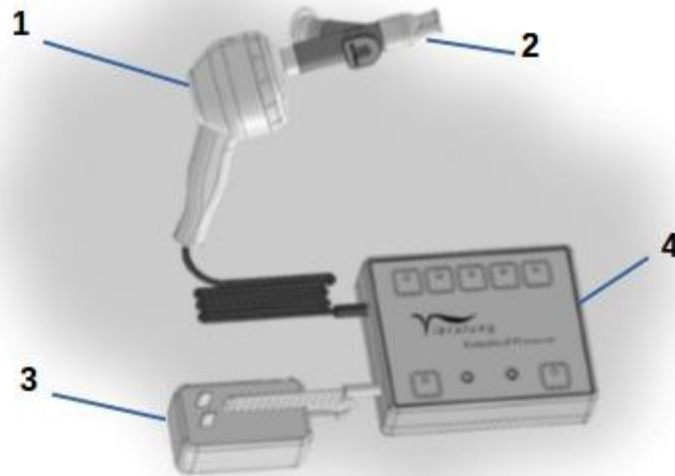




PRESENTING THE

## VIBRALUNG® ACOUSTICAL PERCUSSOR

~AN INNOVATION IN AIRWAY CLEARANCE THERAPY~



### Vibralung Acoustical Percussor

- |                               |                                 |
|-------------------------------|---------------------------------|
| 1. Hand Held Transducer (HHT) | 2. Patient kit                  |
| 3. Charger                    | 4. Treatment Control Unit (TCU) |

The Vibralung Acoustical Percussor (Vibralung) is a new medically advanced approach for intrapulmonary acoustical airway clearance applying oscillatory sound waves directly to the respiratory system for greater efficacy in airway clearance. It is a safe, gentle and highly effective therapy.

The Vibralung generates three tonal frequency stepping modes, L-Low, M-Medium, and H-High, which are all 10 minute treatment times, delivering oscillatory sound waves directly into the lungs via a mouthpiece.

During these modes, at or near sympathetic resonance, the mucus, mucus plugs, and/or the airway surfaces themselves will vibrate, causing the mucus to break away from the airway walls, also causing it to thin out and even liquefy, making it easier for the patient to expel.

Low mode is for larger or proximal airways, Medium is for middle airways, and High is for smaller or distal airways. Starting with Low will clear the upper airway path so that mucus cleared further down in the lungs may be expelled as the patient moves to the higher ranges.

Another mode called Random Noise provides drug free bronchial dilation to help reduce constriction, relaxing and opening the airways.

It is suggested to start with the PEP (Positive Expiratory Pressure) valve half open and adjust as needed.

To summarize, the tonal settings (L-Low, M-Medium, and H-High) mobilize mucus for airway clearance, and the random noise settings (R2 and R5) relax and open the airways.

Indications. The Vibr Lung treats and is FDA cleared for these lung diseases: COPD or Chronic Obstructive Pulmonary Disease, chronic bronchitis, bronchiectasis, asthma, cystic fibrosis, pneumonia, patients with neuromuscular disease affecting the ability to effectively cough, and patients with or at risk of developing atelectasis.





Contraindications. Airway Clearance Therapy (ACT including the use of the Vibr Lung, especially with Positive Expiratory Pressure), may be contraindicated in patients who have untreated air leaks, tension pneumothorax, bronchopleural fistula, recent hemoptysis, or pulmonary hemorrhage as it may exacerbate those conditions. Prescribers should weigh the benefits against the risks in patients with these conditions.

Gentle Airway Clearance Therapy (ACT). The Vibr Lung provides a “gentler” form of ACT than oscillatory PEP devices and devices that make contact with the external chest wall. The Vibr Lung may also be used for airway clearance in some conditions where other means cause discomfort, such as with patients with chest injuries, burns, fresh surgical wounds, or injured/broken ribs.

Side Effects. For dry or sore throat or mouth, use a saline nebulizer treatment prior to the Vibr Lung treatment. For dizziness or light-headedness (likely from hyperventilating), relax and breathe normally through the mouthpiece. For sore mouth, jaw or teeth discomfort, have the patient hold the mouthpiece only with their lips. Any other adverse reactions should be fully assessed before continuing therapy with the Vibr Lung. To date no adverse reactions have been reported.



