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:
Text or 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
3701 Wayzata Blvd, Suite 300, Minneapolis, MN 55416 USA
Toll Free Tel: 800.575.1900
Toll Free Fax: 866.569.1912
afflovest.com

Table of Contents

1. Before You Get Started

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

For assistance setting up or using the AffloVest, or to report and 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 a high frequency chest wall oscillation (HFCWO) device that is designed for airway clearance and improvement of bronchial drainage by mobilizing bronchial secretions where external manipulation of the thorax is the physician's choice of treatment. When used daily, the AffloVest can help you manage your chronic respiratory condition, improve your health, and allow you to enjoy a better quality of life. The AffloVest is indicated for patients with a 16-inch chest circumference up to a 75-inch chest circumference. The AffloVest requires a prescription.

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.

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 rate and frequency 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 or age restrictions 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 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
- 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
Nominal power consumption:	Approx. 65W
Power supply:	Battery operated AC/DC power. Please see directions for use that comes with power supply. The provided power supply is specified as part of the AffloVest system.
Lithium-ion battery:	704268-001 OUTPUT: 14.4VDC, 4.9Ah, 70.6Wh, lithium-ion CHARGING VOLTAGE: 18VDC, 2.75A min
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 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 6 "Cleaning and Care."

Explanation of Symbols

The AffloVest symbols adhere to the ISO 15223-1-2021 International Standard.

Safety Symbols

SYMBOL	EXPLANATION	SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
	Caution		Direct Current		Keep Dry
	Prescription Use Only	IP42	Protected against ingress of solid foreign objects ≥0.04" (1.0 mm) in diameter and dripping water (at 15° tilt).		Refer to Instructions for Use
	Type BF Equipment		TÜV SÜD		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
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		Lot Number		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		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 (high: 20 Hz, medium: 13 Hz, low: 5 Hz) 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 rate and frequency 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.

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
S	23 to 35 inches
M	35 to 46 inches
L	46 to 60 inches
XL	60 to 75 inches

If you are between sizes, please contact your DME or AffloVest representative to help you.

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

Carefully unpack the AffloVest and its accessories. Prior to initial use, it is recommended to inspect the AffloVest for any damage to the product, 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 Tactile Medical 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 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 low 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 and plug the power supply into the battery port as shown. 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

⚠ **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 will become lit with one LED blinking. Note, this 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 approximately one minute 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.
- It is not recommended to use the AffloVest without the battery for long term use. If your battery is not working, please contact your DME or afflovestrma@tactilemedical.com.

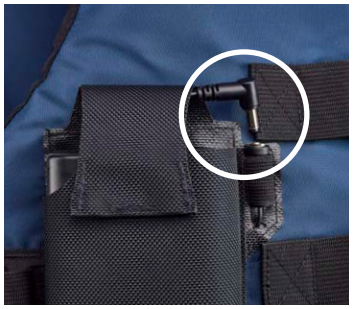
Disconnecting and Reconnecting the Battery

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!

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.

Four motors are located in the front and back of the AffloVest.

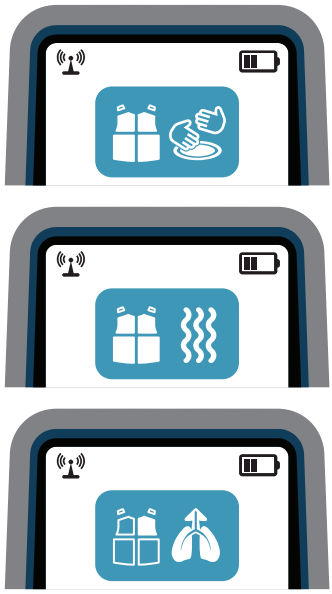
3. Controller

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 HFCWO 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**: offers therapy at 5 Hz ▪ **Medium**: offers therapy at 13 Hz ▪ **High**: offers therapy at 20 Hz
	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 for at least two seconds will pause the treatment or resume. 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



