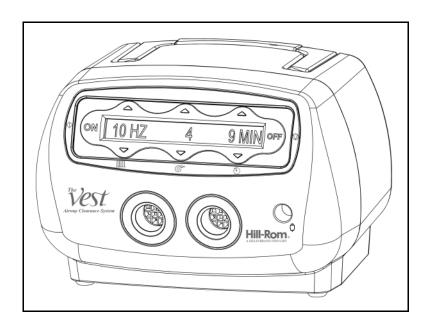
USER MANUAL

The Vest® Airway Clearance System, Model 104

From Hill-Rom



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To order additional copies of this manual (USR150), refer to the back cover for contact information. For countries not listed on the back cover, contact your distributor.

NOTE:

The back cover is a comprehensive list of Technical Support contact information for Hill-Rom. The product discussed in this manual may not be available in all of the countries listed.

Revision	Pages Affected	Date
1		November 2004
2	All	September 2005
3	All	September 2007

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Document Symbols

This manual contains different typefaces and symbols to make the content easier to read and understand:

- Standard text—used for regular data.
- Boldface text—emphasises a word or phrase.
- NOTE:—sets apart special data or important instruction clarification.
- · WARNING or CAUTION



- A WARNING identifies situations or actions that may have an effect on patient or user safety. To ignore a warning could cause patient or user injury.
- A CAUTION identifies special procedures or precautions that persons must obey to help prevent equipment damage.
- ELECTRICAL SHOCK HAZARD WARNING



Safety Tips

When you use electrical products, always obey safety precautions and these important safety tips:

READ ALL INSTRUCTIONS BEFORE PRODUCT USE

A WARNING:

To reduce the risk of electrocution, obey these instructions. Failure to do so could cause personal injury or equipment damage.

• Unplug this system immediately after you use it.

A WARNING:

Do not use the system near flammable anaesthetics. To do so could cause personal injury or equipment damage.

• Do not use this system near flammable anaesthetics.

A WARNING:

To reduce the risk of burns, electrocution, fire, or personal injury, obey these instructions. Failure to do so could cause personal injury or equipment damage.

 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 The Vest[®] Airway Clearance System, Model 104 therapy. Please consult your physician to determine if additional therapy is appropriate.

- Use close supervision throughout the treatment when this system is used by or near children or patients with physical limitations or impaired cognitive abilities.
- Use this system only for its intended use. Use only those attachments that are specified by the manufacturer.
- If this system has a damaged Power Cord or plug, does not operate correctly, or has been dropped or damaged; do not operate it. For test and repair, call Hill-Rom Technical Support. For contact information, refer to the back cover.
- Keep the unit and its Power Cord away from heated surfaces.
- Never drop or insert inappropriate objects into any opening on the unit.
- Plug this system into a known-good outlet **only**.
- Read and obey all instructions for setup, use, and maintenance of the unit. Failure to do so could cause patient injury or equipment damage.
- If the patient has a condition that prevents the use of the unit, do **not** use the system. Death or serious injury could occur.
- Federal USA law restricts this device to sale by or on the order of a physician. Sale by or on the order of unauthorized persons may cause patient injury.
- To help prevent cross-contamination, replace the single-patient use inflatable vest between patients. Failure to do so could cause patient injury or equipment damage.
- Only authorized persons should service the unit. Service by unauthorized persons could cause personal injury or equipment damage.

NOTE:

If service is necessary, call Hill-Rom Technical Support. For contact information, refer to the back cover. For countries not listed on the back cover, contact your distributor.

- The potential for electrical shock exists with electrical equipment.
 Failure to follow electrical use protocols may cause death or serious personal injury.
- If the Air Pulse Generator is wet or damp, do **not** plug it into a power source, or use it. Patient injury, personal injury, or equipment damage could occur
- Use a known-good electrical outlet only. Do not use the Air Pulse Generator with an extension cord or multiple-use electrical outlet adapter. Death, serious injury, or equipment damage could occur.
- Before you clean the system, unplug it from its power source. Failure to do so could cause personal injury or equipment damage.
- Do not expose the system to excessive moisture or immerse it in water. Personal injury or equipment damage could occur.
- Do **not** operate the Air Pulse Generator without the inflatable vest and Air Hoses attached. Equipment damage could occur.
- If it is difficult to connect the Air Hose to the Air Pulse Generator or inflatable vest, do **not** use lubricant. Equipment damage could occur.
- If it is difficult to connect the Remote Control to the Air Pulse Generator, do **not** use lubricant. Equipment damage could occur.
- Do not use harsh cleansers, solvents, or detergents. Equipment damage could occur.
- Frequent exposure to phenol-based germicidal detergent may discolor the Air Pulse Generator.
- If you use bleach-based (NaOCI) disinfectants or quarternary ammonium-based disinfectant cleaners, make sure you wipe the unit dry. Failure to do so could cause the build-up of residue or equipment damage.
- If shipping is necessary, the original packing material is designed to protect the unit during shipment. Keep the original packing material so it can be used if it is necessary to ship the system.

KEEP THESE INSTRUCTIONS

Contraindications

A WARNING:

If the patient has a condition that prevents the use of The Vest* Airway Clearance System, Model 104, do **not** use the system. Death or serious injury could occur.

