Inspiratory Time Selected on the Mode Parameters Screen

2. Press the Control Knob. The **I. Time** pop-up window appears (Figure 64)

Figure 64: The I Time Pop-Up Window

3. Turn the Control Knob to change the **Inspiratory Time**. Notice that the I:E ratio is calculated as you adjust the value.
4. To return to Adaptive I. Time™, turn the Control Knob counterclockwise until **Adapt** appears.
5. Press the Control Knob to confirm and accept the settings.

If **Adaptive Inspiratory Time** is selected a blue icon with black circled A is displayed on the **Main** screen (Figure 66). If **Manual Inspiratory Time** is selected, a transparent icon with black circled M is displayed on the **Main** screen (Figure 65).

Figure 65: Manual I Time

Figure 66: Adaptive I Time

If a manual I time is set that does not allow for a 1:1 I:E Ratio, or does not allow the set volume to be delivered within the set I time, **then** the display flashes during the ventilation.

ADJUSTING RISE TIME

The iVent™201 provides four possible values for Rise Time (drive): Mid, High, Max or Auto. These options refer to the speed of the engine acceleration during the inspiratory phase.

In Adaptive Bi-level you can adjust the rise time between 0.1 to 1.5 seconds.

NOTE *The factory default value for rise time is "Auto". It is recommended that this setting not be changed*

To adjust time value:

1. Select the **Rise Time** settings from the lower portion of the **Main** screen (Figure 67):

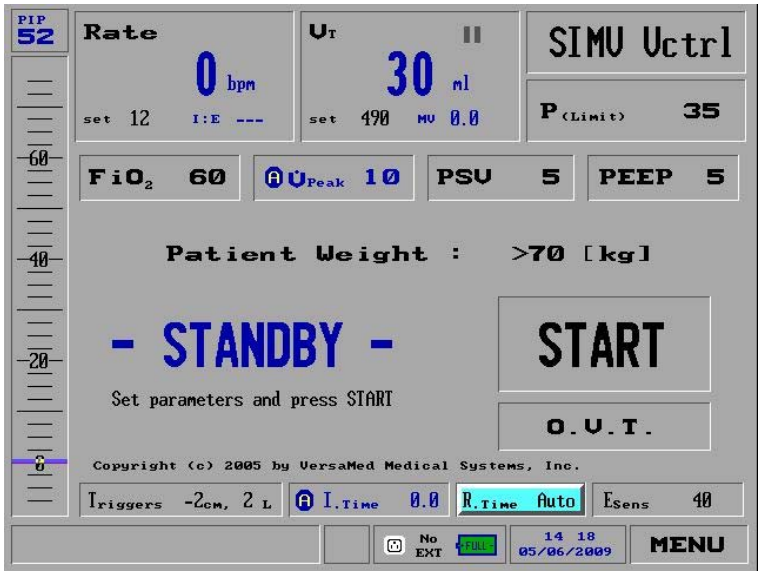


Figure 67: Rise Time Selected on the Main Screen

Or select the **Rise Time** option in the **Mode Parameters** screen (Figure 68):

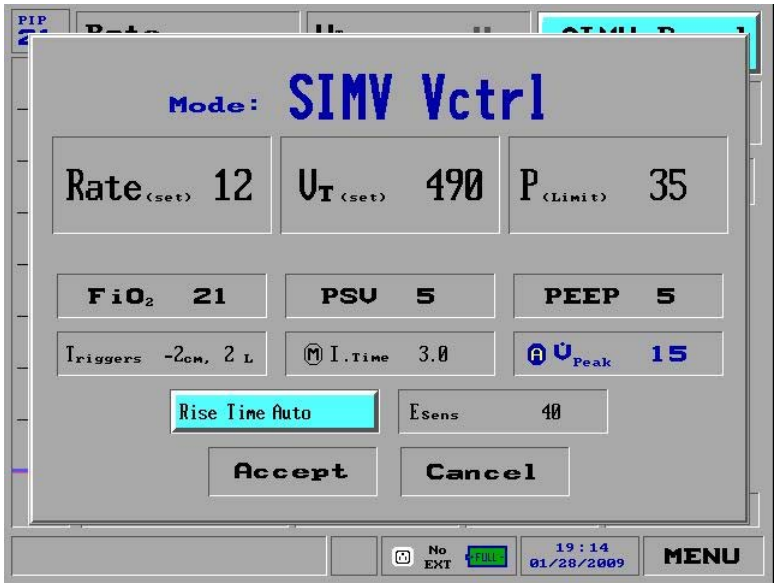


Figure 68: Rise Time Selected on the Mode Parameters Screen

NOTE ***The Rise Time option is located in the top left of the Mode Parameters screen for Adaptive Bi-Level mode.***

2. Press the Control Knob. The **Rise Time** pop-up window appears (Figure 69):

Figure 69: The Rise Time Pop Up Window

In Adaptive Bi-Level ventilation mode the rise time can be adjusted between 0.1 and 1.5 seconds (Figure 70).

Figure 70: The Rise Time pop up window in Adaptive Bi-level ventilation mode

3. Turn the Control Knob to select the required value.
4. Press the Control Knob to confirm and accept the settings.

ADJUSTING FLOW TERMINATION (ESENS)

The iVent™201 terminates the pressure support breath delivery after flow drop detection to an adjustable percentage of the peak flow. The flow termination (exhale sensitivity) can be set between 10 to 90 percentages of the peak flow.

To adjust the flow termination:

1. Select the **Esens** option in the lower portion of the **Main** screen (Figure 71):

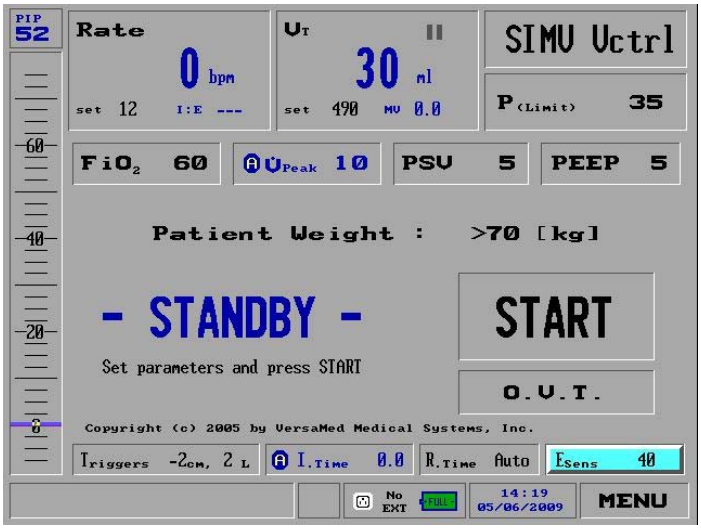


Figure 71: Esens Selected on the Main Screen

Or select the **Esens** option in the **Mode Parameters** screen (Figure 72):

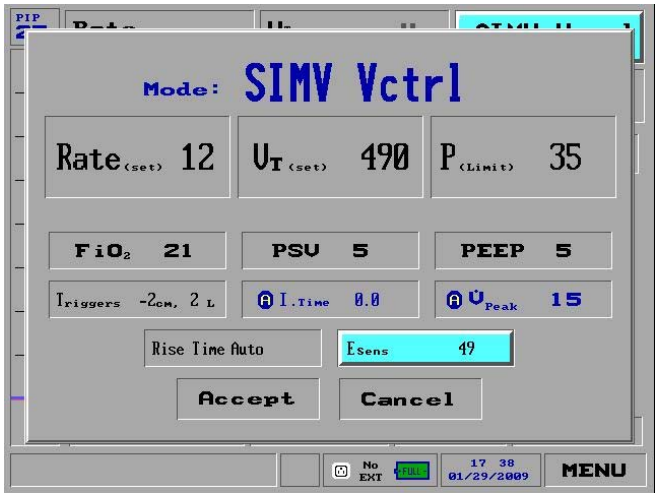


Figure 72: The Esens Option Selected on the Mode Parameters Screen

2. Press the Control Knob. The Set Flow Term pop up window appears (Figure 73):

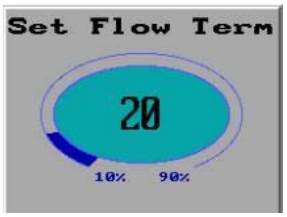


Figure 73: The Set Flow Term Pop Up Window

3. Turn the Control Knob to change Flow termination percentages.
4. Press the Control Knob to confirm and accept the settings.

Notes:

4 THE MAIN MENU

This chapter contains the following sections:

INTRODUCTION

The Main Menu controls many of the iVent™201's key settings and functions. In this section you learn how to use the Main Menu in order to:

- Change the Alarm Settings
- Change Advanced Settings
- Restore default ventilation settings
- Display and choose ranges and views of Graphs, Trends and Loops
- Choose Mechanics for display
- Proceed to the Pulse Oximetry window
- Display a Log Book showing all adjustments and recent history of i iVent™201 use
- Select the display type
- Perform an Operational Verification Test
- Access the Maintenance menu

NOTE *Depending on which model* iVent™201 *you are using, not all of these features may be available.*

NAVIGATING THE MAIN MENU

The following procedures explain how to navigate the options provided in the Main Menu.

To navigate the Main Menu:

1. Access the **Main Menu** from the **Main** screen by dialing the Control Knob until the **MENU** option on the lower right corner is selected in bright blue (Figure 74).

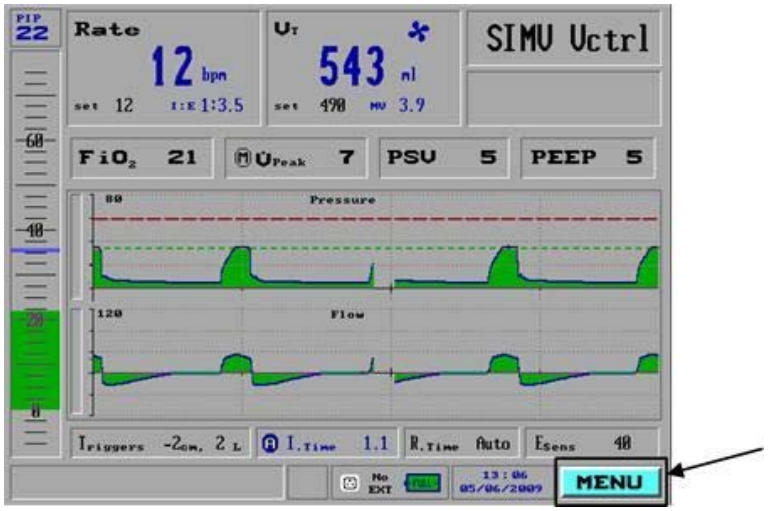


Figure 74: The Menu Option Selected on the Main Screen

2. Press the Control Knob and the **Main Menu** pop-up window appears (Figure 75):

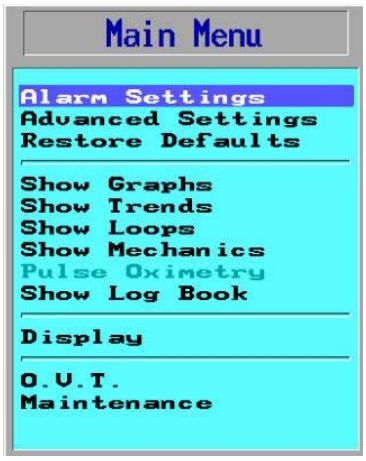


Figure 75: The Main Menu

3. Turn the Control Knob to select a function.
4. Press the Control Knob to open the function you have selected.

To return to the **Main Screen** from anywhere in the **Main Menu** either:

- Press the **Clear** button on the keypad until you return, or
- Use the Control Knob to select **Display** on the **Main** Menu and press the Control Knob, then select **Main** and press the Control Knob.

ALARM SETTINGS

Do not change any Alarm setting without reading Chapter 6: Alarms. For changing the alarm settings see Changing Individual Alarm Settings 145.

ADVANCED SETTINGS

The **Advanced Settings** screen allows you to switch or adjust several patient and ventilator parameters, including:

- Sigh breath (off/interval)
- Easy Exhale™ (on/off)
- Oxygen supply (None/ Low/ Low +M/ High
- Adaptive Peak Flow (Off/Low/Mid/High)
- Humidifier Settings (Off/ HME/ Heated)
- SpO2 enabled
- Nebulizer
- Set time and date

To access the **Advanced Settings** menu:

1. Select and press the **Menu** option in the Main screen to access the Main Menu (Figure 75)
2. Turn the Control Knob to select the second item on the **Main Menu** list, **Advanced Settings**.
3. Press the Control Knob. The **Advanced Settings** menu appears (Figure 76).

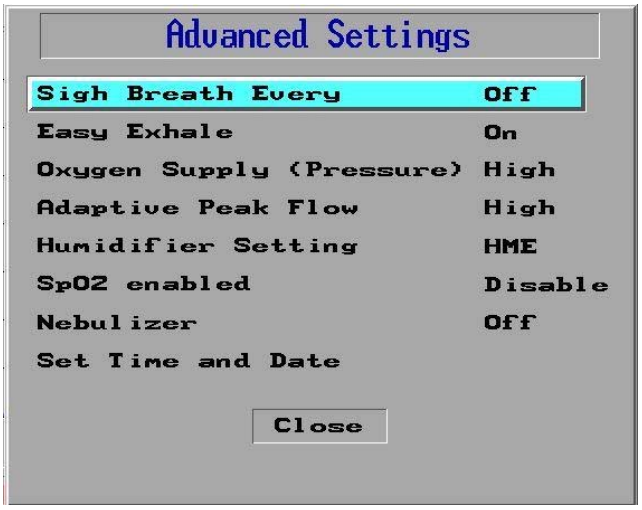


Figure 76: the Advanced Settings Menu

To exit from the **Advance Setting** menu select **Close** on the bottom, and press the Control Knob.

SIGH BREATH

In **Volume** control modes, the iVent™201 supports sigh breaths. You can use the **Sigh Breath** entry of the **Advanced Settings** menu to turn **Sigh Breaths** off or enable it by adjusting its intervals.

The **Sigh Breath** volume is 1.5 times the set tidal volume.

To adjust the **Sigh Breath**:

1. From the **Main** screen select **Menu – Advance Setting**. The **Advance Settings** screen appears.
2. In the **Advance Settings** screen select **Sigh Breath Every**. The current interval is shown in the right column of the screen (Figure 77).

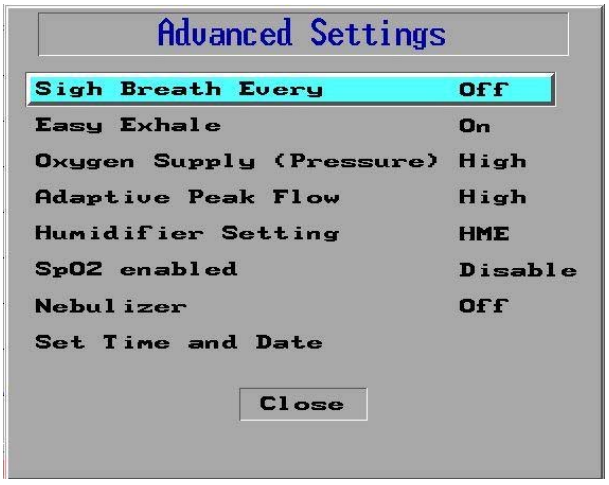


Figure 77: Sigh Breath Selected in the Advanced Settings Screen

3. Press the Control Knob. A pop-up window appears with the values 25, 50, 75, 100, 125, 150, and Off (Figure 78):

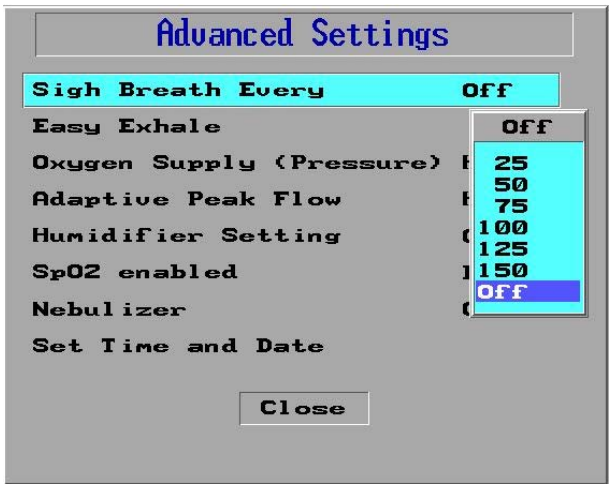


Figure 78: The Sigh Breath Selection Pop-Up Window

4. Turn the Control Knob to select the required value.
5. Press the Control Knob to confirm and accept the settings.

EASY EXHALE™

Easy Exhale™ is an advanced feature when PEEP>0 is selected. It is designed to shorten expiratory time and reduce risk of auto-PEEP (For more information, see Page 137.)

The default setting for Easy Exhale is on. Use the **Advanced Settings** menu to turn Easy Exhale off or on.

To enable or disable the Easy Exhale:

1. From the **Main** screen select **Menu – Advanced Settings**.
2. In the **Advanced Settings** screen select **Easy Exhale**. The current status is shown in the right column of the screen (Figure 79).

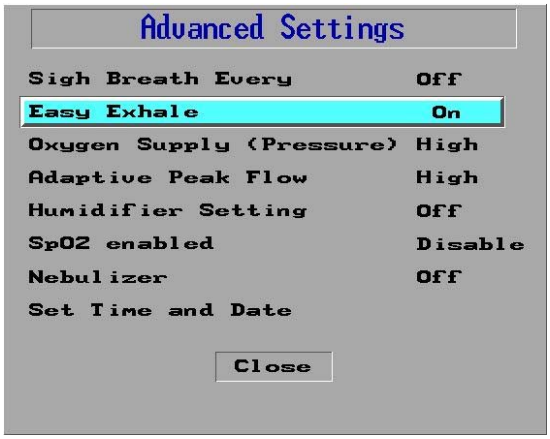


Figure 79: Easy Exhale Selected in the Advanced Settings Screen

3. Press the Control Knob. A pop-up window appears with the values On and Off (Figure 80)

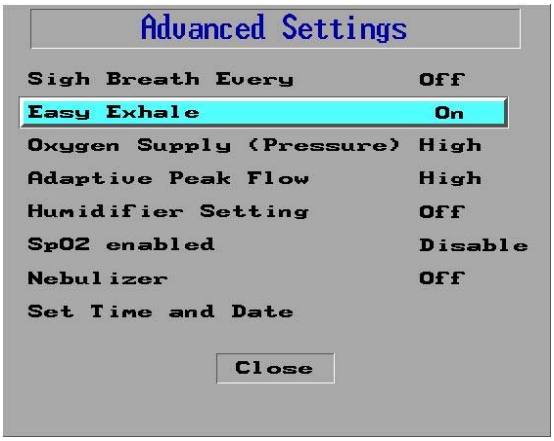


Figure 80: The Easy Exhale Selection Pop-Up

4. Turn the dial to either On or Off.
5. Press the Control Knob to confirm and accept the settings.

OXYGEN SUPPLY

You set the type of oxygen supply used with the iVent™201 from the Advanced Settings menu. There are 4 available options:

- High
- Low + Monitoring
- Low
- None

For more about each option, see description below.

To set the oxygen supply pressure:

1. From the **Main** screen select **Menu – Advanced Settings**.
2. In the **Advanced Settings** screen select **Oxygen Supply (Pressure)**. The current option is shown in the right column of the screen (Figure 81)

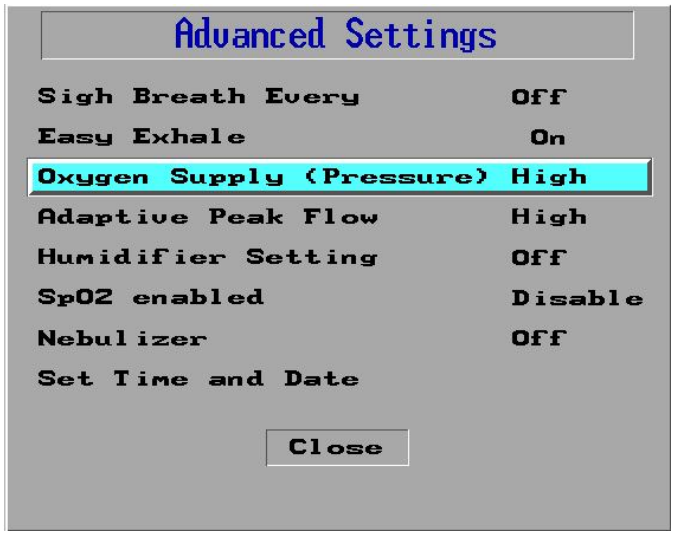


Figure 81: Oxygen Supply Selected in the Advanced Settings Screen

3. Press the Control Knob. A pop-up window appears with the options: **High**, **Low+M**, **Low**, and **None** (Figure 82).

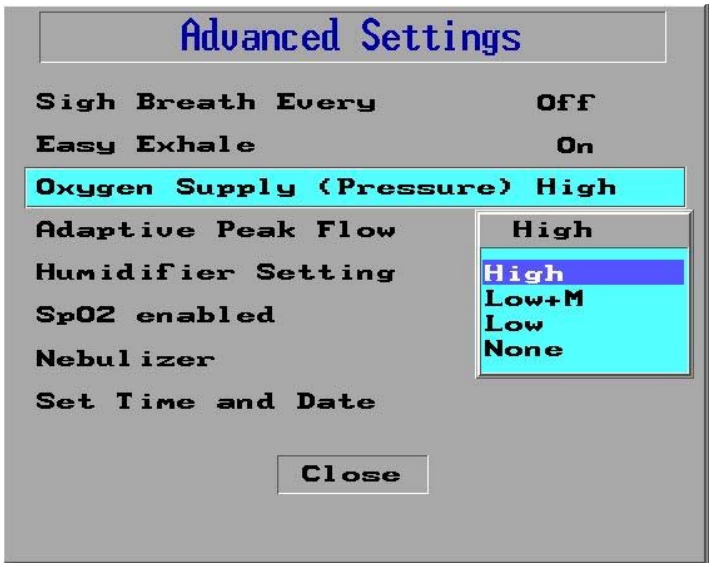


Figure 82: The Oxygen Supply Pop-Up Window

4. Turn the Control Knob to select the appropriate option.
5. Press to accept the option.
6. Press the Control Knob to confirm and accept the settings.

NOTE The 02 Sensor continues to measure the O2 levels, even when, in some options, these measurements are not displayed, and the O2 alarms are not activated. Ensure that you take the entire ventilation time into account when calculating the O2 sensor maintenance (See Cleaning and Maintenance, page 173.

High Option

The High option is used for high-pressure supply, either from a wall outlet or a compressed canister, both of which use the internal O2 mixer. The High option is the factory default setting for the oxygen supply type.

NOTE The nebulizer can be activated only when the High Option is selected.

When the High option is selected, the set value is displayed in the FiO2 field on the iVent™201 screen. All O2 related alarms are enabled (such as Low O2, High O2, and O2 sensor fail).

NOTE To view the measured O2 concentration with a high-pressure oxygen supply, navigate to the Alarm screen [Menu- Alarm Settings]. The blue number next to the FiO2 alarm slider indicates the measured O2 level (See page 150).

Alarm Messages

If the O2 sensor fails, one of the following alarm messages is displayed on the iVent™201 screen. The alarm message depends on whether the iVent™201 device serial number is lower or higher than 15000.

Alarm Message for Serial Number 12000 -14999

NOTE You cannot close this alarm using the **Clear** button.

Select **OK** to close the alarm pop-up window (Figure 83). The FiO2 setting is displayed with a red background that flashes. The FiO2 level is not changed and continues ventilating with the current setting. The two options for the FiO2 setting are 21% or 100%. After this value is changed to 21% or 100%, the new settings are displayed with a yellow background.

Figure 83: Alarm Message: O2 Sensor Failed (For 12000 – 14999 devices)

When the O2 sensor alarm message is activated, the O2 alarm messages, such as High O2 or Low O2, are not activated. The O2 alarm settings bar and the O2 readings are disabled.

A small red icon is displayed on the left corner of the status bar and shows the O2 Sensor. When the O2 sensor failure is corrected, this icon changes to green and can be cleared (Figure 84).

Figure 84: The Status Bar With the O2 Sensor Icon

Alarm Message for Serial Number 15000 or Higher

NOTE You cannot close this alarm using the **Clear** button.

Select **OK** to close the alarm pop-up window. The FiO2 setting is displayed with a yellow background. You can change the FiO2 setting within a range from 21% to 100%.

A small red icon is displayed on the left corner of the status bar, showing O2 Sensor (Figure 84) When the O2 sensor failure is corrected, this icon changes to green and can be cleared.

Low + Monitoring Option

The Low + Monitoring option is used for a low-pressure oxygen supply in combination with VersaMed's low-pressure adapter. If Low+ Monitoring is selected, the FiO2 window in the **Main** screen is grayed out, and the O2 settings cannot be changed. The display in the **Main** screen shows the measured FiO2 (the FiO2 delivered to the patient), as in the **Alarm** screen [Menu - Alarm Settings]. All O2 related alarms are enabled.

If the O2 sensor fails, the following alarm message is displayed:

Figure 85: Low+Monitoring O2 Sensor Failed Alarm Message

NOTE You cannot close this alarm using the **Clear** button.

When the O2 sensor alarm message is activated, the O2 alarm messages, such as High O2 or Low O2, are not activated. The O2 alarm settings bar and the O2 readings are disabled.

A small red icon is displayed on the left corner of the status bar, showing O2 Sensor (see Figure 85 above). When the sensor failure is corrected, this icon changes to green and can be cleared.

Low Option

The Low option is used for a low-pressure supply in combination with VersaMed's low-pressure adapter. When this option is selected, all the O2 related alarms are

disabled, such as Low O2, High O2, and O2 sensor failed. After selecting the Low option, a **Warning** pop-up window is displayed (Figure 86):

Figure 86: Low Option Warning

The alarm settings and readings are disabled, and the FiO2 field displays - -

If the O2 sensor fails, no alarm is displayed.

None Option

The **None** option is used when no O2 Supply is connected to the iVent™201. When this option is selected all the O2 related alarms are disabled. The alarm settings and readings are also disabled, and the FiO2 field displays - -.

If the O2 sensor fails, no alarm is displayed.

ADAPTIVE PEAK FLOW

The rate for **Adaptive Peak Flow** can be adjusted with the **Advanced Settings** menu. (For information about **Adaptive Peak Flow** see Appendix D.)

To change the Adaptive Peak Flow setting:

1. From the **Main** screen select **Menu – Advanced Settings**.
2. In the **Advance Settings** screen select **Adaptive Peak Flow**. The current status is shown in the right column of the screen (Figure 87).

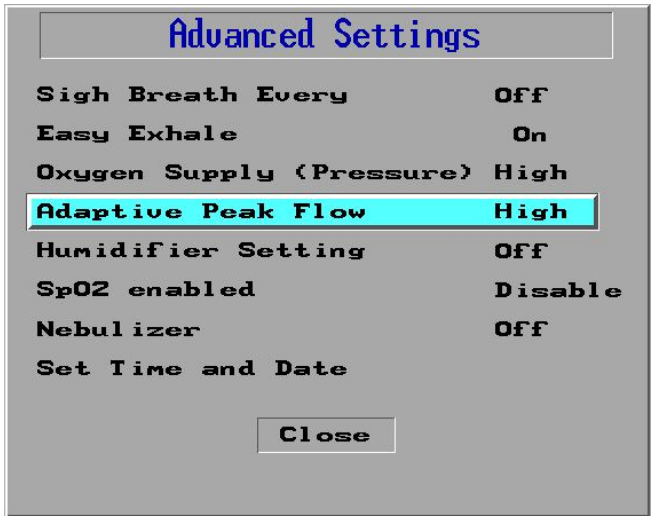


Figure 87: Adaptive Peak Flow Chosen

NOTE The factory default value is **High**. VersaMed recommends that you use **High**.

HUMIDIFIER SETTING

When a Humidifier is connected (See page 44) moisture tends to cluster at the sensor tubes. To prevent this excess moisture, the iVent™201 periodically sends a burst of air through the sensor tubes. The Advanced Settings menu enables the user to determine the frequency of the automated sensor purging.

NOTE This is an optional feature not available in all units.

Possible values are Heated (purge every 1 minute) HME (purge every 10 minutes), and Off. The factory setting is HME.

There are no default settings for the Humidifier. The iVent™201 retains the last settings even if a new patient is selected. The factory settings are used only when new software is installed or the memory data is corrupted.

To adjust the humidifier settings:

1. From the **Main** screen **select Menu – Advanced Settings**.
2. In the **Advanced Settings** screen select **Humidifier Setting** (Figure 88). The current setting is shown in the right column of the screen.

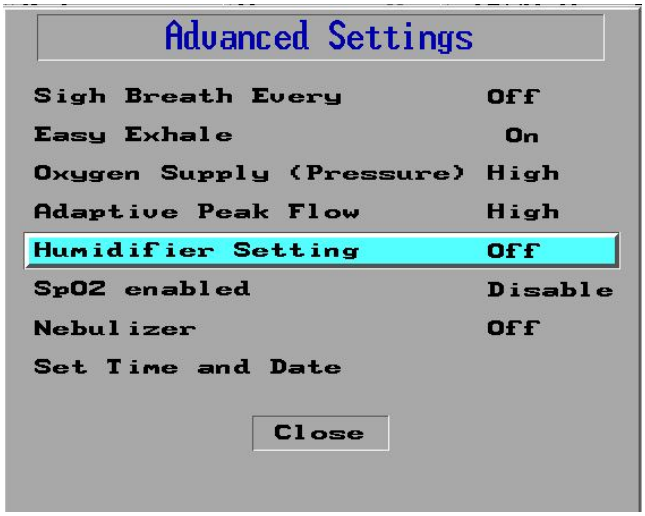


Figure 88: Humidifier Setting Selected

3. Press the Control Knob. A pop-up window appears with the values **Heated**, **HME**, and **OFF**.
4. Turn the dial of the Control Knob to select the setting you want.
5. Press the Control Knob to confirm and accept the settings

NOTE Purge is performed every minute the Nebulizer is activated.

PULSE OXIMETRY

Pulse oximeter is a simple non-invasive method of monitoring the percentage of hemoglobin (Hb) that is saturated with oxygen, which is the amount of oxygen in the blood. The pulse oximeter is a sensor, which is placed on the patient's fingertip, earlobe, or big toe, and is linked to a computerized unit. The unit displays the oxygen saturation percent, a calculated heart rate, and a graphical display of the blood flow past the probe (plethysmograph).

A pulse oximeter can be connected to the iVent™201 ventilator allowing the operator to continuously monitor patient's oxygenation saturation on the iVent™201 screen.

CAUTION *The accuracy of the SpO2 measurement can be affected if the total cable length (including extension cables) is greater than 3 meters.*

The pulse oximeter is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin, such as methemoglobin, might affect the accuracy of the measurement.

The oximeter includes motion tolerant software that minimizes the likelihood that a motion artifact is misinterpreted as good pulse quality. In some circumstances, however, the oximeter may interpret motion as good pulse quality, leading to inaccurate SpO2 measurements.

Inspect the sensor application site at least every 6-8 hours to ensure skin integrity. Patient sensitivity may vary due to medical status or skin condition. Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.

To enable the Pulse Oximetry function:

1. From the Main screen select and press Menu – Advance Setting.
2. In the Advanced Settings screen select SpO2 enable. The current setting is shown in the right column of the screen (Figure 89).

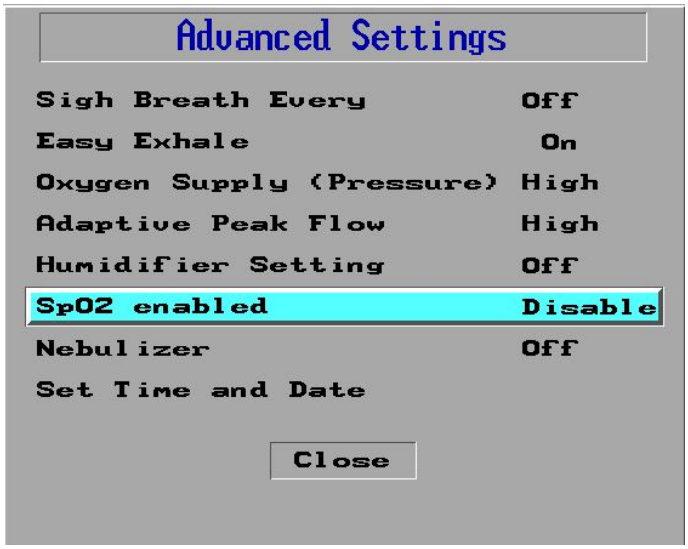


Figure 89: SpO2 Enabled

3. Press the Control Knob. A pop-up window appears with the **Enable** and **Disable** options (Figure 90).

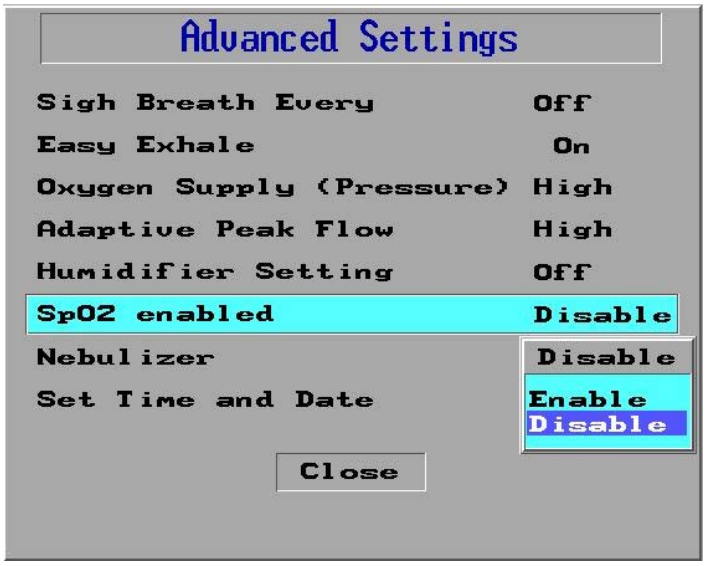


Figure 90: SpO2 Enabled Pop Up Window

4. Turn the dial of the Control Knob to select the option you want.
5. Press the Control Knob to confirm and accept the settings.

To disable the Pulse Oximetry function from the **Main** screen select and press **Menu – Advance Setting – SpO2 enabled – Disable**.

For information regarding the Pulse Oximetry screen operation see page 120.

PNEUMATIC NEBULIZER

A Nebulizer is a pneumatic device that uses compressed gas to deliver aerosolized medication that can be inhaled by patients. During nebulization, the flow is synchronized with the inspiratory phase of each breath. Note that the Nebulizer works during the inspiratory phase only.

For proper installation of the Nebulizer see page 46.

CAUTION *The nebulizer is operational for all tidal volumes greater than 200ml. Do not activate the nebulizer if the set tidal volume is below 200ml.*

To set the Nebulizer:

1. From the **Main screen select Menu – Advanced Settings**.
2. In the **Advanced Settings** screen select **Nebulizer**. The current setting is shown in the right column of the screen (Figure 91).

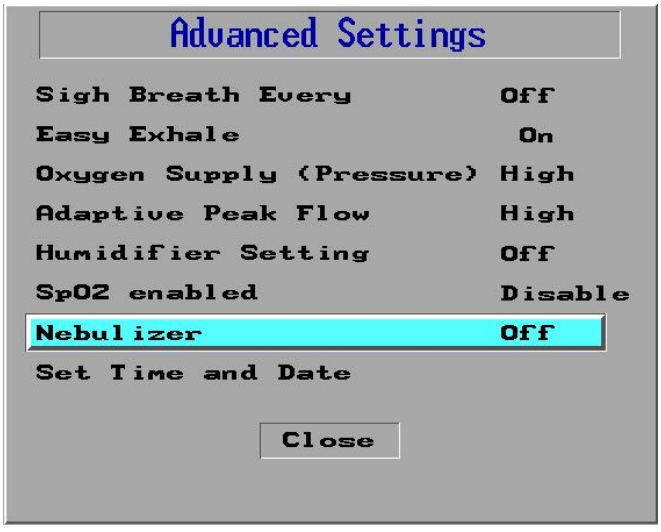


Figure 91: Nebulizer Selected

3. Press the Control Knob. The **Nebulizer** pop-up window appears. The default time is **OFF** (Figure 92)

Figure 92: Nebulizer Pop Up Window

NOTE The **Nebulizer** option is active only during ventilation. You can however, also set the Nebulizer in **Standby** Mode. It is activated after you start ventilation.

