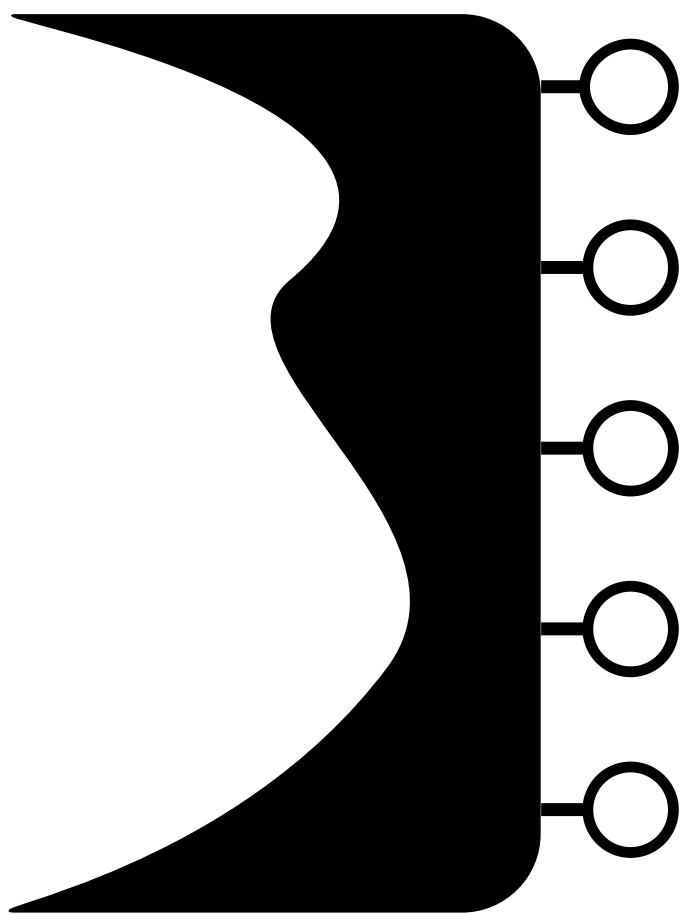


BiPAP[®] Vision

Ventilatory Support System



Clinical Manual

BiPAP[®] Vision[™]

Ventilatory Support System



*Clinical
Manual*



RESPIRONICS[®]

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Chapter 1: Introduction

1.1 Vision Overview

The BiPAP® Vision ventilator, shown in Figure 1-1, is a microprocessor-controlled positive pressure ventilatory assist system. The Vision system incorporates a user interface with multifunction keys, real time graphic displays, and integral patient and system alarms. Figure 1-1 shows the contents of the Vision package.

The system operates in the Continuous Positive Airway Pressure (CPAP) and Pressure Support (S/T) modes.

The Vision ventilator contains a variety of integrated safety and self-diagnostic features. All system functions are checked at start-up and during operation.

Pressure regulation is achieved by monitoring proximal airway pressure and adjusting flows accordingly to ensure that the set pressure equals the proximal pressure.

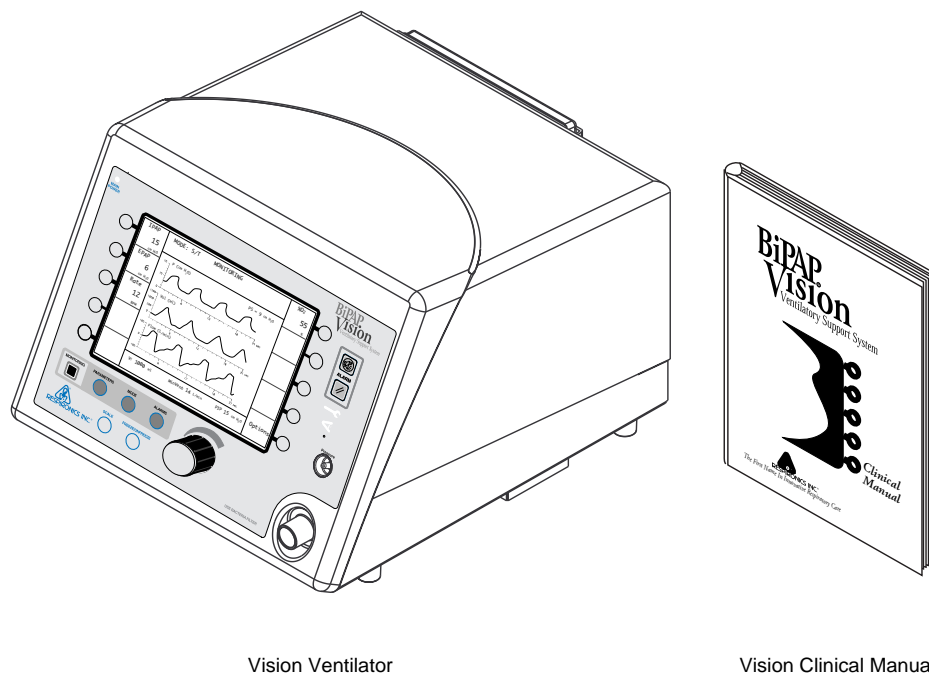


Figure 1-1. Contents of the Vision Package.

NOTE: This manual is for use only in the United States and its territories.

1.2 Manual Overview









This manual describes the Vision ventilator and its operation.

Chapter 1	Introduces the Vision unit.
Chapter 2	Lists the Warnings, Cautions, Notes and Contraindications for the Vision ventilator. Also contains information concerning rebreathing.
Chapter 3	Describes the theory of operation.
Chapter 4	Provides an overview of the output, controls, and graphic display.
Chapter 5	Provides operational flow charts as an introduction and quick reference.
Chapter 6	Provides the set up and start-up procedures for the Vision ventilator.
Chapter 7	Provides the performance verification procedure.
Chapter 8	Details the operation of the CPAP Mode.
Chapter 9	Details the operation of the S/T Mode.
Chapter 10	Details the Options Screen.
Chapter 11	Describes the graphic displays, including modification of display scales.
Chapter 12	Describes the alarms and alarm conditions and provides troubleshooting guidelines for mask discomfort.
Chapter 13	Provides information for adding oxygen to the Vision patient circuit.
Chapter 14	Provides cleaning instructions and routine maintenance procedures.
Chapter 15	Describes the accessories and circuits to be used with the Vision ventilator.
Chapter 16	Lists the Vision ventilator specifications.

NOTE: Occasionally, cosmetic changes may be made to the product that do not affect the performance or specifications of the product. These kinds of changes do not warrant a reprinting of this manual. Illustrations are for reference only.

1.3 Symbol Key

The following symbols are used on the Vision unit:

Symbol	Meaning
 Vent Inop	Ventilator Inoperative
 Check Vent	Check Ventilator
	Audible Alarm Silence
	Alarm Reset
MONITORING	Display the Monitoring Screen
PARAMETERS	Display the Parameters Screen
ALARMS	Display the Change Alarms Screen
SCALE	Adjust the graphic scales
FREEZE/UNFREEZE	Freeze or Unfreeze the graphic display
PRESSURE	Attachment port for proximal pressure line
MAIN POWER	Indicates unit is connected to power source
	Adjustment
	Type BF
	Fuse
	Attention, consult accompanying documents

1.4 Product Support

You may contact Respironics, Inc. with any questions or for product support at the following location:



Chapter 2: Warnings, Cautions, and Notes

WARNING: Indicates the possibility of injury to the patient or the operator.

CAUTION: Indicates the possibility of damage to the device.

NOTE: Places emphasis on an operating characteristic.

2.1 Warnings

- This manual serves as a reference. The instructions in this manual are not intended to supersede the institution's protocol regarding the use of the Vision ventilator.
- The operator must verify that all gas connectors have color codes in accordance with EN 60601-1/A13:1995.
- The following BiPAP Vision System operational characteristics differ from conventional ventilators as described in ASTM F 1100 and should be reviewed before use:
 - The BiPAP Vision provides continuous positive airway pressure (CPAP) and positive pressure ventilation and is indicated for assisted ventilation. This system does not provide ventilation with guaranteed tidal volume delivery. Patients requiring ventilation at predetermined tidal volumes are not candidates for pressure support or pressure-limited ventilation.
 - The BiPAP Vision requires an intentional leak port instead of an actively controlled exhalation valve to remove exhaled gases from the circuit. Therefore, specific masks and circuits using an intentional leak port are required for normal operation. The pressurized air from the Vision causes a continuous flow of air to exhaust from the leak port, flushing exhaled gas from the circuit. The machine should be turned on and the intentional leak port should be checked, both visually and using the exhalation port test, before application. Use only Respironics-specified circuit accessories.
 - The continuous flow of air through the leak port flushes exhaled gases from the circuit. The ability to completely exhaust exhaled gas from the circuit is dependent upon the EPAP setting and I:E ratio. At low EPAP pressures or with short expiratory times (i.e., high breathing rates) the leak rate through the intentional leak port may be inadequate to clear all exhaled gas from the circuit. Some rebreathing may occur.
- The Vision ventilator is an assist ventilator and is intended to augment the ventilation of a spontaneously breathing patient. It is not intended to provide the total ventilatory requirements of the patient.
- The Vision ventilator is intended for use with a Respironics, Inc. patient circuit only. See Chapter 15 for approved patient circuit configurations and accessories.

Warnings (continued)

- Proper operation of the Plateau™ Exhalation Valve or any other exhalation port used with the BiPAP Vision must be regularly verified by inspection during use. Occlusion or partial occlusion of the exhalation port may result in asphyxia.
- To reduce the risk of contamination, a low resistance main flow bacteria filter must be placed in-line between the unit and the patient.
- All patient settings must be determined via appropriate assessment and monitoring as determined by the prescribing physician. Delivered pressures must be monitored at the patient connection with the unit cycling to validate pressure delivery.
- The Vision ventilator is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- The functionality of this machine may be adversely affected by the operation of high frequency (diathermy) equipment, defibrillators, or short wave therapy equipment in the general vicinity.
- When the Oxygen Module is in use, the Vision ventilator will display the **set** oxygen concentration, which may not be the actual oxygen concentration delivered to the patient. An external oxygen analyzer, added to the patient circuit, is recommended to monitor delivered oxygen concentrations. See Chapter 13 for details concerning the use of oxygen with the Vision ventilator.
- When using the Oxygen Module, the operator must verify that the correct supply gas (O₂) is connected to the O₂ inlet.
- Do not use antistatic or electrically conductive hoses or tubing with the Vision system.
- In the event of a power failure, an audible and visual alarm will activate. Disconnect the Vision ventilator from the patient immediately. As in most ventilators with passive exhalation ports, when power is lost, sufficient air will not be provided through the circuit and exhaled air may be rebreathed.
- The air flow for breathing produced by this device can be as much as 10 °F (5.5 °C) higher than room temperature. Caution should be exercised if the room temperature is greater than 95 °F (35 °C).
- If the “Ventilator Inoperative” indicator illuminates, immediately discontinue use, disconnect the patient circuit from the patient, and contact Respironics, Inc. or an authorized service center.
- When the Vision ventilator is used with a humidifier, always position the humidifier lower than both the ventilator and the patient.
- Never attach oxygen tubing or any positive pressure source to the Pressure Port on the front panel of the Vision ventilator.

Warnings (continued)

- If you detect any unexplained changes in the performance or displays of the Vision unit, seek the assistance of a Respironics-approved service person.
- Repairs and adjustments must be performed by Respironics-authorized service personnel ONLY. Service done by inexperienced, unqualified personnel or installation of unauthorized parts could cause injury, invalidate the warranty, or result in costly damage.
- To avoid electrical shock, disconnect the electrical supply before changing the fuses.
- For continued protection against risk of fire, replace fuses with those of the same type and rating only.
- Electrical cords and cables should be periodically inspected.
- To avoid electrical shock, unplug the Vision unit before cleaning it.
- The Nurse Call/Remote Alarm feature should be considered a backup to the Vision unit's primary alarm system. Do not rely solely on the Nurse Call/Remote Alarm feature.

2.2 Cautions

- Federal law (U.S.) restricts this device to sale by or on the order of a physician.
- For pressure monitoring, use only the pressure tubing provided with the Respirationics circuit.
- Take care to avoid exposure of the Vision ventilator to temperatures at or near the extremes of those specified in Chapter 16. If exposure to such temperatures has occurred, the unit should be allowed to come to room temperature before being turned on.
- The unit must be positioned on its base for proper operation.
- Always use an inlet filter when the Vision ventilator is operating.
- If using the Oxygen Module, do not exceed 100 psig oxygen supply pressure.
- Connections to the rear-panel diagnostic connector must be made by authorized service personnel only.
- Before making any connection to the rear-panel nurse call connector, verify that the equipment being connected does not violate the electrical specifications noted in Chapter 16.

2.3 Notes

- The Inspiratory Positive Airway Pressure (IPAP) and Expiratory Positive Airway Pressure (EPAP) controls are coupled. The unit will not deliver an EPAP level that is higher than the set IPAP level.
- This device contains a rechargeable NiCAD battery which is used by the alarms in the event of a power failure.

Additional Warnings, Cautions, and Notes are located throughout this manual.

2.4 Important Information Concerning CO₂ Rebreathing

As with any ventilator used for mask ventilation, there are conditions under which patient CO₂ rebreathing can occur while using the Respironics BiPAP Vision ventilator. The following guidelines are provided to alert the user to these conditions and to suggest methods for reducing the potential for CO₂ rebreathing. If rebreathing is a significant concern for a particular patient and these guidelines are not sufficient to acceptably reduce the potential for CO₂ rebreathing, an alternative means of ventilation should be considered.

- Never leave the mask on the patient while the BiPAP Vision unit is not operating. When the BiPAP Vision unit is not operating, the exhalation port (Respironics Disposable Circuit, Whisper Swivel, or Plateau Exhalation Valve) does not allow sufficient exhaust to eliminate CO₂ from the circuit. Substantial CO₂ rebreathing will occur.
- Patient monitoring should be performed initially and with each change in ventilator settings, circuit configuration, or patient condition to detect changes in respiratory status that may indicate excessive CO₂ rebreathing.
- In general, as pressure decreases, the potential for CO₂ rebreathing increases. Lower pressures produce less flow through the exhalation port, which may not purge all CO₂ from the circuit to prevent rebreathing. Higher tidal volumes further increase the volume of CO₂ rebreathed by the patient in such circumstances. Testing performed with the BiPAP Vision demonstrates that, under certain conditions, CO₂ rebreathing can occur. See Chart 1 in Chapter 16.
- In general, as inspiratory time increases, the potential for CO₂ rebreathing increases. A higher inspiratory time decreases exhalation time, allowing less CO₂ to be purged from the circuit before the next cycle. In such circumstances, higher tidal volumes further increase the volume of CO₂ rebreathed by the patient. Testing performed with the BiPAP Vision system demonstrates that under certain conditions, when approaching an I:E ratio of 1:1, CO₂ rebreathing may occur. See Chart 2 in Chapter 16.
- The Plateau Exhalation Valve reduces the level of CO₂ rebreathing compared to the level associated with the Whisper Swivel when low pressures, long inspiratory time, and/or large tidal volumes are present. Accordingly, Respironics recommends the Plateau Exhalation Valve be used instead of the Whisper Swivel to help reduce CO₂ rebreathing in such situations. See Charts 1 and 2 in Chapter 16.
- Reducing deadspace can also lower potential CO₂ rebreathing. Chart 3 in Chapter 16 provides the approximate total volume of each of the patient interface accessories that can be used with the BiPAP Vision ventilator. Note that except for the Respironics Mouthpiece Adapter, the deadspace volume will be reduced when the mask is placed on the patient's face. Nevertheless, Chart 3 in Chapter 16 can be helpful in selecting an appropriate patient interface to reduce the amount of deadspace in the patient circuit. For comparison purposes, note that the testing which produced the data in Charts 1 and 2 was conducted using a medium nasal mask.

2.5 Intended Use

The Vision ventilator is intended for use in a hospital or alternate care setting as an assist ventilator for the treatment of appropriate adult patients (30 Kg or greater) with acute respiratory failure, acute or chronic respiratory insufficiency, or sleep apnea syndrome.

2.6 Contraindications

The use of the Vision ventilator is contraindicated on patients with severe respiratory failure without a spontaneous respiratory drive.

The use of the Vision ventilator for noninvasive positive pressure therapy may be contraindicated on patients:

- incapable of maintaining life-sustaining ventilation in the event of a brief circuit disconnection or loss of therapy,
- unable to maintain a patent airway or adequately clear secretions,
- at risk for aspiration of gastric contents,
- with acute sinusitis or otitis media,
- with a history of allergy or hypersensitivity to the mask materials where the risk from allergic reaction outweighs the benefit of ventilatory assistance,
- with epistaxis, causing pulmonary aspiration of blood, or
- with hypotension.

2.7 Patient Cautions

- Advise the patient to immediately report any unusual chest discomfort, shortness of breath, or severe headache.
- If skin irritation or breakdown develops from the use of the mask, refer to Chapter 12 for appropriate action.
- The following are potential side effects of noninvasive positive pressure therapy:

Ear discomfort
Conjunctivitis
Skin abrasions due to noninvasive interfaces
Aerophagia (gastric distention)

2.8 Invasive Applications

The Vision ventilator may be used to provide invasive ventilation to appropriate patients. The following guidelines should be considered prior to use:

- The Vision ventilator is an assist ventilator and is intended to augment the ventilation of a spontaneously breathing patient. It is not intended to provide the total ventilatory requirements of the patient.
- The Vision uses a single limb circuit and requires an intentional leak port instead of an actively controlled exhalation valve to remove exhaled gases from the circuit. Therefore, the Respironics invasive circuit and accessories illustrated in Chapter 15 are required for normal operation.
- A heated humidification system should always be used during invasive applications. See Chapter 15 for recommendations concerning humidification.
- In general, as pressure decreases, the potential for CO₂ rebreathing increases. Lower pressures produce less flow through the exhalation port, which may not purge all CO₂ from the circuit to prevent rebreathing. The Plateau™ Exhalation Valve reduces the level of CO₂ rebreathing compared to the level associated with the Whisper Swivel® when low pressures are present. Accordingly, if CO₂ rebreathing is a concern, use the Plateau Exhalation Valve instead of the Whisper Swivel at low EPAP levels.
- Occlusion of the exhalation port could lead to patient asphyxia. Always visually inspect the exhalation port and perform the Exhalation Port Test prior to patient use as described in this manual. The Exhalation Port Test will allow the BiPAP Vision to identify an occluded exhalation port prior to administering therapy. Also, the BiPAP Vision has an exhalation port alarm which is intended to identify a low flow condition (which could be caused by a partial or total occlusion of the exhalation port) during therapy. The exhalation port alarm is not a substitute for operator vigilance in ensuring that the exhalation port remains clear at all times. Periodically check the exhalation port during therapy.

Chapter 3: Principles of Operation

This chapter describes the BiPAP Vision ventilator design and methods of operation. System and patient safety functions are described as well.

3.1 Introduction

The BiPAP Vision ventilator is a microprocessor-controlled assist ventilator that operates in either a Continuous Positive Airway Pressure (CPAP) Mode or a Spontaneous/Timed (S/T) Mode.

The BiPAP Vision ventilator draws ambient air through an inlet filter, pressurizes it in the blower assembly, and then regulates it at the preset pressure level. An oxygen module can provide a controlled source of supplemental oxygen, up to 100%, to the patient. The ventilator continuously monitors machine pressure (set pressure) against proximal airway pressure (patient pressure) to ensure accurate and responsive delivery of pressure, despite most circuit leaks.

The unique design and operation of the ventilator makes it especially suited for mask applications. Designed with the BiPAP® Auto-Trak Sensitivity™ feature that automatically adjusts to changing circuit conditions, the ventilator is capable of ensuring optimum patient-ventilator synchrony despite changes in breathing patterns and circuit leaks.

The patient circuit consists of a smooth inner lumen 22 mm ID tube, a proximal pressure line, and an intentional leak port known as the exhalation port. The exhalation port continually exhausts gas from the circuit during inspiration and expiration.

The BiPAP Vision ventilator incorporates a number of safety features and self-diagnostic systems. All system internal functions are checked automatically at startup and periodically throughout normal operation. Malfunctions of a principal component or system are announced by audible and visual alarms. Integrated patient alarms are provided and are announced on a message display area, as well as with an audible tone.

A Liquid Crystal Display (LCD) video screen mounted on the front of the unit provides the primary user interface for operation of the ventilator. The display includes real time graphics for pressure, volume, and flow, control features, calculated patient parameters, and alarm conditions. User interaction with the device is accomplished by panel selections and rotation of the adjustment knob.

3.2 Design and Operation

3.2.1 ELECTRONICS SYSTEM

The modular system design employs subsystems, each of which provides a specific function. Modules are used to expand the capability of a subsystem. The major subsystems and modules are shown in Figure 3-1.

NOTE: Pressure generated by the PAS is compensated to atmospheric conditions (ATPS).

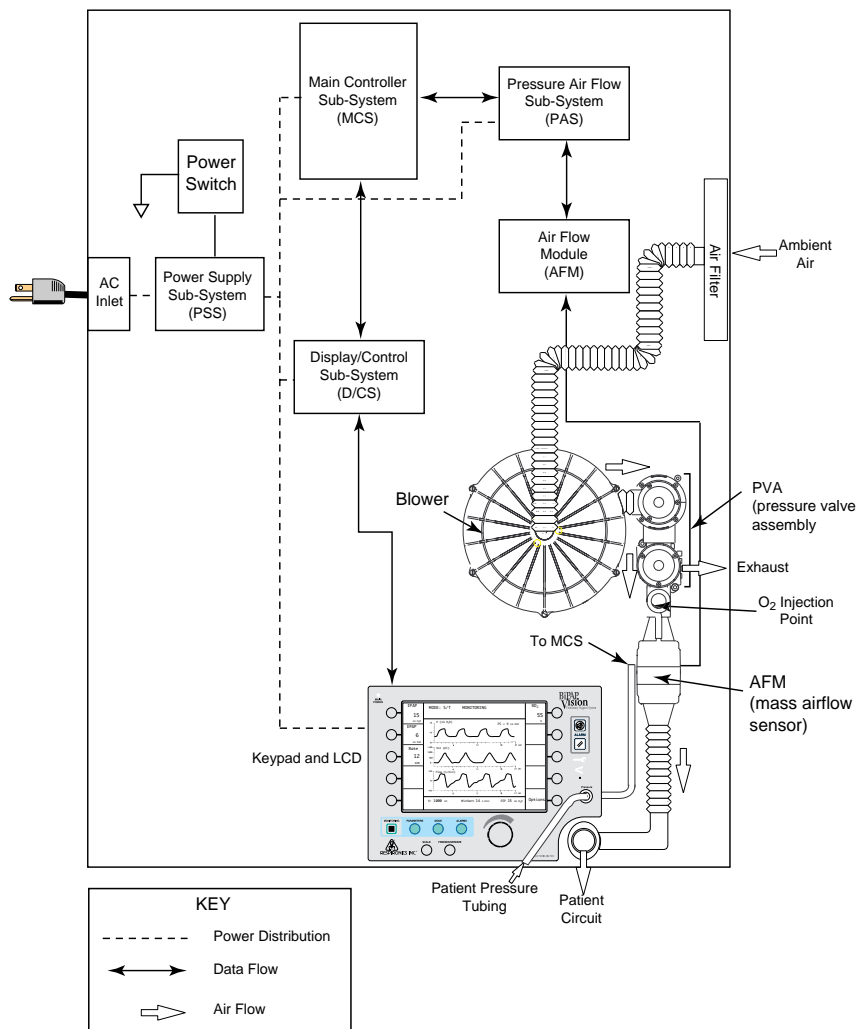


Figure 3-1. BiPAP Vision Electronics and Air Flow Systems.

PSS	The Power Supply Subsystem (PSS) provides DC power to the Vision unit from an AC source.
MCS	The Main Controller Subsystem (MCS) performs all control, data acquisition, and calculations required to deliver the user-selected parameters. In addition, the MCS performs the startup test and is responsible for reporting all errors. This subsystem may also be called the Main Control (MC) Board.
PAS	The Pressure Air Flow Subsystem (PAS) controls the blower and valves to regulate gas flow into the patient circuit to maintain the preset pressure at the patient connection. This subsystem may also be called the Pressure Control (PC) Board.
D/CS	The Display/Control Subsystem (D/CS) processes user input from the keyboard and passes information to the MCS. The D/CS receives relevant display data for the display screen from the MCS. This subsystem may also be called the Display Control (DC) board.
AFM	The Air Flow Module (AFM), including the mass airflow sensor, provides measurement of gas flow from the PAS, allowing the PAS to measure total flow in order to maintain the preset pressure.
PVA	The Pressure Valve Assembly (PVA) regulates system flow and pressure. The In Line Flow Restrictor Valve (ILFR) and the Pressure Regulation Valve (PRV) make up this assembly.

3.2.2 OXYGEN MODULE

The Oxygen Module regulates and proportions oxygen into the air from the blower according to the oxygen concentration level set on the Parameters screen. At settings of 30 percent oxygen or less the delivered oxygen percentage will be the set percentage ± 3 , except that the delivered concentration will not be below the concentration in air (21 percent). At set concentrations above 30 percent the error range is proportional to the set concentration, and the possible range of inspired oxygen can be estimated as the set concentration ± 10 percent of the set concentration. The selectable concentration range is from 21% to 100%.

The graph in Figure 3-2 represents the set oxygen concentration possible for a given circuit flow. The higher the oxygen concentration settings, the higher the oxygen flow rates required from the oxygen module and the lower the air flow rate from the blower.

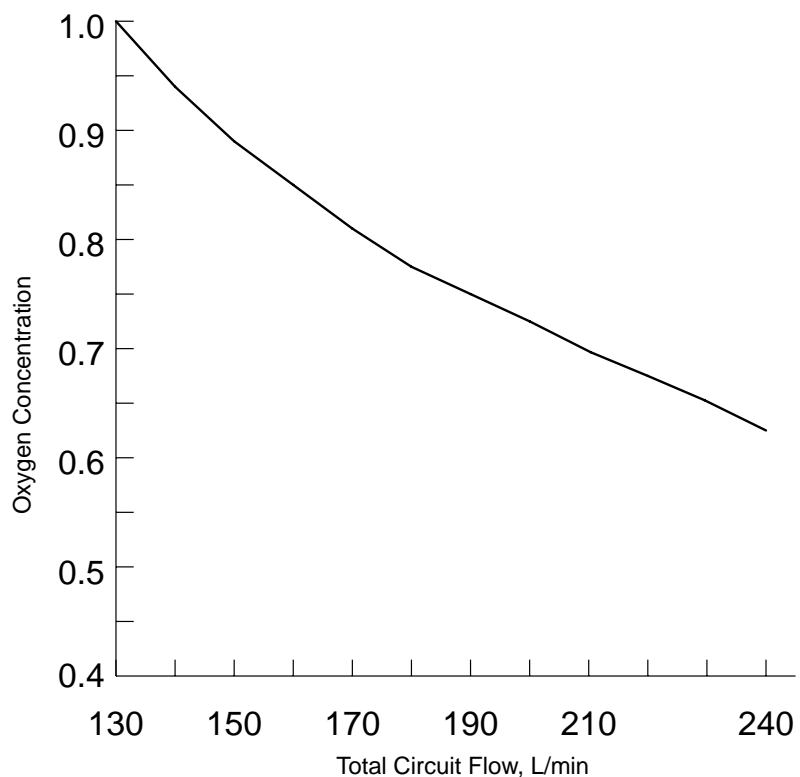


Figure 3-2. Total Flow Available to Maintain a Set Oxygen Concentration.

An “O₂ Flow” alarm is activated if the oxygen inlet supply is lost. See Chapter 13 for further information concerning the alarm.

Refer to Chapter 12 for additional information concerning the use of oxygen with the BiPAP Vision ventilator.

3.2.3 PNEUMATIC SYSTEM

Figure 3-3 provides a representation of the method for generation, control and delivery of therapy.

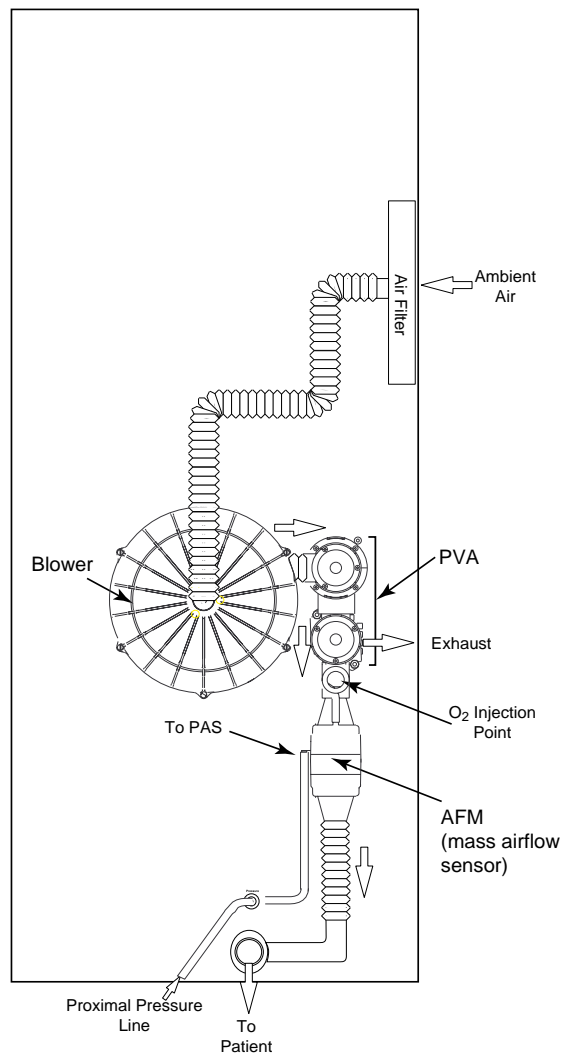


Figure 3-3. The BiPAP Vision Pneumatic System.

Ambient air is drawn through the air inlet filter and pressurized in the blower assembly. System flow and pressure are then regulated at the blower outlet by the Pressure Valve Assembly (PVA). There are two valves in the valve assembly that work in tandem to produce the desired pressure in the circuit. During the IPAP phase, flow from the blower is directed through the patient circuit at the preset pressure. During expiration and transition to the EPAP phase, the PVA responds as necessary to allow excess flow to be exhausted from the system to attain EPAP.

A pneumotach located in the Air Flow Module (AFM) is positioned after the PVA and immediately before the machine outlet. The AFM monitors total gas flow and machine pressure and transmits the data to the main controller system.

The proximal pressure is measured at the patient connection and compared to the set pressure. The delivered pressure is thereby controlled and maintained at the patient connection.

3.2.4 STANDBY MODE

The Standby mode, activated when the Standby key on the Monitoring screen is pressed, decreases the output flow to an idle state. This feature allows the clinician to place the ventilator in Standby while performing mask fittings, setting the prescription, etc. The Standby mode may be selected when no patient is connected to the Vision ventilator.

