Vibralung® Acoustical Percussor FAQs

Q1. Is the Vibralung Acoustical Percussor approved by the FDA?

A1. Yes, the Vibralung was cleared for marketing by the United States Food and Drug Administration (FDA) on May 23, 2014 and was assigned the 510(k) designator K133057.

Q2. How does the Vibralung Acoustical Percussor differ from the vest?

A2. The Vibralung is an acoustical device that applies vibratory sound waves directly to your airways through your mouth, at a multitude of frequencies. The vest is a mechanical device that vibrates your external chest so vigorously, at a single frequency, that the vibrations may be transmitted through the tissues, muscles and bones of your chest wall and finally into your airways.

Q3. How does the Vibralung Acoustical Percussor differ from the Frequencer?

A3. The Vibralung is an acoustical device that applies vibratory sound waves directly to your airways through your mouth, at a multitude of frequencies. The Frequencer is an acoustical device that applies sound waves to your external chest, at a single frequency, so that the vibrations may be transmitted through the tissues, muscles and bones of your chest wall and finally into your airways.

Q4. How long does a treatment last?

A4. A typical treatment session can be 10 or 20 minutes, depending upon what you and your physician or therapist determines you need. A single treatment is 10 minutes. Some patients take 2 treatments back-to-back, for a total of 20 minutes. You might take a single treatment on Low, Medium or High. Or, you might take a treatment on Low followed by Medium, or a treatment on Medium followed by High. There is no single right or wrong protocol, although Low should precede Medium, and Medium should precede High. Beyond that one rule, whatever works best for you is OK.

Q5. How many treatments a day do I have to take?

A5. Most airway clearance therapies require treatments at a frequency ranging from 2 to 4 times daily. The Vibralung is no different. You and your physician or therapist can determine what is best for you based upon your response to therapy and other factors. You should schedule your treatments at a time that is convenient and useful to you, but remember to be consistent and not miss any treatments.

Q6. Can I carry the Vibralung with me when I travel?

A6. Absolutely! The Vibralung Acoustical Percussor is battery-operated and extremely portable. A travel bag is available for home care purchases and the components are small enough to fit into a carry-on bag or backpack for an airplane trip.

Q7. Can I use the Vibralung in a hotel/hospital room without disturbing people in other rooms?

A7. Yes. Just remember to place the mouthpiece in your mouth before you turn the unit on. That way, the ambient sound will be dampened and will not be loud enough to disturb anyone else. And be sure to press "pause" before you take the mouthpiece out to cough or expectorate.

Q8. Can I use the Vibralung in a public place such as a restaurant or theater?

A8. Technically, you could. But in these environments, the external noise it creates would probably be high, in relation to the existing ambient background noise, and would likely call undue attention to you and your treatment. Vibralung use in or near public areas is best done discretely.

Q9. Can I plug in the Vibralung to an electrical outlet?

A9. Yes, but only for charging the internal battery by way of the included power transformer. You cannot take a treatment with the unit plugged in. By design, the Vibralung TCU (Treatment Control Unit) will not operate when it is plugged into the power transformer, regardless of whether the transformer is plugged into an electrical outlet or not. This is a safety feature.

Q10. How many treatments will I get on a full battery charge?

A10. A full charge of the internal lithium ion battery pack should render approximately 40 treatments of 10 minutes duration.

Q11. Is there a "car charger" available for the Vibralung?

A11. No. Because of the extended battery life, a car charger is probably unnecessary. Considering that the Vibralung can accommodate up to 40 ten-minute treatments per full battery charge, you could take 4 10-minute treatments daily for a week before having to charge the batteries.

Q12. Why do I need the PEP Resistor or Variable Expiratory Resistor?

A12. The Variable Expiratory Resistor serves to place your airways under slight positive pressure when you exhale. It is like breathing through "pursed lips." Physiologically, it splints or "props open" all airways to help prevent collapse of the smaller airways, and aid in airway clearance by slightly dilating airways.

Q13. How much PEP does the PEP Resistor provide?

A13. With the PEP Resistor at its most "closed down" position, and during resting breathing, the maximum PEP pressure is about 4 to 5 cm H2O. This is a modest amount of PEP that will help hold airways open and provide a little bit of "shear" force to help separate mucus from the airway surface.

Q14. Is the Vibralung an oscillating PEP device?

A14. No, the Vibralung Acoustical Percussor is a gentler form of airway clearance than oscillating PEP devices. Instead of interrupting the airflow during exhalation to create vibrations in the airway, the Vibralung uses sound waves during both inspiration and exhalation to vibrate the air in the airway. This, in turn, causes the airway and the secretions to vibrate at their own particular natural (resonant) frequency. This helps to separate mucus from the airway surface.

Q15. Why do I have to use a mouthpiece? Why can't I use a mask?

A15. Sound waves travel best when they are directed in a straight line. When the sound waves get into the lungs, they have to make many turns to travel through the tracheobronchial tree. Each of those turns, especially into progressively smaller airways, may result in a dampening of the sound. We can't do anything about what happens inside the lung. However, we want the sound waves to be at their maximum amplitude when they enter the airway. Consequently, the straight mouthpiece and Y-adapter is designed to assure that the sound waves are not dampened before they enter the airways through the mouth.

Q16. Can I use a nebulizer with the Vibralung?

A16. The nebulizer must be the Westmed Circulaire II Hybrid high-efficiency aerosol drug delivery system for 5 reasons. One reason is because it is the only aerosol delivery system or nebulizer that the FDA cleared for use with the Vibralung. The second reason is that the Circulaire II Hybrid has been extensively tested with the Vibralung and its performance in the presence of the various sound wave patterns has been determined to be equivalent to, or better than, its performance in the absence of the sound wave patterns. The third is because the Circulaire functions as a "non-

rebreathing" valve on the Vibralung to prevent you from inhaling your exhaled carbon dioxide. The fourth is because the Circulaire configuration does not block the sound waves and the fifth is that the Circulaire allows the PEP to be maintained. The configuration of other nebulizers would make it impossible to achieve these benefits.

Q17. Is the Vibralung covered by insurance?

A17. As of its date of introduction it is not covered by insurance. However, we hope this will change as soon as possible. Now that the FDA has cleared the Vibralung, Westmed will submit to various insurance companies seeking to garner reimbursement for the Vibralung.

Q18. Is the Vibralung available for direct retail purchase?

A18. Yes, the Vibralung may be purchased directly from Westmed, provided that the order includes a physician's prescription for its use, and also a prescription for the Circulaire II Hybrid high-efficiency aerosol drug delivery system if its simultaneous use if also desired. Further information may be obtained by calling (800) 975-7987 for a referral to a Vibralung clinical specialist who will help determine whether the Vibralung is indicated and will provide information on pricing and the ordering procedure.

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