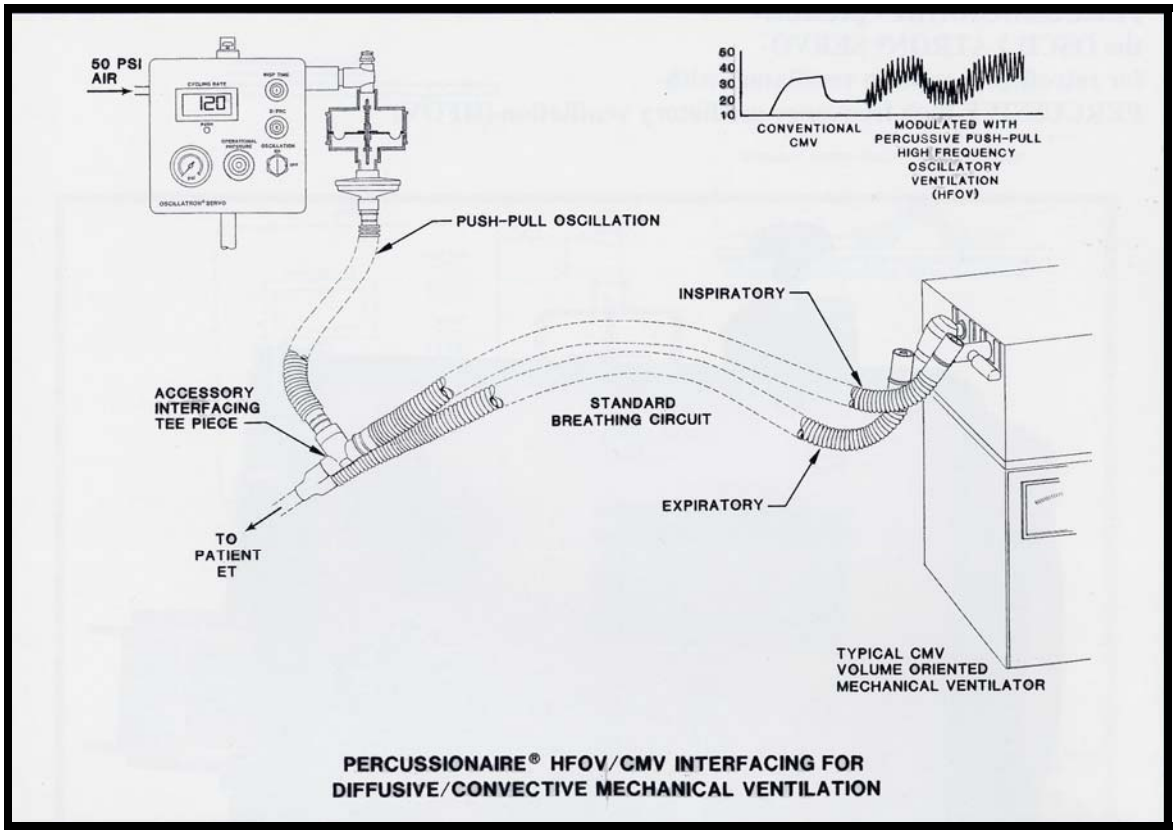
# PART EIGHT

## HIGH FREQUENCY PERCUSSIVE OSCILLATION (HFPOV™)

**<u>Note: For maximal comparative understanding, FIRST read PART SEVEN which defines the concept of High Frequency Oscillatory Ventilation (HFOV).</u>**

**The fluidic logic employed in the design of devices capable of High Frequency Percussive Oscillatory Ventilation (HFPOV™), allows a major reduction in transition penalties when compared to HFOV devices. The primary device for HFPOV™ is called an Oscillatron®, which has cyclic transition penalties at 900 cycles per minute of about 14 milliseconds compared to piston and magnetically servoed HFOV ventilators with transition penalties approaching 42 milliseconds. By subtracting 14 from 42 one can see that the time for effective reciprocating tidal exchange gradients is increased by 28 milliseconds in the Oscillatron® fluidic HFPOV™ design.**




PERCUSSIONAIRE® HFOV/CMV INTERFACING FOR
DIFFUSIVE/CONVECTIVE MECHANICAL VENTILATION

**It follows that a reduction in the high frequency delivery frequencies will result in more time for tidal exchange by any dynamic (push-pull) oscillator design. However, without the intrapulmonary gas-mixing enhancement provided by percussive endobronchial gas mixing, the potential for $CO_2$ recruitment will be minimal.**

**By modulating the tidal delivery waves of certain CMV ventilators, the clinical efficacy can be increased with a potential reduction in PIP and $FIO_2$.**

**It follows that increasing the blood/gas interface by mechanically increasing the D/FRC with an elevated CPAP alone could serve to increase PaO2. However, without a concomitant tidal exchange sufficient to "wash out" $CO_2$, the patient could die (nice and pink) from a $CO_2$ narcosis.**

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

OCT 27 1989

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Percussionaire® Corporation
Attn: Forrest M. Bird
Bird Airlodge
P.O. Box 817
Sandpoint, Idaho 83864

Re: K892886B
Oscillatron-1™ Medical Respirator
Dated: October 16, 1989
Received: October 19, 1989
Regulatory Class: II