When the Standby mode is activated, the graph display area is blanked and STANDBY flashes in the middle of the screen. All measured parameters are zeroed.

In the Standby mode, all patient alarms are deactivated. Only the Vent Inop and CheckVent alarms are active. The following keys remain active:

- PARAMETERS
- MODE
- ALARMS
- Options

If you make any changes to the system (e.g., parameters changes, alarm settings, etc.), the changes are effective when you exit the Standby mode.

The Standby mode is manually deactivated by pressing the Standby key a second time. As a safety feature, the Standby mode is automatically deactivated if the Vision senses that a patient is connected to the circuit and is triggering spontaneous breaths.

3.2.5 FLOW ANALYSIS

The accuracy and responsiveness of the system is maintained by continuous analysis of the delivered flow. The flow measured at the Air Flow Module (AFM) is analyzed to derive a signal proportional to the Total Flow Rate (\dot{V}_{tot}) in the patient circuit. This signal contains a component derived from the flow delivered to the patient (Estimated Patient Flow Rate, $[\dot{V}_{\text{est}}]$) as well as a component derived from circuit leaks (Estimated Leak Flow Rate, $[\dot{V}_{\text{leak}}]$). Circuit leaks are comprised of intentional leak through the exhalation port as well as any unintentional leaks that may be present in the circuit or at the patient connection ($\dot{V}_{\text{leak}} = \text{intentional} + \text{unintentional leaks}$).

$$\dot{V}_{\text{tot}} = \dot{V}_{\text{est}} + \dot{V}_{\text{leak}}$$

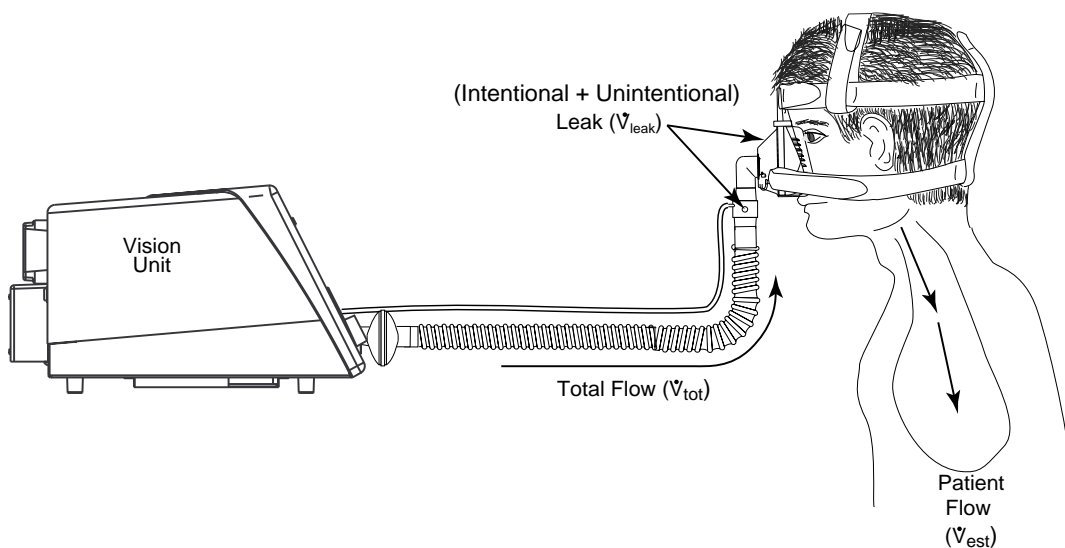


Figure 3-4. Data Locations for Flow Analysis.

3.3 BiPAP® Auto-Trak Sensitivity™

An important characteristic of the BiPAP Vision ventilator is its ability to recognize and compensate for unintentional leaks in the system and to automatically adjust its trigger and cycle algorithms to maintain optimum performance in the presence of leaks. This feature is known as Auto-Trak Sensitivity. The following sections examine this function in detail by describing the leak tolerance function and sensitivity.

3.3.1 LEAK TOLERANCE

Leak tolerance is the unit's ability to respond to changes in leaks. The BiPAP Vision ventilator uses two primary mechanisms to identify and adjust to leaks.

1. Expiratory Flow Rate Adjustment

At end expiration the total flow in the patient circuit should equal the baseline leak (\dot{V}_{leak}) which consists of intentional (exhalation port) and unintentional (mask, mouth) leaks. Once the unit has been in EPAP for 5 seconds, the total flow is compared to the originally established value of \dot{V}_{leak} . At this point, the Vision flow sensing circuit makes the assumption that the patient's flow is zero, so that the total circuit flow, \dot{V}_{tot} , should be equal to \dot{V}_{leak} .

Thus, under this condition of assumed zero patient flow, if \dot{V}_{tot} is not equal to \dot{V}_{leak} , the BiPAP Vision will adjust its calculation of the baseline leak. Figure 3-5 shows graphically how \dot{V}_{leak} is adjusted in the case of an increase in leak.

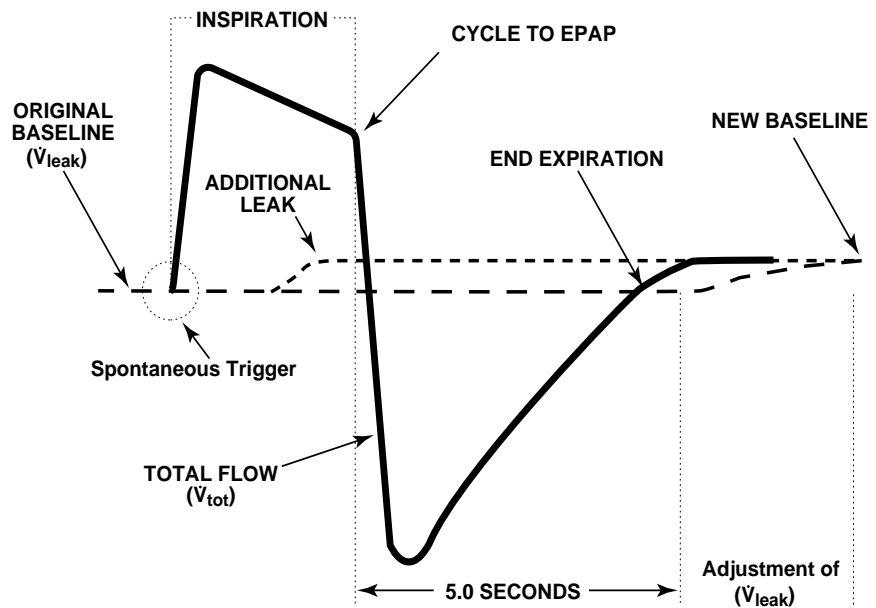


Figure 3-5. Expiratory Flow Rate Adjustment.

2. Tidal Volume Adjustment

Inspiratory (V_{T_I}) and expiratory (V_{T_E}) tidal volumes are determined by the estimated patient flow, and compared on a breath-by-breath basis. If the measured volumes during inspiration differ from expiration, the difference in volume is assumed to be due to an unintentional circuit leak. The baseline (\dot{V}_{leak}) is adjusted in the appropriate direction to reduce the difference in $V_{T_I} - V_{T_E}$ on the next breath. This prevents abrupt changes in sensitivity based on random changes in the breathing pattern, and allows the baseline (\dot{V}_{leak}) to accommodate to the new breathing pattern.

Tidal volume adjustment can be observed on the tidal volume waveform graph as illustrated in Figure 3-6.

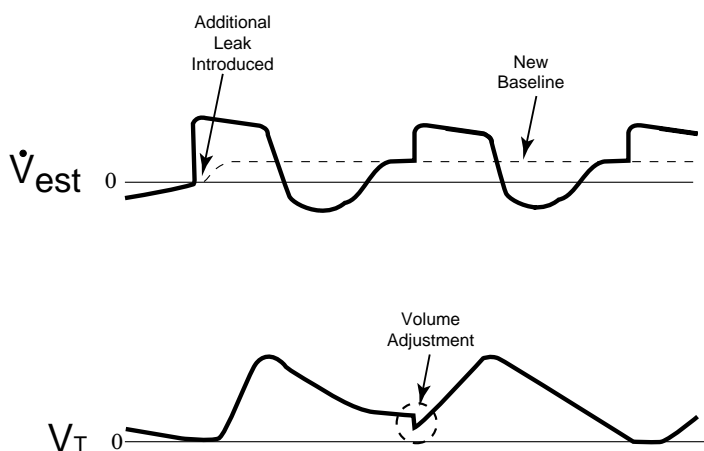


Figure 3-6. Tidal Volume Adjustment.

3.3.2 SENSITIVITY

An essential feature of the BiPAP Vision ventilator while operating in the S/T Mode is its ability to effectively sense spontaneous breathing efforts, which causes the ventilator to trigger to IPAP and cycle to EPAP. Because no preset sensitivity threshold can assure patient and machine synchrony with changing breathing efforts and circuit leaks, the BiPAP Vision ventilator continuously tracks patient breathing patterns and automatically adjusts sensitivity thresholds to ensure optimum sensitivity as breathing patterns change or as circuit leaks change. The algorithms used to ensure optimum sensitivity are the Volume Trigger, Shape Signal, and the Spontaneous Expiratory Threshold (SET).

Volume Trigger (EPAP to IPAP)

The volume trigger is one method used to trigger IPAP during spontaneous breathing in the S/T Mode. The volume trigger threshold is 6 cc of accumulated volume above the baseline leak (\dot{V}_{leak}). When patient effort generates inspiratory flow causing 6 cc of volume to accumulate above baseline (\dot{V}_{leak}), IPAP is triggered:

$$\text{Volume trigger threshold} = 6 \text{ cc volume above } \dot{V}_{\text{leak}} \text{ baseline}$$

Shape Signal (EPAP to IPAP) (IPAP to EPAP)

The shape signal is another method used to trigger IPAP and/or cycle off IPAP to EPAP during spontaneous breathing in the S/T Mode. This signal continuously tracks patient inspiratory and expiratory flow and adjusts the spontaneous trigger and cycle thresholds for optimum sensitivity. The Shape Signal appears as a shadow image of the patient's actual flow. The shape signal functions as a sensitivity threshold at either inspiration or expiration. When the patient's flow rate crosses the shape signal the unit changes pressure levels. Figure 3-7 illustrates how the shape signal is superimposed onto the actual waveform to trigger and cycle off IPAP.

The shape signal is created by offsetting the signal from the actual patient flow by 15 L/min and delaying it for a 300 msec period. This intentional delay causes the shape signal to be slightly behind the patient's flow rate. A sudden change in patient flow will cross the shape signal, causing the pressure level to change.

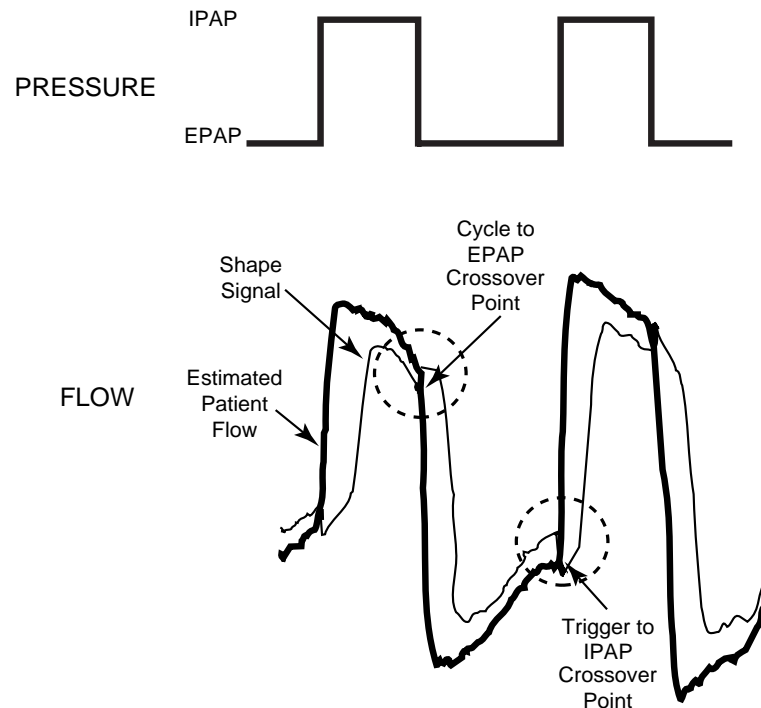


Figure 3-7. Shape Signal.

Tracking the patient's flow pattern with the Shape Signal provides a sensitive mechanism to trigger to IPAP or cycle to EPAP in response to changing breathing patterns and circuit leaks.

Spontaneous Expiratory Threshold (IPAP to EPAP)

A second method used to cycle off IPAP during spontaneous breathing in the S/T Mode is called Spontaneous Expiratory Threshold (SET). The SET is an electronic signal that rises in proportion to the inspiratory flow rate on each breath. When the Spontaneous Expiratory Threshold (SET) and actual patient flow value are equal, the unit cycles to EPAP.

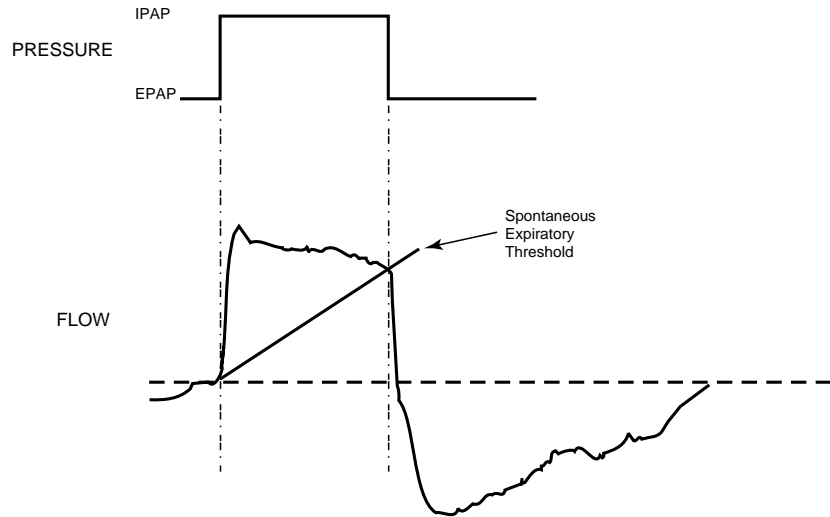


Figure 3-8. Spontaneous Expiratory Threshold.

Maximum IPAP Time (IPAP to EPAP)

A maximum IPAP time of 3.0 seconds acts as a safety mechanism to limit the time spent at the IPAP level during spontaneous breathing in the S/T Mode. Once the time limit is reached, the unit automatically cycles off IPAP to the EPAP level.

Flow Reversal (IPAP to EPAP)

As flow begins to decrease during IPAP, a flow reversal can occur due to a large leak around the mask or because the patient's mouth is open. When the Vision unit senses this flow reversal, the unit automatically cycles to the EPAP level.

Summary

The sensitivity criteria for spontaneous breathing in the S/T mode can be summarized as follows:

Spontaneous Trigger to IPAP

A transition from EPAP to IPAP will occur when one of the following conditions is met:

- Patient flow exceeds the shape signal
- 6 cc inspired volume accumulates above baseline flow (\dot{V}_{leak})

Cycle to EPAP

The transition from IPAP to EPAP will occur when one of the following conditions is met:

- Patient flow is less than the shape signal
- Spontaneous Expiratory Threshold (SET) is achieved
- A 3.0 second maximum IPAP time has occurred (safety feature)
- Flow reversal occurs during IPAP (safety feature)

3.4 Description of System Alarms

The ventilator incorporates self-diagnostic testing capabilities and a number of safety features. System internal functions are checked automatically at start-up and periodically throughout operation. The microprocessors continuously obtain readings from internal sensors to monitor machine functions and operating conditions. Device malfunctions or abnormal operating conditions are analyzed and reported according to the level of severity. Two primary alarm functions, Check Ventilator and Ventilator Inoperative, are available to identify a system malfunction.

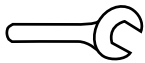
3.4.1 CHECK VENTILATOR



Check Vent

The Check Ventilator alarm alerts the clinician of a potential abnormal operating condition by illuminating the yellow “eye” icon on the display panel and activating an audible alarm. The audible alarm can be silenced with the Alarm Silence Key; the audible alarm will not reactivate after two minutes (as it usually does). The visual indicator cannot be reset and remains illuminated until the error is corrected. The ventilator continues to operate during a “Check Vent” condition but should be referred for service as soon as possible.

3.4.2 VENTILATOR INOPERATIVE



Vent Inop

The Ventilator Inoperative Alarm indicates a machine malfunction by illuminating the red “wrench” icon on the display panel and activating an audible alarm. The ventilator immediately powers down and opens the internal valves, allowing ambient air to be drawn in through the ventilator. The audible and visual alerts remain active and cannot be silenced until the power is turned off.

NOTE: Additional adjustable and system alarms are discussed in Chapter 13—Alarms.

3.4.3 EXHALATION PORT ALARM

The alarm is intended to identify an occlusion or low leak at the exhalation port. The alarm is preset to activate at $< 5 \text{ L/min}$ or 50 % of the baseline flow, whichever is greater, for a period of one minute. During the EPAP phase, the minimal baseline flow in the circuit is a result of the intentional leak at the exhalation port. If the exhalation port becomes occluded, the baseline flow will decrease below the alarm threshold and the alarm will be activated. The alarm message for a low leak condition is “Exh. Port.”

The leak rate of the exhalation port is determined during the Exhalation Port Test and is used to determine the baseline flow. If the test is not performed, a default value is used. The baseline flow is automatically recalculated during a mode change.

WARNING: Always inspect the exhalation port and circuit for partial obstructions before manually activating the Learn Base Flow. Otherwise, the Vision may establish the obstructed baseline flow as “normal,” which could cause the Low Leak alarm to ignore occlusions in the circuit or exhalation port.

Some circuit changes (e.g., oxygen or supplemental flow added to the circuit during operation) can shift the baseline flow and inadvertently activate the alarm. Under these circumstances, the clinician should reestablish the baseline flow for the circuit condition by manually selecting a new learn period. This is done by selecting the Learn Base Flow soft key in the Modify Alarms screen. The unit will learn a new baseline flow for the alarm based on the existing circuit conditions. The learn period is two minutes during which the Learn Base Flow soft key is highlighted.

3.5 User Interface

The primary user interface is the front panel of the Vision ventilator. A Liquid Crystal Display (LCD) screen provides real time graphics for pressure, volume, and flow; control features; calculated patient and machine parameters; and alarm conditions. The front panel also contains the user input controls, consisting of a set of hard and soft keys and a rotary adjustment knob.

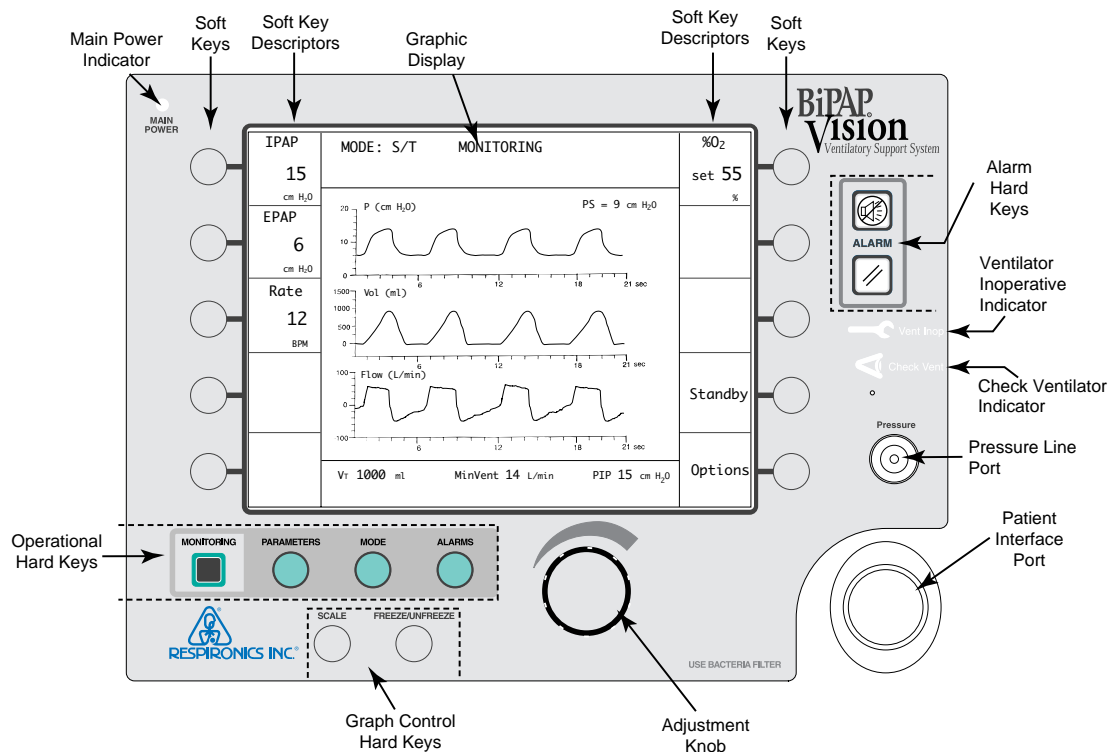


Figure 3-9. The BiPAP Vision Ventilator Front Panel.

See Chapter 4 for a complete description of the user interface.

3.6 Exhalation Port Test

When the Start/Stop switch is turned to **START** and the system completes a self test, the system Start-up screen is displayed. The Start-up screen allows the user to perform the Exhalation Port Test. The Exhalation Port Test characterizes the patient circuit by analyzing the leak rate of the exhalation port. During the test, the system learns the intentional exhalation port leak over the complete pressure range. The learned leak value is then stored in system memory and is used to perform leak calculations and provide an accurate display of patient leak and tidal volume in the Data Display Area. When a test is performed successfully, the Data Display shows the unintentional leak (the display will appear as “Pt. Leak” in the Data Display Area). If the test is not performed or cannot be completed successfully, the system is unable to accurately know the intentional leak and will display the total leak value (intentional + unintentional). The display will appear as “Tot. Leak” in the Data Display Area.

WARNING: Failure to perform the Exhalation Port Test prior to initializing therapy may result in inaccurate estimated tidal volume and minute ventilation readings. Subsequently, inaccurate minute ventilation readings could alter the accuracy of the low minute ventilation alarm when set below 3 L/min.

NOTE: Perform the Exhalation Port Test at system power up and when exhalation ports are changed. See Section 6.2, Starting the Vision System.

NOTE: The Exhalation Port Test must be performed when using the Plateau Exhalation Valve (PEV), because the leak rate of the PEV is significantly different than the Disposable Exhalation Port or the Whisper Swivel.

Chapter 4: Controls and Displays

This chapter describes the front panel controls, displays, and interface connections, the rear panel connections and controls, and the available Vision options.

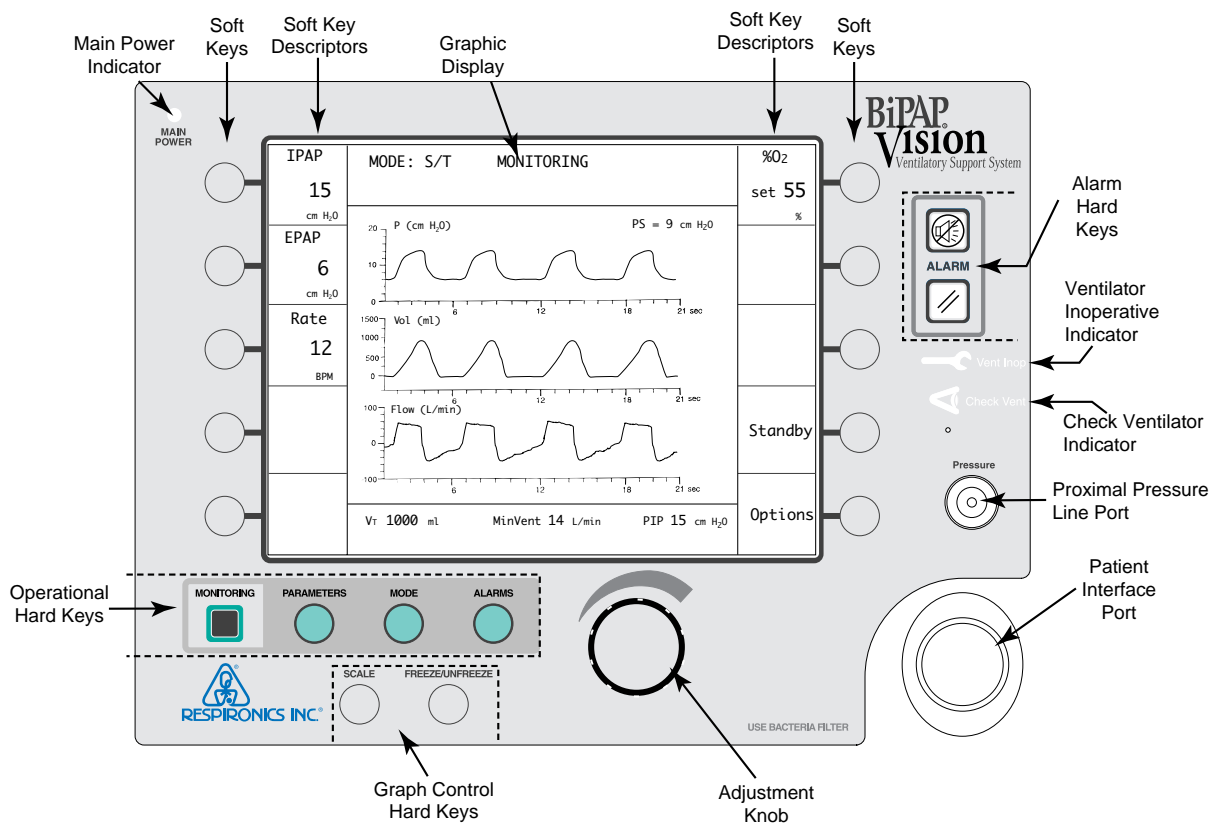


Figure 4-1

4.1 Overview

Figure 4-1 illustrates the Vision front panel. The front panel includes:

- a set of control keys
- a rotary adjustment knob
- a graphic display panel
- a patient interface port
- a pressure line port

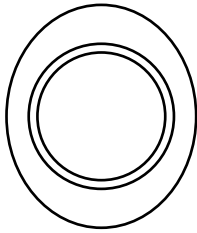
The Vision unit has eight hard keys and ten soft keys to control the ventilator, graphics, and alarms.

A hard key performs a single function regardless of the screen or display. The hard keys are:

- | | |
|--------------|-------------------|
| • MONITORING | • SCALE |
| • PARAMETERS | • FREEZE/UNFREEZE |
| • MODE | • ALARM SILENCE |
| • ALARMS | • ALARM RESET |

The function of a soft key changes with the displayed screen. The soft key function is displayed in its adjacent soft key descriptor.

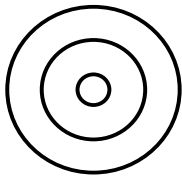
4.2 Patient Circuit Connections



Patient Interface Port

The Patient Interface Port accepts a 22 mm ID bacteria filter.

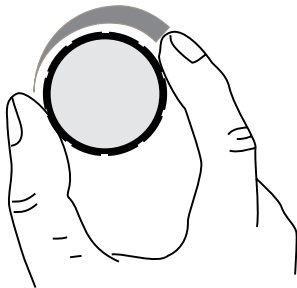
Pressure



Pressure Line Port

The Pressure Line Port accepts the $\frac{1}{8}$ " ID Proximal Pressure Line from the patient circuit to monitor patient pressure.

4.3 Adjustment Knob



The adjustment knob is a rotary knob that changes the value of a parameter that is selected with a soft key. It is active only when a soft key selection has been made.

To increase the value of a selected parameter, turn the knob clockwise; to decrease the value of a selected parameter, turn the knob counterclockwise. The knob has detents, each of which corresponds to one increment of the parameter value. The increment is equal to the resolution of the parameter.

For example, when the IPAP parameter is selected, each detent will change the value of the parameter by 1 cm H₂O.

4.4 Soft Keys

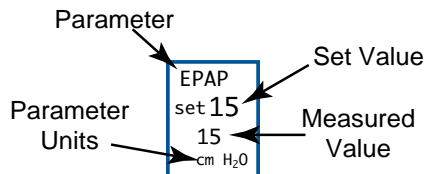
4.4.1 SOFT KEY OPERATION

NOTE: If there is no user activity for three minutes, the display returns to the Monitoring screen.

The BiPAP Vision ventilator has 10 soft keys aligned vertically along the sides of the LCD screen (5 keys on each side). The functions of the soft keys vary with the screen displayed. Soft keys are used to select parameters for adjustment, to display screens, or to provide information. When a soft key is pressed, the adjacent descriptor is highlighted in reverse video indicating the parameter located in the descriptor box is active and can be modified by using the adjustment knob. A second press of the same soft key deselects the descriptor box. If a descriptor area is blank, the soft key adjacent to it is inactive. The soft key controls are described in each pertinent section.

4.4.2 SOFT KEY DESCRIPTORS

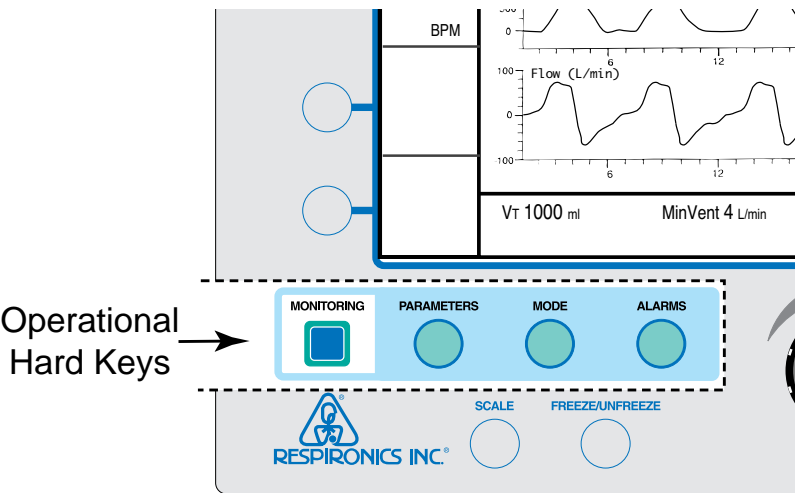
When a soft key is active, the adjacent descriptor is highlighted and displays data pertinent to the soft key.



When modifying or setting parameters, the descriptor displays the set value and the parameter units. The CPAP, IPAP, EPAP, and Rate descriptors also display the *measured* value in a smaller size below the set value when the parameter is selected.

4.5 Hard Keys—Operational

In addition to the soft keys, the Vision ventilator user interface consists of four main screens, each displayed by one of the four Operational Hard Keys.



