



WhisperFlow®

CPAP System - Variable & Fixed


User's Manual

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Respiroics Novamatrix, LLC
5 Technology Drive
Wallingford, CT 06492
USA

USA and Canada: 1-800-345-6443 or 724-387-4000
Europe, Africa, Middle East: +33-1-47-52-30-00
Asia Pacific: +852-3194-2280

 Authorized Representative:
Respiroics Deutschland
Gewerbestrasse 17
D 82211 Herrsching Deutschland
+49 8 15 29 30 60

Made in USA

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Introduction

The WhisperFlow CPAP System delivers continuous positive airway pressure (CPAP) throughout the breathing cycle. It provides CPAP at preset levels throughout inspiration and exhalation, independent of the patient's flow rate. The WhisperFlow System is intended for use on spontaneously breathing patients.

The variable generator WhisperFlow System allows you to vary fractional inspired oxygen (FIO₂) from 28% to 100%. The fixed generator WhisperFlow System delivers FIO₂ from 28% to 33%, depending on the flow and PEEP valve used.

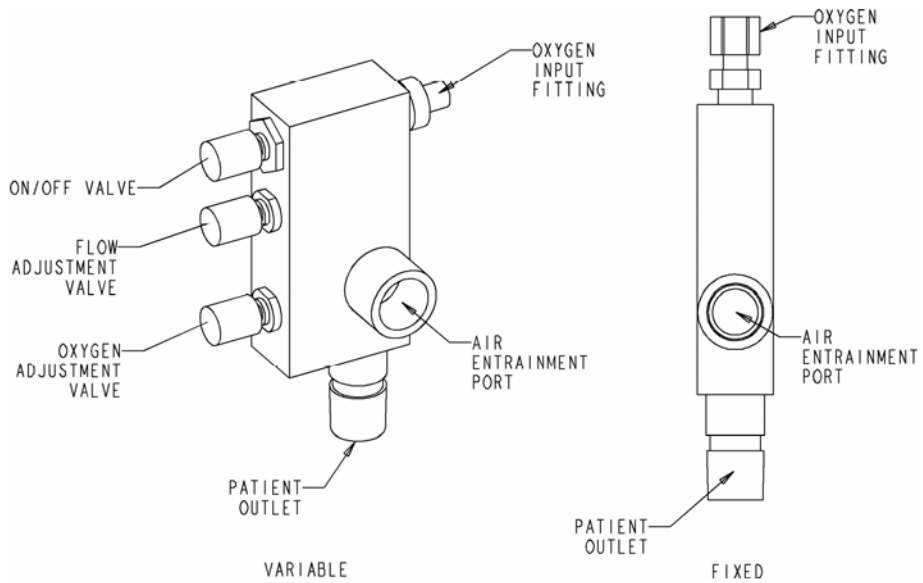


Figure 1. WhisperFlow CPAP System: variable and fixed generators

The WhisperFlow System may be contraindicated for patients with any of these conditions:

- Fluid retention
- Pneumothorax
- Decreased cardiac output and gastric distention
- Severe facial injury (noninvasive use)
- Hypotension secondary to hypovolemia.

How it works

The WhisperFlow CPAP System is a precision venturi device that uses an oxygen supply in conjunction with entrained air to generate an output flow. The WhisperFlow System uses a 60 psi (412 kPa) oxygen supply, and can generate flows over 150 L/min. down to 28% fractional inspired oxygen (FIO₂). The WhisperFlow CPAP valves, which are placed within the circuit, are used to maintain preset positive pressure at flow rates from 10 to 150 L/min.

Setting up the WhisperFlow System

WARNING: Do not use the WhisperFlow System without an oxygen analyzer to alert you to a loss of oxygen wall pressure or other system faults.

WARNING: Always ensure that the PEEP valve is correctly connected to the patient circuit, and that the exhaust port of the PEEP valve is not attached to the circuit.

WARNING: The ON/OFF knob controls a continuous valve. Be sure to turn the knob FULLY counterclockwise, one half turn, for the fully ON position.