Dear Dr. Bird:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

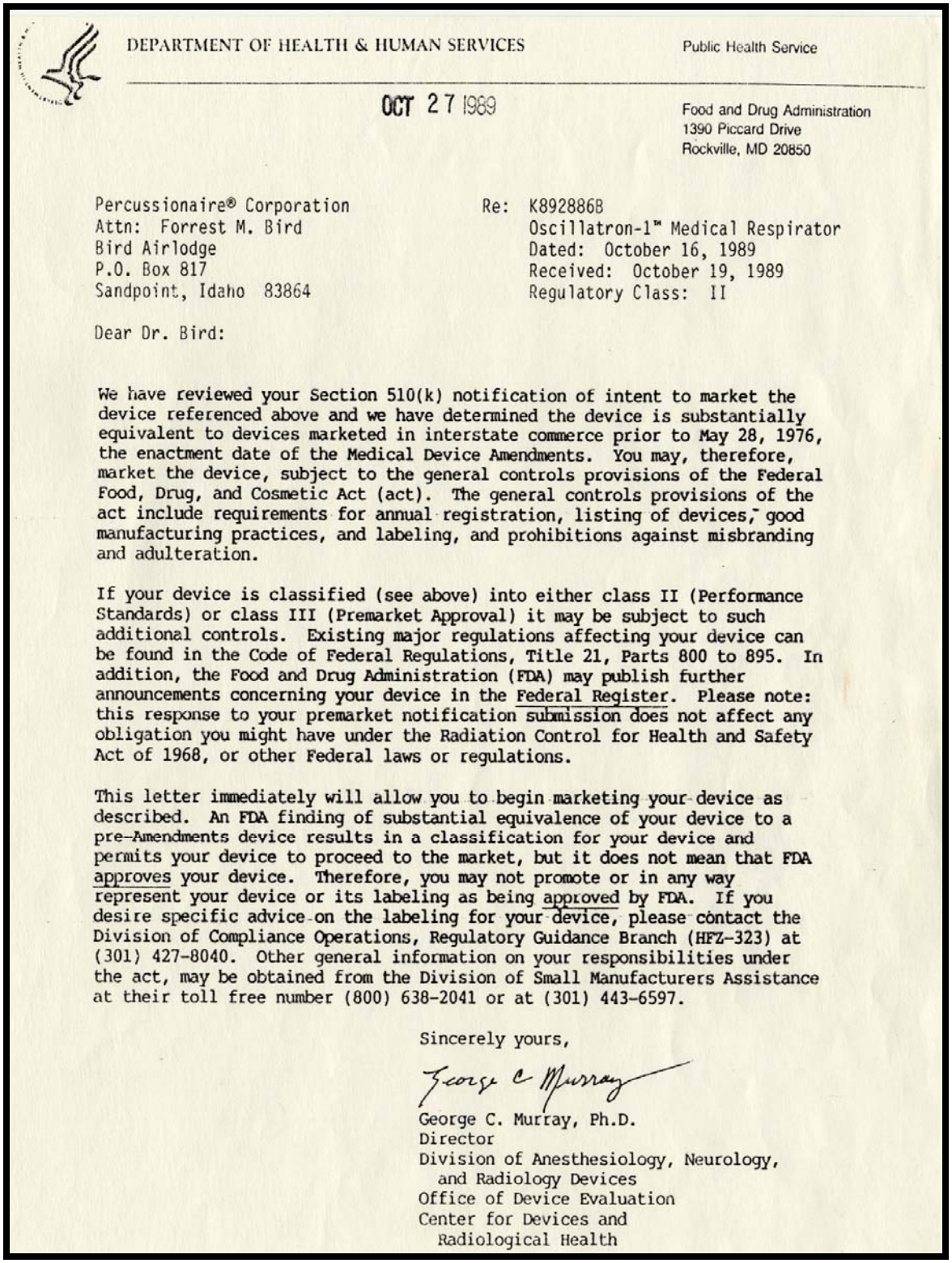
Sincerely yours,

George C Murray

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology,
and Radiology Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

**THE U S FDA CLEARED THE PERCUSSIONAIRE® OSCILLATRON® FOR MARKETING ON OCTOBER 16, 1989.**

**OVER THE MANY YEARS, THE VOLUMETRIC DIFFUSIVE RESPIRATION CONCEPT (VDR®) HAS TAKEN PRECEDENCE OVER THE OSCILLATRON® AS A UNIVERSAL VENTILATOR.**



