WELCOME TO AFFLOVEST®

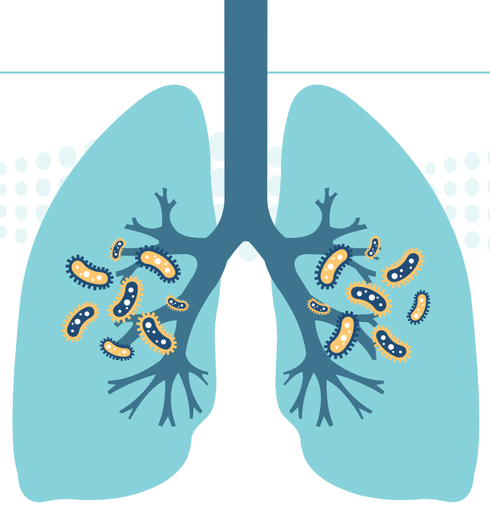
with Mobile Mechanical Oscillation therapy

- FREES PATIENTS.
- MOBILIZES SECRETIONS.
- ADVANCES THERAPY.

AffloVest®

WHAT IS BRONCHIECTASIS?

Bronchiectasis is a chronic condition that occurs when the walls of the airways (bronchi) thicken as a result of chronic inflammation and/or chest infections and result in mucus accumulation.



STUDIES SHOW ALMOST 1 IN 2 COPD PATIENTS MAY HAVE BRONCHIECTASIS,[1] 70,000 NEW PATIENTS EACH YEAR[2]

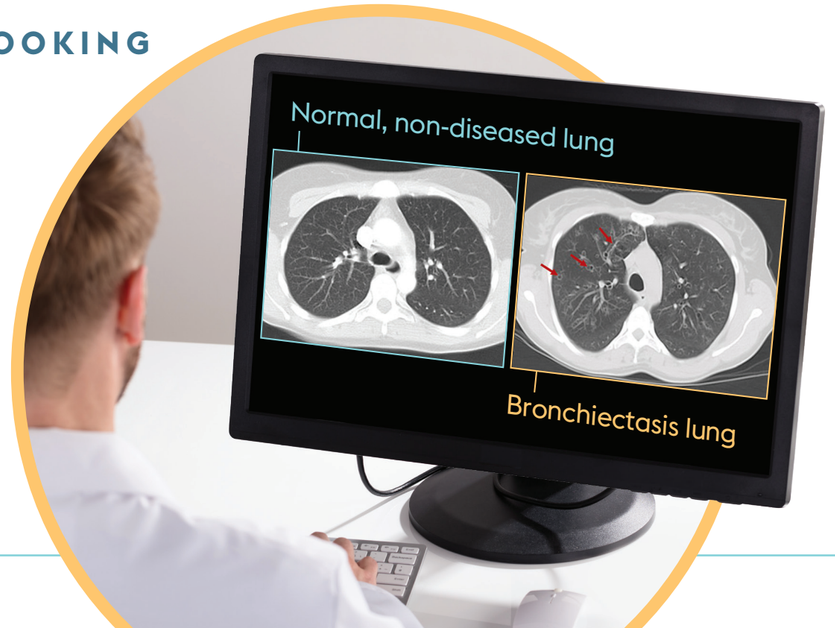
Bronchiectasis can be tricky because it often presents like COPD, but won't respond to COPD therapy. In fact, studies show it's much more prevalent than what's being diagnosed.

PATIENTS SUFFERING FROM:

- Long-term productive cough
- Recurring chest infections
- Frequent exacerbations requiring antibiotics, i.e., recurring pneumonia
- Frequent hospitalizations

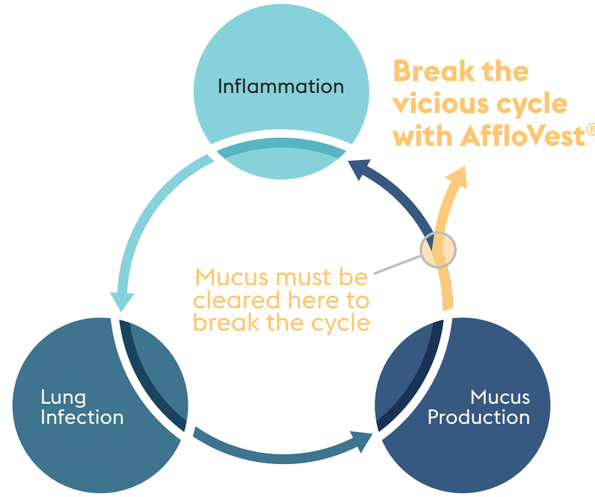
...SHOULD BE SCREENED FOR BRONCHIECTASIS.

