PERCUSSIONAIRE®
CORPORATION

IPV®-2C USER MANUAL

TRUE-IPV® THERAPY DEVICES

EN

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Authorized European Union Representative:
MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany

The devices and products contained in this manual may be covered by one or more patents.

This manual was originally released and supplied in English.
For a list of available translations, contact customerservice@percussionaire.com.

All ventilators should be operated and serviced only by trained professionals. Percussionaire® Corporation's sole responsibility with respect to its ventilators, accessories, components, and software, and their use, are as stated in the warranty provided in the manuals. The information set forth herein is believed to be accurate; it is not a substitute for the exercise of professional judgment.

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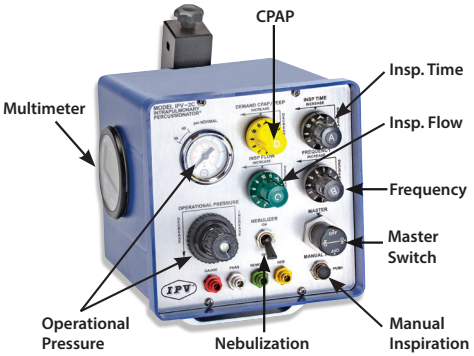
Chapter 1: Introduction

This chapter provides an overview of the IPV®-2C device and TRUE-IPV® therapy.

Intrapulmonary Percussive Ventilation (IPV®)

Designed specifically for non-continuous institutional/hospital use, the IPV®-2C is a pressure-limited and time-cycled ventilator which provides IPV® therapy, a modality of mechanical ventilation "Intrapulmonary Percussive Ventilation" (IPV®). The IPV®-2C provides high frequency percussive pulses between 60-330 cycles per minute. These high frequency percussive pulses ramify throughout the airways and alveolar ducts and augment diffusive ventilation in the gas exchange regions of the lung, allowing improved FRC, CO_2 removal, airway clearance, and lung recruitment.



The IPV®-2C percussive ventilator features 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.

The IPV®-2C provides simultaneous high volume aerosol generation for the topical delivery of saline, sterile water, and/or bronchodilators.

Demand Continuous Positive Airway Pressure (Demand-CPAP)

Demand-CPAP for reducing the work of breathing.

Inspiratory Time

Selects independent i/e ratio control allowing for approximate 1:2.5 clinical default setting.

Inspiratory Flow

Determines the amplitude delivered to the patient during inspiratory time.

Frequency

Controls the rate of high frequency percussions delivered.

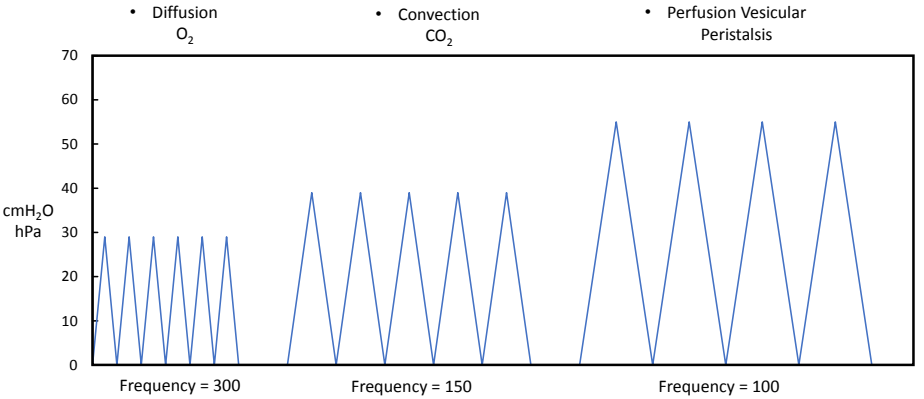
Manual Inspiration

Delivers a regulated source of gas through the orifice of the Phasitron®5 venturi. The longer the button is pressed, the greater the potential for tidal volume delivery.

Operational Pressure Control

Controls the peak operating pressure of the entire unit. This control at maximum output will only provide pressure slightly less than that of the institution. The optimal inlet wall pressure is 50 psi (3.4 bar, 345 kPa).

Three Components of TRUE-IPV®



f=300	f=150	f=100
Percussive Mechanical Mixing Diffusion	Percussive Convective Ventilation with Diffusion	Percussive Perfusion Vesicular Peristalsis

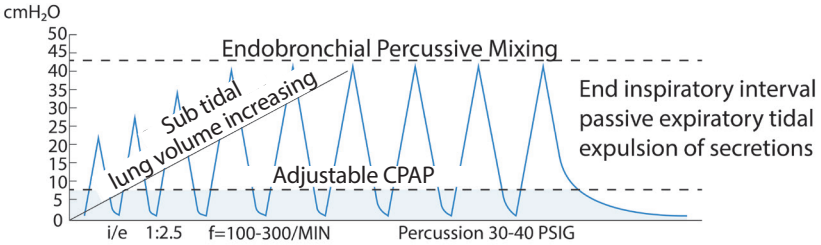
Effects of TRUE-IPV®

The effects of TRUE-IPV® therapy occur with or without the cooperation of the patient.

TRUE-IPV® provides a percussive sub tidal gas exchange within the respiratory bronchioles with associated alveolar recruitment maintaining a minimal mean intrathoracic expiratory pressure increase for peripheral lung stabilization. This allows for mechanical ventilation to provide for peripheral lung recruitment while minimizing the potential for induced barotrauma.

TRUE-IPV® Lung Recruitment Protocol Chart

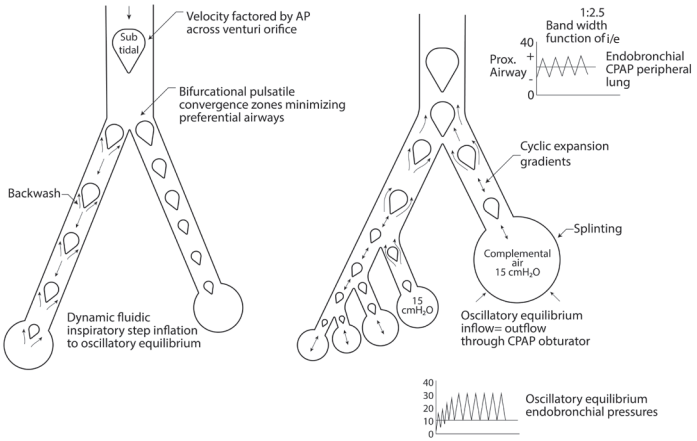
The chart (below) illustrates the typical TRUE-IPV® lung recruitment protocol.



This is a method of preventing recruited bronchial airways and alveoli from deflating to an obstructive end resting position during each expiratory lung deflation. It is accomplished as follows:

1. The positive pressure percussive sub tidal volume is generally delivered in milliseconds with an i/e ratio (approximating 1:2.5) at an endobronchial delivery rate of 100 to 300 cycles per minute. The lung is step inflated to a selected peak oscillatory positive pressure (oscillatory equilibrium) which is cyclically maintained allowing the patient to spontaneously breathe through the oscillatory program at any time. A Newtonian pumping action is created to recruit and raise endobronchial secretions.

"Newton" on the Endobronchial Pump During IPV



2. The Phasitron®5 (positioned at the patient's proximal airway) serves as a physical-physiological interface with a near instantaneous full expiratory opening to full inspiratory closing (in milliseconds). The Phasitron®5 vents the patient's proximal airway to ambient during the cyclic expiratory phase. Almost instantaneously, the patient's proximal airway is vented to ambient after delivery of repetitive sub tidal volumes, venting the patient's endobronchial tree.

