

smartvest[®]

AIRWAY CLEARANCE SYSTEM



SQL Instruction Manual

090491-S-010 Rev E ENG

Making life's important moments possible — one breath at a time.®

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AIRWAY CLEARANCE SYSTEM

BY ELECTROMED, INC.

**Please contact Electromed at: (888) 966-2525 or your
service representative with questions about the
SmartVest[®] Airway Clearance System**

SQL Instruction Manual

090491-S-010 Rev E ENG

Foreword

This manual will help you use the SmartVest SQL Airway Clearance System. It is 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. Ask your doctor about any medical concerns you may have as some pre-existing conditions may become aggravated when using HFCWO therapy.

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 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 SmartVest System, or any other matter, we appreciate your input. If you would like to provide feedback, contact Electromed or your service provider.

WARNING:

NO REPAIR OF THIS SYSTEM IS ALLOWED. WHEN REPAIR IS NEEDED, IT MUST BE RETURNED TO ELECTROMED. DO NOT ATTEMPT TO OPEN THE GENERATOR. THIS ACTION WILL VOID THE WARRANTY.

THE ROUTINE CARE AND CLEANING DESCRIBED IN THIS MANUAL IS ALLOWED.

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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.










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 SQL Airway Clearance System with the power cord supplied.
	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 HFCWO treatment.
	Do NOT use the SmartVest SQL 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 SQL 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.
  	<p>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.</p>
	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 SQL 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 Electromed at (888) 966-2525 or your service representative.
	To report unexpected operation or events, contact Electromed at (888) 966-2525 or your service representative.
	Use only compatible SmartVest SQL Airway Clearance System components supplied by Electromed.
	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 SQL 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

	<p>Medical equipment with respect to electrical shock, fire and mechanical hazards only in accordance with: IEC 60601-1 (2005); ANSI/AAMI ES60601-1 (2005), CAN/CSA-C22.2 No. 60601-1 (2008).</p>
	<p>The SmartVest SQL Airway Clearance System meets class II (double insulation) protection against electrical shock.</p>
	<p>Type BF applied parts: SmartVest and SmartVest Wrap garment(s).</p>
	<p>The SmartVest SQL Airway Clearance System is IP20 classified. Protected against solid foreign objects of 1/2" (12.5 mm) and greater; Not protected against water ingress.</p>
	<p>Do NOT spray.</p>
	<p>The equipment is NOT suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide.</p>
	<p>Waste Electrical & Electronic Equipment (WEEE). Contact Electromed or your service representative for information on recycling the SQL.</p>
	<p>Contains FCC ID 2AA9B04 for 2402 MHz to 2480 MHz and FCC ID QIPELS31-V for 779.5 MHz to 784.5 MHz and 1712.5 MHz to 1752.5 MHz.</p>

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** SQL 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** SQL Airway Clearance System follow the published American Association Respiratory Care (AARC) Clinical Practice Guidelines for Postural Drainage Therapy. For further information regarding indications, contraindications, etc., refer to these Guidelines at:

<http://www.rcjournal.com/cpgs/pdtpcg.html>

Contraindications for Use

Absolute contraindications identified by the 1991 AARC Guidelines for external manipulation of the thorax such as HFCWO include: (1) head and neck injury until stabilized, and (2) active hemorrhage with hemodynamic instability.

The AARC has also identified relative contraindications which require an individualized clinical assessment and careful consideration by the physician prior to prescription including: hemoptysis; subcutaneous emphysema; recent epidural spinal infusion or spinal anesthesia; recent skin grafts on the thorax; burns, open wounds, and skin infections of the thorax; recently placed transvenous pacemaker or subcutaneous pacemaker; suspected pulmonary tuberculosis; lung contusion; bronchospasm; osteomyelitis of the ribs; osteoporosis; coagulopathy and complaint of chest-wall pain.

Additional information regarding the effectiveness of HFCWO treatment on patients with various conditions and diseases can be found at www.smartvest.com.

SmartVest SQL Airway Clearance System

The **SmartVest** SQL Airway Clearance System consists of three primary components - a **SmartVest** garment, the Connecting Hose, and the SQL Air Pulse Generator. In addition, there are 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. 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** 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.



