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Primer:

- CPAP, bilevel, 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 without additional modification to the circuit <u>unless no other</u> <u>options exist.</u>

The ResMed VPAPTM ST is designed to be a *noninvasive* ventilator. Incorporation of supplemental oxygen at > 15 l/min into the circuit anywhere distal to the blower should be undertaken with extreme caution and only after modifying the circuit with a second exhalation valve close to the blower and proximal to the O₂ bleed in.

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

At supplemental oxygen flows of 15 l/min, the maximum achievable FiO_2 will be no higher than 60%. If a patient requires $FiO_2 > 60\%$ or PEEP > 10 cmH₂O, the circuit must be modified with the addition of a second exhalation port, or 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% unless 2 exhalation ports are used!

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Version 3.3 [Jul 07, 2020]

Mount Sinai Health System

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For additional information and associated documents, please see below links: Primer - Theory and Background for Bilevel Repurposing Protocol - Repurposing of Bilevel Devices for Invasive Ventilation Clinical Guidelines / Operating Checklist - Philips Respironics Devices Clinical Guidelines / Operating Checklist - ResMed Devices Monitoring and Alarm Guidelines / Construction Construction of an Anesthesia Circuit Component Diagram Construction of a Bilevel Circuit Component Diagram Frequently Asked Questions

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Primer CPAP, BILEVEL, 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 <u>single</u> pressure. Continuous pressure expands the lung and upper airway and can be useful in hypoxic respiratory failure to deliver PEEP.

CPAP <u>does not</u> provide ventilation (assisted breathing gas flow).

- Common US Manufacturers:
 - Philips Respironics DreamStation CPAP, E30
 - ResMed AirSense[™] 10
 - Fisher & Paykel Healthcare ICON and Sleepstyle[™]

Bilevel Ventilator

Bilevel is a generic term; BiPAP[™] (Respironics) is often used synonymously. This form of respiratory support provides an oscillating pressure (high and low, thus bilevel). 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:
 - Philips Respironics 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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Primer

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 bilevel 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:
 - Philips Respironics DreamStation BiPAP, V60, V680, Trilogy, E30
 - \circ ResMed VPAPTM S9, AirCurveTM 10

Invasive Ventilation

Any device to move air in and out while connected to an endotracheal tube. Technically, CPAP and PEEP are <u>not</u> ventilation, but some authorities include them as forms of ventilation if they are connected to an endotracheal tube. Bilevel 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
 - Philips Respironics Trilogy, V60, V680, E30
 - ResMed AstralTM, StellarTM

<u>Circuits to Connect Devices to Non-Intubated Patients</u>

Mask Circuits

The usual circuit in home use (e.g. for OSA) consists of a tube connecting the blower to a nasal or full face mask with a vent built into the mask. This spews out ~20-30 I/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
 - o ResMed
 - Philips Respironics

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
- Philips Respironics 1065832
 - Full circuit
 - Exhalation port alone (use with regular tubing) 1065775
- ResMed
 - o Full Circuit
 - o Exhalation port alone

<u>Circuits to Connect Devices to Intubated patients</u>

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 <u>non</u>-vented masks. Such circuits differ from the double tube circuits in that they must have an exhalation port, but this can be attached to a filter.

Accessories for CPAP, Bilevel and HFNC, and Issues Affecting Therapy

These vary in importance whether used in mask 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 bilevel 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, <u>essential</u>, as high flows of unhumidified air will dry and irritate nasal mucosa and cause pain.
- For all forms of intubated ventilation humidity is <u>essential</u> to prevent airway drying and inspissation of mucus

Aerosolization of infectious particles in exhaled gases and possible virus dispersion

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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 bilevel vented mask risk is moderately high
- For CPAP and bilevel <u>non-vented masks</u> risk can be mitigated by filters, but remains for unintended leak (around mask/face interface)
- For CPAP and bilevel 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 bilevel 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.
 - \circ O₂ is added after the blower by bleeding in 100% O₂ at a variable rate.
 - The final O₂ at the patient is influenced by total flow through the circuit and thus dependent on leak through the exhalation port, as this flow dilutes the O₂ with room air.
 - Total flow through the exhalation port in the circuit (and thus FiO₂ delivered) is dependent on the pressure in the circuit. This is because circuit pressure determines the flow out the exhalation port.
 - $\circ~$ Thus, at higher pressures (CPAP, IPAP or EPAP ~20), even 15 l/min of O_2 input may result in only 40% FiO_2 to the patient!
 - This can only be overcome by increasing flow of 100% O₂ into the circuit 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. However, if the total O₂ flow is greater than the flow out the leak port, O₂ will back up in the circuit, and the blower flow may drop to zero. Adding a second exhalation port <u>before</u> the point of addition of O₂ bleed in will mitigate this situation, and allow high (near 100% O₂) at flows that do not back up O₂ into the blower.

