



Whisperflow 2 CPAP System

User's Manual

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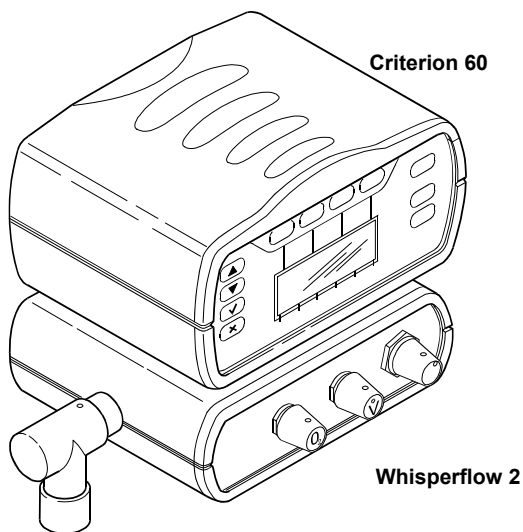
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Introduction

The Whisperflow 2 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 2 is intended for use on spontaneously breathing patients, and allows you to adjust FIO₂ from 28 to 100%.

The Whisperflow 2 controls are easy to use, and a swivel elbow outlet port simplifies circuit configuration. An internal safety valve eliminates the need for a separate pressure relief valve and tee.

The Whisperflow 2 can be pole or bench mounted, and can be attached to Caradyn's Criterion monitors (Figure 1) to create a system that delivers CPAP and measures applicable



parameters.

Figure 1. Whisperflow 2 CPAP System with Criterion Monitor

The Whisperflow 2 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 2 CPAP System is a precision venturi device that uses an oxygen supply in conjunction with entrained air to generate an output flow. The Whisperflow 2 System uses a 60 psi (412 kPa) oxygen supply, and can generate flows over 140 L/min with a minimum fractional inspired oxygen (FIO₂) of 28%. The Whisperflow 2 CPAP valves use constant force springs to maintain the preset positive pressure at flow rates from 10 to 140 L/min.

Setting up the Whisperflow 2 System

WARNING:

- **Always use the Whisperflow 2 System with an oxygen analyzer to alert you to a loss of oxygen wall pressure or other system faults. For complete control of the CPAP therapy, Caradyne recommends using the Criterion 60 Pressure and Oxygen monitor.**
- **Always ensure that the CPAP valve is correctly connected to the patient circuit, and that the exhaust port of the CPAP valve is not attached to the circuit.**
- **Use an in-line tee to insert a pressure gauge or pressure monitor (such as the Criterion 40 or Criterion 60) between the output port of the Whisperflow 2 and the patient interface.**
- **The Whisperflow 2 (as is typical of other CPAP systems) does not include a non-rebreathing valve for use with tracheal tubes. Oxygen supply failure during tracheal tube connection can result in rebreathing and asphyxiation.**

CAUTION: To avoid damage to the Whisperflow 2 System by entraining particles into the device, always install a filter (P/N 8-100471-00) on the fresh gas intake port.

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 CPAP valve (see the parts list for a complete list of available CPAP valve sizes and part numbers).

3. Assemble the circuit according to Figures 3 through 7, depending on the mask, oxygen analyzer, and humidifier used. As you assemble the circuit, please note:
- The Whisperflow 2 includes an internal safety valve that automatically relieves pressure at approximately 28 cmH₂O or above. To relieve pressure at lower levels, use a separate pressure relief valve (use safety valve tee, Caradyne part number 8-202502-00, to insert a separate safety valve into the circuit).
 - To ensure accurate measurement of the FIO₂ delivered to the patient, use an inline oxygen analyzer upstream of the humidification device (if used).
 - The Whisperflow 2 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 Whisperflow 2 to entrain less air).
 - The Whisperflow 2 System's location upstream of the patient and the high flows it produces make contamination and cross-infection highly unlikely. However, if cross contamination is a concern, attach a 22-mm filter to the output port of the Whisperflow 2.
 - Use the Whisperflow 2 with accessories supplied by Caradyne, Ltd. or authorized representative. Caradyne supplies face masks with an integral one-way valve that prevents exhalation into the supply gas tubing in the event of supply gas failure. However, when used with a tee piece, exhalation into the supply tubing can result in rebreathing and asphyxia.
 - Caradyne supplies face masks with an integral one-way valve that minimizes the risk of asphyxia in case of supply gas failure. However, a face mask with one-way valve results in an increased work of breathing in the event of loss of oxygen that may not be well tolerated by all patients. Do not use a mask or tracheal tube connection when there is no oxygen flow from the Whisperflow 2.