WARNING: Place a pressure gauge or pressure monitor in-line, between the generator outlet and the patient interface by use of an in-line tee. Alternatively, pressure can be monitored by attaching pressure monitoring tubing to the mask port.

CAUTION: To avoid damage to the WhisperFlow System by entraining particles into the device, always install a filter on the fresh gas intake port.

CAUTION: The WhisperFlow System, as with similar systems from other manufacturers, does not include a non-rebreathing valve for use with tracheal tubes. If the oxygen supply fails while the patient's tracheal tube is connected to the system, the patient will rebreathe the gas in the supply tubing and may be asphyxiated.

1. Select a sealing face mask or endotracheal (ET) tube as the patient connection. Ensure that the mask fits comfortably, seals the bridge of the nose, and fully covers the nose and mouth.
2. Choose the PEEP valve. (See the parts list for a complete list of available PEEP valve sizes and part numbers.)
3. Assemble the circuit according to Figures 2 through 6, depending on the mask, oxygen analyzer, pressure gauge or monitor, and humidifier you are using. As you assemble the circuit, please note:
 - Use a pressure relief valve to protect the patient's lungs from trauma in the event that the PEEP valve becomes occluded. Select a PEEP valve at least 5 cmH₂O higher than the expiratory PEEP valve.
 - To ensure accurate measurement of the FIO₂ delivered to the patient, use an inline oxygen analyzer upstream of the patient connection and humidification device (if used).
 - To assist in detecting adequate flow from the generator, place a pressure gauge, 0-30cmH₂O, or pressure monitor, in-line between the generator outlet and the patient interface, or attach a pressure monitor line to the patient mask. Should the registered pressure decrease significantly during patient inhalation, then the flow to the patient needs to be increased.

- The WhisperFlow System can deliver a minimum FIO₂ of 28-29% to the patient. However, the longer the tube lengths used, the higher the minimum FIO₂. (Longer tubing increases the resistance of the patient circuit, allowing the generator to entrain less air.)
- The WhisperFlow System's location upstream of the patient and the high flows it produces make contamination and resulting cross-infection highly unlikely. However, if cross contamination is a concern, attach a 22-mm OD/ID filter to the output port of the generator.

