



RESPIRONICS®

BiPAP® *Focus*TM
Noninvasive Ventilator System

Operator's Manual

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Manufactured for:
Respiroics California, Inc.
2271 Cosmos Court
Carlsbad, California 92011
USA
Made in USA

Authorized Representative:
Respiroics Deutschland GmbH
Gewerbestr. 17
D-82211 Herrsching
Germany
+49-8-15-29-30-60



Philips Healthcare Australia
65 Epping Road
North Ryde NSW 2113
Australia

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Chapter 1: System Description

About BiPAP Focus

The BiPAP Focus Ventilator System provides noninvasive breathing support for adult patients weighing 30 kg (66 lbs.) or greater.

The BiPAP Focus System offers two ventilation modes:

- Continuous positive airway pressure (CPAP), which provides a single level of positive pressure to the patient.
- Spontaneous/Timed (S/T), which provides two levels of positive pressure (one during inspiration and one during exhalation), and delivers timed breaths if the patient does not initiate a breath.

The BiPAP Focus System alarms announce when high or low pressure regulation, apnea, patient disconnect, low power, or loss of mains power conditions occur. The system displays a real-time estimated delivered pressure bar graph.

An Apnea Rate (#Apnea) Alarm is provided to alert the caregiver to repeated periods of short apneas of 10 seconds or more. The caregiver can set the value for how many apnea periods (10 seconds or more) can occur within an hour before alarming. The total number of Apnea periods (10 seconds or more) for the previous hour is displayed as part of the patient data. Because the previous hours data is displayed, the number of apnea periods for the first hour is an estimate only.

The BiPAP Focus System includes Alarm Silence and Alarm Pre-silence features. Battery backup provides a minimum of 45 minutes of backup power at default settings in case AC power is not available (for example, during transport within the hospital).

The BiPAP Focus System features Digital Auto-Trak™, which allows it to recognize and compensate for unintentional leaks and promote synchrony by adjusting its trigger and cycle algorithms to maintain optimum performance.

Intended Use

The BiPAP Focus Ventilator is a noninvasive, pressure support ventilator used to augment the breathing of patients suffering from acute or chronic

System Description

respiratory insufficiency or to maintain airway patency and provide ventilatory support to patients who experience obstructive sleep apnea. It is not intended to provide the total ventilatory requirements of the patient.

Intended population: Adults > 30 kg

Environments of use: Hospital, subacute and intrahospital transport under qualified clinician direction and supervision

Contraindications

The BiPAP Focus System is contraindicated for patients with any of the following conditions:

- Lack of spontaneous respiratory drive
- Inability to maintain a patent airway or adequately clear secretions
- At risk for aspiration of gastric contents
- Acute sinusitis or otitis media
- Hypotension

Patient Precautions

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 the mask instructions for appropriate action.

Potential side effects of noninvasive positive pressure therapy include: ear discomfort, conjunctivitis, skin abrasions due to noninvasive interfaces, gastric distention (aerophagia).

Restrictions

Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Chapter 2: Warnings

WARNING: To avoid the risk of fire, use this device in well-ventilated areas away from flammable anesthetics. Do not use in a hyperbaric chamber or other similarly oxygen-enriched environments.

WARNING: When using the BiPAP Focus System, an alternative means of ventilation should always be available.

WARNING: To reduce the risk of electric shock, ensure that the AC power cord is undamaged and always disconnect the device from AC power before opening the enclosure. To ensure that AC power is disconnected, always disconnect the mains supply at the wall outlet.

WARNING: The BiPAP Focus System should not be used adjacent to or stacked with other equipment. If adjacent use is necessary, the BiPAP Focus System should be observed to verify stable orientation and normal operation.

WARNING: To minimize the risk of overheating the device, do not operate adjacent to heaters or other heat sources.

WARNING: The patient should be disconnected if operating in any mode other than Normal operating mode.

WARNING: Failure to enter Standby mode before switching the ON/OFF switch on the back of the unit to the OFF position (O) will cause the unit to alarm for two minutes indicating the unit was not powered off correctly. This is a safety feature. If it occurs, turn the unit back ON (I) in Normal mode and then shut it down correctly.

WARNING: Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in this user manual.

WARNING: All components of the breathing circuit are intended for single patient use only: do not attempt to sterilize or reuse. Follow all applicable federal and local regulations for disposal or recycling.

Warnings

WARNING: Do not use antistatic or electrically conductive tubing.

WARNING: This device is not for use with intubated patients.

WARNING: Do not use this device close to MRI or high-frequency devices, such as electro surgery or diathermy equipment.

WARNING: Do not use this device with anesthetic gases.

WARNING: Do not use flammable disinfectants on or near this device.

WARNING: Before using the BiPAP Focus System on a patient, allow the device to acclimate to conditions of use following transport or storage.

WARNING: Do not use the system if the screen is unreadable. If this occurs turn the ON/OFF switch to the OFF position (O).

WARNING: Service on this device should only be performed by qualified service technicians. See the BiPAP Focus System Service Manual for equipment repair information.

WARNING: Do not make any unauthorized changes to the ventilator.

WARNING: Use only Respironics recommended batteries.

WARNING: Keep any sources of ignition as far as possible from the device when using oxygen-enriched gas.

WARNING: Use the BiPAP Focus System with Respironics-approved patient interfaces and circuits only, to assure accuracy of patient data and correct alarm performance. To avoid the risk of increased mask pressure during exhalation, do not use any component or accessory other than those listed in this manual.

WARNING: Do not cover or block the exhalation port on the Vision circuit, to assure accuracy of patient data and correct alarm performance.

WARNING: Use of the bacteria filter at the outlet port of the machine is mandatory. The displayed pressure compensates for the pressure

drop due to the BiPAP Vision single patient use circuit and the bacteria filter (see “Accessories” on page 87 for ordering information).

WARNING: Check that the orientation of the oxygen safety valve is correct.

WARNING: Connect oxygen only on order of a physician.

WARNING: When connecting oxygen to the circuit, use an in-line safety valve and do not allow oxygen to be entrained through the air inlet.

WARNING: Observe the patient and monitor continuously using pulse oximetry and arterial blood gas measurements as needed during oxygen administration.

WARNING: Inspired oxygen concentration can vary according to settings, patient breathing patterns, and leak rate.

WARNING: To avoid oxygen accumulation in the ventilator, put it into Normal operating mode before turning the oxygen ON, and turn oxygen OFF before putting it into Standby or turning the unit OFF.

WARNING: Do not use a Heat and Moisture Exchanger (HME) with the BiPAP Focus due to high resistance to flow.

WARNING: The BiPAP Focus System can deliver pressures up to 30 cmH₂O. In the unlikely event of certain fault conditions a maximum static pressure of 42 cmH₂O is possible.

WARNING: It is important to inspect and replace the air inlet filters at the recommended intervals to avoid introducing foreign matter into the system

WARNING: The BiPAP Focus System is shipped with the battery disconnected. The battery must be connected before the BiPAP Focus System will operate.

WARNING: To avoid the risk of fire, use only Respiration-approved batteries. All battery connections are keyed to ensure proper connection.

Warnings

WARNING: When running on battery, the high flows that occur during a patient disconnect will cause the battery to deplete in as little as 2 minutes. Connect AC power immediately if the Battery Depleted Alarm sounds to avoid total loss of power.

WARNING: To avoid the risk of electrical shock, do not touch the communication ports on the ventilator and the patient simultaneously.

WARNING: Do not perform the Preoperational Check with a patient attached.

WARNING: To avoid the risk of electrical shock, this equipment must only be connected to AC mains with protective earth.

WARNING: The AC power mains outlet used for the ventilator shall be easily accessible by the operator. This is to provide the ability to disconnect the BiPAP Focus system from electrical mains if this should be necessary.

WARNING: The DC power supply provided with the BiPAP Focus system is part of the equipment. Use only the DC power supply approved for use with the BiPAP Focus system. Failure to use the approved DC power supply can result in improper operation or failure of the BiPAP Focus system.

WARNING: Do not remove the power cord retaining clip from the device.

WARNING: If placing the BiPAP Focus System on a flat surface or the stand, ensure that the surface is stable.

WARNING: To prevent possible patient injury, verify that the battery is fully charged before putting a patient on the ventilator and before unplugging the ventilator for transport or other purposes. The battery is fully charged when the BATTERY CHARGING light is off while the ventilator is connected to AC power.

WARNING: Do not use the BiPAP Focus for physical support.

WARNING: Stow the machine, patient circuits, power cords and accessories safely when not in use.

WARNING: When using oxygen bleed-in, verify that the orientation of the oxygen safety valve is correct before use.

WARNING: (Chapter 7, Care and Maintenance) Maintenance and service work not listed in this chapter shall only be done by a qualified service technician. Only a qualified service technician can assure that the BiPAP Focus system is properly serviced for safe operation.

WARNING: Do not connect any device other than remote alarm cables if the unit is on a patient. Only use cables recommended by Respironics.

WARNING: This product consists of devices that may contain mercury, which must be recycled or disposed of in accordance with local, state, or federal laws. (Within this system, the backlight lamps in the monitor display contain mercury.)

Warnings

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Chapter 3: Setup

When unpacking the BiPAP Focus System, ensure that all parts listed on the packing list are included in the shipment. Inspect all parts for damage before use, and immediately report any discrepancies to your Respiration representative.

System Components

The BiPAP Focus System includes the ventilator, a DC power supply with mains (AC) power cord, and a reusable inlet filter.

Setup

WARNING:

- ***Set up the device so that cables and hose do not pose a tripping hazard. Do not use the device for physical support if moving a person.***
- ***Use proper technique for lifting the device.***
- ***Use Respiration-approved patient circuits and interfaces only.***
- ***Lift the unit as shown in Figure 1. Do not lift the unit by the inlet filter at the rear of the unit or by the front panel.***

Lifting the BiPAP Focus Unit

CAUTION: Lift the unit as shown in Figure 1. Do not lift the unit by the inlet filter at the rear of the unit or by the front panel.



Figure 1: Lifting the BiPAP Focus Unit

After removing all packaging materials, remove the protective plastic cover from the display, and wipe the exterior of the BiPAP Focus clean with a damp cloth and mild detergent solution before the first use (see “Care and Maintenance” on page 57). Also clean the ventilator exterior between each patient use and as needed.

The BiPAP® Focus™ Ventilator is shipped with the battery disconnected. The battery must be connected before the BiPAP Focus Ventilator will operate. Connecting the battery is a routine action, therefore a qualified service technician is not required. Follow these simple steps to connect the battery:

1. Ensure that the ON/OFF switch is in the OFF position (O) and that the power cord is disconnected.

2. Turn the unit over, remove the two battery compartment cover screws, and battery cover as shown in Figure 2.

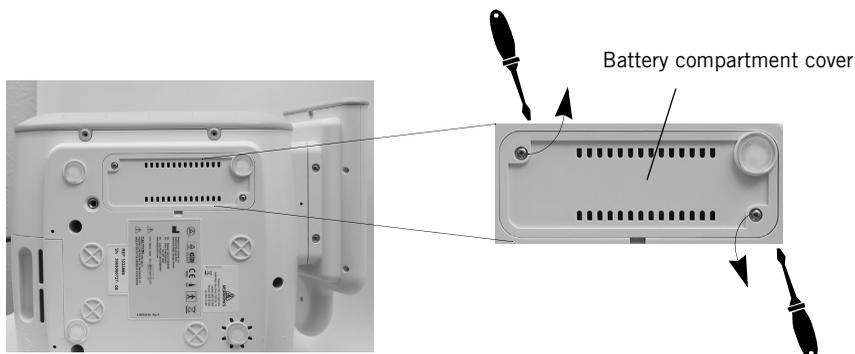


Figure 2: Remove the battery compartment cover.

3. Remove the battery pack. Connect the battery by plugging the white-keyed battery cable connector into the keyed slot. Push the connector in until it locks in place as shown in Figure 3.