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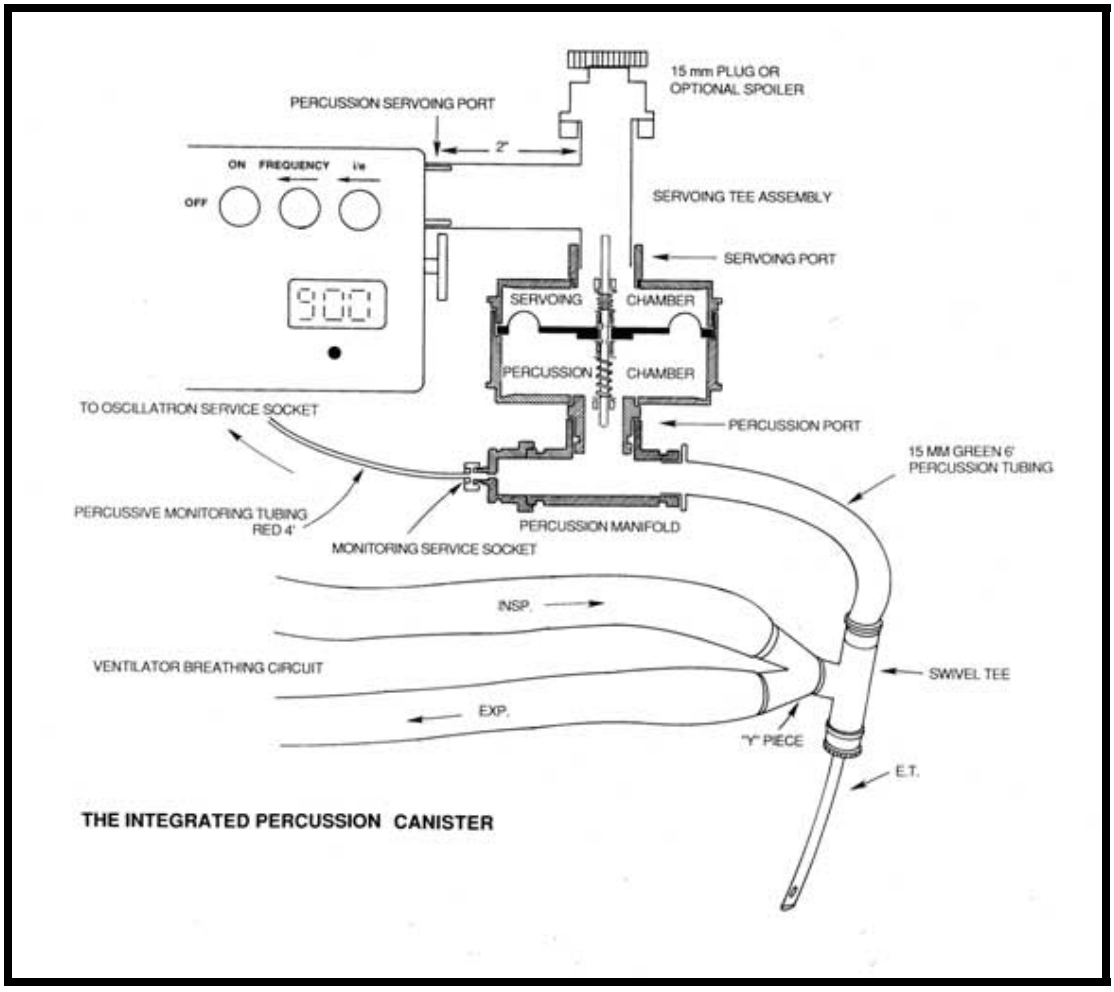
**On October 26, 1990, the FDA provided Dr. Bird with the only 510K frequency increase for high frequency oscillatory ventilators.**

**<u>This allowed other piston and magnetically servoed high frequency oscillators to increase their cyclic frequency, based upon Dr. Bird's prior state of the art available on May 28, 1976.</u>**

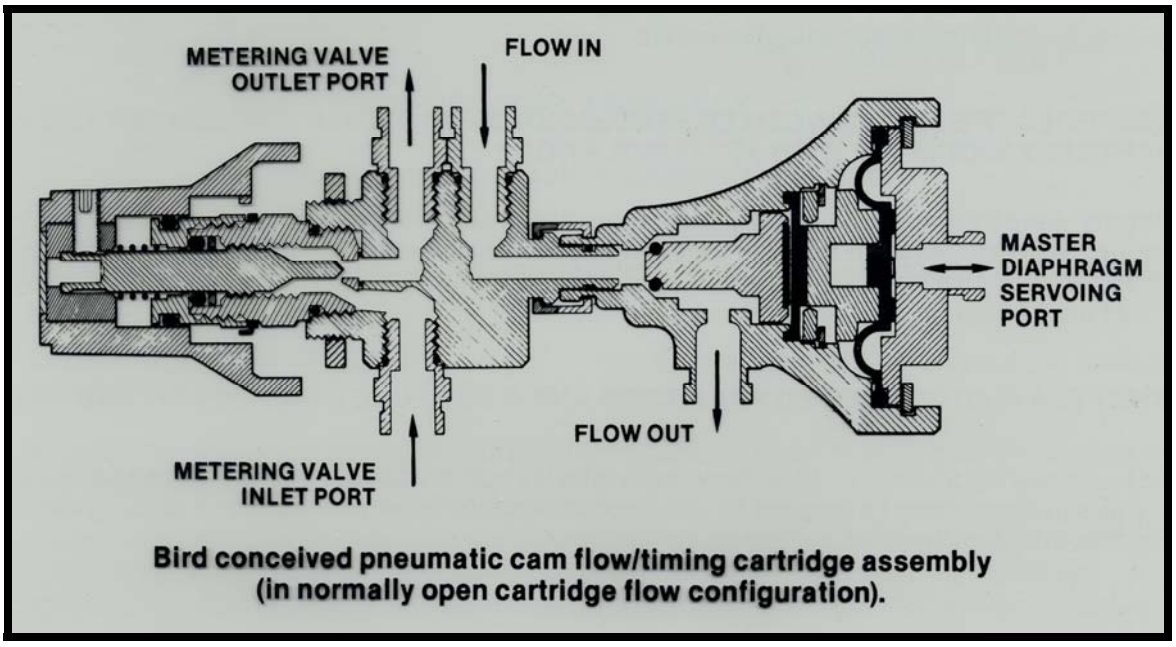
**Essentially, the "Oscillatron 1" defines the extension of the (positive phase) Phasitron® enabling a potential sub ambient expiratory phase.**

