EnVe™ Ventilator

LCD Touch Screen Interface

Operator's Manual

CareFusion

P/N 12431-001
Rev. D

Revision History

Revision Level	Date	Changes
A	Oct. 2009	Production Release per ECO 6141
B	Nov. 2010	Release per ECO 6256
C	Nov. 2010	Release per ECO 6834
D	Aug. 2011	Release per ECO 7084

Warranty

The En$\dot{V}$e™ ventilator systems are warranted to be free from defects in material and workmanship and to meet the published specifications for two (2) years or 15,000 hours, whichever occurs first. The ventilator system is defined as the En$\dot{V}$e™ ventilator, PTV® Series Docking Station and the PTM™ Graphics Monitor. The ventilator system does not include external power supplies.

The liability of CareFusion, (referred to as the Company) under this warranty is limited to replacing, repairing or issuing credit, at the discretion of the Company, for parts that become defective or fail to meet published specifications during the warranty period; the Company will not be liable under this warranty unless (A) the Company is promptly notified in writing by Buyer upon discovery of defects or failure to meet published specifications; (B) the defective unit or part is returned to the Company, transportation charges prepaid by Buyer; (C) the defective unit or part is received by the Company for adjustment no later than four weeks following the last day of the warranty period; and (D) the Company's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

Any authorization of the Company for repair or alteration by the Buyer must be in writing to prevent voiding the warranty. In no event shall the Company be liable to the Buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder.

The Company warranties as herein and above set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by the Company or its agents in connection with the Buyer's order of the products furnished hereunder.

Limitation of Liabilities

This warranty does not cover Routine or Extended maintenance such as cleaning, adjustment and updating of equipment parts. This warranty shall be void and shall not apply if the equipment is used with accessories or parts not manufactured by the Company or authorized for use in writing by the Company or if the equipment is not maintained in accordance with the prescribed schedule of maintenance.

The warranty stated above shall extend for a period of two (2) years from date of shipment or 15,000 hours of use, whichever occurs first, with the following exceptions:

- Elastomeric components and other parts or components subject to deterioration including the ventilator air inlet filter, cooling filter, exhalation port and diaphragm, over which the Company has no control, are warranted for sixty (60) days from date of receipt
- All batteries are warranted for ninety (90) days from the date of receipt

The foregoing is in lieu of any warranty, expressed or implied, including, without limitation, any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of the Company.

Contents

Notices

Copyright

CareFusion
22745 Savi Ranch Parkway
Yorba Linda, California 92887-4645
USA

Trademarks

PTV®, EnVe™, ReVel™, ActivCore™, and PTM™ are registered trademarks of CareFusion in the U.S. and some other countries. All other product names or brands referred to in this document are trademarks, registered trademarks or trade names of their respective holders.

PTV® Series of Products

The PTV® Series of products encompasses the Enve™ and Revel™ ventilators, a Docking Station, the PTM™ Graphics Monitor and various accessories (e.g. AC Adapter, SpO_2 Module/Sensor, FIO_2 Sensor, Patient Circuits, etc.) for use with the ventilators.

Contact CareFusion for a complete list of available accessories.

Documentation Updates

The information contained in this document is applicable to the product with which it was shipped. Product features are subject to change without notice.

Electromagnetic Fields and Radio Frequency Energy

PTV® Series Ventilators require special precautions regarding EMC (Electromagnetic Compatibility) and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF (Radio Frequency) communications equipment can also affect the ventilator.

The following list of accessories and cables available for use with PTV® Series Ventilators are in compliance with the requirements of 60601-1-2 © IEC: 2001(E) sections 36.201 and 36.202.

- AC Adapter and its associated cables
- Docking Station and its associated cables and power supplies
- FIO_2 Sensor
- PTM™ Graphics Monitor and its associated cables
- SpO_2 Module and Sensor

Indications for Use

The Enve™ ventilator is designed for use on patients who require respiratory support or mechanical ventilation and weigh a minimum of 5 kg (11 lbs). It is suitable for service in hospital and transport environments as a source of continuous or intermittent positive pressure ventilatory support, delivered invasively or non-invasively. It is not intended for homecare use.

PTV® Series ventilators are restricted medical devices intended for operation by trained personnel under the direction of a physician and in accordance with all applicable state laws and regulations.

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

Classification

Type of Equipment: Medical Equipment, Internally Powered Equipment, Type BF

Safety Information

Review the following safety information prior to operating the ventilator.

Operating the Enve™ ventilator without a complete understanding of its attributes may cause harm to the patient or operator. This manual should be read and understood in its entirety before attempting to operate the ventilator.

Any questions regarding installing, operating, or maintaining the Enve™ Ventilator, should be directed to CareFusion or a service technician certified by CareFusion.

CareFusion
22745 Savi Ranch Parkway
Yorba Linda, California 92887-4645, USA

Technical/Clinical Support and Parts Ordering:
Toll-Free: 800.554.8933 (U.S. and Canada)
Office: 714.685.8021 (Worldwide)
Fax: 714.283.8471
Email: support.vent.us@carefusion.com

Product or Accessories Ordering:
Toll-Free: 800.231.2466 (U.S. and Canada)
Office: 714.283.2228 (Worldwide)
Fax: 714.283.8473
Hours: 7:00 AM to 4:00 PM (PST) Monday – Friday
Website: www.carefusion.com

Document Conventions

For clarity, the following written conventions are used throughout this manual:

WARNING

Bold Heading - Double boxed text. Alerts the reader to potentially hazardous situations which, if not avoided, could result in death or serious injury.

CAUTION

Bold Heading - Double boxed text. Alerts the reader to potentially hazardous situations which, if not avoided, could result in equipment damage.

NOTE

Single boxed text. Contains additional information regarding the proper operation of the Enve™ ventilator.

Bold Text: Words that appear in **bold text** typically represent text as it appears on the ventilator itself, or as it is displayed on the ventilator user interface. Bold is also occasionally used as emphasis.

Italicized Phrases: Phrases that are *shown in italics* cross-reference other sections of the manual where the associated subject matter is addressed in greater depth.

Abbreviations: Enve™ ventilator, Enve™ and the ventilator are used interchangeably throughout this document. See *Appendix D - Glossary* for other abbreviations and acronyms used in this document.

Warnings and Cautions

General Warnings and Cautions, which apply any time you use the ventilator, are listed here, while specific Warnings and Cautions appear throughout the manual where pertinent.

Read these carefully before operating the ventilator.

WARNING

Use of Unapproved Cables or Accessories - The use of accessories and cables other than those specified, with the exception of those sold by CareFusion as replacement parts for internal components, may result in increased emissions or decreased immunity of the Enve™ ventilator. This could affect the safe and effective operation of the ventilator or other adjacent equipment, resulting in possible patient harm.

Adjacent or Stacked Equipment - The Enve™ ventilator should not be used adjacent to or stacked with other equipment. This could adversely affect the safe and effective operation of the ventilator or other adjacent equipment, resulting in possible patient harm. If adjacent or stacked use is necessary, observe the ventilator carefully, prior to use on a patient, to verify normal operation in the configuration in which it will be used.

Risk of Electrical Shock - To avoid the risk of an electrical shock or ventilator damage;

- Use only batteries, adapters, cables or external power supplies recommended by CareFusion
- Do not use batteries, adapters, cables or external power supplies with visible signs of damage
- Do not touch internal components
- Refer all servicing or repairs to CareFusion or a service technician certified by CareFusion

Vent Inop Alarm - If a Vent Inop alarm occurs during operation, immediately ventilate the patient using an alternative method, disconnect the ventilator and contact CareFusion or a service technician certified by CareFusion. CareFusion recommends that an alternate means of ventilation be available and the procedures to be followed if the ventilator ceases to function properly.

Operating a ventilator that does not appear to be working properly may be hazardous. If the ventilator is damaged, fails any test or malfunctions in any way, discontinue use and contact CareFusion or a service technician certified by CareFusion.

Fan Inlet and Exhaust Ports - The cooling fan inlet and exhaust ports must be kept clean and unobstructed. Failure to do so could result in a dangerous build-up of oxygen and/or damage to the ventilator due to overheating.

Review Adjustable Ventilation and Alarm Controls Regularly - Patient safety relies on appropriate, functional and properly set ventilation and alarm controls. Review and adjust (if necessary) all user adjustable ventilation and alarm control settings regularly. Periodically (per the *Maintenance Schedule* in Chapter 11 – Maintenance and Cleaning) verify that the ventilator's alarms are functioning properly. If any alarm malfunctions, contact CareFusion or a service technician certified by CareFusion. Failure to immediately identify and correct audible alarm situations may result in serious patient injury or death.

Diminished Audible Alarms – In order to avoid diminished sound levels of audible alarms and possible consequent harm to patients, do not allow the ventilator's Alarm Sounder Ports to become covered or obstructed in any way by stickers, labels, or other equipment/devices applied, set, or mounted on or over them.

WARNING

Trained Personnel – Only properly trained personnel should operate the ventilator. The Enve™ ventilator is a restricted medical device designed for use by trained personnel under the direction of a physician in accordance with applicable state laws and regulations.

Patients who are dependent on a ventilator should be constantly monitored by trained personnel prepared to respond to alarms and address circumstances where equipment becomes inoperative. An alternative method of ventilation should be available for all patients dependent on the ventilator and caregivers should be familiar with emergency ventilation procedures.

Risk of Fire - Leaks at oxygen inlet connections can cause dangerous O_2 levels in the vicinity of the O_2 fitting. To avoid the risk of fire, visually inspect oxygen fittings before and after connecting high-pressure oxygen (to avoid unsealed connections) and take measures to properly ventilate the area.

Operating the ventilator in the presence of flammable gases could cause a fire or explosion. Under no circumstances operate the ventilator when explosive gases are present. The presence of flammable anesthetic gases presents a danger to patient and operator.

Operating Environment - To avoid the risk of equipment malfunction, do not operate the ventilator outside of a 0 °C to 40 °C temperature range, or a 5% to 95% relative, non-condensing humidity range.

Extreme Operating Conditions - Attempting to operate the ventilator in environmental conditions outside of those recommended in the specifications may result in ventilator failure and harm to the patient.

Exposure to Gases - To avoid the risk of exposure to gases, do not use Nitric Oxide (NO) unless external measures are taken to properly ventilate waste gases.

Patient Breathing Circuit – Exercise extreme care when adjusting or handling the patient circuit. Inadvertent disconnection of the patient from the patient breathing circuit can be dangerous.

The patient circuit must be tested for leaks (*Circuit Test*) before it is used for the first time and after any changes have been made to the configuration of the circuit. Harm to the patient or ineffective ventilation may result from failure to detect and correct leaks in the patient breathing circuit before connection to a patient.

To avoid the risk of patient injury, only use patient circuits and accessories expressly approved by CareFusion for use with PTV® Series Ventilators.

Ventilator Service and Repair - To avoid ventilator malfunction and possible operator or patient injury, all servicing or repair of the ventilator must be performed by a service technician certified by CareFusion.

Electrostatic Shock – Do not use electrically conductive (anti-static) hoses or tubing with the ventilator. Use of such material increases the hazard of electrical shock to the patient.

Blank LCD Touch Screen Display – A blank LCD touch screen display during normal operation/ventilation, it is an indication that the ventilator is not functioning properly. To avoid the possibility of inadvertent ventilation control selection/activation, do not touch the display screen, immediately remove the patient, use an alternative method of ventilation and contact CareFusion or a service technician certified by CareFusion.

Improperly Functioning Ventilator or Attached Accessories - Operating a ventilator that does not appear to be functioning properly may be hazardous to both patient and operator. If the ventilator or any attached accessory is damaged, fails any tests or malfunctions in any way, immediately discontinue use and contact CareFusion or a service technician certified by CareFusion.

CAUTION

Cleaning and Sterilization - To avoid irreparable damage to the ventilator, do not attempt to sterilize it.

Do not spray liquids directly on or into any part of the ventilator. Do not allow liquids to drip onto or pool on the ventilator.

Do not immerse the ventilator in liquids.

Risk of Equipment Damage - To avoid the risk of equipment damage and consequent malfunction, do not allow the ventilator to be dropped or subjected to excessive impact or vibration. If the ventilator is dropped, perform the UVT and EST tests before placing the unit on a patient (see Chapter 2 – Functional Testing in Startup Mode). Discontinue use and contact CareFusion or a service technician certified by CareFusion if damage is evident.

Risk of Equipment Interference – Increased RF emission can be generated if CareFusion supplied cables are altered or replaced with unauthorized cables.

Risk of Equipment Malfunction – Portable and mobile RF communication equipment can affect ventilator performance.

Storage Temperature - Storing the ventilator at temperatures outside of its specified storage temperature range can damage the ventilator and its batteries.

Ventilator Functional Testing - Functional testing of the ventilator (as specified in Chapter 2 – Installation and Setup, Testing) must be performed before connecting a patient to the ventilator. Rerun the tests monthly and whenever a question about the ventilator's operation arises

Use of the PTV® Series Carry Case – The PTV® Series Carry Case is a protective, portable case for PTV® Series ventilators. In order to conform to the Free Fall environmental test conditions specified in International Standard IEC 68-2-32 and avoid equipment damage if accidentally dropped, the ventilator must be enclosed within the carry case.

Symbols

The following symbols may be referenced on the device or in accompanying documentation.

Symbol	Source	Description	Usage
	ISO 3864 No.B.3.1	Attention, see accompanying documents	Directs the user to the instruction manual for specific instructions involving safety.
	No. 417-IEC-5333	Type BF equipment	To mark type BF equipment
	No. 417-IEC-5031	Direct Current	Indicates direct current (DC).
	No. 3.8 – ISO 15223	Keep Dry	Identifies an area of equipment requiring a degree of protection from liquids.
IPX1	IEC 60529	Enclosure protection	Indicates a degree of enclosure protection against liquid ingress.
	CareFusion	Filled Wave or Loop	Displayed waveform or loop with a colored fill.
	CareFusion	Trace Wave or Loop	Displayed waveform or loop as a trace only with no fill.
	CareFusion	Flow	Indicates monitored airway flow.
	CareFusion	Patient Effort	When highlighted, indicates a patient effort to trigger a breath.
	CareFusion	Expiratory limb of patient circuit	Indicates connection point for the expiratory limb of patient circuit to the ventilator.
	CareFusion	Inspiratory limb of patient circuit	Indicates connection point for the inspiratory limb of patient circuit to the ventilator.
	CareFusion	Wye Flow Sensor	Indicates connection point for the Wye flow Sense Lines to the ventilator.
	CareFusion	Accept	In configuration pages, indicates acceptance and initiation of the values.
	CareFusion	Cancel	Cancels a configuration setup prior to initiation. The device continues operating on previous settings.
	CareFusion	Audible Signal	Indicates the Display/Alarm **Check** button.

Symbol	Source	Description	Usage
	CareFusion	Battery	Indicates the Battery/Power **Check** button.
	CareFusion	Eject	Indicates location of battery release.
	CareFusion	Nebulizer	Indicates the location of the nebulizer port.
	CareFusion	Increase/Decrease	Signifies direction of value increase or decrease on rotary knob encoder.
	CareFusion	Battery Status LEDs	Indicates degree of charge remaining in the Removable Battery Pack.
	CareFusion	Down Arrow	When displayed, indicates multiple alarms have occurred.
	Directive 2002/96/EC	Waste Container	WEEE symbol to identify Waste Electrical and Electronic Equipment not to be disposed of as unsorted municipal waste.
	CareFusion	Time Terminated	When displayed, indicates a time terminated Pressure Support, Volume Targeted Pressure Support, or Spontaneous breath.
	CareFusion	Flow Terminated	When displayed, indicates a flow terminated Pressure Control or Pressure Regulated Volume Control breath.
	EN 980	Manufacturer	Indicates name and contact information of the manufacturer.

Chapter 1 - INTRODUCTION

This Operator's Manual contains detailed information and instructions to enable you to safely set up and use your Enve™ ventilator.

The manual is designed for use by trained and qualified personnel, under the direction of a physician. It is very important that you familiarize yourself with the contents of this manual before attempting to operate the ventilator.

WARNING

Trained Personnel – Only properly trained personnel should operate the ventilator. The Enve™ ventilator is a restricted medical device designed for use by properly trained personnel under the direction of a physician and in accordance with applicable state laws and regulations.

Patients who are dependent on a ventilator should be constantly monitored by trained personnel prepared to respond to alarms and address circumstances where equipment becomes inoperative. An alternative method of ventilation should be available for all patients dependent on the ventilator and caregivers should be familiar with emergency ventilation procedures.

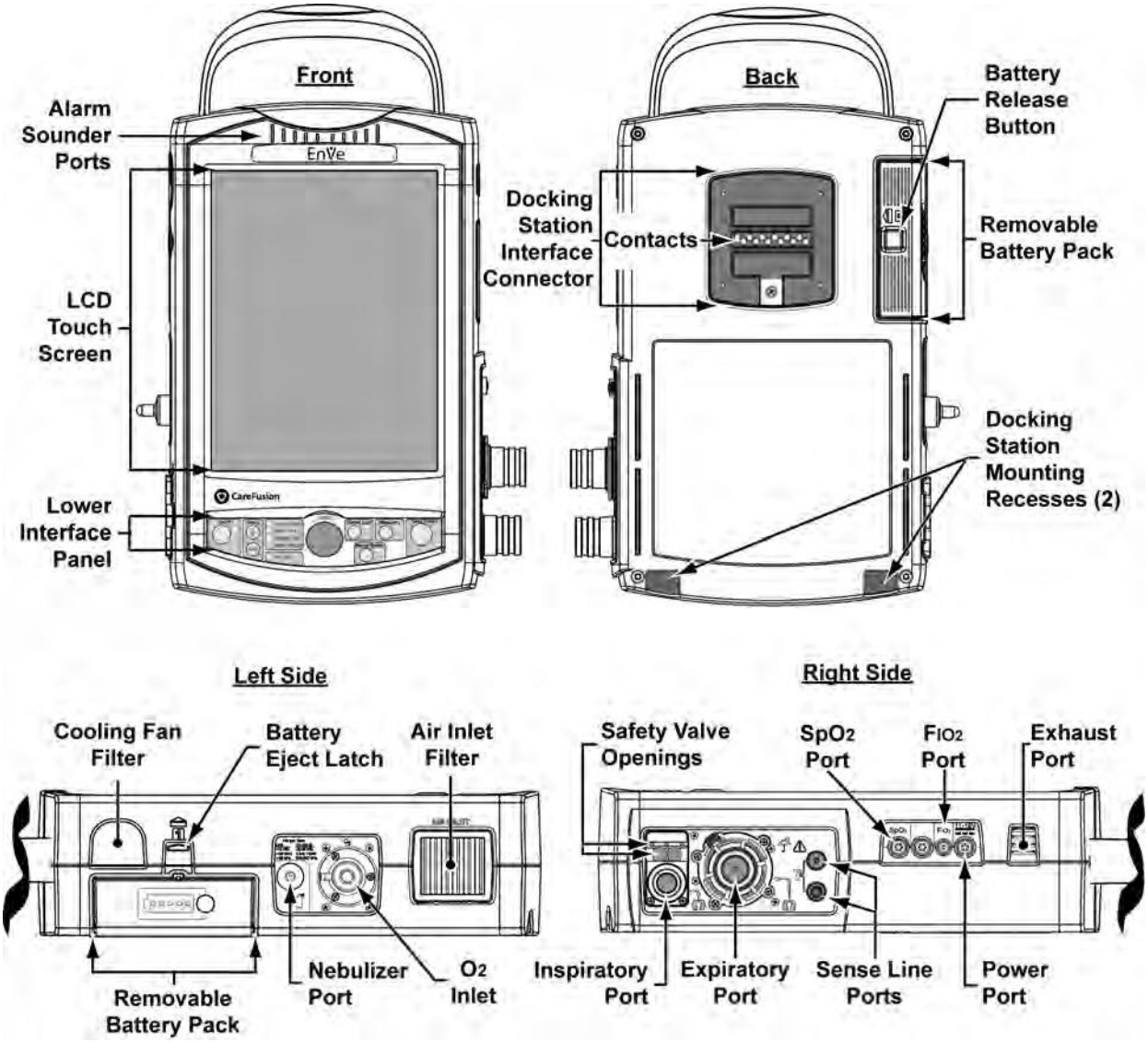
If you have any problems or questions as you follow the instructions contained in this manual, call CareFusion using the contact information provided in *Appendix A - Contact Information.*

WARNING

Ventilator Service and Repair - To avoid ventilator malfunction and possible operator or patient injury, all servicing or repair of PTV® Series Ventilators must be performed by a service technician certified by CareFusion.

WARNING

Diminished Audible Alarms – In order to avoid diminished sound levels of audible alarms and possible consequent harm to patients, do not allow the ventilator's Alarm Sounder Ports to become covered or obstructed in any way by stickers, labels, or other equipment/devices applied, set, or mounted on or over them.



NOTE

Keep all ventilator interfaces, connectors, contacts, ports, etc. clean, dry and unobstructed.

Ventilator Overview

PTV® Series Ventilators are lightweight, high performance ventilators designed for maximum functionality in an unprecedented small package.

The Enve™ ventilator provides for the following features:

- High performance ventilation in a small lightweight package
- ActivCore™ technology, allowing the ventilator to operate without an external compressed gas source
- Four distinct breath modes offering a range of treatment options: Continuous Positive Pressure Ventilation (CPAP) with optional Pressure Support, Synchronized Intermittent Mandatory Ventilation (SIMV) and Assist/Control
- Apnea Backup ventilation, configurable in CPAP/PSV and NPPV breath modes
- Non-Invasive Positive Pressure Ventilation (NPPV)
- Volume Control, Pressure Control, Pressure Support, Pressure Regulated Volume Controlled (PRVC), Pressure Regulated Volume Support (CPAP/V_tPSV) and Spontaneous breath types
- A range of maneuvers including Inspiratory and Expiratory Hold
- Adjustable alarm settings including High and Low Peak Pressure, High and Low Minute Volume, Apnea and others
- Oxygen blending from a high-pressure oxygen source or low-pressure oxygen bleed-in
- Lockable front panel controls
- A wide range of monitors including Breath Rate, I:E Ratio, Mean Airway Pressure, Exhaled Minute Volume, Positive End Expiratory Pressure (PEEP), Peak Inspiratory Pressure and Exhaled Tidal Volume
- Dynamic waveform and loop displays
- Graphic trending histogram display
- Real-time patient circuit pressure display
- Variable termination options for Pressure Support, Pressure Regulated Volume Support and Spontaneous breaths, including maximum inspiratory time and percentage of peak inspiratory flow
- Selectable percentage of Peak Flow termination for Pressure Control and Pressure Regulated Volume Controlled (PRVC) breaths
- Leak Compensation to improve patient triggering when a airway leak is present
- Operation from a variety of power sources including a Removable Battery Pack and external AC and DC power sources
- F_{IO_2} Sensor package
- SpO_2 Pulse Oximetry software

The PTV® System

The Docking Station

At the bedside, the Enve™ ventilator can be placed into a Docking Station, which expands its capabilities further. The Docking Station provides a stable base for the ventilator with a quick connect/disconnect mechanism to allow the ventilator to be moved quickly. It mates with the Enve™ via a custom connector and supplies DC power to the ventilator. Docking Station enhancements include:

- interface to a nurse call system
- patient monitoring interface (e.g., VOXP protocol)
- interface with the PTM™ Graphics Monitor

A removable memory card enables information transfer between the ventilator and a computer. The Docking Station also has a service and maintenance port to allow upgrades and maintenance to be performed on the ventilator by authorized service personnel.

The Enve™ Ventilator

The Enve™ ventilator is a high performance portable critical care ventilator. It achieves a significant reduction in size, weight and power consumption over previous systems resulting in a highly portable device which is also suitable for a wide range of life support and critical care applications.

The pneumatic system is designed around ActivCore™ technology, which includes a blower that draws in room air through a filter and delivers gas at the correct flow, volume and/or pressure to the patient. The Enve™ has an internal exhalation valve, supporting dual limb patient circuits.

The ventilator delivers blended gases from an internal oxygen blender. The blended gas delivery can be monitored with an external FIO_2 Sensor and the values displayed on the user interface. When high-pressure oxygen is attached to the O_2 Inlet port, the ventilator is able to drive a nebulizer to deliver aerosolized drugs to the patient while at the same time compensating for the added gas delivery.

The ventilator normally operates from external DC power. There is an external power port on the side of the ventilator enabling direct connection to a number of approved external DC power sources. The ventilator may also be powered via the custom interface to the Docking Station when the ventilator is docked at the patient bedside.

When the ventilator is portable, a Removable Battery Pack powers the unit. You can easily pull the battery from its bay and replace it with another charged battery without interruption of ventilation. While changing Removable Battery Packs, the internal Transition Battery provides power to the ventilator for up to one (1) minute. Both the Removable Battery Pack and the Transition Battery are charged when an approved external DC power source is connected to the ventilator (see *Chapter 12 - Power Supplies and Batteries* for more information).

PTM™ Graphics Monitor Display

The PTM™ Graphics Monitor is a lightweight color monitor for use with a PTV® Series Ventilator when it is connected to its Docking Station and secured onto a PTV® Series Rolling Stand, Table Stand, or Wall Mount. It displays real time waves, loops, controls, monitored data and trended data from the ventilator on a color LCD display. It has touch screen command capability and scalable graphics.

Optional Components

- A **SpO_2 Oximetry Module** provides pulse oximetry with the ventilator. SpO_2 and Pulse monitors and alarms display on the ventilator interface
- A **FIO_2 Module** enables monitoring of the oxygen concentration in the inspired airflow. FIO_2 related alarms and monitors display on the ventilator interface

Principles of Operation

Pneumatic System

The Enve™ ventilator was specifically designed for high performance, high efficiency and high reliability. It uses advanced technology to achieve an unprecedented small package size and weight and enhanced battery performance in a robust modular design.

The heart of the ventilator is the ActivCore™ blower technology. The ActivCore™ draws room air into the **accumulator/filter** where it is mixed with oxygen from the **O_2 blender module**. Air from the ActivCore™ is precisely delivered through a **filter** and **bias valve** to the inspiratory limb of the patient circuit in a flow pattern to achieve the patient settings. A flow transducer downstream of the ActivCore™ (Blower) provides flow feedback to the ActivCore™ processor.

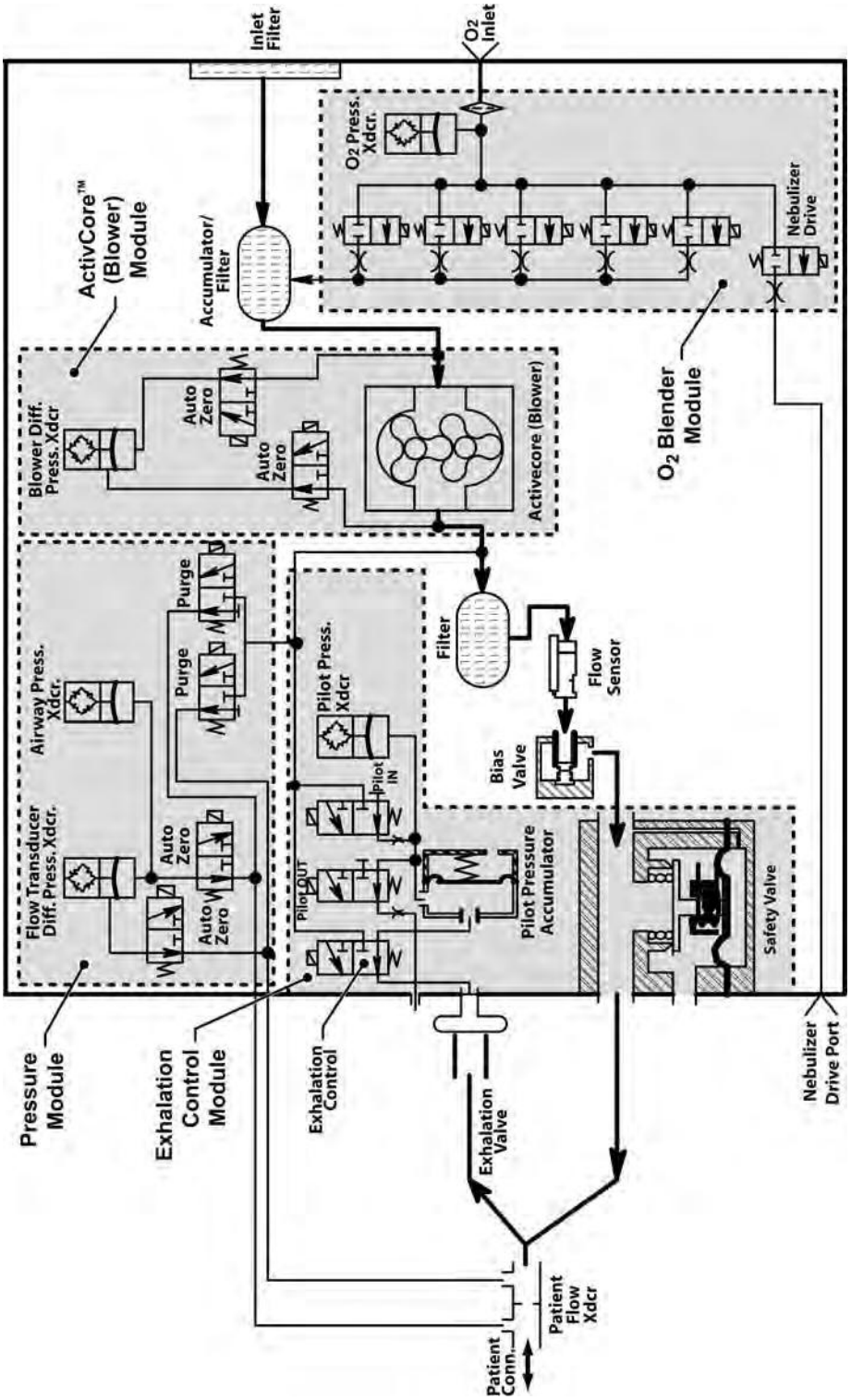
The **exhalation control module** closes the **exhalation valve** during inspiration to direct the air to the patient. During exhalation, the ActivCore™ delivers bias flow and the exhalation valve is servo controlled to achieve the desired amount of positive end expiratory pressure (PEEP). During exhalation, flow is monitored through the **patient flow transducer** to detect patient triggering. With leak compensation enabled, the ActivCore™ assures minimal work of breathing by delivering bias flow at the intended level above leak flow, thereby maintaining PEEP and patient triggering sensitivity, even in the presence of large patient leaks.

Patient flows are sensed by monitoring the differential pressure across a **patient flow transducer**. The patient flow transducer design is a fixed orifice integrated into the patient Wye. This design achieves sensitive breath detection and minimal dead space while adding robustness. It also reduces the costs of replacing/cleaning the flow sensor.

Differential pressure from the patient flow transducer is returned to the ventilator via the Sense Lines, where the pressure transducer module determines both the airway pressure and the patient flow. The transducers on the pressure transducer module are regularly auto-zeroed to assure accurate performance throughout changing environmental conditions, such as patient transport.

A **safety valve** is incorporated into the inspiratory port to ensure the patient does not receive excessive pressure in the event that the expiratory limb gets blocked and to allow the patient to inspire spontaneously if the ventilator is inoperative.

Pneumatic Diagram



Chapter 2 - INSTALLATION AND SETUP

Unpacking the Ventilator

To unpack your Enve™ ventilator;

1) Inspect the exterior of the ventilator transport container for evidence of damage during transit. If damaged, notify the delivery service immediately.
2) Carefully remove the ventilator and all accessories from the transport container. Retain the container for use in ventilator service or maintenance returns.
3) Confirm that you have received all the items listed on the packing slip. Notify an authorized sales representative or CareFusion of any discrepancies.
4) Examine the ventilator and accessories for any obvious damage. If damaged, notify the delivery service.

Operational Setup

Equipment, Accessories and Supplies Required

To setup, test and operate the Enve™ ventilator you will need the following additional equipment, accessories and supplies:

Power Source - The Removable Battery Pack[1] supplied with the ventilator and an approved external source of power (e.g. the AC Adapter[2], or PTV® Series Docking Station[2]);

- An external source of power is required for functional testing of the ventilator

Oxygen Supply – The Enve™ ventilator can utilize either high or low pressure sources of oxygen (as clinically appropriate for the patient):

- A high pressure source of O_2 and an FIO_2 Sensor[2] or external oxygen monitor are required for functional testing of the ventilator

High Pressure

- During normal ventilation: 40 PSI (2.8 BAR, 276 kPa) to 88 PSI (6.0 BAR, 607 kPa)
- During Nebulization: 40 PSI (2.8 BAR, 276 kPa) to 66 PSI (4.5 BAR, 455 kPa)

Low Pressure: < 10 PSI (< 0.69 BAR, < 69 kPa)

Patient Circuit - See *Patient Breathing Circuits* in this chapter for patient circuit options and accessories.

Stylus – A stylus[2] or equivalent dull pointed instrument is recommended for functional testing/calibration of the ventilator's LCD Touch Screen display.

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[1] Airline carriers typically allow only dry cell batteries (such as the lithium-ion Removable Battery Pack supplied with your ventilator) on board aircraft. Some airlines may allow an electrical cord to be plugged in if arranged in advance. Check with the carrier in advance before traveling.

[2] For a current/complete list of accessories, availability and ordering information, contact CareFusion (see *Appendix A - Contact Information).*

Electromagnetic Fields and Radio Frequency Energy

The Enve™ ventilator system, including the Docking Station uses and can radiate radio frequency energy. The ventilator system, including the accessories and cables listed at the front of this manual, has been tested and complies with limitations as specified in IEC 60601-1-2 for Medical Products which provide some protection against interference when operated in accordance with the instructions in this manual.

The ventilator system also contains components that can be affected by intense electromagnetic fields. The ventilator system functioning may be adversely affected by the operation of other nearby equipment, such as high frequency surgical diathermy equipment, short-wave therapy equipment, defibrillators or MRI equipment.

Before proceeding with setup of the ventilator, refer to the tables in *EMC and RF Environments* in Appendix C - Reference Information for detailed information about the use of the ventilator in these environments.

WARNING

Use of Unapproved Cables or Accessories - The use of accessories and cables other than those specified, with the exception of those sold by CareFusion as replacement parts for internal components, may result in increased emissions or decreased immunity of the ventilator. This could affect the safe and effective operation of the ventilator or other adjacent equipment, possibly resulting in patient harm.

Adjacent or Stacked Use of Equipment - The ventilator should not be used adjacent to or stacked with other equipment. This could adversely affect the safe and effective operation of the ventilator or other adjacent equipment, possibly resulting in patient harm. If adjacent or stacked use is necessary, observe the ventilator carefully, prior to use on a patient, to verify normal operation in the configuration in which it will be used.

PTV® Series Carry Case

The PTV® Series Carry Case is intended to provide a protective, portable case for PTV® Series ventilators.

Although not shown in subsequent illustrations for clarity of individual installation and setup instructions, the PTV® Series Carry Case must be installed on the ventilator in order to avoid damage if accidentally dropped.

CAUTION

Use of the PTV® Series Carry Case – The PTV® Series Carry Case is a protective, portable case for PTV® Series ventilators. In order to conform to the Free Fall environmental test conditions specified in International Standard IEC 68-2-32 and avoid equipment damage if accidentally dropped, the ventilator must be enclosed within the carry case.

Installing/Cleaning the Carry Case

Refer to the Instructions for Use (P/N 13564-001) provided with the Carry Case for detailed installation and cleaning information.

Patient Breathing Circuits

On the Enve™ ventilator, the Exhalation module and PEEP control are integral components of the ventilator itself and are not part of the patient circuit configuration. CareFusion offers patient circuits suitable for use with the Enve™ ventilator in adult and pediatric applications. Carefully follow the instructions for assembly, use and cleaning provided with each circuit.

- Contact CareFusion for a complete list of available Patient Circuits and accessories. See *Appendix A - Contact Information* for contact and ordering information.

WARNING

Risk of Patient Injury - To avoid the risk of patient injury, only use patient circuits expressly approved by CareFusion for use with the Enve™ ventilator.

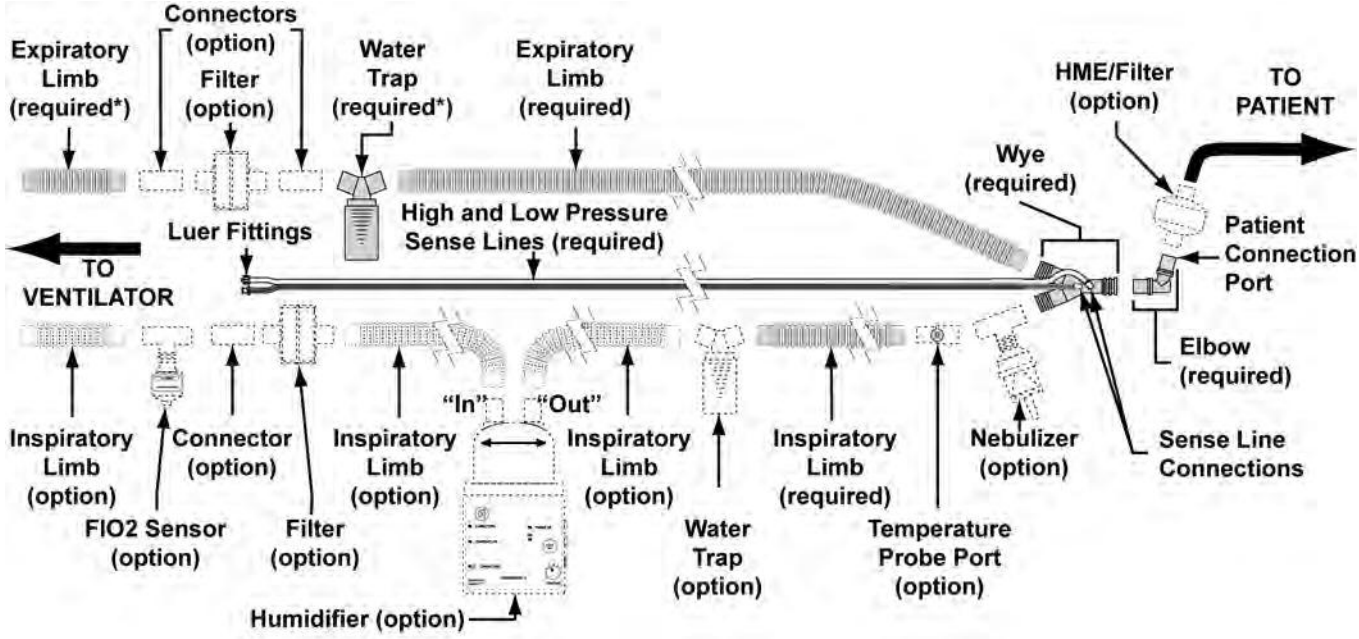
NOTE

Patient circuits and accessories are shipped clean, not sterile. The reusable patient circuit should be cleaned prior to initial use, and after each patient use.

Patient Circuit Accessories

Various patient circuit accessories are available for use with PTV® Series patient circuits. The exploded view diagram shown is not intended to be representative of any particular configuration. It is a compilation of possible variations of a standard assembly with optional components and accessories, and is shown for reference only.

To assemble and clean accessories, refer to the Instructions For Use provided with each item. To order, contact CareFusion (see *Appendix A - Contact Information*). Assemble the patient circuit incorporating any optional accessories and refer to the Instructions For Use provided with your circuit for full assembly instructions.



Example of Patient Circuit and Optional Accessories
(Asterisks (*) identify accessories not required for use with Dual Limb Heated Wire Patient Circuits)

Connecting the Patient Circuit

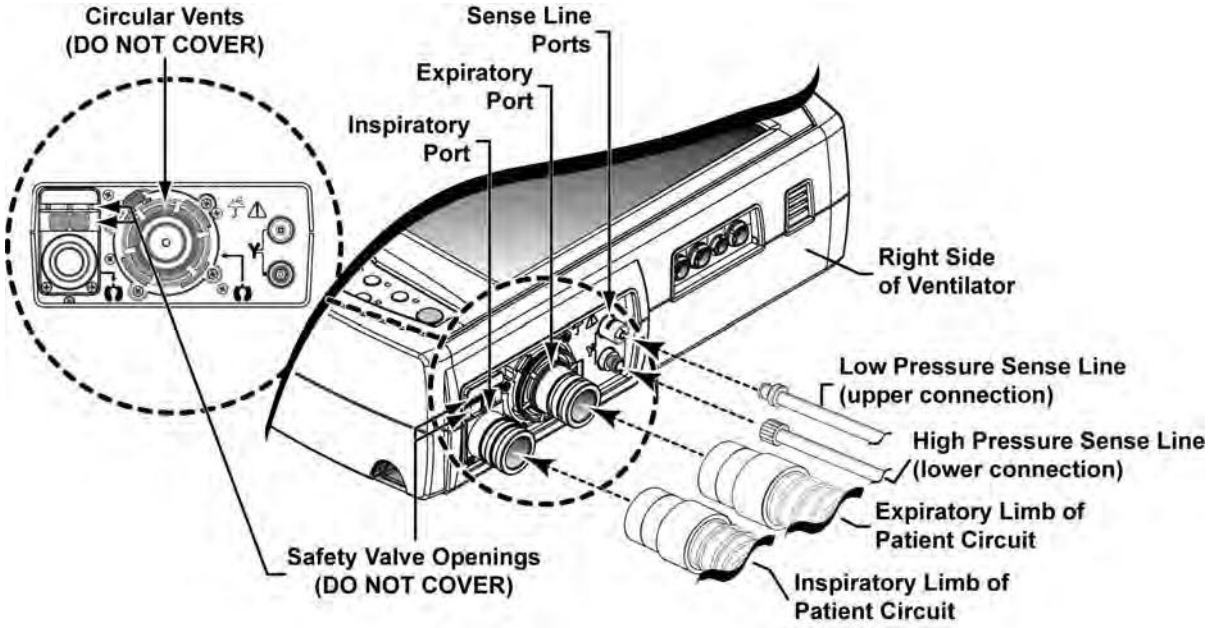
WARNING

Circuit Test – Test the patient circuit for leaks with all accessories before connection to the patient (see *Circuit Test* later in this chapter). Failing to detect and eliminate leaks can result in ineffective ventilation or patient harm. When using a heated humidifier, include it in the circuit when performing leak testing.

1) Connect the inspiratory limb of the patient breathing circuit to the inspiratory port on the right side of the ventilator labeled with the symbol shown here.

2) Connect the expiratory limb of the patient breathing circuit to the expiratory port on the right side of the ventilator labeled with the symbol shown here.

3) Connect the patient circuit Wye Sense Lines (two, each with non-interchangeable Luer fittings) to the Sense Line ports on the right side of the ventilator labeled with the symbol shown here.



WARNING

Risk of Patient Injury - Do not cover or occlude the safety valve openings located above the inspiratory port of the ventilator. Patient injury could result.

Use care when routing the patient circuit tubing to minimize the risk of obstructing the patient's airway.

CAUTION

Patient Circuit Wye Installation – To prevent fluids from entering the sensors, always install the Wye in the patient circuit so that the Sense Lines are oriented up during ventilation.

Oxygen Connection

High Pressure O_2

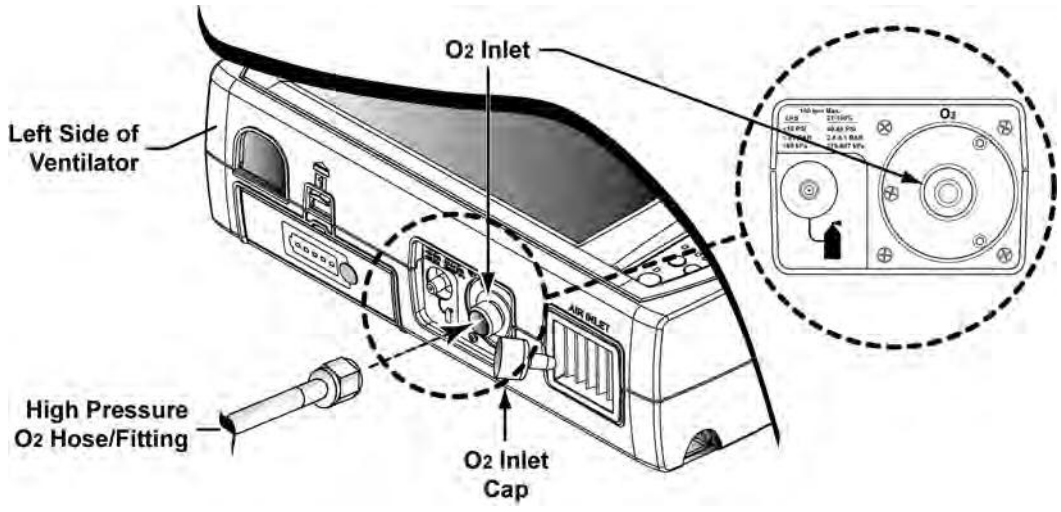
WARNING

Risk of Fire - Leaks at oxygen inlet connections can cause dangerous levels of O_2 in the vicinity of the O_2 inlet fitting. To avoid the risk of fire, inspect all oxygen fittings before and after connecting high-pressure oxygen (to avoid unsealed connections) and take measures to properly ventilate the area.

Oxygen Supply Contamination - The accuracy of oxygen delivery can be compromised by debris contamination in the oxygen supply system. To reduce the risk of contaminants entering the ventilator, ensure that the oxygen supply connected to the ventilator is clean, medical grade oxygen. When not in use, protect the O_2 inlet fitting on the ventilator from dirt and contamination by using the plastic cap supplied.

For operation from a high pressure oxygen source, connect a compatible oxygen hose/fitting to the DISS[3] O_2 inlet port on the left side of the ventilator.

- The O_2 inlet port is labeled **O_2**

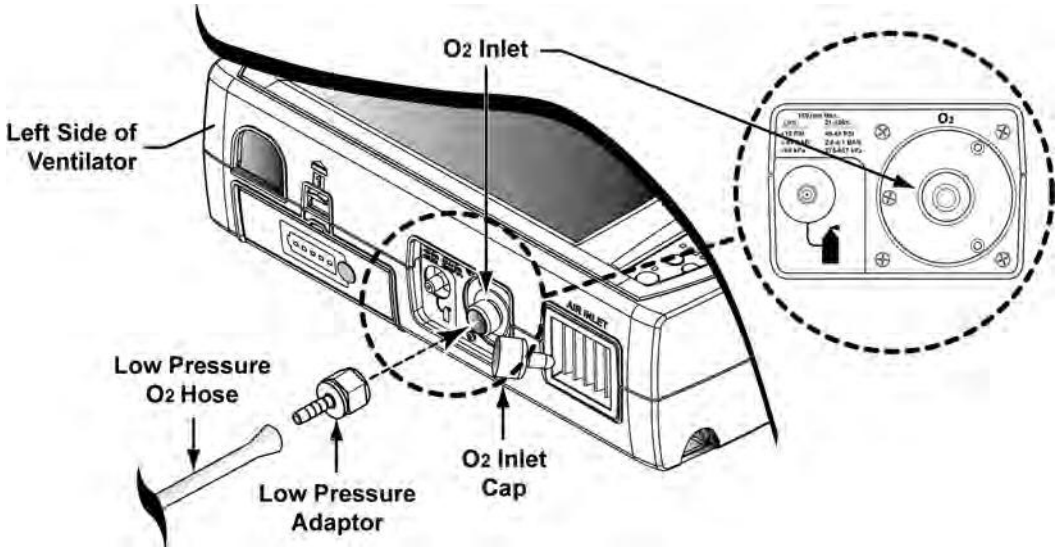


[3] DISS - Diameter-Index Safety System #1240, per GGA V5-1989

Low Pressure O_2 Source (LPS)

For operation from a low pressure (less than 10 PSIG, .69 BAR or 69 kPa) oxygen source such as a flow meter:

1) Attach a DISS[4] Low Pressure Adapter[5] to the DISS O_2 Inlet port on the left side of the ventilator.
    - The O_2 Inlet port is labeled **O_2**
2) Attach the oxygen supply line to the hose barb on the adapter.
3) Set the **FiO_2** control on the **Main** screen, **Controls** page to **LPS** (Low Pressure O_2 Source) (see *FIO2 (Inspired Oxygen)* in Chapter 5 – Controls for detailed information).
4) Adjust the flow of the low pressure O_2 source as appropriate for the patient (see *Setting the Flow for Low Pressure Oxygen Blending:* in Chapter 5 – Controls for additional information).



WARNING

Inspired Oxygen (FIO_2) Concentration – Minute volumes can fluctuate if the patient has a variable respiratory rate. If *exact concentrations* of inspired oxygen (FIO_2) must be delivered to the patient, it is recommended that the optional FIO_2 Sensor or a separate oxygen analyzer with alarms be used. If using the optional FIO_2 Sensor set the ventilator High and Low FiO_2 alarms appropriately (see *High FiO2* and *Low FiO2* alarms in Chapter 8 – *Ventilator Alarms* for additional information).

NOTE

If a high pressure O_2 source is attached when the ventilator **FiO_2** setting is **LPS** (Low Pressure O_2 Source), a High O_2 Inlet Pressure alarm will activate and the ventilator will automatically switch the **FiO_2** setting to **21%.** See *High O2 Inlet Pressure* in Chapter 8 - Ventilator Alarms for more details.

[4] DISS - Diameter-Index Safety System #1240, per GGA V5-1989.
[5] The DISS Low Pressure Adapter is available from CareFusion.

Power Connection

The Enve™ ventilator operates on Direct Current (DC) (11 to 16 VDC), which can be supplied by any one of the following sources of power:

- AC Adapter
- Automobile Adapter
- Docking Station
- Removable Battery Pack

Refer to *Chapter 12 - Power Supplies and Batteries* for detailed information.

To Connect External Power (other than a Docking Station)

Both the optional AC and Automobile Adapters are connected to the ventilator as follows:

WARNING

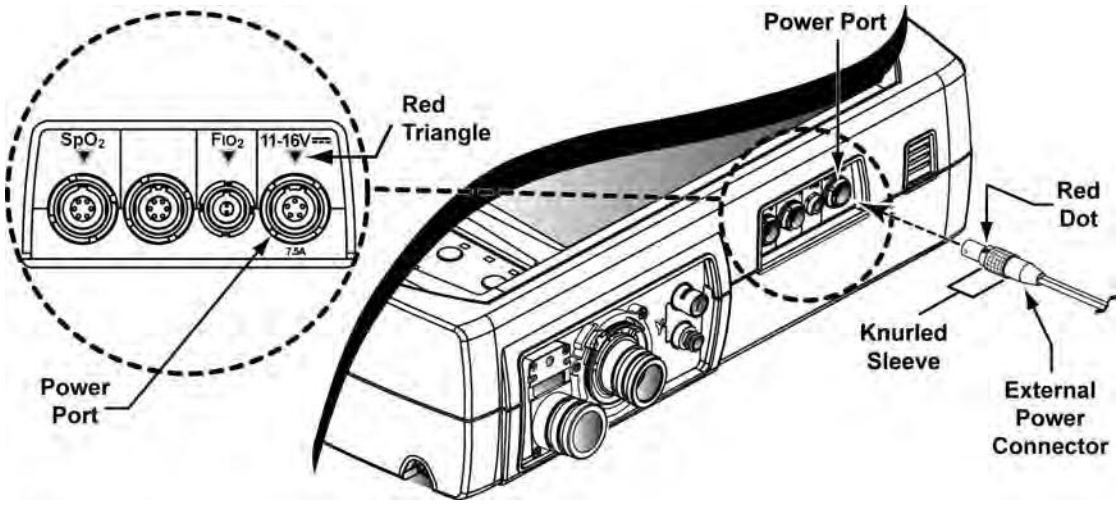
Risk of Electrical Shock - To avoid the risk of an electrical shock or ventilator damage;

- Use only batteries, adapters, cables or external power supplies recommended by CareFusion
- Do not use batteries, adapters, cables or external power supplies with visible signs of damage
- Do not touch internal components
- Refer all servicing or repairs to CareFusion or a service technician certified by CareFusion

NOTE

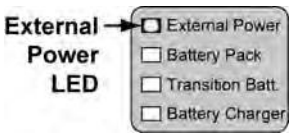
When using PTV® Series Ventilators in combination with a Docking Station, CareFusion recommends connecting external power only to the Docking Station (the Docking Station in turn provides power to the ventilator).

1) Position the power connector with the red dot on the connector aligned with the red triangle on the ventilator port labeled **11-16V** (on a gray background). Insert as shown in the illustration.
    - The connector is keyed to fit only one way and will lock into place when properly inserted.



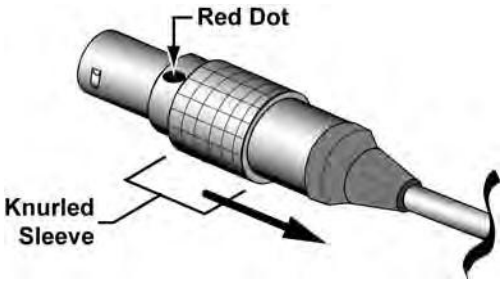
2) Connect the external power cable to a valid external power source.

3) Verify the **External Power** LED on the Lower Interface Panel illuminates green. If not, recheck the power supply.



To Disconnect External Power (other than a Docking Station)

The external power connector has a safety locking mechanism to prevent accidental disconnection. To disconnect the safety locking mechanism, grasp the knurled sleeve of the connector and pull away from the ventilator as shown below. This retracts the locking mechanism and releases the connector from the ventilator power port.



CAUTION

Connector Removal - To avoid damaging the ventilator or the connector, grasp only the knurled sleeve of the connector to remove it from the ventilator's port. Do not pull on the cord.

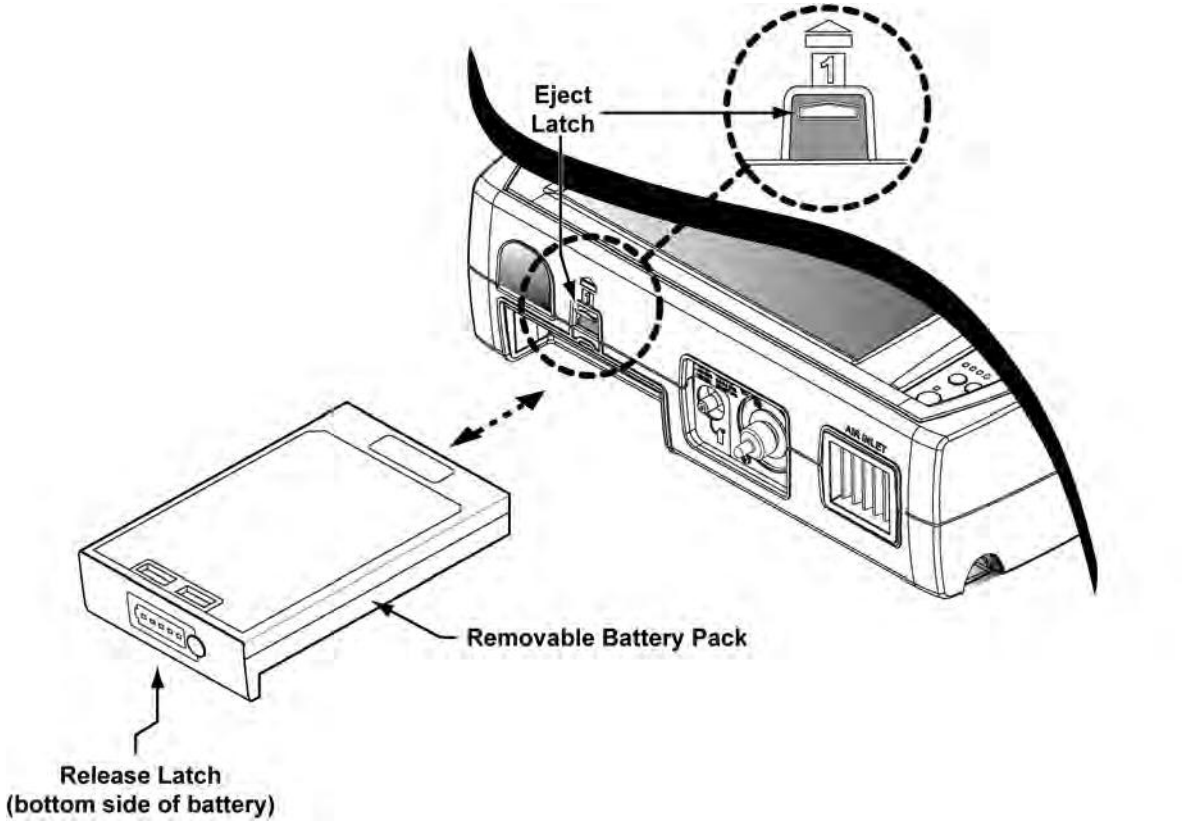
Removable Battery Pack Installation

For safety there are two latch mechanisms securing the Removable Battery Pack. The first is above the battery (see illustration). The second is on the underside of the battery at the leading edge. Both will engage when installing and must be sequentially released to safely remove the battery.

To Install the Removable Battery Pack

> **NOTE**
> The Removable Battery Pack can be charged before installation using the Desktop Battery Charger. Once installed, it is charged by the ventilator when connected to external power.

Position the Removable Battery Pack as shown and push firmly into the Removable Battery Pack slot on the left side of the ventilator. If the ventilator is turned on, an audible signal sounds when the battery is acknowledged by the ventilator. The battery only fits into the slot one way (as shown) and will lock into place when fully inserted.



To Remove the Removable Battery Pack

To remove the battery, pull the Eject Latch up. The battery will partially eject. Press the Release button located on the bottom of Removable Battery Pack and pull the battery out of the battery slot as shown.

Optional Use Accessories Connection

Although the Enve™ Ventilator accommodates the following accessories, their connection, configuration and use is up to the discretion of the operator and the clinical needs of the patient.

- Pulse Oximetry (SpO_2) Sensor
- FIO_2 Sensor
- Nebulizer

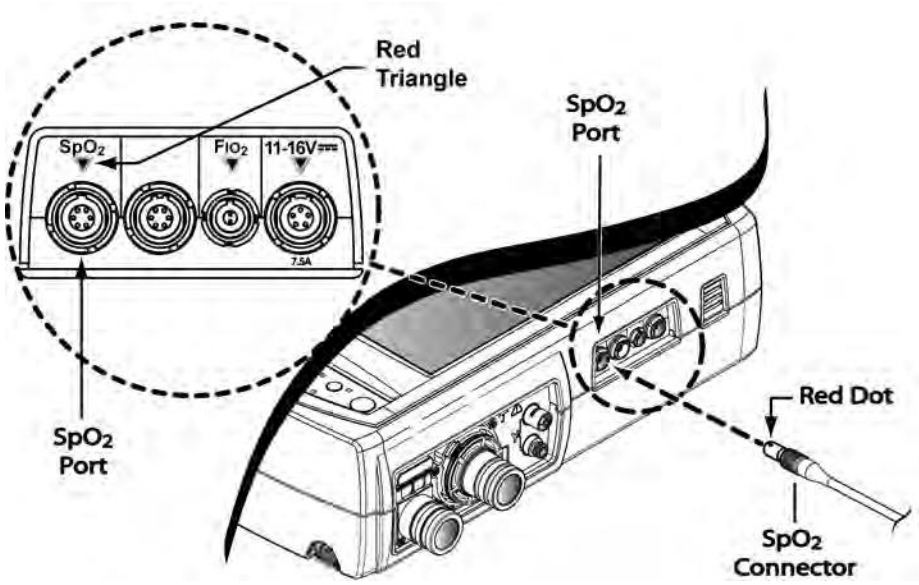
Pulse Oximetry (SpO_2)

The Pulse Oximetry Module (option) for use with PTV® Series Ventilators is CareFusion P/N 18602-001. For specifications, warranty information and assembly and cleaning instructions, refer to the Instructions for Use provided with your Oximetry Module.

- See *Accessories* in Appendix C – Reference Information for additional information[6]

To Connect the Pulse Oximetry (SpO_2) Sensor

1) Position the module connector with the red dot on the connector aligned with the red triangle on the ventilator port labeled **SpO_2** (on a blue background). Insert as shown in the illustration**.**
    - The connector is keyed to fit in only one position (when the red dot aligns with the red triangle) and will lock into place when properly inserted.



[6] For a current/complete list of accessories, availability and ordering information, contact CareFusion (see *Appendix A - Contact Information).*

To Configure Pulse Oximetry (SpO_2) Monitoring

Pulse Oximetry monitoring is configured (enabled, disabled, average interval and pulse tone volume configuration values set) while the ventilator is in a normal ventilation mode from the **Utility** screen, **Option Config** page.

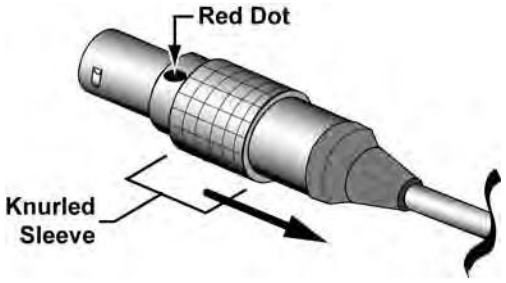
See *SpO2 Configuration* in Chapter 10 – The Utility Screen for detailed instructions.

> **NOTE**
> If the sensor is not on a patient when SpO_2 is enabled, an alarm will sound.

To Disconnect the Pulse Oximetry (SpO_2) Sensor

The SpO_2 Sensor connector has a safety locking mechanism to prevent accidental disconnection. To disconnect the safety locking mechanism, grasp the knurled sleeve of the connector and pull away from the ventilator as shown below. This retracts the locking mechanism and releases the connector from the ventilator SpO_2 port.

> **CAUTION**
> **Connector Removal -** To avoid damaging the ventilator or the connector, grasp only the knurled sleeve of the connector to remove it from the ventilator's port. Do not pull on the cord.



FIO_2 Sensor

In order for the Enve™ ventilator to monitor/report the FIO_2 (Fraction of Inspired Oxygen) level in the inspiratory limb of the patient circuit, an optional oxygen sensor (and attendant connectors/cables) must be assembled together, inserted into a patient circuit, connected and calibrated to the ventilator.

Contact CareFusion for oxygen sensor part numbers and pricing information. See *Appendix A - Contact Information* for contact and ordering information.

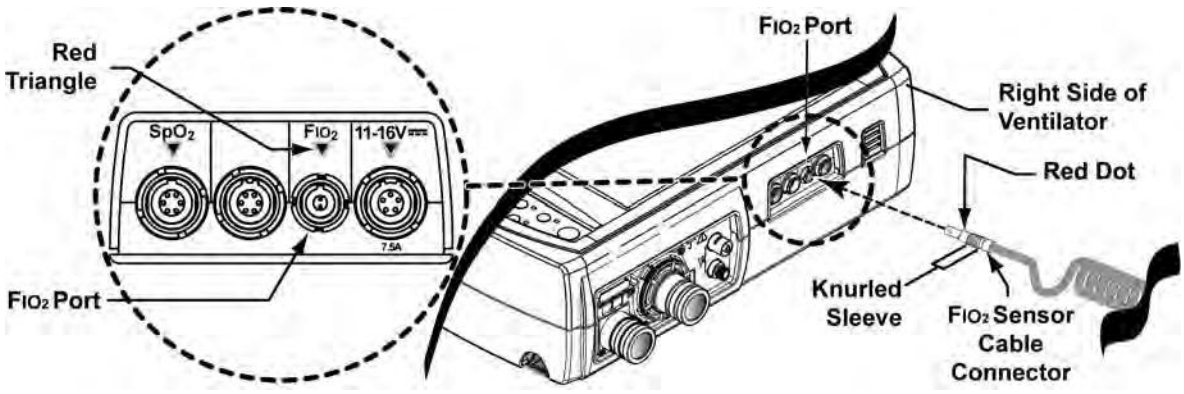
To Assemble the FIO_2 Sensor Assembly

See the Instructions for Use provided with the FIO_2 Sensor Cable Assembly for detailed instructions concerning assembling the FIO_2 Sensor Assembly and inserting it into the patient circuit.

To Connect the FIO_2 Sensor

Position the FIO_2 Sensor connector with the red dot on the connector aligned with the red triangle on the ventilator port labeled **FIO_2** (on a green background). Insert as shown in the illustration**.**

- The connector is keyed to fit in only one position (when the red dot aligns with the red triangle) and will lock into place when properly inserted



CAUTION

Calibration of Sensor - Accurate monitored FIO_2 readings cannot be obtained until the ventilator has been calibrated with the sensor that is connected. Follow the connection and calibration instructions given in this chapter to ensure that the ventilator and the external oxygen sensor are calibrated and communicating properly.

Off Patient Calibration - All sensor calibration is performed with the ventilator off the patient and in the Startup mode of operation.

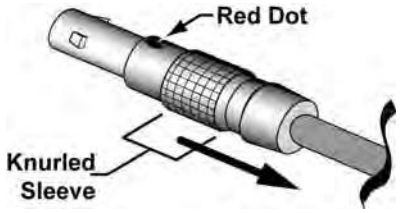
To Configure FIO_2 Monitoring

FIO_2 monitoring is configured (enabled, disabled, and calibrated) while the ventilator is in Startup mode from the **Vent Setup**, **EST**[7] screen. See *FIO2 Configuration and Calibration* in Chapter 3 – Using the Ventilator for detailed instructions

- Once setup, enabled and calibrated, communication with the FIO_2 sensor may be enabled/disabled during normal ventilation modes using the **FIO_2** control on the *Option Config Page* in Chapter 10 – The Utility Screen

To Disconnect the FIO_2 Sensor

The FIO_2 Sensor connector has a safety locking mechanism to prevent accidental disconnection. To disconnect the safety locking mechanism, grasp the knurled sleeve of the connector and pull away from the ventilator (as shown below). This retracts the locking mechanism and releases the connector from the ventilator port.



CAUTION

Connector Removal - To avoid damaging the ventilator or the connector, grasp only the knurled sleeve of the connector to remove it from the ventilator's port. Do not pull on the cord.

[7] Extended Systems Test

Nebulizer

The Nebulization procedure can be performed on the Enve™ ventilator during Volume breaths in Assist/Control mode only. When the Nebulizer is activated, a six (6) L/min nominal flow is delivered to the nebulizer drive port. This drives an aerosol nebulizer that doses medication into the patient circuit.

To perform this procedure, the ventilator must be connected to a high pressure oxygen source and a Nebulizer.

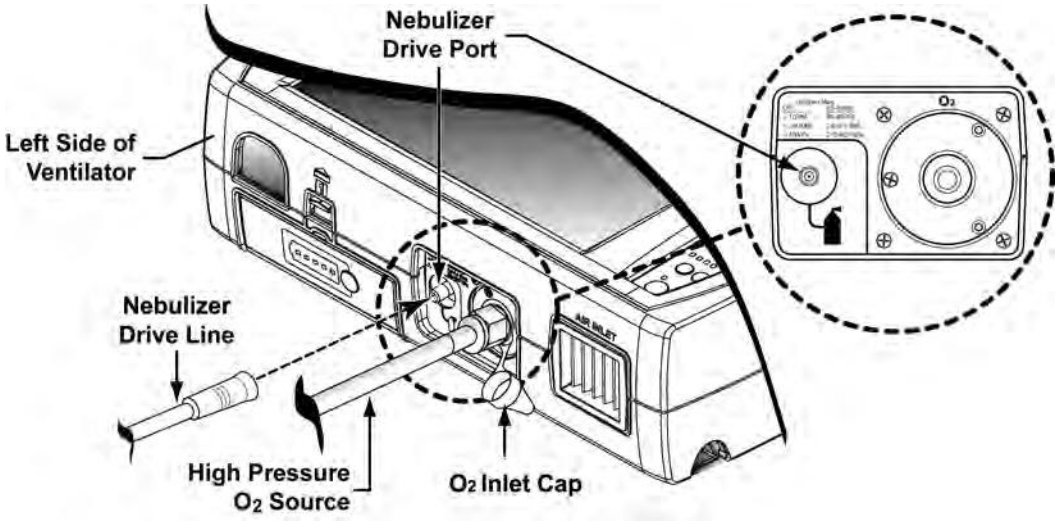
To Connect the Nebulizer

1) Align the nebulizer drive line as shown and push it straight onto the nebulizer drive port barb on the left side of the ventilator. The nebulizer drive port is labeled with the symbol shown here.

WARNING

Risk of Injury - If the nebulizer drive system fails, medication can be delivered at an incorrect rate. Monitor medication consumption rate and discontinue use if it does not meet patient needs.

If the nebulizer drive system fails, medication can be delivered during exhalation phase resulting in a release of medications into the room. Monitor medication consumption rate and discontinue use if rate is excessively high.



NOTE

The Nebulizer should be removed from the patient circuit and the ventilator when not in use.

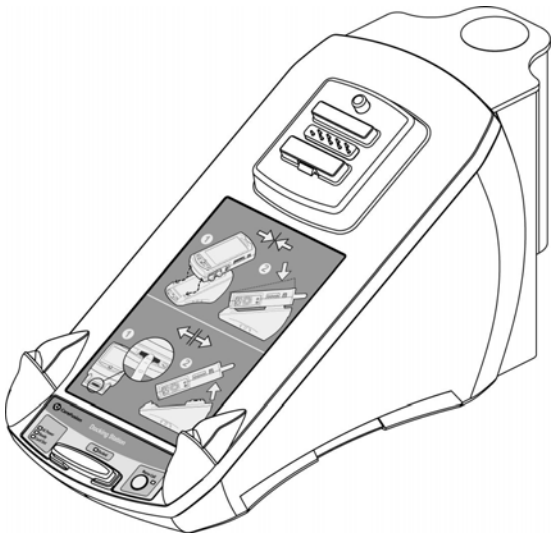
To Configure Nebulization

Nebulization is configured and activated while the ventilator is in a normal ventilation mode from the **Main** screen, **Nebulizer** page. See *Nebulization* in Chapter 9 – Maneuvers, Procedures and Standby Mode for detailed information and instructions.

PTV® Series Docking Station (Option)

The ventilator can be docked to a PTV® Series Docking Station that provides power to the ventilator, accommodates the PTM™ Graphics Monitor and expands the ventilator interface capabilities to include:

- AC Power
- Memory Card Interface with automatic copying/storage of ventilation data
- Nurse Call Interface
- Patient Monitor System Interface
- PTM™ Graphics Monitor Mounting and Communication (Option)
- Rolling Stand Mounting (Option)
- Wall Mounting (Option)
- Table Top Stand Mounting (option)



For additional information and detailed connection instructions, see the PTV® Series Docking Station Operator's Manual, P/N 12433-001.

PTM™ Graphics Monitor (Option)

The PTM™ Graphics Monitor accessory is a thin, lightweight color graphics monitor for use with PTV® Series Ventilators when connected to a Docking Station and secured onto a PTV® Series Rolling Stand, Table Stand, or Wall Mount. The PTM™ offers the following capabilities:

Data Screen	Current ventilator settings and monitored data
Loop Screen	Flow/volume and volume/pressure loops
Summary Screen	Collection of displays consisting of graphs and data from the Waveform, Loop and Data screens and ventilator settings
Trend Screen	Trend graphs for long term display of monitored data
Wave Screen	Pressure, flow, volume and plethysmograph waveforms

For instructions and detailed use information, see the PTV® Series Docking Station Operator's Manual, P/N 12433-001, and the PTM™ Graphics Monitor Operator's Manual, P/N 14069-001.

Ventilator Testing

Perform the following tests and use the Ventilator Tests Worksheet located at the end of this chapter to record each test result.

WARNING

Startup Mode – The ventilator does not deliver gas to the patient in Startup mode.

Improperly Functioning Ventilator or Attached Accessories - Operating a ventilator that does not appear to be functioning properly may be hazardous to both patient and operator. If the ventilator or any attached accessory is damaged, fails any tests or malfunctions in any way, immediately discontinue use and contact CareFusion or a service technician certified by CareFusion.

To verify the functional operation of the Enve™ ventilator, the following tests are to be performed as required in the *Maintenance Schedule* in Chapter 11 – Maintenance and Cleaning.

Test	Type of Test	Operating Mode Performed In
POST	Power On Self Tests	Startup mode
Button Test	User Verification Tests (UVT)	Startup mode
Touch Screen Calibration	User Verification Tests (UVT)	Startup mode
Circuit Test	Extended Systems Test (EST)	Startup mode
Battery/Power Test	Functional Test	Normal mode
Display/Alarm Test	Functional Test	Normal mode
Alarm Response Tests	Functional Test	Normal mode

Test Preparation

Preparation Required for All Tests:

1) Starting with the ventilator off, connect the ventilator to a valid, external source of power (see *Power Connection* in this chapter and/or the PTV® Series Docking Station Operator's Manual (P/N 12433-001), as applicable.
2) Insert a fully charged Removable Battery Pack (see *Removable Battery Pack Installation* in this chapter).

Additional Preparation Required for the Circuit Test:

3) Assemble the patient circuit to be used/tested (see *Patient Breathing Circuits* in this chapter and include all accessories to be used, i.e. humidifiers, water traps, filters, etc.) except:
    - Do not include a Nebulizer in the circuit
4) Connect the patient circuit to the ventilator (see *Connecting the Patient Circuit* in this chapter).
    - Do not attach an oxygen supply to the ventilator at this time
    - Do not connect the patient circuit to a patient

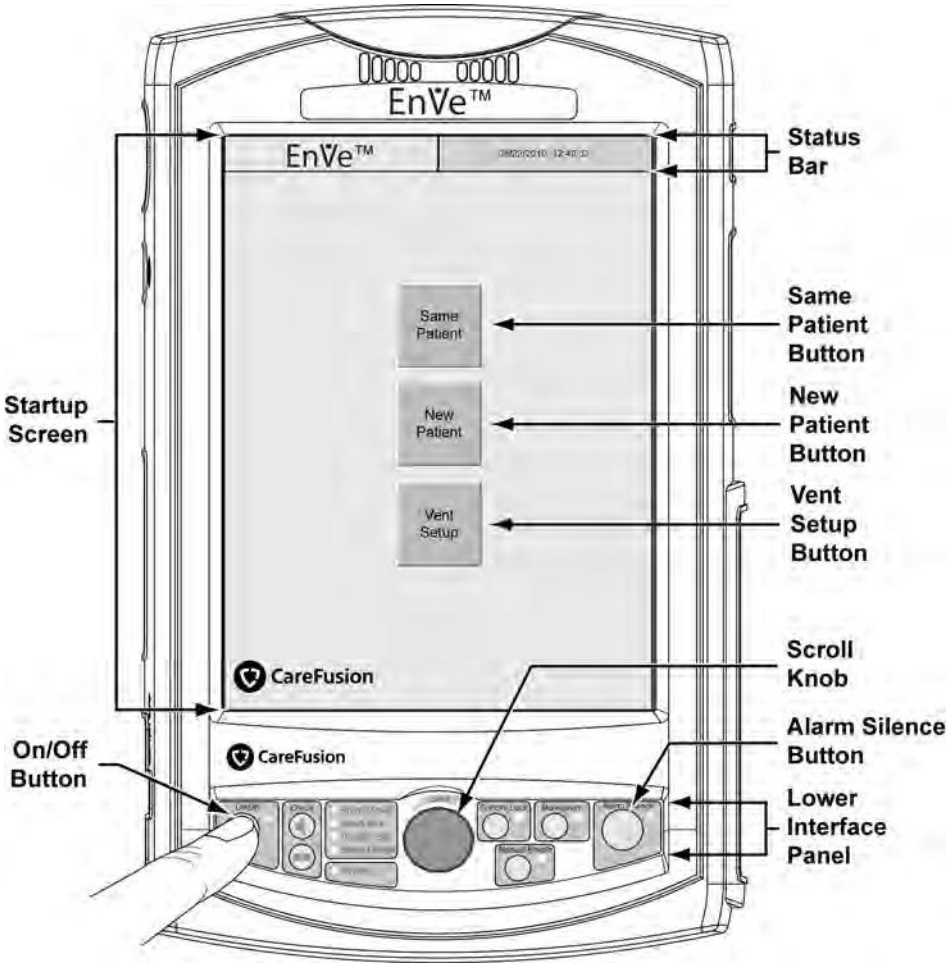
Additional Preparation Required for Alarm Response Tests:

5) Connect a Test Lung to the Patient Connection Port on the Elbow of the assembled patient circuit attached to the ventilator. Refer to the patient circuit illustration under *Patient Circuit Accessories* earlier in this chapter for location of Patient Connection Port.

Power On Self Tests (POST) in Startup Mode

The Power On Self Tests (POST) are a set of self-tests the ventilator performs when turned on to verify the operational integrity and the validity of all stored configuration values, event log, RAM and program memory.

To turn the ventilator on and perform POST, momentarily push the **On/Off** button on the **Lower Interface Panel**. Verify that the ventilator powers up, and displays the initial Startup screen.,



NOTE

Exiting Startup Mode – Startup mode can be exited at any time and from any screen by simply holding down the **On/Off** button on the Lower Interface Panel until the ventilator powers down.

Functional Testing in Startup Mode

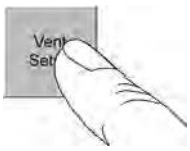
UVT and EST Testing

User Verification Tests (UVT) and Extended Systems Test (EST) (Button Test, Touch Screen Calibration and Circuit Test) are performed while the ventilator is in the Startup mode.

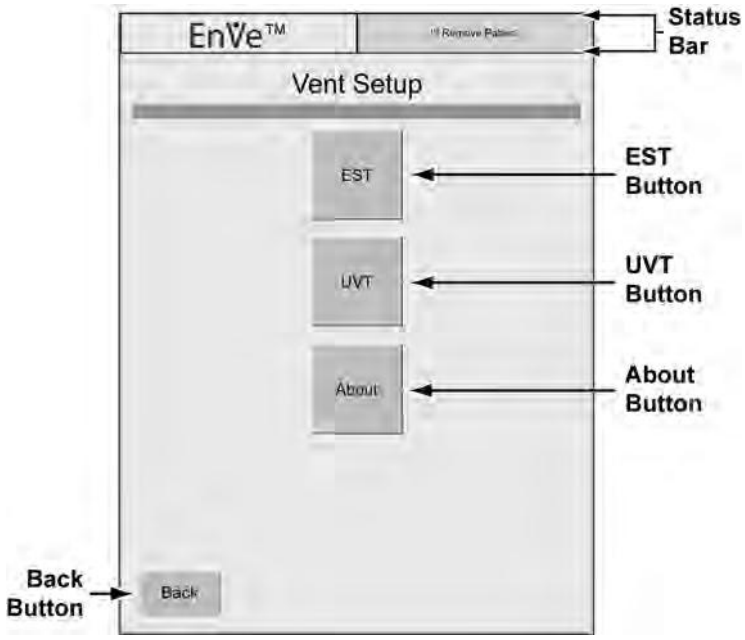
WARNING

Improperly Functioning Ventilator or Attached Accessories - Operating a ventilator that does not appear to be functioning properly may be hazardous to both patient and operator. If the ventilator or any attached accessory is damaged, fails any tests or malfunctions in any way, immediately discontinue use and contact CareFusion or a service technician certified by CareFusion.

1) To perform testing in Startup mode, prepare and turn the ventilator on as previously described in this chapter.
   - See *Test Preparation* and Power On Self Tests (POST) in Startup Mode earlier in this chapter for detailed information



2) Touch the **Vent Setup** button on the initial Startup screen to display the **Vent Setup** screen.
3) To clear the **Remove Patient** audible alarm and clear the displayed message for two (2) minutes, touch the Status Bar and then the Alarm Reset button (when displayed). Touch the Back button to return to the Startup screen.

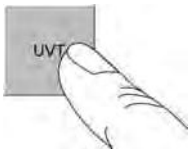


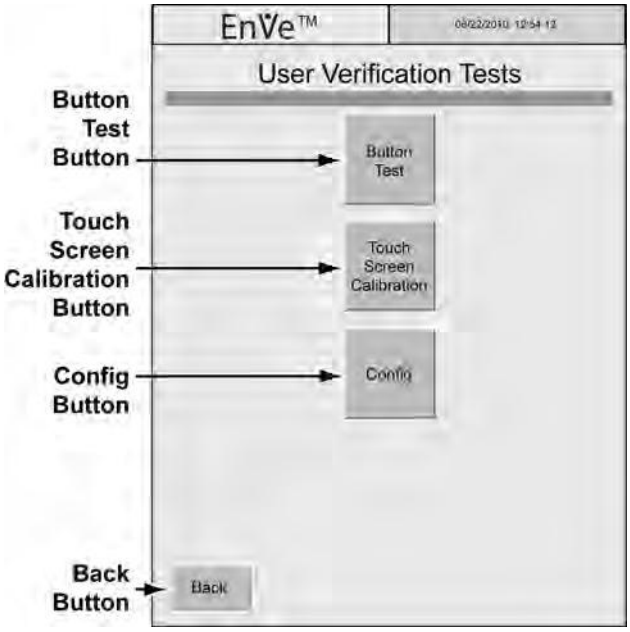
Button Test

The Button Test checks the functioning of the mechanical controls (buttons and knob) on the ventilators' Lower Interface Panel.