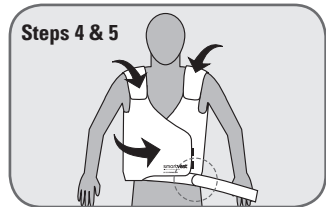
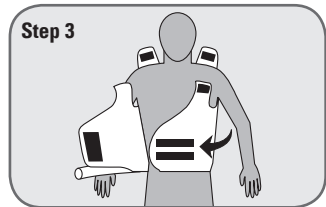
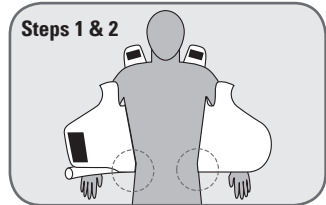
Wearing the SmartVest or SmartVest Wrap

For a proper fit, the patient should wear a single layer of clothing underneath the **SmartVest** or the **SmartVest Wrap**.

Fitting the SmartVest

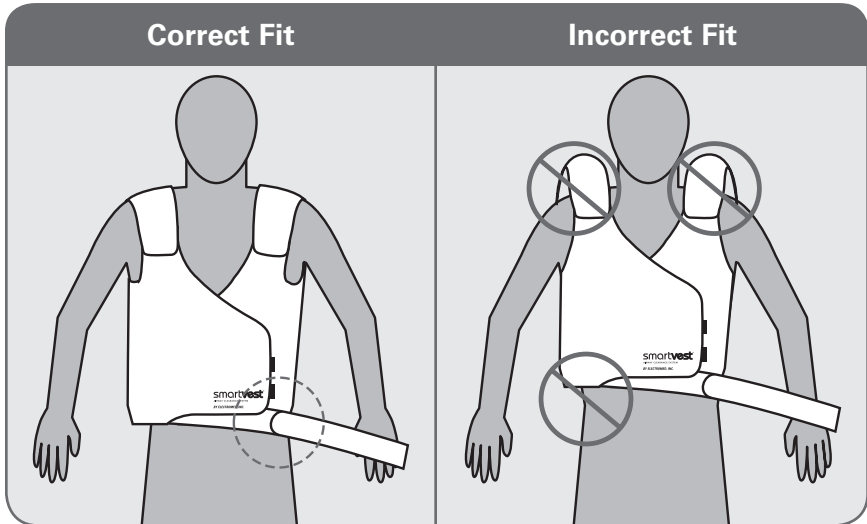
Steps:

1. Put on the **SmartVest** (without securing any of the closures).
2. Position the bottom of the **SmartVest** at or slightly below the patient's waist.
3. Secure the front closure. Make sure the **SmartVest** fits snugly around the patient's 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.



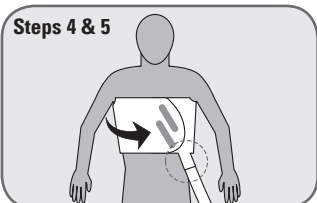
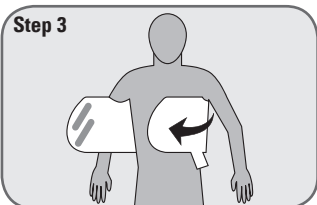
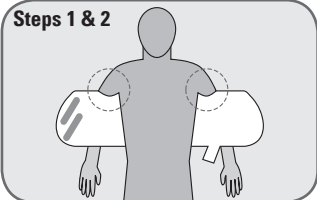
Fitting the **SmartVest Wrap**

Steps:

1. Position the **SmartVest Wrap** around the patient's back.
2. Position the arm cutouts beneath underarms.
3. Place the connector-side of the **SmartVest Wrap** across chest.
4. Layer the other side of the **SmartVest Wrap** over the connector-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 (36 cm) of chest coverage.