**The clinical concept of Volumetric Diffusive Respiration (VDR®) has confirmed the clinical efficacy of combining "Diffusive Percussive Ventilation" with the traditional Convective CMV ventilation of the lung. Therefore, it became a natural timely transition to enable standard conventional CMV ventilators to increase their level of clinical efficacy by combining "Diffusive Intrapulmonary Percussive Ventilation" with the CMV programmed convective tidal exchange. The Oscillatron® alone (among all other HFOV ventilators) enables the modulation of a conventional tidal exchange (with PIP's approaching 100 cm H2O), providing for the enhanced diffusion of the intrapulmonary gases in lungs with very low compliance.**



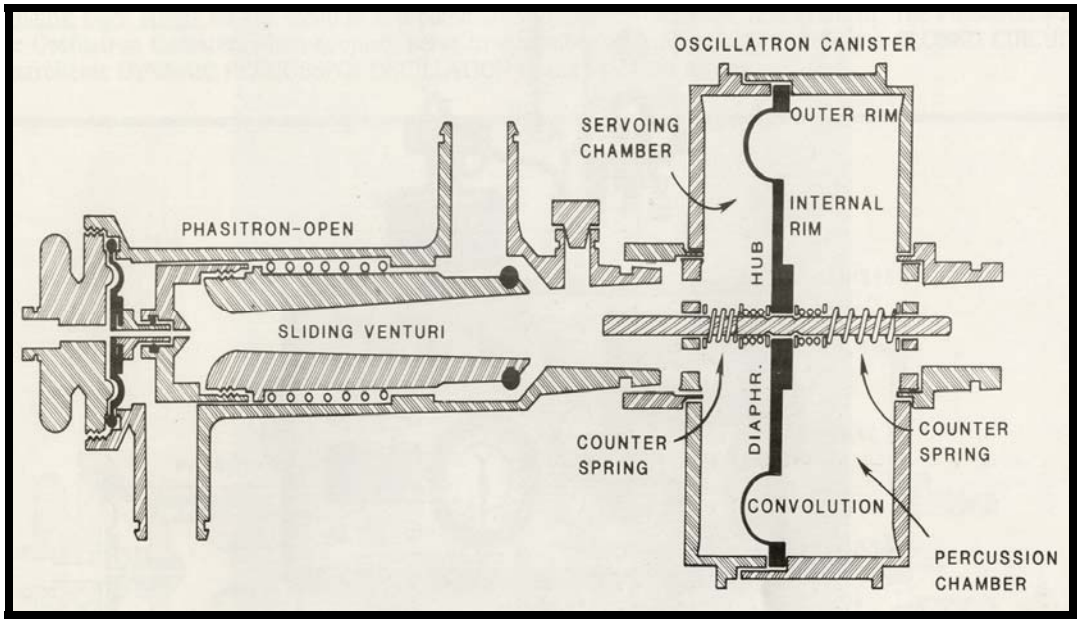

**The Oscillatron® is essentially a unique Canister which is servoed by the Phasitron to generate a potential sub ambient phase during High Frequency Percussive Oscillatory Ventilation (HFPOV™).**

**The fluidic design employed in the percussive Oscillaton® logic is advanced by a "Differential Flow Interrupter Cartridge" with near instantaneous opening and closing thus providing repetitive flow interruption to an encapsulated sliding venturi injector exhalation valve called a Phasitron®".**




**Bird conceived pneumatic cam flow/timing cartridge assembly (in normally open cartridge flow configuration).**

**In turn, the Phasitron® near instantaneously pressurizes an encapsulated diaphragm centered in the chamber by opposing counter springs. The percussive forward movement of the diaphragm injects a high velocity tidal volume of gas into the breathing circuit to modulate a selected positive pressure at the patient's proximal airway. The inspiratory percussive flow gradient is near instantly reversed, creating an immediate follow on expiratory flow gradient, which generates a potential distal–proximal sub ambient pressure gradient at the proximal airway.**

