



The Vest APX System Patient Guide

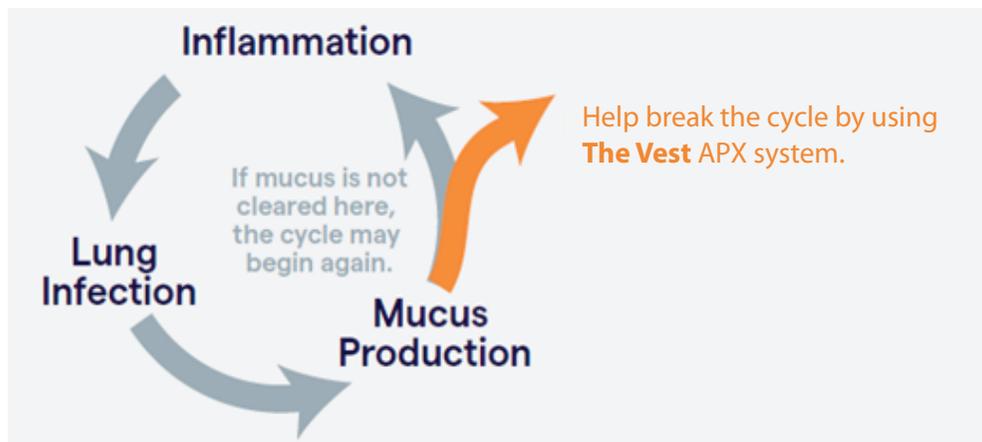


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Why is Airway Clearance important?

When mucus is unable to be cleared from the lungs, it can build up and create an environment in which bacteria can grow. This leads to repeated, serious lung infections which cause more damage to the airways of the lungs and can become a cycle of infections. This cycle may lead to irreversible lung damage and respiratory failure.



The Vest APX system therapy generates airflow to help thin and mobilize mucus from the small airways to the larger airways, where it can be coughed out or suctioned.

Intended Use

The Vest APX system was developed to provide effective Airway Clearance Therapy. The system consists of an inflatable garment attached to an Air Pulse Generator that rapidly inflates and deflates the inflatable garment. This causes the chest wall to be gently compressed and released, which creates airflow within the lungs. This process moves the mucus toward the large airways where it can be cleared by coughing or suctioning. This type of Airway Clearance Therapy is referred to as High Frequency Chest Wall Oscillation (HFCWO).

Contraindications

If the patient has a contraindicated condition, use of **The Vest** APX system may present a risk to the patient. If so, do not use the unit except as directed by a physician. Death or serious injury could occur.

The Vest APX system is contraindicated if these conditions are present:

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

Relative Contraindications

Use of the system for Airway Clearance Therapy requires careful consideration and assessment of the individual patient's case if the following conditions exist:

- Intracranial pressure (ICP) greater than 20 mm Hg
 - Recent spinal surgery or acute spinal injury
 - Bronchopleural fistula
 - Pulmonary edema associated with congestive heart failure
 - Large pleural effusions or empyema
 - Pulmonary embolism
 - Rib fractures, with or without flail chest
 - Surgical wound or healing tissue or recent skin grafts or flaps on the thorax
 - Uncontrolled hypertension
 - Distended abdomen
 - Recent esophageal surgery
 - Active or recent gross hemoptysis
 - Uncontrolled airway at risk for aspiration such as tube feeding or a recent meal
 - Subcutaneous emphysema
 - Recent epidural spinal infusion or spinal anesthesia
 - Burns, open wounds, and skin infections on the thorax
 - Recent placement of transvenous or subcutaneous pacemaker
 - Suspected pulmonary tuberculosis
 - Lung contusion
 - Bronchospasm
 - Osteoporosis or osteomyelitis of the ribs
 - Coagulopathy
 - Complaint of chest wall pain
-

Warnings

WARNINGS:

The Vest APX system warnings include:

Warning—Do not eat or drink during a therapy session. To do so could cause a choking hazard.



