

ELECTROMED, INC.

Maker of the

SmartVest[®]
AIRWAY CLEARANCE SYSTEM



Model SV2100/SV2100-I
Instruction Manual

070098-S-010 Rev N

ENG 

H&R

Foreword

This Instruction Manual is designed to help you gain a thorough understanding of the proper use of the **SmartVest®** Airway Clearance System. It is strongly recommended that you read this Manual in its entirety before using the System. This Manual is not meant to replace your health care provider's instructions. Neither this Manual nor Electromed, Inc. provide medical advice in any capacity. Any medical concerns you may have should be addressed solely with your physician.

The System is intended for use only as prescribed by your physician. Although simple to use, it is recommended that young or compromised patients have a parent or caregiver present during System use.

Electromed, Inc. welcomes feedback on methods for improving the quality of our products and service. Whether this feedback is regarding information presented in this Manual, the operation of the System itself, or any other matter, we truly appreciate your input. If you would like to provide feedback, do not hesitate to contact us using one of the methods shown below. We thank you in advance for your assistance.

WARNING: NO MODIFICATION OR REPAIR OF THIS EQUIPMENT IS ALLOWED.

WITH THE EXCEPTION OF THE ROUTINE CARE AND CLEANING PROCEDURES DESCRIBED IN THIS MANUAL, THE SMARTVEST® AIRWAY CLEARANCE SYSTEM MUST BE RETURNED TO ELECTROMED, INC. AT THE ADDRESS BELOW FOR ANY REPAIR OR SERVICE. DO NOT ATTEMPT TO OPEN THE AIR PULSE GENERATOR. THIS WILL VOID THE WARRANTY.

ELECTROMED, INC.

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For immediate assistance, call the Patient Services Helpline at 888-966-2525.

What is High Frequency Chest Wall Oscillation (HFCWO)?	1
Safety	2
Warnings	2
Cautions	3
Equipment Classifications	4
Indications for Use	5
SmartVest® Airway Clearance System	5
SmartVest® Garments	6
Wearing the SmartVest® or SmartVest Wrap®	6
Fitting the SmartVest®	6
Fitting the SmartVest Wrap®	7
Fitting Accessories	8
Using a Vest Extender.....	8
Using a Foam Pad.....	8
Cleaning the Long-Term Use (LTU) SmartVest®	8
Removing the Inner Bladder.....	8
Reinserting the Inner Bladder	9
Cleaning the Long-Term Use (LTU) SmartVest Wrap®	9
Connecting Hose	10
SV2100 Air Pulse Generator	11
Power Cord	11
Control Panel Overview	12
Setting Treatment Protocols.....	13
Setting Manual Mode	13
Setting Program Mode	14
Starting the Treatment Protocol.....	16
Using Sleep Mode	16
Checking Hours of Operation.....	16
Routine Care of the Air Pulse Generator	17
Cleaning the Air Pulse Generator	17
Replacing a Filter	17
Replacing a Fuse	17

Wheeled Carrier and Accessory Bag	18
Institutional Products	19
Single Patient Use (SPU) <i>SmartVest</i> ®	19
Single Patient Use (SPU) <i>SmartVest Wrap</i> ®	19
SV2100-I and Mobile Pedestal.....	19
Single Patient Use (SPU) Connecting Hose	19
Troubleshooting	20
Specifications	22
Electromagnetic Compatibility	23
Prescription Record	26

What is High Frequency Chest Wall Oscillation (HFCWO)?




High Frequency Chest Wall Oscillation (HFCWO) has been an effective form of airway clearance therapy for more than 20 years. HFCWO, administered by the patented **SmartVest**®, creates a "squeeze and release" action around the chest and torso from 5-20 times per second. The **SmartVest**® inflates and delivers vigorous, yet comfortable, air pulses to the body through a single-hose powered by a programmable air pulse generator. The rapid squeeze and release action of an HFCWO treatment simulates repetitive "mini-coughs," which have been reported to effectively

- Shear mucus away from the walls of a lung's airways.¹
- Reduce the viscosity of the secretions.²
- Propel the mucus toward the larger airways where it can be expectorated or suctioned more easily.^{1,2}

1- Chang HK, Weber ME, King M. Mucus transport by high-frequency nonsymmetrical oscillatory airflow. *J Appl Physiol* 1988; 65(3): 1203-1209.

2- Majaesic C, Montgomery M, Jones R, King M. Reduction in sputum viscosity using high frequency chest compressions compared to conventional chest physiotherapy. *Pediatr Pulmonol* 1996; Suppl 13: A358.






Safety**Warnings**

	Attention! Read these Safety Instructions and the entire Instruction Manual before using this device.
	Consult instructions for use.
	Follow instructions for use.
	Dangerous voltage within the device may constitute a risk of electric shock.
	Always use the SmartVest® Airway Clearance System with the power cord supplied with the device plugged into a properly grounded 3-prong outlet.
	Do NOT eat or drink during a HFCWO treatment. If using a chronic enteral feeding tube, discontinue feeding a half hour prior to and a half hour after completing a HFCWO treatment.
	Do NOT use the SmartVest® Airway Clearance System with an extension cord.
	Do NOT use the SmartVest® Airway Clearance System near water, near any wet surface or in highly humid environment. If the system becomes wet, allow it to dry completely before plugging it in again.
	Cord and hose may pose a strangulation or entanglement hazard. Do NOT route components near neck or leave at-risk individuals unattended.
	Items applied to the SmartVest® Airway Clearance System may become choking hazards to unattended at-risk individuals if removed or dislodged.
	Do NOT apply items anywhere on the SmartVest® shell that would come in direct patient contact during use.
	Keep packaging materials away from babies and children. Do NOT use in cribs, beds, carriages, or playpens. The plastic materials may cling to nose and mouth and prevent breathing. Packaging materials is not a toy.
	No modification or repair of this equipment is allowed.

Cautions

Rx	Federal law restricts this device to sale by or on the order of a physician.
	Do NOT operate the SmartVest® Airway Clearance System on any soft surface such as a carpet or towel while in the horizontal (flat) position as the cooling fan may be blocked.
	Do NOT attempt to repair the system yourself. If you experience any problems, contact your Service Representative.
	Use only compatible SmartVest® Airway Clearance System components supplied by Electromed, Inc.
	Do NOT staple, sew, or apply any items to the SmartVest® shell that could penetrate the inner bladder.
	Do NOT apply adhesives, tapes, hot glue or hot irons to the SmartVest® shell while inner bladder is installed.
	Do NOT allow any foreign materials to enter the SmartVest® Airway Clearance System through openings in the device, hose, or garment.
	Moving air in the SmartVest® garment along with multiple layers of clothing may cause you to become warm during use. Use system in a cooled or ventilated room and wear a single layer of clothing underneath the SmartVest® garment.
	Do NOT share or allow a different patient to use your SmartVest® or SmartVest Wrap® garment. Doing so may lead to cross contamination of harmful microorganisms.
	Do NOT place generator in a position that limits access to the electrical inlet connection.

Equipment Classifications

	Medical equipment with respect to electrical shock, fire and mechanical hazards only in accordance with: IEC 60601-1 (2005); EN 60601-1 (2006); CAN/CSA-C22.2 No. 60601-1 (2008); ANSI/AAMI ES60601-1 (2005); IEC 60601-1 (1988); UL60601-1
	The SmartVest® Airway Clearance System meets class 1 protection against electrical shock.
	Type BF applied parts: SmartVest® and SmartVest Wrap® garment
	The SmartVest® Airway Clearance System is IPX0 classified - ordinary equipment against the ingress of water.
	The equipment is NOT suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. If potential electromagnetic conditions exist that cause interference or affect this device, you may have to reposition the device to avoid this condition.

Indications for Use

Electromed, Inc. has received clearance to market from the FDA for the following indications: "The Electromed, Inc. **SmartVest®** Airway Clearance System is designed to deliver High Frequency Chest Wall Oscillation (HFCWO) to promote airway clearance and improve bronchial drainage. The **SmartVest®** is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport."

Indications for use of the **SmartVest®** Airway Clearance System follow the published American Association Respiratory Care (AARC) Clinical Practice Guidelines for external manipulation of the thorax. Absolute contraindications identified by the AARC include: (1) head and neck injury, and (2) active hemorrhage with hemodynamic instability. For further information regarding indications, contraindications, etc., refer to AARC Clinical Practice Guideline: Postural Drainage Therapy. These guidelines can be found at <http://www.rcjournal.com/cpgs/pdtpcg.html>.

Additional information regarding the effectiveness of HFCWO treatment on patients with various conditions and diseases can be found at www.electromed.com/pc/indications_for_use.html.

SmartVest® Airway Clearance System

The **SmartVest®** Airway Clearance System consists of three primary components - a **SmartVest®** garment, the Connecting Hose, and the SV2100 Air Pulse Generator. In addition to these components, there are various other accessories designed to aid in the use of the **SmartVest®** System that are discussed in the following sections.



SmartVest® Garments

The **SmartVest®** delivers full coverage air pulses to the front, back, and sides of the torso. It is made of a soft, breathable fabric that minimizes perspiration and itching (refer to section on Cleaning the **SmartVest®**).

The **SmartVest®** is available in two styles – the **SmartVest®** and the **SmartVest Wrap®**.

- The **SmartVest®** has the appearance of a vest. It is constructed of an inner bladder with a soft, breathable fabric shell and Velcro®¹-type closures.
- The **SmartVest Wrap®**, designed for ease of application, is intended for patients finding it difficult to fit or apply the standard **SmartVest®**. The **SmartVest Wrap®** is reversible, allowing the hose to connect to either the right or left side.

SmartVest®
AIRWAY CLEARANCE SYSTEM



SmartVest Wrap®
AIRWAY CLEARANCE SYSTEM



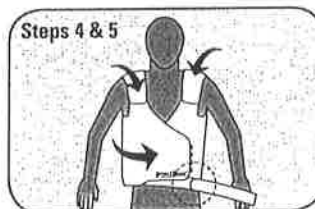
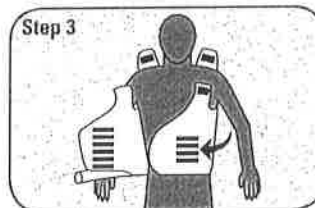
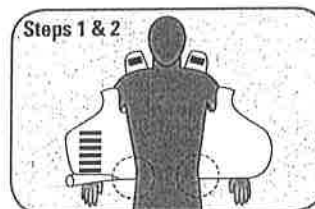
Wearing the **SmartVest®** or **SmartVest Wrap®**

For a proper fit, make sure you wear a single layer of clothing underneath the **SmartVest®** or the **SmartVest Wrap®**.

Fitting the **SmartVest®**

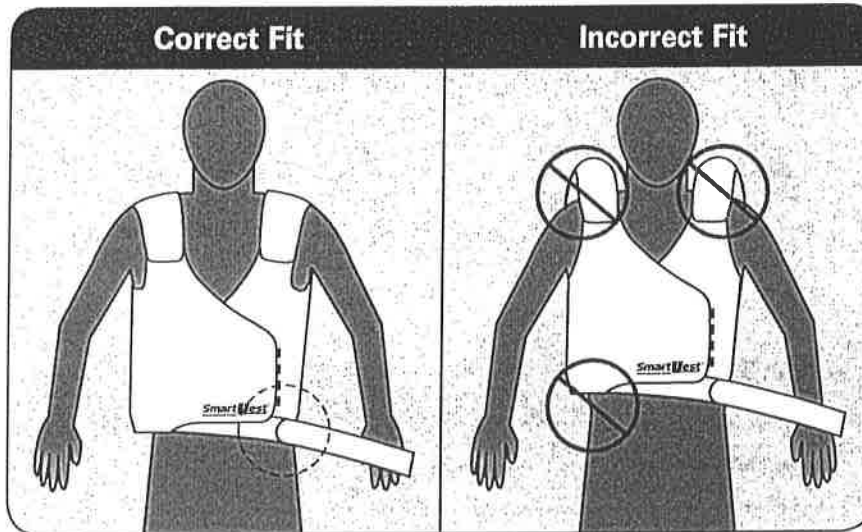
Steps:

1. Put on the **SmartVest®** (without securing any of the closures).
2. Position the bottom of the **SmartVest®** at or slightly below your waist.
3. Secure the front closure. Make sure the **SmartVest®** fits snugly around your chest.
4. Adjust the shoulder closures.
5. Attach the hose to the **SmartVest®** (refer to the section on Connecting Hose).



¹Velcro® is a registered trademark of Velcro Industries B.V.

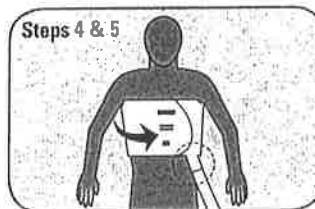
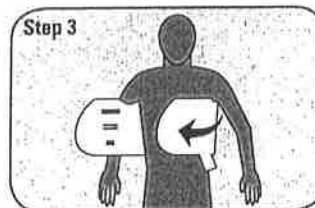
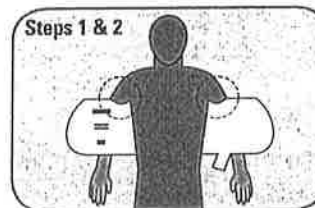
NOTE: If the front closure opens during treatment, it can be secured by opening the small strap on the left side of the *SmartVest*, lacing it through the D ring, and securing it with the Velcro-type closure.