3.	With a longer expiratory time than inspiratory time (i/e ratio of about 1:2.5) and a selected cycling rate of between 100 and 300 cycles per minute, the peripheral airways and alveolar pressures are not allowed to reach ambient before the next sub tidal volume delivery (re-pressurization) is initiated.
4	The peripheral airway and alveolar patency are typically maintained before a peripheral end expiratory airway air trapping can occur. This is important in patients with bronchiolar flow restrictions secondary to mucosal and sub mucosal edema and retained airway secretions, which are often associated with peripheral pulmonary infections..
5.	This cyclic percussive endobronchial sub tidal ventilation, timed in milliseconds, recruits and maintains the peripheral airways, allowing an alveolar gas exchange without maintaining an alveolar hyperinflation.
6.	The continuous pulsatile percussive sub tidal inflow serves to progressively recruit the bronchiolar airways, allowing an alveolar gas exchange without maintaining alveolar hyperinflation.
7.	After peripheral lung recruitment, a minimal cyclic expiratory oscillatory CPAP is maintained within the recruited bronchioles and alveoli to maintain the patency of the recruited structures during the expiratory interval.
8.	This intrapulmonary end expiratory pressure hold helps to maintain the functional residual capacity (FRC) between pulses. During TRUE-IPV® lung recruitment programming, the tracheal bronchial tree is vented to ambient during the cyclic expiratory phase of each delivered sub tidal volume during Oscillatory CPAP scheduling.
9.	During CPAP programming, reciprocating inspiratory flow gradients are created to deliver and recover endobronchial sub tidal volumes from the bronchioles and the pulmonary alveoli.
10.	The percussive endobronchial sub tidal inflows produce a directional compressive "stripping action" within the vessels of the intrathoracic circulations attached to the walls of the expanding endobronchial airways. This is called an enhanced pulmonary vesicular peristalsis.

NOTE: *Intrapulmonary Percussive Ventilation (IPV®) serves as a lung recruitment means by percussive intrapulmonary gas mixing and exchange as well as enhancing the physiological vesicular peristalsis within the three intrathoracic circulations.*

Chapter 2: Intended Use

Indications for Use

The IPV®-2C is indicated for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis. It can also provide supplemental oxygen when used with compressed oxygen.

Patient Population

IPV®-2C ventilator is for use on neonatal, pediatric, and adult patient populations.

Absolute Contraindications

• Untreated tension pneumothorax	• Untrained or unskilled operator

Relative Contraindications

• History of pneumothorax	• Myocardial infarction
• Recent pneumonectomy	• Vomiting
• Pulmonary hemorrhage	• Pulmonary air leak (without functioning chest tube)

Possible Adverse Reactions

• Decreased cardiac output	• Increased intracranial pressure
• Pneumothorax	• Increased air trapping
• Hyper-oxygenation	• Pulmonary air leak
• Pulmonary hemorrhage	• Hyperventilation
• Gastric distension	• Apnea

Physiological Benefits of TRUE-IPV®

• Recruitment of atelectatic lung	• Mechanical bronchodilation
• Improved FRC	• Improved breathing pattern
• Decreased work of breathing	• Increased secretion mobilization

Clinical Limitations/Restrictions

Use of the IPV®-2C is limited to individuals who have received proper training.

For invasive applications or patients supported by Continuous Mandatory Ventilation (CMV).

⚠ **WARNING:** Due to the therapeutic nature of these devices, they do not have disconnect alarms . Consequently, the patient MUST be under continuous observation by a clinician.

⚠ **WARNING:** When used on a patient with an artificial airway (i.e. endotracheal or tracheostomy 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. Partial deflation of the cuff during therapy may be necessary; re-inflation per hospital protocol post-therapy.

⚠ **WARNING:** Because pulmonary alveoli cannot be ventilated when their transmitting airways are obstructed, suction should be performed as necessary.

NOTE: *A **WARNING** icon indicates a risk of injury to patient or operator.*
*A **CAUTION** icon indicates a risk of equipment damage.*

Document Symbols

⚠	WARNING		Type BF Applied Part
⚠	CAUTION		Single Patient Use
	Read the manual before use	℞	Prescription Only
CE	CE marking	REF	Catalog Number
	Manufacturer	LOT	Lot Number
	Manufacture Date	EC REP	European Representative
NON STERILE	Non-Sterile	LATEX	Not Made with Natural Rubber Latex
PHT DEHP DIBP DBP BBP	Does Not Contain the Phthalate Plasticizers DEHP, DIBP, DBP, or BBP		Disposal

Chapter 3: TRUE-IPV® In-Line Valve with a Ventilator

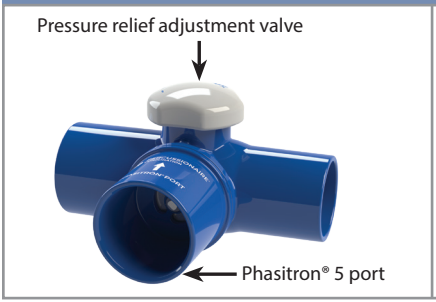
TRUE-IPV® In-Line Valve
22mm I.D. x 22mm O.D.
Single Patient

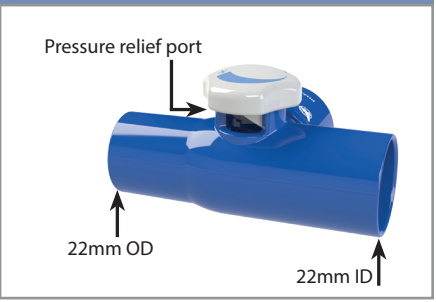
Intended Use

The TRUE-IPV® In-Line Valve is intended to be used to provide IPV® (Intrapulmonary Percussive Ventilation) therapy to intubated patients while assisted by Conventional Mandatory Ventilation (CMV) using pressure-control, volume-control, SIMV-PC etc., when direct connection of IPV® is not indicated.

NOTE: *For use only with Percussionaire® TRUE-IPV® ventilator devices. Compatible with all Percussionaire® single patient Phasitrons. The IPV® In-Line Valve is indicated for neonatal, pediatric, and adult patient populations, for whom IPV® therapy has been prescribed.*

TRUE-IPV® In-Line Valve



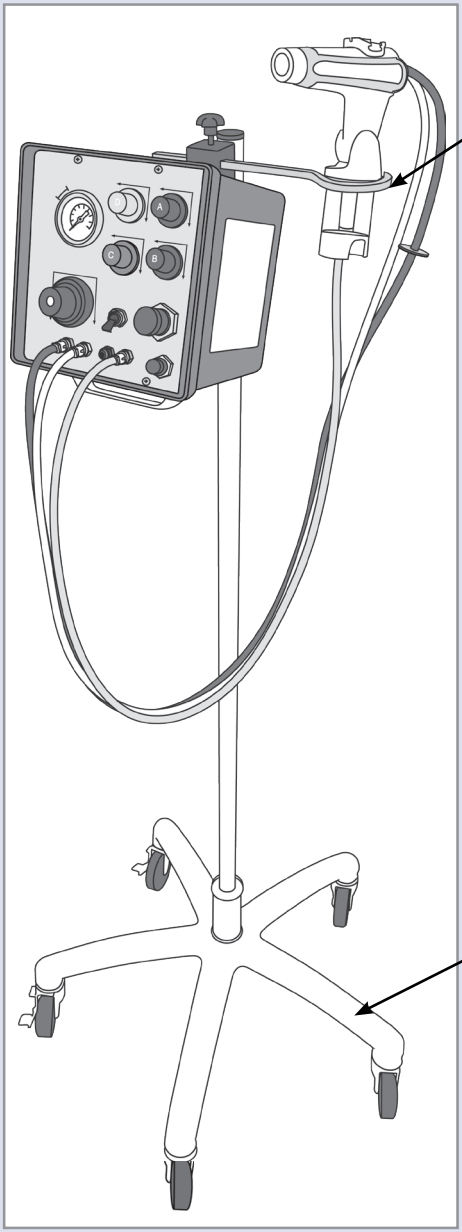


Treatment Frequency

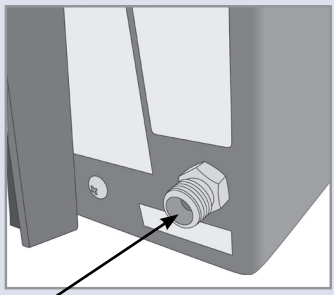
TRUE-IPV® in-line use with a ventilator is based on patient need, from 2 times per day up to 6 times per day (every 4 hours), as recommended by physician. Always use institutional/ hospital protocol when possible.

⚠ **WARNING:** Follow institutional protocols before disconnecting ventilator inspiratory limb prior to installation of Percussionaire® TRUE-IPV® In-Line Valve.

IPV®-2C and Stand



Phasitron® 5 holder bracket

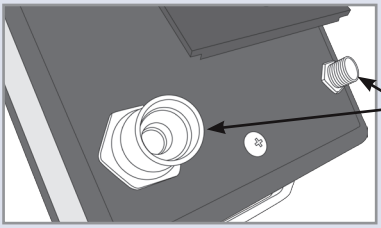


DISS supplied oxygen hose for incoming gas between 50 - 80 psig (345 - 551 kPa) Normally supplied to USA devices

Pole and stand assembly

Rear Panel

Blended Gas/Air Connection



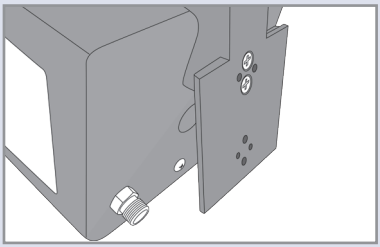
The IPV®-2C can be connected to hospital single gas source or blended gas.

