*i*Vent$_{201}$

Operator's Manual

VersaMed

***i*Vent$_{201}$ Operator's Manual Part Number OM-01-04**
Rev: 11 **Revised:** December 2006

CE 0473

Manufacturer's Address

P.O. Box 1512, Blue Hill Plaza, Pearl River, New York 10965 USA.

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Calling for Help

Owner's Record

The model number and serial number of your *i*Vent$_{201}$ are on the rear panel of your ventilator. Record the serial number in the space provided below to have this information should you need to call for service or support.

Model Number:	
Serial Number:	

Customer Support and Service

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

800-475-9239 - Customer Care and Service Assistance Line

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

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

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1 Introduction

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

The *i*Vent$_{201}$ supports many modes:

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

(Note: Certain modes are optional features and may not be operational in some *i*Vent$_{201}$ models.)

In addition, the *i*Vent$_{201}$ has these advanced features:

- Rise time is adjustable
- Preset Parameters by Patient Weight enables quick setup
- Adaptive Peak Flow™ can determine and deliver Inspiratory Peak Flow Rate according to a target mandatory tidal volume, maintaining a 1:2 I:E ratio
- Adaptive I-Time™ allows the ventilator to determine and deliver a respiratory cycle time to sustain a 1:2 I:E ratio
- The *i*Vent$_{201}$'s Adaptive Bi-Level feature enables leak-tolerance for facemask ventilation or other specialized high-leak tube ventilation
- Easy Exhale™ is an advanced PEEP mode designed to reduce expiratory work of breathing
- Firmware is upgradeable via a PC connection
- The *i*Vent$_{201}$ is designed to operate according to specifications in any physical orientation – such as during transport use

1.1 How To Use This Manual

You must read this manual before you use the *i*Vent$_{201}$. In particular, the first several sections are critical for an understanding of the *i*Vent. This manual is primarily organized according to the available screens, menus, options and settings and begins with a look at the hardware, including power considerations and patient circuit setup.

Study them with the *i*Vent close at hand, 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

Just about every function or operation of the *i*Vent is accessible through one of these screens. Be aware of the **notes, warnings,** and **cautions**, generally marked in **bold print**.

⇒ **Useful user tips are in bold and set off with an arrow.**

Refer to the index if you need information. Table 1.1 may also be used as a general guide.

If you are not familiar with Adaptive Bi-Level feature, read Section 05 (page 179).

1.2 Looking at the *i*Vent$_{201}$

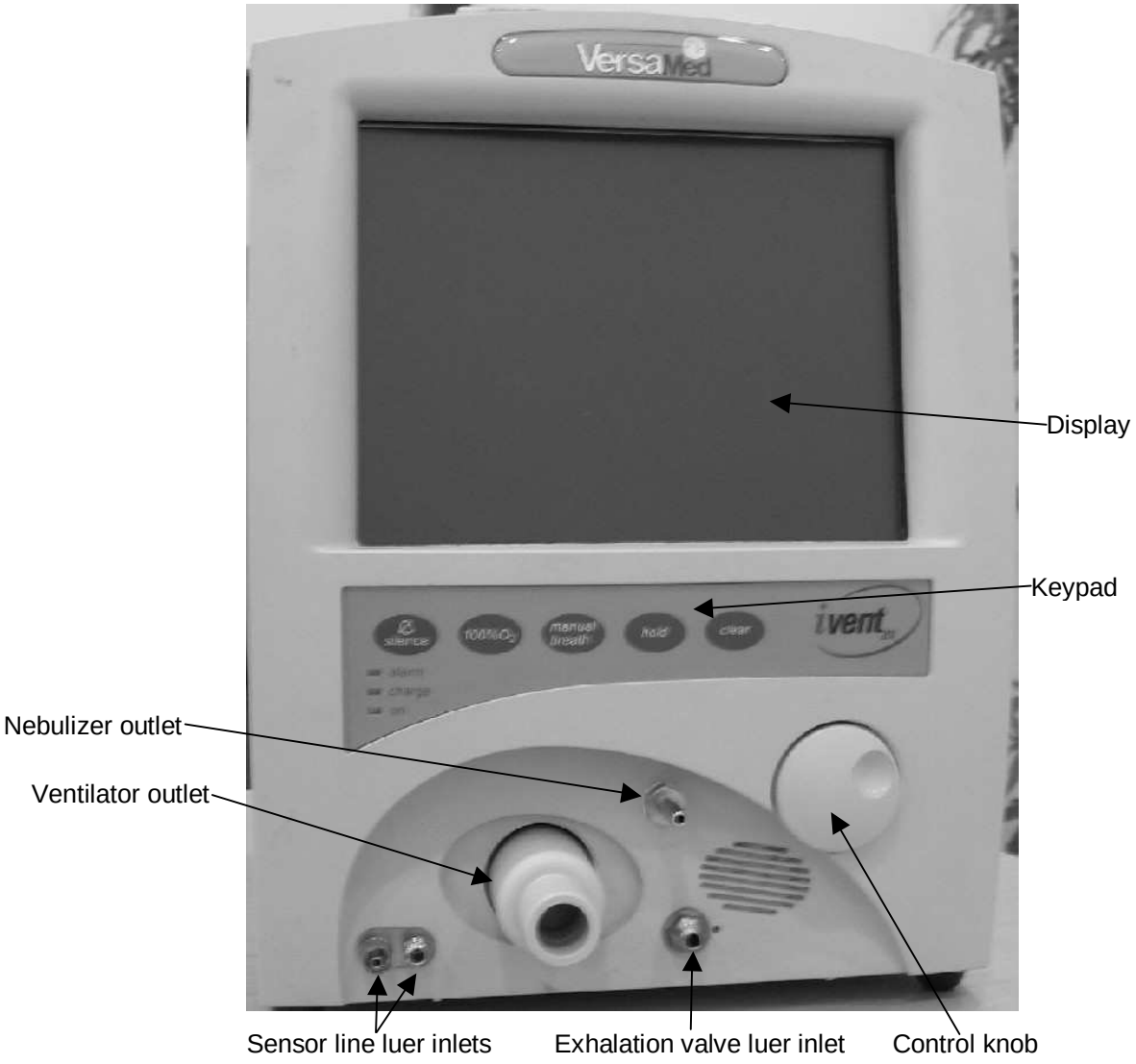


Figure 1.1 Front View of the *i*Vent$_{201}$

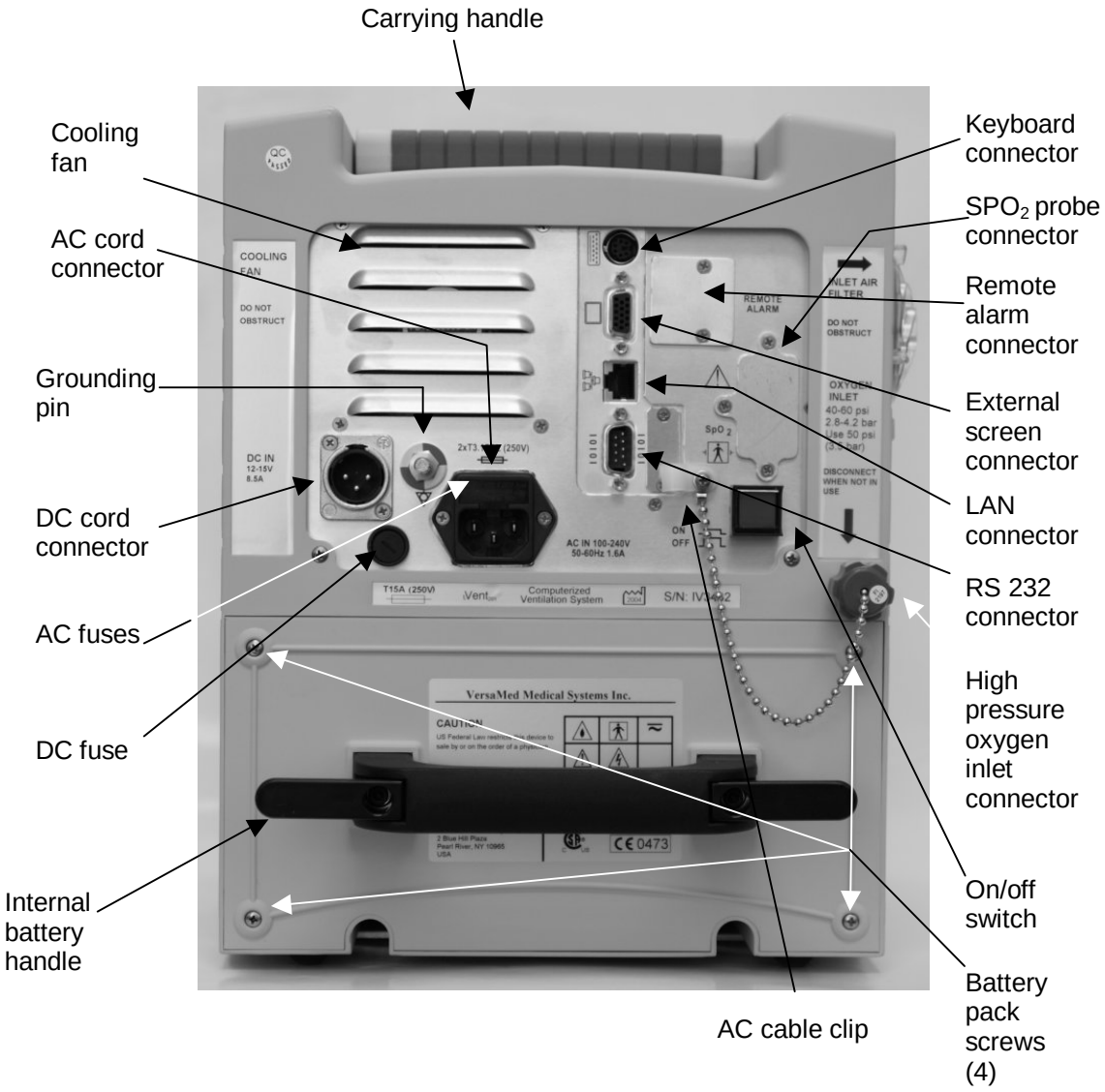


Figure 1.2 Rear View of the *i*Vent$_{201}$

1.3 Cautions and Warnings

WARNING: The *i*Vent$_{201}$ 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.

CAUTION: The *i*Vent$_{201}$ is a restricted medical device to be operated by qualified medical personnel under the direction of a qualified medical practitioner.

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

CAUTION: 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.

WARNING: Do not use the *i*Vent$_{201}$ ventilator to treat infants weighing less than 10 kg/ 22 lb.

CAUTION: The factory default setting for “Leak Alarm” is set to ”off.” Users must manually set the leak alarm to enable it.

WARNING: To prevent explosion hazard, do not use the ventilator in the presence of flammable anaesthetics.

CAUTION: Using the *i*Vent$_{201}$ 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 *i*Vent$_{201}$.

WARNING: Do not cover the *i*Vent$_{201}$ while it is in use. Make sure that the *i*Vent$_{201}$ is positioned so that its inlet ports and cooling vents are open to freely circulating air.

CAUTION: The *i*Vent$_{201}$ must not be operated immediately following storage or transport outside the recommended operation condition.

CAUTION: The *i*Vent$_{201}$ internal battery contains lead and must be disposed of in accordance with local ordinances and environmental regulations.

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

1.4 Symbols and Labels

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

1.5 Performance and Parameters

Ventilation Component	Parameters/ Range	Unit of Measure	Accuracy	Set	Displayed	Page
Respiratory rate	1-12 12-80	bpm	±1 ±2	Y	Y	80
Inspired Tidal Volume Measurement	50-2000	mL	±10%	Y	Y	83
Exhaled Tidal Volume Measurement	50-300 300-2000	mL	±10 mL or ±15% whichever is greater ±10%	Y	Y	
Inspiratory Pressure Limit	5 to 80	cmH_2O	±5	N	Y	87
Inspiratory Time	0.2 to 3 or Adaptive I-Time™	sec.	±10%	Y	Y	98
Peak Flow	up to 120 or Adaptive Flow™	L/min	±10%	Y	Y	91
Peak Flow (Spontaneous)	up to 180	L/min	±10%	Y	Y	91
Oxygen Mix (FiO_2)	21 to 100%		±5%	Y	Y	89
PEEP	0 to 40	cmH_2O	±1 or ±10%, whichever is greater	Y	Y	95
Trigger sensitivity	1 to 20, off -0.5 to –20, off	L/min cmH_2O		Y	Y	96

Ventilation Component	Parameters/ Range	Unit of Measure	Accuracy	Set	Displayed	Page
PSV	0 to 60	cmH_2O	±10%	Y	Y	93
Positive Pressure relief valve	80	cmH_2O		N	N	
Controlled Pressure	5 to 80	cmH_2O	±5	Y	Y	
FiO_2 at power up	21%, 40%, 60%, 100% (selectable)			Y	Y	234
Purging cycle	1, 2, 5, 10, off	minutes		Y	Y	141

1.6 Specifications

1.6.1 Monitored Data Range, Resolution and Accuracy

Parameter	Range, resolution, accuracy
Breath type	**Range:** Type: - Control, assist, spontaneous, 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%

Parameter	Range, resolution, accuracy
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

Parameter	Range, resolution, accuracy
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
Time Constant	**Range:** 0.0 to 9.9 sec **Resolution:** 0.1 sec **Accuracy:** ±20%

1.6.2 Size and Weight

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

1.6.3 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 not operational in all *i*Vent$_{201}$ models.

1.6.4 Environmental Specifications

Operating Temperature	-15 to +50 °C / +5 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

1.6.5 Power Supply

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)

1.6.6 O2 Supply Specifications

Pressure Range	40-60 psi (2.8-4.2 bar)
Minimum flow	120L/min at 40 psi (2.8 bar)

1.6.7 Ventilation Performance and Controlled Parameters

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 Respiratory 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 140 ±10% L/min
Oxygen Mix (FiO_2)	21% to 100% ±5% O_2
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
Controlled Pressure	5 to 80 cm ±5 cm
FiO_2 at Power up	21%, 40%, 60%, 100% (configurable)
Purging Cycle	1, 2, 5, 10 minutes, Off (configurable)

1.7 Standards and Safety Requirements

The *i*Vent$_{201}$ meets or exceeds the following international standards:

ISO 10651-1	**Lung Ventilators for medical use**
ISO 10651-2	**Particular requirements for Home Care Ventilators**
ISO 10651-3	**Requirements for Emergency and Transport Ventilators**
ASTM F1100-90	**Standard Specifications for Ventilators intended for use in Critical Care**
IEC 60601-1	**Electrical Safety**
IEC 60601-1-2	**Electromagnetic Compatibility (EMC)**
IEC 60601-2-12	**Medical Electrical Equipment – Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators**
UL 60601-1	**Medical Electrical Equipment, part1: General Requirements for Safety**
ASTM F1246-96	**Standard Specification for Electrically Powered Home Care Ventilation.**

1.8 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
Exhaled Tidal Volume (V_T)	mL	+	+
Rate	bpm	+	+
Ventilation Mode		+	+

Parameter	Unit of Measure	Set	Displayed
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	+	
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.)			+
In Adaptive Bi-Level Mode:			
P High (Ins Pressure)	cmH_2O	+	+
P Low (Exp. Pressure)	cmH_2O	+	+
Tidal Volume (estimated)	mL		+
Leak (estimated)	LPM		+
Rise Time Setting		+	
Non-Displayed Additional Parameters			
Sigh Breath Setting		+	
Purge Cycle Setting		+	

1.9 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
F_1O_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

1.10 Additional Alarms

Alarms	Indicators and Icons
Low O_2 Pressure	Battery Charge
AC Power Disconnect	Alarm Silence Icon & Timer
Low Battery	Work Hour Counter
Empty Battery	Date and Time
Battery Disconnect	LEDs: ON, Charge, Alarm

Alarms	Indicators and Icons
Over Temperature	Power Source Icon
Check Sensor	Breath Type: Mandatory, Spontaneous, Assist, Hold, or Sigh
Tube Disconnect	Zeroing
Sensor Disconnect	Purging
Patient Disconnect	100% O_2 suction mode
	External DC
Service Notice	
High PEEP	
Need Cal (Calibration)	
Patient Circuit Failed	

1.11 Waveforms and Diagnostics Packages

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

1.12 Intended Use

The *i*Vent$_{201}$ 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 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 *i*Vent$_{201}$ ventilator (with or without the non-invasive Pulse Oximeter option) is suitable for use in the ICU and all other hospital areas, in all hospital-type facilities, alternate-care sites, transport, emergency, and in home environment. The non-invasive Pulse Oximeter is intended for non-invasive monitoring of oxygen saturation and pulse rate and is suitable for use in all the above mentioned areas.

The *i*Vent$_{201}$ ventilator is a restricted device intended for use be qualified, trained personnel under physician supervision.

1.13 Use of the iVent201 with MRi

The *i*Vent$_{201\ MRi}$ model (serial number 5000 and greater) maintains full functionality when operated within the MRI (Magnetic Resonance Imaging) environment, at magnetic field strengths up to 3 tesla, enabling clinicians to perform full body or head scanning without disconnecting the patient from the ventilator.

The Ventilator cannot be subjected to field strengths greater than 100 Gauss and must be kept outside of 100 Gauss perimeter, typically about 2.5 meters from the magnet's Iso-center.

For maximum safety, VerdaMed recommends that each facility measure the Gauss field around their imaging device, and map the strength levels, to insure that the ventilator is not placed inside its safe operating range distance (see the procedure at the end this section).

The mapping should result in placing permanent marking on the floor at 5, 50, 100, and 200 Gauss strength lines with a durable tape. The best practice that we have seen is when the clinical staff put tape marks on the floor where certain equipment can be safely placed within the MRi suite. The safe distances for ventilators may require a special patient circuit to reach the patients while they are internal to the imaging magnets. In such cases, VersaMed offers a 3.8 patient circuit.

It is very probable that older MRi Units may not have magnetic shielding that is 100% effective. Therefore the Gauss levels at a given distance may differ within the same given radius from the center of the magnet core. Hence, this is the importance of correctly mapping out the Gauss levels for each MRi suite.

Warning!	**Use of the ventilator not in accordance with these instruction may cause the ventilator to malfunction.**
Caution!	**Connect the potential equalization pin on the back of the ventilator to ground during battery (DC power) operation.**
	Remove the green cover and attached chain from the high-pressure oxygen fitting.
	To avoid degrading image quality, do not use the static mechanics function during Mri scanning.
	Lock the ventilator cart wheels to prevent inadvertent movement.
Note	**VersaMed recommends using its longer (3.8m/ 12.5 ft) patient circuit when operating in the MRi environment.**

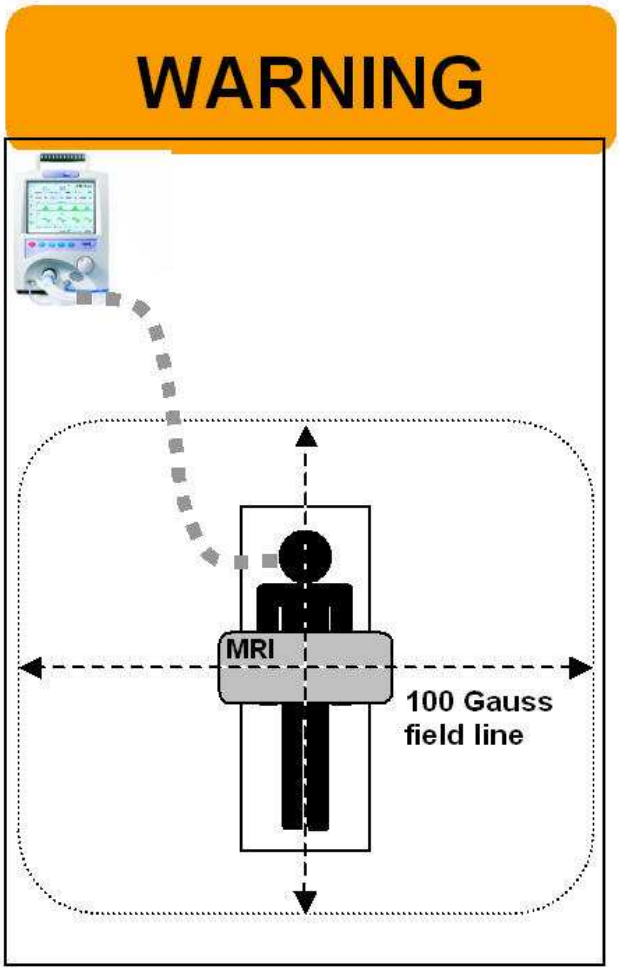


Figure 1.3 Warning Label

The iVent201 was tested with GE-Signa and Intra, Philips-Intera MR scanners of the following maximum performance:

- Static field strength –3 T
- Spatial field gradient – 240 G/cm
- Shielded

The outcomes of the test results were:

- There was no detectable magnetic attraction of the ventilator.
- The operation of the ventilator was not affected.

2 Setting Up

This section shows you how to set up the *i*Vent$_{201,}$ including:

- 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 synchronized nebulizer
- Connecting a pulse oximeter
- Installing filters at the ventilator's inlet and outlet
- Packing the unit in its optional transportation case

2.1 Power Connection

2.1.1 External power

The *i*Vent$_{201}$ 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 2.1). 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 external battery please use VersaMed cable P/N 507A2019

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.

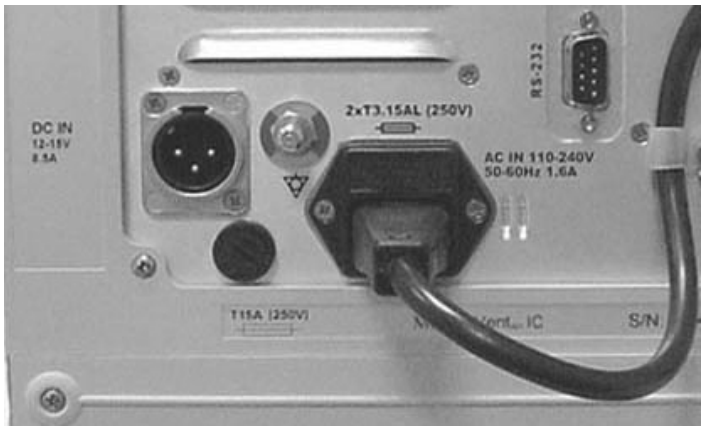


Figure 2.1 External AC and DC power supply sockets. The AC power cord is connected to the power inlet and fastened with the clip.

⇒ **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 *i*Vent$_{201}$ it must be placed in Standby mode. See section 3.1.3, page 69.

When the ventilator is operating, icons at the bottom section of the screen indicate the power state.

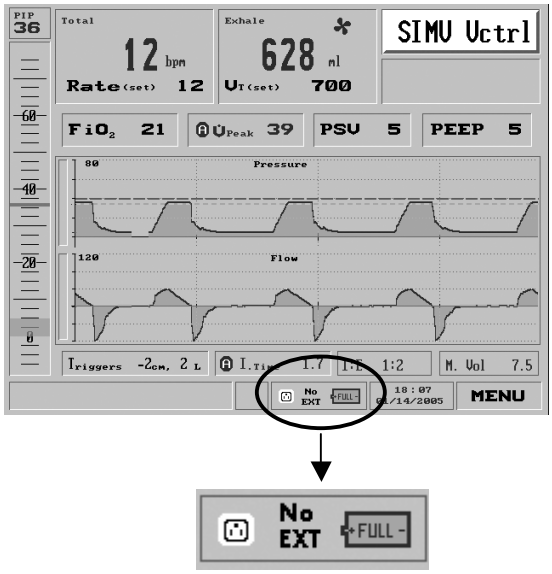


Figure 2.2 On-Screen Power Status Indicator. The ventilator is under AC power, no external battery is connected, and the internal battery is fully charged.

When the *i*Vent$_{201}$ is connected to AC power, the screen shows a 3-pronged power outlet icon:

Figure 2.3 AC power icon

When disconnected from AC power the 3-pronged oulet icon is displayed with a red "X" through it:

Figure 2.4 AC power disconnect icon

When connected to an external DC power source such as a battery, the screen shows "EXT" in blue:

Figure 2.5 On-Screen Power Status Indicator, showing DC power connected and AC power connected.

When disconnected from DC power, the screen shows "No EXT" in black.

Figure 2.6 No External battery connected icon

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.

CAUTION: If the external battery connector is removed from the *i*Vent$_{201}$ IT MUST REMAIN DISCONNECTED FOR 40 SECONDS before plugging it back in.

(The *i*Vent$_{201}$ 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 will draw variable current while it is running, 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 will switch 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.)

2.1.2 Internal Battery

The ventilator will switch to internal battery use 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.

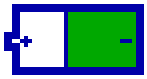
> **CAUTION: The *i*Vent$_{201}$ should only be used with a properly functioning battery.**

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 90 days during normal use**
- **If after 8 hours charging, the battery indicator fails to indicate a full charge**

Table 2.1 The battery indicator

Indicator	Colors	Description	Remarks
	Green	Battery is fully charged	
	Gray/Green	Battery partly discharged	Indicator moves downward in 10% increments
	Gray / Green	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.

2.1.2.1 Full Recharge Procedure

CAUTION: If the "Low Battery" or "Empty Battery" alarm appears, the internal battery must be fully 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.

⇒ **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.
3. Switch on the ventilator. When the opening window appears, select the 70kg patient weight setting.
4. Set the pressure alarm to 60 (cmH_20).
5. Connect the ventilator with a patient circuit to the Rp20 resistor and test lung.
6. Press "START" on the ventilator. (See Section 3.1.1, page 63 for directions on starting the *i*Vent$_{201}$.)
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 battery alarm will sound and a pop-up window will appear. Press the red Silence button on the keypad to remove the pop-up window and stop the alarm.
9. Now 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 (see page 69), then switch it off. Connect the AC power cord.
11. Let the unit charge for at least 10 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.

2.1.2.2 Battery Pack Replacement

12. Disconnect the unit from external power.
13. With a #1 Phillips-head screwdriver, remove all four screws from the battery pack plate.

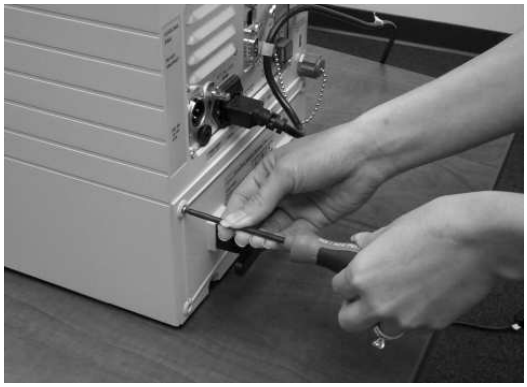


Figure 2.7 Unscrewing the battery pack

14. Using the handle, pull the battery pack out.

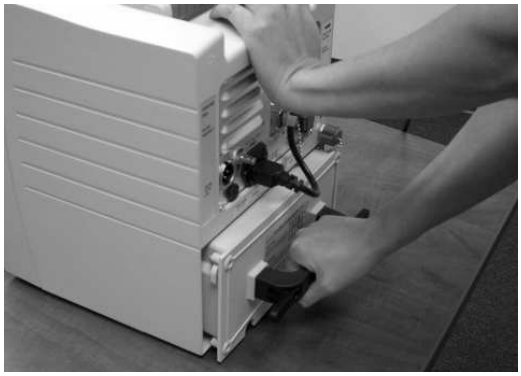


Figure 2.8 Removing the battery pack

15. Carefully slide the new battery pack into the chassis. Be sure it is properly aligned.
16. 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.
17. Reattach the four screws.
18. Charge the battery by following the instructions in Section 2.1.2.1, "Full Recharge Procedure."

2.2 Oxygen Supply

The *i*Vent$_{201}$ can use medical-grade oxygen from either

- a high-pressure source such as a central supply system or cylinder at 40-60 psi, or
- a low-pressure oxygen source -- oxygen concentrator or flow meter device -- using the optional Low Flow Oxygen Enrichment System (part nos. 660L0001-12, 620B0009-01, 620B0010-01)

When connecting the *i*Vent$_{201}$ to an oxygen supply, you must ensure that the correct type of oxygen source is selected in Advanced Settings. [Main Screen/Menu/Advanced Settings/Oxygen Supply (Pressure)] (See section 4.3.4, page 132.) The factory default is High pressure.

2.2.1 High Pressure Oxygen Supply

If using pressurized oxygen, connect the oxygen supply to the oxygen DISS inlet connector at the back of the ventilator.

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

CAUTION: Verify that the oxygen supply is at the correct pressure before connecting to the DISS inlet.

When High O_2 is selected, and the unit is ventilating the measured concentration of delivered oxygen may be viewed on the Alarm Settings screen. (See section 4.3.4, page 132 for more information about using the *i*Vent$_{201}$ with an oxygen supply.)

