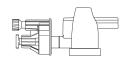
USER'S GUIDE

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VORTRAN-IPPB™

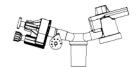
Unique single patient, multiple-use disposable IPPB



□ VORTRAN-IPPB[™] only IP-4020



□ VORTRAN-IPPB™ with Water Trap IPW-4021



□ VORTRAN-IPPB[™] with Manometer IPM-4022

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VORTRAN Medical Technology 1, Inc.

I. Functional and Operational Characteristics

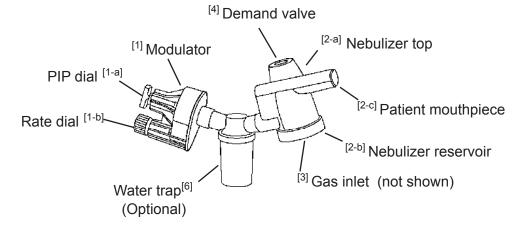
The VORTRAN-IPPB™ is a disposable IPPB device intended to provide an intermittent positive pressure aerosol treatment.

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The VORTRAN-IPPBTM is a ^[1] modulator coupled with a ^[2] nebulizer and provides the same ventilatory affect as the VAR® (VORTRAN® Automatic Resuscitator) combined with aerosol from the nebulizer. The nebulizer provides ^[3] continuous flow of gas and a ^[4] patient demand valve.

When pressure reaches the peak inspiratory pressure (PIP) as set by the $^{[1-a]}$ PIP dial on the modulator, the modulator opens and exhalation begins through the $^{[1-b]}$ rate dial. As with the VAR®, flow and inspiratory time control the tidal volume (see Table 1). Inspiratory time is controlled, once the flow is set, by the PIP dial. The VORTRAN-IPPBTM is intended to be used primarily in the pressure support mode so each inhalation is triggered by the patient.

Figure 1 VORTRAN-IPPB™ Component Description



OPERATIONAL CHARACTERISTICS

Suitable patient body weight	Greater than 30 kg (adults)
Adjustable peak pressure range	20 to 50 cm H ₂ O
PEEP	2 to 5 cm H ₂ O
Supply pressure	50 ± 5 PSIG
Aerosol output during inhalation	Up to 1 mL/min
Operating environmental limits	10 to 50° C
Storage environmental limits	20 to 60° C
Nebulizer reservoir	20 mL
Gas inlet	DISS oxygen connection

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II. Clinical Considerations

The VORTRAN-IPPB™ provides short term, pressure cycled, constant flow ventilatory support in combination with aerosol. The VORTRAN-IPPB™ is pressure cycled on inhalation and exhalation (PIP and PEEP) which minimizes the possibility of gas trapping. During inhalation, exhalation will not start until peak pressure is reached. During exhalation, inhalation will not begin until the patient draws the pressure to baseline. Unlike the VAR®, the VORTRAN-IPPB™ only provides the spontaneous mode pressure support for most settings. Pressure control is not available.

Set up and use of the VORTRAN-IPPBTM is simple (see Section III - Protocol: Setup Instructions). Set desired flow, adjust pressure dial to obtain desired pressure, I-time or tidal volume (see Table 1- Estimated Tidal Volume (mL) at Various Flow Rate), and adjust rate dial to obtain desired sensitivity. The rate dial actually controls the rate of exhalation and typically the VORTRAN-IPPBTM will be in the pressure support mode when delivering a treatment. If the patient has trouble initiating inhalation, it is possible that the sensitivity has been set too high and may be decreased by turning the rate dial counter clockwise. If rotating the rate dial counter clockwise substantially does not re-initiate cycling, an adequate seal may not exist between the patient and mouthpiece.

The VORTRAN-IPPBTM runs on a continuous flow of gas (inspiratory flow) of up to 40 L/min. When connected to a 50 PSIG flow source, the VORTRAN-IPPBTM will automatically deliver 40 L/min. Peak pressure may be adjusted from 20 and 50 cm- H_2O , set PEEP is typically $1/10^{th}$ of peak pressure. Inspiratory time and rate are adjustable over a wide range.

