



# The AffloVest

From International Biophysics Corp.

## The History and the Future of the HFCWO Market

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# About International Biophysics Corp. (IBC)

International Biophysics Corporation (IBC) founded in 1992 is a 20+ year old, FDA registered, ISO 13485 certified medical device developer and manufacturer. Our headquarters and main factory are located in Austin, Texas. IBC develops and produces medical products of our own design as well as medical products on an OEM contract basis. Our expertise as a medical device manufacturer is both diverse and in depth. IBC manufactures a large line of both single use/disposable and capital equipment. IBC has developed and manufactured cardiovascular heart pumps, bio sensors, surgical instruments, medical laser systems and portable oxygen concentrators.

IBC has extensive experience bringing new innovative products to the HME/DME market. IBC originally developed and manufactured the LifeChoice POC which is now part of Inova Labs. IBC is committed to bringing additional innovative and cost effective products to the HME/DME markets. Homecare is a large and growing part of the healthcare industry, and IBC is dedicated to being a leader in this market



# What is HFCWO

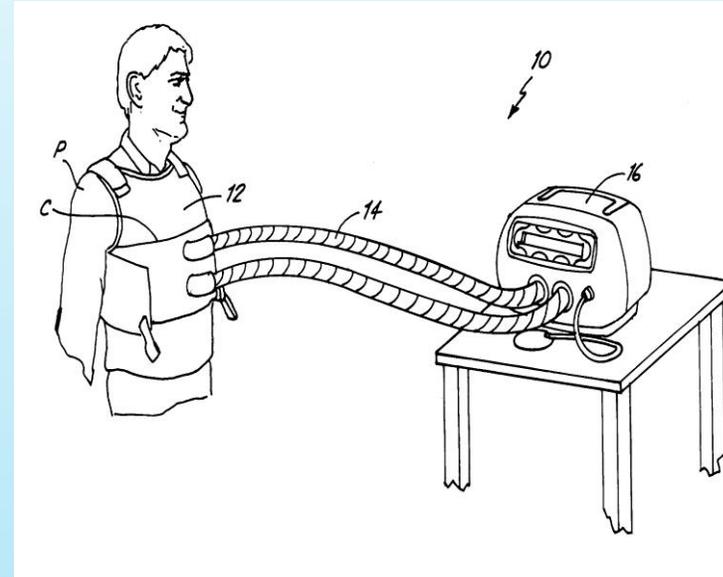
- ▶ HFCWO stands for High Frequency Chest Wall Oscillation

The mechanisms of HFCWO

- ▶ Decrease Mucosal Viscosity
- ▶ Creation of Staccato Coughs
- ▶ Non-symmetrical Oscillatory Airflow (Shearing Forces)

# Origins of HFCWO

- ▶ HFCWO therapy was originally aimed at replacing CPT (Chest Physiotherapy)
- ▶ The first disease HFCWO was designed to treat was CF (Cystic Fibrosis)
- ▶ The aim of the therapy was clearing mucosal secretions from the respiratory tract to improve lung function
- ▶ Early prototypes of HFCWO devices designed in the late 80's
  - ▶ Thairapy Vest - ARI Inc.
    - ▶ Now owned by Hill-Rom



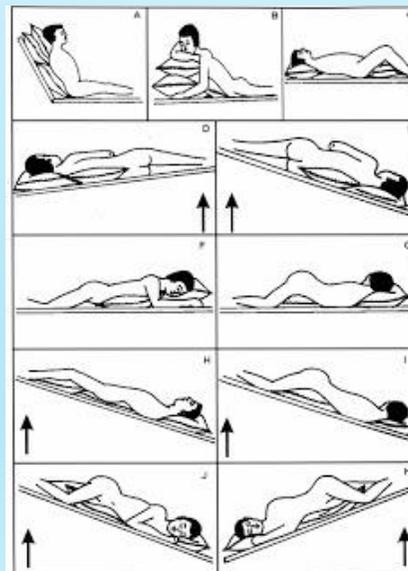
# Design of Traditional HFCWO Devices

- ▶ Inflatable Air Vest with Inlet/Outlet Ports
- ▶ Corrugated Hosing
- ▶ Air Generator Unit
- ▶ Weighs 17lbs
- ▶ Sound: 50-75dB depending on treatment level
- ▶ Cannot Run Without Connection to an Electrical Outlet
- ▶ Cannot Be Transported or Moved While in Use
- ▶ Air generator is Bulky and Heavy