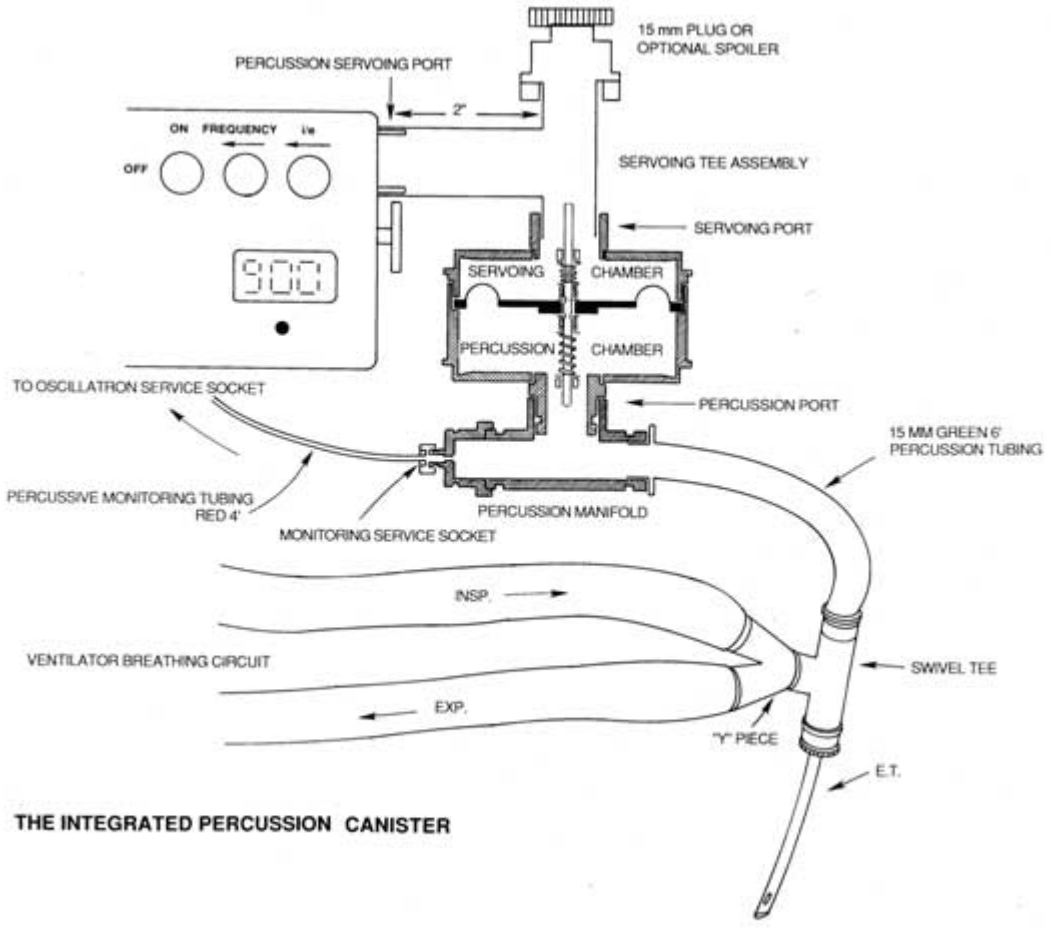


**The advantage of employing a fluidic "flow interruption" logic as opposed to "piston and magnetic flow generations" includes a number of factors, encompassing:**

1. **A virtually unlimited source of regulated high pressure gas exerts continuous pressures of about 40 psig against the flow interrupter valve gate. When the flow interrupter cartridge valve gate near instantaneously opens, a sustained percussive burst of regulated high pressure gas is released against the jet of the Phasitron® venturi for a timed interval.**

2. **In turn, the velocity of the flow leaving the distal end of the venturi tube is amplified and accelerated.**

3. **Finally, the percussive inspiratory flow generated within the venturi tube impacts upon the servoing side of the diaphragm encapsulated within the canister servoing chamber, causing a near immediate forward diaphragmatic implosion into the percussion chamber.**