The VORTRAN-IPPB $^{\text{TM}}$ nebulizer is equipped with an air entrainment valve which allows the patient to entrain additional air through the nebulizer, when desired, and allows the VORTRAN-IPPB $^{\text{TM}}$ to respond to the demands of the patient (pressure support). When the patient entrains outside air, the percent oxygen delivered to the patient will decrease; otherwise, the patient receives the concentration of oxygen supplied to the VORTRAN-IPPB $^{\text{TM}}$. The design of the modulator is similar to that of a pop-off valve and is inherently safe. The VORTRAN-IPPB $^{\text{TM}}$ is not equipped with a redundant pop-off valve.

Table 1 - Estimated Tidal Volume (mL) at Various Flow Rate (LPM)

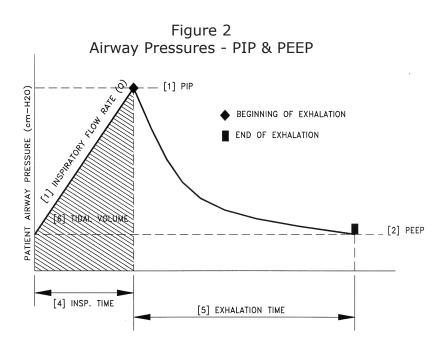
Flow	Inspiratory Time (Seconds)						
(L/min)	0.5	1	1.5	2	2.5	3	
20	167	333	500	667	833	1000	
25	208	417	625	833	1042	1250	
30	250	500	750	1000	1250	1500	
35	292	583	875	1167	1458	1750	
40	333	667	1000	1333	1667	2000	

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II. Clinical Considerations (continued)

Peak pressures listed on the side of the pressure dial are only approximate. A manometer may be connected between the modulator and the nebulizer. The VORTRAN-IPPB $^{\text{TM}}$ will still function when there is some leaking. In the presence of a leak, VORTRAN-IPPB $^{\text{TM}}$ will still cycle between peak pressure and PEEP. Noticeable changes in the presence of a leak are increased inspiratory times and decreased expiratory times. When reassembling the VORTRAN-IPPB $^{\text{TM}}$, it is important to ensure that the nebulizer cap is screwed on securely and that the modulator is firmly connected to the nebulizer.

The VORTRAN-IPPB™ may be cleaned by disconnecting the modulator from the nebulizer, removing the nebulizer cap, rinsing, and allowing it to air dry. Additionally, if needed, the rate dial may also be removed to facilitate cleaning. Inhalation and exhalation are audibly detectable and easily recognizable during operation of the VORTRAN-IPPB™.



- 1 PIP Set by **PIP DIAL**, control INSPIRATORY TIME (t_{insp})
- 2 PEEP Approximately 1/10th of PIP setting
- 3 INSPIRATORY FLOW RATE (Q) Maximum 40 L/min (= 667 mL/sec)
- 4 INSPIRATORY TIME (t_{insp}) Time required to reach PIP
- 5 EXHALATION TIME (t_{exhl}) Time required to drop from PIP to PEEP
- 6 Tidal Volume = $Q \times t_{insp}$
- 7 RESPIRATORY RATE (RR) = $60 / (t_{insp} + t_{exhl})$
- 8 RATE DIAL Set exhalation resistance and change RR

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III. Protocol: Setup Instructions - VORTRAN-IPPB™

Policy Number:	Institution:	Department:
Date Adopted:	Date Revised:	Date Reviewed:
Approved by:	Name:	Title:

- 1.0 PURPOSE: To give guidance and direction in the proper set up and delivery of the VORTRAN-IPPB™.
- 2.0 APPLICABILITY: All respiratory therapy clinical staff.
- 3.0 AUTHORITY:
 - 3.1 Medical Director of Respiratory Therapy
 - 3.2 Department Manager of Respiratory Therapy
- 4.0 DEFINITIONS:
 - 4.1 IPPB Intermittent positive pressure breathing
- 5.0 REFERENCES:
 - 5.1 AARC Clinical Practice Guidelines, Respiratory Care, November 93, Vol 38, No 11. Intermittent Positive Pressure Breathing.
- 6.0 POLICY:
 - 6.1 IPPB treatments are given only on the order of a physician. 6.1.1 Said order must include the frequency and the medication with the dosage.
 - 6.2 Caution should be used in regard to pressures and rates achieved during IPPB treatments to avoid possible pneumothorax or hyperventilation.
 - 6.3 When medication is ordered, add normal saline up to 20 mL solution for treatment.
 - 6.4 If the tidal volume is not specified, use the least amount of pressure to deliver 10 to 15 mL per kilogram of body weight.
 - 6.5 If oxygen percentage is not ordered, use air mix attached to the oxygen. If the patient is a COPD with carbon dioxide retention, compressed air should be used.
 - 6.6 If orders are incomplete, the physician must be contacted and the situation clarified.

III. Protocol: Setup Instructions - VORTRAN-IPPB™ (continued)

- 7.0 PROCEDURES:
 - 7.1 Age-specific considerations age 12 or greater.
 - 7.2 Equipment
 - 7.2.1 VORTRAN-IPPB™
 - 7.2.2 Compressed air source
 - 7.3 Indications
 - 7.3.1 Atelectasis when other forms of therapy have been unsuccessful, incentive spirometry, chest PT, deep breathing exercises) or the patient cannot cooperate.

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- 7.3.2 Inability to clear secretions adequately because of pathology that severely limits the ability to ventilate or cough effectively.
- 7.3.3 To deliver aerosol medications when other techniques (MDI or nebulizer) have been unsuccessful.
- 7.4 Contraindications
 - 7.4.1 Intracranial pressure > 15 mm Hg
 - 7.4.2 Hemodynamic instability
 - 7.4.3 Recent facial, oral, or skull surgery
 - 7.4.4 Tracheoesophageal fistula
 - 7.4.5 Recent esophageal surgery
 - 7.4.6 Active hemoptysis
 - 7.4.7 Nausea
 - 7.4.8 Air swallowing
 - 7.4.9 Active untreated tuberculosis
 - 7.4.10 Radiographic evidence of bleb
 - 7.4.11 Singulation (hiccups)
- 7.5 Hazards/Complications
 - 7.5.1 Increased airway resistance
 - 7.5.2 Barotrauma, pneumothorax
 - 7.5.3 Nosocomial infection
 - 7.5.4 Hypocarbia
 - 7.5.5 Hemoptysis
 - 7.5.6 Gastric distention
 - 7.5.7 Impedance of venous return
 - 7.5.8 Hypoventilation
 - 7.5.9 Air trapping
 - 7.5.10 Increased ventilation / perfusion mismatch
 - 7.5.11 Impaction of secretions

III. Protocol: Setup Instructions - VORTRAN-IPPB™ (continued)

- 7.6 Procedure
 - 7.6.1 Preparing the patient
 - 7.6.1.1 Check the patient's chart for specific orders. The order must include frequency and medication.

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- 7.6.1.2 Review the patient's chart for history, lab work, medications, allergies, and any known history of adverse reactions to IPPB.
- 7.6.1.3 Enter the patient's room and introduce yourself. Check the patient's identification band. Explain the therapy.
- 7.6.2 Setting up the equipment
 - 7.6.2.1 Wash hands.
 - 7.6.2.2 Attach the IPPB device to the appropriate 50 PSIG outlet.
 - 7.6.2.3 Place the appropriate medication in the nebulizer cup.
- 7.6.3 Patient Application
 - 7.6.3.1 Position the patient in the most comfortable and advantageous way to receive therapy.
 - 7.6.3.1.1 Sitting in a chair or on the edge of the bed.
 - 7.6.3.1.2 Postural drainage positions may improve efficacy of therapy depending on the patient.
 - 7.6.3.2 Turn on the flow. The normal flow for VORTRAN-IPPB™ is 30 L/min to maximum of 40 L/min.
 - NOTE: Using a flowmeter that covers the range from 0 -75 L/min (such as a Timeter Classic™ Series Flowmeter 0-75 L/min Model # A-75 for air or Model # O-75 for oxygen, Allied Healthcare Products, Inc.)
 - 7.6.3.3 Initially adjust the pressure low, then slowly adjust until the desired level is obtained.
 - 7.6.3.4 Nebulizer will stay on during expiration as well as inspiration to keep mist in dead space.
 - 7.6.3.5 Take the patient's pulse rate, respiratory rate, and listen to breath sounds.
 - 7.6.3.6 During therapy, have the patient relax and let the machine do the work for him/her. RCP must stay in the room or close proximity.
 - 7.6.3.7 Have the patient breathe slowly and evenly through the mouth, with the mouthpiece between the teeth and keeping lips tight.
 - 7.6.3.8 When the mouthpiece is in front of the teeth, the medication is not being delivered to the lungs.
 - 7.6.3.9 Have the patient perform breathing exercises, making sure to relax the accessory muscles. Coaching is important.