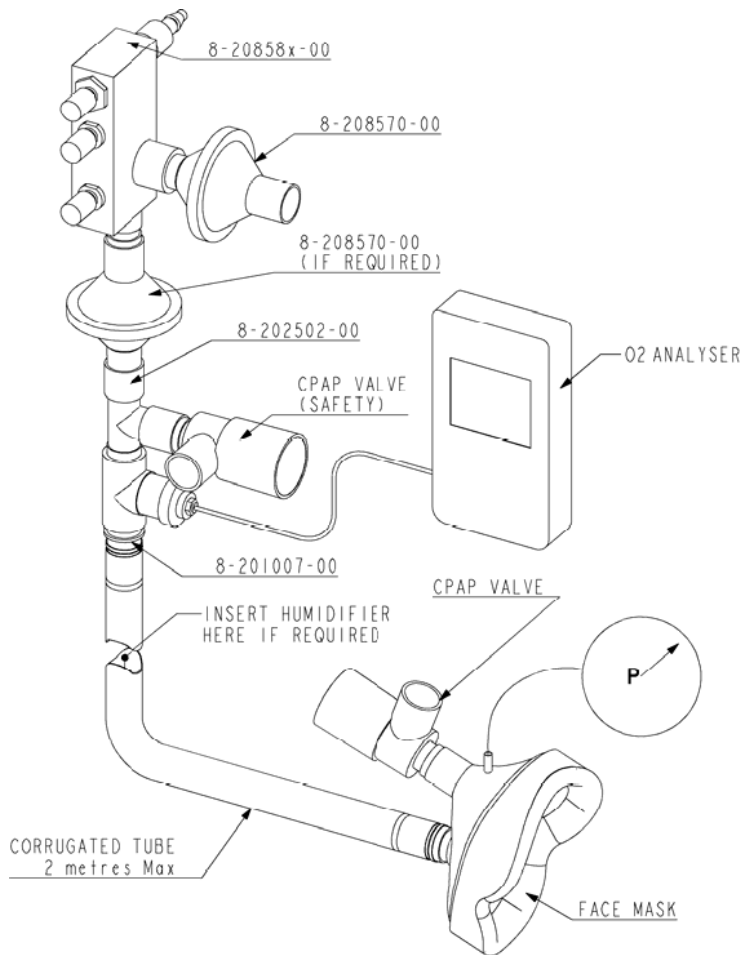


Figure 2. Dual-port mask, oxygen probe with integrated tee piece

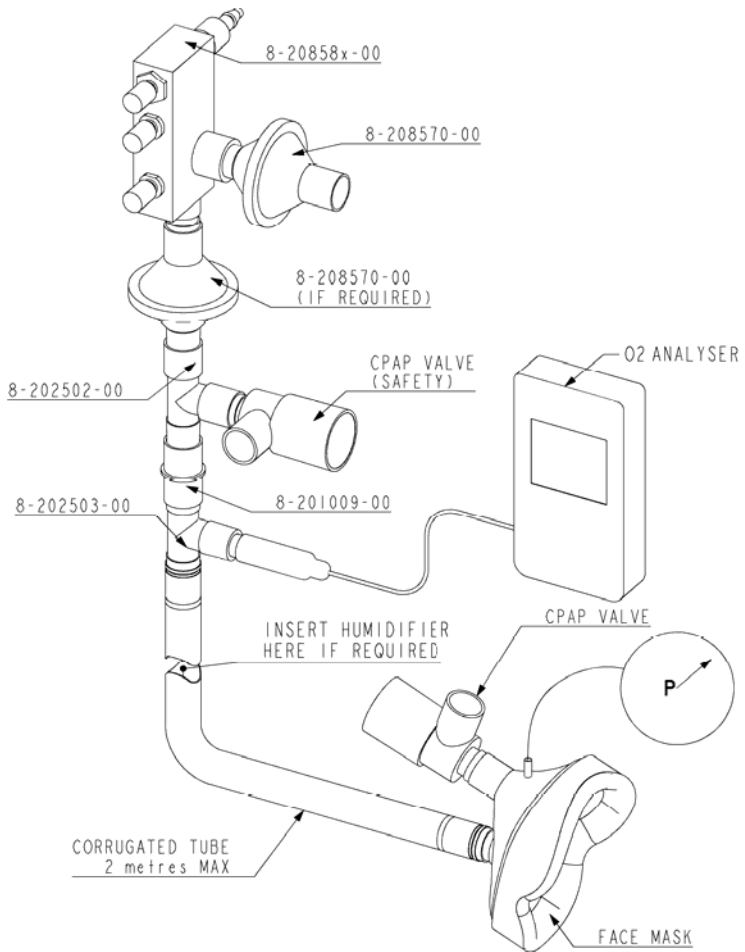


Figure 3. Dual-port mask, 15-mm oxygen probe

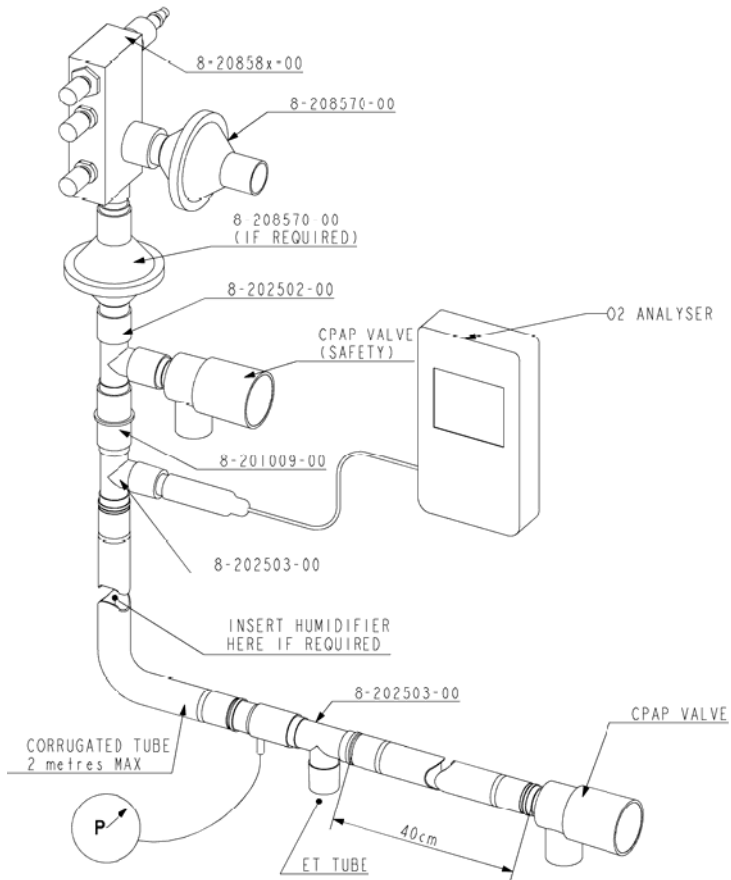


Figure 4. ET tube connection, 15-mm oxygen probe

CAUTION: The WhisperFlow System, as with similar systems from other manufacturers, does not include a non-rebreathing valve for use with tracheal tubes. If the oxygen supply fails while the patient's tracheal tube is connected to the