# ReVel<sup>™</sup> Ventilator

**LED Panel Interface** 







# **Revision History**

| Revision<br>Level | Date      | Changes                         |
|-------------------|-----------|---------------------------------|
| Α                 | Sep. 2011 | Production release per ECO 7100 |
|                   |           |                                 |
|                   |           |                                 |
|                   |           |                                 |

# Warranty

The ReVel<sup>™</sup> 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 ReVel<sup>™</sup> ventilator, PTV<sup>®</sup> Series Docking Station and the PTM<sup>™</sup> Graphics Monitor. The ventilator system does not include external power supplies.

The liability of CareFusion, Respiratory Care Division, (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 and cooling filter, 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.

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# **Notices**

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# PTV<sup>®</sup> Series of Products

The PTV<sup>®</sup> Series of products encompasses the Enve<sup> $^{\text{IM}}$ </sup> and Revel<sup> $^{\text{IM}}$ </sup> ventilators, a Docking Station, the PTM<sup> $^{\text{IM}}$ </sup> Graphics Monitor and various accessories (e.g. AC Adapter, SpO<sub>2</sub> Module/Sensor, FiO<sub>2</sub> 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<sup>®</sup> Series Ventilators require special precautions regarding EMC (Electromagnetic Compatibility) and need 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<sup>®</sup> 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<sub>2</sub> Sensor
- PTM<sup>™</sup> Graphics Monitor and its associated cables
- SpO<sub>2</sub> Module and Sensor

### Indications for Use

The Revel<sup>™</sup> 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 homecare, hospital and transport environments as a source of continuous or intermittent positive pressure ventilatory support, delivered invasively or non-invasively.

PTV<sup>®</sup> 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 Revel<sup>™</sup> ventilator without a complete understanding of its attributes may cause harm to the patient or operator. It is important that this manual is read and understood in its entirety before operating the ventilator.

Any questions regarding installing, operating, or maintaining the Revel<sup>™</sup> ventilator should be directed to CareFusion or a service technician certified by CareFusion.

#### **CareFusion Respiratory Systems**

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763.398.8403 (Product Orders)

Email: revelservice@carefusion.com

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 to assist in the proper operation of the Revel  $^{\text{\tiny TM}}$  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:** Revel<sup>™</sup> ventilator, Revel<sup>™</sup> 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. 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/or 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 Revel<sup>™</sup> 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 Revel  $^{\text{TM}}$  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 -

- Use only CareFusion recommended Power Sources
- Do not use batteries, AC 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 Revel<sup>™</sup> 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, noncondensing 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<sup>®</sup> 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.

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**<sup>®</sup> **Series Carry Case** – The PTV<sup>®</sup> Series Carry Case is a protective, portable case for PTV<sup>®</sup> 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   |
|-------------|-------------------------|---------------------------------------|---|
| $\triangle$ | ISO 3864<br>No.B.3.1    | Attention, see accompanying documents | Directs the user to the instruction manual for specific instructions involving safety.  |
| *           | No. 417-<br>IEC-5333    | Type BF equipment.                    | To mark a type BF equipment   |
| ===         | No. 417-<br>IEC-5031    | Direct current                        | Indicates direct current (DC).  |
| Ť           | No. 3.8 –<br>ISO 15223  | Keep Dry                              | Identifies an area of equipment requiring a degree of protection from liquids.  |
| IPX1        | IEC 60529               | Enclosure protection                  | Indicates degree of enclosure protection against liquid ingress.  |
| V           | CareFusion              | Flow                                  | Indicates monitored airway flow.  |
|             | CareFusion              | Patient breathing circuit             | Indicates connection points for the patient breathing circuit inspiratory limb, expiratory drive line and Wye flow sense lines to the ventilator. |
|             | CareFusion              | Audible signal                        | Indicates the Display/Alarm <b>Check</b> button.  |
|             | CareFusion              | Battery/Power                         | Indicates the Battery/Power <b>Check</b> button.  |
|             | CareFusion              | Eject                                 | Indicates location of battery release.  |
| 4           | CareFusion              | Nebulizer                             | Indicates the location of the nebulizer port.   |
| Scroll      | CareFusion              | Increase/Decrease                     | Signifies direction of value increase or decrease on rotary knob encoder.   |
| (00000      | CareFusion              | Battery status LEDs                   | Indicates degree of charge remaining in the Removable Battery Pack.   |
|             | Directive<br>2002/96/EC | Waste Container                       | WEEE symbol to identify Waste Electrical and Electronic Equipment not to be disposed of as unsorted municipal waste.                              |
| ***         | EN 980                  | Manufacturer                          | Indicates name and contact information of the manufacturer.   |

# **Chapter 1 - INTRODUCTION**

This Operator's Manual contains information and instructions to enable you to safely set up and use your Revel<sup>™</sup> 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 Revel<sup>™</sup> 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

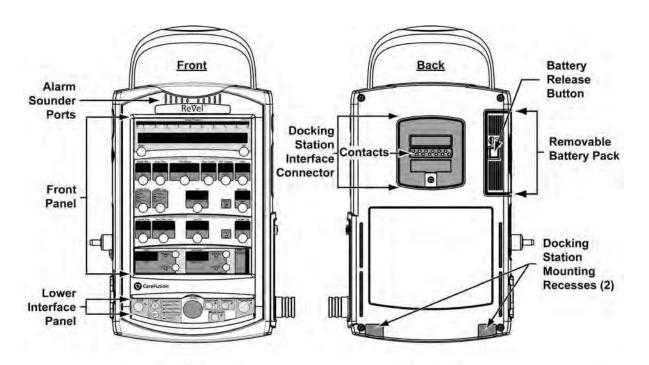
If you have any problems or questions as you follow the instructions contained in this manual, call CareFusion using the contact information provided in *Appendix A* - *Contact Information*.

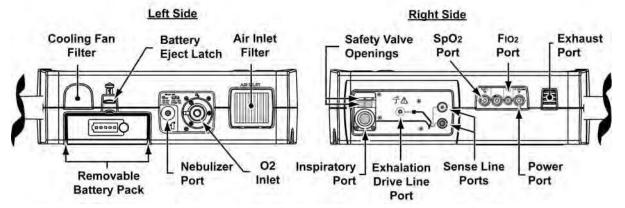
### **WARNING**

**Ventilator Service and Repair** - To avoid ventilator malfunction and possible operator or patient injury, all servicing or repair of the PTV<sup>®</sup> 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<sup>®</sup> Series Ventilators are lightweight, high performance ventilator designed for maximum functionality in an unprecedented small package.

The Revel<sup>™</sup> ventilator provides the following features:

- High performance ventilation in a small, lightweight package
- ActivCore<sup>™</sup> 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+PS and NPPV breath modes
- Non-Invasive Positive Pressure Ventilation (NPPV)
- Volume Control, Pressure Control, Pressure Support, Pressure Regulated Volume Controlled (PRVC), Volume Targeted Pressure Support and Spontaneous breath types
- A range of maneuvers including Inspiratory and Expiratory Hold
- Adjustable alarm settings including High Peak Pressure, Low Peak Pressure, 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
- 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 an airway leak is present
- Operation from a variety of power sources including a Removable Battery Pack and external AC and DC power sources
- FIO<sub>2</sub> Sensor package
- SpO<sub>2</sub> Pulse Oximetry software

# The PTV® System

# The Docking Station

At the bedside, the Revel<sup>™</sup> 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 Revel<sup>™</sup> 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 system)
- interface with the PTM<sup>™</sup> 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 Revel<sup>™</sup> Ventilator

The Revel<sup>™</sup> 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 can also support a wide range of life support and critical care applications.

The pneumatic system is designed around ActivCore<sup>™</sup> technology, which includes a blower that draws in room air through a filter and delivers gas at the correct flow, volume and/or pressure for the patient.

The ventilator delivers blended gases from an internal oxygen blender. The blended gas delivery can be monitored with an external  $FlO_2$  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 the 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<sup>™</sup> Graphics Monitor Display

The PTM<sup>™</sup> Graphics Monitor is a lightweight color monitor for use with a PTV<sup>®</sup> Series Ventilator when it is connected to its Docking Station and secured onto a PTV<sup>®</sup> 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**

- The **SpO2 Oximetry Module** provides portable pulse oximetry with the ventilator. SpO<sub>2</sub> and Pulse monitors and alarms display on the ventilator interface
- The Fio<sub>2</sub> Module enables monitoring of the oxygen concentration in the inspired airflow. Fio<sub>2</sub> related alarms and monitors display on the ventilator interface

# **Principles of Operation**

# Pneumatic System

The Revel<sup>™</sup> 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<sup> $^{\text{IM}}$ </sup> blower technology. The ActivCore<sup> $^{\text{IM}}$ </sup> draws room air into the **accumulator/filter** where it is mixed with oxygen from the **O**<sub>2</sub> **blender module**. Air from the ActivCore  $^{\text{IM}}$  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  $^{\text{IM}}$  (Blower) provides flow feedback to the ActivCore  $^{\text{IM}}$  processor.

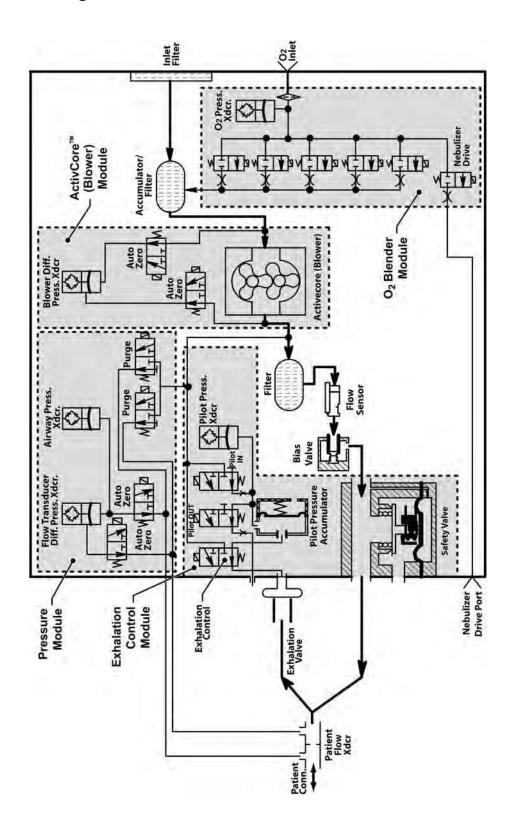
The **exhalation control module** closes the **exhalation valve** during inspiration to direct the air to the patient. During exhalation, the ActivCore<sup>™</sup> delivers bias flow and the exhalation valve is servo controlled to achieve the desired amount of positive end expiratory pressure (PEEP). During exhalation, flow is monitored through the **patient flow transducer** to detect patient triggering. With leak compensation enabled, the ActivCore<sup>™</sup> 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 Revel<sup>™</sup> ventilator;

- 1) Inspect the exterior of the ventilator transport container for evidence of damage during transit. If damaged, notify the delivering 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 items listed on the packing slip. Notify an authorized sales representative or CareFusion of any discrepancies.
- 4) Examine the ventilator and accessories for visible damage. If damaged, notify the delivering service.

# Operational Setup

# Equipment, Accessories and Supplies Required

To setup and operate the Revel<sup>™</sup> ventilator you will need the following additional equipment, accessories and supplies:

**Power Source** – The Removable Battery Pack<sup>1</sup> supplied with the ventilator and an approved external source of power (e.g. the AC Adapter<sup>2</sup>, or PTV<sup>®</sup> Series Docking Station<sup>2</sup>)

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

**Oxygen Supply** – The Revel<sup>™</sup> ventilator can utilize either high or low pressure sources of oxygen (as clinically appropriate for the patient):

 A high pressure source of O<sub>2</sub> and an FiO<sub>2</sub> Sensor<sup>2</sup> 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.

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> 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 Revel<sup>™</sup> 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, 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 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.

# PTV<sup>®</sup> Series Carry Case

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

Although not shown in subsequent illustrations for clarity of individual installation and setup instructions, the PTV<sup>®</sup> 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 Revel<sup>™</sup> ventilator, PEEP control is an integral function of the ventilator itself, and the external Exhalation Valve is integrated into the patient circuit. CareFusion offers patient circuits suitable for use with the Revel<sup>™</sup> ventilator in adult, pediatric and infant 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 Revel<sup>™</sup> ventilator.

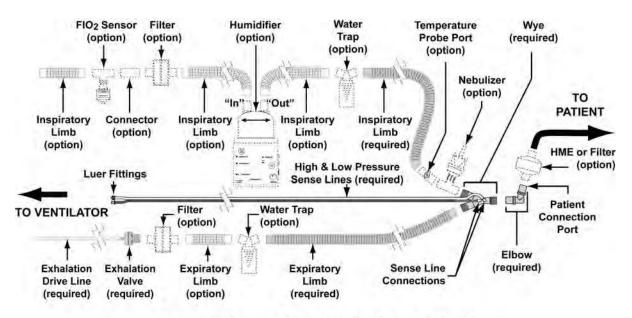
#### NOTE

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<sup>®</sup> 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. Refer to the instructions provided with your circuit for full assembly instructions.



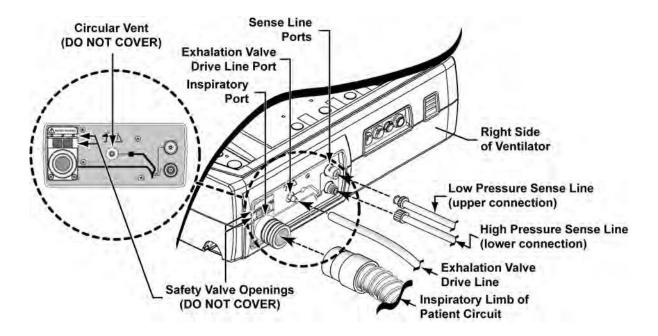
**Example of Patient Circuit and Optional Accessories** 

### **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, as shown below.
- 2) Connect the Exhalation Valve Drive Line of the patient breathing circuit to the exhalation valve Drive line port (hose barb) on the right side of the ventilator, as shown below.
- 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, as shown below.



### **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<sub>2</sub>

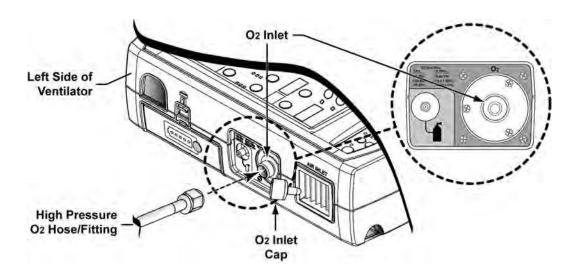
### **WARNING**

**Risk of Fire** - Leaks at oxygen inlet connections can cause dangerous  $O_2$  levels in the vicinity of the  $O_2$  inlet fitting. To avoid the risk of fire, inspect 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<sup>3</sup> O<sub>2</sub> inlet port on the left side of the ventilator.

The O<sub>2</sub> inlet port is labeled O<sub>2</sub>



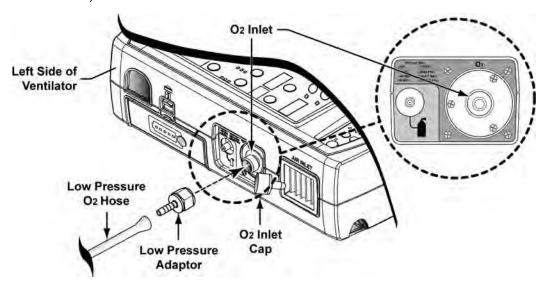
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<sup>&</sup>lt;sup>3</sup> DISS - Diameter-Index Safety System #1240, per GGA V5-1989

### Low Pressure O<sub>2</sub> 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<sup>4</sup> Low Pressure Adapter<sup>5</sup> to the DISS O<sub>2</sub> Inlet port on the left side of the ventilator.
  - The O<sub>2</sub> Inlet port is labeled O<sub>2</sub>
- 2) Attach the oxygen supply hose to the hose barb on the adapter.
- 3) Set the **O**<sub>2</sub> control on the front panel to **LPS** (Low Pressure Source) (see *O*2 (*Oxygen Percentage and Flush*) in Chapter 5 -Controls for detailed information).
- 4) Adjust the flow of the low pressure O<sub>2</sub> 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<sub>2</sub>) Concentration** – Minute volumes can fluctuate if the patient has a variable respiratory rate. If *exact concentrations* of inspired oxygen (FIO<sub>2</sub>) must be delivered to the patient, it is recommended that the optional FIO<sub>2</sub> Sensor or a separate oxygen analyzer with alarms be used. If using the optional FIO<sub>2</sub> Sensor set the ventilator Low FiO<sub>2</sub> alarm appropriately (see *Low FIO2* alarm in Chapter 8 –Ventilator Alarms for additional information).

#### NOTE

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

<sup>&</sup>lt;sup>4</sup> DISS - Diameter-Index Safety System #1240, per GGA V5-1989.

<sup>&</sup>lt;sup>5</sup> The DISS Low Pressure Adapter is available from CareFusion.

#### **Power Connection**

The Revel<sup>™</sup> 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 Adapter and the Automobile Adapter are connected to the ventilator as follows:

#### **WARNING**

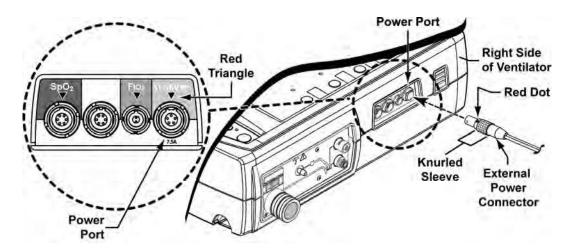
Risk of Electrical Shock - To avoid the risk of an electrical shock or ventilator damage;

- 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

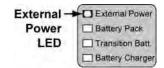
#### NOTE

When using the PTV<sup>®</sup> 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

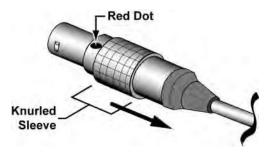


- 2) Connect the external power cable to a valid external power source.
- 3) Verify the **External Power** LED on the lower interface panel illuminates green. If not, recheck the power supply.



#### 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**

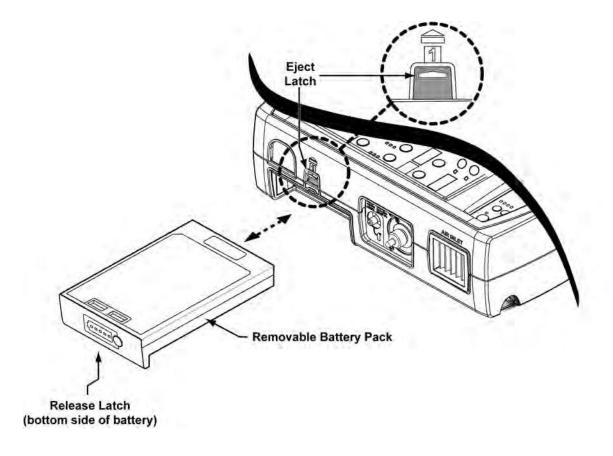
For safety there are two latch mechanisms securing the Removable Battery Pack. The first is above the battery (see illustration). The second is on the underside of the battery at the leading edge. Both will engage when installing the battery and must be sequentially released to safely remove the battery.

#### 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. Push 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 Revel<sup>™</sup> 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<sub>2</sub>) Sensor
- FIO<sub>2</sub> Sensor
- Nebulizer

# Pulse Oximetry (SpO<sub>2</sub>)

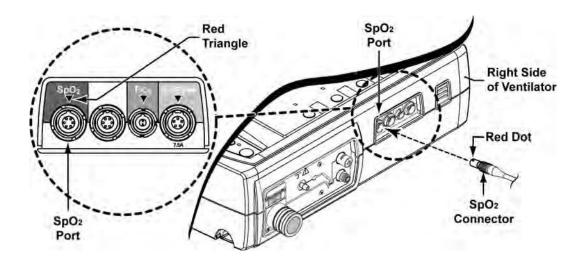
The Pulse Oximetry Module for use with PTV<sup>®</sup> Series Ventilators is CareFusion P/N 18602-001. For specifications, warranty information, assembly and cleaning instructions, refer to the Instructions for Use provided with your Oximetry Module.

• See Accessories in Appendix C – Reference Information for additional information<sup>6</sup>

### To Connect the Pulse Oximetry (SpO<sub>2</sub>) Sensor

Position the module connector with the red dot on the connector aligned with the red triangle on the ventilator port labeled **SpO**<sub>2</sub> (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



-

<sup>&</sup>lt;sup>6</sup> For a current/complete list of accessories, availability and ordering information, contact CareFusion (see *Appendix A - Contact Information*).

### To Configure Pulse Oximetry (SpO<sub>2</sub>) Monitoring

Pulse Oximetry monitoring is enabled/disabled and it's high and low alarm limits are set using front panel controls.

See Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 –
Using the Ventilator and Front Panel, Pulse Oximeter in Chapter 5 – Controls for
additional information

Pulse Oximetry average interval and pulse tone volume configuration values are set using the Extended Features menus.

 See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator and Pulse Ox (Pulse Oximetry) in Chapter 10 – Extended Features for additional information

#### **NOTE**

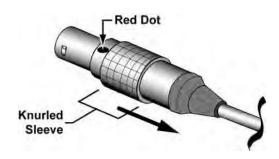
If the sensor is not on a patient when SpO<sub>2</sub> is enabled, an alarm will sound.

### To Disconnect the Pulse Oximetry (SpO<sub>2</sub>) Sensor

The SpO<sub>2</sub> Module 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<sub>2</sub> 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<sub>2</sub> Sensor

In order for the Revel<sup>™</sup> ventilator to monitor/report the F<sub>IO2</sub> (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.

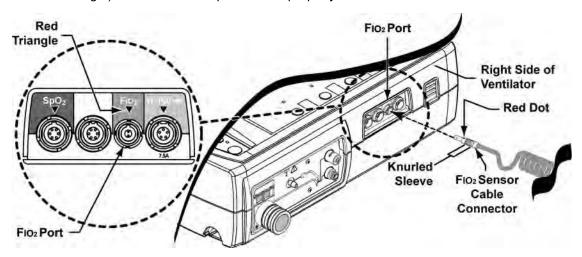
#### To Assemble the Fio<sub>2</sub> Sensor Assembly

See the Instructions for Use provided with the Fio<sub>2</sub> Sensor Cable Assembly for detailed instructions concerning assembling the Fio<sub>2</sub> Sensor Assembly and inserting it into the patient circuit.

#### To Connect the Fio2 Sensor

Position the  $Flo_2$  Sensor connector with the red dot on the connector aligned with the red triangle on the ventilator port labeled  $Flo_2$  (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<sub>2</sub> 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 manual 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 F102 Monitoring

FIO<sub>2</sub> monitoring is enabled/disabled and calibrated while the ventilator is in Startup mode.

• See Navigating Startup and Extended Features Menus and FIO2 Sensor Configuration and Calibration in Chapter 3 – Using the Ventilator for detailed instructions

Once setup, enabled and calibrated, communication with the F<sub>1O2</sub> sensor may be enabled/disabled during normal ventilation modes using the Extended Features menus.

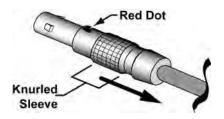
 See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator and FIO2 SENSOR in the Extended Features, Option Cnfg menus in Chapter 10 – Extended Features for additional information

The Low FIO<sub>2</sub> alarm limit is set using the front panel while the ventilator is operating in a normal ventilation mode.

See Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 –
 Using the Ventilator and Low FIO2 in Chapter 5 – Controls for additional information

#### To Disconnect the F<sub>102</sub> Sensor

The  $F_{1O_2}$  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.

# Nebulizer

The Nebulization procedure can be performed on the Revel  $^{\mathsf{T}}$  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

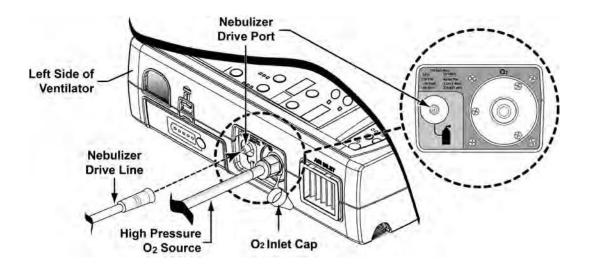
1) Align the nebulizer drive line as shown and push it straight onto the nebulizer drive port barb on the left side of the ventilator. The nebulizer drive port is labeled with the symbol shown here.



# **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 using the Extended Features menus while the ventilator is in a normal ventilation mode.

 See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator and Nebulization in Chapter 9 - Maneuvers and Procedures for additional information

# PTV<sup>®</sup> Series Docking Station (Option)

The ventilator can be docked to a PTV<sup>®</sup> Series Docking Station that provides power to the ventilator, accommodates the PTM<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup> Graphics Monitor (Option)

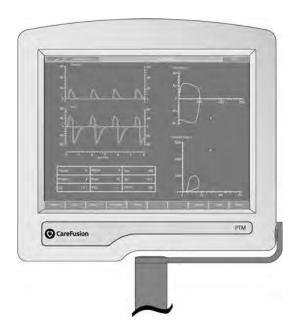
The PTM<sup>™</sup> Graphics Monitor accessory is a thin, lightweight color graphics monitor for use with the PTV<sup>®</sup> Series Ventilators when connected to a Docking Station and secured onto a PTV<sup>®</sup> Series Rolling Stand, Table Stand, or Wall Mount. The PTM<sup>™</sup> offers the following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

**Data Screen**Current ventilator settings and monitored data **Loops 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

**Trends Screen** Trend graphs for long term display of monitored data **Waves Screen** Pressure, flow, volume and plethysmograph waveforms



For instructions and detailed use information, see the PTV<sup>®</sup> Series Docking Station Operator's Manual, P/N 12433-001, and the PTM<sup>™</sup> 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 while 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 Revel<sup>™</sup> 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<br>Performed In |
|----------------------|-------------------------------|--------------------------------|
| POST                 | Power On Self Tests           | Startup mode                   |
| Button Test          | 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:

- 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<sup>®</sup> Series Docking Station Operator's Manual, P/N 12433-001).
- 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:

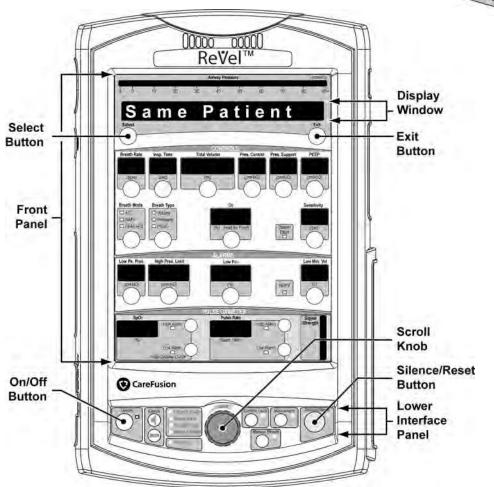
5) Connect a Test Lung to the Patient Connection Port on the Elbow of the assembled patient circuit attached to the ventilator. Refer to the patient circuit illustration under *Patient Circuit Accessories* earlier in this chapter for location of Patient Connection Port.

# 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, displays either the ventilator model name (**Revel**) or part number (**XXXXX-XXX**) followed by **Same Patient** in the display window.



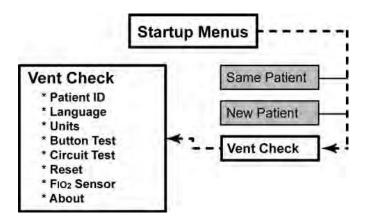


#### NOTE

**Exiting Startup Mode** – Startup mode can be exited at any time by simply holding down the **On/Off** button on the lower interface panel until the ventilator powers down.

# **Functional Testing in Startup Mode**

The Button Test 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.

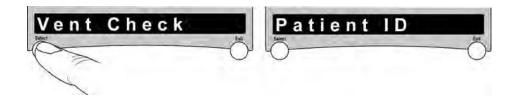
 To perform testing in Startup mode, prepare and turn the ventilator on as previously described in this chapter and **Same Patient** is displayed in the display window on the front panel.



 See Test Preparation and Power On Self Tests (POST) in Startup Mode in this chapter for detailed information



2) Rotate the Scroll knob on the lower interface panel until Vent Check is displayed. Push the Select button and reset the Remove Patient alarm (!!! Remove Ptnt) by pushing the Silence/Reset button twice. The ventilator enters the Vent Check menus and Patient ID is displayed.



### **Button Test**

The Button Test checks the functioning of the mechanical controls (buttons and knob) on the ventilator's front and lower interface panels.

#### To Perform the Button Test:

 When Patient ID is displayed, rotate the Scroll knob on the lower interface panel until Button Test is displayed and push the Select button. Select is momentarily displayed (while the Select button is being pushed), followed by None Pressed when the Select button is released.





2) Test the control buttons and the Scroll knob on the front and lower interface panels by pushing each button (except the Exit button), one at a time and rotating the Scroll knob, left and right. As each button is pushed or knob rotated, verify that the corresponding name of the control pushed/rotated replaces the displayed None 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 front and lower interface panels are suspended, except as follows:

- Pushing the Exit button will cause the ventilator to exit the Button Test
- During testing, the Silence/Reset button retains its functionality and will continue to silence/reset alarms when pushed
- When testing the On/Off button, briefly push the button and an On/Off message replaces
  the displayed None Pressed message. However, pushing 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 Button | Name Displayed |
|----------------|----------------|
| Select         | Select         |
| Breath Rate    | Breath Rate    |
| Insp. Time     | Insp. Time     |
| Tidal Volume   | Tidal Volume   |
| Pres. Control  | Pres. Control  |
| Pres. Support  | Pres. Support  |
| PEEP           | PEEP           |
| Breath Mode    | Breath Mode    |
| Breath Type    | Breath Type    |
| O <sub>2</sub> | O2 %           |
| Sensitivity    | Sensitivity    |
| Low Pk. Pres.  | Low Pres       |

| Control Button                     | Name Displayed        |
|------------------------------------|-----------------------|
| High Pres. Limit                   | High Pres             |
| Low FIO <sub>2</sub>               | Low FIO <sub>2</sub>  |
| Low Min. Vol.                      | Low Min Vol           |
| SpO <sub>2</sub> High Alarm        | High SpO <sub>2</sub> |
| SpO <sub>2</sub> Low Alarm         | Low SpO <sub>2</sub>  |
| Pulse Rate High Alarm              | High Pulse            |
| Pulse Rate Low Alarm               | Low Pulse             |
| On/Off                             | On/Off                |
| Check                              | Display Chk           |
| Check                              | Battery Chk           |
| Scroll (knob rotated to the right) | Rotate Right          |
| Scroll (knob rotated to the left)  | Rotate Left           |
| Control Lock                       | Control Lock          |
| Manual Breath                      | Manual Brth           |
| Maneuvers                          | Maneuvers             |
| Silence/Reset                      | Silence               |

When all controls have been pushed/rotated (except the **Exit** button) and the corresponding name has been verified as being correctly displayed, the Button Test has been successfully completed.

3) To exit the Button Test, push the **Exit** button and **Circuit Test** is displayed.



#### Circuit Test

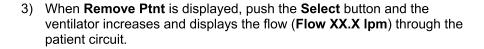
The Circuit Test measures the air flow across the patient circuit Flow Sensors, checks the airway circuit for leaks and checks the ventilator's Safety Valve for over-pressure relief.

# **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*, *Power On Self Tests (POST) in Startup Mode* and *Functional Testing in Startup Mode* earlier in this chapter for detailed instructions before proceeding.
- 2) When **Patient ID** is displayed, rotate the **Scroll** knob on the lower interface panel until **Circuit Test** is displayed and push the **Select** button.
  - Waiting xx (xx is a numeric count-down from 60 seconds) is displayed when the ventilator transducers have not yet warmed up after power up, followed by displaying Remove Ptnt OR
  - Remove Ptnt is initially displayed





#### 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 alarm (**HW Fault**) will be displayed 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.

Observe and follow the on screen instructions.

- Unblock Wye is displayed if the flow is less than 7 lpm
- Failed Flow is displayed if the flow is not 7 13 lpm for more than 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<sub>2</sub>O 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 Flow** is displayed and the ventilator stops the test if the acceptance criteria (flow 0 0.9 lpm 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.

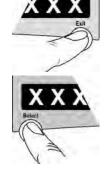
- **Failed Flow** is displayed and the ventilator stops the test if the acceptance criteria (flow 0 0.9 lpm for 2 seconds) is not met within 10 seconds
- Failed SV is displayed if the pressure does not drop
- Passed is displayed when the measured values are within acceptable limits

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) To repeat the Circuit Test, proceed as follows, otherwise skip to the next step:
  - Push the Exit button and Circuit Test is displayed
  - Push the Select button twice to display Remove Ptnt and restart the Circuit Test

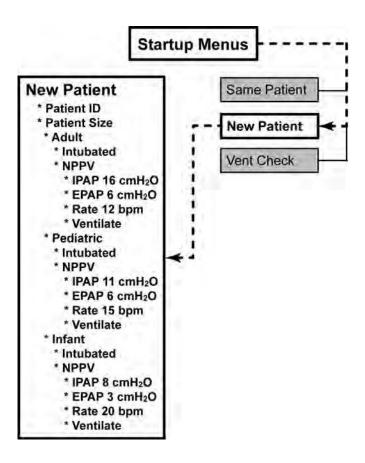


7) To prepare for testing in a normal ventilation mode, exit Vent Check menus by repeatably pushing the **Exit** button until **Same Patient** is displayed.



# **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<sup>7</sup> values for controls and alarm limits settings for a new patient.



#### NOTE

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

#### WARNING

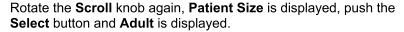
Improperly Functioning Ventilator or Attached Accessories - Operating a ventilator that does not appear to be functioning properly may be hazardous to both patient and operator. If the ventilator or any attached accessory is damaged, fails any tests or malfunctions in any way, immediately discontinue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

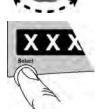
<sup>&</sup>lt;sup>7</sup> Presets – Automatically set ventilation control and alarm limit values initially clinically appropriate for the patient size and patient circuit type selected by the operator during ventilator setup for a New Patient.

- 1) To perform testing in a normal ventilation mode, prepare and turn the ventilator on as previously described in this chapter and **Same Patient** is displayed in the display window on the front panel.
  - See Test Preparation and Power On Self Tests (POST) in Startup Mode in this chapter for detailed information



2) Rotate the **Scroll** knob on the lower interface panel until **New Patient** is displayed, push the **Select** button and **Patient ID** is displayed.





- 3) When **Adult** is displayed, push the **Select** button and **Intubated** is displayed. Push the **Select** button once again to:
  - Clear existing Patient ID, Trend data<sup>8</sup> 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 Ventilation Controls and Presets Values for Alarm Configurations/Limits in Chapter 3 – Using the Ventilator for additional information.

#### NOTE

The Presets  $O_2$  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 **Low O<sub>2</sub> Pres** alarm is generated and must be reset in order to proceed when the ventilator begins normal ventilation.

#### To Reset the Low O<sub>2</sub> Pres Alarm:



 When !! Low O<sub>2</sub> Pres is displayed, push the Silence/Reset button twice on the lower interface panel to reset the alarm (temporarily silence the sounder and clear the alarm message).

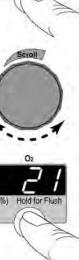


<sup>&</sup>lt;sup>8</sup> Trend data stored by the Revel ventilator can be displayed on a PTM™ Graphics Monitor when the ventilator is docked to a PTV<sup>®</sup> Series Docking Station with an attached PTM™ Graphics Monitor.



Push the O<sub>2</sub> control button on the front panel to select it, and rotate the Scroll knob on the lower interface panel to change the setting to 21 (%).

Push the O<sub>2</sub> control button once again to confirm the new setting.



- 3) Observe the front panel display window for any/all alarm messages displayed (e.g. text preceded by !, !! or !!!):
  - If any alarm messages 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
  - If scrolling monitored data (VE, MAP, PIP, etc.) is displayed (i.e. no alarm messages), 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 display window at the top of the front panel), indicating their detection and current status<sup>9</sup>. 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 Batt 50% (or less) is displayed, it is an indication that the displayed source of power (Batt, Ext, Dock or T-Bat) has been detected, is <u>not</u> 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)

<sup>&</sup>lt;sup>9</sup> 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.

To verify the status of the ventilator's LED 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 all front panel window displays 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<sup>10</sup> that sounds at the set alarm volume, and no "Fault" messages are displayed.

| Panel  | LED Color    |
|--|--------------|
| Front Panel:   |              |
| Airway Pressure Manometer LEDs <sup>11</sup>   | Amber        |
| Signal Strength Display LEDs <sup>12</sup>   | Amber        |
| All other LED indicators and displays  | Red or Green |
| Lower Interface Panel:   |              |
| <ul> <li>All Power Status indicator LEDs<sup>13</sup></li> <li>External Power</li> <li>Battery Pack</li> <li>Transition Bat.</li> <li>Battery Charger</li> </ul> | Amber        |
| All other indicator LEDs   | Red or Green |

3) If any indicator LED, display window LED (includes all LED segments within the window) 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).

<sup>&</sup>lt;sup>10</sup> Refer to *Sound Types*, *Patterns and Volumes* in Chapter 8 - Ventilator Alarms for additional information.

<sup>&</sup>lt;sup>11</sup> Refer to *Airway Pressure Manometer* in Chapter 6 - Displays and Indicators for additional information.

<sup>&</sup>lt;sup>12</sup> Refer to Oximetry Signal Strength Display in Chapter 6 - Displays and Indicators for additional information.

