PART SEVEN

THE HISTORY AND APPLICATION OF HIGH FREQUENCY OSCILLATORY VENTILATION (HFOV)

Reciprocating pistons with an eccentric travel speed, moving to and fro within a cylinder (with a common inlet/outlet), can provide the mechanical means for a symmetric suck and blow (push-pull) oscillation. If the common outlet is obstructed, a potential positive as well as a sub ambient pressure is generated above the head of the dynamic piston. <u>Oscillation is generically defined as "a to and fro movement neither positive nor negative."</u>

When a compression chamber is created above the piston, the piston travel can provide for single or over-lapping air compressions (positive pressure generation) or can create a potential and/or a sub ambient (negative) pressure within combining mechanical and physiological airways. An extended compression chamber could be formed by a combination of mechanical tubings interconnecting to the airways of a mammalian lung.

When reciprocating pistons are employed to provide for gas exchange within mammalian lungs, their to and fro movements can be designed to provide for positive, sub ambient, or combined positive and negative pressure/flow gradients at the proximal airway. Flow gradients are said to exist when a pressure is mechanically created above, below or across a neutral ambient baseline sufficient to cause a mass molecular flow from the area of higher pressure into an area of lower pressure.

Peak to peak pressures can be any measured pressure differential above, below or across the ambient baseline. Accepted arbitrary scales such as cm H2O can be used to perceive the potential pressure differences.

The cross section and the stroke of the piston will determine the potential volume displacement which can be moved in either direction.

1. **An Adult "positive phase valved PISTON OSCILLATOR" would be generally designed to exchange tidal volumes of up to about one liter (1000 cc) at reciprocating rates of under 20 times per minute.**

2. **A Pediatric "positive phase valved PISTON OSCILLATOR" would be generally designed to exchange tidal volumes of up to about one quarter liter (250 cc) at reciprocating rates up to about 50 times per minute.**

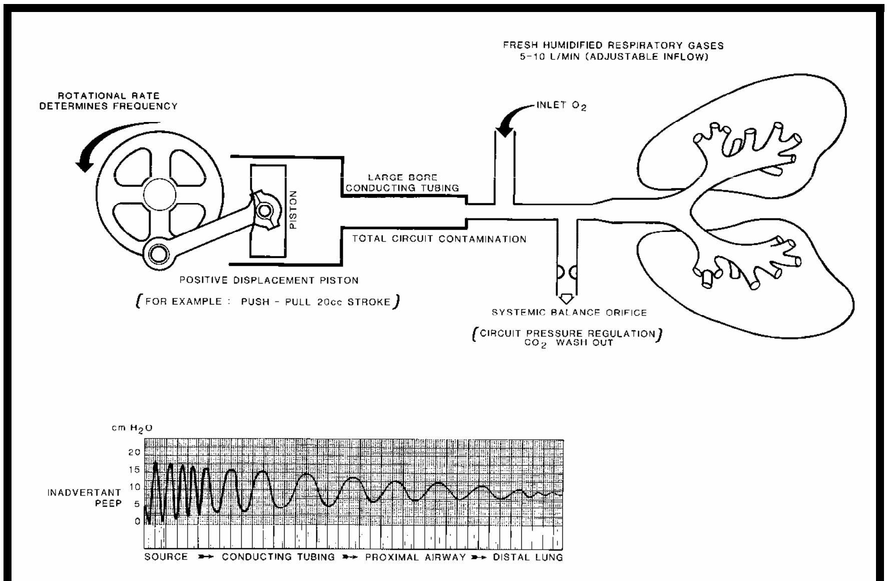
3. **A Neonatal "positive phase valved PISTON OSCILLATOR" would be generally designed to exchange tidal volumes of up to about (50 cc) at reciprocating rates up to about 150 times per minute".**

4. **A Neonatal reciprocating (push-pull) PISTON OSCILLATOR with a common inlet/outlet would be generally design to exchange small tidal volumes of under (20 cc) at frequencies of up to 950 cycles per minute.**

In order to better understand NEONATAL HIGH FREQUENCY OSCILLATORY VENTILATION (HFOV) THE FOLLOWING CAN BE RELEVANT:

The three general types of Clinical Oscillators, are:

1. The symmetric Piston Oscillator.



POSITIVE DISPLACEMENT OSCILLATOR (NEONATAL)

THEORETICAL SINGLE WAVE FORM PROPAGATION.
FADE OUT FROM ENERGY SOURCE TO PERIPHERAL LUNG.