system, the patient will rebreathe the gas in the supply tubing and may be asphyxiated.

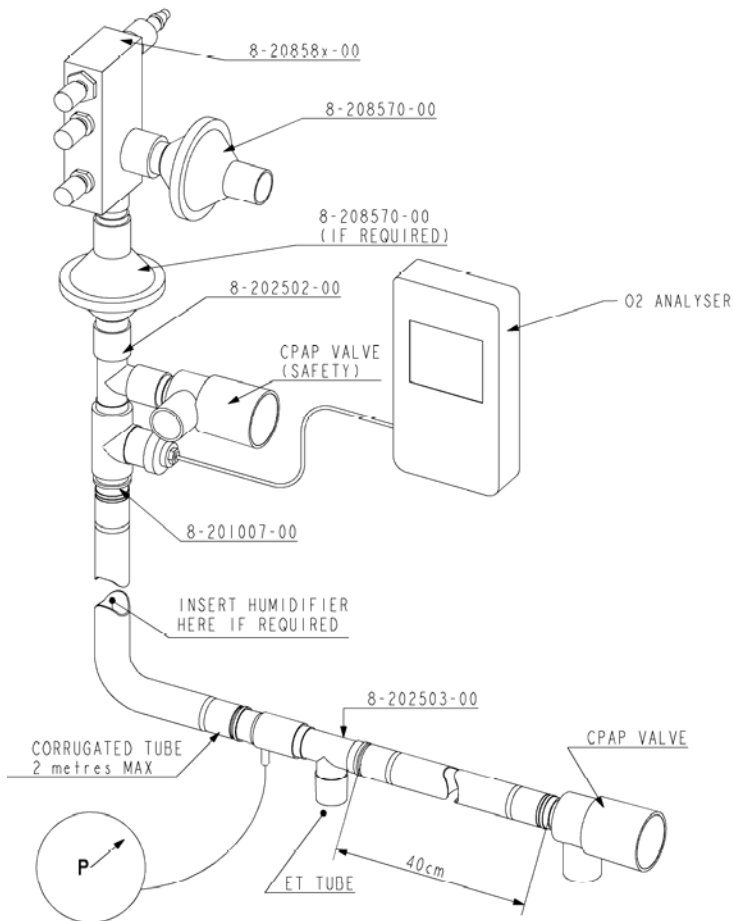


Figure 5. ET tube connection, oxygen probe with integrated tee piece

CAUTION: The WhisperFlow System, as with similar systems from other manufacturers, does not include a non-rebreathing valve for use with tracheal tubes. If the oxygen supply fails while the patient's tracheal tube is connected to the system, the patient will rebreathe the gas in the supply tubing and may be asphyxiated.

Notes to Figures 2 through 5

The notes below apply to Figures 2 through 5 above:

- Figures 2 through 5 show how to assemble the WhisperFlow system and WhisperFlow accessories. The WhisperFlow unit should only be used with the accessories supplied by the manufacturer, Respirationics, or its authorized agent. In particular, the face mask has an integral one-way valve, which prevents exhalation into the delivery tubing in the event of no fresh gas flow. When used with a tee-piece however, exhalation into the delivery tubing will result in CO₂ rebreathing, and may result in asphyxia.
- If the fresh gas flow fails, the one-way valve will minimize the risk of asphyxia when there is no oxygen pressure. However, if there is no fresh gas flow, the patient will have to inhale at ambient pressure, though will still continue to exhale at the PEEP pressure (see Table 1); this will result in an increased work of breathing and may not be well tolerated by some patients. Therefore, when there is no oxygen flow from the WhisperFlow System, the mask should not be worn, and nor should the device be connected to a tracheal tube.
- External monitoring should be used to ensure that the WhisperFlow generator setting is suitable for the patient. An in-line pressure gauge or pressure monitor will show a constant pressure approximately the same as the PEEP valve specification. If the delivered flow is too low, the pressure exhibited will indicate a significant drop when the patient inhales. This inadequate flow can be corrected by increasing the flow from the WhisperFlow generator.
- The oxygen monitor with alarms is used in setting and monitoring the FIO₂ delivered by the unit. It may alert the user to the loss of oxygen flow if the patient continues to draw fresh gas without oxygen through the air inlet of the WhisperFlow generator.
- The safety PEEP valve is placed in the circuit line in the event that the PEEP valve attached to the face mask or endotracheal tube becomes occluded. Thus any excess circuit pressure above the prescribed PEEP pressure will be relieved.

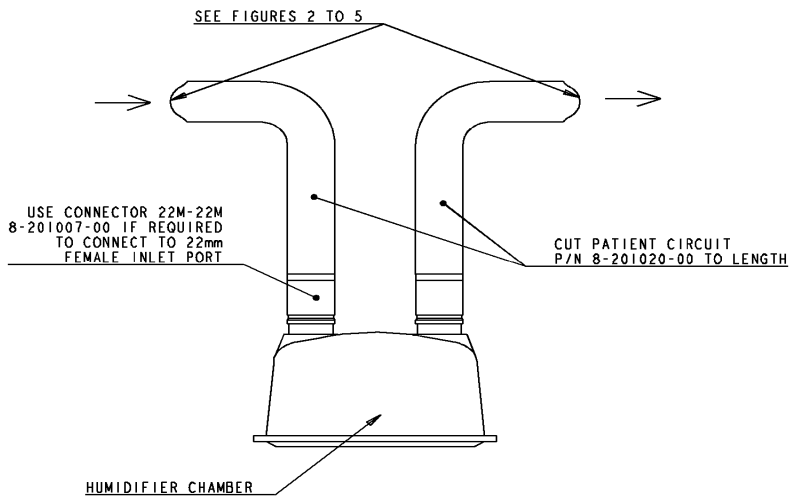


Figure 6. Installing a humidifier

Operating the WhisperFlow System

1. Turn all control valves off by turning fully clockwise (*finger-tight only*).
2. Connect the oxygen supply, then listen for leaks:
 - Variable generator: Connect directly to the oxygen supply or connect an oxygen hose between the WhisperFlow System oxygen fitting and the oxygen supply.
 - Fixed generator: Connect directly to flowmeter capable of delivering at least 13 L/min. at 60 psi (412 kPa).

WARNING: Do not connect any gas supply other than oxygen to the Whisper-Flow System.

NOTE: The WhisperFlow should not be connected directly to oxygen tanks with pressures over 230 bar (3336 PSI). Frost may form on the regulator and the device when FIO₂ settings are higher than 30%.

3. Turn the ON/OFF valve fully on (one-half turn). Turn the flow adjustment valve fully on and check that the output flow from the patient outlet varies accordingly.

WARNING: The ON/OFF knob controls a continuous valve. Be sure to turn the knob fully counterclockwise, one half-turn, for the full ON position

4. For higher concentrations (variable generator only), turn the oxygen adjustment valve counter-clockwise until the oxygen analyzer displays the appropriate FIO₂ for 30 seconds.
5. Leave the oxygen and flow controls as you have just set them, then turn the ON/OFF valve fully off (clockwise). Attach the circuit to the patient, and then turn the ON/OFF valve fully on (counter-clockwise).
6. Watch the PEEP valve to ensure that it remains open during inspiration. Gradually reduce the circuit flow by turning the flow adjustment valve down to point when you can still feel a slight flow at the CPAP valve when the patient inspires. Monitor the FIO₂ as you reduce the circuit flow: as the circuit flow decreases, the FIO₂ rises slightly. You can reduce the FIO₂ by closing the oxygen adjustment valve.
7. Monitor the in-line pressure gauge or monitor. If the pressure drops significantly then the flow is inadequate.

Monitoring the patient

During operation, be sure to check the following on regular basis:

- Ensure that there are no leaks at the patient connection.
- Ensure that there is flow from the PEEP valve during inspiration (which means that the generator is supplying adequate flow to meet patient demand).
- Monitor the in-line pressure gauge or monitor during inspiration. If the pressure drops significantly, then the flow is inadequate.
- Monitor the patient's arterial blood oxygen saturation (SaO₂).
- Monitor the patient for signs of dehydration and discomfort in the upper airways.
- Monitor the patient's delivered FIO₂.

Maintenance

Under normal conditions, the WhisperFlow System does not require any special maintenance or sterilization. However, the WhisperFlow System generator can be gas-sterilized using ethylene oxide (EtO). Following sterilization, open all the valves fully, connect to an oxygen supply for five minutes, and verify performance before reuse.

CAUTION: Do not autoclave or immerse the WhisperFlow System or any of its components in any solution. The circuit, including the inlet filter, is for single patient use.

Follow these steps to test the WhisperFlow System's minimum FIO₂ annually:

1. Variable generator only: set the flow adjustment to its maximum, and the oxygen adjustment valve to its minimum.
2. Attach a 10-cmH₂O PEEP valve to the generator using a patient circuit.
3. Ensure that the FIO₂ at a circuit pressure of 10 cmH₂O does not exceed 30%.

Environmental specifications

Temperature

- Operating: 5 to 45 °C at 15 to 95% relative humidity
- Storage: -40 to 60 °C at 95% relative humidity

Oxygen supply

- 40 to 80 psi (275 to 550 kPa)
- For flow requirements see Figure 10.

NOTE: The WhisperFlow should not be connected directly to oxygen tanks with pressures over 230 bar (3336 PSI). Frost may form on the regulator and the device when FIO₂ settings are higher than 30%.

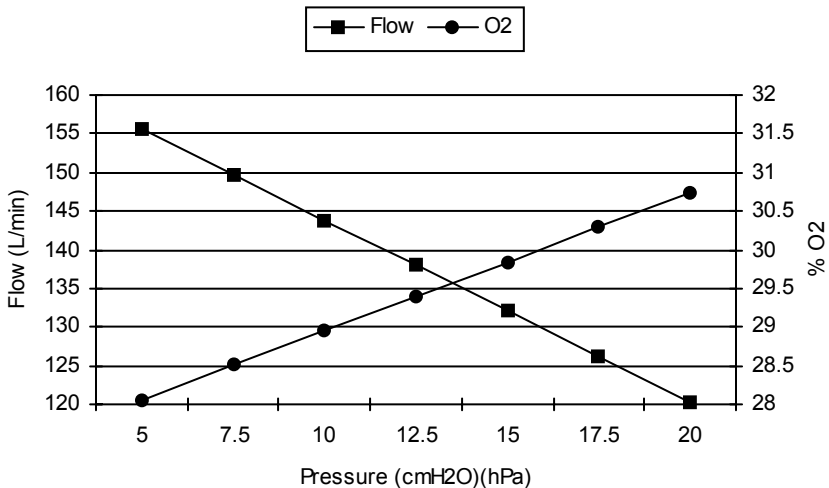


Figure 7. Maximum flow and minimum oxygen versus pressure

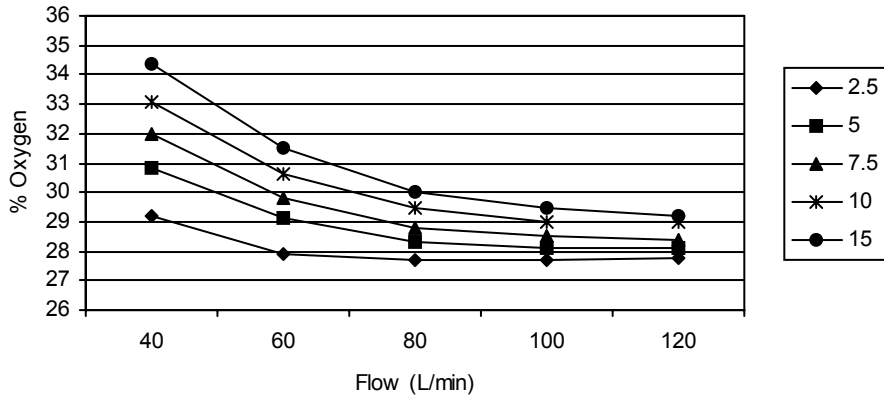


Figure 8. Minimum oxygen achievable at different flow settings for different PEEP values