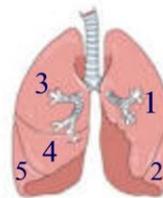
# Shortcomings of Traditional HFCWO

- ▶ Restricts Bodily Movement and Positioning
  - ▶ Hoses can become dislodged from ports
  - ▶ Vest Bladder can be compressed by Body Weight
- ▶ Cannot Incorporate Postural Drainage Techniques
- ▶ Air Generator Very Loud
- ▶ Bladder design dampens effect on lungs
  - ▶ Need to beat harder to transfer wave form
  - ▶ Inefficient
- ▶ Squeezes patient.
  - ▶ Minn. Protocol



# Shortcomings of Traditional HFCWO Cont.

- ▶ No flexibility in targeting specific lobes or chest wall regions
- ▶ High Pressure and Level of Intensity
- ▶ Devices sold through just a few channels direct to patients
  - ▶ Unavailable to DME/HMEs



# Design of the AffloVest

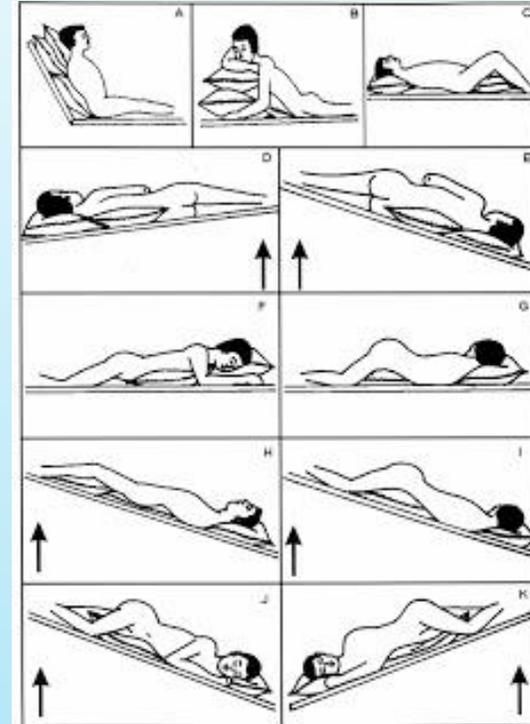


- ▶ Mechanically generated waveform
  - ▶ Direct Pt contact. Channels Directing Pneumatic Energy from OCMs to chest wall
  - ▶ More efficient
  - ▶ Targeting lobes of lung
- ▶ Wearable Vest Made of Water-Resistant Material
- ▶ 8 Oscillating Compressor Modules Sewn into vest
- ▶ Lithium Ion Battery
- ▶ Can run off of battery, DC outlet, or electrical outlet
- ▶ Fully Portable when Battery Operated
- ▶ Oscillating Compressor Modules Utilize Light and Ergonomic Design



# Design of The AffloVest Cont.

- ▶ Completely Posturally Independent
  - ▶ OCMs not affected by body positioning
- ▶ Can be used while incorporating Postural Drainage Techniques
- ▶ Weighs approx. 10lbs
- ▶ 3 treatment levels with 3 treatment setting for 9 treatment variations
- ▶ OCM noise dampened by AffloVest Lining/Padding - Very quiet
- ▶ The OCMs can be Operated Simultaneously or in Succession, Targeting Specific Lobe Regions
- ▶ The AffloVest Focuses on the Mechanisms of HFCWO and has Demonstrated its Efficacy in a Clinical Study