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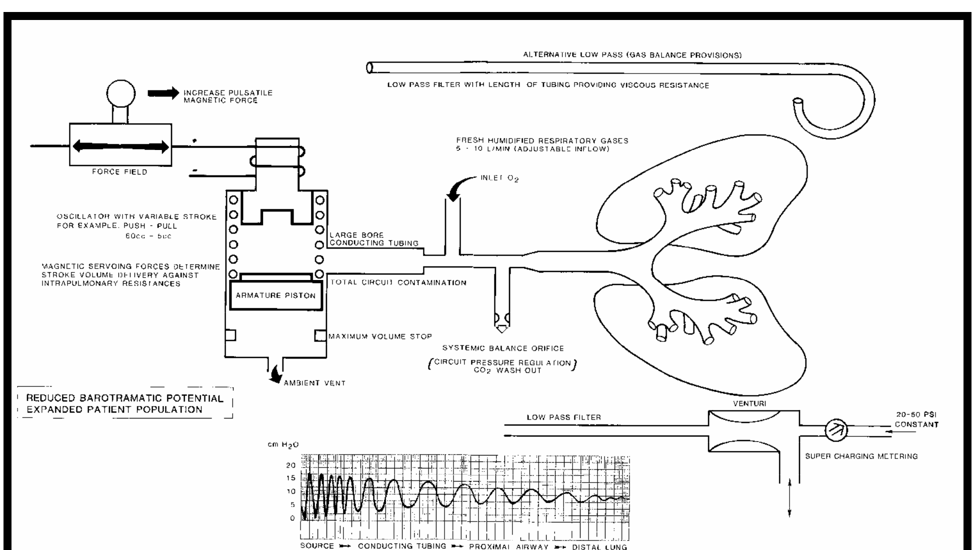
The Magnetically controlled diaphragm (push-pull) Oscillator.



VARIABLE DISPLACEMENT OSCILLATOR (NEONATAL)

THEORETICAL SINGLE WAVE FORM PROPAGATION.
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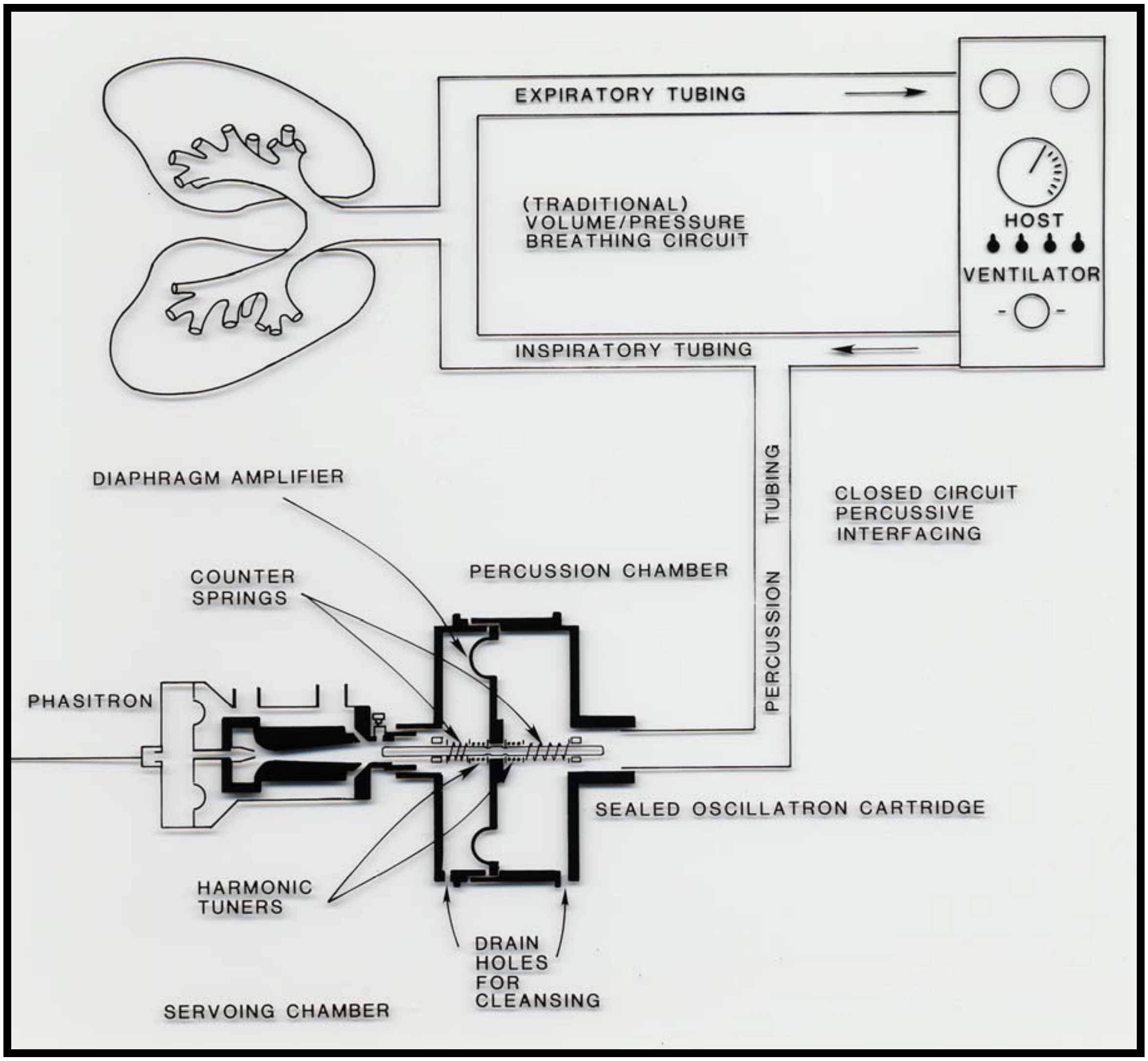
3. The Universal Fluidic Flow Interruption Percussive Oscillator.



