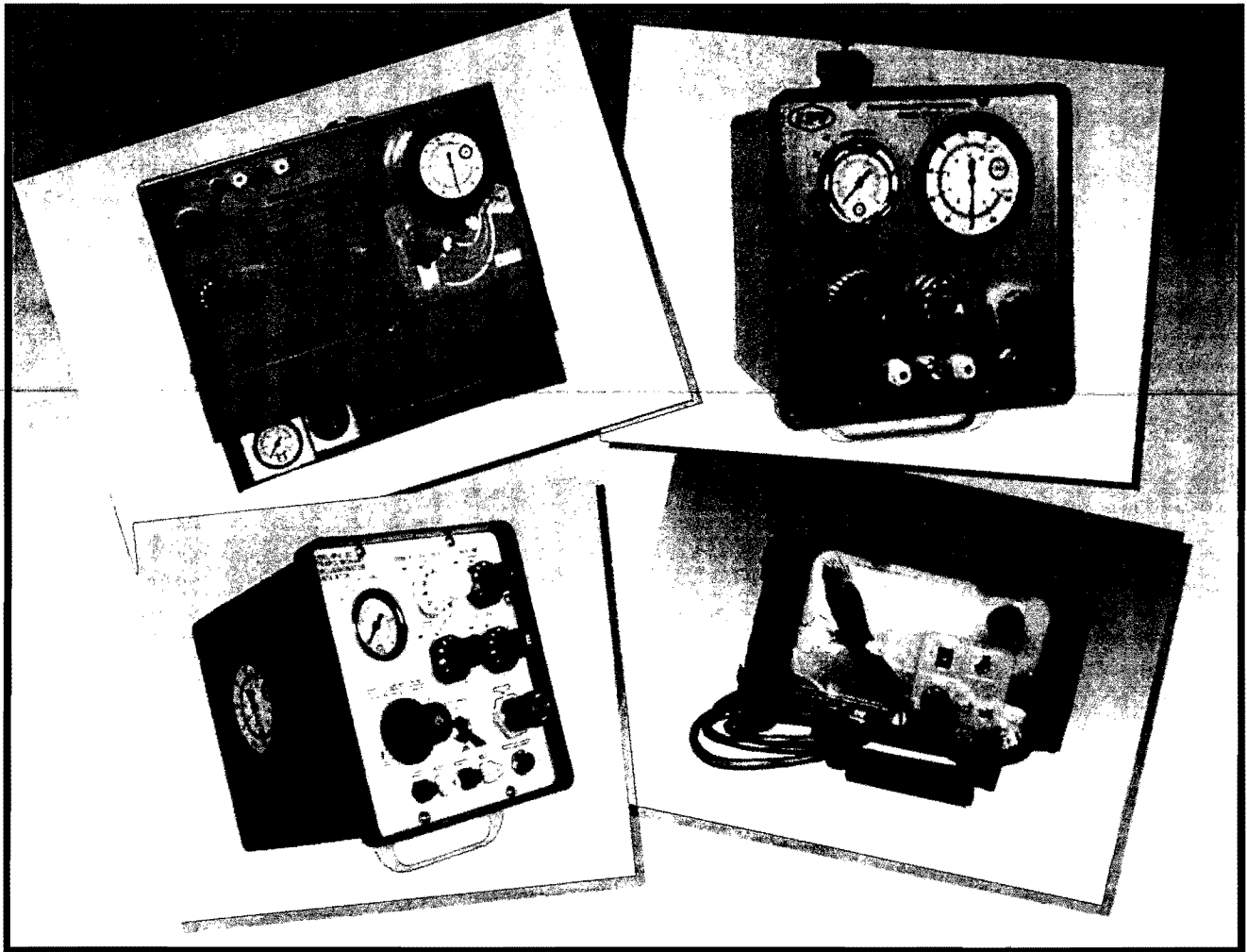


PRESENTS:

AN IPV® OPERATIONAL MANUAL

INTRAPULMONARY PERCUSSIVE VENTILATION (IPV®)



THE FAMILY OF IPV® PERCUSSIONATORS®

INDICATIONS FOR USE

Use of Percussionaire® IPV® is indicated for the mobilization and raising of endobronchial secretions, bronchodilation, reducing mucosal edema, and the resolution of diffuse patchy atelectasis in all patient populations.

CONTRAINDICATIONS

Contraindications for use include but are not limited to:

- Untreated tension pneumothorax
- Lack of adequate, skilled supervision

PHYSIOLOGICAL EFFECTS OF IPV®

Many positive effects of IPV® include:

- Recruitment of atelectatic lung
- Mechanical Bronchodilation
- Larger Vt
- Improved breathing pattern
- Decreased work of breathing
- Increased secretion mobilization

The IPV® Percussionators® have inherent risks similar to all positive pressure breathing devices. These risks include but are not limited to under/over ventilation, under/over humidification, pneumothorax, and pneumediastinum, PIE, pneumoperitoneum, and hemoptysis.

CLINICAL LIMITATIONS/RESTRICTIONS

Use of IPV Percussionators is limited to individuals who have received proper training in their use.

The use of standard therapeutic IPV® Percussionators will be restricted to a mouthpiece only. Under no circumstances will a standard IPV® breathing head with a gated aerosol generator be used with other than a mouthpiece (with lip seal only).



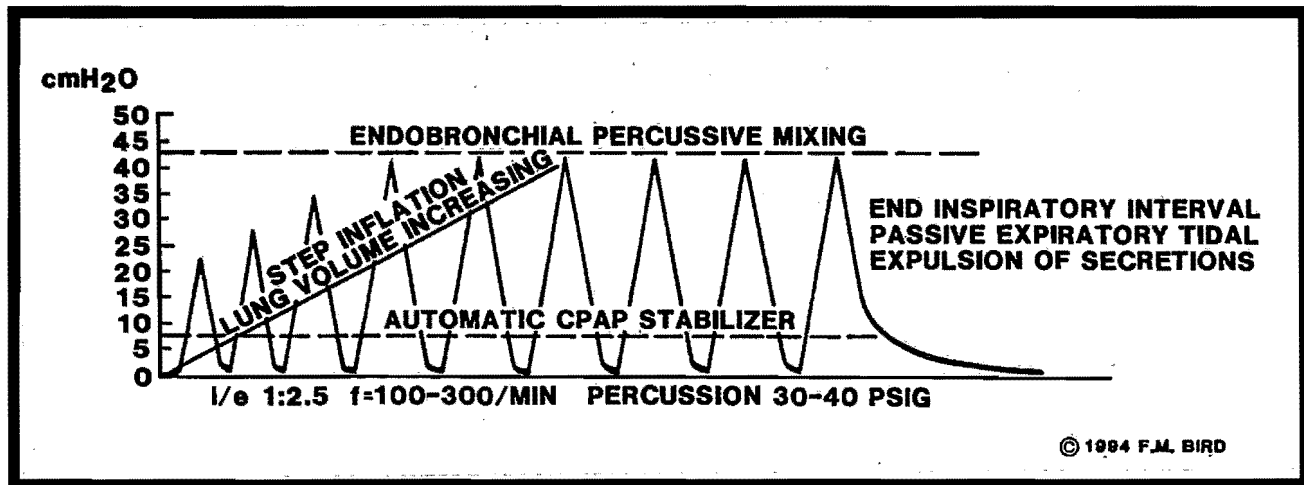
CAUTION

If an IPV® Percussionator® is used on a patient with an indwelling airway (i.e. endotracheal or tracheotomy tube), a clinician must be present so that a one to one relationship exists. These devices enhance secretion clearance. Patients must be assessed pre and post treatment for a reduced vital capacity/FRC or the need for assistance in clearing airway secretions. A patient cannot breathe through an obstructed airway! If an artificial airway is in place, a special gated aerosol generator must be used to relieve any transient/unwanted pressure rises.

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INTRAPULMONARY PERCUSSIVE VENTILATION (IPV®)



INTRODUCTION

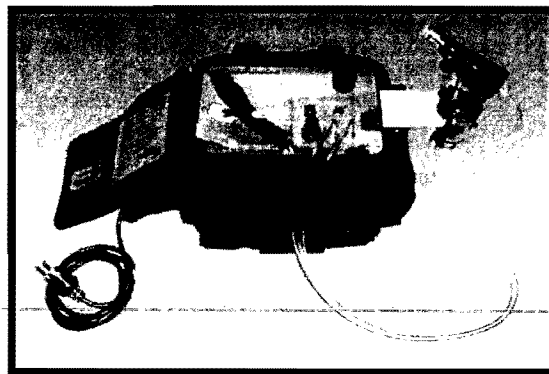
Created by Dr. Forrest M. Bird in the mid 1980's, Intrapulmonary Percussive Ventilation (IPV®) was primarily conceived to recruit and therapeutically maintain the insidious loss of bronchiolar blood supply in patients with progressive COPD.

During acute care COPD ventilation, the IPV® concept has proven to eliminate the barotrauma (lung damage) associated with preferential airway created during attempted lung recruitment of COPD patients with electronic volume-pressure limiting (CMV) ventilators.

IPV® PERCUSSIONATORS® CONSIST OF THE FOLLOWING KEY DEVICES:

1. THE HOME CARE IPV® HC™ manual Bi-phasic™ SELF CONTAINED TRANSPORTABLE IMPULSATOR® allows home patients to travel while maintaining their daily Bi-phasic™ home care IPV® therapeutic treatment schedules.
2. THE IPV®-1C IS THE ROUTINE INSTITUTIONAL IPV® PERCUSSIONATOR®.
3. THE IPV®-2C a PROGRAMMABLE OSCILLATORY DEMAND CONTINUOUS POSITIVE AIRWAY PRESSURE (OD-CPAP) FOR INSTITUTIONAL PERCUSSIVE THERAPEUTIC LUNG RECRUITMENT IN ALL PATIENT POPULATIONS.
4. THE INSTITUTIONAL AND HOME CARE IPV® HEAVY IMPULSATOR IS THE SELF CONTAINED ELECTRICAL PLUG IN AIR COMPRESSOR VERSION OF THE IPV®-1C.

THE HOME CARE IPV®-HC IMPULSATOR®

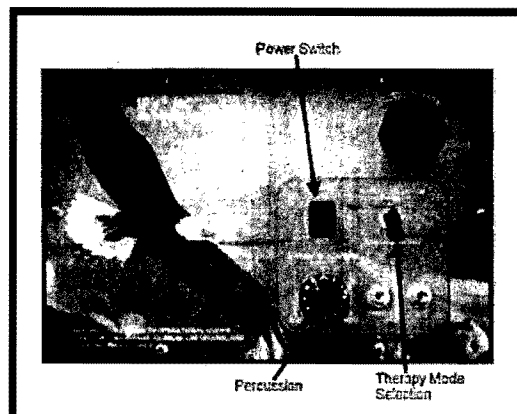


The advanced technology lightweight 15 pound Home Care IPV®-HC™ Impulsator® manual Bi-phasic™ IPV therapy Percussionator® is packaged in a deluxe ruggedized camera type airline luggage pack. This transportable IPV® HC™ Impulsator® allows home Care COPD patients to maintain the same effective IPV® routine treatment schedules they use in their homes when they want to travel on cruises, to the grandkids, or to visit friends. Additional information may be obtained in the IPV®-HC Instruction Manual, Document ID F-051009.

POWER SWITCH –
 I ON
 O OFF

PERCUSSION – Determines frequency of delivered breaths.

THERAPY SELECTION – Toggles between Bi-Phasic percussion with nebulization or nebulization only.