The hard keys are:

- MONITORING
- PARAMETERS
- MODE
- ALARMS

4.5.1 MONITORING HARD KEY

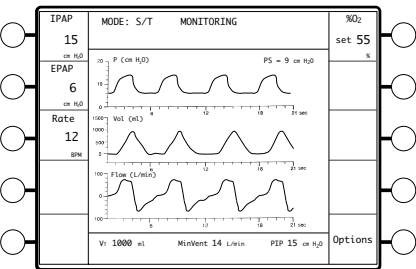
MONITORING



Purpose: Display the Monitoring screen for the active mode. Allows the operator to return to the Monitoring screen from any screen. No parameter, alarm, or mode changes can be made while the Monitoring screen is displayed.

Active: At all times

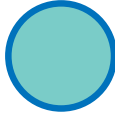
Note: If there is no user activity (e.g., pressing any keys) for three minutes while displaying any other screen, the system automatically returns to the Monitoring screen.



The Monitoring screen can be considered the “home” screen of the display. It displays the current operating mode, contains graphic displays of pressure, tidal volume, and flow, and includes numerical data displays for calculated and measured parameters. When using the optional oxygen module, the screen also displays the set oxygen concentration.

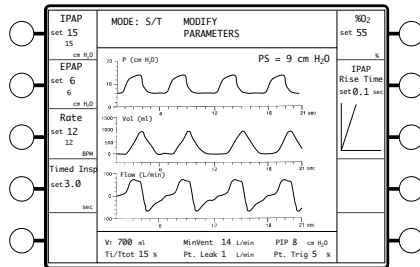
4.5.2 PARAMETERS HARD KEY

PARAMETERS



Purpose: Display the Modify Parameters screen for the active mode. The Modify Parameters screen allows the operator to change a parameter for the active mode.

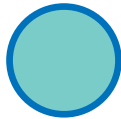
Active: At all times



The Modify Parameters screen allow the operator to review and adjust the parameters for the current operational mode. It displays the current operating mode, contains graphic displays of pressures, tidal volume, and flow, and includes numerical displays for calculated and measured parameters.

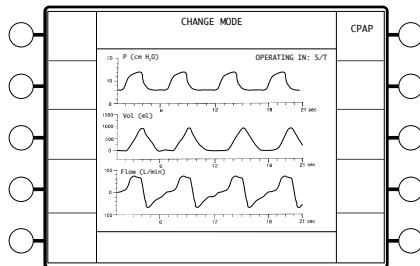
4.5.3 MODE HARD KEY

MODE



Purpose: Display the Change Mode screen. Real time graphic and numeric displays for the current mode provide for continuous monitoring of the patient and ventilator while making changes.

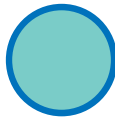
Active: At all times



The Change Mode screen allows the operator to review and select a new operating mode. Selecting a new mode from the Change Mode screen will initiate the change mode sequence and permit the user to adjust the parameters for the new mode before activating the mode.

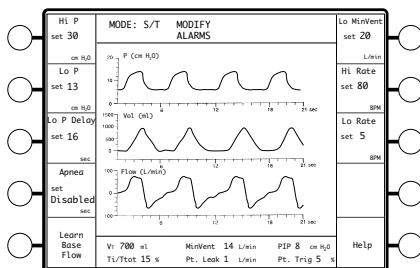
4.5.4 ALARMS HARD KEY

ALARMS



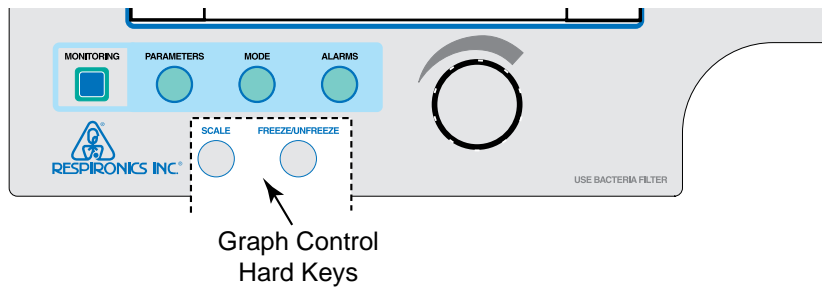
Purpose: Display the Modify Alarms screen.

Active: At all times



The Modify Alarms screen allows the operator to review and change the alarm limits for the active mode. While viewing the Modify Alarms screen, real-time graphic and calculated numeric displays for the active mode provide for continuous monitoring of the patient and ventilator.

4.6 Hard Keys—Graph Control

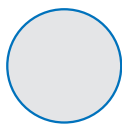


The Graph Control Hard Keys are:

- SCALE
- FREEZE/UNFREEZE

4.6.1 SCALE HARD KEY

SCALE

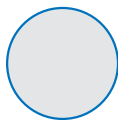


Purpose: Display the Modify Scale screen. The Modify Scale screen allows the operator to change the graph scales.

Active: At all times, except in the Change Mode screen.

4.6.2 FREEZE/UNFREEZE HARD KEY

FREEZE/UNFREEZE

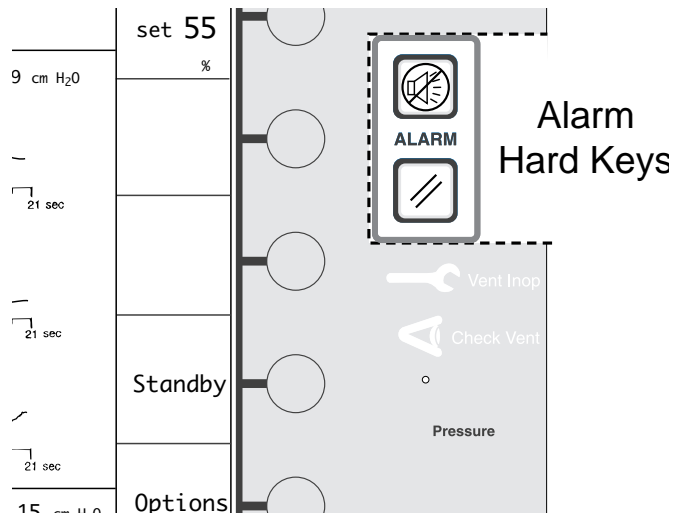


Purpose: Freeze the graph displays if the displays are scrolling when the key is pressed. Conversely, it unfreezes the display if the displays are frozen when the key is pressed.

Active: At all times except in the Change Mode screen.

Note: Real-time pressure, flow, and volume data are not plotted when the graphs are frozen. When the Freeze Key is active the message “Freeze Active” is displayed in the Mode/Message Area.

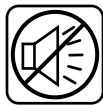
4.7 Hard Keys—Alarm



The Alarm Hard Keys are:

- SILENCE
- RESET

4.7.1 ALARM SILENCE HARD KEY



Purpose: Turns off the audible alarm for two minutes. Any further pressing of the Alarm Silence Hard Key has no effect on the alarm. When the alarm silence is active, the message “Alarm Silenced” appears in the Mode/Message Area for the duration of the silence period. Any new alarm conditions that occur during the silence period will provide a visual alert, but will not trigger the audible alarm.

Active: At all times

NOTE: The Ventilator Inoperative Alarm and the Apnea Alarm will override Alarm Silence.

4.7.2 ALARM RESET HARD KEY



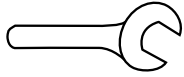
Purpose: Cancels the alarm silence period, resets the visual alarms, returns the Mode/Message and Graphic Display Areas to their normal formats, and resets the alarm detection logic. The alarm reactivates if the condition causing the alarm has not been corrected.

Active: At all times

CAUTION: To ensure the timely detection of any new alarm condition, never leave a patient unattended while the alarm is silenced.

4.8 Ventilator Warning Indicators

4.8.1 VENTILATOR INOPERATIVE INDICATOR

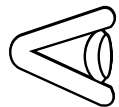


Vent Inop

Purpose: Alerts of a machine malfunction by illuminating the red “wrench” icon on the display panel and activating an audible alarm. The ventilator immediately powers down and opens the internal valves allowing ambient air to be drawn through the ventilator by spontaneous breathing.

The audible and visual alerts remain active and cannot be silenced until the Start/Stop switch is placed in the Stop position.

4.8.2 CHECK VENTILATOR INDICATOR



Check Vent

Purpose: Alerts of a potential abnormal operating condition by illuminating the yellow “eye” icon on the display panel and activating an audible alarm. The audible alarm can be temporarily silenced with the Alarm Silence Key. However, the visual indicator cannot be reset and remains illuminated until the error is corrected. The unit should be referred for service.

4.9 Graphic Display

As shown in Figure 4-2, the Graphic Display consists of three areas: the Mode/Message Area, the Graphic Display Area, and the Data Display Area.

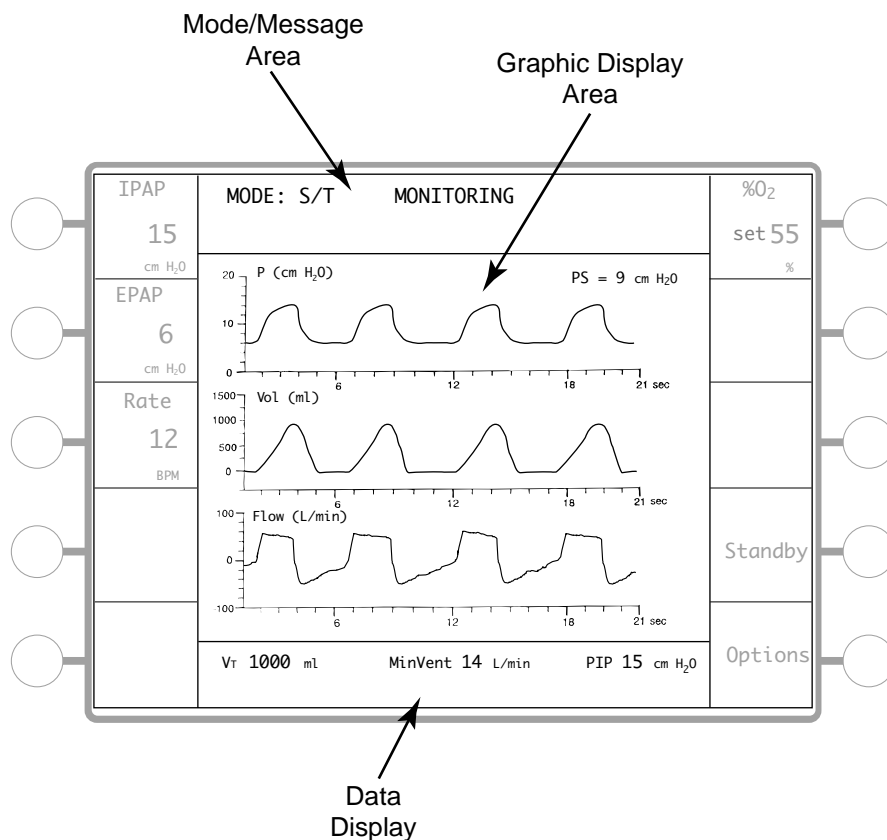


Figure 4-2. Graphic Display Areas.

4.9.1 MODE/MESSAGE AREA

During normal operation, the Mode/Message Area displays the active mode and the screen type. In alarm conditions, the Mode/Message Area displays the alarm messages.

4.9.2 GRAPHIC DISPLAY AREA

The Graphic Display Area displays the real-time graphs for pressure, volume, and patient flow. A Timed Breath Indicator (V) appears on the Volume graph in the S/T mode to mark the start of a time-triggered machine breath.

4.9.3 DATA DISPLAY AREA

The Data Display Area can show up to six nonadjustable ventilation parameters, depending on the active mode. The display includes:

- Estimated Tidal Volume
- Estimated Minute Ventilation
- Peak Inspiratory Pressure
- Inspiratory Time/Total Cycle Time
- Patient or Total Leak
- % Patient Triggered Breaths

4.9.4 DATA VALUES

Monitoring Screen (see Figure 4-3)

The Monitoring screen provides measured values for:

- CPAP (When operating in the CPAP Mode, the CPAP value is displayed instead of the IPAP and EPAP values.)
- IPAP
- EPAP
- Peak Inspiratory Pressure (PIP)

Three calculated values are displayed in the Data Display Area:

- Estimated Exhaled Tidal Volume (V_T)
- Estimated Exhaled Minute Ventilation (MinVent)
- Rate (total respiratory rate)

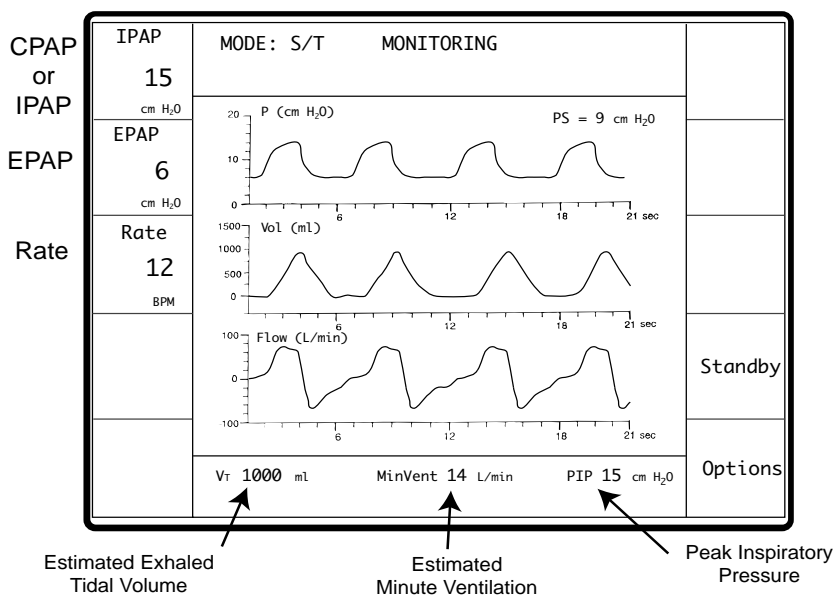


Figure 4-3. Data Values Displayed in the Monitoring Screen.

CPAP, IPAP, and EPAP (cm H₂O) - The CPAP, IPAP, and EPAP displays are measurements taken at the patient connection. Displays are real-time measurements for each breath.

Rate (BPM) - The total breathing rate is a running average from the six previous breaths (spontaneous + machine). All display values are updated at the end of each breath.

Estimated Exhaled Tidal Volume (ml) - Displays an estimated exhaled tidal volume reading for the previous breath. The display is updated at the end of each breath. The estimated exhaled tidal volume is obtained by integration of patient flow, uncorrected to BTPS. If large variations in flow (>15 L/min) occur between breaths, the tidal volume display value will flash, signaling an unstable reading. When the volumes are stabilized the display value remains constant.

Estimated Exhaled Minute Ventilation (L/min) - Displays the estimated exhaled minute ventilation based on a running average of the previous six breaths. The display is updated at the end of each breath.

Peak Inspiratory Pressure (cm H₂O) - Displays the peak pressure level obtained during the breath. The measurement is proximal to the patient connection. The display is updated at the end of each inspiration.

Parameters Screen (see Figure 4-4)

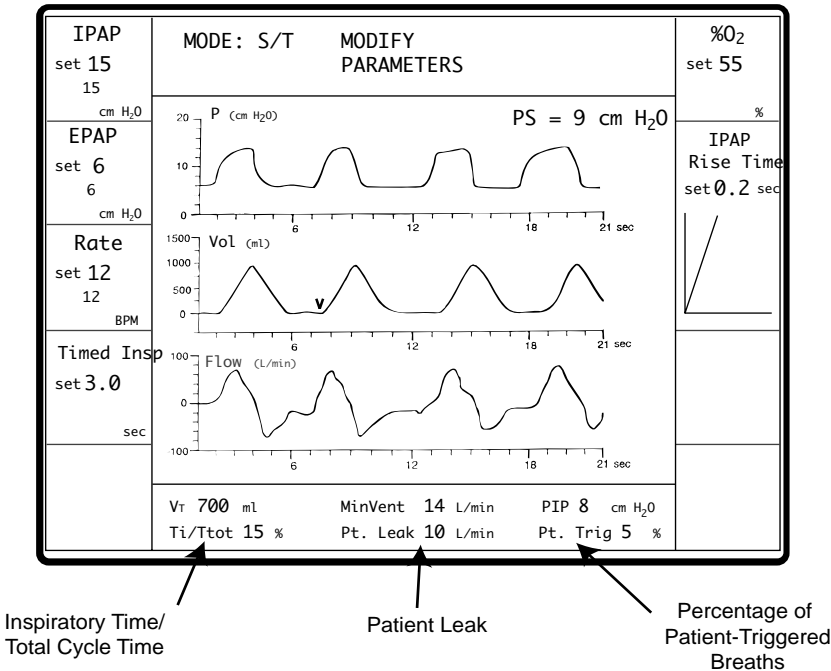


Figure 4-4. Data Values Displayed in the Parameters Screen.

Additional calculated values are displayed in the Data Display Area when the Parameters screen is active for the CPAP or S/T Mode.

Leak (L/min) - Displays either the Patient Leak or Total Leak.

Patient Leak - When the exhalation port test is successfully performed, the ventilator learns the intentional leak rate at the exhalation port and subtracts this value from the total leak. Therefore, the remaining leaks are a result of unintentional leaks typically found at the patient connection. The patient leak is the average leak value calculated over the entire breathing cycle. The display value is updated after each breath.

Total Leak - If the exhalation port test is not performed, the total (intentional + unintentional) leak is displayed. Total leak is the average leak value calculated during the entire breathing cycle. The display value is updated after each breath.

Ti/Ttot (%) - Inspiratory Time/Total Cycle Time- Displays the ratio of inspiratory time (Ti) to the duration of the total respiratory cycle (Ttot). Display is updated at the end of each breath.

% Pt. Triggered (%) - Percentage of Patient-Triggered Breaths - Displays the ratio of breaths triggered by the patient to total breaths. This value is obtained by dividing the number of patient-triggered breaths over the previous 30 minute period by the total number of breaths (machine + patient) over the same period. The display is updated every minute and is reset by a mode change or power-off condition. Active in the S/T mode only.

4.10 Rear Panel

Figure 4-5 shows the rear panel of the Vision unit. The rear panel includes:

- Power entry module
- Inlet filter and cover (see section 15.3)
- Oxygen Module (see chapter 14)
- Start/Stop switch
- Power cord retainer

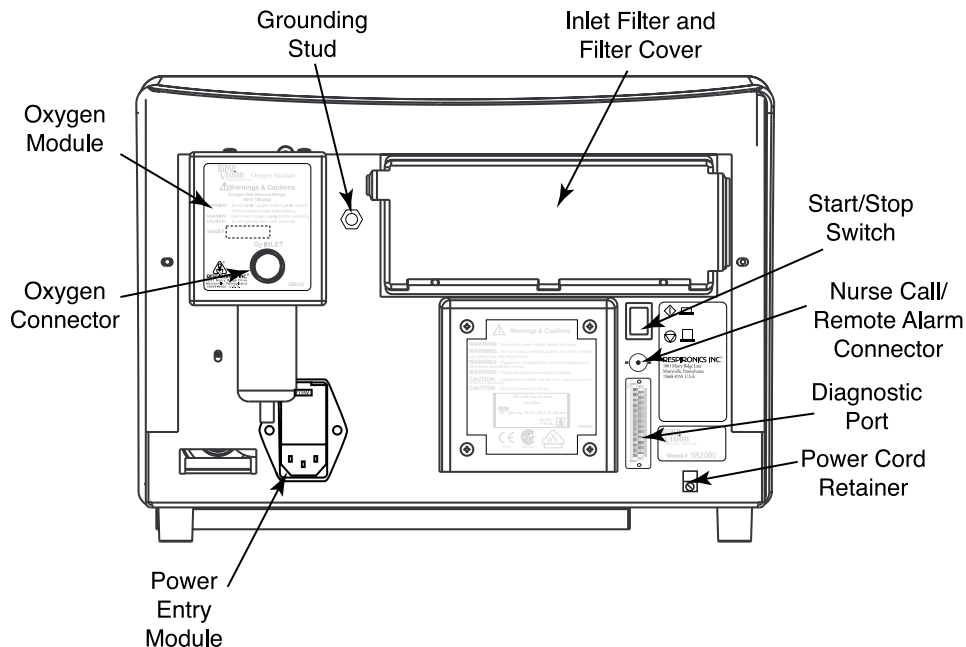
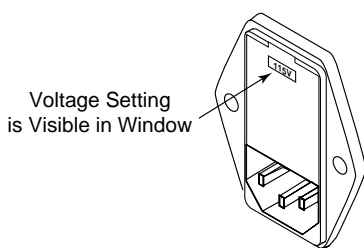


Figure 4-5. BiPAP Vision Rear Panel.

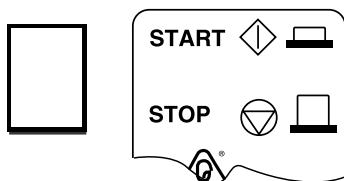
4.10.1 POWER ENTRY MODULE



The AC Inlet accepts a standard hospital-grade grounded power cord.

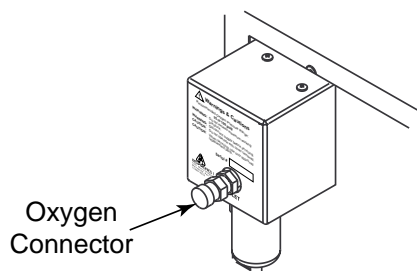
The module contains two fuses, placed in individual fuse drawers. The factory-set inlet voltage is set to the proper voltage for the country of operation. Chapter 14 describes how the fuses are inserted. See Chapter 16 for the proper fuse size and rating.

4.10.2 START/STOP SWITCH



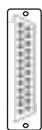
The Start/Stop switch is a push-button type switch, with "START" at the in position. The Start switch begins operation, but power is always applied to the Vision unit when the power cord is plugged into an operational wall outlet.

4.10.3 OXYGEN MODULE



The Oxygen Module provides a means of controlling the oxygen concentration delivered to the patient. The module can control the oxygen concentration from 21 to 100%.

4.10.4 DIAGNOSTIC CONNECTOR



The Diagnostic connector is for use by Respironics-authorized service personnel only.

4.10.5 NURSE CALL/ REMOTE ALARM CONNECTOR



The Nurse Call/Remote Alarm connector is a BNC-type connector that can be used to connect to most hospital call and alarm systems. It can also be used to connect to the Respironics Remote Alarm unit (Respironics part number 34003). Refer to Chapter 13 for a discussion of the Nurse Call/Remote Alarm operation.

4.10.6 GROUNDING STUD

The grounding stud is provided as a chassis ground connection for testing purposes.

4.11 Internal Alarm Battery

The Vision unit contains an internal NiCAD battery to sound the audible alarm and illuminate the Vent Inop indicator for greater than 2 minutes if AC power is lost. The battery does not support the operation of the Vision unit.

NOTE: When the Vision is started for the first time, the internal alarm battery may be discharged, causing the Check Vent visual and audible indicators to activate. If this happens, start the unit and operate in the Standby mode for a minimum of 2 hours to recharge the battery enough to eliminate the low battery alarm. See section 14.7 for complete battery maintenance information.

After the battery is charged, you must access the Options screen and clear the error codes. See Section 10.2.1.

4.12 Parameter Retention

The Vision unit uses a lithium battery to store information on the mode, parameters, and alarm limits in use. The information is retained in memory for at least seven years with no AC power applied..

4.13 Options

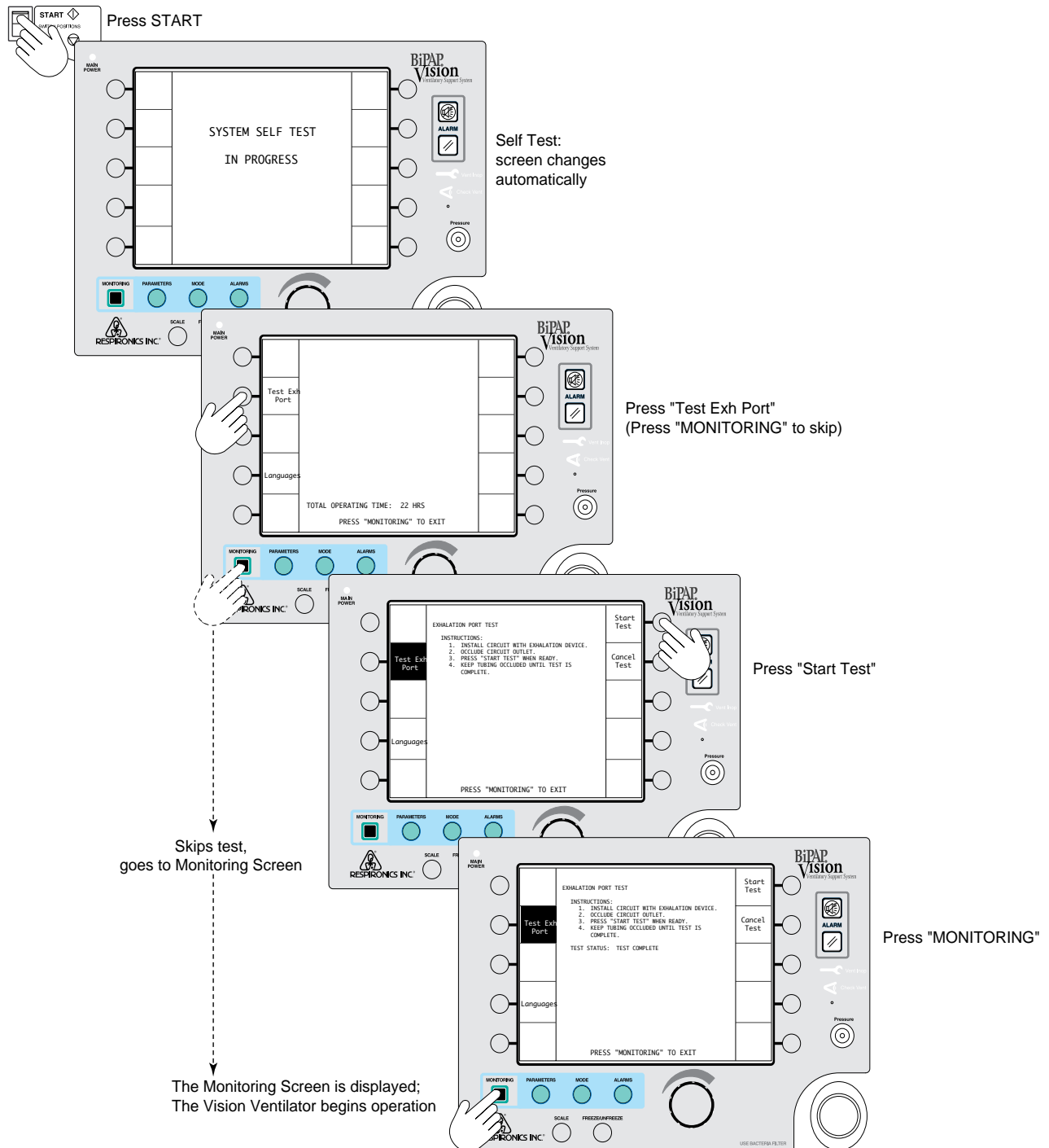
To display which, if any, of the options are installed on your machine, press the **OPTIONS** Soft Key on the Monitoring screen, then press the System Info Soft Key on the Options screen. The Mode/Message Area displays the software version and which modules are installed. Chapter 10 details the operation and display of the Options screen.

Chapter 5: Operational Flow Charts

This chapter presents the four primary Vision ventilator operations as flow diagrams. The operations are Start-up, Change Mode, Change Parameters, and Modify Alarms. The instructions are abbreviated to show only the major steps. To review an operation in detail, refer to Chapters 6 through 11.

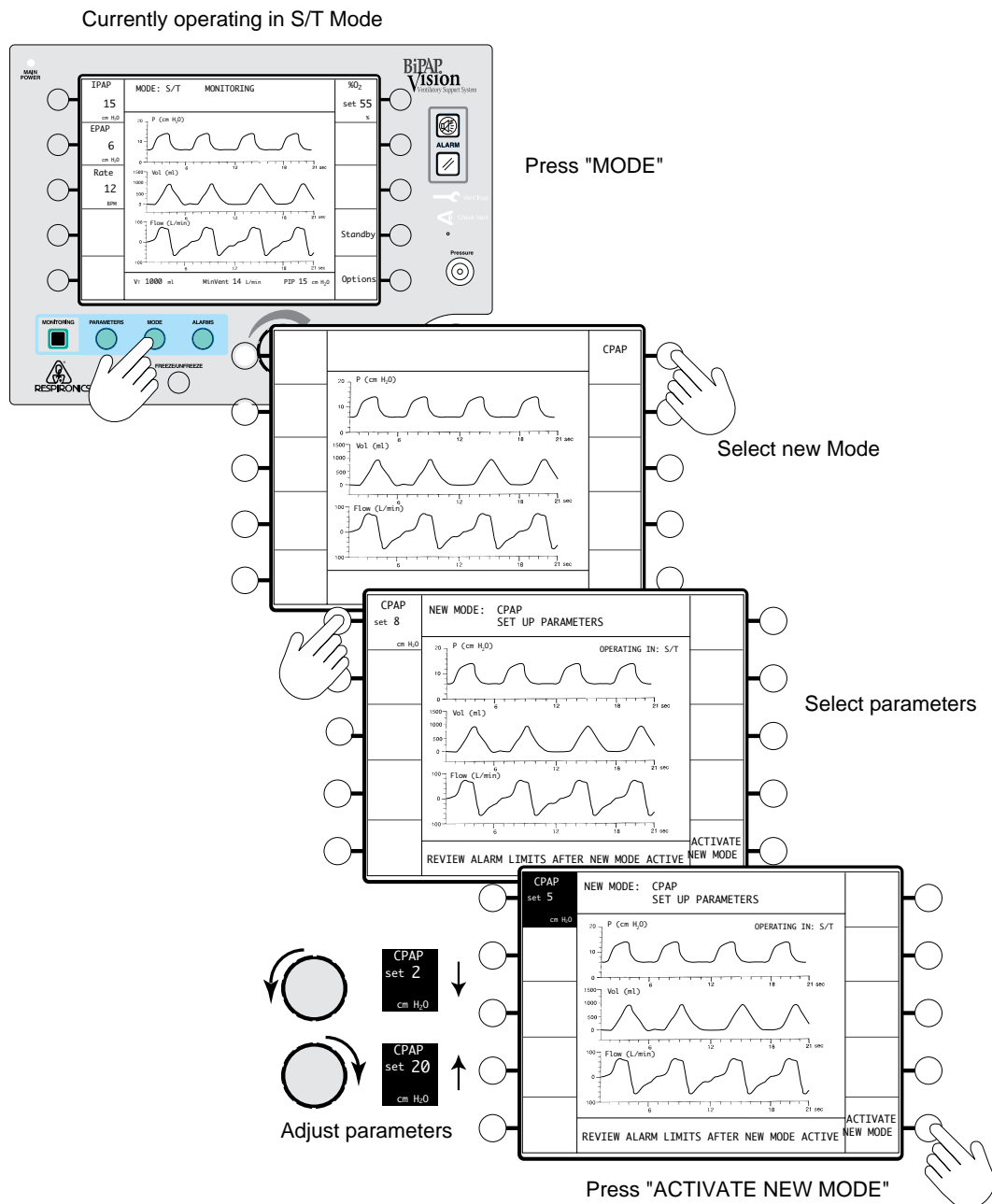
5.1 Start-up Flow Chart

The Start-up operation is described in Chapter 6.



