

INTERNATIONAL BIOPHYSICS CORPORATION

Over a quarter of a century legacy
of unwavering commitment to
creating innovative and disruptive
medical devices and technologies
that improve treatment therapies
and patient outcomes.

For more information, please visit afflovest.com.

REFERENCES

1. Jan Tecklin, High Frequency Chest Wall Oscillation (HFCWO) for Neuromuscular Patients with Airway Clearance Needs: A Case for Reimbursement. *Respiratory Therapy* 2005: 28-33
2. Tackett, MW, et al. Lung function improvement with AffloVest® HFCWO use: a clinician's perspective on PFT score data from 25 patients with cystic fibrosis. Cooper, M. An evidence-based study of adolescents with cystic fibrosis demonstrated that AffloVest® by International Biophysics contributed to improved lung function scores. Cooper, M. Clinician's Data Analysis: Lung function improvement maintained over 16 to 24 months with use of AffloVest™ HFCWO vest by International Biophysics.
3. The comparison measurements were conducted at F2 Labs, an independent, 3rd party, ISO/IEC 17025 accredited testing laboratory. 16740 Peters Road, Middlefield, Ohio 44062. www.f2labs.com.

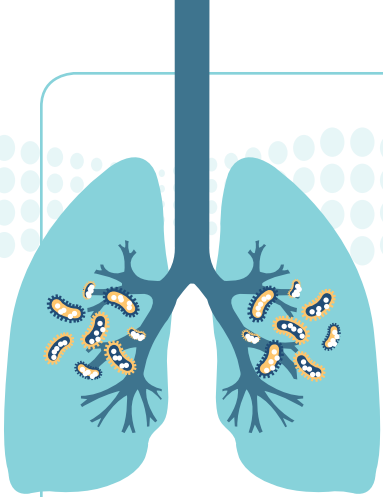
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MOBILE HFCWO AIRWAY CLEARANCE THERAPY FOR NEUROMUSCULAR INDICATIONS



AffloVest®



Mobile High Frequency Chest Wall Oscillation (HFCWO) airway clearance can be an effective modality for individuals with neuromuscular disorders. The symptoms sometimes associated with these conditions can result in major respiratory impairment and infection. ⁽¹⁾

AIRWAY CLEARANCE IN NEUROMUSCULAR DISORDERS

HFCWO airway clearance therapy is a cornerstone technique in managing respiratory disorders associated with neuromuscular diseases such as MD, ALS, MS and Quadriplegia.

If desired, a variety of airway clearance therapies may be combined during use with the AffloVest to help optimize airway clearance. With its unique design and the ability to take full, deep breaths during treatment, nebulizer treatments and postural drainage techniques can be combined with AffloVest therapy with the goal of improving lung function and helping improve a person's quality of life.



AFFLOVEST HFCWO AIRWAY CLEARANCE THERAPY

As the first truly portable during use, battery-operated HFCWO therapy vest, AffloVest was specifically engineered to mimic the gold standard of manual CPT to give patients the freedom and mobility to streamline therapy, enhance airway clearance, help mobilize lung secretions, and promote adherence. AffloVest was designed with ease-of-use in mind for patients, families and caregivers, to deliver airway clearance therapy that can be managed at home or in the hospital. With no bulky hoses and generators as found in other therapies, the AffloVest can be utilized in any postural position (i.e. laying down, standing, sitting, inclined, reclined etc). All to help improve the quality of life for patients with MS, MD, ALS, and other neuromuscular and respiratory diseases.

The AffloVest advantage - A therapy tailored for patient needs



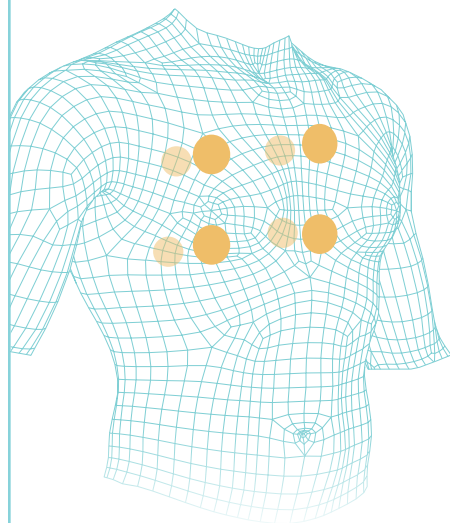
ADVANCED TECHNOLOGIES, ADVANCING THERAPY

PORTABLE THERAPY THAT FITS.

By incorporating eight oscillating motors into AffloVest, our patented Direct Dynamic Oscillation™ technology creates eight individual pressure waves that target the lobes of the lungs, much like manual Chest Physical Therapy (CPT)—in order to help effectively mobilize secretions.

Chest Physical Therapy when and where you need it

- Engineered to mimic manual CPT
 - 8 oscillating motors target the lobes of the lungs, front and back
 - Helps loosen mucus so it can be coughed up
- Anatomically-targeted treatment
- Not postural dependent
- Designed to increase patient adherence
- Fully mobile and adaptable to multiple treatment positions and settings



Patient home treatment plans can be customized for the targeted motors using the digital controller to specify different levels of intensity for 3 different treatment options.

