Invasive Bi-level Positive Airway Pressure (BiPAP): An Innovative Alternative to Ventilatory Management for COVID-19 Patients

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Which of the following devices can be adapted to meet the need for emergency invasive ventilation?¹

- [ ] Hospital BiPAP
- [x] Home-use BiPAP
- [x] CPAP

Pulmonary features of COVID-19 associated ARDS

- COVID-19 associated acute respiratory distress syndrome (ARDS) is hypoxic respiratory failure that results from inflammatory pulmonary responses to the SARS-CoV-2 virus\(^1\)
  - inflamed, dysfunctional alveolar epithelium
  - impaired surfactant function
  - reduced alveolar fluid clearance; alveoli collapse or fill, resulting in ventilation/perfusion (V/Q) mismatch

- Patients show varying degrees of hypoxemia\(^1\)

- Unlike typical ARDS, however, respiratory system compliance is often near normal\(^2\)

Formal guidelines for ARDS care

Standard of ARDS care is a low tidal volume (TV) strategy on ventilator support (6 cc/kg ideal weight)¹

A global need: emergency sources of ventilation appropriate for the COVID-19 lung

COVID-19 caseloads are growing

• CDC estimates as many as 160 to 214 million persons in the US could become infected, resulting in more than 2.4 million hospitalizations¹

• An estimated 1% of those infected by the SARS-CoV-2 virus will require ventilatory support²

• Many countries, including the US, anticipate or currently experience critical shortages of mechanical ventilators

• Only an estimated 62,000 full-featured ventilators and approximately 99,000 older ventilators exist in US hospitals nationwide³

An emergency solution: adapt BiPAP for invasive use to delay or remove need for mechanical ventilation

- Bi-level Positive Airway Pressure (BiPAP) machines are widely available hospital and at-home devices providing bi-level positive airway pressure
- Use of BiPAP on an emergency basis for ventilation in appropriate COVID-19 patients may conserve ICU beds and delay or reduce the hospital’s need for mechanical ventilation equipment
  - Can meet need for low tidal volume ventilation
  - Caution: using BiPAP without intubation may disperse aerosolized virus into the treatment environment
What is invasive BiPAP?

• Adaptors, filters, and use of appropriate device settings can enable BiPAP to be used with endotracheal tubes
  – The U.S. Food and Drug Administration is temporarily waiving objections to such device modifications when they do not create an undue risk\(^1\)

• Among hospitals adapting BiPAP devices for use in COVID-19 are:
  – Northwell Health, NY
  – Massachusetts General Hospital, MA
  – Emory Health, GA
  – Broward Health Medical, FL

• Do not confuse with CPAP devices for obstructive sleep apnea, which cannot be used for ventilation and provide no ventilatory support

Non-invasive or invasive: which BiPAP modality to use?

Non-invasive BiPAP:
Early in the course of care

- Non-invasive ventilation (NIV) should only be used in selected patients with hypoxemic respiratory failure

- Patients treated with either high-flow nasal oxygen or NIV should be closely monitored for clinical deterioration

- Clinicians may consider use of helmet interface or face mask with BiPAP to support respiratory status

- Risks include delayed intubation, large tidal volumes, and injurious transpulmonary pressures

- To reduce risk to healthcare providers:
  - Use local best practices for non-invasive ventilation
  - Bag valve masks (BVMs) and other ventilator equipment should be equipped with HEPA filtration to filter expired air and minimize aerosolization

Invasive BiPAP:
If the patient isn’t stabilized quickly

- If the patient isn’t stabilized in a monitored setting within 60 minutes after non-invasive BiPAP, clinicians may elect to intubate and continue use with the BiPAP machine

- This can provide a means to ventilate/oxygenate patients until a standard ventilator and ICU bed become available, or in lieu of these resources if they are not available

How to adapt BiPAP for invasive ventilation support*

- Replace mask with adaptor/coupler that enables connection to endotracheal tube
- Provide humidification (active HME or with filter [HMEF])
  - COVID-19 patients (especially those with underlying respiratory conditions and/or bacterial infections) have been reported to have difficulty adequately humidifying the airways and patients develop tenacious, thick secretions that are occluding their endotracheal tubes
- A leak port **must be open** to allow expiratory outflow
  - HEPA filter on the leak port to prevent virus-containing aerosols from contaminating room
  - Contact manufacturer to obtain appropriate filter
- Program BiPAP device settings for invasive ventilation