Single or double air/oxygen gas connections available.

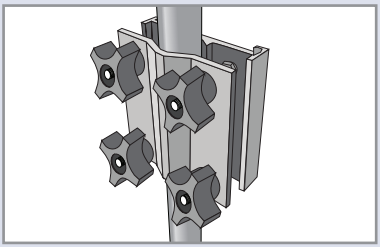
Current Gas/Air Connectors Available:

DISS	USA	NIST	European
AFNOR	French	UNIFOR	Italian
DIN	German	AGA	Scandinavian
BS	British		

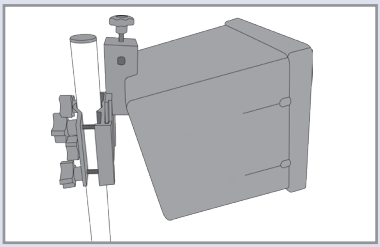
Pole Mount



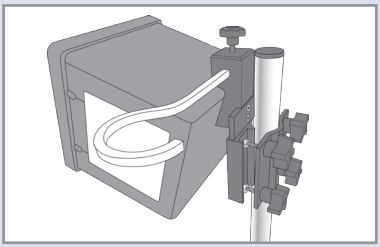
Supplied rear mounting bracket for pole mounting the IPV®-2C device



Adjustable pole mount to attach IPV®-2C device



IPV®-2C device mounted to stand



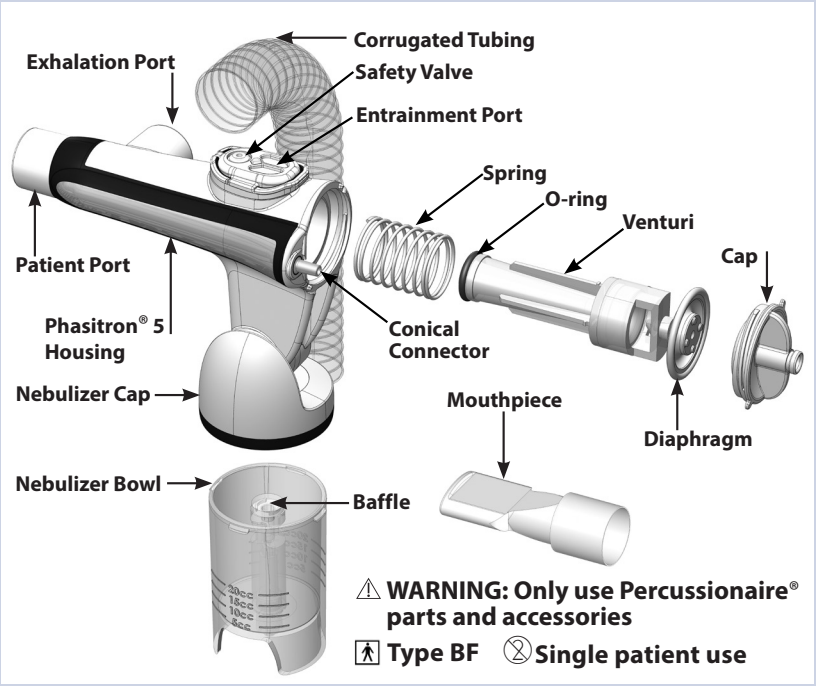
Side panel holder bracket for convenient storage/placement of the Phasitron®5

Phasitron®5 Breathing Circuit Setup

The patented Phasitron®5 uses a unique venturi as a "clutch" mechanism to protect the lung from over pressure. By automatically adjusting to the resistance of the lung, the Phasitron®5 precisely and safely delivers the optimal amount and flow of air required by the alveolar space. When lung resistance is low, as in a compliant lung, all the pulsed air from the IPV®-2C device enters the mouth of the venturi. Each air pulse draws up to four times as much additional air into the venturi tube. This low-pressure entrained air automatically fills the available space in the lung. The Phasitron®5 continuously and instantaneously adjusts to keep a gentle and safe air pressure, even in a compromised lung.

NOTE: *TRUE-IPV® therapy can only be achieved using the Phasitron® 5.*

Phasitron®5 Diagram

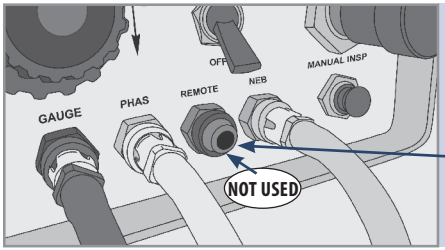


Configurations

Phasitron® 5 kit can be used with or without a mouthpiece or standard mask (as shown below). Connection sizes, 15mm ID or 22mm OD.

Phasitron®5 without mouthpiece or mask	Phasitron®5 with mouthpiece (included)	Phasitron®5 with face mask (sold separately)

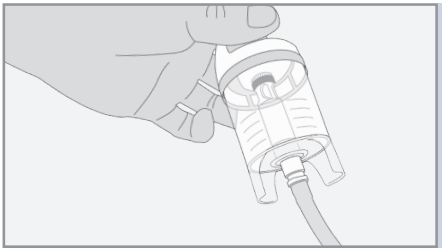
Connecting to the IPV®-2C



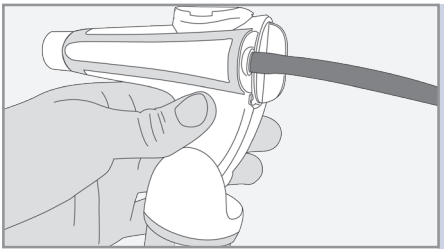
Connect red, clear, and yellow tubing connectors to IPV®-2C controller device.

⚠ **WARNING:** Green remote bulkhead is vented, do not obstruct

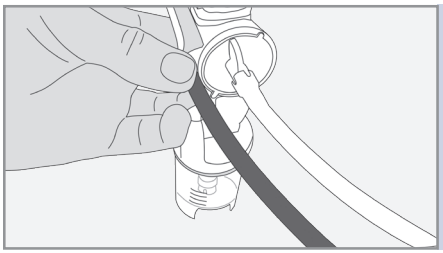
Connect the Tubing Harness to Phasitron® 5



Connect yellow tubing quick-connect fitting to nebulizer bowl.

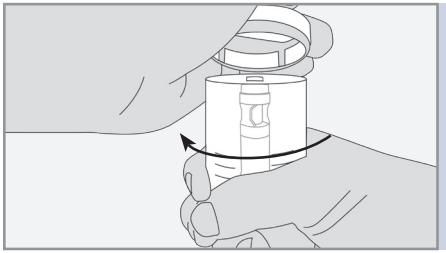


Press red tubing onto conical connector at rear of Phasitron® 5 body.

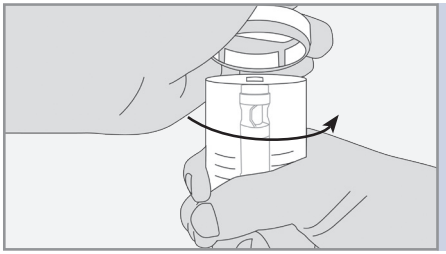


Connect the clear tubing quick-connect fitting to the cap at the rear of the Phasitron®5 body.

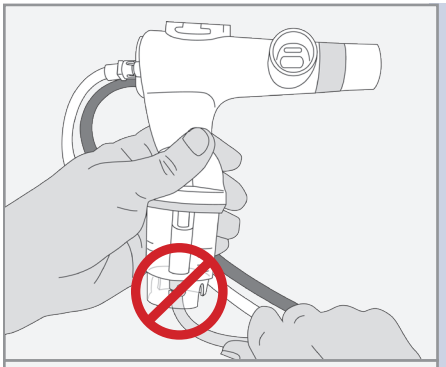
Adding Saline Solution or Medication



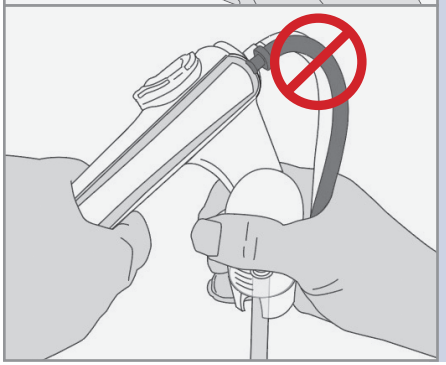
Twist clockwise to open nebulizer bowl.
Add saline and/or prescribed medication.



