VAPOTHERM®

Mask-Free NIV®

Take the stress out of respiratory distress

Meet
High Velocity Therapy

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.

The journey of Mask-Free NIV

1999

Vapotherm invents high velocity therapy, introducing the concept of high flow for clinical use

2009

Dysart *et al.* present mechanism of action for high velocity and high flow[1]

2013

Collins *et al.* prospective, randomized, controlled trial suggests Vapotherm high velocity therapy is similarly effective to CPAP for post-extubation respiratory support in neonates[2]

2016

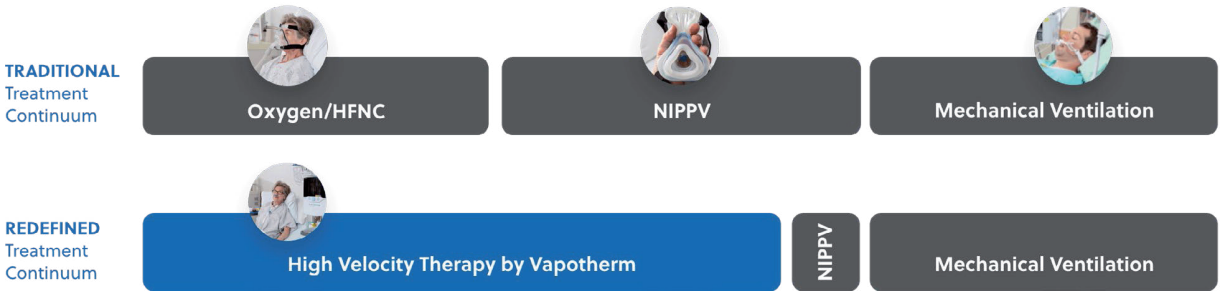
Lavizarri *et al.* randomized, monocentric noninferiority trial suggests Vapotherm high velocity therapy is similarly effective to NiPPV for primary respiratory support of neonates with RDS[3]

Miller *et al.* computational fluid dynamics modeling comparison study shows Vapotherm high velocity flushes the upper airway dead space more effectively than generic high flow[4]

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



2018

Doshi *et al.* prospective, multi-center randomized controlled trial shows Vapotherm high velocity therapy similarly effective to NiPPV for undifferentiated respiratory failure in adults[5]

2019

Haywood *et al.* subgroup analysis suggests Vapotherm high velocity therapy may be similarly effective to NiPPV for adult CHF patients[6]

2020

Cesar *et al.* randomized controlled pilot study suggests high velocity therapy similarly effective to CPAP for severe bronchiolitis in pediatric patients[7]

Doshi *et al.* subgroup analysis suggests Vapotherm high velocity therapy may be similarly effective to NiPPV for adult COPD patients[8]

Leonard *et al.* computational modeling of aerosol dispersion during high velocity therapy suggests that a simple surgical mask may capture the majority of expelled particles[9]

2021

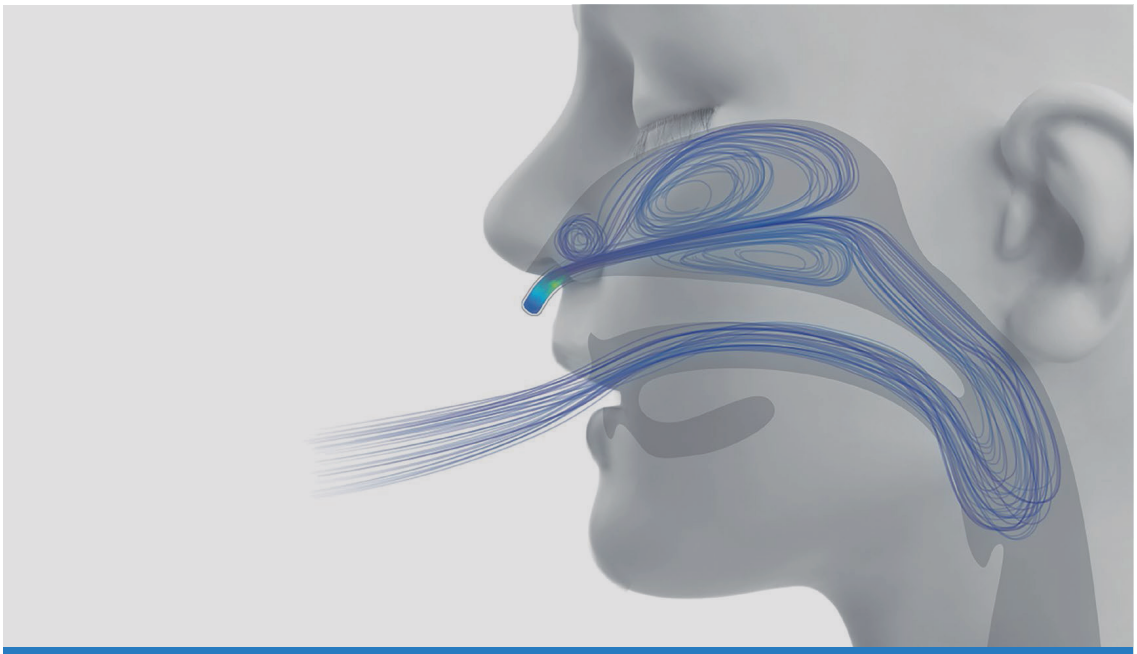
Plotnikow *et al.* multi-center, prospective, observational pilot study supports use of Vapotherm High Velocity Therapy as First-Line Support on Severely Hypercapnic COPD Patients[10]

