

AffloVest® User Guide



AFFLOVEST®
MOBILE AIRWAY CLEARANCE THERAPY

Tactile
MEDICAL®

Welcome to AffloVest

Dear Customer,

Congratulations on your purchase of an AffloVest from Tactile Medical! We are excited to help you manage your health with this innovative at-home therapy that has been used by people just like you. To receive maximum benefit from the AffloVest and to ensure your safety, please familiarize yourself with the information in this AffloVest User Guide. It contains important safety and technical data. With proper care, the AffloVest will reward you with a long, trouble-free service life. We greatly value the satisfaction of our customers and hope you are completely satisfied. For assistance setting up or using the AffloVest, or to report an unexpected issue, please contact the local durable medical equipment (DME) provider that supplied you with your device or Tactile Medical.

How to contact Tactile Medical

If you have questions about the AffloVest system, please contact Tactile Medical at:

Call: 1.800.575.1900

Fax: 1.866.569.1912

Email: afflovestinfo@tactilemedical.com

If you have medical questions, please contact your physician or healthcare provider.

Manufactured by Tactile Medical

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1. Before You Get Started

This User Guide provides the information needed to set up and use your AffloVest. Read the entire User Guide before attempting to connect or operate this product. Please keep this User Guide for future reference.

For assistance setting up or using the AffloVest, or to report an unexpected issue, please contact the local durable medical equipment (DME) provider that supplied you with your device or Tactile Medical.

Indications for Use

The AffloVest is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment. The AffloVest may be used for the pediatric population (≥ 6 months of age) to geriatric population.

Intended Use

The AffloVest is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment. It can be used in a home, hospital, or clinic setting. Not intended to be used in the emergency medical services (EMS) environment.

 **CAUTION** Federal law restricts this device to sale by or on the order of a physician.

 **CAUTION** Clearing excess mucous or "secretions" is important. When device is used with patients, including infants and young children, make sure that you can assist clearing the airway with appropriate equipment (bulb syringe, Yaunkauer) to facilitate secretion clearance and help prevent aspiration.

 **CAUTION** To ensure safe and proper use when therapy is used on infants and children, close adult supervision is required.

 **CAUTION** Patients with cognitive impairments or physical limitations should be closely supervised throughout therapy to ensure safe and proper use.

 **CAUTION** To prevent accidental changes to treatment program settings when used for infants, children or users with cognitive impairments, LOCK the treatment program setting as instructed on page 18 of this user guide.

 **CAUTION** Do not eat or drink during treatment to reduce choking hazard.

 **CAUTION** For patients with an unstable head or neck injury, or those experiencing active hemorrhage with hemodynamic instability, the risks and benefits of using AffloVest therapy should be discussed with their physician.

 **CAUTION** Increasing therapy intensity and/or duration settings that are greater than prescribed, may potentially cause musculoskeletal injury.

 **CAUTION** Patients who have difficulty clearing airway secretions may need additional airway clearance therapies in addition to the AffloVest system. Please consult your physician to determine if additional therapy is appropriate.

 **CAUTION** Electromagnetic Interference (EMI) may disrupt the operation of implanted pacemakers or implantable cardioverter defibrillators as well as other devices that might be subject to EMI if they come into direct contact with the AffloVest.

Mechanism of Action

The AffloVest generates vibration and oscillation of the user's chest wall through integrated motor modules installed into various parts of the vest. The patient controls the intensity and mode at which these motors oscillate the thoracic region with the use of a controller attached to the vest that can increase or decrease intensity to address the volume of mucus present in the air pathways, in compliance with a physician's prescription and orders.

Application

The AffloVest may be prescribed for one of these conditions*:

- Bronchiectasis
- Cystic fibrosis
- Neuromuscular conditions
- Late effects of poliomyelitis
- Other deficiencies of circulating enzymes
- Anterior horn cell diseases
- Multiple sclerosis
- Quadriplegia
- Muscular dystrophy
- Myotonic disorders
- Myopathies
- Disorders of the diaphragm

*Not all conditions allow for insurance reimbursement; contact your provider for details.

Contraindications

There are no contraindications to using the AffloVest.

According to the American Association for Respiratory Care (AARC) Guidelines for Postural Drainage Therapy, the decision to use the unit for airway clearance therapy (ACT) requires careful consideration and a doctor's assessment of the individual patient's case if the following conditions exist:

- Intracranial pressure (ICP) greater than 20 mmHg
- Recent spinal surgery or acute spinal injury
- Bronchopleural fistula
- Pulmonary edema associated with congestive heart failure
- Large pleural effusions or empyema
- Pulmonary embolism
- Acute illness
- Pregnancy or nursing mothers
- Electronic implants

- 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

Technical Data

Nominal voltage:	14.4VDC
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Nominal power consumption:	Approx. 65W
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Power supply:	INPUT: 100–240 V~ 50–60 Hz OUTPUT: +18 V $\equiv$ 0–3.62 A Please see directions for use that comes with power supply. The provided power supply is specified as part of the AffloVest system.
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Lithium-ion battery:	704268-001 OUTPUT: 14.4VDC, 4.9Ah, 70.6Wh, lithium-ion CHARGING VOLTAGE: 18VDC, 2.75 A min
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Manufacturer:	Tactile Medical 3701 Wayzata Blvd, Suite 300 Minneapolis, MN 55416 USA Toll Free Tel: 800.575.1900 Toll Free Fax: 866.569.1912
Sizes:	Five sizes available: XS Extra Small S Small M Medium L Large XL Extra Large
Treatment times:	Vary depending on physician prescription
Modes of operation:	Eight oscillation motors, eight pressure waveforms

Safety Features

- The AffloVest was designed with safety in mind, therefore it contains the following safety features:
- Motors operate at safe, low voltages.
 - Controller contains a fuse in the event of electrical problems.
 - The controller operates on a timer to ensure automated shutoff.
- ⚠ CAUTION** The AffloVest should always be worn over clothing. In a hospital or clinic setting, a fabric shield should be used to prevent cross-contamination when more than one patient uses the unit. The AffloVest should be cleaned appropriately between patient use. See Section 7, Cleaning and Care.

Explanation of Symbols

The AffloVest symbols adhere to the ISO 15223-1:2021/Amd 1:2025 International Standard.

	SYMBOL	EXPLANATION	SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
Safety Symbols		Recycle at battery recycling facility.		Caution		Direct Current
		Keep Dry		MR Unsafe		Prescription Use Only
		Refer to Instructions for Use		Type BF Equipment		TÜV SÜD
		TÜV Rheinland		Protected against ingress of solid foreign objects ≥0.04" (1.0 mm) in diameter and dripping water (at 15° tilt). Rating applies for both battery and controller inside and outside of vest pockets.		Waste electrical and electronic equipment must be disposed of separately from any household waste at the end of their service. Dispose of equipment in accordance with all relevant local, state and federal regulations.