- Use an external monitor (such as a Criterion monitor) to ensure that the Whisperflow 2 is supplying adequate flow to the patient. If flow is adequate, an in-line pressure gauge or pressure monitor shows a constant pressure approximately equal to the PEEP valve specification. A significant (2 cmH₂O or more) pressure drop when the patient inhales indicates inadequate flow: increase flow from the Whisperflow 2.
- Use an oxygen monitor with alarms (such as the Criterion 60 Pressure and Oxygen monitor) to set and monitor the FiO₂ delivered by the Whisperflow 2. An oxygen monitor can signal loss of oxygen flow if the patient continues to draw fresh gas without oxygen through the air inlet of the Whisperflow 2.
- The Whisperflow 2 is shipped with covers for the oxygen sensor and pressure ports. Keep these covers in place whenever the ports are not in use. Remove the oxygen sensor cover before installing a Criterion 60 oxygen sensor. Remove the pressure port cover when installing a pressure line to the Whisperflow 2.
- When using the Whisperflow 2 pressure port, take into consideration that the pressure reading includes the pressure drop due to the resistance of the patient circuit. For example, if the pressure at the patient's mask is 5 cmH₂O and the pressure drop due to the resistance of the circuit at the current flow is 2 cmH₂O, then the monitor pressure reading is 7 cmH₂O. Because high pressure alarms are typically set 10 cmH₂O or more above peak inspiratory pressures, the Whisperflow 2 pressure port is appropriate for use where the pressure drop due to patient circuit resistance is not significant. At very low patient ventilation pressures when small variations in pressure can be significant, measure pressure at the patient connection to eliminate the effect of patient

circuit resistance. Replace pressure tubing and filter monthly during normal use.

Using Whisperflow 2 with Criterion 60

The Whisperflow 2 System is designed to be compatible with all Criterion monitors. Follow these steps to attach the Whisperflow 2 to the Criterion 60 Pressure and Oxygen Monitor (Figure 2):

1. Remove the rubber feet from the base of the Criterion 60.
2. Remove the rubber feet from the base of the Whisperflow 2.
3. If using the pole mounting kit (P/N 8-100315-00), connect the mounting bracket to the Criterion 60 and Whisperflow 2 as described in the kit instructions.
4. Turn the Criterion 60 upside down, set the Whisperflow 2 on top of the Criterion 60, and align the mounting locations.
5. Use the four M3 x 25 screws to connect the Criterion 60 and Whisperflow 2.
6. Replace the rubber feet to the base of the Whisperflow 2.
7. Once the Whisperflow 2 and Criterion 60 are attached, connect the oxygen sensor and pressure line as shown in Figures 3, 5, or 7.