ARE YOU LOOKING FOR IT?



AIRWAY CLEARANCE AND BRONCHIECTASIS

Airway Clearance Therapy (ACT) is considered the cornerstone of therapy aimed at minimizing the effects of airway obstruction, infection, and inflammation in lung diseases such as bronchiectasis.



Mobile High Frequency Chest Wall Oscillation (HFCWO) is an airway clearance therapy that can help mobilize and loosen secretions in the lungs, which may help reduce exacerbations, hospitalizations, and antibiotic use.

WHAT IS THE POTENTIAL IMPACT OF BREAKING THE VICIOUS CYCLE ?

REDUCING
antibiotic prescriptions

DECREASING
days and cost of hospitalization

REDUCING
outpatient encounters

Bronchiectasis patients averaged $5,681[4] higher medical care expenditures with averages of :

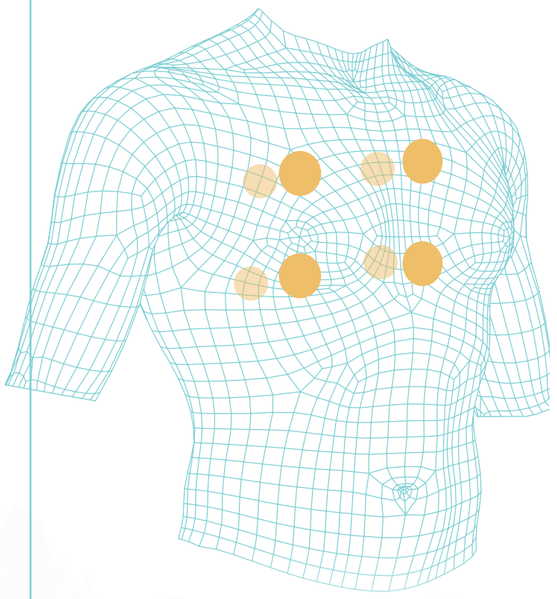
27 more days of antibiotic therapy [4,5]

2 additional days of hospitalization [3,4,5]

6 more outpatient encounters such as ER visits [4,5]

BREAK THE VICIOUS CYCLE OF BRONCHIECTASIS WITH

AFFLOVEST® MOBILE MECHANICAL OSCILLATION THERAPY



The fully mobile AffloVest is engineered to mimic anatomically targeted chest PT. It can be an effective airway clearance therapy for improving bronchial drainage by enhancing mobilization of secretions. It can be used for the treatment of respiratory diseases, such as bronchiectasis, cystic fibrosis, and neuromuscular diseases.

- Anatomically targeted therapy
- Engineered to mimic manual Chest PT
- Designed to increase patient adherence
- Fully mobile during use – Mobile CPT

The AffloVest is the first fully mobile battery operated HFCWO vest scientifically engineered to closely mimic manual Chest PT.

Patented Direct Dynamic Oscillation™ technology with eight oscillating motors creating individual pressure waveforms, providing disruption in the lungs to mobilize secretions.

- 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

> "The AffloVest has given me a new sense of freedom. I immediately noticed a difference and am now doing anything and everything I want."
>
> *—Abby P., AffloVest Patient*

COMMITMENT TO CLINICAL EVIDENCE

IRB Clinical Study demonstrates HFCWO vests do not increase cephalad airflow bias in the lungs during use. HFCWO vests are cleared as oscillation vests.[6]

Lung function improvement demonstrated in clinician papers.[7]

Noise study demonstrates that AffloVest® is the quietest HFCWO vest.[8]

Peak Magnetic Field test shows Afflovest is 4x lower than the threshold limit value for active medical device wearers and implanted medical devices.[8]

The Institutional Review Board (IRB) published clinical study, *Effect of High Frequency Chest Wall Oscillation Vest on Spirometry Measurements*, demonstrated that High Frequency Chest Wall Oscillation (HFCWO) vests do not increase cephalad airflow bias in the lungs during use. HFCWO vests are cleared as oscillation vests.