The nebulizer is activated only when you set the **Oxygen Supply** to **High** option (See page 38).

4. Turn the dial to set the time duration for nebulization. You can set the time between 5 minutes and 4 hours. Each rotational detent of the knob increases or decreases the nebulization time by 5 minutes.

The set time appears in the center of the ellipse and at the bottom of the screen. A thick blue line surrounding the ellipse depicts the set time. The elapsed time is displayed at the bottom of the screen and is depicted by a thick gray line.

You can set more nebuliziation time while the nebulizer is activated. The new set time is the sum of the time you have added and the elapsed time.

5. Press the dial to activate the nebulizer and accept the settings.

During the nebulization process you can re-enter the Nebulizer screen and view the elapsed time. Note that the remaining time is displayed in the **Advanced Settings** Menu.

6. When the set time for the nebulizer operation has elapsed, the nebulizer is deactivated automatically, and the nebulizer icon in the lower bar grays out

SET TIME AND DATE

The time and date, which are displayed in the **Main** screen, are adjusted from the Advanced Setting screen.

To set the time and date:

1. From the **Main** screen select **Menu – Advanced Setting**.
2. In the **Advanced Settings** screen select **Set Time and Date** (Figure 93)

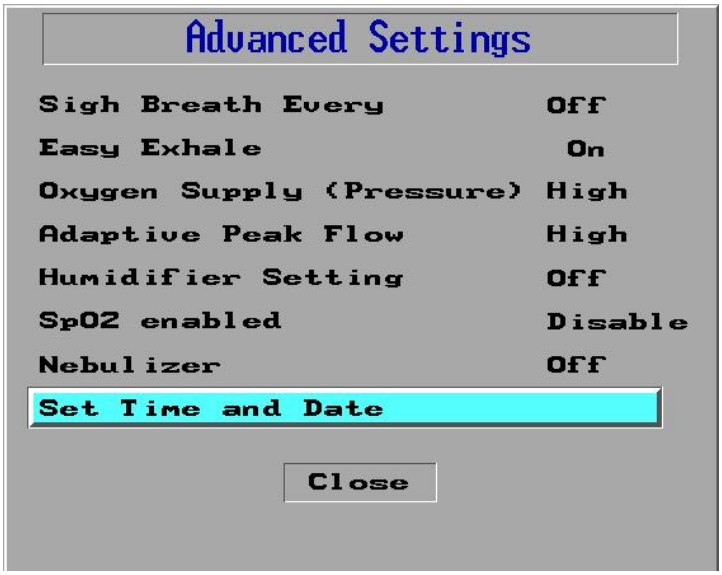


Figure 93: Set Time and Date Chosen

3. Press the Control Knob. The **Set Time** and **Date** pop-up window appears, showing the currently set time, with the hour (in 24-hour mode) selected (Figure 94).

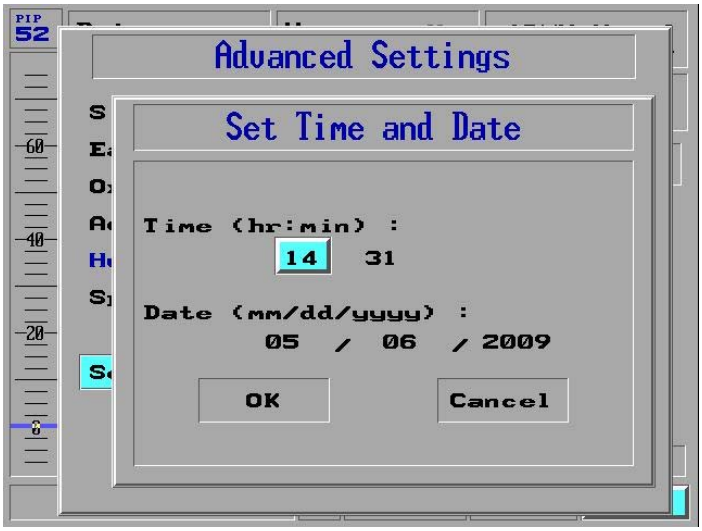


Figure 94: The Set Time and Date Pop-Up Window

4. To change the hour, make sure the hour is selected, then press the Control Knob. Turn the dial to adjust the clock – clockwise to set the clock to a later hour, counterclockwise to set it earlier.
5. Press the Control Knob to confirm and accept the setting.
6. Turn the Control Knob to select the minute, day, month, and year fields. Press the Control Knob, and turn the knob to adjust the time and date.
7. Turn the dial to select **OK** and press the knob to confirm and accept the settings.

8. Close the **Advanced Settings** screen and verify that the time and date has changed on the Main screen clock, which is situated on the lower right of the screen.

RESTORE DEFAULT SETTINGS

To clear ALL settings and return the iVent™201 to its default startup state, use Restore Defaults. The factory startup default state is based on a patient weight of 70+kg, SIMV Volume Control mode.

WARNING **Restoring Defaults resets all parameters and settings to their default.** .

To restore the defaults settings:

1. Select the Menu option in the Main screen to display the Main Menu.
2. In the Main Menu, select Restore Defaults (Figure 95).

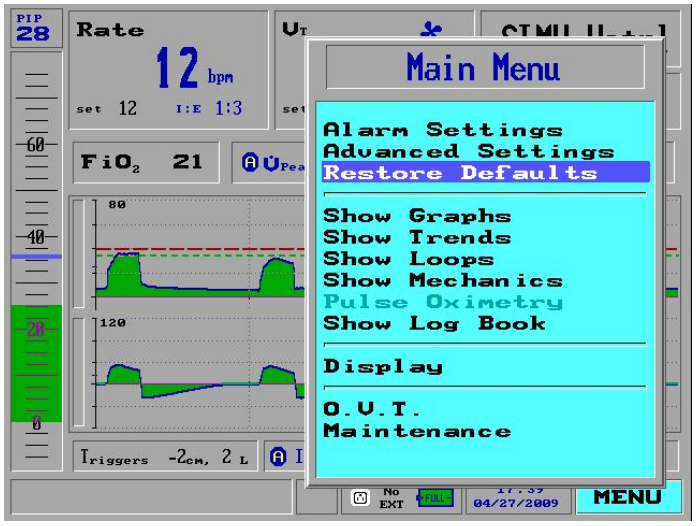


Figure 95: Restore Defaults Selected

3. Press the Control Knob. A large red Warning pop-up window appears (Figure 96):

Figure 96: The Restore Defaults Warning Pop-Up Window

4. Turn the Control Knob to **Confirm** and press.
5. The **Restore Default Params** pop-up window appears, and instructs you to select a **Default Weight**. Choose a **Default Weight** by dialing the Control Knob. The factory default is 70+kg.
6. Press the Control Knob again. The iVent™201's settings return to their defaults and the **Main** screen is displayed.

DEFAULT PARAMETERS SETTINGS

The following tables summarize the default parameters and alarm values for the iVent™201 by patient weight:

Table 1: Default Start Parameters for Volume Ventilation for 10 kg to 70 kg

Patient Weight		bpm Rate	Tidal Volume	Max. Pressure (PLimit)
(Kg)	(lb)	(bpm)	(mL)	(cMH_2O)
10	**22**	**30**	**70**	**18**
15	**33**	**25**	**105**	**20**
20	**44**	**20**	**140**	**25**
30	**66**	**18**	**210**	**28**
40	**88**	**16**	**280**	**30**
50	**110**	**14**	**350**	**35**
60	**132**	**12**	**420**	**35**
70+	**154**	**12**	**490**	**35**

Table 2: Alarm Default Parameters for Volume Ventilation for 10 kg to 70 kg

Alarm Parameter	**Weight (kg)**							
	10	15	20	30	40	50	60	70+
High Pressure (cmH_2O)	23	25	30	33	35	40	40	40
High Rate (bpm)	40	35	30	30	30	30	30	30
Low Rate (bpm)	10	10	10	8	6	6	6	6
High Min Vol. (LPM)	4	5	7	10	12	14	15	16
Low Min Vol. (LPM)	1	1	1	1	2	2	2	2

Table 3: Default Alarms Settings

Low Pressure	5 cmH_2O
Apnea Time	20 Sec
High FiO_2	Set FiO_2 Value + 20% (Factory Setting 80%)
Low FiO_2	Set FiO_2 Value - 10% (Factory Setting 50%)
Leak (%)	100% (off)
Inverse I:E Ratio	ON
Low V_T Alarm Range	85%

Table 4: Default Parameters for Pressure Ventilation for 10 kg to 70 kg

Patient Weight		**RATE**	**$P_{Insp.}$ (above PEEP)**	**I Time**	**Volume Limit**
(kg)	(lb)	(bpm)	(cmH_2O)	(sec)	(mL)
10	22	30	20	0.6	200
15	33	25	20	0.8	300
20	44	20	20	1.0	400
30	66	18	20	1.1	600
40	88	16	20	1.2	800
50	110	14	20	1.4	1000
60	132	12	20	1.7	1100
70+	154	12	20	1.7	1200

Table 5: Alarm Default Parameters for Pressure Ventilation for 10 to 70 kg

Alarm Parameter	Weight (kg)							
	10	15	20	30	40	50	60	70+
Volume Limit Reached, mL	200	300	400	600	800	1000	1100	1200
High Pressure (cmH2O)	30 for all weights							

All other alarm default parameters are the same as for Volume Ventilation (See Table 1, Table 2).

SHOW GRAPHS

The **Show Graphs** function in the **Main Menu** is the gateway to the iVent™201's waveforms package. You can perform the following:

- View real-time ventilation waveforms in a variety of scales
- Scan through patient ventilation waveforms for up to 7.2 hours

NOTE The Waveforms package is an optional feature and not available on all units.

The iVent™201 defaults to displaying the waveform graphs while ventilating. The **Main Menu** allows the operator to choose to display only the waveform graphs (default), or to split the view between waveform graphs and Trends, Loops, or Mechanics.

To access the graphs:

1. Select **Menu** on the **Main** screen to view the **Main Menu**.
2. In the **Main Menu** select the **Show Graphs** option and press the control-knob. The Graphs are displayed, as shown Figure 97.

NOTE If the iVent™201 display is split between Graphs and an additional parameter -- Trends, Loops or Mechanics, then it returns to display only Graphs.

The Graphs view displays Pressure and Flow waveforms. The zero coordinate is colored blue. The pressure limit is displayed as a dashed green line. The high pressure alarm setting is shown as a dashed red line.

BROWSE WAVEFORMS

You can browse forwards or backwards to examine the patient ventilation history (up to 7.2 hours).

To browse the waveforms:

1. On the **Main** screen choose either the **Pressure waveform** or the **Flow waveform** by rotating the dial so that the Select bar of either is chosen (Figure 97).

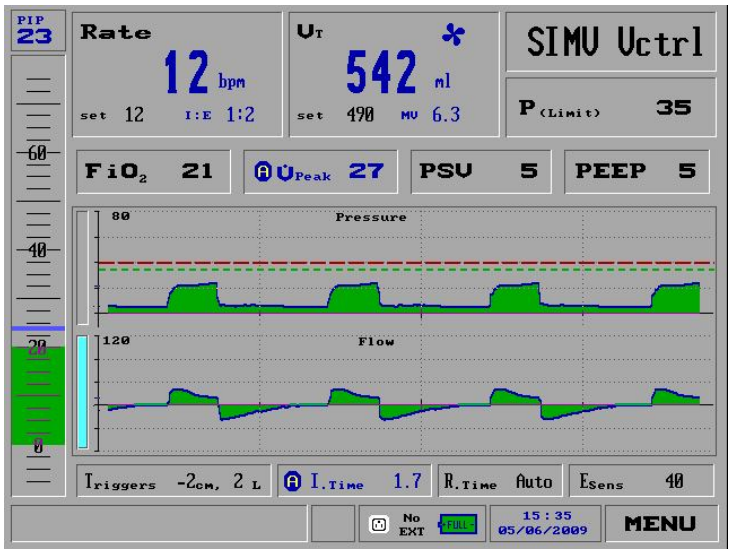


Figure 97: The Flow Waveform Selected

2. Press the Control Knob to display the **Graph Choice** bar:
3. From the **Graph Choice** bar, select **Browse** with the Control Knob, and press the Control Knob.

A pop-up window appears (Figure 98), time stamped at the moment you pressed **Browse**.

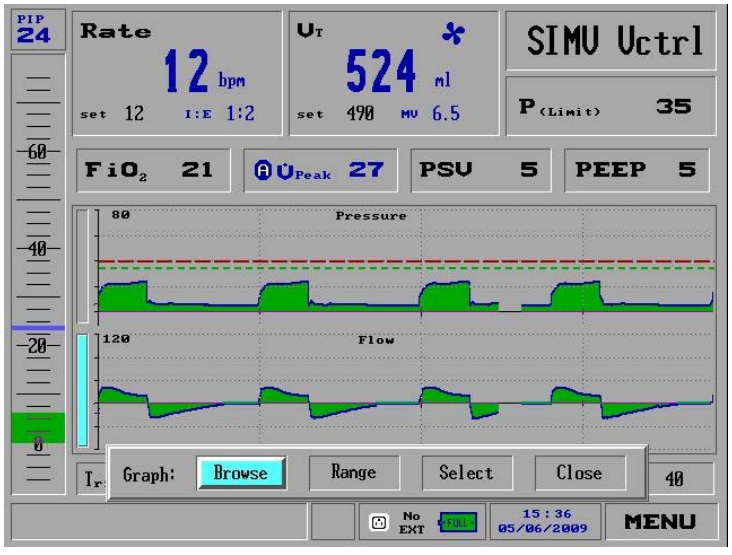


Figure 98: The Browse Pop Up Window

The waveform display pauses at that moment, although it continues to record and the results are stored.

4. Turn the dial counterclockwise, and the time coordinate cursor moves backward along the time axis. Turn the dial clockwise and the time coordinate cursor moves forward along the time axis.

NOTE The **Select** option on the bar is not active.

SELECT RANGE

The iVent™201 automatically selects an appropriate range to display waveforms based on the selected ventilation parameters. If you wish to change the view scale of **Pressure** or **Flow waveforms**, use the **Range** function.

To change the waveform range:

1. From the **Main** screen, choose either the **Pressure** waveform or the **Flow** waveform by rotating the dial so that the Select bar of either is chosen (Figure 97).
2. Press the Control Knob to display the **Graph Choice** bar (Figure 99).

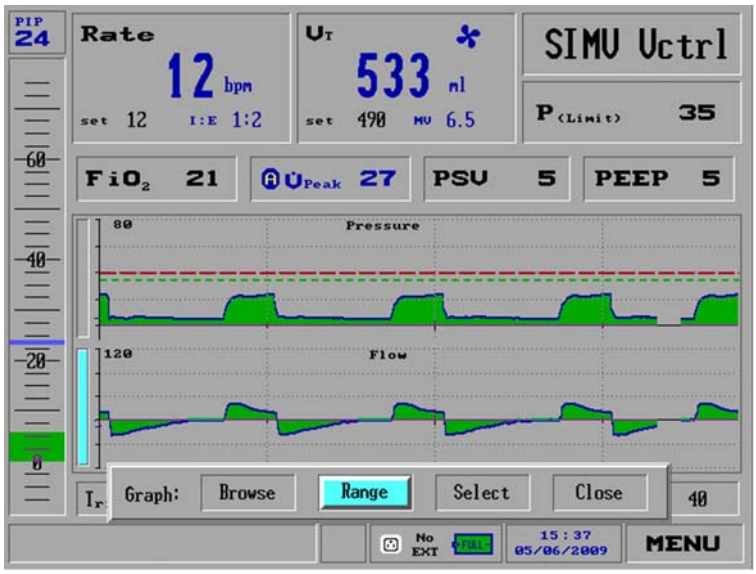


Figure 99: The Graphic Choice Bar With Range Selected

3. From the **Graph Choice** bar select **Range** with the Control Knob, and then press the Control Knob. A pop-up window appears which displays optional **Ranges** (Figure 100).

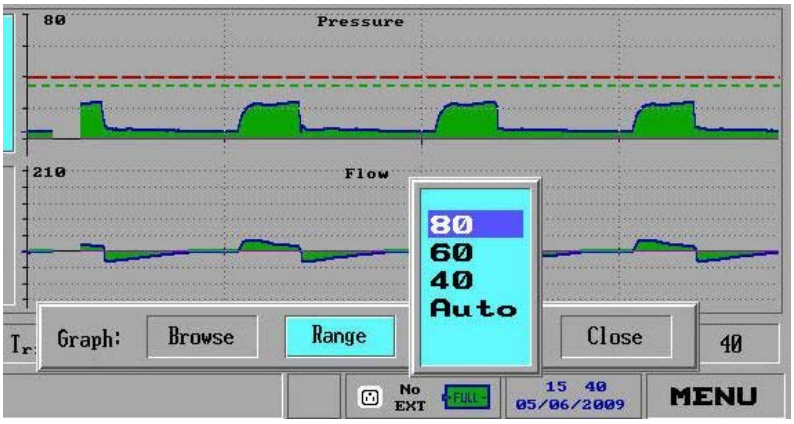


Figure 100: Pressure Ranges

4. If you select the **Pressure** graph, the choices are 80, 60, 40 cmH2O and Auto (the default). Move the dial to choose the required value, and press the dial to accept the new range.

If you select the **Flow** graph, the choices are 210, 150, 120, 90, 60 L/minute and Auto (the default). Turn the dial to select the required value, and press to accept the new range.

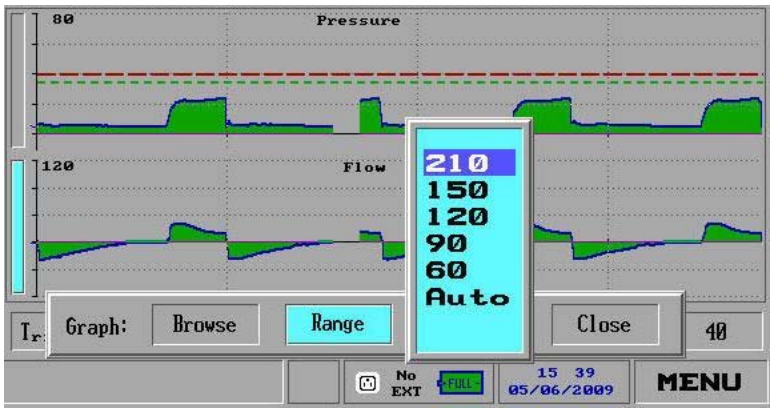


Figure 101: Flow Ranges

If you select the **Flow** graph, the choices are 210, 150, 120, 90, 60 L/minute and Auto (the default) (Figure 101). Turn the knob to select the required value, and press to accept the new range.

5. Turn the dial until Close is selected on the **Graph Choice** bar, and press the dial to return to the **Main** screen.

NOTE The **Select** option on the bar is not active

SHOW TRENDS

You can view trends in any of 14 parameters and calculated patient response characteristics over a period up to 72 hours. All of the following can be displayed using the **Show Trends** menu:

- Peak Flow
- Peak Pressure
- Minute Volume
- Total Rate
- Mandatory Rate
- Spontaneous Rate
- Mandatory Volume
- Spontaneous Volume
- Spontaneous inspiratory time
- Mandatory inspiratory time
- I:E Ratio
- Mean Airway Pressure
- Resistance
- Compliance

Up to three trends at a time can be displayed.

To view trends:

1. Select and press the **Menu** option in the **Main** Screen to view the **Main** Menu.
2. Turn the Control Knob until **Show Trends** is selected, then press to select (Figure 102).

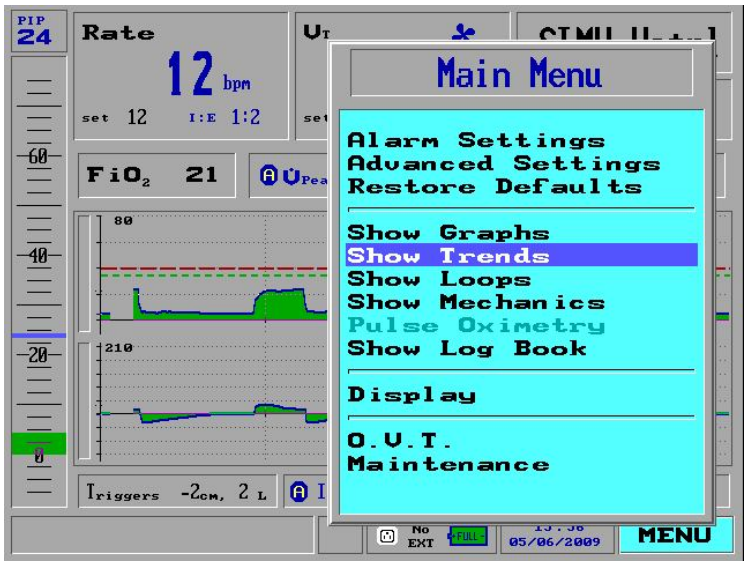


Figure 102: Show Trends selected on the Main Menu

3. If **Show Trends** is viewed while the ventilator is in **Standby Mode**, three Trends (default Trends shown are **Peak Flow, Peak Pressure**, and **Minute Volume**) appear in a pop-up window on the right side of the screen (Figure 103):

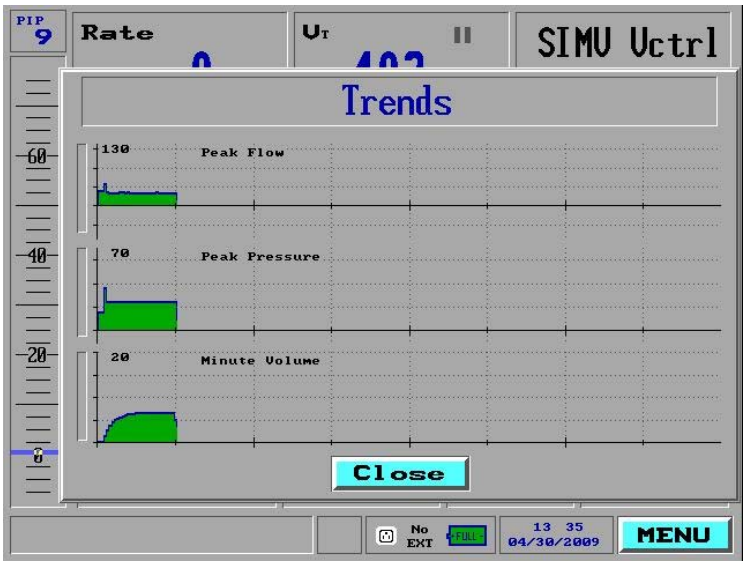


Figure 103: Trends Pop-Up Window in Standby Mode

If the ventilator is in operation, the three displayed Trends appear in a window beside the waveforms (Figure 104):

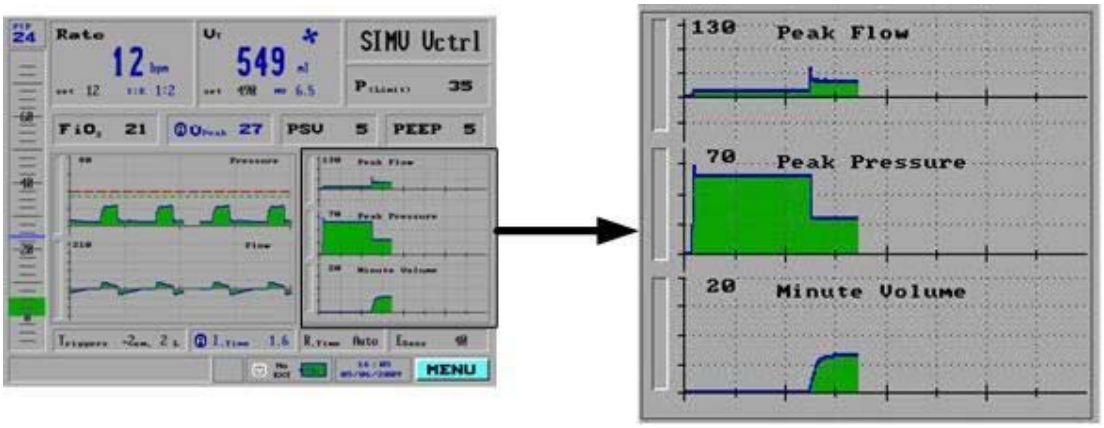


Figure 104: Trends Pop-Up Window During Ventilation

To turn OFF trends display:

1. Select and press **Menu** in the **Main Screen** to view the **Main Menu**.
2. Turn the Control Knob until **Display** is selected, then press to select.
3. In the **Display** pop up window select **Main**.

SELECTING TRENDS TO DISPLAY

To select trends you want to view:

1. Turn the Control Knob to the **Select** bar of the Trend graph you want to change (Figure 105).

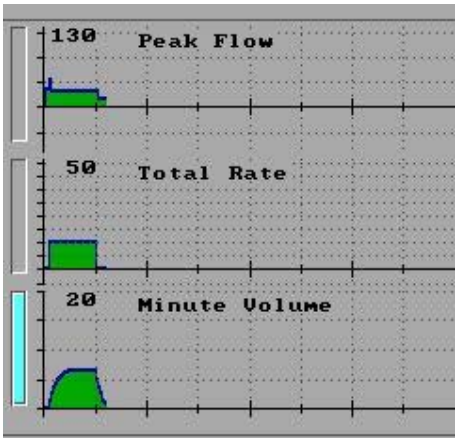


Figure 105: The Minute Volume Graph is Selected

2. Press the Control Knob. The **Trends Choice** window appears.
3. Turn the Control Knob to Select, then press. A pop-up window appears with a choice of parameters and diagnostic variables (Figure 106)

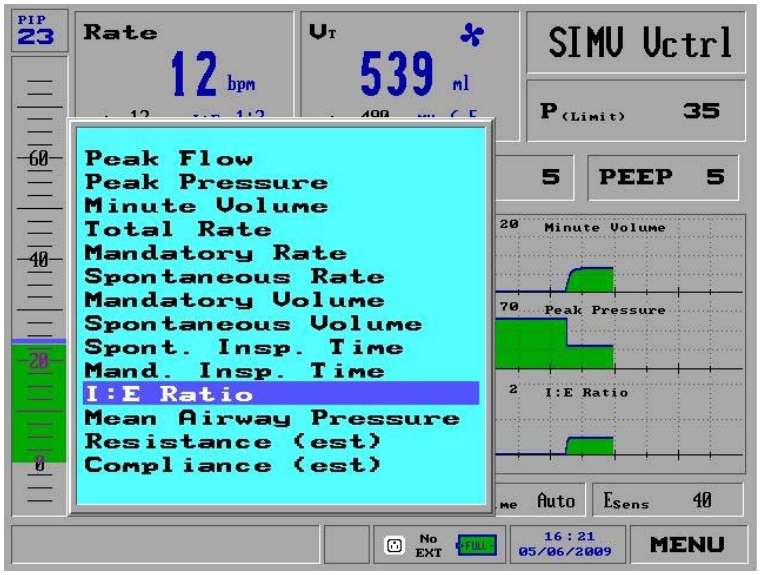


Figure 106: The Trends Selections Pop-Up. I:E Ratio Has Been Selected

4. Dial to select one, then press to make your selection. The selected parameter is displayed in the **Trends Graph** window (Figure 107).

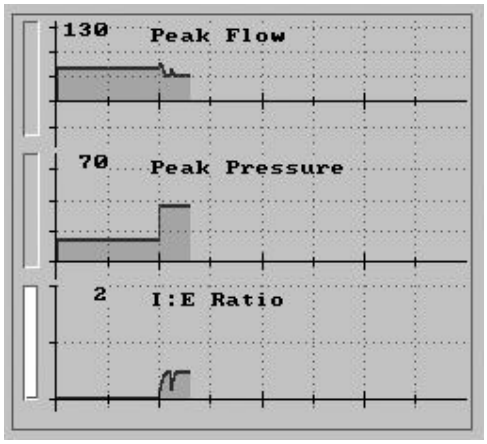


Figure 107: I:E Ratio Displayed

You can continue to choose alternative Trends to view by selecting the Select bar of each graph and then use the **Trends Choice** option to make your choice.

BROWSING TRENDS

You can recall trend information over a 72-hour period using the Browse feature.

To browse the trends:

1. Turn the Control Knob to select the Select bar of the **Trend** graph you want to browse (Figure 104). Press the Control Knob to display the **Trends Choice** option (Figure 108).
2. Dial the Control Knob to select **Browse**, and then press the dial.

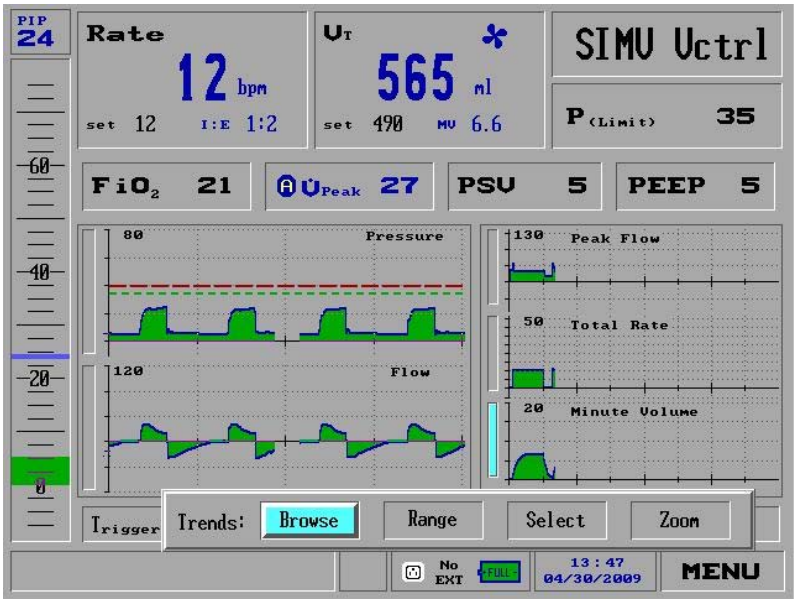


Figure 108: The Trends Choice Bar, with Browse Selected

3. A small blue selected option marked **Browse** appears, with the time and graph's cursor in center of the viewable data (Figure 109)

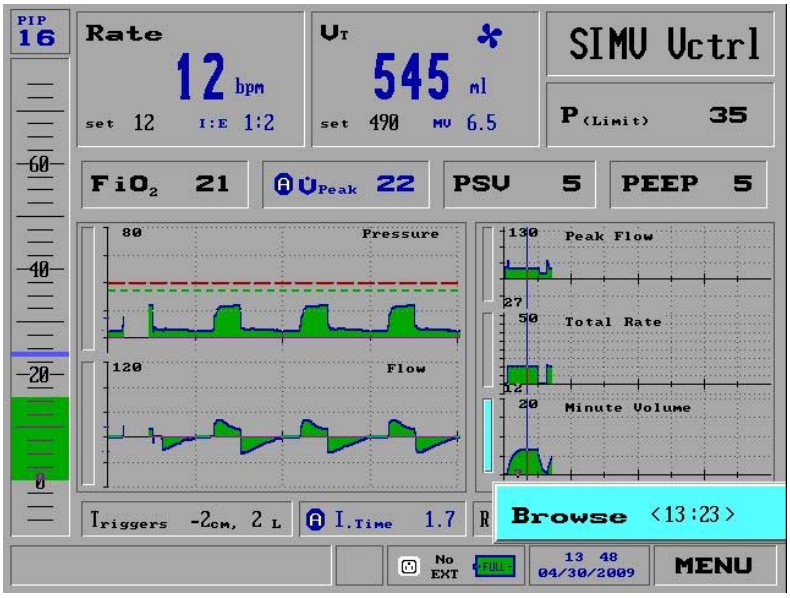


Figure 109: The Browse Trends Pop-Up Window

4. Rotating the dial clockwise moves the time cursor indicator forward. Rotating the dial counterclockwise moves the indicator backwards along the timeline.
5. You can change the scale of the time coordinate on which the **Trends** display. Select any of the graphs and press the Control Knob to display the **Trends Choice** pop-up window. Select **Zoom** (Figure 110).

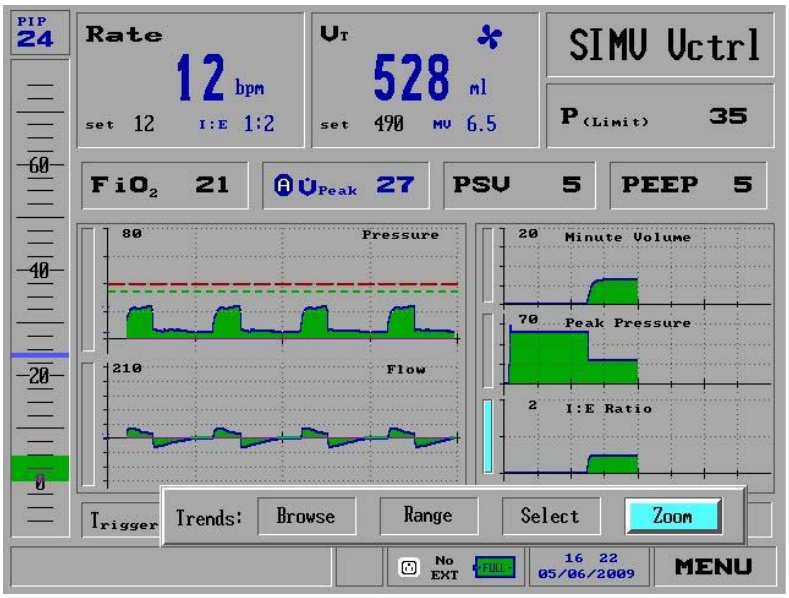


Figure 110: The Trends Choice Pop-Up Window, with Zoom Selected

6. The **Zoom** popup window appears. Turning the Control Knob adjusts the scale of the time shown, to enable viewing of larger or smaller-scale trends over time.

To switch back to the default Pressure/Flow graph view:

1. Select and press the **Menu** option in the **Main** screen to view the **Main Menu** pop-up window.
2. Select the **Show Graphs** option and press the Control Knob. The **Trends** pop-up window closes and only the graphs are displayed.

SHOW LOOPS

You can view Loops in four ways:

- Volume - Flow
- Pressure - Flow
- Pressure - Volume
- All three

You can select one Loop to display, or show all three Loops at once.

To display loops:

1. Select and press the **Menu** option in the **Main** screen to view the **Main Menu** (Figure 111).

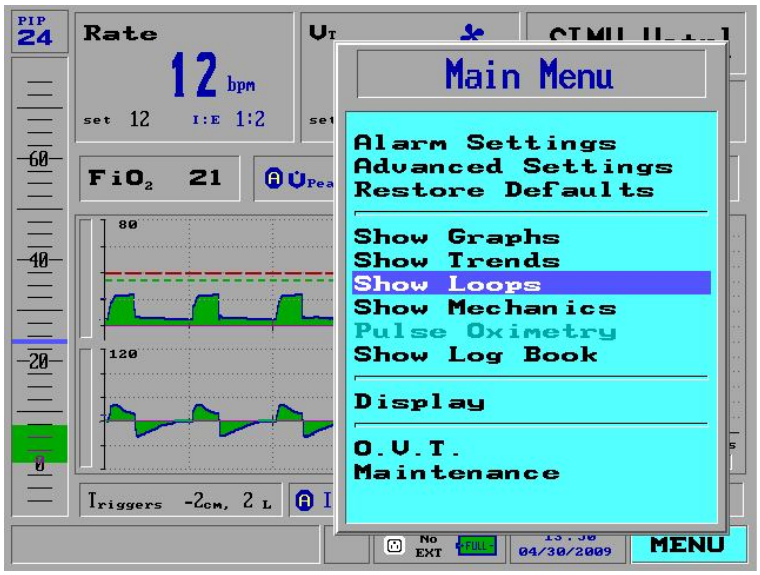


Figure 111: Show Loops selected on the Main Menu

2. Select the **Show Loops** option and press the Control Knob. The **Show Loops** menu pop-up window appears:

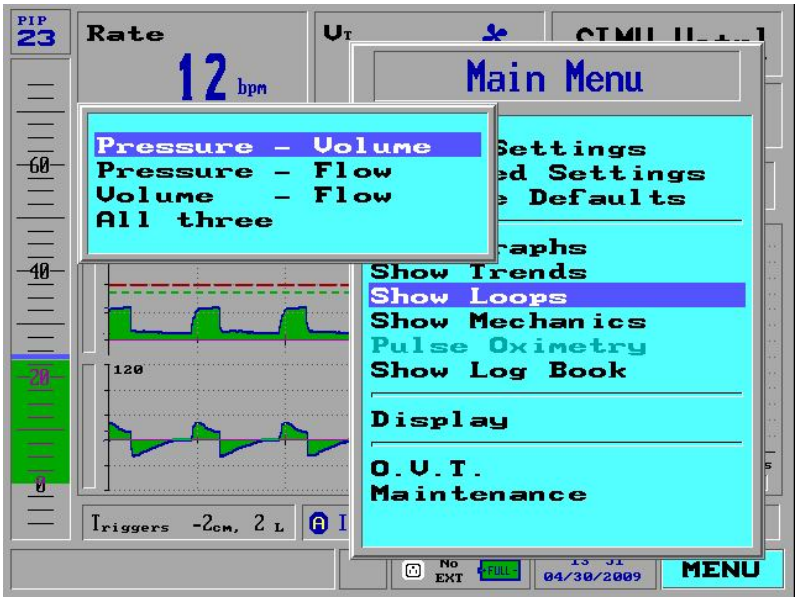


Figure 112: The Show Loops Pop-Up Window

3. Select any of the loops, or all three. The loops appear on the right side of the **Main** screen. A sample of a **Pressure/Volume Loop** is displayed below (Figure 113):

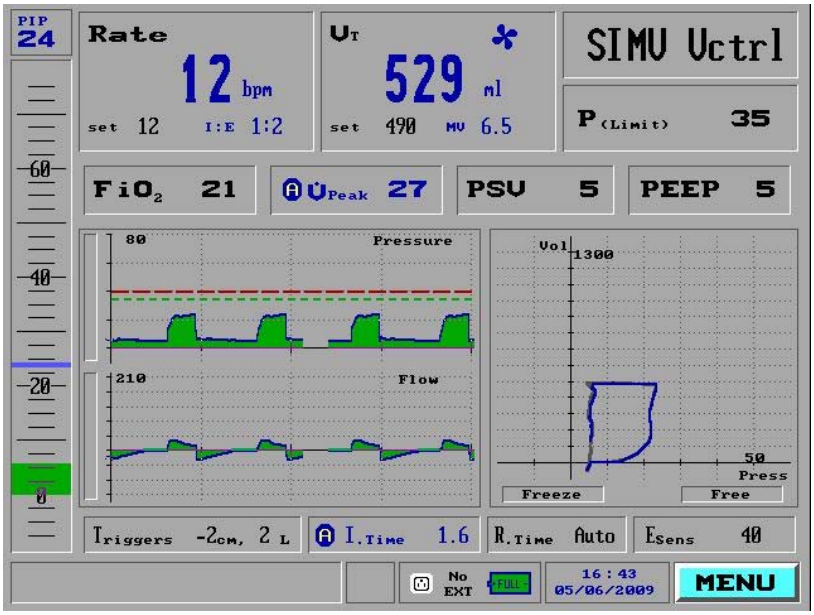


Figure 113: A Pressure/Volume Loop

Each new loop is drawn in blue, and turns to dark gray once the inspiratory cycle begins. The display retains the previous two loops.

Note that when in single-loop display, the Loop window has two selection buttons marked **Freeze** and **Free** (Figure 114):

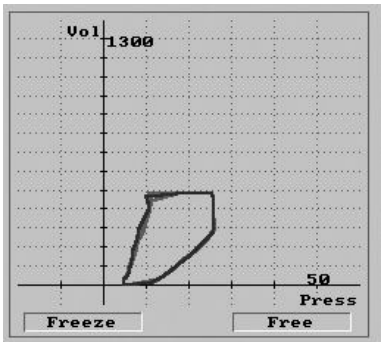


Figure 114: One Loop Loops Screen

You can use these to freeze a single loop on the display for purposes of clinical comparison.

NOTE This feature is only possible when one loop is displayed

To freeze a loop:

Rotate the Control Knob to select the **Freeze** button, then press. The current inspiratory cycle changes to red. Only the present loop (drawn in blue) and the previous loop (dark gray) continue to be displayed in the foreground, while the frozen loop appears in red in the background.

To unfreeze the currently-displayed loop:

Rotate the Control Knob until **Free** is selected, then press. As soon as the current breath is completed, the frozen loop disappears and the display resumes its default behavior, drawing each new loop in blue and displaying the two previous loops in black

To switch back to the default pressure/flow graph view:

1. Select and press the **Menu** option in the **Main** screen to view the **Main Menu.**
2. Select the **Show Graphs** option and press the Control Knob. The **Trends** pop-up window is closed and only the graphs are displayed.

SHOW MECHANICS

The iVent™201 calculates and displays Mean Airway Pressure, Resistance, Compliance, RR/Vt, Static Compliance, Plateau Pressure, Auto-PEEP, and Time Constant.

To display the mechanics screen:

1. Select and press the **Menu** option in the **Main** screen to view the **Main Menu.**
2. Select the **Show Mechanics** option (Figure 115).

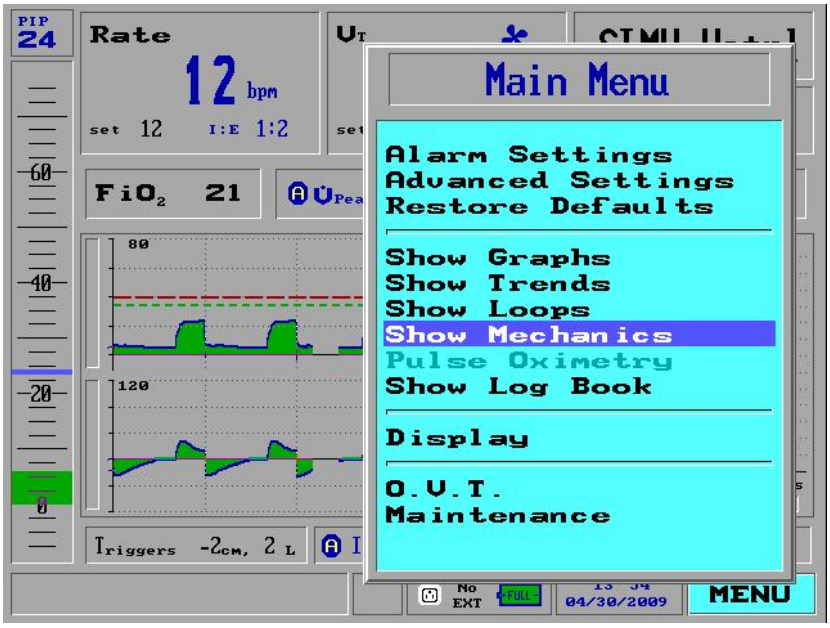


Figure 115: Show Mechanics Selected

3. Press the Control Knob. The right section of the screen shows the selection of numeric values:

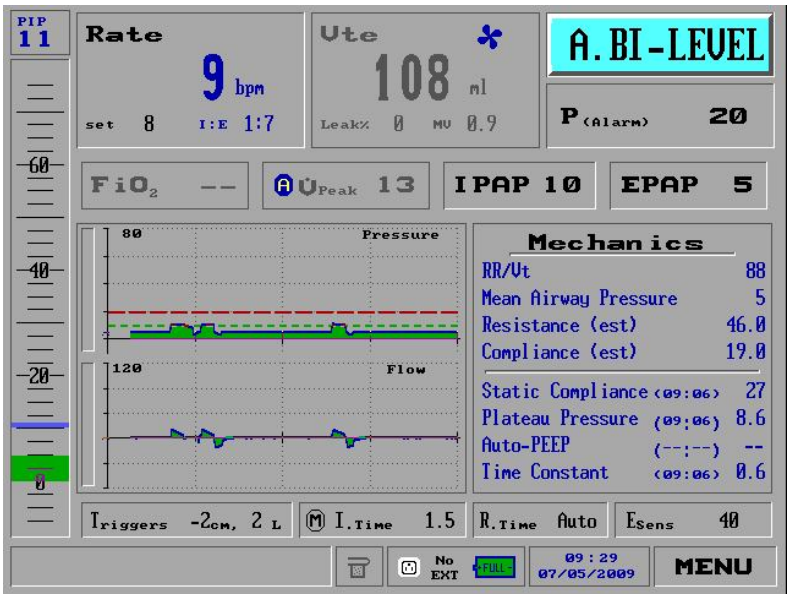


Figure 116: The Mechanics Pop-Up Window

PULSE OXIMETRY SCREEN

The Pulse Oximetry screen (Figure 117) displays the following measurements:

- **SpO2** – displays the oxygen saturation percent in the patient blood. This measurement is available in numeric format on all screens.
- **Heart Rate** – displays the heart rate (in bpm) in numeric format.

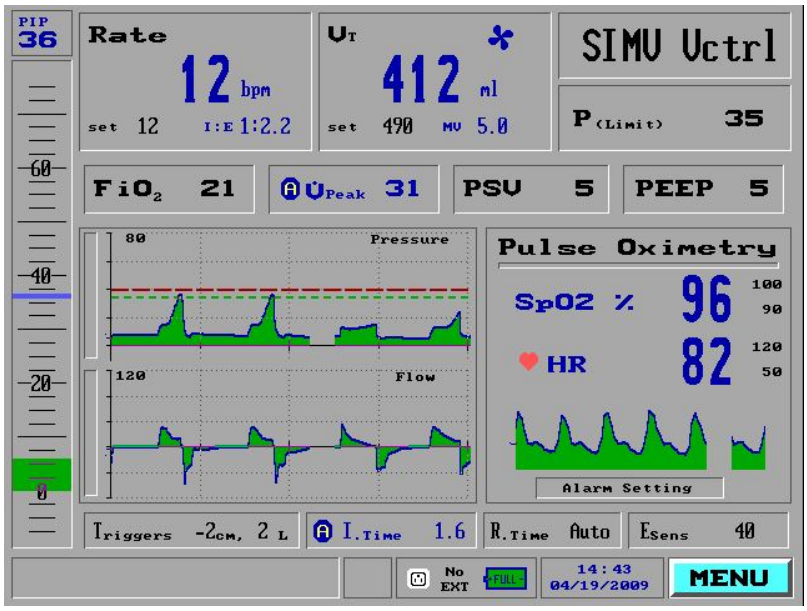


Figure 117: The Pulse Oximetry Screen on the Main Screen

The upper and the lower alarm limits settings are displayed in black on the right side of the screen. The actual measurements are displayed in blue. The plethysmography waveform is displayed on the screen lower section (Figure 118)

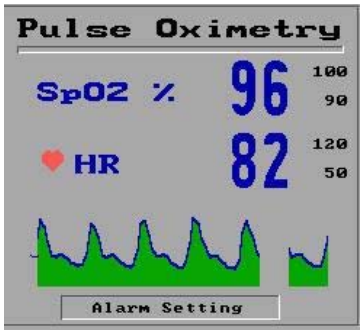


Figure 118: The Pulse Oximetry screen

To display the Pulse Oximetry screen:

1. Select and press the **Menu** option in the **Main** screen to view the **Main Menu**.
2. Turn the Control Knob until **Pulse Oximetry** is selected, then press to select.

The **Pulse Oximetry** screen is active even when the iVent™201 is in standby mode, to allow continued monitoring of patients' oxygenation and the heart rate. When the iVent™201 is in standby mode the **Pulse Oximetry** screen is expanded (Figure 119).

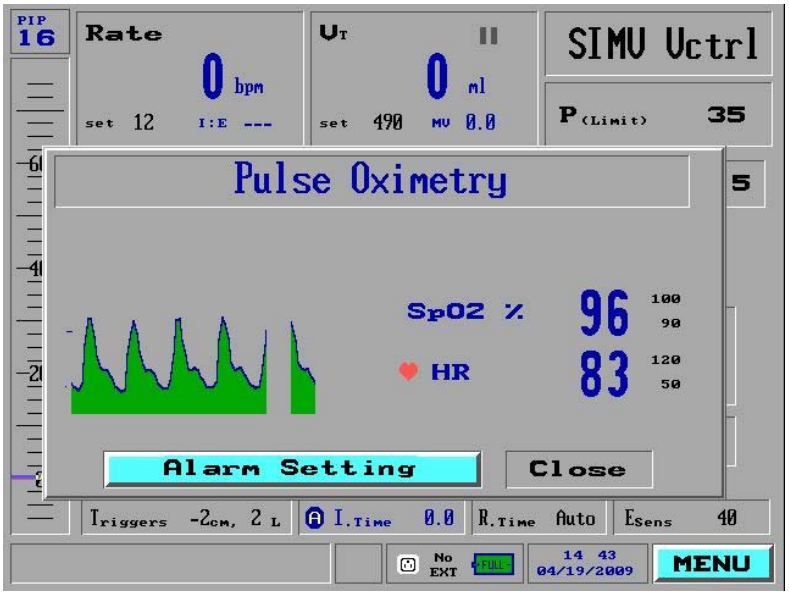


Figure 119: .Pulse Oximetry Screen in Standby mode

To close the Pulse Oximetry screen:

In the **Pulse Oximetry** screen select **Close**.

To re-open the Pulse Oximetry screen in standby mode:

From the **Main** menu select **Menu** – **Pulse Oximetry**.

PULSE OXIMETERY ALARMS

The following alarms are the pulse oximetry alarms. They are activated only when the **Pulse Oximetry** screen is enabled:

- SpO2 reading failed
- SpO2 Patient disconnect
- SpO2 Sensor disconnect
- Low SpO2
- High SpO2
- High Heart Rate
- Low Heart Rate

You can set the alarms for the high and low ranges for the SpO2 and Heart Rate alarms.

To set the alarms:

1. From the **Pulse Oximetry** screen, use the Control Knob to select **Alarm Settings**. The **SpO2 Alarm Settings** screen appears (Figure 120).

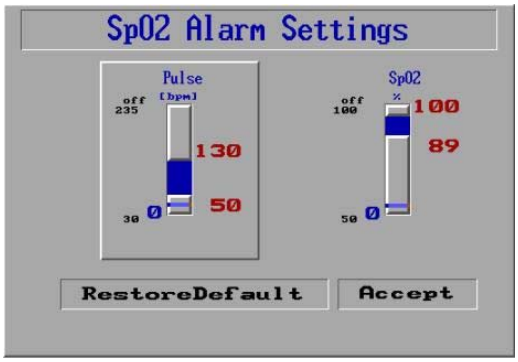


Figure 120: SpO2 Alarms Settings Screen

2. Use the Control Knob to select the following alarms:
   - Pulse (heart rate)
   - SpO2 (SpO2 level).
3. The top of the slider is selected bright blue. Turn the Control Knob to adjust the alarm upper limit, and press the Control Knob for acceptance.
4. The bottom of slider is selected in bright blue. Turn the Control Knob to adjust the alarm lower limit, and press the Control Knob for acceptance.
5. Select **Accept** and press the Control Knob for confirming and accepting the settings.

SHOW LOG BOOK

Beginning each time it is powered up, every time the ventilator enables a setting, sounds an alarm, or an operator makes an adjustment to the iVent™201, an entry is noted in the Log Book. The iVent™201 retains up to 1500 events in its memory, of which up to 500 can be accessed from the Log Book function of the Main menu.

To display the log book:

1. Select and press the **Menu** option in the **Main Screen** to view the **Main Menu.**
2. Select the **Show Log Book** option (Figure 121).

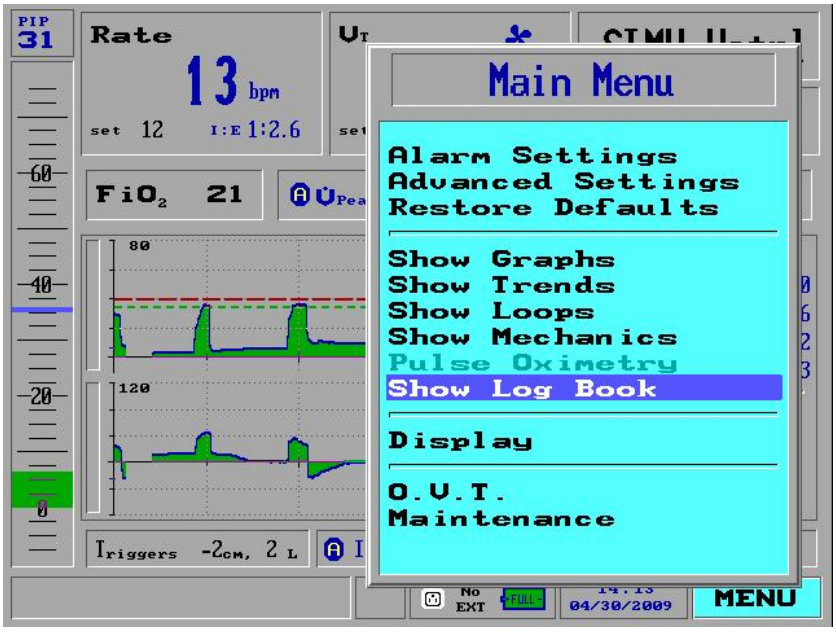


Figure 121: Show Log Book Selected on the Main Menu

3. Press the Control Knob. A bright blue screen appears, which shows in chronological order, each event stamped with the date and time. Rotating the dial counterclockwise moves the selected bar backwards for the log of events. Rotating the dial clockwise advances the log book forward in time.

DISPLAY

You can choose from among three displays: **Main**, **Monitoring**, and **Home Care**.

NOTE

Depending on which iVent™201model you have purchased, determines which display is available.

On the **Display Choices** menu, **Brightness** is not active

The **Main** display is most commonly used. The Monitoring display features a scaled-down menu with quick access to **Mode**, **Parameters**, **Alarms**, and **Waveforms** reference.

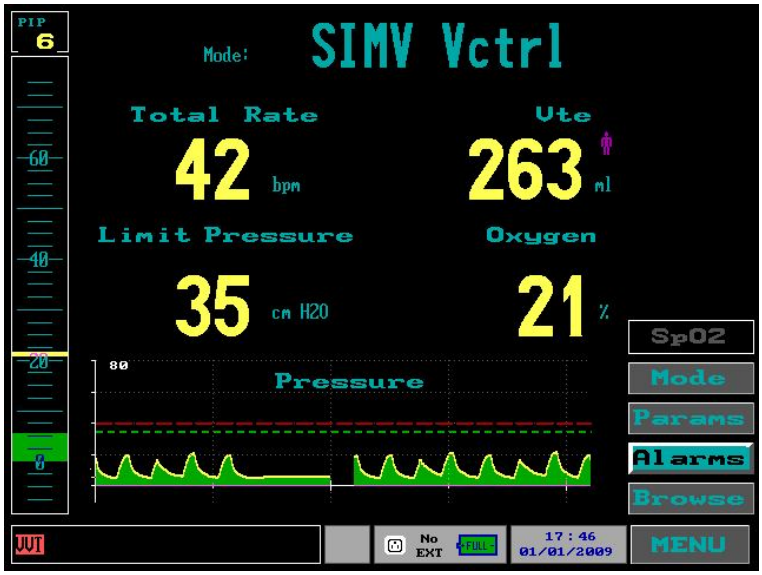


Figure 122: The Monitoring Display

The **Monitoring** display (Figure 122) is designed for optimal readability, and shows yellow letters over a black screen with yellow numerals showing key ventilation parameters.

The **Pulse SpO2** pop-up window can be viewed on the **Monitor** display.

To display the **SpO2 pop-up** window on the monitoring screens select and press the **SPO2** option on the lower left side of the screen.

The **SpO2** pop-up window appears on right side of the screen (Figure 123).

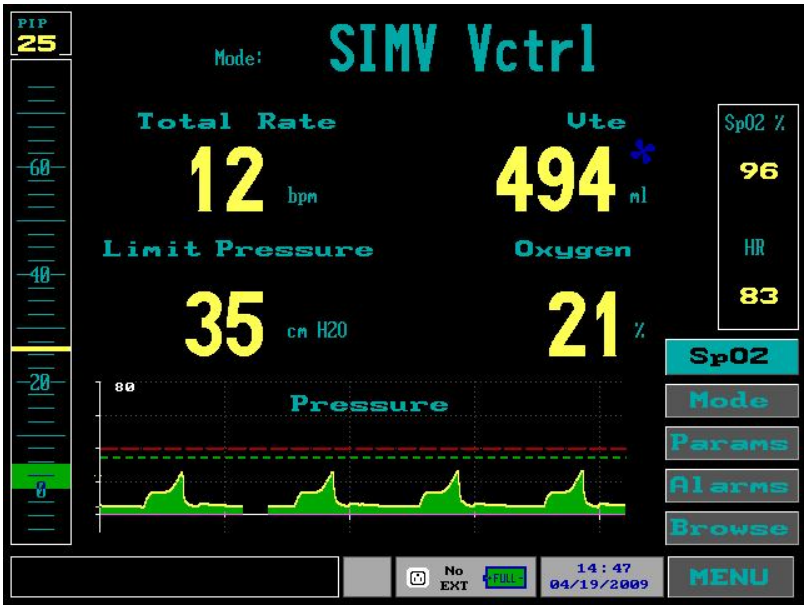


Figure 123: The Pulse Oximetry Pop-Up Window in the Monitor Display

The **Home Care** display only shows the essential data.

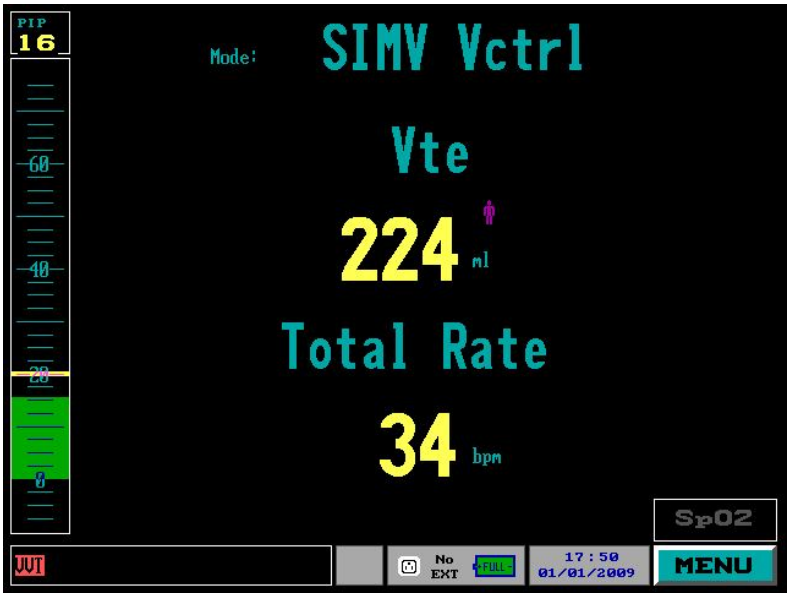


Figure 124: The Home Care Display

The pulse SpO2 window can be viewed on the **Monitor** display.

To display the SpO2 pop-up window on the monitoring screens select and press the **SPO2** option on the lower left side of the screen.:

The SpO2 pop-up window appears on right side of the screen (Figure 125).

Figure 125: The Pulse Oximetery Option in the Home Care Display

To access settings from the **Monitoring** or the **Home Care** screen, rotate the Control Knob to select the required option. Press the Knob to accept your selection.

The **Home Care** display shows the **Mode**, the **Exhale Volume** and the **Total Rate**. It is designed primarily for the simplest kind of monitoring. If you want to change settings or view ventilator information, proceed to the Main menu display.

To switch to any display:

1. Select and press the Menu option on the Main screen to view the Main Menu.
2. Select Display.
3. The Display menu pop up window appears. Select the display you require and press the Control Knob.

O.V.T.

The O.V.T. (Operational Verification Test) tests the patient circuit and the alarm sound. It must be performed every time a new circuit is connected.

In **Monitor** and **Home Care** displays you can access the O.V.T only through the **Main** menu. In the **Main** screen you can activate the O.V.T from the O.V.T option on the screen.

For a further description of the O.V.T. option see page 60.

MAINTENANCE

The Maintenance screen is described with maintenance procedures in Chapter 7.

Notes:

5 ADAPTIVE BI-LEVEL

This chapter contains the following sections:

INTRODUCTION

In this section the following is discussed:

- The fundamentals of Adaptive Bi-Level mode
- Which patients indicate for Adaptive Bi-Level mode
- How to set up the ventilator for A-B
- How to resolve patient-ventilator asynchrony

ABOUT ADAPTIVE BI-LEVEL

In VersaMed's Adaptive Bi-Level mode the iVent™201 can accommodate high leak situations - for instance, when using a facemask (sometimes referred to as non-invasive ventilation) or pressure support for high leak ET tube ventilation (Passy Muir® and cuffless applications). It is an important component in the arsenal of therapies that can be applied to patients presenting with respiratory insufficiency.

Adaptive Bi-level is a support mode of ventilation with a settable minimum rate. If the patient fails to breathe above this minimum rate the ventilator will initiate extra breaths to maintain the minimum rate. These extra ventilator-initiated breaths are flow terminated like the patient initiated support breaths.

GUIDE TO ADAPTIVE BI-LEVEL

Adaptive Bi Level is a support mode of ventilation, where spontaneous breathing efforts are pressure supported at a high (inspiratory) and low (expiratory) pressure. In the absence of spontaneous breathing efforts, the ventilator provides mandatory breaths at a rate indicated by the "respiratory rate" setting. The default setting should be lower than the spontaneous breathing rate to reduce dysynchrony with patient breathing efforts.

Breaths can be terminated by a reduction in peak flow to a pre-selected percentage. In high leak situations, cycling to exhalation by reduced flow could be compromised and an appropriate (maximum) I-time which acts as a backup to the flow termination mechanism should be set to prevent breath stacking.

Either Nasal CPAP masks or full facemasks can be used with Adaptive Bi-Level. Patients who breathe with their mouths should use a full facemask or if not available, a nasal mask with suitable chinstrap support. When using higher inspiratory pressures, it is also recommended to use a full facemask to prevent the escape of inflationary pressure via the oral cavity. See Table 9 at the end of this section for recommended masks.

INDICATIONS AND WARNINGS

INDICATIONS

Adaptive Bi-Level is indicated for patients who exhibit clinically appropriate conditions for facemask ventilation. Such patients include those with acute or chronic respiratory insufficiency secondary to acute exacerbation of COPD; hypercapnic acute respiratory failure, or decompensated heart failure.

WARNINGS

WARNING **Patients exhibiting an altered level of consciousness requiring intubation for mechanical ventilation, inability to tolerate facemask ventilation (injury, burn etc.), or severe decompensated respiratory failure requiring intubation should not be treated with a face mask.**

SETUP

To set up and apply facemask ventilation:

1. Power up the ventilator.
2. Select Patient Weight based on ideal body weight.
3. Select the Adaptive Bi-Level mode, by proceeding to the Ventilation Modes option and using the Control Knob to choose Adaptive Bi-level.

Figure 126: Adaptive Bi-Level Selected

4. Accept or adjust the parameters on the pop-up window. The factory default settings are displayed below (Table 6):

Table 6: Adaptive Bi-Level Default Settings

Respiratory Rate	= 8 bpm
IPAP	= 10 cmH_2O
Easy Exhale™	= On
EPAP	= 5 cmH_2O
Rise Time	= Auto
I-Time	= 1.5 sec
Peak Flow Termination (Esens)	= 40%
Triggering	= -2 cmH_2O for pressure and 2 L/min for flow triggering.

5. If facemask ventilation is required, apply a facemask to the patient. Connect the ventilator breathing circuit to the facemask.
6. Adjust the ventilator parameters for optimal ventilator patient synchrony and adequate ventilation (See page 134).
7. Select suitable patient alarms by proceeding to the Main Menu and selecting the Alarm Settings option. Enter the appropriate alarms according to facility protocol.

NOTE Adaptive Bi-Level provides a backup respiratory rate if spontaneous patient breathing efforts are not detected.

In cases where a severe leak is present, the Patient Disconnect alarm can be disabled via the **Alarm Settings** screen (See page 144)

ADAPTIVE BI-LEVEL ALARM SETTINGS

The Default Alarm Settings for Adaptive Bi-Level are provided below (Table 7):

Table 7: Adaptive Bi-Level Default Alarm Settings

Rate	Default for High Rate is Off Default for Low Rate is 6
Minute Volume	Default for Low Minute Volume set to 0 Default for High Minute Volume is based on weight
Pressure	Default for High Pressure is 20 Default for Low Pressure is 5
Apnea Time	Default for Apnea Time is 20 seconds
FiO_2	Default for High FiO_2 is +20% from set value Default for Low FiO_2 is 21% or –10% from set value
Leak	Default for Leak is 100%

NOTE Auto Settings are disabled in Adaptive Bi-Level

OTHER ALARM OPTIONS

In addition to the Alarm Settings the operator can disable the Inverse I:E Ratio alarm and the patient circuit disconnect alarm.

- Inverse I:E Ratio (ON – OFF option, default set to OFF)
- Tidal Volume not Delivered (field deactivated)
- Patient Circuit Disconnect (ON or OFF – default set to ON)

ADJUSTING ADAPTIVE BI-LEVEL PARAMETERS

Use the **Mode** screen to set parameters for Adaptive Bi-Level ventilation (Figure 127)

Figure 127: Adaptive Bi-Level Mode Parameters

The ranges for Adaptive Bi-Level parameters are as follows:

Table 8: Adaptive Bi-Level Parameters' Range

Rate	1 to 80 bpm
FiO_2	21% to 100%
Rise Time	0.1 to 1.5 sec Note: Rise time cannot exceed inspiration time.
IPAP	7 to 60 cmH_2O; with CAUTION indication at 41 cmH_2O Note: IPAP cannot be set below P-Low +2.
EPAP	0 to IPAP minus 2 or Maximum 30 cmH_2O
Esens	10% to 90%
I-Time	0.2 to 3 seconds; with **CAUTION** indication at 2.0 seconds or when rate setting I:E ratio reaches 1:4 **NOTE: If I-Time flashes, inspiration is terminated when the set I-Time is reached. When breath termination occurs due to decreased flow, the I-Time display is steady.**

NOTE Apnea Back Up ventilation operates in the same manner as in other ventilation modes. See Appendix E for more details.

ADAPTIVE BI-LEVEL WINDOW

This is what the iVent™201 Adaptive Bi-Level mode screen looks like (Figure 128):

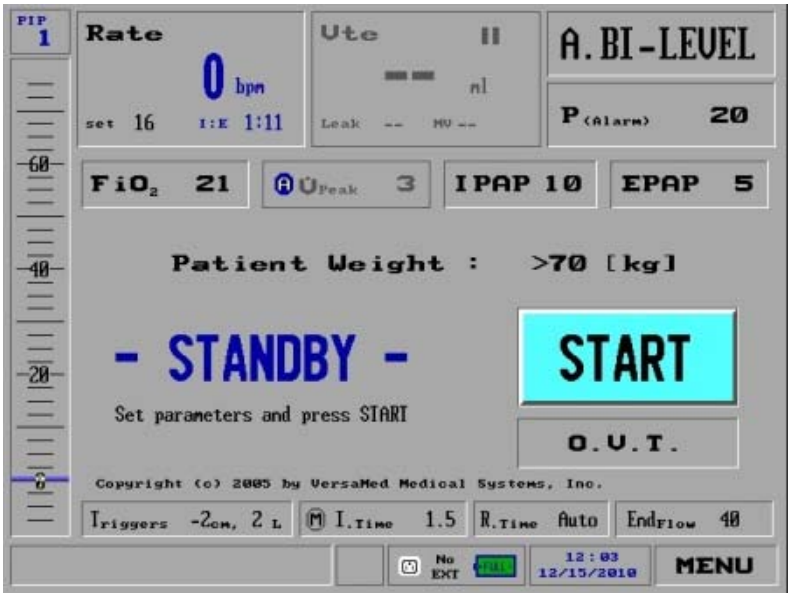


Figure 128: Adaptive Bi-Level Mode

The **Vte** display shows the estimated **Tidal Volume** delivered to the patient calculated using the measured flow leak during EPAP. An estimated Leak is shown below the Tidal Volume field of the display.

The Leak Estimate value is measured in lpm (See Figure 129)

Figure 129: Leak Estimated Value in LPM

In SW version 19.18.01 estimated leak in adaptive Bi-Level mode is presented in % (See Figure 130). Estimates Vti/Vte (Inhale/Exhale tidal volume ratio) are disregarded at leaks above 40 Liters/minute.

Figure 130: % Leak Estimated Value as Shown in Version 19.18.01

EASY EXHALE

Easy Exhale is an advanced feature of the iVent™201, minimizing the imposed exhalation valve resistance when PEEP > 0 is selected. By minimizing the exhalation valve resistance, we ensure as short exhalation time as possible thus reducing the risk of auto-PEEP.

Easy Exhale works by fully opening the exhalation valve at the early stages of exhalation, allowing the patient to exhale faster, compensating for the system and patient resistance. After this initial fully open position, the valve re-inflates to the set PEEP pressure in order to maintain the set PEEP in the patient's lungs. The duration of Easy Exhale is determined by the measured time constant of the lung, ensuring that the pressure inside the lung never falls below the set PEEP, even though the pressure at the airway might do so for a short time.

NOTE The default setting for Easy Exhale in **Adaptive Bi-Level** mode is **On**. This default can be disabled through the Advanced Settings screen at the operator's discretion (See page 93).

OPTIMIZING THE PATIENT VENTILATOR INTERFACE

Setting up the Patient Ventilator interface is straightforward. Either a nasal CPAP mask or a full-facemask can be used. If the mask incorporates an anti-asphyxia device, make sure that it closes on pressurizing the mask and does not require continuous uni-directional flow to remain closed.

Connect the facemask to the circuit using an OmniFlex or a double swivel elbow to increase circuit flexibility. Connect the circuit directly, without the use of an HME filter or a bacterial filter, between the flow sensor and the facemask. Finally, ensure that the sensor lines are not kinked or disconnected.

RESOLVING PATIENT VENTILATOR DYSYNCHRONY

EXCESSIVE VENTILATION

If there is excessive ventilation reduce either the respiratory rate or the IPAP level.

EXCESSIVE LEAK

Detection - Excessive leak is confirmed by visually examining the mask interface about the patient's face.

Intervention - Ensure that an approved and suitably sized nasal mask or facemask is being used (see manufacturer's instructions). Adjust the headgear and ensure that there is equal tension among all of the straps. If necessary, apply padding across the nasal bridge and chin.

NON-TRIGGERED BREATHS (INSPIRATORY TRIGGER FAILURE)

Detection - Failure to trigger the ventilator is detected by patient dysynchrony with mechanical breaths. These are apparent as spontaneous efforts, on the flow waveform, which do not result in a rise in pressure on the pressure waveform.

Intervention - Make sure that the enclosed volume of the facemask is not too large, or that the facemask is not poorly applied (see section under excessive leak). If the pressure trigger is greater than -0.5cmH2O, decrease the pressure trigger level, Also ensure that flow triggering is set higher than 2 L/M, and try decreasing this value.

EXCESSIVE TRIGGERING (AUTO CYCLING):

Detection - Auto cycling is detected by the observation of a rapid auto cycling pattern independent of the patient's breathing pattern.

Intervention – Increase the flow trigger setting first. Then after observing the patient and confirming the persistence of auto cycling, try increasing the pressure trigger setting. Confirm that the facemask interface has a tight seal. If the situation persists, consider recalibrating the unit.

I:E CYCLING DYSYNCHRONY

Detection – Delayed I:E cycling is indicated by High Pressure alarms or obvious ventilator patient dysynchrony and breath stacking.

Intervention – Increase the percent of peak flow termination value (Esens) from the menu. Additionally, consider decreasing I-time. An air leak can lead to "inspiratory hang up". This can be corrected by adjusting the full facemask or if a nasal mask is used, consider switching to a facemask. To exclude the presence of breath stacking, briefly disconnect the patient to allow spontaneous decompression. If the dysynchrony is resolved as a result, ensure that the settings for I-time and percentage leak flow termination are consistent with clinical guidelines.

Optimizing expiratory synchrony is of particular importance to patients with obstructive ventilatory disorders. These patients generally require prolonged expiratory periods to optimize airway emptying that minimizes breath stacking. In these patients it is essential to titrate the end inspiratory flow threshold to achieve good expiratory synchrony. A high flow threshold (70–90% of peak flow - Esens) is recommended. As previously mentioned, the I-time should also be regulated to minimize breath stacking if a lower end inspiratory threshold is chosen.

PREMATURE I:E CYCLING

Detection – Premature I:E cycling is indicated by patient ventilator dysnchrony, with no plateau on the pressure waveform concomitant with a negative flow deflection.

Exclusion – Re-evaluate the patient's clinical status for causes of high respiratory drive to exclude premature I:E cycling and manage appropriately.

Intervention – Lower the percent peak flow termination (Esens) and/or decrease the rise time. Use the waveform package to visualize waveforms and prolong the I-time until a visually detectable inspiratory flow termination pattern appears prior to pressure release.

Table 9: Recommended Masks

Part Number	Description
Nasal Masks :	All Types (chin strap may be required for mouth breathers
	Respironics Image 3 SE disposable version
	Resmed Mirage 2- reusable version (no vent holes)
M1162031	Koo Medical Equipment- Bluestar Plus NIV Face Mask Kit, **Ultra Large (KM-310)**
M1162032	Koo Medical Equipment- Bluestar Plus NIV Face Mask Kit, **Large (KM-311)**
M1162033	Koo Medical Equipment- Bluestar Plus NIV Face Mask Kit, **Medium (KM-312)**
M1162034	Koo Medical Equipment- Bluestar Plus NIV Face Mask Kit, **Small (KM-313)**
M1162035	Koo Medical Equipment- Bluestar Plus NIV Face Mask Kit, **Child (KM-314)**

6 ALARMS

This chapter contains the following sections:

INTRODUCTION

In this section you will learn how to:

- Quickly respond to iVent™201 alarms
- Determine and select optimal alarm settings
- Set alarm parameters and perform troubleshooting
- Perform Alarm tests
- The iVent™201 operates when the sensor disconnect alarm is activated or when it senses patient disconnection

HOW ALARMS WORK

As soon as the iVent™201 detects an alarm condition, it sounds an alert and displays a pop-up window on the LCD screen. After the alarm is minimized using the **Silence** or **Clear** key, it is minimized to the bottom left of the screen. In that position it performs the following:

- Appears red as long as the alarm condition persists
- Turns green if the alarm condition resolves itself without user intervention

RESPONDING TO AN ALARM

To silence an alarm:

1. Rectify the condition which causes the alarm. This stops the alarm sound and minimizes the pop-up alarm. The minimized alarm appears in red with a brief text message describing the alarm condition (Figure 131).

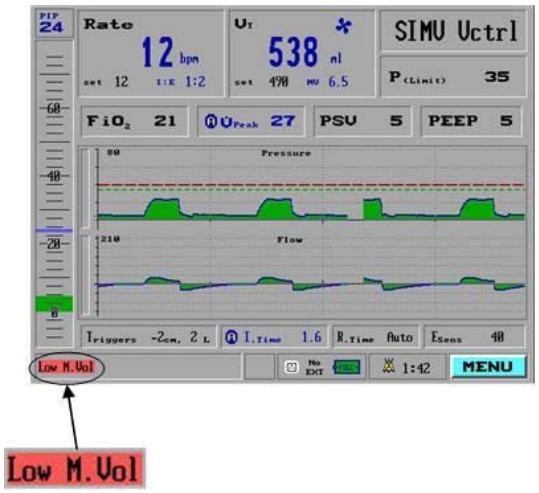


Figure 131: Low Minute Volume alarm on the Main screen

2. Press the **Clear** button on the keypad. This silences the alarm and minimizes the alarm pop-up window. If the condition which caused the alarm is not resolved, the minimized alarm appears red and is labeled with a text message that describes the alarm condition. After 30 seconds, the alarm pop-up window maximizes and sounds an audible alert.

WARNING **Rectify all alarm conditions immediately. Always make sure that the patient is safe. An alternate means of ventilation must be available at all times.**

3. Press the red **Silence** button on the keypad. This stops the alarm sound and minimizes the alarm pop-up window. A two-minute timer starts, which shows in the bottom right beside an icon showing a crossed-out bell (Figure 132)

Figure **132: Silenced Alarm Icon**

For as long as the condition causing the alarm is not corrected, the minimized alarm appears red with a text message that describes the alarm condition. If the alarm condition is not resolved within two minutes, the alarm pop-up window maximizes and sounds an audible alert.

WARNING **Rectify all alarm conditions immediately. Always make sure that the patient is safe. An alternate means of ventilation must be available at all times.**

NOTE If more than one alarm condition occurs, the alarm messages appear sequentially according to their order of appearance from left to right on the minimized alarm bar.

To clear a minimized green alarm indicator from the bottom of the LCD screen, press clear for two seconds.

All alarms are logged in the logbook. Clearing an alarm also creates a log entry in the logbook

ALARM SETTINGS

The following alarms are user-adjustable:

- High and Low Respiratory Rate
- High and Low Minute Volume
- High and Low Pressure

The Low Pressure alarm is updated automatically when setting the PEEP value. It can also be adjusted from the Alarm Settings screen

- Apnea Time

- High and Low O2
- This alarm is updated automatically when setting the FiO2 parameter and can also be adjusted from the **Alarm Settings** screen
- Leak %

NOTE For the Pulse Oximetry related alarms see page 122

The following alarm values are configurable:

- Volume Limit Reached (for pressure controlled modes only).

This alarm can be adjusted from the Tidal Volume pop-up window in the Main screen, whereas the other alarms are set from the Alarm Settings screen.

- Audio Alarm Volume
- Inverse I:E Ratio Alarm
- Tidal Volume not delivered
- Patient Circuit Disconnect (Enable/ Disable – On/Off)

The following alarms are always operational:

A/C Power disconnect	High PEEP
Low Battery	Low O_2 pressure
Battery Empty	Check Sensor
Over Temperature	Sensor Disconnect
Patient Circuit Failed	Auto Start
Service Notice	Need calibration

CHANGING INDIVIDUAL ALARM SETTINGS

Select and press **Alarm Settings** in the **Main Menu** to view the **Alarm Settings** screen (Figure 133):

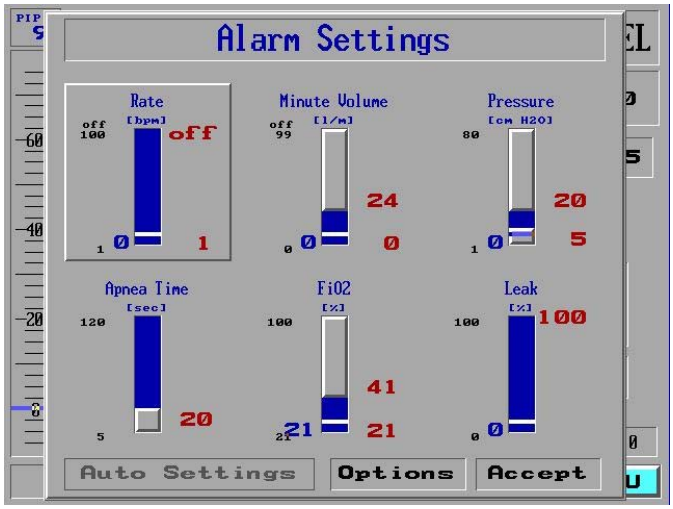


Figure 133: The Alarm Settings Screen

The first Alarm Settings screen presents six slide indicators that control the range of values for triggering alarms. Some of these Alarm Conditions have a high and a low value (Rate, Minute Value, Pressure, FiO2), while Apnea accepts only a time value, and Leak a percentage value.

Note that the blue ribbon indicates the scale of an active alarm threshold within the entire possible range of values. The red number(s) beside each indicator show the currently selected alarm value(s). The small black numerals to the left of each gauge show the absolute maximum or minimum allowed alarm setting. The larger blue numbers to the left of each gauge are displayed only during ventilation showing each parameter's current operative value.

NOTE To save any alarm change, the **Accept** button must be selected. Exiting the alarm screen by any other means cancels all changes that have been made.

SETTING THE RESPIRATORY RATE ALARM

To adjust the respiratory rate alarms upper and lower limits:

1. Select and press the **Menu** option in the **Main Screen** to view the **Main Menu**.
2. Select and press the first item on the **Main Menu**, **Alarm Settings**.
3. In the **Alarm Settings** screen, dial the Control Knob until **Rate** is selected in relief on the top left (Figure 134).

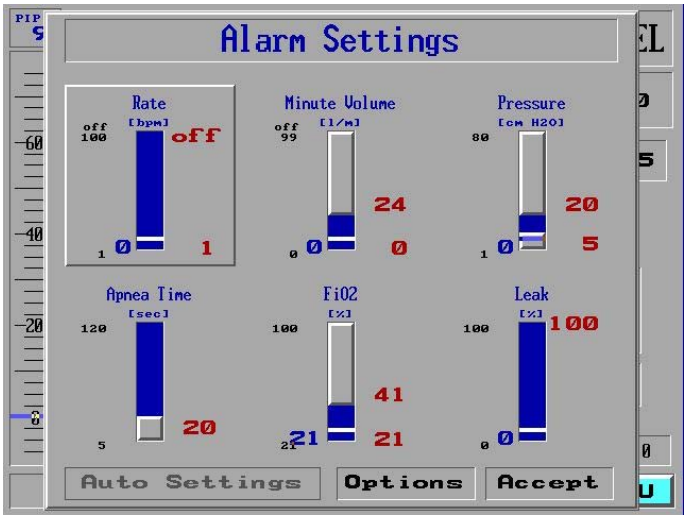


Figure 134: The Respiratory Rate Alarm Slider Selected

4. Press the Control Knob to change the alarm setting for the **Respiratory Rate**.
5. The top of the slider is selected in bright blue. Turn the dial to adjust the alarm rate for the upper limit in **Breaths per Minute**. Note that if you attempt to adjust the upper limit of the alarm rate below the currently-selected lower limit, you push the lower limit down.
6. Press the Control Knob to confirm your selection.
7. The bottom of the slider is selected in bright blue. Turn the dial to adjust the alarm rate for the lower limit in **Breaths per Minute**. Note that adjusting the lower limit higher than the currently-selected higher limit moves the higher limit up.
8. Press the Control Knob to confirm the alarm settings.
9. The **Alarm Setting** screen is re-displayed. You can dial and select an **additional** alarm setting to adjust **or dial and select Accept to** accept all the alarm settings and return to the **Main** screen.

Setting the Minute Volume Alarm

To adjust the minute volume alarms upper and lower limits:

1. Select the **Menu** option in the **Main** screen to view the **Main Menu**.
2. Select and choose the first item on the **Main** Menu, **Alarm Settings**.
3. In the **Alarm Settings** screen, dial the Control Knob until **Minute Volume** is selected in relief (Figure 135).

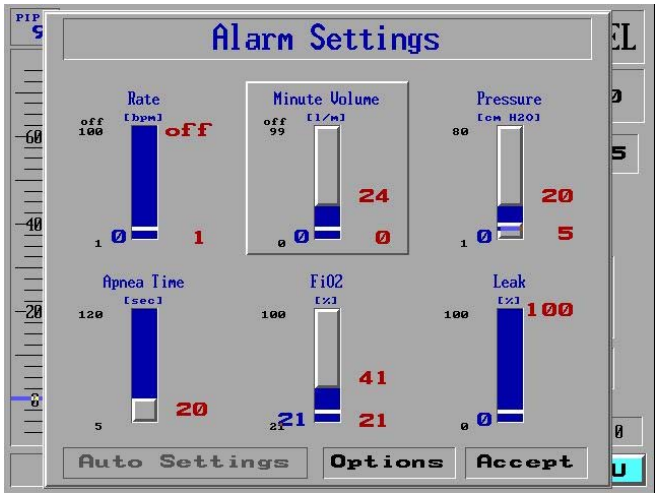


Figure 135: The Minute Volume Alarm Slider Selected

4. Press the Control Knob to change the alarm settings for the **Minute Volume**.
5. The top of the slider is selected bright blue. Turn the dial to adjust the alarm for the upper limit in liters per minute. Notice if you attempt to adjust the upper limit of the alarm below the currently-selected lower limit, you push the lower limit down. Setting the **Minute Volume** alarm over the maximum level of 99 turns off the alarm's upper limit.
6. Press the Control Knob to confirm your selection.
7. The bottom of the slider is selected bright blue. Turn the dial to adjust the alarm for the lower limit in liters per minute. Note that adjusting the lower limit higher than the currently-selected higher limit moves the higher limit up.
8. Press the Control Knob to confirm the settings.
9. The **Alarm Setting** screen is re-displayed. You can dial and select an additional alarm setting to adjust, or dial and select **Accept** to accept all the alarm settings and return to the **Main** screen.

Setting the Pressure Alarm

To set the pressure alarm upper and lower limits:

1. Select and press the **Menu** option in the **Main** screen to view the **Main Menu**.
2. Select and press the first item on the **Main Menu**, **Alarm Settings**.
3. In the **Alarm Settings** screen, dial the Control Knob until **Pressure** is selected in relief (Figure 136).

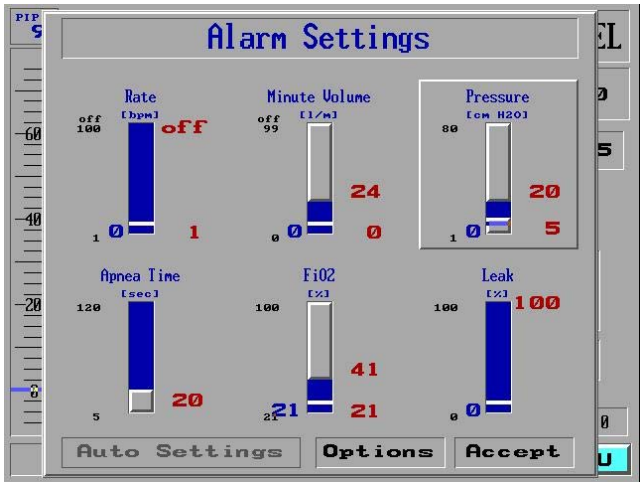


Figure 136: The Pressure Alarm Slider Selected

4. Press the Control Knob to change the alarm settings for the **Pressure**.
5. The top of the slider is selected bright blue. Dial the knob to adjust the alarm for the upper limit in cmH2O up or down. Note that if you attempt to adjust the upper limit of the alarm below the currently-selected lower limit, you push the lower limit down.
6. Press the Control Knob to confirm your selection.
7. The bottom of the slider is selected bright blue. Turn the dial to adjust the alarm for the lower limit in cmH2O. Note that adjusting the lower limit higher than the currently-selected higher limit moves the higher limit up.
8. Press the Control Knob to confirm the settings.
9. The **Alarm Setting** screen is re-displayed. You can dial and select an additional alarm setting to adjust, or dial and select **Accept** to accept all the alarm settings and return to the **Main** screen.

Setting the Apnea Time Alarm

1. Select the **Menu** option in the **Main** screen to view the **Main Menu**.
2. Select the first item on the **Main Menu**, **Alarm Settings**.
3. In the **Alarm Settings** screen, dial the Control Knob until **Apnea Time** is selected in relief (Figure 137).

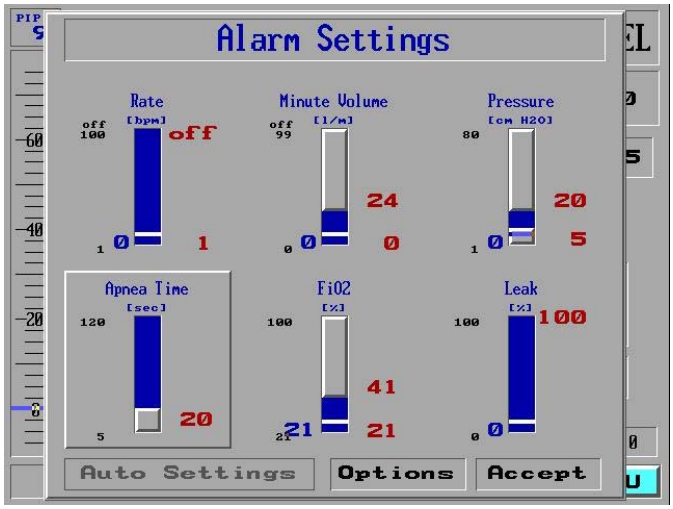


Figure 137: The Apnea Time Alarm Slider Selected

4. Press the Control Knob to change alarm setting for the **Apnea Time**.
5. Dial the Control Knob to select a time between the minimum and maximum ranges.
6. Press the Control Knob to confirm the settings.
7. The **Alarm Setting** screen is re-displayed. You can dial and select an additional alarm setting to adjust, or dial and select **Accept** to accept all the alarm settings and return to the **Main** screen.

Setting the FiO2 Alarm

To set the FiO2 alarm upper and lower limits:

1. Select the **Menu** option in the Main screen to view the **Main Menu**.
2. Select the first item on the **Main Menu**, **Alarm Settings**.
3. In the Alarm Settings screen, dial the Control Knob until FiO2 is selected in relief (Figure 138).

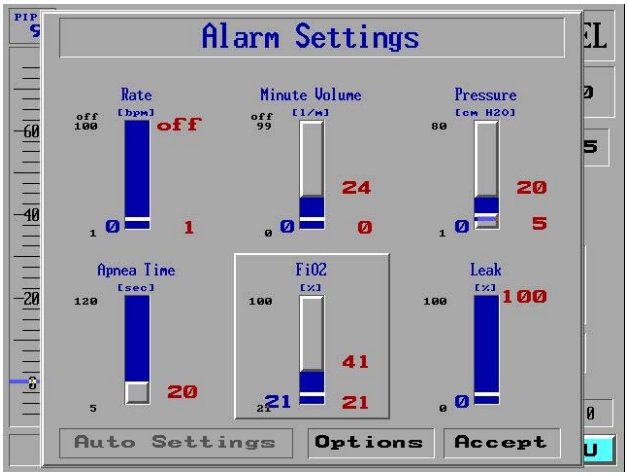


Figure 138: The FiO2 Alarm Slider Selected

4. To change the **FiO2** alarm, press the Control Knob.
5. The top of the slider is selected bright blue. Turn the dial to adjust the alarm rate for the upper FiO2 percentage limit, from 21% to 100%, up or down. Note that if you attempt to adjust the upper limit of the alarm below the currently-selected lower limit, you push the lower limit down.
6. Press the Control Knob to confirm your selection.
7. The bottom of the slider is selected bright blue. Turn the dial to adjust the alarm for the lower percentage limit. Note that adjusting the lower limit higher than the currently-selected higher limit moves the higher limit up.
8. Press the Control Knob to confirm the settings.
9. The **Alarm Setting** screen is re-displayed. You can dial and select another alarm setting to adjust, or dial and select **Accept** to accept all the alarm settings and return to the **Main** screen.

Setting the Leak Alarm

To set the leak percentage limit:

1. Select the **Menu** option in the **Main** screen to view the **Main Menu**.
2. Select the first item on the **Main Menu**, **Alarm Settings**
3. In the **Alarm Settings** screen, dial the Control Knob until **Leak** is selected in relief (Figure 139).

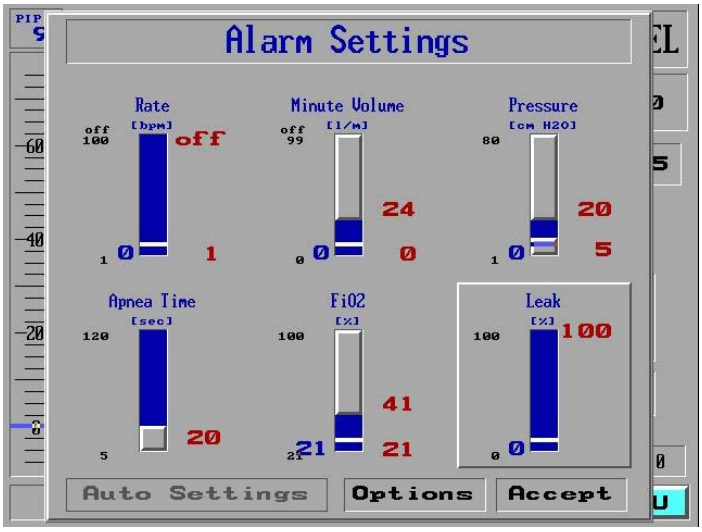


Figure 139: The Leak alarm Slider Selected

4. Press the Control Knob to change the alarm setting for the Leak.
5. Adjust the Control Knob to select a percentage between 0 and 100%.
6. Press the Control Knob to confirm the settings.
7. The **Alarm Setting** screen is re-displayed. You can dial and select another alarm setting to adjust, or dial and select **Accept** to accept all the alarm settings and return to the **Main** screen.

AUTO SETTINGS

The Auto Settings feature sets all the alarms in the **Alarm Settings** option to suit the currently measured ventilation parameters for the patient. By selecting **Auto Settings** the measured values for each parameter in the **Alarm Settings** window with the appropriate limits for those parameters are displayed.

WARNING **The operator should carefully review and assess the automatic alarm settings. Adjust alarms that are not compatible with specific patient needs or facility policy.**

CAUTION *The factory default setting for "Leak Alarm" is set to OFF. You must manually set the leak alarm to enable it.*

NOTE The Auto settings option is available only when the iVent™201 is ventilating.

To choose auto settings:

1. Select the **Menu** option in the **Main** screen to view the **Main Menu**.
2. Select the first item on the **Main Menu**, **Alarm Settings**.
3. In the **Alarm Settings** screen, dial the Control Knob until **Auto Settings** is selected (Figure 140).

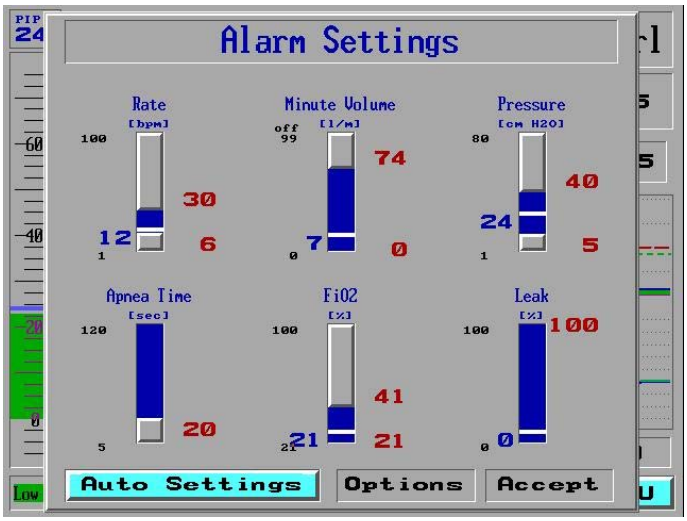


Figure 140: The Auto Settings Selected on the Alarm Settings Screen

4. Press the Control Knob. The **Alarm Settings** are now reset in accordance with current ventilation parameters.
5. Dial and select **Accept** to accept the **Auto Settings** and return to the **Main** screen.

ALARM OPTIONS

The Alarm Options menu allows you to:

- Set the alarm volume (loudness)
- Enable or disable the **Inverse I:E Ratio** alarm
- Adjust or disable the **Low Tidal Volume** alarm
- Enable or disable the **Patient Circuit Disconnect** alarm

To access the Alarm Options menu:

1. From the Main screen select **Menu - Alarm Settings**. The **Alarm Settings** screen is displayed (Figure 141).
2. Select Options and press the knob.

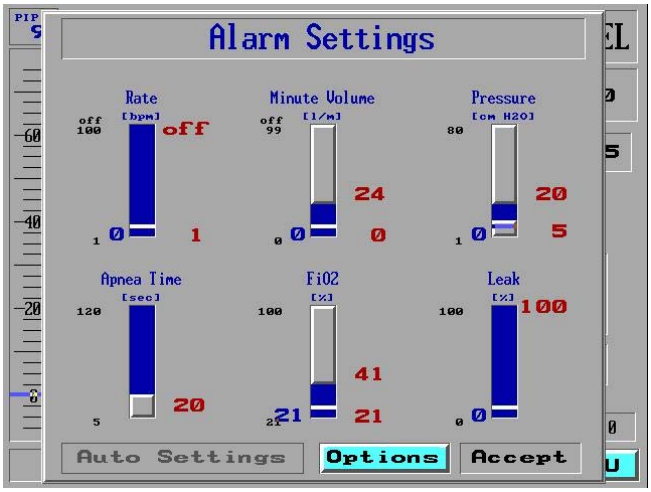


Figure 141: The Options Selection Selected on the Alarm Settings Screen

3. The **Alarm Options** screen appears (Figure 142).

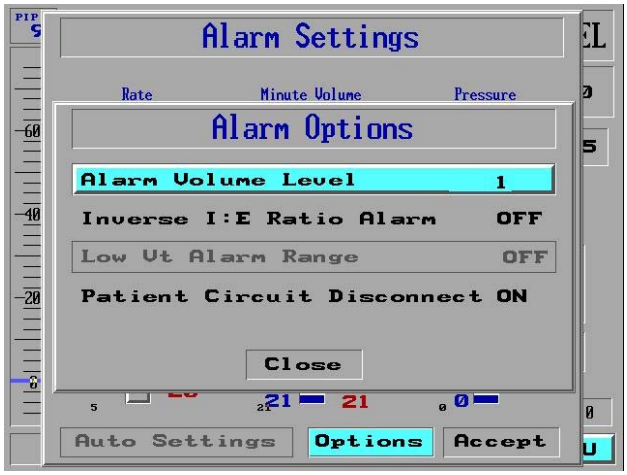


Figure 142: The Alarm Options Screen

Setting the Alarm Volume

NOTE The Alarm volume default is level 8.

To set the alarm volume:

1. From the screen select Menu – Alarm Setting - Options.
2. On the **Alarm Options** screen, select the first option **Alarm Volume** Level.
3. Press the Control Knob to display the **Alarm Volume** pop-up window (Figure 143).

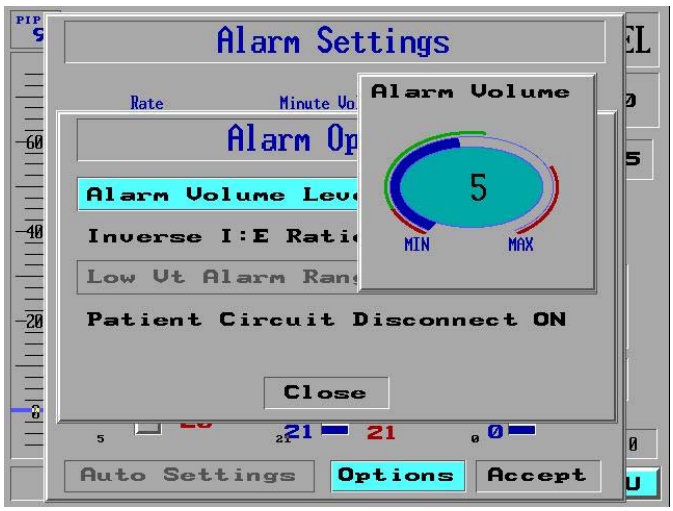


Figure 143: The Alarm Volume Pop-Up Window

4. Turn the dial to adjust the alarm volume from 1 (low) to 10 (high). As you turn the dial, the iVent™201 produces a sample of the level. If you set the level under 2 or over 8, a **Caution!** pop up window appears.
5. Press the Control Knob to confirm the settings.
6. You are returned to the **Alarm Settings** screen. Dial and select **Accept** to accept the **Alarm Options** settings.

Setting the Inverse I:E Ratio Alarm

WARNING **The default setting for Inverse I:E Ratio Alarm is ON. Before disabling any alarms, ensure that you are operating in accordance with facility policy and patient needs.**

To disable or enable the inverse I:E Alarm:

1. From the Main screen select **Menu – Alarm Settings - Options**. The **Alarm Option** menu is displayed.
2. Turn the Control Knob until **Inverse I:E Ratio Alarm** is selected.

3. Press the knob. An **ON/OFF** selection pop up window appears (Figure 144).

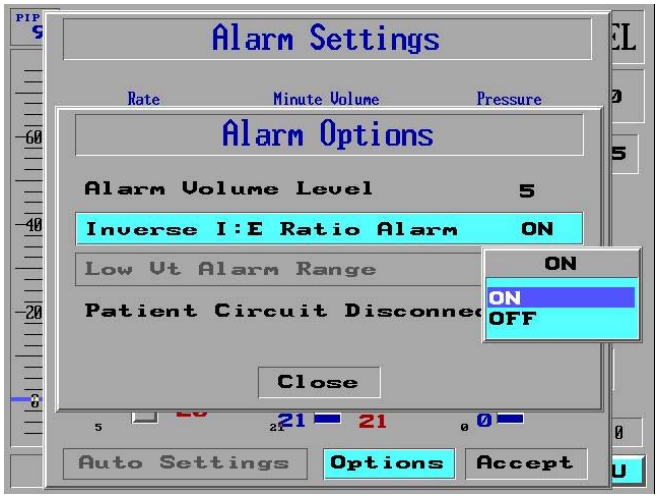


Figure 144: The Inverse I:E Ratio Alarm Selection Menu Pop-Up Window

4. Turn the dial to select **ON** or **OFF.**
5. Press the dial to accept and confirm the settings.
6. You are returned to the **Alarm Settings** screen. Dial and select **Accept** to accept the **Alarm Options** settings.

Setting the Tidal Volume Not Delivered Alarm

WARNING **The default setting for Tidal Volume Not Delivered Alarm is 85%. Before disabling or adjusting any alarms, be sure that you are operating in accordance with facility policy and patient needs.**

NOTE **This option is not available in Adaptive Bi-Level ventilation mode.**

To set the low Vt Alarm Range:

1. From the **Main** screen select **Menu – Alarm Settings - Option**. The **Alarm Option** screen is displayed.
2. Turn the Control Knob until **Low Vt Alarm Range** is selected. The currently-selected percentage range is shown in the right column of the screen.
3. Press the Control Knob. The **Set Low Vt** pop-up window appears (Figure 145).

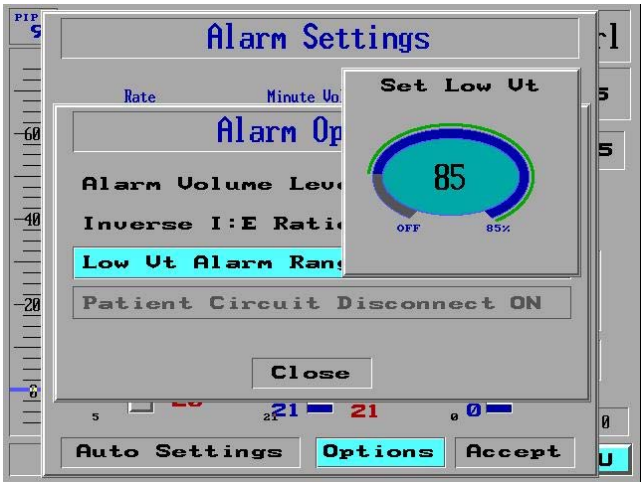


Figure 145: The Low Tidal Volume Alarm Range Pop-Up Window

4. Turn the Control Knob to adjust the percentage between 0% (Off) and 85%.
5. Press the dial to confirm the settings.
6. You are returned to the **Alarm Settings** screen. Dial and select **Accept** to accept the **Alarm Options** settings.

Disabling or Enabling the Patient Circuit Disconnect Alarm

When ventilating with Adaptive Bi-Level, under some circumstances it is appropriate to turn off the Patient Circuit Disconnect Alarm.

WARNING **The default setting for the Patient Circuit Disconnect Alarm is ON. It should be shut off under medical discretion ONLY if necessary. Be sure that you are operating in accordance with facility policy and patient needs.**

NOTE **This option is available in Adaptive Bi-Level mode only.**

To disable the patient disconnect alarm:

1. From the **Main screen select Menu – Alarm Settings - Options**. The **Alarm Options** screen is displayed.
2. Dial the Control Knob until **Patient Circuit Disconnect** is selected. The state of the Alarm (ON or OFF) is shown in the right column of the screen.
3. Press the Control Knob. An **ON/OFF** selection pop up window appears (Figure 146).

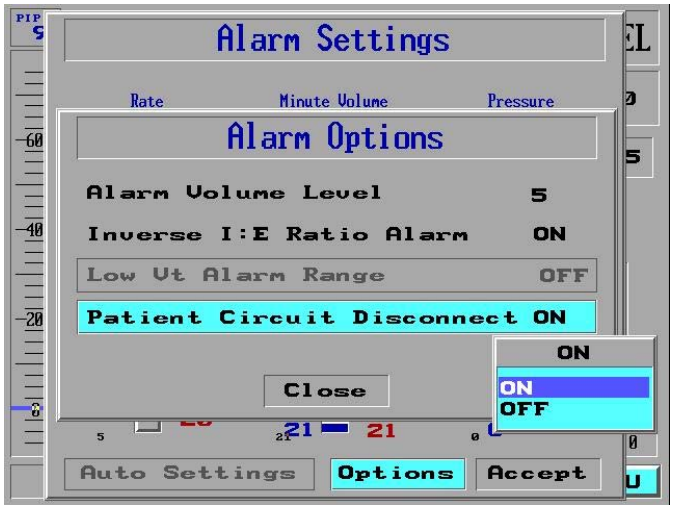


Figure 146: The Patient Circuit Disconnect Alarm Pop-Up Window

4. Turn the knob to select **ON** or **OFF**.
5. If you select **OFF**, a warning pop-up window appears (Figure 147):

Figure 147: The Patient Circuit Disconnect Alarm Off Warning

6. Press **Yes** by using the Control Knob to confirm.
7. You are returned to the **Alarm Settings** screen. Dial and select **Accept** to accept the **Alarm Options** settings.
8. When the Patient Disconnect Alarm is turned **OFF**, the **Main Screen** displays a warning in the bottom left corner (Figure 148):

Figure 148: The Patient Circuit Disconnect Alarm Off Icon

GUIDE TO ALARM DEFINITIONS AND PRIORITIES

iVent™201 alarms differ by sound according to degree of severity. Table 10 shows categories and characteristics of alarms.

Table 10: Alarm and Audible Alarm Patterns

Priority	Audible Pattern	When the criterion for clearing an alarm is met:
High (life-threatening - LT)	Continuous beep	Alarm pop-up is removed. Message remains (minimized green). Log is updated.
High	Triple beep every 5 secs.	Alarm pop-up is removed. Message remains (minimized green) Log is updated.
High - Mid	Continuous beep	Alarm pop-up is removed. Message remains (minimized green) Log is updated.
Mid	Triple beep every 5 secs.	Alarm pop-up is removed. Message is removed. Log is updated.
Low	Single beep	No pop-up. Message is removed. Log is updated.

Table 11 below shows alarm definitions and guides you through troubleshooting procedures, which include the following:

Set Count or **Time of Condition** shows the number of occurrences or amount of time (breath cycles or minutes) during which the condition exists before the alarm is triggered.

Numbers in parenthesis e.g., (20 with setting change) indicates an alternative Set Count that takes effect immediately after ventilation or after mode change.

Message is the small text message in the minimized alarm pop-up window in the bottom left of the display.

Auto resetting indicates that clearing of the alarm is done automatically, when the criterion is met.

Table 11: Alarms Definition and Troubleshooting Table

Warning **Set Count or Time of Condition**	**Mode of Failure**	**Priority**	**Probable Cause**	**Criterion for Clearing Alarm**	**Corrective Action**
AC Power disconnect immediate	AC power loss Ventilator switches automatically to internal or external battery	Mid	AC power source Electrical cord Internal failure Fuse	AC power restored	Connect ventilator to alternative AC outlet Verify connection or replace electrical cord or fuse Change to DC external power source
Apnea 20 sec delay (user selectable)	No breath detected during apnea period set by operator, ventilator switches to apnea backup mode	High (LT)	Clinical situation Ventilator not detecting patient efforts or mandatory breath rate set too low	One minute of apnea mode activation followed by 3 patient breaths within one minute	Verify patient is adequately ventilated Check changes in patient symptoms and vital signs Correct setting
Battery Empty ~10 min operating time left	Internal battery is nearly depleted; operating time is dependent on ventilation parameters	High	Ventilator operating with internal battery only	Battery/ Charging detected	Connect unit to external power source (AC or DC) Recharge battery
Leak 1 breath delay	Leak exceeds alarm setting	High	Clinical condition Patient circuit and/or endotracheal tube leak Incorrect alarm setting Incorrect Calibration	Leak less than alarm setting for more than 2 breaths	Check patient circuit Readjust alarm leak setting Continue ventilation according to clinical judgment
High Breath Rate *6 breath delay*	Breath rate exceeds high rate alarm setting	Mid	Patient breath rate has increased Ventilator is auto triggered (self cycling)	Rate is lower than alarm set, for more than 2 breaths	Assess patient condition Increase alarm setting if appropriate Decrease trigger sensitivity and/or breath rate setting

Warning Set Count or Time of Condition	Mode of Failure	Priority	Probable Cause	Criterion for Clearing Alarm	Corrective Action
High O_2 20 breath delay	Oxygen concentration exceeds the high alarm setting	High	Improper alarm setting Change in patient breathing pattern with low flow adapter O_2 sensor out of calibration	FiO_2 is lower than alarm setting for 2 breaths	Adjust alarm setting Verify O_2 concentration with external analyzer Refer unit to qualified service technician for calibration of O_2 sensor
High Heart Rate *2 breath delay*	The heart rate exceeds the upper rate limit	Mid	Clinical Condition	Heart rate is lower than the alarm settings for 1 breath	Check the patient's condition.
High Minute Volume 4 breath delay (20 with setting change)	Minute volume exceeds high alarm setting	High	Clinical condition Alarm set too low Breath rate set too high	Volume is lower than alarm setting, for more than 2 breaths	Assess patient Increase alarm setting if appropriate Decrease trigger sensitivity

Warning Set Count or Time of Condition	Mode of Failure	Priority	Probable Cause	Criterion for Clearing Alarm	Corrective Action
High Pressure 2 breath delay	Airway pressure reaches the High Pressure alarm threshold	High	Clinical condition No synchronization between the ventilator operation and patient breaths Incorrect alarm settings Delivery tubes occluded or partially occluded	Pressure is lower than alarm threshold for 3 breaths	Subject to clinical judgment, correct setting as necessary
High SpO2 *2 Breaths delay*	SpO2 level exceeds the upper SpO2 limit	Medium	The patient clinical condition, FiO_2 level set too high, or the SpO2 settings are too low	The SpO2 level is lower than the alarm limit for 1 breath	Assessing the patient clinical condition, decreasing the FiO_2 level, or increasing the SpO2 alarm settings.
Inverse I:E Ratio (for Volume Control modes only) 20 mandatory breaths delay	The I:E ratio has changed to an inverse ratio	Low	Improper setting of Tidal Volume, Breath Rate, P-limit, Peak Flow, Trigger settings and/or Inspiratory Time	Inverse I:E ratio corrected for 5 breaths	Correct setting(s)
Low Battery Approx. 20 min of operating time left	Internal battery is running low	High	Operating without external power supply – time dependent on parameter settings	Charging is detected	Connect unit to external power source (AC or DC) Recharge battery
Low Breath Rate 3 breath delay (5 with settings change)	Breath rate is lower than low alarm setting	High	Clinical condition Trigger sensitivity set too high Alarm set too high	Rate is higher than alarm set for more than 2 breaths	Assess patient Decrease alarm setting if appropriate Increase trigger sensitivity

Warning Set Count or Time of Condition	Mode of Failure	Priority	Probable Cause	Criterion for Clearing Alarm	Corrective Action
Patient Circuit Failed *10 breath delay*	Insufficient resistance from one way valve	High	One way valve has been removed from patient circuit or has deteriorated (ripped or torn or missing membrane)	Substitute one way valve with new one	Replace patient circuit (disposable) or replace and/or service one way valve (re-useable)
Low Heart Rate *2 breaths delay*	The heart rate is below the rate limit	High	Clinical Condition	Heart rate exceeds the lower alarm limit for 1 breath	Check the patient condition.
Low O_2 *15 breath delay*	Oxygen concentration is below alarm setting	High (LT)	Alarm set too high No or low oxygen flow to system Calibration required High variability in patient breathing	F_iO_2 is higher than alarm setting for 2 breaths	Check oxygen supply Verify delivered O_2 concentration with an external analyzer Refer unit to qualified service technician for calibration Decrease alarm settings Change from Adaptive Flow™ to fixed manual flow
Low O_2 Pressure* 10 seconds after the detection of O_2 inlet pressure below 10 PSI	External oxygen supply pressure is low or disconnected	High (LT)	Oxygen supply is disconnected Low oxygen pressure Nebulizer is activated without Oxygen supply.	N/A Adequate O_2 pressure is detected	Reconnect or replace oxygen supply source Ensure proper regulation of external oxygen pressure
* While "Low O2 Pressure" alarm condition is active the FiO2 field on the Main screen flashes red and instead of the set FiO2, the measured FiO2 value is displayed.					

Warning Set Count or Time of Condition	Mode of Failure	Priority	Probable Cause	Criterion for Clearing Alarm	Corrective Action
Low Pressure 3 breath delay (4 with setting change)	Airway pressure during inspiration is lower than the Low Pressure alarm threshold	Mid	Clinical condition Incorrect alarm setting Patient disconnect or high leak	Pressure is higher than alarm threshold for 2 breaths	Subject to clinical judgment, correct setting as necessary Verify patient circuit
Low SpO2 *2 breaths delay*	SpO2 level is below the set lower SpO2 limit	High	The patient clinical condition, FiO_2 level set too low, or SpO2 alarm setting too high	SpO2 level is higher than the alarm limit from 1 breath.	Assessing the patient clinical condition, increasing the FiO_2 concentration, or decreasing the SpO2 alarm setting.
Auto Start	Patient is connected but the unit is in Standby mode	High Mid	User enters Standby mode unintentionally User connects the ventilator to the patient but fails to press Start	N/A	Clear the alarm and set the required ventilation parameters
Service Notice	Technical irregularity (needs Technical Support Services)	High	Power surge Multiple sensor disconnection Calibration required Ventilator Malfunction	N/A	Turn the system OFF and ON again If the alarm is not cleared, remove the unit for inspection and servicing by qualified technical personnel
Warm start-up service notice	Software detected technical irregularity	High	Software exception	N/A	1. Single event – no action required – resumed ventilation with previous settings in up to 30 seconds. 2. Multiple repeated event – remove the unit for inspection and servicing by

Warning Set Count or Time of Condition	Mode of Failure	Priority	Probable Cause	Criterion for Clearing Alarm	Corrective Action
					qualified technical personnel
Needs Cal (Calibration)	System needs calibration	Mid	Calibrated values irregularity	N/A	Perform full calibration by qualified technician
Over Temperature Immediate	Internal temperature of ventilator has exceeded 80°C	High	Cooling vents of the ventilator are blocked High external heat Malfunction of internal cooling fan Temperature sensor failure	N/A	Perform Planned Maintenance procedures Verify cooling vents are clear and clean Remove or protect unit from external heat source Remove unit for inspection and servicing by qualified service personnel
Patient Disconnect 2 breaths delay	Loss of patient resistance detection Loss of exhaled volume	High (LT)	Patient has been disconnected Leak in patient circuit or in endotracheal tube Improper settings	Reconnection of patient detected	Reconnect patient Correct leak Correct setting
Sensor Disconnect 0.5 – 1 second delay	Blockage, disconnection or incorrect connection of the 3 tubes -- ventilator enters Open Loop mode	High	Blockage of tubes Disconnection or incorrect connection of the 3 tubes	Sensor tubes detected (Note: the mode must be manually restored if alarm occurs 3 times in 1 minute)	Reconnect tubing Restore normal ventilation mode Replace patient circuit

Warning Set Count or Time of Condition	Mode of Failure	Priority	Probable Cause	Criterion for Clearing Alarm	Corrective Action
Check Sensor Immediate	Sensor providing unreliable information - ventilator enters Open Loop mode	High	Soiled sensor Excessive water in sensor Sensor tubing disconnected or broken	Normal sensor reading	Replace patient circuit Remove unit for inspection and servicing by qualified service personnel
SpO2 Patient Disconnect	The iVent identifies that the SpO2 sensor is connected but that no signal is received from it	Mid	The patient is disconnected from the oximeter cable	When the patient is reconnected to the SpO2 sensor for 2 breaths	Check the patient condition. Reconnect the patient to the SpO2 sensor.
SpO2 Reading Failed	Low signals from the SpO2 sensor	Mid	A bad connection between the patient and the SpO2 sensor, or SpO2 connectors are not firmly connected.	The signals from the SpO2 sensor return to normal values	Check if the sensor is placed correctly on the patient; try to find a better place for connecting the patient. Reconnect the patient to the SpO2 sensor
SpO2 Sensor disconnect	No signal is received from the SpO2 sensor.	Mid	The SpO2 sensor is not connected to the iVent although the patient might be connected to the sensor, the power to the sensor is disconnected, or if the cable is damaged	When a signal from the SpO2 sensor is received by the iVent.	Connect the SpO2 sensor to the iVent
Tube Disconnect Immediate	Tubing disconnected at ventilator outlet	High-Mid	Disconnection of tubing	Reconnection of tubes detected	Reconnect tubing
V_T not delivered (Low V_T) 4 breaths delay (10 with setting change)	Set tidal volume has not been delivered	Mid	I time set too low Rate set too high Blue tube disconnected Pressure limit set too low Clinical situation	Measured Exhale Volume is higher than set volume minus 15% for more than 2 breaths	Increase pressure limit and/ or inspiratory time if appropriate Reconnect blue tube

Warning Set Count or Time of Condition	Mode of Failure	Priority	Probable Cause	Criterion for Clearing Alarm	Corrective Action
					Assess patient
Volume Limit Reached *4 breaths delay*	Set volume limit has been reached in pressure control modes	Mid	Clinical situation Inspiratory pressure set too high Volume limit is set too low	Limit volume (V_T) is not reached for 2 breaths	Assess patient Reduce Inspiratory pressure Increase volume limit
High PEEP Alarm 2 breath delay	Actual PEEP value more than 10 cmH_2O from set value	High	Exhalation Valve occlusion Improper parameter setting	PEEP pressure decrease to set value + 10 for 1 breath	Check exhalation valve Check parameter setting
Low Minute Volume 2 breath delay (20 with setting change)	Minute volume lower than low alarm setting	High	Clinical Condition Alarm set too High	Volume is higher than the alarm set for more than 1 breath	Assess patient Increase alarm setting if appropriate Decrease trigger sensitivity

ALARMS TEST

Alarms tests check the following alarms:

- Tube Disconnect
- Patient Disconnect
- Sensor Disconnect (Open Loop)
- AC Disconnect
- Low O2 Pressure
- Low Minute Volume
- High Pressure
- High O2
- Low O2
- Apnea
- High PEEP
- Auto Start

WARNING **Do not perform these tests while the patient is connected to the machine.**

To perform an alarm test:

1. Connect the ventilator to AC power and oxygen supply according to the iVent™201 specification (See page 32).
2. Power up the ventilator. It automatically runs a self-test.
3. Select the default set for patient weight 70kg. Set FiO2 to 40% (if default set is configured to a different value).
4. Run O.V.T. (See page 60).
5. Attach a 2L test lung with Rp20 resistance to the patient circuit through an HME filter and start ventilation.
6. **Tube Disconnect alarm test**. Wait for at least 30 seconds after the ventilation starts, and disconnect the patient circuit from the ventilator outlet port. Verify that the **Tube Disconnect** alarm is activated during the first inhale after disconnection. Reconnect the patient circuit to the ventilator and verify that the **Tube Disconnect** alarm disappears automatically.
7. **Patient Disconnect alarm test**. Disconnect the test lung from the patient circuit. Verify that the Patient Disconnect alarm is activated. In case a remote alarm cable is connected, verify that alarm at remote station is also activated.

   Reconnect the test lung to the patient circuit, and verify that the **Patient Disconnect** alarm disappears automatically.

8. **Sensor Disconnect (Open Loop) alarm test**. Disconnect the two sensors lines from the ventilator simultaneously. Verify that the **Sensor Disconnect** alarm is activated, and that the unit switches to **Open Loop** ventilation. Reconnect the sensor lines to the ventilator, and verify that the Sensor Disconnect alarm disappears, and that the ventilator is restored to the previous mode automatically.

9. **AC Disconnect alarm test**. Disconnect the AC cable from the ventilator. Verify that the AC Disconnect alarm is activated. Reconnect the AC cable to the ventilator, and verify that AC Disconnect alarm disappears automatically.

10. **Low O2 Pressure alarm test**. Disconnect the oxygen supply from the ventilator. Verify that the O2 Pressure alarm is activated. Reconnect the O2 supply and verify that the O2 pressure alarm disappears automatically.

11. **Low Minute Volume alarm test**. Press Menu and go to the **Alarm Settings** screen. Set the Low minute volume alarm setting to a value above the measured value for Min. Volume (in blue in the alarm setting bar), and press **Accept**. Verify that Low Minute Volume alarm is activated after consecutive breaths after **Accept** was pressed. Close the alarm pop up window, and restore the alarm setting to its default value.

12. **High Pressure alarm test**. Press Menu and open the **Alarm Settings** screen. Set the High pressure alarm setting to a value below the measured value for PIP (in blue in the alarm setting bar) and press Accept. Verify that the High Pressure alarm is activated on the first breath Accept was pressed. Close the alarm pop up window and restore the alarm setting to its default value.

13. **High O2 alarm test**. Press **Menu** and open the **Alarm Settings** screen. Set the High O2% alarm setting to a value below the measured value for FiO2 (in blue in the alarm setting bar) and press **Accept**. Verify that the High O2 alarm is activated on the twentieth breath after Accept was pressed. Close the **Alarm** pop up window and restore the alarm setting to its default value.

14. **Low O2 alarm test**. Press **Menu** and open the **Alarm Settings** screen. Set the Low O2% alarm setting to a value above the measured value for FiO2 (in blue in the Alarm setting bar) and press **Accept**. Verify that the Low O2% alarm is activated on the tenth breath after **Accept** was pressed. Close the alarm pop up window and restore the alarm setting to its default value.

15. **Apnea alarm test**. Set the **Respiratory Rate** to 2 bpm. Verify that the **Apnea** alarm is activated after 20 seconds and the unit switches to **Apnea Back-up** ventilation. Wait for one minute and then squeeze the test lung twice to simulate two subsequent patient initiated breaths. Verify that the **Apnea** alarm disappears and the unit restores the previous parameters automatically. Restore respiratory rate setting to its default value.

16. **High PEEP alarm test**. Occlude the exhalation valve with a cup. Verify that the **High PEEP** alarm is activated. Remove the cup from the exhalation valve. Verify that the **High PEEP** alarm disappears automatically.

17. **Auto Start alarm test**. Restart the unit with a test lung connected to the patient circuit. Wait for about one minute and verify that the **Auto Start** alarm is activated, and that the unit starts ventilation in **Pressure Control** mode in the preset parameters. Close the alarm pop up window and switch the ventilator to **Standby**.

THE SENSOR FAILURE ALARM

When the iVent™201 detects a **Sensor Disconnect** alarm or **Check Sensor** condition it enters **Open Loop** ventilation backup mode. During **Open Loop**, ventilation is provided based on an average of the previous inhaled tidal volumes (See Appendix E).

If the **Sensor Disconnect** alarm triggers the following message pop-up window (Figure 149):

Figure 149: the Sensor Disconnect Pop-Up Window

- Press the **Clear** button.
- Check the connection of flow transducer tubing to the ventilator.
- Then, check for excessive amounts of water or secretions, which can set off the sensor alarm, in the tubing and flow transducer.
- If no water or secretions are visible, wait approximately 10 breaths – sometimes coughing can cause **Check Sensor** or **Sensor Disconnect** alarms.
- If the ventilator does not automatically return to the previous mode and setup, press the Restore option in the Backup Mode Activated message and check the setting values: PEEP, Rise-Time (auto).

WARNING **If the Check Sensor alarm persists repeatedly, provide an alternative source of ventilation. Then replace the patient circuit and run the O.V.T. test.**

If the "Patient Disconnect" alarm is available and switched off, the Sensor Failure alarm and backup mode is not activated.

NOTE If the **Sensor Disconnect** alarm is detected three (3) times within a minute, the ventilator does not restore the previous mode automatically, but remains in Open Loop instead. Press the **Restore** option in the **Backup Mode Activated** pop-up window to restore the ventilator to the previous mode.

PATIENT DISCONNECT ALARM

The **Patient Disconnect** alarm is activated if low inspiratory pressure or the low exhaled tidal volume is detected during two consecutive breaths. After alarm activation the unit continues ventilation at the previously set parameters with the following settings:

1. The flow trigger sensitivity switches to OFF to eliminate false triggering.
2. The ventilator stops oxygen control and keeps the oxygen blender in the position it was in prior to alarm activation.

The ventilator automatically restores the previous settings when one full breath is detected.

NOTE During ventilation under high leak conditions (e.g., non-inflated cuff of the endotracheal tube), a Patient Disconnect alarm is activated if the exhaled tidal volume criteria is not met. In this case, ventilating the patient in Bi-Level mode (See Appendix D) is recommended. To disable the Patient Disconnect alarm see page 156.

An irregular ventilation condition such as patient coughing can cause short periods of Patient Disconnect alarm.

PATIENT CIRCUIT FAILED ALARM

If the one-way valve at the Wye sensor becomes blocked or is otherwise inoperable, a Patient Circuit Failed pop-up window appears:

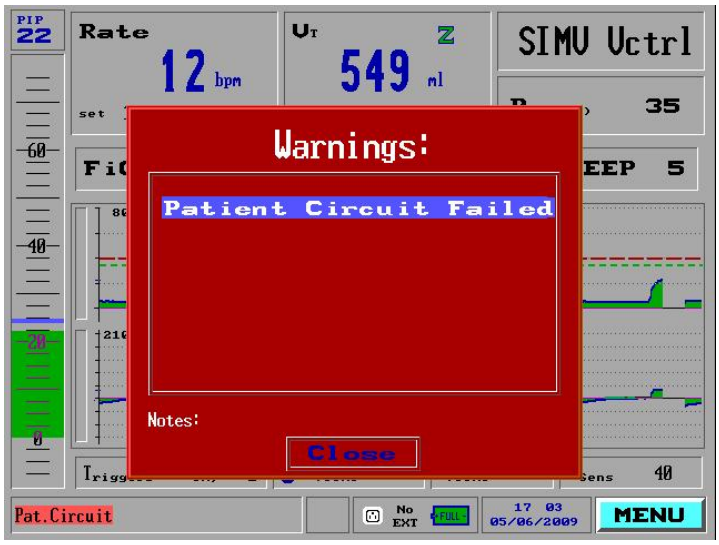


Figure 150: The One-Way Exhalation Valve Pop-up Window

The patient circuit should be replaced at once.

7 CARE, MAINTENANCE AND TESTS

This chapter contains the following sections:

INTRODUCTION

This section shows you how to:

- Clean and maintain the iVent™201
- Keep the iVent™201 operable with the help of planned maintenance
- Calibrate and perform diagnostic tests on the iVent™201

CLEANING AND MAINTENANCE

While the iVent™201 has been designed to resist damage, staining, and wear, it is recommended to perform occasional cleaning and basic maintenance procedures to enhance its lifecycle.

The following chart summarizes cleaning and routine maintenance procedures and, where appropriate, time intervals.

Table 12: Maintenance Procedures and Intervals

Part	Procedure	Comments
Ventilator	Wipe exterior clean with a damp cloth and mild detergent.	
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.
Cooling Vents & Cooling Inlet Filter	Clean every 1500 hours (or 3 months) of use, or as necessary.	Use vacuum device to clean the vents and cooling air inlet filter.
Battery Pack	Recharge after every three months of storage. Replace every year or as necessary.	Actual life depends on history of use and storage.
O_2 sensor	Calibrate every 6 months	It is good practice to calibrate every 3 months
	Replace every 2 years	Perform O2 Calibration and VVT after unit returns from service
Pneumatic unit	Replace every 15,000 hours of operation or every 4 years, whichever comes first.	
Inlet and outlet mufflers	Replace annually or as necessary	Actual life depends on history of use and storage.
Other accessories	Follow manufacturer instructions.	

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.

PLANNED MAINTENANCE

Observing the following maintenance intervals helps keep the iVent™201 operating trouble-free. Follow the iVent™201 Service Manual procedure for instructions.

Table 13: Planned Maintenance Procedures

Frequency	Part	Maintenance
As necessary	Ventilator enclosure	Wipe clean the exterior
	Patient tubing	Replace and perform O.V.T.
	Cooling air filter and vents	Clean and replace air filter as needed
	O2 sensor	Replace the O2 sensor
Every 500 hours or 1 month or whichever comes first	Air Inlet Filter	Remove the used air inlet filter and replace it with a new inlet filter
1500 hours or 3 months of use	O2 System	O_2 Calibration
	Battery	Charge the battery
	Ventilator	Perform VVT
3,000 hours or every 6 months of use (whichever comes first)	O2 System	O2 calibration
	Battery	Deep discharge and recharge
	Ventilator	Perform VVT
Annually	Air Inlet Filter	Replace Air Inlet Filter
	Inlet muffler assembly. Outlet muffler assembly	Replace Inlet muffler assembly and Outlet muffler assembly

	Cooling Air inlet filter	Replace Cooling Air inlet filter
	Battery	Replace Battery
	Ventilator	Perform full calibration It is good practice to perform O2 calibration every 3 months. Perform VVT Perform safety checks Replace listed parts by an authorized VersaMed Service Technician
Every 2 years	O2 sensor	Replace the O2 sensor
Every 15000 hours or every 4 years, whichever is first	Pneumatic Assembly	Replace parts by authorized VersaMed Service Technician

STORAGE PLANNED MAINTENANCE

When Storing ventilators for an extended period of time observe the following recommendations:

Table 14: Storage Planned Maintenance

FREQUENCY	PART	MAINTENANCE PROCEDURE
As Necessary	Ventilator	Wipe clean the exterior of the device.
	O2 Sensor	O2 Sensor Replacement. After replacing the O2 sensors, you MUST perform O2 calibration.
Every 3 months	Battery	Charge the battery
Every 6 Months.	Battery	Deep discharge and recharge. Disconnect the battery from the device
	Ventilator	Perform VVT.
Annually	Battery	Replace the battery
	Ventilator	Full calibration Perform VVT
Every 2 years	O2 sensor	Replace O2 sensor

THE O.V.T

O.V.T. (Operational Verification Test) should be performed each and every time a new patient circuit is used. The O.V.T. procedure is covered in detail on page 60.

THE MAINTENANCE SCREEN

WARNING **Never attempt to access ANY Maintenance Screen functions while the ventilator is connected to a patient.**

Several Maintenance Screen functions involve service functions that are critical to ventilator operation. Do not attempt to change any setting you do not completely understand

CALIBRATION

WARNING **Only trained personnel should perform calibration procedures.**

For a complete description of the Calibration procedure refer to VersaMed Service Manual.

O2 Calibration

It is recommended to perform O2 calibration every 3 months to ensure system integrity. The calibration process comprises two separate calibration procedures, one for 100% oxygen and another for 21% oxygen.

NOTE You are required to perform O2 calibration every 6 months

To calibrate the O2:

1. Turn the control-knob on the **Main** screen to select **Menu – Maintenance**. A caution pop up window appears, which warns that the menu is a restricted maintenance area, and is for service personnel only.
2. Select **Yes**. The **Maintenance** screen is displayed (Figure 151).

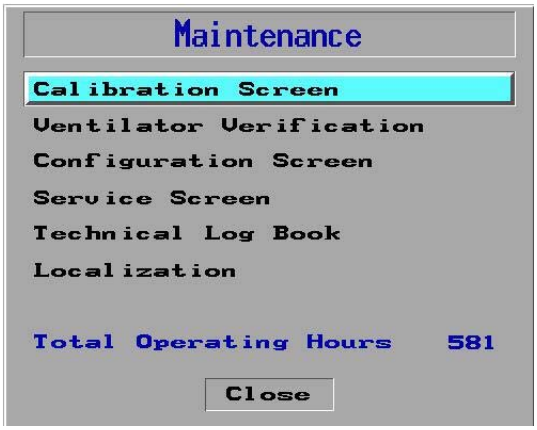


Figure 151: Maintenance Screen

3. Select **Calibration**. The **Calibration** screen is displayed (Figure 152).

Figure 152: Calibration Screen

4. Select **Calibrate O2 System**.

The **O2 System Calibration** screen is displayed (Figure 153).

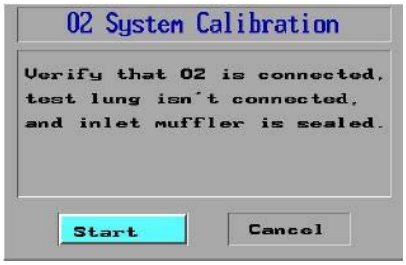


Figure 153: O2 System Calibration for 100% O2

5. Follow the instructions on the screen, and verify the following:
   - A high pressure oxygen source is connected to the device.
   - The patient circuit is open (not sealed by any component).
6. Remove the inlet filter, on the side of the ventilator, and install the O2 calibration cover (Figure 154).

Figure 154: O2 Calibration Filter Cover

7. In the **O2 System Calibration** screen select **Start** to proceed.

This calibration takes approximately 30 seconds during which the message 'working' is displayed on screen.

After the calibration is completed the **O2 System Calibration for 21%** is displayed (Figure 155).

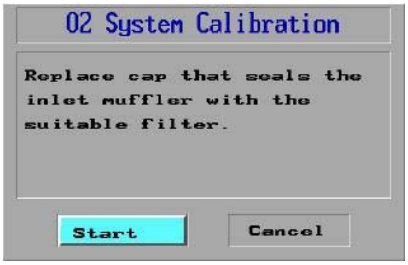


Figure 155: O2 System Calibration for 21%

8. Remove the Calibration Cover, and put the Inlet Filter back in place.
9. Select **Start**.

This calibration takes approximately 90 seconds during which the message **Working** is displayed on screen.

When the calibration is completed the **Calibration** screen is displayed.

10. Select **Close**.

The **Save** pop-up window appears (Figure 156).

Figure 156: Save Calibration pop-Up Window

11. Select **Yes** to save the calibration and to close the **Calibration** screen.

VENTILATOR VERIFICATION TESTS

The Ventilator Verification Test (VVT) is a set of simple self-tests designed to confirm ventilator functionality. It is designed as a troubleshooting procedure to check the operation of a multitude of functions. A series of simple user prompts guides the user through each step.

NOTE The Ventilator Verification Test should be performed quarterly, or whenever a **Call Service** pop-up window appears.

It is necessary to perform a VVT after a software update.

When the iVent™201 detects that a VVT has not been performed, or if for any reason the iVent™201 has failed to pass a VVT previously, a warning pop-up window appears (Figure 157).

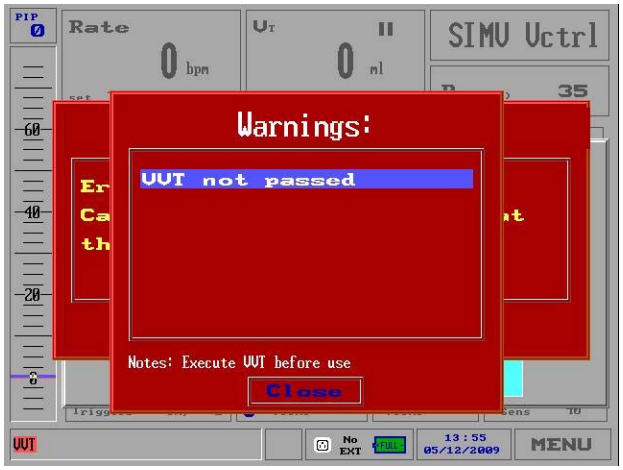


Figure 157: VVT Not Passed Pop-Up Window

Immediately perform the VVT, as described below.

WARNING **Never perform the Ventilator Verification Test while a patient is connected to the ventilator.**

- System buzzers (two)
- Patient pressure measurement and pressure performance
- Blower pressure measurement
- Transducer tubes leak
- Motor speed measurement
- Positive relief valves
- Solenoid valves (two)
- Flow performance
- Flow zeroing accuracy
- 21% FiO2
- Pressure switch status at 21%
- Demand Valve leak
- 100% FiO2
- Pressure Switch status at 100%
- Battery status
- Motor watchdog safety device
- PC watchdog safety device

Required Equipment and Supplies:

- Plug for blocking the breathing circuit

- O2 supply
- O2 hose

Starting the VVT

The following procedures explain how to start the Ventilator Verification Test (VVT).

To start the VVT procedures:

1. Connect a breathing circuit to the iVent™201.
2. Make sure the ventilator is plugged into a working AC supply and switch on the ventilator's power.
3. Select a patient weight to enable the ventilator to enter standby mode.

CAUTION *Prior to performing the VVT, the unit must be in a "warm" condition. Connect the breathing circuit to a test lung and operate the ventilator for at least 15 minutes.*

4. Proceed to the **Main Menu** from the **Main** screen.
5. From the **Main** menu, select **Maintenance**.
6. A caution pop-up window appears. Select **Yes** to proceed.
7. Dial the Control Knob to select **Ventilator Verification Test**, and press.
8. The **Ventilator Verification** pop-up window appears (Figure 158).

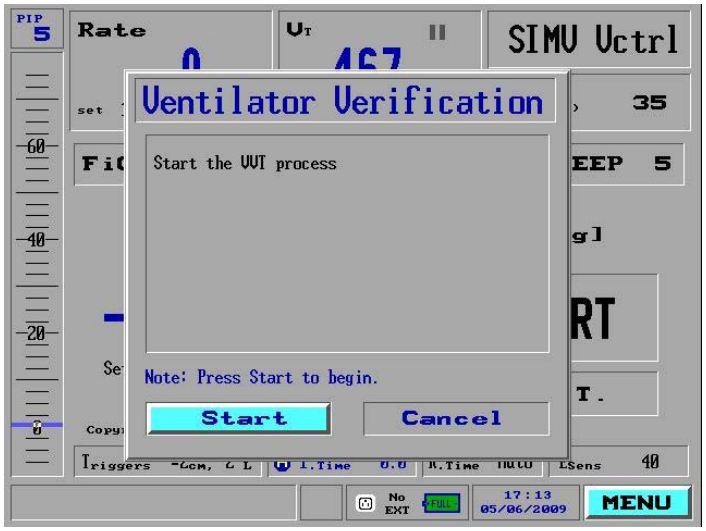


Figure 158: The Ventilator Verification Pop-Up Window

9. Select **Start** and press the Control Knob.

The Alarm Sound Test

The following procedures explain how to perform the Alarm Sound Test.

To perform the alarm sound test:

1. The VVT window asks if the first alarm is audible. If you can hear it, select **Continue** to proceed (Figure 159).

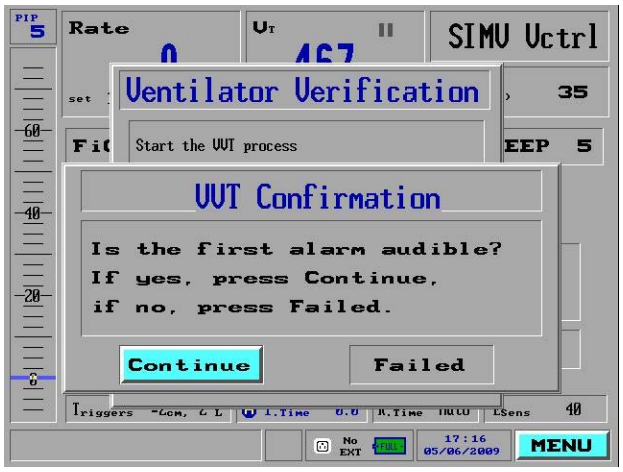


Figure 159: The VVT Alarm Test Pop-Up Window

2. The window asks if the second (louder) alarm is audible. If you can hear it, select **Continue** to proceed.

Pressure Tests

The following procedures explain how to perform an O2 Tests.

To perform O2 tests:

1. Block the patient circuit with a rubber stopper or equivalent.
2. Select and press **OK** to proceed. The unit automatically proceeds through a number of tests for approximately 30 seconds. The **VVT** instruction pop-up window appears.

Flow Tests

The following procedures explain how to perform an O2 Tests.

To perform O2 tests:

1. A pop-up window appears, and instructs you to unblock the patient circuit. Remove the stopper, and then select and press **OK**.
2. The test is completed in approximately six (6) seconds. The **VVT** instruction pop-up window appears.

O2 Tests

The following procedures explain how to perform O2 Tests.

To perform O2 tests:

1. The VVT screen asks you to confirm that there is no O2 supply connected to the ventilator. Make sure no O2 supply is connected. Then select and press **OK**.

2. The test takes about 1 minute. When it is completed, the VVT screen instructs you to connect an O2 supply. This test takes about 2 minutes to complete (Figure 160). The VVT instruction pop-up window appears.

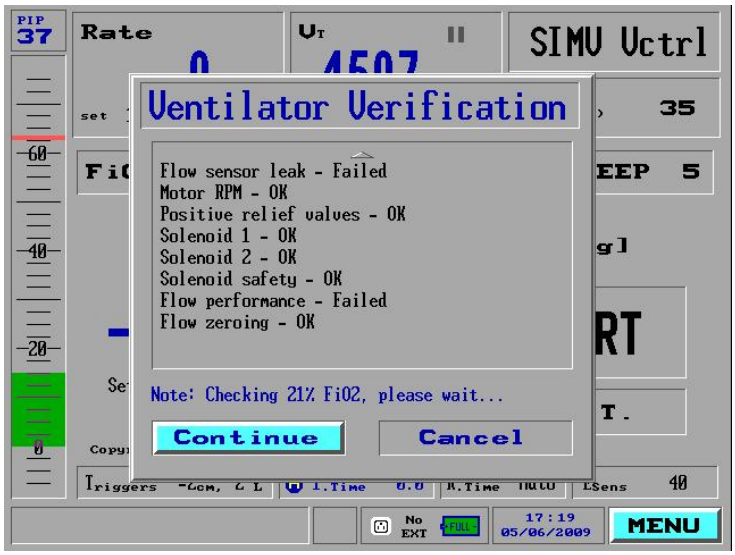


Figure 160: The 21% FiO2 Test

Battery Test

The following procedures explain how to perform a Battery Test.

To perform a battery test:

1. The VVT screen prompts you to disconnect the AC cable. Pull the cable out from the back of the ventilator.
2. Verify that the amber "charge" LED is off and that the AC plug icon at the bottom of the LCD display is crossed out.
3. Press **OK**. Once the test has completed, which takes approximately 20 seconds, the VVT Instruction pop-up window appears.

Watchdog Timer Tests

The following procedures explain how to perform Watchdog Timer Tests.

To perform watchdog timer tests:

1. Reconnect the AC power cable when the VVT screen prompts you to do so.
2. Select **Finish** and press. The screen indicates that the motor watchdog is checked, after which the ventilator restarts.

VVT Completion

The following procedures explain how to perform VVT completion.

To perform VVT completion:

1. When the VVT is completed, a **System Message** pop-up window indicates either success or failure.

2. If the ventilator has failed the VVT, verify that the flow sensor and exhalation valve control tubes are adequately mated to the front panel luer fittings, perform the calibration procedure (See Calibration, page 176) and repeat the test. If VVT failure persists, contact your authorized service facility.

NOTE In the case that VVT fails, on each power up the ventilator posts an alarm pop-up window that indicates a VVT must be done before it is put into use.

CONFIGURATION SCREEN

Use the Configuration Screen to adjust:

- Default startup weight
- Default start screen
- Default FiO2 setting

To access the Configuration screen:

1. From the **Main** screen select **Menu - Maintenance**.
2. A red **Caution** pop-up window appears. Select **Yes**.
3. The **Maintenance** menu appears. Select **Configuration** Screen.

WARNING **Several functions on the Configuration Screen are designed only as service indicators and are not accessible. Do not attempt to change any settings on the iVent™201 unless you are certain of the options you intend to alter. Make sure settings are in accordance with standard protocol within the hospital or patient facility.**

CHOOSING A DIFFERENT STARTUP SCREEN

Use the Default start screen option if you would like the iVent™201 to power up with a different screen.

To set the startup screen:

1. From the **Configuration** screen dial the Control Knob to select **Default Start** screen, then press the knob to confirm.
2. A menu pop-up window appears and shows **Main, Monitoring, and Home Care** screens. Select the required screen, and press the knob to confirm.

NOTE Not all screens are operational in all iVent™201 models.

The **Configuration** screen reappears with the newly-selected startup screen selected. When the iVent™201 is restarted, the screen you have chosen appears.

SETTING THE STARTUP WEIGHT

The iVent™201 default patient weight is set to >70kg. You can change the default weight.

To change the startup default:

1. From the **Configuration** screen dial the Control Knob to select Default Start weight, then press the knob.
2. A pop-up window appears and shows a range of choices from 10 to >70, as well as Last. Select the required weight, and press the knob to confirm.

The **Configuration** screen reappears, with the newly-selected weight selected. When the iVent™201 is restarted, the first screen appears with the weight you have selected, now selected.

NOTE Note that the weight selection does not take effect until the ventilator is restarted. If you need to change or restore the currently select weight, use **Restore Defaults** un the **Main Menu** (See page 105).

DEFAULT FIO2 SETTING

Use the Default FiO2 setting option if you need to change the default iVent™201 FiO2setting.

To set the default FiO2:

1. From the Configuration screen dial the Control Knob to select **Default FiO2 Setting**, then press.
2. A pop-up window appears which offers a range of choices: 21%, 40%, 60%, and 100%. Make the required selection and press the knob to confirm.
3. The **Configuration** screen reappears with the newly-selected startup screen selected. When the iVent™201 is restarted, the default O2 setting is displayed.

VERSAMED SERVICE FUNCTIONS

WARNING **The service screen is meant for use by VersaMed qualified and trained personnel only. The technical log book is also meant only for VersaMed authorized personnel. Do not make changes to the service screen menus unless you are told to do this by trained VersaMed service technicians.**

COMMUNICATION PORT

The iVent™201 has two communication ports, located on the right side of the rear panel. If you connect a device to the iVent™201, then you need to configure the communication port.

To configure the communication port:

1. From the **Service** screen dial the Control Knob to select the Communication Port option, then press.
2. A menu pop-up window appears offering two communication ports; Com 1, or Com 2. Select the com you need and press the knob to confirm.

COMMUNICATION RATE

The iVent™201 has a serial port installed for remote communication with other devices. The default data transfer rate is 115,200 bps. Ordinarily there should be no reason to change this setting.

To change the communication rate:

1. From the **Service** screen dial the Control Knob to select Communication Rate, then press.
2. A pop-up window appears offering a range of choices: 1200, 2400, 4800, 9600, 19200, 38400, 57600, and 115200. Make the required selection and press the knob to confirm.

The **Maintenance** screen returns with the selected communication rate selected. The ventilator restarts with the new communication rate.

LOCALIZATION

Localization is used to change the language set for the iVent™201.

WARNING **Do not access the Localization menu unless you are sure you intend to change the language the iVent™201 uses. Remember, if you change the selected language, you change all the screens, menus, and messages.**

To change the selected language:

1. From the Maintenance screen select **Localization**. A red warning pop-up window appears (Figure 161).

Figure 161: The Localization Warning Pop-Up Window

2. Select **Yes** and press the Control Knob. The **Localization** screen appears.
3. Make sure **Language** is selected, and press the Control Knob. A pop up window appears with a choice of several languages (Figure 162)

Figure 162: Language Choices

4. Dial the Control Knob to select the language you require. When you press to confirm your selection, the machine restarts in the language you selected.

On this screen it is also possible to select the date format for the display as Month Day Year (MDY), Day Month Year (DMY) or Year Month Day (YMD). The character that separates the day month and year can also be selected by choosing the Date Interfield Character menu. This character can be either a forward slash '/', a colon ':' or a period '.'.

TOTAL OPERATING HOURS

The **Maintenance** screen also shows the total number of hours the ventilator has been turn on (Figure 163):

Figure 163: Total Operating Hours Screen

Notes

APPENDIX A: GLOSSARY

Term	Definition
Adaptive Bi-Level	A combination of face mask and invasive modes of ventilation utilizing two levels of pressure for each breath, P_{High} for Inspiration and P_{Low} for Expiration and Pause.
Adaptive Peak Flow™	An Inspiratory Peak Flow Rate determined and delivered to meet the target mandatory tidal volume, while maintaining a 1:2 I:E ratio.
Adaptive I. Time™	A ventilator determined inspiratory time to maintain a 1:2 I:E ratio.
Airway Pressure	Pressure measured at the proximal airway of the breathing circuit by the flow sensor. (Unit of measure cmH_2O).
Alarm	A combined audible and visual notification generated when the ventilator detects an operating condition requiring immediate operator intervention.
Alarm Pressure	Adjustable pressure level at which a high-pressure alarm occurs.
Apnea	Apnea occurs when the patient fails to receive or perform a breath during a period of 20 seconds or as set.
Apnea Mode	A ventilation mode that automatically starts when a patient apnea is detected.
Assist Breath (patient initiated mandatory breath)	Any positive pressure breath that is initiated by the patient, and controlled and terminated by the ventilator. (Available in Assist / Control and SIMV modes).
Assist / Control Mode	A mode of ventilation in which the patient receives a set rate of mandatory breaths. The patient may trigger some or all of the breaths. The total measured respiratory rate may be greater than the set rate.
Auto Start	A safety mode of ventilation that ventilates in a Pressure mode and begins when resistance is detected at the end of startup phase or when -2 cmH_2O pressure is detected in the Standby mode.
Baseline	The pressure at which the patient is maintained by the ventilator between breaths. PEEP or CPAP.

Term	Definition
bpm	Breaths Per Minute. Breathing cycles per minute. The respiratory rate.
Breath Period	The length of time between ventilator initiated breaths (60 sec/ bpm).
CMV Mode	Controlled Mechanical Ventilation. A mode of ventilation in which the patient receives only a fixed number of ventilator breaths per minute. (May occur in Assist/Control or SIMV modes when the patient fails to trigger breaths).
Compliance (Dynamic)	A measure of the stiffness of the lung and chest wall at peak inspiratory pressure.
Compliance (Static)	A measure of the stiffness of the lung and chest wall during a static pause after peak inspiration.
CPAP	Continuous Positive Airway Pressure. A mode of ventilation in which the patient breaths spontaneously from a positive pressure baseline as continuous positive pressure is applied throughout the breath cycle.
Easy Exhale™	When active this feature relieves the exhalation valve diaphragm of pressure immediately at the end of inspiration.
Exhalation Phase	The part of the breath cycle in which the ventilator does not perform mandatory inspiration.
Exhalation Time	The time required for the patient to exhale.
Exhaled Tidal Volume	The exhaled volume measured by the flow sensor for all breath types.
Flow	Inspired gas flow to the patient in liters per minute.
Flow Trigger	A method of initiating breath in response to patient effort, by measuring an increase in inspiratory flow.
I:E Ratio	Inspiration time to Expiration time ratio.
Initiate	The process of starting an inspiration.
Inspiratory Phase	The phase of the breath in which the patient inhales or inspiratory flow is delivered into the lungs under positive pressure.
Inspiratory Time	The length of the inspiratory period measured from the start of inspiration to the start of exhalation (all breath types).

Term	Definition
Limit Pressure	Adjustable pressure level at which patient pressure is limited. No alarm occurs. Tidal volume delivery may decrease when Limit Pressure is reached.
Mandatory Breath	Any breath that is controlled and terminated by the ventilator in order to achieve a preset tidal volume (volume controlled breath) or a target pressure for a preset time (pressure control breath).
Manual Breath	An operator-initiated ventilator breath that is delivered when the Manual Breath button on the keypad is pressed. The ventilator delivers the type of mandatory breath currently set. If a mandatory breath is not set, the ventilator uses the patient weight and the volume control setting to deliver a manual breath.
Maximum Inspiratory Time	A predetermined time limit for inspiratory time for all breath types (normally 3 seconds).
Mean Airway Pressure	The average airway pressure throughout the breath cycle.
Minimum Exhalation Time	A period of time starting at the beginning of the exhalation phase, during which any type of breath cannot be initiated.
Nebulizer	Nebulizer is a pneumatic device that uses compressed gas to deliver aerosolized medication that can be inhaled by patients. During nebulization, the flow is synchronized with the inspiratory phase of each breath.
Patient Breathing Circuit	The tubing, valve and flow sensor that provides the ventilatory interface between patient and ventilator.
Patient Breath (spontaneous or pressure support breath)	Any ventilator-delivered breath that is initiated and terminated by the patient. Initiation is by flow or pressure trigger and termination is by decrease in flow or increase in pressure. Available in SIMV, PCV, Adaptive Bi-Level and CPAP modes.
Patient Effort	Any inspiratory effort initiated by the patient.
Paw	Airway pressure (cmH_2O).
Pressure Controlled Ventilation (PCV)	A type of ventilation in which the ventilator breaths are controlled by pressure, terminated by time, and limited by volume.

Term	Definition
PEEP	Positive End Expiratory Pressure. Positive pressure in the lung during expiration.
PIP	Peak Inspiratory Pressure. The maximum airway pressure to occur during inspiration.
pulse oximetry	Pulse oximetry is a simple non-invasive method of monitoring the percentage of hemoglobin (Hb) that is saturated with oxygen, meaning the amount of oxygen in the blood. The pulse oximeter is a sensor, which is placed on the patient and connected to a unit. The unit displays the oxygen saturation percent, a calculated heart rate, and a graphical display of the blood flow past the probe.
Purge System	Two high-pressure pumps (up to 700 cmH2O) intended to periodically clean up the sensor lines. Purging cycle may be chosen through the Advanced Menu.
Pressure Support Breath	A patient breath in which the ventilator elevates the inspiratory pressure above the baseline (i.e. PEEP). Available in SIMV and CPAP/PSV modes.
Pressure Trigger	A method of initiating a breath in response to patient effort by measuring a decrease in airway pressure below the baseline.
O_2	Oxygen.
Rise Time	The acceleration of pressure to reach the set target pressure level.
RPM	Revolutions Per Minute.
SIMV	Synchronized Intermittent Mandatory Ventilation. A mode of ventilation in which all breath types (ventilator, assist, and patient) is allowed. Mandatory breaths are synchronized with patient efforts.
Spontaneous Breath	A patient initiated breath.
Termination	The transition from the inspiratory phase to the exhalation phase of a breath.
Tidal Volume (V_T)	The amount of volume inhaled and exhaled in a breath (measured in milliliters).

Term	Definition
Total Breath Rate	Total number of breaths per minute, including both patient and mandatory breaths.
Total Minute Volume	The volume delivered for all breath types to the patient during a one-minute period (measured in liters).
Transducer / Sensor	A device used to measure pressure and flow.
Ventilator Breath	A ventilator delivered breath that is initiated, controlled, and terminated by the ventilator. Available in Assist / Control and SIMV modes.
Volume Controlled Ventilation	A type of ventilation in which the ventilator breath is controlled by flow and terminated by volume, as long as airway pressure is lower than the Limit Pressure.

Notes:

APPENDIX B: WARRANTY

WARRANTY

VersaMed (the Supplier) guarantees the Purchaser the materials and workmanship used in the manufacture of the iVent™201 ventilator (the Product) sold to the Purchaser, and will repair any defects which may develop within 12 months from the delivery date to the Purchaser, which are not due to fire, dampness, willful or accidental damage, or improper use or care, or for reasons beyond the control of the Supplier. This 12 month warranty does not extend to expendable items such as membranes, hoses, and filters which are warranted to be free from defects only at the time of the original delivery.

The express warranties set forth above, specifically exclude defects in the Products that are (1) caused through no fault of Supplier during shipment to or from the Purchaser, (2) caused by the use or operation of the Products in any application or environment other than that instructed, intended or recommended by the Supplier, (3) caused by modifications or alterations made to the Products by the Purchaser or any third party, (4) caused by unauthorized maintenance performed on the Products by the Purchaser or any third party, (5) caused by failure of the Purchaser to comply with any of the return procedures (6) are the result of the Products being subjected to unusual physical and / or electrical stress.

Except for the above express limited warranties or conditions, Supplier makes and Purchaser receives no warranties in connection with the Products, express and/or implied and/or statutory, and the Purchaser specifically disclaims any implied warranty or condition or merchantability or fitness for a particular purpose. In no event shall the Supplier be liable for any damages, including loss of profits, incidental or consequential damages, arising out of or in connection with the use, or inability to use the Products.

Subject to the following, the Purchaser shall send Products with defects that are covered by this warranty to the Supplier repair center.

The Purchaser shall request a written return authorization from the Supplier prior to the return of each defective Product for repair or replacement by the Supplier. Upon request, the Supplier will provide the Purchaser with a Return Goods Authorization (RGA) number to be prominently displayed on the shipping container for the defective Products.

Once the Supplier authorizes the return of defective Products, the Purchaser shall ship such Products to the repair facility, freight and insurance expenses prepaid in its original container and without relieving the Purchaser from its responsibility for the shipment. If such defective Products are received by the Supplier during the applicable warranty period, the Supplier shall, at its sole discretion and expense, repair or replace such Products, employing at its discretion, new or used parts or Products to make such repair or replacement, and shall ship the repaired or replaced Products to the Purchaser.

In any case, and subject to the terms hereof the Supplier be responsible for the repair of or the replacement of such defective Products only.

Items returned without such approval shall be returned to the Purchaser at its expense. The Purchaser undertakes that the Products be shipped by a certified carrier experienced in handling sensitive freight. The Products returned by the Purchaser for repair or replacement must include a report indicating the type of failure.

Supplier reserves the right at any time to change the specifications or design of the Products. In the event of any such change in specifications or design, Supplier shall be under no obligation to make the same or similar change in the Products previously produced or sold by the Supplier, unless the change is made to correct a safety or operational deficiency, or is required by the US Food and Drug Administration.

Neither this Warranty nor any of the rights of the Purchaser under this Warranty may be assigned, transferred, or conveyed by operation of law or otherwise, without the prior written consent of the Supplier nor shall this Warranty or any rights of the Purchaser inure to the benefit of any trustee in bankruptcy, receiver, creditor, trustee or successor of the Purchaser's business or its property, whether by operation of law or otherwise, or to a purchaser or successor of the business or of any of the assets of the Purchaser, without the written consent of the Supplier.

This Warranty applies only to Products purchased by end users directly from VersaMed and provided they are paid for in full. This warranty shall not apply to distributors or resellers ("Distributor"). VersaMed may provide individual warranty protection to its authorized Distributors, according to the terms and conditions agreed upon between VersaMed and each Distributor.

APPENDIX C: OPERATING THEORY

OPERATING THEORY

THEORY

The iVent™201 is a positive pressure mechanical ventilator. This appendix describes the ventilator's components and depicts a schematic flow of the electro-pneumatic system. The function of each component is described below.

AMBIENT AIR FILTER

Air is drawn from the external environment through this filter. The filter captures particles greater than 5 microns with an efficiency of 99.0%.

CBRN FILTER (OPTIONAL)

An optional configuration enables air to be drawn in through a Chemical, Biological, Radiological, and Nuclear (CBRN) filter.

LOW PRESSURE O2 ADAPTER AND FILTER (OPTIONAL)

An optional configuration that enables the usage of low pressure O2 sources, such as concentrators, to provide O2 enrichment.

AIR/OXYGEN BLENDING SYSTEM

The blending system consists of an air entrainment port and a PSV (Proportional Solenoid Valve) High Pressure O2 Enrichment Valve. The ventilator software controls both the port and PSV account for variations in the inspired flow to achieve the required oxygen concentration.

NOTE Units with serial numbers below 14999 have a different type of Oxygen blender based on a demand valve and slider, drive by a stepper motor.

INLET MANIFOLD

The inlet manifold houses the air entrainment port, PSV or demand valve, and fail-safe bypass port.

TURBINE UNIT

The turbine unit consists of a variable speed DC motor and a rotary compressor. The turbine unit generates flow and pressure by changing motor speeds.

TURBINE PRESSURE SENSOR

This sensor measures the pressure at the ventilator outlet. The ventilator software uses this value and the RPM of the turbine's motor to control PEEP. The sensor also performs as a backup device to the airway pressure sensor.

TURBINE VALVES

The two turbine valves of different sizes are electromechanical solenoid valves normally closed during the inspiratory phase allowing the gas mixture to flow from the turbine unit to the patient breathing circuit. During the expiratory phase, the valves are open to release pressure in the patient circuit. An air path from the patient breathing circuit to the manifold and air inlet filter is present.

OVER PRESSURE RELIEF VALVE

If the control system fails to limit the turbine pressure to a maximum level of 80 cmH2O, this valve relieves at 80 cmH2O.

AIRWAY FLOW AND PRESSURE SENSORS

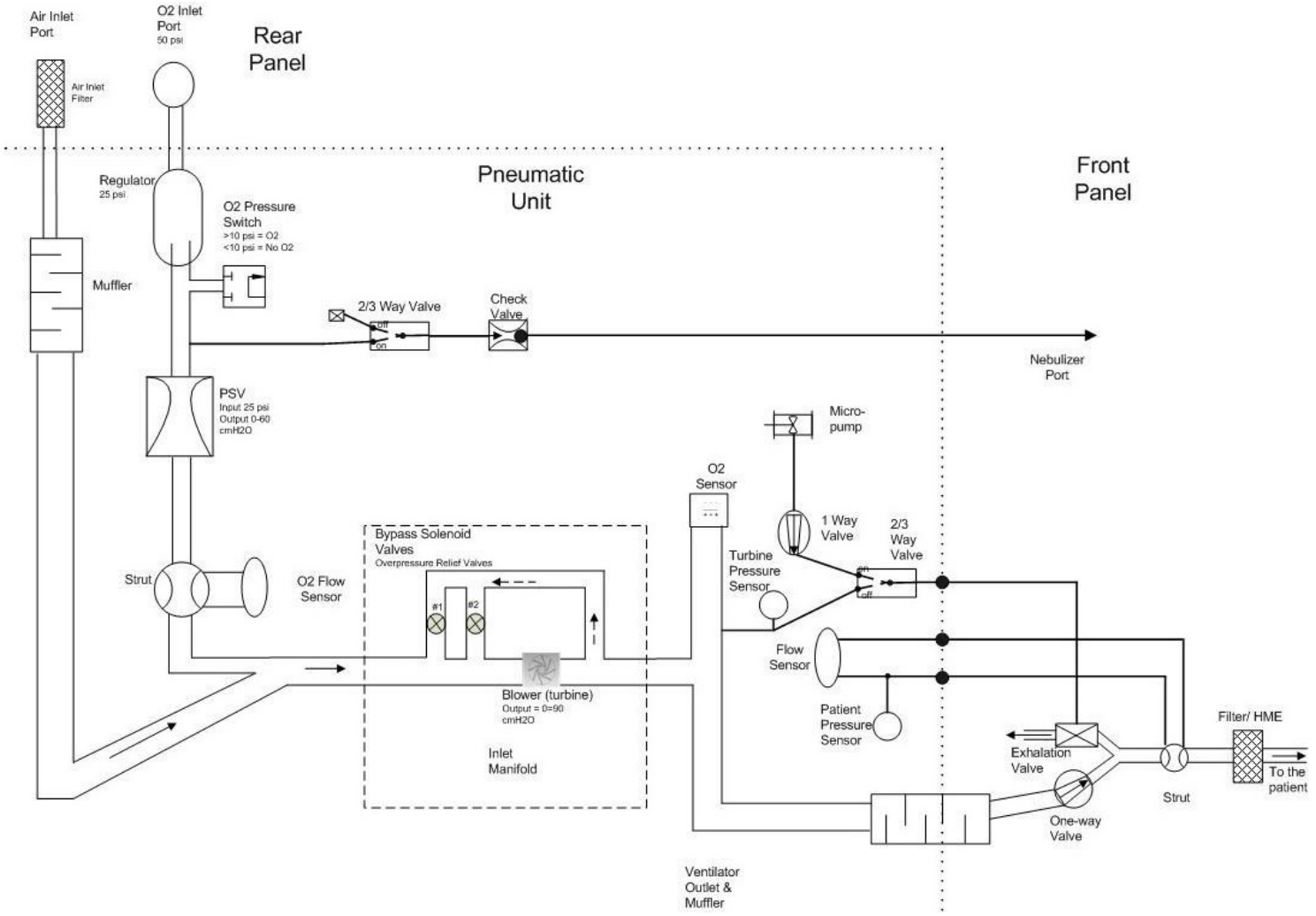
A differential pressure transducer is attached to the patient breathing circuit at the proximal airway. This device measures both inspired and expired values.

PRESSURE SWITCH

A pressure switch in the iVent™201 monitors whether sufficient Oxygen pressure is connected to the unit (approximately 0.7 bar). If insufficient oxygen pressure is available, a low O2 pressure alarm occurs.

INLET AND OUTLET MUFFLERS

An inlet muffler that sits just behind the air inlet filter and an outlet muffler just after the turbine unit reduce the level of noise generated by the air flow in the system.


Air Inlet Port
O2 Inlet Port
50 psi
Rear Panel
Air Inlet Filter
Pneumatic Unit
Front Panel
Regulator
25 psi
O2 Pressure Switch
>10 psi = O2
<10 psi = No O2
Muffler
2/3 Way Valve
off
on
Check Valve
Nebulizer Port
PSV
Input 25 psi
Output 0-60 cmH2O
Micro-pump
O2 Sensor
1 Way Valve
2/3 Way Valve
Bypass Solenoid Valves
Overpressure Relief Valves
Turbine Pressure Sensor
Strut
O2 Flow Sensor
#1
#2
Flow Sensor
Blower (turbine)
Output = 0=90 cmH2O
Patient Pressure Sensor
Filter/ HME
Exhalation Valve
To the patient
Strut
Inlet Manifold
One-way Valve
Ventilator Outlet & Muffler

Notes:

APPENDIX D: THEORY OF BREATH DELIVERY

BREATH DELIVERY

The iVent™201 is a positive pressure mechanical ventilator that delivers air or air/oxygen mixture to the patient's lungs under positive pressure. Each breathing cycle consists of two phases as described below (Figure 164).

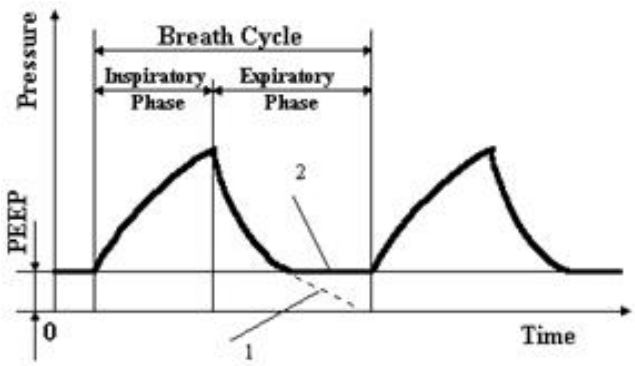


Figure 164: Pressure Breath Cycle

1. An inspiratory phase, in which gas is delivered to the patient's lungs and airway pressure increases. At the end of the inspiratory phase, the ventilator stops delivering flow and allows the patient to exhale.
2. An exhalation phase, in which air flows out from the patient's lungs and pressure returns to the baseline pressure. The baseline pressure may be either the ambient pressure - curve 1, or a higher positive end-expiratory pressure (PEEP) - curve 2.

The ventilator's control system accomplishes the ventilation cycle by a mechanism which:

- Initiates inspiration
- Controls the flow or pressure during the inspiration phase
- Ends inspiration or begins exhalation (termination)

PATIENT TRIGGERING

A patient may trigger a breath by creating an inspiratory effort detected by the ventilator. The iVent™201 has three operator selectable methods for triggering breaths as illustrated below:

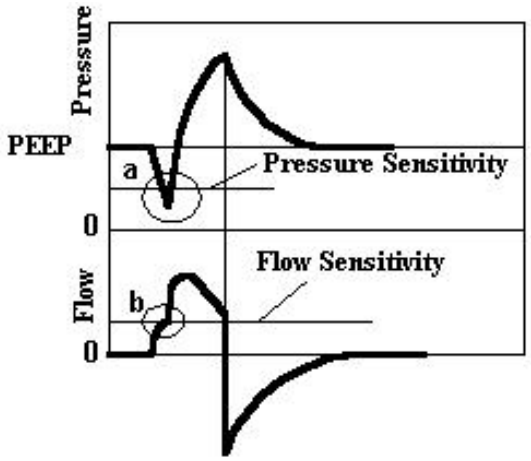


Figure 165: Pressure and Flow Triggering by Patient

1. **Pressure trigger**. The breath is initiated when airway pressure drops below the baseline in an amount greater than the set sensitivity value. (a in the figure above).
2. **Flow trigger**. The breath is initiated when initial inspiratory flow generated by patient's effort is greater than the set sensitivity value. (b in the figure above).
3. **Dual trigger**. The breath is initiated when either flow or pressure exceeds the set sensitivity values.

The triggering type and level of effort required to initiate a breath are set using the Sensitivity Control. When the dual pressure/flow trigger is selected, the patient breath can be initiated by flow or pressure sensitivity levels which ever is exceeded first.

For patient safety it is not possible to disable flow or pressure triggering when using the Adaptive Bi-level Mode.

BREATH TYPES

The ventilator delivers two primary breath types:

1. Mandatory Breath. A breath in which the ventilator controls and terminates phase. This breath type is divided into three secondary types according to the method by which the inspiratory phase is initiated:

- **Ventilator breath** - initiated by the ventilator (time triggered). A blue fan icon appears in the VT display.
- **Assist breath** - initiated by the patient (pressure or flow triggered). A pink fan icon appears in the VT display.
- **Manual breath** - initiated by the operator by pressing the manual breath button. A blue fan icon appears in the VT display.

Each of the above breaths may be delivered in one of two inspiratory methods:

- **Volume control breath** - mandatory breath in which the ventilator delivers the tidal volume set during a certain time interval at a set or Adaptive inspiratory flow.

- **Pressure control breath** - mandatory breath in which the ventilator provides constant pressure at a preset level during inspiration.
- **Patient Breath**. Any breath in which the patient initiates and terminates the inspiration phase. This breath type is divided into two secondary types according to the method by which the inspiratory phase is controlled:
    - **Spontaneous breath** - the ventilator helps the patient to breathe by maintaining the inspiratory pressure at the baseline level (PEEP).
    - **Pressure Support breath** - the ventilator elevates the inspiratory pressure to the preset support pressure level above the baseline and maintains this pressure during the inspiration phase.

ADAPTIVE FLOW AND ADAPTIVE I-TIME

Unique to the iVent™201, Adaptive Flow™ and Adaptive I-Time™ are patient responsive controls to establish appropriate peak flow and inspiratory time during volume control breath delivery. The main goal of the algorithm is to match the patient demand for flow during inhalation while reducing airflow hunger and increasing patient comfort.

Should the Adaptive Flow algorithm determine that the peak flows achieved by the patient's spontaneous breathing exceed the peak flows that are determined necessary to achieve the set tidal volume, then the algorithm matches the patient's peak flow so as to avoid the feeling of "air hunger" in the patient. In this situation, the ventilator does not realize an I:E ratio of 1:2.

In the absence of sufficient spontaneous patient efforts, Adaptive Flow and Adaptive I-Time work together in volume control modes (SIMV and A/C). When used together (The default state for SIMV Volume Control mode) these two features seek to achieve an I:E ratio of 1:2 (As close as possible within clinical limitations, such as Pressure Limit and Alarm Pressure Cutoff settings as well as minimum and maximum Inspiratory Time allowed).

Changes in the overall breath rate are tracked and the Adaptive I-Time algorithm adjusts the inspiratory time over approximately 10 breaths in order to maintain the I:E ratio at 1:2. The Adaptive Flow algorithm accommodates changes in the i-time and automatically adjusts the peak flow so that the delivery of the set tidal volume for the i-time determined by the Adaptive I-Time algorithm is assured.

- The Adaptive I-time changes inspiratory time as required to achieve a 1:2 I:E ratio.
- If respiratory rate increases, the inspiratory time decreases and the mandatory peak inspiratory flow increases to deliver the set tidal volume.
- If respiratory rate decreases, the inspiratory time increases and the mandatory peak inspiratory flow decreases to deliver the set tidal volume.

If flow is insufficient to deliver the tidal volume, inspiratory time gradually increases in an attempt to deliver the set tidal volume. In this situation the ventilator does also not achieve I:E ratios of 1:2. For this reason, the user is advised to leave the inverse I:E ratio alarm "ON" when using Adaptive Flow and adaptive I-Time. If inverse I:E ratios are achieved, it is recommended that the ventilator controls are set manually.

The speed of change for peak flows and inspiratory times is based upon the difference between the current flow/ time and the required flow/ time. The greater the difference, the greater the step changes in peak flow or inspiratory time during the next breath. Most changes are gradual and may take 8 to 10 breaths to make a full change to the new patient condition. The iVent™201 turbine delivers peak inspiratory flow rates to a maximum of 120 liters per minute. Factors limiting the delivery of gas flow are patient lung compliance, airway resistance and ventilator circuit compliance and resistance. Inspiratory time is limited to 3 seconds or a 1.2 :1 I:E ratio based upon the set rate.

Another feature of Adaptive Flow is its ability to track and match the mandatory breath inspiratory flow rate to the patient's spontaneous inspiratory flow demand during SIMV. The ventilator constantly monitors the patient's spontaneous breath flow rate. If the mandatory breath inspiratory flow is less than the patient's average spontaneous inspiratory flow demand, the mandatory inspiratory flow is increased to the same value to minimize the feeling of "air hunger" experienced by some patients during mandatory breath delivery.

The Adaptive Flow value is shown on the display at all times and is depicted by a circled A symbol next to the peak inspiratory flow value.

Adaptive Flow can be disabled at any time by manually changing the peak inspiratory flow control setting. The flow value for the manually set flow rate that the ventilator uses, is depicted by a circled M symbol next to the peak inspiratory flow value.

NOTE:

- When setting a manual inspiratory flow during low flow conditions, this flow target may briefly over shoot as the ventilator controls the flow to the patient. However, the average flow is maintained at the set value.
- If the target flow is set higher than the ventilator is able to provide, due to high resistance and/or low compliance of the patient/ventilator circuit, then the ventilator attempts to deliver as high a flow as possible during the inspiratory phase. Under these conditions, inspiratory time increases in order to deliver the set tidal volume and the set peak flow reading flashes.
- During SIMV, Adaptive FlowTM is always operational, even if a manual peak flow is set. If the patient's average spontaneous flow exceeds the set manual peak flow, the Adaptive Flow drives the delivered mandatory breath flow to approximately 80% of the spontaneous inspiratory flow.

MANDATORY VOLUME CONTROL BREATH

Mandatory volume control breath is pressure limited mandatory breath in which the ventilator delivers a set tidal volume at an Adaptive FlowTM or manually set value. The flow is controlled by the ventilator in a way that the flow at the end of the inspiratory phase is half of the peak inspiratory flow. This breath type can be initiated by the ventilator (time-triggering – a in the figure below), or by the patient (pressure or flow triggering – b in the figure below). Once initiated, it is always controlled and terminated by the ventilator. The tidal volume, breath rate, inspiratory time (adaptive or manual) and pressure limit are set by the operator using the front panel controls and display.

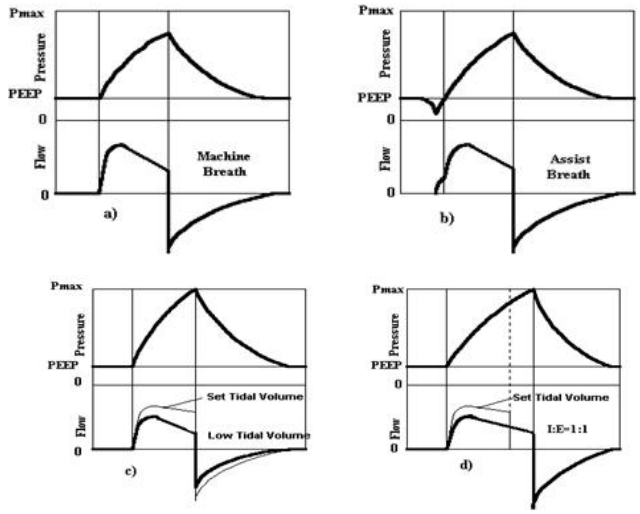


Figure 166: Volume Control Breath Waveform

Inspiratory phase is terminated when set tidal volume (VT) is delivered. If Limit Pressure is set lower than Alarm Pressure, tidal volume may be decreased, when Limit Pressure is reached (c in the figure above). If the Adaptive Flow is selected, the inspiratory time is increased to reach the set tidal volume (d in the figure above).

PRESSURE CONTROL BREATH

A pressure control breath is a mandatory breath in which the ventilator provides a constant pressure set during the inspiratory phase. The inspiratory pressure, inspiratory time, rate and maximum delivered tidal volume values are set by the operator. This breath type can be initiated both by the ventilator (ventilator pressure control breath) and by the patient (assist pressure control breath). The inspiratory phase is terminated by the ventilator when inspiration time is elapsed or set limit for tidal volume is delivered prior to the end of the inspiratory phase.

The figure below demonstrates how pressure and flow behave when the ventilator delivers a pressure control breath. When a pressure control breath is initiated, the ventilator delivers the maximum possible flow until the patient airway pressure exceeds the set level. Once this pressure level is exceeded, the ventilator adjusts the flow to whatever rate is required to maintain the airway pressure between the target pressure and a value, which is about 2 cmH2O lower. At the end of the inspiratory phase, the ventilator allows the patient to exhale.

Pressure control breaths terminate when set inspiratory time elapses.

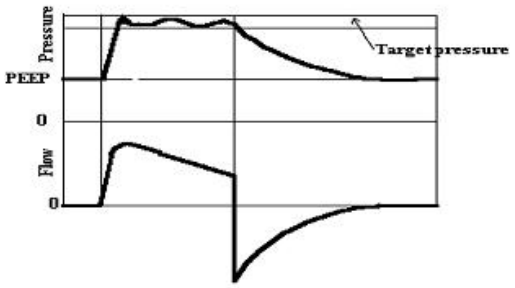


Figure 167: Pressure Control Breath Waveform

MANUAL MANDATORY BREATH

A manual mandatory breath at the currently set parameters may be delivered at any time by pressing the Manual Breath button on the keypad. If this function is pressed during inspiration or during the minimum exhalation time, the ventilator waits and delivers the manual breath at the end of the minimum exhalation time.

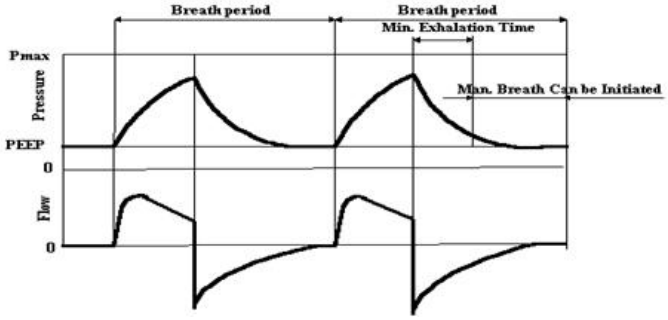


Figure 168: Delivery of Manual Breath

This breath type may be delivered in all ventilation modes.

In the CPAP/PSV ventilation mode, where there is no definition for machine breath, the Manual breath is set according to the default volume control for the specified patient weight.

PATIENT PRESSURE SUPPORT BREATH

A patient pressure support breath is a positive pressure patient breath in which the ventilator maintains an elevated target pressure during inspiration. The Pressure Support setting is a pressure above PEEP when PEEP is in use. Pressure Support breaths are always initiated and terminated by the patient and controlled by the ventilator. When the patient initiates a pressure support breath, the ventilator raises the inspiratory flow to meet the patient's demand at the airway pressure set level.

The termination of a pressure support breath occurs when:

- The flow decreases to a set value of the peak flow (esens); or
- The airway pressure exceeds a value 5 cmH2O above target pressure; or
- After three seconds.

At that point, the ventilator terminates flow, allowing the patient to exhale.

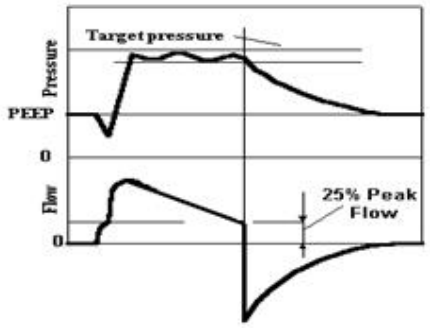


Figure 169: Pressure Support Breath Waveform

PATIENT SPONTANEOUS BREATH

A spontaneous breath is a patient breath which is initiated and terminated by the patient like a patient support breath. The only difference between these two subtypes of breaths is that the spontaneous breath pressure is maintained at the PEEP level (PSV=0) during the inspiratory phase. Flow is regulated by the ventilator to meet the patient's inspiratory flow demand and to maintain airway pressure at the PEEP level. An inspiratory phase in this breath type continues until:

- The flow decreases to a set value of the peak flow (Esens); or
- The airway pressure exceeds a value 5 cmH2O above PEEP; or
- Three seconds or two breath periods have elapsed; whichever occurs first.

At this point, the ventilator terminates flow, allowing the patient to exhale.

SUMMARY

The classification of breaths, for the purpose of this manual, are summarized in the following table.