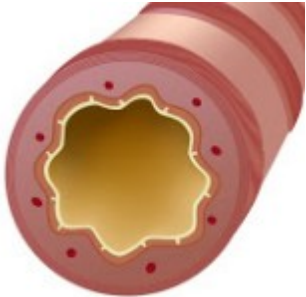
**How the Vibr Lung works:** The Vibr Lung's mechanism of action occurs during both inspiratory and expiratory phases of the patient's breathing cycle, as the patient breathes normally.

The mechanisms of action for the L-Low, M-Medium, and H-High modes (10 minutes each) are shown below:

|   |   |
|---|---|
| <p>The Vibr Lung generates a four tone plus pause frequency pattern over the three frequency ranges. The oscillatory sound waves are directly coupled into the patient's airways via a mouthpiece. Every 20 seconds the pattern moves upward at least a half pitch through its range.</p> |  <p>A cross-sectional diagram of a human airway. The airway wall is shown in red and pink. Inside, there is a thick layer of yellowish mucus. Blue and grey curved lines represent sound waves traveling through the airway. The mucus is shown as a solid, continuous layer.</p> |
| <p>At or near the point of sympathetic resonance, the mucus or mucus plugs will begin to vibrate due to the sound's oscillation. The back-and-forth vibratory motion will cause the mucus to break away from the airway walls.</p>  |  <p>The same airway diagram as above, but the mucus layer is now shown with a textured, vibrating appearance. The blue and grey sound waves are more pronounced, and the mucus is beginning to pull away from the airway walls.</p>  |
| <p>As the mucus continues to vibrate, it will thin out, and even liquefy.</p>   |  <p>The mucus layer is now significantly thinner and more fragmented. The sound waves continue to pass through, and the mucus is breaking into smaller pieces.</p>  |
| <p>These safe and gentle treatments allow for easier mobilization of mucus secretions out of the lungs and for a more productive cough.</p> <p>As the airways are cleared the patient should experience easier breathing and improved lung function.</p>                                  |  <p>The airway is now mostly clear of mucus. Only small, thinning remnants remain. The sound waves are traveling through the clear airway.</p>  |

If you like, you may feel the vibrations during a treatment by placing your hand over the lungs, front or back, or even on the head.

The mechanisms of action for the Random Noise modes, R2 (two minutes) and R5 (five minutes) treatments are shown below:

|  |  |
|--|--|
| <p>The airways may be inflamed and constricted due to bronchial muscle spasms or bronchoconstriction.</p> <p>The Vibr Lung modes R2 and R5, called Random Noise appear to relax and open the airways. These are two and five minute treatments respectively.</p>   |  A 3D cross-sectional diagram of a bronchus. The airway lumen is significantly narrowed by thickened, reddish-brown walls, representing bronchoconstriction. The internal structure shows a central yellow lumen surrounded by a complex, star-shaped network of smaller airways. |
| <p>It is theorized that the generation of random vibrational frequencies over the range of 5 - 1,200 Hz promotes relaxation of the smooth muscle of the airways. It is also theorized in the case of pneumonia, Random Noise helps to move the fluid in the lungs back into the vascular system.</p>       |  A 2D cross-sectional diagram of a bronchus. The airway lumen is wider and more open compared to the first diagram. The walls are thinner and less inflamed, indicating relaxation of the smooth muscle.   |
| <p>It is also theorized that this may be similar to massage techniques used to relax tense muscles of the back using the sides of the hands in an up and down motion.</p> <p>Random noise would be a very gentle application to the airways of this type of massage, opening and relaxing the airways.</p> |  A 3D cross-sectional diagram of a bronchus. The airway lumen is at its widest and most open, with very thin, relaxed walls. The internal structure shows a central yellow lumen surrounded by a complex, star-shaped network of smaller airways.                               |

