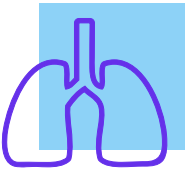
GUIDELINES + BEST PRACTICES

Mask-Free NIV™ for Spontaneously Breathing Patients

NEONATAL
POCKET GUIDE

VAPOTHERM®
Hi-VNI® Technology



PATIENT SELECTION

Patient presents with one or more of the following symptoms:

- Hypoxemia
- Retractions
- Tachypnea
- Mild apnea and bradycardia
- Grunting
- Nasal flaring
- Difficulty weaning from Nasal CPAP
- Difficulty weaning from mechanical ventilation

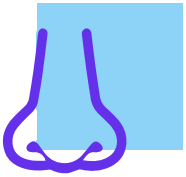
DIAGNOSES

These symptoms are indicative of but not solely attributed to:

- Infant Respiratory Distress Syndrome (RDS)*
- Bronchopulmonary Dysplasia (BPD)
- Prematurity
- Congenital Heart Defects
- Congenital diaphragmatic hernia (CDH)
- Transient Tachypnea of the Newborn (TTN)
- Meconium aspiration
- Persistent Pulmonary Hypertension (PPHN)

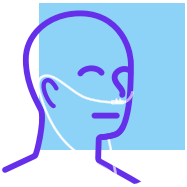
***Randomized Clinical Trials show efficacy equivalent to nCPAP and NiPPV for primary support of RDS[1,2]**

1. Kugleman et al, "A randomized pilot study comparing heated humidified high-flow nasal cannulae with NIPPV for RDS", Pediatric Pulmonology, 2014 Mar 12; 50(6) 576-83. (Clinical Trial, Prospective, Randomized, Single Site, n=76).
2. Lavizzari et al, "Heated, humidified high-flow nasal cannula vs nasal continuous positive airway pressure for respiratory distress syndrome of prematurity – a randomized clinical noninferiority trial", JAMA Pediatrics. 2016 Aug 8. (Clinical Trial, Prospective, Randomized, Single Site, n=316).



FITTING THE PRECISION FLOW® CANNULA

- Make sure not to occlude greater than 50% of the internal diameter of each of the nares.
- The Precision Flow Cannula prongs should be wide enough to not pinch the nasal septum (erosion risk).
- The SOLO is a single prong interface that can be used in neonates and infants. The single prong design ensures less than 50% nostril occlusion, and is as effective as a dual prong interface. The single prong also allows for placement of a NG tube.



PRECISION FLOW CANNULA APPLICATION

- Only Precision Flow Cannulas should be used with any Vapotherm Precision Flow systems
- Select the appropriate Precision Flow Cannula based on the sizing chart below
- Place the Precision Flow Cannula on the patient before attaching the delivery tube
- Allow the system to reach the set point (temperature display will stop flashing) before connecting delivery tube to the Precision Flow Cannula
- The operational L/min range of Vapotherm's Hi-VNI Technology is locked depending on the disposable patient circuit (DPC) selected:
  - PF-DPC-HIGH (Blue packaging): 5-40 L/min
  - PF-DPC-LOW (Red packaging): 1-8 L/min

PRECISION FLOW CANNULA SIZES	FLOW RANGE	TIP OD
Premature	1-8 L/min	1.5 mm
Neonatal	1-8 L/min	1.5 mm
SOLO (single prong)	1-8 L/min	1.9 mm
Infant	1-8 L/min	1.9 mm
Intermediate Infant	1-8 L/min	1.9 mm
Pediatric Small	1-20 L/min	1.9 mm
Pediatric/Adult Small	5-40 L/min	2.7 mm
Adult	5-40 L/min	4.8 mm

THERAPY IMPLEMENTATION & MAINTENANCE

L/min

The recommended starting flow rate is 4-6 L/min, even in VLBW infants[3,4]. Titrate to clinical effect to maximum of 8 L/min as needed.

FiO_2

Start and titrate FiO_2 as needed to achieve target SpO_2.

Temperature

Set temperature to 36-37°C.

WEANING PATIENTS BY L/MIN OR FIO_2

Vapotherm Hi-VNI Technology parameters (L/min & FiO_2) are independent of each other. Adjustment of L/min will impact work of breathing while adjustment of FiO_2 maintains patient SpO_2. Monitoring patients' response to each change requires continuous assessment of breath sounds, respiratory rate, physical characteristics (e.g nasal flaring, grunting and retractions).

Weaning by L/min

1. Wean in 0.5-1 L/min increments as patient tolerates.
2. Consider further wean titrated on clinical assessment of work of breathing.
3. If at less than 4 L/min you see rainout, consider dropping temperature to no lower than 34°C.
4. Assess for further wean and/or discontinuation.
5. Conventional cannula or room air.

Weaning by FiO_2

1. Adjust FiO_2 to range acceptable for SpO_2 requirement.
2. Patient assessment of HR, RR, SpO_2.
3. Continue FiO_2 wean to maintain SpO_2 targets.

