

Mask-Free NIV® **Take the stress out of respiratory distress**

Meet High Velocity Therapy



2

Imagine the ventilatory support of NiPPV with the comfort of humidified high flow

Non-invasive Positive Pressure Ventilation (NiPPV) is considered the gold standard for treating undifferentiated respiratory failure patients.

While it is a crucial tool in the clinical arsenal, about a third of adult patients fail it because they cannot tolerate the tight-fitting mask or pressure.¹¹ This NiPPV limitation is in part what makes mask-free NIV an appealing alternative for patients in respiratory failure.

Although the adoption of medical devices is understandably slow, after decades of clinical studies and millions of patients treated worldwide, more and more hospitals are adopting Vapotherm mask-free NIV as a frontline tool for patients in undifferentiated respiratory distress, including hypercapnia, hypoxemia, and dyspnea.

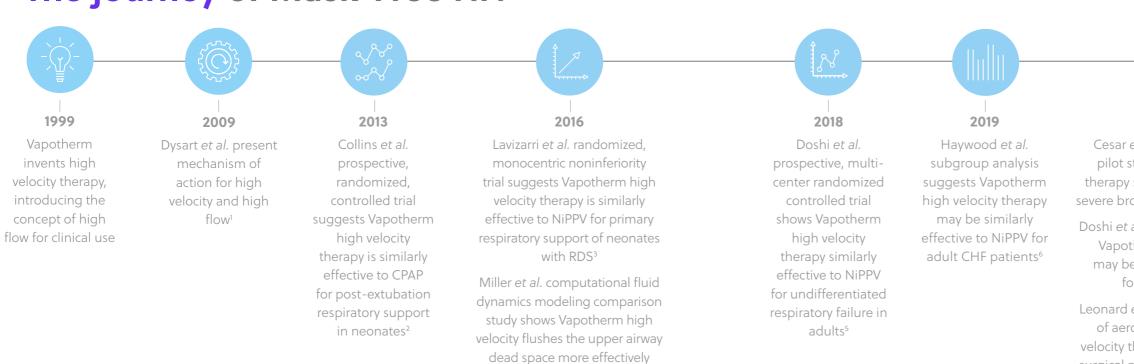
Invented to enhance ease of care

Mask-Free NIV provides similar outcomes to NiPPV for patients in respiratory failure, while mitigating or eliminating some of the possible limitations of NiPPV, including:

- Mask-intolerant patients who either fail on NiPPV or must be sedated or coached
- Difficulty communicating with patients wearing a mask interface
- Needing to pause or decrease efficacy of therapy for patients to eat, drink, or take oral medication
- Development of pressure injuries from mask interfaces
- Workflow inefficiency in mask interface fitting, especially for bearded patients
- Patient discomfort in wearing a pressure-based modality
- Risk of pneumothorax via a pressure-based modality



The journey of Mask-Free NIV



than generic high flow⁴

Leonard et al. computational modeling of aerosol dispersion during high velocity therapy suggests that a simple surgical mask may capture the majority of expelled particles⁹



2020

Cesar et al. randomized controlled pilot study suggests high velocity therapy similarly effective to CPAP for severe bronchiolitis in pediatric patients⁷

Doshi et al. subgroup analysis suggests Vapotherm high velocity therapy may be similarly effective to NiPPV for adult COPD patients⁸



Plotnikow et al. multicenter, prospective, observational pilot study supports use of Vapotherm High Velocity Therapy as First-Line Support on Severely Hypercaphic COPD Patients¹⁰

How does it work?

Meet High Velocity Therapy

4

Mask-Free NIV supports alveolar ventilation via an open system by delivering high velocity therapy. If we consider how alveolar ventilation can be achieved, high velocity therapy most greatly impacts Dead Space while NiPPV impacts Tidal Volume.

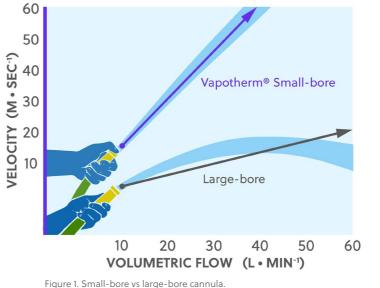
Either of these two support ventilation, but the flush-based mechanism of action allows the high velocity ventilatory support to be mask-free and not rely primarily on pressure.



Alveolar ventilation = (Tidal volume – Dead space) x Respiratory rate

Isn't this just like high flow?

High velocity therapy is often confused with generic high flow nasal cannula (HFNC). Though Vapotherm is the inventor of high flow, high velocity therapy is a sufficiently advanced form to be mechanistically different from high flow and have different patient outcomes.