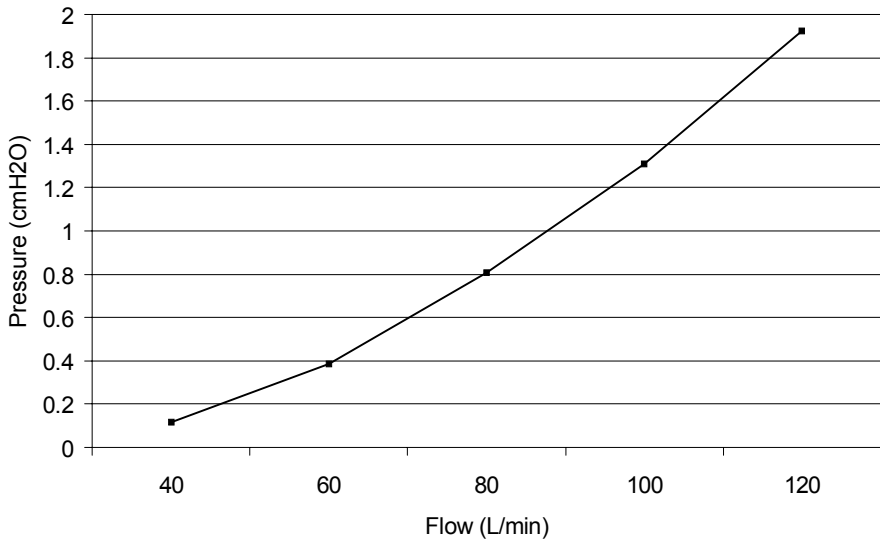


Figure 9. Circuit pressure loss per meter of tubing

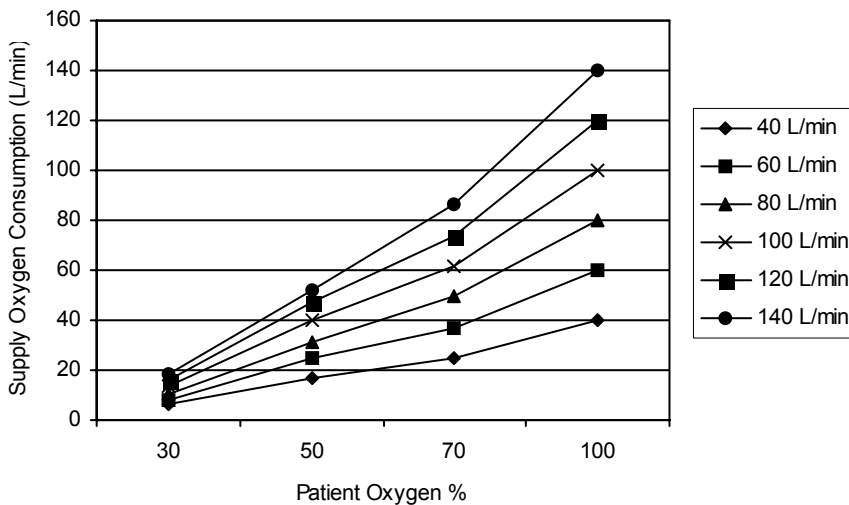


Figure 10. Oxygen supply consumption at several flow and oxygen settings

Inspiratory Flow (L/min.)	Approximate Pressure Drop (cmH ₂ O)
20	-1.0
40	-2.7
60	-3.9
80	-4.9
100	-5.1

Table 1: Pressure required to breathe through a system comprising a face mask, 1.8m tubing, and a CPAP generator in the instance where oxygen supply is lost.

Accessories

The following accessories are compatible with the WhisperFlow CPAP System:

- Mounting pole: Any pole with a clamp range of 10 to 40 mm.
- Humidifier: Fisher and Paykel MR730 and MR480. The MR410 Humidifier can also be used when inspiratory flow rates are set to less than 50 L/min.
- Oxygen monitor: You can use any in-line oxygen monitor with the WhisperFlow System. Some WhisperFlow procedure packs include a connector for attaching the oxygen monitors using a silicone tee or 15-mm probe.

Please contact your local dealer before using other accessories with the WhisperFlow System.

Customer Service and Product Support

Full service and repair is available from the manufacturer.

USA and Canada
Phone 1-800-345-6443 or 724-387-4000
Customer Service Fax 1-800-886-0245
Product Support Fax 1-724-387-5236
International Customer Service Phone 724-387-4000
International Customer Support Fax 724-387-5012

Europe/Africa/Middle East +33-1-47-52-30-00
Asia Pacific +852-3194-2280

service@respironics.com
clinical@respironics.com
www.respironics.com

Manufacturer

Respironics Novamatrix, LLC.
5 Technology Drive
Wallingford, CT 06492
USA

USA 800-345-6443 or 724-387-4000
Europe/Africa/Middle East +33-1-47-52-30-00
Asia Pacific +852-3194-2280
www.respironics.com
service@respironics.com
clinical@respironics.com

Approvals



The WhisperFlow System complies with the requirements of directive 93/42/EEC concerning medical devices and therefore bears the CE mark.

Authorized Representative:
Respironics Deutschland
Gewerbestrasse 17
82211 Herrsching
Deutschland
Telephone: +49 8-152930640

Year of manufacture

The fifth and sixth digits of the serial number indicate the WhisperFlow System's year of manufacture.

Parts list

Description	Part number
WhisperFlow CPAP System, variable generator (where x indicates the gas fitting, hose, and country). Contact your local dealer for further details.	8-20860x-00
WhisperFlow CPAP System, fixed generator	8-208530-00
CPAP valve, 2.5 cmH ₂ O	8-208503-00
CPAP valve, 5 cmH ₂ O	8-208505-00
CPAP valve, 7.5 cmH ₂ O	8-208507-00
CPAP valve, 10 cmH ₂ O	8-208510-00
CPAP valve, 12.5 cmH ₂ O	8-208512-00
CPAP valve, 15 cmH ₂ O	8-208515-00
CPAP valve, 20 cmH ₂ O	8-208520-00
Filter, 22 mm	8-208570-00
Tee piece, safety valve, 22M/22F/22F ports	8-202502-00
Tee piece, oxygen analyzer, 22M/22M/(22M/15F) ports	8-202503-00
Connector, 22M/22F with Pressure Port	8-100327-00
Connector, 22F/22F ports	8-201009-00
Connector, 22M/22M ports	8-201007-00
Mask, dual-port, large	8-209000-00
Mask, dual-port, medium	8-209001-00
Mask, dual-port, small	8-209002-00
Head strap, four-point, latex	8-209102-00
Head strap, four-point, nonlatex	8-209103-00
WhisperFlow Mounting Kit	8-100068-00
Several CPAP procedure packs are available: please contact your local dealer for further details.	

Notes:



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8-100335-00 Rev E