*Note: This is general guidance and they should contact the manufacturers for any specific modification questions as each BiPAP is likely different.
Invasive BiPAP experience has been positive in resource-poor settings or when mechanical ventilators have been unavailable

**Pakistan**
In comatose COPD patient responders, invasive BiPAP significantly (P<0.01) improved coma scale scores, pH, and PaCO$_2$\(^1\)

**India**
In comatose COPD patient responders, invasive BiPAP significantly improved (P≤0.001) coma scales scores, pH, PaCO$_2$, respiratory rate, and SOFA score\(^2\)

There are reports of invasive BiPAP use in COVID-19 from **Washington State, China\(^3\)**, **Italy, France**

Virus containment considerations
Which of these can transmit SARS-CoV-2?¹

- ✔ Droplets
- ✔ Copper
- ✔ Paper
- ✔ Aerosols
- ✔ Aluminum
- ✔ Glass
- ✔ Steel
- ✔ Wood
- ✔ Latex Gloves

Intubation may reduce aerosol leakage

- The following aerosol-generating procedures should be performed in Airborne Infection Isolation Rooms:
  - CPR
  - Endotracheal intubation
  - Non-invasive ventilation

- Aerosolized virus may leak from NIV masks, especially if multiple mask manipulations occur

- Personal protective equipment (PPE) remains mandatory

Each mask manipulation creates an aerosol risk equivalent to a one-time intubation

Risk of SARS Transmission to HCWs Exposed and Not Exposed to Aerosol-Generating Procedures, and Aerosol Generating Procedures as Risk Factors for SARS Transmission¹

<table>
<thead>
<tr>
<th>Aerosol Generating Procedures</th>
<th>Odds ratio (95% CI)</th>
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<tbody>
<tr>
<td></td>
<td>Point estimate</td>
</tr>
<tr>
<td>Manipulation of oxygen mask (2 cohort studies)</td>
<td>17.0 (1.8, 165.0)</td>
</tr>
<tr>
<td></td>
<td>2.2 (0.9, 4.9)</td>
</tr>
<tr>
<td>Tracheal intubation (4 cohort studies)</td>
<td>3.0 (1.4, 6.7)</td>
</tr>
<tr>
<td></td>
<td>22.8 (3.9, 131.1)</td>
</tr>
<tr>
<td></td>
<td>13.8 (1.2, 161.7)</td>
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<tr>
<td></td>
<td>5.5 (0.6, 49.5)</td>
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<tr>
<td>Non-invasive ventilation (2 cohort studies)</td>
<td>2.6 (0.2, 34.5)</td>
</tr>
<tr>
<td></td>
<td>3.2 (1.4, 7.2)</td>
</tr>
<tr>
<td>Mechanical ventilation (1 cohort study)</td>
<td>0.9 (0.4, 2.0)</td>
</tr>
</tbody>
</table>

When to intubate?
Which of these are potential benefits of earlier intubation?

- Reduces negative pressure that could worsen pulmonary edema and lower oxygenation
- Improves patient comfort via ventilation support
- Airway protection allows sedation and lowers aspiration risk
- Removes dead space of trachea from ventilation and oxygenation considerations
- Avoids high risk of NIV failure and need for rush intubation
Sedation may offer advantages

Sedation options:
All are available options and can be provided to a patient with airway protected
Algorithms and device settings
Ventilation considerations relevant to COVID-19 ARDS

In patients using excessive inspiratory effort, intubation is high priority
- Avoids excessive negative intrathoracic pressures and self-inflicted lung injury\(^1\)

**Treatment targets**

- \(\text{PaO}_2 > 55 \text{ mm Hg}\)
- \(\text{SaO}_2 > 88\%\)
- Blood pH: 7.35 to 7.45

Which patients are candidates for emergency invasive BiPAP?