	SYMBOL	EXPLANATION	SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
Transport and Storage Symbols		Device Transport and Storage Temperature Limits		Device Transport and Storage Humidity Limits		
Operating Limit Symbols		Device Operating Temperature Limits (5°C to 35°C)		Device Operating Humidity Limits		Device Operating Atmospheric Pressure Range
Cleaning and Care Symbols		Do Not Bleach		Do Not Iron		Do Not Machine Wash
		Do Not Tumble Dry		Do Not Wet Clean		
Informational Symbols		Information		Manufacturer		Reference Number
		Serial Number				
Controller Buttons		Go		Intensity		On/Off
		Play/Pause		Up, Down, Left and Right		Vest Modes
On-screen Symbols		App		Back Arrow		Battery (full and low battery)
		Bluetooth®		Cancel		Confirm
		Cough Prompt		Drainage		Information
		Instructions		Lock		Percussion
		Program Settings		Resume		Treatment Time
		Usage Record		Vest Zones		Vibration
		Wi-Fi				

Essential Performance

The essential performance of the device is to perform high frequency chest wall oscillation via vibratory vest. The motors vibrate at various frequencies to provide oscillation directly to thorax on the front and back of the vest garment. The AffloVest generates vibration and oscillation of the user’s chest wall through integrated motor modules installed into various parts of the vest. The patient controls the intensity at which these motors oscillate the thoracic region with the use of a controller attached to the vest that can increase or decrease intensity to address the volume of mucus present in the air pathways, in compliance with a physician’s prescription and orders. If electromagnetic (EM) disturbances impact the device’s performance, it will generate errors as describe in Section 9, Troubleshooting.

Measuring for Proper Fit of Your AffloVest

Typically, your DME provider will measure you for your AffloVest; however, if you need to do the measurements yourself, please follow these steps:

- Remove any outerwear and stand straight with arms at your side.
- Using a tailor’s or sewing tape, take the chest measurement under the arms across the **largest** part of the chest.
- Pull the measuring tape around without stretching or tightening the tape (a relaxed measurement).

The inches are used to determine the AffloVest size you need. Write down your chest circumference to determine the correct size. A 1-inch overlap (2.5 cm) of the vertical black seams on the front of the AffloVest is acceptable for all sizes. A 1 to 5-inch gap (2.5 cm to 12.7 cm) between the two sides of the AffloVest is also acceptable for all sizes.

Chest Circumference

XS	16 to 23 inches	If you are between sizes, please contact your DME provider or AffloVest representative to help you.
S	23 to 35 inches	
M	35 to 46 inches	
L	46 to 60 inches	
XL	60 to 75 inches	

Fit and sizing will vary from person to person. Using the front adjustment straps and the side straps, adjust the AffloVest so that there is a snug fit around the chest. The AffloVest should never limit the ability to take a deep breath. If needed, adjust the shoulder straps so that the upper front oscillation motors are on the upper chest, just below the collar bone. The AffloVest should fit from just below the collarbone to the bottom of the rib cage.

2. Setting Up Your AffloVest

Unpacking and Using Your AffloVest for the First Time

CAUTION Please follow the steps in order to ensure proper setup. Battery must be fully charged before use.

Unpack the AffloVest

Prior to initial use, it is recommended to inspect the AffloVest for any damage to the product (including opening or fraying at the seams and cracks in the fabric), wiring, battery, accessories, and the controller. This may be performed by the user or authorized service personnel. If any damage is noted, do not use or charge the device and contact your DME provider for assistance.

Package Contents



AffloVest



Rechargeable lithium-ion battery



Power supply



Go Anywhere travel case



Quick Start Guide



Patient Training Guide

Battery and Charging

CAUTION Use only the supplied rechargeable battery and the power supply to ensure safe and reliable operation of the AffloVest. Please contact your DME provider or afflovestrma@tactilemedical.com if you need a new power supply or an additional battery.



Fuel Gauge



Make sure the battery is fully charged before its first use. It can take up to three hours to initially charge the battery. To check the battery, turn on the controller and look at the battery icon. If fully charged, the icon will show a full battery. The battery can be charged by inserting the charging port into the bottom input port of the battery while in the power supply connector and plugging the power supply into an outlet.

While in use, the controller will display the battery icon.

You can also check the battery level by removing the battery from the battery pouch and pressing the battery icon on the fuel gauge.

To charge the battery, connect the power supply to a wall outlet. The power supply LED will turn on when connected to the wall outlet.

Next, plug the power supply into the AffloVest battery. There is a small opening at the bottom of the battery pouch where the battery port can be accessed.

AffloVest charging



Disconnecting and Reconnecting the Battery

The AffloVest battery comes connected inside of the battery pouch. The battery should not require disconnection or removal from the AffloVest during normal use.

Battery connected



To disconnect the battery from the AffloVest, simply unplug the battery plug from the vest.

Battery disconnected



The battery can now be removed from the AffloVest. When reconnecting the AffloVest battery, the controller beeps briefly when the battery is connected. Keep the AffloVest battery pouch closed to protect the battery and wires from potential damage.

Your AffloVest is now ready for use!

CAUTION

- When the power supply is plugged into the battery, pay close attention not to place any strain on the power supply cord. Rough handling of the vest and power supply while plugged into the battery could cause damage to the battery.
- When the battery is charging, the LEDs turn on and blink. Note, it may take 5–10 seconds for the LEDs to light after plugging in the power supply.
- It is recommended to allow the battery to fully charge for at least three hours or until the battery icon on the controller screen is full. When charging is completed, disconnect the power supply from the battery. It is recommended that the power supply be unplugged from the wall outlet and stored until next use.
- The battery fuel gauge LEDs will remain lit for 10–12 seconds after removing the power supply.
- Unplug the power supply from outlet when not in use. If the battery has not been used for more than 30 days, please recharge prior to using.

Putting the AffloVest On

Anytime the AffloVest is used, please ensure that a garment or gown is worn underneath.

Putting on and adjusting the AffloVest:

- If needed, loosen the side straps to maximize size.
- Unbuckle the chest buckles on the AffloVest and set the buckles to maximum size.
- Put on the AffloVest and fasten the chest buckles starting with the bottom buckle then work your way to the top buckle.
- Pull the chest buckle straps so that the AffloVest fits snugly on the body, but does not restrict a deep, full breath. If needed, adjust the side straps by gently pulling them in to offer a more comfortable fit.
- After adjusting the chest straps and the side straps of the AffloVest, you should have less than a 5-inch (12.7 cm) gap. The two front vest panels may overlap up to 1 inch (2.5 cm).
- Adjust the shoulder straps so that the front upper AffloVest motors are on the upper chest, just below the collar bone. If you change positions during treatment, you can adjust the shoulder straps as needed.