<sup>&</sup>lt;sup>13</sup> 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.

| Ver | Ventilator Settings and Procedure   |                 | Requirement   |  |
|-----|---|-----------------|---|--|
| A)  | Refer to Chapter 3 - Using the Ventilator and Chapter 8 - Ventilator Alarms to configure the ventilator settings as follows:  Breath Mode: Breath Type: Volume Breath Rate: 12 bpm Tidal Volume: 500 ml Insp. Time: 1.0 sec Pres. Support: "" cmH <sub>2</sub> O O <sub>2</sub> : 21 % Sensitivity: 3 lpm Low PEEP Alarm: "" (off) PEEP: 0 cmH <sub>2</sub> O High Pres. Limit: 100 cmH <sub>2</sub> O Low Pk. Pres.: 5 cmH <sub>2</sub> O Low Min. Vol: 1.0 L Do not attach an oxygen supply to the ventilator at this time. |                 | No alarms activate Selected Monitors shou Vte: I:E Ratio: Breath Rate: VE:  Lower Interface Panel L External Power: Battery Pack: Transition Batt.: | Vte 383 to 633 ml<br>I:E 1:3.8 to 1:4.2<br>f 12 bpm<br>VE 4.6 to 7.6 L |
|     | Run the equipment for at leas   | st two minutes. |   |  |
| B)  | Set the O <sub>2</sub> control to 22%.  |                 | Low O₂ Pres alarm acti  | vates  |
| C)  | <ul> <li>Return the O₂ control to 21% and reset the alarm.</li> <li>Set the Low Min. Vol. alarm to 10 L.</li> </ul>   |                 | Low Min Vol alarm acti  | vates  |
| D)  | Polynomials (Pierre Personal)  Return the <b>Low Min. Vol.</b> alarm to 1.0 and reset the alarm.  Set the <b>Low Pk. Pres.</b> alarm to 10 cmH <sub>2</sub> O above the Peak Inspiratory Pressure (PIP).  |                 | Low Peak Pres alarm a   | activates  |
| E)  | Return the <b>Low Pk. Pres.</b> alarm to 5 and reset the alarm.  Set the <b>High Pres. Limit</b> alarm to 10 cmH <sub>2</sub> O below the Peak Inspiratory Pressure (PIP) displayed.  |                 | High Pres alarm activat   | tes  |
| F)  | Return the <b>High Pres. Limit</b> alarm to 100 and reset the alarm.  |                 |   |  |
| G)  | ) Connect 40 to 88 PSI oxygen to the unit and set the $O_2$ control to 60%. Connect and enable an FIO <sub>2</sub> Sensor (see Chapter 2 - FIO2 Sensor for information) and set the Low FIO <sub>2</sub> Alarm to 54 % or connect an external oxygen monitor to the patient circuit.  |                 | No alarms activate FIO <sub>2</sub> monitor or external read: <b>55</b> to <b>65% O<sub>2</sub></b> +/- t external oxygen monitor.                  | he tolerances of the   |

| Ver | ntilator Settings and Proced   | lure   | Requirement   |  |
|-----|--|--|---|--|
| H)  | Return the $O_2$ control to 21%, disable and disconnect the FIO <sub>2</sub> Sensor (see <i>Chapter 2 - FIO2 Sensor</i> for information) or external oxygen monitor. Disconnect the High Pressure Sense Line (lower connection) from the ventilator. |  | Pat Circuit alarm activat   | tes on the next breath.  |
| I)  | Reconnect the High Pressure and reset the alarm. Disconnect the Low Pressure (upper connection) from the v   | e Sense Line   | Pat Circuit alarm activat   | es on the next breath.   |
| J)  | Reconnect the Low Pressure reset the alarm.  | Sense Line and   |   |  |
| K)  | Change the ventilator settin Breath Type: Pres. Control: High PEEP Alarm: PEEP: Rise Time:   | gs as follows:  Pressure  40 cmH <sub>2</sub> O  25 cmH <sub>2</sub> O  20 cmH <sub>2</sub> O  4 | No alarms activate Selected Monitors should PIP: PEEP:  | d read as follows:<br>PIP 54 to 66 cmH₂O<br>PEEP 18 to 22 cmH₂O                                |
| L)  | Disconnect the external pove the ventilator.   | ver source from  | ExtPwr Lost alarm activ If disconnected from a Doc Dock Discon alarm is also Lower Interface Panel LE External Power: Battery Pack: Transition Batt.: Battery Charger: Ventilator continues to op | cking Station, a<br>o activated.<br>ED Status:<br>Off<br>Green<br>Off<br>Off or flashing amber |
| M)  | Reset the alarm(s) and rem<br>Removable Battery Pack fro<br>ventilator for one minute.   |  | Insert Batt then T-Batt L Lower Interface Panel LE External Power: Battery Pack: Transition Batt.: Battery Charger: Ventilator continues to open  | ED Status:<br>Off<br>Flashing red<br>Green<br>Off  |
| N)  | Reinsert the Removable Bareconnect the external powereset all alarms.  |  | No alarms activate Lower Interface Panel LE External Power: Battery Pack: Transition Batt.: Battery Charger: Ventilator continues to open   | ED Status: Green Off Off Off, green, amber, or flashing amber                                  |
| O)  | Turn off the ventilator by push<br>the <b>On/Off</b> button. Observe t<br>at least 15 seconds then rese  | he ventilator for  | Saving Config is moment<br>The Vent Inop alarm soun<br>seconds<br>The Vent Inop LED flashe  | tarily displayed.<br>ds for the full 15-   |

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.<br>VALUE | REQUIREMENT | PASS<br>/ FAIL |
|------------------|----------------|-------------|----------------|
|------------------|----------------|-------------|----------------|

# Functional Testing in Startup Mode:

| Power On Self Tests<br>(POST) | The ventilator:                               |  |
|-------------------------------|---|--|
|                               | Powers up                                     |  |
|                               | Performs POST                                 |  |
|                               | Displays model name or p/n, then Same Patient |  |
| Button Test                   | Correct messages for each control displayed:  |  |
| Circuit Test                  | Passed is displayed                           |  |

#### Functional Testing in Normal Ventilation Mode:

| Battery/Power Tests Push & hold Battery/Power <b>Check</b> button.  | Displayed messages are consistent with ventilator/power accessories configuration and no "Fault" messages displayed | yed.     |
|---|---|----------|
|   | Batt % (Removable Battery Pack)   |          |
|   | Ext (External DC Power)   |          |
|   | Dock (Docking Station Power)  |          |
|   | T-Bat (Transition Battery)  |          |
| Display/Alarm Tests Push Battery/Power <b>Check</b> button.   | Display / LEDs illuminate as specified, audible alarm syste sounds, and no "Fault" messages are displayed           | em       |
|   | Front Panel   |          |
|   | Lower Interface Panel   |          |
|   | Two audible tones & High Priority Alarm signal  |          |
| Alarm Response Tests  | Control values set as specified, and no alarms activated  |          |
| Configure ventilator settings:  | Selected Monitors should read as follows:   | <u> </u> |
| Breath Mode: A/C  |   |          |
| Breath Type: Volume   | Vte: Vte 383 to 633 ml  |          |
| Breath Rate: 12<br>Tidal Volume: 500  | I:E Ratio: I:E 1:3.8 to 1:4.2   |          |
| Insp. Time:   | Breath Rate: f 12 bpm   |          |
| Pres. Support: ""   | '   |          |
| <b>O</b> <sub>2</sub> : 21  | VE: <b>VE 4.6</b> to <b>7.6</b> L   |          |
| Sensitivity: 3  | Lower Interface Panel LED Status:   |          |
| Low PEEP Alarm: "" PEEP: 0  | External Power: Green   |          |
| High Pres. Limit: 100   | Battery Pack: Off   |          |
| Low Pk. Pres. 5 Low Min Vol: 1  | Transition Batt.: Off   |          |
| Set the O2 control to 22%.  | Low O <sub>2</sub> Pres alarm activates   |          |
| Return <b>O</b> <sub>2</sub> to 21% and reset the alarm.<br>Set the <b>Low Min. Vol.</b> alarm to 10 L.   | Low Min Vol alarm activates   |          |
| Return the <b>Low Min. Vol.</b> alarm to 1.0 and reset the alarm.  Set the <b>Low Pk. Pres.</b> alarm to 10 cmH <sub>2</sub> O above Peak Inspiratory Pressure (PIP). | Low PeakPres alarm activates  |          |

| TEST DESCRIPTION   | MEAS.<br>VALUE | REQUIREMENT   | PASS<br>/ FAIL |
|--|----------------|---|----------------|
| Return the <b>Low Pk</b> . <b>Pres</b> . alarm to 5 and reset the alarm. Set the <b>High Pres</b> . <b>Limit</b> alarm to 10 cmH <sub>2</sub> O below the PIP displayed.   |                | High Pres alarm activates   |                |
| Return the <b>High Pres</b> . <b>Limit</b> alarm to 100 and reset the alarm.   |                |   |                |
| Connect 40 to 88 PSI O <sub>2</sub> to the unit and set  |                | No alarms activate  |                |
| the <b>O</b> <sub>2</sub> control to 60. Connect and enable an FIO <sub>2</sub> Sensor and set the <b>Low FIO</b> <sub>2</sub> <b>Alarm</b> to 54% or connect an external O <sub>2</sub> monitor to the patient circuit. |                | FIO <sub>2</sub> Sensor or external oxygen monitor reads: 55 to 65% O <sub>2</sub> +/- the tolerances of the external oxygen monitor. |                |
| Return the $O_2$ control to 21%, disable and disconnect the Fio <sub>2</sub> Sensor or external oxygen monitor. Disconnect the High Pressure Sense Line from the ventilator.   |                | Pat Circuit alarm activates on the next breath  |                |
| Reconnect Sense Line and reset the alarm.  |                |   |                |
| Disconnect the Low Pressure Sense line from the ventilator.  |                | Pat Circuit alarm activates on the next breath  |                |
| Reconnect Sense Line and reset the alarm.  |                |   |                |
| Change ventilator settings as follows:  Breath Type: Pressure  |                | No alarms activate  |                |
| Pres. Control: 40  |                | Selected Monitors should read as follows:   | 1              |
| High PEEP Alarm: 25  |                | PIP: PIP 54 to 66 cmH <sub>2</sub> O  |                |
| PEEP: 20<br>Rise Time: 4   |                | PEEP: PEEP 18 to 22 cmH <sub>2</sub> O  |                |
| Disconnect external power source.  |                | Ext Pwr Lost alarm activates.  Dock Discon 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) and take out Removable Battery Pack for one (1) minute.   |                | Insert Batt then T-Batt Use alarms display  |                |
| (1)  |                | Lower Interface Panel LED Status:   | I              |
|  |                | External Power: Off   |                |
|  |                | Battery Pack: Flashing Red Transition Batt.: Green  |                |
|  |                | Transition Batt.: Green Battery Charger: Off  |                |
|  |                | Ventilator continues to operate   |                |
| Insert Removable Battery Pack, connect   |                | No alarms activate  |                |
| external power source and reset all alarms.  |                | Lower Interface Panel LED Status:   | <u> </u>       |
|  |                | External Power: Green   |                |
|  |                | Battery Pack: Off   |                |
|  |                | Transition Batt.: Off   |                |
|  |                | Battery Charger: Off, green, amber, or flashing amber   |                |
|  |                | Ventilator continues to operate   |                |
| Turn the ventilator off. Observe the ventilator  |                | Saving Config is momentarily displayed.   |                |
| for at least 15 seconds and reset alarm.   |                | Vent Inop audible alarm sounds for the full 15-seconds  |                |
|  |                | Vent Inop LED flashes for the full 15-seconds   |                |

# **Chapter 3 - USING THE VENTILATOR**

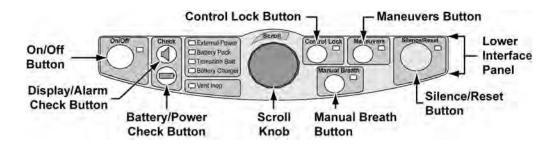
# **User Interface(s)**

This section describes the three main user interfaces utilized by the Revel<sup>™</sup> ventilator:

| Lower Interface Panel<br>Push Buttons | Used to power the ventilator on or off, silence/reset audible alarms, check/test displays, alarms and power, or initiate specific procedures or maneuvers.         |
|---------------------------------------|--|
| Lower Interface Panel<br>Scroll Knob  | Used to change selected feature configurations, ventilation control or alarm limit values, and scroll through monitored data, Startup and Extended Features menus. |
| Front Panel<br>Push Buttons           | Used to select and confirm most ventilation control and alarm limit values and Startup and Extended Features menus.  |

# The Lower Interface Panel

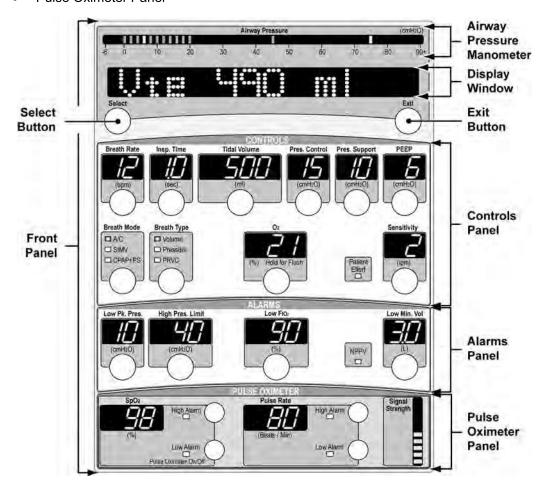
For detailed descriptions of each individual control's function and complete instructions for their use, see *Lower Interface Panel* in Chapter 5 - Controls.



# **The Front Panel**

The front panel consists of five main areas:

- Airway Pressure Manometer
- Display Window (with associated Select and Exit buttons)
- Controls Panel
- Alarms Panel
- Pulse Oximeter Panel



For detailed descriptions of each individual display, control and alarm function, see:

- Airway Pressure Manometer and Display Window in Chapter 6 Displays and Indicators
- Front Panel, Display Window, Front Panel, Controls, Front Panel, Alarms and Front Panel, Pulse Oximeter in Chapter 5 Controls

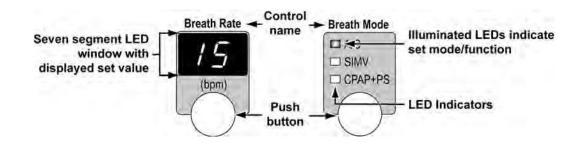
#### Front Panel Ventilation and Alarm Controls

There are three main types of ventilation and alarm controls on the Revel  $^{\text{\tiny TM}}$  front and lower interface panels:

- Adjustable Controls
- Push Buttons
- Scroll Knob

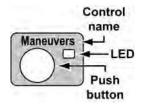
### Adjustable Controls

Ventilation and alarm controls that have segmented LED front panel displays, or LED indicators with an associated push button. The ventilation settings and alarm values displayed or modes/functions indicated can be modified within a preset range.



#### **Push Buttons**

Momentary push buttons (with or without associated displays or LED indicators) used to select and confirm settings and options, or initiate a pre-determined function.



#### Scroll Knob

A rotary encoder knob on the lower interface panel used to change the settings of selected adjustable controls, or scroll through various configuration menus displayed in the front panel display window.



# **Display Characteristics**

### Bright, Dim and Blank Segmented LED Control Displays

Variable control segmented LED displays can be illuminated at normal or dimmed intensity, or may be blank (extinguished).

#### An LED display is illuminated at normal intensity:

- When it is active in the current ventilation mode. Dimmed displays are not active in the current mode
- When it is selected for change. All other displays will be dimmed

#### An LED display illumination is dimmed:

- When another control is selected for change
- When it is not active in the current ventilation mode

#### **WARNING**

**Apnea Backup Controls** - Be sure to set any controls used in Apnea Backup ventilation to appropriate values for your patient. Even though the associated displays are dimmed during normal ventilation, they will be used if Apnea should occur.

#### An LED display is blank:

- To conserve battery power when operating on the Transition Battery (to turn the displays back on, push any button or rotate the Scroll knob)
- When a control feature is not available, such as during ventilator checkout tests
- When the sensor for an installed option, such as SpO<sub>2</sub>, is not connected to, or communicating with the ventilator

# Flashing LEDs

LED displays/indicators associated with adjustable controls may display solid or flashing. A flashing display/indicator means one of the following things:

- If a control's segmented LED display is flashing, you have reached the upper or lower limit for the control, or a special condition such as the time termination of a Pressure Support breath has occurred. Control limiting is discussed in this section, for Time Termination see *Chapter 5 - Controls*
- If a control's LED indicator is flashing, it indicates that the control has been selected within the last 15 seconds and the indicated mode or function (changed or not) has not yet been confirmed
- If the Control Lock LED indicator is flashing, the ventilator's controls are locked and the On/Off, or a ventilation or alarm control button has been pushed within the last 5 seconds. For more information, see Chapter 5 Controls
- If an alarm's segmented LED display is flashing, it indicates that an alarm has occurred or is occurring. See *Chapter 8 Ventilator Alarms* for more information

# Dashes Displayed

When dashes ("--") are displayed in a control's segmented LED display, it's an indication that the associated control or alarm is turned off.

# Setting Adjustable Front Panel Ventilation Controls and Alarm Limits

Most of the ventilators' front panel adjustable ventilation and alarm limit controls use a simple three step method of "Select, Change and Confirm" to set configuration values.

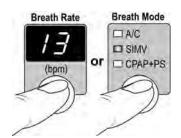
#### Select

Select the active control to be changed by pushing its associated control push button.

 Controls with segmented LED displays – The displays remain at full intensity and all other active control displays are dimmed

or

Controls with LED indicators – The LED indicator begins flashing



#### Change

Change the displayed value or indicator illuminated by rotating the **Scroll** knob on the lower interface panel.



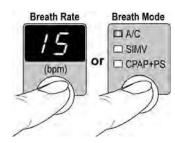
#### Confirm

Confirm the change by pushing the associated control push button again.

 Controls with segmented LED displays – All other active control displays return to their full intensity and the ventilator accepts the new setting

or

 Controls with LED indicators – The LED indicator stops flashing and the ventilator accepts the new setting



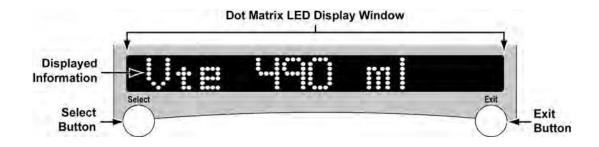
#### **NOTE**

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

Pushing a control button while another control is already selected de-selects the previous control without changing its value, mode, or function. You must confirm a change, by pushing the associated control button a second time, before the ventilator accepts a new value, mode, or function.

# Automatic or Manual Data Display Scrolling

Monitored data displays may be automatically or manually scrolled in the front panel display window during normal ventilation modes. When automatically scrolled, each value is displayed for three seconds and is updated in real time.



1) To pause automatic scrolling of displayed data, push the **Select** control button and scrolling will halt on the data currently displayed.



2) To cycle through data manually from a halted scan, rotate the **Scroll** knob on the lower interface panel to increment the display.



#### **NOTE**

You cannot manually scroll through monitored data while in the Extended Features menus.

3) Push the **Exit** control button to resume auto-scrolling in normal ventilation mode.

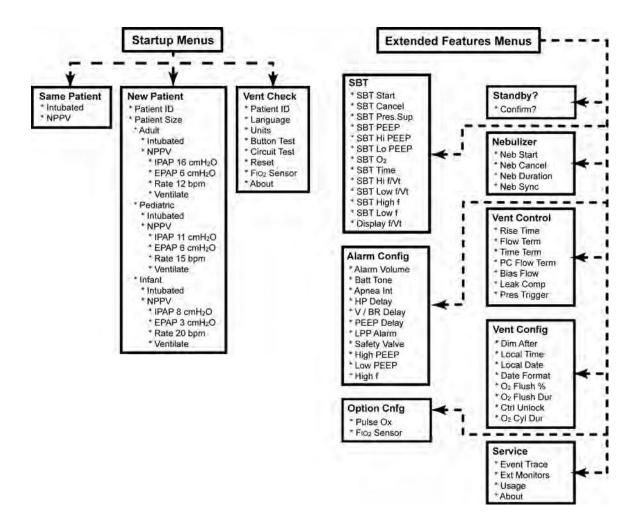


For additional information concerning monitored data displayed, see Chapter 7 - Monitored Data.

# **Navigating Startup and Extended Features Menus**

When displayed in the front panel display window, Startup and Extended Features menus provide access to controls, monitors, features and options that do not have dedicated front panel controls or displays.

• For additional information concerning these menus, see *Startup Mode and Menus* later in this chapter and *Extended Features Menus* in Chapter 10 – Extended Features.



#### NOTE

Startup menus are only displayed and accessed when the ventilator is initially turned on and the ventilator is in Startup mode.

Extended Features menus are only displayed and accessed while the ventilator is in a normal ventilation mode. Extended Features menus cannot be accessed when the front panel controls are locked.

# To Enter and View Startup Menus

To enter Startup menus while the ventilator is in Startup mode, rotate the **Scroll** knob on the lower interface panel until the desired menu is displayed (e.g. **Same Patient**, **New Patient** or **Vent Check**) and push the **Select** control button.

- To view the next menu item, rotate the Scroll knob clockwise
- To view the previous menu item, rotate the Scroll knob counterclockwise





# To Access, Enter and View Extended Features Menus

1) To access Extended Features menus while the ventilator is in a normal ventilation mode, push and hold the **Select** control button for three seconds.



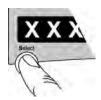
- 2) To enter a displayed Extended Features menu, rotate the Scroll knob on the lower interface panel until the desired menu is displayed (e.g. Standby, SBT, Nebulizer, Alarm Config, Vent Control, Vent Config, Option Cnfg, or Service) and push the Select control button.
  - To view the next menu item, rotate the Scroll knob clockwise
  - To view the previous menu item, rotate the Scroll knob counterclockwise





# To Select, Change and Set Startup or Extended Features Control Values and Feature Configurations

- 1) To select an Extended Features displayed control value or feature configuration, push the **Select** control button.
- 2) To change the control value or feature configuration of a selected menu item, rotate the **Scroll** knob until the desired value or feature configuration is displayed and push the **Select** control button. The new value or configuration is accepted and the previous menu item is displayed.







# To Exit Startup or Extended Features Menus

#### Startup Menus

To exit a selected Startup menu once entered, push the **Exit** button (repeatedly, as necessary) until the desired previous menu or **Same Patient** is displayed.

#### **Extended Features Menus**

To exit a selected Extended Features menu once entered, push the **Exit** button (repeatedly, as necessary) until the desired previous menu is displayed, or auto-scrolling of monitored data is resumed.

#### **NOTE**

You can select and configure a different menu item at any point during the exit sequence.

# Starting the Ventilator

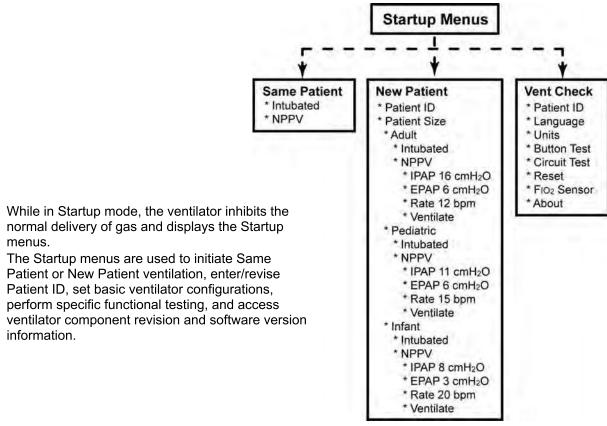
With the ventilator powered off, push the **On/Off** button on the lower interface panel momentarily. The ventilator powers up, performs POST (Power On Self Test), briefly displays **Revel** followed by **Same Patient**.



# **Startup Mode and Menus**

# **WARNING**

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

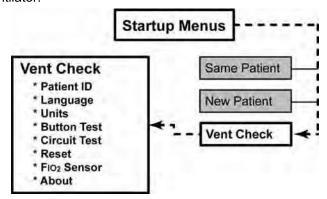


# To Exit Startup Mode

Startup mode can be exited by entering a normal ventilation mode via the **Same Patient** and **New Patient** menus, or by turning the ventilator off by pushing and holding down the **On/Off** button on the lower interface panel.

### To View Patient ID

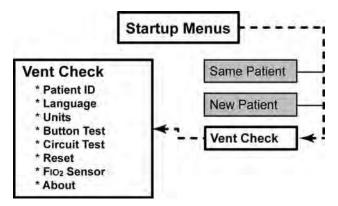
The Vent Check, Patient ID menu is used to view the current patient identification number (if any) entered into the ventilator.



- 1) While in Startup mode, rotate the **Scroll** knob until **Vent Check** is displayed, push the **Select** button and reset the Remove Patient alarm (!!! **Remove Ptnt**) by pushing the Silence/Reset button twice. **Patient ID** is displayed.
- 2) Push the **Select** button and the last patient identification number entered is displayed.
  - 12 dashes are displayed if a patient identification number has not been entered

# To Set Language and Units

The Vent Check, Language and Units menus are used to set the language and units of measure used and displayed by the ventilator. Changing these settings will have a universal affect on the language and units of measure displayed.



- 1) While in Startup mode, rotate the **Scroll** knob until **Vent Check** is displayed, push the **Select** button and reset the Remove Patient alarm (!!! **Remove Ptnt**) by pushing the Silence/Reset button twice. **Patient ID** is displayed.
- 2) Rotate the **Scroll** knob until the **Language** or **Units** menu is displayed (as desired), push the **Select** button and the applicable current configuration setting for language (e.g. **English**<sup>14</sup>), or the unit of measure (e.g. **cmH**<sub>2</sub>**O** / **PSI**<sup>15</sup>) is displayed.
- 3) Rotate the **Scroll** knob until the desired language or unit of measure is displayed, push the **Select** button, the change is accepted and the previous menu (**Language** or **Units**) is displayed.

<sup>&</sup>lt;sup>14</sup> The **Language** menu options are presently fixed at **English**.

<sup>&</sup>lt;sup>15</sup> The **Units** menu options are presently fixed at **cmH₂O / PSI**.

# To Perform Functional Testing (Button and Circuit Test)

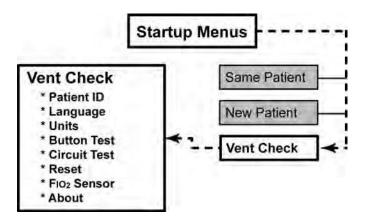
To perform functional testing in Startup mode (Button or Circuit Test), see *Functional Testing in Startup Mode* in Chapter 2 – Installation and Checkout for detailed instructions.

 See Maintenance Schedule in Chapter 11 – Maintenance and Cleaning for recommended periodic maintenance and testing schedules

### To Reset to Default Values

The Vent Check, Reset menu is used to reset all adjustable controls, alarms and configuration settings, with the exception of the Language, Units, Date/Time settings, Patient ID, and Fio<sub>2</sub> calibration and Circuit Test results, to their original factory-set default values.

 See Factory Settings in Appendix C - Reference Information for a complete list of the original factory-set configuration values



### **NOTE**

Using the **Reset** menu/function can have a universal affect on the basic configuration of the ventilator (e.g. ventilation mode used, ventilation controls and alarm limits settings, etc.).

- 1) While in Startup mode, rotate the **Scroll** knob until **Vent Check** is displayed, push the **Select** button and reset the Remove Patient alarm (!!! **Remove Ptnt**) by pushing the Silence/Reset button twice. **Patient ID** is displayed.
- 2) Rotate the **Scroll** knob until **Reset** is displayed, push the **Select** button and **Confirm**? is displayed.
- 3) To confirm resetting the ventilator's adjustable controls, alarms and configuration settings to factory-set default values, push the **Select** button, **ConfigReset** is displayed and the settings changes are accepted. Push the **Exit** button twice to display the **Reset** menu.

or

To cancel resetting the ventilator's adjustable controls, alarms and configuration settings to factory-set default values and exit the **Confirm?** menu option, push the **Exit** button and **Reset** is displayed.

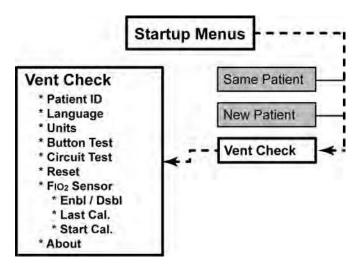
# FIO<sub>2</sub> Sensor Configuration and Calibration

The Vent Check, FIO<sub>2</sub> Sensor menus are used to enable or disable ventilator communication with an FIO<sub>2</sub> sensor, view the date of the last successful calibration, and calibrate the sensor.

- Contact CareFusion for oxygen sensor part numbers and pricing information. See
   Appendix A Contact Information for contact and ordering information
- To assemble the FiO<sub>2</sub> Sensor Assembly and insert it into the patient circuit (after calibration), see the Instructions for Use provided with the FiO<sub>2</sub> Sensor assembly

Once setup, enabled and calibrated, communication with the FIO<sub>2</sub> sensor may be enabled/disabled during normal ventilation modes using the Extended Features menus.

See FIO2 SENSOR in the Extended Features, Option Cnfg menus in Chapter 10 –
Extended Features for additional information



# To Enable or Disable FIO<sub>2</sub> Monitoring

- 1) While in Startup mode, rotate the **Scroll** knob until **Vent Check** is displayed, push the **Select** button and reset the Remove Patient alarm (!!! **Remove Ptnt**) by pushing the Silence/Reset button twice. **Patient ID** is displayed.
- 2) Rotate the **Scroll** knob until **Fio**<sub>2</sub> **Sensor** is displayed, push the **Select** button and **Enbl** / **Dsbl** is displayed.
- 3) Push the Select button and either Enable or Disable is displayed. If necessary, rotate the Scroll knob until the desired menu is displayed and push the Select button again. The selected communication status is set and Enbl / Dsbl is displayed.

# To View Last Successful FIO<sub>2</sub> Calibration

- 1) While in Startup mode, rotate the **Scroll** knob until **Vent Check** is displayed, push the **Select** button and reset the Remove Patient alarm (!!! **Remove Ptnt**) by pushing the Silence/Reset button twice. **Patient ID** is displayed.
- 2) Rotate the **Scroll** knob until **Fio**<sub>2</sub> **Sensor** is displayed, push the **Select** button and **Enbl** / **Dsbl** is displayed.
- 3) Rotate the **Scroll** knob until **Last Cal.** is displayed, push the **Select** button and the date of the last successful FiO<sub>2</sub> sensor calibration is displayed.
  - \_\_\_/ \_\_ is displayed if no previous successful calibration data is available

# To Calibrate the FIO<sub>2</sub> Sensor

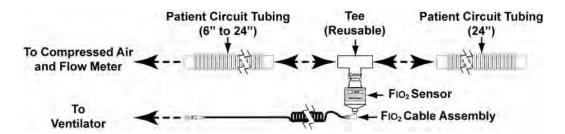
The Vent Check,  $F_{1O_2}$  Sensor menus are used to perform a two-point (21% and 100%  $O_2$ ) calibration of an attached  $F_{1O_2}$  Sensor.

### WARNING

**Calibration of Sensor** - Accurate monitored  $F_{1O_2}$  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  $F_{1O_2}$  monitor reading, recalibrate the  $F_{1O_2}$  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<sub>2</sub> 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<sub>2</sub> sensor assembly for detailed instructions
- 2) Attach the F<sub>1O2</sub> 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<sub>2</sub> Sensor calibration, clear the alarm by pushing the Silence/Reset button two times. The FiO<sub>2</sub> Sensor calibration is not interrupted if the alarm occurs.

- 5) Turn the ventilator on and enter the Startup mode, **Vent Check** menu, as previously described, then rotate the **Scroll** knob until **Fio**<sub>2</sub> **Sensor** is displayed, push the **Select** button and **Enbl / Dsbl** is displayed.
- 6) Push the **Select** button and either **Enable** or **Disable** is displayed. If necessary, rotate the **Scroll** knob until **Enable** is displayed and push the **Select** button again.
  - Communication with the F<sub>1O2</sub>sensor is enabled and **Enbl / Dsbl** is displayed
- 7) Rotate the **Scroll** knob until **Start Cal.** is displayed, push the **Select** button and **Apply 21% O**<sub>2</sub> is displayed in the front panel display window.



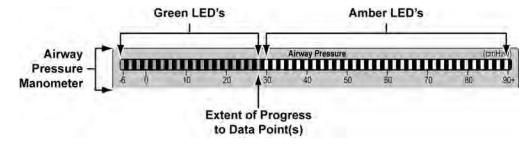
8) Expose the Fio<sub>2</sub> Sensor to 21% O<sub>2</sub> (compressed air source) for up to five (5) minutes using a Flow Meter and apply 3 to 10 lpm (nominal 5 lpm) through the patient Circuit past the Fio<sub>2</sub> sensor until the displayed message changes to **Apply 100% O<sub>2</sub>**, then push the **Select** button.

### NOTE

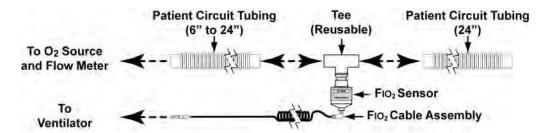
It is important to expose the sensor to 21% and  $100\% O_2$  without an increase in pressure. Enclosing the sensor (for example in a bag) to apply the gas may increase pressure and cause inaccuracies in the calibration.

While the ventilator is processing the data, the LED's in the Airway Pressure Manometer at the top of the front panel are fully illuminated (amber) and progress toward the 21% data point is illuminated by green LED's (left to right).

When completed, **Apply 100% O<sub>2</sub>** is displayed in the front panel display window.



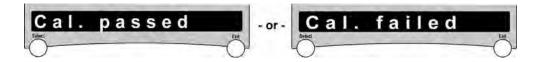
9) When **Apply 100% O<sub>2</sub>** is displayed, disconnect the patient circuit tubing from the source of compressed air and reattach it to a flow metered source of 100% oxygen (O<sub>2</sub>), also set for a flow of 5 lpm (range 3 to 10 lpm).



10) Turn the source of oxygen (O<sub>2</sub>) on, exposing the sensor to a 5 lpm (range 3 to 10 lpm) of flow until the displayed message changes to **Cal. passed** or **Cal. failed** (this also, may take up to five (5) minutes).

Again, while the ventilator is processing the data, progress toward the 100% data point is displayed in the Airway Pressure Manometer.

11) When completed, either **Cal. passed** or **Cal. failed** is displayed in the front panel display window.



If **Cal. passed** is displayed, the most recent successful FiO<sub>2</sub> Sensor calibration date is updated to the current date, and the calibration process is complete.

or

If Cal. failed is displayed, calibration failed and must be performed again.

### NOTE

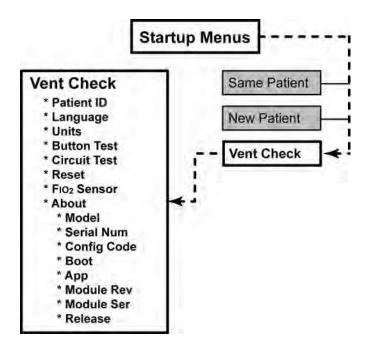
When calibration fails, it is possible that the sensor is bad. Try calibrating another sensor with the ventilator. If you are unable to calibrate the second sensor, contact CareFusion or a service technician certified by CareFusion for assistance.

To ensure accurate  $FlO_2$  measurements, the  $FlO_2$  Sensor must be calibrated to the ventilator upon initial ventilation of a new patient and if  $FlO_2$  measurements become inaccurate based on the  $\mathbf{O}_2$  ventilator setting.

# To View Ventilator, Component and Software Configuration Information

The Vent Check, About menus are used to view specific information not accessible on the front panel, including the ventilator model name, serial number, and hardware/software versions.

 The About menu and related sub-menus/information is also available during normal ventilation via the Extended Features menus. See *About* in Chapter 10 – Extended Features for detailed information



- 1) While in Startup mode, rotate the **Scroll** knob until **Vent Check** is displayed, push the **Select** button and reset the Remove Patient alarm (!!! **Remove Ptnt**) by pushing the Silence/Reset button twice. **Patient ID** is displayed.
- 2) Rotate the **Scroll** knob until **About** is displayed, push the **Select** button and **Model** is displayed.
- 3) Rotate the **Scroll** knob to view the available sub-menus, push the **Select** button to view the related information of displayed menus and the **Exit** button to return to the previous menu(s).

# **Normal Ventilation Modes**

After turning the ventilator on and silencing/resetting the alarm (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 ventilation controls and alarm configurations/limits automatically set to initial values clinically appropriate for a new patient (**New Patient**).

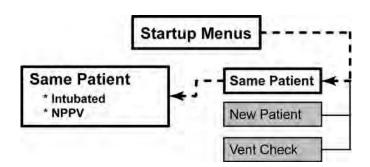
 See Presets Values for Ventilation Controls and Presets Values for Alarm Configurations/Limits later in this chapter for additional information

# **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

The Same Patient menus are used to initiate ventilation using the ventilation control and alarm configurations/limits settings that were in effect the last time the ventilator was powered down.



### **NOTE**

When a **ConfigReset** alarm has been generated or an operator has utilized the **Reset** control, all user adjustable settings (except Language, Units, Local Date, Local Time/Date Format, Patient ID and FIO<sub>2</sub> calibration, and Circuit Test results) are reset to the original factory-set default values. Selecting the **Same Patient** button/option will <u>not</u> restore the previous patient settings.

- 1) While in Startup mode, rotate the **Scroll** knob until **Same Patient** is displayed, push the **Select** button and **Intubated** is displayed.
- 2) To select an intubated type of patient circuit to patient interface and initiate ventilation, push the **Select** button.

or

To select a non-invasive type of patient circuit to patient interface and initiate ventilation, rotate the **Scroll** knob until **NPPV** is displayed and push the **Select** button.

### **NOTE**

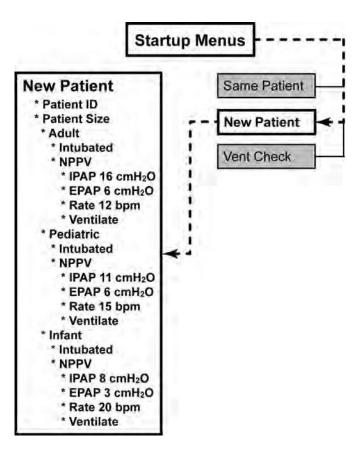
When the Same Patient menu is selected in Startup mode and;

- If the ventilator to patient interface selected is Intubated and the previous setting was NPPV, the Breath Mode and Breath Type will be set to their last selected / preset Intubated interface settings
- If the ventilator to patient interface selected is NPPV and the previous setting was
   Intubated, the Breath Mode will be set to CPAP+PS and the Breath Type will be set to
   Pressure

# To Initiate Normal Ventilation Modes Using Presets Settings

The Presets<sup>16</sup> feature allows operators to use the New Patient menus to enter a patient ID number, set patient size and type of patient circuit to patient interface, and initiate ventilation using ventilation controls and alarm configurations/limits automatically set to initial values clinically appropriate for a new patient.

 See Presets Values for Ventilation Controls and Presets Values for Alarm Configurations/Limits later in this chapter for additional information

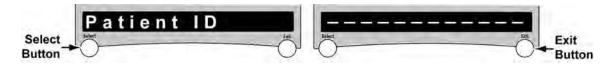


Presets – Automatically set ventilation control and alarm limit values initially clinically appropriate for the patient size and patient circuit type selected by the operator during ventilator setup for a New Patient.

# To Enter a Patient Identification Number (optional)

The New Patient, Patient ID menu is used to enter an up to 12 character patient identification number (if desired).

- To proceed to the next menu item without entering a Patient ID number, simply rotate the Scroll knob until Patient Size is displayed
- While in Startup mode, rotate the Scroll knob until New Patient is displayed, push the Select button and Patient ID is displayed. Push the Select button again and twelve (12) dashes are displayed.



2) Push the **Select** button again and the first dash in the patient identification display begins flashing. Rotate the **Scroll** knob until the desired number or dash is displayed and push the **Select** button to confirm the selection.

The displayed number or dash is accepted (stops flashing) and the next dash to the right begins flashing.

Range: Each of the 12 spaces will accept numeric (**0** through **9**) digits, or a " – " (dash).

- 3) Repeat the process of rotating the **Scroll** knob and pushing the **Select** button to fill each of the 12 available character spaces with a number or dash, as desired.
  - To cancel Patient ID editing, push the Exit button at any time prior to setting the 12<sup>th</sup> (final) character. The previous Patient Identification is restored and the Patient ID menu is displayed



4) When all spaces have been edited, push the **Select** button again to accept the new patient identification, exit the Patient ID edit mode and display the **Patient ID** menu.

#### To Set the Patient Size

The New Patient, Patient Size menus are used to set the patient size to be used by the ventilator to calculate ventilation control and alarm configurations/limits to initial values clinically appropriate for a new patient of the selected size/weight.

- While in Startup mode, rotate the Scroll knob until New Patient is displayed, push the Select button and Patient ID is displayed.
  - Rotate the **Scroll** knob again, **Patient Size** is displayed, push the **Select** button and **Adult** is displayed.
- 2) Rotate the **Scroll** knob (if necessary) until the applicable patient size is displayed and push the **Select** button.

Range: Adult (>40 kg), Pediatric (10-40 kg), or Infant (5-10 kg)

# To Set the Type of Patient Circuit to Patient Interface and Initiate Ventilation

The New Patient, Intubated or NPPV menus are used to set the type of patient circuit to patient interface to be used by the ventilator to calculate ventilation control and alarm configurations/limits to initial values clinically appropriate for the type of interface selected.

- 1) When the applicable patient size menu (Adult, Pediatric, or Infant) has been displayed and selected (Select button pushed), Intubated is displayed.
- 2) To select an intubated type of patient circuit to patient interface and initiate ventilation, continue; otherwise skip to the next step.
  - When **Intubated** is displayed, push the **Select** button, the ventilator clears the existing Patient ID, Trend data<sup>17</sup>, Maneuvers history, accepts the new settings and begins a normal ventilation mode using the Presets ventilation control and alarm configurations/limits values associated with the patient size and type of patient circuit to patient interface settings selected.
- 3) To select a non-invasive type of patient circuit to patient interface when **Intubated** is displayed, rotate the **Scroll** knob until **NPPV** is displayed, push the **Select** button and **IPAP xx cmH<sub>2</sub>O** is displayed.
- 4) To change the displayed default Inspiratory Positive Airway Pressure (IPAP) value, continue; otherwise skip to the next step.

When the default IPAP value is displayed, push the **Select** button (all but the numeric value of the displayed message is dimmed), rotate the **Scroll** knob until the desired value is displayed and push the **Select** button. The new IPAP value is accepted and **EPAP x cmH<sub>2</sub>O** is displayed.

The actual default IPAP numeric value initially displayed is dependent on the patient size previously selected;

Adult default IPAP value: 16 cmH<sub>2</sub>O, Adjustable Range: 6 to 60 cmH<sub>2</sub>O
 Pediatric default IPAP value: 11 cmH<sub>2</sub>O, Adjustable Range: 6 to 60 cmH<sub>2</sub>O
 Infant default IPAP value: 8 cmH<sub>2</sub>O, Adjustable Range: 3 to 60 cmH<sub>2</sub>O

5) To accept the displayed IPAP value, rotate the **Scroll** knob until **EPAP x cmH₂O** is displayed.

-

<sup>&</sup>lt;sup>17</sup> Trend data stored by the Revel ventilator can be displayed on a PTM™ Graphics Monitor when the ventilator is docked to a PTV<sup>®</sup> Series Docking Station with an attached PTM™ Graphics Monitor.

6) To change the default Expiratory Positive Airway Pressure (EPAP) value, continue; otherwise skip to the next step.

When the default EPAP value is displayed, push the **Select** button (all but the numeric value of the displayed message is dimmed), rotate the **Scroll** knob until the desired value is displayed and push the **Select** button. The adjusted EPAP value is accepted and displayed.

The actual default EPAP numeric value initially displayed is dependant on the patient size previously selected;

- Adult default EPAP value: 6 cmH<sub>2</sub>O, Adjustable Range: 0 to 16 cmH<sub>2</sub>O
- Pediatric default EPAP value: 6 cmH<sub>2</sub>O, Adjustable Range: 0 to 11 cmH<sub>2</sub>O
- Infant default EPAP value: 3 cmH₂O, Adjustable Range: 0 to 8 cmH₂O
- 7) To accept the displayed EPAP value, rotate the **Scroll** knob until **Rate xx bpm** is displayed.
- 8) To change the displayed default breath rate (Rate) value, continue; otherwise skip to the next step.

When the default Rate value is displayed, push the **Select** button (all but the numeric value of the displayed message is dimmed), rotate the **Scroll** knob until the desired value is displayed and push the **Select** button. The adjusted Rate value is accepted and displayed.

The actual default Rate numeric value initially displayed is also dependant on the patient size previously selected;

Adult default Rate value:
 Pediatric default Rate value:
 Infant default Rate value:
 20 bpm, Adjustable Range:
 0 to 80 bpm
 20 bpm, Adjustable Range:
 0 to 80 bpm

- 9) To accept the displayed Rate value, rotate the **Scroll** knob until **Ventilate** is displayed.
- 10) To <u>retain the prior</u> Patient ID, Trend data, Maneuvers history and <u>cancel the new settings</u>, continue; otherwise skip to the next step.

Push the **Exit** button repeatedly until either the **New Patient** or **Same Patient** menu is displayed (as desired) and repeat the process of initiating ventilation from the beginning of this section.

or

Push and hold down the **On/Off** button on the lower interface panel until the ventilator powers down.

11) To <u>clear the prior</u> Patient ID, Trend data, Maneuvers history, <u>accept the new settings</u> and begin normal ventilation using the Presets configuration values as shown in the tables on the following pages, push the **Select** button when **Ventilate** is displayed.

#### NOTE

The Presets  $O_2$  control value is 40%. Consequently, a Low  $O_2$  Pres alarm is generated and must be reset in order to proceed when the ventilator begins normal ventilation.

12) When the !! Low O<sub>2</sub> Pres alarm message is displayed, push the Silence/Reset button twice on the lower interface panel to reset the alarm (temporarily silence the sounder and clear the alarm message).

