Vibralung®

Acoustical Percussor

Electro-Mechanical Acoustical Airway Clearance™

Comprehensive Online Manual for Healthcare Professionals

Note: This online manual is a supplement to the Instructions for Use that is packaged with each P/N 9500 Vibralung Treatment Control Unit.
This is an online users manual, subject to periodic change without notice.
Always consult the online manual in the event that updates have occurred.

Vibralung® Acoustical Percussor

Electro-Mechanical Acoustical Airway Clearance™

Online Manual for Healthcare Professionals

Online at: **www.vibralungACT.com**

www.westmedinc.com

Copyright
© 2014 Westmed, Inc. All rights reserved.
Version 3.0, March 2015, Manual PN: 71942 Rev 03
No part of this document, software or educational materials may be reproduced or transmitted in any form or by any means or translated into another language without the prior written consent of Westmed, Inc.

Trademarks
Vibralung® and Vibralung Acoustical Percussor™ are registered trademarks, respectively, of VibraLung, Inc.
EMAAC™ is a trademark of Westmed, Inc.
Circulaire® is a registered trademark of Westmed, Inc.
Circulaire *Hybrid*™ is a trademark of Westmed, Inc.

Patents
This product has US and worldwide patents issued and pending. US Patents: 5,829,429; 5,893,361; 6,058,932 and 6,167,881

Table of Contents

SECTION 1 – OVERVIEW and BACKGROUND

Abbreviations & Acronyms Used in This Manual

ACT	Airway Clearance Therapy or Therapies
CPT	Chest Physiotherapy
db /dbA	Decibels / Decibels, A-weighting
EMAAC	Electro-Mechanical Acoustical Airway Clearance
HHT	Hand-held Transducer
Hz	Hertz (cycles per second)
IPV	Intrapulmonary Percussive Ventilation
LED	Light Emitting Diode
PEP	Positive Expiratory Pressure
RF	Resonant Frequency
RGA	Returned Goods Authorization
R2	Random Noise for 2 minutes
R5	Random Noise for 5 minutes
SPL	Sound Pressure Level in decibels (db)
TCU	Treatment Control Unit
VER	Variable Expiratory Resistor

Symbols Used in This Manual

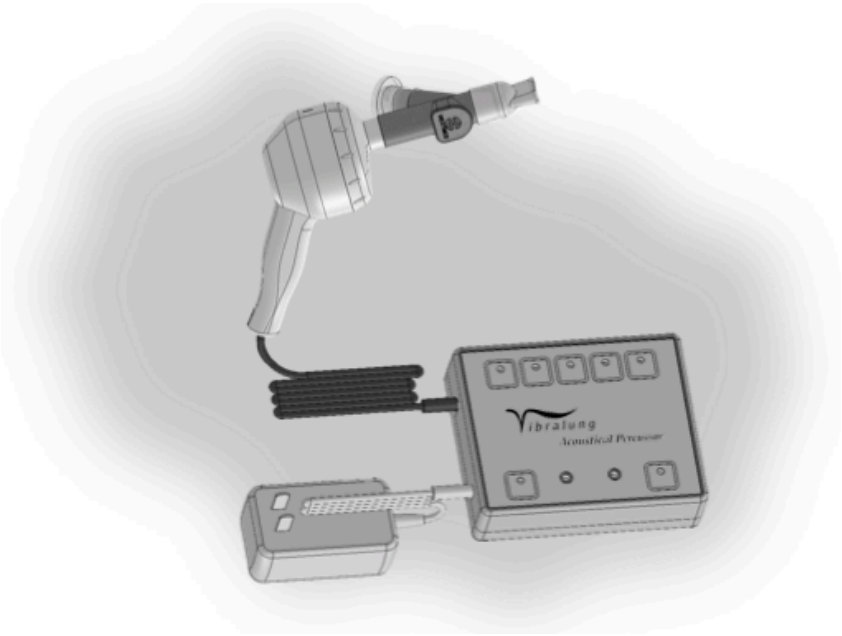
Symbols are required by various standards organizations to denote critical safety, and other information.

	The **manufacturer** is Westmed, Inc.		This document contains **Instructions for Use**.		**For indoor use only**
	**WARNING** Failure to abide by the WARNING information may result in serious injury and can be life-threatening.		**CAUTION** Failure to abide by the CAUTION information may result in moderate injury and/or property or product damage.		**Type BF (Mouthpiece)** Type BF applied part according to EN 60601-1.
	**Direct Current** **A** device described herein operates on **direct current** electrical power.		Alternating Current **A** device described herein operates on **direct current** electrical power.		Power supply meets **Level V** requirements
	Storage and transport **temperature** range: -25°C to 70°C		Storage and transport **humidity** range: 0% to 93% RH		Storage and transport **atmospheric pressure** range: 70 kPa to 106 kPa
	**Class II Equipment** according to IEC 61140		When used on a package insert or label, indicates the manufacturer's **Reference** number		When used on a package insert or label, indicates the **Lot** Number.

Device Description

The Vibralung® Acoustical Percussor provides Airway Clearance Therapy **(ACT)** and promotes mucokinesis by vibrating the column of gas in the airways with sound waves at different frequencies. It is an acoustic device that induces oscillatory sound waves by means of an electro-mechanical acoustical transducer (audio loudspeaker), which is contained in an ergonomic hand-held audio reflex housing, hereafter referred to as the "Hand-held Transducer" or **HHT.** The HHT is interfaced to the patient's airway through a Y-adapter and mouthpiece. The Y-adapter is a waveguide that directs the acoustical energy to the patient mouthpiece, while allowing separate gas flow pathways for inhalation and exhalation to minimize CO2 rebreathing and allow Positive Expiratory Pressure **(PEP)** to be applied.

The HHT is connected to electronic frequency generator circuitry, inside the Treatment Control Unit **(TCU).** The TCU is capable of producing audio frequencies between approximately 5 and 1,200 Hz. The HHT induces sound waves in the patient's airways at, above and below the lung's resonant frequencies, thereby vibrating the boundary between mucus and the airway surface. As with many ACT devices, this may be effective in mobilizing mucus accumulation, enhancing the lung's inherent mucociliary clearance mechanism and facilitating expectoration.



The TCU is a reusable medical device that, if handled and maintained properly, will function at peak performance throughout its lifetime. The TCU connects to the HHT by means of a 4-foot long interface cable. A Patient Kit contains an HHT, two unique Y-adapters, a Variable Expiratory Resistor **(VER)** for PEP and a mouthpiece. The TCU includes a pole-mounting slide on its rear panel for attachment to a pole-mounting clamp (not included). The pole mounting option secures the device against accidental falls and damage. Alternately, the TCU may simply be positioned on a flat surface adjacent to the patient. Four self-adhesive rubber feet (supplied) are provided to level the device and minimize sliding on hard flat surfaces.

Benefits of the Vibralung

The Vibralung Acoustical Percussor is a gentle form of ACT that induces airway vibration at a variety of frequencies, rather than employing a single frequency, as many of the other ACT devices do. The Vibralung Acoustical Percussor generates sound waves in either a programmed sequence or a random noise pattern. While generally equivalent to other methods and devices of ACT, the Vibralung Acoustical Percussor does not make contact with the external chest wall. Thus, it may be useful in some patients as an alternative to manual techniques or the various forms of vest therapy, or other modes where a transducer is placed against the chest wall.

WARNINGS

PATIENT INJURY OR INEFFECTIVE THERAPY CAN RESULT FROM IMPROPER ASSEMBLY OR OPERATION. PLEASE READ THE FOLLOWING WARNINGS BEFORE ASSEMBLING OR OPERATING DEVICE.

1. Federal law restricts this device to sale by or on the order of a physician. Read the complete Instruction Manual before use.
2. Unskilled or untrained personnel should not operate or apply this device to patients.
3. Use only as intended and described in this manual and supporting documentation.
4. Use only on cooperative patients who can properly self-administer following training.
5. Use only with the supplied mouthpiece and accessory adapters. If used for simultaneous aerosol delivery and/or PEP, use only the supplied Aerosol Y-adapter and Circulaire® II *Hybrid™* aerosol delivery system. Do not use other nebulizers or PEP devices.
6. Be prepared to assist patient with removal of secretions (cough coaching, suction) as needed.
7. The HHT, Cone and related Y-adapters are for single patient use, multiple treatment sessions during single hospitalization and should be changed as directed.
8. Do not hold Hand-held Transducer up to your ear. Hearing damage may result. Foam ear plugs are provided to lessen the sound to which your ears are exposed. Wear the ear plugs during each treatment.

CAUTIONS

DEVICE DAMAGE CAN RESULT FROM IMPROPER HANDLING, INSTALLATION, ASSEMBLY OR CLEANING. READ THE FOLLOWING PRECAUTIONS FOR PROPER CARE OF THE DEVICE.

1. Do not open or attempt to disassemble either the TCU or the HHT. There are no user-serviceable parts inside. Internal batteries are not user-serviceable. The TCU must be returned to Westmed for service. The HHT is disposable and should be discarded and replaced as needed.
2. Do not over-tighten the “Cone” onto the HHT. Ensure the outlet port of the Cone is properly aligned to the “3 o’clock” position.
3. Do not use the TCU and HHT in wet conditions.
4. Do not immerse the TCU or HHT in liquid or allow liquid to seep into the case.
5. Do not attempt to disinfect either the HHC or the TCU with boiling water, steam, baby bottle sterilizers, dishwashers or microwave ovens.
6. Use only the AC Battery Charger that is supplied with the TCU. Use of a different charger may damage the batteries and/or the electronics.
7. Do not operate the Vibralung Acoustical Percussor in potentially explosive, highly flammable or oxygen-enriched atmospheres such as an operating room during use of flammable anesthetics or in an oxygen tent, croup tent, head hood or incubator with oxygen flowing.
8. Do not connect or interface the Vibralung Acoustical Percussor to any airway clearance device or aerosol delivery system other than the Westmed Circulaire II or Circulaire II *Hybrid* aerosol drug

delivery system and Westmed Circulaire II Variable Expiratory Resistor for Positive Expiratory Pressure (PEP).

9. Do not use the Vibralung Acoustical Percussor with a facemask; due to the uncertainty of coupling the acoustic energy to the lower airways, it may diminish the effectiveness of the product.

Review of Airway Clearance Therapy

Airway Clearance Therapy is the contemporary name applied to a variety of techniques that are used to enhance mucokinesis. Mucokinesis is the normal movement of mucus from all depths of the lungs to the back of the throat, where it is either swallowed or spit out (expectorated). There are a number of respiratory diseases and conditions (see *Indications*, below) that involve increased mucus production, decreased mucokinesis, pooling and inspissation of mucus in the airways, plus infection of pooled mucus secretions. Infected or excessive mucus is frequently referred to as sputum or phlegm when therapeutic efforts are aimed at assisting a respiratory patient to effectively remove it.

The goal of ACT is to enhance mucokinesis and facilitate expectoration of sputum. A wide variety of ACT procedures are in common use, and include numerous manual (that is, "hands on") techniques in the realm of chest physiotherapy (CPT), and the application of a number of respiratory therapy devices that have been devised for this purpose.

One of the natural physiological mechanisms for mucokinesis and expectoration is the cough, which vigorously vibrates the airways and subjects them to exceptionally high pressures (>100 cmH2O). Coughing both breaks the adhesive and cohesive bonds of mucus with the airway surface and propels the secretions up the airway toward the pharynx. Unfortunately, many patients with respiratory disease and excessive respiratory secretions are unable to muster an effective cough because it is often hindered by the disease itself or the inability to take a deep breath and produce sufficiently forceful cough pressures.

The fundamental goals of ACT are as follows:

- disrupt the interface of mucus with the airway surface to which it adheres
- enhance the lung's inherent physiological mucociliary clearance mechanism
- generate sufficiently high airway pressure gradients to propel secretions outward

The typical methods for accomplishing these goals are as follows:

- vibrate the external chest wall, lung tissue and airways at a variety of frequencies
- vibrate the "column" of gas in the airways at a variety of frequencies
- alternately interrupt the flow of gas in the airways, particularly during exhalation, at a variety of frequencies
- apply Positive Expiratory Pressure (PEP) to the airways
- apply specific breathing techniques and maneuvers
- artificially induce a deep breath followed by an explosive expiratory breath

EMAAC™

Electro-Mechanical Acoustic Airway Clearance (EMAAC) with the Vibralung Acoustical Percussor uses sound waves (acoustics) to provide some of the aforementioned methods for achieving airway clearance, principally airway vibration and PEP. The Vibralung Acoustical Percussor has been designed to incorporate PEP at all times and to allow simultaneous aerosol therapy with drugs or wetting agents as needed.

It is the responsibility of the prescribing and treating practitioner(s) to assess the patient for EMMAC therapy to determine if the Vibralung Acoustical Percussor is appropriate for any given patient, either as sole therapy or adjunct therapy, and to assess whether therapeutic goals are being achieved.

Indications for Use

The Vibralung Acoustical Percussor is indicated as an airway secretion clearance device that creates vibrations in the airways and as a lung expansion device that applies Positive Expiratory Pressure (PEP) as a patient breathes through the device. It may be used to promote bronchial drainage, airway clearance and expectoration. The Vibralung may be used simultaneously with aerosol drug delivery.

Patient Population. Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems, patients with neuromuscular disease affecting the ability to effectively cough, and patients with or at risk of developing atelectasis. Anyone who is able to read and/or understand the instructions may use the Vibralung Acoustical Percussor.

Environment of Use. Hospital and home.

Clinical Application

The Vibralung Acoustical Percussor for patients with respiratory diseases and related conditions that involve:

- increased mucus production,
- infection and inspissation of respiratory secretions,
- and defective mucociliary clearance.

These conditions are typical in patients diagnosed with:

- cystic fibrosis,
- chronic bronchitis,
- bronchiectasis,
- pneumonia,
- ciliary dyskinesia syndromes,
- asthma,
- muscular dystrophy,
- post-operative atelectasis plus neuromuscular respiratory impairments,
- thoracic bellows defects,
- and any other cardiorespiratory or neuromuscular diseases that inhibit effective cough, mucokinesis, airway clearance and expectoration.