The fluidically servoed encapsulated diaphragm can be scheduled with a selected static CPAP for a HFOV ventilation or for a combined diffusive/convective percussive ventilation (HFPOV™) when interfacing a CMV critical care ventilator. Proximal airway tidal pressure waves of up to 100 cm H2O PIP can be effectively modulated.

The initial and continuing justifications for Neonatal (push-pull) Oscillators were and are:

1. **The initial concept was to maintain a zero (ambient) pressure at the proximal airway by means of a symmetric inspiratory positive pressure rise to a selected value, followed by a reciprocal potentially sub ambient pressure, down to a like sub ambient value, at frequencies of about 900 cycles per minute. The rationale was to maintain a near ambient mean intra-thoracic pressure without a "Continuous Positive Proximal Airway Pressure" to reduce the potential for barotrauma.**

2. **It was soon discovered that this low lung compartment ventilatory strategy, while capable of diffusing oxygen toward the peripheral pulmonary airways, was not sufficient to produce an intrapulmonary gas exchange capable of effectively "washing out" CO_2.**

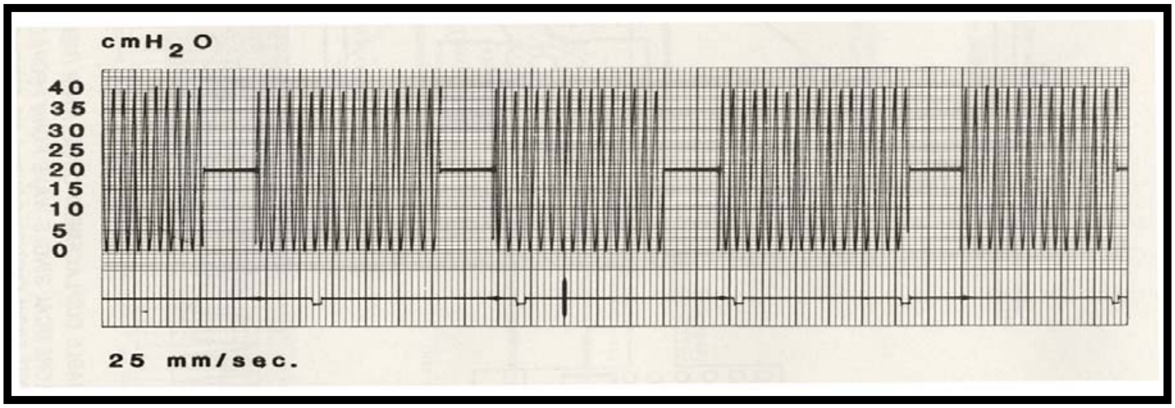
3. **Taking advantage of the normally hyper-perfused neonatal physiological circulations capable of tolerating considerably elevated mean intrathoracic pressures while still maintaining an acceptable cardiac output, the "Proximal Airway Continuous Positive Pressures" were considerably increased.**

