PRESENTS:

THE VDR®-4 MANUAL OF UNDERSTANDING

THE INTUITIVE VDR®-4  MODEL F00008-1
(SHOWN WITH ACCESSORY MONITRON® II  MODEL F00007-1)
CONTRAINDICATIONS

Contraindications relative to the VDR®-4 Servolator® Percussionator® would be those associated with all Volume/Pressure Limited Ventilators. Among these would be:

1. Unvented Pneumothoracies.
2. The maintenance of a High Mean Intrathoracic Pressure, with low Vascular Volumes.
3. The maintenance of a sustained Intrathoracic Pressure sufficient to block normal venous return.
4. Using a VDR-4 Servolator on a Patient without the general Operational Knowledge contained in this Manual.
5. Do not employ VDR as a constant Oscillation Device without programming Baseline Interruptions.

CLINICAL QUALIFICATION

The VDR-4 Sinusoidal Percussionator is to be used only under the direction of a Qualified Physician.

The VDR-4 can be scheduled for Intrapulmonary Percussive Ventilation (IPV) with Volumetric Diffusive Respiratory (VDR) Programming as a "Stand Alone" full time Diffusive/Convective Mechanical Percussionator®.

The greater the Clinicians knowledge of his or her Basic Sciences as well as of Administering to those Critical Cardiopulmonary Impaired Patients, where the Clinicians functional knowledge and judgment is paramount in terms of Survival; the greater the qualification to Program and Administer Percussive Diffusive/Convective Ventilatory Scheduling; HIGH FREQUENCY OSCILLATORY VENTILATION (HFOV).

WARNINGS

1. As is inherent to all positive pressure ventilators, improved compliance and increased intrathoracic pressures may cause a decrease in venous return, which in turn may result in decreased cardiac output and may increase the risk for intraventricular hemorrhage for neonates.
2. During VDR-4 ventilation it is important to maintain an unobstructed and unrestricted airway. Only proximal airway pressure is monitored, which in the event of an obstructed or restricted airway, alarming may not occur. Proper succioning procedures should be followed to maintain a patent airway. Regular patient assessment along with continuous monitoring of TcPO2, TcPCO2, SpO2, End tidal CO2, are needed to ensure that blood gases are at the proper level.
3. Deviation from manufacture suggested assembly could cause the VDR-4 to malfunction. Any questions regarding the assembly should be made to Percussionaire Corporation.
4. If the VDR-4 is connected with a Monitron Waveform analyzer, a hospital grade AC power plug is provided. Grounding reliability can only be guaranteed if connected to a tested hospital grade outlet. Any alteration to proper connection may cause damage to equipment and could cause harm to the patient or personnel associated with the device.
5. The VDR-4 failsafe breathing circuit is specifically designed for use with the VDR-4 Percussionator®. Any attempt to substitute another circuit or configuration could result in injury to patients or operator and damage to the equipment.

6. Proper care needs to be taken during set-up operation to ensure all lines running to or from patient circuit are not crimped or perforated. Failure to conform could cause malfunction of alarms and or pressure limit controls.

7. Proper support and orientation of patient circuit must be made to avoid inadvertent disconnection.

8. Functional evaluations and start-up procedures must be followed before ventilation of a new patient commences. If during the functional evaluation and start-up procedure any abnormal function is noted with the VDR-4 Percussionator® do not start with patient ventilation. Failure to comply could cause injury or death to the patient.

9. Proper operation must be verified prior to each use. Alarm functions tested in this guide verify the capability of the device to detect conditions that could have deleterious effects to the patient.

10. Audible alarming could indicate a potentially harmful situation and should be attended to immediately. Failure to comply could result in injury or death to the patient and or damage to the Percussionator®.

11. While the VDR-4 is being used to ventilate a patient, trained personnel should be in attendance to monitor and react to any alarms or other problems.

12. Administration of excessive oxygen to a patient may be harmful. The prescribed oxygen concentration delivered by the blending system should be verified with an oxygen analyzer.

13. Water traps should be drained at intervals to prevent the possibility of injury to the patient or damage to the equipment.

14. Maintenance procedures must be complied with. Failure may result in injury to the patient or operator and could result in damage to the equipment.

15. Proximal airway filter should be changed between patients and when moisture is noted to be downstream of filter. Failure to replace filter when necessary could result in patient injury and/or damage to the equipment.

16. The user must not open Percussionator® or its attached Monitron. To avoid electrical shock and possible damage to the equipment refer all servicing to an authorized Maintenance/Calibration Center.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contraindications/Warnings</td>
<td>2</td>
</tr>
<tr>
<td>Introduction</td>
<td>5</td>
</tr>
<tr>
<td>Description of Controls</td>
<td>6</td>
</tr>
<tr>
<td>Functional Evaluation</td>
<td>8</td>
</tr>
<tr>
<td>General Discussion and Historical Review</td>
<td>14</td>
</tr>
<tr>
<td>Clinical Evaluations</td>
<td>22</td>
</tr>
<tr>
<td>Exploring New Directions for Ventilator Designs</td>
<td>24</td>
</tr>
<tr>
<td>The Technological Challenges of Effective High Frequency Ventilation</td>
<td>26</td>
</tr>
<tr>
<td>The Logic for Intrapulmonary Percussive Ventilation (IPV®)</td>
<td>29</td>
</tr>
<tr>
<td>The Historical Profile and Logic of Volumetric Diffusive Respiration (VDR®)</td>
<td>29</td>
</tr>
<tr>
<td>Understanding VDR®-4 Scheduling Logic</td>
<td>40</td>
</tr>
<tr>
<td>VDR®-4 Percussionator® Clinical Programming</td>
<td>42</td>
</tr>
<tr>
<td>Immediate Preclinical Inservice</td>
<td>42</td>
</tr>
<tr>
<td>Programming the Monitron II</td>
<td>43</td>
</tr>
<tr>
<td>General Patient Programming</td>
<td>43</td>
</tr>
<tr>
<td>Prepare Airway Connection</td>
<td>44</td>
</tr>
<tr>
<td>Make Physiological Airway Connection</td>
<td>44</td>
</tr>
<tr>
<td>Procedural Logic</td>
<td>45</td>
</tr>
<tr>
<td>On-Patient Programming</td>
<td>46</td>
</tr>
<tr>
<td>Trend Analysis</td>
<td>47</td>
</tr>
<tr>
<td>Blood Gas Analysis</td>
<td>48</td>
</tr>
<tr>
<td>To Wean</td>
<td>48</td>
</tr>
<tr>
<td>Post Recovery</td>
<td>49</td>
</tr>
</tbody>
</table>

## APPENDICES

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit Specifications</td>
<td>50</td>
</tr>
<tr>
<td>Troubleshooting</td>
<td>50</td>
</tr>
<tr>
<td>Service and Repair</td>
<td>52</td>
</tr>
<tr>
<td>Storage</td>
<td>52</td>
</tr>
<tr>
<td>Disposal of Equipment</td>
<td>53</td>
</tr>
<tr>
<td>Shipping Information</td>
<td>53</td>
</tr>
<tr>
<td>Glossary of Symbols</td>
<td>54</td>
</tr>
<tr>
<td>Glossary of Terms</td>
<td>55</td>
</tr>
<tr>
<td>General Cleaning and Decontamination</td>
<td>59</td>
</tr>
</tbody>
</table>
INTRODUCTION

VOLUMETRIC DIFFUSIVE RESPIRATION (VDR®) was conceived as a clinical rationale by Dr. Forrest M. Bird in the late 1970’s AS AN EFFECTIVE UNIVERSAL DIFFUSIVE/CONVECTIVE VENTILATION FOR NEONATES THROUGH PEDIATRICS TO THE LARGEST ADULTS

THE PERCUSSIONAIRE® VDR®-4 HIGH FREQUENCY PERCUSSIVE VENTILATION (HFPV™) IS THE PROFESSIONAL VENTILATOR FOR “THE PROFESSIONAL CLINICIAN”

HIGH FREQUENCY OSCILLATORY DEMAND CPAP SUPPORTING SPONTANEOUS RESPIRATION

TYPICAL MULTIPLE STAGE VDR®PERCUSSIVE LUNG INFLATION

THE UNIQUE VDR®-4 CRITICAL CARE VENTILATOR provides DIFFUSIVE/CONVECTIVE CARDIOPULMONARY SUPPORT to the most critical Neonates through Pediatrics to the largest Adult
DESCRIPTION OF CONTROLS

Interface Harness to Phasitron/Patient

1. PULSATILE FLOWRAT
2. Insp.
3. Exs.
4. Oscillator
5. Dem.
6. Pressure
7. Interface
8. Interface
9. Interface
10. Interface
11. Interface
12. Interface
13. Interface
14. Interface
15. Selected Operating Pressure
16. Proximal Airway Pressure
17. Increase
18. Decrease
19. Integrated Manometer

MAXIMUM OPERATIONAL PRESSURE RISE LIMITED BY INSTITUTIONAL DEMAND FLOW/PRESSURE
DESCRIPTION OF CONTROLS

FRONT FACE PANEL

1. Pulsatile Flowrate:
   Determines the amplitude or peak inspiratory pressure (PIP) delivered to the patient during inspiratory time.

2. Inspiratory Time:
   Selects the time interval (programmable from 0.5 seconds to 5 seconds) that high frequency volumes are delivered to which the amplitude or PIP is determined by the Pulsatile Flowrate control.

3. Expiratory Time:
   Selects the interval (programmable from 0.5 seconds to 5 seconds) that high frequency volumes are not being delivered. Expiratory time can be programmed for Oscillatory/Demand CPAP/PEEP or a static baseline.

4. Oscillatory CPAP/PEEP:
   Provides for a high frequency baseline pressure during the expiratory phase.

5. Demand CPAP/PEEP:
   Provides for the establishment of “static PEEP” that automatically increases flow to the patient as the inspiratory demand warrants.

6. Convective Pressure Rise:
   Programmed to occur 1 second into the inspiratory phase when activated and controls the pressure rise above that programmed with the Pulsatile Flowrate. To be used with caution and when low compliance requires very high delivery pressures.

7. Pulse i/e Ratio:
   Controls the i/e ratio of the high frequency volumes delivered.

8. Pulse Frequency:
   Controls the rate of the high frequency volumes delivered.

9. Reset Alert:
   Reset Alarm Circuit

10. Nebulization:
    Controls the flow of gas to the aerosol circuit.

11. Manual Inspiration:
    Deliver a regulated source of gas through the orifice of the Phasitron Venturi. The longer the button is held depressed the greater the potential for tidal volume delivery.

12. Master:
    Activates unit when placed into the on position. When master switch is in off position Manual Inspiration, Nebulization, Demand CPAP/Peep are still functional for weaning purposes.

13. Failsafe Sensitivity:
    Limits a maximum sustained pressure over a programmed time.

14. Alarm Body

TOP PANEL

15. OPERATING PRESSURE CONTROL:
    Controls the peak operating pressure of the entire Percussionator®. This control at maximum output will only provide pressure slightly less than that of the institution. In the USA optimal pressure is 50 psi.

16. Operating Pressure Gauge

17. Proximal Airway Pressure Gauge

18. FiO₂:
    Allows selection of oxygen concentrations from 21% to 99+ %

19. INTEGRATED MANOMETER:
    In the on position manometer will display orficed pressure readings, collected over time that approximate carinal pressures. In the off position an orficed breath by breath proximal airway pressure is displayed on the manometer.
FUNCTIONAL EVALUATION
FOR:
VDR®-4
Models: F00008-1

PURPOSE:  The post calibration check and in-service functional evaluation must be periodically performed on the SERVOLATOR® VDR-4® PERCUSSIONATOR by a qualified individual.

For process of evaluation, it shall be assumed that the VDR®-4 has been calibrated in accordance with Percussionaire® Calibration Procedures and is in operational configuration.

The VDR®-4 must be set up with a standard VDR® Failsafe breathing circuit with the Percussionaire® Phasitron® outlet obstructed. Evaluation provides for broad calibration.

Check the box and fill in all values where applicable at each step after satisfactory function is confirmed. The Individual performing the Inspection must sign and date on the last page.

REQUIRED TEST EQUIPMENT

Waveform Monitron® II Analyzer Part#: F00007-1
Stop Watch, Analog or Digital. Note: if using analog stopwatch 30 second version advised.
Standard Percussionaire® VDR® Breathing Circuit Part # A50094
Waveform Monitron® II Interfacing Harnesses are needed if Waveform Monitron® II is not attached to unit, Part#: A99544

PERFORM FUNCTION EVALUATION

Steps

1. Program and check as follows:

   A. Rotate all Alpha control knobs until their Arrows are under their Indexes, except DEMAND CPAP. NEBULIZATION toggled OFF.

   B. Rotate MASTER Switch to "OFF".

   C. Switch INTEGRATED MANOMETER to "OFF"

   D. Observe Manometer, for Needle at zero.

   E. Observe Operating Pressure Needle at zero (source gases Air and Oxygen OFF).

   F. Adjust PRESSURE REDUCTION regulator by rotating the control knob full counterclockwise, then four (4) turns (clockwise).

   G. Inspect Housing for condition and cleanliness.

   H. Check Handle Bar for condition and frictional locking.

   I. Check labeling and entry coding seal.

   J. Check all retention screws and washers for security.
K. Carefully examine all visible components and fittings for integrity.