The Vibralung Acoustical Percussor provides a "gentler" form of ACT than oscillatory PEP devices and devices that make contact with the external chest wall and may also be used for airway clearance in some conditions where other means of airway clearance (e.g., vests and hand-held chest percussors) cannot be used, such as with patients with chest injuries, burns, fresh surgical wounds or injured/broken ribs.

Contraindications. ACT or use of the Vibralung Acoustical Percussor, 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.

Adverse Reactions. If the patient complains of dry throat or mouth brought about by treatment with the Vibralung, consider adding nebulization with normal saline if it is not already being done. If the patient complains of sore mouth, jaw or teeth brought about by using the Vibralung device, the healthcare practitioner should assess the patient to make sure the patient is not "clamping down" or chewing on the mouthpiece with his/her teeth. If the patient complains of dizziness or light-headedness, assess the patient for possible hyperventilation while using the device. If the patient appears to be hyper-ventilating, pause the treatment and coach the patient to alter their breathing pattern appropriately. Any other adverse reactions should be fully assessed before continuing therapy with the Vibralung Acoustical Percussor.

Theory of Operation

The Vibralung Acoustical Percussor uses acoustics (sound waves) as its fundamental operating principle. The sound waves (quasi-musical tones and "white noise") are generated by an electronic digitally controlled signal generator and reproduced with a high-fidelity audio loudspeaker.

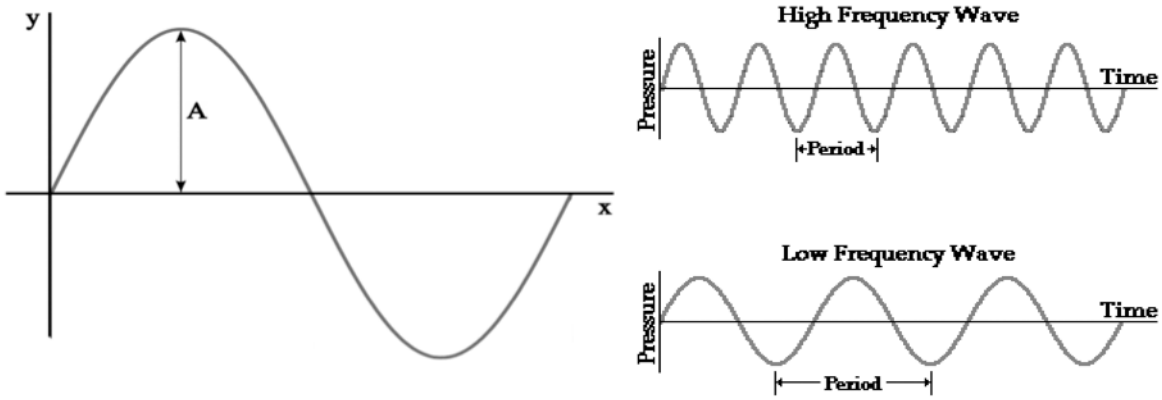
Among the physical characteristics of sound is the fact that it can be conducted through tubes. Tubes that conduct sound from one location to another are known as "waveguides." The tracheobronchial airways function to some extent as a series of waveguides inasmuch as they are capable of conducting sound bidirectionally. Recognizing that the airways comprise a series of waveguides, and that sound can be conducted bidirectionally within them, it is possible to transmit sound directly into and throughout the airways for therapeutic purposes.

The Vibralung Acoustical Percussor generates and couples sound energy to the column of gas in the patient's airways through a simple mouthpiece assembly. In turn, the sound energy vibrates the column of gas in the airways during both the inspiratory and expiratory phases of the patient's breathing cycle. As the patient breathes normally through the mouthpiece attached to the HHT, the acoustic sound waveforms are superimposed over the normal respiratory waveforms and travel throughout the lungs via the conducting airway system.

A useful analogy for the manner in which various waveforms superimpose themselves over each other would be the way multiple ripples form on a pond, even ripples emanating from different directions, can pass through each other and continue along their intended pathway. Consequently, application of this technique is relatively effort-independent on the part of the patient, and does not require the patient to perform specialized breathing maneuvers, because the sound waves pass through normal respiratory pressure waves during resting breathing.

Attributes of Sound

Sound has both objective and subjective attributes. Objective attributes are ones that we can measure, such as Amplitude or Sound Pressure Level (SPL) and Frequency, as shown below.



Attributes of Sound. [Left] Sinusoidal sound wave, 1 cycle. 'A' denotes the amplitude of the sine wave expressed as Sound Pressure Level (SPL) in decibels (db). 'y' is the amplitude (pressure) axis while 'x' is the time axis. [Right] Frequency (cycles per second) normally expressed in Hertz (Hz).

Frequency Spectrum

The Vibralung Acoustical Percussor generates a sinusoidal waveform composed of a continuous spectrum of overlapping frequencies (musical tones) ranging from 5 to 1,200 Hz. Most of these tones are within the audible range of human hearing and can be heard by the patient and people close by. The 5 Hz tone is generated while no other tone is being generated and represents the digital "off state." Although it is below the normal lower limit of human hearing, it is nevertheless present.

The frequencies are separated into five operating ranges that have been labeled as "Low," "Medium," "High", "R2" and "R5" to simplify description. The tones emitted at the Low, Medium and High settings deliberately resemble a series of musical notes to provide a predictable sequence of frequencies. The tones at the R2 and R5 settings are described as "random noise" or "white noise" and cover the full available spectrum.

Mode Setting	Frequency Stepping	Continuous Frequency Spectrum
Actual frequencies are in decimal fractions; rounded off frequencies are listed here.		
L (Low)	55 to 350 Hz	5 to 350 Hz
M (Medium)	69 to 660 Hz	5 to 660 Hz
H (High)	124 to 1182 Hz	5 to 1200 Hz
R2 (2 minutes)	---	5 to 1200 Hz
R5 (2 minutes)	---	5 to 1200 Hz

During operation on the L, M or H settings, the Vibralung Acoustical Percussor emits a sequence of repeating tones in a predictable pattern that has been programmed into the signal generator portion of the device. Technically, the pattern consists of 4 musical notes one-half step apart (for example, C, C#, D and D#). After repeating the 4-note sequence for 20 seconds, the pattern shifts up at least a half step (for example, C#, D, D# and E), and then repeats another 20 seconds, and so forth for 10 minutes. The pattern gradually moves from low frequencies to higher frequencies so that the airways are exposed to a full and deliberately overlapping spectrum of acoustical energy. Conversely, the R ("random noise") settings are exactly that: random frequencies melded together to create "white noise" with no discernible pattern.

Acoustic Resonance

Acoustic resonance is the tendency of an acoustic system to absorb more energy when it is forced or driven at a frequency that matches one of its own natural frequencies of vibration (also known as resonant frequency) than it does at other frequencies. The lung and system of conducting airways qualifies as an acoustic system for the purposes of this discussion.

The rationale behind using a continuous overlapping acoustic spectrum in treating patients with respiratory disease relates to the regional nonhomogeneities that can exist in the diseased human respiratory system and the desire to vibrate the airways at or near their resonant frequency **(RF)**. The RF is the frequency at which the lungs and airways tend to oscillate at the greatest amplitude. The human respiratory system has an RF in the range of 5 – 40 Hz measured at the airway opening (mouth), but the exact RF of any particular patient's lungs may be dependent on the type, severity and location(s) of any disease process and is unknown unless complex testing is performed.

The RF of the human respiratory system is not easy to measure and attempts at doing so typically render an "average" value when measured at the mouth. Bench testing of sound transmission through tubes of different lengths and diameters has revealed different resonant frequencies. As a generalization, long and wide tubes tend to have a lower RF while short and narrow tubes have a higher RF.

While there is no direct evidence to support the theory for any of the available airway clearance devices, most operate on the assumption that vibrating the lungs and airways at or near the RF is at least partially

responsible for breaking the adhesive and cohesive bonds between mucus and the airway surface, as well as producing the mucokinesis seen in all of the airway clearance therapies.

However, due to its complexity, the respiratory system may have multiple resonant frequencies, especially in disease. Airway clearance devices that generate only one specific frequency, or a narrow frequency range, could easily miss the required frequency and would likely fall short of its goals. Further, the respiratory system, especially one with pulmonary consolidation or significant airway occlusion due to mucus impaction, may also act to dampen some frequencies. Therefore, the Vibralung Acoustical Percussor is designed to operate within an exceptionally wide range of overlapping continuous frequency spectra to compensate for dampening of some frequencies and to approach and cover the lung's various resonant frequencies during the treatment period.

The Vibralung Acoustical Percussor and the Normal Human Sonic Environment

Inasmuch as the Vibralung Acoustical Percussor deliberately emits sound waves with a frequency range of 5 to 1,200 Hz directly into the lungs, the question of its safety, with respect to lung damage, or the appropriateness of its frequencies may arise.

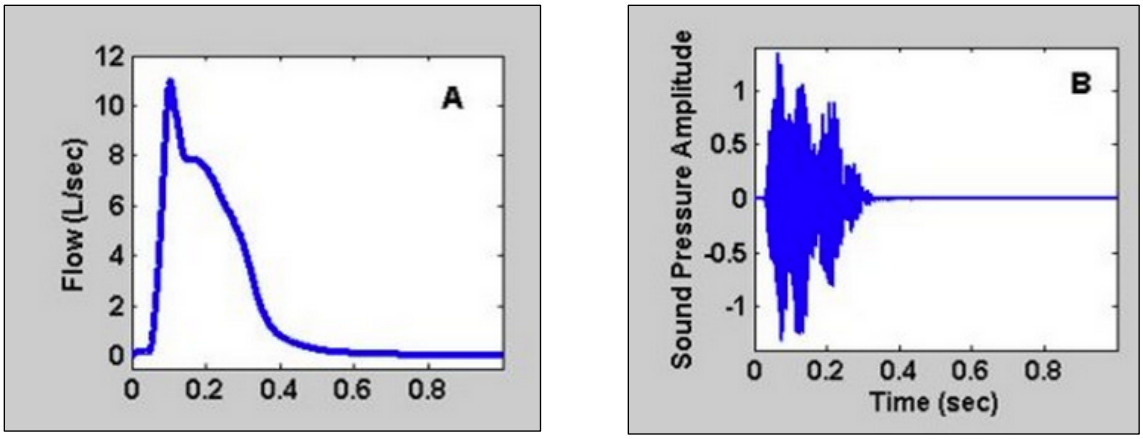
There is no evidence that the lungs will suffer any adverse effects from this therapy because the sound waves emitted by the Vibralung device are within a range of frequency and amplitude that fall within the human lung's **normal sonic environment.** Further, because the lung normally exists in a full–time sonic environment, exposing the lung to sound waves approximating the range of the human voice should not constitute a hazard.

The human lung is mechanically robust and capable of withstanding significantly high stress in the form of acoustic energy. The lung consists of three major types of structures: (1) the tracheobronchial airways (trachea, bronchi, bronchioles and alveolar ducts), (2) the lung parenchyma (elastic and alveolar tissue), and (3) blood vessels.

These structures are routinely and continually subjected to mechanical stress in the form of volume and pressure change due to breathing. Further, they are occasionally subjected to even higher amounts of mechanical stress when coughing takes place.

Coughing, which is a normal protective measure of the lung, creates exceptionally high lung pressures, often in excess of 100 mmHg, with expulsive airflow velocities as high as 500 miles per hour. High velocity gas flow, combined with dynamic airway compression, creates huge shear forces that displace mucus from the airway walls into the air stream.[1]

Coughing also produces acoustical energy (sound waves) that travel bidirectionally into the lung as well as out of the lung.[2]

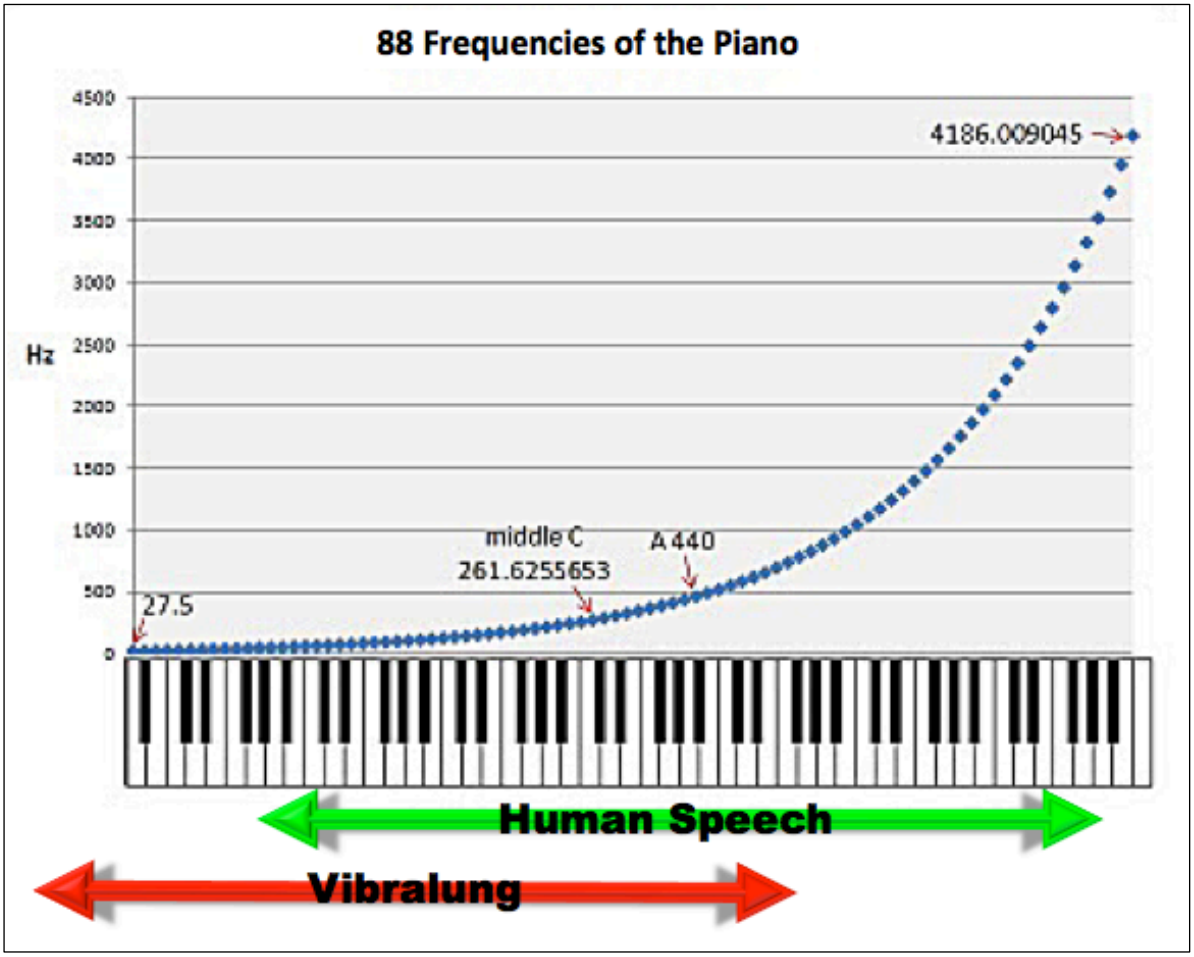


Left: High peak expiratory flow rate plotted against time (seconds) associated with coughing. Right: Bidirectional burst of sound waves associated with coughing. (From Ref. 2).