WARNING – The RESMED S9 VPAPTM and AIRCURVETM have a feature that may result in unexpected shutdown of the blower when flows of O₂ higher than 15 l/min are used with a single exhalation port. This is because the software responds to the drop in blower flow to zero. This problem is mitigated only if 2 exhalation ports (one at blower proximal to O₂ bleed in) are used. PLEASE SEE FULL WARNING AT START OF THIS DOCUMENT.

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Alarms

Most critical if using devices for invasive "life-support"

- Most CPAP and bilevel devices designed for OSA and home use <u>do not have alarms</u>. 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)
 - o Low/high tidal volume, minute ventilation (less reliable in mask vent)

USE OF REPURPOSED DEVICES FOR COVID-19 PATIENTS

<u>Non-invasive (Mask) CPAP or Bilevel</u>: 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.
 - Difficult to mitigate. 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 H₂O as higher pressures usually result in air leakage at the mask interface (most NIV devices deliver max pressure of 35 cm H₂O)

<u>CPAP and Bilevel for intubated patients</u> (note: CPAP can provide useful PEEP, but DOES NOT ventilate. Bilevel can 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 bilevel devices do not have alarms
- Humidifiers are needed
 - Internal humidifiers cannot be refilled without disconnecting circuit
- High FiO₂ delivery requires large amounts of O₂

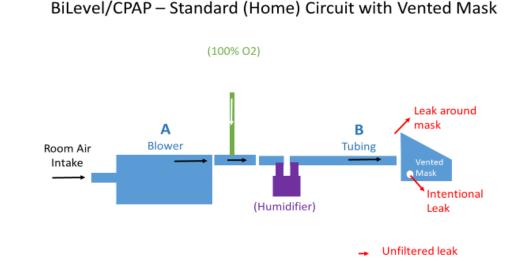
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Clinical Scenarios

- ICU: Switching relatively stable intubated patients (especially those with low peak pressures and lower O₂ needs) to CPAP and NIV will 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

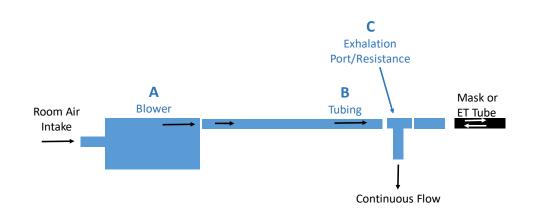
STEPS FOR CONVERTING STANDARD CPAP/BILEVEL TO ISOLATION CIRCUIT FOR USE WITH NON-VENTED MASK OR INTUBATED PATIENT.

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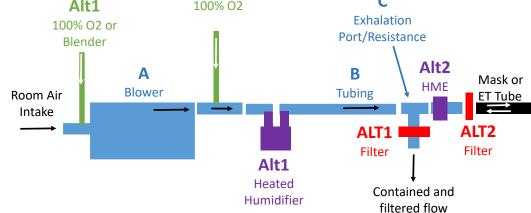
BiLevel/CPAP (Non-Vented Mask or Intubated Patient) Circuit



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Notes:

- Filtering at exhalation port (Alt 1) Advantages
 - Minimizes deadspace to patient
 - Allows change of filter without discontinuing ventilation
- Filtering closer to patient (Alt 2)

Advantages

- Captures both inspiration and expiration
- Protects circuit from contamination and minimizes changes in expiratory resistance when filter accumulates water

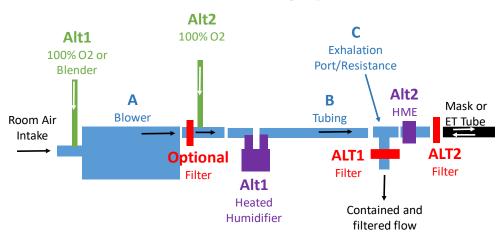
Disadvantage

- Increases deadspace

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IIc.

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



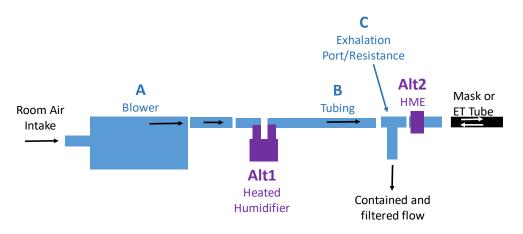
Note:

Optional filter at blower output is not really needed, as flow is uni-directionl towards the patient but can be added without compromising any functions. Replacing this will require removing the patient from ventilatory support, but will be infrequently required if humidity is added after the filter.