NO EVIDENCE of increased cephalad airflow bias in the lungs during use

REDUCED FVC/FEVI shown in compressor style vest group

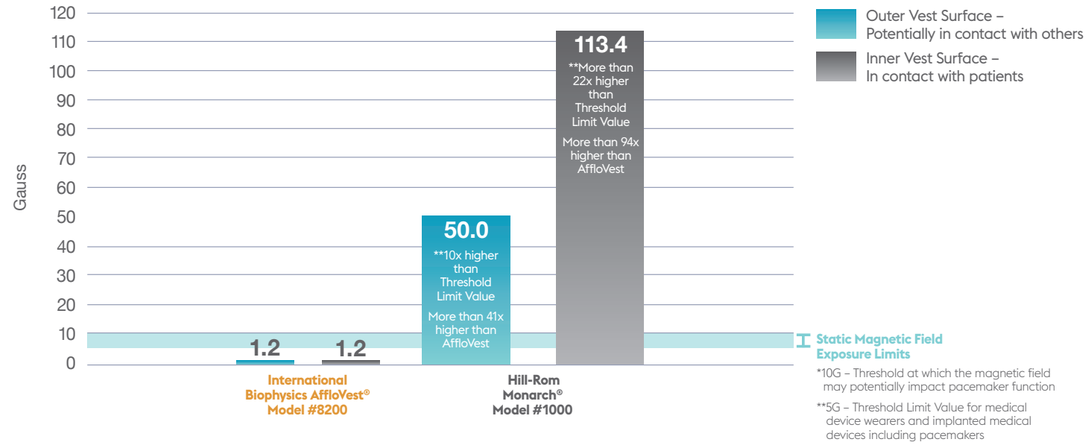
Compressor style vests showed a decline of 14% during use, 3x more than the AffloVest's decline in FEF25-75% during use

Study Results

Parameter	Baseline Mean [range]	AffloVest Mean [range]	p-Value	Compressor Mean [range]	p-Value	p-Value AffloVest vs. Compressor
*TV(L)	0.93 [0.30-2.32]	1.00	n.s.	1.07 [0.24-2.69]	n.s.	n.s.
*PEF(L/s)	8.19 [3.96-11.82]	8.28 [3.50-12.00]	n.s.	8.13 [4.23-12.89]	n.s.	n.s.
*FVC(L)	4.29 [2.48-6.57]	4.25 [2.50-7.42]	n.s.	4.12 [2.29-6.73]	0.019	n.s.
*FEVI(L)	3.51 [2.05-5.54]	3.46 [2.00-6.19]	n.s.	3.30 [1.92-5.53]	< 0.005	< 0.005
*FEF25-75%(L)	3.71 [1.77-6.43]	3.54 [1.63-6.37]	0.031	3.19 [1.19-6.22]	< 0.005	< 0.005

*American Thoracic Society (ATS) guidelines for lung function parameters.

Peak Magnetic Field Comparison of AffloVest® and Monarch® HFCWO Vests



*1) Electromagnetic Compatibility (EMC) Chart for Medtronic Pacemakers and Defibrillators (ICD), 04/16/2010, page 45 https://wwwp.medtronic.com/medtronicconnect/resources/dynamicarea/EMC_ChartForMedtronicPacersAndICDs-US-Apr2010.pdf 2) Electromagnetic Interference of Pacemakers, Umashankar Lakshmanadoss MD, Priya Chinnachamy MD and James P Daubert MD, http://cdn.intechopen.com/pdfs/13783/intech-electromagnetic_interference_of_the_pacemakers.pdf

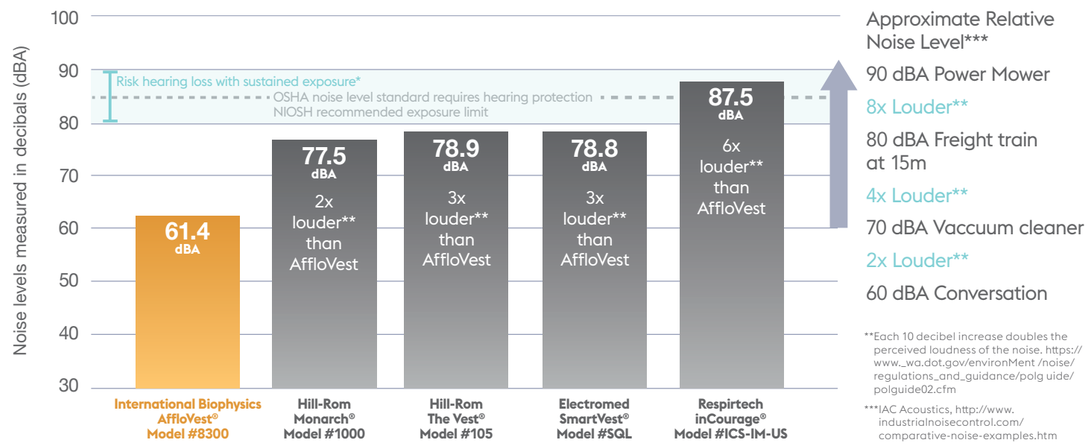
**1) 2018 TLVs® and BEIs® Based on the documentation of the Threshold Limit Values for chemical substances and physical agents & biological exposure indices, ACGIH Worldwide, Signature Publications, page 139, ISBN: 978-1-607260-97-4 2) Static Magnetic Fields Quick Reference Sheet, AIHA NIR Committee, Rev 1 – 3/4/13; ACGIH: Static Magnetic Fields TLV Documentation (2012) https://www.aiha.org/get-involved/VolunteerGroups/Documents/NONIONRAD-StaticMagneticFieldsQuickReferenceGuide.pdf 3) EMFs.info: Electric and magnetic fields and health: ACGIH, 2018; ACGIH 2015 TLVs http://www.emfs.info/limits/limits-organisations/acgih/

