DISPOSABLE PATIENT CIRCUIT

- Attach High or Low Flow Vapor Transfer Cartridge to Disposable Water Path
- Attach patient delivery tube to Disposable Water Path
- Open door and install Disposable Water Path into docking station so there is no gap between bottom of the Disposable Water Path and the Docking Station Floor
- Hang sterile water bag or bottle
- Disinfect water spike with alcohol pad or equivalent and insert into sterile water bag
- Allow a minimum of 200ml of water to fill into the Disposable Patient Circuit
- Precision Flow® Hi-VNI is ready for start up

START UP AND ADJUSTING PARAMETERS

- Install oxygen sensor. Replace sensor annually
- Install gas inlet filters on back with filter bowls vertical (glass side down). Replace gas inlet filters every six months
- Attach air & O_2 hoses. Plug in power cord
- Rotate the blue Setting Control Knob to illuminate display
- Press in Setting Control Knob to select the parameter and rotate to adjust the value
- Press and release (do not hold) the Run/Standby button once to start
  A GREEN light indicates RUN mode (AMBER light indicates STANDBY mode, No Flow)
- Green light will stop flashing once temperature is reached

CONNECT TO PATIENT

- The flashing green LED becomes steady when the set variables are reached
- Place the cannula on the patient. Once the unit has reached at least 33°C, connect to delivery tube
- The unit should not be placed in Standby mode for extended periods of time. For pauses in therapy, keep unit in RUN mode, remove cannula from the patient, and set the parameters to the lowest available setting. To reinitiate therapy, before cannula is placed on patient, clear accumulated condensate

INTERNAL BATTERY BACK-UP

- The back-up battery is designed for temporary use only, when AC power to the unit has been interrupted
- The unit will enter into battery mode and will maintain flow and oxygen percentage for at least 15 minutes
- The battery icon will flash
- Replace battery every two years
- Battery recharges in two hours

SHUT DOWN

- Press and hold the Run/Standby button for 2 seconds. Unit will enter Standby mode (No Flow), indicated by the AMBER light
- Clamp the water inlet tube. Open the door, remove the Disposable Patient Circuit (includes delivery tube & cartridge) by sliding it upwards out of the docking station
- Discard all disposables according to hospital guidelines
- Disconnect unit from AC power
- Wipe down with Super Sani-Cloth®. In addition, if hospital procedures require, the following may be used: 70-90% Isopropyl Alcohol, 2% (maximum) chlorine cleaning solution, 6% (maximum) Hydrogen Peroxide cleaning solution, CaviWipes™, AF3 Germicidal, Incidin® OxyWipe, Bacillol® 30 Tissues, Clinell® Alcohol Wipes, or Tuffie Disinfectant Wipes