Fitting the *SmartVest Wrap*®

Steps:

1. Position the *SmartVest Wrap*® around your back (similar to a towel after a bath).
2. Position the arm cutouts beneath underarms.
3. Place the unprinted side of the *SmartVest Wrap*® across chest.
4. Layer the printed side of the *SmartVest Wrap*® over the unprinted side using the Velcro-type closure.
NOTE: The garment should fit "snugly" but not tightly.
5. Attach the hose to the *SmartVest Wrap*® (refer to the section on Connecting Hose).



Fitting Accessories

Using the SmartVest® Extender

An extender is available for those using an adult size **SmartVest®** and requiring additional chest circumference but not additional height. This accessory provides up to an additional 14 inches of chest coverage.

Using a Foam Pad

If you are experiencing tenderness from a new G-tube or central catheter, your Service Representative can provide you with a foam pad to help protect the area and make your treatment more comfortable.

Cleaning the Long-Term Use (LTU) SmartVest®

The LTU **SmartVest®** is made up of the inner bladder and the outer shell. Special care must be taken to ensure proper function and maintain its appearance.

- Always remove the **inner bladder** before attempting any vest cleaning methods. The inner bladder may be wiped off with a damp cloth. **Do not machine wash or dry clean the inner bladder.**
- The **outer shell** may be wiped off with a damp cloth, machine washed, or dry cleaned. Once the bladder is removed, fully secure all Velcro-type closures. Wash the shell by itself in a washing machine. Use the gentle cycle with cool water (<100 degrees F, <38 degrees C) and mild soap such as Ivory Snow®, Dreft®, or Woolite®. Hang dry. **Do not machine dry.** Do not use the shell before it is completely dry. The shell can also be spot cleaned with a stain stick.

Removing the Inner Bladder

Steps:

1. Lay the **SmartVest®** on a flat surface.
2. Open the **SmartVest®** completely.
3. Unzip the zipper.
4. Reaching inside the shell, release the five Velcro-type strips that hold the bladder in position.
5. Remove the bladder from the shell.

CAUTION: Take care not to puncture or cut the bladder material with any sharp objects.

Reinserting the Inner Bladder

NOTE: Prior to inserting the bladder, make sure the outer shell is completely dry.

Steps:

1. Lay the outer shell on a flat surface.
2. Open the outer shell completely.
3. If the zipper is not already unzipped from removing the bladder, do so now.
4. Slide the bladder up into the outer shell.
5. Tuck the four shoulder straps of the bladder into the Velcro-type attachment points, working the ends into the corresponding pockets.
6. Attach the fifth strip near the air hose connector.
7. Check the bladder position and readjust the Velcro-type attachments where necessary.
8. Close the zipper.

Cleaning the Long-Term Use (LTU) SmartVest Wrap®

Use the following care when laundering this garment.

- **Do not machine wash.** Spot clean only with a damp cloth and/or stain stick.
- Hang dry.
- **Do not machine dry.**
- **Do not iron.**

Connecting Hose

The single-hose transmits air pulses from the air pulse generator to the **SmartVest**®. The hose connection point is the same on both ends. Therefore, whether connecting to the generator or the **SmartVest**® garment, the insertion steps are the same.

Steps:

1. With one hand supporting either the generator or the **SmartVest**® garment connection point, use the other hand to insert the hose connector.
2. Give a slight twist.

NOTE: It is not necessary for all three o-rings on the connector to be fully inserted for a proper seal.





SV2100 Air Pulse Generator

The air pulse generator creates air pulses that are transmitted to the chest via the connecting hose and vest. Its Soft Start® technology reduces “squeeze effect” and “vest creep” on start-up.

CAUTION: Do not start the generator until the hose and *SmartVest®* or *SmartVest Wrap®* are attached to the air pulse generator, as this may cause damage to the unit.

The generator is designed to operate in either the upright or horizontal position. Anytime the generator is stopped or paused and the orientation of the device changes, the display will automatically appear in the proper position.

Power Cord

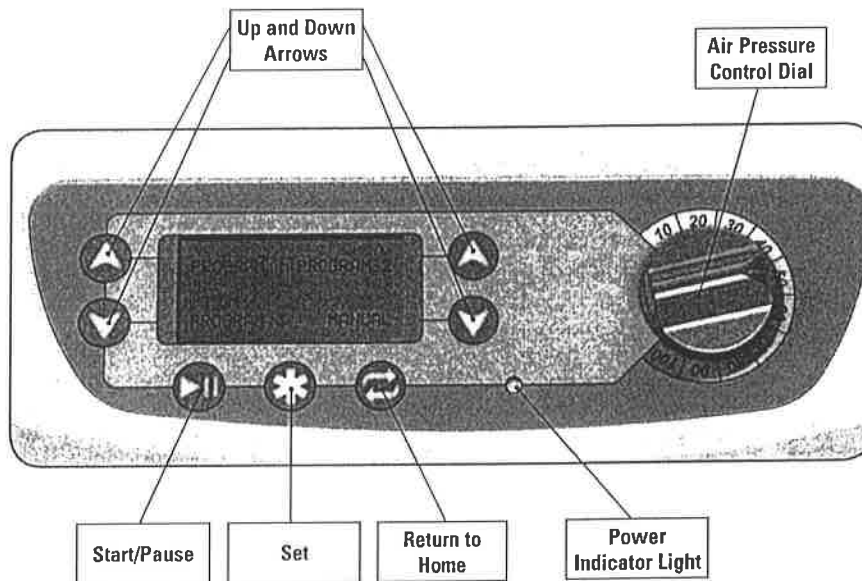
A grounded 3-prong power cord is supplied with the device and must be connected to a properly grounded electrical outlet. Once the power cord is connected to the generator and outlet, the generator will automatically power up. This automatic feature replaces the need for an on/off switch (refer to the section on Using Sleep Mode).

NOTE: International cords are available by contacting your Service Representative.

NOTE: Even when the power cord is removed, such as during transport, all programmed treatment protocols are retained (refer to the section on Setting Program Mode).

Control Panel Overview

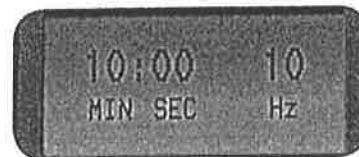
All treatment sessions begin from the Home screen of the **SmartVest®** Air Pulse Generator. The elements of the generator controls are described below.



- **Up and Down Arrows:** Press these buttons to select either Manual or Program mode or to increase or decrease a time or frequency.
- **Start/Pause:** Press this button to start, stop, or resume a treatment protocol.
- **Set:** Press this button to store the displayed values.
- **Return to Home:** Press this button to return to the main screen.
- **Power Indicator Light:** This light will be visible when the generator is plugged in and receiving power.
- **Air Pressure Control Dial:** Adjust this dial to set the amount of “hug” felt from the **SmartVest®** during treatment.

In addition, there are a few abbreviations used to identify the time and pulse frequency.

- **MIN:** Minutes
- **SEC:** Seconds
- **Hz:** Pulses per second



Setting Treatment Protocols

The **SmartVest®** System has two operating modes, Manual and Program.

- In **Manual** mode you set the prescribed protocol each time you perform a treatment.
- In **Program** mode you can set and save three separate prescribed protocols (PROGRAM 1, PROGRAM 2, and PROGRAM 3). This allows multiple users to save individual prescriptions or one user to set three different treatment protocols.





Setting Manual Mode

Steps:

1. From the Home screen, press  next to the word **MANUAL**.



2. Set the following items.

- Set the **Time** by pressing  and  buttons to the left of the screen.
NOTE: The time setting can only be changed when unit is not pulsing.
- Set the **Frequency** by pressing  and  buttons to the right of the screen.
NOTE: Frequency settings can be changed at any time in Manual mode. This allows the patient to vary the frequency during a treatment session.



Press  to store the displayed values as the new default values (refer to the section on Starting the Treatment Protocol).

Setting Program Mode**Steps:**

1. From the Home screen, press either ▲ or ▼ next to PROGRAM 1, PROGRAM 2, or PROGRAM 3.

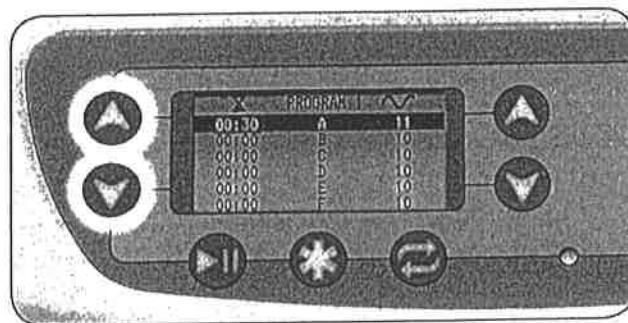


2. From the selected **PROGRAM** mode screen, press ★ to select the first interval of the treatment protocol.



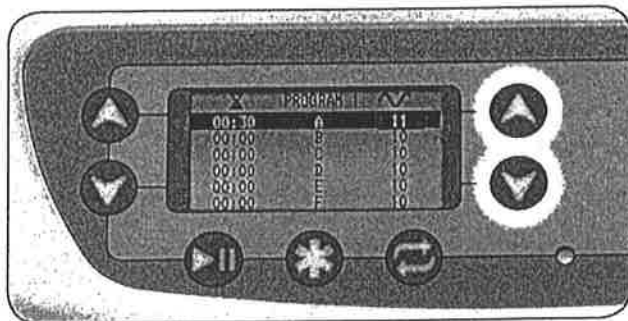
3. With line A highlighted, use ▲ or ▼ to the left of the display screen to set the required **Time**.

NOTE: Time is adjustable in 30 second increments up to 30 minutes.

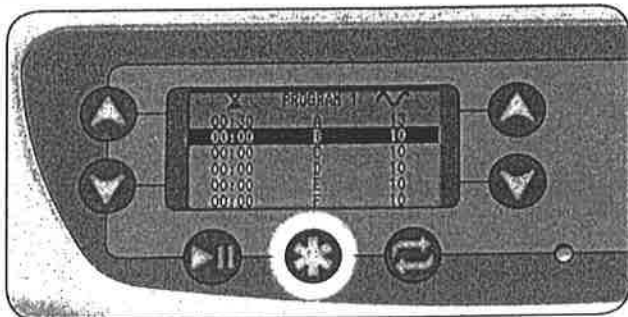


4. Continuing with line A highlighted, use ▲ or ▼ to the right of the display screen to set the required **Frequency**.

NOTE: Frequency is adjustable in 1 Hz increments from 5 to 20 Hz.



5. Press * to save the setting and advance to the next line.



6. Repeat this process for lines B-F or for as many intervals as are required (up to a maximum of 6) by your prescribed treatment protocol.






NOTE: Any line left as 0:00 will be skipped during treatment.

This same procedure can now be repeated to set additional PROGRAM modes (PROGRAM 1, PROGRAM 2, or PROGRAM 3).

Starting the Treatment Protocol

Select the desired treatment protocol from the Home screen and follow the steps below.



Steps:

1. Press  to begin your treatment interval.
 - To **pause** your treatment, press  again. The remaining time will be displayed.
 - To **resume** treatment, press  again.
2. When the treatment interval is complete,
 - The timer will show 0:00.
 - The air pulses will stop.
 - The unit will beep twice.
3. **IMPORTANT: Huff, cough, or suction to clear secretions.** 
4. Repeat steps 1-3 until all intervals of prescribed treatment are complete.
5. Press  at any time to return to the Home screen.

Using Sleep Mode

In order to conserve energy, the *SmartVest*® Airway Clearance System will automatically enter sleep mode after 15 minutes of inactivity. While in sleep mode the display and fan will be off, but the power indicator light will remain lit.


To manually place the system into sleep mode,

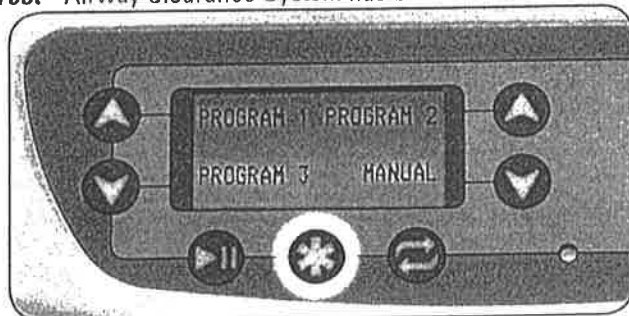
- From the Home screen, press and hold both  and  at the same time. The buttons on either side of the display may be used.

To awaken the system from sleep mode,

- Press any button on the control panel.

Checking Hours of Operation

Press and hold  while at the Home screen to check the total number of hours the *SmartVest*® Airway Clearance System has been used.



Routine Care of the Air Pulse Generator

Cleaning the Air Pulse Generator

WARNING: Always remove the power cord before cleaning or servicing the air pulse generator.

The exterior of the air pulse generator and connecting hose may be cleaned with a damp cloth and a mild household disinfectant. Any cleaning liquids should first be sprayed on a cloth and then used. Avoid getting water or cleaning liquid inside the air pulse generator.

Replacing a Filter

Routine preventive maintenance requires the air input filter to be replaced every six months or every 200 hours, whichever occurs first. No tools are required to perform this task. If you need additional filters, contact your Service Representative.

Steps:

1. Remove the filter access door on the bottom of the generator. To do this,
 - a. Press the release tab.
 - b. Pull up on the access door.

2. Remove and discard the old filter.

NOTE: The old filter may not look much different than the new filter. Therefore, it is important to discard the filter immediately to avoid confusion.

3. Install the new filter. **Do not operate the device without a filter in place.**
4. Replace the access door.



Replacing a Fuse

Steps:

1. **WARNING: First unplug the power cord from the generator.**
2. Remove the fuse holder located at the power inlet.
3. Remove both fuses.

NOTE: Bad fuses appear identical to good fuses. Therefore, it is important to discard the old fuses immediately to avoid confusion.

4. Replace the original fuses provided with the generator with the new fuses.



Wheeled Carrier and Accessory Bag

The wheeled carrier and accessory bag make transporting your **SmartVest®** Airway Clearance System easier. The wheeled carrier case is durable and the generator easily slides in and out, while the telescoping handle adjusts to your height needs.

The customized accessory bag has specific compartments for your **SmartVest®**, hose, power cord, filter and fuse kits, and training materials. The back of the accessory bag has a convenient slot where the handle of the carrier fits through. This feature allows the accessory bag to sit snugly on top of the generator bag and against the telescoping handle as you wheel the carrier, resulting in a single wheeled component.

CAUTION: The wheeled carrier is designed to carry only the weight of the **SmartVest®** Airway Clearance System components. Do not place additional equipment or luggage on the carrier.

CAUTION: Remove the generator from the carrier prior to use.



Institutional Products

The following items are intended to be used only in hospitals and other institutional settings.

Single Patient Use (SPU) SmartVest®

The SPU **SmartVest®** is intended for use by a single patient during a hospital or clinic stay. The SPU **SmartVest®** should not be used for multiple patients. It is **not** designed to be cleaned and should be disposed of after it becomes soiled, the patient is discharged, or it is no longer needed, whichever comes first.

Single Patient Use (SPU) SmartVest Wrap®

The SPU **SmartVest Wrap®** is intended for use by a single patient during a hospital stay. It is **not** designed to be cleaned and should be disposed of after it becomes soiled, the patient is discharged, or it is no longer needed, whichever comes first.

SV2100-I and Mobile Pedestal

The **SmartVest®** Model SV2100-I Air Pulse Generator is available for institutions requiring easy mobility of the **SmartVest®** Airway Clearance System. This model is specifically designed to mount to a Mobile Pedestal, which features

- Rugged attachment of the air pulse generator.
- Stable 5 caster-base with 2 locking casters.
- Foot-operated lever for height adjustment.

To properly utilize the Mobile Pedestal,

- Press down on foot release ring to raise pedestal height.
- Press down on foot release ring and side handles simultaneously to lower pedestal height.
- Adjust height to the “down” position while transporting between rooms.
- Set brakes by twisting axle levers on casters.



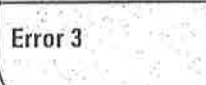


Single Patient Use (SPU) Connecting Hose


The SPU Connecting Hose is intended for use by a single patient during a hospital stay. As a complement to the Single Patient Use garments, it is intended to be replaced as needed or disposed of after the patient is discharged.

Troubleshooting

In response to various environmental conditions, the generator screen will display an error message. Understanding these messages will help you quickly troubleshoot the problem. If the suggested actions below do not resolve the situation, contact your Service Representative.

Display shows...	Problem is...	Take this action...
	The motor temperature is above the maximum acceptable limit. The unit will NOT start in this state, as damage may occur.	<p>If the system is sitting in a warm location, move it to a cooler location and try again later.</p> <p>If this does not resolve the issue, contact your Service Representative.</p>
	The motor temperature is below 50 degrees Fahrenheit (10 degrees Celsius) and needs to warm up.	<p>Leave the unit plugged in and turned on so the fan can assist in warming up the unit. With the unit power on, the device will periodically check the motor temperature and after warming up, it will automatically proceed to the Home screen.</p> <p>If this does not resolve the issue, contact your Service Representative.</p>
	Motor rotation has not been detected.	Contact your Service Representative.

At times you may experience additional issues. If the suggested actions below do not resolve the issue, contact your Service Representative.


Problem is...	Take this action...
There is no power to the air pulse generator, or the vest does not pulse.	<p>Confirm whether the device is in Sleep mode. Is the Power Indicator Light illuminated?</p> <ul style="list-style-type: none"> • If Yes, press any button to awaken the device (refer to the section on Using Sleep Mode). • If No, confirm or take action in the following order. <ul style="list-style-type: none"> ✓ The power cord is firmly connected to the generator. ✓ The power cord is firmly connected to the wall outlet. ✓ The wall outlet has power. ✓ Replace the fuses (refer to the section on Replacing a Fuse).
The garment does not fully inflate.	<p>Confirm or take action in the following order.</p> <ul style="list-style-type: none"> ✓ The hose is firmly attached to the couplings and the air pulse generator. ✓ The connecting hose is free of leaks. ✓ SmartVest® inner bladder is free of tears. ✓ The inner bladder of the SmartVest® is attached smoothly inside the outer shell. The Velcro-type closures are lying flat and are free from buckling. ✓ Replace the air input filter (refer to the section on Replacing a Filter).
It is difficult to breathe during treatment.	<p>The garment will slightly compress the chest during treatment. Reduce pressure with the Pressure dial until you are comfortable with the sensation. Soon you will become used to the feeling and will be able to increase the pressure. You may also need to reduce the pressure when you are ill.</p>
The data on the display does not appear to be in the correct position.	<p>In rare cases static discharge may cause the display to become irregular. To reset the display press .</p>
The vest no longer fits.	<p>Contact your Service Representative for a replacement.</p>

Specifications

Operational Parameters	<ul style="list-style-type: none"> • Time: 0 – 30 minutes ± 2% • Frequency: 5 – 20 Hz ± 1 Hz
Air Pulse Generator	<ul style="list-style-type: none"> • Weight: 23 lbs (10.5 kg) • Dimensions: 15 3/4" x 15" x 7 1/4" (40 x 38 x 18.5 cm)
Vest(s)	Available in eight sizes for long-term and single patient use.
Wrap(s)	Available in six sizes for long-term and single patient use.
Electrical	<ul style="list-style-type: none"> • 100 – 240 V~, 50/60 Hz • 3.3 Amps at 100 V~ • 1.6 Amps at 240 V~ • Fuses: Two (2) 5mm x 20mm 5 Amp 250VAC Fast-Acting, 1500 Amp Breaking Capacity
Operation Conditions	<ul style="list-style-type: none"> • 50°F – 84°F (10°C – 29°C) • 15% – 93% relative humidity, non-condensing • 70 kPa to 106 kPa
Transport and Storage Conditions	<ul style="list-style-type: none"> • -4°F – 140°F (-20°C – 60°C) • 5% – 95% relative humidity, non-condensing • 50 kPa to 106 kPa

Electromagnetic Compatibility

Guidance and Manufacturer's Declarations – Electromagnetic Immunity			
The SmartVest® Airway Clearance System Model SV2100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model SV2100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines N/A for input/output lines	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) ± 2 kV line(s) to earth	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	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model SV2100 requires continued operation during power mains interruptions, it is recommended that the Model SV2100 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declarations – Electromagnetic Immunity			
The SmartVest® Airway Clearance System Model SV2100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Model SV2100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Model SV2100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,17 \sqrt{P}$</p> <p>$d = 1,17 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,33 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol. </p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model SV2100 is used exceeds the applicable RF compliance level above, the Model SV2100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model SV2100.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended separation distances between portable
and mobile RF communications equipment and the
SmartVest® Airway Clearance System, Model SV2100**

The **SmartVest®** Airway Clearance System Model SV2100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model SV2100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model SV2100 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,17 \sqrt{P}$	80 MHz to 800 MHz $d = 1,17 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,33 \sqrt{P}$
	0,01	0,12	0,12
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,70	11,70	23,30

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.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Prescription Record Rx

SmartVest® Airway Clearance System Model SV2100/SV2100-I

Serial # _____

Prescribed Protocols

User One _____ **User Two** _____ **User Three** _____

Date _____ Date _____ Date _____

_____ times/day _____ times/day _____ times/day

_____ minutes/treatment _____ minutes/treatment _____ minutes/treatment

_____ pressure setting _____ pressure setting _____ pressure setting

Frequency	Duration	Frequency	Duration	Frequency	Duration
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Aerosols _____ Aerosols _____ Aerosols _____

NOTE: Do not change your protocol without first consulting your health care provider.

HER



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