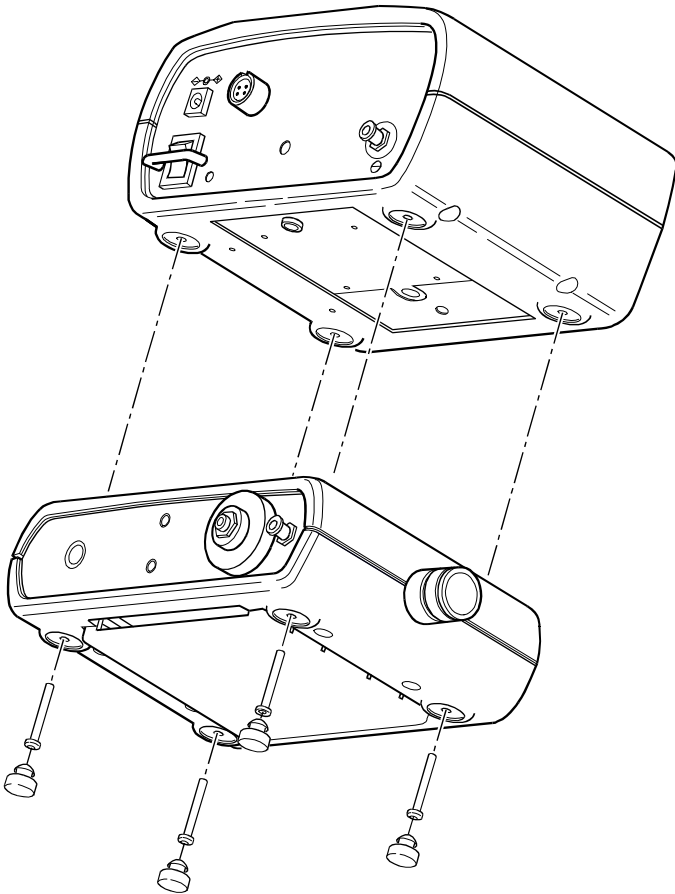


Figure 2. Attaching the Whisperflow 2 to the Criterion 60

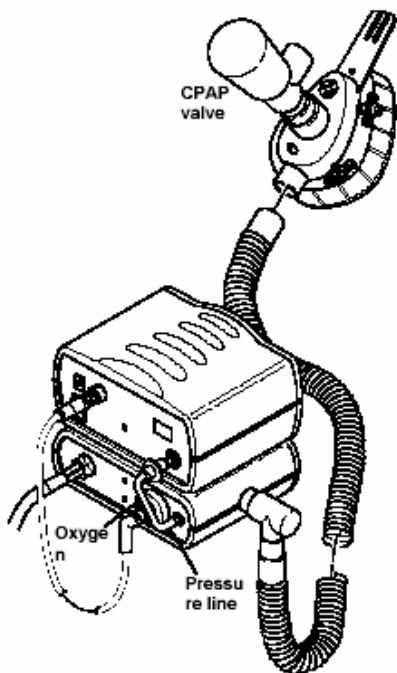


Figure 3. Whisperflow 2 and Criterion 60, dual-port mask

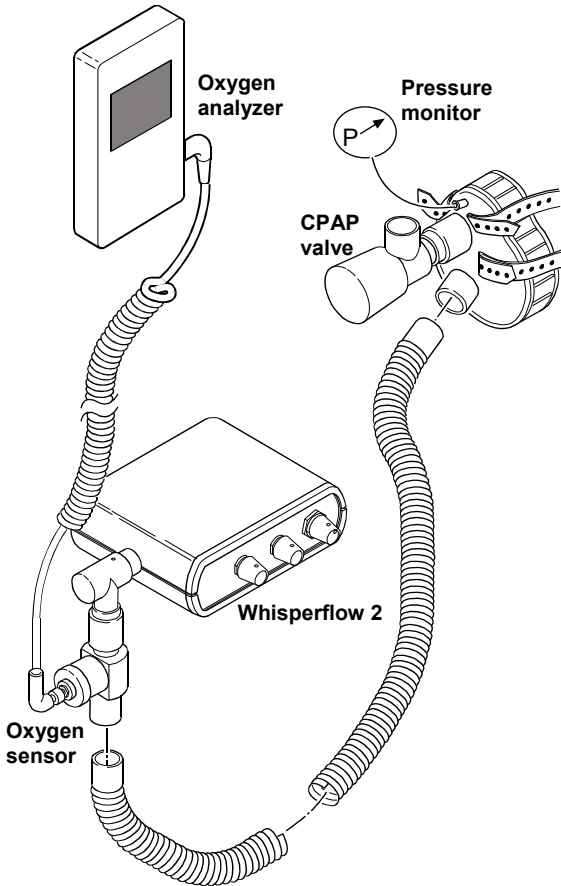


Figure 4. Whisperflow 2 and oxygen analyzer, dual-port mask

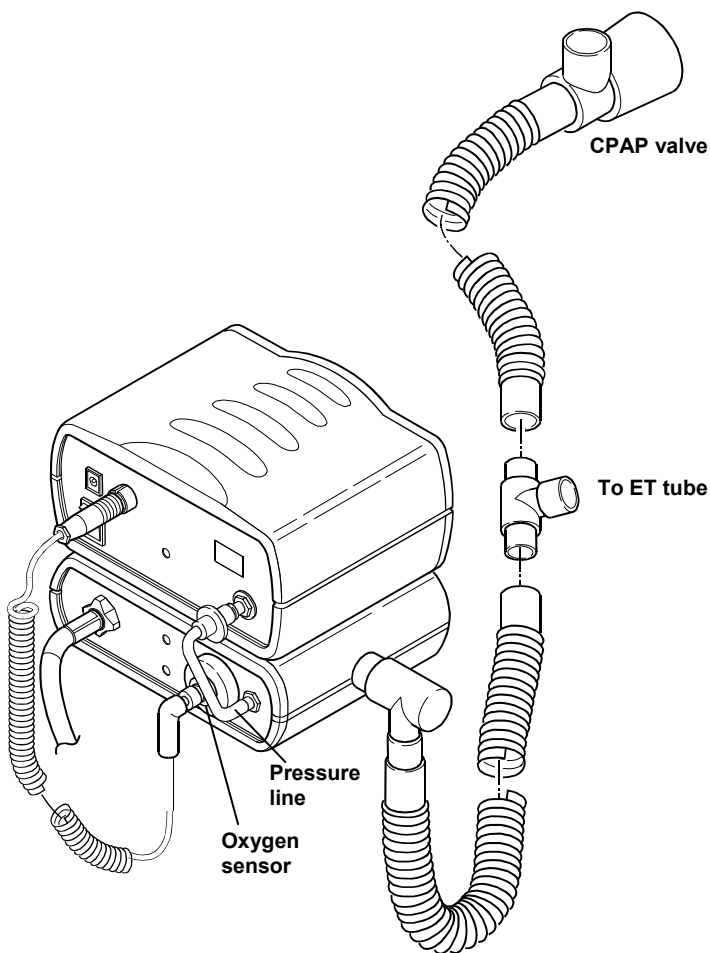


Figure 5. Whisperflow 2 and Criterion 60, ET tube connection

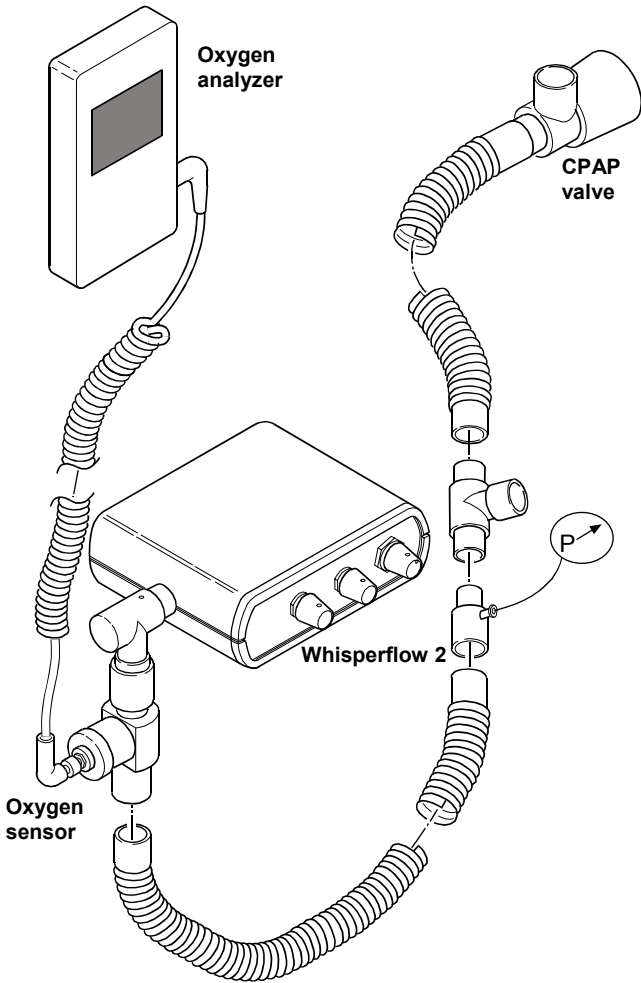


Figure 6. Whisperflow 2 and oxygen analyzer, ET tube connection

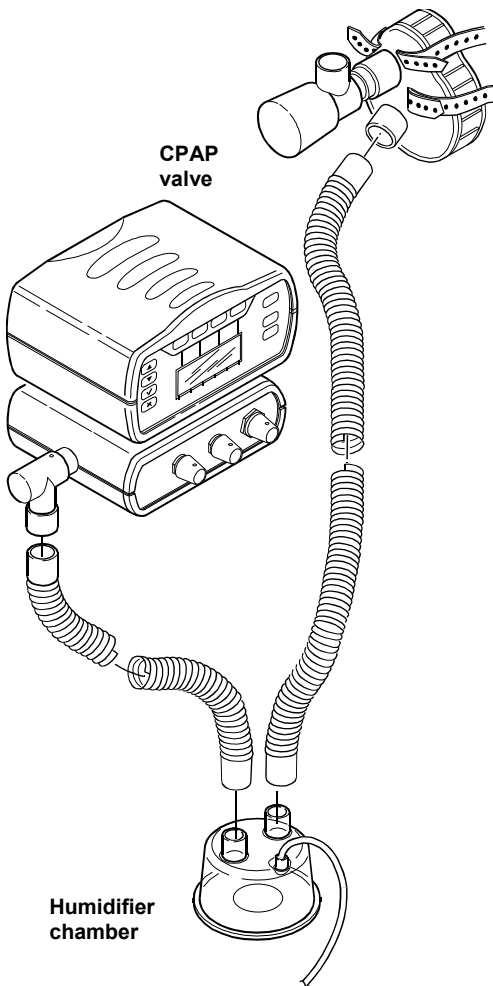


Figure 7. Installing a humidifier

Operating the Whisperflow 2 System

1. Turn control valves off by turning fully clockwise (finger-tight only).
2. Connect the oxygen hose to the port on the Whisperflow 2 back panel, then listen for leaks. (Connect directly to the oxygen supply or connect an oxygen hose between the oxygen inlet and the oxygen supply.)

WARNING: Do not connect any gas supply other than oxygen to the Whisperflow 2 System.