Warning—Unplug the control unit from its power source. Failure to disconnect the unit from its power source during cleaning could cause injury or equipment damage.



Warning—Some patients may experience nausea, dizziness, or headache when using the therapy. It is recommended that patients refrain from doing any therapy for a period after eating. If patients experience these symptoms, it is recommended that they take breaks during therapy.

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

Warning—Applying therapy intensity, frequency, and/or duration settings that are lower than prescribed, may cause ineffective therapy or lead to patient injury.

Warning—Patients that may have difficulty clearing secretions from the upper airway may require specialized therapy in addition to **The Vest** APX system therapy. Please consult your physician to determine if additional therapy is appropriate.

For a full list of WARNINGS and SAFETY information associated with **The Vest** APX system, see the Instructions for use 214281, or contact Customer Service at 800-426-4224 to obtain a copy.

What is included in the Vest APX System?



THE VEST APX Control Unit



Air hoses (2)



Vest Garment Bladder



Vest Garment



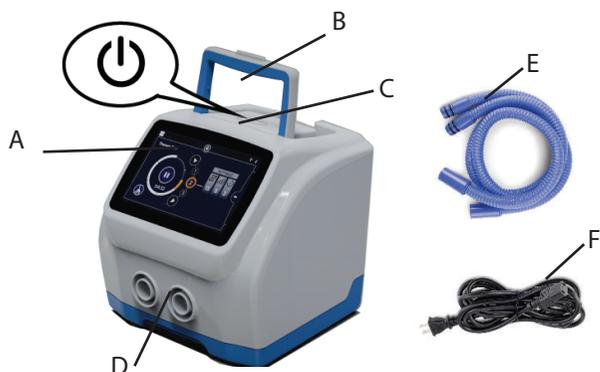
Power Cord



Carrying Case

Features and Controls

Control Unit



Item	Feature
A	Touchscreen
B	Handle
C	Power button
D	Air hose ports
E	Hoses
F	Power cord

Storage and Handling



To store or transport **The Vest** APX system, follow these steps:

1. Lay the carrying case flat on a stable surface so that it does not wheel away.
2. Put the control unit with the touchscreen facing up in the carrying case.

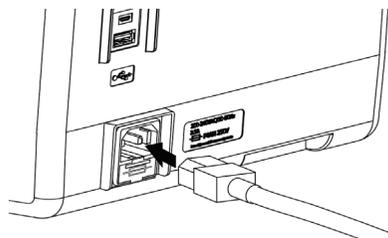
NOTE:

Avoid placing any objects that may scratch the touchscreen in the same compartment.

3. Cover the control unit with the protective flap. The protective flap should cover the control unit touchscreen to avoid any damage.
4. Place the garment, air hoses, and power cord in the remaining compartments.
5. Close the carrying case to secure the product inside.
6. Store the product in a safe location within the recommended environmental conditions. See **The Vest** APX system Instructions for use, 214281, for more information about environmental conditions for transport and storage.

Set up the Control Unit

1. Set the control unit on a dry, flat, and hard surface. Make sure that the control unit is away from curtains, blankets, or any heat-generating devices.
2. Plug the power cord into the power inlet on the back of the control unit.

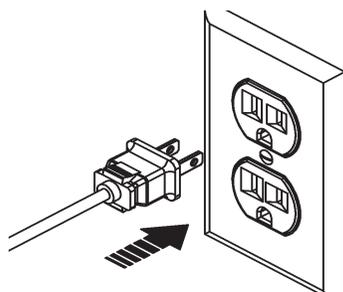


3. Plug the power cord into an applicable power outlet.

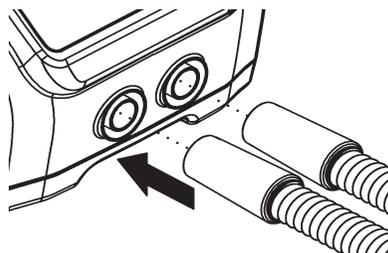


NOTE:

The power cord shown is for illustrative purposes and may differ from the one required for your country.