4. **By mechanically increasing the intrapulmonary Dynamic Functional Residual Capacities D/FRC, the general airway patency to the prevailing blood/gas interface was increased, enhancing gas diffusion within the higher lung compartments.**

5. **By modulating the mechanically induced CPAP carrier with consecutive tidal pulsatile endobronchial deliveries, the gaseous diffusion within the pulmonary structures was enhanced, favoring oxygen transport.**

6. **While CO_2 is some 20 times more diffusible than oxygen, the ability to maintain a normal CO_2 clearance with a HFOV program is a continual challenge. Whether or not the mechanically induced blood/gas interface enhancements secondary to increased CPAP levels of some 20 cm H2O or the diffusive pulsatile sub tidal ventilation during HFOV plays the greater role in oxygenation remains questionable.**

7. **High Frequency Oscillatory Ventilation (HFOV) generated with a direct reciprocating floating center piston driven by magnetic attraction, requires mechanically induced (in and out) changes in proximal airway flow gradients to create tidal exchanges.**



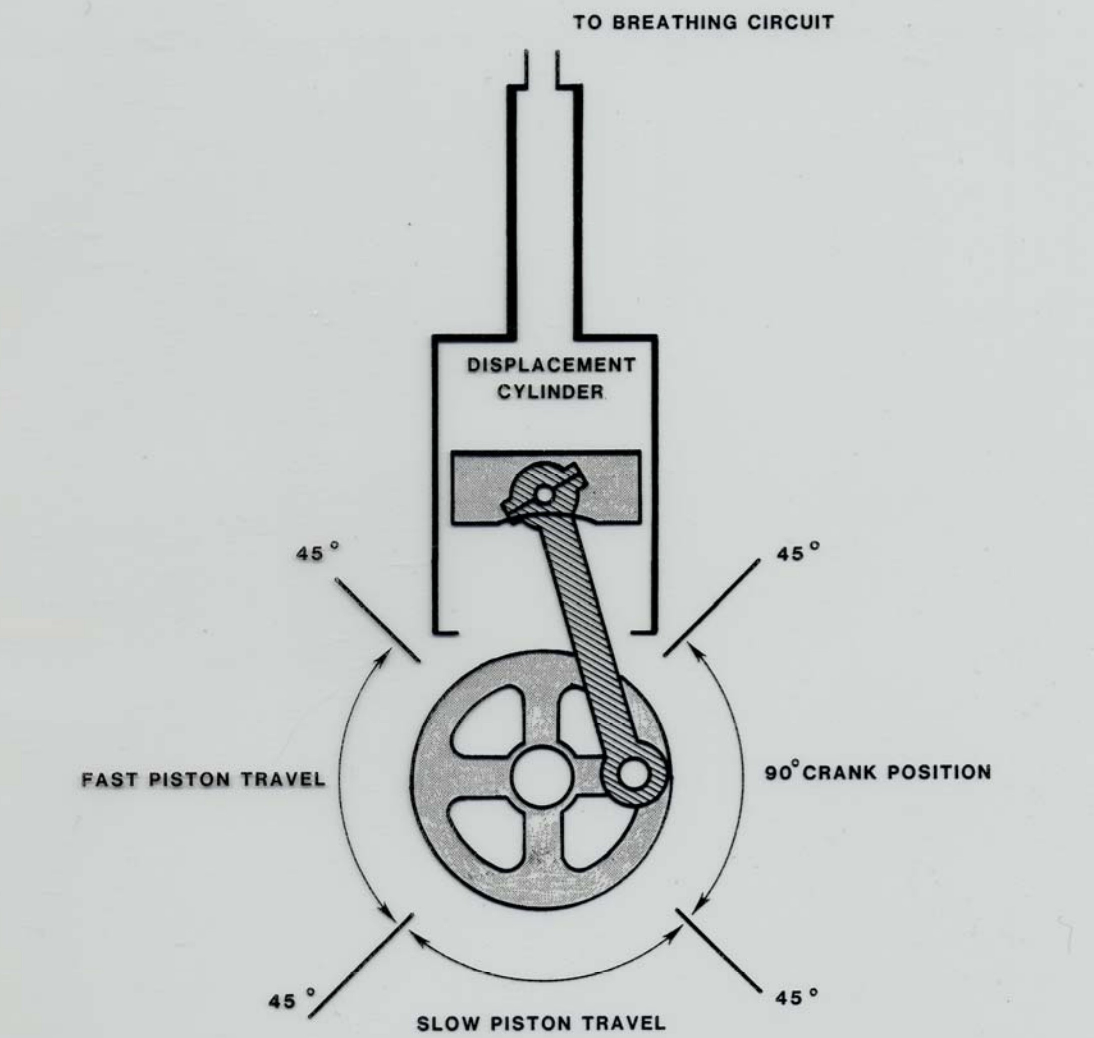
SYMMETRIC OSCILATORY VENTILATION (HFOV)