The AffloVest chest portion should cover your chest from just below your collar bone to the bottom of your rib cage to ensure that the motors are placed in right position across the lung lobes.

Taking the AffloVest Off

To remove the AffloVest, unbuckle the chest buckles across the chest and remove the AffloVest.



3. Controller

Controller Layout

The controller has nine key buttons for user interaction:



SYMBOL	BUTTON	ACTION
	On/Off button will turn the controller on or off.	Press and hold to turn controller on and off.
	GO button will start treatment at preprogrammed settings automatically.	Press to start preprogrammed GO settings.
	Vest modes button navigates through the modes of therapy.	▪ Percussion: all motors operate in a pulsed fashion. ▪ Vibration: all motors operate continuously. ▪ Drainage: all motors operate in a preprogrammed sequential fashion.
	Intensity button navigates through the intensity levels of the oscillation.	Intensity can be adjusted at anytime during the treatment based on comfort. ▪ Low ▪ Medium ▪ High
	Play/Pause button starts or pauses therapy and is the value selection and enter button.	Press and hold Play/Pause to start a treatment. A short press will pause and resume the treatment. To cancel treatment, press Play/Pause for 2 seconds or more. Play/Pause can also be used to change treatment settings once highlighted or acts as an enter button.
	Up, Down, Left and Right navigation buttons enable movement across the screen to make selections.	Press to navigate to the menus and highlight setting that will be changed.

Vest Modes



Percussion: All motors operate in a pulsed fashion.



Vibration: All motors operate continuously.



Drainage: All motors operate in a preprogrammed sequential fashion.

On Screen Icons



SYMBOL BUTTON



Program Settings



Vest Modes
Displayed only when an active treatment is not running



Usage Record



Zones
Displayed anytime an active treatment is running



Intensity



Treatment Time

SYMBOL BUTTON



Confirm



Cough Prompt



Wi-Fi



Bluetooth®



Battery



Cancel

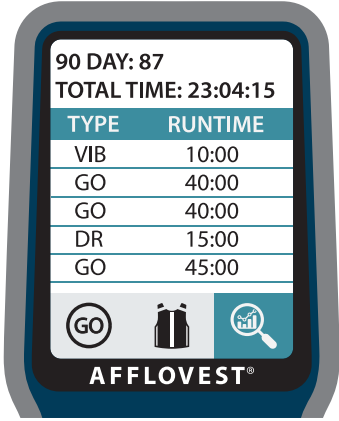
Controller Screens

This section reviews the controller screens of your AffloVest.

Power On screen



Usage menu



Main menu



Connectivity menu
(Wi-Fi connection)



Program settings



Connectivity menu
(Bluetooth® connection)



4. Using the AffloVest

Starting a Treatment

When the AffloVest is properly set up, press and hold  (On/Off) on the controller to power on the AffloVest. After a brief start-up period, the controller will navigate to the Main Menu.

GO Treatment

A GO mode treatment consists of three preprogrammed treatment sequences. Pressing the  button will begin a treatment with these settings automatically. By factory default, the system will perform the following treatments sequentially:

1. **Percussion mode:** 10 minutes duration at medium intensity
– Followed by a 10 second pause with a cough prompt on the controller
2. **Vibration mode:** 10 minutes duration at medium intensity
– Followed by a 10 second pause with a cough prompt on the controller
3. **Drainage mode:** 10 minutes duration at medium intensity



Note: When viewing the Main Menu, the zone indicator is shown as the vest icon. This shows you which zones are active during your treatment.

The preprogrammed GO settings can be changed and saved as customized GO settings using the program settings. For more information on changing GO settings, see Program Settings Menu on page 17.

Individual Treatments

On the Main Menu screen, individual treatments settings can be customized and a treatment can be started. Unlike a GO treatment that uses a preprogrammed sequence of three treatment settings, an individual treatment is intended for a single treatment setting that will reset after one use.

To program an individual treatment, navigate to the Main Menu. Use the  (Up)  (Down)  (Left) or  (Right) navigation buttons on the controller to highlight different settings on the screen. To change the vest mode, highlight the vest mode icon and press play/pause to toggle through the vest modes to the desired setting (Percussion, Vibration, or Drainage). To change treatment intensity, use the arrow keys to highlight the intensity icon and use the play/pause button to change the treatment intensity level (low, medium, high). To change the time duration of an individual treatment, use the arrow keys to highlight the time icon on the screen and use the play/pause button to program the desired treatment time. Individual treatments can be programmed from 5 to 45 minutes in 5 minute intervals.

Stopping a Treatment

Any treatment can be paused while running by pressing the  (Play/Pause) button. Pressing it again will allow the treatment to start again at the programmed settings. To fully stop and exit a treatment, press and hold the Play/Pause button.

Using the Controller Buttons

Vest Modes: You can change mode at any time by pressing the mode button on controller.



Changing the mode while the device is on will update the mode whether the treatment is running or not.



Intensity: At any time during treatment, you can change the intensity level to high, medium, or low based on comfort by pressing the intensity button on the controller.



Play/Pause: While a treatment is running, the device may be paused at any time by pressing the play/pause button. To fully stop and exit a treatment, press and hold the play/pause button. The AffloVest will shut off automatically if a treatment has been paused for 10 minutes.

Menus

Menus are available to make changes to your treatments, see your history, and connect digitally to either Bluetooth® or Wi-Fi. To access any menu, use the ▲ (Up) ▼ (Down) ◀ (Left) or ▶ (Right) arrows to highlight the menu you would like to view and press ▶|| (Play/Pause) to access the menu.

	Main Menu: Shows all active treatment data.
	Digital Connectivity Menu: Use this menu to enable Wi-Fi or Bluetooth® connectivity.
	Program Settings Menu: Use this menu to customize preprogrammed GO settings.
	Usage Menu: Use this menu to view history of use.

Main Menu

The Main Menu displays current treatment information including mode, intensity, and time left in treatment. You can use the ▲ (Up) ▼ (Down) ◀ (Left) or ▶ (Right) arrows to highlight the settings on screen and use the ▶|| (Play/Pause) button to change any values. The Main Menu also displays the battery level indicator.

Digital Connectivity Menu

To access the Digital Connectivity Menu, press the ▲ (Up) arrow until the Wi-Fi or Bluetooth® icon is highlighted. In this menu, you can enable either Wi-Fi or Bluetooth® connectivity.

Accessing the digital connectivity menu



Program Settings Menu

From the Main Menu, use the ◀ (Left) or ▶ (Right) arrows to highlight the Program Settings Menu. Once it is highlighted, press ▶|| (Play/Pause) on the controller to view the Program Settings Menu.