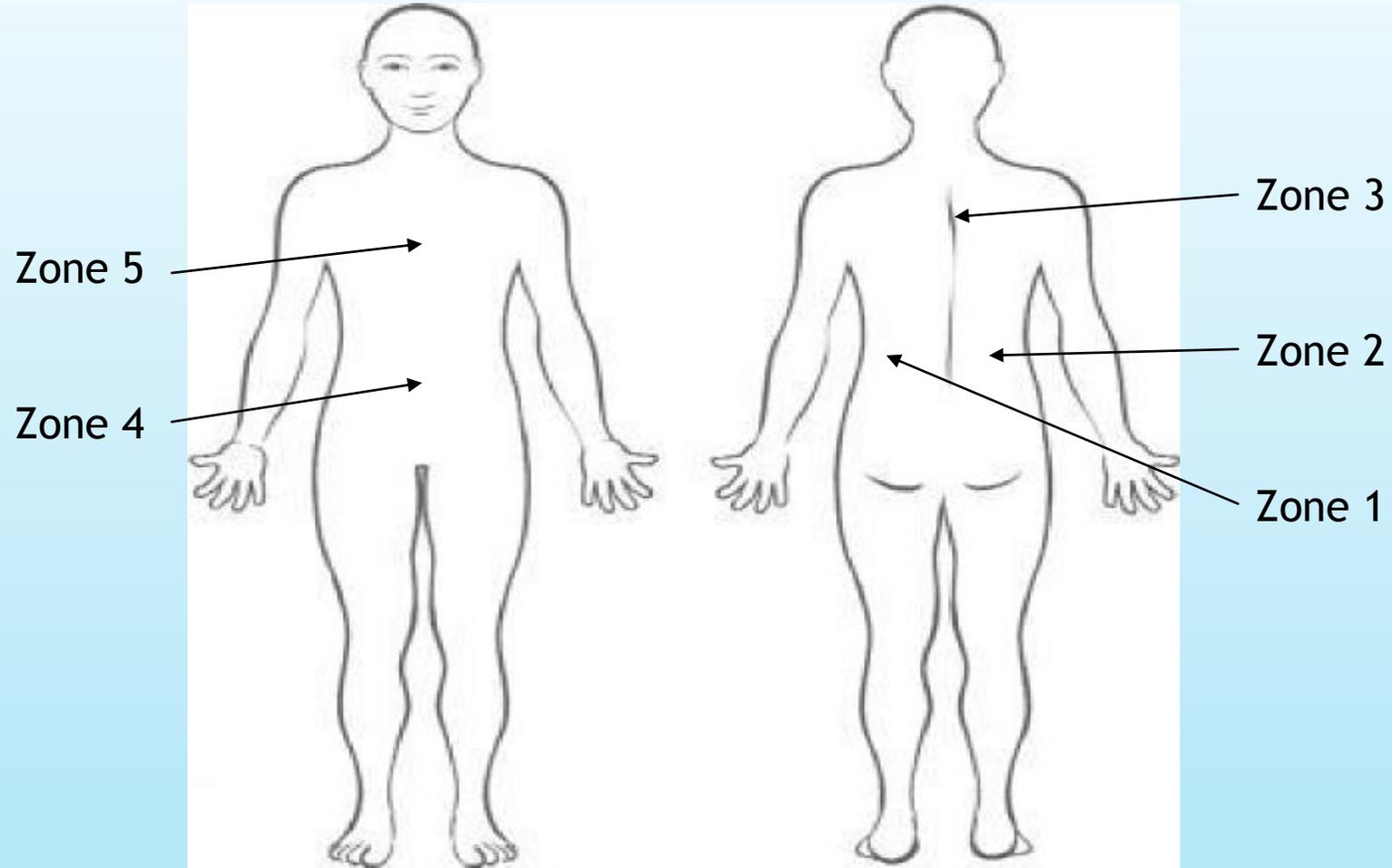
# Why the AffloVest works without the “Squeeze”

