Where Therapy is Moving
Monarch® Airway Clearance System
The Monarch® Airway Clearance System is a high frequency chest wall oscillation (HFCWO) therapeutic device with revolutionary new technology. The therapy combines mobility with targeted kinetic energy and airflow to thin and mobilize secretions from the airways. By allowing patients to move about freely during therapy, it empowers them to take control of their therapy—and lives.

Connected in care to you, their health care team via the VisiView® Health Portal, patients can collaborate in their treatment planning. A game-changer in HFCWO.

Mobile therapy that works.¹,²,³

Mobile and connected.

The Monarch® System helps motivate and empower patients to collaborate in their therapy by offering key attributes:
- Enabled with either LTE or WiFi connectivity.
- Connects patients wirelessly to their care team via the VisiView® Health Portal.
- Provides access to patient therapy session feedback.
- Encourages adherence through collaboration between patient and physician.

Patient-friendly features.

- Sportswear-inspired design is made for freedom of mobility. Its quiet operation enables easy conversation.¹
- Fun colors and patterns let patients personalize their device.
- Pendant controls are intuitive and simple to use.
- Rechargeable battery powers therapy on the move.
- Handy rolling case with retractable handle and backpack straps looks like ordinary luggage, and makes it easy for patients to travel with their device.
- Mobile app, used with Bluetooth® connectivity, streamlines device operation for patients.

VisiView® Health Portal – Easy, automatic therapy tracking to enhance collaboration in care.
The Monarch® System offers a **new mobile option** for HFCWO therapy.

**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. HFCWO creates kinetic energy designed to increase airflow to help mobilize secretions from the airways.

- **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. 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 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.

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**Summary of Impulse Force and Airflow Testing**

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* 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.

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

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

Contraindications

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:

• The Monarch® device uses Pulmonary Oscillating Discs (PODs) that create a magnetic field which is present whether the device is turned on or off. Due to the presence of the magnetic field, people who have an active implantable medical device, such as any of the following, are contraindicated (if they cannot keep the susceptible component at least 6 inches away from the Monarch® device):
  i. Pacemakers
  ii. Neurostimulators
  iii. Infusion Pumps, including Insulin Pumps
  iv. Circulatory Support Devices
  v. Implantable Cardioverter Defibrillators (ICDs)

• Head and/or neck injury that has not yet been stabilized.

• Active hemorrhage with hemodynamic instability.

Warnings

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 regimens involving manually or mechanically assisted coughing or other techniques in conjunction with Monarch Airway Clearance System, Model 1000 therapy. Please consult your physician to determine if additional therapy is appropriate.

• The Monarch® Airway Clearance System has been prescribed by your physician for your use only. Do not let others try on your device, whether it is turned 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). See the contraindications section in the manual for further description of an active implantable medical device.

For a complete list of Warnings refer to the User Manual.
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**References:**

1. Bench testing conducted in 2017. Testing was performed at the following therapy settings: The Vest® System Model 105 and the Monarch® 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 REF8200 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 Monarch® 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 REF8200 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.


