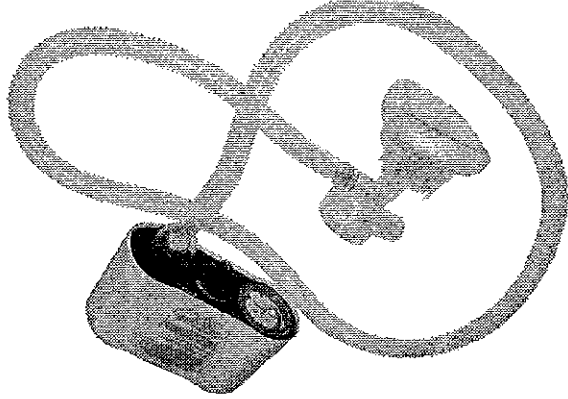


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PORTO²VENT™ **CPAP^{OS}**

Operator's Manual



PORTO²VENT™ CPAP^{OS} System Operator's Manual
Part Number 1900-140 Rev C

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SAFETY

Before you attempt to set up and use your PORTO²VENT™ CPAP^{OS} System ("System"), read this manual in its entirety. The PORTO²VENT™ CPAP^{OS} System is to be used by authorized, trained personnel under the supervision of a physician. If you have any questions regarding the operation of your CPAP^{OS} System an Emergent Respiratory Products Inc. representative will be able to assist you. You may also contact the Emergent Respiratory Products, Inc. Customer Care and Service Assistance Line, Toll Free, at 866-411-4368 or e-mail: customerare@eresp.com

1. Introduction

1a. Definitions

NOTE: A NOTE surrounded by this box indicates a technical or clinical point that may enhance the use of or protect the device.

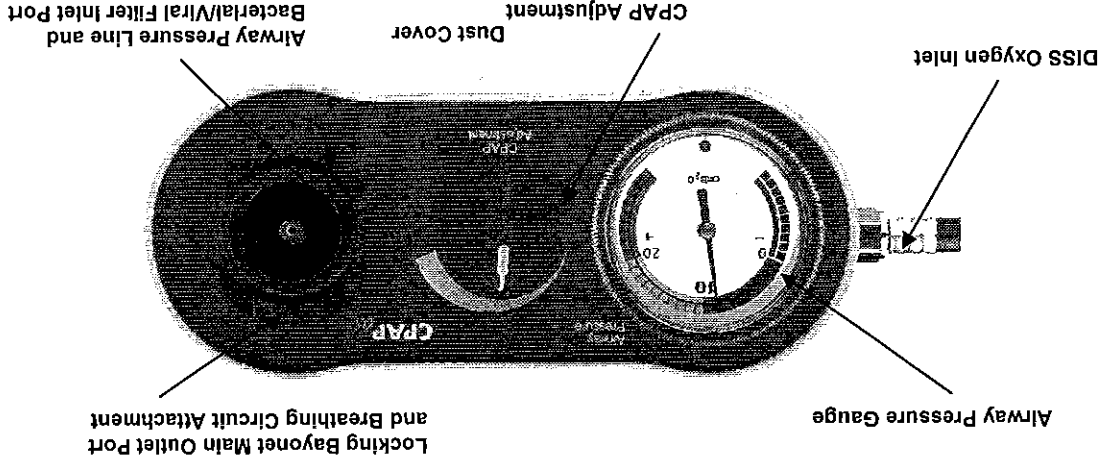
CAUTION: A CAUTION surrounded by this box is an indication to exercise special care for the safe and effective use of the device.

WARNING: A WARNING in bold typeface surrounded by this box is an indication of problems that may lead to death or serious injury.

1b. General Description

The PORTO²VENT™ CPAP^{os} System is a gas-powered system that delivers Continuous Positive Airway Pressure (CPAP) at operator adjustable levels throughout the breathing cycle, independent of the patient's flow rate. The System conserves the gas supply by terminating gas flow during the expiratory phase of the breath. The System is intended for use on spontaneously breathing patients.

CPAP^{os} Unit



1c. Intended Use

To provide Continuous Positive Airway Pressure (CPAP) to spontaneously breathing patients in hospital and prehospital (EMS) environments.