Reverse to close.

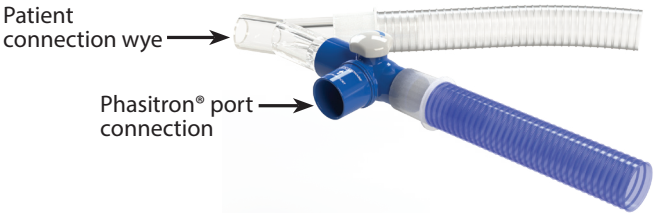


⚠ **CAUTION:** Ensure yellow nebulizer tubing is not bent. This may cause undue stress on connector.



⚠ **CAUTION:** Do not bend nebulizer bowl while holding the tubing. This may cause undue stress on the red line conical connector.

TRUE-IPV® In-Line Valve Setup



Pediatric to Adult	**Neonatal**
Recommended to install as close to the patient wye as allowable	Recommended to install between heater and inspiratory limb.

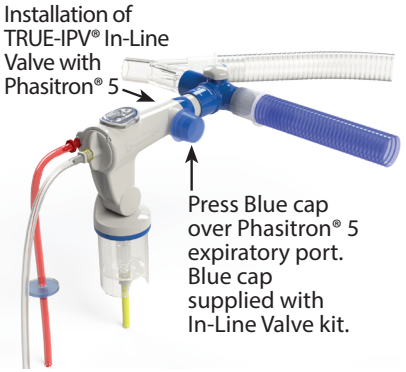
Insert TRUE-IPV® In-Line Valve into inspiratory limb of ventilator circuit.

⚠ **WARNING:** Ensure Pressure Relief valve is closed.

⚠ **WARNING:** Allow ventilator to cycle with valve in place.

⚠ **WARNING:** Ensure TRUE-IPV® In-Line Valve is inserted into inspiratory side of ventilator circuit.

Adding Phasitron®5 to In-Line Valve



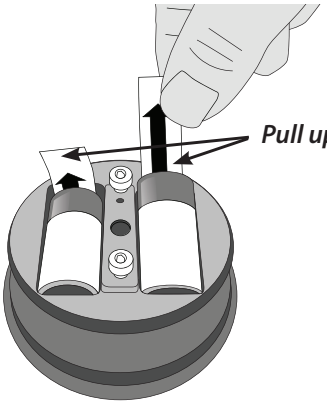
Install provided blue cap (color may vary) onto the Phasitron®5 expiratory port. Port must be occluded for proper use and treatment. The cap is provided with TRUE-IPV® In-Line Valve kit.

Fill nebulizer with 15 to 20 cc normal saline or prescribed medication. Aerosol consumption approximately .75 cc per minute.

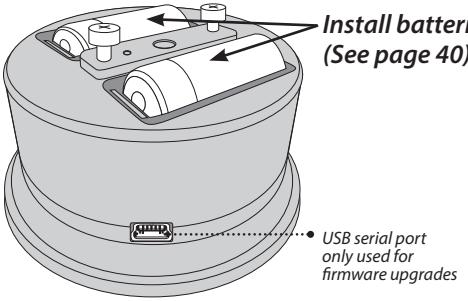
⚠ **WARNING:** Blue cap must be removed when giving a direct treatment, either by mouth, mask or directly connected to endotracheal tube.

Percussionaire® Digital Multimeter (PDM) Setup

NOTE: *Remove the PDM from the IPV®-2C device, to access battery pull tabs, by turning the PDM counterclockwise.*



NOTE: *To ensure correct atmospheric pressure calibration at start up, remove batteries, wait 30 seconds and re-install. Allow 15 seconds for power on self test. When screen goes blank, the multimeter can be installed into the device.*



Side view of PDM

NOTE: *The PDM has a USB serial port that is used for manufacturing, calibration and firmware upload. It is not enabled during normal operation.*

Knob, Switch and Button

Knob	Functions
DEMAND CPAP/PEEP 	Demand Continuous Positive Airway Pressure **(Demand-CPAP)** for reducing the work of breathing • Lifts the baseline in a static way • Affects peak and mean airway pressure • Used to reduce work of breathing (WOB), stabilize upper airways
INSP TIME 	The **Inspiratory Time** control knob arrow when rotated (counterclockwise) to the 12:00 default position increases the **Inspiratory Time** while simultaneously decreasing the **Expiratory Time**. • Sub-tidal inspiratory/expiratory ratio • Ranges from 1:1 to 1:3 • Affects mean airway pressure
INSP FLOW 	The **Inspiratory Flow** control knob determines the amplitude delivered to the patient during inspiratory time. • Set according to patient's need or tolerance. • Chest wiggle
FREQUENCY 	The **Frequency** knob controls the rate of high frequency volumes delivered. • Ranges from 60 to 330 cycles per minute • Affects peak and mean airway pressure
MASTER 	The **Master Switch** turns the IPV®-2C controller ON and OFF. The patient receives TRUE-IPV® treatment when the **Master Switch** is in the ON position.

Knob	Function
	The **Manual Inspiration** button controls the delivery of a regulated source of gas through the orifice of the Phasitron®5 venturi. • To remove CO_2 • To induce a cough ⚠ **WARNING:** The longer the **Manual Inspiration** button is pressed, the greater the potential for tidal volume delivery. ⚠ **WARNING:** NOT FOR USE WITH NEONATES.
	The **Nebulizer** ON/OFF Switch turns the aerosol delivery ON and OFF. • Recommended to always use nebulization
	The **Operational Pressure** knob controls the peak operating pressure of the entire unit. The optimal pressure is 40 psig (3.4 bar, 345 kPa) for Pediatrics and Adults and 30 psig (2.07 bar, 207 kPa) for Neonates.

Percussionaire® Digital Multimeter (PDM)

The Percussionaire® Digital Multimeter (PDM) has six different operating modes: Post, Wake, Active, Report, Sleep and Fault.

Power-On Self-Test (POST) Mode

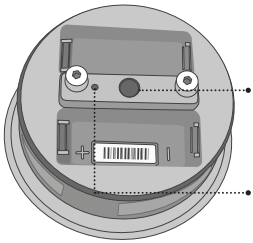
When batteries are installed in a system, the Percussionaire® Digital Multimeter (PDM) software displays the software revision, battery voltage, total usage time and serial number for 15 seconds. This Start-Up mode allows the software to perform additional tests on the hardware that are part of the **Power-On Self-Test**. If any errors are detected the PDM enters the Fault mode. It is required that the measurement port be left disconnected and exposed to the atmosphere for the entire duration of the Power-On Self-Test.

NOTE: *Do not install PDM until the POST check is complete and the screen is blank, indicating Sleep mode.*

System Information Display

```
Percussionaire
Digital Multimeter
(C) 2014, RDI
Bat: 3.05V
Total Time: 23,075h 27
Code Rev: 2.XX
Serial #: 2140604-001
```

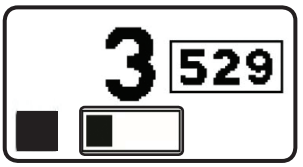
Rear view of PDM



Wake Mode

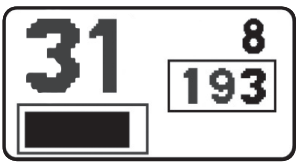
To wake up the PDM, ensure the ventilator pressure is greater than 2.5 cmH_2O or 2 hPa at the Phasitron®5 patient delivery port for more than 1 second.

The PDM remains on for the first 15 seconds, showing the Bar-Graph timer.
If usage is stopped within 12 seconds, the PDM enters Report mode. After 15 seconds, the current session continues counting from 16 seconds, which turns into Active mode.



US IPV: IPV®-2C

PDM display screens in Wake mode



EUR Therapy: IPV®-2C

NOTE: *Display numbers are for reference only.*

Active Mode

Model: US IPV
Device: IPV®-2C
Display Metrics: Pulse Frequency Rate, Pulse Amplitude Bar Graph, Mean Airway Pressure, Session Usage Time

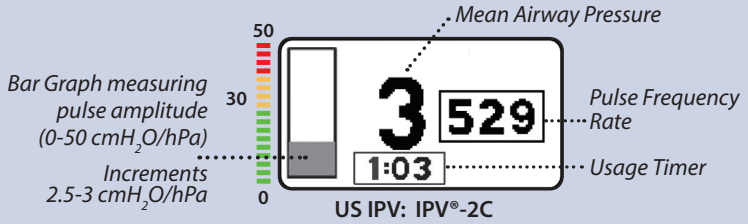
At 16 seconds the PDM enters **Active** mode. The timer bar will change to a numeric display, showing the current usage Session Timer. The display on the right shows the currently measured Pulse Frequency rate.