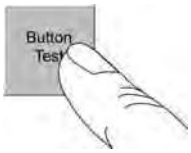
To Perform the Button Test:

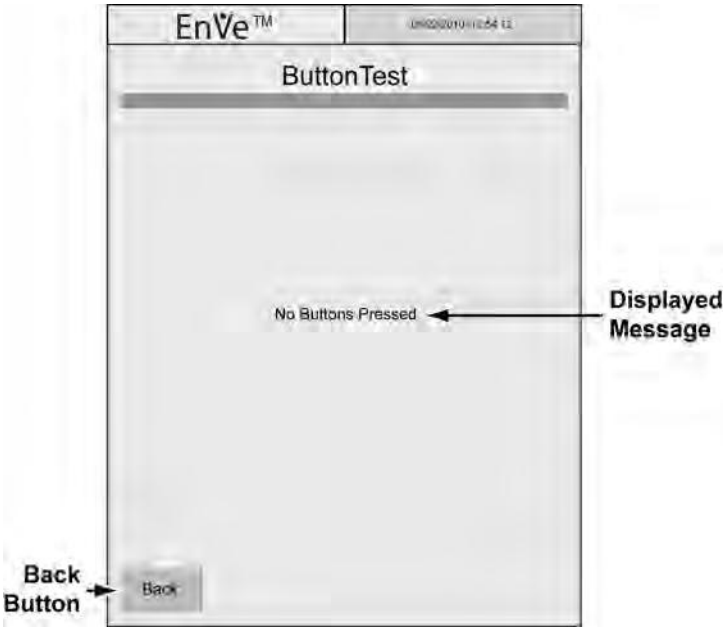
1) Touch the **UVT** button on the **Vent Setup** screen to display the **User Verification Tests** screen.





2) From the **User Verification Tests** screen, touch the **Button Test** button and the **Button Test** screen is displayed with a **No Buttons Pressed** message displayed on it.



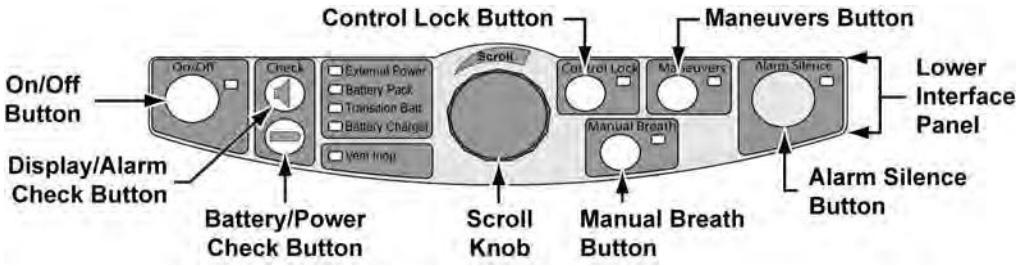


3) Test the control buttons and the **Scroll** knob on the Lower Interface Panel by pressing each button, one at a time and rotating the **Scroll** knob. As each button is pressed or knob rotated, verify that the corresponding name of the control pressed/rotated replaces the displayed **No Buttons Pressed** message and matches the name of the control, as shown in the following table.

NOTE

During the Button Test the normal function of each button on the Lower Interface Panel is suspended, except as follows:

- During testing, the **Alarm Silence** button retains its functionality and will continue to silence/reset alarms when pressed
- When testing the **On/Off** button, briefly press the button and an **On/Off** message replaces the displayed **No Buttons Pressed** message. However, pressing and holding the **On/Off** button for more than three (3) seconds will cause the ventilator to exit the Button Test and power off



Control	Name Displayed
On/Off	**On/Off**
Check	**Alarm Display Test**
Check	**Battery Check**
Scroll (knob rotated to the right)	**Rotate Right**
Scroll (knob rotated to the left)	**Rotate Left**
Control Lock	**Control Lock**
Manual Breath	**Manual Breath**
Maneuvers	**Maneuvers**
Alarm Silence	**Alarm Silence**

When all controls have been pressed/rotated and the corresponding name has been verified as being correctly displayed, the Button Test has been successfully completed.

4) Touch the **Back** button once to return to the **User Verification Tests** screen.

Touch Screen Calibration

Alignment of the LCD touch screen to displayed controls/buttons may drift with time and usage.

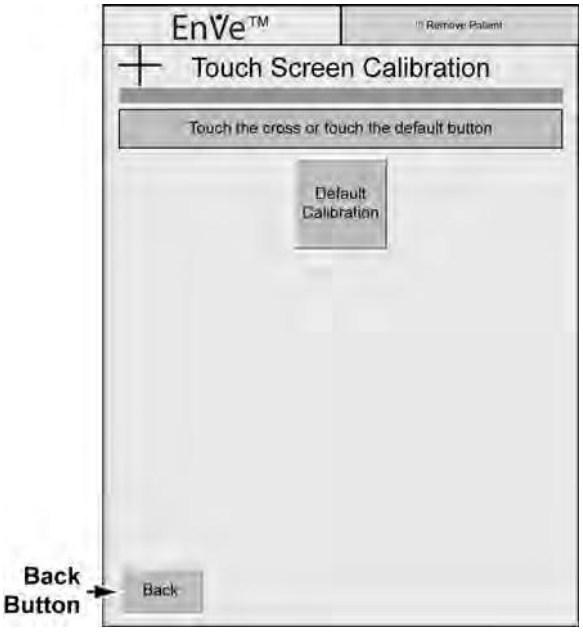
Performing the calibration procedure fine tunes the alignment of the LCD touch screen to the displayed underlying controls.

NOTE

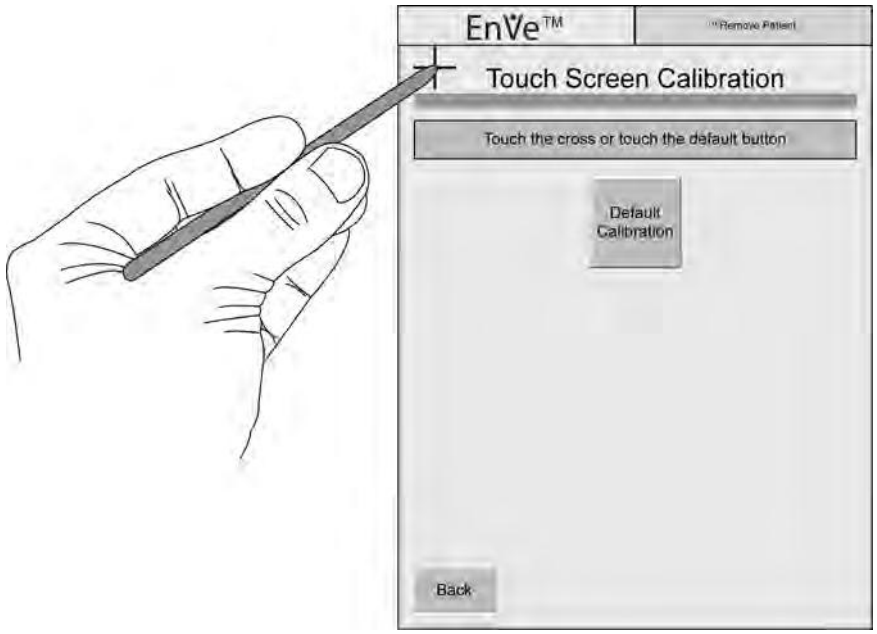
- For the most precise alignment of the LCD touch screen to displayed controls/buttons, CareFusion recommends using a stylus (or equivalent dull pointed instrument) to touch the center of the displayed crosses during the calibration procedure
- If at any time controls/buttons other than those intended are being selected when the touch screen is touched, use this calibration procedure to correct the alignment.

To Perform the Calibration Procedure:

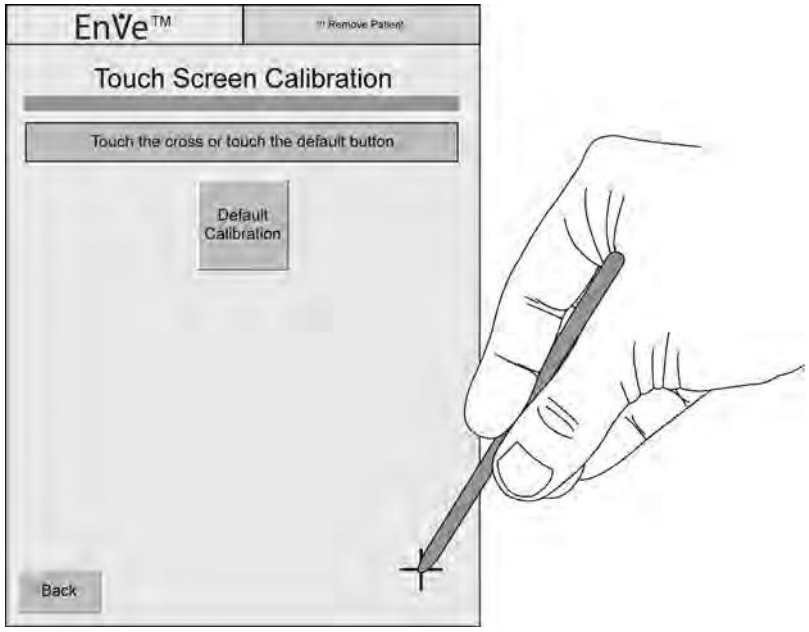
1) Touch the **Touch Screen Calibration** button on the **User Verification Tests** screen to display the **Touch Screen Calibration** screen.



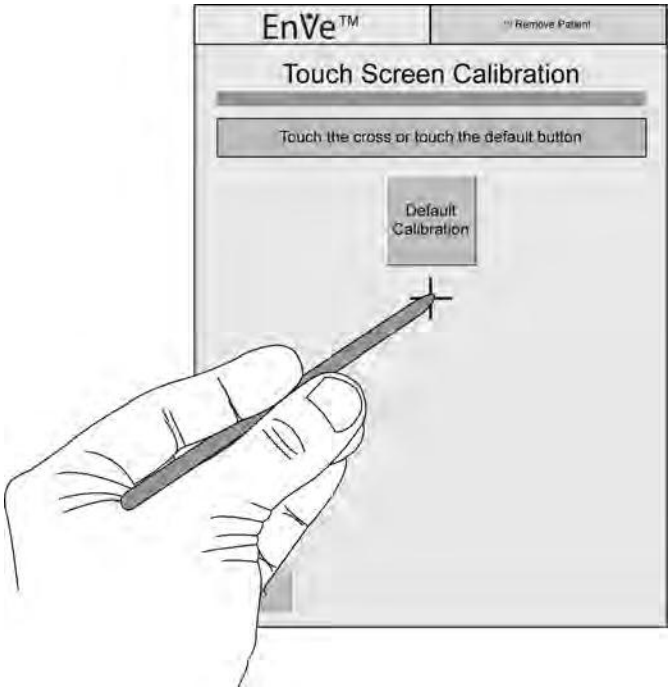
2) Touch the *center* of the cross in the upper left corner of the screen. When the touch is detected by the ventilator, the cross will move to the lower right corner of the screen.



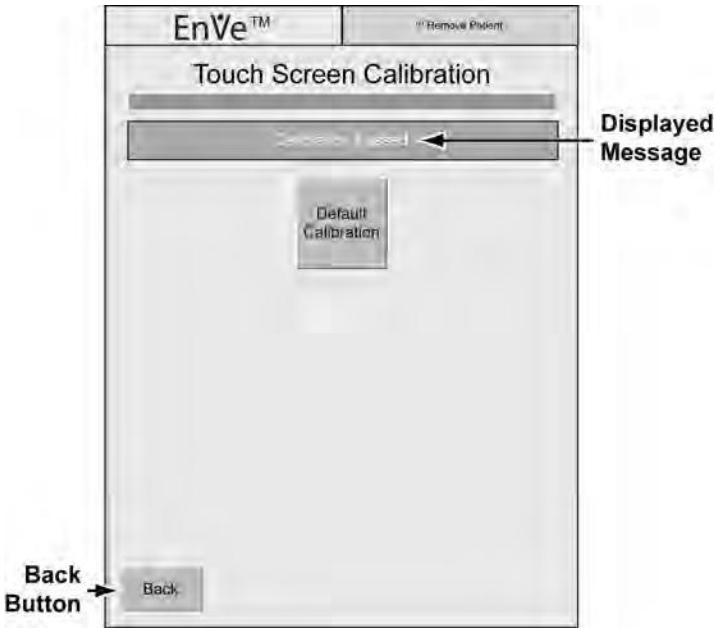
3) Touch the *center* of the cross again. When the touch is detected by the ventilator, the cross will move to the center of the screen.



4) Touch the *center* of the cross once again.

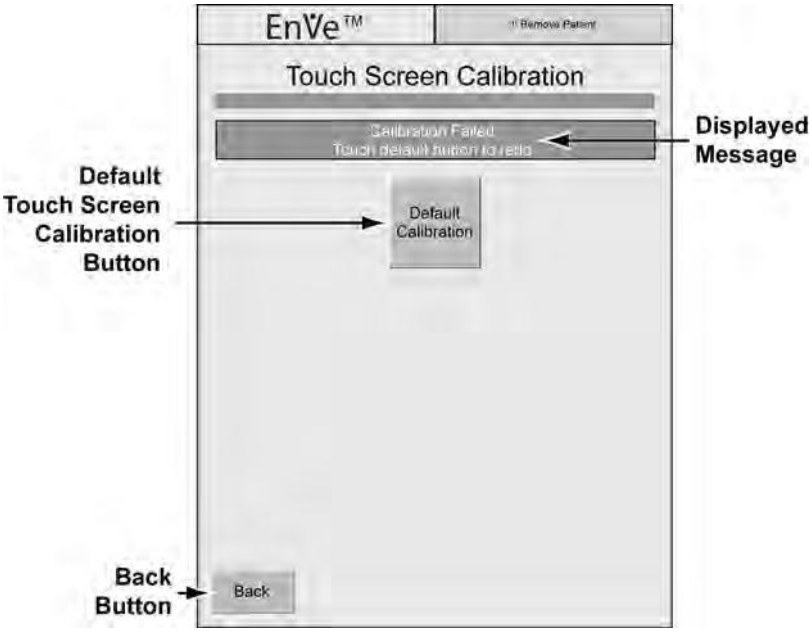


5) If calibration is successful (within acceptable parameters);
   - The cross is removed
   - The displayed message, "**Touch the cross or touch the default button**", is replaced with "**Calibration Passed**"
   - The ventilator automatically accepts and uses the new calibration data
   - The calibration procedure has been successfully completed

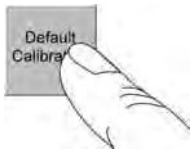


Touch the **Back** button to return to the **User Verification Tests** screen. Touch the **Back** button a second time to return to the **Vent Setup** screen.

6) If calibration is not successful, the displayed message, "**Touch the cross or touch the default button",** is replaced with **"Calibration Failed. Touch default button to redo."** Proceed as follows.



7) Touch the **Default Touch Screen Calibration** button to redisplay the cross in the upper left corner of the page and repeat the calibration procedure.

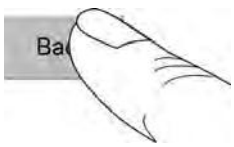


8) If after three (3) attempts calibration is still not successful, touch the **Default Touch Screen Calibration** button again to have the ventilator accept and use the default factory-set calibration data.
   - Although not as precise as manual calibration, the factory-set default values are within acceptable parameters

NOTE

Calibration Failures - If the ventilator fails touch screen calibration and the factory-set default values do not provide for acceptable user access to touch screen buttons or controls, contact CareFusion or a service technician certified by CareFusion.

9) Touch the **Back** button to return to the **User Verification Tests** screen. Touch the **Back** button a second time to return to the **Vent Setup** screen.



Circuit Test

The Circuit Test measures the air flow across the patient circuit Flow Sensors, checks the airway circuit for leaks and checks the ventilator's Safety Valve for over-pressure relief.

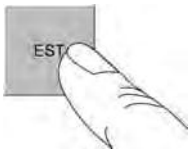
WARNING

Patient Breathing Circuit – The patient circuit must be tested for leaks (Circuit Test) before it is used for the first time and after any changes have been made to the configuration of the circuit. Harm to the patient or ineffective ventilation may result from failure to detect and correct leaks in the patient breathing circuit before connection to a patient.

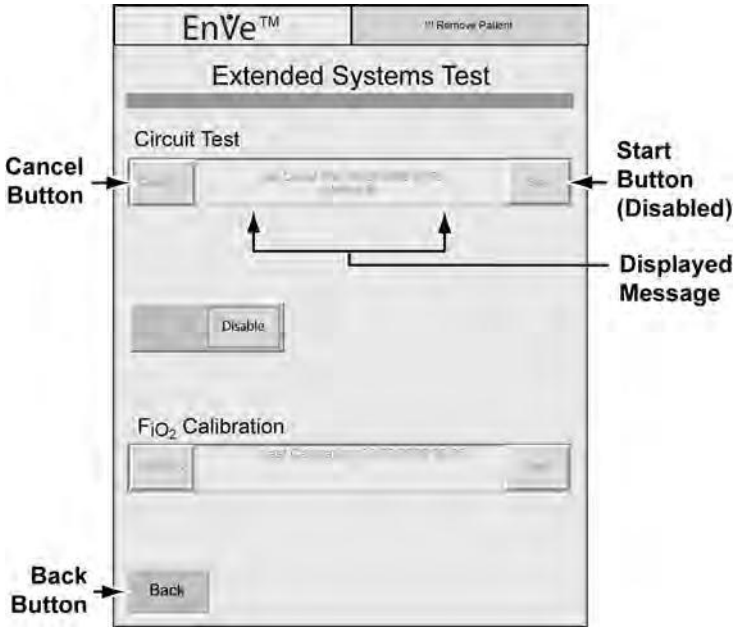
To Perform the Circuit Test:

1) Attach the assembled patient circuit to be tested to the ventilator. If the patient circuit has not been previously assembled and attached to the ventilator, see Test Preparation and Power On Self Tests (POST) in Startup Mode earlier in this chapter for detailed instructions before proceeding.

2) Touch the **EST** button on the **Vent Setup** screen to display the **Extended Systems Test** screen with the Circuit Test controls and message display area.



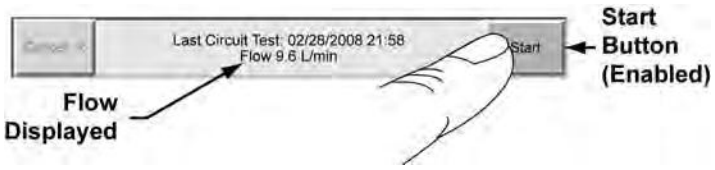
- A **Last Circuit Test: xx/xx/xxxx xx:xx** and **Waiting xx** message (counting down from 60 seconds) are displayed and the Circuit Test **Start** button is disabled while the ventilator transducers are warming up after power up, OR



- A **Last Circuit Test: xx/xx/xxxx xx:xx** and **Remove Patient** message is displayed and the Circuit Test **Start** button is enabled (ventilator transducers have warmed up sufficiently enough to proceed with the test)

3) When the **Waiting xx** portion of the message is changed to **Remove Patient** and the **Start** button is enabled, press the **Start** button. The ventilator increases and displays the flow (**Flow xx.x L/min**) through the circuit.

   Observe and follow the on screen instructions.

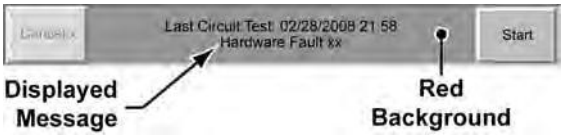


NOTE

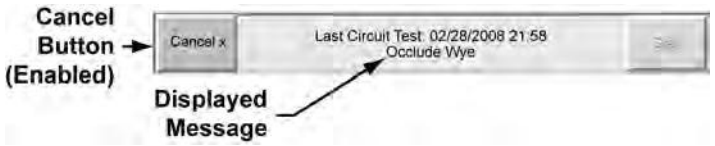
Do not block the patient connection port of the patient circuit Wye, or of any accessory connected to the Wye (such as a filter, inline suction catheter, etc.) at this point in the test. Flow across the sensors must be unimpeded to establish the flow measurement.

WARNING

Failed Auto Zero - If the ventilator transducers fail to “auto zero” at the beginning of the Circuit Test, a Hardware Fault message (**Hardware Fault xx**) will be displayed (on red background in the Circuit Test message display area) and the test will be stopped. To avoid possible harm to the patient, do not use the ventilator and contact CareFusion or a service technician certified by CareFusion.



- **Unblock Wye** is displayed if the flow is less than 7 L/min
- **Failed: Check flow sensor** is displayed if the flow does not meet the acceptance criteria (7 – 13 L/min for 3 seconds) within 10 seconds
- **Occlude Wye** is displayed when an acceptable flow has been maintained continuously for 3 seconds



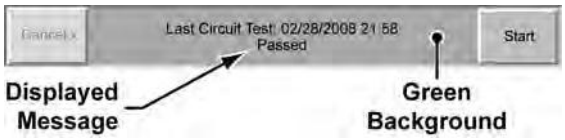
4) When **Occlude Wye** is displayed, occlude the patient circuit at the patient end (patient connection port of the Elbow on the patient circuit Wye, filter or other attached accessory). The ventilator will maintain pressure in the circuit at 60 cmH_2O and display the delivered flow from the inspiratory port. Continue to keep the patient circuit end occluded through this step and the next step.

   - **Failed: Check for leaks** is displayed (on red background) and the ventilator stops the test if the acceptance criteria (flow 0 – 0.9 L/min for 3 seconds) is not met within 10 seconds

5) When an acceptable rate of flow (or no flow) has been maintained for 3 seconds, the ventilator will reduce flow and open the safety valve. Continue to keep the circuit occluded until **Passed** or **Failed** is displayed.

   A measured drop in pressure should occur when the safety valve opens, indicating that the valve is functioning correctly and relieving pressure in the circuit.

   - **Failed: Check for leaks** is displayed (on red background) and the ventilator stops the test if the acceptance criteria (flow 0 – 0.9 L/min for 2 seconds) is not met within 10 seconds
   - **Failed: Check safety valve** is displayed (on red background) if the pressure does not drop
   - **Passed** is displayed (on green background) when the measured values are within acceptable limits



When **Passed** is displayed, the Circuit Test has been successfully completed.

WARNING

Circuit Test Failure – To avoid possible harm to the patient, do not use a system (ventilator/patient circuit) which fails the Circuit Test. See *Chapter 13 - Troubleshooting* for more information.

6) Touch the **Back** button to return to the **Vent Setup** screen. Touch the **Back** button a second time to return to the **Startup** screen.

Functional Testing in Normal Ventilation Mode

The Battery/Power Test, the Display/Alarm Test and the Alarm Response Tests are performed while the ventilator is operating in a normal ventilation mode initiated using Presets[8] values for controls and alarm limits settings.

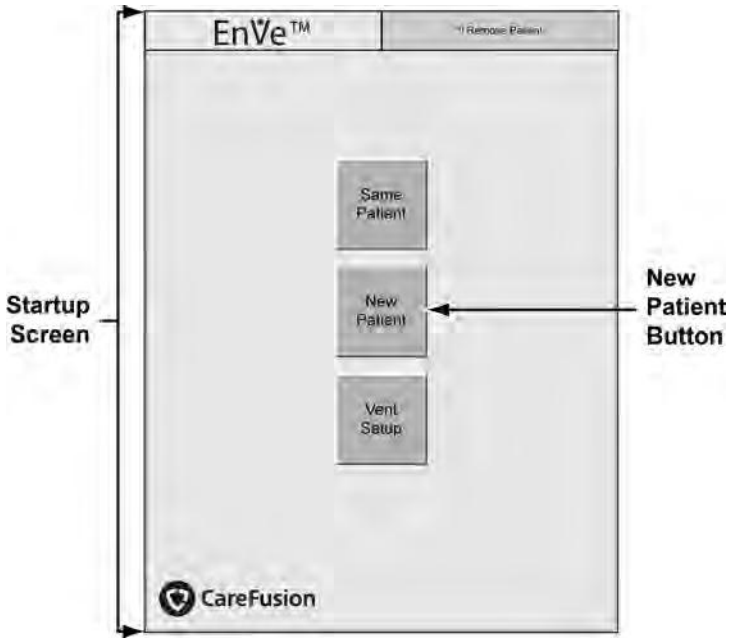
NOTE

Always perform the Button Test, Touch Screen Calibration procedure and the Circuit Test in Startup mode to verify controls and circuit integrity before performing Functional Testing in normal ventilation mode.

WARNING

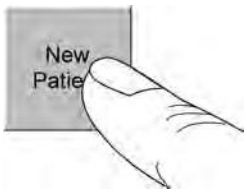
Improperly Functioning Ventilator or Attached Accessories - Operating a ventilator that does not appear to be functioning properly may be hazardous to both patient and operator. If the ventilator or any attached accessory is damaged, fails any tests or malfunctions in any way, immediately discontinue use and contact CareFusion or a service technician certified by CareFusion.

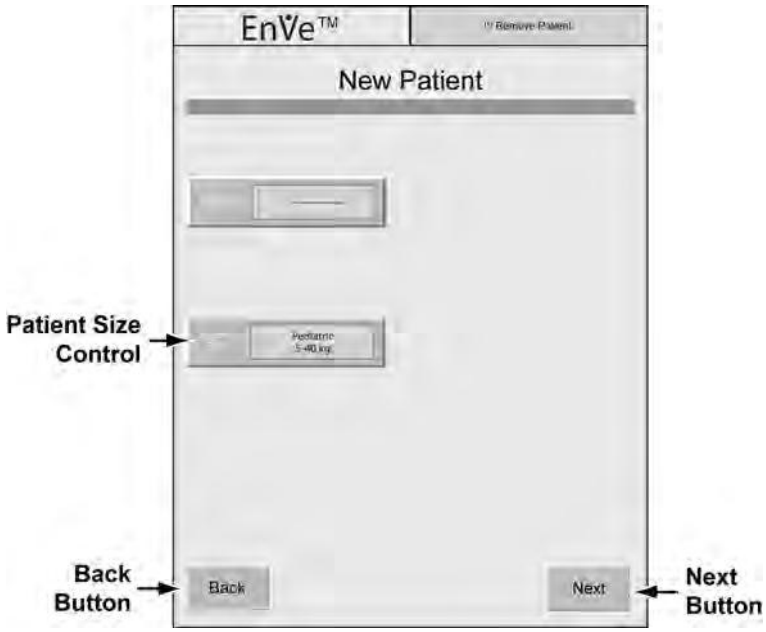
1) To perform testing in normal ventilation mode, prepare and turn the ventilator on as previously described in this chapter and the initial Startup screen is displayed.
    - See *Test Preparation a*nd Power On Self Tests (POST) in Startup Mode earlier in this chapter for detailed information and instructions.



[8] Presets – Automatically set ventilation control and alarm limit values initially clinically appropriate for the patient size and patient circuit type selected by the operator during ventilator setup for a New Patient.

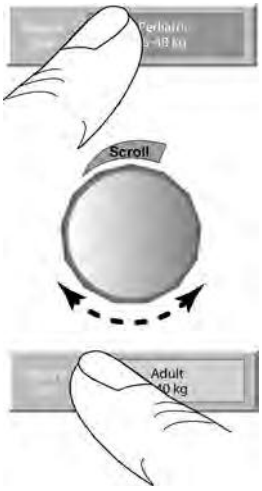
2) Touch the **New Patient** button when the Startup screen is displayed and the **New Patient** screen is displayed.



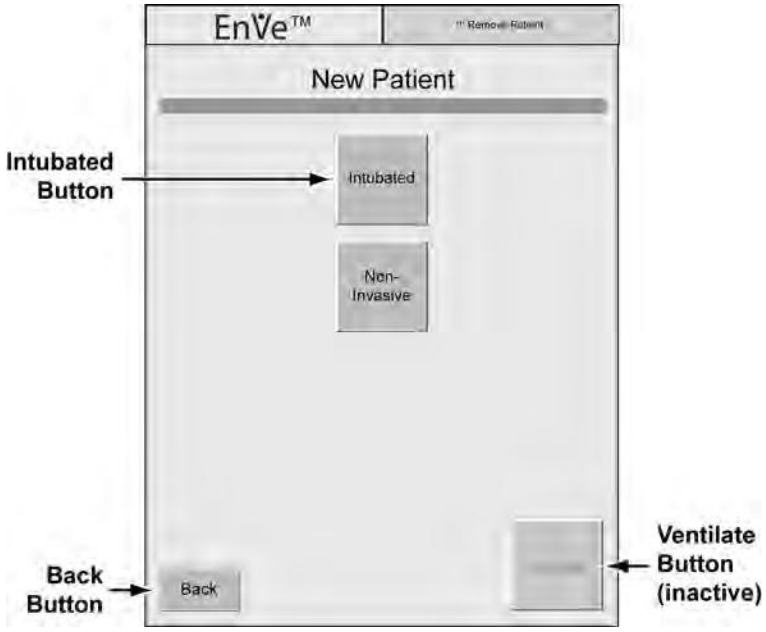


3) When the **New Patient** screen is displayed, touch the **Patient Size** control to select it, and rotate the **Scroll** knob on the Lower Interface Panel to change the setting to **Adult >40 kg**.

Touch the **Patient Size** control once again to confirm the new setting.



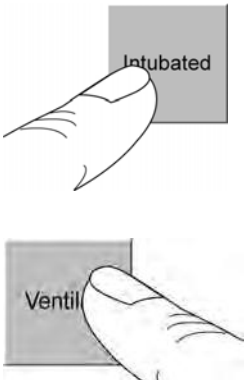
4) Touch the **Next** button and the next **New Patient** screen is displayed.



5) Touch the **Intubated** button to select it and enable the **Ventilate** button. Then touch the **Ventilate** button to:

   - Clear existing Patient ID, Trend data and Maneuvers history
   - Accept the New Patient settings and begin normal ventilation using Presets controls and alarm limits values initially appropriate for the Patient Size and patient circuit type selected.

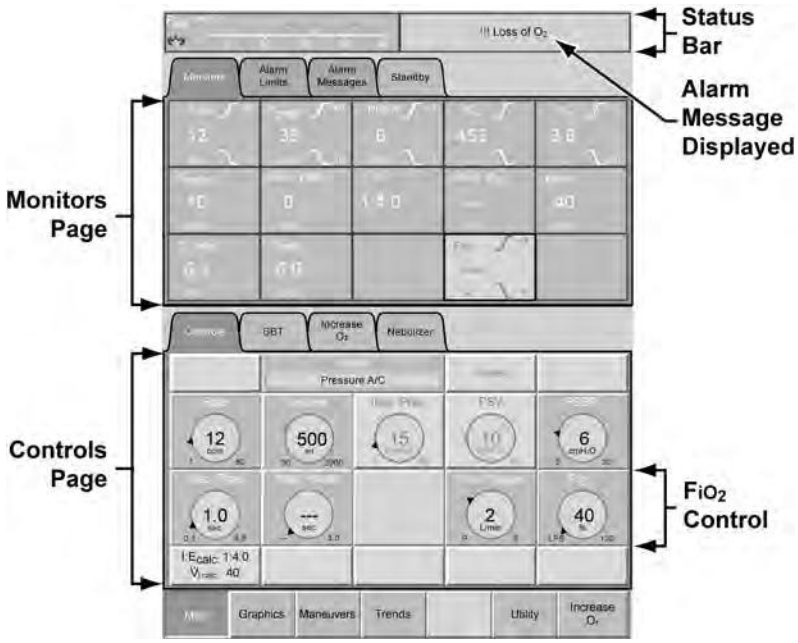
     See *Presets Values for Controls*, *Presets Values for Alarm Limits* and *Presets Values for Utility Controls/Alarms* in Chapter 3 – Using the Ventilator for additional information.
   - Display the **Main** screen, **Controls** and **Monitors** pages



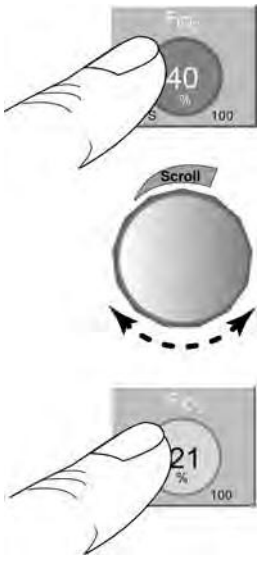
NOTE

The Presets **FiO_2** control value is **40%** and during Functional Testing in a normal ventilation mode, oxygen is not connected to the ventilator until midway through the Alarm Response Tests. Consequently, a **Loss of O_2** alarm is generated and must be cleared in order to proceed when the **Main** screen, **Controls** and **Monitors** pages are displayed.

To Clear the Loss of O_2 Alarm:



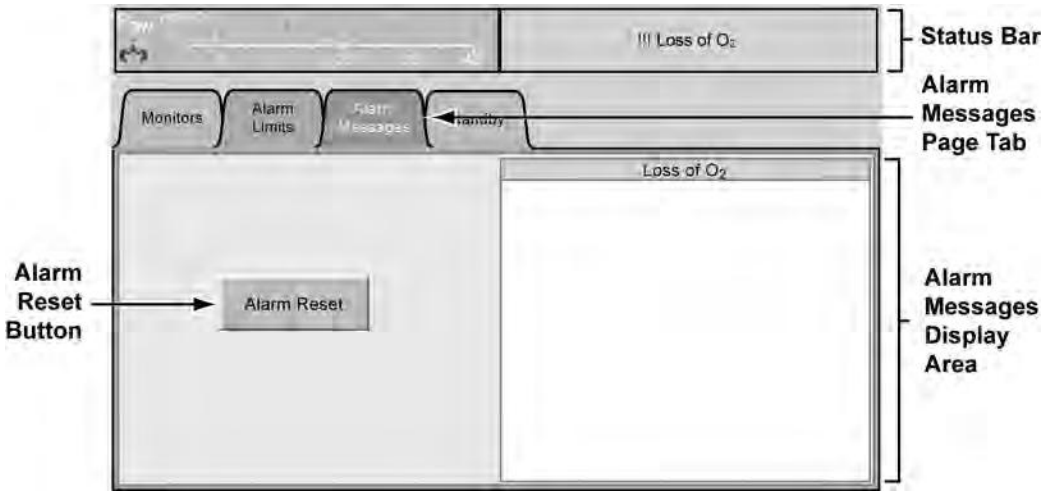
1) When the **Main** screen, **Controls** and **Monitors** pages are displayed, press the **Alarm Silence** button on the Lower Interface Panel to temporarily silence the **Loss of O_2** alarm.



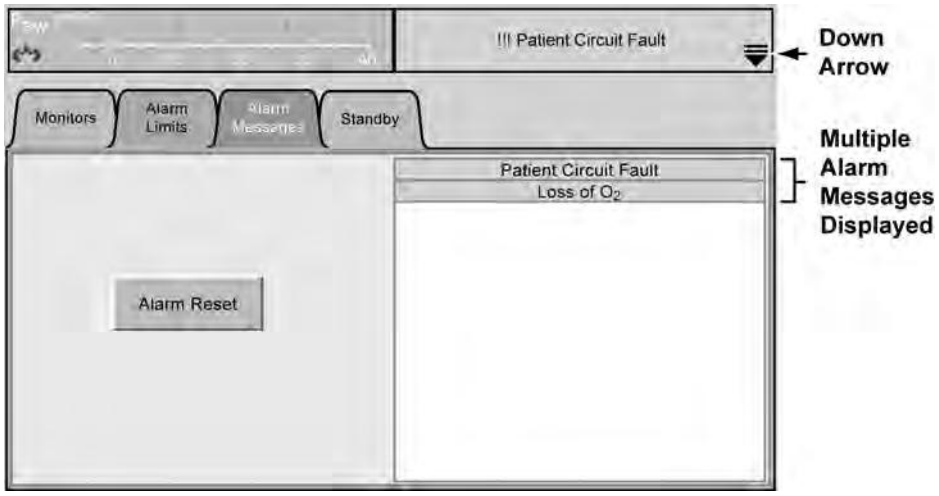
2) Touch the **FiO_2** control to select it and rotate the **Scroll** knob on the Lower Interface Panel to change the setting to **21%.**

   Touch the **FiO_2** control once again to confirm the new setting.

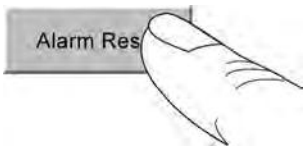
3) Touch the **Status Bar** or the **Alarm Messages** page tab and the **Alarm Messages** page is displayed.



4) Review the Alarm Messages Display Area for any/all alarm messages displayed:
   - if only the **Loss of O_2** message is displayed, proceed to the next step
   - if any messages other than the **Loss of O_2** message are displayed, take action as necessary to resolve all alarm conditions before proceeding. See *Chapter 8 - Ventilator Alarms* and *Chapter 13 - Troubleshooting* for additional information and recommended action.



5) Touch the **Alarm Reset** button, the audible alarm is silenced, **!!! Loss of O_2** is removed, the current date and time is displayed in the Status Bar and **<No Alarms>** is displayed in the Alarm Messages Display area.



After the **Loss of O_2** alarm and/or any additional alarms have been reset/resolved, the ventilator is now in a normal ventilation mode and ready for Functional Testing.

Battery/Power Test

To verify the status of the ventilator's batteries and external power supplies;

1) Push and hold the Battery/Power **Check** button on the Lower Interface Panel (pushing this button does not interfere with ventilation).

   The ventilator displays a message for each of the four possible sources of power (scrolled in the Status Bar at the top of the LCD touch screen), indicating their detection and current status[9] See *Battery/Power* in Chapter 5 – Controls for a detailed list of messages possibly displayed.

2) Verify that the displayed status message for each power source is consistent with the power source actually attached to the ventilator; e.g.:

   - If a properly functioning AC Adapter is attached to a valid source of power and the ventilator, the External DC Power status message displayed should be **Ext OK.** Conversely, if the ventilator is instead powered from a Docking Station, **Ext Removed** should be displayed.

If any fault message (**xxxxx Fault**) or **Removable Battery 50%** (*or less*) is displayed, it is an indication that the displayed source of power (**Removable Battery**, **Ext**, **Dock** or **T-Bat**) has been detected, is not adequate to power the ventilator and is a test failure for either the accessory and/or the ventilator.

- Replace Removable Battery Packs that have failed to charge to more than 50% remaining capacity when fully charged and correct any/all fault conditions prior to using the ventilator (see *Chapter 13 - Troubleshooting* for additional information)

[9] Refer to *Power Status LEDs* in Chapter 6 - Displays and Indicators for additional information concerning the status of various sources of power.

Display/Alarm Test

WARNING

Check Alarms – Alarm function should be tested periodically to ensure proper operation (see *Maintenance Schedule* in Chapter 11 – Maintenance and Cleaning, and *Display/Alarm Test* in Chapter 2- Installation and Setup for detailed instructions). If any alarm malfunctions, contact CareFusion or a service technician certified by CareFusion. Failure to immediately identify and correct alarm situations may result in serious patient injury or death.

Blank LCD Touch Screen Display – A blank LCD touch screen display during normal operation/ventilation, it is an indication that the ventilator is not functioning properly. To avoid the possibility of inadvertent ventilation control selection/activation, do not touch the display screen, immediately remove the patient, use an alternative method of ventilation and contact CareFusion or a service technician certified by CareFusion.

To verify the status of the LCD displays, indicators and audible alarm without interfering with the ventilator operation;

1) Push the Display/Alarm **Check** button on the Lower Interface Panel.

2) Verify that the entire LCD Touch Screen and all Lower Interface Panel indicator LEDs fully illuminate in the colors as indicated in the table below, the sound system generates two audible tones of similar volume followed by a High Priority Alarm Signal[10] that sounds at the set alarm volume, and no “Fault” messages are displayed.

Screen / Panel	Screen / LED Color
LCD Touch Screen:	
• Entire Touch Screen (top to bottom, side to side) turns into and cycles through a colored test pattern (colors/sequence as listed)	Red
	Blue
	Green
	White
	Black
Lower Interface Panel:	

• All Power Status indicator LEDs[11]
  • **External Power**
  • **Battery Pack**
  • **Transition Batt.**
  • **Battery Charger**
	Amber

• All other indicator LEDs	Red or Green

3) If screen pixels fail to illuminate, or illuminate in colors other than as specified above such that it impairs the user’s ability to properly view and interpret Touch Screen controls or data, it is a test failure. If any indicator LED fails to fully illuminate, or illuminates in a color other than as specified above, it is a test failure.
Any test failure must be corrected prior to using the ventilator (see *Chapter 13 - Troubleshooting* for additional information).

[10] Refer to *Sound Types, Patterns and Volumes* in Chapter 8 - Ventilator Alarms for additional information.
[11] Refer to *Power Status LEDs* in Chapter 6 - Displays and Indicators for additional information.

Alarm Response Tests

These tests verify the proper functioning of the ventilator and its alarms. To perform the Alarm Response Tests, a Test Lung must be attached to the patient circuit. *See Additional Preparation Required for Alarm Response Tests:* earlier in this chapter for detailed instructions.

Ventilator Settings and Procedure	Requirement
A) Refer to *Chapter 3 - Using the Ventilator* and *Chapter 8 -Ventilator Alarms* to configure ventilator settings as follows: **Breath Mode:** A/C **Breath Type:** Volume **Rate:** 12 bpm **Volume:** 500 ml **Insp. Time:** 1.0 sec **PSV:** -- cmH_2O **FiO_2:** 21% **Flow Trigger:** 3 L/min **Low PEEP Alarm** "- -" (off) **PEEP:** 0 cmH_2O **High P_{peak}:** 100 cmH_2O **Low P_{peak} :** 5 cmH_2O **Low V_e**: 1.0 L Do not attach an oxygen supply to the ventilator at this time. Run the equipment for at least two minutes.	No alarms activate Selected Monitors should read as follows: V_{te}: **V_{te} 383** to **633 ml** I:E Ratio: **I:E 1:3.8** to **1:4.2** Rate: **f 12 bpm** V_e: **V_e 4.6** to **7.6 L** Lower Interface Panel LED Status: External Power: Green Battery Pack: Off Transition Batt.: Off
B) Set the **FiO_2** control to 22%	**Loss of O_2** alarm activates
C) Return **FiO_2** to 21% and reset the alarm. Set the **Low V_e** alarm to 10 L	**Low V_e** alarm activates
D) Return the **Low V_e** alarm to 1.0 and reset the alarm. Set the **Low P_{peak}** alarm to 10 cmH_2O above the Peak Inspiratory Pressure (P_{peak}).	**Low P_{peak}** alarm activates
E) Return the **Low P_{peak}** alarm to 5 and reset the alarm. Set the **High P_{peak}** to 10 cmH_2O below the Peak Inspiratory Pressure (P_{peak}).	**High P_{peak}** alarm activates
F) Return the **High P_{peak}** alarm to 100 and reset the alarm.	
G) Connect 40 to 88 PSI oxygen to the unit and set the **FiO_2** control to 60%. Connect and enable an FIO_2 Sensor (see *Chapter 2 - FIO2 Sensor* for information) and set the **Low FIO_2 Alarm** to 54 % or connect an external oxygen monitor to the patient circuit.	No alarms activate FIO_2 monitor or external oxygen monitor should read **55** to **65% FiO_2** +/- the tolerances of the external oxygen monitor.

Ventilator Settings and Procedure	Requirement
H) Return **FiO_2** control to 21%, disable and disconnect the FIO_2 Sensor (see *Chapter 2 - FIO2 Sensor* for information) or external oxygen monitor. Disconnect the High Pressure Sense Line (lower connection) from the ventilator.	**Patient Circuit Fault** alarm activates on the next breath
I) Reconnect the High Pressure Sense Line and reset the alarm. Disconnect the Low Pressure Sense Line (upper connection) from the ventilator.	**Patient Circuit Fault** alarm activates on the next breath
J) Reconnect the Low Pressure Sense Line and reset the alarm.	
K) Change the ventilator settings as follows: **Breath Type**: Pressure **Insp. Pres:** 40 cmH_2O **High PEEP Alarm:** 25 cmH_2O **PEEP:** 20 cmH_2O **Insp. Rise:** 4	No alarms activate Selected Monitors should read as follows: P_{peak}: **54** to **66 cmH_2O** PEEP: **18** to **22 cmH2O**
L) Disconnect the external power source from the ventilator.	**External Power Lost** alarm activates. If disconnected from a Docking Station, a **Dock Disconnect** alarm is also activated. Lower Interface Panel LED Status: **External Power:** Off **Battery Pack:** Green **Transition Batt.:** Off **Battery Charger:** Off or flashing amber Ventilator continues to operate
M) Reset the alarm(s) and remove the Removable Battery Pack from the ventilator for one minute.	**Insert Battery** then **Transition Battery Use** alarms display Lower Interface Panel LED Status: **External Power:** Off **Battery Pack:** Flashing red **Transition Batt.:** Green **Battery Charger:** Off Ventilator continues to operate
N) Reinsert the Removable Battery Pack, reconnect the external power source and reset all alarms.	No alarms activate Lower Interface Panel LED Status: **External Power:** Green **Battery Pack:** Off **Transition Batt.:** Off **Battery Charger:** Off, green, amber, or flashing amber Ventilator continues to operate
O) Turn off the ventilator by pushing and holding the **On/Off** button. Observe the ventilator for at least 15 seconds then reset the alarm.	**Saving Configuration** is momentarily displayed. The Vent Inop alarm sounds for the full 15 seconds The **Vent Inop** LED flashes for the full 15 seconds

Testing is now complete.

Ventilator Testing Worksheet

Perform the testing procedures starting on page 2-17 and record each test result on this worksheet.

SERIAL NUMBER:	_____	**CONDUCTED BY:**	_____
DATE:	_____		

Tests:

TEST DESCRIPTION	MEAS. VALUE	REQUIREMENT	PASS / FAIL
Functional Testing in Startup Mode			
Power on Self Tests (POST)		The Ventilator	
		Powers up	
		Performs POST	
		Displays initial startup screen	
Button Test		Correct messages for each control displayed	
Touch Screen Calibration Procedure		**Calibration Passed** message displayed	
Circuit Test		**Passed** displayed	
Functional Testing in Normal Ventilation Mode			
Battery/Power Tests Push & hold Battery/Power **Check** button.		Displayed messages are consistent with ventilator/power accessories configuration and no "**Fault**" messages displayed.	
		Removable Battery _ _ _ %	
		Ext _ _ _ (External DC Power)	
		Dock _ _ _ (Docking Station Power)	
		T-Bat _ _ _ (Transition Battery)	
Display/Alarm Tests Push Display/Alarm **Check** button.		Entire Touch Screen and all LEDs illuminate in specified color(s), audible alarm system sounds and no "**Fault**" messages are displayed	
		Touch Screen	
		Lower Interface Panel	
		Two audible tones & High priority audible alarm	
Alarm Response Tests Configure ventilator settings: **Breath Mode**: A/C **Breath Type:** Volume **Rate:** 12 **Volume:** 500 **Insp. Time:** 1 **PSV:** -- **FiO_2:** 21 **Flow Trigger:** 3 **Low PEEP Alarm** "- -" **High P_{peak}:** 100 **Low P_{peak}:** 5 **Low V_e:** 1.0 **PEEP:** 0		No alarms activate	
		Selected Monitors should read as follows:	
		V_{te}: **V_{te} 383** to **633 ml**	
		I:E Ratio: **I:E 1:3.8** to **1:4.2**	
		Rate: **Rate 12 bpm**	
		V_e: **V_e 4.6** to **7.6 L**	
		Lower Interface Panel LED Status:	
		External Power: Green	
		Battery Pack: Off	
		Transition Batt.: Off	
Set the **FiO_2** control to 22%		**Loss of O_2** alarm activates	
Return **FiO_2** to 21% and reset the alarm. Set the **Low V_e** alarm to10 L		**Low V_e** alarm activates	
Return the **Low V_e** alarm to 1.0 and reset the alarm. Set the **Low P_{peak}** alarm to 10 cmH_2O above Peak Inspiratory Pressure (P_{peak}).		**Low P_{peak}** alarm activates	

TEST DESCRIPTION	MEAS. VALUE	REQUIREMENT	PASS / FAIL
Return the **Low P_{peak}** alarm to 5 and reset the alarm. Set the **High P_{peak}** to 10cmH_2O below the Peak Inspiratory Pressure (P_{peak}).		**High P_{peak}** alarm activates	
Return the **High P_{peak}** alarm to 100 and reset the alarm.			
Connect 40 to 88 PSI O_2 to the unit and set the **FiO_2** control to 60. Connect and enable an FIO_2 Sensor and set the **Low FIO_2 Alarm** to 54% or connect an external FIO_2 monitor to the patient circuit.		No alarms activate	
		FIO_2 Sensor or external oxygen monitor reads: **55** to **65% FiO_2**, +/- the tolerances of the external oxygen monitor.	
Return **FiO_2** control to 21%, disable and disconnect the FIO_2 Sensor or external oxygen monitor. Disconnect the High Pressure Sense Line from the ventilator		**Patient Circuit Fault** alarm activates on the next breath	
Reconnect Sense Line and reset the alarm			
Disconnect the Low Pressure Sense Line from the ventilator.		**Patient Circuit Fault** alarm activates on the next breath	
Reconnect Sense Line and reset the alarm			
Change ventilator settings as follows: **Breath Type:** Pressure **Inps. Pres:** 40 **High PEEP Alarm:** 25 **PEEP:** 20 **Insp. Rise:** 4		No alarms activate	
		Selected Monitors should read as follows:	
		P_{peak}: **P_{peak} 54** to **66 cmH_2O**	
		PEEP: **PEEP 18** to **22 cmH_2O**	
Disconnect external power source.		**External Power Lost** alarm activates. **Dock Disconnect** alarm also activates if disconnected from a Docking Station.	
		Lower Interface Panel LED Status:	
		External Power: Off	
		Battery Pack: Green	
		Transition Batt: Off	
		Battery Charger: Off or flashing amber	
		Ventilator continues to operate	
Reset alarm(s), take out Removable Battery Pack for one (1) minute.		**Insert Battery** then **Transition Battery Use** alarms display	
		Lower Interface Panel LED Status:	
		External Power: Off	
		Battery Pack: Flashing red	
		Transition Batt: Green	
		Battery Charger: Off	
		Ventilator continues to operate	
Insert Removable Battery Pack, connect external power and reset all alarms.		No alarms activate	
		Lower Interface Panel LED Status:	
		External Power: Green	
		Battery Pack: Off	
		Transition Batt.: Off	
		Battery Charger: **Off, green, amber, or flashing amber**	
		Ventilator continues to operate	

TEST DESCRIPTION	MEAS. VALUE	REQUIREMENT	PASS / FAIL
Turn off the ventilator. Observe the ventilator for at least 15 seconds and reset alarm.		**Saving Configuration** is momentarily displayed.	
		Vent Inop alarm sounds for the full 15-seconds	
		Vent Inop LED flashes for the full 15-seconds	

Chapter 3 - USING THE VENTILATOR

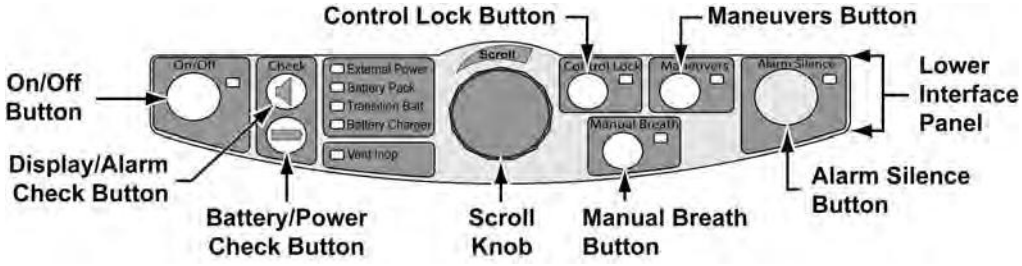
User Interface(s)

This section describes the three main types of user interfaces utilized by the Enve™ ventilator:

Lower Interface Panel Push Buttons	Used to power the ventilator on or off, silence audible alarms, check/test displays, alarms and power, or initiate specific procedures or maneuvers.
Lower Interface Panel Scroll Knob	Used to adjust selected control values, alarm limits, feature configurations, scale graphs, or scroll through data.
LCD Touch Screen Screens, Pages, Tabs, Buttons and Controls	Provides access to and/or control of most ventilation monitors/displays, controls, alarms, graphics, and optional features.

The Lower Interface Panel

For detailed descriptions of each control's function and complete instructions for their use, see *Lower Interface Panel Controls* in Chapter 5 - Controls.

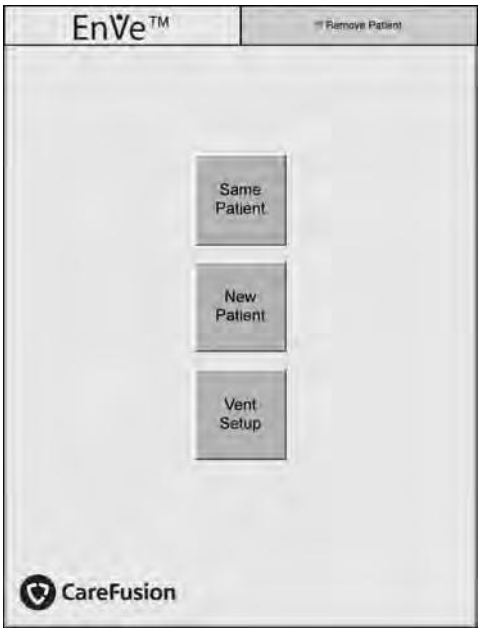


The LCD Touch Screen Interface

The LCD Touch Screen displays multiple types of user interface screens, pages, controls, buttons and graphical displays.

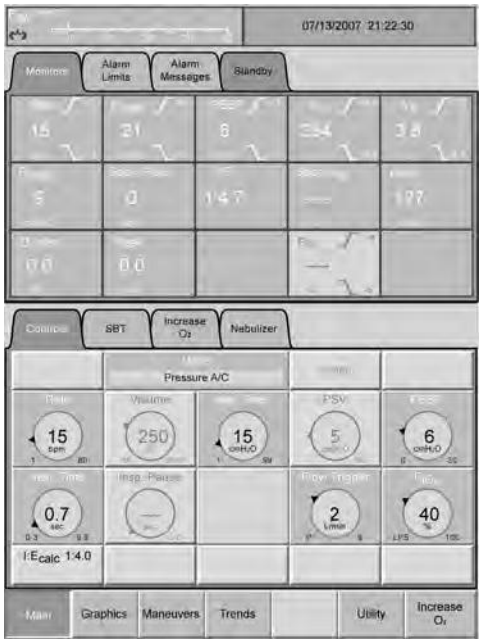
Startup screens providing access to:

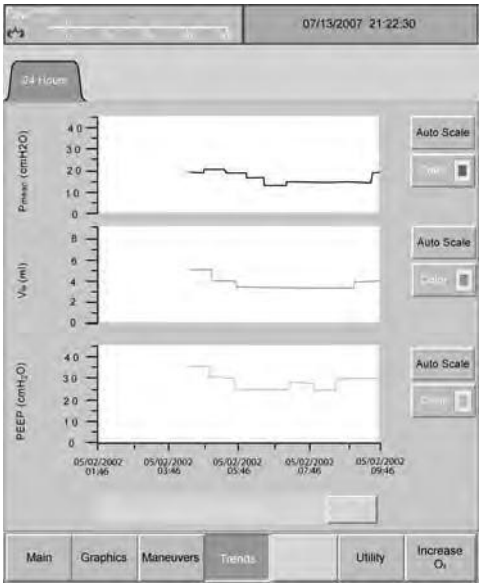
- Same or new patient ventilation
- Ventilator setup and testing



Main screen(s) providing access to:

- Ventilation controls, monitors, alarms
- Optional features, maneuvers and procedures
- Alarm, Ventilator, and Option configuration



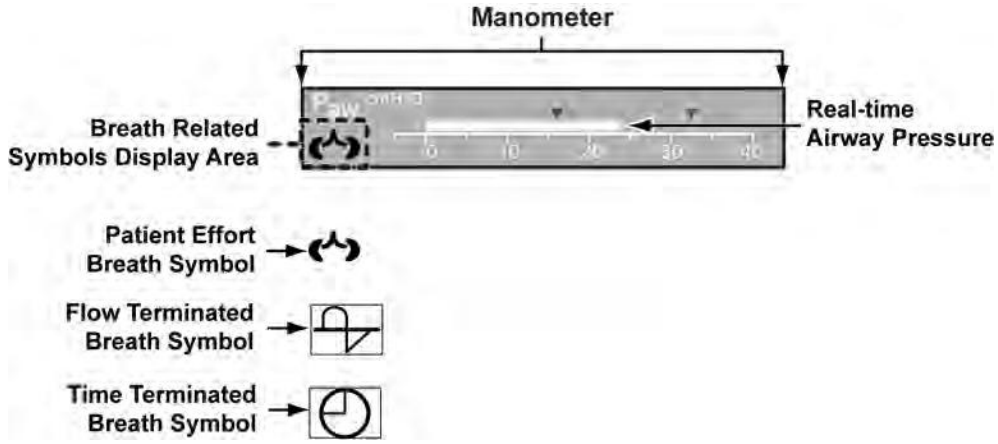


Graphical screens providing access to:

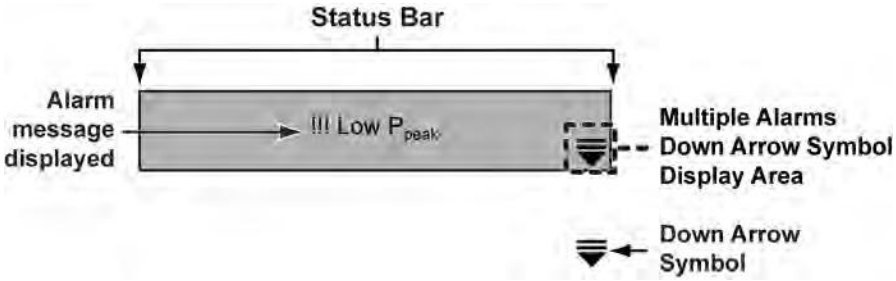
- Trends graphical display of data
- Wave and Loop graphical display of data

General Display Information

The **Manometer** at the top left of the LCD touch screen displays Real Time Airway Pressure, and in the lower left corner, patient breath related symbols. For additional information see *Airway Pressure Manometer* and *Patient Breath Symbols* in Chapter 6 – Displays and Indicators.



The **Status Bar** located at the top right of the LCD touch screen displays alarm, alert and notification messages. For additional information see *Status Bar* in Chapter 6 – Displays and Indicators.



Display Characteristics

Navigation Tools

> **NOTE**
>
> Navigation tools such as the Navigation buttons (when enabled) and Page tabs are immediately effective when touched.
>
> Adjustable controls, which enable adjustments to ventilator functions, require touch confirmation before the ventilator will accept and initiate a change.

Screen Navigation Buttons

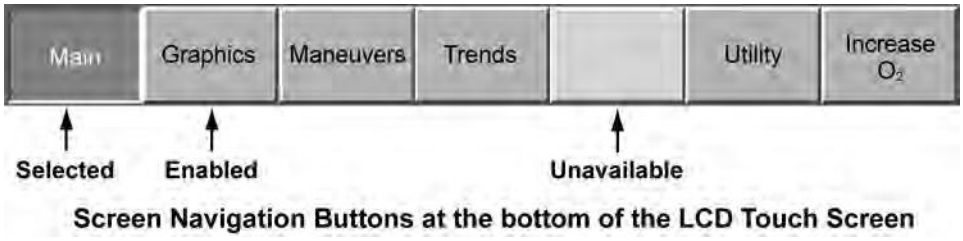
When touched, Screen Navigation buttons (always displayed/visible at the bottom of the LCD touch screen), allow you to easily access/display any one of the main display screens. For additional information, see *Pages* in Chapter 6 – Displays and Indicators.

Screen Navigation buttons may be displayed in any of the following states:

Enabled: The button is not recessed, background color is normal and the name (text) is black. In this state, the button is enabled for use.

Selected: The button appears recessed (touched), background color is highlighted and the name (text) is white. In this state, the button represents the active screen.

Unavailable: The button is grayed out and does not contain text. In this state, the button is not currently available for use.



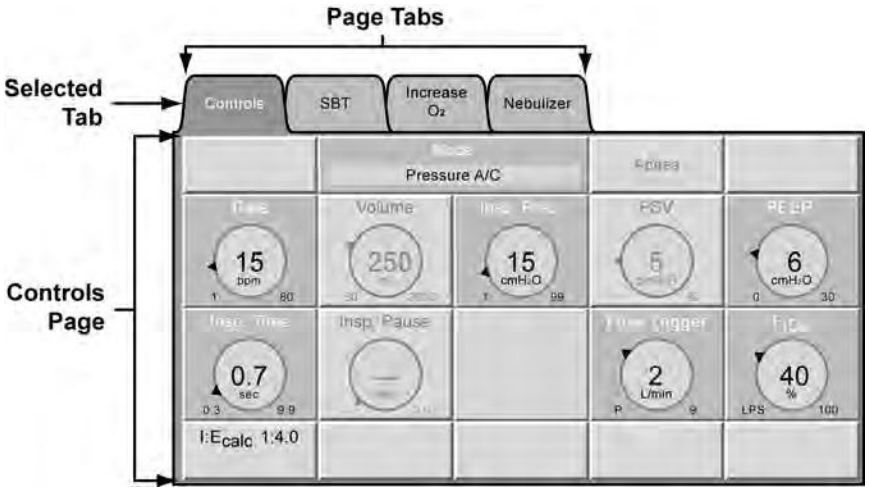
Screen Navigation Buttons at the bottom of the LCD Touch Screen

Page Tabs

When selected/touched Page tabs provide access to pages within screens that display numerous monitors, alarms, ventilation and configuration controls, and graphical displays.

Touch a Page tab to select it. When selected, Page tabs are displayed as follows:

Selected: The background color is highlighted, the Page name (text) is white and the associated page is displayed. In this state, the tab represents the active screen page.



Adjustable Controls

An adjustable control is a graphical touch screen object that displays a value which can be modified.

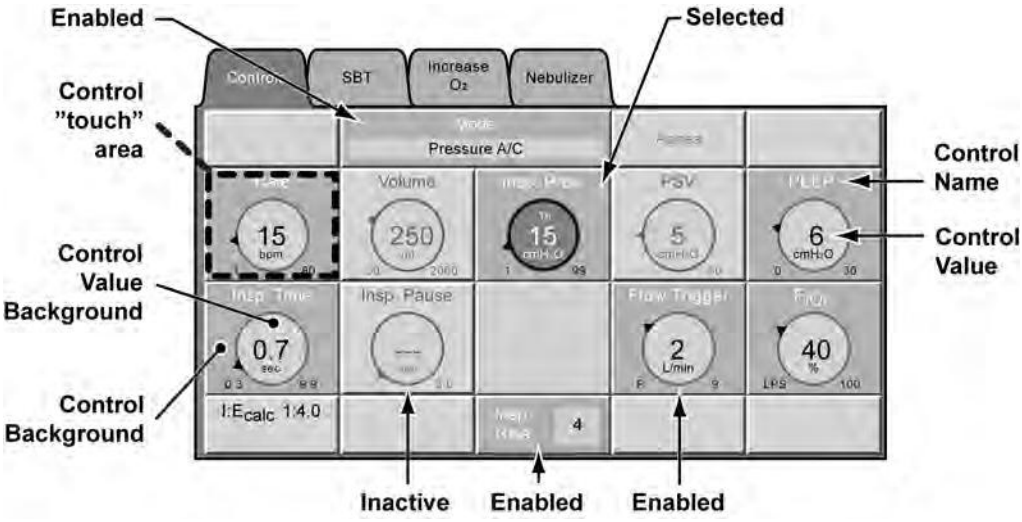
Primary breath controls and Advanced Settings are displayed on the **Main** screen, **Controls** page (shown below).

Adjustable controls may be displayed in any of the following states:

Enabled: The control background color is normal, the control name (text) is white, the background area surrounding the control value is gray, and the displayed control value (center characters) is black. The control is available for use.

Selected: The control background color is normal, the control name (text) is white, the background area surrounding the control value is highlighted, and the displayed control value (center characters) is white. The control is ready for adjustment.

Inactive: The entire control background, name, background area surrounding the control value and the control value are gray. The control can be adjusted, but does not affect breath delivery in the current operating mode.



For additional information, detailed descriptions and complete instructions for the use of adjustable controls, see *Main Screen, Adjustable Ventilation Controls* in Chapter 5 – Controls.

Adjustable Alarm Limits

Adjustable Alarm Limits are also graphical touch screen objects that display values which can be manually modified individually or all at once (all alarms, high and low limits) automatically.

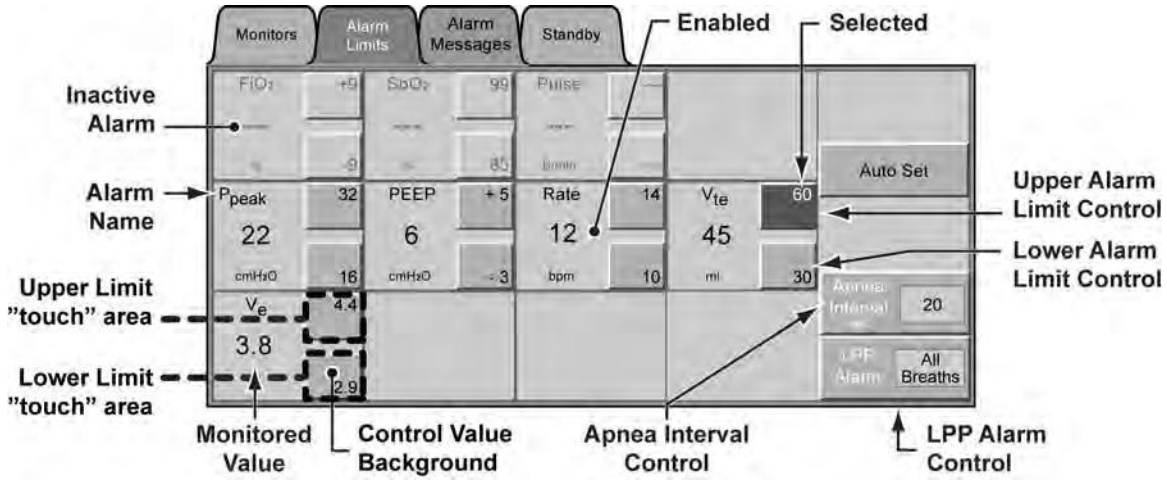
Adjustable alarms are displayed on the **Main** screen, **Alarm Limits** page.

Adjustable alarm limit controls may be displayed in any of the following states:

Enabled: The limit control background colors are normal or yellow (indicating turned off by user) and the control value (characters) is black. The limit controls are available for use.

Selected: The limit control background color is highlighted and the control value (characters) is white. The limit control is ready for adjustment.

Inactive: The entire control name, monitored value, background areas and the control values are gray. The controls can be adjusted, but do not affect the alarm limitations in the current operating mode.



For additional information, detailed descriptions and complete instructions for the use of adjustable alarm limits, see *Adjustable Alarms* in Chapter 8 - Ventilator Alarms.

Setting Adjustable Controls and Alarm Limits

The adjustable controls, Advanced Settings and Alarm Limits use a simple three step method of "Select, Change, and Confirm" to set configuration values.

Select - Touch the Control/Setting/Limit to be changed.

- The background area surrounding the displayed value is highlighted

Change - Rotate the **Scroll** knob on the Lower Interface Panel to change the displayed value.

Confirm - Touch the Control/Setting/Limit again to confirm the change.

- The background area surrounding the displayed value reverts to its previous color and the ventilator accepts the new setting

NOTE

If a selection of, or change to a control is not confirmed within 15 seconds, it automatically returns to the Enabled state and the value (if changed) returns to the original value, unchanged.

Touching a control on the touch screen while another control is already selected de-selects the previous control without changing its value. You must confirm a change, by touching the control a second time, before the ventilator accepts a new value.

The ventilation **Mode** control (on the **Main** screen, **Controls** page) is set or changed in a manner similar to the way all other adjustable controls are changed ("Select, Change, and Confirm"), except the last step requires touching an **Accept** button ("Select, Change, and Accept") rather than touching the control for a second time. See *Mode* in Chapter 5 - Controls for additional information.

Configurable Monitors

A monitor is a graphical touch screen object that displays patient related data values monitored by the ventilator and if applicable, set associated high and low alarm limit values.

- The **Main** screen **Alarm Limits** page also displays monitors which have associated settable alarm limits.

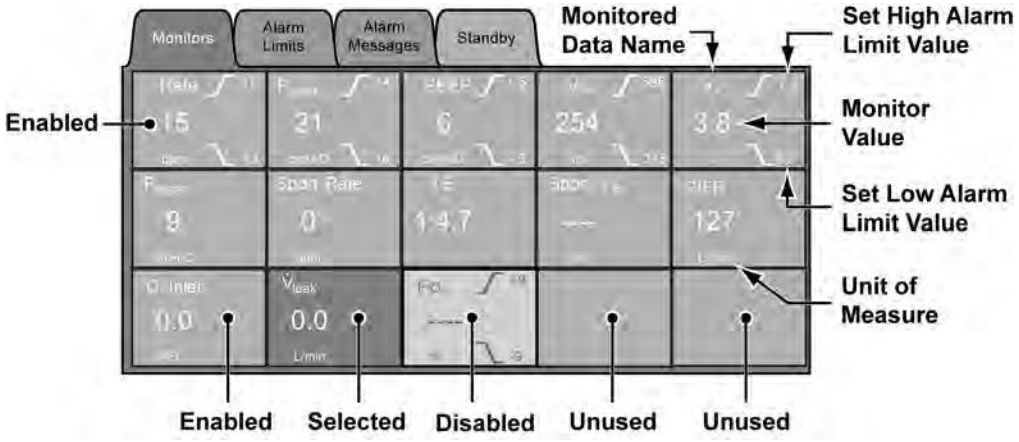
Configurable monitors may be displayed in any of the following states:

Unused: The monitor background color is normal and no data name, value or alarm limits are displayed. The monitor is currently unused and available for use.

Enabled: The monitor background color is normal and the displayed data name, value and alarm limits (if any) are white. The monitor is enabled and currently in use.

Selected: The monitor background color is highlighted and the displayed data name, value and alarm limits (if any) are white. The monitor is ready for adjustment.

Disabled: The entire monitor background, displayed data name, value and alarm limits (if any) are gray. The device (e.g. FIO_2 monitor) associated with the displayed monitor data name is not presently enabled for use.



Each of the individual monitors on the **Main** screen, **Monitors** page can be set to display any one (or none) of the available monitored patient data values (see *Chapter 7 - Monitored Data* for additional information). This in turn allows users to configure the display of the monitors on the **Monitors** page in whatever order, sequence or pattern desired.

Setting Monitor Displays

The monitors also use the simple three step method of “Select, Change, and Confirm” to set which monitored patient data is to be displayed.

Select - Touch the Monitor to be changed.

- The background area surrounding the displayed data name, value and alarm limits (if any) is highlighted

Change - Rotate the **Scroll** knob on the Lower Interface Panel to change the displayed patient data.

Confirm - Touch the Monitor again to confirm the change.

- The background area surrounding the displayed data name, value and alarm limits (if any) reverts to its previous color and the ventilator accepts the new setting

NOTE

If a selection of, or change to a monitor is not confirmed within 15 seconds, it automatically returns to the previous unselected state and displays the original settings.

Touching a monitor on the touch screen while another monitor is already selected de-selects the previous monitor without changing its setting. You must confirm a change, by touching the monitor a second time, before the ventilator accepts a new setting.

Graphics Display Customization

Trends

To view real time Trends displays, touch the **Trends** screen navigation button at the bottom of the LCD display.

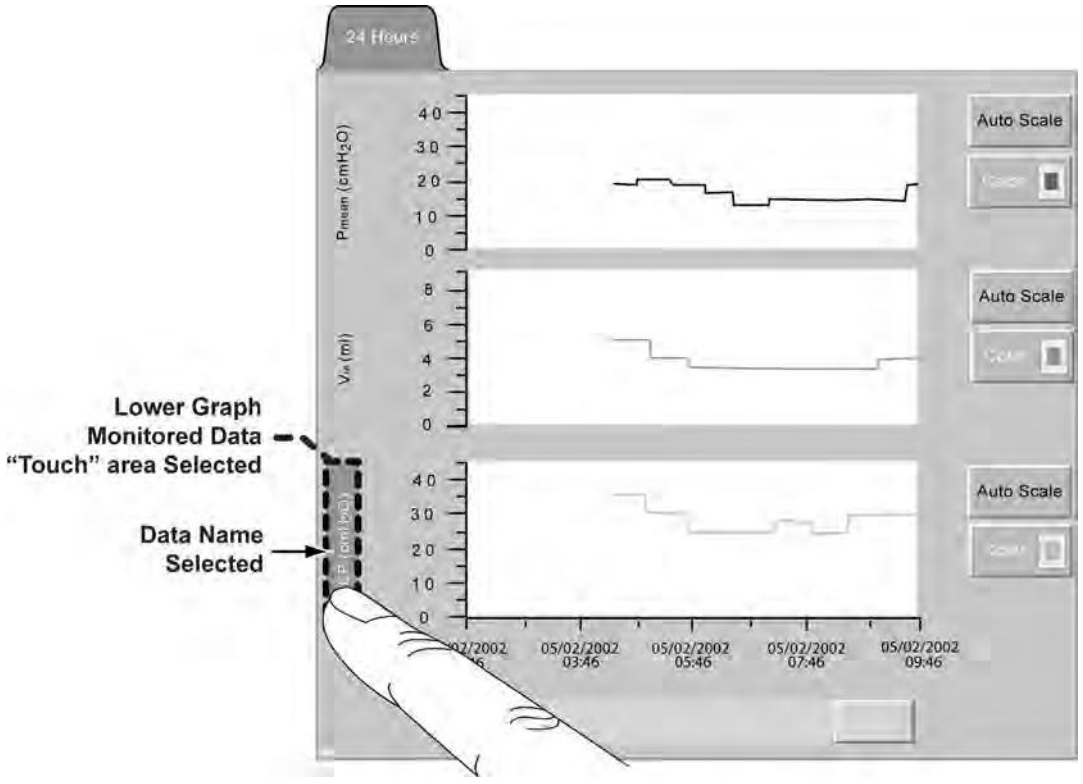
The graphical display features of the Trends line graph that can be customized using the "Select, Change, and Confirm" method, are as follows:

- Type of monitored data displayed
- Line color
- Data (vertical) and Date/Time (horizontal) graph axis scale values

See *Trends* in Chapter 6 – Displays and Indicators and *Graphically Displayed Data* in Chapter 7 – Monitored Data for additional information.

To Change the Type of Data to be Displayed:

1) **Select** the type of monitored data to be changed by touching the name of the data adjacent to the upper, middle or lower graph, as desired. The background behind the current data name is highlighted and the data name is selected (text turns white).



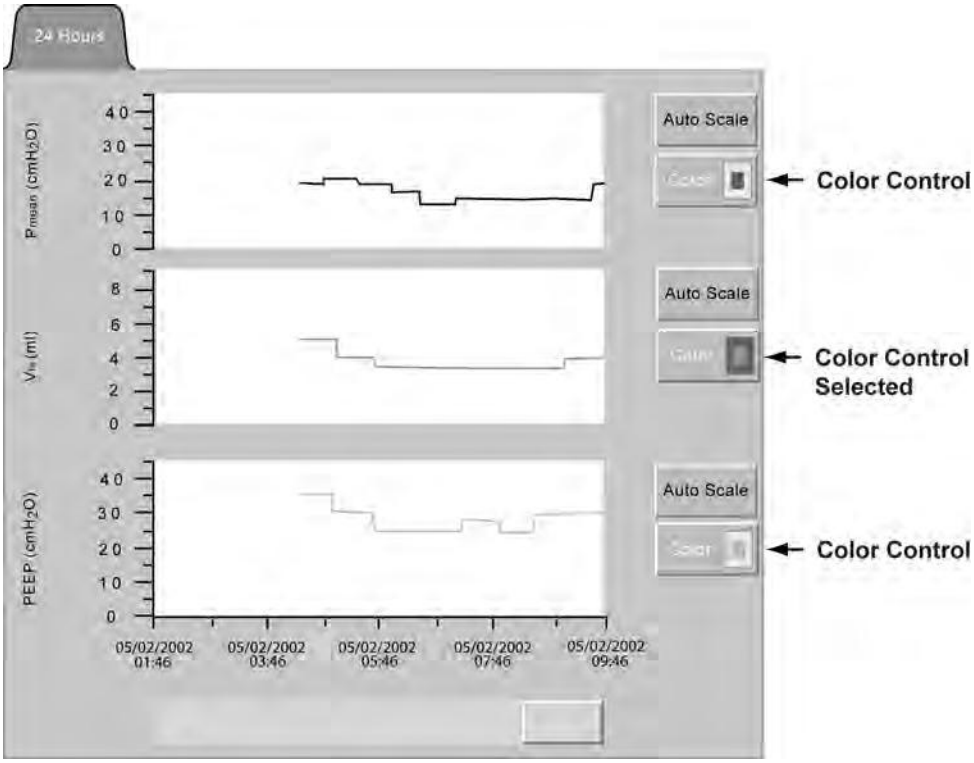
2) **Change** the setting by rotating the **Scroll** knob on the Lower Interface Panel.

3) **Confirm** your selection by touching the name of the data again. The background area surrounding the displayed name reverts to its previous color, the text turns black and the ventilator accepts the new setting.

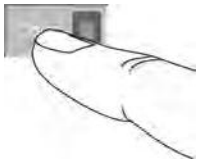
To Change the Color of the Graph Data Lines:

The data line in each of the three (3) graphs (upper, middle or lower) can be changed to any one of six (6) colors;

- Red
- Green
- Blue
- Yellow
- Purple
- Orange



1) **Select** the **Color** control to be changed by touching the desired control. The background of the area surrounding the line color is highlighted.



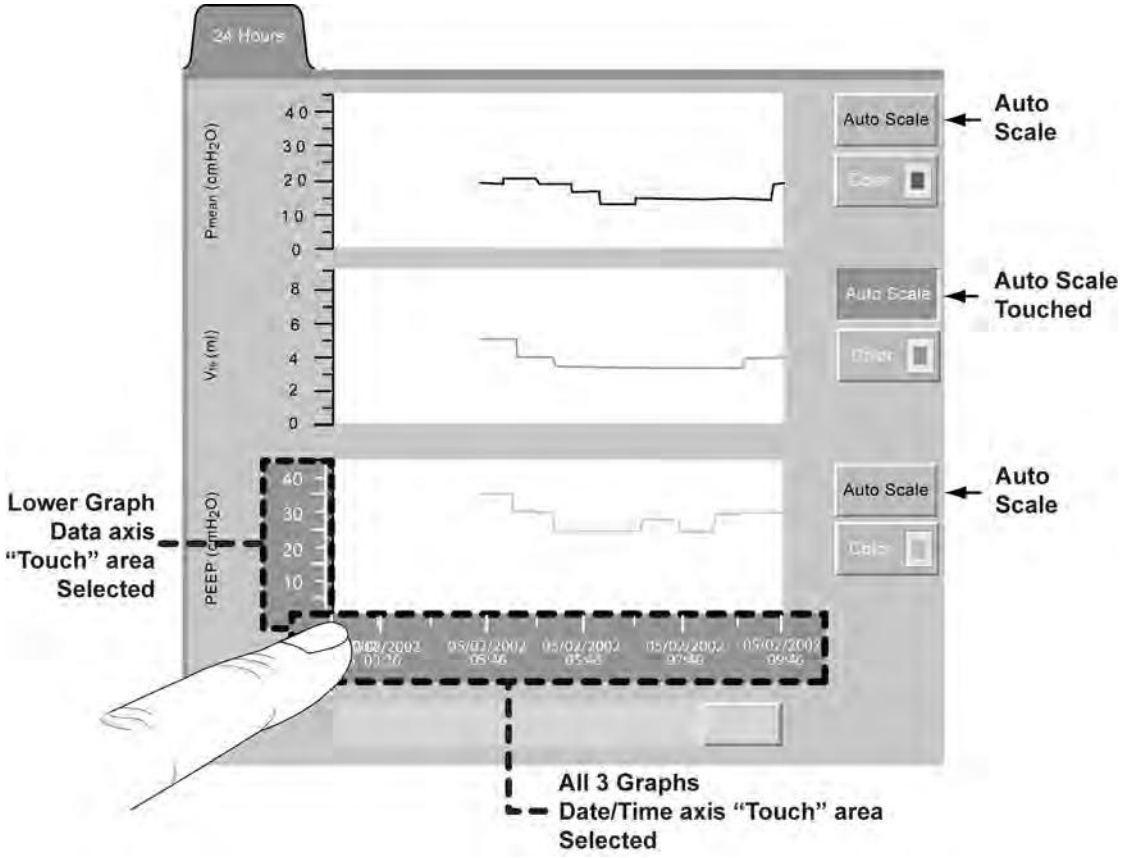
2) **Change** the setting by rotating the **Scroll** knob on the Lower Interface Panel.

3) **Confirm** your selection by touching the control again. The background area surrounding the line color reverts to its previous color and the ventilator accepts the new setting.

Scaling Trends Graphs

Both the Data (vertical) and Date/Time (horizontal) axis of the Trends graphs can be scaled for optimum data display. The Data axis can be scaled automatically or manually, and the Date/Time axis can be scaled manually only.