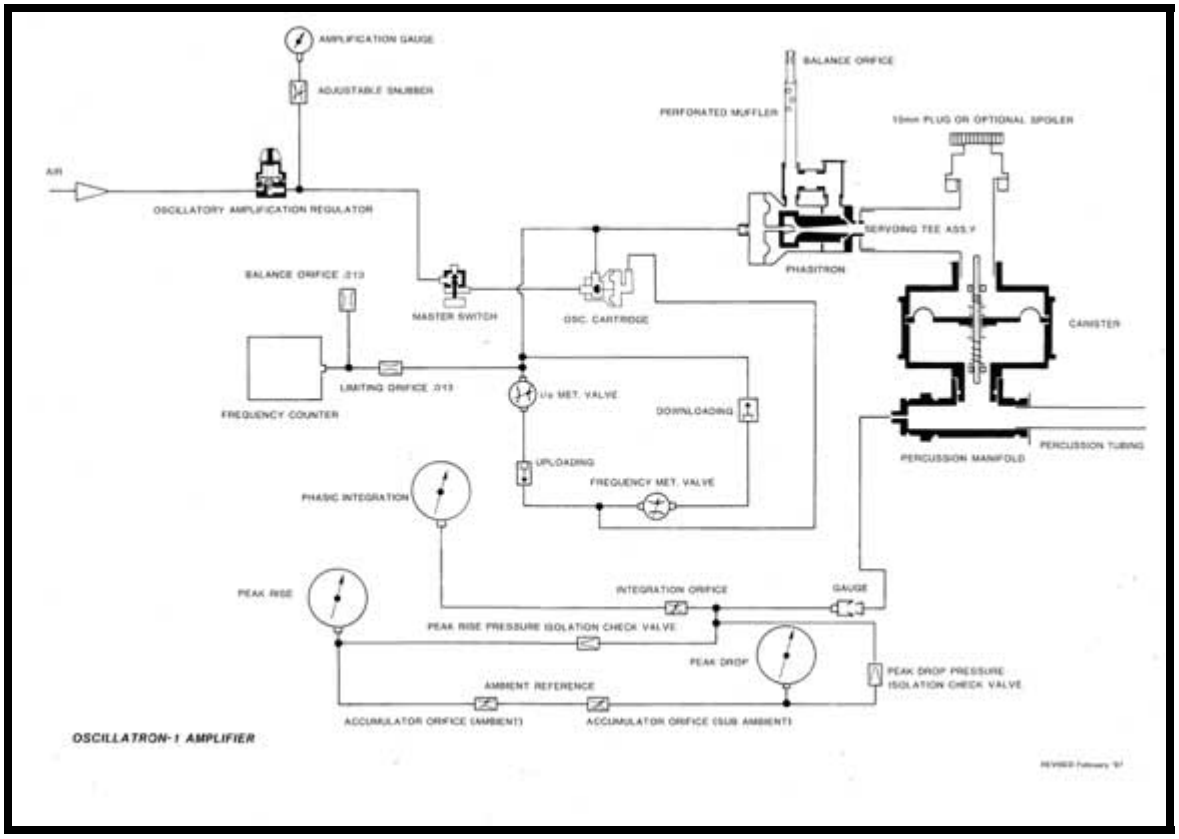



**THE INTEGRATED PERCUSSION CANISTER**

4. **The gas displaced within the percussion chamber is injected into the breathing circuit, creating a near instantaneous percussive pressure rise at the proximal airway. This produces an inspiratory flow gradient into the pulmonary airway.**

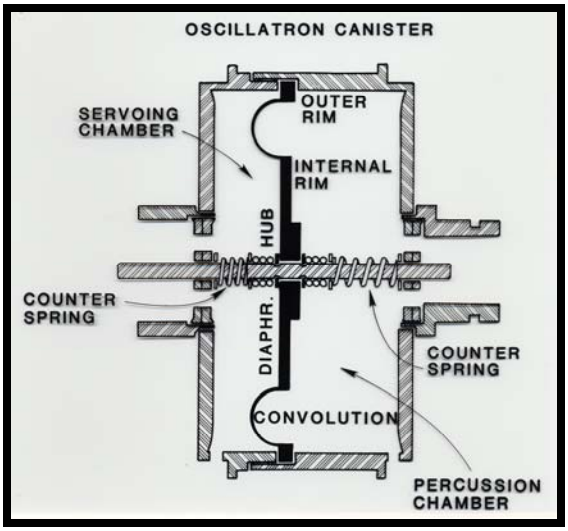
5. **Within about 4 milliseconds following the injection of the percussive tidal volume into the physiological airways, the inspiratory servoing pressure against the diaphragm "collapses" allowing the counter spring (previously compressed during the forward movement of the diaphragm) to expand against the diaphragm, creating a rapid volume expansion within the percussion chamber. As the diaphragm rapidly retreats out of the percussion chamber, a potential sub ambient pressure is created, establishing an expiratory flow gradient at the proximal end of the endotracheal tube.**

6. **It is the combination of a flow interruption valve releasing a gas, already under a selected compression, to the jet of a non-gated ambient referencing venturi which percussively moves the diaphragm forward, compressing the gas within the compression chamber of the canister, followed by the near instantaneous end Inspiratory pressure collapse within the venturi, which limits the inspiratory to expiratory flow gradient reversal time to about 7 milliseconds.**

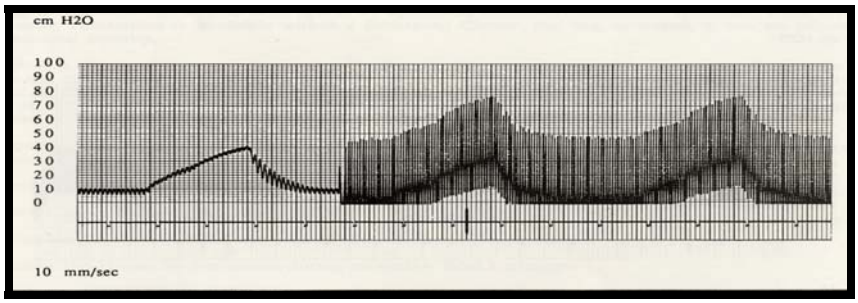



**The functional schematic of the Oscillatron® low inertia fluidic (push-pull) Percussive Oscillator.**

7. **At end inspiration, by the near instantaneous release of any countering venturi servoing pressure against the servoing side of the diaphragm, the compressed counter spring within the compression chamber freely recoils, moving the diaphragm backwards (out of the compression chamber) to create a near instantaneous potentially sub ambient expiratory flow gradient at the proximal end of the Endotracheal Tube.**




8. **Uniquely, the fluidic Oscillatron® design enables successive near constant sub tidal (stroke) volume deliveries for the modulation of convective tidal intrapulmonary CMV Pressures from 5 to 100 cm H2O.**