To change any value in the Program Settings Menu, use the arrows to highlight the value and then use ▶|| (Play/Pause) to select your choice of mode, intensity and time for each sequence. Use the arrows buttons to highlight the ✓ (Confirm) to confirm or the ✗ (Cancel) to cancel. After the Confirm or Cancel are selected, the controller goes back to the Main Menu. The next time you press the Ⓜ (GO) button, your treatment will start on the preprogrammed GO settings that were saved.

Preprogrammed GO settings can be modified as desired within the following allowable ranges:

- **Treatment intensity:** Low, Medium, High
- **Treatment mode:** Percussion, Vibration, Drainage
- **Treatment time:** 5–15 Minutes (in 1 minute intervals)

You can program these settings in 3 sequences:

- Each sequence can be any intensity
- Each sequence mode can be any of the 3 modes
- Each sequence time can be any time between 5–15 minutes

Program Settings menu screens



A LOCK feature is included to help prevent accidental changing of program settings by patients or caregivers. You can lock the programmed GO treatment by pressing (GO) button + (Vest Mode) + (Intensity) for 3–5 seconds while on the Program Settings Menu screen. You can unlock the programmed GO treatment by pressing (GO) button + (Vest Mode) + (Intensity) for 3–5 seconds while on the Program Settings Menu screen.

Lock GO treatments



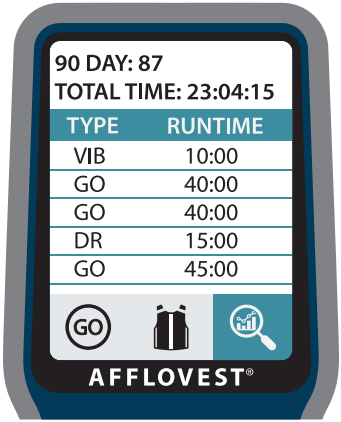
Usage Menu

Navigating to the Usage Menu allows you to view past treatment history information. The total time is the total cumulative treatment time for treatments longer than five minutes, not just from the last 90 days.

To view usage time/history from the main screen, use the arrow keys to highlight the usage icon. Once it is highlighted, press (Play/Pause) and this will open the Usage Menu on the controller.

90 day:	Saves all treatments at least 5 minutes in length from the last 90 days.
Total time:	Total time of all treatments.
Type:	Mode of treatment used. If 'GO', it saves the total run time but does not list individual modes used.

Usage menu screen



Indicators

The Main Menu for the AffloVest contains the following indicators to provide the user with useful information:

Indicators

	Zone Indicator: Displays which motor zones are currently active during treatment.
	The battery indicator is present on the Main Menu screen. If the battery is low, a red low battery icon will flash.
	Wi-Fi Connection
	Bluetooth® Connection

Accessing Your Serial Number

To access your serial number, please turn the controller over and find the number following “SN”.

Controller label



Turning Off the AffloVest

To turn off the AffloVest controller, press and hold  (On/Off) for at least 2 seconds. The system will enter a standby mode.

5. AffloVest Digital Connectivity

AffloVest App

The AffloVest app from Tactile Medical makes tracking your therapy simple. By connecting your AffloVest controller to your phone or tablet via Bluetooth® Low Energy (BLE) 4.0+ and Wi-Fi 6 (or newer), the app automatically records your treatment data. This includes details like session length, number of treatments, and intensity.

Note: For users connecting via Wi-Fi, data is synced on an ongoing basis. For users connecting via Bluetooth®, data is synced only during Bluetooth® connectivity.

Having access to this information puts you in control. It allows for proactive discussions with your DME provider, and you can even export your usage statistics in a shareable report.

The AffloVest app can be used with the following mobile devices:

- Android 14 or newer
- Apple iOS 18 or newer operating systems — for specific device models, please refer to the following link: <https://support.apple.com/guide/iphone/iphone-models-compatible-with-ios-18-iphe3fa5df43/ios>

Connecting Your AffloVest

1. Download the AffloVest app from the Apple iOS Store or Google Play Store on your smartphone or tablet.
 - **For Android devices:** Open the Google Play Store on your device or go to play.google.com on a browser. Search for the “AffloVest App.” When you find the app, tap “Install.”
 - **For Apple devices:** Open the App Store on your iPhone. Search for the “AffloVest App.” When you find the app, tap “Get.”



2. Register your account before setting up Bluetooth®. Start by filling out your name, email address, and password. Then log in with your credentials.

Fill out name, email, and password

A screenshot of the AffloVest registration form on a mobile device. The form is titled 'AFFLOVEST by Tactile Medical' and 'Welcome'. It asks the user to 'Please enter your details to register with the AffloVest Companion App.' The form includes input fields for 'First name*', 'Last name*', 'Email address*', and 'Password*'. Below these fields are two checkboxes: 'I agree to the AffloVest Terms of use' and 'I certify that I am at least 18 years old'. A blue 'Continue' button is at the bottom. At the very bottom, there is a link: 'Already have an account? Log in'.

Verify your account

A screenshot of the AffloVest login form on a mobile device. The form is titled 'AFFLOVEST by Tactile Medical' and 'Welcome'. It asks the user to 'Sign in the AffloVest companion app.' The form includes input fields for 'Email address*' and 'Password*'. Below these fields is a link: 'Forgot password?'. A blue 'Continue' button is at the bottom. At the very bottom, there is a link: 'Don't have an account? Register new account'.

3. To begin pairing your AffloVest to the AffloVest app, navigate to the Digital Connectivity Menu on your AffloVest controller and enable the Bluetooth® feature.
4. The top of the controller will show the pairing status. A 6-digit pairing code will be displayed on both the controller and the AffloVest app. Verify that the PIN characters are a match.

Deleting Your AffloVest App Account

The following instructions will help guide you through safely removing your personal information from the AffloVest app.

To delete your AffloVest app account:

- Open the app on your phone or tablet.
- Go to the Program Settings Menu, then open up "Personal Details," then "Delete Account."
- Next, follow the on-screen directions to confirm the deletion of the account.

Uninstalling the AffloVest App

Please make sure to follow the instructions for deleting the AffloVest app account before uninstalling the app.

- To uninstall for Android: Long press the app icon and select "Uninstall."
- To uninstall for iOS: Tap and hold the app icon, then tap "Remove App."

Connecting Your AffloVest to Wi-Fi Using the Controller

You can connect your AffloVest controller to a Wi-Fi network directly from the controller using the steps below.