Mean Airway Pressure (MAP) averages pulse amplitude over 5 seconds. At 100 samples per second, this is an average of 500 measurements.

The PDM displays the usage Session Timer in minutes and seconds. The Session Timer is the total time of the current usage. The Session Timer can display a maximum of 59 minutes and 59 seconds. If usage has been stopped for more than 5 minutes, the Session Timer will reset and start over.

The Pulsating Bar Graph on the left side displays Pulse Amplitude calculated as average peak amplitude pressure sample in last 5 seconds, minus amplitude pressure sample in last 5 seconds. The Bar Graph is a visual representation better reflecting AIP and AEP values and represents an estimate of airway pressure. PEEP is represented by a solid bar at the base and AIP is represented by the pulsating peaks of the Bar Graph display.

NOTE: *To display most recent usage duration time, see Report Mode.*



Model: EUR Therapy
Device: IPV®-2C (Non-USA)
Display Metrics: Pulse Frequency Rate, Mean Airway Pressure, Session Usage Time, Pulse Amplitude Pressure.

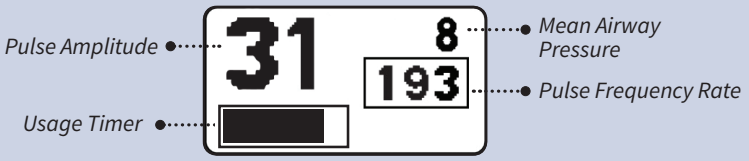
At 16 seconds, the PDM enters Active mode. The timer bar will change to a numeric display, showing the current usage Session Timer. Above the timer reading is the display of the Pulse Amplitude. This is calculated from the pressure measurements at the moment of instantaneous peak and trough amplitude averaged over 5 seconds. The display on the right shows the currently measured Pulse Frequency rate.

Mean Airway Pressure (MAP) averages Pulse Amplitude over 5 seconds. At 100 samples per second, this is an average of 500 measurements.

The PDM displays the usage Session Timer in minutes and seconds. The Session Timer is the total time of the current usage. The Session Timer can display a maximum of 59 minutes and 59 seconds.

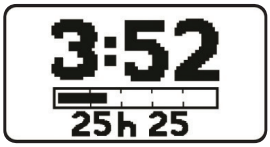
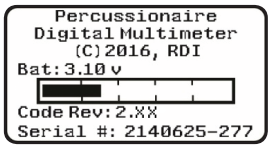
If usage has been stopped for more than 5 minutes, the Session Timer will reset and start over.

NOTE: *To display most recent usage duration time, see Report Mode.*



EUR Therapy: IPV®-2C, display

Report Mode

A. 	The Session Timer and the Total Usage Timer **(A)** are displayed for 2 seconds, followed by the System Information page **(B)** for 2 seconds, alternating. The alternating page display continues for 5 minutes or until usage resumes and the PDM enters **Active** mode.
B. 	During the 5-minute period, a horizontal bar graph indicates the time by moving from left to right at a fixed rate. After 5 minutes of no usage, the system information page is no longer displayed and the time display flashes (2 seconds on, 2 seconds off) **(C)** for an additional 25 minutes.
C. 	The PDM enters **Sleep** mode after 25 minutes.

US IPV: IPV®-2C

The display screen when the IPV®-2C ventilator is switched off.

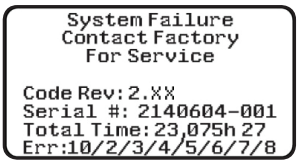
NOTE: *When the IPV®-2C is turned off, the measurements will drop to zeros after a few seconds.*

Sleep Mode

Blank screen, indicating PDM Sleep mode

In **Sleep** mode the LCD is off, but the microcontroller continues to sample and calculate the pressure at the measuring port 5 times a second. Over any 3-second period, if the pressure is greater than 2.5 cmH_2O or 2 hPa at the Phasitron® patient delivery port, for more than 1 second, the PDM enters the **Wake** mode.

Fault Mode



The PDM displays an error message on the LCD stating, "Contact Factory for Service" and stays in **Fault** mode until both batteries are removed.

The displayed information includes the software revision, PDM serial number, the Total Usage time and an error code for the exclusive use of the factory.

In all other modes, the software continuously monitors the hardware for errors as well as verifying that each data sample has a valid value. If an error is detected, the software logs the error and reboots the processor. Rebooting allows the PDM to recover from a transient error. After reboot, the processor returns to the same mode it was in before the reboot. If more than one error is detected in any 10-second period, it is considered a fatal error and the software enters **Fault** mode.

NOTE: *Pressure faults are triggered by a continuous pressure of more than 150 cmH_2O for more than 5 seconds during Wake and Active modes.*

NOTE: *If **System Failure** screen is displayed, remove batteries for 30 seconds. Replace batteries (note that positive terminals face same direction) and wait 30 seconds until the screen turns off. If POST check runs correctly, PDM may be used. If System Failure screen recurs, contact an authorized Percussionaire® service center.*

Fault Logging

The software keeps track of several types of hardware and data faults. All faults are logged in the microcontroller's memory and are retained even if the batteries are removed. If multiple faults happen within 10 seconds of each other, the PDM stops normal operation and enters Fault mode. In this mode, a subset of the collected fault information is displayed on the LCD. This data is intended for manufacturing and repair use only.

The user can exit the Fault mode by removing and replacing the batteries. This resumes normal operation of the PDM but does not erase the faults stored in memory or fix the problem that caused the fault.

Fault Detection

The PDM has both hardware and software fault detection. This is a dedicated hardware "watchdog" that runs on an independent clock source and can continue to operate even if the main microprocessor's clock fails or the microcontroller pauses in any way. The independent fault detection is reset each time a valid pressure reading (free of hardware and software errors) is obtained.

In addition to the hardware fault detection, the software also implements a fault detection "watchdog". This "watchdog" detects if a software task fails to complete within the specified time, logs an error and resets the processor.

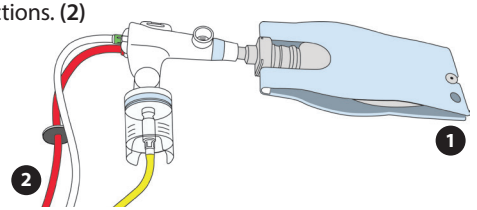
Chapter 6: Pre-Use Check

Pre-Use Check with Blender

If no blender is used, go to next table "Pre-Use Check".

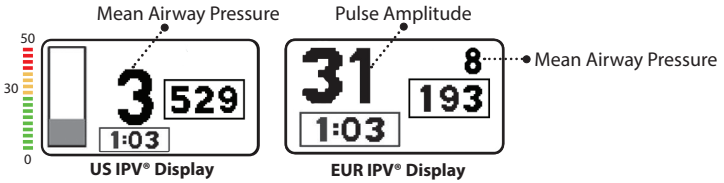
1.	Plug in **Air** high-pressure hose. Listen for blender alarm, then disconnect air hose.
2.	Plug in **Oxygen** high-pressure hose and disconnect air hose. Listen for blender alarm.
3.	Plug in **Air** high-pressure hose. Listen for blender alarm to stop.
4.	Go to step 1 (below).

Pre-Use Check

1.	Connect a Siemens style 1-liter ventilator test lung to the Phasitron®5. **(1)**
2.	Connect the Phasitron®5 tubing connections to the IPV®-2C using the red, clear and yellow connections. **(2)** 
3.	Rotate the **OPERATIONAL PRESSURE** knob full counterclockwise to the stop (OFF) position.
4.	Connect the IPV®-2C to gas source supply.
5.	Rotate the yellow **"D" DEMAND CPAP/PEEP** knob to full clockwise position (OFF).
6	Rotate the green **"C" INSP FLOW** to the center, (UP) position.
7.	Rotate both the **"A"** and **"B"** black knobs to the center, (UP) position.
8.	Push **NEBULIZER** switch to the down (OFF) position.
9.	Rotate the **MASTER** switch to the "ON" position.
10.	Rotate the **OPERATIONAL PRESSURE** knob to "ON" to obtain a pressure between 40-42 psi/2.7-2.9 bar on the operational pressure gauge. Verify pressure by occluding the REMOTE connection for 3 seconds; this will halt percussions and hold the pressure gauge steady. Adjust Operational Pressure knob accordingly.
11.	Turn DEMAND CPAP (yellow knob) counterclockwise slowly to reach a MAP pressure of between 5-7 cmH_2O displayed on the PDM (multimeter).