3. Yoder et al, "Consensus approach to nasal high-flow therapy in neonates", Journal of Perinatology. (2017) 00, 1–5.
4. McQueen et al, "Safety and long term outcomes with high flow nasal cannula therapy in neonatology: a large retrospective cohort study", Journal of Pulmonary Respiratory Medicine. 2014 Dec; 4(6): 216. (Clinical Trial, Retrospective, Not Randomized, Multicenter, Cohort Analysis, n=1363).

The Vapotherm Transfer Unit (VTU) seamlessly transfers patients from Labor & Delivery to the Neonatal Intensive Care Unit (NICU). Patients can then be transferred to procedures and out of the NICU without compromising respiratory support.

WORKFLOW INTEGRATION – "3-STEP HOT SWAP" DISPOSABLE

Once patient is stabilized and ready for transfer:

1. Put Precision Flow unit in Standby, and remove Disposable Patient Circuit (DPC) and water bag from unit. Keep the DPC in an upright position until it is placed in the VTU.
2. Place DPC into the VTU Precision Flow.
3. Enter desired settings on the VTU Precision Flow and press the Run/Standby button to initiate therapy. Patient is now ready to be transferred.

Patient transferred to temporary location (i.e. procedures):

- Simply plug power and gas cables/hoses into wall outlets and close e-cylinders to conserve bottled gases.
- When patient is ready to be transferred again:

Unplug the VTU	Open e-cylinders	Disconnect wall hoses

Patient transferred to NICU/Step Down Unit/ General Care Floor:

- Use above 3-Step Hot Swap instructions to transfer patient to new, stationary Precision Flow unit.
- Close the VTU e-cylinders and return the VTU to its designated storage location.

WARNING: Do not attempt to transfer a patient with <= 250 PSI in either tank.

VTU should remain plugged in when not in use, and whenever possible during use. The VTU battery takes 2 hours to fully charge for a 1 hour run time.

VAPOTHERM TRANSFER UNIT RUNTIME CHART

Duration of use blending from E-size oxygen and E-size air cylinders.

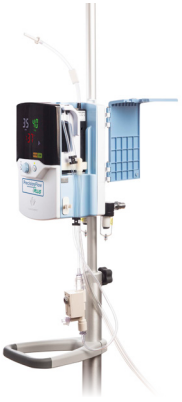
Total Flow	% Oxygen	Time Shown in Minutes							
L/min	21%	30%	35%	50%	60%	70%	80%	90%	100%
1	560	632	681	885	1106	903	750	641	560
2	280	316	340	442	553	451	375	321	280
3	187	211	226	295	369	301	250	214	187
4	140	158	170	221	277	226	187	160	140
5	112	126	136	177	221	181	150	128	112
6	93	105	113	147	184	150	125	107	93
7	80	90	97	126	158	129	107	92	80
8	70	79	85	111	138	113	94	80	70

Above chart applicable for PF-DPC-LOW Disposable only. For complete runtimes, set up and operation of the VTU, please refer to the VTU Quick Reference Guide.

Use with Aerosol Medication

Treating patients with respiratory disorders frequently requires combined use of Hi-VNI Technology with aerosolized medication. For practice considerations to do so, refer to the "Aerosol Delivery with HVNI Pocket Guide" and the "Aerosol Medication Delivery with HVNI Therapy Practice Summary."

Use with Nitric Oxide



- Vapotherm Hi-VNI Technology is verified for use with multiple nitric oxide delivery systems. To confirm your system is compatible with Vapotherm, contact your local representative.
- Vapotherm Nitric Oxide Disposable Patient Circuits (DPCs):
  - PF-NODPC-LOW 1-8 L/min
  - PF-NODPC-HIGH 5-40 L/min

Note: Refer to the Instructions for Use provided with your nitric oxide system and with the Nitric Oxide circuit.

Use with Precision Flow Heliox®

- Vapotherm offers an ideal solution for convenient delivery of conditioned helium-oxygen gas mixtures (Heliox).
- Heliox has a significantly lower density than typical air/oxygen mixtures.
- The lower gas density reduces the work of breathing by reducing the force needed to move gas through the airways.
- Heliox is commonly used on patients with diseases of increased airway resistance, such as bronchiolitis, asthma, post-extubation stridor, airway compression, intra and extrathoracic airway obstruction.
- Precision Flow Heliox strategies follow the same general clinical guidelines for air-oxygen mixtures, except FiO_2 should be titrated between 0.21 and 0.4 since higher oxygen concentrations (and lower helium concentrations) would result in a less significant clinical effect.
- Standard Vapotherm Disposable Patient Circuits (DPCs) may be used with the Precision Flow Heliox.
  - PF-DPC-LOW 1-8 L/min
  - PF-DPC-HIGH 5-40 L/min

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MKT-0138 Rev C 05/19