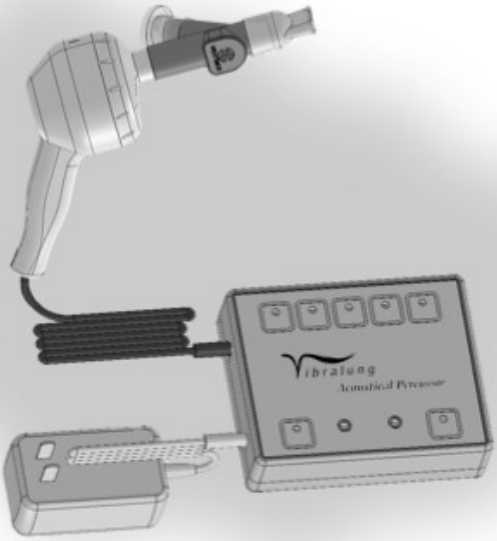
Vibralung®

Acoustical Percussor



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Vibralung®

Acoustical Percussor

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 and to prevent or reverse atelectasis. 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 follow verbal instructions.

Environment of Use. Hospital and home.

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. 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 hyperventilating, 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.

Acoustical Percussor

Instructions for Use

DEVICE DESCRIPTION

The Vibralung Acoustical Percussor® is used for airway clearance therapy and helps patients with lung disease to clear mucus and phlegm from their lungs through the use of sound waves. The patient simply breathes through a mouthpiece attached to the "**Hand Held Transducer**," or **HHT**, while holding on to the handle. The HHT is connected to a small battery-operated electronic box called the "**Treatment Control Unit**" or **TCU**. The TCU generates the sound waves and controls the treatment. See the pictures and instructions inside this pamphlet before operating.

WARNINGS!

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

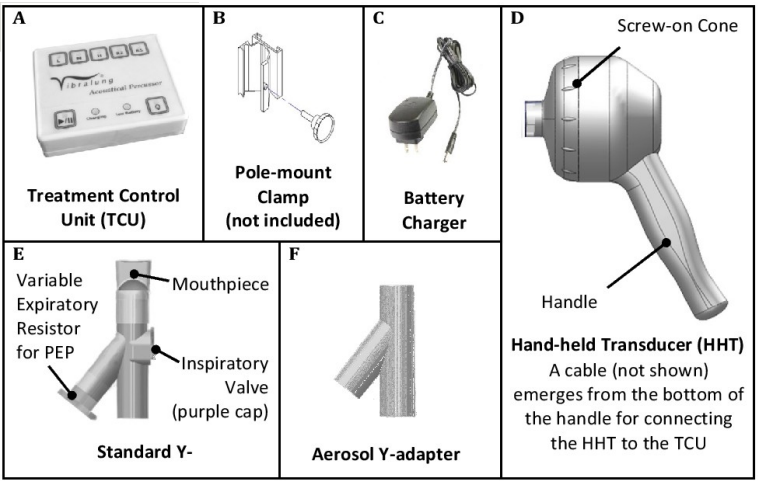
- Federal law restricts this device to sale by or on the order of a physician.
- Read this Instructions for Use manual before use.
- Unskilled or untrained personnel should not operate or apply this device to patients.
- Use only as intended and described in this manual and supporting documentation.
- Use only on cooperative patients who can properly self-administer following training.
- Use only with the supplied mouthpiece and accessory adapters.
- Be prepared to help patient with removal of secretions (cough coaching, suction) as needed.
- The HHT, Cone and related Y-adapters are for single patient use, multiple treatment sessions during single hospitalization and should be changed as directed.
- 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.
- 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 Variable Expiratory Resistor for Positive Expiratory Pressure (PEP) because other devices have not been designed or ascertained to function properly with the inspiratory and exhalation gas flow pathways of the Vibralung.