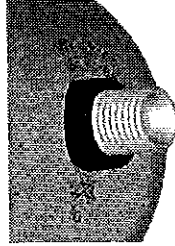
CAUTION: The CPAP^{os} unit and breathing circuit are intended only for use with a positive pressure face mask and should not be connected to endotracheal or oropharyngeal tubes.

CAUTION: Always use appropriate monitoring, such as, oxygen monitor, pulse oximeter, EKG and chest auscultation.

CAUTION: Federal Law restricts this device to sale by or on the order of a physician.

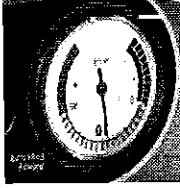
1d. Labels and Symbols

DISS
Oxygen Inlet



CPAP
Adjustment
Knob
Increase clockwise
Decrease counterclockwise

Always
Pressure
Gauge



CPAP^{os} Unit Abbreviated Operating Instructions Label:

CPAP^{os}
Abbreviated Operating Instructions

NOTE: For complete detailed operating instructions please read the CPAP^{os} Operator's Manual in its entirety before use.

1. Attach gas source to the DISS Inlet located on the side of the device.
2. Connect the CPAP^{os} Breathing Circuit.
3. Instruct Patient and Apply Mask.
4. Set CPAP level. To set constant positive airway pressure, turn CPAP Adjustment Knob clockwise and observe the needle indicator on the airway pressure gauge.
5. Observe and Monitor Patient Vital Signs.

CAUTION: Use only the CPAP^{os} Breathing Circuit

CPAP^{os} Model No. 1900-001 Manufactured by
Emergent Respiratory Products, Inc. USA

The System (See figure 1) provides continuous positive airway pressure (CPAP) throughout the breathing cycle (inspiration and expiration), and flow of gas on patient demand during inspiration.

The peak inspiratory flow rate from the CPAP_{OS} unit is determined by the patient inspiratory effort. Prior to inspiration the flow rate of gas from the CPAP_{OS} system is zero liters per minute (lpm) (0 lpm). To initiate flow of gas the patient must “trigger” the CPAP pressure generator.

DISS Oxygen Inlet Port The gas inlet port is a 9/16 standard DISS oxygen connector. The specification for inlet pressure is 40 – 60 psi (2.8 – 4.1 bar).

CPAP Pressure Generator The CPAP Pressure Generator maintains a continuous positive airway pressure and delivers flow from 0 to 100 or greater, liters per minute on demand to a spontaneous breathing patient.

CPAP Adjustment Regulator The CPAP adjustment is an operator adjustable pressure control providing pressure to the patient airway between 0 and 15 cmH₂O.

NOTE: Mask and proximal airway pressure will vary.

Pressure Balanced Patient Valve and Inspiratory Check Valve The inspiratory valve opens to supply flow to a spontaneous breathing patient during the inspiratory phase of breath delivery. The expiratory valve is pressure balanced to precisely maintain CPAP levels and reduce patient effort to open and exhale through the valve. The patient valve gas collector port rotates 360° and is a 22 mm I.D. and 30 mm O.D. port to accept filters and spirometry devices.

CAUTION: Do not use any other make or manufacturer of the pressure balanced patient valve that is not labeled for use with the CPAP^{os} device. The patient breathing circuit must be connected as illustrated in section 2c and described in section 3b of this manual. Failure to do so could result in device malfunction. The patient and equipment must be observed constantly.

Over Pressure Relief Valve In the event of an occlusion and/or pressure build up in the CPAP^{os} system, the Over Pressure Relief Valve is preset to relieve pressure at 22 cmH₂O.

Anti-asphyxiation Port In the event of complete gas supply failure the Anti-asphyxiation Port allows the spontaneous breathing patient access to ambient air.

Outlet Port Connector The Outlet Port Connector is a locking bayonet connector used to attach the corrugated main tube, and engage the airway pressure line.

Airway Pressure Line The Airway Pressure Line is attached from the outlet of the Pressure Balanced Patient Valve through the outlet connector with a standard 1/8" inch I.D. tube.

