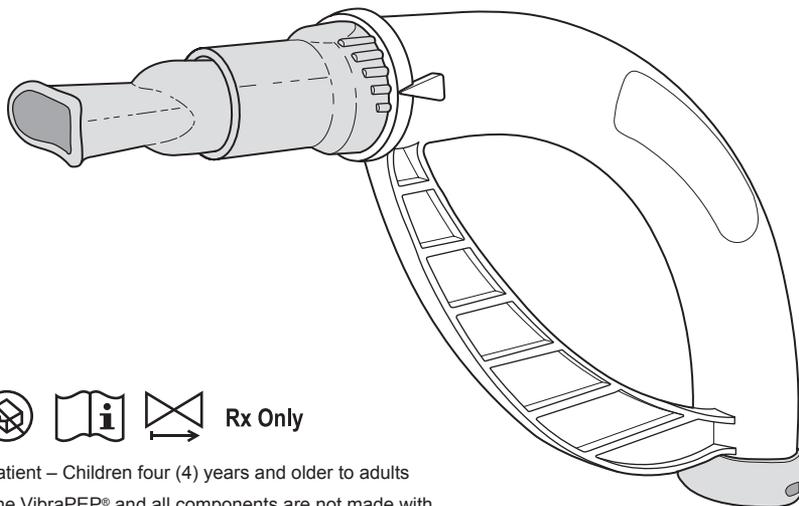


VibraPEP[®]

Oscillatory PEP Therapy Device OPEP

Instructions For Use

REF 44F50 / 44F10



Rx Only

Patient – Children four (4) years and older to adults

The VibraPEP[®] and all components are not made with natural rubber latex.

Single Patient Use.

Australian Sponsor

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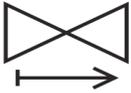
U.S. Pat. No. D768,285S and other

U.S. and international patents pending.

LIT-3313 Rev A (2020-03-08)

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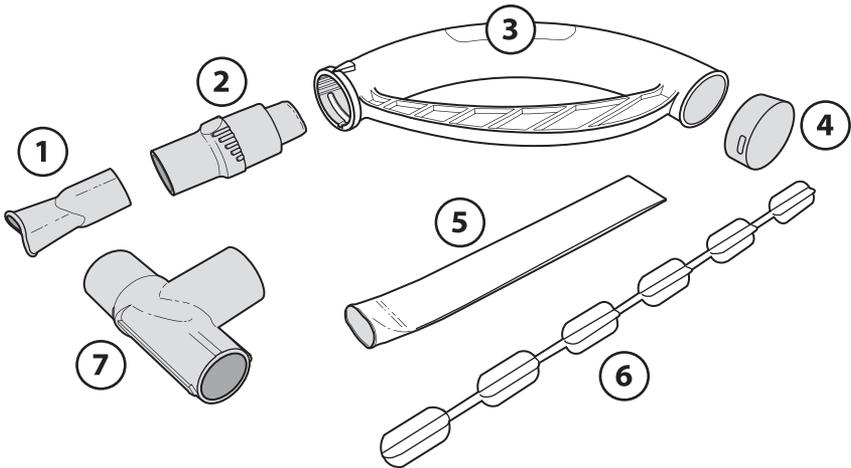
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Valved Tee Adapter contains a valve that allows air flow in only one direction.



Prescription only - Device is restricted to use by or on the order of a physician



PACKAGE CONTENTS:

- | | |
|----------------------------|---|
| 1. Mouthpiece | 5. Valve Hose |
| 2. Therapy Selector | 6. Drying Aid |
| 3. Curved Tube with Handle | 7. Valved Tee Adapter Accessory (Part #12218) |
| 4. Silencer (end cap) | |

VibraPEP® Oscillatory PEP Therapy Device

DESCRIPTION

The VibraPEP Oscillatory PEP Therapy System (OPEP) is a single patient device that provides Positive Expiratory Pressure (PEP) Therapy for Spontaneously Breathing Patients. It helps to assist in the detachment and removal of bronchial secretions, for patients who have Cystic Fibrosis, COPD, Asthma, Atelectasis, or other lung diseases where secretion clearance may be a problem by delivering PEP and airflow oscillation to the lungs. This combination of pressure and flow variation causes vibrations in the thorax resulting in loosening and liquefying of the bronchial mucus which can then be more easily expelled.