CAUTIONS

- 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 VibraLung for service. The HHT is disposable and, if it is damaged, it should be discarded and replaced.
- Do not over-tighten the “Cone” onto the HHT. Ensure the outlet port of the Cone is properly aligned and the outlet port on the Cone should be aligned to the “3 o’clock” position. See inset diagrams on page 4.
- Do not use the TCU and HHT in extremely moist and humid environments such as a shower or outside during rain.
- Do not immerse the TCU or the HHT in liquid or allow liquid to seep into the case.
- Do not attempt to disinfect either the HHC or the TCU with boiling water, steam, baby bottle sterilizers, dishwashers or microwave ovens.
- Use only the Battery Charger that is supplied with the TCU. Use of a different charger may damage the batteries and/or the electronics.
- 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.
- Do not use the Vibralung Acoustical Percussor with a facemask of any kind because of the uncertainty of coupling the acoustic energy to the airways.

COMPONENT PARTS

The Vibralung Acoustical Percussor is supplied in two boxes. One box holds the reusable Treatment Control Unit (A), and Battery Charger (C). The other box holds the disposable Hand-held Transducer assembly (D) plus Standard Y-adapter, mouthpiece and Variable Expiratory Resistor (E), plus an Aerosol Y-adapter (F) that can be used for aerosol delivery. You should have all the following parts (images not to scale):



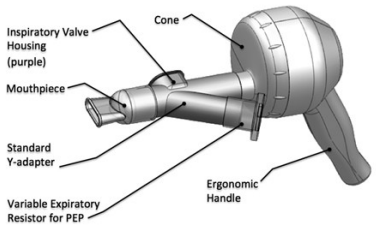
PREPARING THE TCU FOR FIRST USE

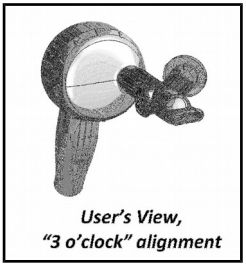
Follow these steps to charge, test and set up the Treatment Control Unit (TCU) for the first time.

1. Remove the TCU (A) and Battery Charger (C) from their shipping box.
2. Peel adhesive backing from the four rubber feet (included in the package), and affix them to the underside of the TCU to level it.
3. Plug the Battery Charger into a standard 120 volt electrical outlet and plug the end of the battery charger cable into the bottom jack on the left side of the TCU. (The Battery Charger plug will not fit in the top jack on the left side of the TCU). All 9 Light Emitting Diodes (LEDs) should flash 3 times quickly and then the Charging and Power LEDs should stay on during the charging process.
4. Leave the Battery Charger plugged in and connected to the TCU until the TCU's internal batteries are fully charged (which should take no more than 4 hours). The Charging LED will go out and the Power LED will flash when the unit is fully charged.
5. Disconnect the Battery Charger after batteries are charged, as the TCU will not operate while the charger is connected.
6. After charging is completed and the charger is disconnected from the TCU, 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 shown 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. Contact Customer Service (see page 10).
7. The Treatment Control Unit (TCU) is now ready for use. Repeat these steps every time the battery needs to be recharged, as indicated by the Low Battery LED.

HHT ASSEMBLY WITHOUT AEROSOL

The assembled Vibralung Acoustical Percussor Hand-held Transducer (HHT) is shown below. This assembly uses the Standard Y-adapter (E). Connect the long end of the Standard Y-adapter to the cone. The mouthpiece should be at the other end and the Variable Expiratory Resistor should be on the tail of the Y. The outlet port of the cone should be at the 3 o'clock position as you are facing it, and the assembly should be aligned as shown in the "user's view" below:

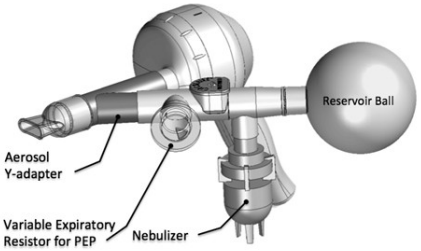


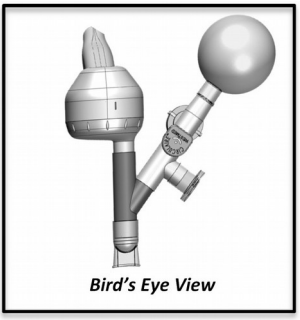


User's View, "3 o'clock" alignment

HHT ASSEMBLY WITH AEROSOL

If simultaneous aerosol therapy is required, obtain and attach the Circulaire II *Hybrid* aerosol delivery system as shown below. Remove the Standard Y-adapter (E), replace with the Aerosol Y-adapter (F), 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 as shown. The outlet port of the cone should be at the 3 o'clock position as you are facing it, and the assembly should be aligned as shown in the 'Bird's Eye View' below:



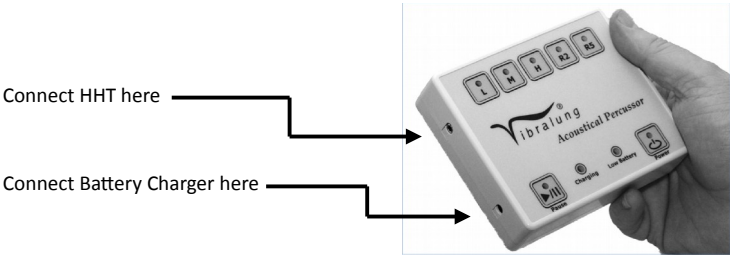

Bird's Eye View

Operate the nebulizer with oxygen or compressed air. Adjust the opening of the Variable Expiratory Resistor to apply PEP. See the Circulaire II or Circulaire II *Hybrid* package insert for further instructions for use.

BUTTONS AND SETTING ON THE TCU

The TCU has 2 electrical jacks on the left side panel. The top jack is for connecting the TCU to the Hand-held Transducer (HHT) and the bottom jack is for connecting the Battery
Charger.

Seven user-selectable buttons contain LEDs that illuminate when pressed. The buttons also make a "clicking" feeling to 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.



Note: The TCU will not operate while the Battery Charger is plugged into it.

BUTTON LABEL	ACTION
	Control button to select “Low” frequency setting (~5 – 350 Hz).
	Control button to select “Medium” frequency setting (~5 – 660 Hz).
	Control button to select “High” frequency setting (~5 – 1,200 Hz).
	Control buttons to select either 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

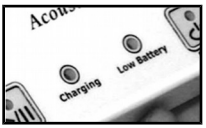
Refer to physician’s prescription or caregivers instructions for appropriate settings for the Vibralung Acoustical Percussor. Regardless of which Y-adapter is used, operation of the Vibralung Acoustic Percussor is the same. The patient should hold the device in one or both hands while inserting the mouthpiece 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, and then press the Power On/Off button.

- The LEDs embedded in the Power and Start/Pause buttons illuminate.
- The Low Battery LED illuminates if the battery is in need of recharging.
- The Unit is in Pause mode upon powering on.

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.
- Press the Pause button to activate the device and emit sound at the selected setting.
  - The LED embedded in the Pause button extinguishes.
- Unless stopped, paused, or held (see #5 Treatment Hold below) the unit will operate at the selected setting for 10 minute and then terminate.



- Press the Pause button at any time while activated to pause the session.
  - The LED embedded in the Pause button illuminates.
- Press the Pause button while paused to resume the session.
  - The LED embedded in the Pause button extinguishes.
- If a paused session is not resumed within 2 minutes by pressing the Pause button again, the session automatically terminates.

Important: If a different treatment mode is desired before 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 take the 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 the total treatment time.

6. **Patient Position.** Avoid recumbent patient positioning while using the Vibralung Acoustical Percussor. Patient should be sitting upright or at no more than a 30° recumbent angle to facilitate coughing and expectoration.

7. **Breathing Pattern.** The patient should breathe normally during the treatment. As with any breathing treatment, hyperventilation or excessively deep or fast breathing may result in dizziness or light-headedness. The treatment may be paused at any time and resumed 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 then 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 10 to 20 times or as often as desired for the patient.

TREATMENT SETTINGS

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 or held at any time. Five settings, representing a designated sequence of frequency ranges, have been programmed into the Treatment Control Unit as shown in the following table. Note that the four tone sequence is approx. 5 Hz.

SETTING	DESCRIPTION
L (Low) ~ 5, 55-350 Hz	10 minutes of Low Frequency Tones
M (Medium) ~ 5, 70-660 Hz	10 minutes of Medium Frequency Tones
H (High) ~ 5, 130-1,200 Hz	10 minutes of High Frequency Tones
R2 5-1,200Hz	2 minutes of Random Noise
R5 5-1,200Hz	5 minutes of Random Noise

TREATMENT SETTINGS (continued)

A treatment session may consist of the application of one or more settings, depending upon the target area(s) of the lungs to which therapy should be directed, patient preference and patient response to therapy. In theory, lower frequency tones are effective on larger, wider airways while higher frequency tones are effective on smaller, thinner airways. Therapeutic benefit(s) may not necessarily be rendered on the first treatment, or even the first few treatments. It may require an indeterminate number of treatment sessions, 2 to 4 times daily, before benefits become apparent.