1. Using the arrow buttons on the controller, navigate to the Digital Connectivity Menu. Press the ► (Play/Pause) button to select the Connectivity icon.
2. Select the Wi-Fi icon, turn Wi-Fi On, and choose "Connect to New Networks."
3. Select "Connect Manually."
4. Select your Wi-Fi network from the list of available networks.
5. Using the on-screen keyboard and keypad, enter the Wi-Fi password and select the green checkmark.
6. A confirmation screen will display: "Success! You have connected to the Wi-Fi network."
7. After connecting to Wi-Fi, authenticate your AffloVest. On the controller, select Authenticate My Device.
8. Select Start Authentication. A code will appear on the controller screen.
9. On your computer or smart device go to <https://auth.app.afflovest.com/activate>. Enter the code and select Continue. Verify the code and select Confirm.



10. Register or sign in to an AffloVest account.
11. A confirmation message will appear on both the controller and the web page when authentication is complete.

6. Firmware Updates

Updating Your AffloVest Controller Firmware

You can update your AffloVest controller's software in two ways: using a Bluetooth® connection with your phone (or tablet) or using a Wi-Fi connection.

- The firmware update is available for both iOS and Android mobile devices

Updating with Bluetooth® (Using Your Phone or Tablet)

First, connect your AffloVest to the mobile AffloVest app on your mobile phone or tablet. This can be found in Section 5, AffloVest Digital Connectivity on page 20. Once they're connected, you'll see a special icon on the app's home screen or in the "My AffloVest" section under "Vest Settings."

If there's a new update available, you'll see an "Update Firmware" button on the app's home screen and in the vest settings. Before you start the update, please remember these important things:

- Make sure your phone or tablet's battery is at least half full (50% charged).
- Ensure the AffloVest battery is fully charged.
- Keep your AffloVest turned on during the entire update.
- Keep your phone or tablet close to your AffloVest (within a few feet) while it's updating.
- The update can take up to 30 minutes to finish.
- To make sure your treatment data is sent correctly to the app, it is best to wait for firmware updates to finish before starting a treatment. Also, make sure to fully complete a treatment before starting a firmware update.

To finish the update process, tap "Update". The app will show you details about what is included in the update.

Next, tap "Update Now" to start the update. The app will check to make sure your phone or tablet can connect to the AffloVest.

- If the connection is good, the app will send the new firmware to your AffloVest.
- The app will tell you if the update was sent successfully.

Your AffloVest controller will then re-start with the new firmware.

Updating with Wi-Fi

- First, connect your AffloVest to its mobile app using Bluetooth®, just like for the Bluetooth® update. Instructions can be found in Section 5, AffloVest Digital Connectivity on page 20. Then the app's home screen will show you if these connections worked.
- If you've recently finished an AffloVest treatment, your Wi-Fi connected AffloVest will automatically check for updates. If there's a new update, your AffloVest will start updating on its own.
- Important notes:
 - If you have manually connected to Wi-Fi with the AffloVest controller instead of the app, firmware updates will still be delivered to your device.
 - It is recommended to wait at least 30 minutes after a treatment session ends before attempting to run another treatment session to avoid potential data loss.
 - The controller might not respond while the update is in progress.
 - Your AffloVest will restart with the new software after the update is finished.

Removing Stored Data from the Controller

The following steps of completing a hard reset will safely remove your treatment data from the AffloVest controller.

Note: It is advised that a hard reset of the AffloVest controller only be completed by a DME provider.

To complete a factory reset of the controller:

- Make sure the controller is turned on. Navigate to the usage menu.
- Press and hold the Mode, GO, and ► (Right) arrow buttons at the same time.
- Keep holding them for 2 seconds.

The screen will turn blank, and the controller will turn back on by itself. When it restarts, the controller will be like new, and all information stored on it will be erased. The serial number will not be erased.

Note: A hard reset does not remove data already synced to the cloud. To ensure complete data removal, delete your account from the AffloVest app before performing the hard reset.

7. Cleaning and Care

Cleaning the AffloVest

Clean the AffloVest in the following situations:

- When the AffloVest becomes visibly soiled.
- Between patient uses in multi-patient care environments.
- In a single-user environment; it is recommended that the AffloVest be cleaned monthly.

To clean the AffloVest, utilize a broad-spectrum disinfecting wipe or spray rated to kill at least 99.9% of bacteria and viruses and follow the manufacturer's instructions for use. Use appropriate protective equipment, including disposable latex-free gloves. Follow the instructions below to clean the AffloVest using the disinfecting wipe or spray. Follow the disinfecting wipe or spray label with regards to concentration, contact time, rinsing and drying after cleaning.

1. Ensure the AffloVest is unplugged from all power sources.
2. Remove the battery from the battery pouch and remove the controller from the controller pouch.

3. Unbuckle chest buckles and shoulder straps and lay AffloVest flat so that the inside of AffloVest is exposed.
 - a. Wipe the outer edges of the AffloVest, starting in the collar area, tracing the outer edges all the way around the AffloVest and repeat.
 - b. Wipe all exposed fabric thoroughly, pressing into creased areas, and repeat.
4. Turn AffloVest over and lay it flat.
 - a. Starting at the top, wipe the exposed AffloVest fabric thoroughly, pressing into creased areas, and repeat.
 - b. Wipe all surfaces of buckles and straps.
 - c. Wipe inside and outside of buckles and buckle connectors.
 - d. Wipe inside and outside of battery pouch, including the plug protruding from the vest.
 - e. Wipe inside and outside of controller pouch.
5. Wipe battery thoroughly, including the battery cable.
6. Wipe controller thoroughly, including controller cable.
7. Wipe all accessories thoroughly including all cables.
8. Wipe carry case thoroughly (inside and outside).

AffloVest
inside view



AffloVest
outside view



Cleaning and Care Warnings

CAUTION



Do Not
Machine Wash



Do Not Iron



Do Not Bleach



Do Not Wet Clean



Do Not
Tumble Dry

Preventative Inspection, Calibration, and Maintenance

On a periodic basis, the AffloVest should be cleaned as described in the Cleaning the AffloVest section. After cleaning, it is recommended to inspect the Afflovest for any damage to the product (including opening or fraying at the seams and cracks in the fabric), wiring, battery, accessories, and the controller. This may be performed by the user or by authorized service personnel. If any damage is noted, do not use or charge the device and contact Tactile Medical for assistance.

The AffloVest is designed to operate without any periodic calibration or maintenance required. Only Tactile Medical may replace parts or perform repair on the AffloVest.

Transportation, Operation, and Storage Conditions



CAUTION Please observe the following during transportation, storage, and operation of the AffloVest.