The VibraPEP consists of a flat Valve Hose inserted inside a Curved Tube. As the patient blows through the VibraPEP, the hose pressure increases and buckles at the bending of the tube. When the peak pressure is reached, the hose end opens and is catapulted against the wall, releasing its pressure. This process is repeated, providing an oscillation effect at a constant pressure and flow-rate during the entire exhalation phase.

INDICATIONS

The VibraPEP Mucus Clearing Device is a Positive Expiratory Pressure, PEP, Device. It was designed to exercise patient's lungs and to improve secretion clearance. The device may be connected via a Valved Tee Adapter for use with a jet nebulizer for aerosol drug delivery.

Patient – Children four (4) years and older to adults

Environment – Hospital, clinics, physician offices, home setting

CONTRAINDICATIONS

Although no absolute contraindications to the use of PEP Therapy have been reported, the following should be carefully evaluated before a decision is made to initiate therapy:

- Inability to tolerate increased work of breathing
- Hemodynamic instability
- Intracranial pressure (IPC) > 20 mm Hg
- Acute sinusitis
- Recent facial, oral or skull surgery or trauma
- Epistaxis
- Esophageal surgery
- Active hemoptysis
- Untreated pneumothorax
- Nausea
- Known or suspected tympanic membrane rupture or other middle ear pathology
- Acute abdominal pathology
- Abdominal aortic aneurism
- Hiatal hernia
- Pregnancy
- Presence of reduced coronary artery perfusion such as in acute cardiac myocardial infarction.

SIDE EFFECTS

Some side effects may be experienced including:

- Hyperventilation
- Low grade dizziness
- Numbness of mouth and hands

WARNINGS

Use of this device at excessive pressures may have adverse effects. Expiratory pressures above 20 cm H₂O in patients sensitive to increased transpulmonary pressure may develop one or more of the adverse side effects listed herein.

Clinical judgment should be used to guide the adjustment of the appropriate settings for each individual patient. Failure to match the appropriate resistance setting on the different marks of the Therapy Selector with the patient's expiratory flow may result in failure to achieve the therapeutic objectives of Oscillatory PEP Therapy or one or more of the following adverse side effects.

- Increased work of breathing that may lead to hypoventilation and hypercarbia
- Increased intracranial pressure
- Cardiovascular compromise
- Myocardial ischemia
- Decreased venous return
- Air swallowing, with increased likelihood of vomiting and aspiration
- Claustrophobia
- Pulmonary barotraumas

BEFORE USE

Visually inspect the device to ensure that the unit is free of contamination and foreign objects. PEP therapies for bronchial hygiene require spontaneously breathing patients.

INSTRUCTIONS FOR USE

The VibraPEP has five settings as indicated by the position of the Therapy Selector. The device comes preset at position zero. If this is the first use, insure it is set to this position.

ADJUSTING THE SETTINGS

Direct the patient to exhale through the VibraPEP to functional residual capacity (FRC). Exhalation should be active but not forced. Adjust the Therapy Selector on the VibraPEP as needed to result in an inspiratory to expiratory ratio of approximately 1:3 over a period of 3 to 4 seconds. Have the patient perform several forced expiratory maneuvers (“huff coughs”) to raise secretions