4. Connect the metal ring end of each air hose into each air hose port on the front of the control unit.



5. Assemble the garment. See **The Vest** APX system Instructions for use, 214281, for information about assembling the garment.
6. Fit the garment. See **The Vest** APX system Instructions for use, 214281, for information about garment fitting.
7. Connect the double O-ring end of each air hose into the garment air hose and twist into the garment air hose port to ensure a secure fit. Repeat with other air hose.



Starting Therapy

Start Therapy in Basic Mode

Make sure that the device is in Basic Mode before completing the steps in this section. See **The Vest APX** system Instructions for use, 214281, for information about enabling or disabling basic mode.

1. Power on **The Vest APX** system.
2. To start the therapy, tap the **Start** control on the display.



- To pause the therapy, tap the **Pause** control on the display.



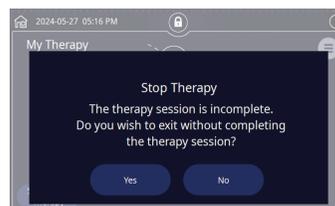
- To resume the therapy, tap the **Start** control again.



- To stop and exit the therapy, tap the **Stop and Exit** control on the display.

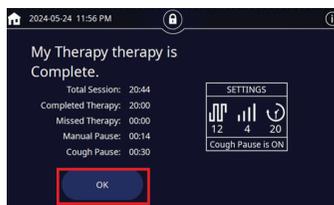


- A prompt asking if you would like to stop therapy appears. Tap **Yes** to confirm. Otherwise, tap **No** to cancel.



3. When therapy is complete, a summary screen appears with details about the recent therapy session:

- When the therapy is complete, tap **OK** to exit and return to the Home screen.



- When the therapy is incomplete, tap **OK** to exit and return to the Home screen.



Start Therapy in Advanced Mode

1. Power on **The Vest** APX system.
2. To select a therapy, tap the desired therapy on the home screen. In Advanced Mode, there will be more than one therapy on the left side of the screen.



3. To begin the therapy, tap the **Start** control on the display.



- To pause the therapy, tap the **Pause** control.



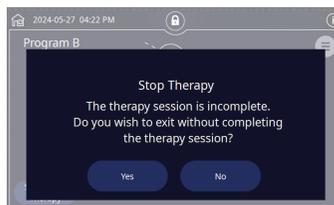
- To resume the therapy, tap the **Start** control again.



- To stop and exit the therapy, tap the **Stop & exit** therapy control on the display.



- A prompt asking if you would like to stop therapy appears, tap **Yes** to confirm. Otherwise, tap **No** to cancel.



- When therapy is complete, a summary screen appears with details about the recent therapy session:

- When the therapy is complete, tap **OK** to exit and return to the Home screen.
- When the therapy is incomplete, tap **OK** to exit and return to the Home screen.



Cleaning



WARNING:

Warning—Unplug the control unit from its power source. Failure to disconnect the unit from its power source during cleaning could cause injury or equipment damage.



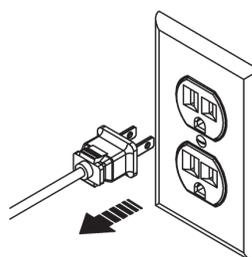
Clean all components of **The Vest APX** system following the instructions in this section. Cleaning removes dirt and organic matter.

Control Unit and Air Hoses—Cleaning

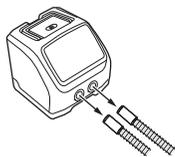
Follow these steps to clean and then disinfect the control unit after each use.

Preparing for Cleaning

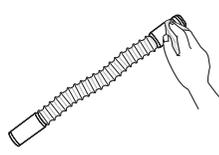
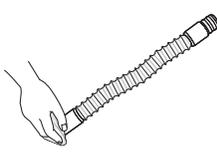
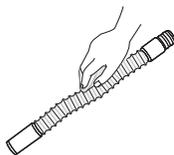
- Turn off the control unit and unplug it from its power source.



2. Disconnect the air hoses from the garment and the control unit.



3. Wipe down thoroughly the control unit and air hoses (including the hose ends) using a clean, damp cloth and a mild household soap or solution or alcohol (concentration <70%). The solution is a mix of one teaspoon of a mild household soap and 4 cups of water.



4. Inspect the control unit and the air hoses to make sure that there is no visible soil remaining. If necessary, repeat steps 1 - 3.

Cleaning the Outer Garment

Use a piece of clear tape to remove any lint and fluff caught on the hook and loop closures. Clean the outer garment at least once a month.

For thorough cleaning, follow these steps:

1. Wash the outer garment after the bladder has been removed.
2. Machine wash, or hand wash, in a cold cycle only (86°F (30°C) maximum) with detergent. Non-chlorine bleach may be used as necessary. Do not machine wash or dry the bladder.
3. Hang dry or tumble dry on lowest temperature (120°F (49°C) maximum).
4. Cool iron (250°F (110°C) maximum) as necessary. Do not iron the logo design.

See **The Vest APX** system Instructions for use, 214281, for information about how to reassemble the garment after washing.

Cleaning Hard to Clean Spots

To remove difficult spots or stains, we recommend that you use standard household cleansers. To loosen heavy, dried-on soil, saturate the spot first.

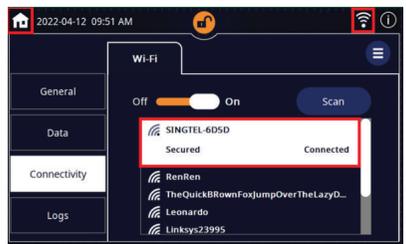
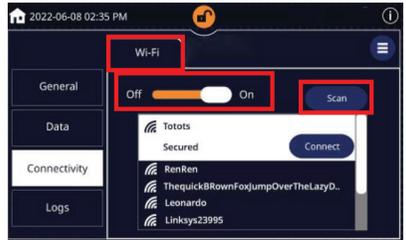
Connect to a Wireless Connection **Wi-Fi** Technology



NOTE:

Available only in the US and users registered with the **Connex** Health Portal.
Make sure that the router for connection is powered on and operating normally.

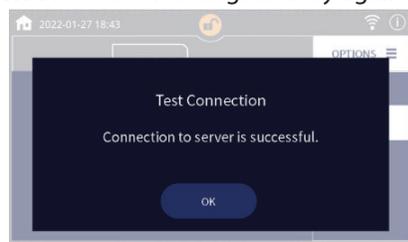
1. Tap the **Options** icon and tap **Device Settings**.
2. Tap **Connectivity**.
3. Tap **Wi-Fi**.
4. Drag the slider to **On**.
5. Tap **Scan**.
The list of available networks shows.
6. Select the network to connect to and tap **Connect**.
7. If prompted, enter the **Wi-Fi** network password and tap **Enter**.
8. Once connected, the **Wi-Fi** network icon shows in the top right corner of the screen.
Tap the **Home** icon to go to the Home screen.



Follow these steps to make sure that this device is connecting successfully to the **Connex** Health Portal. This makes sure that the most current data is synced to your device.

1. Tap the **Options** icon.
2. Tap **Server Settings**.
3. Tap **Test Connection**.

- If connection is successful, a confirmation screen shows. Tap **OK** to exit.
- If connection is unsuccessful, check the **Wi-Fi** network settings and try again.



Frequently Asked Questions

How does THE VEST APX system work?

The device uses a technology called High Frequency Chest Wall Oscillation (HFCWO). The equipment consists of a garment connected by air hoses to a controller. During therapy, the garment inflates and deflates rapidly, applying gentle pressure to the chest wall. This moves mucus toward larger airways where it can be cleared by coughing or suctioning.