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

This test was funded by International Biophysics Corporation, manufacturer of AffloVest, the first fully mobile mechanical oscillation airway clearance therapy vest.

Noise Study Demonstrates that AffloVest® is the Quietest HFCWO Vest

Peak Audible Noise Levels of HFCWO vests at 0.3 meters (1 foot), per IEC 60601-1



*Decibel Level Comparison Chart – Yale Environmental Health and Safety, https://ehs.yale.edu/sites/default/files/files/decibel-level-.pdf

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AFFLOVEST® BRONCHIECTASIS REIMBURSEMENT CONSIDERATIONS

AffloVest is reimbursed by Medicare, Medicaid, and most private insurance for qualified patients whose medical records document*:

Daily productive (mucus) cough for at least 6 continuous months

OR

Frequent (i.e., more than 2/year) exacerbations/chest infections requiring antibiotic therapy

AND

Well-documented failure of other treatment to adequately mobilize retained secretions/airway clearance

AND

Diagnosis confirmed via a CT scan

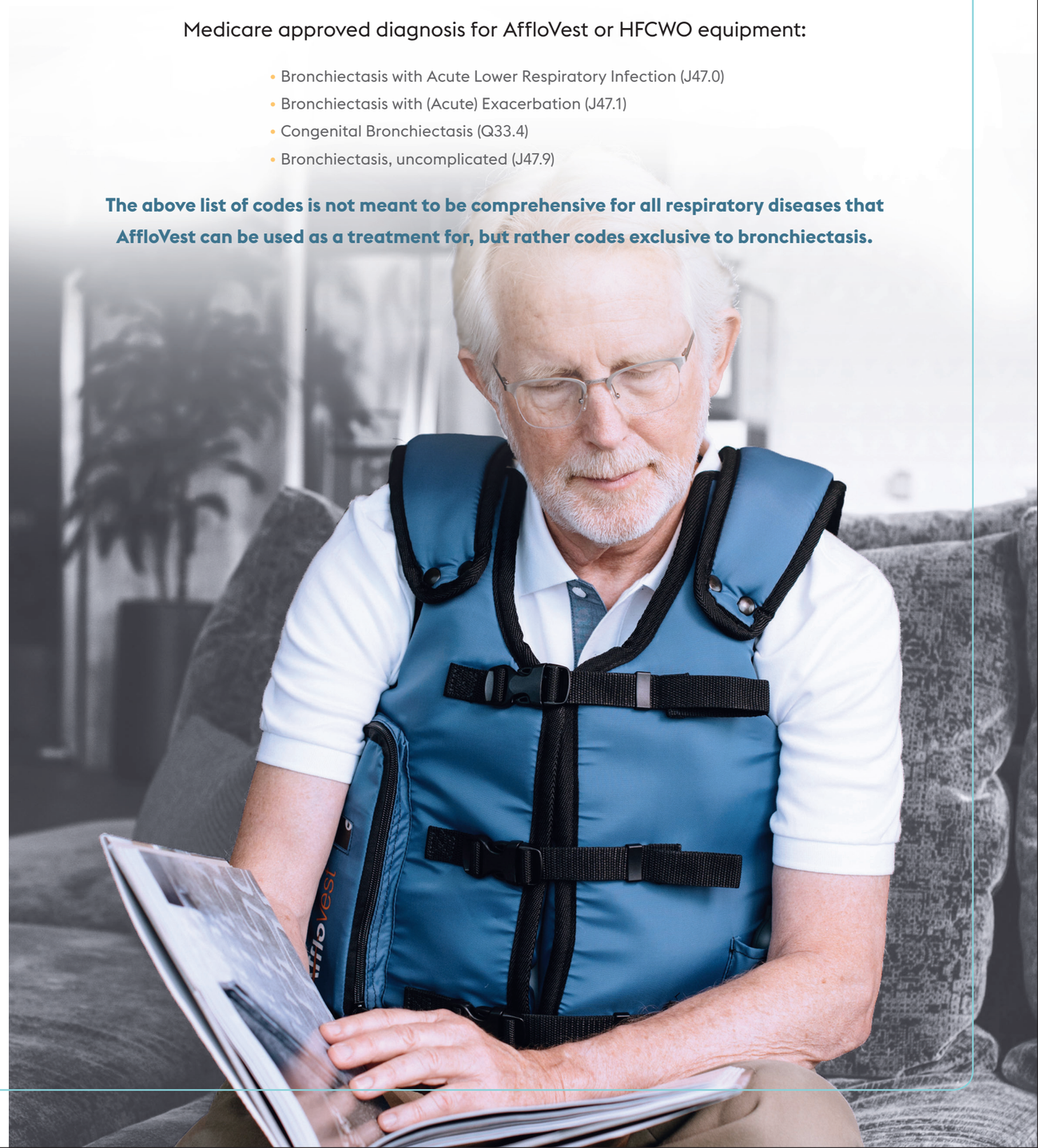
* AffloVest requires a doctor's prescription for treatment by High Frequency Chest Wall Oscillation (HFCWO). The AffloVest has received the FDA's 510k clearance for U.S. market availability, and is approved for Medicare, Medicaid, and private health insurance reimbursement under the Healthcare Common 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.