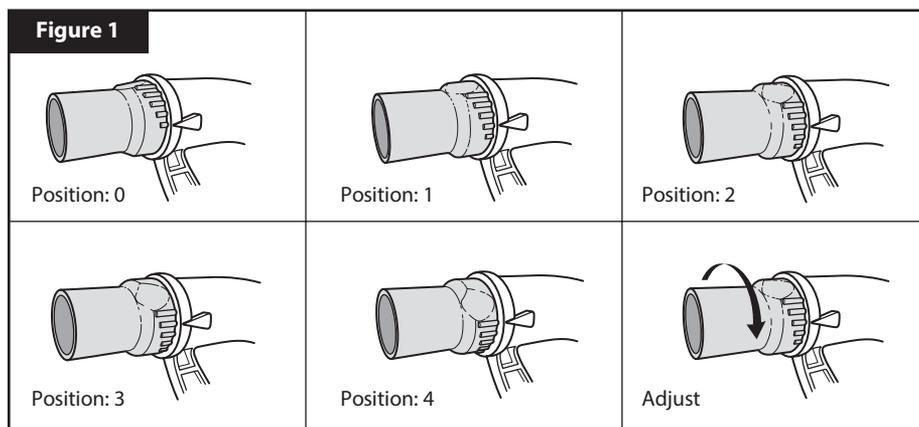
For patients requiring a permanent PEP with added pressure oscillations above baseline, (CombinedPEP begin therapy at the initial position 0 (smallest marking) of the VibraPEP and adjust to positions 1 and 2 respectively (arrow points to the first, second or third marking on the Therapy Selector). (see Figure 1)

Positions 3 or 4. provides a gradual rising pressure followed by a sudden pressure drop (DynamicPEP) The arrow on the tube should point to the third or fourth marking of the Therapy Selector. (see Figure 1)

Adjusting To Patients Requirements

By rotating the Therapy Selector, pressure and flow can be adjusted to achieve optimal therapy for each patient. Refer to Specifications for the range of airway pressures that may be increased based upon patient efforts. (see Figure 1)

Evaluate the level of breathing effort and the amount of mucus coughed up. If not acceptable, turn the Therapy Selector further to the next setting, and reevaluate. Repeat steps until adjustment is most beneficial for your patient. If not sure, turn the Therapy Selector back to the initial setting and repeat procedure. When optimal adjustment is reached, leave the Therapy Selector at the noted setting and memorize position for future reference.

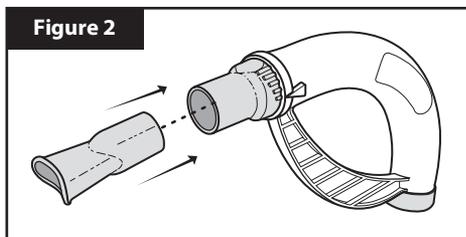


INSTRUCTIONS FOR USE

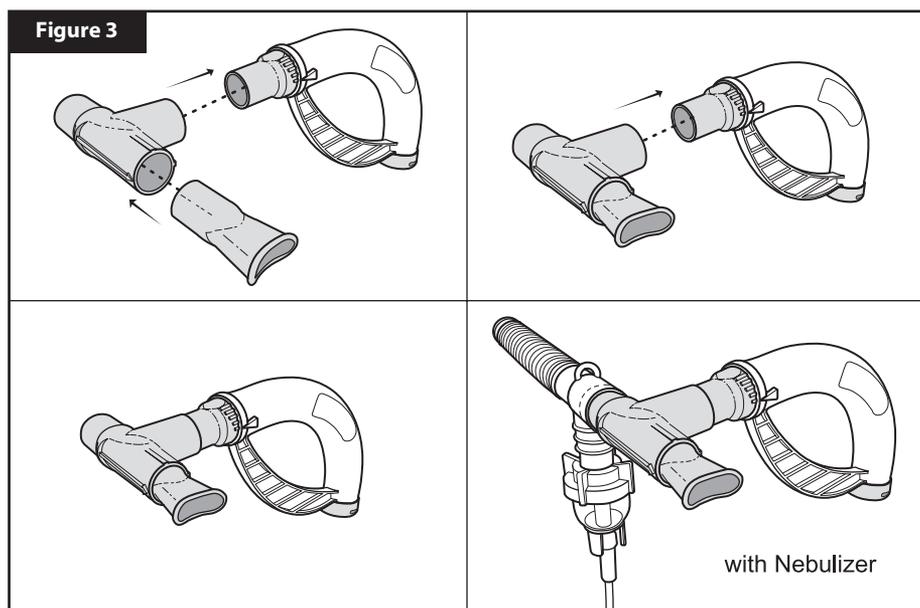
Please note that by rotating the Therapy Selector from Position 0 to Position 4, you can adjust the VibraPEP pressure and flow fluctuations that are most comfortable and effective for you. However, you should always follow directions provided to you by your healthcare provider.

