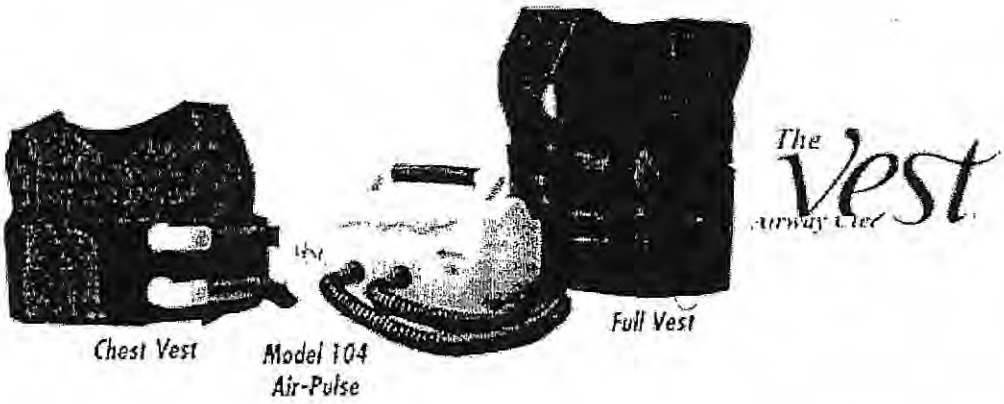
The Vest

The Vest™ Airway Clearance System - Model 104
(Information obtained from website www.thevest.com and all information is intended as a guide when caring for clients...use your professional judgement.)



About The Vest™ system

The Vest™ system is an easy-to-use airway clearance device for both children and adults. It was originally introduced in 1988. Model 104 was cleared to market in February, 2003. The Vest™ airway clearance system administers a method of airway clearance therapy called high-frequency chest wall oscillation (HFCWO). The Vest™ system is also intended for sputum induction for diagnostic evaluation. The Vest™ system consists of an inflatable vest connected by tubing to an air-pulse generator.

How does The Vest™ system work?

The air-pulse generator rapidly inflates and deflates the vest, gently compressing and releasing the chest wall up to 20 times per second. This process, called high-frequency chest wall oscillation (HFCWO), creates mini-coughs that dislodge mucus from the bronchial walls, increase mobilization, and move it along toward central airways. The action also works to thin thick secretions, making them easier to clear. Once the mucus has moved from the smaller to larger airways, it can be easily removed by coughing or suctioning.

Treatments are easy

Most users manage therapy without any help. Unlike manual chest percussion therapy (CPT), The Vest™ system treatment does not require special positioning or breathing techniques. The technology is technique-independent because user or caregiver factors do not compromise its effectiveness. A typical treatment takes 15-20 minutes.

Proven effective

HFCWO has been widely described in medical literature. More than 80 studies in more than 60 facilities – spanning 18 years of research – demonstrate the efficacy and safety of HFCWO for a variety of clients.

Device Performance Data

The Vest™ system has an adjustable frequency setting that provides delivery of HFCWO at frequencies from 5 to 20 Hz.

The pressure delivered to the vest is adjustable with a range in mean pressure of approximately 3 to 27 cmH_20. Pressure is relatively stable across the range of frequencies but varies somewhat depending on vest size. Typical pressure measurements for vest sizes (at the maximum device pressure setting) are listed below.

Chest Vest Size	Mean Oscillation Pressure ($cm H_2O$)	Peak Oscillation Pressure ($cm H_2O$)
Small	27	53
Medium	27	48
Large	26	41
Extra-Large	25	41
Full and Single Client Use Vest Size	**Mean Oscillation Pressure ($cm H_2O$)**	**Peak Oscillation Pressure ($cm H_2O$)**
Child Medium	27	46
Child Large	26	42
Adult Small	25	39
Adult Medium	23	35
Adult Large	24	34

Indications

The following conditions are indications for use of The Vest™ system:

1. Documented need for airway clearance as defined by the American Association for Respiratory Care (AARC)[1] clinical practice guidelines. These guidelines include:

    a) Evidence of difficulty with secretion clearance
        - Difficulty clearing secretions with expectorated sputum production greater than 25 - 30 ml/day (adult)
        - Evidence or suggestion of retained secretions in the presence of an artificial airway

    b) Presence of atelectasis caused by or suspected of being caused by mucus plugging

    c) Diagnosis of disease such as cystic fibrosis, bronchiectasis, or cavitating lung disease

2. Need for sputum sample for diagnostic evaluation

Contraindications

The Vest™ system is contraindicated if the following conditions are present:

- Head and/or neck injury which has not yet been stabilized
- Active hemorrhage with hemodynamic instability

Relative Contraindications

The decision to use The Vest™ system for airway clearance therapy in the presence of the conditions listed below requires careful consideration and assessment of the individual client's case.

