smartvest® clearway®

AIRWAY CLEARANCE SYSTEM

BY ELECTROMED, INC.

SmartVest® Clearway® Instruction Manual

Please contact Electromed at: (888) 966-2525 or your service representative with questions about the SmartVest Clearway

126004-S-010 Rev G ENG

Foreword

This manual will help you use the **SmartVest® Clearway®**, a high frequency chest wall (HFCWO) therapy. 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 **SmartVest 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 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 Clearway**, or any other matter, we appreciate your input. If you would like to provide feedback, contact Electromed or your service provider.

For Warranty Information, Contact Electromed at 1.800.462.1045.

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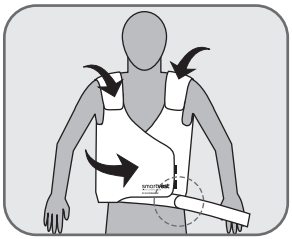
Quick Start Guide

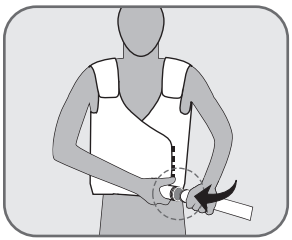
Therapy programs are quickly accessible and easy to start on the **SmartVest Clearway** device. The following steps demonstrate how to get started and begin a desired therapy. For more detailed information on how to program therapies, see pages 16-26.

Put On Vest



1. Position the bottom of the **SmartVest** at or slightly below the patient's waist.
2. Secure the front closure. Make sure the **SmartVest** fits snugly around the patient's chest.
3. Adjust the Velcro®-like shoulder closures.

Connect Tubing



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.

Wake Up Device

1a. If unplugged, plug the power cord into an electrical outlet.

1b. If plugged in, touch the screen to wake up the device.

Choose a Therapy

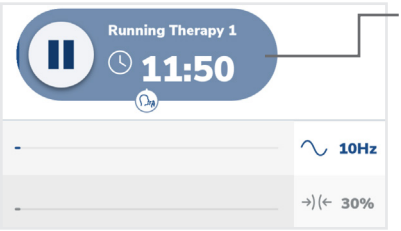
1. Scroll through prior programmed therapies, or select from Manual Mode.

Alternatively, press the page icon associated with the desired therapy.

Start the Therapy

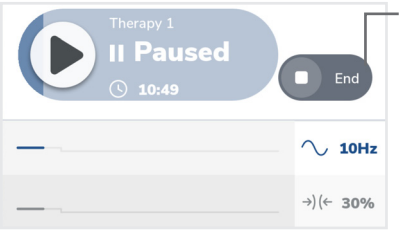
1. Press on the **Blue Button** to start therapy.

Pause the Therapy



1. Press the **II** button to pause therapy.

Stop the Therapy



1. While therapy is paused, press the **End** button to stop therapy.

Cough Breaks

1. When a programmed pause is reached:
   The air pulses will stop.
   The unit will beep twice.
2. **IMPORTANT: Huff, cough, or suction to clear secretions.**

Refer to pages 11 and 12 for Cleaning

Refer to page 38 for SmartVest Connect and set up instructions.

Warnings

	No repair of the **SmartVest** 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.
	Always remove the power cord before servicing the generator.
	Dangerous voltage within the device may constitute a risk of electric shock.
	Always use the **SmartVest Clearway** with the power cord supplied.
	Do NOT eat or drink one half hour before or after HFCWO treatment. 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 Clearway** near water, near any wet surface or in a 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 Clearway** 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 contact with patient 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 are not toys.
	Use of the **SmartVest** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the **SmartVest** and the other equipment should be observed to verify that they are operating normally.

Cautions

	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **SmartVest**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
℞	Federal law restricts this device to sale by or on the order of a physician.
	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 operations, or in the event a serious incident has occurred in relation to the device, contact Electromed at (888) 966-2525. For incidents occurring within the European Union, the user and/or patient should also contact the competent authority of the Member State in which the user and/or patient is established.
	Use only compatible **SmartVest** components supplied by Electromed.
	Do NOT staple, sew, or apply any items to the **SmartVest** garment shell that could penetrate the inner bladder.
	Do NOT apply adhesives, tapes, hot glue or hot irons to the **SmartVest** garment shell while inner bladder is installed.
	Do NOT allow any foreign materials to enter the **SmartVest** 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 or blocks air inlet vents.
	Patients with breast implants, implanted pacemakers, or external chest catheters should discuss HFCWO therapy with their physician prior to starting treatment.
	Patients prone to seizures should discuss HFCWO therapy with their physician prior to starting treatment.

Cautions continued

	Some patients who have been prescribed HFCWO have reported experiencing mild chest pain and/or nausea, which generally resolved after the first 2 to 3 days of therapy.
	Avoid resting the hose across the patient's body during treatment, which may pose a risk due to vibration of the hose, resulting in an abrasion or potential burn to the area in contact with the hose.

Symbols

	Attention! Read these Safety Instructions and the entire Instruction Manual before using this device.
	Consult instructions for use.
	Follow instructions for use.
	Pulses per second. Units are Hz.
	Percent of pressure. Units are %.
	Time.
	Bluetooth is connected.
	Bluetooth is not connected.
	Press button to decrement. Press and hold button to repeatedly decrement.
	Press button to increment. Press and hold button to repeatedly increment.
	Press to select the previous item or the item to the left.
	Press to select the next item or the item to the right.
	Number of pills indicates the number of therapy pages that can be selected. (This number can be as few as 3 and as many as 5.) The blue/dark pill indicates the currently selected therapy in page order. Press a gray/light pill to select the therapy associated with that page.

Symbols continued

	Edit.
	Settings.
	Favorite.
	Information.
	Save/Restore.
	Screen brightness.
	Sleep.
	Good Day Therapy Label. *This feature is only available for Homecare use and not available for hospital devices.*
	Bad Day Therapy Label. *This feature is only available for Homecare use and not available for hospital devices.*
	Remove, Discard, Delete.
	Add a cycle to the therapy.
	Pause for cough.
	Pause a therapy.
	Start a paused therapy.
	Access the menu.
	Close or cancel.

Equipment Classifications

	Medical equipment with respect to electrical shock, fire and mechanical hazards only in accordance with: IEC 60601-1 Edition 3.1; ANSI/AAMI ES60601-1 (2012)
	The **SmartVest Clearway** meets class II (double insulation) protection against electrical shock.
	Type BF applied parts: **SmartVest** and **SmartVest Wrap** garment(s).
	The **SmartVest Clearway** is IP21 classified. Protected against solid foreign objects of 1/2" (12.5 mm) and greater; protected against vertically falling water drops.
	The equipment is NOT suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide.
	Waste Electrical & Electronic Equipment (WEEE). Contact Electromed or your service representative for information on recycling the Clearway.
	Electromed, Inc. has been accredited by The Joint Commission to meet the requirements for the Home Care Accreditation Program.
	Contains FCC ID X8WBT832 for 2402 MHz to 2480 MHz. Wireless connectivity feature is intended for use within the 50 United States.