While using this device it is important to not expand your cheeks during exhalation, and to try and keep them flat. You should also not force exhalation, you should exhale naturally.

To begin, adjust the Therapy Selector to the setting your healthcare provider has previously advised (position 0-4). If the healthcare provider did not advise a specific setting, adjust the Therapy Selector to Position 0 (see Figure 1). Then, insert Mouthpiece into VibraPEP device (see Figure 2).



Insert the VibraPEP into your mouth and form a tight seal with your lips around the Mouthpiece. Breathe in through your nose, then naturally exhale into the device keeping your cheeks flat. Repeat this procedure for 15 breaths, breathing in through your nose, and out through the VibraPEP. Again, always follow your healthcare provider's instructions, as they may differ. If you are unable to coordinate breathing through the VibraPEP, you can use the Valved Tee Adapter accessory if included in your kit, to facilitate breathing through the device (See Figure 3 below).



Recommended Application Cycle:

Follow the instructions from your healthcare provider

Instructions for Coughing:

When you blow into the VibraPEP and feel that you must cough, try to breathe out through the device as long as possible. When you must cough, remove your mouth from the Mouthpiece and attempt to “huff” out the mucus instead of an exertion cough. Huffing usually results in more effective mucus removal from bronchi.

You may notice that, while exhaling into the device and slowly rotating the VibraPEP, the pressure necessary for blowing will gradually increase, and that the sounds created will change. The VibraPEP operates independent of gravity and therefore is NOT dependent on the patients’ position. It can be used in a lying, sitting or standing position.

INSTRUCTIONS FOR USE, VibraPEP WITH NEBULIZER

Nebulizer Compatibility: Use only a jet nebulizer that has a 22 mm fitting.

Medications to be Used: Your healthcare professional will advise which medication to use for combined treatments.

CAUTION

Users that combined use of the VibraPEP with a nebulizer delivering particularly viscous/sticky medication solutions may potentially alter the VibraPEP Valve Hose physical properties.

NOTE

The VibraPEP Mucus Clearing Device is not intended to be used while connected to a jet nebulizer which is delivering nebulized steroidal drugs or antibiotics.

COMPATIBILITY WITH AEROSOLIZED MEDICATIONS:

- Medications which open your airways or help to thin mucus would be good choices to use with your VibraPEP Oscillating PEP because they would help remove or thin the mucus in your lungs.
- Medications you want to stay in your lungs, like antibiotics and steroids, should be taken after you have completed your VibraPEP Oscillating PEP treatment.

Nebulizer Set-Up: Assemble the jet Nebulizer as described in the nebulizer supplied Instructions For Use. Remove the Mouthpiece from the Therapy Selector and place the Valved Tee Adapter over the Therapy Selector opening of the VibraPEP as indicated. Connect the nebulizer to the Valved Tee Adapter and insert the mouthpiece into the opposite end. (see Figure 3 for proper placement) Note: Valved Tee Adapter can only connect one way.

NEBULIZER OPERATION

Turn on the air source or compressor to drive the nebulizer. Place mouth to the Mouthpiece connected to the Valved Tee Adaptor. Sit in a relaxed, upright position. Once you have inhaled completely, exhale completely through the VibraPEP at a slow constant rate. Repeat breathing phases until medication is gone, or you hear sputtering at the end of inhalation. Increased intervals or prolonged treatment time may be required in cases of increased breathing difficulty or increased mucus accumulation.

CARE AND CLEANING INSTRUCTIONS

WARNING

- The VibraPEP is for single patient use (one person) only
- Product should be replaced after 6 months of use or immediately if damaged.
- Do NOT share your VibraPEP with other patients
- The VibraPEP may be cleaned by following the instructions below.
- Failure to follow the cleaning instructions may have an adverse effect on device performance

Note:

If used in combination with a nebulizer, the device should be cleaned before next use to remove any residue that may have deposited on exhalation.

DISASSEMBLE

As needed, remove the Mouthpiece (figure 4), followed by Therapy Selector with attached Valve Hose from the VibraPEP by rotating the Therapy Selector counterclockwise past position 0. (see Figure 5). Pull the Therapy Selector out and away from the Curved Tube with Handle (see Figure 6). Remove cap from bottom of Curved Tube with Handle (see Figure 7).