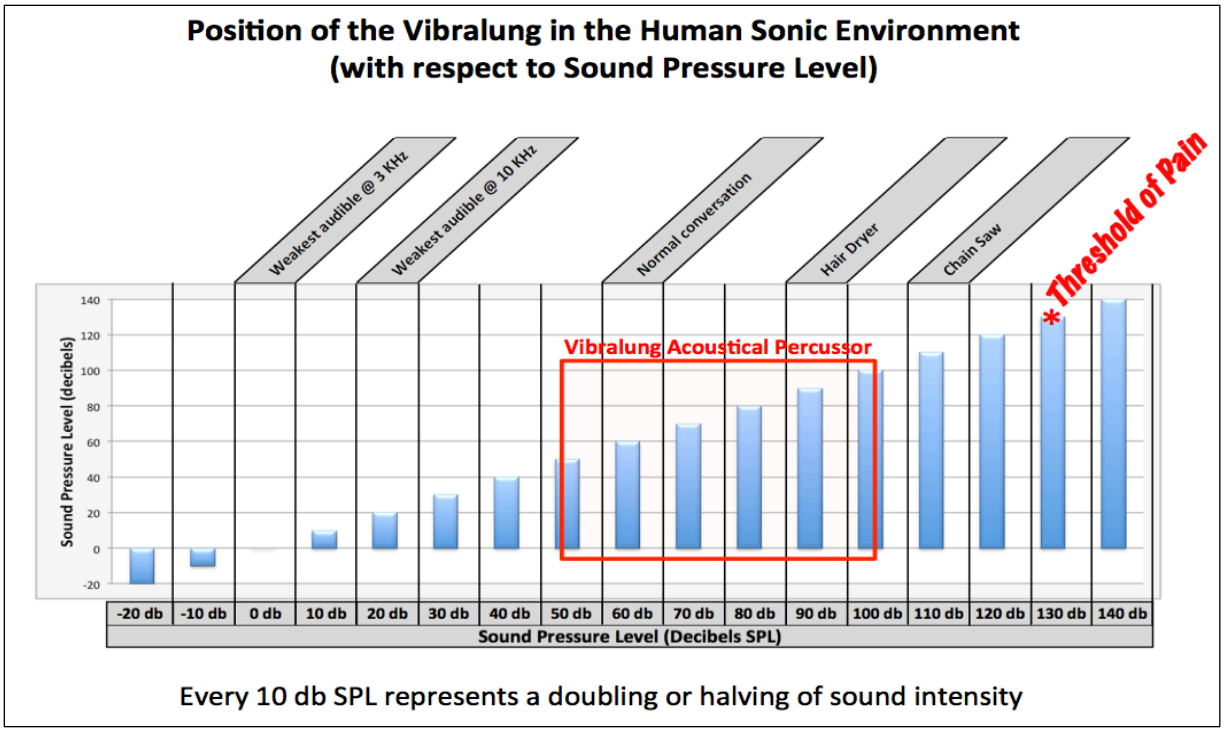
The high intensity sound associated with coughing is a normal byproduct of that physiological function and may occur many times a day. The lung is constantly being bombarded with sounds waves because it interfaces directly with the atmosphere through the nose and mouth. Further, the normal production of speech takes place in an anatomical structure that is an integral part of the human respiratory system, namely the larynx or "voice box."

The normal sonic environment of the lungs and airways is comprised of a highly diverse range of sound waves that are created endogenously in airways, lungs tissue and the larynx. Some sounds, known as "breath sounds," are created within the airways and lung tissue as a result of airflow passing through bronchial tubes, or secretions moving within the airways, or even sections of lung tissue rubbing upon itself or the internal chest wall. Lung sounds are well known to pulmonologists using the art and science of "auscultation" to listen, detect and classify them according to established principles. Lung sounds have diagnostic significance and range from very low to very high in terms of frequency. Amplitude, however, is relatively low. Exogenous sounds would be, for example, those associated with playing a musical wind instrument wherein the frequencies that are produced by blowing into the instrument are transmitted into the lung.

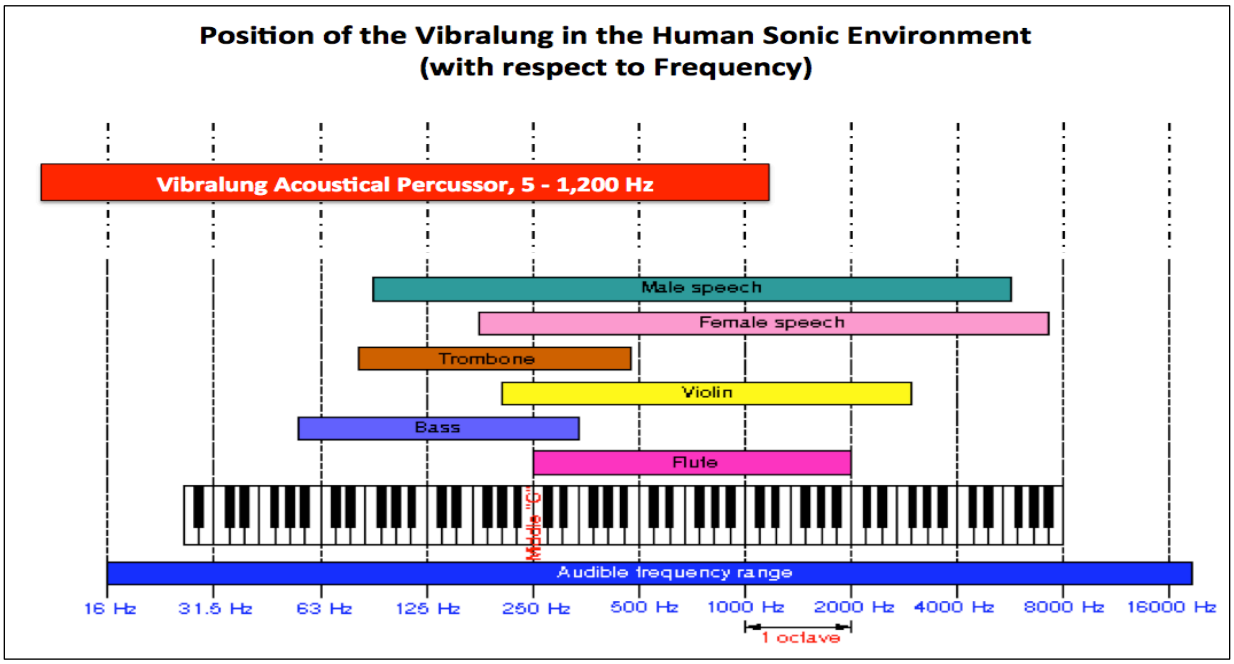
To understand the range of frequencies to which the lungs are normally exposed, let us refer to the piano as a corollary. The 88 keys on a standard piano span about 7½ octaves and range from a low frequency of 27.5 Hz (lowest A note) to a high frequency of slightly over 4,186 Hz (highest C note). Normal human speech has a frequency range of roughly 50 to 3,400 Hz, with the majority of the energy concentrated between 300 and 3,000 Hz. Trained singers can slightly exceed these limits at both ends of the range. During talking, shouting and singing, the sound waves produced by the larynx travel bidirectionally so that the lungs simultaneously receive the same sounds that are emitted through the mouth.



In terms of amplitude, normal human speech occurs at a Sound Pressure Level (SPL) of about 60 db but is capable of going as high as 100 db in untrained individuals, during activities such as shouting. Trained opera singers, singing musically acceptable notes, have been measured with vocal amplitudes as high as 120 db, while amateur singers have achieved SPL of 126 db although the notes have not been "musically acceptable."[3]

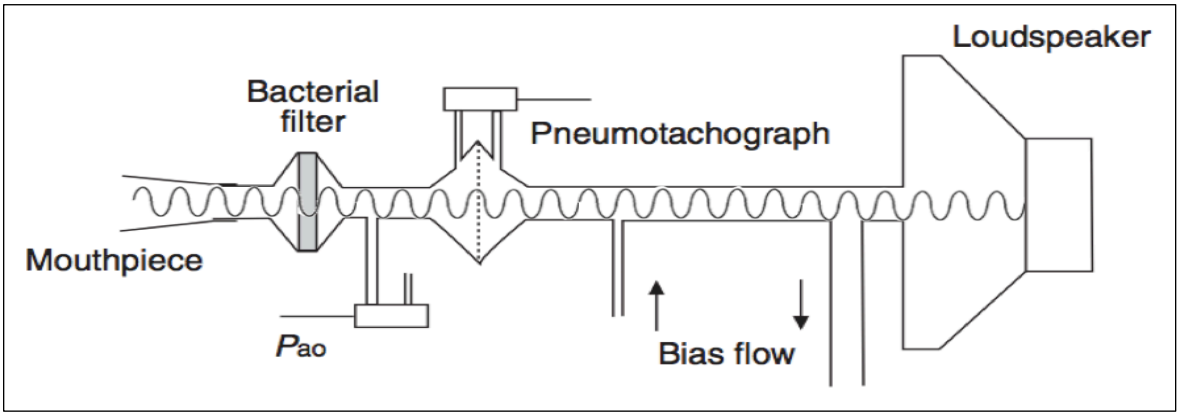


Musicians playing a variety of wind instruments, particularly brass and woodwinds (reeds), likewise expose their respiratory system to a vast range of frequencies and will couple their respiratory tract directly to the airflow pathways of those instruments. The coupling between the respiratory system and the instruments affords the opportunity for the respiratory system to experience nearly the same resonance as the instrument. Therefore, the resonance, vibration and harmonic overtones, which occur by playing instruments, are transmitted throughout the respiratory tract as well, with no ill effects.



Thus, the normal sonic environment of the human respiratory system includes frequent and prolonged exposure to frequencies as high as 3,500 Hz or greater with amplitudes up to 100 db, or higher in some circumstances. Historically, there has never been a question of respiratory system damage associated with the frequency/amplitude characteristics of phonation (speech), singing or playing of wind instruments, although spontaneous pneumothorax has been reported with certain wind instruments

Diagnostic uses of sound in pulmonary physiology. Acoustical sound has been used in pulmonary physiology for decades for diagnostic purposes. The principle procedure utilizing acoustical sound is the Forced Oscillations Technique (FOT) for measuring total respiratory impedance and/or airway resistance.[4] In this method, oscillations of sound generated by a loudspeaker are superimposed over normal respiratory breathing patterns by having the subject breathe through a special device. The FOT sound waves are a sinusoidal waveform at a frequency that may vary between roughly 5 and 30 Hz, although higher frequencies have been used. To briefly summarize a technically challenging principle of operation, changes in respiratory impedance will create phase shifts in the forced oscillations waveforms that can be measured and used to calculate impedance.



Diagnostic use of sound in pulmonary physiology. Apparatus for the Forced Oscillations Technique wherein sound waves generated by a loudspeaker are superimposed over tidal breathing, thereby exposing the patient's airway to the acoustic energy.[4]

The FOT is somewhat limited in scope because it can only measure the respiratory system as a whole, i.e., the algebraic sum of the entire system, as detected at the airway opening (mouth), rather than distinct portions of the airways (e.g., upper, middle, lower, etc.). Nevertheless, the application of acoustic sound to the respiratory system for diagnostic purposes is widely regarded as being intrinsically safe and free from adverse effects and is used in patients of all ages.

Ultrasound. Do not confuse acoustic airway sound or vibration with diagnostic sonography or medical ultrasonography ("ultrasound"). In physics, the term "ultrasound" applies to all sound waves with a frequency above the audible range of human hearing, about 20,000 Hz (20 KHz). The spectrum of frequencies employed in the Vibralung Acoustical Percussor (5 – 1,200 Hz) are within the low audible range of human hearing and are not considered ultrasound.

Diagnostic sonography (ultrasonography) is an imaging technique used for visualizing subcutaneous body structures and internal organs for possible pathology. Medical ultrasound is employed to make images of tissues and structures within the body that can either reflect or absorb ultrasound energy. Even ultrasound, which utilizes frequencies much higher than the Vibralung, is generally considered safe when used in accord with approved guidelines for exposure and with specifically approved diagnostic instruments.

Studies by the US Navy. Because of its use of underwater sonar, the US Navy has had an ongoing interest in the potential for *in vivo* tissue damage by exposure of both marine mammals and humans to underwater sound. A number of studies sought to determine the sound intensity needed to create tissue damage with frequencies between 100 and 500 Hz. This is mentioned herein because this frequency range is incorporated within the frequency range of the Vibralung Acoustical Percussor.