- ▶ Principles at work at the same time....frequency (hertz), vibration force (amplitude) and the acceleration force which is transmitted inside the lungs. This acceleration force in the lungs is what mobilizes the secretions.
- ▶ Air is a temperature insulator, but it also insulates and dampens force waves. So, the competitors need to have a lot of vibration force (amplitude) at a given frequency (hertz) to achieve the required acceleration force needed in the lungs to mobilize secretions.
- ▶ Since the AffloVest utilizes mechanical percussion (no air bladder, so no dampening of the vibration force/amplitude) it therefore transmit its vibration force directly into the patient, and thus it can achieve the same transmitted internal lung forces at a given Hertz with less Amplitude than air bladder vests.
- ▶ Our amplitude is equivalent to their amplitude since we directly transmit the vibration force directly into the patient and targeted at the lung lobes with no air dampening.
- ▶ It's not magic why the AffloVest works with less vibration force (amplitude) at the same given frequency (hertz), it's just physics.

# Psychological Benefit

- ▶ With traditional therapy, user is secluded in a room by themselves
  - ▶ Too loud to be around others
  - ▶ Thumps too hard to be able to work on computer etc
- ▶ Afflovest allows the user to be with others while doing treatment
- ▶ “My 12 year old daughter with CF just received her Afflovest from ups about 15 minutes ago. She was more excited about this than she has ever been even about Christmas. She told me she can be more like a regular girl and do sleepovers and things like that now. Thank you Afflovest for making this journey with cystic fibrosis a little easier on my daughter. For portability I give this a 10 out of 5 stars. Thank you again.”

# Treatment Zones



# Intensity Settings



**P3-Percussion Program.** All Motors operate in a pulsing/tapping mode. Percussion of the upper body with a regular rhythm

**P2-Vibration Program.** All motors operate uniformly at these intensity level. Deep oscillation of the thoracic cavity

**P1-Drainage Program.** The individual zones are activated in succession. Travelling oscillation up and down the thoracic cavity

# AffloVest FAQs

- ▶ What is the warranty on the AffloVest?
  - ▶ The AffloVest has a Limited Lifetime Warranty
    - ▶ This covers all integral components of the device and the controller.
  - ▶ The Battery is under warranty for 12 Months
    - ▶ The Battery should last many years, however, depending on usage and care
- ▶ How many treatments can be performed on a single battery charge?
  - ▶ The battery will last for between 6 and 10 treatments before requiring recharging
    - ▶ This is dependent on usage (i.e. intensity and program settings, duration protocols)



# AffloVest FAQs Cont.

- ▶ What are the Treatment Protocols?
  - ▶ They differ with each patient
    - ▶ AffloVest Operates in the same frequency ranges as other HFCWO devices
      - ▶ Soft - 5 Hz | Medium - 12 Hz | Intense - 20 Hz
      - ▶ Pulmonologists familiar with these ranges in HFCWO can see the connection to our intensity level settings to customize protocols when needed
    - ▶ Treatment Durations/ Should be Similar to Other HFCWO Devices
      - ▶ Typical protocol is 30 min.
- ▶ Most common-P2 Medium for 2 sessions then P2 Intense for 2 treatments



# Proof the AffloVest Works

- ▶ A Clinical Study was conducted in the AffloVest's original German market
  - ▶ It was conducted by a pulmonologist in a prestigious pulmonary clinic - Klinik Bad Reichenhall
- ▶ Over 1,000+ AffloVests in Use in Germany
  - ▶ Been on the market already for 2+ years in Germany
- ▶ FDA 510(k) approved. The FDA deemed the AffloVest to be “Substantially Equivalent” to its predicate device

# How Do We Educate Patients and Caregivers To Use The AffloVest?

- ▶ The AffloVest is Simple To Use
  - ▶ A How-To Video is available to better understand device operation
  - ▶ Comprehensive Owner's Manual
  - ▶ Patient training checklist