3. Turn the ON/OFF knob on. Turn the flow adjustment valve fully on and check that the output flow from the patient outlet varies accordingly.
4. Turn the oxygen adjustment valve counter-clockwise until the Criterion 60 or other oxygen analyzer displays the appropriate FIO_2 for 30 seconds.
5. Leave the oxygen and flow controls as you have just set them, then turn the ON/OFF knob off. Attach the circuit to the patient, then turn the ON/OFF knob on.
6. Watch the CPAP 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. If you are using a Criterion monitor, watch the bar graph to verify sufficient flow.
7. Monitor the FIO_2 as you reduce the circuit flow: as the circuit flow decreases, the FIO_2 rises slightly. You can reduce the FIO_2 by turning the oxygen adjustment clockwise.

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 CPAP valve during inspiration (which means that Whisperflow 2 is supplying adequate flow to meet patient demand). If you are using the Whisperflow 2 with a Criterion monitor, watch the pressure bar graph: flow is adequate if pressure fluctuations are minimal (± 2 cmH₂O).
- Monitor the patient's arterial blood oxygen saturation (SaO₂).
- Monitor the patient for signs of dehydration and discomfort in the upper airways.
- Use the Criterion 60 or other reliable oxygen analyzer to monitor the FIO₂ delivered to the patient.

Maintenance

Under normal conditions, the Whisperflow 2 System does not require any special maintenance or sterilization. However, the Whisperflow 2 System 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 2 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 2 System's minimum FIO₂ annually:

1. Set the flow adjustment to its maximum, and the oxygen adjustment valve to its minimum.
2. Attach a 10-cmH₂O CPAP valve to the Whisperflow 2 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)

See Figure 11 for flow requirements.

Performance

Figures 8 through 11 characterize Whisperflow 2 performance.