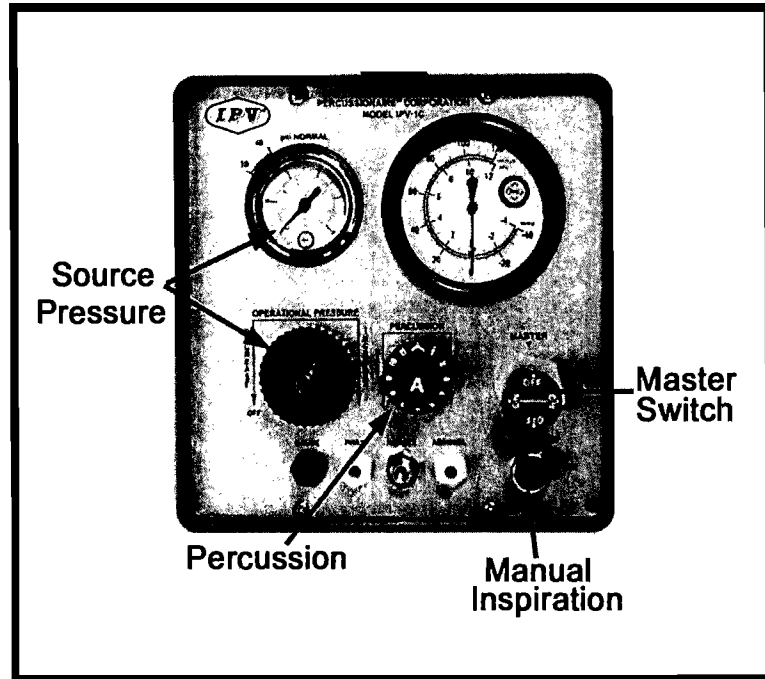
THE HOSPITAL STANDARD "WORKHORSE" IS THE IPV®1-C

OPERATIONAL PRESSURE-
determines amplitude
(pressure rise) of delivered
sub tidal breaths.

PERCUSSION- determines i/e
ratio of selected percussive
sub tidal breath delivery rate.

MANUAL INSPIRATION-
provides for a convective
(Tidal Volume) lung inflation
when depressed.

MASTER SWITCH- ON/OFF
On position - patient receives
percussive treatment.



As with all IPV® Percussionators®, the IPV-1C is capable of percussively mobilizing bronchiolar airways and their associated alveoli in all cardiopulmonary patient populations with mixed bronchiolar airway obstructions, from minimal toward total airway obstruction as well as associated diffuse unobstructed **PREFERENCHAL AIRWAYS** without barotraumatic hyperinflation of the alveoli served by the unobstructed preferential bronchiolar airways. This is accomplished in neonates through pediatrics to large adults **WHILE MAINTAINING A LUNG PROTECTIVE STRATEGY.**

THE Percussionaire® LUNG RECRUITER IS THE IPV®-2C

Programmable **OSCILLATORY DEMAND CONTINUOUS POSITIVE AIRWAY PRESSURE (OD-CPAP)** – for reducing the work of breathing in all patient populations.

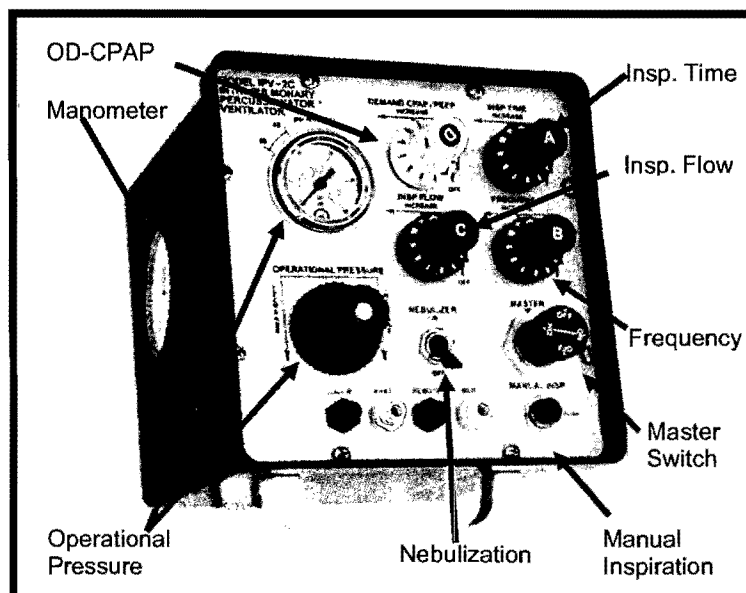
OPERATIONAL PRESSURE- determines amplitude (pressure rise) of delivered sub tidal breaths.

PERCUSSION- determines i/e ratio of selected percussive sub tidal breath delivery rate.

MANUAL INSPIRATION- provides for a convective (Tidal Volume) lung inflation when depressed.

NEBULIZATION – ON/OFF On position – patient receives aerosol.

MASTER SWITCH- ON/OFF On position - patient receives percussive treatment.



The IPV®-2C Percussionator® is a High Frequency percussive Ventilator (HFPV™) with:

- ❖ Selectable percussive amplitude and frequency for the mobilization and airway clearance of retained endobronchial secretions and the resolution of diffuse patchy atelectasis during mechanical airway recruitment.
- ❖ Simultaneous high volume aerosol generation for the topical delivery of water, saline, bronchodilators, vasoconstrictors and certain other IV pharmaceuticals.
- ❖ An ideal non-invasive or invasive universal ventilator for acute mechanical cardio respiratory care in all patient populations from initial resuscitation to stabilization and transport.

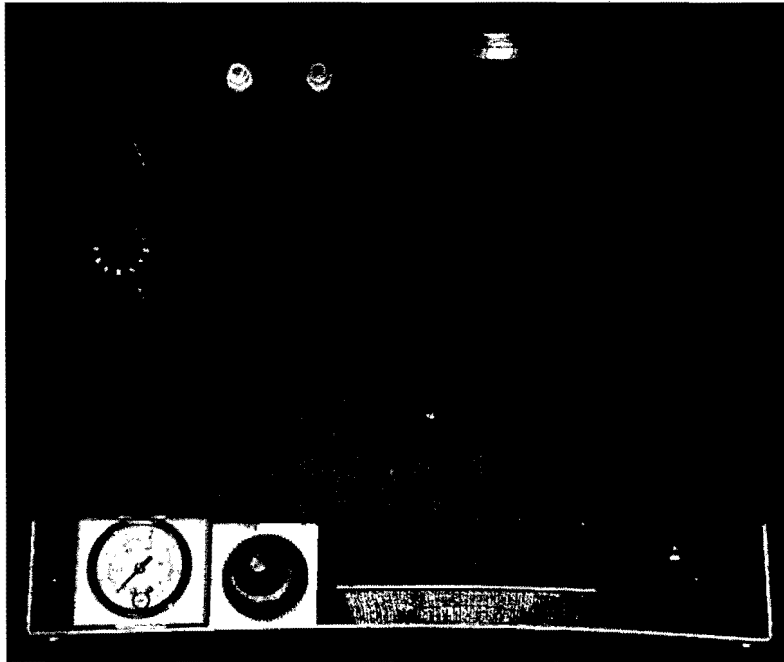
OSCILLATORY DEMAND CPAP (OD-CPAP) FOR UNIVERSAL PERCUSSIVE THERAPEUTIC LUNG RECRUITMENT.

OD-CPAP FOR TRANSITION INTO INTRAPULMONARY PERCUSSIVE VENTILATION (IPV®)

INDEPENDENT DEMAND CPAP FOR POST VENTILATOR WEANING.

Standard Percussionaire® IPV® Phasitron® Breathing Circuits can be used with the IPV®-2C for invasive or non-invasive ventilation.

**THE BASIC DISPENSARY OR HOME CARE IMPULSATOR®
PERCUSSIONATOR® Model F00012**



The RUGGEDIZED packaging of the heavy Impulsator® has been designed for functional durability. The unique self-contained, shock mounted air compressor is designed for a relative 10,000 hour time period between Percussionaire® factory overhauls with thousands in service since the 1980s.

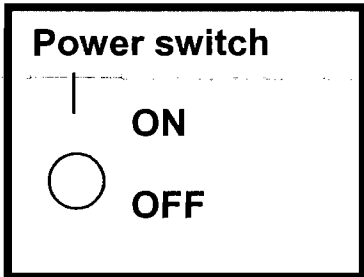
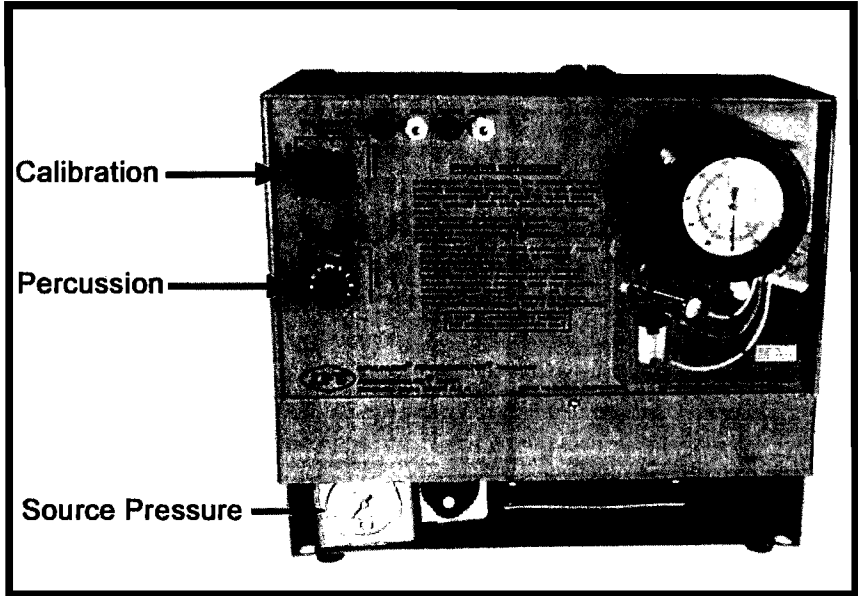
1. The pneumatic IPV® PERCUSSION scheduling circuit has infinite years of life.
2. The various IPV® Breathing circuits are manufactured for long-term (years) of use. However, to provide for multiple use it is wise to have spare IPV® Breathing Circuits.
3. Compressors over ten years old needing repair require a new style compressor.

BRIEF DESCRIPTION OF IMPULSATOR® CONTROL FUNCTIONS

Calibration- Used to adjust i/e percussion ratios, kept in 12:00 position (arrow straight up) for patient use.

Percussion- Determines frequency of delivered breaths.

Source pressure- Determines amplitude of percussive Sub Tidal breath deliveries.



TRADITIONAL OPTIONS FOR COPD CLINICAL MANAGEMENT AND THEIR LIMITATIONS ARE:

- 1. If a conventional powered aerosol nebulizer is employed to deliver a bronchodilator into the patient's proximal airway during spontaneous inhalation, the penetration into the airway would be limited at best, and ineffective against peripheral mucosal and sub-mucosal edema.**
- 2. If the delivery of an aerosolized mucolytic agent is attempted, there would be limited means with a depressed cough to mobilize and raise the secretions from the upper bronchiolar airways, much less the periphery of the lungs.**
- 3. If an anti-cholinergic agent like Atropine is aerosolized for inhalation into the pulmonary airways directed toward bronchodilation, the potential drying effect upon the goblet cells could serve to increase the viscosity of the retained endobronchial secretions.**
- 4. Bronchoscopy cannot initiate or maintain the clearance of the diffuse obstructed peripheral airways.**
- 5. Aerosol delivered by positive pressure devices such as those designed for Intermittent Positive Pressure Breathing (IPPB), while providing increased levels of endobronchial secretion mobilization, cannot provide for the phasic expiratory patency of airways recruited during the positive pressure inspiratory phase.**
- 6. Coughlator type devices designed to produce an artificial cough in patients with Polio (who essentially had normal lungs) generally only serve to help clear the upper airway of normal, less viscid secretions.**
- 7. Chest physiotherapy, while effective, requires a Physical (Respiratory) Therapist with specific skills to administer effective lung secretion clearance at least twice daily.**
- 8. Chest THUMPERS may mobilize upper airway secretions like a Vest or Coughlator, however they do not recruit Bronchiolar airways and their Alveoli.**
- 9. Therefore, the general methods employed by clinicians to clear retained endobronchial secretions from chronically obstructed pulmonary airways (COPD) "which are insulted by transient infections" would be limited in the PATIENT with an ACUTE rapid onset of major mucosal and sub-mucosal edema with associated airway secretion retention.**