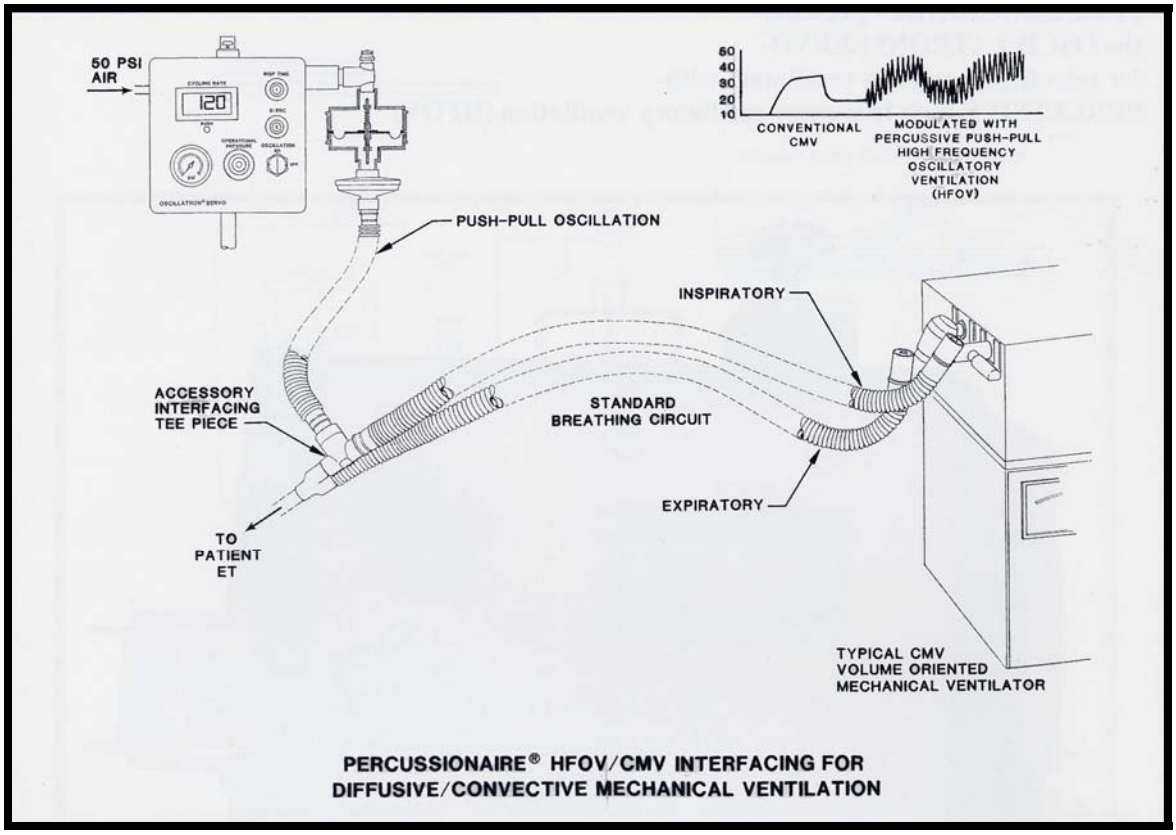



9. **The fluidic design allows the end expiratory position of the diaphragm to compensatorily over-travel into the servoing chamber in proportion to the end inspiratory proximal airway pressure increase.**

10. **This diaphragmatic re-set allows the Oscillatron® to modulate the tidal waves of CMV ventilators with near constant sub tidal volumes, with peak delivery pressures approaching 100 cm H2O.**

11. **In order to have a clinically effective percussive injection of a tidal volume into the breathing circuit, the available injection time at each frequency must maintain a near constant flow gradient, with sufficient time to deliver a scheduled tidal exchange. Without a near immediate effective expiratory potentially sub ambient flow gradient, an inadvertent PEEP would increase with frequency, mandating an increased D/FRC.**

**Another major advantage of the fluidic Oscillatron® design is that of being able to inject (near constant) high frequency tidal volumes with percussive velocities into a breathing circuit with convective tidal waves rising from near ambient to PIP's of up to 100 cm H2O.**




PERCUSSIONAIRE® HFOV/CMV INTERFACING FOR
DIFFUSIVE/CONVECTIVE MECHANICAL VENTILATION

**When High Frequency Percussive Ventilation (HFPOV™) is compared to High Frequency Oscillatory Ventilation (HFOV), the importance of the "Oscillatory Transition Penalty" becomes evident.**

**The principal clinical efficacies of High Frequency Oscillatory Ventilation (HFOV) are based upon key primary factors, which are:**

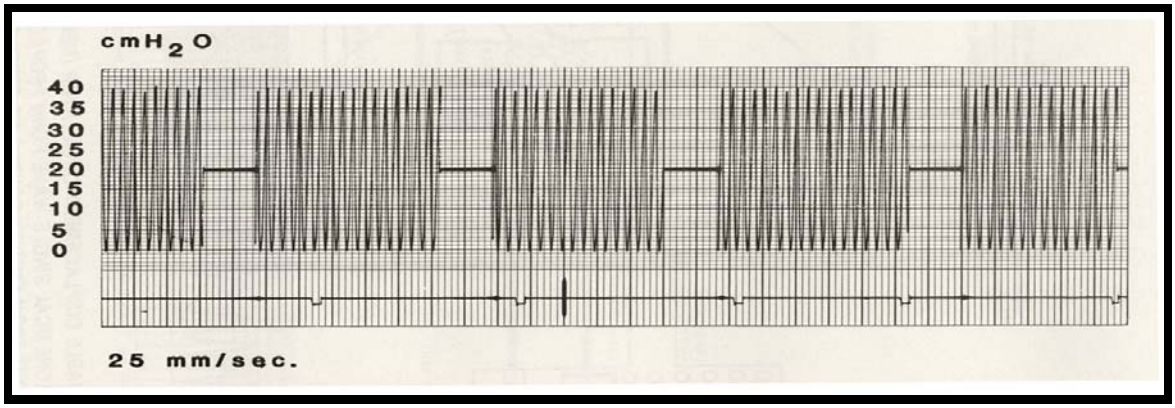
1. **Increasing the blood/gas interface by means of a Continuous Positive Airway Pressure (CPAP) to increase the Dynamic Functional Residual Volume (D/FRC).**