### **Presets Values for Ventilation Controls**

| Controls                 | Infant<br>(5-10 kg)    | Pediatric<br>(10-40 kg) | Adult<br>(>40 kg)      |
|--------------------------|------------------------|-------------------------|------------------------|
| Bias Flow                | 3 lpm                  | 5 lpm                   | 5 lpm                  |
| Breath Mode              | Assist/Control         | Assist/Control          | Assist/Control         |
| Breath Rate              | 20 bpm                 | 15 bpm                  | 12 bpm                 |
| Breath Type (Intubated)  | Pressure <sup>18</sup> | Pressure <sup>18</sup>  | Volume <sup>18</sup>   |
| Breath Type (NPPV)       | Pressure <sup>19</sup> | Pressure <sup>19</sup>  | Pressure <sup>19</sup> |
| EPAP (NPPV Only)         | 3 cmH <sub>2</sub> O   | 6 cmH <sub>2</sub> O    | 6 cmH₂O                |
| Flow Term                | 35 %                   | 25 %                    | 25 %                   |
| Insp. Time               | 0.3 sec                | 0.7 sec                 | 1.0 sec                |
| IPAP (NPPV Only)         | 8 cmH₂O                | 11 cmH <sub>2</sub> O   | 16 cmH <sub>2</sub> O  |
| Leak Comp                | On                     | On                      | On                     |
| O <sub>2</sub>           | 21 %                   | 21 %                    | 21 %                   |
| O <sub>2</sub> Flush %   | +20 %                  | +79 %                   | +79 %                  |
| O <sub>2</sub> Flush Dur | 2 min                  | 3 min                   | 3 min                  |
| PC Flow Term             | Off                    | Off                     | Off                    |
| PEEP                     | 3 cmH <sub>2</sub> O   | 6 cmH₂O                 | 6 cmH₂O                |
| Pres. Control            | 15 cmH <sub>2</sub> O  | 15 cmH₂O                | 15 cmH <sub>2</sub> O  |
| Pres. Support            | 5 cmH₂O                | 5 cmH <sub>2</sub> O    | 10 cmH <sub>2</sub> O  |
| Pres Trigger             | 3 cmH <sub>2</sub> O   | 3 cmH <sub>2</sub> O    | 3 cmH <sub>2</sub> O   |
| Rise Time                | 5                      | 3                       | 4                      |
| SBT O <sub>2</sub>       | 21 %                   | 21 %                    | 21 %                   |
| SBT PEEP                 | 3 cmH <sub>2</sub> O   | 6 cmH₂O                 | 6 cmH₂O                |
| SBT Pres.Sup             | 10 cmH <sub>2</sub> O  | 5 cmH <sub>2</sub> O    | 10 cmH <sub>2</sub> O  |
| SBT Time                 | 20 min                 | 20 min                  | 20 min                 |
| Sensitivity              | 2 lpm                  | 2 lpm                   | 2 lpm                  |
| Tidal Volume             | 50 ml                  | 250 ml                  | 500 ml                 |
| Time Term                | 0.5 sec                | 1.0 sec                 | 2.0 sec                |

# **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.

Refer to Chapter 5 - Controls for detailed information concerning all controls.

<sup>&</sup>lt;sup>18</sup> Presets Breath Type settings when **Intubated** patient circuit to patient interface selected during Startup.

<sup>&</sup>lt;sup>19</sup> Presets Breath Type settings when **NPPV** patient circuit to patient interface selected during Startup.

# **Presets Values for Alarm Configurations/Limits**

| Alarms                 | Infant<br>(5-10 kg)  | Pediatric<br>(10-40 kg) | Adult<br>(>40 kg)     |
|------------------------|----------------------|-------------------------|-----------------------|
| Apnea Int              | 20 sec               | 20 sec                  | 20 sec                |
| High f                 | 80 bpm               | 60 bpm                  | 40 bpm                |
| High PEEP              | 8 cmH <sub>2</sub> O | 11 cmH₂O                | 11 cmH <sub>2</sub> O |
| High Pres              | 30 cmH₂O             | 30 cmH₂O                | 40 cmH <sub>2</sub> O |
| HP Delay               | Delay 0 Brth         | Delay 0 Brth            | Delay 0 Brth          |
| Low FIO <sub>2</sub>   | 18 %                 | 18 %                    | 18 %                  |
| Low Min Vol            | 0.5 L                | 1.0 L                   | 3.0 L                 |
| Low PEEP               | 1 cmH <sub>2</sub> O | 3 cmH <sub>2</sub> O    | 3 cmH <sub>2</sub> O  |
| Low Pk Pres            | 10 cmH₂O             | 10 cmH₂O                | 10 cmH <sub>2</sub> O |
| LPP Alarm              | Control Only         | Control Only            | Control Only          |
| Pulse Rate, High Alarm | " <b></b> " (Off)    | " <b></b> " (Off)       | "" (Off)              |
| Pulse Rate, Low Alarm  | " <b></b> " (Off)    | " <b></b> " (Off)       | "" (Off)              |
| Safety Valve           | 10 cmH₂O             | 10 cmH₂O                | 10 cmH <sub>2</sub> O |
| SBT High PEEP          | 8 cmH <sub>2</sub> O | 11 cmH₂O                | 11 cmH <sub>2</sub> O |
| SBT Low PEEP           | 1 cmH₂O              | 3 cmH₂O                 | 3 cmH <sub>2</sub> O  |

# **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 *Alarms*, *Detailed Descriptions* in Chapter 8 - Ventilator Alarms for detailed information concerning all alarms.

# **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 and 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 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  $O_2$ % control and adjust the flow of the connected source. See  $O_2$  (Oxygen Percentage and Flush) in Chapter 5 – Controls.

# **WARNING**

**Inspired Oxygen (FIO<sub>2</sub>) Concentration** – If *exact concentrations* of inspired oxygen (FIO<sub>2</sub>) must be delivered to the patient, it is recommended that the optional FIO<sub>2</sub> Sensor or a separate oxygen analyzer with alarms be used. If using the optional FIO<sub>2</sub> Sensor set the ventilator Low FiO<sub>2</sub> alarm appropriately (see *Low FIO2* alarm in Chapter 8 –Ventilator Alarms for additional information).

- 4) Connect any optional accessories, such as an Fio<sub>2</sub> Sensor or SpO<sub>2</sub> Module and Sensor. See Optional Use Accessories Connection in Chapter 2 - Installation and Setup and Option Cnfg (Option Configuration) in Chapter 10 Extended Features for detailed instructions.
- 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 breath type and mode and set the controls to appropriate values for your patient. See *Breath Types*, *Breath Modes*, and in Chapter 4 Breath Types and Modes and *Front Panel*, *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 *Extended Features Menus* in Chapter 10 – Extended Features for detailed information.

### 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 Revel<sup>™</sup> ventilator.

- Inspiratory Hold
- Expiratory Hold

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

# **Procedures**

The following procedures can be performed on the Revel<sup>™</sup> ventilator;

- O<sub>2</sub> Flush
- Nebulization
- SBT (Spontaneous Breathing Trial)

See *Procedures* in Chapter 9 - Maneuvers and Procedures 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? (Standby mode) in Chapter 10 – Extended Features for detailed information and instructions.

# **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 **On/Off** LED is extinguished, the audible alarm sounds continuously and the **Vent Inop** LED begins flashing red.



3) Push the **Silence/Reset** 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 Revel $^{\text{TM}}$  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 Revel<sup>™</sup> ventilator provides the following breath types:

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

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 given. Breaths may be triggered by a patient demand, a push of the <b>Manual Breath</b> button, or by the ventilator based on the set <b>Breath Rate</b> 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 lpm -10%/+20% (applies to Volume breath types only)
- Maximum Spontaneous Peak Flow is 180 lpm (applies to all breath types except Volume)

## **NOTE**

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

See Sensitivity in Chapter 5 – Controls and Pres Trigger (Pressure Trigger) in Chapter 10 – Extended Features for additional information.

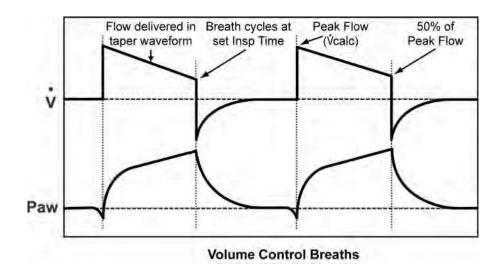
# Machine Breaths

Machine and Assist Breaths may be delivered as:

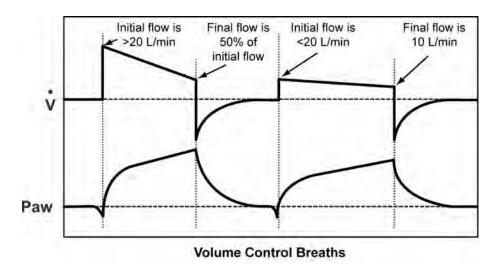
- Volume Control
- Pressure Control
- Pressure Regulated Volume Control (PRVC)

## **Volume Control Breaths**

In volume control breaths a set Tidal Volume is delivered over a set Inspiratory Time. Flow is delivered in a decelerating waveform. Peak flow is calculated based on the **Tidal Volume** and Inspiratory Time (**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.



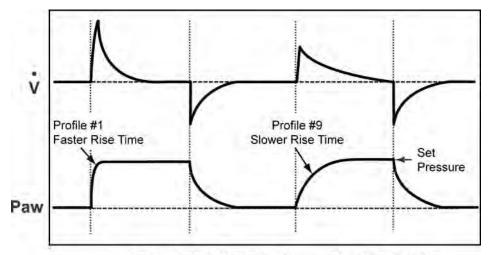
When the initial flow is <20 lpm, the final flow remains at 10 lpm and the waveform is flattened.



### **Pressure Control Breaths**

For Pressure Control breaths, flow is delivered according to the **Rise Time** setting to elevate the circuit pressure to the Pressure Control (**Pres. Control**) setting (above set **PEEP**<sup>20</sup>) and maintain it at that pressure for the set Inspiratory Time (**Insp. Time**). Pressure Control breaths may be Machine or Assist breaths. A Pressure Control breath can be either flow or time cycled.

Adjusting the **Rise Time** setting changes the flow and pressure waveforms for Pressure Control breaths (see *Rise Time* in Chapter 10 – Extended Features).



Adjusting Rise Time on Pressure Control Breaths

If Pressure Control Flow Termination (**PC Flow Term**) is on (**Term On**), Pressure Control breaths may be flow terminated. If the flow drops to the set Flow Termination (**Flow Term**) level (e.g. **Flow 10% - Flow 40%**) before the inspiratory time is completed, the breath is cycled. See *PC Flow Term (Pressure Control Flow Termination)* and *Flow Term (Flow Termination)* in Chapter 10 – Extended Features.

<sup>&</sup>lt;sup>20</sup> Pressure Control and Pressure Support breaths compensate for PEEP. Delivered pressure is the setting plus PEEP. e.g. a setting of 20cmH<sub>2</sub>O with a PEEP of 10cmH<sub>2</sub>O delivers a max pressure of 30cmH<sub>2</sub>O.

# **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 **Tidal 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.

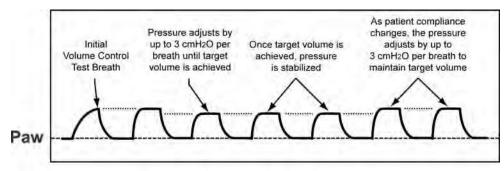
#### **Test Breaths**

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

- The PRVC breath mode is initiated
- The set Tidal Volume is changed
- A Volume Limited alarm (Vol Limited) occurs (see Volume Limited in Chapter 8 Ventilator Alarms)
- The delivered Tidal Volume ≥1.5 times the set Tidal Volume
- The next breath following a High Airway Pressure alarm (High Pres), a Safety Valve
  High Pressure Relief alarm (SVHP Relief), a Patient Circuit Fault alarm (Pat. Circuit), a
  Low Peak Pressure alarm (Low Pk Pres), or active exhalation
- The set Inspiratory Time (Insp. Time) is changed
- The set Inspiratory Rise Time (Rise Time) 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. The pressure adjustment from a previous breath however is never more than 3 cmH<sub>2</sub>O
- The Target Pressure is at least 5 cmH<sub>2</sub>O below the High Airway Pressure alarm (**High Pres**) setting
- Flow is delivered according to the set Inspiratory Rise Time (Rise Time)
- Breaths are terminated based on the set Inspiratory Time (Insp. Time), or the set Flow Termination (Flow Term) level, whichever comes first.
  - If Pressure Control Flow Termination (PC Flow Term) is on (Term On), pressure breaths may be flow terminated. If the flow drops to the set Flow Termination level (e.g. Flow 10% Flow 40%) before the inspiratory time is completed, the breath is cycled. See PC Flow Term (Pressure Control Flow Termination) and Flow Term (Flow Termination) in Chapter 10 Extended Features.



Pressure Regulated Volume Control Breaths

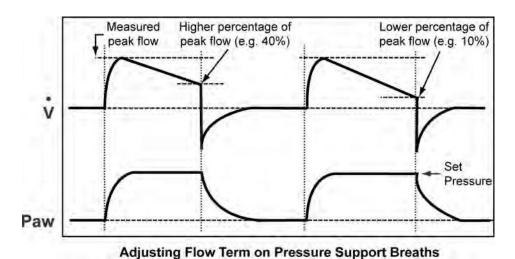
# Patient Breaths

Patient breaths may be delivered as:

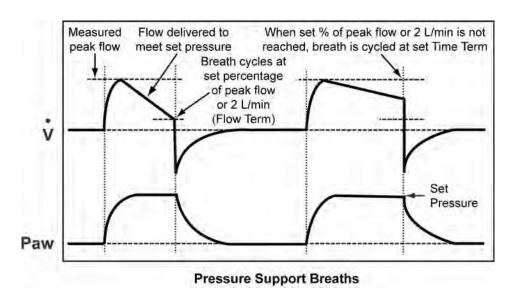
- Pressure Support
- Spontaneous
- Volume Targeted Pressure Support

# **Pressure Support Breaths**

In Pressure Support breaths, flow is delivered according to the set Rise Time to elevate the circuit pressure to the Pressure Support (**Pres. Support**) setting and maintain it until the flow drops below a pre-set percentage of Peak Flow for that breath, or below 2 lpm (see *Flow Term (Flow Termination*) in Chapter 10 – Extended Features). The breath then cycles to exhalation.

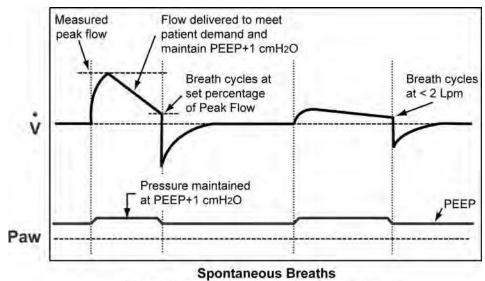


Pressure Support breaths may also be cycled by the set Time Termination (**Time Term**) (see *Time Term (Time Termination*) in Chapter 10 – Extended Features).



# **Spontaneous Breaths**

Spontaneous breaths are a subset of Pressure Support breaths, where the circuit pressure is elevated to PEEP+1 cmH<sub>2</sub>O during inspiration. This is achieved when the Pressure Support control (**Pres. Support**) setting is either **1** or "- -" (off)



Shown with example flow for two different patient conditions

# **Volume Targeted Pressure Support Breaths**

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 Flow Termination (Flow Term) or 2 lpm, whichever comes first
- The Pressure Support control (**Pres. Support**) is inactive when Breath Mode CPAP+PS and Breath Type PRVC are selected

### **NOTE**

The Inspiratory Time control (**Insp. Time**) is active during the Volume Control test breath only.

# **Breath Modes**

The Revel<sup>™</sup> ventilator provides the following modes of breath delivery:

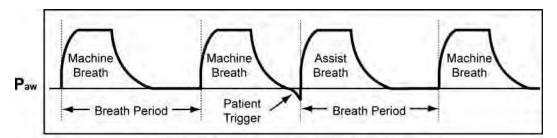
- Assist/Control (A/C)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Continuous Positive Airway Pressure Plus Pressure Support (CPAP+PS)
- Apnea Backup Ventilation
- Non-Invasive Positive Pressure Ventilation (NPPV)

# Assist/Control (A/C)

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

In Assist/Control mode (**Breath 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.

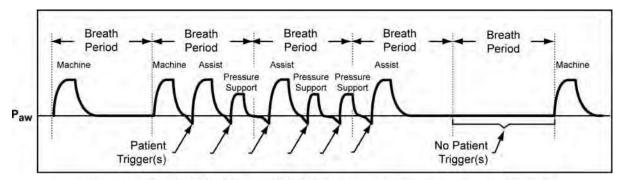


**Pressure Control Machine and Assist Breaths** 

# Synchronized Intermittent Mandatory Ventilation (SIMV)

In SIMV mode, Machine, Assist, Pressure Support and 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 Pressure Support (**Pres. Support**) setting. Although the breath period is not reset by patient triggers, it is reset when a Manual Breath is initiated.

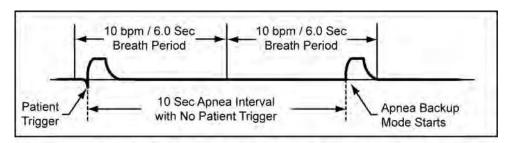
At the beginning of a breath period, if no patient breaths have occurred in the previous breath period, a Machine breath is given.



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 <u>not</u> give a Machine breath in the current breath period unless the set Apnea Interval (**Apnea Int**) is exceeded (see *Apnea Backup Ventilation* in this chapter).

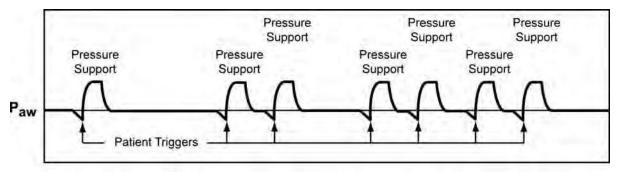


Example of SIMV Mode, Breath Rate 10 bpm, Apnea Interval 10 Seconds

# Continuous Positive Airway Pressure Plus Pressure Support (CPAP+PS)

In CPAP+PS breath mode, when a patient trigger is detected, a Patient breath is given. Breaths may be Pressure Support or Spontaneous breaths depending on the Pressure Support (**Pres. Support**) setting.

For **CPAP+PS** breath mode with **PRVC** breath type settings, the breaths are PRVS.



**Pressure Support Patient Breaths** 

## **NOTE**

**Flow Triggering Threshold Level** – The flow triggering threshold level (**Sensitivity**) is automatically set to 2 lpm when the **Breath Mode** is changed to **CPAP+PS** and the **Sensitivity** control was previously set to "P" (Pressure Trigger).

# Apnea Backup Ventilation

The Revel<sup>™</sup> ventilator provides an Apnea Backup mode of ventilation. When the set Apnea Interval (**Apnea Int**) (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** - Check and configure the controls affecting Apnea Backup ventilation before initiating CPAP+PS 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

**Dimmed Controls -** Controls which need to be set for Apnea Backup ventilation may be dimmed as they are not active in CPAP+PS or NPPV modes. The controls should be set while dimmed and will become active when Apnea Backup ventilation initiates.

Apnea Backup ventilation is initiated when the time since the start of the last breath exceeds the set Apnea Interval (**Apnea Int**). The Apnea Interval is set using the Extended Features menus (see *Apnea Int (Apnea Interval)*) in Chapter 10 – Extended Features).

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.

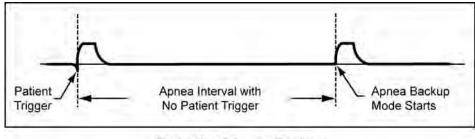
The Apnea Backup ventilation breath rate is determined as follows:

• If the set **Breath Rate** is <12 bpm, the Apnea Backup ventilation breath rate is the highest rate allowed by control limiting, up to 12 bpm

In CPAP+PS and NPPV ventilation modes only:

• If the set **Breath Rate** is equal to or higher than 12 bpm, then the Apnea Backup ventilation breath rate will be the set **Breath 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 Revel<sup>™</sup> ventilator provides Non-Invasive Positive Pressure Ventilation (NPPV) as a secondary, supplementary mode that may be selected with the primary ventilation mode. When **NPPV** with **A/C** or **NPPV** with **CPAP+PS** modes are selected, ventilation is delivered according to the selected mode.

The ventilator is capable of performing non-invasive positive pressure ventilation 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.

When either of the NPPV modes are selected the leak compensation function (**Leak Comp**) 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, 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.

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 Revel<sup>™</sup> 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** with A/C Mode

NPPV with A/C breath mode is delivered as a Pressure Control breath. Any patient trigger will receive a Pressure Control breath and the breathing pattern can be terminated by PC Flow Termination.

## **NPPV** with CPAP+PS Mode

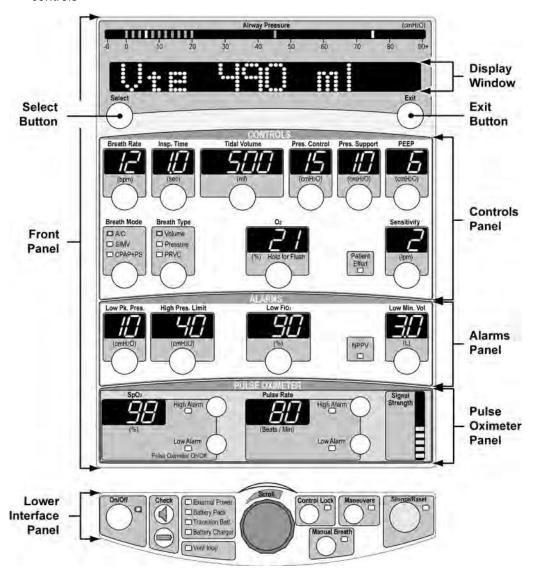
NPPV with CPAP+PS breath mode consists of CPAP breathing at the user preset baseline pressure with the option of using Pressure Support as an adjunctive adjustable pressure. The breath will be terminated by PC Flow Termination.

# **Chapter 5 - CONTROLS**

This chapter provides a description of the ventilator controls on the front and lower interface panels, their use, function, ranges and limitations.

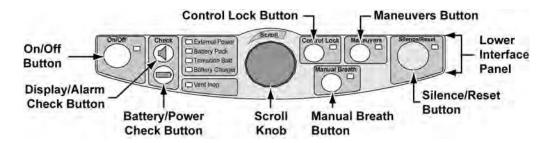
Additional adjustable controls not directly represented on the front or lower interface panels are accessed, configured and set using the Startup and Extended Features menus.

 See Navigating Startup and Extended Features Menus and Startup Mode and Menus in Chapter 3 – Using the Ventilator, and Extended Features Menus in Chapter 10 – Extended Features for additional information regarding available options, features and controls



# **Lower Interface Panel**

This section provides a description of the controls on the lower interface panel, their use, function, ranges and limitations.



### Check Buttons

# **Battery/Power**

The Battery/Power **Check** button is used to check the status of the battery and power system without interfering with the ventilator's operation.

If you push and hold the Battery/Power **Check** button, the ventilator displays a message in the Display Window for each of the four possible sources of power (in the sequence shown), indicating their detection and current status<sup>21</sup>.





#### **Power Source**

|                                | Removable<br>Battery Pack | External DC<br>Power | Docking<br>Station | Transition<br>Battery |
|--------------------------------|---------------------------|----------------------|--------------------|-----------------------|
|                                | Batt xxx%                 | Ext OK               | Dock OK            | T-Bat OK              |
| Possible<br>Status<br>Messages | Batt Removed              | Ext Low              | Dock Low           | T-Bat Low             |
|                                | Batt Fault                | Ext Removed          | Dock Removed       | T-Bat Remove          |
| Displayed                      |                           | Ext Fault            | Dock Fault         | T-Bat Chrg            |
|                                |                           |                      |                    | T-Bat Fault           |

<sup>&</sup>lt;sup>21</sup> Refer to Power Status LEDs in Chapter 6 - Displays and Indicators for additional information concerning the status of various sources of power.

## **NOTE**

- **Batt 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 (**Batt**, **Ext**, **Dock** or **T-Bat**) has been detected and is <u>not</u> adequate to power the ventilator.

See Chapter 13 - Troubleshooting for additional information.

## 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 is used to check the displays, indicators and audible alarm system without interfering with the ventilator's operation.

If you push and hold the Display/Alarm **Check** button, the ventilator illuminates all front panel and lower interface panel window displays and indicator LEDs in the colors as indicated below, and sounds two audible tones of similar volume followed by the High Priority Alarm Signal <sup>22</sup> at the set volume.



| Panel   | LED Color    |  |  |
|---|--------------|--|--|
| Front Panel:  |              |  |  |
| <ul> <li>Airway Pressure Manometer LEDs<sup>23</sup></li> <li>Oximetry Signal Strength Display LEDs<sup>24</sup></li> </ul>             | Amber        |  |  |
| All other LED indicators and displays   | Red or Green |  |  |
| Lower Interface Panel:  |              |  |  |
| <ul> <li>All Power Status indicator LEDs<sup>25</sup></li> <li>External Power</li> <li>Battery Pack</li> <li>Transition Bat.</li> </ul> | Amber        |  |  |
| Battery Charger      All other indicator LEDs   | Red or Green |  |  |

If the audible alarm fails to sound or any indicator or display window LED (includes all LED segments within the window) fails to fully illuminate, or illuminates in a color other than as specified above, refer to *Chapter 13 - Troubleshooting* for additional information.

<sup>&</sup>lt;sup>22</sup> Refer to Sound Types, Patterns and Volumes in Chapter 8 - Ventilator Alarms for additional information.

<sup>&</sup>lt;sup>23</sup> Refer to *Airway Pressure Manometer* in Chapter 6 - Displays and Indicators for additional information.

<sup>&</sup>lt;sup>24</sup> Refer to *Oximetry Signal Strength Display* in Chapter 6 - Displays and Indicators for additional information.

<sup>&</sup>lt;sup>25</sup> Refer to *Power Status LEDs* in Chapter 6 - Displays and Indicators for additional information.

## **Control Lock**

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 illuminated whenever the front panel controls are locked.

Although ventilation controls and alarm limits settings (including those in Extended Features menus) can not be changed when the Control Lock is enabled, the **Select** and **Exit** buttons can be used to pause or restart the automatic scrolling of monitored data.

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

- The Control Lock LED flashes
- Locked is displayed in the display window
- 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 using Extended Features menus (see *Ctrl Unlock* (*Control Unlock*) in Chapter 10 – Extended Features for additional information).

- 1) To turn the Control Lock off with **Easy** unlocking set, simply push the **Control Lock** button. The LED is extinguished and the controls unlock.
- 2) To turn the Control Lock off with **Hard** unlocking set, push and hold the **Control Lock** button for 3 seconds. The LED is extinguished and the controls unlock.

#### NOTE

The O<sub>2</sub> Flush procedure and the **Select, Exit, Manual Breath**, Battery/Power **Check**, Display/Alarm **Check** and **Silence/Reset** controls are not affected by the Control Lock and operate even when it is on.

#### Maneuvers

The **Maneuvers** button is used to display, select and activate a maneuver.

For more details on how to set up and run maneuvers, see *Maneuvers* in Chapter 9 – Maneuvers and Procedures.



#### Manual Breath

Pushing the **Manual Breath** button will deliver one (1) Machine breath. The breath is a Machine breath as defined by the current **Breath Type** settings. The **Manual Breath** LED is illuminated during the Manual Breath inspiration.



When in **CPAP+PS** breath 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

The **On/Off** button is used to turn the ventilator on or off.

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

# On/Off C

#### To turn the ventilator on:

Push the On/Off button.

#### 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 is illuminated.

 To silence the alarm and extinguish the Vent Inop LED, push the Silence/Reset button

## Scroll

The **Scroll** knob is a rotary knob encoder used to scroll through a paused display of monitored data, change ventilation feature configurations, selected control or alarm limit values and navigate through Startup and Extended Features menus.



- Rotating the Scroll knob clockwise displays the next available monitored data in a
  paused display, increases selected control/alarm limit values, changes selected feature
  configurations, or displays the next available menu in Startup or Extended Features
  menus
- Rotating the Scroll knob counter-clockwise displays the previous available monitored data in a paused display, decreases selected control/alarm limit values, changes selected feature configurations, or displays the previous available menu in Startup or Extended Features menus

Monitored data, control/alarm limit values, feature configurations or Startup or Extended Features menus stop incrementing when control/alarm range limits are reached (or limited by another control setting), or no further configurations, displays or menus are available.

- The Scroll knob is speed sensitive; when rotated quickly, each detent changes selected control/alarm limit values more than when rotated slowly
- If the Scroll knob is not rotated within 15 seconds after a control has been selected, the control or alarm limit is automatically deselected
- If monitored data is not paused, controls are not selected, or Startup or Extended Features menus are not displayed, rotating the **Scroll** knob has no effect

## Silence/Reset

The **Silence/Reset** button is used to temporarily silence active audible alarms, remove visible alarm messages in the display window and reset alarms:



- If pushed once when no alarms are activated, a sixty (60) second silence period is initiated and the Silence/Reset LED is illuminated
  - If pushed again during the 60 second silence period, the silence period is cancelled
- If pushed once during an active alarm condition (alarm sounding, alarm message flashing in the display window) the audible alarm is silenced for 60 seconds and the Silence/Reset LED is illuminated
  - A second push removes the visible (highest priority) flashing alarm message, and subsequent lower priority alarms (if actively occurring) are displayed
  - Each subsequent push removes the next visible alarm message in order of priority (see Alarm Priorities in Chapter 8 – Ventilator Alarms)
  - Active recurring alarms are suppressed for 15 seconds after the last button push to allow lower priority alarm messages to be reviewed
  - Once the lowest priority message has been removed, pushing the Silence/Reset button again reinstates all active alarm messages and visual alarm indicators (flashing controls), reactivates the audible alarm and extinguishes the Silence/Reset LED
- If alarm conditions are resolved during the 60 second silence period, the audible alarm will not be reactivated
- If the **Silence/Reset** button is pushed once all alarm conditions have been resolved, visible flashing alarm messages are removed and the **Silence/Reset** LED is extinguished

## Silencing the Vent Inop alarm:

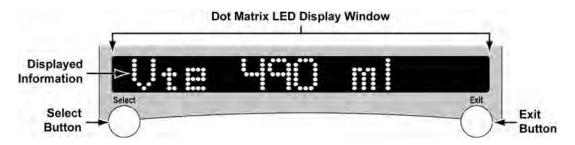
To silence the **Vent Inop** alarm, push the **Silence/Reset** button. The audible alarm is permanently silenced and the **Vent Inop** LED is extinguished.

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

# Front Panel, Display Window

The Display Window is used to display a variety of types of information. The adjacent **Select** and **Exit** buttons are used in conjunction with the **Scroll** knob (on the lower interface panel) to access, select, initiate, cancel, change and/or exit displayed data, menus options, maneuvers or procedures.

• See Display Window in Chapter 6 – Displays and Indicators for additional information



#### Select

The **Select** button is used to pause automatic scrolling of monitored data on the LED display window, and select or confirm displayed menu options and configuration value settings displayed (in Startup and Extended Features menu options). See the following manual sections/chapters for detailed information:

- Automatic or Manual Data Display Scrolling and Navigating Startup and Extended Features Menus in Chapter 3 - Using the Ventilator
- Chapter 9 Maneuvers and Procedures
- Standby? (Standby mode) in Chapter 10 Extended Features

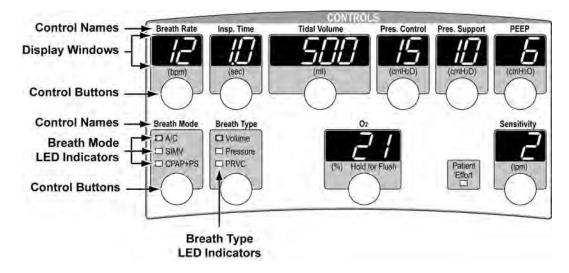
#### Exit

The **Exit** button is used to restart automatic scrolling of monitored data on the LED display window, exit Standby mode, and exit Startup and Extended Features menus or configuration settings displayed (without changing the setting). See the following manual sections/chapters for detailed information:

- Automatic or Manual Data Display Scrolling and Navigating Startup and Extended Features Menus in Chapter 3 Using the Ventilator
- Chapter 9 Maneuvers and Procedures
- Standby? (Standby mode) in Chapter 10 Extended Features

# Front Panel, Controls

This section provides a description of the controls on the Controls panel, their use, function, ranges and limitations.



## **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 initial flow of 10 lpm for Volume Controlled breaths
- To ensure a maximum initial flow of 120 lpm for Volume Controlled breaths
- To ensure that flow trigger sensitivity (Sensitivity) is less than Bias Flow
- To ensure a maximum Pressure Control pressure of 99 cmH<sub>2</sub>O
- To ensure a maximum Pressure Support of 60 cmH<sub>2</sub>O

When you are updating a control and have reached 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 outside the limit range, you need to modify the settings for other controls involved in the limit condition. For instance, if the Breath Rate is set to 12, the maximum allowed Inspiratory Time is 4.0 seconds. To set the Inspiratory Time to more than 4.0 seconds, you must first decrease the Breath Rate.

## **Active Controls by Breath Mode and Type**

The following matrix shows which controls are active in all **Breath Mode** and **Breath Type** settings.

- The LED displays of active front panel controls are illuminated at normal intensity
- The LED displays of inactive front panel controls which do not affect breath delivery in a specific breath mode or breath type are dimmed

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.

#### **Breath Mode and Type**

| Controls                   | A/C + Volume                | A/C + Pressure  | A/C + PRVC      | SIMV + Volume | SIMV + Pressure | SIMV + PRVC | CPAP+PS + Volume | CPAP+PS + Pressure | CPAP+PS + PRVC                                 | A/C + Pressure  | CPAP+PS Pressure |
|----------------------------|-----------------------------|-----------------|-----------------|---------------|-----------------|-------------|------------------|--------------------|--|-----------------|------------------|
| Bias Flow <sup>26</sup>    | Х                           | Х               | Х               | Χ             | Χ               | Χ           | Χ                | Χ                  | Х  | Х               | X                |
| Breath Rate                | Χ                           | Х               | Х               | Х             | Х               | Х           |                  |                    |  | Χ               |                  |
| Flow Term <sup>26</sup>    |                             | X <sup>27</sup> | X <sup>27</sup> | Χ             | Χ               | Х           | Х                | Χ                  | Х  | X <sup>27</sup> | X                |
| Insp. Time                 | X                           | Х               | Х               | Х             | Χ               | Х           |                  |                    | X  | Χ               |                  |
| Leak Comp <sup>26</sup>    | Х                           | Х               | Х               | Х             | Χ               | Х           | Х                | Х                  | Х  | Х               | Х                |
| O <sub>2</sub>             | Х                           | Х               | Х               | Х             | Χ               | Х           | Х                | Х                  | Х  | Х               | Х                |
| PC Flow Term <sup>26</sup> |                             | Х               | Х               |               | Χ               | Х           |                  |                    |  | Х               |                  |
| PEEP                       | Х                           | Х               | Х               | Χ             | Χ               | Х           | Х                | Χ                  | Х  | Х               | Х                |
| Pres Trigger <sup>26</sup> | Х                           | Х               | Х               | Х             | Χ               | Х           | Х                | Х                  | Х  | Х               | Х                |
| Pres. Control              |                             | Х               |                 |               | Х               |             |                  |                    |  | Χ               |                  |
| Pres. Support              |                             |                 |                 | Χ             | Χ               | Х           | Х                | Χ                  |  |                 | Х                |
| Rise Time <sup>26</sup>    |                             | Х               | Х               | Χ             | Χ               | Х           | Х                | Χ                  | Х  | Х               | Х                |
| Sensitivity                | Х                           | Х               | Х               | Х             | Χ               | Х           | Х                | Х                  | Х  | Х               | Х                |
| Tidal Volume               | Х                           |                 | Х               | Х             | -               | Х           |                  |                    | Х  |                 |                  |
| Time Term <sup>26</sup>    |                             |                 |                 | Χ             | Χ               | Χ           | Χ                | Χ                  |  |                 | Х                |
|                            | Intubated Patient Interface |                 |                 |               |                 |             |                  |                    | Non-Invasive<br>Patient<br>Interface<br>(NPPV) |                 |                  |

<sup>&</sup>lt;sup>26</sup> Control accessed while in normal ventilation modes through the Extended Features menus.

<sup>&</sup>lt;sup>27</sup> Available when Pressure Control Flow Termination (PC Flow Term) is on.

## **Breath Mode**

The **Breath Mode** control is used to select between the following ventilation breath modes:

- A/C (Assist/Control)
- SIMV (Synchronized Intermittent Mandatory Ventilation)
- CPAP+PS (Continuous Positive Airway Pressure plus Pressure Support)



Breath Type

Volume

☐ Pressure

□ PRVC

See *Breath Modes* in Chapter 4 - Breath Types and Modes for detailed descriptions of breath modes.

#### To Set Breath Mode:

Use the three step "Select, Change and Confirm" method to set the Breath Mode (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## **Breath Type**

The **Breath Type** control is used to select between the following ventilation breath types:

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



See *Breath Types* in Chapter 4 - Breath Types and Modes for detailed descriptions of breath types.

## To Set Breath Type:

Use the three step "Select, Change and Confirm" method to set the Breath Type (see Front Panel Ventilation and Alarm Controls and Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 – Using the Ventilator for detailed instructions).

#### **Breath Rate**

The **Breath Rate** control is used to establish the minimum number of machine or assist breaths that the ventilator delivers per minute.

Range: 1 through 80 bpm

The **Breath 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:Ecalc) is shown in the display window while **Breath Rate** is being changed.

In CPAP+PS mode, the **Breath 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).

## To Set Breath Rate:

Use the three step "Select, Change and Confirm" method to set the Breath Rate (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## Insp. Time (Inspiratory Time)

The **Insp. Time** (Inspiratory Time) control is used to set the duration of the inspiratory phase of Volume Controlled, Pressure Controlled and PRVC (Pressure Regulated, Volume Controlled) breaths.

Range: 0.3 through 9.9 sec

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

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

#### NOTE

- The calculated peak flow (**Vcalc**) monitor is updated while **Tidal Volume** or **Insp. Time** settings for a volume breath are being changed.
- The calculated I:E Ratio (I:Ecalc) monitor is updated while **Breath Rate** or **Insp**. **Time** settings are being changed.
- In CPAP+PS 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).

## To Set Inspiratory Time:

Use the three step "Select, Change and Confirm" method to set the Inspiratory Time (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).



## O<sub>2</sub> (Oxygen Percentage and Flush)

The  $O_2$  control is a dual function control (also used for the  $O_2$  Flush procedure) and for the purpose of these instructions is used to adjust the percentage of oxygen to be delivered through the ventilator's oxygen blending system. See O2 Flush in Chapter 9 – Maneuvers and Procedures for additional information and instructions.

## Using a High Pressure O<sub>2</sub> 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% O<sub>2</sub>

#### **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 ventilator is attached to a low pressure O<sub>2</sub> 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 Revel<sup>™</sup> ventilator requires a high pressure oxygen source and is active only when the Low Pressure Source (LPS) setting on the  $O_2$ % 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 O<sub>2</sub> Percentage:

Use the three step "Select, Change and Confirm" method to set the O<sub>2</sub> Percentage (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## **WARNING**

**Inspired Oxygen (FIO<sub>2</sub>) Concentration** – If *exact concentrations* of inspired oxygen (FIO<sub>2</sub>) must be delivered to the patient, it is recommended that the optional FIO<sub>2</sub> Sensor or a separate oxygen analyzer with alarms be used. If using the optional FIO<sub>2</sub> Sensor set the ventilator Low FiO<sub>2</sub> alarm appropriately (see *Low FIO2* alarm in Chapter 8 –Ventilator Alarms for additional information).

## Using a Low Pressure O<sub>2</sub> Source:

When the  $O_2$ % control is set to **LPS** (Low Pressure Source), 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 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<sub>2</sub>.

When the  $O_2\%$  control is set to LPS, the following conditions are applicable:

- The O<sub>2</sub> inlet flow must be set to obtain the desired oxygen percentage (see chart)
- The Low O<sub>2</sub> Inlet Pressure (**Low O<sub>2</sub> Pres**) alarm is inactive
- The High O<sub>2</sub> Inlet Pressure (**Hi O<sub>2</sub> Pres**) alarm activates at 10 PSI (69 BAR, 69 kPa)

When the  $O_2$ % control is set greater than 21% (22 - 100%), the following conditions are applicable:

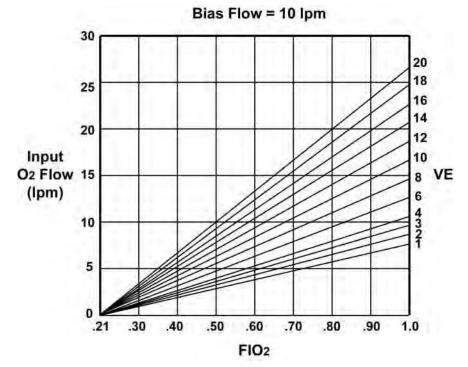
• The Low O<sub>2</sub> Inlet Pressure (**Low O<sub>2</sub> Pres**) alarm activates at 39 PSI (2.69 BAR, 269 kPa)

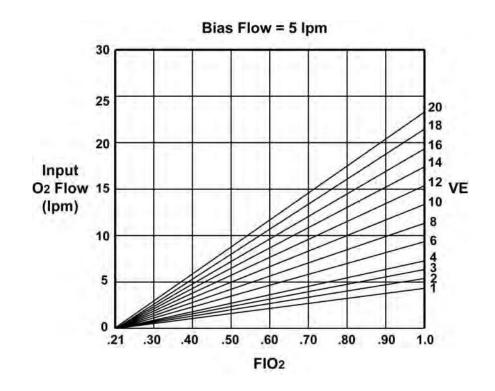
## WARNING

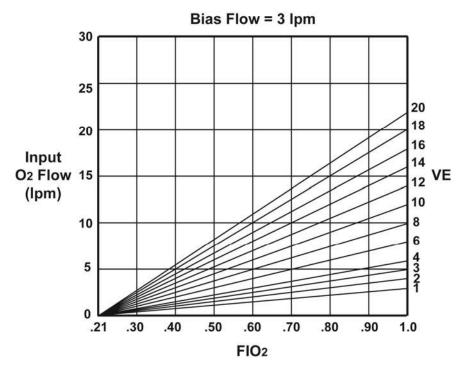
**Inspired Oxygen (FIO<sub>2</sub>) Concentration** - Minute Volume fluctuates if a patient has a variable respiratory rate. If *exact concentrations* of inspired oxygen (FIO<sub>2</sub>) must be delivered to the patient, it is recommended that the optional FIO<sub>2</sub> Sensor or a separate oxygen analyzer with alarms be used. If using the optional FIO<sub>2</sub> Sensor set the ventilator Low FiO<sub>2</sub> alarm appropriately (see *Low FIO2* alarm in Chapter 8 –Ventilator Alarms for additional information).

## Setting the Flow for Low Pressure Oxygen Blending:

Use one of the three (3) following charts and the accompanying instructions to determine the required low pressure  $O_2$  flow setting to deliver the desired  $Flo_2$ .