Note: VDR®-4 must be connected to both Oxygen and Air with 50+ psi sources activated, providing for sufficient Demand Flow.

2.

A. Establish a static Operational Pressure of 40 psig. LISTEN FOR GAS LEAKS.

B. Toggle NEBULIZER Switch UP to ON. Check for Nebulizer flow. Then move Toggle Switch down to OFF.

C. Evaluate MANUAL INSPIRATION by Depressing Black Button until pressure rises to over 20 cm H2O and then release. Actual

3.

Evaluate Inspiratory Time:

A. Rotate MASTER SWITCH “ON”.

B. Rotate INSPIRATORY TIME control knob full (counterclockwise). Observe time of under one (1) second. Actual

C. Rotate INSPIRATORY TIME control knob full (counterclockwise) against stop. Observe time between 10-25 seconds. Actual

D. Return INSPIRATORY TIME control knob to Arrow under Index position. Observe time of about two (2) seconds. Actual

4.

Evaluate Expiratory Time:

A. Rotate EXPIRATORY TIME control knob full (clockwise). Observe time of under one (1) second. Actual

B. Rotate EXPIRATORY TIME control knob full (counterclockwise) against stop. Observe time of 10-25 seconds. Actual

C. Return EXPIRATORY TIME control knob to arrow under Index position. Observe time of about two (2) seconds. Actual

5.

Check Failsafe Alarming:

A. Rotate INSPIRATORY TIME control knob with (3) under the 12:00 index.

B. Rotate CONVEXTIVE PRESSURE RISE to the full (counterclockwise) position.

C. With the FAILSAFE SENSITIVITY control knob arrow under the index, alarming and associated pressure drop should occur after about two (2) seconds.

D. Observe a major airway pressure drop.
E. Re-set the FAILSAFE SENSITIVITY Alarm by depressing and releasing the Red Re-Set Button. The Failsafe Alarm and Pressure drop should occur again within several seconds.

F. Rotate the CONVECTIVE PRESSURE RISE control knob (C) clockwise to the full "OFF" position. Silence Alarming, by depressing Red Reset Button and releasing.

G. Occlude the white Phasitron tubing in the Interfacing Harness. Alarming should occur in about two to three seconds. Release occlusion then push and release ALERT RESET button to de-activate alarm.

H. Occlude green Accessory tubing of Interfacing Harness. Little, if any, change should be observed.

NOTE: If a functional change does occur, the oscillatory frequency may decrease with a peak delivery pressure rise of not over 15 cm H2O. Upon release of occlusion, normal function must return.

6. Check Blender with unit running:

Note: In order to have a High Flow Blender Alarm function it is necessary to have a High Flow through the VDR-4.

A. Turn only Oxygen valve to "OFF". Note: Blender alarming with operating pressure rise to over 20 psig. Turn Oxygen source "ON".

B. Turn only Air valve to "OFF". Note: Blender alarming with operating pressure rise to over 20 psig.

C. With both Air and Oxygen sources back "ON", alarm should mute.

D. Rotate oxygen selection knob (FiO2) full clockwise then full counterclockwise and finally to 60%. Observe, there should be little, if any, operational pressure change.

7. Check PULSE FREQUENCY:

Rotate ALL control knobs with their Arrows under their 12:00 indexes except the DEMAND CPAP control knob Arrow full (clockwise).

A. Observe a Pulse Frequency between 500 and 650 cycles per minute.

   Actual___________

B. Rotate PULSATILE FLOWRATE and INSPIRATORY TIME control knobs until (3) is under their 12:00 indexes.

C. Rotate PULSE FREQUENCY and i/e RATIO control knobs full (clockwise).

D. Observe a Pulse Frequency below 200 cycles per minute.
E. Rotate all control knob Arrows under their 12:00 indexes except the DEMAND CPAP control knob full (clockwise).

F. Rotate PULSE FREQUENCY (I) and PULSE i/e RATIO (E) control knobs full (counterclockwise).

G. Observe Monitron for a pulse frequency of over 800 cycles per minute.

---

8. Evaluate Integrated Manometer System:

Note: With a fixed orifice the pressure drop across the orifice will determine flow. Therefore, the Integrated Pressure will drop progressively slower as the gas volumes locked up in the Integrated Monitoring circuit are bled off to ambient.

To check Calibration:

A. Rotate INSPIRATORY TIME control knob with (3) under the 12:00 index.

B. Select a 60 cm H2O peak oscillatory pressure on the Manometer with the PULSATILE FLOWRATE control knob.

C. When pressure reaches above 60 cm H2O on Manometer, simultaneously rotate Integrated Manometer switch to “ON” and Master Switch to “OFF.”

D. Immediately start Stop Watch. Time for a Manometer needle pressure drop from 50 to zero in about fifteen to thirty (15-30) seconds.

9. Check operating pressure ranges:

A. Rotate INTEGRATED MANOMETER switch to "OFF".

B. Rotate MASTER switch "ON".

C. Rotate INSPIRATORY TIME control knob with the arrow under the 12:00 index for about a two (2) second interval.

D. Rotate PULSATILE FLOWRATE, PULSE FREQUENCY and PULSE i/e RATIO control knobs with their arrows under their indexes.

E. Rotate CONVECTIVE PRESSURE RISE, PULSATILE FLOWRATE and OSCILLATORY CPAP/PEEP control knobs until (4) is under their indexes.

NOTE: If FAILSAFE ALARM sounds, rotate red FAILSAFE control knob Arrow full (clockwise). If it still sounds reduce CONVECTIVE PRESSURE rise to 100 cm H2O by rotating convective Pressure Rise Control knob clockwise.
F. Reduce operational pressure with Reduction Regulator control knob to an operational Gauge pressure of 35 psig.

G. Observe a continuous pulse frequency with a three step pressure rise, each being over 5 cm H2O during progressive Phasing.

H. Increase operational pressure to 40 psi during cycling.

I. Rotate PULSATILE FLOWRATE and OSCILLATORY CPAP/PEEP control knobs until their arrows are under their Indexes.

J. Rotate CONVEXTIVE PRESSURE RISE (C) control knob Arrow (counterclockwise) until five (5) is under the 12:00 index.

K. Observe, proximal airway manometer for a pressure rise of over 60 cm H2O.

L. Rotate Master Switch to "OFF".

M. Select a static Operational Pressure of 40 psig.

N. Rotate Master Switch back "ON".

O. Observe, Flow acceleration must start after one (1) second into the inspiratory interval.

P. Rotate CONVEXTIVE PRESSURE RISE (C) control knob until arrow is under the index.

Q. Rotate PULSATILE FLOWRATE (F) control knob full (counterclockwise).

R. Observe the Proximal airway Manometer for a pressure rise of over 70 cm H2O.

S. Rotate PULSATILE FLOWRATE (F) control knob until Arrow is under 12:00 index.

10. Check OSCILLATORY CPAP/PEEP:

A. Rotate OSCILLATORY CPAP/PEEP (O) control knobs full (counterclockwise).

B. Observe an Oscillatory CPAP/PEEP of between 25-35 cm H2O.

C. Rotate OSCILLATORY CPAP/PEEP (O) control knob Arrow under the 12:00 index.

11. Rotate MASTER SWITCH to OFF.

A. Rotate DEMAND CPAP/PEEP control knob full counterclockwise for a static CPAP/PEEP of 15-20 cm H2O.
B. Then rotate DEMAND CPAP/PEEP control knob arrow under the 12:00 index for a static CPAP/PEEP of 4-6 cm H2O.

Actual__________

C. Rotate DEMAND CPAP/PEEP control knob Arrow full (clockwise) to OFF.

Check interval phasing rate (pulsatile interruptions):

A. Rotate MASTER SWITCH to ON.

B. Rotate PULSATILE FREQUENCY and PULSE i/e RATIO (E) control knobs full (counterclockwise).

C. Rotate INSPIRATORY TIME (I) and EXPIRATORY TIME (E) control knobs full (clockwise).

D. Observe a Phasing Rate of over 40 cycles per minute.

Actual__________

E. Rotate all Alpha control knob arrows under their 12:00 indexes except DEMAND CPAP/PEEP, which is to be rotated full (clockwise).

F. Rotate MASTER SWITCH to "OFF". Re-torque ALL control knob set screws.

The broad span SERVOLATOR® VDR®-4 functional evaluation is now complete. This functional evaluation checks individual indexed values within specified limits while maintaining interlocking of functions. If all parameters do not comply, investigate causes of deviation and correct before entering the device into clinical service.

COMPLIANCE INSTRUCTIONS

Check the box and fill in all values where applicable at each step after satisfactory function is confirmed. The Individual performing the Inspection must sign and date on the last page.

DEVICE SERIAL NUMBER: ________________________________

Name: ________________________________________________

Date: ________________________________________________

If not at Percussionaire® Corporation Sandpoint, Idaho, USA location, fill out the following:

Company: ______________________________________________
Address: ______________________________________________
________________________________________
________________________________________

F-070505FE DCO 10274 06-07-10
GENERAL DISCUSSION AND HISTORICAL REVIEW

The next few pages provide a critical review of the impact anesthesiology and pathophysiology have had upon the various controls imposed upon cardiopulmonary functions in patients under stress.

VOLUMETRIC DIFFUSIVE RESPIRATION (VDR®): the CRITICAL CARDIOPULMONARY CARE VERSION OF INTRAPULMONARY PERCUSSIVE VENTILATION (IPV®)

NOTE:
The purpose of this document is to provide clear and concise clinical differences between CMV volume-pressure limited ventilators designed to ventilate near normal lungs and VOLUMETRIC DIFFUSIVE RESPIRATION (VDR®) conceived to recruit and maintain lungs with major pathologic alterations.

The oversimplified concept for the Continuous Mechanical Ventilation of the lungs (CMV) was based upon engineering concepts and not pathophysiological consequences. Original CMV scheduling was designed upon the selection of a tidal volume to be delivered intrapulmonarily under a selected arbitrary peak delivery pressure at a cyclic breathing rate determined by the size of the patient. First generation constant volume pressure variable ventilators were controllers only. That is, they did not assist a patient’s spontaneous ventilation. Therefore, they functioned best on an apneic patient.

After WW II, Dr. Forrest M. Bird, who was basically an Aeronautical Engineer with extensive knowledge in the realm of fluid dynamics (air flows), received a substantial medical education directed more toward the understanding of clinical cardiopulmonary pathophysiology than everyday routine patient care. By 1951 Dr. Bird employed logic he had conceived in the development of an anti g suit regulator for pilots, along with other innovative considerations, to ventilate diseased lungs with a unique flow variable pressure limited device.

Dr. Bird’s exposure to Anesthesiology had provided him with a number of critical learning experiences that would influence his respirator design as a universal variable flowrate, sensitivity (patient effort) and pressure selectable assister controller respirator. Among these were:

1. The “educated hand” of the Anesthetist on their anesthesia bags allowed them to control a patient’s ventilation by varying the “inspiratory flowrate” in accordance with the ever changing compliance of the patient’s lungs.
2. Rarely if ever did the Anesthetist experience hyper-inflational barotrauma.

3. There were no numbers on the anesthesia bag. The patient was monitored by looking or feeling the excursion of the chest.

   In other words, the bag was squeezed, controlling the “inspiratory flowrate” until the arbitrary desired tidal exchange was obtained. Flow and Pressure was respected as being two different entities, realizing that when a constant flow of gas is obstructed, the pressure is increased, thus sensed in the bag. Backing up the Anesthetist perceptions were their ability to respond to changes in vital signs.

4. While a sub-ambient phase was not employed by Anesthetists, they were aware that with small endotracheal tubes used on babies, the mechanical expiratory resistance within the tube opposing the physiologically exhalation of inhaled gases could be reduced by a controlled initial expiratory sub-ambient expiratory pressure at the proximal end of the tube.

5. One concept was to rapidly fill the lungs with a very high inspiratory flowrate under a steep proximal to distal flow gradient with a very short inspiratory time. This considered the fact that it is not the instantaneous peak endobronchial delivery pressures, which create barotraumas, it is the sustenance of high intrapulmonary (e.g. apneustic plateau) pressures which produce the hyperinflational barotraumas. This logic produced PREFERENTIAL AIRWAY DELIVERY into the most patent airways hyper-inflating the most dependent alveoli.

6. Initially Volume oriented pressure limited mechanical ventilators would produce hyperinflational barotrauma (which usually was not reported).
One particular CMV ventilator delivered a programmed tidal volume into the lungs which was followed by a post inspiratory timed proximal airway “lock up.” The claim was that intrapulmonary pressures and alveolar volumes would equalize.

7. This did not consider intrapulmonary pendelluft, which, due to elastomeric tissue differentials, hyper-inflated the already maximally inflated dependent alveoli thus creating hyperinflational barotrauma with a constant pressure.

8. CMV with constant tidal exchange delivered under variable pressure limits functions on the principal that a constant flow x time = a tidal volume. If the programmed tidal exchange is delivered against a lung with a very low compliance, a potential high pressure dissecting square wave is created.

These potential square tidal waves were usually modified by high compliance (amount of give for the amount of push) in the ventilator breathing circuits as well as the elastomeric give within the patient’s lungs, providing the patient’s peripheral airways had minimal obstruction, thus reducing barotraumatic potential.