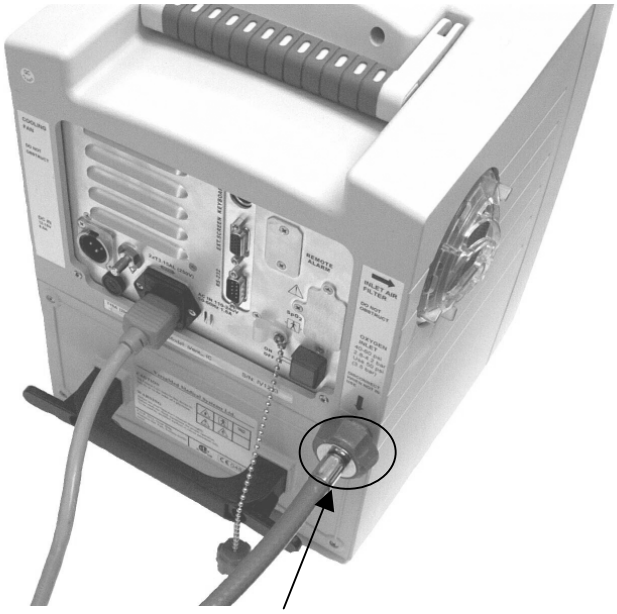


Figure 2.9 The oxygen DISS inlet connector

CAUTION: When using the *i*Vent$_{201}$ with a pressurized oxygen supply, the accuracy of the oxygen concentration should be verified periodically with an external calibrated oxygen analyzer.

2.2.2 Low Pressure Oxygen Supply

1. Connecting a Low Pressure O_2 Supply Adapter requires a Low Pressure O_2 Filter/Adapter, fitted with a 22mm female port. Remove the air inlet filter by turning it counterclockwise. Then install the Low Pressure O_2 Filter/Adapter with a clockwise turn.
2. You are now ready to connect the Low Pressure O_2 Supply Adapter to the air inlet port of the ventilator.

Figure 2.10 Low Pressure O_2 supply adapter and filter installed

3. Be sure that "Low" is selected under "Oxygen Supply (Pressure)" in the Advanced Settings menu (see page 132).

CAUTION: Do not attempt to use the FiO_2 option above 60% when using a low pressure oxygen supply.

CAUTION: When not **using a Low Pressure O_2 Supply, the Low Pressure O_2 Filter must** NOT **be used, as the 22mm port could easily be blocked.**

When Low O_2 pressure is selected in the Advanced Settings window, the analyzed FiO_2 level is displayed in the Main window of the screen.

2.3 Breathing Circuit

The *i*Vent$_{201}$ breathing circuit is disposable and intended only for single-patient use. Never reuse or attempt to clean a single-use breathing circuit or any of its components.

⇒ **Only breathing circuit accessories approved by VersaMed or authorized VersaMed dealers should be used with the *i*Vent$_{201}$.**

- The Inspiratory Limb consists of a connector at one end of corrugated tubing, with a one-way valve connected to the Patient Wye (also referred to as the Wye Sensor) at the other end.

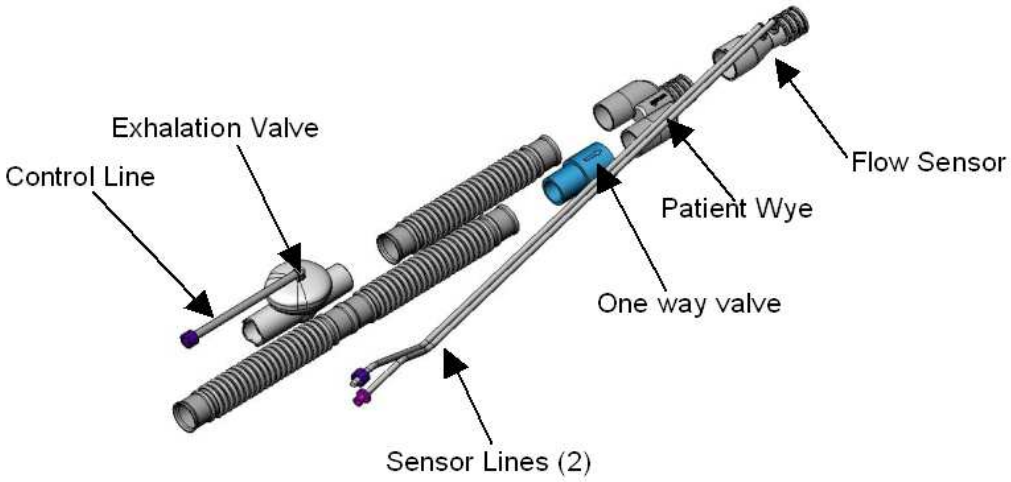


Figure 2.11 Patient circuit connections (breathing circuit)

- The Patient Wye contains a flow sensor which is connected by two sensor tubes to 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, leading back to the ventilator front panel. (See Figure 2.11).

To connect a patient circuit:

1. Twist the knurled, light-blue connector of the inspiratory limb onto the main hose connector. The connector should fit snugly.
2. Connect the first flow sensor tube – closer to the end of the patient Wye, to the left male luer inlet of the ventilator by pushing the opening of the tube inside the inlet and twisting it clockwise until it is locked in place. (Notice that the bayonet-style male luer is different from the screw-fitting female luer mount of the second sensor inlet.)
3. Connect the other flow sensor tube to the second sensor inlet of the ventilator by twisting the knurled end of the tube onto the luer lock.
4. Fasten the blue Expiratory Valve Control Line to the female luer connector on the right side of the ventilator, marked with a blue dot, by twisting the knurled end piece of the tube onto the inlet.

5. Ensure that all connections are secure and airtight.

WARNING: Before connecting a patient to the ventilator with a new circuit, you must perform a complete Operational Verification Test (O.V.T.). See Section 3.1.2, page 65.

2.3.1 Circuit Resistance

It is important to check the inspiratory and expiratory resistance specficiation of the patient circuits used with the *i*Vent$_{201}$ 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 (6cmH_2O) at 60 L/min for adult patients.
- O.5 KPA (5cmH_2O) at 30 L/min for pediatric patients.

2.4 Other Connections

2.4.1 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 *i*Vent$_{201}$ breathing circuit may increase the pressure gradient.

2.4.2 MDI

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

2.4.3 Using the *i*Vent$_{201}$ with Heated Humidification (1.4 models only)

To use the *i*Vent$_{201}$ with a heated humidifier:

1. Disconnect the Inspiratory Limb from the ventilator outlet of the *i*Vent$_{201}$ 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. Now, 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 *i*Vent$_{201}$ as described above in section 2.3. Connect the blue expiratory sensor tube to the luer connector marked with a blue dot on the front of the ventilator.

Figure 2.12a The iVent201 shown connected to a Fisher and Paykel heated humidifier model MR850

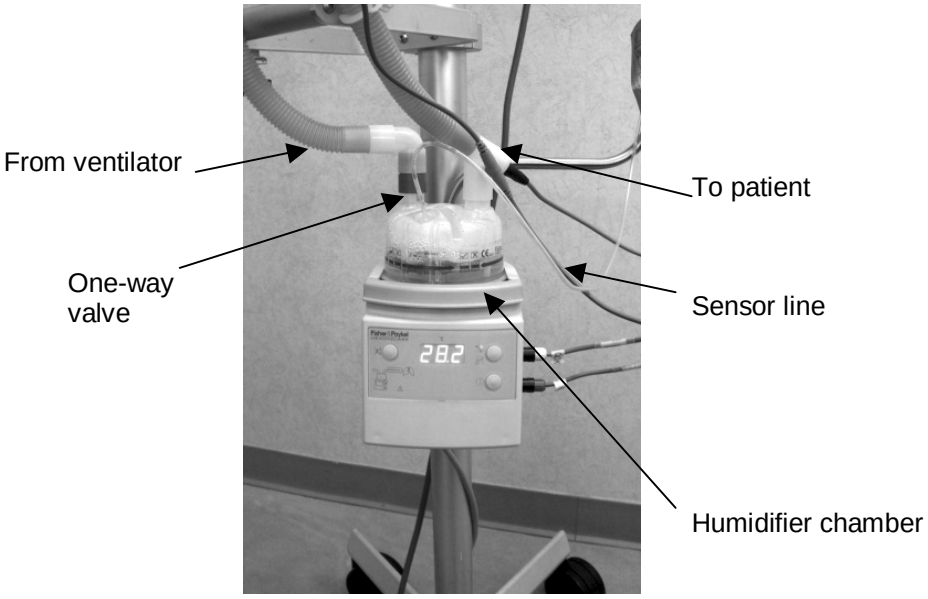


Figure 2.12b Heated humidifier connections

⇒ **If not using a heated wire circuit, placement of a water trap at the lowest point of the inspiratory limb is highly recommended.**

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

NOTE: 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 tubings, always keep the patient sensor tilted upward.

2.4.4 Synchronized Nebulizer Device

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

⇒ **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 in the Oxygen Supply in the advance menu (see section 4.3.4 on page 132).

1. Connect the Nebulizer tube to the Nebulizer outlet on the front panel. The nebulizer icon appears in the lower bar of the display, showing that the nebulizer is connected but not activated.

figure 2.13 Nebulizer connected icon

2. Install the Nebulizer with the desired medication to the patient circuit after the Wye and the flow sensor, without or after the HME filter.
3. Connect the other side of the Nebulizer tube to the Nebulizer.

2.4.5 Pulse Oximeter

A pulse oximeter can be connected to the *i*Vent$_{201}$ ventilator allowing the operator to continuously monitor patient's oxygenation saturation on the iVent screen.

⚠ **Warnings**

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 iVent201 ventilator:

1. Remove the pulse oximetry 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. See the figure below.

Figure 2.14 Pulse Oximetry Connectors

2. Connect the pulse oximetry sensor to the gray end of the unit connector cable (see the figure below).

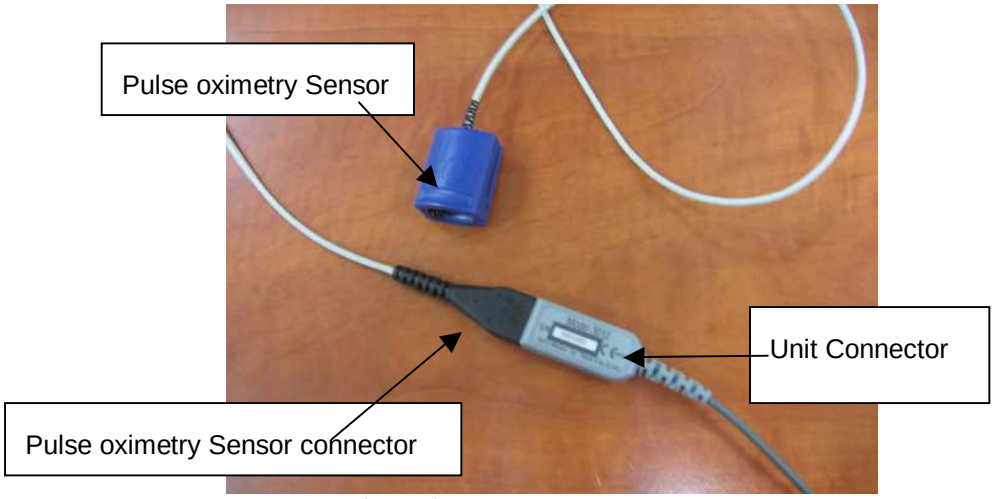


Figure 2.15 The Pulse oximetry Sensor

3. At the rear panel of the *i*Vent$_{201}$ device, connect the following:

- The **Keyboard** connector to the **Keyboard** port.
- The **RS-232** connector to the **RS-232 (COM-2)** port, the port on the right side of the machine. (See the figure below).

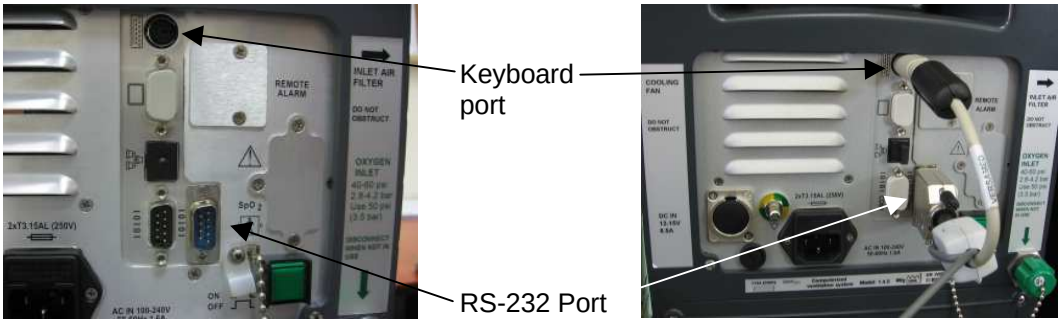


Figure 2.16 *i*Vent$_{201}$ Rear panel

2.4.6 Sensor Line Maintenance

The *i*Vent$_{201}$ monitors the sensor lines and periodically sends pressurized air through the lines to clear them of any accumulated material. Nevertheless it is possible for secretions and/or condensation to accumulate. Should these become evident:

1. Do not attempt to clean sensor lines while a patient is connected to the *i*Vent$_{201}$.
2. Disconnect the sensor lines from the connectors on the *i*Vent$_{201}$.
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.

2.5 Patient Connection

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

Also, the patient Wye should be angled downward, to help prevent fluid accumulation.

2.6 Filters

WARNING: Do not use the *i*Vent$_{201}$ without the air-inlet filter and a bacterial filter before the patient circuit.

2.6.1 Air Inlet Filter

The air inlet filter (part no. 660A0001-12) screens out particulate matter from ambient air.

Figure 2.17 Air inlet filter

WARNING: Failure to use an air inlet filter may result in severe damage to the internal components of the *i*Vent$_{201}$.

The air inlet filter must be replaced every 500 hours or every thirty days of operation. See Section 7.1, page 221 for air filter maintenance procedure.

2.6.2 Bacterial Filter

A user-supplied bacterial filter prevents contamination of the patient circuit components, and prevents bacteria, excessive humidity and liquids from entering the *i*Vent$_{201}$

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

2.6.3 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 *i*Vent$_{201}$ via an optional air inlet adapter (item 504A0110-A0). First, remove the air inlet filter from the *i*Vent$_{201}$ 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.

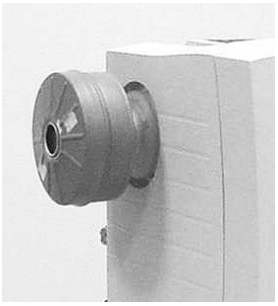


Figure 2.18 CBRN filter

2.7 Operational Case

With an optional soft case (item 375B0004-01) the *i*Vent$_{201}$ can be operated in inclement conditions, such as rain or snow. Padding and protected ventilation ports enable full function in a variety of situations.

Figure 2.19 Soft case

Operating the *i*Vent$_{201}$:Overview

This section shows you how to operate the *i*Vent$_{201}$:

- Introduction to the user interface
- Controls and powering up
- Operation

2.8 The *i*Vent$_{201}$ User Interface

Take some time to acquaint yourself with the *i*Vent$_{201}$ and how the control knob is integrated with the screen and the operation of the *i*Vent$_{201}$. Connect a test lung with an Rp20 resistor and patient circuit. Switch on the unit, and proceed through the first several parts of 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 *i*Vent$_{201}$ and selecting the patient's ideal body weight.

2.9 Controls and Powering Up

2.9.1 The Front Panel

Located above and to the right of the ventilator outlet, the **rotational control knob** allows control of and access to all the ventilator functions via the LCD screen. Turning the knob will change a value, or move through a menu screen or through a roster of choices. Press the knob and the *i*Vent$_{201}$ will respond

Figure 2.20 The *i*Vent$_{201}$ front panel

with a tactile click and audible feedback – to select or confirm a choice, or to access another menu. Where a numeric value is required, selection is as simple as 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, then immediately return you to the previous screen.

Five dedicated keys are positioned below the LCD:

- **silence** is used to immediately mute the audible alarm and minimize the corresponding red pop-up message. It then activates a two-minute timer and appears in the lower right corner of the display instead of the time-date field, alongside the Silenced alarm icon.

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

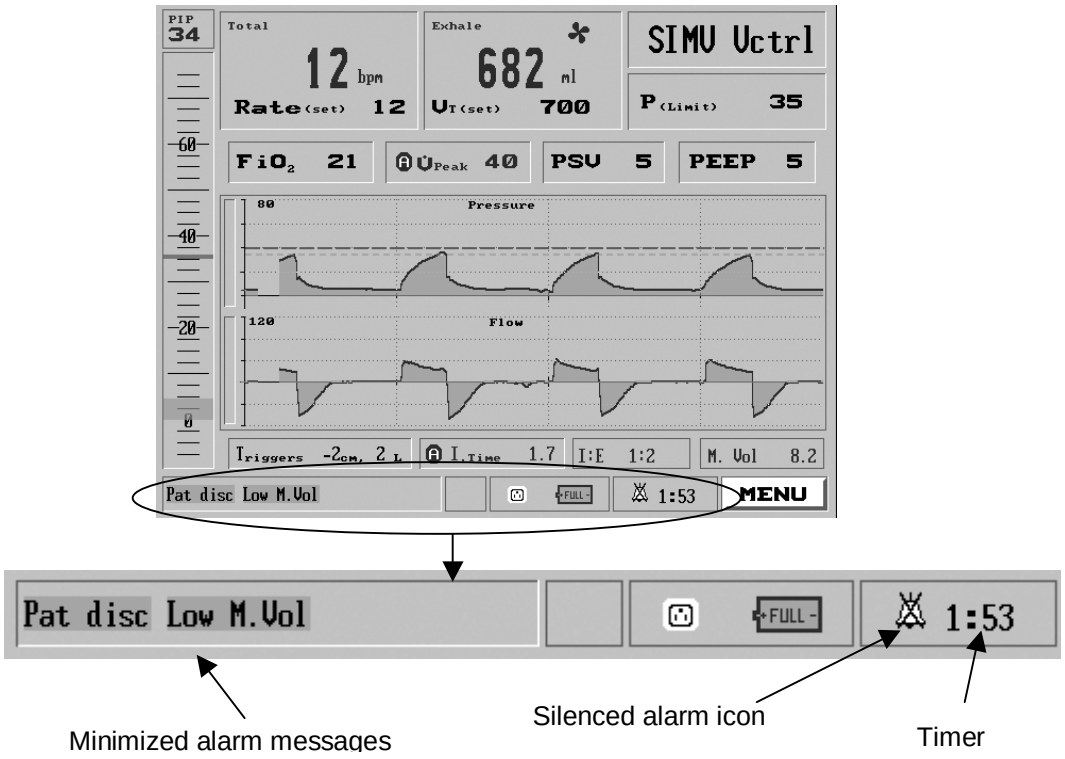


Figure 2.21 Status window after alarm has been silenced

- **100% O_2**, when activated, provides three (3) minutes of 100% oxygen and two minutes of alarm silence.
- **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 will be set according to the default volume control for the specified patient weight chosen at startup.
- **hold** activates and/or cancels the Hold manuever. Pressing the button once initiates an inspiratory hold manuever, which will allow the calculation of static compliance. Pressing it twice will initiate an end expiratory hold manuever, which will allow the calculation of intrinsic PEEP. For more details see Appendix F page 277.
- **clear** has several functions. Pressing it will:
  - **a)** 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
  - **b)** minimize any red alarm-warning pop-up box and mute the alarm sound for 30 seconds

i) If **clear** is pressed again within 30 seconds, an alarm warning pop-up appears.

c) When **clear** is pressed and held, all corrected alarm messages (displayed in green) are cleared.

2.9.2 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 *i*Vent$_{201}$ detects an alarm condition.
- The amber **charge** LED lights to indicate that the *i*Vent$_{201}$ is connected to external power.
- The green **on** LED shows that power is switched on.

2.9.3 The Screen

The LCD screen is organized to allow rapid access to all of the ventilator's functions. Monitoring or control of any critical parameter is never more than a couple of clicks away.

- Baseline indicators and alarms – emergency alerts and alert status indicators, power and battery state, date and time, and the Menu access button -- are 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 2.19) is the first screen displayed when the *i*Vent$_{201}$ 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 portion of the screen, a large box 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. **Selecting** the Respiratory Rate box enables changing the number of breaths per minute.

Beside the Respiratory Rate box is the Tidal Volume box. This displays the exhaled Tidal Volume and allows adjustment to the set Tidal Volume. (Refer to section 3.3.2, page 83 for more detail about the Tidal Volume display.)

On the top right of the screen is the **Mode Selection** box. It shows the current ventilation mode. Select this box to change modes (see section 3.1.4 , page 69).

Selecting and clicking on a mode brings up the **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 section 4.5, page 157 for a guide to the waveform package.)

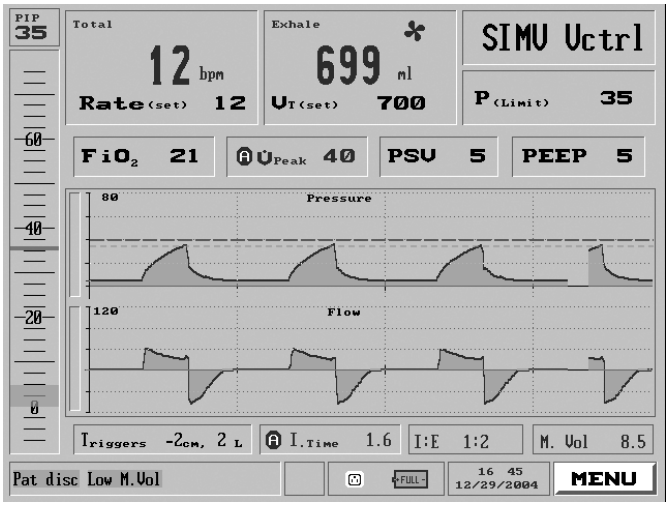


Figure 2.22 The Main Screen

If a pulse oximeter is connected to the iVent the SpO2 levels and Heart rate are displayed on the lower right side of the screen.

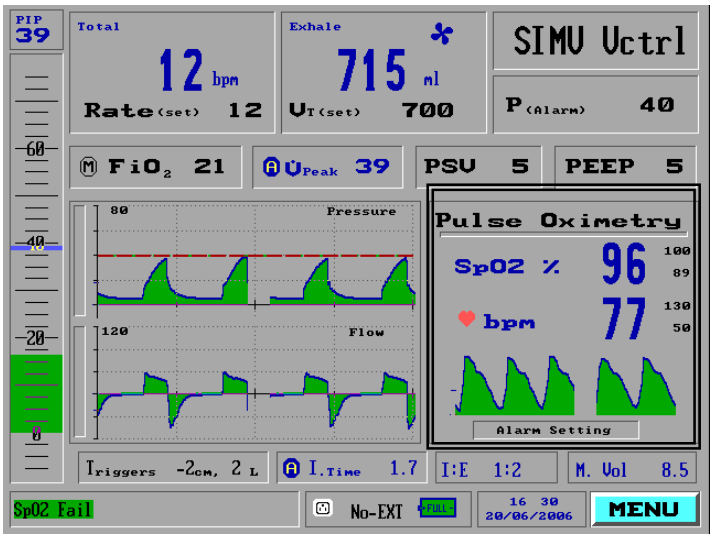


Figure 2.23 The Main Screen with the pulse oximetery monitoring

3 Operating the *i*Vent$_{201}$ – Setting Modes and Parameters

The *i*Vent$_{201}$ offers advanced capabilities for adjusting ventilation parameters for each mode. In this section you will learn how to

- Start the ventilator by 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 *i*Vent$_{201}$
- Reset parameters to default values
- Change Alarm controls and parameters
- Recall and adjust data with the optional Waveforms package
- Use and control of features such as Autostart

3.1 Operation

3.1.1 Power Up and Weight Selection

If you have installed a patient circuit you are ready to begin operating the *i*Vent$_{201}$. 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 bootup process completes (after approximately thirty seconds) you will hear a beep and the screen asks you to select the patient's body weight which sets the default ventilation parameters.

Figure 3.1 The patient weight selection pop-up

⇒ **Parameters for all the *i*Vent$_{201}$'s possible ventilation modes are set when you choose a patient weight upon startup. For a view of the default parameters according to weight, see Tables 4-1 through 4-4 in Section 4.4.1, page 153.**

⇒ **The default selection for patient weight range for the *i*Vent$_{201}$ is 70+kg. This may be changed using the Configuration utility described in Section 7.5.2, page 233.**

As a safety measure, within a few seconds after the patient weight selection pop-up appears, the *i*Vent$_{201}$ generates airflow to see if resistance is encountered in the patient circuit. (The patient may be connected). If a possible patient connect is confirmed, the *i*Vent$_{201}$ enters an auto-start mode of pressure control that will be safe for pediatric through adult patients.

- If the *i*Vent$_{201}$ 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 *i*Vent detects no airway resistance, it enters Standby mode. During this state, if flow is detected in the patient circuit the *i*Vent$_{201}$ will also auto-start.

3.1.2 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 a minute, checks the integrity of the breathing circuit.

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. Switch on the *i*Vent$_{201}$. When it has finished booting and you are presented with the opening *i*Vent$_{201}$ pop-up, press the control knob to accept the patient weight (70+ kg is the default). Notice that the START box is highlighted bright blue. The *i*Vent$_{201}$ is now in Standby mode.

If this is the first time you have used the *i*Vent$_{201}$ turn the control knob to see how the highlighted section of the screen changes. The control knob is how you will control almost all functions and choices on the *i*Vent$_{201}$.

2. Since you wish to perform an O.V.T., rotate the knob until the O.V.T. box is highlighted in bright blue. Now, press the control knob until you hear a click. The screen will display a box labeled "O.V.T. Instructions."

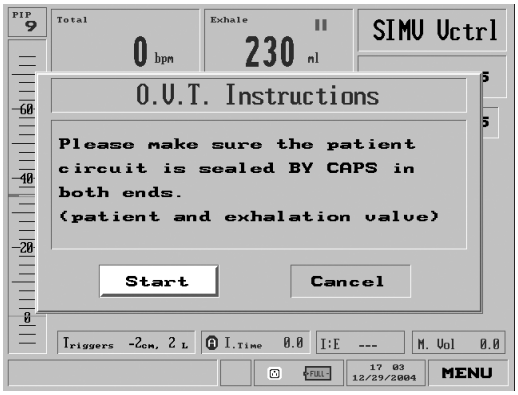


Figure 3.2 The initial O.V.T. pop-up

3. Follow the instructions on the screen. Use the plastic caps to seal off:
   - **a)** the patient Wye sensor, and
   - **b)** the exhalation valve.
4. Press the knob to begin the test. A pop-up appears, indicating the test has begun.
5. After several seconds, another pop-up directs you to remove the cap on the exhalation valve, leaving the cap on the Wye sensor.
6. After the ventilator performs further testing, it will sound an alarm. If you can hear the alarm, press the control knob to complete the O.V.T.

Once the *i*Vent$_{201}$ has successfully completed the O.V.T., the patient circuit and ventilator are ready for use.

If the O.V.T. fails to complete successfully:

a) Verify that both Flow Sensor tubes are properly and snugly connected to the correct luer ports on the front of the *i*Vent$_{201.}$ (Remember: two lines go to the patient Wye connectors, and the blue line goes to the Expiratory Valve Control connector.) Repeat the test.

b) If the O.V.T. fails once again, then replace the patient circuit.

c) 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.

3.1.3 Standby and Patient Ventilation

When you have selected the weight, the *i*Vent$_{201}$ will enter Standby, ready to ventilate the patient with a press of the control knob. By default *i*Vent$_{201}$ starts up in SIMV Volume control.

To start ventilation from Standby, return to the Main Screen, rotate the control knob until the Start box is highlighted, then press the control knob.

To return the ventilator to Standby mode: return to the Main screen, turn the control knob to highlight the Mode Selection box on the top right of the LCD display, and press the control knob. At the bottom of the drop-down menu is Standby. Dial the knob until Standby is selected, and press. The ventilator will suspend operation, and can be started again by selecting Start on the Main screen and pressing the control knob.

⇒ **Always return the *i*Vent$_{201}$ to Standby mode before powering down.**

3.1.4 Changing Ventilation Mode

The Mode Selection box is on the top right side of the LCD display:

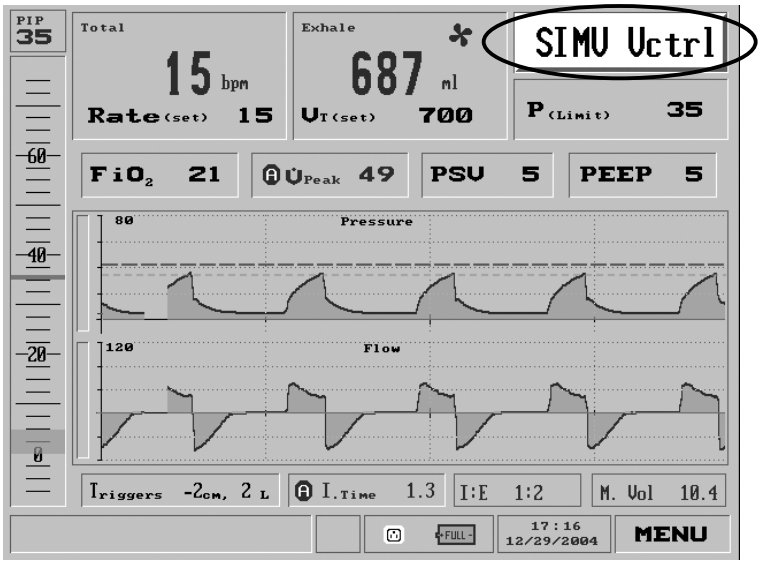


Figure 3.3 The Mode Selection box highlighted

NOTE: Depending on which *i*Vent201 model you have purchased, not every mode may be available.