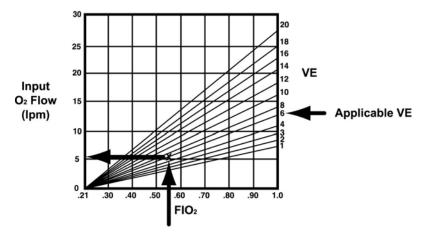






## To Determine the Required O<sub>2</sub> Input Flow:

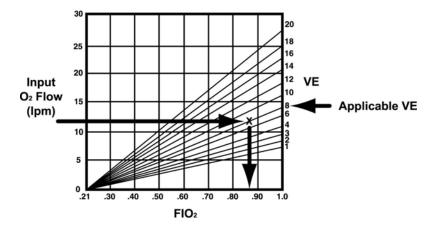
- 1) Select the appropriate chart based on the **Bias Flow** setting. When Leak Compensation is on, the patient leak should be added to the Bias Flow value.
- 2) Identify the desired Fio<sub>2</sub> (bottom of chart).
- 3) Calculate the patient's Minute Volume (VE) rate by using the formula: Tidal Volume X Breath Rate. Locate the Minute Volume reading (right side of chart).
- 4) Follow the vertical FiO<sub>2</sub> line up to the applicable slanted VE (Minute Volume) line.
- 5) From where they intersect, read across horizontally to the left side of chart to the required Input O<sub>2</sub> Flow (Ipm).



Example - To determine the required O2 input flow

## To Determine the Estimated Delivered O<sub>2</sub> Concentration:

- 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<sub>2</sub> Flow (left side of chart).
- 3) Follow the Input O<sub>2</sub> Flow across horizontally to the right to the applicable slanted VE (Minute Volume) line.
- 4) Read down to the FIO<sub>2</sub> (bottom of chart).



Example - To determine the delivered O2 concentration

## PEEP (Positive End Expiratory Pressure)

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

Range: 0 through 20 cmH<sub>2</sub>O

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

# (cmHzO)

Pres. Control

#### To Set PEEP:

Use the three step "Select, Change and Confirm" method to set PEEP (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## Pres. Control (Pressure Control)

The **Pres. Control** (Pressure Control) control is used to set 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 cmH₂O

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



Use the three step "Select, Change and Confirm" method to set the Pressure Control (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

#### NOTE

- Flow Termination is available for Pressure Control breaths (see Flow Term (Flow Termination) and PC Flow Term (Pressure Control Flow Termination) in Chapter 10 Extended Features for detailed instructions). The Pres. Control display flashes briefly after a Pressure Control breath that is flow terminated.
- The Rise Time profile for Pressure Control breaths can be adjusted using the **Rise Time** menu (see *Rise Time* in Chapter 10 Extended Features for detailed instructions).
- In CPAP+PS (Pressure) and NPPV CPAP+PS (Pressure) settings, the Pres. Control control setting establishes the target pressure above PEEP in Apnea Backup ventilation.
  - In CPAP+PS (Volume) and NPPV CPAP+PS (Volume) settings, the Tidal Volume control establishes the delivered Tidal Volume in Apnea Backup ventilation.
  - Be sure to set them appropriately (see *Apnea Backup Ventilation* in Chapter 4 Breath Types and Modes for additional information)

## Pres. Support (Pressure Support)

The **Pres. Support** (Pressure Support) control is used to set the target pressure above PEEP for Pressure Support patient breaths. If **Pres. Support** 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: 1 through 60 cmH<sub>2</sub>O, or "--" (off)

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

## **To Set Pressure Support:**

Use the three step "Select, Change and Confirm" method to set the Pressure Support (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

#### NOTE

- Flow or Time Termination is available for Pressure Support breaths (see *Flow Term* (*Flow Termination*) and *Time Term (Time Termination*) in Chapter 10 Extended Features for detailed instructions). The **Pres. Support** display flashes briefly after a Pressure Support or Spontaneous breath is Time Terminated or terminated by the elapse of two (2) breath periods.
- The Rise Time profile for Pressure Support breaths can be adjusted using the **Rise Time** menu (see *Rise Time* in Chapter 10 Extended Features for detailed instructions).
- The Pressure Support control is inactive in CPAP+PS (PRVC) mode. Support breaths are delivered as PRVS breaths.

## Sensitivity

The **Sensitivity** control is used to set the flow threshold level to allow the patient to trigger breaths.

Range: P, or 1 through 9 lpm

- 1 is the most sensitive, 9 is the least sensitive for flow triggering
- P indicates pressure triggering is enabled and that flow triggers are disabled

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

#### **NOTE**

**Bias Flow** - The Revel<sup>™</sup> ventilator provides a bias flow during exhalation to assist with patient triggering. The level of Bias Flow is selected using the **Bias Flow** menu (see *Bias Flow* in Chapter 10 – Extended Features).

While the flow trigger **Sensitivity** control is being set, the current Bias Flow setting is displayed and when a patient demand is detected, the **Patient Effort** indicator LED is illuminated briefly.

Flow Triggering Threshold Level – The flow triggering threshold level (Sensitivity) is automatically set to 2 lpm when the **Breath Mode** is changed to **CPAP+PS** and the **Sensitivity** control was previously set to "P" (Pressure Trigger).

**Pressure Trigger Setting -** A **Check P Trig** message is displayed in the front panel display window when the **Sensitivity** control value is set to "**P**" to remind the operator to check the **Pres Trigger** (Pressure Trigger) set threshold level for patient appropriateness.

- Push the Exit button to clear the Check P Trig message
- See *Pres Trigger (Pressure Trigger)* in Chapter 10 Extended Features for additional information

#### A flow trigger occurs when:

- The Sensitivity control is set to a value from 1 to 9
- The ventilator is in exhalation phase
- The minimum exhalation time has expired
- The flow is equal to or greater than the Sensitivity setting

#### A backup breath is delivered when:

- The airway pressure drops below -3 cmH<sub>2</sub>O
- The ventilator is in exhalation phase
- The minimum exhalation time has expired

## **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.

## To Set Sensitivity:

Use the three step "Select, Change and Confirm" method to set Sensitivity (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## Tidal Volume

The **Tidal Volume** control is used to set 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).

Tidal Volume

500
(ml)

Range: 50 through 2000 ml

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

#### To Set Tidal Volume:

Use the three step "Select, Change and Confirm" method to set the Tidal Volume (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

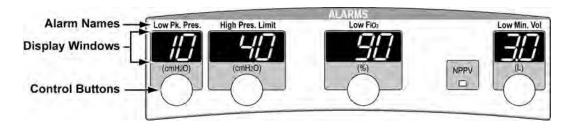
## **NOTE**

The Calculated Peak Inspiratory Flow (**Vcalc**) is updated in the display window while **Tidal Volume** or **Insp. Time** settings for a volume breath are being changed.

In **CPAP+PS** (**Volume**) and **CPAP+PS** (**PRVC**) mode, the **Tidal 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)

# Front Panel, Alarms

This section provides a description of the controls on the Alarms panel, their use, function, ranges and limitations.



## Low Pk. Pres. (Low Peak Pressure)

The **Low Pk. Pres.** (Low Peak Pressure) control is used to set the low peak pressure alarm limit value. See *Low Peak Pressure* in Chapter 8 – Alarms for detailed alarm information.

Range: 1 through 60 cmH<sub>2</sub>O in increments of 1, or "--" (off)

#### To Set the Low Pk. Pres. Alarm:

Use the three step "Select, Change and Confirm" method to set the low peak pressure alarm (see Front Panel Ventilation and Alarm Controls and Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 – Using the Ventilator for detailed instructions).

# High Pres. Limit (High Airway Pressure Limit)

The **High Pres**. **Limit** (High Airway Pressure Limit) control is used to set the high airway pressure limit alarm value. See *High Airway Pressure* in Chapter 8 – Alarms for detailed alarm information.

Range: 5 through 100 cmH<sub>2</sub>O in increments of 1

## To Set the High Pres. Limit Alarm:

Use the three step "Select, Change and Confirm" method to set the high pressure limit alarm (see Front Panel Ventilation and Alarm Controls and Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 – Using the Ventilator for detailed instructions).

## Low FIO<sub>2</sub>

#### **NOTE**

To enable the Low  $F_{1O_2}$  alarm control, the  $F_{1O_2}$  Sensor option must first be enabled using the Startup,  $F_{1O_2}$  Sensor menus. Once setup, enabled and calibrated, communication with the  $F_{1O_2}$  sensor may also be enabled/disabled during normal ventilation modes using the Extended Features,  $F_{1O_2}$  Sensor menus.

 See Navigating Startup and Extended Features Menus and FIO2 Sensor Configuration and Calibration in Chapter 3 – Using the Ventilator and FIO2 Sensor in Chapter 10 – Extended Features for additional information

The **Low Fio<sub>2</sub>** control is used to set the low  $Fio_2$  alarm limit value. See *Low FIO2* in Chapter 8 – Alarms for detailed alarm information.

Range: 18 through 95% in increments of 1, or "--" (off)

## To Set the Low FIO<sub>2</sub> Alarm:

When the Fio<sub>2</sub> Sensor option is enabled, use the three step "Select, Change and Confirm" method to set the low Fio<sub>2</sub> alarm (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## Low Min. Vol. (Low Exhaled Minimum Volume)

The **Low Min. Vol.** (Low Minimum Volume) control is used to set the low exhaled minimum volume alarm limit value. See *Low Exhaled Minute Volume* in Chapter 8 – Alarms for detailed alarm information.

Range: **0.1** through **99** L, or "- -" (off)

#### To Set the Low Minimum Volume Alarm:

Use the three step "Select, Change and Confirm" method to set the low minimum volume alarm (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

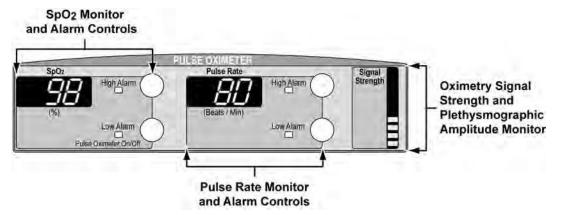
# Front Panel, Pulse Oximeter

The Pulse Oximeter panel controls are used to enable/disable patient SpO<sub>2</sub>, Pulse Rate and Oximetry Signal Strength monitoring, and to set their associated high and low alarm limits.

• See *Pulse Oximetry (SpO2)* in Chapter 2 – Installation and Setup for additional information

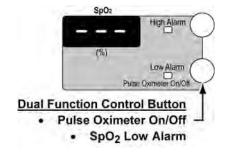
Pulse Oximetry average interval and pulse tone volume configuration values are set using the Extended Features menus.

 See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator and Pulse Ox (Pulse Oximetry) in Chapter 10 – Extended Features for additional information



## Pulse Oximeter On/Off

The **Pulse Oximeter On/Off** control is a dual function control (also used for SpO<sub>2</sub> monitor low alarm limit setting) and for the purpose of these instructions is used to enable/disable patient SpO<sub>2</sub>, Pulse Rate and Oximetry Signal Strength monitoring and their associated alarm limit controls.



#### To turn Pulse Oximetry on:

Push the Pulse Oximeter On/Off button.

• When pulse oximetry is enabled (on), the SpO<sub>2</sub>, Pulse Rate, and Signal Strength display windows are illuminated and after a short delay will display the applicable monitored data

#### NOTE

If a SpO<sub>2</sub> sensor is not on a patient and properly connected to a SpO<sub>2</sub> module and the ventilator when Pulse Oximetry is enabled, a pulse oximetry alarm(s) will be activated.

#### To turn Pulse Oximetry off:

Push and hold the **Pulse Oximeter On/Off** button for 3 seconds. A Vent Inop alarm occurs and the **Vent Inop** LED is illuminated.

## **NOTE**

Pulse oximetry alarm limits (SpO<sub>2</sub> and Pulse Rate, high and low alarm limits) are set and changed in a manner similar to the way all other front panel adjustable controls are changed ("Select, Change, and Confirm"), except that pulse oximetry must first be enabled by pushing the dual function **Pulse Oximeter On/Off** control button as previously described.

## High Alarm (SpO<sub>2</sub>)

The SpO<sub>2</sub> monitor **High Alarm** control is used to set the SpO<sub>2</sub> high alarm limit value.

Range: **80** through **99%**, or "--" (off)



## To Set the SpO<sub>2</sub> Monitor High Alarm:

Once pulse oximetry is enabled, use the three step "Select, Change and Confirm" method to set the SpO<sub>2</sub> high alarm limit value (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## Low Alarm (SpO<sub>2</sub>)

The  $SpO_2$  monitor **Low Alarm** control is a dual function control (also used for enabling/disabling the Pulse Oximeter monitors) and for the purpose of these instructions is used to set the  $SpO_2$  low alarm limit value.

Range: **60** through **99%**, or "--" (off)



## To Set the SpO<sub>2</sub> Monitor Low Alarm:

Once pulse oximetry is enabled, use the three step "Select, Change and Confirm" method to set the SpO<sub>2</sub> low alarm limit value (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## High Alarm (Pulse Rate)

The Pulse Rate monitor **High Alarm** control is used to set the pulse rate high alarm limit value.

Range: 18 through 299 (Beats / Min.), or "- -" (off)



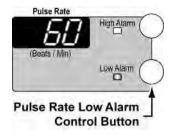
## To Set the Pulse Rate Monitor High Alarm:

Once pulse oximetry is enabled, use the three step "Select, Change and Confirm" method to set the pulse rate high alarm limit value (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

## Low Alarm (Pulse Rate)

The Pulse Rate monitor **Low Alarm** control is used to set the pulse rate low alarm limit value.

Range: 19 through 300 (Beats / Min.), or "- -" (off)



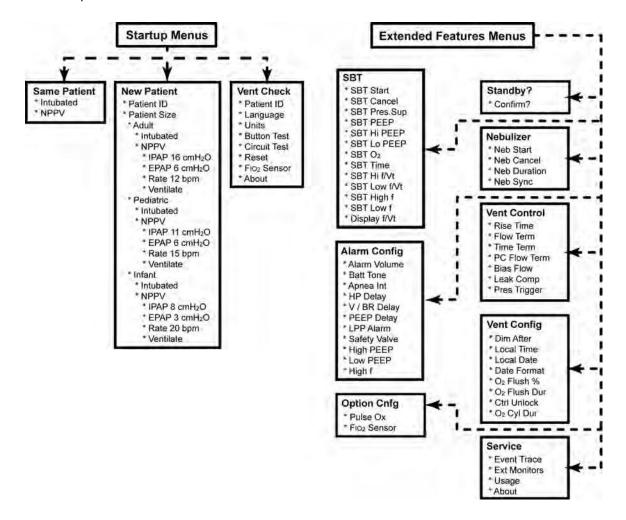
#### To Set the Pulse Rate Monitor Low Alarm:

Once pulse oximetry is enabled, use the three step "Select, Change and Confirm" method to set the pulse rate low alarm limit value (see *Front Panel Ventilation and Alarm Controls* and *Setting Adjustable Front Panel Ventilation Controls and Alarm Limits* in Chapter 3 – Using the Ventilator for detailed instructions).

# **Startup and Extended Features, Controls**

Additional adjustable controls not directly represented on the front or lower interface panels are accessed, configured and set using the Startup and Extended Features menus.

 See Navigating Startup and Extended Features Menus and Startup Mode and Menus in Chapter 3 – Using the Ventilator, and Extended Features Menus in Chapter 10 – Extended Features for information regarding additional controls, available features and option



#### NOTE

Startup menus are only displayed and accessed when the ventilator is initially turned on and the ventilator is in Startup mode.

Extended Features menus are only displayed and accessed while the ventilator is in a normal ventilation mode. Extended Features menus cannot be accessed when the front panel controls are locked.

## **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, Startup)
- During a sub-ambient relief condition (see below)
- To provide over-pressure relief during a sustained high pressure condition (see High Airway Pressure in Chapter 8 – Ventilator Alarms)
- To provide backup over pressure relief in conjunction with the High Airway Pressure alarm setting and the Delta Pressure setting (see Safety Valve High Pressure Relief in Chapter 8 –Ventilator Alarms)

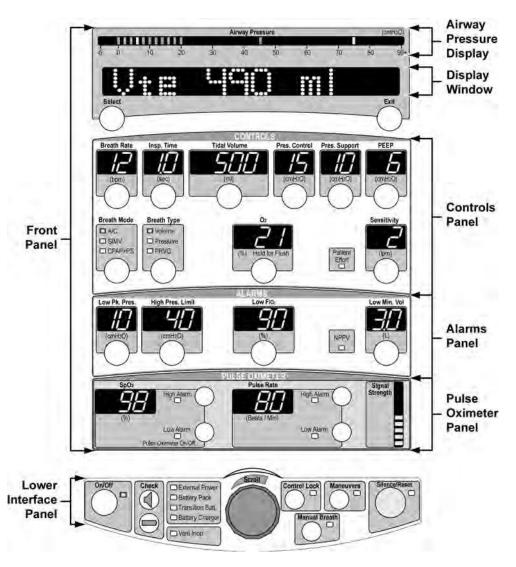
## Sub-Ambient (Anti-Asphyxia) Relief

The safety valve provides sub-ambient relief when the airway pressure is  $\leq$  -5 cmH<sub>2</sub>O.

# Chapter 6 - DISPLAYS AND INDICATORS

This chapter describes the displays and indicators on the Revel $^{^{\top}}$  ventilator front and lower interface panels.

- Front Panel
  - Airway Pressure Display (Manometer)
  - Display Window
  - Controls Panel
  - Alarms Panel
  - Pulse Oximeter Panel
- Lower Interface Panel



See *Display Characteristics* in Chapter 3 – Using the Ventilator for additional information.

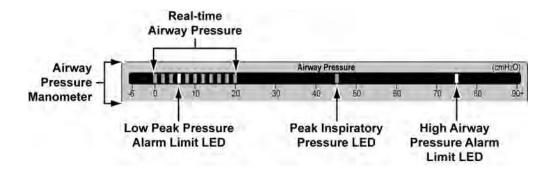
# **Front Panel Displays and Indicators**

## Airway Pressure Manometer

The Airway Pressure Manometer at the top of the front panel displays a bar of bi-color LEDs which are illuminated to display the real-time, breath by breath Airway Pressure.

The display includes the following elements:

**Display Range** -6 cmH<sub>2</sub>O through 90+ cmH<sub>2</sub>O Each illuminated LED represents a pressure increment of 2 cmH<sub>2</sub>O, except for **90+** which represents air pressure of 90 cmH<sub>2</sub>O or higher **Low Peak Pressure Limit** A single amber LED at the set Low Peak Pressure (Low Pk. Pres.) alarm limit value **Airway Pressure** A continuous bar of green LEDs that display the realtime breath by breath Airway Pressure A single green LED which remains illuminated at the **Peak Inspiratory Pressure** Peak Inspiratory Pressure (PIP) value until the start of the next breath **High Airway Pressure Limit** A single amber LED at the set High Airway Pressure (High Pres. Limit) alarm limit value

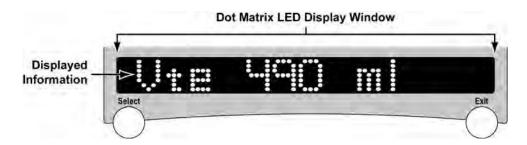


- Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 Using the Ventilator
- Front Panel, Alarms in Chapter 5 Controls
- Alarms, Detailed Descriptions in Chapter 8 Ventilator Alarms

## **Display Window**

The display window near the top of the front panel is an alpha/numeric, 12 character, dot matrix LED array which displays a variety of types of information, in a prioritized (highest to lowest) sequence, as follows:

- Alarm Messages
- Battery/Power Check Information
- Test Results
- Startup and Extended Features Menus
- Alert Messages
- Monitored Data (automatic scrolling or paused)



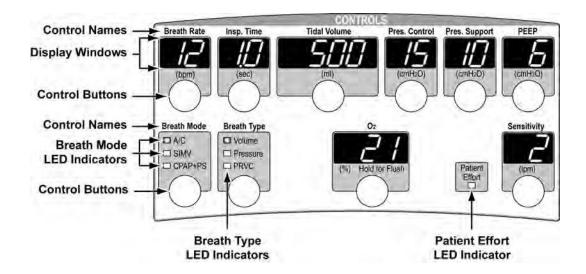
The display window may appear in the following LED illumination states;

- Bright The entire display is at full intensity to indicate a control value is active
- **Dim** The entire display is at half intensity to indicate a control value is inactive
- Blanked The display is not illuminated to save battery power
- Flashing The display alternates between bright and blanked for alarm messages
- **Selected** A portion of the display is bright with all other characters are dimmed to indicate the location of a value to be changed

- Automatic or Manual Data Display Scrolling and Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator
- Front Panel, Display Window in Chapter 5 Controls
- Front Panel Display Window in Chapter 7 Monitored Data
- Visual Alarm Displays and Alarms, Detailed Descriptions in Chapter 8 Ventilator Alarms
- Dim After in Chapter 10 Extended Features

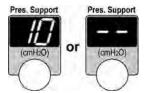
#### Controls Panel

The Controls panel contains various ventilation controls and associated push buttons with seven segment LED display windows or LED indicators, and the Patient Effort LED indicator.



## Seven Segment LED Display Windows

The seven segment LED display window is used to display either the particular ventilation control's set or selected value (active or not), including off ("- - ").



## **Breath Mode or Type LED Indicators**

When illuminated, the Breath Mode or Type LED indicators indicator which particular ventilation breath mode and type are set or selected.



#### **Patient Effort LED Indicator**

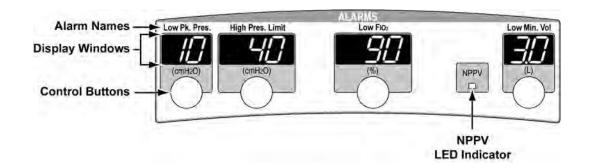
The Patient Effort LED indicator is illuminated (green) briefly each time a patient triggers a breath.



- Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 Using the Ventilator
- Front Panel, Controls in Chapter 5 Controls

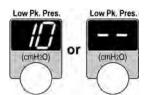
## Alarms Panel

The Alarms panel contains various ventilation alarm controls and associated push buttons with seven segment LED display windows, and the NPPV LED indicator.



## Seven Segment LED Display Windows

The seven segment LED display window is used to display either the particular alarm control's set or selected value (active or not), including off ("--").



#### **NPPV LED Indicator**

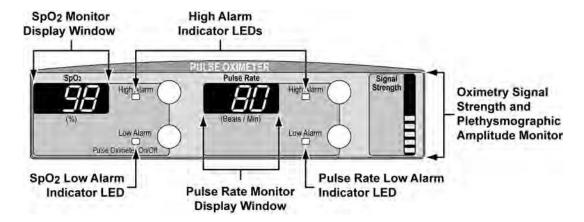
The **NPPV** LED indicator LED is illuminated (red) when an NPPV ventilation mode is active.



- Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 Using the Ventilator
- Front Panel, Alarms in Chapter 5 Controls
- Alarms, Detailed Descriptions in Chapter 8 Ventilator Alarms

#### Pulse Oximeter Panel

The Pulse Oximeter panel contains the SpO<sub>2</sub>, Pulse Rate, and Oximetry Signal Strength monitors, the SpO<sub>2</sub> and Pulse Rate High and Low Alarm controls and associated push buttons and LED indicators.



## **Seven Segment LED Display Windows**

When Pulse Oximetry is enabled and a  $SpO_2$  module and sensor are properly attached to the ventilator and patient, the  $SpO_2$  and Pulse Rate seven segment LED display windows are used to display the associated  $SpO_2$  and Pulse Rate monitored values and the set (when selected) High and Low alarm limit values.



## **High and Low Alarm LED Indicators**

When an SpO<sub>2</sub> or Pulse Rate, High or Low Alarm LED indicator is illuminated, the associated seven segment LED display window is used to display the alarm's set limit value (including off ("- - -")).



## **Oximetry Signal Strength Display**

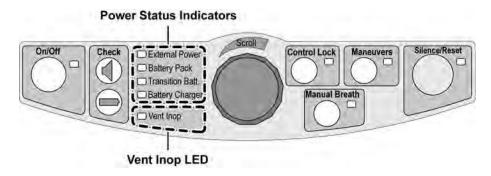
LEDs within the oximetry Signal Strength display window are illuminated (green, amber, or red) to indicate the strength of the signal being received from the external oximetry module. Additionally, the height to which the LEDs are illuminated fluctuates in unison with the Plethysmographic amplitude.



- Pulse Oximetry (SpO2) in Chapter 2 Installation and Setup
- Setting Adjustable Front Panel Ventilation Controls and Alarm Limits and Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator
- Front Panel, Pulse Oximeter in Chapter 5 Controls
- Pulse Oximetry Signal Strength and Pulse Rate in Chapter 7 Monitored Data
- Alarms. Detailed Descriptions in Chapter 8 Ventilator Alarms
- Pulse Ox (Pulse Oximetry) in Chapter 10 Extended Features

## **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.



#### Power Status LEDs

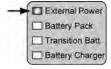
The Power Status LEDs indicate the active power source and battery charging status.

- 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 (Ext Pwr Low) alarm is active

Flashing Red The ventilator is connected to an external source of power that is faulted

• The External Power Fault (ExtPwrFault) alarm is active

## WARNING

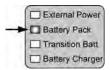
**Flashing Red External Power LED** - A flashing red **External Power** LED indicates that the external source of power connected to the ventilator is not usable and should be serviced. The ventilator will automatically switch to the Removable Battery Pack if present, or the Transition Battery. Insert a charged Removable Battery Pack or connect the ventilator to a CareFusion approved alternate source of power.

#### NOTE

The **External Power** LED is also 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 equal to or less than 25% capacity.

• The Battery Low (Bat Low) alarm is active

Red The ventilator is operating on power from a Removable Battery Pack with

a charge level equal to or less than 5% capacity.

• The Battery Empty (Bat Empty) alarm is active

**Flashing Red** The currently installed Removable Battery Pack is not usable.

 The Battery Fault (Bat Fault) alarm or the Insert Battery (Insert Batt) alarm is active

## **WARNING**

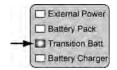
**Flashing Red Battery Pack LED** - A flashing red **Battery Pack** LED indicates that the currently installed Removable Battery Pack is not usable. Insert a different, charged Removable Battery Pack or connect the ventilator to a CareFusion approved alternate source of power.

#### 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 (**T-Bat 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 (T-Bat Use) alarm is active

**Flashing Red** The ventilator is operating on power from a Transition Battery which may

be unreliable.

• The Transition Battery Fault (T-Bat 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.

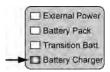
**Flashing Red Transition Battery LED** - A flashing red **Transition Batt** LED indicates that the ventilator's internal Transition Battery may be unreliable. Discontinue use of the ventilator and contact CareFusion or a service technician certified by CareFusion.

#### 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 is completed)

**Green** The Transition Battery is 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 DC 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 Silence/Reset 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 by pushing the **Silence/Reset** 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

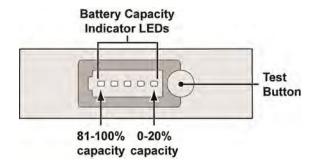
While in the Vent Inop state, the ventilator is set to a condition which allows the patient to breathe spontaneously from room air.

# **Removable Battery Pack LED Indicators**

A button on the Removable Battery Pack, linked to a series of five LEDs, allows you to check the percentage of charge remaining regardless of whether the Removable Battery Pack is installed in the ventilator.

Each LED increments approximately 20% as follows:

| LEDs<br>Illuminated | Approximate<br>Charge Level |
|---------------------|-----------------------------|
| 1                   | 0-20%                       |
| 2                   | 21-40%                      |
| 3                   | 41-60%                      |
| 4                   | 61-80%                      |
| 5                   | 81-100%                     |

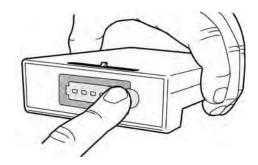


If the battery is being charged, the LED that is representative of the of the battery's current charge level flashes while the test button is being pushed.

### 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 Revel<sup>™</sup> ventilator monitors, updates and displays the following patient and device related data:

#### **Monitored Patient Data**

- Airway Pressure
- Exhaled Minute Volume (VE)
- Exhaled Tidal Volume (Vte)
- Fraction of Inspired Oxygen (FIO<sub>2</sub>)
- I:E Ratio, Calculated (I:Ecalc)
- I:E Ratio, Measured (I:E)
- Mean Airway Pressure (MAP)
- Nebulizer Time Remaining (Neb)
- O<sub>2</sub> Flush level and Time Remaining (O<sub>2</sub>+)
- Oxygen Saturation (SpO<sub>2</sub>)
- Peak Inspiratory Flow Rate (Vpeak)
- Peak Inspiratory Flow, Calculated (Vcalc)
- Peak Inspiratory Pressure (PIP)
- Positive End Expiratory Pressure (PEEP)
- Pulse Oximetry Signal Strength (Signal Strength) and Plethysmographic Amplitude
- Pulse Rate (Pulse Rate)
- SBT Breath Rate (SBT f)
- SBT f/Vt
- SBT Time Remaining (SBT)
- Spontaneous Breath Rate (Sp f)
- Spontaneous Exhaled Tidal Volume (SpVte)
- Total Breath Rate (f)
- Trend Log (not displayed by the ventilator)

#### **Monitored Device Data**

- · Leak, Measured (Leak)
- O<sub>2</sub> Source Pressure (O<sub>2</sub>)
- Peak Expiratory Flow Rate, Measured (Vepk)
- Power Status
- · Removable Battery Fuel Gauge
- Vent Usage Meter, Non-Resettable (Total Hrs)
- Vent Usage Meter, Resettable (Trip Hrs)

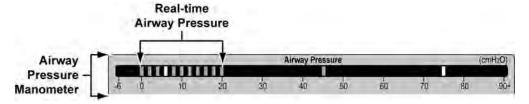
### **NOTE**

When using the ventilator in transport situations, excessive movement may cause variations in monitored values. Values will self recover once disturbance has been removed.

# Front Panel Airway Pressure Manometer

Airway pressure is continuously displayed in the Airway Pressure segmented bar display at the top of the front panel.

 See Airway Pressure Manometer in Chapter 6 – Displays and Indicators for additional information



# Front Panel Display Window

Monitored data is automatically scrolled continuously in the front panel display window during normal ventilation mode. The display is actively updated whenever alarms and/or extended features are not displayed. Each value is displayed for three seconds and is updated in real time.

To pause the display of data and/or manually scroll the display, see *Automatic or Manual Data Display Scrolling* in Chapter 3 – Using the Ventilator for detail instructions. For additional information, see:

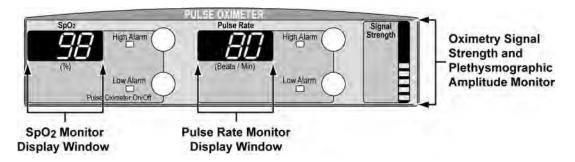
- Front Panel, Display Window in Chapter 5 Controls
- Display Window in Chapter 6 Displays and Indicators



### Pulse Oximeter Panel

 $SpO_2$ , Pulse Rate, Oximetry Signal Strength and Plethysmographic Amplitude monitored data are displayed on the Pulse Oximeter Panel. For additional information, see:

- Front Panel, Pulse Oximeter in Chapter 5 Controls
- Pulse Oximeter Panel in Chapter 6 Displays and Indicators



# **Monitored Patient Data**

Except for those data displayed in the Airway Pressure Manometer and on the Pulse Oximeter panel, monitored patient data is displayed in the front panel display window.

 LPPS / LMV alarm status messages, when applicable, are displayed in the front panel display window along with monitored data. See Alerts, LPPS / LMV Status Messages in Chapter 8 – Ventilator Alarms for detailed information.

### Airway Pressure

Airway Pressure is continuously measured at the patient Wye and displayed real time, on the Airway Pressure manometer segmented bar display at the top of the front panel.

Range -6 through 90+ (cmH<sub>2</sub>O)

# Exhaled Minute Volume (VE)

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: VE 0 through 99.9 L

# Exhaled Tidal Volume (Vte)

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 lpm (Adult/Ped/Infant) are not included in the integration.

Range: Vte 0 through 4000 ml

# Fraction of Inspired Oxygen (FIO<sub>2</sub>)

The  $F_{1O_2}$  monitored data is only visible when an optional  $F_{1O_2}$  Sensor is correctly installed, calibrated and  $F_{1O_2}$  monitoring is enabled.

Range: Fio<sub>2</sub> 12 through 103 %

### NOTE

To ensure accurate  $F_{1O_2}$  measurements, the  $F_{1O_2}$  Sensor must be calibrated to the ventilator upon initial ventilation of a new patient and if  $F_{1O_2}$  measurements become inaccurate based on the  $O_2$  ventilator setting.

### I:E Ratio, Calculated (I:Ecalc)

Calculated I:E Ratio is the calculated inspiratory time divided by the expiratory time, based solely on the **Insp. Time** and **Breath Rate** settings.

Range: I:Ecalc 1:99 through 4.0:1

# I:E Ratio, Measured (I:E)

Measured I:E Ratio is the measured inspiratory time divided by the measured exhalation time.

Range: I:E 1:99 through 45:1

# Mean Airway Pressure (MAP)

Mean Airway Pressure is calculated as 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 is updated at least every 10 seconds.

Range: MAP 0 through 99 cmH<sub>2</sub>O

# **Nebulizer Time Remaining (Neb)**

When a Nebulizer procedure is started, the remaining time for the procedure, beginning at the set duration time (**Neb Duration**) and reducing every second and minute until no time is left, is displayed.

Range: Neb 00:00 through Neb 30:00

# O<sub>2</sub> Flush Level and Time Remaining (O<sub>2</sub>+)

When an  $O_2$  Flush procedure is started, the percentage of  $O_2$  increased ( $O_2$  Flush %) and the remaining time for the procedure, beginning at the set duration time ( $O_2$  Flush Dur) and reducing every second and minute until no time is left, is displayed.

Range: O<sub>2</sub>+0 through 79% 02:00 through 03:00 (MM:SS)

# Oxygen Saturation (SpO<sub>2</sub>)

The  $SpO_2$  monitor (located on the Pulse Oximeter panel) displays an estimate of the patient's functional oxygen saturation of arterial oxyhemoglobin saturation, measured by the external Oximetry Module, when installed and enabled.

Range: **0** through **100** (%)



# Peak Inspiratory Flow Rate (Vpeak)

Peak Inspiratory Flow Rate is the peak inspiratory flow of the previous breath, measured at the patient Wye.

Range: **Vpeak 3** through **190 lpm** 

# Peak Inspiratory Flow, Calculated (Vcalc)

Peak Inspiratory Flow is calculated from the **Tidal Volume** and **Insp. Time** settings for Volume breaths.

Range: Vcalc 10 through 120 lpm

### NOTE

Calculated Peak Inspiratory Flow (Vcalc) is only displayed when Volume modes are selected.

# Peak Inspiratory Pressure (PIP)

Peak Inspiratory Pressure is the greatest airway pressure measured during the inspiratory phase and minimum exhalation time of the exhalation phase.

Range: PIP 0 through 120 cmH₂O

# Positive End-Expiratory Pressure (PEEP)

Positive End Expiratory Pressure is the pressure in the airway circuit at the end of exhalation.

Range: PEEP 0 through 99 cmH₂O

# Pulse Oximetry Signal Strength

LEDs within the pulse oximetry **Signal Strength** monitor display window (located on the Pulse Oximeter panel) are illuminated to indicate the strength of the signal being received from an external oximetry module, when installed and enabled.

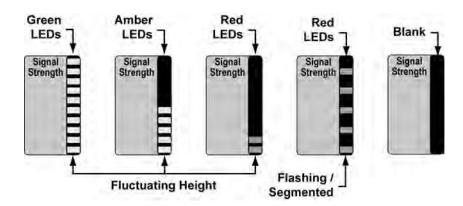
• The height to which the LEDs are illuminated fluctuates in unison with the Plethysmographic amplitude.

Range: Green, Amber, or Red

Indications:

Green LEDs, fluctuating height
 Amber LEDs, fluctuating height
 Red LEDs, fluctuating height
 Red LEDs, flashing/segmented
 ARTF or OOT condition occurring

Blank 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<sub>2</sub> module and are typically caused by patient/finger movement. Neither is an indication of a faulty or defective SpO<sub>2</sub> module.

### Pulse Rate

The Pulse Rate monitor (located on the Pulse Oximeter panel) displays the patients' heart rate, as measured by the external Oximetry module, when installed and enabled.



Range: Blank (off), "- - -" (no data), or 18 through 300 (Beats / Min)

# SBT Breath Rate (SBT f)

SBT Breath Rate is the Total Breath Rate during an SBT procedure.

Range: SBT f 1 through 120 bpm

### SBT f/Vt

When an SBT procedure is being performed, SBT f/Vt is the calculated value f/Vt, where f is the monitored SBT Breath Rate and Vt is the average Exhaled Tidal Volume in liters.

The SBT f/Vt monitor updates when the Breath Rate or Exhaled Minute Volume changes during the SBT period and the displayed data values remain visible during the SBT period and for five minutes after it has been completed.

Range: **0** through **998 bpm/L**, or "--" (no data)

# SBT Time Remaining (SBT)

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.

Range: SBT 00:00 (mm:ss) through SBT 02:00:00 (hh:mm:ss)

# Spontaneous Breath Rate (Sp f)

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: Sp f 0 through 120 bpm

# Spontaneous Exhaled Tidal Volume (SpVte)

The Spontaneous Exhaled Tidal Volume monitor displays the Exhaled Tidal Volume of Spontaneous and Support breaths. '----' is displayed 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: SpVte 0 through 4000 ml

# Total Breath Rate (f)

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: f 0 through 120 bpm

# **Trend Log**

Twenty-four (24) hours of monitored data can be stored in the ventilator's Trend Log (not displayed by the ventilator). 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 (**Pat Circuit**) alarm is active, or when no data is available (e.g. ventilator is not ventilating or feature is disabled) no data is entered in the Trend Log.

When the ventilator is docked onto a PTV<sup>™</sup> 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<sup>™</sup> Series Docking Station Operator's Manual, P/N 12433-001 for detailed information

| • | Auto PEEP                   | • | Measured Leak                    | • | Pulse Rate               |
|---|-----------------------------|---|----------------------------------|---|--------------------------|
| • | Delta Pressure              | • | Oxygen Saturation                | • | SBT Breath Rate          |
| • | Exhaled Minute Volume       | • | Peak Expiratory Flow             | • | SBT f/Vt                 |
| • | Exhaled Tidal Volume        | • | Peak Inspiratory Flow            | • | Spontaneous Breath Rate  |
| • | Expiratory Pressure         | • | Peak Inspiratory Pressure        | • | Spontaneous Tidal Volume |
| • | Fraction of Inspired Oxygen | • | Plateau Pressure                 | • | Static Compliance        |
| • | Mean Airway Pressure        | • | Positive End-Expiratory Pressure | • | Total Breath Rate        |

# **Monitored Device Data**

Except for the battery capacity indicator LEDs on the Removable Battery Pack itself, monitored device data is displayed in the front panel display window using the Extended Features menus. For additional information, see:

- Navigating Startup and Extended Features Menus in Chapter 3 Using the Ventilator
- Extended Features Menus in Chapter 10 Extended Features

# Leak, Measured (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.

 To view Measured Leak data, see Ext Monitors (Extended Monitors) in the Extended Features, Service menus in Chapter 10 – Extended Features for additional information

Range: Leak 0.0 through 30.0 lpm

### NOTE

- Values Not Reported The Measured Leak monitor 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 Leak monitor and the set Bias Flow.

# O<sub>2</sub> Source Pressure (O<sub>2</sub>)

O<sub>2</sub> Source Pressure is the pressure measured at the O<sub>2</sub> Inlet.

• To view O<sub>2</sub> Source Pressure data, see *Ext Monitors (Extended Monitors)* in the Extended Features, Service menus in Chapter 10 – Extended Features for additional information

Range: O<sub>2</sub> 2.0 through 99.9 PSI

# Peak Expiratory Flow Rate, Measured (Vepk)

Measured Peak Expiratory Flow Rate is the Peak Expiratory Flow of the previous breath, measured at the patient Wye.

 To view Peak Expiratory Flow Rate data, see Ext Monitors (Extended Monitors) in the Extended Features, Service menus in Chapter 10 – Extended Features for additional information

Range: **Vepk 0** through **190 lpm** 

### **Power Status**

The status of any power supply connected to the ventilator is monitored and relevant data displayed in the front panel display window when the Battery/Power **Check** button is pushed on the lower interface panel. For additional information, see:

Battery / Power Button

- Battery/Power in Chapter 5 Controls
- Lower Interface Panel Indicators in Chapter 6 Displays and Indicators
- Chapter 12 Power Supplies and Batteries

| 1 | Po | w | er | S | วน | rc | е |
|---|----|---|----|---|----|----|---|
|   |    |   |    |   |    |    |   |

|                    | Removable<br>Battery Pack | External DC<br>Power | Docking<br>Station | Transition<br>Battery |
|--------------------|---------------------------|----------------------|--------------------|-----------------------|
|                    | Batt xxx%                 | Ext OK               | Dock OK            | T-Bat OK              |
| Possible           | Batt Removed              | Ext Low              | Dock Low           | T-Bat Low             |
| Status<br>Messages | Batt Fault                | Ext Removed          | Dock Removed       | T-Bat Remove          |
| Displayed          |                           | Ext Fault            | Dock Fault         | T-Bat Chrg            |
|                    |                           |                      |                    | T-Bat Fault           |

### **NOTE**

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

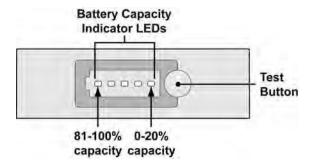
If any fault message (xxxxx Fault) is displayed, it is an indication that the displayed source of power (Batt, Ext, Dock or T-Bat) has been detected and is <u>not</u> adequate to power the ventilator.

# Removable Battery Fuel Gauge

The status of the Removable Battery Pack is also displayed on the end of the Removable Battery Pack when the battery's **Test** button is pushed. For additional information, see:

• Removable Battery Pack in the Chapter 12– Power Supplies and Batteries

Range: 0-20% through 81-100%



| LEDs Lit | Approximate Charge<br>Level |  |
|----------|-----------------------------|--|
| 1        | 0-20%                       |  |
| 2        | 21-40%                      |  |
| 3        | 41-60%                      |  |
| 4        | 61-80%                      |  |
| 5        | 81-100%                     |  |
|          |                             |  |

# Vent Usage Meter, Non-Resettable (Total Hrs)

The Non-Resettable Usage monitor displays the total number of hours of ventilator operation and is updated every 0.1 hours.