MEDICARE ICD-10 CODES FOR AFFLOVEST®

Medicare approved diagnosis for AffloVest or HFCWO equipment:

- Bronchiectasis with Acute Lower Respiratory Infection (J47.0)
- Bronchiectasis with (Acute) Exacerbation (J47.1)
- Congenital Bronchiectasis (Q33.4)
- Bronchiectasis, uncomplicated (J47.9)

The above list of codes is not meant to be comprehensive for all respiratory diseases that AffloVest can be used as a treatment for, but rather codes exclusive to bronchiectasis.



AffloVest®

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.

AFFLOVEST ORDERING INFORMATION

- Provide a prescription for E0483 HFCWO vest therapy with recommended frequency
- Gather all medical records and chart notes documenting:
  - **If a DX of any type of Bronchiectasis is the primary DX, the following applies:**
    - Most insurances require CT scan for a diagnosis of bronchiectasis, but requirements vary by payer
    - 6 continuous months of productive cough **OR** 3 or more exacerbations requiring antibiotics (both must be within the previous 12 months)
    - Previous treatments aimed at mobilizing secretions that patient has tried and failed, is unable to tolerate, or is unable to use
  - **If any other qualifying DX (CF or Neuromuscular) is the Primary DX, the following applies:**
    - Qualifying diagnosis with chart notes that support this DX
    - Previous treatments aimed at mobilizing secretions that patient has tried and failed, is unable to tolerate, or is unable to use
  - Chart notes must occur within 12 months prior to the prescription
- Fax all the information above to **888.793.2319**

For more information, please visit **afflovest.com**

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2. Weycker D, et al., Prevalence and Incidence of Non-cystic Fibrosis BE Among US Adults in 2013. Chron Respir Dis 2017. Nov;14(4): 377-384.
3. Ford ES, Murphy LB, Khavjou O, Holt JB, Croft JB., Total and State-Specific Medical and Absenteeism Costs of COPD Among Adults Aged 18 Years in the United States for 2010 and Projections Through 2020; CHEST American College of Chest Physicians; CDC; 2014
4. Weycker D, et al., Prevalence and Economic Burden of Bronchiectasis. CLIN PULM MED 2005;12:205.
5. Pamela J. McShane, Edward T. Naureckas, Gregory Tino, et al., Concise Clinical Review Non-Cystic Fibrosis Bronchiectasis; University of Chicago Medicine, Chicago, Illinois; University of Pennsylvania Medical Center, Philadelphia, Pennsylvania; Am J Respir Crit Care Med Vol 188, Iss. 6, pp 647–656, Sep 15, 2013 Copyright * 2013 by the American Thoracic Society
   Originally Published in Press as DOI: 10.1164/rccm.201303-0411CI on July 30, 2013
6. O'Brien TW, et al., Effect of High Frequency Chest Wall Oscillation Vests on Spirometry Measurements. Respiratory Therapy online issue August 8th, 2018.
7. 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.
8. 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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