III. Protocol: Setup Instructions - VORTRAN-IPPB™ (continued)

7.6.3.10 Have the patient do inspiratory holds 2 to 3 times every 10 to 20 breaths.

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- 7.6.3.11 Take the pulse rate and respiratory rate. If the pulse rate increases 20% over baseline, stop the treatment and have the patient rinse his/her mouth. Notify the physician, RN, and complete Occurrence Report.
- 7.6.3.12 Ask the patient how he/she feels mid treatment as far as dizziness, nausea, tingling fingers, or any other strange feeling. Tell the patient to let you know as soon as any of these things occur.
- 7.6.3.13 Observe the patient for respiratory distress or other adverse reactions.
- 7.6.3.14 Mid treatment, have the patient take a rest, deep breath, and cough.
- 7.6.3.15 At completion of therapy, take the pulse rate, respiratory rate, and listen to breath sounds.
- 7.6.3.16 Have the patient take a deep breath and cough.
- 7.6.3.17 Clean up area and wash hands.
- 7.6.3.18 Document treatment, Refer to 7.8.
- 7.7 Assessment of Outcome
 - 7.7.1 Chest x-ray improved.
 - 7.7.2 Tidal volume during IPPB greater than during spontaneous breathing (by at least 25%).
 - 7.7.3 More effective cough.
 - 7.7.4 Increase in peak flow or FEV.
 - 7.7.5 Improvement in breath sounds.
- 7.8 Documentation
 - 7.8.1 Complete all charting and place into the patient's medical chart.
 - 7.8.1.1 Tolerance to therapy
 - 7.8.1.2 Complications
 - 7.8.1.3 Medication and dosage
 - 7.8.1.4 Vital signs pre and post (heart rate, respiratory rate, and pattern)
 - 7.8.1.5 Date and time
 - 7.8.1.6 Other relative information
 - 7.8.1.7 Operating pressure (cm-H₂O)
 - 7.8.1.8 Cough effort and production
 - 7.8.1.9 FiO₂ (air mix, 100%)
 - Note: Do not include in charting any reference that an Occurrence Report was completed.
 - 7.8.2 Outpatient charting is to be completed on a PIC (Patient Information Card). Place yellow copy in metal filing bin located in RT report room.)

IV. Cautions and Warnings

Cautions

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- 1. Federal law restricts the use of this device to sale by or on order of a physician (or properly licensed practitioner). To be used only by persons having adequate training.
- 2. Patients connected to this device are to be monitored continuously by persons having adequate training. Do not leave patients unattended.
- 3. Positive End Expiratory Pressure (PEEP) is intrinsic to this device. PEEP will typically be $1/10^{\rm th}$ PIP and will range from 2 to 5 cm $\rm H_2O$ depending on pressure settings. Verify actual PEEP with a manometer.
- 4. Smoking or open flames in an oxygen enriched environment is extremely dangerous.

Warnings

This device is to be used by properly trained personnel to deliver intermittent positive pressure breathing aerosol.