SYMBOL	BUTTON
	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

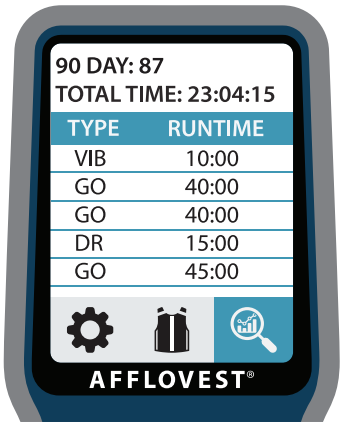
SYMBOL	BUTTON	SYMBOL	BUTTON
	Program Settings		Confirm
	Vest Modes Displayed only when an active treatment is not running		Cough Prompt
	Usage Record		Wi-Fi
	Zones Displayed anytime an active treatment is running		Bluetooth®
	Intensity		Battery
10:00	Time		Cancel

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 GO 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 1 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 vest mode button on controller.

Changing the modes while the device is on will update the modes 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.
	**Program Settings Menu:** Use this menu to customize preprogrammed GO settings.
	**Usage Menu:** Use this menu to view history of use.

Bluetooth® Pairing

Wi-Fi Authentication

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.

Connectivity Menu

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.

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

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.

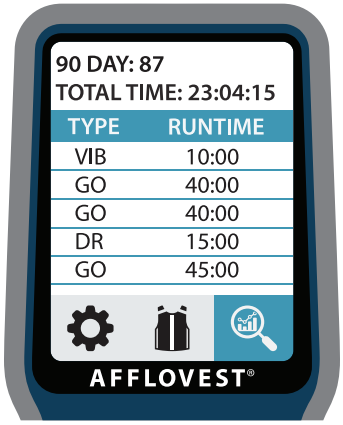
Lock GO Treatments

Usage Menu

Navigating to the Usage Menu allows you to view past treatment history information.

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.

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 Mobile

Using Digital Connectivity with Your AffloVest

The AffloVest can be used with Bluetooth® and/or Wi-Fi to track usage data.

AffloVest Mobile App

AffloVest Mobile is a free mobile application provided by Tactile Medical. With AffloVest Mobile, you can keep a record of your treatment sessions to help you track your therapy and adherence. The AffloVest Mobile app makes pairing and connecting your AffloVest device easy. Once a connection is established between the app and the device, usage data can be transferred.

The data is transferred into an activity report on the app and/or a portal where you can share your treatment data with your DME or healthcare provider.

> The AffloVest does not have to be connected digitally to Wi-Fi or Bluetooth® to run a treatment.

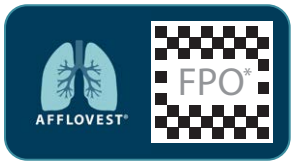
Connectivity Options

The AffloVest has two ways to connect the device so that therapy and adherence can be tracked.

1. Bluetooth® syncing
2. Wi-Fi connection

To download the AffloVest Mobile app, please go to the Apple iOS Store or Google Play Store on your smartphone or tablet.

AffloVest Mobile app



*This QR code will become active upon FDA clearance and commercial launch of the AffloVest Mobile app.

Bluetooth® Syncing

Bluetooth® syncing is available for your Android and iPhone devices.

Android:
Open the Google Play Store on your device or go to play.google.com on a browser. You can search for the AffloVest Mobile app by name or browse through the apps. Tap "Install."

Apple iOS:
Open the App Store on your iPhone home screen. You can search for the AffloVest Mobile app or browse through the apps. To download the AffloVest Mobile app, tap "Get."

1. Register account before pairing by filling out your password and email address.
2. To connect to the AffloVest Mobile app, enable the Bluetooth® feature on your AffloVest controller while on the connectivity screen. The controller will display a six-digit PIN number. Please verify the PIN number when prompted on your smartphone or tablet.
3. The top of the controller will show the pairing status.
4. A PIN will be displayed on both the controller and the application. Please verify that the PIN characters are a match.

