This guide reviews the clinical evidence supporting the benefits of the PB980 in providing respiratory support in the neonatal intensive care unit (NICU).

Providing lung protective ventilation that accurately controls pressure and tidal volume levels while preventing atelectasis and injury is an essential element to managing neonatal respiratory care. Three key components that are vital to ensuring lung protective ventilation is delivered: Tidal Volume Accuracy, Synchrony, and Leak Management.
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INTRODUCTION

Lung protective ventilation that precisely delivers pressure and volume levels while maintaining synchrony with the patient’s breathing efforts is essential to preventing atelectasis and injury when managing neonatal respiratory care. However, neonatal airway interfaces interfere with precise air delivery as they are designed and applied to protect fragile tissues by limiting skin and tracheal contact. These loose-fitting interfaces allow air leakage, which places patients at risk for inaccurate tidal volumes, particularly in non-invasive ventilation, and patient-ventilator-asynchrony.

- Patient-ventilator-asynchrony
  - Air leaks interfere with the ability of the ventilator to recognize patients’ spontaneous breathing efforts and have the potential for causing triggering and cycling asynchrony.
  - Asynchronous patient ventilator interactions increase the work of breathing, have been associated with elevated markers of stress and blood pressure variability, and may increase the duration of mechanical ventilation.
  - Patient triggered ventilation, when compared to controlled ventilation, improves oxygenation, stabilizes blood pressure, and when synchronized to the patient may also reduce barotrauma and bronchopulmonary dysplasia.

- Inaccurate tidal volumes
  - The volume of air that leaks around the endotracheal tube or nasal prongs may be read by the ventilator as part of the patient’s delivered volume and therefore cause the ventilator to over or underestimate tidal volume.
  - High volume delivery has been linked to bronchopulmonary dysplasia and barotrauma.
  - Conversely, even moderate hypercapnia resulting from low tidal volumes may put patients at risk for neurological injury.

Compensating for leaks is crucial to avoiding the added stress of asynchronous breathing, providing appropriate tidal volume, and reducing time on mechanical ventilation. Most acute care ventilators have leak compensation technology that “corrects” for leaks in the circuit, though some devices provide more accurate compensation than others (see publications below). The PB980 ventilator Leak Sync software improves accuracy of tidal volume delivery, compensates for leaks, improves synchrony in neonates, and facilitates the delivery of non-invasive ventilation.

- Leak Sync software allows for the precise delivery of tidal volumes, even in the presence of airway leaks:
  - Out of the four ventilators assessed in a neonatal lung model study, the PB980 was one of two ventilators to achieve the targeted tidal volume across multiple leak scenarios during invasive ventilation.
  - Compared to the V500 ventilator, the PB980 ventilator was the only ventilator that adequately managed leaks in dual mode during invasive ventilation.

- Leak Sync software reduces the rate of leak-related ventilator asynchrony:
  - Compared to three other competitor ventilators, PB980 ventilator is the only ventilator that could trigger and maintain low asynchrony rates across multiple leak scenarios during both invasive and non-invasive ventilation in a neonatal lung model study.
MOON 2018


STUDY INFORMATION

PURPOSE
To evaluate the accuracy of tidal volume (Vₜ) in the presence of leaks

STUDY DESIGN
Bench study using a lung model and leak generator to create 3 leak scenarios with 3 respiratory mechanics under 3 ventilation settings with and without leak compensation.

METHODS

End Points: Error of reported tidal volume (compared to actual); incidence of clinically unacceptable error (>25% difference between reported and actual Vₜ, reported in % of breaths)

Methods: Controlled ventilation in pressure-controlled (PC) or dual-control noninvasive (N) or invasive (I) positive pressure ventilation (PPV) was used to ventilate two simulated patient sizes (3 kg or 1.5 kg) with three respiratory mechanics types (normal, obstructive and restrictive). An adjustable valve was used to generate leaks and a pneumotachometer was used to measure actual Vₜ.

Ventilators: Medtronic PB840, Medtronic PB980, Maquet Servo-i™, Hamilton C3 and C5, Carefusion Avea™ and Dräger Babylog™ VN500 ventilators

RESULTS

• An increase in leaks had a clinically significant effect on reported Vₜ with VN500 and Hamilton G5 ventilators under non-invasive modes (with leak compensation); and, the VN500 ventilator was the only ventilator that showed similar results under invasive modes.

• PB980 ventilator showed <0.5% unacceptable error rates in reported Vₜ under leak compensation in invasive and non-invasive modes, whereas the VN500 ventilator showed 26.7-42.5% unacceptable error rates under similar conditions.

• Without the availability of leak compensation, the Servo-I, C3, G5 and Avea ventilators showed 95.8-100% unacceptable error in reported Vₜ in PC-IPPV and the PB840 and Servo-I ventilators showed similar results in Dual-IPPV.

• Respiratory mechanics had a significant effect (statistically and clinically) on the error of reported Vₜ in invasive modes.

CONCLUSION
Acceptable error in reported Vₜ was only achieved by the PB980 ventilator under all testing conditions. This study showed that differences among ventilators and respiratory mechanics affect the accuracy of Vₜ reporting in invasive and non-invasive modes.
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STUDY INFORMATION

**PURPOSE**
To evaluate the ability of leak compensation algorithms in all-age ICU ventilators to support synchronous breathing in the presence of leaks during premature/neonatal patient-triggered invasive ventilation and NIV.