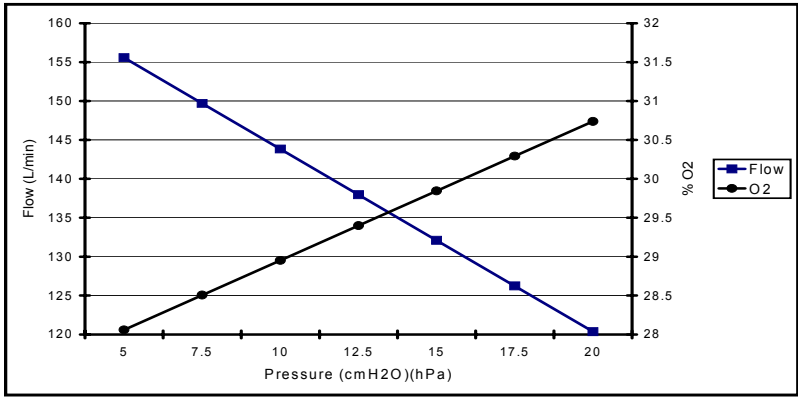


Figure 8. Maximum flow and minimum oxygen versus pressure

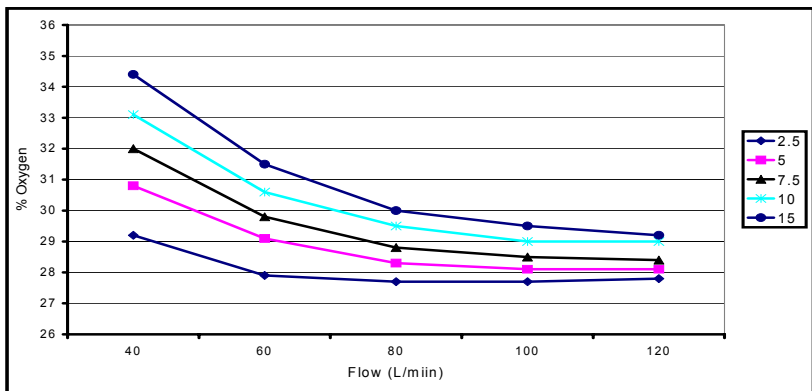


Figure 9. Minimum oxygen achievable at different flow settings for different PEEP values

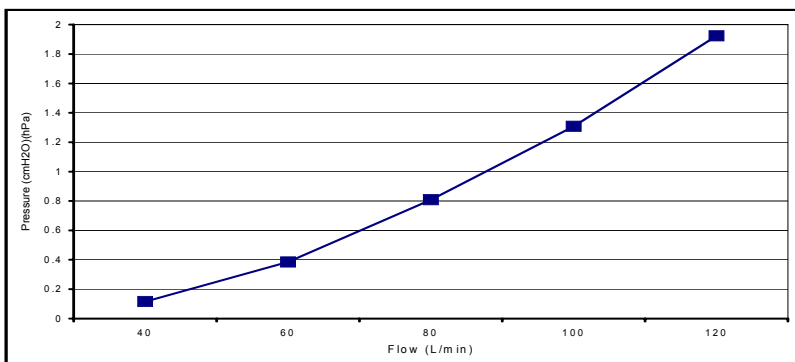


Figure 10. Circuit pressure loss per square meter of tubing

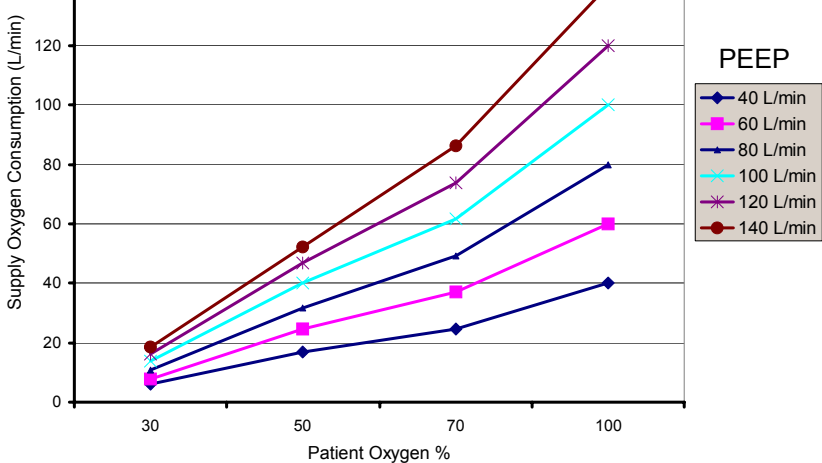


Figure 11. Oxygen supply consumption at several flow and oxygen settings

Accessories

The following accessories are compatible with the Whisperflow 2 CPAP System:

- 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 2 System. Caradyne recommends the Criterion 60 Pressure and Oxygen Monitor.