Figure 4

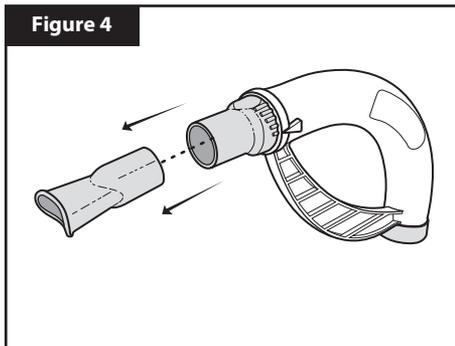


Figure 5

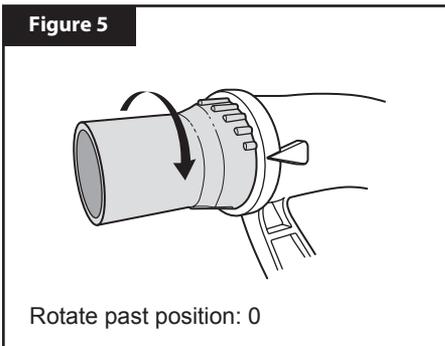


Figure 6

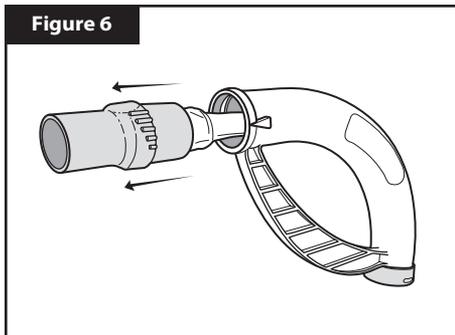
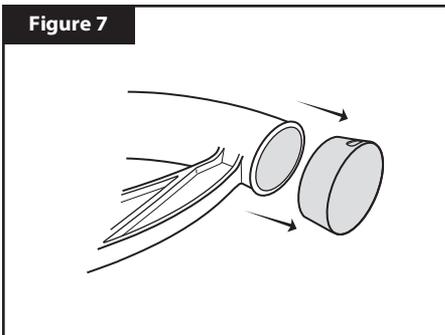


Figure 7

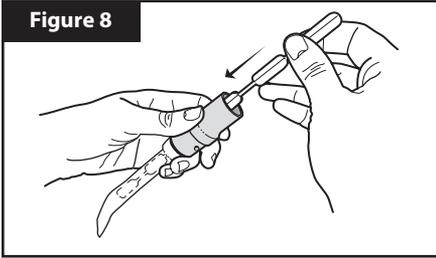


Note:

It is not necessary to remove the Valve Hose from the Therapy Selector

CLEANING

Figure 8



To facilitate cleaning, simultaneously run water through the Valve Hose Assembly while inserting the Drying Aid. This will allow cleaning and rinsing solutions to flow freely (see figure 8).

Note:

The Drying Aid should be inserted in the Valve Hose during all cleaning procedures.

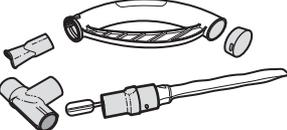
After disassembly, the VibraPEP can be cleaned using the following methods:

Rinse: Insert the Drying Aid (See packaged components #6) and run water through the Therapy Selector and Valve Hose to clear any particulate. Shake out excess water from components, and air dry.

Hand Wash: Gently wash all parts in warm soapy water, using common dishwashing liquid. To remove visible contaminants, you may soak the Valve Hose, Therapy Selector, Curved Tube with Handle, Mouthpiece, Valved Tee Adapter and Silencer in warm, soapy water as required. Thoroughly rinse all components in water. Allow parts to air dry completely before reassembling.

Boiling: The VibraPEP may be disinfected by boiling all parts in water (212° F/100° C) for 10 minutes. NOTE: Place a heat resistant material on the bottom of the pan to prevent plastic parts from coming in contact with the bottom of the pot.

Dishwasher: The VibraPEP may be cleaned using a dishwasher. NOTE: Place parts in a dishwasher basket on the top shelf.