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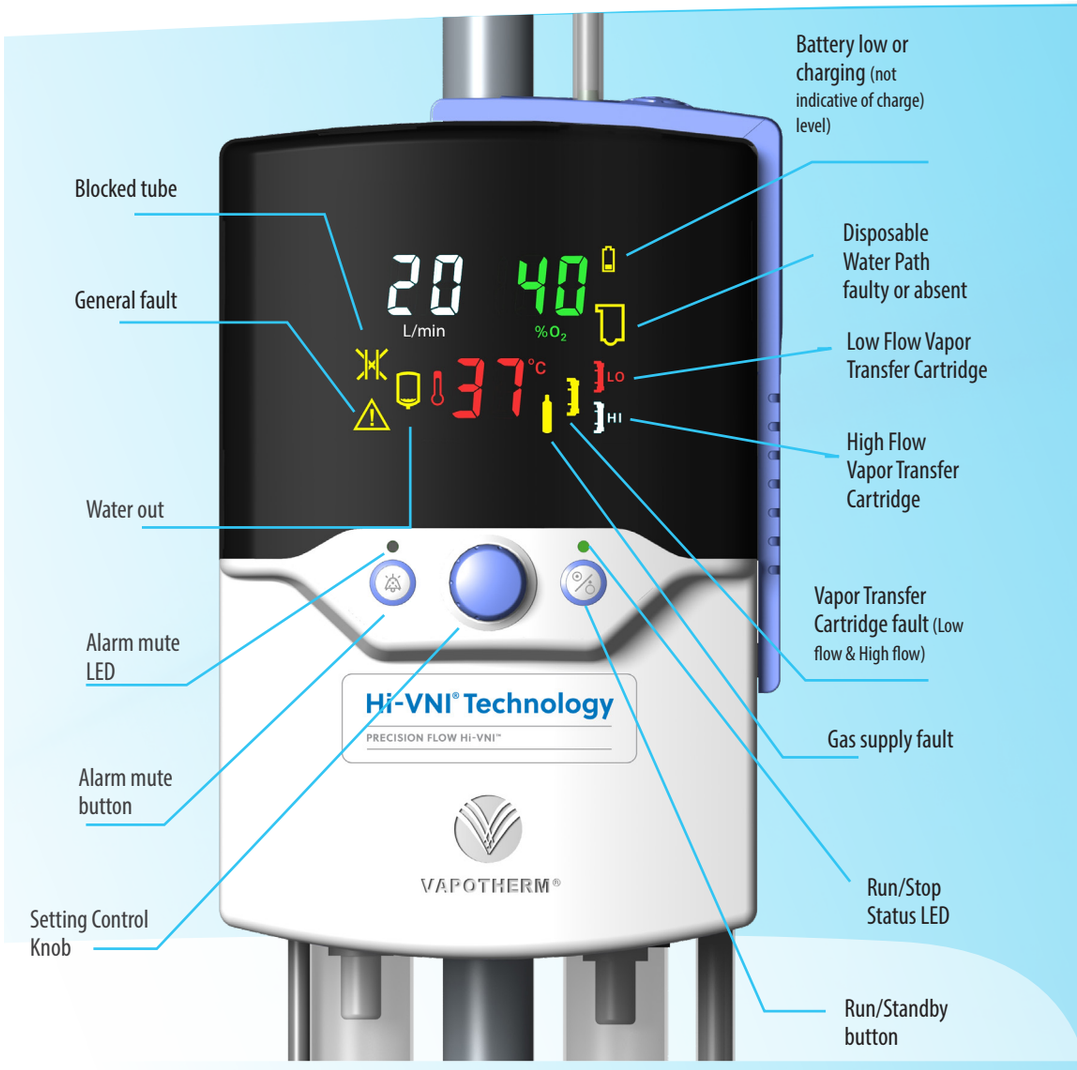
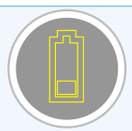
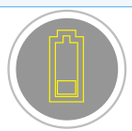
Hi-VNI® Technology

PRECISION FLOW Hi-VNI™

QUICK REFERENCE GUIDE



This guide provides you with basic instructions on how to set up and operate the Precision Flow® Hi-VNI. Before operating the Vapotherm Precision Flow® Hi-VNI, please review the Instructions for Use which can be found at our website: vtherm.com/pfreference.

ALARM ICON	WARNING	INDICATES	CAUSE	ACTION
	**GENERAL FAULT and – – IN FLOW** (FLASHING)	Malfunction of sensor or control system	Internal component failure	Check gas supply. If not corrected, disconnect patient. Unplug AC power, press and hold Run/Standby button for 3 seconds to clear the alarm, send for service.
	**GENERAL FAULT and – – IN O_2** (FLASHING)	O_2 sensor fault	Depleted or defective O_2 sensor	Unplug AC power, press and hold Run/Standby button for 3 seconds to clear the alarm. Replace O_2 sensor. Restart unit.
	**GENERAL FAULT and – – IN TEMP** (FLASHING)	Temperature out of range.	Overheating or temperature sensor malfunction.	Cannot be corrected by user: disconnect patient. Unplug AC power, press and hold Run/Standby button for 3 seconds to clear the alarm, send for service.
	**WATER OUT**	No water in disposable water path. Gas flow continues without heating or water circulation.	Sterile water empty, or obstructed inlet tube.	Replace water bag or straighten inlet tube. Restart unit. If alarm persists, disconnect patient from therapy.
	**DISPOSABLE WATER PATH** (FLASHING)	Disposable water path faulty or not detected. Unit will not run.	Disposable water path defective, not properly seated or not installed.	If disposable water path is present, place unit into Standby, remove and replace disposable patient circuit to reset detector. Restart unit.
	**BATTERY CHARGING** (STEADY)	The internal battery backup is not fully charged. The unit would not run on battery for the full rated time in the event of a power failure. No action is necessary.		
	**BATTERY** (FLASHING)	The unit is running in BATTERY mode. Gas flow and blending continues without heat or water circulation.	AC power is disconnected	Reconnect AC power.
	**BLOCKED TUBE** (FLASHING)	High back pressure	Obstructed or kinked cannula/delivery tube, incorrect cannula for flow rate or DPC improperly seated	Clear obstruction, check cannula type, re-install DPC
	**GENERAL FAULT ALARMS:** Failures in the control or measurement systems will cause a General Fault alarm indicated by this icon accompanied by the Temp display showing numbers between 50 & 84 (error codes) and dashes in O_2 and Flow displays. When an error code is displayed, gas delivery is stopped. The user needs to monitor the treatment and respond to general fault alarms. General Fault alarms cannot be silenced with the mute button. To reset, first disconnect the unit from AC power and then press the Run/Standby Button. With the exception of O_2 sensor replacement, the unit must be repaired by an approved service facility.			