Wi-Fi Connection

The AffloVest can automatically sync with the Tactile Medical network using Wi-Fi. To access Wi-Fi, go to the Digital Menu and select Wi-Fi. Connect to the desired Wi-Fi network and then use the controller to put in your Wi-Fi password.

You can now use the QR code to register your device or type in the URL app.afflovest.com. Register by creating a username and password and inputting your email address. A PIN will be displayed on both the controller and the application. Please verify that the PIN characters are a match.

If you do not have access to a mobile device to scan the QR code, you can enter your Wi-Fi password on the controller screen in the Digital Menu.

Wi-Fi Authentication

Data Transfer

When the controller and mobile application are successfully paired and have opened a communication channel or an active Wi-Fi connection, the controller will begin a data transfer of the current treatment/parameter set and any stored historical data.

The usage data that will be collected from your controller is as follows:

- Date of treatment
- Time of treatment
- Treatment settings
- Mode (percussion, drainage, vibration)
- Intensity level (high, medium, low)
- Duration of treatment

6. 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, 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)

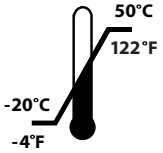
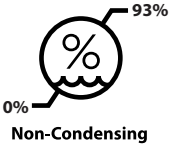
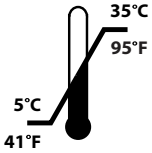
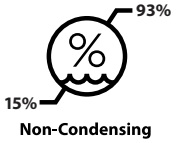
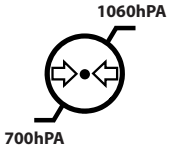
Operating Conditions

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 700 hPa–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.

Device Transport and Storage Temperature Limits	Device Transport and Storage Humidity Limits	Device Operating Temperature Limits (5˚C to 35˚C)	Device Operating Humidity Limits	Device Operating Atmospheric Pressure Range
				

7. 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.
- Children and disabled persons should not use the AffloVest without supervision.
- 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.

Electromagnetic Guidelines for Clinical Applications

The AffloVest is intended for use in the electromagnetic environment specified below. The customer or user of the AffloVest should ensure that it is used in such an environment.

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	

INTERFERENCE IMMUNITY TESTS	IEC 60601-TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Electrostatic discharge (ESD) as per IEC 61000-4-2	±6 kV Contact Discharge ±8 kV Air Discharge	±6 kV Contact Discharge ±8 kV Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%
Fast Electrical Transients/ Bursts as per IEC 61000-4-4	±2 kV for Power Supply Lines ±1 kV for Input/Output Lines	±2 kV for Power Supply Lines ±1 kV for Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment
Surge Voltages (Surge) as per IEC 61000-4-5	±1 kV Normal-Mode Voltage ±2 kV Common-Mode Voltage	±1 kV Normal-Mode Voltage ±2 kV Common-Mode Voltage	Mains power quality should be that of a typical commercial or hospital environment
EVoltage Dips, Short-Term Interruptions and Fluctuations in Supply Voltage as per IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 0% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip Ut) for 5 s	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 0% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip Ut) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AffloVest requires continued operation during interruptions in the power supply, it is recommended that the AffloVest be powered from an uninterruptible power supply or battery
Power Frequency (50 Hz) Magnetic Field as per IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a location in a commercial or hospital environment

Note: Ut is the mains AC voltage prior to application of the test level.

INTERFERENCE IMMUNITY TESTS	IEC 60601-TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDELINES
Conducted RF interference as per IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the AffloVest, including the cables, than the recommended distance calculated from the equation applicable to the transmit frequency. Recommended distance: d = 1.2 m P d = 1.2 m P for 80 MHz to 800 MHz d = 2.3 m P for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended distance in meters (m). The field strength of fixed RF transmitters, as determined by an electromagnetic site survey (a) should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF interference as per IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

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

(a) The field strength from fixed transmitters, such as base stations for radio telephones and mobile terrestrial radio equipment, amateur radio stations, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in terms of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AffloVest is used exceeds the applicable compliance level specified above, the AffloVest should be observed to verify normal operation. If abnormal performance features are observed, additional measures may be necessary, such as reorienting or relocating the AffloVest.