CLINICIAN'S GENERAL LUNG RECRUITMENT PROTOCOL

IPV®-1C or HEAVY IMPULSATOR®

- 1) Introduce yourself as a clinician and explain IPV® procedure to your patient.
- 2) IPV-1C Connects to any respiratory 50- 80 psig gas power source:
 - A) IPV®-1C: 50 psi. / 3.2 bar gas source. Master Switch - OFF.
 - B) IMPULSATOR®: USA and JAPAN etc.115Vac/60Hz.
 - C). Europe etc. 220Vac/50 Hz. Impulsator® Rocker Switch – OFF.
- 3) Patient should be in an upright comfortable arm-chair and/or in a pillow elevated head and shoulder position. Note: Patient's gravitational position is not a factor with IPV® Therapeutic Lung Recruitment (TLR)™.
 - A) Patient should be auscultated for breath sounds, heart and respiratory rate or follow institution guidelines.
- 4) Short end of Percussionator® interfacing harness assembly must be connected to Percussionator® Service sockets using matching color-coding.
- 5) Long end of Percussionator® interfacing harness assembly must be inter-connected to Phasitron® and Nebulizer sockets using matching color-coding.
- 6) Service Nebulizer with prescribed medications and dilute Bronchodilators with Normal Saline and/or Alpha/Beta Racemic Epinephrine .5 cc. diluted with Water in this case to the 20 cc scribe line on the Nebulizer Bowl. Assemble Phasitron® to Nebulizer and/or Nebulizer Bowl to Body with the Phasitron® Duo™ breathing head.
- 7) Rotate FREQUENCY control knob Arrow full (counterclockwise) to the EASY position.
- 8) With IPV®-1C Gas Supply ON or Impulsator® Compressor Switch ON, Rotate OPERATIONAL PRESSURE control regulator knob for an operating pressure of 30 to 35 psig.
- 9) Teach patient to position mouthpiece aimed at lips. Have patient insert mouthpiece between lips then breathe dense aerosol from the nebulizer for approximately 1 to 2 minutes etc.
10. While patient is comfortably breathing aerosol, explain Intrapulmonary Percussion when the activation button is manually started by depressing the Nebulizer Switch and/or releasing the finger from over Phasitron® Duo™ STOP PERCUSSION vent hole. The patient may still be surprised when Percussion abruptly begins.

11. The patient must be instructed to inhale and exhale through the programmed percussive impactions, most patients will initially allow percussive bursts of air to leak through their nose at the expense of an observable chest oscillation (shake). Use the Soda Straw analogy, to teach patient how to forcefully breathe in and out of the Mouthpiece as if it were a Soda Straw.

Start to notice the chest oscillation (shake) as the patient exhales (blow out) through the mouthpiece. Advise the patient to relax taking normal (spontaneous) breaths through the Percussive Oscillation whenever they desire. The objective is to perform a protracted period of Percussive IPV® breathing for a 15 to 20 minute treatment. Cheek puckering fatigue may be an early consideration, however, this is soon eliminated.

Note: The individual clinician teaching the patient how to use Therapeutic IPV® must themselves be proficient in Percussing their own lungs.

- A) The manually initiating active Percussive breathing cycle must last at least 15 to 25 seconds to allow the start of bronchiolar airway recruitment.

The patient should be instructed to keep lips and cheeks splinted to avoid nasal air venting. As the patient learns to prevent air from leaking out of the lip seal around the mouthpiece, the PERCUSSION control knob Arrow can be gradually rotated (clockwise) toward the 12:00 index.

- 12) If the patient cannot understand instructions the therapist may have to use an appropriate mechanical airway to administer therapy such as a mask. Note: When other than a mouthpiece is used select a Percussionaire® Nebulizer with a green pressure rise Failsafe Band.



A typical mother administering to a child with diagnosed cystic fibrosis

- 13) Breaks between the “active percussive breathing” should be as often as necessary for expectoration and/or therapist directed coughing. The patient is instructed to continue breathing the aerosol if resting between “percussive breathing “ cycles.
- 14) After the ability to prevent the leaking of percussive air deliveries from the nose and around the lips is learned, the entire Percussion frequency band should be scanned by briefly rotating the PERCUSSION control knob Arrow from EASY to HARD back and forth (a number of times) then back to the 12:00 Arrow position to raise secretions from the Bronchial Airways. Kleenex® availability is a must.

As the learning period progresses the selected Source Pressure should be increased for effective Endobronchial Percussion by assessing “chest percussion (shaking). Nominal Operating Pressure is 40 psig.

- 15) Ideally Patient IPV® Treatment should continue for 15 to 20 minutes.
 - A) For prolonged Therapeutic Lung Recruitment (TLR)® with mechanical airways etc. additional diluents or medication may be used to service the Nebulizer.
- 16) When treatment is complete unit should be turned OFF. Breathing head should be removed then dismantled and mechanically washed and dried for next SAME patient treatment. IPV® Breathing Heads may be cleansed for multi patient use, per Hospital-Percussionaire® recommendations.

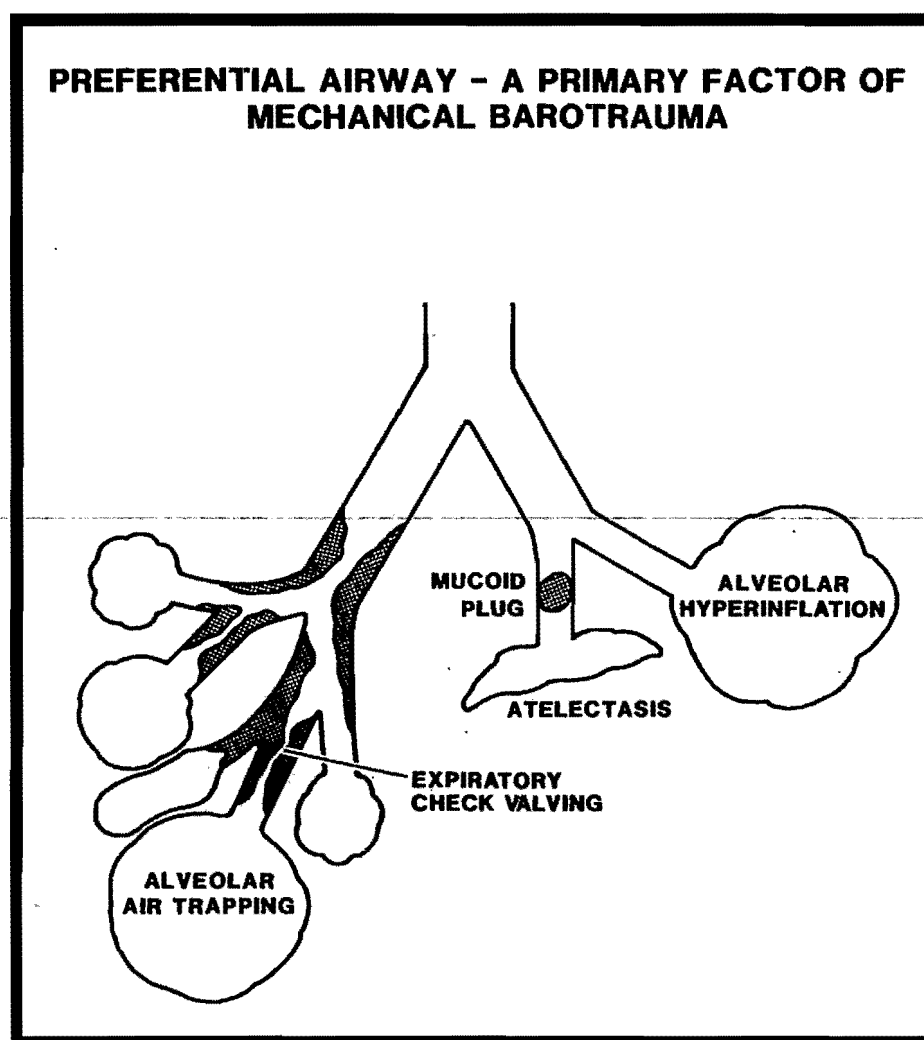
Notes:

MAJOR DISCUSSIONS INVOLVING COPD AND MANAGEMENT:

PREFERENTIAL AIRWAY

Intrapulmonary Percussive Ventilation (IPV®) has a designed lung protective strategy to prevent lung injury that can occur with the electronic pressure-volume ventilators used on hospitalized patients with acute obstructive lung diseases.

By employing step (sub tidal) inflation of the lungs in patients with various degrees of airway obstructions, IPV® eliminates "Preferential Airway Delivery." Step inflation allows the lungs time to accommodate to their accumulating sub tidal inflationary volumes. This rationale is termed "pulmonary conformance" which is a designed form of a "lung protective strategy."



THE ABOVE SCHEMATIC REPRESENTS THE
TYPICAL PULMONARY PATHOLOGY OF A PATIENT WITH
ACUTE OR CHRONIC OBSTRUCTIVE LUNG DISEASE (COPD).

Note the PREFERENTIAL AIRWAY "ALVEOLAR HYPERINFLATION".

OF MAJOR CONCERN

When volume-pressure oriented ventilators are programmed to deliver a tidal volume under a selected peak inspiratory pressure (PIP), with an associated constant inspiratory flowrate of gas into the lungs of patients with diffuse peripheral obstructive lung disease, the most patent endobronchial airways “become preferential to tidal inflation with an increasing potential for PREFERENTIAL AIRWAY BAROTRAUMA (lung damage) TO THE MOST DEPENDENT ALVEOLAR STRUCTURES”.

A volume-pressure cycled ventilator creates a preferential mechanical inflow gradient from the proximal airway into the most patent (open) peripheral bronchial airways and their interconnected alveoli. The greater the inspiratory inflow rate (proximal-distal flow gradient) the greater the distending bronchiolar inflow velocity into the preferential endobronchial airways.

During sub tidal volume deliveries the selected operational pressures will determine the peak inspiratory delivery pressure (PIP), which, in turn, will control the mechanically created inspiratory flowrate gradients.

PATHOPHYSIOLOGICAL UNDERSTANDINGS

The greater the pressure-drop from the proximal airway down into the distal pulmonary alveoli, the greater the inflow velocity into the most PATENT PULMONARY AIRWAYS. This produces selective PREFERENTIAL ALVEOLAR HYPERINFLATION with BAROTRAUMATIC POTENTIAL.