What are the maintenance requirements for THE VEST APX system?

The Vest APX system requires minimal routine maintenance. Periodic cleaning is required. If service is necessary, contact Baxter Customer Service at 800-426-4224.

Can THE VEST APX system also be run on an electrical power inverter?

The Vest APX system has not been validated to run on an electrical power inverter. The electrical requirements are outlined in **The Vest** APX system Instructions for use, 214281.

What garment styles are available?

The Vest APX system has two styles of garments: the vest garment and the wrap garment. They are designed for different body shapes and types and provide equivalent airflow with therapy.

How does the patient ensure the garment will fit correctly?

It is important to provide an accurate chest measurement as a baseline to fit the garment. Adjust the sizing strips and straps ensure a comfortable fit. See the fitting instructions for each garment style in **The Vest** APX system, Instructions for use, 214281.

What languages are available for THE VEST APX system display?

The Vest APX system display can appear in two languages, English and Spanish.

Can patients take prescribed aerosol or nebulizer treatments while using THE VEST APX system?

There is no contraindication for conducting both treatments at the same time. Patients should consult their health care teams with further questions.

Can patients change their prescribed settings?

Patients should consult their health care teams to determine if the prescribed settings should be changed.

What should patients do if their stomach gets upset during treatment?

Patients should consult their health care teams to discuss possible remedies for the upset stomach. Possible recommendations by the health care teams may be conducting the treatment before meals, relieving pressure in the stomach area by leaning forward or backward, or changing garment style.

What should patients do if they feel their port and would like to improve that comfort?

Patients may feel the port inside the garment prior to the garment inflating. If the patients continue to feel the port after the garment inflates, they may benefit from using a contour foam pad (available by Baxter) to help provide comfort for the area of a Hickman catheter, portacath, G-tube, etc. They may also benefit from a different style garment. Contact Baxter Customer Service to order the contour foam.

What happens if THE VEST APX system causes patients to feel itchy?

For the most comfort, it is recommended patients wear a single layer of cotton clothing, such as a t-shirt, beneath the inflatable garment. Heavier clothing can become hot and itchy. If the patient's skin becomes itchy, using lotion before treatment may help. An itchy

nose during treatment may happen from airflow generated from the therapy. If itchiness continues, these patients should talk to their health care teams.

Will the insurance company cover the costs of THE VEST APX system?

Ultimately, the cost to the patient for **The Vest** APX system depends on the specific insurance plan: what it covers, what co-payments it requires, what deductible is needed, etc. To meet financial needs, Baxter offers several options to assist with payments. If you have further questions, call Baxter Customer Service, and please have the insurance card handy.

Will the settings be lost if THE VEST APX system is unplugged?

If the device is unplugged, the settings will not be lost. **The Vest** APX system is equipped with internal memory so it will default to the previous settings.

Who can service THE VEST APX system?

Only authorized personnel can service the system. Please see **The Vest** APX system Instructions for use, 214281, for troubleshooting or contact Baxter Customer Service:

- In the USA, call Baxter at 800-426-4224, or go to hillrom.com/en/products-category/non-invasive-respiratory-therapy/.
- Outside of the USA, contact your distributor or local Baxter representative, or go to baxter.com.

Can I travel internationally with THE VEST APX system?

The system is designed to be used with international voltages. The patient should use a grounded plug adapter rated for at least 10 amps. Do NOT use a voltage converter/transformer.

Can I travel with THE VEST APX system on an airplane?

When preparing for air travel, review the latest medical device regulations on the TSA website, www.tsa.gov. The travel agent or airline should also be able to answer questions regarding the requirements for traveling with medical devices. **The Vest** APX system is classified as carry-on luggage and the carry case will fit into the overhead bin of most aircrafts. It may be helpful to carry a copy of your prescription. It is not recommended the device is checked-in as regular luggage.

How can I see the hour meter reading on my device?

To see the hour run time on the device, go to Device Information, Total Therapy Runtime.

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