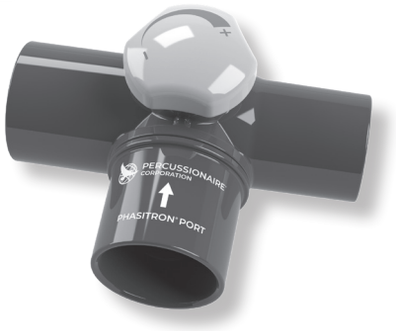
TRUE-IPV® SYSTEM

In-Line Valve



PERCUSSIONAIRE® CORPORATION

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P20020 Rev E

EN

TRUE-IPV® In-Line Valve, 22 mm ID x 22 mm OD Single Patient, Instructions for Use

Intended Use
The TRUE-IPV® In-Line Valve is intended to be used to provide IPV® (Intrapulmonary Percussive Ventilation) therapy to patients while assisted by Conventional Mechanical Ventilation (CMV) using pressure-control, volume-control, SIMV-PC etc., when direct connection of IPV® is not indicated.
For use only with Percussionaire® TRUE-IPV® Control Devices.
Compatible with all Percussionaire® single-patient Phasitrons.

Patient Population
Neonates to adults, for whom IPV® therapy has been prescribed.

Absolute Contraindications:
- Untreated tension pneumothorax
- Untrained operator

Relative Contraindications:
- History of pneumothorax
- Myocardial Infarction
- Vomiting
- Recent pneumonectomy
- Pulmonary hemorrhage
- Pulmonary air leak (Without functioning chest tube)

Possible Adverse Reactions:
- Decreased cardiac output
- Pneumothorax
- Hyper-oxygenation
- Pulmonary hemorrhage
- Gastric distension
- Increased intracranial pressure
- Increased air trapping
- Pulmonary air leak
- Hyperventilation

Symbols

⚠ WARNING	Type BF Applied Part
⚠ CAUTION	Single Patient Use
Read the manual before use	℞ Only Prescription Only
Manufacturer	REF Catalog Number
Manufacture Date	LOT Lot Number
	Non-Sterile

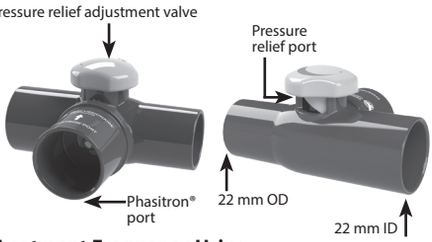
Read these instructions before setting up and using your IPV® In-Line Valve kit.

Precautions
⚠ **WARNING: Indicates the possibility of injury to the user or operator.**

⚠ **CAUTION: Indicates the possibility of damage to the device.**

US Federal law restricts this device to sale by or on the order of a physician.
- All persons providing IPV® treatment must be trained in the use of Percussionaire® Corporation devices.
- Therapist should evaluate patient's response and tolerance to therapy. Adjust inspiratory flow or operating pressures up or down as appropriate. Auscultation and observation of the mechanical vibrations of the chest and abdomen are primary indicators of effective treatment. Utilize $ETCO_2$ before and after treatments and SaO_2 as secondary indicators.
- Use only genuine Percussionaire® Corporation parts and accessories.

TRUE-IPV® In-Line Valve
Pressure relief adjustment valve



Treatment Frequency Using TRUE-IPV® In-Line Therapy
TRUE-IPV® in-line use with a ventilator is based on patient need.
2 times per day or up to every 4 hours is recommended.
Always use institutional/hospital protocol when possible.

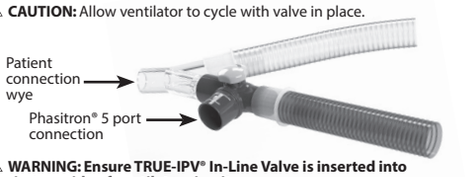
⚠ **WARNING: Follow your institutional protocols for infection control.**

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

TRUE-IPV® In-Line Valve Setup
Pediatric to Adult Application: recommended to install as close to the patient wye as allowable.
Neonatal Application: recommended to install in between heater and inspiratory limb.
Insert TRUE-IPV® In-Line Valve into inspiratory limb of ventilator circuit.

⚠ **CAUTION:** Ensure pressure relief adjustment valve is closed.