~~WHEN A COPD PATIENT BECOMES INCREASINGLY OBSTRUCTED (HOWEVER CAUSED) AND IS FIGHTING FOR THEIR EVERY BREATH, WHETHER IN THE HOSPITAL OR IN THEIR HOME; MECHANICALLY GENERATED THERAPEUTIC IPV® LUNG RECRUITMENT (TLR)™ CAN BE CLINICALLY EFFECTIVE BEYOND ALL OTHER KNOWN CLINICAL MEANS. THE VARIOUS CHOICES OF IPV® PERCUSSIONATORS® WILL ALLOW ANY COPD PATIENT TO MAINTAIN IPV® LUNG RECRUITMENT AND MAINTENANCE WITHIN THE HOSPITAL, HOME OR DURING RECREATIONAL OR BUSINESS TRAVEL.~~

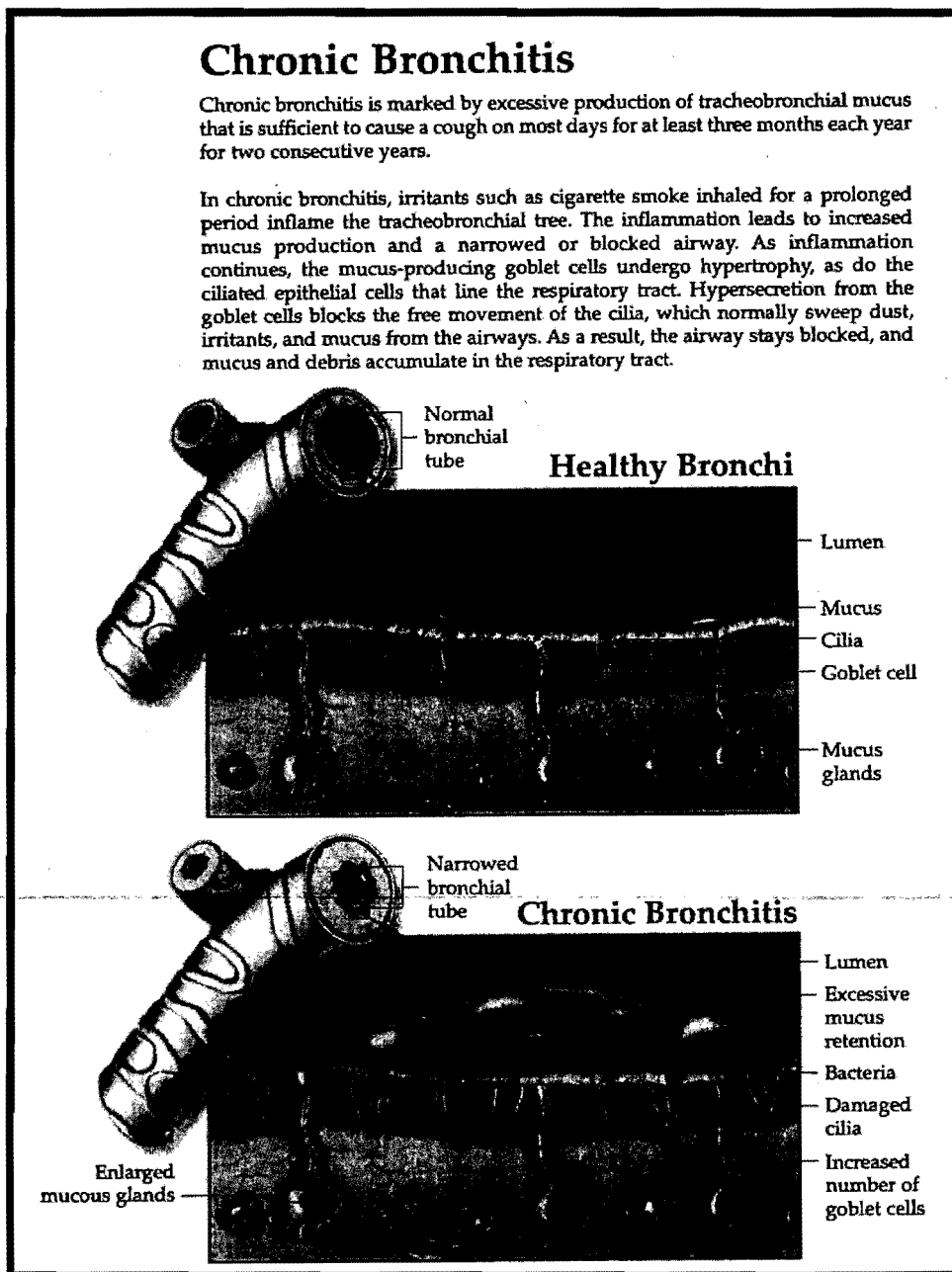
Notes:

THE GENERAL CLINICAL RATIONALE FOR THERAPEUTIC LUNG RECRUITMENT (TLR)TM is as follows:

Chronic Bronchitis

Chronic bronchitis is marked by excessive production of tracheobronchial mucus that is sufficient to cause a cough on most days for at least three months each year for two consecutive years.

In chronic bronchitis, irritants such as cigarette smoke inhaled for a prolonged period inflame the tracheobronchial tree. The inflammation leads to increased mucus production and a narrowed or blocked airway. As inflammation continues, the mucus-producing goblet cells undergo hypertrophy, as do the ciliated epithelial cells that line the respiratory tract. Hypersecretion from the goblet cells blocks the free movement of the cilia, which normally sweep dust, irritants, and mucus from the airways. As a result, the airway stays blocked, and mucus and debris accumulate in the respiratory tract.



Chronic Bronchitis is a progressive peripheral lung disease. When the small bronchial airways transfer breathing air in and out of the pulmonary alveoli become narrowed by swelling within their walls, they trap air within the alveoli which they serve. This is called Alveolar air trapping.

It is important to realize that the multitude of small bronchiolar airways are not all obstructed to the same degree. Some are semi obstructed; that is, they marginally open at the peak of inhalation and close early in exhalation, trapping alveolar air, creating a reduction in alveolar air exchange.

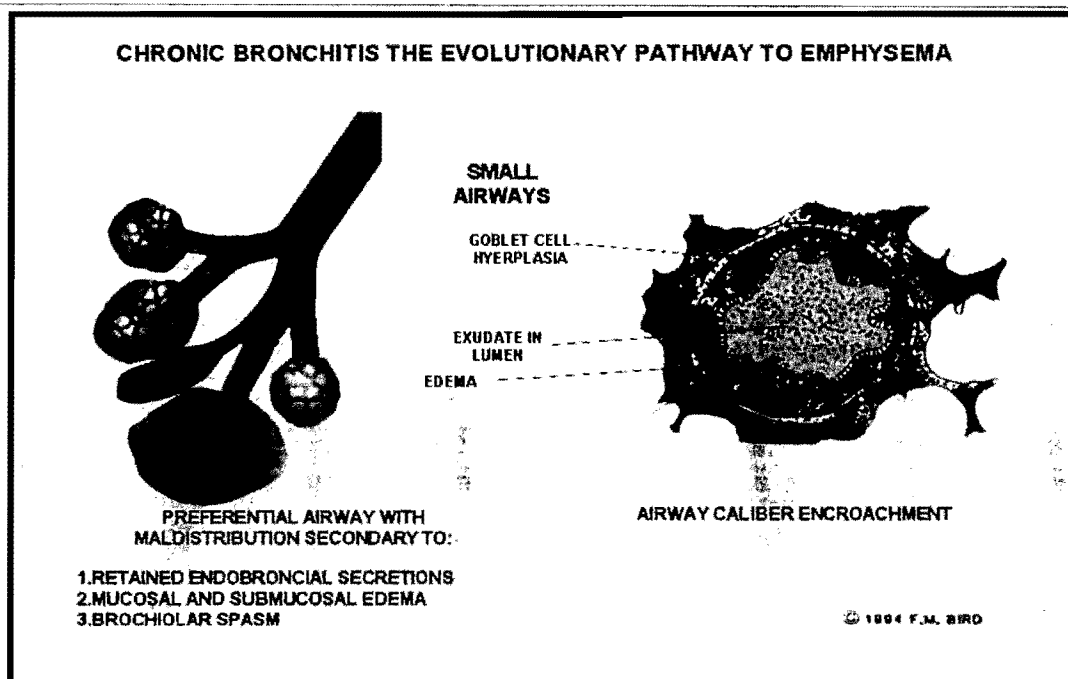
Others are totally obstructed, creating what is called pulmonary atelectasis; that is, the air that was trapped in the alveoli has been absorbed, leaving them elastomerically deflated.

Still other Alveoli are normal without or very limited bronchiolar airway obstruction. These are called the **PREFERENTIAL AIRWAYS** providing for the life supporting oxygenation processes.

Thus, in ventilating a patient with acute chronic bronchitis, there is no way of clinically knowing the degree of bronchiolar obstruction which would limit the normal expected amount of effective tidal air exchange that can be mechanically delivered into the lungs without over expanding the unknown number of available **PREFERENTIAL AIRWAYS** that are providing for the total alveolar gas exchange (oxygenation). Therefore, when mechanically ventilating COPD lungs with a volume-pressure ventilator, how can a tidal volume and pressure limit be selected to prevent hyperinflation of the life sustaining **PREFERENTIAL AIRWAYS AND THE PULMONARY ALVEOLI THEY SERVE?**

The pulmonary (breathing) structures within the chest have their own blood supply, called the Bronchiolar circulation, which normally receives about 2% of the arterialized blood from the left ventricle of the heart to nourish the lung tissues.

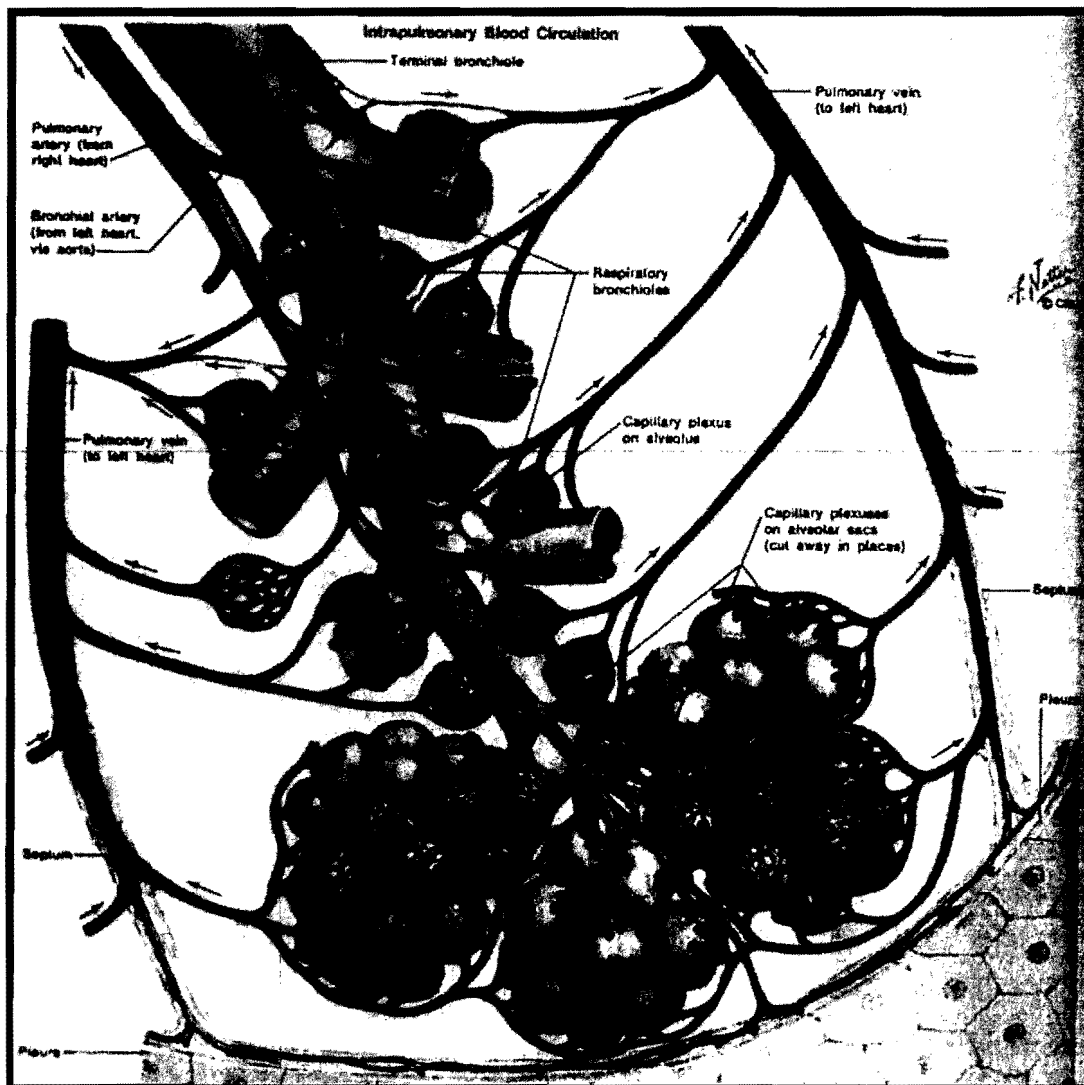
Chronic Bronchitis insidiously encroaches upon the Bronchial blood circulation which supplies the tissues of the lungs with required nutrients and oxygen to keep the pulmonary structures from becoming Ischemic and necrotic (dying). Progressive Chronic Bronchitis eventually will create the end stage circulatory lung disease called Pulmonary Emphysema.



During inspiratory breathing, the pulmonary airways become larger as the patient inhales to fill the pulmonary alveoli (air sacks) of the lungs. The deeper the breath the more the airways expand.