5.2 Change Mode Flow Chart

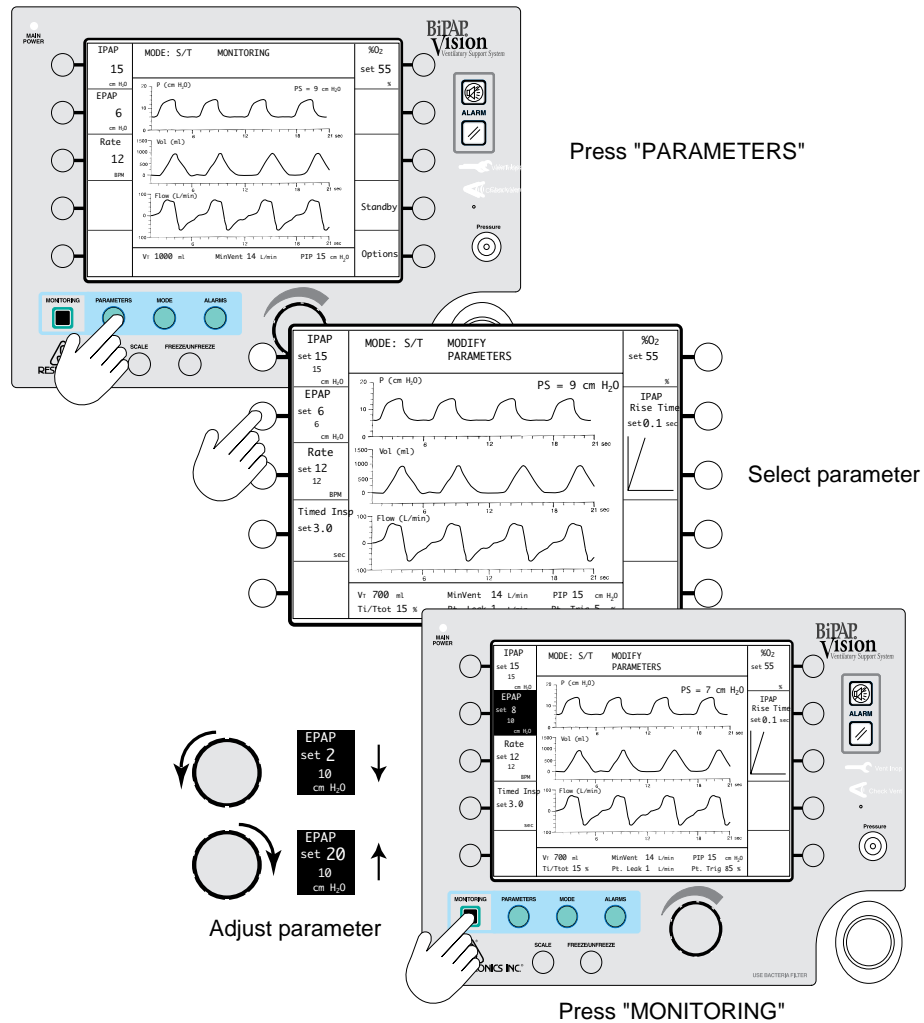
The Change Mode operation for changing to CPAP is described in Chapter 8. The operation for changing to S/T is described in Chapter 9.



5.3 Modify Parameters Flow Chart

The Modify Parameters operation for changing to CPAP is described in Chapter 8. The operation for modifying S/T parameters is described in Chapter 9.

Operating in S/T Mode, for example

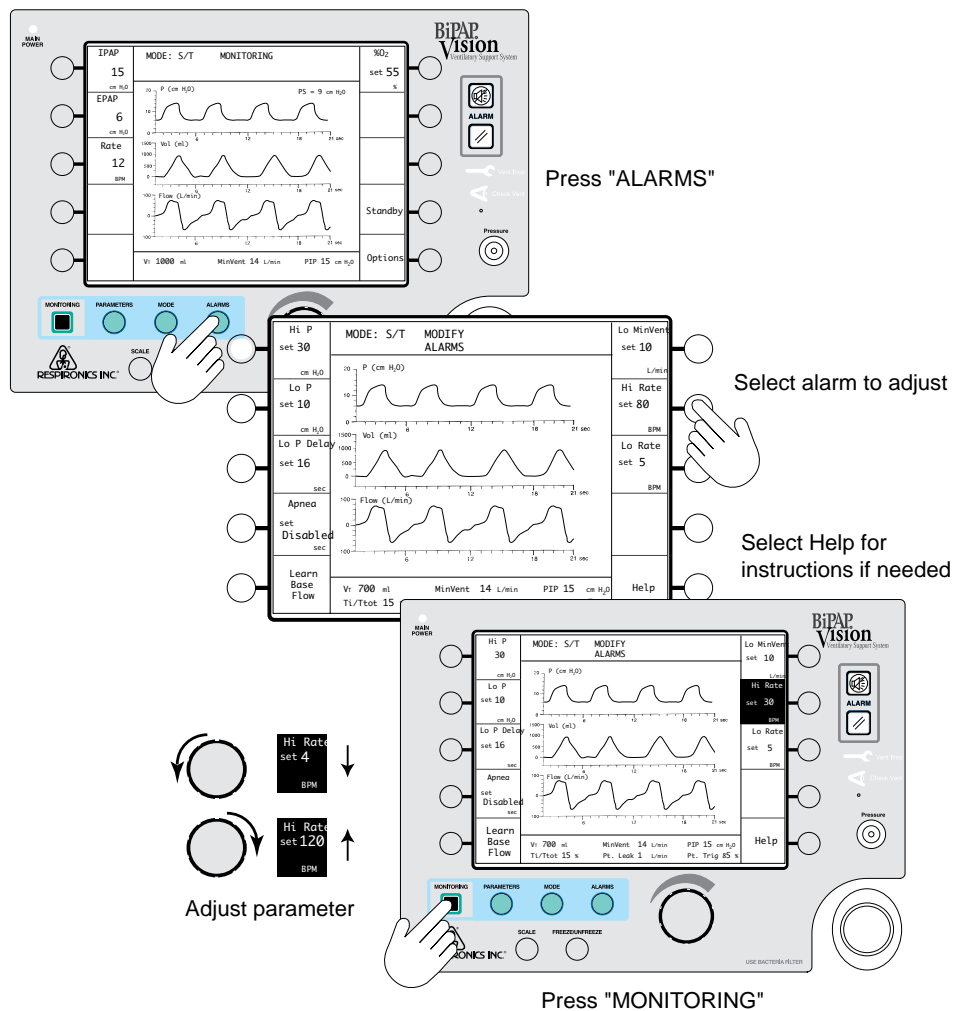


5.4 Modify Alarms Flow Chart

The Modify Alarms operation for changing to CPAP is described in Chapter 8. The operation for modifying S/T alarms is described in Chapter 9.

The sample displays show the optional Alarm Module installed.

Operating in S/T Mode, for example



Chapter 6: Setting Up and Starting the Vision System

6.1 Setting Up the Vision System

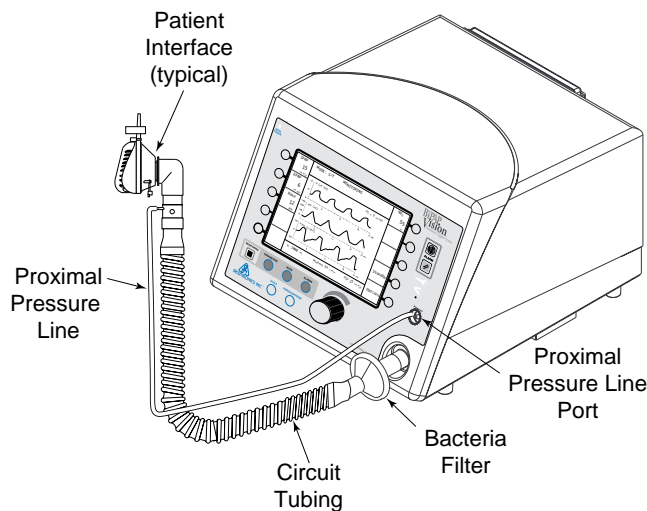
NOTE: The Vision Nurse Call/Remote Alarm port must be connected to nurse call systems that meet the relevant local safety standards according to the Nurse Call manufacturer's specification. See Chapter 17 for electrical specifications.

WARNING: Proper operation of any exhalation port used with the BiPAP Vision System must be verified by inspection during use. Occlusion or partial occlusion of the exhalation port may result in asphyxia.

STEP 1 If you are using the Nurse Call/Remote Alarm feature, connect the Vision unit to the remote alarm. You must verify whether the institution's system is a Normally OPEN or Normally CLOSED circuit. A Normally OPEN system refers to an alarm system that detects an open circuit in normal conditions and a closed circuit during alarm conditions. A Normally CLOSED system detects a closed circuit in normal circumstances and an open circuit during alarm conditions. The Vision unit is manufactured with a Normally CLOSED configuration. The Vision unit may be changed to interface with either system. Refer to the BiPAP Vision Service Manual for details.

STEP 2 Assemble the patient circuit according to the configuration illustrated in Chapter 15.

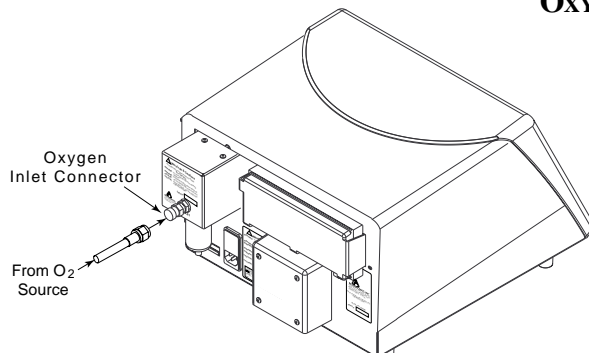
STEP 3 Connect the main flow bacteria filter to the patient interface port of the Vision unit. Connect the patient circuit to the bacteria filter. Connect the proximal pressure line to the Pressure inlet on the Vision unit.



If you are using a humidifier, it should be placed after the bacteria filter.

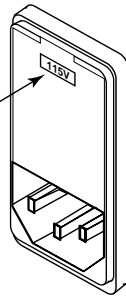
The circuit at left is an example of a Respiration approved circuit for noninvasive applications.

OXYGEN MODULE



If you are using the Oxygen Module, connect the high pressure oxygen source to the Oxygen Module's inlet connector now.

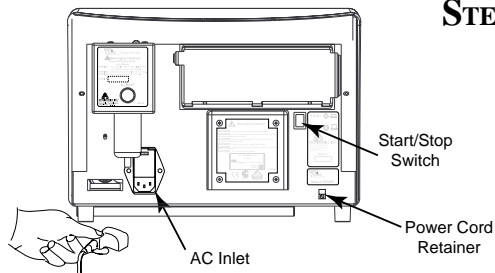
Voltage setting
is visible in window



NOTE: In the United States and Canada, the voltage setting should be 120 V. In European and other countries, check the country's line voltage requirements for the correct setting.

STEP 4 Verify that the voltage is set to the correct voltage for the country in which the unit is to be used.

The inlet voltage should be factory set for the correct line voltage in your country. If the inlet voltage needs to be changed, contact your medical equipment supplier.



STEP 5 Plug the electrical cord into the AC Inlet in the back of the Vision unit.

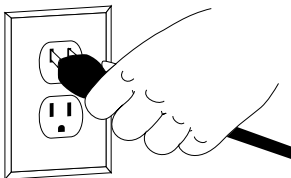
NOTE: For power cords that have a straight plug-to-cord connection, you must leave a small elbow in the power cord before the retainer to prevent excessive strain on the cord and plug. For power cords that have a 90-degree plug-to-cord connection, you can run the wire straight to the retainer.

STEP 6 Unscrew the power cord retainer. Place the electrical cord into the retainer.

Reattach the power cord retainer to the Vision unit.

NOTE: The use of an adaptor or extension cord is not recommended.

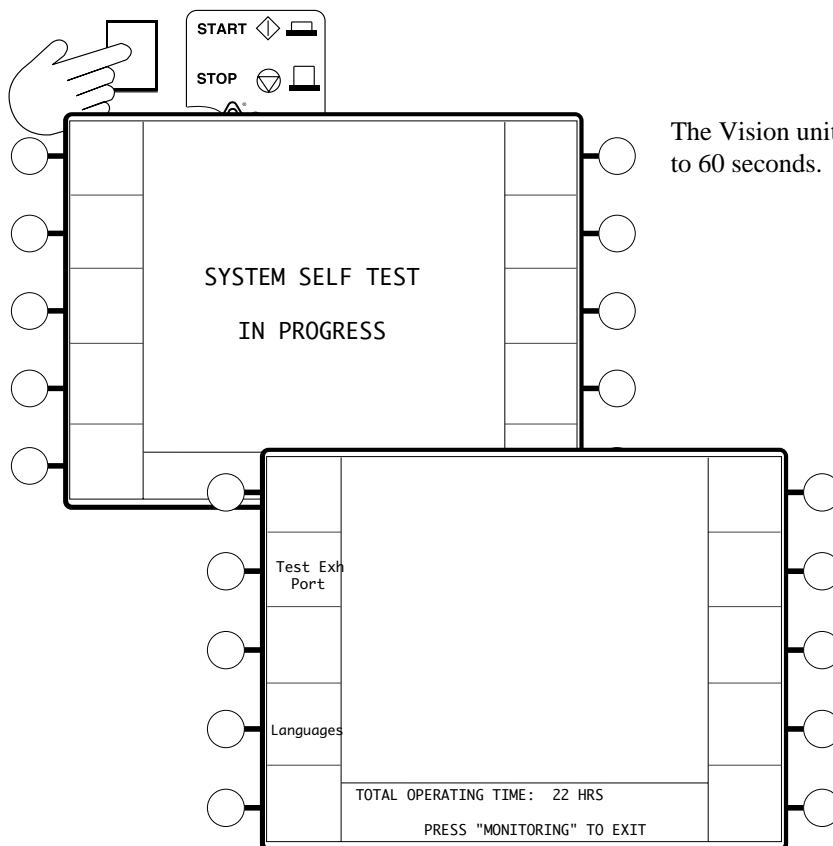
STEP 7 Verify that the Start/Stop switch is in the **STOP** position, then plug the electrical cord into a three-prong outlet.



STEP 8 If you are using the Nurse Call/Remote Alarm feature, verify that the Nurse Call/Remote Alarm system is compatible with the electrical specifications in Chapter 17. If it is acceptable, attach the Nurse Call/Remote Alarm system cable to the Vision rear-panel BNC connector.

6.2 Starting the Vision System

STEP 1 Turn the Start/Stop Switch to the **START** position.



The Vision unit initiates the self-test, which takes from 15 to 60 seconds.

After completing the self-test, the unit displays the Set Up screen.

The Set Up screen contains soft keys to run the Exhalation Port Test and to change languages.

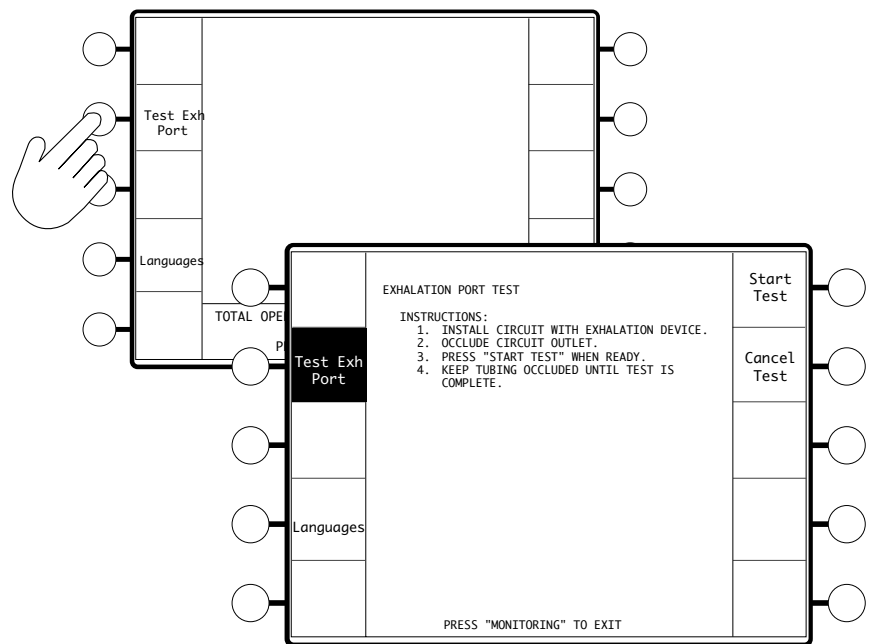
The bottom of the graphic display shows the total number of operating hours and instructions to exit the Set-up Screen.

WARNING: Failure to perform the Exhalation Port Test prior to initializing therapy may result in inaccurate estimated tidal volume readings and failure of the Low Minute Ventilation Alarm to sound at settings below 3 L/min. If an emergency situation requires initiation of therapy without performing the Exhalation Port Test, the Exhalation Port Test should be performed as soon as possible after the patient has been stabilized.

The Exhalation Port Test characterizes the patient circuit by analyzing the leak rate of the exhalation port. During the test, the system learns the intentional exhalation port leak over the complete pressure range. The learned leak value is then stored in system memory and is used to perform leak calculations and provide an accurate display of patient leak and tidal volume in the Data Display Area. When a test is performed successfully, the Data Display shows the unintentional leak. The display will appear as "Pt. Leak" in the Data Display Area. If the test is not performed or cannot be completed successfully, the system is unable to accurately know the intentional leak and will display the total leak value (intentional + unintentional). The display will appear as "Tot. Leak" in the Data Display Area.

NOTE: The Exhalation Port Test is recommended before each use, with circuit changes, or with changes in the exhalation port. Completing the test ensures the accuracy of leak calculations and displays.

STEP 2 Press the **Test Exh Port** soft key.



The Test Exh Port descriptor is highlighted; the system displays the Test Exh Port Screen.

The screen provides instructions to perform the test.

NOTE: The exhalation port must be connected to the circuit to successfully complete the Exhalation Port Test.

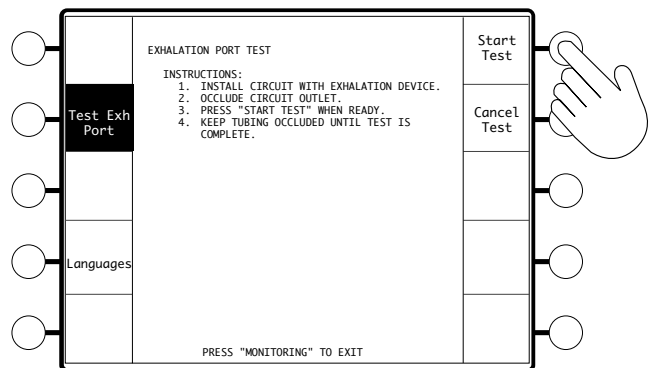
NOTE: If the exhalation port is designed as an integral part of the mask, the mask must be attached when performing the Exhalation Port Test.

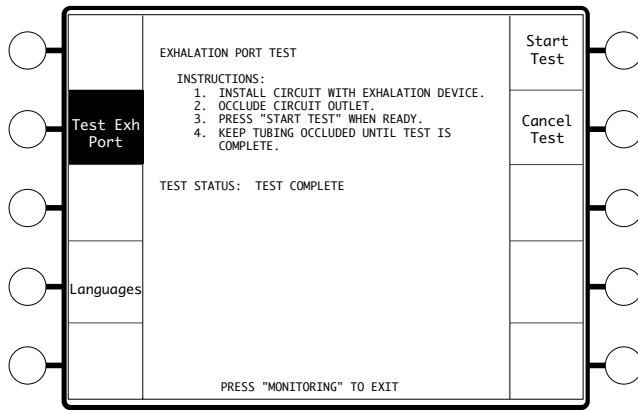
NOTE: When using a Spectrum® Full Face Mask, the preferred technique to test the exhalation port is to remove the mask and occlude the mask connection port of the exhalation valve. The Spectrum Full Face Mask uses a fresh air entrainment valve that may interfere with the Exhalation Port Test.

NOTE: To cancel the test at any time, press the Cancel Test soft key.

STEP 3 Verify the assembly of the patient circuit. Completely occlude the mask or circuit outlet during the test sequence.

STEP 4 Press the **Start Test** soft key to initiate the Exhalation Port Test. The test will take approximately 15 seconds to complete.





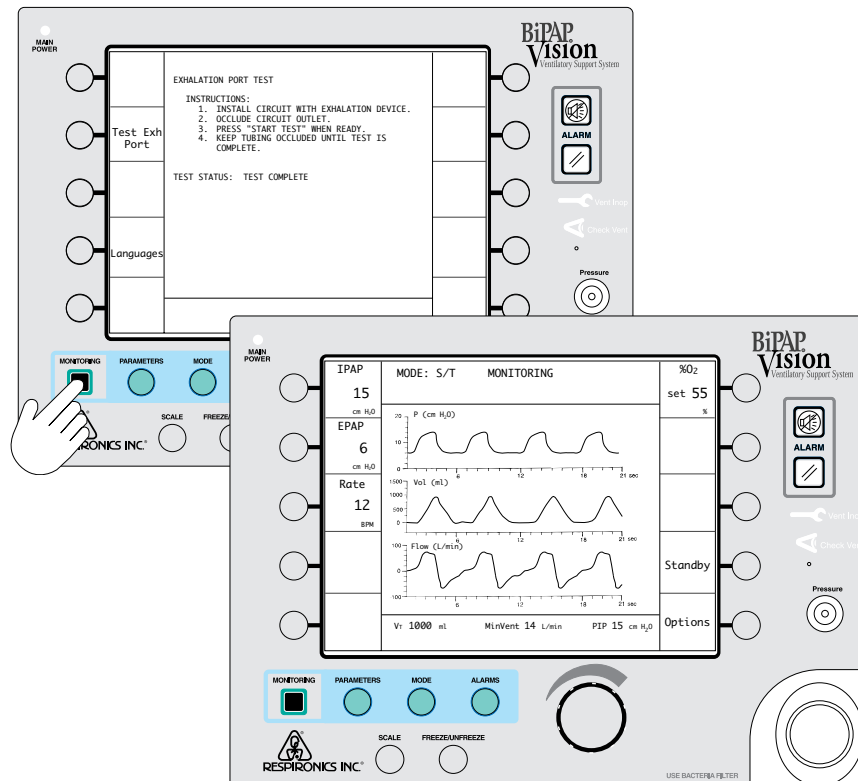
The system begins the Exhalation Leak Test.

Three status messages are possible:

- TEST COMPLETE**—The circuit displays normal leak conditions at the exhalation port—See STEP 5A.
- LOW FLOW, CHECK CIRCUIT, REPEAT TEST**—See STEP 5B.
- EXCESSIVE FLOW, CHECK CIRCUIT, REPEAT TEST**—See STEP 5C.
- OCCLUDED EXHALATION PORT, CHECK CIRCUIT, REPEAT TEST**—See STEP 5D.
- PROXLINE DISCONNECT, CHECK CIRCUIT, REPEAT TEST**—See STEP 5E.
- PRESSURE REGULATION ERROR, CHECK CIRCUIT, REPEAT TEST**—See STEP 5F.
- INTERMITTENT EXCESSIVE FLOW, CHECK CIRCUIT, REPEAT TEST**—See STEP 5G.

STEP 5A Status: Test Complete.

Press the **MONITORING** hard key to begin system operation.



The system begins operation in the last mode and at the settings in use before the unit was powered down.

STEP 5B Status: Low Flow. The leak rate was intermittently low during the test.

Potential causes:

- The exhalation port was open but then partially blocked during the test

Repeat the test.

STEP 5C Status: Excessive Flow. The circuit displays a higher than normal leak rate at the exhalation port .

Potential causes:

- Excess leak in circuit; check tubing and connectors
- Not a tight seal; check seal at circuit outlet or mask during test

Repeat the test.

STEP 5D Status: Occluded exhalation port. The leak rate was less than predicted.

Potential causes:

- No exhalation port; add exhalation port
- Exhalation port blocked

Repeat the test.

STEP 5E Status: Proxline disconnect. The proximal pressure line is disconnected.

Potential causes:

- Disconnected proximal pressure line
- Obstruction (possible kink) in circuit
- Obstruction (possible kink) in proximal pressure line

Repeat the test.

STEP 5F Status: Pressure regulation error. The leak test pressures cannot be attained.

Potential causes:

- An internal pressure line or sensor malfunction

Repeat the test.

STEP 5G Status: Intermittent excessive flow. The leak rate was intermittently high during the test.

Potential causes:

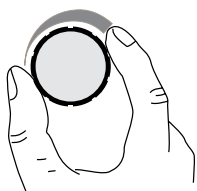
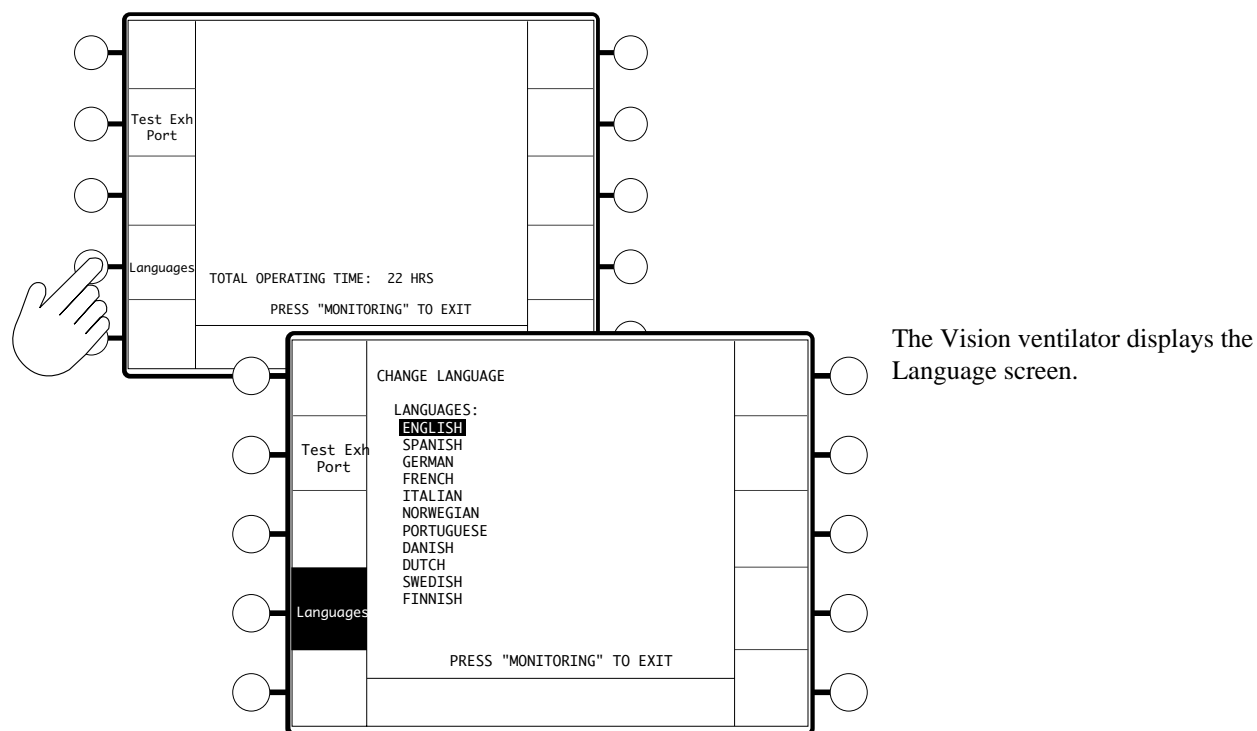
- The circuit was occluded, but the circuit end was opened or poorly sealed during the test

STEP 6 Complete the Performance Verification in Chapter 7 before each new patient setup.

6.3 Changing the Language

The Vision ventilator supports 11 languages: English, Spanish, German, French, Italian, Norwegian, Portuguese, Danish, Dutch, Swedish, and Finnish. The language may be changed from the Start Up screen.

STEP 1 Press the **Languages** soft key.



STEP 2 Turn the adjustment knob to highlight the language that you wish to activate, then press the **Language** soft key a second time to activate the language.

STEP 3 Press the **MONITORING** key to begin operation.

Chapter 7: Performance Verification

This procedure allows the clinician to confirm that the ventilator is functioning properly. Performance verification should be completed before each new patient setup.

NOTE: If the Vision unit loses power, and power is restored in less than 10 seconds, the unit will return to operation at the same settings that were in effect before power was lost. If the power is restored after 10 seconds, the unit parameters will have to be reset.

NOTE: This procedure does not verify performance of the optional oxygen module. If this module is installed and a performance verification is required, refer to Chapter 8 of the Vision Service Manual.

- STEP 1** Connect the patient circuit to the Vision ventilator as shown in Chapter 6.
- STEP 2** Start the unit. When the Set-up screen is displayed, pull the AC cord out of the wall socket. Verify that the Ventilator Inoperative visual (wrench icon) and audible alarms are activated. Switch the unit to **STOP**. Verify that the alarms are deactivated. Verify that the remote alarm (if used) is activated.
- STEP 3** Wait 30 seconds, then plug the unit back into the wall outlet and switch the unit to **START**. Perform the Exhalation Port Test as described in Chapter 6. (After successful completion of the test, press the **MONITORING** hard key to proceed to the Monitoring screen.)
- STEP 4** Occlude the patient circuit. Press the **Options** soft key to access the Options screen. If an alarm is active, press the **Reset** hard key.

NOTE: Each alarm function has both an audible and visual component. Verify that both components are active during the alarm test. If either component is not active, have the ventilator serviced.