Do **not** use The Vest* Airway Clearance System, Model 104 if the patient has one or more of these conditions:

- Head and/or neck injury that has not been stabilised
- · Active hemorrhage with hemodynamic instability

Relative Contraindications

If the patient has one or more of the conditions below, before you use The Vest* Airway Clearance System, carefully consider and assess the patient's case, in accordance with the American Association for Respiratory Care (AARC) Guidelines for Postural Drainage:

- Intracranial pressure (ICP) >20 mm Hg, or patients in whom increased intracranial pressure is to be avoided
- · Recent spinal surgery or acute spinal injury
- · Bronchopleural fistula
- Pulmonary edema associated with congestive heart failure
- · Large pleural effusions or empyema
- · Pulmonary embolism
- · Rib fractures, with or without flail chest
- Surgical wound or healing tissue or recent skin grafts or flaps on the thorax
- Uncontrolled hypertension
- · Distended abdomen
- · Recent esophageal surgery
- Active or recent gross hemoptysis
- Uncontrolled airway at risk for aspiration such as Air Hose feeding or a recent meal
- · Subcutaneous emphysema

- · Recent epidural spinal infusion or spinal anesthesia
- · Burns, open wounds, and skin infections on the thorax
- Transvenous or subcutaneous pacemaker
- Hemodynamic instability
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Osteoporosis or osteomyelitis of the ribs
- Coagulopathy
- Complaint of chest wall pain

Cleaning



A WARNING:

Follow the product manufacturer's instructions. Failure to do so could cause personal injury or equipment damage.



SHOCK HAZARD:

The potential for electrical shock exists with electrical equipment. Failure to follow electrical use protocols may cause death or serious personal injury.



SHOCK HAZARD:

Unplug the unit from its power source before you clean it. Failure to do so could cause personal injury or equipment damage.



SHOCK HAZARD:

Do not expose the unit to excessive moisture. Personal injury or equipment damage could occur.



A CAUTION:

Do not use harsh cleansers, solvents, or detergents. Equipment damage could occur.

The Vest® Airway Clearance System, Model 104 has been tested for compatibility with these detergents:

A CAUTION:

Frequent exposure to phenol-based germicidal detergent may discolor the Air Pulse Generator.

- · Phenol-based germicidal detergent
- Alcohol-based disinfectants.

A CAUTION:

If you use bleach-based (NaOCI) disinfectants or quarternary ammonium-based disinfectant cleaners, make sure you wipe the unit dry. Failure to do so could cause in the build-up of residue or equipment damage.

- · Bleach-based disinfectants
- · Quarternary ammonium-based disinfectant cleaner

General Cleaning

Home Care Environment

We recommend that you clean the Air Pulse Generator and inflatable vest with a soft cotton cleaning pad that is slightly moist from detergent and warm water. Do not use excessive liquid or harsh cleansers. Do **not** put The Vest* Airway Clearance System, Model 104 in water or let liquids enter the Air Pulse Generator.

After you clean the system, wipe it dry.

Acute Care Environment



To help prevent cross-contamination, replace the single-patient use inflatable vest and Air Hoses between patients. Failure to do so could cause patient injury or equipment damage.

NOTE:

In the Acute Care environment, the inflatable vests and Air Hoses are single-patient use, latex-free, disposable products for use on individual patients over multiple treatment sessions.

Clean The Vest* Airway Clearance System, Model 104 between patients, or when visibly soiled if used on the same patient. Replace the inflatable vest and Air Hoses between patients or when it is damaged.

We recommend that you clean the Air Pulse Generator and Remote Control with a soft cotton cleaning pad that is slightly moist from detergent and warm water.

Do not use excessive liquid or harsh cleansers. Do **not** immerse The Vest* Airway Clearance System, Model 104 in water or allow liquids to enter the Air Pulse Generator.

After you clean the system, wipe it dry.

Steam Cleaning

Do not use any steam cleaning device on the unit. Excessive moisture can damage mechanisms in this unit.

Cleaning Hard to Clean Spots

Air Pulse Generator—To remove difficult spots or stains, we recommend that you use standard household cleansers and a soft bristle brush. To loosen heavy, dried-on soil, you may first need to saturate the spot.

Do **not** put any component of The Vest* Airway Clearance System, Model 104 in water

Disinfecting

When there is visible soil and between patient use, we recommend that you disinfect the unit with an intermediate level, tuberculocidal disinfectant

Use the disinfectant as specified in the disinfectant manufacturer's instructions

Intended Use

A WARNING:

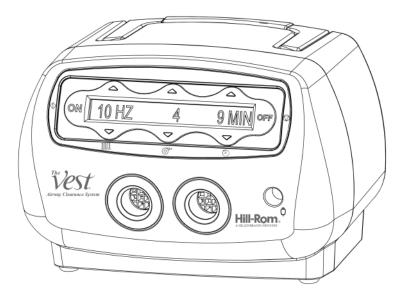
Read and obey all of the instructions for setup, use, and maintenance for The Vest* Airway Clearance System, Model 104. Failure to do so could cause patient injury or equipment damage.

This manual includes instructions for setup, use, and maintenance of The Vest* Airway Clearance System, Model 104. Before you use the system, carefully read all of this manual, and make sure you obey the instructions for your safety and to get the best therapeutic benefit. Most importantly, obey all warnings, cautions, and notes in this manual.

NOTE:

This manual is **not** intended as a substitute for information you receive from your physician or other healthcare providers. Use The Vest* Airway Clearance System, Model 104 as prescribed by your physician.

Introduction

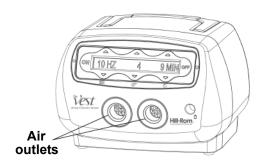


The Vest* Airway Clearance System, Model 104 was developed to help supply effective Airway Clearance Therapy. The system has an inflatable vest attached by Air Hoses to an Air Pulse Generator. The Air Pulse Generator rapidly inflates and deflates the inflatable vest to gently compress and release the chest wall which creates airflow within the lungs. This process, which mimics coughing, moves mucus toward the large airways where it can be cleared by coughing or suctioning. This type of Airway Clearance Therapy is referred to as High Frequency Chest Wall Oscillation (HFCWO).