# How to Fit to a Patient

- ▶ Each Patient Will Prefer A Different Fit
- ▶ Vest Sizing Roughly Follows Clothing Sizes
- ▶ The Vest should be snug around the patient
  - ▶ The fit should be secure enough that the vest remains in place even with the shoulder snaps unfastened



5 Sizes Available

# Elevator Pitch

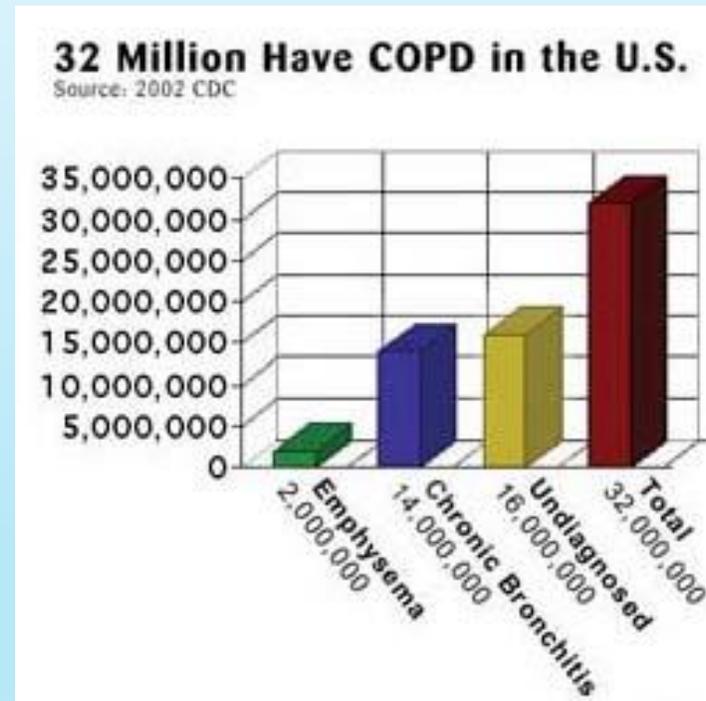
- ▶ When turn on, do not expect to see the “squeeze” you may be familiar with, nor will you see the thumping you may be use to
- ▶ Afflovest is designed with 8 oscillating motors sewn into vest to deliver wave form with out having to squeeze and thump.
- ▶ Quiet
- ▶ Target upper lobes of lung
- ▶ Patients are more compliant
- ▶ Mobility

# Population Potentially Eligible for HFCWO Therapy

- ▶ Cystic Fibrosis
  - ▶ 30,000 Patients in the U.S.
- ▶ Bronchiectasis
- ▶ ALS (Amyotrophic Lateral Sclerosis)
  - ▶ 30,000 Patients in the U.S.
- ▶ Multiple Sclerosis
  - ▶ 400,000 Patients in the U.S.
- ▶ Hereditary Muscular Dystrophy
  - ▶ 400-600 New Patients Each Year in U.S.
- ▶ Quadriplegia
  - ▶ 120,000 Patients in the U.S.

# COPD market potential/growth

- ▶ COPD Patients with a Bronchiectasis component
  - ▶ How often does a COPD patient return to Doctors office due to infection?
- ▶ Bronchiectasis-Potential Market
  - ▶ ~ 60% of COPD patients
    - ▶ 9-12 Million Patients in the U.S.