To automatically scale the Data axis on a Trends graph, simply touch the **Auto Scale** button adjacent to the graph to be scaled. The Data axis is automatically scaled.



To Manually Scale a Trends Graph;

1) **Select** the axis to be scaled by touching the desired axis "Touch" area, as shown in the illustration. The background behind the axis is highlighted and the scale is selected (numbers turn white).

2) **Change** the scale by rotating the **Scroll** knob on the Lower Interface Panel.

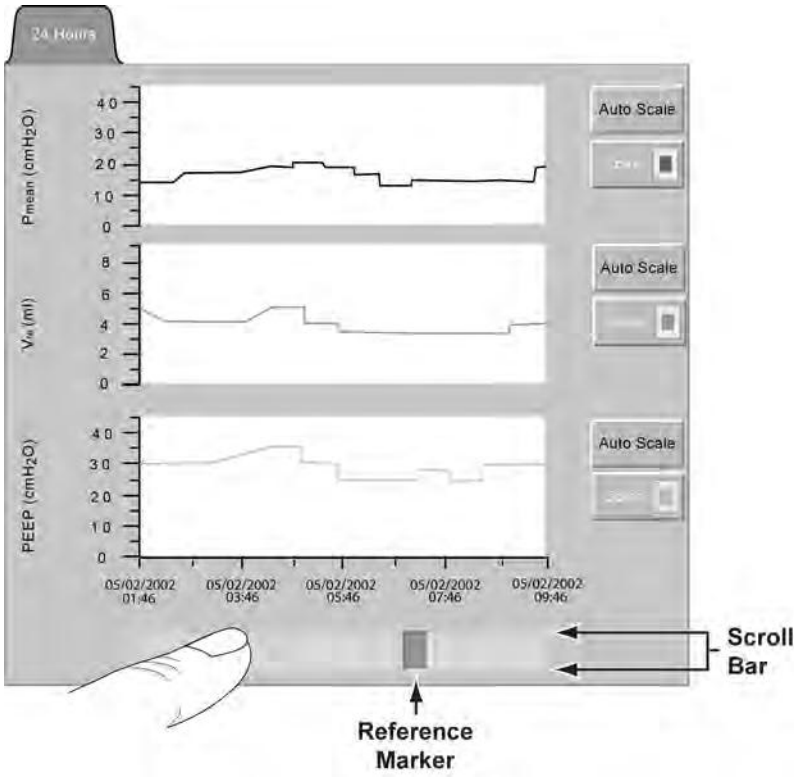
   - Changing the Date/Time (horizontal) axis scale affects all three graphs

3) **Confirm** your selection by touching the highlighted axis "Touch" area again. The background behind the axis reverts to its previous color, the numbers turn black and the ventilator accepts the new scale.

To Display Stored Data;

To display/scroll through up to 24 hours of stored data without changing the graphs' set Date/Time (horizontal) axis scale value, perform the following.

1) Touch the **Scroll Bar** at the bottom of the **24 Hours** page to enable scrolling of data to be displayed. The **Reference Marker** is highlighted.



2) Turn the **Scroll** knob on the Lower Interface Panel counter-clockwise to scroll any available older data into the display windows and turn it clockwise to display the newest data.

- Touching the **Scroll Bar** a second time (prior to the expiration of 30 seconds) reverts the **Reference Marker** to its previous color/state and freezes the graphs/data as currently displayed
- Or, after 30 seconds of inactivity, the **Reference Marker** automatically reverts to its previous color/state, and the newest data is once again displayed in all three graph windows
- Selecting another screen and returning to the Trends screen resets the displayed data to the most current data and current scale settings

Waves

To view Waves graphical displays, touch the **Graphics** screen navigation button at the bottom of the LCD display and then the **Waves** page tab to display the desired page and graphs.

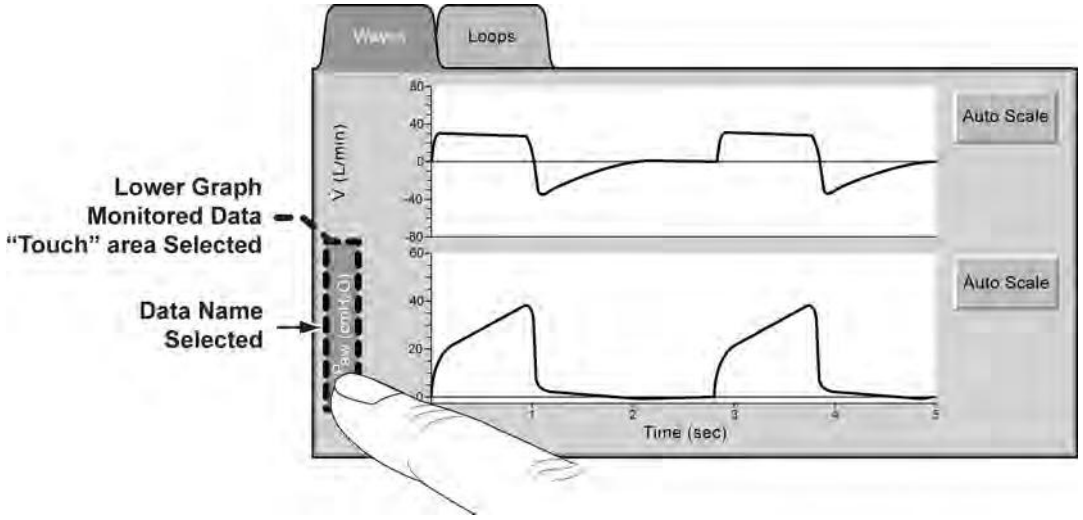
The graphical display features of Waves that can be customized using the "Select, Change, and Confirm" method, are as follows:

• Monitored data displayed	• Wave fill[12]
• Wave display mode	• Data (vertical) graph axis scale
• Wave color	• Time (horizontal) graph axis scale

See *Waves i*n Chapter 6 – Displays and Indicators and *Graphically Displayed Data* in Chapter 7 – Monitored Data for additional information.

To Change the Data to be Displayed:

1) **Select** the monitored data to be changed by touching the name of the data adjacent to the upper or lower graph, as desired. The background behind the data name is highlighted and the data name is selected (text turns white).



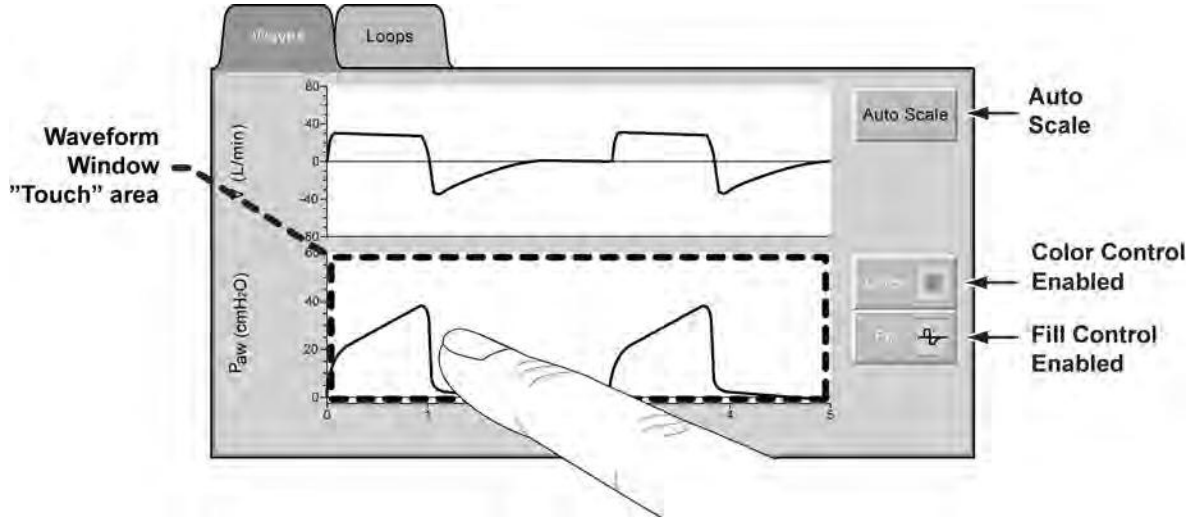
2) **Change** the setting by rotating the **Scroll** knob on the Lower Interface Panel.

3) **Confirm** your selection by touching the name of the data again. The background area surrounding the displayed name reverts to its previous color, the text turns black and the ventilator accepts the new setting.

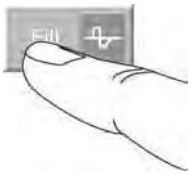
[12] The Wave fill feature is not available on Plethysmographic displays.

To Customize the Waves Display:

Touch the waveform window of the graph to be customized (upper or lower). The wave **Color** and **Fill** controls for that graph are displayed and enabled.



1) **Select** the **Color** or **Fill** control to be changed by touching the desired control. The background of the area behind the display color or fill type is highlighted.



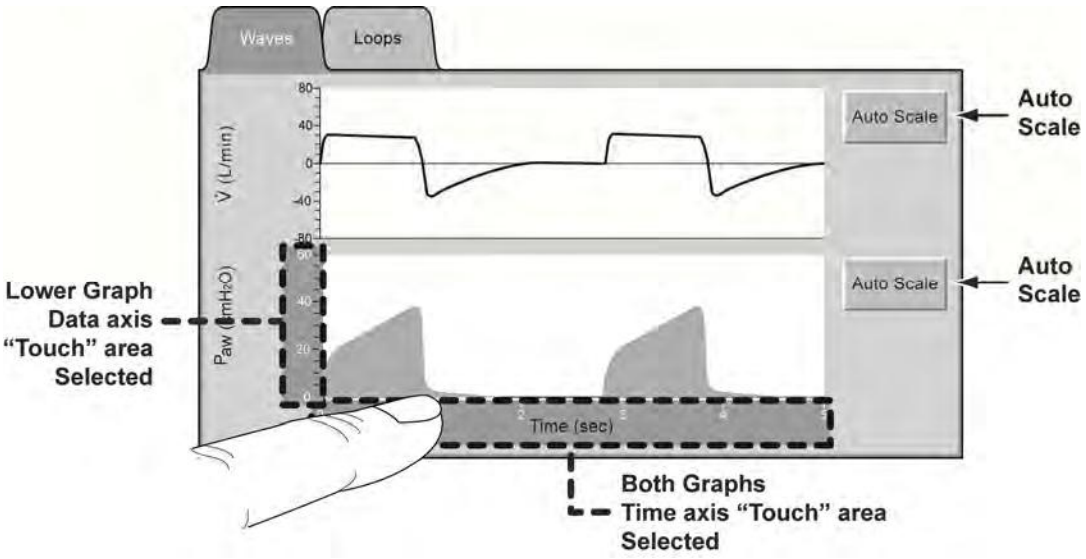
2) **Change** the setting by rotating the **Scroll** knob on the Lower Interface Panel.

3) **Confirm** your selection by touching the control again. The background area surrounding the displayed setting reverts to its previous color and the ventilator accepts the new setting.

Scaling Wave Graphs

Both the Data (vertical) and Time (horizontal) axis of the Waves graphs can be scaled for optimum data display. The Data (vertical) axis can be scaled automatically or manually, and the Time (horizontal) axis can be scaled manually only.

To automatically scale the Data axis on a Waves graph, simply touch the **Auto Scale** button adjacent to the graph to be scaled. The Data axis is automatically scaled.



To Manually Scale a Waves Graph;

1) **Select** the axis to be scaled by touching the desired axis "Touch" area, as shown in the illustration. The background behind the axis is highlighted and the scale is selected (numbers turn white).

2) **Change** the scale by rotating the **Scroll** knob on the Lower Interface Panel.
   - Changing the Time (horizontal) axis scale affects both the upper and lower graphs

3) **Confirm** your selection by touching the highlighted axis "Touch" area again. The background behind the axis reverts to its previous color, the numbers turn black and the ventilator accepts the new scale.

Loops

To view Loops graphical displays, touch the **Graphics** screen navigation button at the bottom of the LCD display and then the **Loops** page tab to display the desired page and graphs.

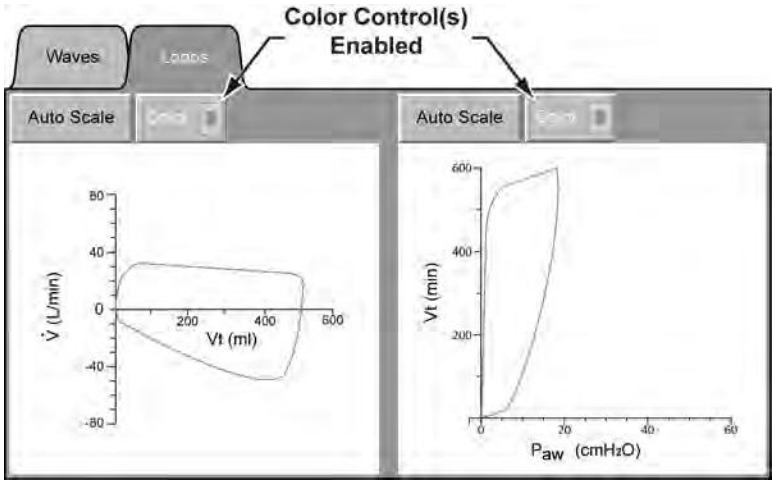
The graphical display features of Loops that can be customized using the "Select, Change, and Confirm" method, are as follows:

- Loop color
- Loop graph scales

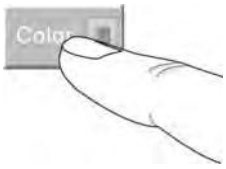
See *Loops* in Chapter 6 – Displays and Indicators and *Graphically Displayed Data* in Chapter 7 – Monitored Data for additional information.

To Customize the Loops Display:

The Loop **Color** control for both graphs is always displayed and enabled.



1) **Select** the **Color** control by touching the control. The background of the area behind the display color is highlighted.



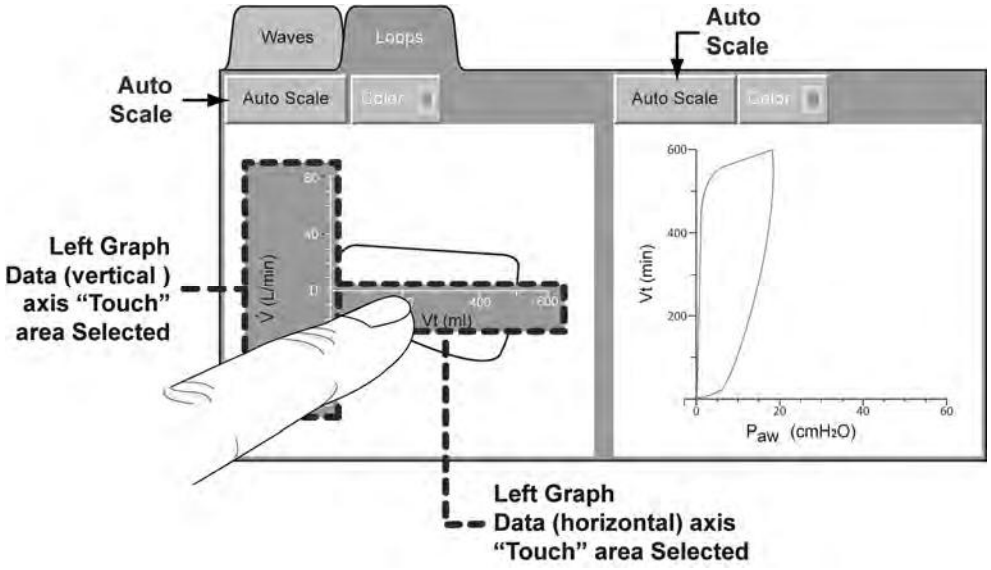
2) **Change** the setting by rotating the **Scroll** knob on the Lower Interface Panel.

3) **Confirm** your selection by touching the control again. The background area surrounding the display color reverts to its previous color and the ventilator accepts the new setting.

Scaling Loop Graphs

Both the Data (vertical) and Data (horizontal) axis of the Loops graphs can be automatically or manually scaled for optimum data display.

To automatically scale a Loops graph, simply touch the **Auto Scale** button above the graph to be scaled. Both axes are automatically scaled.



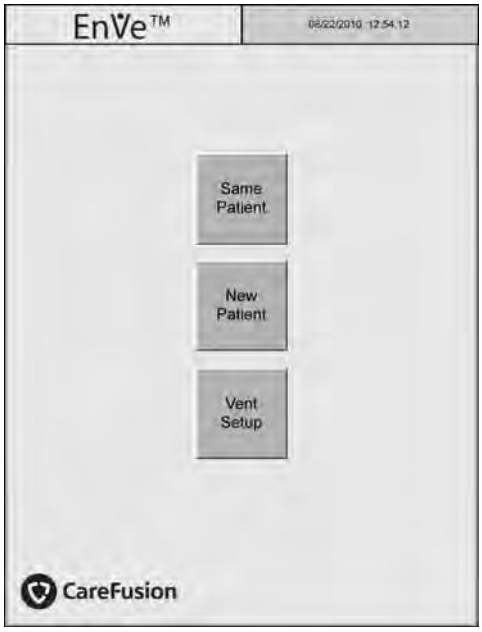
To Manually Scale a Loops Graph;

1) **Select** the axis to be scaled by touching the desired axis "Touch" area, as shown in the illustration. The background behind the axis is highlighted and the scale is selected (numbers turn white).

2) **Change** the scale by rotating the **Scroll** knob on the Lower Interface Panel.

3) **Confirm** your selection by touching the highlighted axis "Touch" area again. The background behind the axis reverts to its previous color, the numbers turn black and the ventilator accepts the new scale.

Starting the Ventilator



With the ventilator powered off, push the **On/Off** button on the Lower Interface Panel momentarily. The ventilator powers up, performs POST (Power On Self Test), displays the initial Startup screen and sounds an audible alert to indicate that the ventilator is waiting for user input prior to beginning ventilation.

- The Startup screen contains three (3) buttons, **Same Patient**, **New Patient** and **Vent Setup**

Startup Mode

> **WARNING**
> **Startup Mode** – The ventilator does not deliver gas to the patient while in Startup mode.

While in Startup mode, the ventilator inhibits the normal delivery of gas so that ventilator setup and/or specific testing can be performed (see *Screens and Controls Accessible During Startup Mode:* in Chapter 6 – Displays and Indicators for additional information):

- Extended Systems Test (EST) and User Verification Tests (UVT) (see *Maintenance Schedule* in Chapter 11 – Maintenance and Cleaning for recommended periodic maintenance and testing schedules.)
- FIO_2 enable/disable control and calibration
- Ventilator configuration controls (**Language**, **Units** and **Reset to Factory Defaults**)
- Access to ventilator component revision and software version information (i.e. the **About** screen)

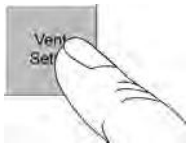
To Exit Startup Mode:

Startup mode can be exited at any time and from any screen by simply holding down the **On/Off** button on the Lower Interface Panel until the ventilator powers down.

To Perform EST or UVT Testing

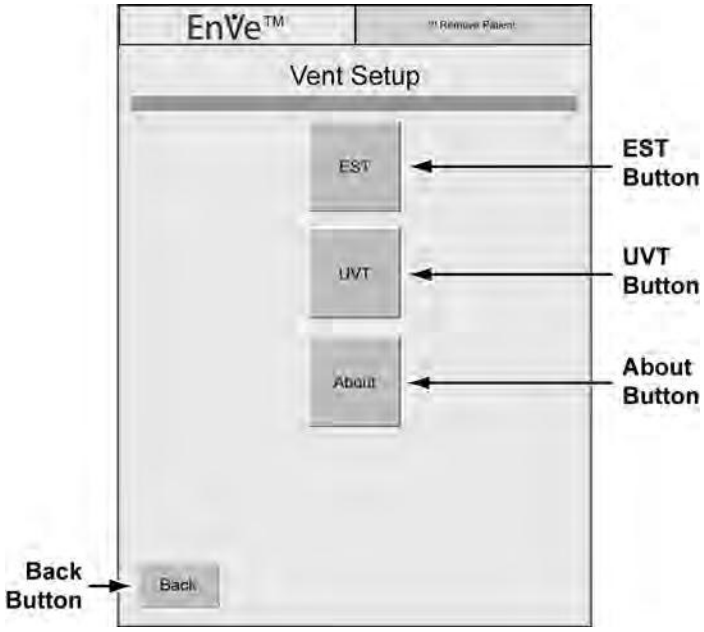
To perform EST or UVT testing in Startup mode, see *UVT and EST Testing in Startup Mode* in Chapter 2 – Installation and Checkout for detailed instructions.

To Access Ventilator Setup Related Screens/Controls



To access various ventilator setup related screens and controls, touch the **Vent Setup** button on the initial Startup screen and the **Vent Setup** screen is displayed. A **!!! Remove Patient** message is displayed and two audible tones of similar volume followed by a High Priority Alarm Signal indicate that the ventilator is in Vent Setup mode.

To silence the audible alarm and clear the displayed message for two (2) minutes, touch the **Status Bar** and then the **Alarm Reset** button (when displayed). Touch the **Back** button to return to the Startup screen.



To Exit Ventilator Setup Related Screens

Touch the **Back** button located near the bottom of the **Vent Setup** screen (and on all subsequent ventilator setup related screens) to close the current screen and return to the previous screen until the initial Startup screen is displayed.

FIO_2 Configuration and Calibration

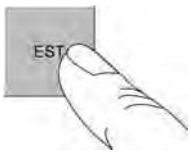
In order for the Enve™ ventilator to monitor and accurately report the FIO_2 (Fraction of Inspired Oxygen) level in the inspiratory limb of the patient circuit, an FIO_2 Sensor and other necessary components must be assembled, inserted into a patient circuit, connected to the ventilator, enabled and calibrated.

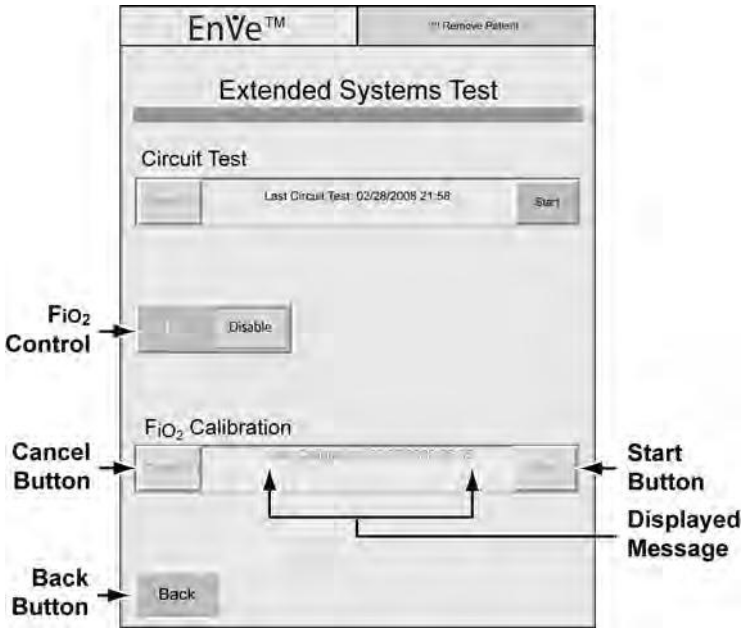
- To assemble the FIO_2 Sensor Assembly and insert it into the patient circuit, see the Instructions for Use provided with the FIO_2 Sensor Cable Assembly
- To connect the FIO_2 Sensor to the ventilator, see *To Connect the FIO2 Sensor* in Chapter 2 – Installation and Setup for detailed instructions

To Enable FIO_2 Monitoring

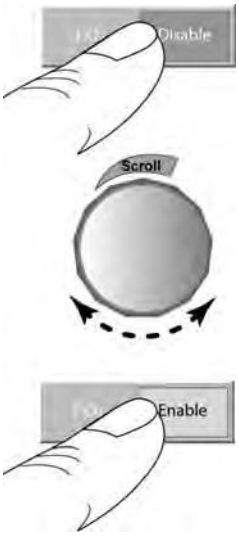
The **FiO_2** control is used to enable or disable communication with a FIO_2 sensor connected to the ventilator.

1) To enable FIO_2 monitoring, touch the **EST** button on the **Vent Setup** screen to display the **Extended Systems Test** screen.





2) When the **Extended Systems Test** screen is displayed, touch the **FiO_2** control to select it, rotate the **Scroll** knob on the Lower Interface Panel to change the setting and touch the **FiO_2** control again to confirm the new setting.



   - Setting the **FiO_2** control to **Enable**, also enables the **Last Calibration:** Date and time display and the **Start** button
   - Communication with a FIO_2 sensor may also be enabled/disabled (although not calibrated) during normal ventilation modes. See *Option Config Page* in Chapter 10 – The Utility Screen for more information.

   Range: **Disable** or **Enable**

To Calibrate the FIO_2 Sensor:

The FIO_2 calibration procedure is used to perform a two-point (**21%** and **100% O_2**) calibration of an attached FIO_2 Sensor Assembly.

NOTE

Before initiating the FIO_2 Sensor calibration procedure;

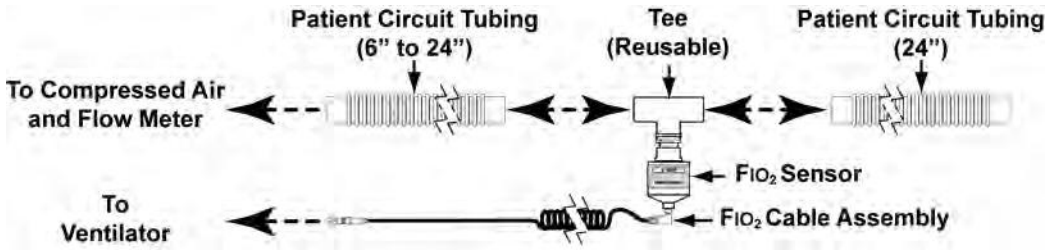
- Connect an FIO_2 Sensor Assembly to the ventilator
- Start the ventilator
- Set the FiO_2 control value to Enable in the Vent Setup, Extended Systems Test screen
- Have a patient circuit and external supply of 100% oxygen available

WARNING

Calibration of Sensor - Accurate monitored FIO_2 readings cannot be obtained unless the O_2 Sensor has been enabled and properly calibrated to the ventilator. If a discrepancy is observed between the O_2 blender setting and the **FiO_2** monitor reading, recalibrate the FIO_2 Sensor. If the discrepancy persists, contact CareFusion or a service technician certified by CareFusion for assistance. See *Chapter 13 - Troubleshooting* for more information.

Off Patient Calibration - All sensor calibration is performed with the ventilator off the patient and in the Startup mode of operation.

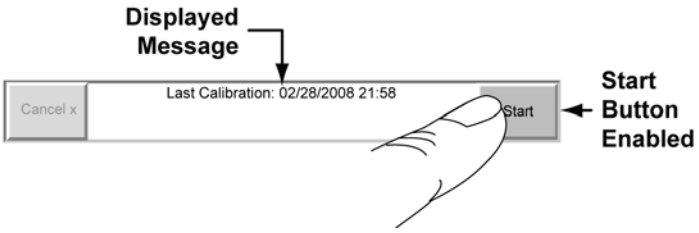
1) Assemble the reusable tee (p/n 13037-001), FIO_2 cable assembly (p/n 13897-001), and oxygen sensor (p/n 13036-001) to be calibrated.
    - See the Instructions for Use (p/n 13677-001) provided with the FIO_2 sensor assembly kit for detailed instructions
2) Attach the FIO_2 cable assembly to the ventilator.
    - See *To Connect the FIO2 Sensor* in Chapter 2 – Installation and Setup for detailed instructions
3) Attach a 6” to 24” length of patient circuit tubing between one end of the reusable tee and a flow metered source of compressed air, set for a flow of 5 lpm (range 3 to 10 lpm).
4) Attach a 24” length of patient circuit tubing to the other end of the reusable tee.



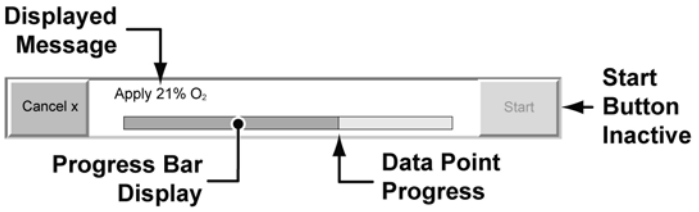
NOTE

- Calibration of the Oxygen Sensor should not be attempted until the sensor has reached thermal equilibrium with the ambient room temperature. Depending on the temperature variation the sensor may have recently been exposed to, this can take up to 2 hours. Additionally, holding the sensor in your hand for more than a few minutes can affect the temperature tracking which appears as a slow drift displayed by the ventilator.
- If the **Remove Ptnt** alarm occurs during the FIO_2 Sensor calibration, clear the alarm by pushing the Silence/Reset button two times. The FIO_2 Sensor calibration is not interrupted if the alarm occurs.

5) Touch the **Start** button to begin the calibration procedure.



6) Expose the FIO_2 Sensor to 21% O_2 (compressed air source) for up to five (5) minutes using a Flow Meter and apply 3 to 10 lpm (nominal 5 lpm) through the patient Circuit past the FIO_2 sensor until the displayed message changes to **Apply 100% O_2**.

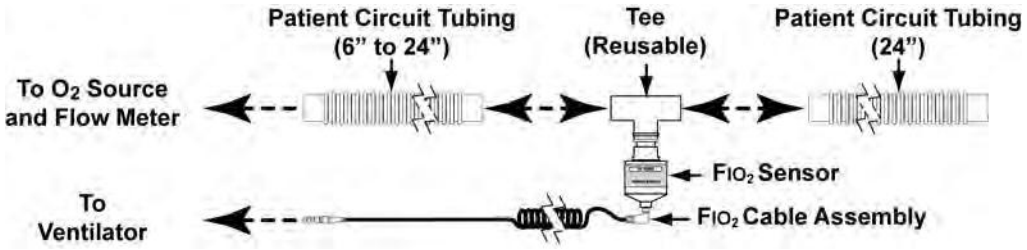


NOTE

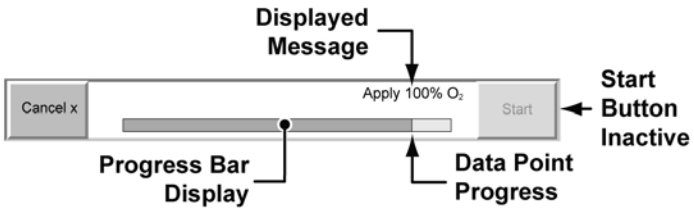
It is important to expose the sensor to 21% and 100% O_2 without an increase in pressure. Enclosing the sensor (for example in a bag) to apply the gas may increase pressure and cause inaccuracies in the calibration.

7) Expose the FIO2 Sensor to 100% O2 for up to five (5) minutes. CareFusion recommends the following method:

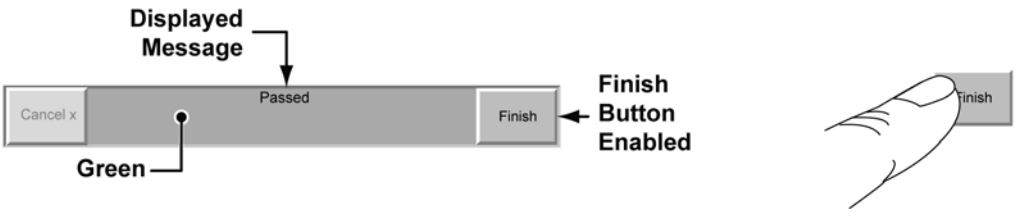
   - Insert the sensor into a patient circuit not connected to the ventilator
   - From an O_2 source not connected to the ventilator, run low pressure 100% O_2 through the patient circuit past the FIO_2 Sensor and using a Flow Meter apply 3 to 10 lpm (nominal 5 lpm) through the patient Circuit past the FIO_2 sensor



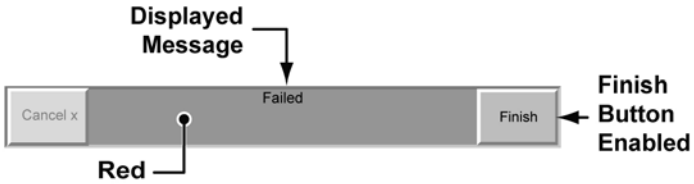
8) When the sensor has been exposed to 100% O_2 for up to (5) minutes the displayed message will change to **Passed** or **Failed**.



   - If **Passed** is displayed on a green background and the **Finish** button is displayed, the calibration procedure was successful. Touch the **Finish** button to end the procedure and display updated **Last Calibration:** Date and time information.



- If **Failed** is displayed on a red background and the **Finish** button is displayed, the calibration procedure failed and must be performed again. Touch the **Finish** button to restart the calibration procedure and the **Start** button is displayed again.



NOTE

When calibration fails, it is possible that the sensor is bad. Try calibrating another sensor with the ventilator. If you are unable to calibrate the second sensor, contact CareFusion or a service technician certified by CareFusion for assistance.

To ensure accurate F_{IO_2} measurements, the F_{IO_2} Sensor must be calibrated to the ventilator upon initial ventilation of a new patient and if F_{IO_2} measurements become inaccurate based on the **F_{IO_2}** ventilator setting.

Language, Units and Reset to Factory Defaults Controls

The language and units of measure displayed by the ventilator are configured and set using the **Language** and **Units** controls on the **Configuration** screen while the ventilator is in Startup mode.

Additionally, all adjustable Controls, Alarms and configuration values (with the exception of the Language, Units, Date/Time settings, and FiO_2 calibration, Touch Screen calibration and Circuit Test results) can be reset to their original factory-set default values using the **Reset To Factory Defaults** control, which is also located on the **Configuration** screen.

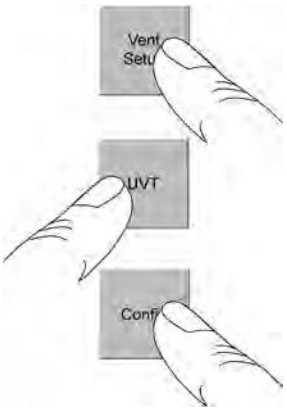
To Display the Configuration Screen:

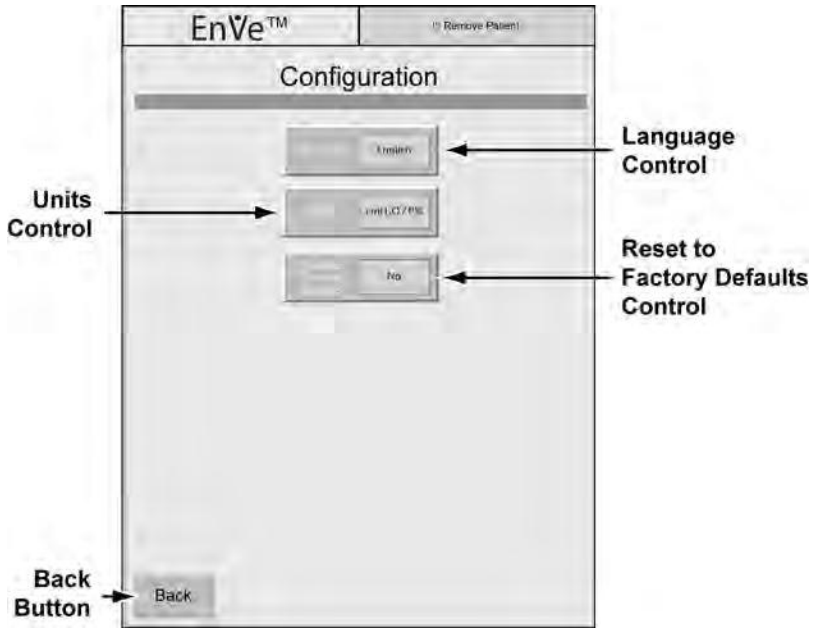
1) Touch the **Vent Setup** button on the initial Startup screen and the **Vent Setup** screen is displayed.

2) Touch the **Status Bar** when !!! **Remove Patient** is displayed and touch the **Alarm Reset** button clear the alarm.

3) Touch the **UVT** button on the **Vent Setup** screen and the **User Verification Tests** screen is displayed.

4) Touch the **Config** button on the **User Verification Tests** screen and the **Configuration** screen is displayed.





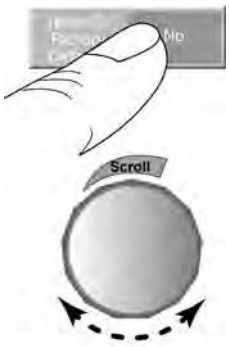
To Change Language, Units or Reset to Factory Default Values:

Changing the settings of any, or all of these configuration controls (**Language**, **Units** or **Reset to Factory Defaults**) can have a universal affect on the basic configuration of the ventilator (e.g. language/units of measure displayed, ventilation Mode used, ventilation controls and alarm limits settings, etc.).

> **NOTE**
>
> Using the **Reset To Factory Defaults** control/function will not reset the Language, Units, Local Date, Local Time/Date Format settings and FiO_2 calibration, Touch Screen calibration and Circuit Test results. All other user adjustable settings will be reset to the original factory values. See *Factory Settings* in Appendix C - Reference Information for a complete list of the original factory-set configuration values.

All three configuration controls can be changed using the same Select, Change and Confirm method; for example:

1) Select the **Language**[13], **Units**[14] or **Reset to Factory Defaults** control to be changed by touching the control. The background of the area behind the displayed language (e.g. **English**), units of measure (e.g. **cmH_2O / PSI**) or reset to factory defaults setting (e.g. **Yes** or **No**) is highlighted and the text turns white.



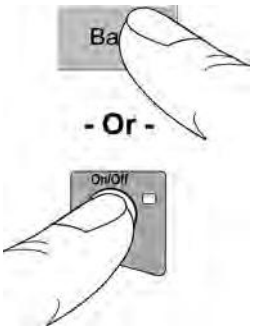
2) Change the displayed setting by turning the **Scroll** knob on the Lower Interface Panel.

3) Confirm the new value by touching the control again. The background area and text of the control returns to its previous color.
   - All control changes are tentative until the **Back** button is touched

4) To close the **Configuration** screen when the desired changes have been confirmed, touch the **Back** button. All setting changes made are accepted, the **Configuration** screen is closed and the **User Verification Tests** screen is displayed,

   or

   To close the **Configuration** screen without any control changes taking affect and exit Startup mode, press and hold down the **On/Off** button on the Lower Interface Panel until the ventilator powers down.



[13] The **Language** control is presently fixed at **English**.

[14] The **Units** control is presently fixed at **cmH_2O / PSI**.

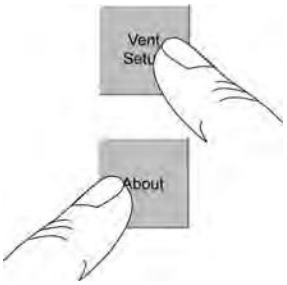
Ventilator, Component and Software Configuration Information

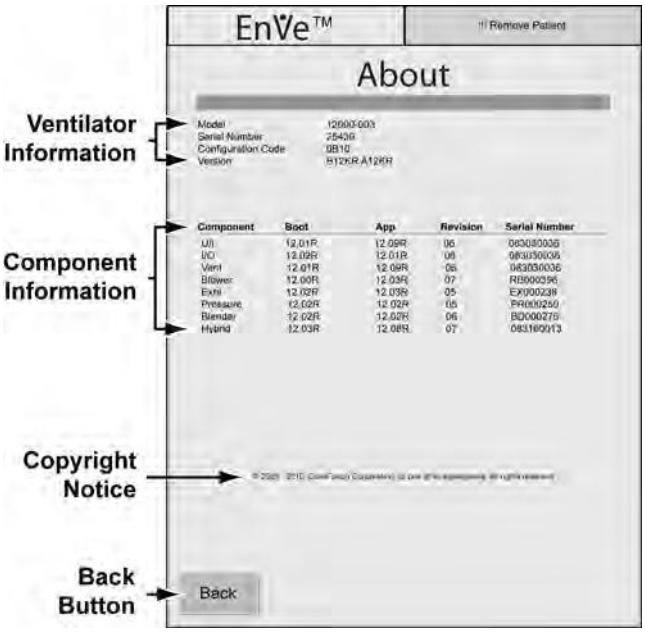
The **About** screen displays information concerning the ventilator's components revision and software configuration.

- Contact Information (company name, website address, email address, phone number)
- Device Information (ventilator model, serial number, configuration code)
- Component(s) Information (name, boot and application software versions, hardware revision, serial number)
- Copyright Notice

To Display the About Screen:

1) Touch the **Vent Setup** button on the initial Startup screen and the **Vent Setup** screen is displayed.
2) Touch the **Status Bar** when !!! **Remove Patient** is displayed and touch the **Alarm Reset** button clear the alarm.
3) Touch the **About** button on the **Vent Setup** screen and the **About** screen is displayed.





NOTE

All the information displayed on the **About** screen in Startup mode can also be viewed on the **Utility** screen **About** page while the ventilator is operating in normal ventilation modes.

Normal Ventilation Modes

After turning the ventilator on (see *Starting the Ventilator* earlier in this chapter for instructions) normal ventilation modes can be initiated using either the patient ventilation settings that were in effect the last time the ventilator was powered down (**Same Patient**), or Presets ventilation controls and alarm limits automatically set to initial values clinically appropriate for a new patient (**New Patient**).

- See *Presets Values for Controls, Presets Values for Alarm Limits*, and *Presets Values for Utility Controls/Alarms* later in this chapter for additional information

WARNING

Review Adjustable Control and Alarm Settings Regularly - To avoid possible harm to the patient, operators should review and adjust (if necessary) all user adjustable ventilation and alarm control settings regularly to assure they are set at appropriate values for the patient.

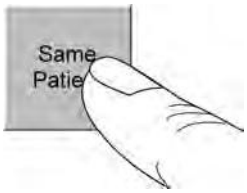
To Initiate Normal Ventilation Modes Using Existing Settings

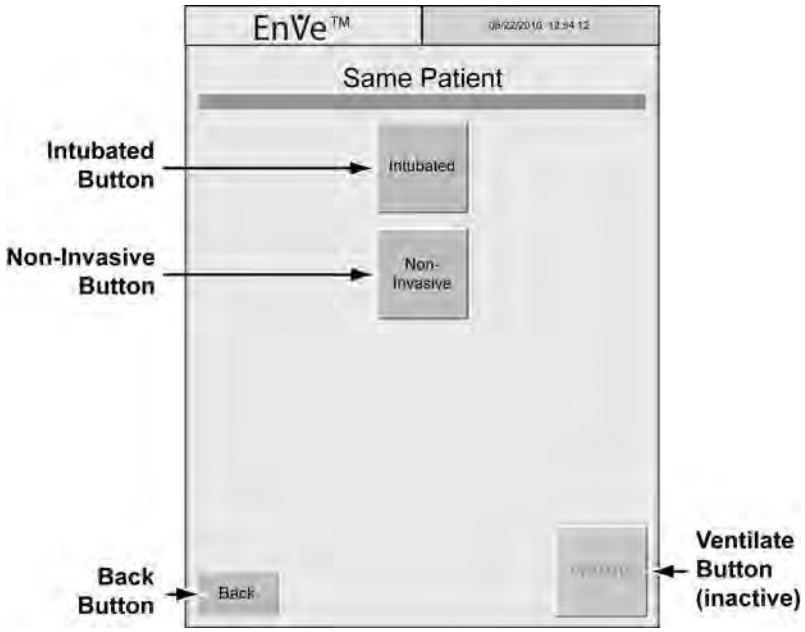
1) Turn the ventilator on as instructed in *Starting the Ventilator* earlier in this chapter.

NOTE

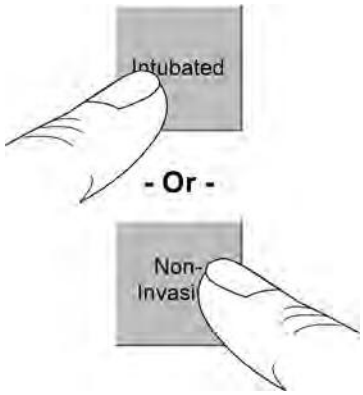
When a **Configuration Reset** alarm has been generated or an operator has utilized the **Reset to Factory Defaults** control, all user adjustable settings (except Language, Units, Local Date, Local Time/Date Format and FiO_2 calibration, Touch Screen calibration and Circuit Test results) are reset to the original factory values. Selecting the **Same Patient** button/option will not restore the previous patient settings.

2) Touch the **Same Patient** button on the initial Startup screen and the **Same Patient** screen is displayed.





3) When the **Same Patient** screen is displayed, touch the **Intubated** or the **Non-Invasive** button to select the type of ventilator to patient interface being used. When either of the two buttons is selected, the **Ventilate** button is activated.



NOTE

When **Same Patient** is selected on the **Startup** screen and;

- If the ventilator to patient interface selected is **Intubated** and the previous setting was **Non-Invasive**, the ventilation **Mode** will be the last selected / preset Intubated ventilation mode
- If the ventilator to patient interface selected is **Non-Invasive** and the previous setting was **Intubated**, the ventilation **Mode** will be set to **NPPV CPAP/PSV**

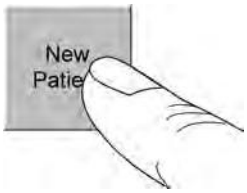
4) Touch the **Ventilate** button to display the **Main** screen and initiate the ventilation mode and patient ventilation settings that were in effect the last time the ventilator was powered down.

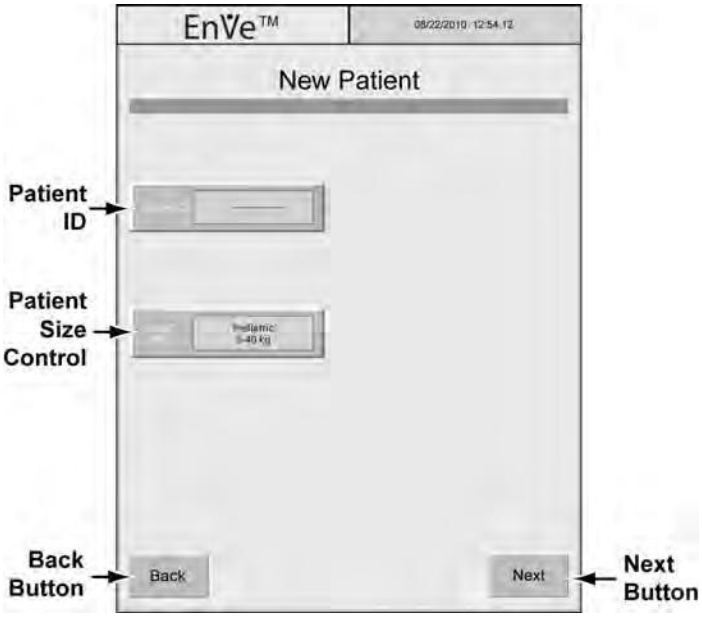
To Initiate Normal Ventilation Modes Using Presets Settings

The Presets[15] feature allows operators to use the **New Patient** screen(s) to enter a patient ID number, and enter basic patient size and patient circuit related information to be used by the ventilator to automatically set most ventilation controls and alarm limits to initial values clinically appropriate for a new patient.

1) Turn the ventilator on as instructed in *Starting the Ventilator* earlier in this chapter.

2) Touch the **New Patient** button on the initial Startup screen and the **New Patient** screen is displayed.

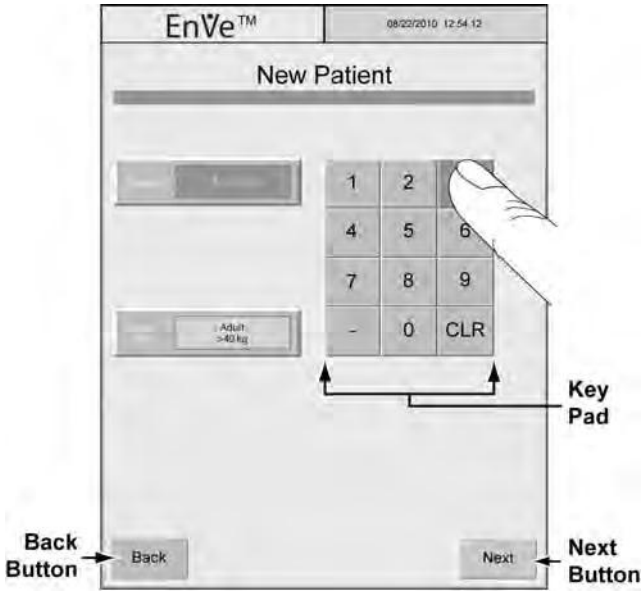




3) To enter a Patient ID number, touch the **Patient ID** control. The area behind the displayed patient ID is highlighted and a numeric keypad is displayed. Use the keypad (touch the individual keys) to enter the desired Patient ID number (12 numbers maximum).

   Touch the **Patient ID** control again, the area behind the displayed patient ID reverts to its previous color, the Patient ID is set, the keypad is removed and the **Next** button is activated.

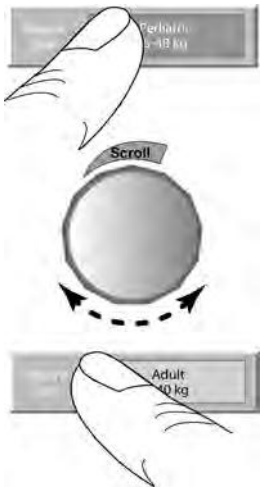
To start over or change previous selections, touch the **Back** button to return to the intial Startup screen.



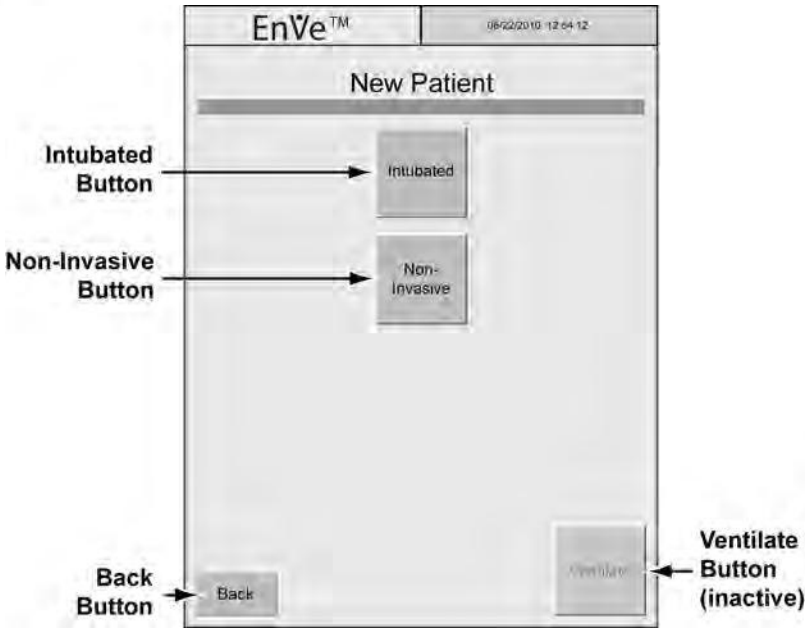
[15] Presets – Automatically set ventilation control and alarm limit values initially clinically appropriate for the patient size and patient circuit type selected by the operator during ventilator setup for a New Patient.

4) Touch the **Patient Size** control to select it and the area behind the displayed patient size is highlighted. Rotate the **Scroll** knob on the Lower Interface Panel clockwise or counter-clockwise to display the description that most closely reflects your patient size;
   - **Adult >40 kg,** or
   - **Pediatric 5 - 40 kg**

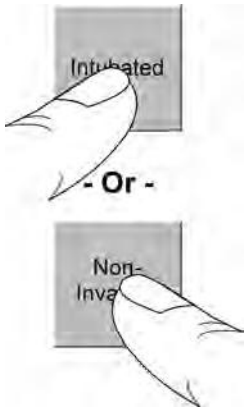
   Touch the **Patient Size** control again, the area behind the displayed patient size reverts to its previous color, the Patient Size is set and the **Next** button is activated.



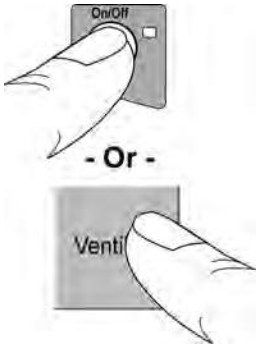
5) Touch the **Next** button and the next **New Patient** screen is displayed.



6) When the next **New Patient** screen is displayed, touch the **Intubated** or the **Non-Invasive** button to select the type of patient circuit to patient interface being used. When either of the two buttons is selected, the **Ventilate** button is activated.

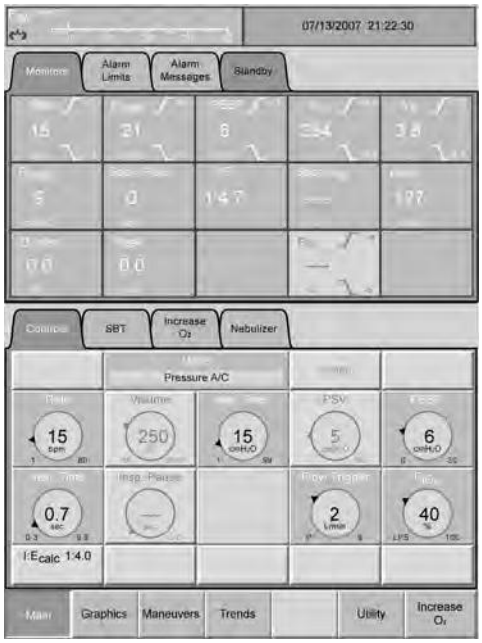


7) To retain the prior Patient ID, Trend data, Maneuvers history and cancel the new settings, touch the **Back** button to close the current screen and return to the previous screen until the intial Startup screen is displayed, or press and hold down the **On/Off** button on the Lower Interface Panel until the ventilator powers down;



or

To clear the prior Patient ID, Trend data, Maneuvers history, accept the new settings and begin normal ventilation using the Presets configuration values as shown in the tables on the following pages, touch the **Ventilate** button. The **Main** screen is displayed.



Presets Values for Ventilation Controls

Controls	Pediatric (5-40 kg)	Adult (> 40 kg)
Bias Flow	5 L/min	5 L/min
FiO_2	21 %	21 %
Flow Cycle	"- -" (Off)	"- -" (Off)
Flow Trigger	2 L/min	2 L/min
Increase O_2 - Duration	3 min	3 min
Increase O_2 - Level	+79 %	+79 %
Insp. Pause	"- - -" (Off)	"- - -" (Off)
Insp. Pres	15 cmH_2O	15 cmH_2O
Insp. Rise	3	4
Insp. Time	0.7 sec	1.0 sec
Leak Comp	On	On
Mode (Intubated)	Pressure A/C[16]	Volume A/C[16]
Mode (Non-Invasive)	NPPV CPAP/PSV[17]	NPPV CPAP/PSV[17]
PEEP	6 cmH_2O	6 cmH_2O
Pressure Trigger	3 cmH_2O	3 cmH_2O
PSV	5 cmH_2O	10 cmH_2O
PSV Cycle	25 %	25 %
PSV Rise	3	4
PSV T_{max}	1.0 sec	2.0 sec
Rate	15 bpm	12 bpm
SBT FiO_2	21 %	21 %
SBT PEEP	6 cmH_2O	6 cmH_2O
SBT PSV	5 cmH_2O	10 cmH_2O
SBT Time	20 min	20 min
Volume	250	500

NOTE

Ventilation controls not listed in the table above are unaffected by the Presets feature and normal ventilation will begin using the settings that were in effect the last time the ventilator was powered down.

[16] Presets ventilation Mode setting when **Intubated** ventilator to patient interface selected during Startup.
[17] Presets ventilation Mode setting when **Non-Invasive** ventilator to patient interface selected during Startup.

Presets Values for Alarm Configuration/Limits

Alarms	Pediatric (5-40 kg)	Adult (> 40 kg)
Apnea Interval	20 sec	20 sec
High PEEP	11 cmH_2O	11 cmH_2O
High P_{peak}	30 cmH_2O	40 cmH_2O
High Pulse	"- - -" (Off)	"- - -" (Off)
High Rate	60 bpm	40 bpm
High V_e	"- - -" (Off)	"- - -" (Off)
High V_{te}	"- - - -" (Off)	"- - - -" (Off)
Low PEEP	3 cmH_2O	3 cmH_2O
Low P_{peak}	10 cmH_2O	10 cmH_2O
Low Pulse	"- - -" (Off)	"- - -" (Off)
Low V_e	1.0 L	3.0 L
Low V_{te}	"- - - -" (Off)	"- - - -" (Off)
LPP Alarm	Control Only	Control Only
LPS Low FiO_2	18 %	18 %
LPS High FiO_2	60 %	60 %
SBT High PEEP Alarm	11 cmH_2O	11 cmH_2O
SBT Low PEEP Alarm	3 cmH_2O	3 cmH_2O

NOTE

Alarms not listed in the table above are unaffected by the Presets feature and normal ventilation will begin using the settings that were in effect the last time the ventilator was powered down.

Refer to the individual alarms listed in *Alarm Details* in Chapter 8 - Ventilator Alarms for detailed information.

Presets Values for Utility Controls/Alarms

Utility Controls/Alarms	Pediatric (5-40 kg)	Adult (> 40 kg)
HP Delay	0 (no delay)	0 (no delay)
Safety Valve Delta Pressure	10 cmH_2O	10 cmH_2O

NOTE

Utility controls/alarms not listed in the table above are unaffected by the Presets feature and normal ventilation will begin using the settings that were in effect the last time the ventilator was powered down.

Refer to the individual controls/alarms listed in Chapter 5 – Controls, Chapter 8 – Ventilator Alarms and Chapter 10 - The Utility Screen for detailed information.

Before Connecting to a New Patient

Before connecting a new patient to the ventilator, perform the following procedures:

1) Connect a patient circuit appropriate for your patient size and weight. Connect any patient circuit accessories such as humidifiers, water traps or filters into the circuit. See *Connecting the Patient Circuit* in Chapter 2 – Installation and Setup for information.
2) Test the patient circuit with the ventilator as described in *Circuit Test* in Chapter 2 - Installation and Setup. Ensure that all other testing as required by the *Maintenance Schedule* in Chapter 11 – Maintenance and Cleaning has been performed.

NOTE

Circuit testing should always be performed with all the accessories to be used included in the circuit.

3) Connect an oxygen source to the ventilator, if required. See *Oxygen Connection* in Chapter 2 – Installation and Setup for connection information.

NOTE

If the ventilator is connected to a low pressure oxygen source, select the **LPS** (Low Pressure O_2 Source) setting on the **FiO_2** control and adjust the flow of the connected source. See *FIO2 (Inspired Oxygen)* in Chapter 5 – Controls.

WARNING

Inspired Oxygen (FIO_2) Concentration – If exact concentrations of inspired oxygen (FIO_2) must be delivered to the patient, it is recommended that the optional FIO_2 Sensor or a separate oxygen analyzer with alarms be used. If using the optional FIO_2 Sensor set the ventilator High and Low FiO_2 alarms appropriately (see *High FiO2* and *Low FiO2* alarms in Chapter 8 – *Ventilator Alarms* for additional information).

4) Connect any optional accessories, such as an FIO_2 Sensor or SpO_2 Module and Sensor. See *Optional Use Accessories Connection* in Chapter 2 – Installation and Setup and *Option Config Page* in Chapter 10 – The Utility Screen for detailed information.
5) Initiate normal ventilation using the Presets settings. See *To Initiate Normal Ventilation Modes Using Presets Settings* earlier in this chapter for detailed instructions.
6) Select the desired ventilation **Mode** (breath type and breath mode combined) and set the controls to appropriate values for your patient. See *Breath Types*, *Breath Modes* and *Ventilation Modes* in Chapter 4 – Breath Types and Modes and *Main Screen, Adjustable Ventilation Controls* in Chapter 5 – Controls for detailed information.

7) Set appropriate alarm limits and Apnea Backup settings. See *Adjustable Alarms* in Chapter 8 – Ventilator Alarms.

WARNING

Factory-Set Alarm Values - To avoid patient injury, always check the set alarm limits of all adjustable alarms for appropriateness prior to using the ventilator on a patient.

Apnea Backup Settings - Always check and configure the controls affecting Apnea Backup ventilation prior to using the ventilator on a patient. If you do not set appropriate backup controls, Apnea Backup ventilation will be delivered at previous or factory-set values which may not be appropriate.

8) Set appropriate alarm, ventilator and option configuration values or settings. *See Alarm Config Page, Vent Config Page,* and *Option Config Page* in Chapter 10 -The Utility Screen for detailed instructions.

NOTE

To avoid an unexpected depletion of internal battery power, always check the Removable Battery Pack level of charge prior to disconnecting external power or operating the ventilator solely on the Removable Battery Pack (such as during transport

situations).

See *To Check the Level of Charge:* in Chapter 12 – Power Supplies and Batteries for detailed instructions.

Maneuvers

The following maneuvers are available on the Enve™ ventilator*;*

- Inspiratory Hold (I-Hold)
- Expiratory Hold (E-Hold)

See *Maneuvers* in Chapter 9 – Maneuvers, Procedures and Standby Mode for detailed information concerning maneuvers.

Procedures

The following procedures can be performed on the Enve™ ventilator;

- Increase O_2
- Nebulization
- SBT (Spontaneous Breathing Trial)

See *Procedures* in Chapter 9 – Maneuvers, Procedures and Standby Mode for detailed information concerning these procedures.

Standby Mode

Standby mode is an operator initiated temporary suspension of patient ventilation which can be used to accommodate changing or reconfiguration of accessories, gas delivery methods, patient movement or transport, and does not require changing ventilation settings or shutting down and restarting the ventilator.

WARNING

Standby Mode – When Standby mode is initiated, patient ventilation is suspended until Standby mode is exited and normal ventilation is resumed. To avoid serious injury or death, provide alternative ventilation to the patient until such time as a normal ventilation mode is resumed and the patient is reconnected to the ventilator.

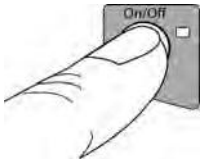
See *Standby Mode* in Chapter 9 – Maneuvers, Procedures and Standby Mode for detailed information concerning the Standby Mode.

Turning the Ventilator Off

To Turn the Ventilator Off:

1) Disconnect the ventilator from the patient.

2) Push and hold the **On/Off** button for 3 seconds. The ventilator stops ventilating, the audible alarm sounds continuously and the **Vent Inop** LED is flashing red.



3) Push the **Alarm Silence** button once to silence the audible alarm and extinguish the **Vent Inop** LED.

NOTE

The ventilator continues to charge the Transition Battery and the Removable Battery Pack (when installed) as long as it is connected to an external power source. The exhaust/cooling fan may continue to run while the ventilator is off but charging a battery.

Chapter 4 - BREATH TYPES AND MODES

This chapter contains information about the breath types and modes available on the Enve™ ventilator. It details the types of breaths and how breaths are initiated, limited and cycled. It also discusses breath modes and how they are delivered by the ventilator.

Breath Types

The Enve™ ventilator provides the following breath types:

- Pressure Control
- Pressure Regulated Volume Control (PRVC)
- Pressure Support (PSV)
- Spontaneous
- Volume Control
- Volume Targeted Pressure Support (V_tPSV)

Breaths are defined by how they are initiated (triggered), limited and cycled.

The following terms are used in discussing how breaths are given:

Trigger is what causes a breath to be delivered. Breaths may be triggered by a patient demand, a push of the Manual Breath button, or by the ventilator based on the set breath rate and mode of ventilation.

Limit is how the breath is controlled. Breaths may be limited to a set maximum circuit pressure or a set maximum flow.

Cycle is what causes the breath to transition from the inspiratory phase to the exhalation phase. Breaths may be cycled by the ventilator when a set time has been reached, or when a preset flow or percentage of the maximum flow delivered during a breath is reached depending on the breath type and the settings. Breaths can also be cycled when an alarm condition such as a high pressure limit has been reached.

Breaths can be **Machine** breaths, **Assist** breaths or **Patient** breaths.

The following table gives an overview of how these different breath types are controlled:

	Machine	**Assist**	**Patient**
Triggered By	Ventilator	Patient	Patient
Limited By	Ventilator	Ventilator	Ventilator
Cycled By	Ventilator	Ventilator	Patient

The following parameters apply as indicated:

- Minimum Inspiratory Time is 300 ms (all breath types)
- Minimum Exhalation Time is 346 ms (all breath types)
- Maximum Calculated Peak Flow is 120 L/min -10%/+20% (applies to Volume breath types only)
- Maximum Spontaneous Peak Flow is 180 L/min (applies to all breath types except Volume)

NOTE

Patient triggers are detected during exhalation, after the Minimum Exhalation Time has expired.

See *Flow Trigger* or *Pressure Trigger* in Chapter 5 – Controls for additional information.

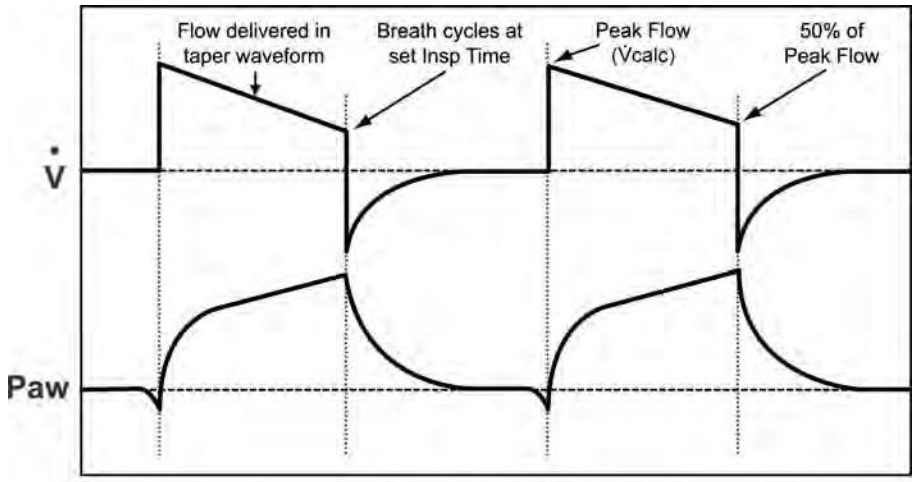
Machine Breaths

Machine and Assist Breaths may be delivered as:

- Volume Control
- Pressure Control
- Pressure Regulated Volume Control (PRVC)

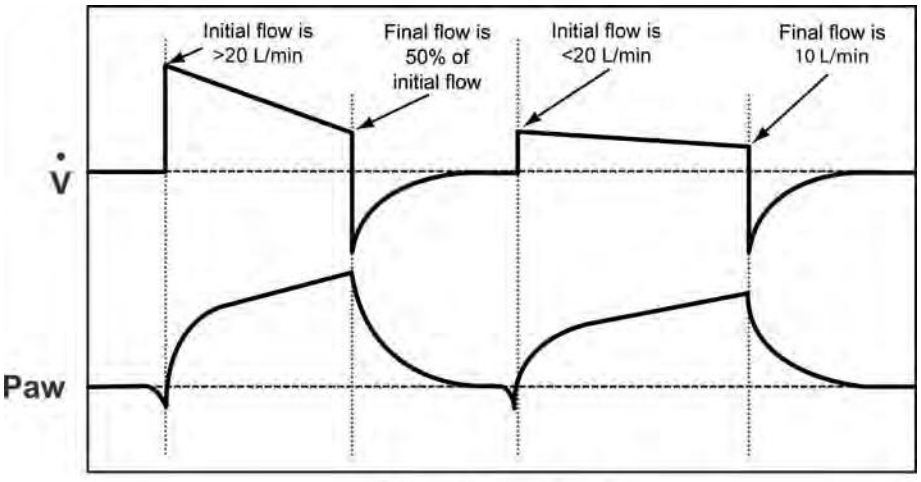
Volume Control Breaths

In volume control breaths a set Tidal Volume (**Volume**) is delivered over a set Inspiratory Time (**Insp. Time**). Flow is delivered in a decelerating waveform. Peak flow is calculated based on the **Volume** and **Insp. Time** settings and the final flow being 50% of the peak flow. Volume Control breaths may be Machine or Assist breaths. A Volume Control breath is cycled by time.



Volume Control Breaths

When the initial flow is <20 L/min, the final flow remains at 10 L/min and the waveform is flattened.

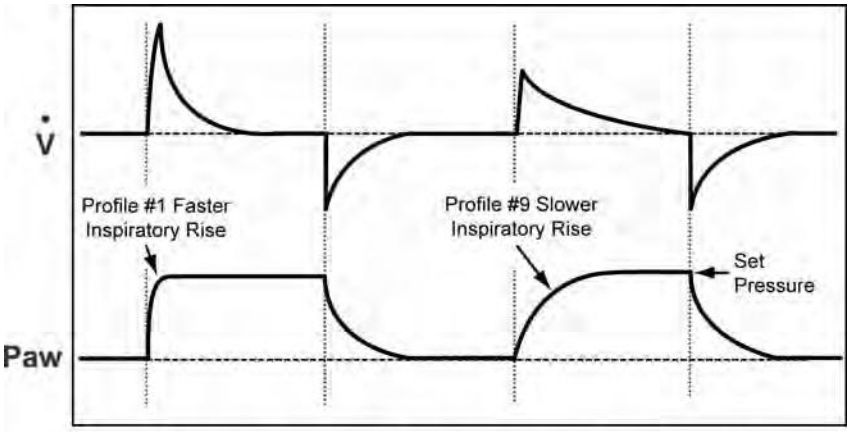


Volume Control Breaths

Pressure Control Breaths

For Pressure Control breaths, flow is delivered according to the **Insp. Rise** setting to elevate the circuit pressure to the Pressure Control setting (above set **PEEP**[18]) and maintain it at that pressure for the set **Insp. Time**. Pressure Control breaths may be Machine or Assist breaths. A Pressure Control breath can be either flow or time cycled.

Adjusting the **Insp. Rise** setting changes the flow and pressure waveforms for Pressure Control breaths (see *Insp. Rise* in Chapter 5 – Controls).



Adjusting Inspiratory Rise on Pressure Control Breaths

If **Flow Cycle** is on (e.g. **10%** - **40%**), Pressure Control breaths may be flow terminated. If the flow drops to the set **Flow Cycle** percentage before the inspiratory time is completed, the breath is cycled. See *Flow Cycle* in Chapter 5 - Controls.

[18] Pressure Control and Pressure Support breaths compensate for PEEP. Delivered pressure is the setting plus PEEP. e.g. a setting of 20cmH_2O with a PEEP of 10cmH_2O delivers a max pressure of 30cmH_2O.

Pressure Regulated Volume Control Breaths (PRVC)

For Pressure Regulated Volume Control (PRVC) breaths, the ventilator delivers pressure breaths at a target pressure which is calculated before each breath. The target pressure is the pressure needed to deliver a Tidal Volume equal to the **Volume** setting. The target pressure for the current breath is calculated based on the target pressure and the delivered Tidal Volume of the previous breath (measured at the ventilator) as follows.

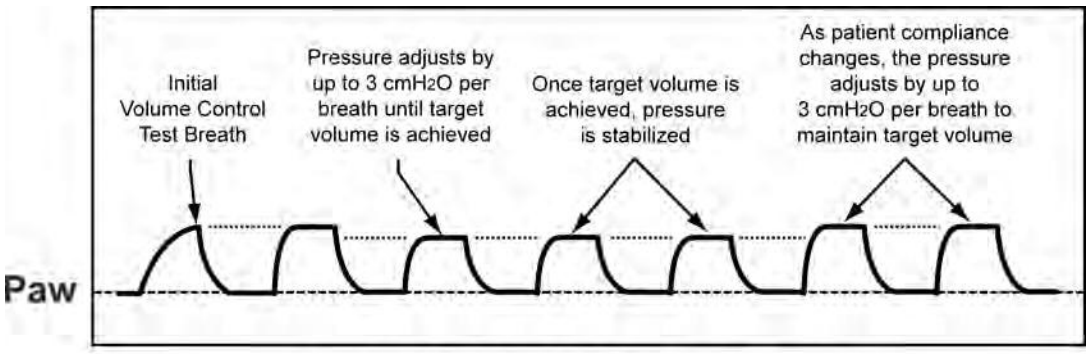
Test Breaths

The ventilator delivers a volume control Test Breath at the set **Volume** when:

- The PRVC breath mode is initiated
- The set Volume is changed
- A **Volume Limited** alarm occurs (see *Volume Limited* in Chapter 8 – Ventilator Alarms for detailed information)
- The delivered Tidal Volume ≥1.5 times the set Volume
- The next breath following a High Pressure alarm, a Safety Valve High Pressure alarm, a Patient Circuit Fault alarm, a Low Peak Pressure alarm, or active exhalation
- The set Inspiratory Time (**Insp. Time**) is changed
- The set Inspiratory Rise Time **(Insp. Rise**) is changed
- The set PEEP is changed

For breaths other than Test Breaths:

- Using the pressure and delivered volume of the previous breath as a basis for calculation, the target pressure of the next PRVC breath is adjusted to achieve the set Tidal Volume (**Volume**). The pressure adjustment from a previous breath however is never more than 3 cmH_2O
- The Target Pressure is at least 5 cmH_2O below the High Pressure (**High P_{peak}**) alarm setting
- Flow is delivered according to the set Inspiratory Rise Time (**Insp. Rise**).
- Breaths are terminated based on the set Inspiratory Time (**Insp. Time**), or the set Flow Termination (**Flow Cycle**), whichever comes first.
    - If **Flow Cycle** is on (e.g. **10% - 40%**), pressure breaths may be flow terminated. If the flow drops to the set **Flow Cycle** level before the inspiratory time is completed, the breath is cycled. See *Flow Cycle* in Chapter 5 – Controls



Pressure Regulated Volume Control Breaths

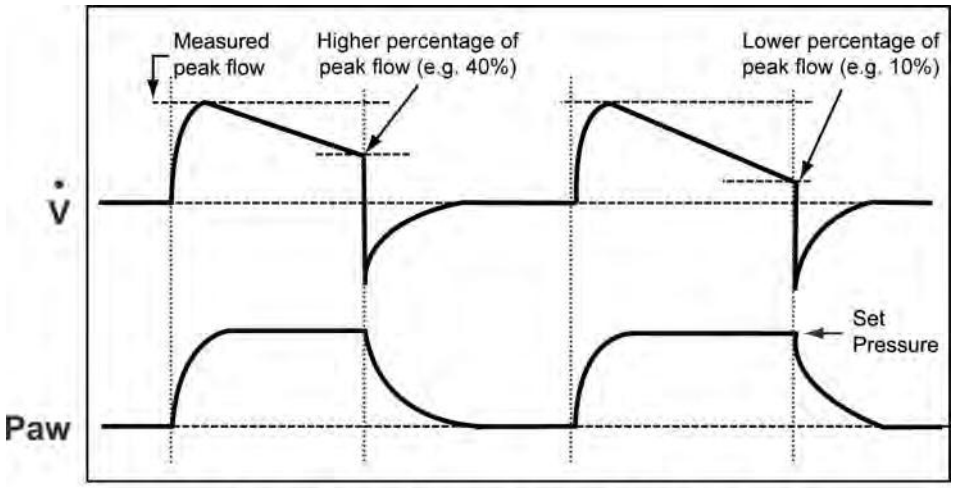
Patient Breaths

Patient breaths may be delivered as:

- Pressure Support (PSV)
- Spontaneous or
- Volume Targeted Pressure Support (V_t PSV)

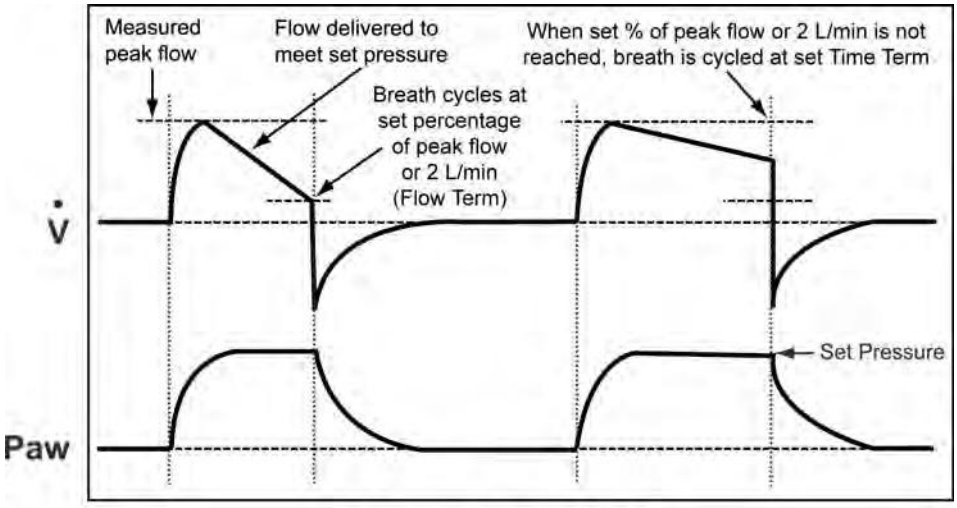
Pressure Support Breaths (PSV)

In Pressure Support breaths, flow is delivered according to the **PSV Rise** setting, to elevate the circuit pressure to the **PSV** setting and maintain it until the flow drops below a pre-set percentage of Peak Flow for that breath, or below 2 L/min (see *PSV Cycle* in Chapter 5 - Controls). The breath then cycles to exhalation.



Adjusting Flow Term on Pressure Support Breaths

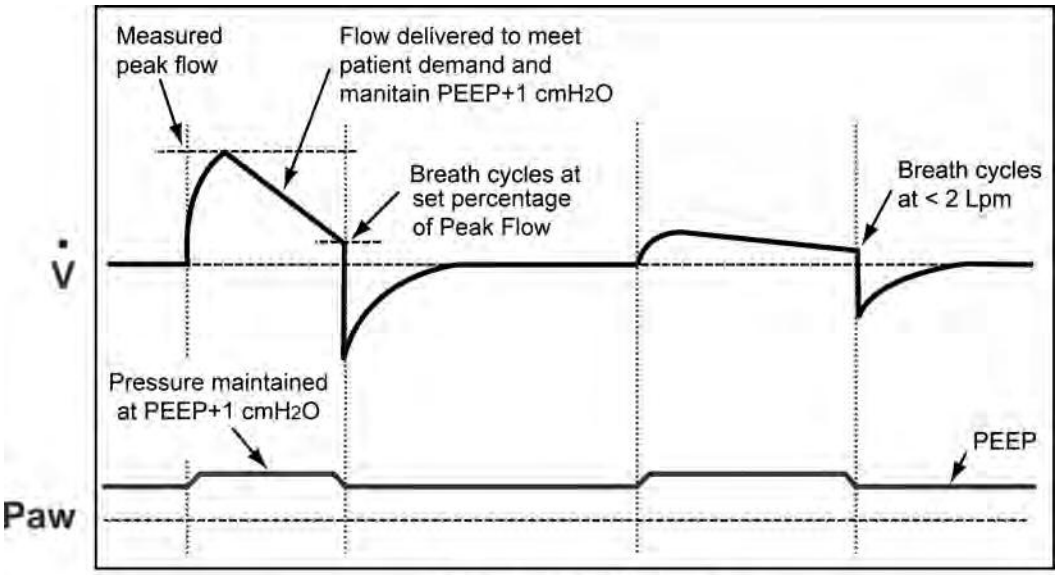
Pressure Support breaths may also be cycled by the set **PSV T_{max}** (see *PSV Tmax* in Chapter 5 - Controls).



Pressure Support Breaths

Spontaneous Breaths

Spontaneous breaths are a subset of Pressure Support breaths, where the circuit pressure is elevated to PEEP+1 cmH_2O during inspiration. This is achieved when the PSV control setting is set to either 1 or "- -" (Off).



Spontaneous Breaths

Shown with example flow for two different patient conditions

Volume Targeted Pressure Support Breaths (V_tPSV)

Volume Targeted Pressure Support breaths are calculated and delivered the same as PRVC breaths with the following exceptions:

- The breath is terminated when the breath inspiration time exceeds the set inspiration time. The breath may also be cycled when the flow drops below the set **PSV Cycle** or 2 L/min, whichever comes first.
- The **PSV** control is inactive in CPAP/V_tPSV

> **NOTE**
> The **Insp. Time** control is active during the Volume Control test breath only.

Breath Modes

The Enve™ ventilator provides the following modes of breath delivery:

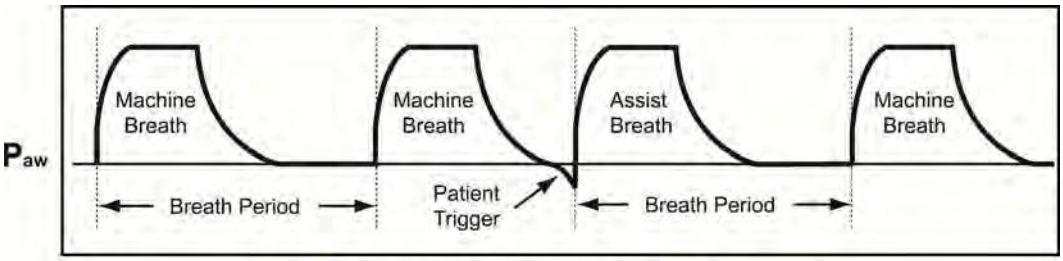
- Assist/Control (A/C)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Continuous Positive Airway Pressure (CPAP/PSV)
- Apnea Backup Ventilation
- Non-Invasive Positive Pressure Ventilation (NPPV)

Assist/Control (A/C)

The breath period in Assist/Control mode is determined by the Breath Rate (**Rate**) setting.