- In general, if patients have lung failure and not more than 2 organ systems in failure, BiPAP devices may support them adequately
  - Caveat: An endotracheal tube with BiPAP has not been evaluated in COVID-19 patients, nor are there formal recommendations from critical care societies or associations
- Bedside clinicians should consider the severity of failure in multiple organs or other symptoms of worsening ARDS

<table>
<thead>
<tr>
<th>Mean SOFA ≤2</th>
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</thead>
<tbody>
<tr>
<td>COVID-19 (+) or pending status</td>
</tr>
<tr>
<td>Those considered for use of NIV with face mask</td>
</tr>
<tr>
<td>Moderate ARDS (P/F ratio of 100–200)</td>
</tr>
<tr>
<td>Hemodynamically stable</td>
</tr>
<tr>
<td>Those with any chronic illness not in exacerbation during ICU stay</td>
</tr>
</tbody>
</table>
Algorithms: Smart BiPAP

Available for download at www.covid-bipapinfo.com

How to use Smart BiPAP for ventilation

Intubate
Average Volume-Assured Pressure Support (AVAPS)
Initial settings

1. Choose Pmax setting
   Close to the Mean Airway Pressure that the machine is giving back

2. AVAPS mode will adjust Pressure Support to desired TV

3. May need to change EPAP to:
   >10 to achieve saturation >90%
   adjust FiO2 to maintain PaO2 >60

Before proceeding, check these 3 settings

ABG 30 minutes, make adjustment as necessary based on pH levels or O2

If pH is not over 7.25
Then will likely need adjustment of Pmax

If O2 saturations are less than 90%
Then adjust EPAP as necessary

When to use the AVAPS capability

Many newer standard NIV devices are equipped with an algorithm-based BiPAP mode for AVAPS, providing functionality much closer to that of a standard mechanical ventilator.

AVAPS allows clinicians to set:
• TV (average)
• Expiratory positive airway pressure level
• Respiratory rate
• Higher concentration of oxygen

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Algorithms: Standard BiPAP

Available for download at www.covid-bipapinfo.com
THE FOLLOWING PROTOCOL HAS BEEN DEVELOPED BY NORTHWELL HEALTH FOR EMERGENCY SITUATIONS ARISING OUT OF THE COVID-19 PUBLIC HEALTH EMERGENCY ONLY.
NORTHWELL IS SHARING THIS PROTOCOL WITH YOU, AT YOUR REQUEST, FOR INFORMATION PURPOSES ONLY.
YOU SHOULD REVIEW AND ANALYZE THE PROTOCOL FOR YOUR OWN SPECIFIC EMERGENCY USE PURPOSES AND MAKE YOUR OWN DETERMINATION AS TO WHETHER AND WHEN DEPLOYMENT OF THIS PROTOCOL IS NECESSARY.

Emergency protocol for using Philips Respironics V60 ventilator with pressure control ventilation (PCV) option as a pressure-controlled ventilator using a conventional bipap circuit

Authored by Hugh Cassiere, MD, Stanley John RT, Todd Goldstein, PhD

You may use the conventional exhalation valve and/or circuit sold by Philips Respironics

**In situations where the manufacturer’s connection is unavailable, Northwell Health has successfully replicated and tested a 3D printed solution that is autoclavable and reusable. As the 3D printed solution should only be used in an emergency situation, it is recommended that the bacterial or viral filter be placed between the ET tube and the 3D printed adapter. (Photo at end of document.)**
Preliminary results
Northwell Health Experience – Philips Respironics V60 BiPAP

Started using the Philips Respironics V60 BiPAP March 2020

First experience was on patients with non-COVID-19 respiratory failure

- Allowed us to free up FDA-approved invasive ventilators
- Over the course of 3 weeks we invasively ventilated 50–60 such patients
- As of last week we continued to ventilate 12–15 patients

Second experience was on “surge” COVID-19 patients

- On occasion, sites were depleted of ventilators due to surges of COVID-19 patients being intubated
- Providers used the protocol and adapters were set up to rescue these patients while awaiting ventilator resupply

Third experience was upfront use on COVID-19 ARDS respiratory failure patients

- At peak of our pandemic up to 80 patients were invasively ventilated using the V60 BiPAP
Add 2 HEPA filters, one immediately connected to the V60 main gas port outlet and the second HEPA gets connected to the exhalation valve port closer to the ET/Trach

We recommend that the HEPA filter on the exhalation valve port be connected to a blind reservoir

*In order to connect to an ETT tube you need to use the Philips Respironics conventional exhalation valve and/or circuit kit
Turn on machine and hit the **Menu** tab. Please ensure the patient is not connected to the V60 machine
- Under the Menu tab select the option for **Mask/Port**
- Select → **ET/Trach** option (extreme left)
- Hit **Accept**

Then choose type of exhalation port
- Select → **Other**
- Hit **Accept**
Perform exhalation port test

- Keep circuit open
- The machine will detect the open circuit and ask you to occlude the outlet port that connects to the patient end of the circuit

Now occlude the outlet keeping the exhalation valve port open

- Hit **Start Test**
- Test takes 4-5 seconds; when you see the green bar the test was completed successfully, or you passed the test
Place patient on the appropriate pressure settings parameters prior to activating mode as follows:

- The EPAP will be the same as the PEEP
- For IPAP use the plateau pressure measured on the conventional ventilator as a baseline
- The FiO2 would be the same
- **The ramp should be turned off**
- The rise time can be adjusted based on patients demand. We recommend a rise time of 3
Now activate the batch change by hitting **Select (Active Batch Change)**
3D printing protocol

There are many different types of 3D printing modalities that can be used for this adapter. Please ensure that the STL is printed with a biocompatible material.