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 Clearway** is designed to deliver High Frequency Chest Wall Oscillation (HFCWO) to promote airway clearance and improve bronchial drainage. The **SmartVest Clearway** is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport."

Indications for use of the **SmartVest Clearway** 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:

https://www.aarc.org/wp-content/uploads/2014/08/12.91.1418.pdf

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; pulmonary edema associated with congestive heart failure; bronchopleural fistula; pulmonary embolism; empyema; intracranial pressure greater than 20 mm Hg; large pleural effusions; rib fracture, with or without flail chest; 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.

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 Clearway**, creates a "squeeze and release" action around the chest and torso from 5-20 times per second. The **SmartVest** inflates through a single-hose powered by a programmable air pulse generator and delivers rapidly repeating pulses of air that gently squeeze and release the upper body. The squeeze and release action of the 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.

SmartVest Clearway

The **SmartVest Clearway** consists of three primary components - a **SmartVest** garment, the Connecting Hose, and the Clearway Air Pulse Generator. In addition, there are accessories designed to aid in the use of the **SmartVest Clearway** that are discussed on pages 8-13.

SmartVest Garments

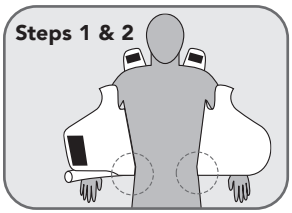
The **SmartVest** delivers full coverage air pulses to the front, back, and sides of the torso for 360-degree oscillation. It is made of a soft, breathable fabric. The **SmartVest** is available in two styles – the **SmartVest** and the **SmartVest Wrap®**.

- The **SmartVest** has the appearance of a vest. It is constructed of an inner bladder with a soft, breathable fabric shell and Velcro®-like 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.

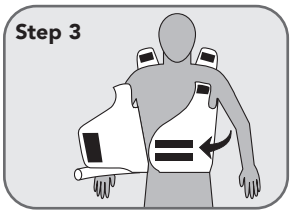
Wearing the SmartVest or SmartVest Wrap

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

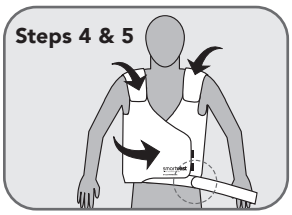
Fitting the



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.

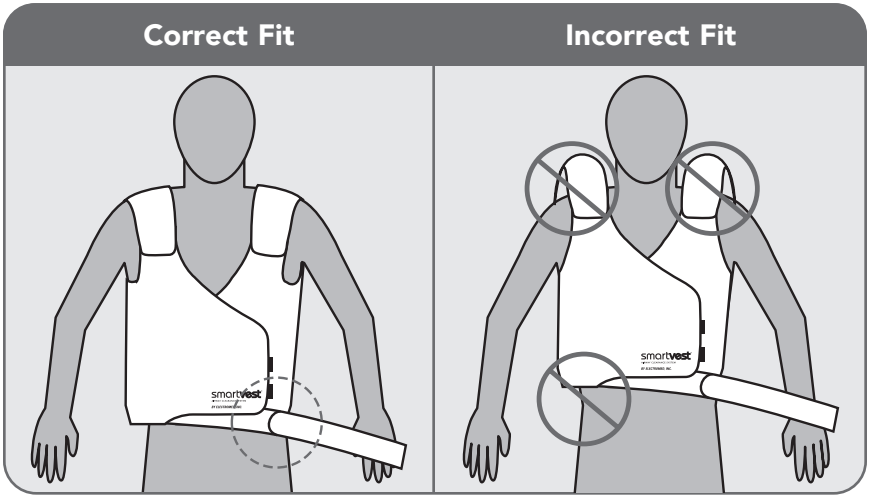


3. Secure the front closure. Make sure the **SmartVest** fits snugly around the patient's chest.

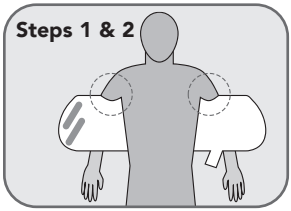


4. Adjust the shoulder closures.
5. Attach the hose to the **SmartVest** (refer to the section on Connecting Hose).

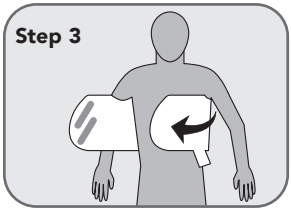
NOTE: If the front closure opens during treatment, it can be secured by opening the small strap on the left side of the **SmartVest**, lacing it through the D-ring, and securing it with the Velcro®-like closure.



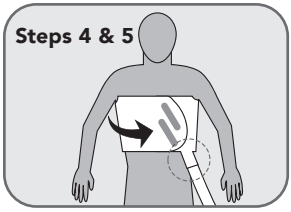
Fitting the SmartVest



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®-like closure.

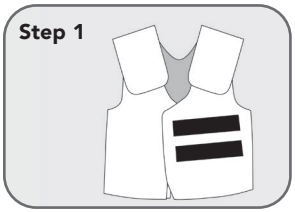
   NOTE: The garment should fit "snugly" but not tightly.
5. Attach the hose to the **SmartVest Wrap** (refer to the section on Connecting Hose).

Fitting Accessories

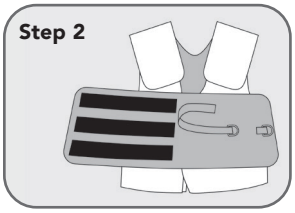
Using the SmartVest Extender

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.

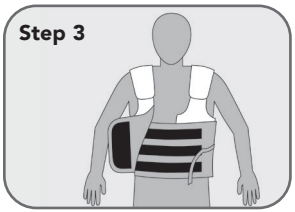
Fitting the SmartVest Garment Extender



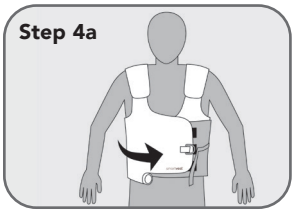
1. Lay the closed garment on a flat surface with the soft-sided Velcro-like material side on top.



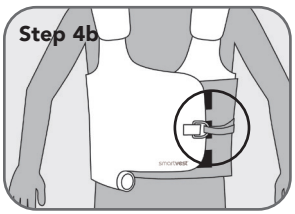
2. Attach the rough-sided Velcro-like material of the extender to the soft-sided Velcro-like material of the garment.



3. Put on the garment as normal. Tuck extender in and around body while holding logo side of garment away from body.



4a. Cross logo side of garment over to attached rough Velcro-like material on garment to soft Velcro-like material on extender.



4b. Slip the strap through the D-ring and secure extender in place, as needed.