(Continued on p.29)

NOTE: *If using the "EUR" multimeter, MAP is in a different position on display.*



12.	Adjust **INSP FLOW** (green knob) until MAP reaches 10 cmH_2O displayed on the PDM (multimeter).
13.	Observe pulsing grey bar on left side of multimeter.
14.	Rotate both **"A"** and **"B"** knobs to the left, full counterclockwise position.
15.	Confirm pulse frequency rate of over 300.
16.	Rotate both **"A"** and **"B"** knobs to the right, full clockwise position.
17.	Confirm pulse frequency rate of under 100.
18.	Rotate both **"A"** and **"B"** knobs to the center, up position.
19.	Rotate yellow **"D" DEMAND CPAP/PEEP** knob full clockwise position (OFF).
20.	Verify **INSP FLOW** (green knob) will achieve a MAP of 10-40 cmH_2O.
21.	Rotate **INSP FLOW** (green knob) full clockwise position (OFF).
22.	Switch **NEBULIZER** up to ON and listen for gas flow out of the Phasitron®, then switch OFF.
23.	Rotate **INSP FLOW** (green knob) to the center, up position.
24.	Trigger the failsafe alarm by pinching off clear Phasitron® tubing.
25.	Alarm should reset and mute when clear tubing is released.
26.	Occlude green port and observe that pulsations stop. Remove occlusion from green port.
27.	Rotate the **MASTER** switch to OFF position. Return all knobs to protocol/default position.
28.	Disconnect gas source supply.

Chapter 7: TRUE-IPV® Therapy Parameters

Amplitude and Flow Frequency: Depend on treating goal/pathology.

Choosing parameters depends on:

1. Pathology	4. Tolerance
2. Ventilation parameters	5. Chest Wiggle
3. Clinical conditions	

The proximal pressure variation depends on:

1. Installed parameters	2. Resistance of the interface	3. The patient • Lung resistance • Thoraco-pulmonary compliance • Spontaneous breathing

Chapter 8: General TRUE-IPV® Therapy Protocol

General TRUE-IPV® Therapy Protocol for Pediatric/Adult

1.	Connect the IPV®-2C to 50-80 psig (345-551 kPa) gas power source. Master Switch is "OFF".
2.	The patient may sit in an upright, comfortable position or lie down with head and shoulders elevated.
	NOTE: *Patient's gravitational position is not a factor with TRUE-IPV®.*
3.	Auscultate patient for breath sounds, heart and respiratory rate, or follow institution guidelines.
4.	Connect the Phasitron®5 kit as indicated on package insert or pages 14-17.
5.	Put prescribed medications into nebulizer and add diluent as directed by physician to a maximum of 20 ml. If no medications are prescribed, use normal saline or sterile water, as directed by physician. Turn Nebulizer on.
6.	Rotate Inspiratory Time and Frequency knobs to the 9:00 position which produces an approximate Pulse Frequency rate of 300-350. The i:e ratio will be approximately 1:1 (May be used for recruiting alveoli) .
7.	With Master switch "ON", rotate Operational Pressure control knob for an operating pressure of 35 to 40 psig (206-275 kPa).
8.	Adjust Inspiratory Flow for a Amplitude pressure (PIP) of 5-10 cmH_2O. Usually a mean of around 6-7 cmH_2O.
9.	Turn Demand CPAP to ~ 2 - 4 cmH_2O, then turn the Inspiratory Flow control knob on for mild percussion.
10.	When using a mouthpiece, instruct the patient to inhale and exhale through the pulses. Most patients will initially allow percussive bursts of air to leak through their nose at the expense of an observable chest movement (wiggle).
11.	Start to notice the chest movement (wiggle) as the patient exhales through the mouthpiece. Advise the patient to relax, taking normal (spontaneous) breaths through the pulses whenever they desire. When a patient has an artificial airway, the process is similar. The patient must be observed carefully for signs of distress. While cheek fatigue will be less of a consideration, pauses or breaks may still be necessary for the patient.
12.	Instruct the patient to keep lips and cheeks splinted to avoid nasal venting. As the patient learns to prevent air from leaking out of the lip seal around the mouthpiece, the Inspiratory Flow control knob arrow can be slowly rotated counterclockwise, gradually increasing flow until desired chest wiggle/Amplitude is reached.

(Continued on p.32)

13.	After several minutes of therapy, change both knobs to the 12:00 position, which produces an approximate Pulse Frequency rate of 150-200. The i:e ratio will be approximately 1:2 (most frequently used for airway clearance – increased secretions). End therapy on these settings.
14.	TRUE-IPV® treatment should continue for 15 to 20 minutes total.
15.	When treatment is complete, the IPV®-2C controller should be turned OFF. The Phasitron®5 should be rinsed, cleaned and stored in the supplied bag, as per hospital infection control policy, until the next treatment.
	NOTE: *The Phasitron® 5 is a SINGLE PATIENT, MULTIPLE USE DEVICE.*
	NOTE: *Percussionaire® recommends cleaning per your institution's approved practice between treatments.*

General TRUE-IPV® Therapy Protocol for Neonates

1.	Verify infant has a properly placed Oral Gastric (OG) Tube, open to room air before starting IPV treatments. OG tube must remain open as a vent throughout duration of IPV therapy.
2.	Infant should be positioned in the supine position with head elevated > 15 degrees. Recommended semi-Fowler's or Fowler's position for non-intubated patients.
3.	Set Operational working pressure to ~ 30 psig; this will soften the percussion and allow increased modulation of adjustment for Flow (ie. fine adjustment). An Oxygen Blender and O_2 Analyzer should always be utilized with this population. This will allow appropriate adjustment of FiO_2 and weaning of FiO_2 as oxygen requirements improve. Generally a reduction in oxygen requirements will be seen as the infants V/Q match is optimized.
4.	Set Demand CPAP for 2 cmH_2O by occluding Phasitron® to create seal.
5.	Adjust Inspiratory Flow for a MAP of 6-7 cmH_2O, this is approximately an Amplitude pressure of 8-10 cmH_2O.
6.	Apply to Patient and adjust to achieve desired chest movement. A **mild** chest wiggle is required for good therapy. Carefully monitor infant for signs of hyperventilation. **WARNING:** It is important to keep a respiratory drive while watching for spontaneous breathing efforts which could lead to hyperventilation leading to apnea after completion of therapy.

(Continued on p.33)

7.	Adjust Inspiratory Time and Frequency knobs together; adjusted for patient comfort and effectiveness.
8.	Start treatment with the Inspiratory Time and Frequency knobs set at the 9:00 position, which produces an approximate Pulse Frequency rate of 300-350. The i:e ratio will be approximately 1:1 (may be used for recruiting alveoli).
9.	After several minutes of therapy, change both knobs to the 12:00 position, which produces an approximate Pulse Frequency rate of 150-200. The i:e ratio will be approximately 1:2 (most frequently used for airway clearance – increased secretions). End therapy on these settings.
	NOTE: *As the rate is lowered there may be a need to decrease the flow due to increased CO_2 removal, always titrate to the patient.*
10.	Adjust Inspiratory Flow for a MAP of 6-7 cmH_2O, this is approximately an Amplitude pressure of 8-10 cmH_2O.
11.	Nebulizer must ALWAYS be ON – will use ~ 0.75 ml/min of solution; fill Nebulizer with 20 ml of solution. Normal Saline (NS) should be used unless a medication is ordered.
12.	***Important/Remember:*** Due to the effectiveness of the treatment, it is easy to lower the CO_2 and remove the respiratory drive. The patient should be monitored closely for signs of hyperventilation. If CO_2 levels drop below an acceptable level reduce the Amplitude pressure and observe a reduction in chest wiggle.
13.	TRUE-IPV® treatment should continue for 15 minutes total.
14.	When treatment is complete, the IPV®-2C controller should be turned OFF. The Phasitron®5 should be rinsed, cleaned and stored in the supplied bag, as per hospital infection policy, until the next treatment.
	NOTE: *The Phasitron® 5 is a SINGLE PATIENT, MULTIPLE USE DEVICE.*
	NOTE: *Percussionaire® recommends cleaning per your institution's approved practice between treatments.*

Administering TRUE-IPV® Therapy with In-Line Valve

When administering TRUE-IPV® Therapy with an In-Line Valve, a pressure control (PC) mode is recommended or follow your institutional protocol.