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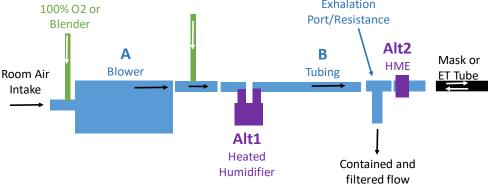


Notes:

- 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 (Alt 2 HME) Advantage
 - Doubles as filter

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Notes:

All versions of this circuit require large amounts of O₂ to increase FiO₂

O₂ added <u>after</u> 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 I/min are used. PLEASE SEE FULL WARNING AT START OF THIS DOCUMENT

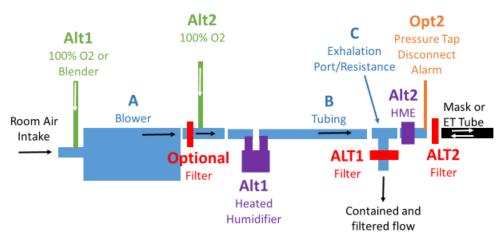
- O₂ added <u>at blower intake</u> port (Alt 1) Advantages
 - No limit on FiO₂
 - Can use 100% O₂ or provide fixed FiO₂ with blender/venturi

Disadvantages

- 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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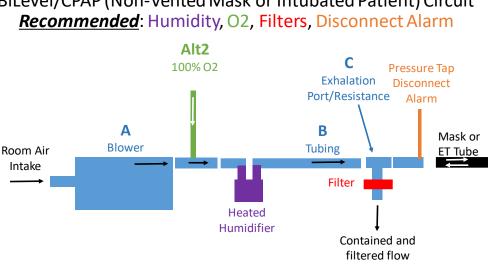




Notes:

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

Home Bilevel 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 shut off 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% O_2 limits the FiO₂ that can be achieved to ~60%). The problem is mitigated by addition of a second exhalation port at the blower proximal to O₂ bleed in.

AirCurve[™] ST (ResMed) – link to detailed setup http://researchroadmap.mssm.edu/reference/covid-19-guidance/#ventilator-repurpose

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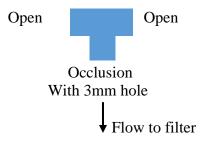
WARNING

The present AirCurve[™] has a feature that, whenever the pressure is set above 10 cm H20, the device will <u>unexpectedly shut off</u> 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%). The problem is mitigated by addition of a second exhalation port at the blower proximal to O₂ bleed in.

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

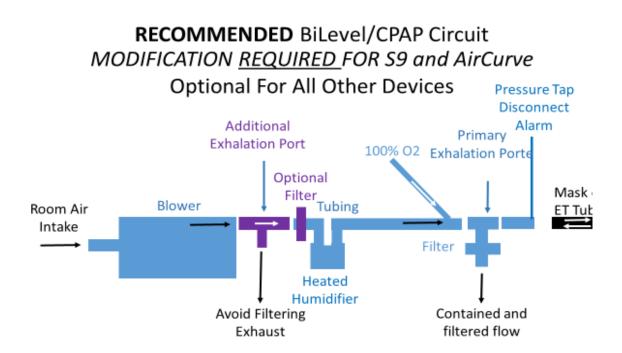
Replacements options when commercial parts are not available:

- <u>Humidification</u>: If not available, heated humidifier can be replaced by humidity moisture exchanger (HME)
- Water Reservoir: Ideal is "auto-refill" type (Fisher & Paykel) that can be refilled without disrupting circuit
- <u>Tubing Containing Exhalation Port:</u> Integrated tubing and exhalation port can be replaced by standard respiratory tubing and separately purchased exhalation port. If separate port is not available, one can be 3D printed. Alternatively, a standard respiratory 22mm "T" or "Y" at the patient, with occluded limb on base of T and 3mm hole drilled into occlusion can be used:



<u>Alarm</u>: Can be from any ICU monitoring system (e.g. GE or Masimo) or a simple "low pressure" alarm circuit

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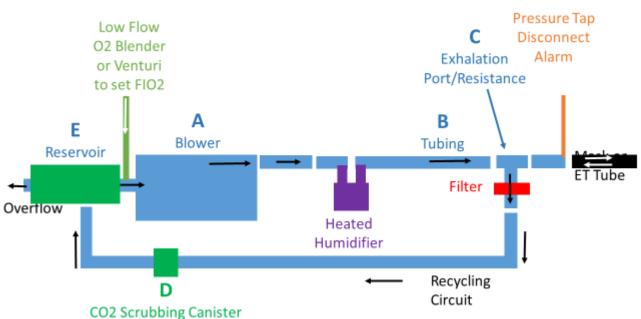


Notes: This circuit has been bench-tested and is the safest one to use with most devices on the market, including the ResMed S9 and Aircurve[™]. It is permissible to leave the secondary exhalation port out of this circuit when using devices other than the ResMed S9 or Aircurve[™].

Because this circuit adds an additional exhalation port, it provides an additional buffer between the flow that is needed to achieve high (>90%) FiO₂ using very high bleed-in of supplemental of O₂ and the flow that causes back up into the blower.

For most devices, use of this second exhalation port is optional. However, in the ResMed S9 and AirCurveTM devices. supplemental O_2 flow high enough to cause back up into the blower will cause an unanticipated shutoff of the device. For this reason, we recommend the above circuit be used for all bilevel and CPAP devices when used with high O_2 and PEEP/CPAP>10 (as is usually needed in COVID-19 patients).

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BiLevel/CPAP (O2 Conserving Circuit for Intubated Patient)

Notes

- Advantage
 - 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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