**TRUE-IPV® In-Line Valve**

**Pressure relief adjustment valve**

- Ventilator inspiratory limb prior to installation of Percussionaire®
- Always use institutional/hospital protocol when possible.
- TRUE-IPV®

**• Use only genuine Percussionaire® Corporation parts and**

- All persons providing IPV® treatment must be trained in the**

- US Federal law restricts this device to sale by or on the order**

**Y**

**Y**

**Possible Adverse Reactions:**

- Decreased cardiac output
- Pulmonary edema
- Hyper-oxygenation
- Pulmonary hemorrhage
- Gastric distension

**Symbols**

- Absolute Contraindications:
  - Untrained operator

**Relative Contraindications:**

- History of pneumothorax
- Myocardial infarction
- Venous thrombosis

- Possible Adverse Reactions:
  - Increased intrathoracic pressure
  - Increased air trapping
  - Hyper-oxygenation

**Injectable**

- 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.
- TRUE-IPV® 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, SWV IC, etc., when direct connection of IPV® is not indicated.

**For use only with Percussionaire® TRUE-IPV® Control Devices.**

**Patient Population:**

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

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

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

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

**WARNING:** Source pressure, percpicuous, and inspiratory flow can be adjusted and decrease amount of “chest wibble”.

**WARNING:** Suctioning should be performed as needed. Note 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 pressure level for each patient.

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

**CAUTION:** Reset occasional high-pressure alarms as they occur. When applying TRUE-IPV®, watch 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 trach or CPAP sprinting may be taken off of the ventilator for the IPV® treatment utilizing a flex adater. Decreasing cuff pressure still applies to this patient population.

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

**NOTE:** Lowering of the cuff pressure facilitates secretion removal into the oral cavity when 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. Cuff was deflated during treatment, rest cuff pressure 2. Turn OFF TRUE-IPV® device.
3. Close pressure relief adjustment valve.
4. Disconnect Phasitron® 5 from 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.

**TRUE-IPV® In-Line Valve Setup**

- Pediatric to Adult Application recommended to install as close to the patient nose as possible.
- 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.

**Patient connection**

- Phasitron® 5 port connection

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

**Adding Phasitron® 5 to In-Line Valve**

- Initial preferred blue cap (cap may vary into 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.

**WARNING:** Never re-use cap.

**Installation of Percussionaire® In-Line Valve with Phasitron® 5**

- Press blue cap over Phasitron® 5 expiratory port.
- Blue cap supplied with In-Line Valve kit.

**TRUE-IPV® Control Device**

- 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 10 psi 2.5 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/0.13 bar, Pediatric 20 psi/0.17 bar, Adult 30 psi/0.20 bar, with a percussive frequency of approximately 100 ppm (pulses per minute) is recommended.

5. Perfusion 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 auscultation in mid-lower bronch.

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

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7. Store In-Line Valve in the ventilator circuit with cap inserted until next use.

**TRUE-IPV® In-Line Valve**

- 22 mm ID x 22 mm OD Single Patient Instructions for Use

**Intended Use**

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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 profit, overhead, or consequential damages which may be claimed to arise from any sale or use of this product.