Aside from the obvious fact that the sonar devices operate in and under water, the characteristics of sound transmission in water are much different than in air thereby creating an even greater hazard to humans and marine mammals under water. As seen in the chart below, sound propagates over 4 times faster in water than in air.

SOUND PROPAGATION RATES	
Medium	**Velocity of Sound at 0°C (M/sec)**
Air	331
Water	1,435

In the US Navy white paper, it was stated that the intensity for the onset of transluminal (hydraulic) damage is on the order of 190 db or greater. Vascular damage thresholds from cavitation in individuals exposed to low frequency sound are in the 240 db regime. The intensity for shear tissue damage is on the order of 190 db or greater.[5]

For comparison, the SPL of the Vibralung Acoustical Percussor is shown in the following table. The highest SPL measured during a bench test with the Vibralung was 104 db at 1-inch from the mouthpiece.

Bench Test of Vibralung Sound Pressure Levels (SPL)

SPL output of the Vibralung Acoustical Percussor was measured with a sound level meter, set for the A weighting scale, in a carpeted conference room in a manufacturing plant setting. The door to the room was closed and the ambient SPL was ~50 to 60 dbA. The Vibralung Acoustical Percussor was run at RN, Low, Medium and High frequencies settings while the SPL was measured at 1-inch and 1 Meter away from the mouthpiece and the outlet port on the Variable Expiratory Resistor (VER).

		Sound Pressure Level (SPL) in dbA			
		At Mouthpiece		At VER	
		Distance from Source			
VER°	**Frequency Setting**	**1 inch**	**1 Meter**	**1 inch**	**1 Meter**
60°	Random Noise	104	74	100	72
"	Low	77	54	63	54
"	Medium	72	57	71	54
"	High	72	57	72	57
35°	Random Noise	101	72	99	70
"	Low	63	53	67	51
"	Medium	63	55	69	54
"	High	61	56	72	57
10°	Random Noise	100	70	99	70
"	Low	70	53	71	53
"	Medium	71	56	72	56
"	High	71	57	73	58

VER° = Variable Expiratory Resistor setting in “degrees open.”

The SPL at 1-inch from the source represents the SPL to which the patient’s airway opening would be exposed. The SPL at 1 Meter from the source represents the ambient “noise” level in the room adjacent to the patient. Maximum SPL measured 1-inch from the mouthpiece was 104 dbA. Maximum SPL measured at 1 Meter from the source (ambient noise level) was 74 dbA.

Airway Pressure

Under a number of different operating frequencies and settings on a mechanical test lung model, at both typical representative adult and pediatric breathing patterns, the range of pressure gradient at the mouthpiece rendered by the Vibralung Acoustical Percussor was measured.

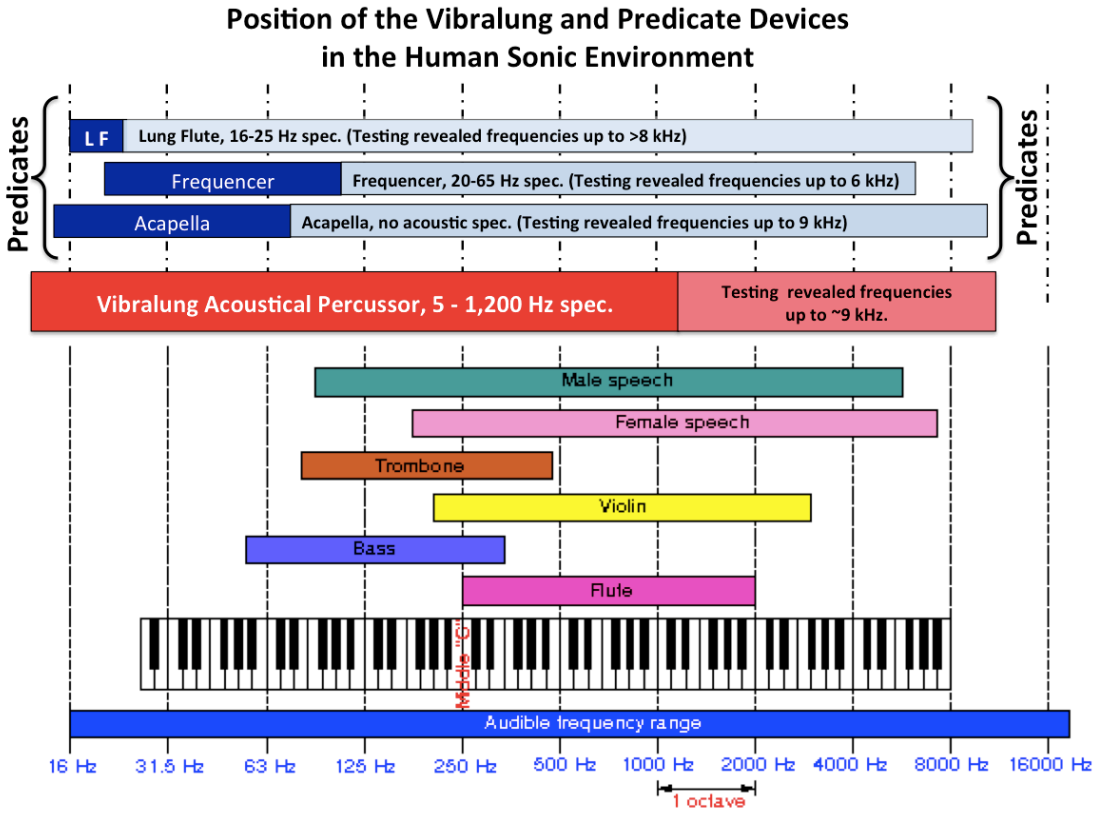
During operation without aerosol, (in other words, without the Circulaire II connected to the Hand-held Transducer), the greatest inspiratory airway pressure measured was 1.2 cmH2O for the adult breathing pattern and 0.8 cmH2O for the pediatric breathing pattern.

During operation of the Vibralung Acoustical Percussor with the Circulaire II aerosol delivery system, inspiratory airway pressure for the adult breathing pattern was no higher than 3 cmH2O while expiratory pressure was no higher than 4.0 cmH2O. For the pediatric breathing pattern maximum inspiratory and expiratory pressures were 0.8 and 0.7 cmH2O, respectively.

If elevated airway pressure is required, for example 10 to 20 cmH2O for an intentional PEP maneuver, the Westmed Variable Expiratory Resistor (VER) may be adjusted to a smaller opening than its default position of 60°. Then the patient may be coached to perform the traditional PEP maneuver. An optional PEP Manometer Assembly is available in order to measure PEP during Vibralung therapy.

Comparison to other ACT devices

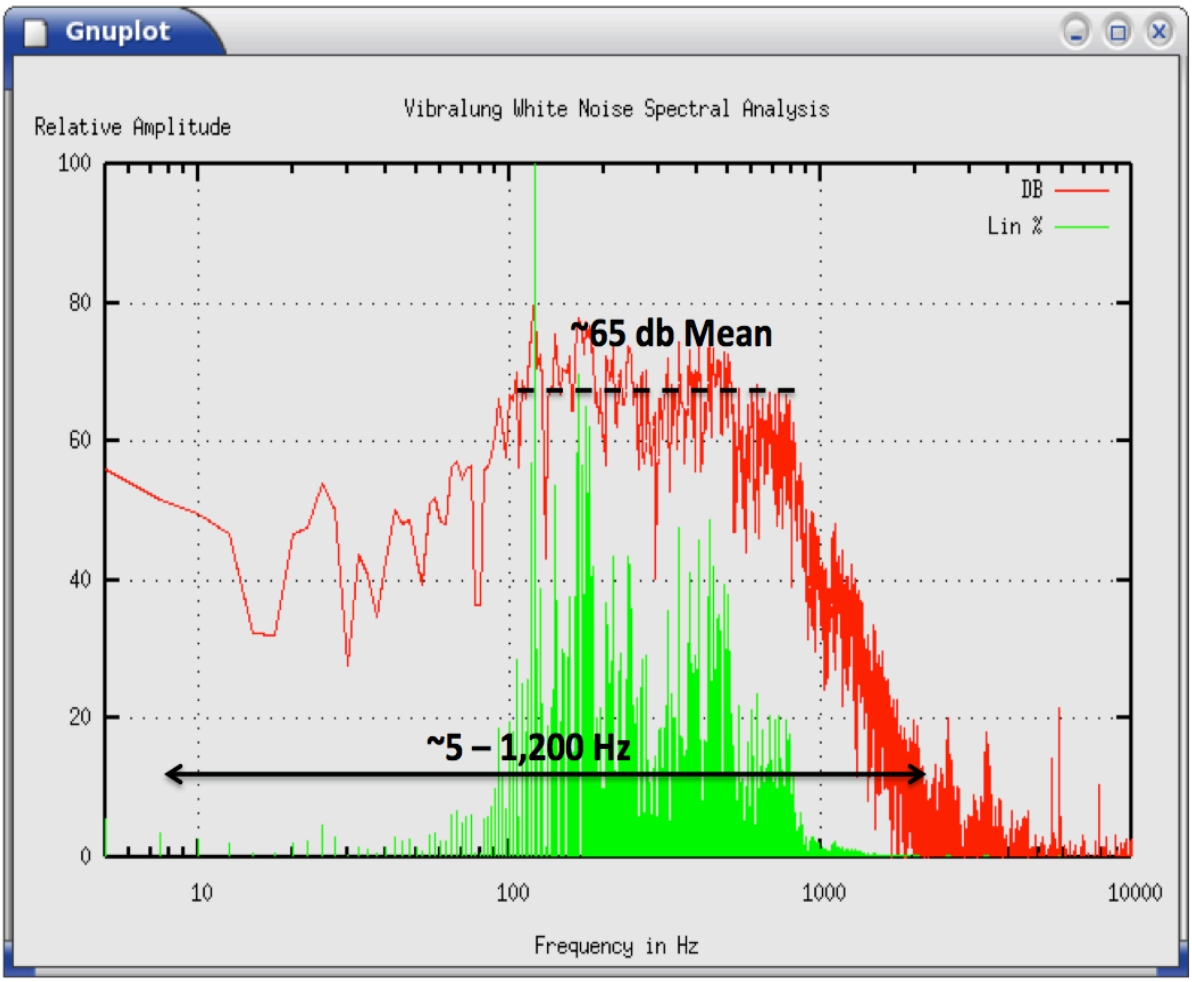
The chart below shows the normal human sonic environment with the Vibralung frequency range (in red) and the frequency ranges (in blue) of 3 predicate airway clearance devices that cause acoustic vibrations in the lungs at particular frequencies.



The frequency range of the Vibralung encompasses the same frequency range as other airway clearance therapy devices as well as portion of the frequency range of the human voice.

Spectral Analysis

When reproduced by enclosed loudspeakers, different frequencies tend to have different sound pressure levels across the spectrum. This is partially due to resonance in the loudspeaker housing as well as other parts of the system. Spectral analysis is a means of visualizing this relationship (note the logarithmic scale on the horizontal axis). In this example, a microphone was placed on the anterior chest wall of a normal subject to pick up sound emanating through it. The test subject breathed on the Vibralung through a mouthpiece. The Vibralung was set to a "random noise" mode so that all frequencies between 5 and 1,200 Hz were generated.



Spectral Analysis. Frequency in Hz is on the logarithmic X-axis, Amplitude in db is on the Y-axis.

The spectral analysis shows a varying amplitude (sound pressure level) of between ~55 db to 65 db between 5 Hz and 100 Hz. Between 100 and ~800 Hz, the sound pressure level is more "flat" and averages about 65 db with some peaks slightly above 80 db. After ~800 Hz, the sound pressure level falls off rapidly. Although the Vibralung deliberately limits generated frequency to 1,200 Hz, the spectral analysis shows frequency activity beyond 1,200 Hz due to harmonics and other sounds generated in the lungs as a result of airflow.

Sonic Environment Summary

With respect to sound wave frequency, the human lung exists in a sonic environment in which it is frequently and chronically exposed, without any resulting damage, to a multitude of acoustic frequencies that both include and exceed the range produced by the Vibralung Acoustical Percussor.

The frequency range of the Vibralung Acoustical Percussor is not unique or excessive. The frequency range of the Vibralung Acoustical Percussor encompasses the same frequency range as other airway clearance devices plus a portion of the frequency range of the human voice.

With the exception of the US Navy data, a literature search was unable to reveal any studies or evidence suggesting any possibility of lung damage due to sound waves. The US Navy studies reveal that lung damage due to sound waves is possible in extreme circumstances (underwater with sound pressure levels of 190 db or greater) but these would not pertain to the use of the Vibralung. Further, because every 10 db increase in SPL represents a doubling of sound intensity, the 190 db value cited in the US Navy study would represent a quadrupling of the sound intensity emitted by the Vibralung Acoustical Percussor. Thus, the sound levels of the Vibralung Acoustical Percussor do not approach the threshold for tissue damage.

Based upon SPL level determinations, physical pressure measurements at the airway opening and spectral analysis, the sound waves emitted by the Vibralung Acoustical Percussor do not produce high airway pressures during tidal breathing. Pressures are typically below those seen in some of the oscillatory PEP devices and, in particular, the Intrapulmonary Percussive Ventilation (IPV) devices. Further, the frequencies utilized are intrinsically safe and the sound pressure levels at the airway opening are far below the threshold for lung or airway damage

The conclusion of this analysis is that the sound level to which the lungs are exposed is well within safe limits and is actually below the level that is considered likely to produce hearing loss (85 db continuous).

References

1. Irwin RS, Boulet L-P, Cloutier MM, et al. Managing cough as a defense mechanism and as a symptom: A consensus panel report of the American College of Chest Physicians. Chest 1998; 114(2) Suppl 133S-181S.

2. Abaza AA, Day JB, Reynolds JS, et al. Classification of voluntary cough and airflow patterns for detecting abnormal pulmonary function. Cough. 2009 Nov 20;5:8.