Mean Airway Pressures will increase slightly with the administration of TRUE-IPV® in-line therapy with the ventilator. The respiratory care practitioner must be aware of this effect and monitor the patient closely for any adverse side effects.

When using the IPV®-2C in pressure-control mode, the In-Line Valve may remain closed. When using the ventilator in volume-control, the In-Line Valve may be opened to create a leak.

⚠ **WARNING:** NEVER run device without liquid in nebulizer during treatment. This is required for airway hydration.

⚠ **WARNING:** Note the current ventilator alarm and mode settings.

⚠ **WARNING:** Reset occasional CMV high-pressure alarms as they occur. When applying TRUE-IPV® in-line, adjust the pressure relief valve to achieve desired Amplitude Pressure per your institutional/hospital protocol. High-pressure alarms should not occur on a regular basis if the Pressure Relief Adjustment valve is set correctly.

NOTE: *Patients who are performing T-tube trials or CPAP sprinting may be taken off the ventilator for the IPV® treatment utilizing a flex adapter. Decreasing cuff pressure still applies to this patient population.*

NOTE: *Following your institutional protocols for cuffed endotracheal tubed patient, the cuff pressure may be lowered.*

NOTE: *Lowering of the cuff pressure facilitates secretion removal into the oral cavity where they may be suctioned. This also helps in the prevention of tube obstruction in the event copious secretions are mobilized.*

1.	Ensure the IPV®-2C is "OFF" and connected to a 50 psi/3.2 bar gas source.
2.	Connect the IPV®-2C to 50-80 psig (345-551 kPa) gas power source. Master Switch is "OFF".
3.	Put prescribed medications into nebulizer and add diluent as directed by physician to a maximum of 20 ml. If no medications are prescribed, use normal saline or sterile water, as directed by physician. Nebulizer should always be on.
4.	With IPV®-2C Master switch "ON", rotate Operational Pressure control knob for an operating pressure of 35 to 40 psig (206-275 kPa).
5.	Rotate Inspiratory Time and Frequency knobs to the 9:00 position which produces an approximate Pulse Frequency rate between 300-350. The i:e ratio will be approximately 1:1 (may be used for recruiting alveoli).
6.	Turn on Inspiratory Flow control knob slowly adjust for desired chest wiggle and amplitude.

(Continued on p.35)

7.	Percussion should continue through two complete ventilator cycles to allow ventilator to deliver several machine breaths.
8	Adjust pressure relief valve, depending on which ventilator mode is used, and observe visible chest movement.
9.	Monitor breath sounds and observe pulse oximeter for oxygen saturation improvement.
10.	Observe aerosol mist in nebulizer bowl.
11.	Therapy should continue for approximately 15 to 20 minutes, or per institutional/hospital protocol.

NOTE: *If chest percussion is inadequate, increase inspiratory flow or raise drive pressure (psi gauge) and scan frequency rate to mobilize secretions.*

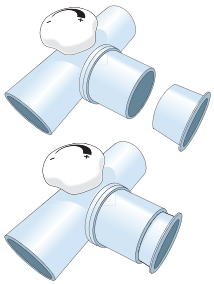
NOTE: *Percussive frequency and inspiratory flow can be adjusted to increase and decrease the amount of "chest movement (wiggle)".*

NOTE: *Suctioning should be performed as needed.*

NOTE: *It may take multiple treatments to identify optimal therapeutic effect for each patient.*

Completion of Therapy with In-Line Valve

1.	If cuff was deflated during treatment, reset cuff pressure.
2.	Turn off IPV®-2C controller.
3.	Close Pressure Relief valve (knob).
4.	Disconnect Phasitron® 5 from TRUE-IPV® In-Line Valve and store appropriately.
5.	Restore ventilator to settings that were present before starting TRUE-IPV® treatment.
6.	Remove cap from Phasitron® 5.



7. In-Line Valve remains in the ventilator circuit between uses. Insert plug into the Phasitron® 5 port of the In-Line Valve until the next use.

8. Keep In-Line Valve in the ventilator circuit with plug inserted until next use.

NOTE: *Clean and disinfect In-Line Valve as needed per institutional protocols. In-Line Valve is intended to stay in the ventilator circuit.*

Chapter 9: Cleaning and Disinfection

IPV®-2C and Stand

Clean the IPV®-2C and stand according to hospital/institutional protocols. Always clean between patients and when visibly soiled. Clean the controller and stand with a clean, lint-free cloth or paper towel moistened with the cleaner.

⚠ **CAUTION:** Do not spray any cleaning solution directly on the IPV®-2C or stand.

⚠ **CAUTION:** Do not immerse or allow liquids to access the controller.

⚠ **CAUTION:** Use only approved cleaners.

Percussionaire® Digital Multimeter (PDM)

Clean the PDM when visibly soiled or according to facility protocols.
Do not spray any type of cleaner directly onto the multimeter. Clean the glass with a product or chemical approved for cleaning glass only.

⚠ **CAUTION:** Use of cleaning methods not outlined in these instructions may cause damage to the multimeter.

⚠ **WARNING:** The cell used in this device may present a risk of fire or chemical burn hazard if mistreated. Do not recharge, disassemble, heat above 100°C (212°F) or incinerate. Replace cell with type recognized CR123A only, or Percussionaire® part PRT-B13350. Use of another cell may present a risk of fire or explosion.

Dispose of in accordance with appropriate regulations, country, local and state laws.

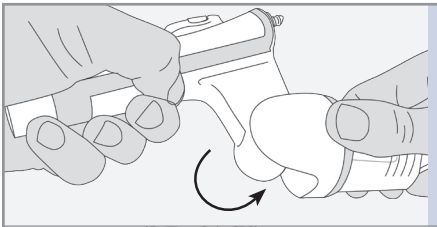
Phasitron®5 Breathing Circuit

Follow hospital/institutional guidelines for cleaning or storage between treatments. It is not necessary to clean the Phasitron®5 after each use; however, rinsing with sterile water is advised. When disassembling the Phasitron®5, visually inspect the exterior of all parts, including tubing, for corrosion, discoloration, pitting, and missing O-rings.

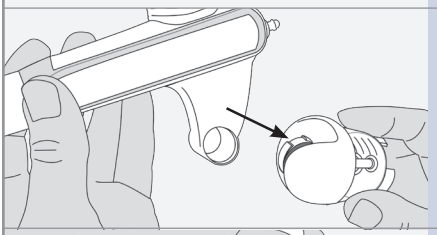
⚠ **CAUTION:** Do NOT immerse the antibacterial filter of the tubing harness.

Disassembly of the Phasitron®5

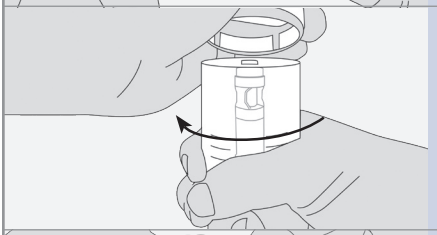
Disconnect tubing from IPV®-2C device and Phasitron®5.



1. Gently rotate nebulizer bowl towards the rear of the Phasitron®5 until it stops.

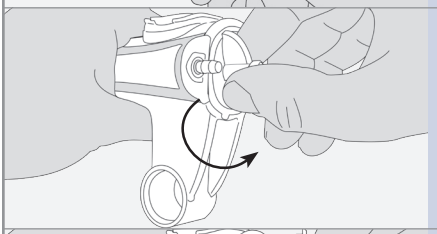


2. Gently separate nebulizer from Phasitron®5.

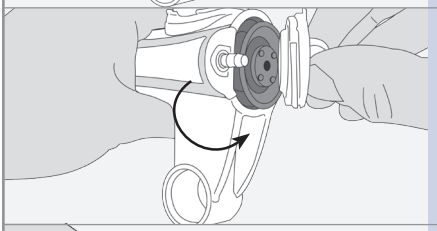


3. Holding the nebulizer cap, twist the nebulizer bowl to remove bowl from cap.

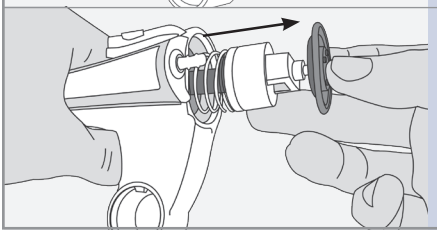
Discard any unused medication in accordance with hospital/institutional protocol.