2. **Increasing the Final Inspiratory Oxygen Concentration ($FIO_2$).**

3. **Increasing the endobronchial mechanical mixing to enhance intrapulmonary diffusion by continuously delivering high frequency intrapulmonary tidal exchanges.**

**It follows that:**

**The less clinically effective the intrapulmonary mechanical mixing to enhance endobronchial diffusion, the greater the mandate to increase the blood/gas interface with:**




**<u>An increasing static Continuous Positive Airway Pressure (CPAP).</u>**

**An Increase in the Final Inspiratory Oxygen Concentration ($FIO_2$).**

**Therefore, the greater the high frequency pulsed tidal exchange volume, the less the required CPAP and $FIO_2$ to maintain acceptable $PaO_2$ and $PaCO_2$.**

**The higher the mandated CPAP, the higher the mean intrathoracic pressure.**

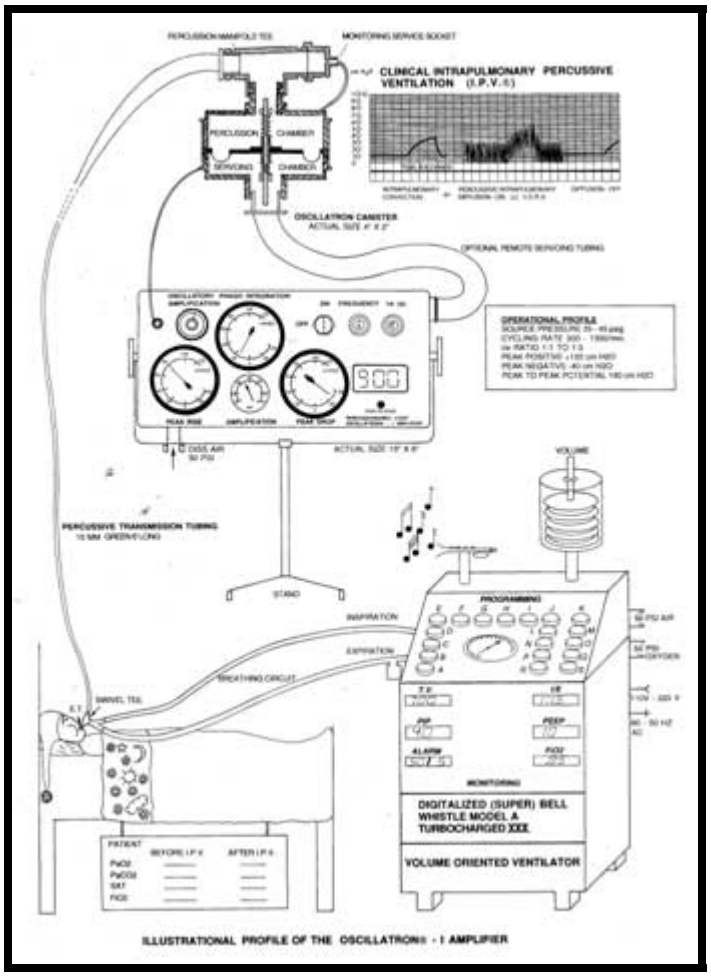
**The greater the increase in the mean intrathoracic pressure, the greater the induced pulmonary arterial pressure.**

**The greater the pulmonary arterial pressure, the greater the right heart strain and/or failure.**

**Therefore, the pulsatile (oscillatory) exchange limits of the mechanical design of the HFOV ventilator will determine the clinical efficacy of the HFOV concept.**

**Technologically, it is the high transition penalty mandated by the design of piston and magnetic HFOV oscillators that serves to inhibit their clinical efficacy. The fluidic dynamic (push-pull) percussive Oscillatron® design reduces the Oscillation transition penalty from about 42 milliseconds for HFOV to about 14 milliseconds for HFPOV™.**

**This major reduction in the HFPOV™ transition penalties allows a more effective intrapulmonary gas mixing, greatly reducing the required CPAP and $FIO_2$ requirements of HFPOV™, and effectively reducing the mean intrathoracic pressure and the imposition upon right heart function".**



ILLUSTRATIONAL PROFILE OF THE OSCILLATRON® - I AMPLIFIER

**IN SUMMARY, THE OSCILLATRON® CAN PROVIDE CERTAIN CMV VENTILATORS WITH INCREASED CLINICAL EFFICACY BY INCREASING THEIR ENDOBRONCHIAL MECHANICAL DIFFUSION.**

**THE OSCILLATRON® SERVO FOR INTERFACING CMV VENTILATORS**