Using a Foam Pad

If the patient is experiencing tenderness from a new G-tube or central catheter, Electromed can provide a foam pad to help protect the area and make the patient's 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 cleaning the vest. 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 detergent. 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.**

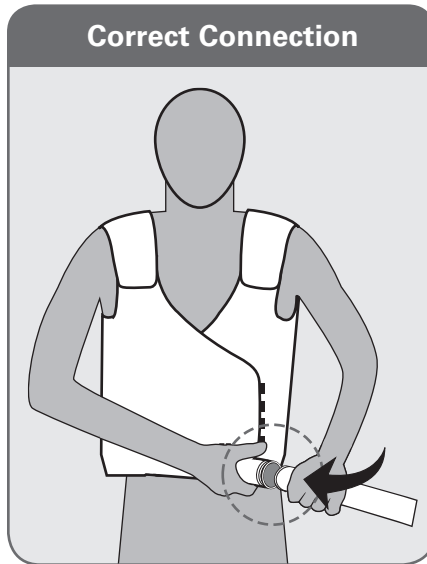
Connecting Hose

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

Steps:

1. With one hand supporting either the generator or the 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.





SQL Air Pulse Generator

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

CAUTION: Do not start the generator until the hose and *SmartVest* garment 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.

Powering the Generator

There are three elements that effect the power to the generator: the power cord, the on/off switch, and the sleep mode.

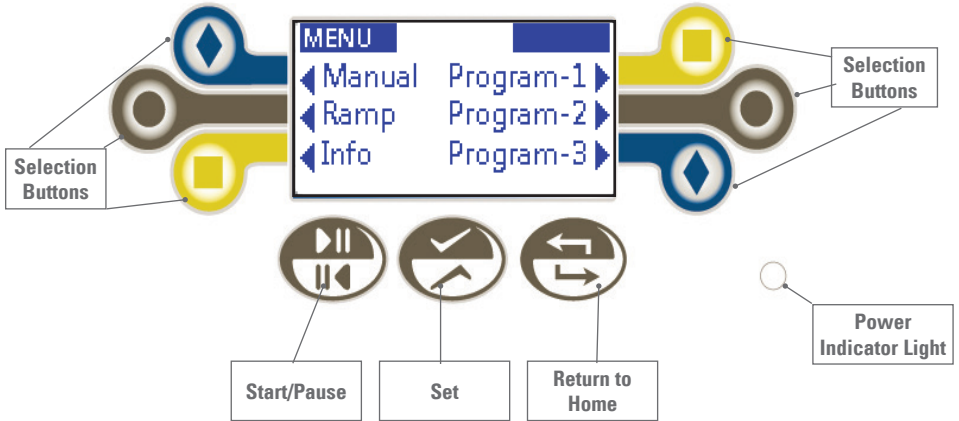
- **Power Cord** - Connect the supplied power cord to an electrical outlet to power the generator. The system will not function, however, until the on/off switch is turned to on.
- **On/Off Switch** - Use the power switch to turn the generator on or off.
- **Sleep Mode** - To conserve energy, the system enters sleep mode automatically after 15 minutes of inactivity. The display and fan are off during this time, but the light remains lit. To awaken the system from sleep mode, press any button on the control panel.

NOTE: Contact Electromed or your service representative for an international power cord.

NOTE: All treatment protocols are retained when the power cord is removed or the power switch is shut off.

Display and Control Panel Overview

All treatment sessions begin from the Home display of the generator. From Home, you can select an operating mode (Manual, Program (1-3), or Ramp) or learn about System information (Info).



Display and Control Panel Elements:

• **Selection buttons:** Press these buttons to select an operating mode (manual, program, or ramp), increase or decrease a setting, or to choose a yes/no option.

Note: The ◀ ▶ are only visible if the button next to it can be selected.



- **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 is visible when the generator is powered on.

In addition, there are a few abbreviations and symbols used to identify elements of the setting:

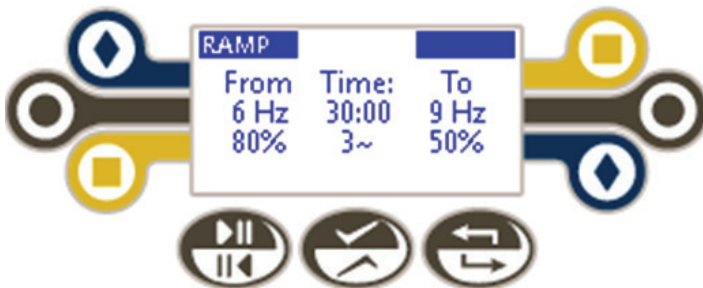
- **MIN:** Minutes
- **SEC:** Seconds
- **Hz:** Pulses per second
- **%:** Percent of pressure
- **~:** Intervals per treatment

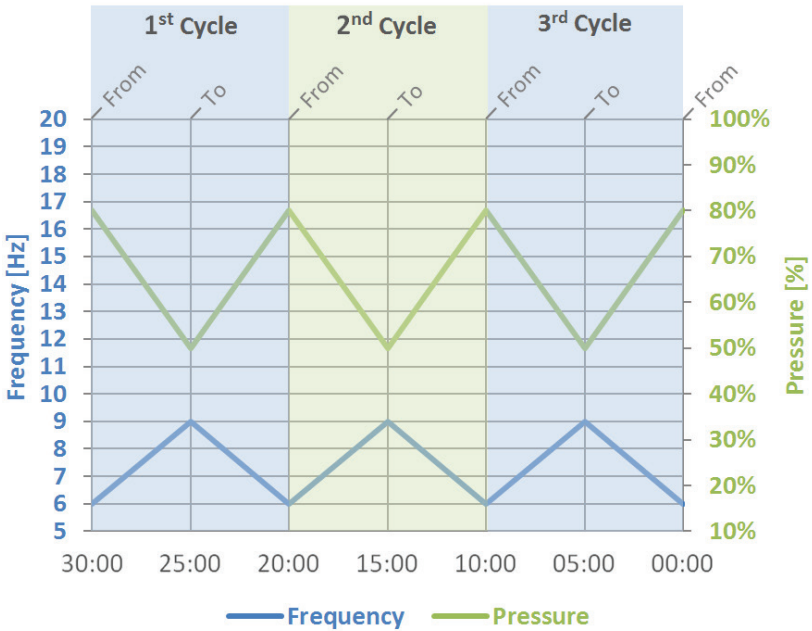
RAMP	Time:	
From	30:00	To
6 Hz	Cycles:	12 Hz
80%	5~	50%

Setting Treatment Protocols

The **SmartVest** System has three operating modes: Manual, Program (1-3) and Ramp.

- In **Manual** mode you set one prescribed protocol with one interval that you can repeat or adjust 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). Each program can have multiple intervals (A-F) with a unique frequency, pressure, and time setting. This allows multiple users to save individual prescriptions or one user to set three different treatment protocols.
- In **Ramp** mode you set a start ("From") and end ("To") frequency and pressure to be run for a select treatment length and divided by the number of chosen intervals. In the example shown, the treatment length is 30 minutes. During this 30 minutes the System automatically adjusts in small increments between the From and To and back again- 3 times. There is no need to program the frequency and pressure manually for each interval, as you do the other operating modes.

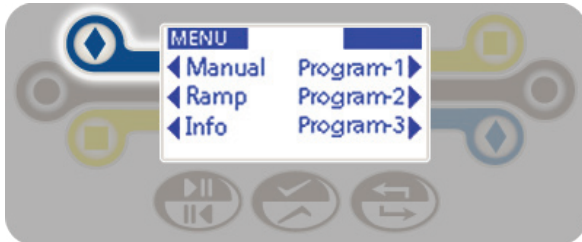









Setting Manual Mode

Steps:

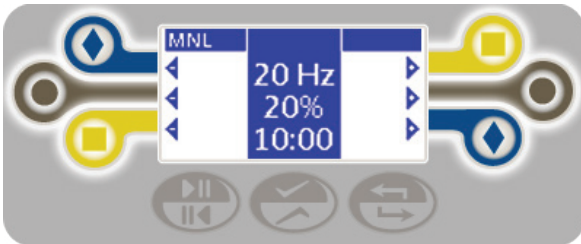
1. From the Home screen, press  to select the Manual mode.




2. To adjust the following settings:

- **Frequency** - Press  or  to the left or right of the frequency display. Adjust in 1 Hz increments from 5 to 20 Hz.
- **Pressure** - Press  to the left or right of the pressure display. Adjust in increments of 5% from 10%-100%.
- **Time** - Press  or  to the left or right of the time display. Adjust in 30 second increments from :30 - 60:00 minutes.