Please contact your local dealer before using other accessories with the Whisperflow 2 System.

Service

Full service and repair is available from:

Caradyne

Parkmore Business Centre

Parkmore West

Galway, Ireland

Telephone: +353 (0)91-709010

Fax: +353 (0)91-758929

Caradyne

2055 Executive Drive

Indianapolis, IN 46241

USA

Telephone: 317-246-9010

Fax: 317-246-9011

Or contact your local dealer.

Warranty

The Whisperflow 2 System is warranted against defects in material and workmanship for two years from the time of sale.

Approvals



0050

The Whisperflow 2 System complies with the requirements of directive 93/42/EEC concerning medical devices and therefore bears the CE mark.

Manufacturer

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Parkmore West
Galway, Ireland
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Fax: +353 (0)91-758929

E-mail: info@caradyne.com

Internet: <http://www.caradyne.com>

Year of manufacture

The fifth and sixth digits of the serial number indicate the Whisperflow 2 System's year of manufacture.

Parts list

Description	Part number
Whisperflow 2 CPAP Systems	
Whisperflow 2 CPAP System, Europe	8-100474-00
Whisperflow 2 CPAP System, USA/Canada	8-100475-00
CPAP valves, 22-mm connection	
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
CPAP valves, 30-mm connection	
CPAP valve, 2.5 cmH ₂ O	8-209503-00
CPAP valve, 5 cmH ₂ O	8-209505-00
CPAP valve, 7.5 cmH ₂ O	8-209507-00
CPAP valve, 10 cmH ₂ O	8-209510-00

Description	Part number
CPAP valve, 12.5 cmH ₂ O	8-209512-00
CPAP valve, 15 cmH ₂ O	8-209515-00
CPAP valve, 20 cmH ₂ O	8-209520-00
CPAP masks, SealFlex	
Mask, dual-port, large	8-209000-00
Mask, dual-port, medium	8-209001-00
Mask, dual-port, small	8-209002-00
CPAP masks, AirSeal	
Mask, dual-port, large	4-005000-00
Mask, dual-port, medium	4-005001-00
Mask, dual-port, small	4-005002-00
CPAP masks, multi-strap	
Mask, SealFlex multi-strap, 30-mm, large	4-005520-00
Mask, SealFlex multi-strap, 30-mm, medium	4-005521-00
Mask, SealFlex multi-strap, 30-mm, small	4-005522-00
Mask, SealFlex multi-strap, 22-mm, large	4-005523-00
Mask, SealFlex multi-strap, 22-mm, medium	4-005524-00
Mask, SealFlex multi-strap, 22-mm, small	4-005525-00
Filter, 22M/22F ports	8-208570-00
Filter, Whisperflow 2	8-100471-00
Connectors	
Connector, 22F/22F ports	8-201009-00
Connector, 22M/22M ports	8-201007-00
Connector, 22F/30F ports	8-100264-00
Connector, 22M/30M ports	4-005053-00
Headstraps	
Headstrap, multi-strap kit-cap-white, large	4-005572-00
Headstrap, multi-strap kit-cap-black, large	4-005573-00
Headstrap, multi-strap kit-cap-white, medium	4-005574-00

Description	Part number
Headstrap, multi-strap kit-cap-black, medium	4-005575-00
Headstrap, multi-strap kit 'H' white	4-005576-00
Headstrap, multi-strap kit 'H' white	4-005577-00
Head strap, four-point, latex	8-209102-00
Head strap, four-point, non-latex	8-209103-00
Whisperflow 2 CPAP System User's Manual	8-100482-00
Pole mounting kit	8-100315-00
Patient monitors	
Criterion 40 Pressure Monitor, UK/Ireland	8-100210-00
Criterion 40 Pressure Monitor, Europe	8-100324-00
Criterion 40 Pressure Monitor, USA/Canada	8-100325-00
Criterion 60 Pressure/Oxygen Monitor, UK/Ireland	8-100352-00
Criterion 60 Pressure/Oxygen Monitor, Europe	8-100351-XX
Criterion 60 Pressure/Oxygen Monitor, USA/Canada	8-100353-00

Caradyne continues to develop new accessories. Contact your local dealer for an updated list.