SIMULTANEOUS AEROSOL THERAPY

The Circulaire II *Hybrid* aerosol delivery system may be used with the Vibralung Acoustical Percussor if wetting agents or inhalation medications are prescribed. The Circulaire II *Hybrid* is the only nebulizer system approved for use with the Vibralung Acoustical Percussor. The Vibralung includes an Aerosol Y-adapter that allows connecting the Circulaire II *Hybrid* to the HHT, as shown in the bottom figure on page 5.

The Circulaire II *Hybrid*, when attached to the Vibralung Acoustical Percussor with the Aerosol Y-adapter, provides a direct pathway for inhalation and exhalation. The Aerosol Y-adapter provides a direct pathway for the sound waves to travel through to enter the mouth and the lung. In this manner, the acoustical energy remains coupled to the patient's lungs during inhalation and exhalation while the aerosol treatment is taking place.

Further, PEP therapy can also be administered by way of the Circulaire II *Hybrid*, which has a Variable Expiratory Resistor on the exhalation port. Finally, because many of the patients who may benefit from airway clearance therapy and aerosol therapy with the Vibralung Acoustical Percussor also have pulmonary infections, an exhalation filter is included in the exhalation pathway of the Circulaire II *Hybrid* to prevent medications and patient droplets from being emitted into the room and possibly inhaled by caregivers or other patients.

WARNING - 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 HybridTM aerosol drug delivery system and/or Westmed Variable Expiratory Resistor for Positive Expiratory Pressure (PEP) because other devices have not been designed or ascertained to function properly with the inspiratory and exhalation gas flow pathways of the Vibralung.

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 Customer Service.
Batteries not holding a charge after being recharged.	Always use the charger supplied with the Vibralung Acoustical 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 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 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 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 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 Acoustical Percussor. 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.
TCU becomes hot to the touch.	Discontinue use immediately and contact 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 Customer Service.
Case components of the HHT case 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 the 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.

Vibralung Cleaning Instructions for Home Use

1. **After each treatment:**
   - Wipe down all surfaces of the control unit with a pre-moistened germicidal wipe such as CaviWipesTM, Super Sani Cloth® Germicidal Wipes, Clorox® Disinfecting Wipes, Lysol® Wipes or equivalent. Follow product instructions for the amount of contact time or leave visibly wet for at least 4 minutes. Be careful not to allow liquid into the seams on the side of the control unit or the two electrical ports on the end of the unit.
   - Wipe down all surfaces of the handheld transducer and allow to air dry in the same manner as the control unit.
   - Wipe down the surfaces of the disposable plastic components that are attached to the handheld transducer with a pre-moistened alcohol wipe or pad and allow to air dry.
2. **At the end of the treatment day:**
   - Remove the disposable plastic components from the handheld transducer by unscrewing the cone. These items include the cone, the standard Y adapter with valve, the aerosol Y adapter, the variable resistor for PEP and the mouthpiece. Be careful not to damage the speaker.
   - Cleaning Instructions:
     i. Wipe the disposable plastic parts with a pre-moistened alcohol pad.
     ii. Or, clean these components with dish soap and water. Rinse with tap water and allow to air dry on a fresh, dry paper towel.
     iii. Or, disinfect these components, after washing and drying, using one of the following cold disinfectant methods approved by the Cystic Fibrosis Foundation:
        a. Soak in 70% isopropyl alcohol for 5 minutes
        b. Soak in 3% hydrogen peroxide for 30 minutes.
     iv. 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 not to contaminate the inside parts while moving them. If pre-packaged sterile or filtered water is unavailable, use water that has been boiled for 1 minute and allowed to cool to rinse off residual chemicals.
     v. Or, follow instructions recommend by your health care provider.

The disposable HHT and all associated plastic parts may be discarded into the usual waste stream in accord with local regulations. The TCU contains a lithium-ion battery pack, which, in most states, can be disposed of via normal waste management procedures. If in doubt, please check your local regulations.

