

Primer:

- **CPAP, bi-level, high flow, and non-invasive ventilation**
- **How to repurpose devices for use in COVID-19 pandemic**

Advisory on the Use of ResMed VPAP ST

(ResMed, Australia; ResMed USA, San Diego)

Because of an automatic shut-off feature in the ResMed bilevel (S9 VPAP and AirCurve), these devices should NOT be used for invasive ventilation unless no other options exist.

The ResMed VPAP ST is designed to be a *noninvasive* ventilator. Incorporation of supplemental oxygen at > 15 LPM into the circuit anywhere distal to the blower should be undertaken with extreme caution.

At a set CPAP or EPAP > 10 cmH₂O, oxygen flows > 15 LPM in a circuit with a standard exhalation port can result in an unanticipated device shut-off and patient harm. This shut-off does not occur at EPAP ≤ 10 cm H₂O or when O₂ flow < 15 LPM.

At supplemental oxygen flows of 15 LPM, the maximum achievable FiO₂ will be no higher than 60%. If a patient requires FiO₂ > 60% or PEEP > 10 cmH₂O, the use of another brand of bilevel or a conventional invasive ventilator should be considered.

Exercise extreme caution when EPAP requirements exceed 10 cmH₂O and FiO₂ requirements exceed 60%!

Primer:

- **CPAP, bi-level, high flow, and non-invasive ventilation**
- **How to repurpose devices for use in COVID-19 pandemic**

Version 2.1 [Apr 17, 2020]

Mount Sinai Health System

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This document should be used as a clinical adjunct to the protocol “Repurposing bi-level ventilators for use with intubated patients while minimizing risk to health care works during insufficient supply of conventional ventilation for patients with COVID-19” and is shared with our health care colleagues to increase knowledge about potential solutions to increase the capacity and access to mechanical ventilation during the COVID-19 crisis. Icahn School of Medicine does not warrant the contents or effectiveness of the protocol, and the use and implementation of this protocol should be first reviewed and evaluated with each hospital’s medical staff.

CPAP, BI-LEVEL, HIGH FLOW, AND NON-INVASIVE VENTILATION

Devices

Continuous Positive Airway Pressure (CPAP)

Originally developed for treating obstructive sleep apnea in the home, CPAP is essentially similar to positive end-expiratory pressure (PEEP) as used in intensive care ventilators; this simpler device is increasingly used in the hospital setting.

The key characteristic of CPAP is that it provides a constant single pressure. Continuous pressure expands the lung and upper airway and can be useful in hypoxic respiratory failure to deliver PEEP.

CPAP does not provide ventilation (assisted breathing gas flow).

- Common US Manufacturers:
 - Respiromics/Philips – DreamStation CPAP, E30
 - ResMed – AirSense™ 10
 - Fisher & Paykel Healthcare – ICON and Sleepstyle™

Bi-level Ventilator

Bi-level is a generic term; BiPAP™ (Respiromics) is often used synonymously. This form of respiratory support provides an oscillating pressure (high and low, thus bi-level). It provides a form of assisted breathing or ventilation, similar to pressure support or pressure control, while also giving PEEP as in conventional ICU ventilators. If the device only responds to patient initiated (triggered) breaths, it is labelled “S”; if it can initiate its own breaths (backup rate), it is labelled “ST.” The latter is necessary for intubated patients who are sedated and often paralyzed.

- Common US Manufacturers:
 - Respiromics/Philips – DreamStation BiPAP, E30
 - ResMed – VPAP™ S9, AirCurve™ 10

High Flow by Nasal Cannula (HFNC)

This approach is sometimes called Nasal High Flow (NHF). It uses a generator of a high flow (>20 L/min) connected to a nasal prong leaky interface to provide humidity, dead space washout, and low levels of PEEP. It does not provide ventilation.

- Common US Manufacturers:
 - Fisher & Paykel Healthcare – Airvo™, myAirvo™
 - Vapotherm – Hi-VNI®
 - Maxtec – MaxVenturi®

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Non-Invasive Ventilation (NIV)

NIV refers to using any pressure source or other device to assist the breathing efforts of a patient without intubation (i.e. by mask).