• See *Usage* in the Extended Features, Service menus in Chapter 10 – Extended Features for additional information

Range: **0.0** through **500000.0** hrs

# Vent Usage Meter, Resettable (Trip Hrs)

The Resettable Usage monitor tracks and displays the number of hours of ventilator usage since the last time the monitor was reset by an operator.

• See *Usage* in the Extended Features, Service menus in Chapter 10 – Extended Features for additional information

Range: 0.0 through 500000.0 hrs

# 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 number of breaths. For instance, a High Airway Pressure alarm (**High Pres**) can be delayed for one or two breaths to prevent activation during patient coughing. See *HP Delay* (*High Pressure Delay*) in the Alarm Configuration menus in Chapter 10 – Extended Features 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 Exhaled Minute Volume (**Low Min. Vol.**) and Low Peak Pressure (**Low Pk. Pres.**) 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 front panel display window in the order of the priority sequence, with active alarms displayed first.

# **Audible and Visual Elements**

# Sound Types, Patterns and Volumes

The Revel<sup>™</sup> 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<br>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) <sup>28</sup> | Sounds between >45 dBa and 80 ± 5 dBA, and is automatically adjusted to a higher audible volume level than that of Low Priority alarms <sup>29</sup> |  |
| 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   |  |
| Accessory Attach signal            | A group of 2, ascending pitch, pulsed tones                              | automatically adjusted to a<br>lower audible volume level<br>than that of High and Medium<br>Priority alarms <sup>29</sup>                           |  |
| Key Click signal                   | A single medium frequency note   |  |  |
| Battery Use alarm                  | A periodic audible tone, once per minute                                 | Sounds at set Battery Use<br>Tone volume   |  |
| SpO <sub>2</sub> 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 tone and/or the  $SpO_2$  Pulse Tone signal, see *Alarm Config (Alarm Configuration)* and *Option Cnfg (Option Configuration)* in Chapter 10 – Extended Features for detailed instructions.

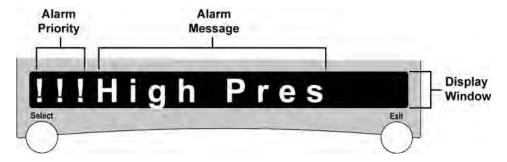
<sup>&</sup>lt;sup>28</sup> Alarm tones Patterns are per ISO 9703-2

<sup>&</sup>lt;sup>29</sup> Allows operators to differentiate between High/Medium and Low Priority alarm audible volume levels.

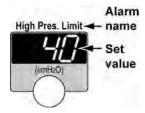
# Visual Alarm Displays

There are multiple components to the visual display portion of an alarm condition.

- Alarm messages are displayed flashing off and on in the Display Window near the top of the front panel.
  - When multiple alarms are occurring, only the alarm with highest priority is displayed until it has been resolved and/or reset. Once the highest priority alarm has been resolved, the others are displayed in order of importance



- 2) To help identify alarm priorities, active high priority alarm messages displayed are preceded by three (3) exclamation points (!!!), active Medium priority alarm messages are preceded by two (2) exclamation points (!!), and active Low priority alarm messages are preceded by one (1) exclamation point.
- 3) The set/displayed values of associated front panel adjustable alarm or ventilation controls (if any) flash. See *Display Characteristics* in Chapter 3 Using the Ventilator for additional information.



# 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 front panel adjustable alarm or ventilation control displays (if any) flash (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 **Silence/Reset** button on the lower interface panel once to silence an active audible alarm for 60 seconds. Pushing the **Silence/Reset** button a second time cancels the 60 second silence period.



• See Silence/Reset 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 audible alarm is silenced.

See Silence/Reset in Chapter 5 – Controls for additional information

### To Reset Alarms

To reset alarms (silence the alarm sounder and clear the alarm message(s)), push the **Silence/Reset** button on the lower interface panel. A second push removes the visible (highest priority) flashing alarm message, and subsequent lower priority alarms (if actively occurring) are displayed.



### **WARNING**

**Resetting Alarms** - Before resetting/removing alarm messages from the display window, operators should review each alarm message displayed and be fully aware of its meaning and applicability to the patient. When necessary, refer to the *Alarms, Detailed Descriptions* section located later in this chapter for an alphabetical listing of all alarms with detailed explanations of each alarm.

Each subsequent push removes the next visible alarm message in order of priority (see *Alarm Priorities* in Chapter 8 – Ventilator Alarms). Additionally, the following alarm messages are also reset/removed, even if they are active.

- Apnea (Apnea)
- Button Stuck (ButtonStuck)
- Configuration Reset (ConfigReset)
- Docking Station Disconnect (**Dock Discon**)
- External Power Lost (ExtPwr Lost)
- External Power Low (Ext Pwr Low)
- FiO<sub>2</sub> Sensor Fault (FIO<sub>2</sub> Fault)
- Insert Battery (Insert Batt) (reoccurs after 60 sec's)

- Preventive Maintenance Required (**P Maint xxx**)
- Removable Battery Low (Bat Low)
- Remove Patient (Remove Ptnt)
- SBT Off (SBT Off)
- SBT Time (**SBT Time**)
- Schedule Service (SchedSvcxxx)
- Transition Battery Use (**T-Bat Use**) (one time only, 60 sec's)
- Ventilator Reset (Vent Reset)

# **Adjustable Alarms**

The Revel<sup>™</sup> ventilator has Front Panel and Extended Features accessible 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

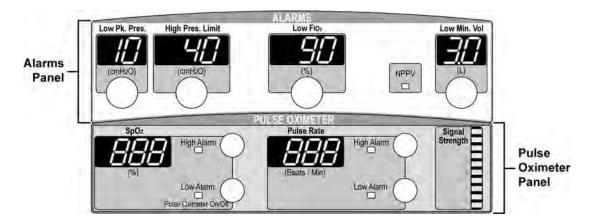
### **WARNING**

**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.

# Front Panel Adjustable Alarms

The following adjustable alarm limits are set using the Alarms and Pulse Oximeter front panel controls:

- Low Peak Pressure (Low Pk. Pres)
- High Pressure (High Pres. Limit)
- Low FIO<sub>2</sub>
- Low Minute Volume (Low Min. Vol.)
- SpO<sub>2</sub> High and Low Alarms
- Pulse Rate High and Low Alarms



### To Set Front Panel Adjustable Alarms

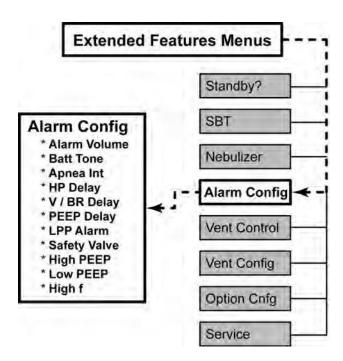
Use the three step "Select, Change and Confirm" method to set the front panel adjustable alarm limits. For additional information and detailed instructions, see:

- Front Panel Ventilation and Alarm Controls and Setting Adjustable Front Panel Ventilation Controls and Alarm Limits in Chapter 3 – Using the Ventilator
- Front Panel, Alarms and Front Panel, Pulse Oximeter in Chapter 5 Controls

# Extended Features Adjustable Alarms

The following adjustable alarm limits are set using the Extended Features, Alarm Configuration (**Alarm Config**) menus:

- High Positive End Expiratory Pressure (High PEEP)
- Low Positive End Expiratory Pressure (Low PEEP)
- High Breath Rate (High f)



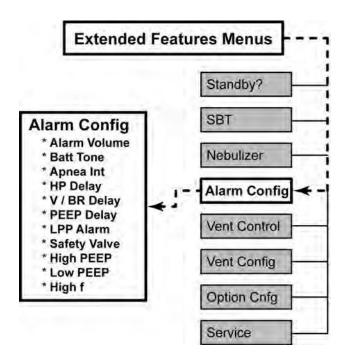
# To Set Extended Features Adjustable Alarms

See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator and Alarm Config (Alarm Configuration) in Chapter 10 - Extended Features for additional information and detailed instructions for setting Extended Features adjustable alarm limits.

# **Alarm Configuration in Extended Features**

The Extended Features, Alarm Configuration (**Alarm Config**) menus are used to set alarm configuration parameters:

- Alarm Volume
- Battery Use Tone (Batt Tone)
- Apnea Interval (Apnea Int)
- High Pressure Delay (**HP Delay**)
- Minute Volume/Breath Rate Alarm Delay (V/BR Delay)
- Positive End Expiratory Pressure Delay (PEEP Delay)
- Low Peak Pressure Alarm (LPP Alarm)
- Safety Valve



# **To Set Alarms Configuration Parameters**

See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator and Alarm Config (Alarm Configuration) in Chapter 10 - Extended Features for additional information and detailed instructions for the configuration of alarm parameters.

# Alarms, Detailed Descriptions

### 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 10

#### When an Apnea alarm occurs:

- The ApneaBackup alarm message is displayed
- A high priority audible alarm sounds
- The displays for controls active in Apnea Backup mode are illuminated and all other control displays are dimmed
- The ventilator initiates Apnea Backup ventilation 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 **ApneaBackup** alarm 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 two consecutive breaths:

- Apnea Backup Ventilation terminates and the ventilator returns to the previous mode
- An Apnea alarm message is displayed and remains flashing
- The audible alarm is silenced
- Control displays return to normal ventilation mode

Pushing the Silence/Reset button clears the Apnea message.

# **Apnea Interval**

### To set the Apnea Interval:

The Apnea Interval is set using Extended Features menus. See *Apnea Int (Apnea Interval)* in the Extended Features, Alarm Configuration menus in Chapter 10 – Extended Features.

For additional information concerning Apnea Backup ventilation, see *Apnea Backup Ventilation* in Chapter 4 – Breath Types and Modes.

# Battery Empty (Bat 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 Vent Inop immediately insert a charged Removable Battery Pack or connect the ventilator to an external source of power.

### When a Battery Empty alarm occurs:

- The Batt 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 (Bat 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 may be 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 Bat 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 (Bat 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 Bat 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 (RBatTempFlt)

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 **RBatTempFlt** 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**, using the Extended Features, Alarm Configuration (**Alarm Config**) menus.

 See Batt Tone (Battery Use Tone) in Chapter 10 – Extended Features for additional information and detailed instructions

# Blower Demand Exceeded (Blwr Demand)

The Blower Demand Exceeded alarm (a fixed alarm) is generated when the average current demand of the ActiveCore<sup>™</sup> 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 Blwr Demand alarm message is displayed
- A high priority audible alarm sounds
- The ventilator stops delivering mandatory machine breaths

# **Button Stuck (ButtonStuck)**

A Button Stuck alarm (a fixed alarm) is generated when the ventilator detects pressure on any front or lower interface panel button, other than the On/Off control button, 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 **ButtonStuck** 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 Button Test in Chapter 2 – Installation and Setup for instructions to perform the Button Test.

# Configuration Reset (ConfigReset)

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<sup>30</sup>.

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 occurs:

- The ConfigReset alarm message is displayed
- A high priority audible alarm sounds
- All adjustable Controls, Alarms or 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

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A Configuration Reset alarm is not generated if the ventilator configuration has been manually reset to factory settings using the Reset menu in Startup mode.

 $<sup>^{30}</sup>$  Non-volatile memory is memory that is  $\underline{not}$  erased when the ventilator is turned off or disconnected.

# Dock Disconnect (Dock Discon)

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 Discon alarm message is displayed
- · A medium priority audible alarm sounds

# **Docking Station Fault (Dock Fault)**

The Docking Station 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 Docking Station Fault alarm occurs:

- The Dock Fault alarm message is displayed
- A medium priority audible alarm sounds

# External Power Fault (ExtPwrFault)

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 alternate power source for the ventilator.

#### When an External Power Fault alarm occurs:

- The ExtPwrFault 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 (ExtPwr 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 ExtPwr 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)

# External Power Low (Ext Pwr 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 External Power 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 Ext Pwr Low alarm message is displayed
- A medium priority audible alarm sounds
- The External Power LED on the lower interface panel is illuminated amber

# FIO<sub>2</sub> Sensor Fault (FIO<sub>2</sub> Fault)

The FiO<sub>2</sub> Sensor Fault alarm (a fixed alarm) is generated when FiO<sub>2</sub> has been enabled (in Startup mode) and the ventilator detects a FiO<sub>2</sub> Sensor failure.

### CAUTION

FIO<sub>2</sub> Sensor Fault Alarm – This alarm indicates that the FIO<sub>2</sub> Sensor in use may not be working properly with the ventilator. Replace the FIO<sub>2</sub> Sensor.

#### When an Fio<sub>2</sub> Sensor Fault alarm occurs:

- The Fio<sub>2</sub> Fault alarm message is displayed
- A medium priority audible alarm sounds

# Hardware Fault (HW Faultxxx)

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 Revel<sup>™</sup> ventilator with an active Hardware Fault alarm may result in inaccurate measurements or ventilation. If this occurs, 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 HW Faultxxx alarm message is displayed showing 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 *Event Trace* in Chapter 10 – Extended Features.

# High Airway Pressure (High Pres)

The High Airway Pressure alarm (a user adjustable alarm) is generated when the monitored airway pressure exceeds the set High Airway Pressure (**High Pres**) alarm limit for the set number of High Pressure Delay breaths (**HP Delay**).

Range: 5 through 100 cmH<sub>2</sub>O in increments of 1

#### When a High Airway Pressure alarm occurs:

- The **High Pres** alarm message is displayed
- A high priority audible alarm sounds
- The High Pres. Limit alarm control display flashes
- Inspiration is terminated and the exhalation valve is opened to relieve pressure

### WARNING

**Sustained High Airway Pressure** - During a sustained High Airway Pressure 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 (SVHP Relief)* in this chapter for additional information.

If the high pressure condition does not recover within 1.5 seconds or if Airway Pressure  $\geq$  110 cmH<sub>2</sub>O, 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<sup>31</sup>, if the circuit pressure exceeds the set **High Pres**. **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 (**HP Delay**) setting

Recovery from the sustained high pressure condition requires either an alarm reset or 10 seconds to have elapsed.

#### To set the High Airway Pressure alarm limit:

To set the High Airway Pressure alarm, see *Front Panel*, *Alarms* in Chapter 5 – Controls for instructions.

#### To set delayed notification for the High Airway Pressure alarm:

To set a delay for High Airway Pressure alarms, see *HP Delay (High Pressure Delay)* in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features. The audible alarm will sound whenever a high pressure condition persists which stops the Blower, regardless of the delay setting.

<sup>&</sup>lt;sup>31</sup> 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 Breath Rate (High f)

The High Breath Rate alarm (a user adjustable alarm) is generated when the monitored Total Breath Rate exceeds the set High Breath Rate (**High f**) alarm limit for the set Minute Volume/Breath Rate Delay (**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 f alarm message is displayed
- A medium priority audible alarm sounds
- The Breath Rate control display flashes

#### To set the High Breath rate alarm:

To set the High Breath Rate alarm value, see *High f (High Breath Rate)* in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features.

#### To set delayed notification for the High Breath Rate alarm:

To set a delay for the Low Exhaled Minute Volume (**Low Min Vol**) and the High Breath Rate (**High f**) alarms, see *V/BR Delay (Minute Volume/Breath Rate Alarm Delay)* in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features.

# High O<sub>2</sub> Inlet Pressure (Hi O<sub>2</sub> Pres)

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<sup>32</sup> O<sub>2</sub> 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<sub>2</sub> Inlet Pressure alarm occurs:

- The Hi O<sub>2</sub> Pres alarm message is displayed
- A medium priority audible alarm sounds
- If the set O<sub>2</sub> control value is LPS (Low Pressure Source) and the O<sub>2</sub> Inlet pressure is set above 40 PSI, the ventilator automatically switches to High Pressure O<sub>2</sub> Source mode and changes the active<sup>32</sup> O<sub>2</sub>% control value to 21%

<sup>&</sup>lt;sup>32</sup> The "active" O<sub>2</sub> value is the **O**<sub>2</sub> control setting during normal ventilation, the Extended Features **O**<sub>2</sub> **Flush** % setting during an O<sub>2</sub> Flush procedure, or the Extended Features **SBT O**<sub>2</sub> setting during an SBT procedure.

# High PEEP

The High PEEP alarm (a user adjustable alarm) is generated when the monitored PEEP is greater than the active PEEP control setting<sup>33</sup>.

### NOTE

If the active PEEP control setting<sup>33</sup> 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 40 cmH<sub>2</sub>O, or "--" (off)

#### When a High PEEP alarm occurs:

- The **High PEEP** alarm message is displayed
- A medium priority audible alarm sounds
- The **PEEP** control display flashes

#### To set the High PEEP alarm limit:

To set the High PEEP alarm limit, see High PEEP in the Extended Features, Alarm Config menus in Chapter 10 - Extended Features.

### To set delayed notification for the PEEP alarms:

To set a delay for the High PEEP and Low PEEP alarms (PEEP Delay), see PEEP Delay in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features.

# High Pulse Rate (High Pulse)

The High Pulse Rate alarm (a user adjustable alarm) is generated when the monitored Pulse Rate exceeds the set Pulse Rate, High Alarm limit. The High Pulse Rate alarm is only active when the SpO<sub>2</sub> Module is connected, enabled and attached to a patient.

Range: 18 through 299 Beats/min, or "- -" (off)

### When a High Pulse Rate alarm occurs:

- The High Pulse alarm message is displayed
- A high priority audible alarm sounds
- The Pulse Rate display flashes

#### To set the High Pulse Rate alarm limit:

To set the High Pulse Rate alarm limit see Front Panel, Pulse Oximeter in Chapter 5 - Controls for instructions.

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The "active" PEEP control setting is the PEEP control setting during normal ventilation, or the SBT PEEP control setting (in Extended Features) during an SBT procedure.

# High SpO<sub>2</sub>

The High  $SpO_2$  alarm (a user adjustable alarm) is generated when the monitored  $SpO_2$  exceeds the set  $SpO_2$ , High Alarm limit. The High  $SpO_2$  alarm is only available when an Oximetry Module is connected, enabled and attached to a patient.

Range: **80** through **99%**, or "--" (off)

#### When a High SpO<sub>2</sub> alarm occurs:

- The High SpO<sub>2</sub> alarm message is displayed
- A high priority audible alarm sounds
- The SpO<sub>2</sub> display flashes

### To set the High SpO<sub>2</sub> alarm limit:

To set the High SpO<sub>2</sub> alarm limit see *Front Panel, Pulse Oximeter* in Chapter 5 – Controls for instructions.

# Insert Battery (Insert Batt)

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 Batt alarm message is displayed
- · A medium priority audible alarm sounds
- 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.

# Low Exhaled Minute Volume (Low Min Vol)

The Low Exhaled Minute Volume alarm (a user adjustable alarm) is generated when the monitored Exhaled Minute Volume (**VE**) is less than the **Low Min. Vol.** alarm limit setting for the set Minute Volume/Breath Rate Alarm Delay (**V/BR Delay**) (in seconds) and at least eight (8) breaths have occurred since the **Low Min. Vol.** alarm was last reset.

Range: **0.1** through **99 L** or "- -" (off)

### **WARNING**

**Low Minute Volume Control Values** - The Low Exhaled Minute Volume limit should be set to its highest clinically appropriate value. If there is a need to set the Low Exhaled Minute Volume 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 Exhaled Minute Volume (Low Min Vol), Low Peak Pressure (Low Pk Pres), Low PEEP and/or Patient Circuit Fault (Pat. Circuit) alarms could indicate a patient circuit leak. Check patient circuit integrity if one or more of these alarms is repeatedly activated.

#### When a Low Exhaled Minute Volume alarm occurs:

- The Low Min Vol alarm message is displayed
- A high priority audible alarm sounds
- The Low Min. Vol. alarm control flashes

#### To set the Low Exhaled Minute Volume alarm limit:

To set the Low Exhaled Minute Volume alarm limit see *Front Panel, Alarms* in Chapter 5 – Controls for instructions.

 LPPS / LMV alarm status messages, when applicable, are displayed in the front panel display window along with monitored data. See Alerts, LPPS / LMV Status Messages later in this chapter for detailed information.

#### To set delayed notification for the Low Exhaled Minute Volume alarm:

To set a delay for the Low Exhaled Minute Volume (**Low Min Vol**) and the High Breath Rate (**High f**) alarms, see *V/BR Delay (Minute Volume/Breath Rate Alarm Delay)* in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features.

### Low FIO<sub>2</sub>

The Low  $F_{1O_2}$  alarm (a user adjustable alarm) is generated when the monitored  $F_{1O_2}$  (Fraction of Inspired Oxygen) is equal to or less than the **Low F\_{1O\_2}** alarm setting. The Low  $F_{1O_2}$  alarm is only available when an  $F_{1O_2}$  Sensor is installed in the patient circuit, connected to the ventilator and enabled.

Range: **18** through **95% O**<sub>2</sub> or "--" (off)

#### When a Low FIO<sub>2</sub> alarm occurs:

- The Low Fio<sub>2</sub> alarm message is displayed
- · A High priority audible alarm sounds
- The Low Fio₂ alarm control display flashes

#### To set the Low Fio<sub>2</sub> alarm

To set the Low FIO<sub>2</sub> alarm, see Front Panel, Alarms in Chapter 5 – Controls for instructions.

See *Procedures* in Chapter 9 – Maneuvers and Procedures for additional information.

# Low O<sub>2</sub> Inlet Pressure (Low O<sub>2</sub> Pres)

The Low  $O_2$  Inlet Pressure alarm (a fixed alarm) message is generated when the monitored  $O_2$  Inlet Pressure is less than 39 PSI and the active  $^{34}$   $O_2$ % control is set to more than 21%. The alarm may also be triggered when the  $O_2$ % is set to 21% if the  $O_2$  Flush procedure or the **Nebulizer** procedure is active.

The Low O<sub>2</sub> Inlet Pressure alarm is inactive when the O<sub>2</sub> control is set to LPS

#### When a Low O<sub>2</sub> Inlet Pressure alarm occurs:

- The Low O<sub>2</sub> Pres alarm message is displayed
- A high priority audible alarm sounds

See Procedures in Chapter 9 – Maneuvers and Procedures for additional information.

<sup>&</sup>lt;sup>34</sup> The "active" O<sub>2</sub> value is the O<sub>2</sub> control setting during normal ventilation, the Extended Features O<sub>2</sub> Flush % setting during an O<sub>2</sub> Flush procedure, or the Extended Features SBT O<sub>2</sub> setting during an SBT procedure.

# Low Peak Pressure (Low Pk Pres)

The Low Peak Pressure alarm (a user adjustable alarm) is generated when the monitored Peak Inspiratory Pressure (**PIP**) for a selected breath is less than the set **Low Pk Pres** alarm limit.

Range: 1 through 60 cmH<sub>2</sub>O, or "--" (off)

## **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 Peak Pressure alarm generation. Set the Low Pk Pres alarm limit high enough to detect a disconnect when using these accessories, or use an alternate method (e.g. Low Exhaled Minute Volume alarm) to ensure disconnect detection.

## NOTE

Activation of the Low Peak Pressure (**Low Pk Pres**), Low Exhaled Minute Volume (**Low Min Vol**), **Low PEEP**, and/or Patient Circuit Fault (**Pat. Circuit**) 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 Peak Pressure alarm occurs:

- The Low Pk Pres alarm message is displayed
- A high priority audible alarm sounds
- The Low Pk Pres. alarm control display flashes

#### To set the Low Peak Pressure alarm:

To set the Low Peak Pressure alarm, see *Front Panel*, *Alarms* in Chapter 5 – Controls for instructions.

## To set the applicable breath type for the Low Peak Pressure alarm

The Low Peak Pressure alarm can be configured to apply to **All Breaths** or to **Control Only**. In SIMV mode, selecting **Control Only** allows the Low Peak Pressure alarm to apply to Machine breaths only. It has no effect in A/C or CPAP modes. See *LPP Alarm* (*Low Peak Pressure Alarm*) in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features for detailed instructions.

• LPPS / LMV alarm status messages, when applicable, are displayed in the front panel display window along with monitored data. See *Alerts, LPPS / LMV Status Messages* later in this chapter for detailed information.

# Low PEEP

The Low PEEP alarm (a user adjustable alarm) is generated when the monitored PEEP is less than the active PEEP control setting<sup>35</sup>.

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 20 cm H<sub>2</sub>O

#### When a Low PEEP alarm occurs:

- The Low PEEP alarm message is displayed
- A high priority audible alarm sounds
- The PEEP control display flashes

# **NOTE**

- If the active PEEP control setting<sup>35</sup> is changed, the Low PEEP (**Low PEEP**) alarm is delayed for 30 seconds to allow the PEEP to stabilize.
- Activation of the Low PEEP (Low PEEP), Low Peak Pressure (Low Pk Pres), Low
   Exhaled Minute Volume (Low Min Vol) and/or Patient Circuit Fault (Pat. Circuit) 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.

#### To set the Low PEEP alarm limit:

To set the Low PEEP alarm limit, see *Low Peep* in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features.

## To set delayed notification for the PEEP alarms:

To set a delay for the Low PEEP and High PEEP alarms (**PEEP Delay**), see *PEEP Delay* in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features.

<sup>35</sup> The "active" PEEP control setting is the PEEP control setting during normal ventilation, or the SBT PEEP control setting (in Extended Features) during an SBT procedure.

# Low Pulse Rate (Low Pulse)

The Low Pulse Rate alarm (a user adjustable alarm) is generated when the monitored pulse rate is less than the **Pulse Rate, Low Alarm** limit setting. The Low Pulse Rate alarm is only active when the SpO<sub>2</sub> Module is connected, enabled and attached to a patient.

Range: 19 through 300 Beats/min, or "--" (off),

## When a Low Pulse Rate alarm occurs:

- The Low Pulse alarm message is displayed
- A high priority audible alarm sounds
- The Pulse Rate display flashes

#### To set the Low Pulse Rate alarm:

To set the Low Pulse Rate alarm limit, see *Front Panel, Pulse Oximeter* in Chapter 5 – Controls for instructions.

# Low SpO<sub>2</sub>

The Low  $SpO_2$  alarm (a user adjustable alarm) is generated when the monitored  $SpO_2$  is less than the  $SpO_2$ , Low 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: **60** through **99** %, or "--" (off),

# When a Low SpO<sub>2</sub> alarm occurs:

- The Low SpO<sub>2</sub>alarm message is displayed
- A high priority audible alarm sounds
- The SpO<sub>2</sub> display flashes

#### To set the Low SpO<sub>2</sub> alarm:

To set the Low SpO<sub>2</sub> alarm limit, see *Front Panel, Pulse Oximeter* in Chapter 5 – Controls for instructions.

# Patient Circuit Fault (Pat. Circuit)

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 Airway Pressure (**High Pres**), Low Peak Pressure (**Low Pk Pres**), **Low PEEP** and Low Exhaled Minute Volume (**Low Min Vol**) alarms are set appropriately to prevent patient risk.

## NOTE

- If a High Airway Pressure (High Pres) or Safety Valve High Pressure Relief (SVHP 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 Peak Pressure (Low Pk Pres), Low PEEP and/or Low Exhaled Minute Volume (Low Min Vol) 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 Pat. Circuit 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 (P Maint xxx)

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 **P Maint 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 (Remove Ptnt)

The Remove Patient alarm (a fixed alarm) is activated when the ventilator enters the Vent Check menu 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 Ptnt** 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, Pediatric or Infant) and patient breathing circuit type selections (Intubated or NPPV) are being made
- During NPPV IPAP, EPAP, and Rate control values selection
- While ventilator configuration selections (Language, Units and Reset) are being made
- While the Button and Circuit Tests are being performed (Vent Check)

#### When a Remove Patient alarm occurs:

- The Remove Ptnt alarm message flashes
- 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 **Silence/Reset** button on the lower interface panel twice to silence the audible alarm and remove the visible flashing alarm message.

While the Remove Patient alarm is active, the **Remove Ptnt** alarm message and its audible tone will be reactivated after being reset by the **Silence/Reset** button and 120 seconds of user inactivity.

# Safety Valve High Pressure Relief (SVHP Relief)

The Safety Valve High Pressure Relief Alarm is generated when:

- Airway Pressure<sup>36</sup> is ≥ 110 cmH<sub>2</sub>O, or
- Airway Pressure<sup>36</sup> ≥ the High Airway Pressure alarm (**High Pres**) setting plus the Safety Valve Delta Pressure setting (see *Safety Valve* in the Extended Features, Alarm Configmenus in Chapter 10 Extended Features)

## When a Safety Valve High Pressure Relief alarm occurs:

- The SVHP Relief alarm 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. Refer to *Chapter 13 - Troubleshooting* for detailed corrective actions.

# SBT High Breath Rate (SBT > f)

The SBT High Breath Rate alarm (a user adjustable alarm) is generated when the monitored SBT breath rate (**SBT f**) exceeds the set SBT High Breath Rate alarm limit continuously for 30 seconds during a Spontaneous Breathing Trial.

Range: 15 through 80 bpm, or SBT Hi f Off

#### When an SBT High Breath Rate alarm occurs:

- The SBT > f alarm message is displayed
- A medium priority audible alarm sounds
- The SBT procedure terminates if the alarm is active continuously for 5 minutes

#### To set the SBT High Breath Rate Alarm limit:

To set the SBT High Breath Rate alarm limit, see SBT High f in the Extended Features, SBT menus in Chapter 10 – Extended Features.

<sup>&</sup>lt;sup>36</sup> Blower Estimated Airway Pressure is a redundant measure of airway pressure based on the blower differential pressure transducer.

# SBT High f/Vt (SBT > f/Vt)

The SBT High f/Vt alarm (a user adjustable alarm) is generated when the SBT f/Vt ratio is greater than the set SBT High f/Vt alarm limit continuously for 30 seconds during a Spontaneous Breathing Trial.

Range: 70 through 900 bpm/L, or Hi f/Vt Off

## When an SBT High f/Vt alarm occurs:

- The SBT > f/Vt alarm message is displayed
- A medium priority audible alarm sounds
- The SBT procedure terminates if the alarm is active continuously for 5 minutes

#### To set the SBT High f/Vt alarm limit:

To set the SBT High f/Vt alarm limit, see *SBT Hi f/Vt* in the Extended Features, SBT menus in Chapter 10 – Extended Features.

# 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<sup>37</sup> 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 40 cm $H_2O$ , or "--" (off)

## When a SBT High PEEP alarm occurs:

- The SBT Hi PEEP alarm message is displayed
- A medium priority audible alarm sounds

#### To set the SBT High PEEP alarm limit:

To set the SBT High PEEP alarm limit, see *SBT Hi PEEP* in the Extended Features, SBT menus in Chapter 10 – Extended Features.

#### To set delayed notification for the PEEP alarms:

To set a delay for the High PEEP and Low PEEP alarms (**PEEP Delay**), see PEEP Delay in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features.

<sup>&</sup>lt;sup>37</sup> The "active" PEEP control setting is the **PEEP** control setting during normal ventilation, or the **SBT PEEP** control setting (in Extended Features) during an SBT procedure.

# SBT Low Breath Rate (SBT < f)

The SBT Low Breath Rate alarm (a user adjustable alarm) is generated when the monitored SBT breath rate (**SBT f**) is less than the set SBT Low Breath Rate alarm limit continuously for 30 seconds during a Spontaneous Breathing Trial.

Range: 1 through 40 bpm, or SBT Lo f Off

## When an SBT Low Breath Rate alarm occurs:

- The SBT < f alarm message is displayed</li>
- · A medium priority audible alarm sounds
- The SBT procedure terminates if the alarm is active continuously for 5 minutes

# To set the SBT Low Breath Rate alarm limit:

To set the SBT Low Breath Rate alarm limit, see *SBT Low f* in the Extended Features, SBT menus in Chapter 10 – Extended Features.

## 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 <sup>38</sup> 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 20 cmH<sub>2</sub>O

## When a SBT Low PEEP alarm occurs:

- The SBT Lo PEEP alarm message is displayed
- A high priority audible alarm sounds

## NOTE

Activation of the SBT Low PEEP (**SBT Lo PEEP**), Low Peak Pressure (**Low Pk Pres**), Low Exhaled Minute Volume (**Low Min Vol**) and/or Patient Circuit Fault (**Pat. Circuit**) 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.

#### To set the SBT Low PEEP alarm limit:

To set the SBT Low PEEP alarm limit, see *SBT Lo PEEP* in the Extended Features, SBT menus in Chapter 10 – Extended Features.

## To set delayed notification for the PEEP alarms:

To set a delay for the High PEEP and Low PEEP alarms (**PEEP Delay**), see PEEP Delay in the Extended Features, Alarm Config menus in Chapter 10 – Extended Features.

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<sup>&</sup>lt;sup>38</sup> The "active" PEEP control setting is the **PEEP** control setting during normal ventilation, or the **SBT PEEP** control setting (in Extended Features) during an SBT procedure.

# SBT Low f/Vt (SBT < f/Vt)

The SBT Low f/Vt alarm is generated (a user adjustable alarm) when the SBT f/Vt ratio is less than the set SBT Low f/Vt limit continuously for 30 seconds during a Spontaneous Breathing Trial.

Range: 5 through 90 bpm/L, or Lo f/Vt Off

#### When an SBT Low f/Vt alarm occurs:

- The SBT < f/Vt alarm message is displayed
- A medium priority audible alarm sounds
- The SBT procedure terminates if the alarm is active continuously for 5 minutes

#### To set the SBT Low f/Vt Alarm limit:

To set the SBT Low f/Vt alarm limit, see *SBT Low f/Vt* in the Extended Features, SBT menus in Chapter 10 – Extended Features.

## 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

## 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

# Schedule Service (SchedSvcxxx)

The Schedule Service alarm (a fixed alarm) is generated when the ventilator detects a non-critical internal component failure or an invalid event log.

# **CAUTION**

**Schedule Service Alarm** - Repeated or continuous Schedule Service 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 Schedule Service alarm occurs:

- The SchedSvcxxx alarm message is displayed, with a numeric reference code (xxx)
  representing the specific condition that initiated the alarm (record the xxx code to report
  when scheduling servicing)
- A low priority audible alarm sounds

# SpO<sub>2</sub> Check Sensor Placement (SpO<sub>2</sub> Sensor)

The SpO<sub>2</sub> Check Sensor Placement alarm (a fixed alarm) is generated when the SpO<sub>2</sub> Module reports that the sensor is providing unusable data for analysis and the Oximetry option is still enabled.

## When an SpO<sub>2</sub> Check Sensor Placement alarm occurs:

- The SpO<sub>2</sub> Sensor alarm message is displayed
- A high priority audible alarm sounds

# SpO<sub>2</sub> Low Signal (SpO<sub>2</sub> LowSig)

The SpO<sub>2</sub> Low Signal alarm (a fixed alarm) is generated when the SpO<sub>2</sub> Module detects that the signal from the SpO<sub>2</sub> Sensor is too low while the Pulse Oximetry option is enabled.

## When an SpO<sub>2</sub> Low Signal alarm occurs:

- The SpO<sub>2</sub> LowSig alarm message is displayed
- A high priority audible alarm sounds

# SpO<sub>2</sub> Module Fault (SpO<sub>2</sub> Module)

The SpO<sub>2</sub> Module Fault alarm (a fixed alarm) is generated when the ventilator cannot establish proper communication with the SpO<sub>2</sub> Module while the Pulse Oximetry option is enabled.

#### When an SpO<sub>2</sub> Module Fault alarm occurs:

- The SpO<sub>2</sub> Module alarm message is displayed
- A high priority audible alarm sounds

# SpO<sub>2</sub> Sensor Disconnect (SpO<sub>2</sub> Discon)

The SpO<sub>2</sub> Sensor Disconnect alarm (a fixed alarm) is generated when the SpO<sub>2</sub> Module or Sensor is faulty while the Pulse Oximetry option is enabled.

#### When an SpO<sub>2</sub> Sensor Disconnect alarm occurs:

- The SpO<sub>2</sub> Discon alarm message is displayed
- · A high priority audible alarm sounds

# Transition Battery Fault (T-Bat 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 T-Bat 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 (TBatTempFlt)

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 TBatTempFlt 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 (T-Bat 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 **T-Bat 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 (( $80 \pm 5 \text{ dBA}$ ) 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 **Silence/Reset** button.

# Ventilator Reset (Vent 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 Vent Reset alarm message is displayed
- · A medium priority audible alarm sounds
- An error code is written to the Event Trace log 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 (Vol Limited)**

The Volume Limited alarm (a fixed alarm) is generated when the active Breath Type is set to **PRVC** and the set **Tidal Volume** cannot be achieved without the Target Pressure exceeding the High Airway Pressure (**High Pres**) alarm setting minus 5 cmH<sub>2</sub>O.

#### When a Volume Limited alarm occurs:

- The Vol 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.

# SpO<sub>2</sub> Pulse Tone

The SpO<sub>2</sub> 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<sub>2</sub> Pulse Tone volume level:

To set the SpO2 Pulse Tone volume level, see *Pulse Tone* in the Extended Features, Option Cnfg menus in Chapter 10 – Extended Features.

# Alerts, LPPS / LMV Status Messages

The ventilator generates the following Low Peak Pressure (**Low Pk Pres**) and Low Exhaled Minimum Volume (**Low Min Vol**) alarm status messages to alert the operator about disabled alarm settings:

- LMV Off
- LMV On
- LMV/LPPS Off
- LPPS Off

#### NOTE

These are informational messages only and are displayed (as applicable) whenever monitored data is being scrolled automatically or manually.

# LMV Off

The **LMV Off** message is displayed when the Low Exhaled Minute Volume (**Low Min Vol**) alarm has been turned off by setting it to dashes ("- -") and the Low Peak Pressure (**LPP Alarm**) alarm configuration menu value has been set to **All Breaths**.

# LMV On

The **LMV On** message is displayed when the Low Exhaled Minute Volume (**Low Min Vol**) alarm value is set to a numerical value (**1** through **60**) and the Low Peak Pressure (**LPP Alarm**) alarm configuration menu value has been set to **All Breaths**.

# LMV/LPPS Off

The **LMV/LPPS** Off message is displayed when the Low Exhaled Minute Volume (**Low Min Vol**) alarm has been turned off by setting it to dashes ("- -") and the Low Peak Pressure (**LPP Alarm**) alarm configuration menu value has been set to **Control Only**.

## LPPS Off

The LPPS Off message is displayed when the Low Exhaled Minute Volume (Low Min Vol) alarm value is set to a numerical value (1 through 60) and the Low Peak Pressure (LPP Alarm) alarm configuration menu value has been set to Control Only.

# **Chapter 9 - MANEUVERS AND PROCEDURES**

# **Maneuvers and Procedures General Information**

Maneuvers and Procedures availability by Breath Mode and Type.

| Breath Mode & Type | I-Hold   | E-Hold   | Nebulizer | SBT     | O <sub>2</sub> Flush |
|--------------------|----------|----------|-----------|---------|----------------------|
| A/C / Volume       | Enabled  | Enabled  | Enabled   | Enabled | Enabled              |
| A/C / Pressure     | Disabled | Enabled  | Disabled  | Enabled | Enabled              |
| A/C / PRVC         | Disabled | Enabled  | Disabled  | Enabled | Enabled              |
| SIMV / Volume      | Enabled  | Enabled  | Disabled  | Enabled | Enabled              |
| SIMV / Pressure    | Disabled | Enabled  | Disabled  | Enabled | Enabled              |
| SIMV / PRVC        | Disabled | Enabled  | Disabled  | Enabled | Enabled              |
| CPAP+PS / Volume   | Disabled | Disabled | Disabled  | Enabled | Enabled              |
| CPAP+PS / Pressure | Disabled | Disabled | Disabled  | Enabled | Enabled              |
| CPAP+PS / PRVC     | Disabled | Disabled | Disabled  | Enabled | Enabled              |
| NPPV Pressure      | Disabled | Disabled | Disabled  | Enabled | Enabled              |
| NPPV CPAP+PS       | Disabled | Disabled | Disabled  | Enabled | Enabled              |

Maneuvers and Procedures combinations that the Revel<sup>™</sup> ventilator is capable of performing simultaneously.

| Maneuver / Procedure | SBT | I-Hold | E-Hold | Nebulizer | O <sub>2</sub> Flush |
|----------------------|-----|--------|--------|-----------|----------------------|
| 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                   |
| O <sub>2</sub> Flush | No  | No     | No     | No        | N/A                  |

# **Maneuvers**

The following maneuvers are available on the Revel<sup>™</sup> 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 ( $\Delta$  Pres xx), Plateau Pressure (P Plat xx) and Static Lung Compliance (P Static xx).

## **NOTE**

- The ventilator cannot perform an Inspiratory or Expiratory Hold maneuver during a NPPV
  Pressure or NPPV CPAP+PS ventilation mode (Non-Invasive), or perform multiple
  maneuvers simultaneously.
- Lung Compliance (C Static xx) calculation includes circuit compliance.

# **Expiratory Hold**

During an Expiratory Hold maneuver, the ventilator monitors Expiratory Pressure (**P Exp x**), calculates the value for **AutoPEEP** and displays both.

## NOTE

The E-Hold maneuver is disabled if the Nebulizer Synchronization menu (**Neb Sync**) selection is set to **Continuous** and the Nebulizer procedure has been activated.

# Setting Up and Running I-Hold and E-Hold Maneuvers

Setting up and running a maneuver is accomplished in the following stages:

- Select
- Arm
- Run

## NOTE

Maneuvers are disabled when Extended Features are being accessed.

## To Select the Maneuver

Push and release the **Maneuvers** button located on the lower interface panel. **I-Hold** is displayed in the front panel display window and the **Maneuvers** LED does not illuminate at this stage.

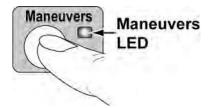


To perform an Inspiratory Hold, arm and run the maneuver as follows, or to perform an Expiratory Hold, rotate the **Scroll** knob until **E-Hold** appears in the display window, then proceed as follows.



#### To Arm the Maneuver

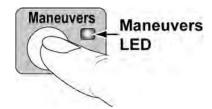
When the name of the desired maneuver is displayed, push and release the **Maneuvers** button again. The **Maneuvers** LED begins flashing to indicate that the displayed/selected maneuver is armed and ready to run.