STEP 5 Press the **Test Alarms** soft key to verify that both the audible tone and the alarm messages activate for all available alarms. The Ventilator Inoperative and Check Ventilator icons should illuminate during the test. The Vision front panel should look like Figure 7-1

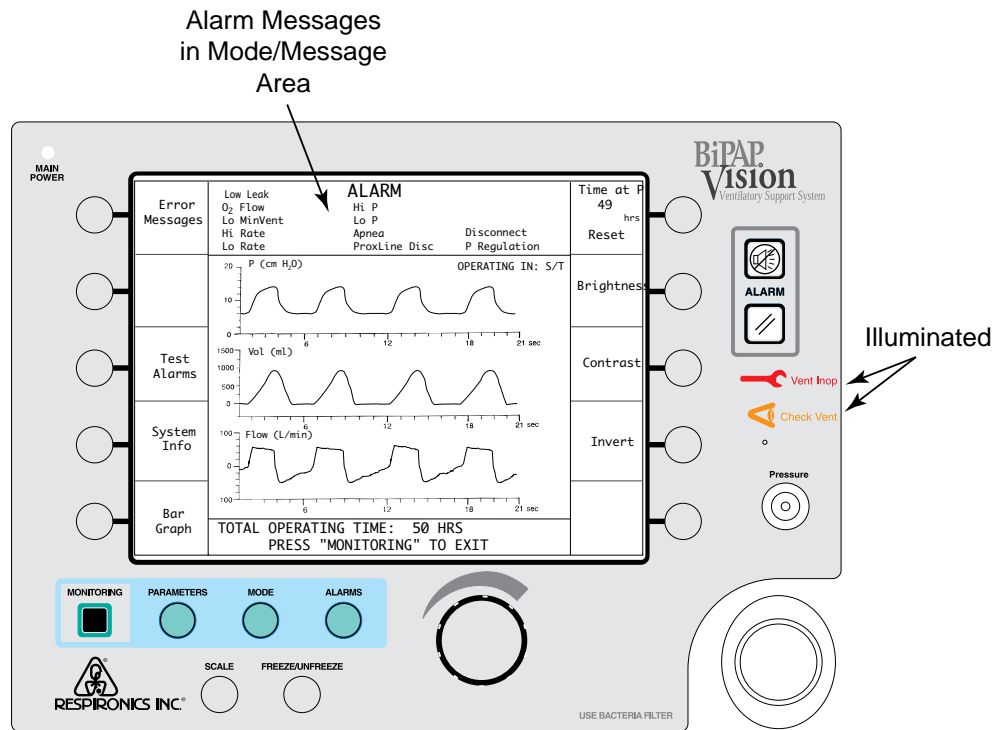


Figure 7-1. The Alarm Test Screen.

STEP 6 If the CPAP Mode is active, press the **MODE** hard key, select the **S/T Mode** key, and set the parameters as shown below. Activate the new mode. If the S/T Mode is active, press the **MONITORING** hard key then press the **PARAMETERS** hard key. In either case, set the parameters as follows:

IPAP = 15 cm H₂O
 EPAP = 5 cm H₂O
 Rate = 16 BPM
 Timed Insp = 1.0 sec
 IPAP Rise Time = 0.1 sec

NOTE: If you are using the Nurse Call/Remote Alarm feature, verify that the alarm conditions are activated at the remote location as well as at the Vision unit.

STEP 7 Press the **ALARMS** hard key and set the following alarm parameters:

Hi P = 20 cm H₂O
 Lo P = 10 cm H₂O
 Lo P Delay = 20 sec
 Apnea = Disabled
 Lo MinVent = 0 L/min
 Hi Rate = 40 BPM
 Lo Rate = 10 BPM

STEP 8 Press the **MONITORING** hard key to return to the Monitoring screen. Verify the following parameters from the Monitoring screen:

- The Rate soft key indicator flashes when each timed breath is activated.
- The timed breath is approximately 1 second in duration.
- The IPAP during a timed breath is 15 cm H₂O.
- The EPAP during a timed breath is 5 cm H₂O.
- The Timed Breath Rate is 16 BPM as indicated in the Timed Breath Indicator display.

STEP 9 Create a small leak at the patient connection to simulate a spontaneous trigger. Verify that the unit cycles to IPAP and that the Rate Indicator did not flash. After the breath is triggered, occlude the patient connection again.

STEP 10 Press the **ALARMS** hard key to display the Alarms screen.

STEP 11 Select the **Hi P** soft key and adjust the parameter to 10 cm H₂O. Wait for the audible and visual alarms indicating a High Pressure alarm. Return the Hi P parameter to 20 cm H₂O and press the **Alarm Reset** hard key to remove the alarm message.

STEP 12 Open the circuit to atmosphere for approximately 20 seconds to verify the following audible and visual alarms:

- The Lo P Alarm is activated.

Occlude the patient outlet on the circuit and press the **Alarm Reset** hard key to clear both the audible and the visual alarms.

WARNING: The Vision ventilator requires service if it fails to perform within the stated specifications.

STEP 13 Press the **Apnea** soft key and adjust the parameter to 20 sec. Maintain the occlusion of the patient connection for a minimum of 20 seconds to verify that the audible tone and the Apnea Alarm Message are activated. Adjust the Apnea setting to the Disabled setting. Press the **Alarm Reset** key to clear the visual alarms.

The Vision ventilator is ready for use if it has successfully passed the Performance Verification.

Adjust the Vision ventilator to the appropriate patient settings after the Performance Verification and before patient use.

Chapter 8: CPAP Mode

8.1 Overview

The CPAP Mode delivers Continuous Positive Airway Pressure to the patient circuit.

The active CPAP controls are:

- CPAP
- %O₂

During operation, the Monitoring screen continuously displays measured data for:

- CPAP
- Rate (total breaths per minute)

NOTE: If the Vision unit loses power, and power is restored in less than 10 seconds, the unit will return to operation at the same settings that were in effect before power was lost.

The Data Display Area (in Monitoring screen) displays:

- Estimated Exhaled Tidal Volume
- Estimated Minute Ventilation
- Peak Inspiratory Pressure

In the Modify Parameters screen, the Data Display Area also displays:

- Ti/Ttot
- Leak (Patient or Total)

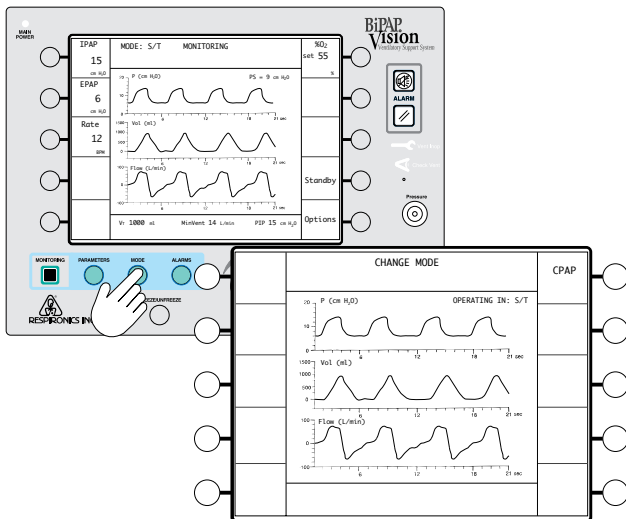
The Graphic Display Area shows real-time graphic displays for:

- Pressure
- Tidal Volume
- Flow

Alarms are available and are immediately activated once the mode is in operation. Alarms for the CPAP Mode are accessed from the Alarms screen when the CPAP Mode is activated.

8.2 Changing to the CPAP Mode

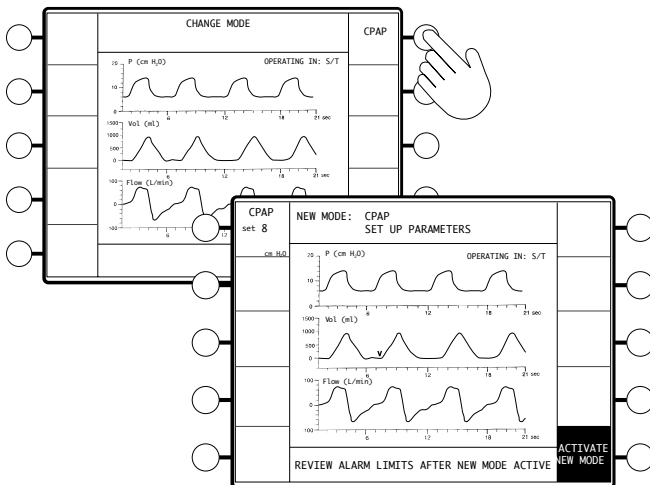
STEP 1 If the unit is operating in the S/T Mode, press the **MODE** Key.



The Change Mode screen is displayed. Available modes are displayed in the right column of descriptors.

NOTE: The S/T Mode remains active and is displayed in the graphics area on the screen until the **ACTIVATE NEW MODE** soft key is pressed.

STEP 2 Press the **CPAP** soft key.



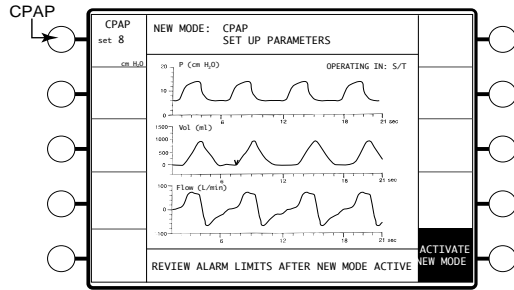
The New Mode screen for the CPAP Mode is displayed.

This screen allows you to review or make adjustments to the CPAP parameters before activating the new mode.

WARNING: At low baseline CPAP pressures, the flow through the exhalation port may not adequately clear all exhaled gas from the tubing. Some rebreathing may occur. Refer to Chapter 2 for guidelines on rebreathing.

NOTE: The **ACTIVATE NEW MODE** descriptor flashes to indicate that the CPAP Mode and selected parameters are not active until you press the **ACTIVATE NEW MODE** soft key.

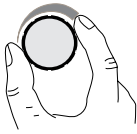
STEP 3 Press the soft key corresponding to the parameter you wish to adjust.



The selected parameter is highlighted.

STEP 4 Turn the adjustment knob to modify the selected parameter.

Adjusting CPAP



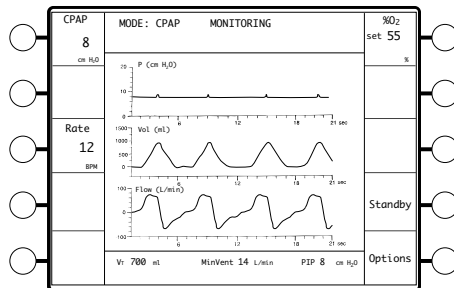
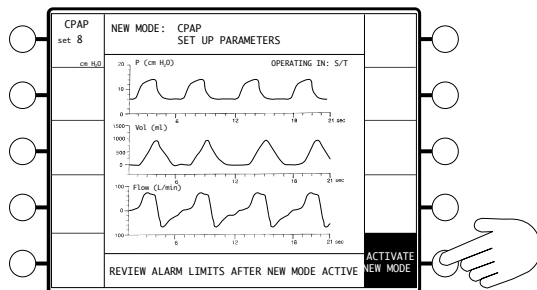
CPAP
set 4
cm H₂O

Increment: 1 cm H₂O

Range: 4 to 20 cm H₂O

Press the CPAP soft key and turn the adjustment knob.

STEP 5 When you have completed parameter adjustments, press the flashing **ACTIVATE NEW MODE** soft key.



The unit begins CPAP delivery and the display immediately changes to the Monitoring screen.

Verify CPAP operation at the intended parameters by viewing the parameter and graphics displays on the screen. The Mode/Message Area should indicate CPAP.

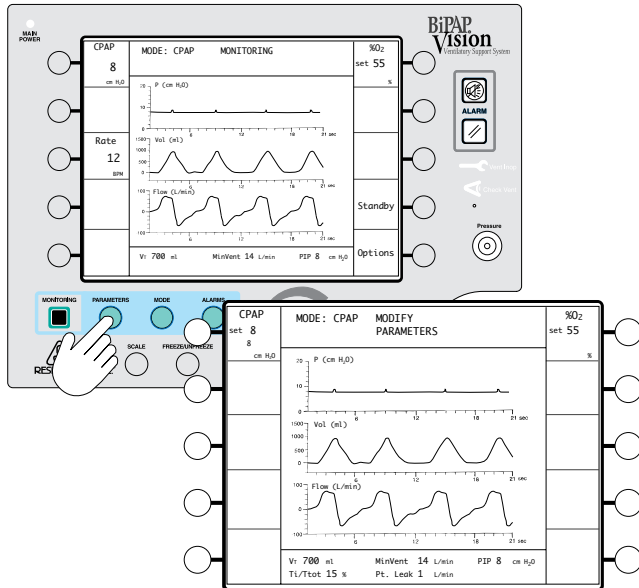
NOTE: When CPAP settings are determined and the mode is activated, press the ALARMS key to view the CPAP alarm settings. See Section 8.4, “Modifying Alarm Parameters,” for instructions.

If no user interaction occurs for a 3-minute time span, the unit defaults to the Monitoring screen.

8.3 Modifying Parameters in the CPAP Mode

NOTE: This section assumes that the unit is operating in the CPAP Mode and that the Monitoring screen is currently displayed.

STEP 1 Press the **PARAMETERS** hard key.



The Modify Parameters screen is displayed.

CPAP and Set %O₂ values are displayed.

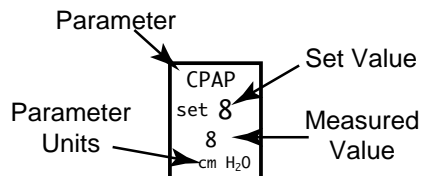
The parameters may be adjusted in any order.

The Data Display Area shows:

- Exhaled Tidal Volume (**V_T**)
- Minute Ventilation (**MinVent**)
- Peak Inspiratory Pressure (**PIP**)
- Inspiratory Time/Total Cycle Time (**Ti/Ttot**)
- Patient Leak (**Pt. Leak**) or Total Leak (**Tot. Leak**)

STEP 2 Press the soft key corresponding to the parameter you wish to adjust.

The selected parameter is highlighted.

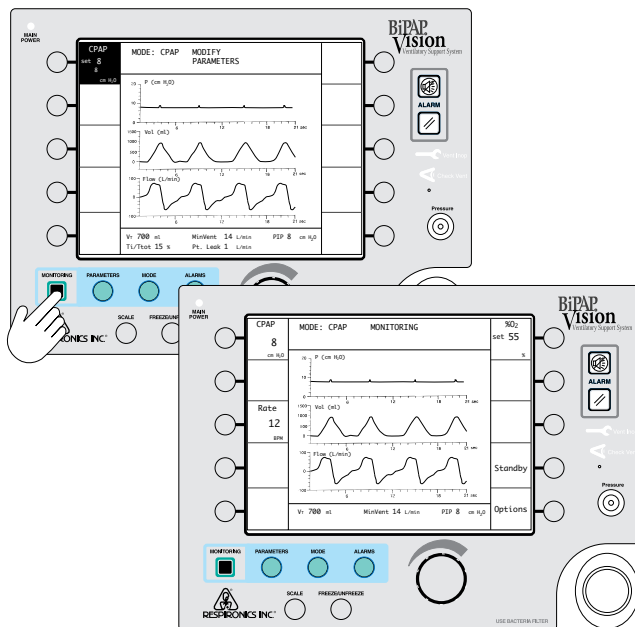


In the descriptor box, the set value is displayed directly under the parameter name and the measured value, with units of measure, is displayed below the set value.

Parameter changes become effective as you enter them.

STEP 3 Turn the adjustment knob to modify the selected parameter. See Section 8.2 for range values.

STEP 4 Press the **MONITORING** hard key to return to the Monitoring screen.



Verify that parameter changes are active by monitoring the patient and the measured values.

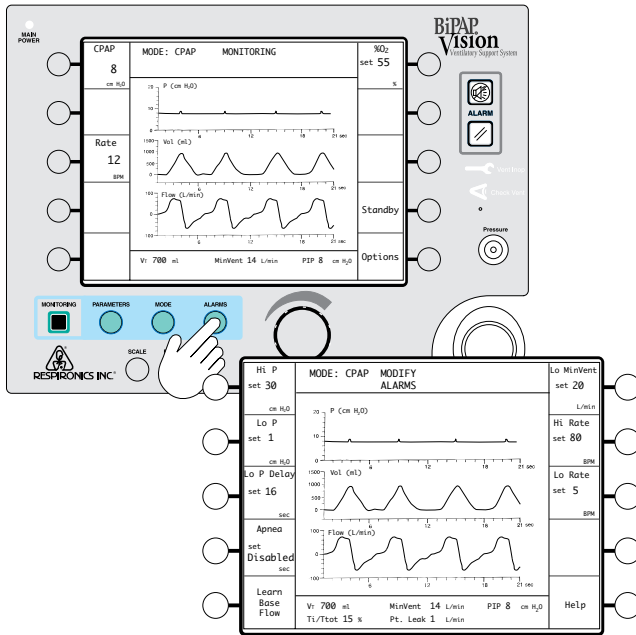
When the CPAP settings are determined, press the **ALARMS** hard key to verify that the alarm settings are correct. See Section 8.4 for instructions to modify alarms.

NOTE: If no user interaction occurs for a 3-minute time span, the unit defaults to the Monitoring screen.

8.4 Modifying Alarm Parameters

This section provides instructions for viewing or modifying adjustable alarms in the CPAP Mode. Additional details concerning alarm functions and troubleshooting are discussed in Chapter 12, Alarms and Troubleshooting.

STEP 1 Press the **ALARMS** hard key.



The Modify Alarms screen is displayed.

You may select:

- High Pressure Limit (Hi P)
- Low Pressure Limit (Lo P)
- Low Pressure Alarm Delay (Lo P Delay)
- Apnea
- Learn Base Flow
- Low Minute Ventilation (Lo MinVent)
- High Rate (Hi Rate)
- Low Rate (Lo Rate)

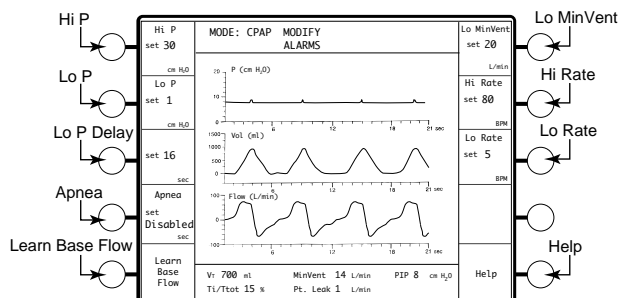
You may modify the alarms in any order.

NOTE: New alarm values are active as soon as they are entered.

NOTE: Alarm values are stored during power off conditions.

A Help screen is available to describe each adjustable alarm function available for the CPAP Mode. To access the Help screen, press the Help soft key.

STEP 2 Press the soft key of the alarm you wish to modify, or press the **Learn Base Flow** soft key to initiate a baseline measurement. Check the exhalation port for occlusions before initiating a Learn Base Flow sequence.



The alarm parameter is highlighted.

STEP 3 Turn the adjustment knob to modify the selected parameter.

NOTE: See Chapter 12, Alarms and Troubleshooting, for additional details on alarm functions.



Hi P
set 50
cm H₂O

High Pressure Alarm

Increment: 1 cm H₂O

Range: 5 to 50 cm H₂O

The High Pressure Alarm should be set above the CPAP level.

Lo P
set 10
cm H₂O

Low Pressure Alarm

Increment: 1 cm H₂O

Range: "Disabled" to 40 cm H₂O

The Low Pressure Alarm should be set below the CPAP level.

WARNING: The Vision ventilator is designed to compensate for circuit leaks. With the Low Pressure Alarm below the CPAP level, the Vision ventilator may not always detect circuit disconnects due to pressure compensation. The alarm should be tested with the intended circuit configuration before therapy is initiated. If the low pressure alarm does not detect a circuit disconnect, consider using the Apnea Alarm to detect circuit disconnects.

Lo P Delay
set 60
sec

Low Pressure Alarm Delay

Increment: 1 second

Range: 0 to 60 seconds

The Lo P Delay works in conjunction with the Lo P Alarm. Set the Lo P Delay for the maximum acceptable time the pressure can drop below the Lo P set value before the alarm is activated.

Apnea
set 40
sec

Apnea

Increment: 10 seconds

Range: Disabled, 20 to 40 seconds

Set the Apnea interval appropriate to the patient.

The Apnea Alarm senses and reacts to spontaneous breaths.



Learn Base Flow

Press the Learn Base Flow soft key to manually activate the Learn function. The learn period is two minutes and has no effect on unit operation.

NOTE: Normally, the unit automatically learns the base flow. Activate Learn Base Flow only when you make any circuit changes or add supplemental oxygen to the mask. Adding supplemental flow to the circuit (i.e., oxygen at the mask) may alter the baseline flow and activate the Exhalation Port alarm. Activate Learn Base Flow to reestablish the baseline flow alarm threshold. See Section 3.4.3 for further information.

WARNING: Always inspect the exhalation port and circuit for partial obstructions before manually activating the Learn Base Flow. Otherwise, the Vision may establish the obstructed baseline flow as “normal,” which could cause the Exhalation Port alarm to ignore occlusions in the circuit or exhalation port.

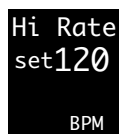


Low Minute Ventilation

Increment: 1 L/min

Range: “Disabled” to 99 L/min

Set the Low Minute Ventilation at a value appropriate to the patient. Reference the measured exhaled minute ventilation value (MinVent) displayed in the Data Display Area.

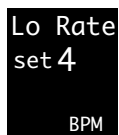


High Rate

Increment: 1 BPM

Range: 4 to 120 BPM

Set the High Rate Alarm at a value appropriate to the patient. Reference the measured breathing rate displayed in the Rate Descriptor.



Low Rate

Increment: 1 BPM

Range: 4 to 120 BPM

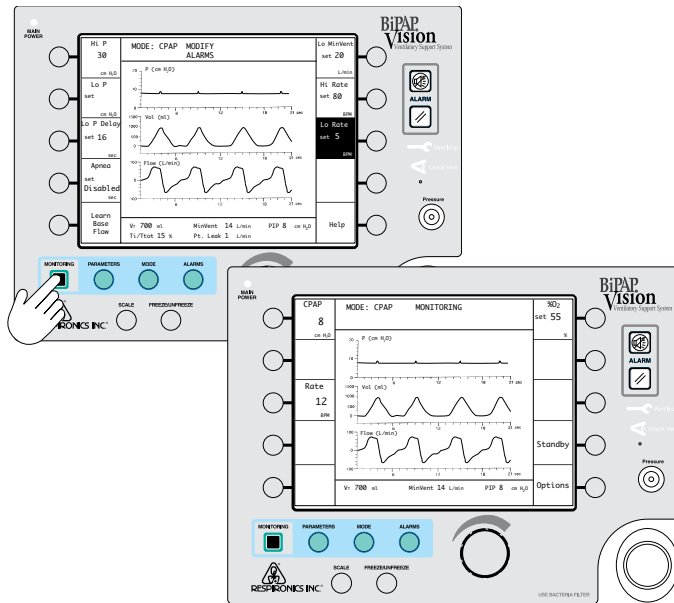
Set the Low Rate appropriate to the patient. Reference the measured breathing rate displayed in the Rate Descriptor.

Help



Press the Help soft key to display a list of alarms and descriptions of alarm settings.

STEP 4 When all alarms are set as desired, press the **MONITORING** key to return to the Monitoring screen.



NOTE: If no user interaction occurs for a 3-minute time span, the unit defaults to the Monitoring screen.

Chapter 9: S/T Mode

9.1 Overview

The S/T Mode of the BiPAP Vision ventilator delivers pressure support with PEEP. The unit triggers Inspiratory Positive Airway Pressure (IPAP) in response to spontaneous inspiratory effort and cycles to Expiratory Positive Airway Pressure (EPAP) during exhalation.

The level of pressure support (PS) delivered is determined by the difference between the IPAP and EPAP settings ($PS = IPAP - EPAP$). The pressure support level (PS) is calculated and continuously displayed on the graphic screen. The value is updated with changes to either the IPAP or EPAP settings.

The S/T Mode ensures that patients will receive a minimum number of breaths per minute if their spontaneous breathing rate drops below the Rate setting. If the patient fails to initiate an inspiration within the interval determined by the Rate control, the unit triggers a timed breath resulting in a pressure-control (machine-triggered, pressure-limited, time-cycled) breath at the set IPAP level. The rate of timed breaths can be adjusted from 4 to 40 BPM and the duration of each breath is controlled by an Inspiratory Time control. The on-screen Rate display flashes when a timed breath is actuated. A (V) marker also appears on the Tidal Volume (V_T) graph to mark the start of a timed breath. See Figure 9-1 for an example.

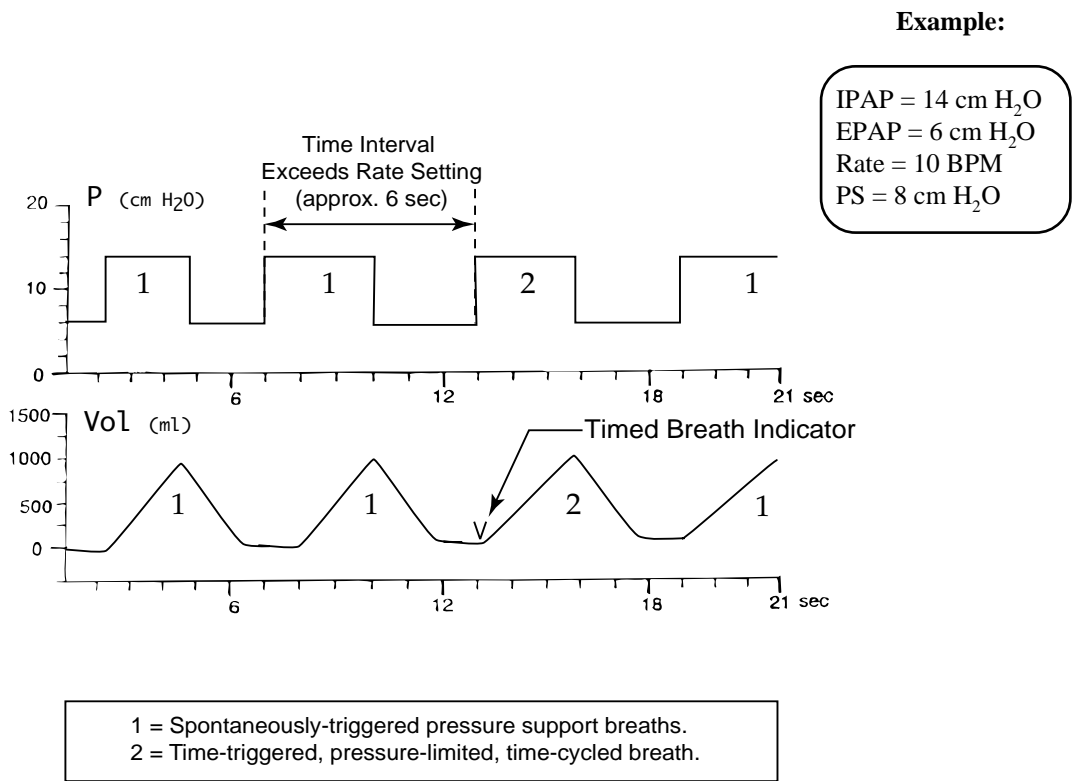


Figure 9-1. Example of Patient-Triggered and Machine-Triggered Breaths.

The active S/T controls include:

- IPAP
- EPAP
- Rate
- Timed Inspiration
- IPAP Rise Time
- %O₂

During operation, the Monitoring screen continuously displays measured data for:

- IPAP
- EPAP
- Rate (total breaths per minute)

The Data Display Area (in the Monitoring screen) displays:

NOTE: If the Vision unit loses power, and power is restored in less than 10 seconds, the unit will return to operation at the same settings that were in effect before power was lost.

- Estimated Exhaled Tidal Volume
- Estimated Minute Ventilation
- Peak Inspiratory Pressure

In the Modify Parameters screen, the Data Display Area also displays:

- Ti/Ttot
- Leak (Patient or Total)
- % Patient-Triggered Breaths

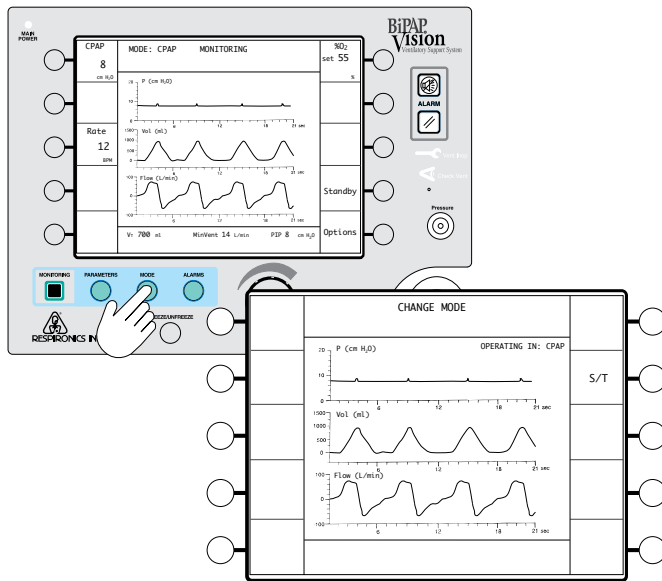
The Graphic Display Area shows real-time graphic displays for:

- Pressure
- Tidal Volume
- Flow

Alarms are available and are immediately activated once the mode is in operation. Alarms for the S/T Mode are accessed from the Alarms screen when the S/T Mode is activated.

9.2 Changing to the S/T Mode

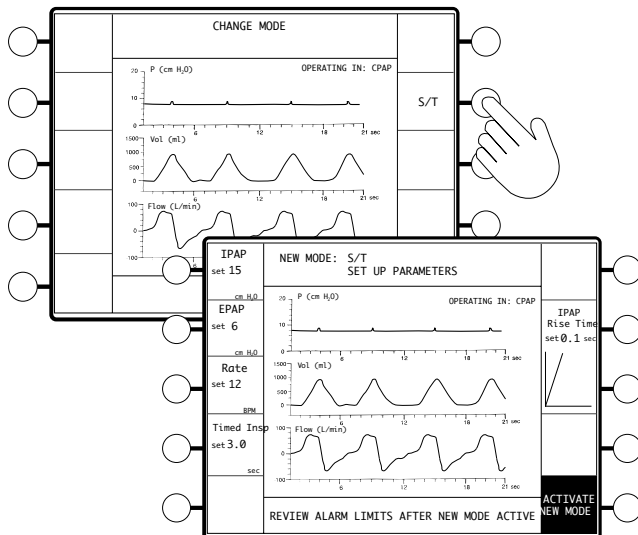
STEP 1 If the unit is not operating in the S/T Mode, press the **MODE** hard key.



The Change Mode screen is displayed. Available modes are displayed in the right column of descriptors.

NOTE: The CPAP Mode remains active and is displayed in the Graphic Area on the screen until you press the **ACTIVATE NEW MODE** soft key.

STEP 2 Press the **S/T** soft key.

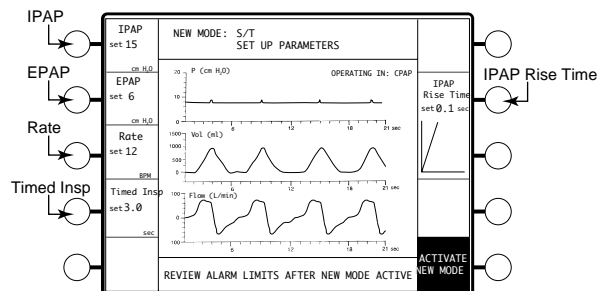


The New Mode/Set-up Parameters screen for the S/T Mode is displayed. You may select for adjustment:

- IPAP
- EPAP
- Rate
- Timed Inspiration
- IPAP Rise Time

NOTE: The **ACTIVATE NEW MODE** descriptor flashes to indicate that the S/T Mode and selected parameters are not active until you press the **ACTIVATE NEW MODE** soft key.