How does it work?

Meet High Velocity Therapy

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.

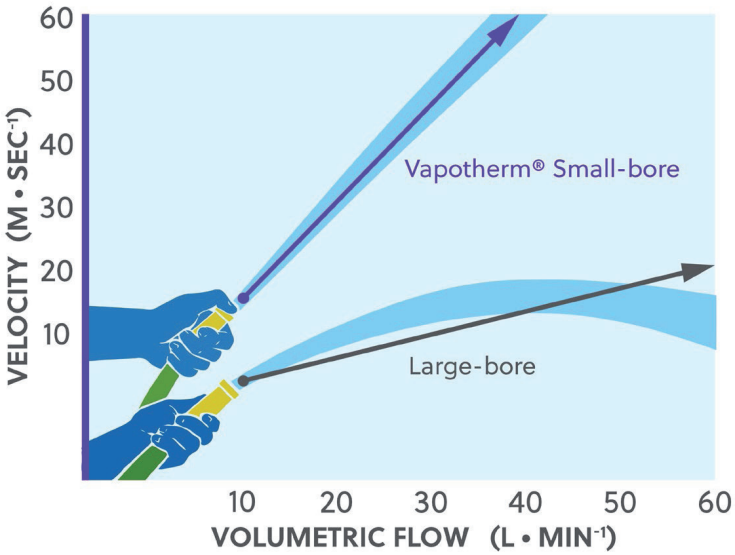


Figure 1. Small-bore vs large-bore cannula.

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.*)

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.

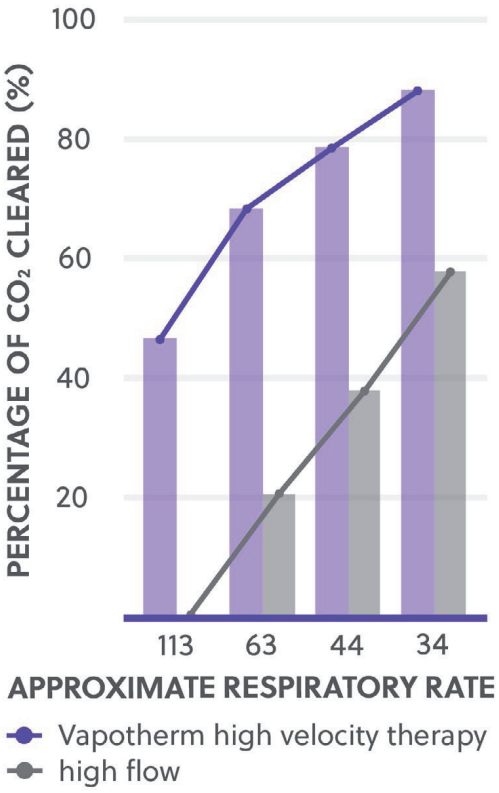
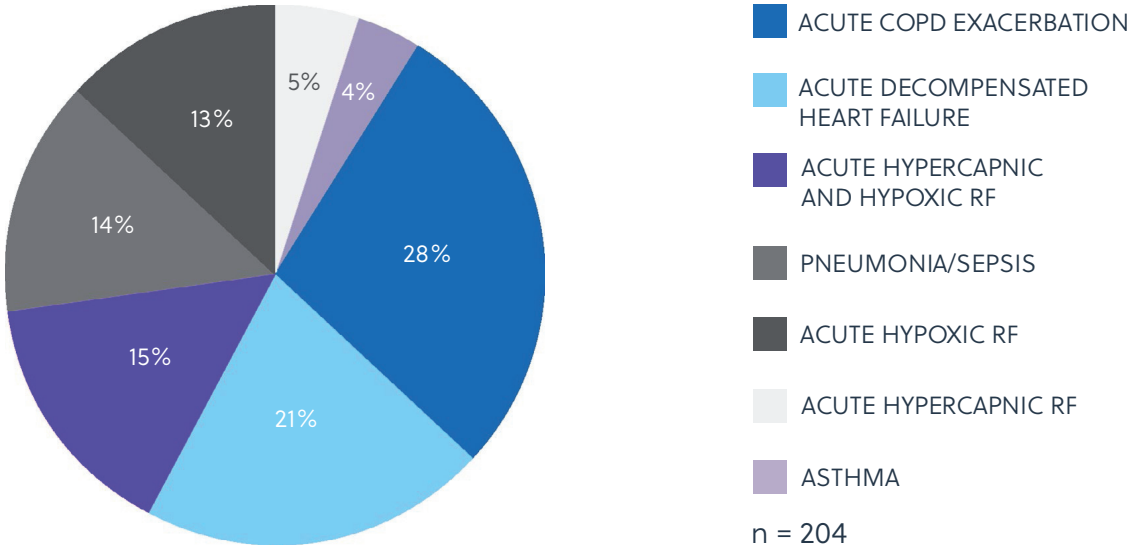