Both generic HFNC and high velocity therapy flush the upper airway dead space to help reduce the patient's work of breathing. However, at higher breathing rates, when there is less and less time between breaths to flush the dead space, generic HFNC cannot keep up as effectively as high velocity therapy in rapidly providing the oxygenated gas patients need, as seen in Fig 2.

This difference enables high velocity therapy to treat respiratory failure in higher acuity patient populations that are comparable to those traditionally treated with NiPPV.



Generic high flow uses low velocity, large bore cannulas. This means that at the same L/min settings, HFNC generates much less velocity than high velocity therapy (Fig 1 adapted from Miller *et al.*)

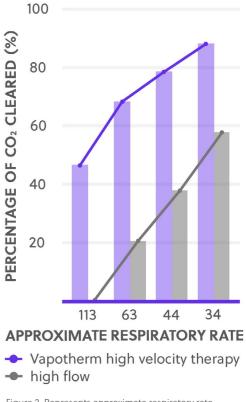


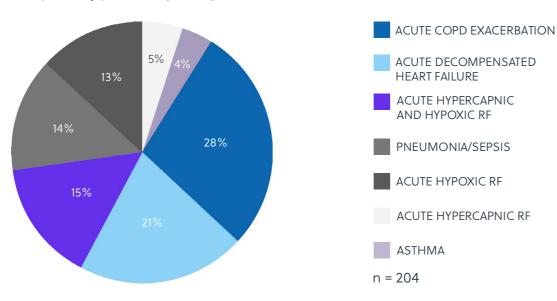
Figure 2. Represents approximate respiratory rate based on interpretation of data from Miller *et al.* 2016. Miller (2016) used a computer simulation of CO2 clearance in a human model at 20L/min.

Clinical evidence shows effective first line therapy

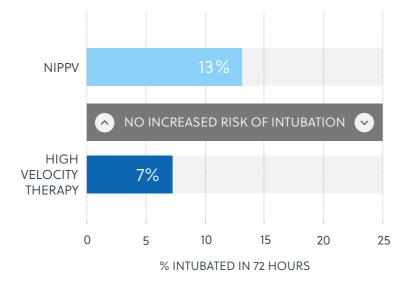
There are several clinical trials demonstrating the efficacy of Mask-Free NIV. Selected below are data from a large, randomized clinical trial.⁵ The study evaluated how Vapotherm high velocity therapy compares to the gold standard of NiPPV in the treatment of adult all-comers in respiratory distress presenting in the Emergency Department.

High Velocity Therapy Discharge Diagnoses

6



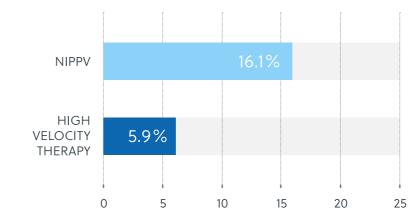




The study included any patients that presented to the Emergency Department in undifferentiated respiratory distress, where the clinician felt there was a need for non-invasive ventilation

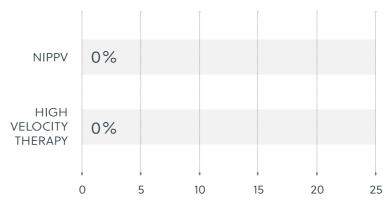
COPD and CHF subgroups show no increased risk of intubation

COPD subgroup, n= 65



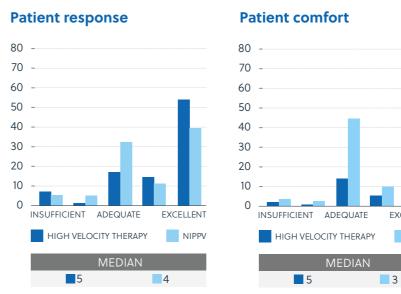


CHF subgroup, n= 42



INTUBATED IN 72 HOURS (%)

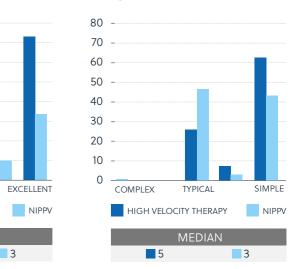
Comfortable for patients and easy to use



Perception of patient response, patient comfort and simplicity of use as reported by physicians in Doshi, et al. study