V. VORTRAN-IPPB™ COMPETENCY

How to set up and deliver IPPB (Intermittent Positive Pressure Breathing) treatments using the VORTRAN-IPPB $^{\text{TM}}$ - a single patient use device that is easier to set up and more cost effective than the conventional IPPB machine.

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<u>Objectives</u>

- 1. To be able to set up, clean and care for the VORTRAN-IPPB™.
- 2. To know the recommended flow and pressure settings for the IPPB.
- 3. To know the total amount of medication and saline (diluent) that should be used for a 15 minute treatment.

Troubleshooting

If the patient complains that it is hard to exhale, I should adjust the rate dial clockwise to increase exhalation resistance.							
[] True	[] False						
	on of medication with saline (diluent), my patient ime amount of medication after completing the						
[] True	[] False						
	RTRAN-IPPB™ competency, the Respiratory Care o set up the IPPB and troubleshoot problems that						
Name:	Institution:						
Department:	Date Completed:						

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VI. FAQ (Frequently Asked Questions)

_	Question	Answer
1.	What is the sensitivity or pressure drop required to trigger the VORTRAN-IPPB™ into inhalation?	The VORTRAN-IPPB $^{\text{TM}}$ is pressure cycled between PIP and PEEP. Therefore, as soon as the patient draws a breath to the baseline PEEP (1/10 $^{\text{th}}$ of PIP) inhalation will start. Sensitivity may be set as light as 1 cm H_2O or less.
2.	Does the VORTRAN- IPPB™ work with a mask or an endotracheal tube?	The VORTRAN-IPPB™ is inherently safe but is not equipped with a redundant pop-off valve. Therefore, the VORTRAN-IPPB™ should never be used with an endotracheal tube and used cautiously with a mask.
3.	Peak pressure ranges are indicated on the pressure dial but what is the expected PEEP?	Peak pressure indications on the pressure dial are approximate only. PEEP is typically $1/10^{\rm th}$ peak pressure. Peak pressure ranges between 20 and 50 cm-H ₂ O, and PEEP ranges between 2 and 5 cm-H ₂ O respectively. Pressures may be verified by connecting a manometer between the modulator and the nebulizer.
4.	Can I use a manometer to record patient PIP?	Yes. You can connect an in-line manometer between the modulator outlet and water trap inlet.
5.	How can I measure tidal volume when using the VORTRAN-IPPB™?	Tidal volume may be determined by using the tidal volume chart included with the instructions. Tidal volume is the inspiratory time multiplied by the flow rate.
6.	If I connect to a 15 L/min flowmeter and dial it all the way up, what flow will I get through the VORTRAN-IPPB™?	Orifice type flowmeters similar to those commonly used on "E" cylinders will flow at a maximum of what is indicated on the gauge. Timeter and other flowmeters using a floating ball as an indication of flow are capable of being adjusted to flows above what is indicated. If connecting to a Timeter flowmeter and adjusting the dial all the way open, the float will be slightly above the 15 L/min flow mark, but 40 L/min will actually be flowing through the VORTRAN-IPPB™. As long as the hospital gas supply or cylinder regulators are adjusted to 50 PSIG, which is the standard, the design flow going through the VORTRAN-IPPB™ is 40 L/min.
7.	Can I connect the VORTRAN-IPPB™ directly to a wall source of 50 PSIG?	Yes, when connected directly to a 50 PSIG source, the maximum flow is 40 L/min (± 10%). Page 11

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VI. FAQ (continued)