CANNULA FLOW RATES

CARTRIDGE	CANNULA TYPE	OPERATIONAL FLOW RATES
High Flow	Adult, Pediatric/Adult Small, Pediatric Small*	5-40 liters per minute (L/min)
Low Flow	Premature, Neonatal, Infant, Intermediate Infant, Solo, Pediatric Small*	1-8 liters per minute (L/min)

*Pediatric Small cannula is intended to deliver flow rates of 1-20 L/min

ALARM ICON	WARNING	INDICATES	CAUSE	ACTION
	**CARTRIDGE FAULT**	Cartridge and/or DPC not detected. Unit will not run.	RUN mode: faulty sensor or cartridge not detected.	Disconnect patient. Remove disposable patient circuit. Check cartridge installation. Check sensor windows are clean.
		Gas bubbles in water circulation. Unit continues to operate.	Excessive gas diffusion through cartridge fibers.	Disconnect patient. Place unit into Standby. Replace disposable patient circuit including water path, cartridge & delivery tube.
		Cartridge and/or DPC not detected.	STANDBY mode: missing cartridge.	Remove disposable patient circuit. Check cartridge installation.
	**CARTRIDGE TYPE**	Indicates type of cartridge installed (low or high flow). Not an alarm.		
	**GAS SUPPLY** (FLASHING) **GAS SUPPLY** (CONTINUOUS AND FLOW RATE NUMERIC DISPLAY FLASHES)	Gas supply pressure outside 4-85 psi (28-586 kPa) range. Unit will not operate.	Gas supply is disconnected or exhausted.	Check gas supply and correct as necessary.
		Selected flow can not be provided from current gas supply.	Inlet gas pressure too low for selected flow rate.	Increase gas pressure or decrease flow setting.
	TEMPERATURE NUMERIC DISPLAY FLASHES	Temperature 2° > set point	User enters set point much lower than previous temperature.	Silence alarm and wait for temperature to drop.
		Temperature 2° < set point	Very low water temperature after bag replacement.	Silence alarm and wait for temperature to rise.

INDICATIONS, WARNINGS AND CAUTIONS

Primary Indications:

Precision Flow® Hi-VNI is intended for use to add warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital and subacute institutions settings. It adds heat and moisture to a blended medical air/ oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula.

Precision Flow® Hi-VNI provides high velocity nasal insufflation (HVNI) with simultaneous oxygen delivery to provide ventilatory support to spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting. Precision Flow® Hi-VNI is not intended to provide total ventilatory requirements of the patient and not for use during field transport.

Contraindications: General:

- Not appropriate for patients who are not spontaneously breathing, are unable to protect their airway or have anatomic or injury induced blockage of the nasal pathway to the nasopharyngeal space
- Not for treating OSA and snoring
- The Precision Flow® Hi-VNI is not for field transport
- The Precision Flow® Hi-VNI is MRI unsafe. Do not use it in an MR environment.

Additional patient monitoring including pulse oximetry is necessary if the Precision Flow® Hi-VNI is used to give supplementary oxygen.

Precision Flow® Hi-VNI Packaging contains:

Precision Flow® Hi-VNI Unit	Quick Reference Guide	O2 Sensor cell
Power Cord	Air & Oxygen Inlet Particulate Traps with Connectors	Delivery Tube clip
US ONLY - Air and Oxygen Hoses	Nurse Call / EMR Communication Cable with three adapter cables (varies by country)	