

Circum-Vent Patient Circuit

Non-Invasive Positive Pressure Ventilation

Problem - COVID-19 Ventilator Shortage

COVID-19 is surging around the globe taxing health care systems as well as the supply chain for vitally needed equipment. One key piece of equipment in critically low supply are filterable, non-invasive ventilators that can provide respiratory support at the standard of care, at capabilities between a HFNC and intubated mechanical ventilation.

Answer - CPAP-based non-invasive ventilation

Existing home-use CPAP and BiPAP systems used to treat obstructive sleep apnea can be used to apply PEEP and high FiO2 to a patient with a non-invasive oxygen helmet interface with an expiratory filter that can avoid exposing health care workers to exhaled droplets.

Existing home-use CPAP and BiPAP machines can be used directly with the oxygen hoods and patient circuits already used in hospitals. Parts needed in the patient circuit are:

1. Oxygen bleed valve to connect to a low-flow oxygen regulator (adjustable up to 35L/min)
2. Expiratory viral filter
3. Leak Port (inspiratory end)
4. PEEP valve (expiratory end)
5. Standard 22mm tubing

How the Clinician Uses the Circum-Vent System

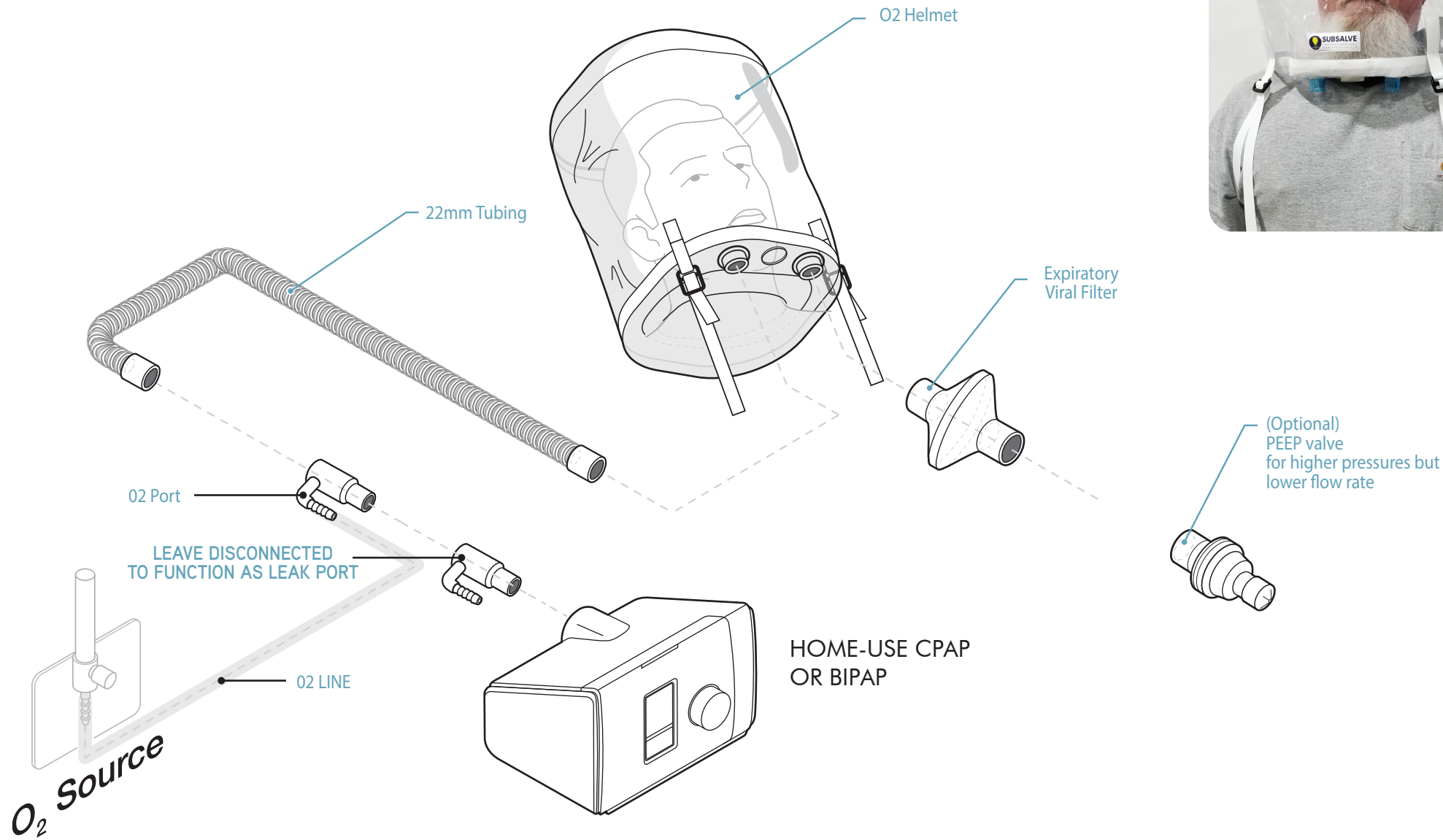
A pulmonologist familiar with ventilator theory and practice will quickly understand the Circum-Vent System. A minimal amount of training will be required for safe and effective use. Detailed operating instructions are on the reverse side.