In Assist/Control mode, (**Mode** is set to **A/C**) both Machine Breaths and Assist Breaths may be given. When a breath period expires without a patient effort being detected, the ventilator delivers a Machine Breath and the breath period is reset. When a patient effort is detected before the breath period expires, an Assist Breath is given at the pre-selected ventilation settings and the breath period is reset.

If the patient is triggering breaths at a faster rate then the set rate, it is possible for all breaths to be patient triggered.

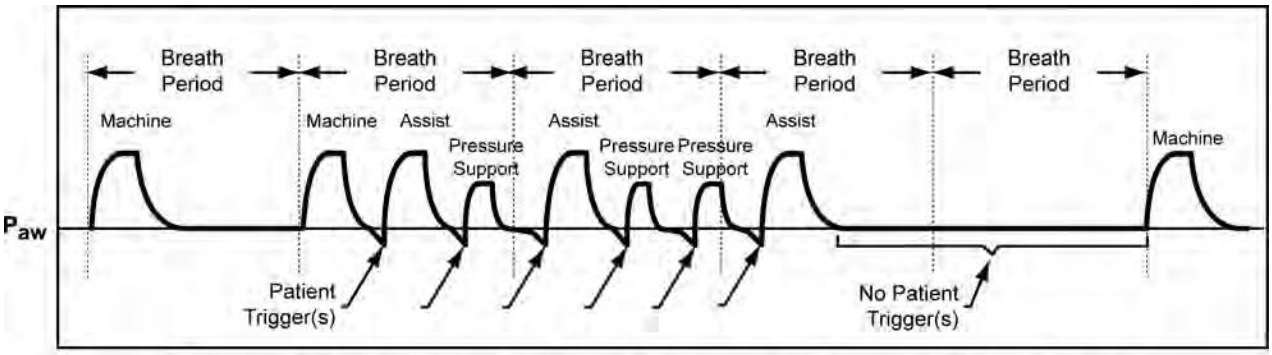


Pressure Control Machine and Assist Breaths

Synchronized Intermittent Mandatory Ventilation (SIMV)

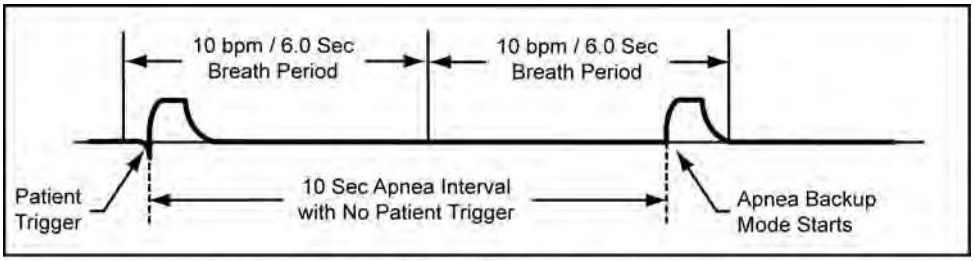
In **SIMV** mode, Machine, Assist and either Pressure Support or Spontaneous breaths may be given. For the first patient trigger detected within a breath period, an Assist breath is given. For all subsequent patient triggers within the same breath period, Pressure Support or Spontaneous patient breaths are given depending on the **PSV** setting. Although the breath period is not reset by patient triggers, it is reset when a Manual Breath is initiated.

At the beginning of a breath period, if no triggered breaths have occurred in the previous breath period, a Machine breath is given.



Pressure Control Machine and Assist Breaths, and Pressure Support Breaths

> **NOTE**
> If there was a patient triggered breath in the previous breath cycle, the ventilator will not give a Machine breath in the current breath period unless the set **Apnea Interval** is exceeded (see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes).

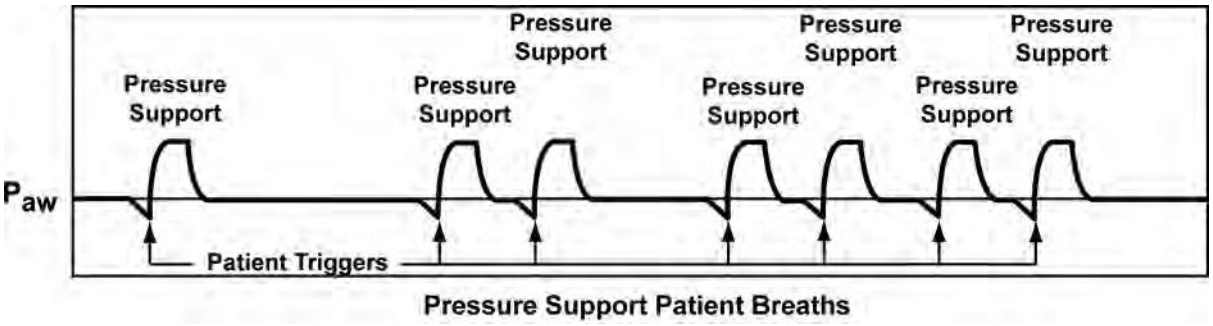


Example of SIMV Mode, Breath Rate 10 bpm, Apnea Interval 10 Seconds

Continuous Positive Airway Pressure (CPAP/PSV)

In CPAP/PSV mode, when a patient trigger is detected, a patient breath is given. For **CPAP/PSV (Volume)** or **CPAP/PSV (Pressure)** settings, breaths may be Pressure Support or Spontaneous breaths depending on the **PSV** setting. The apnea back up breath is indicated at the end of the breath mode description; for example:

- **CPAP/PSV (Volume)** setting will have a volume type apnea breath
- **CPAP/V_tPSV** setting, the breaths are Volume Targeted Pressure Support (see *Volume Targeted Pressure Support Breaths (VtPSV)* in this chapter).



Pressure Support Patient Breaths

Apnea Backup Ventilation

The Enve™ ventilator provides an Apnea Backup mode of ventilation. When the set **Apnea Interval** (maximum time allowed between the beginning of one breath and the beginning of the next breath) is exceeded, the Apnea alarm is generated and the ventilator will enter Apnea Backup ventilation mode based on current ventilator settings.

WARNING

Apnea Backup Settings - Always check and configure the controls affecting Apnea Backup ventilation before initiating CPAP/PSV mode. If you do not set appropriate backup controls, Apnea Backup ventilation will be delivered at previous or factory-set values which may not be appropriate.

NOTE

- **Inactive Controls** - Controls which need to be set for Apnea Backup ventilation may appear inactive in CPAP/PSV or NPPV modes. The controls should be set while inactive and will become active when Apnea Backup ventilation initiates.
- **Apnea Control –** The **Apnea** control button on the **Main** screen, **Controls** page is only enabled during CPAP modes of ventilation.

Apnea Backup ventilation is initiated when the time since the start of the last breath exceeds the set **Apnea Interval**. The Apnea Interval is set from the **Main** screen, **Alarm Limits** page (see *Apnea* and *Apnea Interval* in Chapter 8 – Ventilator Alarms for additional information).

When an apnea alarm occurs, the ventilator initiates Apnea Backup ventilation in Assist/Control mode at the previously set breath type and control settings.

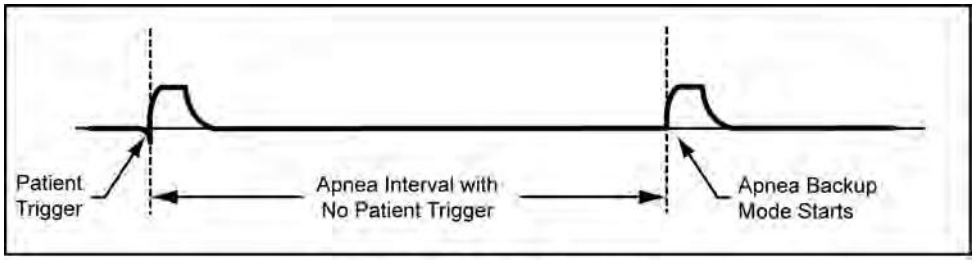
The Apnea Breath Rate is determined as follows:

- If the set Breath Rate (**Rate**) is < 12 bpm the Apnea Breath Rate is the highest rate allowed by control limiting, up to 12 bpm

In **CPAP/PSV and NPPV** ventilation modes only:

- If the set Breath Rate is equal to or higher than 12 bpm, then the Apnea Backup Rate will be the set Breath Rate (**Rate**)

The ventilator returns to the previous mode when the **Apnea** alarm is reset or when the patient triggers two consecutive breaths.



Example of Apnea Backup

Non-Invasive Positive Pressure Ventilation (NPPV)

WARNING

NPPV Breath Modes - NPPV breath modes are not life support modes and are not suitable for patients that require life support ventilation. NPPV breath modes should only be used for supplemental ventilation of non-life support patients.

The Enve™ ventilator provides Non-Invasive Positive Pressure Ventilation (NPPV) as a secondary, supplementary mode that may be selected with the primary ventilation Mode. When **NPPV Pressure** or **NPPV CPAP/PSV** mode is selected, ventilation is delivered according to the selected mode.

The ventilator is capable of performing non-invasive positive pressure ventilation (NPPV) with a standard dual-limb circuit. Adjust sensitivity to accommodate patient effort without auto-cycling. Activating leak compensation or increasing the level of Bias Flow may help overcome leaks and optimize the sensitivity setting. Set the alarms to avoid unnecessary alerts while maintaining adequate monitoring. NPPV Modes include NPPV Pressure and NPPV/CPAP/PSV.

When either of the NPPV modes are selected the leak compensation function is automatically enabled, and when either NPPV mode is exited the leak compensation function returns to its previous or default setting.

To provide Non-Invasive Positive Pressure Ventilation (NPPV) a face mask or nasal mask is employed to connect the patient to the ventilator. The ventilator will produce positive pressure breaths to either deliver a mandatory breath or assist the patient's inspiration in either of the NPPV modes (see below).

Since the connection to the patient via a mask may introduce leaks, a leak compensation mechanism is employed to maintain the preset pressures even with introduced leakage up to 30 lpm.

NOTE

- The mask itself may introduce additional rebreathed volume when compared to a tracheal or tracheostomy tube. The user must consider that additional rebreathed volume may be introduced.
- The volume of the oro and/or nasopharyngeal airway of the patient should be considered. Even though this volume is the same as a spontaneously breathing patient, it is an additional rebreathed volume when compared to a tracheal tube connection.
- Normally a small amount of leakage will occur around the mask as the patient moves or the mask is repositioned. This small mask leakage, in many cases, can carry with it some of the exhaled carbon dioxide from the mask, thus reducing added dead space.
- Only masks, specifically labeled and intended for non-invasive ventilation, should be employed on the Enve™ ventilator. Masks should not have valves or leak vents.
- Mask Leakage compensation is effective up to 30 lpm.
- It is important that a reasonably good mask seal, with the patient's face, should be achieved. Excessive leakage will adversely affect exhaled volume measurement accuracy.

NPPV Pressure

NPPV Pressure is delivered as a Pressure Control breath. Any patient trigger will receive a Pressure Control breath and the breathing pattern can be terminated by flow cycling.

NPPV CPAP/PSV

NPPV CPAP/PSV consists of CPAP breathing at the user preset baseline pressure with the option of using Pressure Support as an adjunctive adjustable pressure. The breath will be terminated by flow cycling.

Ventilation Modes

Which ventilation Modes (Breath Modes and Breath Types combined) the Enve™ ventilator displays for selection is dependant on the type of ventilator to patient interface (**Intubated** or **Non-Invasive**) selected by the operator on either the **Same Patient** or **New Patient** screens during the initial power up of the ventilator. See *Normal Ventilation Modes* in Chapter 3 – Using the Ventilator for detailed information.

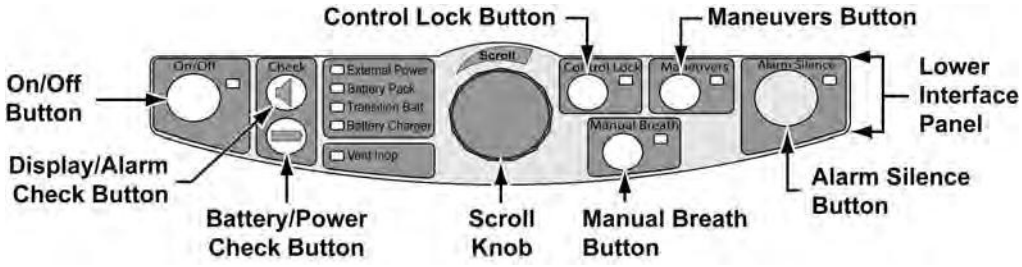
Intubated / Non-Invasive Interface Selected	Ventilation Modes Available
Intubated	Volume A/C
	Pressure A/C
	PRVC A/C
	Volume SIMV
	Pressure SIMV
	PRVC SIMV
	CPAP/PSV (Volume)
	CPAP/PSV (Pressure)
	CPAP/V_tPSV
Non-Invasive	NPPV Pressure
	NPPV CPAP/PSV

Chapter 5 - CONTROLS

This chapter provides a description of the ventilator's Main screen controls, their purpose, ranges and limits. Additional adjustable controls not represented on the Main screen are accessed, configured and set using the Utility screen. See Chapter 10 - *The Utility Screen* for additional information.

Lower Interface Panel Controls

The Lower Interface Panel controls are common to all LCD touch screen models of the PTV® Series Ventilators.



Alarm Silence Button

The **Alarm Silence** button temporarily silences an active audible alarm. The **Alarm Silence** LED is lit whenever the alarms are silenced by the **Alarm Silence** button:

- If pushed once when an alarm is sounding, **Alarm Silence** silences the audible alarm for sixty (60) seconds.
- A second push reactivates the audible alarm and extinguishes the **Alarm Silence** LED.
- If not manually reactivated (**Alarm Silence** button pushed a second time) and the original alarm conditions still exists, the audible alarm is automatically re-engaged after 60 seconds has elapsed
- If alarm conditions are resolved during the 60 second silence period, the audible alarm will not be re-engaged

Silencing the Vent Inop Alarm:

To silence the **Vent Inop** alarm, push the **Alarm Silence** button. The audible alarm is permanently silenced and the **Vent Inop** LED extinguishes.

For more about the **Vent Inop** condition, see *Vent Inop* in Chapter 8 – Ventilator Alarms.

Check Buttons

Battery/Power

The Battery/Power **Check** button allows the user to check the status of the battery and power system without interfering with the ventilator operation.

If you push and hold the Battery/Power **Check** button, the ventilator displays a message in the **Status Bar** for each of the four possible sources of power (in the sequence shown), indicating their detection and current status[19]

	Power Source			
	Removable Battery Pack	External DC Power	Docking Station	Transition Battery
Possible Status Messages Displayed	**Removable Battery xxx%**	**Ext OK**	**Dock OK**	**T-Bat OK**
	Removable Battery Removed	**Ext Low**	**Dock Low**	**T-Bat Low**
	Removable Battery Fault	**Ext Removed**	**Dock Removed**	**T-Bat Chrg**
		Ext Fault	**Dock Fault**	**T-Bat Removed**
				T-Bat Fault

NOTE

Removable Battery xxx% indicates the remaining percentage capacity of the Removable Battery Pack (**xxx** is the numeric percentage).

If a Removable Battery Pack fails to charge to more than 50% remaining capacity after 12 hours, it is time to replace it.

The power status display associated with the Battery/Power **Check** button times out after the status of all power sources has been displayed once.

If any fault message (**xxxxx Fault**) is displayed, it is an indication that the displayed source of power (**Removable Battery**, **Ext**, **Dock** or **T-Bat**) has been detected, is not adequate to power the ventilator and is a test failure for either the accessory and/or the ventilator.

See *Chapter 13 - Troubleshooting* for additional information.

[19] Refer to *Power Status LEDs* in Chapter 6 - Displays and Indicators for additional information concerning the status of various sources of power.

Display/Alarm

> **WARNING**
>
> **Check Alarms** – Alarm function should be tested periodically to ensure proper operation (see *Maintenance Schedule* in Chapter 11 – Maintenance and Cleaning, and *Display/Alarm Test* in Chapter 2- Installation and Setup for detailed instructions). If any alarm malfunctions, contact CareFusion or a service technician certified by CareFusion. Failure to immediately identify and correct alarm situations may result in serious patient injury or death.

The Display/Alarm **Check** button allows the user to check the displays, indicators and audible alarm system without interfering with the ventilator operation.

If push the Display/Alarm **Check** button, the ventilator illuminates the entire LCD Touch Screen and all Lower Interface Panel indicator LEDs in the colors as indicated below, and sounds two audible tones of similar volume followed by the High Priority Alarm Signal[20] at the set volume.

Screen / Panel	Screen / LED Color
LCD Touch Screen:	
• Entire Touch Screen (top to bottom, side to side) turns into and cycles through a colored test pattern (colors/sequence as listed)	Red
	Blue
	Green
	White
	Black
Lower Interface Panel:	

• All Power Status indicator LEDs[21]
  • **External Power**
  • **Battery Pack**
  • **Transition Batt.**
  • **Battery Charger**
	Amber

• All other indicator LEDs	Red, Green or Amber

If the audible alarm fails to sound, LCD screen pixels fail to illuminate, or illuminate in colors other than as specified above such that it impairs the users ability to properly view and interpret Touch Screen controls or data, refer to *Chapter 13 - Troubleshooting* for additional information.

[20] Refer to *Sound Types, Patterns and Volumes* in Chapter 8 - Ventilator Alarms for additional information.
[21] Refer to *Power Status LEDs* in Chapter 6 - Displays and Indicators for additional information.

Control Lock Button

Ventilation Controls and Alarm Limits settings can be locked to prevent accidental changes. To turn Control Lock on, push the **Control Lock** button. The **Control Lock** LED is lit whenever the front panel controls are locked.

Although ventilation Controls and Alarm Limits settings can not be changed when the Control Lock is enabled, the Monitors page and the monitored data to be displayed remain active and configurable.

If a ventilation control or alarm limits button is pushed while the controls are locked:

- The **Control Lock** LED flashes
- **Control is Locked** is displayed in the Status Bar
- The button push is ignored

Unlocking Controls

Two levels of difficulty (**Easy** or **Hard**) can be set for the unlocking mechanism; **Easy** unlocking is the factory-set value. The unlock difficulty setting can be changed from the **Vent Config** page on the **Utility** screen (See *Control Unlock* in Chapter 10 – The Utility Screen for additional information).

To turn the Control Lock off with **Easy** unlocking set, simply push the **Control Lock** button. The LED turns off and the controls unlock.

To turn the Control Lock off with **Hard** unlocking set, push and hold the **Control Lock** button for 3 seconds. The LED turns off and the controls unlock.

> **NOTE**
> The Increase O_2 procedure, **Manual Breath,** Battery/Power **Check**, Display/Alarm **Check** and the **Alarm Silence** controls are not affected by the Control Lock and operate even when it is on.

Maneuvers Button

The **Maneuvers** button activates a maneuver which has already been configured and armed using touch screen options.

For more details on how to set up and run maneuvers, see *Chapter 9 - Maneuvers, Procedures and Standby Mode*.

Manual Breath Button

Pushing the **Manual Breath** button will deliver one (1) Machine breath. The breath is a Machine breath as defined by the current ventilator settings. The **Manual Breath** LED is on during the Manual Breath inspiration. When in CPAP/PSV mode, the ventilator will deliver one (1) breath based on the A/C setting for the current breath type.

The **Manual Breath** button is only enabled during exhalation.

On/Off Button

The **On/Off** button turns the ventilator on or off.

- When the ventilator is on, the **On/Off** LED is lit
- When the ventilator is off, the **On/Off** LED is off

To turn the ventilator On:

Push the **On/Off** button once.

To turn the ventilator Off:

Push and hold the **On/Off** button for 3 seconds. A Vent Inop alarm occurs and the **Vent Inop** LED lights up. To silence the alarm and extinguish the **Vent Inop** LED, push the **Alarm Silence** button.

Scroll Knob

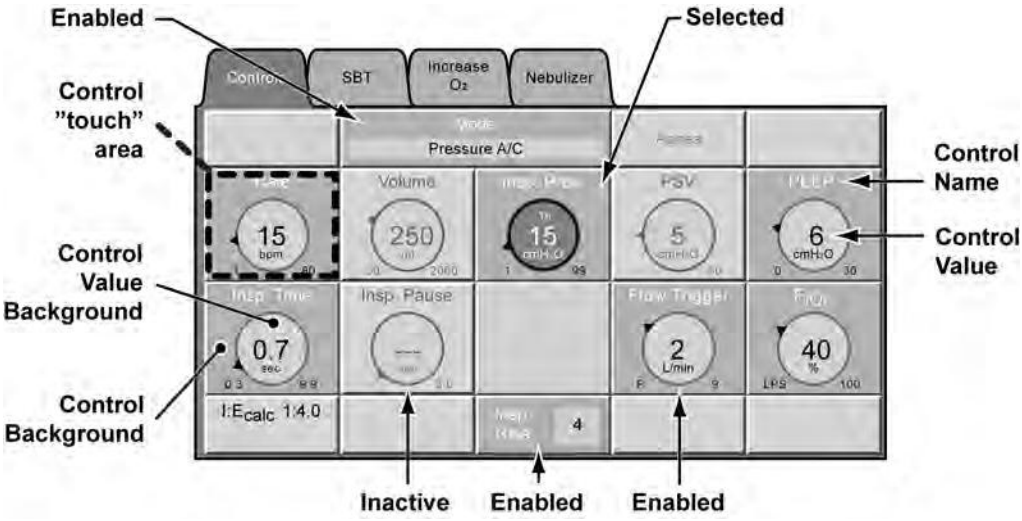
The **Scroll** knob is a rotary knob encoder used to change the setting of a selected adjustable control.

Rotating the **Scroll** knob clockwise increases the value of a selected control or alarm. Rotating the **Scroll** knob counter-clockwise decreases the selected value. The selected value stops incrementing when it reaches its low or high range limit or when it is limited by another control setting. The Scroll knob is speed sensitive, meaning that when you rotate it quickly, each detent changes the setting more than when you rotate it slowly.

For the Scroll knob to function, a control has to be selected. If no adjustable controls or alarms are selected, rotating the Scroll knob has no effect. If the Scroll knob is not rotated within 15 seconds after a control has been selected, the control or alarm limit is automatically deselected.

Main Screen, Adjustable Ventilation Controls

The controls shown below can be adjusted to affect breath delivery. They are modified via the touch screens', **Main** screen, **Controls** page.



Control Limiting

Adjustable control settings may be limited to less than their specified range for any of the following reasons:

- To prevent inverse I:E ratios of greater than 4:1
- To ensure a minimum inspiration time of 300 ms
- To ensure a minimum exhalation time of 346 ms
- To ensure a minimum flow of 10 L/min for Volume Controlled breaths
- To ensure a maximum initial flow of 120 L/min for Volume Controlled breaths
- To ensure that Flow Trigger sensitivity is less than Bias Flow
- To ensure a maximum Pressure Control pressure of 99 cmH_2O
- To ensure a maximum Pressure Support pressure of 60 cmH_2O

When you are adjusting a control and reach a pre-imposed limit, the following things happen:

- The control stops updating and displays a constant value (the high or low limit)
- The control flashes
- The displays for other controls involved in the limited condition flash

To set the control to a value that is limited by other controls, you must modify the settings for the other controls involved in the limit condition. For instance, if the Breath Rate (**Rate**) is set to 12 breaths per minute, the maximum allowed Inspiratory Time to achieve that rate is 4.0 seconds. To set the Inspiratory Time (**Insp. Time**) to more than 4.0 seconds, you must first decrease the Breath Rate.

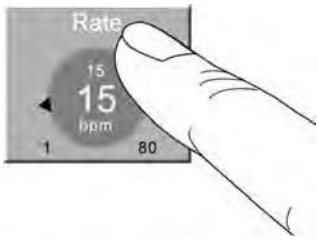
Active Controls by Ventilation Mode

The following matrix shows which controls are active in each Mode of ventilation. Active controls display normally while inactive controls which do not affect breath delivery in a specific mode or breath type appear with gray text with gray background. The inactive controls may still be modified for the purposes of modifying a “limit” situation or to set up Apnea Backup parameters but they will not affect the delivery of a breath in the currently selected mode.

	Ventilation Modes										
Controls	**Volume A/C**	**Pressure A/C**	**PRVC A/C**	**Volume SIMV**	**Pressure SIMV**	**PRVC SIMV**	**CPAP/PSV (Volume)**	**CPAP/PSV (Pressure)**	**CPAP/Vt PSV**	**NPPV Pressure**	**NPPV CPAP/PSV**
Bias Flow	X	X	X	X	X	X	X	X	X	X	X
FiO_2	X	X	X	X	X	X	X	X	X	X	X
Flow Cycle		X	X		X	X				X	
Flow Trigger	X	X	X	X	X	X	X	X	X	X	X
Insp. Pause	X			X							
Insp. Pres		X			X					X	
Insp. Rise		X	X		X	X				X	
Insp. Time	X	X	X	X	X	X			X	X	
Leak Comp	X	X	X	X	X	X	X	X	X	X	X
PEEP	X	X	X	X	X	X	X	X	X	X	X
Pressure Trigger	X	X	X	X	X	X	X	X	X	X	X
PSV				X	X	X	X	X			X
PSV Cycle				X	X	X	X	X	X		X
PSV Rise				X	X	X	X	X	X		X
PSV t_{max}				X	X	X	X	X			X
Rate	X	X	X	X	X	X				X	
Volume	X		X	X		X			X		
	Intubated Patient Interface									**Non-Invasive Patient Interface**	

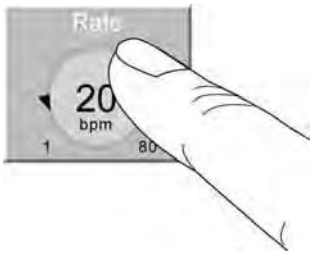
To Set a Primary Breath Control:

1) **Select** the control by touching the screen directly over the control to be changed. The background area surrounding the displayed value is high-lighted and a reference value is displayed above the original setting value.



2) **Change** the setting by turning the **Scroll** knob on the Lower Interface Panel clockwise or counter-clockwise. The displayed value will change but will not yet affect ventilator function.

3) **Confirm** the new value by touching the screen directly over the control again. The background area surrounding the displayed value reverts to its previous color and the ventilator accepts the new value.



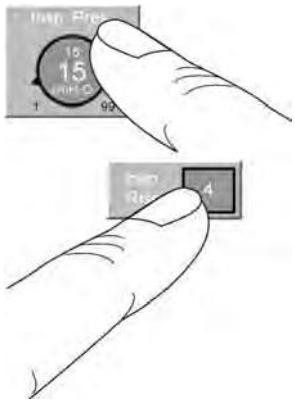
To Set an Advanced Setting:

Advanced Settings controls are only displayed at the bottom of the **Main** screen, **Controls** page when its associated Primary breath control is selected, as follows:

Ventilation Modes	Primary Breath Control Selected	Associated Advanced Settings Controls Displayed			
		Flow Cycle	**Insp. Rise**	**PSV Rise, PSV Cycle, & PSV T_{max}**	**Pressure Trigger, Bias Flow, & Leak Comp**
Volume A/C Volume SIMV Pressure A/C Pressure SIMV CPAP/PSV (Volume) CPAP/PSV (Pressure)	**Insp. Time**	X			
	Insp. Pres.		X		
	PSV			X	
	Flow Trigger				X
PRVC A/C PRVC SIMV	**Insp. Time**	X			
	Volume		X		
	PSV			X	
	Flow Trigger				X
CPAP/V_tPSV	**Volume**			X	
	Flow Trigger				X

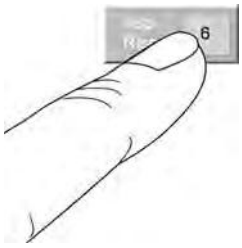
1) **Select** the Advanced Settings control by first touching the screen directly over the associated Primary breath control. The Primary control is selected and the associated Advanced Settings control(s) is displayed and enabled.

   Select the Advanced Settings control to be changed by touching the screen directly over it. The background area surrounding the displayed value is high-lighted.



2) **Change** the setting by turning the **Scroll** knob on the Lower Interface Panel clockwise or counter-clockwise. The displayed value will change but will not yet affect ventilator function.

3) **Confirm** the new value by touching the screen directly over the control again. The background area surrounding the displayed value reverts to its previous color and the ventilator accepts the new value.



Controls Page, Adjustable Controls

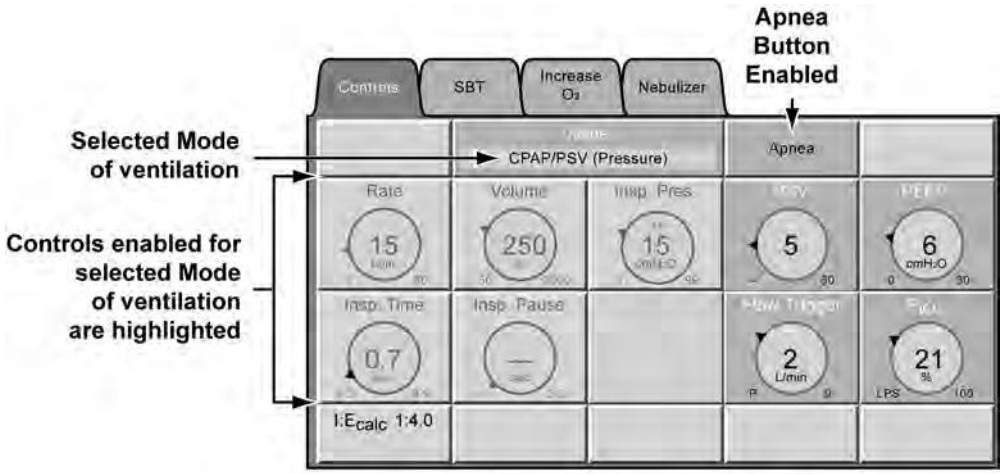
Apnea

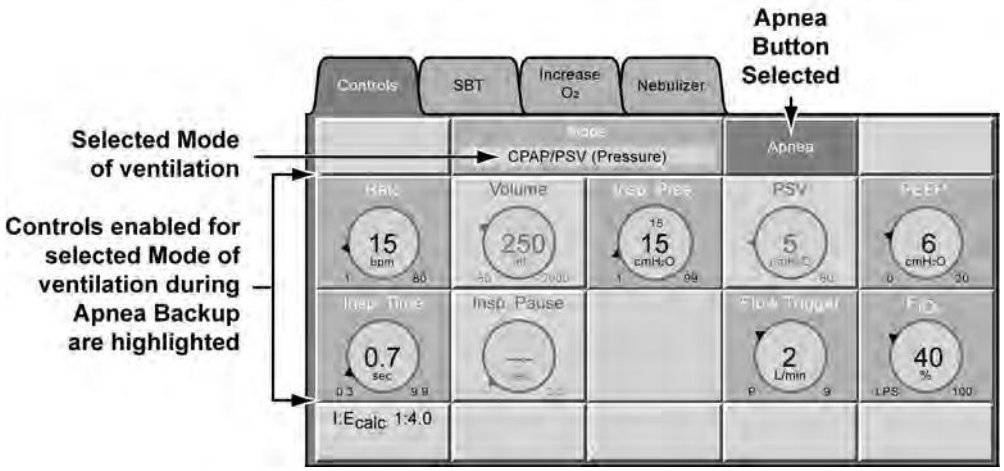
Touch (select) the **Apnea** button (accessible on the **Main** screen, **Controls** page) to highlight/indentify the controls that will be enabled during Backup Apnea ventilation for the selected mode.

- Touching the **Apnea** button a second (2nd) time returns the controls to their normal state (the controls enabled for the selected mode are highlighted)
- This button automatically deactivates after 30 seconds of inactivity

NOTE

Apnea Control – The **Apnea** control button on the **Main** screen, **Controls** page is only enabled during CPAP modes of ventilation.





See *Apnea* and *Apnea Interval* in Chapter 8 – Ventilator Alarms for detailed information about the Apnea alarm and setting the Apnea Interval.

Bias Flow

The **Bias Flow** control provides a continuous flow through the patient circuit during the exhalation phase of breaths.

Range: **3 L/min** through **10 L/min,** in increments of 1 L/min

Bias Flow reduces the work of breathing by providing a flow source for flow triggering. Bias Flow not consumed by the patient exits the patient circuit through the exhalation valve.

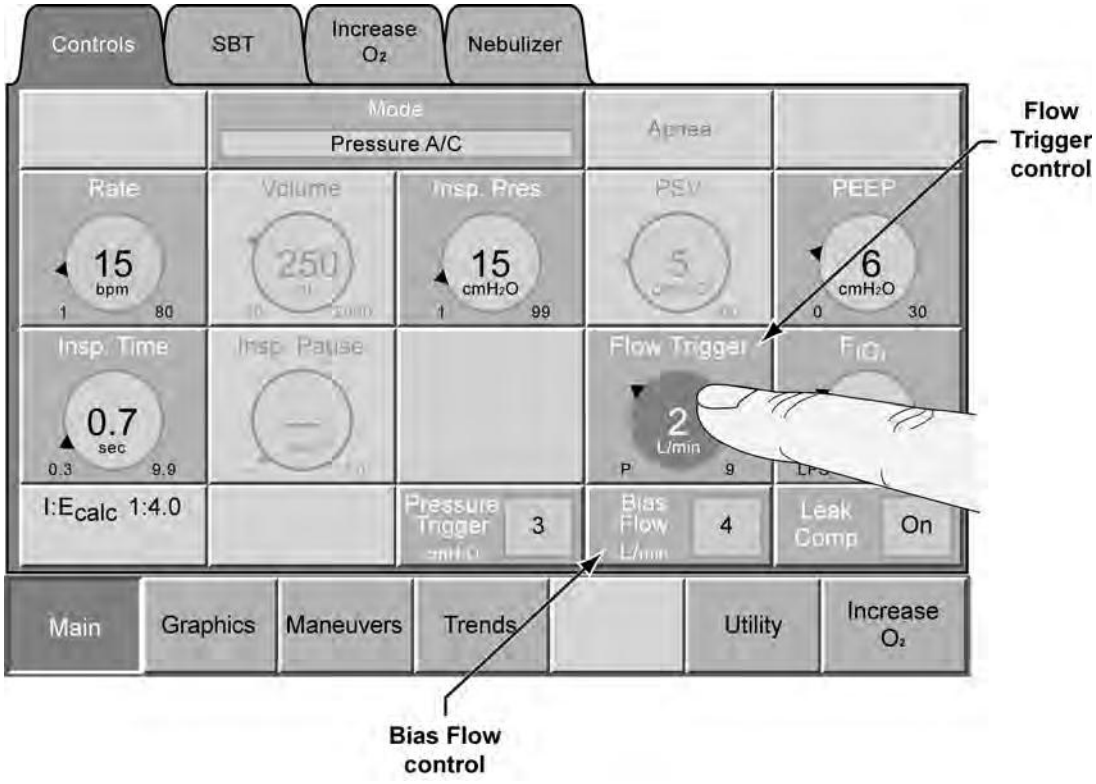
To Set Bias Flow:

Select Touch the **Flow Trigger** control to display the **Bias Flow** control, and then touch the **Bias Flow** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The **Bias Flow** control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

Confirm Touch the **Bias Flow** control again.



NOTE

When Leak Compensation is enabled (**On**), the Bias Flow is automatically increased by the amount of the measured leak.

The Air/O_2 mix of the Bias flow is dependent on the set **F_{IO_2}** control value and therefore affects Oxygen consumption.

FIO_2 (Inspired Oxygen)

Using a High Pressure O_2 Source:

When the ventilator is attached to a high pressure oxygen source of 40 PSI (2.8 bar, 276 kPa) to 88 PSI (6.1 bar, 607 kPa), this control is used to adjust the percentage of oxygen to be delivered through the ventilator's oxygen blending system.

Range: **LPS, 21** through **100%**

NOTE

- During an active Nebulization procedure the High O_2 Inlet source pressure must be limited to **40 PSI** (2.8 BAR, 276 kPa) to **66 PSI** (4.5 BAR, 455 kPa).
- When the FiO_2 setting is changed (FiO_2 Control setting, Increase O_2 Procedure started, or SBT FiO_2 Control setting) the **High FiO_2** alarm is deactivated for 120 seconds.

When the ventilator is attached to a low pressure O_2 source such as an oxygen concentrator or line mounted flow meter, this control must be set to **LPS** (Low Pressure Source). See *Using a Low Pressure O2 Source:* in this chapter for additional information.

WARNING

Oxygen Blending - Oxygen blending on the Enve™ ventilator requires a high pressure oxygen source and is active only when the Low Pressure Source (**LPS**) setting on the **FiO_2** control is *not* selected. If **LPS** is selected and the ventilator is using a low pressure O_2 source of <10 PSI (< 0.69 bar, < 69 kPa), the percentage of oxygen in the patient circuit is *not* controlled by the ventilator's oxygen blender and must be controlled from the gas source.

To Set FIO_2:

Select Touch the **FiO_2** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

WARNING

Inspired Oxygen (FIO_2) Concentration – If exact concentrations of inspired oxygen (FIO_2) must be delivered to the patient, it is recommended that the optional FIO_2 Sensor or a separate oxygen analyzer with alarms be used. If using the optional FIO_2 Sensor set the ventilator High and Low FiO_2 alarms appropriately (see *High FiO2* and *Low FiO2* alarms in Chapter 8 – *Ventilator Alarms* for additional information).

Using a Low Pressure O_2 Source:

When the **FiO_2** control is set to **LPS**, oxygen can be supplied from a low pressure / low flow oxygen source of < 10 PSI (< 69 BAR, < 69 kPa) such as a flow meter. Oxygen from the low pressure source is mixed with air inside the ventilator. When connected to a low pressure source, the estimated O_2 percent delivered to the patient is determined by the O_2 inlet flow and the total minute volume and is *not* regulated by the ventilator. Use the Input O_2 Flow chart (shown below) to determine the correct O_2 flow for the desired FIO_2.

When the **FiO_2** control is set to **LPS**, the following conditions are applicable:

- The O_2 inlet flow must be set to obtain the desired oxygen percentage (see chart)
- The Low O_2 Inlet Pressure alarm (**Loss of O_2**) is inactive
- The **High O_2 Inlet Pressure** alarm activates at 10 PSI (69 BAR, 69 kPa)

When the **FiO_2** control is set greater than 21% (**22 - 100%**), the following conditions are applicable:

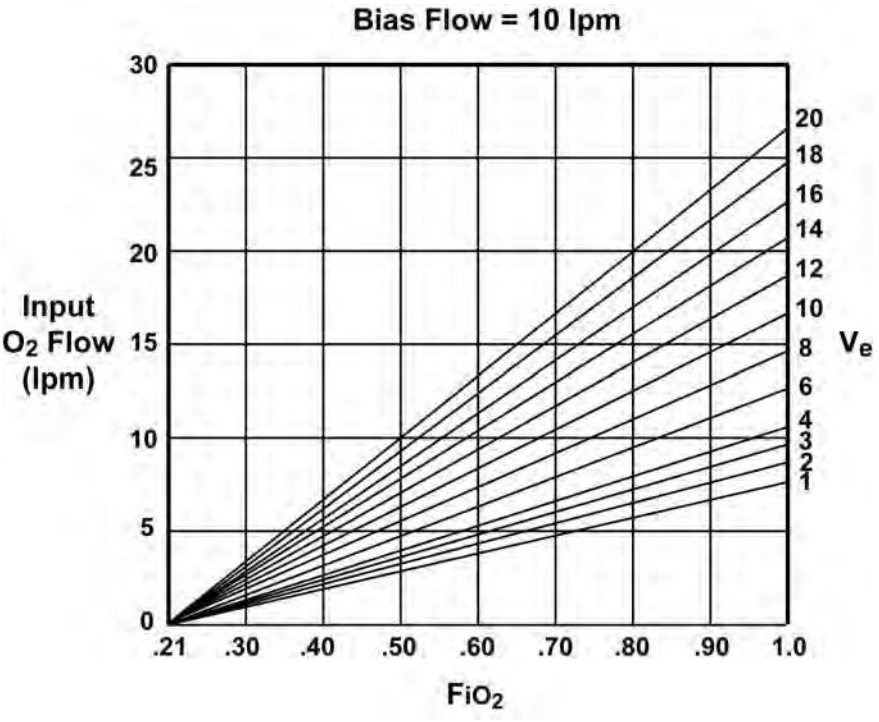
- The Low O_2 Inlet Pressure alarm (**Loss of O_2**) activates at 39 PSI (2.69 BAR, 269 kPa)

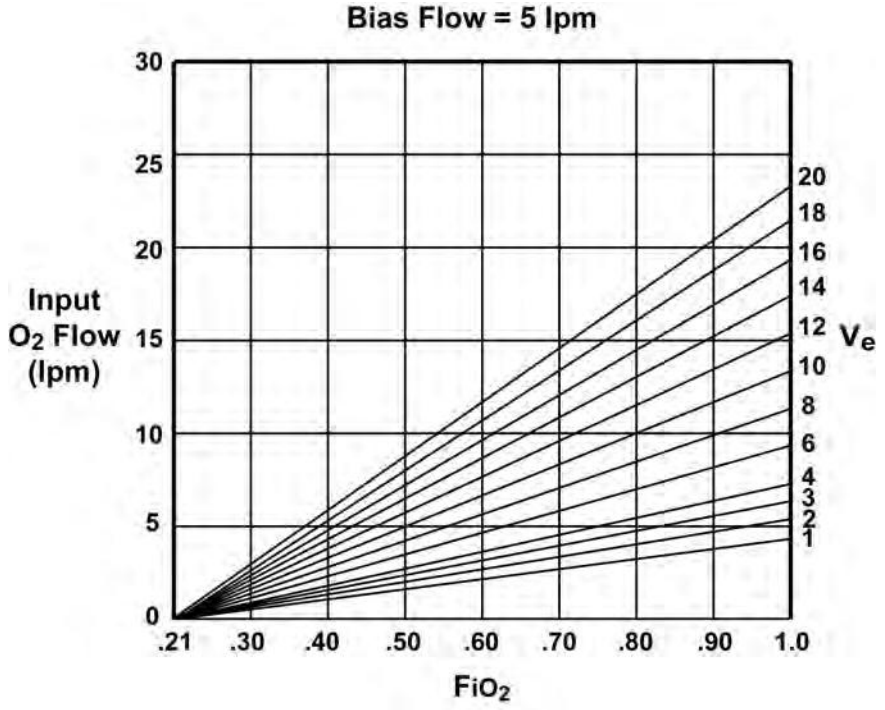
WARNING

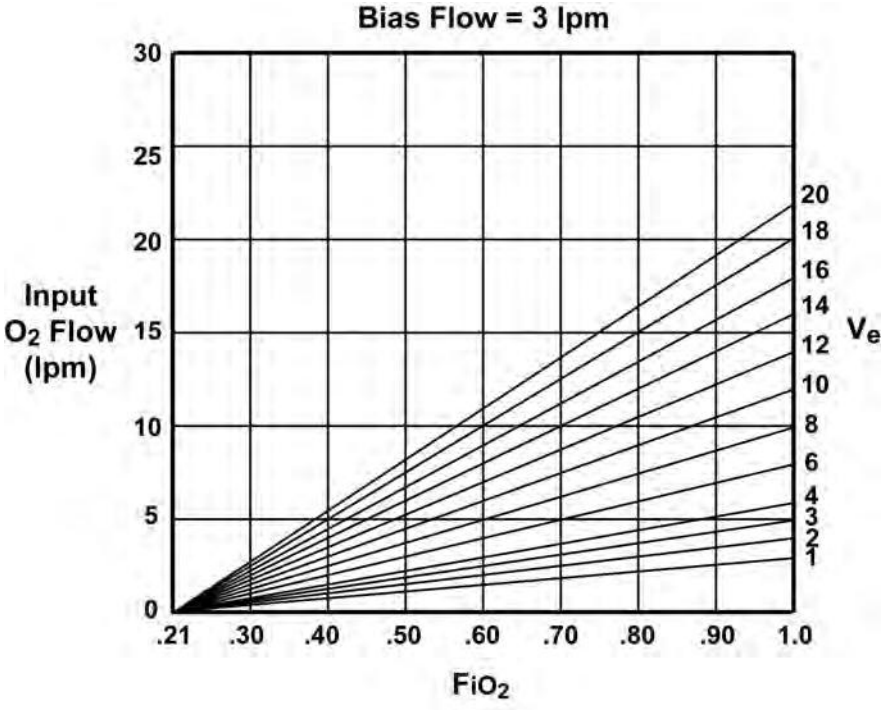
Inspired Oxygen (FIO_2) Concentration – Minute volumes can fluctuate if the patient has a variable respiratory rate. If *exact concentrations* of inspired oxygen (FIO_2) must be delivered to the patient, it is recommended that the optional FIO_2 Sensor or a separate oxygen analyzer with alarms be used. If using the optional FIO_2 Sensor set the ventilator High and Low FiO_2 alarms appropriately (see *High FiO2* and *Low FiO2* alarms in Chapter 8 – *Ventilator Alarms* for additional information).

Setting the Flow for Low Pressure Oxygen Blending:

Use one of the 3 following charts and the accompanying instructions to determine the required low pressure O_2 flow setting to deliver the desired FIO_2.

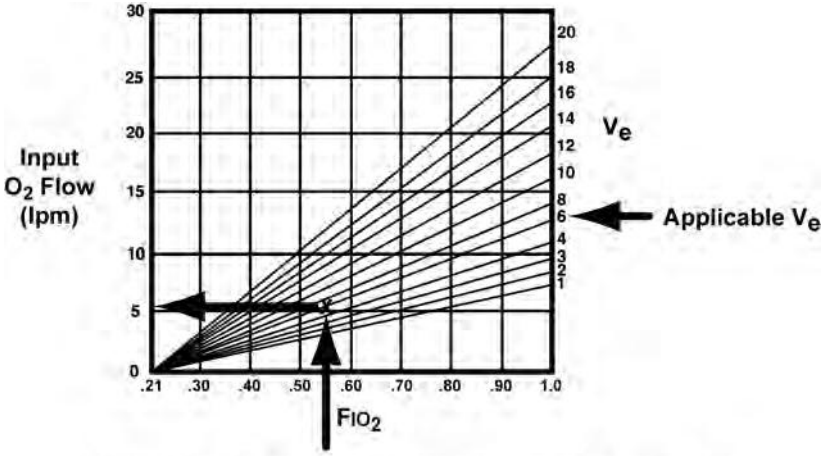



Bias Flow = 5 lpm
Input
O_2 Flow
(lpm)
30
25
20
15
10
5
0
.21
.30
.40
.50
.60
.70
.80
.90
1.0
FiO_2
20
18
16
14
12
10
8
6
4
3
2
1
V_e


Bias Flow = 3 lpm
Input
O_2 Flow
(lpm)
30
25
20
15
10
5
0
.21
.30
.40
.50
.60
.70
.80
.90
1.0
FiO_2
20
18
16
14
12
10
8
6
4
3
2
1
V_e

To Determine the Required O_2 Input Flow:

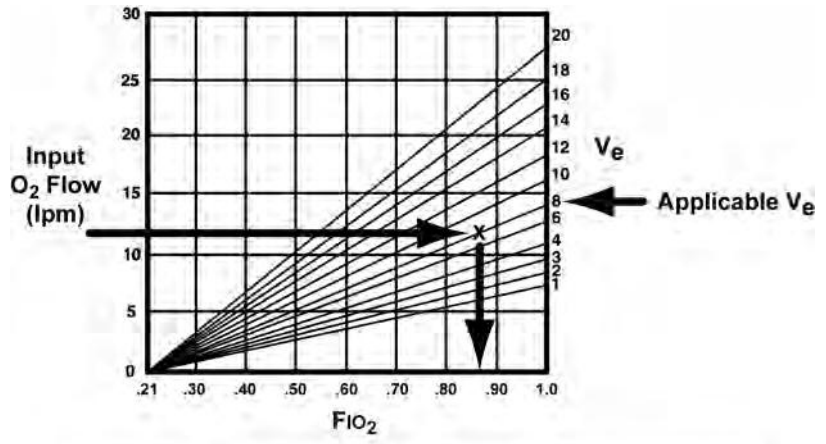
1) Select the appropriate chart based on the **Bias Flow** setting. When Leak Compensation is on, the patient leak should be added to the Bias Flow value.
2) Identify the desired F_{IO_2} (bottom of chart).
3) Calculate the patient's Minute Volume (V_e) rate by using the formula: Tidal Volume x Breath Rate. Locate the Minute Volume reading (right side of chart).
4) Follow the vertical F_{IO_2} line up to the applicable slanted V_e (Minute Volume) line.
5) From where they intersect, read across horizontally to the left side of chart to the required Input O_2 Flow (L/min).



Example - To determine the required O_2 input flow

To Determine the Estimated Delivered O_2 Concentration:

1) Select the appropriate chart based on the **Bias Flow** setting. When Leak Compensation is on, the patient leak should be added to the Bias Flow value.
2) Find the Input O_2 Flow (left side of chart).
3) Follow the Input O_2 Flow across horizontally to the right to the applicable slanted V_e (Minute Volume) line.
4) Read down to the F_{IO_2} (bottom of chart).



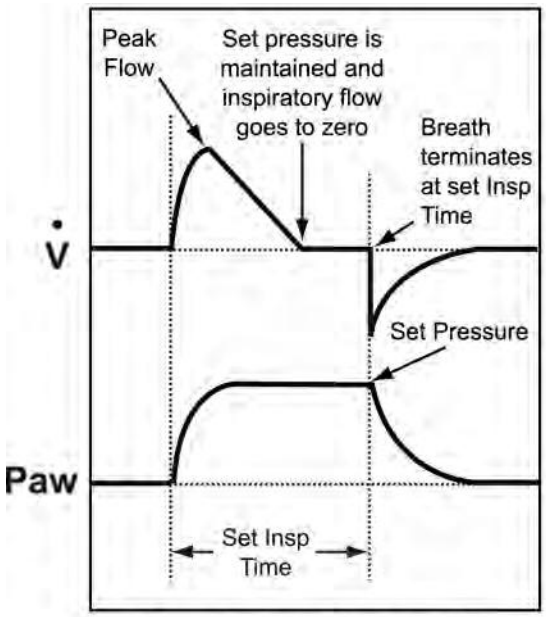
Example - To determine the delivered O_2 concentration

Flow Cycle

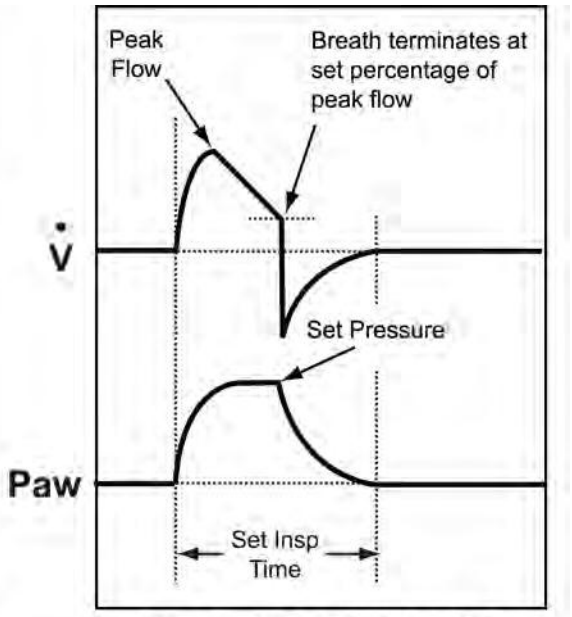
The **Flow Cycle** control sets the percentage of Peak Flow at which Pressure Control and PRVC breaths are cycled. The breath is cycled from inspiration to exhalation when the flow is less than the set **Flow Cycle** setting, or when the flow is less than 2 L/min.

When the **Flow Cycle** control is set to "**- -**" (off), the Pressure Control and PRVC breaths are not flow cycled - they will cycle at the set **Insp. Time**.

Range: "**- -**"(off), or **10** through **40%**



Flow Cycle set to "- -" (Off)
Breath terminates at set Insp. Time



Flow Cycle set to 10% - 40%
Breath terminates at the set percentage of Peak Flow

NOTE

A Flow Terminated breath symbol is displayed in the Airway Pressure Manometer (until the next breath is initiated) to indicate that a Pressure Control or Pressure Regulated Volume Control breath has been flow terminated.

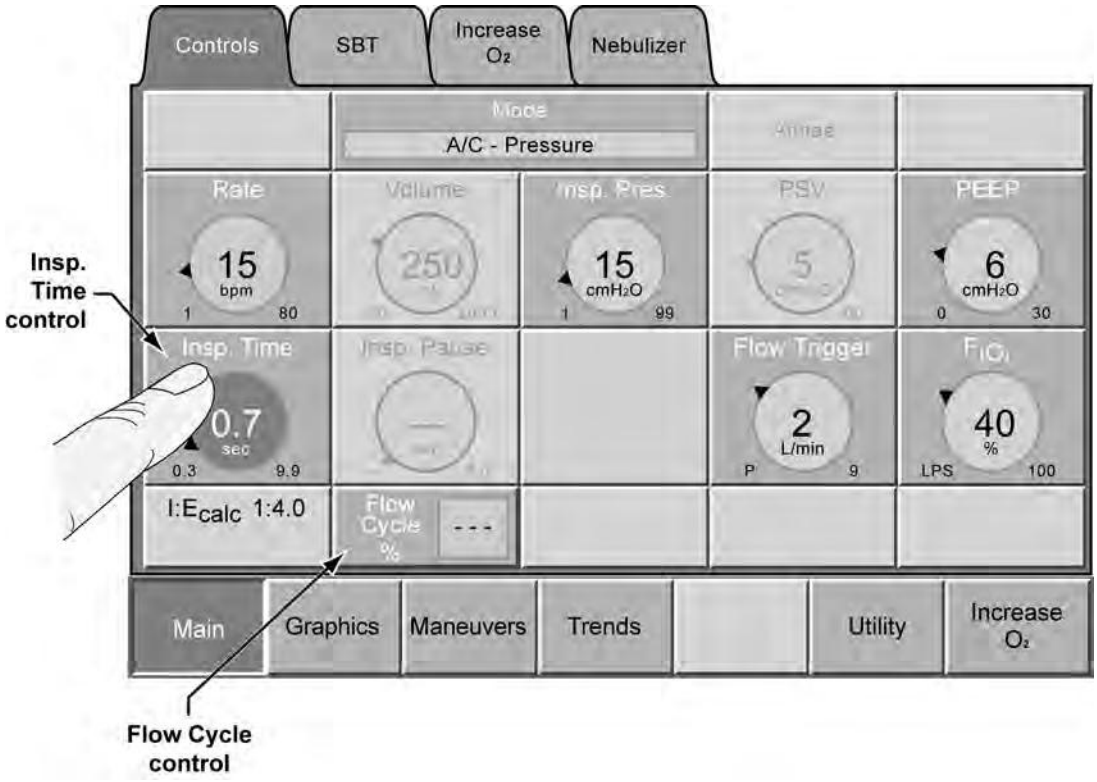
In **CPAP/PSV (Pressure), CPAP/V_tPSV** and **NPPV CPAP/PSV** settings, the **Flow Cycle**. control establishes the flow termination criteria for Apnea Backup ventilation. Be sure to set it appropriately (see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes for additional information).

To Set Flow Cycle:

Select Touch the **Insp. Time** control to display the **Flow Cycle** control, and then touch the **Flow Cycle** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.



Flow Trigger

The **Flow Trigger** control establishes the threshold level to allow the patient to trigger breaths.

Range: "**P**", or **1** through **9 L/min**

1 is the most sensitive, **9** is the least sensitive for flow triggering,

P indicates pressure triggering is enabled (see *Pressure Trigger* in Chapter 5 – Controls).

NOTE

Bias Flow - To assist with flow triggering, the ventilator provides a level of bias flow during exhalation which is set using the **Bias** control (see *Bias Flow* in Chapter 5 – Controls).

When a patient demand is detected, the **Patient Effort** symbol in the Airway Pressure Manometer is briefly highlighted.

Flow Trigger – The Flow Trigger is automatically set to 2 lpm when the **Breath Mode** is changed to **CPAP/PSV (Volume)**, **CPAP/PSV (Pressure)**, **CPAP/V_tPSV**, or **NPPV CPAP/PSV** and the **Flow Trigger** control was previously set to "**P**" (Pressure Trigger).

A flow trigger occurs when:

- The **Flow Trigger** is set to a value from **1** to **9,**
- The ventilator is in exhalation phase,
- The minimum exhalation time has expired, and
- The flow is greater than or equal to the **Flow Trigger** setting

A backup breath is delivered when:

- The ventilator is in exhalation phase,
- The minimum exhalation time has expired, and
- The airway pressure drops below -3 cmH_2O

NOTE

When using the ventilator in transport situations, excessive movement of the patient circuit may cause auto cycling. Consider adjusting **Flow Trigger** sensitivity or utilizing pressure triggering ("**P**").

To Set Flow Trigger:

Select Touch the **Flow Trigger** control.

- When the **Flow Trigger** control is touched, the **Pressure Trigger, Bias Flow** and **Leak Comp** controls are displayed

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The **Flow Trigger** control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

Confirm Touch the control again.

Insp. Pause

Inspiratory Pause extends the inspiratory phase of Volume Control and Volume Assist breaths by the set **Insp. Pause** interval. During the pause, there is no flow in or out of the circuit.

Range: "**- -**"(off), or **0.1** through **3.0 sec**

To Set Insp. Pause:

Select Touch the **Insp. Pause** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The **Insp. Pause** control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

Confirm Touch the control again.

Insp. Pres

This control establishes the target pressure above PEEP for Pressure Control breaths. The ventilator controls inspiratory flow to maintain the set circuit pressure for the inspiratory time.

Range: **1** through **99 cmH_2O**

To Set Insp. Pres:

Select Touch the **Insp. Pres** control.

- When the **Insp**. **Pres** control is touched, the **Insp**. **Rise** control is displayed

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The **Insp. Pres** control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

Confirm Touch the control again.

NOTE

Flow Termination is available for Pressure Control breaths (see *Flow Cycle* in this chapter).

A Flow Terminated breath symbol is displayed in the Airway Pressure Manometer (until the next breath is initiated) to indicate that a Pressure Control or Pressure Regulated Volume Control breath has been flow terminated. 

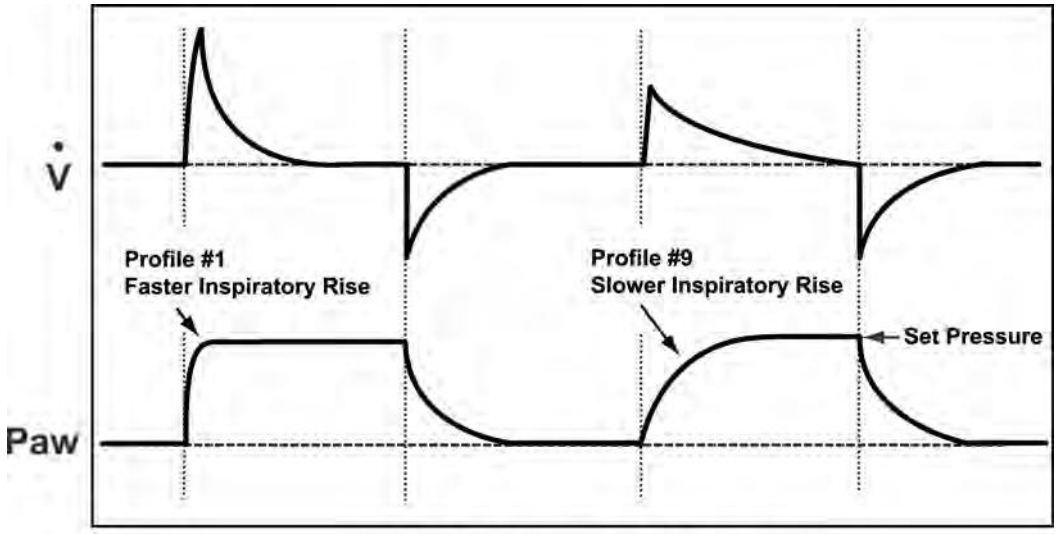
The inspiratory rise time for pressure Control breaths can be adjusted using the **Insp**. **Rise** control (see *Insp. Rise* in this chapter).

In **CPAP/PSV (Pressure)** and **NPPV CPAP/PSV** settings, the **Insp**. **Pres**. control establishes the target pressure above PEEP for Apnea Backup ventilation. Be sure to set it appropriately (see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes for additional information).

Insp. Rise

The **Insp. Rise** control allows you to select a inspiratory rise time profile for Pressure Control and PRVC breaths. The rise time profiles are numbered 1 through 9 where 1 is the fastest rise time and 9 is the slowest rise time. Starting with the fastest rise time (Profile 1), each increment in rise time is approximately 33% longer than the previous one. The rise time setting takes effect on the next Pressure Control or Pressure Support breath.

Range: **1** through **9**, in increments of 1



Adjusting Inspiratory Rise on Pressure Control Breaths

NOTE

In **CPAP/PSV (Pressure), CPAP/V_tPSV** and **NPPV CPAP/PSV** settings, the **Insp**. **Rise** control establishes the inspiratory rise time profile for Apnea Backup ventilation. Be sure to set it appropriately (see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes for additional information).

To Set Insp. Rise:

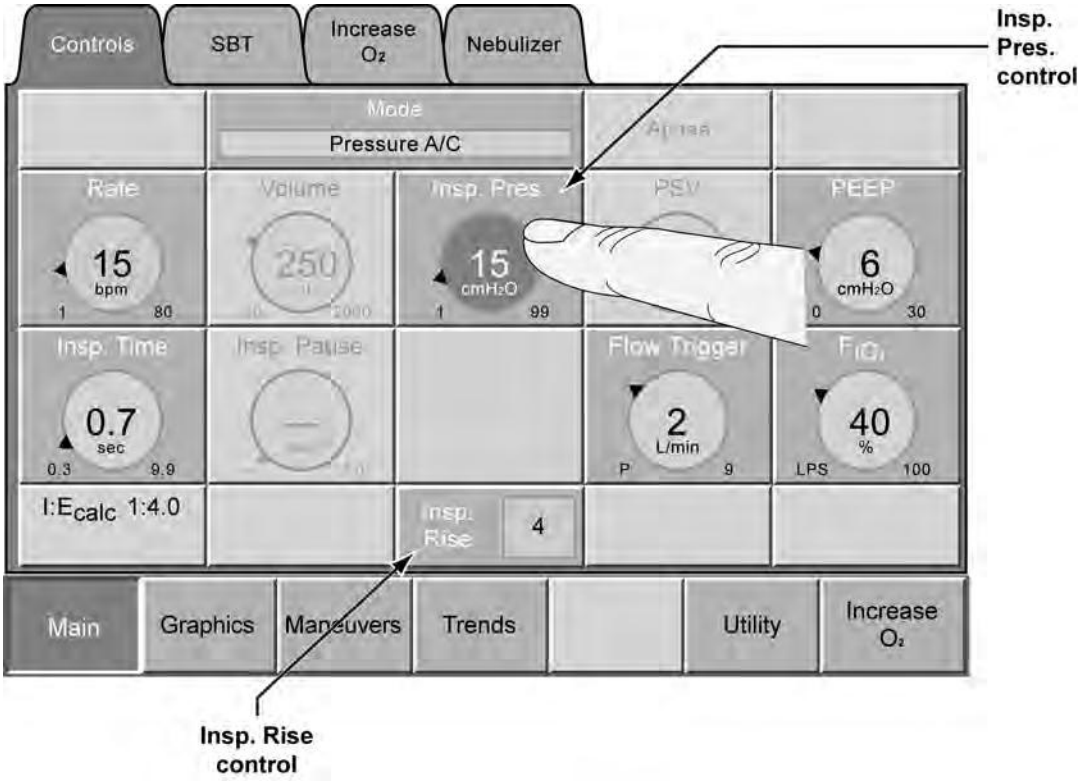
Select Touch the **Insp. Pres.** control to display the Insp. Rise control, and then touch the **Insp. Rise** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

NOTE

If the set **Insp. Rise** profile exceeds the set Inspiration Time value, the target pressure may not be achieved.



Insp. Time

The **Insp. Time** control sets the duration of the Inspiratory phase of Volume Controlled, Pressure Controlled and PRVC breaths.

Range**:** **0.3** through **9.9 sec**

> **NOTE**
>
> The calculated peak flow ($\dot{V}_{I\ calc}$**)** monitor is updated while **Volume** or **Insp. Time** settings for a volume breath are being changed.
>
> The calculated I:E Ratio (**I:E**$_{calc}$) monitor is updated while Breath Rate (**Rate**) or **Insp**. **Time** settings are being changed.

To Set the Insp. Time:

Select Touch the **Insp. Time** control.

- When the **Insp**. **Time** control is touched, the **Flow Cycle** control is displayed

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The **Insp. Time** control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

Confirm Touch the control again.

The **Insp. Time** setting, along with the **Volume** settings are used to determine peak flow for Volume controlled breaths.

> **NOTE**
>
> When in any CPAP/PSV ventilation mode, the **Insp. Time** control establishes the inspiratory time in Apnea Backup ventilation. Be sure to set it appropriately (see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes for additional information).

Leak Comp

Leak Compensation tracks steady state exhaled flow to improve monitored patient flow accuracy in the presence of a stable circuit leak.

NOTE

- **Leak Stability** - If a leak is unstable during exhalation, it will not be detected and will not be compensated for
- **Expiratory Limb Leak –** A leak on the expiratory limb may not be detected and may not be compensated for depending on the size of leak
- **Limitation of Compensation** - The limitation of compensation is determined by the range and accuracy of the $\dot{V}_{leak}$ (Measured Leak) monitor and the set Bias Flow.

When set to **On**, the following measurements are compensated:

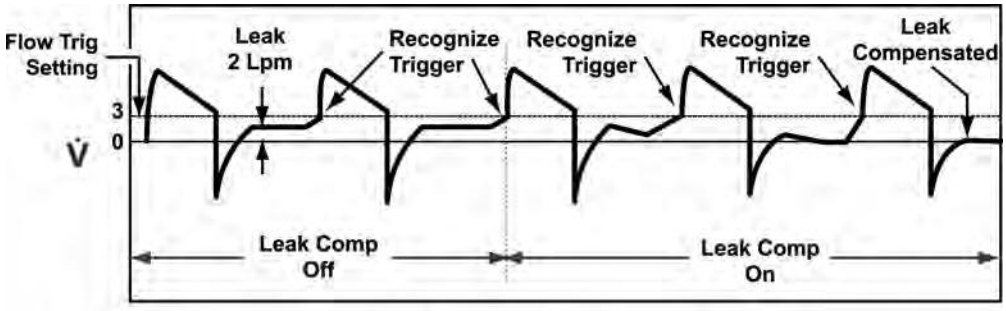
- Flow Triggering
- Flow Waveform
- Exhaled Tidal Volume Monitor
- Spontaneous Exhaled Tidal Volume Monitor
- Inspiratory Tidal Volume Monitor
- Volume Waveform
- Delivered Bias Flow (leaks up to 30 L/min)

The **Leak Comp** control is used to turn the Leak Compensation feature on or off.

Range: **On** or **Off**

If auto cycling occurs, it may be helped by the following procedure:

1) Set **Flow Trigger** to a value higher than the leak amount (see *Flow Trigger* in this chapter).
2) Set **Leak Comp** to **On**.
3) Wait for a period of 10 through 15 breaths.
4) Reset **Flow Trigger** to desired level.



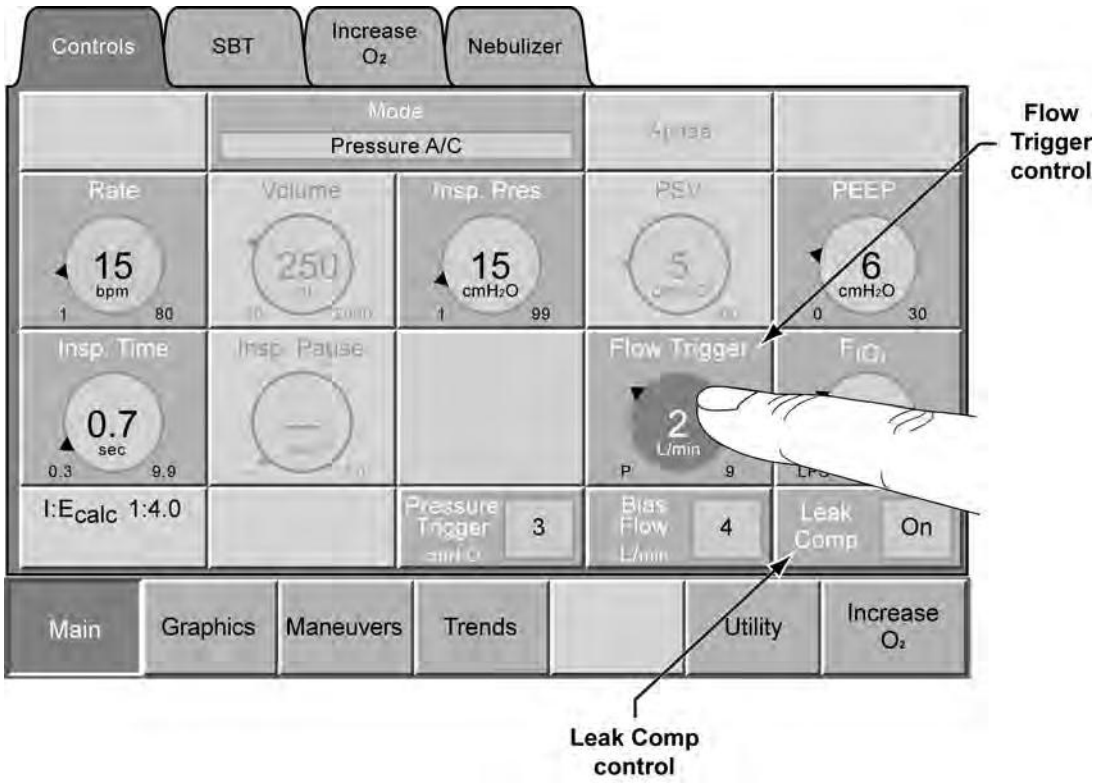
Leak Compensation - Off to On

To Set Leak Comp

Select Touch the **Flow Trigger** control to display the **Leak Comp** control, and then touch the **Leak Comp** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise or counter-clockwise to change the setting.

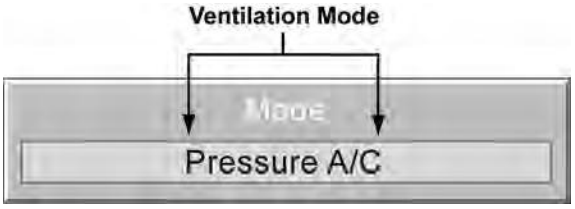
Confirm Touch the control again.



Mode

Use the **Mode** control to select between the following ventilation Modes (Breath Mode and Breath Type combined):

Intubated / Non-Invasive Interface Selected	Ventilation Modes Available
Intubated	Volume A/C
	Pressure A/C
	PRVC A/C
	Volume SIMV
	Pressure SIMV
	PRVC SIMV
	CPAP/PSV (Volume)
	CPAP/PSV (Pressure)
	CPAP/VtPSV
Non-Invasive	NPPV Pressure
	NPPV CPAP/PSV



For more detailed information concerning ventilation modes, see *Breath Types*, *Breath Modes* and *Ventilation Modes* in Chapter 4 - Breath Types and Modes.

To Set the Mode:

The ventilation **Mode** is set or changed in a manner similar to the way all other adjustable controls are changed ("Select, Change, and Confirm"), except the last step requires touching an **Accept** button ("Select, Change, and Accept") rather than touching the control for a second time.

Select Touch the **Mode** control.

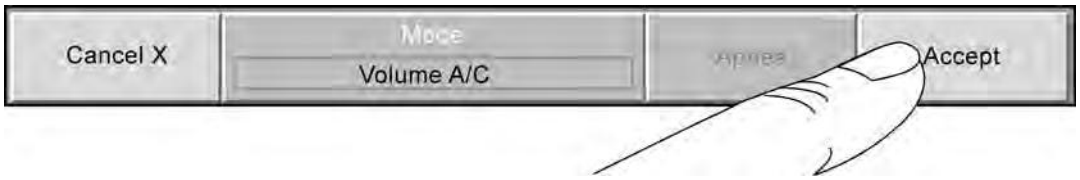
- The background for the **Mode** control, its displayed ventilation mode and all controls associated with that control are highlighted indicating Batch mode. In Batch mode all control changes are tentative until the **Accept** button is touched.
- Flashing **Accept** and **Cancel** pop up buttons are displayed

Change Rotate the **Scroll** knob on the Lower Interface Panel until the desired ventilation mode is displayed.

- As each mode is displayed, the background of the controls that would be active for that particular ventilation mode are highlighted
- ***If desired***, any other control value may also be selected/changed at this time using the normal "Select, Change and Confirm" process for those controls. Again, the ventilator is in Batch mode and these changes will not take effect until the **Accept** button is touched.

Accept Touch the **Accept** button within 30 seconds of last activity to accept all Batch mode changes

- All controls changed while in Batch mode will affect ventilation at the same time when (and only when) the **Accept** button is touched
- Touching the **Cancel** button reverts all control changes to their previous state, as does 30 seconds of inactivity



PEEP

The **PEEP** control establishes Positive End Expiratory Pressure, which is the pressure maintained in the circuit at the end of exhalation.

Range: **0** through **30 cmH_2O**

To Set PEEP:

Select Touch the **PEEP** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The **PEEP** control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

Confirm Touch the control again.

Pressure Trigger

The **Pressure Trigger** control establishes the threshold level to allow the patient to trigger breaths.

Range: **1** through **20 cmH_2O** below PEEP

> **NOTE**
>
> When a patient demand is detected, the **Patient Effort** symbol in the Airway Pressure Manometer is briefly highlighted. 

A Pressure trigger occurs when:

- The **Flow Trigger** is set to **P**,
- The ventilator is in exhalation phase,
- The minimum exhalation time has expired, and
- The airway pressure drops below or equal to the **Pressure Trigger** setting

A backup breath is delivered when:

- The ventilator is in exhalation phase,
- The minimum exhalation time has expired, and
- The airway pressure drops below -3 cmH_2O

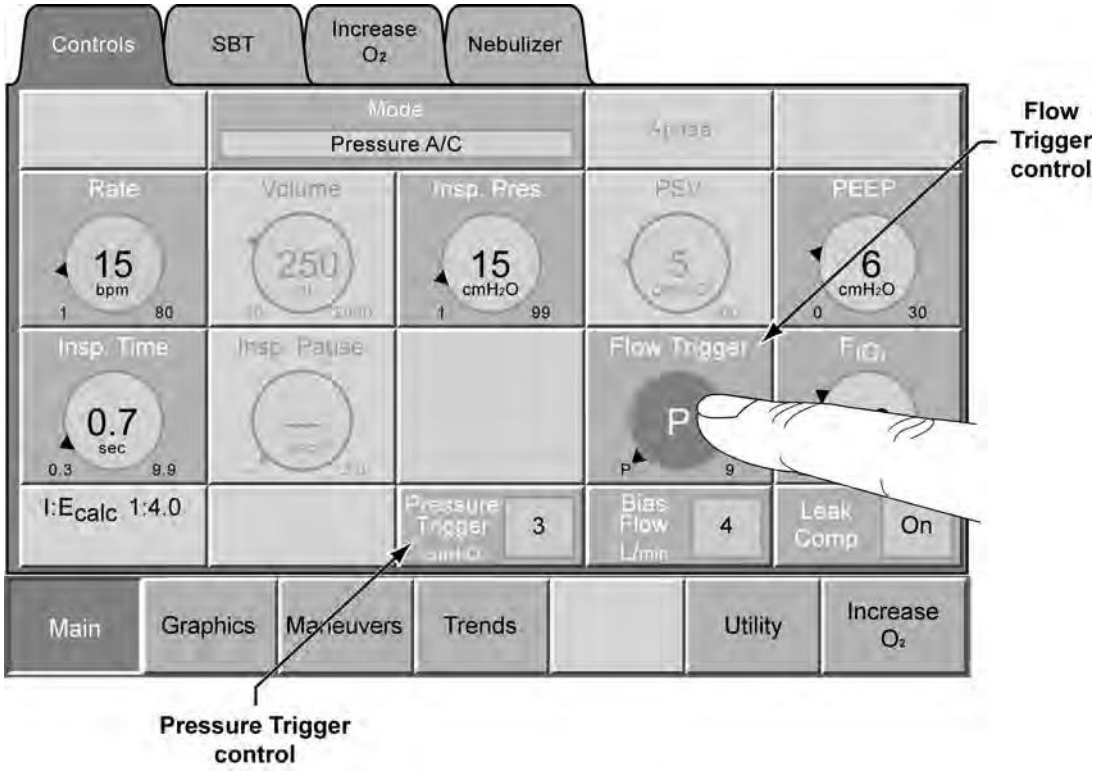
> **NOTE**
>
> When pressure triggering is enabled, always set the Low PEEP alarm limit above the Pressure Trigger setting to ensure proper Low PEEP alarm functionality.
>
> When using the ventilator in transport situations, excessive movement of the patient circuit may cause auto cycling. Consider adjusting trigger sensitivity.

To Set Pressure Trigger

Select Touch the **Flow Trigger** control to display the **Pressure Trigger** control, and then touch the **Pressure Trigger** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise or counter-clockwise to change the setting.

Confirm Touch the control again.



PSV

The **PSV** control establishes the target pressure set above PEEP for Pressure Support patient breaths. If **PSV** is set to "- -" (off), all patient breaths are given as Spontaneous breaths. Inspiratory flow for Pressure Support and Spontaneous breaths is controlled to meet the patient demand.

Range: "**- -**" (off), or **1** through **60 cmH_2O**

To Set PSV:

Select Touch the **PSV** control.

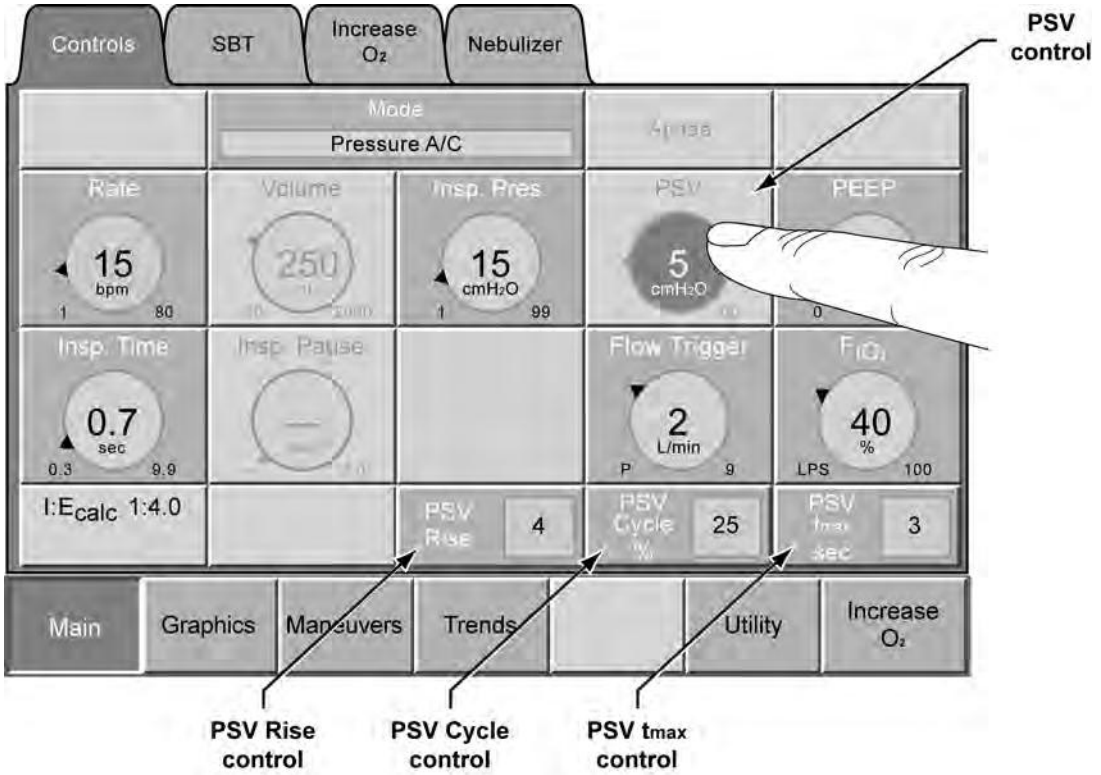
- When the **PSV** control is touched, the **PSV Rise**, **PSV Cycle** and **PSV T_{max}** controls are displayed

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The PSV control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

Confirm Touch the control again.

> **NOTE**
>
> A Time Terminated breath symbol is displayed in the Airway Pressure Manometer (until the next breath is initiated) to indicate that a Pressure Support, Volume Targeted Pressure Support or Spontaneous breath has been terminated by this method (see *PSV Tmax* in this chapter) or terminated by the elapse of two breath periods.