4. Twist white cap on the rear of Phasitron®5 to remove.



5. Remove cap.



6. Remove sliding venturi with spring from Phasitron®5 body.

Cleaning Phasitron®5

1.	Thoroughly rinse each of the disassembled parts (except for tubing harness and filter) under warm running tap water for approximately 10 seconds.
2.	Use fragrance-free liquid soap added to a clean bowl or basin with warm water.
3.	Hand wash all parts of the Phasitron®5 kit and accessories in the warm soapy water.
4.	Rinse all parts thoroughly using sterile water.
5.	Gently shake all parts to remove as much water as possible, then dry with a clean lint-free cloth or paper towel.
6.	Use a clean, damp cloth to wipe the exterior of the tubing harness with an approved alcohol based cleaner.
7.	Reassemble the Phasitron®5 and place in the supplied bag until next use.
8.	Do not disinfect the Phasitron®5 for reuse with more than one patient.

Cleaning and Disinfecting Solutions

NOTE: *The Phasitron®5 breathing circuit has been tested for biocompatibility with the following cleaning and disinfecting solutions:*

Chemical Class	Active Ingredient
Bleach	5.25% Sodium hypochlorite
Alcohol	70% Isopropyl alcohol
Peroxide	3% Hydrogen peroxide
Benzyl Ammonium Chloride	N-alkyl dimethyl ethyl benzyl ammonium chlorides N-alkyl dimethyl benzyl ammonium chloride
Phenolic	Ortho-phenylphenol Ortho-benzyl-para-chlorophenol
Quaternary Ammonium Chloride	Didecyl dimethyl ammonium chloride Alkyl dimethyl benzyl ammonium chloride

Chapter 10: Troubleshooting

Problem	Examine	Repair
No pressure indication on the Operational Pressure gauge	Check inlet gas source. Rotate Operational Pressure knob clockwise until 40 psi is indicated. Check MASTER switch ON.	Connect to Gas Source. Service required. Replace or repair MASTER switch..
No percussions	Check inlet gas source. Check MASTER switch ON/OFF. Check REMOTE connector for blockage. Check Operational Pressure regulator.	Connect to Gas Source Replace or repair MASTER switch. Service required. Service required .
Slow percussion rate	Check REMOTE connector for external blockage. Percussion knob doesn't change rate.	Rotate percussion knob counterclockwise. Service required.
Percussion works, but stalls	Witnessed stall event.	Service required.
No display on PDM	Check battery orientation and strength. Check both tubing connections. Check if Phasitron® 5 patient port is occluded or connected to patient.	Replace batteries. Reconnect red connections. Occlude patient end of Phasitron® 5 if not connected to a patient.
Nebulizer not aerosolizing	Disconnect yellow tubing from IPV®-2C to verify constant flow. Check both yellow tubing connections. Check nebulizer bowl for flow out of nebulizer baffle (Phasitron® 5 diagram).	No flow from aerosol connector, service required. Reconnect Yellow Connections. Clean or replace Phasitron® 5.

⚠ **CAUTION:** I*f you notice any unexplained changes in the performance of the device, if the device is making unusual sounds, or if the device is dropped or damaged in any way, discontinue use and contact an authorized Percussionaire® service center.*

Changing PDM Batteries

A Low Battery indicator is displayed when battery capacity is nearing depletion.

1.	Press on the PDM's bezel and twist counterclockwise approximately 20 degrees.
2.	Gently pull on the multimeter to remove it from the housing.
3.	Remove the two old batteries.
4.	Install two new batteries. Note that the positive terminals face the same direction. Wait 30 seconds until screen turns off.
5.	Install the PDM back into the housing and twist clockwise until the stop is felt.
6.	See POST mode instructions to verify display operation.

Chapter 11: Technical Specifications

IPV®-2C

Dimensions (W x H x D)	17cm x 24.13cm x 24.13cm (6.7" x 9.5" x 9.5")
Weight	1.99 kg (4.4 lbs)
Operating Range	Temp., 0°C to 49°C (32°F to 120°F), Humidity 5%-95%
Storage and Transport	Temp., -20°C to 60°C (-4°F to 140°F) Humidity < 93% non-condensing
Gas Source	Hospital Wall Gas: 50-80 PSI, 3.45-5.5 BAR Flow: 25 LPM
Battery Type	Multimeter uses (2) CR123A batteries
Pulse/Interval Ratio	Automatic
Run Time	Non-continuous
Aerosol Flow	25 LPM
Pulse Amplitude	Digital display, 0-99 cmH_2O/hPa, accurate to +/- 1 cmH_2O/hPa
Pulse Frequency	60-330 pulses per minute
Mean Airway Pressure (MAP)	Digital display, 0-99 cmH_2O/hPa
Amplitude Bar Graph	Digital display, 0-50 cmH_2O/hPa
Session Usage Timer	Digital display, max 59:59
Accessories	Phasitron® kit P5-10
Required Maintenance	3 years

Phasitron®5 Technical Specifications

Size	13.5 mm x 17 mm (5 ¼" x 6 ¾")
Weight	123 g (0.27 lb)
Operating Range	Temp., 0°C to 49°C (32°F to 120°F) Relative humidity range15% to < 90% non-condensing
Storage and Transport	Temp., -40°C to 60°C (-40°F to 140°F),
Rate Range	0-999 pulses per minute
Pressure Range	0-150 cmH_2O/hPa
Liquid Consumption	.75 cc per minute
Safety Valve Release	30-50 cmH_2O/hPa
Red Line Filter	1-3 micron hydrophobic
Disposal	Recycle according to local laws
Service Life	6 months or 540 uses, whichever is less
Shelf Life	2 years from date of manufacture

Percussionaire® Digital Multimeter (PDM) Specifications

Size	73 mm (2.87 inch) diameter
Mass	165 g (0.36 lb)
Storage and Transport Range	Temp -20°C to 60°C (-4°F to 140°F) Humidity <93% non-condensing
Operating Range	Temp -20°C to 60°C (-4°F to 140°F), Humidity <93% non-condensing
Display	128 x 64 pixel FSTN chip on glass LCD with reflector
Fault Detection	Independent Hardware and Software Watchdogs
Serial Port	USB (Firmware Upgrade)
Rate Range	50-999 pulses per minute
Pressure Range	1-150 cmH_2O/hPa
Pressure Resolution	1 cmH_2O/hPa
Pressure Accuracy	Greater of ±0.5% of reading or 1 cmH_2O/hPa
Battery Type	CR123A 3.0V (2)
Battery Duration	3,250 Operational hours at 35°C (95°F)
Shelf Life	3.5 Years at 35°C (95°F)

Chapter 12: Service and Repair

Percussionaire® Corporation recommends an annual preventive maintenance (PM) for each device. An annual PM consists of a thorough cleaning, functional evaluation and if necessary, recalibration. A mandated overhaul 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 overhaul consists of all new components including front panel, metering valves elastomeric seals, sleeves and cartridges. The device is factory calibrated and receives a functional evaluation, conformance certification and a one-year warranty on all parts replaced. A device which has not received a mandated overhaul for a period of 10 years, whether in use during that period or not, is considered beyond economic repair. Intervention by an unauthorized individual or repair maintenance facility will cause the immediate expiration of the clinical readiness of the device.

To return a Percussionaire® device to factory service center for repair, overhaul or annual preventive maintenance, contact your distributor.

Chapter 13: Disposal of Equipment

At the end of useful life of an IPV®-2C unit, disposal should be in accordance with local, state, federal, and international laws.

Chapter 14: Limited Warranty

Percussionaire® warrants that the IPV®-2C shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one year from the date of first use (proof of delivery will be required). If the product fails to perform in accordance with the product specifications, Percussionaire® will repair or replace – at its option – the defective material or part. Percussionaire® will pay customary freight charges to and from Percussionaire® or an authorized Percussionaire® service center. This warranty does not cover damage caused by non-approved cleaning or sterilization, accident, misuse, abuse, alteration and other defects not related to material or workmanship. Percussionaire® disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product.

PERCUSSIONAIRE®
CORPORATION

130 McGhee Road, Suite 109, Sandpoint, Idaho 83864 USA
MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany
percussionaire.com +1.208.263.2549

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