Storage and Transport Conditions Between Uses

In between uses, please observe the following:

- Keep the AffloVest dry
- Protect the AffloVest from direct sunlight
- Remove the battery from the AffloVest during transport/storage
- Keep the AffloVest between -20°C (without relative humidity control) and 50°C (93% relative humidity, non-condensing)

Operating Conditions

While using the AffloVest, please observe the following:

- Keep the AffloVest dry
- Protect the AffloVest from direct sunlight
- Keep the AffloVest between 5°C – 35°C , 15%–93% relative humidity (non-condensing) and 700hPa–1060hPa

Traveling with Lithium-ion Batteries

Lithium-ion batteries can be considered hazardous by the Federal Aviation Administration (FAA). Familiarize yourself with any travel guidelines before you travel. Contact your carrier or visit their website for guidance.

8. Safety Information

Battery Warning Information

CAUTION

- Do not throw battery into fire or incinerate.
- Do not immerse in liquid such as water, sea water or beverages.
- Avoid getting wet.
- Keep away from young children and babies.
- Do not place in microwave. It may combust, resulting in smoke and fire.
- Do not subject battery to pressure.
- Do not drop battery on hard surface.
- Do not dismantle battery, as this may cause internal short-circuits, resulting in gas emissions, fire and explosion or other problems.
- Do not attempt to open the battery case. The electrolytes and electrolyte vapors contained within the case of lithium-ion batteries may be harmful to humans. If the battery case breaks or is compromised, avoid direct contact with the electrolytes within. If electrolytes come in contact with the skin, eyes or other parts of the body, immediately flush or rinse with fresh water and seek medical attention as soon as possible.
- Do not expose the battery to direct sunlight.
- Store battery on a noncombustible, heat-resistant and nonconductive surface.

General

- **WARNING:** No modifications of this equipment is allowed. The patient is intended to be an operator for the AffloVest. All functions of the AffloVest may be safely used by the patient.
- To protect the AffloVest from potential damage, avoid leaving in direct sunlight for extended periods of time. Keep AffloVest clean of dust, lint and debris.
- Avoid leaving the AffloVest in areas where it may be damaged by pets, pests or children.
- Wear the AffloVest over comfortable clothing to avoid potential skin irritation.
- Only use the AffloVest with included accessories. Do not use unapproved accessories with the AffloVest. Do not puncture the AffloVest with sharp objects or needles.
- Do not use the AffloVest in damp environments such as in the bathroom or at a swimming pool.
- Remove the handheld controller from the AffloVest pocket before cleaning with any type of liquid disinfectant or cleaning solution.
- Never put the AffloVest cords over sharp edges. Never allow cords on the AffloVest to kink or bind. Never carry or lift the AffloVest by any of its cables or components.
- Never operate the device where the controller's cable will present a risk of strangulation or asphyxiation.

Power Supply and Battery

- Properly store power supply between uses to avoid potential strangulation hazard for small children. The use of any other power supply may lead to fire or electric shock.
- The use of any other power supply will void the AffloVest warranty.
- Always unplug the AffloVest when not in use.
- Unplug the AC power supply if the AffloVest malfunctions while powered.
- Never disconnect the power supply from an electrical outlet with wet hands.
- Unplug the AffloVest from the electrical wall outlet prior to cleaning with any type of liquid disinfectant or cleaning solution.
- Never put the AffloVest power supply cords over sharp edges.
- Never allow power supply cords on the AffloVest to kink or bind.
- The battery may only be charged with the supplied power supply in accordance with the instructions herein. Remove the battery prior to cleaning the AffloVest with any type of liquid disinfectant or cleaning solution.

Environmental Protection



Waste electrical and electronic equipment must be disposed of separately from any household waste at the end of their service. Dispose of equipment in accordance with all relevant local, state and federal regulations.

Correct disposal of products will help protect the environment and avoid harmful effects to human beings and the environment that may arise from incorrectly handling devices at the end of their service life. Please contact local authorities to determine the proper method of disposal.

Note: Prior to disposal of a controller, it is required that a factory (hard) reset be completed. Please see Section 6, page 23.

Do NOT Dispose with General Household Waste. Tactile Medical complies with the Waste Electric and Electronic Equipment Directive (WEEE) 2002/96/EC. Our device controller contains a battery and circuit board and therefore should be recycled at an electronic recycling location. For your nearest electronic recycling location please search online for "electronic recycling near me" or visit the U.S. EPA website. Please note, contaminated medical devices must be disposed of at a medical/biohazard waste facility. For a facility near you, please search online for "medical/biohazard waste facility near me."

Electromagnetic Guidelines for Clinical Applications

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: 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 AffloVest, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The AffloVest is intended for use in the electromagnetic environment specified below. The AffloVest has not been evaluated for safety in the MR environment. It has not been tested for heating or unintended movement in the MR environment. The safety of AffloVest in the MR environment is unknown. The AffloVest should not be worn during an MR exam. Use of the device in the MR environment may result in injury or device malfunction. The customer or user of the AffloVest should ensure that it is not used in such an environment.

 **CAUTION** Device performance degradation may occur in the presence of other medical equipment (i.e., diathermy and electrocautery). If degradation occurs, increase the separation distance between the AffloVest device and the medical equipment.

EMITTED INTERFERENCE MEASUREMENT	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
RF emissions as per CISPR 11	Class B	The AffloVest is suitable for use in all establishments, including domestic, and those directly connected to the public power supply network that supplies buildings used for domestic purposes.
Harmonic component emissions as per IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions as per IEC 61000-3-2	Compliant	

NO.	TEST/STANDARD	PORT (ENCLOSURE, AC, I/O)	EMISSIONS CLASS AND GROUP/ IMMUNITY TEST LEVEL
1	CISPR 11, Conducted Emissions	100 VAC/60 Hz 240 VAC/60 Hz	Group 1, Class B
2	CISPR 11, Radiated Emissions	120 VAC/60 Hz	Group 1, Class B
3	IEC 61000-3-2 Harmonic Current Emissions	230 VAC/50 Hz	Class A
4	IEC 61000-3-3 Voltage Fluctuations and Flicker	230 VAC/50 Hz	All parameters
5	IEC 61000-4-2 Electrostatic Discharge	Enclosure	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
6	IEC 61000-4-3 Radiated RF EM Fields	Enclosure	10 V/m, 80-2700 MHz, 80% 1 kHz AM
7	IEC 61000-4-3 Proximity Fields from RF Wireless Equipment	Enclosure	Table 9 of IEC 60601-1-2
8	IEC 61000-4-4 Electrical Fast Transients/Bursts	120 VAC/60 Hz	±2 kV, 100 kHz repetition rate
9	IEC 61000-4-5 Surge	120 VAC/60 Hz	±0.5 kV, ±1 kV line-to-line
10	IEC 61000-4-6 Conducted Disturbances	120 VAC/60 Hz	6 V, 0.15–80 MHz, 80% 1 kHz AM
11	IEC 61000-4-8 Rated Power Frequency Magnetic Fields	Enclosure	30 A/m, 60 Hz
12	IEC 61000-4-11 Voltage Dips	100 VAC/60 Hz 240 VAC/50 Hz	0%, 0.5 cycle 0%, 1 cycle 70%, 0.5 seconds
13	IEC 61000-4-11 Voltage Interruptions	100 VAC/60 Hz 240 VAC/50 Hz	0%, 5 seconds
14	IEC 61000-4-39 Proximity Magnetic Fields	Enclosure	Table 11 of IEC 60601-1-2

The AffloVest controller uses Bluetooth® Low Energy (BLE) 4.0+ to (BLE) 4.2+ that supports authenticated pairing with data signing which complies to IEE 802.15.4 and supports AES-CMAC encryption (FIPS-compliant, AES-128 via RFC 4493) during communications. The controller also uses Wi-Fi 6 that complies with 802.11a/b/g/n/ac/ax and will utilize TLS 1.2 for encryption.