Features

Air Pulse Generator

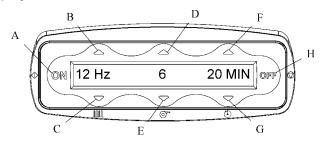
When correctly connected, the Air Pulse Generator controls the inflatable vest and supplies pulsations to the chest wall.



Air Outlets

Air Hoses connect at the two air outlets on the front of the Air Pulse Generator.

Display and Controls



Item	Control	Description
A	ON	Press to fill the inflatable vest and start or pause the Air Pulse Generator.
B and C	Frequency Up and Down	Press to adjust the Frequency setting until the prescribed treatment session Frequency shows on the display.
D and E	Pressure Up and Down	Press to adjust the Pressure setting until the prescribed treatment session Pressure shows on the display.
F and G	Treatment Time Up and Down	Press to adjust the treatment Time until the prescribed treatment session Time shows on the display.
Н	OFF	Press to stop the Air Pulse Generator.

The display shows the current Frequency, Pressure, and treatment Time settings and system messages.

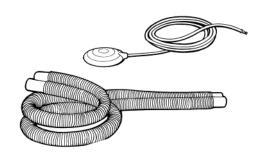
NOTE:

The display shows its messages in **English**. For a translation of the messages in your language, refer to "Display Messages" on page 47.

Remote Control and Air Hoses

The Remote Control can be used instead of the **ON** control to start or pause the Air Pulse Generator.

The Air Hoses connect the inflatable vest to the Air Pulse Generator.



Power Cord

The Power Cord plugs into the Air Pulse Generator and a grounded outlet.

NOTE:

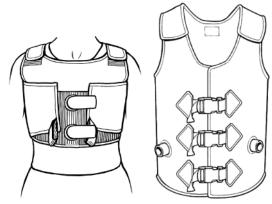
The Power Cord necessary for your country may be different than the one shown



Inflatable Vests

For use in the home care environment, these reusable, inflatable vests are available in several standard sizes of these two types:

- · Chest Vest
- Full Vest



Reusable Chest Vest Reusable Full Vest

For use in an acute care facility, these disposable, single-patient use, inflatable vests are available in several standard sizes of these two types:

- Wrap SPU Vest
- · Full SPU Vest



Disposable Wrap SPU Vest



Disposable Full SPU Vest

Product Symbols

Symbol	Definition
†	Type B equipment with an F-type applied part, according to EN 60601-1.
₹	Dangerous voltage within the device may constitute a risk of electrical shock.
♦ ON	ON control—starts the Air Pulse Generator
OFF 🗇	OFF control—stops the Air Pulse Generator
	Frequency setting
	Pressure setting
	treatment Time setting

Symbol	Definition
	Up arrow control—increases the Frequency, Pressure, or treatment Time setting
	Down arrow control—decreases the Frequency , Pressure , or treatment Time setting
	Remote Control port
<u></u>	Attention: Consult accompanying documents.
	Class II equipment (double insulated), according to EN60601-1
IPX 0	Not protected against water ingress
CUL US	Medical Equipment with respect to electric shock, fire, mechanical, and other specified hazards only in accordance with UL/EN/IEC 60601-1 and CAN/CSA C22.2 No. 601.1

a. The UL logo is a registered trademark of Underwriters Laboratories Inc.

Symbol	Definition
((0123	Conforms to the European Medical Device Directive 93/42/EEC
-	Identifies a replaceable fuse link in an electronic circuit
	Manufacturer or distributor complies with the Waste Electric and Electronic Equipment Directive 2002/96/EC

Specifications

Feature	Dimension
Air Pulse Generator weight	17 lb (8 kg)
Air Pulse Generator height	9.5" (24.1 cm)
Air Pulse Generator width	13" (33 cm)
Air Pulse Generator depth	9.5" (24.1 cm)
Inflatable vest material— Reusable Chest Vest	Polyvinyl chloride (PVC)-coated polyester with polyurethane-coated nylon
Inflatable vest material— Reusable Full Vest	Polyurethane-coated nylon
Inflatable vest material— Disposable Wrap and Full SPU Vest	PVC-coated, thermally-bonded nylon
Electrical requirements	100 V AC to 230 V AC, 50 Hz to 60 Hz, 2.9 A at 100 V, 2.0 A at 230 V
Fuse requirement	2 each 4 A, 5 x 20 mm (Littelfuse part number F4AL250V)

Environmental Conditions for Transport and Storage

Condition	Range
Temperature	-40°F to 158°F (-40°C to 70°C)
Relative humidity	95% non-condensing
Atmospheric pressure	500 hPa to 1060 hPa

Environmental Conditions for Use

Condition	Range
Temperature	50°F to 93°F (10°C to 34°C) ambient temperature
Relative humidity range	30% to 75% non-condensing
Atmospheric pressure	700 hPa to 1060 hPa

Classification and Standards

Technical and Quality Assurance	UL/EN/IEC 60601-1
	CAN/CSA C22.2 No.
	601.1 ISO 13485
Equipment Classification	Class II
Degree of Protection Against Electric	BF with type F applied
Shock	part
Classification According to Directive	IIa
93/42/EEC	
Degree of Protection Against Ingress of	IPX 0
Water	

The Vest* Airway Clearance System, Model 104 is a continuous operation device classified with Underwriters Laboratories Inc.®¹ (UL) in the United States and licensed with Health Canada.

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Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility and needs to be installed and put into service according to the information provided in these tables. Portable and mobile radio-frequency (RF) communications equipment can affect medical electrical equipment.

Guidance and Manufacturer's Declaration— Electromagnetic Emissions

The Vest® Airway Clearance System, Model 104 is intended for use in the electromagnetic environment specified below. The customer or user of the Model 104 should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance	
RF emissions CISPR 11	Group 1	The Model 104 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The Model 104 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		

Guidance and Manufacturer's Declaration— Electromagnetic Immunity

The Vest* Airway Clearance System, Model 104 is intended for use in the electromagnetic environment specified below. The customer or user of the Model 104 should make sure it is used in such an environment.

Test Level	Compliance Level	Electromagnetic Environment— Guidance	
± 6 kV contact ± 6 kV air	± 6 kV contact ± 6 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.	
± 2 kV for power supply lines ± kV for input/output lines	± 2 kV for power supply lines ± kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.	
± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.	
$<$ 5% $U_{\rm T}$ (>95% dip in $U_{\rm T}$) for 0,5 cycle 40% $U_{\rm T}$	$<5\%$ $U_{\rm T}$ (>95% dip in $U_{\rm T}$) for 0,5 cycle 40% $U_{\rm T}$	Mains power quality should be that of a typical commercial or hospital environment. If it is necessary for the user to have continued operation of the Model 104 during power mains interruptions, it is recommended that the Model 104 be powered from an uninterruptible power supply or a battery.	
(60% dip in $U_{\rm T}$) for 5 cycles 70% $U_{\rm T}$	(60% dip in $U_{\rm T}$) for 5 cycles 70% $U_{\rm T}$		
$U_{ m T}$) for 25 cycles <5% $U_{ m T}$	U _T) for 25 cycles <5% U _T		
U _T) for 5 seconds	U _T) for 5 seconds		
3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	
	contact ± 6 kV air ± 2 kV for power supply lines ± kV for input/output lines ± 1 kV differential mode ± 2 kV common mode <5% UT (>95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 seconds 3 A/m	$\begin{array}{c} {\rm contact} \\ \pm 6 {\rm kV air} \\ \end{array} \qquad \begin{array}{c} \pm 2 {\rm kV for} \\ {\rm power supply} \\ {\rm lines} \\ \pm kV {\rm for} \\ {\rm input/output} \\ {\rm lines} \\ \end{array} \qquad \begin{array}{c} \pm 2 kV {\rm for} \\ {\rm power supply} \\ {\rm lines} \\ \pm kV {\rm for} \\ {\rm input/output} \\ {\rm lines} \\ \end{array} \qquad \begin{array}{c} \pm kV {\rm for} \\ {\rm input/output} \\ {\rm lines} \\ \end{array} \qquad \begin{array}{c} \pm 1 kV \\ {\rm differential} \\ {\rm mode} \\ \pm 2 kV \\ {\rm common} \\ {\rm mode} \\ \end{array} \qquad \begin{array}{c} \pm 1 kV \\ {\rm differential} \\ {\rm mode} \\ \end{array} \qquad \begin{array}{c} \pm 2 kV \\ {\rm common} \\ {\rm mode} \\ \end{array} \qquad \begin{array}{c} \pm 2 kV \\ {\rm common} \\ {\rm mode} \\ \end{array} \qquad \begin{array}{c} \pm 2 kV \\ {\rm common} \\ {\rm mode} \\ \end{array} \qquad \begin{array}{c} \pm 2 kV \\ {\rm common} \\ {\rm mode} \\ \end{array} \qquad \begin{array}{c} -5\% UT \\ (>95\% {\rm dip in} \\ UT) {\rm for} 0.5 \\ \end{array} \qquad \begin{array}{c} <5\% UT \\ (>95\% {\rm dip in} \\ UT) {\rm for} 0.5 \\ \end{array} \qquad \begin{array}{c} {\rm cycle} \\ \end{array} \qquad \begin{array}{c} 40\% UT \\ (60\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} {\rm cycles} \\ \end{array} \qquad \begin{array}{c} 70\% UT \\ (30\% {\rm dip in} \\ UT) {\rm for} 25 \\ \end{array} \qquad \begin{array}{c} {\rm cycles} \\ <5\% UT \\ (>95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} {\rm cycles} \\ <5\% UT \\ (>95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} {\rm cycles} \\ <5\% UT \\ \end{array} \qquad \begin{array}{c} <95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} {\rm cycles} \\ <5\% UT \\ \end{array} \qquad \begin{array}{c} <95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} {\rm cycles} \\ <5\% UT \\ \end{array} \qquad \begin{array}{c} <95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} <5\% UT \\ \end{array} \qquad \begin{array}{c} <95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} <5\% UT \\ \end{array} \qquad \begin{array}{c} <95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} <5\% UT \\ \end{array} \qquad \begin{array}{c} <95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} <5\% UT \\ \end{array} \qquad \begin{array}{c} <95\% {\rm dip in} \\ UT) {\rm for} 5 \\ \end{array} \qquad \begin{array}{c} <5\% {\rm UT} \\ \end{array} \qquad \begin{array}{c} <95\% {\rm dip in} \\ \end{array}$	

Guidance and Manufacturer's Declaration— Electromagnetic Immunity

The Vest* Airway Clearance System, Model 104 is intended for use in the electromagnetic environment specified below. The customer or user of the Model 104 should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 104, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = \left[\frac{3.5}{3}\right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = \left[\frac{3.5}{3}\right] \sqrt{P} \begin{array}{l} 80 \text{ MHz to} \\ 800 \text{ MHz} \end{array}$
			$d = \begin{bmatrix} \frac{7}{3} \end{bmatrix} \sqrt{P} \qquad \begin{array}{c} 800 \text{ MHz to} \\ 2.5 \text{ GHz} \end{array}$
			where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).
			Field strengths from fixed RF transmitters, as
			found by an electromagnetic site survey, should be less than the compliance level in
			each frequency range ^b .
			Interference may occur in the vicinity of
			equipment marked with this symbol:
			((()))

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, the electromagnetic site used should be considered. If the measured field strength in the location in which the Model 104 is used is more than the applicable RF compliance level above, the Model 104 should be monitored to make sure it operates correctly. If it operates incorrectly, additional measures may be necessary, such as a change in the Model 104's position or location.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Model 104

The Vest* Airway Clearance System, Model 104 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Model 104 can help prevent electromagnetic interference if they maintain the minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 104. The recommended distances, in accordance, are shown below:

Rated Maximum Output Power of the Transmitter	Separation Distance According to the Frequency of the Transmitter			
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right] \sqrt{P}$	
0,01 W	0,12 m	0,12 m	0,23 m	
0,1 W	0,37 m	0,37 m	0,74 m	
1 W	1,2 m	1,2 m	2,3 m	
10 W	3,7 m	3,7 m	7,4 m	
100 W	12 m	12 m	23 m	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated with the use of the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Instructions for Use

Protocol for Use and Special Instructions for the Home Care Patient

Your physician has prescribed The Model 104 to be used		
Additional Instructions:		
NOTES:		
If you have any questions or concer For contact information, refer to th	rns, call Hill-Rom Technical Support. e back cover.	

Set Up the Unit

NOTE:

If your physician has prescribed aerosol therapy to be used during your treatment session, set up the applicable equipment.



SHOCK HAZARD:

If the Air Pulse Generator is wet or damp, do **not** plug it into a power source or use it. Patient injury, personal injury, or equipment damage could occur.

- 1. Make sure the Air Pulse Generator is **not** wet or damp.
- 2. Plug the Power Cord into the back of the Air Pulse Generator.

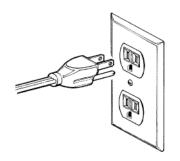


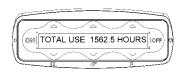


SHOCK HAZARD:

Use a known-good electrical outlet **only**. Do **not** use the Air Pulse Generator with an extension cord or multiple-use electrical outlet adapter. Death, serious injury, or equipment damage could occur.

- Plug the Power Cord into a known-good electrical outlet.
 Once the unit is plugged in, the display shows this data:
 - a. Software revision
 - b. Total number of hours the device has been used by the current patient





NOTE:

The Power Cord necessary for your country may be different than the one shown.

NOTE:

To temporarily turn on the backlight on the display, press any one of the six **Up** or **Down** arrow controls.

A CAUTION:

Do **not** operate the Air Pulse Generator without the inflatable vest and Air Hoses attached. Equipment damage could occur.

4. Connect the Air Hoses to the air outlets on the front of the Air Pulse Generator.



A CAUTION:

If it is difficult to connect the Air Hose to the Air Pulse Generator or inflatable vest, do **not** use lubricant. Equipment damage could occur.

- 5. Slightly twist each Air Hose into its air outlet to help keep it in position. If it is difficult to connect the Air Hose to the Air Pulse Generator, do **not** use lubricant.
- 6. Put on an inflatable vest (see "Put on the Inflatable Vest" on page 29).

- 7. Connect the Air Hoses to the Air Hose ports on the inflatable vest. If it is difficult to connect the Air Hose to the inflatable vest, do **not** use lubricant.
 - Reusable or disposable Full
 Vest—slide the end of each
 Air Hose over the inflatable
 vest Air Hose ports. To help
 keep the Air Hoses in
 position, slightly twist the
 Air Hoses as you push them
 over the inflatable vest Air
 Hose ports.
 - Reusable Chest Vest—slide
 the end of each Air Hose into
 the inflatable vest Air Hose
 ports. To help keep the Air
 Hoses in position, slightly
 twist the Air Hoses as you
 push them in the inflatable
 vest Air Hose ports.
 - Disposable Wrap SUP
 Vest—slide the end of each
 Air Hose into the
 disposable vest Air Hose
 slits, and then use the
 Velcro®¹ loops to hold the
 Air Hoses in position.







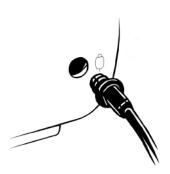


^{1.} Velcro® is a registered trademark of Velcro Industries, BV (a Dutch Corporation).

A CAUTION:

If it is difficult to connect the Remote Control to the Air Pulse Generator, do **not** use lubricant. Equipment damage could occur.

8. If the optional Remote Control is to be used instead of the **ON** control, plug the Remote Control into the Remote Control port on the front of the Air Pulse Generator. If it is difficult to connect the Remote Control to the Air Pulse Generator, do **not** use lubricant.



Put on the Inflatable Vest

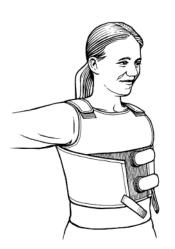
NOTE:

For comfort, a single layer of cotton clothing should be worn under the inflatable vest. The inflatable vest should be adjusted so that it is comfortable.

Reusable Chest Vest (Home Care Environment)

- Pull the back panel tabs from the main hook-and-loop fastener, and separate the front and back panels of the inflatable vest.
- 2. Turn the inflatable vest so the Air Hose ports are in front.
- 3. Slide the inflatable vest over the head
- 4. With the inflatable vest deflated, temporarily attach both back panel tabs of the inflatable vest to the front panel.
- Adjust the hook-and-loop fasteners on the shoulder straps so the bottom of each arm opening is comfortably close to the underarm.
- 6. Pull both back panel tabs from the front of the inflatable vest.
- 7. For the best fit, inhale deeply, and then attach both back panel tabs to the front panel.





- 8. Make sure the inflatable vest is close to the body but not uncomfortably tight.
 - To **tighten** the fit at the bottom edge, angle the back panel tabs **upward**.



 To loosen the fit at the bottom edge, angle the back panel tabs downward.



Reusable Full Vest (Home Care Environment)

- Put the Full Vest on so its connectors are in front
- 2. Attach the connectors so the inflatable vest is loose over the chest.
- 3. Use the shoulder straps to adjust the length of the inflatable vest so the bottom edge is level with the top of the hip bone.





- 4. Use the front connectors to adjust the inflatable vest to be close to the body, but not uncomfortable.
 - Tighten—hold the buckle, and pull the end of the strap to the patient's right.
 - **Loosen**—gently lift the back of the buckle, and lengthen the strap.
- If too much inflatable vest material is under the front connectors, fold the material under itself to make sure the fit is correct.
 - a. Loosen the front connectors.
 - b. Fold the top of the material under itself.
 - c. Tighten the front connectors.





Disposable Wrap SPU Vest (Acute Care Environment)

- 1. Turn the patient towards you.
- 2. With the disposable vest deflated, begin to lay it flat on the bed so it is perpendicular with the patient's torso.
- 3. Roll the patient away from you and on the open portion of the Wrap SPU Vest.
- Put the Wrap SPU Vest in position just beneath the patient's underarms, and continue to pull the Wrap SPU Vest around the patient's torso.
- 5. Roll the patient to a supine position.
- 6. Pull both ends of the Wrap SPU Vest around the patient's chest, and use the Velcro®¹ fasteners to temporarily attach both ends to each other.
- 7. Have the patient inhale deeply, and then attach the ends of the Wrap SPU Vest so it fits close to the body, but is not uncomfortable.







^{1.} Velcro® is a registered trademark of Velcro Industries, BV (a Dutch Corporation).

Disposable Full SPU Vest (Acute Care Environment)

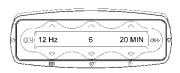
- Separate the front flaps of the disposable vest at the Velcro®¹ fasteners.
- 2. Turn the disposable vest so the front flaps will meet in front of the patient. Then put the patient's arms through the arm openings in the disposable vest.
- 3. With the disposable vest deflated, use the Velcro® fasteners to attach the front flaps of the disposable vest to each other.
- 4. Make sure there is approximately 3" to 4" (8 cm to 10 cm) between the bottom edge of the front of the disposable vest and the patient.
- 5. Adjust the Velcro® fasteners at the shoulder straps so the bottom edge of the disposable vest is level with the top of the patient's hip bone.



^{1.} Velcro® is a registered trademark of Velcro Industries, BV (a Dutch Corporation).

Use The Vest[®] Airway Clearance System, Model 104

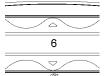
- 1. Make sure the unit is set up correctly (see "Set Up the Unit" on page 25).
- Press the ON control. The inflatable vest fills and the display shows the previously used Frequency and Pressure settings and the remaining treatment session Time.
- 3. Look at the settings on the display. If the settings match your prescribed treatment session, continue to step 4. Otherwise, adjust the settings to match your prescription as follows:



To adjust the Frequency setting, press the left-hand Up and Down arrow controls until your prescribed treatment session Frequency shows on the display. The Frequency or Hertz (Hz) may be set between 5 and 20 cycles per second.



b. To adjust the **Pressure** setting, press the middle **Up** and **Down** arrow controls until the prescribed treatment session Pressure shows on the display. The Pressure may be set between 1 and 10.



c. To adjust the treatment **Time**, press the right-hand **Up** and **Down** arrow controls until the prescribed treatment **Time** shows on the display. The treatment session Time may be set between 1 and 60 minutes.



NOTE:

It is not necessary to stop the treatment session to adjust the settings.

4. To begin the treatment session, press the **ON** control. The remaining treatment Time shows as it counts down to zero. **or**

If you use the optional Remote Control, do as follows:

- Make sure the Remote
 Control is plugged into the
 Remote Control port on the
 front of the Air Pulse
 Generator.
- b. Press and release the Remote Control. Four seconds after the Remote Control is first pressed, the inflatable vest inflates and automatically begins the treatment session.



- 5. If it is necessary to temporarily stop the treatment session, do as follows:
 - a. Press the ON control or Remote Control once. The unit will stop the pulsations, but the display will continue to show the settings.
 - b. To start the treatment session again, press the **ON** control or the Remote Control again.

NOTE:

If the treatment session is stopped for 10 minutes, the unit automatically turns off

6. If it is necessary to end the treatment session before it is complete, press the **OFF** control.

NOTE:

The **OFF** control does **not** turn off the display.

 When the OFF control is pressed, the inflatable vest deflates, and the INCOMPLETE- XX MIN REMAIN message shows briefly on the display.



- 8. When the treatment session is complete, these actions occur:
 - The SESSION
 COMPLETE message
 shows briefly, and then the
 TOTAL USE message
 shows.



- The pulsations stop.
- The inflatable vest deflates.
- The backlight on the display goes off.



NOTE:

The **TOTAL USE** message shows on the display until the system is unplugged from its power source.

- 9. To temporarily turn the backlight on, press any one of the six **Up** or **Down** arrow controls.
- 10. When the treatment session is complete, do as follows:
 - a. Immediately unplug the system from its power source.
 - Remove the Air Hoses from the Air Hose ports on the inflatable vest.
- 11. For a unit in the **home care environment**, do one of these after therapy:
 - Full Vest—disconnect the front connectors, and remove the inflatable vest.
 - Chest Vest—disconnect both back panel tabs from the main hook-and-loop connector, and lift the inflatable vest over the head.

or

If the **Chest** Vest can not be lifted over the head, disconnect one of the shoulder straps and back panel tabs, and remove the inflatable vest.

NOTE:

If a shoulder strap on a **Chest** Vest is disconnected, the inflatable vest will have to be adjusted when it is next used.

or

For a unit in the **acute care environment**, do as follows after each therapy:

a. Remove the diaposable vest from the patient.

A WARNING:

To help prevent cross-contamination, replace the single-patient use disposable vest between patients. Failure to do so could cause patient injury or equipment damage.

- b. If one of these occurs, **discard** the diaposable vest:
- Airway Clearance Therapy is no longer necessary for the patient.
- The diaposable vest is damaged.
- The diaposable vest is excessively soiled.

Maintenance

A WARNING:

Only authorized persons should service The Vest® Airway Clearance System, Model 104. Service by unauthorized persons could cause personal injury or equipment damage.

Minimal routine maintenance is necessary for The Vest[®] Airway Clearance System, Model 104. Periodic cleaning is necessary (see "Cleaning" on page 7).

If service is necessary on The Vest* Airway Clearance System, Model 104, call Hill-Rom Technical Support. For contact information, refer to the back cover

Professional healthcare facilities should do these examinations and safety tests annually:



SHOCK HAZARD:

Unplug the unit from its power source. Failure to do so could cause personal injury or equipment damage.

- Unplug the Air Pulse Generator from its power source.
- 2. Examine The Vest[®] Airway Clearance System, Model 104 for damaged or lost parts.
- 3. Examine the Power Cord and connectors for cuts, scrapes, or other damage.
- Do electrical safety tests in accordance with IEC 60601. 4.
- 5 Connect the Air Pulse Generator to the inflatable vest and to the power supply. Make sure the The Vest[®] Airway Clearance System, Model 104 and all functions operate correctly.
- Clean and disinfect the The Vest® Clearance System, Model 104 (see "Cleaning" on page 7).
- 7 Put a label on the Air Pulse Generator that shows this data:
 - Tested by
 - Date
 - Result of the examination and test

Service Calls

When you contact Hill-Rom about The Vest* Airway Clearance System, Model 104, be prepared to give the serial number from the product identification label. The product identification label is on the back of the Air Pulse Generator.

Replacement Parts

Reusable Chest Vest (Home Care Environment)

Part Number	Description
P300230000	Small (28" to 35" (71 cm to 89 cm))
P300231000	Medium (>35" to 46" (89 cm to 117 cm))
P300232000	Large (>46" to 61" (117 cm to 155 cm))
P300233000	Extra large (>61" to 67" (155 cm to 170 cm))

Reusable Full Vest (Home Care Environment)

Part Number	Description		
P300282001	Child Medium (23" to 27" (58 cm to 69 cm))		
P300284001	Child Large (>27" to 31" (69 cm to 79 cm))		
P300286001	Adult Small (>31" to 36" (79 cm to 91 cm))		
P300288001	Adult Medium (>36" to 45" (91 cm to 114 cm))		
P300290001	Adult Large (>45" to 52" (114 cm to 132 cm))		

Single-Patient Use, Disposable Wrap SPU Vest (Acute Care Environment)

Part Number	Description
P300630005	Small, Package of 5 (23" to 33" (58 cm to 84 cm))
P300631005	Medium, Package of 5 (>33" to 43" (84 cm to 109 cm))
P300632005	Large, Package of 5 (>43" to 53" (109 cm to 135 cm))
P300633005	Extra Large, Package of 5 (>53" to 67" (135 cm to 170 cm))

Single-Patient Use, Disposable Full SPU Vest (Acute Care Environment)

Part Number	Description
P300200000	Child Medium (23" to 27" (58 cm to 69 cm))
P300205000	Child Large (>27" to 31" (69 cm to 79 cm))
P300210000	Adult Small (>31" to 36" (79 cm to 91 cm))
P300215000	Adult Medium (>36" to 45" (91 cm to 114 cm))
P300220000	Adult Large (>45" to 52" (114 cm to 132 cm))

Troubleshooting

A WARNING:

Only authorized persons should service The Vest[®] Airway Clearance System, Model 104. Service by unauthorized persons could cause personal injury or equipment damage.

If service is necessary on The Vest* Airway Clearance System, Model 104, call Hill-Rom Technical Support. For contact information, refer to the back cover

Air Pulse Generator Does Not Power On

- Make sure the Power Cord is fully plugged into the electrical inlet on the rear panel of the Air Pulse Generator. If necessary, unplug the Power Cord from the Air Pulse Generator, and then plug it in again.
- Make sure the Power Cord is fully plugged into a known-good outlet.
- 3. If the problem is not corrected, call Hill-Rom Technical Support. For contact information, refer to the back cover.

Inflatable Vest No Longer Fits (Home Care Environment)

- 1. Adjust the inflatable vest to adapt to normal growth (see "Put on the Inflatable Vest" on page 29).
- 2. If the problem is not corrected, call Hill-Rom Technical Support. For contact information, refer to the back cover.

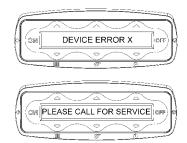
No Air Pulses into the Inflatable Vest

- If the Remote Control is in use, make sure it is firmly connected to the Remote Control port on the front panel of the Air Pulse Generator
- Make sure the Air Hoses are connected to the inflatable vest and Air Pulse Generator.
- 3. If the problem is not corrected, call Hill-Rom Technical Support. For contact information, refer to the back cover.

Display Alternates between "Please Call for Service" and "Device Error X" Messages

The system has experienced an unexpected user input, or the blower motor or diaphragm motor failed. Do as follows:

 Unplug the Power Cord from the Air Pulse Generator, and then plug it in again.



2. If the problem is not corrected, call Hill-Rom Technical Support. For contact information, refer to the back cover.

An Air Hose Comes Out of the Air Pulse Generator or Inflatable Vest during Operation

- Fully disconnect the Air Hose from the Air Pulse Generator and the inflatable vest.
- 2. Clean the inside and outside of these (see "Cleaning" on page 7):
 - Ends of the Air Hose
 - Air Hose ports on the inflatable vest
 - Air outlets on the Air Pulse Generator
- 3. Connect the Air Hose to the Air Pulse Generator and inflatable vest (see "Set Up the Unit" on page 25).
- 4. If the problem is not corrected, call Hill-Rom Technical Support. For contact information, refer to the back cover.

Storage and Handling

Storage Bag (Home Care Environment)

To store or transport The Vest* Airway Clearance System, Model 104, put the unit in its storage bag:

- Put the Air Pulse Generator in the center of the storage bag.
- Put each Air
 Hose in a separate compartment on each side of the Air Pulse Generator.
- 3. Put the inflatable vest in one side pocket.
- 4. Put the Remote Control and Power Cord in the other side pocket.
- 5. Close the top of the storage bag.

Shipping the Unit

A CAUTION:

If shipping is necessary, the original packing material protects the system during shipment. Keep the original packing material for use if you need to ship the system. Failure to adequately package the system for shipment could cause equipment damage.

If shipping is necessary, ship the unit in its original packing material.

Frequently Asked Questions

- Is The Vest* Airway Clearance System, Model 104 as effective as chest physiotherapy?
 - Research has shown that the system is nearly three times as effective as the use of chest physiotherapy to move airway secretions.
- Does The Vest* Airway Clearance System, Model 104 effectively treat all areas of the lungs?
 - Yes. Since the system oscillates the chest wall to create airflow, it applies percussion to all lung areas to effectively treat all lobes of the lung at once.
- How long should each Airway Clearance Therapy treatment session last?
 - Common prescriptions specify a treatment session Time to be between 10 and 30 minutes. Prescribed treatment session times may be different. Refer to the physician's orders.
- How often should treatment sessions be given?
 - The Frequency of treatment sessions depends on the patient's underlying disease, age, and state of health. The patient's physician will prescribe a schedule for the individual patient.
- · Is chest physiotherapy still necessary?
 - In a number of studies, The Vest* Airway Clearance System, Model 104 has been shown to supply more effective Airway Clearance Therapy than conventional chest physiotherapy. Typically, it is not necessary to do chest physiotherapy along with therapy treatment sessions with The Vest* Airway Clearance System, Model 104.
- Is postural drainage still necessary?
 - The system moves mucus by generating airflow within the lungs. It works in any position, so generally it should not be necessary to do postural drainage.
- What will happen if a patient's treatment session is skipped?
 - One missed treatment session of the system may or may not immediately impact the patient's health. However, the key to help maintain the patient's health is consistent, effective

- therapy. Try to follow the patient's care plan as closely as possible.
- Is there a best time to do The Vest* Airway Clearance System, Model 104 therapy?
 - Establish a schedule that is satisfactory for the patient and lets you do the therapy consistently. Usually, it is best to do therapy before meals.
- Do all patients receive the same benefits from The Vest* Airway Clearance System, Model 104?
 - Almost all patients will experience an increase in the amount of mucus that is moved. The overall benefit depends on many factors, which include the underlying disease, patient's age, and his or her present state of health.
- Does The Vest* Airway Clearance System, Model 104 make patients feel better?
 - Patients often report that they are able to breathe better and have more energy after he or she receives therapy.

Display Messages

Display Message	French	Italian	German
Total Use: XXXX.X Hours	Total utilisation: XXXX.X hrs	Uso totale: XXXX,X ore	Betriebsstunden: XXXX.X Std
Incomplete- XX Min Remain	Incomplet-Reste XX min	Incompleto- XX Min rimanenti	Unterbrochen- XX Minuten rest
Session Complete	Session complète	Sessione completata	Anwendung komplett
Device Error X	Erreur Matériel N° X	Errore sistema X	Gerätefehler X
Please Call For Service	Contact Service Client	Per favore, chiamare per assistenza	Service erforderlich

Display Message	Dutch	Spanish	Swedish
Total Use:	Totaal gebruik	Total Uso:	Total tid:
XXXX.X Hours	XXXX.X uur	XXXX.X Horas	XXXX.X
			timmar
Incomplete-	Incompleet- XX	Incompleto-	Ej klar- XX min
XX Min Remain	min resteren	XX Min	återstår
		Restantes	
Session	Sessie compleet	Sesion	Behandling klar
Complete		completada	
Device Error X	Materiaal	Error de	Enhetsfel X
	storing no. X	dispositivo X	
Please Call For	Bel voor service	Llame al servicio	Kontakta service
Service	AUB	Tecnico	



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