8. The cycle time required by a mechanical ventilator for one single delivery and retraction event, that is, to change from an inspiratory flow gradient to an expiratory flow gradient, then from the expiratory flow gradient to an inspiratory flow gradient, is called the "OSCILLATORY TRANSITION GRADIENT or HANDICAP".

9. Hypothetically, in a symmetric dynamic piston or magnetically cycled (push-pull) oscillator delivering at a frequency of 900 cycles per minute, the cycle time is about 64 milliseconds. The self-canceling time required (Transition Penalty) to transition from an inspiratory flow gradient to an expiratory flow gradient is about 22 milliseconds. The same penalty exists during the transition from the expiratory flow gradient to an inspiratory flow gradient. Thus, at delivery frequencies of 900 cycles per minute, some 42 milliseconds of effective flow time can be hypothetically cancelled in the reversal of flow gradients.

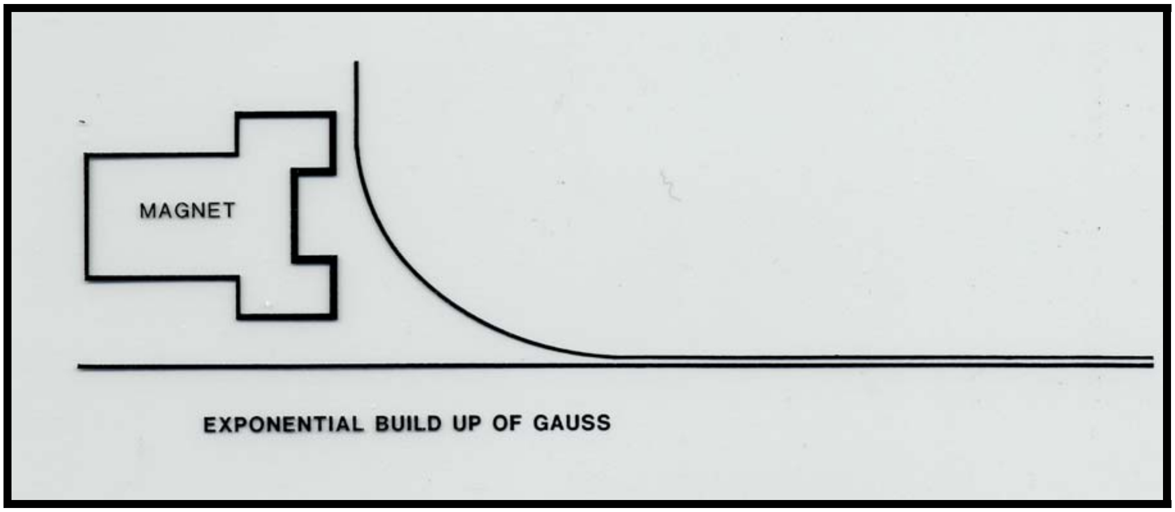
10. Thus, only about 20 milliseconds remain available to provide for the inspiratory and expiratory flow gradients to deliver and recover a sub tidal volume. Therefore, the greater the design transition penalty, the less the effective tidal exchange at increasing High Frequency oscillatory programming.

11. It is this major oscillatory flow gradient transition penalty, which limits the pulsatile diffusive intrapulmonary gas exchange, thereby mandating a major CPAP, to statically hold the lung in a major apneustic position (high lung compartment) to enhance the available blood/gas interface.



MANDATED PHASE SHIFT PENALTY OF A CRANK DRIVEN PISTON OSCILLATOR

The 90 degree areas of slow piston travel top and bottom are where the pressure gradients are reversed, effectively cancelling each other. As noted, with a constant crank shaft speed the excentricity of the articulated rod that connects to the piston causes the piston to use more time during the over the top and over the bottom travel flow gradient reversal transition than during the effective 90 degree flow gradient compression and evacuation time.



THE MANDATED DESIGN TRANSITION PENALTY OF A MAGNETICALLY SERVOED OSCILLATOR FOR HFOV IS A FACTOR OF DESIGN.