PSV Cycle

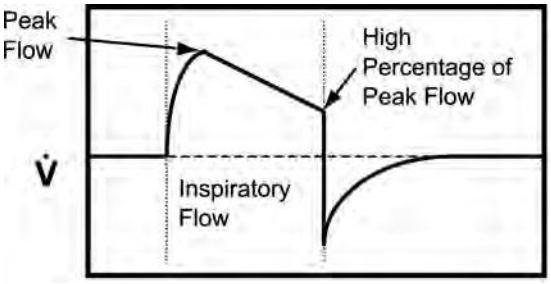
The **PSV Cycle** control sets the percentage of Peak Flow at which Pressure Support, Pressure Regulated Volume Support (PRVS) and Spontaneous breaths are cycled. The breath is cycled from inspiration to exhalation when the flow is less than the set **PSV Cycle** setting. The breath also cycles when the flow is less than 2 L/min.

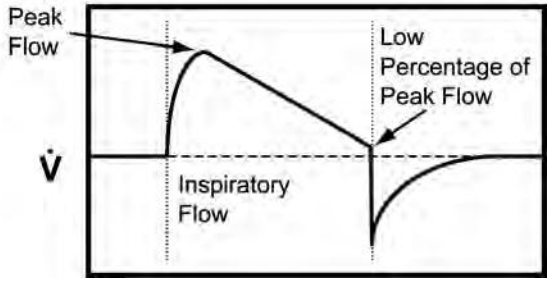
Range**:** **10%** through **40%,** in increments of 5

NOTE

Inspiration is also terminated if the inspiration time exceeds the **PSV T_{max}** setting or two breath periods.

A Flow Terminated breath symbol is displayed in the Airway Pressure Manometer (until the next breath is initiated) to indicate that a Pressure Control or Pressure Regulated Volume Control breath has been terminated.





To Set PSV Cycle:

Select Touch the **PSV** control to display the **PSV Cycle** control, and then touch the **PSV Cycle** control.

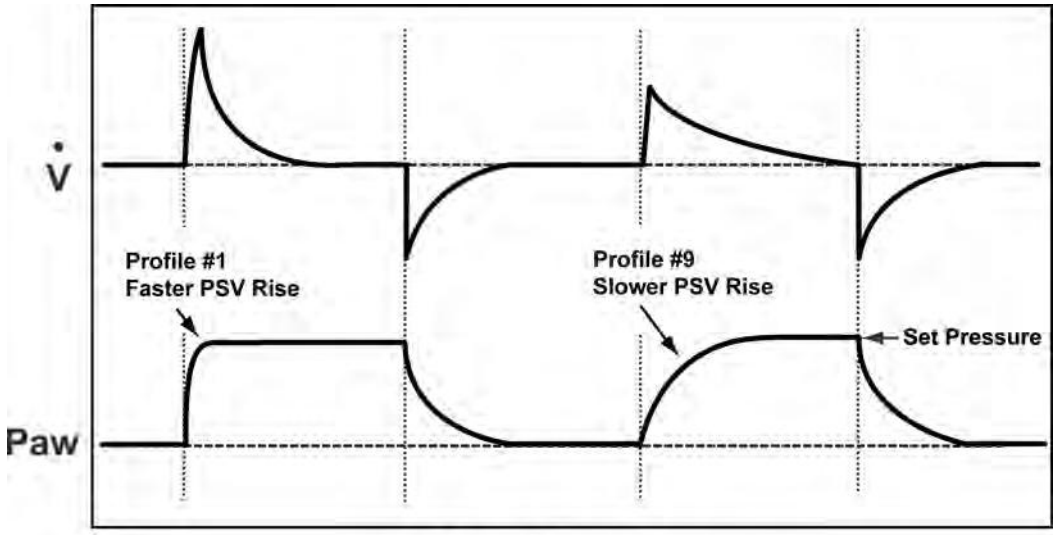
Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

PSV Rise

The **PSV Rise** control selects the inspiratory rise time profile for Pressure Support, PRVC and Spontaneous breaths. The rise time profiles are numbered 1 through 9 where 1 is the fastest rise time and 9 is the slowest rise time. Starting with the fastest rise time (Profile 1), each increment in rise time is approximately 33% longer than the previous one. The rise time setting takes effect on the next Pressure Support breath.

Range: **1** through **9** (profiles), in increments of 1



Adjusting PSV Rise on Pressure Support Breaths

To Set PSV Rise:

Select Touch the **PSV** control to display the **PSV Rise** control, and then touch the **PSV Rise** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

> **NOTE**
> If the set **PSV Rise** profile exceeds the set **PSV T_{max}** value, the target pressure may not be achieved.

PSV T_{max}

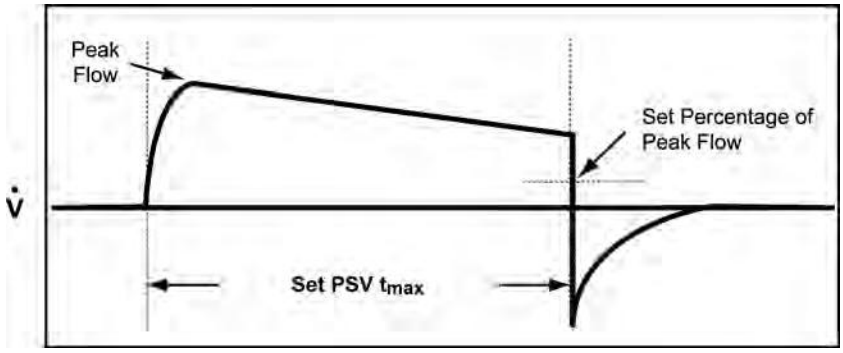
The **PSV T_{max}** control sets the maximum inspiratory time for terminating Pressure Support, and Spontaneous breaths.

Range**:** **0.3** through **3.0 sec**, in increments of 0.1 sec

Breaths are time cycled from inspiration to exhalation if the set **PSV T_{max}** value is reached before the flow reaches the set percentage of the peak flow for flow termination to take effect.

NOTE

A Time Terminated breath symbol is displayed in the Airway Pressure Manometer (until the next breath is initiated) to indicate that a Pressure Support, Volume Targeted Pressure Support or Spontaneous breath has been terminated by this method or terminated by the elapse of two breath periods.



To Set PSV T_{max}:

Select Touch the **PSV** control to display the **PSV T_{max}** control, and then touch the **PSV T_{max}** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

Rate (Breath Rate)

The Breath Rate control (**Rate**) is used to establish the minimum number of Machine or Assist breaths that the ventilator delivers per minute.

Range: **1** through **80 bpm**

To Set the Rate:

Select Touch the **Rate** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The **Rate** control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

NOTE

The calculated I:E Ratio (**I:E$_{calc}$**) monitor is updated while Breath Rate (**Rate**) or Inspiratory Time (**Insp. Time**) are being changed.

Confirm Touch the control again.

NOTE

When in any CPAP/PSV ventilation mode, the **Rate** control affects Apnea Backup ventilation. Be sure to set it appropriately (see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes for additional information).

Volume

Use the **Volume** control to establish the volume of gas delivered during Volume Control, PRVC and PRVS breaths (see *Chapter 4 - Breath Types and Modes* for additional information concerning Volume and PRVC breaths).

Range: **50** through **2000 ml**

To Set Volume:

Select Touch the **Volume** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

- The **Volume** control setting may be limited to less than its specified range; see *Control Limiting* in this chapter for detailed information

Confirm Touch the control again.

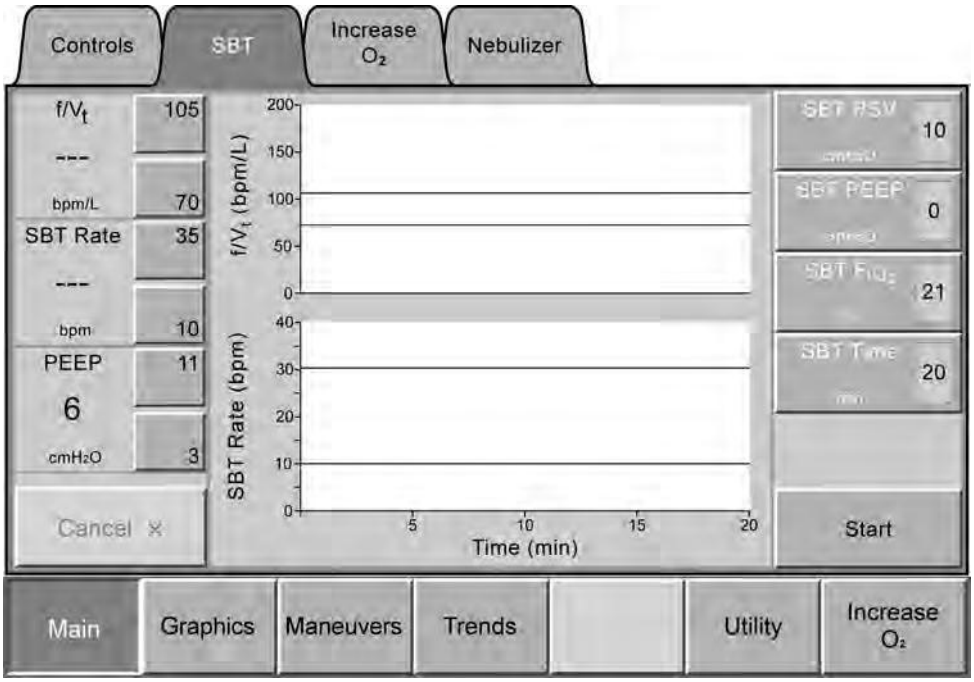
NOTE

The Peak Inspiratory Flow, Calculated ($\dot{V}_{i\ calc}$) monitor is updated while **Volume** or **Insp. Time** settings for a volume breath are being changed.

In the **CPAP/PSV (Volume)** setting, the **Volume** control establishes the Tidal Volume for Apnea Backup ventilation. Be sure to set it appropriately (see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes for additional information).

SBT Page, Adjustable Controls

The SBT adjustable controls are accessed via the **Main** screen, **SBT** page.



The Spontaneous Breathing Trial (**SBT**) controls are used to temporarily minimize ventilatory support and perform clinical assessments of a patient's dependence on, or ability to be removed from positive pressure ventilation. Refer to *SBT* in Chapter 9 – Maneuvers, Procedures and Standby Mode for starting instructions and additional information.

The SBT procedure should be used only while attended by a Respiratory Therapist or other properly trained and qualified personnel.

SBT FiO_2

This control sets the percentage of oxygen to be delivered in the gas flow during a spontaneous breathing trial procedure. It is only effective for the SBT procedure but cannot be adjusted during the procedure.

Range: **LPS**, **21%** through **100%**

To Set SBT FiO_2:

Select Touch the **SBT FiO_2** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

NOTE

When the FiO_2 setting is changed (FiO_2 Control setting, Increase O_2 Procedure started, or SBT FiO_2 Control setting) the **High FiO_2** alarm is deactivated for 120 seconds.

SBT PEEP

The **SBT PEEP** control sets the level of PEEP to be in effect during a spontaneous breathing trial procedure. It is only effective for the SBT procedure but cannot be adjusted during the procedure.

Range: **0** through **30 cmH_2O**

To Set SBT PEEP:

Select Touch the **SBT PEEP** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

SBT PSV

The **SBT PSV** control sets the target pressure above set **SBT PEEP** for SBT patient breaths. It is only effective for the SBT procedure but cannot be adjusted during the procedure.

Range: "**- -**" (off), or **1** through **30 cmH_2O**

To Set SBT PSV:

Select Touch the **SBT PSV** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

SBT Time

The **SBT Time** control sets the maximum run time of the SBT procedure. It is only effective for the SBT procedure but cannot be adjusted during the procedure.

Range: **15** min through **120** min, in increments of 5 minutes

To Set SBT Time:

Select Touch the **SBT Time** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

SBT, Adjustable Alarms

The SBT adjustable alarms limit values are set or changed in the same manner as all other touch screen adjustable alarm limit control values are changed, using the 3 step method of “Select, Change, and Confirm”.

SBT Rate

The **SBT Rate** alarm limit control is used to set the high and low alarm limits for the monitored breath rate (**SBT Rate**) during a Spontaneous Breathing Trial. Refer to *SBT High Breath Rate* and *SBT Low Breath Rate* in Chapter 8 - Ventilator Alarms for additional information.

To Set SBT Rate Alarms:

Select Touch the **SBT Rate** high or low alarm limit control to be changed.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

f/V_t

The f/V_t alarm limit control is used to set the high and low alarm limits for the f/V_t ratio during a Spontaneous Breathing Trial. Refer to *SBT High f/Vt* and *SBT Low f/Vt* in Chapter 8 - Ventilator Alarms for additional information.

To Set SBT f/V_t Alarms:

Select Touch the **f/V_t** high or low alarm limit control to be changed.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

PEEP

The PEEP alarm limit control is used to set the high and low alarm limits for the PEEP during a Spontaneous Breathing Trial. Refer to *SBT High PEEP* and *SBT Low PEEP* in Chapter 8 - Ventilator Alarms for additional information.

To Set SBT PEEP Alarms:

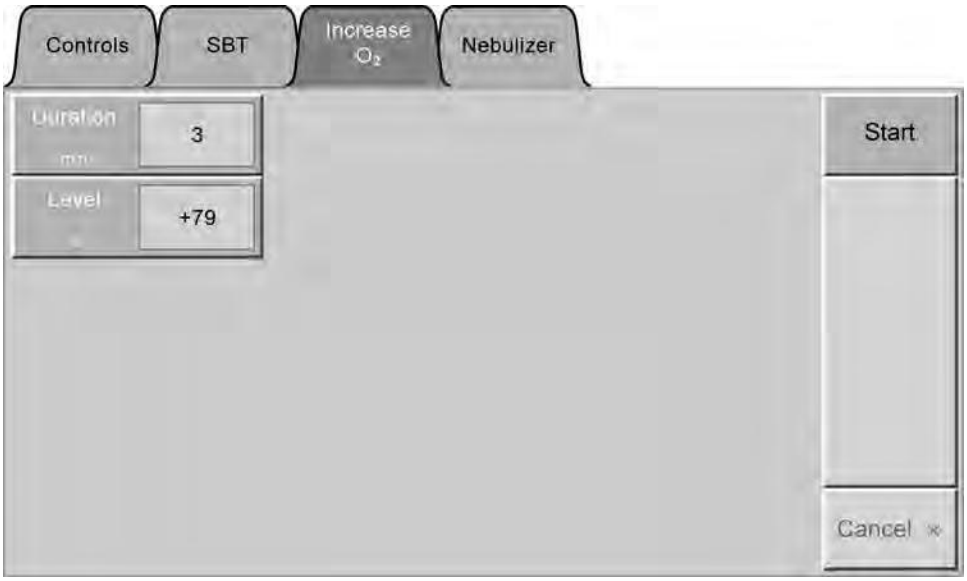
Select Touch the **PEEP** high or low alarm limit control to be changed.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

Increase O_2 Page, Adjustable Controls

The Increase O_2 adjustable controls are accessed via the **Main** screen, **Increase O_2** page.



The Increase O_2 procedure allows delivery of a pre-set elevated percentage of oxygen to the patient for a specified duration of time. Refer to *Increase O2* in Chapter 9 – Maneuvers, Procedures and Standby Mode for additional information.

NOTE

- To perform this procedure, the ventilator must be connected to a high pressure oxygen source.
- When the FiO_2 setting is changed (FiO_2 Control setting, Increase O_2 Procedure started, or SBT FiO_2 Control setting) the **High FiO_2** alarm is deactivated for 120 seconds.
- The Increase O_2 and Nebulization procedures cannot be performed simultaneously. When either one of these procedures is initiated, the **Start** button for the other is deactivated until the in-process procedure has been cancelled or completed.

Duration

The Duration control sets the duration of time for which an elevated level of oxygen is delivered to the patient.

Range: **2** through **3** min, in increments of 1 minute

To Set Duration:

Select	Touch the **Duration** control.
Change	Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.
Confirm	Touch the control again.

Level

The **Level** control is used to set the "increased" percentage of oxygen (above the current **FiO_2** control setting) to be delivered to the patient during the set duration of time. For example:

- a +50% **Level** control setting combined with a 21% **FiO_2** control setting would result in 71% oxygen being delivered to the patient during the set duration of time
- a +50% **Level** control setting combined with a 40% **FiO_2** control setting would result in 90% oxygen being delivered to the patient during the set duration of time
- Any combination of **Level** and **FiO_2** control settings that exceed 100% would result in 100% oxygen being delivered to the patient during the set duration of time

Range: **+0** through **+79 %**, in increments of 1%

To Set Level:

Select Touch the **Level** control.

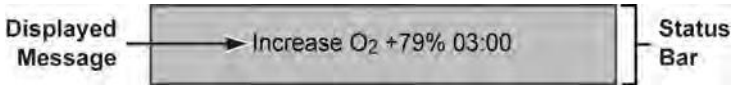
Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

Start

To start the delivery of an elevated level of oxygen to the patient, touch the **Start** button.

When an Increase O_2 procedure is started, the percentage of O_2 increased and the remaining time for the procedure, beginning at the set **Duration** time and reducing every second and minute until no time is left, is displayed in the **Status Bar** at the top of the LCD touch screen.

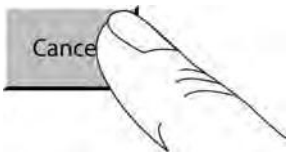


The delivery of the elevated level of oxygen will continue for the set **Duration** or until the **Cancel** button is touched.

> **NOTE**
>
> When the **FiO_2** control is set to **LPS**, the **Start** button is grayed out indicating that the feature is unavailable.
>
> When the Increased O_2 procedure ends, it may take the oxygen several seconds to flush out of the patient circuit and for the **FiO_2** monitors to return to set levels.

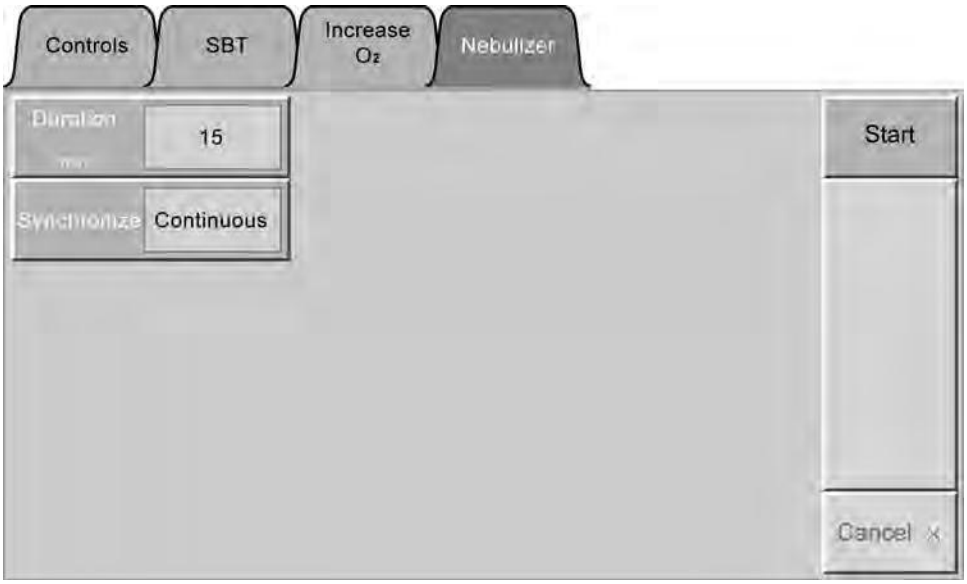
Cancel

To cancel the delivery of the elevated level of oxygen to the patient before the set **Duration** has expired, touch the **Cancel** button.



Nebulizer Page, Adjustable Controls

The Nebulizer adjustable controls are accessed via the **Main** screen **Nebulizer** page.



The Nebulizer controls set parameters for controlling an aerosol nebulizer that doses medication into the patient circuit. Refer to *Nebulization* in Chapter 9 – Maneuvers, Procedures and Standby Mode for additional information.

NOTE

- To activate the Nebulizer **Duration** control, **Synchronize** control and **Start** button, the ventilator must have the **Mode** control set to **Volume A/C**, the **Bias Flow** control set to 10 L/min.
- The Increase O_2 and Nebulization procedures cannot be performed simultaneously. When either one of these procedures is initiated, the **Start** button for the other is deactivated until the in-process procedure has been cancelled or completed.
- Use of the Nebulizer feature requires that the ventilator be connected to a Nebulizer, and a high pressure oxygen source of **40 PSI** (2.8 BAR, 276 kPa) to **66 PSI** (4.5 BAR, 455 kPa).

To connect O_2 and a Nebulizer to the ventilator, see *High Pressure O2* and *Nebulizer* in Chapter 2 - Installation and Setup for instructions. See *Nebulization* in Chapter 9 – Maneuvers, Procedures and Standby Mode for additional information.

Duration

The Duration control sets the total length of time that a Nebulizer treatment session is active.

Range: **1** through **30** min, in increments of 1 minute

To Set Duration:

Select Touch the **Duration** control.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again.

Synchronize

The Synchronize control sets whether the nebulizer treatment is synchronized with the patient's breath pattern.

Range: **Continuous** or **Insp Only**

To Set Synchronize:

Select	Touch the **Synchronize** control.
Change	Rotate the **Scroll** knob on the Lower Interface Panel clockwise or counter-clockwise to change the setting.
Confirm	Touch the control again.

Start

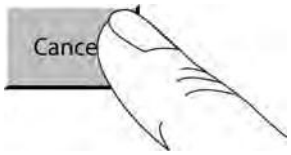
To initiate nebulization treatment, touch the **Start** button.

When a Nebulizer procedure is started, the remaining time for the procedure, beginning at the set **Duration** time and reducing every second and minute until no time is left, is displayed in the **Status Bar** at the top of the **LCD Touch Screen**.

While the procedure is in progress, the **Cancel** button is active.

> **NOTE**
>
> **Breath Settings** - The **Duration** control, **Synchronize** control and **Start** button are grayed out when the ventilator has settings inconsistent with the Nebulizer mode (e.g. Pressure Control, Pressure Support or Spontaneous breaths, or Bias Flow <10 L/min).
>
> See *Nebulization* in Chapter 9 – Maneuvers, Procedures and Standby Mode for additional information.

Cancel



To cancel the nebulization treatment before the set **Duration** has expired, touch the **Cancel** button.

Utility Screen, Adjustable Controls

Additional controls are accessed via the **Utility** screen. See *Chapter 10 - The Utility Screen* for information on accessing and setting these controls.

Fixed Controls

Safety Valve

The ventilator has a safety valve that automatically opens during the following conditions:

- During all ventilator operating states *other* than normal ventilation (e. g., Off, POST, Vent Check)
- During a sub-ambient relief condition (see below)
- To provide over-pressure relief during a high pressure condition (see *High Ppeak (High Airway Pressure)* in Chapter 8 – Ventilator Alarms)
- To provide backup over pressure relief in conjunction with the High P_{peak} alarm setting and the Delta Pressure setting (see *Safety Valve High Pressure Relief* in Chapter 8 – Ventilator Alarms)

Sub-Ambient (Anti-Asphyxia) Relief

The safety valve provides sub-ambient relief when the airway pressure is ≤ -5 cmH_2O.

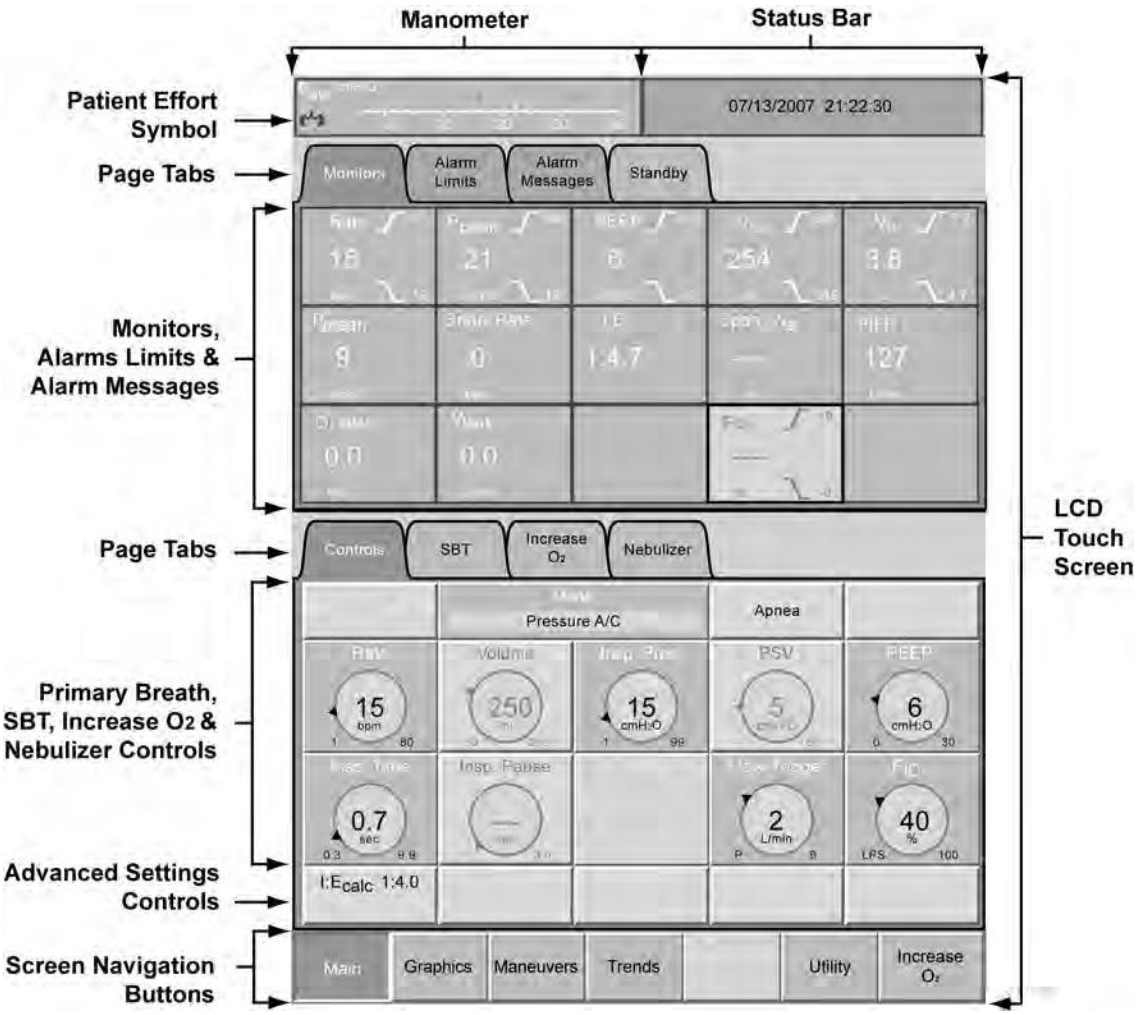
Chapter 6 - DISPLAYS AND INDICATORS

This chapter describes the displays on the Enve™ ventilator LCD touch screen and the LED indicators on the Lower Interface Panel.

LCD Touch Screen Displays

The LCD touch screen is a graphical user interface comprised of an active matrix LCD display with a variable back light and a touch panel overlay. It contains elements such as:

- A real time airway pressure manometer display
- A Status Bar for displaying miscellaneous ventilator status information and alarm messages
- Monitor displays and associated adjustable alarm limits
- Adjustable interactive ventilation controls
- Screen Navigation buttons to move between screens and tabs to view pages within screens
- Configurable Trend, Waveform and Loop real time graphical displays
- Controls for maneuvers such as Inspiratory Hold and Expiratory Hold

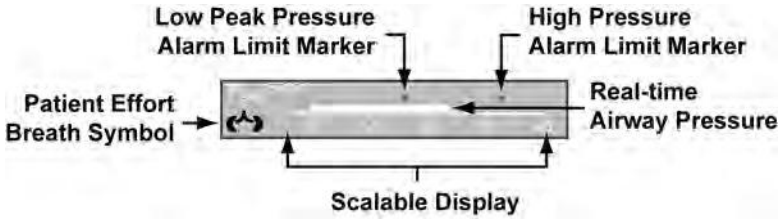


The Airway Pressure Manometer, Status Bar and Screen Navigation buttons (top/left, top/right and bottom center respectively) and are continuously displayed (during normal ventilation), regardless of ventilation Mode used, sub-screen or page displayed and/or maneuver or procedure being performed.

Airway Pressure Manometer

The Airway Pressure Manometer is a bar graph continuously displayed at the top left of the LCD touch screen which displays the real-time breath by breath Airway Pressure (**P_{aw}**).

Range: –**2** through **150 cmH_2O**.

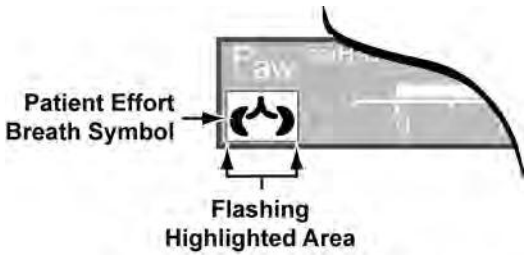


To adjust the Manometer display scale, see *Airway Pressure Manometer, Monitored Data* in Chapter 7 – Monitored Data.

Patient Breath Symbols

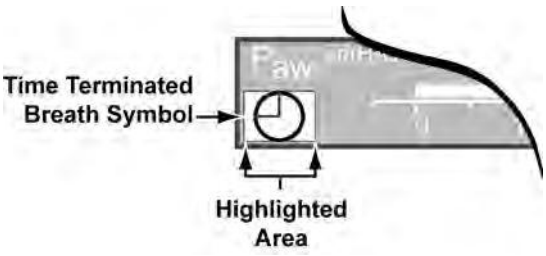
Patient Effort Breath Symbol

A Patient Effort breath is indicated by the appearance of a flashing highlighted area behind the **Patient Effort** breath symbol in the Airway Pressure Manometer display, as shown here.



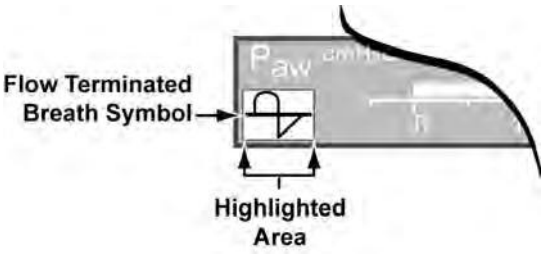
Time Terminated Breath Symbol

A Time Terminated breath is indicated by the appearance of the **Time Terminated** breath symbol surrounded by a steady state highlighted area in the Airway Pressure Manometer display, as shown here. See *PSV Tmax* in Chapter 5 – Controls for additional information.



Flow Terminated Breath Symbol

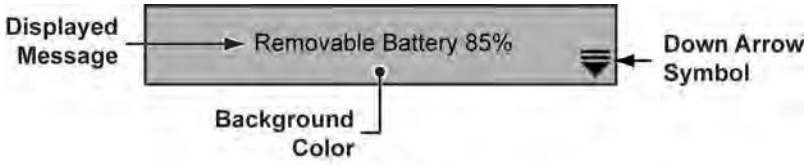
A Flow Terminated breath is indicated by the appearance of the **Flow Terminated** breath symbol surrounded by a steady state highlighted area in the Airway Pressure Manometer display, as shown here. See *Flow Cycle* in Chapter 5 – Controls for additional information.



Status Bar

The Status Bar is continuously displayed at the top right of the LCD touch screen and displays various types of information about the current operating state of the ventilator, such as;

- The current date and time on a green background during normal ventilation when there are no active alarms
- Alarm messages on a red, yellow or cyan background (see *Visual Alarm Displays* in Chapter 8 – Ventilator Alarms for additional information)
- Informational messages and monitored data on a green background concerning maneuvers or procedures when being performed by the ventilator (see *Status Bar, Monitored Data* in Chapter 7 – Monitored Data and *Chapter 9 - Maneuvers, Procedures and Standby Mode* for additional information)
- The type and state of the any power supply connected to the ventilator on a gray background when the Battery/Power **Check** button on the Lower Interface Panel is pushed (see *Battery/Power* in Chapter 5 - Controls for additional information)



Status Bar

Screen Navigation Buttons

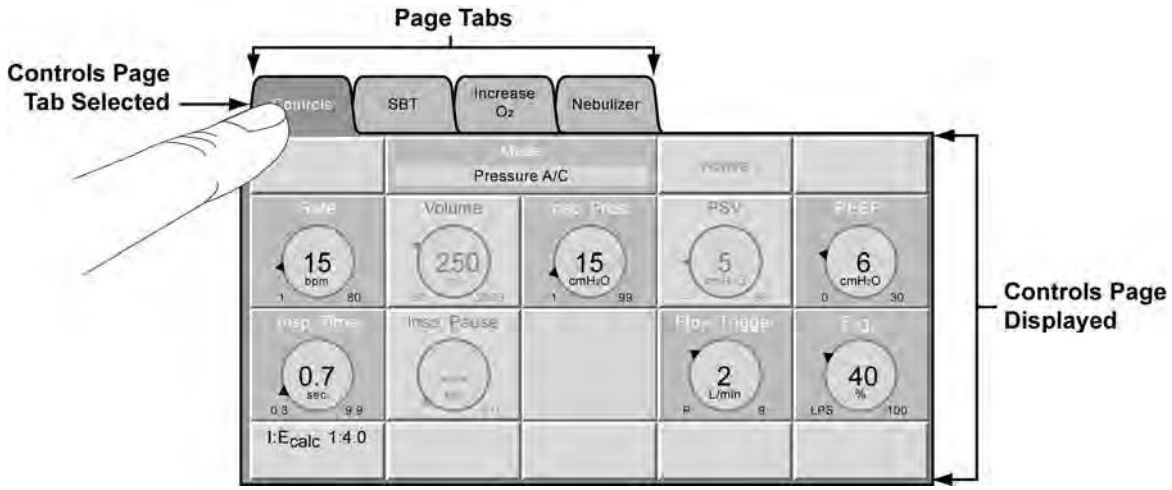
The Screen Navigation buttons are continuously displayed at the bottom of the LCD touch screen and provide a quick and convenient means of navigating from display screen to display screen. When enabled, they activate on a single touch and require no confirmation before the selected screen is displayed.

See *Screen Navigation Buttons* in Chapter 3 – Using the Ventilator for additional information.

Page Tabs

Page tabs are positioned at the top of individual pages and provide access to pages within display screens.

To display a particular page, simply touch the corresponding Page Tab and the selected page is displayed.



See *Page Tabs* in Chapter 3 – Using the Ventilator for additional information.

Pages

Pages are located within display screens and contain/display numerous monitors, alarms, ventilation and configuration controls, and graphical displays, each described in detail in appropriate section(s) throughout the manual.

To display a particular page, simply touch the Screen Navigation button the page is accessed from and then touch the corresponding Page Tab. The selected screen and page are displayed.

Screens and Pages Accessible During Normal Ventilation:

Screens	Main	Graphics	Maneuvers	Trends	Utility	Increase O_2
Pages	Monitors	Monitors	Monitors	24 Hours	Alarm Config	Monitors
	Alarm Limits	Alarm Limits	Alarm Limits		Vent Config	Alarm Limits
	Alarm Messages	Alarm Messages	Alarm Messages		Option Config	Alarm Messages
	Controls	Waves	I-Hold		Event Trace	Controls
	SBT	Loops	E-Hold		About	SBT
	Increase O_2					Increase O_2
	Nebulizer					Nebulizer

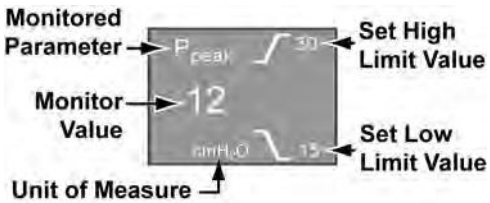
Screens and Controls Accessible During Startup Mode:

Screens	Startup	Same Patient	New Patient	Vent Setup	EST[22]	UVT[23]	Config
Controls	Same Patient	Intubated	Patient ID	EST	Circuit Test	Button Test	Language
	New Patient	Non-Invasive	Patient (Adult/Ped)	UVT	FiO_2	Touch Screen Calibration	Units
	Vent Setup	Ventilate	Intubated	About	FiO_2 Calibration		Reset to Factory Defaults
			Non-Invasive				
			Ventilate				

[22] Extended Systems Test (EST)
[23] User Verification Tests (UVT)

Monitors

Monitors are displayed on the **Main** screen, **Monitors** and **SBT** pages with the name of the monitored parameter, the monitor value, unit of measure and the set high and low alarm limits, as shown in the illustration.

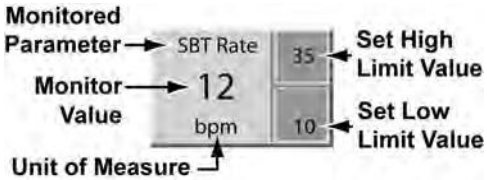


- Monitored data of parameters with adjustable alarms is also displayed in the associated Alarm Limits displays (see below)

See *Chapter 7 - Monitored Data* for additional information.

Alarm Limits

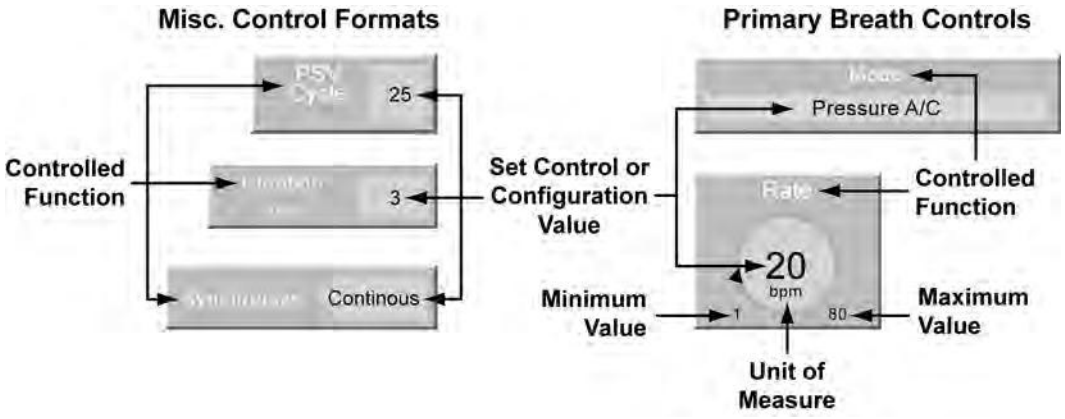
Alarm Limits are displayed on the **Main** screen, **Alarm Limits** and **SBT** pages with the name of the associated monitored parameter, the associated monitor value, unit of measure and the set high and low alarm limits, as shown in the illustration.



See *Adjustable Alarm Limits* in Chapter 3 – Using the Ventilator and *Chapter 8 - Ventilator Alarms* for additional information.

Controls

Controls are displayed on various screen pages in several graphical formats (square, round and rectangular), but they function and are adjusted in similar manners. Each contains the name of the controlled function, the associated set control/configuration value and unit of measure (when applicable). Primary Breath Controls also display the minimum and maximum values as applicable.



See *Adjustable Controls* In Chapter 3 – Using the Ventilator and *Chapter 5 - Controls* for additional information.

Graphic Displays

SBT, I-Hold and E-Hold

SBT (**Main** screen, **SBT** page), I-Hold and E-Hold (**Maneuvers** screen, **I-Hold** and **E-Hold** pages) related data is graphically displayed (waveforms) on the associated screens and pages while these maneuvers or procedures are being performed.

For more information see *Chapter 9* - Maneuvers, Procedures and Standby Mode.

Waves

Monitored data is graphically displayed as waveforms on the **Graphics** screen, **Waves** page. Any two (2) of the following monitored values can be selected to display:

- Flow ($\dot{V}$)
- Airway Pressure ($\mathbf{P_{aw}}$)
- Tidal Volume ($\mathbf{V_t}$)
- Plethysmograph (**Pleth**)

See *Waves* in Chapter 3 - Using the Ventilator and *Waves* in Chapter 7 Monitored Data for additional information.

Loops

Monitored data is graphically displayed as loops on the **Graphics** screen, **Loops** page.

- Flow ($\dot{V}$) : Tidal Volume ($\mathbf{V_t}$) loop, and
- Tidal Volume ($\mathbf{V_t}$) : Airway Pressure ($\mathbf{P_{aw}}$) loop

See *Loops* in Chapter 3 - Using the Ventilator and *Loops* in Chapter 7 Monitored Data for additional information.

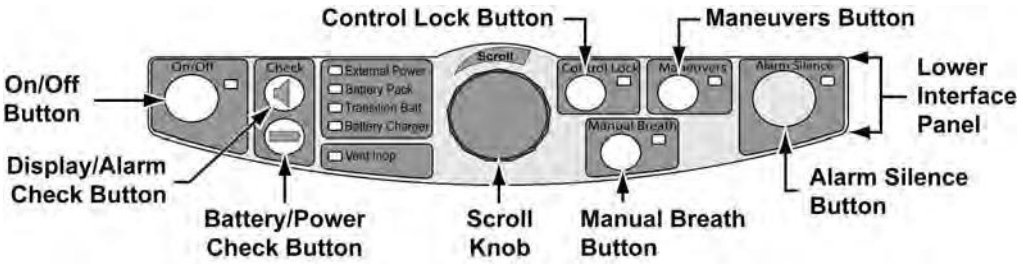
Trends

Twenty-four (24) hours of stored monitored data (Trend Log) can be graphically displayed in three (3) bar graphs on the **Trends** screen, **24 Hours** page. Any three (3) monitored values can be selected to display.

See *Trends* in Chapter 3 - Using the Ventilator and *Trends* in Chapter 7 - Monitored Data for additional information.

Lower Interface Panel Indicators

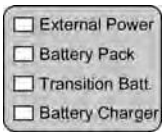
The following section describes the purpose of the LED indicators on the Lower Interface Panel that *do not* have associated controls. For information about the controls on the Lower Interface Panel, see *Lower Interface Panel Controls* in Chapter 5 - Controls.



Power Status LEDs

The Power Status LEDs indicate the active power source and battery charging status.

- External Power
- Battery Pack
- Transition Batt.
- Battery Charger



External Power

The **External Power** LED indicates the status of external sources of power for the ventilator (external DC (side) port and the Docking Station port), whether the ventilator is on or off.

When the **External Power** indicator LED is;

Off - The ventilator is not connected to usable external power.

Green - The ventilator is connected to a usable external source of power that is adequate to properly run the ventilator.

Amber - The ventilator is connected to an external power source with low voltage.

- The **External Power Low** alarm is active

Flashing Red - The ventilator is connected to an external source of power that is faulted.

- The **External Power Fault** alarm is active

WARNING

Flashing Red External Power LED - A flashing red **External Power** LED indicates that the external source of power connected to the ventilator is not usable and should be serviced. The ventilator will automatically switch to the Removable Battery Pack if present or the Transition Battery. Insert a charged Removable Battery Pack or connect the ventilator to a CareFusion approved alternate source of power.

NOTE

The **External Power** LED is illuminated when the Display/Alarm **Check** button is pushed (to check the status of the displays), even when the ventilator is not being powered by external power.

Battery Pack

The **Battery Pack** LED indicates the status of the Removable Battery Pack installed in the ventilator. When the **Battery Pack** indicator LED is:

Off - The ventilator is not operating on power from a Removable Battery Pack.

Green - The ventilator is operating on power from a Removable Battery Pack with a charge level greater than 25% capacity.

Amber - The ventilator is operating on power from a Removable Battery Pack with a charge level greater than 5% and less than or equal to 25% capacity.

- The **Battery Low** alarm is active

Red - The ventilator is operating on power from a Removable Battery Pack with a charge level less than or equal to 5% capacity.

- The **Battery Empty** alarm is active

Flashing Red - The currently installed Removable Battery Pack is not usable.

- The **Battery Fault** alarm, the **Battery Temperature Fault** alarm, or the **Insert Battery** alarm is active

WARNING

Flashing Red Battery Pack LED - A flashing red **Battery Pack** LED indicates that the currently installed Removable Battery Pack is not usable. Insert a different, charged Removable Battery Pack or connect the ventilator to a CareFusion approved alternate source of power.

NOTE

The **Battery Pack** LED is also illuminated when the Battery/Power **Check** button is pushed (to check the status of power), or when the Display/Alarm **Check** button is pushed (to check the status of the displays), even when the ventilator is not being powered by the battery.

Transition Battery

The **Transition Batt.** LED indicates the status of the Transition Battery installed in the ventilator.

> **NOTE**
> The internal Transition Battery is only intended for use as a short duration source of power for the ventilator when changing depleted Removable Battery Packs, or switching the ventilator to, or between, external sources of power. Do not operate the ventilator using the Transition Battery as the source of power for more than one (1) minute.

When the **Transition Batt.** indicator LED is:

Off - The ventilator is not operating on power from the Transition Battery.

Green - The ventilator is operating on power from the Transition Battery which has a normal charge level.

- The **Transition Battery Use** alarm is active

Red - The ventilator is operating on power from the Transition Battery which has a low charge level.

- The **Transition Battery Use** alarm is active

Flashing Red - The ventilator is operating on power from a Transition Battery which may be unreliable.

- The **Transition Battery Fault** alarm, or the **Transition Battery Temperature Fault** alarm is active

> **WARNING**
> **Transition Battery Use Alarm** - A **Transition Battery Use** alarm indicates the ventilator is only being powered by the Transition Battery and will shut down soon. Immediately insert a charged Removable Battery Pack or connect the ventilator to an external source of power. As the Transition battery is depleted the audible and visual Transition Battery Use alarms will continue to be displayed/sounded. However, the LED indicator may transition from Green to Off.
> **Flashing Red Transition Battery LED** - A flashing red **Transition Batt.** LED indicates that the ventilator's internal Transition Battery may be unreliable. Discontinue use of the ventilator and contact CareFusion or a service technician certified by CareFusion.

> **NOTE**
> The **Transition Batt.** LED is also illuminated when the Battery/Power **Check** button is pushed (to check the status of power), or when the Display/Alarm **Check** button is pushed (to check the status of the displays), even when the ventilator is not being powered by the battery.

Battery Charger

The **Battery Charger** LED indicates the charging status of the Removable Battery Pack and the Transition Battery installed in the ventilator.

When the **Battery Charger** indicator LED is;

Off -	The battery charger is *not* charging a Removable Battery Pack or the Transition Battery (no external power connected, or charging completed).
Green -	The Transition Battery has been fully charged or faulted and the battery charger is charging a Removable Battery Pack with constant voltage (nearing end of charge cycle)
Amber -	The Transition Battery has been fully charged or faulted and the battery charger is charging a Removable Battery Pack with constant current (in bulk charge portion of charge cycle)
Flashing Amber -	The battery charger is charging the Transition Battery

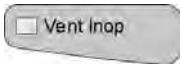
NOTE

When both the Transition Battery and the Removable Battery Pack require charging, and the ventilator is connected to a valid external power source, the battery charger will charge the Transition Battery to full capacity or “Faulted” status before charging the Removable Battery Pack.

To avoid depleting the Removable Battery Pack, when the ventilator is being powered by the Removable Battery Pack, it will only partially charge a depleted Transition Battery.

Vent Inop LED

The **Vent Inop** LED indicates the operational status of the ventilator.



When the **Vent Inop** LED is:

Off - The ventilator is in the Off, POST, Startup, or Normal state

Flashing Red - The ventilator is inoperative, or in the process of shutting down

- The flashing LED is accompanied by a High Priority alarm tone until both are disabled by pushing the **Alarm Silence** button

WARNING

Vent Inop Alarm - If a Vent Inop alarm occurs during operation, immediately ventilate the patient using an alternative method, disconnect the ventilator and contact CareFusion or a service technician certified by CareFusion.

Alternative Ventilation - CareFusion recommends that an alternate means of ventilation be available and the procedures to be followed if the ventilator ceases to function properly.

NOTE

If not cleared using the **Alarm Silence** button, the **Vent Inop**. LED will remain illuminated for a minimum of 5 minutes after the ventilator is shut off.

The ventilator enters an inoperative state when:

- The ventilator is powered off by pushing the **On/Off** button for 3 seconds
- All ventilator power sources are insufficient to operate the ventilator
- The ventilator detects any condition that is deemed to make the ventilator unsafe

NOTE

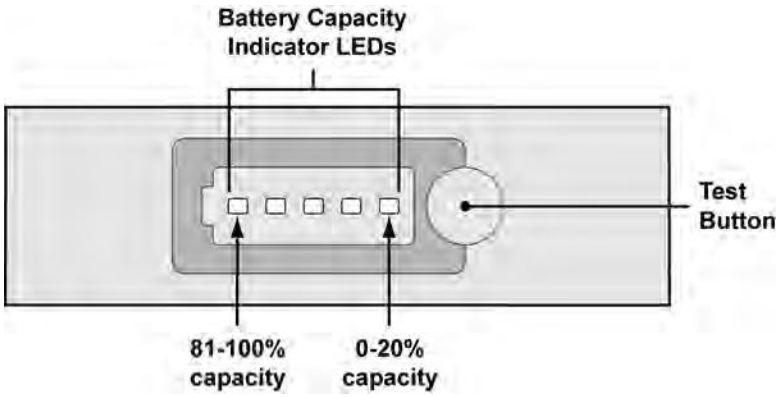
While in the Vent Inop state, the ventilator is set to a condition which allows the patient to breathe spontaneously from room air.

Removable Battery Pack LED Indicators

The **Test** button on the Removable Battery Pack is linked to a series of five LEDs and allows you to check the percentage of charge remaining and charging status, regardless of whether or not the Removable Battery Pack is installed in the ventilator.

Each LED increments approximately 20% as follows:

LEDs Lit	Approximate Charge Level
1	0-20%
2	21-40%
3	41-60%
4	61-80%
5	81-100%

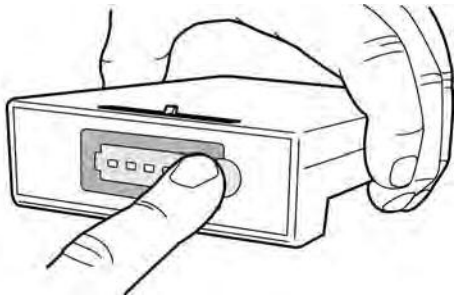


If the battery is being charged, the LED that is representative of the of the battery's current charge level flashes while the test button is being pushed.

NOTE

Battery Replacement - Capacity is measured as a percentage of the battery's capacity when it was new. When a fully-charged battery does not display at least 50% capacity, the battery has reached the end of its useful life and it is time to replace that battery.

To check the battery charge, push and hold the Test button as shown.



Chapter 7 - MONITORED DATA

General Information

The Enve™ ventilator monitors, updates and displays the following data:

- Airway Pressure (P_{aw})
- Exhaled Minute Volume (V_e)
- Exhaled Tidal Volume (V_{te})
- Fraction of Inspired Oxygen (FIO_2)
- Increase O_2 Time Remaining
- I:E Ratio, Measured (I:E)
- I:E Ratio, Calculated ($I:E_{calc}$)
- Mean Airway Pressure (P_{mean})
- Nebulizer Time Remaining
- Leak, Measured ($\dot{V}_{leak}$)
- Loops (graphical display)
- O_2 Source Pressure (O_2 Inlet)
- Peak Expiratory Flow Rate, Measured (PEFR)
- Peak Inspiratory Flow Rate, Measured (PIFR)
- Peak Inspiratory Flow, Calculated ($\dot{V}_{i\ calc}$)
- Peak Inspiratory Pressure (P_{peak})
- Positive End Expiratory Pressure (PEEP)
- Pulse Rate (Pulse)
- SBT Breath Rate (SBT Rate)
- SBT f/V_t (f/V_t)
- SBT Time Remaining (SBT Time)
- Oxygen Saturation (SpO_2)
  - Oximetry Signal Strength
  - Plethysmographic Amplitude
- Spontaneous Breath Rate (Spon. Rate)
- Spontaneous Exhaled Tidal Volume (Spon V_{te})
- Power Status
- Total Breath Rate (Rate)
- Trends (graphical display)
- Waves (graphical display)
- Plethysmograph

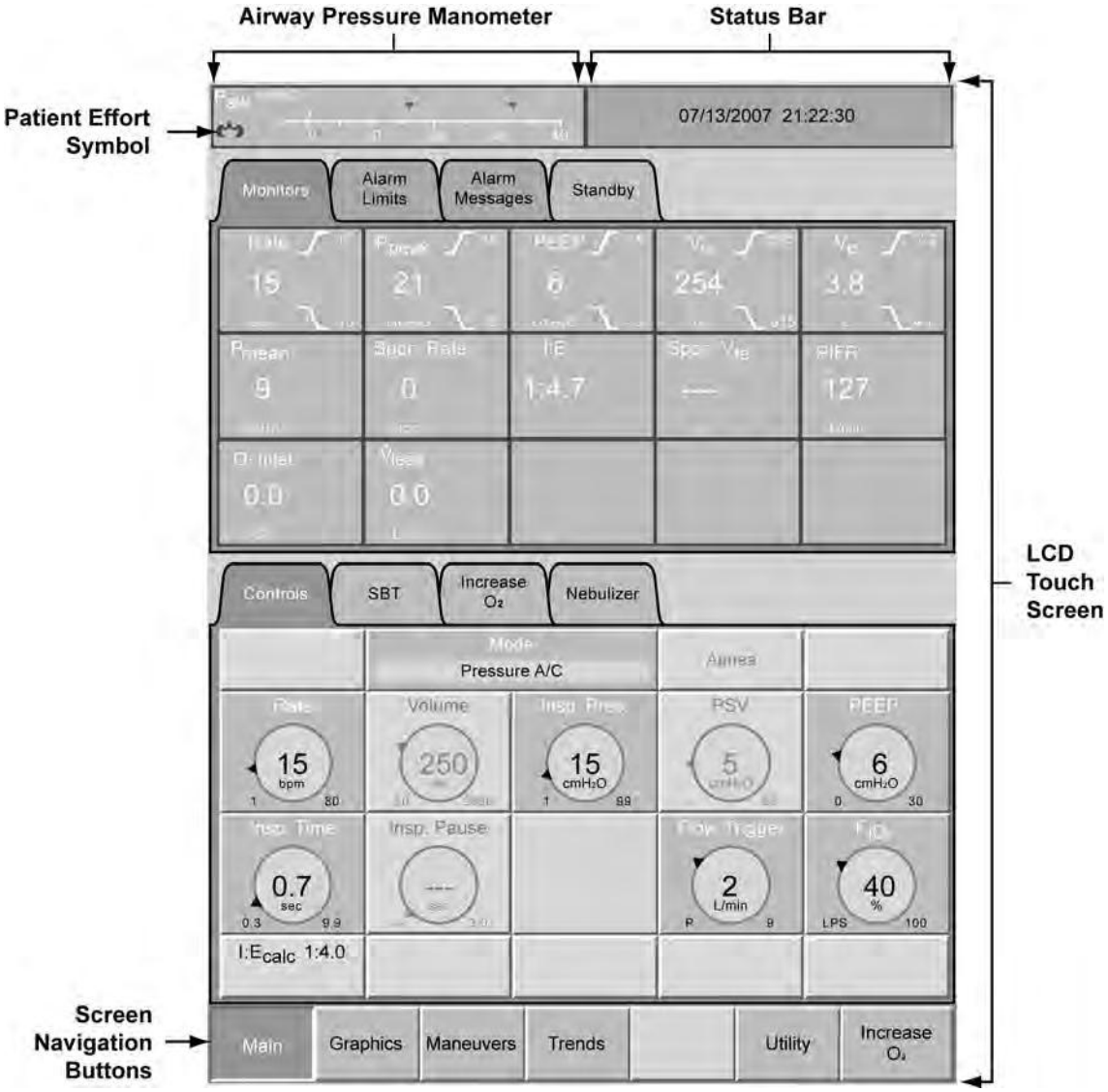
In addition to this patient related data, the ventilator also monitors and updates certain device data which can be used for service diagnostics.

NOTE

When using the ventilator in transport situations, excessive movement may cause variations in monitored values. Values will self recover once disturbance has been removed.

LCD Touch Screen, Monitored Data

The Airway Pressure Manometer, Status Bar and Screen Navigation buttons are located on the LCD Touch Screen (top/left, top/right and bottom center respectively) and are continuously displayed by the ventilator, regardless of ventilation Mode used, sub-screen or page displayed and/or maneuver or procedure being performed.

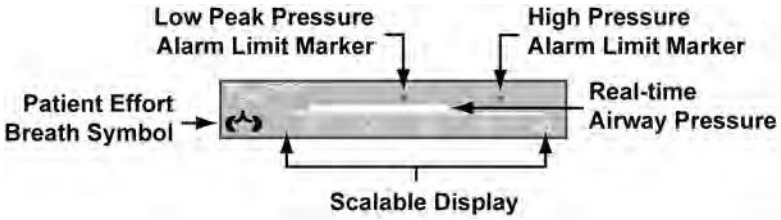


Airway Pressure Manometer, Monitored Data

Airway Pressure (P_{aw})

Airway pressure is continuously measured at the patient Wye and displayed real time on the **Airway Pressure Manometer** bar graph display at the top of the **LCD Touch Screen**.

Range: **-10** through **150 cmH_2O**



To Adjust the Manometer Display Scale;

1) **Select** the manometer by touching the LCD screen directly over the display. The entire manometer is highlighted.

2) **Change** the scale as desired by rotating the **Scroll** knob (clockwise or counterclockwise) on the Lower Interface Panel.

3) **Confirm** your selection by touching the highlighted display again. The display reverts to its previous color and the ventilator accepts the new scale.

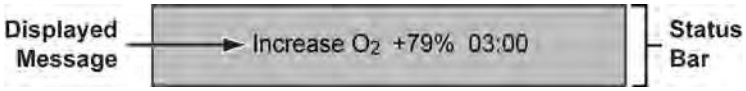
See *Airway Pressure Manometer* in Chapter 6 – Displays and Indicators for additional information concerning graphic symbols displayed within the Airway Pressure Manometer.

Status Bar, Monitored Data

The Enve™ ventilator displays the following patient related monitored data on the **Status Bar** at the top of the **LCD Touch Screen**.

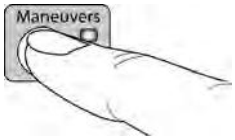
Increase O_2 Percentage and Time Remaining

When an Increase O_2 procedure is started, the percentage of O_2 increased and the remaining time for the procedure, beginning at the set **Duration** time and reducing every second and minute until no time is left, is displayed in the **Status Bar**.



Maneuvers in Progress

While an E-Hold or I-Hold maneuver is being performed (maneuver armed and the **Maneuvers** button on the Lower Interface Panel is being held down), **E-Hold In Progress** or **I-Hold In Progress** (as applicable) is displayed in the **Status Bar**.



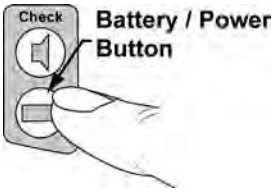
Nebulizer Time Remaining

When a Nebulizer procedure is started, the remaining time for the procedure, beginning at the set **Duration** time and reducing every second and minute until no time is left, is displayed in the **Status Bar**.

SBT Time Remaining (SBT Time)

When an SBT procedure is started, the remaining time for the procedure, beginning at the set **SBT Time** and reducing every second and minute until no time is left, is displayed in the **Status Bar**.

Power Status



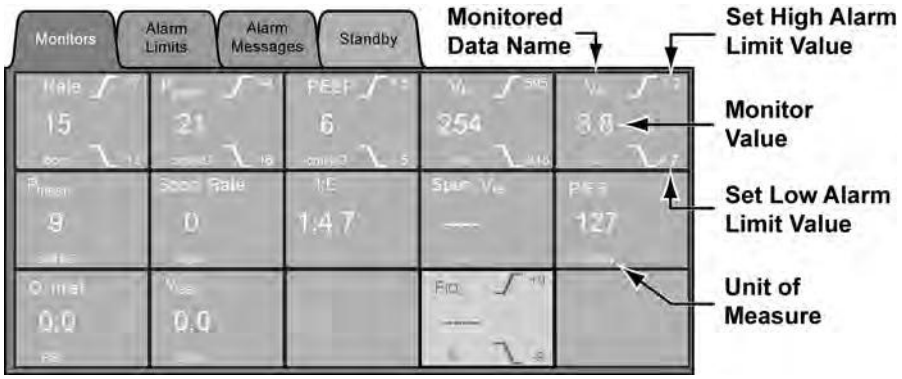
The status of any power supply connected to the ventilator is monitored and relevant data displayed in the **Status Bar** when the Battery/Power **Check** button is pushed on the Lower Interface Panel.

- One of multiple possible messages shown as an example
- See *Battery/Power* in Chapter 5 - Controls and *Lower Interface Panel Indicators* in Chapter 6 – Displays and Indicators for additional information

Main Screen, Monitors Page, Monitored Data

The Enve™ ventilator displays the following patient related monitored data on the **Main** screen, **Monitors** page.

- Each of the individual monitors can be set to display any one (or none) of the available monitored data values. This in turn allows users to configure the display of the monitors in any order, sequence or pattern desired (see *Configurable Monitors* in Chapter 3 – Using the Ventilator for detailed instructions).
- The **Main** screen **Alarm Limits** page also displays those monitors which have associated settable alarm limits (See *Alarm Limits Page, Adjustable Alarms* in Chapter 8 – Ventilator Alarms for additional information)



Exhaled Minute Volume (V_e)

Exhaled Minute Volume is calculated from the average Tidal Volume for the last eight (8) breaths times the Total Breath Rate. When less than eight breaths are available, only the available breaths are used.

Range: **0** through **99.9 L**

Exhaled Tidal Volume (V_{te})

Exhaled Tidal Volume is calculated by integrating the flow from the patient through the patient circuit Wye during the exhalation phase of the breath. Tidal volumes are displayed as BTPS (Body Temperature Pressure Saturated) compensated, however it does not compensate for circuit compliance.

Flows of less than 2 L/min (Adult/Ped) are not included in the integration.

Range: **0** through **4000 ml**

Fraction of Inspired Oxygen (FiO_2)

The FIO_2 monitored data is only visible when an optional FIO_2 Sensor is correctly installed, calibrated and FIO_2 monitoring is enabled.

For installation and calibration of the FIO_2 Sensor see *Optional Use Accessories Connection* in Chapter 2 - Installation and Setup.

Range**:** **12** through **103 %**

NOTE

To ensure accurate FIO_2 measurements, the FIO_2 Sensor must be calibrated to the ventilator upon initial ventilation of a new patient and if FIO_2 measurements become inaccurate based on the FIO_2 ventilator setting.

I:E Ratio, Measured (I:E)

Measured I:E Ratio is the measured inspiratory time divided by the measured exhalation time.

Range: **1:99** through **54:1**

Mean Airway Pressure (P_{mean})

Mean Airway Pressure is a running average of the airway pressure for the last 60 seconds. When less than 60 seconds of data is available, the running average of the available data is used.

The mean airway pressure monitor display ($\mathbf{P_{mean}}$) is updated at least every 10 seconds.

Range: **0** through **99 cmH_2O**

Leak, Measured ($\dot{V}_{leak}$)

Measured Leak is a measure of the steady state flow through the patient circuit Wye toward the patient during exhalation, as determined by the Leak Compensation function.

Range: **0.0** through **30.0 L/min**

NOTE

- **Values Not Reported** - The Measured Leak monitor ($\dot{V}_{leak}$) reports no value during a patient circuit disconnect condition that lasts longer than 60 seconds or whenever a stable leak cannot be detected for 60 seconds or more
- **Limitation of Compensation** - The limitation of compensation is determined by the range and accuracy of the $\dot{V}_{leak}$ (Measured Leak) monitor and the set Bias Flow

O_2 Source Pressure (O_2 Inlet)

O_2 Source Pressure is the pressure measured at the O_2 Inlet.

Range**:** **2.0** through **99.9 PSI**

Peak Expiratory Flow Rate, Measured (PEFR)

Measured Peak Expiratory Flow Rate is the Peak Expiratory Flow of the previous breath, measured at the patient Wye.

Range: **0** through **190 L/min**

Peak Inspiratory Flow Rate (PIFR)

Peak Inspiratory Flow Rate is the peak inspiratory flow of the previous breath, measured at the patient Wye.

Range**:** **3** through **190 L/min**

Peak Inspiratory Pressure (P_{peak})

Peak Inspiratory Pressure is the greatest airway pressure measured during the inspiratory phase and minimum exhalation time of the exhalation phase.

Range: **0** through **120 cmH_2O**

Positive End-Expiratory Pressure (PEEP)

Positive End Expiratory Pressure is the pressure in the airway circuit at the end of exhalation.

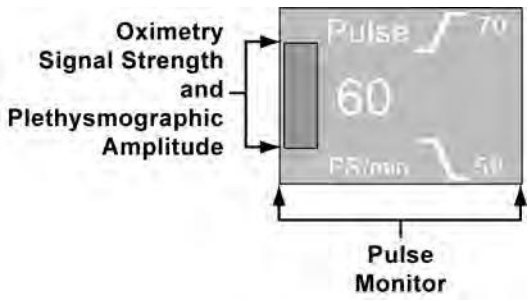
Range: **0** through **99 cmH_2O**

Pulse Rate (Pulse)

Pulse Rate is a measure of the patients' heart rate, measured by the external Oximetry module, when installed and enabled.

Range**:** "**- -**" (no data), or **18** through **300 PR/min**

The Oximetry Signal Strength and Plethysmographic Amplitude indicator bar is displayed within the **Pulse** monitor display when a SpO_2 module is connected to the ventilator, enabled and attached to a patient when the **SpO_2** monitor is not being displayed.



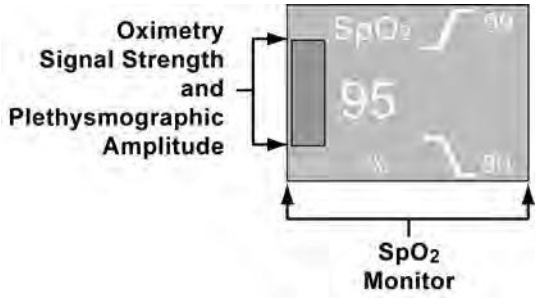
SpO_2

SpO_2 is an estimate of the patient's functional oxygen saturation of arterial oxyhemoglobin saturation, measured by the external Oximetry Module, when installed and enabled.

Range: "**- -**" (no data), or **0** through **100 %**

Oximetry Signal Strength Monitor

The Oximetry Signal Strength monitor is a bar shaped indicator located within the **SpO_2** monitor display. When a SpO_2 module is connected to the ventilator, enabled and attached to a patient, the Oximetry Signal Strength monitor is illuminated to indicate the strength of the signal being received from the external oximetry module. Additionally, the height of the indicator bar fluctuates in unison with the Plethysmographic amplitude[24].



Indications: **Green** fluctuating height indicator bar - Maximum strength signal
Yellow fluctuating height indicator bar - Medium strength signal)
Red fluctuating height indicator bar - Minimum strength signal)
Red flashing/segmented indicator bar - ARTF or OOT condition occurring
Off - No signal being received

> **NOTE**
>
> **ARTF** (Artifact) – A detected pulse beat didn't match the current pulse interval (typically additional/erroneous signal(s).
>
> **OOT** (Out of Track) – An absence of consecutive good pulse signals.
>
> Both are caused by variations in/of the signal(s) from the SpO_2 module and are typically caused by patient/finger movement. Neither is an indication of a faulty or defective SpO_2 module.

The Oximetry Signal Strength indicator bar is displayed within the **Pulse** monitor display when SpO_2 is connected/enabled as previously described, but the **SpO_2** monitor is not displayed.

[24] Plethysmographic amplitude can be displayed on the **Graphics** screen, **Waves** page.

Spontaneous Breath Rate (Spon. Rate)

Spontaneous Breath Rate is the rate per minute of Spontaneous and Support breaths, based on the last eight (8) breath periods. When fewer than eight Spontaneous or Support breaths have occurred, the available number of breaths is used.

Range: **0** through **120 bpm**

Spontaneous Exhaled Tidal Volume (Spon. V_{te})

The Spontaneous Exhaled Tidal Volume monitor (Spon. V_{te}) displays the Exhaled Tidal Volume of Spontaneous and Support breaths. The monitor displays '----' if none of the last eight breaths were patient triggered. The Spontaneous Exhaled Tidal Volume monitor is updated at the end of the exhalation phase of Spontaneous breaths. Tidal volumes are displayed as BTPS (Body Temperature Pressure Saturated) compensated, however it does not compensate for circuit compliance.

Range: **0** through **4000 ml**

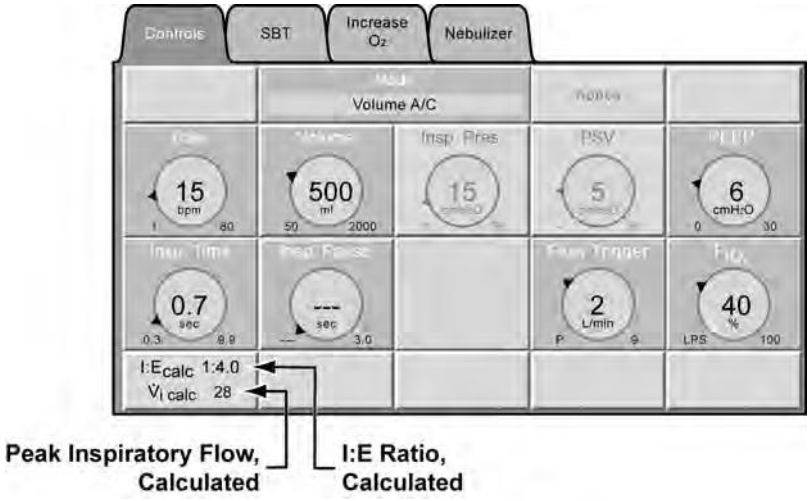
Total Breath Rate (Rate)

Total Breath Rate is the patient breath rate, based on the last eight (8) breath periods. When fewer than 8 breaths have occurred, the available number of breaths is used. All breath types are included in the computation.

Range: **0** through **120 bpm**

Main Screen, Controls Page, Monitored Data

The Enve™ ventilator displays the following monitored data on the **Main** screen, **Controls** page, **Advanced Settings** windows.



I:E Ratio, Calculated ($I:E_{calc}$)

Calculated I:E Ratio is the calculated inspiratory time divided by the expiratory time, based solely on the **Insp**. **Time**, **Insp**. **Pause** and **Rate** settings.

- Inspiratory Pause is not considered during Pressure breaths.

Range: **1:99** through **4.0:1**

Peak Inspiratory Flow, Calculated ($\dot{V}_{i\ calc}$)

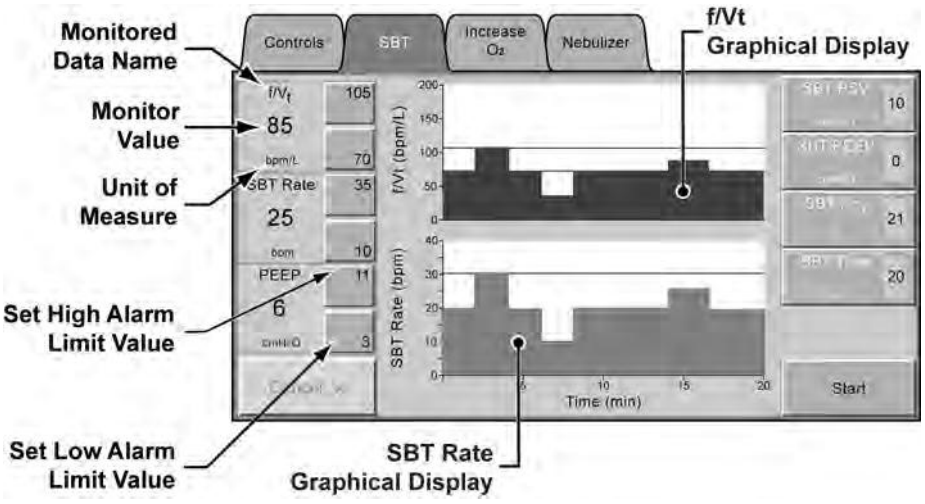
Peak Inspiratory Flow is calculated from the **Volume** and **Insp. Time** settings for Volume breaths.

Range: **10** through **120 L/min**

> **NOTE**
> Calculated Peak Inspiratory Flow ($\dot{V}_{i\ calc}$) is only displayed beneath the control values when Volume modes are selected.

Main Screen, SBT Page, Monitored Data

The Enve™ ventilator displays the following monitored data on the **Main** screen, **SBT** page.



SBT Breath Rate (SBT Rate)

The SBT Breath Rate is the Total Breath Rate during an SBT procedure.

Range: **0** through **120 bpm**

SBT f/V_t (f/V_t)

When an SBT procedure is being performed, the SBT f/V_t monitor (**f/V_t**) displays the calculated value f/V_t, where f is monitored SBT Breath Rate and V_t is average Exhaled Tidal Volume in liters.

The SBT f/V_t monitor (**f/V_t**) updates when the Breath Rate or Exhaled Minute Volume changes during the SBT period and the displayed data values/graphic images remain visible during the SBT period and for five minutes after it has been completed.

Range: "**- -**" (no data), or **0** through **998 bpm/L**

Graphically Displayed Data

The Enve™ ventilator graphically displays monitored data in the following formats:

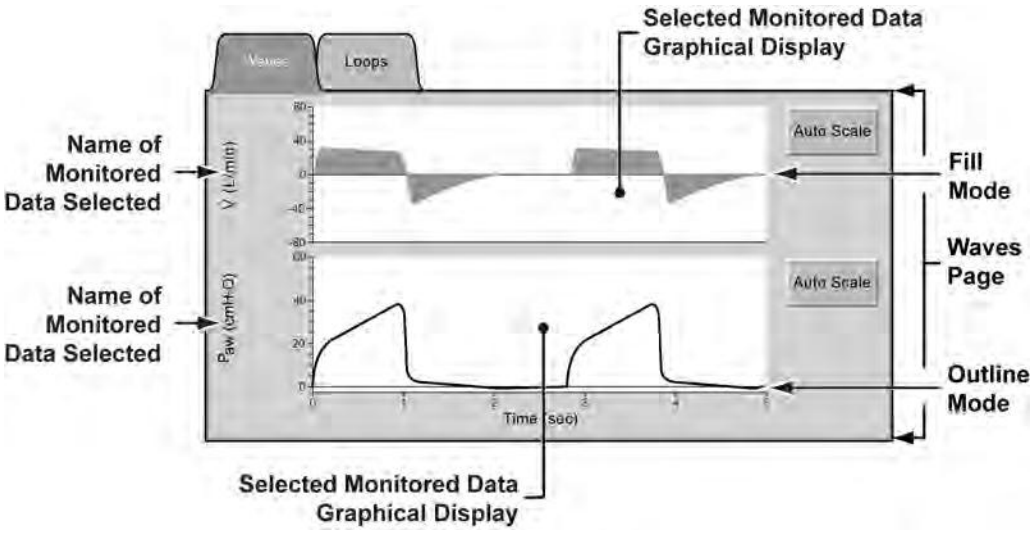
- Waves
- Loops
- Trends

Waveforms during maneuvers such as Inspiratory Hold and Expiratory Hold and the Trends of a Spontaneous Breathing Trial procedure are shown graphically in the appropriate pages during the maneuver/procedure. For more information see *Chapter 9* - Maneuvers, Procedures and Standby Mode.

Waves

The Enve™ ventilator graphically displays monitored data as waveforms on the **Graphics** screen, **Waves** page. Any two (2) of the following monitored values can be selected to display on screen as waveforms:

- Flow (**$\dot{V}$ (L/min)**)
- Airway Pressure (**P_{aw} (cmH_2O)**)
- Tidal Volume (**V_t (ml)**)
- Plethysmograph (**Pleth**)



Waveforms can be displayed either scrolling or wrapping. In Scroll mode, data enters on the right and moves to the left. In Wrap mode, data is drawn starting at the left and then wraps around and re-draws when the right margin is reached. A moving cursor marks the point at which the wave is re-drawn.

Waveforms have a horizontal base line indicating the zero point and can be displayed in a choice of colors and as filled[25] or outlined. When Fill mode is selected, the area between the waveform trace and the zero line is colored. In outline mode, only the waveform trace is colored.

Waveforms are drawn real-time.

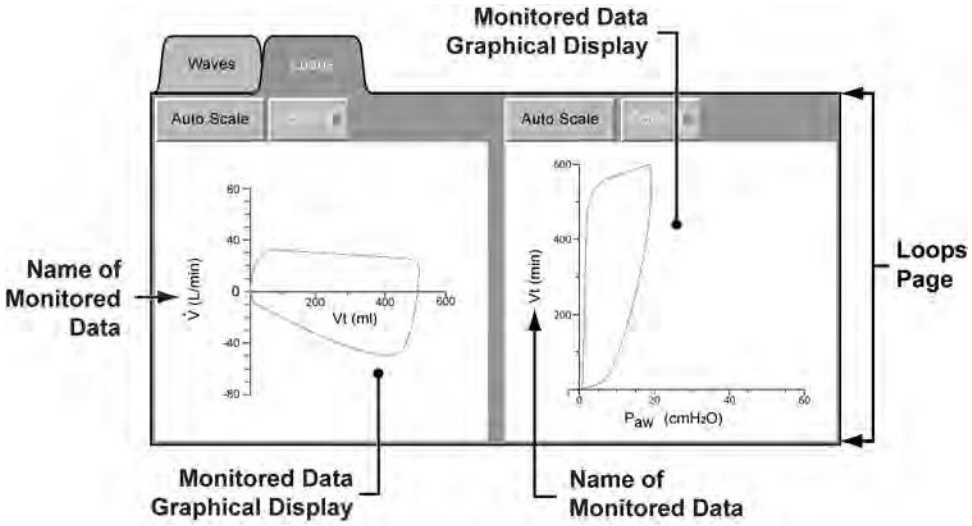
For instructions on how to use and configure the display, see *Graphics Display Customization* in Chapter 3 - Using the Ventilator.

[25] The Wave fill feature is not available on Plethysmographic displays.

Loops

The Enve™ ventilator graphically displays the following monitored data as loops on the **Graphics** screen, **Loops** page:

- Flow (**$\dot{V}$ (L/min)**) : Tidal Volume (**V_t (ml)**) loop, and
- Tidal Volume (**V_t (ml)**) : Airway Pressure (**P_{aw} (cmH_2O)**) loop.



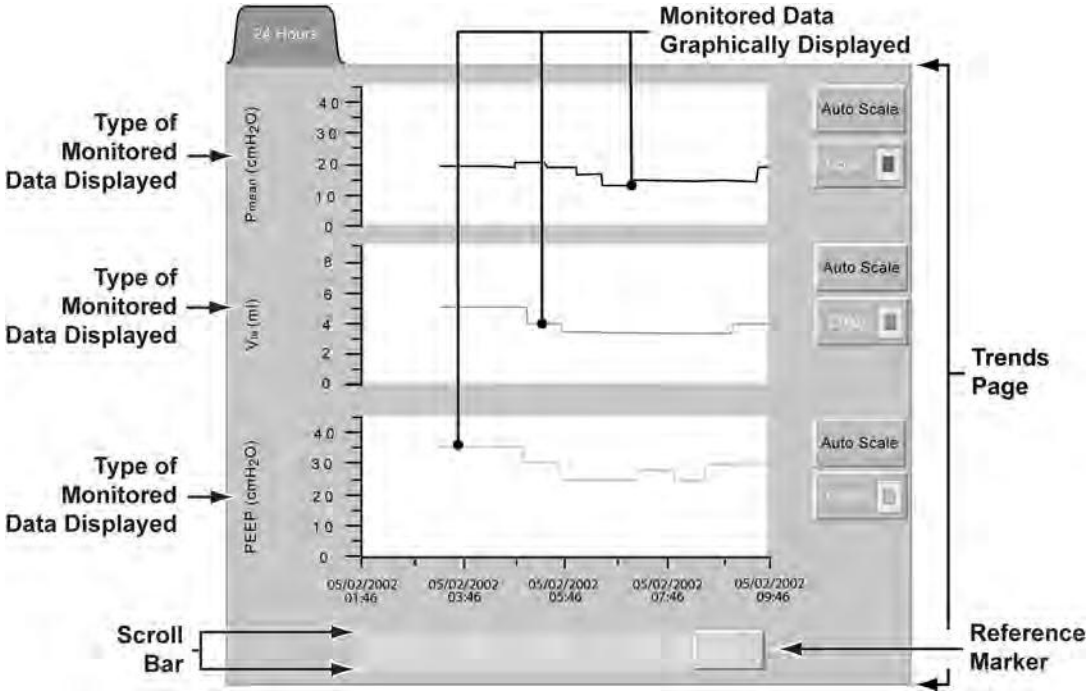
The two (2) Loop graphs are drawn real time. The previous loop is erased at the start of the next inspiration.

For instructions on how to use and configure the display see *Graphics Display Customization* in Chapter 3 - Using the Ventilator.

Trends

Twenty-four (24) hours of monitored data can be stored in the ventilator's Trend Log and graphically displayed on the **Trends** screen, **24 Hours** page. Any three (3) monitored values can be selected and displayed at one time.

For instructions on how to use and configure the displays, see *Graphics Display Customization* in Chapter 3 - Using the Ventilator.



Trend Log

Data values are entered into the Trend Log once per minute. The value entered is the average for the previous minute. Data older than 24 hours is discarded. When the **Patient Circuit Fault** alarm is active, or when no data is available (ventilator is not ventilating or feature is disabled) no data is entered in the Trend Log.

