CLINICAL EVIDENCE GUIDE

MANAGING RESPIRATORY DISTRESS IN NEONATES

Puritan Bennett[™] 980 Ventilator

This guide reviews the clinical evidence supporting the utility of the Puritan Bennett[™] 980 ventilator (PB980) to help manage respiratory distress in the neonatal intensive care unit (NICU).

Evidence has shown that the inherent stress associated with many common interventions in the NICU has both acute and long-term negative effects on neonatal recovery and development.¹ Efforts to reduce or minimize the stress experienced by the infants have been shown to be effective, thereby improving clinical outcomes.²⁻³

However, other stressors, such as respiratory stress, cannot be avoided completely due to the invasive nature of the intervention. Nonetheless, recent advances by biomedical engineers have been developed with the intention to help alleviate respiratory stress on the NICU patient population.One example of these advances is by managing the asynchrony that occurs between the patient and the ventilator, which is associated with elevated markers of stress and blood pressure variability.⁴







TABLE OF CONTENTS

> TABLE OF CONTENTS

- > INTRODUCTION
- > ITAGAKI 2017 (EFFECTS)
- > ITAGAKI 2017 (PERFORMANCE)
- > MARCHESE 2009
- > REFERENCES

3	INTRODUCTION	Overview of the clinical evidence supporting the current state of non-invasive and invasive ventilation.
4	ITAGAKI 2017 (EFFECTS)	A study comparing patient-ventilator synchrony during non-invasive and invasive ventilation on several ventilators with leak compensation.
5	ITAGAKI 2017 (PERFORMANCE)	A study comparing the impact of leak compensation on $V_{\scriptscriptstyle T}$ delivery during volume targeted neonatal ventilation delivered via all age ventilators.
6	MARCHESE 2009	A study comparing neonatal ventilation delivered with adult ventilators versus a dedicated neonatal ventilator.
7	REFERENCES	List of works cited



INTRODUCTION

Respiratory distress is a primary cause of admission to NICU — there is a need to reduce the stress caused by interventions to support ventilation.

Respiratory distress syndrome (RDS), or hyaline membrane disease, is one of the most common and fatal complications in neonates.⁵ RDS occurs in premature infants because of impaired surfactant synthesis and secretion leading to atelectasis, ventilation-perfusion (V/Q) inequality, and hypoventilation with resultant hypoxemia and hypercarbia. Bronchopulmonary dysplasia (BPD), a frequent consequence of the invasive ventilation intervention used to treat RDS, may result in compromised lung function and is an independent risk factor for neurodevelopmental impairment.⁶

Lung protective ventilation that accurately controls pressure and tidal volume levels while preventing atelectasis and injury, such as BPD, is an essential element to managing neonatal respiratory care.⁷ Ventilation modes, such as Synchronized Intermittent Mechanical Ventilation (SIMV), can be applied during both non-invasive and invasive ventilation and has become a common non-invasive mechanical ventilation mode used in the treatment of neonates with RDS.^{8,9} Synchronized modes are considered lung protective as they have been shown to improve oxygenation as well as reduce sedation levels and duration of mechanical ventilation.¹⁰ Unfortunately, only ventilators that do not require a proximal flow sensor to recognize a patient effort, and thereby trigger a breath, can provide SIMV non-invasively. Therefore, the concurrent benefits of SIMV and NIV are only available on select ventilators such as the PB980 or PB940.

To protect the fragile tissues of neonates, airway interfaces are designed and applied to limit skin and tracheal contact. Unfortunately, this often results in air leaking around the patient interface (i.e., nasal prongs or endotracheal tube). The presence of air leak, a major problem with NIV, interferes with the ability of the ventilator to appropriately respond to patients' spontaneous breathing efforts and has the potential for causing volume delivery inaccuracies as well as triggering and cycling asynchrony. 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 manage volume and expiratory synchrony inappropriately.¹¹ The flow exiting through the leak between breaths may cause triggering 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.^{4,12} Therefore, compensating for leaks is crucial to avoiding the added stress of asynchronous breathing, providing appropriate tidal volume, and reducing time on mechanical ventilation.¹³⁻¹⁵ 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 Igataki publications below^{12,16}).

An appropriate respiratory management strategy is vital for neonates, as respiratory disease is the main diagnosis driving NICU admissions.¹⁷ Important components of such a strategy should include various alternatives for providing invasive and non-invasive ventilation modes as well as accurate leak compensation capability. The following article summaries demonstrate some of the features of the PB980 ventilator that make it a good option to address the ventilation demands of the NICU population. These results show:

- The Medtronic PB980 and Dräger Evita^{™*} Infinity^{™*}V500 ventilators achieved the targeted tidal volume in the presence of all leak scenarios, whereas the Maquet Servo-i^{™*} and Carefusion Avea^{™*} ventilators did not.¹⁶
- Leaks caused persistent volume overshooting in the Carefusion Avea[™] ventilator.¹⁶
- The change in tidal volume after a leak could not be recorded with the Maquet Servo-i^{™*} ventilator as five consecutive synchronous breaths could not be measured.¹⁶
- The Medtronic PB980 ventilator was the only ventilator, out of the five ventilators in the study, that could maintain a low asynchrony rate across all leak scenarios during both invasive and non-invasive ventilation.¹²

> TABLE OF CONTENTS

> INTRODUCTION

- > ITAGAKI 2017 (EFFECTS)
- > ITAGAKI 2017 (PERFORMANCE)
- > MARCHESE 2009
- > REFERENCES

ITAGAKI 2017 (EFFECTS)