3. Coleman RF, Mabis JH, Hinson JK. Fundamental frequency-sound pressure level profiles of adult male and female voices. J Speech Hearing Research 1977; 20(6): 197-204.

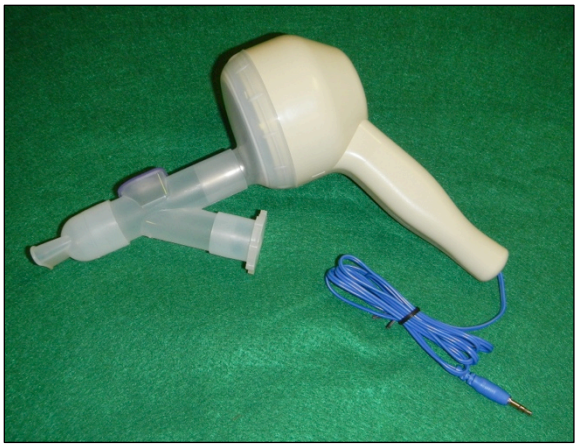
4. Oostveen E, MacLeod D, Lorino H, et al. The forced oscillation technique in clinical practice: methodology, recommendations and future developments. Eur Respir J 2003; 22: 1026-1041.

5. Cudahy E, Ellison WT. A review of the potential for *in vivo* tissue damage by exposure to underwater sound. White Paper, 2002. Department of the Navy, Naval Submarine Research Laboratory, Groton CT.

SECTION 2 – INSTRUCTION MANUAL for HEALTHCARE PROFESSIONALS

Components of the Vibralung Acoustical Percussor

Two major component parts make up the basic Vibralung Acoustical Percussor:



Left: Treatment Control Unit (TCU); Right: Hand-held Transducer (HHT) with Standard Y-adapter, Variable Expiratory Resistor and mouthpiece attached.

Unpacking and Preparing the Vibralung Acoustical Percussor for First Use

Refer to these drawings for identification of other components:

The Vibralung Acoustical Percussor is packaged in two cartons. One carton contains the reusable TCU and associated accessories and the other contains the disposable HHT assembly with mouthpiece, two different Y-adapters and Variable Expiratory Resistor

Vibralung Patient Kit. Top, Left to Right: Cone, Mouthpiece, Hand-Held Transducer (HHT).
Bottom, Left to Right: Standard Y-adapter with Variable Expiratory Resistor, Aerosol Y-adapter.

Steps. Follow these steps to unpack, test and set up the Vibralung Acoustical Percussor:

1. Remove the TCU and electrical transformer (battery charger) from their shipping carton.
2. Optionally, mount the TCU on any pole between ¾ and 1¼ inch in diameter using the optional pole-mounting bracket as shown in the figure below.
3. Plug the charger into an electrical outlet and into the TCU. Charge the TCU's internal batteries until fully charged (which should take no more than 4 hours). All 9 Light Emitting Diodes (LEDs) should flash 3 times quickly and then the Charging and Power LEDs should remain illuminated during the charging process. Disconnect charger after batteries are charged, as the TCU will not operate while the charger is connected.
4. After charging is complete, perform a Power On Self Test (POST) to verify that the TCU software and processor is operating properly: Turn the TCU on by pressing the Power control button once. The POST will occur immediately as evidenced by all 9 LEDs flashing 3 times. If the TCU passes the POST, the Pause and Power LEDs will remain illuminated. If other LEDs are illuminated, or if no LEDs are illuminated, the TCU failed the POST and should not be used.
5. Remove the HHT and cable from the shipping carton and connect the HHT to the TCU. Straighten the cable to eliminate kinks and plug the cable coming out of the bottom of the HHT handle into the jack located on the left side of the TCU.
6. Attach the appropriate Y-adapter:
   a. For EMAAC therapy ***without simultaneous aerosol therapy***, attach the "Standard Y- adapter" to the Cone of the HHT as shown in the top figure on page 18. The mouthpiece and Variable Expiratory Resistor is already attached.

      Note: The "Standard Y-adapter" is the one with the small square purple cap on the inspiratory valve housing located on the longer limb of the Y with the mouthpiece and Variable Expiratory Resistor already attached. The Vibralung may now be used in this configuration.

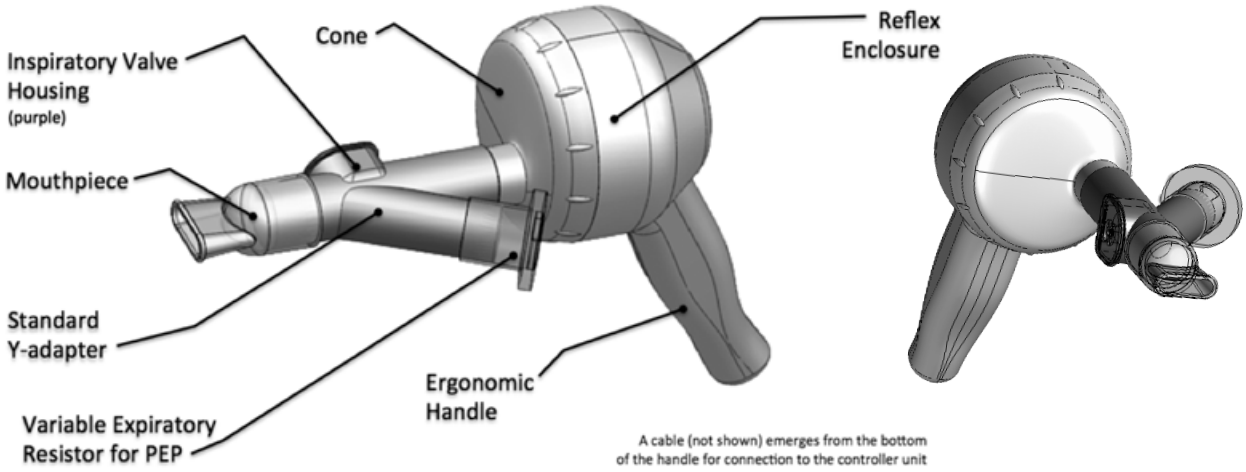
   b. For EMAAC therapy ***with simultaneous aerosol therapy***, attach the "Aerosol Y-adapter" to the Cone of the HHT as shown in the bottom figure on page 17.

      Note: The "Aerosol Y-adapter" is the plain one without any attachments or the aforementioned "square purple cap." It is for use with the Westmed Circulaire II *Hybrid* Aerosol Drug Delivery device and the HHT. The Circulaire II *Hybrid* may be attached as shown on page 18.
7. Orient the TCU so that it is easily accessible while leaving a small amount of slack on the cord between the TCU and the HHT.

Vibralung Acoustical Percussor Treatment Control Unit (TCU) mounted with the supplied pole-mount slide bracket and optional pole-mount clamp.

The Vibralung Acoustical Percussor may be assembled in two configurations only. The default configuration is shown below. Connect the long end of the Standard Y-adapter to the cone. The mouthpiece should be at the opposite end and the Variable Expiratory Resistor should be on the tail of the Y. The outlet port of the cone should approximate the 3 o'clock position as you are facing it, as shown in the "user's view" inset drawing below:

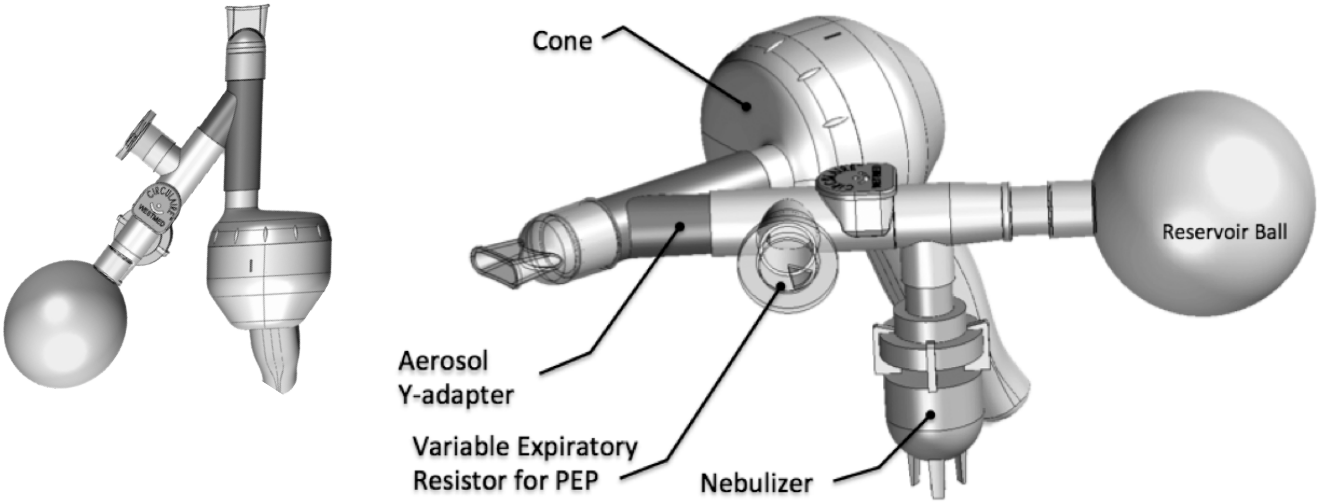
User's view,
"3 o'clock" alignment



HHT with "Standard Y-adapter," configured for use without aerosol therapy.

If simultaneous aerosol therapy is required, obtain and attach the Circulaire II *Hybrid* aerosol delivery system as shown below. Remove the Standard Y-adapter, replace with the Aerosol Y-adapter, and transfer the mouthpiece to the Aerosol Y-adapter. Insert the Circulaire II *Hybrid* aerosol delivery system on to the tail of the Aerosol Y-adapter. The outlet port of the cone should approximate the 3 o'clock position as you are facing it as shown in the "bird's eye view" inset drawing below:

Bird's eye view,
"3 o'clock" alignment



HHT with "Aerosol Y-adapter," configured for use with the Circulaire II *Hybrid* aerosol delivery system.

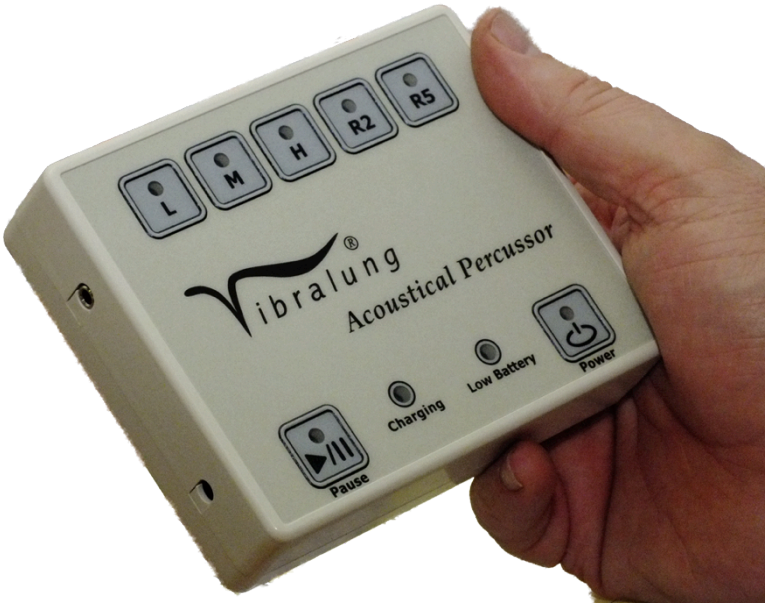
Patient Positioning. One optimal position for taking a Vibralung treatment is sitting straight up in a chair, if possible. Such a position allows the lungs to ventilate optimally and positions the patient in an ideal position to cough and expectorate. However, other positions are not necessarily contraindicated. Patients have reported taking treatments in a recumbent position, lying on one side for 10 minutes and then switching to the other side for 10 minutes, in order to favor the uppermost lung. Patients and therapists should feel free to evaluate alternative positions based upon the patient's perception of therapeutic benefit and ability to cough and expectorate in a given position.

Proper positioning of patient and HHT during EMAAC therapy with Vibralung Acoustical Percussor.

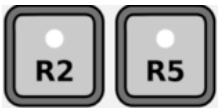
Adults may hold the HHT in many different acceptable ways.

Buttons and Settings on the Treatment Control Unit

The TCU has 7 user-selectable buttons that illuminate when activated. The buttons provide tactile feedback when they are pressed. These buttons enable the user to select from 5 control settings as shown in the legend below, as well as a "Start/Pause" function and Power On/Off. Additionally, two LED indicators ("Charging" and "Low Battery") illuminate as needed to show the status of the internal battery.



Front panel of Vibralung Acoustical Percussor, Treatment Control Unit, showing mode selection buttons on the top row, Pause and Power (on/off) buttons and indicators on the bottom row plus connector jacks on left side.

Button Label	Action
	Control button to select "Low" frequency setting (5 – 350 Hz). Also use to select "Treatment Hold" during Low Frequency mode.
	Control button to select "Medium" frequency setting (5 – 660 Hz). Also use to select "Treatment Hold" during Medium Frequency mode.
	Control button to select "High" frequency setting (5 – 1,200 Hz). Also use to select "Treatment Hold" during High Frequency mode.
	Control buttons to select a 2- or 5-minute period of Random Noise.
	Control button to Start, Pause or Resume a treatment session.
	Control button to turn the TCU on or off.

Operating Instructions

Refer to physician's or caregiver's prescription or instructions for appropriate settings for the Vibralung Acoustical Percussor.

Regardless of which Y-adapter is used, operation of the Vibralung Acoustic Percussor is the same. The patient should hold the device in one or both hands while inserting the mouthpiece into the mouth and breathing normally throughout the treatment.

1. **Power**. To power on the TCU, disconnect it from the charger, plug the HHT into it, then press the Power button.

    - The LEDs embedded in the Power and Pause buttons flash 3 times and remain illuminated when the TCU passes its Power On Self Test (POST).
    - The Unit is in Pause mode upon powering on.
    - The Low Battery LED illuminates if the battery needs recharging.