<p>Figure 9</p> <p>CLEANING INSTRUCTIONS</p>	 SOAP & WATER	 BOILING WATER	 DISHWASHER	 AIR DRY
		 	 Top Shelf	 Overnight

Inspect the VibraPEP®

Following cleaning, inspect all components making sure they are working properly. Parts must fit together with ease and function correctly. The VibraPEP Valve Hose could lose elasticity over time and it is recommended that the device be replaced if it shows signs of cracking, tearing, or loss of elasticity.

Visually inspect the parts to assure that they are clean, if not then repeat the cleaning cycle.

REASSEMBLE

Should the Valve Hose become detached or mis-aligned during cleaning, it is very important for the Valve Hose to line up correctly with the Therapy Selector when reassembling (see figure 10).

With your thumb, hold the top edge of the valve hose to the lip of the Therapy Selector outlet. Using your thumb and index finger of your other hand, grab the opposite side of the hose and stretch it over the Therapy Selector outlet. Make sure that the hose is flat against the Therapy Selector and not curled.

Rotate the Valve Hose on the Therapy Selector until both hose edges line up to the middle of the Therapy Selector ridges. Insure the triangle on the Valve Hose is aligned with the notch on the top of the Therapy Selector.

Reinserting Valve Hose and Therapy Selector into Tube

After reassembling the Valve Hose to the Therapy Selector, insert the combined Therapy Selector and Valve Hose (1) into the Curved Tube with Handle (2) (see figure 11). Once inserted, make sure the indicators line up with the arrow on the tube (3). (see figure 12). Adjust the Therapy Selector to the setting your healthcare provider has previously advised (position 0-4) (see figure 13).

Figure 10

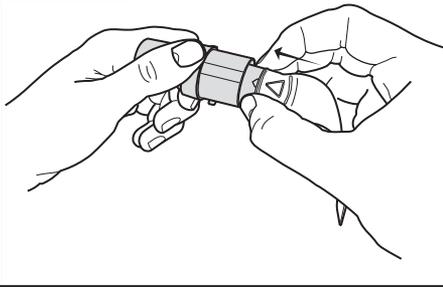


Figure 11

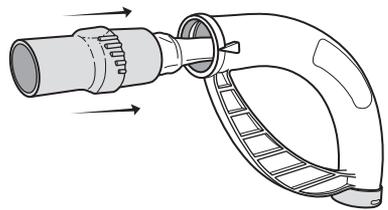


Figure 12

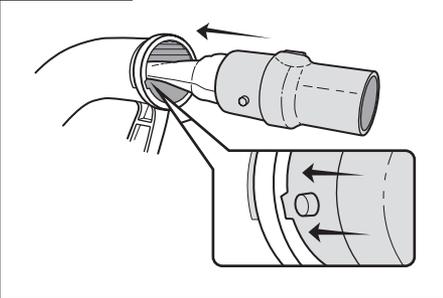
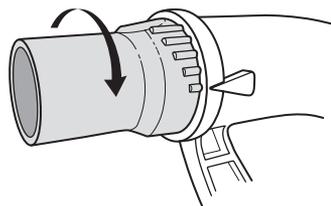


Figure 13



SPECIFICATIONS

WITHOUT VALVED TEE ADAPTER			
	FLOW RATE		
PARAMETERS	10 lpm	20 lpm	40 lpm
Average Pressure (cmH ₂ O) across all settings	10-13	18-21	27-41
Average Pressure Amplitude (cmH ₂ O) across all settings	7-17	22-28	51-76
Frequency (Hz) across all settings	8-16	12-17	19-22

WITH VALVED TEE ADAPTER			
	FLOW RATE		
PARAMETERS	10 lpm	20 lpm	40 lpm
Average Pressure (cmH ₂ O) across all settings	9-13	18-21	29-40
Average Pressure Amplitude (cmH ₂ O) across all settings	5-13	19-24	46-58
Frequency (Hz) across all settings	8-15	13-17	18-21

Note: Testing was performed at a fixed flow rate. Actual values are dependent upon individual effort.