WIRELESS TECHNOLOGY	
Technology Used	Bluetooth®, Wi-Fi
Connection types	Bluetooth® SPP, iAP2, GATT, Wi-Fi 2.4GHz and 5GHz dual-band
Frequency	Bluetooth® 2405 to 2482.5 MHz, Wi-Fi 2400-2472, 5150-5895MHz
Max RF Power Output	Bluetooth® +3 dBm, Wi-Fi +19 dBm

9. Troubleshooting

Troubleshooting

IMPORTANT: Before attempting any troubleshooting, ensure that the battery is fully charged.

ISSUE	POSSIBLE CAUSE	TROUBLESHOOTING STEPS
AffloVest controller will not power on.	Battery discharged OR Battery not connected properly OR Possible damaged controller OR Possible damaged battery	Ensure battery is fully charged. Attempt to power on when connected to power supply. Verify that the battery is connected to the AffloVest correctly. Attempt to power on the AffloVest when connected to the power supply. Contact your DME provider for further assistance.
The selected program function has suddenly switched off.	The therapy cycle has finished and a new therapy cycle must be started OR Battery discharged OR Battery not connected properly	Start a new therapy cycle. Ensure battery is fully charged. Attempt to operate when connected to power supply. OR Battery not connected properly. Contact your DME provider for further assistance.
Controller is on but motors will not turn on.	Battery discharged OR Possible damaged controller	Ensure battery is fully charged. Attempt to operate when connected to power supply. Contact your DME provider for further assistance.
Wireless connection is lost.	Interference from another wireless device	Maintain a minimum separation distance of 1.5 feet (0.4 meters) between the AffloVest device and other wireless devices.

Note: While the AffloVest can temporarily operate connected directly to the power supply for troubleshooting and battery issues, please contact your DME provider as the AffloVest is not intended to run this way.

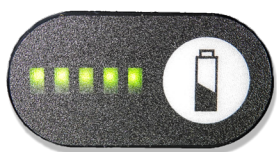
Resetting the AffloVest

Resetting the device does not delete treatment data. To delete treatment data, please refer to Section 6, page 23.

Step 1: Verify the Battery is Fully Charged

Press the button on the battery.

Battery fully charged:
all five LED bars on the
Fuel Gauge should be lit
after pressing the button
on the battery.



Step 2: Disconnect the Battery from the AffloVest

Wait 60 seconds and reconnect battery. The controller will beep twice when the battery is plugged back in.

Open battery
compartment and
disconnect battery as
shown, leave
disconnected 60 seconds.



Plug the battery
back in.
The controller should beep
twice when plugged in.



Step 3: Attempt to Run the AffloVest

Press and hold the  (On/Off) button for 3–5 seconds until the screen turns on.



10. Warranty

AffloVest Limited Warranty

Tactile Medical provides a limited warranty for the AffloVest and associated accessories, controller, and battery. For original purchasers within the United States¹, the AffloVest, associated accessories, controller and battery² are warranted to be free from defects in material and workmanship for a period of 5 years from the date of shipment. The AffloVest “Go Anywhere” case is warranted to be free from defects in material and workmanship for a period of 1 year from the date of shipment.

Expected Service Life

The expected service life for S–XL sizes is 5 years, assuming 1 hour of daily use. The expected service life for XS size is 2 years assuming 40 minutes of daily use. The associated accessories, controller, and battery have an expected service life of 5 years. Usage for greater than these timelines may decrease the expected life of AffloVest. The expected service life of the AffloVest “Go Anywhere” case is 1 year. **WARNING:** Use for >1 hr/day may decrease expected life of AffloVest.

Additional Terms

For “Non U.S.” original purchasers³, the AffloVest and associated accessories, controller battery² and “Go Anywhere” case are warranted to be free from defects in material and workmanship for period of 1 year from the date of shipment from Tactile Medical to original purchaser.

Tactile Medical’s sole obligation in the event of a breach of this warranty is expressly limited to the replacement of defective parts. Replacement parts may be new or refurbished parts as solely determined by Tactile Medical. No representation or other affirmation of fact set forth in this agreement, including but not limited to statements regarding suitability for use or performance of the AffloVest, shall be deemed to be a warranty or representation by Tactile Medical for any purpose, nor give rise to any liability or obligation of Tactile Medical.

EXCEPT FOR THE FOREGOING, TACTILE MEDICAL MAKES NO OTHER WARRANTY. THE WARRANTIES SET FORTH HERE ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY THE MANUFACTURER, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE AND ALL OBLIGATIONS OR LIABILITIES ON THE PART OF TACTILE MEDICAL FOR DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE, REPLACEMENT OR PERFORMANCE OF THE AFFLOVEST. IN NO EVENT SHALL TACTILE MEDICAL BE LIABLE FOR ANY SPECIAL, DIRECT, INDIRECT, OR CONSEQUENTIAL DAMAGES.

Some states, provinces, or countries do not allow exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply.

This warranty is available only to the original purchaser if their account is in good standing and not to any other subsequent owner. This warranty is not transferable. Abuse, misuse, failure to comply with the User Guide, product alterations, tampering or modification to the product not conducted by Tactile Medical shall void these warranties.

To the extent permitted by applicable law, the warranty coverage will not be extended or renewed by virtue of Tactile Medical’s compliance with this Limited Warranty. Any products, components, or parts which are repaired or replaced will be warranted for the unexpired term of the Original Limited Warranty.

These warranties provide specific legal rights; there may be other available rights, which may vary by state, province, or country. This Limited Warranty may not be expanded or modified by anyone (including but not limited to any authorized distributor) except in writing by an authorized employee of Tactile Medical.

 **CAUTION** Unauthorized service of the device can result in injury or damage to the device.

If you have questions or to obtain warranty service, contact your authorized AffloVest distributor.