9. By the end of the 1970’s, with the Anesthesiologist’s transition out of the ICUs they had earlier created, came a new group of clinicians who called themselves “Pulmonologists”. The Pulmonologists for the most part had a background in internal medicine, which directed their management toward chronic cardiopulmonary patients who were treated more on a pharmacological basis rather than from a point of combined mechanical pharmacological management.

The training of the Anesthesiologist was based upon the need for near instantaneous decision making, when a patient became acute with a life-threatening cardiopulmonary emergency during a surgical procedure.
In contrast, the Pulmonologist’s clinical protocols were based upon clinical regimes that became effective over hours, days or even months in the management of chronic cardiopulmonary diseases.

In terms of respiratory management, the Anesthesiologist, beyond their standard medical education, developed a clinical sixth sense based upon the ability to recognize an impending cardio-respiratory failure by the observance of the patient’s vital signs.

The Anesthesiologist learned to manage the patient with acute rapid circulatory and respiratory changes secondary to a vast array of elective and trauma related surgical procedures. This prepared the well-trained Anesthesiologist to manage post operative as well as routine CRITICAL CARE in the Surgical and Trauma Intensive Care Unit (SICU) on an immediate response basis.

The Anesthesiologist learned to ventilate the patient based upon each patient being their own control, instead of assuming all patients would respond essentially the same in terms of cardiopulmonary management. The Pulmonologist, lacking this clinical “sixth recognition sense” possessed by the Anesthesiologist, established the measurement of a TIDAL EXCHANGE VOLUME assuming all patients would initially respond essentially the same.

Knob twisting Clinicians are becoming increasingly dependent upon a high echelon of certain Respiratory Therapists and Critical Care Nurses to use their overall knowledge of many procedural alternatives as well as hands on patient experience to mechanically titrate PATIENTS with acute cardiopulmonary compromise. All to often the supervising Clinician may be limited to the basic understanding of CMV volume oriented pressure limited ventilators which are limited by design (FDA 510K operational restrictions circa 5-28-1976) to the ventilation of near normal peripheral lungs.

Continuous Mechanical Ventilation (CMV) has become accepted as CONVENTIONAL MECHANICAL VENTILATION OF THE LUNG, which basically means a ventilatory device designed to deliver a selected tidal volume (based upon a nomogram) under an arbitrary SELECTED peak delivery pressure (PIP).

The amount of the peak selected delivery pressure used to deliver the tidal volume will be determined by the selected tidal volume and the gross pulmonary compliance. The only other effective selectable variable available to clinicians programming the typical CMV Ventilator is the FIO2.

In effect, when a ventilator patient’s gross pulmonary compliance is altered by increasing diffuse airway obstruction and interstitial resistances, the CMV ventilators provide the clinician with only two BASIC options, one of which is FIO2 the other is increasing the peak delivery pressure (PIP).

Ventilator monitors looking at ventilatory wave-forms and digital programming are all based upon sensors looking at FLOW, PRESSURE, TIME and VOLUME, wherever the site of measurement is located.

In the end, no matter how a CONVENTIONAL CMV device delivers inspiratory tidal exchanges or provides for expiratory PEEP or CPAP under a selected FIO2, the COPD
patient will experience progressive mandated hyperinflational barotraumas dependent upon programming.

In the end, CMV scheduling with all the compensatory programming with decreasing gross pulmonary compliance will provide the clinician with only two options, which are:

1. Stop CMV ventilation before a tidal volume delivered under a PIP produces preferential barotraumas, allowing the patient to expire.

2. Continue increasing the peak inspiratory delivery pressures (PIP) required to deliver the selected tidal volume, inserting chest tubes as the pneumothoracies occur.

Finally, the procedural caused Infant or Adult (ACUTE) Respiratory Distress Syndrome or hyperinflationally induced barotrauma will ultimately cause death.

With the advantages and limitations of CMV constant flow/volume oriented pressure limited ventilation explored, the text will revert back in time to various rationales Dr. Bird employed to conceive four progressive generations of mechanical cardiopulmonary support devices.

This earlier exploration lead toward 2006 when this document was created, much of which data is abstracted from Dr. Bird’s lifetime of documentation.
In 1947 Dr. Bird designed a "manual positive pressure device" with an expiratory retard and concomitant aerosol delivery for COPD patient's use during home care. Later this device was used in a study to determine the inspiratory flowrates intuitively selected by patients with the various forms of chronic cardiopulmonary diseases. For example:

Patients with fibrotic lungs selected a long slow fill of the lungs.

Patients with advanced pulmonary emphysema filled their lungs with moderate inspiratory rates, creating an expiratory resistance (retard) to end exhalation.

Patients with chronic left ventricular failure filled their lungs with short inspiratory bursts, maintaining a partial inflation of the lungs (CPAP) by shortening the expiratory phase.

While Dr. Bird rationalized the pathophysiological factors associated with the mechanical ventilation of the lungs, as they would impact upon a respirator design, he also considered associated mechanical factors based upon his knowledge of fluid dynamics.

A review of the learning curves developed during the operational perfection of the aircraft rubber deicing boots used to crack accumulated ice from the forward part of aircraft wings is relevant to respirator design.

Initially, the boots functioned well in breaking up the ice on the wing areas nearest to the airplane fuselage (cabin). However, the tapering airplane wing panels were not proportionately deiced outward toward the wing tips, allowing dangerous ice accumulations on the outer wings.

The expandable rubber deicing boots were designed with lengthwise labyrinthic (channel type) bladders starting at the fuselage decreasing in size as they traveled outward toward the wingtips.

The deicing boots were periodically inflated by a reservoir of compressed air delivered from a valve with a timed opening phase. Initial programming provided for a rapid short (timed) high flowrate blast of compressed air into the bladders of the deicing boots (delivering into
the large end of the bladders), which proportionately decreased in size toward the outer wing panels leading to the wing tips. This resulted in preferential boot expansion.

It was discovered that by restricting the flow rate of the expansive air into the deicing boots and lengthening the filling (inspiratory) time of the elastomeric boots, the boots expanded all the way to the wing tips, deicing the entire wing.

By analogy, when a long tapering funnel-type elastic tube is being used with a positive pressure (as during inspiration) to fill an elastic reservoir at the distal end, it requires more inflational energy to inflate the reservoir than it does to empty the gas from the expanded elastic reservoir through the constantly expanding tubing caliber, venting to a lower ambient pressure. This is in part due to a rudimentary venturi effect.

These physical factors are expanded upon when one considers there are some thirty or more bifurcating pulmonary airways providing flow in and out of the millions of very small pulmonary bronchioles serving their alveoli. Pulmonary airways vary in size from some four fifths of an inch within the trachea to a diameter about the size of a human hair as they enter the alveoli.

During exhalation, as the collateral flow from the alveoli under a positive pressure (created by the recoil of the expanded elastomeric alveoli and peripheral bronchioles) is discharged into expanding bifurcating airways leading out of the lungs, a multiple rudimentary central venturi system is created, thus enhancing the physiological expiratory flow of gases out of the lungs.

Another well recognized fact, is that during the mechanical ventilation of the lung it requires much less mean inflationary pressure to assist a spontaneous inspiration to a tidal volume than it does to deliver a controlled tidal volume into the lungs of an apneic patient.

The lessons learned from the inflation and deflation of aircraft deicing wing boots taught Dr. Bird that his projected medical respirator must have a manually adjustable inspiratory flowrate to enhance alveolar distribution.

In principal, by lengthening the inspiratory time and decreasing the inspiratory flowrate, the flow gradient from the proximal to distal airways would be decreased allowing a more uniform alveolar gas distribution.

It follows that patients with fibrotic lung structures and COPD require much less inspiratory flowrate than a patient with polio having essentially normal lungs.

While Dr. Bird’s manually adjustable inspiratory flowrate selection did allow the skilled clinician to approximate a more uniform alveolar distribution, the constant selected inspiratory flow, when endobronchially obstructed, was capable of a disproportionate alveolar inflational pressure rise.

In practice, Dr. Bird had to imitate the “educated hand” on the anesthesia bag. In other words, a programmed inspiratory flowrate had to automatically vary nearly instantaneously to comply with the constantly changing variable resistances to endobronchial inflow during the mechanical inflation of the lung.
Dr. Bird, from his knowledge of fluid dynamics, designed a venturi tube employing a circular airfoil design used on the straight wings of aircraft. The proximal (entrainment) end of the venturi tube accessed ambient. The distal end of the venturi tube directed flow into the proximal physiological airway through a mechanical exhalation valve.

The adjustable inspiratory flowrate delivered a constant selected flow of a cyclic respiratory gas into the jet of the venturi. The basic velocity of flow through the throat of the venturi (without resistance to distal outflow from the end of the venturi tube) would entrain (suck in) about 5 molecules of ambient mixing air for each pressurized molecule of oxygen injected from the jet into the venturi throat.

As the lungs were inspiratorily inflated (at a selected inspiratory flowrate) by venturi outflow, the ever increasing inflationary pressures developed by intrapulmonary resistances to endobronchial inflow were retrograded back into the distal end of the venturi tube, decreasing the primary jet flow velocity through the throat of the venturi.

As the jet flow velocity through the venturi throat was variably impaired by physiological airway pressure regression, the secondary venturi entrainment gradient to ambient would vary downward from a maximum entrainment ratio of 1:5 all the way down to 1:1, against a near total endobronchial obstruction. Thus, the programming of a constant venturi jet flow by inspiratory flowrate selection establishing a maximum entrainment gradient which was constantly modified as inflationary pressures increased or decreased during lung inflation.
Essentially, the primary manual inspiratory flowrate selection with the secondary automatic pneumatic clutching within the venturi produced a physiological pressure feedback loop controlling the rate of lung inflation. This served to enhance alveolar distribution with the virtual elimination of hyperinflational barotrauma. As Inspiratory (jet) flowrates selections are manually increased, the fluidic clutching will tolerate more physiological pressure regression and deliver higher PIP’s.

Dr. Bird would later call the physiologically modulated automatic flow variance of his inspiratory flowrate controlled respirators “PULMONARY CONFORMANCE.” This essentially means the lungs would have time to comply (get out of the way) during the period of their inspiratory inflation, as inspiratory flowrates decreased in proportion to the increasing endobronchial resistances.

CLINICAL EVALUATIONS

Prototypes of the magnetically controlled Bird Residual Breather (assister controller) were initially evaluated on animals and terminal patients at the USAF Willford Hall Hospital. The initial military investigations were followed by civil studies at Columbia University’s Bellvue hospital facilities.

The Belview studies (under the direction of the Cournand Group) were designed to compare the more physiological cardiac output of body respirators (iron lungs) with cyclic sub-ambient pressure changes around the body (with the nose and mouth outside the body chamber) to those patients on the Bird® positive pressure (trach positive) respirators.
In other words, to discover how the increased mean positive intrathoracic pressures interfered with venous return to the right heart in various patient populations.

The Cournand group, being deeply involved in circulatory dynamics, projected the following consequences relating to patients being mechanically ventilated with positive pressure devices applied to the proximal airway with existing Resuscitators:

1. The inspiratory phase of a positive pressure respirator delivering an intrapulmonary tidal volume under a positive pressure causes the lungs to be inflated with an increasing intra-pulmonary pressure, which is associated with an intra-thoracic pressure rise.

As the intra-thoracic pressures increase during the positive phase inspiratory interval, the pulmonary artery pressure rise serves to reduce the right heart refilling of the pulmonary circulation while concomitantly increasing the filling pressures of the left heart.

2. Therefore, during the positive phase inspiratory interval, the pulmonary blood volume decreases in proportion to the mean sustained intra-thoracic pressure, leading to a potential pulmonary hypovolemia. This is aggravated by any patient with a reduced circulatory blood volume.

3. Cournand, et al, in his “Cournand number three ventilation curve for trach positive pressure ventilation” suggested that the inspiratory/expiratory programming of a positive phase medical respirator, schedule a longer expiratory interval as compared to the inspiratory interval. This programming would allow more time for the right heart to re-load the pulmonary circulation, thus reducing the potentials for a positive phase respirator induced pulmonary hypovolemia. I/E ratios of 1 to 1.5 etc. were suggested.

Dr. Bird was most likely the first biomedical innovative technologist to employ both physical principals and pathophysiology to determine the ultimate design logic for a "pulmonary Percussionator® device" based upon the clinical effectivity of the respirator on normal, traumatized or diseased lungs. In other words, his respirators were conceived and designed to comply with the patient’s pathophysiology instead of forcing the patient to comply with a continuous mechanical ventilation (CMV).

It must be remembered that the body respirator was designed to ventilate near normal lungs. The follow-on trach positive CMV ventilators were designed (in part) to get the polio patients out of the body respirator for bodily access and general convenience.

Over time, all CMV ventilation became totally dependent upon tidal volume programming. Thus, the now digital society uses nomograms etc. to dial in volumes that are accepted as being ARBITRARILY correct, negating unknown cardiopulmonary pathophysiologies. In fact, the clinicians have become more legally correct than clinically efficacious.

Most clinicians use rote Tidal Volume programming on one type of ventilator based upon individual experience, while not having a basic understanding of the mechanical ventilation of the diseased lung.
While today’s “state of the art” CMV ventilators are aesthetic electronic marvels with video screens and all the bells and whistles, they are still primarily designed to ventilate non-obstructed lungs, without variable bronchiolar-alveolar resistances interspersed with dependent non-obstructed preferential airways. It must be remembered that all existing US volume-pressure ventilators are limited to the “more of the same” May 28, 1976 technologies, mandated by the 510K restraints of the US FDA.