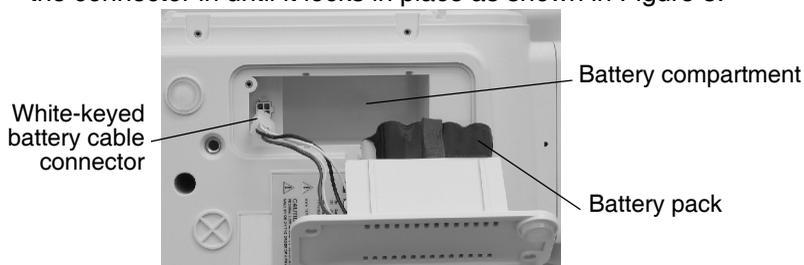


Figure 3: Connect the battery cable connector to the keyed slot.

4. Replace the battery pack in the battery compartment, close the cover, and tighten the screws. Connect the power cord.

Mounting

The BiPAP Focus System can be placed on a flat surface or secured to a stand as seen in Figure 4.

WARNING: If placing the BiPAP Focus System on a flat surface or the stand, ensure that the surface is stable.



Figure 4: BiPAP Focus on the Mobile Stand

Connecting to Power

WARNING: To avoid the risk of electrical shock, this equipment must only be connected to AC mains with protective earth. To avoid the risk of electrical shock, this equipment must only be connected to AC mains with protective earth.

WARNING: The AC power mains outlet used for the ventilator shall be easily accessible by the operator. This is to provide the ability to disconnect the BiPAP Focus system from electrical mains if this should be necessary. The AC power mains outlet used for the ventilator shall be easily accessible by the operator. This is to provide the ability to disconnect the BiPAP Focus system from electrical mains if this should be necessary.

WARNING: The DC power supply provided with the BiPAP Focus system is part of the equipment. Use only the DC power supply approved for use with the BiPAP Focus system. Failure to use the approved DC power supply can result in improper operation or failure of the BiPAP Focus system. The DC power supply provided with the BiPAP Focus system is part of the equipment. Use only the DC power supply approved for use with the BiPAP Focus system. Failure to use the approved DC power supply can result in improper operation or failure of the BiPAP Focus system.

WARNING: To prevent the premature depletion and reduced life expectancy of the battery, store the ventilator with AC power connected and the ON/OFF switch in the ON (I) position. When the ventilator is stored disconnected from AC power with the power ON/OFF switch ON (I) and in standby, the battery may become depleted within two weeks. When the ventilator is stored with the ON/OFF switch in the OFF (O) position, the battery typically becomes depleted in three months.

If a 343 error code is displayed, contact Service. The battery needs replacement.

CAUTION: The battery is intended for back-up and intra-hospital transport only, and is not intended to be the main power source.

The BiPAP Focus System is powered by a DC power supply connected to AC mains (Figure 5). The unit also has an internal battery as a backup power source. The internal battery can run the system for a minimum of

Setup

45 minutes at default settings (see “Specifications” on page 67 for default settings).

The internal battery charging cycle is active whenever the system is connected to AC power and the back panel **ON/OFF** switch is **ON** (|) and the **BATTERY CHARGING** LED is illuminated.

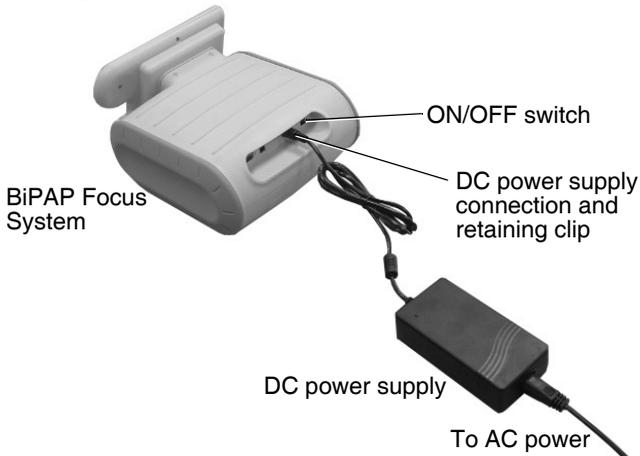


Figure 5: Connecting to AC (Wall) Power

NOTE: The BiPAP Focus System is shipped with the battery disconnected. The battery must be connected before the BiPAP Focus System will operate. Connect battery during initial setup (see page 11).

NOTE: If the unit is being set-up for the first time (out of the box), it is recommended that the unit gets a full battery charge. This also applies after the unit has been stored for 2 weeks or longer.

NOTE: For maximum battery performance, a new battery or a battery that has been in storage should be fully charged and discharged two to three times.

Connecting to an External Device

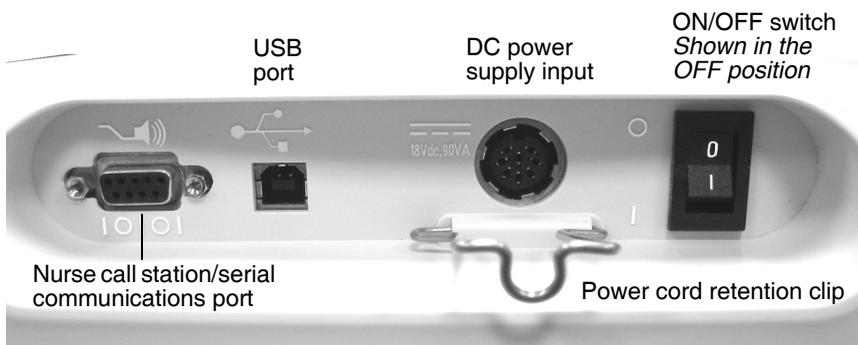


Figure 6: BiPAP Focus Back Panel

The nurse call station/serial communications port can connect the BiPAP Focus System to a nurse call monitoring station or provide serial communications output for service purposes.

The nurse call station alarm is activated when the ventilator is turned **OFF**, or put into Standby, an alarm occurs, or a system error occurs. The nurse call station alarm is deactivated when all active alarms are silenced or auto-reset.

Most nurse call station systems require only normally open (NO) or normally closed (NC) connections. NO and NC nurse call station cables are available from Respironics. See “Accessories” on page 87 for cable ordering information. See “Specifications” on page 67 for pinout information.

The communication and USB ports allow service technicians to upgrade system software.

WARNING: To avoid the risk of electrical shock, do not touch the communication ports on the ventilator and the patient simultaneously.

Setup

CAUTION: The nurse call station port is intended to connect only to a SELV (Safety Extra-Low Voltage) and ungrounded system with basic insulation to ground, in accordance with IEC 60601-1. To prevent damage to the nurse call circuit, the signal input should not exceed the maximum rating of 24 VAC (Volts of Alternating Current) or 36 VDC (Volts of Direct Current) at 500 mA (milliamps), with a minimum current of 1 mA.

Installing Air Inlet Filters

Install the air inlet filter(s) as shown (Figure 7). To avoid introducing foreign matter into the system, a reusable air inlet filter must be installed. (See “Care and Maintenance” on page 57 for information on how to clean the reusable air inlet filter.) An additional ultra-fine disposable filter is also recommended for enhanced particulate filtering.



Figure 7: Installing Air Inlet Filters

Language Selection

The following instructions describe how to select the desired language that the BiPAP Focus will display in Normal Mode.

WARNING: The patient should be disconnected if operating in any mode other than Normal operating mode.

1. Connect mains power to the unit and turn the **ON/OFF** switch at the rear of the unit to the **ON (|)** position.
2. Simultaneously press and hold the **Alarm Reset** and **Alarm Silence** keys.
3. Press the **Standby** key once, while continuing to hold the **Alarm Reset** and **Alarm Silence** keys.

- The unit will power up and will display the following screen:



Figure 8: Warning Screen

- Press **ENTER** to continue past the Warning screen. The Menu screen shown in Figure 9 will appear:

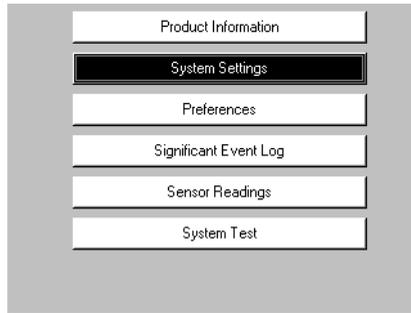


Figure 9: Menu Screen

- Scroll using the **DOWN** arrow key until **System Settings** is highlighted, and then press **ENTER**.

- Press **ENTER** again to display a list of available languages (Figure 10). Use the **UP** and **DOWN** arrow keys to scroll through the list. Highlight the desired language, and then press **ENTER** to select that language.



Figure 10: System Settings Screen

- After selecting the desired language, the unit will display the message below and will power off automatically after 5 seconds.

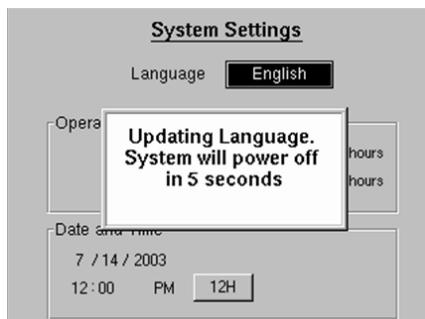


Figure 11: Updating Languages Screen

- The unit must be restarted to activate the language selection.

Connecting the Patient Circuit

WARNING: All components of the breathing circuit are intended for single patient use only: do not attempt to sterilize or reuse. Follow all applicable federal and local regulations for disposal or recycling.

WARNING: Use the BiPAP Focus System with Respiration-approved patient interfaces and circuits only, to assure accuracy of patient data and correct alarm performance. To avoid the risk of increased mask pressure during exhalation, do not use any component or accessory other than those listed in this manual.

WARNING: Do not use a Heat and Moisture Exchanger (HME) with the BiPAP Focus due to high resistance to flow.

The BiPAP Focus System patient interface (Figure 13) includes:

- Patient interface (nasal or full face mask)
- Breathing circuit tubing
- Proximal pressure line (this line is not used, but should be terminated on the output port mounting post to avoid introducing a leak)
- Bacteria filter
- Humidifier (optional)

Connecting the Pressure Tube and Filter

Connect the pressure tube and filter in the following order:

1. Connect the proximal pressure line
Attach the pressure tubing to the proximal pressure mounting post (Figure 12). This terminates the line to avoid introducing a leak when using the BiPAP Vision circuit.
2. Connect the bacteria filter
The use of the bacteria filter is mandatory

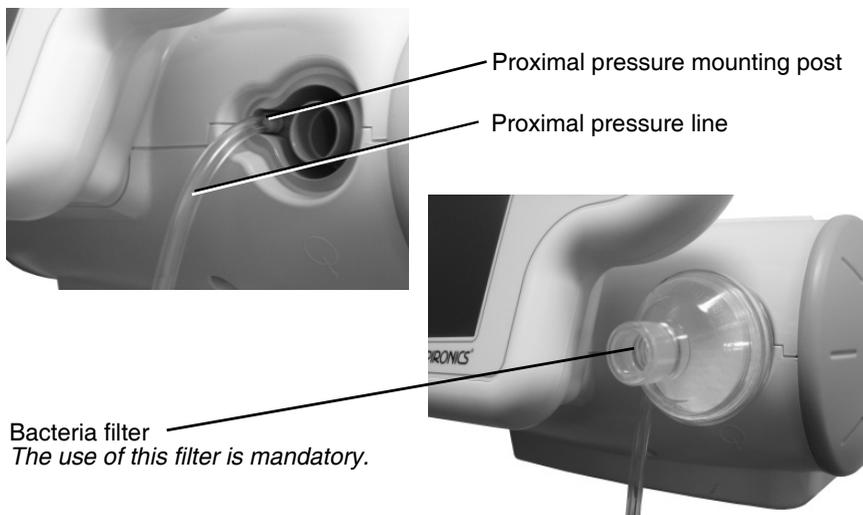


Figure 12: Attaching the pressure tube and filter

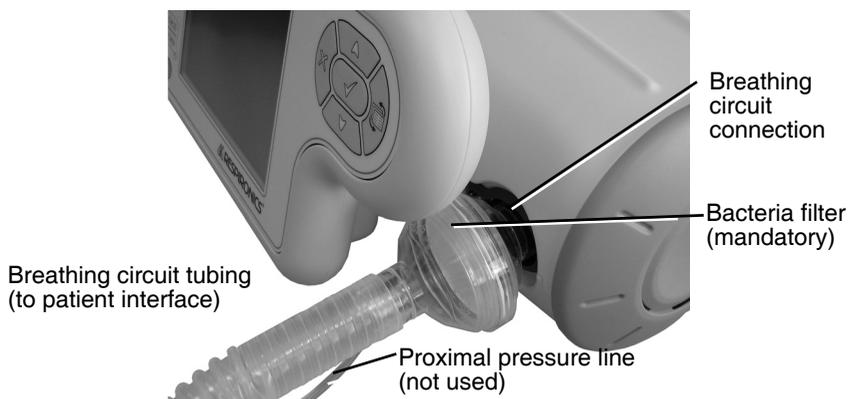


Figure 13: Patient Circuit

WARNING: Use of the bacteria filter at the outlet port of the machine is mandatory. The displayed pressure compensates for the pressure drop due to the BiPAP Vision single patient use circuit and the bacteria filter (see “Accessories” on page 87 for ordering information).