To change the mode, simply turn the control knob to highlight the Mode Selection box, then press. You will be presented with a screen offering six choices, plus Standby:

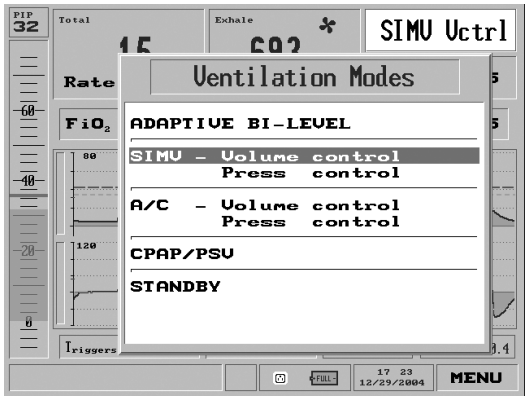


Figure 3.4 The Ventilation Modes Selection pop-up menu

Turning the control knob moves the highlight bar through the choices. When the desired mode is highlighted, press the knob to accept it. This will bring up a parameter screen 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 you are in the Main window.

⇒ **To return to the Main window, press the clear key on the keypad below the display. This will cycle you back through all previous screens until you return to the Main screen.**

2. From the Main screen, turn the control knob until you highlight the Mode Selection Box. By default, the *i*Vent$_{201}$ starts in SIMV Volume Control, abbreviated "SIMV Vctrl."

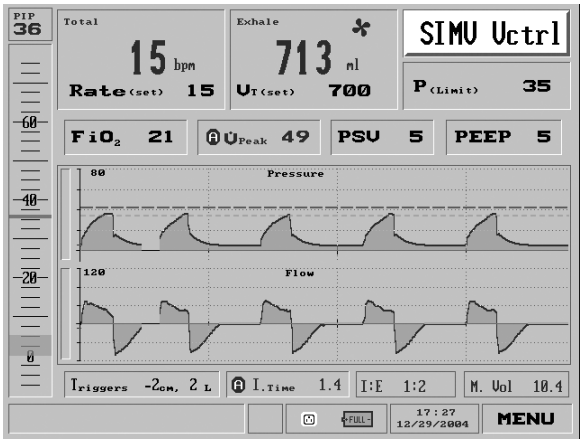


Figure 3.5 SIMV Vctrl mode shown selected

3. Pressing the control knob brings up the Mode Choice screen. Turn the knob clockwise one click to highlight Pressure Control:

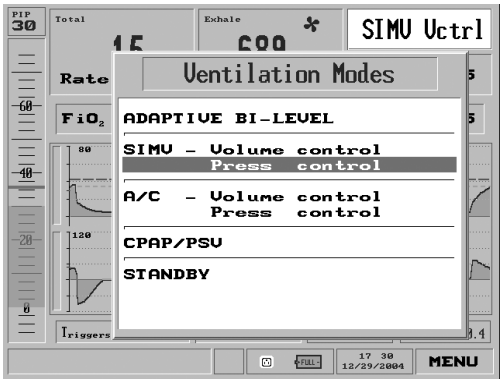


Figure 3.6 Pressure Control highlighted on the Ventilation Modes choice pop-up

4. Press the knob to accept the selection. This will bring up the Parameters window for SIMV Pressure Control:

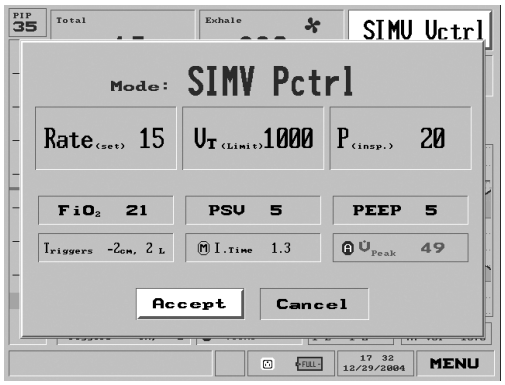


Figure 3.7 The SIMV Pressure Control parameters screen

5. Notice the Accept box is automatically highlighted, making it possible to accept the default parameters immediately and go directly into patient ventilation, once you have verified the settings are correct for the patient.

NOTE: The mode is not changed, and changed parameters are not accepted, until the user presses Accept.

3.1.5 Changing Ventilation Parameters - Overview

CAUTION: Only a fully qualified professional should change these settings.

The *i*Vent$_{201}$ provides two different ways to change ventilation parameters: through the Main screen and through the Mode Parameters screen.

⇒ **If you wish to quickly change one parameter setting, the fastest way is through the Main screen. If you need to adjust several settings at once, call up the Mode Parameters screen and make each required adjustment. When you have set each parameter, you can accept all of them at once.**

1. Through the Main screen:
   - **a)** Return to the Main screen -- if you are not already there, press the Clear button until you return to it.
   - **b)** Turn the control knob to select the parameter you want to adjust.
   - **c)** Press the control knob
   - **d)** Adjust the setting to the desired value.

e) Press the control knob again to confirm your changes and return to the Main screen.

2. Through the Mode Parameter screen:

a) If you are not already in the desired Parameter window, from the Main window, choose the Mode Selection box and select the desired ventilation mode.

b) Dial the control knob to select the particular setting you wish to change.

c) Press the knob to call up the setting's control window.

d) Turn the knob until the parameter has been changed to the desired level or value.

e) Press the knob again to "lock in" the setting. You will be returned to the Mode screen.

f) Continue through the other parameter options, choosing and changing until you have set all the values you want. Once you have finished, return to the Main Window by highlighting **Accept** on the bottom of the screen. Press the knob and your new selections will be saved.

⇒ **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:**

a) Return to the Main window

b) Select the **Menu** box, then press the control knob to call up the Main Menu choices pop-up window

c) Select **Restore Defaults** on the pop-up

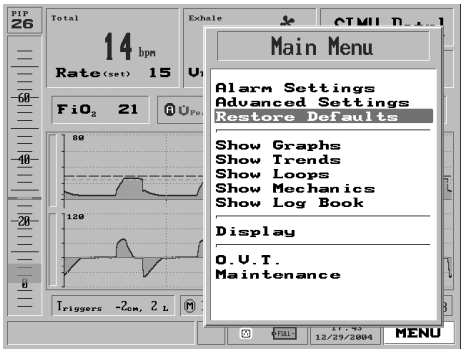


Figure 3.8 Restore Defaults highlighted on the Menu pop-up

d) Then press the control knob. A large red Warning pop-up will appear:

Figure 3.9 The Restore Defaults warning

e) Be sure you wish to restore the defaults. Move the control knob to **Confirm** and press.

f) The **Restore Default Params** pop-up will appear. Make sure the patient weight selection is correct. If it is not, adjust it using the control knob.

g) Press the control knob again. All the *i*Vent$_{201}$'s settings will immediately return to defaults and you will be returned to the Main Menu.

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 Section 4.4.1, page 153.

3.2 Common Parameters

This section details how to change

- Breath rate
- Tidal volume
- Pressure limit
- Oxygen level
- Peak flow
- Pressure support
- PEEP
- Triggers
- Inspiratory time

3.3 The Selection Interface

Most of the quantitative parameters are presented in the form of an oval dial featuring black numerals – in the iVent201 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 recommended ranges are outlined in red.

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 will take you back to the Main screen. The new value(s) you have selected will now be shown in black.

⇒ **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:**

a) Return to the Main window

b) Select the **Menu** box, then press the control knob to call up the Menu choices pop-up window

c) Select **Restore Defaults** on the pop-up

3.3.1 Adjusting Breath Rate

Select the Respiratory Rate settings box from the topmost left side of the Main screen

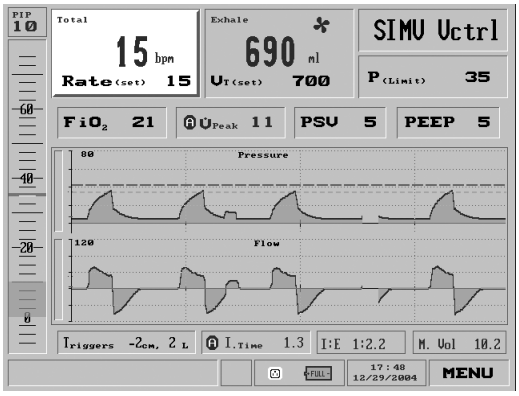


Figure 3.10 The Respiratory Rate selection highlighted on the Main screen (SIMV Volume)

or the Mode Parameter screen

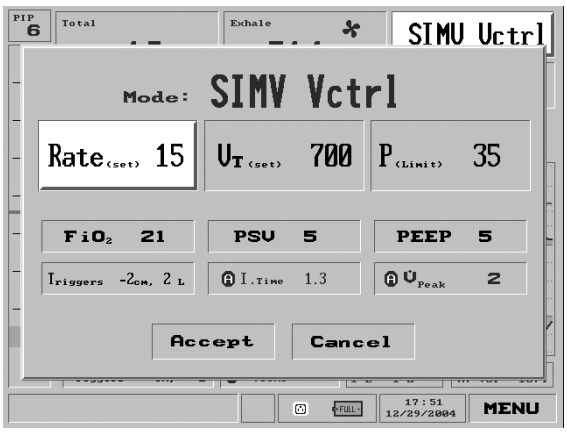


Figure 3.11 Respiratory Rate selection highlighted on the Mode Parameter screen (SIMV Volume)

Press the control knob to call up the Set Rate pop-up.

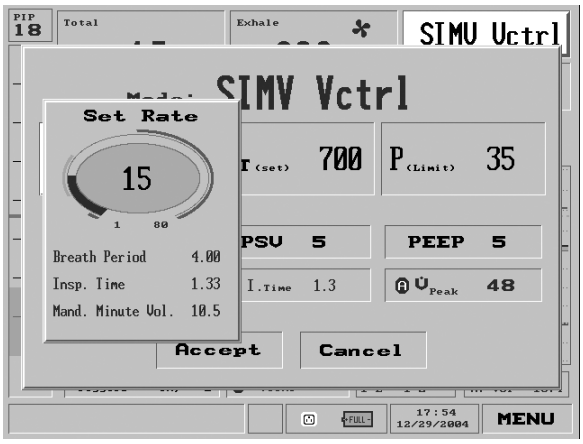


Figure 3.12 The Set Rate pop-up

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. As a precaution, if a rate exceeds or fails to meet recommended settings for the patient weight, a bright yellow Caution! flag appears.

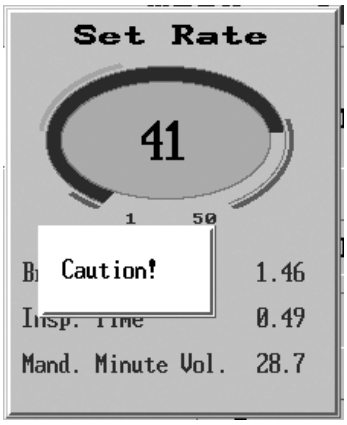


Figure 3.13 This Respiratory Rate setting of 41 exceeds the recommended value

When you have chosen the new value, press the control knob to confirm and accept.

Note: Certain modes and values described in this section are not operational in all *i*Vent$_{201}$ models.

Notes:

a) 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 T_{insp} above 2 seconds.

b) When the setting for Inspiratory Time is "Manual" this set value is continuously displayed at all breath rate values.

3.3.2 Adjusting Tidal Volume

Select the Tidal Volume (or in Pressure Control Volume Limit) setting from the top middle section of the Main screen:

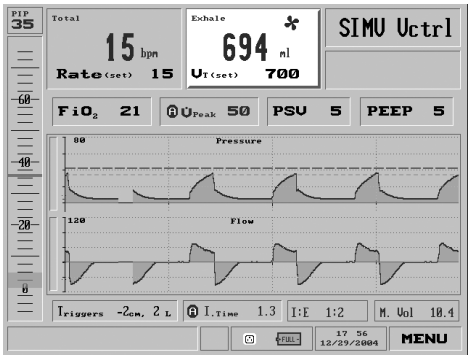


Figure 3.14 Tidal Volume shown selected on the Main screen

or the Mode screen:

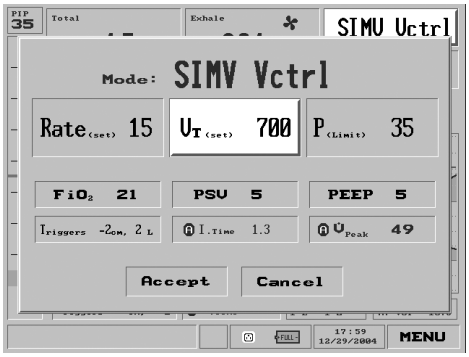


Figure 3.15 Tidal Volume shown selected on the Mode screen

to bring up the Tidal Volume pop-up.

Figure 3.16 the Tidal Volume pop-up

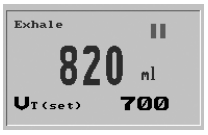
Turn the control knob to change the Tidal Volume. When you have set the knob to the desired level, press to confirm and accept the new value. If you wish to abort the change, press the **clear** button.

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

3.3.2.1 Breath Types

The upper left corner of the Tidal Volume portion of the Main Screen (see Figure 3.17) also indicates the type of breath delivered, by displaying one of several icons beside the exhale volume.

1. **Double Bar – no measurement**



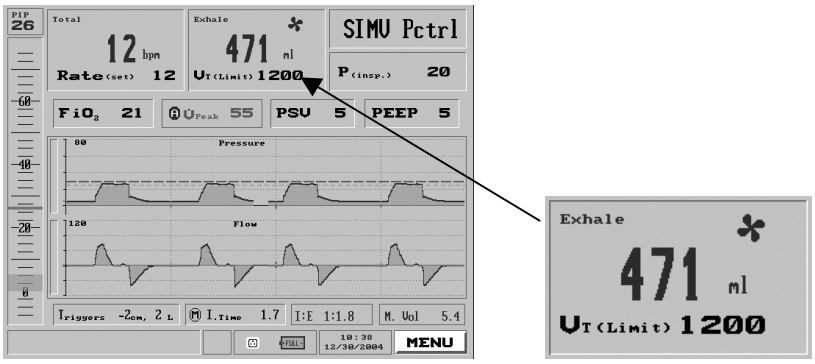
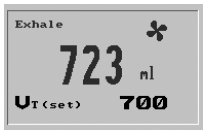


Figure 3.17 The Tidal Volume window, with the breath type icon displayed

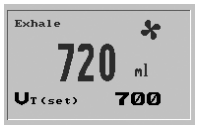
2. Mandatory Breaths

a) Pink Fan: Mandatory Assist Breath (patient initiated)



The *i*Vent201 has responded to patient initiation by delivering a breath

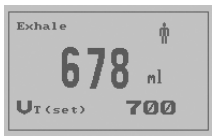
b) Blue Fan: Mandatory Ventilator Breath (ventilator initiated)



The *i*Vent201 has delivered a breath without patient initiation

3. **Green Sigh: Sigh Breath**

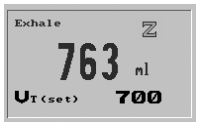
4. **Pink Man: Pressure Support Breath**



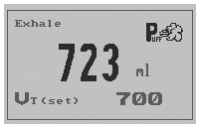
In SIMV and CPAP/PSV modes, the ventilator has delivered a patient breath that has elevated the inspiratory pressure above PEEP.

5. **Green Z: Automatic Zeroing of Sensors**

The *i*Vent$_{201}$ has calibrated itself to ensure that the sensors are measuring accurately.



6. **Blue P: Purge sensor lines function activated**



Periodically, the *i*Vent$_{201}$ will send a puff of high-pressure air through the sensor lines to clean them. You can set the purging interval through the Advanced Menu (see section 4.3.6, page 141). This icon indicates that the sensor lines have just been purged.

3.3.3 Adjusting Pressure Limits in Volume Control Ventilation Modes

When the *i*Vent$_{201}$ is in a Volume Control ventilation mode, to adjust the cutoff pressure or **P(Limit)**, select the box in the top right corner of the Main screen, below the Mode Selection (in Pressure control modes the box becomes $P_{(insp)}$):

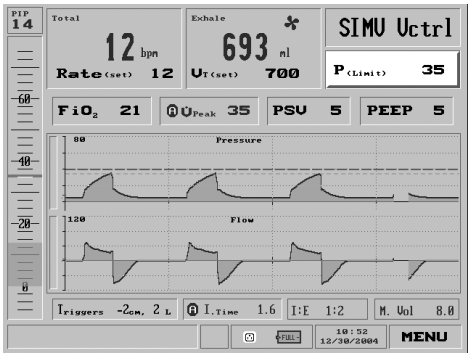


Figure 3.18 Pressure Limit shown selected on the Main screen

or the Mode Parameters screen:

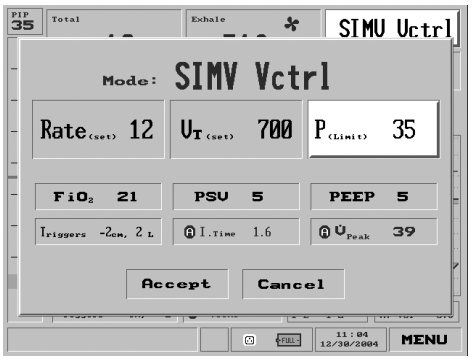


Figure 3.19 Pressure Limit shown selected on the Mode Parameters screen

to bring up the Set Pressure pop-up.

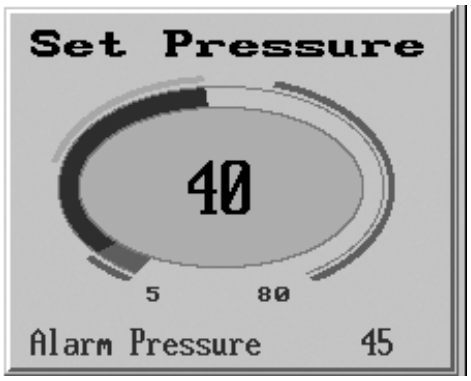


Figure 3.20 the Set Pressure pop-up

The Set Pressure dial will allow you to change the pressure threshold. Turn the control knob to choose the desired numeric pressure value. The high pressure alarm is adjusted automatically to the value P_{Limit} + 5 cmH_2O**.** **(**It can also be set to any desired value using the Alarm menu: see section 4.2.1.3, page 109.)

Press the control knob to confirm and enter your selection. You will be immediately returned to the previous screen, either the Main screen or the Mode Parameters screen, with your selection chosen.

3.3.4 Adjusting FiO_2

Selecting the FiO_2 setting from the top left portion of the Mai+n screen:

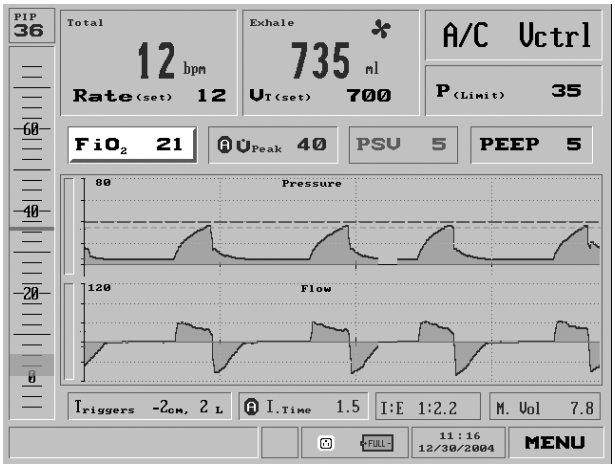


Figure 3.21 FiO_2 shown selected on the Main screen

or any of the Mode Parameter screens:

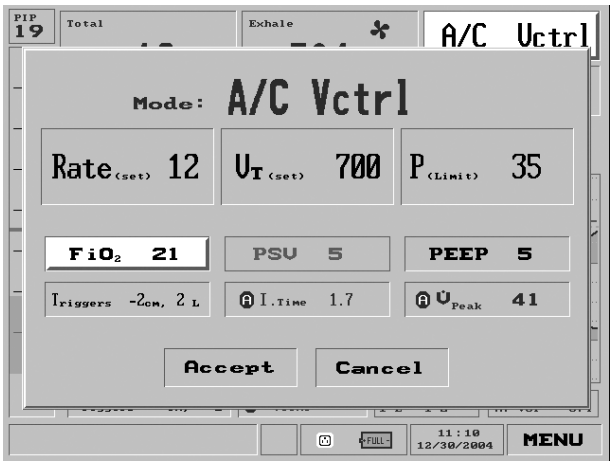


Figure 3.22 FiO_2 shown selected on the Mode screen (A/C Vctrl)

will bring up the FiO_2 pop-up.

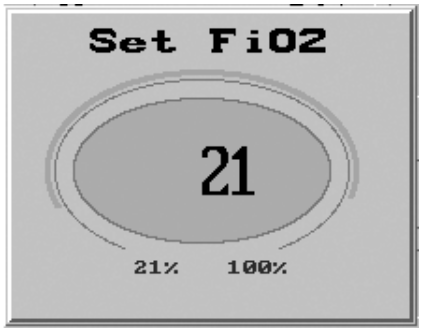


Figure 3.23 The FiO_2 pop-up

When the FiO_2 pop-up appears, turning the control knob adjusts the FiO_2 level. The range is 21% to 100%. When you have set the knob to the desired level, press to confirm and accept the new value. If you wish to abort the change, press the **clear** button.

Changing the FiO_2 percentage will automatically change the O_2 alarm based on a default margin of +20%, - 10% O_2. (The O_2 alarm parameters can be adjusted from the Alarm Settings screen: see section 4.2.1.5, page 113.)

If while the ventilator is operating the Low O_2 Pressure Alarm is triggered, pressing **clear** or **silence** will clear the Alarm pop-up. Once the pop-up is minimized, the FiO_2 box on the Main screen will turn red and display the measured FiO_2 in flashing black numerals.

3.3.5 Adjusting Peak Flow

Select the Peak Flow setting from the second row of boxes on the Main screen:

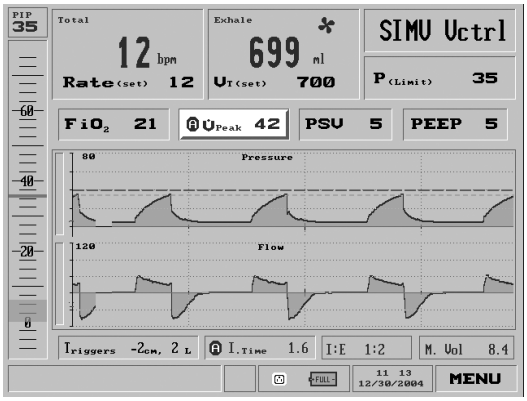


Figure 3.24 Peak flow highlighted on the Main screen

or the Mode Parameters screen:

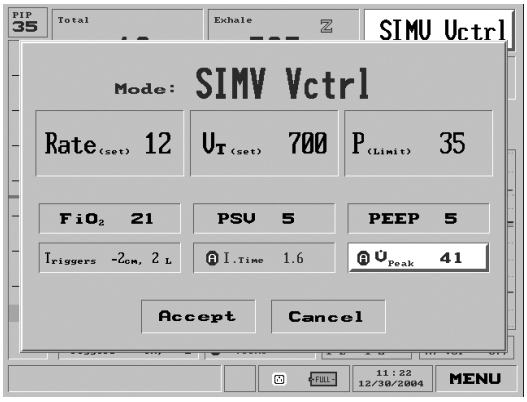


Figure 3.25 Peak flow highlighted on the Mode Parameters screen

Press the control knob if you wish to change the Peak Flow value. The Set Peak Flow pop-up window appears:

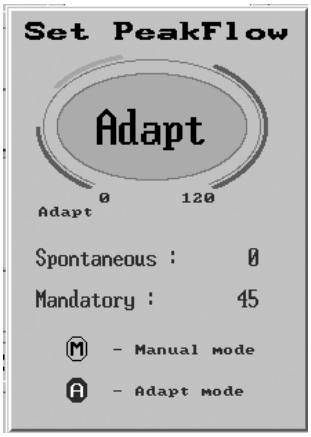


Figure 3.26 The Set Peak Flow pop-up window

Turn the control knob to change the value to a manual mode value. To return to Adaptive Flow™, turn the control knob counterclockwise until "**Adapt**" is displayed.

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

Figure 3.27 Adaptive Flow™ selected

If a Manual Peak Flow is set, a blue icon with a black circled **M** is displayed on the Main screen.

Figure 3.28 Manual Peak Flow selected

3.3.6 Adjusting Pressure Support Ventilation

Select Pressure Support Ventilation setting from the box marked PSV in the second row of boxes on the Main screen:

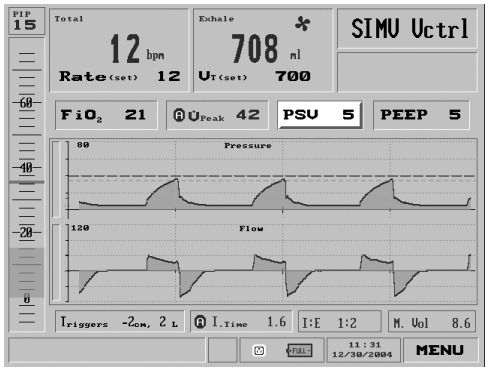


Figure 3.29 Pressure Support Ventilation selected on the Main screen

or the Mode Parameters screen:

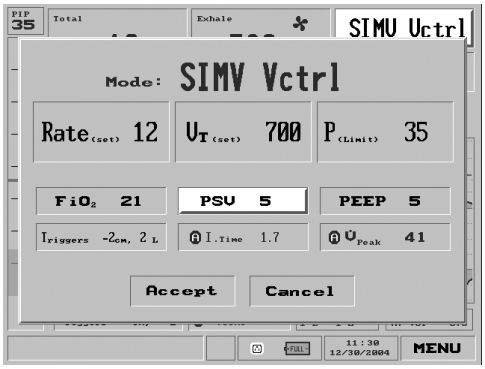


Figure 3.30 Pressure Support Ventilation selected on the Mode screen

Press the control knob. The PSV pop-up window appears:

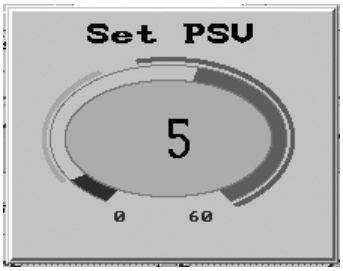


Figure 3.31 The PSV pop-up window

Turn the control knob to adjust the Pressure Support Ventilation level. If you wish to abort any changes, press the **clear** button. When you have set the knob to the desired level, press to confirm and accept the new value. You will be returned to the previous screen with the value you selected displayed.

Note: The PSV value cannot be set to a value greater than P(Limit) – PEEP or a maximum value of 60 cmH_2O.

3.3.7 Adjusting PEEP

Select PEEP from the second row on the Main screen:

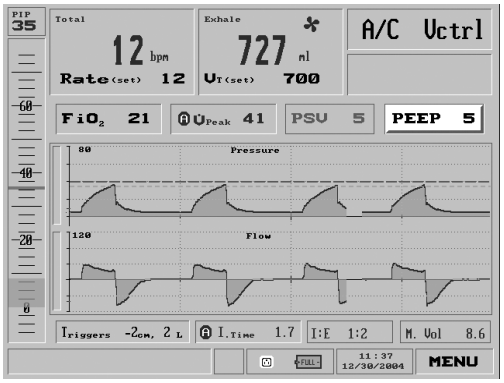


Figure 3.32 PEEP selected on the Main screen

or the Mode Parameters screen:

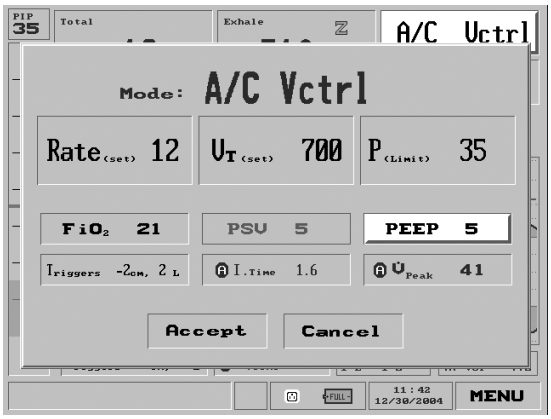


Figure 3.33 PEEP selected on the Mode screen

Press the control knob. The Set PEEP pop-up window appears:

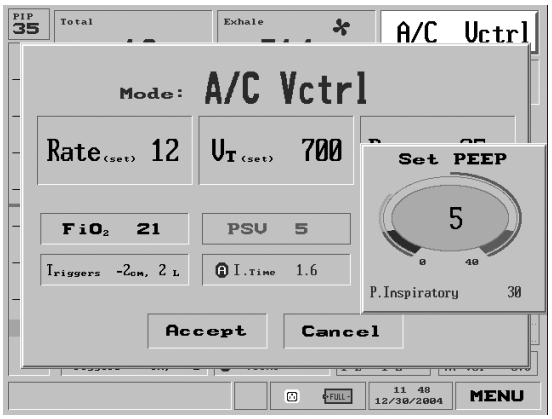


Figure 3.34 The PEEP pop-up window

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 as adjustments are made. If you wish to abort the change, press the **clear** button. When you have set the knob to the desired level, press to confirm and accept the new value, and you will be returned to the previous screen.