2. **Mode Selection.** To select and activate a setting, press one of the 5 setting buttons in the top row (L, M, H, R2 or R5). The LED embedded in the selected setting button illuminates.

    a. Press the Pause button to activate the device and emit sound at the selected setting. The LED embedded in the Pause button extinguishes.
    b. Unless stopped, paused, or held (see #5 Treatment Hold below), the unit will operate at the selected setting for 10 minutes and then terminate.
    c. Press the Pause button at any time while activated to pause the session. The LED embedded in the Pause button illuminates.
    d. Press the Pause button while paused to resume the session. The LED embedded in the Pause button extinguishes.
    e. If a paused session is not resumed within 2 minutes by pressing the Pause button again, the session automatically terminates.
    f. Important: If a different treatment mode is desired <u>before</u> the currently selected mode has terminated, it is necessary to power the TCU off, then power it on again and select the desired mode.

3. **Resume, Terminate, Repeat.** To resume an automatically terminated session, or repeat a session with the same settings, or start a different session with different settings, repeat steps 1 and 2 above and select the appropriate settings.

4. **Treatment Mode.** To initiate treatment, the patient should place the mouthpiece in his or her mouth and seal their lips around it just tightly enough to maintain a comfortable seal. The teeth may rest gently on the mouthpiece but the patient should be cautioned to not bite down or chew on the soft plastic mouthpiece.

5. **Treatment Hold.** The patient has the option to hold the therapy for up to 2 minutes. This may be indicated if the patient perceives a point in time that the treatment feels especially beneficial. The treatment hold is applied by pressing and releasing the mode button (L, M, or H) that is currently selected. The treatment hold will be indicated by the blinking LED embedded in the Power button. The treatment hold may be discontinued before the 2 minutes has expired by again pressing and releasing the mode button that is currently selected. The LED embedded in the Power button will stop blinking. Treatment hold time will be added to total treatment time.

6. **Patient Position.** Avoid recumbent patient positioning when first using the Vibralung Acoustical Percussor. Patient should be sitting upright or at no more than a 30° recumbent angle to facilitate coughing and expectoration. Other positions may be used when the patient becomes more familiar with the device.

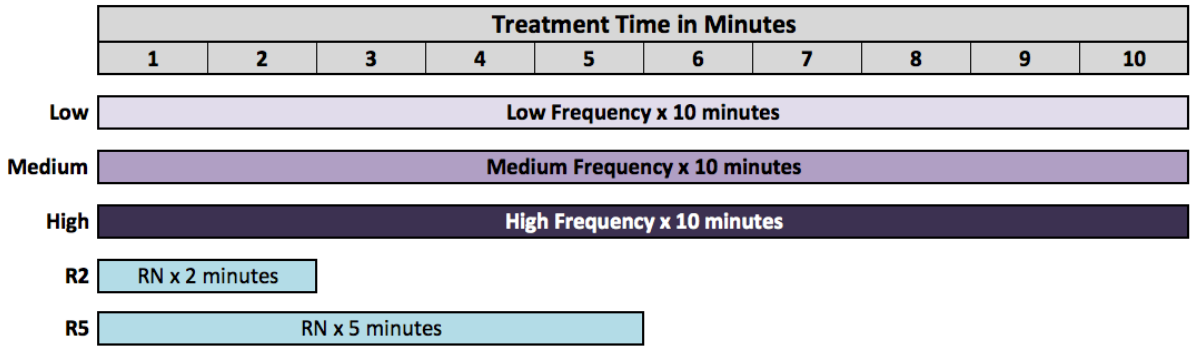
7. **Breathing Pattern.** The patient should breathe normally during treatment. As with any breathing treatment, alveolar hyperventilation may result in dizziness or light-headedness. The treatment may be paused at any time and resumed within 2 minutes if the patient needs to rest.

8. **Positive Expiratory Pressure (PEP) Therapy.** Adjust the Variable Expiratory Resistor to apply PEP during resting breathing. Minimal PEP is applied when the orifice is wide open (60°) and maximal PEP when the orifice is at the minimal position (10°). An optional PEP manometer is available so that PEP levels can be monitored. Minimal PEP levels will be observed during quiet tidal breathing due to relatively low respiratory flowrates. If desired, the patient may be instructed to perform an extended PEP maneuver by taking a deep breath and exhaling slowly while maintaining an expiratory flowrate sufficient to keep the PEP manometer in the 10 to 20 cmH2O pressure range for 3 to 5 seconds. This maneuver can be repeated as often as prescribed for the patient.

Treatment Protocol

A selected treatment setting with the Vibralung Acoustical Percussor takes up to 10 minutes, depending upon the setting that has been selected, and provided the session has not been paused at any time.

Five settings, representing a designated sequence of frequency ranges (Low, Medium, High and Random Noise (R), have been coded into the signal generator portion of the Treatment Control Unit as shown in the following table:



As seen in the chart above, the treatment times for the Low, Medium and High frequency settings are 10 minutes each. However, if the Treatment Hold feature is used, any additional Treatment Hold time will be added to the total treatment time. Two additional settings for brief sessions of Random Noise only, 2 minutes and 5 minutes, are also available for supplemental use.

A single frequency setting may be selected for a single treatment session, or two or more settings may be conducted sequentially, in which case total treatment time is additive. Frequency settings may be selected depending upon the target airways to which therapy should be directed, patient preference and patient response to therapy. In accord with the principles of acoustic resonance, lower frequency tones may be effective on larger, wider airways while higher frequency tones may be effective on smaller, thinner airways. It may therefore be appropriate to start with Low Frequency Tones first to clear larger airways, and then progress to Medium Frequency and/or High Frequency Tones to gradually target smaller airways. For example, Low Frequency followed by Medium Frequency, or Medium Frequency followed by High frequency.

Typically, the Vibralung Acoustical Percussor treatment regimen may consist of 2 to 4 treatments daily, depending on severity of disease and patient tolerance. Factors such as the patient's comfort level, degree of dyspnea (if any), sputum production, cough frequency, cough difficulty and cough productivity may also influence that decision.

It is important to remember that therapeutic benefit may not necessarily be rendered on the first treatment, or even the first few treatments. It may require an indeterminate number of treatment sessions before benefits become apparent. Therefore, tracking of treatment times, settings and sputum production and characteristics may be a useful method of gauging patient response over time.

Simultaneous Aerosol Therapy

The Circulaire II *Hybrid* aerosol delivery device may be coupled with the Vibralung Acoustical Percussor if wetting agents or inhalation medications are prescribed. The Circulaire II *Hybrid* is the only nebulizer system cleared for use with the Vibralung Acoustical Percussor. The Vibralung includes an Aerosol Y-adapter that allows interfacing the Circulaire to the HHT, as shown in the bottom figure on page 18.

The Circulaire II *Hybrid*, when coupled with the Vibralung Acoustical Percussor via the Aerosol Y-adapter, provides a pathway for inhalation and exhalation with minimal mechanical dead space, while the Aerosol Y-adapter provides a straight and unimpeded waveguide for the sound waves to travel through. In this manner, the acoustical energy remains coupled to the patient's airway during inhalation and exhalation.

Further, Positive Expiratory Pressure (PEP) can also be administered by way of the Circulaire II, which has a Variable Expiratory Resistor on the exhalation port.

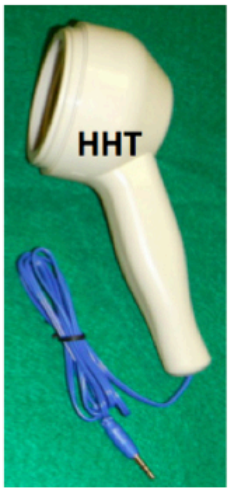
Finally, because many of the patients who may benefit from ACT and simultaneous aerosol therapy via the Vibralung Acoustical Percussor also have pulmonary infections, an exhalation filter is included in the exhalation pathway of the Circulaire to prevent fugitive medications and patient droplets from being emitted into the room and possibly inhaled by caregivers, other patients or family members.

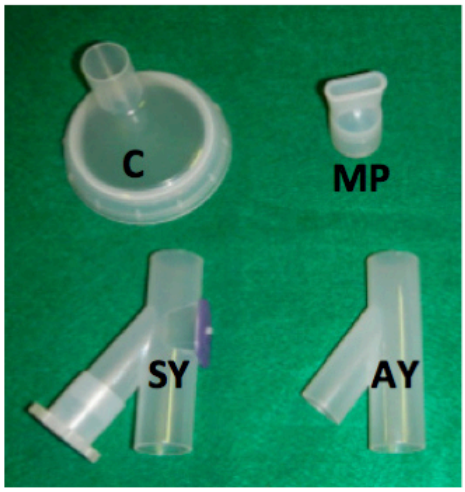
WARNING – Do not connect or interface the Vibralung Acoustical Percussor to any other airway clearance device or aerosol delivery system other than the Westmed Circulaire II or Circulaire II *Hybrid* aerosol drug delivery system and/or Westmed Variable Expiratory Resistor for Positive Expiratory Pressure (PEP) because other devices have not been specifically designed or ascertained to function properly with the inspiratory and expiratory gas flow pathways of the Vibralung Acoustical Percussor. {This part is taken from the System IFU and repeated here for consistency}

Cleaning and Care Instructions

Westmed recommends that principles and practices related to cleaning and disinfection of nebulizers and related respiratory equipment, as published in the "Infection Prevention and Control Guidance for Cystic Fibrosis: 2013 Update,"[1] be followed to the greatest extent possible by hospitals, durable medical equipment (DME) dealers and home-care patients when using the Westmed Vibralung® Acoustical Percussor for airway clearance therapy. Accordingly, this document outlines cleaning and disinfection techniques for Westmed airway clearance and aerosol delivery products that are consistent with those guidelines.

Part I - Vibralung Parts Identification (referred to in subsequent cleaning instructions)





Left to right: Treatment Control Unit (TCU), Hand-Held Transducer (HHT), and Daily Charge Kit comprised of the following parts: C – Cone, MP – Mouth-piece, SY – Standard Y-adapter (with inspiratory valve and PEP resistor, and AY – Aerosol Y-adapter.

---

1. Treatment Control Unit (TCU). The TCU is a reusable medical device that must be properly maintained to prevent infection, worsening of existing infection, or cross-infection.

2. Hand-Held Transducer (HHT). The HHT is a single-patient use disposable device that is designed to be used for the duration of a patient's hospital stay (but not to exceed 30 days in the hospital), or for 6 months in the home. It is supplied non-sterile and is not warranted against damage due to falls or misuse.

3. Daily Change Kit. The Daily Change Kit contains the disposable parts that interface the HHT to the patient's mouth. These inexpensive parts may be discarded at intervals as short as every 24 hours.

4. Optional Circulaire II or Circulaire II Hybrid Aerosol Drug Delivery System. The Circulaire II or Circulaire II *Hybrid* is a high-efficiency aerosol drug delivery system that may be used in conjunction with the Vibralung Acoustical Percussor to provide concomitant aerosol therapy with isotonic saline, hypertonic saline or specific nebulizer solutions.

Part II - Instructions for Cleaning & Disinfection in the Hospital

1. Treatment Control Unit (TCU)

In general, the TCU should undergo surface disinfection:

- ideally, after each treatment
- after the last treatment of the treatment day
- if it should become contaminated with sputum or bodily fluids
- when it is moved from one patient to another

Surface disinfection technique for the TCU:
Clean all external surfaces of the TCU with a hospital-approved pre-moistened germicidal wipe or cloth product containing dimethyl-benzyl-ammonium chloride and/or dimethyl-ethylbenzyl-ammonium chloride (for example, CaviWipes™, Super Sani Cloth® Germicidal Wipes, Clorox® Disinfecting Wipes, Lysol® Wipes or equivalent). Note: Clorox® Disinfecting Wipes do not contain sodium hypochlorite (bleach).

Wipe surface to be disinfected, i.e., the TCU. Be sure to allow the appropriate contact time as specified by the product's instructions; use enough wipes for treated surface to remain visibly wet for at least 4 minutes. Take care that liquid does not enter the case of the TCU at the seams or at the two electrical ports (battery charger and HHT) on the side of the TCU. The control buttons on the faceplate are sealed against moisture entry. Allow surface to air-dry completely before handling again.

2. Hand-Held Transducer (HHT)

In general, the HHT should undergo surface disinfection:

- ideally, after each treatment
- after the last treatment of the treatment day
- if it should become contaminated with sputum or bodily fluids

Westmed recommends that the HHT undergo surface disinfection after each treatment. In addition, if the device should become contaminated with sputum or bodily fluids, it should be disinfected immediately. The disposable cone that attaches to the HHT with a screw-on thread is designed with an internal diaphragm that will protect the speaker element of the HHT in the event that a patient expectorates sputum directly through the mouthpiece. When the device is discontinued from use on a patient, the entire HHT should be immediately discarded as it is labeled as a single-patient use device for the hospital.

Surface disinfection technique for the HHT:
Clean all external surfaces of the HHT with a hospital-approved pre-moistened germicidal wipe or cloth product containing dimethyl-benzyl-ammonium chloride and/or dimethyl-ethylbenzyl-ammonium chloride (for example, CaviWipes™, Super Sani Cloth® Germicidal Wipes, Clorox® Disinfecting Wipes, Lysol® Wipes or equivalent). Wipe surface to be disinfected, i.e., the handle and casing of the HHT. Take care not to contact the speaker as it may be punctured. Be sure to allow the appropriate contact time as specified by the product's instructions; use enough wipes for treated surface to remain visibly wet for at least 4 minutes. Allow surface to air-dry completely before handling again.

3. Daily Change Kit

The #9640 Daily Change Kit contains one each of the following disposable parts:

- Cone
- Standard Y-adapter (with inspiratory valve)
- Aerosol Y-adapter (no inspiratory valve)
- Variable Expiratory Resistor for PEP
- Mouthpiece

When used for patients with Cystic Fibrosis, the Daily Change Kit is intended to be used for no more than a single day *in the hospital*. Optionally, if the hospital believes it to be warranted, the Daily Exchange Kit could be used once and then discarded.