During exhalation, the inspiratory lung inflationary muscles relax and the elastomeric fibers (and surface tensions) within the walls of the pulmonary alveoli and airways normally contract, causing the alveoli and airway contraction to generate an outflow of air from the lungs.

The Pulmonary and Bronchial circulatory blood supplying vessels within the lungs are attached to the outer walls of the pulmonary airways and the alveoli of the lungs. During inhalation the pulmonary airways increase in diameter (expand), this causes the pulmonary blood vessels attached to their outer walls to be stretched and narrowed, increasing the resistance to blood flow. During exhalation, as the pulmonary airways passively contract (get smaller), the attached blood vessels get larger and refill with blood. This is a normal physiological occurrence.

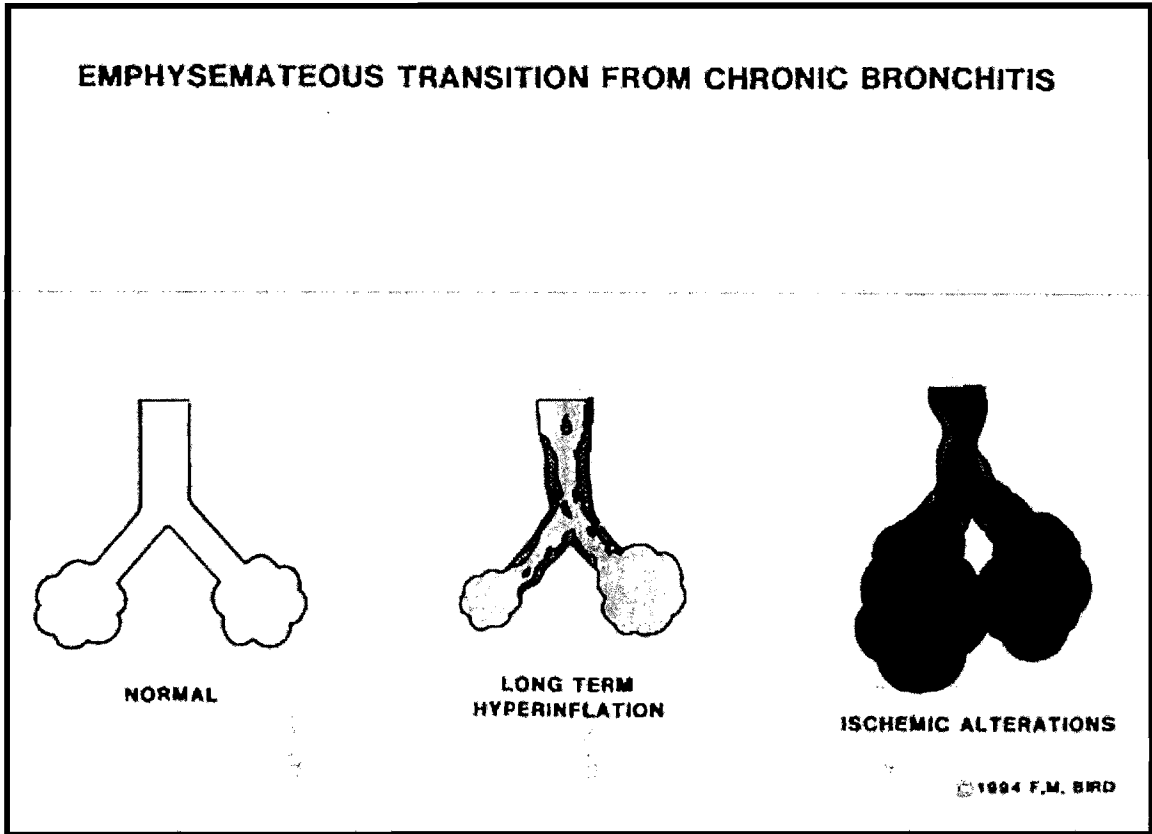


Pulmonary circulation by Netter courtesy of Ciba® 1976

Patients with peripheral lung diseases like Chronic Bronchitis transitioning into Emphysema, as well as general COPD patients, have within their Bronchiolar airways varying degrees of narrowing causing the small Bronchiolar airways to become obstructed during early exhalation, before the normal amount of alveolar deflation (emptying) has occurred. This causes sections of the Bronchiolar airways and their Alveoli to be maintained in a partial degree of inflation after end exhalation. This partial exterior Bronchiolar airway and Alveolar distension increases resistances within the attached stretched blood vessels which, because of the near continuous partial airway expansion, will determine the degree of resistance to blood flow through the narrowed vessels.

Over time, as this population of patients age, they experience an advancing chronicity (worsening) of their disease with continuing encroachment upon Bronchial blood flow. This condition can be exacerbated (increased) by transient acute pulmonary infections.

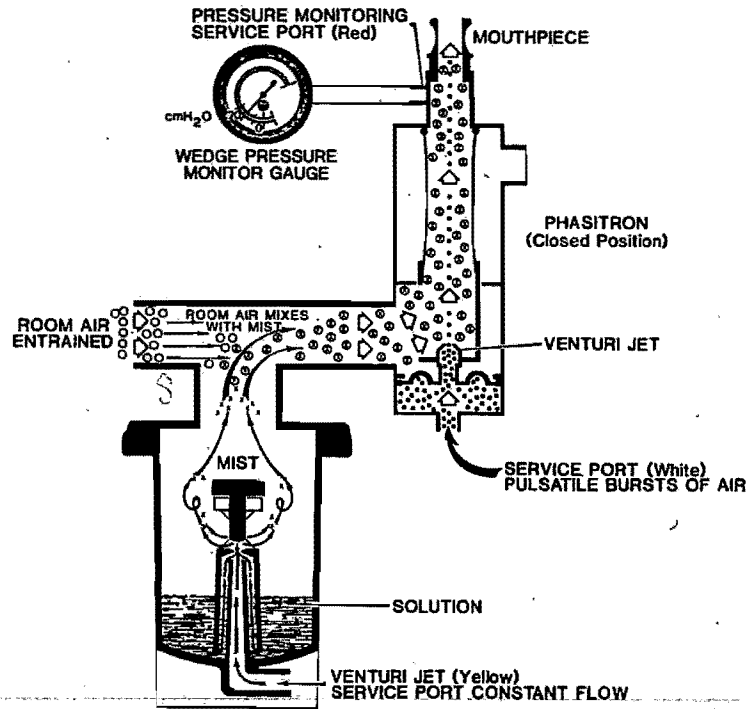
Alveolar air trapping is a component of COPD increasing with acute pulmonary infections, which together can ultimately cause an insidious decrease in Bronchiolar blood flow, thus creating a diffuse pulmonary tissue ischemia. This is the classical textbook pathway toward the progressive end stage lung disease called Pulmonary Emphysema.



THE VARIOUS IPV® DEVICES AND GENERAL CHARACTERISTICS ARE ESSENTIALLY THE SAME BECAUSE THEY ALL INTERFACE THE PATIENT'S AIRWAY WITH A DEVICE CALLED A PHASITRON®

UNDERSTANDING THE PHASITRON® RESPIRATOR

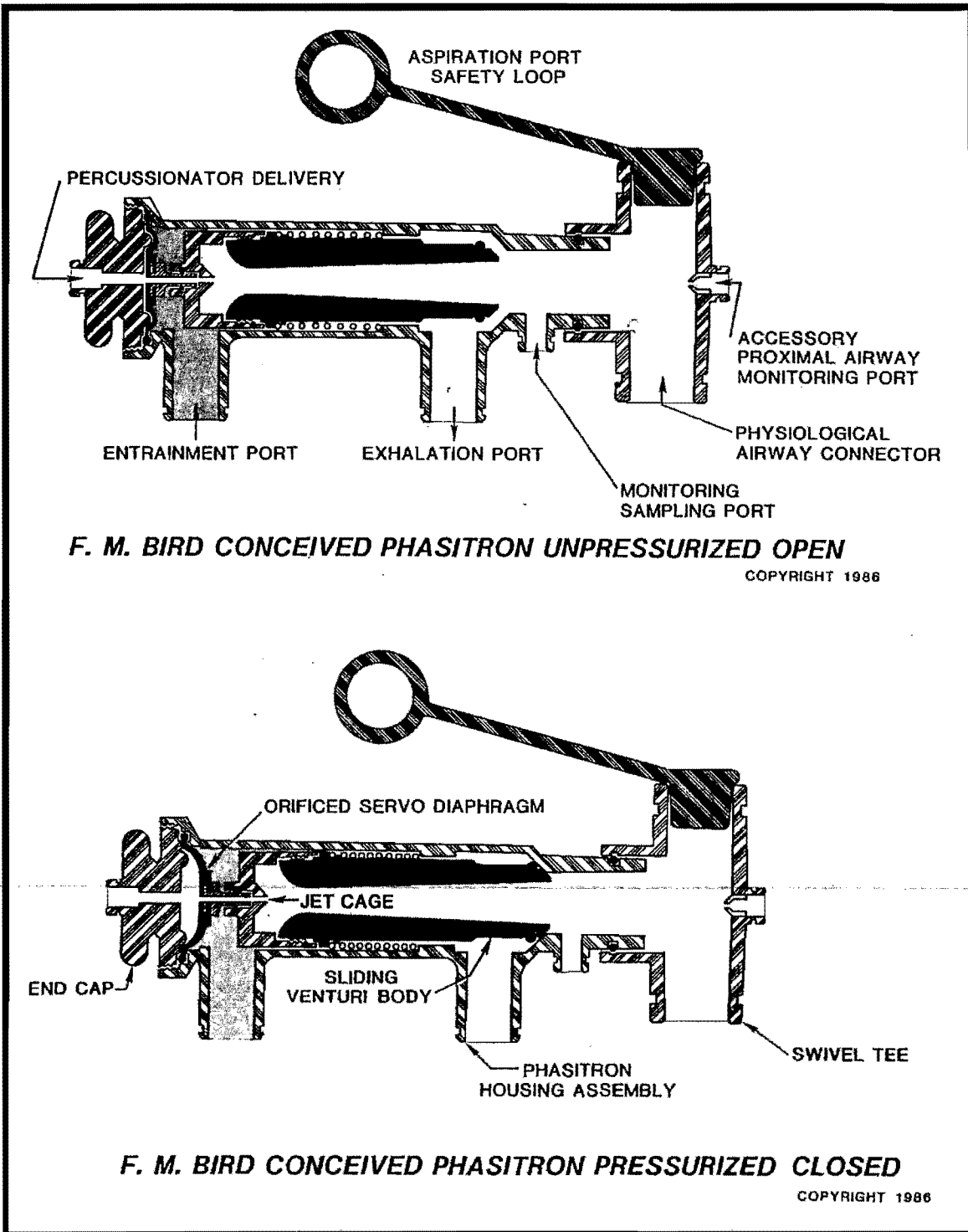
THE DYNAMIC IPV THERAPEUTIC BREATHING CIRCUIT IN CROSS SECTION



© 1994 F.M. BIRD

THE PHASITRON® INJECTRON® NEBULIZER BREATHING HEAD

Notes:

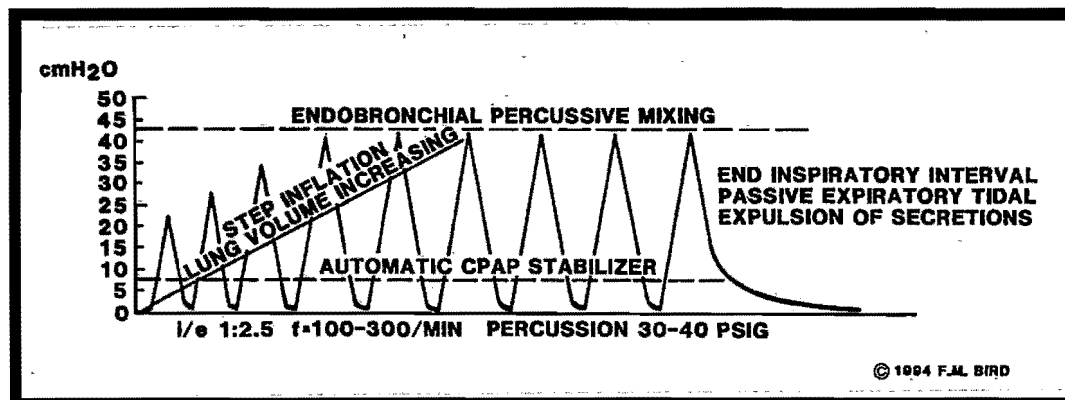


DURING THERAPEUTIC LUNG RECRUITMENT (TLR™), THE PHASITRON® BECOMES THE RESPIRATOR POSITIONED AT THE PATIENT'S PROXIMAL AIRWAY.