Note: The PEEP value cannot be set higher than P(limit) – PSV or a maximum value of 40 cmH_2O.

3.3.8 Adjusting Trigger Sensitivity

Select the Triggers box from the bottom left section of the Main screen:

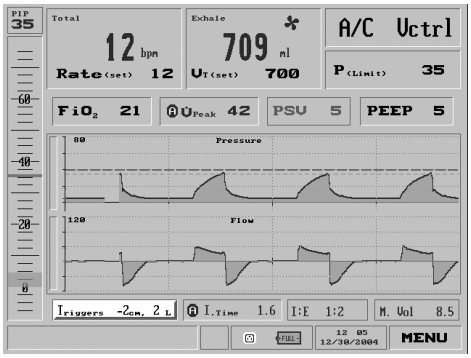


Figure 3.35 Triggers selected on the Main screen

or the Mode Parameters screen:

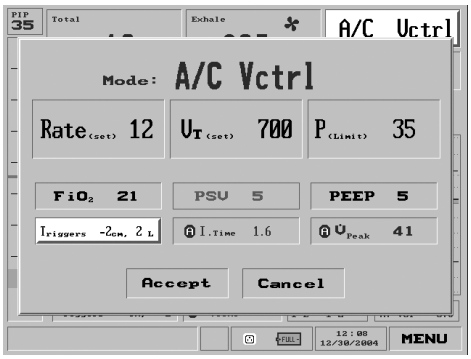


Figure 3.36 Triggers selected on the Mode Parameters screen

Press the control knob. Two sliding numeric gauges appear.

Figure 3.37 The Triggers slider gauges

First, dial the control knob to select the desired Pressure value, then press the knob to enter the value and highlight the Flow gauge. Dial to select the desired Flow value, then press the knob to confirm and enter. You will be returned to the previous screen, with the values you selected displayed.

3.3.9 Adjusting Inspiratory Time

Select the Inspiratory Time setting from the middle of the lower portion of the Main screen:

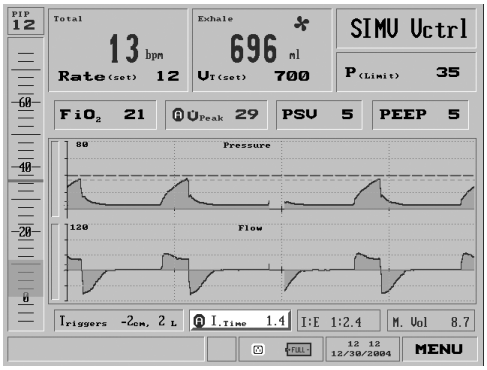


Figure 3.38 Inspiratory Time selected on the Main screen

or the Mode Parameters screen:

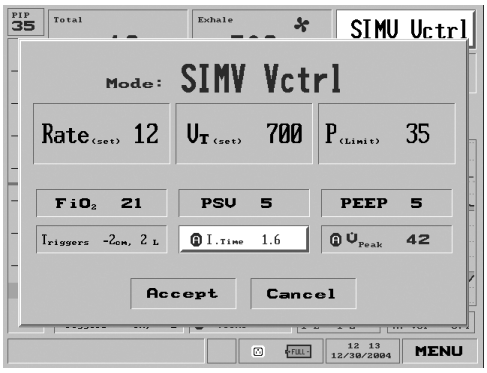


Figure 3.39 Inspiratory Time selected on the Mode Parameters screen

Press the control knob. The I. Time pop-up window appears:

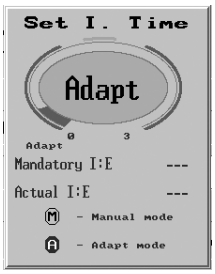


Figure 3.40 The I. Time pop-up window

Turn the control knob to change the Inspiratory Time. Notice that the I:E ratio is recalculated as you adjust the value.

To return to Adaptive I. Time™, turn the control knob counterclockwise until "Adapt" appears. When you return to the Main screen, a circled **A**(daptive) will replace the circled **M**(anual) indicator in the I Time window.

Figure 3.41 Manual I Time

Figure 3.42 Adaptive I Time™

If a manual I time is set that will not allow for a 1:1 I:E Ratio, or will not allow the set volume to be delivered within the set I time, the display will flash.

When you have set the knob to the desired level, press to confirm and accept the new value. If you wish to abort the change, press the **clear** button.

4 The Main Menu

The Main Menu controls many of the *i*Vent$_{201}$'s key settings and functions. In this section you will learn how to use the Main Menu to

- Change Alarm Settings for the *i*Vent$_{201}$
- Change Advanced Settings
- Restore default ventilation settings
- Display and choose ranges and views of Graphs, Trends and Loops
- Choose Mechanics for display
- Display a Log Book showing all adjustments and recent history of *i*Vent$_{201}$ use
- Perform an Operational Verification Test
- Access the Maintenance menu

Note: Depending which model *i*Vent$_{201}$ you are using, not all of these features may be available.

4.1 Navigating the Main Menu

Access the Main Menu from the Main Sceen by dialing the control knob until the MENU box on the lower right corner is highlighted in bright blue

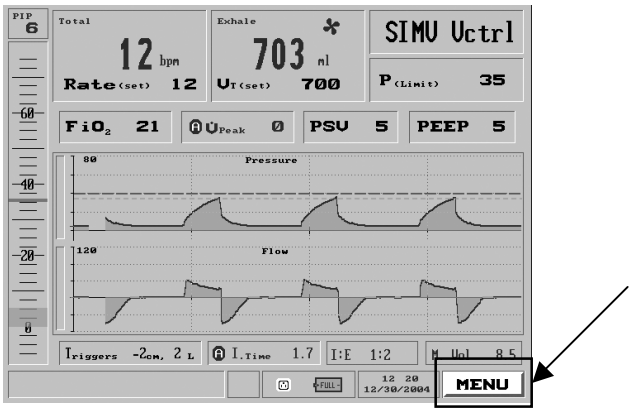


Figure 4.1 The Menu box highlighted on the Main Screen

then press the control knob:

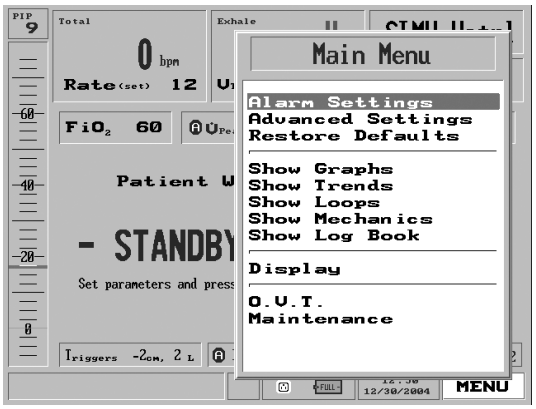


Figure 4.2 The Main Menu

Turn the control knob to highlight a function, then select it by pressing the control knob.

⇒ **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 highlight Display on the Main Menu and press the control knob, then select Main and press the control knob.**

4.2 Alarm Settings

In this section you will learn how to change the *i*Vent$_{201}$'s alarm settings. Please do not change any of these settings without reading Chapter 6: Alarms.

4.2.1 Changing Individual Alarm Settings

Highlighting and clicking **Alarm Settings** on the Main Menu will bring up the Alarm Settings screen:

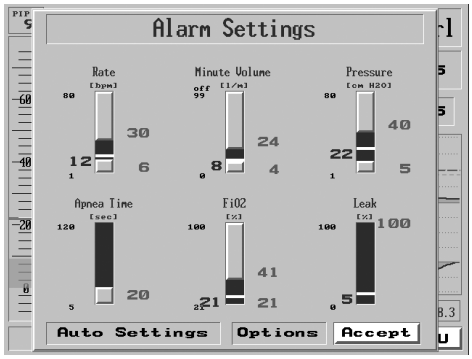


Figure 4.3 The Alarm Settings Screen

The first Alarm Settings screen presents 6 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, FiO_2), while Apnea accepts only a maximum value, and Leak accepts a percentage.

Notice 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 allowable alarm setting. The larger blue numbers to the left of each gauge show each parameter's current operative value.

Note: To save any alarm change, the "Accept" button must be highlighted and selected. Exiting the alarm screen by any other means will cancel all changes that have been made.

4.2.1.1 Setting the Respiratory Rate Alarm

1. Click the Menu box on the Main Screen to get to the Main Menu.
2. Highlight and select the first item on the Main Menu, Alarm Settings.
3. On the Alarm Settings pop-up, dial the control knob until Rate is highlighted in relief on the top left.

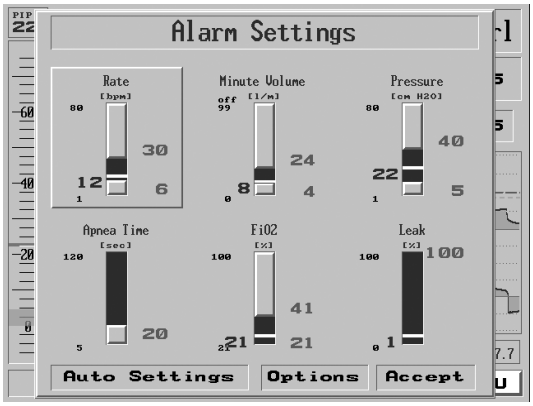


Figure 4.4 The Respiratory Rate Alarm slider highlighted

4. Press the control knob to change the Alarm setting for Respiratory Rate.

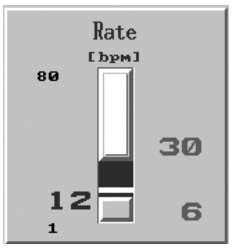


Figure 4.5 The Respiratory Rate Alarm slider selected

5. The top of the slider is highlighted bright blue. Turn the dial to adjust the alarm rate for the UPPER limit in Breaths per Minute, up or down. Notice if you attempt to adjust the upper limit of the alarm rate below the currently-selected lower limit, you will push the lower limit down.

6. When you have selected the desired limit, press the control knob to confirm your selection.

7. Next, the bottom of the slider is highlighted bright blue. Turning the control knob will 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 will move the higher limit up, just as the higher limit pushed down the lower limit. Once you've selected the desired lower limit, press the control knob. The numbers in red to the right of the slider will now indicated the new values you have selected.

8. Now, with the Respiratory Rate slider highlighted in relief, you may either press the control knob to change the Respiratory Rate settings again, or you may dial the control knob to select another alarm setting to adjust, or select Accept at the bottom right of the Alarm Settings window to accept all the alarm settings and return to the Main Screen.

4.2.1.2 Setting the Minute Volume Alarm

1. Click the Menu box on the Main Screen to get the Main Menu.
2. Highlight and select the first item on the Main Menu, Alarm Settings.
3. On the Alarm Settings pop-up, dial the control knob until Minute Volume is selected in relief.

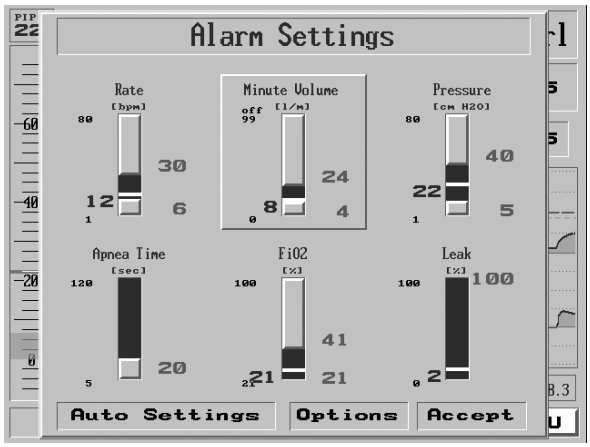


Figure 4.6 The Minute Volume alarm slider highlighted

4. To change the Minute Volume alarm, press the control knob.

5. The top of the slider is highlighted bright blue. Turn the dial to adjust the alarm for the UPPER limit in liters per minute, up or down. Notice if you attempt to adjust the upper limit of the alarm below the currently-selected lower limit, you will push the lower limit down. Setting the Minute Volume alarm over the maximum level of 99 will turn off the alarm's upper limit.
6. When you have selected the desired limit, press the control knob to confirm your selection.
7. Next, the bottom of the slider is highlighted bright blue. Turning the control knob will adjust the alarm for the LOWER limit in liters/minute. Note that adjusting the lower limit higher than the currently-selected higher limit will move the higher limit up. Once you've selected the desired lower limit, press the control knob. The numbers in red to the right of the slider will now indicated the new values you've selected.

8. Now, with the Minute Volume slider highlighted in relief, you may either press the control knob to change the Minute Volume alarm settings again, or turn the control knob to select another alarm setting to adjust, or select Accept at the bottom right of the Alarm Settings window to accept all the alarm settings and return to the Main Screen.

4.2.1.3 Setting the Pressure Alarm

1. Click the Menu box on the Main Screen to get the Main Menu.
2. Highlight and select the first item on the Main Menu, Alarm Settings.
3. On the Alarm Settings pop-up, dial the control knob until Pressure is selected in relief.

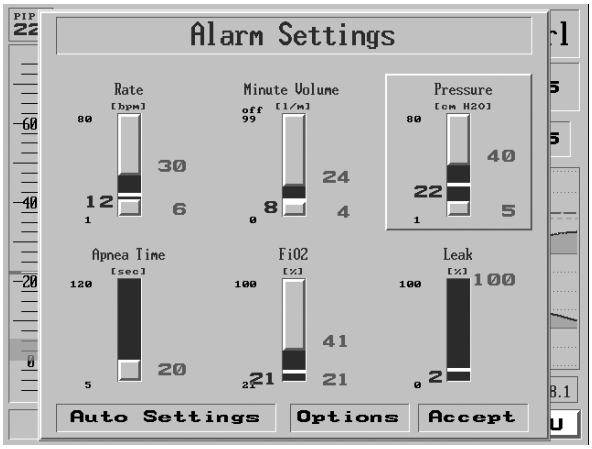


Figure 4.7 The Pressure alarm slider highlighted

4. To change the Pressure alarm, press the control knob.
5. The top of the slider is highlighted bright blue. Dial the knob to adjust the alarm for the UPPER limit in cmH_2O up or down. Notice if you attempt to adjust the upper limit of the alarm below the currently-selected lower limit, you will push the lower limit down.
6. When you have selected the desired limit, press the control knob to confirm your selection.

7. Next, the bottom of the slider is highlighted bright blue. Turning the control knob will adjust the alarm for the LOWER limit in cmH_2O. Note that adjusting the lower limit higher than the currently-selected higher limit will move the higher limit up. Once you've selected the desired lower limit, press the control knob. The numbers in red to the right of the slider will now indicated the new values you've selected.
8. Now, with the Pressure slider highlighted in relief, you may either press the control knob to change the Pressure Alarm settings again, or turn the control knob to select another alarm setting to adjust, or select Accept at the bottom right of the Alarm Settings window to accept all the alarm settings and return to the Main Screen.

4.2.1.4 Setting the Apnea Time alarm

1. Click the Menu box on the Main Screen to get the Main Menu.
2. Highlight and select the first item on the Main Menu, Alarm Settings.

3. On the Alarm Settings pop-up, dial the control knob until Apnea Time is selected in relief.

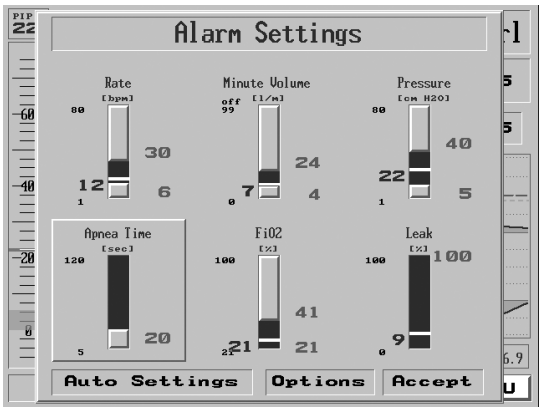


Figure 4.8 The Apnea Time alarm slider highlighted

4. To change the Apnea Time alarm setting, press the control knob.
5. Dial the control knob to select a time between the minimum and maximum ranges.
6. When you have selected the desired alarm limit, press the control knob to confirm your selection.

7. With the Apnea Time slider highlighted in relief, you may either press the control knob to change the Apnea Time settings again, or turn the control knob to select another alarm setting to adjust, or select Accept at the bottom right of the Alarm Settings window to accept all the alarm settings and return to the Main Screen.

4.2.1.5 Setting the FiO_2 Alarm

1. Click the Menu box on the Main Screen to get the Main Menu.
2. Highlight and select the first item on the Main Menu, Alarm Settings.
3. On the Alarm Settings pop-up, dial the control knob until FiO_2 is selected in relief.

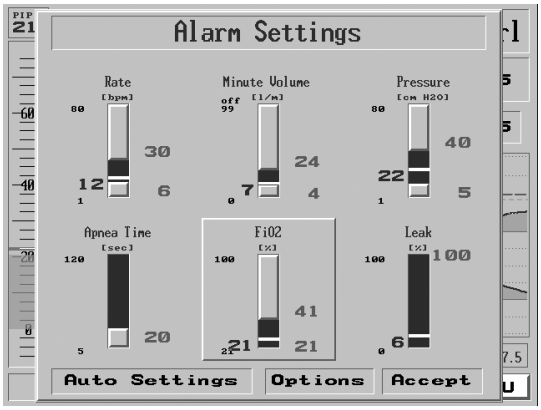


Figure 4.9 The FiO_2 alarm slider highlighted

4. To change the FiO_2 alarm, press the control knob.
5. The top of the slider is highlighted bright blue. Turn the dial to adjust the alarm rate for the UPPER FiO_2 percentage limit, from 21% to 100%, up or down. Notice if you attempt to adjust the upper limit of the alarm below the currently-selected lower limit, you will push the lower limit down.
6. When you have selected the desired upper FiO_2 limit, press the control knob to confirm your selection.

7. Now the bottom of the slider is highlighted bright blue. Turning the control knob will adjust the alarm for the LOWER percentage limit. Note that adjusting the lower limit higher than the currently-selected higher limit will move the higher limit up. Once you've selected the desired lower limit, press the control knob. The numbers in red to the right of the slider will now indicated the new values you've selected.

8. Now, with the FiO_2 slider highlighted in relief, you may either press the control knob to change the FiO_2settings again, or turn the control knob to select another alarm setting to adjust, or select Accept at the bottom right of the Alarm Settings window to accept all the alarm settings and return to the Main Screen.

4.2.1.6 Setting the Leak Alarm

1. Click the Menu box on the Main Screen to get the Main Menu.
2. Highlight and select the first item on the Main Menu, Alarm Settings
3. On the Alarm Settings pop-up, dial the control knob until Leak is selected in relief.

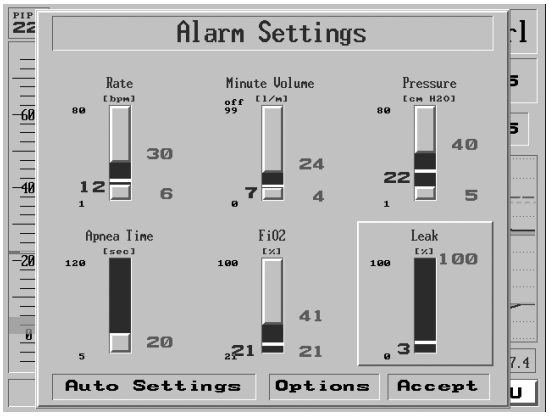


Figure 4.10 The Leak alarm slider highlighted

4. To change the Leak alarm setting, press the control knob.
5. Adjust the control knob to select a percentage between 0 and 100%.

6. When you have selected the desired alarm limit, press the control knob to confirm your selection.
7. With the Leak slider highlighted in relief, you may either press the control knob to change the Leak settings again, or dial the control knob to select another alarm setting to adjust, or select Accept at the bottom right of the Alarm Settings window to accept all the alarm settings and return to the Main Screen.

4.2.2 Auto Settings

The Auto Settings feature sets all the alarms in the Alarm Settings window to suit the currently measured ventilation parameters for the patient. Selecting Auto Settings will bracket the measured values for each parameter in the Alarm Settings window with appropriate limits for those parameters.

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.

To choose Auto Settings, bring up the Alarm Settings window from the Main Menu. Turn the control knob until Auto Settings is selected.

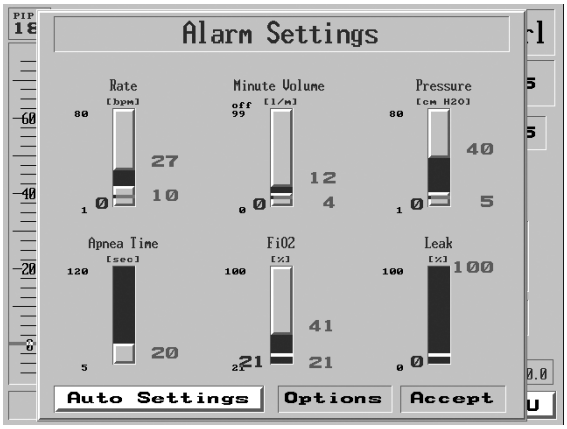


Figure 4.11 The Auto Settings selection highlighted on the Alarm Settings screen

Press the control knob. The Alarm Settings are now reset in accordance with current ventilation parameters.

4.2.3 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. Highlight Alarm Settings and press the knob. The Alarm Settings window is now displayed. Highlight the "Options" box and press the knob.

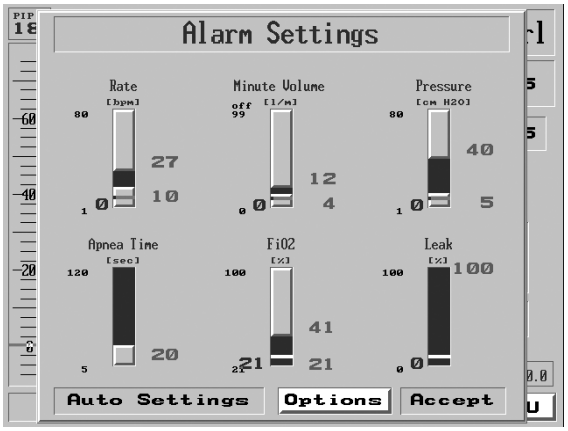


Figure 4.12 The Options selection highlighted on the Alarm Settings screen

2. The Alarm Options screen appears.

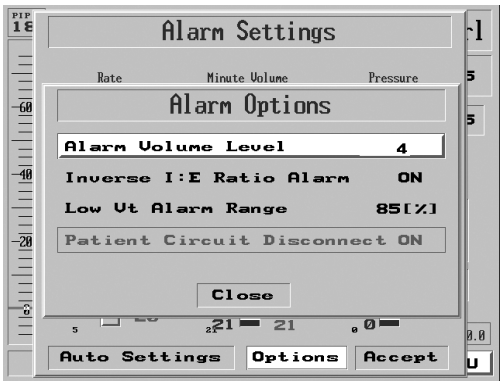


Figure 4.13 The Alarm Options screen

4.2.3.1 Setting the Alarm Volume

To set the Alarm Volume:

a) Access the Alarm Options menu using the procedure shown above.

b) On the Alarm Options page, Alarm Volume Level is the first entry in the list. Make sure it is highlighted, then press the control knob to call up the Alarm Volume pop-up. The factory default is level 8.

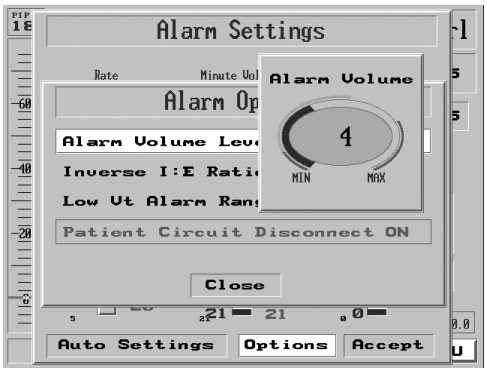


Figure 4.14 The Alarm Volume pop-up over the Alarm Options screen

c) Turn the dial to adjust the alarm volume from 1 (low) to 10 (high). As you turn the dial, the *i*Vent$_{201}$ will play a sample of the level. If you set the level under 2 or over 8, a Caution! flag will pop up.

d) When you have selected the desired volume, press the control knob to accept it and return to the Alarm Options menu.

NOTE: Setting the alarm volume below 5 is not recommended.

4.2.3.2 Setting the Inverse I:E Ratio Alarm

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

a) Access the Alarm Options menu using the procedure shown in Section 4.2.3, page 118.

b) Turn the control knob until "Inverse I:E Ratio Alarm" is highlighted.

c) Press the knob. An ON/OFF selection window appears.

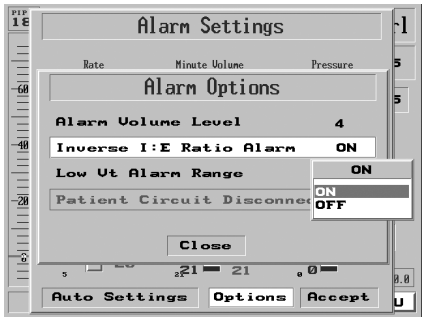


Figure 4.15 The Inverse I:E Ratio Alarm selection menu over the Alarm Options screen

d) Turn the dial to select ON or OFF.

e) Press the dial to confirm your selection and return to the Alarm Options menu.

4.2.3.3 Disabling or 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 in accord with facility policy and patient needs.

a) Access the Alarm Options menu using the procedure shown in Section 4.2.3, page 118.

b) Turn the control knob until "Low Vt Alarm Range" is highlighted. The currently-selected percentage range is shown at the end of the line.

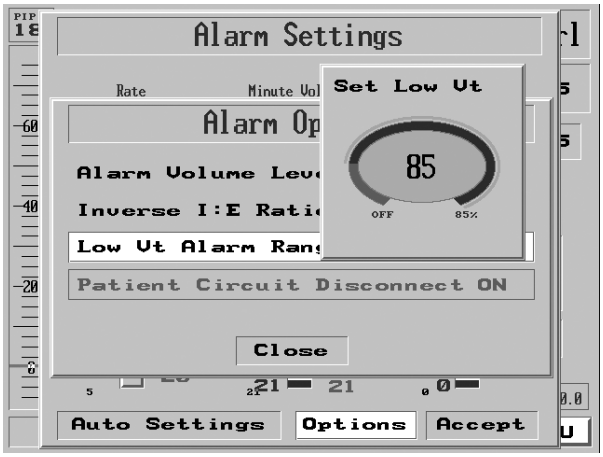


Figure 4.16 The Low Tidal Volume Alarm Range pop-up over the Alarm Options screen

c) Press the control knob. The "Set Low Vt" pop-up appears.

d) Turn the control knob to adjust the percentage between 0% (Off) and 85%.

e) Press the dial to confirm your selection and return to the Alarm Options menu.

4.2.3.4 Disabling or Enabling the Patient Circuit Disconnect Alarm

When ventilating with Adaptive Bi-Level, under some circumstances it may be desirable 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. Before disabling or adjusting any alarms, be sure that you are in accord with facility policy and patient needs.

a) If the ventilator is in Adaptive Bi-Level mode, access the Alarm Options menu using the procedure shown in Section 4.2.3, page 118.

b) Dial the control knob until "Patient Circuit Disconnect" is highlighted. The state of the Alarm (ON or OFF) is shown at the end of the line.

c) Press the control knob. An ON/OFF selection window appears (for Adaptive Bi-Level Mode only).

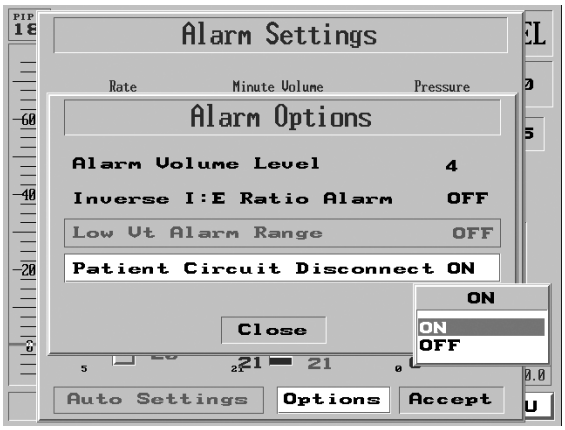


Figure 4.17 The Patient Circuit Disconnect Alarm pop-up

d) Turn the knob to select ON or OFF. If you select OFF, a warning will appear:

Figure 4.18 The Patient Circuit Disconnect Alarm Off Warning

e) Confirm "Yes" by pressing the control knob. You will be returned to the Alarm Options menu. When the Patient Disconnect Alarm is turned OFF, the Main Screen displays a warning in the bottom left corner:

Figure 4.18a The Patient Circuit Disconnect Alarm Off icon

4.3 Advanced Settings

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

- Sigh breath (on-off/interval)
- Rise time level
- Easy Exhale™
- Oxygen supply (None/High Pressure/Low Pressure)
- Adaptive Peak Flow (on-off/Low/Mid/High)
- Purge sensors (on-off/interval)
- Nebulizer device
- Set time and date

To access the Advanced Settings menu:

1. Click the Menu box on the Main Screen to get the Main Menu.
2. Turn the control knob to highlight the second item on the Main Menu list, Advanced Settings.

