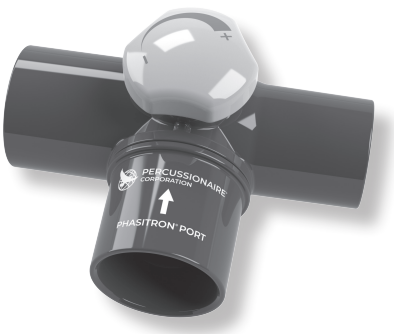
sentec.

In-Line Valve



Percussionaire®, 130 McGhee Rd., Suite 109, Sandpoint, Idaho 83864
sentec.com +1.208.263.2549

P20020 Rev F
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EN IPV® In-Line Valve, 22 mm ID x 22 mm OD Single Patient, Instructions for Use

Intended Use
The 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® 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 Multiple Use
Read the manual before use	Rx only Prescription Only
Manufacturer	REF Catalog Number
Manufacture Date	LOT Lot Number
	Use-by Date

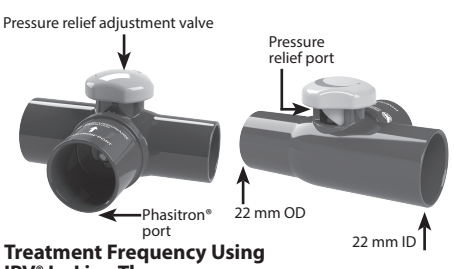
Read these instructions before setting up and using your IPV® In-Line Valve kit.

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®, Inc. 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®, Inc. parts and accessories.

P5-TEE In-Line Valve



Treatment Frequency Using IPV® In-Line Therapy
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.

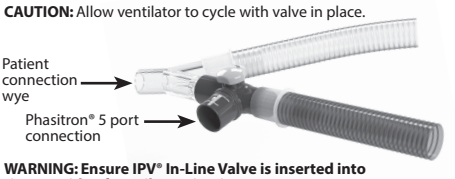
⚠ **WARNING: Follow your institutional protocols for infection control.**

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

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 on dry side of heater, in between heater and inspiratory limb.
Insert 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 IPV® In-Line Valve is inserted into inspiratory side of ventilator circuit.**

Adding Phasitron 5® to In-Line Valve
Fill nebulizer with 15 to 20 cc of normal saline or prescribed medication. Aerosol consumption approximately .75 cc per minute.

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

⚠ **CAUTION:** Mean Airway Pressures will increase slightly with the administration of 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.

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 operational 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 operational pressure 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: When P5-TEE is installed at the patient wye, NEVER perform IPV treatment without liquid in Phasitron® nebulizer during treatment. This is required for airway hydration.**

⚠ **WARNING: Expiratory port on Phasitron® 5 is to remain unobstructed throughout therapy when used in line or direct to airway.**

⚠ **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.

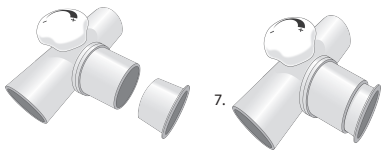
⚠ **CAUTION:** Reset occasional high-pressure alarms as they occur. When applying IPV® in line, adjust the pressure relief adjustment valve (see 6 above) to achieve desired institutional/hospital protocol Peak Inspiratory Pressure (PIP). High-pressure alarms should not occur on a regular basis if the 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 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 IPV® treatment.
6. Insert cap into In-Line Valve port as shown below.
7. Store In-Line Valve in the ventilator circuit until next use.



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Specifications

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

The manufacturer warrants to the initial purchaser that each new In-Line Valve will be free from defects in workmanship and materials. The manufacturer's sole obligation under this warranty is to, at its own choice, repair or replace any component – for which the manufacturer acknowledges the warranty coverage – with a replacement component.

Warranty Exclusions and System Performance

Sentec can neither guarantee nor verify product performance characteristics, nor accept warranty claims or product liability claims, if the recommended procedures are not carried out, if the product has been subject to misuse, neglect, or accident, if the product has been damaged by extraneous causes, or if accessories other than those recommended by Sentec are used.

Any serious incident that has occurred in relation to the IPV® system has to be reported to Sentec (customerservice.us@sentec.com) and/or to the competent authority of the country where the incident occurred. If unsure whether an incident is a reportable event, contact Sentec.