Serving as an injector exhalation valve referencing ambient, the phasitron® adjusts the programmed inspiratory air flow velocity by pressure feedback from the constantly changing intrapulmonary lung resistances to near instantaneously regulate inspiratory flow rate.

THUS, THE PHASITRON® SERVES AS A FLUIDIC CLUTCH AGAINST THE PHYSIOLOGICAL AIRWAY, WHICH IS EXPLAINED BY BERNOULLIAN LOGIC.

THEREFORE THE PHASITRON® PROVIDES FOR A BASIC LUNG PROTECTIVE STRATEGY TO PREVENT PREFERENTIAL AIRWAY BAROTRAUMA.

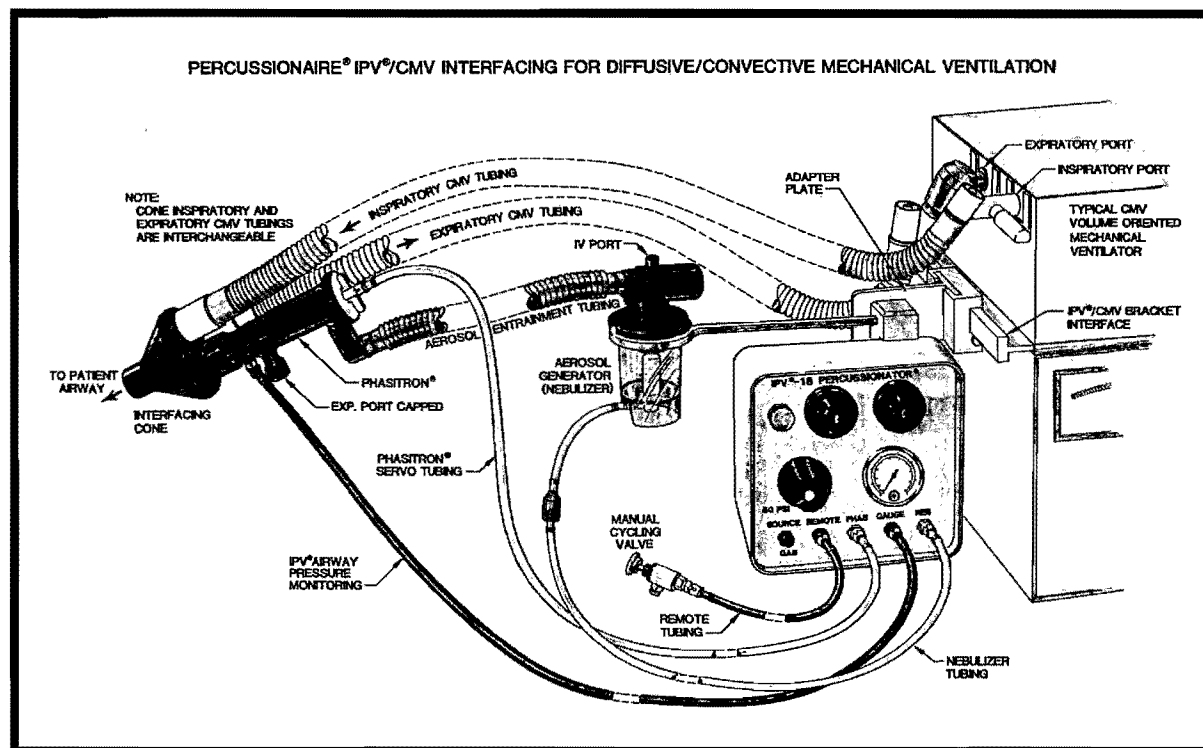


The patient breathes through a physiological interface called a Phasitron® delivering high flow sub tidal (mini-bursts) of air into the lungs at rates of from 100-300 times each minute. During the delivery of the percussive bursts of air into the lungs, a continued wedge pressure is maintained to stabilize the pulmonary airways, while a percussive high velocity flow penetrates the airways and enhances endobronchial secretion mobilization. A dense aerosol mist is delivered into the lungs during therapeutic percussion, which serves to reduce the adhesive and cohesive forces of retained airway secretions. During the therapeutic percussive interval there is a cyclical intrapulmonary exchange of respiratory gases, which serve to flush out Carbon Dioxide and renew oxygen. This therapeutic lung recruitment (TLR™) is administered by the IPV® family of Percussionators®.

Notes:

THE IPV® CONE INTERFACE ADAPTER

Therapeutic Lung Recruitment (TLR)[™] can be administered to patients being ventilated with Electronic Volume/Pressure cycled critical care ventilators with the IPV® Cone Interface Adapter kit # A50474-2.



Set up consists of:

Obtaining specific IPV® interfacing information for a specific “host ventilator” from Percussionaire® or appropriate authority.

1. Interfacing the Percussionaire® Cone Interface between the patient’s 15 mm indwelling airway catheter and the Inspiratory and Expiratory interfacing tubing’s of typical Volume/Pressure cycled ventilators is accomplished by using the Cone’s patient end port as well as, the aft flat side Inspiratory and Expiratory ports. See above.
2. Select and set up an appropriate IPV® Percussionator® and Cone Breathing interfacing circuit with the Phasitron® inserted into the Cone Phasitron® port.
 - a. Program the Volume/Pressure cycled ventilator in a compatible mode with IPV® Percussive Programming.
 - b. Document maximal clinical efficacy by programming the electronic Volume/Pressure cycled ventilator.
 - c. Establish a 40 psig Operational Pressure on the IPV® Percussionator®.

- d. Rotate the PERCUSSION control knob Arrow under the 12:00 index.
- e. Start Percussion, observing a “bilateral chest percussion (shaking)”.
 - i. If PaO₂ is low- select the 12:00 or (counterclockwise) Arrow position with the PERCUSSION control knob Arrow to deliver a more DIFFUSIVE (higher rate) Percussion.
 - ii. If PaCO₂ is elevated- select the 12:00 or (clockwise) Arrow position with the PERCUSSION control knob Arrow to deliver a more CONVECTIVE (lower rate) Percussion.
- f. Wait for about fifteen minutes and evaluate saturation, PaO₂ or PaCO₂. Appropriate Diffuse or Convective Oscillatory Percussion selections can be evaluated over time.
- g. IPV® can remain a continuous enhancement to the Tidal Exchange of the Volume/Pressure cycled ventilator and/or manually turned ON or OFF at clinicians choice.



IMPORTANT NOTE: “PULMONARY ALVEOLI CAN NOT BE VENTILATED WHEN THEIR TRANSMITTING AIRWAYS ARE OBSTRUCTED”.

FUNCTIONAL EVALUATION / ROUTINE MAINTENANCE

The inlet filters for the Impulsator and the IPV®-HC Percussionators® should be checked:
Impulsator: Check quarterly by removing the protective cap at top of unit and inspecting filters. Check more often if in dusty environments. The two filters should be changed as necessary. Black filter, P/N B12450; Felt filter, P/N B12585.

IPV®-HC: Check every 6 months. Replace as needed.

PREPARING FOR FUNCTIONAL EVALUATION FOR Bi-Phasic™ IPV®-HC, IPV-1C and IMPULSATOR®

The functional evaluation is used to determine if units are in conformance with Percussionaire® calibration standards. Functional evaluations should be performed annually or when clinical efficacy of the device is questioned.

The following is the minimum equipment needed to perform a functional evaluation:

Standard Breathing Circuit part # A50095-1

WARNING

If the i/e Inspiratory/Expiratory Time ratios are not properly calibrated to an approximate 1 to 2.5 i/e ratio the CLINICAL EFFICACY OF THE THERAPEUTIC IPV® LUNG RECRUITMENT PROCESS IS IN JEOPARDY. THIS IS A MAJOR TRAVESTY WHEN WELL MEANING INDIVIDUALS WITHOUT PROPER CURRENT PERCUSSIONAIRE® CALIBRATIONAL KNOWLEDGE ATTEMPT TO CALIBRATE AN IPV® PERCUSSIONAIRE® DEVICE.

TROUBLESHOOTING FOR THE IPV-1C® (Model F00001-1C) and IMPULSATOR® Model F00012)

PROBLEM: IMPULSATOR® WILL NOT START

CAUSE	FIX
IMPULSATOR NOT CONNECTED TO AN APPROVED POWER SOURCE	PLUG UNIT INTO AN APPROVED POWER SOURCE
LOOSE WIRE CONNECTION OR GROUNDING DEFECT	SEND TO AN APPROVED MAINTENANCE CENTER
FUSE NOT FUNCTIONING PROPERLY	CHECK FUSE INTEGRITY AS WELL AS PROPER SECURING OF FUSE, LOCATED AT ON/OFF SWITCH UNDER THE RED COVER. PART # B12792 USA AMP 5 PART# B12791 EUR AMP 3

PROBLEM: IMPULSATOR HAS DELAYED STARTUP

CAUSE	FIX
CAPACITOR FAILURE	REPLACE CAPACITOR PART # B12458 (REFER TO AUTHORIZED SERVICE CENTER)
COMPRESSOR FAILURE	DISCOVER CAUSE OF COMPRESSOR POWER DEFECT

PROBLEM: IMPULSATOR FAILS TO MAINTAIN PEAK INSPIRATORY PRESSURE

CAUSE	FIX
WORKING PRESSURE NOT CORRECTLY SET	SET WORKING PRESSURE TO ACHIEVE APPROPRIATE PEAK PRESSURE
REDUCTION REGULATOR PRESSURE GAUGE MALFUNCTION	REPLACE REDUCTION REGULATOR PART # A50084-1 (REFER TO AUTHORIZED SERVICE CENTER)

IPV-1C AND IMPULSATOR TROUBLE SHOOTING CONTINUED-

PROBLEM	CHECK	FIX
Breathing head (Phasitron, Nebulizer assembly will not function.	Breathing harness connected backwards,	Disconnect harness and reconnect properly with arrows on one way valves pointing toward the breathing head.
Nebulizer not aerosolizing properly.	Check to see if Nebulizer diffuser is in place. Check yellow line while device is running for gas flow.	Replace or snap diffuser back into place, part # A50481. If there is no gas flow from yellow tubing find cause
Frequencies of percussions do not change as frequency control knob is rotated.	Check if unit has been abused, fallen etc. Check last calibration or functional check performed. Check for contamination of hospital gas service.	Rotate CALIBRATION control knob back and forth full travel 10 times. Unit must be sent to authorized maintenance center.
Proximal manometer not functioning properly or needle is not zeroed.	Check red proximal airway harness for inter-connection to red Service Socket and Proximal Airway Monitoring port on Phasitron.	Reconnect interfacing harness for inter connection.
	Dampening orifice clogged inside unit.	Refer to authorized maintenance center. Replace harness part # A91005.
	Repeated use, time may cause needle on manometer to read at a higher or lower pressure when in the off position.	Carefully remove gauge cover then with a small flathead screwdriver, zero manometer. With Device in the OFF position.
Continuous percussive oscillations without manual activation of Percussive pulsing.	Check green tubing bayonet O rings for fitting leak. To determine if an external fitting leak is present disconnect green tubing from green Service Socket. Place finger over Service Socket to form an airtight seal. Turn unit on if pulsatile percussion stops leak is external.	Examine O-rings if cracked or worn replace part # B10526 Examine QD fittings for cracks or breakage replace part # A50036.
	If an external tubing fitting leak is present the Pulsatile percussions will continue.	If leak is Internal refer to authorized maintenance center.
Remote Nebulizer button is sticky, stuck or leaking.	Certain medications saline, (Acetylcystiene), physical abuse, or time may cause this problem.	Unscrew part # B11009 and B11017 being careful not to lose spring B10972, washer B11043 or O-ring B10124

TROUBLESHOOTING THE IPV®-HC

Unit fails to start	Unit not connected to approved power source.	Plug unit into approved power source
	Loose wire or poor grounding	Unit must be sent to authorized service center
	Fuse not working properly	Check for integrity and proper installation of fuse located in left pocket above the power cord. For Model F00012-HT use Fuse Buss BK/MDL-5. For Model F00012-HT220 use Fuse Buss BK/MDL-3
Unit has delayed startup	Compressor Failure	Unit must be sent to authorized service center
	Bad Capacitor	Unit must be sent to authorized service center
Frequency of Percussions does not change as frequency control knob is rotated	Check to see if unit has been abused, fallen, etc. Check for moisture in tubing. Check for contamination of hospital gas service	Unit must be sent to authorized service center
Nebulizer not aerosolizing properly	Check to see if nebulizer baffle is in place. With unit running, check yellow line for gas flow.	Replace or snap baffle back into place (See drawing A50010-3, page 41). If there is no aerosol from yellow line while unit is running, send unit to authorized service center.
Unit fails to maintain peak pressures		Unit must be sent to authorized service center
Breathing head (Phasitron, nebulizer assembly) will not function	Breathing harness connected backwards	Disconnect harness and reconnect properly with arrows on one way valves pointing toward the breathing head.