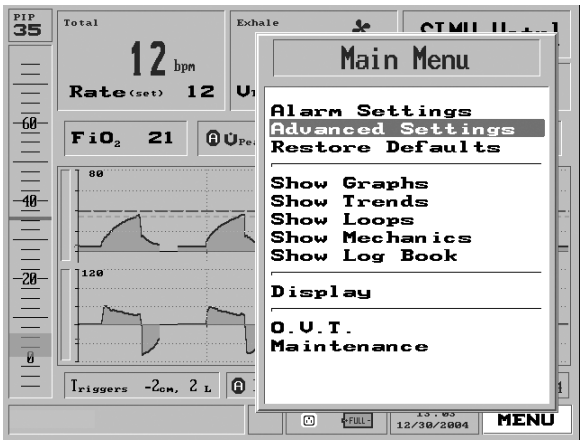


Figure 4.19 Advanced Settings highlighted on the Main Menu

3. Press the control knob. The Advanced Settings menu appears.

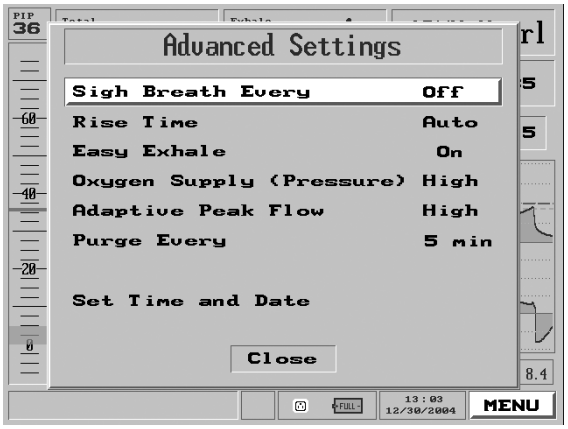


Figure 4.20 The Advanced Settings menu

4.3.1 Sigh Breath

In Volume control modes, the *i*Vent201 permits sigh breaths. (The Sigh Breath volume is 1.5 times the set tidal volume.) You can use the Sigh Breath entry of the Advanced Settings menu to turn Sigh Breaths off or enable it by adjusting the interval.

1. From the Advanced Settings menu (see section 4.3), highlight the "Sigh Breath Every" selection. The factory default is "Off".
2. Press the control knob. A pop-up appears with the values 25, 50, 75, 100, 125, 150, and Off:

Figure 4.21 The Sigh Breath selection pop-up

3. Turn the dial to select the desired value.
4. Press to accept the value. The chosen value will now be displayed beside "Sigh Breath Every" in the Advanced Settings menu.
5. To return to the Main Window, turn the control knob to select "Close," then press.

4.3.2 Rise Time

The *i*Vent$_{201}$ allows four possible values for Rise Time: Mid, High, Max or Auto. Use the Advanced Settings menu to select the Rise Time value.

1. From the Advanced Settings menu (see section 4.3 on page118), turn the dial so that the "Rise Time" selection is highlighted.

Figure 4.22 Rise Time selection highlighted on the Main Menu pop-up

2. Press the knob. A pop-up offers the choices of Mid, High, Max and Auto. The factory default setting is "Auto."

Figure 4.23 The Rise Time selection pop-up

3. Turn the dial to select the desired value.

4. Press to accept the value. The value you chose will now be displayed next to "Rise Time" in the Advanced Settings menu.

5. To return to the Main Window, turn the control knob to select "Close," then press.

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

4.3.3 Easy Exhale™

Easy Exhale™ is an advanced PEEP mode designed for use with severe obstructive airway flow. It introduces PEEP late in expiration in order to prevent airway pressure from falling below alveolar pressure in situations where critical airway closure tends to create intrinsic PEEP. (For more information, see Appendix D and Appendix E.)

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

1. From the Advanced Settings menu (see section 4.3 on page 125), highlight the "Easy Exhale" selection.

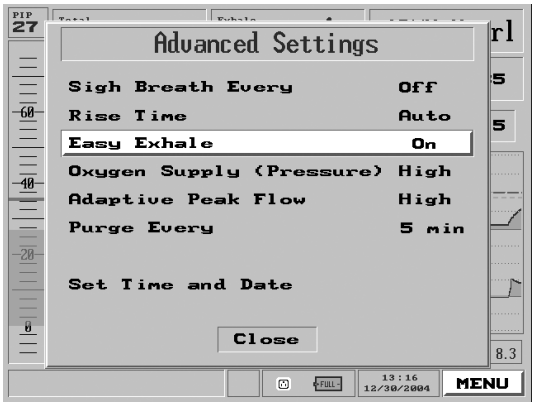


Figure 4.24 Easy Exhale highlighted on the Main Menu pop-up

2. Press the control knob. A pop-up appears with the values On and Off.

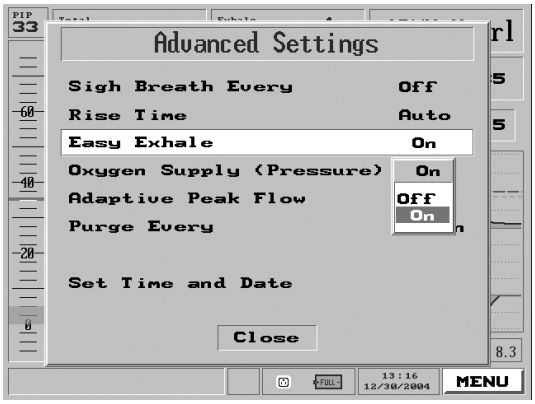


Figure 4.25 The Easy Exhale selection pop-up

3. Turn the dial to On or Off.

4. Press to accept the value. The value will now be displayed beside "Easy Exhale" in the Advanced Settings menu.

5. To return to the Main Window, turn the control knob to select "Close," then press it.

4.3.4 Oxygen Supply

You set the type of oxygen supply used with the *i*Vent$_{201}$ from the Advanced Settings menu. There are 4 available options:

- High
- Low + Monitoring
- Low
- None

For more about each option, see sections 4.3.4.1, 4.3.4.2, 4.3.4.3, and 4.3.4.4 below.

1. From the Advanced Settings menu (see section 4.3 in the Operator manual), select **Oxygen Supply (Pressure)**. The option is highlighted.

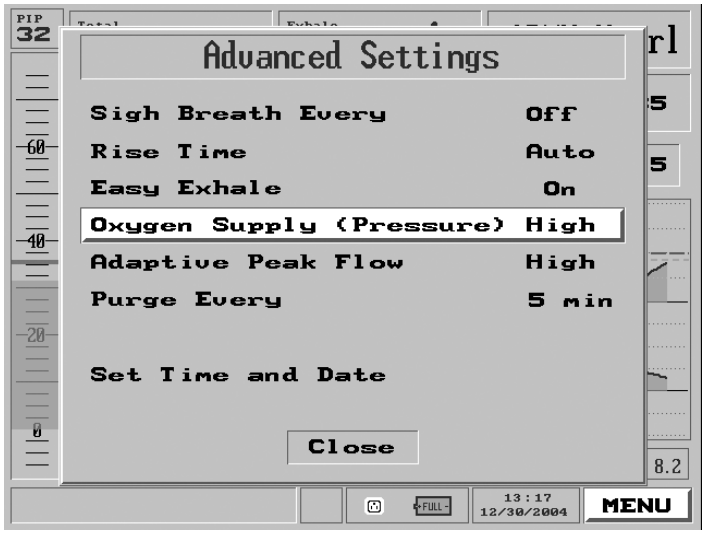


Figure 4.26 Oxygen Supply Selected on the Main Menu Pop-up

2. Press the control knob. A pop-up appears with the options: **High**, **Low+M**, **Low**, and **None**.

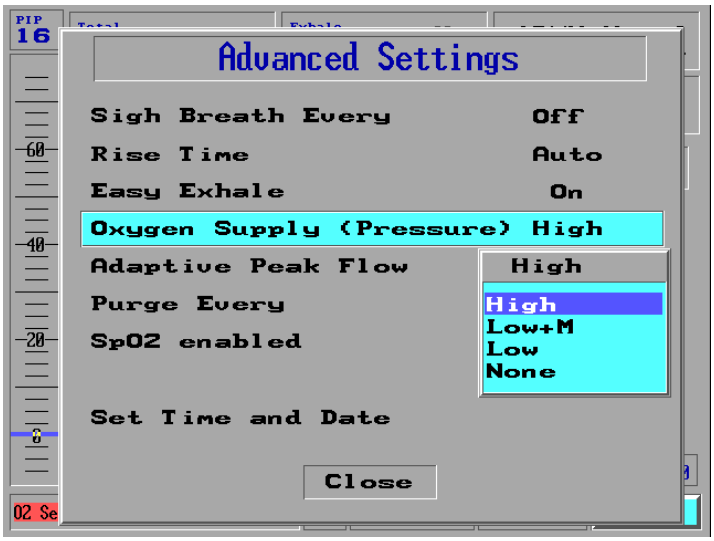


Figure 4.27 The Oxygen Supply Pop-up

3. Turn the dial to select the appropriate option.
4. Press to accept the option. It is displayed next to "**Oxygen Supply (Pressure)"** in the Advanced Settings menu.
5. To return to the Main Window, turn the control knob to select **Close**, and then press the knob.

⇒ **The 0_2 Sensor continues to measure the O_2 levels, even when, in some options, these measurements are not displayed, and the O_2 alarms are not activated. Ensure that you take the entire ventilation time into account when calculating the O2 sensor maintenance (refer to section 7.1 "Cleaning and Maintenance" in the Operator Manual).**

4.3.4.1 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 O_2 mixer. The **High** option is the factory default setting for the oxygen supply type.

⇒ **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 FiO_2 field on the iVent screen. All O_2 related alarms are enabled (such as Low O_2, High O_2, and O_2 sensor fail).

⇒ **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 (Refer to section 4.2.1.5 "Setting the FiO2 Alarm" in the Operator Manual).**

If the O_2 sensor fails, one of the following alarm messages is displayed in the lower part of the iVent screen. The alarm message depends on whether the iVent machine serial number is lower or higher than 15000.

Alarm Message for Serial Number 12000 -15000

Figure 4.28 Alarm Message: O_2 Sensor Failed (For 12000 – 15000 Machines)

You cannot close this alarm using the Clear button.

Press the **OK** button to close the alarm box. The FiO2 setting is displayed with a red blinking background. 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 changing this value to 21% or 100%, the new settings are displayed with a yellow background.

When the O_2 sensor alarm message is activated, the O_2 alarm messages, such as High O_2 or Low O_2, will not be activated. The O_2 alarm settings bar and the O_2 readings will be disabled.

A small red icon is displayed on the left corner of the status bar, showing "O_2 Sensor." When the O_2 sensor failure is corrected, this icon changes to green and may be cleared (see Figure 4.29 below).

Figure 4.29 The Status Bar with O_2 Sensor Icon

Alarm Message for Serial Number 15000 or Higher

Figure 4.30 Alarm Message - High O_2 Sensor Failed

You cannot close this alarm using the Clear button.

Press the **OK** button to close the alarm box. The FiO_2 setting is displayed with a yellow background. You can change the FiO_2 setting within a range from 21% to 100%.

In all machines, a small red icon is displayed on the left corner of the status bar, showing "O_2 Sensor." When the O_2 sensor failure is corrected, this icon changes to green and may be cleared.

4.3.4.2 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 FiO_2 box on the main screen will be grayed out, and the O_2 settings cannot be changed. The display in the main screen will show the measured FiO_2 (the FiO_2 delivered to the patient), as in the Alarm screen [Menu - Alarm Settings]. All O_2 related alarms are enabled.

If the O_2 sensor fails, the following alarm message is displayed:

Figure 4.31 Low+Monitoring O_2 Sensor Failed Alarm Message

You cannot close this alarm using the Clear button.

When the O_2 sensor alarm message is activated, the O_2 alarm messages, such as High O_2 or Low O_2, will not be activated. The O_2 alarm settings bar and the O_2 readings will be disabled.

A small red icon is displayed on the left corner of the status bar, showing "O_2 Sensor" (see Figure 4.29 above). When the sensor failure is corrected, this icon changes to green and may be cleared.

4.3.4.3 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 O_2 related alarms are disabled, such as Low O_2, High O_2, and O_2 sensor failed. After selecting the **Low** option, a message box is displayed:

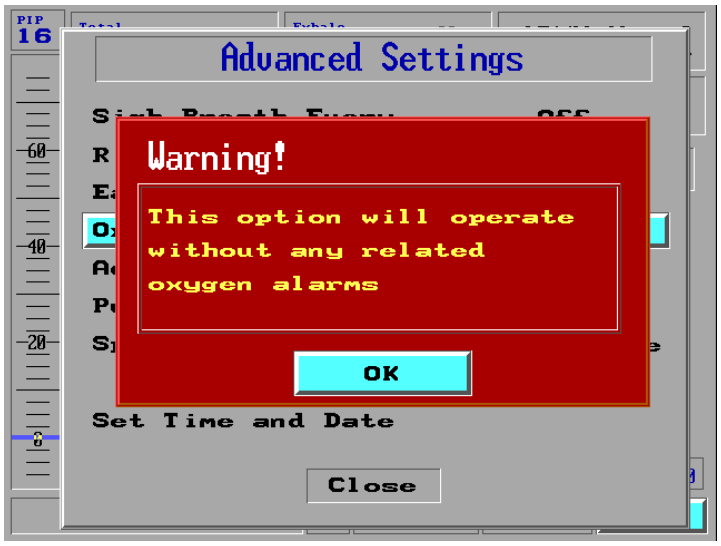


Figure 4.32 Low Option Warning

The alarm settings and readings are disabled, and the FiO_2 field will display
" - -".

If the O_2 sensor fails, no alarm will be displayed.

4.3.4.4 None Option

The **None** option is used when no O_2 Supply is connected to the iVent$_{201}$. When this option is selected all the O_2 related alarms are disabled. The alarm settings and readings are also disabled, and the FiO_2 field will display " - -".

If the O_2 sensor fails, no alarm will be displayed.

4.3.5 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 Advanced Settings menu (see section 4.3 on page 125), highlight the "Adaptive Peak Flow" selection.

Figure 4.33 Adaptive Peak Flow highlighted on the Main Menu

2. Press the control knob. A pop-up appears with the values Off, Low, Mid and High.

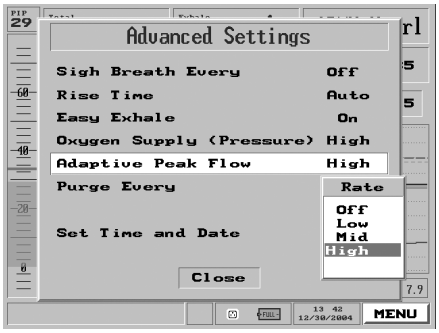


Figure 4.34 The Adaptive Peak Flow pop-up

3. Turn the dial to select the desired setting.

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

4. Press to accept the value. The value will now be displayed beside "Adaptive Peak Flow " in the Advanced Settings menu.
5. To return to the Main Window, turn the control knob to select "Close," then press the knob.

4.3.6 Set Purge Interval

The *i*Vent$_{201}$ periodically sends a burst of air through the sensor tubes in order to clean them. The Advanced Settings menu allows the user to determine the frequency of the automated sensor purgings.

Note: This is an optional feature not available in all units.

Possible values are 1, 2, 5 and 10 minutes, and Off. The factory setting is 5 minutes.

1. From the Advanced Settings menu (see section 4.3 on page 125), highlight the "Purge Every" selection.

Figure 4.35 Purge interval selection highlighted on the Main Menu pop-up

2. Press the control knob. A pop-up appears with the values 1, 2, 5, 10 and Off.

Figure 4.36 The "Purge Every" pop-up

3. Turn the dial to select the desired setting.
4. Press to accept the value. The value will now be displayed beside "Purge Every " in the Advanced Settings menu.

To return to the Main Window, turn the control knob to select "Close," then press the knob.

NOTE: When using active humidification it is recommended that the purge frequency be set to one minute intervals.

4.3.7 Pulse Oximetery

Pulse oximeter is a simple non-invasive method of monitoring the percentage of hemoglobin (Hb) that is saturated with oxygen, which, put simply, is the amount oxygen in the blood. The pulse oximeter is a sensor, which is placed on the patient fingertip, earlobe, or the 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 *i*Vent$_{201}$ ventilator allowing the operator to continuously monitor patient's oxygenation saturation on the iVent screen.

Caution

The accuracy of the SpO2 measurement may 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 arterieal 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 open the Oximetry Screen:

- On the *i*Vent201 use the control knob to select **Menu – Advance Setting – SpO2 – Enable**.

The **Pulse Oximetry** screen (highlighted in Figure 4.37 below) displays the following measurements:

- **SPO2** – displaying the oxygen saturation percent in the patient blood. This measurement is available in numeric format on all screens.
- **Hart Rate** – displaying the heart rate (in bpm) in numeric format.

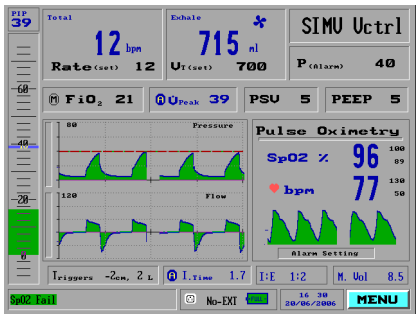


Figure 4.37 The Pulse Oximetry screen on the Main screen

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 (see Figure below).

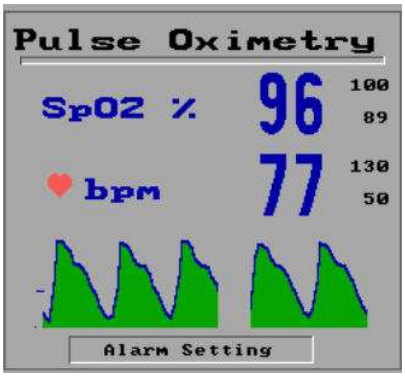


Figure 4.38 The Pulse Oximetry screen

To close the Pulse Oximetry screen:

- On the *i*Vent$_{201}$, use the control knob to select **Menu – Advance Setting – SpO2 – Disable**.

The **Pulse Oximetry** screen is active even when the *i*Vent$_{201}$ is in standby mode, to allow continued monitoring of the patients' oxygenation and the heart rate. When the iVent is in standby mode the **Pulse Oximetry** screen will expanded, as shown in figure 4.39 below.

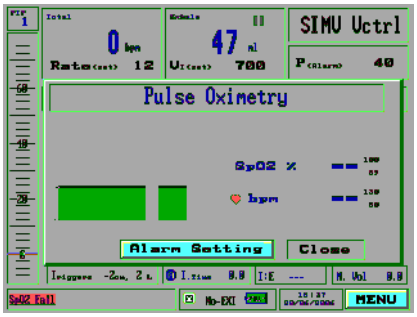


Figure 4.39 Pulse Oximetry screen in Standby mode

4.3.7.1 pulse oximetery Alarms

The following alarms are the pulse oximetery alarms. They are activated only when the pulse oximetery Screen is enabled:

- SpO2 Low Perfusion
- Sensor Patient disconnect
- Sensor iVent disconnect
- Low SpO2
- High SpO_2
- High Heart Rate
- Low Heart Rate

You can set the alarms for the the high and low ranges for the SpO_2 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.

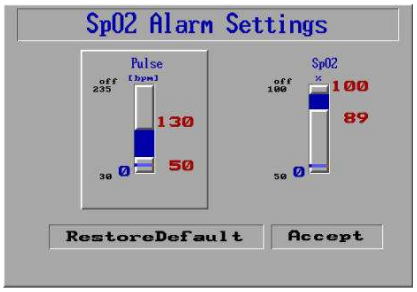


Figure 4.40 SpO2 Alarms Settings screen.

2. Use the control knob to select one of the following alarms:

- **Pulse** (heart rate)
- **SpO2** (SpO_2 level).

3. The top of the slider is highlighted 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 highlighted 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.

The **SpO2 Alarm Setting** screen is closed, with the alarms settings you set.

4.3.8 Synchronized 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 will be 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 section 2.4.4, on 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 nebuilzer:

1. From the Advanced Setting menu (see section 4.3 on page 125) turn the control knob to highlight “Nebulizer”.

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

The nublizer is activated only when you set the Oxygen Supply to High option (see section 4.3.4 on page 132).

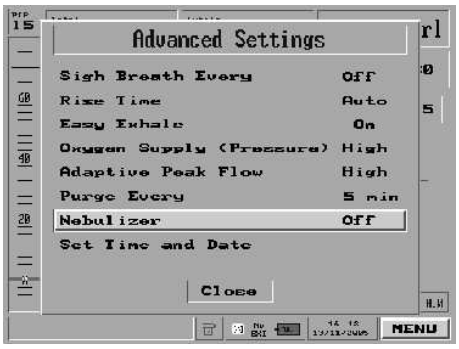


Figure 4.41 Nebulizer highlighted on the Main Menu pop-up

2. Press the control knob. The Nebulizer pop-up window appears. The default time is OFF.

Figure 4.42 The Nebulizer pop-up

3. Turn the dial to set the time duration for nebulization. You can set the time between 5 minute and 4 hours. Each rotational detent of the knob increase or decrease 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 also 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 will be the sum of the time you have added and the elapsed time.

4. Press to activate the nebulizer and exit. During the nebulization process you may reenter the Nebulizer screen and view the elapsed time. Note that the remaining time is displayed in the Advance Menu.

4.3.9 Set Time and Date

From the Advanced Settings menu, turn the control knob to highlight ”Set Time and Date.”

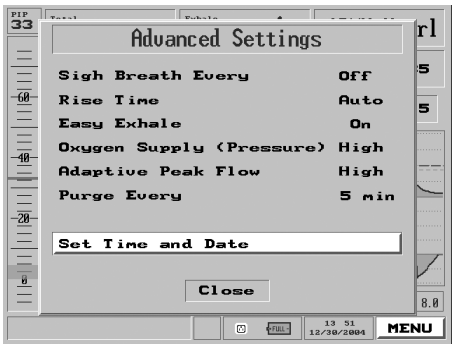


Figure 4.43 Set Time and Date highlighted on the Main Menu pop-up

1. 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.

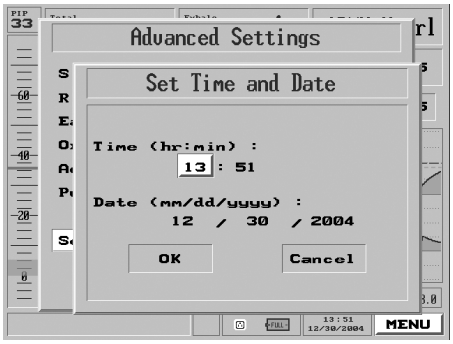


Figure 4.44 The Set Time and Date pop-up

2. To change the hour, make sure the hour is selected, then press the control knob. Now, turn the dial to adjust the clock – clockwise to set the clock to a later hour, counterclockwise to set it earlier. When you have set it properly, press the control knob.
3. Turn the knob one click to select the minute field. Press the control knob, then turn the knob to adjust the clock.
4. Continue to adjust the date variables until you have set the correct date and time. When you are done, turn the dial to select "Ok," and press. You will be returned to the Advanced Settings window.
5. To return to the Main Window, turn the control knob to select "Close," and press the knob.

4.4 Restore Default Settings

To clear ALL settings and return the *i*Vent$_{201}$ 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.

4.4.1 To Restore Defaults:

1. Click the Menu box on the Main Screen to get the Main Menu.
2. Highlight the third item on the Main Menu list, Restore Defaults.

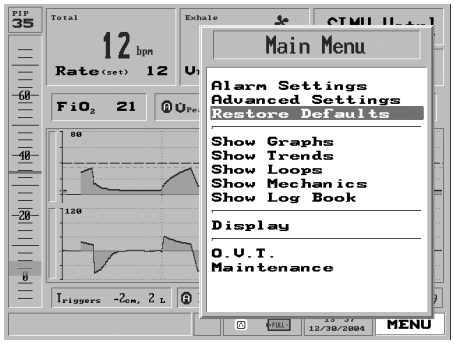


Figure 4.45 Restore Defaults highlighted on the Menu pop-up

3. Press the control knob. A large red Warning pop-up appears:

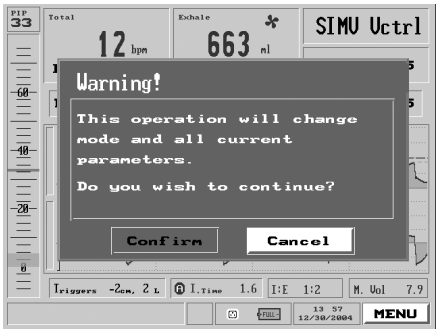


Figure 4.46 The Restore Defaults warning

4. If you are sure you wish to restore the defaults, turn the control knob to **Confirm** and press.
5. The **Restore Default Params** pop-up will appear, asking 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 *i*Vent$_{201}$'s settings will return to their defaults and you will be returned to the Main Menu.

The following tables summarize the default parameters and alarm values for the *i*Vent$_{201}$ by patient weight:

Table 4.1 Default Start Parameters for Volume Ventilation for 10 kg to 70 kg

Patient Weight		bpm Rate	Tidal Volume	Max. Pressure (P_{Limit})
(kg)	(lb)	(bpm)	(mL)	(cmH_2O)
10	22	30	100	18
15	33	25	150	20
20	44	20	200	25
30	66	18	300	28
40	88	16	400	30
50	110	14	500	35
60	132	12	600	35
70+	154	12	700	35

Table 4.2 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)	5	7	10	14	17	20	24	24
Low Min Vol. (LPM)	1	1	2	2	3	3	4	4

The following alarms remain constant for all weights:

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 4.3 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 4.4 Alarm Default Parameters for Pressure Ventilation for 10 kg 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 (cmH_2O)	30 for all weights							

All other alarm default parameters are the same as for Volume Ventilation (tables 4.1 and 4.2).

4.5 Show Graphs

The Show Graphs function on the Main Menu is the gateway to the *i*Vent$_{201}$'s waveforms package. You can

- 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 *i*Vent$_{201}$ defaults to displaying the waveform graphs while ventilating. The Main Menu allow the operator to choose to display only the** waveform graphs **(default), or to split the view between waveform graphs and** Trends**,** Loops**, or** Mechanics**.**

Access Graphs by calling up the Main Menu from the Main Screen (dial the control knob until the MENU box on the lower right corner is highlighted in blue, then press the control knob), then use the control knob to select and click Show Graphs. If the *i*Vent$_{201}$ display is split between Graphs and something else -- Trends, Loops or Mechanics, then it will return 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 broken green line. The high pressure alarm setting is shown as a broken red line.

NOTE: Select is not active.

4.5.1 Browse Waveforms

You may browse forward or backward to examine the patient ventilation history, up to 7.2 hours. First, choose either the Pressure waveform or the Flow waveform by rotating the dial so that the Select bar of either is chosen.

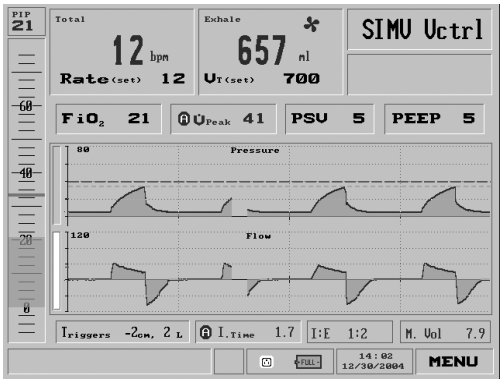


Figure 4.47 The Flow waveform selected

Next, press the control knob to call up the Graph Choice bar:

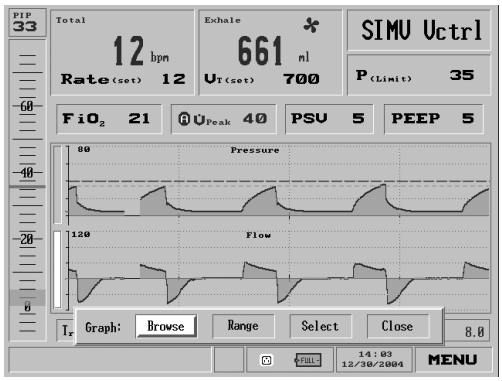


Figure 4.48 The Graph Choice bar

When the Graph Choice bar first comes up, Browse should be selected. If it is not, select it with the control knob. Then, press the control knob.

A pop-up will appear, time stamped at the moment you pressed Browse.

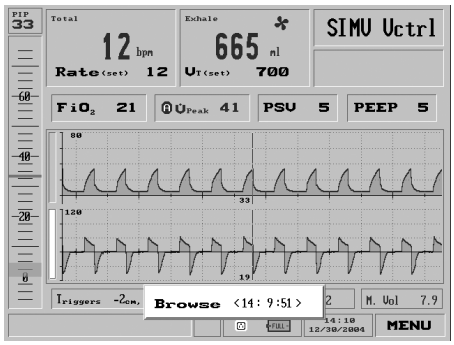


Figure 4.49 The Browse pop-up

The waveform display will hold at that moment, although it is continuing to record, and the results are being kept in memory. Turn the dial counterclockwise, and the time coordinate cursor will move backward along the time axis; turn the dial clockwise and the time coordinate cursor will move foward along the time axis.