Maneuver arming automatically terminates if 60 seconds elapse in the same phase of a maneuver without a button press.

## To Run the Maneuver

To activate the maneuver, push and hold the **Maneuvers** button. 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

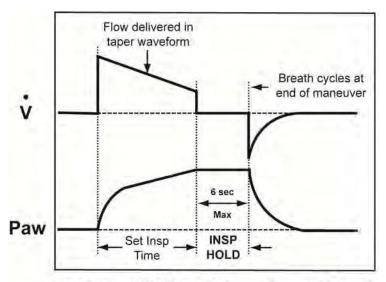
- If the **Maneuvers** button is released *before* the Hold maneuver has begun, the ventilator returns to the armed state.
- If the **Maneuvers** button is released *after* the maneuver has begun, the maneuver ends and the ventilator displays the maneuver results.

To clear scrolling maneuver data or exit a Maneuver at any time, push the **Exit** button on the front panel.



# **During an Inspiratory Hold:**

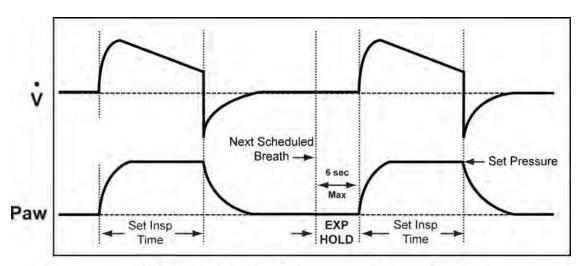
- The exhalation valve remains closed
- Flow is set to 0 lpm
- The breath remains in inspiration so no breath triggers are allowed
- The breath period timing and apnea timing are compensated for while the hold is performed
- If High Airway Pressure (High Pres) alarm occurs, the maneuver exits the hold phase but remains armed



Inspiratory Hold on Volume Control Breath

# During an Expiratory Hold:

- The exhalation valve is closed
- Flow is set to 0 lpm
- · 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 Airway Pressure (**High Pres**) alarm occurs, the maneuver exits the Hold state, remains armed, and the exhalation valve opens as normal



**Expiratory Hold on Pressure Control Breath** 

## **Maneuver Results**

# Inspiratory Hold

When the Inspiratory Hold maneuver has completed successfully:

- The Maneuver LED is extinguished 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

The maneuver results are displayed in the front panel display window while the maneuver is in progress and cycled every two (2) seconds when completed for two (2) minutes unless the **Exit**, **Select** or **Maneuver** button is pushed:

- $\Delta$  **Pres xxx** where **xxx** is the final airway pressure minus PEEP from the previous breath
- C Static xxx where xxx is the set Tidal Volume divided by Delta Pressure
- P Plat xxx where xxx is the airway pressure at the end of the Hold

# **Expiratory Hold**

When the Expiratory Hold maneuver has completed successfully:

- The Maneuver LED is extinguished and the calculated data is displayed
- The inspiration phase begins
- The flow servo operates normally

The maneuver results are displayed in the front panel display window while the maneuver is in progress and cycled every two (2) seconds when completed for two (2) minutes unless the **Exit**, **Select** or **Maneuver** button is pushed:

- AutoPEEP xxx is displayed, where xxx is Expiratory Pressure at the end of the
  Expiratory Hold maneuver minus the Expiratory Pressure measured immediately before
  closing the exhalation valve to start the maneuver
- P Exp is calculated as Expiratory Pressure measured at end of the Expiratory Hold maneuver

# **Procedures**

The following procedures may be performed on the Revel<sup>™</sup> ventilator:

- O<sub>2</sub> Flush
- Nebulization
- Spontaneous Breathing Trial (SBT)

# O<sub>2</sub> Flush

The O<sub>2</sub> Flush procedure allows you to deliver a pre-set elevated percentage of oxygen to the patient for a specified duration of time.

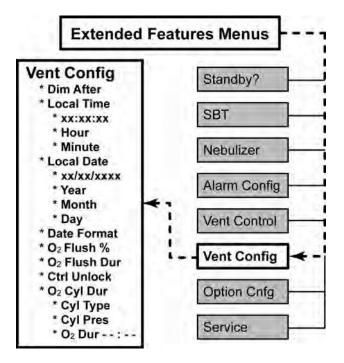
## NOTE

- To perform this procedure, the ventilator must be connected to a high pressure oxygen of 40 PSI (2.8 BAR, 276 kPa) to 66 PSI (4.5 BAR, 455 kPa).
- O<sub>2</sub> Flush and Nebulization procedures cannot be performed simultaneously. When either one of these procedures is in-process, the other procedure is deactivated until the in-process procedure has been cancelled or completed.

# To Configure the O<sub>2</sub> Flush Procedure:

The O<sub>2</sub> Flush procedure elevated percentage of oxygen delivered (O<sub>2</sub> Flush %) and for what duration of time (O<sub>2</sub> Flush Dur) is configured and set using the Extended Features menus.

 See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator and O2 Flush % and O2 Flush Dur (O2 Flush Duration) in the Extended Features, Vent Config menus in Chapter 10 – Extended Features for detailed instructions



# To Start the O<sub>2</sub> Flush Procedure:

The  $O_2$  control on the ventilator's front panel is a dual function control. Although primarily used to adjust the percentage of oxygen to be delivered through the ventilator's oxygen blending system, it is also used to initiate the  $O_2$  Flush procedure.

See O2 (Oxygen Percentage and Flush) in Chapter 5 – Controls for additional information

To start the  $O_2$  Flush procedure once the  $O_2$  Flush % and  $O_2$  Flush Dur Extended Features menus have been configured/set, push and hold the  $O_2$  (%) control button on the front panel for ~3 seconds.

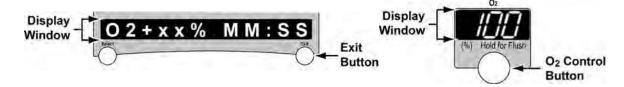


## NOTE

When the  $O_2\%$  control is set to LPS, pushing and holding the  $O_2\%$  control button does not start the procedure.

When an  $O_2$  Flush procedure is started, displayed monitored values will stop scrolling in the front panel display window and the percentage of  $O_2$  increased and the remaining time for the procedure (beginning at the set duration of time and reducing every second and minute until no time is left), is displayed. Additionally, the total percentage of oxygen being delivered to the patient will be flashed in the  $O_2$  control display window while the procedure is being performed.

To view other monitored data values during the O<sub>2</sub> Flush procedure, rotate the Scroll knob on the lower interface panel



# To Cancel the O<sub>2</sub> Flush Procedure:

The delivery of the elevated level of oxygen will continue until the set duration of time expires, the  $O_2$  control button is pushed a second time, or the **Exit** button is pushed.

## **NOTE**

When the  $O_2$  Flush procedure ends, it may take the oxygen several seconds to flush out of the patient circuit and for the  $O_2$  monitors to return to set levels.

## Nebulization

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

# **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 **Tidal Volume** and the ventilator's Extended Features nebulization procedure control menus Start Nebulizer (**Neb Start**), Stop Nebulizer (**Neb Cancel**), Nebulizer Duration (**Neb Duration**) and Nebulizer Synchronization (**Neb Sync**) 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.

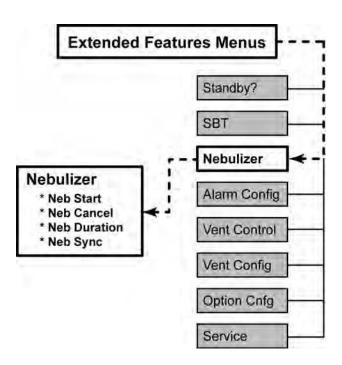
# **NOTE**

- To perform the Nebulization procedure, the Bias Flow must be set to 10 lpm, the Breath Mode set to A/C, the Breath Type set to Volume, and 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).
- O<sub>2</sub> Flush, SBT and Nebulization procedures cannot be performed simultaneously. When
  one of these procedures is in-process, the other procedures are deactivated until the inprocess procedure has been cancelled or completed.

# **To Configure the Nebulization Procedure:**

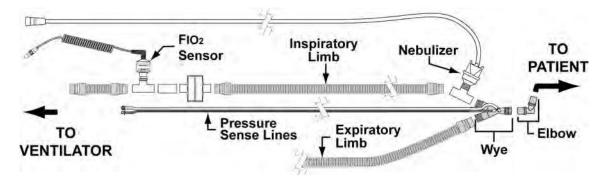
The total length of time that a Nebulizer treatment session is active and how it is synchronized with the patient's breath pattern is configured and set using the Extended Features menus.

 See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator and Neb Duration (Nebulizer Duration) and Neb Sync (Nebulizer Synchronization) in the Extended Features, Nebulizer menus in Chapter 10 – Extended Features 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  $F_{102}$  Sensor and the Nebulizer in a typical patient circuit setup.



## NOTE

Due to the relative positioning of the FiO<sub>2</sub> 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.

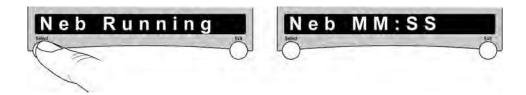
#### To Start the Nebulization Treatment

To start the nebulization treatment once the Nebulizer Duration (**Neb Dur**) and Nebulizer Synchronization (**Neb Sync**) Extended Features menus have been configured/set, push the **Select** button on the front panel when the Nebulization Start (**Neb Start**) menu is displayed.



 See Neb Start (Nebulizer Start) in Chapter 10 – Extended Features for detailed instructions

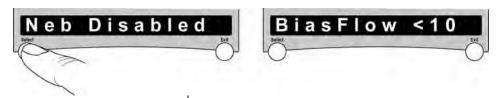
When a Nebulizer procedure is started, displayed monitored values will stop scrolling in the front panel display window and **Neb Running** is displayed. To view monitored data values during the Nebulizer procedure (including the minutes and seconds remaining for the Nebulization treatment (**Neb MM:SS**), push the **Select** button on the front panel.



# **Nebulizer Disabled Message**

The **Neb Disabled** message is displayed when the **Select** button is pushed (when **Neb Start** is displayed) and the current ventilator settings do not support a nebulizer procedure.

Push the **Select** button when **Neb Disabled** is displayed to view the reason or reasons why the nebulizer is disabled. If more than one reason occurs, rotate the **Scroll Knob** to scroll through the reasons.



| Displayed Message       | Reason   |  |  |
|-------------------------|--|--|--|
| O <sub>2</sub> Flush ON | An O <sub>2</sub> Flush procedure is in Progress             |  |  |
| SBT ON                  | An SBT procedure is in Progress                              |  |  |
| NOT Vol A/C             | Ventilator Breath Mode and Breath Type not set to Volume A/C |  |  |
| Bias Flow <10           | Bias Flow is setting is less than 10 lpm                     |  |  |

## To Cancel the Nebulization Procedure

The Nebulizer procedure will continue until the set duration of time expires, or the **Select** button on the front panel is pushed when the Nebulization Cancel (**Neb Cancel**) menu is displayed.

 See Neb Cancel (Nebulizer Cancel) in Chapter 10 – Extended Features for detailed instructions

# SBT (Spontaneous Breathing Trial)

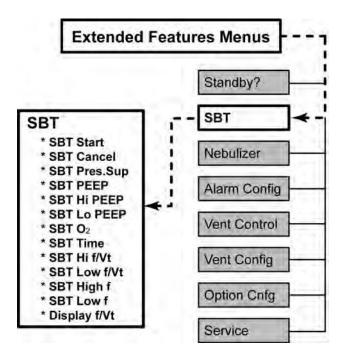
The Spontaneous Breathing Trial (SBT) procedure provides temporarily minimized ventilatory support so a clinician can perform clinical assessments of a patient's dependence on, or ability to be removed from positive pressure ventilation. SBT mode should be used only while attended by a Respiratory Therapist or other properly trained and qualified personnel.

• SBT can be performed with all patient types

# To Configure the SBT Procedure:

The SBT procedure controls (SBT Pres. Sup, SBT PEEP, SBT O<sub>2</sub>, and SBT Time) and alarm limits (SBT Hi f/Vt, SBT Low f/Vt, SBT High f and SBT Low f) are configured and set using the Extended Features menus.

- See Navigating Startup and Extended Features Menus in Chapter 3 Using the Ventilator and SBT (Spontaneous Breathing Trial) and To Configure and Initiate the SBT Procedure in the Extended Features, SBT menus in Chapter 10 – Extended Features for detailed instructions
- See Alarms, Detailed Descriptions in Chapter 8 Ventilator Alarms for detailed information about SBT related alarms



## To Start the SBT Procedure:

To start the SBT procedure, configure/set the SBT related controls and alarm limits appropriate for the patient, and push the **Select** button on the front panel when the **SBT Start** menu is displayed.

See SBT Start in Chapter 10 – Extended Features for detailed instructions



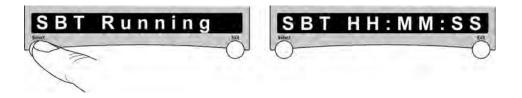
## NOTE

You cannot perform SBT when the ventilator is in **NPPV Pressure** or **NPPV CPAP+PS** ventilation modes (Non-Invasive).

When the SBT procedure is started, **SBT Running** is displayed in the front panel display window and the ventilator begins the SBT procedure functioning in the **CPAP+PS** mode using the current SBT menu settings (i.e., factory-set values, or previously reconfigured SBT ventilation control and alarm limit settings).

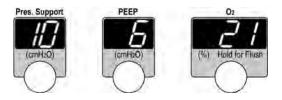
To view monitored data values (including the hours, minutes and seconds remaining for the SBT procedure, push the **Exit** button on the front panel until **SBT HH:MM:SS** (for ≥ 1 hour) or **SBT MM:SS** (for < 1 hour) is displayed. Data values are viewed by rotating the **Scroll Knob** or pushing the **Exit** button again for the data to automatically scroll.

 If the SBT menu item Display f/Vt is set to On, SBT f/Vt and SBT f monitored data is also displayed during an SBT procedure



When an SBT procedure is active, SBT Pres. Sup, SBT PEEP and SBT O<sub>2</sub> monitored values are displayed in the front panel Pres. Support, PEEP and O<sub>2</sub> control display windows, respectively.

 See Monitored Patient Data in Chapter 7 – Monitored Data for detailed information about SBT related monitored data displayed by the ventilator



The SBT trial ends when any of the following occur:

- The **SBT Cancel** menu is selected (in Extended Features)
- An **SBT Off** alarm occurs (indicating that SBT ran for the full set time duration)
- An Apnea or Patient Circuit Fault (Pat. Circuit) alarm occurs
- A High Airway Pressure alarm (**High Pres**) or Safety Valve High Pressure Relief alarm (**SVHP Relief**) condition persists for more than 1.5 seconds
- The SBT high / low breath rate alarms (SBT High / Low f), or SBT high / low f/Vt alarm
- Any ventilation or alarm control is selected and confirmed other than Control Lock,
   Silence/Reset, or the SBT High/Low f and SBT Hi/Low f/Vt alarms

When the SBT ends, the ventilator automatically reverts to the settings in use prior to initiating the SBT procedure.

#### To Cancel the SBT Procedure:

- 1) To cancel an in-process SBT procedure:
  - If SBT Running is displayed, push the Exit button and SBT Start is displayed.
     OR
  - If **SBT Running** is <u>not</u> displayed, navigate back to the **SBT** Extended Features menu, push **Select** and **SBT Start** is displayed.
- 2) Rotate the **Scroll** knob until **SBT Cancel** is displayed, push the **Select** button, the SBT procedure is terminated, normal ventilation resumes and **Cancelled** is displayed.
  - See SBT Cancel in Chapter 10 Extended Features for detailed instructions

# **Chapter 10 - EXTENDED FEATURES**

This chapter describes the controls, alarms, monitors, features and options that do not have dedicated front panel controls or displays and are accessed through the Extended Features menus.

# **Extended Features Menus**

# To access/enter Extended Features menus

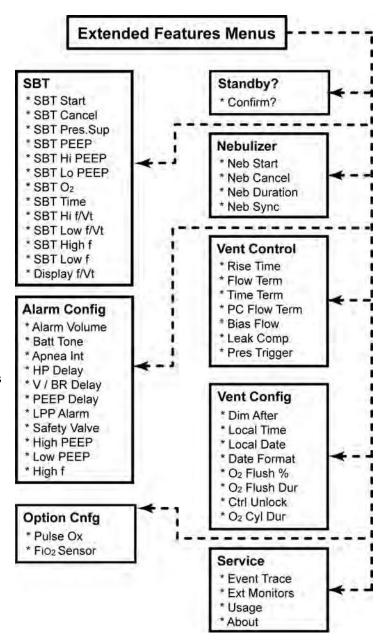
To access/enter Extended Features menus while the ventilator is in a normal ventilation mode, push and hold the **Select** control button on the front panel for three seconds.

 See Navigating Startup and Extended Features Menus in Chapter 3 – Using the Ventilator for detailed instructions

# To exit Extended Features menus

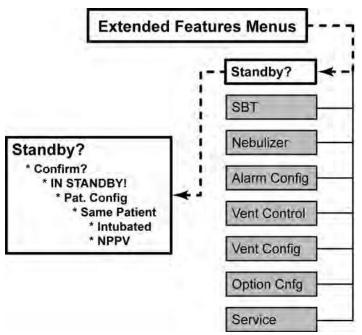
To exit specific Extended Features menus, push the **Exit** button on the front panel to exit the current/displayed menu and display the previous level menu (if any).

To exit all Extended Features menus, repeatedly push the **Exit** button until scrolling monitored data is displayed.



# Standby? (Standby mode)

The **Standby?** menus are used by operators to initiate a 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 may be momentarily displayed, followed by IN STANDBY! flashing in the front panel display window
- Any in-process I-Hold or E-Hold maneuvers, or SBT, Nebulization, or O<sub>2</sub> Flush procedures are exited
- O<sub>2</sub> is set to 21% and the O<sub>2</sub> Flush Procedure is disabled
- 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 front panel ventilation 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 **NPPV**) and then exit Standby mode and resume patient ventilation

- Disabled ventilation and clinical alarms are enabled
- The front panel ventilation and alarm controls are unlocked (Control Lock disabled, LED extinguished)

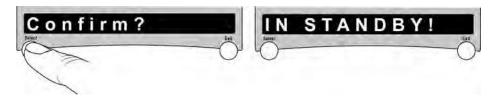
# **To Initiate Standby Mode**

# 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) Enter the Extended Features menus from a normal mode of ventilation; rotate the **Scroll** knob until **Standby?** is displayed, push the **Select** button and **Confirm?** is displayed.
- 2) To suspend patient ventilation and initiate the Standby mode, push the **Select** button when **Confirm?** is displayed.

Patient ventilation is suspended and **Stopping** is momentarily displayed, followed by **IN STANDBY!** flashing in the front panel display window.



## 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.

3) 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

 To change the type of patient circuit to patient interface configuration (Intubated versus NPPV) prior to exiting the Standby mode and resuming patient ventilation, continue; otherwise skip to the next step.

While **IN STAND BY!** is displayed, push the **Select** button and **Pat. Config** is displayed. Push the **Select** button again and **Same Patient** is displayed. Push the **Select** button a third time and **Intubated** is displayed.

To select an intubated type of patient circuit to patient interface, exit Standby mode and initiate ventilation, push the **Select** button.

#### OR

To select a non-invasive type of patient circuit to patient interface, exit Standby mode and initiate ventilation, rotate the **Scroll** knob until **NPPV** is displayed and push the **Select** button.

When either **Intubated** or **NPPV** is selected (**Select** button pushed), Standby mode is exited and ventilation is resumed using the patient circuit to patient interface configuration selected.

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 **NPPV**) is changed before exiting Standby mode:

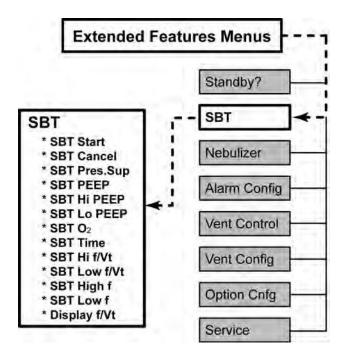
- If the type of patient circuit to patient interface selected is Intubated and the previous setting was NPPV, the Breath Mode and Breath Type will be set to their last selected / preset intubated interface settings
- If the type of patient circuit to patient interface selected is NPPV and the previous setting
  was Intubated, the Breath Mode will be set to CPAP+PS and the Breath Type will be set
  to Pressure
- 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, push the **Exit** button.

When the **Exit** button is pushed, 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).

## **SBT (Spontaneous Breathing Trial)**

The **SBT** (Spontaneous Breathing Trial) menus are used to configure SBT related ventilation controls and alarm limits, and initiate the SBT procedure.

- See SBT (Spontaneous Breathing Trial) in Chapter 9 Maneuvers and Procedures for detailed information about the SBT procedure
- See *Monitored Patient Data* in Chapter 7 Monitored Data for detailed information about SBT related monitored data displayed by the ventilator
- See Alarms, Detailed Descriptions in Chapter 8 Ventilator Alarms for detailed information about SBT related alarms



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 Initiate the SBT Procedure

Factory-set or reset SBT menu configuration values are retained and used by the ventilator (through shut downs and power ups) until re-set by an operator. Accordingly, all SBT menu settings should be reviewed for appropriateness and/or reset as necessary, prior to initiating an SBT procedure.

1) Enter the Extended Features menus from a normal mode of ventilation; rotate the **Scroll** knob until **SBT** is displayed, push the **Select** button and **SBT Start** is displayed.

### SBT Start

The SBT Start menu is used to initiate an SBT procedure.

- 1) Rotate the **Scroll** knob until **SBT Start** is displayed.
- 2) Push the **Select** button, **Running** is displayed and the ventilator begins the SBT procedure using the current SBT menu settings (i.e., factory-set values, or previously reconfigured SBT ventilation settings).

### SBT Cancel

The SBT Cancel menu is used to cancel/end an in-process SBT procedure.

- 1) When the ventilator is performing an SBT procedure, push the **Exit** button while **Running** or **SBT xx:xx** is displayed and **SBT Start** is displayed.
- 2) Rotate the **Scroll** knob until **SBT Cancel** is displayed, push the **Select** button. The SBT procedure is terminated, normal ventilation resumes and **Cancelled** is displayed.

## SBT Pres.Sup (SBT Pressure Support)

The **SBT Pres.Sup** (SBT Pressure Support) menu is used to set the target pressure above set **SBT PEEP** for SBT patient breaths. During the SBT procedure, this control is disabled.

- 1) Rotate the **Scroll** knob until **SBT Pres.Sup** is displayed, push the **Select** button and the set SBT Pressure Support value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT Pressure Support value is set and **SBT Pres.Sup** is displayed.

Range: 1 through 20 cmH<sub>2</sub>O in increments of 1

### SBT PEEP

The **SBT PEEP** menu is used to set the level of PEEP to be in effect during a Spontaneous Breath Trial procedure. During the SBT procedure, this control is disabled.

- 1) Rotate the **Scroll** knob until **SBT PEEP** is displayed, push the **Select** button and the set SBT PEEP value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT PEEP value is set and **SBT PEEP** is displayed.

Range: 0 through 20 cmH<sub>2</sub>O in increments of 1, or "--" (off)

### SBT Hi PEEP

The SBT Hi PEEP menu is used to set the upper limit of the SBT Hi PEEP alarm.

- 1) Rotate the **Scroll** knob until **SBT Hi PEEP** is displayed, push the **Select** button and the set SBT Hi PEEP value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT Hi PEEP value is set and **SBT Hi PEEP** is displayed.

Range: 3 through 40 cmH<sub>2</sub>O in increments of 1, or "--" (off)

### SBT Lo PEEP

The SBT Lo PEEP menu is used to set the lower limit of the SBT Lo PEEP alarm.

- Rotate the Scroll knob until SBT Lo PEEP is displayed, push the Select button and the set SBT Lo PEEP value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT Lo PEEP value is set and **SBT Lo PEEP** is displayed.

Range: "--" (off), or 1 through 20 cmH<sub>2</sub>O in increments of 1

### SBT Low f/Vt

The SBT Low f/Vt menu is used to set the lower limit of the SBT Low f/Vt alarm.

- 1) Rotate the **Scroll** knob until **SBT Low f/Vt** is displayed, push the **Select** button and the set SBT Low f/Vt value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT Low f/Vt value is set and **SBT Low F/Vt** is displayed.

Range: 5 through 90 bpm/L in increments of 5, or Lo f/Vt Off

### SBT O<sub>2</sub>

The **SBT O<sub>2</sub>** menu is used to set the percentage of oxygen to be delivered in the gas flow during a Spontaneous Breath Trial procedure. During the SBT procedure, this control is disabled.

- 1) Rotate the **Scroll** knob until **SBT O<sub>2</sub>** is displayed, push the **Select** button and the set SBT O<sub>2</sub> value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT O<sub>2</sub> value is set and **SBT O<sub>2</sub>** is displayed.

Range: 21 through 100% in increments of 1, or LPS

### SBT Time

The **SBT Time** menu is used to set the maximum run time of the SBT procedure. During the SBT procedure, this control is disabled.

- Rotate the Scroll knob until SBT Time is displayed, push the Select button and the set SBT Time value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT Time value is set and **SBT Time** is displayed.

Range 15 through 120 min in increments of 5

### SBT Hi f/Vt

The **SBT** Hi f/Vt menu is used to set the upper limit of the SBT Hi f/Vt alarm.

- 1) Rotate the **Scroll** knob until **SBT Hi** f/**Vt** is displayed, push the **Select** button and the set SBT Hi f/Vt value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT Hi f/Vt value is set and **SBT Hi F/Vt** is displayed.

Range: 70 through 900 bpm/L in increments of 5, or Hi f/Vt Off

### SBT Low f/Vt

The SBT Low f/Vt menu is used to set the lower limit of the SBT Low f/Vt alarm.

- Rotate the Scroll knob until SBT Low f/Vt is displayed, push the Select button and the set SBT Low f/Vt value is displayed.
- Rotate the Scroll knob until the desired value is displayed, push the Select button, the new SBT Low f/Vt value is set and SBT Low F/Vt is displayed.

Range: 5 through 90 bpm/L in increments of 5, or Lo f/Vt Off

## SBT High f

The **SBT High f** menu is used to set the upper limit of the SBT High Breath Rate alarm.

- 1) Rotate the **Scroll** knob until **SBT High f** is displayed, push the **Select** button and the set SBT High f value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT High f value is set and **SBT High f** is displayed.

Range: 15 through 80 bpm/L in increments of 1, or SBT Hi f Off

### SBT Low f

The SBT Low f menu is used to set the lower limit of the SBT Low Breath Rate alarm.

- 1) Rotate the **Scroll** knob until **SBT Low f** is displayed, push the **Select** button and the set SBT Low f value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new SBT Low f value is set and **SBT Low** f is displayed.

Range: 1 through 40 bpm in increments of 1, or SBT Lo f Off

## Display f/Vt

The **Display f/Vt** menu is used to set the scrolling display (in the front panel display window) of the f/Vt (Rapid Shallow Breathing Index) monitor value on or off.

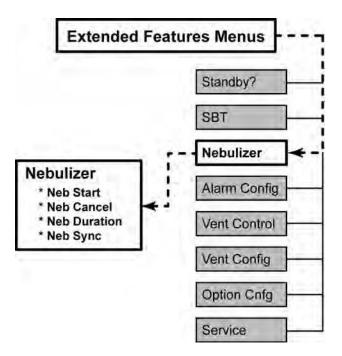
- 1) Rotate the **Scroll** knob until **Display f/Vt** is displayed, push the **Select** button and the set Display f/Vt value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new Display f/Vt value is set and **Display f/Vt** is displayed.

Range On or Off

## Nebulizer

The **Nebulizer** menus are used to configure the ventilators nebulization treatment related controls, and initiate the Nebulization procedure.

 See Nebulization in Chapter 9 – Maneuvers and Procedures for detailed information about the Nebulization procedure



## To Configure and Initiate the Nebulization Procedure

Enter the Extended Features menus from a normal mode of ventilation; rotate the **Scroll** knob until **Nebulizer** is displayed, push the **Select** button and **Neb Start** is displayed.

### **NOTE**

- To perform the Nebulization procedure, the **Bias Flow** must be set to 10 lpm, the Breath Mode set to **A/C**, the Breath Type set to **Volume**, and 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).
- O<sub>2</sub> Flush, SBT and Nebulization procedures cannot be performed simultaneously. When
  either one of these procedures is in-process, the other procedure is deactivated until the
  in-process procedure has been cancelled or completed.

## Neb Start (Nebulizer Start)

The **Neb Start** (Nebulizer Start) menu is used to initiate a Nebulization procedure.

- 1) Rotate the Scroll knob until Neb Start is displayed.
- 2) Push the Select button, Neb Running is displayed and the ventilator begins the Nebulization procedure using the current Nebulizer Duration (Neb Dur) and Nebulizer Synchronization (Neb Sync) menu settings (i.e., factory-set values, or previously reconfigured nebulization settings).

Or

If **Neb Start** is selected and **Neb Disabled** is displayed, the Nebulization procedure is not available because the ventilator is not operating in **Volume A/C** mode, the **Bias Flow** is not set to 10 lpm, and/or an **SBT** or **O**<sub>2</sub> **Flush** procedure is in progress. Push the **Select** button while **Neb Disabled** is displayed and rotate the scroll knob to view all applicable reasons why the nebulizer is disabled.

## Neb Cancel (Nebulizer Cancel)

The **Neb Cancel** (Nebulizer Cancel) menu is used to cancel/end an in-process Nebulization procedure.

1) While **Neb Running** is displayed, rotate the **Scroll** knob until **Neb Cancel** is displayed and push the **Select** button. The Nebulization procedure is terminated, normal ventilation resumes and **Cancelled** is displayed.

## Neb Duration (Nebulizer Duration)

The **Neb Duration** (Nebulizer Duration) menu is used to set the total length of time that a Nebulization procedure is active. During the Nebulization procedure, this control is disabled.

- 1) Rotate the **Scroll** knob until **Neb Duration** is displayed, push the **Select** button and the set nebulization time duration value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new nebulization time duration value is set and **Neb Duration** is displayed.

Range 1through 30 min in increments of 1

## Neb Sync (Nebulizer Synchronization)

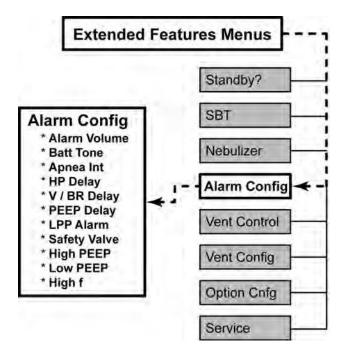
The **Neb Sync** (Nebulizer Synchronization) menu is used to set how the Nebulization procedure is synchronized with the patient's breath pattern. During the Nebulization procedure, this control is disabled.

- 1) Rotate the **Scroll** knob until **Neb Sync** is displayed, push the **Select** button and the set nebulizer synchronization value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new nebulizer synchronization value is set and **Neb Sync** is displayed.

Range Continuous or Insp Only

## **Alarm Config (Alarm Configuration)**

The **Alarm Config** (Alarm Configuration) menus are used to configure/set alarm features and limits that are not available on the front panel.



## To Use the Alarm Config Menus

Enter the Extended Features menus from a normal mode of ventilation; rotate the **Scroll** knob until **Alarm Config** is displayed, push the **Select** button and **Alarm Volume** is displayed.

### Alarm Volume

The **Alarm Volume** menu is 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.

- Rotate the Scroll knob until Alarm Volume is displayed, push the Select button and the set alarm volume value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new alarm volume value is set and **Alarm Volume** is displayed.

Range: Vol 1 through 6

## Batt Tone (Battery Use Tone)

The **Batt Tone** (Battery Use Tone) menu is used to set the audible volume at which the ventilator sounds the Battery Use tone. 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.

- 1) Rotate the **Scroll** knob until **Batt Tone** is displayed, push the **Select** button and the set battery tone volume value is displayed.
- Rotate the Scroll knob until the desired value is displayed, push the Select button, the new a battery tone volume value is set and Batt Tone is displayed.

Range: Vol 1 through 3 in increments of 1, or Off

## Apnea Int (Apnea Interval)

The **Apnea Int** (Apnea Interval) menu is used to set the maximum time allowed between the beginning of one breath and the beginning of the next breath, before initiating Apnea Backup ventilation and sounding the Apnea alarm.

- 1) Rotate the **Scroll** knob until **Apnea Int** is displayed, push the **Select** button and the set apnea interval is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new apnea interval value is set and **Apnea Int** is displayed.

Range: Apnea 10 through Apnea 60 sec in increments of 5

## HP Delay (High Pressure Delay)

The **HP Delay** (High Pressure Delay) menu 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 Airway Pressure (**High Pres**) alarm condition.

- The High Pressure Delay setting does not affect the pressure limiting function of the High Airway Pressure alarm. For more information on the High Airway Pressure alarm, see High Airway Pressure (High Pres) in Chapter 8 – Ventilator Alarms
- 1) Rotate the **Scroll** knob until **HP Delay** is displayed, push the **Select** button and the set HP Delay value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new HP Delay value is set and **HP Delay** is displayed.

Range: **Delay 0** through **Delay 2 Brth** in increments of 1

## V/BR Delay (Minute Volume/Breath Rate Alarm Delay)

The V/BR (Minute Volume/Breath Rate Alarm Delay) menu is used to set the delayed notification (in seconds) for the Low Exhaled Minute Volume (Low Min Vol) and the High Breath Rate (High f) alarms.

- 1) Rotate the **Scroll** knob until **V/BR Delay** is displayed, push the **Select** button and the set V/BR Delay value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new V/BR Delay value is set and **V/BR Delay** is displayed.

Range: Delay 0 through Delay 60 sec in increments of 1

## **PEEP Delay**

The **PEEP Delay** menu is used to set the delayed notification period (in seconds), for the high and low limits of the PEEP alarm.

- 1) Rotate the **Scroll** knob until **PEEP Delay** is displayed, push the **Select** button and the set PEEP Delay value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new PEEP Delay value is set and **PEEP Delay is** displayed.

Range: **Delay 0** through **Delay 60 sec** in increments of 1

## LPP Alarm (Low Peak Pressure Alarm)

The **LPP Alarm** (Low Peak Pressure Alarm) menu is used to set the breath types for which the Low Peak Pressure (**Low Pk Pres**) alarm is applicable.

The LPP Alarm limit can be set to apply to all breaths (**All Breaths**), or only to Machine and Assist breaths in SIMV mode, and all breaths in A/C and CPAP+PS modes (**Control Only**).

- See Low Peak Pressure (Low Pk Pres) in Chapter 8 Ventilator Alarms for more information about the Low Peak Pressure alarm
- LPPS / LMV alarm status messages, when applicable, are displayed in the front panel display window along with monitored data. See Alerts, LPPS / LMV Status Messages in Chapter 8 – Ventilator Alarms for detailed information.

### NOTE

In CPAP+PS mode, all breaths are monitored for Low Peak Pressure.

- 1) Rotate the **Scroll** knob until **LPP Alarm** is displayed, push the **Select** button and the set LPP Alarm breath type is displayed.
- 2) Rotate the **Scroll** knob until the desired breath type is displayed, push the **Select** button, the new LPP Alarm breath type is set and **LPP Alarm** is displayed.

Range: All Breaths or Control Only

## Safety Valve

The **Safety Valve** menu is used to set the Safety Valve over-pressure (Delta Pressure) activation level. This setting, in conjunction with the High Airway Pressure (**High Pres**) alarm setting, determines the level at which the Safety Valve will open to provide high pressure relief in a high pressure condition.

• See High Airway Pressure (High Pres) and Safety Valve High Pressure Relief (SVHP Relief) in Chapter 8 - Ventilator Alarms for additional information

### **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 (**SVHP**) alarm occurs. Otherwise, it is recommended to set this value at its factory-set value (10 cmH<sub>2</sub>O) or lower.

- 1) Rotate the **Scroll** knob until **Safety Valve** is displayed, push the **Select** button and the set **Safety Valve** value is displayed.
- 2) Rotate the **Scroll** knob until the desired Safety Valve value is displayed, push the **Select** button, the new Safety Valve value is set and **Safety Valve** is displayed.

Range: 5 through 30 cmH<sub>2</sub>O in increments of 5

## High PEEP

The **High PEEP** menu is used to set the High PEEP alarm limit. See *High PEEP* in Chapter 8 – Ventilator Alarms for additional information.

- 1) Rotate the **Scroll** knob until **High PEEP** is displayed, push the **Select** button and the set High PEEP value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new High PEEP value is set and **High PEEP** is displayed.

Range: PEEP+ 3 through PEEP+ 20 cmH<sub>2</sub>O in increments of 1, or "--" (off)

## Low Peep

The **Low PEEP** menu is used to set the Low PEEP alarm limit. See *Low PEEP* in Chapter 8 – Ventilator Alarms for additional information.

- 1) Rotate the **Scroll** knob until **Low PEEP** is displayed, push the **Select** button and the set **Low PEEP** value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new Low PEEP value is set and **Low PEEP** is displayed.

Range: PEEP- 1 through PEEP- 20 cmH<sub>2</sub>O in increments of 1, or "--" (off)

## High f (High Breath Rate)

The **High f** (High Breath Rate) menu is used to set the High Breath Rate alarm limit. See *High Breath Rate (High f)* in Chapter 8 – Ventilator Alarms for additional information.

- 1) Rotate the **Scroll** knob until **High f** is displayed, push the **Select** button and the set High f value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new High f value is set and **High f** is displayed.

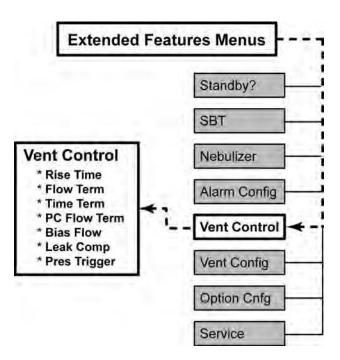
Range: 1 through 120 bpm in increments of 1, or "--" (off

### To set delayed notification for the High Breath Rate alarm:

To set a delay for the Low Exhaled Minute Volume (**Low Min Vol**) and the High Breath Rate (**High f**) alarms, see *V/BR Delay (Minute Volume/Breath Rate Alarm Delay)* in this chapter.

## **Vent Control (Ventilator Controls)**

The **Vent Control** (Ventilator Controls) menus are used to set ventilator controls that are not available on the front panel.



### To Use the Vent Control Menus

Enter the Extended Features menus from a normal mode of ventilation; rotate the **Scroll** knob until **Vent Control** is displayed, push the **Select** button and **Rise Time** is displayed.

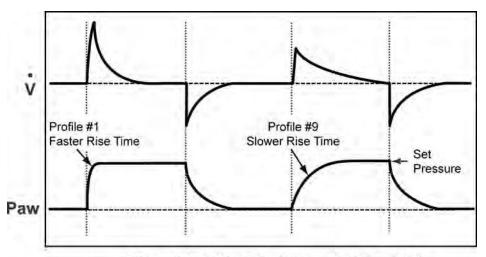
### Rise Time

The **Rise Time** menu is used to select a rise time profile for Pressure Control, Pressure Support, Spontaneous, PRVC and Volume Targeted Pressure Support 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.

- 1) Rotate the **Scroll** knob until **Rise Time** is displayed, push the **Select** button and the current Rise Time profile is displayed.
- 2) Rotate the **Scroll** knob to until the desired profile is displayed, push the **Select** button, the new Rise Time profile is set and **Rise Time** is displayed.

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



Adjusting Rise Time on Pressure Control Breaths

### **NOTE**

In **CPAP+PS** (**Pressure**) and **NPPV CPAP+PS** settings, the **Rise Time** 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).

## Flow Term (Flow Termination)

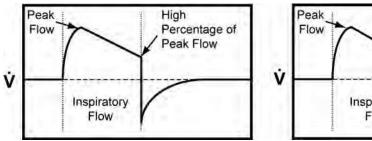
The **Flow Term** (Flow Termination) menu is used to set the percentage of Peak Flow at which Pressure Support, Spontaneous and Volume Targeted Pressure Support breaths are cycled. The breath is cycled from inspiration to exhalation when the flow is less than the set **Flow Term** setting. The breath also cycles when the flow is less than 2 lpm.

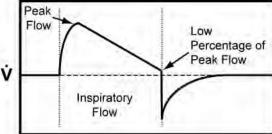
### NOTE

Inspiration is also terminated if the inspiration time exceeds the Time Termination (**Time Term**) setting or two breath periods.

When Pressure Control Flow Termination (**PC Flow Term**) is on (**Term On**), the set Flow Termination percentage is used for flow termination of Pressure Control and Pressure Regulated Volume Control (PRVC) breaths as well.

• See PC Flow Term (Pressure Control Flow Termination) in this chapter and Pres. Control (Pressure Control) and Pres. Support (Pressure Support) in Chapter 5 - Controls for additional information regarding Flow Termination





- Rotate the Scroll knob until Flow Term is displayed, push the Select button and the set Flow Term value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new Flow Term value is set and **Flow Term** is displayed.

Range: Flow 10 through Flow 40 % in increments of 5

## Time Term (Time Termination)

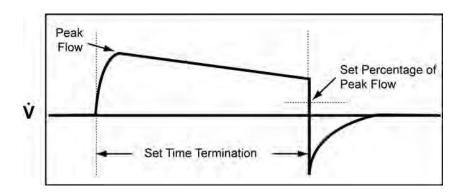
The **Time Term** (Time Termination) menu is used to set the maximum inspiratory time for terminating Pressure Support and Spontaneous breaths.

Breaths are time cycled from inspiration to exhalation if the set **Time Term** is reached before the flow reaches the set percentage of the peak flow for flow termination to take effect.

• See *Pres. Support (Pressure Support)* in Chapter 5 - Controls for additional information regarding Time Termination

### NOTE

The Pressure Support display flashes briefly after each Time Terminated breath.



- 1) Rotate the **Scroll** knob until **Time Term** is displayed, push the **Select** button and the set Time Term value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new Time Term value is set and **Time Term** is displayed.