- Intracranial pressure (ICP) > 20 mm Hg, or clients in whom increased intracranial pressure is to be avoided
- Uncontrolled hypertension
- Hemodynamic instability
- Pulmonary edema associated with congestive heart failure
- Bronchopleural fistula
- Subcutaneous emphysema

- Large pleural effusions or empyema
- Recent esophageal surgery
- Active or recent gross hemoptysis
- Pulmonary embolism
- Uncontrolled airway at risk for aspiration (tube feeding or recent meal)
- Distended abdomen
- Bronchospasm
- Suspected pulmonary tuberculosis
- Transvenous pacemaker or subcutaneous pacemaker
- Recent epidural spinal infusion or spinal anesthesia
- Recent spinal surgery or acute spinal injury
- Rib fractures, with or without flail chest
- Surgical wound or healing tissue, recent skin grafts or flaps on the thorax
- Burns, open wounds and skin infections on the thorax
- Lung contusion
- Osteomyelitis of the ribs
- Osteoporosis
- Coagulopathy
- Complaint of chest wall pain

Warnings

- Do not plug in or use the air-pulse generator if it is wet or damp.
- Use The Vest™ system only with a properly grounded electrical outlet.
- Do not disassemble the air-pulse generator, as this may expose you to electric shock or other risks.
- Do not use The Vest™ system in the presence of flammable anesthetics (risk of explosion).

Precautions

The Vest™ system is prescription medical equipment; as such, federal law (USA) restricts the device to sale by or on the order of a physician.
The Vest™ system is intended for use as an airway clearance therapy and/or for sputum induction for diagnostic evaluation.
Each client should be evaluated individually by his/her physician to determine the safety and appropriateness of therapy by The Vest™ system.
Caution should be used when performing the first few treatments of The Vest™ system on clients who have the potential to mobilize large volumes of secretions and/or who have significant retained secretions because of ineffective clearance for an extended period of time (e.g. certain bronchiectasis clients, neuromuscular weakness clients, or clients with artificial airways). When using The Vest™ system with these clients, preparation should be made for proper evacuation of mobilized secretions (e.g. preparation of suction equipment or preparation for assistance with coughing).

Individualization of Treatment

Each client should be evaluated individually by his/her physician to determine the safety and appropriateness of therapy or use of The Vest™ system for sputum induction.
Hill-Rom has not developed specific protocols for use of The Vest™ system in individual clients or specific client populations.
Commonly prescribed protocols for use of The Vest™ system are available from Hill-Rom.

Client Counseling

Therapy by The Vest™ system may be administered in the home. Hill-Rom provides both training and support for home use of The Vest™ system.

Conformance to Standards

The FDA has designated The Vest™ system as a class II device, but no FDA standards have been established under Section 514.
The Vest™ system complies with:

- UL 544, Standard for Safety for Medical and Dental Equipment
- C22.2, Canadian Standard for Electromedical Equipment
- The electromagnetic compatibility requirements defined in FCC Part 15 and European Standard EN 55011.
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How The Vest™ System is Supplied

- The Vest™ system is available from Hill-Rom
- The air-pulse generator comes fully assembled
- The system includes the air-pulse generator, a vest, connecting tubing, power cord, and a remote control
- All equipment and accessories are non-sterile

User Manual

The Vest™ system User Manual includes instructions for set-up, use and maintenance of The Vest™ system Model 104. It is intended as a reference guide and to provide instructions for the safe and effective use of the device. The manual is intended for operators and clients.

See Research and Evidence for further clinical applications and outcomes information about HFCWO and The Vest™ system.

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[1] AARC Clinical Practice Guideline: Postural Drainage Therapy, *Respiratory Care* 1991;36:1418-1426.
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