APPENDICES

GENERAL TECHNICAL DATA

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

UNIT SPECIFICATIONS

UNIT	MODEL #	Weight lb k	Height in cm	Width in cm	Depth in cm
IPV-1C®	F00001-C	4.4 2.1	9.5 24.1	6.7 16.5	9.5 24.1
IPV-2C®	F00002-C	4.5 2.1	9.5 24.1	6.7 16.5	9.5 24.1
IPV®-HC™ (115V)	F00012-HT	13.0 5.9	8.0 20.3	15.0 38.1	11.0 27.9
IPV®-HC™ (220V)	F00012-HT220	13.0 5.9	8.0 20.3	15.0 38.1	11.0 27.9
ACUTE CARE	F00019	0.7 0.3	3.7 9.5	2.7 7.0	5.5 14.0
IMPULSATOR®	F00012	23.0 10.4	11.7 29.8	13.0 33.0	8.2 21.0
SINUSOIDAL BRONCHOTRON®	F00038-1	4.8 2.2	9.5 24.1	6.7 16.5	9.5 24.1
VDR®-4	F00008-1	13.9 6.3	8.0 20.3	13.0 33.0	10.0 25.4
UNIVERSAL MONITRON®	F00007-B	3.6 1.6	9.5 24.1	6.7 16.5	9.5 24.1
MONITRON® II	F00007-1	9.8 4.5	8.0 20.3	13.0 33.0	9.2 23.4
OSCILLATRON® SERVO	F00036-2	4.6 2.1	9.5 24.1	6.7 16.5	9.5 24.1
TRANS RESPIRATOR®	F00038-2	12.6 5.7	9.5 24.1	17.5 44.5	12.5 31.8
TXP™	F00013	1.5 0.7	4.5 11.4	3.5 8.9	4.5 11.4

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

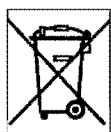
surrounding unit. A packaging slip must accompany box with information including RGA#, PURCHASE ORDER #, SERIAL# of device, name and address of packager, work requested, shipping address and phone number. If work beyond the flat rate fee is required, a PERCUSSIONAIRE® service representative will contact 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

TELEPHONE/FAX

Phone (208) 263-2549
Fax (208) 263-0577

UPS SHIPPING ADDRESS

Percussionaire® Corporation
1655 Glengary Bay Rd. Sandpoint ID 83864

FedEx SHIPPING ADDRESS

Percussionaire® Corporation
1655 Glengary Bay Rd. Sagle ID 83860

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 CONSTITUTE A RISK OF ELECTRICAL SHOCK (Impulsator®, IPV®-HT™, Monitron II)



STOP! READ EXTRA CARE PRECAUTIONS



**CLASS 1 EQUIPMENT
TYPE BF EQUIPMENT**



PROPER GROUNDING



ALTERNATING CURRENT



POWER SWITCH ON



POWER SWITCH OFF



YEAR OF MANUFACTURE (xxxx = YEAR)

XXXX

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 ventilator 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.

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 ALARMING- 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.

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 and/or decontaminated.

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.**

The decision to use 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-S-(with “S” denoting silicone followed by a length designation.**

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 (with no “S” in the part number)**
- 3. These parts can withstand temperatures < 140° Fahrenheit (60° Celsius)**

Percussionaire® medical devices are not submersible.

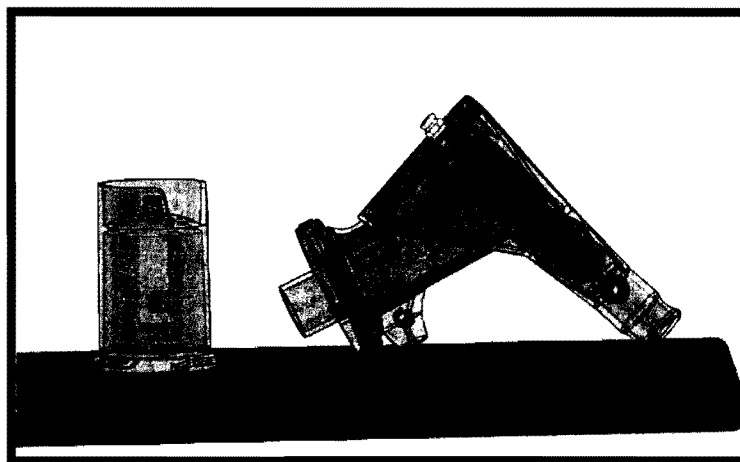
HOME CARE DISINFECTION

The breathing head should be disassembled and rinsed after each treatment.

The Phasitron® Duo® was designed for ease of cleansing. It is molded from LEXAN PLASTIC thus is dishwasher safe or can be cleansed with dishwashing soap and water and/or typical hospital cold sterilization means.



DO NOT AUTOCLAVE

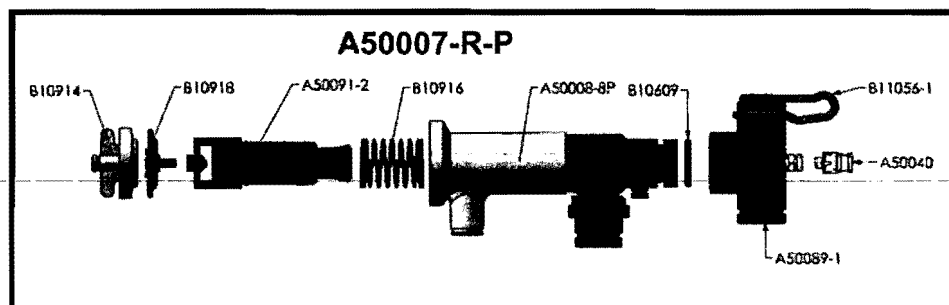
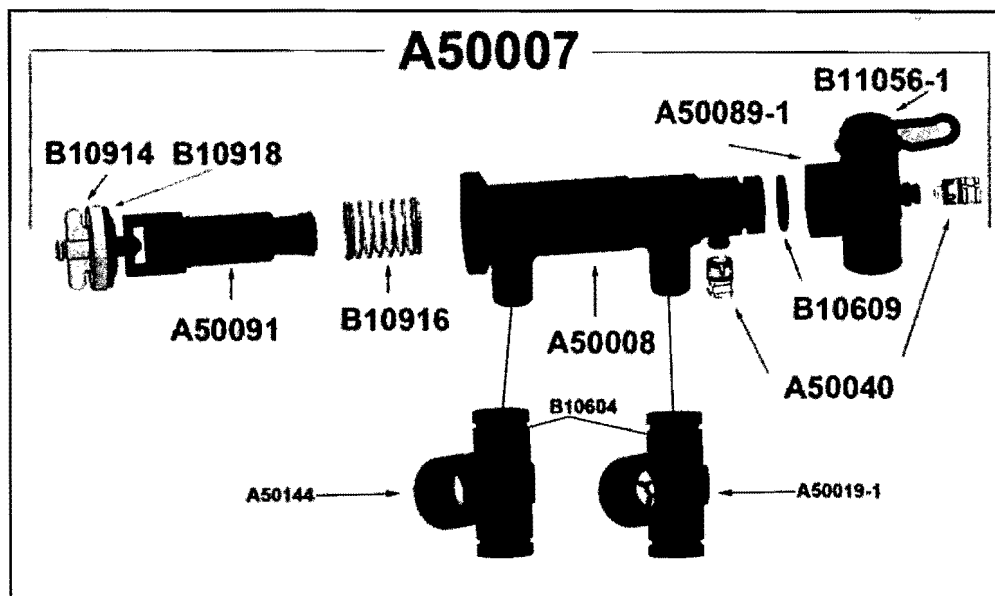


PHASITRON® DUO® IN "KNEELING" POSITION ON COUNTER

To clean-

1. Rotate nebulizer bowl (counterclockwise) to remove from top.
2. Mechanically rinse bowl and Phasitron® in water, then cleanse as desired.
3. Shake nebulizer bowl and Phasitron® to remove excess water then set upside down to dry.
4. To dry, place Phasitron® in kneeling position to allow back drainage, and nebulizer turned upside down.

**Disassembly of Percussionaire® Phasitron®
Part Numbers A50007, A50007-R-P**

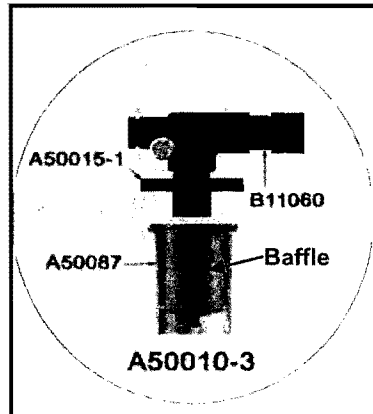


1. Disconnect colored tubing from service sockets.
2. Unscrew Phasitron® end cap part B10914.
3. Withdraw venturi assembly from Phasitron® body by pulling out upon orificed diaphragm part B10918 attached to green or alternative red venturi assembly, parts.

Phasitron Body exterior component disassembly steps.

4. Remove green Inspiratory Failsafe Tee assembly by a pulling rotation.
5. Remove red Expiratory Failsafe tee assembly.
6. Remove proximal airway Swivel Tee assembly by a pulling rotation.
7. Remove Phasitron® Outlet Plug loop assembly, from Swivel Tee assembly by pulling and rotating.

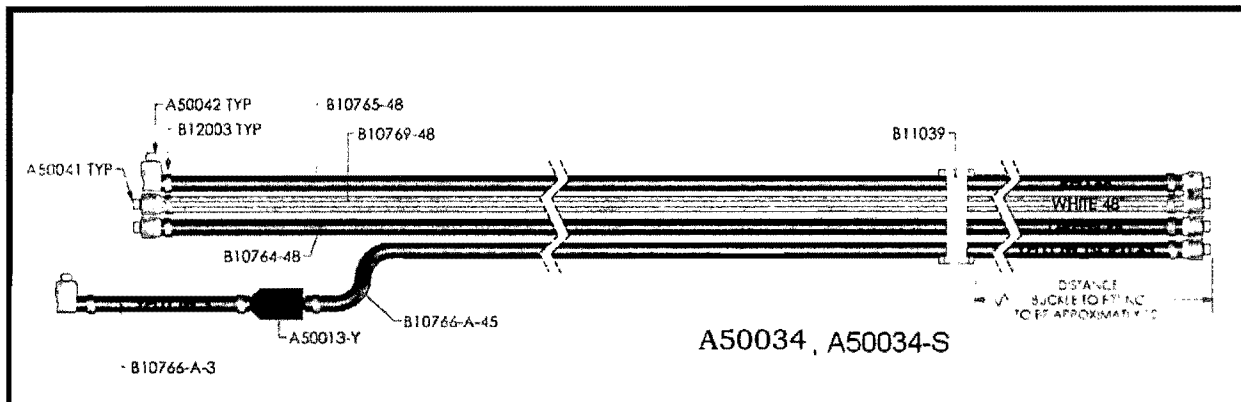
Disassembly of Percussionaire® Aerosol Generator
Part Numbers A50010, A50010-1, A50010-2, A50010-3, A50010-5



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 $\frac{1}{4}$ turn.