1 14	(continued)	
	Question	Answer
8.	Does the gas supplied to the VORTRAN-IPPB flow continuously during exhalation and inhalation?	Yes.
9.	I have a patient who needs to use the VORTRAN-IPPB™ at home. Will it work with the Pulmoaide?	No, the maximum flow generated by the Pulmoaide and other similar compressors used with small volume nebulizers is about 10 L/min. Most hospital equipment rental agencies rent larger compressors. If the compressor generates enough pressure and flow for the patient to be comfortable and to produce aerosol, it is sufficient. The nebulizer will start generating aerosol at about 15 L/min at a pressure of 15 - 20 PSIG. Most patients will desire more than 15 L/min of flow to be comfortable.
10	. How much and what kind of medication do I place in the nebulizer?	A physician must prescribe the medication and amount for each treatment. Commonly used medications are b_2 agonists, anticholinergics, and mucolytics.
11	I. How do I get 20 mL of fluid in the nebulizer?	To mix the medication, first place the prescribed amount of medication into the nebulizer reservoir, then add saline or respiratory quality water to make a total volume of 20 mL.
12	. Is there a problem with my IPPB if it leaks a little fluid?	A small amount of fluid leakage is inherent in any non-sealed pressurized vessel.
13	. The VORTRAN- IPPB™ I am using was working fine on prior treatments and is now not cycling well. What's wrong?	It is important to assemble the VORTRAN-IPPB™ tightly. If a large leak is present, it will not work as well. This is particularly important after cleaning. Be sure the nebulizer cap is screwed on tightly and the modulator has been pushed firmly in place. Lastly, ensure that you are still providing adequate flow and there is a good seal between the patient and the mouthpiece.

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VII. Clinical Reference

Shawan Huff, RRT, <u>COMPARISON OF THE MEASURED TIDAL VOLUME VS. THE CALCULATED TIDAL VOLUME IN THE PIPER-IPPB</u>, presented at 46th AARC International Respiratory Congress in Cincinnati, Ohio October 7-10, 2000.

BACKGROUND: Intermittent Positive Pressure Breathing (IPPB) is a technique used to provide short-term or intermittent mechanical ventilation for the purpose of augmenting lung expansion, delivering aerosol medication, or assisting ventilation (1). To assess the therapeutic efficacy of an IPPB treatment, tidal volume may be measured. This study compares the measured tidal volume and the calculated tidal volume of the Piper-IPPB device.

Methods: The Piper-IPPB is connected via a custom adapter to a Wrights Respirometer Mark 14 and then to a Michigan Instruments Inc. Vent Aid TTL. Timing is accomplished using a Sportline Alpha 1 410 Splitimer. A Timeter flow meter is connected to a 50-PSI air source and 40 LPM is supplied to Piper-IPPB nebulizer. The inspiratory time is controlled by adjusting PIP and lung compliance. For ten breaths cycles both I-time and delivered tidal volume are summed and averaged. Fifteen points are collected and the average tidal volumes obtained. The calculated tidal volume is obtained using the calculation (I-time x Flow = Tidal Volume). Flow = 40 LPM

Results: The average measured and calculated tidal volumes are summarized below.

I-time (Sec)	Meas.	Vt (L) Calc. Vt (L)	% Difference
1.0	.565	.663	14.76%
1.2	.707	.829	14.79%
1.5	.862	1.033	16.57%
1.9	1.157	1.290	10.30%
2.2	1.210	1.451	16.65%

Discussion: To assess the therapeutic efficacy of an IPPB treatment, tidal volume may be measured. Handheld spirometers and venticomp bags are two of the volume measuring devices currently used. Tidal volume can also be calculated using the calculation (I-time x Flow). There is only an approximate 15% difference between the measured tidal volume of the Piper-IPPB and the calculated tidal volume. This may be due to inherent leaks or timing errors. **Conclusion:** Since there is only an approximate 15% difference between the calculated and measured tidal volumes, The calculated value may be a more efficient and cost effective way to monitor patient tidal volume when giving IPPB treatments. Further studies are warranted.

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(1) Agency for Health Care Policy and Research (AHCPR). Health Technology Reports: intermittent positive pressure breathing (IPPB) therapy. 1991, Number 1.

Walter J. O'Donohue, Jr., M.D., F.C.C.P.: <u>Maximum Volume IPPB for the Management of Pulmonary Atelectasis</u>, Chest, December 1979, 76:6, 683-687.

There are few therapeutic modalities in medicine that are more controversial than the use of inspiratory positive pressure breathing (IPPB). Studies which have failed to separate the therapeutic effect of bronchodilators from possible mechanical effects of IPPB have clouded the issue considerably. Today, there is substantial evidence that the delivery of a bronchodilator by means of a positive pressure breathing device does not enhance bronchodilation. Additionally, there is no evidence that IPPB is beneficial as part of the routine management program for patients with stable chronic obstructive lung disease. It is possible that there are subgroups of patients with obstructive pulmonary disease who may derive some beneficial effects from IPPB, but substantiating data are not currently available.

The lack of demonstrable efficacy of IPPB, as it has been commonly employed, along with strenuous attempts at cost containment of medical care, has resulted in the general assumption by some that IPPB is of no value under any circumstance. The swing of the pendulum against IPPB has led to the substitution of other therapeutic techniques which are unproven by critical evaluation.

The assumption that IPPB is not useful for any pulmonary disorder simply because it has been abused and misused in the past is unjustified and scientifically naive. The use of IPPB as a technique to provide large inspiratory volumes when patients will not or cannot take deep breaths has been found to be beneficial in the management of atelectasis where other approaches have failed to correct the problem. The following case reports are presented to demonstrate the usefulness of IPPB in hospitalized patients with atelectasis when it can be documented that the inspiratory capacity is increased by means of this therapy.

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VII. Clinical Reference (continued)

Mario Romano, RCP, CLINICAL COMPARISON OF TWO IPPB DEVICES: PIPER-IPPB™ & BIRDâ IPPB, presented at 45th AARC International Respiratory Congress in Las Vegas, Nevada, December 13-16, 1999.

BACKGROUND: Intermittent Positive Pressure Breathing (IPPB) is a technique used to provide short-term or intermittent mechanical ventilation to augment lung expansion, deliver aerosol medication, or assist ventilation ^[1] for the treatment of atelectasis. The use of IPPB to provide large inspiratory volumes when patients cannot take deep breaths has been found to be beneficial in the management of atelectasis where other approaches have failed ^[2]. Since the Bird® IPPB is no longer being manufactured, the shortage of spare parts makes it difficult to maintain existing units. This study compares a new single patient use IPPB device, the Piper-IPPBTM (VORTRAN Medical Technology 1), with the conventional IPPB - Bird® Mark 7® Positive Phase Medical Respirator (Bird Corporation).

METHODS: Two clinically stable female patients, one with COPD and one with CHF (ages 72 and 74), received 10 minutes of the Bird IPPB and the Piper-IPPB in alternate therapy sessions. Each treatment included 0.5 cc albuterol (2.5 mg), unit dose ipartropium bromide (0.5 mg), and 10 cc normal saline. A compressed gas source was used for both devices and pulse oximetry (O_2 Sat.), heart rate (HR), blood pressure (BP), and breath sounds (BS) were monitored before and after each therapy session.

RESULTS: Patients' vital signs are summarized below:

Dx	COPD				CHF				
Device	Piper-I	PPB™	Bird®	IPPB	Piper-IPPB™		Bird® IPPB		
PIP Set	20 cr	n-H ₂ O	15 cr	n-H ₂ O	25 cm-H ₂ O		25 cm-H ₂ O		
FiO ₂ Set	Rooi	m air	Roo	m air	100% O ₂		100% O ₂		
Тх	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
O ₂ Sat.	93	93	94	93	93	99	93	98	
HR	92	90	100	101	105	103	104	107	
ВР	136/67	128/64	141/70	142/70	148/45	154/50	139/46	151/49	
BS		Crackle	at bases		Diminished at base				

DISCUSSION: One patient reported that the work of breathing was easy and that the inspiratory flowrate was just right for both devices. The other patient reported that the inspiratory flowrate for both IPPBs was too slow and that the work of breathing for Piper-IPPB was slightly harder. No significant changes in vital signs were noted with either device. Both patients found the Piper-IPPB easy to use and preferred it to the conventional Bird-IPPB.

CONCLUSIONS: The Piper-IPPB can be a safe and effective method of delivering IPPB treatment without the need for conventional IPPB capital equipment. Using a larger patient population in a future study can help establish the Piper-IPPB as a safe and effective treatment modality.

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^[1] Agency for Health Care Policy and Research (AHCPR). Health Technology Report: Intermittent Positive Pressure Breathing (IPPB) Therapy. 1991, Number 1.

^[2] Walter J. O'Donohue, Jr., M.D., F.C.C.P.: <u>Maximum Volume IPPB for the Management of Pulmonary Atelectasis</u>, Chest, December 1979, 76:6, 683-687.

VIII. Coding Information

HCPCS - HCFA (Health Care Financing Administration)

Common Procedure Coding System

PRODUCT----- VORTRAN-IPPB™

CODE ----- E0500

DESCRIPTION ----- IPPB machine, all types, with built-in nebulization; manual

or automatic valves; internal or external power source.

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INSTRUCTIONS --- Coverage issue, CIM 60-9 (Rental only)

CPT - Current Procedure Terminology

(American Medical Association)

PRODUCT----- VORTRAN-IPPB™

CODE ----- 94640

DESCRIPTION----- The code for the nebulizer treatment (94640 "Pressurized or nonpressurized inhalation treatment for acute airway

obstruction or for sputum induction for diagnostic purposes; e.g., with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing

[IPPB] device").

CODE ----- 94664

DESCRIPTION ----- The code for the nurse's instructions (94664 "Demonstration

and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB

device").

REMARKS ----- You should submit the appropriate evaluation and

management (E/M) office visit code and the correct J code for the supply of the nebulizer drug. You should also add modifier -25 to the E/M code to indicate that it was a significant, separately identifiable service from the other

services described.

IX. Troubleshooting

Cause / Action

Rev: 05/20/2013

- Flowmeter only goes to 15 or 16 L/min
- 1. <u>Flush open</u> / Typical flowmeters with 50 PSIG source pressure will deliver up to 40 L/min
- 2. <u>Use a high flow flowmeter</u> / goes to 75 L/min
- No visible aerosol output
- Increased gas flow / an increase in supply gas flow may increase nebulizer output (maximum 40 L/min)
- 2. <u>Out of solution</u> / refill reservoir (requires 3 to 5 mL solution minimum to charge the nebulizer)
- Exhalation is too hard
- 1. High supply flow / reduce supply gas flow
- 2. Low PIP setting / increase PIP as needed
- High exhalation resistance / adjust rate dial out (counter-clockwise) or remove rate dial completely

X. Ordering Information

			Accessories			
Product Description	Order Number	Quantity	7'-0 ₂ tubing	Manometer	Water trap	
VORTRAN-IPPB™ only	IP-4020	10				
VORTRAN-IPPB™ with Water Trap	IPW-4021	10	1		√	
VORTRAN-IPPB™ with Manometer	IPM-4022	10	V	V		

XI. Quick Guide

1 Add Medication

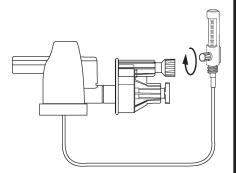
Step 1: Rotate the nebulizer bottom a quarter turn and remove it. Measure the prescribed amount of medication and dilute with saline to obtain the desired total volume. There should be 1 mL of solution for every minute of treatment.



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2 Connect Tubing

Step 2: Connect the oxygen supply tubing and set the desired flow. Perform a quick function check on the IPPB prior to connecting it to the patient. Observe the aerosol coming from the mouthpiece, then occlude the mouthpiece and watch for aerosol flowing from the rate dial.

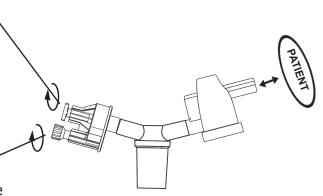


3 Set Desired Flow

Step 3: Instruct the patient to create a seal on the mouthpiece.

4 Set Pressure

Step 4: Set the pressure dial to achieve the desired peak inspiratory pressure as prescribed by the physician.



5 Adjust Rate

Step 5: Adjust the rate dial to the patient's comfort.

This Quick Guide is intended to help you gain a general understanding of the VORTRAN-IPPB™ product. Please be certain to read, understand, and follow the information listed in this User's Guide before using this product. © 2005 - VORTRAN Medical Technology 1, Inc., Sacramento, California U.S.A.