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 to maintain its appearance. Both the inner bladder and the outer shell should be cleaned on an as-needed basis.

- 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®-like 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®-like 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®-like 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®-like attachments where necessary.
8. Close the zipper.

Visual cleaning instructions are available on the SmartVest YouTube channel.

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.**

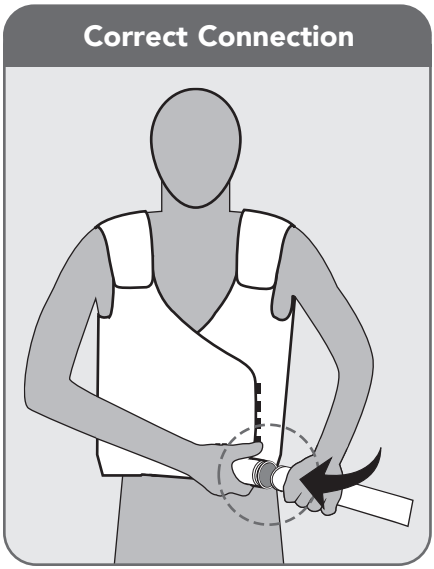
Connecting Hose

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.



Clearway 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.

The generator is designed to operate in a horizontal position.

Powering the Generator

There are two elements that affect the power to the generator: the power cord and the sleep mode.

- **Power Cord** - Connect the supplied power cord to an electrical outlet to power the generator.
- **Sleep Mode** - To conserve energy, the system enters sleep mode automatically after 3 minutes of inactivity on the home screen, 10 minutes of inactivity when editing settings, and 30 minutes of inactivity when paused in a therapy. The display and fan are off during this time, but the power indicator light remains lit. To awaken the system from sleep mode, touch anywhere on the display.

NOTE: SmartVest Clearway is equipped with the wireless connectivity feature. The FC label can be found on the bottom of the air pulse generator.

Device Diagram

Ambient Light Sensor
Will adjust screen brightness based on ambient light in the room

Touch Screen User Interface

Power Indicator Light
Will always be lit when the device is plugged in

Cooling Air Vents

Power Cord Connection

Device Handle

Therapy Types

The **Clearway** System has three types of therapies that can be customized to your needs and physician recommendations. Custom settings will be saved when the power is disconnected.

1. **Program Mode**: set and save up to 6 cycles (A-F) that can each have their own duration, frequency and pressure per cycle. The system will transition through each cycle sequentially until all are complete.
2. **Ramp Mode**: set a minimum ("from") and maximum ("to) frequency and pressure which allows the system to slowly ramp up and back down between the minimum and maximum settings for the set time interval.
3. **Manual Mode**: press start to receive therapy at default settings, or adjust frequency, pressure and therapy time while therapy is being delivered, based on what is most comfortable for the patient.

Categorize Therapy

Patients may choose to create therapies depending on how they are feeling. On days the patient is feeling well, select a Good Day therapy for a maintenance, routine therapy. On days when the patient is feeling more congested, a Bad Day therapy could be selected for a more robust therapy. Good/Bad Day labels allow patients to categorize therapies by the type of day for which they are best suited.

This feature is only available for Homecare use and not available for hospital devices.

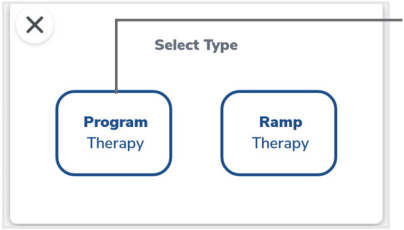
Add Therapy

Program Therapy

Program Therapy allows users to create up to 6 cycles of therapy, each with unique settings for frequency, duration and pressure. The system will move sequentially through each cycle as therapy progresses.

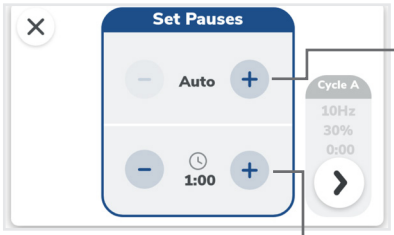
Setting Program

1. From the Home screen, scroll to **Add Therapy**. Press the **Add Therapy** button.



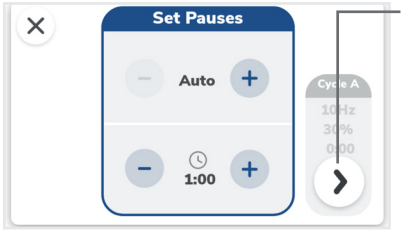
2. Select **Program Therapy.**

The 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.

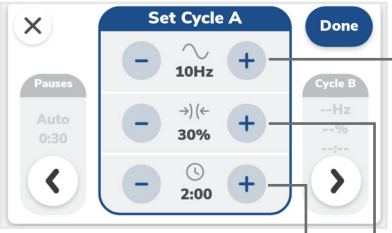


3. Adjust the Pause settings:
Number of Pauses: Press the **+** and **-** buttons to the left or right of the number display. Adjust from 0-5 pauses or select Auto. With Auto, therapy is paused at the completion of each Cycle.

Duration: Press the **+** and **-** buttons to the left or right of the time display. The default pause duration is 1:00 minute and can be adjusted from 00:15 - 5:00 minutes in increments of 15 seconds, or select Hold. With Hold, therapy pauses are held until the user presses the Start button on the pause screen to resume therapy.



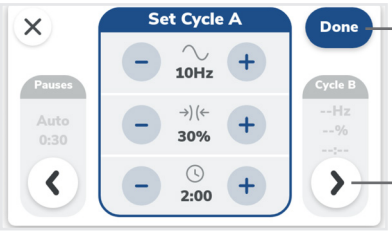
4. Continue to next screen by pressing the **>** button.



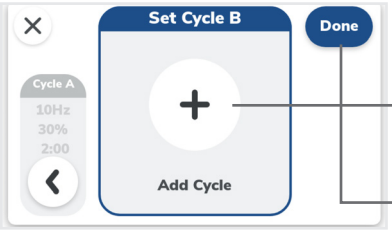
5. Adjust the cycle settings:
Frequency: Press the **+** and **-** buttons to the left or right of the frequency display. Adjust in 1 Hz increments from 5 to 20 Hz. Hold the **+** or **-** button to repeatedly increment or decrement.

Pressure: Press the **+** and **-** buttons to the left or right of the pressure display. Adjust in increments of 5% from 10% to 100%.

Time: Press the **+** and **-** buttons to the left or right of the time display. Adjust in 1 minute increments from 1:00 to 60:00 minutes.



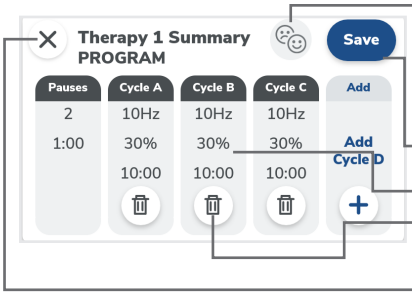
6. If only one cycle is desired, press **Done**.
If multiple cycles are desired, press the **>** button.