Surface disinfection technique for the Daily Exchange Kit:
Clean all external surfaces of the Cone, Y-adapter, Variable Expiratory Resistor and Mouthpiece with a pre-moistened alcohol pad or wipe after each treatment. Place on a clean surface, such as a fresh, dry paper towel, and allowed to air dry. Remove from the HHT and discard all component parts of the Daily Exchange Kit after the last treatment of the day.

4. Optional Circulaire II or Circulaire II Hybrid Aerosol Drug Delivery System.

After each treatment, the VixOne nebulizer should be removed from the manifold of the Circulaire device and cleaned and disinfected according to hospital policy. Alternately, the residual medication should be discarded, and the nebulizer rinsed out with sterile water and placed on a fresh, dry paper towel and allowed to air dry.

At the end of the treatment day, the VixOne nebulizer should be removed from the manifold of the Circulaire device after each treatment and the residual medication discarded. Next, the external parts of the Circulaire system, including the mouthpiece, should be wiped with a pre-moistened alcohol pad or wipe and set aside to dry.

The VixOne nebulizer parts should be disinfected using one of the following cold methods approved by the CFF:

a. Soak in 70% isopropyl alcohol for 5 minutes
b. Soak in 3% hydrogen peroxide for 30 minutes

Then, rinse off the cold-method disinfectant using sterile or ≦0.2 micron filtered water, not tap water. Then place the rinsed parts on a fresh, dry paper towel and allow to air dry, taking care to not contaminate the inside parts of the nebulizer while moving them.

Alternately, the entire Circulaire II system can be discarded and replaced on a daily basis, as long as the VixOne nebulizer is properly cleaned in between treatments and discard at the end of the treatment day.

Part III - Instructions for Cleaning & Disinfection in the Home

1. Treatment Control Unit (TCU)

Westmed recommends that the TCU undergo surface disinfection after every treatment.

Surface disinfection technique for the TCU:
Clean all external surfaces of the TCU with a hospital-approved pre-moistened germicidal wipe or cloth product containing dimethyl-benzyl-ammonium chloride and/or dimethyl-ethylbenzyl-ammonium chloride (for example, CaviWipes™, Super Sani Cloth® Germicidal Wipes, Clorox® Disinfecting Wipes, Lysol® Wipes or equivalent). Note: Clorox® Disinfecting Wipes do not contain sodium hypochlorite (bleach).

Wipe surface to be disinfected, i.e., the TCU. Be sure to allow the appropriate contact time as specified by the product's instructions; use enough wipes for treated surface to remain visibly wet for at least 4 minutes. Take care that liquid does not enter the case of the TCU at the seams or at the two electrical ports (battery charger and HHT) on the side of the TCU. The control buttons on the faceplate are sealed against moisture entry. Allow surface to air-dry completely before handling again.

2. Hand-Held Transducer (HHT)

The HHT is a single-patient use disposable device that is designed to be used for 6 months *in the home*. It is supplied non-sterile and is not warranted against damage due to falls or misuse. In general, Westmed recommends that the HHT should undergo surface disinfection after each treatment, at the same time as the TCU is being disinfected.

Surface disinfection technique for the HHT:
Clean all external surfaces of the HHT with a pre-moistened germicidal wipe or cloth product containing dimethyl-benzyl-ammonium chloride and/or dimethyl-ethylbenzyl-ammonium chloride, such as but not limited to, Clorox® Disinfecting Wipes or equivalent product. Note: Clorox® Disinfecting Wipes do not contain sodium hypochlorite (bleach).

Wipe surface to be disinfected, i.e., the HHT. Be sure to allow the appropriate contact time as specified by the product's instructions; use enough wipes for treated surface to remain visibly wet for at least 4 minutes. Take care not to contact the speaker forcibly as doing so may puncture it. Let surface dry.

3. Daily Change Kit

The #9640 Daily Change Kit contains one each of the following disposable parts:

- Cone
- Standard Y-adapter (with inspiratory valve)
- Aerosol Y-adapter (no inspiratory valve)
- Variable Expiratory Resistor for PEP
- Mouthpiece

When used for patients with Cystic Fibrosis at home, the Daily Change Kit, while intended to be used for no more than a single day *in the hospital*, may be used for a single day or multiple days, up to one week, *in the home*, provided that it is appropriately cleaned after each treatment.

Surface disinfection technique for the Daily Exchange Kit:
Clean all external surfaces of the Cone, Y-adapter, Variable Expiratory Resistor and Mouthpiece with a pre-moistened alcohol pad or wipe after each treatment. Place on a clean surface, such as a fresh, dry paper towel, and allow to air dry. Remove from the HHT and discard all component parts of the Daily Exchange Kit after the last treatment of the day.

Alternately, the Cone, Y-adapter, Variable Expiratory Resistor and Mouthpiece can be cleaned according to the instructions for the VixOne nebulizer listed below.

4. Optional Circulaire II or Circulaire II Hybrid Aerosol Drug Delivery System.

The Circulaire II or Circulaire II *Hybrid* is a high-efficiency aerosol drug delivery system that may be used in conjunction with the Vibralung Acoustical Percussor to provide concomitant aerosol therapy with isotonic saline, hypertonic saline or specific nebulizer solutions.

After each treatment, the Circulaire mouthpiece should be wiped with a pre-moistened alcohol pad or wipe. The VixOne nebulizer should be removed from the manifold of the Circulaire device, the residual medication discarded, and the nebulizer rinsed out with sterile water and placed on a fresh, dry paper towel and allowed to air dry.

At the end of the treatment day, the VixOne nebulizer should be removed from the manifold of the Circulaire device after each treatment and the residual medication discarded. Next, all remaining parts of the Circulaire system (including the reservoir ball and the VixOne nebulizer) should be disassembled and cleaned with dish soap and water. All parts except the nebulizer should be rinsed in tap water and placed on a fresh, dry paper towel and allowed to air dry. The reservoir ball may be stood upright on its flange for drainage and then laid on its side for air-drying.

The VixOne nebulizer parts should be disinfected using one of the following cold methods approved by the CFF:

a. Soak in 70% isopropyl alcohol for 5 minutes
b. Soak in 3% hydrogen peroxide for 30 minutes

Then, rinse off the cold-method disinfectant using sterile or ≦0.2 micron filtered water, not tap water. Then place the rinsed parts on a fresh, dry paper towel and allow to air dry, taking care to not contaminate the inside parts of the nebulizer while moving them.

If pre-packaged sterile or filter water is unavailable, use water that has boiled for 1 minute and allowed to cool to rinse off residual chemicals.

> ***Important Note:*** *The plastics used for the Vibralung Acoustical Percussor and Circulaire II aerosol delivery systems are not designed to withstand the high temperatures (~ 212° F / 100° C) associated with use of heat or steam disinfection methods (boiling, baby bottle sterilizers, or microwavable steam bags). Some or all of the parts may deform when exposed to these temperatures. However, the reusable VixOne nebulizer (purple cap and purple-tinted cup) may be placed in most household dishwashers without damage.*

Guidance from the Cystic Fibrosis Foundation

The following information is extracted from the 2013 Update:[1]

Care of Nebulizers in the Hospital

47. The CF Foundation recommends the following:

a. Nebulizers are for single-patient use only
b. Aseptic technique is always followed when handling the nebulizer and dispensing medications
c. Single-dose vials of medication used in nebulizers are always preferred
d. Handheld *disposable* nebulizers are managed as follows:

i. *After each use*, rinse out residual volume with sterile water and wipe mask/mouthpiece with an alcohol pad
ii. Discard the nebulizer every 24 hours

e. Handheld *reusable* nebulizers (eg, home equipment) are managed as follows:

i. *After each use*, clean, disinfect, rinse with sterile water (if applicable, following cold disinfection method), and air dry away from sink
ii. *After each use*, the nebulizer can be reprocessed (eg, by steam sterilization) if the reprocessing is performed according to the manufacturer's instructions and the CF Foundation recommendations for home care (rec. 59) and if the nebulizer can be returned to the patient in time for the next treatment

Source of supporting evidence: 2003 CF IP&C guideline, *Category II*; 2003 pneumonia guidelines, *Category IB*; 2008 sterilization and disinfection guidelines, *Category IB*
2013 CF IP&C guideline consensus: 100%
Sections in the text: III.D.2; IV.E.2

Nebulizers: Cleaning and Disinfecting

59. The CF Foundation recommends that the following steps be performed for nebulizers used in the home as soon as possible after each use:

a. *Clean* the nebulizer parts with dish detergent soap and water
b. *Disinfect* the nebulizer parts using *one* of the following methods:

Heat methods:

a. Place in boiling water and boil for 5 minutes
b. Place in a microwave-safe receptacle submerged in water and microwave for 5 minutes
c. Use a dishwasher if the water is more than or equal to 70° C or 158° F for 30 minutes
d. Use an electric steam sterilizer

Cold methods:

a. *Soak* in 70% isopropyl alcohol for 5 minutes
b. *Soak* in 3% hydrogen peroxide for 30 minutes

i. *Rinse* off the cold-method disinfectant using sterile water, not tap water; the *final rinse* must be with sterile or filtered (less than or equal to 0.2-micron filter) water
ii. *Air dry* the nebulizer parts before storage

Source of supporting evidence: 2003 CF IP&C guideline, *Category II*
2013 CF IP&C guideline consensus: 100%
Sections in the text: III.D.1; IV.E.3

60. The CF Foundation recommends that nebulizers used in the home should *not* be disinfected with acetic acid (vinegar), bleach solutions, or benzalkonium chloride (eg, "Control III").

2013 CF IP&C guideline consensus: 100%
Sections in the text: IV.E.3

References

1. Saiman L, et al (Committee Members). Cystic Fibrosis Foundation Guideline. Infection Prevention and Control Guidance for Cystic Fibrosis: 2013 Update. Infect Control Hosp Epidemiol 2013; 35 (Aug): S1-S67.

Troubleshooting

PROBLEM	SOLUTION(S)
Patient develops difficulty breathing or other medical problem while using the device.	Pause or discontinue the treatment, and then teach and coach the patient on proper and effective cough techniques. Assist patient where possible. Suction patient if indicated. Pause or discontinue the treatment and then assess the patient.
TCU does not power on.	If the battery charger is plugged in to the TCU, disconnect it. The TCU will not function when the battery charger is connected to it. Connect the HHT to the TCU. If the problem persists, contact Westmed Customer Service.
Batteries not holding a charge after being recharged.	Always use the charger supplied with the Vibralung Acoustic Percussor. The batteries in the TCU will hold their charge for 500 charge/recharge cycles. If the TCU has not been in use long enough to have been charged about 500 times, contact Westmed Customer Service.
TCU unexpectedly shuts down in the middle of a treatment.	Charge the TCU's internal battery. Restart the TCU. If the problem persists, contact Westmed Customer Service.
TCU powers on but does not respond (or responds incorrectly) to button selections.	Restart the TCU and insure that the HHT is connected to it. If the problem persists, contact Westmed Customer Service.
TCU powers on and works as intended but fails to illuminate appropriate LED indicator(s).	Restart the TCU. If the problem persists, contact Westmed Customer Service.
Patient complains of discomfort or interference with dental work or natural teeth during treatment with Vibralung Acoustical Percussor.	Consider removing dental work during treatment with the Vibralung. Encourage patient to not "clamp down" on plastic mouthpiece with teeth.
Patient has difficulty holding the HHT or holding it in the proper position.	The HHT is ergonomically designed to be easily held without fatigue by most patients for periods of up to 10 minutes. Patient must not be lying recumbent. Reposition patient to at least a 30° head up position. As a generalization, patients 6 years old and above should be able to use the Vibralung in the absence of other mitigating factors.

PROBLEM	SOLUTION(S)
TCU becomes very hot to the touch.	Discontinue use immediately and contact Westmed Customer Service.
Case components of the TCU case become loose or separate altogether.	Retighten screws if all are present. If some screws are missing, contact Westmed Customer Service.
Case components of the HHT become loose or separate altogether.	Discard faulty disposable unit and replace with a new HHT.
Interface cable between the TCU and HHT becomes damaged from the HHT, or the mini-plug becomes damaged.	Discard faulty HHT and replace with a new HHT.
Patient or caregiver unable to assemble parts; i.e., parts do not seem to fit together or mate properly.	Refer to Instruction Manual to confirm proper parts. Inspect parts for physical damage or deformation (e.g., out-of-round, rough edges). Replace parts that have been damaged.
Variable Expiratory Resistor for PEP and/or Circulaire II *Hybrid* for aerosol therapy do not seem to fit properly.	Refer to Instruction Manual to confirm proper Y-adapter and orientation. Inspect parts for physical damage or deformation (e.g., out-of-round, rough edges). Replace parts that have been damaged.
Unable to attach non-Westmed nebulizer or PEP device to the Vibralung Acoustical Percussor.	Use only the Westmed Circulaire II or Circulaire II *Hybrid* for aerosol therapy and Westmed Variable Expiratory Resistor for PEP.

For any unexpected changes in normal operation, suspected malfunction, or failure of the device, contact the Westmed Customer Service Department at (800) 975-7987.