The following specifications were established via performance test using an eight-stage cascade impactor at a flow rate of 28 L/min equipped with USP <601> induction port throat. Three (3) device samples were tested with 3 runs each, for a total of 9 samples points per each drug for a total of 27 data points. Aerosol was sampled directly from the outlet. The specifications are listed below based upon a 95% confidence level.

TABLE 2 - AEROSOL ONLY MODE AT 28 LPM - PARTICALE SPECIFICATIONS						
Measurement (Mean)	Standalone Configuration	with VibraPEP T-adapter	Standalone Configuration	with VibraPEP T-adapter	Standalone Configuration	with VibraPEP T-adapter
Westmed - VixOne®						
	Albuterol		Cromolyn Sodium		Ipratropium Bromide	
NMAD (µm)	1.7	1.37	1.67	1.43	1.53	1.37
GSD	2.24	2.21	2.04	1.75	2.11	2.09
Total Dose (µg)	1256	1050	6295	5212	262	252
Total Respirable Dose (0.5-5 µm)	896	790	4939	4106	174	147
Coarse Particle > (4.7 µm)	266	154	881	555	72	83
Fine Particle	990	896	5413	4657	190	169
Ultra-Fine Particle (< 1.0 µm)	347	351	1804	2460	64	69
Statistical analysis Significant differences	No		No		No	
Hudson RCI Micro Mist®						
	Albuterol		Cromolyn Sodium		Ipratropium Bromide	
NMAD (µm)	1.77	1.40	1.60	1.43	1.53	1.47
GSD	2.94	2.28	2.69	2.75	2.74	2.83
Total Dose (µg)	863	779	2803	2482	127	119
Total Respirable Dose (0.5-5 µm)	497	493	1696	1556	62	60
Coarse Particle > (4.7 µm)	277	193	782	564	52	44
Fine Particle	586	586	2022	1918	75	75
Ultra-Fine Particle (< 1.0 µm)	231	250	828	878	31	34
Statistical analysis Significant differences	No		No		No	

Note: Course particles (oropharyngeal deposition) and ultrafine particles (exhaled) are not likely to deposit in the patient's airway and thus provide clinical benefit.

QUICK REFERENCE GUIDE

- 1 Twist the Therapy Selector to line up with the marking at the desired setting. Position 0-2 (Combined PEP) can be used to treat patients requiring a permanent PEP with added pressure oscillations above baseline. Position 3-4 (Dynamic PEP) can be used to treat patients requiring a gradual rising pressure followed by a sudden pressure drop. (see figure 14 on right)
- 2 Insert the VibraPEP into your mouth and form a tight seal with your lips (see figure 15).

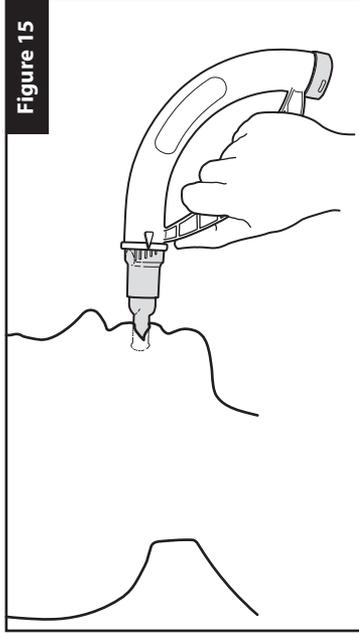
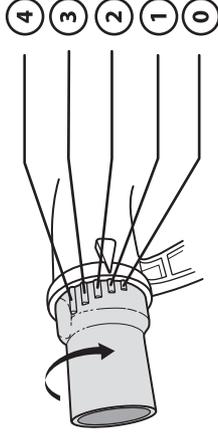


Figure 15

- 3 Breathe in through your nose and exhale into the device. Do not force the exhalation breathe out naturally (keep your cheeks flat).
- 4 Repeat _____ times (15 times unless otherwise instructed).

Figure 14

Position:



Rotate the Therapy Selector to select levels 0-4. The sound will change as the pressure changes.

NOTE: This technology does not depend on gravity so you can use the VibraPEP™ standing, sitting, or lying down.

Instructions For:

Therapy Selector Setting:

Of Repetitions:

Additional Instructions / Or Reminders:
