

Hillrom. The Vest® Airway Clearance System, Model 205

> Instructions for Use Product No. P205





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- Outside of the USA, contact your distributor or local Hill-Rom representative, or go to <u>respiratorycare.hill-rom</u>.

# **Reference Documents**

*The Vest® Airway Clearance System, Models 104, 105, and 205 Service Manual* (183192 – North America; 150754 – International)

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### NOTES:

### INTENDED USE

The Vest<sup>®</sup> Airway Clearance System, Model 205 was developed to provide effective Airway Clearance Therapy. The system consists of a disposable garment attached to an Air Pulse Generator that rapidly inflates and deflates the disposable garment. This causes the chest wall to be gently compressed and released, which creates airflow within the lungs. This process 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).

### **INDICATIONS FOR USE**

The Vest<sup>®</sup> Airway Clearance System, Model 205 is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, The Vest<sup>®</sup> Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation.

#### INTENDED PATIENT POPULATION

The Vest<sup>®</sup> Airway Clearance System, Model 205 can be used for the pediatric to geriatric population. The system accommodates use across the targeted population by providing a selection of garment sizes which is used along with the air pulse generator.

#### **INTENDED USERS**

The users of the system are designated caregivers in the acute care environment.

# INTRODUCTION

This manual includes instructions for setup, use, and maintenance of The Vest<sup>®</sup> Airway Clearance System, Model 205. It is to be used as a reference guide. Please review all sections carefully before you use the system.

The Vest® Airway Clearance System, Model 205 is intended for use as prescribed by a physician.

# SYMBOLS

### **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**—emphasizes 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.

## **PRODUCT SYMBOLS**

These symbols may or may not be used on your model of The Vest<sup>®</sup> Airway Clearance System:

Symbol	Definition
	Type B equipment with an F-type applied part, according to EN 60601-1. (The Vest <sup>®</sup> garment is the applied part and the maximum temperature on it will not exceed 107.1°F (41.7°C) under operating conditions.)
Í	Dangerous voltage within the device may constitute a risk of electrical shock. (Not applicable to units compliant with ANSI/AAMI ES60601-1(2005) + AMD(2012).
	<b>ON</b> button—starts the Air Pulse Generator (starts therapy, inflates the disposable garment, moves to the next screen during programming, starts the unit after being paused).

Symbol	Definition
	<b>OFF</b> button—stops the Air Pulse Generator (stops therapy, deflates the disposable garment, pauses therapy, moves to previous screen during programming).
	Frequency setting
	<b>Pressure</b> setting
	Time setting
$\bigtriangleup$	<b>Up</b> arrow button—increases the <b>Frequency</b> , <b>Pressure</b> , or <b>Time</b> setting.
$\frown$	<b>Down</b> arrow button—decreases the <b>Frequency</b> , <b>Pressure</b> , or <b>Time</b> setting.
$\bigcirc$	Remote Control Port
<u>_!</u>	Attention: Consult accompanying documents. (Applicable to UL60601-1 compliant units.)
	Class II equipment (double insulated), according to EN 60601-1.
IP21	Protected against ingress of an object of diameter 12.0 mm and vertically falling water drops.

Symbol	Definition
ĺ	Read the operating instructions.
C C C C C C C C C C C C C C C C C C C	Medical— General Medical Equipment as to Electrical Shock, Fire, and Mechanical Hazards Only in Accordance with: ANSI/AAMI ES60601-1(2005) + AMD (2012) CAN/CSA-C22.2 No. 60601-1:14 E336914
CULSEF	Devices with serial numbers 51-XXXXX and 52-XXXX are in compliance with these standards: Medical Equipment with respect to electrical shock, fire, mechanical, and other specified hazards only in accordance with UL/EN/IEC 60601-1 and CAN/CSA C22.2 No. 601.1.
<b>C E</b> 0297	The Vest® Airway Clearance System, Model 205 conforms to the European Medical Device Directive 93/42/EEC.
	Identifies a replaceable fuse link in an electronic circuit.
	Environmental Protection: Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your Local Authority or a retailer for recycling advice.
	Do Not Spray.
REF	Catalog number
LOT	Batch number

Symbol	Definition
SN	Serial number
MD	Medical Device
EC REP	Authorized Representative in the European Community
UDI	Unique Device Identification
-35 <c< th=""><th>Temperature for transport and storage</th></c<>	Temperature for transport and storage
-03% -03%	Relative humidity for transport and storage
Tions - Toolars	Atmospheric pressure for transport and storage
	Fragile
<u>11</u>	This way up
Ť	Keep Dry
5	Stacking limit. The maximum number of identical packages which may be stacked on the bottom package.
YYYY-MM-DD	Date of manufacture

Symbol	Definition
	Manufacturer
YYYY-MM-DD	Manufacturer and date of manufacture
NON	Non sterile
(117)	For multiple use on a single patient
Rx Only	Physician prescription required (for US only).
Segurança	(Only for products to the Federative Republic of Brazil) InMetro Net Connection Corporation (NCC) logo
<b>↓↓</b>	Tear open here
	Maximum safe working load
	Mass of equipment weight

# SAFETY INSTRUCTIONS

### CONTRAINDICATIONS

# WARNING:

**Warning**—If patient conditions exist that cause the use of The Vest<sup>®</sup> Airway Clearance System to present a risk to the patient, **do not use the unit except as directed by a physician**. Death or serious injury could occur.

The Vest<sup>®</sup> Airway Clearance System is **contraindicated** if these conditions are present:

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

## **RELATIVE CONTRAINDICATIONS**

If the patient has one or more of the conditions below, carefully consider and assess the patient's case before you decide to use The Vest® Airway Clearance System.

- Intracranial pressure (ICP) >20 mm Hg, or patients 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 such as tube feeding or recent meal
- Distended abdomen
- Bronchospasm
- Suspected pulmonary tuberculosis
- Recently placed 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, healing tissue, recent skin grafts, or flaps on thorax
- Burns, open wounds, and skin infections on the thorax
- Lung contusion
- Osteomyelitis of the ribs
- Osteoporosis
- Coagulopathy
- Complaint of chest wall pain

# READ ALL INSTRUCTIONS BEFORE USING

### NOTE:

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following important safeguards.



# WARNING:

**Warning**—Obey all **warnings** throughout the manual and also the safety information below to help prevent injury and/or equipment damage:

- Warning—Unplug this system immediately after you use it.
- **Warning**—Do not use the system near flammable chemicals or products, including flammable anaesthetics. To do so could cause personal injury or equipment damage.
- **Warning**—Adult supervision is required to use the therapy on children.
- **Warning**—Federal USA law restricts this device to sale by or on the order of a physician.
- **Warning**—Use close supervision when this system is used by or near children or patients with physical limitations or impaired cognitive abilities.
- **Warning**—Keep the hoses and power cord away from children to avoid strangulation.
- **Warning**—Do not store or use the device around pets, pests, or unsupervised children.
- **Warning**—Use this system only for its intended use. Use only those attachments that are specified by the manufacturer.

# WARNING:

(Warnings continued) Obey all **warnings** throughout the manual and also the safety information below to help prevent injury and/or equipment damage:

- **Warning**—Do not use unauthorized parts or accessories with this device.
- **Warning**—Use only Hill-Rom authorized hoses and vests to avoid allergic skin reactions.
- **Warning**—Do not use the device near to any heat source such as a fireplace or radiant heater.
- Warning—Do not use the device in a dusty environment.
- **Warning**—Do not use the device in a heavy moisture environment.
- **Warning**—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 205 therapy. Please consult your physician to determine if additional therapy is appropriate.
- **Warning**—To help prevent cross-contamination, replace the singlepatient use, disposable garment between patients.
- Warning—Only authorized persons should service the unit.

## NOTE:

If service is necessary, use this contact information:

- In the USA, call Hill-Rom at 800-426-4224.
- Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.
- **Warning**—Do **not** operate the Air Pulse Generator without the disposable garment and Air Hoses attached.
- **Warning**—If it is difficult to connect the Air Hoses to the Air Pulse Generator or disposable garment, do **not** use lubricant.
- **Warning**—If it is difficult to connect the Remote Control to the Air Pulse Generator, do **not** use lubricant.
- Warning—Do not use harsh cleansers, solvents, or detergents.

# WARNING:

(Warnings continued) Obey all **warnings** throughout the manual and also the safety information below to help prevent injury and/or equipment damage:

- Warning—Do not eat or drink during a therapy session.
- **Warning**—Do not leave the garment on a patient for extended periods of time without a cloth barrier between the patient and the garment.
- **Warning**—If it is necessary to disconnect/isolate the device from the main power supply, disconnect the power cord plug from the power inlet socket on the back of the air pulse generator or disconnect the plug from the power outlet in the wall.
- **Warning**—Make sure the position of the air pulse generator is such that you can quickly, without obstruction, disconnect the power cord from the main power supply if necessary.
- **Warning**—Discard The Vest<sup>®</sup> Airway Clearance System, Model 205 product in accordance with your local government regulations.
- **Warning**—To protect the patient and caregiver from the total acoustical energy from the use of this device, make sure of these:
  - The device is not used by a patient and/or a caregiver more than a total of 12 hours each day.
  - When the device is in use, keep a distance of at least 1.64'
     (0.5 m) between the device and the patient and caregiver.
- **Warning**—This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.
- Warning—The Vest® Airway Clearance System, Model 205 is MR Unsafe. Do not expose the system to any magnetic resonance (MR) environment.

## NOTES:

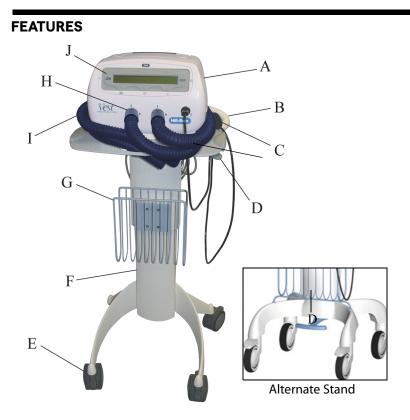
- The system may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- The system may not function properly due to the strong magnetic and radio frequency fields generated by the MR equipment.
- **Warning**—Some patients with seizure history may experience seizure during or after the therapy.

# WARNING:

(Warnings continued) Obey all **warnings** throughout the manual and also the safety information below to help prevent injury and/or equipment damage:

- **Warning**—Some patients may experience nausea, dizziness or headache when using the therapy. It is recommended that patients refrain from doing any therapy for a period of time after eating. If patients experience these symptoms, it is recommended that they take breaks during therapy.
- **Warning**—Patients that have external ports or equipment (for example, catheters, feeding tubes, tracheostomy tubes) should take care to cushion the site and/or support the equipment before initiating therapy.
- **Warning**—For patients with breast implants, make sure that you follow the doctor's prescriptions and exercise caution before you conduct the therapy.

# SAVE THESE INSTRUCTIONS



А	Air Pulse Generator	F	Stand
В	Push Bar	G	Storage Basket
С	Remote Control	Н	Air Hose Connector Ports
D	Height Adjustment Release Lever	I	Air Hoses
Е	Four Locking Casters	J	Control Panel

## AIR PULSE GENERATOR

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

# PUSH BAR

The Push Bar permits the unit to be moved around in a room or from room to room.

## **REMOTE CONTROL**

The Remote Control can be used instead of the **ON/OFF** button to pause or resume the Air Pulse Generator.

## HEIGHT ADJUSTMENT RELEASE LEVER

The Height Adjustment Release Lever can be used to raise or lower the Air Pulse Generator to a comfortable working height.

## LOCKING CASTERS

The Locking Casters keep the stand and Air Pulse Generator from unintentionally moving.

## STAND

The Stand holds the Air Pulse Generator.

## STORAGE BASKET

The Storage Basket can be used to store disposable garments.

# **AIR HOSE CONNECTOR PORTS**

The Air Hoses connect to the Air Hose Connector Ports on the front of the Air Pulse Generator.

# **AIR HOSES**

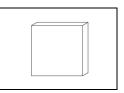
The Air Hoses connect the disposable garment to the Air Pulse Generator.

# CONTROL PANEL

The Control Panel shows the modes, system settings, and system messages.

# CONTOUR FOAM (OPTIONAL)

The contour foam (P/N 300177000) is an optional accessory. The foam helps to provide comfort for the patient who has a Hickman catheter, portacath, and/or G-tube.



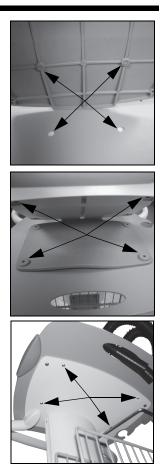
# ASSEMBLY

- 1. Align the two posts on the rubber mat with the holes in the top of the stand.
- 2. Align the holes on the bottom of the Air Pulse Generator with the posts on the rubber mat.

### NOTE:

The screen on the Air Pulse Generator faces the side of the stand that the basket is on.

- 3. Install the four screws to attach the Air Pulse Generator to the stand.
- 4. Tighten, but do not over-tighten, the four screws with the supplied wrench.



# **INSTRUCTIONS FOR USE**

# WARNING:

**Warning**—Changing prescribed settings, an unadjusted or ill-fitting garment may cause an ineffective therapy or lead to patient injury.

## PUT ON THE DISPOSABLE, SINGLE-PATIENT USE (SPU) VESTS

### NOTE:

It is recommended that a single layer of cotton clothing be worn beneath the disposable garment to prevent static charge build-up.

## Wrap SPU Vest

- 1. Turn the patient towards you.
- 2. With the Wrap SPU Vest deflated, begin to lay it flat on the bed so it is perpendicular with the patient's torso.
- Roll the patient away from you and on the open portion of the Wrap SPU Vest.
- 4. 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 hook-and-loop fasteners to temporarily attach both ends to each other.

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. You should be able to fit a flat hand between the Wrap SPU Vest and the body.



# Full SPU Vest

## NOTE:

It is recommended that a single layer of cotton clothing be worn beneath the disposable garment to prevent static charge build-up.

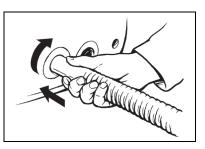
- 1. Separate the front flaps of the Full SPU Vest at the hook-and-loop fasteners.
- 2. Turn the Full SPU Vest so the front flaps will meet in front of the patient. Then put the patient's arms through the arm openings in the Full SPU Vest.
- 3. With the Full SPU Vest deflated, use the hook-and-loop fasteners to attach the front flaps of the Full SPU Vest to each other. You should be able to fit a fist between the Full SPU Vest and the body before you inflate the garment.
- Make sure there is approximately 3" to 4" (8 cm to 10 cm) between the bottom edge of the front of the Full SPU Vest and the patient.
- Adjust the hook-and-loop fasteners at the shoulder straps so the bottom edge of the Full SPU Vest is level with the top of the patient's hip bone.



# **CONNECT THE AIR HOSES**

1. Connect each Air Hose as follows:

Slide one end of each Air Hose into each Air Hose Connector Port on the front of the Air Pulse Generator. Use a slight twist motion as you push the Air Hose to help keep it in position.



### NOTE:

If the patient has a Hickman catheter, portacath, and/or G-tube, for the patient's comfort, it may help to use a contour foam (P/N 300177000) around the port site.

### Install the foam as follows:

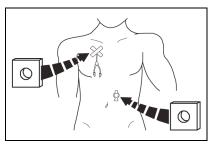
#### NOTE:

The contour foam is not sterile.

2. Cut out a center hole to form a "donut" shape in the foam.



 Put the open hole of the "donut" directly over the port site.



4. Connect the Air Hoses to the disposable garment.

### Wrap SPU Vest

a. Remove the tear label from the disposable garment.



#### Instructions for Use

 b. Slide the other end of each Air Hose into the disposable garment Air Hose slits at least 2" (5 cm).

c. Use the hook-and-loop loops on the side of the disposable garment to hold the Air Hoses in position.

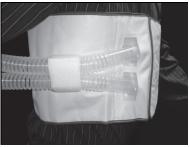
### NOTE:

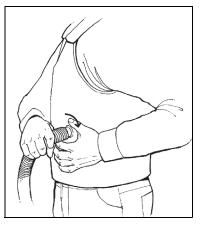
The garment can be worn with the Air Hose Connector Ports anywhere around the chest that is comfortable.

### Full SPU Vest

Slide the other end of each Air Hose over the disposable garment Air Hose Ports. To help keep the Air Hoses in position, slightly twist the Air Hoses as you push them over the Full SPU Vest Air Hose Ports.







### NOTE:

The Vest® Airway Clearance System can be use with patient in a sitting, lying down, or standing position.

### SET UP THE AIR PULSE GENERATOR

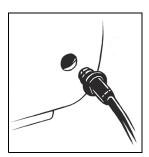
1. Install the Remote Control into the Air Pulse Generator.

### NOTE:

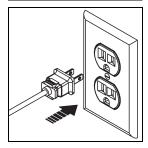
Use of the Remote Control is optional.

2. Plug the Power Cord into the power inlet on the back of the Air Pulse Generator.

3. Plug the Power Cord into an applicable power outlet.

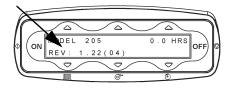






# SOFTWARE VERSION

The software version is displayed on the opening screen when the unit is connected to AC power. X.XX is the software version; (XX) is the software revision.



Software Version	Instructions
1.20	Go to "Use The Vest® Airway Clearance System, Software Version 1.20" on page 20.
1.22	Go to "Use The Vest® Airway Clearance System, Software Version 1.22" on page 35.

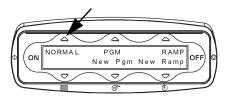
# USE THE VEST® AIRWAY CLEARANCE SYSTEM, SOFTWARE VERSION 1.20

Make sure the unit is set up correctly. Once power is connected, the unit will show a blank screen for up to 15 seconds. Then it will show the model number and the total therapy hours for the unit. This screen shows for 10 seconds or until you press the **ON** button.

## NOTE:

To show the total therapy hours, press the **OFF** button when the unit is on the main menu.

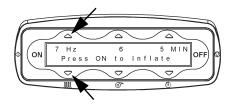
1. Press the **Up** arrow above **NORMAL** for the standard mode. The screen will show the previously programmed Frequency, Pressure, and treatment Time settings



(or the default settings, depending on how it was programmed).

2. Confirm the settings on the screen. If the settings match the prescribed treatment, continue to step 3. Otherwise, adjust the settings to match the prescription.

a. To adjust the Frequency setting, press the left **Up** or **Down** arrow buttons until the prescribed treatment shows on the screen. The Frequency or Hertz



(Hz) may be set between 5 and 20 cycles per second.

- To adjust the Pressure setting, press the middle **Up** or **Down** b. arrow buttons until the prescribed treatment Pressure shows on the screen. The Pressure may be set between 1 and 10.
- To adjust the treatment Time, press the right **Up** or **Down** arrow c. buttons until the prescribed treatment Time shows on the screen. The treatment Time may be set between 1 and 60 minutes.

### NOTE:

It is not necessary to stop the treatment to adjust the settings. If the backlight turns itself off, press any button to turn it back **ON**.

3. Press the **ON** button. The disposable garment will inflate.

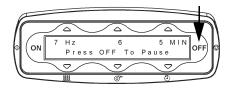
### NOTE:

4.

If the unit is left in this mode for 10 minutes, it will turn off.

counts down to zero.

- Press the **ON** button again to begin the treatment. The set treatment Time shows as it
- If it is necessary to pause the treatment during a session, do as 5. follows:
  - Press the **OFF** button а. or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.



## NOTE:

When the unit is paused, the disposable garment will deflate.



- b. To resume treatment, press the **ON** button or the Remote Control again.
- If it is necessary to end the treatment session before it is complete, press the **OFF** button.



### NOTE:

Pressing the **OFF** button does not turn off the screen.

7. When the **OFF** button is pressed, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must press **ON** to continue to the main screen.

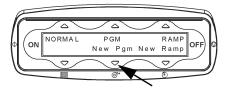


- 8. When the treatment session is complete:
  - a. The "Session Complete" message shows.
  - b. The pulsations stop.
  - c. The disposable garment deflates.
  - d. Immediately unplug the system from its power source.
  - e. Remove the Air Hoses from the Air Hose Ports on the disposable garment.
  - f. Remove the disposable garment from the patient.

## SETTING AND USING A NEW PROGRAM MODE

New Program Mode allows the caregiver to program up to eight (8) points with various settings within a single therapy session.

1. Press the **Down** arrow below **New Pgm** to create



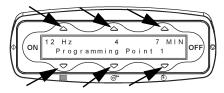
a new program. The screen will show the Frequency, Pressure, and treatment Time settings for the first Programming Point.



# NOTE:

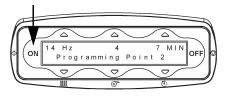
All the settings can be adjusted. You can program up to 8 different Programming Points, each with its own combination of Frequency, Pressure, and treatment Time.

2. For Programming Point 1, if the settings match the prescribed treatment, continue to step 3. Otherwise, adjust the settings to match the prescription by pressing



the **Up** and **Down** arrows associated with Frequency, Pressure, and treatment Time.

3. Once you have Programming Point 1, proceed to Programming Point 2 by pressing the **ON** button (to move to a previous Programming Point, press the **OFF** 



button). Adjust the settings to match the prescription and repeat for all 8 Programming Points.

4. If the prescription does not call for all 8 Programming Points, **after** Programming Point 2, set the Time to 0 MIN for the following segments, press the **ON** button to advance through the remaining Programming Points.

## NOTE:

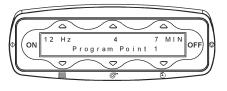
Once you change the Programming Point Time to 0 MIN and press the **ON** button, it will take you to the start of the program to begin therapy.

- Press the **ON** button. The disposable garment will inflate.
- 6. Press the **ON** button again to begin the treatment program. The set treatment Time shows as it



counts down to zero for each Programming Point.

- Therapy will automatically end after it has gone through each Programming Point.
- If it is necessary to pause the treatment during a session, do as follows:



a. Press the **OFF** button or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.

## NOTE:

When the unit is paused, the disposable garment will deflate.

- b. To resume treatment, press the **ON** button or the Remote Control again.
- 9. If it is necessary to end the treatment session before it is complete, press the **OFF** button.



## NOTE:

Pressing the **OFF** button does not turn off the screen.

10. When the **OFF** button is pressed, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must press **ON** to continue to the main screen.



- 11. When the treatment session is complete:
  - The "Session Complete" message shows.
  - b. The pulsations stop.
  - c. The disposable garment deflates.



- d. Immediately unplug the system from its power source.
- e. Remove the Air Hoses from the Air Hose Ports on the disposable garment.

f. Remove the disposable garment from the patient.

### USING THE PROGRAM MODE

Allows the caregiver the capability to use a previously created New Program Mode, See "Setting and Using a New Program Mode" on page 22.

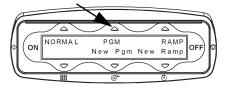
- Press the Up arrow above PGM to run the previously created program, or selected default program.
- 2. Press the **ON** button. The disposable garment will inflate.
- 3. Press the **ON** button again to begin the treatment program. The set treatment Time shows as it counts down to zero for each Programming Point.
- The therapy will automatically end after it has gone through each of the Programming Points.
- 5. If it is necessary to pause the treatment during a session, do as follows:
  - a. Press the **OFF** button or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.

### NOTE:

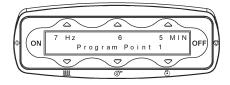
When the unit is paused, the disposable garment will deflate.

- b. To resume treatment, press the **ON** button or the Remote Control again.
- If it is necessary to end the treatment session before it is complete, press the **OFF** button.









Use The Vest® Airway Clearance System, Software Version 1.20

# NOTE:

Pressing the **OFF** button does not turn off the screen.

7. When the **OFF** button is pressed, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must press **ON** to continue to the main screen.



- 8. When the treatment session is complete:
  - a. The "Session Complete" message shows.
  - b. The pulsations stop.
  - c. The disposable garment deflates.

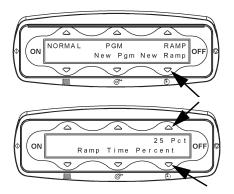


- d. Immediately unplug the system from its power source.
- e. Remove the Air Hoses from the Air Hose Ports on the disposable garment.
- f. Remove the disposable garment from the patient.

## SETTING AND USING A NEW RAMP MODE

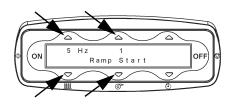
Allows the caregiver capability to create a new Ramp Program to ease the patient from a lower setting to a higher setting within the percent of the total therapy session.

- Press the **Down** arrow below **New Ramp** to adjust the program settings.
- 2. Look at the settings on the screen. Ramp Time Percent is the portion of the treatment Time required to increase from the initial settings (**Ramp Start**) to the final settings

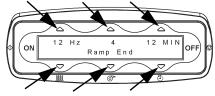


(**Ramp End**). To adjust the percent to the prescribed therapy, press the right **Up** or **Down** arrows.

- 3. Press the **ON** button to advance to the next screen.
- 4. Review the settings for Frequency and Pressure for the initial setting, Ramp Start.
  - a. To adjust the Frequency setting, press the left **Up** or **Down** arrow buttons until the prescribed treatment shows on the screen. 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 or Down arrow buttons until the prescribed treatment Pressure shows on the screen. Pressure may be set between 1 and 10.



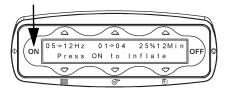
- 5. Press the **ON** button to advance to the next screen.
- 6. Review the settings on the screen. Frequency and Pressure for the final setting, **Ramp End**, are shown as treatment Time.
  - To adjust the Frequency setting, press the left Up or Down arrow buttons until the prescribed setting shows on the screen.
     Frequency or Hertz (Hz) may be set between the Ramp Start setting and 20 cycles per second.
  - b. To adjust the Pressure setting, press the middle **Up** or **Down** arrow buttons until the prescribed setting shows on the screen. Pressure may be set between the Ramp Start setting and 10.
  - c. To adjust the treatment Time, press the right **Up** or **Down** arrow buttons until the prescribed treatment Time shows on the screen. The treatment Time



may be set between 1 and 60 minutes.

7. Press the **ON** button to advance to the next screen. This screen shows the summary of the ramp program you have just created.

8. Press the **ON** button. The disposable garment will inflate.



9. Press the **ON** button again to begin the therapy. The screen will show the word Ramping during the ramp portion of the program. The total treatment Time shows as it counts down to zero.



## NOTE:

Therapy settings **cannot** be changed during Ramping stage.

- 10. If it is necessary to pause the treatment during a session, do as follows:
  - a. Press the **OFF** button or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.

## NOTE:

When the unit is paused, the disposable garment will deflate.

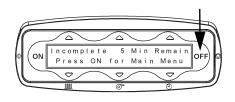
- b. To resume treatment, press the **ON** button or the Remote Control again.
- 11. If it is necessary to end the treatment session before it is complete, press the **OFF** button.

# ON 7 Hz 4 5 MIN Press ON To Resume OFF

### NOTE:

Pressing the **OFF** button does not turn off the screen.

12. When the **OFF** button is pressed, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must press **ON** to continue to the main screen.



- 13. When the treatment session is complete:
  - a. The "Session Complete" message shows.
  - b. The pulsations stop.
  - c. The disposable garment deflates.
  - d. Immediately unplug the system from its power source.
  - e. Remove the Air Hoses from the Air Hose Ports on the disposable garment.
  - f. Remove the disposable garment from the patient.

## USING THE RAMP MODE

Allows the caregiver to run a previously created Ramp Program, See "Set and Use the New Ramp Mode" on page 45.

Ramp e" on

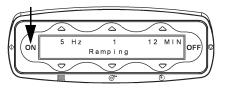
- Press the **Up** arrow above **RAMP** to run the previously created ramp program.
- 2. The programmed points will be shown. Press the **ON** button to advance to the next screen.
- Press the **ON** button. The disposable garment will inflate.







4. Press the **ON** button again to begin the program. The screen will show the word Ramping during the ramp portion of the program. The total treatment Time shows as it counts down to zero.



## NOTE:

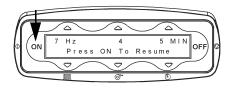
Therapy settings **cannot** be changed during Ramping stage.

- 5. If it is necessary to pause the treatment during a session, do as follows:
  - a. Press the **OFF** button or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.

## NOTE:

When the unit is paused, the disposable garment will deflate.

- b. To resume treatment, press the **ON** button or the Remote Control again.
- If it is necessary to end the treatment session before it is complete, press the **OFF** button.



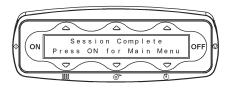
## NOTE:

Pressing the **OFF** button does not turn off the screen.

7. When the **OFF** button is pressed, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must press the **ON** button to continue to the main screen.



- 8. When the treatment session is complete:
  - a. The "Session Complete" message shows.
  - b. The pulsations stop.
  - c. The disposable garment deflates.



- d. Immediately unplug the system from its power source.
- e. Remove the Air Hoses from the Air Hose Ports on the disposable garment.
- f. Remove the disposable garment from the patient.

## CHECK THE HOUR METER READING

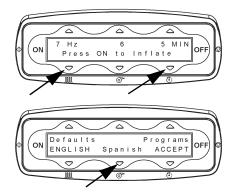
The Hour Meter Reading will show on the screen when you first plug your device in. You can also access the Hour Meter Reading as follows:

 With the device plugged in, press the ON button and then press the OFF button.

The Hour Meter Reading will show on the screen.

## CHANGE THE LANGUAGE

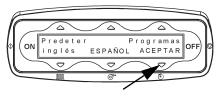
- 1. Press the **Up** arrow button above **NORMAL**. The Normal mode screen shows.
- 2. Press the two **outside Down** arrow buttons for a minimum of 3 seconds (or until the screen changes).
- 3. Press the middle **Down** arrow button until the desired language shows in all capital letters.



31



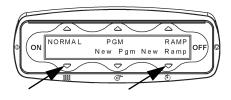
- 4. To accept the change, press the far right **Down** arrow button.
- Once you have accepted the change, the system will automatically re-boot and go back to the main screen in the applicable language.



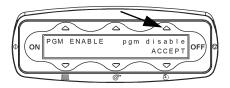
6. Once the main screen is visible, unplug the unit and plug it back in. The unit will automatically reconfigure in the applicable language.

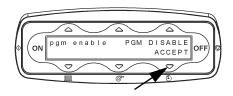
## DISABLE THE PROGRAM MODES (PROGRAM AND RAMP)

- 1. Press the left **Up** arrow button above **NORMAL**. The Normal mode screen shows.
- Press the two outside Down arrow buttons for a minimum of 3 seconds, or until the screen changes.
- 3. Press the right **Up** arrow button above **Programs**.
- Press the right Up arrow button above pgm disable (it will turn to PGM DISABLE).
- 5. To accept the change, press the right **Down** arrow below **ACCEPT**.

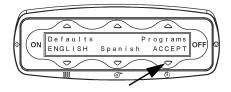








- To accept all changes and exit out of the menu, press the right Down arrow button below the word ACCEPT.
- Once you have accepted the change, the system will automatically re-boot



and go to the main screen of **NORMAL** Mode. You will no longer be able to see the Program or Ramp mode programs.

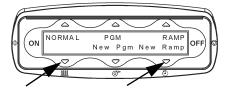
8. To switch back to Program Mode, repeat the steps starting at step 2.

## NOTE:

Press the **Up** arrow button above **pgm enable** at step 4 to enable the Program Mode (it will turn **pgm enable** to **PGM ENABLE**).

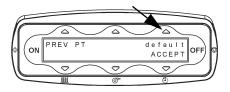
## Set Facility Custom Default Settings

- 1. Press the left **Up** arrow button above **NORMAL**.The Normal mode screen shows.
- Press the two outside Down arrows for a minimum of 3 seconds, or until the screen changes.
- 3. Press the left **Up** arrow button above **Defaults**.

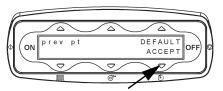


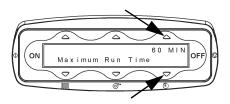


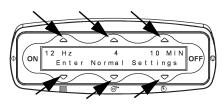
 Press the right Up arrow button above default (the default will change to DEFAULT).



- 5. To accept the change, press the right **Down** arrow button below **ACCEPT**.
- To adjust the Maximum **Run Time** use the **Up** and **Down** arrow buttons above and below **MIN** and press the **ON** button.
- 7. To set default Frequency, Pressure, and Time settings, for Normal Mode, adjust each by using the respective the **Up** and **Down** arrow buttons and press the **ON** button.



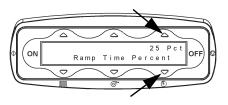




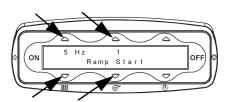
- 8. To adjust the default settings for **Program Mode**, set each **Programming Point** sequentially. Press the **ON** button to advance to the next Programming Point.
- Adjust Frequency, Pressure, and Time for each **Program Point** (1 through 8) or change the time to zero, after Programming Point 3, to make the previous point the last point.
- 10. Press the **ON** button to advance to the next default setting.

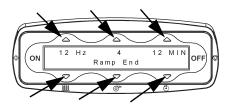


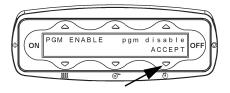
11. Adjust the **Ramp Time Percent** for the **Default Ramp** mode using the right **Up** and **Down** arrow buttons, and press the **ON** button.



- 12. Adjust the **Ramp Start**, **Frequency**, and **Pressure** settings for default **Ramp Mode** by using the left and middle **Up** and **Down** arrow buttons, and press the **ON** button.
- 13. Adjust the **Ramp End** settings for default **Ramp Mode**, Frequency, Pressure, and Time using the **Up** and **Down** arrow buttons, and press the **ON** button.
- 14. To accept all of the changes, press the right **Down** arrow below **ACCEPT**.
- 15. Once you have accepted the change, it will automatically re-boot the system and go back to the main screen.









 To switch back to previous patient default mode, repeat the steps and select prev pt instead of default.

# USE THE VEST® AIRWAY CLEARANCE SYSTEM, SOFTWARE VERSION 1.22

Make sure the unit is set up correctly. Once power is connected, the unit will show a blank screen for up to 15 seconds. Then it will show the model number, the total therapy hours for the unit, and software revision. This screen shows for 10 seconds or until you press the **ON** button.

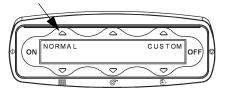
## NOTE:

To show the total therapy hours, press the **OFF** button when the unit is on the main menu.

## NORMAL MODE

Normal Mode is using one Frequency, Pressure and Time settings for the entire therapy session.

1. Press the **Up** arrow button above **NORMAL** for the standard operation mode. The screen will show the previously programmed Frequency, Pressure, and treatment Time settings



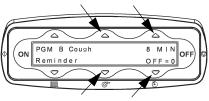
(either factory settings or settings programmed by your clinical trainer based on your doctor's prescription).

- 2. Confirm the settings on the screen. If the settings match the prescribed treatment, continue to step 3. Otherwise, adjust the settings to match the prescription.
  - a. To adjust the Frequency setting, press the left Up or Down arrow buttons until the prescribed treatment shows on the screen. The Frequency or Hertz (Up) may be set between



(Hz) may be set between 5 and 20 cycles per second.

 b. To adjust the Pressure setting, press the middle Up or Down arrow buttons until the prescribed treatment Pressure shows on the screen. The Dressure ho set between 1 a



Pressure may be set between 1 and 10.

c. To adjust the treatment Time, press the right **Up** or **Down** arrow buttons until the prescribed treatment Time shows on the screen. The treatment Time may be set between 1 and 60 minutes.

## NOTE:

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

5 MIN

ΟN

Ηz

Start

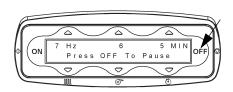
ON

Press the **ON** button. The disposable garment will inflate.

## NOTE:

If the unit is left in this mode for 10 minutes, it will turn off.

- 4. Press the **ON** button again to begin the treatment. The set treatment Time shows as it counts down to zero.
- 5. If it is necessary to pause the treatment during a session, do as follows:
  - a. Press the **OFF** button or Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.



Therapy Press

## NOTE:

When the unit is paused, the disposable garment will deflate.

- b. To resume treatment, press the **ON** button or the Remote Control again.
- If it is necessary to end the treatment session before it is complete, press the **OFF** button twice.

#### 

## NOTE:

Pressing the **OFF** button does not turn off the screen.

 When the OFF button is pressed twice, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must press the ON button to co



press the **ON** button to continue to the main screen.

- 8. When the treatment session is complete:
  - The "Session Complete" message shows.
  - b. The pulsations stop.
  - c. The disposable garment deflates.
- 9. Unplug the system from its power source.
- 10. Remove the Air Hoses from the Air Hose Ports on the disposable garment.
- 11. Remove the disposable garment.

## SET AND USE THE NEW PROGRAM MODE

New Program Mode allows the programming of Program A and Program B modes, each with up to eight (8) points with various settings within a single therapy

session. It also allows the programming of the Cough Pause® feature (reminder to cough).

## NOTE:

All the settings can be adjusted. You can program up to 8 different Programming Points, each with its own combination of Frequency, Pressure and treatment Time.

## WARNING:

**Warning**—Consult your physician before you change the prescribed settings. Failure to do so can cause personal injury.

MODEL

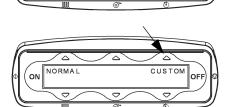
ON

105

Press ON To

1. Press the **ON** button.









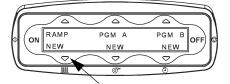
x x x x x . x

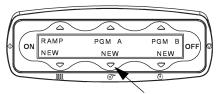
Continue

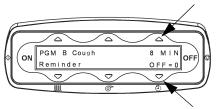
HRS

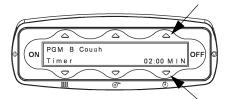
OF

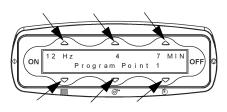
- 3. Do one of these:
  - a. To program the Ramp mode, press the **Down** arrow under **RAMP NEW** and See "Set and Use the New Ramp Mode" on page 45.
  - b. To program Program A or Program B, press the **Down** arrow button below **PGM A NEW,** or **PGM B NEW** and go to step 4.
- Press the Up or Down arrow for Cough Pause<sup>®</sup> Reminder duration (time between cough pauses). A zero (0) time will turn off the Cough Pause<sup>®</sup> feature.
- 5. Press **ON** to go to the next screen.
- 6. Press the **Up** or **Down** arrow to select the pause duration. This will set the duration the unit pauses for coughs.
- 7. Press **ON** to go to the next screen.
- For Programming Point 1, if the settings match the prescribed treatment, continue to step 9.
   Otherwise, adjust the settings to match the prescription by pressing











the **Up** and **Down** arrow buttons associated with Frequency, Pressure and treatment Time.

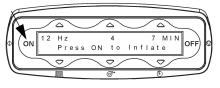
 Once you have set Programming Point 1, proceed to Programming Point 2 by pressing the ON button (to move to a previous Programming Point, press the OFF button). Adjust the settings to match the prescription and repeat for all 8 Programming Points.

## NOTE:

If the prescription does not call for all 8 Programming Points, **after** programming the last prescribed programming point, set the Time to 0 MIN for the following segment.

Once you change the Programming Point Time to 0 MIN and press the **ON** button, it will take you to the start of the program to begin therapy.

- 10. Press the **ON** button. The disposable garment will inflate.
- 11. Press the **ON** button again to begin the treatment program. The set treatment Time shows as it counts down to zero for each Programming Point.



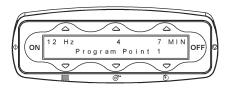
- 12. When the time for a cough pause is reached, these will happen:
  - a. The unit will pause.
  - The display will change to show the pause duration timer.
  - c. The garment will deflate.
- 13. While the pause happens, the patient should cough as prescribed.
- 14. When the timer reaches zero, the garment will inflate, and therapy will resume.

## NOTE:

If additional time is needed, press the **OFF** control to pause the unit.

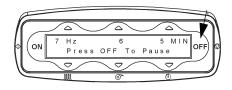
To resume therapy before the cough pause timer expires, you can press **ON** or squeeze the Remote Control.

- Therapy will automatically end after it has gone through each Programming Point.
- 16. If it is necessary to pause the treatment during a session, do as follows:





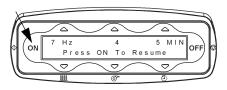
a. Press the **OFF** button or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.



## NOTE:

When the unit is paused, the disposable garment will deflate.

- b. To resume treatment, press the **ON** button or the Remote Control again.
- 17. When the time for a cough pause is reached, these will happen:
  - a. The unit will pause.
  - b. The display will change to show the pause duration timer.
  - c. The garment will deflate.





- 18. While the pause happens, the patient should cough as prescribed.
- 19. When the timer reaches zero, the garment will inflate, and therapy will resume.

## NOTE:

If additional time is needed, press the OFF control to pause the unit.

To resume therapy before the cough pause timer expires, you can press **ON** or squeeze the Remote Control.

20. If it is necessary to end the treatment session before it is complete, press the **OFF** button twice.

## NOTE:

Pressing the **OFF** button does not turn off the screen.

~

NORMAL

ON

21. When the **OFF** button is pressed twice, the disposable garment

deflates and the "Incomplete X Min Remain" message shows on the screen. You must press the **ON** button to

press the **ON** button to continue to the Program and Ramp main screen.
22. When the treatment session is complete:

оn

for

ΟN

Press

- a. The "Session Complete" message shows.
- b. The pulsations stop.
- c. The disposable garment deflates.
- 23. Unplug the system from its power source.
- 24. Remove the Air Hoses from the Air Hose Ports on the disposable garment.

ON

25. Remove the disposable garment.

## USE THE PROGRAM MODE

Runs a previously created **<u>New</u>** Program Mode, See "Set and Use the New Program Mode" on page 38.

## WARNING:

**Warning**—Consult your physician before you change the prescribed settings. Failure to do so can cause personal injury.

1. Press the **ON** button.



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OF

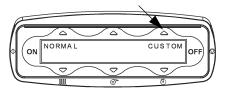


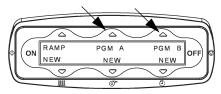
Complete

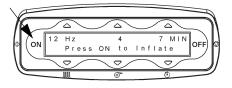
Main

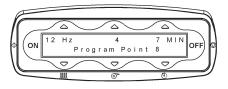
Menu

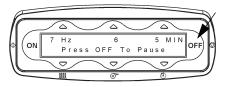
- 2. Press the **UP** arrow button above **CUSTOM**.
- Press the Up arrow button above PGM A or PGM B to run the previously created program, or selected default program.
- 4. Press the **ON** button. The disposable garment will inflate.
- 5. Press the **ON** button again to begin the treatment program. The set treatment Time shows as it counts down to zero for each Programming Point.
- The therapy will automatically end after it has gone through each of the Programming Points.
- 7. If it is necessary to pause the treatment during a session, do as follows:
  - a. Press the **OFF** button or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.











## NOTE:

When the unit is paused, the disposable garment will deflate.

- b. To resume treatment, press the **ON** button or the Remote Control again.
- 8. When the time for a cough pause is reached, these will happen:
  - a. The unit will pause.
  - The display will change to show the pause duration timer.
  - c. The garment will deflate.
- 9. While the pause happens, the patient should cough as prescribed.
- 10. When the timer reaches zero, the garment will inflate, and therapy will resume.

## NOTE:

If additional time is needed, press the **OFF** control to pause the unit.

- 11. To resume therapy before the cough pause timer expires, you can press **ON** or squeeze the Remote Control.
- 12. If it is necessary to end the treatment session before it is complete, press the **OFF** button twice.

## NOTE:

Pressing the **OFF** button does not turn off the screen.

13. When the **OFF** button is pressed twice, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must



press the **ON** button to continue to the Program and Ramp main screen.





Session

ress

Comple te

ON for Main Menu

- 14. When the treatment session is complete:
  - a. The "Session Complete" message shows.
  - b. The pulsations stop.
  - c. The disposable garment deflates.
- 15. Unplug the system from its power source.
- 16. Remove the Air Hoses from the Air Hose Ports on the disposable garment.

ON

17. Remove the disposable garment.

## SET AND USE THE <u>NEW</u> RAMP MODE

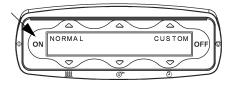
Creates a new Ramp Program to ease the patient from a lower setting to a higher setting during a limited period of the therapy session.

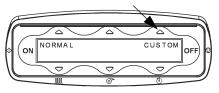


## WARNING:

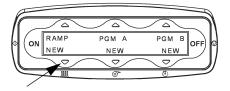
**Warning**—Consult your physician if not using the prescription as provided. Failure to do so can result in personal injury.

- 1. Press the **ON** button.
- 2. Press the **Up** arrow button above **CUSTOM**.

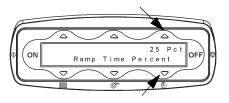




 Press the Down arrow button below New Ramp/New to adjust the program settings.

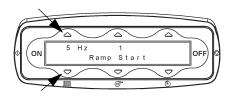


 Look at the settings on the screen. Ramp Time Percent is the portion of the treatment Time required to increase from the initial settings (Ramp Start) to the final settings



(**Ramp End**). To adjust the percent to the prescribed therapy, press the right **Up** or **Down** arrow buttons.

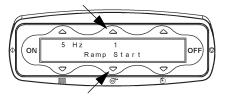
- 5. Press the **ON** button to advance to the next screen.
- 6. Review the settings for Frequency and Pressure for the initial setting, **Ramp Start**.
  - To adjust the Frequency setting, press the left **Up** or **Down** arrow buttons until the prescribed treatment shows on the screen. The Frequency (or Hertz



(Hz)) may be set between 5 and 20 cycles per second.

b. To adjust the

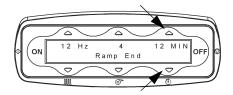
Pressure setting, press the middle **Up** or **Down** arrow buttons until the prescribed treatment Pressure shows on



the screen. Pressure may be set between 1 and 10.

- 7. Press the **ON** button to advance to the next screen.
- 8. Review the settings on the screen. Frequency and Pressure for the final setting, **Ramp End**, are shown as treatment Time.
  - To adjust the Frequency setting, press the left Up or Down arrow buttons until the prescribed setting shows on the screen.
     Frequency or Hertz (Hz) may be set between the Ramp Start setting and 20 cycles per second.
  - b. To adjust the Pressure setting, press the middle Up or Down arrow buttons until the prescribed setting shows on the screen.
     Pressure may be set between the Ramp Start setting and 10.

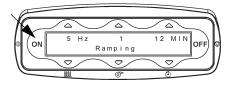
c. To adjust the treatment Time, press the right **Up** or **Down** arrow buttons until the prescribed treatment Time shows on the screen.



The treatment Time may be set between 1 and 60 minutes.

- Press the ON button to advance to the next screen. This screen shows the summary of the ramp program you have just created.
- Press the **ON** button. The disposable garment will inflate.
- 11. Press the **ON** button again to begin the therapy. The screen will show the word "Ramping" during the ramp portion of the program. The total treatment Time shows as it counts down to zero.





## NOTE:

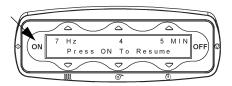
Therapy settings **can not** be changed during Ramping stage.

- 12. If it is necessary to pause the treatment during a session, do as follows:
  - a. Press the **OFF** button or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.

## NOTE:

When the unit is paused, the disposable garment will deflate.

- b. To resume treatment, press the **ON** button or the Remote Control again.
- If it is necessary to end the treatment session before it is complete, press the **OFF** button twice.



#### Use The Vest<sup>®</sup> Airway Clearance System, Software Version 1.22

## NOTE:

Pressing the **OFF** button does not turn off the screen.

14. When the **OFF** button is pressed twice, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must press **ON** to continue to the main screen.

#### 15. When the treatment session is complete:

- a. The "Session Complete" message shows.
- b. The pulsations stop.
- c. The disposable garment deflates.

16. Unplug the system from

- its power source.17. Remove the Air Hoses from the Air Hose Ports on the disposable garment.
- 18. Remove the disposable garment.

## USE THE RAMP MODE

Runs a previously created Ramp Program. See "Set and Use the New Ramp Mode" on page 45.

## WARNING:

**Warning**—Consult your physician if not using the prescription as provided. Failure to do so can result in personal injury.

1. Press the **ON** button.







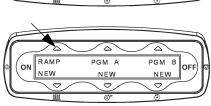
Complete

ON for Main Menu

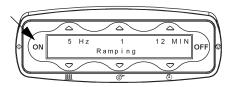
Session

ON

- 2. Press the **UP** arrow button above **Custom**.
- 3. Press the **Up** arrow button above **RAMP** to run the previously created ramp program.
- The programmed points will be shown. Press the ON button to advance to the next screen.
- Press the **ON** button. The disposable garment will inflate.
- Press the ON button again to begin the program. The screen will show the word "Ramping" during the ramp portion of the program. The total treatment Time shows as it counts down to zero.



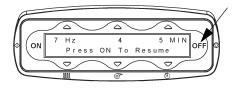




## NOTE:

Therapy settings **can not** be changed during Ramping stage.

- 7. If it is necessary to pause the treatment during a session, do as follows:
  - a. Press the **OFF** button or the Remote Control once. The unit will stop the pulsations, but the settings will continue to show on the screen.



## NOTE:

When the unit is paused, the disposable garment will deflate.

- b. To resume treatment, press the **ON** button or the Remote Control again.
- 8. If it is necessary to end the treatment session before it is complete, press the **OFF** button twice.



Pressing the **OFF** button does not turn off the screen.

9. When the **OFF** button is pressed twice, the disposable garment deflates and the "Incomplete X Min Remain" message shows on the screen. You must

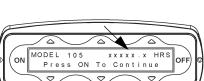
press the **ON** button to continue to the main screen.

- 10. When the treatment session is complete:
  - a. The "Session Complete" message shows.
  - b. The pulsations stop.
  - c. The disposable garment deflates.
- 11. Unplug the system from its power source.
- 12. Remove the Air Hoses from the Air Hose Ports on the disposable garment.
- 13. Remove the disposable garment.

## CHECK THE HOUR METER READING

The Hour Meter Reading will show on the screen when you first plug your device in. You can also access the Hour Meter Reading as follows:

With the device plugged in, press the **ON** button and then press the **OFF** button. The Hour Meter Reading will show on the screen.





5

Min Remain

Menu

Main

Incomplete

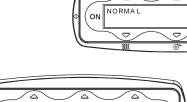
Press ON for

ON



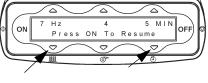
## CHANGE THE LANGUAGE

- 1. Press the **ON** button.
- 2. Press the **Up** arrow button above **NORMAL**. The Normal mode screen shows.
- Press the two outside Down arrow buttons for a minimum of 3 seconds (or until the screen changes).
- 4. Press the middle **Down** arrow button until the desired language shows in all capital letters.
- 5. To accept the change, press the far right **Down** arrow button.
- Once you have accepted the change, the system will automatically re-boot and go back to the main screen in the applicable language.



ON

NORMAL



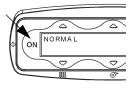


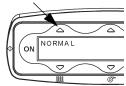


## DISABLE THE PROGRAM MODES (PROGRAM AND RAMP MODES)

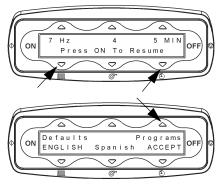
Disable the Program Modes allows the unit to operate in Normal mode only, and removes access to custom modes by the user.

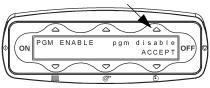
- 1. Press the **ON** button.
- 2. Press the left **Up** arrow button above **NORMAL**. The Normal mode screen shows.

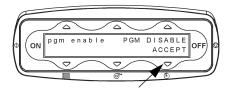




- Press the two outside Down arrow buttons for a minimum of 3 seconds, or until the screen changes.
- 4. Press the right **Up** arrow button above **Programs**.
- 5. Press the right **Up** arrow button above **pgm disable** (it will turn to **PGM DISABLE**).
- 6. To accept the change, press the right **Down** arrow below **ACCEPT**.
- To accept all changes and exit out of the menu, press the right Down arrow button below ACCEPT.







- 8. Once you have accepted the change, the system will automatically reboot and go to the main screen of **NORMAL** Mode. You will no longer be able to see the Program or Ramp mode programs.
- 9. To switch back to Program Mode, repeat the steps starting at step 3.

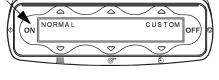
## NOTE:

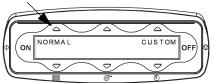
Press the **Up** arrow button above **pgm enable** at step 4 to enable the Program Mode (it will change **pgm enable** to **PGM ENABLE**).

## SET CUSTOM DEFAULT SETTINGS

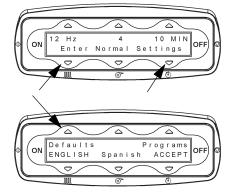
Allows the user to set the default settings for the modes of operation. These settings will be the initial settings for all users.

- 1. Press the **ON** button.
- 2. Press the **Up** arrow button above **NORMAL**. The Normal mode screen shows.





- Press the two outside Down arrows for a minimum of 3 seconds, or until the screen changes.
- 4. Press the left **Up** arrow button above **Defaults**.
- Press the right Up arrow button above default (Defaults will change to DEFAULTS).

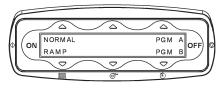


- 6. To accept the change, press the right **Down** arrow button below **ACCEPT**.
- 7. To adjust the **Maximum Run Time** use the **Up** and **Down** arrow buttons above and below **MIN** and then press the **ON** button.

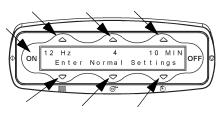
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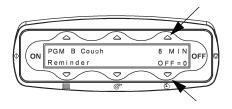
~

- 8. Do one of these:
  - To change the default Normal settings, press the Up arrow above NORMAL, and go to step 9.



- b. To change the default settings of Program A press the **Up** arrow above **PGM A**, or press the **Down** arrow below **PGM B**, and go to step 10.
- c. To change the default Ramp settings, press the **Down** arrow below **RAMP**, and go to step 18.
- d. Press **ON** to accept changes or to advance to the next screen and go to step 21.
- To set default Frequency, Pressure and Time settings for Normal Mode, adjust each by using the respective Up and Down arrow buttons, press the ON button and return to step 8.
- Press the Up or Down arrow for Cough Pause<sup>®</sup> Reminder duration (time between cough pauses). A zero (0) time will turn off the Cough Pause<sup>®</sup> feature.



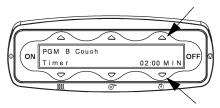


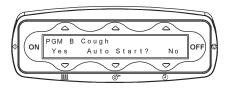
- 11. Press **ON** to go to the next screen.
- 12. Press the **Up** or **Down** arrow to select the pause duration. This will set the duration the unit pauses for coughs.
- 13. Press **ON** to go to the next screen.
- 14. Press the **Down** arrow under *Yes* or *No* for the Auto Start feature.

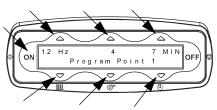
## NOTE:

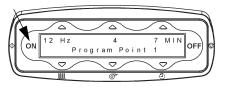
**Auto Start** resumes therapy after cough pause duration expires.

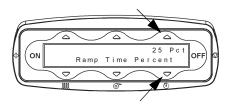
- 15. Press ON to go to the next screen.
- 16. Adjust Frequency, Pressure and Time for each **Program Point** (1 through 8) or change the time to zero, after the last desired Program Point, to make the previous point the last point.
- 17. Press the **ON** button to advance to the next default setting, and return to step 8.
- 18. Adjust the **Ramp Time Percent** for the **Default Ramp** mode using the right **Up** and **Down** arrow buttons, and press the **ON** button.



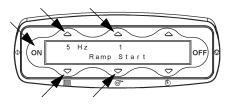




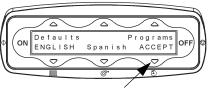




19. Adjust the Ramp Start Frequency, and Pressure settings for default Ramp Mode by using the left and middle Up and Down arrow buttons, and press the ON button.



- 20. Adjust the **Ramp End** settings for default **Ramp Mode Frequency**, **Pressure** and **Time** settings using the **Up** and **Down** arrow buttons, and press the **ON** button and return to step 8.
- 21. To accept all of the changes, press the right **Down** arrow below **ACCEPT**.
- 22. Once you have accepted the change, it will automatically re-boot the system and go back to the main screen.



23. To switch back to previous patient default mode, repeat steps 3 through 5 and select **prev pt** instead of **default**.

## MOVE THE AIR PULSE GENERATOR

- 1. Unplug the Air Pulse Generator from its power source.
- 2. Stow the power cord on the holder on the back of the stand.



## CAUTION:

Caution—Failure to lower the Air Pulse Generator

to the lowest position could cause it to tip over during transport.



- 3. Lower the Air Pulse Generator to the lowest position.
- 4. Lift the brake release on all four casters (two caster styles shown).
- 5. Move the Air Pulse Generator to the applicable location.



Brake released



- 6. Press down on the brake release to set the brakes on all four casters.
- 7. Adjust the height of the Air Pulse Generator to the desired position.
- 8. Plug the Air Pulse Generator into an applicable power outlet.

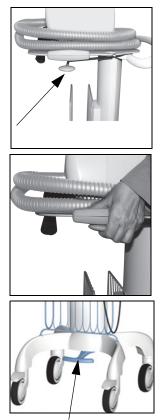


Brake set



# RAISE OR LOWER THE AIR PULSE GENERATOR

- 1. Hold the Height Adjustment Release Lever on the side of the stand.
- 2. Pull the Height Adjustment Release Lever upwards toward to the shelf.
- 3. Push down, or pull up on the shelf, to adjust the height.
- 4. When the desired height is reached, release the Height Adjustment Release Lever.



Alternate Base: press down on foot lever to raise/lower shelf.

## CLEANING

# WARNING:

**Warning**—When you clean and disinfect the device, follow these safety instructions; otherwise, personal injury or equipment damage could occur:

- **Warning**—The potential for electrical shock exists with electrical equipment. Failure to follow facility protocols may cause death or serious injury.
- Warning—Unplug the unit from its power source.
- Warning—Do not expose the unit to excessive moisture.
- **Warning**—Inspect the Air Pulse Generator and Garments before each use. In addition, after each cleaning cycle, visually inspect each component for any wear, tear, or deformity. If you have any concern about a component, do **not** use it, and replace that component before the next therapy session.
- Warning—Do not use harsh cleansers, solvents, or detergents.
- **Warning**—Use cleaning and disinfectant products in accordance with the manufacturer's instructions.

We recommend that you clean the unit with detergent and warm water. Do not use excessive liquid or harsh cleansers.

# 

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

The Vest<sup>®</sup> Airway Clearance System has been tested for compatibility with these cleaning and disinfecting solutions recommended for routine cleaning and disinfection:

Cleaner/Disinfectant	Active Ingredients
Wex-Cide	Ortho-Phenylphenol—0.026% Ortho-Benzyl-para-Chlorophenol—0.023%
Virex <sup>®</sup> II 256	Didecyl dimethyl ammonium chloride—8.704% Alkyl dimethyl benzyl ammonium chloride— 8.19% Alkyl dimethyl ethylbenzyl ammonium chloride
3M™ HB Quat 25L	
Viraguard®	Isopropyl alcohol

## GENERAL CLEANING



**Warning**—To help prevent cross-contamination, replace the singlepatient use disposable garment between patients. Failure to do so could cause patient injury or equipment damage.

## NOTE:

The disposable garments are single-patient use, latex-free, disposable products for use on individual patients over multiple treatment sessions.

Clean The Vest<sup>®</sup> Airway Clearance System between patients, or when visibly soiled if used on the same patient. Replace the disposable garment between patients or when it is damaged. Do **not** attempt to disinfect or sterilize the disposable garment for reuse with more than one patient. We recommend that you clean the Air Pulse Generator and Remote Control with a soft cotton cleaning pad that is slightly moist with detergent and warm water.

Do not use excessive liquid or harsh cleansers. Do **not** immerse The Vest<sup>®</sup> Airway Clearance System in water or let liquids enter the Air Pulse Generator.

Make sure to clean the inside and outside of these:

- Ends of the Air Hoses
- Connection Ports on the garment
- Air Hose Connector Port outlets on 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**

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<sup>®</sup> Airway Clearance System 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. Do **not** attempt to disinfect or sterilize the disposable garment for reuse with more than one patient.

## MAINTENANCE

## WARNING:

**Warning**—Only authorized persons should service The Vest<sup>®</sup> Airway Clearance System. Service by unauthorized persons could cause personal injury or equipment damage.

Minimal routine maintenance and periodic cleaning are necessary for The Vest<sup>®</sup> Airway Clearance System.

Facilities should do these tests and examinations annually:

- Unplug the Air Pulse Generator from its power source.
- Examine the overall condition of the unit for damage or missing parts.
- Examine the Power Cord and connector for cuts, scrapes, or other damage.
- Do electrical safety tests in accordance with facility protocols.
- Clean and disinfect the unit (see "Cleaning" on page 59).
- Connect the Air Pulse Generator to a disposable garment and to an appropriate power source. Make sure the unit is operational, and that all functions operate correctly.

## **EXPECTED LIFE**

The expected service life for the air pulse generator is two years from date of purchase.

The expected service life of the hoses and the remote control is thirty days from date of purchase.

Hill-Rom will repair or replace a defective unit as part of a warranty package specified at the time of purchase of the device, which may extend beyond the expected service life specified above based on servicing and warranty costs.

## **DISPOSAL INSTRUCTIONS**

Users must adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories. If in doubt, the user of the device shall first contact Hill-Rom Technical Support for guidance on safe disposal protocols.

- To ensure safe handling and disposal of this product, follow all relevant warnings, cleaning and disinfection instructions in this manual.
- Always ensure that the product is unplugged or powered off before disposal.
- Always check and comply with all local, national regulations and facility protocols for disposal information.





If applicable, batteries should be recycled. Never dispose of batteries which contain substances that can be dangerous for the environment and health.

Other components, such as electronic components, plastics and metals, are recyclable in many local jurisdictions. Hill-Rom recommends recycling all components that can be recycled locally.

Components which cannot be recycled can be disposed of via standard waste disposal procedures.

## DISPOSABLE GARMENTS AND REPLACEMENT PARTS

#### NOTE:

The disposable vests and air hoses are not made with natural rubber latex.

Part Number	Description
P300629000	X-Small package of 1 (19" to 23" (48 cm to 58 cm))
P300630000	Small package of 1 (>23" to 33" (>58 cm to 84 cm))
P300631000	Medium package of 1 (>33" to 43" (>84 cm to 109 cm))
P300632000	Large package of 1 (>43" to 53" (>109 cm to 135 cm))
P300633000	Extra Large package of 1 (>53" to 67" (>135 cm to 170 cm))
P300634000	XX-Large package of 1 (>67" to 75" (>170 cm to 190 cm))
P300629005	X-Small package of 5 (19" to 23" (>48 cm to 58 cm))
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))
P300634005	XX-Large package of 5 (>67" to 75" (>170 cm to 190 cm))
P300600005	Starter Pack (1 Small, 2 Medium, 1 Large, 1 Extra Large)

## Single-Patient Use, Disposable Wrap SPU Vest

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))
P300208000	Adult, Extra Small, slim (>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))

#### Single-Patient Use, Disposable Full SPU Vest

## Stand and Air Pulse Generator

Part Number	Description
300177000	Contour foam kit assembly
P300177005	Foam, contour box of 5
143512	Caster
142232	Remote Control Assembly
P004982	Disposable Air Hose (1 single)
P0049825	Disposable Air Hose (10/case)
142319	Power Cord
142200	Rubber Mount Pad
140660	Screw Kit (mounting)
167004	HILOW Mobile Stand Assembly
167243	Caster Kit
167185	Basket Assembly Kit
170015	Foot Pedal Kit
143513	Basket Assembly
M06883	Alternate Stand: Vest Alternate Cart Assembly

## SIZE THE DISPOSABLE GARMENTS

To size the disposable garment, do as follows:

- 1. Have the patient take a deep breath and hold it.
- 2. Using a tape measure, loosely measure around the patient at the largest part of their chest. Women should be measured at the bust line.
- 3. Select the disposable garment size based on the measurements provided.
- 4. Disposable garments are designed for patients with a minimum thoracic length (distance from the top of the shoulder to the waist) of 10" (25 cm).

## SERVICE CALLS

If service is necessary on The Vest<sup>®</sup> Airway Clearance System, Model 205, use this contact information:

- In the USA, call Hill-Rom at 800-426-4224.
- Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.

When you contact Hill-Rom, be prepared to give the serial number from the product identification label. The product identification label is on the rear panel of the Air Pulse Generator.

# TROUBLESHOOTING



# WARNING:

**Warning**—Only authorized persons should service The Vest<sup>®</sup> Airway Clearance System, Model 205. Service by unauthorized persons could cause personal injury or equipment damage. Do not modify this device without the authorization of the manufacturer. To do so could cause personal injury or equipment damage.

If service is necessary on The Vest<sup>®</sup> Airway Clearance System, Model 205, use this contact information:

- In the USA, call Hill-Rom at 800-426-4224.
- Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.

## AIR PULSE GENERATOR DOES NOT POWER ON

- 1. 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.
- 2. Make sure the Power Cord is fully plugged into a known-good outlet.
- 3. If the problem is not corrected, contact Hill-Rom.

## NO AIR PULSES INTO THE DISPOSABLE GARMENTS

- 1. If the Remote Control is in use, make sure it is firmly connected to the front panel of the Air Pulse Generator.
- 2. Make sure the Air Hoses are connected to the disposable garment and Air Pulse Generator.
- 3. Make sure the **ON** button has been pressed.
- 4. If the problem is not corrected, contact Hill-Rom.

## SCREEN SHOWS "PLEASE CALL FOR SERVICE" MESSAGE

The system has experienced an unexpected event. Do as follows:

- 1. Unplug the Power Cord from the Air Pulse Generator, and then plug it in again.
- 2. If the problem is not corrected, contact Hill-Rom.

# AN AIR HOSE COMES OUT OF THE AIR PULSE GENERATOR OR DISPOSABLE GARMENTS DURING OPERATION

- 1. Fully disconnect the Air Hoses from the Air Pulse Generator and the disposable garment.
- 2. Clean the inside and outside of these (see "Cleaning" on page 59):
  - Ends of the Air Hose
  - Connection Ports on the disposable garment
  - Air Hose Connector Ports outlets on the Air Pulse Generator
- 3. Connect the Air Hoses to the Air Pulse Generator and disposable garment (see "Set Up the Air Pulse Generator" on page 19).
- 4. If the problem is not corrected, contact Hill-Rom.

## SCREEN SHOWS "RESTARTING"

- 1. The system has experienced an unexpected event and is restarting.
- 2. If the problem is not corrected, contact Hill-Rom.

## 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)
Stand weight Alternate stand weight	35 lb (16 kg) 22 lb (10 kg)
Stand height—lowest position	29" (73.6 cm)
Stand height—highest position	39" (99.1 cm)
Disposable garment material— Wrap SPU Vest and Full SPU Vest	Polyurethane-coated nylon
Electrical requirements	100 V AC to 230 V AC, 50 to 60 Hz, 3.4 Amps @ 100 V AC 2.0 Amps @ 230 V AC
Fuse requirement	4 A, 5 x 20 mm (fast blow, high breaking fuse)

#### **Environmental Conditions for Transport and Storage**

Condition	Range	
Temperature	-13°F to 158°F (-25°C to 70°C)	
Relative humidity	93% non-condensing	

#### **Environmental Conditions for Use**

Condition	Range
Temperature	41°F to 95°F (5°C to 35°C) ambient temperature
Relative humidity range	15% to 93% non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa

### **CLASSIFICATION AND STANDARDS**

Technical and Quality Assurance	ANSI/AAMI ES60601-1 ANSI/AAMI HA60601-1-11 CAN/CSA-C22.2 No. 60601-1 CAN/CSA-C22.2 No. 60601-1 IEC/EN 60601-1 IEC/EN 60601-1-6 IEC/EN 60601-1-11 IEC/EN 62366-1 EN ISO 13485
Technical and Quality Assurance— Devices with serial numbers 51-XXXXX and 52-XXXXX	UL/EN/IEC 60601-1 CAN/CSA C22.2 No. 601.1 EN ISO 13485
Equipment Classification	Class II
Degree of Protection Against Electric Shock	BF with type F applied part
Classification According to Directive 93/42/EEC	lla
Degree of Protection Against Ingress of Water	IP21
Degree of Protection Against the Presence of Flammable Anesthetic Mixtures	Not for use with flammable anesthetics.

The Vest<sup>®</sup> Airway Clearance System, Model 205 is a continuous operation device classified with Underwriters Laboratories Inc.<sup>®</sup> (UL) in the United States and licensed with Health Canada.

#### Guidance and Manufacturer's Declaration— Electromagnetic Emissions

The Vest<sup>®</sup> Airway Clearance System, Model 205 is intended for use in the electromagnetic environment specified below. The customer or user of the Model 205 should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF emissions CISPR 11	Group 1	The Vest <sup>®</sup> Airway Clearance System, Model 205 uses RF energy only for its internal func- tion. 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 Vest® Airway Clearance System, Model
Harmonic emissions IEC 61000-3-2	Class A	205 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	power supply network that supplies buildings used for domestic purposes.

#### Guidance and Manufacturer's Declaration— Electromagnetic Immunity

The Vest<sup>®</sup> Airway Clearance System, Model 205 is intended for use in the electromagnetic environment specified below. The customer or user of the Model 205 should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment— Guidance	
Electrostatic dis- charge (ESD) IEC 61000-4-2	± 8 kV con- tact ± 15 kV air	± 8 kV contact ± 15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.	
Electrical fast tran- sient/burst IEC 61000-4-4	± 2 kV for power sup- ply lines 1± kV for input/output lines	± 2 kV for power supply lines Not applica- ble	Mains power quality should be that of a typical commercial or hospital environment.	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applica- ble	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$0\% U_T \text{ for } 0.5$ cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°. 0% U_T for 1 cycle 70% U_T for 25/30 cycles, single phase at 0°. 0% U_T for 250/300 cycles	$0\% U_T$ for 0.5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°. 0% U_T for 1 cycle 70% U_T for 25/30 cycles, single phase at 0°. 0% U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If it is necessary for the user to have continued opera- tion of the Model 205 during power mains interruptions, it is rec- ommended that the Model 205 be powered from an uninterruptible power supply or a battery.	
Power frequency (50/60 Hz) mag- netic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environ- ment.	
<b>NOTE:</b> $U_T$ is the AC mains voltage prior to application of the test level.				

#### Guidance and Manufacturer's Declaration— Electromagnetic Immunity

The Vest® Airway Clearance System, Model 205 is intended for use in the electromagnetic environment specified below. The customer or user of the Model 205 should make sure it is used in such an environment.				
lmmunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance	
			Portable and mobile RF communications equip- ment should be used no closer to any part of the Model 205, including cables, than the recom- mended 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	$\begin{array}{l} 150 \text{ kHz to} \\ 80 \text{ MHz} \end{array} \qquad d = \left[\frac{3.5}{3}\right] \sqrt{P} \end{array}$	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	80 MHz to 800 MHz $d = \begin{bmatrix} \frac{3.5}{10} \end{bmatrix} \sqrt{P}$ 800 MHz to 2,7 GHz $d = \begin{bmatrix} \frac{7}{10} \end{bmatrix} \sqrt{P}$ where <i>P</i> is the maximum output power rating of the transmit- ter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended sepa- ration distance in meters (m). Field strengths from fixed RF transmitters, as found by an electromagnetic site survey <sup>2</sup> , should be less than the compliance level in each frequency range <sup>b</sup> . Interference may occur in the vicinity of equipment marked with this symbol:	

#### NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- Electromagnetic immunity was examined under normal operation at the time of testing. Normal operation was the essential performance used. Electromagnetic immunity was verified at settings of 4 for intensity and 12 Hz for frequency.
  - 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 can not 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 205 is used is more than the applicable RF compliance level above, the Model 205 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 205'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 Vest® Airway Clearance System, Model 205

The Vest<sup>®</sup> Airway Clearance System, Model 205 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of The Vest<sup>®</sup> Airway Clearance System, Model 205 can help prevent electromagnetic interference by maintaining a the minimum distance between portable and mobile RF communications equipment (transmitters) and The Vest<sup>®</sup> Airway Clearance System, Model 205 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum	Separation Distance According to the Frequency of the Transmitter Meters (m)			
Output Power of the Transmitter Watts (W)	<b>150 kHz to 80 MHz</b> $d = \left[\frac{3.5}{3}\right] \sqrt{P}$	<b>80 MHz to 800 MHz</b> $d = \left[\frac{3.5}{10}\right] \sqrt{P}$	<b>800 MHz to 2,7 GHz</b> $d = \left[\frac{7}{10}\right] \sqrt{P}$	
0,01 W	0,12 m	0,04 m	0,07 m	
0,1 W	0,37 m	0,11 m	0,22 m	
1 W	1,17 m	0,35 m	0,70 m	
10 W	3,69 m	1,11 m	2,21 m	
100 W	11,67 m	3,50 m	7,00 m	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using 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.

#### NOTES:

- At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

#### Guidance and Manufacturer's Declaration— Electromagnetic Immunity to Wireless Communications Equipment

The Vest<sup>®</sup> Airway Clearance System, Model 205 is intended for use in the electromagnetic environment specified below. The customer or user of the Model 205 should make sure it is used in such an environment.

Sides Tested	Frequency (MHz) Test Severity Level		Test Distance (m)
Front, back, left, right	385	27V/m, 50% PM 18Hz	0.3
Front, back, left, right	450	28V/m, FM ± 5kHz,1kHz	0.3
Front, back, left, right	710	9V/m, 50% PM 217Hz	0.3
Front, back, left, right	745	9V/m, 50% PM 217Hz	0.3
Front, back, left, right	780	9V/m, 50% PM 217Hz	0.3
Front, back, left, right	810	28V/m, 50% PM 18Hz	0.3
Front, back, left, right	870	28V/m, 50% PM 18Hz	0.3
Front, back, left, right	930	28V/m, 50% PM 18Hz	0.3
Front, back, left, right	1720	28V/m, 50% PM 217Hz	0.3
Front, back, left, right	1845	28V/m, 50% PM 217Hz	0.3
Front, back, left, right	1970	28V/m, 50% PM 217Hz	0.3
Front, back, left, right	2450	28V/m, 50% PM 217Hz	0.3
Front, back, left, right	5240	9V/m, 50% PM 217Hz	0.3
Front, back, left, right	5500	9V/m, 50% PM 217Hz	0.3
Front, back, left, right	5785	9V/m, 50% PM 217Hz	0.3

## FREQUENTLY ASKED QUESTIONS

- How does The Vest<sup>®</sup> Airway Clearance System effectively treat areas of the lungs?
  - The system is designed to oscillate the chest wall to create airflow by applying percussion to the lung area to treat the lobes of the lung.
- How long should each Airway Clearance Therapy treatment session last?
  - Commonly prescribed treatment session Time to be between 10 and 30 minutes. Prescribed treatment session times may be different. Refer to the physician's orders or facility protocol.
- 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?
  - Refer to the physician's order.
- Is postural drainage still necessary?
  - Refer to the physician's order.
- 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. Consult the prescribing physician if a treatment session is missed.
- Is there a best time to do a therapy with The Vest<sup>®</sup> Airway Clearance System?
  - Establish a schedule that is satisfactory for the patient and lets you do the therapy consistently.
- Do all patients receive the same benefits from The Vest<sup>®</sup> Airway Clearance System?
  - The overall benefit depends on many factors, which include the underlying disease, patient's age, and his or her present state of health.