**STUDY DESIGN**
Bench study using an ASL 5000 Lung Simulator to create four scenarios with differing patient sizes and respiratory mechanics (0.5, 1, 2, and 4 kg).

**METHODS**

**End Points:** Asynchrony Index; breathing frequency, resistance, compliance, occlusion pressure, inspiratory time

**Methods:** Stopcocks were used to create three intentional leak levels in a dry circuit attached to a lung simulator. Spontaneous and Controlled modes were evaluated during invasive and non-invasive ventilation if available on each ventilator for neonatal ventilation.

**Ventilators:** Medtronic PB840, Medtronic PB980, Maquet Servo-i™*, Evita™* Infinity™ V500, Carefusion Avea™ ventilators

**RESULTS**

<table>
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<tr>
<th>Overall Asynchrony Index (Median)</th>
<th>Medtronic PB980</th>
<th>Medtronic PB840</th>
<th>Dräger Evita™* Infinity™ V500</th>
<th>Maquet Servo-i™*</th>
<th>Carefusion Avea™</th>
<th>p-value</th>
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<tr>
<td>IMV*</td>
<td>1%</td>
<td>33%</td>
<td>3%</td>
<td>50%</td>
<td>62%</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>NIV*</td>
<td>2%</td>
<td>75%</td>
<td>NA</td>
<td>100%</td>
<td>NA</td>
<td>&lt;0.05</td>
</tr>
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</table>

* IMV – Invasive Mechanical Ventilation, NIV – Non-Invasive Ventilation

- During IMV, the Medtronic PB980 ventilator showed similar triggering delays to the Dräger Evita™* Infinity™ V500 ventilators in all scenarios and leak levels.
  - Trigger delay data could not be recorded for the Maquet Servo-i™* and Carefusion Avea™ ventilators with most leak levels as 5 consecutive synchronous breaths were not observed.
- During NIV, only the Medtronic PB980 ventilator was triggered in the presence of a baseline leak in the 0.5 kg simulation.
- During IMV, the Carefusion Avea™ ventilator (without flow sensor) was not triggered by inspiratory efforts in the presence of a baseline leak in the 0.5 kg simulation.
- The Medtronic PB980 ventilator showed significantly lower asynchrony index levels than the Maquet Servo-i™* ventilator in non-invasive modes when the smallest two simulated patient sizes (0.5, 1 kg) were assessed (Avea™ and Evita™* Infinity™ V500 ventilators do not support neonatal patient triggered NIV).
- During spontaneous ventilation, a sudden decrease in leak caused ineffective efforts with the Medtronic PB980 and Evita™* Infinity™ V500 ventilators, but backup ventilation with continued spontaneous triggering was activated with the PB980 ventilator and not the Evita™* Infinity™ V500 ventilator.

**CONCLUSION**
The PB980 ventilator was the only ventilator that could trigger and maintain low asynchrony rates across all leak scenarios during both invasive and non-invasive ventilation.
**STUDY INFORMATION**

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<td>Bench study using an ASL 5000 Lung Simulator to create four scenarios with different patient sizes and respiratory mechanics (0.5, 1, 2, and 4 kg).</td>
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| METHODS | **End Points**: difference in tidal volume, asynchronous events, breathing frequency, resistance, compliance, occlusion pressure, inspiratory time  
**Methods**: Stopcocks were used to create two intentional leak levels in a dry circuit attached to a lung simulator. Invasive spontaneous and mandatory ventilation settings were used with the tidal volume set at 6mL/kg and PEEP set at 5cm H2O  
**Ventilators**: Medtronic PB980, Maquet Servo-i™*, Dräger Evita™ Infinity™ V500, Carefusion Avea™ ventilators |

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<th>Invasive Mode</th>
<th>Medtronic PB980</th>
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<th>Carefusion Avea™</th>
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<tr>
<td>ΔV, (%)</td>
<td>PC*</td>
<td>3.1</td>
<td>1.5</td>
<td>*</td>
<td>33.8‡</td>
</tr>
<tr>
<td></td>
<td>PSV*</td>
<td>2.8</td>
<td>9.3</td>
<td>*</td>
<td>Not Available</td>
</tr>
<tr>
<td>Asynchrony Occurrence</td>
<td>PC*</td>
<td>ND</td>
<td>0.3%</td>
<td>22.1%</td>
<td>21.1%</td>
</tr>
<tr>
<td></td>
<td>PSV*</td>
<td>0%</td>
<td>0.3%</td>
<td></td>
<td>26.8%</td>
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</table>

* Pressure Control - Continuous Mandatory Ventilation (PC); Pressure Control - Continuous Spontaneous Ventilation (PSV); No Data (ND)  
‡ p<0.05 when comparing VT before and after leaks were added  
* Could not be calculated as 5 consecutive synchronous breaths were not observed  
* Leaks caused persistent volume overshooting in the Carefusion Avea™ ventilator.  
* The Maquet Servo-i™ ventilator was the only ventilator with baseline tidal volume outside +/- 10% of target setting and was markedly affected by leaks.  

| CONCLUSION | The Medtronic PB980 and Evita™ Infinity™ V500 ventilators were the only ventilators, out of the four assessed in the study, to achieve the targeted tidal volume in the presence of all leak scenarios during invasive ventilation. The Medtronic PB980 and Evita™ Infinity™ V500 ventilators showed significantly lower asynchrony index when compared to the Maquet Servo-i™ ventilator. |
REFERENCES


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6135 Gunbarrel Avenue
Boulder, CO 80301 800.635.5267 medtronic.com/covidien