7. If desired, press the **+** button to add a cycle.
Edit the **Frequency**, **Pressure**, and **Time** settings.
Repeat this process for as many cycles as needed.
Press **Done** when all cycles are added and all settings are selected.

Patients may choose to create therapies depending on how they are feeling. On days the patient is feeling well, select a Good Day therapy for a maintenance, routine therapy. On days when the patient is feeling more congested, a Bad Day therapy could be selected for a more robust therapy. Good/Bad Day labels allow patients to categorize therapies by the type of day for which they are best suited.

8. Select **Good Day** or **Bad Day** Therapy Label if desired. Otherwise select **No Label**.
This feature is only available for Homecare use and not available for hospital devices.

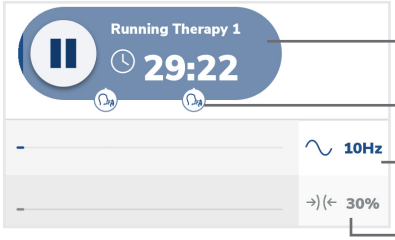


9. Review the Therapy Summary Page:
Press the **Label** icon to change or add Therapy Label.
Press **Save** to save Program Therapy.
Press **Pauses** or any **Cycle** to edit it.
Press the **Trash Can** to delete a cycle.
Press the **X** button to cancel the creation of this Program Therapy.

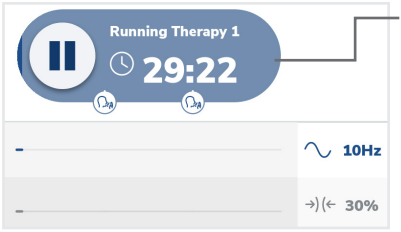
Optional Step 10. Refer to page 38 for SmartVest Connect set up instructions.

Starting Program Therapy

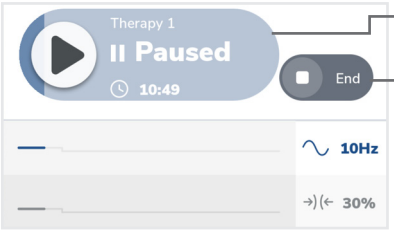
1. From the Home screen, press the < or > button to scroll left or right to select desired Program or Ramp therapy.
Press the ▶ button to begin treatment.



2. This screen will appear:
The blue bar will fill as time passes. When it reaches the end, therapy is complete.
This icon shows when the cough pause will occur during treatment.
This bar shows the current frequency.
This bar shows the current pressure.



3. Press the **II** button to pause therapy.



4. Press the ▶ button to resume therapy, or press **End** to end therapy.

5. When a pause is reached:
   The air pulses will stop.
   The unit will beep twice.
   IMPORTANT: Huff, cough, or suction to clear secretions.

6. Wait for pause timer to run out, or press the ▶ button to resume therapy.

Optional Step: Open SmartVest Connect mobile application to track therapy progress and transmit therapy session data.

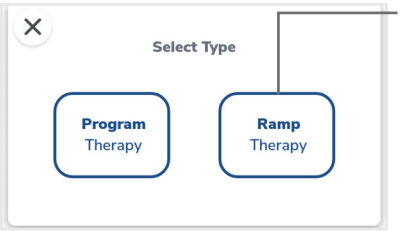
7. Repeat steps 4 through 5 until all intervals or cycles of a prescribed treatment are complete. When complete, this screen will appear.

Ramp Therapy

Ramp therapy allows the patient to set a minimum ("from") and maximum ("to") range for the frequency and pressure delivered over a specified time duration. The system will slowly ramp frequency and pressure up and down within that range.

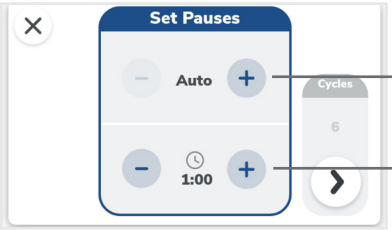
Setting Ramp Therapy

1. From the Home screen, scroll to **Add Therapy**. Press the **Add Therapy** button.

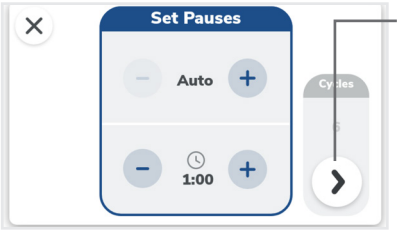


2. Select **Ramp Therapy**.

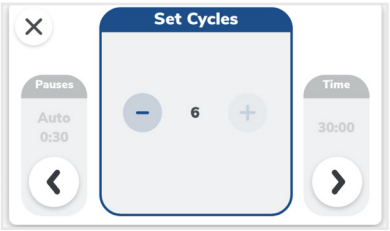
The treatment protocol will pause or hold at the end of an interval. This is the time designated to clear secretions. The default number and duration of a pause is different by operating mode, but can be adjusted.



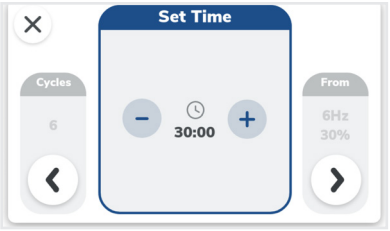
3. Adjust the Pause settings:
   Number of Pauses: Press the **+** and **-** buttons to the left or right of the number display to increase or decrease. Adjust from 0 to 5 pauses or select Auto. With Auto, therapy is paused at the completion of each cycle.
   Duration: Press the **+** and **-** buttons to the left or right of the time display. Adjust from 00:15 to 5:00 minutes in increments of 15 seconds, or select Hold. With Hold, therapy pauses are held until the user presses the Start button on the pause screen to resume therapy.



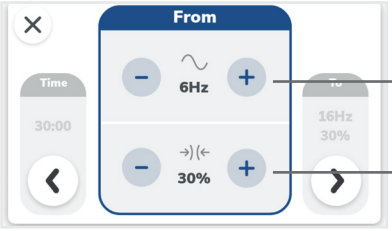
4. Continue to next screen by pressing the **>** button.



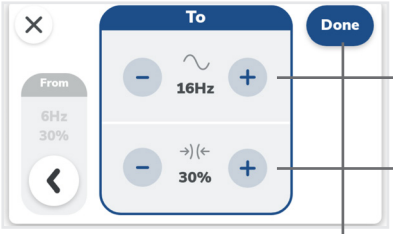
5. Press the **+** and **-** buttons to the left or right of the number display to increase or decrease the **number of cycles**. Adjust from 1 to 6 cycles.