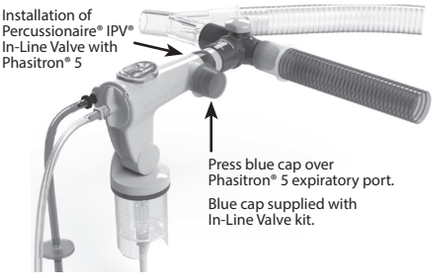
⚠ **CAUTION:** Allow ventilator to cycle with valve in place.



⚠ **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 Percussionaire® TRUE-IPV® In-Line Valve kit.

Fill nebulizer with 15 to 20 cc of 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.**

Administering Treatment:
⚠ **CAUTION:** Notate the current ventilator alarm and mode settings. PCV is recommended or follow institutional protocol.

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

TRUE-IPV® Control Device
⚠ **CAUTION:** When using the ventilator in pressure-control mode, the In-Line Valve may remain closed. When using the ventilator in volume-control mode, the In-Line Valve may be opened to create a leak.

1. Ensure your control device is off and connected to a 50 psi/3.2 bar gas source.
2. Turn incoming air/gas pressure regulator on IPV® device anticlockwise to the stop.
3. Turn IPV® device on.
4. Adjust pressure regulator clockwise to a starting drive pressure. Neonate 15 psi/1.03 bar, Pediatric 20 psi/1.37 bar, Adult 30 psi/2.06 bar, with a percussive frequency of approximately 200 ppm (pulses per minute) is recommended.
5. Percussion should continue through two complete ventilator cycles to allow ventilator to deliver several machine breaths.
6. Adjust pressure relief adjustment valve, depending which ventilator mode is used, and observe visible chest movement.
7. Monitor breath sounds and observe pulse oximeter for oxygen saturation improvement.
8. Observe aerosol mist in nebulizer bowl.

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

⚠ **WARNING: Source pressure, percussive frequency, and inspiratory flow can be adjusted to increase and decrease amount of "chest wiggle".**

⚠ **WARNING: Suctioning should be performed as needed. Notate the current ventilator alarm and mode settings.**

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

⚠ **CAUTION:** May take multiple treatments to identify optimal therapeutic effect for each patient.

Therapy should continue for approximately fifteen to twenty minutes, or per institutional/hospital protocol.

⚠ **CAUTION:** Reset occasional high-pressure alarms as they occur. When applying TRUE-IPV® in-line, adjust the pressure relief adjustment valve (see 6 above) to achieve desired institutional/hospital protocol Peak Inspiratory Pressure (PIP). 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 of the ventilator for the IPV® treatment utilizing a flex adapter. Decreasing cuff pressure still applies to this patient population.

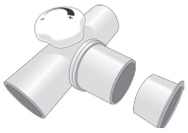
NOTE: Following your institutional protocols for cuffed endotracheal tubed patient, the cuff pressure may be lowered.

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.

At Completion of Therapy
1. If cuff was deflated during treatment, reset cuff pressure.
2. Turn OFF TRUE-IPV® device.
3. Close pressure relief adjustment valve.
4. Disconnect Phasitron® 5 from IPV® In-Line Valve and store appropriately.
5. Restore ventilator to the settings that were present before starting TRUE-IPV® treatment.

⚠ **WARNING: Remove cap from Phasitron® 5, insert into the In-Line Valve.**

6. Insert cap into Phasitron® 5 port of In-Line Valve.
7. Store In-Line Valve in the ventilator circuit with cap inserted until next use.

6. 

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Specifications

Operating Range	Temp., 0°C to 40°C (32°F to 104°F) Relative humidity range 15% to < 90% non-condensing
Storage and Transport Range	Temp., -40°C to 5°C (-40°F to 41°F) without relative humidity control Temp., 5°C to 35°C (41°F to 95°F) with relative humidity up to 90% non-condensing
Service Life	30 days from date of opening Remove and dispose with ventilator circuit Single ventilator circuit use only
Shelf Life	2 years
Disposal	Recycle according to local laws.

Limited Warranty Percussionaire® Corporation warrants that the In-Line Valve shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of 30 days. If the product fails to perform in accordance with the product specifications, Percussionaire® Corporation will replace the defective In-Line Valve. Percussionaire® Corporation will pay freight from Percussionaire® Corporation or an authorized 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® Corporation 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.