WHERE THERAPY IS MOVING

Hillrom™

Monarch®
Airway Clearance System

BREATHE EASIER KNOWING THEY WILL TOO

Imagine how the quality of your patients' lives could be improved if they were given the freedom to do their airway clearance therapy while still doing everyday activities. That's exactly what our Monarch® Airway Clearance System is designed to do.

The Monarch® System employs revolutionary technology to provide High Frequency Chest Wall Oscillation (HFCWO) therapy in a mobile way. Now your patients can move about freely even as they receive targeted kinetic energy and airflow to thin and mobilize airway secretions.

The Monarch System enables collaboration between you and your patients via the Hillrom™ Connex® App and Health Portal—where you can easily see your patients' therapy session results and make informed decisions about their care plans.

Patient-friendly features

- Sportswear-inspired design gives your patients freedom of mobility and personalization of their device with 5 vest shell color and pattern options.
- The device's quiet operation enables easy conversation.[1]
- Pendant controls are intuitive and simple for your patients to use.
- Rechargeable battery powers their therapy on the move.
- Rolling carry case with retractable handle and backpack straps looks like fashionable luggage and makes it easy for your patient to travel with the device.

Mobile and connected

At Hillrom, we've always believed that when patients and their healthcare teams are closely connected, the result is better care. That's why we're leveraging technology and extensive experience working with patients and clinicians to make those vital connections more accessible, powerful and actionable than ever before.

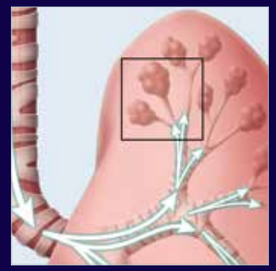
With the groundbreaking Hillrom™ Connex® App and Health Portal, paired with the Monarch® System, we're leading the way in advancing connected care.

POWERED BY PODS

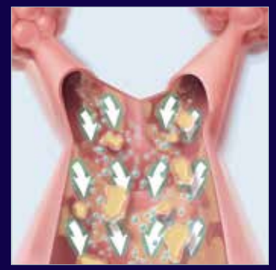
The Monarch® System's eight Pulmonary Oscillating Discs (PODs) are positioned to deliver targeted kinetic energy to the upper and lower lungs. This targeted therapy generates airflow helping to thin mucus and mobilize secretions from the small airways to the large airways, from which they can be coughed or suctioned out to help improve your patient's airway health.[2-7]

Inside front panel

Inside back panel



PODs operate in a pattern designed to loosen mucus and optimize the airway clearance effect.



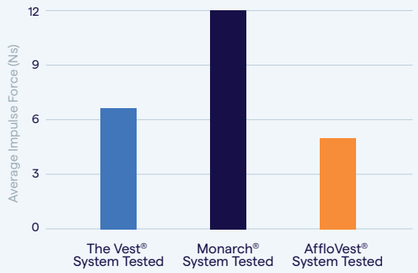
Airflow moves the mucus from small airways toward the large airways, from which they can be more easily expelled or removed.

Understanding HFCWO mechanisms of action*

Expiratory airflow bias is important, and kinetic energy transferred through the chest wall to the lungs is believed to help loosen secretions adhering to lung tissue.[4-9] HFCWO creates kinetic energy designed to increase airflow to help mobilize secretions from the airways.[4,5,7,9,10]

* Comparisons are not based on head-to-head clinical efficacy studies. The clinical significance of these differences has not been established. Airflow test subjects were adult males with healthy lung function. Results for female subjects and patients with lung disease may vary from those in this study.

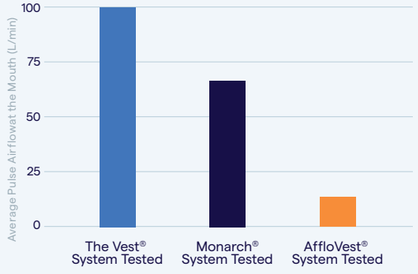
Impulse Force Testing Results[2]



Kinetic energy delivered to the chest wall.

Kinetic energy delivered to the chest wall generates airflow to mobilize secretions and is believed to help loosen secretions.[7,8] Impulse force was used to evaluate the kinetic energy delivered by an airway clearance system. Measuring this force applied over an acute period of time provides insight to the energy transfer through a chest wall to lung tissue.

