

## 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](https://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](https://www.f2labs.com).

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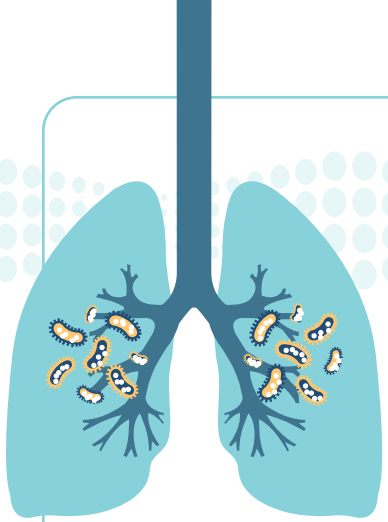
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## MOBILE HFCWO AIRWAY CLEARANCE THERAPY FOR NEUROMUSCULAR INDICATIONS



**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.<sup>1</sup>

## 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

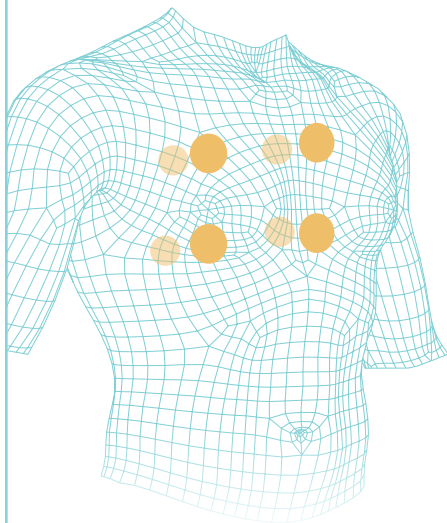
As the first truly portable during use, battery-operated HFCWO therapy vest, AffloVest was specifically engineered to mimic the gold standard of manual CPT to give patients the freedom and mobility to streamline therapy, enhance airway clearance, help mobilize lung secretions, and promote adherence. 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

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

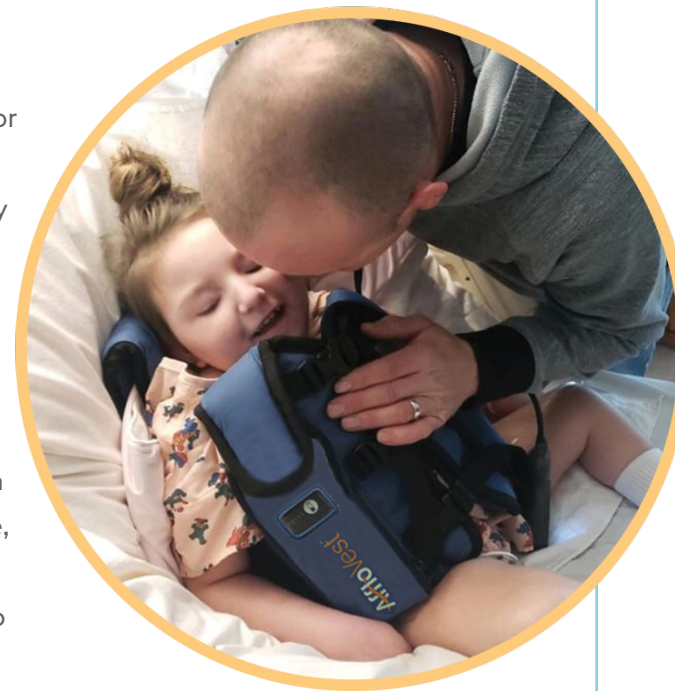
Patient home treatment plans can be customized for the targeted motors using the digital controller to specify different levels of intensity for 3 different treatment options.

- 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



## PORTABLE THERAPY THAT FITS.

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.<sup>2</sup>



Noise study demonstrates that AffloVest is the quietest HFCWO vest.<sup>3</sup>

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

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 E0483 – 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

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