4.5.2 Select Range

The *i*Vent$_{201}$ 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.

1. On the Main Screen, adjust the dial to select either the Pressure or Flow select bar (see Figure 4.38).
2. Press the control knob to select the graph you wish to reconfigure. You will be presented with the Graph Choice bar.

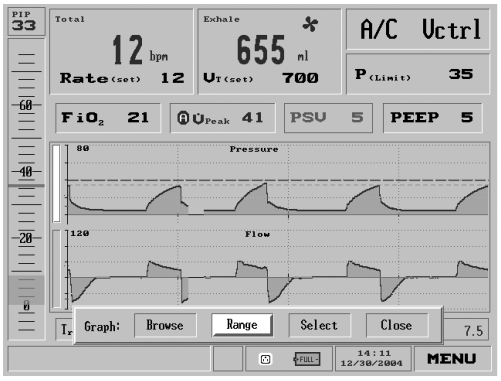


Figure 4.50 The Graph Choice bar, with Range selected

3. Dial the control knob until Range is selected, then press. A pop-up will offer a choice of Ranges.

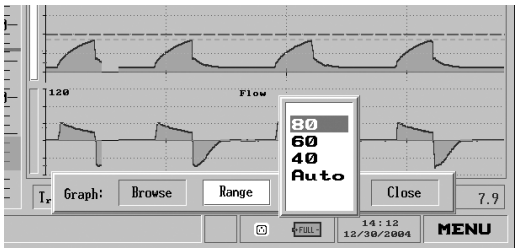


Figure 4.51 Ranges for Pressure

If you have chosen the Pressure graph, the choices are 80, 60, 40 cmH_2O and Auto (the default). Move the dial to choose the desired value. Press the dial to accept the new range and return to the Graph Choice bar.

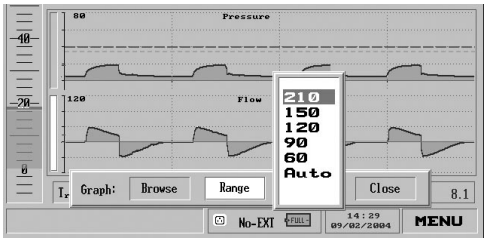


Figure 4.52 Ranges for Flow

a) If you have chosen the Flow graph, the choices are 210, 150, 120, 90, 60 L/minute and Auto (the default). Turn the knob to choose the desired value. Press to accept the new range and return to the Graph Choice bar.

4. Turn the dial until Close is selected on the Graph Choice bar, and click to return to the Main screen.

4.6 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. Call up the Main Menu (dial the control knob until the MENU box on the lower right corner is highlighted in blue, then press the control knob).
2. Turn the control knob until Show Trends is highlighted, then press to select.

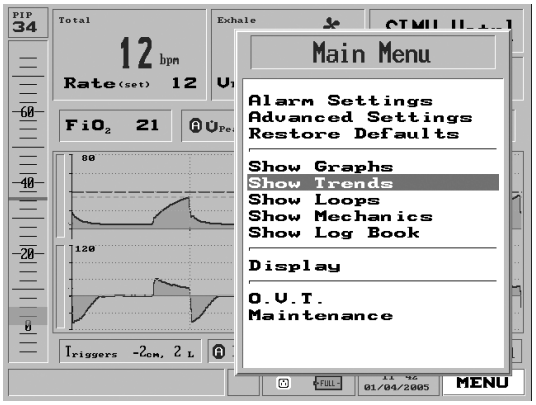


Figure 4.53 Show Trends highlighted on the Main Menu

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

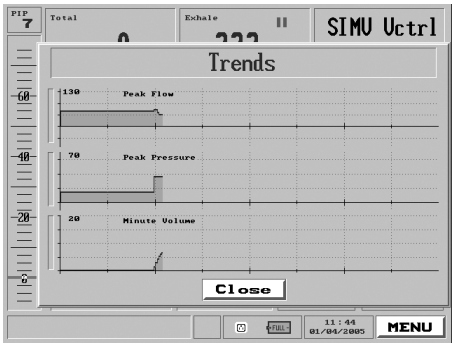


Figure 4.54 Trends pop-up in Standby Mode

4. If the ventilator is operating, the three displayed Trends will appear in a window beside the waveforms:

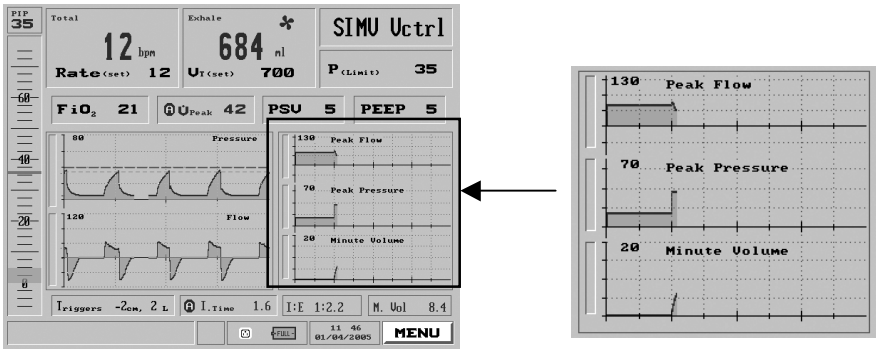


Figure 4.55 Trends window during ventilation

⇒ **To turn OFF Trends display, call up the Main Menu, highlight Display, press the control knob to select, then select Main. You will be returned to the Main screen with only the Pressure and Flow waveforms displayed.**

4.6.1 Selecting Trends To Display

To select the Trends you wish to view:

1. Turn the control knob to highlight the Select bar of the Trend graph you want to change.

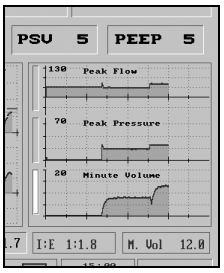


Figure 4.56 The Minute Volume graph is selected

2. Press the control knob. You will be presented with the Trends Choice bar.

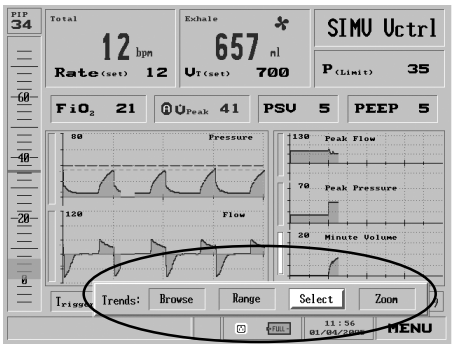


Figure 4.57 The Trends Choice bar, with "Select" chosen

3. Turn the control knob to highlight Select, then press. A pop-up bar will appear offering a choice of parameters and diagnostic variables:

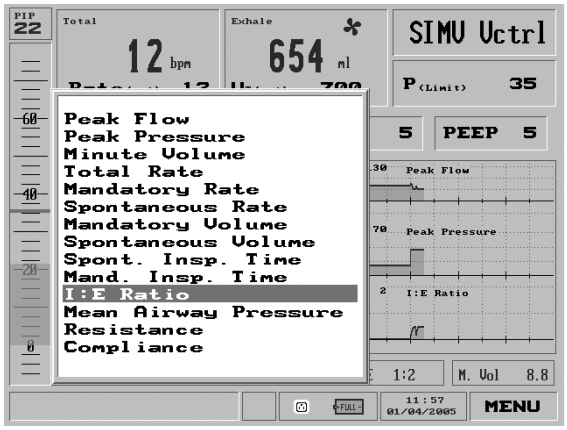


Figure 4.58 The Trends Selections pop-up. I:E ratio has been selected

4. Dial to select one, then press to accept your selection. You will be returned to the Trends graph window, and the selected parameter will be displayed.

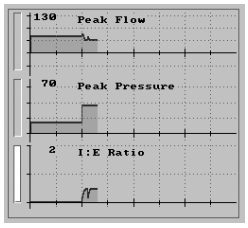


Figure 4.59 I:E ratio is now displayed

You may continue to choose alternative Trends to display in the other graphs by highlighting the Select bar of each graph and then using the Trends Choice bar to choose.

4.6.2 Browsing Trends

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

1. While the Trends are displayed, select any Trend graph by dialing the control knob until a Select bar is highlighted (see figure 4.47). Press the control knob to bring up the Trends Choice bar. Then dial the control knob to highlight Browse.

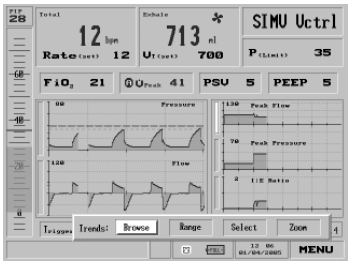


Figure 4.60 The Trends Choice bar, with Browse selected

2. A small blue highlighted window marked Browse appears, with the time and graph's cursor in center of the viewable data.

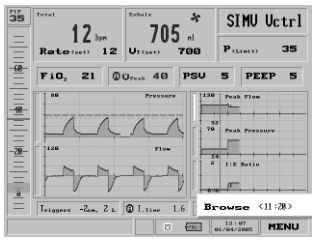


Figure 4.61 The Browse Trends pop-up

Rotating the dial clockwise will move the time cursor indicator forward; rotating counterclockwise will move the indicator backward along the timeline.

3. 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 call up the Trends Choice bar. Select Zoom.

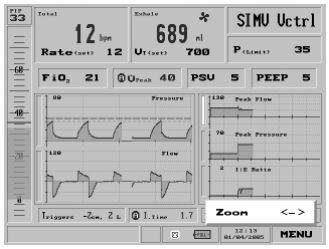


Figure 4.62 The Trends Choice bar, with Zoom selected

The Zoom popup appears. Turning the control knob will adjust 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 and rid the view of Trends, select Show Graphs from the Main Menu.**

4.7 Show Loops

You can view Loops four ways:

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

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

To display Loops

1. Highlight the Menu box.
2. Select Show Loops

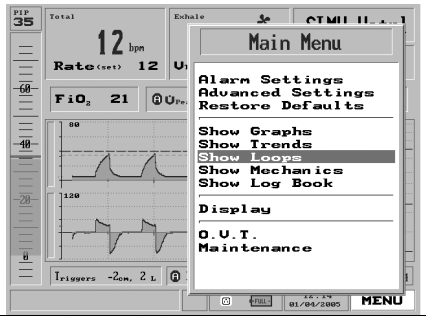


Figure 4.63 Show Loops highlighted on the Main Menu

and press the knob. The Show Loops pop-up menu will appear:

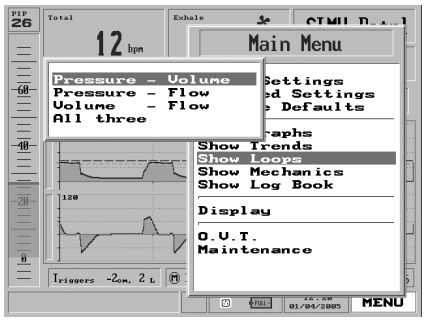


Figure 4.64 The Show Loops pop-up

3. Select any of the loops, or all three. The loops appear on the right side of the Main Screen. Here is a sample Pressure/Volume Loop:

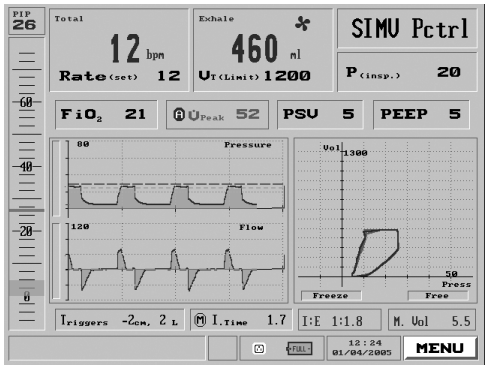


Figure 4.65 A Pressure/Volume loop

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 bars marked ″Freeze″ and ″Free″:

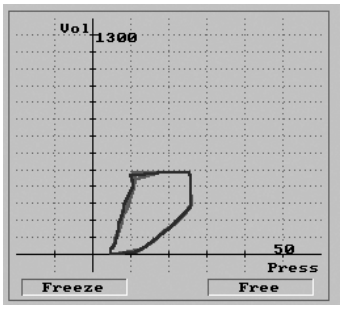


Figure 4.66 Closeup view of the Loops screen

You can use these to freeze a single loop on the display for purposes of clinical comparison. (This feature is only possible when displaying **one** loop.)

4. To **freeze** a loop, rotate the control knob to select the Freeze selection bar, then press. The current inspiratory cycle will change to red. Only the *present* loop (drawn in blue) and the *previous* loop (dark gray) will continue to display in the foreground, while the frozen loop will show in red in the background.

5. To **unfreeze** the currently-displayed loop, rotate the control bar until Free is highlighted, then press. As soon as the current breath is completed, the frozen loop will disappear and the display will resume 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 and get rid of Loops, select Show Graphs from the Main Menu.**

4.8 Show Mechanics

The *i*Vent$_{201}$ will calculate and display Mean Airway Pressure, Resistance, Compliance, RR/Vt, Static Compliance, Auto-PEEP, and Time Constant. Call up the Main Menu (dial the control knob until the MENU box on the lower right corner is highlighted in blue. Then press the control knob), then turn the knob until Show Mechanics is highlighted.

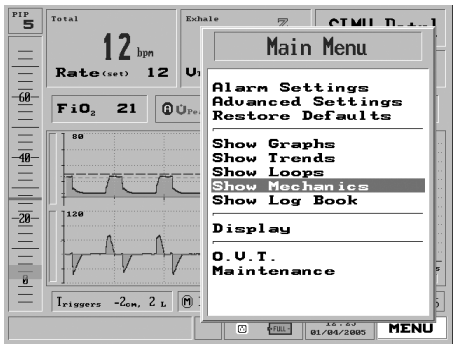


Figure 4.67 Show Mechanics highlighted on the Main Menu

Press the knob. The right section of the screen will show the seven numeric values:

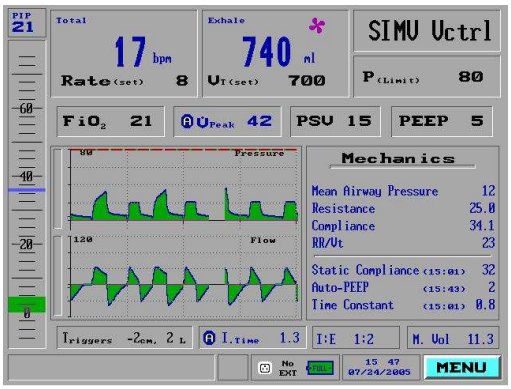


Figure 4.68 The Mechanics window

4.9 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 *i*Vent201, an entry is noted in the Log Book. The *i*Vent201 retains up to 1500 events in its memory, of which up to 300 may be accessed from the Log Book function of the Main menu.

To call up the Log Book:

1. Highlight the Main menu selection box in the bottom right corner of the screen and press.
2. Turn the control knob to select Show Log Book from the Main menu. Press the knob to bring up the Log Book.

Figure 4.69 Show Log Book highlighted on the Main Menu

3. A bright blue screen will appear, showing in chronological order each event, stamped with the date and time. Rotating the dial counterclockwise will move the highlight bar backwards up the log of events; rotating the dial clockwise will advance the log book forward in time.

4.10 Display

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

Note: Depending on which *i*Vent$_{201}$ model you have purchased, not every display may be available.

Note: On the Display choices screen, Brightness is not active.

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

Figure 4.70 The Monitoring Display

The Monitoring display is designed for optimal readability, showing yellow letters over a black screen with yellow numerals showing key ventilation parameters.

The pulse SpO_2 box is also available also on the Monitor display.

To display the SpO2 box on the Monitoring screens:

- Select the **SPO2** button on the lower left side of the screen.

The **SpO2** box appears on right side of the screen.

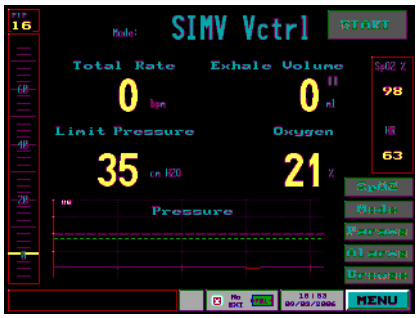


Figure 4.71 The Pulse Oximetry box in the Monitor Display

The Home Care display only shows the essential data.

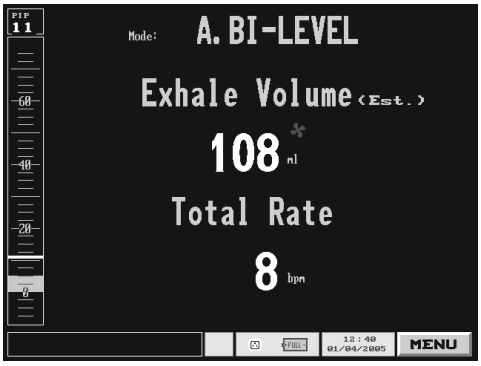


Figure 4.72 The Home Care Display

The pulse SpO_2 box is also available also on the Monitor display.

To display the SpO2 box on the Monitoring screens:

- Select the **SPO2** button on the lower left side of the screen.

The **SpO2** box appears on right side of the screen.

Figure 4.73 The pulse Oximetery box in the Home Care Display

To access settings from the Monitoring or the Home Care screen, rotate the control knob to highlight the desired selection box. Press the knob to accept your selection. (For more information on choosing mode, setting parameters, setting alarms and browsing waveforms, refer to the index or to the table of contents.)

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 wish to change settings or view ventilator information, change to the Main menu display.

To switch to any display, turn the control knob to highlight the Menu selection box in the bottom right section of the screen, and then press. Turn the control knob to highlight Display, then select the desired screen.

4.11 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.

To start the O.V.T., highlight the Main menu selection box in the bottom right corner of the screen and press the control knob. Turn the control knob to select O.V.T. from the Main menu. Follow the on-screen directions. (For more information, see Section 3.3.2.)

4.12 Maintenance

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

5 Adaptive Bi-Level

In this section you will learn

- 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

5.1 About Adaptive Bi-Level

In VersaMed's Adaptive Bi-Level mode the *i*Vent 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 mode is a combination of two standard modes of ventilation: Pressure Control, where the inspiratory and end expiratory pressures, I-Time, and Breath Rate are specified; and Pressure Support Ventilation where breath termination can be controlled by the patient.

5.2 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 will provide 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 will be easier for the patient if the %flow termination value is high. A low percent peak flow termination value will mean that the mandatory I-time will dominate the inspiratory cycle. Therefore, if the % peak flow parameter is set at a low level, the I-time setting must be appropriate to avoid breath stacking.
- Either Nasal CPAP masks or full facemasks may be used with AB. 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. Please refer to Table 5.3 at the end of this section for recommended masks.

5.3 Indications and Warning

5.3.1 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.

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.

5.4 Setup

Here is the suggested procedure for applying facemask ventilation:

1. Power up the ventilator.
2. Select patient weight based on ideal body weight (IBW)
3. Select the Adaptive Bi-Level mode, by opening the Ventilation Modes window and using the control knob to choose "Adaptive Bi-level**".**

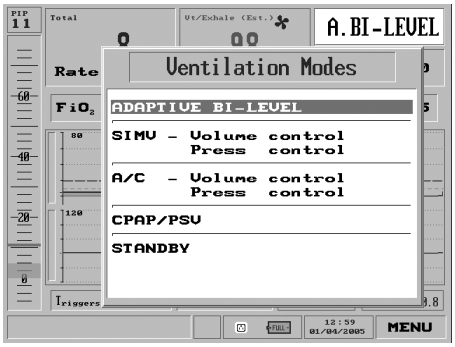


Figure 5.1 Adaptive Bi-Level shown selected on the Modes screen

4. Accept or adjust the parameters on the pop-up window.

The factory default settings are displayed below:

Table 5.1 Adaptive Bi-Level default settings

Respiratory Rate	= 8 bpm
P-High	= 10 cmH_2O
Easy Exhale™	= On
P-Low	= 5 cmH_2O
Rise Time	= 0.5 sec
I-Time	= 1.5 sec
Peak Flow Termination	= 40%
Triggering	= -2 cmH_2O for pressure and 2 L/min for flow triggering (under Trigger settings on the lower left of the main window).

5. If facemask ventilation is desired, 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 Section 5.5 on page 186).
7. Next, select suitable patient alarms by calling up the Main Menu and highlighting and entering the Alarm Settings window. Enter the appropriate alarms according to facility protocol.

NOTE: Adaptive Bi-Level is an SIMV mode and will provide a backup respiratory rate if spontaneous patient breathing efforts are not detected.

NOTE: In cases where a severe leak is present, the Patient Disconnect alarm may be disabled. This may be done via the "Alarm Settings" window (see section 7.4, on page 224) .

5.4.1 Adaptive Bi-Level Alarm Settings

The Default Alarm Settings for Adaptive Bi-Level are given below:

Table 5.2 Adaptive Bi-Level default alarm settings

Rate	Default off
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.

5.4.2 Other Alarm Options

In addition to the Alarm Settings the operator may 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**)

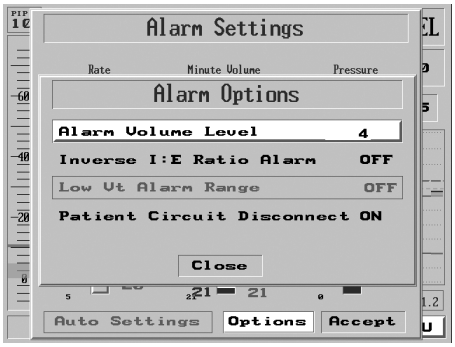


Figure 5.2 Adaptive Bi-Level Alarm Options (the Alarm Settings page)

The Patient Circuit Disconnect alarm may be turned OFF under medical discretion in the Adaptive Bi-Level mode. When selecting OFF, the display shows this warning:

Figure 5.3 Patient Circuit Disconnect Switched Off warning

When Patient Circuit Disconnect alarm is OFF, a warning icon "Disc OFF" appears in the lower left corner of the display.

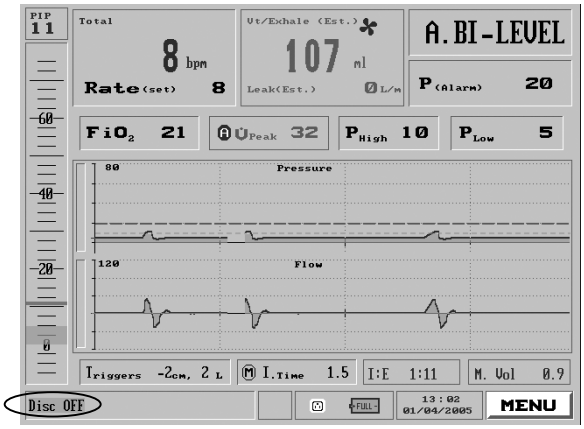


Figure 5.4 Patient Circuit Disconnect Switched Off icon

5.5 Adjusting Adaptive Bi-Level Parameters

Use the Mode screen to set parameters for AB ventilation.

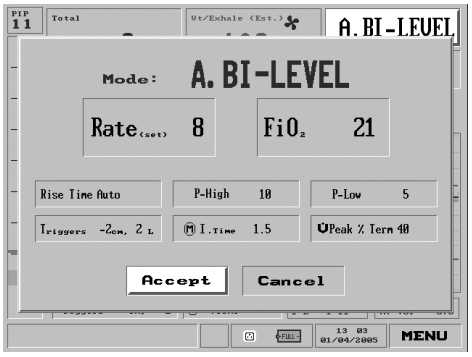


Figure 5.5 Adaptive Bi-Level Mode Parameters

Here are the ranges for Adaptive Bi-Level parameters:

Rate	1 to 50 bpm depending on I time setting selected
FiO_2	21% to 100%
Rise Time	0.1 to 1.5 sec Note: Rise time cannot exceed inspiration time.
P-High	2 to 60 cmH_2O; with CAUTION indication at 41 cmH_2O Note: P-High cannot be set below P-Low +2.
P-Low	0 to P-High minus 2 or Maximum 30 cmH_2O
Vpeak % Term	10% to 90% (default 40%)
I-Time	0.5 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 was terminated by the set I-Time being reached. When breath termination occurs due to decreased flow, the I-Time display is steady.**
Triggers:	
Pressure	–0.5 to –20 cm (default –2)
Flow	1 to 20 L (default 2)

NOTE: Apnea Back Up ventilation operates in the same manner as in other ventilation modes. See Appendix E4 for more details.

5.6 Adaptive Bi-Level Window

This is what the *i*Vent$_{201}$ ventilating in Adaptive Bi-Level mode looks like:

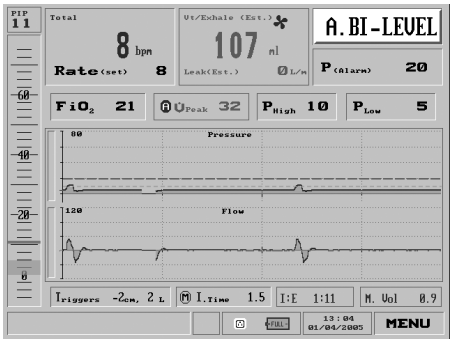


Figure 5.6 Adaptive Bi-Level Mode

The V_T display shows the estimated Tidal Volume delivered to the patient calculated using the measured flow leak during P-low. An estimated Leak is shown below the V_T/Exhale field of the display.

The Leak Estimate value is shown as Liters/Minute. Estimates of V_T/Exhale are disregarded at leaks above 40 Liters/minute.

5.7 Easy Exhale™

Easy Exhale™ is an advanced PEEP mode for use in the circumstance of severe obstructive airway flow limitation in which clinically important critical airway closure results in intrinsic PEEP. Its purpose is to improve downstream airway emptying while potentially matching intrinsic PEEP to optimize alveolar ventilation. In this mode, the ventilator circuit is depressurized through the initial phase of expiration to facilitate downstream dead space ventilation. The introduction of PEEP to the ventilator circuit late in expiration prevents airway pressure from falling below alveolar pressure with resultant auto-PEEP.

NOTE: The default setting for Easy Exhale™ in Adaptive Bi-Level mode is "on." This default may be disabled through the "Advanced Settings" window at the operator's discretion. See Section 4.3.3, page 130.

5.8 Optimizing the Patient Ventilator Interface

Setting up the Patient Ventilator interface is straightforward. Either a nasal CPAP mask or a full-facemask may 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.

5.9 Resolving Patient Ventilator Dysynchrony

Excessive Ventilation:

If there is excessive ventilation decrease either the respiratory rate or the P-high level.

Excessive Leak:

Detection - Excessive leak is evidenced by a large leak flow indicated under the estimated tidal volume (> 30 Lpm) or 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, that 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 persistent, 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 under the AB Mode menu. Additionally, consider decreasing I-time. An air leak may lead to "inspiratory hang up". This may 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 resolves as a result, reconsider settings for I-time and percentage leak flow termination consistent with clinical guidelines.

Optimizing expiratory synchrony is of particular importance in patients with obstructive ventilatory disorders. These patients generally require prolonged expiratory periods to optimize airway emptying and minimize 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) 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 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 5.3 Face Masks

Nasal Masks	**Full Face Masks**
	Respironics Image 3 SE disposeable version
All Types (chin strap may be required for mouth breathers)	Resmed Mirage 2- reuseable version (no vent holes)

6 Alarms

In this section you will learn how to

- Quickly respond to *i*Vent$_{201}$ alarms
- Determine and select optimal alarm settings Access the tables in this manual to reference alarm parameters and troubleshoot
- Perform Alarm tests
- Understand how the *i*Vent$_{201}$ operates when the sensor disconnect alarm is activated or when it senses patient disconnection

6.1 How Alarms Work

As soon as the *i*Vent$_{201}$ 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. There it will:

- show red as long as the alarm condition persists
- turn green if the alarm condition resolves itself without user intervention

6.1.1 Responding to an Alarm

Silence the alarm by:

1. Rectifying the condition which caused the alarm. This will stop the alarm sound and minimize the pop-up alarm. The minimized alarm will show in green with a brief text message describing the alarm condition.

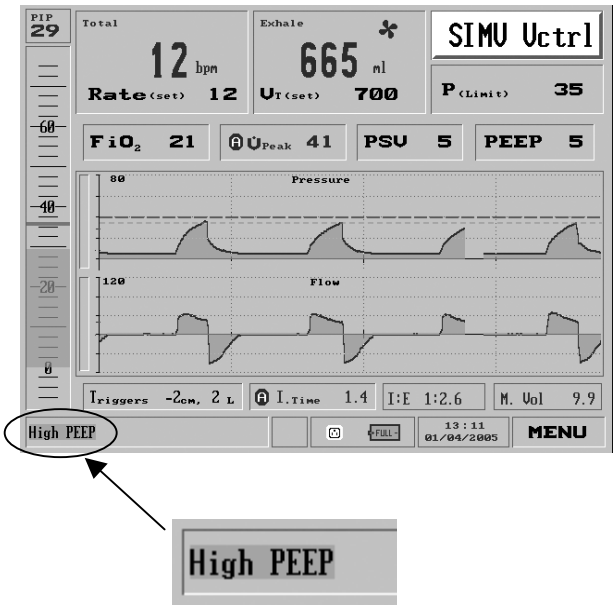


Figure 6.1 Corrected High PEEP alarm

2. Pressing the **clear** button on the keypad. This will silence the alarm sound and minimize the pop-up alarm. If the condition which caused the alarm is not resolved, the minimized alarm is colored red and labelled with a text message describing the alarm condition. After 30 seconds, the alarm pop-up will maximize and sound 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. Pressing the red **silence** button on the keypad. This will silence the alarm sound and minimize the pop-up alarm. A two-minute timer will start, shown in the bottom right beside an icon showing a crossed-out bell.