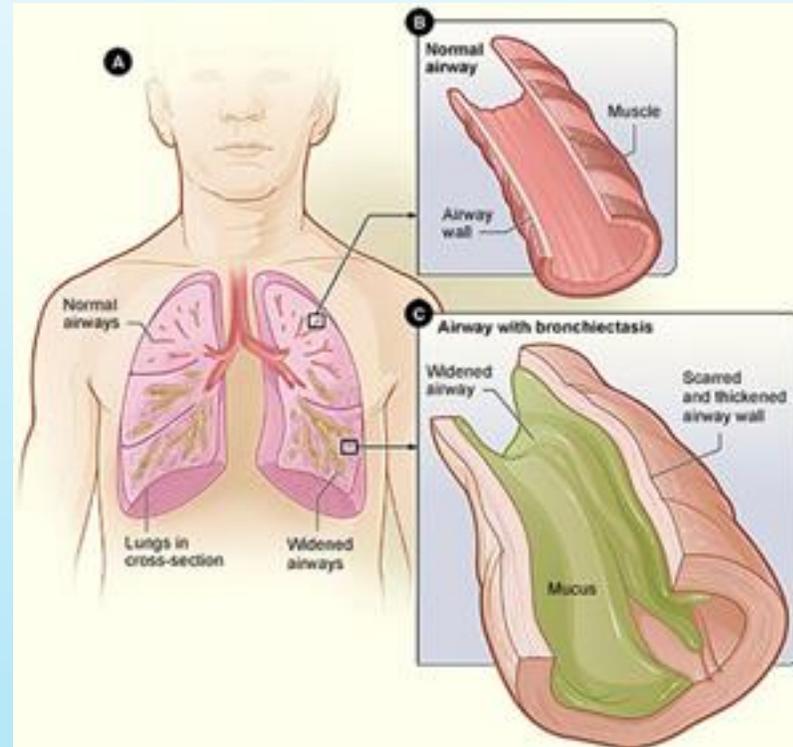


# Hospitals/Departments/Opportunities

- ▶ Pulmonology-
  - ▶ Deal with Bronchiectasis patients.
  - ▶ May also be heavily involved with CF, MDA, ALS and other neuromuscular disease/Patients
- ▶ Neurology-
  - ▶ Does hospital have a CF clinic?
    - ▶ Does Clinic also deal with MDA, ALS etc. type of patients.
    - ▶ Are Pulmonologist involved?
- ▶ Respiratory Therapist-What is there role
- ▶ Who does discharging of different patients?
  - ▶ Discharge Planner? Case Manager? Social Worker? Respiratory Therapist?
- ▶ Other Departments-
  - ▶ Cancer Centers? Lung Transplant Surgeons? Pulmonary ICU? Nursing?

# Bronchiectasis

- ▶ COPD Patients visiting Doctor because of infections
  - ▶ How often does a COPD patient return to Doctors office due to infection?
- ▶ Bronchiectasis-Potential Market
  - ▶ ~ 60% of COPD patients-



- ▶ Figure A shows a cross-section of the lungs with normal airways and widened airways. Figure B shows a cross-section of a normal airway. Figure C shows a cross-section of an airway with bronchiectasis

# Cystic Fibrosis

## What Is Cystic Fibrosis?

- ▶ Cystic fibrosis is an inherited chronic disease that affects the lungs and digestive system of about 30,000 children and adults in the United States (70,000 worldwide). A defective gene and its protein product cause the body to produce unusually thick, sticky mucus that:
  - ▶ clogs the lungs and leads to life-threatening lung infections; and
  - ▶ obstructs the pancreas and stops natural enzymes from helping the body break down and absorb food.
- ▶ In the 1950s, few children with cystic fibrosis lived to attend elementary school. Today, advances in research and medical treatments have further enhanced and extended life for children and adults with CF. Many people with the disease can now expect to live into their 30s, 40s and beyond.

# Cystic Fibrosis

## Symptoms of Cystic Fibrosis

- ▶ People with CF can have a variety of symptoms, including:
- ▶ very salty-tasting skin;
- ▶ persistent coughing, at times with phlegm;
- ▶ frequent lung infections;
- ▶ wheezing or shortness of breath;
- ▶ poor growth/weight gain in spite of a good appetite; and frequent greasy, bulky stools or difficulty in bowel movements.

## Statistics

- ▶ About 1,000 new cases of cystic fibrosis are diagnosed each year.
- ▶ More than 70% of patients are diagnosed by age two.
- ▶ More than 45% of the CF patient population is age 18 or older.
- ▶ The predicted median age of survival for a person with CF is in the early 40s.

# The End

▶ Questions?



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