Tactile Medical may be contacted at:
AffloVest Customer Service
afflovestrma@tactilemedical.com
Toll Free Tel: 800.575.1900
Toll Free Fax: 866.845.2479

1. "United States Purchasers" are those original end-user Purchasers who first took possession of the warranted item in the United States of America, its possessions, or territories for use of that item in the United States.
2. Batteries shall not be deemed defective unless the battery capacity is less than 50% of its original rated capacity.
3. "Non-U.S. Purchasers" are all other Purchasers. A warranty period measured in years begins on the date of original purchase.

Warranty Return Procedure

Prior to returning any product or component, the purchaser must provide prompt written notice to Tactile Medical or its authorized distributor, including a detailed description of the alleged defect at which time purchaser will be provided a Return Material Authorization (RMA) number. Then:

1. Properly package the product per instructions provided with your RMA number. The warranty will not apply if the item is damaged during shipment.
2. Include the following:
 - a. RMA number must be clearly visible on the outside of the box.
 - b. A return address where the item can be returned. PO Boxes are not acceptable.
 - c. A contact name and telephone number where purchaser can be reached.
 - d. Proof of purchase.
3. Ship the item, postage prepaid.

Tactile Medical will pay for standard shipping back to any Purchaser located in the United States for repair or replacement of items properly covered under this Original Limited Warranty. All other shipping charges, freight charges, customs fees, taxes, or tariffs concerning the shipping to Tactile Medical or the return of the repaired or replaced defective item to the Purchaser are the exclusive responsibility of the Purchaser and to be paid by the Purchaser.

11. Cybersecurity

Cybersecurity Introduction

This section contains information related to the cybersecurity and privacy controls that are part of the digital connectivity aspect of the AffloVest with Wi-Fi and mobile app connectivity to help ensure the safe and effective use of the AffloVest.

Tactile Medical has implemented the following secure design practices for all products:

- Risk identification and mitigation
- Design input requirements engineering
- Secure design controls
- Traceability
- Secure implementation
- Verification and validation

These practices are meant to ensure security considerations for all design solutions in development, and to provide a method to quickly address newly discovered security vulnerabilities and threats to products already placed on the market.

Tactile Medical identifies security risks and tests the corresponding mitigations throughout the development process. External third-party penetration testing, vulnerability assessments, and secure code analysis and reviews are also standard practice during the development and final production readiness phases.

The following information addresses the security principles identified in the Food and Drug Administration (FDA) guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 2023), as well as best practices in information security and design.

Security of Data

Tactile Medical follows a secure design lifecycle approach to ensure the confidentiality, integrity, and availability (CIA) of the information assets within the AffloVest system, including Wi-Fi, Bluetooth®, and mobile app connectivity. All data transmissions between the controller, AffloVest app and cloud are encrypted using industry standard protocols (e.g., AES-256, TLS 1.2). Decommissioning actions are logged and can be audited by internal cybersecurity procedures.

Digital and Connectivity Information

Confidentiality

Encryption is used to ensure confidentiality of data. The Advanced Encryption Standard (AES) is used to protect all patient data while it is in a state of transit in the AffloVest app and across the Wi-Fi network. The Bluetooth® link and Wi-Fi signal from the AffloVest device to the AffloVest app uses AES encryption at the application layer to protect the transmission of data. The AffloVest device needs to be paired to the AffloVest app via Bluetooth® or Wi-Fi to transmit data and does not support any other application or system for data exchange.

Pairing and Active Connections

The AffloVest system supports secure device pairing and connection with the following rules:

- Your AffloVest controller can be paired with one device at a time, and will only actively connect to one mobile device at a time.
- The AffloVest app establishes a trusted connection during pairing, ensuring a secure link for data transmission.

The AffloVest device is paired with the AffloVest app and encrypts the device data before transmitting it to the AffloVest app.

Device usage, error, and program data is encrypted on the AffloVest device with the ChaCha20-Poly1305 method before being transmitted over the AES encrypted Bluetooth® connection to the AffloVest app. During transmission of patient data from the AffloVest app to the Tactile Medical network, the data is protected by a Transport Layer Security (TLS) network connection and utilizes the AES-256 method during transfer and rest. If the AffloVest app is unable to complete the transmission to the Tactile Medical network, the AffloVest app will try to transfer the data to the Tactile Medical network. Application layer encryption was implemented as a defense-in-depth strategy to ensure confidentiality of information even if future vulnerabilities and limitations are discovered in the Bluetooth® protocols. The AffloVest app handles Protected Health Information (PHI), but it is considered low risk since the PHI does not include health insurance, billing, or prescription information. Extra precautions have been taken to ensure that the patient data is retained in the AffloVest app only during the data transmission process and is ultimately stored with the Tactile Medical network.

Availability

The AffloVest app is designed to be highly effective with patient data transmission to the Tactile Medical network when the device has reliable Internet connectivity.

Patient data handled by the AffloVest app is not used or reviewed by users in real-time; as such the AffloVest app attempts to transfer the data to the Tactile Medical network until successful. This mitigates against patient data loss due to reductions or outages in the cellular network, Wi-Fi network, or the Tactile Medical network.

Authentication and Authorization

The AffloVest app utilizes authentication to access all application features and requires positive matching of user information to complete pairing to the AffloVest device. To prevent unauthorized access to the AffloVest app, the user is advised to enable either passcode or biometrics-based authentication on the mobile phone or tablet.

The AffloVest app uses AES encryption to protect patient credentials entered into the application and does not store any user passwords.

Accountability

Each AffloVest device has a unique serial number and dynamic patient credentials based on the account logged in. The system allows logging out and logging in with a new account on the same device. The AffloVest app acts as a proxy to serve commands to the AffloVest device. Also, each AffloVest app installation has a secure encryption key that is used to uniquely identify the app when it interacts with the Tactile Medical network.

Summary

The secure design of the AffloVest system and AffloVest app began with development of a preliminary risk analysis and threat model that considered safety and cybersecurity risks. The identified risks were then used to generate the security design input requirements that continue to be updated as new vulnerabilities and threats are discovered in technologies utilized in, and interfaced by, the AffloVest app. The development of requirements has led to a strong security architecture that has been tested and reviewed, both internally and externally. Design controls like strong mobile app security, encryption for data storage, and secure communications were implemented to reduce security risk. The security design controls have effectively reduced security risks and patient safety risks to the lowest rate.

For additional information regarding Tactile Medical's data and privacy policies, please scan the QR codes below:



Our Online Privacy Policy



Our AffloVest App Terms and Conditions

12. FCC Compliance

FCC Compliance

This device contains Wi-Fi FCC ID: X8WWM02C, BLE FCC ID: X8WBT40F. 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. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

NOTE: "Harmful Interference" is defined in 47 CFR by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Tactile Medical

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