Four channel breathing circuit interfacing tubing assemblies:

A50034 non-autoclavable tubing assembly or
A50034-S autoclavable Silicone tubing assembly



PERCUSSIONAIRE® CORPORATION

IMPULSATOR®

MODELS F00012 AND F00012-1

TXP® UNIVERSAL

MODELS F00013-A AND F00013-B

HOW TO CHANGE THE FUSES

Make sure that the condition that caused the fuse to blow has been corrected. Disconnect power cord from unit and wall.

The fuses are located in the power switch.

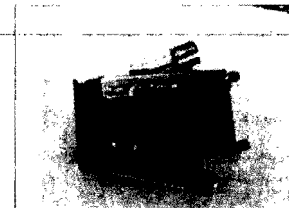
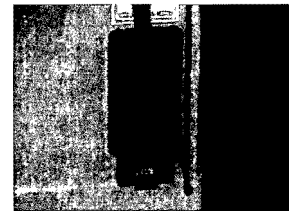
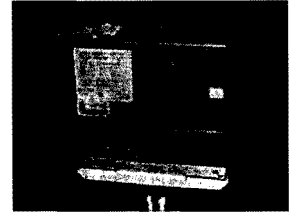
With a small flat blade screwdriver or similar implement, pry the fuse panel out by twisting screwdriver in the small slot at the top.

Pull out the red fuse carrier.

Remove the burned out fuses, and replace with new fuses. Replace fuses with Percussionaire Corporation part number B12792 (BK/MDL-5 115V – US) or B12791 (BK/MDL-3 220V – European) or equivalent. Two extra fuses (B12792 or B12791) are supplied in the Accessory Kit (A50162 – US or A50162-1 European).

Replace red fuse carrier into the fuse panel by squeezing fuses together from sides and sliding fuse holder into housing.

Replace black cover by aligning it with the housing and pushing in until it snaps into place. Make sure both sides are engaged.

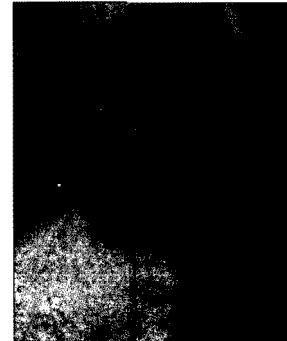
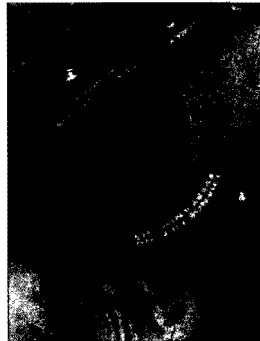
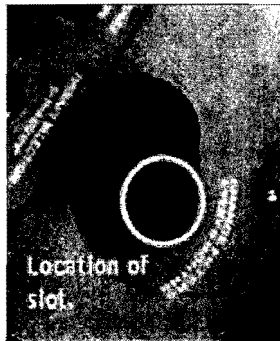


PERCUSSIONAIRE® CORPORATION

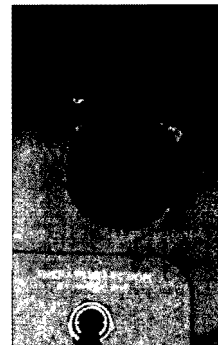
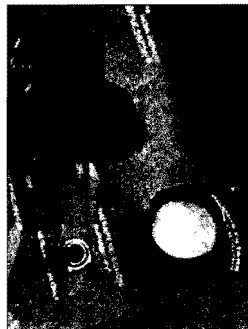
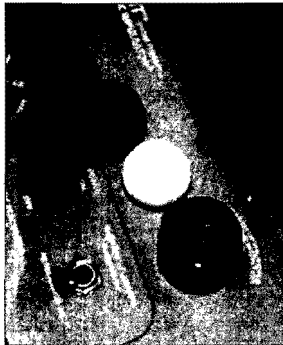
IPV®-HC™ Filter and Fuse Change Instructions

Please check, clean or change filters every 6 months or more often in dusty environments.

To change air intake filter: (Replacement Black Foam filter (P/N B12450, White Felt filter (P/N B12585):



Remove cap by pressing tool into slot and prying up. Lift cap and then remove.



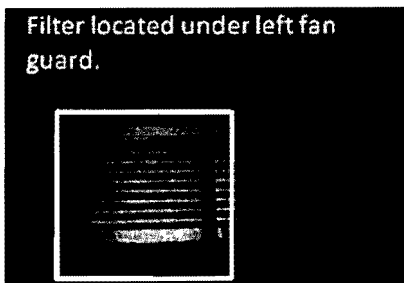
Remove filters.
(OK to discard in household trash)

Insert new white felt filter

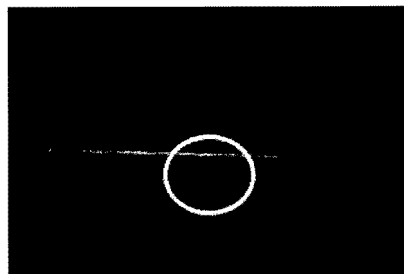
Insert new black foam filter

Replace Cap: Align tabs with slot then press down.

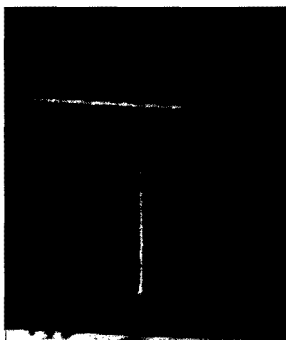
To clean/change cooling fan filter (Replacement 80mm blue filter P/N B13091):



Lay unit on its face



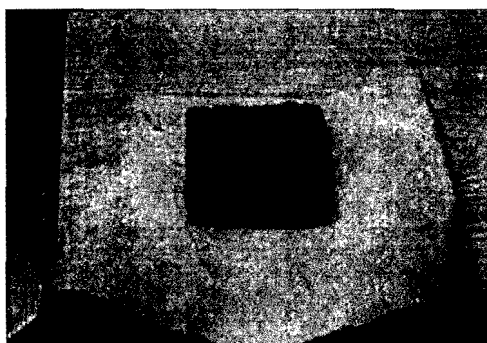
Locate Allen retention screws



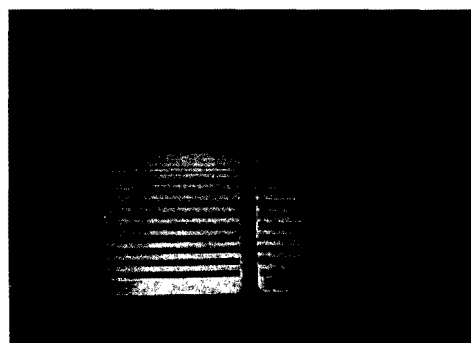
Insert 5/64 Allen tool and turn counter clockwise and remove. Remove guard and filter.



Rinse filter with plain running water or replace.



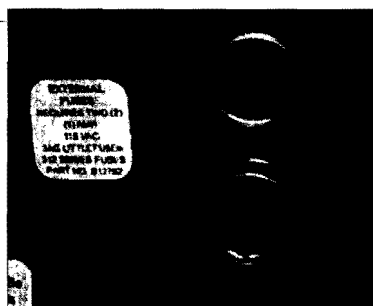
If washed, allow to air dry!



Replace filter and filter guard, making sure to hear it snap on. Then replace retention screw.

To replace fuse

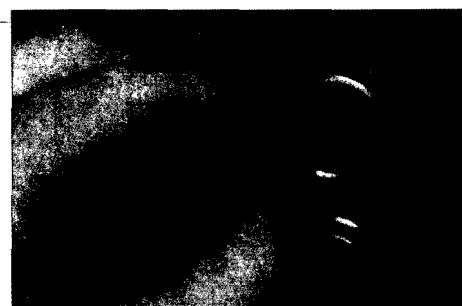
(Replacement fuse for IPV®-HC™ F00012-HT P/N B12792;
Replacement fuse for IPV®-HC™ F00012-HT220 P/N B12791):



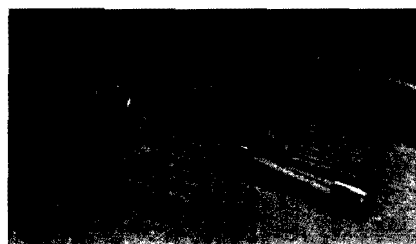
Locate fuse holder above power cord attachment



Remove fuse by pushing holder in and turning to the left (counterclockwise)



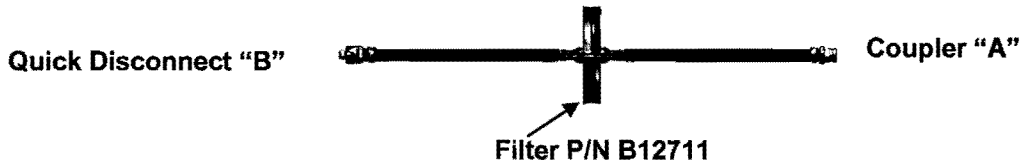
Fuse holder will release. Pull to remove to remove fuse.



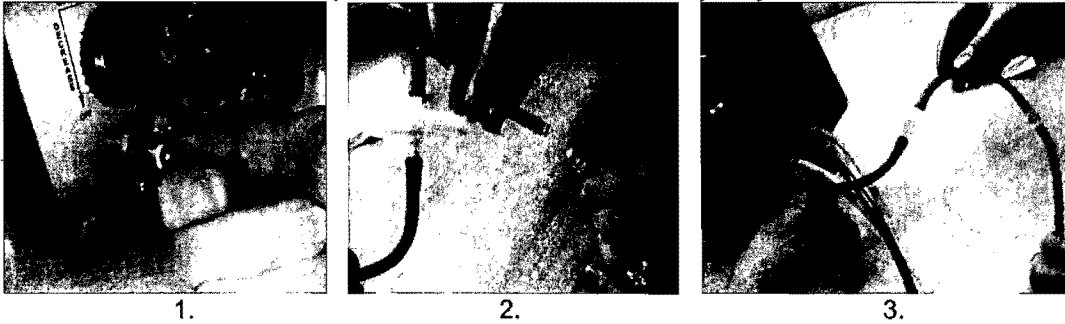
Grasp fuse and cap or open with a screwdriver if required, and separate by pulling apart. Insert new fuse, and reverse steps above to replace in holder.

PERCUSSIONAIRE® CORPORATION
Hydrophobic Filter Harness Connection

Part Number A99509



Note: Disposable filter size and color may vary



1. Disconnect red breathing circuit line from unit.
2. Connect the red line end (just disconnected) to the filter harness coupler "A"
3. Connect red quick disconnect "B" end of filter line to unit.

Hydrophobic Filter Part Number B12711

This product is designed for use with 1/8" to 3/16" hose fittings and is intended for in-line use upstream of a nebulizer. This filter is rated for continuous use up to 48 hours and is bidirectional, but flow directions should be kept constant during use.



WARNINGS: This filter is intended for single use only. Use of sterilization or cleaning solutions may result in retention of harmful residuals, increased pressure drop across media or significantly reduce filtration efficiency.

PRECAUTION: Exposure to internal pressure in excess of 60 p.s.i. may cause the housing enclosure to rupture. Filter membrane is hydrophobic and becomes impervious to gas flow if saturated with water.

Hydrophobic characteristics will be retained at a hydrostatic pressure drop of 3 p.s.i. or less across filter.

LOT



NUMBER

USE BY DATE

DO NOT REUSE

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