6. Press the **+** and **-** buttons to the left or right of the time display to increase or decrease the **duration of therapy**. Adjust in 1 minute increments from 1:00 to 60:00 minutes. Hold the **+** or **-** button to repeatedly increment or decrement.



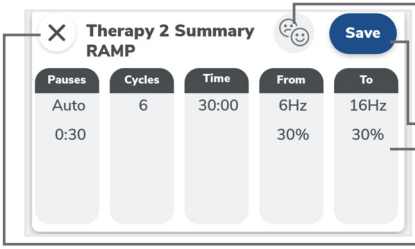
7. Adjust the From settings:
Frequency: Press the **+** and **-** buttons to the left or right of the frequency display. Adjust in 1 Hz increments from 5 to 20 Hz.
Pressure: Press the **+** and **-** buttons to the left or right of the pressure display. Adjust in increments of 5% from 10% to 100%.



8. Adjust the To settings:
Frequency: Press the **+** and **-** buttons to the left or right of the frequency display. Adjust in 1 Hz increments from 5 to 20 Hz.
Pressure: Press the **+** and **-** buttons to the left or right of the pressure display. Adjust in increments of 5% from 10% to 100%.
Press **Done** when finished.

Patients may choose to create therapies depending on how they are feeling. On days the patient is feeling well, select a Good Day therapy for a maintenance, routine therapy. On days when the patient is feeling more congested, a Bad Day therapy could be selected for a more robust therapy. Good/Bad Day labels allow patients to categorize therapies by the type of day for which they are best suited.

9. Select **Good Day** or **Bad Day** Therapy Label if desired. Otherwise select **No Label**.
This feature is only available for Homecare use and not available for hospital devices.

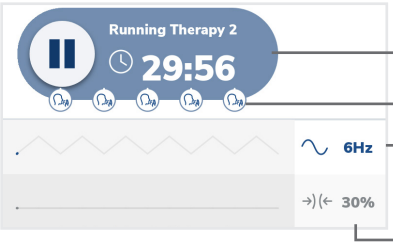


10. Review the Therapy Summary Page:
Press the **Label** icon to change or add Therapy Label.
Press **Save** to save Ramp Therapy.
Press **any column** to edit it.
Press the **X** button to cancel the creation of this Ramp Therapy.

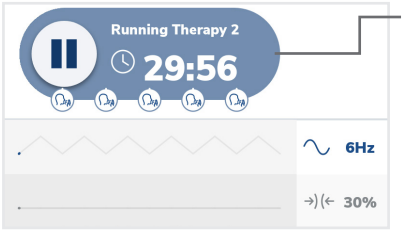
Optional Step 11. Refer to page 38 for SmartVest Connect set up instructions.

Starting Ramp Therapy

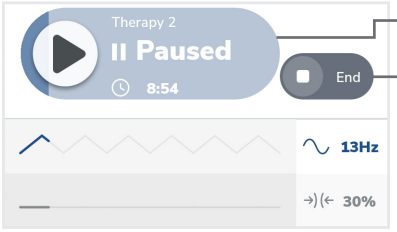
1. From the Home screen, press the < or > button to scroll left or right to select desired Program or Ramp therapy.
   Press the ▶ button to begin treatment.



2. This screen will appear:
   The blue bar will fill as time passes. When it reaches the end, therapy is complete.
   This icon shows when the cough pause will occur during treatment.
   This bar shows the current frequency.
   This bar shows the current pressure.



3. Press the **II** button to pause therapy.



4. Press the ▶ button to resume therapy, or press **End** to end therapy.

5. When a pause is reached:
   The air pulses will stop.
   The unit will beep twice.
   IMPORTANT: Huff, cough, or suction to clear secretions.

6. Wait for pause timer to run out, or press the ▶ button to resume therapy.

   Optional Step: Open SmartVest Connect mobile application to track therapy progress and transmit therapy session data.

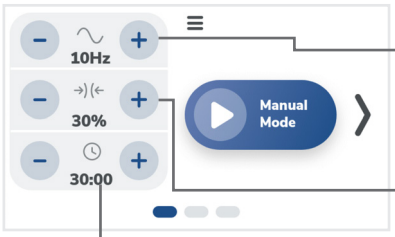
7. Repeat steps 4 through 5 until all intervals or cycles of a prescribed treatment are complete. When complete, this screen will appear.

Manual Mode

Manual Mode allows the patient to quickly start therapy at default settings, then adjust frequency, pressure and therapy time while therapy is being delivered if desired.

Start Manual Mode and Edit Settings

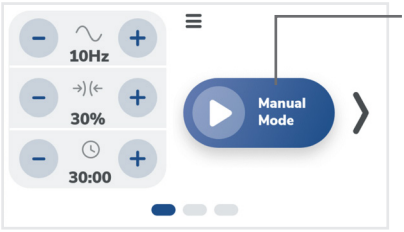
1. From the Home screen, press the < button to scroll to Manual Mode.



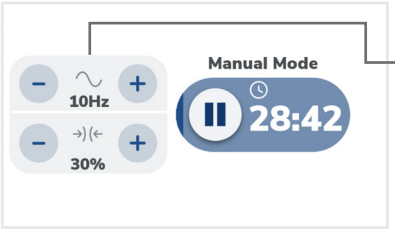
2. Adjust the settings:
Frequency: Press the **+** and **-** buttons to the left or right of the frequency display. Adjust in 1 Hz increments from 5 to 20 Hz.

Pressure: Press the **+** and **-** buttons to the left or right of the pressure display. Adjust in increments of 5% from 10% to 100%.

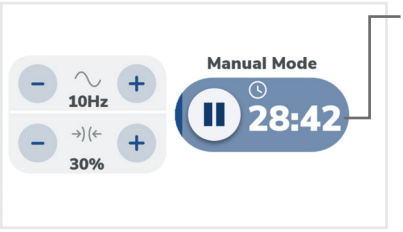
Time: Press the **+** and **-** buttons to the left or right of the time display. Adjust in 30 second increments from :30 to 60:00 minutes.



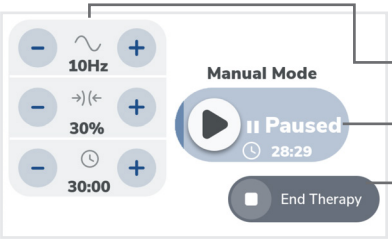
3. Press the ▶ button to begin treatment.



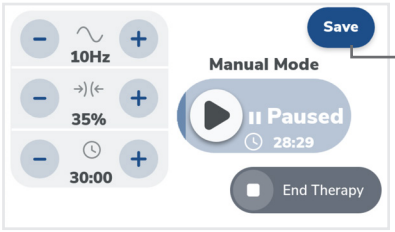
4. Frequency and pressure can be changed at any time during a Manual session by pressing the **+** and **-** buttons.
Time can only be changed when the unit is not pulsing.



5. Press the **II** button to pause therapy as desired, or to change the duration of therapy.



6. Press the **+** and **-** buttons to change **Frequency**, **Pressure**, or **Time**.
Press the ▶ button to resume therapy.
Press **End Therapy** to end therapy.



7. If settings have been changed, press **Save** to save these settings as your manual mode.

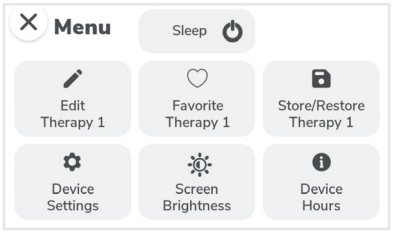
Optional Step: Refer to page 38 for SmartVest Connect set up instructions. Open SmartVest Connect mobile application to track therapy progress and transmit therapy session data.

8. When complete, this screen will appear.

Menu Overview

The menu allows activation of sleep mode, edit a therapy, favorite a therapy, store/restore a therapy, edit device settings, change the brightness of the screen, and check device hours.

1. From the home screen, press the ☰ button to access the Menu.



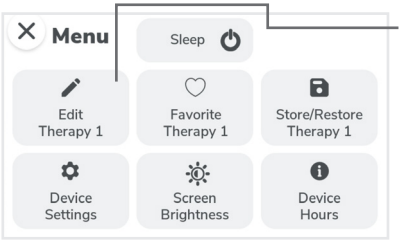
2. The menu will open, providing access to multiple settings.

Therapy Settings

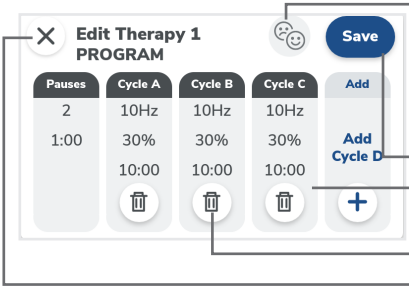
To edit a **Program** or **Ramp Therapy**, follow the steps below.

1. From the Home screen, press the < or > button to scroll to select the desired therapy.

2. Press the ☰ button to access Settings.



3. Press **Edit Therapy** to change the settings of the selected therapy.



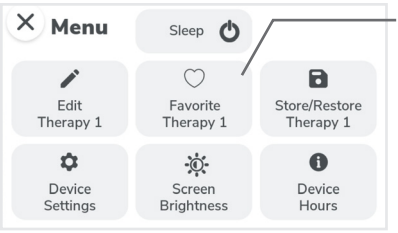
4. On this screen patients can edit the following settings:
   - Press the **Label** icon to change or add Therapy Label.
   - Press **Save** to save Program Therapy.
   - Press **Pauses** or any **Cycle** to edit it.
   - Press the **Trash Can** at the top of the screen to delete the entire therapy.
   - Press the **X** button to cancel editing this Program Therapy.

Favorite a Therapy

Favoriting a therapy will cause it to be the first one shown on the screen when the device is turned on.

1. From the Home screen, press the < or > button to scroll to select the desired therapy.

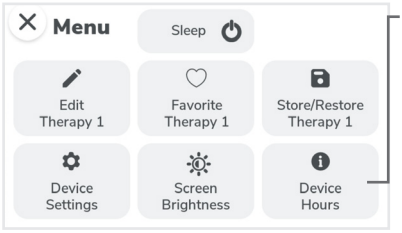
2. Press the ☰ button to access Settings.



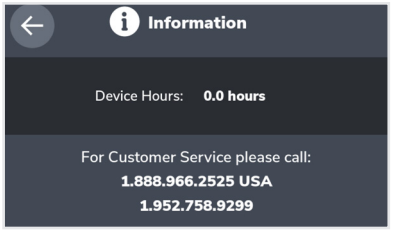
3. Press **Favorite** to select the therapy to be saved as a favorite.

Checking Device Hours

1. From the Home screen, press the ☰ button to access Settings.



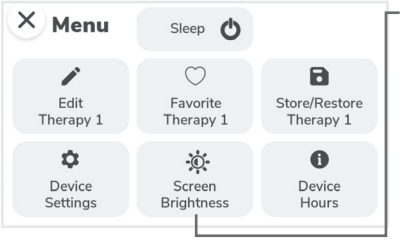
2. Select **Device Hours.**



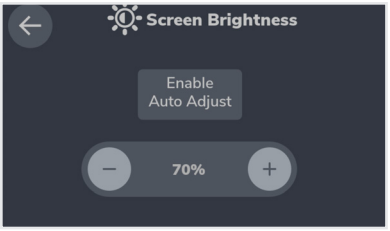
3. The number of hours the device has been used can be seen here, as well as a phone number for customer service.

Changing Screen Brightness

1. From the Home screen, press the ☰ button to access Settings.



2. Select Screen Brightness to adjust the brightness of the device's screen.



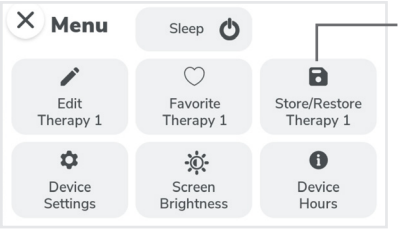
3. Press the **+** and **-** buttons to adjust the brightness, or select **Enable Auto Adjust**.
Auto Adjust will automatically dim or brighten the screen based on the environment's lighting level.
Note: A new device will default as Enable Auto Adjust.

Storing a Therapy

Use this setting to perform a backup of the therapy that can later be restored, if needed. The device will automatically store the settings after a therapy has been performed 30 times without any changes. New therapies are automatically stored when the therapy is created.

1. From the Home screen, press the **<** or **>** button to scroll to select the desired therapy.

2. Press the ☰ button to access Settings.

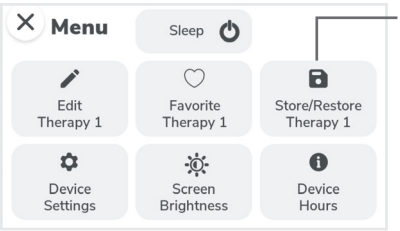


3. In the therapy menu, press **Store/Restore Therapy**.

4. Press **Store to Backup**. Then press **Yes** on the following confirmation screen.

Restoring a Therapy

Use this setting to restore previously saved therapy settings. This is helpful if a number of changes have been made and it is necessary to start over. This may be an easier alternative to return to the original protocols which were configured in the device versus manually adjusting each setting.



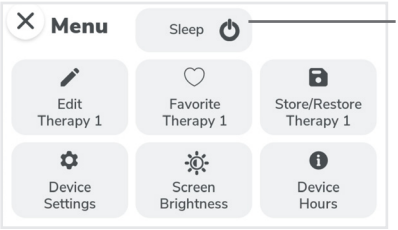
1. In the therapy menu, press **Store/ Restore Therapy**.

2. Press **Restore from Backup**. Then press **Yes** on the following confirmation screen.

Sleep Mode

Sleep mode will dim the device screen and save power. The device will automatically go into sleep mode after a period of inactivity, or can be manually set to sleep mode.

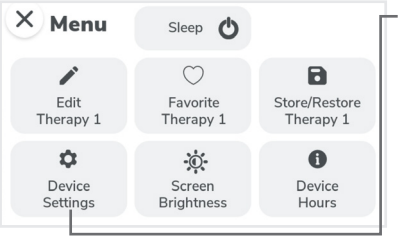
1. From the Home screen, press the ☰ button to access Settings.



2. Press the **Sleep** button.

Access Device Settings

1. From the Home screen, press the ☰ button to access Settings.

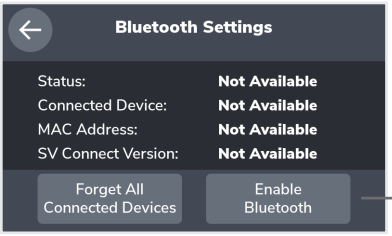


2. Select **Device Settings**.

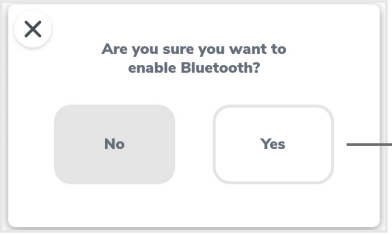
3. Access **Bluetooth Settings**, **Device Version**, **Lock Device**, and **Diagnostics** from this menu. Note: The Bluetooth Settings option is only available for Home Use devices. This setting is not available for hospital devices.

Enable Bluetooth

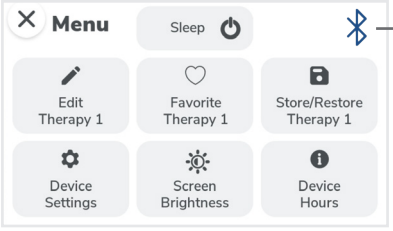
1. Press and hold **Bluetooth Settings** button for 3 seconds.

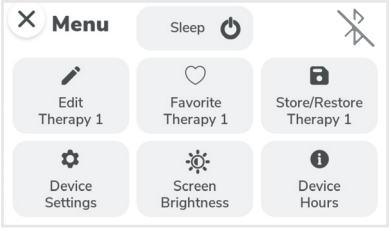


2. To enable Bluetooth, select **Enable Bluetooth** button.



3. Select **Yes** button to confirm enabling Bluetooth.



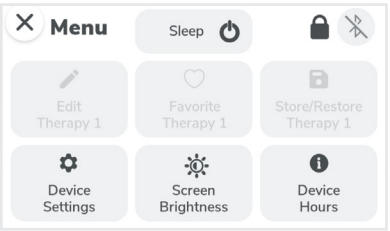


4. When Bluetooth has been enabled and connected to a mobile device the Bluetooth icon will appear to reflect this status. If the icon has a slash through it, the Bluetooth is enabled but is not connected to a device. Adjust the Bluetooth settings by clicking the icon, or going to the Device Settings menu.

   Note: The Bluetooth icon will not be present in hospital use devices.

Locking Device

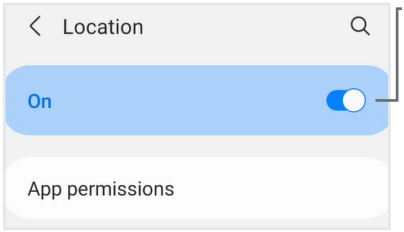
1. Press and hold **Lock Device** button for 3 seconds to enable the device lock. When device is locked, patients will not be able to enter new therapies, change the frequency, pressure, or time of any existing therapies, or Store/Restore therapies. This will also prevent the device from automatically saving therapy after it has been performed 30 times without any changes.



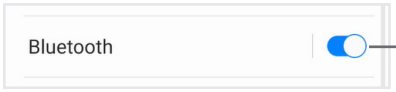
The lock icon will display next to the Bluetooth icon in the Device settings menu when the device is locked.

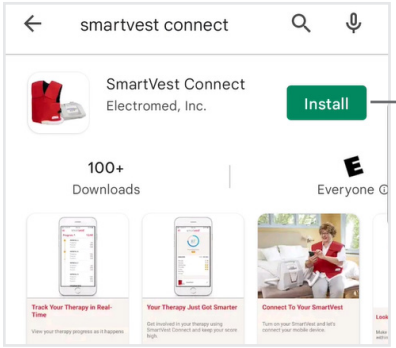
2. To unlock, press and hold **Unlock Device** for 3 seconds.

App Connection

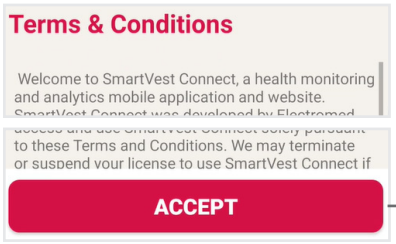


1. Verify mobile device **Bluetooth** and **Location** settings are turned on.

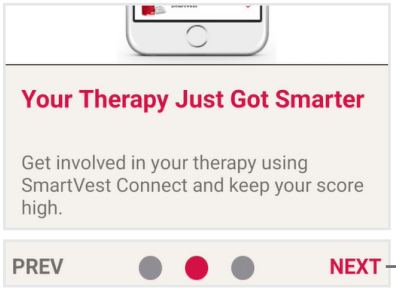




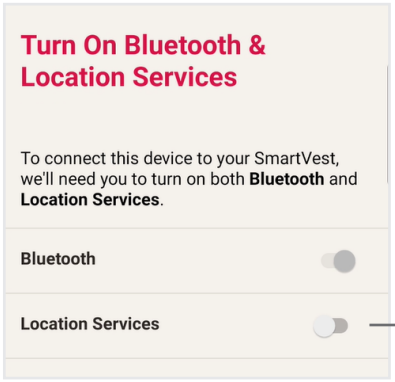
2. Search for and install Smartvest Connect app in the Application Store.



3. Open Smartvest Connect app, review, and accept Terms & Conditions.

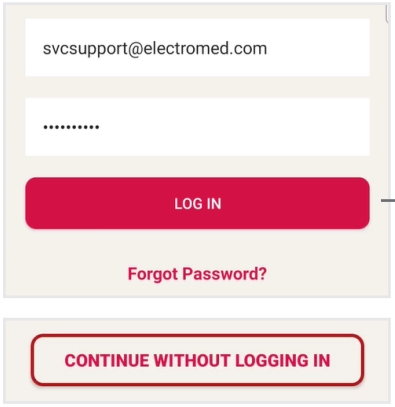


4. Scroll through SmartVest Connect functionality announcements.

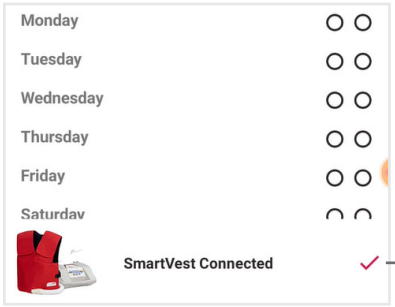


5. Wake up or plug in the **Clearway Device**.

6. Confirm **Bluetooth** and **Location** access is enabled on SmartVest Connect app.



7. Log in with SmartVest Connect account, or continue without logging in.



8. Confirm **SmartVest Connected** banner at the bottom of the SmartVest Connected app.

Routine Care of the Air Pulse Generator

Cleaning the Generator

While the device is unplugged, the exterior of the generator may be cleaned with a damp cloth and a mild disinfectant on an as-needed basis. Any cleaning liquids should first be sprayed on a cloth and then used. Avoid getting liquid inside the generator.