Technical Specifications

GENERAL	
Device Name	Vibralung Acoustical Percussor
Design Type	Electro-acoustic
Configuration	2-piece: Treatment Control Unit + Hand-held Transducer
FDA Classification	Type II; Percussor, Powered Electric
FDA Classification #	868.5665
IEC Classification	Type BF (mouthpiece)
IEC Compliance	60601-1 (3rd Edition) and 60601-1-11
FCC Status	Class B

TREATMENT CONTROL UNIT (TCU)	
Part Number	9500
Dimensions	~4¼ x 5¼ x 1¼ inches; 10.8 x 13.3 x 3.2 cm (HWD)
Weight	0.75 pounds; 332 grams
Material	Flame retardant ABS Plastic; white/off-white
Intended Usage Period	Reusable; multi-patient with proper cleaning
Minimum Lifespan	As long as battery can be recharged
Power	Rechargeable internal batteries; non-user replaceable
Battery Type & Cell Quantity	3.6 VDC Li-ion; 3 cells
Battery Charger (Transformer)	Class II UL Listed, 120 VAC/60 Hz Input; 15 VDC/1.6A/24A Output; Manufacturer: Sceptre Power, P/N: PXX1516AWPL05
Battery Lifespan	500 charge/recharge cycles
Battery Charge Capacity	At least 30 treatments @ 10 minutes each per full charge
Transformer AC Plug Type	2 conductor
Transducer Output Jack	2 conductor mini-phone jack (3.5 mm)
Mounting	Pole-mounting slide supplied attached to rear of TCU.
Atmospheric Pressure	10.2 to 15.4 psig (70 to 106 kPa)
Temperature, Storage & Transport	-13°F to 158°F (-25°C to 70°C)
Temperature, Conditions for Use	41°F to 104°F (5°C to 40°C)
Humidity, Storage & Transport	up to 93% RH, non-condensing
Humidity, Conditions for Use	15% to 93% RH, non-condensing
Explosive Atmosphere Use	Not intended
Outdoor / Wet Area Use	Not intended
EMI / RF Susceptibility	Not affected (complies with IEC 60601-1-2)
EMI / RF Emissions	Low/non-existent (complies with IEC 60601-1-2)
Software	Proprietary, in EPROM, Version Vbvhm-v2r2
Signal Generator:	
Waveform	Sine
"Low" Frequency Tones Range	~5 to 350 Hz continuous; 55 to 350 Hz frequency stepping
"Medium" Frequency Tones Range	~5 to 660 Hz continuous; 69 to 660 Hz frequency stepping
"High" Frequency Tones Range	~5 to 1,200 Hz continuous; 124 to 1,182 Hz freq. stepping
"Random Noise" Range	~5 to 1,200 Hz continuous; 30 to 1,200 Hz transducer output

HAND-HELD TRANSDUCER (HHT)	
Part Number	9600
Dimensions	7.5 x 3.75 x 3.5 inches; 19 x 9.5 x 8.9 cm (HWD)
Interface Cable to Control Unit	4 to 4.5 feet; 1.22 to 1.37 M
Interface Cable Plug Type	2 conductor mini-phone plug (3.5 mm)
Weight	0.51 pounds; 233 grams
Weight with Standard Y-adapter	0.56 pounds; 256 grams
Patient Interface	Plastic Mouthpiece (Contains No Latex)
Intended Patient Population By Age	Anyone who is able to read and/or understand the instructions may use the Vibralung Acoustical Percussor.
Materials:	
Hand-held Case	ABS plastic; White/off-white (Contains No Latex)
Cone	Polypropylene; Translucent Clear (Contains No Latex)
Mouthpiece	Low-Density Polyethylene (LDPE); Translucent Clear
Y-adapters	High-Density Polyethylene (HDPE); Translucent Clear
Speaker Diameter	3-inches; 7.6 cm
Speaker Magnet Material	Neodymium
Speaker Magnetic Field	≤3 gauss (0.3 mTesla) @ 1 inch
Minimum Lifespan	30 days
Intended Usage Period	Single-patient use; Disposable
Mechanical Deadspace, Standard Y-adapter	39 mL, expressed as potential rebreathed volume
Mechanical Deadspace, Aerosol Y	53 mL, expressed as potential rebreathed volume
Inspiratory Flow Resistance	<2 cmH2O/L/sec
Positive Expiratory Pressure (PEP):	
Availability	Yes, via supplied Variable Expiratory Resistor (VER)
Monitoring	Yes, via optional VER with Manometer
During adult tidal breathing pattern	0.9 to 4.0 cmH2O (representative test bench measurement)
During pediatric tidal breathing	0.7 to 2.4 cmH2O (representative test bench measurement)
Aerosol Delivery	Yes, via Circulaire II *Hybrid* aerosol delivery device
Sound Pressure Levels:	
Maximum, 1-inch from Mouthpiece	104 dbA (represents therapeutic level)
Maximum, 1-inch from Expiratory Port	100 dbA (represents ambient 'noise' level)

Aerosol Particle Size Distribution

The effect of the Vibralung Acoustical Percussor on aerosol particle size distribution was determined using a quartz microbalance type cascade impactor. The specific nebulizer used was the Westmed VixOne small volume nebulizer. This device is a component part of the Circulaire II *Hybrid* High-Efficiency Aerosol Drug Delivery System, which is the only aerosol delivery system approved for simultaneous use with the Vibralung Acoustical Percussor.

Three different inhalation medications (two bronchodilator solutions and a steroid suspension) were tested under three different scenarios: (1) with the VixOne nebulizer by itself, (2) with the VixOne nebulizer on the Circulaire II by itself, and (3) the VixOne nebulizer and Circulaire II attached to an operating Vibralung Acoustical percussor. The Vibralung was operated on its Low, Medium, High and Random Noise frequency settings and the results shown in the "Vibralung with Circulaire" column reflect the range of values determined across those different settings.

Parameter*	Drug Tested With	VixOne Nebulizer Only	Circulaire Alone (uses VixOne as its nebulizer)	Vibralung with Circulaire (uses VixOne as its nebulizer)**
MMAD (uM)	albuterol 0.083%	1.60	1.48	1.51 – 1.76
	ipratropium 0.5 mg	1.72	1.13	1.39 – 1.59
	budesonide 0.5 mg	1.80	1.47	1.44 – 1.81
GSD	albuterol 0.083%	2.52	2.40	1.64 – 1.82
	ipratropium 0.5 mg	1.98	2.65	1.71 – 1.89
	budesonide 0.5 mg	2.14	2.33	1.59 – 2.17
Respirable Mass (%)	albuterol 0.083%	90.7%	90.8%	99.3 – 100%
	ipratropium 0.5 mg	98.1%	93.9%	99.2 – 100%
	budesonide 0.5 mg	97.9%	87.5%	96.6 – 99.5%
Coarse Particle Fraction (>5 uM) (%)	albuterol 0.083%	9.3%	9.2%	0 – 0.7%
	ipratropium 0.5 mg	1.9%	6.1%	0 – 0.5%
	budesonide 0.5 mg	2.1%	12.5%	0.4 – 3.3%
Fine Particle Fraction (>1 to <5 uM) (%)	albuterol 0.083%	56.3%	56.3%	68.8 – 76.7%
	ipratropium 0.5 mg	65.5%	50.3%	69.2 – 78.8%
	budesonide 0.5 mg	72.0%	53.1%	63.8 – 75.6%
Ultra-fine Particle Fraction (<1 uM) (%)	albuterol 0.083%	34.5%	34.4%	17.0 – 25.6%
	ipratropium 0.5 mg	32.6%	43.5%	21.1 – 30.6%
	budesonide 0.5 mg	25.9%	34.4%	23.1 – 32.9%

Notes:

* Determined with California Measurements Model PS-2 Quartz Microbalance-type cascade Impactor

** Range of values are reported to account for the different modes of Vibralung Acoustical percussor tested.

Legend: MMAD is the Mass Median Aerodynamic Diameter of the particle size distribution in micrometers (μM). GSD is the Geometric Standard Deviation of the particle size distribution in μM. Respirable Mass % is the percentage of particles less than 5 μM in diameter (actual cut point = 4.6 μM). Coarse Particle Fraction is the percentage of particles greater than 5 μM in diameter. Fine Particle Fraction is the percentage of particles between 1 and 5 μM in diameter. Ultra-fine Particle Fraction is the percentage of particles less than 1 μM in diameter.

Ingress Protection

IP #	Ingress of Solid Objects	Ingress of Liquids
22	Protected against solid objects over 12.5 mm; e.g., hands, large tools, etc.	Protected against falling drops of water if the case is disposed up to 15 degrees from vertical.

EMC Requirements

Manufacturer's Declaration – Electromagnetic Emissions		
The Vibralung Acoustical Percussor is intended for use in the electromagnetic environment specified below. The customer or user of the Vibralung Acoustical Percussor should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The Vibralung Acoustical Percussor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	N/A	The Vibralung Acoustical Percussor must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	EMCI Report, ETRB30430.
RF Emissions CISPR 14-1	Complies	The Vibralung Acoustical Percussor is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The Vibralung Acoustical Percussor is not suitable for interconnection with other equipment.

N/A = Not Applicable.

Manufacturer's Declaration – Electromagnetic Immunity

The Vibralung Acoustical Percussor is intended for use in the electromagnetic environment specified below. The customer or user of the Vibralung Acoustical Percussor should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to lines(s) ± 2 kV line(s) to earth	± 1 kV line(s) to lines(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 5 cycles	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vibralung Acoustical Percussor requires continued operation during power mains interruption, it is recommended that the Vibralung Acoustical Percussor be powered from an uninterruptible power supply or a battery. (Note: By design, the Vibralung Acoustical Percussor cannot be powered by mains as it is powered by internal batteries and cannot be operated when the battery charger is connected).

Power frequency (50/60 Hz) Magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Vibralung Acoustical Percussor

The Vibralung Acoustical Percussor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Vibralung Acoustical Percussor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF equipment (transmitters) and the Vibralung Acoustical Percussor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation Distance According to Frequency of Transmitter [Meters (M) / Feet (Ft.)]**		
	150 kHz to 80 mHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 mHz to 800 mHz** $d = [\frac{3,5}{V_1}]\sqrt{P}$	**800 mHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12 M; 0.4 Ft.	0.12 M; 0.4 Ft.	0.23 M / 0.8 Ft.
0.1	0.37 M / 1.2 Ft.	0.37 M / 1.2 Ft.	0.74 M / 2.4 Ft.
1	1.17 M / 3.8 Ft.	1.17 M / 3.8 Ft.	2.33 M / 7.7 Ft.
10	3.69 M / 12.1 Ft.	3.69 M / 12.1 Ft.	7.38 M / 24.2 Ft.
100	11.67 M / 28.3 Ft.	11.67 M / 28.3 Ft.	23.33 / 76.6 Ft.

For transmitters rated at a maximum output power not listed above, the recommended separation distance (***d)*** in meters (***m***) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power of the transmitter in watts (**W**) according to the transmitter manufacturer.

NOTE 1: At 80 mHz and 800 mHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Parts and Accessories

DESCRIPTION	PART NUMBER
Vibralung Treatment Control Unit, with Battery Charger, and Instructions for Use; single unit. (Vibralung Patient Kit not included).	9500
Vibralung, Full User Kit with Travel Bag (Home): 1 each: #9500 Vibralung Treatment Control Unit (TCU) 1 each: #9600 Vibralung Patient Kit 1 each: #9560 Vibralung Travel Bag	9501
Vibralung, Full User Kit without Travel Bag (Hospital): 1 each: #9500 Vibralung Treatment Control Unit (TCU) 1 each: #9600 Vibralung Patient Kit	9502
Vibralung Patient Kit (Hand-held Transducer, Cone, Standard Y-adapter, Aerosol Y-adapter, Disposable Ear Plugs, Mouthpiece and PEP Resistor), disposable; single unit or package of 10.	9600 / 9600-10
Vibralung Patient Exchange Kit, Cone, Standard Y-adapter, Aerosol Y-adapter, Disposable Ear Plugs, Mouthpiece and PEP Resistor; Single-patient Use, case of 25	9640 / 9640-25
Vibralung Battery Charger, with Instructions for Use; single unit.	9630
Clamp, Pole-mounting, with Instructions for Use; single unit.	4056
Circulaire II *Hybrid*, High-Efficiency Aerosol Drug Delivery System with Reusable VixOne, Variable Expiratory Resistor and Bacterial Viral Expiratory Filter; case of 10.	0391R
Circulaire II *Hybrid*, High-Efficiency Aerosol Drug Delivery System with Reusable VixOne and Variable Expiratory Resistor; case of 10.	0393R
Circulaire II *Hybrid*, High-Efficiency Aerosol Drug Delivery System with Reusable VixOne, Variable Expiratory Resistor, Bacterial Viral Expiratory Filter and PEP Manometer; case of 10.	0394
PEP Accessory Kit with Manometer; case of 10	0262

Warranty

Limited One-Year Warranty

The Treatment Control Unit (TCU) component of the Vibralung Acoustical Percussor has an estimated life span of 5 years and is warranted by Westmed, Inc. against defects in materials and workmanship for 12 months from the date of original purchase. This warranty only applies to the original purchaser. During the warranty period, Westmed will repair or, at its option, replace at no charge, a TCU that proves to be defective, provided you return the TCU, shipping prepaid, to the Westmed Customer Service Department along with a Westmed-assigned Return Goods Authorization (RGA) number.

What is Not Covered:

This warranty does not apply if the TCU has been damaged by accident or misuse or as the result of service or modification by other than Westmed, Inc., including any attempt to open or service the TCU for any reason.

The repair or replacement of a TCU is your exclusive remedy. Except as specifically set forth otherwise in this Document, NO WARRANTIES, EXPRESS OR IMPLIED, ARE GIVEN, AND BUYER WAIVES ALL SUCH WARRANTIES, INCLUDING, BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL WESTMED, INC. BE LIABLE FOR CONSEQUENTIAL DAMAGES.

Service

Prior to considering service, be sure to review the Troubleshooting section beginning on page 31 of this manual.

Only the Treatment Control Unit (TCU) can be serviced. There are no serviceable parts in the disposable Hand-held Transducer (HHT).

Westmed, Inc. is the only authorized service center available for diagnosing or repairing the Vibralung Acoustical Percussor TCU, replacing its internal batteries, or replacing the entire TCU.

To initiate a service request, please contact the Westmed Customer Service Department and request a Returned Goods Authorization (RGA) Number prior to returning the device(s) for service.

Place the RGA Number on the outside of the shipping package when returning goods to Westmed.

Any device received by Westmed without an RGA Number will be returned to sender.

When packaging for return, please perform low-level disinfection on the TCU then place it in a plastic bag and surround with packaging peanuts, bubble wrap or crushed paper for additional protection.

Westmed, Inc. / Customer Service
5580 South Nogales Highway
Tucson, AZ 85706-3333
(800) 975-7987

www.vibralungACT.com