Itagaki T, et al. Effects of Leak Compensation on Patient-Ventilator Synchrony During Premature/Neonatal Invasive and Noninvasive Ventilation: A Lung Model Study. *Respir Care*. 2017; 62(1):22-33¹²

STUDY INFO	DRMAT	ION					
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 Poin Methods Spontane ventilato Ventilate Avea [™] ve	 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 					
	Overall A	synchrony Inde	x (Median)				
		Medtronic PB980	Medtronic PB840	Dräger Evita ^{™*} Infinity ^{™*} V500	Maquet Servo-i™*	Carefusion Avea ^{™*}	p-value
	IMV#	1 %	33 %	3 %	50 %	62 %	<0.05
	NIV [#]	2 %	75 %	NA	100%	NA	<0.05
RESULTS	 *IMV-Invasive Mechanical Ventilation, NIV - Non-Invasive Ventilation During IMV, the Medtronic PB980 ventilator showed similar triggering delays to the Dräger Evita[™] Infinity[™] V500 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[™] (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 showed significantly lower asynchrony index levels than the Maquet Servo-i[™] in non-invasive modes when the smallest two simulated patient sizes (0.5, 1 kg) were assessed (Avea[™] and Evita[™] Infinity[™] V500 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 PB9 scenario	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.					

> TABLE OF CONTENTS

> INTRODUCTION

> ITAGAKI 2017 (EFFECTS)

- > ITAGAKI 2017 (PERFORMANCE)
- > MARCHESE 2009
- > REFERENCES

ITAGAKI 2017 (PERFORMANCE)

Itagaki T, et al. **Performance of Leak Compensation in All-Age ICU Ventilators During Volume-Targeted Neonatal Ventilation: A lung Model Study**. *Respir Care*. 2017; 62(1):10-21¹⁶

STUDY INF	ORMATION	1						
PURPOSE	To confirm previous data that indicated that all-age ventilators performed as well on neonatal patients as neonatal ventilators							
STUDY DESIGN	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).							
METHODS	End Points: dif pressure, insp Methods: Stop spontaneous a 5cm H ₂ O	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 H ₂ O						
	Ventilators: Medtronic PB980, Maquet Servo-i [™] , Dräger Evita [™] Infinity [™] V500, Carefusion Avea [™] ventilators							
		Invasive Mode	Medtronic PB980	Dräger Evita™* Infinity™* V500	Maquet Servo-i ^{™*}	Carefusion Avea ^{™*}		
	ΔV _τ (%)	PC [#]	3.1	1.5	*	33.8 [‡]		
		PSV [#]	2.8	9.3	*	Not Available		
	Asynchrony Occurrence	PC	ND#	0.3 %	22.1 %	21.1 %		
RESULTS		PSV	0 %	0.3 %	26.8 %	Not Available		
	 # Pressure Control - Continuous Mandatory Ventilation (PC); Pressure Control - Continuous Spontaneous Ventilation (PSV); No Data (ND) * Could not be calculated as 5 consecutive synchronous breaths were not observed ‡ p<0.05 when comparing V, before and after leaks were added Leaks caused persistent volume overshooting in the Carefusion Avea[™] ventilator. The Maquet Servo-i[™] was the only ventilator with unacceptable 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 presences 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.							

> TABLE OF CONTENTS

- > INTRODUCTION
- > ITAGAKI 2017 (EFFECTS)
- > ITAGAKI 2017 (PERFORMANCE)
- > MARCHESE 2009
- > REFERENCES

MARCHESE 2009

Marchese AD, et al. **Adult ICU ventilators to provide neonatal ventilation: a lung simulator study**. *Int Care Med*. 2009; 35(4):631-8¹⁸

STUDY INFORMATION		
PURPOSE	To assess the responsiveness of ICU ventilators' neonatal modes in comparison to a neo-specific ventilator.	
STUDY DESIGN	ASL 500 computerized lung simulator was used to compare several ICU ventilators, in neonatal mo to the neo-specific Dräger Babylog [™] 8000 plus ventilator	
	End Points: Pressure, triggering, and durations	
METHODS	Ventilators: Medtronic PB840, Carefusion Avea [™] , Dräger Evita [™] XL, GE Engström [™] , Maquet Servo-i [™] , Dräger Babylog [™] 8000 plus ventilators	
	Each of the 5 ICU ventilators responded better than the Dräger Babylog [™] 8000 plus ventilator in the evaluated end-points:	
	■ Pressure to trigger (except the Maquet Servo-i ^{™*} ventilator)	
	 Time to trigger (except the Dräger Evita XL^{***} ventilator) 	
RESULIS	 Time between trigger and return of pressure to baseline (all ICU ventilators) 	
	■ Time from start to breath to 90% of peak pressure (except the Carefusion Avea ^{™*} ventilator)	
	 Pressure time product of breath activation (all ICU ventilators) 	
	■ Expiratory tidal volume (except the Carefusion Avea [™] ventilator)	
CONCLUSION	All ICU ventilators tested performed at least equally as well as the Dräger Babylog ^{™*} 8000 plus ventilator all variables evaluated.	

> TABLE OF CONTENTS

- > INTRODUCTION
- > ITAGAKI 2017 (EFFECTS)
- > ITAGAKI 2017 (PERFORMANCE)
- > MARCHESE 2009
- > REFERENCES

REFERENCES

> TABLE OF CONTENTS

- > INTRODUCTION
- > ITAGAKI 2017 (EFFECTS)
- > ITAGAKI 2017 (PERFORMANCE)
- > MARCHESE 2009
- > REFERENCES

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