When the chips are down and the patient being ventilated on a state of the art CMV ventilator has three tubes in the right side, and two in the left, is maxed out on FIO2 and tidal exchange pressures, there is no other clinically effective programming that can be accessed.

When the patient goes on to die, the clinicians familiar with only that type of CMV ventilation may honestly believe that nothing else could have been done to prevent the patient from dying of a respiratory failure. To support this fact, over 70% of all ventilator patients can be managed with basic CMV programming.

However, if you are among the other challenging some 20 to 30 percent of the cardiopulmonary patients; your clinician though his or her knowledge, may well determine your outcome.

Today, major world-wide corporations have parlayed the market for CMV volume-pressure critical care ventilators and their accessories into the multi billion dollar range. Yet, underneath the aesthetic displays is an FDA mandated primary volume limited pressure variable ventilator circa May 28, 1976.

EXPLORING NEW DIRECTIONS FOR VENTILATOR DESIGNS

Dr. Bird, starting in 1979, researched potential methodology to conceive a more effective method of managing critical care patients with major cardiopulmonary compromises. Clinical investigators and clinicians assumed that Dr. Bird was developing just another form of High frequency Ventilation (HFV). Still others thought that IPV® was just another form of IPPB. In other words it was believed by some that Dr. Bird was regressing into "old age".

High frequency ventilation, while not new, enjoyed a general resurgence in the early 1980's. This concept served to provide for intrapulmonary diffusion by providing vibratory energy into the proximal pulmonary airway.

Notes:
Pure intrapulmonary diffusion does not engender a variance in reciprocating molecular gas exchange across the proximal physiological airway. Considering the diffusion capacities of carbon dioxide at some twenty times greater than oxygen it was assumed that endobronchial CO2 accumulation would not prevail.
Favorable claims for "High Frequency ventilation of the lung" continued to appear in the literature. Initially the concept was championed as a method of weaning a patient from volume oriented CMV ventilation.

By the mid 1980's there was another form of high frequency re-initiated. Jet Ventilators, developed by many sources, became endemic in the treatment of patients with essentially normal lungs requiring brief ventilatory support. As objective reality overcame subjectivity, it was realized that without a sufficient component of convection, with basic diffusive ventilation, the patient could enter into a respiratory and then a metabolic hypercapnea.

THE TECHNOLOGICAL CHALLENGES OF AN EFFECTIVE HIGH FREQUENCY ENDOBRONCHIAL PERCUSSIVE VENTILATION

For over two decades, Dr. Bird had unsuccessfully attempted to provide a means of percussing the pulmonary structures endobronchially, to provide for a balance between diffusion and convection. In order to have an effective level of endobronchial percussion; the inspiratory flowrates had to be very high in order to deliver programmed sub-tidal volumes endobronchially in milliseconds, at rates of over 150 per minute without inadvertent PEEP as cycling rates were increased.

It was well known that if an anesthesiologist compressed the anesthesia bag too rapidly, a lightly anesthetized patient was said to "buck on the tube". This was in response to the firing of endobronchial "stretch receptors" (a Hering Breuer Reflex). Deep anesthesia obducted the reflexes. To obtain levels of clinical efficacy during the percussive ventilation of the lungs, the firing of the Hering Breuer reflexes served to limit the effective inspiratory (percussive) flowrates.

By the early 1980's Dr. Bird had conceived a fluidic (pneumatic) means of providing for endobronchial percussion.
It was not until the mid 1980's that he had clinically perfected the pneumatic logic for what he called "Intrapulmonary Percussive Ventilation (IPV®)" without firing the Hering Breuer reflexes. This was done in compliance with the US FDA Medical device act requiring an Investigational Device Exemption (IDE) and follow-on PMA compliances.

Dr. Bird's pneumatic Phasitron® in reality was a respirator located at the proximal airway servoed by a pneumatic cartridge capable of near instantaneously fully opening and closing at delivery frequencies of over 7,000 cycles per minute. The Phasitron® was a physical physiological interface located at the patient’s proximal airway.

The Phasiton® and the servoing cartridge was capable of injecting a (time cycled) sub-tidal volume into the endobronchial airways at very high frequencies without a clinical inadvertent PEEP as cycling frequencies were increased.

While simplistic in appearance the sophisticated Phasitron® employed advanced Bernoullian and Newtonian logic to provide a unique ventilatory compliance in each patient population. To this end, Dr. Bird perfected the required fluidic interfacing functions using a single stroke reciprocating venturi body with full opening and closing of the inspiratory and expiratory ports (in milliseconds). In principal the Phasitron® is a physical /physiological interface (combination injector exhalation valve) located at the proximal airway.

Notes:
The clinical and technological provisions for effective Intrapulmonary Percussive Ventilation (IPV®) were confirmed by initial studies. Functional reliability as well as an effective means of endobronchial airway recruitment (for obstruction and atelectasis) along with an effective balanced alveolar diffusion and convection was realized.
Essentially, the clinical concepts and mechanical novelty for IPV® were resultant from the studies of Dr. Forrest M. Bird starting during and after WWII.

THE LOGIC FOR INTRAPULMONARY PERCUSSIVE VENTILATION (IPV®)

Clinical concepts were directed toward the advancement of mechanical therapeutics to facilitate the mobilization of retained endobronchial secretions and the resolution of diffuse patchy atelectasis, often associated with acute and chronic obstructive pulmonary diseases. IPV® is a composite of the clinical justifications for intrapulmonary aerosol delivery, volume oriented Intermittent Positive Pressure Breathing (IPPB) and chest physiotherapy (chest percussion), without requiring the traditional dependence upon gravitational position for supporting postural drainage. IPV® can be clinically or self administered within various patient populations.

Dr. Bird's next challenge was to employ the Intrapulmonary Percussive Ventilation logic in the quest to develop a universal Percussionator® Respirator resolving the traditional clinical limitations of existing CMV volume oriented pressure limited ventilators. Dr. Bird was to name this concept Volumetric Diffusive Respiration (VDR®). Essentially, VDR® provided for a percussive endobronchial gas exchange, balancing diffusion with convection capable of managing PaO2 and PaCO2 “with options not possible with convective volume oriented ventilators”. Therefore, during the FDA IDE studies, IPV® became a component of VDR®.

THE HISTORICAL PROFILE AND LOGIC OF VOLUMETRIC DIFFUSIVE RESPIRATION (VDR®)

In the 1980s Dr. Bird had conceived a novel pneumatic logic named Intermittent Percussive Ventilation (IPV®) enabling the delivery of selective sub-tidal volumes at cyclic delivery rates of up to and over 1300 cycles per minute while limiting the inherent design "state of the art" mandated expiratory retard and PEEP to levels below clinical consequence.

This major innovation, provided for a reliable means of generating a percussive high rate (frequency) diffusive ventilatory component to compliment the traditional convective (mechanically generated) tidal exchange within the pulmonary structures.

Dr. Bird’s novel pneumatic technology was employed to reduce previous design mandated expiratory retardation and PEEP, which progressively increases with cyclic delivery rates, increasing FRC’s to incompatible levels.

This design novelty allowed the precise interrelated programming of Diffusive/Convective Intrapulmonary Percussive Ventilation (IPV®) without triggering the physiological stretch receptors.

Traditional pneumatic logic was employed to provide for a controlled intermittent flow interruption, which followed "existing state of the art" circa 1976; however, this was enhanced by novel technology which allowed the "clean generation" of sub-tidal volumes with precisely calibrated i/e ratios.
By employing differential technology and other means to control inertial forces, the inherent high frequency oscillator design mandated inspiratory, expiratory, inspiratory, transitional delays native to available oscillatory devices, were reduced below clinically perceptible levels as higher diffusive ventilatory rates were scheduled.

In order to deliver percussive, clinically effective, intrapulmonary sub-tidal volumes at the higher cyclic rates, the inspiratory flow gradients must be generated with provisions for a near instantaneous pressure rise followed by a near immediate proximal airway ambient venting.

For example: at a scheduled rate (frequency) of 900 cycles per minute only 67 milliseconds (thousandths of seconds) would be available to mechanically deliver and passively exhale each cyclic sub-tidal Volume. If the Inspiratory and expiratory times were equal at 33.5 milliseconds each (a 1:1 i/e ratio), without providing for any transition time for flow gradient reversal, between the programmed inspiratory and expiratory times, a maximum effective cyclic flow (pressure) gradient reversal would provide for, a maximum sub-tidal volume exchange.

The mandated design-limited delays, during the transition from the intrapulmonary inspiratory to expiratory to inspiratory sub tidal volume cycle, will determine the EFFECTIVE SUB-TIDAL VOLUME EXCHANGE. The inertial design delay in cyclic transition is called a TRANSITION PENALTY. For example, a delay of 15 milliseconds between peak flow gradients during cyclic flow reversals at 900 cycles per minute, while transitioning from the inspiratory to expiratory phase and then again during the expiratory to inspiratory flow reversal could reduce the effective flow gradient by approximately 50% or, in other words, would be a 50% transitional penalty (handicap).

The transitional penalty is very large on available pressure limited as well as volume oriented traditional pneumatic, piston or electronically servoed ventilators because of inherent design handicaps. Therefore, under existing "state of the art" a true clinically effective Percussive Intrapulmonary Ventilation (IPV®) is not possible. The mechanical flow gradient reversal delays are generally created by the "lead lag" between separate means for mechanical intrapulmonary flow generation and the post inspiratory actuation (full opening) of the exhilation valve.
When the enhanced pneumatic flow timing circuits of the Percussionaire® Percussionators® employing the novel Phasitron physical/physiological interface were integrated (with vastly reduced TRANSITIONAL PENALTIES); an effective Percussive Intrapulmonary Ventilation (IPV®) was made clinically possible.

The Phasitron® represents the true key to Intrapulmonary Percussive Ventilation (IPV®), serving as a master flow converter for all fluidic energy delivered to the mono-jet of its sliding venturi assembly. In reality, any percussive (square wave) intermittent (cyclic) energy delivered to the Phasitron will be amplified and analogized by physiological pressure feedback. Essentially, it is a universal amplifier/converter capable of altering integrated multiple flow/pressure formats into a characteristically common intrapulmonary delivery.

Available push pull oscillators have the typical flow gradient reversal delays, which are called “TRANSITION DELAY HANDICAPS”. Dr. Bird’s innovative Phasitron® and pneumatic flow cartridge served to allow Dr. Bird’s unique Intrapulmonary Percussive Ventilation (IPV®) and Volumetric Diffusive Respiration (VDR®) concepts, without measurable transition delays. This explains the unique difference between Dr. Bird’s Lung Recruitment Concepts and all other forms of mechanical lung ventilation.

With the Phasitron®, all square wave or constant flow ventilatory programs are dampened by "fluid clutching" within the ambient vented venturi body. It is the ability of the Phasitron® to near instantaneously comply to physiological feedback as pulmonary structures are mechanically inflated, which serves as a pressure/flow converter to allow near instantaneous pulmonary conformance.
Additionally, the mono-jet feature of the Phasitron® is a major key to adding diffusive percussive programming to traditional, constant flow and/or convective breathing circuits.

Essentially, pulmonary conformance allows the lungs time to comply to inflational pressure/volume relationships, with an associated reduction in preferential airway. THIS IS THE IPV® DESIGNED LUNG PROTECTIVE STRATEGY NOT CONSIDERED IN ALL THE PRESENT volume-pressure CMV ventilators employed during intensive care.

The basic VDR® Percussionator® was designed with an open programming potential. The novel fluidic design concept of the VDR® is based upon as many as thirty-four (34) simultaneous programmable events. Over the past two decades the VDR® programming logic which started with a combination CMV and Percussive format with a CMV tidal delivery followed by a diffusive percussive delivery has advanced to a combined sinusoidal scheduling.
The mechanical integrity and durability of the fluidic VDR® design is equal to or better than any existing pulmonary ventilator serving clinical medicine anywhere in the world. The hundreds of VDR® Percussionators world-wide are now totally integrated into a common programming interface with complete universal access to scheduling, from the smallest neonate through pediatrics to the largest Pickwickian adult.

Notes:
1. THE VOLUMETRIC DIFFUSIVE RESPIRATION (VDR®) CLINICAL CONCEPT WAS CONCEIVED AND CLINICALLY DESIGNED TO RECRUIT AND VENTILATE LUNGS WITH MAJOR AIRWAY OBSTRUCTIONS AND INTERSTITIAL COMPROMISES (WITHOUT THE ARDS POTENTIALS ASSOCIATED WITH VOLUME-PRESSURE CMV SCHEDULING) WHILE MANDATING A LUNG PROTECTIVE STRATEGY.

2. (CONVENTIONAL) CMV VENTILATORS WERE CONCEIVED AND DESIGNED BY ENGINEERS TO GET POLIO PATIENTS (WITH ESSENTIALLY NORMAL LUNGS) OUT OF BODY RESPIRATORS FOR BODY HYGIENE and EXERCISE AS WELL AS, CONVENIENCE.

3. VDR® WILL EFFECTIVELY VENTILATE LUNGS WITH VERY LOW COMPLIANCE THAT WOULD BE BAROTRAUMATICALLY INJURED BY ALL AVAILABLE TIDAL VOLUME ORIENTED CONVECTIVE CMV VENTILATORS.