Airflow Testing Results[3]



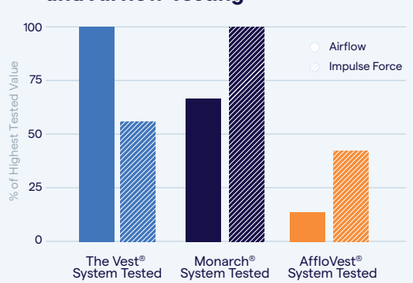
Airflow to mobilize secretions.

Pulse airflow was used to evaluate the airflow created by different airway clearance systems. Each pulse of air flow at the mouth was measured via software customized to measure oscillating airflow.

Testing shows the Monarch System can generate up to 5x the airflow of the AffloVest System.[3**]

** Systems tested were The Vest® System Model 105, the Monarch System Model 1000, and the AffloVest Systems labeled as REF 8200 and 8300.

Summary of Impulse Force and Airflow Testing[2,3]



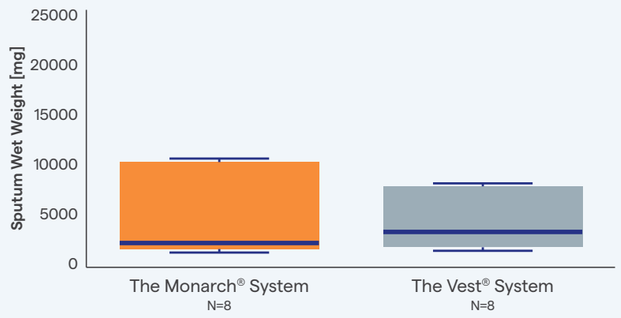
The Monarch System offers a new mobile option for HFCWO therapy.

CLINICAL RESULTS

Data from a clinical evaluation of the Monarch® Airway Clearance System by Leemans G., et al., were presented at the 2018 North American Cystic Fibrosis Conference (NACFC). The researchers reported the Monarch System was comparable to The Vest® System for sputum production.

Post-therapy evaluations of the Monarch System showed statistically significant improvement in Brody scores and FRI results, suggesting the device's relative airway clearance effectiveness.[11]

Comparison of Wet Sputum Weight, Monarch System vs. The Vest® System (p=0.77)[11]



Brody Scores and FRI Measurements for the Monarch System

Parameter	Pre-Monarch System Therapy Measurements	Post-Monarch System Therapy Measurement	P-value
Brody Scores	57.71 ± 16.55	55.2 ± 16.98	p=0.001
FRI (iVaw)	49.442 ± 50.117	44.516 ± 49.637	p<0.001

INDICATIONS FOR USE[12]

The Monarch® Airway Clearance System is intended to provide airway clearance therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.

The Monarch System is intended to be used in the Home Care environment by patients, 15 years and older.

CONTRAINDICATIONS[2]

If any patient conditions exist that could cause the use of Monarch® Airway Clearance System, Model 1000 to present a risk to the patient, do not use the unit except as directed by a physician. Death or serious injury could occur.

Monarch® Airway Clearance System, Model 1000 is contraindicated if these conditions are present:

- Patients who have any of the following active implantable medical devices, due to the presence of the magnetic field created by the Monarch® device, whether it is turned on or off:
  - Pacemakers
  - Neurostimulators
  - Infusion Pumps
  - Circulatory Support Devices
  - Implantable Cardioverter Defibrillators (ICDs)
  - Cochlear Implants
- Head and/or neck injury that has not yet been stabilized.
- Active hemorrhage with hemodynamic instability.

WARNINGS[12]

The Monarch Airway Clearance System warnings include:

- Patients that may have difficulty clearing secretions from the upper airway (such as those with DMD or other advanced neuromuscular or neurological disorders) may require specialized therapy regiments involving manually or mechanically assisted coughing or other techniques in conjunction with Monarch Airway Clearance System.
- The Monarch System has been prescribed by your physician for your use only. No one else should ever try on your device, whether it is on or off. It should never be worn or used by someone with an active implantable medical device due to the presence of the magnetic field created by the Monarch® Pulmonary Oscillating Discs (PODs).