Simplicity of use

8

Helping avoid ICU admissions and reduce cost of care

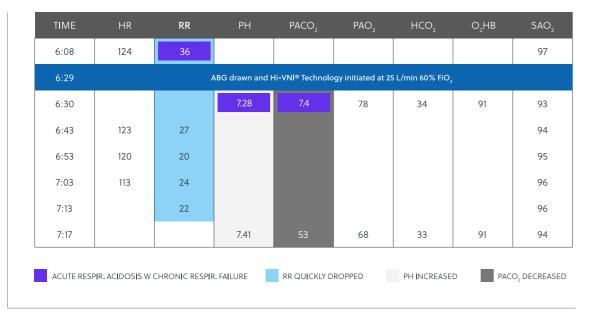
Several Vapotherm mask-free NIV users report a reduction in their ICU admissions after implementing high velocity therapy. This could also reduce cost of care. While all hospitals are different and complex, the patients treated with mask-free NIV in a large, randomized trial spent less time in the ICU than patients treated with NiPPV.^{5,6,8} Mask-free NIV patients spent more time on the Medical Floor and in Step-Down units.^{5,6,8}

A COPD Patient Avoids the ICU with Mask-Free NIV: A Case Study

Although individual results may vary, Vapotherm believes this case story is an example of the clinical benefit Vapotherm's high velocity therapy can have in an Emergency Department setting.

A 60 year-old patient with history of COPD, having been intubated in the past month for a COPD exacerbation, arrived in the Emergency Department. Initial assessment noted tachypnea with nasal flaring and purse lipped breathing, as well as bilateral wheezing and wet cough.

Traditional NIPPV was ordered but not initiated; Vapotherm mask-free NIV was started at 25 L/min with an FiO, of 60%. An ABG was drawn upon immediate application of mask-free NIV and 44 minutes after initiation.



In this patient's case, ICU admission and more invasive treatment modalities were avoided with the use of Mask-Free NIV.

Greater ease of care - less stress for patients, clinicians, and hospitals

Patients can comfortably eat, drink, and take oral medication without therapy disruption. Clinicians may experience workflow streamlining with an easy-to-use, fast-to-set-up therapy that requires no patient coaching or training for compliance. Hospitals could see decreased intensity of case, and possible cost savings.

Conditions Where High Velocity Therapy Could Help

While high velocity therapy doesn't treat diseases, many conditions have symptoms that can be managed with this therapy- from mild hypoxemia to acute hypercapnia. Here are a select few:

- Infant Respiratory Distress Syndrome (RDS)
- Bronchopulmonary Dysplasia (BPD)
- Congenital diaphragmatic hernia (CDH)
- Transient Tachypnea of the Newborn (TTN)
- Persistent Pulmonary Hypertension (PPHN)
- Weaning off Mechanical Ventilation

The only flow-based solution indicated by the FDA for ventilatory support

High velocity therapy is a sufficiently advanced form of high flow that the FDA distinguishes between high velocity and generic high flow products.

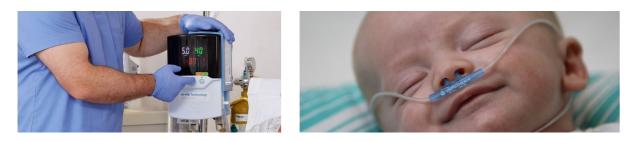
	HFNC Airvo 2	NiPPV V60
FDA Product Code	BTT	MNT/MNS
Respiratory Distress		¥
OSA Humidification		¥
Humidification	\checkmark	
Prong-Free or Mask-Free Interface	¥	
Patient-Focused Alarms		¥
Nurse Call/EMR		¥
30-Day Circuit Life	7-14 days	7-14 days
Transfer/Ambulate Patients		¥
All Patient Ages	¥	



- Asthma
- Prematurity
- Bronchiolitis
- Meconium aspiration
- Congenital Heart Defects
- CHF
- COPD
- COVID-19
- Dyspnea
- Pneumonia

HIGH VELOCITY THERAPY Precision Flow Hi-VNI® System		
QAV		
~		
~		

Meet our portfolio of **Mask-Free NIV solutions**



For the Neonatal Setting - A Gentler Alternative to CPAP

- Give babies developmental care they need with the ease of handling you want
- The Efficacy of nCPAP with the Comfort of High Flow
- The Oxygen Assist Module (OAM) is a closed loop controller that helps keep babies in their prescribed SpO, range a greater proportion of time than manual control, potentially allowing nurses to spend more time with patients and families.14
- As effective as the gold standard CPAP, but with lower risks of complications and discomfort that come with a tight-fitting interface
- Fast set up-ready to go in less than 5 minutes
- Easy interface fitting

Clinical Applications

- Primary care³
- Post-extubation care²
- Delivery room stabilization¹²



Visit our website for more **Precision Flow information:**





For the Pediatric and Adult Setting

- Seamless mobility. Anytime. Anywhere.
- Comfortable ventilatory support across the hospital.
- Simple to use. Fast to set up.
- Built to work for you and your patients.