BEFORE UNDERSTANDING DR. BIRD’S VDR® LUNG PROTECTIVE LOGIC THE LIMITATIONS OF CMV PROGRAMMING MUST BE UNDERSTOOD.

In order to attempt to comply with the vast number of pathophysiological variables involved in the effective mechanical ventilation of the lungs without producing barotraumatic consequences, the application of energy to perform the mechanical work required to inflate the pulmonary structures had to address both physical and physiological consequences.
The diverse physical and clinical abilities one would have to possess to totally understand Dr. Bird’s fourth generation of fluidic logic, employed to universally ventilate normal and diseased lungs, is beyond normal individual comprehension.

In today’s ever increasing digital societies, the individual is taught to accept what happens when buttons are pressed and not question or care what happens behind the buttons.

1. Dr. Bird applied his knowledge of fluid dynamics and cardiopulmonary pathophysiology toward the analog maintenance of cardiopulmonary functions under pathological stress, while limiting known risk factors associated with the positive pressurization of the pulmonary structures.

2. Essentially, Dr. Bird created an analog computer with some thirty-four simultaneous programmable events. In today’s digital society the ability of electronic digital computers to process numbers based upon essentially only two operations consisting of “opening and closing circuits at astronomical speeds” is beyond comprehension by the average person using a lap top computer. The engineering logic native to computation design allowed the insertion of an operating system of such quality that individuals can accomplish self satisfying operations whether they are computerized games or word processing systems.

3. The personal difficulty Dr. Bird faced in the introduction of his advanced protocols for the mechanical maintenance of cardiopulmonary functions is that his devices do not individually reward the user to the extent “that one is willing to spend the time required to program the devices for maximum clinical efficacy in all patient populations”. In other words, spending the time required to clinically understand the depth of “pathophysiological textbook knowledge” required to program Dr. Bird’s VDR® devices in each patient population does not offer a very personal reward in terms of self satisfaction, such as becoming increasingly computer literate.

THE BASIC PREMISE OF A CMV “TRACH POSITIVE” MECHANICAL VENTILATION IS TO CREATE A POSITIVE PRESSURE OF SUFFICIENT MAGNITUDE AGAINST THE PROXIMAL AIRWAY RESISTANCES, TO INFLATE THE LUNGS WITH A SCHEDULED TIDAL EXCHANGE AGAINST GROSS INTRAPULMONARY RESISTANCES.

In order to deliver a tidal volume against the elastic and non-elastic resistances within the lungs, a positive pressure of sufficient magnitude has to be delivered against the proximal airway resistances.

The constant mean inspiratory flowrate against intrapulmonary resistances will determine the positive pressure rise required to create the inspiratory flow gradient (from the proximal to distal pulmonary airways) to overcome the intrapulmonary resistance to inflow.

The greater the sustained pressure gradient, the greater the proximal distal airway pressure differential. In the following proximal airway pressure tracings, the selected inspiratory flowrate is obstructed by intrapulmonary resistances, converting a constant inspiratory flowrate into a rapid increase in proximal airway pressure.
It can be noted that it requires (under these circumstances) a proximal pressure rise of 30 cm H2O to overcome the intrapulmonary resistances sufficient to produce a mass inflow without a further increase in pressure.

In this case, a constant intrapulmonary airway inflow has been converted into a sufficient pressure rise to inflate pulmonary structures with the least elastomeric resistances (preferential airways) during a period of apneustic flow/pressure sustenance.

The greater the inspiratory flowrate against a given intrapulmonary airway resistance, the greater the proximal distal flow gradient, as flow is converted into pressure. Therefore, it follows that the most patent pulmonary airways serving the most dependent alveoli will be PREFERENTIALLY inflated. Thus, alveolar hyperinflation is the precursor of pulmonary barotrauma.

In brief summary, whenever an inspiratory flowrate is sustained beyond a point where intrapulmonary resistances create a proximal distal pressure rise required to deliver a selected tidal volume against pathologically altered high resistance pulmonary structures, PREFERENTIAL AIRWAY SELECTION IS MANDATED.
When the barotraumatic consequence of preferential airway is further insulted by intrapulmonary PENDELLUFT, hyperinflational barotrauma is enhanced.

The CMV concept of delivering a selected constant tidal volume under a variable pressure to a selected PIP, where the ventilator ultimately becomes pressure limited is an ideal method of assuring a selected tidal exchange in patients with near normal unobstructed lungs experiencing moderate changes in gross pulmonary compliances. However, when the gross pulmonary compliance of the pulmonary structures is pathologically altered, the management of inflational energy (flow/pressure) becomes a critical situation.

Flow/pressure relationships were recognized by Dr. Bird as being the critical component of all mechanical designs employed to provide “artificial respiration” starting with his manual flowrate selection on his first IPPB 1947 concept. Dr. Bird’s Mark series Respirators reflected this premise with “MANUALLY SELECTABLE INSPIRATORY FLOWRATE” control, which was automated by his fluidic clutching provided by Bernoullian venturi logic.

By 1976 Dr. Bird had conceived almost every logical means of inspiratory flow deceleration and acceleration as well as time cycled apneustic plateaus. On the expiratory side, he had exploited the variable elevation of expiratory baselines (PEEP-CPAP) to mechanically increase Function Residual Lung Capacities (FRC) at bi-levels to enhance blood gas interfaces within the limits of right heart tolerances. The IMVbird® as well as other Bird Respirator/Percussionators® exhibited the above characteristics.

The current FDA 510K CMV devices have, since 1976, utilized almost every flow/pressure concept advanced by Dr. Bird in his first three generations of medical respirators/Percussionators®. His flow/pressure regulatory concepts have been employed to advance the primary volume/pressure relationships on their 510K (grandfathered) CMV devices.
Dr. Bird’s original concepts have been introduced as new concepts when essentially they were his re-labeled concepts circa May 28, 1976.

Instead of attempting to advance a CMV concept “designed to ventilate near normal lungs to accommodate pathologically altered pulmonary structures,” Dr. Bird started in 1978 to review potential concepts for a fourth generation of mechanical cardiopulmonary resuscitative and support methodology employing a “lung protective strategy”. This resulted in the clinical protocols and technology required to provide for the therapeutic concept of Intrapulmonary Percussive Ventilation (IPV®) and the critical care derivative Volumetric Diffusive Respiration (VDR®).

**INTRAPULMONARY PERCUSSIVE VENTILATION (IPV®) IS BASED UPON THE MANAGEMENT OF PERCUSSIVE INSPIRATORY FLOWRATES DURING TIME CYCLIC ENDOBRONCHIAL DELIVERIES OF SCHEDULED HIGHER FREQUENCY SUB-TIDAL EXCHANGES.**

Rationalizing that it is the sustained potentially high-pressure flow gradients into the PREFERENTIAL pulmonary structures during CMV that produce hyperinflational barotrauma, a means for ventilating lungs (with pathologic alterations creating high intrapulmonary resistances) without hyperinflational barotrauma was mandated.

- By using what is referred to as higher frequency (millisecond) delivery rates to percussively deliver sub tidal volumes under selectable i/e ratios, a step percussive ventilation of the lung with a timed physiological controlled inspiratory flowrate was a rational clinical concept to provide for a “Lung Protective Strategy” while maintaining an effective blood gas interface.

- While the clinical concept was theoretically valid, a CMV ventilator was incapable of cycling at high rates without creating an increasing inadvertent PEEP as cyclic rates are increased.

- Therefore, a clean conceptual page was necessary to design a medical ventilatory device capable of scheduling higher frequency sub tidal programming without mandating an increase in FRC.

The basic logic for IPV® was to never allow a sub-tidal volume greater than the anatomical dead space to be delivered into the lungs of any size patient population. The millisecond cyclic energy release required for a percussive sub-tidal endobronchial delivery is physically related to a Tsunami displacement wave.

A. In other words, a reservoir of a respiratory gas under a controlled high storage pressure is near instantaneously pulsed (released and stopped) in milliseconds into the jet of a venturi tube.

B. This causes a bolus type discharge of a high velocity sub-tidal volume from the venturi body into the proximal pulmonary airway.
C. During the millisecond UP STEPPING LUNG VOLUME expiratory pauses, between repeated cyclic injections a portion of each sub-tidal volume is exhaled to ambient.

D. By controlling the i/e ratio at a frequency of over 100 cycles per minute, the scheduled expiratory time is not sufficient to allow the entire previously delivered sub-tidal volume to be totally exhaled before the next tidal injection occurs. Thus the slight initially increase in Dynamic Functional Residual Capacity (D-FRC) is constantly maintained.

E. This creates a step sub-tidal inflation of the lung until the programmed (fluidic) clutting within the venturi limits the PIP of percussive oscillatory deliveries. This is called “oscillatory equilibrium”. During a stable OSCILLATORY EQUILIBRIUM intrapulmonary gas exchange continues while the lung volume remains constant.

F. To prevent areas of the lung that are progressively recruited by the percussive sub-tidal injections from regressing, an automatic CPAP Stabilizer (positive pressure wedge) is maintained during exhalation to prevent the recruited peripheral airways from re-collapsing.

The clinical and technological means for Intrapulmonary Percussive Ventilation (IPV®) provided for a “Lung Protective Strategy” to develop a universal Intensive Care Percussionator® without the absolute hyperinflational barotrauma mandated by volume-pressure CMV programming in the presence of pathologic lung alterations.

This concept was named Volumetric Diffusive Respiration (VDR®). As the name implies it allows a programmable balance between CONVECTIVE CMV ventilation and spontaneous DIFFUSIVE breathing, whereby the diffusive component is directed toward PaO2 control with the convective component directed toward CO2 “wash out”.
1. A pressure regulator serves to control the 50 pound sources of Air and Oxygen supplies which are blended for a constant selectable FIO2. A regulated 40 psig operational pressure is optimal.

2. A PULSATILE FLOWRATE metering valve selection establishes a PIP.

3. An INSPIRATORY TIME metering valve allows a traditional Inspiratory time selection of from about .5 to 25 seconds, with about 2 seconds at the 12:00 index.

4. An EXPIRATORY TIME metering valve allows a traditional Inspiratory time selection of from .5 to 25 seconds, with about 2 seconds at the 12:00 index.

5. The selected PULSATILE FLOWRATE (Inspiratory Flowrate) is interrupted by a Flow Interrupter cartridge, which is timed by a PULSE FREQUENCY metering valve “which in turn” is modified by an i/e RATIO metering valve controlling the i/e Ratio of the positive phase high frequency oscillation.

6. An OSCILLATORY CPAP/PEEP is limited to about 20% of the selected PIP, which is selected by PULSATILE PRESSURE. This prevents the selection of an incompatible oscillatory PEEP/CPAP during the programmed expiratory interval.

7. A CONVECTIVE PRESSURE RISE metering valve is programmed to accelerate the PULSATILE FLOWRATE after a one (1) second delay. The progressive increase in a convective flowrate is modulated by the pulsatile oscillation increasing the Oscillatory PIP.

FOR DEFAULT PROGRAMMING- ROTATE ALL CONTROL KNOB ARROWS TO THEIR 12:00 POSITIONS.
The logic for Convective Pressure Rise is to allow the airways of the lungs to be initially recruited at a lower PIP to increase the patency (cross section) of the bronchiolar airways before a second stage of inflational pressure rise is employed. This enables bronchiolar airway recruitment at higher pulsed inflational pressures (above 35-40 cm H2O) with limited preferential airway hyperinflation potential.

8. A MASTER SWITCH interrupts all oscillatory programming.

9. A DEMAND CPAP/PEEP for pressure support weaning can be used with the MASTER SWITCH OFF.

10. A NEBULIZER TOGGLE SWITCH provides for a constant flow for nebulization and/or humidification.

11. A FAILSAFE SENSITIVITY CONTROL knob limits a maximum sustained pressure over a programmed time. If the failsafe pressure rise system is activated, a pneumatic alarm is activated by a partial pressure release. A (counterclockwise) control knob rotation increases the Sensitivity of the timed peak oscillatory pressure (alarms with less PIP).

Notes:
THE UNIQUE DIFFERENCE BETWEEN VDR® and volume-pressure CMV IS THAT VDR® PROVIDES FOR PULMONARY AIRWAY SECRETION CLEARANCE AND PROGRESSIVE AIRWAY RECRUITMENT WITHOUT PREFERENTIAL AIRWAY HYPERINFLATION WHILE MAINTAINING ALVEOLAR RECRUITMENT.

ANOTHER MAJOR DIFFERENCE BETWEEN volume-pressure CMV AND VDR® IS THAT THE PATIENT ON IPV® WITH SPONTANEOUS BREATHING, CAN SHIFT BASELINE AT ANY TIME WITHOUT A TIDAL VOLUME BEING DELIVERED ON TOP OF AN ELEVATED BASELINE.

VDR®-4 PERCUSSIONATOR® CLINICAL PROGRAMMING

NOTE: Many institutions have their own VDR programming based upon their years of clinical experience with available attending. The following programming is considered optimal for maximum clinical efficacy; however is not mandated.

THE VDR-4 is the ONLY UNIVERSAL PERCUSSIONATOR® WITH HIGH FREQUENCY PERCUSSIVE VENTILATION (HFPV™)

1. IMMEDIATE PRECLINICAL INSERVICE.

- Set up the VDR-4 with gas and power connections- Attach desired institutional VDR® breathing circuit configuration. Make certain heated Humidifier IF USED is properly integrated into the VDR® Failsafe Breathing Circuit.