(b) The field strength should be less than 3 V/m over the frequency range from 150 kHz to 80 MHz.

Recommended distances between portable and mobile RF telecommunications equipment and the AffloVest:
The AffloVest is intended for use in an electromagnetic environment, in which RF interference is controlled. The customer or user of the AffloVest can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the AffloVest as recommended below — dependent on the maximum output power of the communications equipment.

NOMINAL TRANSMITTER OUTPUT (W)	DISTANCE DEPENDENT ON TRANSMIT FREQUENCY (M)		
	150 kHz to 80 MHz d = 1.2 m P	80 MHz to 800 MHz d = 1.2 m P	800 MHz to 2.5 GHz d = 2.3 m P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The recommended distance d in meters (m) for transmitters with a maximum nominal output not specified in the table above can be calculated using the equation applicable to the transmitter frequency (in the specific column in the table), where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

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

The Afflovest controller uses Bluetooth® Low Energy (BLE) 4.0+ 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 WiFi 6 that complies with 802.11a/b/g/n/ac/ax and will utilize TLS 1.2 for encryption.

WIRELESS TECHNOLOGY	
Technology Used	Bluetooth,® WiFi
Connection types	Bluetooth® SPP, iAP2, GATT, WiFi 2.4GHz and 5GHz dual-band
Frequency	Bluetooth® 2405 to 2482.5 MHz, WiFi 2400-2472, 5150-5895MHz
Max RF Power Output	Bluetooth® +3 dBm, WiFi +19 dBm
Operating Range	Bluetooth® 100 m, WiFi 413 m

8. Troubleshooting

Troubleshooting

⚠ **CAUTION**

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 operate when connected to power supply. Verify that the battery is connected to the AffloVest correctly. Attempt to operate the AffloVest when connected to the power supply. Contact your DME 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 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 for further assistance.

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

Resetting the AffloVest

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.

9. 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 States[1], the AffloVest, associated accessories, controller and battery[2] is 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. The expected service life of the AffloVest and associated accessories, controller, and battery is 5 years. The expected service life of the AffloVest "Go Anywhere" case is 1 year.

For "Non U.S." original purchasers[3], the AffloVest and associated accessories, controller battery[2] 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.

10. 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 application 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.

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 Mobile app and across the Wi-Fi network. The Bluetooth® link and Wi-Fi signal from the AffloVest device to the AffloVest Mobile app uses AES encryption at the application layer to protect the transmission of data. The AffloVest device needs to be paired to the AffloVest Mobile 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:

- A device can be paired with up to two mobile devices, but it can only be actively connected to one mobile device at a time.
- When attempting to pair a third device, the user will need to remove an existing pair to create a new connection.
- The AffloVest Mobile app establishes a trusted connection during pairing, ensuring a secure link for data transmission.

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

Device usage, error, and program data is encrypted on the AffloVest device with ChaCha20-Poly1305 method before being transmitted over the AES encrypted Bluetooth® connection to the AffloVest Mobile app. During transmission of patient data from the AffloVest Mobile 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 Mobile app is unable to complete the transmission to the Tactile Medical network, the AffloVest Mobile 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 Mobile 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 Mobile app only during the data transmission process and is ultimately stored with the Tactile Medical network.

Availability

The AffloVest Mobile 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 Mobile app is not used or reviewed by users in real-time, as such the AffloVest Mobile 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 Mobile 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 Mobile app, the user is advised to enable either passcode or biometrics-based authentication on the mobile phone or tablet. The AffloVest Mobile app uses AES encryption to protect patient credentials when entered in the application and it does not persist 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 Mobile app acts as a proxy to serve commands to the AffloVest device. Also, each AffloVest Mobile 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 Mobile 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 Mobile 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 application 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.

11. FCC Compliance

FCC Compliance

This device contains WIFI 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.

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