Figure 2. Represents approximate respiratory rate based on interpretation of data from Miller *et al.* 2016. Miller (2016) used a computer simulation of CO2 clearance in a human model at 20L/min.

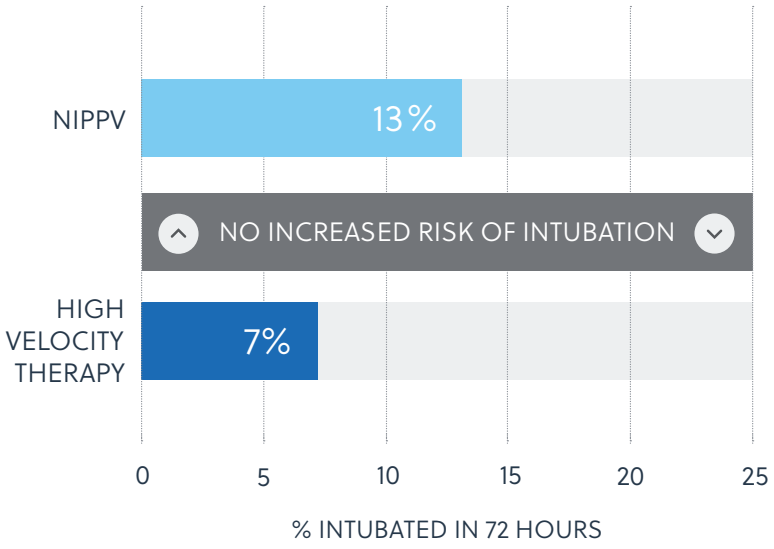
Clinical evidence shows effective first line therapy

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



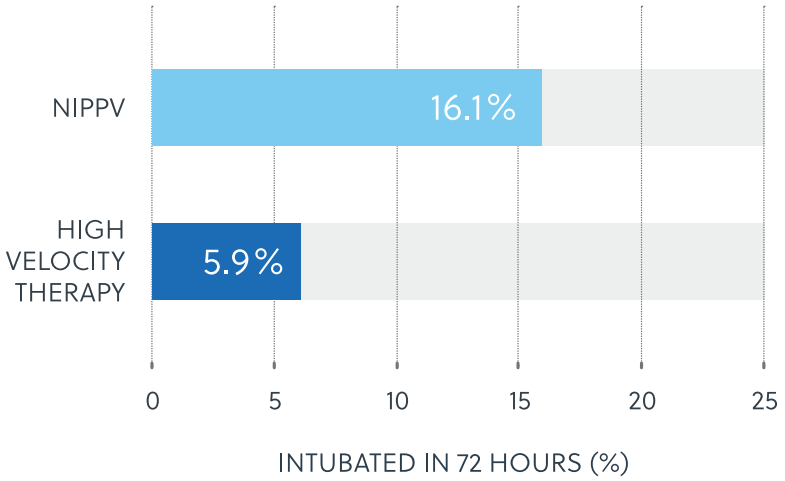
Primary Outcomes - Intubation



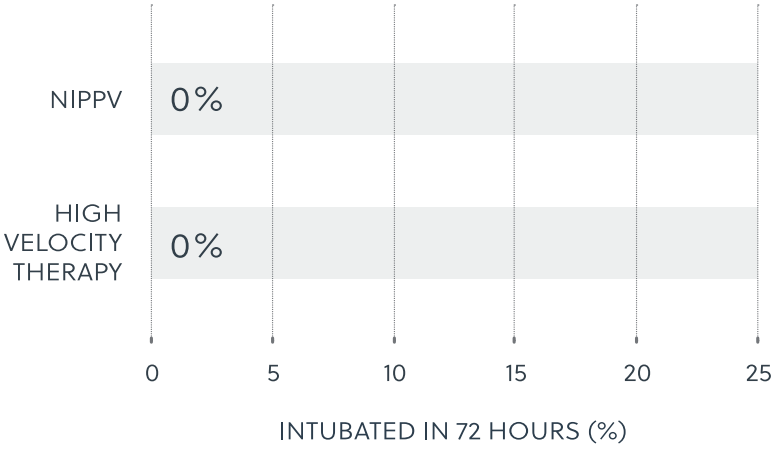
The study included any patients that presented to the Emergency Department in undifferentiated respiratory distress, where the clinician felt there was a need for non-invasive ventilation.