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	~4½ x 5½ x 1½ 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
Charge Capacity	At least 30 treatments@10 minutes each per full charge
Transformer AC Plug Type	2 conductor
Transducer Output Jack	2 conductor mini-phonejack (3.5 mm)
Mounting	Pole-mounting slide supplied attached to rear of TCU. One pole-mounting bracket supplied with each 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 Tone Range	~ 5, 55-350 Hz
“Medium” Frequency Tone Range	~5, 70-660 Hz
“High” Frequency Tone Range	~5, 130-1,200 Hz
“Random Noise” Frequency Tone Range	~5 - 1,200 Hz

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 (3.5mm)
Weight	0.51 pounds; 233 grams
Weight with Standard Y-adapter	0.56 poungs; 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	Polyethylene; 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 m Tesla) @ 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 cm H2O (representative test bent measurement)
During pediatric tidal breathing	0.7 to 2.4 cm H2O (representative test bent 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)

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.

Manufacturer's Declaration – Electromagnetic Emissions		
The Vibralung Acoustical Percussor HCU 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.

ELECTROMAGNETIC EMISSIONS AND ENVIRONMENT (continued)

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 $d=\left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{V1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E1}\right]\sqrt{P}$
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.

Manufacturer's Declaration - Electromagnetic Immunity			
The Vibralung Acoustical Percussor is intended for use in the electromagnetic environment specified below. The customer or user oi 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) IEC 61000-4-2	± 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	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to iines(s) ± 2kV line(s) to earth	± 1kV line(s) to iines(s) ± 2kV 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 25cycles <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 25cycles <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 unlnterruptlble power supply or a battery. (Note: By design, the Vibralung Acoustical Percussor cannot be powered by mains as lt 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.

PARTS AND ACCESSORIES

DESCRIPTION	PART NUMBER
Vibralung, Full User Kit with Travel Bag: 1 each: #9500 VL TCU 1 each: #9600 VL Patient Kit 1 each: #9560 Travel Bag	9501
Vibralung, Full User Kit without Travel Bag: 1 each: #9500 VL TCU 1 each: #9600 VL Patient Kit	9502
Vibralung Treatment Control Unit, with Battery Charger and Instructions for Use; single unit.	9500
Vibralung Patient Kit (Hand-held Transducer, Cone, Standard Y-adapter, Aerosol Y-adapter, Disposable Ear Plugs, Mouthpiece and PEP Resistor), disposable, hospital model; single unit or package of 10.	9600 / 9600-10
Vibralung Patient Change Kit, HHT Single-Patient Use; case of 25.	9640
Vibralung Battery Charger, Instructions for Use; single unit.	9630
Bracket, Pole-mounting, Instructions for Use; single unit.	4056
Vibralung Travel Bag	9560
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

SERVICE

- For any unexpected change in normal operation, suspected malfunction, or failure of the device, please first review the Troubleshooting section above, and if cannot resolve, contact Warranty Service at the telephone number below.
- Only the Treatment Control Unit (TCU) can be serviced. There are no serviceable parts in the disposable Hand-held Transducer (HHT).
- VibraLung, Inc. is an authorized service center available for diagnosing, repairing or replacing the Vibralung Acoustical Percussor TCU.
- To initiate a service request, please contact Warranty Service 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. Any device without an RGA Number will be returned to sender.
- When packaging for return, please perform disinfection on the TCU according to the Care and Cleaning Instructions on page 9, then place it in a plastic bag and surround with packaging peanuts, bubble wrap or crushed paper for additional protection.
- For questions regarding warranty or operation of the device please contact:
-

VibraLung, Inc.
11990 Meadowood Ln. / Parker, CO 80138
(800) 889.5231 / support@vibralung.com

SAFETY AND INFORMATIONAL SYMBOLS

	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.

MANUFACTURING

The Vibralung Acoustical Percussor

Manufactured for VibraLung, Inc. by:

Westmed, Inc.
5580 S. Nogales Highway
Tucson, AZ 85706

800.975.7987 / www.westmedinc.com

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Circulaire II *Hybrid*™ is a trademark of Westmed, Inc.
PN 71944 Rev 03 vbl

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