Figure 6.2 Silenced Alarm icon

For as long as the condition causing the alarm is not corrected, the minimized alarm is colored red and bears a text message describing the alarm condition. If the alarm condition is not resolved within two minutes, the alarm pop-up will maximize and sound 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.

⇒ **If more than one alarm condition occurs, the alarm messages will 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.**

6.1.2 Alarm settings

The *i*Vent$_{201}$'s alarm settings are highly configurable. If you need to change them, refer to Section 6.2, Alarm Settings.

⇒ **Use "Auto Settings" to adjust alarms to fit a particular ventilation mode and parameter setting. See Section 4.2.1.**

The following alarms are user-adjustable:

- High and Low Respiratory Rate (to adjust this rate, see Section 4.2.1.1)
- High and Low Minute Volume (Section 4.2.1.2)

- High and Low Pressure (Section 4.2.1.3)
  - ⇨ The Low Pressure alarm is updated automatically when setting the PEEP value. It can also be adjusted from the Alarm Settings window
- Apnea Time (Section 4.2.1.4)
- High and Low FiO_2 (Section 4.2.1.5)
  - ⇨ This alarm is updated automatically when setting the FiO_2 parameter and can also be adjusted from the Alarm Settings window
- Leak % (Section 4.2.1.6)

The following alarm values are configurable:

- Volume Limit Reached
  - ⇨ This alarm is automatically set from the pressure controlled setting window, whereas the other alarms are set from the Alarm Settings window and can be adjusted from the Tidal Volume window.
- Audio Alarm Volume
  - ⇨ From 1-10: factory default is 8 (Section 4.2.3.1)
- Inverse I:E Ratio Alarm
  - ⇨ On or Off: factory default is On (Section 4.2.3.2)
- Tidal Volume not delivered (Section 4.2.3.3)
  - ⇨ Off or 15%-85% range: default is set to 85%
- Patient Circuit Disconnect (Section 4.2.3.4)

⇨ On or Off: factory default is On. Turning the Patient Circuit Disconnect Alarm Off disables the following alarms: Tube Disconnect, Patient Disconnect, Sensor Disconnect (Check Patient). This option may not be available on all models.

The following alarms are always operational:

A/C Power disconnect

Low Battery

Battery Empty

Over Temperature

Patient Circuit Failed

Service Notice

High PEEP

Low O_2 pressure

Check Sensor

Need calibration

Auto Start

6.2 Guide to Alarm Definitions and Priorities

*i*Vent$_{201}$ alarms differ by sound according to degree of severity. Table 6.1 shows categories and characteristics of alarms.

Table 6.1 Alarm and Audible Alarm Patterns

Priority	**Audible Pattern**	**When criterion for alarm clearing 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 6.2 below shows alarm definitions and will guide you through troubleshooting. In these tables:

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

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

Message is the small text message in the minimized alarm 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 6.2 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

Warning *Set Count or Time of Condition*	**Mode of Failure**	**Priority**	**Probable Cause**	**Criterion for Clearing Alarm**	**Corrective Action**
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
High FiO_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 4 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	The heart rate exceeds the upper rate limit	Mid	Clinical Condition	Heart rate is lower than the alarm settings	Check the patient condition.
High Minute Volume *2 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
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	Pressure is lower than alarm threshold for 3 breaths	Subject to clinical judgment, correct setting as necessary

Warning *Set Count or Time of Condition*	**Mode of Failure**	**Priority**	**Probable Cause**	**Criterion for Clearing Alarm**	**Corrective Action**
			Delivery tubes occluded or partially occluded		
High SpO_2	SpO_2 level exceeds the upper SpO_2 limit	Medium	The patient clinical condition, FiO_2 level set too high, or the SpO_2 setting are too low	The SpO_2 level is lower than the alarm limit	Assessing the patient clinical condition, decreasing the FiO_2 level, or increasing the SpO_2 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*	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
Patient Circuit Failed *30 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)

Warning *Set Count or Time of Condition*	**Mode of Failure**	**Priority**	**Probable Cause**	**Criterion for Clearing Alarm**	**Corrective Action**
Low Heart Rate	The heart rate is below the rate limit	High	Clinical Condition	Heart rate exceeds the lower alarm limit.	Check the patient condition.
Low FiO_2 *15 breath delay* *or* **Low FiO2 Backup** *(available for first 20 breaths)* *5 breath delay*	Oxygen concentration is below alarm setting FiO2 less than 22%	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 4 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 *5 breath delay for units S/N below IV500*	External oxygen supply pressure is low *10 seconds after the detection of O_2 inlet pressure below 10PSI for S/N IV500 and subsequent*	High (LT)	Oxygen supply is disconnected Low oxygen pressure and/or flow 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
Low Pressure *3 breath delay*	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

Warning *Set Count or Time of Condition*	**Mode of Failure**	**Priority**	**Probable Cause**	**Criterion for Clearing Alarm**	**Corrective Action**
Low SpO2	SpO_2 level is below the set lower SpO_2 limit	High	The patient clinical condition, FiO_2 level set too low, or SpO_2 alarm setting too high	SpO_2 level is higher than the alarm limit.	Assessing the patient clinical condition, increasing the FiO_2 concentration, or decreasing the SpO_2 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 desired 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
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℃	High	Cooling vents of the ventilator are blocked High external heat Malfunction of internal cooling fan Temperature sensor failure	N/A	Perform Preventive Maintenance procedures Verify cooling vents are clear and clean Remove or protect unit from external heat source Remove 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 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 *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
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
SpO_2 Low perfusion	A bad connection between the patient and the SpO_2 sensor	Mid	The patient and/or the sensor are disconnected from the oximeter cable	The signals from the SpO_2 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 SpO_2 sensor**.**

Warning *Set Count or Time of Condition*	**Mode of Failure**	**Priority**	**Probable Cause**	**Criterion for Clearing Alarm**	**Corrective Action**
Sensor Patient disconnect	The iVent identify that the SpO_2 sensor is connected but no signal is received from it	Mid	The SpO_2 sensor is disconnected from the patient, while it is still connected to the $iVent_{201}$ machine	When the patient is reconnected s to the SpO_2 sensor	Reconnect the patient to the SpO_2 sensor
Sensor iVent disconnect	The iVent identify that the SpO_2 sensor is connected but no signal is received from it.	Mid	The SpO_2 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 SpO_2 sensor is received by the iVent.	Connect the SpO_2 sensor to the iVent
One Way Valve (Patient Circuit Failed)	One way valve at Wye sensor missing or defective	High	Valve broken or missing	Normal one-way valve operation	Replace patient circuit or one-way valve
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 (fast) Pressure flow set too low Rate set too high Blue tube disconnected Pressure limit set too low	Volume is higher than set volume minus 15% for more than 2 breaths	Increase pressure limit if appropriate Reconnect blue tube Assess patient

Warning *Set Count or Time of Condition*	**Mode of Failure**	**Priority**	**Probable Cause**	**Criterion for Clearing Alarm**	**Corrective Action**
			Clinical situation		
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 then 10 cm from set value	High	Exhalaton Valve occlusion Improper parameter setting	PEEP pressure decrease to set value + 10	Check exhalation valve Check parameter setting
Driver Failure	A failure in the Hold-Nebulizer System	Low	A short circuit in the Hold-Nebulizer card.	N/A	Remove unit for inspection and servicing by qualified service personnel
O2 system Failure	Abnormal O2 flow or pressure.	High	PSV Malfunctioning	N/A	Remove the unit for inspection and servicing by qualified service personal/

6.3 Alarms Tests

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.

1. Connect the ventilator to AC power and oxygen supply according to the iVent specification (refer to section 2.1.1 on page on page 28).
2. Power up the ventilator. It will automatically run self-test.

3. Select the default set for patient weight 70kg. Set FiO_2 to 40% (if default set is configured to an other value).
4. Run OVT (refer to section below on page 223).
5. Attach a 2L test lung with Rp20 resistance to the patient circuit through HME filter and start ventilation.
6. **Tube Disconnect alarm test**. Wait for at least 30 second 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.
   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 restores 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 **O_2 Pressure** alarm is activated.
    Reconnect the O_2 supply and verify that the **O_2 pressure** alarm disappears automatically.

11. **Low Minute Volume alarm test**. Press **Menu** and open the **Alarm Settings** window. 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** window. 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 O_2% alarm test.** Press **Menu** and open the **Alarm Settings** window. Set the High O_2% alarm setting to a value below the measured value for FiO_2 (in blue in the alarm setting bar) and press **Accept.** Verify that the **High O_2** alarm is activated on the twentieth breaths after Accept was pressed. Close the alarm pop up window and restore the alarm setting to its default value.
14. **Low O_2% alarm test.** Press **Menu** and open the **Alarm Settings** window. Set the Low O_2% alarm setting to a value above the measured value for FiO_2 (in blue in the Alarm setting bar) and press **Accept**. Verify that the **Low O_2%** 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 the unit starts ventilation is Pressure Control mode at the preset parameters. Close the alarm pop up window and switch the ventilator to Standby.

6.4 The Sensor Failure Alarm

When the *i*Vent$_{201}$ detects a Sensor Disconnect alarm or Check Sensor condition it will enter 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 this pop-up window:

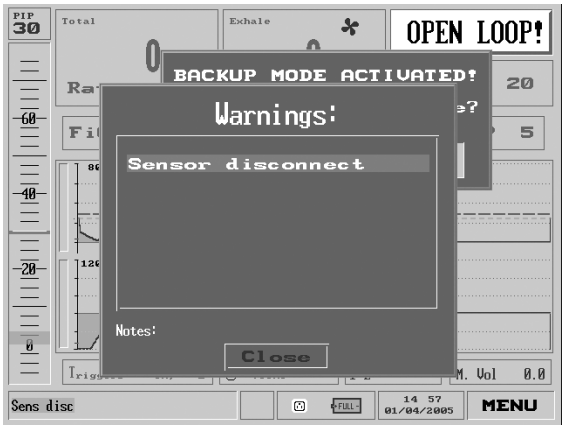


Figure 6.3 The Sensor Disconnect Alarm pop-up

- 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).

CAUTION: 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.

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

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

6.5 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 may be 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 section 5.2.3.4.

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

6.6 Patient Circuit Failed Alarm

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

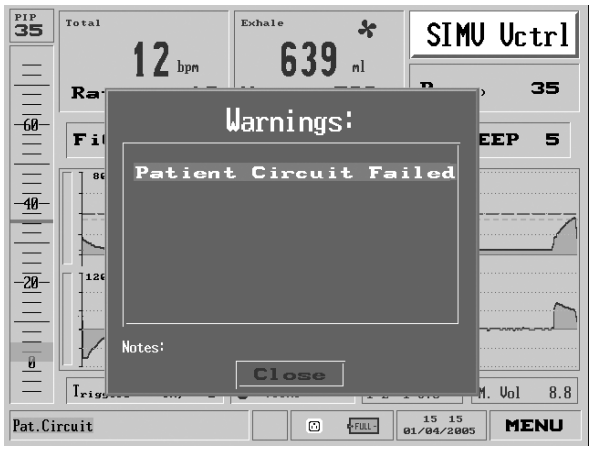


Figure 6.5 The One-Way Exhalation Valve pop-up.

The patient circuit should be replaced at once.

7 Care, Maintenance, and Tests

This section shows you how to

- Clean and maintain the *i*Vent$_{201}$
- Keep the *i*Vent$_{201}$ operable with the help of preventive maintenance
- Calibrate and perform diagnostic tests on the *i*Vent$_{201}$

7.1 Cleaning and Maintenance

While the *i*Vent$_{201}$ has been designed to resist damage, staining, and wear, taking care to perform an occasional cleaning and following basic maintenance procedures will enhance its lifecycle.

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

Table 7.1 Maintenance Procedures and Intervals

Part	Procedure	Comments
Ventilator	Wipe exterior clean with a damp cloth and mild detergent.	Do not allow liquid to penetrate into the ventilator.
Cooling Vents & Cooling Inlet Filter	Clean every 1500 hours (or 3 months) of use, or as necessary.	Use vacuum device to clean the vents and cooling air inlet filter.

Part	Procedure	Comments
Air Inlet Filter	Replace every 500 hours (or 1 month) of operation, or as necessary.	Do not attempt to clean or reuse the air inlet filter.
Battery Pack	Recharge every 90 days of storage. Replace every year or as necessary.	Actual life depends on history of use and storage.
O_2 sensor	Replace every 5000 hours of operation or annually, as necessary	
Inlet and outlet mufflers	Replace every 5000 hours of operation or annually, as necessary	
Pneumatic unit	Replace every 15,000 hours of operation, or every two (2) years, as necessary	
Other accessories	Follow manufacturer instructions.	

7.2 Preventive Maintenance

Observing the following maintenance intervals will help keep the *i*Vent$_{201}$ operating trouble-free.

Table 7.2 Preventive Maintenance Procedures

Frequency	Part	Maintenance
Every 500 hours or 1 month	Air Inlet Filter	Remove the used air inlet filter and replace it with a new inlet filter

Frequency	Part	Maintenance
1500 hours or 3 months of use	None	O_2 Calibration
1500 hours or 3 months of use	Battery	Deep Discharge and Recharge
Every 3 months of storage	Internal Battery	Recharge
Annually	Air Inlet Filter Cooling Air inlet filter Battery Inlet muffler assy. Outlet muffler assy.	Perform safety checks Replace listed parts by an authorized VersaMed Service Technician
Every 15000 hours	Pneumatic Assembly	Replace parts by authorized VersaMed Service Technician

7.3 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 in section 4.1.2.

7.4 The Maintenance Screen

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

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

7.4.1 Calibration

WARNING: Only trained personnel should perform calibration procedures.

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

7.4.2 Ventilator Verification Tests

The Ventilator Vertification 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.

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

It will be necessary to perform a VVT after a software update.

When the *i*Vent detects that a VVT has not been performed, or if for any reason the *i*Vent has failed to pass a VVT previously, a warning pop-up will appear:

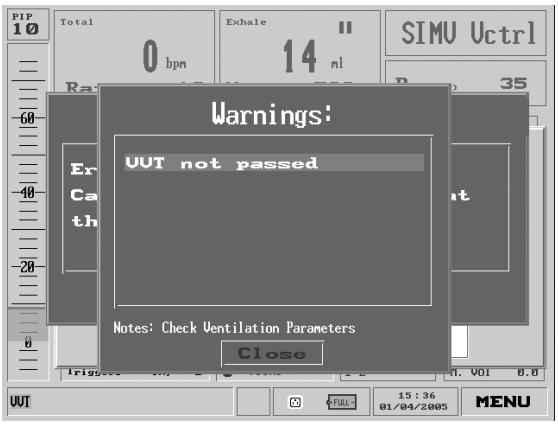


Figure 7.1 The VVT not passed pop-up

Immediately perform the VVT, as described below.

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

The VVT checks the following:

- System buzzers (two)
- Patient pressure measurement and pressure performance
- Blower pressure measurement
- Transducer tubes leak
- Motor speed measurement
- Positive relief valves
- Solenoid valves (two)
- Solenoid safety release mechanism
- Flow performance
- Flow zeroing accuracy
- 21% FiO_2

- Pressure switch status at 21%
- Demand Valve leak
- 100% FiO_2
- Pressure Switch status at 100%
- Battery status
- Motor watchdog safety device
- PC watchdog safety device

7.4.2.1 Required Equipment and Supplies:

- Plug for blocking the breathing circuit
- O_2 supply
- O_2 hose

7.4.2.2 Starting the VVT:

1. Connect a breathing circuit to the *i*Vent$_{201}$.
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. Call up the Main menu from the Main screen.
5. From the Main menu, select Maintenance.
6. You will see a caution pop-up. Select Yes to proceed, otherwise, return to the Main screen by selecting No.

7. Dial the control knob to select Ventilator Verification Test, and press.
8. The Ventilator Verification pop-up window appears.

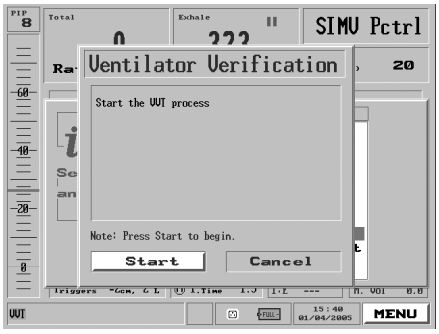


Figure 7.2 The Ventilator Verification pop-up

9. Make sure Start is selected and press the control knob.

7.4.2.3 The Alarm Sound Test

1. The VVT window will ask if the first alarm is audible. If you can hear it, select "Continue" to proceed. If you can't hear it, press "Failed."

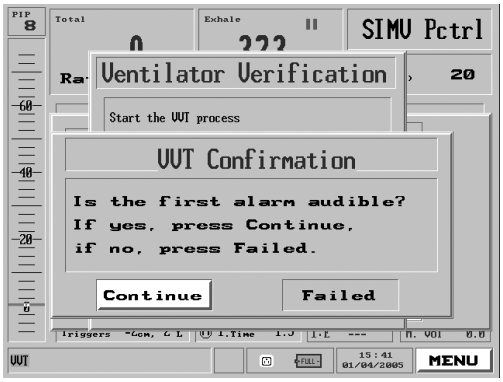


Figure 7.3 The VVT Alarm test

2. Next, the window will ask if the second (louder) alarm is audible. If you can hear it, select "Continue" to proceed. If you can't hear it, press "Failed." The VVT instruction pop-up will appear.

7.4.2.4 Pressure Tests

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

7.4.2.5 Flow Tests

1. A pop-up appears, instructing you to unblock the patient circuit. Remove the stopper, and then select and press OK.
2. The test will complete in approximately six (6) seconds. The VVT instruction pop-up will appear.

7.4.2.6 O_2 Tests

1. The VVT screen will ask you to confirm that there is no O_2 supply connected to the ventilator. Make sure no O_2 supply is connected. Then select and press Ok.

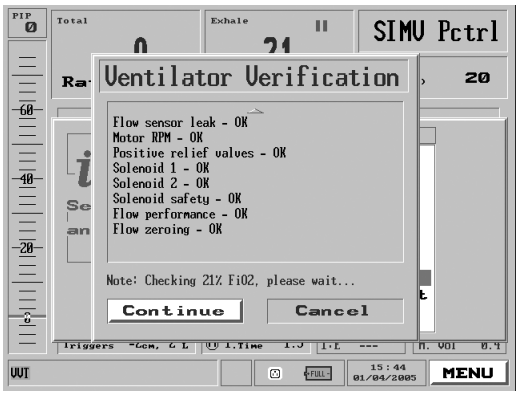


Figure 7.4 The 21% FiO_2 test

2. The test will take about 1 minute. When it is completed, the VVT screen will direct you to connect an O_2 supply. This test takes about 2 minutes to complete. The VVT instruction pop-up will appear.

7.4.2.7 Battery Test

1. The VVT screen will prompt 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 the AC plug icon at the bottom of the LCD display is crossed out.
3. Press Ok. Once the test has completed, after approximately 20 seconds, the VVT Instruction pop-up will appear:

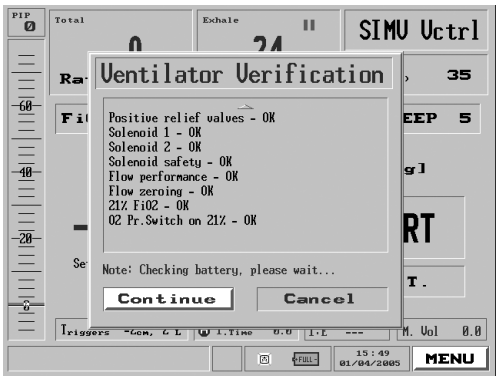


Figure 7.5 The battery test

7.4.2.8 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 will indicate it is checking the motor watchdog, and then the ventilator will restart.

7.4.2.9 VVT Completion

1. When the VVT has completed, a System Message window will indicate 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 (Section 8.4.1, page 224) 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 will post an alarm window that indicates a VVT must be done before it is put into use.

7.5 Configuration Screen

Use the Configuration Screen to adjust:

- Default startup weight
- Default start screen
- Default FiO_2 setting

To access the Configuration screen: call up the Main menu, then choose Maintenance. When the red Caution screen appears, select Yes. 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 *i*Vent$_{201}$ unless you are certain what options you wish to alter. Make sure settings are in accordance with standard protocol within the hospital or patient facility.

7.5.1 Choosing a different Startup Screen

Use the Default start screen option if you would like the *i*Vent$_{201}$ to power up with a different screen.

1. From the Configuration screen dial the control knob to highlight "Default start screen," then press.
2. A pop-up will appear showing Main Screen, Monitoring, and Home Care. Select which screen you prefer, and press the knob again.

NOTE: Not all screens are operational in all *i*Vent$_{201}$ models.

The Configuration screen will return with the newly-selected startup screen highlighted. When the *i*Vent$_{201}$ is restarted, the screen you've chosen will appear.

7.5.2 Setting the startup weight

The *i*Vent$_{201}$ defaults to a patient weight of 70+kg. To change the startup default:

1. From the Configuration screen dial the control knob to highlight "Default start weight," then press.
2. A pop-up will appear showing a range of choices from 10 to >70, as well as Last. Select the desired weight, and press the knob again.

The Configuration screen will return, with the newly-selected weight highlighted. When the *i*Vent$_{201}$ is restarted, the first screen will appear with the weight you've selected highlighted

⇒ **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 from the Main Menu (see section 3.3.5).**

7.5.3 Default FiO_2 Setting

Use the Default FiO_2 setting option if you need to change the default *i*Vent201 FiO_2setting.

1. From the Configuration screen dial the control knob to highlight "Default FiO_2 Setting," then press.
2. A pop-up will appear offering a range of choices: 21%, 40%, 60%, and 100%. Make the desired selection and press the knob again.

The Configuration screen will return with the newly-selected startup screen highlighted. When the *i*Vent201 is restarted, it will default to the new O_2 setting.

7.6 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 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.

7.7 Communication Rate

The *i*Vent$_{201}$ 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. If you wish to change the communication rate:

1. From the Maintenance screen dial the control knob to highlight "Communication Rate," then press.
2. A pop-up will appear offering a range of choices: 1200, 2400, 4800, 9600, 19200, 38400, 57600, and 115200. Make the desired selection and press the knob again.

The Maintenance screen will return with the selected communication rate highlighted. The ventilator will restart with the new communication rate.

7.8 Localization

Localization is used to change the language set for the *i*Vent$_{201}$.

WARNING: Do not access the Localization menu unless you are sure you wish to change the language the *i*Vent$_{201}$ uses. Remember, if you change the selected language, you will change all the menus.

If you wish to change the selected language the *i*Vent uses for all screens, menus, and messages:

1. From the maintenance screen, highlight and select Localization.
2. A red warning pop-up will appear.

Figure 7.6 The Localization Warning Pop-Up

If you are sure you wish to proceed, make sure "Yes" is selected and press the control knob.

3. The Localization screen appears:
4. Make sure Language is Highlighted, and press the control knob. You will be presented with a pop-up offering you a choice of several languages:

Figure 7.7 Language choices

5. Dial the control knob to select the language you wish. When you press to confirm your selection, the machine will restart in the language you chose.

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 may also be selected by choosing the Date Interfield Character menu. This character can be either a forward slash '/', a colon ':' or a period '.'.

7.9 Total Operating Hours

The Maintenance Screen also shows the total number of hours the ventilator has been in use:

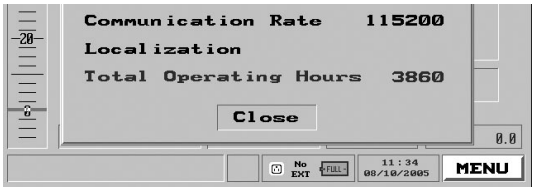


Figure 7.8 Total Operating Hours shown on the maintenance screen

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 will occur.
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).

Term	Definition
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.
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.

Term	Definition
CPAP	Continuous Positive Airway Pressure. A mode of ventilation in which the patient is breathing 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 end-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).
Limit Pressure	Adjustable pressure level at which patient pressure will be limited. No alarm will occur. Tidal volume delivery may decrease when Limit Pressure is reached.

Term	Definition
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 will be 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.

Term	Definition
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.
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 oximetery	Pulse oximetry is a simple non-invasive method of monitoring the percentage of hemoglobin (Hb) that is saturated with oxygen, meaning the amount 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.

Term	Definition
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).
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.

Term	Definition
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 breathes are controlled by flow and terminated by volume, as long as airway pressure is lower than the Limit Pressure.

Appendix B: Warranty

VersaMed ("the Supplier") guarantees to the Purchaser the material and workmanship used in the manufacture of the *i*Vent$_{201}$ 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 to improper use or care, or other causes 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, 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 option and expense, repair or replace such Products, employing at its option, 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 will 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 shall apply 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

The *i*Vent$_{201}$ 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.

C.1 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%.

C.2 CBRN Filter (optional)

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

C.3 Low Pressure O_2 Adapter and Filter (optional)

An optional configuration that enables the usage of low pressure O_2 sources, such as concentrators, to provide O_2 enrichment.

C.4 Air/Oxygen Blending System

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

C.5 Inlet Manifold

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

C.6 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.

C.7 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.

C.8 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 manifold and air inlet filter to the patient breathing circuit is present.

C.9 Over Pressure Relief Valve

If the control system fails to limit the turbine pressure to a maximum level of 80 cmH_2O, this valve will relieve at 80 cmH_2O.

C.10 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.

C.11 Pressure Switch

A pressure switch in the *i*$Vent_{201}$ monitors whether sufficient Oxygen pressure is connected to the unit (approximately 0.7 bar). If insufficient oxygen pressure is available, a low O_2 pressure alarm occurs.

C.12 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.

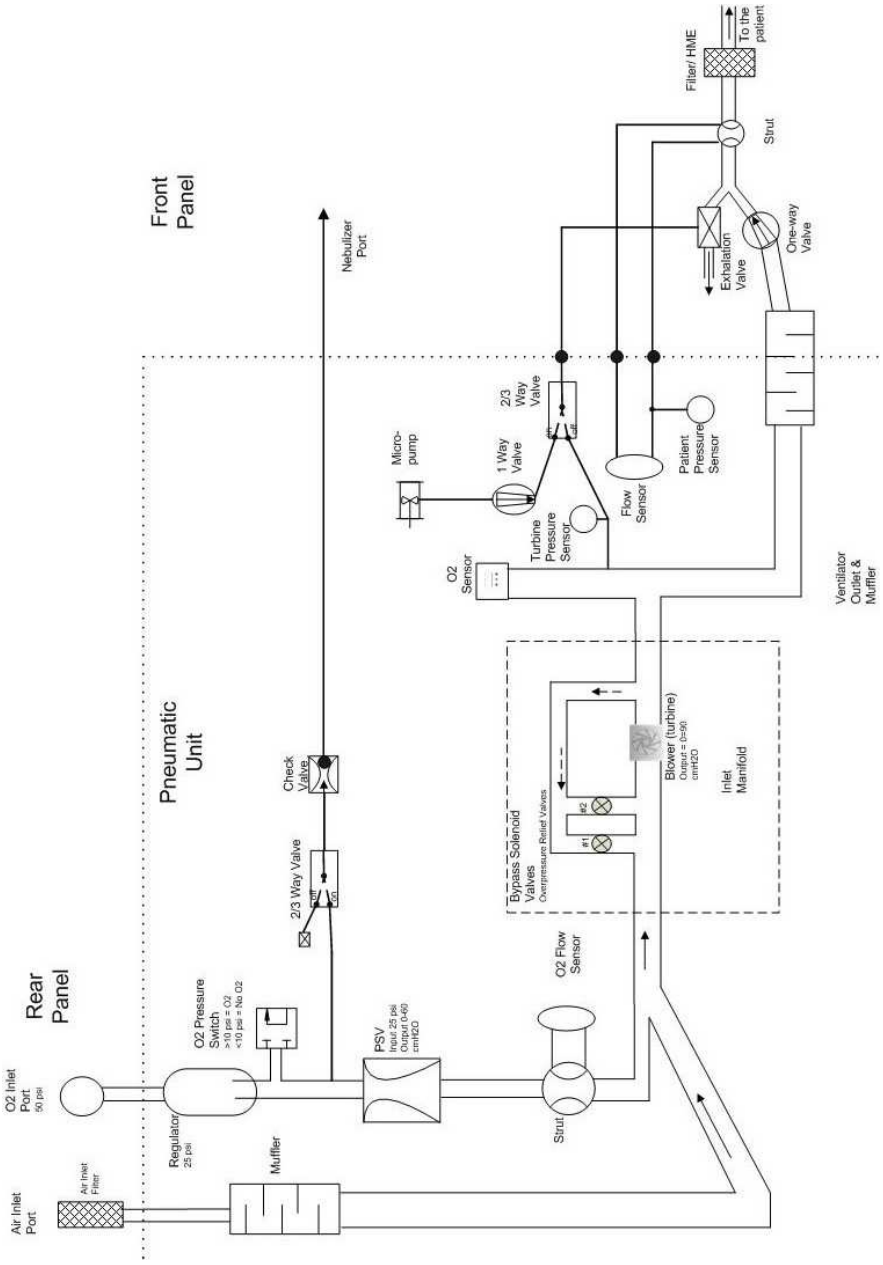


Figure C-1 PC/Pneumatic Schematic Diagram

Appendix D: Theory of Breath Delivery

D.1 Breath Delivery

The *i*Vent$_{201}$ 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.

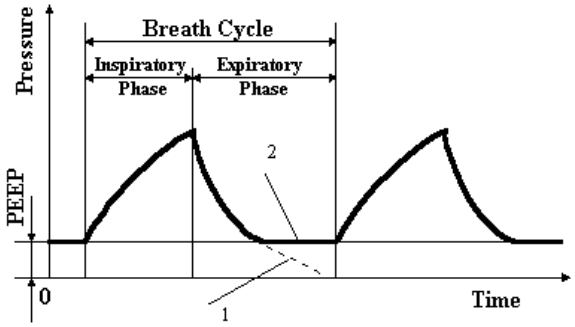


Figure D-1: Pressure Breath Cycle

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 lung 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)

D.2 Patient Triggering

A patient may trigger a breath by creating an inspiratory effort detected by the ventilator. The *i*Vent$_{201}$ has three operator selectable methods for triggering breaths as presented in:

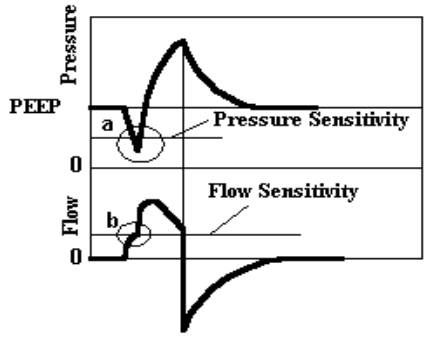


Figure D-2: Pressure and Flow triggering by Patient

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 below).
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 below).
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.

D.3 Breath Types

The ventilator delivers two primary breath types:

4. **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 V_T display.
- **Assist breath** - initiated by the patient (pressure or flow triggered). A red "fan" icon appears in the V_T display.
- **Manual breath** - initiated by the operator by pressing the "manual breath" button.

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.

5. **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.

D.3.1 Adaptive Flow™ and Adaptive I-Time™

Unique to the *i*Vent201, Adaptive Flow™ and Adaptive Time™ are automated ventilator controls to determine peak inspiratory flow and inspiratory time during breath delivery.

Adaptive Flow™ and Adaptive I-Time™ work together only 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.

Changes in the overall breath rate are tracked and the Adaptive I-Time™ algorithm will seek to adjust the inspiratory time over approximately 10 breaths in order to maintain the I:E ratio at 1:2. The Adaptive Flow™ algorithm will accommodate changes in the i-time and automatically adjust 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 will decrease and the mandatory peak inspiratory flow will increase to deliver the set tidal volume.
- If respiratory rate decreases, the inspiratory time will increase and the mandatory peak inspiratory flow will decrease to deliver the set tidal volume.

Should the Adaptive Flow™ algorithm determine that the peak flows achieved by the patient's spontaneous breathing exceed the peak flows that are determined to be necessary to achieve the set tidal volume, the algorithm will match the patient's peak flow so as to avoid the feeling of "air hunger" in the patient. In this situation, the ventilator will not realize an I:E ratio of 1:2.

If flow is insufficient to deliver the tidal volume, inspiratory time will be gradually increased in an attempt to deliver the set tidal volume. In this situation the ventilator will 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 be set manually.

The speed of change for peak flows and inspiratory times is based upon the difference between the target flow / time and the desired 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 *i*Vent$_{201}$ turbine will deliver 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 1:1 I:E ratio based upon the set rate.

During SIMV with a low rate setting, the I:E ratio of all breaths is used to determine the Adaptive Flow™. For example, if the SIMV rate is set to 5 and the patient is breathing once between mandatory breaths for a total rate of 10, the average total cycle time for each breath is 6 seconds. Under these conditions the ventilator will adjust the inspiratory flow to deliver the tidal volume within 2 seconds (I =2, E =4, I:E =2:4 or I:E =1:2). This assures patients will have a normal I:E ratio as they change spontaneous breath frequency.

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 range for manual peak inspiratory flow is 10 to 120 liters per minute. The flow value for the manually set flow rate the ventilator will use, is depicted by a circled **M** symbol next to the peak inspiratory flow value.

NOTE:

1. *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 will be maintained at the set value.*

2. *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, the ventilator will attempt to deliver as high a flow as possible during the inspiratory phase. Under these conditions, inspiratory time will be increased in order to deliver the set tidal volume and the set peak flow reading will flash.*

3. *During SIMV, Adaptive Flow™ is always operational, even if a manual peak flow is set. If the patients average spontaneous flow exceeds the set manual peak flow, Adaptive Flow™ will drive the delivered mandatory breath flow to approximately 80% of the spontaneous inspiratory flow.*

D.3.2 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 Flow™ or manually set value. The flow is controlled by the ventilator in a way that the flow at the end of the inspiratory phase will be half of the peak inspiratory flow. This breath type can be initiated by the ventilator (time-triggering), or by the patient (pressure or flow triggering). 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.

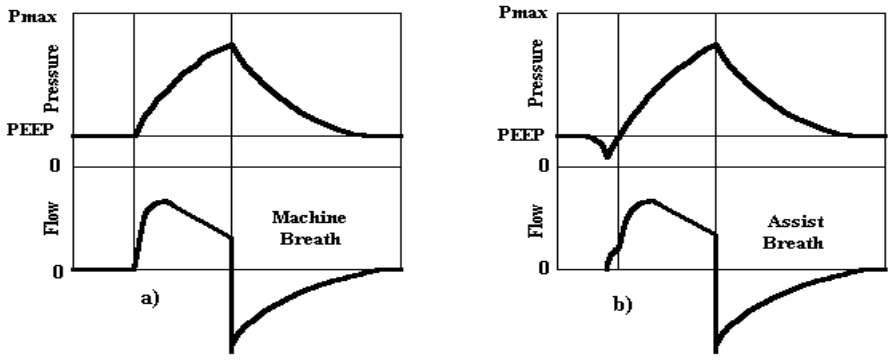


Figure D-3: Volume Control Breath Waveform

Inspiratory phase is terminated when set tidal volume (V_T) is delivered. If Limit Pressure is set lower than Alarm Pressure, tidal volume may be decreased, as inspiration will terminate when Limit Pressure is reached.

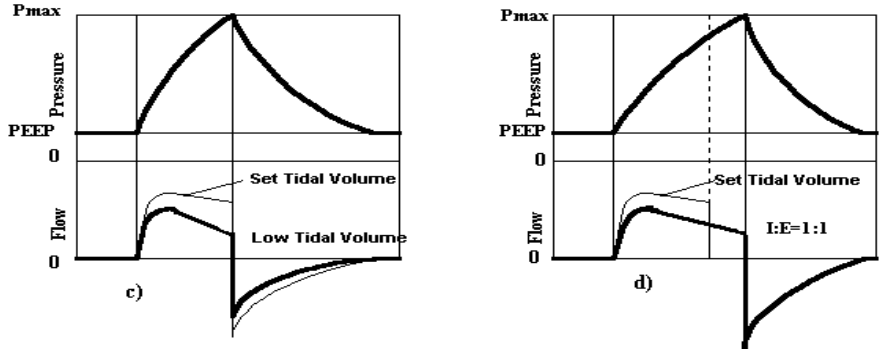


Figure D-4: Volume Control Breath Waveform

D.3.3 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 cmH_2O lower. At the end of the inspiratory phase, the ventilator allows the patient to exhale.

Pressure control breaths will terminate when set inspiratory time elapses.

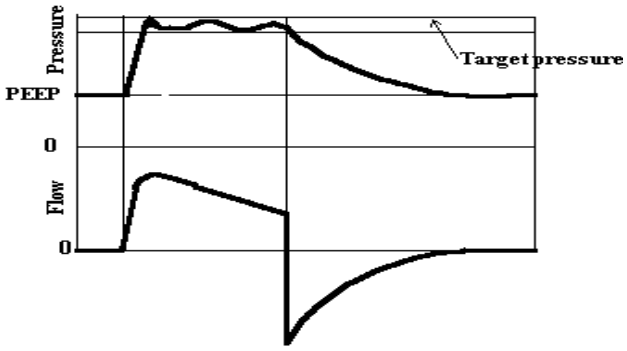


Figure D-5: Pressure Control Breath Waveform

D.3.4 Manual Mandatory Breath

A manual mandatory breath at the currently set parameters may be delivered at any time by depressing 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.

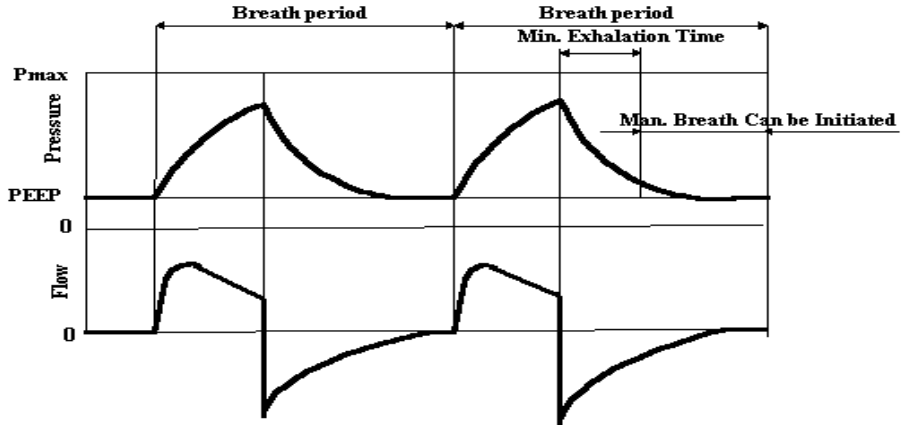


Figure D-6: Delivery of Manual Breath

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 will be set according to the default volume control for the specified patient weight.

D.3.5 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 will occur when:

a) the flow decreases to 25% of the peak flow; or
b) the airway pressure exceeds a value 5 cmH_2O above target pressure; or
c) three seconds or two breath periods have elapsed; whichever occurs first.

At that point, the ventilator terminates flow, allowing the patient to exhale.

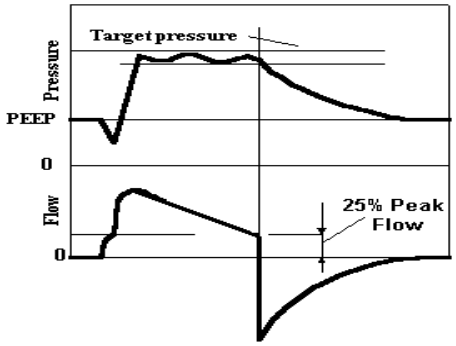


Figure D-7: Pressure Support Breath Waveform

D.3.6 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:

1) the flow decreases to 25% of the peak flow; or
2) the airway pressure exceeds a value 5 cmH_2O above PEEP; or
3) three seconds or two breath periods have elapsed; whichever occurs first.

At this point, the ventilator terminates flow, allowing the patient to exhale and the pressure returns to the PEEP level.

D.4 Summary

The classification of breaths, for the purpose of this manual, are summarized in the following table.

Table D-1: 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 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)

Appendix E: Ventilation Modes

E.1 Assist/Control Mode

E.1.1 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.

E.1.2 Available Breath Types

1. Mandatory ventilator breath
2. Mandatory assist breath
3. Manual breath

All breath types may be either pressure control or volume control.

E.1.3 Description

Figure E-1 demonstrates how breaths are delivered in this mode.

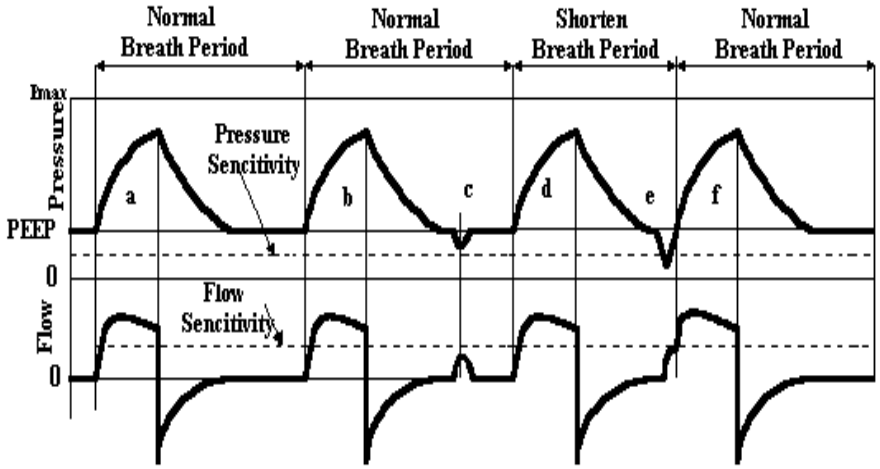


Figure E-1: Breath Pattern in Assist/Control Mode

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.

E.1.4 Parameters Setting

The following parameters may be set:

- Breath Rate (bpm)
- O_2 %
- Tidal Volume

- Peak Flow, Adaptive or set value
- I Time, Adaptive or set value
- Limit Pressure or Alarm Pressure
- Triggering type and sensitivity.

E.2 Synchronized Intermittent Mandatory Ventilation Mode

E.2.1 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 patient initiates an assist breath; therefore, average mandatory bpm does not change.

E.2.2 Available Breath Types

1. Mandatory ventilator breath
2. Mandatory assist breath
3. Manual mandatory breath
4. Patient spontaneous breath
5. Patient pressure support breath

All types of mandatory breaths may be either pressure control or volume control.

E.2.3 Description

During an SIMV breath cycle, mandatory breaths may be initiated and / or occur during:

1. Assist windows (any breath period).
2. 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.

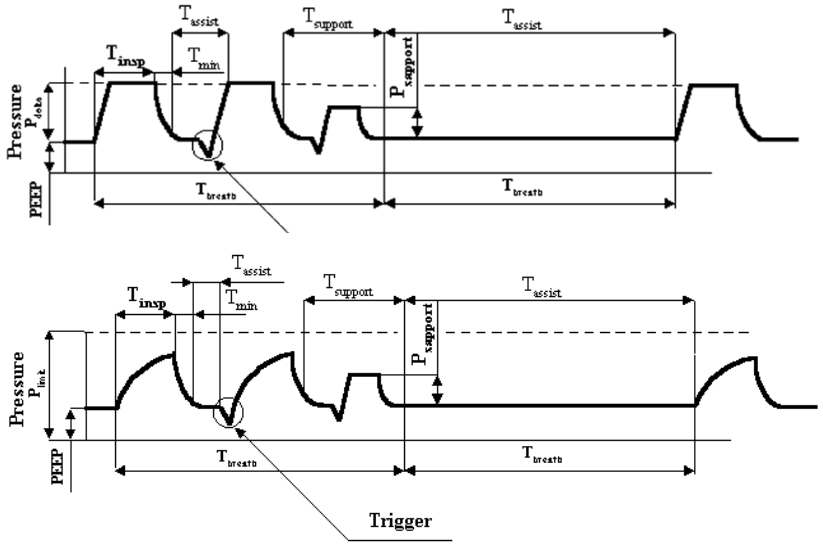


Figure E-2: Breath Patterns in SIMV Pressure Control and Volume Control Modes

If a patient 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:

1. The set tidal volume is delivered.
2. The pressure limit is reached.
3. The I:E ratio reaches 1:1 when an inverse ratio is not manually set.

E.2.4 Parameters Setting

The following parameters shall be set:

- Mandatory Breath Rate
- O_2%
- 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

E.3 Continuous Positive Airway Pressure Mode

E.3.1 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.

E.3.2 Available Breath Types

Patient spontaneous and pressure support breaths can be delivered in this mode. Mandatory breaths are not given (except manual breaths).

E.3.3 Description

Figure E-3 illustrates how breaths are delivered in this mode.

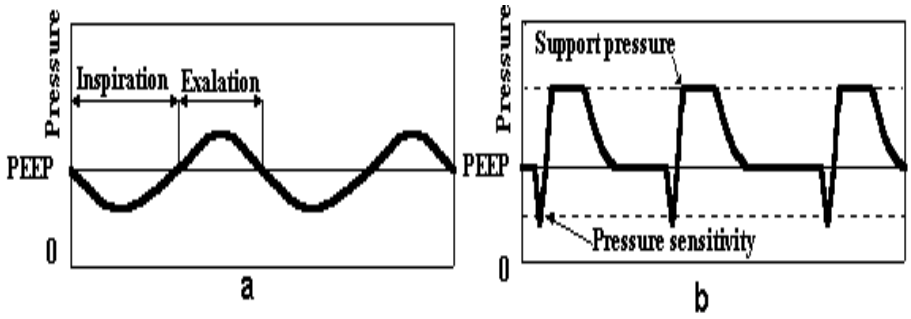


Figure E-3: Pressure During CPAP Mode for Spontaneous Breaths and Pressure Support Breath

Patient triggering results in the delivery of a patient breath (spontaneous or pressure support). The ventilator maintains airway pressure (as in Figure E-3 during the inspiratory phase at PEEP level. If pressure support is selected, the ventilator maintains an elevated support pressure (b in Figure E-3 during the inspiratory phase). Breaths can only be initiated after inspiration has ended and the minimum exhalation time has elapsed.

E.3.4 Parameters Setting

The following parameters shall be set:

- O_2%
- Triggering type and sensitivity
- Support pressure for pressure support breaths.

E.4 Apnea Back-Up Ventilation

Apnea back up ventilation can be activated from all breathing modes. Visual and audible indicators will 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 will be 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 averaging 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 table below.

Table E-1: Parameters for Apnea Ventilation

Set/Average Inhale VT	bpm	Tidal Volume (for CPAP)
(mL)	**(bpm)**	**(mL)**
71-120	30	100
121-170	25	150
171-250	20	200
251-350	18	300
351-450	16	400
451-550	14	500
551-650	12	600
650+	12	700

The ventilator will remain in apnea backup ventilation until the patient initiates 3 consecutive breaths within a 1 minute time period and will then return to the previous mode automatically. (*The unit will not exit from apnea ventilation during the first minute.)* The operator may restore previous ventilation parameters or make appropriate adjustments at any time.

During apnea ventilation, all parameters appear in gray so all adjustments must be make through the Modes Selection window.

E.5 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 failures. While in Open Loop mode, the iVent ventilates without reference to the flow sensor data.

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 E-1. 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.

E.6 Adaptive Bi-Level Mode

See Section 5 of this manual.

Appendix F: Hold Function and Static Mechanics Measurements

F.1 Front Panel Controls

The Hold Button has two functions. Pressing it:

a) One time will initiate an end inspiratory hold maneuver which will allow the calculation of static compliance (See section F.2 Static Compliance Measurements). This maneuver should be administered by clinicians who are knowledgeable about the effect on the patient of this maneuver.

b) Two times in succession will initiate an end expiratory hold maneuver which will allow 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 will cancel the maneuver.

F.2 Static Compliance Measurements

Certain versions of the *i*Vent201 ventilator (version 1.4 model 502i2301-A0 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 *i*Vent201 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.

F.2.1 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.

F.2.2 Respiratory Time Constant

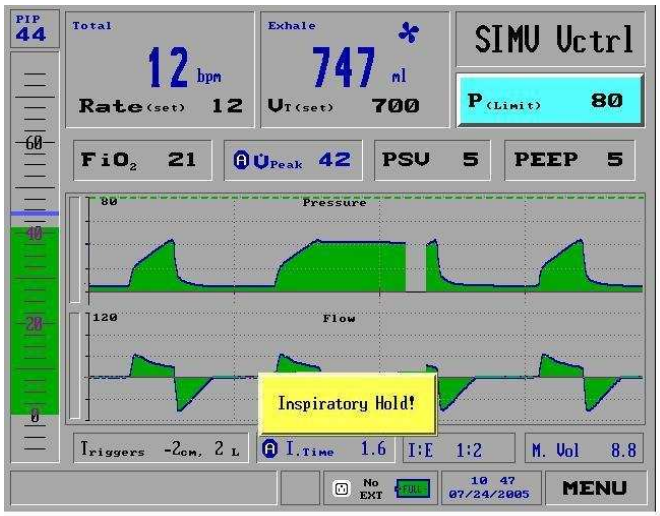
Lastly the ventilator will calculate the time constant of the respiratory system as the product of the dynamic resistance and the static compliance of the respiratory system as calculated using the above technique.

These calculated values can be viewed in the “respiratory mechanics” screen that is described in section F.3.2 Reviewing Static Mechanics and Intrinsic PEEP Measurements.

F.2.3 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 will initiate in the next breath cycle an automated sequence in which the ventilator will wait until the end of inspiratory flow and then hold the exhalation valve closed until a plateau pressure is reached.

You will see the following on the screen of the ventilator:



The ventilator will automatically terminate 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 will also abort the maneuver if a stable plateau pressure is not reached during the hold maneuver. The maximum time that the ventilator will hold the exhalation valve closed for is from 1 to 3 seconds depending on the patient's tidal volume (See Table F.2.3.1)

If the Hold button is pressed again or pressing the Clear button during the maneuver, the hold maneuver will be terminated.

During either inspiratory or expiratory hold maneuvers, the ventilator will not do 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 table below.

F.2.3.1 Table - 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 table below.

F.2.3.2 Table - 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 maneuver was performed (see section F.3.2)

F.2.4 Clinical Considerations

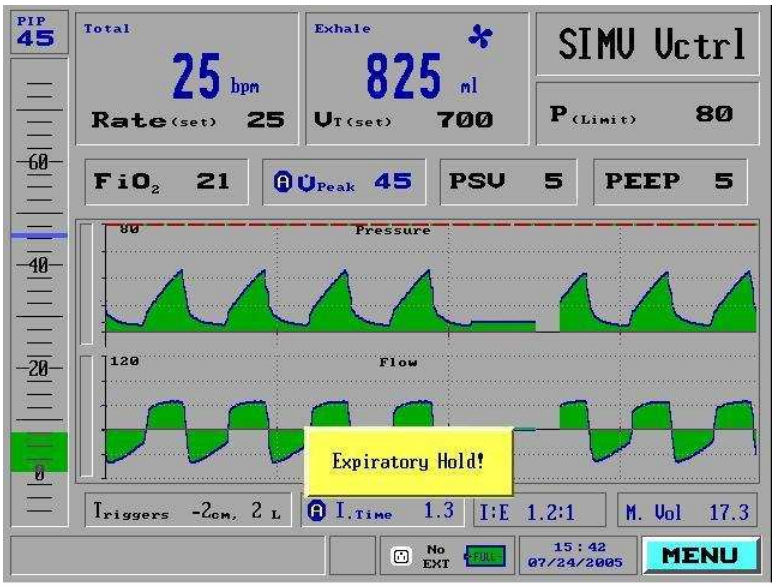
The clinician should note that the use of static hold maneuvers may distress the patient as it prolongs the inspiratory phase of the breath, delaying exhalation. Active breathing during the hold manuever will affect the measurement adversely by creating pressures not related to the relaxed tissue properties 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.

F.3 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 iVent201 can perform 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.

F.3.1 Performing and End Expiratory Hold Maneuver

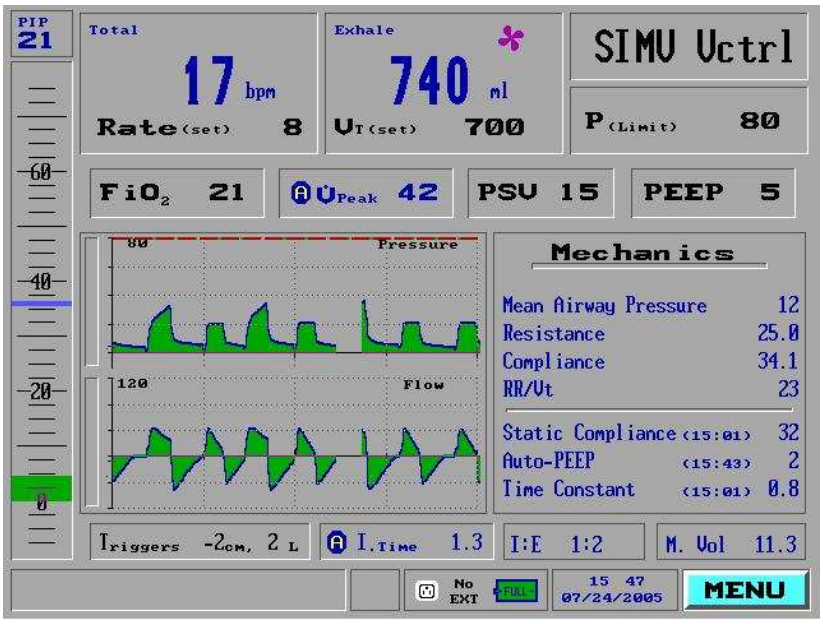
To initiate an end expiratory hold maneuver, press the "hold" button on the front panel twice in succession. After the next breath the expiratory phase will be prolonged and an intrinsic (Auto) PEEP measurement will be made. If the hold button is pressed again or or Clear is pressed at any point in the breath or while the hold maneuver is taking place, the end-expiratory hold is suspended.



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 will suspend the end-expiratory hold maneuver and will deliver a breath.

F.3.2 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” menu from the “Main” menu button.



F.4 RR/Vt Ratio

Clinicians are always looking for simple and 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 will fail spontaneous breathing trials and subsequent extubation.

As a general rule, if a patients RSBI is <105, they are candidates for extubation. There are however clinical conditions that may cause the RSBI index to be higher than 105 and still allow safe removal of mechanical ventilation. Thus it is important to use other clinical observations in addition to this relationship when determining a patients ability to sustain his/her own spontaneous breathing efforts.

Appendix G: Part Numbers and Accessories

Ventilators

Part Number	Description
501I12201-AC/AB	***i*Vent201 IC/AB System**
501I12201-IC	***i*Vent201 IC System**
501I12201-AB	***i*Vent201 AB System**
501I12201-HC	***i*Vent201 HC System**
809A0005-A0-AB	**Adaptive Bi-Level Software Option**
809A0007-A0-IC	**ICU Software Option (for AB systems)**

*i*Vent$_{201}$ Accessories

Part Number	Description
620B0006-20 or **620B0017-20**	Disposable Breathing Circuit, box of 20 includes: Six (6) feet corrugated main tube Exhalation Valve Assembly with Airway Flow and Pressure Sensor
620B0008-A0	Reuseable Multi-use breathing circuit
620B0008-10	Reuseable Multi-use breathing circuit, box of 10
620B0008-20	Reuseable Multi-use breathing circuit, box of 20
660A0001-12	Air inlet filter, box of 12, disposable
504A0110-A0	Adapter for CBRN Filter

Part Number	Description

660L0001-12	Low Pressure Oxygen Adapter and Filter, box of 12, Disposable
630B0001-01	Roll Stand and Mounting Bracket
630B0004-A0	Breathing Circuit Support Arm
404J1516-01	A/C Power Cable, Hospital Grade 115 volt 1.8 m
507A020-A0	D/C Power Cord - 12 volt vehicle adapter HW Ver1.4
507A022-A0	D/C Power Cord - 12 volt clip-on adapters HW Ver1.4
620B0001-01	Oxygen Supply Hose, Six (6) feet, DISS oxygen fittings
620B0002-01	Oxygen Supply Hose, Fifteen (15) feet, DISS oxygen fittings
630B0003-A0	Oxygen Cylinder Holder
503A0012-A0	Power Pack Assy. (Internal) HW Ver1.4
650R0001	Remote Alarm Interface for free standing (Respironics compatible)
650R0002	Remote Alarm Interface for central alarm system (call for details)
504A0050-A0	External Battery Assembly
301B0001-01	External Battery
301C0001-01	External Battery Charger
301D0001-01	External Battery Case
507A019	External Battery Power Cord for use with External Battery Case
504A005-A0	External Power Cord, battery, case, charger
920C0001-01	Calibration Syringe – 500mL
920C0002-01	Calibration Manometer
375B0002	Transportation Case
620B0010-01	Reservoir Bag – 1 liter, non latex
620B0009-01	Manifold/adapter for Low Pressure O_2
OM-01-04	*i*Vent$_{201}$ Operation Manual
SM-01-04	*i*Vent$_{201}$Service Manual
CM-01-04	*i*Vent$_{201}$Training CD ROM
910V0005-01 also	Test lung, 2L, gray
620B0011-01	
910V0004-A0	Resistor, R_P20

910V0003-A0	Resistor, R_P50
311B0005-00	PSV High Pressure O2 Enrichment System
130B0002	O2 sensor
325A0164	Front Panel Filter – Ver1.4
504A0100	Inlet Muffler Assembly – Ver1.4
375A0002-A0	*i*Vent Shipping Package

NOTE: The above list is subject to changes and modifications from time to time. Contact VersaMed or your authorized dealer for further information.

Appendix H: Index