Connecting Supplemental Oxygen

If required, connect supplemental oxygen to the patient circuit as shown (Figure 14).

Bleed in oxygen at the outlet of the BiPAP Focus System, using Respironics-supplied oxygen enrichment adapter and bleed-in safety valve (see “Accessories” on page 87). The oxygen flow into the oxygen valve must not exceed 15 L/min.

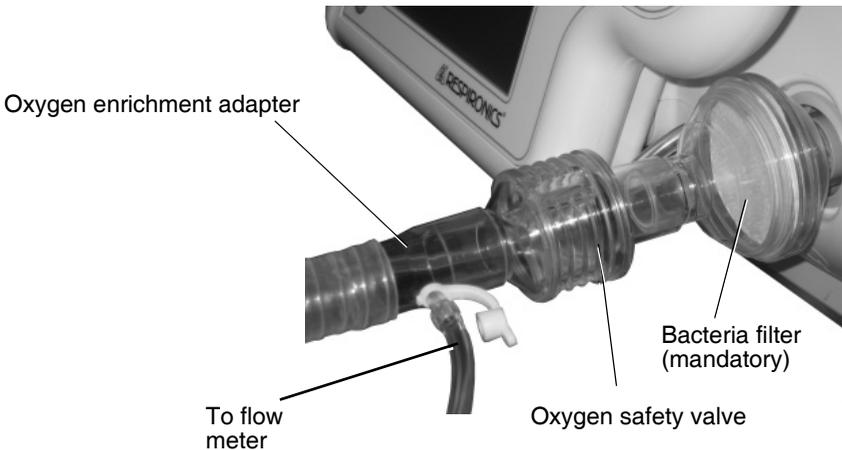


Figure 14: Connecting Oxygen to the Patient Circuit

WARNING: Check that the orientation of the oxygen safety valve is correct.

Table 1 shows the potential range of oxygen concentration for given tidal volume, supplemental oxygen flow, and pressure values. Substantial leaks around the patient interface can reduce the expected oxygen concentration levels. Use this information for reference when beginning oxygen therapy and adjust oxygen flow gradually to meet patient oxygen needs.

CAUTION: The Oxygen Safety Valve introduces a pressure drop of approximately 1 cmH₂O.

Sample FiO_2 values for different tidal volumes with $\text{RR}=20$ I:E = 1:2 10L/min patient leak, and using a Vision Circuit with IPAP/EPAP settings of 10/5,20/5,30/5.

Table 1: Oxygen Concentration

Tidal Volume (mL)	FiO_2 @ 5 L/min Supplemental Flow	FiO_2 @ 10 L/min Supplemental Flow
600	37 +/- 3%	50 +/- 3%
1000	30 +/- 3%	40 +/- 3%

WARNING: Connect oxygen only on order of a physician.

WARNING: When connecting oxygen to the circuit, use an in-line safety valve and do not allow oxygen to be entrained through the air inlet.

WARNING: Observe the patient and monitor continuously using pulse oximetry and arterial blood gas measurements as needed during oxygen administration.

WARNING: Inspired oxygen concentration can vary according to settings, patient breathing patterns, and leak rate.

WARNING: To avoid oxygen accumulation in the ventilator, put it into Normal operating mode before turning the oxygen ON, and turn oxygen OFF before putting it into Standby or turning the unit OFF.

WARNING: To avoid the risk of fire, use this device in well-ventilated areas away from flammable anesthetics. Do not use in a hyperbaric chamber or other similarly oxygen-enriched environments.

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Chapter 4: Operation

Pre-Operational Check

The Pre-Operational Check is a check of LEDs and alarms to be used at the discretion of the clinician. This test is recommended and may be useful for initial setup or following storage periods.

WARNING: Do not perform the Preoperational Check with a patient attached.

Follow these steps to perform a pre-operational check:

1. Connect system to AC power and set the **ON/OFF** switch to the **ON (|)** position.
2. Verify that the **ON AC POWER** and green **BATTERY CHARGING** indicators are on.
3. Press the **STANDBY** button to turn the system on and verify that the red **ALARM** indicator blinks and the audible alarm sounds.

NOTE: If the ventilator has been in storage for 2 weeks or longer, allow the internal battery to charge for at least 30 minutes before performing the following step.

NOTE: If a Low Battery or Battery Depleted alarm occurs during Pre-Operational Check, then the battery requires charging. If a Batt Charge Failure alarm occurs, the battery may be fully depleted. A re-charge is recommended before proceeding. If the battery does not begin to charge after one hour and the Batt Charge Failure persists, contact customer service for a replacement battery.

CAUTION: To prevent the premature depletion and reduced life expectancy of the battery, store the ventilator with AC power connected and the ON/OFF switch in the ON (I) position. When the ventilator is stored disconnected from AC power with the power ON/OFF switch ON (I) and in standby, the battery may become depleted within two weeks. When the ventilator is stored with the ON/OFF switch in the OFF (O) position, the battery typically becomes depleted in three months. For maximum battery performance, a new battery or a battery that has been in storage should be fully charged and discharged two to three times.

If a 343 error code is displayed, contact Service. The battery needs replacement.

4. Once the system begins normal operation, disconnect the power cord from wall power. Verify the following indicators are functioning:
 - Yellow **ON BATTERY** indicator turns on.
 - **ON AC POWER** and green **BATTERY CHARGING** indicators turn off.
 - Red **ALARM** indicator flashes, audible alarm sounds.
5. Press **ALARM RESET**. Verify that the **ALARM** LED and audible alarm turn off.
The audible alarm sounds (beeps) once a minute, alerting the user that unit is running on the internal battery.
6. Reconnect AC power. Verify that the **ON AC POWER** LED is on and the **ON BATTERY** LED is off. Press **ALARM SILENCE** and verify that the yellow **ALARM SILENCE** indicator turns on. Press **ALARM RESET** to cancel the silence and verify that **ALARM SILENCE** indicator turns off.
7. Use the **CHANGE SCREEN**, **UP/DOWN** arrow, **ENTER**, and **CANCEL** keys to step through screens and verify the operation of each key.
8. Enter CPAP mode with a patient circuit attached and allow the ventilator to deliver gas for more than 15 seconds. Verify that a **Disconnect** (i.e., patient disconnect) alarm occurs.

9. Enter S/T mode, then step to the **ALARM SETTINGS** screen. Select an **APNEA** setting of 20 seconds and verify that an **APNEA** alarm occurs after 20 seconds.
10. Reenter CPAP mode, clear any alarms, and connect a nurse call station cable. Turn the **ON/OFF** switch **OFF** and verify:
 - The backup alarm sounds.
 - The nurse call station alarm activates.

Pre-Operational Check is complete.

System Startup

Once the BiPAP Focus System is set up, follow these steps to start operation:

1. Confirm that the back panel **ON/OFF** switch is in the **ON (|)** position.
2. Press the **STANDBY** button on the front panel.
3. Perform the pre-operational check as required.
4. Select the appropriate settings. See "Normal Operation" for more information.
5. Select a mask (See "Accessories" on page 87.) Attach to the patient circuit.

NOTE: Direct the exhalation port gas-flow away from the patient. This helps to maintain patient comfort.

The system is now ready to be connected to the patient.

WARNING: To minimize the risk of personal injury, do not connect the system to the patient until normal operation begins.

Normal Operation

The BiPAP Focus System features these operating modes:

Continuous Positive Airway Pressure (CPAP) Mode

Provides a single level of positive pressure through the patient interface.

Spontaneous/Timed (S/T) Mode

Provides two levels of positive pressure (one during inspiration and another during exhalation) through the patient interface. S/T mode ensures that the patient receives a minimum number of breaths per minute based on the Rate setting. If the patient does not spontaneously breathe within the cycle time determined by the Rate setting, the ventilator delivers a timed breath at the set level of IPAP. The I-Time setting determines the duration of each timed breath.

In S/T mode, the system triggers to deliver Inspiratory Positive Airway Pressure (IPAP) in response to spontaneous inspiratory effort and cycles to Expiratory Positive Airway Pressure (EPAP) during exhalation (see Figure 15). The level of pressure support in S/T mode is the difference between the IPAP and EPAP settings.

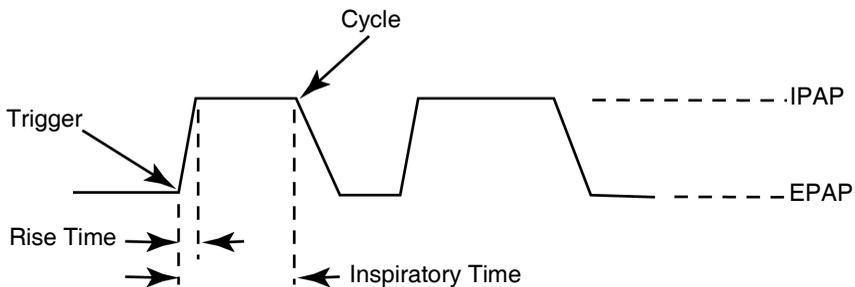


Figure 15: Triggering and Cycling in S/T Mode

The Ramp Time and Ramp Start settings (Figure 16) allow the ventilator to begin at a reduced pressure (the Ramp Start setting) then gradually increase the pressure breath by breath to the prescription pressure (CPAP or EPAP), allowing the patient to fall asleep more comfortably.

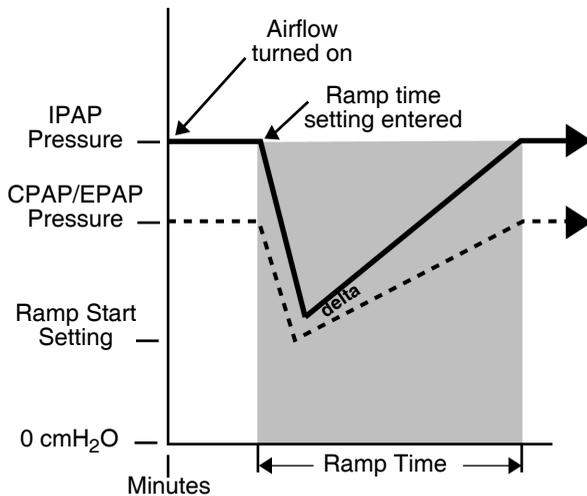


Figure 16: Ramp Time and Ramp Start Settings

Auto-Trak™ Sensitivity Function

The ventilator monitors flow through the patient circuit to determine whether the patient is inhaling or exhaling using Digital Auto-Trak™ Sensitivity technology. The BiPAP Focus System adjusts its output to support breathing and compensates for normal leaks in the patient circuit using Digital Auto-Trak™ leak compensation technology.

Leak Estimation

The system monitors the total flow in the patient circuit and estimates patient leak using leak estimation algorithms.

Sensitivity

An essential feature of S/T mode is effective detection of spontaneous breathing effort, which causes the ventilator to trigger to IPAP and cycle to EPAP. Because no preset sensitivity threshold can ensure patient and machine synchrony with changing breathing efforts and circuit leaks, the BiPAP Focus continuously tracks patient breathing patterns and automatically adjusts its sensitivity thresholds to ensure optimum sensitivity as breathing patterns or circuit leaks change. The system uses volume trigger, shape signal, and Spontaneous Expiratory Threshold (SET) algorithms to ensure optimum sensitivity:

- The Volume Trigger algorithm triggers IPAP during spontaneous and timed breaths. The volume trigger threshold is 6 mL of accumulated patient inspiratory volume. When patient effort generates inspiratory flow causing 6 mL of volume, IPAP is triggered.
- The Shape Signal algorithm (Figure 17) continuously tracks patient inspiratory and expiratory flow and adjusts the spontaneous trigger and cycle thresholds for optimum sensitivity. The shape signal is a shadow image of the patient's actual flow and functions as a sensitivity threshold at either inspiration or exhalation. When the patient's flow rate crosses the shape signal, the system changes pressure levels. The shape signal is created by offsetting the signal from the actual patient flow by 15 L/min and delaying it for 300 milliseconds. This causes the shape signal to be slightly behind the patient's flow rate. A sudden change in patient flow causes the shape signal to be crossed, causing the pressure level to change.

- The spontaneous expiratory threshold (SET) algorithm (Figure 18) raises the threshold in proportion to the inspiratory flow rate for each breath. When the SET and actual patient flow value are equal, the system cycles to EPAP.
- Maximum inspiratory time: 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 S/T mode. If 3.0 seconds elapse in IPAP, the system automatically cycles from IPAP to EPAP.
- Flow reversal: 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 system senses this flow reversal, the unit automatically cycles to EPAP.

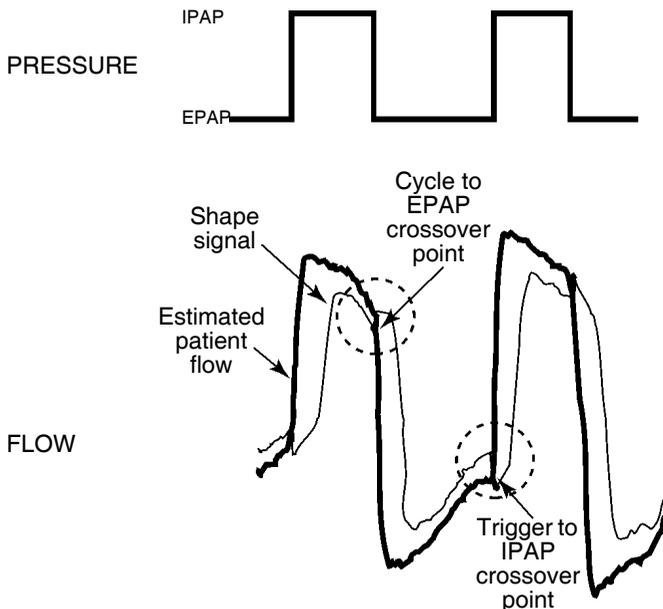


Figure 17: Shape Signal

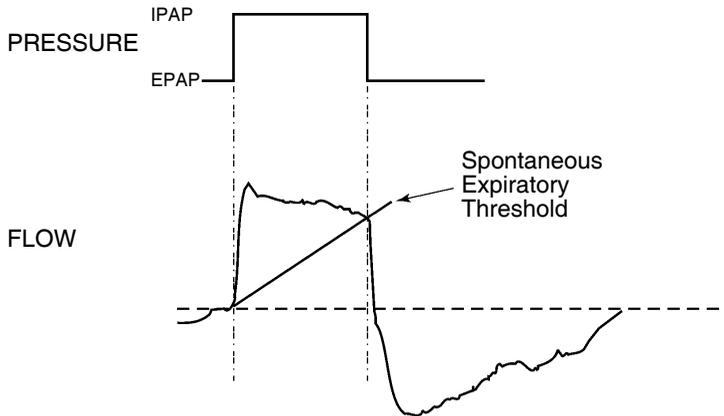


Figure 18: Spontaneous Expiratory Threshold

System Shut Down

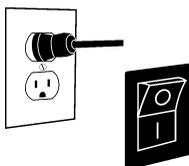
WARNING: Failure to enter Standby mode before switching the ON/OFF switch on the back of the unit to the OFF position (O) will cause the unit to alarm for two minutes indicating the unit was not powered off correctly. This is a safety feature. If it occurs, turn the unit back ON (I) in Normal mode and then shut it down correctly.

CAUTION: To prevent the premature depletion and reduced life expectancy of the battery, store the ventilator with AC power connected and the ON/OFF switch in the ON (I) position. When the ventilator is stored disconnected from AC power with the power ON/OFF switch ON (I) and in standby, the battery may become depleted within two weeks. When the ventilator is stored with the ON/OFF switch in the OFF (O) position, the battery typically becomes depleted in three months.

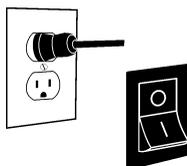
1. Put the system into Standby mode by pressing the **STANDBY** button on the front panel and selecting **OK** to confirm.
2. If AC power is available, store the ventilator connected to AC power and with **ON/OFF** switch set to **ON (I)** (Figure 19). The battery charging cycle will be active.

3. If AC power is unavailable, store the ventilator with **ON/OFF** switch set to **OFF (O)** and disconnected from AC power.

Always recommended:
Battery charging and storage



Not recommended:
Battery NOT charging



Recommended only if AC power is unavailable

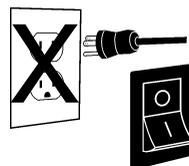


Figure 19: Battery Charging and Storage

The BiPAP Focus Front Panel

Figure 20 shows the English version and Figure 21 shows the international version of the BiPAP Focus front panel. Table 2 summarizes the functions of the front panel elements.

WARNING: To avoid damage to the keypad, do not use pens or other sharp objects to change settings.

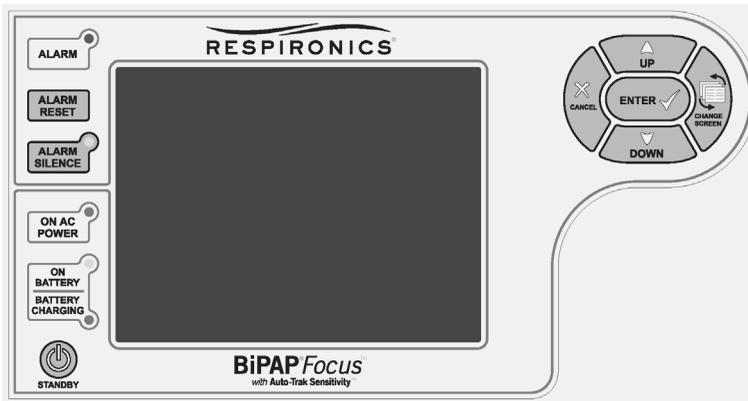


Figure 20: BiPAP Focus System English Front Panel

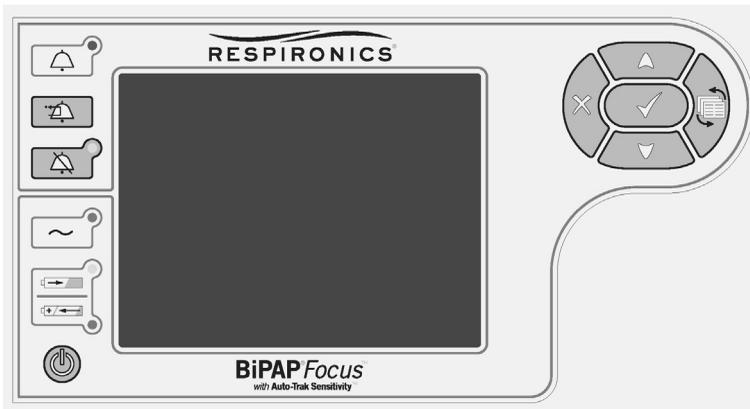


Figure 21: BiPAP Focus System International Front Panel

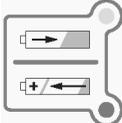
Table 2: BiPAP Focus System Front Panel Controls		
English	Int'l	Description
		ALARM indicator shows if an alarm is active (flashing) or auto-reset (steadily lit indicator). <i>NOTE: In STANDBY mode only, an active ALARM LED indicates a missing or faulty battery or a charging circuit fault.</i>
		ALARM RESET clears active and auto-reset alarms or cancels an alarm silence.
		ALARM SILENCE mutes the audible alarm for 2 minutes. Each key press restarts the 2-minute interval. The indicator lights (yellow) when alarm silence is active. Alarm presilence: press when no alarm is active for two minutes of silence.
		AC indicator lights (green) to show that the system is powered by AC (mains) power.
		Battery Status lights to show if the system is powered by battery power (yellow) or the battery charge cycle is active during AC operation (green). The green indicator turns off when the battery is fully charged during AC operation.
		STANDBY turns the system ON or puts the unit into Standby mode. Standby mode allows the internal battery to charge.
 	 	UP and DOWN arrow keys navigate the on-screen buttons or adjust values.

Table 2: BiPAP Focus System Front Panel Controls

English	Int'l	Description
		CANCEL clears changes. Press and hold CANCEL for 5 seconds to lock and unlock the keypad.
		CHANGE SCREEN steps through available screens.
		ENTER selects or confirms a new setting.

Screen Navigation

Press the Change Screen key to step through the available screens.

The settings screen allows you to view or change the current mode and settings. This screen also displays real-time patient data.

The alarm settings screen allows you to view or change the settings for the Apnea and Apnea Rate (#Apnea) alarms. This screen also displays real-time patient data.

The options screen allows you to view or change the ventilator’s audio and visual settings (display units, alarm volume, contrast, brightness, reverse video, and screen lock timer enable/disable).

WARNING: Do not use the system if the screen is unreadable. If this occurs turn the ON/OFF switch to the OFF position (O).

Changing Settings

1. Use the arrow keys to highlight the desired setting and press **ENTER**. A pop-up window for the setting appears (Figure 22).
2. Use the arrow keys to adjust the setting.
3. Press **ENTER** to put the new setting into effect, or press **CANCEL** to exit without changing the setting.

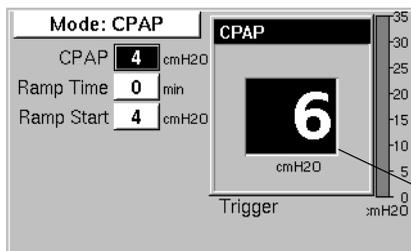


Figure 22: Changing Setting

Pop-up window shows selected setting

Changing Modes

1. Use the **UP** or **DOWN** arrow to highlight the 'Mode CPAP' or 'Mode S/T' button, and press **ENTER** to see the list of modes.
2. Use the **UP** or **DOWN** arrow to highlight the desired mode from the list and then press **ENTER**.
3. Review and adjust the intended settings for the proposed Mode as required.
4. Scroll to highlight **Activate** (Figure 23) at the bottom of the screen to activate the mode change. Note that '**Proposed (Mode)**' will flash at the top of the screen until the new mode is activated or cancelled.

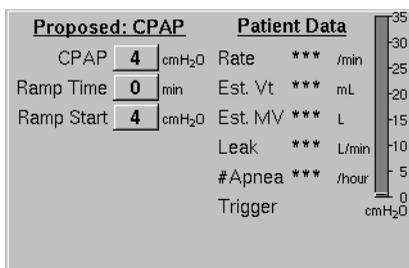


Figure 23: Activating a New Mode

CPAP Mode Settings Screen

Figure 24 shows the CPAP Mode settings screen.

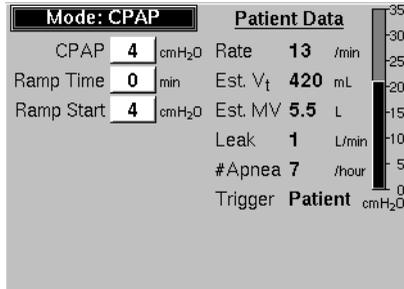


Figure 24: CPAP Mode Settings Screen

The CPAP screen includes these elements:

Settings

- CPAP** The level of continuous positive airway pressure delivered throughout the breath cycle.
- Ramp Time** Period over which the ventilator increases inspiratory pressure from *Ramp Start* setting to *CPAP* setting.
- Ramp Start** The initial CPAP pressure (less than or equal to the *CPAP* setting).

Patient Data

- Rate** Measured respiratory rate.
- Est. V_t** Estimated delivered tidal volume. Flashes when peak inspiratory flow for successive breaths varies by more than 15 L/min.
- Est. MV** Estimated exhaled minute volume.
- Leak** Estimated patient leak.
- #Apnea** The number of periods (10 seconds or more) in the previous hour where the patient has not initiated a spontaneous breath.
NOTE: For the first hour, this value is an estimate only.