Table 15: Summary of Breath Types

Breath Type		Initiation	Controlled parameters	Limiting parameters	Termination
Mandatory Breath	Ventilator Volume Control	By Ventilator (time trigg.)	Flow	Pressure or Time	By Ventilator Set V_T is delivered
	Assist Volume Control	By Patient (pt. trigg.)	Flow	Pressure or Time	By Ventilator Set V_T is delivered
	Ventilator Pressure Control	By Ventilator (time trigg.)	Pressure Level	Volume	By Ventilator Inspiratory Time is elapsed
	Assist Pressure Control	By Patient (pt. trigg.)	Pressure Level	Volume	By Ventilator Inspiratory time is elapsed
	Manual	By Operator	Volume or Pressure Level	Pressure, Volume, or Time	By Ventilator Set V_T is delivered or Inspiratory time is elapsed
Breath Type		**Initiation**	**Controlled parameters**	**Limiting parameters**	**Termination**
Patient Breath	Spontaneous Breath	By Patient (pt. trigg.)	Baseline Pressure (PEEP)	Inspiratory Time	By Patient (flow drop or pressure increase)
	Pressure Support Breath	By Patient (pt. trigg.)	Target Pressure (above PEEP)	Inspiratory Time	By Patient (flow drop or pressure increase)

Notes:

APPENDIX E: VENTILATION MODES

ASSIST/CONTROL MODE

DEFINITION

Assist/Control (A/C) mode combines two traditional modes of ventilation: Assisted Ventilation and Control Mechanical Ventilation (CMV). Unlike a pure Control Ventilation mode, a patient may breathe more frequently than the set respiratory rate by producing inspiratory efforts sufficient to trigger a mandatory assist breath prior to the end of CMV breath cycle.

AVAILABLE BREATH TYPES

- Mandatory ventilator breath
- Mandatory assist breath
- Manual breath

All breath types may be either pressure control or volume control.

DESCRIPTION

Figure 170 demonstrates how breaths are delivered in this mode.

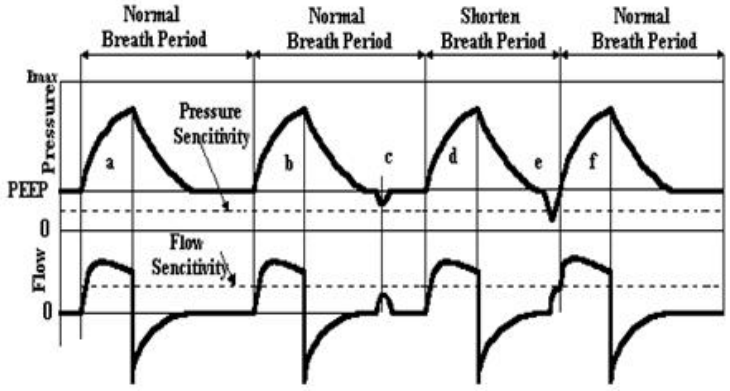


Figure 170: Breath Pattern in Assist/Control Mode

At the beginning of the breath cycle (event a), the ventilator delivers a ventilator breath. After the ventilator breath is delivered, the patient does not attempt to trigger an assist breath. The ventilator then waits for the normal breath period (60/bpm) to elapse and delivers another ventilator breath (event b). An insufficient inspiratory effort (event c) has no effect on the normal delivery of mandatory ventilator breaths. After delivering the third ventilator breath (event d), patient effort reduces the airway pressure below PEEP (pressure triggering) or generates initial inspiratory flow (flow triggering) by an amount equal to or greater than the operator-selected value for sensitivity (event e). Therefore, an assist breath is initiated (event f). This resets the breath cycle, thus breath rate is increased. If the

patient does not initiate an assist breath during the next breath cycle, the ventilator delivers a ventilator breath at the end of the normal breath cycle.

PARAMETERS SETTING

The following parameters can be set:

- Breath Rate (bpm)
- O2 %
- Tidal Volume
- Peak Flow, Adaptive or set value
- I Time, Adaptive or set value
- Limit Pressure
- Triggering type and sensitivity

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION MODE

DEFINITION

Synchronized Intermittent Mandatory Ventilation (SIMV) mode ensures that spontaneously or partially spontaneously breathing patients receive a set number of mandatory breaths. All breath types are available in this mode. This mode is identical to Assist/Control mode except for the following:

- Patient spontaneous breaths are allowed between mandatory breaths.
- Although mandatory breaths are synchronized with the patient's inspiration, the breath period is not reset when the patient initiates an assist breath; therefore, average mandatory bpm does not change.

AVAILABLE BREATH TYPES

- Mandatory ventilator breath
- Mandatory assist breath
- Manual mandatory breath
- Patient spontaneous breath
- Patient pressure support breath

All types of mandatory breaths may be either pressure control or volume control.

DESCRIPTION

During an SIMV breath cycle, mandatory breaths can be initiated and / or occur during:

- Assist windows (any breath period).
- At the end of the Assist window when no patient efforts are detected.

Spontaneous / Pressure Support breaths may be initiated and /or occur during support windows between mandatory breaths.

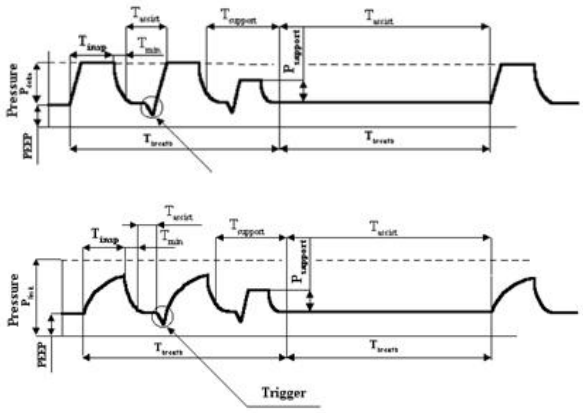


Figure 171: Breath Patterns in SIMV Pressure Control and Volume Control Modes

If a patient's initiated breath overlaps with the next mandatory breath period, an Assist window opens, and the ventilator either waits for the next patient effort or delivers the next mandatory breath at the end of the Breath window.

Mandatory breaths terminate when:

- The set tidal volume is delivered.
- The level of High pressure Alarm is reached.
- The I:E ratio reaches 1.2 :1 when an inspiratory time is not manually set.

PARAMETERS SETTING

The following parameters can be set:

- Mandatory Breath Rate
- O2%
- Mandatory Tidal Volume
- Peak Flow, Adaptive or set value
- I Time, Adaptive or set value
- Limit Pressure
- Triggering type and sensitivity
- Support pressure for pressure support breaths

CONTINUOUS POSITIVE AIRWAY PRESSURE MODE

Definition

Continuous Positive Airway Pressure (CPAP) is a ventilation mode intended for patients who are breathing spontaneously at a rate sufficient to meet their ventilation requirements. During CPAP, the airway pressure remains above ambient at all times, reducing the work of breathing.

Available Breath Types

Patient spontaneous and pressure support breaths can be delivered in this mode. Mandatory breaths are not provided (except manual breaths).

Description

Figure 172 illustrates how breaths are delivered in this mode.

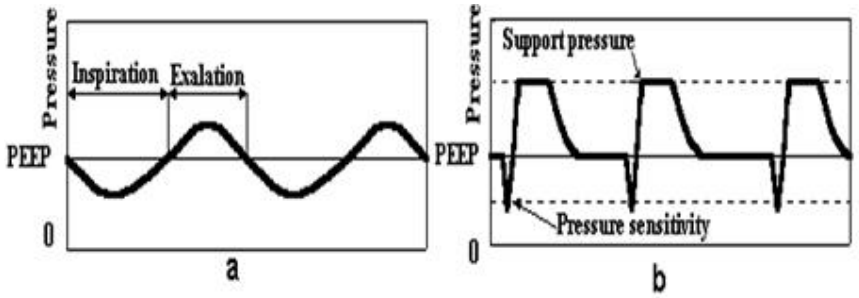


Figure 172: Pressure During CPAP Mode for Spontaneous Breaths and Pressure Support Breath

Patient triggering results in the delivery of a patient breath (spontaneous or pressure support). The ventilator maintains airway pressure (as in Figure 172 during the inspiratory phase at PEEP level. If pressure support is selected, the ventilator maintains an elevated support pressure (b in Figure 172 during the inspiratory phase). Breaths can only be initiated after inspiration has ended and the minimum exhalation time has elapsed.

PARAMETERS SETTING

The following parameters can be set:

- O2%
- Triggering type and sensitivity
- Support pressure for pressure support breaths

APNEA BACK-UP VENTILATION

Apnea back up ventilation can be activated from all breathing modes. Visual and audible indicators indicate an apnea event if breathing has ceased for a period of time determined in the Alarms Settings window (the default value is 20 seconds.) When apnea is detected the patient is ventilated in the current ventilation mode except for CPAP. Rate is determined according to set Tidal volume for volume control, for all other modes the rate is based on an average of the previous inhaled tidal volumes. The average is calculated based on the twelve breaths (whether spontaneous or mandatory) prior to the apnea event. (see table below) . In CPAP the unit switches to SIMV volume control mode with rate and Tidal volume according to the following table.

Table 16: Parameters for Apnea Ventilation

Average VT Range	bpm	Tidal Volume (for CPAP)
(mL)	(bpm)	(mL)
50-90	30	70
91-120	25	105
121-175	20	140
176-245	18	210
246-315	16	280
316-385	14	350
386-455	12	420
456+	12	490

The ventilator remains in apnea backup ventilation until the patient initiates 3 consecutive breaths within a 1 minute time period and then returns to the previous mode automatically. (**The unit does not exit from apnea ventilation during the first minute.**) The operator can restore previous ventilation parameters or make appropriate adjustments at any time.

During apnea ventilation, all parameters appear in gray so all adjustments must be made only after restoring the previous ventilation mode.

OPEN LOOP MODE

The Open Loop mode is an emergency backup mode designed for short-term ventilation. Open Loop is used as a safety mode in the event of ventilator circuit or sensors failures. While in Open Loop mode, the iVent™201 ventilates without reference to the flow sensor data.

When the open Loop mode is activated a Warning message is displayed allowing to restore to the last ventilation mode or to go to Standby mode (Figure 173).

Figure 173: Open Loop Warning Message

If **Standby** was selected, the following **Confirmation** message pop-up window appears (Figure 174):

Figure 174: Standby Confirmation Message

The Open Loop ventilation is an approximation of the Volume Controlled ventilation with pressure limit. Ventilation is based on the average measured inhaled volume similar to apnea ventilation. See Table 16 above. Pressure is measured via an internal pressure sensor.

Upon the restoration of normal conditions, the unit automatically restores the previous ventilation parameters after 2-3 proper breaths are detected. The user is prompted to restore the previous ventilation parameters manually at any time or to select the **Standby Options**.

ADAPTIVE BI-LEVEL MODE

See Chapter 5.

Notes:

APPENDIX F: HOLD FUNCTION AND STATIC MECHANICS MEASUREMENTS

FRONT PANEL CONTROLS

The **Hold** Button has two functions. Pressing it results in the following:

- Pressed once initiates an end inspiratory hold maneuver which allows the calculation of static compliance (See Static Compliance Measurements, page 235). This maneuver should be administered by clinicians who are knowledgeable about the effect on the patient of this maneuver.
- Pressed twice in succession initiates an end expiratory hold maneuver which allows the calculation of intrinsic PEEP. This maneuver should be administered by clinicians knowledgeable about the effect on the patient of this maneuver.

Pressing the **Hold** or **Clear** button when either an inspiratory hold or an expiratory hold maneuver has been initiated cancels the maneuver.

STATIC COMPLIANCE MEASUREMENTS

Certain versions of the iVent™201 ventilator (version 1.4 model iVent™201 MRI IC 1.4 M1171648 and higher only) are capable of measuring static pulmonary mechanics through the addition of a special control mechanism for the exhalation valve.

Two types of static respiratory measurements are available to the user of the iVent™201 ventilator – Static Compliance using end inspiratory hold, and Auto PEEP using end expiratory hold. Due to the fact there is resistance in airways, there is a delay to the equilibration of pressure throughout the respiratory system. In order to characterize tissue properties of the respiratory system independently of airway resistance, it is necessary to stop airflow for a period of time long enough for the pressure in the respiratory system to become equal. The ability to perform either of these static measurements therefore requires that the exhalation valve be actively controlled so that it remains closed during the relevant portion of the breath.

STATIC COMPLIANCE

During a static compliance measurement, the ventilator senses when the end of inspiration occurs and blocks the exhalation valve so that no air can escape the lung. Once the exhalation valve is closed, the airway pressure distributes across the various resistances of the respiratory system until the lungs are at the same pressure as the airway. At this point, the pressure is recorded (plateau pressure) and the exhalation valve is released and the patient is allowed to exhale. Static compliance is then calculated as the volume exhaled following release of the end inspiratory hold maneuver divided by the change in pressure from the plateau pressure to PEEP. The average value for plateau pressure is also displayed in the **Show Mechanics** option (See page 119)

RESPIRATORY TIME CONSTANT

Lastly the ventilator calculates the time constant of the respiratory system as the product of the dynamic resistance and the static compliance of the respiratory system as calculated using the above technique.

These calculated values can be viewed in the **Respiratory Mechanics** screen that is described in page 238 *Reviewing Static Mechanics and Intrinsic PEEP Measurements*.

PERFORMING A STATIC RESPIRATORY MECHANICS MEASUREMENT

In order to execute a static hold maneuver the clinician must press the **Hold** button once on the front panel of the ventilator. This initiates in the next breath cycle an automated sequence in which the ventilator waits until the end of inspiratory flow and then holds the exhalation valve closed until a plateau pressure is reached.

The following pop-up window (Figure 175) appears on the screen of the ventilator:

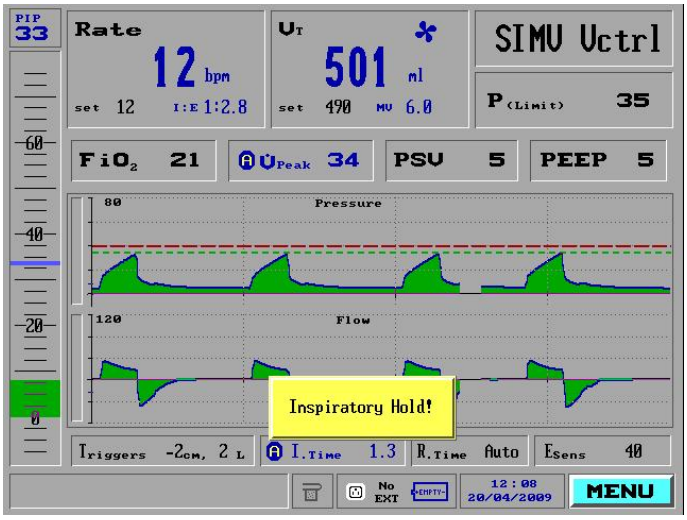


Figure 175: Inspiratory Hold Popup

The ventilator automatically terminates the hold maneuver if the pressure continues to rise once the exhalation valve is closed (signifying a patient is trying to breathe against the exhalation valve). Similarly the ventilator also aborts the maneuver if a stable plateau pressure is not reached during the hold maneuver. The maximum time that the ventilator holds the exhalation valve closed for is from 1 to 3 seconds depending on the patient's tidal volume (See Table 17).

If the **Hold** button is pressed again or the **Clear** button is pressed during the maneuver, then the hold maneuver is terminated.

During either inspiratory or expiratory hold maneuvers, the ventilator does not perform either a purge of the flow sensor lines, or a zeroing of the flow sensor reading.

The duration of the inspiratory hold is dependent on the Tidal Volume of the patient. It is set according to the following table:

Table 17: Maximum Inspiratory Hold Time for Different Tidal Volumes

Tidal Volume	Time
Vt < 200 ml	1.0 sec
200 ml < Vt < 500 ml	2.0 sec
Vt > 500 ml	3.0 sec

The duration of the expiratory hold is also dependent on the Tidal Volume delivered to the patient. It is set according to the following table:

Table 18: Maximum Expiratory Hold Time for Different Tidal Volumes

Tidal Volume	Time
50 ml < Vt < 200 ml	1.0 sec
200 ml < Vt < 500 ml	2.0 sec
Vt > 500 ml	4.0 sec

Note that no compensation needs to be made for the length of the ventilator tubing as the volume measurements are made at the flow sensor which is located at the patient Y connector. The compliance of the respiratory tubing does not contribute to the volume measured during exhalation.

All calculated respiratory static parameters are displayed in the Mechanics window with the appropriate time when the respective hold maneuvers are performed (See page 238 *Reviewing Static Mechanics and Intrinsic PEEP Measurements*.).

CLINICAL CONSIDERATIONS

The clinician should note that the use of static hold maneuvers may distress the patient as it prolongs the inspiratory phase of the breath, which delays exhalation. Active breathing during the hold maneuver affects the measurement adversely by creating pressures not related to the relaxed tissue properties of their respiratory system. It is therefore advised that this maneuver be performed on a patient during sleep, or when the patient is not conscious.

END EXPIRATORY HOLD

In order to allow the respiratory system pressure to equilibrate during the expiratory phase, it is necessary to occlude the patient's airway and allow the lung pressure to equilibrate with the mouth pressure. To achieve this, the iVent™201 performs an expiratory hold maneuver. The resultant equalized pressure indicates the total amount of pressure that resides in the alveoli that does not have time to empty between breaths. This is known as intrinsic PEEP or auto PEEP. Clinicians utilize this measurement to understand if they have set the

proper I:E ratio for this patient. It may be necessary to increase the time interval between breaths in order to allow for more emptying.

PERFORMING AND END EXPIRATORY HOLD MANEUVER

To initiate an end expiratory hold maneuver, press the **Hold** button on the front panel twice in succession. After the next breath the expiratory phase is prolonged and an intrinsic (Auto) PEEP measurement made. If the Hold button is pressed again or Clear is pressed at any point in the breath or while the hold maneuver is taking place, the end-expiratory hold is suspended (Figure 175).

Note that if the patient is conscious and breathing rapidly, it may not be possible to perform an end-expiratory hold maneuver. If the ventilator senses a negative pressure excursion during the end-expiratory hold maneuver that exceeds the current pressure trigger setting, it suspends the end-expiratory hold maneuver and delivers a breath.

REVIEWING STATIC MECHANICS AND INTRINSIC PEEP MEASUREMENTS

To view the results of the static mechanics measurements, including static compliance, expiratory time constant and intrinsic PEEP measurements you need to navigate to the **Show Mechanics** (Figure 176) menu from the **Main** menu.

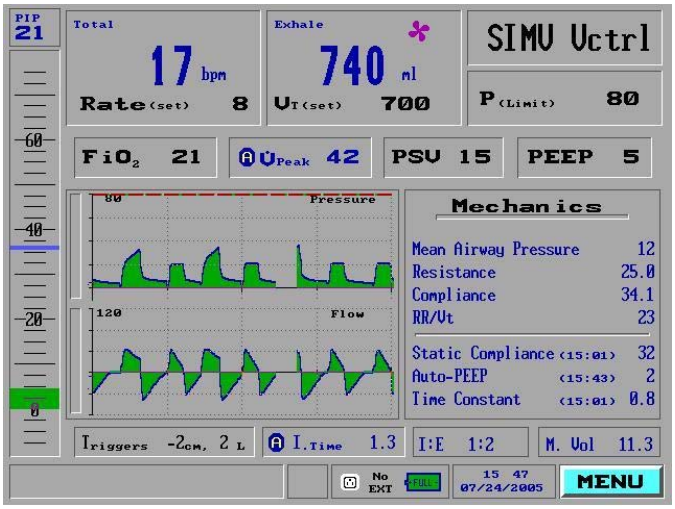


Figure 176: Static Mechanics Measurements

RR/VT RATIO

Clinicians are always looking for uncomplicated methods of determining if patients are capable of sustaining their own respiratory drive and being successfully "weaned" from mechanical ventilation. One of the most popular and easiest methods of predicting this success is through the use of the RR/Vt ratio or Rapid Shallow Breathing Index (RSBI). It is the relationship between the patients spontaneous breathing rate with the exhaled tidal volume. Literature suggests there is a strong relationship between fast and shallow breathing (high RR/Vt indexes) with patients that fail spontaneous breathing trials and subsequent extubation.

Notes:

APPENDIX G: ACCESSORIES

DISPOSABLE BREATHING CIRCUIT

These instructions refer to the following breathing circuits:

Breathing Circuit	REF
Breathing Circuit 1.8M	M1162026/ 620B0020-A0
Breathing Circuit 3.85M	M1173406/ 620B0035-01
Breathing Circuit with heated wire	M1162013/ 620B0022-A0

WARNING **U.S. Federal law restricts the sale of this device and its use by, or on the order, of a physician.**

The patient circuit shall be replaced before new patient connection.

Single use circuit, shall not be used longer than 30 days.

This single-use product is not designed or validated to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy, system performance, or cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization, or reuse.

CAUTION *Single patient use only. Not intended for sterilization.*

This circuit is intended for use only by properly trained medical personnel.

This device contains Phthalates

Risks and Precautionary Measures related to Phthalates:

This instruction pertains to the phthalate symbol marked on the device or its packaging. If this device is used for the treatment of children, or treatment of pregnant or nursing women; please note that the following types of procedures may increase the risk of exposure to phthalates: Exchange transfusion in neonates, total parenteral nutrition in neonates, multiple procedures in sick neonates, haemodialysis in prepuberal males, male foetus and male infant of pregnant women, and lactating women; and massive blood infusion into trauma patients. Although these procedures have the potential for increased risk of exposure, conclusive evidence of human health risks has not been established. As a precautionary measure, to reduce the potential for unnecessary exposures to phthalates, the product must be used in accordance with the instructions for use, and practitioners should refrain from using this product beyond the period of time the product is medically necessary or needed.

Single patient use only, not intended for sterilization.

This circuit is intended for use only by properly trained medical personnel.

NOTE This circuit is appropriate for delivering aerosolized medication (MDI or nebulization)

Instructions for Use

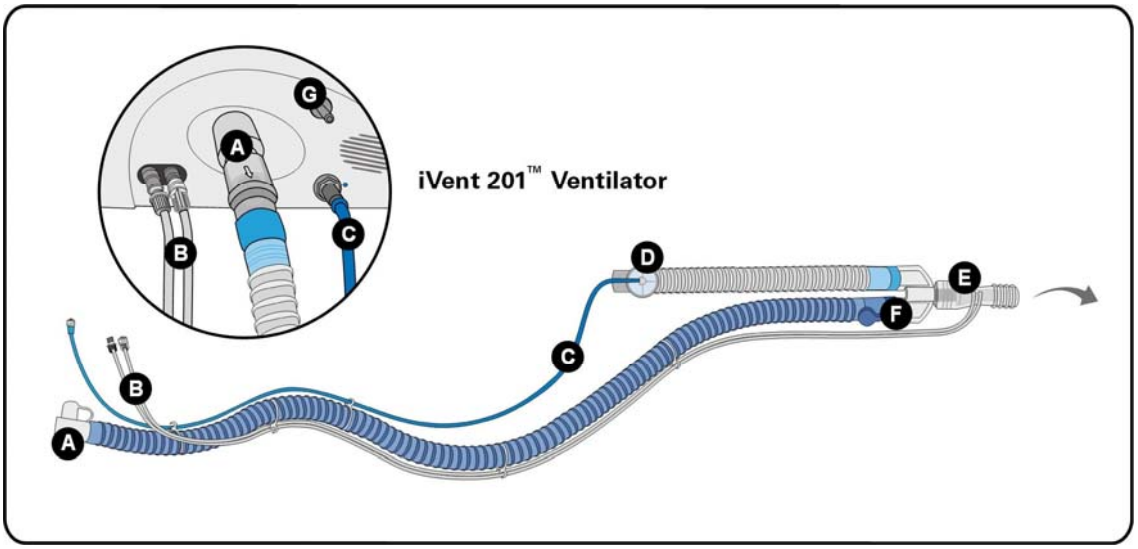


Figure 177: iVent™201 components

A	Ventilator outlet
B	Flow sensor tube
C	External exhalation valve control tube
D	External exhalation valve
E	Flow sensor
F	Wye connector
G	Nebulizer

1. Connect the Inspiratory limb (Figure 177) to the iVent™201 outlet.

NOTE	If using a humidifier see "Other Connections" page 44. See manufacturer's instructions for the correct use and application of the humidifier.

2. Connect the flow sensor tubing (clear tubes, B in Figure 177) to their ports. The male and female luer connectors on the flow sensor tubing ensure correct connections.

3. Connect the external exhalation valve control tube (blue tube, C in Figure 177) to its port.
4. Before use on a patient, perform the "Operation Verification Test (O.V.T)" as described on page 127.

Instructions for Use With a Pneumatic Nebulizer

NOTE To use a pneumatic nebulizer with the ventilator, connect an external high-pressure oxygen supply to the ventilator, and select the high-pressure oxygen supply option from the **Advanced Setting** menu as described on page 94.

1. Connect the nebulizer tube to the nebulizer outlet on the front panel of the ventilator (G in Figure 177).
2. Install the nebulizer with the desired medication to the patient circuit after the Wye connector and the flow sensor.
3. Connect the free end of the nebulizer tube to the respective nebulizer port.
4. For instructions on activating the Nebulizer see page 102.

REUSEABLE PATIENT BREATHING CIRCUIT

These instructions refer to the following reusable circuits:

Breathing Circuit	**REF**
Patient Circuit for adult M/U	620B0008-02/ M1161145
Breathing Circuit W. Trap M/U	620B0023-02/ M1162028
Breathing Circuit Heated W M/U	620B0024-02/ M1162029

Contents

- Non-sterile, reusable patient circuit
- Exhalation Valve with Exhalation Control Tube
- Flow Sensor with 2 Channel Tubing
- 22 mm Cuffed Breathing Tube
- 2 caps for Operational Verification Test (O.V.T)

Warnings and Cautions

WARNING **US Federal laws restrict this device for sale or use by or on the order of a physician.**

The patient circuit must at all times be used with the One-Way valve inserted. Failure to insert the One-Way Valve could result in insufficient oxygenation of the patient and inadequate ventilation of the

patient.

CAUTION

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

Not for use with external nebulizer. It is recommended to provide inhalation therapy by Metered Dose Inhalor (MDI).

One-Way Valve must be inserted properly in the inspiratory limb, as shown in figure 1.

This device is intended for use only by adequately trained medical personnel.

This device is intended for use only with the VersaMed iVent™201 ventilator

Sterilization and Duration of Use

The Breathing Circuit should be sterilized in a steam autoclave. It can be sterilized up to 40 times.

Phthalates

This device contains Phthalates

Risks and Precautionary Measures related to Phthalates:

This instruction pertains to the phthalate symbol marked on the device or its packaging. If this device is used for the treatment of children, or treatment of pregnant or nursing women; please note that the following types of procedures may increase the risk of exposure to phthalates: Exchange transfusion in neonates, total parenteral nutrition in neonates, multiple procedures in sick neonates, haemodialysis in prepuberal males, male foetus and male infant of pregnant women, and lactating women; and massive blood infusion into trauma patients. Although these procedures have the potential for increased risk of exposure, conclusive evidence of human health risks has not been established. As a precautionary measure, to reduce the potential for unnecessary exposures to phthalates, the product must be used in accordance with the instructions for use, and practitioners should refrain from using this product beyond the period of time the product is medically necessary or needed.

Instructions for use

1. Connect the two channel flow sensor tubes to their respective connectors next to the Breathing Gas Outlet. Flow Sensor tubes are equipped with luer connectors - left female and right male (Figure 185 (B)) for differentiation.
2. Connect the Exhalation Control Tube with luer connector to its respective connector on the right side of the front panel (C).
3. Perform the standard Operational Verification (O.V.T) test procedure, as described on page 60, prior to use on a patient.
4. Connect the Flow Transducer to the patient airway when ready.

NOTE It is recommended that an HME filter be used when connecting to the patient

Instructions for use with the humidifier

NOTE	For proper use and application of the Humidifier, refer to the manufacturers operator instructions. the P/N of the circuit with the humidifier configuration is M1161731.

1. Connect the one-way valve to the ventilator outlet (Figure 178 (A))
2. Connect 12-in. length of 22-mm tubing to one-way valve.
3. Connect opposite end of tubing to humidifier inlet, and connect 22-mm tubing (with the installed watertrap) between humidifier outlet and Y-connector (Figure 178 (F)).
4. If using Patient circuit with heated wire: Connect full-length tubing with heated wire to Y-connector (Figure 178 (F)). Note: The P/N of the circuit with the heated wire configuration is M1161732
5. Connect the Exhalation valve (Figure 178 (D)) to the Y-connector (F) with 22-mm tubing (with the installed watertrap). Verify that the arrow on the exhalation valve cup is directed to opposite from the patient.
6. Connect the two channel flow sensor tubing (Figure 178 (B)) to their respective connectors next to the Breathing Outlet. Flow Sensor tubing are equipped with luer connectors - left female and right male for differentiation.
7. Connect the Exhalation Control Tube (Figure 178 (C)) with luer connector to its respective connector on the right side of the front panel, marked with blue dot.
8. Perform the standard Operational Verification (O.V.T) test procedure, as described on page 60, prior to use on a patient.
9. Connect the Flow Transducer to the patient airway when ready.

NOTE Always position the Water trap so that it sits below the patient circuit and

Humidifier to ensure adequate drainage to it.

The Y-transducer should always slope slightly towards the Water trap (greater than 10º) to ensure adequate drainage to the Water trap.

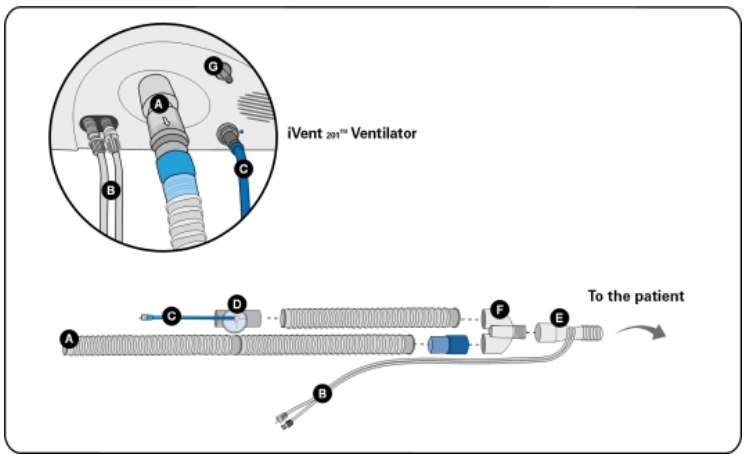


Figure 178: iVent™201 Reusable Patient Breathing Circuit

A- Ventilator outlet B - Flow sensor C- External exhalation valve (
D- External exhalati E- Flow sensor F - Wye connector
G- Nebulizer outlet

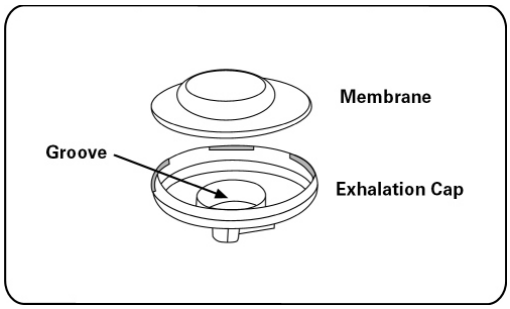


Figure 179: Exhalation Valve components

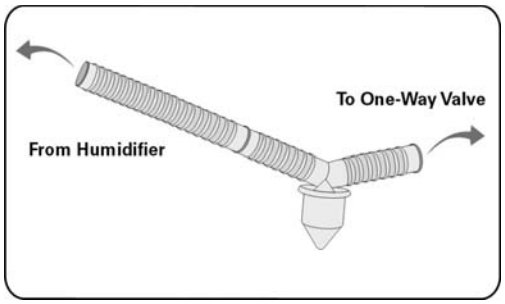


Figure 180: Example of water trap tubing assembly

Cleaning and Sterilization

Disassembly

1. Detach the one-way valve from the Y-Connector and the long (inspiratory) corrugated tube. Note: Do not remove the tube holders that support the sensor tubes from the corrugated tube.
2. Disassemble the exhalation valve as follows: open the top cover together with its control tube, and GENTLY remove the internal membrane. (Note: do

not remove the exhalation control tube from the cover.) Visually check if there are any defects in the membrane. Take apart all three components of exhalation valve (cap, membrane and housing).

3. Disassemble the Flow Sensor and the Y-Connector.

Washing

NOTE It is recommended to use Multi-tierd Endozime AW Plus or similar cleaner solution to remove all bio-burden material. If using Endozime, dilute one-half ounce (15 grams) of Multi-tierd Endozime AW Plus in 1 gal of water (3.8 liters).

1. Immerse the patient circuit components in the diluted Endozime for 10-20 minutes or equivalent cleaner solution. Pass solution through the small diameter tubing by using syringe or connect to flow source of automatic washing equipment.

Remark: It is possible to use automatic "medical standard" washing equipment used in medical institutes for washing purposes. Wash according to preset washing cycles, and use different adapters to pass cleaning solution through the thin tubes.

2. Remove the patient circuit components from the solution and rinse the components with distilled or sterile water. Pass water through the small diameter tubing by using syringe or connect to flow source of automatic washing equipment. Patient circuit components must be dried at 70°C for 2 hours prior to sterilization process.

Sterilization

CAUTION *DO NOT TAKE APART THE THIN SILICONE TUBES WITH THE LUER CONNECTIONS.*

if any component appears discolored or damaged in any way, dispose of the part and replace the patient circuit. Do not use any patient circuit in which the function of a component appears compromised.

Use the following autoclave parameters:

Form of Autoclave:	Steam Autoclave
Sterilizer Type:	Pre-vacuum assisted steam saturated autoclave
Method:	Wrapped
Sterilization Time:	30 minutes

Reassembly

Following sterilization of the components, reassemble the patient circuit as follows:

1. Fill a syringe with room air. Pass at least 20 cc of air through each thin silicone tube to ensure removal of any residual content.
2. Connect the one-way valve to the long corrugated tube.
3. Connect the Flow Transducer and the Y-Connector.
4. Connect the one-way valve to the Y-Connector.
5. Connect the thin silicone tubes to the tube holders on the corrugated tube so that they run parallel to the corrugated tube

WARNING **Ensure that the One-Way Valve is installed in its proper direction**

CAUTION *Verify that the membrane edge is installed properly. The membrane's edge should not overlap the exhalation cap edge.*

NOTE The exhalation cap contains a tube connector for exhalation control. Observe that the membrane is inserted in the proper orientation. Assemble the upper and lower parts exhalation valve together.

6. Check that the groove in the cap mates with the pin in the valve housing in the same orientation.
7. Check that all tube holders on corrugated tube are firmly supported. See that all other connections are stable and that there are no loose ends.
8. Check that all tube holders on corrugated tube are firmly supported. See that all other connections are stable and that there are no loose ends.
9. Follow the Instructions for use given above for connecting the patient circuit to ventilator.
10. Perform the standard Operational Verification (O.V.T) test procedure, as described on page 60. It is recommended that the patient circuit connection be periodically checked for proper integrity and performance.

DUAL LIMB PATIENT CIRCUIT ADAPTER

KIT CONTENTS

The Dual limb kit (GE PN M1169907) includes:

Item no.	Item	Part number
1	Exhalation Valve Adapter	
2	Captive Screw (x2)	
3	Exhalation Valve Holder	
4	Exhalation Valve, Low Resistance	

5	Reusable Barb/Luer Fitting	
6	Reusable VersaMed's Y and Flow Sensor	
7	Reusable One-way Valve	
8	Cap Red	
9	Sleeve Cap	M1161821
10	PEEP pressure line	

PHTHALATES

This device contains Phthalates

Risks and Precautionary Measures related to Phthalates:

This instruction pertains to the phthalate symbol marked on the device or its packaging. If this device is used for the treatment of children, or treatment of pregnant or nursing women; please note that the following types of procedures may increase the risk of exposure to phthalates: Exchange transfusion in neonates, total parenteral nutrition in neonates, multiple procedures in sick neonates, haemodialysis in prepuberal males, male foetus and male infant of pregnant women, and lactating women; and massive blood infusion into trauma patients. Although these procedures have the potential for increased risk of exposure, conclusive evidence of human health risks has not been established. As a precautionary measure, to reduce the potential for unnecessary exposures to phthalates, the product must be used in accordance with the instructions for use, and practitioners should refrain from using this product beyond the period of time the product is medically necessary or needed.