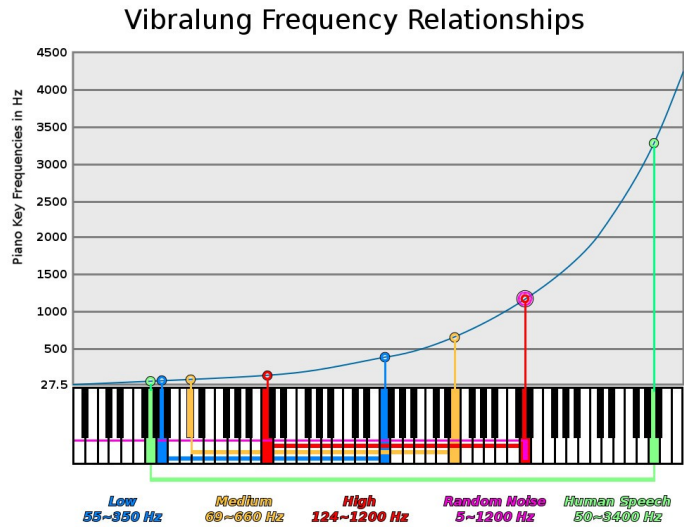
To feel this effect: Using the Hand Held Transducer with just the cone attached, set the Vibr Lung's mode to R2, then hold the end of the cone a short distance from the palm of your hand. You may feel the gentle massage action in this way.

# Vibr Lung Frequency Relationships: Piano and Human Speech

The Vibr Lung's audible sound frequencies are depicted in the piano-graph visual. The full range of the Vibr Lung's frequencies is matched with the corresponding frequencies of the piano.

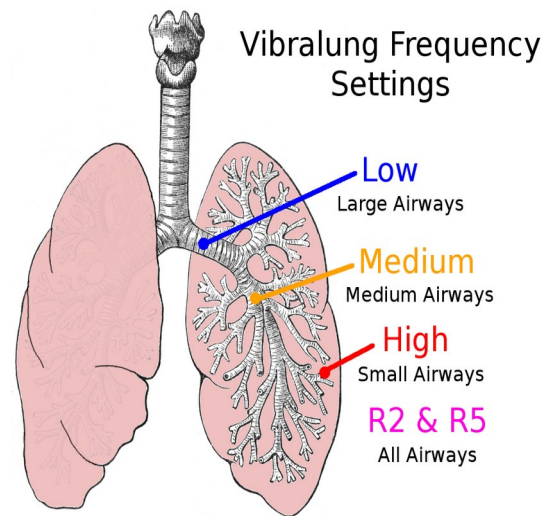
Conclusion:

The Vibr Lung acoustic range is within safe parameters for audible sound.



During use of L-Low, M-Medium or H-High settings, the Vibr Lung emits a sequence of tones progressing upward over the frequency range of each overlapping mode. These are 10 minute treatments. R2 and R5 are Random Noise for two or five minutes respectively.

Our lungs are similar to other acoustical objects such as a pipe organ. The large pipes of a pipe organ have the lowest frequencies, and the smaller ones have higher frequencies. Another analogy of low to high frequencies, is to think of a bass, a cello and a violin. The smaller the structure the higher the frequency.



| Setting   | Range          |
|-----------|----------------|
| L-Low     | 55 to 350 Hz   |
| M-Medium  | 69 to 660 Hz   |
| H-High    | 124 to 1200 Hz |
| R2 and R5 | 5 to 1200 Hz   |

## Vibralung Advantages and Benefits

- The Vibralung's wide range of frequencies promote safe, gentle, and highly effective loosening and mobilization of mucus secretions by delivering the sound waves directly to the respiratory system. This allows for easier mucus clearing and productive cough.
- The Vibralung's efficacy in airway clearance is independent of patient effort or performance while using the device.
- Provides treatment during both inhalation and exhalation phases of the breathing cycle.
- Incorporates Positive Expiratory Pressure (PEP) to further promote mobilization of mucus secretions.
- The unique Random Noise mode relaxes and opens inflamed or constricted airways.
- Easy to operate, lightweight and highly portable.
- May be used virtually anywhere, and patient may be mobile.
- The goals of Vibralung's innovative method of airway clearance are:
  - quick treatment sessions,
  - increased patient compliance,
  - improved lung function,
  - increased blood gas perfusion improving oxygenation,
  - better breathing,
  - greatly improved quality of life, and
  - reduced hospital admissions.