- When the ventilator is docked onto a PTV™ Series Docking Station with a CompactFlash® Memory card installed, all data in the Trend Log is automatically copied onto the memory card. See the PTV™ Series Docking Station Operator's Manual, P/N 12433-001 for detailed information

- Auto PEEP
- Delta Pressure
- Exhaled Minute Volume
- Exhaled Tidal Volume
- Expiratory Pressure
- Fraction of Inspired Oxygen
- Mean Airway Pressure
- Measured Leak
- Oxygen Saturation
- Peak Expiratory Flow
- Peak Inspiratory Flow
- Peak Inspiratory Pressure
- Plateau Pressure
- Positive End-Expiratory Pressure
- Pulse Rate
- SBT Breath Rate
- SBT f/Vt
- Spontaneous Breath Rate
- Spontaneous Tidal Volume
- Static Compliance
- Total Breath Rate

Chapter 8 - VENTILATOR ALARMS

General Information

When the ventilator detects a condition which may require action by the user, it initiates an alarm. The ventilator has both fixed and adjustable alarms. The following sections describe the alarms, what causes them, how to reset them, and how to configure them.

Some alarms can be delayed for a set time or number of breaths. For instance, a High Airway Pressure alarm can be delayed for one or two breaths to prevent activation during patient coughing. See *HP Delay* in Chapter 10 – The Utility Screen for detailed information.

WARNING

Vent Inop Alarm - If a Vent Inop alarm occurs during operation, immediately ventilate the patient using an alternative method, disconnect the ventilator and contact CareFusion or a service technician certified by CareFusion.

Patient Monitoring – Failure to identify and respond to alarm conditions may result in patient injury or death. Ventilator dependent patients should be constantly monitored by personnel trained to address circumstances where equipment becomes inoperative.

Patient Disconnection - The **Low V_e** (Low Minute Volume) and **Low P_{peak}** (Low Peak Pressure) alarms must be appropriately set in order to detect disconnection of the patient from the patient circuit.

Check Alarms – Alarm function should be tested periodically to ensure proper operation (see *Maintenance Schedule* in Chapter 11 – Maintenance and Cleaning, and *Display/Alarm Test* in Chapter 2- Installation and Setup). If any alarm malfunctions, contact CareFusion or a service technician certified by CareFusion. Failure to immediately identify and correct alarm situations may result in serious patient injury or death.

Alarm Priorities

There are multiple priority levels for audible and visual signals generated by the ventilator, depending on the urgency of the condition.

When more than one alarm is activated, the alarm messages will be displayed in the Status Bar at the top of the LCD touch screen and on the **Alarm Messages** page in the order of the priority sequence, with active alarms displayed first.

Audible and Visual Elements

Sound Types, Patterns and Volumes

The Enve™ ventilator generates several unique types of audible alarm and signal notification sound patterns. The volume at which these are generated depends upon on the type of sound and the set audible volume level.
Operators and caregivers should be trained to recognize and respond appropriately to each type of audible alarm or signal sound pattern.

Alarm/Signal Sound Type	Sound Pattern	Audible Volume Level
Vent Inop alarm	A continuously repeated group of 8, pulsed tones	Sounds at fixed volume of 80 ± 5 dBA
High Priority alarm	Continuously repeated groups of 10, pulsed tones (3-2-3-2)[26]	Sounds between >45 dBa and 80 ± 5 dBA, and is automatically adjusted to a higher audible volume level than that of Low Priority alarms[27]
Medium Priority alarm	A continuously repeated group of 3, pulsed tones	
Low Priority alarm	A continuously repeated group of 2, pulsed tones	Sounds between >45 dBa and <80 ± 5 dBA, and is automatically adjusted to a lower audible volume level than that of High and Medium Priority alarms[27]
Accessory Attach signal	A group of 2, ascending pitch, pulsed tones	
Key Click signal	A single medium frequency note	
Battery Use alarm	A periodic audible tone, once per minute	Sounds at set Battery Use Tone volume
SpO_2 Pulse Tone signal	A single audible tone, repeated for each pulse detected	Sounds at set Pulse Tone volume

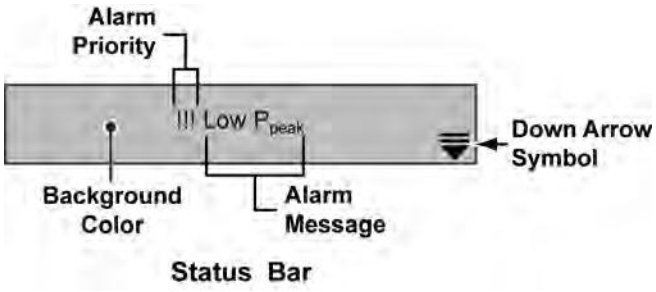
To set the audible volume levels for the High, Medium and Low priority alarms, the Battery Use alarm and/or the SpO_2 Pulse Tone signal, see *Alarm Config Page* in Chapter 10 - The Utility Screen for detailed instructions.

[26] Alarm tones Patterns are per ISO 9703-2
[27] Allows operators to differentiate between High/Medium and Low Priority alarm audible volume levels.

Visual Alarm Displays

There are multiple components to the visual display portion of an alarm condition.

1) Alarm messages are displayed in the Status Bar at the top of the LCD touch screen and on the **Alarm Message** page.
   - When multiple alarms are occurring, the down arrow symbol (▼) is displayed in the Status Bar. Touch the Status Bar to go to the Alarm Message page to view the alarms.



To help identify alarm priorities, active High priority alarm messages displayed in the Status Bar are preceded by three (3) exclamation points (**!!!**) and are displayed on a quickly flashing red background.

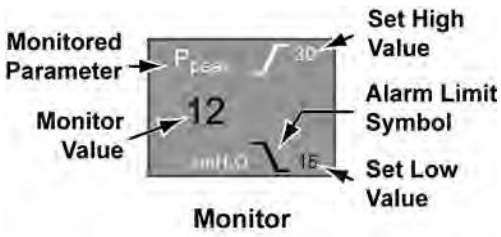
Active Medium priority alarm messages are preceded by two (2) exclamation points (**!!**), are displayed on a flashing yellow background, and active Low priority alarm messages are preceded by one (1) exclamation point (**!**) and are displayed on a slowing flashing cyan background.

When an alarm is no longer active and has not yet been cleared, the background colors are steady state (i.e. not flashing). For example:

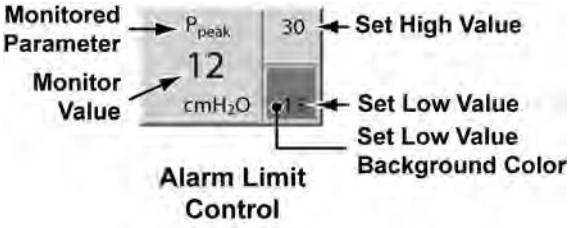
- "**Low P_{peak}**" is a high priority alarm message and is displayed as **!!! Low P_{peak}** on a quickly flashing red background when active, or on a non-flashing red background when inactive and uncleared
- "**High PEEP**" is a medium priority alarm message and is displayed as **!! High PEEP** on a flashing yellow background when active, or on a non-flashing yellow background when inactive and uncleared

The exclamation points are not displayed with the messages on the **Alarm Messages** page.

2) The monitor value, alarm limit symbol and set high or low limit value of the monitored parameter display associated with the active alarm turn red and begin flashing.



3) The background of the set high or low Alarm Limit control value turns red.



When an Alarm Occurs

For most alarm conditions, the following happens when an alarm is activated:

- Alarm message(s) are displayed (see *Visual Alarm Displays* in this chapter)
- An audible alarm sounds (see *Sound Types, Patterns and Volumes* in this chapter)
- Associated Monitors and adjustable Alarm Limit controls are illuminated/flashed (see *Visual Alarm Displays* in this chapter)
- Depending on which alarms were generated, the ventilator may also initiate other actions, such as terminating inspiration and opening the exhalation valve

Exceptions to the above, are as follows:

- The Battery Use alarm has no accompanying displayed message; see *Battery Use* in this chapter for additional information
- The Vent Inop alarm sounds an audible tone and flashes the **Vent Inop** LED; see *Vent Inop* in this chapter for additional information

To Silence an Active Alarm

Push the **Alarm Silence** button on the Lower Interface Panel once to silence an active audible alarm for 60 seconds. Pushing the **Alarm Silence** button a second time cancels the 60 second silence period.

- See *Alarm Silence Button* in Chapter 5 - Controls for additional detailed information

Alarm Recovery

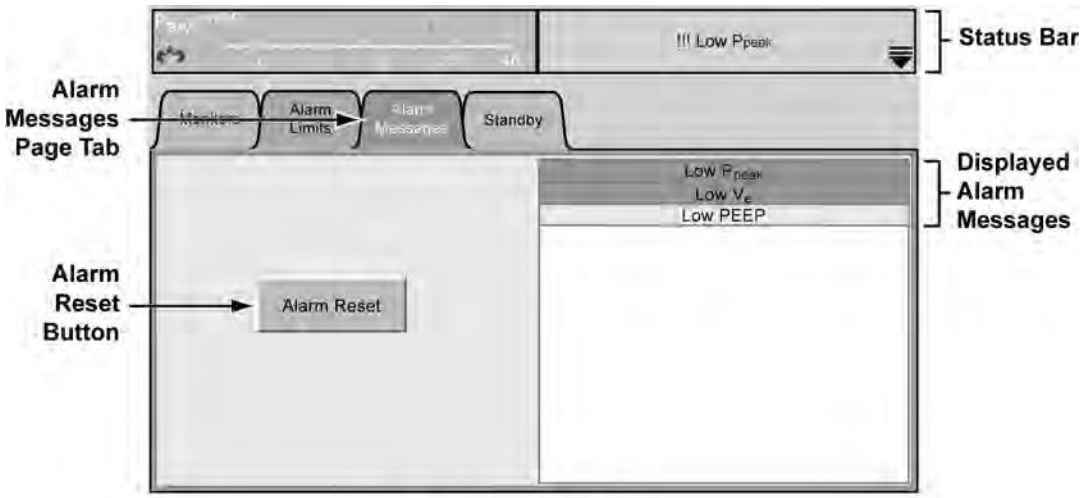
When the conditions that generated an alarm no longer exist and the alarm has not yet been reset, the background color on the Status Bar display automatically stops flashing and the audible alarm is silenced.

- See *Visual Alarm Displays* and *To Reset Alarms* in this chapter for additional information

To Reset Alarms

To reset/remove the display of alarms:

1) Touch the **Status Bar** at the top of the LCD touch screen while an alarm message is being displayed, or touch the **Alarm Messages** page tab on the **Main**, **Graphics**, **Maneuvers**, or **Increase O_2** screens and the **Alarm Messages** page is displayed.



Alarm Messages Page

WARNING

Resetting Alarms - Before resetting/removing alarm messages from the Status Bar and **Alarm Messages** page, operators should review each alarm message displayed and be fully aware of its meaning and applicability to the patient. When necessary, refer to the *Alarm Details* section located later in this chapter for an alphabetical listing of all alarms with detailed explanations of each.

2) Touch the **Alarm Reset** button to reset/remove all inactive alarms from the **Status Bar** and **Alarm Messages** page. Additionally, the following alarm messages are also reset/removed, even if they are active.

- **Apnea**
- **Battery Low**
- **Button Stuck**
- **Configuration Reset**
- **Dock Disconnect**
- **External Power Lost**
- **External Power Low**
- **FiO_2 Sensor Fault**
- **Insert Battery** (reoccurs after 60 seconds)
- **Preventive Maintenance Required xxx**
- **Remove Patient**
- **SBT Off**
- **SBT Time**
- **Service Soon xxx**
- **Transition Battery Use** (one time only, 60 seconds)
- **Ventilator Reset**

Adjustable Alarms

The Enve™ ventilator has both fixed and user adjustable alarms. The adjustable alarm limit values are at factory-set values when the ventilator is manufactured. See *Factory Settings* in Appendix C – Reference Information for a list of factory-set alarm values.

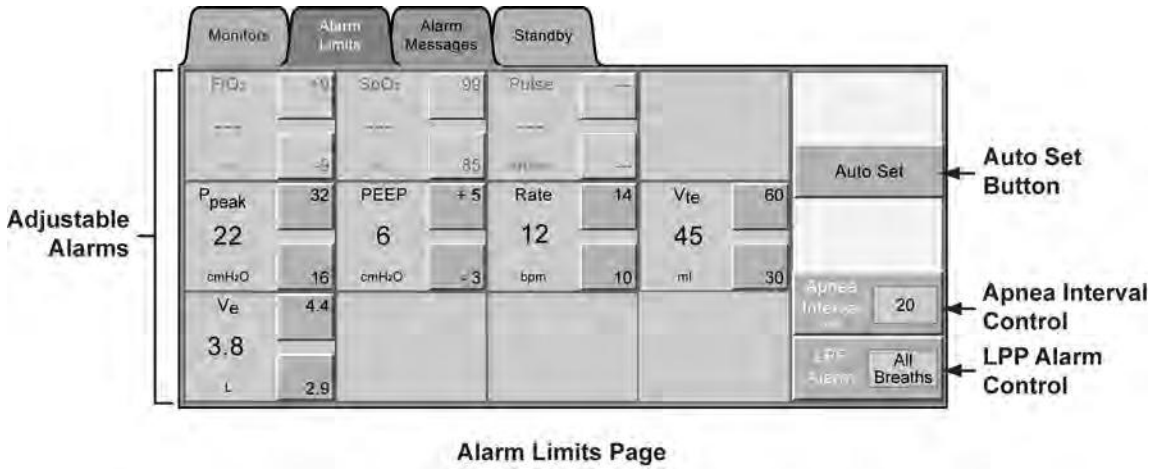
> **WARNING**
>
> **Alarm Values** - To avoid patient injury, always check the alarm limits of all adjustable alarms for appropriateness prior to using the ventilator on a patient.

Alarm Limits Page, Adjustable Alarms

The Enve™ ventilator displays the **Apnea Interval** control, the **LPP Alarm** breath type applicability control, the **Auto Set** button and the following adjustable alarms on the **Main** screen, **Alarm Limits** page.

- **FiO_2** (High & Low FiO_2)
- **Rate** (High & Low Breath Rate)
- **PEEP** (High & Low Positive End Expiratory Pressure)
- **P_{peak}** (High & Low Peak Pressure)
- **Pulse** (High & Low Pulse Rate)
- **SpO_2** (High & Low SpO_2)
- **V_e** (High & Low Exhaled Minute Volume)
- **V_{te}** (High & Low Exhaled Tidal Volume)

Each alarm window displays the name and value of its associated monitored ventilation parameter, and the associated upper and lower alarm limit controls.

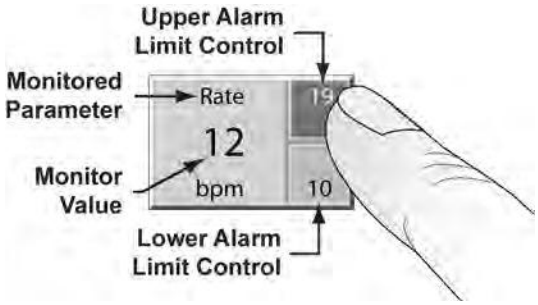


Alarm Limits Page

To Set Individual Adjustable Alarm Limits Values:

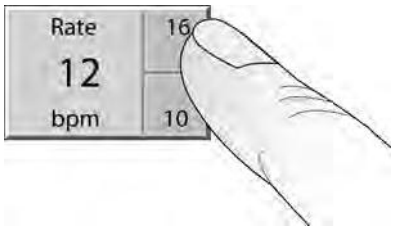
The adjustable alarm limit control values are set or changed in a similar manner as all other touch screen adjustable control values are changed, using the 3 step method of “Select, Change, and Confirm”.

1) **Select** by touching the screen directly over the alarm limit control to be changed. The background behind the value is high-lighted.



2) **Change** the alarm limit value by rotating the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

3) **Confirm** the new value by touching the screen directly over the alarm limit control again. The control reverts to its previous color and the ventilator continues to operate using the new alarm limit value(s).



To Automatically Set All Adjustable Alarm Limits Values:

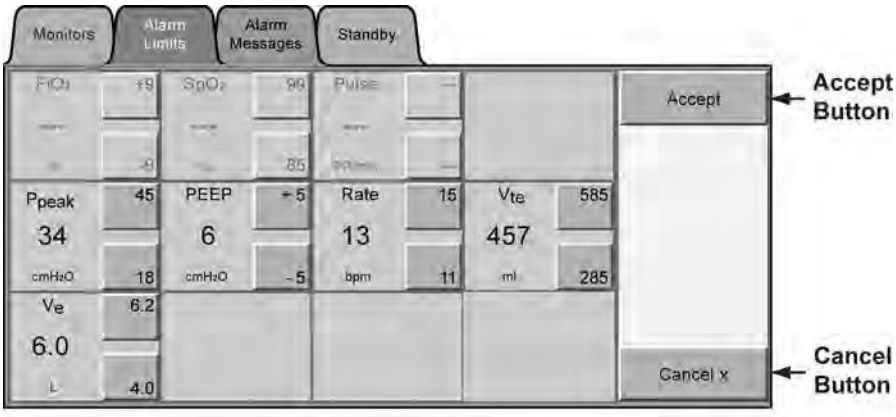
The **Auto Set** button is used to quickly and automatically set all high and low adjustable alarm limits to initial values based on current ventilation data.

> **NOTE**
>
> To use the Auto Set feature properly, the ventilator must be on, in a normal ventilation mode and attached to a stablized patient using current ventilation settings.
>
> The Auto Set feature is not available (**Auto Set** button disabled) during NPPV modes of ventilation.

1) Touch the **Auto Set** button on the **Main** screen, **Alarm Limits** page.

Alarm Limits Page

- All high and low adjustable alarm limits are automatically set to the values shown in the following table
- The **Auto Set** button is replaced by the display of **Cancel** and **Accept** buttons



Alarm Limits Page

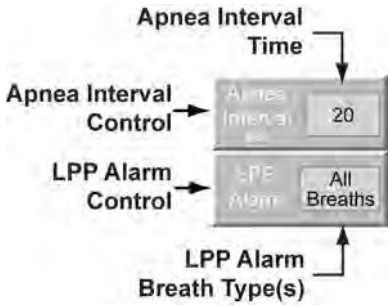
Auto Set Alarm Limits Values

Alarms	Auto Set Values (Adult and Pediatric)	
High P_{peak}	100 cmH_2O or 10 cmH_2O above maximum P_{peak} of previous 8 breaths, whichever is less	
High Rate	120 bpm or 15% above current monitored Breath Rate, whichever is less	
High V_e	99 L or 15% over current monitored V_e, whichever is less	
High PEEP	5 cmH_2O above set PEEP	
High Pulse Rate	299 PR/min or 20 PR/min above current monitored Pulse Rate, whichever is less	
High SpO_2	99% or 5% above current monitored SpO_2, whichever is less	
High V_{te}	2000 ml or 25% above maximum V_{te} of previous 8 breaths, whichever is less	
Low Rate	15% below current monitored Breath Rate	
Low V_e	25% below current monitored V_e, but not less than 0.1 L.	
Low P_{peak}	Minimum of P_{peak} of previous 8 breaths minus 10 cmH_2O, but not less than 5 cmH_2O.	
Low PEEP (based on PEEP control setting)	**PEEP Control Setting**	**PEEP Auto Set Alarm Value**
	8 cmH_2O or greater	-5 cmH_2O below set PEEP
	6 – 7 cmH_2O	-3 cmH_2O below set PEEP
	3 – 5 cmH_2O	-2 cmH_2O below set PEEP
	2 cmH_2O	-1 cmH_2O below set PEEP
	0 – 1 cmH_2O	Off
Low Pulse Rate	19 PR/min or 20 PR/min below current monitored Pulse Rate, whichever is greater	
Low SpO_2	80% or 5% below current monitored SpO_2, whichever is greater	
Low V_{te}	10 ml or 15% under minimum V_{te} of previous 8 breaths, whichever is greater	

2) Carefully review all high and low alarm limits settings.
    - If necessary or desired, use the previously shown 3 step method (“Select, Change, and Confirm”) to change individual Alarm Limit settings until all values are clinically appropriate for your patient
3) Touch the **Cancel** button to cancel all changes/return settings to previous values, or touch the **Accept** button to accept all changes and begin using the displayed Alarm Limit values.

To Set the Apnea Interval and LPP Alarm Breath Type(s):

The **Apnea Interval** and **LPP Alarm** (Low Peak Inspiratory Pressure) control values are set or changed in a similar manner as all other touch screen adjustable control values are changed, using the 3 step method of “Select, Change, and Confirm”.



Select Touch the screen directly over the displayed **Apnea Interval** time limit value or **LPP Alarm** breath type to be changed. The background behind the value is highlighted.

Change Rotate the **Scroll** knob on the Lower Interface Panel clockwise to increase or counter-clockwise to decrease the value.

Confirm Touch the control again. The control returns to its previous color and the ventilator continues to operate using the new Apnea Interval time limit value or LPP Alarm breath type setting, as applicable.

See *Apnea* and *Low Ppeak (Low Peak Inspiratory Pressure)* in this chapter for additional information.

Alarm Configuration in the Utility Screen

The following alarm related configurations can be accessed/set from within the **Utility** screen, **Alarm Config** page.

- Safety Valve Delta Pressure
- Alarm Volume
- Battery Use Tone
- V / BR Delay (Volume / Breath Rate Delay)
- PEEP Delay
- HP Delay (High Pressure Alarm Delay)

See *Alarm Config Page* in Chapter 10 -The Utility Screen for detailed instructions.

Alarm Details

Apnea

The Apnea alarm (a user adjustable alarm) is generated when the time since the start of the last breath is greater than the set **Apnea Interval**.

Range**:** **10** through **60 sec**, in increments of 5 seconds

When an Apnea alarm occurs:

- The **Apnea** alarm message is displayed
- A High Priority audible alarm sounds
- Controls for Apnea Backup mode are active and all other control displays are inactive
- The ventilator initiates Apnea Backup ventilation and breaths are delivered in Assist/Control mode, per the set control values
- The breath period is reset

While in Apnea Backup mode, the alarm continues to sound and the **Apnea** message continues to flash until the operator resets the alarm or the patient triggers two (2) consecutive breaths.

When the **Apnea** alarm is reset by the operator or the patient triggers 2 consecutive breaths:

- Apnea Backup ventilation terminates and the ventilator returns to the previous mode
- Control displays return to normal ventilation mode

Apnea Interval

To set the Apnea Interval:

The **Apnea Interval** is set from the **Main** screen, **Alarm Limits** page. See *To Set the Apnea Interval and LPP Alarm Breath Type(s):* earlier in this chapter.

For more information on Apnea Backup ventilation, see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes.

Battery Empty

A Battery Empty alarm (a fixed alarm) is generated when the ventilator is operating from the Removable Battery Pack and the battery charge level falls below the 5% charge threshold

> **WARNING**
>
> **Battery Empty Alarm** - A Battery Empty alarm indicates the Removable Battery Pack is almost depleted. To avoid possible loss of ventilation immediately insert a charged Removable Battery Pack or connect the ventilator to an external source of power.

When a Battery Empty alarm occurs:

- The **Battery Empty** alarm message is displayed
- A high priority audible alarm sounds
- The **Battery Pack** LED on the Lower Interface Panel is illuminated red

Battery Fault

A Battery Fault alarm (a fixed alarm) is generated when the Removable Battery Pack is installed in the ventilator and any of the following conditions exist:

- Unable to charge the Removable Battery Pack
- Removable Battery Pack is unable to be used to power the ventilator for reasons other than the battery being depleted

> **WARNING**
>
> **Battery Fault Alarm** - Repeated or continuous Battery Fault alarms indicate that the currently installed Removable Battery Pack is unreliable. Insert a reliable, charged Removable Battery Pack or connect the ventilator to an external source of power.

When a Battery Fault alarm occurs:

- The **Battery Fault** alarm message is displayed
- A medium priority audible alarm sounds
- The **Battery Pack** LED on the Lower Interface Panel is illuminated flashing red

Battery Low

A Battery Low alarm (a fixed alarm) is generated when the ventilator is operating from the Removable Battery Pack and the battery charge level falls below the 25% charge level threshold.

WARNING

Battery Low Alarm - A Battery Low alarm indicates the Removable Battery Pack is approaching depletion. Be prepared to insert a fully charged Removable Battery Pack or connect the ventilator to an external source of power.

When a Battery Low alarm occurs:

- The **Battery Low** alarm message is displayed
- A medium priority audible alarm sounds
- The **Battery Pack** LED on the Lower Interface Panel is illuminated amber

Battery Temperature Fault

The Battery Temperature Fault alarm (a fixed alarm) is generated when the Removable Battery Pack is the only power source available and:

- The temperature of the Removable Battery Pack is greater than 60° C
- The temperature of the Removable Battery Pack is less than -20° C

WARNING

Battery Temperature Fault Alarm – The Battery Temperature Fault alarm indicates that the ventilator's Removable Battery Pack is excessively hot or cold. When this alarm occurs, the ventilator shuts down and gas is not delivered to the patient. To avoid patient harm, disconnect the patient and ventilate using an alternate method until the cause of the Battery Temperature Fault alarm condition has been eliminated. See *Chapter 13 - Troubleshooting* for additional information.

When a Battery Temperature Fault alarm occurs:

- The **Battery Temperature Fault** alarm message is displayed
- A high priority audible alarm sounds
- The **Battery Pack** LED on the Lower Interface Panel flashes red
- The ventilator stops delivering mandatory machine breaths and shuts down

Battery Use

The Battery Use alarm (a fixed alarm) is generated when the ventilator begins operating on power from a charged Removable Battery Pack.

When a Battery Use alarm occurs:

- An audible alarm sounds

Although the Battery Use alarm cannot be reset when the ventilator is operating from the Removable Battery Pack, the Battery Use tone volume level can be set within a range of **Off**, or **1** through **3**, from the **Alarm Config** page in the **Utility** screen. *See Alarm Config Page* in Chapter 10 – The Utility Screen for additional information.

Blower Demand Exceeded

The Blower Demand Exceeded alarm (a fixed alarm) is generated when the average current demand of the ActiveCore™ blower exceeds a predetermined limit.

> **WARNING**
>
> **Blower Demand Exceeded Alarm** – During a sustained Blower Demand Exceeded alarm condition, the ventilator blower is stopped and gas is not delivered to the patient. To avoid patient harm, disconnect the patient and ventilate using an alternate method until the cause of the Blower Demand Exceeded alarm condition has been eliminated. See *Chapter 13 - Troubleshooting* for additional information.

When a Blower Demand Exceeded alarm occurs:

- The **Blower Demand Exceeded** alarm message is displayed
- A high priority audible alarm sounds
- The ventilator stops delievering mandatory machine breaths

Button Stuck

A Button Stuck alarm (a fixed alarm) is generated when the ventilator detects pressure on the touch screen for more than 60 seconds or when a button, other than the **On/Off** control button, has been held down for more than 60 seconds.

> **WARNING**
>
> **Button Stuck Alarm** - If this alarm occurs without external stimulus, it indicates that the ventilator may not be working properly. Disconnect the patient from the ventilator, provide an alternative method of ventilation and contact CareFusion or a service technician certified by CareFusion.

When a Button Stuck alarm occurs:

- The **Button Stuck** alarm message is displayed
- A medium priority audible alarm sounds

Remove any objects that may be applying pressure to the ventilator's front panels and see *UVT and EST Testing in Startup Mode* in Chapter 2 - Installation and Setup for instructions to perform Touch Screen calibration and the Button Test.

Configuration Reset

The ventilator is delivered with Controls, Alarms and Configuration settings set to factory values. When changes are made to any of the adjustable settings, the ventilator stores the new values in non-volatile memory[28].

During POST (Power On Self Test), the ventilator checks all stored configuration values. If an invalid value is detected, the Configuration Reset alarm (a fixed alarm) is generated.

When a Configuration Reset alarm is generated:

- The **Configuration Reset** alarm message is displayed
- A high priority audible alarm sounds
- All adjustable Controls, Alarms and Configuration settings are reset to their original factory values

> **WARNING**
>
> **Check Settings** – Check all ventilator settings after a **Configuration Reset** alarm and modify them as necessary for your patient. Settings may no longer be appropriate.
>
> **Multiple Reset Alarms** - Repeated Configuration Reset alarms may indicate a problem with the ventilator's non-volatile memory. Immediately provide alternative ventilation for your patient and contact CareFusion or a service technician certified by CareFusion.

> **NOTE**
>
> A Configuration Reset alarm is not generated if the ventilator configuration has been manually reset to factory values using the **Reset to Factory Defaults** control in Startup mode.

[28] Non-volatile memory is memory that is not erased when the ventilator is turned off or disconnected.

Dock Disconnect (Docking Station Disconnect)

The Dock Disconnect alarm (a fixed alarm) is generated when the ventilator detects power and communications from a Docking Station are lost (such as occurs when undocking the ventilator).

When a Dock Disconnect alarm occurs:

- The **Dock Disconnect** alarm message is displayed
- A medium priority audible alarm sounds

Dock Fault (Docking Station Fault)

The Dock Fault alarm (a fixed alarm) is generated when the ventilator is receiving power from the Docking Station and detects corrupted or no communications; or when the ventilator is receiving communications from the Docking Station and is not receiving power.

When a Dock Fault alarm occurs:

- The **Dock Fault** alarm message is displayed
- A medium priority audible alarm sounds

External Power Low

The External Power Low alarm (a fixed alarm) is generated when the ventilator is using external DC power and the voltage is equal to or less than the Battery Low Limit.

WARNING

External Power Low Alarm - Indicates that the external power voltage is low. Be prepared to provide an alternate power source for the ventilator.

When an External Power Low alarm occurs:

- The **External Power Low** message is displayed
- A medium priority audible alarm is sounded
- The **External Power** LED on the Lower Interface Panel is illuminated amber

External Power Fault

The External Power Fault alarm (a fixed alarm) is generated when the ventilator is operating on external power (from side power port or Docking Station) that has too high of a source impedance to properly power the ventilator.

WARNING

External Power Fault Alarm - Repeated External Power Fault alarms indicate that the ventilator's external power source may be unreliable. Provide an alternative power source for the ventilator.

When an External Power Fault alarm occurs:

- The **External Power Fault** alarm message is displayed
- A medium priority audible alarm sounds
- The **External Power** LED on the Lower Interface Panel is illuminated flashing red
- Either the **Battery Pack** or **Transition Batt**. LED on the Lower Interface Panel illuminates (depending on which is powering the ventilator)

External Power Lost

The External Power Lost alarm (a fixed alarm) is generated when the ventilator is turned on and its external power source is disconnected or drops below the required minimum voltage.

> **WARNING**
>
> **External Power Lost Alarm** - An External Power Lost alarm indicates the ventilator is no longer operating from external power. Insert a charged Battery Pack or connect the ventilator to alternative external power.

When an External Power Lost alarm occurs:

- The **External Power Lost** alarm message is displayed
- A medium priority audible alarm sounds
- The **External Power** LED on the Lower Interface Panel is off
- Either the **Battery Pack** or **Transition Batt.** LED on the Lower Interface Panel illuminates (depending on which is powering the ventilator)

FiO_2 Sensor Fault

The FiO_2 Sensor Fault alarm (a fixed alarm) is generated when FIO_2 has been enabled (in Startup mode) and the ventilator detects a FIO_2 Sensor failure.

> **CAUTION**
>
> **FiO_2 Sensor Fault Alarm –** This alarm indicates that the FIO_2 Sensor in use may not be working properly with the ventilator. Replace the FIO_2 Sensor.

When an FiO_2 Sensor Fault alarm occurs:

- The **FiO_2 Sensor Fault** alarm message is displayed
- A medium priority audible alarm sounds

Hardware Fault

The Hardware Fault alarm (a fixed alarm) is generated when the ventilator detects an internal failure condition that requires immediate operator attention.

WARNING

Hardware Fault Alarm - Operating the Enve™ ventilator with an active Hardware Fault alarm may result in inaccurate measurements or ventilation. If this alarm occurs, immediately disconnect the patient from the ventilator and provide alternative ventilation. Contact CareFusion or a service technician certified by CareFusion.

When a Hardware Fault alarm occurs:

- The **Hardware Fault xxx** alarm message is displayed with a numeric code representing the error condition (record the **xxx** code to report when scheduling servicing)
- A high priority audible alarm sounds

To check the type of hardware fault detected, see the *Event Trace, Service Page* described in Chapter 10 – The Utility Screen.

High Breath Rate

The High Breath Rate alarm (a user adjustable alarm) is generated when the monitored Total Breath Rate exceeds the set High Breath Rate alarm limit for the set V / BR Delay, and at least eight (8) breaths have occurred since the last High Breath Rate alarm was reset.

Range**:** **1** through **120 bpm**, or "**- -**" (off)

When a High Breath Rate alarm occurs:

- The **High Breath Rate** alarm message is displayed
- A medium priority audible alarm sounds
- The **Rate** Alarm Limit control (high) turns red, and the associated values displayed on the **Rate** Monitor turn red and begin flashing

To set the High Breath Rate alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for the High Breath Rate alarm:

A delay can be set for the High Breath Rate alarm in the **Utility** screen. *See HP Delay* in Chapter 10 – The Utility Screen for detailed instructions.

High FiO_2

The High FiO_2 alarm is a fixed alarm when the active **FiO_2** value is set between 21 – 100%. The alarm is generated when the FIO_2 Sensor is connected and the monitored FiO_2 (Fraction of Inspired Oxygen) is equal to or greater than the active **FiO_2** setting[29] plus 9%.

> **NOTE**
> When the FiO_2 setting is changed (FiO_2 Control setting, Increase O_2 Procedure started, or SBT FiO_2 Control setting) the **High FiO_2** alarm is deactivated for 120 seconds.

The alarm is a user adjustable alarm when the active **FiO_2** value is set to **LPS**.

Range (LPS only): **21** through **100 %**, or "---" (off)

When a High FiO_2 alarm occurs:

- The **High FiO_2** alarm message is displayed
- A high priority audible alarm sounds
- The **FiO_2** monitored value turns red

High O_2 Inlet Pressure

The High O_2 Inlet Pressure alarm (a fixed alarm) is generated when the monitored O_2 Inlet Pressure is:

- Greater than 11 PSI when the active[29] **FiO_2** control is set to **LPS** (Low Pressure Source),
- Greater than 67 PSI and the Nebulizer procedure is active
  or
- Greater than 89 PSI

When a High O_2 Inlet Pressure alarm occurs:

- The **High O_2 Inlet Pressure** alarm message is displayed
- A medium priority audible alarm sounds
- If the set **FiO_2** control value is **LPS** (Low Pressure Source) and the **O_2 Inlet** pressure is above 40 PSI, the ventilator automatically switches to High Pressure O_2 Source mode and changes the active[29] **FiO_2** control value to **21%**

[29] The "active" FiO_2 setting is the **FiO_2** control setting during normal ventilation (**Main** screen, **Controls** page), the **Level** control setting during an Increase O_2 procedure (**Main** screen, **Increase O_2** page), or the **SBT FiO_2** control setting during an SBT procedure (**Main** screen, **SBT** page).

High PEEP

The High PEEP alarm (a user adjustable alarm) is generated when the monitored PEEP is greater than the active PEEP control setting[30].

> **NOTE**
> If the active PEEP control setting[30] is changed, the **High PEEP** alarm is delayed for 30 seconds to allow the PEEP to stabilize.

Once the alarm is cleared, it will remain cleared until at least eight (8) breaths have occurred since the alarm was cleared.

Range**:** **3** through **50 cmH_2O**, or "**- -**" (off)

When a High PEEP alarm occurs:

- The **High PEEP** alarm message is displayed
- A medium priority audible alarm sounds
- The **PEEP** Alarm Limit control (high) turns red, and the associated values displayed on the **PEEP** Monitor turn red and begin flashing.

To set the High PEEP alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for the High (or Low) PEEP alarm:

See *PEEP Delay* in Chapter 10 – The Utility Screen.

[30] The "active" PEEP control setting is the **PEEP** control setting during normal ventilation (**Main** screen, **Controls** page), or the **SBT PEEP** control setting during an SBT procedure (**Main** screen, **SBT** page).

High P_{peak} (High Airway Pressure)

The High P_{peak} alarm (a user adjustable alarm) is generated when the monitored airway pressure exceeds the set High P_{peak} alarm limit for the set number of HP Delay breaths.

Range**:** **5** through **100 cmH_2O**

When a High P_{peak} alarm occurs:

- The **High P_{peak}** message is displayed
- A high priority audible alarm sounds
- The **P_{peak}** Alarm Limit control (high) turns red, and the associated values displayed on the **P_{peak}** Monitor turn red and begin flashing
- Inspiration is terminated and the exhalation valve is opened to relieve pressure

> **WARNING**
>
> **Sustained High P_{peak}** - During a sustained High P_{peak} alarm condition, the ventilator blower is stopped and gas is not delivered to the patient. To avoid patient injury, disconnect the patient circuit, assess the patient's airway (ensure patency) and ventilate using an alternate method until the cause of the high pressure condition has been eliminated. See *Chapter 13 - Troubleshooting* and *Safety Valve High Pressure Relief* in this chapter for additional information.

If the high pressure condition does not recover within 1.5 seconds or if Airway Pressure ≥ 110 cmH_2O the following occurs:

- The blower is stopped, the safety valve is opened, the PEEP pilot pressure is vented to ambient and the nebulizer drive (optional) is turned off

After a sustained high pressure condition;

When the ventilator has recovered from the high pressure condition[31], if the circuit pressure exceeds the set High Pressure Limit setting again before another un-terminated breath occurs;

- The Blower is stopped, the Safety Valve is opened, the PEEP pilot pressure is vented to ambient and the nebulizer drive (optional) is turned off without requiring a 1.5 second persistence of the condition
- The audible alarm is sounded immediately regardless of the High Pressure Alarm Delay setting

Recovery from the sustained high pressure condition requires either an alarm reset or 10 seconds to have elapsed.

To set the High P_{peak} alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for the High P_{peak} alarm:

See HP Delay in Chapter 10 – The Utility Screen for detailed instructions. The audible alarm will sound whenever a high pressure condition persists which stops the Blower, regardless of the delay setting.

[31] The blower is restarted, the safety valve is closed, the PEEP pilot pressure is restored and the nebulizer drive (optional) is turned back on.

High Pulse Rate

The High Pulse Rate alarm (a user adjustable alarm) is generated when the monitored Pulse Rate exceeds the set High Pulse Rate alarm limit. The High Pulse Rate alarm is only active when the SpO_2 Module is connected, enabled and attached to a patient.

Range: **18** through **299 PR/min**, or "**- -**" (off)

When a High Pulse Rate alarm occurs:

- The **High Pulse Rate** alarm message is displayed
- A high priority alarm sounds
- The **Pulse** Alarm Limit control (high) turns red, and the associated values displayed on the **Pulse** Monitor turn red and begin flashing

To set the High Pulse Rate alarm limit:

See *Adjustable Alarms* in this chapter.

High SpO_2

The High SpO_2 alarm (a user adjustable alarm) is generated when the monitored SpO_2 exceeds the set High SpO_2 alarm limit. The High SpO_2 alarm is only available when the Oximetry Module is connected, enabled and attached to a patient.

Range**:** **80** through **99%**, or "**- -**" (off)

When a High SpO_2 alarm occurs:

- The **High SpO_2** message is displayed
- A high priority alarm sounds
- The **SpO_2** Alarm Limit control (high) turns red, and the associated values displayed on the SpO_2 Monitor turn red and begin flashing

To set the High SpO_2 alarm limit:

See *Adjustable Alarms* in this chapter.

High V_e (High Exhaled Minute Volume)

The High V_e alarm (a user adjustable alarm) is generated when the monitored Exhaled Minute Volume (V_e) is greater than the set High V_e alarm limit for the set V / BR Delay (in seconds) and at least eight (8) breaths have occurred since the last High V_e alarm was reset (or ventilator Power Up, whichever was last).

Range: **0.1** through **99 Liters**, or "**- -**" (off)

When a High V_e alarm occurs:

- The **High V_e** alarm message is displayed
- A medium priority audible alarm sounds
- The **V_e** Alarm Limit control (high) turns red, and the associated values displayed on the **V_e** Monitor turn red and begin flashing

To set the High V_e alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for the High (or Low) V_e alarm:

See *V / BR Delay* in Chapter 10 – The Utility Screen for detailed instructions.

High V_{te} (High Exhaled Tidal Volume)

The High V_{te} alarm (a user adjustable alarm) is generated when the monitored Exhaled Tidal Volume (V_{te}) is greater than the set High V_{te} alarm limit set for the set V / BR Delay (in seconds).

Range: **50** through **2000 ml**, or "**- -**" (off)

When a High V_{te} alarm occurs:

- The **High V_{te}** alarm message is displayed
- A medium priority audible alarm sounds
- The **V_{te}** Alarm Limit control (high) turns red, and the associated values displayed on the **V_{te}** Monitor turn red and begin flashing

To set the High V_{te} alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for the High (or Low) V_{te} alarm:

See *V / BR Delay* in Chapter 10 – The Utility Screen for detailed instructions.

Insert Battery

The Insert Battery alarm (a fixed alarm) is generated when the Removable Battery Pack is not detected.

When an Insert Battery alarm occurs:

- The **Insert Battery** alarm message is displayed
- A medium priority audible alarm sounds
- The **Battery Pack** indicator on the Lower Interface Panel flashes red

The Insert Battery alarm can be silenced for 60 seconds but will continue to re-activate until a battery is inserted.

Loss of O_2 (Low O_2 Inlet Pressure)

The Loss of O_2 alarm (a fixed alarm) is generated when the monitored O_2 Inlet Pressure is less than 39 PSI and the active[32] **FiO_2** control is set to more than 21%. The alarm may also be triggered when the **FiO_2** is set to 21% if the **Increase O_2** procedure or the **Nebulizer** procedure is active.

- The Loss of O_2 alarm is inactive when the **FiO_2** control is set to **LPS**

When a Loss of O_2 alarm occurs:

- The **Loss of O_2** alarm message is displayed
- A high priority audible alarm sounds

See *Procedures* in Chapter 9 – Maneuvers, Procedures and Standby Mode for additional information.

[32] The "active" FiO_2 setting is the **FiO_2** control setting during normal ventilation (**Main** screen, **Controls** page), the **Level** control setting during an Increase O_2 procedure (**Main** screen, **Increase O_2** page), or the **SBT FiO_2** control setting during an SBT procedure (**Main** screen, **SBT** page).

Low Breath Rate

The Low Breath Rate alarm (a user adjustable alarm) is generated when the monitored Total Breath Rate is less than the Low Breath Rate alarm limit for the set V / BR Delay (in seconds) and at least eight (8) breaths have occurred since the last Low Breath Rate alarm was reset.

Range**:** "**- -**" (off), or **1** through **99 bpm**

When a Low Breath Rate alarm occurs:

- The **Low Breath Rate** alarm message is displayed
- A medium priority audible alarm sounds
- The **Rate** Alarm Limit control (low) turns red, and the associated values displayed on the **Rate** Monitor turn red and begin flashing

To set the Low Breath Rate alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for Minute Volume or Breath Rate alarms:

See *V / BR Delay* in Chapter 10 – The Utility Screen for detailed instructions.

Low FiO_2

The Low FiO_2 alarm is a fixed alarm when the active **FiO_2** value is set between 21 – 100%. The alarm is generated when the FIO_2 Sensor is connected and the monitored **FiO_2** (Fraction of Inspired Oxygen) is equal to or less than the maximum of 18% or the active **FiO_2** value[33] minus 9%

The Low FiO_2 alarm is a user adjustable alarm when the active **FiO_2** value is set to **LPS**.

Range (LPS only): "---" (off), or **18** through **95 %**

When a Low FiO_2 alarm occurs:

- The **Low FiO_2** alarm message is displayed
- A high priority audible alarm sounds
- The **FiO_2** monitored value turns red

See *Procedures* in Chapter 9 – Maneuvers, Procedures and Standby Mode for additional information.

[33] The "active" FiO_2 setting is the **FiO_2** control setting during normal ventilation (**Main** screen, **Controls** page), the **Level** control setting during an Increase O_2 procedure (**Main** screen, **Increase O_2** page), or the **SBT FiO_2** control setting during an SBT procedure (**Main** screen, **SBT** page).

Low PEEP

The Low PEEP alarm (a user adjustable alarm) is generated when the monitored PEEP is less than the active PEEP control setting[34].

Once the alarm is cleared, it will remain cleared until at least eight (8) breaths have occurred since the alarm was cleared.

Range: "**- -**" (off), or **1** through **30 cmH_2O**

When a Low PEEP alarm occurs:

- The **PEEP** Alarm Limit control (low) turns red, and the associated values displayed on the **PEEP** Monitor turn red and begin flashing
- The **Low PEEP** alarm message is displayed
- A high priority audible alarm sounds

To set the Low PEEP alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for the PEEP alarms:

See *PEEP Delay* in Chapter 10 – The Utility Screen for detailed instructions.

NOTE

- Activation of the **Low PEEP**, **Low P_{peak}**, **Low V_e** and/or **Patient Circuit Fault** alarms could indicate a patient circuit leak. Check the patient circuit and exhalation diaphragm integrity if one or more of these alarms is repeatedly activated.
- If the active PEEP control setting[34] is changed, the Low PEEP (**Low PEEP**) alarm is delayed for 30 seconds to allow the PEEP to stabilize.

[34] The "active" PEEP control setting is the **PEEP** control setting during normal ventilation (**Main** screen, **Controls** page), or the **SBT PEEP** control setting during an SBT procedure (**Main** screen, **SBT** page).

Low P_{peak} (Low Peak Inspiratory Pressure)

The Low P_{peak} alarm (a user adjustable alarm) is generated when the monitored Peak Inspiratory Pressure (P_{peak}) for a selected breath is less than the set Low P_{peak} alarm limit.

Range: "**- -**" (off), or **1** through **60 cmH_2O**

WARNING

Patient Circuit Accessories - Accessories such as speaking valves, heat-moisture exchangers and filters create additional patient circuit resistance. In the event of a disconnection, this may compromise **Low P_{peak}** alarm generation. Set the **Low P_{peak}** alarm limit high enough to detect a disconnect when using these accessories, or use an alternate method (e.g. **Low V_e** alarm) to ensure disconnect detection.

NOTE

Activation of the **Low P_{peak}**, **Low V_e**, **Low PEEP** and/or **Patient Circuit Fault** alarms could indicate a patient circuit leak. Check the patient circuit and exhalation diaphragm integrity if one or more of these alarms is repeatedly activated.

When a Low P_{peak} alarm occurs:

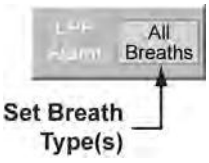
- A **Low P_{peak}** alarm message is displayed
- A high priority audible alarm sounds
- The **P_{peak}** Alarm Limit control (low) turns red, and the associated values displayed on the **P_{peak}** monitor turn red and begin flashing

To set the Low P_{peak} alarm limit:

See *Adjustable Alarms* in this chapter.

To set the applicable breath type for the Low P_{peak} alarm:

The Low P_{peak} alarm can be configured to apply to **All Breaths** or to **Control Only**. In SIMV mode, selecting **Control Only** allows the Low P_{peak} alarm to apply to Machine breaths only. It has no effect in A/C or CPAP modes. See *To Set the Apnea Interval and LPP Alarm Breath Type(s):* in this chapter for detailed instructions.



Low Pulse Rate

The Low Pulse Rate alarm (a user adjustable alarm) is generated when the monitored pulse rate is less than the Low Pulse Rate alarm limit setting. The Low Pulse Rate alarm is only active when the SpO_2 Module is connected, enabled and attached to a patient.

Range: "**- -**" (off), or **19** through **300 PR/min**

When a Low Pulse Rate alarm occurs:

- The **Low Pulse Rate** alarm message is displayed
- A high priority alarm sounds
- The **Pulse** Alarm Limit control (low) turns red, and the associated values displayed on the **Pulse** Monitor turn red and begin flashing

To set the Low Pulse Rate alarm limit:

See *Adjustable Alarms* in this chapter.

Low SpO_2

The Low SpO_2 alarm (a user adjustable alarm) is generated when the monitored SpO_2 is less than the Low **SpO_2** alarm limit setting. The Low SpO_2 alarm is only active when the SpO_2 Module is connected, enabled and attached to a patient.

Range**:** "**- -**" (off), or **60** through **99 %**

When a Low SpO_2 alarm occurs:

- The **Low SpO_2** alarm message is displayed
- A high priority alarm sounds
- The **SpO_2** Alarm Limit control (low) turns red, and the associated values displayed on the **SpO_2** Monitor turn red and begin flashing

To set the Low SpO_2 alarm limit:

See *Adjustable Alarms* in this chapter.

Low V_e (Low Exhaled Minute Volume)

The Low V_e alarm (a user adjustable alarm) is generated when the monitored Exhaled Minute Volume (V_e) is less than the Low V_e alarm limit setting for the set V / BR Delay (in seconds) and at least eight (8) breaths have occurred since the Low V_e alarm was last reset.

Range**:** "**- -**" (off), or **0.1** through **99 L**

WARNING

Low V_e Control Values - The Low V_e limit should be set to its highest clinically appropriate value. If there is a need to set the Low V_e alarm to lower values or "- -" (off), assess whether an alternative monitor (i.e. a Pulse Oximeter with an audible alarm, or a Cardio Respiratory Monitor) should be used.

NOTE

Activation of the **Low V_e, Low P_{peak}**, **Low PEEP** and/or **Patient Circuit Fault** alarms could indicate a patient circuit leak. Check the patient circuit and exhalation diaphragm integrity if one or more of these alarms is repeatedly activated.

When a Low V_e alarm occurs:

- The **Low V_e** alarm message is displayed
- A high priority audible alarm sounds
- The **V_e** Alarm Limit control (low) turns red, and the associated values displayed on the **V_e** Monitor turn red and begin flashing

To set the Low V_e alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for the Low V_e alarm:

See *V / BR Delay* in Chapter 10 – The Utility Screen for detailed instructions**.**

Low V_{te} (Low Exhaled Tidal Volume)

The Low V_{te} alarm (a user adjustable alarm) is generated when the monitored Exhaled Tidal Volume (**V_{te}**) is less than the Low **V_{te}** alarm limit setting for the set **V / BR Delay** (in seconds).

Range**:** "**- -**" (off), or **10** through **2000 ml**

When a Low V_{te} alarm occurs:

- The **Low V_{te}** alarm message is displayed
- A medium priority audible alarm sounds
- The **V_{te}** Alarm Limit control (low) turns red, and the associated values displayed on the **V_{te}** Monitor turn red and begin flashing

To set the Low V_{te} alarm limit:

See *Adjustable Alarms* in this chapter.

To set delayed notification for the Low (or High) V_{te} alarm:

See *V / BR Delay* in Chapter 10 – The Utility Screen for detailed instructions.

Patient Circuit Fault

The Patient Circuit Fault alarm (a fixed alarm) is generated under many conditions in which the integrity of the breathing circuit is compromised. This may be due to, but not limited to, one of the following conditions:

- A Low or High Pressure Sense Line is disconnected or occluded
- Patient Circuit Wye, Patient Connection Port is disconnected from patient
- Patient Circuit Expiratory Limb is occluded
- Patient Circuit Inspiratory Limb is disconnected

WARNING

Disconnection Beyond the Patient Circuit Wye – The Patient Circuit Fault alarm may not activate if a disconnect or blockage occurs beyond the Patient Circuit Wye (in-between wye and connection to patient). Ensure that the **High P_{peak}**, **Low P_{peak}**, **Low PEEP** and **Low V_e** alarms are set appropriately to prevent patient risk.

NOTE

- If a **High P_{peak}** or **Safety Valve High Pressure Relief** alarm occurs before the patient circuit fault detection of an occluded inspiratory or expiratory limb, the patient circuit fault alarm may not occur
- When ventilating at settings likely to cause AutoPEEP, a **Patient Circuit Fault** alarm may occur. Adjust the **High PEEP** alarm appropriately
- Activation of the **Patient Circuit Fault**, **Low P_{peak}**, **Low PEEP** and/or **Low V_e** alarms could indicate a patient circuit leak. Check the patient circuit and exhalation diaphragm integrity if one or more of these alarms is repeatedly activated

When a Patient Circuit Fault alarm occurs:

- The **Patient Circuit Fault** alarm message is displayed
- A high priority audible alarm sounds

Depending on which condition(s) triggered the alarm, the ventilator also performs the following actions:

- When the alarm is triggered by an occluded or disconnected High Pressure Sense Line, or a disconnected Inspiratory Limb, the ventilator;
    - terminates the breath and exhalation begins
- While the alarm is triggered by disconnection of the Patient Connection Port from the patient tubing, or a disconnected Expiratory Limb, the ventilator;
    - terminates the breath and exhalation begins
    - closes the exhalation valve and delivers a constant inspiratory flow
    - stops delivering mandatory machine breaths
    - stops recognizing patient trigger efforts
    - stops delivering nebulizer flow
    - disables Apnea backup alarm and apnea ventilation
- While the alarm is triggered by an occluded Expiratory Limb, the ventilator;
    - terminates the breath and exhalation begins
    - opens exhalation and safety valves
    - stops delivering mandatory machine breaths
    - stops recognizing patient trigger efforts (flow and pressure trigger)
    - stops delivery of all flows
    - disables Apnea backup alarm and apnea ventilation

Preventive Maintenance Required

The Preventive Maintenance Required alarm (a fixed alarm) is generated when any of the numerous internal mechanical actuators (monitored by the ventilator) approach the end of their expected useful life.

> **CAUTION**
>
> **Preventive Maintenance Required Alarm -** A Preventive Maintenance Required alarm is an indication that the ventilator should be scheduled for preventive maintenance service. Contact CareFusion or a service technician certified by CareFusion.

When a Preventive Maintenance Required alarm occurs:

- The **Preventive Maintenance Required xxx** alarm message is displayed, with a numeric reference code representing the specific condition that initiated the alarm (record **xxx** code to report when scheduling servicing)
- A low priority audible alarm sounds

Remove Patient

The Remove Patient alarm (a fixed alarm) is activated when the ventilator enters the Vent Setup mode in the Startup mode of operation.

The alarm is generated to advise operators that ventilation may be compromised and to remove the patient from the ventilator before proceeding.

WARNING

Remove Patient Alarm – To prevent possible harm to the patient, if a **Remove Patient** alarm occurs during normal ventilation, immediately remove the patient and use an alternative method of ventilation.

NOTE

The ventilator operates in Startup mode;

- When initially powered up
- While patient type (**Same Patient** or **New Patient**), patient ID, patient size (**Adult** or **Pediatric**) and patient breathing circuit type selections (**Intubated** or **Non-Invasive**) are being made
- While **Vent Setup** Extended Systems Tests[35] (**EST**), User Verification Tests[36] (**UVT**) tests are being performed and ventilator configuration selections (**Language**, **Units** and **Reset to Factory Defaults**) are being made

When a Remove Patient alarm occurs:

- The **Remove Patient** alarm message is displayed
- A high priority audible alarm sounds

To silence the Remove Patient alarm:

The alarm will be automatically reset when normal ventilation has begun.

1) Push the **Alarm Silence** button on the Lower Interface Panel once to silence the audible portion of the alarm for 60 seconds.

   Or

   Touch the **Status Bar** with the flashing alarm message at the top of the screen to display the **Alarm Messages** page and touch the **Alarm Reset** button to reset/remove all inactive alarms from the **Status Bar** and **Alarm Messages** page.

While the Remove Patient alarm is active, the **Remove Patient** alarm message and its audible tone will be reactivated after being reset by the **Alarm Reset** button and 120 seconds of user inactivity.

[35] Circuit Test and FiO_2 Calibration
[36] Button Test and Touch Screen Calibration

Safety Valve High Pressure Relief

The Safety Valve High Pressure Relief alarm (a fixed alarm) is generated when:

- Airway Pressure[37] is ≥ 110 cmH_2O, or
- Airway Pressure ≥ the **High P_{peak}** alarm setting plus the Safety Valve Delta Pressure setting (see *Safety Valve Delta (∆)*in Chapter 10 – The Utility Screen)

When a Safety Valve High Pressure Relief alarm occurs:

- The **Safety Valve High Pressure Relief** message is displayed
- A high priority audible alarm sounds
- The breath is immediately cycled to exhalation
- The blower is stopped
- The nebulizer drive (optional) is turned off
- The safety valve opens to provide over-pressure relief
- The PEEP pilot pressure is vented to ambient

Many of the conditions which can cause a Safety Valve High Pressure alarm to initiate or to recur can be corrected by the user. See *Chapter 13 - Troubleshooting* for detailed corrective actions.

SBT High Breath Rate

The SBT High Breath Rate alarm (a user adjustable alarm) is generated when the monitored SBT breath rate (**SBT Rate**) exceeds the set high SBT Rate alarm limit continuously for 30 seconds during a Spontaneous Breathing Trial.

Range**:** **15** through **80 bpm**, or "**- -**" (off)

When an SBT High Breath Rate alarm occurs:

- The **SBT High Breath Rate** alarm message is displayed
- A medium priority audible alarm sounds
- The **SBT Rate** Alarm Limit control (high) turns red
- The SBT procedure terminates if the alarm is active continuously for 5 minutes

To set the SBT High Rate alarm limit:

See *SBT, Adjustable Alarms* in Chapter 5 - Controls for detailed instructions.

[37] Blower Estimated Airway Pressure is a redundant measure of airway pressure based on the blower differential pressure transducer.

SBT High f/V_t

The SBT High f/V_t alarm (a user adjustable alarm) is generated when the SBT f/V_t ratio is greater than the set SBT High f/V_t alarm limit continuously for 30 seconds during a Spontaneous Breathing Trial.

Range**:** **70** through **900 bpm/L**, or "**- -**" (off)

When an SBT High f/V_t alarm occurs:

- The **SBT High f/V_t** alarm message is displayed
- A medium priority audible alarm sounds
- The **SBT f/V_t** Alarm Limit control (high) turns red
- The SBT procedure terminates if the alarm is active continuously for 5 minutes

To set the SBT High f/V_t alarm limit:

See *SBT, Adjustable Alarms* in Chapter 5 - Controls for detailed instructions.

SBT High PEEP

The SBT High PEEP alarm (a user adjustable alarm) is generated when the monitored PEEP is greater than the active PEEP control setting[38] during a Spontaneous Breathing Trial.

Once the alarm is cleared, it will remain cleared until at least eight (8) breaths have occurred since the alarm was cleared.

Range**:** **3** through **50 cmH_2O**, or "**- -**" (off)

When a SBT High PEEP alarm occurs:

- The **SBT High PEEP** alarm message is displayed
- A medium priority audible alarm sounds

To set the SBT High PEEP alarm limit:

See *SBT, Adjustable Alarms* in Chapter 5 - Controls for detailed instructions.

To set delayed notification for the High (or Low) PEEP alarm:

See *PEEP Delay* in Chapter 10 – The Utility Screen.

[38] The "active" PEEP control setting is the **PEEP** control setting during normal ventilation (**Main** screen, **Controls** page), or the **SBT PEEP** control setting during an SBT procedure (**Main** screen, **SBT** page).

SBT Low Breath Rate

The SBT Low Breath Rate alarm (a user adjustable alarm) is generated when the monitored SBT breath rate (**SBT Rate**) is less than the set SBT Low Rate alarm limit continuously for 30 seconds during a Spontaneous Breathing Trial.

Range**:** "**- -**" (off), or **1** through **40 bpm**

When an SBT Low Breath Rate alarm occurs:

- The **SBT Low Breath Rate** alarm message is displayed
- A medium priority audible alarm sounds
- The **SBT Rate** Alarm Limit control (low) turns red
- The SBT procedure terminates if the alarm is active continuously for 5 minutes

To set the SBT Low Rate alarm limit:

See *SBT, Adjustable Alarms* in Chapter 5 - Controls for detailed instructions.

SBT Low f/V_t

The SBT Low f/V_t alarm is generated (a user adjustable alarm) when the SBT f/V_t ratio is less than the set SBT Low f/V_t limit continuously for 30 seconds during a Spontaneous Breathing Trial.

Range**:** "**- -**" (off), or **5** through **90 bpm/L**

When an SBT Low f/V_t alarm occurs:

- The **SBT Low f/V_t** alarm message is displayed
- A medium priority audible alarm sounds
- The **f/V_t** Alarm Limit control (low) turns red
- The SBT procedure terminates if the alarm is active continuously for 5 minutes

To set the SBT Low f/V_t alarm limit:

See *SBT, Adjustable Alarms* in Chapter 5 - Controls for detailed instructions.

SBT Low PEEP

The SBT Low PEEP alarm (a user adjustable alarm) is generated when the monitored PEEP is less than the active PEEP control setting[39] during a Spontaneous Breathing Trial.

Once the alarm is cleared, it will remain cleared until at least eight (8) breaths have occurred since the alarm was cleared.

Range: "**- -**" (off), or **1** through **30 cmH_2O**

When a SBT Low PEEP alarm occurs:

- The **SBT Low PEEP** alarm message is displayed
- A high priority audible alarm sounds

To set the SBT Low PEEP alarm limit:

See *SBT, Adjustable Alarms* in Chapter 5 - Controls for detailed instructions.

To set delayed notification for the PEEP alarms:

See *PEEP Delay* in Chapter 10 – The Utility Screen for detailed instructions.

> **NOTE**
>
> - Activation of the **SBT Low PEEP**, **Low P_{peak}**, **Low V_e** and/or **Patient Circuit Fault** alarms could indicate a patient circuit leak. Check the patient circuit and exhalation diaphragm integrity if one or more of these alarms is repeatedly activated.

SBT Off

The SBT Off alarm (a fixed alarm) is generated when the Spontaneous Breathing Trial has completed.

When an SBT Off alarm occurs:

- The **SBT Off** alarm message is displayed
- A low priority audible alarm sounds
- The SBT procedure terminates

[39] The "active" PEEP control setting is the **PEEP** control setting during normal ventilation (**Main** screen, **Controls** page), or the **SBT PEEP** control setting during an SBT procedure (**Main** screen, **SBT** page).

SBT Time

The SBT Time alarm (a fixed alarm) is generated when the Spontaneous Breathing Trial has two minutes left to run.

When an SBT Time alarm occurs:

- The **SBT Time** alarm message is displayed
- A low priority audible alarm sounds

Service Soon

The Service Soon xxx alarm (a fixed alarm) is generated when the ventilator detects a non-critical internal component failure or an invalid event log.

> **CAUTION**
>
> **Service Soon Alarm -** Repeated or continuous Service Soon alarms may indicate a problem with the ventilator that could prevent the ventilator from performing within its specifications. Discontinue use of the ventilator and contact CareFusion or a service technician certified by CareFusion.

When a Service Soon xxx alarm occurs:

- The **Service Soon xxx** alarm message is displayed, with a numeric reference code representing the specific condition that initiated the alarm (record xxx code to report when scheduling servicing)
- A low priority audible alarm sounds

SpO_2 Check Sensor Placement

The SpO_2 Check Sensor Placement alarm (a fixed alarm) is generated when the SpO_2 Module reports that the sensor is providing unusable data for analysis and the Oximetry option is still enabled.

When a SpO_2 Check Sensor Placement alarm occurs:

- The **Check SpO_2 Sensor Placement** alarm message is displayed
- A high priority audible alarm sounds

SpO_2 Low Signal

The SpO_2 Low Signal alarm (a fixed alarm) is generated when the SpO_2 Module detects that the signal from the SpO_2 Sensor is too low while the Pulse Oximetry option is enabled.

When a SpO_2 Low Signal alarm occurs:

- The **SpO_2 Low Signal** alarm message is displayed
- A high priority audible alarm sounds

SpO_2 Module Fault

The SpO_2 Module Fault alarm (a fixed alarm) is generated when the ventilator cannot establish proper communication with the SpO_2 Module while the Pulse Oximetry option is enabled.

When a SpO_2 Module Fault alarm occurs:

- The **SpO_2 Module Fault** alarm message is displayed
- A high priority alarm sounds

SpO_2 Sensor Disconnect

The SpO_2 Sensor Disconnect alarm (a fixed alarm) is generated when the SpO_2 Module or Sensor is faulty while the Pulse Oximetry option is enabled.

When an SpO_2 Sensor Disconnect alarm occurs:

- The **SpO_2 Sensor Disconnect** alarm message is displayed
- A high priority audible alarm sounds

Transition Battery Fault

The Transition Battery Fault alarm (a fixed alarm) is generated when:

- The ventilator is unable to charge the internal Transition Battery
- The Transition Battery voltage is below the minimum usable voltage

WARNING

Transition Battery Fault Alarm - Transition Battery Fault alarms indicate that the ventilator's internal Transition Battery may be unreliable. Discontinue use of the ventilator and contact CareFusion or a service technician certified by CareFusion.

When a Transition Battery Fault alarm occurs:

- The **Transition Battery Fault** alarm message is displayed
- A medium priority audible alarm sounds
- The **Transition Batt.** LED on the Lower Interface Panel flashes red

Transition Battery Temperature Fault

The Transition Battery Temperature Fault alarm (a fixed alarm) is generated when the Transition Battery is the only power source available and:

- The temperature of the Transition Battery is greater than 60° C
- The temperature of the Transition Battery is less than -20° C

WARNING

Transition Battery Temperature Fault Alarm – The Transition Battery Temperature Fault alarms indicate that the ventilator's internal Transition Battery is excessively hot or cold. When this alarm occurs, the ventilator shuts down and gas is not delivered to the patient. To avoid patient injury, disconnect the patient and ventilate using an alternate method until the cause of the Transition Battery Temperature Fault alarm condition has been eliminated. See *Chapter 13 - Troubleshooting* for additional information.

When a Transition Battery Temperature Fault alarm occurs:

- The **T-Bat Temperature Fault** alarm message is displayed
- A high priority audible alarm sounds
- The **Transition Batt.** LED on the Lower Interface Panel flashes red
- The ventilator stops delivering mandatory machine breaths and shuts down

Transition Battery Use

The Transition Battery Use alarm (a fixed alarm) is generated when the ventilator begins operating on the internal Transition Battery.

WARNING

Transition Battery Use Alarm - A Transition Battery Use alarm indicates the ventilator is only being powered by the Transition Battery and will shut down soon. Immediately insert a charged Removable Battery Pack or connect the ventilator to an external source of power. The internal Transition Battery is a short duration source of power for use only when changing depleted Removable Battery Packs or switching between external power sources. It is only intended to power the ventilator for up to one minute.

When a Transition Battery Use alarm occurs:

- The **Transition Battery Use** alarm message is displayed
- A high priority audible alarm sounds
- The **Transition Batt.** LED on the Lower Interface Panel illuminates

NOTE

The Transition Battery Use alarm can be silenced and reset only once for 60 seconds. If the condition is not resolved, the alarm will resume at maximum volume (80 ± 5 dBA) and cannot be silenced again until another power source is connected.

Vent Inop

A Vent Inop alarm (a fixed alarm) is generated when:

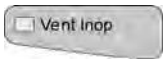
- The ventilator is powered off by pushing the **On/Off** button
- The ventilator detects any condition that is deemed to make the ventilator unsafe
- The Transition Battery charge becomes completely depleted while in storage

WARNING

Vent Inop Alarm - If a Vent Inop alarm occurs during operation, immediately ventilate the patient using an alternative method, disconnect the ventilator and contact CareFusion or a service technician certified by CareFusion.

Alternative Ventilation - CareFusion recommends that an alternate means of ventilation be available and the procedures to be followed if the ventilator ceases to function properly.

When a Vent Inop alarm occurs:



- A Vent Inop audible alarm sounds
- The **Vent Inop** LED on the Lower Interface Panel flashes red

NOTE

A **Vent Inop** alarm is normal when switching the ventilator off. It does not indicate a problem with the ventilator.

To silence the audible alarm and turn the **Vent Inop** LED off, push the **Alarm Silence** button.

Ventilator Reset

A Ventilator Reset alarm (a fixed alarm) is generated when the ventilator restarts following a condition other than being shut down by pushing the **On/Off** button.

The ventilator constantly runs a monitoring program to verify correct operation. If it detects a condition that makes safe operation uncertain, it reinitializes itself to perform the more sophisticated Power On Self Test (POST). If the POST does not detect any problems, the ventilator resumes normal operation and a Ventilator Reset alarm is generated. If the POST detects a problem that could cause unsafe operation, a **Vent Inop** alarm occurs.

CAUTION

Repeated Occurrences - Repeated occurrences of the Ventilator Reset alarm may indicate a problem with the ventilator's hardware. Remove the ventilator from service and contact CareFusion or a service technician certified by CareFusion.

When a Ventilator Reset alarm occurs:

- The **Ventilator Reset** alarm message is displayed
- A medium priority audible alarm sounds
- An error code is written to the Event Trace indicating the type of problem
- The ventilator resets itself and performs the Power On Self Tests (POST)
- If no further problems are detected, the ventilator resumes operation

NOTE

Restarting from the On/Off Button - The ventilator will not generate a Vent Reset alarm if the restart is initiated from the **On/Off** button.

Volume Limited

The Volume Limited alarm (a fixed alarm) is generated when the active Breath Type is set to **PRVC** or **V_t PSV** and the set **Volume** cannot be achieved without the Target Pressure exceeding the High P_{peak} alarm setting minus 5 cmH_2O.

When a Volume Limited alarm occurs:

- The **Volume Limited** alarm message is displayed
- A medium priority audible alarm sounds

Alerts, Audible

Accessory Attach

The Accessory Attach alert is an audible confirmation signal indicating successful communication has been established between the ventilator and a newly attached accessory. The alert is generated each time any of the following occurs;

- A Removable Battery Pack is inserted into and recognized by the ventilator
- An external power source is connected to and qualified by the ventilator
- An external sensor is connected to and recognized by the ventilator
- The ventilator is attached to and communicating with a Docking Station
- An accessory (e.g. Patient Monitor System, Memory Card) is attached to the Docking Station when connected to the ventilator

NOTE

Qualification of an external power source normally occurs within 4 seconds of the source being applied.

Key Click Information

The ventilator generates an audible “Key Click” when a valid section of the LCD touch screen is touched.

SpO_2 Pulse Tone

The SpO_2 Pulse Tone is an informational audible signal which sounds with each detected heartbeat when a Pulse Oximetry module is connected to the ventilator, enabled and placed on a patient.

To set the SpO_2 Pulse Tone volume level:

See *Pulse Tone* in Chapter 10 - The Utility Screen for detailed instructions.

Chapter 9 - MANEUVERS, PROCEDURES AND STANDBY MODE

Maneuvers and Procedures General Information

Maneuvers and Procedures availability by ventilation Mode.

Ventilation Mode	I-Hold	E-Hold	Nebulizer	SBT	Increase O_2
Volume A/C	Enabled	Enabled	Enabled	Enabled	Enabled
Pressure A/C	Disabled	Enabled	Disabled	Enabled	Enabled
PRVC A/C	Disabled	Enabled	Disabled	Enabled	Enabled
Volume SIMV	Enabled	Enabled	Disabled	Enabled	Enabled
Pressure SIMV	Disabled	Enabled	Disabled	Enabled	Enabled
PRVC SIMV	Disabled	Enabled	Disabled	Enabled	Enabled
CPAP/PSV (Volume)	Disabled	Disabled	Disabled	Enabled	Enabled
CPAP/PSV (Pressure)	Disabled	Disabled	Disabled	Enabled	Enabled
CPAP/V_tPSV	Disabled	Disabled	Disabled	Enabled	Enabled
NPPV Pressure	Disabled	Disabled	Disabled	Enabled	Enabled
NPPV CPAP/PSV	Disabled	Disabled	Disabled	Enabled	Enabled

Maneuvers and Procedures combinations that the Enve™ ventilator is capable of performing simultaneously:

Maneuver / Procedure	SBT	I-Hold	E-Hold	Nebulizer	Increase O_2
SBT	N/A	No	No	No	No
I-Hold	No	N/A	No	Yes	No
E-Hold	No	No	N/A	Yes	No
Nebulizer	No	Yes	Yes	N/A	No
Increase O_2	No	No	No	No	N/A

Maneuvers

The following maneuvers are available on the Enve™ ventilator.

- Inspiratory Hold
- Expiratory Hold

Inspiratory Hold

During an Inspiratory Hold maneuver, the inspiratory phase of a breath is held for a period of time sufficient to determine and display Delta Pressure (**dP_{aw}**), Plateau Pressure (**P_{plat}**) and Static Lung Compliance (**C_{static}**).

NOTE

- The ventilator cannot perform an Inspiratory or Expiratory Hold maneuver during a **NPPV Pressure** or **NPPV CPAP/PSV** ventilation Mode (Non-Invasive), or perform multiple maneuvers simultaneously.
- Lung Compliance (C_{static}) calculation includes circuit compliance.

Expiratory Hold

During an Expiratory Hold maneuver, the ventilator monitors Expiratory Pressure (**P_{exp}**), calculates the value for AutoPEEP and displays both.

NOTE

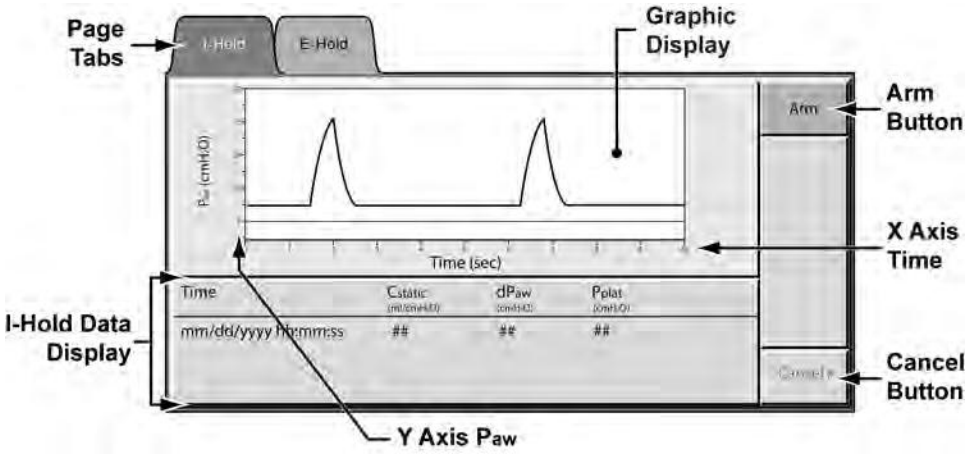
The E-Hold maneuver is disabled if the Nebulizer is set to **Continuous** and the Nebulizer procedure has been activated.

Setting Up and Running I-Hold and E-Hold

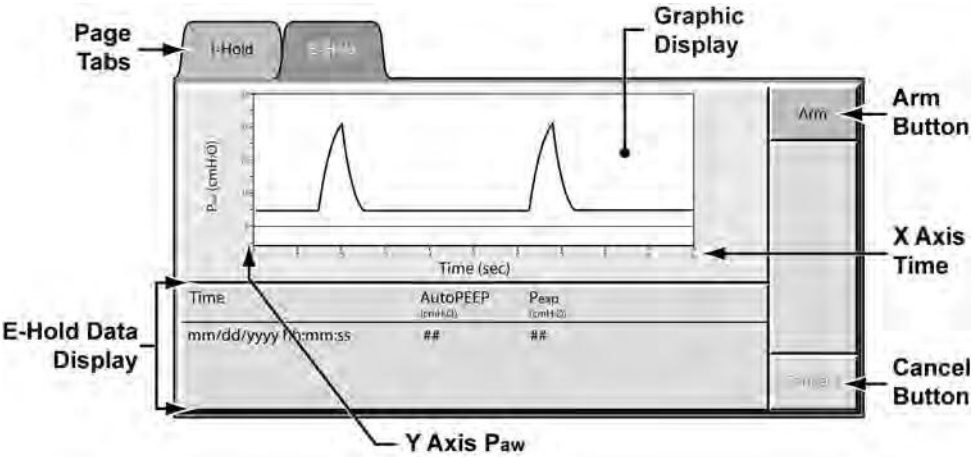
Inspiratory and Expiratory Hold maneuvers are accessed and performed from within the **Maneuvers** screen, **I-Hold** or **E-Hold** page, as applicable. Setting up and running a Hold maneuver is accomplished during a normal ventilation mode in which the desired Hold maneuver is enabled for use (I-Hold or E-Hold, per previous table).

Select the Maneuver:

1) Touch the **Maneuvers** Navigation Screen button at the bottom of the LCD Touch Screen and the **Maneuvers** screen and **I-Hold** page are displayed.

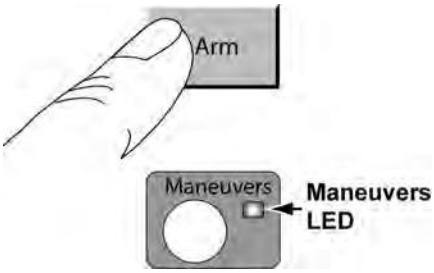


2) To display the **E-Hold** page, touch the **E-Hold** Page Tab.



Arm the Maneuver:

To arm either a **I-Hold** or **E-Hold** maneuver, touch the **Arm** button on the selected I or E Hold page. The **Maneuvers** LED on the Lower Interface Panel begins flashing to indicate that the maneuver is armed and ready to run.



Run the Maneuver:

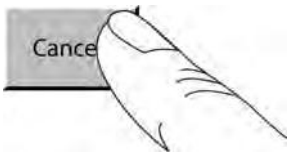
To activate the maneuver, press and hold the **Maneuvers** button on the Lower Interface Panel. The **Maneuvers** LED illuminates continuously and on the next appropriate breath the ventilator will initiate the “Hold”.

The maneuver will occur while the **Maneuvers** button is held for a maximum of six (6) seconds. If the button is released before the six seconds has expired, the maneuver will be terminated. In either case, the ventilator returns to normal ventilation immediately following termination of the maneuver.

> **NOTE**
>
> If the **Maneuvers** button is released *before* the Hold maneuver has begun, the ventilator returns to the armed state.
>
> If the **Maneuvers** button is released *after* the maneuver has begun, the maneuver ends and the ventilator displays the maneuver results.

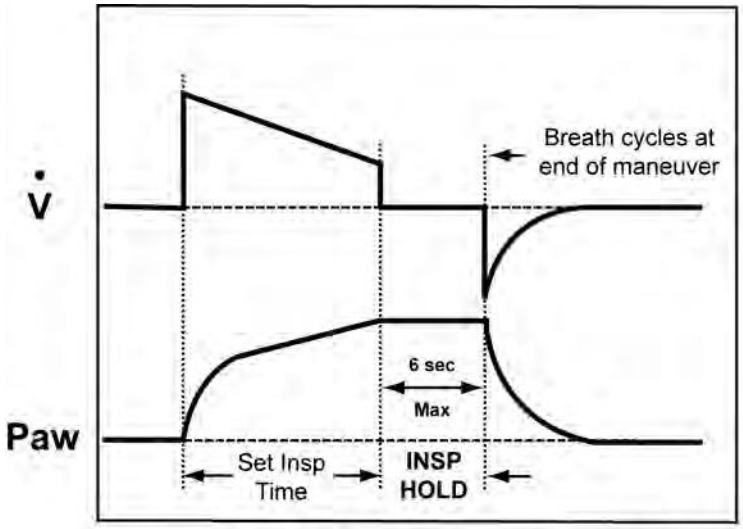
Maneuver arming automatically terminates if 60 seconds elapse in the same phase of a maneuver without a button press.

To exit a Maneuver at any time, touch the **Cancel** button on the on the selected I or E Hold page.



During an Inspiratory Hold:

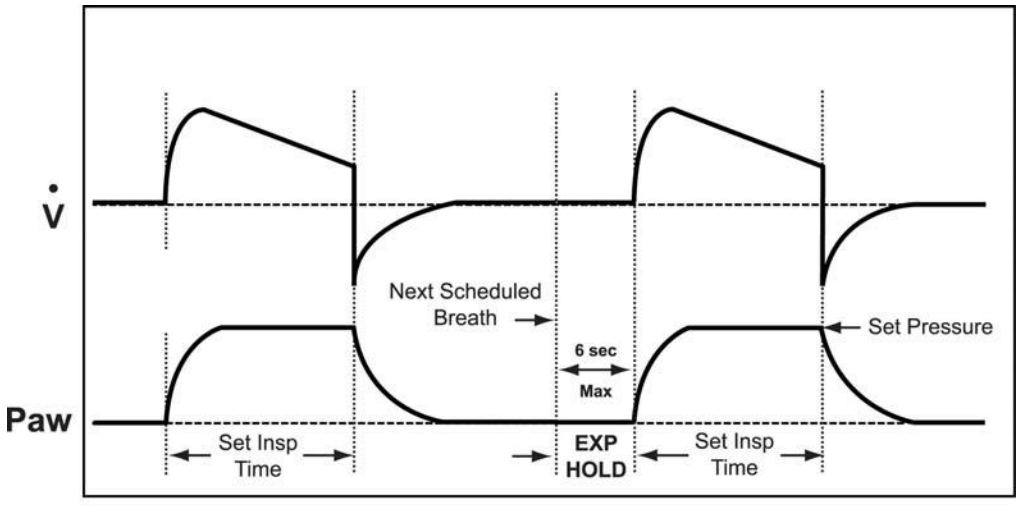
- The exhalation valve remains closed
- Flow is set to 0 L/min
- The breath remains in inspiration so no breath triggers are allowed
- The breath period timing and apnea timing are compensated for while the hold is performed
- If a High P_{peak} alarm occurs, the maneuver exits the hold phase but remains armed



Inspiratory Hold on Volume Control Breath

During an Expiratory Hold

- The exhalation valve is closed
- Flow is set to 0 L/min
- The breath remains in exhalation phase
- The breath period timing and apnea timing are compensated for while the Hold is performed
- If a patient effort is detected, it is ignored
- If a **High P_{peak}** alarm occurs, the maneuver exits the hold state and remains armed, and the exhalation valve opens as normal



Expiratory Hold on Pressure Control Breath

Maneuver Results

Maneuver results are displayed on the maneuvers pages graphically (waveforms) while the maneuver is in progress and in data tables when completed.

Waveform Graphs

Real-time waveform pressure graphs of the “Hold” maneuvers are displayed as the maneuvers progress.

- Graphs are displayed with a 10 second Time (horizontal) axis and an automatically scaled Data (vertical) axis.

Data Tables

The data is displayed in columns below the graphs;

Inspiratory Hold:

Time	the time stamp of the end of the maneuver
C_{static}	or Static Lung Compliance[40] is set tidal volume divided by Delta Pressure
dP_{aw}	final P_{plat} minus PEEP from the previous breath.
P_{plat}	Plateau Pressure is the airway pressure at the end of the hold.

Expiratory Hold:

AutoPEEP	calculated as **P_{exp}** at end of Expiratory Hold maneuver minus **P_{exp}** measured immediately before closing the exhalation valve to start the maneuver.
P_{exp}	Expiratory Pressure measured at the end of the maneuver.

When the maneuver has completed successfully:

Inspiratory Hold:

- The **Maneuvers** LED turns off and the calculated data is displayed
- The exhalation valve is opened and exhalation begins
- The flow servo operates normally
- Breath starts and any **Apnea** alarms that were held off resume

Expiratory Hold:

- The **Maneuvers** LED turns off and the calculated data is displayed
- The inspiration phase begins
- The flow servo operates normally

[40] Lung Compliance (C_{static}) calculation includes circuit compliance.

Procedures

The following procedures may be performed on the Enve™ ventilator.

- Increase O_2
- Nebulization
- SBT (Spontaneous Breathing Trial)

Increase O_2

The Increase O_2 procedure allows you to deliver a pre-set elevated percentage of oxygen to the patient for a specified duration of time. To perform this procedure, the ventilator must be connected to a high pressure oxygen source.

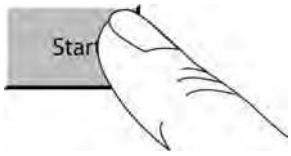
> **NOTE**
> When the FiO_2 setting is changed (FiO_2 Control setting, Increase O_2 Procedure started, or SBT FiO_2 Control setting) the **High FiO_2** alarm is deactivated for 120 seconds.

To Configure Increase O_2 Procedure:

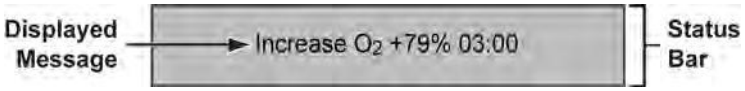
The **Increase O_2** controls are accessed from the **Main** screen, **Increase O_2** page. Refer to *Increase O2 Page, Adjustable Controls* in Chapter 5 - Controls for detailed instructions.

Start

To start the delivery of an elevated level of oxygen to the patient, touch the **Start** button.



When an Increase O_2 procedure is started, the percentage of O_2 increased and the remaining time for the procedure, beginning at the set **Duration** time and reducing every second and minute until no time is left, is displayed in the **Status Bar** at the top of the **LCD Touch Screen**.

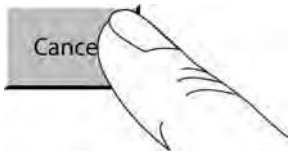


The delivery of the elevated level of oxygen will continue for the set **Duration** or until the **Cancel** button is touched.

> **NOTE**
> When the **FiO_2** control is set to **LPS**, the **Start** button is grayed out indicating that the feature is unavailable.
>
> When the Increased O_2 procedure ends, it may take the oxygen several seconds to flush out of the patient circuit and for the **FiO_2** monitors to return to set levels.

Cancel

To cancel the delivery of the elevated level of oxygen to the patient before the set **Duration** has expired, touch the **Cancel** button.



Nebulization

The Nebulization procedure can be performed on the Enve™ ventilator during Volume breaths in Assist/Control mode only. When the Nebulizer is activated, a six (6) L/min nominal flow is delivered to the nebulizer drive port. This drives an aerosol nebulizer that doses medication into the patient circuit.

To perform this procedure, the ventilator must be connected to a Nebulizer, and a high pressure oxygen source of **40 PSI** (2.8 BAR, 276 kPa) to **66 PSI** (4.5 BAR, 455 kPa).

WARNING

Risk of Injury - If the nebulizer drive system fails, medication can be delivered at an incorrect rate. Monitor medication consumption rate and discontinue use if it does not meet patient needs.

If the nebulizer drive system fails, medication can be delivered during exhalation phase resulting in a release of medications into the room. Monitor medication consumption rate and discontinue use if rate is excessively high.

If the nebulizer drive line is connected to a gas supply/flow meter other than the ventilator's nebulizer drive port during a nebulization procedure, delivered volume to the patient may be higher than the ventilator's set **Volume** and the ventilator's nebulization procedure controls (**Duration**, **Synchronize**, **Start** and **Cancel**) are circumvented. To avoid harm to the patient (e.g., Barotrauma), do not connect the nebulizer drive line to any gas supply/flow meter other than the ventilator's nebulizer drive port.

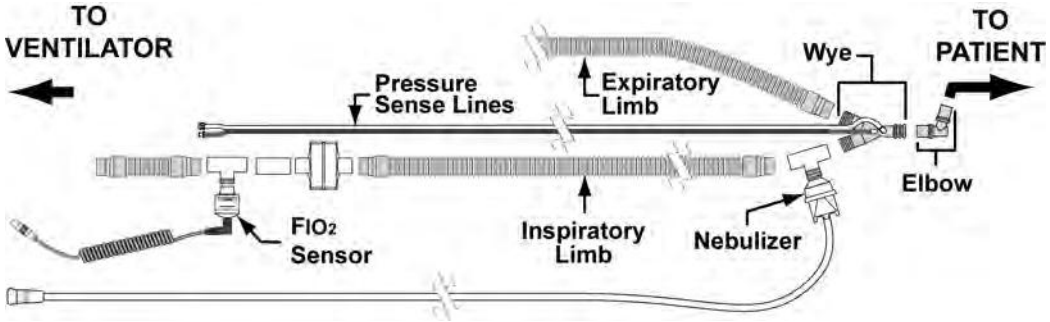
Inspiratory Pause - If an Inspiratory Pause is initiated during the Nebulization procedure, additional volume will be delivered to the patient.

To Configure the Nebulization Procedure:

The **Nebulizer** controls are accessed from the **Main** screen, **Nebulizer** page. Refer to *Nebulizer Page, Adjustable Controls* in Chapter 5 - Controls for detailed instructions.

Automatic Adjustments During Nebulization

The nebulizer flow is 100% oxygen, delivered to the Nebulizer port from the high pressure O_2 inlet. During nebulization, the ventilator decreases the flow to its inspiratory limb to compensate for the addition of the nebulization flow at the patient Wye. However, because the nebulizer is driven by 100% oxygen, the percentage of oxygen in the patient airway increases during nebulizer treatments. The illustration below shows the relative positions of the F_{IO_2} Sensor and the Nebulizer in a typical patient circuit setup.

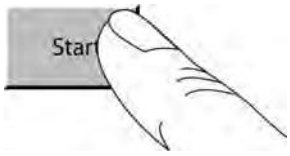


NOTE

Due to the relative positioning of the FIO_2 Sensor and the Nebulizer in a typical patient circuit setup (see diagram), the percentage of oxygen in the patient circuit cannot be accurately measured during nebulization.

The Nebulizer should be removed from the patient circuit and the ventilator when not in use.

Start



To initiate nebulization treatment, touch the **Start** button.

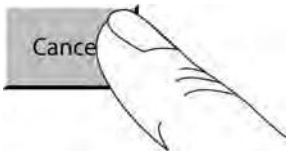
When a Nebulizer procedure is started, the remaining time for the procedure, beginning at the set **Duration** time and reducing every second and minute until no time is left, is displayed in the **Status Bar** at the top of the **LCD Touch Screen**.

While the procedure is in progress, the **Cancel** button is active.

NOTE

To activate the Nebulizer **Duration** control, **Synchronize** control and **Start** button, the ventilator must have the **Mode** control set to **Volume A/C**, the **Bias Flow** control set to 10 L/min.

Cancel



To cancel the nebulization treatment before the set **Duration** has expired, touch the **Cancel** button.

SBT

The Spontaneous Breathing Trial (SBT) procedure provides temporarily minimized ventilatory support so a clinician can perform clinical assessments of a patient's dependence on, or ability to be removed from positive pressure ventilation. SBT mode should be used only while attended by a Respiratory Therapist or other properly trained and qualified personnel.

- SBT can be performed with all patient types

To Configure and Start the SBT Procedure:

The SBT controls and alarm limits are accessed from the **Main** screen, **SBT** page. Refer to *SBT Page, Adjustable Controls* in Chapter 5 - Controls for detailed instructions

Start

Adjust the **SBT** controls and alarm limits appropriate for the patient and touch the **Start** button on the **SBT** page to initiate a Spontaneous Breathing Trial.

NOTE

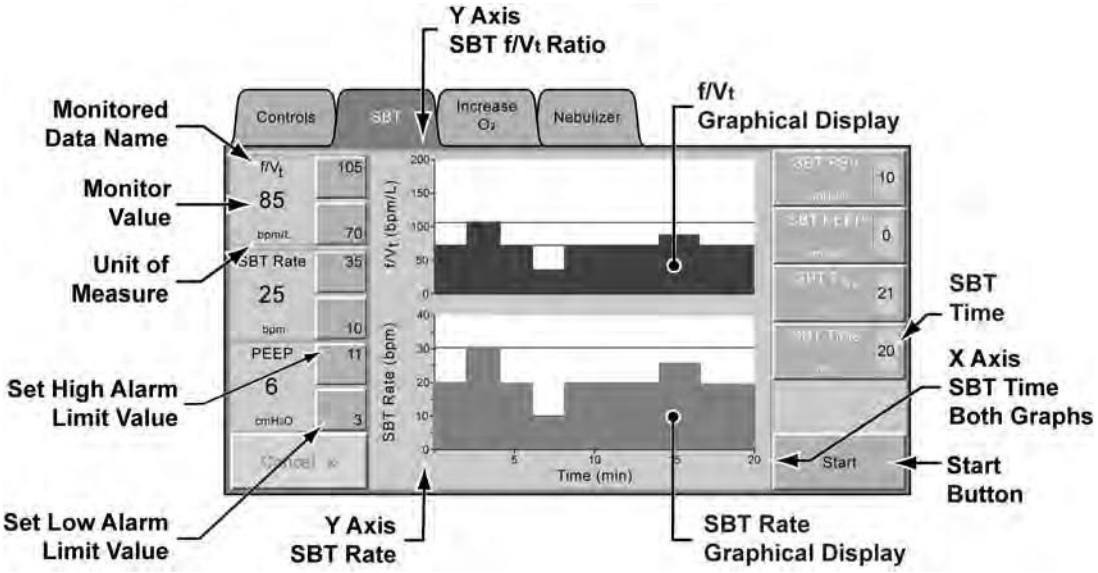
You cannot perform SBT when the ventilator is in **NPPV Pressure** or **NPPV CPAP/PSV** ventilation modes (Non-Invasive).

During SBT, the ventilator functions in CPAP/PSV mode with the SBT control settings you have selected in the **SBT** page. The elapsed time counts down in seconds in the **Status Bar** at the top of the **LCD Touch Screen** as the trial progresses.

The **High** / **Low SBT Breath Rate** and **High** / **Low f/V_t** adjustable alarm limits are enabled for the duration of the SBT procedure.

The results of the Spontaneous Breathing Trial are displayed graphically on two graphs on the **SBT** page as the trial proceeds.

- The upper graph's horizontal axis represents time and the vertical axis represents the f/V_t ratio
- The lower graph's horizontal axis represents time and the vertical axis represents SBT Rate (**Rate**)
- The high and low limits are shown to the left of the graphs for easy reference
- The f/V_t monitor is displayed and updates anytime the **SBT Rate** or Tidal Volume (**V_t**) changes
- The graph is updated once per minute



The trial ends when any of the following occur:

- The **Cancel** button is touched
- An **SBT Off** alarm occurs (indicating that SBT ran for the full set time duration)
- An **Apnea** or **Patient Circuit Fault** alarm occurs
- A **High P_{peak}** or **Safety Valve High Pressure Relief** alarm condition persists for more than 1.5 seconds
- The **SBT High / Low Breath Rate** alarm or **SBT High / Low f/V_t** alarm is activated for 5 minutes continuously
- Any ventilation or alarm control is selected and confirmed other than **Control Lock, Alarm Silence**, or the **SBT High/Low Breath Rate** and **SBT High/Low f/V_t** alarms

NOTE

During the SBT procedure, if the **SBT FiO_2** control setting is different than the **FiO_2** control setting on the **Main** screen, **Controls** page, the High FiO_2 alarm is delayed 30 seconds.

When the trial ends, the ventilator automatically reverts to the control settings which were in use prior to initiating the SBT procedure.

Standby Mode

Standby mode is an operator initiated temporary suspension of patient ventilation which can be used to accommodate changing or reconfiguration of accessories, gas delivery methods, patient movement or transport, and does not require changing ventilation settings or shutting down and restarting the ventilator.

When Standby mode is initiated/confirmed:

- Patient ventilation is suspended
- **STOPPING VENTILATION** may be momentarily displayed, followed by **STANDBY NOT VENTILATING!** displayed on the LCD screen
- Any in-process I-Hold or E-Hold maneuvers, or SBT, Nebulization, or Increase O_2 procedures are exited
- FiO_2 is set to 21%
- PEEP pilot pressure is vented to ambient
- A constant two (2) lpm bias flow is delivered to the patient circuit
- Ventilation and clinical alarms are disabled
- The main screen ventilation controls, the Lower Interface Panel controls (including the **On/Off** button), and alarm controls, are locked (**Control Lock** enabled, LED illuminated).

When Standby mode is exited:

- Patient ventilation can be resumed using the ventilation control and alarm configurations/limits settings that were in effect before Standby mode was initiated,

  OR

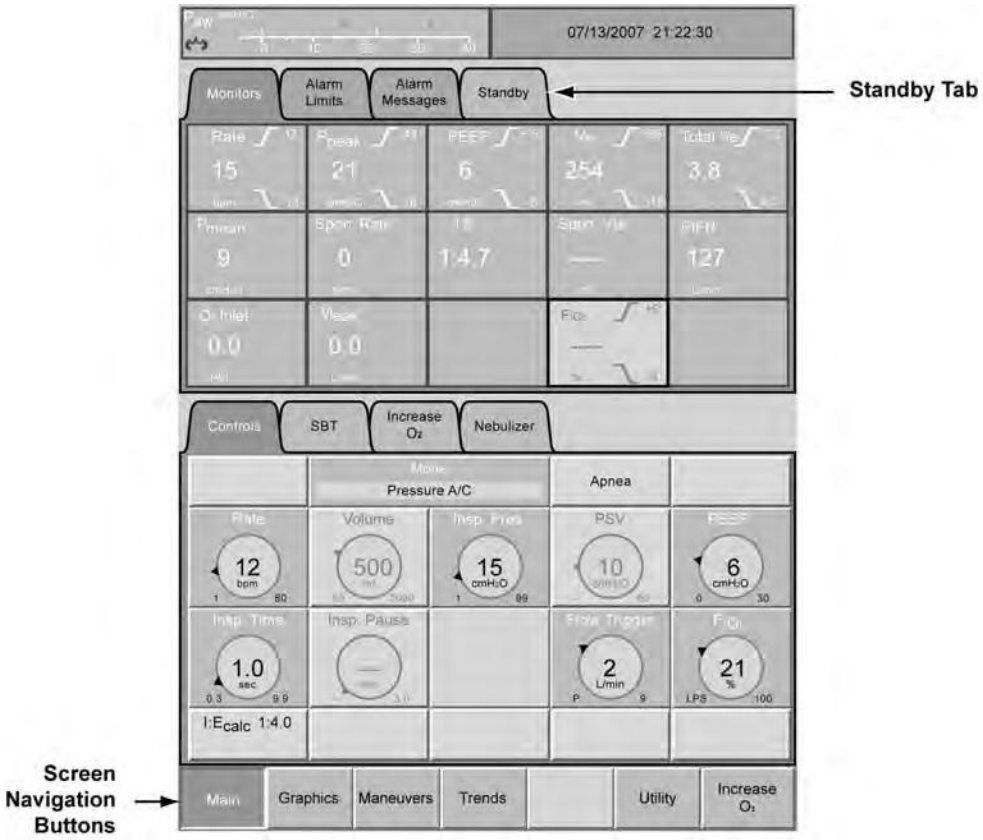
  If desired, the operator can change the type of patient circuit to patient interface configuration (**Intubated** versus **Non-Invasive**) and then exit Standby mode and resume patient ventilation.
- Disabled ventilation and clinical alarms are enabled
- The main screen ventilation and alarm controls are unlocked (**Control Lock** disabled, LED extinguished)

To Initiate Standby Mode

WARNING

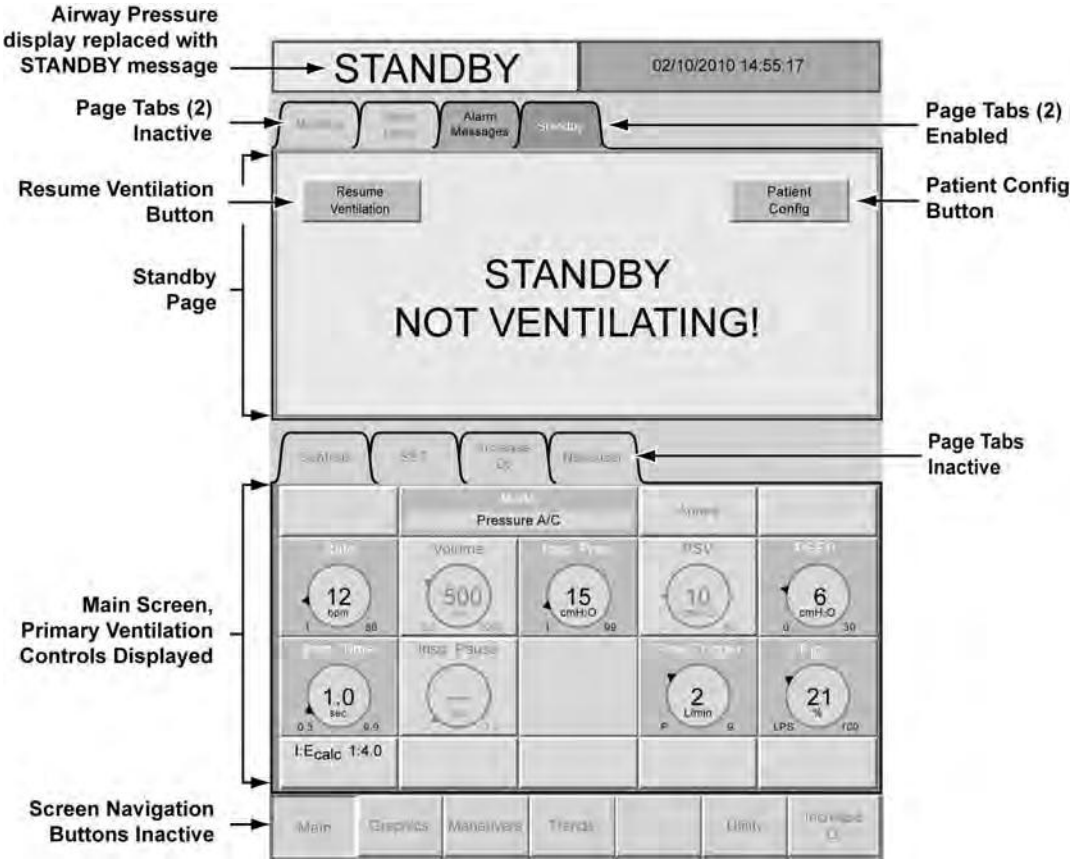
Standby Mode – When Standby mode is initiated, patient ventilation is suspended until Standby mode is exited and normal ventilation is resumed. To avoid serious injury or death, disconnect the patient from the ventilator before initiating Standby and provide alternative ventilation until such time as a normal ventilation mode is resumed and the patient is reconnected to the ventilator.

1) Touch the **Standby** Tab located on the Main Screen.



2) To suspend patient ventilation and enter the Standby Mode, Touch the **Yes** button. Touch the **No** button or the **Monitors** tab to continue normal ventilation, exit the Standby page and display the monitors page.

3) When the **Yes** button is touched, Patient ventilation is suspended and **STOPPING VENTILATION** may be momentarily displayed, followed by **STANDBY NOT VENTILATING!** displayed on the Standby page.



NOTE

During Standby mode ventilation and clinical alarms are disabled (e.g. Low Minute Volume, High PEEP, etc.). However, alarms that would affect normal ventilation when resumed (e.g. hardware/software fault alarms, loss of power, etc.) remain enabled and are generated (visual and audible) whenever the associated alarm conditions arise.

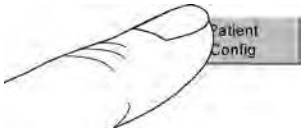
4) If using a heated wire patient circuit, turn the humidifier off (source of power for the heated wire circuit) prior to leaving the ventilator in the Standby mode for an extended period of time.

CAUTION

Patient Circuit Overheating – To avoid damaging active heated wire patient breathing circuits during Standby mode, turn the humidifier off (source of power for the heated wire circuit).

To Exit Standby Mode

1) To change the type of patient circuit to patient interface configuration (**Intubated** or **Non-Invasive**) prior to exiting the Standby mode and resuming patient ventilation, continue; otherwise skip to step 2.



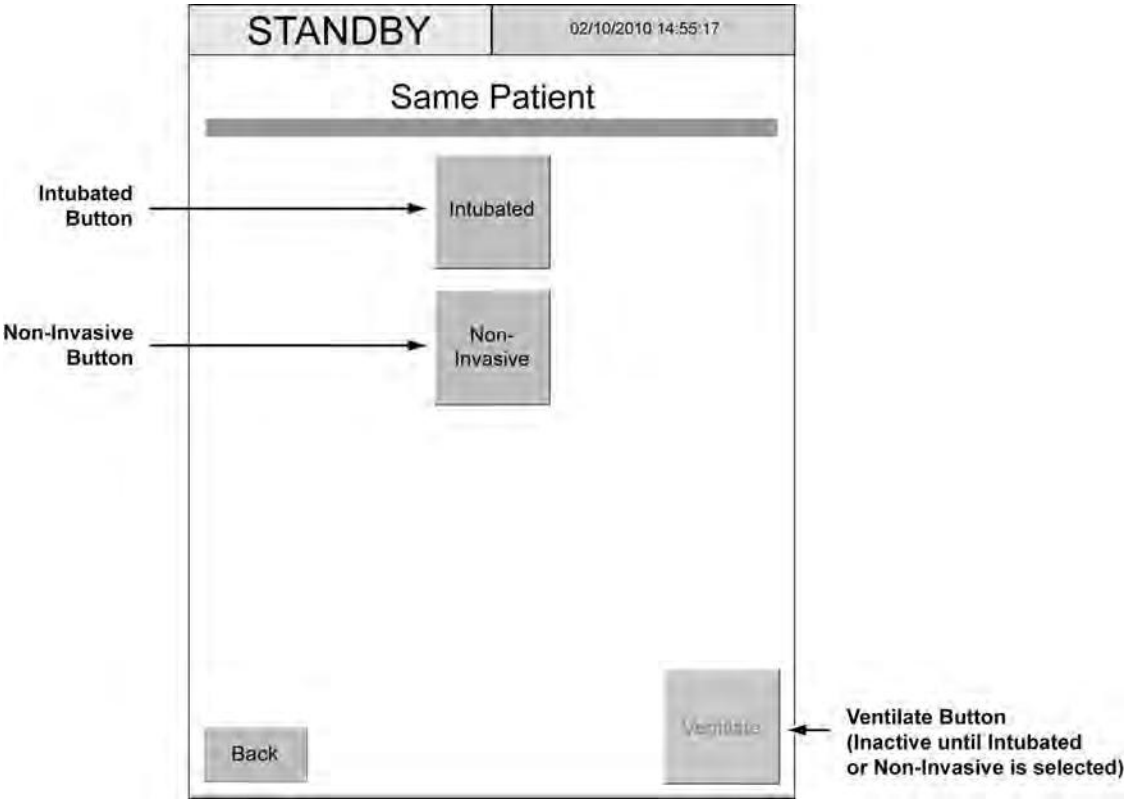
When **STAND BY NOT VENTILATING!** is displayed, press the **Patient Config** button.
Same Patient is displayed with the **Intubated** and **Non-Invasive** buttons displayed below.

To select an intubated type of patient circuit to patient interface, and resume patient ventilation, touch the **Intubated** button and then touch the **Ventilate** button.

OR

To select a non-invasive type of patient circuit to patient interface, and resume patient ventilation, touch the **Non-Invasive** button and then touch the **Ventilate** button.

- If using a heated wire patient circuit, turn the humidifier back on (source of power for the heated wire circuit)



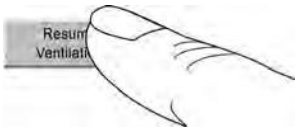
NOTE

When the type of patient circuit to patient interface configuration (**Intubated** or **Non-Invasive**) is changed before exiting Standby mode:

- If the type of patient circuit to patient interface selected is **Intubated** and the previous setting was **Non-Invasive**, the Breath Mode and Breath Type will be set to their last selected / preset intubated interface settings
- If the type of patient circuit to patient interface selected is **Non-Invasive** and the previous setting was **Intubated**, the Breath Mode will be set to **NPPV CPAP/PSV** and the Breath Type will be set to **PSV**

2) To exit the Standby mode and resume patient ventilation using the ventilation control and alarm configurations/limits settings that were in effect before Standby mode was initiated, press the **Resume Ventilation** button.

When the **Resume Ventilation** button is pressed, the Standby mode is exited and ventilation is resumed.



- If using a heated wire patient circuit, turn the humidifier back on (source of power for the heated wire circuit)

Chapter 10 - THE UTILITY SCREEN

This chapter describes the options, features, pages and controls available on the **Utility** screen(s). To display the Utility screen, simply touch the **Utility** Screen Navigation button at the bottom of the LCD touch screen.

When selected, the **Utility** screen displays and provides access to the following pages:

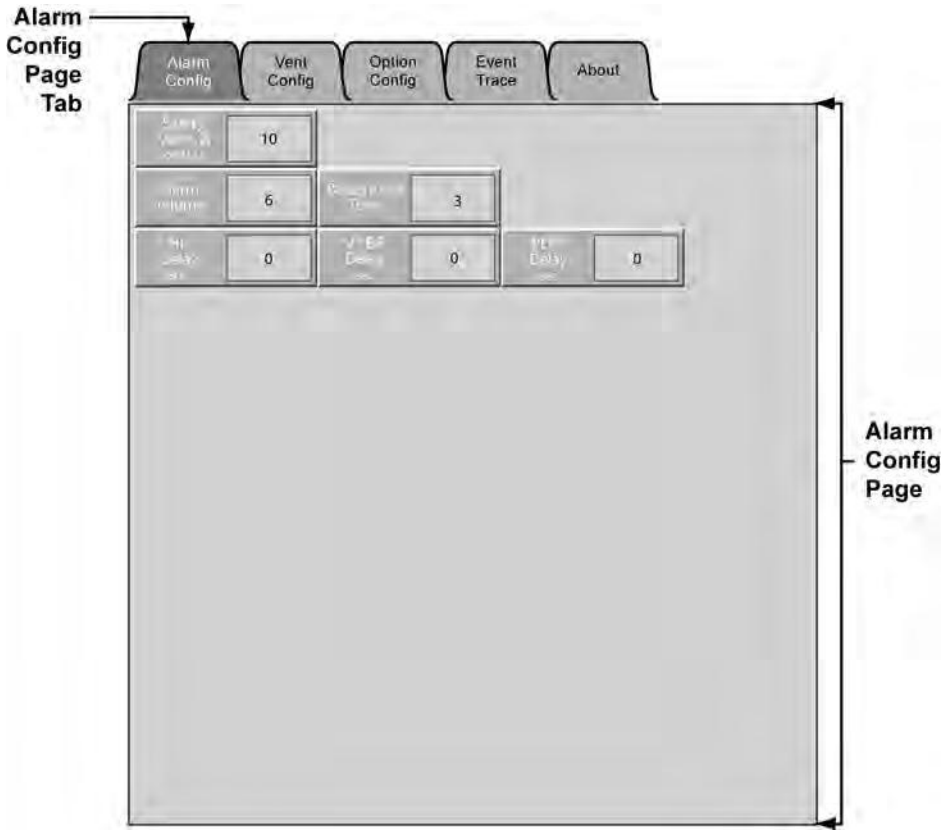
- Alarm Config
- Vent Config
- Option Config
- Event Trace
  - Service
  - Settings
  - All
- About

Alarm Config Page

Safety Valve delta pressure, audible alarms and Battery Use Tone volumes and alarm delay values (HP, PEEP and V / BR) are configured and set using the controls on the **Alarm Config** page.

To Display the Alarm Config Page:

To display the Alarm Configuration page, simply touch the **Alarm Config** page tab.



To Set Alarm Configuration Control Values:

Use the “Select, Change and Confirm” method to set alarm configuration control values (see *Setting Adjustable Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed information/instructions).

Safety Valve Delta (Δ)

The **Safety Valve Δ** control is used to set the Safety Valve over-pressure (Delta Pressure) activation level. This setting, in conjunction with the **High P_{peak}** alarm setting, determines the level at which the Safety Valve will open to provide backup high pressure relief in a high pressure condition. See *High Ppeak (High Airway Pressure)* and *Safety Valve High Pressure Relief* in Chapter 8 – Ventilator Alarms for additional information.

Range: **5** through **30 cmH_2O**

NOTE

It may be necessary to increase the Safety Valve setting when restrictive devices (e.g. dense filters) are used in the inspiratory limb of the patient circuit and the Safety Valve high pressure alarm occurs. Otherwise, it is recommended to set this value at its factory-set value (10 cmH_2O) or lower.

Alarm Volume and Battery Use Tone

The **Alarm Volume** and **Battery Use Tone** controls are used to set the audible volume at which the ventilator sounds alarms. For more information on the set volume versus the actual volume at which each priority of alarm sounds, see *Sound Types, Patterns and Volumes* in Chapter 8 – Ventilator Alarms.

Alarm Volume Range: **1** through **6**

Battery Use Tone Range: **Off**, or **1** through **3**

NOTE

An alarm volume setting of **1** is >45 dBA and an alarm volume setting of **6** is 80 dBA ± 5 dBA.

Incremental increases in volume setting (i.e. 1 – 6) correspond to increases in the dBA volume output level.

HP Delay

The **HP Delay** control is used to set the delay (in number of consecutive breaths), that the ventilator will wait after the circuit pressure exceeds the set high pressure limit, before initiating a **High P_{peak}** alarm condition.

- The High Pressure Delay setting does not affect the pressure limiting function of the High P_{peak} alarm. For more information on the High P_{peak} alarm, see *High Ppeak (High Airway Pressure)* in Chapter 8 - Ventilator Alarms.

Range: **0** through **2 Brth**

V / BR Delay

The **V / BR Delay** control is used to set the delayed notification (in seconds), for both the high and low limits of the Exhaled Minute Volume ($\mathbf{V_e}$), Exhaled Tidal Volume ($\mathbf{V_{te}}$) and the Breath Rate (**Rate**) alarms.

Range: **0** through **60 sec**

PEEP Delay

The **PEEP Delay** control is used to set the delayed notification period (in seconds), for the high and low limits of the **PEEP** alarm.

Range: **0** through **60 sec**

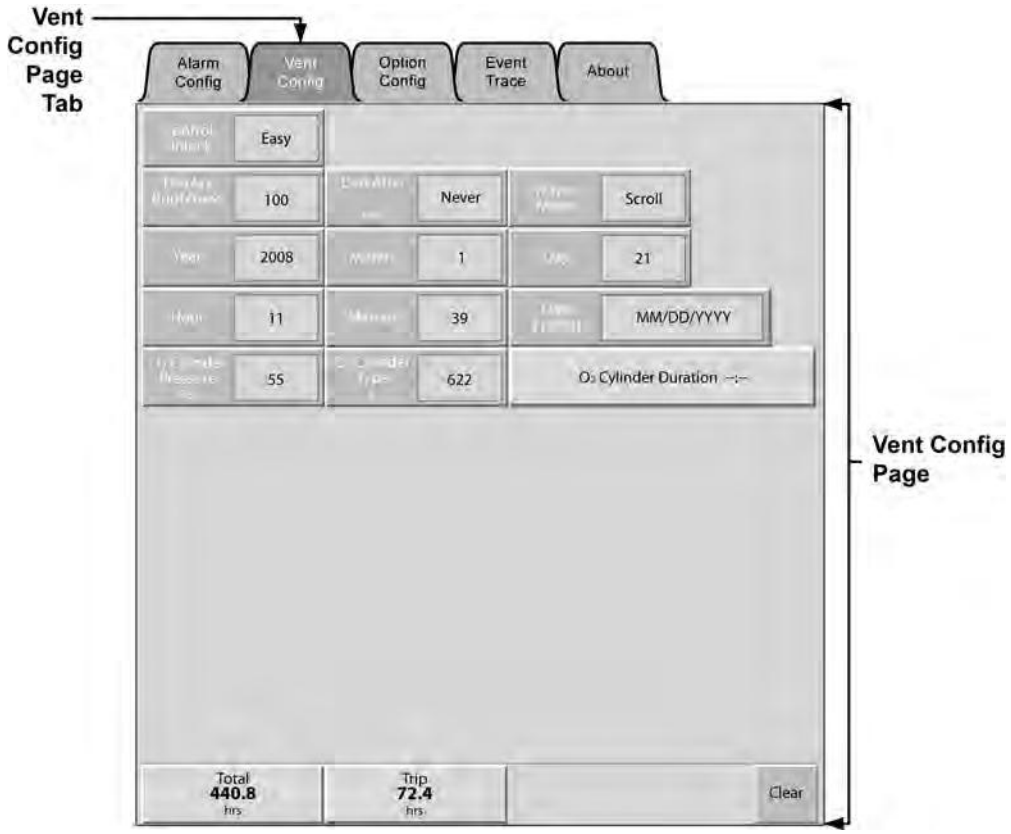
Vent Config Page

Control Locking difficulty, LCD display screen characteristics, graphical Wave display modes, date and time settings, O_2 cylinder pressure and type data are set using the controls on the **Vent Config** page.

Additionally, ventilator usage (Total and Trip hours) and O_2 duration calculations are also displayed on the Vent Config page.

To Display the Vent Config Page:

To display the Ventilator Configuration page, simply touch the **Vent Config** page tab.



To Set Ventilator Configuration Control Values:

Use the “Select, Change and Confirm” method to set ventilator configuration control values (see *Setting Adjustable Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed information/instructions).

Control Unlock

The **Control Unlock** control is used to set the degree of difficulty for control unlocking. To guard against inadvertent use of the controls, particularly in a non-clinical environment, the controls can be locked against change to two degrees of difficulty:

- **Hard** - The **Control Lock** button on the Lower Interface Panel must be held down for a period of 3 seconds before locked controls will be released for use
- **Easy** - A single touch of the **Control Lock** button on the Lower Interface Panel will release the controls for adjustment

LCD Display Characteristics

WARNING

Blank LCD Touch Screen Display – A blank LCD touch screen display during normal operation/ventilation, it is an indication that the ventilator is not functioning properly. To avoid the possibility of inadvertent ventilation control selection/activation, do not touch the display screen, immediately remove the patient, use an alternative method of ventilation and contact CareFusion or a service technician certified by CareFusion.

Display Brightness

The **Display Brightness** control is used to set the level of brightness (%) at which the LCD touch screen is illuminated.

Range**:** **30%** through **100%**

NOTE

Reducing the display brightness helps to prolong the useful life of the LCD backlight and improves battery performance.

Dim After

The **Dim After** control is used to set a period of time after which the LCD touch screen display will automatically dim brightness. Dimming the LCD touch screen when not in use helps to prolong the useful life of the LCD backlight and improves battery performance.

- The activation of any high or medium priority alarm will immediately restore the screen to normal brightness
- Touching the screen, pushing any button or adjusting the **Scroll** knob resets the display dimming time period and returns the display to normal brightness

NOTE

To avoid the possibility of inadvertent control selection, it is recommended that the alarm **Check** button on the Lower Interface Panel be used to restore the LCD screen to full brightness.

Range**:** **Never, 1** through **60 minutes**

Waves Mode

The **Waves Mode** control is used to configure the way dynamic waveforms are displayed on the **Graphics** screen, **Waves** page and the **Maneuvers** screen, **I-Hold** and **E-Hold** pages.

Range**:** **Scroll** or **Wrap**

> **NOTE**
>
> **Scroll Mode** – Waves move from right to left across the screen, displaying the most current data on the right.
>
> **Wrap Mode** – Waves remain fixed on the screen and the most current data replaces the oldest data.

Date and Time Settings

The Date and Time controls are used to set the local date and time and configure the date format displayed by the ventilator.

- **Year**, **Month**, **Day**, **Hour**, **Minute** and **Date Format**

Year Range:	**2004** through **2056**
Month Range:	**1** through **12**
Day Range:	**1** through **31** (depending on the month)
Hour Range:	**0** through **23**
Minute Range:	**0** through **59**
Date Format Range:	**MM/DD/YYYY**, **DD/MM/YYYY** or **YYYY/MM/DD**

> **NOTE**
>
> Until the date and time control values are set differently, the ventilator date-time tags and displays recordable events in the Events Log using factory-set date and time GMT[41] values (see *Event Trace* later in this chapter for additional information).
>
> - When the date and time control values are set to local date and time values, the Event Trace, Settings page displays GMT values in the event description column as a correction factor between the ventilator's internal clock and the user selected local time
> - The ventilator's internal clock does not automatically compensate for Daylight Savings Time (DST) and must be reset accordingly, if desired

[41] GMT – Greenwich Mean Time

O_2 Cylinder Pressure, Type and Duration

The **O_2 Cylinder Pressure** and **O_2 Cylinder Type** controls are used by an operator to enter data used by the ventilator to perform a calculation (based on current ventilation and FIO_2 settings) and display the approximate remaining usable time (in hours and minutes) of an external O_2 cylinder in the **O_2 Cylinder Duration hh:mm** display.

WARNING

O_2 Cylinder Duration Accuracy - The accuracy of the displayed useable amount of oxygen remaining in an external O_2 cylinder is dependent on the precision of the pressure gauge used on the O_2 cylinder and the accuracy of the information provided by the operator. The results of the calculation should be used for reference only.

Ventilation Variables and O_2 Consumption - Variations in the patient's minute ventilation, I:E Ratio and/or ventilator setting changes or equipment status (i.e. circuit leaks) affect the consumption rate of oxygen. When warranted by a patient's condition, a backup cylinder or alternative source of oxygen should be available at all times.

To Calculate the O_2 Cylinder Duration:

Use the "Select, Change and Confirm" method to;

1) Set the appropriate value for the **O_2 Cylinder Type**;

   Range**:** **75** through **9,900 L**, in increments of 1

2) Set the current **O_2 Cylinder Pressure**;

   Range**:** **100** through **2,300 PSI** (**5** through **150 BAR** or **500** through **15000 kPa**)

   The calculated **O_2 Cylinder Duration hh:mm** is displayed.

   Range**:** **0:00** through **99:59** (hh:mm)

NOTE

To obtain an accurate duration time estimate, the current cylinder pressure must be entered prior to *each* calculation. The **O_2 Cylinder Pressure** setting reverts to **"- - - -"** one minute after a value is entered.

Usage Meter Displays

Total hrs

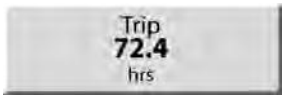
The Non-Resettable Usage Meter (**Total hrs**) is used to track and display the total number of hours of ventilator operation.

- The Non-Resettable Usage Meter updates every 0.1 hours

Range: **0.0** through **500000.0 hours**

Trip hrs

The Resettable Usage Meter (**Trip hrs**) is used to track and display the number of hours of ventilator usage since the user last reset the meter.



- The Resettable Usage Meter updates every 0.1 hours

Range: **0.0** through **500000.0 hours**

To Reset the Trip hrs Display:

1) Touch the **Trip XX.X hrs** button to select the trip meter and activate the **Clear** button.

2) Touch the **Clear** button.

The **Trip hrs** display is reset to zero (**0.0**) hours.

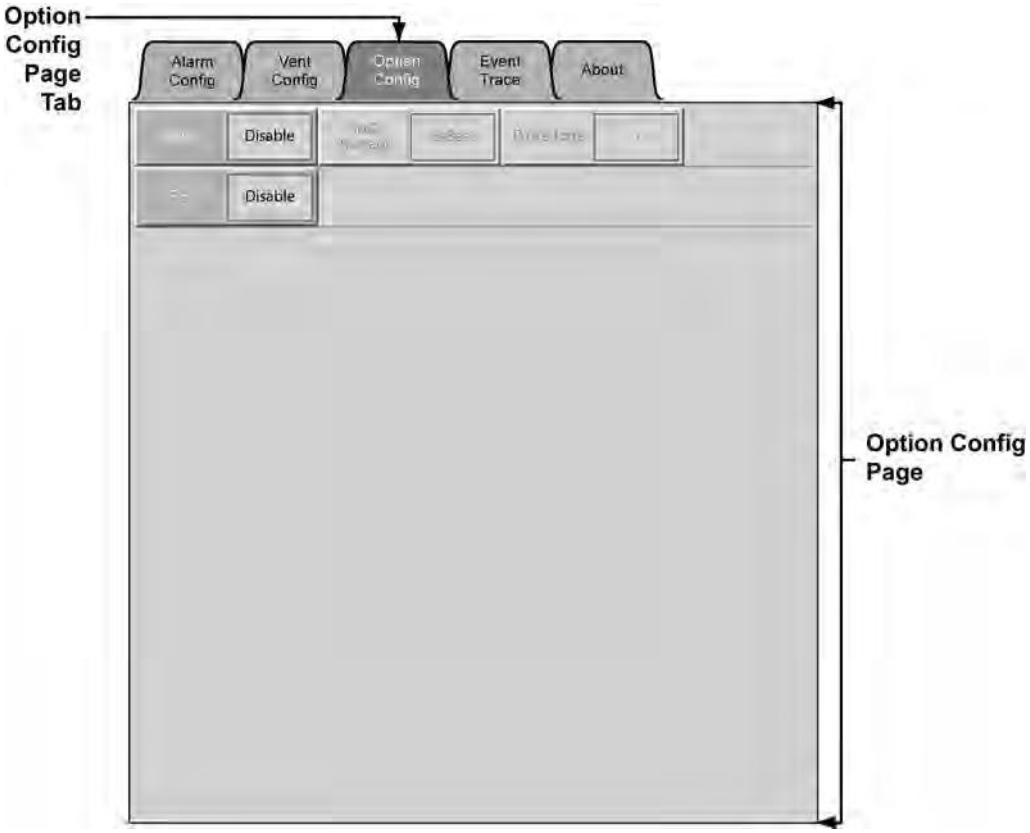
Option Config Page

Optional sensors attached to the ventilator (e.g. SpO_2) are enabled/disabled and configured using the **SpO_2** controls on the **Option Config** page.

After initial installation, configuration and calibration of FIO_2 monitoring while the ventilator is in Startup mode, communication with the FIO_2 sensor may be enabled/disabled during normal ventilation modes using the **FIO_2** control.

To Display the Option Config Page:

To display the Option Configuration page, simply touch the **Option Config** page tab.



To Set Option Configuration Control Values:

Use the “Select, Change and Confirm” method to set option configuration control values (see *Setting Adjustable Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed information/instructions).

SpO_2 Configuration

When a Pulse Oximetry (SpO_2) module is connected to the ventilator (see *Pulse Oximetry (SpO2),* in Chapter 2 - Installation and Setup for detailed instructions), it is enabled or disabled and configured using the following controls on the **Option Config** page.

SpO_2

The **SpO_2** control is used to enable or disable a connected Pulse Oximetry module. Once the module is enabled the ventilator looks for data and sounds an alarm if the sensor is not attached to a patient.

- Setting the **SpO_2** control to **Enable**, also enables the **SpO_2 Average** and **Pulse Tone** controls

Range: **Disable** or **Enable**

> **NOTE**
> If the SpO_2 sensor is not attached to a patient when Pulse Oximetry is enabled, the **SpO_2 Check Sensor Placement** alarm is generated.

SpO_2 Average

The **SpO_2 Average** control is used to set the averaging calculation used by the SpO_2 Module to display readings (e.g. display reading for each pulse beat, fast average, average of 4 pulse beats, or average of 8 pulse beats).

Range**:** **B-B, Fast, 4-Beat,** or **8-Beat**

Settings Definitions:

B-B - Most responsive to changes in O_2 blood saturation and most susceptible to ARTF and OOT conditions.

Fast - Incrementally slower response to changes in O_2 blood saturation than **B-B** setting and less susceptible to ARTF and OOT conditions.

4-Beat - Incrementally slower response to changes in O_2 blood saturation than **Fast** setting and less susceptible to ARTF and OOT conditions.

8-Beat - Least responsive to changes in O_2 blood saturation and least susceptible to ARTF and OOT conditions.

> **NOTE**
> **ARTF** (Artifact) – A detected pulse beat didn't match the current pulse interval (typically additional/erroneous signal(s).
>
> **OOT** (Out of Track) – An absence of consecutive good pulse signals.
>
> Both are caused by variations in/of the signal(s) from the SpO_2 module and are typically caused by patient/finger movement. Neither is an indication of a faulty or defective SpO_2 module.

Pulse Tone

The **Pulse Tone** control is used to set the audible volume level of the SpO_2 Pulse Tone.

- The tone is only active when an Oximetry Module is connected to the ventilator, enabled and the sensor is attached to a patient
- The SpO_2 Pulse Tone is an informational only signal

Range**:** **Off, 1** or **2**

FIO_2 Configuration

The **Utility** screen, **Option Config** page **FiO_2** control is only used to enable or disable communication with a FIO_2 sensor during normal ventilation modes (no need to disconnect the patient or restart the ventilator).

Initial installation, enable/disable and calibration instructions and procedures are provided in detail under *FIO2 Sensor* in Chapter 2 – Installation and Checkout and *FIO2 Configuration and Calibration* in Chapter 3 – Using the Ventilator while the ventilator is in Startup mode.

Range: **Disable** or **Enable**

Event Trace

The Enve™ ventilator retains an Event Log in non-volatile memory. The Event Log is a list of events recorded by the ventilator. These events may be normal conditions, such as ventilation settings, turning the ventilator on or off, or alarm conditions such as **Hardware Fault** or **High Ppeak** (High Airway Pressure).

The Event Log is circular (i.e. the oldest record is displaced by the latest) and can contain at least 300,000 entries.

Types of events logged by the ventilator:

- Ventilator power on and off
- Preset menu selections
- Patient ID information
- EST[42] and UVT[43] test execution and results
    - Circuit Test results
    - Button Test accessed
    - Touch Screen Calibration results
- FIO_2 calibration results
- Battery Check performed
- Display Alarm Check performed
- Ventilator configuration changes
- Ventilation control changes
- Alarm control changes
- Safety Valve activation / deactivation
- Alarm detections
- Alarm recoveries
- Alarm resets by user
- Alarm silence period activated / deactivated by user
- The start and end of any Maneuver or Procedure
- Manual Breaths initiated

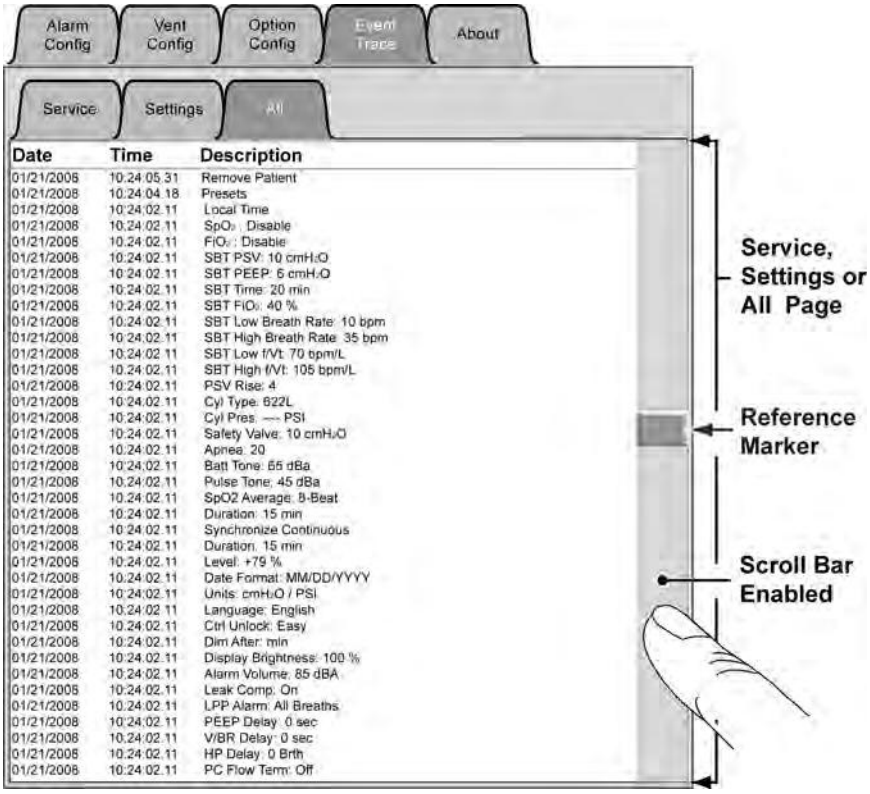
Upon starting ventilation and every 24 hours of continuous operation the ventilator logs all control and alarm settings.

> **NOTE**
> Event log entries are only one of many diagnostic tools used to troubleshoot the ventilator. Additional information is often required to accurately identify the root cause of a problem. See *Chapter 13 - Troubleshooting* for more information.

[42] Extended Systems Test (EST)
[43] User Verification Tests (UVT)

The Events are grouped by category and displayed (scrollable) on three (3) separate **Event Trace** pages;

- **Service** page
- **Settings** page
- **All** page



To Scroll Displayed Events:

1) Touch the **Scroll Bar** on the **Service**, **Settings,** or **All** page to enable scrolling of data to be displayed. The **Reference Marker** is highlighted.

2) Turn the **Scroll** knob on the Lower Interface Panel clockwise to scroll any available older data into the display window and turn it counter-clockwise to display the newest data.

   - Touching the **Scroll Bar** a second time (prior to the expiration of 30 seconds) reverts the **Reference Marker** to its previous color/state and leaves the data as currently displayed
   - Or, after 30 seconds of inactivity, the **Reference Marker** automatically reverts to its previous color/state, and leaves the data as currently displayed
   - Selecting another screen and returning to the Utility screen, resets the data displayed on the **Service**, **Settings** or **All** pages to the most current data

Event Trace, Service Page

The types of Events displayed on the **Event Trace**, **Service** page are;

- Service / Technical related events and conditions
- Alarms and alarm related events (e.g. hardware faults)
- Battery changes

To Display the Event Trace, Service Page:

To display the Event Trace, Service page, simply touch the **Event Trace** page tab, then touch the **Service** page tab.

Event Trace, Settings Page

The types of Events displayed on the **Event Trace**, **Settings** page are:

- Mode or breath changes
- Any settings changes
- All settings, upon completion of POST
- All settings, every 24 hours of continuous operation

> **NOTE**
> Until the date and time control values are set differently, the ventilator records, date-time tags and displays events in the Events Log using factory-set date and time GMT[44] values (see *Date and Time Settings* earlier in this chapter for additional information).
> - When the date and time control values are set to local date and time values, the Event Trace, Settings page displays GMT in the event description column as a correction factor between the ventilator's internal clock and the user selected local time

To Display the Event Trace, Settings Page:

To display the Event Trace, Settings page, simply touch the **Event Trace** page tab, then touch the **Settings** page tab.

Event Trace, All Page

All Events (including Maneuvers, Procedures and Standby Mode) are displayed on the **Event Trace**, **All** page.

To Display the Event Trace, All Page:

To display the Event Trace, All page, simply touch the **Event Trace** page tab, then touch the **All** page tab.

[44] GMT – Greenwich Mean Time

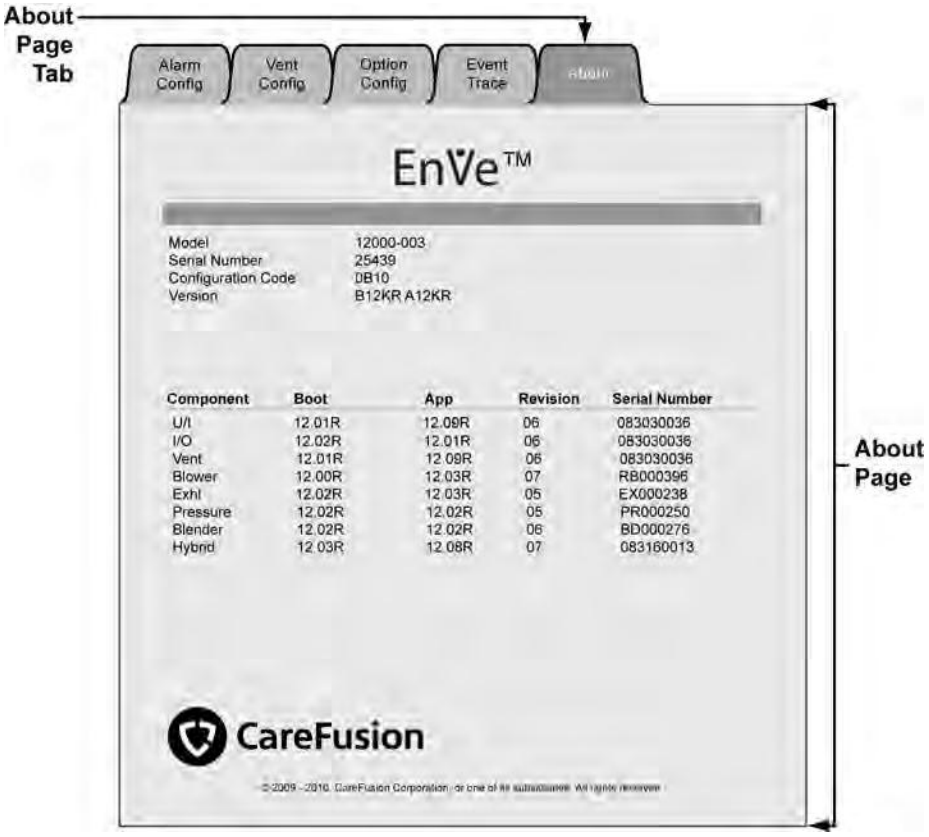
About Page

The **About** page displays information concerning the ventilator configuration.

- Contact Information (company name, website address, email address, phone number)
- Device Information (model name or part number, serial number, configuration code)
- Component(s) Information (name, boot and application software versions, hardware revisions, serial numbers)
- Copyright Notice

To Display the About Page:

To display the About page, simply touch the **About** page tab.



Chapter 11 - MAINTENANCE AND CLEANING

Maintenance Schedule

Routine Maintenance

The Enve™ ventilator is designed to operate for extended periods of time with minimal routine maintenance. The following periodic maintenance is recommended:

Length of Service[45]	Maintenance Required
In storage	• Charge and remove the Removable Battery Pack from the ventilator prior to storage. For minimum aging of the Removable Battery Pack while in storage, store it with approximately 40% charge. Every six months, verify charge of Removable Battery is above 20% and recharge if necessary • Every two months, recharge the Transition Battery[46] by powering the ventilator from an AC power source for at least 5 hours
Prior to initial use	• Charge the Removable Battery Pack and Transition Battery by powering the ventilator from an AC power source for at least 13 hours • Setup the ventilator/accessories as shown in *Chapter 2 - Installation and Setup* • Check the ventilator for proper operation as detailed in *Testing* in Chapter 2 – Installation and Setup
Daily	• Verify alarms are functioning properly • Check the Air Inlet Filter, replace if soiled • Check the Cooling Fan Filter, clean if necessary, replace if damaged or worn
When changing or reconfiguring the patient circuit	• Check the Exhalation Valve Diaphragm, clean if necessary, replace if damaged or worn • Perform the *Circuit Test* as detailed in Chapter 2 – Installation and Testing

If in use, a minimum of once a month	Perform the tests as detailed in *Testing,* in Chapter 2 – Installation and Setup.
	Alternatively, to retain patient settings, do the following:
	• While the ventilator is off patient, perform the:
	  • Button Test
	  • Vent Inop Alarm Test
	  • External power disconnect test
	  • Disconnect external power and Removable Battery Pack test
	• Verify the V_{te} or V_e monitor
	• Verify the P_{aw} or P_{peak} monitor
	• Verify the delivered O_2 concentration, if not using an oxygen analyzer continuously

[45] To check the number of hours the ventilator has been in service, see *Usage Meter Displays* in Chapter 10 – The Utility Screen

[46] The **Vent Inop** alarm will sound if the Transition Battery charge becomes completely depleted while in storage.

Extended Maintenance

Length of Service[47]	Maintenance Required
Every 15,000 hours or three years[48], whichever comes first	• Replace the Cooling Fan Filter • Replace the Air Inlet Filter and Screen • Replace the O_2 Inlet Filter • Replace the Blower Inlet Filter • Perform all Functional and Final Checkout Tests specified in the PTV® Series Ventilators Service Manual
Every 30,000 hours or six years[48], whichever comes first	• Perform 15,000 hours / 3 years Extended Maintenance • Replace the Flow Sensor Filter • Replace the Transition Battery • Perform all Functional and Final Checkout Tests specified in the PTV® Series Ventilators Service Manual

Extreme Environments

The above maintenance schedule is typical for most clinical settings. In some cases, however, environmental conditions may dictate that maintenance procedures are performed more frequently. Check with CareFusion if your ventilator is likely to be subject to extreme conditions.

Battery Maintenance

To ensure that the Removable Battery Pack and the Transition Battery used with the ventilator remain charged and conditioned when the ventilator is not in use, follow the recommended care and maintenance instructions (see *Chapter 12 - Power Supplies and Batteries)*.

[47] To check the number of hours the ventilator has been in service, see *Usage Meter Displays* in Chapter 10 – The Utility Screen

[48] 15,000 hour, three year and/or 30,000 hour, six year Extended Maintenance and ventilator repair must be performed by a CareFusion trained service technician.

Cleaning the Ventilator

CAUTION

Equipment Damage –To avoid irreparable damage to the ventilator, do not attempt to sterilize it.

Damage to the Device from Liquids - Do not immerse the ventilator in liquids. Do not pour or spray cleaning agents directly onto any part of the ventilator. Do not allow liquids to pool on the ventilator. Damage to the device can occur if moisture enters the interior of the ventilator.

Damage to Plastic Components - To avoid damaging the ventilator's plastic components, LCD screen and front panel, do not use cleaning agents containing ammonium chloride or any other chloride compounds, more than 2% glutaraldehyde, phenols, or abrasive cleaners.

Surface Cleaning

Wipe the exterior surfaces of the ventilator with one of the following products using a clean, soft cloth. Never spray products directly onto the ventilator, only onto a cleaning cloth. Be sure to wipe away any residual cleaner.

Clean all ventilator external surfaces before and after each patient use, and as otherwise indicated.

Cleaning Product	Cleaning Method
Isopropyl alcohol	90% solution
White vinegar	Dilute to 50% with cold tap water
Control III®	As labeled by manufacturer, Maril Products, Inc.

Cleaning/Disinfecting/Sterilizing Reusable Patient Circuits

Before cleaning reusable patient circuits, detach the circuit from the ventilator (see *Patient Breathing Circuits* in Chapter 2 – Installation and Setup for detailed instructions) and disassemble circuit components (see Instructions For Use provided with your circuit).

> **NOTE**
>
> Various optional accessories (humidifiers, water traps, etc.) are available from CareFusion for use with PTV® Series patient circuits. For information refer to the manufacturer's instructions included with each accessory.

Detaching the Patient Circuit from the Ventilator

1) Hold the patient circuit hoses by the molded rubber end and pull straight out to detach, do not pull on the hoses.
2) Twist to detach the Sense Line Luer fittings at the ventilator.

Cleaning Patient Circuits

> **WARNING**
>
> **Risk of Patient Infection** – To avoid the risk of patient infection, reusable patient circuits and accessories should be cleaned before reuse. Refer to the detailed cleaning instructions provided with your patient circuit. For humidifiers, filters or other patient circuit accessories, follow the manufacturer's recommended cleaning instructions.
>
> In order to prevent cross-contamination, bacteria filters should be used between the patient and components in the pneumatic pathway that cannot be disinfected between patients (e.g. FiO_2 sensors).

To clean, disinfect or sterilize reusable patient circuits used with your ventilator, follow the detailed instructions included with your particular circuit type.

Reassembling the Patient Circuits

Reassemble the patient circuits per the exploded diagrams provided in the Instructions for Use included with your circuit. Install the patient Wye and proximal Sense Lines in the patient circuit so the proximal Sense Lines are oriented upwards while operating.

Cleaning/Disinfecting/Sterilizing Exhalation Valve

The internal Exhalation Valve on the Enve™ ventilator is an integral part of the Expiratory Port marked with the symbol shown here. 

WARNING

Remove Patient - Cleaning of the Expiratory Port and internal Exhalation Valve area must be performed off patient. Remove the patient and provide an alternative form of ventilation while cleaning is performed.

CAUTION

Damage to the Exhalation Valve - The Exhalation Valve Diaphragm is delicate and can be damaged by;

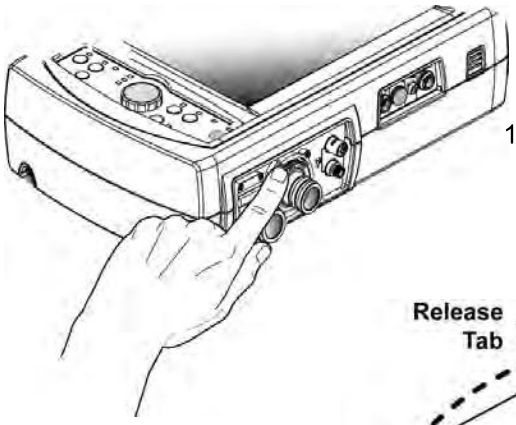
- careless handling when cleaning it or removing it;
- inserting any foreign body into the valve openings;
- using high pressure gas to clean or dry the Exhalation Valve components or port.

CAUTION

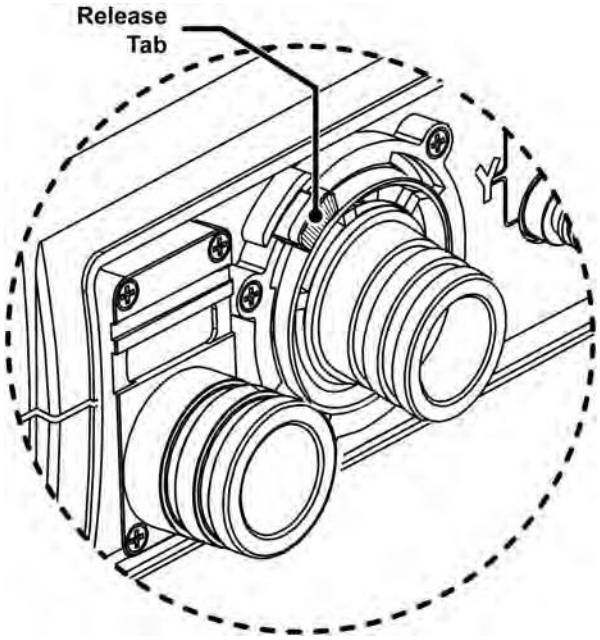
Exhalation Valve Protection from Fluids –Thoroughly dry the area surrounding the Exhalation Valve Diaphragm before removing it for cleaning or replacement. Do not spray any cleaning fluids directly onto the area surrounding the Exhalation Valve and its associated safety valve ports. Fluid migrating into the port behind the Exhalation Valve Diaphragm can damage the ventilator. If this occurs, discontinue use of the ventilator and contact CareFusion or a service technician certified by CareFusion.

Always include the provided water trap(s) in the patient circuits used with your ventilator.

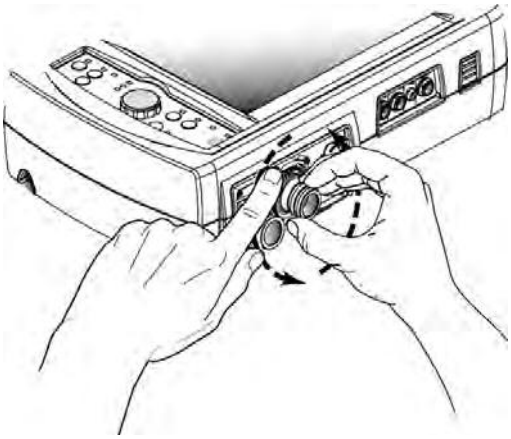
Disassembling the Exhalation Valve

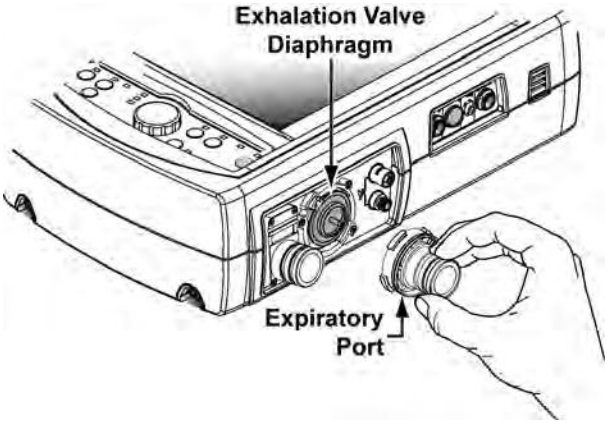


1) Press and hold the release tab to disengage the locking mechanism.



2) While still holding down the release tab, firmly grasp the Expiratory Port and twist counter clockwise.

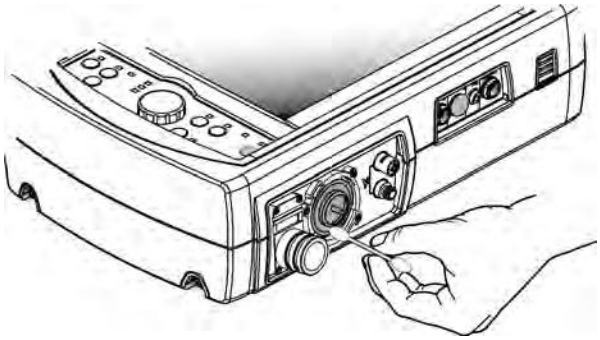


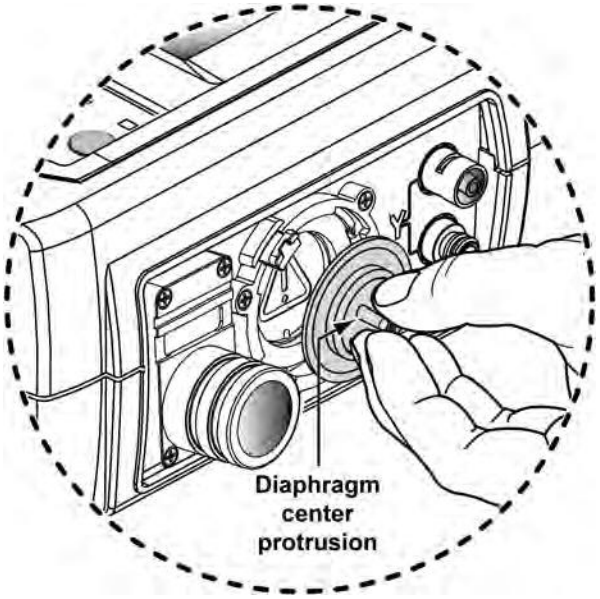


3) When the Expiratory Port stops turning, pull the port straight out.

Wipe fluids from around diaphragm before proceeding.

4) Wipe all excess fluid from around the Exhalation Valve Diaphragm before removing it.





5) Remove the diaphragm by grasping the center protrusion and gently pulling straight out.

Cleaning the Exhalation Valve

> **CAUTION**
>
> **Degradation of Exhalation Valve Components** - To avoid degradation of the exhalation valve components:
>
> - do not ultrasonically clean
> - do not exceed a combined total of 50 cleaning, disinfection, or sterilization cycles, or 1 year of use (whichever comes first)

The Expiratory Port and Exhalation Valve Diaphragm can be cleaned as follows:

1) Disassemble the exhalation valve, per previous instructions.
2) Remove all particulate matter and wash using mild detergent.
3) Rinse gently and thoroughly for two (2) minutes in clean water.
4) Air dry or use a low flow air source to eliminate any residual fluid or debris.
5) Inspect the diaphragm for wear, replace if excessively worn or damaged and reassemble as shown in *Reassembling the Exhalation Valve* later in this chapter.

High Level Disinfecting the Exhalation Valve

CAUTION

Degradation of Exhalation Valve Components - To avoid degradation of the Exhalation Valve components, do not use any of the following solutions to disinfect or sterilize the Exhalation Valve:

- Ketone
- Phenol (>5%)
- Inorganic acids
- Formaldehyde
- Hypochlorite
- Chlorinated solutions
- Chlorinated hydrocarbons
- Aromatic hydrocarbons

The Expiratory Port and Exhalation Valve Diaphragm can be disinfected as follows:

1) Disassemble the exhalation valve and clean per previous instructions.
2) To disinfect the components:
    - Bathe in Cidex™ Plus 28 Days for twenty (20) minutes
3) Rinse gently and thoroughly for two (2) minutes in clean water.

CAUTION

Cleaner Residue – To avoid damage to the Expiratory Port or Exhalation Valve Diaphragm, rinse thoroughly to remove all disinfectant/cleaner residues.

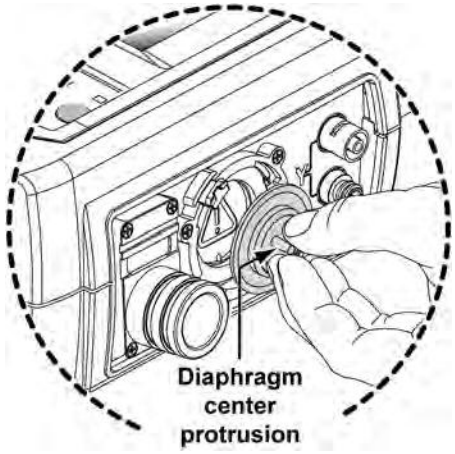
4) Air dry or use a low flow air source to eliminate any residual fluid or debris.
5) Inspect the diaphragm for wear, replace if excessively worn or damaged and reassemble as shown in *Reassembling the Exhalation Valve* later in this chapter.

Sterilizing the Exhalation Valve

The Expiratory Port and Exhalation Diaphragm can be sterilized as follows:

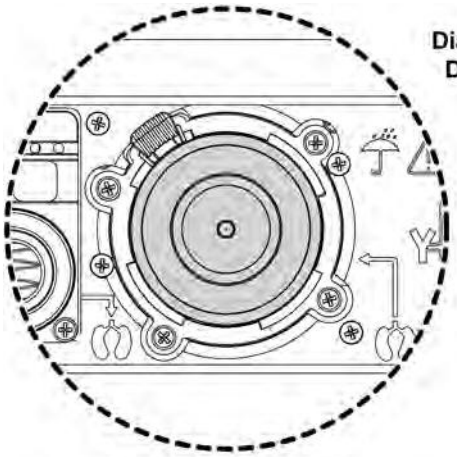
1) Disassemble the exhalation valve and clean per previous instructions
2) To sterilize the components;
    - Autoclave using the following process;
        - Steam 6 minutes @ 20 PSIG @ 275° F (135° C)
        - Dry 6 minutes @ 275° F (135° C)
3) Inspect the diaphragm for wear, replace if excessively worn or damaged and reassemble as shown in *Reassembling the Exhalation Valve* later in this chapter.

Reassembling the Exhalation Valve

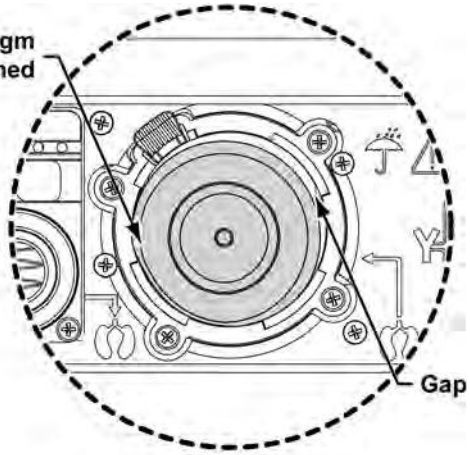


1) Orient and place the clean and dry Exhalation Valve Diaphragm into the Exhalation Valve body on the ventilator, as shown here.

2) Check to ensure that the diaphragm is properly seated and centered within the body of the exhalation valve. Adjust as necessary before proceeding.

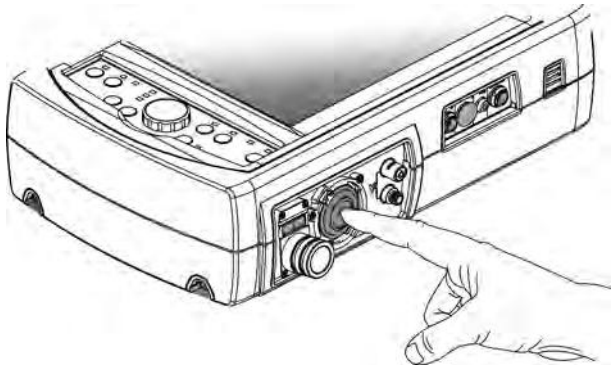


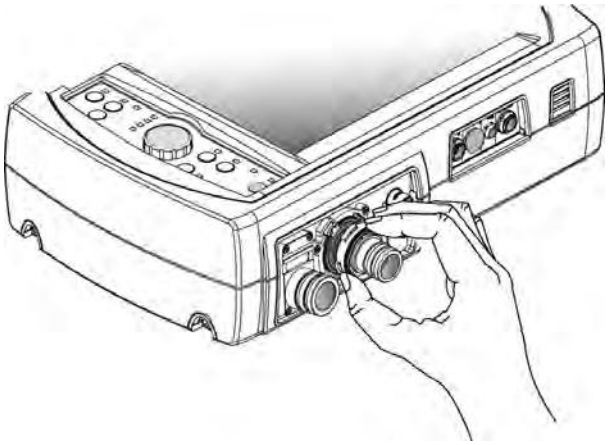
Diaphragm Centered
Acceptable



Diaphragm Not Centered
Unacceptable

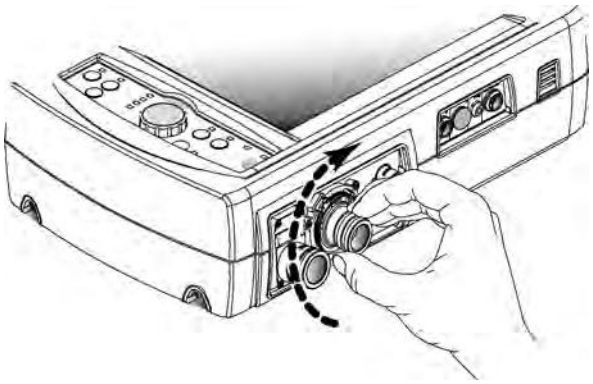
3) Press gently to seat the diaphragm.





4) Align the fins on the Expiratory Port with the corresponding notches on the valve body.

5) Push the Expiratory Port in, then twist clockwise until the tab “clicks” into place.



6) Recheck to ensure that the diaphragm is still centered within the body of the exhalation valve.
    - Remove the Expiratory Port and repeat steps 1 through 5 if necessary

WARNING

Leak Testing Patient Circuits - Leak test the patient circuit with all accessories connected before connection to the patient. Failing to detect and eliminate leaks can result in ineffective ventilation and possible harm to the patient. Refer to *Circuit Test* in Chapter 2 - Installation and Setup for detailed leak testing instructions.

Filter Cleaning and Replacement

The Oxygen Inlet Filter

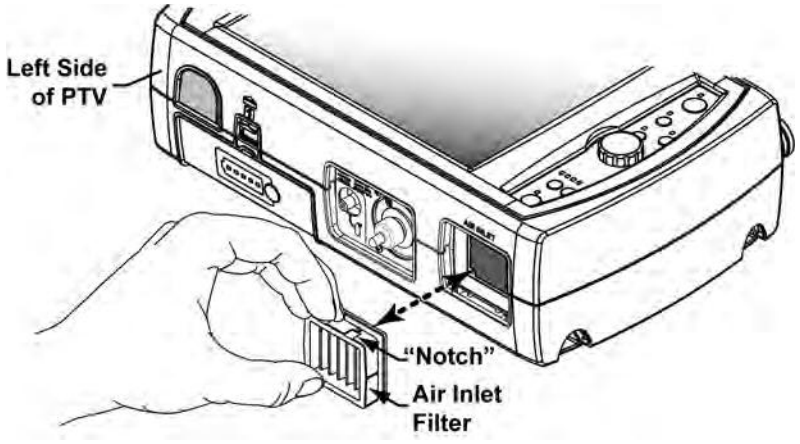
The ventilator has a small “cone” filter which is an integral part of the oxygen inlet connector. This Oxygen Inlet Filter should be replaced by a service technician trained and certified by CareFusion as part of your regularly scheduled maintenance.

The Air Inlet Filter

Check the Air Inlet Filter daily and replace when soiled, worn or damaged. See *Replacement Parts* in Appendix C – Reference Information for replacement part numbers and *Appendix A - Contact Information* for ordering information.

To Remove the Air Inlet Filter

1) Gently remove the worn or soiled filter as shown. Discard the old filter.



To Replace the Air Inlet Filter

Position the new Air Inlet Filter as shown in the illustration (notches in the filter frame oriented up/down and away from ventilator) and push it fully into the filter housing opening, up against the screen.

CAUTION

Damaging the Air Inlet Filter – To avoid damaging the Air Inlet Filter, hold and install it by grasping the outer rubber frame. Do not push on the pleated filter material.

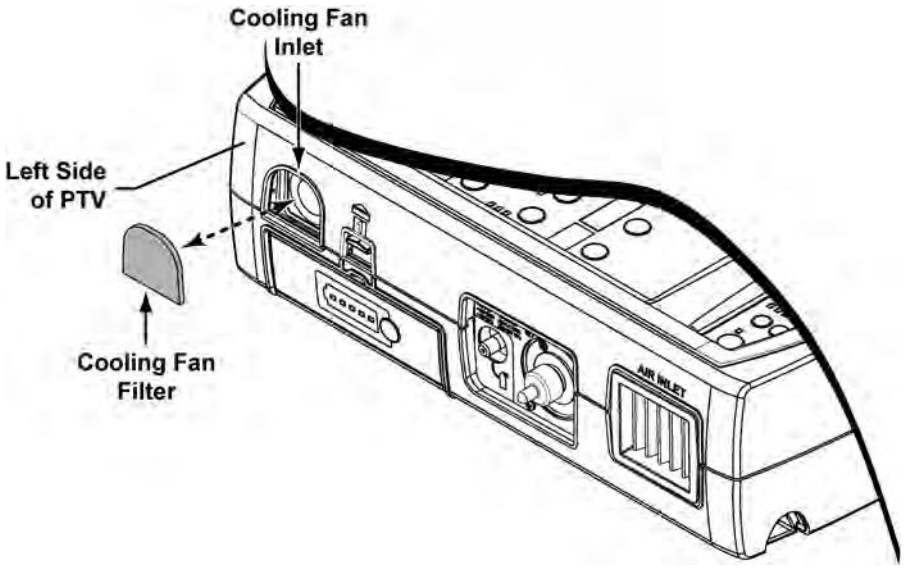
The Cooling Fan Filter

Check the cooling fan filter daily. Clean as detailed below and replace when worn or excessively soiled.

> **CAUTION**
>
> **Keep Filter Clean and Unobstructed –** The Cooling Fan Filter must be kept clean and unobstructed. Failure to do so can result in a dangerous buildup of oxygen and/or damage to the ventilator due to overheating.

To Remove the Cooling Fan Filter

1) To extract the Cooling Fan Filter, gently pinch the foam between thumb and forefinger and remove from the filter housing.
2) Examine the filter for wear or damage. Replace if necessary.



To Clean the Cooling Fan Filter

1) Gently bathe the filter in a solution of mild detergent and warm water.
2) Rinse thoroughly in clean water.
3) Examine the filter for excessive wear or damage (discard and replace when necessary) and allow it to air dry before reinstallation. See *Replacement Parts* in Appendix C – Reference Information for replacement part numbers and *Appendix A - Contact Information* for ordering information.

> **CAUTION**
>
> **Wet or Damp Filters -** Do not install a wet or damp filter into the ventilator. This could damage the ventilator.

To Replace the Cooling Fan Filter

Position the filter as shown in the previous illustration, fully insert it into the filter housing and tuck it behind each of the four retaining tabs (top, bottom and sides).

Chapter 12 - POWER SUPPLIES AND BATTERIES

The Enve™ ventilator operates on Direct Current (DC; 11 to 16 VDC). The following power sources are available to operate the ventilator:

- AC Adapter
- Automobile Adapter
- Docking Station
- Removable Battery Pack
- Transition Battery

NOTE

While the ventilator is connected to any valid source of external power, the Removable Battery Pack and Transition Batteries are charged.

AC Adapter (Option)

The ventilator can be powered from a properly grounded AC supply using the AC Adapter. For complete connection and care instructions see the Instructions For Use supplied with your adapter.

Automobile Adapter (Option)

An optional adapter is available to power the ventilator while operating in an automobile. This adapter is designed to connect to a factory installed +12Volt - 20 Amp auxiliary power outlet or automobile cigarette lighter capable of supplying at least 20 amperes of current. The use of third-party-installed automobile cigarette lighter-style power outlets to power the ventilator is not recommended.

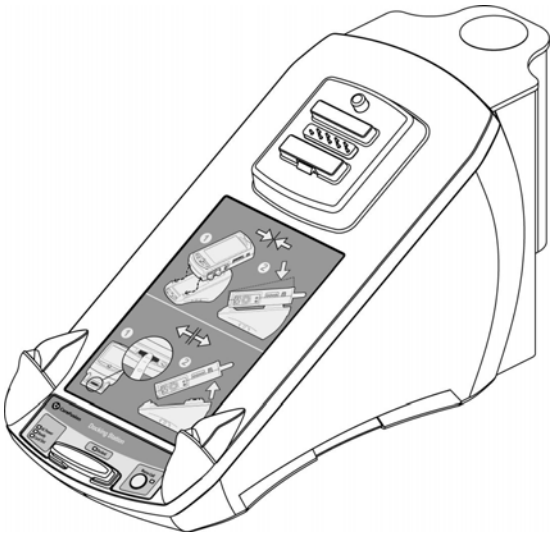
WARNING

Power Surges - Do not operate the ventilator from an automobile power outlet or cigarette lighter while starting or jump starting the automobile. The resulting power fluctuations may cause damage to the ventilator and cause it to stop functioning.

See the Instructions For Use accompanying your Automobile Adapter for detailed care and usage information.

Docking Station (Option)

The Enve™ ventilator can be powered directly from the Docking Station via the custom interface connection. Refer to the PTV® Series Docking Station Operator's Manual, P/N 12433-001 for information and instructions.



NOTE

Docking a PTV® Series Ventilator to a Docking Station which is not connected to a valid source of external power (or is switched off), will result in the ventilator continuing to run on internal battery power (Removable Battery Pack or Transition Battery, as applicable).

When using PTV® Series Ventilators in combination with a Docking Station, CareFusion recommends connecting external power to the Docking Station only (the Docking Station in turn provides power to the ventilator) and confirming that external power is being supplied to the ventilator (**External Power** LED on the ventilators' Lower Interface Panel is illuminated).

Removable Battery Pack

The Enve™ ventilator uses a rechargeable lithium-ion Removable Battery Pack which is supplied with the ventilator. The Removable Battery Pack is exchangeable while the ventilator is running. To install or remove the Removable Battery Pack, see *Power Connection* and *Removable Battery Pack Installation* in Chapter 2 – Installation and Setup for detailed instructions.

WARNING

Risk of Fire, Chemical Burn or Explosion - The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 60°C, or incinerate. Replace battery with CareFusion P/N 13908-001 only. Use of another battery, may present a risk of fire or explosion.

The ventilator can charge a discharged Removable Battery Pack when Docking Station power or external DC power is available. Once the Transition Battery is charged, the Removable Battery Pack can be >90% charged by a ventilator connected to external power within 8 hours, from fully discharged.

The length of time the ventilator will operate using the Removable Battery Pack is a function of many factors such as settings, charge level and condition or age of the battery. Using “Standard Test Settings” settings (see *Removable Battery Pack* in Appendix B – Specifications), a new battery will power the ventilator for more than four (4) hours, although actual run time may vary.

NOTE

Battery operating times may vary significantly based on user settings. Specifically, Pressure Control breaths with fast rise times, high Breath Rates and high Peak Flows will typically decrease battery life.

Reducing the display brightness and dimming the LCD screen when not in use helps to prolong the useful life of the LCD backlight and improves battery performance. See *Display Brightness* and *Dim After* on the Ventilator Configuration (**Vent Config**) Page in Chapter 10 - The Utility Screen for additional information and detailed instructions.

To Check the Level of Charge:

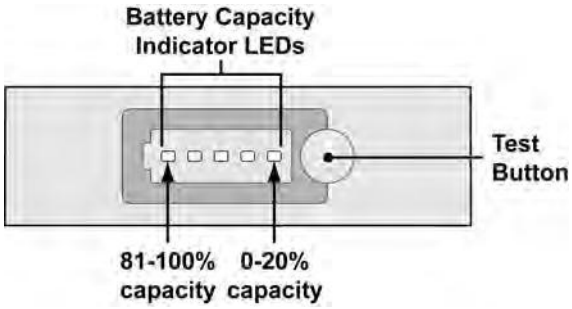
NOTE

To avoid an unexpected depletion of internal battery power, always check the Removable Battery Pack level of charge prior to disconnecting external power or operating the ventilator solely on the Removable Battery Pack (such as during transport situations).

There are two (2) methods for checking the remaining capacity of the Removable Battery Pack.

1) On the Removable Battery Pack there is a “Test” button which lights a series of 5 LEDs on the edge of the battery when pushed.

   Each Removable Battery Pack LED increments approximately 20% as shown.



LEDs Lit	Approximate Charge Level
1	0-20%
2	21-40%
3	41-60%
4	61-80%
5	81-100%

   If the battery is being charged, the LED that is representative of the of the battery’s current charge level flashes while the test button is being pushed.

2) The ventilator monitors the power supplies connected to it. This data is displayed when the Battery/Power **Check** button is pushed.

   See *Check Buttons* in Chapter 5 – Controls for additional information.

NOTE

Battery Replacement - Capacity is measured as a percentage of the battery’s capacity when it was new. When a fully-charged battery does not display at least 50% capacity, the battery has reached the end of its useful life and it is time to replace that battery.

To Preserve Maximum Battery Life During Storage

1) Remove the Removable Battery Pack and store it separately, preferably with approximately a 40% charge.
2) After storage, it is advisable to condition the Removable Battery Pack prior to use using the Desktop Battery Charger.

CAUTION

Storage Temperature - Storing the Enve™ ventilator at temperatures above 60°C (140°F) for long periods can cause battery duration to be reduced.

Transition Battery

The Transition Battery is an internal rechargeable lithium-ion battery which powers the ventilator while changing Removable Battery Packs or switching between external power sources.

When operating on power supplied by the Docking Station or other external source, the ventilator is able to fully recharge the Transition Battery within 5 hours. To avoid depleting the Removable Battery Pack, the Transition Battery is only partially charged by the ventilator when the Removable Battery Pack is the *only* source of power operating the ventilator.

WARNING

Reduced Flow/Pressure – To avoid possible harm to patients requiring a flow rate higher than 120 L/min or pressure greater than 65 cmH_2O, minimize use/length of time of Transition Battery powered ventilation. To conserve power, the ventilator may run with reduced performance, while using the Transition Battery at higher flows and pressures.

NOTE

Transition Battery Use - The Transition Battery is intended for use during very short periods while switching between external power supply connections or when changing Removable Battery Packs. The length of time the ventilator will operate on the Transition Battery is a function of many factors such as settings, charge level and condition or age of the battery. The Transition Battery is only intended to power the ventilator for up to one minute.

Charging Sequence - When the Enve™ ventilator is connected to a valid external power source and both the Transition Battery and the Removable Battery Pack require charging, the internal battery charger will charge the Transition Battery to full capacity *before* charging the Removable Battery Pack.

Chapter 13 - TROUBLESHOOTING

WARNING

Vent Inop Alarm - If a Vent Inop alarm occurs during operation, immediately ventilate the patient using an alternative method, disconnect the ventilator and contact CareFusion or a service technician certified by CareFusion.

This chapter describes troubleshooting for the Enve™ ventilator. Some problems may be easily corrected without any modification to the ventilator. Other problems may require that the ventilator be recalibrated or have parts replaced.

Do not attempt to repair or replace any part of the ventilator unless you are trained and authorized to perform service on the Enve™ ventilator.

This chapter is organized into six sections:

- **Displays and Buttons** - Includes problems with control and window displays and with setting controls
- **Ventilator Performance** - Includes problems with delivered or monitored pressure, volume or PEEP, accuracy, sensitivity and triggering
- **Power and Battery Operation** - Includes problems with turning the ventilator on, operating from external power sources, battery operation or duration, and Vent Inop
- **Alarms** - Includes problems with recurring alarms
- **Test Failures** - Includes problems detected during EST[49], UVT[50] and Functional testing
- **Test Lung Operation** - Includes problems encountered while verifying ventilator performance with a Test Lung

The troubleshooting tables are organized as follows:

- Symptoms
- Possible Causes
- Suggested Action

The troubleshooting tables are organized by symptoms, then by possible causes and suggested methods for diagnosing and resolving the problem. If you do not find the symptom you are looking for under one section, you may find it listed under another section, or you may be able to diagnose the problem by reading sections with related symptoms.

For information on resolving problems that are not listed here, contact CareFusion or a service technician certified by CareFusion.

[49] Extended Systems Test (EST)
[50] User Verification Tests (UVT)

Displays and Buttons

Some of the symptoms listed in this section are part of the normal operation of the ventilator and do not indicate any problem with the ventilator. They are included here for information.

Symptoms	Possible Causes	Suggested Action
Touch screen unresponsive	Controls are locked.	If the controls are locked, a **Locked** message will be displayed when a control is selected. To unlock in **Easy** mode, push the **Control Lock** button. To unlock in **Hard** mode, push and hold the **Control Lock** button for 3 seconds.
	Incorrect touch screen calibration.	Remove patient, enter Startup mode, UVT screen and perform Touch Screen Calibration.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Touch screen display illegible (e.g. a series of horizontal lines) on start up.	Ventilator was shut down without resetting the Inop alarm by pressing the **Alarm Silence** button.	Shut the ventilator off (press and hold the **On/Off** button), reset the Inop alarm (press the **Alarm Silence** button) and restart the ventilator (press the **On/Off** button).
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Waveforms or Loops freeze, do not refresh.	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
High **P_{peak}** alarm limit display turns red and **High P_{peak}** flashes on the Status Bar.	High Airway Pressure alarm occurred.	Review alarm limits settings and check for common causes (i.e. patient cough or patient circuit occlusions).
Low **P_{peak}** alarm limit display turns red and **Low P_{peak}** flashes on the Status Bar.	Low Peak Pressure alarm occurred.	Review alarm limits settings and check for common causes (i.e. patient circuit leaks).
Low **V_e** alarm limit display is red and **Low V_e** flashing on the Status Bar.	Low Exhaled Minute Volume alarm occurred.	Review alarm limits settings and check for common causes (i.e. patient circuit leaks).
FiO_2% monitored value turns red.	Low or High FiO_2 alarm occurred.	Review alarm settings, re-calibrate FIO_2 sensor and check oxygen source.
Control display flashing when setting a control. Value will not change.	Control setting is limited.	A control's value may be limited by the current settings of other controls. Modify the setting of related controls if necessary. The limiting controls flash when the limit is reached. To change the value of the current control, change the value of the flashing controls.

Symptoms	Possible Causes	Suggested Action
Display or LED does not illuminate.	Internal problem with the ventilator.	Push the Display/Alarm **Check** button on the Lower Interface Panel to perform a Display Test. If the display or LED does not illuminate, contact CareFusion or a service technician certified by CareFusion.
Ventilator is running but LCD display is dim.	The set **Dim After** period has expired.	Regardless of the power source, if the display dimming time period expires, the brightness of the LCD is reduced. Touching the LCD, pushing any button or adjusting the **Scroll** knob restarts the display dimming time period and returns the display to normal brightness. The display automatically returns to normal brightness while any high or medium priority alarm is active.
	Internal problem with the ventilator.	Push the Display/Alarm **Check** button on the Lower Interface Panel to perform a Display Test. If the LCD display does not illuminate, contact CareFusion or a service technician certified by CareFusion.
A control or the **Scroll** knob doesn't operate.	Control not active in selected mode.	If an entire control display is gray, it is not active in the currently selected mode and changing its setting does not affect current ventilation.
	Controls are locked.	If the controls are locked, a **Locked** message will be displayed when a control is selected. To unlock in Easy mode, push the **Control Lock** button. To unlock in Hard mode, push and hold the **Control Lock** button for 3 seconds.
	Control is not selected.	Before a control value can be changed, the control must be selected. To select a control (Lower Interface Panel), push the associated button. To select a control (LCD), touch the associated touch screen area.
	Control is limited.	A control's value may be limited by the current settings of other controls. To change the value of the current control you must first modify the value of associated flashing controls.
	Internal problem with the ventilator.	Remove patient, enter Startup mode, UVT screen and perform a Button Test. If the control does not operate, contact CareFusion or a service technician certified by CareFusion.
Can’t unlock the controls.	Hard unlock method selected.	Two unlock methods are available on the ventilator. To unlock in Easy mode, push the **Control Lock** button. To unlock in Hard mode, push and hold the **Control Lock** button for 3 seconds.

Ventilator Performance

Symptoms	Possible Causes	Suggested Action
Ventilator is auto cycling, monitored volumes are very small, negative flows exhibited during exhalation and positive flows during inspiration.	Sense Lines are reversed.	The Sense Lines are not designed to be removed from either the Wye or the Luer fittings. If the Sense Lines have been removed and replaced incorrectly, they may not seal correctly when replaced. Replace the complete patient Wye / Sense Lines assembly with a known functional assembly.
	There is water in the Sense Lines.	Clean or replace the Patient Wye Sense Lines assembly.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Inspiratory pressure rises initially, falls suddenly and then rises back to set pressure.	Rise time too fast; causing ventilator to enter active exhalation.	Reduce rise time (increase **Insp. Rise** setting).
Set **Insp. Pres**. not reached.	**Insp. Rise** setting is too slow for the set **Insp. Time.**	Adjust **Insp. Rise** setting.
	Patient circuit leak.	Perform a Circuit Test.
	Exhalation diaphragm not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
Monitored $\mathbf{V_{te}}$ is high.	Very small ET tube connected directly to Wye.	A very small ET tube connected directly to the Wye may cause turbulence that causes the flow to be read incorrectly. To reduce this turbulence, add a short larger bore extension or elbow adapter between the ET tube and Wye. In this case, the monitored volume is high, but the delivered volume is accurate.
	Low Pressure Sense Line or elbow at patient Wye loose or leaking.	Check High and Low Pressure Sense Lines to be sure they are correctly attached and securely seated at both the ventilator and Wye ends. Check the Luer fitting connections for leaks. Check the elbow connectors at the Wye to be sure they have not loosened or been broken loose.
	High or Low Pressure Sense Lines are occluded. High or Low Pressure Sense Line ports in the Wye are occluded.	Verify lines are not occluded or pinched.

Symptoms	Possible Causes	Suggested Action
Continued, *Monitored* V_{te} *is high.*	Sense Lines are reversed.	The Sense Lines are not designed to be removed from either the Wye or the Luer fittings. If the Sense Lines have been removed and replaced incorrectly, they may not seal correctly when replaced. Replace the patient Wye and Sense Lines with a known functional assembly.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Monitored V_{te} is low.	High Pressure Sense Line or elbow at patient Wye loose or leaking.	Check High and Low Pressure Sense Lines to be sure they are correctly attached and securely seated at both the ventilator and Wye ends. Check the Luer fitting connections for leaks. Check the elbow connectors at the Wye to be sure they have not loosened or been broken loose.
	High or Low Pressure Sense Lines are occluded. High or Low Pressure Sense Line ports in the Wye are occluded.	Verify lines are not occluded or pinched.
	Sense Lines are reversed.	The Sense Lines are not designed to be removed from either the Wye or the Luer fittings. If the Sense Lines have been removed and replaced incorrectly, they may not seal correctly when replaced. Replace the patient Wye and Sense Lines with a known functional assembly.
	Leak Compensation is not on.	Verify that **Leak Comp** is set to **On** in the **Main** screen, **Controls** page.
	Exhalation Diaphragm not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Delivered P_{aw}, P_{peak} or P_{mean} is high. Monitored P_{aw}, P_{peak} or P_{mean} is high.	Exhalation Diaphragm not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	High or Low Pressure Sense Lines are occluded. High or Low Pressure Sense Line ports in the Wye are occluded.	Check High and Low Pressure Sense Lines to be sure they are correctly attached and free of obstructions or kinks.
	Patient Circuit Leak.	Perform a Circuit Test. Check the elbow connectors at the Wye to be sure they have not loosened or been broken loose. Verify lines are not occluded or pinched.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Symptoms	Possible Causes	Suggested Action
Delivered **PIFR** is high or low.	Leaks in the Patient Circuit.	Perform a Circuit Test. Replace leaking circuit or components if necessary.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Flow Trigger does not appear to be accurate and/or ventilator is auto cycling.	Patient Circuit leak.	Perform a Circuit Test and reseat or replace the leaking parts or connections.
	Exhalation Diaphragm not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	There is a leak between patient circuit Wye and the patient.	Adjust the **Flow Trigger** control to compensate or identify and eliminate the source of the leak.
	Sense Lines are reversed.	The Sense Lines are not designed to be removed from either the Wye or the Luer fittings. If the Sense Lines have been removed and replaced incorrectly, they may not seal correctly when replaced. Replace the patient Wye and Sense Lines with a known functional assembly.
	High or Low Pressure Sense Line or elbow at patient Wye loose or leaking.	Check High and Low Pressure Sense Lines to be sure they are correctly attached and securely seated at both the ventilator and Wye ends. Check the Luer fitting connections for leaks. Check the elbow connectors at the Wye to be sure they have not loosened or been broken loose.
	High or Low Pressure Sense Lines are occluded. High or Low Pressure Sense Line ports in the Wye are occluded.	Verify lines are not occluded or pinched.
	Leak Compensation is not on.	Verify that the **Leak Comp** control is set to **On** in the **Main** screen**, Controls** page.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Symptoms	Possible Causes	Suggested Action
FiO_2% is high.	Low O_2 source incorrectly selected.	Verify that the ventilator **FiO_2** is set to **LPS** when using a low flow, low pressure source of O_2 and to a percentage when connected to high pressure O_2.
	O_2 inlet pressure too high when Low Pressure Source (**LPS**) selected. O_2 inlet flow too high when Low Pressure Source (**LPS**) selected.	Verify the low pressure O_2 inlet has been correctly calculated and set using the Input O_2 Flow Chart in Chapter 5. CareFusion recommends the use of an O_2 monitor to verify delivered O_2%. Adjust the entrained O_2 flow so the monitored value shows the desired FiO_2.
	FIO_2 Sensor reading inaccurate.	Recalibrate the FIO_2 Sensor. See *FIO2 Configuration and Calibration* in Chapter 3 for additional information. If calibration of the FIO_2 Sensor fails, replace the FIO_2 Sensor.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Delivered **P_{aw}**, **P_{mean}**, **P_{peak}** or PEEP is low. Monitored **P_{aw}**, **P_{mean}** or **P_{peak}** is low.	Circuit leak.	Perform a Circuit Test and reseat or replace the leaking parts or connections.
	High or Low Pressure Sense Line or elbow at patient Wye loose or leaking.	Check High and Low Pressure Sense Lines to be sure they are correctly attached and securely seated at both the ventilator and Wye ends. Check the Luer fitting connections for leaks. Check the elbow connectors at the Wye to be sure they have not loosened or been broken loose.
	High or Low Pressure Sense Lines are occluded. High or Low Pressure Sense Line ports in the Wye are occluded.	Verify lines are not occluded or pinched.
	Exhalation Diaphragm not properly seated.	Verify the Exhalation valve is not leaking during inspiration (perform a Circuit Test). If it is leaking, unscrew the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	Sense Lines are reversed.	The Sense Lines are not designed to be removed from either the Wye or the Luer fittings. If the Sense Lines have been removed and replaced incorrectly, they may not seal correctly when replaced. Replace the patient Wye and Sense Lines with a known functional assembly.
	Leak Compensation is not on.	Verify that the **Leak Comp** control is set to **On** in the **Main** screen**, Controls** page.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Symptoms	Possible Causes	Suggested Action
FiO_2% is low.	O_2 inlet flow too low when Low O_2 Source selected.	Verify the low pressure O_2 inlet has been correctly calculated and set using the Input FIO_2 Flow Chart in Chapter 5. CareFusion recommends the use of an O_2 monitor to verify delivered O_2%. Adjust the entrained O_2 flow so the monitored value shows the desired FIO_2.
	FIO_2 Sensor reading inaccurate.	Recalibrate the FIO_2 Sensor. See *FIO2 Configuration and Calibration* in Chapter 3 for additional information. If calibration of the FIO_2 Sensor fails, replace the FIO_2 Sensor.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
PEEP not working. PEEP low. PEEP sags during exhalation.	Circuit leak.	Perform a Circuit Test and reseat or replace the leaking parts or connections.
	Exhalation Diaphragm not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	High Pressure Sense Line or elbow at patient Wye loose or leaking.	Check High and Low Pressure Sense Lines to be sure they are correctly attached and securely seated at both the ventilator and Wye ends. Check the Luer fitting connections for leaks. Check the elbow connectors at the Wye to be sure they have not loosened or been broken loose.
	High or Low Pressure Sense Lines are occluded.	Verify lines are not occluded or pinched.
	Leak Compensation is not on.	Verify that the **Leak Comp** control is set to **On** in the **Main** screen**, Controls** Page.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
PEEP is too high.	Exhalation Diaphragm not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	High Pressure Sense Line or elbow at patient Wye loose or leaking.	Check High and Low Pressure Sense Lines to be sure they are correctly attached and securely seated at both the ventilator and Wye ends. Check the Luer fitting connections for leaks. Check the elbow connectors at the Wye to be sure they have not loosened or been broken loose.
	High or Low Pressure Sense Lines are occluded.	Verify lines are not occluded or pinched.

Symptoms	Possible Causes	Suggested Action
Ventilator won't trigger at **Flow Trigger** setting of 1 L/min.	Patient effort inadequate.	Some very small patients and patients with very weak inspiratory efforts may not be able to generate a 1 L/min effort. Review ventilator settings.
	Leak Compensation is not on.	Verify that the **Leak Comp** control is set to **On** in the **Main** screen**, Controls** Page.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Ventilator is on, gas is not delivered and blower is running.	Ventilator detected a disconnected patient circuit.	Perform a Circuit Test. Resolve leaks beyond the patient Wye.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Ventilator gets excessively hot.	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Power and Battery Operation

Symptoms	Possible Causes	Suggested Action
The ventilator does not power up.	Faulty power connection. Faulty AC Adapter or inadequate external DC power source. Removable Battery Pack not present or depleted and depleted Transition Battery.	Connect the ventilator to a verified source of AC power and verify the power cord for the AC Adapter is fully seated (**External Power** LED shows green). Install a fully charged Removable Battery Pack or allow the Removable Battery Pack and Transition Batteries to charge a minimum of 13 hours with the ventilator connected to AC power.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Vent Inop LED is on or flashing and ventilator is not ventilating.	Ventilator was running on Transition Battery and battery became depleted.	Connect the ventilator to a functional external power source or insert a charged Removable Battery Pack.
	Vent Inop due to causes other than normal power down.	If a **Vent Inop** alarm occurs during operation, immediately ventilate the patient using an alternative method, disconnect the ventilator and contact CareFusion or a service technician certified by CareFusion.
	Internal problem with the ventilator.	
The ventilator doesn't operate from external power.	Ventilator connected to Automobile Adapter and power from automobile outlet is faulty or inadequate.	Try turning the Automobile Adapter (plug in connector) to seat it properly and obtain a better connection. Make sure the green light on the adapter is lit, if not, refer to the Automobile Adapter Instructions for Use to change the adapter fuse. Refer to your automobile manual to ensure the automobile power outlet is rated at 20 Amps or more. Turn off other automobile accessories, such as air conditioning. Monitor the remaining ventilator battery capacity and connect to a valid external power source as soon as possible.
	Defective DC power cord.	Replace with a functional DC power cord.
	Ventilator not properly docked onto the Docking Station.	Press the **Eject** button on the front panel of the Docking Station to release the ventilator and re-dock following the instructions in the Docking Station Operator's manual.
	Defective AC source. AC Adapter power cord loose.	Make sure the Docking Station or AC Adapter power cord is fully seated, is securely plugged into a verified source of AC power and is securely connected to the ventilator.
	Defective AC Adapter.	Replace the AC Adapter.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Symptoms	Possible Causes	Suggested Action
The ventilator does not operate from Removable Battery Pack and/or shuts off when external power is removed.	Both the Removable Battery Pack and the Transition Battery are depleted.	Connect the ventilator to a valid source of external power and charge the batteries for at least 13 hours.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Removable Battery Pack doesn't reach full charge or depletes too quickly.	Removable Battery Pack needs to be conditioned or has reached the end of its useful life.	Use the condition cycle on the Desktop Battery Charger to condition the Removable Battery Pack. If the Removable Battery Pack fails to charge after a conditioning cycle, re-place with a functional, fully charged Removable Battery Pack.
Battery Charger LED is amber.	Transition Battery is fully charged and the Removable Battery Pack is charging.	The Transition Battery has been fully charged and Removable Battery Pack charging is < 80% complete. Refer to *Battery Charger* in Chapter 6 – Displays and Indicators for detailed information. Allow up to 8 hours to complete charging.
Battery Charger LED is flashing amber.	Transition Battery is charging.	The **Charge Status** LED will flash slowly amber while the Transition Battery charges. When the Transition Battery is charged the LED will stop flashing. Refer to *Battery Charger* in Chapter 6 – Displays and Indicators for detailed information. Allow up to 5 hours to complete charging.
Battery Charger LED is off.	Both the Transition Battery and the Removable Battery Pack are fully charged.	Not charging (either no external power is applied to the ventilator or charging of both batteries is completed). Refer to *Battery Charger* in Chapter 6 – Displays and Indicators for detailed information. This is nominal performance.

Alarms

Many alarms such as **High P_{peak}** or **Loss of O_2** can occur during normal operation. Single occurrences of some alarms, such as a **Hardware Fault** or **Vent Reset** may be caused by ESD[51]. If these alarms reoccur, and for any other alarms that do not usually occur during normal operation, discontinue use of the ventilator and follow the instructions in this section or contact CareFusion or a service technician certified by CareFusion.

WARNING

Check Alarms – Alarm function should be tested periodically to ensure proper operation (see *Maintenance Schedule* in Chapter 11 – Maintenance and Cleaning, and *Display/Alarm Test* in Chapter 2- Installation and Setup for detailed instructions). If any alarm malfunctions, contact CareFusion or a service technician certified by CareFusion. Failure to immediately identify and correct alarm situations may result in serious patient injury or death.

Symptoms	Possible Causes	Suggested Action
Safety Valve High Pressure Relief alarm occurs.	Sense Lines are occluded (pinched).	Free up the Sense Lines or if damaged, replace the patient circuit Wye and Sense Lines assembly.
	Sense Lines are occluded (contain fluid).	Clean or replace the patient circuit Wye and Sense Lines assembly. Refer to the Instructions For Use included with your patient circuit.
	Exhalation Port is blocked.	See *Chapter 11 - Maintenance and Cleaning* to clean the Exhalation Port and diaphragm. If the small exhalation valve opening is blocked or fluids appear to have entered the ventilator, discontinue use and contact CareFusion or a service technician certified by CareFusion.
	Luer connections on the High and Low Pressure Sense Lines are not properly attached.	Check the Luer connectors on the Sense Lines. If damaged, replace the patient circuit Wye and Sense Lines assembly.
	High resistance circuit or components have been added to the inspiratory limb of the patient circuit.	Remove or replace circuit or components.
		Increase the Safety Valve Delta Pressure setting in the **Utility** screen, **Alarm Config** page.

[51] ESD – Electro Static Discharge

Symptoms	Possible Causes	Suggested Action
A **High P_{peak}** alarm condition occurred but the alarm did not sound.	Alarm silence was already active (**Alarm Silence** LED is red).	The ventilator audible alarm can be silenced for 60 seconds by pushing the **Alarm Silence** button. If the alarm is already silenced (**Alarm Silence** LED is red), it will not sound again until the silence period expires. Push the **Alarm Silence** button again to turn off the silence period.
	High P_{peak} alarm delay is set to a delay of one or two breaths.	Set the **HP Delay** as required. When a high airway pressure condition is detected, if the **HP Delay** option is set to **0** the audible alarm is sounded immediately. When the **HP Delay** option is set to **1** or **2** breaths**,** the audible alarm is not sounded until the second or third consecutive breath of a high pressure condition.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Repeated **High P_{peak}** alarms.	Patient circuit expiratory limb is occluded or pinched.	Resolve pinched/occluded expiratory limb.
	High Pressure Sense Line occluded or pinched.	Check High Pressure Sense Line to be sure it is correctly attached and securely seated at both the ventilator and Wye ends. Verify the line is not occluded or pinched.
	Exhalation Diaphragm not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	Internal problem with the ventilator.	If problem reoccurs, contact CareFusion or a service technician certified by CareFusion.
Ventilator won't exhale, repeated **High P_{peak}** alarms, blower stops and pressure drops, then cycles up to high airway pressure again.	Sense Lines occluded or pinched.	Check High and Low Pressure Sense Lines to be sure they are correctly attached and securely seated at both the ventilator and Wye ends. Verify lines are not occluded or pinched.
	Exhalation Diaphragm not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Symptoms	Possible Causes	Suggested Action
Repeated **Patient Circuit Fault** alarms.	High or Low Pressure Sense Lines disconnected from vent or Wye. High or Low Pressure Sense Line or elbow at patient Wye loose or leaking.	Check High and Low Pressure Sense Lines and connectors to be sure they are undamaged, correctly attached and securely seated at both ends (Luer fittings at ventilator end and elbow connectors on patient circuit Wye). Perform a Circuit Test.
	High or Low Pressure Sense Lines are occluded. High or Low Pressure Sense Line ports in the Wye are occluded.	Verify lines are not occluded or pinched.
	Circuit disconnected from patient, Wye or vent.	Check the circuit to verify it is securely connected.
	Exhalation limb is pinched or occluded.	Resolve pinched/occluded exhalation limb.
	Excessive leak beyond patient Wye.	Resolve leaks beyond the patient Wye.
	Exhalation Diaphragm is dirty or not properly seated.	Remove the Exhalation Port and clean and reseat the diaphragm. If damaged or worn, replace the Exhalation Diaphragm with a new one.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Hardware Fault alarm.	Electro static discharge (ESD).	Clear the alarm. Reduce static causing conditions in the operating environment.
	Internal problem with the ventilator.	If problem reoccurs, contact CareFusion or a service technician certified by CareFusion.
Ventilator Reset alarm occurs.	Electro static discharge (ESD).	Clear the alarm. Reduce static causing conditions in the operating environment.
	Internal problem with the ventilator.	If problem reoccurs, contact CareFusion or a service technician certified by CareFusion.
Ventilator Reset alarm occurs after ventilator is operated on Transition Battery until it is fully depleted.	Ventilator shut off because Transition Battery is fully depleted.	Clear the alarm and charge the Transition Battery by inserting a Removable Battery Pack or connecting external power.
Config Reset alarm. Event Log shows **Config Reset**.	Electro static discharge (ESD).	Clear the alarm. Reduce static causing conditions in the operating environment.
	Internal problem with the ventilator.	If problem reoccurs, contact CareFusion or a service technician certified by CareFusion.

Symptoms	Possible Causes	Suggested Action
Repeated **High PEEP** alarms.	Monitored PEEP exceeds the set High PEEP alarm value.	Check **High PEEP** alarm limit value.
	Internal problem with the ventilator.	If problem reoccurs, contact CareFusion or a service technician certified by CareFusion.
Removable Battery Fault alarm.	Ventilator detects that the Removable Battery Pack cannot operate the ventilator.	Replace with a fully charged Removable Battery Pack.
Removable Battery Temperature Fault alarm.	Ventilating in pressure mode with excessive leak in the patient circuit.	Resolve leaks in the patient circuit and allow battery to cool.
	Ventilator is operating outside of the recommended operating temperature range for extended periods of time.	Operate the ventilator according to the specified operating temperature (see *Environmental Specifications* in Appendix B – Specifications).
	Internal problem with the Removable Battery Pack.	Replace with a fully charged Removable Battery Pack.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Transition Battery Fault alarm during normal ventilation.	Depleted Transition Battery.	Ensure Transition Battery is fully charged. Apply external power until the Transition Battery charging is complete if necessary.
	Internal problem with the ventilator.	If problem reoccurs, contact CareFusion or a service technician certified by CareFusion.
Transition Battery Fault alarm when ventilator is powered on.	The Transition Battery charge is below the minimum usable voltage due to depletion during storage.	Apply external power until the Transition Battery charging is complete and follow charging procedures recommended in the Routine Maintenance Schedule while in storage.
	Aging Transition Battery is failing to retain charge.	If problem reoccurs, contact CareFusion or a service technician certified by CareFusion.
	Internal problem with the ventilator.	Ventilator requires serving. Contact CareFusion or a service technician certified by CareFusion.
Transition Battery Temperature Fault alarm.	Ventilating in pressure mode with excessive leak in the patient circuit.	Resolve leaks in the patient circuit and allow battery to cool.
	Ventilator is operating outside of the recommended operating temperature range for extended periods of time.	Operate the ventilator according to the specified operating temperature (see *Environmental Specifications* in Appendix B – Specifications).
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Symptoms	Possible Causes	Suggested Action
Button Stuck alarm.	Ventilator detects any button, except power control, is on for more than 60 seconds.	Perform a Button Test, if problem persists, contact CareFusion or a service technician certified by CareFusion.
Vent Inop alarm is generated while ventilator is in storage.	The Transition Battery charge is depleted due to charging less frequently than recommended in the Routine Maintenance Schedule.	Apply external power until the Transition Battery charging is complete and follow charging procedures recommended in the Routine Maintenance Schedule while in storage.
	Aging Transition Battery is failing to retain charge.	Ventilator requires serving. Contact CareFusion or a service technician certified by CareFusion.
Blower Demand Exceeded alarm.	Ventilating in pressure mode with excessive leak in the patient circuit.	Resolve any leaks in the patient circuit.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Test Failures

Symptoms	Possible Causes	Suggested Action
Button Test:		
Correct message is not displayed or incorrect message is displayed.	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Touch Screen Calibration:		
LCD touch screen to displayed underlying controls/buttons is misaligned.	Alignment may drift with time, usage or physical shock.	Perform the Touch Screen Calibration procedure. See *Touch Screen Calibration* in Chapter 2 – Installation and Setup for instructions.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Circuit Test:		
Failed: Check flow sensor displays.	Luer fittings not seated.	Reseat the Luer fittings.
	Patient circuit Sense Lines occluded.	Clean/replace patient circuit.
	Internal problem with the ventilator.	Contact CareFusion or a technician certified by CareFusion.
Failed: Check for leaks displays.	Circuit connections or accessories are leaking. Wye is not completely occluded.	Reconnect or replace leaking circuit parts. Perform a Circuit Test and verify the Wye is completely occluded.
Failed: Check safety valve displays.	Internal problem with the ventilator.	Contact CareFusion or a technician certified by CareFusion.

Display/Alarm Test:

Audible alarm level excessive.	Alarm volume set too high.	Set the alarm volume in the **Utility** screen, **Alarm Config** page.
Audible alarm too soft.	Alarm volume set too low.	Set the alarm volume in the **Utility** screen **Alarm Config** page.
	Alarm Sounder ports blocked.	Check the Alarm Sounder ports and remove blockage.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Alarm does not sound.	Alarm Sounder ports blocked.	Check the Alarm Sounder ports and remove blockage.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
The LCD Test Pattern does not display.	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
An LED fails to light on the Lower Interface Panel.	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.

Vent Inop Alarm Test:

Alarm does not sound.	Alarm Sounder ports blocked.	Check the Alarm Sounder ports and remove blockage.
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
The **Vent Inop** LED is not illuminated.	Internal problem with the ventilator.	Contact CareFusion or a technician certified by CareFusion.

Test Lung Operations

Symptoms	Possible Causes	Suggested Action
Delivered **Insp. Pres.** higher than set pressure on Test Lung.	Pressure > 40 cmH_2O used on small Test Lung (CareFusion or Siemens 190).	The compliance characteristics of some small Test Lungs (CareFusion or Siemens 190) cause incorrect readings when high pressures are used. For these lungs, use pressures under 40 cmH_2O or change to a larger lung.
	Rise Time too fast.	Reduce rise time (increase **Insp. Rise** setting).
	Internal problem with the ventilator.	Contact CareFusion or a service technician certified by CareFusion.
Monitored $\mathbf{V_{te}}$ very high on Test Lung.	Test Lung with small aperture connected directly to Wye.	Some Test Lungs have a narrow opening or a restrictor, which may cause jetting and cause the flow to be read incorrectly. To reduce the jetting effect, add a short extension between the Test Lung and the Wye.
	Very small ET tube connected directly to Wye.	A very small ET tube connected directly to the Wye may cause jetting and cause the flow to be read incorrectly. To reduce the jetting effect, add a short larger bore extension or elbow adapter between the ET tube and the Wye.
Blower sounds erratic during inspiration in Pressure Control.	Circuit leak.	Perform a Circuit Test and reseat or replace the leaking parts or connections.

Appendix A - CONTACT INFORMATION

To contact CareFusion, request technical/clinical support, schedule Service, or order parts or supplies for your PTV® Series Ventilator, refer to the contact information as follows.

Manufacturer

CareFusion
22745 Savi Ranch Parkway
Yorba Linda, CA 92887-4645, USA

Product Technical/Clinical Support and Parts Ordering

Technical/Clinical Support and Parts Ordering:

Toll-Free:	800.554.8933 (U.S. and Canada)
Office:	714.685.8021 (Worldwide)
Fax:	714.283.8471
Email:	support.vent.us@carefusion.com

Product or Accessories Ordering:

Toll-Free:	800.231.2466 (U.S. and Canada)
Office:	714.283.2228 (Worldwide)
Fax:	714.283.8473
Hours:	7:00 AM to 4:00 PM (PST) Monday – Friday

Appendix B - SPECIFICATIONS

NOTE

Flow / Volume Measurement – Delivered flow and volume are designed to be accurate at the ventilator's Inspiratory Port. The exact flows/volumes delivered to the patient are dependent upon the compliance of the patient circuit.

All references to compressible flow and compressible volume in the patient pneumatic pathway are BTPS (Body Temperature Pressure Saturated) unless stated otherwise. A BTPS measurement is achieved when the compressible fluid is at 98.6°F (37°C), ambient barometric pressure, and saturated with water vapor. For the Enve™ ventilator, it is assumed that the ambient relative humidity is 30%.

Breath Modes and Breath Types

Breath Modes	Assist/Control (A/C), Synchronized Intermittent Mandatory Ventilation (SIMV), Continuous Positive Airway Pressure (CPAP/PSV), Apnea Backup Ventilation, Non-Invasive Positive Pressure Ventilation (NPPV)
Breath Types	Pressure Control, Pressure Regulated Volume Control (PRVC), Pressure Support (PSV), Spontaneous, Volume Control, Volume Targeted Pressure Support (V_tPSV)

Controls

Lower Interface Panel Buttons

Control	Function
Alarm Silence	Toggles a 60 second silence period on and off for audible portion of alarms. Removes the **Vent Inop** alarm.
Battery/Power Check	Displays the remaining capacity of the Removable Battery Pack as a percentage of its capacity when new, the type and status of the external DC power, the Docking power and the status of the Transition Battery
Control Lock	Locks and unlocks the ventilation controls.
Display/Alarm Check	All LED indicators light up, a test pattern appears on the LCD touch screen, the high priority audible alarm sounds for 2 seconds.
Maneuvers	Activates the I-Hold and E-Hold maneuvers.
Manual Breath	After the minimum exhalation time has elapsed, pushing this button delivers one breath per the current Breath Type settings.
On/Off	Powers the ventilator on or off.

Adjustable Controls

Controls	Range		Accuracy
Bias Flow	3 - 10 L/min		±1 L/min
FiO_2	LPS, 21 - 100%		±3 (21-50)[52] ±5 (51-100)[52]
Flow Cycle	Off, 10% - 40%		±15% or ±2 lpm
Flow Trigger	P, 1 - 9 L/min		+1, -0.5 (<2) ±1 (≥2)
Pressure Trigger	1 - 20 cmH_2O		Greater of ±10% or ±2 cmH_2O
High Pressure Alarm Delay	0, 1, 2 breaths		N/A
Insp. Pause	"**- -**" (off), 0.1 - 3.0 seconds		± 0.03 seconds
Insp. Rise	**Insp. Rise** Setting	Commanded Rise Time (sec)	Pressure commanded to 90% of Target Pressure by specified rise time ±200ms
	1	0.100	
	2	0.133	
	3	0.178	
	4	0.237	
	5	0.316	
	6	0.422	
	7	0.562	
	8	0.750	
	9	1.000	
Insp. Time	0.3 - 9.9 Seconds		±0.05 seconds
Leak Comp	On, Off		N/A
LPP Alarm Control	"All Breaths", "Control Only"		N/A
Mode	Volume A/C, Pressure A/C, PRVC A/C, Volume SIMV, Pressure SIMV, PRVC SIMV, CPAP/PSV (Volume), CPAP/PSV (Pressure), CPAP/V_tPSV, NPPV Pressure, NPPV CPAP/PSV		N/A
PEEP	0 - 30 cmH_2O		Greater of ±1 or ±10%
Insp.Pres.	1 - 99 cmH_2O		Greater of ±8% or ±2 cmH_2O
PSV	"**- -**" (off), 1 - 60 cmH_2O		Greater of ±8% or ±2 cmH_2O
PSV Cycle	10% - 40% of peak flow		Greater of ±15% or ±2 L/min
PSV T_{max}	0.3 - 3.0 seconds		± 0.030 sec

[52] The accuracy given is valid for normal environmental temperatures of 18 to 30 °C and normal environmental pressure of 87 to 101 kPa. When operating outside of this temperature range, but within the specified full temperature range, add an additional ±0.1% for each degree C. When operating outside of this pressure range, but within the specified full environmental pressure range, add an additional ±0.1% for each kPa.

Controls	Range	Accuracy
Rate	1 - 80 breaths per minute	Greater of 1 breath per minute or ±10%
Safety Valve Delta Pressure	5 - 30 cmH_2O	N/A
SBT FiO_2	(See FiO_2)	(See FiO_2)
SBT f/V_t Display	"On", "Off"	N/A
SBT PEEP	0 - 30 cmH_2O	Greater of ±10% or ±1 cmH_2O
SBT PSV	"**- -**" (off), or 1 - 30 cmH_2O	Greater of ±8% or ±2 cmH_2O
SBT Time	15 min - 120 min	±1 min
Volume	50 - 2000 ml	Greater of ±10% or ±10 ml

Maneuvers

Maneuver	Function
E-Hold	Maintains the expiratory phase of a breath for 6 ± 0.1 seconds (Adult/Ped) or until the button is released. Calculates AutoPEEP.
I-Hold	Maintains the inspiration phase of a volume breath for 6 ± 0.1 seconds (Adult/Ped) or until the button is released. Calculates C_{static}.

Procedures

Procedure	Function
Increase O_2	Delivers a pre-selected increase in O_2 percentage for a pre-selected duration.
Nebulization	Provides a flow of 6 L/min ±10% O_2 to drive a nebulizer (optional). Configurable as continuous or inspiration only.
Spontaneous Breathing Trial (SBT)	During the SBT procedure, ventilation is delivered in CPAP/PSV mode with the control settings selected on the **SBT** page. Calculates f/V_t.

Alarms

Adjustable Alarms

Control	Range	Priority
Apnea (Interval)	10 - 60 seconds	High priority audible and visual alarm[53]
High PEEP	3 - 50 cmH_20, or "**- -**" (off)	Medium priority audible and visual alarm[53]
High P_{peak}	5 - 100 cmH_2O	High priority audible and visual alarm[53]
High Pulse Rate	18 - 299 PR/min, or "**- -**" (off)	High priority audible and visual alarm[53]
High Breath Rate	1 - 120 bpm, or "**- -**" (off)	Medium priority audible and visual alarm[53]
High FiO_2 (LPS only)[54]	21 - 100 %, or "- - -" (off)	High priority audible and visual alarm[53]
High SpO_2	80 - 99 %, or "**- -**" (off)	High priority audible and visual alarm[53]
High V_e	0.1 - 99 liters, or "**- -**" (off)	Medium priority audible and visual alarm[53]
High V_{te}	50 - 2000 ml, or "**- -**" (off)	Medium priority audible and visual alarm[53]
Low FiO_2 (LPS only)[54]	18 - 95 %, or "- - -" (off)	High priority audible and visual alarm[53]
Low PEEP	"**- -**" (off), or 1 - 30 cmH_2O	High priority audible and visual alarm[53]
Low P_{peak}	"**- -**" (off), or 1 - 60 cmH_2O	High priority audible and visual alarm[53]
Low Pulse Rate	"**- -**" (off), or 19 - 300 PR/min	High priority audible and visual alarm[53]
Low Breath Rate	"**- -**" (off), or 1 - 99 bpm	Medium priority audible and visual alarm[53]
Low SpO_2	"**- -**" (off), or 60 - 99 %	High priority audible and visual alarm[53]
Low V_e	"**- -**" (off), or 0.1 - 99 liters	High priority audible and visual alarm[53]
Low V_{te}	"**- -**" (off), or 10 - 2000 ml	Medium priority audible and visual alarm[53]
SBT High f/V_t	70 - 900 bpm/L, or "**- -**" (off)	Medium priority audible and visual alarm[53]
SBT High Breath Rate	15 - 80 bpm, or "**- -**" (off)	Medium priority audible and visual alarm[53]
SBT High Peep	3 - 50 cmH_2O , or "- -" (off)	Medium priority audible and visual alarm[53]
SBT Low f/V_t	""**- -**" (off), or 5 - 90 bpm/L	Medium priority audible and visual alarm[53]
SBT Low Breath Rate	"**- -**" (off), or 1 - 40 bpm	Medium priority audible and visual alarm[53]
SBT Low PEEP	"- -" (off), or 1 - 30 cmH_2O	High priority audible and visual alarm[53]

Fixed Alarms

Alarm	Priority
Battery Empty	High priority audible and visual alarm[55]
Battery Fault	Medium priority audible and visual alarm[55]

[53] Alarm Availability - **Normal** – Patient related alarm can only be activated in normal ventilation modes.

[54] The High FiO_2 and Low FiO_2 alarms are only adjustable when the ventilator FiO_2 control is set to **LPS**.

[55] Alarm Availability - **All** – Non-patient related alarm can be activated in all ventilator operating modes; Startup, Vent Setup and normal ventilation modes.

Alarm	Priority
Battery Low	Medium priority audible and visual alarm[55]
Battery Temperature Fault	High priority audible and visual alarm[55]
Battery Use	N/A / Periodic audible tone[55]
Blower Demand Exceeded	High priority audible and visual alarm[55]
Button Stuck	Medium priority audible and visual alarm[55]
Check SpO_2 Sensor Placement	High priority audible and visual alarm[55]
Configuration Reset	High priority audible and visual alarm[55]
Dock Disconnect	Medium priority audible and visual alarm[55]
Dock Fault	Medium priority audible and visual alarm[55]
External Power Low	Medium priority audible and visual alarm[55]
External Power Fault	Medium priority audible and visual alarm[55]
External Power Lost	Medium priority audible and visual alarm[55]
FiO_2 Sensor Fault	Medium priority audible and visual alarm[53]
Hardware Fault xxx	High priority audible and visual alarm[55]
High FiO_2	High priority audible and visual alarm[53]
High O_2 Inlet Pressure	Medium priority audible and visual alarm[53]
Insert Battery	Medium priority audible and visual alarm[55]
Loss of O_2	High priority audible and visual alarm[53]
Low FiO_2	High priority audible and visual alarm[53]
Patient Circuit Fault	High priority audible and visual alarm[53]
Preventive Maintenance Required xxx	Low priority audible and visual alarm[55]
Remove Patient	High priority audible and visual alarm[55]
Safety Valve High Pressure Relief	High priority audible and visual alarm[53]
SBT Off	Low priority audible and visual alarm[53]
SBT Time	Low priority audible and visual alarm[53]
Service Soon xxx	Low priority audible and visual alarm[55]
SpO_2 Low Signal	High priority audible and visual alarm[53]
SpO_2 Module Fault	High priority audible and visual alarm[53]
SpO_2 Off Patient	High priority audible and visual alarm[53]
SpO_2 Sensor Disconnect	High priority audible and visual alarm[53]
Transition Battery Fault	Medium priority audible and visual alarm[55]
Transition Battery Temperature Fault	High priority audible and visual alarm[55]
Transition Battery Use	High priority audible and visual alarm. Resets only once for 60 seconds.[55]
Vent Inop	High priority audible and visual Inop alarm. Pushing the **Alarm Silence** button silences audible indicator.[55]
Ventilator Reset	Medium priority audible and visual alarm[55]
Volume Limited	Medium priority audible and visual alarm[53]

Patient Protection Mechanisms

The ventilator has a safety valve which opens under the following conditions.

Control	Range
Over Pressure Relief	Blower Estimated Airway Pressure ≥ 110 cmH_2O, or Blower Estimated Airway Pressure ≥ High P_{peak} alarm setting + Safety Valve Delta Pressure setting **Resistance with valve open:** ≤ 5 cmH_2O at 10 L/min, measured at the ventilator's inspiratory limb
Sub-Ambient (anti-asphyxia) Relief	Airway Pressure Monitor ≤ -5 cmH_2O, or Airway pressure based on Blower Differential Pressure transducer ≤ -5 (+0/-5) cmH_2O

Internal Compliance

Compliance < 0.1 mL/cm

Monitors

Patient Monitors

Monitor	Range	Accuracy
Airway Pressure Manometer (P_{aw})	-10 - 150 cmH_2O measured at the patient Wye	Greater of ±5% or ±2
Exhaled Minute Volume (V_e)	0 - 99.9 L	Greater of ±15% or ±0.015*f
Exhaled Tidal Volume (V_{te})	0 - 4000 ml	Greater of ±15% or ±15
f/V_t	0 - 999 bpm/L	See Total Breath Rate and Exhaled Minute Volume
Fraction of Inspired Oxygen (FiO_2)	12% - 103%	± 3
I:E Ratio, Calculated ($I:E_{calc}$)	1:99 - 4.0:1	±1 significant digit
I:E Ratio, Measured (I:E)	1:99 - 54:1	Greater of ±50 ms or ±5%
Mean Airway Pressure (P_{mean})	0 - 99 cmH_2O	Greater of ±5% or ±2
Peak Inspiratory Flow Rate (PIFR)	3 - 190 L/min measured at the patient Wye	± 1.5 if $\lvert\dot{V}$ wye $\rvert$ < 10 ±15% or ± 3 if $\lvert\dot{V}$ wye $\rvert \geq 10$ (Adult/Ped)
Peak Inspiratory Flow, Calculated ($V_{i\ calc}$)	10 - 120 L/min	N/A
Peak Inspiratory Pressure (P_{peak})	0 - 120 cmH_2O or hPa	Greater of ±5% or ±2
Positive End-Expiratory Pressure (PEEP)	0 - 99 cmH_2O or hPa	Greater of ±10% or ±2
Pulse Oximetry Signal Strength	Green / Yellow / Red	N/A
Pulse Rate (Pulse)	18 - 300 PR/min	Refer to the Instructions for Use, p/n 13567-001, provided with the SpO_2 module for detailed information.
SBT Time Remaining (SBT Time)	00:00 (mm:ss) - 02:00:00 (hh:mm:ss)	± 1 minute
SpO_2	0 - 100 %	Refer to the Instructions for Use, p/n 13567-001, provided with the SpO_2 module for detailed information.
Spontaneous Breath Rate (Spon. Rate)	0 - 120 bpm	Greater of ±5% or ±1 bpm
Spontaneous Exhaled Tidal Volume (Spon. V_{te})	0 - 4000 ml	Greater of ±15% or ±15
Total Breath Rate (Rate)	0 - 120 bpm	Greater of ±5% or ±1 bpm

Device Monitors

Monitor	Range	Accuracy
Measured Leak ($\dot{V}_{leak}$)	0.0 - 30.0 L/min	± 1.5 if Flow < 10 ±15% or ± 3 if Flow ≥ 10
O_2 Source Pressure (O_2 Inlet)	2.0 - 99.9 PSI	± 2 PSI
Peak Expiratory Flow Rate, Measured (PEFR)	0 - 190 L/min	± 1.5 if Flow < 10 ±15% or ± 3 if Flow ≥ 10
Removable Battery Capacity Remaining	0% - 120%	±20%
Usage Meter, Resettable (Trip Hrs)	0.0 - 500000.0 hours	±5%
Usage Meter, Non-Resettable (Total Hrs)	0.0 - 500000.0 hours	±5%

Maneuvers Monitors

Monitor	Range	Accuracy
AutoPEEP	0 - 99 cmH_2O	See Airway Pressure monitor
Delta Pressure (dP_{aw})	1 - 99 cmH_2O	See Airway Pressure monitor
Expiratory Pressure (P_{exp})	0 - 100 cmH_2O	See Airway Pressure monitor
Plateau Pressure (P_{plat})	1 - 99 cmH_2O	See Airway Pressure monitor
Static Lung Compliance (C_{static})	<1 - 999 ml/cmH_2O	+/- 18%

Physical Dimensions

Size	Approx. 11.3” (28.7 cm) x 7.1” (18.0 cm) x 3.3” (8.4 cm)
Weight	Approx. 9.9 lb. (4.5 kg)

Alarm System

Audible Volume	The sound system is capable of generating sound volumes in the range of 45 to 85 dBA, dependent on the sound type and the set **Alarm Volume**
Conformity	All audible signals conform to ISO 9703-2

Environmental Specifications

Storage[56]

Temperature	-20 to +60 °C
Humidity	5% to 95% Relative, non-condensing

Following storage at extreme temperature conditions ranging from -30°C to + 70°C, the Enve™ ventilator will function as intended for at least 20 minutes when it is returned to room temperature (20 +/- 2°C) for 10 minutes.

Operating

Temperature	0 °C to 40 °C
Humidity	5% to 95% Relative, non-condensing

Altitude

Storage	50,000 ft Maximum (11.6 kPa)
Operating	-2,300 - 10,600 ft (68 - 110 kPa)

Shock and Vibration

The ventilator is designed to withstand shock and vibration in accordance with relevant requirements set forth in the following standards:

- IEC 68-2-6 Vibration; 10-1000 Hz, 0.35mm/49 ms^{-2}, 1 octave/min, 4 sweep cycles in each axis
- IEC 68-2-27 Shock; 30g, 6 ms, half sine
- IEC 68-2-29 Bump; 15g, 6 ms, 4000 bumps, vertical (normal operating position)
- IEC 68-2-32 Free Fall; 0.75m, one fall on each of the six surfaces, when installed in Carrying Case
- IEC 68-2-36 Vibration; Test Fdb, 0.01 g^2/Hz (10-200 Hz), 0.003 g^2/Hz (200-500 Hz), 1.7 g_{rms}, 30 min
- MIL-STD-810G Shock; method 516.6, Section 4.6.2, Procedure I, Functional Shock, Figure 516.6-10, terminal peak sawtooth, 20g, 11 ms, 3 pulses positive and negative in each axis
- MIL-STD-810G Vibration; method 514.6, Procedure I, Category 24, General, Mininum Integrity Exposure, Test Levels per figure 514.6E-1, 7.7 g(r.m.s), 3 axis, 1 hour/axis
- MIL-STD-810G Vibration; Helicopter Minimum Integrity, method 514.6. Procedure I, Category 24, Figure 514.6E-2, 3 axes, 30 min.axis
- RTCA/DO-160F category U2, Vibration – Helicopter, Unknown Frequencies. Performance, Figure 8-7 Curve F, Acceleration = 3.37 grms, 3 axes 10 min/axis

[56] PTV® Series Ventilators stored at temperatures outside of the specified Operating Temperature range must be allowed to stabilize to within the operating temperature range before turning the ventilator on.

Liquids

Spillage	IEC 60601-1 Clause 44.3
Ingress	IEC 60529 IP Code: IPx1 “vertical dripping”

Air Inlet Filtration

The ventilator air filter is removable and replaceable by the operator.

Interfaces

Interface	Specification
Air Intake Port	Accommodates user replaceable filter.
Dock Interface	Proprietary power / communications interface.
FIO_2 Sensor connection	Compatible with cabling to Teledyne R-17 MED O_2 sensor.
Flow Sensor Interface	Proprietary. Consists of two pneumatic Luer connections: Flow Sense High (female) and Low (male).
Nebulizer Port	0.230” OD, straight barb fitting.
O_2 Blender Inlet	O_2 DISS. A filter is incorporated. Meets requirements of CGA V-5 Connection 1240. 2.8 bar (40 PSI or 276 kPa) to 6.1 bar (88 PSI or 607 kPa) inlet pressure. 0 – 180 L/min
Patient Circuit Exhalation Limb	22mm OD, 15mm ID, male conical connector per ISO 5356-1
Patient Circuit Inspiratory Limb	22mm OD, 15mm ID, male conical connector per ISO 5356-1
SpO_2 Module connection	Proprietary power / communications interface.

Equipment Classification

Classification	Internally Powered Equipment per IEC 60601-1
Type	Type BF per IEC 60601-1

Emissions/Immunity

See *EMC and RF Environments*, in Appendix C – Reference Information.

Power Specifications

Input Voltage 11 to 16 VDC

AC Adapter

This AC/DC converter allows PTV® Series Ventilators to be powered from an AC Power Source. It is shipped with complete specifications and instructions for use and care.

Removable Battery Pack

Feature/Spec	Details
Electrical	Nominal Voltage Output: ..... 10.8 VDC Nominal Capacity: ..... 5800 mAHr (at 1C rate), minimum Charge Rating: ..... 12.3 VDC, 2.0 A maximum
Charge Time	The ventilator can charge a discharged Removable Battery Pack when Docking Station power or external DC power is available. Once the Transition Battery is charged, the Removable Battery Pack can be >90% charged by a ventilator connected to external power within 8 hours, from fully discharged.
Battery Duration	A new fully-charged Removable Battery Pack provides at least 4 hours of operating time with controls at Standard Test Condition settings below. **NOTE** Battery operating times may vary significantly based on user settings. Specifically, Pressure Control breaths with fast rise times, high Breath Rates and high Peak Flows will typically decrease battery life. For optimal battery life, set display dimming as low as possible. **Standard Test Condition Settings:** Mode ..... A/C Breath Type ..... Volume PEEP (cmH_2O) ..... 5 Rate (bpm) ..... 15 FiO_2 ..... 21 Volume (ml) ..... 500 Lung Compliance (ml/cmH_2O) ..... 30 Insp. Time (sec) ..... 1.5 ET Resistance ($cmH_2O/L/S$) ..... 20 Flow Trigger (L/min) ..... P Pressure Trigger ..... 10 Ambient Temp (°C) ..... 25 Inspiratory Pause ..... -- Bias Flow (L/min) ..... 5 Leak Comp ..... Off Alarm Vol. ..... 6 Display Brightness (%) ..... 100 Display Dimming (min) 5
Safety Standards	UL Listing per UL 60950-1 (UL 2054); UN Transportation Testing

Transition Battery

Feature	Details
Electrical	Voltage: ..... 10.8 VDC Capacity:..... 1800 mAHr (at 1C rate)
Charge Time	The ventilator can charge a discharged Transition Battery when Docking Station power or external DC power is available, or partially charge the Transition Battery when operating on the Removable Battery Pack. The ventilator will fully recharge the Transition Battery from completely discharged within 5 hours when connected to a valid external power supply.
Transition Battery Duration	When fully charged, a new Transition Battery is designed to provide a minimum of 1 minute of operating time.

WARNING

Reduced Flow/Pressure – To avoid possible harm to patients requiring a flow rate higher than 120 L/min or pressure greater than 65 cmH_2O, minimize use/length of time of Transition Battery powered ventilation. To conserve power, the ventilator may run with reduced performance, while using the Transition Battery at higher flows and pressures.

NOTE

Transition Battery Use - The Transition Battery is intended for use during very short periods while switching between external power supply connections or when changing Removable Battery Packs. The length of time the ventilator will operate on the Transition Battery is a function of many factors such as settings, charge level and condition or age of the battery. The Transition Battery is only intended to power the ventilator for up to one minute.

Reliability

The PTV® Series Ventilator is designed to meet the following reliability requirements:

Product Life: 10 years

National and International Standards

The Enve™ ventilator is designed to comply with the following standards:

Number	Title
ASTM F1100-90	Ventilators Intended for User in Critical Care
ASTM F1463-93	Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care
CGA V-5	Specifications for DISS Connections
EN 865:1997	Pulse Oximeters – Particular Requirements
FDA Ventilator guidance	Draft Reviewer Guidance For Ventilators July 1995
FDA guidance	Reviewer Guidance For Pre Market Notification Submissions November 1993
IEC 529:1989	Degrees of Protection Provided by Enclosures
IEC 60601-1:2005	Medical Electrical Equipment, General Requirements for Safety
IEC 60601-1-2:2001(E)	Medical Electrical Equipment: General Requirements for Safety, Electromagnetic Compatibility Requirements and Tests.
IEC 60601-1-4:1996 +A1:1999	General Requirements for Safety for Programmable Electrical Medical Systems.
IEC 60601-2-12:2001(E)	Medical Electrical Equipment: Particular requirements for the safety of lung ventilators – Critical care ventilators
CEI/IEC 68-2-6:1985	Basic Environmental Testing Procedures – Vibration
CEI/IEC 68-2-27:1987	Basic Environmental Testing Procedures – Shock
CEI/IEC 68-2-29:1987	Basic Environmental Testing Procedures – Bump
CEI/IEC 68-2-32:1975	Basic Environmental Testing Procedures – Free Fall
CEI/IEC 68-2-34:1991	Basic Environmental Testing Procedures – Random Vibration Wide Band
ISO 5356-1:2004(E)	Anesthetic and respiratory equipment – Conical Connectors
ISO 7767:1997(E)	Oxygen Monitors for Monitoring Patient Breathing Mixtures – Safety Requirements
ISO 9703-1:1992(E)	Anesthesia and respiratory care alarm signals Part1: Visual alarm signals
ISO 9703-2:1994(E)	Anesthesia and respiratory care alarm signals Part2: Auditory alarm signals
ISO 9703-3:1998(E)	Anesthesia and respiratory care alarm signals Part 3: Guidance on application of alarms
MDD EEC/93/42	Medical Device Directives, European Council Directive Concerning Medical Devices 1993
MIL-STD-810G	Shock, Ground Transport and Helicopter Transport Vibration. Category 24, General integrity for Helicopters, per Figure 514.6 E-2
RTCA/DO-160F	Environmental conditions and test procedures for airborne equipment.[57] Category U2 – Random Test Curves for Helicopters Fuselage per Figure 8-7 Curve F

[57] Testing performed while the ventilator was operating on Removable Battery Pack power, and with SpO_2 and FIO_2 modules attached.

Shipping Requirements

The ventilator, packed in its shipping container, conforms to the International Safe Transit Association requirements for packaged products weighing less than 100 pounds.

User Interfaces

Lower Interface Panel

Display	Range
Alarm Silence	Off / Red LED
Battery Charger	Off / Flashing Amber / Amber / Green LED
Battery Pack	Off / Red / Flashing Red / Amber / Green LED
Control Lock	Off / Green LED
External Power	Off / Amber / Green / Flashing Red LED
Maneuvers	Off / Flashing green / Green LED
Manual Breath	Off / Green LED
On, Off	Off / Green LED
Transition Batt.	Off / Red / Flashing Red / Green LED
Vent Inop.	Off / Red / Flashing red LED

LCD/Touch Screen

Display

Colors	256 simultaneous colors from a palette of 4096.
Contrast Ratio	300:1 minimum, 400:1 typical @ 25 C
Display Type	Active Matrix Color LCD
Resolution	768 pixels (width) by 1024 pixels (height).
Response Time	20 ms maximum
Viewable Size	128.5 mm (width) by at least 171.3 mm (height)
Viewing Angle	±20 degrees minimum, horizontal ±45 degrees minimum, vertical

Backlight

Backlight Life	at least 15,000 hours until half brightness
Maximum Brightness	at least 200 cd/m^2
Minimum Brightness	at most 80 cd/m^2

Appendix C - REFERENCE INFORMATION

Factory Settings

Controls

The factory-set values for Enve™ ventilator adjustable controls are:

Control	Factory-Set Values
Alarm Volume	6 (80 dBA)
Apnea Interval	20 seconds
Battery Use Tone	3
Bias Flow	5 L/min
Control Lock	Off
Date Format	MM/DD/YYYY
Dim After	Never
Display Brightness	100%
Duration (Nebulizer)	15 min
F_iO_2	21%
F_iO_2 (option configuration)	Disable
Flow Cycle	"- -" (off)
Flow Trigger	2 L/min
HP Delay	0
Increase O_2 minutes	3 Minutes
Increase O_2 Percentage	+79%
Insp. Pause	"- -" (off)
Insp. Pres.	10 cmH_2O
Insp. Rise	4
Insp. Time	1.0 seconds
Language	English
Leak Comp	On
Local Date	GMT[58]
Local Time	GMT[58]
LPP Alarm	All Breaths
Mode (Intubated)	Pressure A/C[59]
Mode (Non-Invasive)	NPPV CPAP/PSV[60]
O_2 Cylinder Pressure	"- - -"
O_2 Cylinder Type	622 L
Patient ID	(blank)

[58] Greenwich Mean Time
[59] Default ventilation **Mode** setting when **Intubated** ventilator to patient interface previously set during Startup.
[60] Default ventilation **Mode** setting when **Non-Invasive** ventilator to patient interface previously set during Startup.

Control	Factory-Set Values
Patient Size	Pediatric 5-40 kg
PEEP	0 cmH_2O
PEEP Delay	0 (No Delay)
Pressure Trigger	3 cmH_2O
PSV	10 cmH_2O
PSV Rise	4
PSV Cycle	25%
PSV T_{max}	3 seconds
Pulse Tone (SpO_2 / Volume)	1
Rate	12 bpm
Safety Valve Delta Pressure	10 cmH_2O
SBT F_{iO_2}	21%
SBT PEEP	0 cmH_2O
SBT PSV	10 cmH_2O
SBT Time	20:00 (mm:ss)
SpO_2 Average	8-Beat
SpO_2 (option configuration)	Disable
Synchronization (Nebulizer)	Continuous
Units (of measure)	cmH_2O / PSI
V / BR Delay	0 (No Delay)
Volume	500 ml

Adjustable Alarm Limits

The factory-set values for Enve™ ventilator adjustable alarm limits are:

Alarm	Factory-set Values
High FiO_2 (LPS only)	50 %
High P_{peak}	20 cmH_2O
High Rate	"**- - -**" (off)
High V_e	"**- -**" (off)
High PEEP	5 cmH_2O
High Pulse Rate	"**- -**" (off)
High SpO_2	99%
High V_{te}	"**- -**" (off)
Low FiO_2 (LPS only)	18 %
Low Rate	"**- -** " (off)
Low V_e	2.5 L
Low P_{peak}	5 cmH_2O
Low PEEP	"- -" (off)
Low Pulse Rate	"**- -**" (off)
Low SpO_2	85%
Low V_{te}	10 ml
SBT High Breath Rate	35 bpm

SBT Low Breath Rate	10 bpm
SBT High f/V_t	105 bpm/L
SBT Low f/V_t	70 bpm/L
SBT High PEEP	5 cmH_2O
SBT Low PEEP	"- -" (off)

Replacement Parts

- Removable Battery Pack
- Air Inlet Filter
- Cooling Fan Filter
- Exhalation Diaphragm

Contact CareFusion for a complete list of replacement parts, part numbers and pricing information. See *Appendix A - Contact Information* for contact and ordering information.

Accessories

CareFusion offers a large variety of accessories for use with PTV® Series Ventilators. Accessories are packaged with individual Instructions For Use providing part numbers, intended use, specifications and cleaning information.

Contact CareFusion for a complete list of available accessories, part numbers and pricing information. See *Appendix A - Contact Information* for contact and ordering information.

WARNING

Patient Circuit Accessories, Risk of Patient Injury - To avoid the risk of patient injury, only use accessories expressly approved by CareFusion for use with PTV® Series Ventilators.

NOTE

The Enve™ ventilator is designed for compatibility with Humidifiers meeting ISO 8185 standards and Bacteria Filters meeting ISO 5356-1 standards.

Patient Circuits / Accessories

- Reusable – Patient Circuit with Water Trap
- Single Use – Patient Circuit with Water Trap(s)
- Single Use – Patient Circuit Heated Wire
- Reusable – Patient Wye w/Flow Sensors and Sense Lines
- Single Use – Patient Wye w/Flow Sensors and Sense Lines
- Humidifiers

Power Accessories

- AC Adapter
- Automobile Adapter
- Desktop Battery Charger
- Docking Station

Mounting and Transporting Accessories

- Carry Case
- Rolling Stand
- Wall Mount
- Table Top Mount

Sensor Accessories

- FIO_2 Sensor Cable
- SpO_2 Module
- SpO_2 Module with Sensor

Monitor Accessories

- PTM™ Graphics Monitor

Miscellaneous Accessories

- Stylus, LCD Touch Screen

EMC and RF Environments

The following tables are provided in compliance with 60601-1-2 © IEC:2001(E), and describe the tested EMC limitations of the Enve™ ventilator system.

Table 201

Guidance and manufacturer's declaration – electromagnetic emissions		
The Enve™ ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Enve™ ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Enve™ ventilator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 202

Guidance and manufacturer's declaration – electromagnetic immunity			
The Enve™ ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Enve™ ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.

NOTE U_T is the A.C. mains voltage prior to application of the test level.

Table 203 - 60601-1-2 © IEC:2001(E)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Enve™ ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz[61] outside ISM bands	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Enve™ ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[62]	10V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	$d = 0.60\sqrt{P}$ 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[62]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[63], should be less than the compliance level in each frequency range.[64] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[61] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[62] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[63] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ventilator.

[64] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 205 - 60601-1-2 © IEC:2001(E)

Recommended separation distances between portable and mobile RF communications equipment and the Enve™ ventilator.

The Enve™ ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Enve™ ventilator as recommended below, based on the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.60\sqrt{P}$	800 MHz to 2,5 GHz $d = 1.2\sqrt{P}$
0.01	0.12	0.12	0.060	0.12
0.1	0.37	0.37	0.19	0.36
1	1.2	1.2	0.60	1.2
10	37	37	19	36
100	12	12	6.0	12

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix D - GLOSSARY

TERM	DEFINITION
AC	Alternating Current (typically mains electrical power).
Airway Pressure	The airway pressure measured at the patient circuit, patient connection port.
Airway Pressure Manometer	A bar graph which displays the real-time breath by breath Airway Pressure (P_{aw}).
Alarm	An audible and visual announcement that an alarm condition has been met. Audible notification includes an oscillating or continuous tone. Visual notification may include red displays, illuminated LEDs, and messages flashing in the **Status Bar** window.
Apnea	Apnea happens when the time between breath starts exceeds the set Apnea Interval.
Apnea Backup Ventilation	Apnea Backup Ventilation begins when an Apnea alarm occurs and continues until the patient initiates 2 consecutive breaths or the alarm is canceled by an operator. Apnea Backup Ventilation is given in the Assist / Control mode.
Apnea Interval	The maximum period of time allowed between breath starts. If the time between breath starts exceeds this interval, an Apnea alarm occurs.
Assist Breath	A volume or pressure breath that the patient triggers, and which is then controlled and cycled by the ventilator. Assist breaths may occur in Assist / Control and SIMV modes.
Assist/Control Mode	A mode of ventilation where the patient receives a minimum number of machine and assist breaths. The available breath types are Volume Control and Pressure Control.
AutoPEEP	Residual pressure trapped in lungs due to incomplete exhalation.
Autozero	Procedure for determining the transducer zero offset for ambient pressure.
Barotrauma	The difference in pressure between internal organs and the outer surface of the body causes injuries to internal organs that contain gas, such as: lungs, gastrointestinal tract, and ears.
BdP	Blower differential pressure
Bias Flow	A constant stream of gas through the patient circuit during the exhalation phase of the breath.
bpm	Breaths per minute
Breath Period	The time between consecutive breaths.
Breath Rate, monitored (Rate)	The quantity of breaths given per minute; includes all breath types.
Breath Rate, set	The minimum quantity of machine breaths given in a minute.
BTPD	Body Temperature and Pressure, Dry.

TERM	DEFINITION
BTPS	Body Temperature Pressure Saturated[65]. A BTPS measurement is achieved when the compressible fluid is at 98.6°F (37°C), ambient barometric pressure, and saturated with water vapor.
Circuit	See Patient Circuit.
Circuit Pressure	See Airway Pressure.
cmH_2O	Centimeters of water. A unit of measure for pressure.
CPAP	Continuous Positive Airway Pressure. A ventilation mode where the patient triggers and cycles all breaths and the ventilator continuously maintains positive gas pressure through the patient circuit during the entire breath cycle.
C_{static}	Static Lung Compliance
DC	Direct Current. Typically electrical current delivered by means of a battery or via a converter which converts the mains supply to one usable by the device.
dP_{aw}	Delta Airway Pressure
E-Hold	Expiratory Hold
EST	Extended Systems Test (screen)
Event	Any condition noted in the ventilator's Event Trace Log. This may include both error conditions and normal operational events.
Exhaled Minute Volume, monitored (V_e)	The total volume exhaled by the patient for the last 60 seconds. V_e is based on the last 8 breaths.
Exhaled Tidal Volume, monitored (V_{te})	The exhaled volume quantified at the patient Wye. Exhaled Volume is measured for all breath types.
Expiratory Hold (E-Hold)	A maneuver which holds the expiratory phase of a delivered breath for a duration sufficient to determine the AutoPEEP of a patient.
f/V_t	Rapid Shallow Breathing Index – Derived during a SBT maneuver by dividing the breath rate by the average monitored tidal volume.
FIO_2	Fraction of Inspired Oxygen
Flow ($\dot{V}$)	The velocity of gas delivery to the patient, quantified in L/min.
Flow Trigger	A patient effort in which the amount of bias flow routed into the patient's lungs exceeds the Flow Trigger setting. A flow trigger will result in delivery of an Assist or Patient breath, according to the ventilation mode.
I:E	The ratio of the inspiration period to the expiration period for a breath. Calculated by dividing the measured Inspiratory Time by the measured Exhalation Time.
$I:E_{calc}$	Calculated Inspiratory: Expiratory ratio, based on Inspiratory Time, Inspiratory Pause and Breath Rate settings.
I-Hold	Inspiratory Hold
Insp. Time	Inspiratory Time
Inspiratory Hold (I-Hold)	A maneuver which holds the inspiratory phase of a volume delivered breath for a duration sufficient to determine the static lung compliance of the patient.

[65] All references to compressible flow and compressible volume in the patient pneumatic pathway are BTPS unless stated otherwise.

TERM	DEFINITION
L	Liters
L/min	Liters Per Minute. Measurement of flow rate.
Leak Compensation	Leak Compensation is a feature that compensates triggering and monitor values for leaks after the patient Wye.
Leak, measured ($\dot{V}_{leak}$)	Measured leak is the steady state exhalation flow measured at the patient Wye. It represents the amount of air leaking out of the system after the patient connection port of the Wye.
LED	Light Emitting Diode
LPS	Low Pressure (Oxygen) Source
Machine Breath	A volume or pressure breath that is started by the operator or the ventilator, and is controlled and cycled by the ventilator.
Manual Breath	A Machine Breath initiated by pushing the **Manual Breath** button.
Mean Airway Pressure, monitored	The average airway pressure over a series of breaths.
Minimum Exhalation Time	The minimum time required for exhalation is 346 msec. Control settings are limited to ensure the Minimum Exhalation Time is provided. Breaths may not be triggered during the Minimum Exhalation Time.
Minimum Inspiratory Time	The minimum time required for inspiration is 300 msec. Control settings are limited to ensure the Minimum Inspiratory Time is provided.
Msec	Millisecond: One one-thousandth of a second.
Non Volatile Memory	Memory that is retained when the ventilator is powered off.
O_2	Oxygen
O_2 Inlet	O_2 Source Pressure
Patient Breath	A Pressure Support or Spontaneous breath that is started by the patient, controlled by the ventilator and cycled by the patient.
Patient Circuit	The airway tubing that connects the ventilator and the patient.
Patient Effort	Inspiratory effort by the patient.
P_{aw}	Airway Pressure, measured at the patient Wye.
Peak Inspiratory Pressure, monitored (P_{peak})	The maximum circuit pressure occurring during the inspiration and first 346 ms exhalation phase of a breath. P_{peak} is measured at the patient Wye.
PEEP	Positive End Expiratory Pressure
PEFR	Peak Expiratory Flow Rate, measured at the patient Wye.
PIFR	Peak Inspiratory Flow Rate, measured at the patient Wye.
P_{mean}	Mean Airway Pressure
Positive End Expiratory Pressure, monitored (PEEP)	The circuit pressure measured at the end of exhalation.
POST	Power On Self Tests. A set of self-tests the ventilator performs when turned on to verify the operational integrity and the validity of all stored configuration values, event log, RAM and program memory.

TERM	DEFINITION
P_{peak}	Peak Inspiratory Pressure, measured at the patient Wye.
P_{plat}	Plateau Pressure
PR/min	Pulse Rate per minute (pulse measured by the Pulse Oximetry Module).
Presets	Automatically set ventilation control and alarm limit values initially clinically appropriate for the patient size and patient circuit type selected by the operator during ventilator setup for a New Patient.
Pressure Control breath	A machine or assist breath where the circuit pressure is elevated to a operator-set pressure for a operator-set period of time. Pressure Control breaths have an optional flow termination criteria.
Pressure Support breath	A patient breath where the circuit pressure is raised to an operator-set pressure and maintained until flow decreases to an operator-set percentage of the peak flow achieved. Pressure Support Breaths may also be terminated by a pre-set maximum time, or by exceeding 2 breath periods without otherwise achieving the termination criteria.
Pressure Trigger	A patient effort in which the airway pressure is less than the set PEEP minus the Pressure Trigger setting.
PRVC	Pressure Regulated Volume Control
PSI / PSIG	Pounds per Square Inch/Gauge. A unit for measuring pressure.
PSV	Pressure Support Ventilation
PSV T_{max}	The PSV T_{max} control sets the maximum inspiratory time for terminating Pressure Support, Pressure Regulated Volume Support (PRVS) and Spontaneous breaths.
Pulse	Pulse Rate
Rate	See “Breath Rate, set”
SBT	Spontaneous Breathing Trial
SIMV	Synchronized Intermittent Mandatory Ventilation
SIMV Mode	A ventilation mode where a minimum number of Machine or Assist breaths are given and the patient is allowed to trigger additional Patient breaths.
SpO_2	Functional oxygen saturation of arterial hemoglobin measured non-invasively by Pulse Oximetry.
Spon. Rate	Spontaneous Breath Rate
Spon. V_{te}	Spontaneous Exhaled Tidal Volume
Spontaneous Breath	A breath which the patient triggers and cycles.
Status Bar	The area at the top of the LCD touch screen in which informational and alarm massages are displayed.
T_i	Inspiratory Time, Measured
Tidal Volume, set	The volume of air delivered to the patient circuit for each volume or PRVC breath.
Total Breath Rate (Rate)	See Breath Rate, monitored.
Transducer	A measuring device. Transducers can be used to quantify flow or pressure.
UART	Universal Asynchronous Receiver/Transmitter

TERM	DEFINITION
UVT	User Verification Tests (screen)
V / BR	Volume Breath Delay
V_e	Exhaled Minute Volume
Volume Control Breath	A machine or assist breath where a pre-set volume is delivered over a pre-set time. Flow is delivered in a decelerating waveform where the peak and final flows are calculated so that the final flow is 50% of the peak flow.
V_t	Tidal Volume
V_{te}	Exhaled Tidal Volume
V_{ti}	Inspiratory Tidal Volume
V_tPSV	Volume Targeted Pressure Support Ventilation
$\dot{V}$	Flow
$\dot{V}_{calc}$	The calculated peak flow for Volume Control breaths. V_{calc} is calculated based on the set Tidal Volume and the Set Inspiratory Insp. Time settings.
$\dot{V}_{i\ calc}$	Peak Inspiratory Flow, calculated.
$\dot{V}_{leak}$	Leak, measured.

Appendix E - INDEX

A

B

C

G

H

I

L

M

N

O

P

R

S

T