NOTE: Frequency and pressure can be changed at any time during a Manual session. Time can only be changed when the unit is not pulsing.

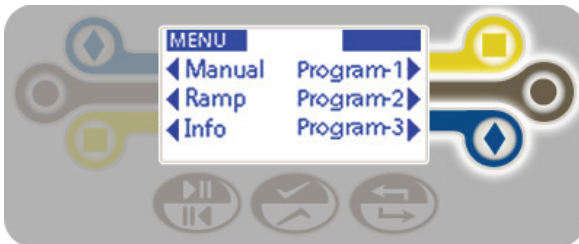


4. Press  to save the displayed values as the new default values (see Starting the Treatment Protocol).

Setting Program Mode






Steps:

1. From the Home screen, press  Program-1,  Program-2, or  Program-3 to select that mode.

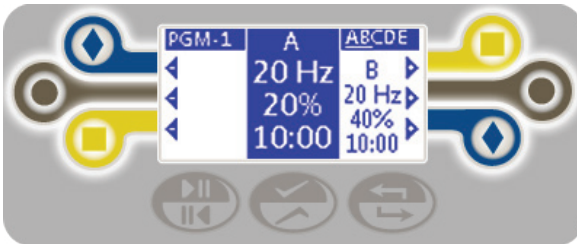



2. From the selected Program mode (PGM-1, PGM-2, PGM-3) screen, press  to select the first column of the treatment protocol.

3. To adjust the following settings:

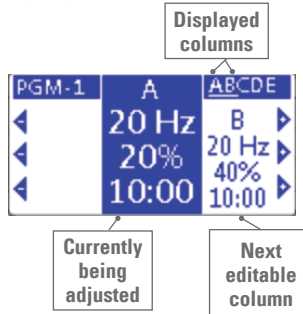
- **Frequency** - Press  or  to the left or right of the frequency display. Adjust in 1 Hz increments from 5 to 20 Hz.
- **Pressure** - Press  to the left or right of the pressure display. Adjust in increments of 5% from 10%-100%.
- **Time** - Press  or  to the left or right of the time display. Adjust in 30 second increments from :30 - 60:00 minutes.

NOTE: Frequency, pressure, and time cannot be changed during a Program session.




4. Press  to save the settings for this interval and move to the next column.

Note: The currently displayed columns are underlined in the top-right corner of the screen. Only three of the 6 (A-F) programmable columns can be shown at a time. The blue column is being adjusted. The column to the right is next.



5. Repeat this process for columns B-F or for as many intervals, as needed.

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

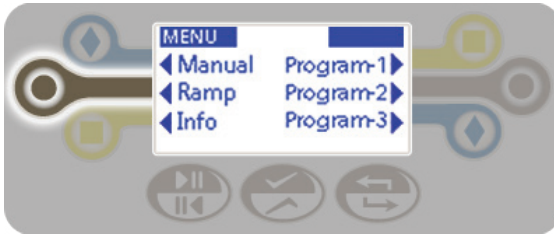
6. Press  to save the displayed values as the new default values (see Starting the Treatment Protocol).

Repeat this same process to set additional Program modes, as needed.

Setting Ramp Mode





Steps:

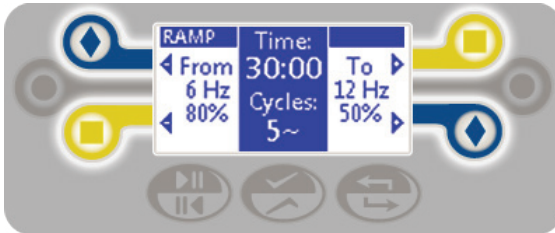
1. From the Home screen, press  to select the Ramp mode.



2. Press  to select the treatment sequence column.

3. To adjust the following settings:

- **Time** - Press  or  to the left or right of the time display. Adjust in 30 second increments from :30 - 60:00 minutes.
- **Cycles** - Press  or  to the left or right of the cycles display.