- WITH HUMIDIFIERS AND NEBULIZERS OFF; Attach Patient breathing port of the Phasitron® to the Patient Simulator on the left side of the VDR® Housing.

- Rotate all alpha control knob arrows under their 12:00 indexes except DEMAND CPAP full clockwise- OFF.

Alpha control knob colors and alpha coding have specific meanings:

Green knobs are for selection of Inspiratory and Expiratory Flowrates.

Yellow knob is for DEMAND CPAP/PEEP selection for weaning- to remain full (clockwise) OFF with VDR® function Switch selected-ON.

DEMAND CPAP is for pressure support only, for use during spontaneous breathing with the VDR® Switch- rotated to-OFF.

Grey knobs are for (High Frequency) PULSATILE FREQUENCY and i/e Ratio control with resultant Frequency selections.
Black are for general INSPIRATORY and EXPIRATORY TIME (convective) I/E phasing Intervals.

Nebulizer Gas Flow into the yellow interfacing tubing is provided by an OFF-ON Toggle Switch.

Normal Operational Pressure Regulator selection (with MASTER SWITCH-OFF) is 42 psig shown on Operational Pressure Gauge.

Note: The basic conventional internal monitoring of Proximal Airway Pressure is presented on the Manometer. If during patient programming an INTEGRATED MEAN PROXIMAL AIRWAY PRESSURE is desired on the MANOMETER, select INTEGRATED MANOMETER-ON.

A battery operated DISCONNECT MONITORING device, is located on right facing side of VDR-4 housing. Toggle Switch to ON for Starting, with Onset Time control knob Arrow under the 12:00 index.

Sustained pressure rise alarming is determined by Red SENSITIVITY knob selection, normally with the control knob Arrow at the 12:00 position a sustained pressure of over 100 cm H2O has to be maintained for over two (2) seconds to activate alarming and associated proximal airway pressure drop.

FOR DIGITALIZED PERCUSSIONATOR® MONITORING- PROGRAM MONITRON® II.

Monitron- ON. Scale- 0-60. Sweep- 0.00 to 5.00.

2. For general patient programming- Select an FIO2 of 60%. THEN:

a). Rotate all Alpha control knobs until their arrows are under their 12:00 indexes except Yellow DEMAND CPAP/PEEP control knob rotated full (clockwise).

b). Black INSPIRATORY TIME- control knob Arrow rotated under the 12:00 index for about a 2 second Inspiratory Interval.

c). Black EXPIRATORY TIME- control knob Arrow rotated under the 12:00 index for about a 2 second Expiratory Interval.

d). Green OSCILLATORY CPAP/PEEP- control knob rotated (counterclockwise) until 3:00 is under the 12:00 index position.

e). Rotate Master switch to- ON.

RESET MONITRON® ALARM
OBSERVE: A two step increase in oscillatory (PIP) on the Monitron Screen). First stage is the OSCILLATORY BASELINE created by an Oscillatory Demand CPAP selection of between 5-10 cm H2O.

a). Second stage is created by PERCUSSIVE FLOWRATE selection of about 25-35 cm H2O.

Note: It is recommended NOT to use yellow DEMAND CPAP/PEEP during VDR programming. If elected, do not use more than 4 cm H2O of DEMAND CPAP/PEEP during OSCILLATORY DEMAND CPAP programming. Non-oscillatory, DEMAND CPAP/PEEP is generally reserved for pressure support during spontaneous breathing to reduce the work of breathing.

Note: If DEMAND CPAP is selected with a programmed OSCILLATORY DEMAND CPAP, it will program an accumulative increase.

THE SIMULATOR IS CALIBRATED TO ASSIMILATE A PATIENT WITH MODERATE COMPLIANCE AND A LEAK AROUND THE ENDOTRACHEAL TUBE CUFF.

3. PREPARE FOR PATIENT AIRWAY CONNECTION.

FIRST- DISCONNECT BREATHING HEAD FROM THE SIMULATOR. THEN:

a). Rotate MASTER Switch to- OFF.

b). Service Nebulizer/Humidifier.

c). Toggle NEB switch up to- ON.

d). Use patient’s SAT to determine FIO2 selection.

e). Rotate MASTER switch back- ON

4. MAKE PHYSIOLOGICAL AIRWAY CONNECTION.

RESET MONITRON ALARM

Observe chest pulsation for BASAL bilateral oscillation.

Monitor PULSE OX for an increase in saturation.

To increase Saturation progressively Rotate the PULSATILE FLOWRATE control knob Arrow (counterclockwise) to increase the AMPLITUDE (PIP) of Percussive Oscillation up to about 35 cm H2O or until the bottom of the Oscillatory Wave starts to depart the Baseline (usually about 40 cm H2O).

IMPORTANT-The PULSATILE FLOWRATE control knob Arrow should NOT be rotated (counterclockwise) beyond the point where the Oscillation down stroke departs the Monitron Baseline. This will provide for a Manometer reading of about 35 to 40 cm H2O.
If recruitment is not reached- increase the INSPIRATORY TIME INTERVAL by rotating the INSPIRATORY TIME control knob Arrow (counterclockwise) to about the 03:00 index position for about 5 to 7 second INSPIRATORY INTERVAL.

VERY IMPORTANT- If recruitment is still not obtained, rotate SLOWLY the CONVECTIVE PRESSURE rise control knob Arrow (counterclockwise) initially to about the 02:00 index position. Observe a third step pressure rise to oscillatory PIP on the Monitron Screen.

Wait for recruitment or effect of updated programming. DO NOT CHASE PROGRAMMING WITHOUT ALLOWING COMPENSATION TIME.

5. PROCEDURAL LOGIC-

After a period of Ventilatory Stabilization Check SAT, or blood-gas determinations to determine Oxygenation.

a.) The Black INSPIRATORY TIME control knob determines the period of OSCILLATORY EQUILIBRIUM providing for Intrapulmonary MECHANICAL GAS MIXING TIME.

b). The Green PULSATILE FLOWRATE control knob should be used to control oscillatory PIP up to about 40 cm H2O.

c). The Green CONVECTIVE PRESSURE RISE control knob Arrow should be gradually rotated (counterclockwise) to increase oscillatory PIP to pressures above 40 cm H2O until recruitment is obtained. Over 100 cm H2O PIP’s can be generated, by CONVECTIVE PRESSURE RISE.

d). When PIP’s exceed 50 cm H2O check for airway obstruction by observing a pulsatile bilateral inflation of the lung bases.

To decrease CO2 or to mobilize and raise retained endobronchial secretions re-program the VDR® as follows:

FIRST write down the existing VDR® program by alpha control knob and clock numbers relative to their respective positions.

a). Rotate the PULSE FREQUENCY and i/e RATIO control knobs until 09:00 is under their 12:00 indexes.

b). Rotate the CONVECTIVE PRESSURE RISE control knob Arrow full (clockwise) OFF.
c). Immediately, rotate the PULSATILE PRESSURE control knob Arrow full (counterclockwise).

d). Observe a moderate bilateral oscillatory percussion of the lung bases.  
NOTE: In a very compliant lung the Percussive Amplitude can be decreased by the progressive (clockwise) rotation of the PULSATILE FLOWRATE control knob Arrow.

e). Increase the INSPIRATORY TIME interval by rotating the control knob (counterclockwise) until 03:00 to 04:00 is under the index, to increase endobronchial mechanical gas mixing.

f). Periodically over about fifteen minutes rotate the i/e RATIO control knob Arrow (clockwise and counterclockwise) to develop an air distal to raise mobilized secretions.

g). Increase the INSPIRATORY TIME interval by rotating the control knob Arrow (counterclockwise) until 03:00 to 04:00 is under the index.

h). The above Intrapulmonary Percussive Ventilation (IPV®) is usually programmed for about 15 minutes.

NOTE: The use of Vasoconstictor Bronchodilator aerosols (Racemic Epinephrine) during the period of Intrapulmonary Percussive Ventilation can enhance airway caliber by reducing Mucosal and Sub Mucosal edema as well as Bronchiolar spasm.

i). Re-program back to initial recorded previous programming.

NOTE: Lung recruitment during Intrapulmonary Percussive Ventilation (IPV®) programming may enable a decrease in oscillatory PIP.

Note: If using a cuffed endo-tracheal airway tube- deflate cuff until a "noticeable but not excessive airway leak" can be determined, to cause mobilized and raised secretions, to enter the pharyngeal areas for oral suctioning as well as, to reduce the re-circulation of CO2.

If required, increase the PULSATILE FLOWRATE to compensate for the leakage caused by the de-flational adjustment of the Cuff.

6. GENERAL ON PATIENT PROGRAMMING.

After at least fifteen minutes of stabilized ventilation, with a stable SAT without noticeable CO2 retention, run a blood gas determination.

If hypo-ventilation is suspected or revealed:
a). First increase the PULSATILE FLOWRATE until the oscillatory baseline starts to leave the baseline (usually from 35 to 40 cm H2O.

b). Increase the INSPIRATORY TIME interval by rotating the control knob until 03:00 to 04:00 is under top 12:00 index to increase the Oscillatory Equilibrium Time, to enhance Intrapulmonary Gas Mixing

c). To further increase intrapulmonary gas exchange- gradually rotate the Green CONVECTIVE PRES. RISE control knob (counterclockwise) to increase oscillatory PIP. Observe an increased periodic oscillatory bilateral phasic chest excursion.

d). If recruitment is not reached by a 50 cm H2O PIP CONVECTIVE PRES. RISE

e). Program Intrapulmonary Percussive Ventilation as described above under (E).

f). Use SAT and clinical judgment to determine oscillatory PIP while observing a uniform by-lateral pulsatile chest excursion.

NOTE: Lungs with very very low compliance may require clinical judgment in terms of oscillatory PIP increases into higher lung compartments with associated MEAN INTRAPULMONARY PRESSURE increases, induced by selected CONVECTIVE PRES. RISE selection.

g). After about fifteen minutes of stabilization determine PaO2 and PaCO2.

Note: Press RESET and SET on Monitron to re-schedule alarms after any change in programming.

7. TREND ANALYSIS-

Note: IMPORTANT- When making TREND ANALYSIS changes in ventilatory parameters, wait a few minutes for each change to take effect before starting the next choice.

If PaO2 is low the options are:

a). Increase- FiO2.

b). Increase INSPIRATORY TIME by rotating black control knob Arrow (counterclockwise) until 03:00 to 04:00 is under the 12:00 index.

c). Re-program- OSCILLATORY DEMAND PEEP/CPAP- rotate green control knob arrow (counterclockwise) to increase pulsatile baseline upward toward 15 cm H2O do not exceed 20 cm H2O. Monitor the effect of increased mean intrathoracic pressures upon cardiac output.

d). Increase- PULSE FREQUENCY- rotate Grey control knob (counterclockwise) until rate is increased above 600 cycles per minute.
e). Decrease- EXPIRATORY TIME- rotate Black control knob arrow (clockwise) under the 12:00 index for about a 2 second Expiratory Interval.

f). Increase- CONVECTIVE PRES. RISE- gradually rotate Green control knob (counterclockwise) increasing oscillatory PIP until recruitment and/or clinical judgment is optioned, based upon pulmonary compliance.

If PaCO2 is high the options are:

a). Rotate- Grey FREQUENCY and PULSE i/e RATIO- control knobs (clockwise) until 10:00 is under their indexes. This programming creates larger sub tidal deliveries for CO2 "wash out".

b). Increase- EXPIRATORY TIME- by rotating black control knob arrow (counterclockwise) for a 3 to 4 second expiratory time.

c). Increase- CONVECTIVE PRES. RISE- by rotating Green control knob arrow (counterclockwise) using PIP incremental increases of 5 cm H2O or a clinical judgment call.

NOTE: For maximal CO2 recruitment follow (E). above.

8. To decrease ventilatory assistance by reference to an improved blood gas analysis.

a). A suggested method of initial weaning after reductions in FiO2, is to gradually first reduce the CONVECTIVE PRES. RISE then PULSATILE FLOWRATE in gradual steps, which reduces the entire program incrementally.

b). If initial weaning is too rapid, reverse weaning by increasing Green PULSATILE FLOWRATE control knob (counterclockwise) in 1 (one) index incremental steps.

c). Gradually- reverse order for programmed O2 or CO2 management.

9. TO WEAN.

a). Gradually- reduce FIO2 to under 30%.

b). Gradually- reduce Green CONVECTIVE PRES. RISE to OFF full (clockwise).

c). Gradually- reduce Green PULSATILE FLOWRATE.

d). Watch oscillatory PIP reduction rate during weaning to maintain acceptable blood gases.

e). Observe chest- for rhythmic spontaneous breathing. THEN:

f). Discontinue Percussive Oscillatory Ventilation- Rotate MASTER switch to OFF.
g). Immediately, Adjust yellow DEMAND CPAP to prevent sternal retraction in neonates and/or notable increased work of spontaneous respiration, in pediatric or adult patients.

h). Do not reduce DEMAND CPAP below 5 cm H2O until ready to extubate.

i). Use non-invasive Mask or Nasal Prongs for non-invasive ventilation after extubation if desired.

j). If blood gases indicate weaning too rapidly, MASTER back-ON. reverse order of weaning.