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

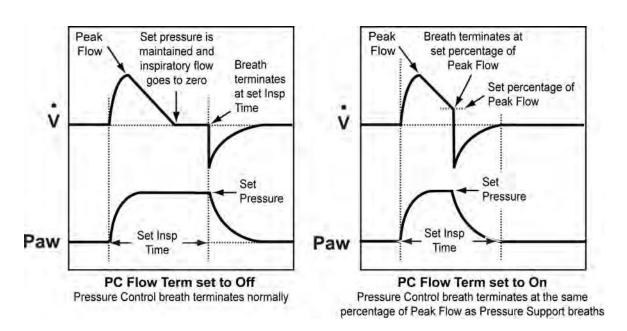
## PC Flow Term (Pressure Control Flow Termination)

The **PC Flow Term** (Pressure Control Flow Termination) menu is used to enable or disable flow termination for Pressure Control and Pressure Regulated Volume Control (PRVC) breaths. The percentage of peak flow used for PC Flow Termination is set using the Flow Termination (**Flow Term**) menu.

• See *Pres. Control (Pressure Control)* in Chapter 5 - Controls for additional information regarding Pressure Control Flow Termination

### **NOTE**

When the Pressure Control Flow Termination option is Off (**Term Off**), Pressure Control breaths are cycled when the set Inspiratory Time (**Insp. Time**) is reached.



### NOTE

In **CPAP+PS** (**Pressure**) and **NPPV CPAP+PS** settings, the **PC Flow Term** 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).

- 1) Rotate the **Scroll** knob until **PC Flow Term** is displayed, push the **Select** button and the set PC Flow Termination value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new PC Flow Termination value is set and **PC Flow Term** is displayed.

Range: Term On or Term Off

## Bias Flow

The **Bias Flow** menu is used to provide a continuous flow through the patient circuit during the exhalation phase of breaths.

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.

- 1) Rotate the **Scroll** knob until **Bias Flow** is displayed, push the **Select** button and the set Bias Flow value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new Bias Flow value is set and **Bias Flow** is displayed.

Range: Flow 3 through Flow 10 lpm in increments of 1

The **Bias Flow** menu setting may be limited to less than its specified range; see *Control Limiting* in Chapter 5 – Controls for detailed information.

### NOTE

- When Leak Compensation (**Leak Comp**) is enabled (**L. Comp On**), the Bias Flow is automatically increased by the amount of the measured leak.
- The Air/O<sub>2</sub> mix of the Bias flow is dependent on the set **O**<sub>2</sub> control value and therefore affects oxygen consumption.

## Leak Comp (Leak Compensation)

The **Leak Comp** (Leak Compensation) menu is used to enable or disable tracking steady state exhaled flow to improve monitored patient flow accuracy in the presence of a stable circuit leak.

- 1) Rotate the **Scroll** knob until **Leak Comp** is displayed, push the **Select** button and the set Leak Comp value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new Leak Comp value is set and **Leak Comp** is displayed.

Range: L. Comp On or L. Comp Off

### **NOTE**

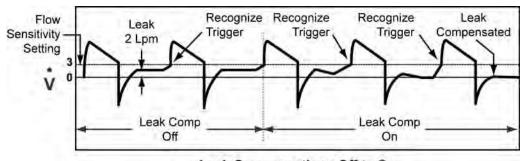
- Leak Stability If a leak is unstable during exhalation, it will not be detected and will not be compensated for
- Expiratory Limb Leak A leak on the expiratory limb may not be detected and may not be compensated for depending on the size of leak
- **Limitation of Compensation** The limitation of compensation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

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

- Flow Triggering
- Exhaled Tidal Volume Monitor (**Vte**)
- Spontaneous Exhaled Tidal Volume Monitor (SpVte)
- Inspiratory Tidal Volume Monitor (Vti)
- Delivered Bias Flow (leaks up to 30 lpm)

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

- 1) Set flow **Sensitivity** to a value higher than the leak amount (see *Sensitivity* in Chapter 5 Controls).
- Set Leak Comp to L. Comp On.
- 3) Wait for a period of 10 through 15 breaths.
- 4) Reset flow **Sensitivity** to desired level.



Leak Compensation - Off to On

## Pres Trigger (Pressure Trigger)

The **Pres Trigger** (Pressure Trigger) menu is used to set the pressure threshold level to allow the patient to trigger breaths.

### A pressure trigger occurs when:

- The **Sensitivity** control is set to **P** (pressure triggering enabled)
- The ventilator is in exhalation phase
- The minimum exhalation time has expired, and
- The airway pressure drops below or is equal to the Pres 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<sub>2</sub>O

### NOTE

When a patient demand is detected, the **Patient Effort** indicator LED on the front panel is briefly illuminated.

- Rotate the Scroll knob until Pres Trigger is displayed, push the Select button and the set Pres Trigger value is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new Pres Trigger value is set and **Pres Trigger** is displayed.

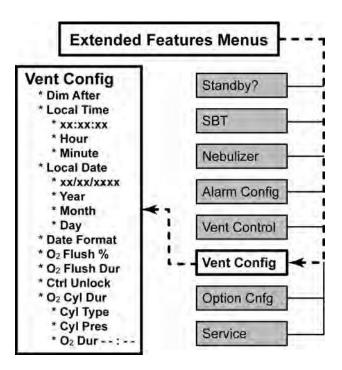
Range: 1 through 20 cmH<sub>2</sub>O below PEEP in increments of 1

### **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.

## **Vent Config (Ventilator Configuration)**

The **Vent Config** (Ventilator Configuration) menus are used to configure ventilator controls that are not available on the front panel.



## To Use the Vent Config Menus

Enter the Extended Features menus from a normal mode of ventilation; rotate the **Scroll** knob until **Vent Config** is displayed, push the **Select** button and **Dim After** is displayed.

### Dim After

The **Dim After** menu is used to conserve battery power by allowing operators to disable or enable display dimming and to set the time after which the illuminated front panel displays will be automatically extinguished.

When the ventilator is operating on power from the Removable Battery Pack or Transition Battery and the set display dimming time expires, the illuminated displays and indicators are extinguished, with the following exceptions:

- All alarm messages
- Airway Pressure display
- On/Off indicator
- Battery Pack indicator (when applicable)
- **Battery Charger** indicator (when applicable)
- **Transition Batt.** indicator (when applicable)
- 1) Rotate the **Scroll** knob until **Dim After** is displayed, push the **Select** button and the set Dim After value is displayed.
- Rotate the Scroll knob until the desired value is displayed, push the Select button, the new Dim After value is set and Dim After is displayed.

Dim 1 through Dim 60 min in increments of 1, or Never Range:

Pushing any control button, rotating the Scroll knob, or ventilator qualification of an external power source restarts the display dimming time period and returns the displays to their normal brightness.

### Local Time

The **Local Time** menu is used to view or set the local time displayed by the ventilator.

#### To View the Local Time

Rotate the Scroll knob until Local Time is displayed, push the Select button and the local time is displayed HH:MM:SS (if previously set) or, - - : - - : - - (if not previously set).

### NOTE

Until the Local Date and Local 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<sup>39</sup> 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 and Time Setting displays GMT values in the event log 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

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<sup>39</sup> GMT - Greenwich Mean Time

### To Change the Local Time Settings

- 1) Access the Local Time menu as described above.
- 2) When the local time is displayed, rotate the **Scroll** knob until **Hour** is displayed, push the **Select** button and the set Hour is displayed.
- 3) Rotate the **Scroll** knob until the desired Hour value is displayed, push the **Select** button, the new Hour value is set and **Hour** is displayed.

Range: 0 through 23 in increments of 1

- 4) Rotate the **Scroll** knob until **Minute** is displayed, push the **Select** button and the set Minute value is displayed.
- 5) Rotate the **Scroll** knob until the desired Minute value is displayed, push the **Select** button, the new Minute value is set (seconds are automatically set to **00**) and **Minute** is displayed.

Range: **0** through **59** in increments of 1

### Local Date

The Local Date menu is used to view or set the local date displayed by the ventilator.

#### To View the Local Date

Rotate the **Scroll** knob until **Local Date** is displayed, push the **Select** button and the Local Date value is displayed in one of the following date formats:

### MM/DD/YYYY, YYYY/MM/DD or DD/MM/YYYY

### To Change the Local Date Settings

- 1) Access the Local Date menu as described above.
- When the currently selected Local Date format is displayed, rotate the Scroll knob until Year is displayed, push the Select button and the set year is displayed.
- 3) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new year is set and **Year** is displayed.

Range: 2004 through 2056 in increments of 1

- 4) Rotate the **Scroll** knob until **Month** is displayed, push the **Select** button and the set Month is displayed.
- 5) Rotate the **Scroll** knob until the desired Month is displayed, push the **Select** button, the new Month is set and **Month** is displayed.

Range: 1 through 12 in increments of 1

- Rotate the Scroll knob until Day is displayed, push the Select button and the set Day is displayed.
- 7) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new day is set and **Day** is displayed.

Range: 1 through 31 in increments of 1

### Date Format

The **Date Format** menu is used to view or set the display format for the current date.

#### To View the Date Format

Rotate the **Scroll** knob until **Date Format** is displayed, push the **Select** button and the set Date Format is displayed.

### **To Change the Date Format Settings**

- Rotate the Scroll knob until Date Format is displayed, push the Select button and the set Date Format is displayed.
- 2) Rotate the **Scroll** knob until the desired value is displayed, push the **Select** button, the new Date Format is set and **Date Format** is displayed.

Range: MM/DD/YYYY, YYYY/MM/DD or DD/MM/YYYY

## O<sub>2</sub> Flush % (O<sub>2</sub> Flush Percentage)

The  $O_2$  Flush % menu is used to set the "increased" percentage of oxygen (above the current  $O_2$  control setting) to be delivered to the patient during the set duration of time when the  $O_2$  Flush procedure is initiated. For example:

- A +50% O<sub>2</sub> Flush % menu setting combined with a 21% O<sub>2</sub> control setting would result in 71% oxygen being delivered to the patient during the set duration of time
- A +50% **O**<sub>2</sub> **Flush** % control setting combined with a 40% **O**<sub>2</sub> control setting would result in 90% oxygen being delivered to the patient during the set duration of time
- Any combination of O<sub>2</sub> Flush % and O<sub>2</sub> control settings that exceed 100% would result in 100% oxygen being delivered to the patient during the set duration of time

See O2 Flush in Chapter 9 – Maneuvers and Procedures for detailed information about the  $O_2$  Flush procedure.

- 1) Rotate the **Scroll** knob until **O<sub>2</sub> Flush** % is displayed, push **Selec**t and the set O<sub>2</sub> Flush % value is displayed.
- 2) Rotate the **Scroll** knob until the desired O<sub>2</sub> Flush % value is displayed, push the **Select** button, the new O<sub>2</sub> Flush % value is set and **O<sub>2</sub> Flush** % is displayed.

Range: +0 through +79 % in increments of 1

## O<sub>2</sub> Flush Dur (O<sub>2</sub> Flush Duration)

The  $O_2$  Flush Dur ( $O_2$  Flush Duration) menu is used to set the duration of time for which an elevated percentage of oxygen is delivered to the patient when the  $O_2$  Flush procedure is initiated. See  $O_2$  Flush in Chapter 9 – Maneuvers and Procedures for detailed information about the  $O_2$  Flush procedure.

- 1) Rotate the **Scroll** knob until **O<sub>2</sub> Flush Dur** is displayed, push **Selec**t and the set O<sub>2</sub> Flush Dur value is displayed.
- 2) Rotate the **Scroll** knob until the desired O<sub>2</sub> Flush Dur value is displayed, push the **Select** button, the new O<sub>2</sub> Flush Dur value is set and **O<sub>2</sub> Flush Dur** is displayed.

Range: 2 through 3 min in increments of 1

## Ctrl Unlock (Control Unlock)

The **Ctrl Unlock** (Control Unlock) menu is used to set the degree of difficulty for control unlocking. See Control Lock in Chapter 5 – Controls for additional information.

- 1) Rotate the **Scroll** knob until **Ctrl Unlock** is displayed, push the **Select** button and the set Ctrl Unlock value is displayed.
- 2) Rotate the **Scroll** knob until the desired Ctrl Unlock value is displayed, push the **Select** button, the new Ctrl Unlock value is set and **Ctrl Unlock** is displayed.

Range: Easy or Hard

## O<sub>2</sub> Cyl Dur (O<sub>2</sub> Cylinder Duration)

The  $O_2$  Cyl Dur ( $O_2$  Cylinder Duration) menus are used by an operator to enter data used by the ventilator to perform a calculation (based on current ventilation and  $O_2$  settings) and display the approximate remaining usable time (in hours and minutes) of an external  $O_2$  cylinder.

### 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<sub>2</sub> Cylinder Duration

- 1) Rotate the **Scroll** knob until **O<sub>2</sub> Cyl Dur** is displayed, push the **Select** button and **Cyl Type** is displayed.
- 2) Push the **Select** button while **Cyl Type** is displayed and the currently set cylinder type is displayed (in compressed liters, **xxxx L**).
- 3) Rotate the **Scroll** knob until the correct cylinder type is displayed (volume in compressed Liters), push the **Select** button, the new cylinder type is set and **Cyl Type** is displayed.

Range: **75** through **9.900** L in increments of 1

This setting is retained by the ventilator (through shut downs and power ups) until re-set by an operator and used to calculate the remaining oxygen.

4) Rotate the **Scroll** knob until **Cyl Pres** is displayed, push the **Select** button and "----" is displayed. Rotate the **Scroll** knob until the correct cylinder pressure is displayed, push the **Select** button, the new cylinder pressure value is set and **Cyl Pres** is displayed.

Range: **100** through **2300 PSI** in increments of 25 (**5** through **150 BAR** or **500** through **15000 kPa**), or "--" (off)

### To View the Calculated O<sub>2</sub> Cylinder Duration

When the cylinder pressure is entered and set, the ventilator uses the current ventilation values and settings to calculate and display the remaining usable time of the external  $O_2$  cylinder specified.

### **NOTE**

To obtain an accurate duration time estimate, the current cylinder pressure must be entered prior to <u>each</u> calculation. The  $O_2$  Cylinder Pressure (**Cyl Pres**) menu setting reverts to "- - - - " one minute after a value is entered.

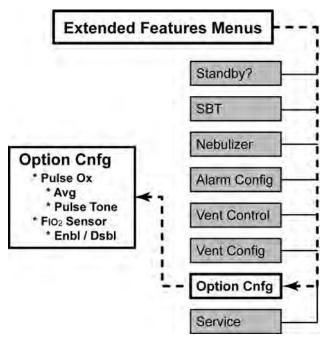
1) To view the calculated O<sub>2</sub> duration in hours and minutes, rotate the Scroll knob until O<sub>2</sub> Dur HH:MM is displayed. The calculated O<sub>2</sub> duration is displayed for 60 seconds, or until the message is acknowledged by pushing the Select or Exit button, or by rotating the Scroll knob on the lower interface panel.

Range: O<sub>2</sub> Dur 00:00 through 99:59 HH:MM

If the Cyl Pres setting has reverted to "- - - - ", O2 Dur - - : - - is displayed

## **Option Cnfg (Option Configuration)**

The **Option Cnfg** (Option Configuration) menus are used to enable, disable, and configure control values for ventilator options that are not directly available on the front panel.



## To Use the Option Cnfg Menus

Enter the Extended Features menus from a normal mode of ventilation; rotate the **Scroll** knob until **Option Cnfg** is displayed, push the **Select** button and **Pulse Ox** is displayed.

## Pulse Ox (Pulse Oximetry)

The **Pulse Ox** (Pulse Oximetry) menus are used to set Pulse Oximetry monitoring averaging and pulse tone volume configuration values. See *Pulse Oximetry (SpO2)* in Chapter 2 – Installation and Setup for additional information

## Avg (Average)

The **Avg** (Average) menu is used to set the averaging calculation used by the SpO<sub>2</sub> Module to display readings (i.e. display reading for each pulse beat, fast average, average of 4 pulse beats, or average of 8 pulse beats).

- 1) Push the **Select** button when **Pulse Ox** is displayed and **Avg** is displayed. Push the **Select** button again and the set Avg configuration is displayed.
- 2) Rotate the **Scroll** knob until the desired Avg configuration is displayed, push the **Select** button, the new Avg configuration is set and **Avg** is displayed.

Range: B-B, Fast, 4-Beat, or 8-Beat

### **Pulse Tone**

The Pulse Tone menu is used to set the audible volume level of the SpO<sub>2</sub> Pulse Tone. The tone is only active when a Pulse Oximetry Module is connected to the ventilator, enabled and a sensor is attached to a patient. The SpO<sub>2</sub> Pulse Tone is an informational only alert; see *Sound Types*, *Patterns and Volumes* and *Alerts*, *Audible* in Chapter 8 – Ventilator Alarms for additional information.

- Push the Select button when Pulse Ox is displayed and Avg is displayed. Rotate the Scroll knob until Pulse Tone is displayed, push the Select button again and the set Pulse Tone value is displayed.
- 2) Rotate the **Scroll** knob until the desired Pulse Tone value is displayed, push the **Select** button, the new Pulse Tone value is set and **Pulse Tone** is displayed.

Range: Vol 1 or Vol 2, or Off

## FIO<sub>2</sub> Sensor

The Fio<sub>2</sub> Sensor sub-menu Enbl / Dsbl (Enable / Disable) is used to enable or disable ventilator communication with an Fio<sub>2</sub> Sensor during normal ventilation modes (no need to disconnect the patient or restart the ventilator).

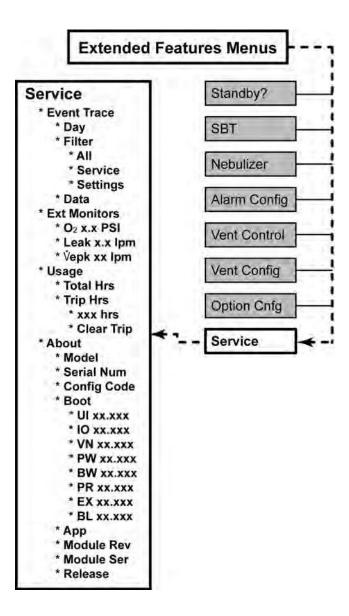
- Rotate the Scroll knob until Fio<sub>2</sub> Sensor is displayed, push the Select button and Enbl / Dsbl is displayed.
- 2) Push the **Select** button again and the set Enbl / Dsbl status is displayed.
- 3) Rotate the **Scroll** knob until the desired Enbl / Dsbl status is displayed, push the **Select** button, the new Enbl / Dsbl status is set and **Enbl / Dsbl** is displayed.

Range: Enable or Disable

To enable/disable or calibrate the  $FlO_2$  sensor in Startup mode, Vent Check menus, see *FlO2* Sensor Configuration and Calibration in Chapter 3 – Using the Ventilator.

## **Service**

The **Service** menus are used to view various types of ventilator operation related information or data that is not directly available on the front panel.



### To Use the Service Menus

Enter the Extended Features menus from a normal mode of ventilation; rotate the **Scroll** knob until **Service** is displayed, push the **Select** button and **Event Trace** is displayed. Rotate the **Scroll** Knob to the desired menu item and push the **Select** button.

### **Event Trace**

The Revel<sup>™</sup> 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 (**HW** Faultxxx) or High Airway Pressure (**High Pres**).

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
- Test execution and results
  - Circuit Test results
  - Button Test accessed
- FIO<sub>2</sub> calibration start and 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.

The Event Trace data may be viewed by selecting the following options in the Event Trace menu:

• **Day** Select a specific day to view the last event for the specified day and use the **Scroll** knob to view events that day and events leading up to that day

 Filter Select Service to view events related to service / technical related events and conditions, alarms and alarm related events (e.g. hardware faults), and battery changes

Select **Settings** to view events related to mode or breath rate changes, any settings changes, all settings upon completion of POST, and all settings logged every 24 hours of continuous operation

Select **All** to view events including maneuvers, procedures, standby mode, service events, and settings events

• Data Select Data to view the event trace information based on the Day and Filter settings

#### To view the Event Trace

- Rotate the Scroll knob until Event Trace is displayed, push the Select button and Day is displayed.
- Push the Select button and the current date is displayed, rotate the Scroll knob to the desired date and push Select. Day is displayed.
- Rotate the Scroll knob until Filter is displayed, push the Select button and rotate the Scroll knob to the desired filter (Service, Settings, or All) and push the Select button. Filter is displayed.
- 4) Rotate the **Scroll** knob until **Data** is displayed and push the **Select** button. Event names are displayed in the Display Window. Event date/time of occurrence and the event number are displayed in the Controls Window.

### NOTE

Until the Local Date and Local 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<sup>40</sup> values (see *Local Time* and *Local Date* 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 and Time Setting displays GMT values in the event log as a correction factor between the ventilator's internal clock and the user selected local time

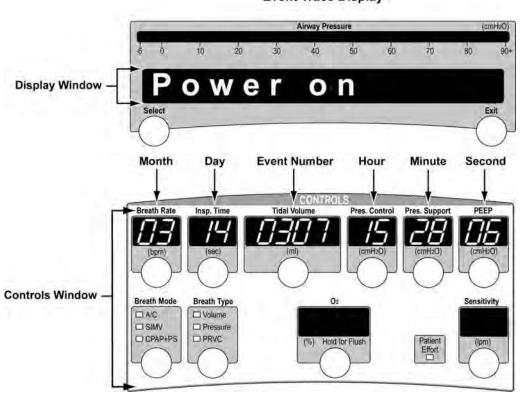
<sup>&</sup>lt;sup>40</sup> GMT – Greenwich Mean Time

Event Trace data is displayed by the name of event, the date/time of occurrence, and the event number.

The event number (displayed in the Tidal Volume control window) is the event number of that day. Example: If the ventilator was powered off with 305 occurrences of events that day, the Power off event number would be logged as 0306. If the ventilator is turned on during the same day, the Power on Event Number would be logged as 0307 (the 307<sup>th</sup> event of that day).

Pushing the **Select** button while an Event is displayed will cycle each information window (Display Window and Controls Window) from dim to bright (inactive to active).

- When the text in the Display Window is bright and the numbers in the Controls Window are dim, rotate the **Scroll** knob to view additional event information in the Display Window (e.g. specific event settings, control values, etc.)
- When the text in the Display Window is dim and the numbers in the Controls Window are bright, rotate the **Scroll** knob to cycle through all events based on the **Filter** setting



### **Event Trace Display**

### NOTE

The O<sub>2</sub> and Sensitivity control windows are blank when the event trace data is viewed.

## Ext Monitors (Extended Monitors)

The **Ext Monitors** (Extended Monitors) menus are used to view O<sub>2</sub> Source Pressure, Measured Patient Circuit Leak, and Measured Peak Expiratory Flow monitored data.

Rotate the **Scroll** knob until **Ext Monitors** is displayed, push the **Select** button and rotate the **Scroll** knob to scroll through and display the available monitored data.

O<sub>2</sub> X.X PSI
 O<sub>2</sub> Source Pressure measured at the O<sub>2</sub> Inlet

Leak XX.X lpm Measured Leak is a measure of the steady state flow through the

patient circuit Wye toward the patient during exhalation

Vepk XXX Ipm
 Peak Expiratory Flow of the previous breath, measured at the patient

Wye

## Usage

The **Usage** menus are used to:

- View the total hours the ventilator has been in use
- View the accumulated hours the ventilator has been in use since the last time the Usage data was cleared
- Clear (reset to 0.0 Hrs) the current **Trip Hours** reading

### To View the Total or Trip Hours

- 1) Rotate the **Scroll** knob until **Usage** is displayed, push the **Select** button and **Total Hrs** is displayed.
- 2) Push the **Select** button to view the total hours the ventilator has been in use (xxx hrs)

### OR

Rotate the **Scroll** knob until **Trip Hrs** is displayed and push the **Select** button to display the accumulated hours the ventilator has been in use since the last time the Usage data was cleared (**xxx hrs**).

### To Clear the Trip Hours

- 1) Rotate the **Scroll** knob while viewing the Trip Hours data (**xxx hrs**) and **Clear Trip** is displayed.
- 2) Push the **Select** button, the accumulated Trip Hours data is reset (**0.0 hrs**) and **Cleared** is displayed.

### **About**

The About menus are used to view specific ventilator configuration information, such as:

- Device Information (model name or part number, serial number, configuration code)
- Component(s) Information (name, boot and application software versions, hardware revisions, serial numbers)

#### To View the About Sub-Menus and Related Data

- Rotate the Scroll knob until About is displayed, push the Select button and Model is displayed.
- 2) Push the **Select** button and the ventilator model name is displayed.
- 3) To view the remaining sub-menus and related data, push the **Exit** button to return to the previously displayed menu, rotate the **Scroll** knob until the desired sub-menu is displayed, push the **Select** button and the related data is displayed:
  - Model
  - Serial Num
  - Config Code
  - App
  - Module Rev
  - Module Ser
  - Release
- 4) Rotate the **Scroll** knob to view additional related data (if any) and push the **Exit** button to return to the previously displayed menu.
- 5) Continue using the **Scroll** knob, **Select** and **Exit** buttons to locate, view and exit the desired menus and related data.

# Chapter 11 - MAINTENANCE AND CLEANING

## **Maintenance Schedule**

### Routine Maintenance

The Revel<sup>™</sup> ventilator is designed to operate for extended periods of time with minimal routine maintenance. The following periodic maintenance is recommended:

| Length of Service <sup>41</sup>                    | Maintenance Required   |
|--|--|
| In storage   | <ul> <li>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</li> <li>Every two months, recharge the Transition Battery<sup>42</sup> by powering the ventilator from an AC power source for at least 5 hours</li> </ul>   |
| Prior to initial use                               | <ul> <li>Charge the Removable Battery Pack and Transition Battery by powering the ventilator from an AC power source for at least 13 hours</li> <li>Setup the ventilator/accessories as shown in Chapter 2 - Installation and Setup</li> <li>Check the ventilator for proper operation as detailed in Ventilator Testing in Chapter 2 - Installation and Setup</li> </ul>  |
| Daily  | <ul> <li>Verify alarms are functioning properly</li> <li>Check the Air Inlet Filter, replace if soiled</li> <li>Check the Cooling Fan Filter, clean if necessary, replace if damaged or worn</li> </ul>  |
| When changing or reconfiguring the patient circuit | <ul> <li>Check the Exhalation Valve Diaphragm, clean if necessary, replace if damaged or worn</li> <li>Perform the <i>Circuit Test</i> as detailed in Chapter 2 – Installation and Testing</li> </ul>  |
| If in use, a minimum of once a month               | Perform the tests as detailed in <i>Ventilator</i> 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 Vte or VE monitor  Verify the Airway Pressure or PIP monitor  Verify the delivered O <sub>2</sub> concentration, if not using an oxygen analyzer continuously |

<sup>&</sup>lt;sup>41</sup> To check the number of hours the ventilator has been in service, see *Usage* in Chapter 10 – Extended Features.

<sup>&</sup>lt;sup>42</sup> The **Vent Inop** alarm will sound if the Transition Battery charge becomes completely depleted while in storage.

### **Extended Maintenance**

| Length of Service <sup>43</sup>   | Maintenance Required   |
|---|--|
| Every 15,000 hours or<br>three years <sup>44</sup> , whichever<br>comes first | <ul> <li>Replace the Cooling Fan Filter</li> <li>Replace the Air Inlet Filter and Screen</li> <li>Replace the O<sub>2</sub> Inlet Filter</li> <li>Replace the Blower Inlet Filter</li> <li>Perform all Functional and Final Checkout Tests specified in the PTV<sup>®</sup> Series Ventilators Service Manual</li> </ul> |
| Every 30,000 hours or six years 44, whichever comes first                     | <ul> <li>Perform 15,000 hours / 3 years Extended Maintenance</li> <li>Replace the Flow Sensor Filter</li> <li>Replace the Transition Battery</li> <li>Perform all Functional and Final Checkout Tests specified in the PTV<sup>®</sup> Series Ventilators Service Manual</li> </ul>                                      |

### Extreme Environments

This schedule of maintenance is typical for most clinical or home 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*).

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<sup>&</sup>lt;sup>43</sup> To check the number of hours the ventilator has been in service, see *Usage* in Chapter 10 – Extended Features.

<sup>44 15,000</sup> 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 and front panels, do not use cleaning agents containing ammonium chloride, 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 all 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 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.

## Filter Cleaning and Replacement

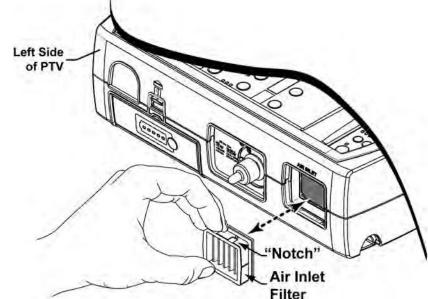
### The Oxygen Inlet Filter

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 in *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



 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

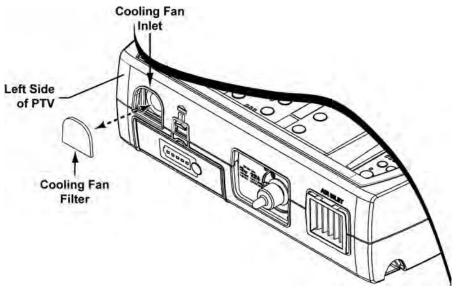
Check the cooling fan filter daily. Clean as detailed below and replace when worn or excessively soiled.

#### **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 Revel<sup>™</sup> 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 Revel<sup>™</sup> ventilator can be powered directly from the Docking Station via the custom interface connection. Refer to the PTV<sup>®</sup> Series Docking Station Operator's Manual, P/N 12433-001 for information and instructions.



### **NOTE**

Docking a PTV<sup>®</sup> 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 Revel<sup>™</sup> 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.

Dimming illuminated displays when not in use helps to improve battery performance. See *Dim After* in the Extended Features, Vent Config menus in Chapter 10 – Extended Features for additional information and detailed instructions.

### To Check the Level of Charge:

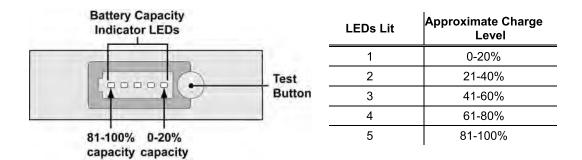
#### NOTE

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.

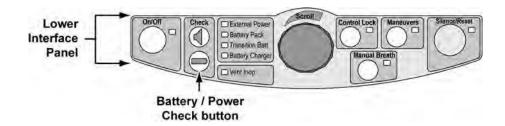
Each Removable Battery Pack LED increments approximately 20% as shown.



If the battery is being charged, the LED that is representative 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 Battery/Power 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 Revel<sup>™</sup> 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 cm $H_2O$ , 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 Revel<sup>™</sup> 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 Revel $^{^{\text{\tiny{M}}}}$  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 Revel  $^{\text{\tiny TM}}$  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, and patient

triggering (sensitivity)

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 test problems detected during Startup or

normal ventilation modes

• Test Lung Operation - Includes problems encountered when operating the

ventilator 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.

# **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   |
|---|--|--|
| Pres. Control display flashing.   | Pressure Control breath<br>terminated by flow –<br>Pressure Control Flow<br>Termination is On. | When a Pressure Control breath is terminated by flow instead of time, the <b>Pres</b> . <b>Control</b> display flashes when Pressure Control Flow Termination is set to a value other than "" (off). This is normal performance. If this is not desired, review ventilator settings. |
| Pres. Support display flashes.  | Pressure Support breath terminated by time rather than flow.                                   | When a pressure support breath is terminated based on time, the <b>Pres. Support</b> display flashes. This is normal performance. If this is not desired, review ventilator settings.  |
| High Pres. Limit<br>alarm display turns<br>red and High Pres<br>flashes in display<br>window. | High Airway Pressure alarm occurred.   | Review alarm limits settings and check for common causes (i.e. patient cough or patient circuit occlusions).   |
| Low Pk. Pres. alarm limit display flashing and Low Pk Pres flashes in display window.         | Low Peak Pressure alarm occurred.  | Review alarm limits settings and check for common causes (i.e. patient circuit leaks).   |
| Low Min. Vol. alarm display flashing and Low Min Vol flashes in display window.               | Low Exhaled Minute<br>Volume alarm occurred.   | Review alarm limits settings and check for common causes (i.e. patient circuit leaks).   |
| Low FIO <sub>2</sub> % display flashing and Low FIO <sub>2</sub> flashes in display window.   | Low F <sub>1O₂</sub> alarm occurred.   | Review alarm settings, re-calibrate FIO <sub>2</sub> 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.       |
| A display or LED does not illuminate.   | Internal problem with the ventilator.  | Push the Display/Alarm <b>Check</b> 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.  |

| Symptoms  | Possible Causes  | Suggested Action   |
|---|--|--|
| Ventilator is running but displays are turned off.                                  | Displays are extinguished while on battery power or the set <b>Dim After</b> period has expired. | To conserve battery life when running from the internal battery, most of the displays are turned off when no control settings are changed for 60 seconds or if the <b>Dim After</b> time, set in Extended Features, has expired.  Pushing any button or adjusting the <b>Scroll</b> 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 <b>Check</b> 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.  |
| A control or the <b>Scroll</b> knob doesn't operate.                                | Control not active in selected mode.   | If a control is dimmed, 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 <b>Locked</b> message will be displayed when a control is selected.  To unlock in Easy mode, push the <b>Control Lock</b> button. To unlock in Hard mode, push and hold the <b>Control Lock</b> button for 3 seconds.  |
|   | Control is not selected.   | Before a control value can be changed, the control must be selected. To select a control, push the associated button.  |
|   | 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 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 <b>Control Lock</b> button. To unlock in Hard mode, push and hold the <b>Control Lock</b> button for 3 seconds.   |
| Ventilator does not turn off when the <b>On/Off</b> button is pushed for 3 seconds. | Internal problem with the ventilator.  | Push and hold the <b>On/Off</b> button for at least 20 seconds to achieve the backup power-off sequence. If the ventilator still does not turn off, contact CareFusion or a Service Technician certified by CareFusion.  |

# **Ventilator Performance**

| Symptoms   | Possible Causes  | Suggested Action   |
|--|--|--|
| Ventilator is auto cycling, monitored volumes are very small, negative flows exhibited during exhalation and | 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. |
| positive flows during inspiration.   | 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.  |
| Ventilator won't allow patient to exhale.  | Diaphragm incorrectly installed or poorly seated in Exhalation Valve.    | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  If using a Single Use patient circuit, replace with a functional assembly.        |
|  | Sense lines occluded or pinched.   | Check high and low pressure Sense Lines at the ventilator and Wye ends. Verify lines are not occluded or pinched.  |
|  | 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;<br>causing ventilator to enter<br>active exhalation. | Reduce rise time (increase <b>Rise Time</b> setting).  |
| Set Pressure ( <b>Pres</b> . <b>Control</b> ) not reached.   | Rise Time setting is too slow for the set Insp. Time.                    | Adjust <b>Rise Time</b> setting.   |
|  | Patient circuit leak.  | Perform a Circuit Test.  |
|  | Exhalation diaphragm not properly seated.                                | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  If using a Single Use patient circuit, replace with a functional assembly.        |

| Symptoms                                 | Possible Causes  | Suggested Action  |
|--|--|---|
| Monitored volume ( <b>Vte</b> ) 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 differential to be read incorrectly. To reduce this turbulence, add a short larger bore extension 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<br>Sense Lines are<br>occluded.                 | Verify lines are not occluded or pinched.   |
|  | High or Low Pressure<br>Sense Line ports in the<br>Wye are occluded. |   |
|  | 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.   |

| Symptoms   | Possible Causes   | Suggested Action   |
|--|---|--|
| Monitored volume ( <b>Vte</b> ) is low.                  | High Pressure Sense<br>Line or elbow at patient<br>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<br>Sense Lines are<br>occluded.  | Verify lines are not occluded or pinched.  |
|  | High or Low Pressure<br>Sense Line ports in the<br>Wye are occluded.  |  |
|  | 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 Compensation is turned On.  |
|  | Exhalation Diaphragm not properly seated.   | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  |
|  |   | If using a Single Use patient circuit, replace with a functional assembly.   |
|  | Internal problem with the ventilator.   | Contact CareFusion or a Service Technician certified by CareFusion.  |
| Delivered pressure is high.  Monitored pressure is high. | Exhalation Diaphragm not properly seated.   | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  If using a Single Use patient circuit, replace with a             |
|  | High or Low Dragouro  | functional assembly.   |
|  | 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 flow is high or low.             | Leaks in the Patient<br>Circuit.  | Perform a Circuit Test. Replace leaking circuit if necessary.   |
|  | Internal problem with the ventilator.   | Contact CareFusion or a Service Technician certified by CareFusion.   |
| Sensitivity does not appear to be accurate | Patient Circuit leak.   | Perform a Circuit Test and reseat or replace the leaking parts or connections.  |
| and/or ventilator is auto cycling.         | Exhalation Diaphragm not properly seated.   | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.   |
|  |   | If using a Single Use patient circuit, replace with a functional assembly.  |
|  | There is a leak between patient circuit Wye and the patient.  | Adjust the <b>Sensitivity</b> 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<br>Sense Line or elbow at<br>patient Wye loose or<br>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 Leak Compensation is turned On.   |
|  | Internal problem with the ventilator.   | Contact CareFusion or a Service Technician certified by CareFusion.   |

| Symptoms                                | Possible Causes  | Suggested Action  |
|---|--|---|
| <b>O</b> ₂% is high.                    | Low O <sub>2</sub> source incorrectly selected.  | Verify that the ventilator $O_2$ % is set to <b>LPS</b> when using a low flow, low pressure source of $O_2$ and to a percentage when connected to high pressure $O_2$ .   |
|   | O <sub>2</sub> inlet pressure too high<br>when Low Pressure<br>Source ( <b>LPS</b> ) selected. | Verify the low pressure $O_2$ inlet has been correctly calculated and set using the Input $O_2$ Flow Chart in the ventilator Operator's manual.   |
|   | ${ m O_2}$ inlet flow too high when Low Pressure Source ( <b>LPS</b> ) selected.               | 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 <sub>2</sub> Sensor reading inaccurate.  | Recalibrate the FIO <sub>2</sub> Sensor. See <i>FIO2 Sensor</i> 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 pressure is low, PEEP is low. | Circuit leak.  | Perform a Circuit Test and reseat or replace the leaking parts or connections.  |
| Monitored pressure is low.              | High or Low Pressure<br>Sense Line or elbow at<br>patient Wye loose or<br>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<br>Sense Lines are occluded.  | Verify lines are not occluded or pinched.   |
|   | High or Low Pressure<br>Sense Line ports in the<br>Wye are occluded.                           |   |
|   | Exhalation Diaphragm not properly seated.  | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  If using a Single Use patient circuit, replace with a functional assembly. |
|   | 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 Comp is not on.   | Verify that Leak Compensation is turned On.   |
|   | Internal problem with the ventilator.  | Contact CareFusion or a Service Technician certified by CareFusion.   |

| Symptoms                     | Possible Causes  | Suggested Action   |
|------------------------------|--|--|
| O₂% is low.                  | O <sub>2</sub> inlet flow too low when Low O <sub>2</sub> Source selected. | Verify the low pressure $O_2$ inlet has been correctly calculated and set using the Input $O_2$ Flow Chart in Chapter 2.  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 <sub>2</sub> . |
|                              | FIO <sub>2</sub> Sensor reading inaccurate.                                | Recalibrate the FIO <sub>2</sub> Sensor. See <i>FIO2 Sensor</i> Configuration and Calibration in Chapter 3 for additional information.  If calibration of the FIO <sub>2</sub> Sensor fails, replace the FIO <sub>2</sub> Sensor.  |
|                              | Internal problem with the ventilator.                                      | Contact CareFusion or a Service Technician certified by CareFusion.  |
| PEEP not working. PEEP low.  | Circuit leak.  | Perform a Circuit Test and reseat or replace the leaking parts or connections.   |
| PEEP sags during exhalation. | Exhalation Diaphragm not properly seated.                                  | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  |
|                              |  | If using a Single Use patient circuit, replace with a functional assembly.   |
|                              | 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<br>Sense Lines are<br>occluded.                       | Verify lines are not occluded or pinched.  |
|                              | Leak Compensation is not on.   | Verify that Leak Compensation is turned On.  |
|                              | Internal problem with the ventilator.                                      | Contact CareFusion or a Service Technician certified by CareFusion.  |

| Symptoms  | Possible Causes  | Suggested Action  |
|---|--|---|
| PEEP is too high.   | Exhalation Diaphragm not properly seated.                                | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one. |
|   |  | If using a Single Use patient circuit, replace with a functional assembly.  |
|   | High Pressure Sense<br>Line or elbow at patient<br>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<br>Sense Lines are<br>occluded.                     | Verify lines are not occluded or pinched.   |
| Ventilator won't trigger at flow <b>Sensitivity</b> 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 Leak Compensation is turned On.   |
|   | 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 ( <b>External Power</b> 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 | 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.  |
| ventilating.  | Vent Inop. Due to causes other than normal power down.   | If a <b>Vent Inop</b> alarm occurs during operation, immediately ventilate the patient using an alternative method, disconnect the ventilator and   |
|   | Internal problem with the ventilator.  | contact CareFusion or a Service Technician certified by CareFusion.   |
| The ventilator doesn't operate from external power.   | Ventilator connected to<br>Automobile Adapter and<br>power from automobile<br>outlet is faulty or<br>inadequate.   | Try rotating 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 into the Docking Station.   | Push the <b>Eject</b> button on the front panel of the Docking Station to release the ventilator and redock following the instructions in the Docking Station Operator's manual.  |
|   | Defective AC source.<br>AC Adapter power cord<br>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       | Both the Removable<br>Battery Pack and the<br>Transition Battery are<br>depleted.                  | Connect then ventilator to a valid source of external power and charge the batteries for at least 13 hours.  |
| when external power is removed.  | Internal problem with the ventilator.  | Contact CareFusion or a Service Technician certified by CareFusion.  |
| Removable Battery<br>Pack doesn't reach full<br>charge or depletes too<br>quickly. | Removable Battery Pack<br>needs to be conditioned or<br>has reached the end of its<br>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 <i>Battery Charger</i> 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 <b>Charge Status</b> LED will flash slowly amber while the Transition Battery charges. When the Transition Battery is charged the LED will stop flashing. Refer to <i>Battery Charger</i> 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<br>Battery and the<br>Removable Battery Pack<br>are fully charged.             | Not charging (either no external power is applied to the ventilator or charging of both batteries is completed). Refer to <i>Battery Charger</i> in Chapter 6 – Displays and Indicators for detailed information. This is nominal performance.   |