- Digital, programmable controller
- Nine total setting variations
- Three modes of oscillation treatment (Percussion, Vibration, Drainage)
- Three adjustable intensity levels—5Hz, 13Hz, 20Hz
- Compliance monitoring
- Quiet during operation
- AC/DC and battery power options



With 7 sizes to choose from and **no age restrictions**, AffloVest is the most inclusive mobile and adaptable HFCWO vest available for patients needing airway clearance therapy for treatment of respiratory impairment associated with neuromuscular disorders. We know how important precise placement and patient positioning is when it comes to anatomically targeting the upper and lower lung lobes with directed therapy. Regardless of size, shape, or body type—from XXS (18" chest circumference) for children up to XXL for adults (up to 65"+ chest circumference)—AffloVest delivers therapy that fits.



ONE SIZE DOES NOT FIT ALL

Beyond being inclusive, AffloVest is adaptable too. Which means that as children or adults grow, their AffloVest can too. Adjustments are made easy by our AffloVest Size Exchange Program*, which allows patients to go up or down in AffloVest size as needed, and be refit into an AffloVest that provides the best fit for targeted airway clearance therapy.

*All exchange requests must be within reasonable limits and are subject to final approval by our patient support team.



TRIED. TRUE. PROVEN.

In order to enhance treatment adherence and patient outcomes, our continuous improvement processes are always developing new ways to optimize important design features such as weight, noise, ergonomics, comfort, and ease-of-use.

All to provide the most efficient and effective balance between activity-compatible design and therapy-optimizing functionality.

Lung function improvement in CF patients demonstrated in clinician papers.²



Noise study demonstrates that AffloVest[®] is the quietest HFCWO vest.³

Peak Magnetic Field test shows AffloVest is 4x lower than the threshold limit value for active medical device wearers and implanted medical devices.³

Patient feedback and testimonials show the AffloVest can provide more comfort and convenience than traditional air-bladder HFCWO vests.

REIMBURSEMENT REQUIREMENTS FOR NEUROMUSCULAR

The AffloVest HFCWO Airway Clearance vest:

- Requires a physician's prescription for treatment by High Frequency Chest Wall Oscillation (HFCWO)
 - Patients must qualify to meet eligibility requirements. Physicians orders must include: AffloVest prescription, qualifying DX, chart notes to support the DX, and well-documented failure of standard treatments to adequately mobilize retained secretions.

The AffloVest has received the FDA's 510k clearance for U.S. market availability, and is approved for Medicare, Medicaid, and private health insurance reimbursement under the Healthcare Common Procedure Coding System (HCPCS) code EO483 – High Frequency Chest Wall Oscillation. The AffloVest is also available through the U.S Department of Veterans Affairs/Tricare. Patients must qualify to meet insurance eligibility requirements.

NEUROMUSCULAR ICD-10 CODES

G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]	G71.19	Other specified myotonic disorders
G12.1	Other inherited spinal muscular atrophy	G71.2	Congenital myopathies
G12.20	Motor neuron disease, unspecified	G71.3	Mitochondrial myopathy, not elsewhere classified
G12.21	Amyotrophic lateral sclerosis	G71.8	Other primary disorders of muscles
G12.22	Progressive bulbar palsy	G72.0	Drug-induced myopathy
G12.23	Primary lateral sclerosis	G72.1	Alcoholic myopathy
G12.24	Familial motor neuron disease	G72.2	Myopathy due to other toxic agents
G12.25	Progressive spinal muscle atrophy	G72.89	Other specified myopathies
G12.29	Other motor neuron disease	G73.7	Myopathy in diseases classified elsewhere
G12.8	Other spinal muscular atrophies and related syndromes	G82.50	Quadriplegia, unspecified
G12.9	Spinal muscular atrophy, unspecified	G82.51	Quadriplegia, C1-C4 complete
G14	Postpolio syndrome	G82.52	Quadriplegia, C1-C4 incomplete
G35	Multiple sclerosis	G82.53	Quadriplegia, C5-C7 complete
G71.00	Muscular dystrophy, unspecified	G82.54	Quadriplegia, C5-C7 incomplete
G71.01	Duchenne or Becker muscular dystrophy	M33.02	Juvenile dermatomyositis with myopathy
G71.02	Facioscapulohumeral muscular dystrophy	M33.12	Other dermatomyositis with myopathy
G71.09	Other specified muscular dystrophies	M33.22	Polymyositis with myopathy
G71.11	Myotonic muscular dystrophy	M33.92	Dermatopolymyositis, unspecified with myopathy
G71.12	Myotonia congenita	M34.82	Systemic sclerosis with myopathy
G71.13	Myotonic chondrodystrophy	M35.03	Sicca syndrome with myopathy
G71.14	Drug induced myotonia	J98.6	Disorders of diaphragm