In some documents and environments, NIV is incorrectly used to include CPAP and HFNC devices, and even sometimes any O₂ therapy.

Most bi-level devices are capable of home and hospital NIV. There are higher-end (and more expensive) devices intended primarily for hospital use but in general these devices are not intended (or approved) for use in an intubated patient.

- Common US Manufacturers:
 - Phillips/Respironics – DreamStation BiPAP, V60, V680, Trilogy, E30
 - ResMed – VPAP S9, AirCurve 10

Invasive Ventilation

Any device to move air in and out while connected to an endotracheal tube. Technically, CPAP and PEEP are not ventilation, but some authorities include them if they are connected to an endotracheal tube. Bi-level devices can provide the driving force for invasive ventilation, but specific FDA approval/clearance is often reserved for specially designed ventilators (as in ICUs)

- US NIV devices approved for invasive ventilation
 - Phillips/Respironics – Trilogy, V60, V680, E30
 - ResMed – Astral, Stellar

Circuits to Connect Devices to Non-Intubated Patients

Mask Circuits

The usual circuit in home use (e.g. for OSA) consists of a tube connected to a nasal or full face mask a vent built into the mask. This spews out ~20-30 l/min of unfiltered gas which includes the patient's exhaled gas and may aerosolize virus in COVID-19 patients.

- Manufacturers of Masks in US:
 - Fisher Paykel Healthcare
 - ResMed
 - Respiration/Phillips

A commercially available modification circuit is intended for use with NON-vented full face masks. This circuit introduces a leak (exhalation port) to replace the mask leak. If designed correctly, this port can be connected to a viral filter.

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- Manufacturers of Vented Circuit or Exhalation Port Alone:
 - Fisher Paykel Healthcare – RT219, RT319
 - Exhalation port alone (use with regular tubing) RT017
- Respironics/Phillips 1065832
 - Full circuit
 - Exhalation port alone (use with regular tubing) 1065775
- ResMed
 - Full Circuit
 - Exhalation port alone

Circuits to Connect Devices to Intubated patients

Double tube circuits

These are used in most ICU ventilators and have one tube to deliver gas and a second tube to receive the exhaled and overflow gases, which are then brought back to the ventilator and can be filtered.

Single tube circuits

These are essentially the same as those used with non-vented masks. Such circuits differ from the double tube circuits in that they must have a exhalation port, but this can be attached to a filter.

Accessories for CPAP, Bi-Level and HFNC, and Issues Affecting Therapy

These vary in importance whether used in masked or intubated situations.

Humidity

- Available as heated humidifiers (internal to device or external in line) and as in-line humidity and moisture exchangers (HME)
- For CPAP and bi-level by mask, humidity is desirable but not essential. It has been shown to improve patient adherence to mask therapy in the home, but is not physiologically critical as the nose performs adequately as a heater/humidifier in most cases.
- For HFNC humidity is however essential, as high flows of dry air will dry and irritate nasal mucosa and cause pain.
- For all forms of intubated ventilation humidity is essential to prevent airway drying and inspissation of mucus

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Aerosolization of infectious particles in exhaled gases and possible virus dispersion

There is a theoretical significantly increased risk of droplet formation and that aerosolization of exhaled gases and possible virus dispersion will occur and will increase the exposure of health care workers (HCW) to coronavirus. However, the data on the magnitude of risk are limited.

Estimated risks prior to further studies are as follows:

- For CPAP and bi-level vented mask – risk is moderately high
- For CPAP and bi-level non-vented masks – risk can be mitigated by filters, but remains for unintended leak (around mask/face interface)
- For CPAP and bi-level intubated uses – risk is low if exhaled gas is captured and filtered.
- For HFNC – risk is high and mitigation has not been proven. A face shield or loose fitting mask may reduce dispersion of droplets but will not affect aerosolization of small particles.

Delivery of high FIO₂ to patient

- Double tube circuits and hospital ventilators have an intake for blended O₂ and thus can set desired FiO₂ in a stable manner. Some bi-level devices can accommodate intake of blended gases, but most do not.
- Single tube circuits with an intentional leak often do not allow oxygen to be bled in without an additional component, FIF
 - O₂ is added after the blower by bleeding in 100% O₂ at a variable rate.
 - The final O₂ delivered to the patient is influenced by the total flow through the circuit, as this dilutes the O₂ with room air.
 - Total flow through the circuit (and thus FiO₂ delivered) is dependent on the pressure in the circuit because it determines the flow out the exhalation port.
 - Thus, at higher pressures (CPAP, IPAP or EPAP ~20), even 15 L/min of O₂ input may result only in 40% FiO₂ to the patient!
 - This can only be overcome by increasing flow into the circuit of 100% O₂ to high flows (up to 50 l/min of 100% O₂ may be required to achieve 100% FIO₂ at the patient end of the circuit) or further modifying the circuit. High FIO₂ is often needed in COVID-19 respiratory failure.

WARNING – The RESMED S9 VPAP has a feature that may result in unexpected shutdown of the blower when flows of O₂ higher than 15 l/min are used. PLEASE SEE FULL WARNING AT START OF THIS DOCUMENT

Alarms

Most critical if using devices for invasive “life-support”

- Most CPAP and bi-level devices designed for OSA and home use do not have alarms. Most hospital units do. Typical displays and outputs used to trigger alarm include
 - Disconnect (low pressure in circuit, but must be measured near the patient)
 - Low/high tidal volume, minute ventilation (less reliable in mask vent)

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USE OF REPURPOSED DEVICES FOR COVID-19 PATIENTS

Non-invasive (Mask) CPAP or BiLevel: Deliver mask therapy to delay or prevent intubation, or to treat after recovery until extubation

Advantages

- Devices are designed to deliver this type of therapy
- Provides PEEP (useful for hypoxia) and NIV assists breathing (ventilation) to a limited extent
- May be effective in supporting patients with COVID-19 moderate ARDS

Limitations

- Risk of aerosol if the unmodified circuit is used
 - Mitigated by using non-vented mask and circuit available for this
- Risk of aerosol from air escaping around mask, which increases risk to health care workers.
 - Cannot be mitigated. Often quoted as reason for intubation.
- Long-term patient tolerance to masks is not optimal.
- Because of mask interface, the peak pressure is likely limited to 30-35 cm H20 as higher pressures usually result in air leakage at the mask interface (most NIV devices deliver max pressure of 35 cm H20)

CPAP and Bilevel to ventilate intubated patients (note: CPAP can provide useful PEEP, but DOES NOT ventilate)

Advantages

- Provides a low-cost alternative to ventilators if these are not available
- Minimizes risk of aerosols if exhalation port is filtered and there is no unintended mask leak
- May be effective treatment for hypoxia (CPAP and Bilevel both provide PEEP) and hypercapnic respiratory insufficiency (bilevel provides ventilation) in moderate to severe ARDS.

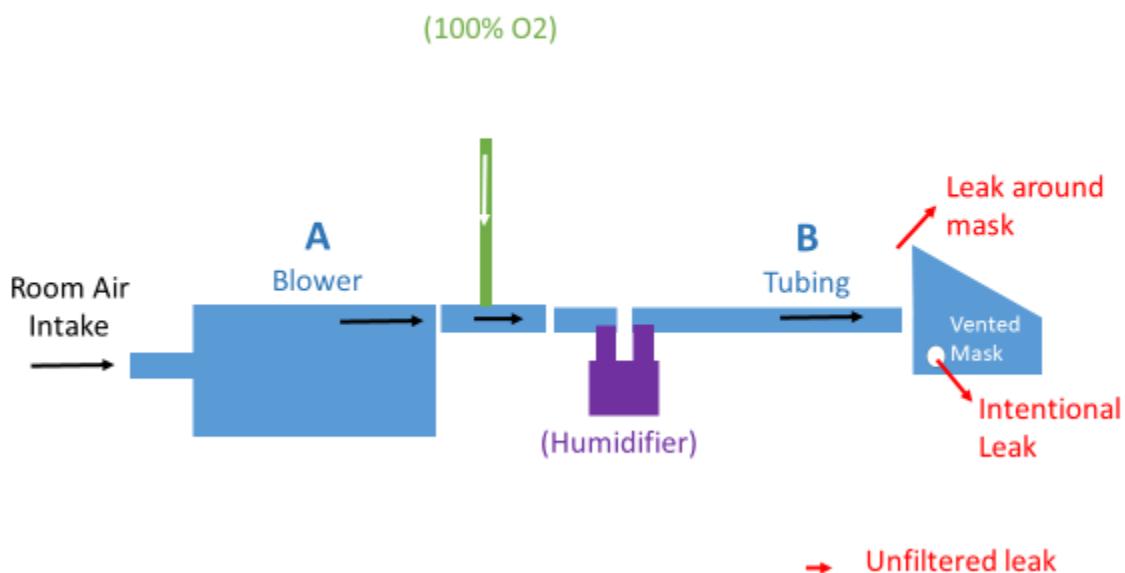
Limitations

- Most CPAP and home bi-level devices do not have alarms
- Humidifiers are needed
 - Internal humidifiers cannot be refilled without disconnecting circuit
- High FiO₂ delivery requires large amounts of O₂

Clinical Scenarios

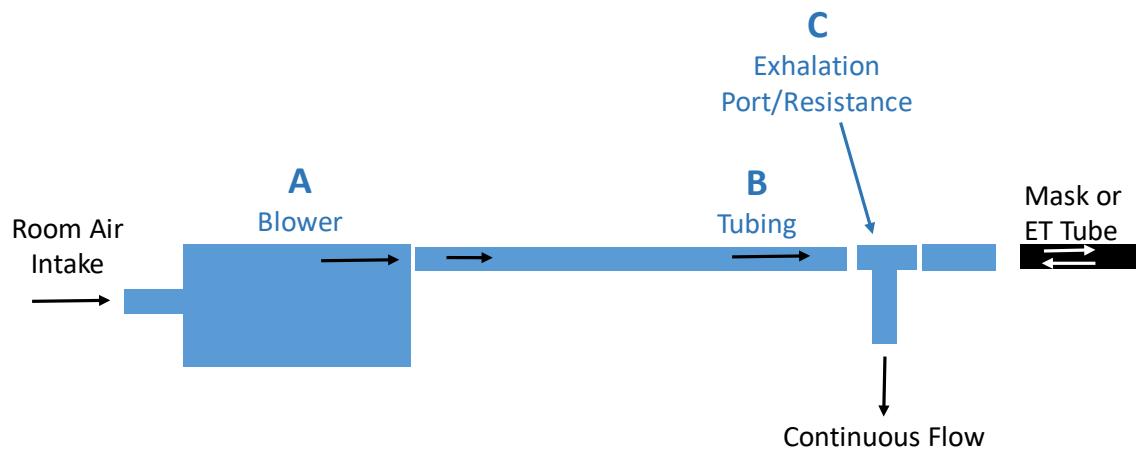
- **ICU:** CPAP and NIV to mask and intubated more stable patients (including low peak pressures and O₂ needs) to free up ventilators for more severe cases
- **Stepdown Unit:** For use in patients recovering but not yet able to be liberated from ventilator by extubation
- **ER or “Front-Lines”:** To tide over patients during surge of cases when ventilators run out

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**STEPS FOR CONVERTING STANDARD CPAP/BILEVEL TO ISOLATION CIRCUIT
FOR USE WITH NON-VENTED MASK OR INTUBATED PATIENT.****I.****BiLevel/CPAP – Standard (Home) Circuit with Vented Mask****IIa.**

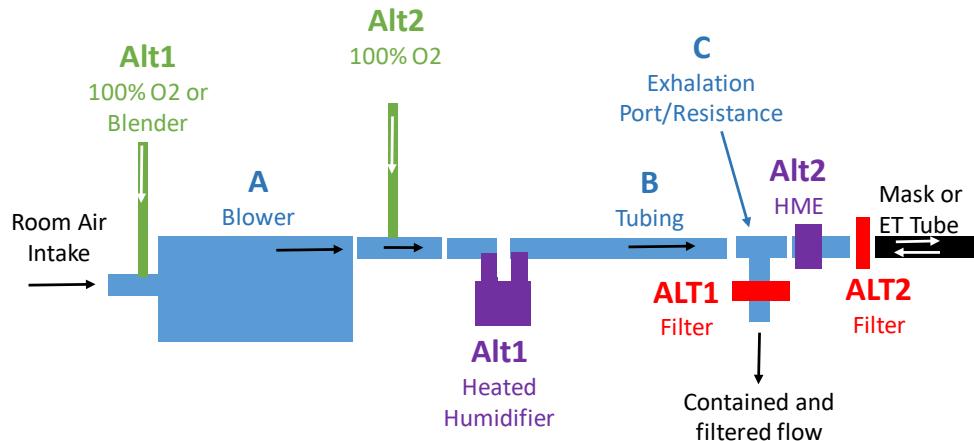
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BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit



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IIb.

BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit
Add: **Filtering**

Notes

*Filtering at exhalation port (Alt 1)

Advantages minimizes deadspace to patient

Allow change of filter without discontinuing ventilation

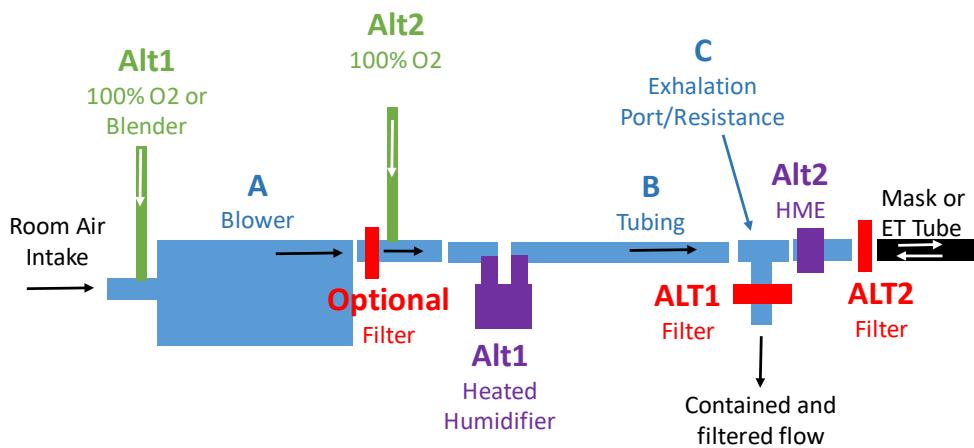
Filtering closest to patient (Alt 2)

Advantages captures both inspiration and expiration

Protects circuit from contamination and minimizes changes in expiratory resistance when filter accumulates water

Increases deadspace

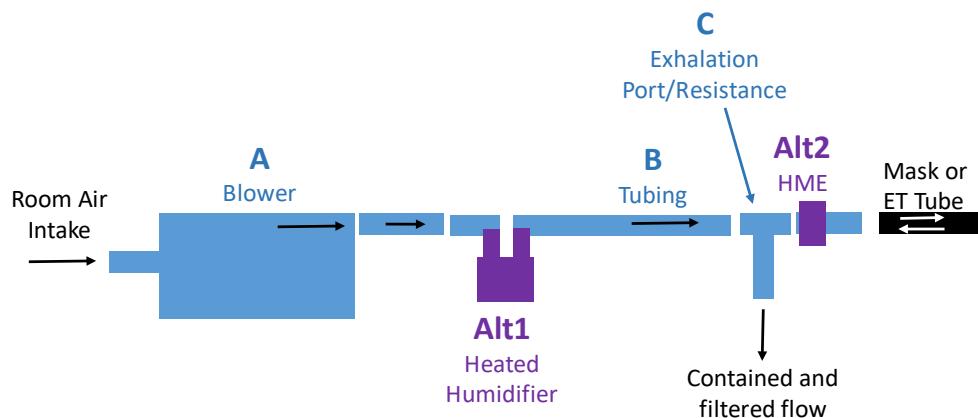
IIc.

BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit
Add: **Machine Filtering (optional)**

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IId.

BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit
Add: Humidity



Notes: Humidity is essential for intubated patients

Heated humidifier in line (Alt 1)

Advantage – maximal humidity
 may cause “rainout”
 no additional deadspace

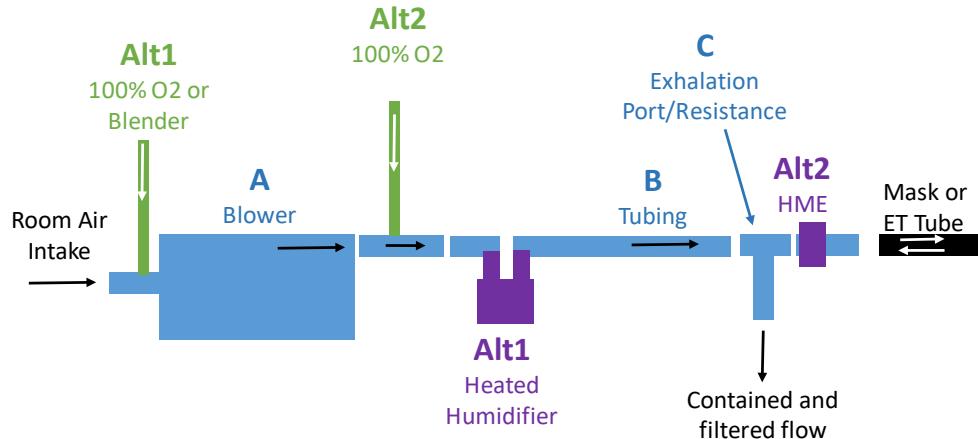
In line humidity moisture exchanger (HME – Alt 2)

Advantage – doubles as filter

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II.d.

BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit Add: O₂



Notes – all versions of this circuit require large amounts of O₂ to increase FIO₂

O₂ added after blower (Alt 2)

Advantages

Easy to find O₂ port that fits in tubing

Avoids passing O₂ through blower

Disadvantage - High flow may cause backup into blower if it exceeds flow through leak port

WARNING – The RESMED S9 VPAP and AIRCURVE 10 have a feature that may result in unexpected shutdown of the blower when flows of O₂ higher than 15 l/min are used. PLEASE SEE FULL WARNING AT START OF THIS DOCUMENT

O₂ added at blower intake port (Alt 1)

Advantages - No limit on FIO₂

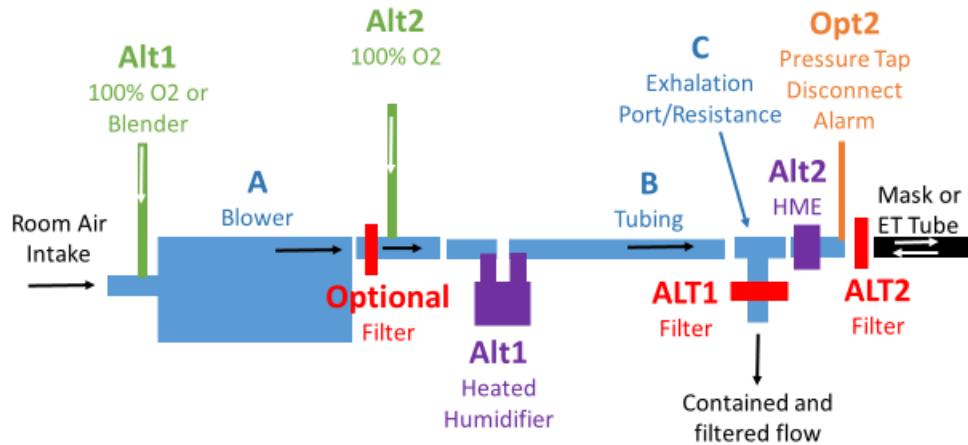
Can use 100% O₂ or provide fixed FiO₂ with blender/venturi

Disadvantage – difficult to connect to intake of blower and may require reservoir
O₂ passing through blower may increase risk of fire if device not rated for O₂ use

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IIe.

BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit
Add: Disconnect Alarm



Notes: Most bilevels intended for home use DO NOT have alarms

External alarm circuit can be part of monitoring system

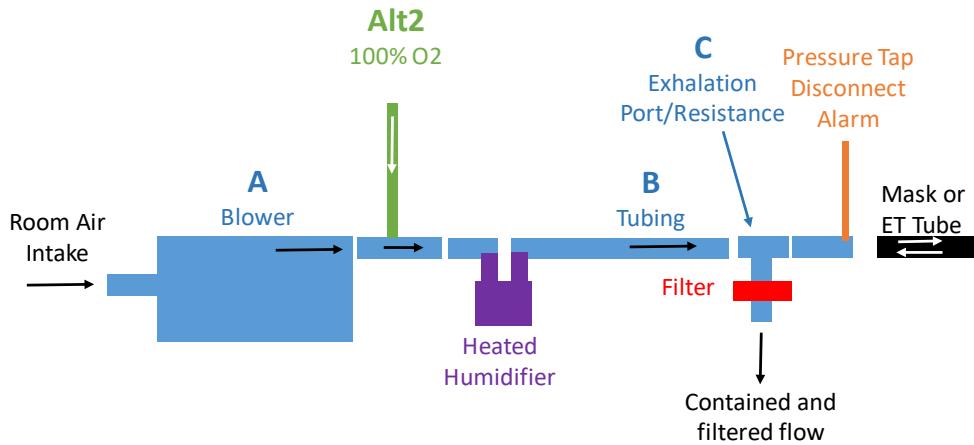
Custom low pressure alarm can be added

Alarm ideally should be remote and outside room if patient in isolation

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III.

BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit
Recommended: Humidity, O₂, Filters, Disconnect Alarm



Home Bi-Level Devices that Can Be Used With The Above Modified Circuit

Dream Station BIPAP (Respironics) – link to detailed setup

<http://researchroadmap.mssm.edu/reference/covid-19-guidance/#ventilator-repurpose>

S9 VPAP ST (Resmed) – link to detailed setup

<http://researchroadmap.mssm.edu/reference/covid-19-guidance/#ventilator-repurpose>

WARNING

The ResMed S9 has a feature that, whenever the pressure is set above 10 cm H₂O, the device will unexpectedly turn off all flow when the flow from the blower drops below 15 l/min. This will occur when a high rate of 100% O₂ is added beyond the blower. Avoiding this high flow of 100% O₂ limits the FIO₂ that can be achieved to ~60%)

No fix to this is available

AirCurve ST (Resmed) – link to detailed setup

<http://researchroadmap.mssm.edu/reference/covid-19-guidance/#ventilator-repurpose>

WARNING

The present AirCurve has a feature that, whenever the pressure is set above 10 cm H₂O, the device will unexpectedly turn off all flow when

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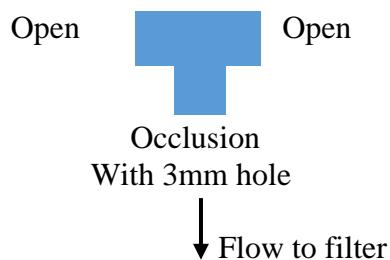
ResMed is working on a version of this device that will disable this feature.

Replacements options when commercial parts are not available:

HUMIDIFICATION – if not available, heated humidifier can be replaced by humidity moisture exchanger (HME)

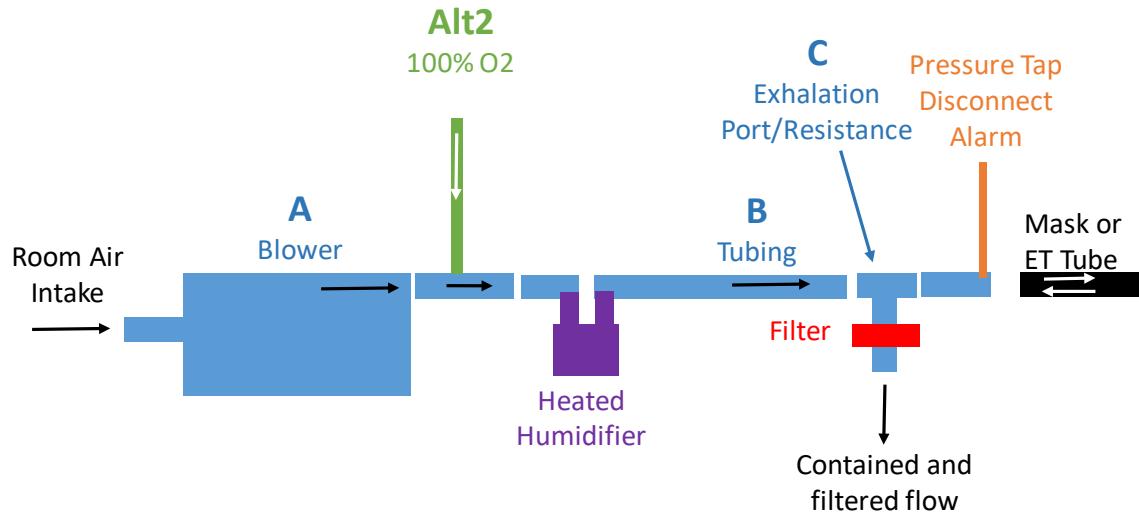
WATER RESERVOIR – ideal is “auto-refill” type (Fisher and Paykel) that can be refilled without disrupting circuit

TUBING CONTAINING EXHALATION PORT - Integrated tubing and exhalation port can be replaced by standard respiratory tubing and separately purchased exhalation port. If the latter is not available, a 3D printed part can be printed or obtained. Alternative is standard respiratory 22mm “T” or “Y” at the patient, with occluded limb on base of T and 3mm hole drilled into occlusion:



ALARM – can be from any ICU monitoring system (e.g. GE or Masimo) or a simple “low pressure” alarm circuit

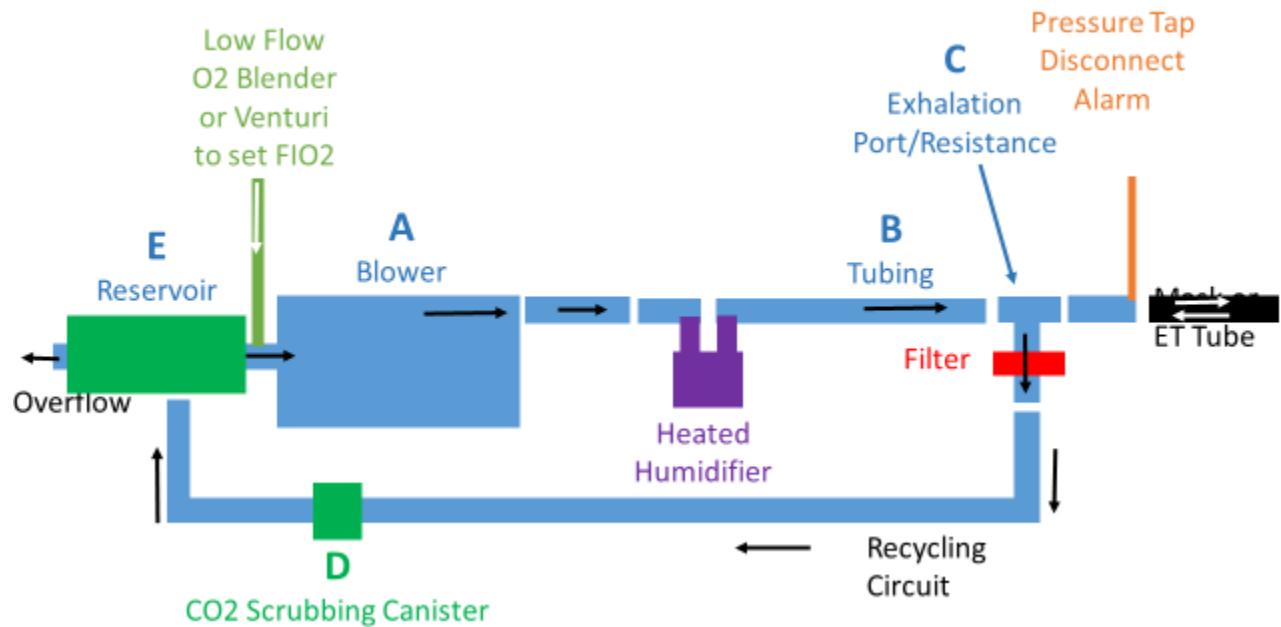
IV.

BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit
Recommended: Humidity, O₂, Filters, Disconnect Alarm

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V.

BiLevel/CPAP (O2 Conserving Circuit for Intubated Patient)



Notes

Advantages This circuit requires addition of much lower O2 (~250-500 cc/min vs 15-30 l/min) to achieve high FIO2 (up to 100%)

Disadvantage CO2 absorbing canister (Soda lime) must be inserted in line

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