Hospital Accessories

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

Contact Electromed for replacement parts at (888) 996-2525.

Single Patient Use (SPU) SmartVest

The SPU SmartVest is intended for use by a single patient during a hospital 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.

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.

Mobile Pedestal

The Model Clearway-I is designed to mount to a mobile pedestal, which features a stable caster-base with 2 locking casters.

Airline Travel with the SmartVest Clearway

The **SmartVest Clearway** 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 Clearway** 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 Clearway**) 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 Clearway** 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.

Troubleshooting

In response to various environmental conditions, the generator will display an error message. Noting the reference code can help provide information that will help customer service diagnose the cause of the error message. If the suggested actions below do not resolve the issue or if the issue occurs frequently, contact Electromed or your service provider.

Problem is...	Take this action...
Processor Connection	Unplug device for 30 seconds, plug back in. Contact customer service if problem is not resolved.
Unexpected Reset	Contact customer service if problem occurs frequently.
Stored Settings Unavailable	Default settings will be used. Contact customer service if problem occurs frequently.
Voltage Range	Unplug device for 30 seconds, check AC power source, plug back in. Contact customer service if problem is not resolved.
Temperature Sensor	Unplug device for 30 seconds, plug back in. Contact customer service if problem is not resolved or occurs frequently.
High Temperature Detected	Unplug device for 30 seconds, check vents, check room temperature, wait 15 minutes, plug back in. Contact customer service if problem is not resolved or occurs frequently.
Low Temperature Detected	Unplug device, allow device to reach normal room temperature, plug back in. Contact customer service if problem is not resolved or occurs frequently.
Generator Motor	Unplug device for 30 seconds, plug back in. Contact customer service if problem is not resolved or occurs frequently.

Problem is…	Take this action…
There is no power to the air pulse generator, or the vest does not pulse.	Confirm whether the device is in Sleep mode (Power Indicator Light is lit). If yes, tap anywhere on the screen to awaken the device. If no, confirm or take action in the following order: The power cord is firmly connected to the generator. The power cord is firmly connected to the wall outlet. The wall outlet has power. To replace a defective or damaged power cord, unplug from wall outlet. Unplug from generator. Plug new power cord into generator and plug into wall outlet.
The air pulse generator is making a different than normal sound.	Contact Electromed or your service provider for replacement.
The air pulse generator is running at a higher than normal temperature.	Unplug device. Verify vents are clear of obstruction. Move to a cooler location. Leave unplugged for 15 minutes. If this does not resolve the issue, contact Electromed or your service provider for replacement.
The Edit, Store/ Restore, and in therapy pressure/ frequency are greyed out.	Confirm whether the device is in Locked mode. If yes, from the Device Settings menu, press and hold the Unlock Device button for three seconds to unlock the device. If no, contact Electromed or your service provider for replacement.

Problem is...	Take this action (Vest Garment)	Take this action (Wrap Garment)
The garment does not fully inflate.	Confirm or take action in the following order: 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. Verify garment is fit snuggly around chest.	Confirm or take action in the following order: The hose is firmly attached to the couplings and the generator. The connecting hose is free of leaks. The wrap and seams are free of tears.
Velcro-type closures are not staying closed.	Confirm or take action in the following order: The garment is right-side out with size label on the inside, against body. Velcro-type material is clean and free of excess lint. Garment is properly sized to allow enough material to stick together. Verify outer vest shell was not machine dried during laundering.	Confirm or take action in the following order: The wrap has not been machine washed or dried. The Velcro-type material is clean and free of excess lint.
Discomfort during treatment.	The garment will slightly compress the chest during treatment. Reduce pressure within the protocol until the patient is comfortable with the sensation. Slowly increase the pressure as the patient becomes acclimated to the treatment. A reduced pressure may be necessary for ill patients. If adjusting the protocols does not resolve the discomfort, adjust the Velcro-type closures to customize shoulder fit and tightness around chest. If this does not resolve the issue, contact Electromed or your service provider for assistance with garment sizing or additional troubleshooting steps.	

Specifications

Operational Parameters	• Time: 1 minute – 60 minutes ± 2% • Frequency: 5 – 20 Hz ± 2 Hz
Air Pulse Generator	• Weight: 13.2 lbs (6.0 kg) • Dimensions: 14 1/2" x 12 3/4" x 5 7/8" (37 x 32.5 x 15 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	• 100 – 240 V~, 50/60 Hz • 3.3 Amps at 100 V~ • 1.6 Amps at 240 V~ • Fuses: One 4A 250V, One 3.5A 250V - not user replaceable
Operation Conditions	• 41°F - 84°F (5°C - 29°C) • 15% - 93% relative humidity, non condensing • 70 kPa to 106 kPa
SmartVest System Time-to-Ready	Generator to come ready after 15 minutes at room temperature if stored outside of operating conditions.
SmartVest System Expected Service and Shelf Life	5 year expected service life 10 year shelf life

Electromagnetic Compatibility

Guidance and Manufacturer's Declarations - Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
Radiated emissions CISPR11	Group 1, Class B	The SmartVest Clearway uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR11	Group 1, Class B	The SmartVest Clearway is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Compatibility

Guidance and Manufacturer's Declarations - Electromagnetic Immunity		
The **SmartVest Clearway** 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	± 8 kV contact ± 15 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	Mains power quality should be that of a typical household environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical household environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% reduction for 0.5 cycle 100% reduction for 1 cycle 30% reduction for 25 cycles at 50Hz and 30 cycles at 60Hz 100% reduction for 250 cycles at 50Hz and 300 cycles at 60Hz	Mains power quality should be that of a typical household 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	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical household environment.
Magnetic Proximity fields IEC 61000-4-39	Magnetic levels listed in IEC 60601-1-2:2020, section 8.11	Proximity magnetic fields should be at levels characteristic of a typical location in a typical household environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Proximity fields from wireless communications equipment IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz RF frequencies listed in IEC 60601-1-2:2020, test levels between 9 and 28V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 

Prescription Record R_x

SmartVest Clearway

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.