INSTALLATION

These instructions describe how to connect a Dual Limb Patient Circuit to the iVent™201 ventilator. Connecting the Patient Circuit is a two step process: first you connect the Exhalation Valve and its accessories to the ventilator, second you connect the tubing.

NOTE Note: The instructions provided below only refer to devices in which the Transport Mounting plate (PN M1169908) is installed. For additional information regarding Transport Mounting plate installation, refer to your local customer support

CAUTION *Insert the Exhalation valve and the Patient Circuit as shown in these instructions.*

The Exhalation Valve should be cleaned or sterilized once a month. Follow the

manufacturer instruction for cleaning and sterilizing.

Installing the Exhalation Valve

1. When facing the device insert the Exhalation Valve Adapter (item no.1) into the right side handle of the Transport Mounting plate (see figure 1), and guide the adapter into its place.
2. Insert the Captive screw (item no.2) into the screw-hole on the adaptor side, and screw it in with a flat screwdriver (See Figure 183).
3. Connect the Exhalation Valve Holder (item no. 3) to the Exhalation Valve Adaptor. Verify that the Exhalation Valve Holder is firmly connected.
4. Connect the Exhalation Valve (item no. 4) to the Exhalation Valve Holder. Verify that the Exhalation Valve is firmly connected.

NOTE	There are three ways to connect the Holder to the Adaptor, as shown in Figure 184 The Exhalation Valve is now connected and ready for use. The next step is to install the tubing to the ventilator

Installing the Patient Circuit

1. Assemble the PEEP pressure line by connecting one end to the barb fitting of the exhalation valve and the other end to the barb fitting of the reusable Luer fitting.
2. Connect the assembled PEEP pressure line by securing the luer lock fitting to the Exhalation valve luer inlet, which is marked with a blue dot on the front panel of the ventilator (see Figure 183, item D).
3. Secure the multi-use One-way valve to the ventilator patient outlet (see Figure 183, item C)
4. Connect the patient circuit inspiratory limb to the One-way valve sitting on the ventilator patient outlet and the expiratory limb to the exhalation valve.
5. If appropriate, fit the patient wye to the inspiratory and expiratory patient circuit tubes.
6. Secure the flow sensor to the patient wye and connect the 2 sensor lines to the ventilator sensor line luer inlets (see Figure 183, item A and B).
   Note: even though the luer lock fittings at the end of the flow sensor sampling lines are non-interchangeable, it is good practice to verify that the left (while facing the ventilator) male luer connector connects to the fitting on the flow sensor which is closest to the patient
7. Perform the standard Operational Verification (O.V.T) test procedure, as described on page 127

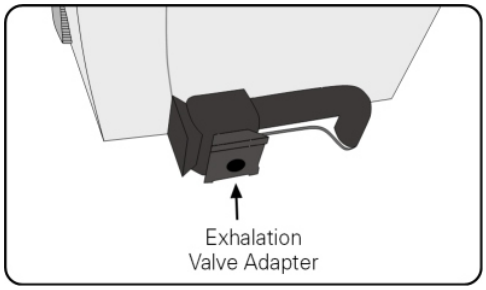


Figure 181: Attaching the Exhalation Valve Adapter

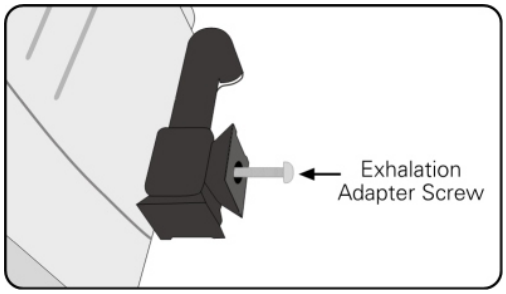


Figure 182: Mounting the Exhalation Valve Adapter

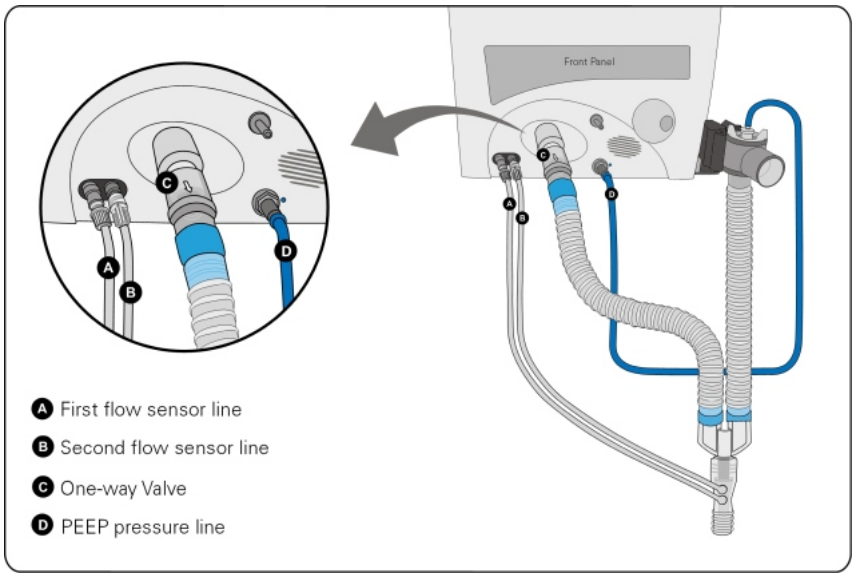


Figure 183: Tubing Connectors on the iVent™201

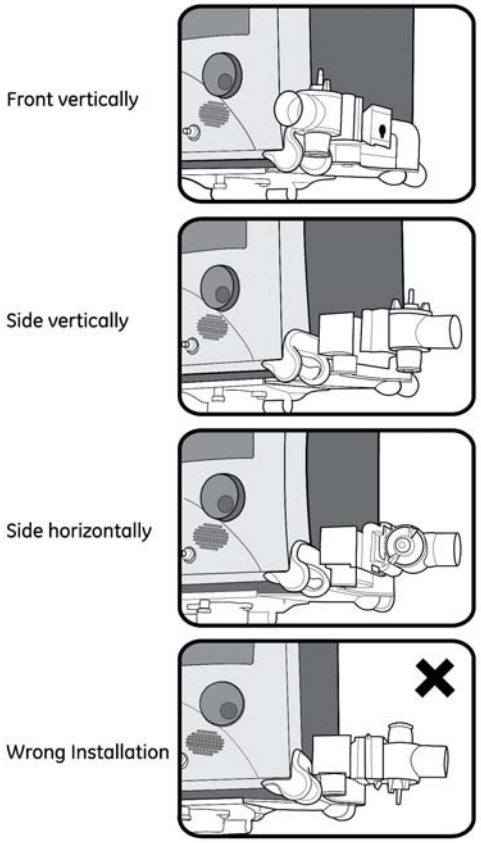


Figure 184: Installing the Exhalation Valve:

EXTENDED BATTERY

The extended battery will allow the Ventilator to operate for up to four hours without being connected to the mains power.

TO REPLACE THE BATTERY:

1. Make sure that the iVent™201 is turned off.
2. Disconnect the iVent™201 from external power.
3. Remove all four screws from the power pack, using a #1 Phillips screwdriver, as shown in the Figure 185.
4. Using the handle, pull the battery pack out, as shown in Figure 186.
5. Open the power pack package, remove the foam protecting the extended battery, and take out the extended battery, as shown in Figure 187.

6. Carefully slide the extended battery into the chassis. Verify that it is properly aligned, as shown in Figure 188.
7. Slide the battery back into its place. Make sure that the female connectors of the battery are in place.
8. You can pack the regular battery in the extended battery package placing back the foam inverted.

Charge the extended battery for at least 24 hours (See Full Recharge Procedure, page 36)

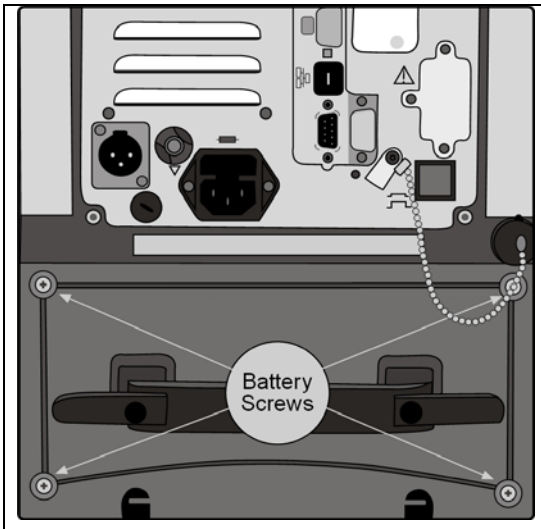


Figure 185: Battery Screw Locations

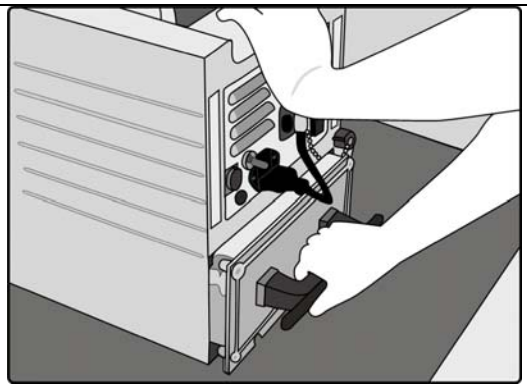


Figure 186: pulling the Battery Pack Out

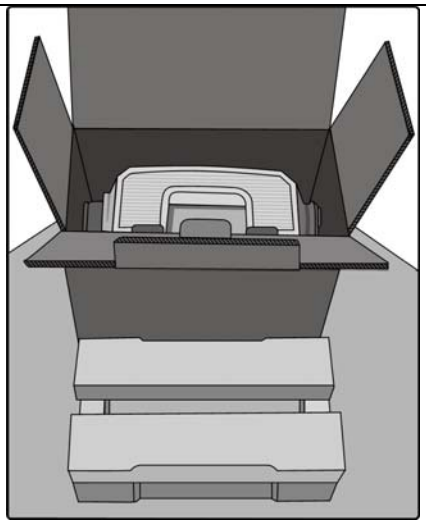


Figure 187: Unpacking the Battery

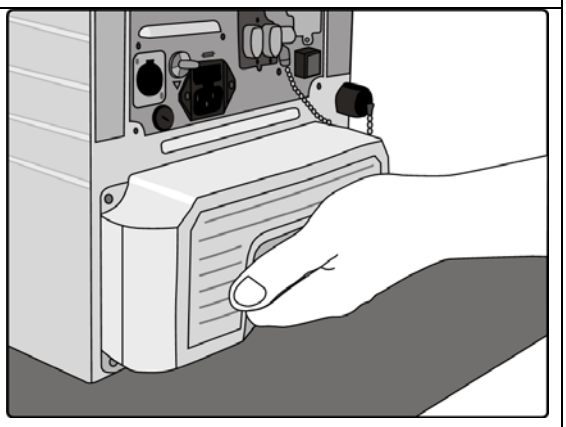


Figure 188: Sliding the Battery In

SPECIFICATIONS

Battery Weight	10.1 lb / 4.6 kg
Material	Sealed Lead-Acid
Voltage	12V
Capacity	24Ah
Recharging time	Over 24 hours, <1 Ampere
Battery Operating Time	Up to 4 hours (varies with ventilation parameters)

MRI EXTENSION TUBING SET FOR PATIENT BREATHING CIRCUIT

WARNINGS

WARNING **For single patient use only, not intended for sterilization.**

WARNING

This device contains Phthalates.

Risks and Precautionary Measures related to Phthalates:

This instruction pertains to the phthalate symbol marked on the device or its packaging. If this device is used for the treatment of children, or treatment of pregnant or nursing women; please note that the following types of procedures may increase the risk of exposure to phthalates: Exchange transfusion in neonates, total parenteral nutrition in neonates, multiple procedures in sick neonates, haemodialysis in peripuberal males, male foetus and male infant of pregnant women, and lactating women; and massive blood infusion into trauma patients. Although these procedures have the potential for increased risk of exposure, conclusive evidence of human health risks has not been established. As a precautionary measure, to reduce the potential for unnecessary exposures to phthalates, the product must be used in accordance with the instructions for use, and practitioners should refrain from using this product beyond the period of time the product is medically necessary or needed

Duration of use should be determined by the appropriate personnel, based on accepted infection control procedures, but no more than 30 days.

INSTRUCTIONS FOR USE

1. Stretch the 22 mm Extension Tube to the desired length.
2. On the front panel, connect the female end of the 22 mm Extension Tube to the Ventilator Outlet (C) as shown in Figure 189
3. Connect the Flow Sensor Double Tubings (transparent tubes) from the Extension Kit to their respective connectors near the Ventilator Outlet. The Flow Sensor Tubings are equipped with luer connectors - left female (A) and right male (B) to help differentiate between them.
4. On the right side of the front panel (D), connect the blue Exhalation Control Tube with a luer connector to the Exhalation valve luer inlet.
5. Connect the open male side of the 22 mm Extension Tube to the female side of the Patient Circuit.
6. On the open side, connect the two transparent Channel Flow Sensor luer connectors to the respective luer connectors - the Flow Sensor in the Patient circuit.
7. Connect the open Exhalation Control Tube with luer connector (blue tube) to its respective Exhalation Valve luer connector in the Patient circuit.
8. Perform a full O.V.T procedure before starting ventilation (See The O.V.T. page 176).

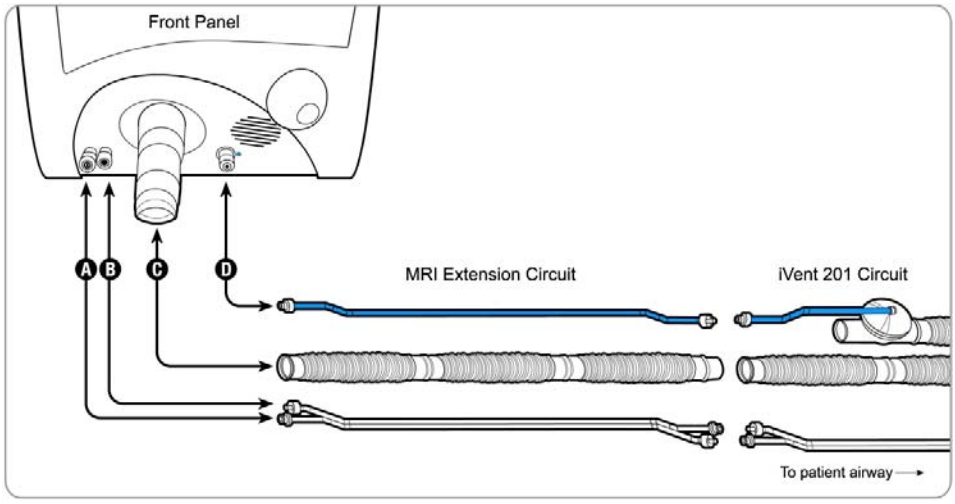


Figure 189: iVent™201 MRI Extension Circuit Attachment0.

INSTRUCTIONS FOR USE WITH THE HUMIDIFIER

See page 44 for instructions for connecting the Humidifier to the Patient circuit.

Connect the Extension tubing between the humidifier outlet and the iVent™201 circuit.

TRANSPORT MOUNTING PANEL

KIT CONTENTS

The Transport Mounting Plate kit (VersaMed Part Number 900K0015-01, GE Part Number M1169908) includes:

ITEM NO.	DESCRIPTION	DIMENSIONS	QUANTITY
1	Transport Mounting plate	305.5 x 117mm	1
2	Screws	M3 x 10mm	4
3	Flat washers		4
4	Spring washers		4
5	Spacers (for Disaster Preparedness devices only)	M3x10mm	4

INSTALLATION

1. Turn off the ventilator and disconnect the power cable and patient circuit tubing from it.
2. Flip the ventilator upside-down.

   Note: If an old model with an old mounting plate (VersaMed P/N. 325A0162-A3, GE P/N. M1161827) is attached to the ventilator, release the 4 screws that hold the old model of the Mounting plate, and remove it (See Figure 190).
3. For Disaster Preparedness models only: Screw the four spacers (item no. 5) into place, using a #6mm socket wrench (See Figure 191).
4. Lay the Transport mounting plate (item no. 1) on the ventilator (see Figure 192).
5. Place a spring washer (item no. 4) and flat washer (item no. 3) on each of the screw holes on the plate (See Figure 193).
6. Insert a screw (item no. 2) into each of the screw holes, and screw the four Philips screws with a Philips screwdriver.
7. Stand the ventilator upright (standing on the Transport mounting plate).

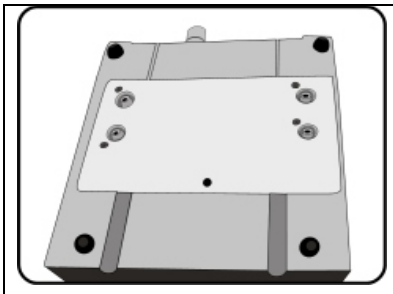


Figure 190: iVent™201 with Old Lower Plate Model

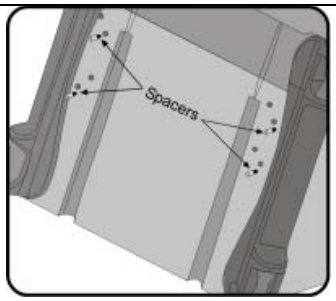


Figure 191: The Spacers Location on the HS Ventilator

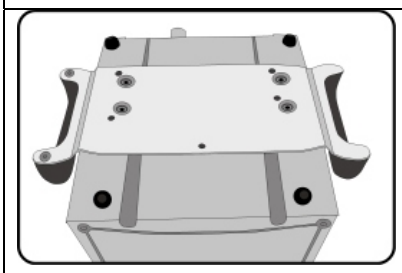


Figure 192: Positioning the Mounting Plate

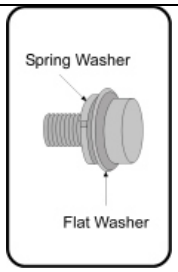


Figure 193: Inserting Screws into Flat Washer and Spring Washer

NOTE The iVent™201 MRI Transport Mounting Plate is an MR conditional accessory which poses no known hazards in all MR environments as per F 2503-05.

SUPPORT ARM FOR BREATHING CIRCUIT

The Support Arm for the breathing circuit is used for securing the patient circuit when the iVent™201 device is mounted on to a roll stand (VersaMed PN 630B0001-02, GE PN. M1162044).

CONNECTING THE PATIENT CIRCUIT TO THE SUPPORT ARM

1. Place the Support Arm base on the roll stand frame, as shown in Figure 194.
2. Turn the lower screw (A in Figure 195) to fasten the Support Arm to the roll stand.

CAUTION *The side screw (B in* Figure 195*) fastens the Support Arm to its base. Do not open this screw.*

Do not over tighten the screws as this might cause damage to the Support Arm

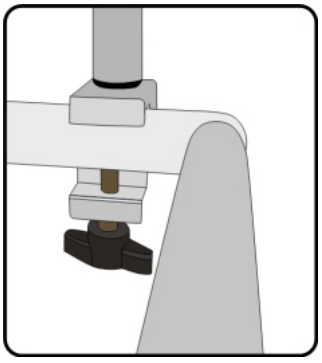


Figure 194: The Support Arm based on Roll Stand frame

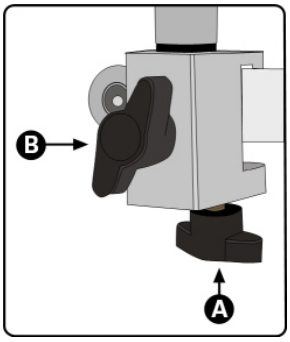


Figure 195: Support Arm Base Screws

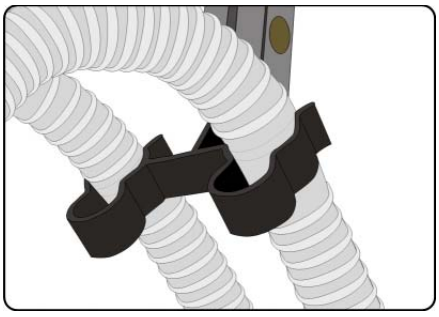


Figure 196: Twin Tube Holder

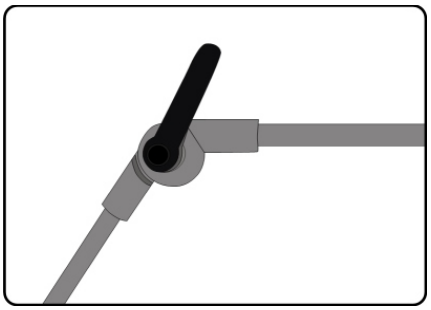


Figure 197: The Support Arm's Latch

3. Connect the Patient circuit to the iVent™201 device as described in page 40.
4. Insert the patient circuit into the twin tube holder, as shown in Figure 196
5. Use the latches on the Support Arm, shown in Figure 197, to adjust the Support Arm to the meet the patient and the healthcare needs

ROLL STAND

The Roll Stand Accessory is used for mounting the iVent™201 ventilator, in which a standard mounting bracket is installed.

This Roll Stand is compatible with the iVent™201 ventilator "grey" and with the iVent™201 ventilator "yellow".

NOTE The iVent™201 MRI Roll Stand is an MR conditional accessory which poses no known hazards in a specified MR environment with specified conditions of use as per F 2503-05.

MOUNTING THE IVENT™201 ON THE ROLL STAND

WARNING **Make sure that the patient is not connected to the ventilator and that the device is in Standby mode, or shut down.**

1. Verify that the standard Transport Mounting Plate M1169908 (Figure 198 (1.1A)) or a Plate Cart Adapter M1161827 (Figure 198(1.1B)) is connected to the ventilator
2. Lock all roll stand casters using the casters' breaks.
3. Pull the locking pin and hold it while sliding the iVent™201 with the Transport Mounting Plate into place.
4. Release the locking pin and verify that the mounting plate is locked to the mounting bracket, and the locking pin is placed inside the hole.

WARNING **Slide the device carefully! When the locking pin is pulled, the device may slide out all the way without stopping.**

5. Tighten the mounting bracket screws to lock the transport mounting plate place

DISMOUNTING THE IVENT™201 FROM THE ROLL STAND

WARNING **Make sure that the patient is not connected to the ventilator and that the device is in Standby mode, or shut down.**

1. Loosen both of the rear brackets mounting plate tightening screws.
2. Pull out the locking pin and hold it while sliding the mounting plate from the mounting bracket.

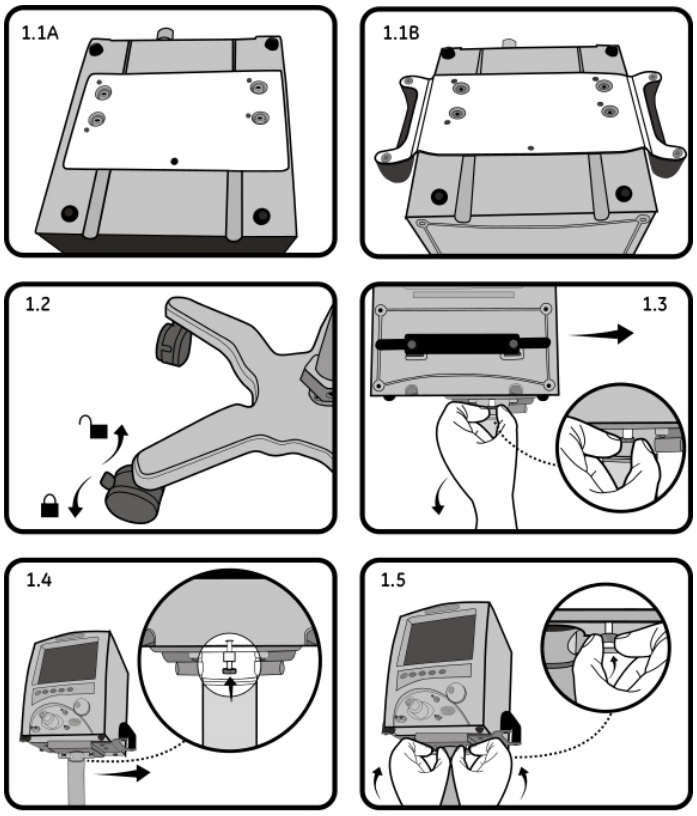


Figure 198: Mounting and Dismounting the Ventilator From the Roll Stand

CONNECTING THE OPTIONAL BATTERY HOLDER ACCESSORY P/N: M1162050

1. Fasten the Battery Holder mount screws to the post using a Philips screwdriver (See Figure 199).
2. Using the Adjustment screw at the end of the Battery holder, tighten or loosen the screw to the required degree as to provide optimal support to the External Battery size.
3. Peel the transparent layer of both 2 of the pair-strips at the inside of the Battery Holder, to expose adhesive.
4. Place the External Battery inside the holder and adjust the holder to its size, fastening the screw at the end of the holder.

5. Fasten the external battery using the strap belt.

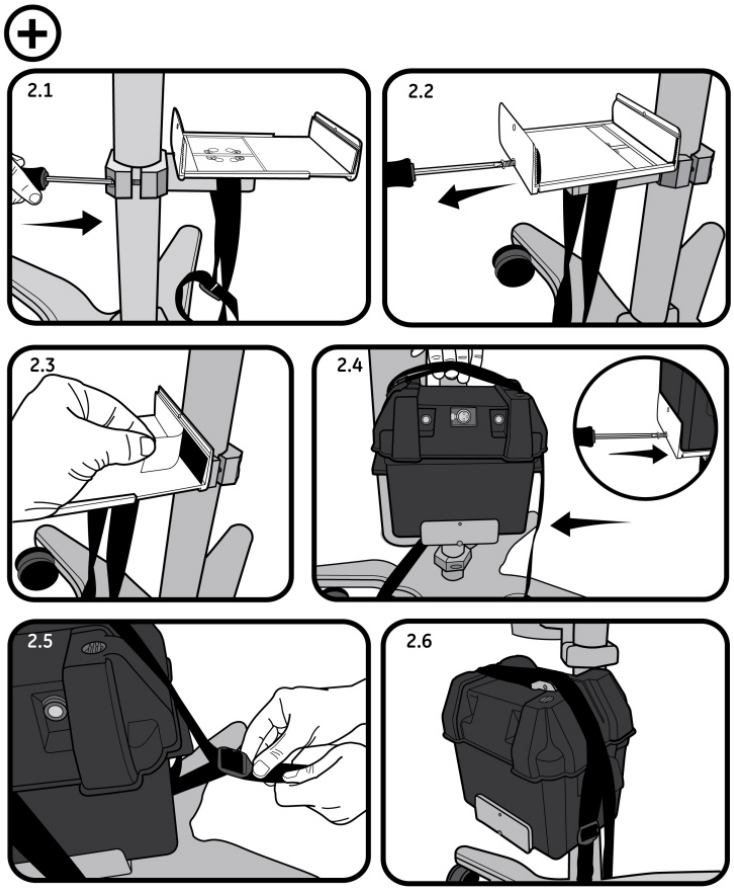
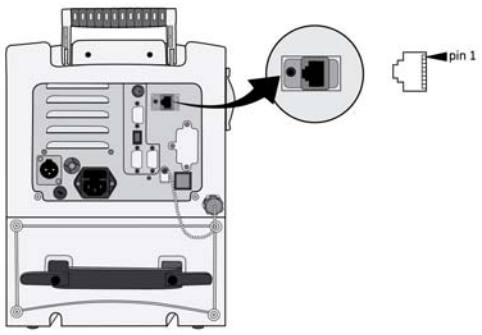


Figure 199: Connecting the Optional Battery Bag

APPENDIX H: REMOTE ALARM CONNECTOR

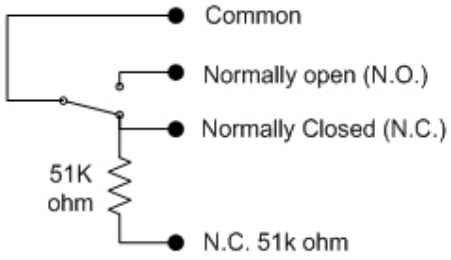
The following table shows the Remote Alarm connector wiring diagram:



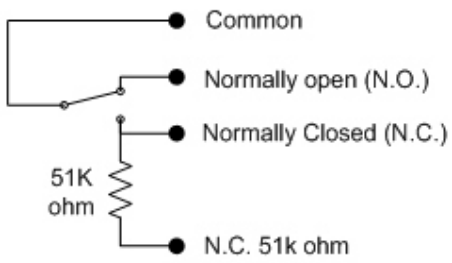
Pinout:

1) Common
2) N.O
3) Do not use
4) Do not use
5) Do not use
6) Do not use
7) N.C.
8) N.C. 51K

Normal Mode:



Alarm Mode:



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.

APPENDIX I: PART NUMBERS AND ACCESSORIES

Part Number	Description
M1161881	375A0002-A0, iVent™201 PACKAGE MODEL 1.4
Manuals	
M1177689	OM-01-06, iVent™201 HS OPERATION MANUAL
M1162065	SM-01-04, iVent™201 SERVICE MANUAL
Breathing Circuits	
M1161009	620B0006-20, DISPOSABLE BREATHING CIRCUIT, Y-TYPE, QTY. 20
M1161013	620B0022-A0, DISPOSABLE BREATHING CIRCUIT, HEATED WIRE
M1161145	620B0008-02, REUSABLE PATIENT CIRCUIT
M1162026	620B0020-A0, PATIENT CIR ADULT S/U
M1162028	620B0023-02, MULTI USE BREATHING CIRCUIT WITH TRAP
M1162029	620B0024-02, MULTI USE BREATHING CIRCUIT WITH HEATED WIRE
M1162030	620B0035-12, DISPOSABLE BREATHING CIRCUIT, 3.8M LENGTH, Y-TYPE, QTY 12
M1173406	620B0035-01, PATIENT CIRCUIT FOR ADULT DISPOSABLE 4M
M1198077	iVent™201 PATIENT CIRCUIT W TRAP MULTI USE QTY 15, Mechanical
M1199141	PATIENT CIRCUITS HW MU QTY 1
Breathing Circuits Components	
M1161015	319G0040-A0, FLOW SENSOR, Y-PIECE, REUSABLE
M1161016	319G0020-A0, FLOW SENSOR, Y-PIECE, DISPOSABLE
M1161029	50801020-A0, DISPOSABLE EXHALATION VALVE
M1161030	50801030-A0, MULTI-USE EXHALATION VALVE
M1173617	620B0019-01, MRI PATIENT CIRCUIT
M1162025	620B0019-20, MRI CIRCUIT EXTENSION 3M, QTY 20
NIV masks	
M1162031	620B0050-01, BLUESTAR KIT, EXTRA LG
M1162032	620B0051-01, BLUESTAR KIT, LARGE
M1162033	620B0052-01, BLUESTAR KIT, MEDIUM
M1162034	620B0053-01, BLUESTAR KIT, SMALL
M1162035	620B0054-01, BLUESTAR KIT, CHILD
Ventilator filters and adapters	
M1162023	620B0012-01, CHEMICAL, BIOLOGICAL, RADIOACTIVE AND NUCLEAR CBRN FILTER
M1161967	504A0110-A1, ADAPTER, CBRN FILTER
M1169753	900K0016-01, DUAL LIMB KIT WITH PLATE
M1169907	900K0014-01, DUAL LIMB ADAPTER KIT

M1161007	660A0001-12, DISPOSABLE AIR INLET FILTER, QTY. 12
M1161008	660L0001-12, DISPOSABLE LOW PRESSURE OXYGEN FILTER, QTY.12
Mounting Equipment	
M1162048	630B0004-A1, BREATHING CIRCUIT SUPPORT ARM, MRI CONDITIONAL
M1169908	900K0015-01, MOUNTING PLATE (TRANSPORTATION KIT)
M1162051	630B0010-01, MOUNTING SYSTEM, BED RAIL
M1162050	630B0007-A1, EXTERNAL BATTERY HOLDER FOR ROLL STAND, MRI-CONDITIONAL
M1206571	630B0013-01, Roll Stand
M1206572	325A0554-01, Cylinder Holder
M1162052	630B0011-01, MOUNTING SYSTEM, POLE
M1161734	MOUNTING BRACKET, POLE 15-50MM, 900MR030
M1162010	510S0001-A0, 6IN ROLL STAND UTILITY BASKET
M1162044	630B0001-02, ROLL STAND AND MOUNTING BRACKET, MRI-CONDITIONAL
M1162046	630B0003-A1, OXYGEN CYLINDER HOLDER, MRI CONDITIONAL
M1174996	Suko Roll Stand Caster Kit
Oxygen	
M1162017	620B0002-01, OXYGEN SUPPLY HOSE, 15FT LENGTH, DISS FITTINGS
M1162020	Adapter For Low Pressure O2
SpO2	
M1176366	611A0005-02, NONINVASIVE SPO2 FOR iVent™201
M1162015	611A0005-02, SPO2 KIT, INCL CABLE AND DISPOSABLE PROBE
Remote Alarm	
M1192088	375HC021-01, REMOTE ALARM BOX
M1161989	507A0052-C0, NORMALLY CLOSED NC, 51K CONNECTOR
M1161990	507A0053-C0, NORMALLY CLOSED NC, PHONE JACK CONNECTOR
M1161991	507A0054-C0, NORMALLY OPEN, NO, PHONE JACK CONNECTOR
M1161992	507A0056-B0, ALARM CABLE BNC 51K
M1199809	900A2242-01,REMOTE ALRM NRS CALL CBLE NC MONO 0.25IN 3M
Humidifiers	
M1162037	620H0001-01, RESPIRATORY HUMIDIFIER KIT, M/U 220V US PLUG
M1162038	620H0002-01, RESPIRATORY HUMIDIFIER KIT, M/U 110V, US PLUG
M1162039	620H0003-01, RESPIRATORY HUMIDIFIER KIT, M/U 220V NO PLUG
M1162040	620H0004-01, RESPIRATORY HUMIDIFIER KIT, M/U 220V BRITISH PLUG

M1162041	620H0005-01, RESPIRATORY HUMIDIFIER KIT, M/U 220V EUROPEAN PLUG
M1162042	620H0010-01, RESPIRATORY HUMIDIFIER KIT, M/U 230V, EUROPEAN PLUG
M1162043	620H0011-01, RESPIRATORY HUMIDIFIER KIT, M/U 115V, US PLUG
M1161735	301C0026-01, HUMIDIFIER 230V, MR810AEU
M1161736	301C0027-01, HUMIDIFIER 115V, MR810JHU
Power Cords	
M1161939	404J1803-02, AC POWER CORD, 115V HOSPITAL GRADE 4M
M1161943	404J2106-01-EU, AC CORD 1.8M PLUG90 CONO
M1161946	404J2110-01, AC POWER CORD 240V, UK STANDARD
M1161996	507A1020-A0, DC POWER CORD, 12V VEHICLE ADAPTER
M1161997	507A1022-A0, DC POWER CORD, 12V CLIP-ON ADAPTERS
M1162000	507A2019-A0, EXTERNAL BATTERY CABLE, 1.4M LENGTH
M1212664	AC Cable 3pin 180 cm Brazil
M1212963	EU AC CORD L=2M
Batteries	
M1161011	504A0051-A0, EXTERNAL BATTERY KIT
M1171502	900K0011-01, EXTENDED POWER PACK KIT
M1171503	900K0011-02, H.S. EXTENDED POWER PACK KIT
M1161022	503A0012-SP, POWER PACK REVISION 1.4 ASSY, iVent™201
M1161960	DHHS POWER PACK ASSY 1.4.5 SN GT 20,000
Ventilator Cases	
M1161822	PVC COVER, NOT COMPATIBLE WITH DHHS UNITS
M1161882	375B0003-01, HARD CASE, TRAVEL
M1161883	375B0004-01, SOFT CASE, NOT COMPATIBLE WITH DHHS UNITS
Test & Calibration Equipment	
M1161188	910V0004-A0, RP20 RESISTOR PLUG
M1162059	910V0003-B0, PNEUMATIC RESISTOR RP 50
M1185991	2-LITER BREATHING LUNG
M1161964	504A0065-A0, O2 SYSTEM CALIBRATION CAP
M1162058	900K0004-01, CALIBRATION KIT INCL SYRINGE, MANOMETER, 2 LUNGS, 2 RP20 RESISTORS, 4 CAPS

NOTE The above list is subject to change and modification. Contact VersaMed or your authorized dealer for further information.

INDEX

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