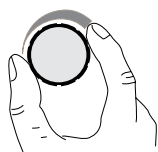
STEP 3 Press the soft key corresponding to the parameter you wish to set.



The selected parameter is highlighted.

STEP 4 Turn the adjustment knob to modify the selected parameter.

Adjusting IPAP



IPAP
set **40**
cm H₂O

Increment: 1 cm H₂O

Range: 4 to 40 cm H₂O

The IPAP Control determines the pressure level during inspiration.

NOTE: IPAP cannot be set lower than EPAP. The Vision ventilator will signal with a soft click if you attempt to set IPAP lower than EPAP and will stop any further adjustment of the value.

Adjusting EPAP

EPAP
set **20**
cm H₂O

Increment: 1 cm H₂O

Range: 4 to 20 cm H₂O

The EPAP Control establishes the baseline pressure (PEEP).

NOTE: EPAP cannot be set higher than IPAP. The Vision ventilator will signal with a soft click if you attempt to set EPAP higher than IPAP and will stop any further adjustment of the value.

WARNING: At low EPAP pressures, the flow through the exhalation port may not adequately clear all exhaled gas from the tubing. Some rebreathing may occur. Refer to Chapter 2 for guidelines on rebreathing.

Adjusting Rate

Rate
set 4
BPM

Increment: 1 BPM
Range: 4 to 40 BPM

The Rate Control determines the frequency of timed breaths.

NOTE: The Rate Control and the Timed Inspiration Control are linked so that the inspiratory time is never longer than the expiratory time or greater than 3 seconds. If the Rate is increased to a value that would exceed a 1:1 Ratio, the Timed Inspiration value is automatically reduced to maintain a 1:1 Ratio.

Adjusting Timed Inspiration

Timed Insp
set 3.0
sec


Increment: 0.1 sec
Range: 0.5 to 3.0 sec

The Timed Inspiration Control determines the duration of a timed breath. Once a timed breath is initiated, the IPAP pressure will be delivered for the duration of the Timed Inspiration setting.

NOTE: The range for Timed Inspiration may be limited by the Rate setting when the Rate is set higher than 10 BPM.

Adjusting IPAP Rise Time

IPAP
Rise Time
set 0.05 sec



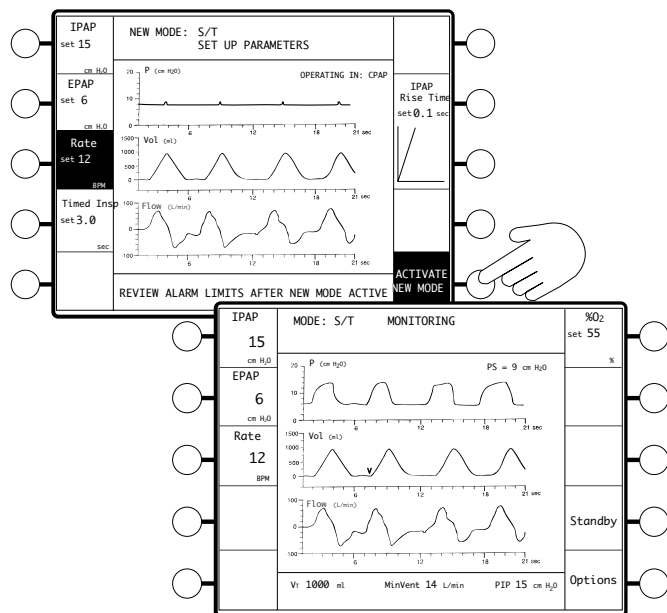
Increments:
0.05, 0.1, 0.2, and 0.4 seconds.
(Four discrete values).

The graph below the set value graphically represents the rise time to assist in determining the proper rise time.

The IPAP Rise Time Control adjusts the pressure rate of change from EPAP to IPAP.

A setting of 0.05 sec represents a rapid rise time; a setting of 0.4 sec represents a slow rise time to IPAP.

STEP 5 Press the flashing **ACTIVATE NEW MODE** soft key.



The unit begins operating in the S/T Mode and the display changes to the Monitoring screen. Verify S/T operation at the intended pressures by viewing the measured values and graphics display on the screen. The Mode/Message Area should indicate S/T Mode.

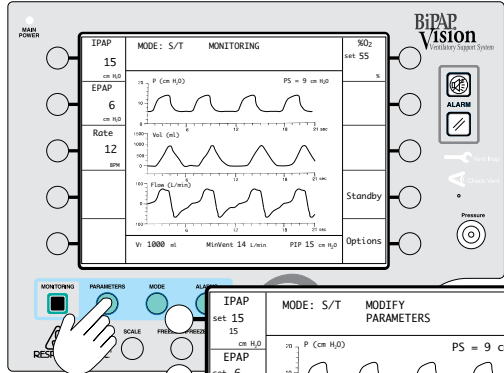
Verify the desired pressure support level by observing the graphic display and the Pressure Support (PS) value displayed above the pressure graphic.

NOTE: Once S/T settings are determined and the mode is activated, press the ALARMS hard key to view the S/T alarm settings. See Section 9.4 for detailed instructions.

9.3 Modifying Parameters in the S/T Mode

NOTE: This section assumes that the S/T Monitoring screen is currently displayed.

STEP 1 Press the **PARAMETERS** hard key.



The Modify Parameters screen is displayed.

Available for modification:

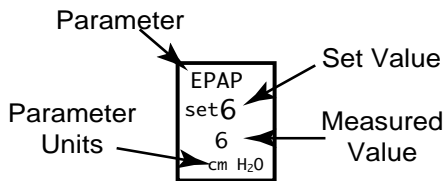
- IPAP
- EPAP
- Rate
- Timed Inspiration
- %O₂
- IPAP Rise Time

The parameters may be modified in any order.

For reference while making changes, the Data Display Area shows:

- Estimated Tidal Volume (**V_T**)
- Estimated Minute Ventilation (**MinVent**)
- Peak Inspiratory Pressure (**PIP**)
- Inspiratory Time/Total Cycle Time (**Ti/Ttot**)
- Patient Leak (**Pt. Leak**) or Total Leak (**Tot. Leak**)
- % Patient-Triggered Breaths (**Pt. Trig**)

STEP 2 Press the soft key corresponding to the parameter you wish to modify.



The selected parameter is highlighted.

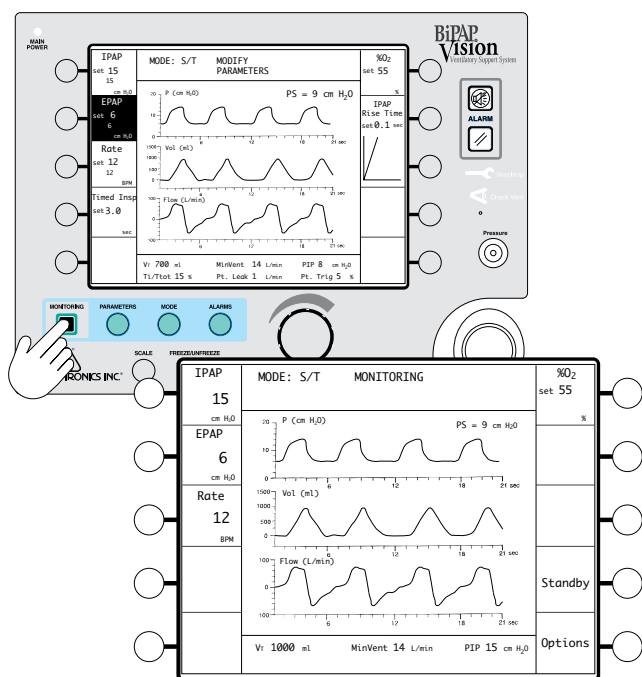
In the Modify Parameters screen, the set value is displayed directly under the parameter name, and the measured value and units of measure are displayed below the set value.

Parameter changes take effect as you enter them.

STEP 3 Turn the adjustment knob to modify the selected parameter.

See Section 9.2 for ranges.

STEP 4 To return to the Monitoring screen, press the **MONITORING** hard key.



The Monitoring screen is displayed.

Verify that parameter changes are active by monitoring the patient and the settings.

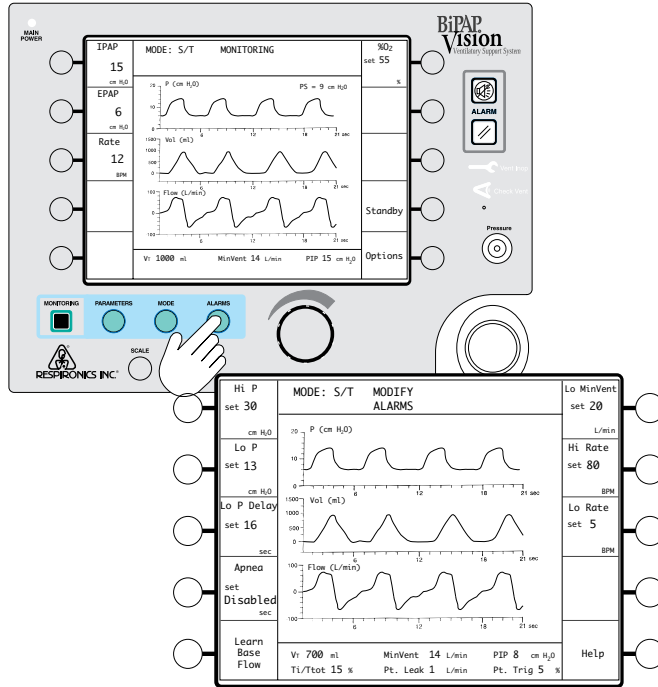
When the S/T settings are confirmed, press the **ALARMS** hard key to verify that the alarm settings are correct. See Section 9.4 for instructions to modify the alarms.

NOTE: If no user interaction occurs for a 3-minute time span, the unit defaults to the Monitoring screen.

9.4 Modifying Alarm Parameters

This section provides instructions for viewing or modifying adjustable alarms in the S/T Mode. Additional details concerning alarm functions and troubleshooting are discussed in Chapter 12, Alarms and Troubleshooting.

STEP 1 Press the **ALARMS** hard key.



The Modify Alarms screen is displayed.

You may select:

- High Pressure Limit (**Hi P**)
- Low Pressure Limit (**Lo P**)
- Low Pressure Alarm Delay (**Lo P Delay**)
- Apnea
- Learn Base Flow
- High Rate (**Hi Rate**)
- Low Rate (**Lo Rate**)
- Low Minute Ventilation (**Lo MinVent**)

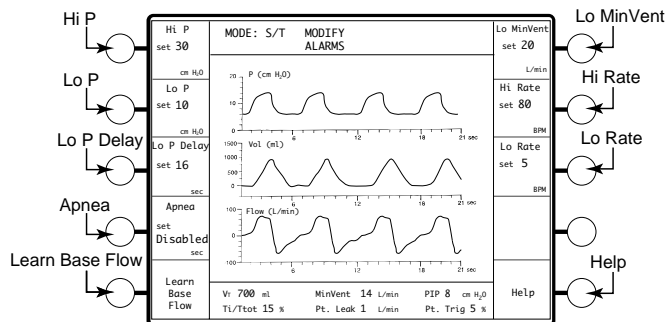
You may modify the alarms in any order.

Also available is a Help screen that describes each adjustable alarm function available for the S/T Mode. To access the Help screen, press the Help soft key.

NOTE: New alarm values are active as soon as they are entered.

NOTE: Alarm values are stored during power off conditions.

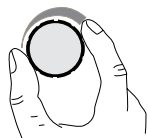
STEP 2 Press the soft key of the alarm you wish to modify, or press the Learn Base Flow soft key to initiate a baseline measurement. Check the exhalation port for occlusions before initiating a Learn Base Flow sequence.



The alarm parameter is highlighted.

STEP 3 Turn the adjustment knob to modify the selected parameter.

NOTE: See Chapter 12, Alarms and Troubleshooting, for additional details on alarm functions.



Hi P
set 50
cm H₂O

High Pressure Alarm

Increment: 1 cm H₂O

Range: 5 to 50 cm H₂O

The High Pressure Alarm should be set above the IPAP level.

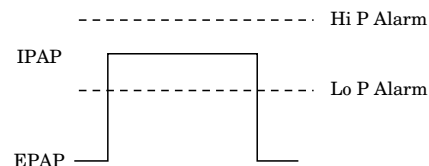
Lo P
set 10
cm H₂O

Low Pressure Alarm

Increment: 1 cm H₂O

Range: "Disabled" to 40 cm H₂O

The Low Pressure Alarm should be set below the IPAP level and above the EPAP level. When set in this manner, the alarm works in conjunction with the Low Pressure Delay to indicate if there is a failure to trigger between the two pressure levels. See the illustration below:



WARNING: In the S/T Mode, the low pressure setting should be set below the IPAP level and above the EPAP level to detect a failure to trigger to the IPAP level. Setting the Low Pressure Alarm below the EPAP level may not detect a failure to trigger.

Lo P Delay
set 60
sec

Low Pressure Alarm Delay

Increment: 1 second

Range: "Disabled" to 60 seconds

The Lo P Delay works in conjunction with the Lo P Alarm. Set the Lo P Delay for the maximum acceptable time the pressure can drop below the Lo P set value before the alarm is activated.

Apnea
set 40
sec

Apnea Alarm

Increment: 10 seconds

Range: Disabled, 20 to 40 seconds

Set the Apnea interval appropriate to the patient. The alarm senses spontaneous breaths only.

Learn Base Flow



Press the Learn Base Flow soft key to manually activate the Learn function. The learn period is two minutes and has no effect on unit operation.

NOTE: Normally, the unit automatically learns the base flow. Activate Learn Base Flow only when you make any circuit changes or add supplemental oxygen to the mask. Adding supplemental flow to the circuit (i.e., oxygen at the mask) may alter the baseline flow and activate the Exhalation Port alarm. Activate Learn Base Flow to reestablish the baseline flow alarm threshold. See Section 3.4.3 for further information.

WARNING: Always inspect the exhalation port and circuit for partial obstructions before manually activating the Learn Base Flow. Otherwise, the Vision may establish the obstructed baseline flow as “normal,” which could cause the Exhalation Port alarm to ignore occlusions in the circuit or exhalation port.

Low Minute Ventilation



Increment: 1 L/min
Range: “Disabled” to 99 L/min

Set the Low Minute Ventilation Alarm appropriate to the patient. Reference the measured exhaled minute ventilation (MinVent) displayed in the Data Display Area.

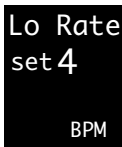
High Rate



Increment: 1 BPM
Range: 4 to 120 BPM

Set the High Rate appropriate to the patient. Reference the measured breathing rate displayed in the Rate descriptor.

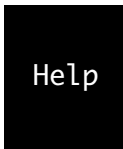
Low Rate



Increment: 1 BPM
Range: 4 to 120 BPM

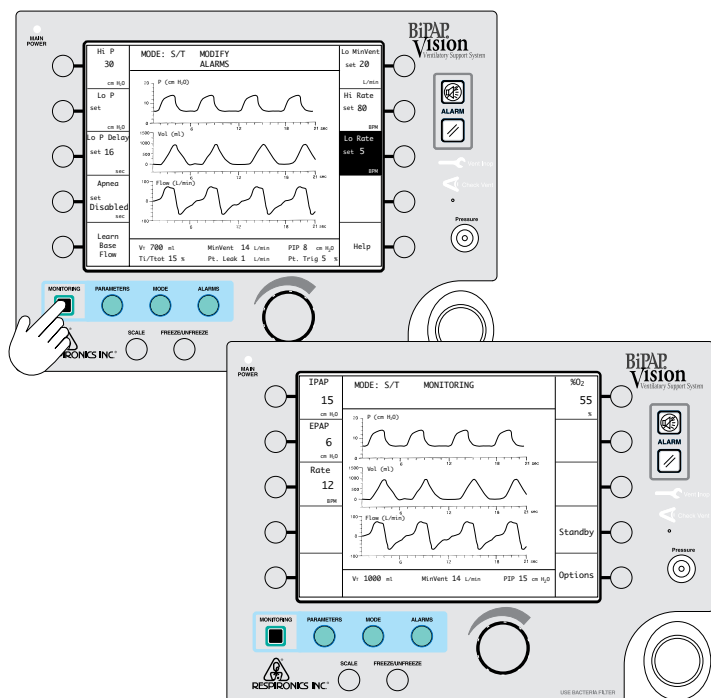
Set the Low Rate appropriate to the patient. Reference the measured breathing rate displayed in the Rate descriptor.

Help



Press the Help soft key to display a list of alarms and descriptions of alarm settings.

STEP 4 When all alarms are set as desired, press the **MONITORING** key to return to the Monitoring screen.



NOTE: If no user interaction occurs for a 3-minute time span, the unit defaults to the Monitoring screen.

Chapter 10: Options Screen

10.1 Overview

This chapter describes how to use the Options screen. The Options screen, available from the Monitoring screen and shown in Figure 10-1, allows you to :

- view and reset the error messages
- test the alarms
- display the system information
- change the graphic display between bar graphs and waveforms
- reset the total time at pressure
- adjust the brightness of the display
- adjust the contrast of the display
- invert the display

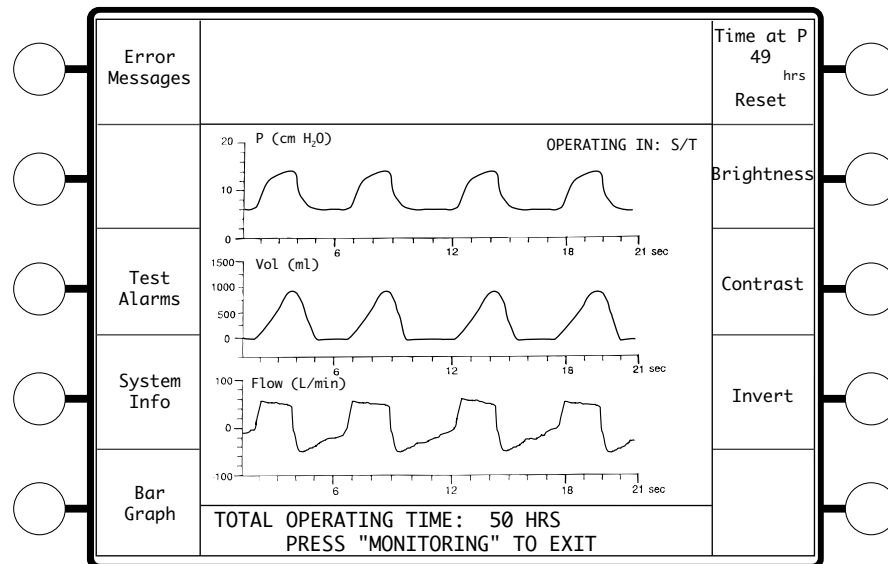
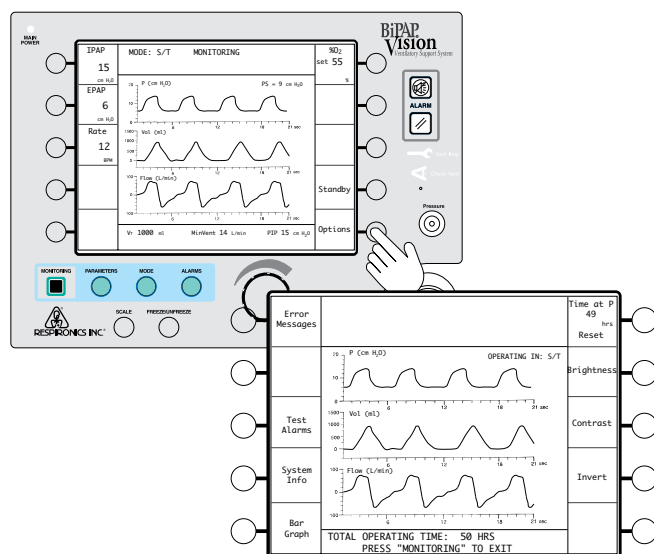


Figure 10-1. The BiPAP Vision Options Screen.

10.2 Using the Options Screen

— Press the **Options** soft key in the Monitoring screen.



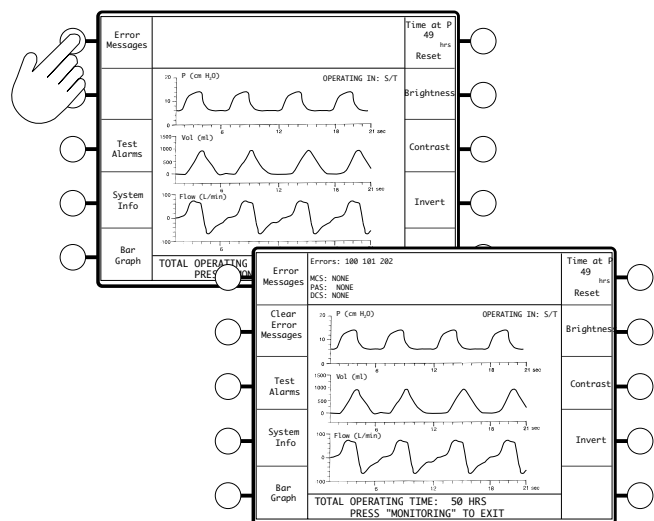
The Options screen is displayed.

You may select:

- Error Messages
- Test Alarms
- System Info
- Bar Graph
- Time at Pressure Reset
- Brightness
- Contrast
- Invert

10.2.1 ERROR MESSAGES

The Check Ventilator condition stores an error message in the Error Message screen. The error message history is helpful for troubleshooting the Vision ventilator and should be checked by the biomedical personnel before contacting an authorized service center or the manufacturer.



Error messages are displayed in the Mode/Message Area for reference to the Service Manual.

When the errors have been corrected, clear the message by pressing the Clear Error Messages soft key.

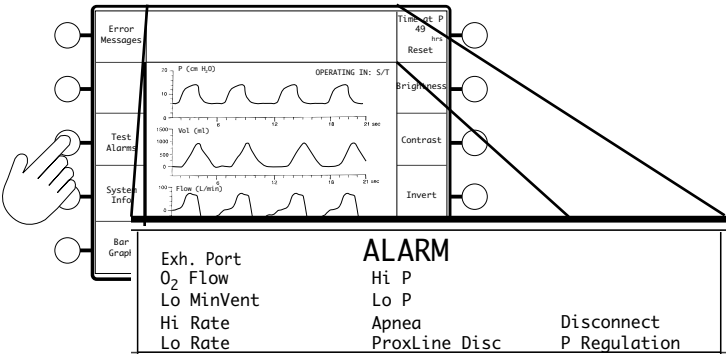
NOTE: Repairs should be performed by authorized service personnel only.

10.2.2 TESTING THE ALARMS

The Vision unit allows you to test all of the audible and visual alarm indicators. The Test Alarms Control activates a solid audible tone and visual alarms for a minimum of 4 seconds.

NOTE: The Alarm Test should be performed before each new setup. Refer to Chapter 7, Performance Verification.

— Press the **Test Alarms** soft key.



All alarm messages are displayed in the Mode/Message area, the Ventilator Inoperative and Check Ventilator indicators activate, and the audible alarm sounds.

NOTE: The alarms should be listed in the Mode/Message Area as shown above. If either the visual or audible alarms fail to operate, discontinue using the unit and refer it for service.

NOTE: For details on each alarm function, see Chapter 12, Alarms and Troubleshooting.

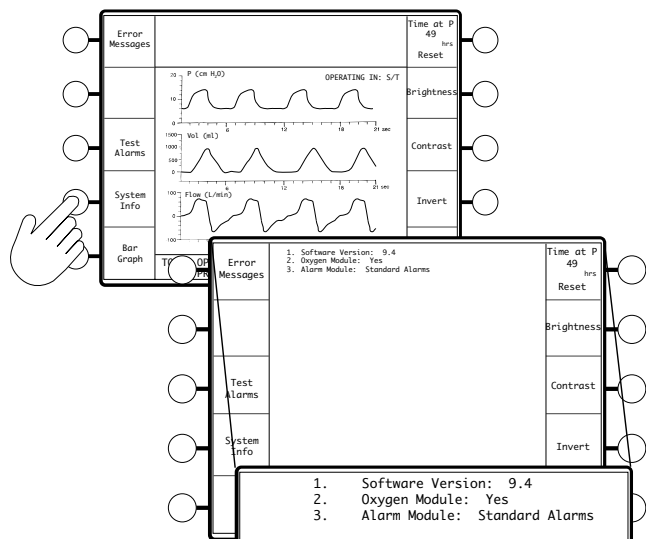
10.2.3 DISPLAYING SYSTEM INFORMATION

System Information provides the following information:

NOTE: In the U.S., the “optional” alarm package is installed in all Vision models.

- The installed software version
- Verifies the installation of the oxygen module
- The alarm package that is installed.

— Press the **System Info** soft key.



The display lists the system information.

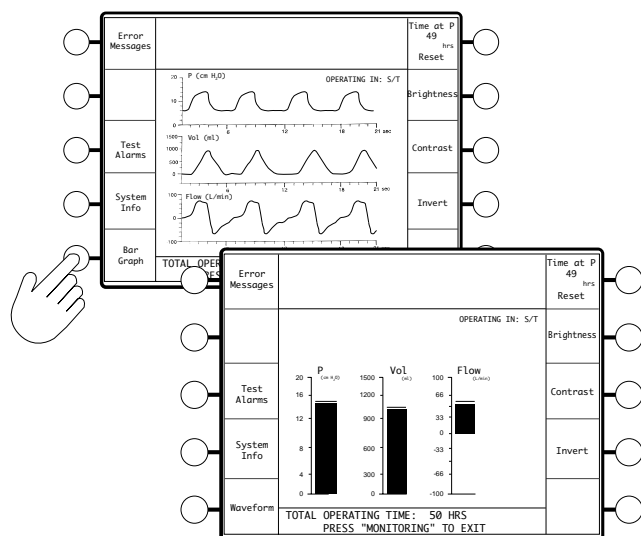
NOTE: A “NO” response in the Oxygen Module line may mean that the module is not functional.

The Alarm Module line will display “Optional Alarm Module” if the optional alarm module is installed.

10.2.4 CHANGING THE GRAPHIC DISPLAY

You may choose to display the Pressure, Volume, and Flow as waveforms or as bar graphs.

— Press the **Bar Graph** soft key.



The Pressure, Volume, and Flow data are displayed as bar graphs. The Bar Graph soft key Descriptor changes to “Waveform”.

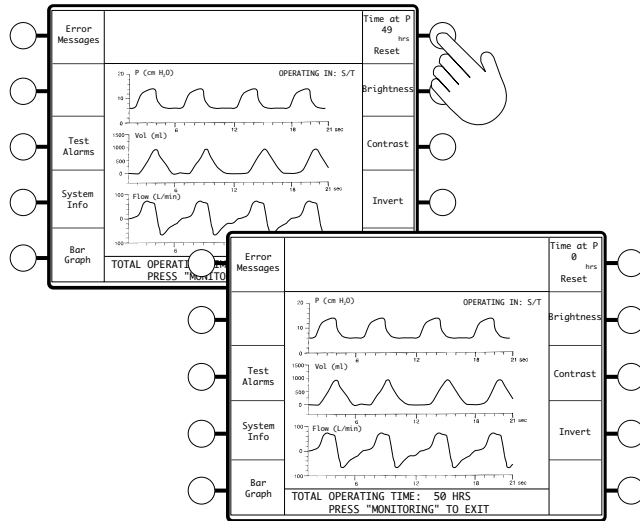
To return to the waveforms, press the Waveform soft key.

10.2.5 RESETTING THE TIME AT PRESSURE

The Time at Pressure records the total time of therapy. The timer only operates when spontaneous or timed breaths are present, and can only be reset manually. The display updates on the hour only.

The Time at Pressure is displayed in the descriptor when you select the Options screen.

— To reset the timer, press the **Time at P** soft key from the Options screen.

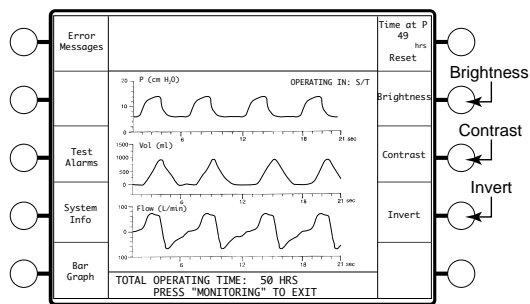


The hours are reset to 0.

10.2.6 ADJUSTING THE DISPLAY

The display options include the brightness, contrast, and invert options.

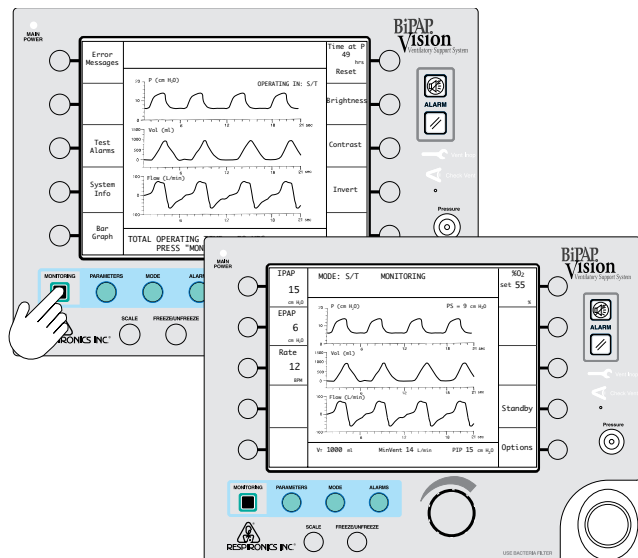
— Press the soft key corresponding to the option you wish to modify.



- For Brightness and Contrast, turn the adjustment knob to change the screen brightness or contrast.
- For Invert, the screen colors reverse when you press the Invert soft key.

10.2.7 TOTAL OPERATING TIME The “Total Operating Time” shown in the Data Display Area is a time meter that runs when the Start/Stop Switch is in the **START** position. The time is stored when the Vision ventilator is stopped, and does not reset.

10.2.8 RETURNING TO THE MONITORING SCREEN — When you have completed the desired modifications, press the **MONITORING** hard key to return to the Monitoring screen.



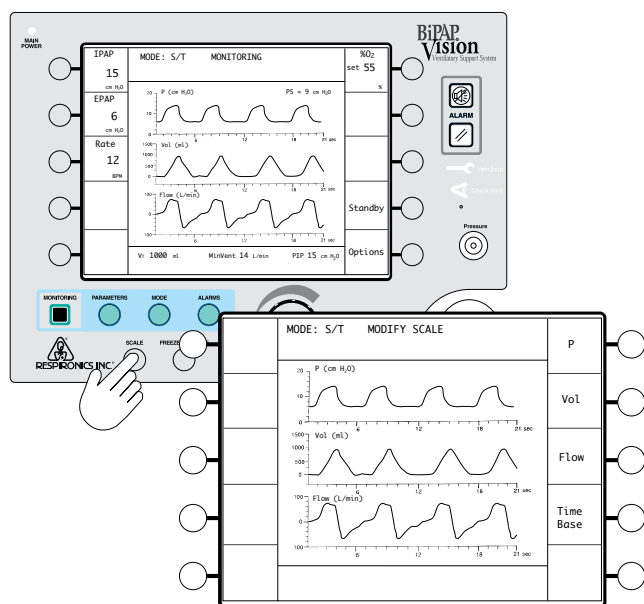
NOTE: If no user interaction occurs for a 3-minute time span, the unit defaults to the Monitoring screen.

NOTE: All modifications described in this chapter, except the Time Base adjustment, apply to both the waveform display and the bar graph display.

11.2 Modifying the Display Graph Scales

The Vision unit allows you to modify the scale of the Pressure, Volume, and Flow graphs and the Time Base.

— Press the **SCALE** hard key.



The Modify Scale screen is displayed.

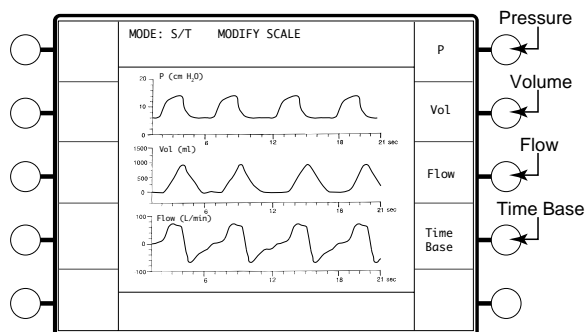
The following scales are active:

- Pressure
- Volume
- Flow
- Time Base

You may modify the scales in any order.

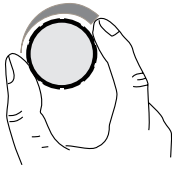
11.2.1 MODIFYING THE SCALES

STEP 1 Press the soft key corresponding to the scale you wish to change.

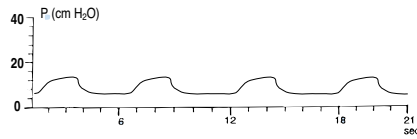


The selected scale is highlighted for change.

STEP 2 Turn the adjustment knob as needed.



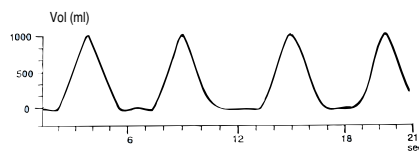
Pressure Scale



Increment: 5 cm H₂O

Full Scale Range: 0 cm H₂O to 50 cm H₂O

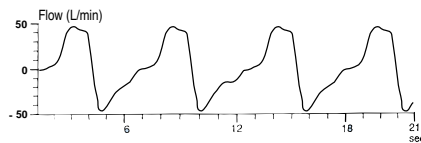
Volume Scale



Increment: 500 ml

Full Scale Range: 0 ml to 4000 ml

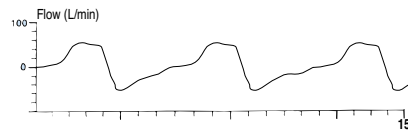
Flow Scale



Increment: 50 L/min

Full Scale Range: -300 L/min to +300 L/min

Time Base



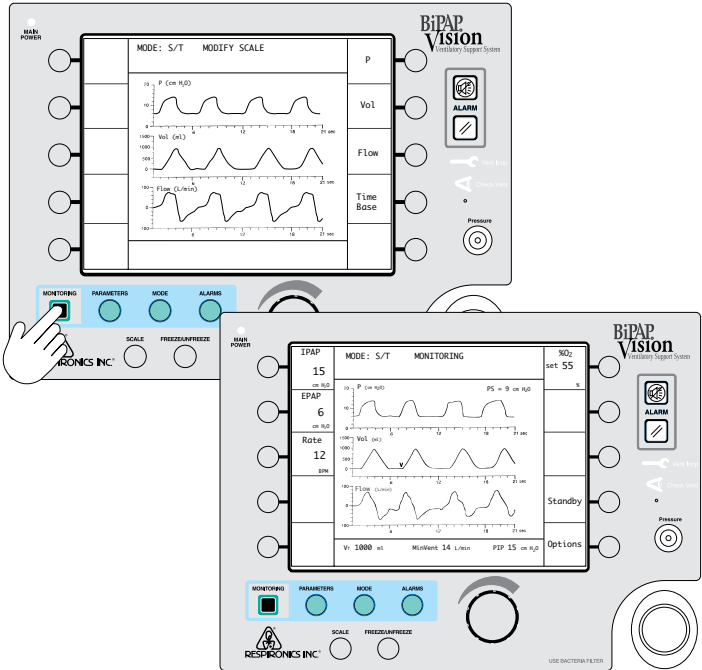
Increment: 3 seconds

Full Scale Range: 3 sec to 24 sec

NOTE: The Time Base adjustment simultaneously adjusts the time base scale of all waveforms.

11.2.2 RETURNING TO THE MONITORING SCREEN

— When you have completed the scale modifications press the **MONITORING** hard key to return to the Monitoring screen.



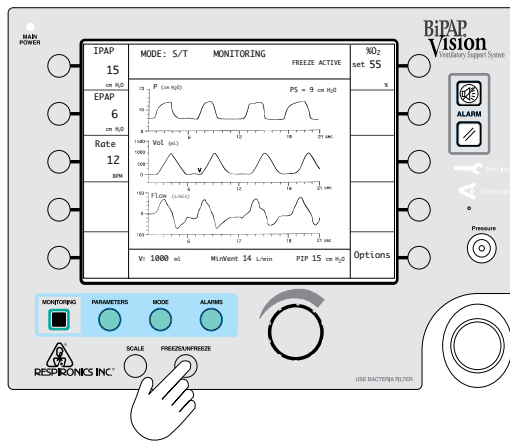
NOTE: If no user interaction occurs for a 3-minute time span, the unit defaults to the Monitoring screen.

11.3 Summary of Display Graph Scale Ranges and Increments

PARAMETER	FULL SCALE RANGE	INCREMENTS
Pressure Scale	5 to 50 cm H ₂ O	5 cm H ₂ O
Volume Scale	0 to 4000 ml	500 ml
Flow Scale	-300 to +300 L/min	50 L/min
Time Scale	3 to 24 sec	3 sec

11.4 Freezing and Unfreezing the Graphs

- Press the **FREEZE/UNFREEZE** hard key.



The graphs stop scrolling but the Data Display Area remains active and continues to update with each breath.

When the Freeze graph is active, the message “FREEZE ACTIVE” appears in the Mode/Message Area.

- To unfreeze the graphs, press the **FREEZE/UNFREEZE** key a second time. The graphs resume scrolling. The screen is erased and starts a new scroll from the left.

Chapter 12: Alarms and Troubleshooting

12.1 Alarms Overview

This chapter describes the alarm parameters, how to troubleshoot alarm conditions, and how to troubleshoot mask problems.

The Vision unit contains two types of alarms: System and Adjustable. System Alarms are integral to the Vision unit to check system operations such as AC power and internal alarm battery. System Alarms are not adjustable.

Adjustable Alarms are used to monitor patient parameters, such as high pressure and apnea. These alarms can be adjusted through the Modify Alarms screen.

The Vision ventilator may be connected from the Nurse Call/Remote Alarm connector to most hospital call and alarm systems. You must verify whether the institution's system is a Normally OPEN or Normally CLOSED circuit. A Normally OPEN system refers to an alarm system that detects an open circuit in normal conditions and a closed circuit during alarm conditions. A Normally CLOSED system detects a closed circuit in normal circumstances and an open circuit during alarm conditions. The Vision unit is manufactured with a Normally OPEN configuration. The Vision unit may be changed to interface with either system. Refer to the BiPAP Vision Service Manual for details.

WARNING: For the following reasons, attention by qualified medical personnel is required whenever a patient is attached to a ventilator:

- a. Some malfunctions require immediate corrective action.
- b. No monitor, or any combination of monitors, can give absolute assurance of warning in the event of any and every form of malfunction of the ventilator or gas delivery system. A trained caregiver should be able to respond in a timely manner to alarm conditions. The attention level required when a patient is attached to an assist ventilator must be determined by the physician based on the requirements of the patient.

WARNING: The Adjustable Alarm settings should be reevaluated whenever a change in settings is made on the ventilator.

NOTE: The alarm test should be performed before using the ventilator, and should be verified daily. Verify that both the audible and visual alarm indicators are active during the alarm test. If either component is not active, have the ventilator serviced.

12.1.1 ALARM INDICATIONS

All alarms contain an audible and visual element. In the event of an alarm condition, the audible alarm sounds and the screen changes to show the alarm condition in the Mode/Message Area. See Figure 12-1. The audible element is described in Section 12.2 for each type of alarm condition.

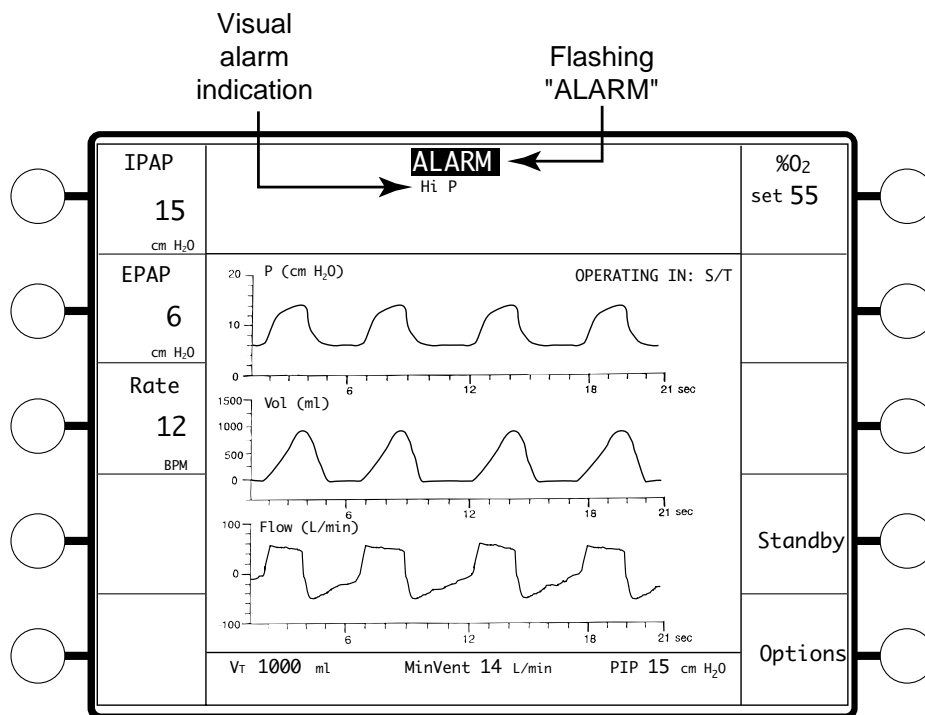


Figure 12-1. Alarm Indications.

12.1.2 ALARM SILENCE AND RESET

NOTE: The Apnea and Ventilator Inoperative alarms override the silence period and trigger both a visual and audible alarm.

NOTE: During an alarm condition, items that are accessed with the Options soft key and that use the Mode/Message area for display are inaccessible. The displays are automatically returned when the alarm condition is cleared and reset.

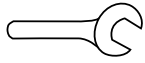
The audible indicator of most alarms is self-cancellable if the alarm condition is corrected. The Alarm Silence hard key turns off the audible alarm for two minutes. Any further pressing of the Alarm Silence hard key has no effect on the alarm. When the alarm silence is active, the message “Alarm Silenced” appears in the Mode/Message Area for the duration of the silence period. Any new alarm conditions, except Apnea and Vent Inop, that occur during the silence period will provide a visual alert, but will not trigger the audible alarm.

The visual indicator in the Mode/Message Area is cancelled only when the Alarm Reset hard key is pressed. The Alarm Reset hard key cancels the alarm silence period and resets the visual indicators and alarm logic. The alarm immediately reactivates if the condition causing the alarm has not been corrected.

The Nurse Call/Remote Alarm feature self-cancels if the alarm condition is corrected. The Alarm Silence key turns off the Nurse Call/Remote Alarm feature for two minutes.

12.2 Alarms

This section describes each alarm display, what it means, some possible causes of the alarm, and what corrective action you should take. All alarms, when activated, will display an alarm message on the screen along with an audible alarm tone.



Vent Inop

Ventilator Inoperative Alarm

Description

A power failure or system malfunction that results in a machine shutdown. The system valves open to atmosphere to permit spontaneous breathing through the system. Note, however, that rebreathing of exhaled air in the circuit will occur in such circumstances. Audible and visual indicators are activated. The audible indicator cannot be silenced, and is a continuous tone: ■■■■■

A Ventilator Inoperative alarm activates the Nurse Call/Remote Alarm feature.

Possible Causes

Corrective Action

AC power failure or system level failure that impairs performance of the unit

1. Discontinue use; verify that power cord is plugged in to a live outlet and into the unit.

2. Discontinue use; unit requires service.



Check Vent

Check Ventilator Alarm

Description

A potential abnormal operating condition has occurred requiring operator attention. Audible and visual indicators are activated. The unit continues to operate. The audible indicator is a pattern of three beeps every 2.5 seconds: ●●●

A Check Ventilator alarm does not activate the Nurse Call/Remote Alarm feature.

Possible Causes

Corrective Action

System error

1. See Section 10.2.1 to display Error Code. Check the Service Manual for code interpretation.

2. Unit may require service.

The remainder of this section describes the adjustable patient alarms. The audible indicator for these alarms is a repeating pattern of three beeps followed by two beeps: ●●● ●●. Adjustable alarms activate the Nurse Call/Remote Alarm feature.

Apnea

Apnea Alarm Description

An adjustable alarm that monitors spontaneously-triggered breaths within a user-selectable time interval. The time interval resets with each spontaneous trigger. If a spontaneous trigger is not detected within the selected apnea time interval, audible and visual alarm indicators are activated. The audible self-cancels when two consecutive spontaneous triggers are detected. The apnea alarm can be disabled.

Possible Causes

Corrective Action

Patient not breathing or unable to trigger ventilator

Reevaluate the patient.

Circuit may be disconnected

Check the patient circuit.

Improperly set alarm limit

Reevaluate the patient and alarm setting.

Disconnect

Patient Disconnect Alarm

Description

A system alarm that monitors outlet flow. Audible and visual alarm indicators are activated if the ventilator measures continuously excessive flow (e.g., patient disconnect). If a spontaneous breath is detected, or the Alarm Reset key is pressed, the ventilator cancels the alarm and attempts to deliver therapy.

Possible Causes

Corrective Action

Patient circuit is disconnected from the ventilator.

Reattach the circuit, press Alarm Reset.

Mask is disconnected from the patient.

Reattach mask, press Alarm Reset.

Exh. Port

Exhalation Port Alarm

Description

A system alarm that monitors baseline circuit flow. If the baseline circuit flow, for a period of one minute, is less than the greater of 5 L/min or 50 %, of the intentional exhalation port leak (e.g., if the patient circuit or exhalation port is obstructed) audible and visual alarm indicators are activated. The audible self-cancels if the flow increases to within 5 L/min or 50 % of the baseline leak. See section 3.4.3 for a description of the baseline.

Possible Causes

Corrective Action

Exhalation port blockage	Examine the exhalation port to verify that the vent is open.
Increase in circuit resistance or a circuit occlusion proximal to the exhalation port	Check the exhalation port for occlusions.
Added supplemental flow at mask (e.g., oxygen administration) without activating Learn Base Flow function	Manually activate Learn Base Flow from the Modify Alarms screen to establish a new baseline flow and alarm threshold (see Section 8.4 or 9.4).

Hi P

High Pressure Alarm

Description

Adjustable alarm that activates audible and visual indicators if the proximal air pressure exceeds the high pressure setting for more than 0.5 second. The inspiration is terminated. The audible indicator self-cancels if the subsequent breath is below the high pressure setting.

Possible Causes

Corrective Action

Improper alarm setting; alarm limit set below set inspiratory pressure	Review high pressure alarm setting.
Patient coughing during inspiratory cycle	Observe patient.

Hi Rate

High Rate Alarm

Description Adjustable alarm that continuously compares the total breath rate (machine + spontaneous) with the Hi Rate alarm setting. If the measured value is higher than the alarm setting, the audible and visual indicators are activated. The audible self-cancels if the total breath rate drops below the alarm setting.

Possible Causes	Corrective Action
-----------------	-------------------

Increase in patient breathing rate	Reevaluate the patient and alarm settings.
------------------------------------	--

Improperly set alarm limit	Reevaluate the patient and alarm settings.
----------------------------	--

Lo MinVen

Low Minute Ventilation Alarm

Description An adjustable alarm that activates audible and visual indicators if the minute ventilation is below the alarm setting. The audible indicator self-cancels if the patient minute ventilation increases above the alarm setting.

Possible Causes	Corrective Action
-----------------	-------------------

Patient disconnect or large leak	Check circuit and patient connection.
----------------------------------	---------------------------------------

Decrease in patient rate or tidal volume	Reevaluate the patient and alarm settings.
--	--

Improperly set alarm limit	Reevaluate the patient and alarm settings.
----------------------------	--

WARNING: The Exhalation Port Test should be performed before starting therapy to ensure the accuracy of estimated tidal volume and minute ventilation readings. Accurate minute ventilation readings are necessary to ensure the accuracy of the low minute ventilation alarm when it is set below 3 L/min.

Lo P

Low Pressure Alarm

Description

An adjustable alarm that activates audible and visual indicators if the proximal airway pressure remains below the low pressure setting for the time set with the Low Pressure Delay control. The audible indicator self-cancels if the pressure rises above the low pressure setting.

Possible Causes

Corrective Action

Patient disconnect or large leak	Check circuit and patient connection.
Patient inspiratory demand exceeds machine delivered flow	1. Check the patient circuit for obstructions. 2. Check filters.
Low Pressure Delay set incorrectly	Review Low Pressure Alarm Delay setting.
Improper alarm setting; alarm limit set above set inspiratory pressure	Review low pressure alarm setting.

Lo Rate

Low Rate Alarm

Description

Adjustable alarm that continuously compares the total breath rate (machine + spontaneous) with the Lo Rate alarm setting. If the measured value is lower than the alarm setting, the audible and visual indicators are activated. The audible self-cancels if the total breath rate increases above the alarm setting.

Possible Causes

Corrective Action

Decrease in patient breathing rate	Reevaluate the patient and alarm settings.
Patient unable to trigger ventilator	Reevaluate the patient and alarm settings.
Improperly set alarm limit	Reevaluate the patient and alarm settings.

02 Flow

Low Oxygen Flow Alarm

Description System alarm that activates audible and visual indicators if the oxygen supply is lost. The audible alarm does not self-cancel after correction. During the alarm condition, the Vision ventilator continues to function.

Possible Causes	Corrective Action
Insufficient oxygen supply pressure	Check the oxygen supply.
Obstructed O ₂ inlet filter	Check the Oxygen Module filter; replace if necessary.

P Regulation

Loss of Pressure Regulation Alarm

Description A system alarm that activates audible and visual indicators if the measured proximal pressure differs more than ± 5 cm H₂O of the set pressure for greater than 5.0 second. The audible indicator self-cancels if the measured proximal pressure returns to within ± 5 cm H₂O of the set value.

Possible Causes	Corrective Action
Large leak	Check the patient circuit.
Occluded patient circuit or proximal pressure line	Check the patient circuit and proximal pressure line.
System error	Unit requires service.

[†] Alarm available with optional oxygen module installed.

ProxLine Disc

Proximal Pressure Line Disconnect Alarm

Description A system alarm that activates audible and visual indicators if the proximal pressure measures less than 1.0 cm H₂O for greater than 1 second. The audible indicator self-cancels if the measured proximal pressure increases above 1.0 cm H₂O. The alarm is automatically disabled when the unit goes into flow limit control.

Possible Causes	Corrective Action
Proximal pressure line disconnection or obstruction	Check the proximal pressure line.

WARNING: If an alarm condition cannot be corrected, discontinue use and refer the unit for service.

12.3 Mask Discomfort and Corrective Actions

Problem	Possible Causes	Corrective Action
1. Mask feels uncomfortable to wear.	Improper Softcap™ or headgear adjustment.	Check the Softcap or headgear adjustment as described in the Softcap or headgear instructions.
	Improper mask fit.	Check for correct mask sizing. Try to refit the mask or try a different size mask.
2. Significant air leak around the mask.	Improper mask fit.	Check for correct mask sizing. Try to refit the mask or try a different size mask.
	Improper Softcap or headgear adjustment.	Check the Softcap or headgear adjustment as described in the Softcap or headgear instructions.
3. Redness occurs where the mask cushion comes in contact with the skin.	Improper mask fit.	Try to refit the mask or try a different size mask.
	Improper mask cleaning. (Reusable mask only)	Be sure to rinse mask after cleaning to remove residue. See the mask cleaning instructions in the mask instruction sheet.
	Irritation or allergic reaction.	Use a barrier between the skin and the mask. If the irritation continues, discontinue use of the mask and consider alternate interfaces.
4. Runny nose or nasal congestion.	Airflow reaction.	Consider the use of a humidifier in the patient circuit.
5. Dryness in throat or nose.	Dry air.	Consider the use of a humidifier in the patient circuit.
6. Nasal, sinus, or ear pain.	Sinus or ear infection.	Notify the physician.

Chapter 13: Oxygen Delivery with the Vision Ventilator

13.1 Overview

The Vision ventilator provides an Oxygen Module to deliver and control oxygen to the patient. The module provides control of oxygen concentration from 21 percent to 100 percent with stable and reliable delivery of the concentration.

WARNING: Oxygen should be administered only on the order of a physician.

WARNING: Oxygen accelerates fires. Keep the Vision ventilator and the oxygen source away from heat, open flames, any oily substance, or other sources of ignition. DO NOT smoke in the area near the Vision ventilator or the oxygen source.

WARNING: Supplemental oxygen should not be added to the breathing circuit by placing the source where the gas will be entrained through the inlet filter on the rear of the unit.

WARNING: Never attach oxygen tubing or any positive pressure source to the Pressure Line Port on the front panel of the Vision ventilator.

WARNING: When administering supplemental oxygen by means other than the optional Oxygen Module, a controlled method of setting and measuring inspired oxygen concentrations cannot be accomplished. At a fixed flow rate of supplemental oxygen, the inspired oxygen concentration will vary, depending on the IPAP and EPAP settings, patient breathing pattern, and the leak rate. Substantial leaks around the mask may reduce the inspired oxygen concentration to less than the expected concentrations.

WARNING: Continuous patient monitoring is recommended while administering oxygen. Patient monitoring should consist of, at a minimum, patient observation and pulse oximetry. Arterial blood gas measurements should be used when necessary.

WARNING: When the Oxygen Module is used in conjunction with the PAV/T mode, excessive patient pressure may result if you exceed the recommended inlet pressure of the oxygen module.

WARNING: When using oxygen with the Vision ventilator, the oxygen supply must comply with local regulations for medical oxygen.

NOTE: When the Oxygen Module is in use, the Vision ventilator will display the set oxygen concentration, which may not be the actual oxygen concentration delivered to the patient. Respironics recommends the use of an external oxygen analyzer added to the patient circuit to measure actual oxygen concentration. Continuous patient monitoring should consist of, at a minimum, patient observation and pulse oximetry. Arterial blood gas measurement should be used when necessary.

13.2 Oxygen Module

The Respironics Oxygen Module is on the rear of the Vision ventilator. The module requires a high-pressure oxygen source for operation. Figure 13-1 shows the Oxygen Module and the O₂ supply connection.

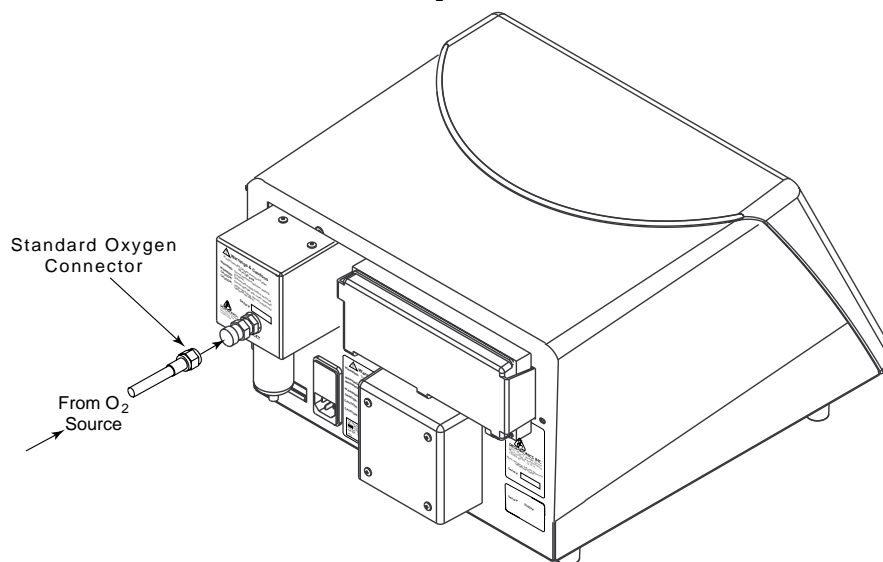


Figure 13-1. Oxygen Supply Attachment.

The Oxygen Module accepts a standard oxygen inlet connector from a medical-grade oxygen source. The source may range from 50 to 100 psig. An inlet filter in the Oxygen Module provides a collection efficiency of 100% for 40.0 micron and larger particles.

Note: The high pressure oxygen source must be capable of supplying the peak inspiratory oxygen flow based on the set oxygen concentration and patient inspiratory flow.

When the module is installed, the %O₂ Descriptor appears in the right column as shown in Figure 13-2.

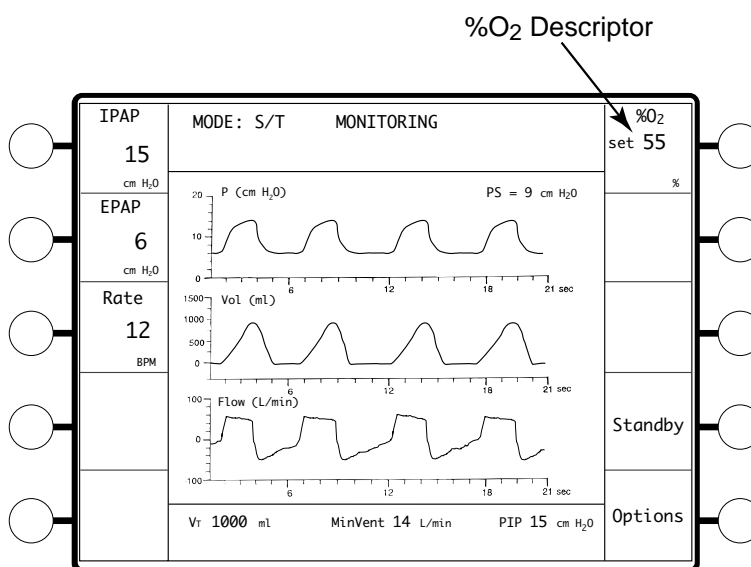


Figure 13-2. Oxygen Concentration Descriptor.

The Oxygen Module is recommended when oxygen delivery with the BiPAP Vision System is needed. It regulates and proportions oxygen into the air from the blower according to the oxygen concentration level set on the Parameters screen. The Vision % FiO₂ (Fraction of Inspired Oxygen) Setting Control is calibrated at a nominal patient setting of 15 breaths per minute (BPM) and 500 ml tidal volume. Under these conditions the delivered FiO₂ is accurate to within the greater of $\pm 3\%$ FiO₂ or $\pm 10\%$ of setting. The selectable concentration range is from 21% to 100%.

Because Vision does not have an internal blender, the clinician should expect some change in delivered FiO₂ with changes in respiratory settings or patient parameters. Actual delivered FiO₂ concentration should be monitored, as appropriate to the patient's condition.

Typical delivered FiO₂ concentration can be estimated from the following table:

Respiratory Parameters	Expected Delivered FiO ₂ vs. Setting
250 ml, 10 BPM	up to 15% FiO ₂ higher than setting
250 ml, 20 BPM	greater of $\pm 3\%$ FiO ₂ or $\pm 10\%$ of setting
250 ml, 30 BPM	up to 10% FiO ₂ lower than setting
500 ml, 10 BPM	greater of $\pm 3\%$ FiO ₂ or $\pm 10\%$ of setting
500 ml, 15 BPM	greater of $\pm 3\%$ FiO ₂ or $\pm 10\%$ of setting
500 ml, 30 BPM	up to 10% FiO ₂ lower than setting
800 ml, 10 BPM	greater of $\pm 3\%$ FiO ₂ or $\pm 10\%$ of setting
800 ml, 20 BPM	up to 10% FiO ₂ lower than setting

An "O₂ Flow" Alarm is activated if the oxygen inlet supply is lost. See Chapter 13 for further information concerning the alarm.

The oxygen concentration is set by pressing the %O₂ Soft Key in the Change Parameters screen, then turning the adjustment knob. See Chapters 8 and 9 for detailed instructions for setting the concentration in the CPAP, S/T, and PAV/T modes. The set oxygen concentration is maintained between mode changes.

Respironics recommends the use of an external oxygen analyzer added to the patient circuit to measure the actual oxygen concentration. The Vision ventilator displays the concentration set by the user, but does not display the actual concentration delivered to the patient.

NOTE: The oxygen analyzer readings may vary due to sampling rate of the analyzer and also the manner in which the measurements are averaged.

Figure 13-3 shows the Vision ventilator set up with the oxygen analyzer attached to the circuit.

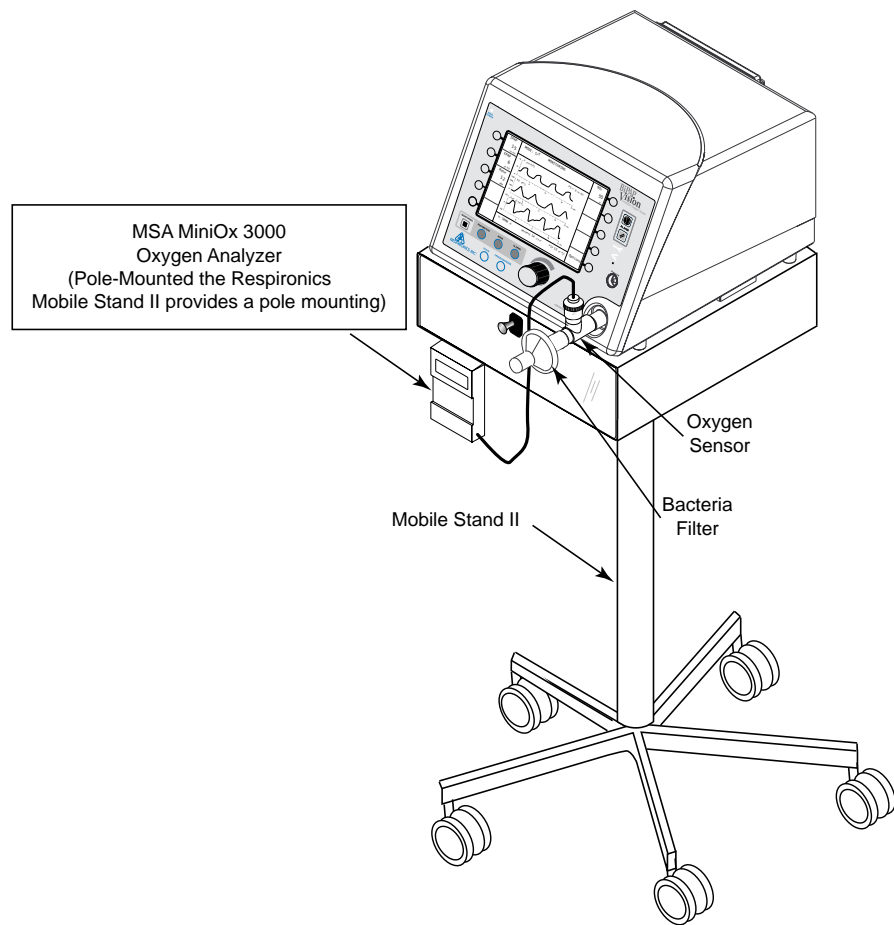


Figure 13-3. Vision Ventilator with Oxygen Analyzer.

The oxygen sensor for the oxygen analyzer should be placed directly at the outlet of the Vision ventilator, before the bacteria filter.

Chapter 14: Cleaning and Routine Maintenance

14.1 Overview

This chapter provides guidelines and illustrates the cleaning and routine maintenance procedures. Refer to the BiPAP Vision Service Manual for the recommended maintenance schedule.

WARNING: Before cleaning or performing any routine maintenance, always switch the Vision unit's Start/Stop switch to the **STOP** position and unplug the electrical cord from the wall outlet and from the rear of the unit.

14.2 Cleaning the Vision Unit

NOTE: The following guidelines for cleaning refer to the Vision unit only. Refer to the individual instructions for cleaning accessories.

CAUTION: Do not immerse the Vision unit in water or allow any liquid to enter the cabinet or the inlet filter.

14.2.1 CLEANING THE FRONT PANEL

Clean the front panel as needed by wiping with water or 70% Isopropyl Alcohol only.

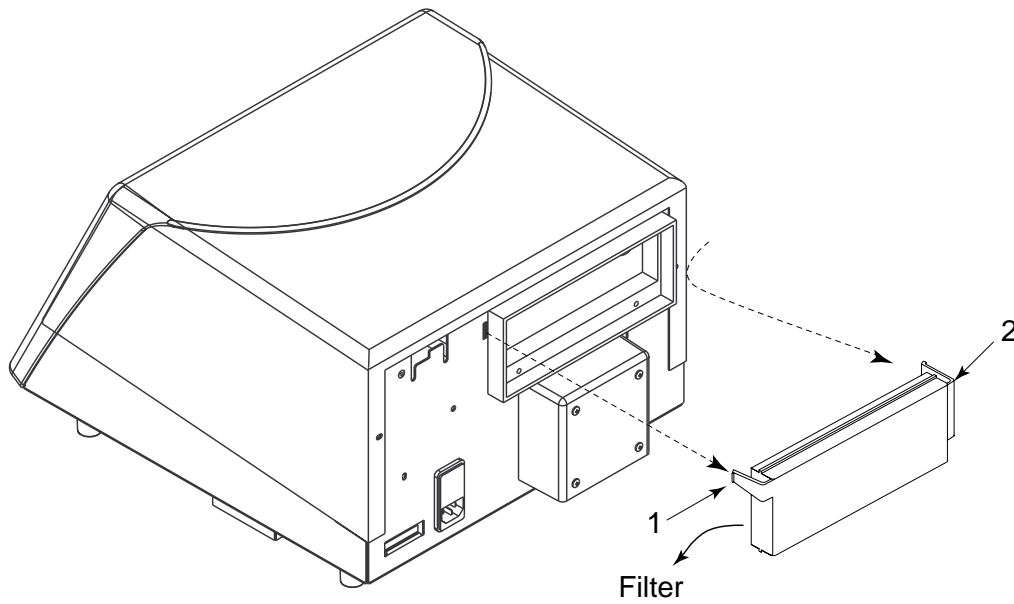
14.2.2 CLEANING THE ENCLOSURE

Clean the exterior of the enclosure as needed by wiping with any bacterial agent but do not allow liquid to enter the inside of the ventilator.

14.3 Replacing the Inlet Filter

CAUTION: A dirty inlet filter may cause high operating temperatures and may affect ventilator performance. Examine the inlet filter for integrity and cleanliness before each use. When the filter becomes dirty, it must be replaced to ensure normal operation.

STEP 1 Turn the Vision unit Start/Stop switch to the **STOP** position and unplug the electrical cord from the wall outlet and from the back of the unit.



Removing the Filter

STEP 2 Remove the inlet filter cap by pinching the catch (1), then rotating the cap until the hinge (2) is free from its slot.

Remove the filter from inside the filter cap.

NOTE: The inlet filter is disposable. Do not attempt to clean the inlet filter. When the filter is dirty replace it with a new filter. Use only Respironics filters; see Chapter 17 for the filter reorder number.

CAUTION: Using a dirty filter or a filter from a manufacturer other than Respironics can alter the system performance.

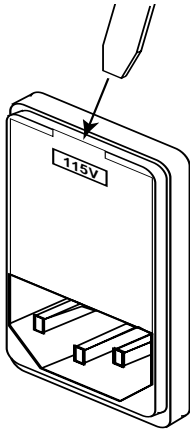
Installing the Filter

STEP 3 Place the filter inside the cap, then reverse Step 2 to reinstall the filter cap.

NOTE: To clean the accessories, refer to each accessory's instruction sheet.

14.4 Changing the System Fuses

WARNING: Unplug the Vision unit before changing the fuses.



STEP 1 Unplug the AC power cord from the wall outlet and from the power entry module on the rear of the Vision unit.

STEP 2 With a small, flat-bladed screwdriver, pry open the fuse holder door from the top. The door hinges downward.

STEP 3 Pry the fuse drawers loose and slide them out of the power entry module.

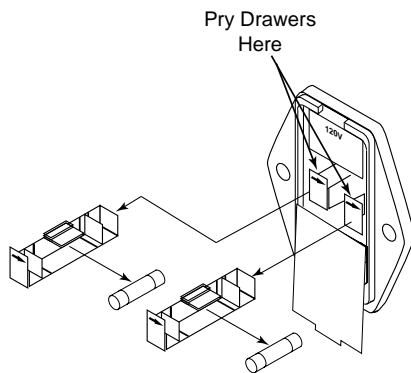
STEP 4 Pull the fuses out of the fuse drawers.

STEP 5 Replace both fuses, even if only one needs to be changed.

STEP 6 Place the new fuses in the fuse drawers and slide the fuse drawers back into the power entry module with the arrows on the front of the drawers pointing to the right.

STEP 7 Swing the fuse drawer door shut and snap it into place.

STEP 8 Plug the AC power cord into the Vision unit and the wall outlet.



NOTE: Use only Respironics-approved fuses. See Chapter 16 for fuse ratings and reorder numbers.

14.5 Voltage Selection

The voltage selection is set at the factory. If you wish to use the Vision unit with a different inlet voltage, contact your medical equipment supplier.

14.6 Preventive Maintenance

A periodic preventive maintenance schedule is provided in the service manual.

14.7 Internal Battery Maintenance

14.7.1 BATTERY FUNCTION

The BiPAP Vision contains an internal NiCAD battery to activate the Ventilator Inoperative visual (Wrench icon) and audible alarm indicators if AC mains power is lost. A fully charged battery can maintain the visual and audible indicators for up to 20 minutes.

14.7.2 LOW BATTERY CONDITION

The NiCAD battery can lose its charge if the Vision unit is not used for an extended time. In a typical hospital environment, a fully charged battery can be stored approximately six months before losing its charge, but the discharge rate depends heavily on temperature.

NOTE: The Vision unit should be checked prior to use if it has been stored for longer than three months.

If the battery voltage is too low to support the alarm indicators, the Check Ventilator visual (Eye icon) and audible alarm indicators will activate. **The time during which the alarm operates may be short due to the low voltage of the battery.** The Vision unit also generates error code 205. If the unit indicates a Check Vent with error code 205:

Step 1 Silence the audible alarm component by pressing the Alarm Reset key.

The audible component will not sound again.

Step 2 Press the **Monitoring** hard key if you are not already in the Monitoring screen.

Step 3 Press the **Options** soft key.

Step 4 In the Options screen, press the **Error** soft key.

Error codes are displayed in the Mode/Message area.

See section 11.2.1 for complete details.

14.7.3 CHARGING THE INTERNAL BATTERY

NOTE: A completely discharged battery requires 24 hours to ensure that it is sufficiently charged and will support the alarm for 20 minutes.

CAUTION: Prolonged storage of the Vision unit at high temperatures, above 80 °F (27 °C) can result in premature battery failure. Failure to recharge a battery when it is being stored for long periods will cause a loss of battery life, activate the Check Ventilator alarm, and generate error code 205.

The battery should be charged every two months when the Vision unit is in storage.

To charge the internal battery:

- Step 1** Remove the unit from patient use.
- Step 2** Press the Alarm Reset hard key to silence the audible component of the alarm.
- Step 3** Plug the unit into an AC source and press the Start/Stop switch to start the unit.
- Step 4** Allow the unit to remain in the Exhalation Port Test screen or in Standby mode for a minimum of two hours.

A minimum two hours of is required to charge a fully discharged battery to a voltage at which the low battery warning will not be activated. The unit will operate and will continue to trickle charge the battery while it is running.

- Step 5** Press the Monitoring hard key to begin operation.
- Step 6** Wait two minutes to determine if the low voltage alarm reactivates.

If the alarm does not reactivate, the unit is ready for use.

Chapter 15: Accessories

15.1 Circuit Configurations

The Vision unit is intended for use with a Respironics, Inc. approved patient circuit. Respironics approved circuits and accessories for noninvasive applications are illustrated in Figures 15-1 to 15-3. Common components of all of the configurations are:

- a bacteria filter
- a transparent smooth inner lumen proximal pressure line ($\frac{1}{8}$ " ID)
- smooth inner lumen tubing
- an exhalation device such as the Whisper Swivel, Respironics Disposable Exhalation Port assembly, or the Plateau Exhalation Valve
- a Respironics patient interface

Additional accessories may be added to the circuit to meet specific needs. Every time changes are made to the circuit configuration, the delivered pressures must be monitored with the unit cycling and the Exhalation Port Test must be performed.

Respironics tubing connectors comply with ISO 5356-1 or 5356-2.

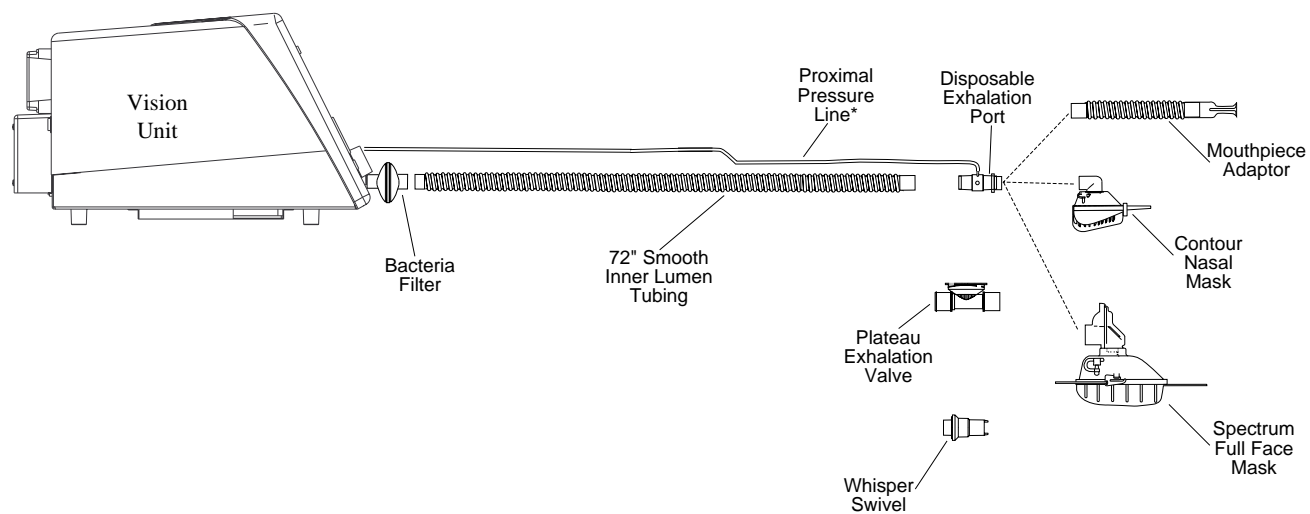
- Figure 15-1 shows the standard noninvasive circuit.
- Figure 15-2 shows the noninvasive circuit with heated humidifier.
- Figure 15-3 shows the recommended invasive circuit configuration.

All circuits and related accessories in Figures 15-1 to 15-3 are available from Respironics.

WARNING: The BiPAP Vision unit requires an intentional leak port (e.g., Disposable Exhalation Port Assembly, Whisper Swivel, or Plateau Exhalation Valve) to remove exhaled air from the circuit instead of an actively controlled exhalation valve. Therefore, specific masks and circuits using an intentional leak port are required for normal operation. The pressurized air from the Vision causes a continuous flow of air to exhaust from the leak port which flushes the exhaled air from the circuit. The machine should be turned on and the intentional leak port should be checked using the Exhalation Port Test before application. Do not use patient circuit accessories other than those specified by Respironics. Please refer to Section 2.5 for additional information on CO₂ rebreathing.

WARNING: Proper operation of the Plateau Exhalation Valve or any exhalation port used with the BiPAP Vision must be verified by regular inspection during use. Occlusion or partial occlusion of the exhalation port may result in asphyxia.

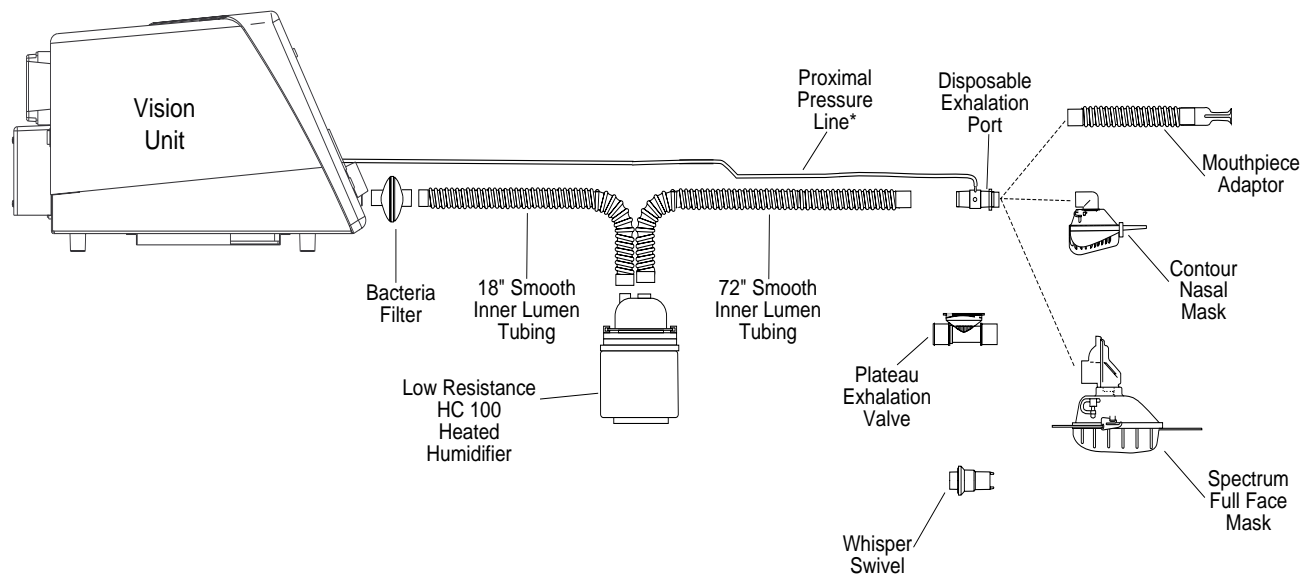
15.1.1 STANDARD NONINVASIVE CIRCUIT



*The proximal pressure line may connect to either the exhalation port or to the mask (when a mask is used).

Figure 15-1. Standard Noninvasive Circuit.

15.1.2 NONINVASIVE CIRCUIT WITH HEATED HUMIDIFIER



*The proximal pressure line may connect to either the exhalation port or to the mask (when a mask is used).

Figure 15-2. Noninvasive Circuit with Heated Humidifier.

15.1.3 INVASIVE CIRCUIT

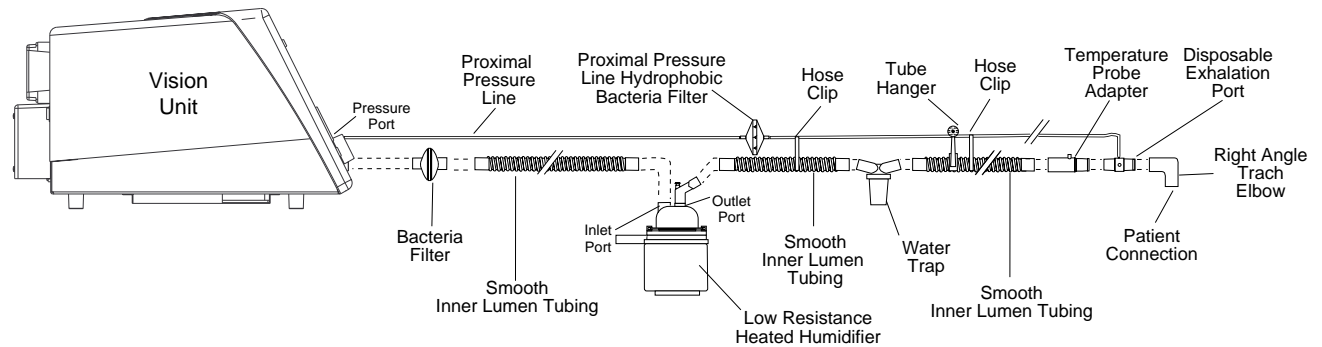


Figure 15-3. Recommended Invasive Circuit Configuration.

NOTE: To ensure adequate humidification during invasive applications, the Fisher & Paykel MR 730 Respiratory Humidifier is recommended.

NOTE: Tubing lengths between circuit components can vary, however, the maximum length of the entire circuit should not exceed 72 inches.

15.2 Circuits and Accessories

The following accessory items may be used with the Vision System:

- Vision Disposable Circuit (noninvasive):
Includes 72" tubing, exhalation port, proximal pressure line, hanger, and hose clips.
- Vision Disposable Circuit (invasive):
Includes tubing, water trap, exhalation port, temperature probe, proximal pressure line, hanger, and hose clips.
- Reusable Circuit
Includes 6' reusable circuit.
- Accessories:
 - 6" disposable circuit tubing
 - 18" disposable circuit tubing
 - 36" disposable humidifier tubing
 - 72" disposable tubing
 - Disposable proximal pressure line
 - O₂ enrichment attachment
 - Bacteria filter
 - Mobile Stand II

15.3 Exhalation Ports

- Disposable exhalation port
- Whisper Swivel exhalation port
- Plateau Exhalation Valve

15.4 Masks and Related Accessories

- Masks:
 - Disposable vinyl nasal masks
 - Reusable contour nasal masks
 - Spectrum® full face masks
 - Comfort Flap® mask accessory
 - Disposable mouthpiece adapter
- Accessories:
 - Disposable headgear
 - Reusable headgear
 - Chin strap
 - Softcap™
 - Slip-on spacers
 - Quick Clip
 - Simplestrap™

15.5 Humidifiers

- Fisher & Paykel HC 100 Heated Humidifier
(recommended for noninvasive applications only)
- Fisher & Paykel MR 730 Heated Humidifier
(recommended for invasive applications)

Chapter 16: Specifications

ENVIRONMENTAL

	Operating	Storage
Temperature	4.4° C to 40° C	-20° C to 60° C
Humidity	0 to 95% Relative (non-condensing)	0 to 95% Relative (non-condensing)
Atmospheric Pressure	83 to 102 kPa	83 to 102 kPa

PHYSICAL

Dimensions: At the base: 16" (L) x 14 ³/₈" (W) x 10 ⁵/₈" (H)
(40.6 cm x 36.5 cm x 27 cm)

Weight: 34 lbs (15.4 kg)

ELECTRICAL

AC Voltage: 100/120/230/240 V~

CAUTION: Use only Respironics replacement fuses.

Mains Fusing: 100 to 120 V~ —3.5 A Time Delay, 250 V, 5 x 20 mm
Respironics Part Number 582259
220 to 240 V~ —T1.6 A, 250 V, 5 x 20 mm
Respironics Part Number 582099

AC Frequency: 50/60 Hz

AC Current: 3.0 A maximum

Protection against electric shock: Class I

Degree of protection against electric shock: BF

Degree of protection against harmful ingress of water: Ordinary Equipment IPX0

Electromagnetic Compatibility: The Vision Ventilatory Support System meets the requirements of IEC 601-1-2 and thus complies with the EMC Directive 89/336/EEC.

PRESSURE

Output: 4 to 40 cm H₂O

Dynamic Regulation: ± 2 cm H₂O at sinusoidal flow @ ± 100 L/min

Static Regulation: ± 2 cm H₂O from -60 to 120 L/min

CONTROL ACCURACY

Timed Inspiration:	± 0.2 sec of the set point
Rate:	± 1 BPM of the set point
Oxygen Concentration:	Within $\pm 10\%$ of setting or $\pm 3\%$ FiO_2 , whichever is greater, at 500 ml tidal volume and a respiratory rate of 15 BPM

DISPLAY ACCURACY

Pressure:	± 1 cm H_2O
Volume:	± 25 ml, + 10% (tested at tidal volume ≥ 500 ml)
Flow:	$\pm 10\%$ (during stable conditions)

TRIGGER

Spontaneous Trigger:	<ul style="list-style-type: none"> —Shape Trigger —Volume 6 cc above \dot{V}_{leak}
Spontaneous Cycle:	<ul style="list-style-type: none"> —Spontaneous Expiratory Threshold (SET) —Shape Cycle —IPAP maximum of 3.0 sec —Flow Reversal

OXYGEN MODULE INLET

Pressure Range:	50 to 100 psig
Inlet Fitting:	DISS male oxygen connector

INTERNAL BATTERIES

Alarm Battery:	NiCAD Supply: 3.6 Vdc, 110 mAh
Data Retention Battery:	Type: Lithium Cell Supply: + 2.8 VDC, 49 mAh

INLET FILTER

Ultra Fine Disposable—Respironics Reorder# 582101 (pack of 6 filters)

NURSE CALL/REMOTE ALARM CONNECTOR

Voltage: 50 VDC or 25 VAC maximum
Current: 1 Amp maximum

CONTROL RANGES & INCREMENTS

PARAMETERS

PARAMETER	CONTROL RANGE	CONTROL INCREMENTS
IPAP	4 to 40 cm H ₂ O	1 cm H ₂ O
EPAP	4 to 20 cm H ₂ O	1 cm H ₂ O
CPAP	4 to 20 cm H ₂ O	1 cm H ₂ O
Rate	4 to 40 BPM	1 BPM
Timed Inspiration	0.5 to 3.0 sec	0.1 sec
IPAP Rise Time	.05 to .4 sec	4 set points: .05, .1, .2, .4 sec
Oxygen Concentration (% O ₂)	21 to 100%	4% from 21 to 25% 5% from 25 to 100%

ALARMS

ALARM	CONTROL RANGE	CONTROL INCREMENTS
High Pressure	5 to 50 cm H ₂ O	1 cm H ₂ O
Low Pressure	0 to 40 cm H ₂ O	1 cm H ₂ O
Low Pressure Delay	0 to 60 sec	1 sec
Apnea	Disabled; 20 to 40 sec	4 set points: Disabled, 20, 30, 40 sec
Low Minute Ventilation	0 to 99 L/min	1 L/min
High Rate	4 to 120 BPM	1 BPM
Low Rate	4 to 120 BPM	1 BPM

DISPLAY RANGES & INCREMENTS

PARAMETER	DISPLAY RANGE	DISPLAY RESOLUTION
IPAP	0 to 50 cm H ₂ O	1 cm H ₂ O
EPAP	0 to 50 cm H ₂ O	1 cm H ₂ O
CPAP	0 to 50 cm H ₂ O	1 cm H ₂ O
Rate	0 to 150 BPM	1 BPM
Exhaled Tidal Volume (V _T)	0 to 4000 ml	1 ml
Minute Ventilation (MinVent)	0 to 99 L/min	1 L/min
Total Leak (Tot Leak)	0 to 300 L/min	1 L/min
Patient Leak (Pt. Leak)	0 to 300 L/min	1 L/min
Peak Inspiratory Pressure (PIP)	0 to 50 cm H ₂ O	1 cm H ₂ O
Percent of Patient Triggerd Breaths (Pt. Trig.)	0 to 100%	1%
Ti/Ttot	0 to 100%	1%

CO₂ REBREATHING CHARTS—NON-INVASIVE APPLICATIONS

All data was generated using a Respironics medium nasal mask and a breathing rate of 20 BPM.

Refer to Section 2.4 for information regarding these charts.

			Volume of CO ₂ Rebreathed per breath	Volume of CO ₂ Rebreathed per breath
IPAP	EPAP	V _T	Whisper Swivel/ Disposable Exhalation Port	Plateau Exhalation Valve
8 cm H ₂ O	4 cm H ₂ O	400 cc	1.0 cc	0.6 cc
12 cm H ₂ O	4 cm H ₂ O	400 cc	1.5 cc	0.6 cc
20 cm H ₂ O	5 cm H ₂ O	400 cc	0.3 cc	0.1 cc
20 cm H ₂ O	10 cm H ₂ O	400 cc	0.1 cc	0.1 cc
30 cm H ₂ O	5 cm H ₂ O	400 cc	1.0 cc	0.2 cc
30 cm H ₂ O	10 cm H ₂ O	400 cc	0.1 cc	0.1 cc
40 cm H ₂ O	5 cm H ₂ O	400 cc	0.3 cc	0.2 cc
40 cm H ₂ O	10 cm H ₂ O	400 cc	0.1 cc	0.3 cc
8 cm H ₂ O	4 cm H ₂ O	800 cc	3.6 cc	1.3 cc
12 cm H ₂ O	4 cm H ₂ O	800 cc	3.1 cc	1.4 cc
20 cm H ₂ O	5 cm H ₂ O	800 cc	0.5 cc	0.5 cc
20 cm H ₂ O	10 cm H ₂ O	800 cc	0.2 cc	0.1 cc
30 cm H ₂ O	5 cm H ₂ O	800 cc	0.4 cc	0.3 cc
30 cm H ₂ O	10 cm H ₂ O	800 cc	0.2 cc	0.1 cc
40 cm H ₂ O	5 cm H ₂ O	800 cc	0.3 cc	0.3 cc
40 cm H ₂ O	10 cm H ₂ O	800 cc	0.5 cc	0.5 cc

Chart 1.

NOTE: The information in Chart 1 was generated from laboratory testing. It does not account for the many variables that can affect the amount of CO₂ rebreathing in actual use.

IPAP	EPAP	V _T	% Inspiration Time	Vol Of CO ₂ Rebreathed per breath	Vol Of CO ₂ Rebreathed per breath
				Whisper Swivel/ Disposable Exhalation Port	Plateau Exhalation Valve
8 cm H ₂ O	4 cm H ₂ O	400 cc	23	1.0 cc	0.1 cc
8 cm H ₂ O	4 cm H ₂ O	400 cc	33	1.4 cc	0.1 cc
8 cm H ₂ O	4 cm H ₂ O	400 cc	50	2.6 cc	0.4 cc
8 cm H ₂ O	4 cm H ₂ O	800 cc	23	3.6 cc	0.2 cc
8 cm H ₂ O	4 cm H ₂ O	800 cc	33	3.6 cc	0.2 cc
8 cm H ₂ O	4 cm H ₂ O	800 cc	50	4.6 cc	1.0 cc

Chart 2.

NOTE: The information in Chart 2 was generated from laboratory testing. It does not account for the many variables that can affect the amount of CO₂ rebreathing in actual use.

Respironics Patient Interface	Deadspace Volume
Petite Nasal Mask	111 cc
Small Nasal Mask	114 cc
Medium-Small Nasal Mask	149 cc
Medium Nasal Mask	154 cc
Medium-Wide Nasal Mask	173 cc
Large-Narrow Nasal Mask	160 cc
Large Nasal Mask	190 cc
Petite Full Face Mask	225 cc
Small Full Face Mask	280 cc
Medium Full Face Mask	400 cc
Large Full Face Mask	532 cc
Mouthpiece Adapter (includes extension tube)	53 cc

Chart 3.

The total volume of the Mouthpiece Adapter, including its extension tube, is 53 cc. However, unlike the masks discussed above, none of this volume is reduced in actual use when it is applied to the patient. Therefore, the total volume of the Mouthpiece Adapter should be considered as deadspace in assessing CO₂ rebreathing potential.

CO₂ REBREATHING CHARTS—INVASIVE APPLICATIONS

All data was generated using approved Respironics invasive circuit at a breathing rate of 20 BPM with I:E = 1:2 (% Inspiration = 50).

Refer to Section 2.4 for information regarding these charts.

IPAP	EPAP	V _T	Vol Of CO ₂ Rebreathed per breath	Vol Of CO ₂ Rebreathed per breath
			Whisper Swivel or Disposable Circuit	Plateau Exhalation Valve
8 cm H ₂ O	4 cm H ₂ O	400 cc	1.0 cc	1.0 cc
12 cm H ₂ O	8 cm H ₂ O	400 cc	1.0 cc	0.5 cc
8 cm H ₂ O	4 cm H ₂ O	800 cc	5.5 cc	0 cc
12 cm H ₂ O	8 cm H ₂ O	800 cc	1.50 cc	0 cc

Chart 4.

NOTE: The information in Chart 4 was generated from laboratory testing. It does not account for the many variables that can affect the amount of CO₂ rebreathing in actual use. Pressures higher than those listed produced zero or negligible CO₂ volume readings. Rebreathed CO₂ volumes are generally lower in invasive applications due to the elimination of mask deadspace.

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Limited Warranty

Respironics, Inc. warrants that the BiPAP Vision System shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace—at its option—the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

Respironics, Inc. disclaims all liability for economic loss, loss of profits, overhead or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. In addition, any implied warranties—including any warranty of merchantability or fitness for the particular purpose—are limited to one year. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To exercise your rights under this warranty, contact your local authorized Respironics, Inc. dealer or contact Respironics, Inc. at:

1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550
1-800-345-6443 (US and Canada only) or 1-724-387-4000



RESPIRONICS INC.®

1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 U.S.A.