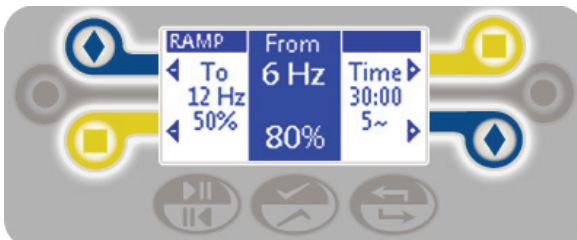
NOTE: Frequency, pressure, and time cannot be changed during treatment.

4. Press  to save the settings and move to the From: column.







5. To adjust the From settings:

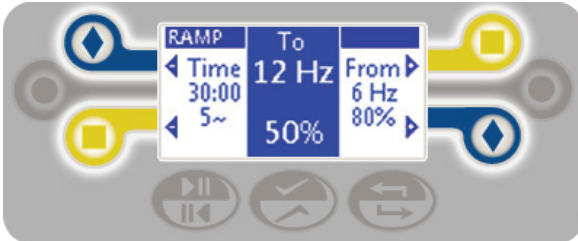
- **Frequency** - Press  or  to the left or right of the frequency display. Adjust in 1 Hz increments from 5 to 20 Hz.
- **Pressure** - Press  or  to the left or right of the pressure display. Adjust in increments of 5% from 10%-100%.




6. Press  to save the settings and move to the To: column.

7. To adjust the To settings:

- **Frequency** - Press  or  to the left or right of the frequency display. Adjust in 1 Hz increments from 5 to 20 Hz.
- **Pressure** - Press  or  to the left or right of the pressure display. Adjust in increments of 5% from 10%-100%.



8. Press  save the displayed values as the new default values (see Starting the Treatment Protocol).

Setting a Pause

Your treatment protocol will pause or hold at the end of an interval. This is the time designated to clear secretions. The default number and duration of a pause is different by operating mode, but can be adjusted.





- Program (1-3) and Ramp - Pauses automatically for 5:00 minutes between each of the defined intervals or cycles.
- Manual - Runs once and then holds.

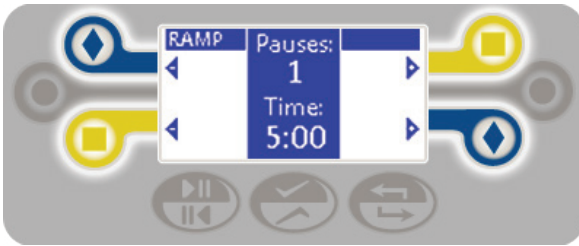
To change these settings, continue on with the following steps, otherwise - skip this section.


1. From within an operating mode, press  for 2 seconds to access the pause settings.



2. Set the following items:

- **Pauses** - Press  or  to the left or right of the Pauses display to increase or decrease the number of pauses. Adjust from 0-5 pauses or Auto.
- **Time** - Press  or  to the left or right of the time display. Adjust from 00:15 - 5:00 minutes or Hold.






3. Press  to save these settings.



Starting the Treatment Protocol

Select the desired treatment protocol (Manual, Program 1-3, Ramp) from the Home screen and follow the steps below.

Steps:

- Press  to begin your treatment.
 - To **pause** your treatment, press  again. The remaining time will be displayed.
 - To **resume** treatment, press  again.



- When the treatment interval is complete,
 - The timer will show 0:00.
 - The air pulses will stop.
 - The unit will beep twice.
- IMPORTANT:**  **Huff, cough, or suction to clear secretions.**
- Repeat steps 1-3 until all intervals or cycles of a prescribed treatment are complete.
- Press  at any time to return to the Home screen.

Checking System Information (INFO)

From the Home screen, press  to confirm the following detail:

- **Hours Run:** Total number of hours used for therapy. It does not include time when the System is paused.
- **Filter Hours Left:** Amount of time left before the filter needs to be replaced. The time starts at 200 hours and subtracts the Hours Run from when the filter was last changed (see Replacing a Filter).
- **Electromed Phone Numbers:** Need help? Call for assistance.
- **Version Number:** Electromed will ask for this when you call for support.

INFO	V20.1
Hours Run:	0068.5
Filter Hours Left:	132.5
1-888-966-2525 (USA)	
1-952-758-9299	






Advanced Settings

Setting Lock

Use this setting to lock a treatment protocol so that it can't be accidentally overwritten. Operating modes that have been locked show a lock icon in the bottom-right corner.

RAMP		
From	Time	To
6 Hz	30:00	12 Hz
80%	5~	50%






Steps:

1. From the Home screen, press .
2. Press  next to Lock.
3. Press  or  to Lock the treatment protocol for all operating modes.
The default is No.
4. Press  to save the setting and return to the Set menu.

Setting Save

Use this setting to perform a backup of your system that can later be restored, if needed.






Steps:

1. From the Home screen, press .
2. Press  next to Save.
3. Press  or  to Save the treatment protocol for all operating modes.
The default is No.
4. Press  to save the setting and return to the Set menu.

Setting Restore

Use this setting to restore a previously saved version of your system. This is helpful if you've made a number of changes and need to start over. You may find it easier to go back to protocols you know were set up properly versus manually adjusting each setting.





Steps:

1. From the Home screen, press .
2. Press  next to Restore.
3. Press  or  to Restore the previously saved system backup.
The default is No.
4. Press  to save the setting and return to the Set menu.

Setting Filter

The System reminds you when a filter change is due and gives you a chance to replace the filter at that time (see Replacing a Filter). You can bypass this reminder and the System will warn you again when it is restarted. Follow these steps if you want to change the filter early without waiting for the "Filter Hours Left" to reach 0 (see Checking System Info).

Steps:

1. From the Home screen, press .
2. Press  next to Filter.
3. Press  or  to confirm you want to reset the System "Filter Hours Left" (see Checking System Info) to 200 hours. The default is No. At this point you would also change the filter (see Replacing a Filter).
4. Press  to save the setting and return to the Set menu.

Routine Care of the Air Pulse Generator

Cleaning the Generator

WARNING: Always remove the power cord before servicing the generator.

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

Replacing a Filter

Routine preventive maintenance requires the air filter to be replaced every six months or every 200 hours, whichever occurs first. A regular slot screwdriver is needed to perform this task. Contact Electromed or your service provider for additional filters.

Steps:

1. Place the generator in the vertical orientation, remove filter access door by loosening two slot-head screws on the top of the generator. The screws are captured and will remain with the door.
2. Rotate and pull up on the access door.
3. Remove the air filter.



4. Install a new air filter.
5. Replace the filter access door screws.

Replacing a Fuse

Steps:

1. **WARNING:** First, unplug the generator.
2. Remove the fuse drawer by releasing the two side snaps with a ball-point pen and pull drawer straight out.



3. Remove the unit's two fuses.
4. Replace both fuses with supplied 5mm x 20mm 5 AMP, 250 VAC Fast Acting. Contact Electromed or your service provider for additional fuses.

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

Wheeled Carrier

The one-piece wheeled carrier makes transporting your SmartVest Airway Clearance System easier. The wheeled carrier is durable and designed to transport all components of the SmartVest Airway Clearance System, while the telescoping handle adjusts to your height needs.

The wheeled carrier has specific compartments for the SQL Air Pulse Generator, SmartVest garment, connecting hose and supplement kit, which includes the air pulse generator power cord, filters, fuse kits, and training materials.

CAUTION: The wheeled carrier is designed to carry only the weight of the System components. Do not place additional items on the carrier.

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



Airline Travel with the SmartVest System

The SmartVest Airway Clearance System is a physician prescribed respiratory therapy device considered to be a medical necessity and should be kept with the patient at all times. It should not be stored away from the airline passenger and **should NOT be checked in as baggage on ANY airline.** The use of the SmartVest device while on the plane is not allowed due to Federal Aviation Administration (FAA) regulations.

The United States Department of Transportation (DOT) has ruled that respiratory therapy devices (i.e. the SmartVest System) brought into the cabin of an airplane shall not count toward the limit of carry-on items.

The United States Transportation Security Administration (TSA) rules state that respiratory therapy devices may be inspected at any and all check-in points but should not be separated from the prescribed owner.

However, as a precautionary measure, a statement from your physician that describes the medical need for the SmartVest System is advised.




In addition, TSA has made a notification card available to an airline passenger on its website that is filled out prior to arriving at the airport to inform TSA of the patient's medical condition. The card is presented to TSA at the time of screening at the airport. This card is recommended by TSA to make check-in easier but may or may not prevent further inspection.


Airplane Mode

If the SmartVest SQL is labeled with **FC**, it is equipped with the wireless connectivity feature. The device should be placed into Airplane Mode before traveling. Airplane Mode is activated automatically each time the air pulse generator is turned off and will remain active for at least 5 days or until the generator is turned on and off again. To assure that Airplane Mode is active during airline travel, on the day of or 1 day prior to travel, plug in the generator, turn on the power switch and then turn off the switch.

Troubleshooting

In response to various environmental conditions, the generator will display an error message. Understanding these messages will help you quickly troubleshoot the problem. If the suggested actions below do not resolve the issue, contact Electromed or your service provider.

Display shows...	Problem is...	Take this action...
<p>Error 1</p> 	<p>The motor temperature is above the maximum acceptable limit. The unit will NOT start in this state, as damage may occur.</p>	<p>If the system is sitting in a warm location, move it to a cooler location and try again later. If this does not resolve the issue, contact Electromed or your service provider.</p>
<p>Error 2</p> 	<p>The motor temperature is below 50 degrees Fahrenheit (10 degrees Celsius) and needs to warm up.</p>	<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 Electromed or your service provider.</p>
<p>Error 3</p> 	<p>Motor rotation has not been detected.</p>	<p>Contact Electromed or your service provider.</p>

Problem is...	Take this action...
<p>There is no power to the air pulse generator, or the vest does not pulse.</p>	<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 (see Replacing a Fuse).
<p>The garment does not fully inflate.</p>	<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 generator. ✓ The connecting hose is free of leaks. ✓ The inner bladder is free of tears. ✓ The inner bladder is attached smoothly inside the outer shell. The Velcro-type closures are lying flat and are free from buckling. ✓ Replace the air input filter (see Replacing a Filter).
<p>It is difficult to breathe during treatment.</p>	<p>The garment will slightly compress the chest during treatment. Reduce pressure within your protocol until the patient is comfortable with the sensation. Soon the patient 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>
<p>The data on the display does not appear to be in the correct position.</p>	<p>In rare cases static discharge may cause the display to become irregular. To reset the display press .</p>
<p>The vest no longer fits.</p>	<p>Contact Electromed or your service provider for a replacement.</p>

Specifications

Operational Parameters	<ul style="list-style-type: none"> • Time: 30 seconds – 30 minutes \pm 2% • Frequency: 5 – 20 Hz \pm 2 Hz
Air Pulse Generator	<ul style="list-style-type: none"> • Weight: 17 lbs (7.7 kg) • Dimensions: 14 5/8" x 14" x 6 1/4" (37 x 35.5 x 16 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.
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 (36 cm) of chest coverage.
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"> • 40°F – 84°F (5°C – 29°C) • 15% – 93% relative humidity, non-condensing • 70 kPa to 106 kPa
Transport and Storage Conditions	<ul style="list-style-type: none"> • -13°F – 158°F (-25°C – 70°C) • 0% – 93% relative humidity, non-condensing • 50 kPa to 106 kPa

Electromagnetic Compatibility

Guidance and Manufacturer's Declarations – Electromagnetic Immunity


The **SmartVest** SQL Airway Clearance System is intended for use in the electromagnetic environment specified below. The customer or the user of the System 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 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System 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: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer’s Declarations – Electromagnetic Immunity

The **SmartVest**® SQL Airway Clearance System is intended for use in the electromagnetic environment specified below. The customer or the user of the System 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,17 \sqrt{P}$ $d = 1,17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,33 \sqrt{P}$ 800 MHz to 2,5 GHz 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 meters (m). 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 . Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE 1: At 80 MHz and 800 MHz, 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.

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 System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.

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 SmartVest SQL Airway Clearance System.

The **SmartVest** Airway Clearance System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System 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	0,23
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 R_x

SmartVest SQL Airway Clearance System

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.

ELECTROMED, INC.

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Accredited by
The Joint Commission



ISO 13485 / ISO 9001 Certified