10. POST RECOVERY- Use IPV® to maintain optimal airway recruitment.

Note: There are many unique programming schedules for VDR (HFPV™), established by Clinicians over the past twenty plus years, secondary to on-patient experiences.

IMPORTANT NOTE: IF at any time obstructed airways, atelectasis or interstitial edema is suspect- program the VDR® for Intrapulmonary Percussive Ventilation (IPV®).

FIRST: Rotate CONVECTIVE PRES. RISE control knob Arrow full (clockwise) to- OFF

1. Rotate (high frequency), PULSE FREQUENCY and i/e RATIO control knob Arrows (clockwise) with 9:00 under their 12:00 indexes.
2. Rotate PULSATILE FLOWRATE control knob Arrow full (counterclockwise).
3. Increase INSPIRATORY TIME by rotating the control knob Arrow (counterclockwise) between the 03:00 and 04:00 position.
4. Observe bilateral CHEST PERCUSSION for about ten to fifteen minutes.
5. Aspirate pharyngeal and/or proximal airways as required.
6. Return to previous ventilatory program.

USE SIMULATOR TO PRACTICE VDR PROGRAMMING UNTIL COMPETENT

VDR® is the first and only High Frequency PERCUSSIONATOR® (HFPV) designed and clinically proven for the universal treatment of neonates, pediatrics and large adults.

VDR® was released to the US market by the U.S. FDA on October 13, 1989 with the first high frequency percussive programming above 150 cycles per minute to 1250 cycles per minute.
APPENDICES

GENERAL TECHNICAL DATA

General specifications and technical data for current Percussionaire® Cardiopulmonary Lung Recruitment Products

UNIT SPECIFICATIONS

<table>
<thead>
<tr>
<th>UNIT</th>
<th>MODEL #</th>
<th>Weight (lb)</th>
<th>Height (in)</th>
<th>Width (in)</th>
<th>Depth (in)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VDR®-4</td>
<td>F00008-1</td>
<td>13.9</td>
<td>8.0</td>
<td>13.0</td>
<td>10.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>25.4</td>
</tr>
<tr>
<td>UNIVERSAL MONITRON®</td>
<td>F00007-B</td>
<td>3.6</td>
<td>9.5</td>
<td>6.7</td>
<td>9.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>24.1</td>
</tr>
</tbody>
</table>

TROUBLESHOOTING THE VDR

**DROP IN PIP**

<table>
<thead>
<tr>
<th>CAUSE</th>
<th>FIX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of working pressure</td>
<td>Reestablish working pressure by increasing working pressure</td>
</tr>
<tr>
<td>Blender failure</td>
<td>Check blender by disconnecting patient and manually ventilate. Proceed</td>
</tr>
<tr>
<td>Failsafe alarming</td>
<td>Correct problem (refer of failsafe alarming problem)</td>
</tr>
<tr>
<td>Cuff leak increased</td>
<td>Reestablish appropriate leak, adjust PIP</td>
</tr>
<tr>
<td>Leak or disconnect in red gauge line</td>
<td>Disconnect patient and manually ventilate, replace or reconnect</td>
</tr>
<tr>
<td>Gauge filter wet</td>
<td>Disconnect patient and manually ventilate, replace filter, reset PIP</td>
</tr>
<tr>
<td>Patient disconnect</td>
<td>Reconnect patient</td>
</tr>
<tr>
<td>↑ Compliance ↓ resistance</td>
<td>Re-adjust PIP as necessary</td>
</tr>
<tr>
<td>Pulse frequency control</td>
<td>Re-adjust PIP as necessary</td>
</tr>
<tr>
<td>Pulse i/e ratio control</td>
<td>Readjust PIP as necessary (maybe small change)</td>
</tr>
</tbody>
</table>
## INCREASE IN PIP

<table>
<thead>
<tr>
<th>CAUSE</th>
<th>FIX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuff leak decreased</td>
<td>Reestablish appropriate leak, adjust PIP</td>
</tr>
<tr>
<td>Pulse Frequency control decreased</td>
<td>Adjust PIP as needed</td>
</tr>
<tr>
<td>Increased working pressure</td>
<td>Reestablish working pressure to previous settings or adjust PIP</td>
</tr>
<tr>
<td>↑Resistance ↓compliance</td>
<td>Assess patient for cause, adjust PIP</td>
</tr>
<tr>
<td>Red line disconnect</td>
<td>If red proximal gauge line becomes disconnected when using Demand CPAP/PEEP, flow acceleration could cause undetectable high PIPs while monitoring system sounds low-pressure alarm.</td>
</tr>
<tr>
<td>Pulse i/e ratio control increased</td>
<td>Readjust PIP as needed</td>
</tr>
</tbody>
</table>

## FAILSAFE ALARMING

<table>
<thead>
<tr>
<th>CAUSE</th>
<th>FIX</th>
</tr>
</thead>
<tbody>
<tr>
<td>High sustained (1 to 2 seconds) pressure delivered to Phasitron above programmed limits.</td>
<td>Disconnect patient and manually ventilate, evaluate and correct problem. If problem is not corrected return for service.</td>
</tr>
<tr>
<td>White Phasitron line has become occluded or obstructed.</td>
<td>Disconnect patient and manually ventilate, evaluate and correct problem. If problem is not corrected return for service.</td>
</tr>
<tr>
<td>Patient becomes disconnected when using high demand CPAP/PEEP levels.</td>
<td>Manually ventilate, evaluate and correct problem. If problem is not corrected return for service.</td>
</tr>
</tbody>
</table>
SERVICE AND REPAIR

PERCUSSIONAIRE® CORPORATION recommends an annual preventive maintenance (PM) for each device. An annual PM consists of a thorough cleaning, filter change, functional evaluation, and, if necessary, recalibration.

A mandated remanufacture (overhaul) (OH) is required every three (3) years after the device is initiated into service or not later than four (4) years after first date of purchase. A factory remanufacture consists of replacing all elastomeric seals, sleeves, and diaphragms, with inspection of all components. The device is factory calibrated and receives a functional evaluation, conformance certification, and a one-year warranty on all parts installed during overhaul. If replacement parts other than those specified for overhaul or preventive maintenance are required for repair, the cost of the parts will be quoted to the customer in addition to the cost of the Preventive Maintenance (PM) or Overhaul (OH). Cleaning time allowed for OH or PM fifteen is (15) minutes, any extra cleaning time will be charged at current hourly rate. ($105.00/hour)

A device which has not received a mandated overhaul for a period of 10 years, whether in use during that period or not, will be considered to be beyond economic repair. If appropriate mandated preventive maintenance and overhauls are conducted, a device may continue to be used. If, due to damage, lack of mandated overhauls, voided warranty, or other misuse, a device is considered by the Repair Department to be beyond economic repair, a letter will be sent advising the owner of the device of the findings, and requesting disposition instructions. Under no circumstances will a device considered by Percussionaire® Corporation Repair Department to be beyond economic repair be returned to active service.

NOTE: CERTAIN BREATHING CIRCUIT COMPONENTS, BLENDERS, COMPRESSORS, FREQUENCY COUNTERS, AIRWAY PRESSURE ALARMS and MONITRON WAVEFORM ANALYZERS WILL BE SERVICED IN PERCUSSIONAIRE'S DESIGNATED MAINTENANCE CENTERS ON CONDITION.

Intervention by an unauthorized individual or repair maintenance facility will cause the immediate expiration of the clinical readiness of the device. Adulteration or invasion of any aeromedical product manufactured by Percussionaire® that violates the intent of the supervising agencies could be judged a federal offence.

To return a PERCUSSIONAIRE® MEDICAL DEVICE to factory service center for repair, overhaul or annual preventive maintenance contact: 800-850-7205 or (208) 263-2549 for a return goods authorization number (RGA #). A return goods authorization number (RGA#) will be issued for each device identified by the serial number. The device shipped must be disinfected, cleaned, placed in a plastic bag and placed in a sturdy box with packaging material thoroughly surrounding unit. A packaging slip must accompany box with information including RGA#, PURCHASE ORDER #, SERIAL# of device, name and address of packager, work requested, shipping address and phone number. If work beyond the flat rate fee is required, a PERCUSSIONAIRE® service representative will contact customer with an estimated cost for additional repair work. Work will not start until Percussionaire®
receives a documented approval of Percussionaire® cost estimates. Return delays will be the responsibility of the owner of the device for not immediately advising Percussionaire® Remanufacturing cost for the Impulsator and VDR®-4 include the cost of a replacement housing. If the housing is still in good condition, this cost will be removed.

Any device showing damage may be subject to additional charge if the repairs require parts not normally replaced during remanufacturing.

STORAGE

The Percussionaire® units should be stored in a clean environment and covered when not in use. Temperature should be maintained between -40°C to +40°C. (-40°F to +104°F) Humidity range is 0-95% non-condensing.

DISPOSAL OF EQUIPMENT

At the end of useful life of a unit, disposal should be in accordance with local, state, federal and international laws. The unit may also be packaged according to instructions found within this manual and shipped to authorized maintenance centers below for disposal.

SHIPPING INFORMATION

POSTAL ADDRESS
Percussionaire Corporation
P.O. Box 817
Sandpoint ID 83864 USA

TELEPHONE/FAX
Phone (208) 263-2549
Fax (208) 263-0577

UPS SHIPPING ADDRESS
Percussionaire® Corporation
1655 Glengary Bay Rd. Sandpoint ID 83864 USA

FedEx SHIPPING ADDRESS
Percussionaire® Corporation
1655 Glengary Bay Rd. Sagle ID 83860 USA

WEBSITE ADDRESS
www.percussionaire.com
GLOSSARY OF SYMBOLS

ATTENTION! READ THE SAFETY INSTRUCTIONS AND THE ENTIRE INSTRUCTION MANUAL BEFORE USING THIS DEVICE

DANGEROUS VOLTAGE WITHIN THE DEVICE MAY CONSISTITUTE A RISK OF ELECTRICAL SHOCK (Impulsator®, IPV®-HC™, Monitron II)

STOP! READ EXTRA CARE PRECAUTIONS

CLASS 1 EQUIPMENT
TYPE BF EQUIPMENT

PROTECTIVE EARTH GROUND

ALTERNATING CURRENT

POWER SWITCH ON

POWER SWITCH OFF

YEAR OF MANUFACTURE (xxxx – year)

ELECTRICAL AND ELECTRONIC EQUIPMENT SHOULD NOT BE PLACED IN MUNICIPAL WASTE. PLEASE CHECK LOCAL REGULATIONS FOR DISPOSAL OF ELECTRONIC EQUIPMENT. THE UNIT MAY ALSO BE PACKAGED ACCORDING TO PRECEDING INSTRUCTIONS AND SHIPPED TO AUTHORIZED MAINTENANCE CENTER FOR DISPOSAL.
GLOSSARY OF TERMS

TERMS AS THEY MAY RELATE TO THE DIFFUSIVE/CONVECTIVE MECHANICAL VENTILATION OF THE PULMONARY STRUCTURES.

CONTINUOUS MECHANICAL VENTILATION (CMV) – A mechanically programmed intrapulmonary tidal volume delivery. Based upon an arbitrary scheduled volume delivery; with a selected cyclic I/E delivery rate, under an arbitrary peak positive pressure limit.

CONVECTIVE TIDAL VOLUME DELIVERIES – The delivery into the pulmonary structure of programmed volumes of a respiratory gas (measured in cubic centimeters) that exceed the anatomical dead space, favoring the wash out of carbon dioxide.

DEMAND CONSTANT POSITIVE AIRWAY PRESSURE (DEMAND-CPAP) - A pneumatically energized flow accelerator that is servoed by a physiological proximal airway pressure change. A certain minimal proximal airway pressure is selected (such as 5 cm H2O) for maintenance during the spontaneous physiological expiratory phase, which additionally provides a mechanically programmed inspiratory flow acceleration to accommodate physiological inspiratory demand to reduce the work of spontaneous breathing. DEMAND-CPAP is a form of Inspiratory Pressure Support.

DIFFUSIVE SUB TIDAL VOLUME DELIVERY - The mechanical programming of repetitive intrapulmonary percussive volume deliveries (measured in milliliters and/or cubic centimeters) that are less than the patient’s anatomical dead space. Higher frequency sub tidal volume deliveries favor diffusive activities within the pulmonary structures, enhancing oxygen uptake.

DIGITAL FREQUENCY MONITORING - A COMPONENT OF THE VDR® MONITORING OF pulsatile frequencies generated by a VDR® Percussionator® which can be presented in a traditional format.

DYNAMIC FUNCTIONAL RESIDUAL CAPACITY (D/FRC) - The average amount of gas remaining within the pulmonary structures during oscillatory equilibrium, when the elastomeric and frictional forces within the lungs are in equilibrium with the pulsatile sub tidal volume delivery pressures, without further increase in lung volumes. (D-FRC) is resultant from either an inspiratory or expiratory oscillatory equilibrium.

EFFECTIVE ALVEOLAR VENTILATION - The amount of physiological sub tidal exchange delivered into peripheral pulmonary structures providing for an effective intrapulmonary diffusion and perfusion.