*HEPA Filter placed after the adapter.
Equipment useful at bedside during invasive BiPAP

Use of BiPAP with intubation may require equipment normally used for patients on mechanical ventilation:

- **Suction device**
  to remove pulmonary secretions

- **Pulse oximeter**
  to measure saturation of oxygen in blood

- **BVM (often referred to as an Ambu® bag)**
  to provide positive pressure ventilation

- **Telemetry system**
  to measure vital signs (e.g., heart rate, breathing, blood pressure)

- **Capnography**
  to monitor CO2, if available
# Patient monitoring and intervention considerations

## AARC Recommendations\(^1\)

<table>
<thead>
<tr>
<th>Monitor:</th>
<th>Other considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Tidal volume; Target tidal volume to 6 mL/kg predicted tidal volume</td>
<td>• Titration</td>
</tr>
<tr>
<td>• (S_pO_2): target 88%–95%</td>
<td>• Physical assessment – LOC</td>
</tr>
<tr>
<td>• Arterial blood gases</td>
<td>• RR comfort therapy</td>
</tr>
<tr>
<td>• Capnography is not necessary unless needed as a disconnect alarm</td>
<td>• Observations: accessory muscles, pulse oximetry, HR, vitals</td>
</tr>
<tr>
<td>• Also important to set alarms – particularly the disconnect alarm</td>
<td>• Secondary driver or device back-up</td>
</tr>
<tr>
<td></td>
<td>• Review of analyzing blood gas (TcCO(_2) or EtCO(_2)?)</td>
</tr>
<tr>
<td></td>
<td>• Safety considerations</td>
</tr>
<tr>
<td></td>
<td>• Ongoing management – potential clinical complications (pneumothorax, gastric distention); and potential mechanical complications (inadequate ventilation)</td>
</tr>
</tbody>
</table>

## When to progress to mechanical ventilation

<table>
<thead>
<tr>
<th>ED to ICU</th>
<th>ICU</th>
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<tbody>
<tr>
<td>• Prolonged stay in ICU bed shortage vs. short term</td>
<td>• Need to prone patient due to refractory hypoxia</td>
</tr>
<tr>
<td>• Signs of treatment failure</td>
<td>• Need for paralytics due to refractory hypoxia</td>
</tr>
<tr>
<td></td>
<td>• Multiple organs in failure</td>
</tr>
<tr>
<td></td>
<td>• SOFA mean score 3 or more</td>
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<td></td>
<td>• Hemodynamic instability</td>
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</table>
Conclusion
**Conclusion**

- BiPAP machines are widely available devices providing bi-level positive airway pressure

- Use of BiPAP on an emergency basis for ventilation in appropriate COVID-19 patients may conserve ICU beds and delay or reduce the hospital’s need for mechanical ventilation equipment

- Invasive BiPAP minimizes healthcare worker exposure to aerosols
  - PPE must be worn and standard precautions taken at all times
More information about invasive BiPAP

AARC Guidance

Additional training:
https://www.aarc.org/resources/clinical-resources/bilevel-devices-converted-to-ventilators/

FDA Guidance

HHS Guidance

NIH Treatment Guidelines
https://covid19treatmentguidelines.nih.gov/critical-care/

Northwell Health
Coronavirus Digital Resource Center:
https://www.northwell.edu/coronavirus-covid-19

3D design and innovation:
https://www.northwell.edu/3d-design-innovation

Syneos Health
www.COVID-BiPAPInfo.com
References


Aloud A. Average volume-assured pressure support. SW Respir Crit Care Chron. 2018;6:29-37.


Questions?

Visit [www.COVID-BiPAPinfo.com](http://www.COVID-BiPAPinfo.com) for free educational materials

More information:
- AARC
- FDA
- HHS
- NIH
- Northwell Health