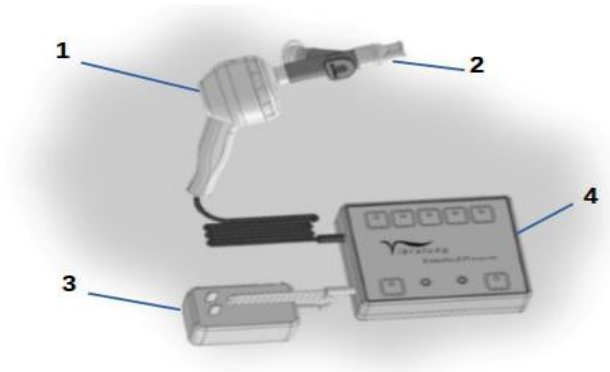




VIBRALUNG® ACOUSTICAL PERCUSSOR
~AN INNOVATION IN AIRWAY CLEARANCE THERAPY~

**A CRITICAL ADJUNCT THERAPY
FOR
COVID-19 INDUCED PNEUMONIA**



Vibralung Acoustical Percussor
Intrapulmonary Acoustical Airway Clearance

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

April 27, 2020

You may not have heard of the Vibralung Acoustical Percussor (Vibralung), an airway clearance device which was FDA 510(k) cleared in May 2014 (K133057). Please let me introduce this safe, gentle and highly-effective intrapulmonary acoustical airway clearance device, with over 1,200 units in the field.

The Vibralung uses sound waves directly to the airways (via a mouthpiece) in several ways:

- Mucus or secretion mobilization
- Opening and relaxing inflamed and constricted airways
- Helping patients recover from pneumonia. By moving the fluid and debris caused by the COVID-19 out of the lungs, this will also improve blood gas perfusion at the same time. Anecdotally, a couple of patients have been on antibiotics for over 3 weeks; when they added the Vibralung to their treatment regimens, the pneumonia was cleared in the next 2-4 days.
- Help with recovery and healing of lungs damaged by COVID-19. Again, several patients with scarring in the lungs have been helped with the Vibralung.

The Vibralung could be a **critical adjunct therapy** for those patients with COVID-19 induced pneumonia or other indicated respiratory issues.

The Vibralung consists of a Treatment Control Unit (4. TCU) which is cleared for multi-patient use. It should be disinfected between patients according to hospital guidelines. The other parts are cleared for single patient use only and are considered disposable. They are the Hand Held Transducer (1. HHT), along with the Patient Change Kit (2. mouthpiece assembly), as well as other accessories. A bacterial/viral (BV) filter (22mm x 22mm) may be inserted before the PEP valve on the exhalation port to trap any possible aerosolized virus.

The Vibralung generates oscillating sound (acoustical) waves which are delivered to the respiratory system via a mouthpiece. The Vibralung generates three tonal frequency stepping modes, Low, Medium, and High, which are all 10-minute treatments. Low is for larger airways, Medium is for middle airways, and High is for smaller airways. These modes cover a range from 55 to 1,200 Hz. During these treatments, at or near sympathetic resonance, the mucus, mucus plugs, and/or the airway surfaces themselves will vibrate due to sound's oscillatory effect, causing the mucus to break away from the airway walls, thin out, and liquefy. This makes it easier for the patient to expel.

Another mode called Random Noise appears to help reduce constriction and inflammation of the airways. Random noise is both random acoustic energy and random frequencies. This delivers a massaging and restorative effect to the airway structures. For treating pneumonia, it is thought this random acoustic energy with random frequencies creates a higher amount of energy against the fluid that the amount of energy on the other side of the permeable membrane, the alveoli. This will cause an osmosis effect drawing the fluid from the lungs back into the vascular system, improving blood gas perfusion as well.

The Vibralung has a variable expiratory PEP valve, and may be used with the Circulaire II Hybrid nebulizer or a tracheotomy interface kit.

The Vibralung is indicated for: Chronic Obstructive Pulmonary Disease (COPD), chronic bronchitis, bronchiectasis, asthma, cystic fibrosis, **pneumonia**, neuromuscular respiratory disease, and patients with or at risk of developing atelectasis.

A combined report of the Vibralung's safety and efficacy study may be found at:
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5961921/>

We look forward to helping you meet the pulmonary needs of your patients, and particularly those with COVID-19 lung complications at this time.

With best regards,

The VibraLung Team
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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 in the several hours following the treatment, 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 lobes or more distal, start with mornings with R2 then M-Medium then R5nd R2 then for other times R2 then M-Medium or H-High followed by R5.

Continue treatments until symptoms abate.