## Administering treatments with the Vibralung

For patients who have excessive airway secretions, bronchoconstriction, or other indicated conditions:

As summarized above, the tonal settings (L-Low, M-Medium, and H-High) mobilize mucus for airway clearance, and the random noise settings (R2 and R5) relax and open the airways.

Note: If the patient is experiencing a pulmonary exacerbation, more treatments may be administered per day. A lower mode treatment may be given in the morning and a higher mode treatment may be given later in the day. If the patient is wheezing, a R2 or R5 treatment may be given first.

In general, to clear mucus from the airways:

Start with Low followed by R2. Continue these treatments two to three times per day, generally morning, noon, and evening, until the amount of mucus expelled has diminished. Start with Low to create a clear pathway as clearing occurs further into the lungs.

Now treat with Medium followed by R2, or use Low followed by R2 in the morning and Medium followed by R2 at noon and evening. Continue these treatments two to three times per day, generally morning, noon, and evening, until the amount of mucus expelled has diminished.

Now treat with High followed by R2, or use Low or Medium followed by R2 in the morning and High followed by R2 at noon and evening. Continue these treatments two times per day, generally morning and evening, until the amount of mucus expelled has diminished.

For most chronic pulmonary conditions, fewer treatments may now be given. It is important to rotate through the Low, Medium and High settings (followed by R2), and to continue to do a few treatments every week or even every month.

**Dry Asthma Recommended Usage Directions:**

For conditions such as dry asthma, up to three R5 treatments may be given one after the other for a total of 15 minutes. Such treatments may be administered up to four or five times a day, with reduced number of treatments over time as airways relax and open.

**Pneumonia Recommended Usage Directions:**

For severe pneumonia, such as Covid-19 induced, increase the number of treatments up to 5 per day.

- Start with R2 then L-Low then R5 for two to three treatments. If little or no secretions are expelled on L-Low, move to R2 then M-Medium followed by R5.
- Continue with: Mornings R2, then L-Low or M-Medium then R5, and R2 then for other times R2 then M-Medium or H-High followed by R5.
- If pneumonia appears to be in the lowest or more distal lobes, start mornings with R2 then M-Medium then R5 and for other times R2 then M-Medium or H-High followed by R5.

Continue treatments until symptoms abate.

## Clinical Trials

### 1. pre-FDA Safety and Efficacy Studies:

#### Study Population:

Subjects with mild to moderate lung disease and confirmed diagnosis of Cystic Fibrosis.

#### Safety Conclusion:

No evidence of lung damage could be found using the Vibralung Acoustical Percussor.

#### Efficacy Conclusion:

There was no difference between the Vibralung Acoustical Percussor and the Hill-Rom Vest, so that is the Vibralung Acoustical Persussor was found to be equivalent, in statistical significance, to Vest therapy, as measured by dry sputum production.

#### Published Study:

"Influence of the Vibralung Acoustical Percussor on pulmonary function and sputum expectoration in individuals with cystic fibrosis"

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5961921/>

### 2. South Carolina COPD or Pneumonia 90 day Readmission Study

#### Study Population:

Inpatient subjects with a discharge diagnosis of COPD or pneumonia, who started using the Vibralung in the hospital and continued at home for a period of 90 days.

#### Study Results:

Two patients were readmitted in the 90 day period, with only one patient was readmitted for the same diagnosis as at discharge. This is a 5% readmission rate.

This is compared to other studies which found readmission rates of 2 to 4.5 (5) patients, with readmission rates from 22.6% to 33% as found in this study:

Predicting and preventing hospital readmission for exacerbations of COPD  
Chia Wei Kong, Tom M.A. Wilkinson

#### Study Conclusion:

This evaluation has provided insight to the use of airway clearance therapy and its potential role in reducing 30 and 90 day readmission rates. Further studies focused on airway clearance therapy will enrich clinical evidence regarding different airway clearance devices.

Based on these results, patient feedback, and provider input – airway clearance therapy post-acute care discharge may be effective in reducing readmissions.