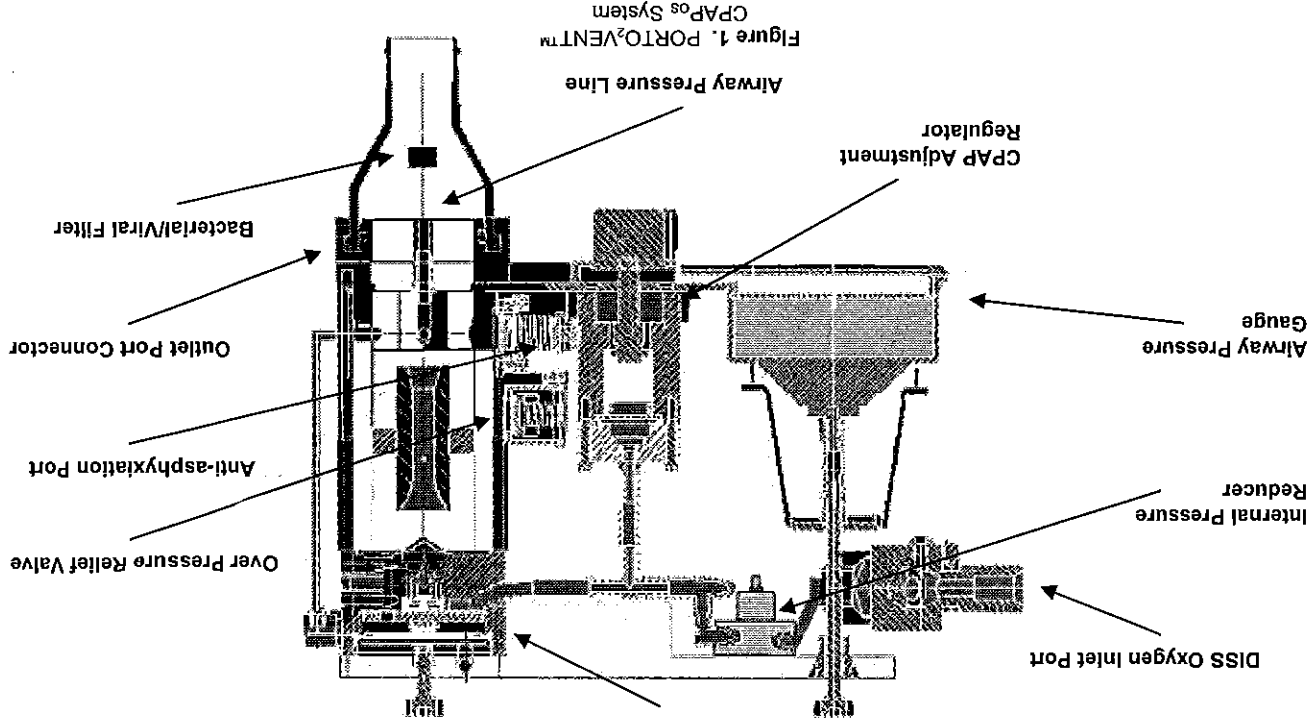
CAUTION: The airway pressure line is connected internally to the pressure gauge. Disconnection or occlusion of this line may not be detected. The patient and equipment must be observed constantly to check for such problems.

Bacteria/Viral Filter The bacteria/viral filter is connected to the Airway Pressure Line and outlet connector.

Corrugated Breathing Tube The corrugated main tube directs gas flow from the CPAP^{os} outlet port through the inspiratory valve to the patient and Pressure Balanced Patient Valve. It is six (6) feet in length.

Positive Pressure Face Mask The Positive Pressure Face Mask is a standard single-ported mask. It is available in small, medium and large adult sizes.

Black Neoprene Head Harness The Black Neoprene Head Harness is used to secure the positive pressure facemask to the patient's face. It is a one size fits all adjustable design.



2. Installation and Assembly

2a. Suggested functional testing of Control unit prior to initial use.

Attach the included oxygen hose to the unit and to an oxygen source.

With the CPAP pressure control knob turned completely in the counterclockwise direction (against the stop), apply an inlet pressure of 50 PSI to the Control Module. If the unit free-flows upon initial application of supply pressure, momentarily (3-5 seconds) block the outlet. Unblock the outlet and the flow shall have ceased.

Block the outlet. Rotate the CPAP Adjustment Knob clockwise until the Airway Pressure Gauge indicates approximately 5 cmH₂O. Unblock the outlet. The unit should fully flow.

Block the outlet, being careful to not block the Airway Pressure Line (small plastic tube). Slowly rotate the CPAP Adjustment Knob to the fully clockwise position. Observe that the pressure rise indicated on the gauge needle is smooth. An outlet pressure of 15 cmH₂O or greater on the Airway Pressure Gauge indicates the unit is operating properly.

Unblock the outlet. Turn the pressure control knob back to off position. **Do not force the knob against the stop.** In the majority of cases, the unit will continue to flow. Momentarily (3-5 seconds) block the outlet and then unblock. The unit should shut off.

Contact Emergent Customer Service if unit fails to pass these tests.

2b. Oxygen Supply

The CPAP^{OS} device can use oxygen from a cylinder or from a central supply system of 40 to 60 psi. When ready to administer CPAP therapy, connect the oxygen supply to the DISS inlet located on the side of the device.

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

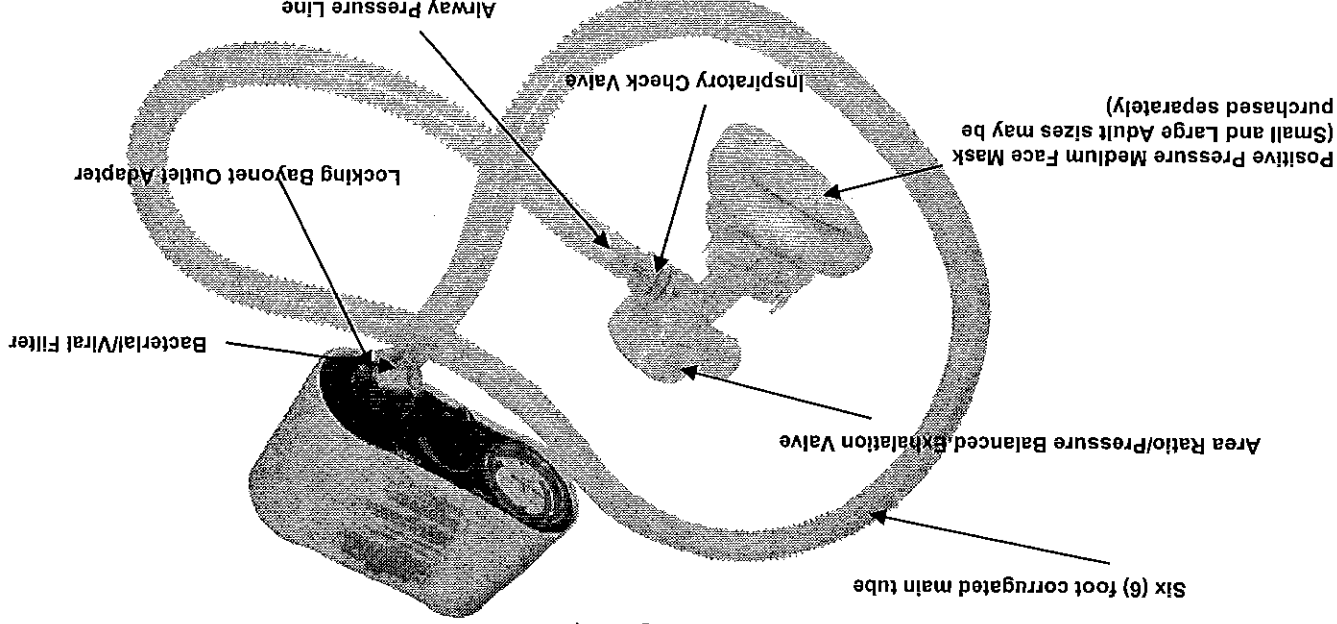
NOTE: To turn the CPAP^{OS} unit off, disconnect the O₂ supply hose from the source or turn off at the O₂ cylinder.

CAUTION: Certain data on the use of high concentrations of inspired oxygen show adverse effects on cardiac function in patients who have congestive heart failure or other specific conditions. When attached to an oxygen source, the CPAP^{OS} provides an F_IO₂ of up to 95% dependent upon outlet flow.

NOTE: To monitor F_IO₂ accurately the use of an in-line oxygen monitor is recommended.

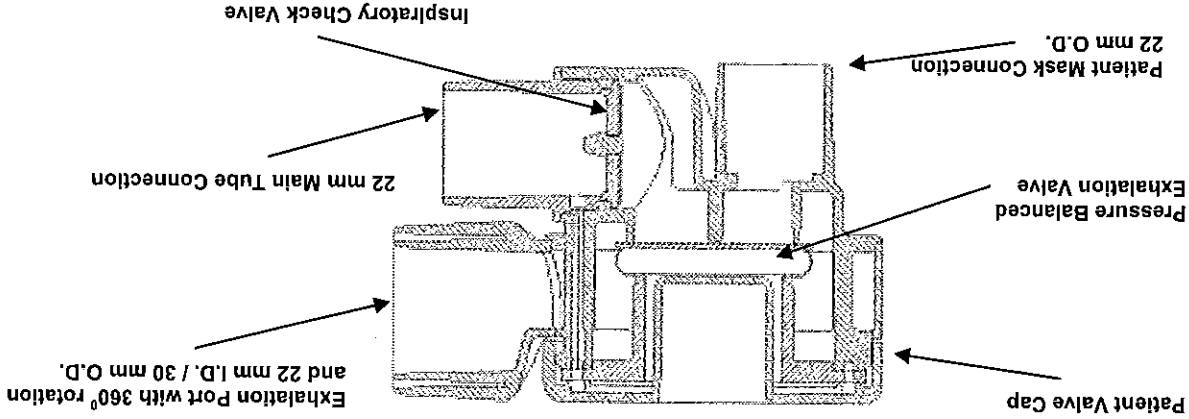
2c. PORTO₂VENT™ Breathing Circuit

The CPAP_{os} Breathing Circuit contains the following components:



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Area Ratio/Pressure Balanced Patient Exhalation Valve and Components



NOTE: The CPAP^{OS} Breathing Circuit and all of its components are sold clean and non-sterile.

3. Operating Instructions

3a. Setting the CPAP Level

Prior to setting the pressure always observe that the airway pressure gauge needle indicator is at the zero (0) value with the CPAP adjustment knob in the fully counterclockwise position and the breathing circuit connected. The zero point may be adjusted by adjusting the small screw on the face of the gauge. To set continuous positive airway pressure, turn the CPAP adjustment clockwise and observe the needle indicator on the airway pressure gauge.

3b. Applying the Breathing Circuit and Mask

Assembly Instructions: The CPAP^{os} Breathing Circuit is pre-assembled at the factory. To attach the breathing circuit to the CPAP^{os} unit insert and align the locking bayonet outlet adapter to the unit and turn clockwise until securely engaged.

CAUTION: Inspect the patient (yellow mushroom) valve to assure that it is properly seated and not cocked. The valve may be re-seated properly by completely unscrewing the patient cap and then re-installing the cap. The valve will automatically re-seat itself without the need to handle the valve.

CAUTION: Do not use any other make or manufacturer of the pressure balanced exhalation valve that is not labeled for use with the CPAP^{OS} device. The patient breathing circuit must be connected as illustrated in section 2b of this manual. Failure to do so could result in device malfunction. The patient and equipment must be observed constantly.

CAUTION: Do not clean or reuse the single-use, disposable breathing circuit or components. Do not autoclave or submerge the CPAP^{OS} unit or any of its components in any solution. Do not connect a filter directly into the airway path. This could compromise the operation of the control unit.

3c. Getting Started

1. Connect the oxygen supply to the DISS oxygen inlet located on the side of the CPAP^{os} unit.
2. Connect the Breathing Circuit as illustrated in this manual. (p 13)
3. Instruct the patient and apply the mask to the patient as per your protocol.
4. Set the CPAP level as per your protocol by turning the CPAP adjustment knob clockwise and observe the needle indicator on the airway pressure gauge.

3d. Monitoring the Patient

During operation, monitor the following periodically.

1. Monitor to assure that there are no leaks at the patient connection.
2. Monitor the Airway Pressure Gauge.
3. Monitor the patient's arterial blood oxygen saturation (S_aO₂).
4. Monitor the patient's blood pressure and EKG.
5. Monitor the patient's delivered F_IO₂.
6. Monitor the patient's breathing with chest auscultation.
7. Monitor the patient for signs of dehydration and discomfort in the upper airways.

CAUTION: Check the airway pressure gauge while the patient is breathing to assure that pressure is maintained within specifications (see CPAP^{os} Specifications page 21). As the patient breathes, larger changes in pressure shows that CPAP is not being effectively delivered. Possible causes are insufficient source gas pressure and flow or possibly a malfunction of the CPAP unit and/or breathing circuit. Excessive pressure variation during CPAP treatment can cause fatigue and respiratory failure.

WARNING: Potential side effects of continuous positive airway pressure may include fluid retention, pneumothorax, decreased cardiac output and gastric distension.

4. Care and Maintenance

The housing and faceplate of the CPAP^{os} unit may be cleaned with mild soap and water. A glutaraldehyde solution may be used as a disinfectant on all external surfaces of the CPAP^{os} housing.

CAUTION: Do not clean or reuse the single-use, disposable breathing circuit or components. Do not autoclave or submerge the CPAP^{os} unit or any of its components in any solution.

CAUTION: Do not attempt to disassemble or repair the CPAP^{os} unit.

Annual inspection and maintenance is recommended.

Service and Repair: For all service and repair of the CPAP^{OS} unit return it to an authorized Emergent Respiratory Products, Inc. authorized service and repair center. To return a CPAP^{OS} unit call 1-866-411-4368 to obtain a Return Goods Authorization (RGA) number.

Warranty: Emergent Respiratory Products, Inc. warrants the CPAP^{OS} unit and its accessories to be free from defects in materials and workmanship for a period of one year from date of purchase.

5. Accessories

The following accessories are compatible with the CPAP^{OS} Unit.

Mounting: Any pole or rail system with universal clamp.

Oxygen Monitor: Any in-line oxygen monitor.

6. Specifications

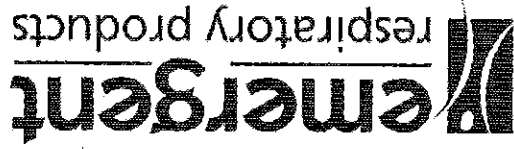
CPAP Treatment Range:	Adjustable from 2.5 to 15 cmH ₂ O
Maximum Inspiratory Flow:	100 liters (or greater) per minute (lpm)
FiO ₂ :	up to 95% dependent upon outlet flow.
Inspiratory Effort	Less than 2 cmH ₂ O
Exhalation Resistance	Less than 2 cmH ₂ O*
Patient Valve Dead Space:	15 ml
Inlet Pressure:	40-60 psi (2.7 to 4.1 bar)
Operating Temperatures:	0° F to 120° F (-18 to 50° C)
Storage Temperatures:	-40° F to 160° F (-40 to 70° C)
Over Pressure Relief:	22 cmH ₂ O (max 35 cmH ₂ O @ 100 lpm)
Anti-asphyxiation Valve:	- 8 cmH ₂ O @ 50 liters per minute (lpm)
Positive Pressure Face Masks	Small, Medium and Large sizes
Dimensions:	3 $\frac{1}{2}$ h x 5d x 8 $\frac{1}{2}$ w in (9 x 12.5 x 21.5 mm)
Weight:	3.50 lbs (1.50 kg)

*Expiratory Resistance is measured from airway pressure at beginning of expiratory cycle to peak expiratory pressure.

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For warranty registration of your CPAP^{os} unit visit www.ersp.com



Emergent Respiratory Products, Incorporated
420 Exchange
Suite 250
Irvine, Ca 92602
714-263-3777 Telephone
714-263-3788 Fax
www.ersp.com