Trigger Indicates whether the patient (*Patient*) or ventilator (*Timed*) is triggering a breath.

Bar graph Continuous display of measured patient circuit pressure.

NOTE: '+++' is displayed for any parameter outside of upper ranges. '---' is displayed for any parameter outside of lower ranges.

See "Specifications" on page 67 for more information.

S/T Mode Settings Screen

Figure 25 shows the S/T Mode settings screen.

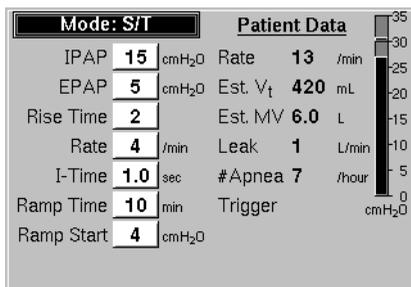


Figure 25: S/T Mode Settings Screen

The S/T screen includes these elements:

Settings

IPAP Inspiratory positive airway pressure, the inspiration pressure setting. *IPAP* cannot be set below *EPAP*.

EPAP Expiratory positive airway pressure, the exhalation pressure setting.

Rise-Time How quickly the ventilator increases inspiratory pressure from *EPAP* pressure to 67% of the pressure support level.

Ramp Time Period over which the ventilator increases respiratory pressure from *Ramp Start* setting to *EPAP* setting.

Operation

<i>Ramp Start</i>	The initial EPAP pressure (less than or equal to the <i>EPAP</i> setting).
<i>Rate</i>	Respiratory rate, used to determine if a timed breath is delivered. <i>I-Time</i> and <i>Rate</i> settings cannot allow <i>I-Time</i> to exceed expiratory time. The system will reduce the <i>I-Time</i> automatically as required to satisfy this rule.
<i>I-Time</i>	Inspiratory time. <i>I-Time</i> and <i>Rate</i> settings cannot allow <i>I-Time</i> to exceed expiratory time. The system will reduce the <i>I-Time</i> automatically as required to satisfy this rule.

NOTE: Pressure support = IPAP - EPAP.

Patient Data

<i>Rate</i>	Measured respiratory rate.
<i>Est. Vt</i>	Estimated delivered tidal volume. Flashes when peak inspiratory flow for successive breaths varies by more than 15 L/min.
<i>Est. MV</i>	Estimated exhaled minute volume.
<i>Leak</i>	Estimated patient leak.
<i>#Apnea</i>	The number of periods (10 seconds or more) in the previous hour where the patient has not initiated a spontaneous breath. <i>NOTE: For the first hour, this value is an estimate only.</i>
<i>Trigger</i>	Indicates whether the patient (<i>Patient</i>) or ventilator (<i>Timed</i>) is triggering a breath.
<i>Bar graph</i>	Continuous display of measured patient circuit pressure.

NOTE: '+++' is displayed for any parameter outside of upper ranges. '---' is displayed for any parameter outside of lower ranges.

See "Specifications" on page 67 for more information.

Alarm Settings Screen

Figure 26 shows the Alarm Settings screen.

NOTE: The system automatically selects all other alarm settings.

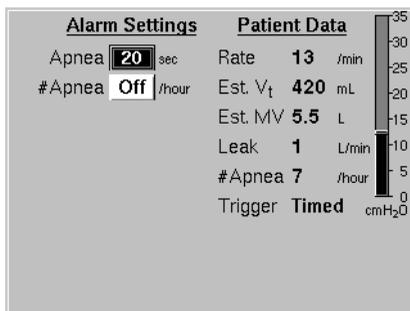


Figure 26: Alarm Settings Screen

The Alarm Settings screen includes these elements:

Settings

Apnea The length of time without a spontaneous breath that triggers Apnea alarm. **OFF** setting disables the alarm (no apnea detection).

#Apnea The number of apnea periods (10 seconds or more) within 60 minutes that triggers an *Apnea Rate (#Apnea)* alarm.

Patient Data

Rate Measured respiratory rate.

Est. V_t Estimated delivered tidal volume. Flashes when peak inspiratory flow for successive breaths varies by more than 15 L/min.

Est. MV Estimated exhaled minute volume.

Leak Estimated patient leak.

#Apnea The number of periods (10 seconds or more) in the previous hour where the patient has not initiated a spontaneous breath.
For the first hour, this value is an estimate only.

Bar graph Continuous display of measured patient circuit pressure.

Options Screen

Figure 27 shows the Options screen.

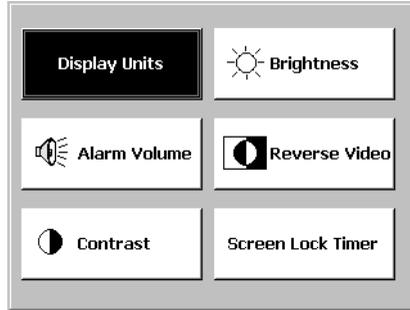


Figure 27: Options Screen

The Options screen includes these elements:

- | | |
|--------------------------|---|
| <i>Display Units</i> | Selects units of pressure: centimeters of water (cmH ₂ O), hectoPascals (hPa), or millibars (mbar). |
| <i>Alarm Volume</i> | Selects audible alarm volume. |
| <i>Contrast</i> | Selects screen contrast from 20% to 100%. |
| <i>Brightness</i> | Selects screen brightness from 10% to 100%. |
| <i>Reverse Video</i> | Toggles reverse video ON and OFF . |
| <i>Screen Lock Timer</i> | Toggles screen lock timer ON or OFF .
When the screen lock timer is ON , the keypad locks if no key is pressed for 2 minutes. If any key other than CANCEL is pressed, a pop-up message will appear stating “Hold Cancel button for 5 sec. to unlock.” Press OK to remove this pop-up before proceeding to the next step. Then, press and hold CANCEL for 5 seconds to unlock the keypad.

NOTE: You can manually lock the keypad by pressing and holding CANCEL for 5 seconds. |

Battery Back-up Operation

The BiPAP Focus contains an internal battery. When the internal battery is fully charged, the Battery Back-up feature allows the unit to continue operation for a limited time in the event of mains power loss or during intra-hospital transport. If loss of mains power occurs, the unit will automatically switch to operate from the internal battery and will generate the **Loss of AC** alarm (this alarm can be silenced, see “Alarms” on page 47). The internal battery is NOT intended to serve as a primary power source.

When the BiPAP Focus is operating on the internal battery, the **ON AC POWER** LED (green) will extinguish, the **ON BATTERY** LED (yellow) will illuminate, and the **On battery** message will appear on the screen.

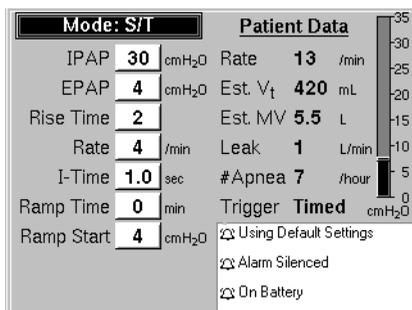


Figure 28: Running on Internal Battery

When the BiPAP Focus estimates that there are approximately 10 minutes of internal battery power remaining, the unit will generate a silenceable **Low Battery** alarm. Mains power should be reconnected immediately to avoid loss of power.

When up to 2 minutes of internal battery power remain, the **Battery Depleted** alarm (non-silenceable) will occur. Mains power must be reconnected immediately to avoid loss of power to the ventilator.

CAUTION: When using the Focus for patient intra-hospital transport, ensure that the DC power supply and power cord are also transported with the unit to recharge the battery whenever AC power is available.

Battery Operating Time

The amount of time the ventilator will operate on the internal battery depends primarily on the machine settings being used. The following table shows the approximate internal battery life expectancy for a fully charged battery.

Table 3: Internal Battery Life Expectancy

CPAP or IPAP Setting	Approximate Battery Life
10 cmH ₂ O	60 minutes
15 cmH ₂ O	50 minutes
20 cmH ₂ O	40 minutes
25 cmH ₂ O	30 minutes
30 cmH ₂ O	20 minutes

WARNING: *When running on battery, the high flows that occur during a patient disconnect will cause the battery to deplete in as little as 2 minutes. Connect AC power immediately if the Battery Depleted Alarm sounds to avoid total loss of power.*

Battery Charging

The internal battery technology is NiMH (Nickel Metal Hydride). The battery will automatically charge when the unit is connected to mains power (AC) via the DC power supply and when the power switch on the back of the ventilator is in the **ON** (|) position. The **ON AC POWER LED** will illuminate indicating that mains is connected and the **BATTERY CHARGING LED** will illuminate indicating that the charging cycle is in progress. The battery is fully charged when the **BATTERY CHARGING LED** turns off.

The charging cycle operates in Normal mode and in Standby mode. Battery charge time is typically less than 5 hours, but can be longer depending on environmental conditions (primarily temperature).

It is important to maintain a fully charged internal battery in case of a mains power outage. Any time the BiPAP Focus has been in storage, a

full charge cycle should be run. A fully charged battery will deplete within 3 months if unused and not charged. This is the normal depletion rate when the unit is stored with the **ON/OFF** switch in the **OFF (O)** position. If the unit is left in Standby mode with the **ON/OFF** switch in the **ON (I)** position and it is not connected to AC mains power, the internal battery will deplete within 2 weeks.

CAUTION: *To prevent the premature depletion and reduced life expectancy of the battery, store the ventilator with AC power connected and the ON/OFF switch in the ON (I) position. When the ventilator is stored disconnected from AC power with the power ON/OFF switch ON (I) and in standby, the battery may become depleted within two weeks. When the ventilator is stored with the ON/OFF switch in the OFF (O) position, the battery typically becomes depleted in three months.*

If a 343 error code is displayed, contact Service. The battery needs replacement.

CAUTION: *During battery charging, disconnecting AC mains power before charging completes may result in a Battery Depleted message. Connect AC power immediately if Battery Depleted alarm annunciates to avoid total loss of power.*

NOTE: *For maximum battery performance, a new battery or a battery that has been in storage should be fully charged and discharged two to three times.*

Battery Care

It is recommended that the battery be tested every 3 months, at a minimum, as described in “Testing the Battery” on page 61. A fully charged battery is designed to operate for a minimum of 45 minutes at default settings (see “Battery backup” on page 73). If it appears that the battery does not meet these specifications, perform this test and replace the battery as needed.

When the unit is in Standby mode, if the red **ALARM** LED illuminates this indicates that there is a problem with the battery charging cycle. If the **BATTERY CHARGING** and the **ON BATTERY** LEDs are illuminated simultaneously then contact Respironics Customer Service.

The BiPAP Focus self tests will also indicate when the battery needs to be replaced by displaying a **Batt Charge Failure** message (see “Alarms” on page 47). Contact Customer Service to purchase a replacement battery.

Chapter 5: Alarms

When an alarm is active:

- The **ALARM** indicator flashes,
- The alarm message is displayed, and
- The system sounds a repeating sequence of beeps.



Certain alarms can be auto-reset, meaning that the system automatically resets the alarm once the alarm condition is corrected. Alarms that do not auto-reset must be manually reset.

The options screen allows you to select alarm volume. If an alarm auto-resets, the **ALARM** indicator remains steadily lit to indicate that the alarm occurred.

Alarm Reset



Press **ALARM RESET** to clear audible and visual alarm indicators, or to cancel an Alarm Silence.

Alarm Silence



The **ALARM SILENCE** key silences the audible portion of an alarm for two minutes. Pressing the **ALARM SILENCE** key again restarts the two-minute interval.

ALARM SILENCE is cancelled by a new alarm or by pressing the **ALARM RESET** key.

The **ALARM SILENCE** key does not affect the visual **ALARM** indicator. The **ALARM SILENCE** key lights when Alarm Silence is active.

Alarm Pre-silence

Press **ALARM SILENCE** when no alarms are active to silence any alarm that may occur in the two minutes following the key press. Alarm Pre-silence is useful for avoiding nuisance alarms during certain procedures. A new alarm will not sound if Alarm Pre-silence is active.

Press **ALARM RESET** when Alarm Pre-silence is no longer required.

Alarm Message Window

An alarm message window appears when an alarm occurs (Figure 29). The window can display up to three alarm messages in order of priority.

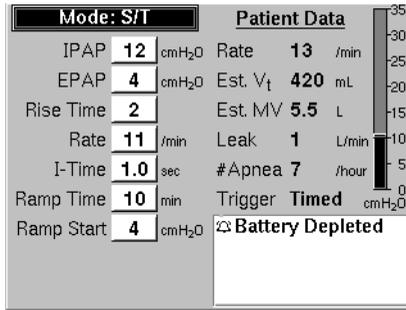


Figure 29: Alarm Message Window

Alarm Descriptions

Table 4 summarizes alarms. When more than one corrective action is listed, follow them in order until the alarm is resolved. If the suggested corrective actions do not resolve the problem, provide alternate breathing support and contact a qualified service technician.

Table 4: BiPAP Focus Alarms		
Alarm Message	Description	Corrective Action
Apnea (<i>auto-resets</i>)	The patient has not triggered a spontaneous breath within the set Apnea Alarm period. Auto-resets when patient triggers a spontaneous breath. <i>NOTE: Timed breaths are not used in determining apnea duration.</i>	Check patient and settings.
Apnea Rate (#Apnea) (<i>no auto-reset</i>)	The number of periods (10 second or more) in the previous hour where the patient has not initiated a spontaneous breath, has exceeded the #Apnea per hour alarm setting. <i>NOTE: The number of periods for the first hour is estimated.</i> <i>NOTE: Pressing Alarm Reset when the Apnea Rate (#Apnea) Alarm is active, will clear the #Apnea display to 0.</i>	Check patient and settings.
Batt. Charge Failure (<i>no auto-reset</i>)	Battery not connected or voltage remains low after recharge.	Check battery connection. Replace battery.

Table 4: BiPAP Focus Alarms

Alarm Message	Description	Corrective Action
Battery Depleted <i>(auto-resets)</i>	Up to 2 minutes of battery power remain. Auto-resets when AC power is connected. Cannot be manually reset or silenced.	Check connection to AC power and verify that AC POWER and green BATTERY STATUS indicators are lit. If battery was depleted earlier than expected, refer to “Testing the Battery” on page 61. Replace battery if necessary.
Disconnect <i>(auto-resets)</i>	Ventilator has detected a patient disconnect condition for at least 15 seconds. Auto-resets when disconnect condition no longer exists.	Check patient. Check breathing circuit connections.
Hi P Reg <i>(no auto-reset)</i>	High pressure regulation alarm. Circuit pressure 5 cmH ₂ O above set CPAP or IPAP for 500 msec.	Check patient and settings. Verify that breathing circuit is not obstructed.
High Batt Temp <i>(auto-resets)</i>	Battery is overheating. Battery may be almost depleted; or there may be a patient or breathing circuit disconnect, causing the blower to run at high speed. Auto-resets when AC power is connected.	Check patient. Connect ventilator to AC power. Check for causes of overheating, including a patient or breathing circuit disconnect.

Table 4: BiPAP Focus Alarms

Alarm Message	Description	Corrective Action
High Temperature	High temperature detected inside the ventilator.	Check room temperature is within specified operating conditions. Allow the ventilator to acclimate to the ambient conditions.
Key Stuck	One or more of the user interface keys has been detected as permanently pressed or stuck closed.	Check the keypad. Run pre-use check. Contact customer service.
Lo P Reg (no auto-reset)	Low pressure regulation alarm. Circuit pressure is 5 cmH ₂ O below set CPAP or IPAP for 60 sec.	Check patient and settings. Check for leaks in breathing circuit or mask fitting. Press ALARM RESET to clear.
Loss of AC (auto-resets)	Ventilator has switched to battery operation. This is a notification alarm. Auto-resets when AC power is connected. After the Alarm Reset is pressed the unit beeps once a minute when on battery.	If not in use for transport, check connection to AC power and verify that AC POWER and green BATTERY STATUS indicators are lit.

Table 4: BiPAP Focus Alarms

Alarm Message	Description	Corrective Action
Low Battery (<i>auto-resets</i>)	Approximately 10 minutes of battery power remain. Auto-resets when AC power is connected.	Check connection to AC power and verify that AC POWER and green BATTERY STATUS indicators are lit. If battery was depleted earlier than expected, refer to “Testing the Battery” on page 61. Replace battery if necessary.
Low Temperature	Low temperature detected inside the ventilator.	Check room temperature is within specified operating conditions. Allow the ventilator to acclimate to the ambient conditions.
System Error: XXX (<i>no auto-reset</i>)	The system has halted and is not providing breathing support to the patient.	Check patient and provide alternate breathing support. Cycle power: if problem persists, remove ventilator from use and contact a qualified service technician.
Any alarm not shown above		Contact customer service.

Chapter 6: Symbols

Symbol	Meaning
	Canadian Standards Association approval.
IPX1	Drip-proof enclosure ingress protection.
	Type BF protection rating.
	Compliant with the Waste Electrical and Electronic Equipment (WEEE) Recycling Directive.
	Keep dry
	Fragile, handle with care.
	This side up.
	Nurse call station connection.
	Serial port connection.
	Universal Serial Bus (USB) connection.
	18V Direct Current (DC) input.
	Alternating Current (AC)

Symbols

Symbol	Meaning
	ON/OFF switch (press “O” to turn OFF; press “I” to turn ON).
	Manufacturer approved power supply for use with the ventilator.
	Electrical Input
	Gas inlet port
	Gas output port
	LOT code
	Serial number
	Catalogue number
	Battery (battery compartment door)
	Alarm indicator. Shows if an alarm is active (flashing) or autoreset (steadily lit indicator).
	Alarm reset. Clears active and autoreset alarms or cancels an Alarm Silence.
	Alarm Silence. Mutes the audible alarm for 2 minutes. Each key press restarts the 2-minute interval. The indicator lights (yellow) when Alarm Silence is active.
	Standby turns the system ON or puts it into Standby mode.
	Power indicator LED lights up to show that the ventilator is operating from an AC power source.

Symbol	Meaning
	<p>Battery Status LEDs indicate that either the system is powered by internal battery power (yellow) or the battery charge cycle is active during AC operation (green). The green indicator turns off when the battery is fully charged during AC operation.</p>
	<p>Mandatory - Consult ACCOMPANYING DOCUMENT (IEC 60601-1:2005 + CORR. 1 [2006] + CORR. 2 [2007])</p>
	<ul style="list-style-type: none"> • Attention, consult ACCOMPANYING DOCUMENTS (IEC 60601-1:1988 + A1:1991 + A2:1995) • Caution! (IEC 60601-1:2005 + CORR. 1 [2006] + CORR. 2 [2007])
	<p>Consult ACCOMPANYING DOCUMENT (IEC 60601-1:2005 + CORR. 1 [2006] + CORR. 2 [2007])</p>

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Chapter 7: Care and Maintenance

WARNING: Maintenance and service work not listed in this chapter shall only be performed by a qualified service technician. Only a qualified service technician can assure that the BiPAP Focus system is properly serviced for safe operation.

Table 5 summarizes maintenance procedures for the BiPAP Focus System.

To ensure correct operation, perform all maintenance at the recommended intervals.

Table 5: BiPAP Focus System Maintenance

Part	Interval	Procedure
Battery	Replace the battery if a Batt Charge Failure alarm occurs, or as indicated in “Battery Care” on page 46	The battery must be connected before use. Follow “Setup” instructions beginning on page 9. <i>NOTE: If the unit has been in storage without DC power or has not been used for 3 months, the battery will require a full charge. For maximum battery performance, a new battery or a battery that has been in storage should be fully charged and discharged two to three times.</i>
Patient Circuit (including bacteria filter)	Between patients or as needed.	Replace circuit and interface. Do not attempt to clean or reuse single patient use circuit components.

Table 5: BiPAP Focus System Maintenance

Part	Interval	Procedure
Air inlet filter(s)	<p>Reusable: clean monthly or as needed.</p> <p>Reusable: every year or as needed.</p> <p>Disposable: replace as needed.</p> <p><i>NOTE: The air path cannot be cleaned.</i></p>	<p>Follow the “Cleaning the Reusable Air Inlet Filter” on page 8.</p> <p>Replace.</p> <p>Do not attempt to clean or reuse disposable filters.</p>
Internal valve assembly	<p>Every 10,000 hours of operation.</p> <p><i>Refer to the BiPAP Focus Service Manual to check hours of operation.</i></p>	<p>Qualified service technician only.</p>
System exterior	<p>As needed.</p>	<p>Clean the exterior of the ventilator with a soft damp cloth moistened with any of the following solutions:</p> <ul style="list-style-type: none"> • Mild detergent or soapy water • 10% bleach solution (90% water) • Isopropyl alcohol (91%) • Quaternary ammonium germicides (sprays or disposable cloths) <p>Do not spray or immerse in liquid. Do not allow liquid to penetrate the system.</p>

Storing the BiPAP Focus

When the BiPAP Focus is not in use for periods of 2 weeks or longer, it is recommended that the unit be stored in a clean, sanitized plastic bag.

While the unit is being stored, ensure that the power switch on the back of the unit is in the **OFF (O)** position. If the switch is not turned **OFF**, the internal battery will be depleted within two weeks. If the unit is stored with the power switch in the **OFF (O)** position, the internal battery will deplete within 3 months.

CAUTION: *To prevent the premature depletion and reduced life expectancy of the battery, store the ventilator with AC power connected and the ON/OFF switch in the ON (I) position. When the ventilator is stored disconnected from AC power with the power ON/OFF switch ON (I) and in standby, the battery may become depleted within two weeks. When the ventilator is stored with the ON/OFF switch in the OFF (O) position, the battery typically becomes depleted in three months.*

If a 343 error code is displayed, contact Service. The battery needs replacement.

CAUTION: *During battery charging, disconnecting AC mains power before charging completes may result in reduced battery life when system is used.*

NOTE: *For maximum battery performance, a new battery or a battery that has been in storage should be fully charged and discharged two to three times.*

Cleaning the Reusable Air Inlet Filter

Follow these steps to clean the reusable air inlet filter (Figure 30):

1. Remove the filter and examine for damage or debris.
2. Wash using one of the following solutions, then rinse thoroughly:
 - Palmolive® or Dawn® dishwashing detergent
 - White distilled vinegar (5% acidity)
 - Isopropyl alcohol (99.9%)
 - Hydrogen peroxide (3%)
 - Clorox Ultra® bleach
 - Sodium hypochlorite (6%)
3. Allow the filter to dry completely before reinstalling.



CAUTION: Never reinstall a wet filter.

CAUTION: Use only Respirationics-approved filters.

CAUTION: Replace any filter that is damaged.

CAUTION: Do not attempt to clean or reuse disposable air inlet filters.

Replacing the Air Inlet Filter(s)

WARNING: It is important to inspect and replace the air inlet filters at the recommended intervals to avoid introducing foreign matter into the system

The reusable air inlet filter (gray) must be installed and replaced every year. An additional ultra-fine disposable filter (white) is also recommended for enhanced particulate filtering.

Testing the Battery

Follow these steps to test the battery. The battery should be tested every three months at a minimum and whenever it does not meet specifications.

WARNING: The patient should be disconnected if operating in any mode other than Normal operating mode.

NOTE: Make sure nothing is attached to the ventilator outlet while you run this test.

1. With AC power connected, turn on the ventilator, set the mode to **S/T**, and set **IPAP** to 20 cmH₂O.
2. Make sure the **BATTERY CHARGING** LED is off, indicating a fully charged battery. If the battery is not fully charged, allow it to fully charge.
3. Turn the ventilator off.
4. Simultaneously press and hold the **ALARM RESET** and **ALARM SILENCE** keys.
5. Press the **STANDBY** key once, while continuing to hold the **ALARM RESET** and **ALARM SILENCE** keys.

- The unit will power up and will display the following screen.

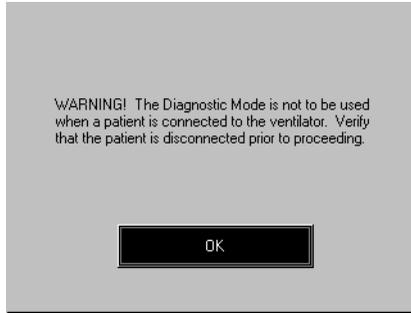


Figure 31: Warning Screen

- Press **ENTER** to continue past the Warning screen. The Menu screen will appear:

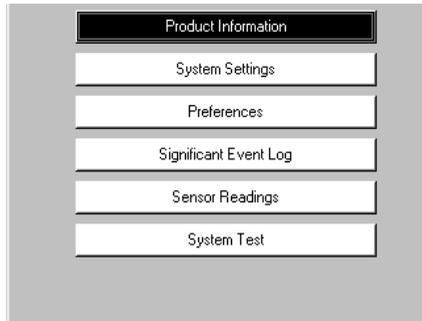


Figure 32: Menu Screen

8. If the blower is on, turn it off as follows:
 - a. Scroll using the **DOWN** arrow key until **System Test** is highlighted, and then press **ENTER**. The System Test screen shown in Figure 4 will appear.

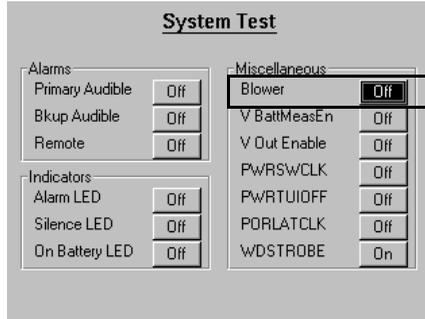


Figure 33: System Test Screen

- b. Scroll using the **DOWN** arrow key until the Blower status is highlighted, and then press **ENTER** to toggle it **Off**.
 - c. Press **CHANGE SCREEN** to return to the Menu screen.
9. Disconnect the ventilator from AC power.
10. Record the VBATT reading with the blower off, as follows:
 - a. From the Menu screen, scroll using the arrow keys until **Sensor Readings** is highlighted, and then press **ENTER**. The Sensor Readings screen will appear (Figure 5).

<u>Sensor Readings</u>				
+3.3V	3.26V	918	+18VINCOMP	1
+5V	4.89V	911	+18VBSTCOMP	1
+12V	11.92V	930	BattChrgFault	0
+18Vin	18.34V	963	BattOnChrg	0
+18V Boost	18.51V	971	BattChrgToc	1
VBATT	10.29V	881	BattChrgRdy	1
VDptoCap	3.96V	732	PORLATCH	0
Board Temp	28 °C	364	PwRSWMON	1
Ambient Temp	28 °C		PwRSWLATCH	1

Figure 34: Sensor Readings Screen

Care and Maintenance

- b. Record the VBATT reading.
11. Press **CHANGE SCREEN** to return to the Menu screen.
12. Turn the blower on by repeating step 8, but setting Blower to **On**.
13. Wait 1 minute for the VBATT reading to stabilize. Record the VBATT reading by repeating step 10.
14. Subtract the second VBATT reading from the first reading. If the difference is greater than 2.5 V, install a new battery. If the difference is less than 2.5 V, the battery is acceptable.

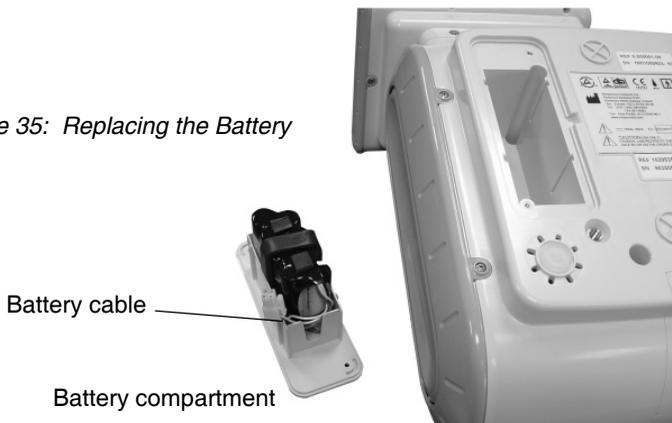
Replacing the Battery

WARNING: To avoid the risk of fire, use only Respiration-approved batteries. All battery connections are keyed to ensure proper connection.

Replace the battery (Figure 35) if a **Batt. Charge Failure** alarm occurs, or as indicated in “Battery Care” on page 46.

NOTE: If a Low Battery or Battery Depleted alarm occurs during Pre-Operational Check, then the battery requires charging. If a Batt Charge Failure alarm occurs, the battery may be fully depleted. A re-charge is recommended before proceeding. If the battery does not begin to charge after one hour and the Batt Charge Failure persists, contact customer service for a replacement battery.

Figure 35: Replacing the Battery



Follow these steps:

1. Turn the system **OFF** and disconnect the DC power supply.
2. Remove the two screws that secure the battery compartment door.
3. Unplug the battery cable and remove the old battery from its compartment.
4. Insert a new Respiration-approved battery (see “Accessories” on page 87) into the compartment and plug the battery cable into its connector.

Care and Maintenance

5. Replace the battery compartment door and screws.
6. Reconnect the DC power supply.

WARNING: Use only Respironics recommended batteries.

Chapter 8: Specifications

Default Settings

S/T mode	RR = 4/min
IPAP = 12 cmH ₂ O	I-Time = 1 sec
EPAP = 4 cmH ₂ O	Ramp Time = 0 min
Rise-Time = 2	Ramp Start = 4 cmH ₂ O

Settings: CPAP Mode

CPAP	Range: 4-20 cmH ₂ O (4-20 hPa)
<i>Continuous Positive Airway Pressure</i>	Resolution: 1 cmH ₂ O (1 hPa) Dynamic accuracy: ±5 cmH ₂ O (5 hPa)
Ramp Time	Range: 0-45 min.
<i>Period over which the ventilator increases inspiratory pressure from Ramp Start setting to CPAP setting.</i>	Resolution: 5 min. Accuracy: ±10% of setting
Ramp Start	Range: 4 cmH ₂ O to CPAP setting (4 hPa to CPAP setting)
<i>Initial inspiratory pressure</i>	Resolution: 1 cmH ₂ O (1 hPa)

Specifications

Settings: S/T Mode

IPAP <i>Inspiratory positive airway pressure, the inspiration pressure setting</i>	Range: 4-30 cmH ₂ O (4-30 hPa) Resolution: 1 cmH ₂ O (1 hPa) Dynamic accuracy: ±5 cmH ₂ O (5 hPa) IPAP cannot be set below EPAP.
EPAP <i>Expiratory positive airway pressure, the exhalation pressure setting</i>	Range: 4-25 cmH ₂ O (4-25 hPa) Resolution: 1 cmH ₂ O (1 hPa) Dynamic accuracy: ±5 cmH ₂ O (5 hPa)
Rise-Time <i>How quickly the ventilator increases inspiratory pressure from EPAP pressure to 67% of pressure support level</i>	Range: 1-6 (where 1 = 0.1 sec and 6 = 0.6 sec) Resolution: 1 Accuracy: ± (0.15 + 10% of setting) sec
Rate <i>Respiratory rate, used to determine if a timed breath is delivered</i>	Range: 1-30/min Resolution: 1/min Accuracy: ±1/min or ±10% of setting, whichever is greater over a 4-minute period. I-Time and Rate settings cannot allow I-Time to exceed expiratory time.

Settings: S/T Mode

I-Time <i>Inspiratory time</i>	Range: 0.5-3 sec Resolution: 0.1 sec Accuracy: $\pm (0.1 + 10\% \text{ of setting})$ sec I-Time and Rate settings cannot allow I-Time to exceed expiratory time.
Ramp Time	Range: 0-45 min Resolution: 5 min Accuracy: $\pm 10\%$ of setting
Ramp Start <i>Initial inspiratory pressure</i>	Range: 4 cmH ₂ O to EPAP (4 hPa to EPAP) Resolution: 1 cmH ₂ O (1 hPa)

Measured Data

Patient circuit pressure bar graph (continuous display)	Range: 0-35 cmH ₂ O (0-35 hPa) Resolution: 1 cmH ₂ O (1hPa) Accuracy: $\pm 10\%$ of scale In the event of total loss of power, the inspiratory and expiratory pressure measured at the patient exhalation port at 60 L/min is less than 1 cmH ₂ O by virtue of mask and ventilator design.
Rate <i>Measured respiratory rate</i>	Range: 0-60/min Resolution: 1/min Accuracy: $\pm (1 + 10\% \text{ reading})$

Specifications

Measured Data

Est. Vt	Range: 0-4000 mL
<i>Estimated delivered tidal volume</i>	Resolution: 1 mL Accuracy (S/T Mode): \pm (50 mL + 10% reading) (when leak <60 L/min, using the Vision circuit) Accuracy (CPAP Mode): \pm (100 mL + 10% reading) (when leak <60 L/min, using the Vision circuit) Vt display flashes when peak inspiratory flow for successive breaths varies by more than 15 L/min.

Est. MV	Range: 0-99 L/min
<i>Estimated exhaled minute volume</i>	Resolution: 0.1 L/min Accuracy: \pm 1 L or \pm 10% actual, whichever is greater (when leak is <60 L/min using the Vision circuit).

Leak	Range: 0-150 L/min
<i>Estimated Patient leak</i>	Resolution: 1 L/min Accuracy: \pm (15 L/min +10%)

#Apnea	Range: 0-99/hour
<i>Brief apnea periods</i>	Resolution: 1/hour Accuracy: \pm 1/hour (after 1 hour)

Trigger	Range: Patient or Timed (ventilator)
<i>Breath trigger</i>	

NOTE: Est. Vt and Est. MV estimates are at ambient temperature and pressure, dry (ATPD). Pressure signals are filtered using a 50-Hz low pass Butterworth filter.

Alarm Settings

Apnea	Range: 20, 40, 60 sec or OFF
<i>The length of time without a spontaneous breath that triggers the Apnea alarm</i>	Default setting: 20 sec

Alarm Settings

#Apnea	Range: 5, 10, 20, or OFF
<i>The number of periods (10-seconds or more) in the previous hour where the patient has not initiated a spontaneous breath.</i>	Default setting: OFF
<i>NOTE: For the first hour, this value is an estimate only.</i>	

Options

Display Units	Range: cmH ₂ O, hPa, or mbar
<i>Unit of pressure: centimeters of water (cmH₂O), hectoPascals (hPa), or millibars (mbar).</i>	
Alarm Volume	Range: OFF, or minimum volume, to maximum volume, in 5 discrete settings.
<i>Audible alarm volume</i>	
Contrast	Range: 20% to 100%
<i>Screen contrast</i>	
Brightness	Range: 10% to 100%
<i>Screen brightness</i>	
Reverse Video	Range: ON or OFF
<i>Toggles reverse video</i>	
Screen Lock Timer	Range: ON or OFF

Specifications

Nurse Call Station/Serial Communications Connector Pinout

Pin	Signal
Nurse Call Station	
1	Nurse call station common
6	Normally open (NO) during normal (non-alarm) operation
9	Normally closed (NC) during normal (non-alarm) operation
Serial Communications	
2	Respironics advanced serial protocol (RASP) RS-232 Transmit (Tx)
3	RASP RS-232 Receive (Rx)
4	Not used
5	RS-232 signal ground
7	RS-232 Tx (reserved for Respironics Technical Support)
8	RS-232 Rx (reserved for Respironics Technical Support)

NOTE:

- When pins 1 and 6 are used, the relay is open during normal operation, and closed during an alarm condition including loss of power.
- When pins 1 and 9 are used, the relay is closed during normal operation, and open during an alarm condition including loss of power.
- Female DB9 connector pin configuration:



WARNING: Use only Respironics-supplied cables with the nurse call station/serial communications connector.

Physical

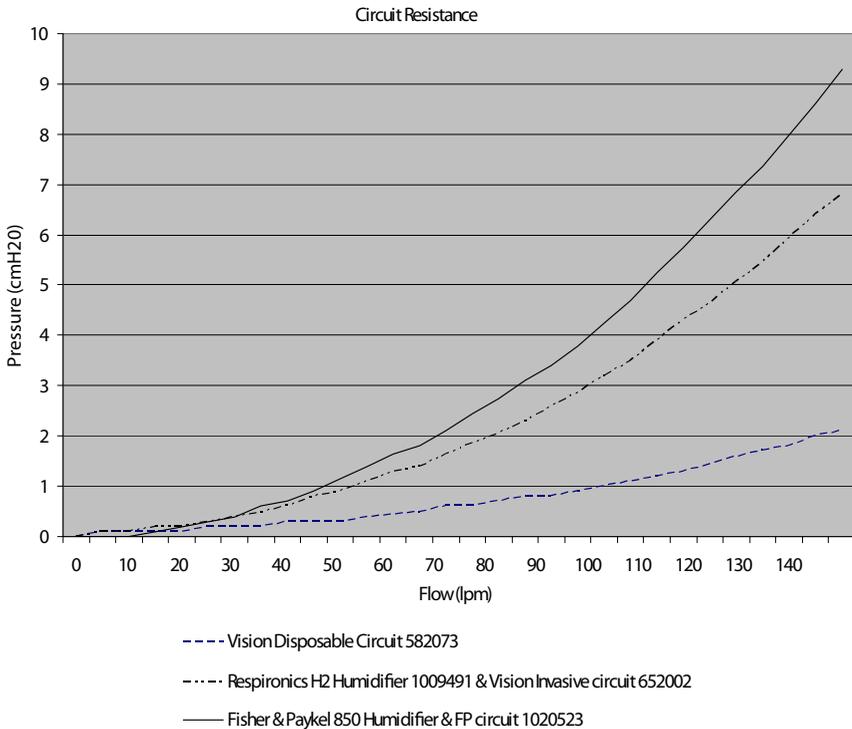
BiPAP Focus System Dimensions	355-mm H x 290-mm W x 140-mm D (14.0-in. H x 11.4-in. W x 5.5-in. D) Excluding accessories, gas inlets, patient connections.
Weight	4.5 kg (10 lbs.)

Power	
Input range	100-240 V~, 50/60 Hz, 3.0-1.5 A
Battery backup	<p>3.8 amp-hour (Ah) nickel metal hydride (NiMH) battery provides a minimum of 45 minutes of operation at default settings. System automatically activates the battery charge cycle when connected to AC power and the ON/OFF switch is ON () (during normal operation or Standby mode).</p> <p>Recharge time is typically under 5 hours, but may extend further depending on machine settings if operating on battery prior to recharge, or if operating in elevated ambient temperature (above 28°C). Charge is complete when the green CHARGING LED extinguishes.</p>
Nurse call station relay	The nurse call station port is intended to connect only to a SELV (Safety Extra-Low Voltage) and ungrounded system with basic insulation to ground, in accordance with IEC 60601-1. To prevent damage to the nurse call circuit, the signal input should not exceed the maximum rating of 24 VAC (Volts of Alternating Current) or 36 VDC (Volts of Direct Current) at 500 mA (milliamperes), with a minimum current of 1 mA.
Fuse type	No replaceable fuses.
Power cord	<p>Use the BiPAP Focus System only with the following power cords:</p> <p>Europe: Plug type CEE 7/7 (P/N 1029985)</p> <p>UK/Ireland: Plug type BS 1363 (P/N 1029982)</p> <p>USA/Canada: Plug type NEMA 5-15 (P/N 1029989)</p> <p>Contact your local distributor for other countries.</p>

Patient Circuit Details

Pressure Drop Versus Flow for Patient Circuits

The BiPAP Focus System automatically compensates for pressure drops associated with a Vision® single patient use circuit and the mandatory bacteria filter (see “Accessories” on page 87 for ordering information). The pressure drop increases as restrictive elements (for example, humidifiers) are added to the circuit. Always use a manometer to verify patient mask pressure.



Maximum Pressure Drop for Disconnect

The Disconnect alarm relies on a fixed relationship between the patient pressure settings and the open circuit flow of the Vision® single patient use circuit. The alarm works correctly unless the circuit is excessively restrictive. Use the pre-operational check to confirm that the Disconnect alarm operates properly with the circuit.

Triggers and Cycles

Volume-based trigger
 Flow reversal cycle
 Shape signal
 Timed trigger
 IPAP maximum of 3.0 seconds
 Peak flow cycle

Supplemental Oxygen

Flow and pressure into oxygen valve	Maximum flow: 15 L/min at ambient pressure
-------------------------------------	--

Environmental

Temperature	Operating: +5 to +35°C at 10 to 95% relative humidity Storage: -20 to 60°C at 95% relative humidity
Atmospheric pressure	Operating: 83 to 102 kPa (830 to 1020 mBar)
Storage	When the BiPAP Focus is not in use for periods of 2 weeks or longer, it is recommended that the unit be stored in a clean, sanitized plastic bag.

Specifications

Bacteria Filter

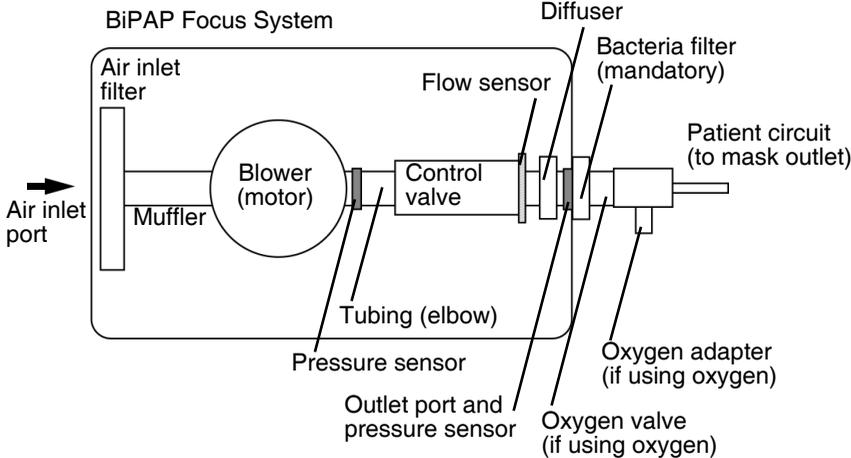
Dead space	68 mL
Bacteria/viral filter efficiency	>99.99% P/N 342077
Resistance	0.7 cmH ₂ O/L/s at 0.5 L/s
Connectors	Male connector 15-mm I.D./22-mm O.D. Female connector 22-mm I.D.

Date of Manufacture

The 12-digit serial number located on the base of the unit indicates the date of manufacture. From left to right, the fifth and sixth digits indicate the year; the seventh and eighth, the month; the ninth and tenth, the day. For example, the serial number *0001050903-20* indicates that the device was manufactured 3 September, 2005.

Pneumatics

BiPAP Focus System pneumatic diagram:



Specifications

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Chapter 9: Compliance

International Standards

- IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) IEC 60601-1:1988 + A1:1991 + A2:1995
Medical Electrical Equipment Part 1: General Requirements for Safety, plus 1st and 2nd Amendments to the standard
- EN 60601-1-2 + A1:2000, Second Edition
Medical Electrical Equipment - Electromagnetic Compatibility Requirements and Tests
- EN ISO 10651-6:2004
Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance

IEC 60601-1 Classification

Class I, Type BF, internally powered, drip-proof equipment, continuous operation.

Electromagnetic Emissions

WARNING: Using cables other than those supplied by Respirationics may result in increased emissions and/or decreased immunity of the BiPAP Focus System.

Guidance and manufacturer's declaration: electromagnetic emissions, IEC 60601-1-2 + A1:2000.

The BiPAP Focus System is suitable for use in the specified electromagnetic environment. The customer and/or the user of the BiPAP Focus System should ensure that it is used in an electromagnetic environment as described below:

Emissions Test/Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11/Group 1	The BiPAP Focus System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11/Class B	The BiPAP Focus System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2/ (not applicable)	
Voltage fluctuations/flicker emissions IEC 61000-3-3/ (not applicable)	

Guidance and manufacturer's declaration: electromagnetic immunity, IEC 60601-1-2 + A1:2000.

The BiPAP Focus System is suitable for use in the specified electromagnetic environment. The customer and/or the user of the BiPAP Focus System should ensure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Compliance

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial and/or hospital environment. If the BiPAP Focus System user requires continued operation during power mains interruptions, it is recommended that the BiPAP Focus System be powered from an uninterruptable power supply or a battery.
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration: electromagnetic immunity, IEC 60601-1-2.

The BiPAP Focus System is suitable for use in the specified electromagnetic environment. The customer and/or the user of the BiPAP

Focus System should ensure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BiPAP Focus System, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80MHz to 800MHz}$ $d = 2.3\sqrt{P} \text{ 800MHz to 2.5GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80mHz to 2.5GHz	3 V/m	

Compliance

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BiPAP Focus System is used exceeds the applicable RF compliance level above, the BiPAP Focus System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BiPAP Focus System.
- b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Recommended separation distances between portable and mobile RF communications equipment and the BiPAP Focus IEC 60601-1-2:

Frequency of transmitter	150 kHz to 80 MHz	150 kHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
Rated maximum output power of transmitter (W)	Separation distance (m)	Separation distance (m)	Separation distance (m)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p><i>NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</i></p>			

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Chapter 10: Accessories

Use the BiPAP Focus System with the following Respiration accessories. Please contact your local Respiration representative before using other accessories with the BiPAP Focus System.

Description	Order Code
BiPAP Focus Ventilator System <i>Contact your local dealer for complete part number, which is determined by country and configuration.</i>	Contact your Respiration representative
Breathing circuits and components	
Adapter, oxygen enrichment, Qty 10	312010
BiPAP Vision® single patient use circuit, for use without humidifier, Qty 10	582073
BiPAP Vision single patient use circuit, for use with humidifier, Qty 10	652002
Single-limb heated wire circuit, Qty 10	1020523
Safety valve, oxygen bleed-in, Qty 1	302418
Patient interfaces	Contact your Respiration representative
Other parts	
Filter, bacteria	342077
Filter, particulate, disposable (white)	1005945
Filter, particulate, reusable (gray)	1005964
Battery, BiPAP Focus	1028006
Nurse call station cable, BiPAP Focus, normally closed (NC), 50 ft.	1027712

Accessories

Description	Order Code
Nurse call station cable, BiPAP Focus, normally open (NO), 50 ft.	1027713
Operator's Manual, BiPAP Focus System, English	1027404
Service Manual, BiPAP Focus System	1029568
Power supply, DC, BiPAP Focus System	1025775
Universal roll stand (also requires BiPAP Focus mounting plate, P/N 1048874, and power brick holder, P/N 1004829)	1041139
O ₂ cylinder kit for universal roll stand	1048903

Chapter 11: Warranty

Warranty

Respironics warrants the BiPAP® Focus™ Ventilator to be free from defects in material and workmanship for a period of 12 months from the date of purchase, provided that the unit is operated under conditions of normal use as described in this manual. At its discretion, Respironics will make replacements, repairs, or issue credits for equipment or parts that are found to be defective.

THE WARRANTY SET FORTH ABOVE IS THE SOLE AND EXCLUSIVE WARRANTY WITH RESPECT TO THE PRODUCT AND RESPIRONICS DOES NOT MAKE, AND HEREBY SPECIFICALLY DISCLAIMS, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. THE REPAIR, REPLACEMENT OR CREDIT REMEDY SET FORTH ABOVE WILL BE THE SOLE REMEDY FOR BREACH OF WARRANTY. IN NO EVENT SHALL RESPIRONICS BE LIABLE FOR LOST PROFITS, LOSS OF GOOD WILL, OR INCIDENTAL OR CONSEQUENTIAL DAMAGES EVEN IF RESPIRONICS HAS BEEN ADVISED OF THE POSSIBILITY OF THE SAME.

Exclusions

This warranty does not apply to any unit or individual parts which have been repaired or altered in any way that in Respironics' judgement, affect its ability or reliability, or which has been subjected to misuse, negligence, abuse, or accident.

Unauthorized service and/or failure to perform periodic maintenance may void this warranty.

This warranty does not cover damage that may occur in shipment.

This warranty does not cover internal battery replacement.

Warranty

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Respironics welcomes your feedback.

Please help us provide you with the best ventilation systems available by letting us know what you think.

Philips Healthcare Customer Service

In the United States: +1-800-345-6443

Outside the United States: +1-724-387-4000

Fax: +1-724-387-5012

email: respironics.service@philips.com or

respironics.clinical@philips.com

www.philips.com/healthcare