For a complete list of Warnings refer to the Monarch System User Manual.

ABOUT HILLROM

Hillrom is a global medical technology leader whose 10,000 employees have a single purpose: enhancing outcomes for patients and their caregivers by advancing connected care. Around the world, our innovations touch over 7 million patients each day. They help enable earlier diagnosis and treatment, optimize surgical efficiency and accelerate patient recovery while simplifying clinical communication and shifting care closer to home. We make these outcomes possible through connected smart beds, patient lifts, patient assessment and monitoring technologies, caregiver collaboration tools, respiratory care devices, advanced operating room equipment and more, delivering actionable, real-time insights at the point of care. **Learn more at hillrom.com**.

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For more information about products or services, please contact your Hillrom sales representative or Hillrom customer service at 1-800-426-4224.

mymonarch.com

References

[1] Bench testing conducted in 2017. Testing was performed at the following therapy settings: The Vest® System Model 105 and the MonarchTM System Model 1000 with intensity/pressure set at 10, frequencies settings at 5, 14, and 20 Hz; the AffloVest® System was tested at the "Vibration" setting at "Low", Medium" and "High" settings, which according to the AffloVest® web site operate at 5Hz, 13Hz, and 20Hz respectively. The AffloVest® Systems used were labeled as REF 8200 and 8300. Testing consisted of measuring impulse force, or applied force over a timeframe of 30 seconds, via 4 force sensors placed on a mannequin in upper and lower chest locations. Comparisons are not based on head to head clinical efficacy or safety studies.

[2] Independent lab testing conducted in 2017. Data was analyzed and compared average pulse airflows at the mouth generated by high frequency chest wall oscillation (HFCWO) therapy in 10 human subjects using home care garments. Airflows were measured via pneumotachometer at settings of the following: The Vest® System Model 105 and the MonarchTM System Model 1000 with intensity/pressure set at 10, frequencies settings at 5, 10, 15, and 20 Hz; the AffloVest® System was tested at the "Vibration" setting at "Low", Medium" and "High" settings, which according to the AffloVest® web site operate at 5Hz, 13Hz, and 20Hz respectively. The AffloVest® Systems used were labeled as REF 8200 and 8300. Comparisons are not based on head to head clinical efficacy or safety studies. Airflow test subjects were adult males with healthy lung function. Results for female subjects and patients with lung disease may vary from those in this study.

[3] Sound testing per International Standard IEC 60601-1, 3rd Edition at a distance of 30 cm. Sound testing results found the Monarch System operates at a level at or below that considered as a "normal conversation"; reference https://www.nidcd.nih.gov/health/noise-induced-hearing-loss.

[4] King M, Phillips D, Gross D, Vartian V, Chang HK, Zidulka A. Enhanced tracheal mucus clearance with high frequency chest wall compression. Am Rev Respir Dis, 1983; 128:511-5.

[5] Dosman CF and Jones RL. High-frequency chest compression: a summary of the literature. Can Respir J, 2005. 12(1): p. 37-41.

[6] Freitag L, et al. Removal of excessive bronchial secretions by asymmetric high-frequency oscillations. J Appl Physiol 1989; 67: 614-9.

[7] McCarren B, Alison JA. Physiological effects of vibration in subjects with cystic fibrosis. Eur Resp J 2006; 27: 1204-9.

[8] Murray M, et al. Critical Care Medicine Perioperative Management Second Edition by Lippincott Williams & Wilkins, 2002: p. 435.

[9] Chest physical therapy. www.healthofchildren.com/C/Chest-Physical-Therapy.html, accessed on 5 April 2017.

[10] Kendrick A. Airway Clearance Techniques in Cystic Fibrosis: Physiology, Devices and the Future, Cystic Fibrosis. InTech, 2012. Available from https://www.intechopen. com/books/cystic-fibrosis-renewed-hopes-through-research/airway-clearance-techniques-in-cystic-fibrosis-physiology-devices-and-the-future.

[11] Leemans G, De Hondt A, Ides K, et al. Evaluation of a mobile HFCWO device in patients with cystic fibrosis. Pediatric Pulmonology. September 2018;53(S2):S1-S481.

[12] The Monarch Airway Clearance System Model 1000 User Manual (195292).