The Circum-Vent protocol detailing the clinical practice is always available at <http://ventilatorproject.org/protocol>

Regulatory Issues

Home-use CPAP and BiPAP systems are FDA-approved Class 2 devices, available by doctor's prescription only in the US. The FDA guidance released on 3.25.20, *Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* allows for use of home-use CPAP and BiPAP machines to treat COVID-19 patients without requiring explicit authorization by the FDA.

The oxygen hood has received EUA approval from the FDA on August 6, 2020.



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S8 CPAP Operating Table

PEEP delivered to patient

		Low Pressure REMOVE PEEP VALVE						High Pressure USE PEEP VALVE
		5 cm H2O	6 cm H2O	7 cm H2O	8 cm H2O	9 cm H2O	10 cm H2O	
21%	FiO2 delivered to patient		10	12	14	15	15	16
			0	0	0	0	0	0
30%			9	10	12	14	15	16
			10	10	10	11	14	9
35%			9	10	12	14	15	16
			15	15	20	18	21	16
40%			9	10	12	13	15	16
			20	20	25	24	29	23
45%		8	9	10	12	13		16
		20	25	25	30	30		30
50%		8	9	10	12	13		16
		25	30	31	35	35		33
55%		8	9					
		29	35					
60%		8						
		34						



CPAP Setting (cm H2O)
Oxygen Flow (L/min)

All operating values have been tested to provide a minimum of 50L/min expiratory flow


- For first time users, go to <http://ventilatorproject.org/getting-started>
- Detailed clinical protocol at <http://ventilatorproject.org/protocol>

Operating Instructions



- (1) Clinician determines the FiO2 and PEEP setting to deliver to patient
- (2) Clinician looks up the relevant setting in the operating table to find the CPAP setting and oxygen flow required
- (3) If setting is in the yellow LOW PRESSURE section of the table, remove the PEEP valve from the patient circuit
If setting is in the orange HIGH PRESSURE section of the table, use a PEEP valve at the expiratory end of the patient circuit.
IMPORTANT ensure that PEEP valve is set to the lowest setting, 5 cm H2O
- (4) Set CPAP settings through the CPAP's Clinical Menu (see reference below)
- (5) Set oxygen flow setting on oxygen regulator

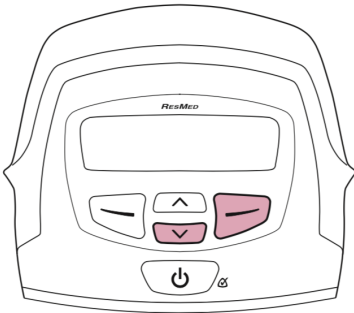


ResMed S8







Acessing the Clinical Menu

You can access the Clinical Menu from the VPAP (Ramp) screen by holding down  and  simultaneously for at least three seconds.



To navigate and make selections within the Clinical Menu:

- 1 Press  or  to scroll through items within a level.
- 2 Press  to enter a submenu and to apply an option choice.
- 3 Press  to navigate out of a menu or submenu and to exit without changing options.