The build up of magnetic gauss between the magnetic source and its soft iron armature is not linear, causing an initial slow acceleration of compressive diaphragm travel, with an exponential travel acceleration toward end inspiration, requiring considerable mechanical force to reverse the inertia of the mechanical components creating the inspiratory flow gradient. Therefore, the oscillatory transition penalty approaches that of the piston design.

Additionally, the diameter of the magnetically servoed diaphragm is increased to create the desired volume exchange within a very limited magnetic design mandated deflection (stroke) as opposed to a piston design, creating greater energy demands and causing unwanted heating during magnetic Gauss generation.

12. **The potential sub ambient expiratory phase created by a neonatal high frequency dynamic (push-pull) oscillator can only serve to decrease the expiratory flow resistance within the endotracheal tube. If the potential sub ambient pressure is transmitted into the pulmonary airways with sufficient magnitude, it will create a physiological airway collapse. In this application a sub ambient expiratory phase does not serve any known physiological considerations.**

13. **The uploading of pulmonary structures can be greatly increased by means of a controlled proximal airway positive pressure. However, the passive physiological downloading of the lungs (caused by physiological retractile forces) can only be mechanically augmented by maintaining positive distal to ambient proximal airway flow gradients compatible with the continuing patency of the airway. These gradients are obtained by the maintenance of an ebbing positive to ambient pressure across the airway.**

IN BRIEF SUMMARY

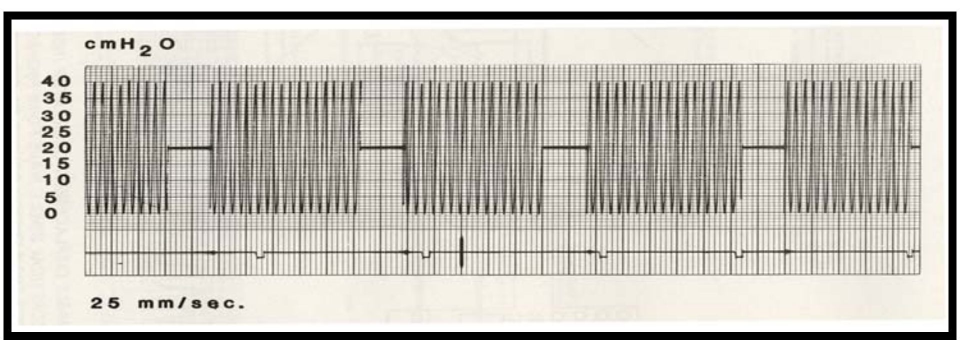
The clinical efficacy of any ventilator designed for Dynamic High Frequency Oscillatory Ventilation (HFOV) is primarily determined by the rate at which the mechanically programmed intrapulmonary flow gradients can be reversed without collapsing the physiological airways. This becomes increasingly important as cyclic frequencies increase.

In order to compensate for the elevated design-mandated pulsatile transition penalties and enhance the blood/gas interface, a Continuous Positive Airway Pressure (CPAP) is employed to increase the Dynamic Functional Residual Capacity (D/FRC). Thus, by moving the pulsatile tidal forces into higher lung compartments, intrapulmonary diffusion can be mechanically enhanced.

While neonatal lungs with their normal hyper-perfusion can generally tolerate the mechanically induced increased intra-thoracic pressures, a patient with cardiac embarrassments may not tolerate the induced pulmonary arterial pressures retrograding against the right heart. Therefore, dynamic high frequency oscillation can be tolerated by neonates who have normal pulmonary hyper-perfusion pressures without cardiac compromises.

Dynamic high frequency ventilators have limited abilities with increasing patient size because of their limited pulmonary convective gas exchange required to "wash out" CO_2. Additionally, pediatric and adult patients do not tolerate the high induced continuous intra-thoracic pressures required to increase blood/gas interfaces without encroaching upon cardiac output.

In order to enable the pulsatile modulation of the static positive pressure, Dynamic High Frequency Oscillatory Ventilation (HFOV) must employ continuously elevated proximal positive airway pressures to transport the pulsatile tidal exchanges into the peripheral airways. Additionally, without enhancing the blood/gas interface by mechanically increasing the D/FRC, pulsatile oscillation alone could diffuse endobronchial oxygen without "washing out" sufficient CO_2, potentially leading to a CO_2 narcosis.



Continuous Positive Airway Pressure (CPAP) being modulated by a symmetric dynamic (push-pull) mechanically induced oscillation for HFOV.