Clinical Applications

- Post-Operative Ambulation
- Primary Respiratory Support⁵
- Post-Extubation Support
- Secretion Mobilization
- Tracheostomy weaning



Visit our website for more HVT 2.0 information:

www.vapotherm.com/hvt2

References

- 1. Dysart K, Miller T, Wolfson M, Shaffer T. Research in high flow therapy: Mechanisms of action. Respiratory Medicine. 2009; 103: 1400-05.
- 2. Collins C, Holberton J, Barfield C, Davis P. "A randomized controlled trial to compare heated humidified high-flow nasal cannulae with nasal continuous positive airway pressure postextubation in premature infants." J Pediatrics, 2013 May: 162: 949-54
- 3. Lavizzari A, Colnaghi M, Ciuffini F, Veneroni C, Musumeci S, Cortinovis I, Mosca F. "Heated, humidified high-flow nasal cannula vs nasal continuous positive airway pressure for respiratory distress syndrome of prematurity - a randomized clinical noninferiority trial." JAMA Pediatr. 2016 Aug 8.
- 4. Miller TL, Saberi B, Saberi S (2016) Computational Fluid Dynamics Modeling of Extrathoracic Airway Flush: Evaluation of High Flow Nasal Cannula Design Elements. J Pulm Respir Med 6:376. doi: 10.4172/2161-105X.1000376
- 5. Doshi, Pratik et al. High-Velocity Nasal Insufflation in the Treatment of Respiratory Failure: A Randomized Clinical Trial, Annals of Emergency Medicine, 2018
- 6. Haywood ST, Whittle JS, Volakis LI et al. HVNI vs NiPPV in the Treatment of ADHF: Subgroup analysis of a multi-center trial in the ED. American Journal of Emergency Medicine, 2019.
- 7. Cesar, Regina Grigolli, Bibiane Ramos Pinheiro Bispo, Priscilla Helena Costa Alves Felix, Maria Carolina Caparica Modolo, Andreia Aparecida Freitas Souza, Nelson K. Horigoshi, Alexandre T. Rotta. High-Flow Nasal Cannula versus Continuous Positive Airway Pressure in Critical Bronchiolitis: A Randomized Controlled Pilot. J Pediatr Intensive Care. April 2020. DOI: 10.1055/s-0040-1709656

- 8. Doshi P, Whittle JS, Dungan G et al., The ventilatory effect of high velocity nasal insufflation compared to noninvasive positive-pressure ventilation in the treatment of hyperca respiratory failure: A subgroup analysis Lung. 2020 Apr 6. https://doi.org/10.1016/j.hrtlng.2020.03.008
- 9. Leonard S, Strasser W, Whittle J. Volakis LI, DeBellis RJ, Prichard R, Atwood CW, Dungan GC. High resolution computational fluid dynamics simulations of particle behavior during high velocity nasal insufflation with a simple surgical mask. Reducing aerosol dispersion by high flow therapy in COVID-19:. JACEP Open 2020;1–14. 26 May 2020
- 10. Plotnikow G, et al. Crit Care Explorations, 2021 DOI:10.1097/CCE.000000000000337
- 11. Carron M. et al. Complications of non-invasive ventilation techniques: a comprehensive qualitative review of randomized trials. British Journal of Anaesthesia. 110(6):896-914. (2013) https://www.ncbi.nlm.nih.gov/pubmed/23562934
- 12. Siva NV, Reynolds PR. Stabilisation of the preterm infant in the delivery room using nasal high flow: A 5-year retrospective analysis. Acta Paediatr. 2021;00:1-7. https://doi.org/10.1111/ apa.15824
- 13. Spivey S, Ashe T, Dennis R, et al. Assessment of high flow nasal cannula therapy use in the emergency department setting: observations of practice across four systems. Respiratory Therapy. Winter 2015;10(1):30-34.
- 14. Reynolds P, et al. Randomised cross-over study of automated oxygen control for preterm infants receiving nasal high flow. Arch Dis Child Fetal Neonatal Ed. 2019 Jul;104(4):F366-F371.

10











Vapotherm, Inc. 100 Domain Drive Exeter, NH 03833 603.658.0011

For a complete list of accessories, visit the Vapotherm website: www.vapotherm.com