### **Alarms**

Many alarms such as High Airway Pressure or Low or Loss of  $O_2$  Inlet Pressure can occur during normal operation. Single occurrences of some alarms, such as a Hardware Fault or Vent Reset may be caused by ESD<sup>45</sup>. 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   |
|--|---|--|
| SV HP Relief (Safety<br>Valve High Pressure<br>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. |
|  | Luer connections on the<br>High and Low Pressure<br>Sense Lines are not<br>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.  |

-

<sup>&</sup>lt;sup>45</sup> ESD – Electro Static Discharge.

| Symptoms   | Possible Causes  | Suggested Action   |
|--|--|--|
| A <b>High Pres</b> alarm condition occurred but the alarm did not sound.   | Alarm silence was already active (Silence/Reset LED is red). | The ventilator audible alarm can be silenced for 60 seconds by pushing the <b>Silence/Reset</b> button. If the alarm is already silenced (LED is red), it will not sound again until the silence period expires. Push the button again to turn off the silence period. |
|  | High Airway Pressure   | Set the High Pressure Delay as required.   |
|  | alarm delay is on is set to a delay of one or two breaths.   | When a high airway pressure condition is detected, if the High Pressure Delay option is set to <b>0</b> the audible alarm is sounded immediately.  |
|  |  | When the High Pressure 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 <b>High Pres</b> alarms.  | Patient circuit expiratory limb is occluded or pinched.      | Resolve pinched/occluded expiratory limb.  |
|  | High Pressure Sense<br>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.                    | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  |
|  |  | If using a Single Use patient circuit, replace with a functional assembly.   |
|  | Internal problem with the ventilator.                        | If problem reoccurs, contact CareFusion or a service technician certified by CareFusion.   |
| Ventilator won't exhale, repeated High Pres 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.                    | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  If using a Single Use patient circuit, replace with a       |
|  |  | functional assembly.   |
|  | Internal problem with the ventilator.                        | Contact CareFusion or a Service Technician certified by CareFusion.  |

| Symptoms   | Possible Causes   | Suggested Action  |
|--|---|---|
| Repeated <b>Pat Circuit</b> 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 in patient circuit.  | Resolve leaks beyond the patient Wye.   |
|  | Exhalation Diaphragm is dirty or not properly seated.   | If using a Reusable patient circuit, open the Exhalation Valve, clean and reseat the diaphragm and snap the Valve Cap back in place. If damaged or worn, replace the Exhalation Diaphragm with a new one.  If using a Single Use patient circuit, replace with a functional assembly. |
|  | Internal problem with the ventilator.   | Contact CareFusion or a Service Technician certified by CareFusion.   |
| HW Fault alarm.  | Electro static discharge (ESD).   | Reset 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.  |
| Vent Reset alarm occurs.   | Electro static discharge (ESD).   | Reset 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.  |
| Vent Reset alarm occurs after ventilator is operated on Transition Battery until it is fully depleted. | Ventilator shut off because Transition Battery is fully depleted.   | Reset the alarm and charge the Transition Battery by inserting a Removable Battery Pack or connecting external power.   |

| Symptoms   | Possible Causes  | Suggested Action  |
|--|--|---|
| Config Reset alarm. Event Log indicates Configuration Reset. | Electro static discharge (ESD).  | Reset 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.  |
| Repeated <b>High PEEP</b> alarms.                            | Monitored PEEP exceeds the set High PEEP alarm value.  | Check <b>High PEEP</b> alarm value.   |
|  | Internal problem with the ventilator.  | If problem reoccurs, contact CareFusion or a Service Technician certified by CareFusion.  |
| Batt Fault alarm   | Ventilator detects that the Removable Battery Pack cannot operate the ventilator.                            | Replace with a fully charged Removable Battery Pack.  |
| RBatTempFlt 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 <i>Environmental Specifications</i> 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.   |
| T-Bat Fault alarm during normal ventilation.                 | Depleted Transition<br>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.  |
| T-Bat 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.  | Replace Transition Battery.   |
|  | Internal problem with the ventilator.  | Contact CareFusion or a Service Technician certified by CareFusion.   |
| TBatTempFlt 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 <i>Environmental Specifications</i> in Appendix B – Specifications).                       |

| Symptoms   | Possible Causes   | Suggested Action  |
|--|---|---|
|  | Internal problem with the ventilator.   | Contact CareFusion or a service technician certified by CareFusion.   |
| 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.   | Replace Transition Battery.   |
| Blower Demand<br>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<br>not displayed or<br>incorrect message is<br>displayed. | Internal problem with the ventilator. | Contact CareFusion or a Service Technician certified by CareFusion. |
| Circuit Test:  |                                       |   |
| Failed FS message is   | Luer fittings not seated.             | Reseat the Luer fittings.   |

| Failed FS message is displayed. | 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 Service Technician certified by CareFusion.   |
| Failed Flow is displayed.       | 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 SV message is displayed. | Internal problem with the ventilator.   | Contact CareFusion or a Service Technician certified by CareFusion.   |

# Display/Alarm Test:

| Audible alarm level excessive.        | Alarm volume set too high.            | Reset the alarm volume.   |
|---------------------------------------|---------------------------------------|---|
| Audible alarm too soft.               | Alarm volume set too low.             | Reset the alarm volume.   |
|                                       | 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. |
| A display or LED fails to illuminate. | Internal problem with the ventilator. | Contact CareFusion or a Service Technician certified by CareFusion. |

| Symptoms                                     | Possible Causes                       | Suggested Action  |
|--|---------------------------------------|---|
| 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 <b>Vent Inop</b> LED is not illuminated. | Internal problem with the ventilator. | Contact CareFusion or a Service Technician certified by CareFusion. |

# **Test Lung Operations**

| Symptoms   | Possible Causes   | What to Do  |
|--|---|---|
| Delivered Pressure<br>higher than set<br>pressure on Test<br>Lung. | Pressure > 40 cmH <sub>2</sub> O 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 <sub>2</sub> O or change to a larger lung. |
|  | Rise Time too fast.   | Reduce rise time (increase Inspiratory Rise setting).   |
|  | Internal problem with the ventilator.   | Contact CareFusion or a Service Technician certified by CareFusion.   |
| Monitored volumes 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 differential 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 differential to be read incorrectly. To reduce the jetting effect, add a short larger bore extension 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<sup>®</sup> 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

#### **CareFusion Respiratory Systems**

17400 Medina Rd., Suite 100 Minneapolis, MN 55447-1341, USA

Office: 763.398.8500 (Worldwide)

Toll-Free: 800.754.1914 (U.S. and Canada) Fax: 763.398.8592 (Tech Support)

763.398.8403 (Product Orders)

Email: revelservice@carefusion.com

Website: www.carefusion.com

# **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 Revel ventilator, it is assumed that the ambient relative humidity is 30%.

# **Breath Modes and Breath Types**

| Breath Types | Volume Control, Pressure Control, PRVC (Pressure Regulated Volume Control) PRVS (Pressure Regulated Volume Support), Pressure Support, Spontaneous  |
|--------------|---|
| Breath Modes | Control, Assist Control, Synchronized Intermittent Mandatory Ventilation (SIMV), Continuous Positive Airway Pressure (CPAP) plus Pressure Support, Non-Invasive Positive Pressure Ventilation (NPPV), Apnea Backup. |

### **Controls**

#### Lower Interface Panel Buttons

| Control                | Function   |
|------------------------|--|
| Battery/Power<br>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 Dock Docking Station power and the status of the Transition Battery. |
| Control Lock           | Locks and unlocks the ventilation controls.  |
| Display/Alarm<br>Check | All LED indicators and displays are illuminated, the high priority audible alarm sounds for 2 seconds.   |
| Maneuvers              | Enables access to setup for 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.   |
| Silence/Reset          | Toggles a 60 second silence period on and off for audible portion of alarms. Removes, or suppresses for 15 seconds, the visual alarms display.   |

### Adjustable Controls

| Control                           | Range   |                              | Accuracy   |
|-----------------------------------|---|------------------------------|--|
| Bias Flow                         | 3 through 10 lpm  |                              | ±1 lpm   |
| Breath Rate                       | 1 through 80 bpm  |                              | Greater of 1 breath per minute of ±10%,                        |
| Breath Type                       | Volume Control, Pressure<br>Control, Pressure Regulated<br>Volume Controlled (PRVC) |                              | N/A  |
| Flow Termination                  | 10 through 40 percentage of peak flow   |                              | Greater of ±15% or ±2 lpm                                      |
| High Pressure Alarm<br>Delay      | 0, 1, 2 breaths   |                              | N/A  |
| Inspiratory Time                  | 0.3 through 9.9 Seconds   |                              | ±0.05 seconds  |
| Leak Comp                         | On, Off   |                              | N/A  |
| LPP Alarm Control                 | "All Breaths", "C   | Control Only"                | N/A  |
| NPPV                              | On, Off   |                              | N/A  |
| O <sub>2</sub> %                  | LPS, 21 through 100 %   |                              | ±3 (21-50) <sup>46</sup><br>±5 (51-100) <sup>46</sup>          |
| PEEP                              | 0 through 20 cmH <sub>2</sub> O   |                              | Greater of ±1 or ±10%,   |
| Pressure Control                  | 1 through 99 cmH <sub>2</sub> O   |                              | Greater of ± 8% or ±2 cmH <sub>2</sub> O                       |
| Pressure Support                  | Off, 1 through 60 cmH₂O   |                              | Greater of ± 8% or ±2 cmH <sub>2</sub> O                       |
| Pressure Trigger                  | 1 through 20 below PEEP   |                              | Greater of ±10% or ±2 cmH <sub>2</sub> O                       |
| Pressure Control Flow Termination | On, Off   |                              | N/A  |
| Rise Time                         | Rise Time<br>Setting  | Commanded<br>Rise Time (sec) | Pressure commanded to 90% of Target Pressure by specified rise |
|                                   | 1   | 0.100                        | time ±200ms  |
|                                   | 2   | 0.133                        |  |
|                                   | 3   | 0.178                        |  |
|                                   | 4   | 0.237                        |  |
|                                   | 5   | 0.316                        |  |
|                                   | 6   | 0.422                        |  |
|                                   | 7   | 0.562                        |  |
|                                   | 8   | 0.750                        |  |
|                                   | 9   | 1.000                        |  |
| Safety Valve Delta<br>Pressure    | 5 through 30 cmH <sub>2</sub> O   |                              | N/A  |
| P, 1 through 9 lpm                |   | +1, -0.5 (<2)<br>±1 (≥2)     |  |

<sup>&</sup>lt;sup>46</sup> 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.

| Control              | Range  | Accuracy                                   |  |
|----------------------|--|--|--|
| Tidal Volume         | 50 through 2000 ml   | Greater of ±10% or ±10 ml                  |  |
| Time Termination     | 0.3 through 3.0 seconds  | ± 0.030 seconds                            |  |
| Ventilation Mode     | Assist/Control (A/C), Synchronized Intermittent Mandatory Ventilation (SIMV), Continuous Positive Airway Pressure (CPAP) plus Pressure Support (PS). | N/A  |  |
| SBT O <sub>2</sub>   | LPS, 21 through 100 %  | ±3% O <sub>2</sub> (21-50)<br>±5% (51-100) |  |
| SBT PEEP             | 0 through 20 cmH <sub>2</sub> O  | ±1 or ±10%                                 |  |
| SBT Pressure Support | '—" (Off), 1 through 30 cmH <sub>2</sub> O   | Greater of ±8% or ±2 cmH <sub>2</sub> O    |  |
| SBT Time             | 15 min through 120 min   | ±1 min                                     |  |
| SBT f/Vt Display     | "On", "Off"  | N/A  |  |

# **Maneuvers**

| Maneuver | Function  |
|----------|---|
| E-Hold   | Maintains the expiratory phase of a breath for 6 ± 0.1 seconds (Adult/Ped/Infant) 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/Infant) or until the button is released. Calculates C Static. |

# **Procedures**

| Procedures                           | Function   |
|--------------------------------------|--|
| O <sub>2</sub> Flush                 | Delivers a pre-selected increase in O <sub>2</sub> percentage for a pre-selected duration.   |
| Nebulization                         | Provides a flow of 6 L/min ±10% O <sub>2</sub> to drive a nebulizer (optional). Configurable as continuous or inspiration only.                  |
| SBT (Spontaneous<br>Breathing Trial) | During the SBT procedure, ventilation is delivered in CPAP+PS mode with the selected SBT control settings in Extended Features. Calculates f/Vt. |

# **Alarms**

# Adjustable Alarms

| Alarm                 | Range  | Priority                                 |
|-----------------------|--|--|
| Apnea (Interval)      | 10 through 60 seconds                        | High priority audible and visual alarm   |
| High Pres             | 5 through 100 cmH₂O                          | High priority audible and visual alarm   |
| High f                | 1 through 120 bpm, or "" (off)               | Medium priority audible and visual alarm |
| High PEEP             | 3 through 40 cmH <sub>2</sub> O, or "" (Off) | Medium priority audible and visual alarm |
| High Pulse            | 18 through 299, Beats/min or "" (off)        | High priority audible and visual alarm   |
| High SpO <sub>2</sub> | 80 through 99 %, or '' (Off)                 | High priority audible and visual alarm   |
| Low FIO <sub>2</sub>  | "" (off), or 18% through 95%                 | High priority audible and visual alarm   |
| Low Min Vol           | "" (off), or 0.1 through 99 liters           | High priority audible and visual alarm   |
| Low Pk Pres           | "" (off), or 1 through 60 cmH <sub>2</sub> O | High priority audible and visual alarm   |
| Low PEEP              | "" (off), or 1 through 20 cmH <sub>2</sub> O | High priority audible and visual alarm   |
| Low Pulse             | ''(Off), or 19 through 300 Beats/min         | High priority audible and visual alarm   |
| Low SpO <sub>2</sub>  | ''(Off), or 60 through 99 %                  | High priority audible and visual alarm   |
| SBT > f               | 15 through 80 bpm, or SBT Hi f Off           | Medium priority audible and visual alarm |
| SBT > f/Vt            | 70 through 900 bpm/L, or Hi f/Vt Off         | Medium priority audible and visual alarm |
| SBT < f               | SBT Lo f Off, or 1 through 40 bpm            | Medium priority audible and visual alarm |
| SBT < f/Vt            | Lo f/Vt Off, or 5 through 90 bpm/L           | Medium priority audible and visual alarm |
| SBT Hi PEEP           | 3 through 40 cmH <sub>2</sub> O, or "" (off) | Medium priority audible and visual alarm |
| SBT Lo PEEP           | "" (off), or 1 through 20 cmH <sub>2</sub> O | High priority audible and visual alarm   |

### Fixed Alarms

| Alarm       | Priority/Type                            |
|-------------|--|
| Bat Empty   | High priority audible and visual alarm   |
| Bat Fault   | Medium priority audible and visual alarm |
| Bat Low     | Medium priority audible and visual alarm |
| Battery Use | N/A / Periodic audible tone              |
| Blwr Demand | High priority audible and visual alarm   |
| ButtonStuck | Medium priority audible and visual alarm |
| ConfigReset | High priority audible and visual alarm   |
| Dock Discon | Medium priority audible and visual alarm |
| Dock Fault  | Medium priority audible and visual alarm |
| ExtPwrFault | Medium priority audible and visual alarm |
| ExtPwr Lost | Medium priority audible and visual alarm |

| Ext Pwr Low             | Medium priority audible and visual alarm   |
|-------------------------|--|
| FIO <sub>2</sub> Fault  | Medium priority audible and visual alarm   |
| HW Faultxxx             | High priority audible and visual alarm   |
| Hi O <sub>2</sub> Pres  | Medium priority audible and visual alarm   |
| Insert Batt             | Medium priority audible and visual alarm   |
| Low O <sub>2</sub> Pres | High priority audible and visual alarm   |
| Pat. Circuit            | High priority audible and visual alarm   |
| P Maint xxx             | Low priority audible and visual alarm  |
| RBatTempFlt             | High priority audible and visual alarm   |
| Remove Ptnt             | High priority audible and visual alarm   |
| SVHP Relief             | High priority audible and visual alarm   |
| SBT Off                 | Low priority audible and visual alarm  |
| SBT Time                | Low priority audible and visual alarm  |
| SchedSvcxxx             | Low priority audible and visual alarm  |
| SpO₂ Fault              | High priority audible and visual alarm   |
| SpO <sub>2</sub> LowSig | High priority audible and visual alarm   |
| SpO <sub>2</sub> Module | High priority audible and visual alarm   |
| SpO <sub>2</sub> Discon | High priority audible and visual alarm   |
| SpO <sub>2</sub> Sensor | High priority audible and visual alarm   |
| T-Bat Fault             | Medium priority audible and visual alarm   |
| TBatTempFlt             | High priority audible and visual alarm   |
| T- Bat Use              | High priority audible and visual alarm. Resets only once for 60 seconds  |
| Vent Inop               | High priority audible and visual Inop Alarm. Pushing the alarm <b>Silence/Reset</b> button silences the audible indicator. |
| Vent Reset              | Medium priority audible and visual alarm   |
| Vol Limited             | Medium priority audible and visual alarm   |

# **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 <sub>2</sub> O, or   |
|                      | Blower Estimated Airway Pressure ≥ High Airway Pressure Alarm setting + Safety Valve Delta Pressure setting   |
|                      | Resistance with valve open:   |
|                      | ≤ 5 cmH <sub>2</sub> O at 10 lpm, measured at the ventilator's inspiratory limb   |
| Sub-Ambient (anti-   | Sub-ambient activation: Sub-ambient activation:   |
| asphyxia) Relief     | Airway Pressure Monitor ≤ -5 cmH <sub>2</sub> O, or   |
|                      | Airway pressure based on Blower Differential Pressure transducer ≤ -5 (+0/-5) cmH₂O   |
|                      | Sub-ambient recovery:   |
|                      | Airway Pressure > -5 cm $H_2O$ , $\geq$ 250 ms after activation, and Airway pressure based on Blower Differential Pressure transducer > -5 (+0/-5) cm $H_2O$ , $\geq$ 250 ms after activation |

# Internal Compliance

Compliance < 0.1 mL/cm

# **Monitors**

## **Patient Monitors**

| Monitor   | Range   | Accuracy   |
|---|---|--|
| Airway Pressure (Paw)                           | -6 through 90+ cmH <sub>2</sub> O measured at the patient Wye | Greater of ±5% or ±2   |
| Exhaled Minute Volume (VE)                      | 0 through 99.9 L  | Greater of ±15% or ±0.015*f                                    |
| Exhaled Tidal Volume (Vte)                      | 0 through 4000 ml   | Greater of ±15% or ±15   |
| Fraction of Inspired Oxygen (FIO <sub>2</sub> ) | 12% through 103% O <sub>2</sub>                               | ± 3  |
| I:E Ratio, Calculated (IEcalc)                  | 1:99 through 4.0:1  | ±1 significant digit   |
| I:E Ratio, Measured                             | 1:99 through 45:1   | Greater of ±50 ms or ±5%                                       |
| Inspiratory Tidal Volume (Vti)                  | 0 through 4000 ml   | Greater of ±15% or ±15   |
| Mean Airway Pressure (MAP)                      | 0 through 99 cmH <sub>2</sub> O                               | Greater of ±5% or ±2   |
| Peak Inspiratory Flow                           | 3 through 190 lpm measured at the patient Wye                 | See Wye Flow monitor   |
| Peak Inspiratory Flow, Calculated               | 10 through 120 lpm  | Greater of ±10% or ±2  |
| Peak Inspiratory Pressure (PIP)                 | 0 through 120 cmH <sub>2</sub> O or hPa                       | Greater of ±5% or ±2   |
| Positive End-Expiratory Pressure (PEEP)         | 0 through 99 cmH₂O or hPa                                     | Greater of ±10% or ±2  |
| Pulse Oximetry Signal Strength                  | Green / Amber / Red   | N/A  |
| Pulse Rate                                      | 18 through 300 beats/min                                      | ± 3 (no motion)  |
| SBT f/Vt  | 0 through 999 bpm/L   | See Total Breath Rate and<br>Exhaled Minute Volume<br>monitors |
| SBT Time Remaining                              | 00:00 (mm:ss) through 01:59:59 (hh:mm:ss)                     | ± 1 minute   |
| SpO <sub>2</sub>                                | 0 through 100 %   | ± 2 (no motion)  |
| Spontaneous Breath Rate (Sp f)                  | 0 through 120 bpm   | Greater of ±5% or ±1 bpm                                       |
| Spontaneous Tidal Volume (SpVte)                | 0 through 4000 ml   | Greater of ±15% or ±15   |
| Total Breath Rate (f)                           | 0 through 120 bpm   | Greater of ±5% or ±1 bpm                                       |

### **Device Monitors**

| Monitor                                 | Range                      | Accuracy  |
|---|----------------------------|---|
| Measured Leak                           | 0.0 through 30.0 lpm       | ±1.5 if flow is < 10,<br>±15% or ±3 if flow is ≥ 10 |
| O <sub>2</sub> Source Pressure          | 0.0 through 99.9 PSI       | ± 2 PSI   |
| Peak Expiratory Flow                    | 0 through 190 lpm          | ±1.5 if flow is < 10,<br>±15% or ±3 if flow is ≥ 10 |
| Removable Battery<br>Capacity Remaining | 0% through 120%            | ±20%  |
| Vent Usage Meter, Non re-settable       | 0.0 through 500000.0 hours | ±5%   |
| Vent Usage Meter, re-<br>settable       | 0.0 through 500000.0 hours | ±5%   |

# **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 55 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<sup>47</sup>

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 Revel<sup>™</sup> ventilator will function as intended for at least 20 minutes when it is returned to room temperature (20 +/- 2°C) for 10 minutes. (Ref: EN 13748-1)

## **Operating**

Temperature 5 °C to 40 °C

Humidity 5% to 95% Relative, non-condensing

#### Altitude

Storage 50,000 ft Max

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 its carrying case
- IEC 68-2-36 Vibration; Test Fdb, 0.01 g<sup>2</sup>/Hz (10-200 Hz), 0.003 g<sup>2</sup>/Hz (200-500 Hz), 1.7 g<sub>rms</sub>, 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 minutes/Axis

<sup>&</sup>lt;sup>47</sup> PTV<sup>®</sup> 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"

### Inlet Air Filtration

The ventilator air filter is removable and cleanable by the operator.

## **Interfaces**

| Interface                           | Specification  |
|-------------------------------------|--|
| Air Intake Port                     | Accommodates user replaceable filter   |
| Dock Interface                      | Proprietary power / communications interface.  |
| Exhalation Valve Drive Port         | 1/8" ID hose barbed fitting accommodates the Exhalation Valve Drive line.  |
| FIO <sub>2</sub> Sensor connection  | Compatible with cabling to Teledyne R-17 MED O <sub>2</sub> sensor.  |
| Flow Sensor<br>Interface            | Proprietary. Consists of two pneumatic Luer connections: Flow Sense High (female) and Low (male).  |
| Nebulizer Port                      | 0.230" OD, straight barb fitting.  |
| O <sub>2</sub> Blender Inlet        | O <sub>2</sub> 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 lpm |
| Patient Circuit<br>Inspiratory Limb | 22mm OD, 15mm ID, male conical connector per ISO 5356-1.   |
| SpO <sub>2</sub> Module connection  | Proprietary power / communications interface.  |

# **Equipment Classification**

Classification Internally Powered Equipment per IEC 60601-1

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.                |                              |  |
|                  | Test Settings:   |                              |  |
|                  | Mode A/C   | Sensitivity (lpm)P           |  |
|                  | Breath Type Volume   | Pressure Trigger10           |  |
|                  | PEEP(cmH <sub>2</sub> O) 5   | Ambient Temp (°C)25          |  |
|                  | Breath Rate (bpm) 15   | Bias Flow (lpm)5             |  |
|                  | O2 (%)       21       Leak Comp L. Comp Off         Tidal Volume (ml)       500       Alarm Vol (dBA)  |                              |  |
|                  |  |                              |  |
|                  | Lung Compliance (ml/cmH <sub>2</sub> O ) 30  | Display Dimming (min)5       |  |
|                  | Insp. Time (sec)   |                              |  |
|                  |  |                              |  |
| Safety Standards | UL Listing per UL 60950-1 (UL 2054)  | ; UN Transportation Testing. |  |

## **Transition Battery**

| Feature/Spec                      | 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<br>Battery<br>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 lpm or pressure greater than 65 cm $H_2O$ , 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<sup>®</sup> Series Ventilator is designed to meet the following reliability requirements:

Product Life: 10 years

# **National and International Standards**

The Revel<sup>™</sup> ventilator is designed to comply with the following standards:

| Number                         | Title   |  |
|--------------------------------|---|--|
| ASTM F1100-90                  | Ventilators Intended for User in Critical Care  |  |
| ASTM F1246-91                  | Electrically Powered Home Care Ventilators  |  |
| 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-<br>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 Part 1: Visual alarm signals  |  |
| ISO 9703-2:1994(E)             | Anesthesia and respiratory care alarm signals Part 2: 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                      |  |
| prEN 13718-1                   | Air, Water, and difficult terrain ambulances – Medical device interference requirements for the continuity of patient care.                           |  |
| RTCA/DO-160F                   | Environmental conditions and test procedures for airborne equipment. Category U2 – Random Test Curves for Helicopters Fuselage per Figure 8-7 Curve F |  |

 $<sup>^{48}</sup>$  Testing performed while the ventilator was operating on Removable Battery Pack power, and with SpO<sub>2</sub> and FIO<sub>2</sub> 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  |
|--------------------|--|
| Battery Charger    | Off / Flashing Amber / Amber / Green LED     |
| Battery Pack       | Off / Red / Flashing Red / Amber / Green LED |
| Control Lock       | Off / Green LED                              |
| External Power     | Red / Amber / Green/ Flashing Red LED        |
| Maneuvers          | Off / Flashing green / Green LED             |
| Manual Breath      | Off / Green LED                              |
| On, Off            | Off / Green LED                              |
| Silence/Reset      | Off / Red LED                                |
| Transition Battery | Off / Red / Flashing Red / Amber / Green LED |
| Vent Inop.         | Off / Red/Flashing red LED.                  |

### Front Panel

The front panel interface consists of the following major components:

- Airway Pressure Bar Graph display
- Alpha Numeric, dot matrix LED display, information bar
- Controls Area consisting of 7-segment numeric displays, indicators, and associated push buttons
- Alarms Area consisting of 7-segment numeric displays and associated push buttons
- Oximeter Area consisting of 7-segment numeric displays, and a Signal Strength Bar Graph

Primary control selection for the front panel is accomplished using momentary contact push buttons. Seven segment LED Displays display numeric information. These displays are associated with a push button:

## Alpha Numeric Display

A single row of 12, 5x7 dot matrix LED, displays both text and numeric information.

## **Function LEDs**

Individual LEDs indicate activation of specific features. An associated push button activates and de-activates the function.

# Appendix C - REFERENCE INFORMATION

# **Factory Settings**

## **Controls**

| Control                         | Factory-Set Values     |
|---------------------------------|------------------------|
| Alarm Volume                    | 6 (80 dB A)            |
| Apnea Interval                  | 20 seconds             |
| Battery Use Tone                | 3                      |
| Bias Flow                       | 5 lpm                  |
| Breath Mode                     | Assist/Control         |
| Breath Rate                     | 12 bpm                 |
| Breath Type                     | Pressure               |
| Control Unlock                  | Off                    |
| Date Format                     | MM/DD/YYYY             |
| Default Units                   | cmH <sub>2</sub> O/PSI |
| Dim After time                  | Never                  |
| Flow Termination                | 25%                    |
| High Pressure Alarm Delay       | Delay 0 Brth           |
| Inspiratory Time                | 1 second               |
| Language                        | English                |
| Leak Compensation               | L. Comp On             |
| Local Date                      | GMT <sup>49</sup>      |
| Local Time                      | GMT <sup>49</sup>      |
| LPP Alarm                       | All Breaths            |
| MV/BR Delay                     | No Delay               |
| Nebulizer Duration              | 15 min                 |
| Nebulizer Synchronization       | Continuous             |
| NPPV                            | OFF                    |
| O <sub>2</sub> Flush Duration   | 3 Minutes              |
| O <sub>2</sub> Flush Percentage | 100%                   |
| O <sub>2</sub> %                | 21%                    |
| PC Flow Termination             | Off                    |
| Patient                         | N/A                    |
| Patient Size                    | N/A                    |
| PEEP                            | 0 cmH <sub>2</sub> O   |
| PEEP alarm delay                | No Delay               |
| Pressure Control                | 10 cmH <sub>2</sub> O  |
| Pressure Support                | 10 cmH <sub>2</sub> O  |

<sup>49</sup> Greenwich Mean Time

| Control                     | Factory-Set Values    |
|-----------------------------|-----------------------|
| Pulse Tone Volume           | 1                     |
| Rise Time                   | 4                     |
| Safety Valve Delta Pressure | 10 cmH <sub>2</sub> O |
| SBT Time                    | 20:00 (mm:ss)         |
| SBT O <sub>2</sub>          | 21%                   |
| SBT PEEP                    | 0 cmH <sub>2</sub> O  |
| SBT Pressure Support        | 10 cmH <sub>2</sub> O |
| Sensitivity                 | 2 lpm                 |
| SpO <sub>2</sub> Averaging  | 8-beat                |
| Tidal Volume                | 500 ml                |
| Time Termination            | 3 seconds             |

# Adjustable Alarm Limits

The factory-set values for the Revel<sup>™</sup> ventilator adjustable alarm limits are:

| Alarm                     | Factory Setting                |
|---------------------------|--------------------------------|
| High Airway Pressure      | 20 cmH <sub>2</sub> O          |
| High Breath Rate          | " " (Off)                      |
| High PEEP                 | 5                              |
| High Pulse Rate           | "" (Off)                       |
| High SpO <sub>2</sub>     | 99                             |
| Low FIO <sub>2</sub>      | 18% (when sensor is connected) |
| Low Exhaled Minute Volume | 2.5 L                          |
| Low Peak Pressure         | 5 cmH₂O                        |
| Low PEEP                  | "" (Off)                       |
| Low Pulse Rate            | "" (Off)                       |
| Low SpO <sub>2</sub>      | 85                             |
| Low Tidal Volume          | 10 ml                          |
| SBT Hi f                  | 35                             |
| SBT Low f                 | 10                             |
| SBT Hi f/Vt               | 105                            |
| SBT Low f/Vt              | 70                             |

# **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<sup>®</sup> 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<sup>®</sup> Series Ventilators.

#### NOTE

The Revel<sup>™</sup> 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
- Single Use Patient Circuit
- 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
- Table Top Mount
- Wall Mount

#### **Sensor Accessories**

- FIO<sub>2</sub> Sensor Cable
- SpO<sub>2</sub> Module
- SpO<sub>2</sub> Module with Sensor

#### **Monitor Accessories**

PTM<sup>™</sup> Graphics Monitor

## **EMC** and RF Environments

The following tables are from 60601-1-2 © IEC:2001(E)

#### Table 201

#### Guidance and manufacturer's declaration – electromagnetic emissions

The Revel 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<br>CISPR 11                                    | Group 1    | The Revel <sup>™</sup> 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<br>CISPR 11                                    | Class B    | The Revel <sup>™</sup> ventilator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-  |
| Harmonic emissions<br>IEC 61000-3-2                         | Class A    | voltage power supply network that supplies buildings used for domestic purposes.  |
| Voltage fluctuations/ flicker<br>emissions<br>IEC 61000-3-3 | Complies   |   |

#### Table 202

#### Guidance and manufacturer's declaration - electromagnetic immunity

The Revel<sup>TM</sup> 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.

| Volumeter official account that it is account out of the first of the first out of the firs |   |   |  |
|--|---|---|--|
| Immunity Test  | IEC 60601 test level  | Compliance Level  | Electromagnetic environment – guidance   |
| Electrostatic<br>discharge (ESD)<br>IEC 61000-4-2  | ± 6 kV contact<br>± 8 kV air  | ± 6 kV contact<br>± 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<br>transient/burst<br>IEC 61000-4-4  | ± 2 kV for power supply lines<br>± 1 kV for input/output lines  | ± 2 kV for power supply lines<br>± 1 kV for input/output lines  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5   | ± 1 kV differential mode<br>± 2 kV common mode  | ± 1 kV differential mode<br>± 2 kV common mode  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage dips, short<br>interruptions and<br>voltage variations<br>on power supply<br>input lines<br>IEC 61000-4-11   | $ \begin{array}{c} <5 \% \ U_{\rm T} \\ (>95 \% \ {\rm dip \ in} \ U_{\rm T}) \ {\rm for} \ 0.5 \ {\rm cycle} \\ 40 \% \ U_{\rm T} \\ (60 \% \ {\rm dip \ in} \ U_{\rm T}) \ {\rm for} \ 5 \ {\rm cycles} \\ 70 \% \ U_{\rm T} \\ (30 \% \ {\rm dip \ in} \ U_{\rm T}) \ {\rm for} \ 25 \ {\rm cycles} \\ <5 \% \ U_{\rm T} \\ (>95 \% \ {\rm dip \ in} \ U_{\rm T}) \ {\rm for} \ 5 \ {\rm sec} \\ \end{array} $ | $<5\%\ U_{\rm T}$<br>$(>95\%\ {\rm dip\ in}\ U_{\rm T})$ for 0,5 cycle<br>$40\%\ U_{\rm T}$<br>$(60\%\ {\rm dip\ in}\ U_{\rm T})$ for 5 cycles<br>$70\%\ U_{\rm T}$<br>$(30\%\ {\rm dip\ in}\ U_{\rm T})$ for 25 cycles<br>$<5\%\ U_{\rm T}$<br>$(>95\%\ {\rm dip\ in}\ U_{\rm T})$ for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Revel 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<br>(50/60 Hz)<br>Magnetic field<br>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 Revel<sup>™</sup> 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   |
|-------------------------------|--|------------------|--|
|                               |  |                  | Portable and mobile RF communications equipment should be used no closer to any part of the Revel <sup>™</sup> ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
|                               |  |                  | Recommended separation distance  |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz <sup>50</sup><br>outside ISM bands | 3V               | $d = 1.2\sqrt{P}$  |
|                               | 10 Vrms<br>150 kHz to 80 MHz in<br>ISM bands <sup>51</sup>     | 10V              | $d = 1.2\sqrt{P}$  |
| Radiated RF<br>IEC 61000-4-3  | 10 V/m<br>80 MHz to 2.5 GHz                                    | 10 V/m           | $d = 0.60 \sqrt{P}_{80~\mathrm{MHz}~\mathrm{to}~800~\mathrm{MHz}}$ $d = 1.2 \sqrt{P}_{800~\mathrm{MHz}~\mathrm{to}~2.5~\mathrm{GHz}}$  |
|                               |  |                  | $a = 1.2\sqrt{P}$ 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)51.   |
|                               |  |                  | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>52</sup> , should be less than the compliance level in each frequency range. <sup>53</sup>  |
|                               |  |                  | 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.

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<sup>&</sup>lt;sup>50</sup> 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.

<sup>&</sup>lt;sup>51</sup> 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.

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.

 $<sup>^{53}</sup>$  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)

The Revel<sup>™</sup> ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Revel<sup>™</sup> ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Revel<sup>™</sup> ventilator as recommended below, based on the maximum output power of the communications equipment.

|   | Separation distance according to frequency of transmitter (m) |                                   |                    |                    |
|---|---|-----------------------------------|--------------------|--------------------|
| Rated maximum output power of transmitter (W) | 150 kHz to 80 MHz<br>outside ISM bands                        | 150 kHz to 80 MHz in<br>ISM bands | 30 MHz to 800 MHz  | 800 MHz to 2,5 GHz |
|   | $d = 1.2\sqrt{P}$   | $d = 1.2\sqrt{P}$                 | $d = 0.60\sqrt{P}$ | $d = 1.2\sqrt{P}$  |
| 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<br>Display  | A bar graph type display composed of 60 LEDs. This display shows the real-time breath by breath Airway Pressure.  |
| 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 flashing displays, illuminated LEDs, and text messages shown in the front panel display window. |
| Apnea                       | Apnea happens when the time between breath starts exceeds the set Apnea Interval.   |
| Apnea Backup<br>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                    | The 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 the lungs, gastrointestinal tract, and ear.   |
| BdP                         | Blower differential pressure.   |
| Beats/min                   | Pulse Rate per minute (pulse measured by the Pulse Oximetry Module).  |
| 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 (f)  | The quantity of breaths given per minute; includes all breath types.  |

| Term                          | Definition  |
|-------------------------------|---|
| Breath Rate, set              | The minimum quantity of machine breaths given in a minute.  |
| BTPD                          | Body Temperature, Pressure Dry.   |
| BTPS                          | Body Temperature Pressure Saturated <sup>54</sup> . A BTPS measurement is achieved when the compressible fluid is at 98.6°F (37°C), ambient barometric pressure, and saturated with water vapor.                                      |
| C Static                      | Static Lung Compliance.   |
| Circuit                       | See Patient Circuit.  |
| Circuit Pressure              | See Airway Pressure.  |
| cmH <sub>2</sub> O            | Centimeters of water. A unit of measure for pressure.   |
| СРАР                          | 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. |
| CPAP+PS Mode                  | A ventilation mode where the patient triggers all breaths. Available breath types are Pressure Support and Spontaneous.   |
| 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.  |
| Display Window (LED)          | A set of 12 dot-matrix displays used to show monitored data, alarm messages, Startup and Extended Features menu items.  |
| E-Hold                        | Expiratory Hold   |
| EPAP                          | Expiratory Positive Airway Pressure   |
| Event                         | Any condition noted in the ventilator's Event Trace Log. This may include both error conditions and normal operational events.  |
| Exhaled Minute Volume, (VE)   | The total volume exhaled by the patient for the last 60 seconds. VE is based on the last 8 breaths.   |
| Exhaled Tidal Volume<br>(Vte) | The exhaled tidal 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.   |
| Extended Features             | A set of ventilator controls and options that is set/configured via menus that are displayed and accessed through the front panel display window.   |
| f                             | See Breath Rate, monitored.   |
| f/Vt                          | Rapid Shallow Breathing Index – Derived during a SBT maneuver by dividing the breath rate by the average monitored tidal volume.  |
| FIO <sub>2</sub>              | Fraction of Inspired Oxygen.  |
| Flow (V)                      | The velocity of gas delivery to the patient, quantified in lpm.   |

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<sup>&</sup>lt;sup>54</sup> All references to compressible flow and compressible volume in the patient pneumatic pathway are BTPS unless stated otherwise.

| Term                               | Definition   |
|------------------------------------|--|
| Flow Trigger                       | A patient effort in which the amount of bias flow routed into the patient's lungs exceeds the flow trigger <b>Sensitivity</b> setting. A flow trigger will result in delivery of an Assist or Patient breath, according to the ventilation mode. |
| I Time                             | Inspiratory Time, measured   |
| 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.  |
| l:Ecalc                            | Calculated Inspiratory: Expiratory ratio, based on Inspiratory Time, Inspiratory Pause and Breath Rate settings.   |
| I-Hold                             | Inspiratory Hold   |
| 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.  |
| IPAP                               | Inspiratory Positive Airway Pressure   |
| L                                  | Liters   |
| 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.   |
| Leak Compensation                  | Leak Compensation is a feature that compensates triggering and monitor values for leaks after the patient Wye.   |
| LED                                | Light Emitting Diode   |
| lpm                                | Liters Per Minute. Measurement of flow rate.   |
| 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 <b>Manual Breath</b> button.   |
| MAP                                | Mean Airway Pressure   |
| Mean Airway Pressure,<br>monitored | The average airway pressure over a series of breaths.  |
| Minimum Exhalation<br>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<br>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 ventilator is powered off.  |
| O <sub>2</sub>                     | Oxygen   |
| O <sub>2</sub> Inlet               | O <sub>2</sub> 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.  |

| Term   | Definition   |
|--|--|
| Patient Effort   | Inspiratory effort by the patient.   |
| Paw  | Airway Pressure, measured at the patient Wye.  |
| Peak Inspiratory<br>Pressure, monitored<br>( PIP )         | The maximum circuit pressure occurring during the inspiration and first 346 ms exhalation phase of a breath. PIP 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.   |
| PIP  | Peak Inspiratory Pressure, measured at the patient Wye.  |
| Positive End Expiratory<br>Pressure, monitored<br>( 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.  |
| 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 ( <b>Pres Trigger</b> ) setting.  |
| Δ Pres   | Delta Airway Pressure  |
| PRVC   | Pressure Regulated Volume Control  |
| PS   | Pressure Support Ventilation   |
| PSI/PSIG   | Pounds per Square Inch Gauge. A unit for measuring pressure.   |
| SBT  | Spontaneous Breathing Trial  |
| Scrolling, Monitored<br>Data Display                       | Allows the user to display the monitored values statically or automatically scroll them. While scrolling is active, each monitored value will be displayed for 3 seconds then the next value will be automatically displayed.  |
| 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.   |
| Sp f   | Spontaneous Breath Rate  |

| Term                  | Definition   |
|-----------------------|--|
| SpO <sub>2</sub>      | Functional oxygen saturation of arterial hemoglobin, measured non-invasively by Pulse Oximetry.  |
| Spontaneous Breath    | A breath which the patient triggers and cycles.  |
| SpVte                 | Spontaneous Exhaled Tidal Volume   |
| Startup Menus         | A set of menus accessed while the ventilator is in Startup mode and used to initiate Same or New Patient ventilation, enter/revise Patient ID, set basic ventilator configurations, perform specific functional testing and access ventilator component revision and software version information. |
| Tidal Volume, set     | The volume of air delivered to the patient circuit for each volume or PRVC breath.   |
| Time Term             | The Time Term menu is used to set the maximum inspiratory time for terminating Pressure Support, Pressure Regulated Volume Support (PRVS) and Spontaneous breaths.   |
| Total Breath Rate     | See Breath Rate, monitored.  |
| Transducer            | A measuring device. Transducers can be used to quantify flow or pressure.  |
| UART                  | Universal Asynchronous Receiver/Transmitter  |
| V/BR                  | Volume Breath Delay  |
| VE                    | 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.   |
| Vte                   | Exhaled Tidal Volume, monitored  |
| Vti                   | Inspiratory Tidal Volume   |
| Ů                     | Flow   |
| Vcalc                 | The calculated peak flow for Volume Control breaths. Vcalc is calculated based on the set Tidal Volume and the Set Inspiratory Time.   |
| Vepk                  | Peak Expiratory Flow   |
| <b>V</b> peak         | Peak Inspiratory Flow  |

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