COPD and CHF subgroups show no increased risk of intubation

COPD subgroup, n= 65

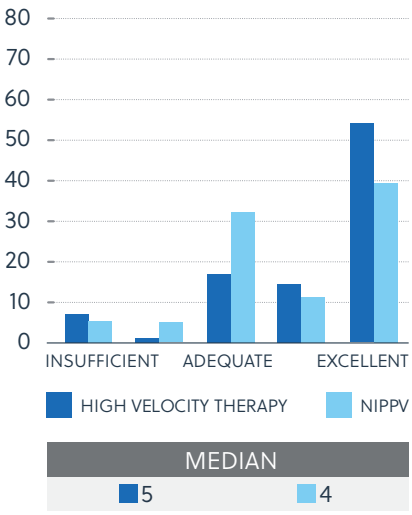


CHF subgroup, n= 42

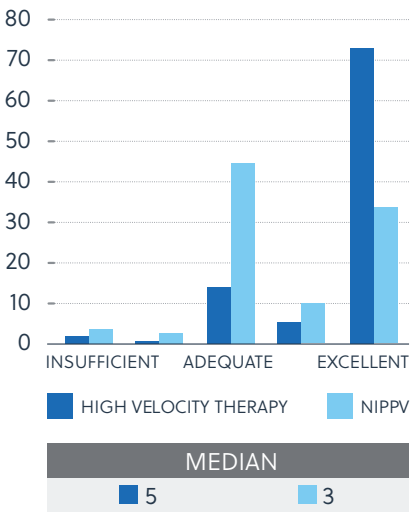


Comfortable for patients and easy to use

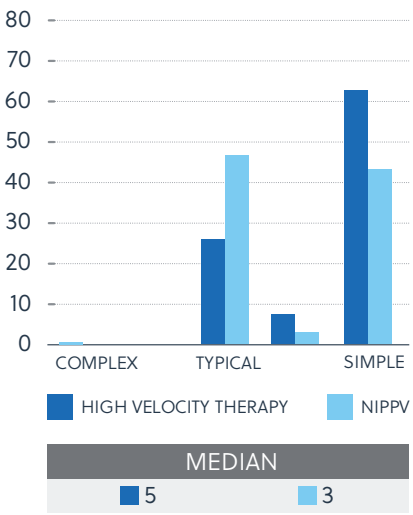
Patient response



Patient comfort



Simplicity of use



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

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_2 of 60%. An ABG was drawn upon immediate application of mask-free NIV and 44 minutes after initiation.

TIME	HR	RR	PH	$PACO_2$	PAO_2	HCO_2	O_2HB	SAO_2
6:08	124	36						97
6:29	ABG drawn and Hi-VNI® Technology initiated at 25 L/min 60% FiO_2							
6:30			7.28	7.4	78	34	91	93
6:43	123	27						94
6:53	120	20						95
7:03	113	24						96
7:13		22						96
7:17			7.41	53	68	33	91	94

ACUTE RESPIR. ACIDOSIS W CHRONIC RESPIR. FAILURE | RR QUICKLY DROPPED | PH INCREASED | $PACO_2$ DECREASED

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

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	HIGH VELOCITY THERAPY Precision Flow Hi-VNI® System
	FDA Product Code	BTT	MNT/MNS	QAV
INTENDED USE	Respiratory Distress or Failure		✔	✔
INTENDED USE	OSA		✔	
INTENDED USE	Humidification	✔		✔
	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	✔		✔

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_2 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 care[3]
- Post-extubation care[2]
- Delivery room stabilization[12]

Visit our website for more Precision Flow information:

www.vapotherm.com/precision-flow

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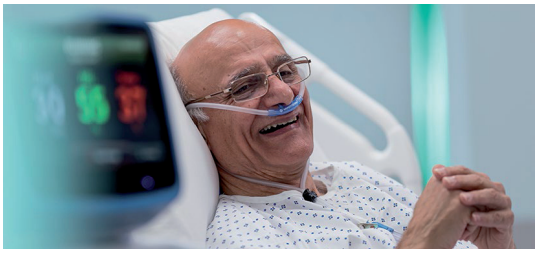

For the Pediatric and Adult Setting

- 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 Support[5]
- Post-Extubation Support
- Secretion Mobilization
- Tracheostomy weaning

Visit our website for more HVT 2.0 information:

www.vapotherm.com/hvt2

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