EXPIRATORY INTERVAL - A COMPONENT OF VENTILATORY PROGRAMMING, describing the scheduled time at a selected baseline between repetitive inspiratory oscillatory intervals. And/or the time at an oscillatory baseline during Volumetric Diffusive Ventilation (VDR®)

FAILSAFE SENSITIVITY - VDR® HIGH PRESSURE FAILSAFE SECURITY PROVISION, guarding against an internal Percussionator® failure and/or an obstructed Phasitron delivery tubing. Whenever the Phasitron delivery pressures exceed the selected pressure rise for approximately two (2) seconds, an aural alarm is sounded concomitant with a regulated drop in patient delivery pressures. The Failsafe Sensitivity selection determines the sustained pressure required (within programmable limits) within the patient servoing circuit to provoke a pressure rise alarming.

FUNCTIONAL RESIDUAL CAPACITY - The amount of gas remaining within the pulmonary structures at the end of passive exhalation, when the elastomeric forces within the lung are in equilibrium with ambient pressures.
GROSS TIDAL VOLUME- A COMPONENT OF VDR® SCHEDULING, relating to a passive convective intrapulmonary gas exchange, realized during the scheduled expiratory interval when lung volumes are decreased to their scheduled baseline.

HIGH FREQUENCY PULMONARY VENTILATION (HFPV)- A loose definition of methods employed in attempting to create a greater diffusive component of intrapulmonary ventilation than would normally be expected with conventional mechanical lung ventilation (CMV).

“i/e” PULSE RATIO- A COMPONENT OF VDR® SCHEDULING, expressing the pulsatile (sub tidal volume) flow – no flow relationships in milliseconds. Valve open = flow time/valve closed = no flow time.

INTEGRATED MANOMETER- A COMPONENT OF VDR® MONITORING, whereby a rotary switch allows the selection of a highly dampened integrated proximal airway pressure. The manometric mechanism is calibrated with a time constant well beyond repetitive (cyclic) programming. Information is clinically significant in determining the efficacy of the selected program in terms of “mean functional pressures” as they reflect upon blood gases and cardiac output.

INTERMITTENT MANDATORY VENTILATION (IMV)- A mechanical ventilatory program scheduled to deliver a certain number of controlled tidal volumes per minute while allowing the patient to breathe spontaneously with a reduced work of breathing.

INTRAPULMONARY PERCUSSION- A method of delivering repetitive (partially accumulative) high velocity bursts (sub tidal volumes) of respiratory gases into the proximal physiological airway with precise pneumatic control over pressure/flow/volume relationships for maximum bilateral intrapulmonary distribution, with impactions below “stretch receptor” threshold and barotraumatic potentials.

INTRAPULMONARY PERCUSSIVE VENTILATION (IPV® expanded)- A cyclic method of controlled percussive intrapulmonary (sub tidal) breath stacking, increasing the existing functional residual capacity of the pulmonary structures to a selected level (pulsatile equilibrium) at which point repetitive sub tidal volume delivery does not further increase lung volumes.

Each percussive inspiratory interval (timed in seconds) is associated with a diffuse intrapulmonary pulsatile gas mixing concomitant with aerosol delivery, followed by a passive exhalation to a selected oscillatory baseline.

INTRAPULMONARY PERCUSSIVE VENTILATION (IPV)- A mechanical means of introducing (aerosol laden) successive sub tidal intrapulmonary breath stacking, reaching a controlled percussive apneustic plateau within the pulmonary structures for the purpose of endobronchial secretion mobilization and the resolution of associated diffuse patchy atelectasis.

JET INSUFFLATOR (VENTILATOR)- A mechanical device usually consisting of a solenoid valve with control over valve opening and closing ratios as well as over the flowrate of pulsatile gas delivery into the physiological airways, through an uncuffed indwelling airway catheter with a tip located immediately above the carina.

MANOMETRIC DAMPENING- A COMPONENT OF VDR® MONITORING – A method of dampening the needle of a manometer looking at proximal airway pressure change during VDR® programming. A standard calibration provides the clinician with a “mean pressure interpretation” of the phasic pressure alterations at the physiological proximal airway.

MECHANICAL PULSE GENERATOR (FLOW INTERRUPTER)- A pneumatically energized, diaphragm controlled, differential flow valve for the controlled cyclic interruption of a pressure/flow regulated respiratory gas.
MINUTE VENTILATION- The amount of mechanically delivered respiratory gas (measured in liters) cyclically delivered into the pulmonary structures each minute.

OSCILLATORY APNEUSTIC PLATEAU- is resultant from an oscillatory inspiratory equilibrium, after the inspiratory increase in lung volume has been satisfied, and the lung is being ventilated by percussive sub tidal volume deliveries through an inspiratory pressure wedge, without a further increase in lung volume.

OSCILLATORY DEMAND CONSTANT POSITIVE AIRWAY PRESSURE (OD-CPAP) – A COMPONENT OF VDR® PROGRAMMING, allowing the selection of an oscillatory expiratory baseline, while maintaining a positive end expiratory pressure with an inspiratory flow acceleration to assist a spontaneous inspiratory effort.

PERCUSSION/BASELINE RATIO (B/P RATIO)- A COMPONENT OF VDR® PROGRAMMING, expressing the ratio of the percussive sub tidal (inspiratory) interval in relation to the time at baseline (expiratory) interval. A method of describing the VDR® I/E ratio.

PERCUSSIONATOR® - A mechanical device providing sub tidal volume deliveries in milliseconds.

PHASING RATE- A COMPONENT OF VDR® PROGRAMMING, describing the number of cyclic inspiratory/ expiratory intervals per minute counted as returns to a programmed expiratory baseline.

PHYSIOLOGICAL DEAD SPACE- A pulmonary gas re-breathing volume that is void of blood/ gas exchange.

POSITIVE DISPLACEMENT OSCILLATOR VENTILATOR- A mechanical piston type device with a reciprocating relatively fixed stroke, causing (to and fro positive and sub ambient) potential displacements of a respiratory gas into and out of a mechanical breathing circuit. A biased proximal airway inflow and outflow is often employed to control the exchange of respiratory gases.

PRESSURE LIMITED VENTILATION- A peak inspiratory pressure limit PIP (measured in cm H₂O) established to limit the maximum inspiratory delivery pressure within the pulmonary structures during the mechanical ventilation of the lung.

PRESSURE RISE AND FALL ALARMIN- VDR® HIGH and LOW PRESSURE FAILSAFE SECURITY PROVISIONS, available systems to monitor and alarm on a rapid or sustained proximal airway pressure rise.
A battery operated HI/LO SIG-ALERT selectable time related pressure drop can provoke an alarm as well as a pressure rise above a programmed value. Additionally, a Wave Form Monitor (Monitron®) can perform a similar task with programming accomplished on a CRT.

PROXIMAL AIRWAY PRESSURE- A sampling point adjacent to the proximal physiological airway where mechanical and/or physiologically altered pressures are recorded. Proximal airway pressure alterations provide the pulmonary (proximal/distal) pressure gradients for potential intrapulmonary inflow and outflow.

PROXIMAL AIRWAY WAVE FORM ANALYSIS- A COMPONENT OF VDR® MONITORING, whereby proximal airway pressures are directed against a transducer with sufficient capacities to relate the rapid (millisecond) pressure changes associated with VDR®/IPV® scheduling. Therefore, a means for presenting proximal airway pressure changes on a cathode ray tube (CRT) are enhanced. Desirable pressure scales and sweep speeds can be selected, allowing the clinician to program and interpret proximal airway pressure potentials as they may affect physiological parameters. Additionally, proximal airway pressure tracings can be documented on strip chart recorders.
PULSATILE AMPLITUDE and/or PULSATILE FLOWRATE- A COMPONENT OF VDR® SCHEDULING, describing the (proximal airway) pressure rise during selected sub tidal volume deliveries, secondary to the scheduled flowrate of respiratory gases delivered from the orifice of the Phasitron®.

PULSE FREQUENCY- A COMPONENT OF VDR® SCHEDULING, describing the number of pulsatile sub tidal volume deliveries per minute.

VDR “I/E” RATIO- A COMPONENT OF VDR® SCHEDULING, describing the ratio between the length of time (in seconds) that sub tidal volumes are intrapulmonarily delivered (oscillatory inspiratory interval) to the length of time a scheduled interruption at baseline (expiratory interval) is scheduled. Oscillatory Inspiratory interval/expiratory interval.

VDR®/IPV® PERCUSSIONATOR®- A mechanical device capable of delivering sequential percussive bursts (sub tidal volumes) of a selected respiratory gas with flow generated at the proximal physiological airway for delivery into the pulmonary structures through a mechanical/physiological interface (combination injector exhalation valve) called a Phasitron®. A sinusoidal pressure change pattern can be programmed.

VENTILATOR – A mechanical device providing tidal volume deliveries in seconds.

VOLUME LIMITED VENTILATION- A selected volume (measured in milliliters) programmed for intrapulmonary delivery under a preselected pressure limit, whereby the mechanical ventilator will cycle on either the selected volume and/or pressure limit, based upon which limit is first reached.

VOLUMETRIC DIFFUSIVE RESPIRATION (VDR expanded)- A cyclic method of precisely controlling the intrapulmonary delivery of successive (aggregate) sub tidal volumes to a selected equilibrium (increase in lung volume) ultimately reaching an oscillatory apneustic plateau (oscillatory equilibrium) followed by the passive exhalation of a gross tidal volume down to a programmed static and/or pulsatile baseline.

VOLUMETRIC DIFFUSIVE RESPIRATION (VDR®)- A sinusoidal wave form applied against the physiological proximal airway to more independently (mechanically) control PaO₂, PaCO₂ and cardiac output.
EQUIPMENT CLEANING AND DECONTAMINATION PROCEDURES

These cleaning procedures supersede all others prior to July 1st, 2010.

All new Percussionaire® products are packaged clean. They should not be considered sterile or decontaminated. Prior to use it is recommended that breathing circuit components be disassembled then cleansed.

GENERAL CLEANSING PROTOCOLS

1. The devices may be sprayed by aerosolized Lysol Brand III or similar Hospital Grade Disinfectant.

***DO NOT USE BUTCHER’S QUEST 256, THE USE OF THIS PRODUCT WILL DAMAGE THE MACHINE AND THIS DAMAGE IS NOT COVERED UNDER WARRANTY.

***Professional Lysol® brand III Disinfectant spray meets AOAC Germicidal Spray product Test standards for hospital aerosol disinfectants.

2. The devices after being sprayed down and allowed to dry are re sprayed with hospital wide spectrum aerosol consisting of the same germicidal agents with a timed exposure per labeling.

3. After device has dried it is then mechanically wiped with a similar germicidal agent impregnated in a saturated wiping vehicle and allowed to dry per labeling instructions.

4. Further in-depth mechanical cleansing and rinse is accomplished with Lysol Brand III. As well as other germicidal household cleansers to remove any grime, dirt or other materials during the disassembly processes.

Percussionaire® does not deliver sterile devices, which are appropriately labeled per FDA.

Follow instructions below on how to disassemble Percussionaire® breathing circuits.

1. Mechanically wash and dry all parts completely.

2. Process following local institution guidelines.

3. Reassemble circuit.

OTHER TECHNIQUES

The decision to use other proven decontamination techniques should be based upon the following parameters:

1. Standard Phasitron® part # A50007, A50007-1
2. Aerosol Generator part # A50010, A50010-1, A50010-3, A50010-5
3. Interfacing tubing made of SILICONE part # A50034-1

The above components can withstand temperatures < 280° Fahrenheit (137.8° Celsius)

The following components are not autoclavable:

1. Phasitron® Duo part # A50007-10
2. Interface tubing assembly part # A50034
3. These parts can withstand temperatures < 140° Fahrenheit (60° Celsius)

Percussionaire® medical devices are not submersible.

DISASSEMBLY OF PERCUSSIONAIRE® PHASITRON®
Part Numbers A50007, A50007-1

1. Disconnect colored tubing from service sockets.
2. Unscrew Phasitron® end cap part B10914.
3. Withdraw venturi assembly from Phasitron® body by pulling out upon orificed diaphragm attached to green or alternative red venturi assembly.
5. Remove opening spring B10916 from around Venturi tube.

Phasitron Body exterior component disassembly steps.

6. Remove green Inspiratory Failsafe Tee assembly part A50144 by a pulling rotation.
7. Remove red Expiratory Failsafe tee assembly.
8. Remove proximal airway Swivel Tee assembly by a pulling rotation. Remove Phasitron® Outlet Plug loop assembly, from Swivel Tee assembly part A50089-1 by pulling and rotating.
DISASSEMBLY OF PERCUSSIONAIRE® AEROSOL GENERATOR
Part Numbers A50010, A50010-1, A50010-2, A50010-3, A50010-5

1. Disconnect colored tubing from service sockets.
2. Release nebulizer cap part # A50015-1 by holding aerosol bowl assembly part A50087, then rotating nebulizer cap counterclockwise ¼ turn.

FOUR CHANNEL BREATHING CIRCUIT INTERFACING TUBING ASSEMBLIES:

A50034 non-autoclavable tubing assembly or
A50034-1 autoclavable Silicone tubing assembly
This document was prepared and edited with data from the Achieves of Forrest M. Bird, M.D., Ph.D., Sc.D. based upon facts and textbook understandings with no commercial overtones. Strict ethical comparisons are employed without re-inventing cardiopulmonary pathophysiology or physical principals. It is realized that very few clinicians will take the time to read and understand the TOTAL contents of this document; however, for those who do, a wealth of justificational information has been presented.